



Challenges of Clinical Research in Physical Medicine & Rehabilitation: Considerations from a Working Group from Brazil, USA and Canada

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Abstract

Background: In coming years, the need for clinical research in Physical Medicine and Rehabilitation (PMR) will increase. In face of an aging population and greater emphasis on evidence-based medicine, the field must be prepared to examine treatments and disseminate findings effectively. However, clinical research in PMR needs improvement.

Objectives: The “Rehabilitation Medicine Summit: Building Research Capacity” met to address this issue in 2005. Five years later, a meeting of Brazilian, American and Canadian PMR clinician researchers examined 11 questions regarding the same problem and compared results to past findings.

Major Findings: Responses were discussed during a meeting in São Paulo, Brazil. After, summaries and a synthesis of group and literature findings were completed. Major issues identified in these three countries are: lack of funding, time, training, and institutional support, and issues with patients and methodology. Positive changes seen include: greater interest in PMR and investment in training.

Conclusions: Despite increasing concern for the situation, it is clear changes in PMR clinical research are still needed.

Keywords: Physical Medicine and Rehabilitation (PMR); Clinical Research; Brazil; United States; Canada

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Introduction

The relative importance of Physical Medicine and Rehabilitation (PMR) in the realm of health services will increase in the coming years. This is due in large part to the fact that the global population is aging and the presence of chronic disease is on the rise, as well as the increased survival from external agents and violence. As a result, a major issue in healthcare is how to ensure independence and high quality of life most effectively and for as many people as possible [1,2]. As PMR addresses both of these issues, a strong focus must be placed on PMR now and in the future.

In order to provide patients with the best treatments, well-trained doctors, and economical costs, medical practitioners must adhere to the concept of Evidence-Based Medicine (EBM). EBM depends on evidence provided by large clinical trials to guide decisions regarding treatment options [3] and thus research is imperative to all medical fields, including PMR. Despite the necessity of PMR to global health efforts, the field is not fit to meet such demands at present. In order for PMR to attain this functional capacity, higher levels of research and an increase in the number of Randomized Controlled Trials (RCTs) are needed [4]. Not only more RCTs, but also naturalistic studies and observational studies are required to evaluate the effectiveness of both new and old interventions, thereby ensuring the best methods of treatment are utilized [5]. In fact, many existing treatments in physical medicine have never been assessed using RCTs and therefore their efficacy is based solely on observation and tradition, and not on evidence [1]. Lastly, it should be noted the

medical specialty of rehabilitation medicine does not receive adequate recognition due to a lack of high-caliber research and the fact that PMR treatments are often difficult to test [6]. This status must change for PMR to succeed in the future of health care as an accredited source of trusted treatments, and increasing research capacity is a necessary step toward this goal [7]. Despite all of these considerations, clinical research in the field of PMR continues to falter.

To date, numerous challenges to clinical research on the American continent in rehabilitation have been identified. One such challenge is the lack of an established system of evaluation to prove the effectiveness of specific interventions [1,5]. In addition, researchers have cited issues with participants in terms of recruitment, the presence of multiple medical problems, and the influence of patients' individual goals and motivations on intervention outcomes [5,8]. More importantly, the number of qualified researchers continues to decrease due to numerous factors such as lower salary than that of medical practice, lack of prestige associated with research, and an overall lack of education about clinical research [2]. Finally, a major issue in PMR research is a lack of funding. To illustrate, in 2002 NIH funded 5,917 grants totaling US\$2,545,552,648 for the department of internal medicine in medical schools. In comparison, the department of PMR received funding for only 49 grants at a total of US\$15,431,590, representing just 0.17% of the funds allocated by the NIH to medical school departments that year [7]. Over the following years, there was a clear trend that the funding situation for PMR even got worse: In 2009 the department of PMR only received US\$12,812,938 in comparison to the department of internal medicine, which received US\$3,183,748,972 [9]. The PMR

department only got 0.12% of the NIH funds of that year [9]. Though the funding situation might be different in other countries, working group members from Brazil and Canada agreed that funding for PMR research is relatively smaller compared to other specialties. Clearly, the problems of PMR clinical research need to be addressed in order for the field to reach its true potential. In 2005, the Rehabilitation Medicine Summit: Building Research Capacity (RMS 2005) was held to identify difficulties and recommend changes [4]. Due to the rapid changes seen in clinical research in PMR in the last few years, we convened a panel of experienced Brazilian, American and Canadian clinical researchers in PMR from different settings to look at the issues of PMR research once more. The purpose of this paper is therefore to investigate further the challenges facing clinical research through the insight and findings of those directly involved in research itself using experiences from these three countries in America. The questions discussed by the group are addressed in individual sections that integrate the participant responses with further information from the literature in order to provide expert opinions that will serve to guide future efforts in PMR.

