

Summary Report:

Consultation on Advancing Technological Innovation for Older Persons in Asia















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ABBREVIATIONS/ACRONYMS

AD	Assistive Device
AHWP	Asian Harmonization Working Party
ALC	Ageing and Life Course
AUSAID	Australian Government Overseas Aid Program
ASEAN	The Association of Southeast Asian Nations
ASERNIP-S	Australian Safety and Efficacy Registry of New Surgical Procedures -Surgical
BP	Blood Pressure
CDB	RIKEN Center for Development Biology
CEO	Chief Executive Officer
COI	Conflict of Interest
COPD	Chronic Obstructive Pulmonary Disease
CRPD	UN Convention on the Rights of Persons with Disabilities
ICT	Information and Telecommunications Technology
DALY	Disability-Adjusted Life Year
DAR	Disability and Rehabilitation
DITTA	Global Diagnostic Imaging Healthcare IT and Radiation Therapy Trade Association
DIM	Diagnostics Imaging and Medical Devices Unit, WHO
DHS	Health Sector Development
ENT-HNS	The Ear, Nose, Throat-Head and Neck Surgery Center
EMP	Essential Medicines and Health Products
FWC	Family, Women's and Children's Health
GHTF	Global Harmonization Task Force
GMDN	Global Medical Device Nomenclature
GMTA	Global Medical Technology Alliance
GPFD	Global Partners for Development
HBD-STED	Harmonization By Doing- Summary Technical Document
HCF	Health Care Financing
HIS	Health Systems and Innovation Cluster, WHO
HITAP	Health Intervention and Technology Assessment Program
HTA	Health Technology Assessment
HTM	Malaria and Neglected Tropical Diseases cluster, WHO
IAPO	International Alliance of Patients' Organizations
IMDRF	International Medical Device Regulators Forum
IVD	In Vitro Diagnostic
ISO	International Organization for Standardization
JACE	Japan Association for Clinical Engineers
JIRA	Japan Medical Imaging and Radiological Systems Industries Association
JFMDA	Japan Federation of Medical Devices Associations
LT	Long-Term
NCVC	National Cerebral and Cardiovascular Center
NIH	National Institutes of Health
NGO	Non-Government Organization

NMH	Non-Communicable Diseases and Mental Health
NCAR	National Competent Authority Report
NRCD	National Rehabilitation Center for Persons with Disabilities
PPP	Public-Private Partnership
R&D	Research and Development
ROI	Return on Investment
TDR	Special Programme for Research and Training in Tropical Disease
TRIPS	Trade-Related aspects of Intellectual Property Rights
SARA	Service Availability and Readiness Assessment
UDI	Unique Device Identifier
UHC	Universal Health Coverage
VIP	Violence and Injury Prevention & Disability unit, WHO
WHO	World Health Organization
WHA	World Health Assembly
WKC	WHO Kobe Centre
WIPRO	Western India Products Limited
WIPT	Working Integrated Product Team
WPRO	Western Pacific Region Office
WIPT	World Trade Organization
YLD	Year Lived with Disability

EXECUTIVE SUMMARY

The global population, particularly in the Asia Pacific region, is rapidly ageing with implications for swiftly rising health care and social costs, and maximizing the potential of this population's contributions to society. In the next 20 to 30 years, the greatest growth in ageing populations will be in low and middle income countries. A WHO priority is to enable ageing populations to remain healthy, active and independent for as long as possible. Achieving the aforementioned goals requires early diagnosis, prevention and treatment of prevalent diseases (e.g., non-communicable diseases), reduction of their risk factors, ensuring rehabilitation services and managing disability, and delay, management, and prevention of functional and cognitive decline. Creating socially supportive and inclusive environments whilst reducing inequities are essential. In all of these contexts health technologies, in particular medical and assistive devices, , are indispensable t tools to help achieve these goals.

Advancing the availability and affordability of medical and assistive devices , and their integration into community-based health and social service systems, requires **innovation** that addresses the needs and contexts of older populations, particularly in low income and emerging economy countries.

Many these health technologies are, however, expensive, not adapted to various contexts, not available, durable, or acceptable to the user. In countries where various devices are financially supported by the health or social-care system, access may be inequitable and costs will rise placing significant burdens on health and social financing systems and personal incomes. In places where they are not covered by insurance systems, many older people simply cannot afford them. Apart from the total cost of ownership, including consumables and maintenance, are issues of availability of various technologies to meet expressed needs, the durability of devices given environmental conditions in many countries (e.g. heat, humidity, electricity availability), safety and effectiveness criteria, and a host of acceptability issues on the part of the users. Medical and assistive devices further require community-based systems to support their proper use and maintenance. Consideration of the safe use of devices in homes or in circumstances where there are few or no health care workers is also needed.

The Consultation convened experts from government, industry, academia, non-governmental organizations representing the perspective of those using technologies, and from WHO. In addition, with support from the Japanese Ministry of Health, Labour and Welfare, WHO commissioned two systematic reviews/studies of the availability and status of medical and assistive devices (respectively) in eight Asian countries, preliminary findings of which were presented during the Consultation.

Objectives of the Consultation were to identify:

- needs for technological solutions for medical and assistive devices to support ageing populations
- core gaps in information and priority actions to advance availability of affordable medical and assistive devices for ageing populations
- next steps for WHO to consider to advance the Initiative on Innovation for Older Populations, along with identifying potential partners and funders

The ultimate goal was to identify priority needs, actions, and possible solutions to advance innovation.

The Consultation highlighted the need to address many inter-twined spheres of action to ultimately increase the availability of affordable, acceptable, safe and effective health technologies. Underlying discussions was a recognition of an end-to-end process for innovation that recognized the link between needs articulation, design, development, production, assessment, regulatory oversight, financing, procurement, use, maintenance, and continued post-marketing surveillance.

Health technologies were also seen as critical tools that must be part of integrated health and social care/service delivery systems. Advancing development of such systems involves multiple stakeholders, government ministries/agencies/offices, and communities. Thus, there is a need for and important opportunity to consider a unified approach to advancing innovation. These efforts have many synergies with the emerging Universal Health Coverage (UHC) approach, and with systems surrounding support for disability (including rehabilitation and assistive devices). UHC enables countries to develop programmes and policies to ensure coverage of a range of health services (prevention, promotion, treatment, rehabilitation, and palliation) whilst protecting individuals and communities from financial ruin due to health care costs.

A priority suggestion was to have different actors and sectors communicate with each other to develop health technologies responsive to the needs and preferences of individuals and care providers, as well to ensure product/process design, rapid diffusion, and scale up (inclusive of affordability).

Common issues and suggested actions in the Consultation focused on aspects of health systems and the product development / innovation cycle:

- **Policy environment.** Whether national policy frameworks include medical and assistive devices (both or just one category), and to what extent they are linked to available policies for the aged.
- **Regulatory environment**. Issues such as rapid reviews for safety and effectiveness; available methods/evidence base to review safety/effectiveness; greater harmonization of regulatory procedures across countries;
- Health technology assessment (HTA). As a critical tool for government decision making and prioritization, need to improve HTA methods to include the full spectrum of clinical, economic, social and ethical benefits. How HTA is linked to funding decisions for devices and innovation also needs to be considered.
- Health technology management, including needs assessment, selection, procurement, logistics, maintenance and training for safe use, as key processes and mechanisms required to increase access of devices by the final user.
- **Reimbursement decisions:** A recognition that different ministries and reimbursement systems may support medical and assistive devices, as well as other health technologies, differentially. The role of incentives for industry should be explored.
- The concept of "assistive solutions" was proposed (as opposed to assistive devices) providing an approach for integrated and holistic community support, maintenance services for assistive devices, as well as streamlined approaches for making them available.
- Investigating the role and needs of **health and social service workers** is important, particularly ways to support ageing health workers needs.
- Better understanding of the epidemiology of underlying diseases, risk factors, co-morbidities, are important to establish the needs for various devices. In turn, such models should focus on transitions from wellbeing to ill-health to frailty rather than on chronological age.
- Additional research is required to further assess the country context for, need, availability, and rational supply of medical and assistive devices in each country.

In summary, a holistic and integrated strategy for increasing the availability, affordability, acceptability, safe use, and effectiveness of health technologies specially medical and assistive devices, for ageing populations is needed.

INTRODUCTION

The Consultation was the first of its kind in WHO exploring how best to address the emerging needs of ageing populations, the potential use of health technologies—notably medical and assistive devices, and strategies to encourage greater innovations that are frugal and adaptable to specific national and local contexts. Whereas the issues covered in the Consultation are germane to all countries, special emphasis was given to low income countries and emerging economies. Unique to the meeting was representation from government, academia, nongovernmental organizations and those representing users, industry, and from several departments and units of WHO. Greater technological and social innovation (e.g., health technologies—including medical and assistive devices, and their integration into community based health and social delivery systems) contribute significantly to achieving higher order goals for ageing populations, for example as shown in the adjacent box.

The Consultation further contributed to an initiative announced by the Director-General in 2012 to support greater availability and access to frugal innovations that could increase the wellbeing and quality of life of ageing populations, improve their health, and ensure they are independent for as long as possible, particularly for low income countries and emerging economies. As the Director-General noted in a speech to the Pacific Health Forum in June 2012,¹ "not all innovation needs rocket science. Given the world's most pressing health problems, the true genius of innovation these days resides in simplicity. The quest for simplicity and ease of use is not a natural one. Unlike other fields of technical innovation, like computers or mobile phones, advances in medical



- Increased quality of life
- Prevention and compression of morbidity
- Increased independence and productivity
- Reduced social isolation
- Reduced hospitalizations
- Reduced health and social costs

technology nearly always come with greater complexity and a much higher price. The complexity increases the costs further as highly skilled workers are needed." With support from the Japanese Ministry of Health, Labour and Welfare WHO has begun work to identify priority medical and assistive devices for ageing populations by commissioning two initial systematic reviews for medical and assistive devices (see below).

The meeting builds upon past WHO work in Ageing and Life Course approaches, Medical Devices, Assistive Devices (notably within the disability field), related work within the WHO Western Pacific Region, and the WHO Centre for Health Development (Kobe--WKC). WKC's work focuses on various aspects and frameworks related to innovation for ageing populations, measurement of "age-friendliness" of cities and communities, community-based systems in support of this population, as well as leading WHO's work on building the evidence base for urban health issues (including measurement of inequities, developing and documenting approaches on intersectoral action for health, urban health governance, and urban health emergency management).

Background

The global population, particularly in the Asia Pacific region, is rapidly ageing with implications for swiftly rising health care and social costs, and maximizing the potential of this population's contributions to society. In the next 20 to 30 years, the greatest growth in ageing populations will be in low and middle income countries. A WHO priority is to enable ageing populations to remain healthy, active and independent for as long as possible.

¹ http://www.who.int/dg/speeches/2012/health_technologies_20120613/en/index.html

Achieving this requires early diagnosis, prevention and treatment of prevalent diseases, such as non-communicable diseases, reduction of their risk factors, and management, prevention or delay of functional and cognitive decline. Creating socially supportive environments whilst reducing inequities are essential. Medical and assistive devices, along with other health technologies, are important tools to help achieve these goals.

Many of these devices are, however, expensive and unaffordable, not adaptable to various contexts, not available, durable, and/or acceptable to the user. In countries where various devices are financially supported by the health or social-care system, access may be inequitable and costs will rise placing significant burdens on social financing systems and personal incomes. In places where they are not covered by insurance systems (especially for assistive devices), many older people simply cannot afford them. Apart from the total cost of ownership, including consumables and maintenance, are issues of the availability of various devices to meet expressed needs, the durability of devices given environmental conditions in many countries (e.g. heat, humidity, electricity availability), safety and effectiveness criteria, and a host of acceptability issues on the part of the users. Medical and assistive devices further require community-based systems to support their proper use and maintenance. Consideration to the safe use of devices in homes or in circumstances where there few or no health care workers is also needed.

WHO's approach to encouraging innovations in devices and health technologies stresses that they should be simple and transformative, frugal and affordable, and relate to the expressed needs of local populations. WHO advocates that assistive and medical devices also meet certain attributes as note in the adjacent box. Additional innovations in health and social delivery systems and non-health domains are required to enable efficient and universal rollout of new technologies for ageing populations: these include use of information communication technologies (ICT), urban planning, and integrative service delivery and financing models.

Identifying immediate needs and gaps faced by ageing populations in different countries will lessen health, social, and financial burdens confronting many families, communities and countries. In such cases,



there are many known unmet needs that require relatively lower tech solution such as managing hearing loss, vision, and mobility, as well as social programmes to ensure increased social inclusion and minimizing isolation. Due consideration to emerging issues confronting ageing populations, such as dementia and maintaining cognitive functioning, must be given.

Objectives

Meeting objectives were to identify:

- needs for technological solutions for medical and assistive devices to support ageing populations
- the core gaps in information and priority actions to advance availability of affordable medical and assistive devices for ageing populations
- next steps for WHO to consider to advance the Initiative on Innovation for Older Populations, along with identifying potential partners and funders

METHODS

The Consultation assembled a limited number of participants with expertise in areas relevant to understanding the priority needs of older populations for medical and assistive devices. In pursuit of the Consultation's objectives, participants discussed challenges and ways forward to drive further technological and social innovations and solutions to increase access to these health technologies. Participants were drawn from government, academia, industry associations, civil society, and WHO officials; and included the key investigators responsible for the systematic review/ survey. They came from different country settings, largely drawn the eight Asian countries participating in the Systematic Review and Survey. The Consultation did not address issues germane to the availability/accessibility/affordability of essential medicines or vaccines for ageing populations.

Systematic Review Studies

With funding from the Japanese Ministry of Health, Labour and Welfare, WHO commissioned two initial systematic reviews/surveys of the needs of older people for medical and assistive devices in eight WHO Western Pacific Regional Office (WPRO) countries: Australia, China, Fiji, Japan, Malaysia, Philippines, South Korea and Vietnam. This is a first step to better understand the knowledge gaps in identifying various country-context specific needs and required actions.

SUMMARY OF THE CONSULTATION

Opening Remarks

Mr Alex Ross, Director of the WHO Kobe Center (WKC)—On behalf of Dr Marie-Paule Kieny, Assistant Director General, and WHO, Mr Ross greeted and welcomed the participants. He presented WKC's expertise and experience in addressing urban health, health equity, ageing and social determinants of health issues. He mentioned that innovative use of health and social systems are essential to ensuring that the needs of the elderly are understood and to deliver any products and approaches to ensure healthy, independent ageing. Finally, Mr Ross highlighted that, in the past year, attention to ageing and chronic diseases has increased are now recognized as important global public health issues. WHO's aim is to better understand the needs of older populations, and to help encourage greater innovation and its diffusion for where and how various technologies, and their integration into broader health and social systems, can increase the ability of older persons to remain functionally independent and to reduce isolation.

Dr Oua Tanaka, Deputy Director of the Ministry of Health Labour and Welfare of Japan, opened the consultation by sharing Japan's latest information on ageing trends. Notably, the number of rapidly growing elder population (approximately 25 percent of Japan's population of 120 million are over 60 years old) are creating new challenges, such as growing health expenditure, unmet needs for health and social care workers, and the need to adapt health insurance systems to improve access to devices for the elderly.

Dr Francis Moussy, Technical Officer, WHO, described a new WHO initiative that was created in early 2012 to facilitate the development and access to appropriate and affordable medical and assistive devices globally.

A. Context Priority Ageing Issues in Asia

Priority issues related to aging globally and in Asia, along with specific updates relevant to the WHO Western Pacific Region (WPRO) were presented respectively by Dr John Beard, Director of the Ageing and Life Course Department, WHO and Dr Anjana Bhushan, Technical Officer, Health Care Finance, WHO WPRO.

Global trends in ageing indicate rapid growth in low and middle income countries, and particularly in the Asia Pacific Region (with Japan, Korea, and China among particularly affected countries). Not only are people living longer, but the pace at which growth of the population is occurring is much faster today than it was for countries experiencing this in the past hundred years (see Annex 6). For example, whereas it took France a hundred years to double its percentage of persons over 60, China will achieve this in 25 years. This demographic transition is the result of remarkable gains in health (such as child survival) as well as increased socio-economic development. It is an opportunity for countries and communities to rethink how to encourage greater quality of life, independence, and economic productivity of ageing persons. It also raises important public policy questions, such as understanding the intersection between demography, economics, population growth, and social support for the elderly. Changes in society, as experienced in many countries, will have implications for shared family and government responsibilities, Asian culture (regarding longer term care), urban planning design and age friendly cities/environments, as well as social participation. From a health standpoint, preventing non-communicable diseases and addressing their risk factors, is a priority. The elderly should be seen as assets and not as burdens to society. WHOs approach to ageing is embedded in a Life Course approach to health that includes early prevention and health promotion, access to primary care and long term care, age-friendly environments, and rethinking ageing to reduce misconceptions and stereotypes. Key data were also shared related to changes in global burdens of disease (a shift from communicable to non-communicable diseases), and its impact on ageing populations and on health systems. (see www.who.int/ageing/en/, Figures 1 - 4, and Annex 6).

It was noted that innovations could be considered to a) maintain functional status (medical and assistive devices), b) support better health (early detection/diagnosis, treatment, rehabilitation), c) support social integration/contribution (connectivity, lifelong learning), and d) support carers/caregivers.



Complementing a global overview of the ageing and health situation, dynamics in the Western Pacific Region (WPR) are important to understand. In particular, male/female disaggregation, equity, and morbidity/disability patterns help guide what types of innovation are needed. Some age-related challenges for all sectors of society include: a) increasing disease burden requiring health prevention and promotion b) weak health systems and services, requiring special attention to the needs of older populations c) assessing social and economic impacts d) understanding the equity, gender, and human rights issues, and e) obtaining more evidence.

