

# Concept Note: Opening the GATE for Assistive Health Technology: Shifting the paradigm

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## A. Background: the need for change

Today only 5–15% (approximately 1 in 10 persons) of the population in need has access to assistive products – e.g. wheelchairs, canes, prosthetic and orthotic devices, spectacles, low vision aids, hearing aids, and augmentative and alternative devices to cope with functional decline. Even production of important assistive products such as hearing aids barely meets

10% of global need, and less than 3% in developing countries (1). There is thus an urgent need to change the way we have traditionally perceived, designed, produced, manufactured, distributed, serviced and financed assistive products or devices – collectively called assistive technology.

The United Nations Convention on the Rights of Persons with Disabilities (CRPD) identified access to mobility aids, assistive devices and technologies as a human rights obligation that every Member State must fulfil and the importance of international cooperation to improve access (2).

Assistive products and technology need to be redefined on a broader basis taking into consideration its wider roles and needs, going beyond the common traditional perception that

‘these are only for people with disabilities’. The current definition of assistive products and technology merely sustains this perception. Considering this, WHO is proposing a paradigm shift – redefining assistive technology as Assistive Health Technology (AHT) and assistive products as Assistive Health Products (AHP) based on the International Classification of Functioning, Disability and Health (ICF)(3).

The current gap in access to assistive products will be magnified in the future by the immense projected population growth, especially as the number of older people worldwide increases from 841 million in 2013 (11.7% of the world’s population) to more than 2 billion (21.1%) by

2050(4). The public health situation in the 21<sup>st</sup> century is therefore going to be quite different from what it was in the 20<sup>th</sup> century. In the last century, people who would have died young because of communicable and noncommunicable diseases are now surviving longer because of better healthcare and a host of related factors, yet invariably they survive with some form of functional decline, bringing new challenges to public health and to health technology in particular.

Gradual functional decline is an unavoidable and integral part of the ageing process, whether one has a disease or not. The 21<sup>st</sup> century will see populations that live longer and thus need to remain independent, healthy and productive, even with chronic conditions and a growing proportion of older adults. Medicines alone cannot solve this new emerging challenge: there will most certainly be a greater need for AHT. Recent years have also witnessed a dramatic rise in injuries, noncommunicable diseases and musculoskeletal conditions, all of which make huge demands on the AHT sector.

Urgent action and greater investment is required to ensure that all persons (people with

disabilities, elderly and others in need), irrespective of their age and health condition, enjoy better health, especially in terms of functioning, independence and quality of life. To ensure this, stakeholders need to move beyond business as usual and establish a new paradigm of universal access to AHT.

This paradigmatic shift in AHT would create a clear and better future in which industries can develop, produce and provide AHT products and solutions in an increasingly high-volume market that caters to everyone's needs by responding to health and related challenges that limit functioning and restrict social participation. Without assistive technology, people are often confined to their homes – excluded from participating in society, and locked into poverty and isolation. We need to “open the GATE” (5)!

WHO fully recognizes existing and projected realities: the WHO's General Programme of Work for 2014–2019 describes “increasing access to high-quality and affordable medical products” as one of its six leadership priorities. One of the four key functions of the Universal Health Coverage (UHC) is the provision of essential medicines and health technology (6). Improving access to assistive technology is also a fundamental component of the WHO Global Disability Action Plan 2014–2021 (7). Greater investment in AHT would contribute towards the success of all these initiatives.

All sectors and stakeholders are urged to move the global AHT agenda forward to meet current and future challenges. It is not only a problem of funding, product design, pricing, distribution and services; it is also a challenge for health and social systems, for professional training, and for policy in general. Meeting these challenges is the key objectives of the **Global cooperation on Assistive Health Technology** or **GATE**, a WHO global initiative, which will engage in partnerships with all the key stakeholders for improving access to AHT.

## **B. Understanding Assistive Health Technology (AHT)**

It is important to have a clear understanding of what AHT is, what it achieves and its relationship with other Health Technology sectors, medical devices in particular. It is a fact that in some countries, a small number of assistive health products such as wheelchairs and hearing aids are classified under medical devices. It is more so for insurance purpose or reimbursement than its merit. Acknowledging there will be some grey areas but to keep all assistive health products under medical devices is problematic and counterproductive, for at least three important reasons:

1. It conflates the essential purpose and rationale of assistive technology to enhance human functioning, and therefore well-being, with the equally valuable but conceptually

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very different purpose of diagnosing, preventing or treating a disease or compensating an injury.