Methods

To gather the data required to investigate the challenges of clinical research in PMR, a closed group meeting was organized by F.F., M.I., and L.R.B. involving researchers from several leading academic institutions. There was a total of 19 participants from three different countries including Brazil, Canada and United States of America as to sample different research settings and conditions on the American continent. The participants are all working in the field of PMR research or are closely connected to it and are therefore representatives of

this medical research field. In addition, we selected a diverse group of investigators, from the young clinical investigator to the senior, chair of department investigator, as to collect a wide range of opinions (Table 1). In preparation for the meeting, the group first decided upon which questions regarding the issue of PMR research to include, after which each participant spent 20-30 minutes recording responses to the 11 chosen questions (Table 2). Next, the organizing committee prepared a summary of the responses for the live meeting. The meeting took place in person in São Paulo, Brazil on October 9, 2009, with some of those located in the United States and Canada participating via Teleconference (Adobe® Connect™). Each contributor presented his/her individual answers, after which the group discussed the most important points identified. After the

meeting, some participants were responsible for writing a summary of the responses to one question. The final step of this process was the synthesis of all of the information into one final draft that was circulated and reviewed by all authors. Furthermore, there was a PubMed search for articles published from January 1990 to December 2010 in order to systematically review evidence of challenges in clinical research in PMR and to compare the results from the meeting with those already evident. Search terms included “challenge(s)” OR “clinical research” OR “research” AND “physical medicine” OR “rehabilitation”. The abstracts of retrieved citations were reviewed and prioritized by relevant content. Full articles were obtained and references were checked for additional material when appropriate

Table 1: Characteristic of Group Participants. Number in parentheses indicates number of participants of given characteristic.

Country where work/practice	Investigator Level	Time dedicated to research	Academic Title
Brazil (13)	Young clinician/researcher (2)	<4hrs/wk (7)	MD, PhD (7)
Canada (1)	Clinician/researcher (9)	4-8 hrs/wk (3)	PhD only (3)
United States (5)	Senior clinician/researcher (2)	8-16 hrs/wk (4)	MD only (8)
	Lab/Research center director (6)	>16 hrs/wk (5)	Masters (1)
			DO (1)

Table 2: Questions chosen and discussed by working group meeting.

	Questions
1.	How does clinical research change your decision making in the clinical practice?
2.	What are the challenges you face to perform clinical research in general?
3.	What are the specific challenges to perform clinical research in PMR?
4.	Has the situation changed in the past 5 years? Why?
5.	What are the opportunities (or facilitators) you identify to perform clinical research in PMR?
6.	Can you identify the difficulties and separate in the ones that can potentially be changed and the ones that will hardly be changed?
7.	Can you also identify changes to improve clinical research as short-term and long-term changes?
8.	What have you done to improve research capacity recently?
9.	How can the situation be improved?
10.	Have you published all the results of your studies, if not, why?
11.	How to measure improvement in clinical research capacity?

Summary of Responses

Question 1: How does clinical research change your decision making in clinical practice?

As many are medical practitioners, the participants note they strive to find and use the best possible treatments for their patients. Many of them state that to do so, they consider those treatments which are well-supported by research evidence and are published in respected journals. Similarly, many rely on clinical research to provide evidence against ineffective medical practices as to inhibit their use in the future. In a paper by [1] the authors emphasize the importance of ensuring all

treatments administered are supported by clinical evidence. Many current treatments have never been examined using RCTs, and often practitioners only use those techniques they already know [1]. Though the panel participants understand the importance of clinical research to the practice of medicine, some mention it is difficult to keep up with new publications and treatments. They note a need for sources of information other than textbooks and individual studies, such as meta-analyses, and studies of prognosis and cost-effectiveness of which there is a current lack. Additionally, group members add clinicians working in academic centers have the advantage of access to grand rounds and journal clubs, as well as

residents and medical students who constantly question their medical practices. In contrast, those practicing independently are susceptible to feeling overwhelmed by the volume of data and as a result, vulnerable to biased medical information. In his paper, Joel A. DeLisa notes there is also a need to better train physicians in the evaluation of clinical research to ensure they use those treatments best supported by evidence [7]. Moreover, as the respondents in this study were chosen due to their participation in clinical research, their answers may be biased. Additionally, their relatively less intense daily clinical routine might represent another bias. While the majority respond they depend on clinical research in choosing treatments, the same is not true in the majority of PMR practices. A study from 2003 has found that many doctors rely solely on current treatments regardless of whether or not their effectiveness has been assessed [8].

