The Future of Rehabilitation

WHO Gate Challenge

We currently Care for 30% of potential global market

10,000 CPOs cover 3m amputees if we have them?

Integration of Product & Services may provide 60%!

AOPA
Saeed Zahedi
Agenda

- Scale of Socio Economic Need
- WHO GATE RG Challenges
- The Core Biomechanical Need
- Factories of Future - Integration
- Healthcare cost Falls Ulceration
- Long Term Rehabilitation/Care
- Conclusions

Rehabilitation of 1bn Disabled, 10m Amputee
UN Challenge for 2016 - 2020
Review Aims of GATE initiative

*Improve access to*

**high-quality affordable Assistive Health Technology**

one of the six WHO leadership priorities to address the challenge of rehabilitation of 1bn Disabled people (2050 it will be 2bn). Estimated 8m amputees in Asia

*Responding to the call to*

increase access to essential (UN List in preparation), high-quality, safe, effective and affordable medical products, through Provision of services/products

**Develop Policies that can be legislated nationally**
Vision

A world where barriers to social inclusion and mobility are reduced or eliminated as a result of improved access to P&O care and mobility devices.
**North America**
- User groups are numerous and very well organized
- Key themes: Increasing employment opportunities for people with disabilities
- Action on independent living and accessible environments

**Europe**
- User groups are numerous and very well organized
- Accessibility and inclusion are key themes.
- Successes take the form of new EU initiatives and proposing new legislation to advance disabled people’s rights
- National level as well as EU umbrella organization for each disease area

**South America**
- Action on improved access to care and to assistive devices
- Growing awareness of diabetic necrosis and resulting disability

**Africa**
Mainly regional or international groups as opposed to national organisations
- Limited national actions or stakeholders except in South Africa
- Cross-disability and inclusive disability movements, using the human rights approach, aim is to build leadership amongst persons with disability for advocacy

**Middle East**
Very few organizations but those who are active have a humanitarian mission, in view of the various recent wars in the region and hence mainly provide rehabilitation services, information, training, support to employment

**Asia**
- Diverse region - User groups are numerous and some are well organised while others are new and work on access to basic services.
- Strong theme: Action on the need for employment opportunities and inclusion

**Australia**
- Very strong and unique advocacy culture in Australia as illustrated by the wide range of user organizations who have advocacy as their primary goal.
- Aim to raise the government’s awareness on the rights of people with disabilities, etc. and achieve changes in legislation, government policy and community attitudes

Building a picture of disability/mobility advocacy by region
Mobility Need and Solutions to Demographic Changes

Graph 1.6.8: Population age structure by major age groups, EU-27, 1990-2060 (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>0-19 years</th>
<th>20-64 years</th>
<th>65-79 years</th>
<th>80+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>23.7%</td>
<td>50.7%</td>
<td>12.3%</td>
<td>3.3%</td>
</tr>
<tr>
<td>2010</td>
<td>21.3%</td>
<td>51.3%</td>
<td>12.7%</td>
<td>4.7%</td>
</tr>
<tr>
<td>2020</td>
<td>20.5%</td>
<td>59.5%</td>
<td>14.4%</td>
<td>5.7%</td>
</tr>
<tr>
<td>2030</td>
<td>19.7%</td>
<td>56.7%</td>
<td>16.0%</td>
<td>9.0%</td>
</tr>
<tr>
<td>2040</td>
<td>18.5%</td>
<td>54.2%</td>
<td>12.0%</td>
<td>2.9%</td>
</tr>
<tr>
<td>2050</td>
<td>17.6%</td>
<td>52.3%</td>
<td>17.8%</td>
<td>11.0%</td>
</tr>
<tr>
<td>2060</td>
<td>16.0%</td>
<td>51.1%</td>
<td>17.8%</td>
<td>12.1%</td>
</tr>
</tbody>
</table>

EU-27 excludes France’s overseas departments.
Source: Eurostat (online data codes: demo_pjan and proj_08c2150p)

Figure 3.1. Prevalence of disability by age and severity category. Source: OPCS, 1988.
Mobility – Empowering Disabled and Elderly

Royal Academy of Engineering – Biomedical Eng. Policy
Accelerated Access - NHS
WHO - Mobility # 1

Opportunity for Global non competing Networks in O&P
Challenges Leading to Opportunities

