The prevention of disability for people affected by leprosy: whose attitude needs to change?

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Summary This paper reflects on the current emphases in the domain of prevention of disability (POD). A review of literature is presented and issues relating to the challenges that affect POD, in the changing scenario of services for leprosy-affected people are considered. A notable conclusion is that the preservation of peripheral nerve function is primarily dependent on early detection; due to challenges that may compromise that essential service, it is suggested that a sharper focus needs to be given to interventions that prevent secondary disabilities. The paradox of pragmatic and simple interventions is that they are difficult to implement. The main issue is that there is a requirement for a commitment to a fundamental change in the relationship between health providers (at all levels) and recipients.

Introduction†

In August 2002, the 16th International Leprosy Congress was held in Salvador, Brazil. Significant messages that continue to resonate from that event are that assumptions should be challenged, that the clinical judgment of experts should be questioned and that any further developments that have the potential to impact on the lives of people affected by leprosy must be based on sound evidence. Prior to the congress, an ILA Technical Forum was tasked with reviewing research findings and with compiling a report which was first presented at the congress. That report may be considered an authoritative foundation upon which further developments could be made: it provided a model for critical thinking that encouraged commitment to evidence based practice at every level of programme design and implementation.2

A section of the ILA Technical Forum Report was devoted to the prevention of disability in leprosy. It presented a comprehensive review of literature which indicated key evidence-based developments and also emphasised spheres of the domain where further research was needed.

†For definitions of technical terms related to disability, as used in this paper, please refer to the International Classification of Function (ICF).1
indicated. A notable statement in that report challenged an assumption that is still commonly held: i.e. the assumption that MDT prevents disability. Citing the findings of Richardus et al.\(^3\) it was stressed that arresting the progress of the disease at an early stage will significantly reduce the risk of nerve impairment, but as a measure to prevent nerve damage, MDT \textit{per se} appears to have very limited efficacy. Richardus’ statement was made more relevant with the publication of the now widely cited ‘prediction rule’ that Croft \textit{et al.} calculated.\(^4\) With the risk of nerve damage well established, the rationale for research to be focused on nerve function impairment and the treatment thereof was clear and convincing. The principal objective of POD was that primary impairment should be prevented.

**Prevention of Primary Impairments: Reaction and Neuritis**

By 2002, BANDS,\(^5\) AMFES\(^6\) and TRIPOD\(^7\)–\(^9\) had already greatly added to our understanding of the epidemiology, detection and prevention of nerve impairment and in 2005 results began to be published from the INFIR study which contributed significantly to understanding of the order and sequence of effects of neuropathology on sensibility and motor function.\(^10\) However, the identification of an ideal treatment to address the threat of nerve function impairment, either as a sequela of frank reaction or of silent neuritis, has yet to be accomplished.

To establish whether there was robust evidence to support the efficacy of corticosteroid treatments as a measure to prevent nerve damage, Van Veen \textit{et al.} recently conducted a Cochrane review. According to their criteria, three randomised control trials provided reliable outcomes: two were components of TRIPOD\(^8\)–\(^9\) and the third was conducted more recently by Rao \textit{et al.}\(^11\) but the trials were too small and heterogeneous to allow for the level of detailed analysis that might have given more compelling conclusions. Van Veen \textit{et al.} did conclude that for the treatment of either long-standing nerve function impairment or mild sensory impairment corticosteroids were no more effective than placebo (outcomes from TRIPOD). They also confirmed that the recovery of nerve function appears to be dependent more on the duration and/or severity of impairment before it is treated. However, they also drew a slightly more positive conclusion: claims from other studies that prolonged steroid courses were more efficacious than short courses were supported by the findings from the trial conducted by Rao \textit{et al.} (a short course is considered to be the standard 12 week course). Van Veen \textit{et al.} cautiously concluded that ‘‘longer duration of prednisolone treatment gave less poor outcomes than short course prednisolone’’ (pp 8).

