Advanced assistive products presription

Karel Moses, MD, Rehabilitation Institute Kladruby, Czech Republic

E-mail: karel.moses@rehabilitace.cz

Sources:

1) New York State Medicaid Wheeled Mobility Equipment, Seating and positioning component Guidelines, Revised 2008, https://www.emedny.org/providermanuals/DME/PDFS/nys_medicaid_wme_spc_guidelines_10-08.pdf
2) Dolan M, J, Clinical standards for National Health Service wheelchair and seating services in Scotland, Disabil Rehabil Assist Technol. 2013 Sep;8(5):363-72, http://www.ncbi.nlm.nih.gov/pubmed/23256726
3) NHS Scotland Wheelchair and Seating Services - Clinical Standards Consultation, NHS Scotland, 6.12.2010, http://www.scotland.gov.uk/Resource/Doc/333704/0108951.pdf

4) GATE – EASTIN Milano meeting, April 2015

5) Moses Karel, Vašíčková Lia, Faltýnková Zdeňka, Prouzová Pavlína, Concept of methodology for presription of wheelchairs, wheelchairs accessories, anti-decubitus seats (pressure relieve seats) from the position Evidence Based Medicine - Koncept metodiky pro preskripci vozíků a příslušenství vozíků včetně antidekubitních sedáků z pohledu medicíny založené na důkazech, XXIV. konference rehabilitační, fyzikální a balneo medicíny Jáchymov, 6.2. – 7. 2. 2015,; second presentation: Setkání spinálních jednotek a spinálních rehabilitačních jednotek, Harrachov, 23. – 24.4.2015

6) http://www.etna-project.eu/eastin20.html

7) http://www.eastin.eu/en/searches/products/index

8) http://www.rehadat-hilfsmittel.de/de/

Assistive products presription

There is a question of basic assistive product.

Based on ISO definition, Proposed WHO definition (Milano April 2015):

Assistive product

is a subset of health products, which includes any external product (including devices, equipment, instruments and software) especially 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.

It is also to:

i) protect, support, train, measure or substitute for body functionsú structures and activities;

or

ii) prevent impairments, activity limitations or participation restrictions

Reasons for suggested change:

- accepting the fact that all assistive products users are not the persons with disabilities
- considering the ultimate purpose of an assistive product - to assist/improve functioning
- linking it with more public health agenda; health products in particular.

Question: Is a city bike assistive product?

World Health Organisation (WHO) coordinates Global Cooperation on Assistive Technology (GATE), and next notes are from my meeting with GATE in Milano 27.4.2015

Chapal Khasnabis - e-mail: khasnabisc@who.int

http://www.who.int/phi/implementation/assistive_technology/phi_gate/en/

Context: Changing public health scenarion

Comparison between 1950 - 2000 - 2050?

Decreasing - Communicable disease (CD)

Increasing - Road Traffic Injuries (RTI)

- Non-communicable disease (NCD)
- Ageing

Disability perception and experience

1950 - poliomyelitis, young

2015 ... 2050 - Old-age

Pace of ageing

from 7% till 14% of population

France 1860 - 1980

Sweden 1890 - 1970

UK 1930 - 1975

USA 1945 - 2010

Japan 1970 - 1995

China 2000 - 2022?

Brazil 2010 - 2030?

Disabled person in family

1950 - Joint family

2000 - Nuclear family

Disability and income

... very little diference between LMIC and HIC

... more age = More Age More Assistive Products

Functioning and age

increase of functioning till 30

decrease of functioning till death - functioning could be supported by assistive products

... more age = More Age More Assistive Products

90% of 75 years old have some assistive product

Healt care system

20 Century - Preventive + Curative + Promotive + Rehabilitative (PCPR)

21 Century - Assistive + PCPR

Health Technology

- 4 pillars of health products -

- Medicines

- Vaccine

- Medical devices

- Assistive products

Access to assistive products

Need:

more than 1 billion people now

2 billion by 2050

But only 1 in 10 can access Assistive Products (10%)

4 major obstacles

Awareness, Availability, Cost and System of Provision

Cost:

Electric powered wheelchair in comparison with car

Advanced prostesis for transfemoral amputation in comparison with family house

Service provision fragmented sector

- Prosthesis; Orthosis; Assistive devices; Wheelchair; Mobility aids
- Eye glasses; Low-vision aids
- Hearing aid
- Rehab Clinic; Physiotherapy/Occupational Therapy

Need for change - need for innovation

- Learn from other successful initiatives
  - essential medicines list (EML); GAVI
- Disruptive innovation
  - creating a nwe market and value network
  - displacing an earlier concept
  - setting an example of change

A familiar scenaion of the past

- WHO model list of essential medicines 1977
  - some medicines are more essential than others
  - essential medicines needs to be available at an affordable cost
  - not restricive, flexible and adaptable in different context - selecting the list of medicines thos are essential in a national responsibility
  - a peaceful revolution in International Public Health

An example ... hearing aide

Manufacturer ... 1000 Dollars

Distributor

Retailer

Doctor

Audiologist

Technician ...