- Demographic change opening New markets
- Socio Economic benefits of Maintaining mobility
- Longer independence in mobility impaired people
- Solving Budget cuts in health services
- Sharing Expertise through Technological advances
- Volume provision of More advanced devices
- Customisation Bespoke fabrication aided process
Gate Research Working Group

- **GATE** (Global Cooperation on Assistive Health Technology)
- 1\textsuperscript{st} meeting of WG 1 Since July initial launch
- Most active of the 4 WG initiated in Geneva
- Establish the key areas of Research needed
- 62 participants from 24 countries (30 US, 30 EU)
- 4 key Actions to Implement
  - Research and Advocacy
  - Products
  - Training
  - Provision of Service
Overall Conclusions

- WHO can fund 1-2 Research areas – Needs Map
- Better Understand variations of each countries
- Innovate alternative training and assessment
- Modelling of Health care Economic Gains with AT
- Pilot Model and evaluate outcome – White paper
- Data collection of impact to provide evidence
- Formulate Policies & implement through legislate
- Raise the level of education to SMARTER level
What are the Critical Research areas?

Regarding:

1. Identification of the facilitators & barriers, including cultural and/or contextual factors affecting the use of assistive products/services?

2. Development of successful models for the delivery, implementation & support of assistive products and services, including human resources required?

3. How assistive technology products and services and their delivery systems should be monitored and evaluated?

4. Policy development promoting the provision of assistive technology products and services, including the role of different stakeholder groups?
GAP Analysis to fulfil the aim

To identify strategic research priorities regarding knowledge gaps that need to be filled in order to be able to achieve the goals of the GATE initiative

The Focus of Meeting was on what research needs to be done to support the GATE initiative?

The conclusion of the meeting, together with the survey done, intends to lead to a Global Research Agenda for Improving Access to high-quality affordable assistive health technology.

(fill the gap between high quality expensive and low quality low cost) – Need for removal of Barrier to Access and provide model care services

Identified the need to map of scale of disability and provision of services Economic of Health care during life cycle (Social cost V Wealth creation)
Systematic Review: Effectiveness and cost effectiveness of prosthetics & orthotics services

Objective: To establish what is known from the existing literature about the effectiveness and cost effectiveness of prosthetics and orthotics services?

Study selection: Studies reporting primary research on the effectiveness or cost effectiveness of prosthetics and orthotics services

- initially with a focus on randomised controlled trials, later to expand to other study designs.
- since there is very little research on “services”, we have focussed on “interventions” than “service set-up”.

Records identified through database searching (n = 36,069)
- Web of Science (n=9,796)
- Medline (n=9,784)
- SCOPUS (n=7,092)
- PubMed (n=2,458)
- CINAHL Plus (n =2,587)
- Embase (n=1,335)
- Rehabdata (n=1,035)
- PsycInfo (n=1,039)
- ERIC (n=57)
- Education Research Complete (n=144)
- Business Source Complete (n=136)
- IEEE (n=317)
- NIHR (n=288)
- CEA Registry (n=1)

Records after duplicates removed (n = 28,958)

Records screened (n = 28,958)

Records excluded (n = 19,730)

Remainder articles for title and abstract screening (n = 9,228)

"All field" search of remaining articles for words "randomi*ed" OR "cost" or "economic" (n = 2639)

Full-text articles assessed for eligibility (n = 973)

Remaining articles (n = 6,589)

Recorded excluded (n = 1,666)

Inclusion
- Randomised control trials (RCTs); Controlled (non-randomised) clinical trials; Controlled before-after studies; Prospective and retrospective comparative cohort studies; Case-control studies; Delphi method studies; Reviews/systematic reviews; Guidelines; Studies reporting on cost/cost effectiveness

Participants of all ages and medical conditions
- Valid outcome measure(s) (scale/measurement; structured/semi structured interview)
- Device (orthotic or prosthetic) has to be prescribed for a clinical problem
- Device (orthotic or prosthetic) used during activities of daily living

Exclusion
- Case series; Case report/study; Expert opinion articles; Letters to editor; Commentaries; Cross sectional studies/no follow up
- Healthy participants/participants without a medical condition
- Devices used for prevention of injuries
- Novel/Research devices (not currently available on the market)
- Device (orthotic or prosthetic) used within therapy/training sessions