Schreuder’s finding was that 35% of nerve function impairment cases either did not improve or deteriorated and, 2 years later, Croft came to a very similar conclusion.\(^12\)–\(^13\) A more optimistic perspective on these conclusions is that about 60% did improve. However, that optimism is dampened by the probability that many cases would have improved without prednisolone anyway. Even though its efficacy is not optimal, recourse to prednisolone to treat neuritis remains the only ready option. In a component of the INFIR project, Marlow \textit{et al.}\(^14\) sought an alternative to prednisolone for the treatment of nerve function impairment. They compared Azathioprine with Prednisolone, but found no benefits of the drug over Prednisolone. A salutary conclusion is that if people are to be spared from nerve function impairment as a sequela of leprosy, the most important factor remains early detection and treatment so that the disease process can be arrested before the onset of peripheral neuropathy. With the erosion of diagnostic ability, which is almost inevitable as a consequence of lower case detections, the prognosis for people who will contract leprosy in the future is poor.
An important conclusion is that people will continue to develop secondary impairments with associated activity limitations and participation restrictions. A stronger focus on interventions to address such issues is, therefore, a pragmatic necessity.

Secondary Disabilities

In 2004 the WHO estimated that there could be 2 to 3 million people worldwide already disabled by leprosy. It is unclear how this statistic was generated. Very few national programmes adequately record disability; most that do so record only the percentage of people with WHO Grade 2 disability at diagnosis. If the statistic is based on disability at diagnosis, it is likely to be a gross underestimate. This concern echoes that of Deepak who cited references from India, Indonesia and Myanmar which showed that surveys of people affected by leprosy, conducted after MDT completion, revealed prevalence rates of disabilities to be between 17% and 50%. If the 2–3 million figure cited by WHO was based on 4% with WHO grade 2 disability at diagnosis the difference will be large.

The realities of leprosy-related disability in the changing scenario of leprosy services challenged the delegates at the Consensus Development Conference (CDC) on POD in 2006. A consensus was reached that further research on reaction and neuritis should be pursued, but that the fundamental POD research theme that required concentration was how to achieve a greatly enhanced global coverage of self-care and footwear requirements. The prevention of secondary and tertiary disabilities is now recognised as a significant concern by the WHO which, in ratifying its revised strategy in 2006, finally brought the issue of disability prevention and management squarely into the domain of leprosy control.

Whilst the commitment to the development and provision of quality services for people affected by leprosy is laudable, it is also problematic; sound evidence to support the development of meaningful POD strategies is actually very sparse. Much of the current best practice is based on experience and assumptions (some of which are based on outdated research). Compared with the research that has elucidated our understanding of reaction and neuritis, there is a dearth of peer reviewed science to support recommendations for interventions relating to the two central themes of impairment management: footwear and self-care.

Prevention and Management of Secondary Disabilities: The Issue of Footwear

Research on the efficacy of footwear is very problematic. Well designed protocols to examine the properties of footwear and of materials used to relieve pressure are relatively straightforward, there has been a plethora of such studies. Most studies of material properties, however, are based on the assumption that ulceration is caused by repetitions of moderate applications of pressure at foci on the insensible foot. That assumption is inadequate. In reviewing the literature to establish the context for a study of biomechanical factors that might be implicated in foot ulceration, the author concluded that it would not be prudent to suggest that high pressure will cause ulceration independent of other variables.