2. Characterizing AHT as “medical device” has the administrative effect of requiring the same regulatory framework that has been designed to guard against potential harms. Unlike some of the medical devices/products, all assistive health products are external devices and do not reside within, the human body. A different innovative regulatory framework is required for those AHPs that require assurance for their safety.
3. Viewing assistive health products as a kind of medical “instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator,” strongly implies that these devices and products are designed for medical purposes (8). In fact, an increasingly large proportion of AHT has near universal application across the life course, and especially into old age, and has nothing to do with diagnosis or treatment.

Considering these factors, it makes sense to redefine assistive technologies/products as AHT and AHP in order to clarify their intended purpose, namely to enhance human functioning to ensure inclusion, full participation and well-being. This would also mark a break from the “medical model/devices/technology” terminology that has often captured this enabling technology within a medical regulatory framework, hindering innovation and widespread uptake. There is, however, always the risk that defining and classifying AHT may give the false impression that these are stand-alone devices when in fact, they are often used in concert with other domains of health technology, Information and Communication Technology (ICT), Accessible Technology, Universal Design, environmental adaptations and personal assistance.

However, considering the ultimate purpose and to ensure better clarity, WHO is proposing an updated definition of Assistive Health Technology (AHT) and Assistive Health Product (AHP) which is as follows:

**Assistive health technology (AHT)** can be defined as the application of organized knowledge and skills, procedures and systems related to provision of assistive health products. AHT is an umbrella term that covers both assistive health products and service provision, including its scientific application.

**Assistive health product (AHP)** is any form of external tool specially designed and produced or generally available, whose primary purpose is to maintain or improve an individual's functioning and independence, to facilitate participation, and to enhance overall well-being.

A consensus is also needed to review this term vis-à-vis ISO terminology of assistive products to ensure better synergy with the health or medical products (9).

The range of assistive health products is quite large. However, most of these products can be broadly divided into the following classes:

1. Products for mental functions, e.g. memory devices, pill box reminders, GPS devices
2. Products for sensory functions, e.g. spectacles, magnifiers, hearing aids
3. Products related to orthotics and prosthetics, e.g. artificial limbs (prosthesis), spinal orthosis, cervical collar
4. Products for personal mobility, e.g. wheelchairs, canes, crutches

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5. Products for activities of daily living including personal care and protection, e.g. toilet chairs, diapers, robots
  
6. Products for communication and skills training, e.g. devices for voice and speech training, Braille apparatus, screen readers
  
7. Products for recreation and sports, e.g. modified sports equipment, camera holder, audio-tactile chess board
  
8. Products for housing, work and environmental improvement, e.g. modified chairs or furniture, handrails or grab bar, controlling illumination.

The indirect benefits of providing AHT are often overlooked. Properly fitted and affordable AHT can delay functional decline and improve health outcomes, thereby reducing direct health-care costs. Assistive health products such as walking frames or crutches can help avoid falls and fractures, especially in older populations. AHT also helps older people remain independent in their own homes, delaying the need for residential living and long-term care.

There is a fragmentation within the AHT sector – traditional impairment-specific definition, classification, training and service delivery models result in lower access. For example, hearing aids, low-vision aids, mobility aids are often provided by the different service providers from different locations with very little synergy among them. A combined comprehensive single-window service delivery system linked to the three levels of health-care delivery system (primary, secondary and tertiary) will ensure greater ease and access to AHT for potential users and more cost-effectiveness for the providers.

### C. Growing need of AHT

The AHT industry currently remains limited and specialized, with a handful of private/public-sector actors who more or less monopolistically determine how research and development resources are directed, what products reach the market and what they cost. The industry is seen, and sees itself, as producing “specialized products” that primarily serve high-income markets. There is a tendency among reimbursing authorities or insurance agencies to feel that AHP are overpriced, have high service delivery costs, and are not as essential as other health products, since they do not cure diseases or save lives. All of these factors results in low coverage. If, however, industry lowers cost and takes advantage of economies of scale – it will be a win-win for all parties concerned.