The participants in this panel provide suggestions to improve the current situation. They advise the following to medical societies and physiatrists: (i) training physicians to read scientific papers critically and to appraise medical literature that is not produced by or linked to industry in a manner of funding or conflict of interest [10]; elaborating meta-analyses and guidelines, and participating in those proposed by other specialties [10]; fostering critical appraisal of interventions of low commercial interest, such as lifestyle modifications, exercises and therapeutic modalities, that are so critical to physical and rehabilitation medicine; (iv) providing equal publicity to positive and negative results. Specifically to physiatrists, the group suggests: (i) reading and applying available guidelines, both international and local [10]; comparing competing drugs or devices using evidence from literature or through original

research such as via RCTs, as they often reveal each other's flaws.

Question 2: What are the challenges you face to perform clinical research in general?

The participants in this questionnaire cite numerous challenges they face in performing clinical research in general. First, it is noted there is a lack of centers in which research trials may be conducted and within existing centers, inadequate infrastructure to meet the needs of a research team (i.e.: space for fellows and computers with updated research software). In addition to solid infrastructure, research centers must have a supportive chair, well-defined processes, and clear institutional expectations in terms of appointments and promotions in order to create a healthy research culture [11]. There is also a shortage of researchers to perform research at all. This deficiency is noted not only by the respondents, but also throughout literature related to clinical research [1,2,7]. DeLisa offers insight into this issue, listing factors such as the increasing cost of medical school, the need to be more productive in clinical practice, a lack of mentors, and the fact that grant applications are so time consuming [7]. Similarly [1] claims careers in research are unappealing to recent medical school graduates as the training is long, there are few mentors, and the salary is lower than that earned through medical practice [2]. The members of the meeting also name the lower salary as a challenge; and according to DeLisa, in order to retain individual researchers they must feel financially supported and see potential for personal growth [7]. However, in terms of salaries, there are differences across countries and institutions which may accentuate the problem. For instance, in some countries such as Brazil, clinical researchers are rarely paid by their institutions for research time. Other factors which may be at play are revealed in

the group's responses to the question. A participant from an American institution states from his individual experience that American universities reward individual effort and penalize teamwork, thus discouraging the pursuit of research. Similar problems with appreciation and support are noted in published papers as well [2,4]. The studies of [12,13] also brought up the issue of lack of teamwork feedback and evaluation, and that the main focus of previous research was on individual competence. These articles also discussed the overall resulting impact on the daily clinical performance [12,13]. Finally, research requires long-term investment for junior investigators as grant cycles are long and it may take several years for the junior researcher to obtain his first large grant. As a result, it is difficult for newcomers to conduct studies and establish themselves as researchers.

Not only are there not enough researchers, but amongst those researchers engaged in studies, not all are fully qualified. This is due in large part to a lack of education about clinical research, which is deemed a challenge to the field by the participants and other publications alike. According to the group's response as well as the findings of RMS 2005, a major contributor to this issue is that clinical research is usually taught superficially in Brazilian and US and Canada medical schools to medical students [1]. Furthermore, the International Society of Physical and Rehabilitation Medicine education committee demonstrates awareness of the issue through its support of the establishment of a clinical trials course available to PMR specialists worldwide [14]. Questionnaire participants add that coursework alone is not sufficient; there must also be collaboration among researchers via regular meetings, journal clubs, conferences, etc. for sufficient awareness to be achieved. The need for a

better system of education about clinical research is elucidated by other challenges noted in the group's responses. For instance, participants note difficulty writing scientific papers, analyzing data using statistics, and adhering to proper methodology for data compilation, all of which could be taught in clinical research courses. Hence, the availability of clinical research training is vital to PMR as it would provide the foundation needed to perform clinical trials successfully and effectively [14].