Examining a diabetic population, Ctercteko et al. found that the contralateral feet of subjects with ulceration also displayed pressures not significantly different from feet with ulcers. In 1992, Veves et al. reported findings from a prospective study they conducted. They demonstrated that only 35% of subjects that were recorded as presenting with high foot
pressures at baseline did develop plantar ulcers. Veves’ findings were supported by Pham et al.\(^\text{21}\) whose analysis was that peak pressure was a highly specific indicator (i.e. in Pham’s study all people who had ulceration had been recorded earlier as presenting with high peak pressure). However, they also reported that peak pressure is not a sensitive indicator (i.e. not everybody with high peak pressures did develop ulceration). There are others who have questioned the pre-eminence of peak pressure as a causative factor of ulceration and some have voiced their reservations relating to this issue.\(^\text{22–24}\)

Examining footwear materials is straightforward, but the assessment of footwear *per se* is problematic. The obvious outcome measure is skin integrity, but analysis can be confounded by diverse variables: extent of deformity, levels of self-care practice, distances walked on a daily basis, types of occupation and other daily activities. These variables would be very difficult to control, which is likely to be one reason why such trials have not been attempted. However, the issue needs to be addressed because in the lack of alternative evidence, specially made footwear for people with insensible feet due to leprosy is still considered by many to be mandatory. Very few have challenged the concept even though it was a development contemporaneous with Dapsone treatment.\(^\text{25}\)

There are some footwear studies that should be considered. The study conducted by Seboka *et al.*\(^\text{26}\) in Ethiopia was perhaps the first to generate an alternative hypothesis: ‘is ordinary commercial, soft soled footwear an appropriate intervention to prevent ulceration?’ From a randomised control trial, Seboka *et al.* found that 75% of subjects with ulcers who used canvas shoes had no ulcer at the end of the study, while no significant change was recorded for subjects who wore bespoke molded plastazote sandals. It is the author’s opinion that the finding of interest was not the difference between the two groups, but that 75% of people with deformities and ulceration did not have ulceration after 1 year of wearing commercial shoes.

Relating to the foot, the secondary impairments as sequelae of diabetes mellitus (DM) are similar to those of leprosy. With the lack of evidence relating to footwear efficacy in the leprosy literature, recourse to the literature related to DM can also be considered. Reiber *et al.* recently conducted a well-designed randomised control trial of footwear for people with foot insensibility due to DM.\(^\text{27}\) They nominated foot reulceration as the principal outcome measure in their study and concluded that there was no evidence to suggest that people with insensible feet, but no severe deformity, derived any significant benefit from wearing footwear modified by their experimental insoles. (The experimental insoles were a sophisticated construction using materials considered to be optimal for pressure reduction.)

The two studies alluded to above are interesting, not least because of the contextual contrasts they represent. It appears that in either a developed or under developed environment access to ordinary commercial footwear appears to have been more beneficial than specialised footwear. A probable reason that commercial footwear has become more appropriate is because developments in material science and footwear manufacture have meant that footwear is being produced which generally has far superior force-attenuating properties than footwear produced in the decades when Bauman and his contemporaries first recorded the benefits of using micro cellular rubber (MCR). MCR is indeed an excellent material, but there are others in production, used in commercial footwear, which may be as good.

In 1996 Linge conducted a study that compared the properties of MCR with an open-celled microcellular urethane product produced by the Rogers Corporation and marketed under the trade name of PORON\(^\text{®}\). He found that PORON\(^\text{®}\) yielded better results than MCR when compared on pressure relief. Birke *et al.* also studied the properties of PORON\(^\text{®}\) and
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were able to identify the optimal density for pressure relief (22, 27 and 32 shore). PORON® is used in the manufacture of commercial footwear but is not as commonly used as EVA, a copolymer of ethylene and vinyl acetate. EVA is extensively manufactured under many different trade names. It is less expensive than PORON® and is currently in wide use in the manufacture of inexpensive footwear. The efficacy of EVA as a force attenuating agent in footwear remains to be tested.

