



Report

"Development of Quality Control Tools for Prosthetics and Orthotics"

12 - 14 December 2011

Mobility India, Bangalore



Participants

Representatives from P&O schools, Members of SPO (NMS of ISPO in India), P&O practitioners, representatives from National Institutes & International P&O schools

Contents:

- Background & Introduction
- Delegate List
- Presentations
- Day wise proceedings
- Deliberations & Recommendations
- The way forward
- Picture Gallery
- Acknowledgements
- Quality Control Protocols (Annexure 1)

Background/ introduction

Perceptions of quality control measures and protocols are varied across the Indian P&O schools and amongst practitioners. It has been an issue discussed constantly at various professional forums. This has a direct impact on the quality of assistive devices used by people with disabilities. Dealing with people with disabilities has also been a very sensitive issue and special care has to be taken from all perspectives.

The issue of quality control in prosthetics and orthotics service delivery is the key and holds high importance. On ethical grounds having clear fabrication and service protocols for P&O devices is the need of hour. The need of the hour is to come together under one umbrella and develop quality protocols with clear consensus among all the P&O schools and practitioners.

This could be done with an effort that similar protocols are followed by all the P&O schools at all levels creating human resources to address the need of persons with disabilities. This could ensure that prosthetics and orthotics devices with acceptable quality are made available for the people with disabilities.

Interventions

Mobility India and CMC, Vellore with support of the ICRC-Special fund for the Disabled planned the 3- day consensus seminar on the development of quality control tools for prosthetics and orthotics appliances. This was the first seminar of its kind as far as the Indian P&O field is concerned.

The ICRC-SFD, an organization with strong focus on strengthening institutions and ensuring sustainability of physical rehabilitation services through capacity building, took keen interest in this regard and come forward to support the seminar. Apart from the key representatives from various P&O schools in India, ICRC and ICRC-SFD were also instrumental in bringing in representations from international schools in Vietnam, and organisations in Laos and Bangladesh. The presence of representatives from other countries was to help realise the quality standards that are in practice.

ISPO supported the participation of Mr. Carson Harte, senior member from the education committee in the seminar. Mr. Amit Mukerji, Director (Business development) of Otto Bock healthcare Limited, India agreed to support the seminar with valuable participation and contribution.

Objectives: Ensuring quality rehabilitation service provision to bring in positive changes in the quality of life of people with disabilities and special needs should be the prime objective. The efforts to be directed to develop uniform quality control tools in prosthetics and orthotics that could follow in all the schools, and other centres ensuring similar quality of the products and services.

The prime objectives of the seminar focussed on the following-

- *To raise awareness on need to develop and apply qc procedures and protocols*
- *To understand and work on the concept and come out with proposals*

- *To test and validate the development through practical exercises with users and devices*

The 3-day seminar involved presentations and talks from representatives of various schools and interactive sessions with the resource persons. There were consultation groups to work on the development of quality tools for various prosthetics and orthotics devices. The draft was presented to the floor and feedback, suggestions collected to finalise the same.

The fabrication and fitment steps of major appliances from the level of assessment were evaluated based on the protocols and outcome reviewed. At the end of the third day the final draft was made ready that each school can have their copy to take things forward.

DELEGATES DETAILS

| | |
|---------------------|---------------------------------------|
| Soikat Ghosh Moulic | Mobility India, Bangalore |
| Mr. Thanh | Vietcot, Vietnam |
| | |
| Rajesh Tiwari | Treasurer, SPO (NMS of ISPO in India) |
| Mr. Nigam | P&O, Govt P&O School, Ahmedabad |
| Sri Kanth Moharana | P&O, (NIRTAR), Orissa |
| Anand Samuel | Christian Medical College, Vellore |
| Mr. Achille | ICRC Delhi |
| | |
| Tarun K | EC member, SPO (NMS of ISPO in India) |
| Nanda A N | Jr. Lecturer, NIRTAR, Orissa |
| Mukesh Doshi | POCL, Mumbai |
| Jagadish Pandey | P&O, (AIIMS), Delhi |
| Imran S | Bangladesh |
| Dr. Samuel Solomon | Ortho surgeon, SLRTC. Karigiri |
| Sanjoy Oinam | MI, Bangalore |
| Amit Mukerjee | Otto Bock, India |
| | |
| Anil Singh | P&O, ICRC, New Delhi |
| Raghavan M.V | Consultant P&O |
| Indulkar A G | HOD- P&O, AIIPMR, Mumbai |
| Pandian G | Workshop manager, IPH, Delhi |
| Jannat. Ms | Bangladesh |
| Arul Thomas | CMC, Vellore |
| Bert Van Koll | ICRCSFD, Vietnam |
| Mamta Kumari | Program manager- Trng, MI, bangalore |
| Rajdeep Kumar | Program manager- Trng, MI, bangalore |
| | |
| Miguel Fernandes | Head of Delegation, ICRCSFD |
| Carson Harte | ISPO |
| Roopa Thirumalai | Consultant- Rapporteur |