Figure 3 Asia: Demographic transitions.



Varying demographic transitions

Source: United Nations Dept of Economic and Social Affairs, Population Division, World Population Prospects: The 2008 Revision, 2008.

Figure 4 Time taken for population aged 60 years and above to double, selected countries, Western Pacific Region



Source: Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat, World Population Prospects: The 2010 Revision

Figure 5: Morbidity and disability in older people

Top 10 causes of DALYs lost for men, 60-79 years, Western Pacific Region (2004)





Source: World Health Statistics, WHO

The WHO WPRO is also conducting an ongoing comparative study on health of older people in selected countries, review of national policy frameworks for the aged, and the preparation of a draft regional framework of action to be considered by the WPRO Regional Committee in October 2013 (for more information: www.wpro.who.int/topics/ageing/en).

Medical and Assistive Devices – WHO Work to Date

The following section is based on presentations by Dr Adriana Velazquez (Coordinator, Medical Devices, Department of Essential Medicines and Health Products, WHO) and Ms Kristen Pratt (WHO Technical Officer on Disability and Rehabilitation) on the scope of WHO's work and current issues for medical and assistive devices respectively.

The role of health technology in supporting ageing populations – WHO and medical devices

WHO's imperative is to increase access to safe, effective, quality medical devices. The World Health Assembly Resolution WHA60.29², approved by all Member States, endorsed the fact that health technologies, particularly medical devices, are indispensable for diagnostic, treatment and rehabilitation. WHO has developed guidelines and standards related to medical devices, a technical series on policies, needs assessment, health technology assessment, procurement, and is developing guidance on selection and safe use of medical devices as well as the list of medical devices needed per clinical intervention. Figure 6 presents an illustrative pathway to increase access to safe, quality medical devices. It begins with research and development (innovation) for new devices that leads to regulatory review, assessment and management.

² WHA 60.29 in http://apps.who.int/gb/ebwha/pdf_files/WHASSA_WHA60-Rec1/E/reso-60-en.pdf

Figure 6: Pathway from innovation to safe use of medical devices

To ensure improved access of safe, quality medical devices



For the purpose of all WHO documents, medical devices are defined as "an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose." They are not pharmacological, immunological or metabolic in nature.

WHO has conducted surveys of countries and the medical device industry to better understand their constraints. Some results are provided in Annex 7. Among the greatest barriers to access are: **cost, regulations, information for selection and training of the end user.** Moreover, WHO has issued calls for innovative technologies for (al devices, assistive devices and ehealth) and published a compendiums of these. (see <u>www.who.int/medical devices.en</u>). Box 3: KEY ISSUES CONCERNING MEDICAL DEVICES FOR THE AGED

- Older populations are not a priority in health systems
- No financial schemes for purchasing needed devices
 - Reliance on family out-of-pocket payment and some insurance to pay for treatment and products.
- Medical device industry is starting to look at ageing needs.
- Most are devices for chronic diseases
- High demand for innovative affordable devices for home health care and for limited settings where no specialized human resources are available.

WHO work to date on Assistive devices to support older populations

Seminal work on disabilities and required technologies was presented in the 2011 WHO-World Bank World Report on Disability (<u>www.who.int/disabilities/world_report/2011/en/</u>). The report highlights the value and benefits of assistive devices, barriers to access, and what works to ensure appropriate assistive devices are available.

The number of people with disability is increasing due to ageing, noncommunicable diseases and road traffic accidents among other causes. Yet, large gaps exist in availability. From the World Report www.who.int/disabilities/en/:

- More than a billion people, or 15% of the population experience disability, of which 110-190 million adults experience very significant disability
- Unmet need for Assistive Devices is considerable in low, middle, and high-income countries

- In many low-income and middle-income countries, only 5%-15% of people who need them have them. For example;
 - 360 million people globally with disabling hearing loss (5.3% of the world's population).
 - An estimated one-third of those over 65 years of age are affected by disabling hearing loss.
 - About 20% of people with hearing loss require hearing aids.
 - Current hearing aid production meets around only 10% of the global need and only 3% of the need in developing countries.

Looking ahead, better understanding of ageing and functional limitation (physical and mental) are required. With nearly half (46%) of people over 60 experiencing some disability, and that both those disabled and the elderly are living longer due to improvements in health, requirements for support (technologies) will increase significantly. Rehabilitation, assistive devices, and social innovations can improve functioning, independence, and reduce isolation.

Evidence from the World Report regarding some of the known health-systems-level barriers to accessing rehabilitation, including assistive devices – noting that people with disability are more than twice as likely to find healthcare provider skills or equipment inadequate to meet their needs; nearly three times more likely to be denied care; and four times more likely to be treated badly. A major recommendation of the World Report is, in addition to ensuring that people with disabilities have access to mainstream services, to "invest in specific programs and services to meet the special needs of people with disability"- this particularly refers to the provision of rehabilitation services and assistive technologies.

Some barriers to overcome include:

- Leadership and governance low priority, lack of policies
- Financing and affordability
- Service delivery
- Human resources
- Production
- Awareness, cultural and social barriers

National strategies and frameworks

A panel (moderated by Dr Moussy) presented illustrative examples of national strategies and frameworks to promote health innovations (devices) for ageing populations. The following examples were presented by Dr Oua Tanaka (Japan), Dr Tiemei Zhang (China), and Dr Josephine Bundoc (Philippines), with group discussion.

Japan's Medical Innovation Strategy and Japan's priorities for ageing populations

Rising health expenditures (overall population USD 400 billion in 2012), along with ageing of the population, are growing concerns for Japan. Life expectancy has been the highest in the word, and that the population of persons over 65 is growing at 2 to 3 percent annually. As a result a set of integrated strategies have been adopted to increase medical device innovation by the government:

- a) support for basic science development through "clusters"
- b) encourage hospital-device company collaborations for development
- c) revision of the regulatory framework (PMDA); and
- d) assessing reimbursement rates.

The government is focusing on strengthening availability of home health services (and thus the home health devices market). Reimbursement is seen as a driver for some devices' use at home (e.g., portable oxygen, infusion pumps, mechanical ventilators). Additional pilots are looking into remote health care management

using Information Communication technologies. The government is placing priority on assessing effectiveness, and looking at incentives for home-use devices as innovation to meet the needs of older populations. Similar to home accessories, the reimbursement system is revised and modified to ensure the safe use of medical devices independently.

Medical Innovation Strategy and Priorities for Ageing in China

The Chinese Government adopted a new strategy for ageing populations in 2011. Strategies, including for innovation, focus on the development of Elderly Affairs to integrate innovation, evidence-based and economically-viable devices. The strategy has six goals covering strategic decisions and long term planning; social security (endowment insurance, medical insurance); health care provision (primary care network, health education/self-care); care service (assistive devices); age-friendly environments; and management. All devices should be needs based, have wide coverage, evidence based, and cost-effective. Medical devices need to have a functional assessment, and can be targeted to prevention, diagnosis, management and rehabilitation. For assistive devices, characteristics need to include support for environment/devices, dynamic monitoring, include functional training, and communication and management.

An example of innovation being developed is Virtual Nursing Homes where home services are delivered via telecommunications. This is a way to ensure that the elderly stay at home longer and to compensate for the lack of home care workers. It was also mentioned that the focus on health education and health prevention to support communities and the elderly in China. Whereas local government has financially supported the programme, end user costs vary according to income level.

Medical Innovation Strategy and Priorities for Ageing in Philippines

Strategic elements encouraging innovation in the Philippines are designed to achieve four goals for devices: accessibility, affordability, acceptability, and appropriateness of medical and assistive devices. The elements include having a data base/registry of end users and service providers, cost effectiveness and local sourcing (including research into adaptable devices); technical expertise and support in the community; and community based implementation (ranging from satellite clinics, family and community caregivers, training, and facilitation of education). It was noted that national frameworks often do not include psychosocial (e.g. stigma) aspects linked to the use of assistive devices.

In addition, a set of useful incentives were identified to leverage more innovation: funding (e.g. scholarships, research grants, training); accreditation (Department of Health, other governmental/quasi-public institutions); market access (e.g. equipment/component suppliers, prostheses manufacture); tax exemptions (e.g. for importation); network/linkages; and providing national policy priority (e.g. through health insurance reimbursement). The example of the 'Walking Free Program' (a programme providing prostheses) identified how various incentives helped to scale up a local project to a national policy priority. It was emphasized that assistive devices need a community based support system for fitting, communication, maintenance.

During discussion, a comment was made on the need for patient privacy and cybersecurity. More broadly are issues of intended use of a given device, and risks for misdiagnosis or improper use.

B. Key Requirements to Increase Access

A second panel (moderated by Ms Adriana Velazquez) explored, using examples from various national contexts, key requirements to increase the access to medical/assistive devices in the WHO Western Pacific Region, and the role of innovation. Five presentations and discussion: a) Assessing demand and priority needs (low

resource environments and wealthier countries) (Mr Minh Tuan (Vietnam), b) Assessing product/technology availability (Ms Kylie Mines (Australia), c) Role of regulation (Mr Zamane Abdul Rahman (Malaysia)), d) the Role of health technology assessments (Dr Yot Teerwattananon (Thailand)), and Ensuring financing/assessing affordability. Each topic was contextualized and the content summarized as follows:

Overview of Vietnamese experience in assessing demand and priority needs of the Elderly

As the ageing population increases very quickly there is clear demand for more accessible medical and assistive devices. Vietnam's policy (Law of the Elderly, 2009) has placed communities and family units at the heart of health policies and health needs assessment related to the elderly. As an example, it was mentioned that since 2011, the General Office for Population & Family Planning has organized the implementation of "Advising and caring for the elderly with community supports" project with the main objective being to improve both physical and mental health of the elderly, contribute for improving life's quality and bring into full play the role of the elderly. Community based care includes periodic health examinations (free); and provision of monthly allowance for poor over 80.

Changes in patterns of disease are marked towards NCDs, with about 95% of older persons having at least one NCD, but most coping. Prevalence includes joint degradation (41%), cardiac diseases and high blood pressure (46%), prostate disorders (64%) and urinary tract disorders (36%). There are significant differences in access, with rural populations low. General awareness and knowledge of elderly health issues is low. In response, these are two priorities for issues to overcome, as well as increasing social and health insurance protection for the elderly.

Identifying key requirements for increasing access to medical and assistive devices and the role of innovation

General perspectives on ageing in Asia and the Pacific were presented that highlighted key requirements for increasing access to medical and assistive devices:

- the need to have a universal framework that categorizes assistive devices,
- the need to assess available needs and access pathways, and the
- importance of ensuring equitable access to all elderly in need.

Through examples taken from the Australian context, a strong point was made to find cost effective solutions and to involve elderly in the assessment of needs as well as in the development of inclusive policies to increase access.

Box 4: Assessment of 'availability' needs to encompass the 'access pathway':

- Design / production: are there appropriate devices that meet the priority needs of elderly people within the environmental, economic and cultural context in which they live designed and in production?
- Supply / procurement / affordability: are these devices available at an affordable cost and can they be procured easily by individuals / service providers? To note that, in the past, a key difference between medical devices and assisted devices was that medical devices are purchased by clinics and assisted devices are usually bought by the person.
- Universal health coverage-related issues are evolving, thus presenting a need to better focus the linkage with assistive devices and rehabilitation.
- Service delivery: what support services are required; what information / access points are there for elderly people; what training, follow up, support and maintenance is required and is this available?
- Outcomes / end result for the user: 'Available' in itself is not a measure of success more research with elderly users and their families as key informants is required to identify whether products are increasing quality of life.
- Equitable access how is availability affected at national and regional level by factors such as income; culture; ethnicity; gender; living remote from urban centres etc

Challenges and opportunities to/for assessing future **availability** of devices include:

- Development of a universal framework for categorising assistive devices;
 - Use the International Classification of Functioning (ICF) as a starting point to categorise assistive devices;
- Prioritising assistive devices given the different demands, expectations, economic, cultural and environmental factors;
 - With better rationalisation of devices there is an opportunity to reduce cost at national / sub-regional level;
- Affordability there is limited evidence or exploration of strategies to reduce cost.
 - Areas of research:
 - Service delivery models what is needed, what works and is cost effective;
 - How to scale up there is very limited research re how assistive devices can be provided on a large scale;
 - Cultural influences on assistive devices demand and use;
 - Involve elderly people in research as the drivers of what they need and what works for them.

Issues of stigma and dignity were raised, particularly in the context of hearing aids. Decision-makers and product designers need to consider perceptions of being "old" or "disabled", that aesthetics is important, and the role of a device in lifestyle values. Ensuring patient/client **compliance**, **adherence**, **and avoiding abandonment** are important issues. Obtaining user inputs at the initial stage and providing training were two potential solutions.

Role of Regulation

Regulation is an imperative for public safety and is a tool that can help encourage local industry in making devices available. At the same time, the compliance to internationally recognized frameworks such as the **Global Harmonization Task Force (GHTF)**³ **now the International Medical Devices Regulators Forum (IMDRF)**, principles is essential to support the harmonization of medical devices . The challenge is to develop the balance needs for cost-effective and affordable production/design/availability, with ethics, safety and usability of the devices in various contexts and for various needs. Similarly challenges in expediting regulatory reviews remain, are seen as a hindrance by industry. Some additional challenges include:

- Classification of device variations and the safety and performance differences.
- Regulatory aspects don't target service and disposal (all steps in the life cycle).
- Matching safety and Efficacy with intended use.
- Need and scope of clinical trials and pre-market approvals.

Discussion within the group highlighted several points:

- National Health Plans may or may not include reference to health technologies (medical or assistive devices) nor to the relevant to different population groups. Fragmentation is an issue.
- Similarly, fragmentation and confusion exists as which Ministry or Office is responsible for different device groups. Different laws and regulations may consequently apply.
- Government agencies may also differ: one agency being responsible for safety and efficacy; others for reimbursement.
- The regulatory environment and innovations/products themselves are changing rapidly what are the implications for governments, and access/availability of devices?

³ See <u>http://www.imdrf.org/</u>

Role of Health Technology Assessments (HTA) in increasing access to medical and assistive devices: a case of Thailand

The role of HTA is to provide support for decision makers at national level. The main concerns refer to the safety, the benefits, the cost effectiveness, the social/ethical and institutional aspects of devices that may be prioritized by governments to be part of social insurance schemes. Roles of HTA were further delineated along two key dimensions—a) market authorization (define quality, safety, and effectiveness) and reimbursement (defining value for money).

The HTA process is described below:

HTA process

- 1. Identifying topic for assessment
 - identifying policy gap
- 2. Assessment- generating policy relevant evidence
- 3. Appraisal (appeal)
- 4. Result dissemination

- Empowering stakeholder participation in policy process
 Making resource allocation decisions to be more accountable and transparent
- Ensuring effective implementation

With its different phases, the emphasis is on inclusiveness. This has been demonstrated in Thailand. A sophisticated HTA system has been implemented to classify interventions under Thailand's Universal Health Coverage Scheme. However, a few case studies highlighted the benefits and the limits of the HTA when it comes to political decision making. In cases where safety, efficacy/effectiveness, and value for money parameters were all met for several interventions for the elderly, only one was agreed for coverage. The main obstacles to more favorable decisions for the adoption of devices were:

- Better understanding of social values of assistive devices, medical devices in comparison to other treatment e.g. giving a higher value for end of life or critically ill over dysfunction or disability
- lack of information regarding social, health and economic impact of disability or impairment of ageing population
- ack of information regarding effective and cost effectiveness of medical and assistive devices
- the need of multidisciplinary approach which is lacking in many governmental authorities

Increasing ageing of the population may increase the political will to understand the needs and HTA factors that go beyond clinical interventions. This, in turn, will help advance technology and will be supported by Universal Health Coverage.

Discussion on the role of HTA in decision making raised the following points. HTA and its related methods can help elucidate decision making. Concerning rapidly changing medical and assistive devices, and that they are not traditional medical interventions, a number of issues and challenges need to be dealt with:

- Data is often immature, particularly for safety, efficacy and value for money, and to demonstrate impact.
 - WHO can play a role by providing statistics and international comparable data, as well as to weigh for different diseases/conditions, and epidemiologic data across a broad spectrum of patients, diseases, etc.
 - Industry can provide data

- Role of devices for self-diagnosis and management of care (e.g., pharmacies/ supermarkets having sphygmomanometers)
 How to link this to increasing access to prevention and care
- Prioritization of devices requires assessment of socio economic value. However, a related question is "what is the socioeconomic risk and costs and impact of <u>not</u> having the device (benefit Risk Analysis). An example is whether the benefit of an "adult diaper" that allows a person to be able and comfortable to go out and work and increases personal dignity, social inclusion, and economic productivity (household and community) is considered?
- Decision makers need to include more uncertainty in the HTA process, including as the process is weighted towards clinical decision makers, financing, and settings. Balancing assessments (impact, outcomes, socio-economic benefit) is needed.
- Nature of financial decision making in a country needs to be assessed—for example, a Ministry of Health may only be able to finance hospitals—what are financing options for community based care?
- If assisted devices are seen as welfare, different government financing pathways are implicated.
- Other examples of measures include those to measure quality of life, cost of informal care(e.g. 24 hour care)
- Assessing impact is also important, particularly to help in prioritizing different medical devices or assist devices in relation to clinical conditions. How much does a specific device impact on a disease or condition? (e.g., surgical procedure vs. non-invasive).
 - Special attention is needed to also devices that help early detection (a high social value).
- There is a need to update HTA methods.