Two other major challenges to clinical research in general receive great attention in both the group's responses and published papers. Insufficient funding to support clinical research is cited in participant responses and in six of the papers reviewed [1,2,4,5,7,8]. The group delineates the three budget components which must be met in order for research to proceed: direct costs, indirect costs, and institutional commitments (in-kind contributions) [15]. In order to overcome the lack of funding, each of these components must be filled, either by the institution, external grants, or other financial resources. Finally, a major portion of respondents (8 out of 18) list a lack of protected time as one of the chief challenges they face in the pursuit of clinical research. As individuals involved in clinical research themselves, this overwhelming response deserves attention. The perception is that there is not enough time to do research is the result of many underlying issues, such as a lack of institutional support and a lower salary. The need for more time to be allocated to researchers is presented in reviewed papers as well [1,2].

Question 3: What are the specific challenges to perform clinical research in PMR?

The respondents note multiple challenges specific to PMR clinical research in their home countries. First, in terms of successful execution of

clinical studies, numerous challenges have been revealed. These problems include difficulty blinding subjects, transporting patients to the research site, retaining patients due to social issues, dealing with patients with major disabilities, and working with patients under multiple treatments/interventions. Information gathered from the literature also includes working with patients with multiple interventions and patients with varying personal goals as important challenges [5,8]. Another key issue in terms of patients is due to the fact that tradition-based knowledge is a major part of rehabilitation. As a result, patients will rarely agree to any trial that excludes part of the “traditional” treatment program, which responses indicate make study design more difficult. Additionally, clinical researchers in PMR face the challenge of choosing a good placebo for use in the control group. Four of the eighteen participants list this in their response, making it the most popular answer to Question 3. The challenge of placebo use is not only seen in the responses of the group. In February 2009, at the inaugural International Symposium in Placebo in São Paulo, Brazil, a working group was organized to address the challenge of placebo use in PMR. In addition to defining issues related to placebo use, participants also mentioned issues such as difficulty blinding subjects, designing standard placebo therapies, and understanding the biological effects of placebo, the group report also emphasizes the importance of placebos to research: the use of placebos minimizes both performance bias and detection bias, thereby leading to more reliable results [6]. Performance bias is defined as a systematical error due to different treatment of patients exclusive the intervention, whereas detection bias refers more to a deviation in the assessment of the research results. Moreover, multicentric studies in PMR are inhibited by the fact that standardized procedures

are quite few, and there is wide variation in terms of dosing, methods, and frequency of application of techniques and modalities, all of which require massive efforts to improve. Finally, in response to the question, group participants state the majority of PMR research is conducted in isolated studies by postgraduate students. This is a challenge to PMR because it results in research projects that are not part of a unified research line, and thus do not result in a continuous development of knowledge.

According to the group’s responses, even when a study is successfully completed, there are further challenges. Chief among these problems is outcome measurement, which three of the eleven include in their answer. The respondents note it is difficult to measure functionality and pain, and thus complicated to analyze results. Numerous outside sources allude to this research challenge as well. Currently, little guidance is available on what metrics and measures to use [4], making it clear that a better system of outcome measurement is needed [7]. Other experts state that in addition to difficulty choosing outcome measures, a related issue is that PMR research often does not use quality of life as an endpoint [5].

The results of the questionnaire also reveal broad challenges specific to clinical research in PMR. As seen previously, one major challenge is a lack of knowledge in the field attributable to the few post-graduate rehabilitation medicine programs available, lack of research publications, and little staff training. Another challenge addressed earlier, but reiterated in answers to this question as well as in the literature, is the lack of funding [1,2,4,5,7,8]. Also mentioned in responses to previous questions, and again here, is the little value given to the field of PMR by public health policies. Published sources have cited this as an issue for PMR research as well [2,4], and add there is too much

dependence on current treatments and a lack of understanding of the need to evaluate these treatments and discover new options through research [8]. Other overarching challenges included in responses and the reviewed literature include difficulty in partnering with the pharmaceutical industry, which is vital as 80% of RCTs are for drug trials [1], and in achieving collaboration between multiple departments [4]. Finally, it should be noted that some literature sources believe clinical research in PMR does not face any specific challenges different from those experienced in research in other medical fields [8].

Question 4: Has the situation changed in the past 5 years? Why?