Proceedings- Day 1

12th December 2011

Objective Day 1 - To raise awareness on need to develop and apply qc procedures and protocols

The day's proceedings began on a specific note with Miguel Fernandes of ICRC (SFD) talking about quality control requirements in prosthetic & orthotic services and the need to develop a Tool Box that would help practitioners to apply consensual procedures. Presenters from across the P&O spectrum that included the National Institutes in India, Private Practitioners, International bodies like ISPO, Otto Bock health care Limited, International P&O school from Vietnam, research scholar from Indian Institute of technology (IIT) , the Quality Control Manager of a multi – speciality hospital and representatives from private enterprise spoke about their perceptions of QC.

Presenter Summaries

Dr. Sujatha Srinivasan - Associate Professor in the Machine Design Section, Department of Mechanical Engineering at IIT Madras.

Her research has been on Prosthetics, Orthotics, Bio mechanics & Mechanisms. She has worked on projects like - Design of adjustable braces for children affected by polio and improvements to the design and manufacturing of the Jaipur foot.

In the context of quality Dr. Sujatha talked about the need for collaboration, innovation and engineering as there are many people with disabilities in India. While innovating, designing, fabricating a prosthetic / orthotic device the user needs are paramount and both user and the professional need to be actively involved in the feedback process as an unbiased and honest feedback - determines quality of collaboration and the service delivered.

Miguel Fernandes, Head of the Regional Office for Asia, ICRC Special Fund for the Disabled

Miguel talked about the need for promoting Systematic Quality Control Procedures in P&O services. A lack of systematic Quality Control Procedures could be because of various interconnected factors like lack of resources, policies, proper working practices and low priority at the institutional level and in the health care sector itself. The P&O schools need to bring about a change by promoting a broader professional mindset and developing a recognized and consensual professional "tool box" for technical and managerial aspects.

Carson Harte -Executive Director, Cambodia Trust & Chairman- Sub – Committee on Standards & Guidelines, ISPO.

While speaking about Quality, Carson said that Quality can only be improved and it is an ongoing process which is measured against the customer's satisfaction and against the industry. As a P&O one needs to check quality at every step from Assessment, Prescription, Design, Manufacture, Fitting to Delivery. Quality begins with the P&O practitioner and we need to regulate ourselves, before others do it.

Highlighting the role of ISPO, Carson said that ISPO is a global interdisciplinary organization improving the quality of life for persons who may benefit from prosthetic, orthotic, mobility and assistive devices by mainly supporting the development of related education programs & the recognition of schools. In collaboration with WHO, ISPO has made an impact on the standards of P&O Education and consequently it's Practice.

Soikat Ghosh –Assistant Director, Rehabilitation Services on Quality Control –Check Out System followed at Mobility India
Mobility India has 3 guiding principles in its pursuit of Quality Control – Focus, Principle & Method. This approach places an emphasis on three aspects:

- Elements such as controls, job management, defined and well managed processes, performance and integrity criteria, and identification of records
- Competence, such as knowledge, skills, experience, and qualifications.
- Soft elements, such as personnel integrity, confidence, organizational culture, motivation, team spirit, and quality relationships

To achieve these, methods followed are documentation and record keeping, earmarking areas of check outs, feedback collection, and review of the feedback, staff capacity building and a service – user meet to share and learn. Appropriateness of the prosthetic/ orthotic device to the user's needs, lifestyle and living conditions is the ultimate test in the QC process.