Table 1.

Besides, , WHO is developing a set of "core" or "priority" devices for health care conditions Concerning regulatory issues, the IMDRF and WHO are working to support convergence or harmonized regulations that would enhance a more efficient regulatory Concerning procurement, WHO is working on Technical specifications that would allow better procurement, this specifications are more linked with the variability of the device (e.g., whether manual, semi-automatic, automatic).

C. Systematic Reviews - Progress to Date

Dr Moussy provided an overview of the WHO-commissioned studies, the systematic review of medical devices for diseases relevant to ageing populations and the survey on assistive devices, respectively, in eight Asian countries. As this was the first phase to understand the nature of availability of and barriers to medical and assistive devices, respectively, the researchers relied on surveys and literature reviews. There were a number of limitations, including gathering country information, scanning the horizon for early product development, assessment of clinical safety and effectiveness, and availability of cost-effectiveness data. The executive summaries of the **final** systematic reviews (issued since the Consultation) are attached at Annex 4 and 5.⁴

The following table summarizes the device categories for each of the reviews/studies:

Assistive Devices	Medical Devices
Assistive devices responsive to conditions causing most YLDs in persons 60+ (2004):	Medical devices to address health conditions that were the top three causes of disability-adjusted life year (DALY) for older people (60-79 years of age). Due to time and financial constraints, the systematic review will be limited to the list of three main health

⁴ These can be accessed on the WHO Kobe Centre website: www.who.int/kobe_centre/ageing/en/

Assistive Devices	Medical Devices
	conditions and 13 specific topics
 Barriers to access: Category 1: Lack of awareness is main barrier [may be available and affordable but a lack of information/awareness affects uptake] Category 2: Lack of affordability is the main barrier [may be available but not affordable] Category 3: Lack of suitability/appropriateness is the main barrier [may be both available and affordable but not suitable or appropriate] Category 4: Lack of availability is the main barrier [not available] [Category 5: Insufficient information] 	 Each medical devices was analyzed as: Preventive Diagnostic (including In Vitro Diagnosis) Therapeutic Specific mode of action (e.g. imaging, cauterizing, recording) Status at an international level
Categories for Review	Categories for Review
 Sense organ diseases Cataract Refractive errors Hearing loss, adult onset Macular degeneration and others Neuropsychiatric conditions Alzheimer + other dementia Cardiovascular diseases Ischemic heart disease Cerebrovascular disease Hypertensive heart disease Respiratory diseases COPD Musculoskeletal diseases Osteoarthritis 	 Cardiovascular diseases Ischemic heart disease Cerebrovascular disease Cerebrovascular disease Hypertensive heart disease Malignant neoplasms Trachea, bronchus, lungs Colon, rectum Prostate Lymphoma Breast Stomach Liver Oesophagus Mouth + oropharynx Respiratory diseases COPD Sense organ diseases Glaucoma
	 Cataract Refractive errors Hearing loss, adult onset Macular degeneration and others Neuropsychiatric conditions Alzheimer + other dementia

Assistive Devices

Ms Beth Sprunt, Senior Technical Adviser, CBM-Australia – Nossal Institute Partnership for Disability Inclusive Development and Prof. Guy Maddern, Surgical Director of the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) group of the Royal Australasian College of Surgeons (ASERNIP-S/INAHTA), outlined the goals of the two studies commissioned by WHO on the Needs, Availability and Affordability of Assistive and Medical Devices for Older People in 8 countries in the WHO Western Pacific Region.

Ms Sprunt outlined the goals of the study on assistive devices in the Western Pacific (specifically reviewing the

following countries: Australia, China, Fiji, Japan, Malaysia, Philippines, Republic of Korea and Vietnam). She indicated that the vast majority of people which are over 60 years old, fall in the categories of disabilities as per ISO 9999 classifications, and that most of their needs are on personal mobility devices, and are neither widely available nor affordable products for most of the population. More examples of common assistive devices included in the Review are included below:

Class of assistive device	Examples of assistive devices
Orthoses and Prostheses	Upper limb orthoses, lower limb orthoses, upper limb prostheses, lower
	limb prostheses, orthopaedic footwear
Assistive products for personal care	Assistive products for dressing and undressing; toileting; incontinence
and protection	management; bathing, showering and washing;
Assistive products for personal	Assistive products for walking (e.g. walking sticks, crutches, walking
mobility	frames); manual wheelchairs; powered wheelchairs; assistive products for
	orientation (e.g. white canes); assistive products for lifting people (e.g.
	hoists)
Assistive products for house keeping	Assistive products for dishwashing; housecleaning; chopping and
	measuring food; preparing and cooking food.
Assistive products for communication	Assistive products for seeing (e.g. spectacles, magnifiers); hearing (e.g.
and information	hearing aids, amplifiers, headphones); adapted alarms; telephones;
	writing boards; Braille typewriters; computers, computer software and
	technology (e.g. Braille printers, audible computer displays, screen
	magnifiers); calculation products
Assistive products for handling	Assistive products for carrying and transporting objects; reaching and
objects and devices	grasping objects;

Table 2: Examples of Common Assistive Devices

Box 5: High level findings from the preliminary report on Assistive Devices include:

- Personal mobility devices (walking sticks, crutches, frames, wheelchairs) were most available.
- Devices for handling objects and for housekeeping (e.g. preparing food) were not widely available and where they were, were often considered unaffordable (often not covered by subsidy schemes, where these existed).
- Quality is a concern for devices requiring customisation (e.g. for hearing aids, wheelchairs and spectacles).
- Affordability of devices is a key concern, with subsidy schemes playing a key part in making devices affordable for elderly people and their absence proving a barrier to affordability.
- In **Fiji** (and most other Pacific Islands countries) lack of availability of devices is a critical issue.
- Lack of information about assistive devices a major barrier (for consumers, service providers, planners, etc.).
- Broader context of access to health systems:
 - affordability of transport to urban centres where the majority of assistive devices are available;
 - availability of therapists or technicians to fit and maintain assistive devices;
 - Channels for identification and referral (e.g. CBR, HCW);
 - Service delivery infrastructure
 - Capacity development of technicians and therapists is critical.
- Korea and Japan appear to have good availability of assistive devices both in cities and rural areas; in addition, the cost of prostheses and orthesis is a barrier everywhere except Japan and Korea. The modes of delivery and funding in these two countries may be worth further investigation.
- The supply and subsidisation of appropriate assistive devices is only one component of a successful assistive technology 'solution'. Environmental, social and cultural factors should also be considered, e.g. concerns around wearing hearing aids
- Decisions around production and provision of assistive devices should take into account existing programs such as Community Based Rehabilitation programs or other local responses.

Additional issues raised:

- Tension between increasing access versus risk of sub-optimal quality
- Mechanisms for quality control of assistive devices and of the training
- Mechanisms for maintenance and parts replacement
- Partnerships between health systems and NGOs in many places this has been the domain of NGOs
- Who determines eligibility for subsidy schemes
- Options around loans schemes
- Access to information for consumers and service providers centralised database? Independent Living Centres?
- Mechanisms for technology transfer between countries
- Addressing barriers related to taxation

Key discussion points included:

- Rural /Urban need to think about when it's appropriate to be available? Is it appropriate to do the activity in identified in the rural region or should patient go to centralized location. No one solution is appropriate. Roving team vs. at location.
- Differences between urban and rural but also, urban variations discussed.
- A need to understand urban/rural differences in access and availability, as well as intra-urban environments, and across countries.
- Analysis into drivers for and barrier to access for assistive devices and related services (e.g.; need for additional community support services for assistive devices), cultural differences, perceived need and perception, and where people obtained/serviced their devices would be helpful. (e.g.; getting their limb at a center vs. getting it in their rural area)
- Recommendations for adapting a whole home, especially given differences in housing?
- More understanding of the preliminary findings that some personal devices (e.g. white cane in China/Japan) are not subsidized. What is the role of the population group (e.g., elderly vs. visually handicapped) or on nature of device (e.g. prosthetic or not) on funding?
- Greater clarity for assisted device terminology (e.g. guide dog? Animal inclusion?), definition of access (e.g. walking or driving time?) --variation by characteristics of the community, and at perceived vs epidemiologic based need.

Medical Devices

Prof. Guy Maddern, Director of ASERNIP, presented the results from a systematic review of medical devices conducted for 19 disease conditions which represent the largest burden of disease in 5 categories: cardiovascular diseases, malignant neoplasms, respiratory diseases, sense organ disease and neuropsychiatric conditions. Focus was on older people aged from 60-79 years old.⁵ It was noted that a prioritized list of

⁵ From the **Systematic Review on Needs for Medical Devices for Older People**, Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S), February 2013: There is no clear, universally accepted **definition of elderly or aged**; the concept of ageing encompasses chronological age, changes in social roles and changes in physical, mental and functional capabilities. The age at which someone is considered elderly varies between countries and is often associated with the age at which a person becomes eligible for pension schemes or retirement: this is usually between 60 and 65 years. Defining old age is challenging as its onset is not defined by a single physiological phenomenon and its manifestation varies across individuals. The process of ageing involves physical, physiological and social changes and is considered by many to be a stage of life in which a person's functional, mental and physical capacity is declining. Older age is also associated with an increased propensity to disability and disease as a consequence of the cumulative effect of a range of deleterious changes in the body. Whilst chronological age is the common basis for determining old age by governments, demographers and researchers, it may not be equivalent with an individual's biological age. An increase in a person's chronological age does not necessarily lead to ill health. The United Nations applies 60 years as the cut-off for older people, so the health conditions which are the subject of this project were identified by examining the top five causes of DALYs in persons 60 to 79 years in the Western Pacific Region.

needed devices will likely benefit from a consideration of other methods, including those of economic evaluation and social impact, input regarding clinical, policy, organizational and infrastructure issues, together with research contextualising the results to each country.

The leading causes of mortality in the Western Pacific Region are represented in Table 3. Communicable, maternal, perinatal and nutritional conditions accounted for 10 per cent of all-cause mortality, injuries accounted for nine per cent and non-communicable diseases accounted for 81 per cent. Table 4 includes the major causes (10 per cent or more) of projected DALYs for 2008 in the Western Pacific region. The largest proportion of mortality due to non-communicable diseases occurred in persons over the age of 60.

Cause of mortality	All ages: total	All ages: all	Persons > 60	Persons > 60
	estimated	causes of	years: total	years vs all
	deaths	mortality (%)	estimated	ages estimated
			deaths	deaths (%)
All causes of mortality	12,673,680	NA	9,095,745	80
Non-communicable diseases	10,237,989	81	8,161,242	80
Cardiovascular disease	4,734,713	37	4,058,705	86
Cerebrovascular disease	2,504,051	20	2,167,963	87
Ischaemic heart disease	1,383,104	11	1,173,219	85
Malignant neoplasm	2,659,967	21	1,791,910	67
Respiratory diseases	1,586,931	13	1,459,320	92
COPD	1,373,136	11	1,293,907	94

Table 3	Estimates of deaths by cause for	2008 in the WHO Western Pacific Region, major causes of de	eath
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NA – Not applicable, COPD - chronic obstructive pulmonary disease. Note: table figures numbers should not sum. **Source:** Health Statistics and Informatics Department of the World Health Organization. Causes of death 2008 summary tables. Geneva: World Health Organization; 2011 [cited 2013 Jan 25]. Available from: http://www.who.int/evidence/bod

Table 4 Major contributions to projected DALYs for 2008 in the WHO Western Pacific Re

Cause of DALY	All ages: total estimated DALY	All ages: all causes of DALY (%)	Persons > 60 years: total estimated DALY	Persons > 60 years vs all ages estimated DALY (%)
All causes of DALY	255,142,224	NA	64,201,717	25
Non-communicable	185,165,801	73	58,513,149	32
diseases				
Cardiovascular disease	31,545,792	12	18,627,426	59
Malignant neoplasm	26,508,614	10	10,877,197	41
Sense organ diseases	26,308,739	10	7,604,496	29
Neuropsychiatric	49,135,862	19	5,058,346	10
conditions				
Communicable disease	38,759,236	15	3,264,626	8

NA – not applicable, DALY – disability-adjusted life years.

Source: Health Statistics and Informatics Department of the World Health Organization. Global burden of disease 2004 summary tables. Geneva: World Health Organization; 2008 [cited 2013 25 Jan]. Available from: http://www.who.int/evidence/bod

The methodology used relied on a systematic review of over 3000 papers, with an ultimate reliance on 1535 papers (PubMed) covering medical devices and the aged. The team reviewed a number of examples for each of

the five core disease conditions along prevention, diagnosis, and therapy dimensions. All three were seen as key to management of various disease conditions. The report identified a robust list of devices over a range of conditions (the Executive Summary is at Annex 5), along with some key issues.

It was recognized that there were different clinical options and outcome values for each of the devices. Clinical practice guidelines were not often required as a supplementary resource and results had broad clinical applicability. However, the absolute and comparative clinical safety, effectiveness and cost-effectiveness of devices was usually not clear. It was noted that clinical practice guidelines are valuable in determining appropriate clinical management and use of devices—but they are often country-specific and are written within the context of the skills, resources and infrastructure applicable to that jurisdiction (usually developed countries). Moreover, in developed countries, access to and use of complex and expensive medical devices are more common. Devices associated with performing surgery were commonly not reported. Concerning ageing populations, some minimally-invasive devices were identified, but clinical effectiveness was not clear.

A few examples from the Review highlight a few findings as well as issues for further consideration.

- Magnetic resonance imaging and computed tomography were common imaging devices across cancers and cerebrovascular conditions. Various forms of endoscope were used frequently for diagnostic and therapeutic purposes for a range of gastrointestinal cancers. Ultrasound was commonly used for diagnosis and in providing guidance for biopsy and surgical procedures.
- In cases where there are many medical device options for a given intervention, it was difficult to assess what the more common techniques were, and the clinical benefits of each device. For example, a wide range of imaging devices may be used during diagnosis and staging for cancers. In these circumstances, the device used may be informed by its availability, and may also be guided by clinical preference. Medical practice thus determines use and choice of certain devices. Imaging devices, as with all other medical devices, are under continual improvement, with new versions offering improved image quality and specificity with less risk to the patient. The absolute and comparative clinical need of these additional tests was often unclear, and detailed studies of comparative safety and effectiveness would be needed to further inform on these issues.
- Similarly, radiotherapy devices are offering more accurate, image-guided delivery of higher doses of
 radiation, which has the potential benefit of offering an equivalent therapeutic dose of radiation with
 fewer sessions and fewer potential adverse events. This may be more acceptable to older patients, and
 may also be of great convenience to patients living in rural or remote areas where regular access to the
 larger hospitals in major metropolitan centres is difficult. The absolute or comparative clinical
 effectiveness or safety of these newer types of radiotherapy devices was not clear from the preliminary
 research. Other benefits for people in remote areas include the use of remote programming technologies
 in cochlear implants and also for monitoring cardiac resynchronisation therapy implant function. These
 and other similar telemedicine facilities would depend on the availability of appropriate infrastructure for
 service delivery.
- There is **significant variability in the costs** of the identified medical devices, with some basic items being very cheap, and other larger and more complex devices being very expensive to purchase, use and maintain. The Study did not allow a more detailed examination of the comparative or absolute cost effectiveness of these devices, and this issue may benefit from further research.
- The use of pathology equipment used to test biopsy samples was infrequently reported and imprecisely

described. This may reflect an assumption that pathology equipment or testing protocols are similar across jurisdictions and points to the limitations in transferability of results obtained in high resource settings and their application in low resource settings. For many of the in vitro diagnostic tests, the test was mentioned in the absence of any specific instrument or equipment. However, it is likely that some form of medical device would have been involved for most, if not all, of these tests. In general, diagnostic tests were poorly represented in the identified literature.

 Medical devices with applications in palliative care or in chronic diseases may be of particular importance in the elderly as patients often present with co-morbidities or be unsuitable for surgical interventions. Newer medical devices may offer new or alternative treatment options, but even where these alternatives are available the final decision regarding the treatment may also be informed by a range of personal choice and belief together with other society and cultural considerations.

Discussion pointed out the need for determining optimization of outcomes by device, as well as to be informed by the needs of health workers, older persons themselves, clinical guidelines for specific conditions, as well as location of the use of the device: clinical setting or home. Country, and subnational, variations need to be assessed for requirements, outcomes, as well as available resources. Recommendations for device use should be within a context, particularly to identify whether they are essential. Driving this is the need to understand the prevalent disease states inherent in a country context. Additional constraints are available budget. In some countries (e.g. Malaysia) urban centers have a good deal of medical devices, but rural areas are weaker. Decisions thus need to be taken whether to make resources available in rural areas or to transfer patients to urban areas. In addition to the majority of medical devices used In clinical settings, are needs to identify those medical devices that are of benefit in the home or community for diagnosis, management, and treatment, and can lead to reduced hospitalizations. Incorporating e-Health or m-Health technologies and processes into use of these medical devices is an essential need to ensure continuity of care and safety.

Additional suggestions were that prevention, and potential need for and use of medical devices, be taken up more aggressively, with consideration given to critical elements of device classification, cost, training needs, and resources in determining need and availability. Most clinical guidelines assume that essential devices are available—a false assumption, as well as that they tend to focus on very specific, specialized technologies. A change in perspective is thus required. Guidelines have to be adapted, particularly in the context of available country infrastructure.