Although the prospect of the availability of adequate footwear is encouraging, caution should be observed. Some studies have found that poorly fitting footwear and inappropriate footwear have been a significant causative factor in the development of foot ulcers in DM.28,29 MacFarlane and Jeffcoat’s study was very robust. They found that poor footwear was implicated in 21% of the foot ulcer cases they recorded.29 Those studies are salutary and should serve to stimulate concern about the advice given to individuals with loss of sole sensibility. It is also justifiable to suggest that where possible, if people can avail of more specialised services, they should be encouraged to do so. People with foot deformities will continue to require such services to produce footwear according to their individual specifications. There is also evidence that some individuals, with feet that are not deformed, will be more at risk of ulceration than others due to common aberrations from ideal foot function. Such people and others with simple ulceration can benefit if they are able to avail of programmes that offer podiatric appliance services.30

Prevention and Management of Secondary Disabilities: Self-Care

In December 1995, the ILEP Medical Commission published a bulletin which presented the findings of a survey. The survey had been conducted with the objective of establishing the extent to which POD activities were being conducted in ILEP-supported projects worldwide; it reflected responses from 200 vertical and non-vertical projects in 25 countries. The projects surveyed represented 50,000 new patients, 135,000 registered patients and 330,000 people who had completed MDT; in total, a little over half a million people affected by leprosy. Listed among the major findings of the survey were that ‘95% of the projects reported that POD activities were included in the organization of their leprosy control work’ and that ‘94% of projects train patients in self-care and 90% give advice on footwear’.31 Given such an astonishing accomplishment, it is salutary to consider that the effect on the issue of disability since 1995 appears to have been relatively insignificant. The issue of disability has not diminished. As acknowledged above:

- The WHO suggests that the provision of ‘quality services’ is an inclusive term that should address the burden of disability that leprosy will continue to impose on individuals.18
- The Consensus Development Conference on POD in 2006 was deemed necessary to realign thinking and strategy on POD so that attention to it might be reinvigorated and that pragmatic advice to strengthen WHO commitment could be validated.

We have no clear idea of the scale of the issue of leprosy-related disability or the rate at which people are becoming more disabled with the passing of time, but it is suggested here that if 95% of projects in the ILEP survey were providing effective POD services, the impact on the flow of people emerging from MDT with disabilities since 1995 should have been significantly reduced. However, this does not appear to have been the reality. The efficacy
and impact of such programmes needs to be examined. Accomplishment targets can too easily obfuscate impact.

Self-care is, and will continue to be, the essential component of POD where prevention of nerve impairment cannot be realised. However, the dearth of evidence to underpin policies on footwear is also reflected in the literature relating to the practice and effects of self-care. This is a serious issue which, in the author’s opinion, reflects a far too casual attitude to what is a fundamentally important intervention.

While there is some evidence of the efficacy of self-care procedures as an intervention to address ulceration, the more complex issues associated with the general impact of self-effected impairment control have not been extensively researched. Most of the studies that have reported outcomes of self-care teaching were not rigorously designed. They are pre and post observations of selected groups that were targeted for intervention. Positive findings from such studies do associate self-care with improvements in ulceration and as such they do support the face validity of self-care as an intervention, but analysis is limited by methodological issues. A control study conducted in Nepal demonstrated reduced hospital admissions associated with an intensive self-care training programme, but a limitation was that the sampling was not randomised.

The issue of the sustainability of self-care practice has hardly been encroached upon at all. When people apply the mechanics of self-care (rest, soaking, scraping, oiling and exercise) the body is able to repair itself; if not flawlessly, at least optimally. The logic is simple and the required actions are easy, but the sustained application of self-care is subject to a very complex array of health expectations and motivational factors. It is the author’s opinion that unless a concerted effort is undertaken to understand such issues and to remodel our perspectives on health delivery, the objective of sustainable disability prevention through self-care will remain unmet. In an earlier paper, current evidence and developments on self-care as a global issue for the care of chronic conditions was reviewed. A model currently promoted by the WHO is the Innovative Care for Chronic Conditions (ICCC). At the core of the model, the impact of chronic conditions is determined by affected individuals who are supported by adequately prepared practice teams of health workers and also by informed and activated communities. Professionals relinquish control, but as consultants their role is realigned so that they provide advice and encouragement for people to make the most appropriate choices. Recent research of health behaviour has also shown that motivation to implement health advice and to persist in positive health behaviour is dependent primarily on the extent to which individuals perceive their levels of self-efficacy (this marks a radical departure from the popular belief that motivation is an effect of perceptions of either negative or positive health outcomes). The most important role for health workers intending to change health behaviour, therefore, is that they should develop skills to be facilitators of internal empowerment.