User ..... 4000 Dollars

What WHO is doing?

- Ensuring access to assistive technology a global priority

- Redefining assistive technology/products

- Working towards implementing the article 32 of the CRPD - International cooperation on assistive technology

- Taking appropriate initiatives to assist the Member States to improve access to high-quality affordable assistive products

WHO Model Priority Assistive Products List (APL)

Proposed definition

Environment -

- Vision
- Mobility
- Hearing
- Speech
- Mental

Priority Assistive Products (APP) may be defined as: those products, which are highly needed, a must/absolutely necessary to maintain or improve an individual´s functioning and health; they should therefore be available at a price the community/State can afford.

Proposed criteria

1. Priority assistive products for community level (APPC)

- those priority assistive products, which can be provided at community level by the health workers/ nurses/ community-based rehabilitation (CBR) workers and others (non-specialists) with a short comprehensive training programme.

2. Priority assistive products for referral level (APPR)

- those priority assistive products, which can be provided at the referral level by the specialist professionals on the subject matter.

WHO Model

Priority assistive products list (APL)

1. scoping rewiew

2. conducing a Delphi study to identify priority assistive products (APP)

3. conducting a global survey

4. regional/ global consultation - consensus

25 APP for community - 25 APP for referral

Brainstorming in Milano 28.4.2015

List of criteria for defining as "highest priority"

- supporting and/or expressing basic needs - maintaining and protect health/ functioning

- supporting function in environment/ improving body function on the best way (be supported by ICF and be correlated with ISO:9999)

- give the opportunity to perform daily life activities to stay independent as long as possible

- each country can refine the priorities based on resources and provision mechanism - Guide

Criteria to guide the decision whether professional provision required:

- highly individualised products must be prescribed and evaluated by professionals providing training where necessary

- if more than one product is required to be connected together or extra components are involved

- complex products should be defined by professional

- required to correct a clinical condiion, and/ or the incorrect use of the product could lead to a deformity or worsening of a condition

Prescription - who:

community level

- social and health workers with no specialised training
- working in primary health or social care, at the frontline
- have the option of consulting a specialist

Specialist professions

- rehabilitation professional e.g. therapists (occupational, physio, speech)
- technicians who work with the equipment
- physician in rehabilitation technology, sensory or cognitive impairments

People need advice even for simple products and the advice needs to be objective - firms want to promote their products.

Community products still need enough information where to go.

General definition need and glosssary

- safety, reliability, affordability
- glossary

Description of products

- category (mobility, vision, etc.)
- age group (children, adult, older)
- name of product (WHO?)
- Title (ISO) + ISO code + description
- function of the product - NO technical parameters
- product related intended use (in relation to ICF)
- examples! (incl. black/ white illustrations - icons)
- exclusion
- non-professional key words e.g. for search purposes
- type (community/referral)

Delphi working group

Result:

confidential list of 25 products for community and 25 products for refferal.

Situation in Czech Republic

Assistive products –

Rules of Ministry of Health and Rules of Ministry of social welfare

Payment (direct reimbursement) from health system (medical devices and some other assistive devices)

Payment (limited reimbursement) from social system (non-medical assistive devices)

Reason for creation of new methodology: demand for the methodology of the payer (health insurance providers), dissatisfaction with the current methodology of General Health Insurance Provider (Všeobecná zdravotní pojišťovna - VZP), categorization of outpatient medical devices under direction of the Ministry of Health CR.

Objective: The selection of clinically and cost effective equipment - wheelchairs and strollers, accessories, anti-decubitus cushions for seating systems (the wheelchairs-accessories-seats: shortened as WAS).

1. Research

When creating a methodology we did not found scientific evidence for effective equipment aids in the nature of the sources of meta-analyzes, systematic reviews. We found several randomized trials and scientific works with less evidence for a very small part of the WAS.

Expert opinion for prescription WAS is available in most of developed countries, in the form of guides, methodologies and "good practices", which are regularly revised (1), some are made on rules of evidence-based medicine (EBM) (Scotland, the NHS system) . (2,3)

Expert opinion in the Czech Republic:

a) The existing methodology VZP - Reimbursement catalog VZP - ZP, Methodology, Version 969, Valid from 1 1.2015 available on http://www.vzp.cz/uploads/document/metodika-pzt-969.pdf

b) indication criteria for the regulation of medical devices for patients with impaired mobility - created by professional societies for the working group of the Ministry of Health (October 23, 2012) - For the categorization tree - see below.

c) training courses STEPS (physiotherapists, doctors, occupational therapists).

d) many years of experience of experts, including experts in patient organizations

Affected populations (inclusion criteria): - patients/ clients, which need prescrisriptiond aids for permanent use (meaning a longer period than one year), except of basic wheelchairs and basic seats.