D. Perspectives: Industry and Users

Global Industry Perspective

Dr Satoshi Kimura Vice-Chair of Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (DITTA), advocated for the use of technologies to help face the challenges in health care, and to change the paradigm from "sick care" to "health care". DTTA is a parent association to a number of regional trade associations in the area of medical devices. Perspectives also reflected those of the Global Medical Technology Alliance. It was noted that industry believes it is appropriate to ensure equality of opportunities and fair access, appropriateness of technology, improve connectivity for healthcare professionals and monitoring management for older people. On a regular basis, the industry is innovating with new and emerging products for public and private care that can support the health provision for older populations.

Additional points raised concerning industry's actions and perspectives:

- Shortening the gap between research and the market.
- Developing integrated care solutions easy to use aimed at improving patient care (better quality of life), access (patient empowerement), effectiveness (individualized intervention) and reducing costs (reduced hospitalizations): to benefit to clinical staff, patients and society.
- **Technology** can play an important role
 - Provide accessible, affordable, appropriate diagnostic, imaging and therapy health solutions
 - Adapt homes: Provide aging people with a safe environment; helping remain at home longer
 - Education: Technology improves connectivity for healthcare professionals and older people
 - Ensure equality of opportunities and fair access
 - To benefit from advanced use of information and communication technology and ensure information is shared in a secured manner, including protection and privacy of citizens

Some key challenges

- General economic crisis and healthcare national budget constraints
- Growing concerns: PIP; Hip implant, breaking thin pacemaker leads, Pelvic floor meshes → Zero Risk is not a practical goal
- Regulatory science labours to keep up with rapid pace of device innovations, and consideration of costs to register in many countries
 - Need to engage patients, and understand different risks
 - Combination and integration of diverse technologies bringing innovative solutions for the benefits of patients but also increasing complexity
 - Without concerted efforts of regulators, countries and industry will have continued global products while still facing challenges for multiple local regulations
 - Other regulations outside IMDRF control: radiation, dose reduction, RoHS, WEEE etc...
 - Decentralization of healthcare (i.e., remote diagnosis, mHealth): implications for needs and for regulatory oversight

New trends include:

- New and emerging technologies (MR/PET, biomarkers, biosensors, etc.)
- Integrated technologies (product and services) to cover the continuum of care
- Public Private Partnerships (establishment of consortia)
- Development of telehealth, mobile Health, cloud computing, remote care... with more ICT players
- Collaborative partnerships with academia, users and professional organizations (optimization programs- e.g. CT dose, user training).
 - Shift towards personalized, preventive and predictive medicine

Global manufacturing influenced by:

- Regulatory pressure
- Cost of labor
- Closeness to appropriate resources and to raw materials
- Proactive approaches towards Green Technology for more sustainable solutions (e.g. Eco-Design)
- Contribute to recycling economy
- Supply Chain Integrity:
 - Industry supports efficient supply chain integrity, especially as technological solutions become complex (including reliability, consistency and trust in the system)
 - Industry desire for use of established references already existing in International standards used in other sectors

Box 6: Among recommendations for the future, several points were raised by industry representatives:

- Innovative technology has to be considered as long-term investment
- Stakeholders should partner in the implementation and uptake of innovative technology
 - o Governments should:
 - Invest in health information campaigns and social programs to improve awareness and tackle key issues
 - Secure human resources and improving social welfare
- Need for faster transfer of innovation from research to market
- Accelerate the adoption of new methods and technologies into clinical practice
- Trends are today showing the uptake of technologies (more integrated solutions with key role of eHealth)
- Increase procurement efficiency and transparency
- Harmonize regulatory frameworks and product approval processes to foster innovation and improve global trade
- Compile healthcare best practices amongst Member States
- **Consider** multi-stakeholders approach
- Take advantage of technologies ensuring better access for patients, better quality and safety, and cost-efficiency

Discussion presented a new trend of rapidly evolving three dimensional printing/ manufacturing, and use of open source (hardware and software) that influences design of product. This will have a profound impact on devices, and presents a need for standards for customizable point-of-care manufacturing. Many industry groups and industry organizations like DITTA are looking at such standards.

Users perspective

Mr KP Tsang, Chair Elect of the International Alliance of Patients' Organizations (IAPO), an alliance of 215 national, regional and international groups representing patients (50 countries, 365 million people). He particularly focused on three important elements to consider when addressing the needs of elderly in terms of assistive and medical devices.

First, there is a need and value to address patient's needs and advocate for patient-centered approaches to innovation. Patients have expertise for their own conditions, and often are able to highlight unanticipated benefits and preferences. Patients should be the center, not the disease or body part.

Second, a key role of the civil society is to capture the voice of patient and to make sure that they are involved in decision that will affect their own life.

Third, IAPO is supporting five key priorities for patients based on the IAPO Declaration on Patient-Centred Healthcare to increase patients' voice and to *answer the needs of patients* :

- **Respect and support** for the individual patient, their wants, preferences, values, needs and rights (inclusive of families and patients). Dignity is essential. Does the device help to empower?
- Choice and empowerment
- Patient engagement in health policy
- Access and support

• Information that is accurate, relevant and comprehensive In local language and lay person terminology to support patients understanding?

It was noted that patient-centered approaches can vary across cultures and regions. Recommendations included:

- supporting patient networks and to enhance patient perspective,
- include patient groups in broader collaborations with all stakeholders in healthcare sector, i.e., decision-making committees with providers
- engaging patients in the design process (both patient's organizations' and individual patients)
- Research on what patients' value

Discussion raised the question of respecting patients' rights in the context of patient assessment and engagement. Caution was raised on protecting privacy and data, and to understand national laws in this context. Regional and cultural variation exist. Concerning prevention, IAPO noted that they contribute to changing personal health behaviours (e.g., stop smoking).

E. Roundtable Discussions - Needs, Barriers, Solutions

Theme 1: Identifying Needs and Criteria for Prioritization

This session intended to allow exchange of views, expertise and experience on needs and criteria to prioritize medical and assistive devices, taking into account the diversity of country contexts.

Concerning Assistive Devices, mention was made to think about altering their nomenclature to 'Assistive solutions' as a way to include the systems that encompass such devices.

Table 5: Needs and Criteria for Prioritization

Μ	edical Devices	As	sistive Devices
Ke	y Elements to consider:	Key	y elements to consider:
1.	Burden of Diseases as a fundamental base of	1.	'Appropriateness' (or capacity to meet the needs
	assessment		of the patients)
2.	Regulatory bodies to ensure the safety and	2.	Health Equity to ensure socially responsible
	effectiveness of the devices		decision-making
3.	ISO Standards as a benchmark to evaluate devices	3.	Burden of Disease to provide a base for decision
4.	Affordability of the devices take into		making
	consideration	4.	Environmental context to identify which
			'solution' are most appropriate
Ne	eds for information:	Ne	eds for information:
1.	Burden of existing conditions: physical, social,	1.	Prevalence data for various conditions, including
	economic impact on the individual, society, extended		co-morbidities
	family, as well as future burden trends	2.	Total costs associated with delivering technology
2.	Reasonable understanding of basic profiles for	3.	Research on individual cost-benefit of Assistive
	products – the needs		Devices; as well as cost to the health system of

Medical Devices	Assistive Devices		
 Understanding of what is available – existing technologies. Are they safe and effective Feasibility: maintenance, training needs, technical support needs, regulationResources in place to ensure delivery? Capacity building, infrastructure needs? Outcome—to what extent does a technology address burden/need? 	 providing it versus not having it 4. Identification of the total package of services required for an assistive device – ie. the "assistive solution", including training, infrastructure required, etc. 5. Personal preferences, perceptions, realities, and barriers to obtaining/using assistive devices 6. Unmet need 7. Needs of ageing health workers 		
 cost what resources must be used to denete outcome? Available? 7. Decision analysis—model different sets of allocations. 8. Modularity/complementarity- build devices on earlier generation, but avoid redundancy 9. Evolving trends 10. Quantitative factors and qualitative judgements to allocate resources. E.g., do you spend \$10,000 on 10,000 pairs of \$1 glasses or on a few patients? Means to obtain information: Evidence based approaches Maximize transparency and participatory approaches Fair representation of all stakeholders (epidemiologists, economists, stakeholders). 	 Means to obtain information: Cyclical data gathering (older people and families and carers, and health professionals) – including focus group discussions, surveys, in-depth interviews, participant observation, including what are the reasons people do and don't take up ADs Talking to: consumers about their needs Industry about R&D progress on ADs, including horizon scanning (outcome measures) health professionals Getting data from NGOs and health services who provide ADs to look at their current provision Online survey which consumers can feed into; and feeding information from other countries through 		
	is comparability, e.g. in "access)		
 Additional Points: Burden of disease in any context to include: individual, societal, economic, & health care burden. Screening and detection important Common mortality and factors affecting most on quality of life Euroctionality 	 Additional Points: Appropriateness" – meets the user's physical, social and lifestyle needs and environmental conditions; provides proper fit and support; is safe and durable; is available in the country; and 		
 Regulatory review: safety (designed well, good manufacturing, must be safe) Post market surveillance and methods of recall Reaching ISO standards Devices –are they the best? Choice? Use of HTA, Developed and developing countries—quality of life 	 can be obtained and maintained and services sustained in the country at an affordable cost. Not only needs but Rights (eg. CRPD) Equity across impairment groups, and in socioeconomic, ethnic, geographic, gender, etc. Burden of the functional loss (proxy – disability provalence disagregated into impairment type) 		
 differences? Industry support for burden of disease evaluation—focused on greatest need; reduce expensive interventions. Disability associations with burden? Stop early death, then focus on quality of life, then disease burden Need to stop diseases at early stages. But need 	 The impact of the Assistive Device on the functional capacity The cost of not having the AD What support systems exist in the settings in which the AD would be used The environmental context for the AD – ie. condition of 		
 treatment options. Alzheimers: what approach to take? Affordable devices need to be considered. Unmet need a criteria for priorititization 	 roads in villages in relation to selection of wheelchair Explanation of why cost is not a criteria – ie. need based on function (activity and participation limitations) would be the basis for decision-making, 		

Medical Devices			Assistive Devices						
•	Differentiate low and high resource settings. Latter could include BP measurements, glaucoma screening, etc	and affor	that dable	innovation devices avai	would lable	follow	this	to	make

Discussions further identified key parameters in helping to shape priority identification:

- Medical and Assistive devices (or Assistive solutions) needs are different
- The burden of diseases is an important factor to discuss, however the focus on burdens associated with age is not a relevant issue
- Consideration of device needs also to address prevention and health promotion, such as risks factors-hypertension and smoking
- The use of ICT technologies, particularly in developing countries, offer promising potential
- There is a general gap of information provided to the industry, hence a tendency to manufacture complicated, expensive and not user friendly devices for elderly that also take into account access to electricity, extreme heat/cold, and other environmental factors.

Theme 2: Identifying Barriers

This session allowed exchange of views, expertise and experience on the key barriers to ensure that needed devices are designed, delivered, financed, used and improved appropriately and within country specific contexts.

Summary details of the group work are given in Table 2. Main points are highlighted below:

For Medical Devices, the participants identified 5 key barriers to consider:

- Lack of harmonization of regulatory schemes
- Limited monitoring systems to assess the performance of devices
- Intellectual Property issues hindering technology transfer
- Unaffordability of the devices due to poor reimbursement mechanisms and maintenance needs
- Poor health literacy of users/patients and lack of training of medical personnel

For Assistive Solutions, participants identified 7 key barriers to consider:

- Insufficient market research
- Design focuses on innovation against simplicity
- Lack of harmonization of regulation (though overregulation can also be a danger)
- Obsolescence of devices and lack of 'trial' mechanisms
- Lack of trained personal and weaknesses of service delivery
- Lack of intersectoral collaboration across care pathways
- Insufficient insurance systems with limited reimbursement possibilities

Key conclusions were drawn from group discussions:

- The design of devices which responds to both the needs of patients of medical personnel is a challenge. Litigation fears due to changes in regulation and security issues might be deterrent factors for the development of such devices (in some countries)
- Too often, devices lack an enabling environment to be effective, a.i. patient's health literacy and medical personal training, especially in low and middle income countries
- Everyone agrees that for the specific needs of the elderly, the barriers can be the obsession of technology, and obscure the need for simplification (which might increase reliability and usability)
- Ultimately, lack of regulation and weaknesses in the service delivery system pose the greatest barriers and need to be addressed through better guidance for policy development and device production.

Medical devices

		Product Development			Utilized examples to
Service Delivery	Governance	(incl. differentiated between simple	Users	General	walk through the
		& high tech devices)			discussion
Financial: lack of reimbursement	Policies – whether devices are	-Insufficient budget (possibly structure of	-Training for patients,	-Training across the spectrum is key	Home Use Device, Sphyg :
- Availability: lack of location	included in national health plan	budget for innovation)	medical personnel,	Information is imperative to making	Availability and patient
availability	Inadequate prioritization.	-Insufficient innovation of design inputs	family	optimal solutions	compliance and regulatory
Procurement-related:	Budget & Insurance is missing	-Lack of challenging speed for Venture	-Total costs as seen by	-Governance and policy key to	implications,
avoiding conflict of interest (COI).	Inadequate evidence base	Capital Companies	patients	supporting financial access	Imaging Device for Digital
Having a transparent purchasing	Lack of harmonized regulatory	-Regulation is an obstacle	-Unmet needs	Maintenance costs out of pocket or	X-Ray Machine: Cost and
process. Throughout the system	processes	-Unaffordable intellectual property (hi	-No information for	paid for?	maintenance activities and
the Financial, Professional (Clinical	Safety and efficacy implications,	tech devices)	user,	-Clarity on conflicts of interest and	regional challenges,
Studies and Bias), Medical	Lack of coherent policies and	-Technology Transfer, Lack of human	-Lack of understanding	the implications on practice of	Start-up costs vs.
Decision (Surgery norm decision)	process for approval	resources (Low tech devices)	of information by	medicine,	Maintenance Costs
Need to be cautious of stepping	-Inconsistent regulatory requirements	-Inadequate incentives for industry to	consumers	-Discussion of maintenance costs	covered by different
into the practice of medicine	-Inadequate financing,	develop		and implications (location impacts	organizations, ROI
Rapidly evolving requirements	-Lack of incentives			CT in large city, less of impact than	
with many actors	-Lack of funding for maintenance			in rural community)	
Transparency, Insufficient target				 -Affordability for maintenance, 	
in the medical device arena,				initial costs, Who provides	
Performance of device post				maintenance, funding? Initial and	
market surveillance systems				long term? Will vary between high	
lacking for long-term performance				end/ home use	
monitoring,				-Significant research needed	
Lack of "total" solutions is the				(globally coordinated and	
lack of availability having				non-duplicative)	
complete system					
Inadequate training of					
professionals; skills					
Supporting infrastructure					
inadequate					

Assistive Devices

	General	Middle/High Income Settings	Less Resourced Countries/Settings
Design/ Production	 Knowledge about the users and the need Insufficient market research, understanding of environmental; cultural; social; lifestyle and gender needs Possibility for elderly population and creating a demand? Investment is difficult for Small Market designers/producers (commercial sector) to justify, Note: Assumption for product needs to be marketable, potential different partnerships not based on profit 		Not enough design, innovation around affordable, appropriate product development to meet the needs, Lack of robust systems for procurement
Governance, Regulatory Issues, Financing Incentives,	Product and regulations are time consuming and expensive Regulation and regulatory mechanisms vary between countries. Creates complexity, cost for producers and countries, Lack of minimum standards and taxation	'Over-regulation' can act as a barrier for access to a broader range of products and potentially innovation, Lack of adequate reimbursement and minimal standard products cover 'finance scheme', product not sufficient for quality, standard, suiting the needs Connection between the medical, social welfare funding pools	 Lack of government awareness, commitment, capacity, provision of assistive devices, no budget provision. Assistive devices are not a priority, Corruption, Lack of regulation and minimum standards results in sub-standard provision, donated second hand products, unacceptable standards of 'service provision', Lack of financing schemes Note: over-regulation can be an issue in developing countries as well, In small country contexts costs are more expensive due to lack of ability to purchase in higher quantities; freight costs are increased
Service delivery	Regulations around service delivery standards	Lack of collaboration, coordination across the care pathway, Services provided for medical setting need to follow up in the community	 Assessment, prescription, product preparation, fitting, user training & follow up, maintenance and repair, Lack of knowledge and understanding to deliver assistive device services in less resourced settings, Lack of personnel with skills to support provision of assistive devices, Lack of service delivery 'access points' distribution of access points is less in rural areas, Lack of financing for service delivery, recognition of the value, importance of service delivery

	General	Middle/High Income Settings	Less Resourced Countries/Settings
End users and	Not enough evidence around the reasons for abandonment		Poor quality options only available,
communities	Lack of information, understanding of availability,		Gender considerations: e.g. women have less
	Lack of opportunities for people to trial, test of product before		literacy; lack of awareness of need; women's
	choosing, Isolation may have a link to lack of uptake		needs not prioritized
	Discrimination not a priority, attitude (service deliverers, society,		
	family) elderly person without same aspirations, rights, Some elderly		
	people have attitude not wanting to spend money on themselves;		
	saving this for the younger generation,		
	Financial barriers may be linked to lack of uptake, Insurance systems		
	are weak payment out of pocket, co-payments difficult,		
	Obsolescence by the time a product is due for repair, maintenance,		
	AD not needed permanently,		
	Lack of back up of product; design; service delivery process offer		
	feedback to increase outcomes for elderly people		
	Note: range of stakeholders, systems involved loop back process,		
	complexity		

Theme 3: Identifying Solutions

Identification of priority action to overcome barriers and enable new innovations, their access, and affordability. This session allowed exchange of views, expertise and experience on the key solutions to ensure that needed devices are designed, delivered, financed, used and improved appropriately and within country specific contexts.