Amit Mukerjee, Director Business Development, Otto Bock HealthCare.

At Otto Bock, the P&O's equate Quality to Satisfaction. This presentation too outlined the importance of process documentation. A typical Otto Bock service cycle would have the following procedures: Process documentation, Business software & IT environment, Patient documentation and Quality management. There is no manual that deals with the real business of quality and the most important aspect of all is caring about what you are doing. Often patients and doctors do not have the expertise to judge quality. In such situations it is important for the P&O professional to take ethical responsibility to deliver a quality device and not compromise for short – term financial gain.

Mukesh Doshi - Private practitioner with 2 clinics in the suburbs of Mumbai.

Mukesh spoke about Quality control in private practices and the importance of upgrading knowledge/ skills to stay updated on the latest trends and developments on the P& O front. He also raised the issue of many traders/ pharmacists selling rehab products over the counter without much concern over the suitability of the product to the user. Private clinical establishments must ensure privacy for their users, however small their facilities are and overall maintain a conducive ambience for the person with disability to try the device.

Tarit Kumar Datta - Lecturer in Prosthetics and Orthotics N.I.O.H. (Kolkata).

In his presentation, Tarit brought forth that there is no legally authenticated body for bringing about quality standards in the P& O industry. To bring about standardization in the P& O fabricating procedures, efforts have to be made in standardizing the education systems across the country.

Mr. Tarun Kumar Kulshreshtha –Consultant with 20 years of progressive experience within the Orthotics & Prosthetics (O&P) industry

Tarun talked about Quality Control pathways from a practitioner's perspective. To understand quality broadly- it is consistent conformance to customer's expectations. A P& O has to consider the following aspects while fabricating the device –

- *Functionality-* How well an O&P device does the job
- *Appearance-* The Sensory Characteristic
- *Reliability-* Consistency of performance
- *Durability-* Total useful life of the O&P device
- *Recovery-* The ease with which problems can be rectified

Tarun also mentioned that although there are standardization bodies like the International Organization for Standardization (ISO) and the Bureau of Indian Standards (BIS) in India there is no uniform standard available for a final Orthotic & Prosthetic Product.

Nguyen Hai Thanh is a Prosthetist/ Orthotist and the Director of Vietcot since 2007. He is also the Dean of Orthopaedic Faculty of University Labour and social affairs.

Thanh talked about the developments related to QC procedures in Vietnam. Following the workshop and meeting held in 2010 of P& O and orthopaedic personnel in the country, they have come to an understanding that common guidelines are required to ensure quality. 2 persons to go through the process to ensure quality supported by good documentation and Clear Check list for each stage from assessment to final check out. QC guidelines have to become a habit and one needs to go one step at a time.

H. Arul Thomas - Prosthetic & Orthotic Services of Christian Medical College, Vellore

Arul made a presentation about the Quality Control procedures followed at CMC. The procedures were developed after team members of CMC -P&O Dept. attended the Regional Workshop on Quality

Management in P&O conducted in VIETCOT, Hanoi in September 2010. The key aspects followed by the CMC team are -Inspecting and documenting the entire process of production by a qualified person, careful selection of material, user guidelines (in local languages) & periodical follow-up of appliances to ensure satisfaction and quality.

Panel Discussion -1

The day's proceedings concluded with a panel discussion. Carson Harte chaired the session with Thann as Co – chair and Amit Mukerjee as the Moderator. They opened the forum to discuss the following points:

- Awareness of QC procedures across the sector
- Opinion of stake holders from the education sector
- Of message that needs to be conveyed to the regulatory bodies about QC



Here are key points raised by the participants:

- There was a consensus among the group about the need to raise awareness of QC procedures. As there is no uniformity across P& O schools, the graduates / trained professionals coming out of the schools too have varying benchmarks for QC procedures. Hence, it is good to start with the educational /training centres to have a uniformity and a conformance to QC procedures
- P& O professionals/ Private practitioners need to follow QC procedures as individuals before looking beyond to schools and regulatory bodies
- Hence, there is a need for uniform QC standards across the P & O profession that would percolate to every professional/ technician. If these procedures are ingrained at training stage at the schools then QC would become a habit.
- Though the country adheres to standardization norms like the ISO & BIS, there is no legally authenticated QC procedure for P&O that could be validated by a regulatory body
- Measure of quality is conformance to customer expectations and where the user's needs are paramount

Proceedings- Day 2

13th December 2011

Objective Day 2 - To understand and work on the concept and come out with proposals

The day's proceedings began with two orthosis users from diverse backgrounds and experiences speaking about their perceptions of quality. The salient point brought forth on the 1st day about the User's needs being paramount in determining the quality of a prosthetic /orthotic device was reaffirmed through the views of the presenters. As one of the professionals shared, users are the best teachers and the P& O professional should work closely with each other to benefit the larger good of people with disability – a quality prosthetic /orthotic device to eventually improve their quality of life.

Presenters:

- **Dr. Elizabeth Thomas**
- **S. Saraswathi**

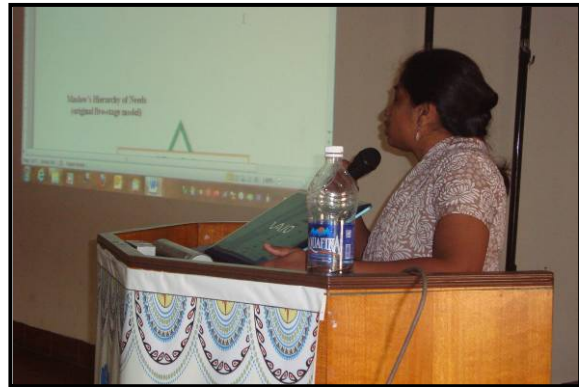


Dr. Elizabeth Thomas, aged 65 is a person with PPRP. She had polio when she was 5 years old and has been an orthosis (**knee ankle foot orthosis**) user for the last 60 years. She shared her experiences of changing times and most importantly changing orthosis with changing needs in her entire life cycle from being a teenager, to a working professional to being a mother and her needs in her current phase of life.

Here is a summary of her presentation:

- When a person with disability looks for a Prosthesis/ Orthosis there are 3 aspects to be considered – Availability, Accessibility & Affordability – Another “A” from the perspective of QC that needs to be added to the list is Acceptability of the orthotic /prosthetic device by the user taking into account alignment, durability and aesthetics
- Another aspect that is often ignored or not given the required attention by a P&O is - counseling the user /parent/ care giver about the realities of the disability and what the appliance could achieve
- The P& O's need to understand the importance of networking with craftsmen like shoemakers to get the right kind of footwear
- A mutual give & take between the user and P&O professional is important in achieving a quality service while fitting and follow –up of assistive devices
- More women P& O's need to be trained

S. Saraswathi, aged 33 is a person with PPRP. She has been an orthosis (knee ankle foot orthosis) user for the last 12 years. She managed mobility with a hand to knee gait and a her foot draped across a wooden stick in her growing up years. The importance of rehabilitation interventions came to her after she joined Mobility India as staff.



Here is a summary of her presentation:

Saraswathi talked about the Maslow's hierarchy of needs and its correlation with a person with disability having a good quality prosthetic/ orthotic device to fulfill his/her needs.

- Biological & Psychological needs
 - Safety needs
 - Belongingness & Love needs
 - Esteem Needs
 - Self-actualization
-
- To fulfill all these needs PWD's require a good quality Prosthetics /Orthotic device ...
 - Product or service is the degree to which a set of inherent characteristics fulfills the requirement or need of the users
 - Need a sustainable and durable orthosis
 - Collecting all information relevant to the users's working, lifestyle before making the prosthetic /orthotic device
 - A kit with instructions to manage in case of small breakages, loss of parts and a feedback not at the time of check-out but maybe after a month or so of using the device

Development of quality control tools for primary rehabilitation aids and appliances

Working Groups : Each group had a representative across the P & O spectrum from educationists from national and international training institutes to private practioners, professional working at rehabilitation centres attached to hospitals / ngos, multi national companies and also from the educational committee of ISPO.