Basic rules of EBM methodology in prescription WAS

According to foreign experience, the methodology does not create one person, it is teamwork.

Methodology - In our opinion, must meet:

a) in the prescription and use of aids for whose use we have no clear scientific evidence, it is necessary to proceed as clinical (scientific) study - including follow-up of patients. One person is responsible for the regulation and follow-up (prescriber). It is not a clinical study in the strict sense, ie including reporting, ethics committees and insurance - it is a "scientific" way of working. We want to document that the traditionally established methods of treatment (care) are good practice (work).

b) uniformly implemented method for testing and evaluation - see below "Assessment of mobility"

c) thoroughly document the patient's condition and selection WAS in accessible way (method)

d) secured funding

It may also meet:

e) teamwork (interdisciplinary)

f) knowledge sharing within the network of prescribing workplaces

g) sharing knowledge with patient organizations

h) centered care for complicated cases, cooperation between the workplaces. For example: At first, several centers - like rehabilitation centers. Activity of centers to expand in collaborations around these centers - tutors, workshops, courses. Quality collaboration may lead to less congestion of centers. Gradually, 14-30 - (40) workplaces.

Assessment of physical function and mobility skills

Objective assessment of physical function and mobility skills (abbreviated - Mobility Assessment) is to get the information to decide whether from a health perspective it is useful to equip the client / patient with aids due serious difficulties in movement and to ensure the correct (optimal) sitting. These include documents for prescription WAS.

Mobility assessment is carried out under the coordination of interdisciplinary prescribing physician (general practitioner, rehabilitation medicine specialist, orthopedist, neurologist ...). The interdisciplinary team provides care to a client / patient, based on the needs of the client / patient and his/her caregivers. In the interdisciplinary team are present - physician(doctor), physiotherapist, occupational therapist, distributor/supplier of medical devices, techniques, ...

The report "Mobility Assessment" provides prescriber.

The report "Mobility Assessment" is the basis of an application for approval of payment (for payer).

Prescribers in collaboration with the medical device dispensaries ensures ordering supplies from a supplier, testing, adapting and configuring the new equipment.

It is useful if prescriber invites the client / patient to check whether the aid meets the needs of the client.

Mobility Assessment report should not be tied to a particular type of form, may be in a style that the doctor uses for other purposes, but it must contain the necessary information. From the minutes must be clear that the main reason is the difficulty in testing the mobility of the client / patient.

The report "Mobility Assessment" for payer (health insurance)

It includes the following:

1. Basic demographic information on the client / patient

2. Basic information on health and functional status

(Summarizes the history, details of the client / patient, course of problems in functioning of the client / patient's disease according to the available documentation)

a) current problems / diseases

aa) history and the course of problems in functioning (Why doctor came into contact with the client, why is doctor considering to prescribe mobility aids)

ab) How long has the patient/ client current problems/disease, what is the progression of difficulties in mobility, what interventions were carried out, and with what results, which mobility aids were used with what results - canes, manual wheelchair, scooter, electric powered wheelchair

ac) a list of all wheeled devices for difficulties in movement (difficulty in mobility), and a list of accessories, seating systems, anti-decubitus cushions

ad) an explanation of why the existing aid(s) does not meet the health aspect, or the cost factor (eg. an estimate of repair costs of aids)

b) other problems and malfunctions (including personal histories) (eg. breathing difficulties - impaired respiratory function, skin defects - bedsores)

c) examinations (X-ray, ergometer - spiroergometric, EMG and others)

d) surgery performed

e) current therapy

f) labor and social history

fa) occupation, employment, leisure activities, family involvement, other caregivers

fb) a description of the usual environment of the client, caregivers

g) The care plan (planned operation, examination ...)

3. Record of identifying short- and long-term goals

- From the perspective of the user (client), from the perspective of caregivers

4. Record of limitations activities and participations

a) If client/ patient is using canes, walker, other tools, assistance during activities?

b) What tools or methods can ensure better participation?

c) management activities of daily living (ADL - such Barthel test, SCIM)

ca) managing food intake (including swallowing)

cb) management excretion of urine and faeces

cc) shifts - from wheelchair and back, bed (couch), chair, car, toilet, toilet- or a combined chair, from the floor

cd) walk in the usual environment - distance, speed, balance while walking

5. Record of problems in body structures and functions

a) breathing, vision, hearing, communication, cognitive function, behavioral problems, skin, pain

b) documented relevant examination - PRM, neurological, orthopedic, ophthalmology, internal, psychiatric, clinical psychologist