Summary details of the group work are given in Table 3. Main points are highlighted below:

For both medical and assistive devices, the main conclusions to moving forward are:

- Improve market research, including economic analysis of the cost-efficiency of medical and assistive devices for ageing populations
- Develop standards and guidelines for the provision of services (ISO certification)
- Rationalize taxation
- Improve service delivery
- Develop monitoring and evaluations practices to ensure constant improvement of the health system
- Develop inclusive service delivery strategies for medical and assistive devices for older persons
- Develop training packages—for health and social care workers, older persons, their caretakers, and technicians—for use, fitting and maintenance of devices
- Develop minimum standards for and harmonize national regulatory frameworks
- Engage civil society to build partnership for including the voices, needs and preferences of older persons in the design of medical and assistive devices.
- Similarly, to identify strategies to link academia, civil society, government, and industry regarding the design, assessment, distribution, payment, and use of medical and assistive devices relevant to different country contexts.
- Increase national policy coherence, supported by international efforts, to encourage innovation for older persons by linking focus on ageing populations with medical and assistive devices. This includes linkage of policies, regulatory oversight, financing, and incentives for research and development, procurement, distribution, and use in the community.
Table 7: SOLUTIONS

Assistive Devices

	General	Middle/High Income	Less Resourced Countries/Settings
Design/ Production	 Market research need to understand the needs and priorities of user's in relation to environmental; cultural; social; lifestyle and gender factors. To include: the whole 'system'/cycle for assistive devices & encompass all stakeholders (users, designers, producers, regulators, service providers, financing systems), Prevalence of disability/impairment to assist in identifying the market size and priorities, Finance systems/affordability, what is affordable, Strategies for carrying out research, Access research that has already been carried out, what is already available (non-published literature & non-English), Regionally coordinated research carried out in partnership, National research Utilisation of existing research methodologies carried out by companies in developed markets and see whether this methodology (and potentially the information) could be utilised to gather relevant information in less resourced settings Economic analysis to build the case for appropriate assistive devices to support innovation Market size Increase the market by combining disability/ageing, Consider universal design (Nintendo) Government/donor subsidy to support innovation for products, and/or 		Promotion of need for design innovation and production of appropriate Guidelines on Provision of Manual Wheelchairs, potential definition that Meets the user's needs and environmental conditions, Provides proper f obtained and maintained and services sustained in the country at an affo Additional strategies Advocacy at the UN high level meeting on disability, Regional solutions, this will not be solved at national level alone Utilising design/engineering knowledge (potentially external) to design in-country, Student competitions for design/innovation challenges Sharing of good ideas, e.g. by website Procurement Regional procurement for smaller countries, managing a defined list of products. (WPRO has a web based price registry for essential medicines), Would require a multi-stakeholder management group and strong governance to mitigate risk for corruption/conflict of interest, Learn from procurement and logistics systems that are working in these countries for other products (IT), Corporate responsibility , opportunities for support with procurement/freight, Ensure that procurement technical specifications do not duplicate guidelines/minimum standards/regulations already developed/set
Governance	Minimum standards and guidelines for provision of devices Strength and	Silo funding Understand where	Governance Strengthen Governance and capacity amongst policy
Governance Regulatory Issues, Financing	durability (ISO) of products (some discussion around fact that ISO is not covering all assistive devices), Usability testing (specific product testing incl. user's) should be a requirement in design/production process; and a minimum standard, that a	the funding for assistive devices is (within different ministries), Suggestion to get the Ministry of Finance involved, Identify the	makers understanding ISO, Strengthen knowledge of policy makers Financing Tax incentives for corporates to become involved in design innovation/production of products for less resourced markets Corruption Strengthening governance and systems for transparency:
Incentives	product has in fact gone through usability, Service delivery/human support required, Pricing, transparency around the	focal ministry; foster Government inter-coordination.	Increase strength and capacity of user groups

	General	Middle/High Income	Less Resourced Countries/Settings
Service delivery	 'cost' of a product which includes the service delivery (service delivery includes repair and maintenance) Taxation rationalisation of taxation issues in each country (research) and political advocacy Rationalising regulations An assistive devices regulations liaison point/body (neutral third party) to assist in rationalising regulations Breakdown between service delivery sectors, Include into the Monitoring & Evaluation systems to observe linkages and outcomes across the care pathway, Use of technology to better link the different service providers and sectors, Utilise local government to coordinate across the care-pathway 	Financing Market research will help to build stronger advocacy to increase reimbursement, Rental options, Hire/purchase	 Lack of service delivery strategies include: Urgent need for Multi stakeholder working group to develop guidelines regarding the cost effective provision of assistive devices for people with main impairment groups (hearing, visual), The guidelines should consider products, service delivery, training requirements, policy and planning, Leading potentially to relevant and practical competency based training tools, WHO's work on guidelines for provision of manual wheelchairs offers an example of both the process for carrying out this work and potential output, Use of a wide range of personnel/volunteers who can provide service delivery and tailor training appropriately, This solution should not necessarily focus on the aged impairment focus less resourced settings cannot afford two parallel systems, Also urgent: Strengthening of health systems and at the same time education/advocacy to support health systems to support provision of
End users and communiti es.	Information/awareness/ discrimination As a strategy to support elderly people in accessing information; raising awareness; providing feedback on products; supporting market research Government/NGO/local government support for user groups, Public awareness campaigns (mainstreamed) Feedback loop Increase linkages between designers, producers and service providers and user groups as a means of passing on information and accessing their input by: Regular meetings, Potentially a website platform, Usability trials Opportunities to try/test assistive devices Demonstration centres, facilities for people (anyone with an impairment) to go and try different assistive devices with support from allied health professionals,		assistive devices including budget provision, procurement and human resource requirements including training Gender Need to better understand barriers that women may face, Potential to tap into mainstream women's groups Opportunities to trial/test equipment and also increase service access points Mobile demonstration/service (adapted van/off road trailer) opportunities visiting rural centres (Western Australia Independent Living Centre: http://www.ilc.com.au/pages/country-services)

General	Middle/High Income	Less Resourced Countries/Settings
Demonstration tours, mobile demonstration (adapted van/off road trailer)		
opportunities visiting rural centres (Western Australia Independent Living		
Centre: http://www.ilc.com.au/pages/country-services). Equipment loans		
so that people can trial for longer. Trial 'homes' where there are a number		
of assistive devices integrated to provide an overall solution		
Obsolescence Options for short/longer term rental		

Medical Devices

Users	Service Delivery	Governance	Product Development
Focus on ageing	Develop a list of essential	Regulations and industry	Product Development with more R&D, market research across all the stakeholders, transition in
populations and their	devices (WHO lead?)	should target post market	medicine to research institution, clinical train essentials, HBD-STED and Clinical activities
needs:	 Device used at the 	activities to share and for	- National list of approved medical devices, that are visible and shared across for leveraged
- Mobility issues	community level by Older	visibility across other countries,	information across roles and activities and also confidentiality
- Sensory issues	People or care givers;	NCAR to be utilized (IMDRF)	- Evidence based decision making
- Cognitive dysfunction	 Institutional devices used 	and no user blame	- Potential areas for academia and industry need to work to collect and identify
- Multiple diseases,	by paramedics or	Financing Affordability for	
atypical presentation	physicians	older people =	Monitoring and evaluation on use and coverage of devices
- Low or no income		 Policy level work; 	- Base-line, continuing evaluation plans and Government to lead with the help of NGOs
- Isolated	Promoting awareness on	coherence between	
- Older women	- technical specification on	national policies for Older	Potential solutions:
- Dependence on	devices	People, medical devices	- Manufacturer supplies training to institution and train the trainer
intermediary health	 For community level 	and free or subsidized	- Overcoming language barriers
workers	devices;	provision of assistive	- Conflict of Interest and Code of Ethics for Professional societies and industry groups
- Literacy challenges	institutionally-based	devices,	- Budget opportunities of Fee for service, bundled
	devices, and user-friendly	 Innovation Fund to be set 	- Patent issues for WIPO/WTO/WHO and TRIPS agreement
	devices keeping sensory	up by industry to ensure	- Distributor roles must be communicated in detailed purchase order
	issues, illiteracy and others	new devices are made	- Alignment with ASEAN, AHWP, IMDRF and some requirements of mandated implementations
	aspects in view,	according to local needs	with 3 Countries in ASEAN are in IMDRF
	(WHO to lead, industry to	and for technology	- Nomenclature challenges for GMDN for UDI not free and not viable in Japanese and Chinese,
	follow up)	transfer.	Significant implication to all aspects of lifecycle
	Target activities effectively to	- Consortium of	- Opportunity to move care from hospital to the home
	process steps and check list for	Government funds to buy	- Media attention and how much money is already being spent to look and utilization
	all stakeholder engagement in	devices in larger quantities	- Lack of evidence or collected information and the needs more research and publications to
	the process	to reduce the cost	support

Users	Service Delivery	Governance	Product Development
	Total integrated solutions:		
	home healthcare, nursing	Remove physical barriers	
	home, community homes with	Infrastructural development for	
	integrated solutions that are	roads, transportation and	
	evidenced based	improve devices that reach to	
	Training interventions For	communities and vice-versa	
	end-users (to be taken up by	Spread the initiative beyond	
	NGOs),	WPRO region, globally	
	for health providers (by		
	Government and NGOs)		

Need for a Comprehensive Approach

The results of the two day Consultation highlighted many inter-related needs, challenges, and solutions that require action across a large spectrum of the health system, different stakeholders, and at different stages of the product development cycle. Whereas specific work must be undertaken for each topic, having an overview of the inter-related workstreams may help. The Figure on the next page was developed as background to the meeting, which was further refined. It provides a beginning to identify the many issues, and a number of gaps will exist. However, elucidating how different parts of the system can affect innovation---for example whether national plans/strategies address ageing populations, medical and assistive devices together; the impact of evidence and regulation on reimbursement, which in turn affects affordability, the market, and whether industry chooses to produce those items responding the needs of the people, or whether community based systems are in place to support persons and communities with assistive devices—is key to ensuring that innovations are developed and scaled up.



F. Comments by Dr Marie-Paule Kieny, Assistant Director-General, WHO

Dr Marie-Paule Kieny, WHO Assistant Director General, Health Systems and Innovation, was able to join the Meeting through a live video hookup. She noted the importance and uniqueness of the Consultation. She further outlined needs for greater innovation to increase access to medical and assistive devices, need to foster cross- sector collaboration to increase access to health for all and to develop community based information and actions, and to assess the need for more health care providers and social workers. With the rising ageing population, cost of healthcare becomes a matter of concern and Ministries of Health must balance needs, economic argument and cost benefits. Dr Kieny noted the importance of the Industry in the process to optimize health outcomes and to ensure fair partnerships.

She mentioned that the engagement with patient groups is also critical to ensure better acceptability and observance with some of the requirements of medical and assistive devices such as safety issues. She also praised Health Technology Assessments as key to assist policy-making decision and should be expanded to ensure that costs and benefits are assessed in a more holistic way, inclusive of taking and not taking action.

Dr Kieny highlighted that the recent movement supporting UHC (Universal Health Coverage) that provides great opportunities to streamline community involvement in health service delivery. Ultimately, what matters are the needs, and capacity of end users to afford and use devices. Although the question of stigma may be a barrier to their adoption, it can be an opportunity to 'redesign' not only devices but also interventions to defeat the stigma.

The availability and affordability of medical and assistive devices are very important. Finally, Dr Kieny concluded by engaging the participants to embrace the broader issues of the governance of health systems, regulation and taxation, monitoring and evaluation of intervention to better address the needs of elderly in WPRO when it comes to medical and assistive devices, irrespective of the socio-economic context.

G. Next steps

Systematic Reviews/Studies

Several next steps were highlighted in response to the preliminary review findings highlighted in the Consultation to enable greater availability of and access to new devices, to drive technological innovation, develop demand for available suitable devices, and encourage social innovation to increase uptake. These include: additional in-country surveys of needs and available technologies, identifying parameters for innovative technologies, encouraging industry to transform complex high tech products into simple to use technological alternatives suitable for specific markets, promoting development of appropriate and cost effective strategies, tools, products, approaches such as Preferred Product Profiles (to be shared with industry to match new products to population needs), encouraging Technology Transfer programmes, and use of product development partnerships.

This initial work is also providing valuable insights for a new focus area of the WHO Centre for Health Development (Kobe Centre (WKC)) on Innovation for Ageing Populations. Future activities undertaken by WKC in this area will build on this initial work.

First WHO Global Forum on Innovations for Ageing Populations, Kobe

WHO will convene the First Global Forum on Innovations for Ageing Populations on 10-12 December 2013, in Kobe. The WHO Kobe Centre is organizing the Forum with a number of departments within WHO. The Forum will convene government, research community/innovators, industry, health care workers and civil society. The objectives are to:

--Highlight specific examples of successful innovations

--Communicate core set of information on ageing populations' needs to drive future innovations

--Identify inter-linkages between technological innovations and health/social delivery systems

--Identify priority research needs and actions

Participants in the meeting further identified a set of ideas for near-term activities to advance innovations for medical and assistive devices:

WHO	Countries	Civil Societies	Industry
Expand Medical Devices Compendium of Innovative Technologies to include assistive devices	Reach out to ASEAN Harmonization Effort for regulations.	HTA: Global Meeting (June 2013, Korea) and Euroscan, June 2013.	Identify solutions in existence/development that target or support elderly (and disabled)
Base Line Country Survey	Increase policy development for medical and assistive devices	WHO Collaboration Centres – 1.Build a network in China. Info exchange. 2.Databank or framework – international and domestic. 3.National & Province level of pricing for drugs. Unique province cost structure. 4.Education Program continuation. National credit for continuing education.	Identify how AAMI/ANSI HE75 Human Factors with focus on access and usability testing and proof to support.
Use WHO SARA Indicators (Healthcare Facility Assessment) to include medical/assistive devices and related use in health sysem	Look at integration & leverage of disabled programs with elderly programs.	Research funding with academia – linkages with posted country policies and programs.	Look at how Usability and AAMI/ANSI HE75 Human Factors are used in the assistive device arena.
Develop minimum priority or core lists of products (Medical Devices for maternal and child care is in process) - Health facilities and clinical intervention. Priority for Assistive Devices.	Assess opportunities for collaboration with Regional Development Banks, including research activities.	Participate in public-private partnership consortia opportunities.	Technical support from industry on procurement process and service pathway (training, installation, matching and partnership)
Identify minimum standards/guidelines – product and service delivery requirements (e.g.; WHO Guidelines for Wheelchair) (Hearing, Vision Sphygmomanometers, Other?)	Include health technologies in Universal Health Coverage (UHC)	AUSAID (GPFD)	

Table 8: Medical Devices and Assistive Devices – Some near term activities

WHO	Countries	Civil Societies	Industry
SAGE Epidemiological Data Collection and Analysis		Helpage: Survey Capacity Building to document community needs IAPO – increased	
		engagement and participation in the data analysis and collection. Extend out invitation to participate back to countries.	
Mainstream device information collection and analysis into		Grants – Research	
UHC/Health System			
already occurring . Opportunity for medical devices?			

CONCLUSIONS

The rapid growth of ageing populations in Asia demands attention to how a prioritized list of health technologies—notably medical and assistive devices—can improve the quality of life, functioning, and independence of these persons. The moral, social and economic imperative to maximize the contribution of older persons to society, enhance their social inclusion, and reduce health care and social costs, requires greater attention to how innovations in technologies are designed, developed, produced, procured, purchased, used, and evaluated. WHO is committed to helping Member States and communities find innovative solutions for ageing populations. Meeting the expressed needs of the people in different country/community settings and for various levels of ill-health and frailty and needs for care are very important. The Consultation illustrated the value of innovation for all stakeholders, and they <u>all</u> needed to be engaged with each other: the people, academia/innovators, industry, government, health care workers, and civil society organizations – particularly in prioritizing the needs for innovations. The aim is to listen to the need, without imposing technology, to be open minded and to have empathy with final users.

Common issues and suggested actions in the Consultation focused on aspects of health systems and the product development / innovation cycle:

- **Policy environment.** Whether national policy frameworks include medical and assistive devices (both or just one category), and to what extent they are linked to available policies for the aged.
- **Regulatory environment**. Issues such as rapid reviews for safety and effectiveness; available methods/evidence base to review safety/effectiveness; greater harmonization of regulatory procedures across countries;
- Health technology assessment (HTA). As a critical tool for government decision making and prioritization, need to improve HTA methods to include the full spectrum of clinical, economic, social and ethical benefits. How HTA is linked to funding decisions for devices and innovation also needs to be considered.
- Health technology management, including needs assessment, selection, procurement, logistics, maintenance and training for safe use, as key processes and mechanisms required to increase access of devices by the final user.
- Reimbursement decisions: A recognition that different ministries and reimbursement systems may support medical and assistive devices, as well as other technologies, differentially. The role of

incentives for industry should be explored.

- The concept of "assistive solutions" was proposed (as opposed to assistive devices) providing an approach for integrated and holistic community support, maintenance services for assistive devices, as well as streamlined approaches for making them available.
- Investigating the role and needs of **health and social service workers** is important. In particular, ways to support ageing health workers needs to be considered.
- Better understanding of the epidemiology of underlying diseases, risk factors, co-morbidities, are important to establish the needs for various devices. In turn, such models should focus on transitions from wellbeing to ill-health to frailty rather than on chronological age.
- Additional research is required to further assess the country context for, need, availability, and rational supply of medical and assistive devices in each country.