There is an important issue that we are compelled to consider: the principles of the ICCC do not fit easily within the prevailing ‘Industrial Age’ model of health delivery. Most of the developing world still adheres to that model. Whilst self-care is harmonious with ‘Information Age’ medicine, the concept is at variance with ‘Industrial Age’ health structures. Where ‘Industrial Age’ medicine is the norm, physicians and health workers are considered experts. Patients bring nothing to the interaction other than their illness (self-care, therefore, contradicts the foundation on which the paradigm is established). The dominant feature of ‘Industrial Age’ medicine is that control and responsibility, along with the status that these represent, are maintained by health professionals. According to Parsons’ ‘sick role’ paradigm, any challenge to the power structure in the model is perceived as an influence that destabilises the foundation of
‘Industrial Age’ societies and as such it is opposed by almost all the role players in such societies.42

The Effects of Environmental Barriers on the Capacity of Individuals to Function

Accepting the definitions in the International Classification of Function (ICF), disability is an umbrella term that covers impairments, activity limitations and participation restrictions.1 This is wholly appropriate as these issues are not independent features in an individual’s experience. Describing how people assume health behaviour, Schwarzer and Fuchs explained that regardless of how powerful individuals’ resolve may be, if there are insurmountable environmental barriers (perceived or actual) such individuals will abandon attempts at developing advantageous health behaviour.43 Poverty, marginalisation and discrimination are disabling conditions and as such cannot be disregarded when plans for POD are being constructed. However, hasty interventions to address disadvantaged economical situations, before establishing a sound foundation of internal empowerment, may be unwise. Orr and Patient suggested that such a foundation is established when individuals and/or communities have the following features: positive identity, aspirations and a conviction that life is valuable. They also suggested that if these features are not established other community development initiatives are likely to fail.44 (They contend that most people do not view life positively but rather that they are preoccupied with actions to relieve or circumvent negative perceptions and realities.)

Findings from some studies of community based self-care group activities do appear to support the opinion stated by Orr and Patient. An interesting feature of the studies that fall into this category was that the target groups were poor and marginalised relative to the general populations in which they functioned.45–47 Indications of development amongst the groups that were studied were noted, but they were outcomes that were complex effects of self-care, they were not primary interventions. It is the author’s opinion that self-care is an intervention that can be applied even in very adverse physical environments because the most significant environmental barriers to implementing it are not physical or economical, but psychological. Where perceived self-efficacy is supported by functional optimism and encouragement by significant others, an individual’s potential to function can be optimised in almost any situation when psychological barriers are overcome.43 The author suggests that the role of appropriately trained facilitators could be the most significant advancement toward achieving the vision of POD in the 21st century. It is necessary to acknowledge that in the changing leprosy scenario, specialist services are likely to become ever less accessible. The essential feature of POD will be self-care; it will not be an option, it will be an imperative.

Conclusion

With the expertise that is available to intensify research, we continue to anticipate that a more effective treatment will eventually be developed to address the risk of nerve function impairment. However, pragmatism dictates that, in the interim, interventions for the management of secondary impairments should be refined. There is another issue: there are considerable numbers of people who are compelled to live under the threat of deteriorating function due to established leprosy related impairments. It is imperative that a concerted
effort is undertaken, with them, to surmount that challenge. Science and technology have given us a broader understanding of the underlying issues that need to be addressed, but ultimately the development of POD will not require advanced technology, it will require advanced thinking.

References

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