Medical prescribers, for their part, implicitly support the situation since it reinforces their own power and gatekeeping authority. The market has tended to be controlled by third-party payers, either private or public, with reimbursement rates that do not reflect actual demand. This tends to raise costs and limit access, producing a distorted high-margin, low-volume market situation. In the case of medications, the rise of the consumer movement and increased competition has led to cost reductions and a dramatic increase in access to medicines over the last few decades. Even though many assistive health products, unlike medications, must often be fitted or otherwise individualized to the user, AHT can benefit from a broader and more open market.

In the case of AHT, demand is also distorted by lack of consumer information and is fundamentally shaped by the stigma associated with products that are seen by society as “designed for the invalid”. This distorting feature of assistive technology often has a negative impact on the elderly population who, although they can greatly profit from AHT (for instance, the incidence of arthritis affecting people over age 65 is nearly 50%, hearing problems nearly 35%), may shy away from using it (10).

In 2011, WHO released its World Report on Disability, which provided the evidence base to empirically substantiate the global unmet need for assistive technology of all varieties (11). There are already large underserved populations for basic assistive health products such as hearing aids,

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especially among the elderly even in Europe and USA (12). Where available, an astonishingly high proportion (estimates run as high as 75%) of assistive products are abandoned by consumers. This represents not only failure of production, marketing, follow-up service and maintenance, but also a wider failure of systems and policies designed for the AHT sector.

Low- and middle-income countries have the additional challenges of limited funding for development and production, weak or non-existent procurement systems, absence of safety measures and inadequate servicing and user training. A lack of clear understanding of the need for and benefit of AHT is compounded by lack of needs assessment, inappropriate design and fitting, failure of a service infrastructure to produce and maintain devices, and the absence of a properly trained workforce.

The whole AHT sector would benefit from a clearer partnership with information and communication technology (ICT) and its rapid technological advances. Many assistive health products have a direct link with some ICT applications (e.g. memory devices with a synchronized mobile telephone). Through partnership, these advances could be exploited by both ICT and AHT, thereby benefiting from the ever-expanding potential market for all of these products. ICT can also help to ensure that all information related to AHT can be available everywhere and people can make informed decisions before accessing an appropriate assistive health product.

AHT should embrace the principles of Universal Design (13). When products and systems are designed with the largest range of functional usage in mind – that is, as near as universal as is feasible – then the market for these products increases because more people can use them. It is a plain fact that all of us at some time in our lives, either temporarily or permanently, will live with mobility, sensory, communication or cognitive functional deficits. Whether or not the dream of Universal Design can ever be fully realized, the fact remains that everyone will need, or will continue to require, some form of AHT to accommodate or compensate for less-than-optimally functioning body or mind.

The AHT sector has one of the highest potentials for growth: if only 10% of those needing AHT currently have it, and if the number of potential users doubles in the next decades because of the increased numbers of older adults, then the industry has the potential of a considerable growth by nearly twentyfold. This extremely favourable market potential can and should be exploited.

#### **D. Way forward for AHT**

The current AHT scenario is neither desirable nor sustainable. To effect change, WHO in partnership with the Government of Philippines and the United Nations Department for Economic and Social Affairs hosted a unique multi-agency event, “Assistive Technology Opens Doors” during the UN General Assembly on Disability and Development (HLMDD), which was held at UN Headquarters on 23 September 2013. During the side event, WHO was requested by the key stakeholders to develop and provide leadership to a global initiative to realize several articles of the CRPD, article 32 in particular – Global cooperation on Assistive Technology (14).

WHO has considerable experience making health products affordable and accessible through innovation, partnership, transfer of technology, local production and bulk-purchase (15, 16). This expertise is very much relevant to the AHT sector. Based on this valuable expertise, WHO is developing the GATE initiative in order to improve access to AHT at an affordable cost. However, in order to achieve the paradigm shift envisioned here, WHO needs the active participation of international organizations including donor agencies, professionals and their organizations, researchers, AHT industries, and very importantly, consumers and their advocacy organizations. WHO envisages GATE to be a merger of expertise, competence and entrepreneurial ingenuity and dynamism aimed at innovation, development, production,

**Opening the GATE for Assistive Health Technology: Shifting the paradigm** distribution and financing solutions that are designed to meet the crucial and ever-increasing need to secure access to AHT for all people in need – across the globe.