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|-------------|-----------------------------------|------------------------------|-------------------------|
| | | | |
| WG 1 | Prakash Mehta | SPO (NMS of ISPO in India) | KAFO |
| | Dhiren Joshi | Paraplegic Hospital, Ahmd | KAFO |
| | Tarit Datta | NIOH | KAFO |
| | Amit Kumar | MI, Kolkata | KAFO |
| | Ki S | COPE, Laos | KAFO |
| | | | |
| | Soikat Ghosh Moulic | MI, Bangalore | Facilitator |
| | Mr. Thanh | Vietcot, Vietnam | Expert support |
| | | | |
| WG 2 | Rajesh Tiwari | SPO (NMS of ISPO in India) | AFO |
| | Mr. Nigam | Paraplegic Hospital, Ahmd | AFO |
| | Sri Kanth Moharana | NIRTAR | AFO |
| | | | |
| | Anand Samuel | CMC, Vellore | Facilitator |
| | Mr. Achille | ICRC Delhi | Expert support |
| | | | |
| WG 3 | Tarun K | SPO (NMS of ISPO in India) | Trans tibial prosthesis |
| | Nanda A N | NIRTAR | Trans tibial prosthesis |
| | Mukesh Doshi | POCL | Trans tibial prosthesis |
| | Jagadish Pandey | AIIMS, Delhi | Trans tibial prosthesis |
| | Imran S | Bangladesh | Trans tibial prosthesis |
| | P&O Slrtc | SLRTC. Karigiri | Trans tibial prosthesis |
| | | | |
| | Sanjoy Oinam | MI, Bangalore | Facilitator |
| | Amit Mukerjee/ Mr. Achille | Otto Bock, ICRC Delhi | Expert Supports |
| | | | |
| WG 4 | Anil Singh | ICRC | Transfemoral prosthesis |
| | Raghavan M.V | Consultant P&O | Transfemoral prosthesis |
| | Indulkar A G | AIIPMR, Mumbai | Transfemoral prosthesis |
| | Pandian G | IPH, Delhi | Transfemoral prosthesis |
| | Jannat. Ms | Bangladesh | Transfemoral prosthesis |
| | | | |
| | Arul Thomas | CMC, Vellore | Facilitator |
| | Bert Van Koll | ICRCSFD, Vietnam | Expert Support |

Before working on the protocols for the 4 prosthetic / orthotic devices, the working groups discussed points for “information gathering” of a person with disability at the time of first visit to the centre/ clinic.

Following this the group also discussed the key production stages that need to be validated for QC:

- **Negative casting**
- **Positive mold**
- **Static alignment, dynamic alignment- ensured?**
- **Checkouts, pre –checkouts**
- **How will the final finish be validated? What points will you check for final check outs before delivery?**
- **What other points will you consider?**

The day’s proceedings wound up with a panel discussion chaired by AN Nanda and AG Indulkar. After reviewing the objectives of the day the group also agreed to be part of an Internet forum **to exchange thoughts and experiences.**

Proceedings –Day 3

14th December 2011

Objective Day 3 - To test and validate the development through practical exercises with users and devices

The day's proceedings began with the Working groups outlining together the QC evaluation steps for each production process and draft protocols for the following P&O devices.

1. Ankle Foot Orthosis
2. Knee Ankle Foot Orthosis
3. Trans Tibial Prosthesis
4. Transfemoral Prosthesis



After the drafts were ready the groups worked with positive & negative molds, a fabricated/ assembled device and finally fit the device to users to validate their drafts before presenting it to the panel of experts.