In summary, a holistic and integrated strategy for increasing the availability, affordability, acceptability, use, and effectiveness of devices, and health technologies, for ageing populations is needed.

A strong perceived need was expressed to develop consensus/universal agreements around the definition and classification of assistive devices in order to have a universal framework. It is important to assess the current availability of assistive devices through the use of a framework for design, products, procurement and supply, service delivery and user outcomes. At the same time, there was a perceived need to increase the number of stakeholder groups engaged in this discussion (e.g. the elderly). However, to a large extent, the discussion about functional limitation and disability reinforced the fact that a number of solutions should not necessarily be applied specifically for aged populations but universally to all disable peoples.

In relation to pricing, discussions took place were made about taxation and political advocacy, discussing silo issues and how to overcome them. The question of the obsolescence of devices and their maintenance was also widely discussed, with calls for flexible ways to increase product offerings.

Concluding remarks from Alex Ross (WKC)

On behalf of the WHO Secretariat present at the meeting, and Dr Marie-Paule Kieny, Assistant Director-General for Health Systems and Innovation, Mr Ross (WKC) concluded the meeting thanking all participants for their hard work and significant contributions. Feedback provided from participants at the Consultation was very positive concerning the opportunity to look at the issues relevant to advancing innovations comprehensively and across different disciplines and sectors (as represented by the participants). It was emphasized that, as health professionals, working for private or public organizations, we have to design, develop, manufacture and provide solutions that meet the needs of the ageing populations for various levels of care and different economic settings. Innovation and technologies are instrumental in meeting needs. An important point in the debates and discussions between the participants was related to the need to have better national and international health systems supporting the delivery of assistive and medical devices to elderly, through intersectoral action and with a focus on equity. WHO frameworks, consultations and metrics are part of the support provided to Member States to identify best options and processes to ensure that the demand for devices for elderly is met.

Key characteristics of devices were reiterated during the meeting: they need to be safe, effective, affordable, appropriate, acceptable and accessible. Additionally, there was consensus to keep as central the perspective and needs of the end user, patient or health worker. Finally, the value of Health Technology Assessments was highlighted as one tool to provide evidence for decision makers, and that access to medical and assistive devices should be considered in the development and implementation of regulatory frameworks.

All of the above should be considered to increase access and use of affordable medical and assistive devices when deploying Universal Health Coverage.

Annex 1: Meeting Agenda



Consultation on Advancing Technological Innovation

for Older Populations in Asia

Kobe, Japan, 20–21 February 2013

WHO Centre for Health Development (WHO Kobe Centre – WKC)

Day 1: 8:30am-6:15pm Day 2: 8:30am-5:45pm

AGENDA (REV. 1)

Meeting purpose and objectives:

- Priority needs of older populations for medical and assistive devices
- To identify needs for technological solutions supporting ageing populations (medical and assistive devices)
- To identify the core gaps in information and priority actions to advance availability of affordable medical and assistive devices for ageing populations
- Identification of next steps for WHO to consider to advance the Initiative on Innovation for Older Populations, along with identifying potential partners/funders

		Day 1: 20 February 2013 (Wednesday)	
	TIME	Meeting Item	NAME
1.	08:30 – 09:10	Welcome and Introduction of participants	Mr Alex Ross , Director, WHO Kobe Centre Dr Oua Tanaka , Deputy
			Director, Ministry of Health Labour and Welfare, Japan
2.	09:10 – 09:20	Introduction A. Presentation of consultation context, objectives and expected achievements	Dr Francis Moussy (WHO)
	09:20 – 09:50	B. Priority ageing issues in Asia (presentations + questions)	Dr John Beard (WHO) Dr Anjana Bhushan (WHO)
3.	09:50 – 10:35	Setting the Stage: The role of technology (medical and assistive devices) in supporting ageing populations (presentations + questions)	Dr Adriana Velazquez (WHO) Dr Kristen Pratt (WHO)
	10:35 – 10:45	COFFEE/TEA BREAK	
4.	10:45 – 11:30 11:30 – 12:45	 Panel 1 Examples from selected countries of National's strategies/framework to promote health innovation for elderly people: Japan's Medical Innovation Strategy and Japan priorities for Ageing China Philippines Panel 2 Identifying key requirements for increasing access to medical and assistive devices and the role of innovation: Assessing demand and priority needs (low resource environments and wealthier countries) Assessing product/technology availability Role of regulation Role of health technology assessments Ensuring financing/assessing affordability 	Dr Francis Moussy (WHO) Dr Adriana Velazquez (WHO)

	12:45 - 13:45	LUNCH BREAK	
6.	13:45 –15:00	 Progress to date on systematic reviews (presentations and discussion): a) needs for <u>Assistive Devices</u> for older people in WPRO b) needs for <u>Medical Devices</u> for older people in WPRO 	Beth Sprunt (CBM, Australia) Guy Maddern (INAHTA)
7.	15:00 – 15:45	Perspectives from industry and users a) Industry (DITTA) b) Users (IAPO)	
	15:45 - 16:00	COFFEE/TEA BREAK	
8.	16:00 - 17:30	Roundtables discussion Theme 1 (NEEDS): Identifying priority medical and assistive device needs for different country situations	All
9.	17:30 – 18:15	Plenary : Roundtables reporting back, review of key points from Day 1 and outline of Day 2 tasks	All

Day 2: 21 February 2013 (Thursday)			
	TIME	Meeting Item	NAME
10.	08:30 - 08:45	Recap conclusions day 1 and introduction day 2 Group Photo	Mr Alex Ross (WHO)
11.	08:45 – 10:15	Roundtables discussion Theme 2 (BARRIERS): What are key barriers/obstacles to ensuring that desired devices are designed, delivered, financed/affordable, used, and improved (by country context)?	All
12.	10:15 – 10:45	Plenary: Roundtables reporting back	

	10:45 - 11:00	COFFEE/TEA BREAK	
13.	11:00 - 13:00	Roundtables discussion Theme 3 (SOLUTIONS): Identification of priority action to overcome barriers and enable new innovations, their access, and affordability.	All
	13:00 - 14:00	LUNCH BREAK	
14.	14:00 - 14:30	Plenary: Roundtables reporting back	All
15.	14:30 - 16:00	Plenary: Develop required actions and next steps to advance the agenda (milestones and deliverables)	All
16.	16:00 – 16:30	Plenary: (Video Link) Discussion with Dr Marie Paule Kieny, Assistant Director General WHO HQ	All
	16:30 - 16:45	COFFEE/TEA BREAK	
18.	16:45 – 17:45	PLENARY: Further identification of specific actions by participants; points of view of participants Conclusion: End of the consultation	Mr Alex Ross (WHO)

Annex 2: List of Participants

Australia

Professor Guy Maddern

(maddern@adelaide.edu.au) Director Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) International Network of Agencies of Health Technology, Technology Assessment (INAHTA) North Adelaide

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Ms Beth Sprunt (b.sprunt@unimelb.edu.au) Senior Technical Adviser CBD-Nossal Institute Partnership for Disability Inclusive Development Nossal Institute for Global Health The University of Melbourne, Carlton

China

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Mr Hiroki Igeta

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Philippines

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Viet Nam

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International Association of Patient's Organizations (IAPO)

Mr Kin Ping Tsang (kptsang@retina.org.hk) Chair-Elect International Alliance of Patients' Organizations (IAPO)

Global Diagnostic Imaging Healthcare IT and Radiation Therapy Trade Association (DITTA)

Mr Satoshi Kimura (kimura@jira-net.or.jp) Vice-Chair, International Congress of Diagnostic Imaging and Therapy Systems Trade Association (DITTA);

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Mr Alex Ross (rossa@who.int) Director

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Ms Johanna Chow-Chuen (chowchenj@who.int) Volunteer

Annex 3: Evaluation of the meeting

An evaluation of the meeting was conducted immediately after its ending. Out of the 41 participants, 25 completed the evaluation sheet which comprised 7 questions and one free comment box. For each question, the results are presented hereafter:













Q7: Are there other ways we could have made your participation more fruitful and comfortable?

- Have a shared meal or social gathering
- Notice the meeting at least 10 weeks in advance to facilitate planning
- Provide meeting agenda with material more in advance
- Encourage to think about contributions to the meeting in advance
- Have a better skype linkage with Adelaide
- Host the meeting in a hotel to reduce distance accommodation/meeting venue
- Better manage the temperature of the meeting room (too cold the first day)

Q8: Are there other ways we could have made your participation more fruitful and comfortable?

Several comments appreciative of the opportunity given to some participants to participate in the meeting and exchange, learn, share expertise and experience. Some participants however regretted that the participation during the concluding session had been only active from a few participants.

Many participants expressed their interest in being updated regularly on the follow-ups to the meeting that WHO is intending to implement.

One participant noted the emergence of the concept of 'Health Care devices' as intellectually challenging and interesting.

Some noticed that the specificities of the Pacific Island would have benefited from the participation of one of their representative.

The question of the definition of 'assistive devices' vs 'assistive technologies' could have been explored more deeply. The definition of medical devices was seen as clearly delineated.

Finally, a key missing group in the meeting, were representatives of the elderly.

Annex 4: Executive Summary of Systematic Review on Assistive Devices



Systematic review commissioned by the World Health Organisation

The Needs, Availability and Affordability of Assistive Devices for Older People in 8 Countries in the Asia Pacific Region: Australia, China, Fiji, Japan, Malaysia, Philippines, Republic of Korea and Vietnam

"Higher disability prevalence at older ages, combined with an ageing population ... will require a comprehensive social policy approach and forward-looking policies that simultaneously address both ageing and disability-related concerns" (UNESCAP 2012)

By Elena Down, Clare Hanley and Beth Sprunt CBM-Australia – Nossal Institute Partnership for Disability Inclusive Development

EXECUTIVE SUMMARY

The goal of this review was to identify needed assistive devices and the main barriers to accessing them for older people in eight countries in the Asia Pacific region. There are a range of definitions for assistive devices, technologies and products used. This review adopted the definition of assistive device provided in the International Organization for Standardization (ISO) 9999:2011 "Assistive products for persons with disability--Classification and terminology". Assistive devices are:

"any product (including devices, equipment, instruments, technology and software) specially produced or generally available, for preventing, compensating for, monitoring, relieving or neutralizing impairments, activity limitations and participation restrictions."⁶

The review focused on the health conditions that were the top causes for Years Lost to Disability (YLDs) in 2004 for older people (60 + years) in the Western Pacific Region, which were:

- Sense organ diseases: cataract, refractive errors, hearing loss (adult onset), macular degeneration and others
- Neuropsychiatric conditions: Alzheimer + other dementia
- Cardiovascular diseases: ischemic heart disease, cerebrovascular disease, hypertensive heart disease
- Respiratory diseases: chronic obstructive pulmonary disease (COPD)
- Musculoskeletal diseases: osteoarthritis
- Diabetes.

For each of the health conditions, the International Classification of Functioning Health and Disability (ICF) Core sets were used to determine functional and activity limitations associated with each health condition. From this, a range of assistive devices were identified for each of the various functional limitations for each specified condition, using the classifications in ISO 9999: 2011⁷ (these are detailed in Table 3 in the report).

ICF categories and assistive devices for each of the health conditions

There are 12 classes of assistive technology in *ISO 9999:2011 Assistive Products for Persons with Disability* – *Classification and Terminology.*⁸ Of these, six classes were assessed as being most relevant for this review (See Appendix 4 for an outline of each class of assistive device and the rationale for its inclusion or exclusion in the review). Table 1 sets out the six classes and provides examples for each.

Table 1 - Classes of the assistive devices included in the review

⁸ ISO 9999 accessed 11 December 2012 at

http://www.iso.org/

⁷ ISO 9999:2011 Assistive Products for Persons with Disability is an internationally agreed classification of assistive products, especially produced or generally available, for persons with disability. It classifies assistive products based on a product's function. ISO 9999 makes use of the terminology and definitions of the <u>ICF</u>. At its highest level, ISO 9999 defines 12 functional areas called "classes," each of which is subdivided into "subclasses." Within most subclasses, more specific categories called "divisions" are listed. ISO 9999 is produced by the International Organization for Standardization, an international federation of national standards bodies. The following items are specifically excluded from ISO 9999:2011: medicines; assistive products and instruments used exclusively by healthcare professionals; non-technical solutions, such as personal assistance, guide dogs or lip-reading; implanted devices; and financial support.

http://www.abledata.com/abledata.cfm?pageid=194670&ksectionid=19327

Class of assistive device	Examples of assistive devices
Orthoses and Prostheses	Upper limb orthoses, lower limb orthoses, upper limb prostheses, lower
	limb prostheses, orthopaedic footwear
Assistive products for personal care	Assistive products for dressing and undressing; toileting; incontinence
and protection	management; bathing, showering and washing;
Assistive products for personal	Assistive products for walking (e.g. walking sticks, crutches, walking
mobility	frames); manual wheelchairs; powered wheelchairs; assistive products for
	orientation (e.g. white canes); assistive products for lifting people (e.g.
	hoists)
Assistive products for house keeping	Assistive products for dishwashing; housecleaning; chopping and
	measuring food; preparing and cooking food.
Assistive products for communication	Assistive products for seeing (e.g. spectacles, magnifiers); hearing (e.g.
and information	hearing aids, amplifiers, headphones); adapted alarms; telephones;
	writing boards; Braille typewriters; computers, computer software and
	technology (e.g. Braille printers, audible computer displays, screen
	magnifiers); calculation products
Assistive products for handling	Assistive products for carrying and transporting objects; reaching and
objects and devices	grasping objects;

A review of published literature, government websites and service provider websites on relevant assistive devices in each country was conducted, as well as a survey of 42 key informants; both methods focused on the availability and affordability of a range of assistive devices. The survey was disseminated to key informants in each of the eight countries including representatives from Disabled Peoples Organisations, Councils on Ageing, peak bodies, civil society organisations, and Government ministries where available. The findings were presented and discussed at the WHO Consultation on Advancing Technological Innovation for Older Populations in Asia⁹ in February 2013 and a working group of experts discussed questions related to needs, barriers and solutions for assistive devices (see list of participants in Appendix 3). The results in this report include the findings from the assistive devices working group. The draft report was shared with the organisations that had completed the survey, for their feedback on the findings and to check whether the data had been represented accurately. Changes were made accordingly. In addition, following the experts consultation, Malaysian and Philippine delegates undertook further data collection (a survey, and a focus group discussion on the draft report, respectively).

The literature, survey results, experts' consultation results and the additional information gathered following the first draft were combined to produce the findings in this report.

High level findings

- Assistive devices for the elderly are frequently the same devices that are required for people with disability (regardless of age) – and therefore system responses to increase access to assistive devices for either population group would benefit the other. It is important that systems for assistive devices are established, or strengthened, based on a partnership between both the disability and ageing sector, and in a way that draws together the strengths and resources and meets the needs of the two sectors.
- Personal mobility devices (walking sticks, crutches, frames, wheelchairs) were most available;
- Devices for handling objects and for housekeeping (e.g. preparing food) were not widely available and where they were, were often considered unaffordable (often not being covered by subsidy schemes where these existed).
- Appropriateness and quality assurance is a concern for devices requiring customisation (e.g. hearing aids, wheelchairs and spectacles).

⁹ The focus of this consultation was the Western Pacific Region, which includes the Pacific. Delegates did not include stakeholders from the Pacific however two delegates work extensively in disability programming across the Pacific and the needs and context of the region were brought into assistive devices discussions throughout the consultation.

- Affordability of devices is a key concern, with subsidy schemes playing a key part in making devices affordable for elderly people and their absence proving a barrier to affordability;
- In Fiji (and most likely in other Pacific Islands countries) lack of availability of devices is a critical issue.
- The supply and subsidisation of appropriate assistive devices is only one component of a successful assistive technology 'solution'. Environmental, social and cultural factors should also be considered, for example people not accessing hearing aids because of a perception of stigma related to being identified as someone with a hearing impairment.
- Ready availability of information about products and services is lacking. This information is required by consumers, families, health providers and planners, assistive device suppliers and manufacturers, insurers, policy makers and researchers.
- There is a need to contextualise the provision of assistive devices in the broader context of barriers to health systems generally. Some of these factors to be considered include:
 - Affordability of transport to urban centres where the majority of assistive devices are available
 - Access to health and rehabilitation services for diagnosis and provision, and
 - Availability and capacity of trained personnel to fit and maintain assistive devices. As health and health-related professionals mediate the provision of assistive devices, as well as often making the devices themselves, the need for service delivery infrastructure and in-country professional development of personnel with the appropriate skills is critical.
- Access to assistive devices in rural and remote areas is problematic everywhere except in Korea and Japan; in addition, the cost of prostheses and orthoses is a barrier everywhere except Japan and Korea. The modes of delivery and funding in these two countries may be worth further investigation.
- Decisions around production of assistive devices should take into account national policies including issues such as minimum standards of product, procurement processes and existing import / export regulations.
- Decisions around service delivery of assistive devices should take into account programs such as Community Based Rehabilitation programs and other local program responses.

The *Madrid Plan of Action on Ageing 2002* highlights the 'need to ensure that persons everywhere are able to age with security and dignity and to continue to participate in their societies as citizens with full rights'. Assistive devices can be essential for older people with disability to achieve this aim.