There is widespread agreement within the group that the situation of clinical research in PMR has changed in the past five years for various reasons. Only one participant notes a negative change in the past five years, referring to a significant decrease in U.S. federal grant money available for clinical research trials [16]. In comparison, the department of PMR received funding at a total of US \$18,674,212 in 2006, representing 0.183% of the funds allocated by the NIH to medical school departments that year, whereas in 2010 the total amount of funding relatively decreased to US\$17,117,467, being only 0.155% of all funds of that year. [17] The rest of the responses point to improvements, and includes the following changes. There are now more incentives for recent medical school graduates and those in residence programs to pursue clinical research. On a similar note, training courses are now offered in greater numbers and are at a higher quality than in the past. Along these lines, increased access to information via the internet, open access journals and the NIH policy of open access to research sponsored by federal grants have

contributed to better conditions, particularly for smaller academic PMR programs with limited funding. There also has been an increase in awareness about and attention to clinical research in PMR. Respondents note greater concern for the research field as the concept of evidence based medicine spreads, as well as a prevalence of PMR doctors interested and qualified in research pursuits. One participant even stated, “Physiatrists are waking up to research”. Finally, there has been an increase in clinical research in the field of PMR, likely as a result of the combination of these widespread changes. Studies have seen a great increase in PMR research from the 1970s to the 2000s [5] and the number of RCTs in rehabilitation are increasing [7]. To illustrate this point, a study conducted by Denise G. Tate, found that from 2000 to 2005, PMR “published almost half of what has been published since 1950” [18].

One change not mentioned by the participants is the official endorsement of the WHO International Classification of Functioning, Disability, and Health (ICF) by all 191 WHO Member States on May 22, 2001. The ICF allows for all health conditions to be measured using a common system and adds social components to the consideration of disability. This is a significant change as the classification system in place previously was for field trials only, while the ICF is established as the international standard [19].

Question 5: What are the opportunities (or facilitators) you identify to perform clinical research in PMR?

In general, the participants agree upon the opportunities to perform clinical research in PMR. First, responses indicate the presence of a global effort to produce better scientific papers, and one participant notes the development of relationships

and professional networking - especially with well published researchers and editors - might facilitate publication in international journals. The need to improve scientific writing and the ability to publish research results is clearly demonstrated by the fact that PMR is second to last in publications in well-established journals in Brazil [14]. However, it is important to note a panel of editors-in-chief found that PMR journals are very interested in publishing international articles, which will facilitate improvement [20]. Three of the group members name the overall lack of scientific evidence in the relatively new field of rehabilitation medicine as a major catalyst to future research. According to the group, there is much to investigate and study within the field of PMR, and therefore the area for research is expansive, ranging from the assessment of new interventions to the development of new techniques and devices. Similarly, as medical advancements continue to improve life expectancy, there is an increase in the number of patients with disabilities and chronic diseases, and thus PMR research is in high demand. Furthermore, sources from the literature note that as PMR aims to assist those suffering from long-term, disabling conditions, clinical research in the field is boundless [7]. Finally, participants state that the nature of PMR is collaborative in principle and supports the creation of multidisciplinary teams. This is an advantage as the NIH is pushing for more multidisciplinary and translational research, thus making PMR an ideal field to receive the institutes' support.

Moreover, the participants note growing concern for rehabilitation research amongst doctors, researchers, and patients alike as an important facilitator to the pursuit of research. One aspect of this increased interest is now both new and established physiatrists want to become better

educated in clinical research. [16,21] highlight and explain the significance of this growing interest and the need of a better scientific education among physicians in PMR in their articles [16,21]. The widening comprehension that extensive training in clinical research is necessary to facilitate increased levels of PMR trials in the future is evident in the group's responses. Five of the participants name the establishment of programs designed to improve skills in scientific methodology as a clear facilitator to perform clinical research. It is important to note that of these five, three specifically reference the annual clinical trials course available to interested clinicians worldwide through Harvard Medical School and the University of São Paulo. The group notes not only will the founding of training courses produce better researchers, but also as more doctors are trained, these doctors will impose the necessity for widespread improvement in data quality. The increased opportunities to PMR research provided by better training in methodological skills have been identified in published papers as well. Specifically, one author notes a solution is to establish better methodological techniques [5] and the RMS 2005 acknowledges the need to institute a model of rehabilitation research [4].