Following the first draft presentation by each Working group, the Expert Group came together to compile the work of all groups and give it a structure and finally make the draft protocols. The expert group had the following members:

- Amit Mukerjee, Ottobock India
- Achille Otou, ICRC, New Delhi
- Nguyen Hai Than, VIECOT, Vietnam
- Bert Van Koll, ICRC, SFD

The expert committee then presented all the protocols and the participants collectively made suitable changes to finalize each protocol. (Annexure 1 – Protocols Developed)

Way forward

The group then offered the following suggestions for the way forward:

For implementing the protocols and carrying out a pilot study to collect evidence:

- MI & CMC to compile a report and send it to participants for remarks
- Protocols – all professionals to put it to practice
- Training institutes should implement for a month – and then make a recommendation to the RCI for including into the curriculum
- Private sectors / practioners also need to implement the protocols
- Evidence collected on trial of protocols to be submitted to Organiser (Mobility India and CMC Vellore)

For approaching ministries/ agencies/ regulatory bodies for authenticating and legalizing the protocols:

- The organizers of the seminar MI, CMC with the support of ICRC, Country Office –New Delhi and representative from National Institutes could approach the Ministry of Social Justice & Empowerment, in particular the Disability Commissioner, the Secretary, Joint Secretary and also the Rehabilitation Council of India to present the findings/ evidence collected on using the protocols by P&O's across the profession
- Suggestions were also made to invite heads of National Institutes to meet the Disability Commissioner but the Pilot study would be important to show a proof of the results

Closing Remarks:

Carson Harte: Complimented the group for an interesting 3 days and stressed the importance about the way forward in transmitting the outputs to the govt to bring about a recognition of the protocols. He suggested a 6-month piloting across institutions/ private practioners to gather sufficient evidence to be able to convince the regulatory bodies to take a decision about the protocols. He reiterated the importance of staying united on the issue and also the support ISPO could offer in a consultative role to make recommendations in P & O curricula.

Miguel Fernandes: Complimented the group for the quality of discussions and also in achieving the objectives that had been set for the Seminar. A milestone has been achieved and he is looking forward to receive the feedback on how the protocols find acceptance in the respective institutions.









Participants

- **Mukesh Doshi:** MI taking the lead is commendable and people with disabilities will get a quality of life
- **AN Nanda:** It is important that the recommendations reach the relevant regulatory bodies
- **Tarun Kulshreshtha:** There are a lot of take- aways from the seminar and it is important each of us implements the protocols
- **AG Indulkar:** Changes in P& O long overdue, but better late than never and QC procedures must become a habit with every practioner
- **Imran Shoaib:** In my country (Bangladesh), I am the highest qualified P& O person. There are few professionals with many people with disabilities in need of quality P& O devices to bring a change in their lives. We professionals need benchmarks to follow and a platform of this nature with people from across the P& O spectrum providing their inputs helps build our capacity as professionals.

Picture Gallery



Acknowledgements

-  **Mobility India & CMC Vellore would like to thank the main sponsor of the Seminar, ICRC SFD with Miguel Fernandes taking the lead and backing the programme all through.**
-  **To ICRC, New Delhi with special thanks to Achille Otou**
-  **To Carson Harte for sharing his experience and bringing to the group the ISPO vision**
-  **To Nguyen Hai Than for sharing experience on QC in Vietnam**
-  **To Otto Bock India and to Amit Mukerjee for supporting the seminar representing the expert panel and sharing the quality standards.**
-  **To all the representatives from P&O schools, National Institutes and private practitioners**
-  **To Roopa Thirumalai for being the rapporteur and drafting the proceedings.**
-  **Dr. Elizabeth Thomas and Saraswathi for presenting the perspective of the service users.**

Glossary / Acronyms

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|------------------|-----------------------------------------------------------------------------|
| ICRC –SFD | International Committee of Red Cross – Special Fund for the Disabled |
| MI | Mobility India |
| CMC | Christian Medical College |
| ISPO | International Society for Prosthetics & Orthotics |
| AIIPMR | All India Institute of Physical Medicine & Rehabilitation |
| NIRTAR | National Institute of Rehabilitation Training and Research |
| NIOH | National Institute for the Orthopaedically Handicapped |
| IPH | Institute for the Physically Handicapped |
| AIIMS | All India Institute of Medical Sciences |
| SLRTC | Schieffelin Institute of Health Research & Training Centre |
| COPE | Cooperative Orthotic and Prosthetic Enterprise |
| VIETCOT | Vietnamese Training Centre for Orthopaedic Technologists |
| SPO | Society for Prosthetist and Orthotist (NMS of ISPO in India) |