The UN Convention on the Rights of Persons with Disabilities (CRPD), World Health Assembly Resolution WHA58.23, the United Nations Standard Rules on the Equalization of Opportunities for Persons with Disabilities, the Incheon Strategy and the WHO Western Pacific Region Regional Framework for Action on Community-based Rehabilitation 2010-2020 all highlight the importance of assistive devices. Most of the countries in this review are States Party to the UN CRPD, (and all are at least signatories). This provides a strong mandate for regional and international cooperation and assistance on improving the availability, affordability and appropriateness of assistive devices in the region.

Analysis of findings by Country

These findings represent the results from the survey and the literature review. Appendix 2 provides the list of organisations that responded to the survey. Number of respondents per country varied widely, ranging from 1 (Republic of Korea) to 16 (Australia).

Australia

Spectacles, walking sticks, crutches, walking frames, white canes, magnifiers, amplified telephones, hearing aids, devices for grasping and grip attachments were widely available and affordable. All other

devices were considered to be available only by accessing cities. There are however programs which facilitate people living in rural/remote areas to access these services.

There are many different subsidy and support schemes available at either federal or state level to assist the supply and acquisition of assistive devices with varying eligibility criteria and benefits. However both literature and survey responses indicated that 'on the ground' availability of many devices was still limited outside of cities, and that affordability of many devices was still an issue. In particular, availability, affordability and appropriateness of many devices for Indigenous Australians were flagged as serious issues. Some categories of devices are not subsidised by any schemes (e.g. Braille typewriters). Survey respondents noted that availability was an issue in some aged care facilities where government subsidy schemes do not apply.

Devices considered unaffordable to most included: Prostheses and orthoses and modified footwear; products to assist with toileting, incontinence management, bathing and showering; assistive products to assist lifting; portable personal radio FM systems (for hearing impairment); laptops with refreshable Braille; Braille typewriters; calculation products; computer software and technology and assistive devices for dishwashing. It was noted by one survey respondent that small devices such as those for grasping objects and for housekeeping whilst largely considered affordable become unaffordable when the cumulative total of them is taken into account.

Suitability was an issue in relation to customisable assistive devices in rural and remote areas such as wheelchairs where technicians or therapists are not available to fit them.

Interestingly, most survey respondents reported that hearing aids were unavailable other than in cities and unaffordable to most. However Australian Hearing supplies basic hearing aids for free to pensioners and to all Indigenous people over 50 years. It was reported by a group of elderly people that the basic hearing aids do not work well enough so they have to upgrade, and for some, this is unaffordable. Literature suggests that other barriers, such as attitudes, prevent the uptake of hearing aids.

China

In China, most devices were thought to be available only in cities. Mobility devices were most widely available and communication devices and devices for grasping and housekeeping less available. China Disabled Peoples Federation also noted availability was better in east China than west China. Whilst availability of most devices was greater in Hong Kong, affordability was a bigger issue. Awareness of both the availability of devices and of health conditions also appears to impact on access.

Walking sticks and crutches were widely available and affordable, whereas walking frames and white canes whilst available were unaffordable to many. Other mobility devices including wheelchairs and hoists were available in cities only and were not affordable, and may not in many cases be suitable due to over the counter sales and a lack of therapists to fit these properly.

While spectacles were widely available and affordable, poor quality and a lack of awareness of their availability were reported in the literature as barriers limiting their uptake in some parts of China.

Affordability was a problem for most assistive devices. Mobility devices seem to be better covered by subsidies than devices for activities of daily living such as bathing, eating and housekeeping. Local governments also provide some subsidies for assistive devices. ¹⁰ The Government's 12th Five Year Plan (2011-2015) outlines plans for the government to invest more than 1 billion yuan (US\$160 million) to help more people with disabilities to buy and use enabling devices. In Hong Kong a Comprehensive Social

¹⁰ Committee on the Rights of Persons with Disabilities (2010) *Initial reports submitted by States Parties under Article 35 of the Convention: China*,

Security scheme includes reimbursement for items deemed necessary by a medical professional.

Fiji

Fiji faces serious barriers to availability of assistive devices, with the vast majority of assistive devices not available <u>at all</u>. Those that were available are available in Suva only, and most are donated, raising issues around suitability or appropriateness (e.g. wheelchairs, prostheses and spectacles). When equipment is donated to local Disabled Peoples Organisations, it is made available free of charge to those who request them. However when orthoses and prosthetics are available at Government hospitals, they are provided on a user pays basis which renders them unaffordable to most.

A lack of trained allied health workers is an ongoing issue that needs to be addressed in addition to the supply of assistive devices.

Respondents in Fiji, including the Pacific Disability Forum, indicated that the situation in Fiji was likely to be similar to (or slightly better than) other Pacific Island countries, indicating that the Pacific almost certainly lags behind Asia with regards to availability, affordability and suitability of assistive devices.

Japan

Most devices for mobility, personal care, and communication were widely available in Japan. Devices for handling objects and housekeeping were less available and less was known about their affordability.

Interestingly, in Japan most larger devices can be hired under the long term care insurance scheme which seems to make them affordable. Smaller items however are not available for hire and must be bought. Thus devices such as wheelchairs, prosthetics etc were rated by survey respondents as more affordable than smaller items such as white canes. The literature also noted that with the introduction of the insurance scheme the cost of all devices has increased dramatically, meaning people are more reliant on subsidies and rental schemes than they were before.

Malaysia

A key finding was that most assistive devices were available only in cities. Walking sticks, crutches, prosthetics, orthoses, wheelchairs, hearing aids and 'devices for activities of daily living' were all available, but not in rural areas.

All devices are subsidised which should in theory mean they are affordable to the majority of elderly people. However there is evidence that schemes are 'fragmented and patchy', are not easily and readily accessible, and that benefits payable to older persons may need to be updated.

People with disability living in rural areas were only slightly aware of the range of available assistive devices,¹¹ suggesting that in many cases, lack of information and awareness is the main barrier to accessing aids.

Philippines

Most assistive devices were available in cities but not rural areas. Some survey respondents emphasised that even in cities some devices (Braille Button telephones, captioned phones) are not available at all. Survey respondents also noted the importance of NGOs in distributing assistive devices – and noted that community based rehabilitation programs would often provide or make devices for grasping, house-keeping etc.

¹¹ UNESCAP (2002).

Most assistive devices were rated as unaffordable. The main government program provides a 20% discount on assistive devices however this wasn't thought to be enough to make them affordable for most elderly people. Some suppliers reportedly also do not honour the discount.

Republic of Korea

Korea has generous subsidies available to assist with the purchase of assistive devices. Those who register with Korea's Ministry of Health and Welfare have 80% of cost of assistive devices subsidised.

The review found that in Korea many devices were both widely available and affordable. Exceptions to this were hoists, computing devices, devices for handling objects and devices for housekeeping which were available in cities only and which were considered to be unaffordable to most.

Braille button phones, captioned phones and Braille typewriters, laptops with refreshable Braille and other computer technology were available in cities but unaffordable to most.

The survey indicated that hearing aids were widely available and affordable, although literature suggests they may not be and that negative social attitudes to hearing loss are also a barrier to people choosing to access the hearing aids.

Walking sticks, crutches, walking frames, white canes and manual wheelchairs were available and affordable. Whilst powered wheelchairs were available in cities only they were considered affordable to most.

All assistive products for handling objects and devices and products for housekeeping were considered by the survey respondent as limited to cities only and unaffordable, consistent with the findings of a UNESCAP study in 2002 that few had access to them.

Vietnam

Most assistive devices are only available in cities with the exception of walking sticks, crutches and spectacles. Many assistive devices for activities of daily living (handling objects, housekeeping and some communication devices) were not available <u>at all</u>. Lack of awareness about the availability of such devices and concerns about quality of some devices were also raised as issues.

With the exception of spectacles, walking sticks and crutches, most assistive devices were found to be unaffordable. In general there is a lack of welfare schemes available for elderly people– health insurance schemes exist but do not cover costs of assistive devices. The Government provides some free basic assistive devices (hearing aids, wheelchairs and prostheses).

Limitations

This review was impeded by some significant limitations. The dearth of available published research relating to the situation in the Asia Pacific region meant a fully-fledged "systematic review" of the literature for these countries would not have provided answers to the questions in the terms of reference. Due to time and budgetary constraints, this review did not investigate the opinions and experiences of primary users/consumers of assistive devices. It sought to mitigate this by including key informants from Disabled Peoples Organisations and Councils of Ageing. The limited number of survey respondents in some countries, and the equivocal nature of some survey responses underline the need for further research in each country to strengthen the findings.

Due to resource constraints, some classes of assistive device were left out. It would be important for country level studies to consider including other ISO 9999 classes such as Assistive products for recreation. The methodology did not include investigating what medical interventions or other approaches are available to mitigate the effects of the health condition. Assistive devices were investigated based on activity and participation limitations that are experienced related to the affected body function. In the case of cataract, it needs to be questioned as to whether providing assistive devices is the best way forward or strengthening health systems to facilitate access to corrective surgery. It would be important for further research and national-level planning processes to take into account the availability and merits of medical options for mitigating the effects of the health condition which may be more effective and efficient than assistive devices.

Recommendations

The recommendations arise from the literature review, the survey findings and the experts' consultation. Because there has not been a process of prioritising recommendations with stakeholders, the entire list of recommendations from the main report is included in the Executive Summary. These include:

- That the definition of appropriate assistive devices be discussed further and formalised. Suggested starting point is: "a device that meets the user's needs and environmental conditions; provides proper fit and support; is safe and durable; is available in the country; and can be obtained and maintained and services sustained in the country at the most economical and affordable price"¹².
- The issue being addressed by assistive devices is largely 'functional limitation' (or disability) amongst older people, and there are important efficiencies in establishing or bringing together systems for people with functional limitation across the lifespan.
- Provide guidelines for a process of country-level situation analysis and priority setting to determine which devices are most needed.
- Advocate at the UN High Level Meeting on disability regarding the need for greater emphasis on assistive devices, including promotion of and incentives for design innovation and production of appropriate assistive devices.
- Increase means of information and awareness amongst older people and their families regarding assistive devices options.
- Develop a multi-stakeholder working group to develop international guidelines regarding the cost-effective provision of assistive devices for the major impairment groups, such as hearing impairment and vision impairment along the lines of the WHO *Guidelines on the provision of manual wheelchairs in less resourced settings*¹³. The guidelines should consider products, service delivery, training requirements, policy and planning. These may lead to relevant and practical competency based training tools.
- Provide guidelines for a process of country-level situation analysis (including research) and priority setting.
- Information systems:
 - Develop country-specific information systems on assistive devices linked to a regional information system; this would help consumers access clear, objective information on products and prices; could be linked to online training in use of the device; guidelines for maintenance; enable direct feedback from users to producers and policy makers; and

¹² Adapted from the WHO (2008) *Guidelines on the provision of manual wheelchairs in less resourced settings.*

¹³ WHO's work on the wheelchair guidelines offers an example of both the process for carrying out this work and potential outputs.

enable sharing good design ideas. Investigate options for recording person-specific data using mobile phone technology¹⁴.

- Support the national and regional development of robust procurement systems for assistive devices. Regional procurement for smaller countries, managing a defined list of products, would require a multi-stakeholder management group and strong governance to mitigate risk for corruption / conflict of interest.
- Rationalisation of taxation of assistive devices.
- Develop an assistive devices regulations liaison body (neutral third party) to assist in rationalising regulations.
- Identify the focal ministry and foster inter-government coordination to increase efficiencies and reduce confusion amongst consumers. Strengthen governance and capacity amongst policy makers, for example, increasing understanding of the ISO.
- Establish short-term rental or equipment loans schemes.
- Establish 'one-stop shop' demonstration centres facilities for people to try different assistive devices in simulated home settings with support from trained professionals to provide advice. Independent Living Centres in Australia and other countries are a useful model for this concept.
- Establish mobile demonstration tours adapted vans/trailers with a variety of assistive devices, which visit rural areas15.
- Health systems strengthening:
 - Ensure that assistive devices are seen as a health systems strengthening priority, and not simply an issue that is left to the non-government sector;
 - Address gaps between service delivery sectors (government health system to community settings) through use of information technology; monitoring and evaluating linkages and outcomes across the care pathway. Local governments may be the best medium for coordinating.
 - National health action plans need to include assistive devices.
 - Capacity development of personnel in the use, fitting and maintenance of assistive devices.
 - Ensure quality control mechanisms for assistive devices, service delivery and training of personnel.
- Address the perception that the market size is too small for investment in assistive devices; work
 to bring the ageing and disability 'markets' together to increase the size of the populations for
 whom the devices are developed and to whom the services are provided.
- Develop programs and policies that increase incentives for design and innovation around affordable, appropriate product development for low-income countries; include an emphasis on universal design for mainstream products; investigate tax incentives for corporate agencies to prioritise design innovation and production of products for low income countries.
- Decisions around production of assistive devices should take into account national policies including issues such as minimum standards of product, procurement processes and existing import/export regulations. Ensure that procurement and technical specifications do not duplicate or contradict guidelines/minimum standards/regulations already in place.

¹⁴ This has been undertaken in the Philippines by Physicians for Peace.

¹⁵ An example of the mobile demonstration tour is that run by the Western Australia Independent Living Centre: <u>http://www.ilc.com.au/pages/country-services.Accessed</u> 31 March 2013.

- Increase capacity of user groups to: monitor systems; advocate policy makers; inform and advise consumers on assistive devices; increase linkages for older people to information; raise public awareness; provide feedback on products; and support market research.
- Create competitions for design students to design appropriate assistive devices
- A principle that was discussed in relation to processes for prioritising assistive devices was that
 cost should not be a criterion, which may seem counter-intuitive. The need for the device should
 be based on the extent of activity and participation limitations in a population, and innovation
 would follow demand. It was also discussed that incentives and advocacy may be needed to
 increase the focus by designers and manufacturers on assistive device needs of populations in
 low-income countries.
- Linking with existing WHO initiatives:
 - WHO WPRO has a web-based price registry for essential medicines; this could be expanded to include assistive devices.
 - The Compendium¹⁶ of new and emerging technologies could be improved to include assistive devices.
 - The WHO Service Availability and Readiness Assessment (SARA) survey¹⁷ may be an option for including assistive device indicators.
 - The annual WHO Baseline Country Survey on Medical Devices Project ¹⁸ could be improved to include assistive devices.

Recommendations for further research:

There are a large number of issues that require further research to inform the strengthened provision of assistive devices:

- The intersection between Community Based Rehabilitation and health system approaches to production and provision of assistive devices.
- Greater understanding of mechanisms for service delivery¹⁹ of assistive devices in particular those which respond well to the needs of people in rural and remote areas; collation of country-specific schemes and programs, using Appendix 6 (Australian schemes) as an example.
- Investigation into procurement and logistics systems that are working for other products, for example, information technology products.
- The availability of medical interventions which may be more cost-effective than assistive devices, e.g. cataract surgery.
- Mechanisms and effectiveness of different reimbursement schemes; processes for determining eligibility for these schemes also requires research.
- More detailed country-specific research to gather more detailed information than what this overview has been able to ascertain (except in Australia where this has recently been conducted)²⁰. This should include:

¹⁶ <u>http://www.who.int/ehealth/en/</u> Accessed 31 March 2013.

¹⁷ http://www.who.int/healthinfo/systems/SARA_CoreQuestionnaire.pdf

¹⁸ http://www.who.int/medical_devices/med_dev_survey/en/ Accessed 31 March 2013

¹⁹ The term 'service delivery' encompasses assessment, prescription, fitting, user training, follow up, maintenance.

- Greater investigation into existing unpublished²¹ country-specific research, secondary 0 analysis of national datasets, and access to NGO and health services data to look at trends in provision of assistive devices. Disability prevalence data is useful at estimating needs for assistive devices however methods for gathering disability data have to be reviewed with caution as these are still very variable and may not produce comparable results.
- Primary research with older people and older peoples peak bodies to better understand 0 a range of factors including: priorities and needs for assistive devices²², implications of gender, sociocultural, environmental²³, economic and lifestyle factors; to understand from people who have received assistive devices whether they are using them and if not, why not (including issues of stigma), and whether there is adequate training for the user in how to use the device. From the perspective of commercial developers, this market research is standard practice and it would make sense for the research to be undertaken in partnership to benefit from each sector's strengths in their approaches to this work.
- Assessment of support systems in the settings in which the assistive device would be 0 provided and used, including human resources who may be skilled (or strengthened) in assistive devices service provision.
- Include a range of stakeholders as key informants: for example, assistive device groups 0 (including users, designers, manufacturers, regulators, Health Technology Assessment groups, service providers), financing systems, women's groups, etc.
- 0 Investigate options for Public Private Partnerships for manufacture and/or procurement of assistive devices to achieve economies of scale to reduce the costs for consumers.
- Investigate health insurance, funding mechanisms, incentive schemes, where 0 responsibility and funding for assistive devices sits within various ministries.
- Investigate regulatory bodies 0
- Research into lower cost assistive devices (ie. assistive products for personal care and 0 protection, for housekeeping, for communication and information, and for handling objects and devices) which are not well understood in many of the countries in this review.
- Investigate options for small scale equipment loans²⁴ 0
- Economic analysis that provides evidence of cost-benefit of assistive devices in relation to family income and the broader economy will support prioritisation of these schemes, including the cost to the health system of not providing the assistive devices.
- Greater detail of availability of "assistive solutions", which includes a spectrum from design, products, procurement, policies, subsidies and schemes, supply systems, service delivery and user outcomes.

²⁰ In Australia, a recent research report has been released which provides an extensive review of the situation in Australia. Pearson (2013) Research for the National Disability Agreement Aids and Equipment Reform Final Report. Available at:

http://www.dprwg.gov.au/research-development/publications/research-national-disability-agreement-aids-and-equi pment-reform-f²¹ Or research which is published in non-English languages and which therefore was excluded from this review.