Metadata analysis of the 2,639 studies was completed to gain an understanding of how research in this area has evolved over the last 20 years and to identify the countries where this research was completed and the languages in which studies were published. There has been a steady rise in the number of publications per year in the area of prosthetics and orthotics: from 44 in 1995 to 244 in 2014.
Results so far…

<table>
<thead>
<tr>
<th>Randomised controlled trials</th>
<th>Number of studies:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Orthotics</td>
</tr>
<tr>
<td>a  Provision of an orthotic Vs. non provision (e.g. brace vs. no brace)</td>
<td>143</td>
</tr>
<tr>
<td>b  Provision of a prosthetic/orthotic Vs. prosthetic/orthotic comparator (e.g. prosthetic/orthotic A Vs. prosthetic/orthotic B)</td>
<td>107</td>
</tr>
<tr>
<td>c  Provision of a prosthetic/orthotic Vs. non prosthetic/orthotic comparator (e.g. surgery/casting/wheelchair/crutches)</td>
<td>108</td>
</tr>
<tr>
<td>TOTAL</td>
<td>358</td>
</tr>
</tbody>
</table>

Of the 143 studies in this RCT category the majority of the research has been on the adult population (87% of studies) and has examined lower limb orthoses.

Majority of the studies on the adult population examined the provision of orthotics services for arthritis (wrist/hand splints; knee braces; foot orthoses), stroke (AFO; wrist/hand splints) and ACL (post-surgery knee braces).

The majority of studies which had a paediatric population focused on Cerebral Palsy (AFO; Lycra garment; foot orthosis).

Of the 362 RCTs only 4 were on prosthetics services and examined lower limb prostheses (Datta et al. 2014, Selles et al. 2005, Traballesi et al. 2012 and Vigier et al. 1999).

All of these studies compared lower limb socket systems.
Conclusion for now…

- The included RCTs used a wide range of qualitative and quantitative outcome measures to examine effectiveness of interventions.
- Questionnaires and scales were utilised to assess pain, quality of life, and functional improvements (e.g. SF-36, Cincinnati knee score, Lyshom Knee Score, WOMAC pain score, Oswestry Disability Index, Foot Health Status Questionnaire and Gross Motor Function Measure (GMFM) score, Manchester Foot Pain and Disability Questionnaire and DASH (Disabilities of arm, shoulder and hand)).
- Clinical quantitative measures such as walking speed, functional reach and timed up and go tests and Cobb angle were used.
- Some studies utilised biomechanical (e.g. range of motion, muscle torque, grip strength, plantar pressure) and physiological (Physiological Cost Index) quantitative assessments.

.. the work needs to continue. We need to look at (1) conducting detailed analysis of various reports (2) effective tools to measure QoL (focusing on P & O) (3) conducting appropriate research in relevant geographical locations focusing on the local needs.
What is Missing?
Core medical / clinical focus is needed

• Pressure (becoming critical) from payers to demonstrate medical value, health care economics case.
• Requires, statistically valid, peer reviewed scientific evidence.
• What to focus on?
Impact on Outcome Measure studies

Quantification of Clinical Needs / Experiences

Needs for strong strategic and scientific basis for Needs discovery and efficacy of solution
Core Biomechanical Studies – Key to Mobility

example; Ankle – foot complex motion

7+11+9 ~ 27 degrees of complex motion
Elastic (spring) vs Viscoelastic (hydraulic + spring) findings

<table>
<thead>
<tr>
<th>Spring</th>
<th>Hydraulic + Spring</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Resistance doesn’t change with speed</td>
<td>• Resistance <strong>does</strong> change with speed</td>
</tr>
<tr>
<td>• Resistance doesn’t change with position</td>
<td>• Resistance <strong>does</strong> change with position</td>
</tr>
<tr>
<td>• <strong>System is Always stressed when loaded</strong></td>
<td>• Resistance changes with both speed (time) and position</td>
</tr>
<tr>
<td></td>
<td>• <strong>System always tends to relax when loaded</strong></td>
</tr>
</tbody>
</table>
MPF (Elan) Papers Published: Key Findings

1: Increased negative ankle work verified
2: Reduced shank angular velocity
3: Reduced residual knee flexion and work

The brake provided by the ankle results in less load/demand on residual limb joints, and slower more controlled descent