6. Record of relevant physical examination

a) signs / symptoms

b) the presence of deformities, trophic disorders, including trophic skin changes, skin defects, scars, posture and mobility of the body segments (head, neck, chest, lumbar spine, pelvis, upper and lower limbs), range of motion, muscle tightness, spasticity, muscle strength, reflexes, coordination of movement of the head, torso, arms and legs, balance in sitting and standing (balance - eg. Berg Balance Scale, Tinneti). Sensitivity (in particular at the contact point with the aid - for example, the thigh).

c) examination in lying down (on a firm surface - examination table), sitting examinations (at the edge of bed)

d) to carry the load (weight) while standing, sitting,

e) anthropometry (doctor or physiotherapist)

f) relevant measurement of height, weight and other parameters

g) other - documenting significant deformities (fault structures) using accessible method (available means) (different length legs, scoliosis, etc.)

h) diagnosis (in relation to difficulties in mobility)

i) diagnosis of other

7. Mobility Assessment / Evaluation

a) Does patient use assistive device appropriate to current conditions and expected developments of functional status?

aa) It is a progressive disease?

ab) description of expected changes in the health and functional status.

b) What is the optimal posture for optimal mobility and to prevent complications?

c) How do you achieve this optimal posture?

d) Are they present deformity fixed or flexible (active / passive correction)?

e) What is the seating system was chosen and why?

f) What was the setting of sitting in a wheelchair, and why?

e) What were the chosen means to correct (flexible) deformities, to relieve fixed deformities, to promote stability and ensure optimal posture during various activities in a wheelchair, to ensure the stability (security) of the client in a wheelchair?

8. Record of imitation (simulation), using new equipment - "testing tools"

a) clinical verification of the proposed sitting in a wheelchair

b) ability to safely control aids and its practical use

ba) in the environment of healthcare facilities, distributor of medical devices

bb) at home, in the community (in the village ...), at school, at work - access to the building, into elevators, to the rooms, the bathroom, and the toilet, the storage space, etc. (upon request of payer - particularly necessary for active wheelchairs, special wheelchairs, scooters and electric wheelchairs - (distributor, technicitian, doctor - GP?)

c) may be needed training

d) documentation in accessible method (available means) may require a photo, video - informed consent of the client required, anonymity suitable (for example, a mask covering part of the face), provides prescriber, available to the distributor and payer on request (common data formats).

e) it is advisable to perform measurement of pressure distribution in a sitting position or pressure distribution in the back support (pressure-mapping), where there is a need to document the effectiveness of the equipment, where in other ways, this can not be ensured.

9. Antropometry in optimal setting WAS (technician) - specific technical list

10. Recommendation

a) with respect to the needs and set goals - to explain why a doctor deviates from the goals proposed by the client or his/her caregivers, if so

b) the documentation must be substantiated why it was not possible to use less costly aid

c) a description of considered alternatives, as relevant

ca) Why these alternative solutions do not meet the health aspects of prescription aids.

cb) For example: Why instead of a manual wheelchair electric wheelchair indicates. Why indicates electrical positioning of the tilt and reclining the seat + electric lift and do not recommend only the electric tilt of the seat positioning.

d) Note to the "Recommendation"

da) the cost effectiveness of using aids are not just the cost of acquisition, maintenance and servicing, but also in relation to the clinical effect of the client.

db) include the costs of prevention and treatment of damage from long-term excessive overloading the client and caregivers and costs associated with short-term overloads significant risk of complicated client (complicated cardiac, ...)

dc) there are very few scientific studies documenting the clinical efficacy of the individual components (seating systems, accessories ...)

11. Plan of care

a) expected average daily time of use tools in the environment the user / client (for example, how many hours a day to sit and ride in a wheelchair)

b) difficulties in managing daily activities of the client solved with using of the aid - which manages without assistance, which manages with the aid, and without aids - especially MRADL - mobility related ADL (those that do not concern excretion)

c) the expected duration of the required use of tools, what changes - modifications to the device or the equipment will be needed over the coming years (3, 5, 7 years, depending on the type of equipment and its useful life).

d) if it is a device that has the ability to be customized when changing body dimensions (such as "growing A-frame"), approximately how many years it will be possible to use this aid.

e) if it is an accessory of wheelchair, seating or equipment for positioning, can be integrated into existing wheelchair / Aids?

f) planned procedures and operations, such as corrective surgery, due to contractures, application of botulinum toxin, when, for what diagnosis?

12. Record of the prescription aids and delivery of aids

a) Code. Item name, quantity ordered, size, catalog number. Price / payment limit of payer

b) Understand of the patient with instructions for use - Instruction manual (supplier, distributor).

c) Ensuring the availability of the instruction manual for payer (supplier).