The proposed GATE initiative has only one goal – improving access to high-quality affordable assistive health products, mirroring the call of one of the six WHO programme priorities. This can be achieved only if the appropriate kinds, quantity and quality of assistive health products are developed and produced, effective distribution and financing infrastructures are in place, professionals and others who provide fitting, repair and maintenance services are properly trained, users are informed and empowered, and there are workable facilitating policies and plans in place.

Considering above-mentioned factors, WHO proposes the core functions of the GATE to be as follows:

1. Engaging in partnerships to promote Assistive Health Technology (AHT) and providing leadership
2. Stimulating the generation, translation and dissemination of valuable knowledge related to AHT
3. Articulating ethical and evidence-based Policies/Norms/Guidelines/Best practices through an impartial global knowledge hub
4. Setting policy, norms and standards and promoting and monitoring their implementation;
5. Shaping the research agenda and promoting research initiatives
6. Encouraging innovation in developing high-quality affordable AHP
7. Providing technical support, catalyzing change, and building sustainable institutional capacity in the field of AHT.

## **E. Proposal for the GATE meeting**

The success of such big initiatives for an emerging sector requires partnership with a common understanding and agreement. As a first step towards developing GATE, WHO has decided to host a meeting of the key stakeholders on 3 and 4 July 2014 at headquarters in Geneva. To develop the meeting agenda, WHO requested the participants to share their views on following three areas:

1. What do you think you or your organization can do?
2. What do you think WHO should do?
3. What do you think we can do together?

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The Secretariat received many good ideas on what GATE should do and among those, the following areas received more attention:

1. Develop appropriate policy, standards, norms and guidelines
2. Create a global knowledge hub including collection of best practices and disseminate the knowledge using various methodologies including social media
3. Develop awareness and create a sense of urgency for greater investment in Assistive Technology
4. Set the research agenda and promote research initiatives
5. Invest in developing new products
6. Develop GATE to foster the network among different stakeholders.

GATE will need to address many specific challenges as the sector grows. Invited participants are expected to come to a consensus on some of the fundamentals outlined in this document and select the top five or six priority actions among the following:

1. identify the worldwide magnitude of the met and unmet need
2. identify top 25 most essential assistive health products and promote their access
3. create a WHO advisory committee on AHT

4. create a “Champions Forum” to promote AHT
5. set the research agenda and encourage research initiatives
6. provide global guidance on norms, standards and a standardized glossary of definitions/ classifications
7. develop a procurement manual for the 25 most essential assistive health products
8. formulate a model for national strategies, plans and policies to establish systems for the assessment, planning, procurement, delivery and management of assistive health products
9. provide technical guidance and support to the Member States, to implement AHT policies suitable to the resource level of each country
10. coordinate among other organizations of the United Nations system, international organizations, academic institutions, International Standard organizations, professional bodies and users’ groups to promote access and use of AHT
11. collaborate with other international organizations in promoting universal design, ICT and accessibility, and to ensure that regulations on AHT are aligned and consistent
12. develop a bias-free global information network one-stop clearing-house providing information and guidance on appropriate AHT according to levels of care, setting, environment and intended outcome, specified to a country or region.

**Opening the GATE** for Assistive Health Technology is an innovative vision – a new paradigm. The time for introducing the concept of disruptive and frugal innovation in the AHT sector is very much needed in order to create a new market and make the quality products available at an affordable cost – across the globe. We cannot ignore the challenge of providing universal access to AHT for those in the world who can profit from it. The paradigm shift described here is driven in part by a conceptual shift and by a more reasoned and realistic understanding of what AHT is, what it achieves, who can benefit from it, and its instrumental relationship to participation and well-being. Finally, the shift points to the readiness of WHO to initiate, develop and lead another global initiative to advance its mandate – improving health for all.

(This concept note has been developed as a background document for the 1st GATE meeting to be held in WHO, Geneva, 3 and 4 July, 2014.)

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