MPF remains experimental - Need for changing Mind-sets
“Interpretation: The greater negative ‘ankle’ work done when using the active hydraulic compared to other two ankle types, explains why there was a corresponding reduction in flexion and negative work at the residual knee. These findings suggest that use of a microprocessor controlled hydraulic foot will reduce the biomechanical compensations used to walk down slopes.”
Complexity of Needs, greatest at K2

Consequences of ageing
- Sensor-motor deficits
- Drop in capabilities
- Factors, compounding management of comorbidities

Consequences of prosthetic rehabilitation
- Increased impact on tissue health
- Loss of Control & thus capability
- Loss of sensory feedback
- Drop in mobility, transitionary activities are more unstable
- Loss in confidence, self-care

Home Mobility / auto Measure

Safety

Complex comorbidities

Tissue Viability
Cost / Economic Benefits, justification for higher reimbursement

Cost Benefits

Disease / injury prevention

Safety

Mobility
Clinical Evidence Base- Education Need

Compendiums

MPF

MPK

Integrated Limbs

Socket Technology
Future - Affordable? User Acceptability? Stakeholder Benefit? Make same as own?

- What is acceptable from market?
- What is possible reimbursement?
- What is accepted by the user?
- Stigmatisation? Elderly market?
- Active/ passive devices?
- Assist when required?
Affordable Technology to meet the need

- Rehab exoskeleton for Paraplegic ~ $100k
- Assistive Technology device for elderly Exo leg ~$5k
- Stroke rehabilitation care, reduce number of workers
- Volume production to reduce cost vs cost of care home
- Incentives Professionals to adopt technology / demand

Above 4 images courtesy of MIT Biomechanics Lab
User Centered from biomechanical Need to fitting
Future Integrated Products & Services

- Customised Bespoke
- Affordability, less Skill
Preparing for 2020 and beyond

- Reshaping infrastructures & supply chain
- Made to measure JIT
- Value added in know how
- Different IP values
Summary – How Can Technology Help?

• Challenges of demographic change
• Support of current and more future cases
• Active/ passive devices – what provides the best cost-benefit ratio?
• Constraints on technological level (battery life, weight, etc.)
• Assistance of technology/ computer driven design
• Assistive devices and overall process of provision
• Relieve clinician/ rehab engineer to focus on key aspects
• Acceptability – from user, clinician, health insurance
• Validation – for reimbursement
• How can user interfaces provide more benefit? Being more intuitive?
• How does the service process of the future looks?
Discussion Points

• Service process of the future?
• How does technology change the current model? Assistance – limitations?
• Acceptability of future devices?
• Role of user interaction via user interfaces?
• Aspects that haven’t been considered yet?
Emerging Considerations

- Alternative method of training and assessment
- Criteria for successful model based on review of previous WHO programs and future trends
- Formal Mentorship network to support implementation and inter professional care
- Dynamic evolving continuous technology transfer
- Measure success & impact on life/employment
- Evaluation of how products/services improved
- Rehabilitation Engineering Services for all AT
Mobility # 1 – P&O + Wheelchair

- Health Care – Outcome, flexible system, Access
- Education – Accessibility, local sustainability
- Policy – Service delivery system, funding, models
- Essential List of 50 has P&O as a key section
- 1 stop shop AT integrated product and services
- ISPO to review alternative education & training
- New professional infrastructure & record impact
- Extend Use of on line & set up mentoring support
- Network with local researcher to collect data
Assistive Health Technology Evidence

- Advances in AHT and Product go hand in hand with evolving regulatory needs.
- The process of verification must meet strict safety requirements and validation on users to ensure the appropriate benefits are delivered safely and efficiently at affordable cost.
- The economics of Health care are intertwined with the need for clear and demonstrable clinical evidence of outcome measures.
Real Living – Real Ability

- Loss of lower limb function and power
- Maintaining mobility and balance
- Social care of disability due age
- Long term care Health and social services
- Away from hospitals, prevent Falls
- Factories of future

Conclusion
Carbon3D 3D Printer Printing the Eiffel Tower (20") in Six Minutes x100 faster Ceramics

TCT 31st Dec 2015 Jan 2016 6,7,8,9th New SLA option materials from silicon to Carbon Fiber

Thank you saeed.zahedi@blatchford.co.uk