²² Bearing in mind the caution that arose in the review that consumers may not always know what their assistive device needs are because they do not have access to information about the options. Researchers must bring a knowledge of assistive device options.

²³ Understanding the environmental context for the assistive device and user is fundamental, including condition of roads in villages, or footpaths in urban slums, in relation to selection of mobility device.

²⁴ In the Philippines the "Happinoy" model was recommended by FGD participants as an example of the use of cooperatives for purchasing power and small scale loans.

- Using a sample of older people with particular health conditions to verify whether the ICF core sets are picking up all the relevant activity and participation limitations and whether the assistive devices selected through the ISO 9999 make sense in the context of the sample.
- Research into country-level health information systems to determine whether assistive device information systems are available.
- In future research, inclusion of Class 30 of the ISO 9999 Assistive products for recreation is recommended. This was excluded in this study due to the limited resources, but it is an important aspect of life for many older people.
- Investigate private sector responses, progress and potential in the area of assistive devices²⁵

²⁵ Ageing Asia P/L holds annual investment forums. The mission of the Ageing Asia Investment Forum series is to increase private sector investments in products and services to enhance the quality of life, health and functional capability of seniors in Asia. <u>http://ageingasiainvest.com/about-ageingasia/</u>

Annex 5: Executive summary of Systematic Review on Medical Devices

ROYAL AUSTRALASIAN COLLEGE OF SURGEONS



SYSTEMATIC REVIEW ON NEEDS FOR MEDICAL DEVICES FOR OLDER PEOPLE

Commissioned to the Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S) by the World Health Organization (WHO)

February 2013

Overview

Overview

Across the Western Pacific Region, as in most countries across the world, the population is rapidly ageing. This is likely to place additional burdens on the provision of healthcare services to this demographic. Many medical devices are available which may benefit the elderly, although these may not be available in all countries or may be expensive. These factors impede equitable access to medical devices.

The clinical focus of this report has been defined as the top five health conditions that caused disability-adjusted life year (DALY) for older people (60–79 years of age) in the Western Pacific Region. Five main health conditions (with 19 associated subtopics) were identified:

- cardiovascular diseases
- malignant neoplasms
- respiratory diseases
- sense organ diseases
- neuropsychiatric conditions.

This report provides a literature-based review of medical devices needed by older people, the results of which have been used to create lists of devices which are catogorised in terms of whether they are preventative, diagnostic or therapeutic. Broad clinical safety and effectiveness information has also been provided when available, although the volume and quality of this information varies widely between each device. Detailed information on the safety, efficacy and cost-effectiveness of each device was beyond the scope of this report. Where possible, all identified medical devices were categorised according to the definitions as presented by the Global Harmonisation Task Force.

The methodology used for this report was that of a rapid systematic review so was limited in one or more areas to shorten the timeline for its completion. Thus, modifications have been made in at least one of the following areas: search strategy, inclusion criteria, assessment of study quality and data analysis. It is considered that these amendments do not significantly alter the overall findings of a rapid review when compared to a full systematic review. These limitations have been adhered to mainly by restricting the specific clinical questions asked. These limits were applied following the requirements of the specific review, in agreement with the WHO. For a more comprehensive understanding of this topic, a broader analysis of the literature may be required. As such, all readers of this document should be aware of the limitations of this review.

Of the 3,278 articles retrieved in the searches, 1,535 have been included in this report. Some topics were highly represented in the literature, for example topics related to cardiovascular diseases. In these cases, criteria (limiting to high quality levels of evidence and more recent publications) were applied to increase the overall quality and relevance of the pool of literature. Other topics were less highly represented, for example cancers of the mouth and oropharynx, and lymphoma; hence these topics were not limited to study type. This variability between each of the 19 independent searches reflects the differences in the research and publication focus of certain specialties, and shows a certain level of publication bias. Some medical devices such as magnetic resonance imaging and endoscopes were commonly identified across many studies and many conditions, other devices including diagnostics, especially in-vitro diagnostics, were identified infrequently. Basic medical devices, such as scalpels, other surgical instruments, surgical tables, anaesthesia machines and physiological monitors were usually not reported in the included studies, and this is probably related to the state of establishment of these standard pieces of equipment. This may reflect the fact that

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medical devices reported in the peer reviewed literature are generally used in locations of medium or high resource settings, and the assumption that these basic devices are readily available and highly diffused across all jurisdictions.

Care was taken not to over-interpret search results and information was provided as identified from the source publications. Some devices were explained in more detail in terms of their use and clinical utility; other devices were described very briefly; some devices were described in a generic manner and others according to their trade name. It is likely that for each example identified a number of alternatives are available beyond the specific devices that were mentioned and the results of this report are not intended to be a comprehensive list. In many cases the specific use of a medical device, how and why it was used, and its clinical significance, was not clear from the information provided in the published study. Many studies report a range of similar types of devices including tests that were used during the course of the study. In many cases there may be a range of options of devices for a specific indication. The clinical application of the information from these studies in a real-world context may not always be clear, and a specific comment on the comparative safety and effectiveness of the alternative devices was not possible.

Although the list of topics was based on the top five causes of DALY for older people in the Western Pacific Region, regionality has not been a constraint in the search methodology; therefore, the outcomes of searches reported here may be broadly applicable to any country worldwide. The specific health problems in ageing populations within the Western Pacific region, and the way in which they are treated, will be highly varied as the region includes a large number of countries over a wide area. The majority of studies were done in high-resource settings, and no studies provided information on devices and outcomes specifically related to low-resource countries. There is a lack of studies reporting on the clinical outcomes of basic or essential devices associated with service delivery, perhaps as these have already had their utility established through historical experience.

Clinical issues of safety and effectiveness are likely to be cross-jurisdictional. Cost-effectiveness for each device would be procedure-based where relevant, and would likely vary from country to country and will be the focus of future research. The basic elements of service delivery would remain similar, although the availability and cost of different parts of the service could vary widely, and be dependent on current skills and infrastructure in each country. It is intended that this report will inform future research, with the aim to improve access of devices to the elderly across the different countries of the Western Pacific Region.

To achieve effective clinical management of any health condition, all aspects of the management pathway must be considered. The true clinical effectiveness of an individual device or intervention can only be established within the framework of preventative, diagnostic and therapeutic strategies.

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1 Introduction

1 Introduction

A strategic objective of the World Health Organization (WHO) plan for 2008–2013¹ is to ensure the improved access, quality and use of medical products and technologies. Furthermore, WHO recognises the important role that medical devices play as a crucial component of healthcare delivery.

Consequently, WHO has established a new initiative to facilitate the development and access to appropriate medical and assistive devices at a lower cost for ageing populations defined as older than 60 years of age, to enable them to remain healthy, active and independent for longer.

With financial support from the Japanese Ministry of Health, Labour and Welfare, the WHO has begun research regarding this initiative in the Western Pacific Region. To prepare a foundation for future decisions, a detailed mapping of the need for medical devices for older people in the region is to be conducted. This will determine the technological needs for diagnosis and treatment of the diseases of this population. Further research and surveys will be conducted at a country-by-country level to ascertain the availability and affordability of these devices. For low income countries and low resource settings, needs of priority core devices will be defined, especially for devices that may not be available. The initial work will allow WHO to develop Preferred Product Profiles for devices identified as essential, but not currently available, to facilitate the development and transfer of suitable technologies to produce devices at lower costs. Finally, centres of excellence for medical and assistive devices for ageing populations in the Western Pacific Region will be strengthened or created to ensure that these devices are used in a clinically appropriate manner.

This initial report is a literature-based systematic review of needed medical devices. It is intended that this report will inform future research, with the aim of determining the need for medical devices and thus improve access to needed devices to the elderly across the Western Pacific Region.

The global and regional challenge of an ageing population

The proportion of the population classified as older is growing worldwide. Current data suggest that approximately one in nine persons are aged 60 years or over. The global population is ageing as a consequence of increased life expectancy at birth and declining fertility rates, and developing countries across the world are expected to experience accelerated rates of population ageing as compared to developed countries.² The rate of population ageing in the Western Pacific Region is expected to be faster than in almost any other WHO region. It is estimated that approximately 23 per cent of the population will be aged over 65 years by 2050. Cambodia, Lao People's Democratic Republic and Papua New Guinea are all expected to double the proportion of their population aged over 60 in less than 30 years, a process which took over 50 years in Australia and New Zealand.³

In Japan the challenge of population ageing is particularly pronounced, as persons over the age of 65 account for 16.7 per cent of the population while persons under the age of 15 years account for only 14.8 per cent of the population.⁴ This is attributed to a combination of low birth rates and the longevity of the population in Japan, which has the world's highest life expectancy. Consequently, the most common causes of death in Japan have shifted from infectious diseases to malignant neoplasms, heart diseases and cerebrovascular diseases.⁵

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The aged population is also characterised by an over-representation of women. In the Western Pacific Region there are only approximately 90 men for every 100 women over the age of 60 years. The preponderance of women in the aged population has increased with the reduction in maternal mortality and a drop in overall fertility rates, which means that a greater number of women reach older age.³

Age-related disease in the Western Pacific Region

Global improvements in medical care, the ageing of the population and increased provision of public health interventions such as vaccinations have caused changes in the types of diseases which affect populations. In the past, infectious diseases were the primary causes of mortality; in the present day, the primary causes of global mortality are non-communicable diseases such as cardiovascular disease and neoplastic disease. In 2004, it was estimated that approximately half of the global burden of disease was attributable to non-communicable diseases. In the Western Pacific Region non-communicable diseases accounted for 81 per cent of estimated all-cause mortality in 2008 and 73 per cent of all projected DALYs for 2008.⁶⁷ Persons over the age of 60 years accounted for 80 per cent of all mortality due to non-communicable disease.

The leading causes of mortality in the Western Pacific Region are represented in Table 1. Communicable, maternal, perinatal and nutritional conditions accounted for 10 per cent of all-cause mortality, injuries accounted for nine per cent and non-communicable diseases accounted for 81 per cent. Only causes which account for more than 10 per cent of all mortality are included in Table 1. Table 2**Error! Reference source not found.** includes the major causes (10 per cent or more) of projected DALYs for 2008 in the Western Pacific region. The largest proportion of mortality due to non-communicable diseases occurred in persons over the age of 60.

Cause of mortality	All ages: total estimated deaths	All ages: all causes of mortality (%)	Persons > 60 years: total estimated deaths	Persons > 60 years vs all ages estimated deaths (%)
All causes of mortality	12,673,680	NA	9,095,745	80
Non-communicable diseases	10,237,989	81	8,161,242	80
Cardiovascular disease	4,734,713	37	4,058,705	86
Cerebrovascular disease	2,504,051	20	2,167,963	87
Ischaemic heart disease	1,383,104	11	1,173,219	85
Malignant neoplasm	2,659,967	21	1,791,910	67
Respiratory diseases	1,586,931	13	1,459,320	92
COPD	1,373,136	11	1,293,907	94

Table 1 Estimates of deaths by cause for 2008 in the Western Pacific Region, major causes of death⁷

NA - Not applicable, COPD - chronic obstructive pulmonary disease. Note: table figures numbers should not sum.

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Cause of DALY	All ages: total estimated DALY	All ages: all causes of DALY (%)	Persons > 60 years: total estimated DALY	Persons > 60 years vs all ages estimated DALY (%)	
All causes of DALY	255,142,224	NA	64,201,717	25	
Non-communicable diseases	185,165,801	73	58,513,149	32	
Cardiovascular disease	31,545,792	12	18,627,426	59	
Malignant neoplasm	26,508,614	10	10,877,197	41	
Sense organ diseases	26,308,739	10	7,604,496	29	
Neuropsychiatric conditions	49,135,862	19	5,058,346	10	
Communicable disease	38,759,236	15	3,264,626	8	

Table 2 Major contributions to projected DALYs for 2008 in the Western Pacific Region⁶

NA - not applicable, DALY - disability-adjusted life years.

Cardiovascular disease and malignant neoplasms account for a large proportion of mortality in both men and women aged 60 years and over, but cancer mortality rates are much higher for men than for women. Age is a non-modifiable risk factor for age-related diseases and some health conditions are strongly associated with ageing, including atherosclerosis, hypertension, diabetic complications, cancer, benign prostate hyperplasia, Alzheimer's and Parkinson's diseases, age-related macular degeneration, osteoarthritis, osteoporosis and seborrheic keratosis.⁸

The leading conditions which bring about death from cardiovascular disease are ischaemic heart disease and cerebrovascular disease. Approximately 57 per cent of deaths from cardiovascular disease are associated with at least one of the following risk factors: high blood pressure, high cholesterol, high blood glucose, physical inactivity, being overweight or obese, and low fruit and vegetable intake. Of these risk factors, high blood pressure is the leading cause of cardiovascular deaths.⁹

Risk factors for specific cancers vary and risk factors for certain cancer sites remain poorly defined. Lung cancer is the leading cause of mortality due to cancer amongst both men and women and tobacco use is associated with the majority of all deaths from lung cancer. High body mass index, low fruit and vegetable intake, physical inactivity, tobacco use, alcohol use, unsafe sex, urban and indoor air pollution, and unsafe healthcare injections are risk factors attributing to 35 per cent of all cancer mortality. Infections including viral hepatitis, liver flukes, human papillomavirus and *Helicobacter pylori* infection are responsible for 18 per cent of mortality from cancer.⁹

Vision and hearing problems are also more likely in older age. In the Western Pacific Region 44 per cent of people aged 60 years or over experience vision loss and 26 per cent experience hearing loss. Of those persons, 10 per cent will become blind and 25 per cent will experience severe hearing loss or deafness. The majority of persons affected by vision or hearing loss live in low and middle income countries.³

Many risk factors for the conditions of interest are associated with modern lifestyle and dietary choices. As societies depart from more traditional modes of living the risk factors for these conditions may become more prevalent across the population. Another consideration is that in older patients comorbidity is almost always present,¹⁰ and this may affect the quality of life and choice or availability of treatment. The health problems in ageing populations within the Western Pacific

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1 Introduction

Region, and the way in which they are treated, are highly varied, as the region accounts for a large number of countries over a wide area and at different stages of development. There is increasing recognition of the role that lifestyle factors play in the development of disease later in life, and the prevalence and distribution of risk factors such as poor nutrition, physical inactivity, tobacco use and high alcohol consumption varies considerably between countries in the Western Pacific Region.

Defining old age

There is no clear, universally accepted definition of elderly or aged; the concept of ageing encompasses chronological age, changes in social roles and changes in physical, mental and functional capabilities. The age at which someone is considered elderly varies between countries and is often associated with the age at which a person becomes eligible for pension schemes or retirement: this is usually between 60 and 65 years.¹¹ Ageing is a diffuse biological process which can be described as the accumulation of deleterious changes in cells and tissues which occur with advancing age. Defining old age is challenging as its onset is not defined by a single physiological phenomenon and its manifestation varies across individuals. The process of ageing involves physical, physiological and social changes and is considered by many to be a stage of life in which a person's functional, mental and physical capacity is declining.² Old age is also associated with an increased propensity to disability and disease as a consequence of the cumulative effect of a range of deleterious changes in the body. Whilst chronological age is the common basis for determining old age by governments, demographers and researchers, it may not be equivalent with an individual's biological age.¹² An increase in a person's chronological age does not necessarily lead to ill health.

The United Nations applies 60 years as the cut-off for older people, so the health conditions which are the subject of this project were identified by examining the top five causes of DALYs in persons 60 to 79 years in the Western Pacific Region.

Ageing and disease

Damage at the cellular level which is attributed to the process of ageing has been linked to the pathology of certain diseases associated with the ageing population such as atherosclerosis and cancers.¹³ The relationship between the aetiology of age-related diseases and the physiological processes which underpin ageing is not well understood. The process of ageing, like all biological processes, is regulated by molecular signalling pathways and genetic transcription factors. There is a research focus on identifying familial aspects to ageing and longevity, including specific genetic mutations that may confer longer life spans and slow the onset of age-related disease.¹⁴

The development of age-related diseases reflects the cumulative effect of the ageing process as well as the impact of lifestyle and environmental factors over many years. Strategies to lower the risk of developing many age-related diseases may be focused on modifying lifestyle or environmental factors, the early initiation of which may help to promote healthy ageing.

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Figure 1 Proportion of Population Over Age 60, 2012 Source: WHO

Source: WHO

Figure 2 Proportion of Population Over Age 60, 2050







Figure 3 Pace of Ageing, World Examples, 1860-2040 Source: WHO



Figure 4 Pace of Ageing, World Examples, 1860-2040 Source: WHO

Figure 5



Source: United Nations, Department of Second and Social Affairs. World Pepulation Agoing 1950-2050

Figure 6



The feminization of ageing

Source: United Nations, Department of Sconomic and Social Affairs. World Pepulation Agoing 1950-2050







Figure 8 Projected deaths by cause for high, middle and low income countries Source: WHO

Global estimate of the number of people visually impaired.





Epidemiological Changes: Increasing NCDs

Cardiovascular disease and diabetes is higher in developing countries



Cancer: death rates per 100,000 population (2008)



191 Consultation on Advancing Technological Innovation for Older Populations in Asia, February 20, 2013

Annex 7: WHO Survey on Access to Medical Devices in Low-Resource Settings, 2012



Survey respondents' fields of expertise





Main barriers to access to medical devices in low-resource settings





World Health Organization Centre for Health Development (WHO Kobe Centre – WKC)



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