The group identifies another result of increased awareness about PMR research that will facilitate research. Members respond that institutions are more willing to sponsor physiatrists to pursue research, whether by supporting enrollment in a clinical trials course or through other incentives, such as special training programs such as the Rehabilitation Medicine Scientist Training Program, which was sponsored by the National Center for Medical Rehabilitation Research [16]. As the ability of an institution to support researchers, particularly those in a new field such as PMR, can vary, the participants state partnering

with well-established institutions is important to take advantage of this opportunity. Evidence from the literature indicates similar findings in terms of the importance of such partnerships [4]. However, the institution with which the group recommends working is not consistent throughout responses. To illustrate this point, a participant from Brazil identifies the Brazilian government as a facilitator of PMR research. The national government has provided funding for a specialized secretary to address issues involving people with disabilities, helped initiate a network of rehabilitation hospitals, and assisted interested candidates to enroll in the clinical research course mentioned above. Thus, the Brazilian government is a strong partner for clinical researchers. In contrast, a group member from the United States responds that clinical researchers should approach private, not federal, foundations to fund pilot studies, as it is very difficult to acquire government grants for preliminary research. Finally, sources from the literature elucidate another area of opportunity for PMR research. By partnering with persons with the impairment or disease of interest, investigators can gain greater insight into their research, such as new techniques or better outcome measurements to develop based on first-hand input [22].

Question 6: Can you identify the difficulties and separate in the ones that can potentially be changed and the ones that will be hardly changed?

The group identifies numerous difficulties in PMR clinical research that are unlikely to change in the future. One issue addressed previously is that of placebos. Due to the numerous challenges using placebos in general and in rehabilitation research specifically, the development of an effective placebo will require great time and effort. Furthermore, for some PMR trials, the use of a

placebo will never be practical regardless of the amount of effort devoted to its design [6]. Another challenge identified as difficult to change is the salary for clinical researchers. It must be noted, as stated previously, researchers' salaries vary across countries and institutions, and that in this case the salary issue has been identified by a participant in Brazil. The responses of the group also indicate an over-arching issue of professional and public opinion in regard to PMR and to research in general. Two of the participants note it will be difficult to alter the established misconceptions about the field of PMR. Many specialists in other fields believe PMR is the same as physical therapy, and treatments are meant to be interminable. Such misunderstandings are especially harmful to PMR because research in the field depends so significantly on a multi-department approach. Similarly, a participant from the U.S. identifies issues with professional opinions that will be difficult to correct. He responds that American universities will always be focused on individual accomplishment, and as clinical trials require a team effort, PMR research will continue to suffer in the U.S. medical reward system. The group's responses also indicate widespread issues with regard to PMR patients that are not likely to be overcome. Two group members argue there will always be a sampling bias of patients, as people with limited access, whether due to physical, economical, or social causes, will always be less likely to participate in studies. Contributors also note other complications related to patients that do not have a solution. These issues include the presence of patients undergoing multiple interventions simultaneously or in close sequence, the multiple symptoms associated with diseases studied in PMR, and educational inequities amongst patients. Finally, participants deem delays in ethical committees and internal problems in such

committees as problems that will be difficult to change. In fact, researchers tend to be more conservative in PMR as compared to other fields as patients do not necessarily experience a significant decline in health status in PMR-related conditions. Therefore, novel treatments associated with some risk might not be tested in this field.

In opposition to the seemingly insurmountable challenges listed above, the group cites numerous current problems in PMR research that have definite potential to change. On a personal level, PMR clinicians can find ways to incorporate research into their work that fits their own personalities and goals. In doing so, they can initiate a change within themselves that will facilitate involvement in clinical research in the future. On a more general scale, group members identify the potential to develop strong connections to scientific institutions, to strengthen the stimulus for clinical research, and to increase protected time for research pursuits. A large portion of the group (7 participants) classifies the number of researchers and their respective levels of qualification and education as current problems that can be eradicated in the future. These responses also include possible solutions such as the creation of a comprehensive program for PMR residents that will provide practical knowledge, training with in- and out-patients, and instruction for the use of the necessary devices.

Finally, the group is not in agreement over the ability of PMR research to overcome certain challenges. While some participants identify difficulty in outcome evaluation as modifiable with time and training, others categorize the same issue as difficult to change. Disagreement also occurs in terms of the availability of funding and of partnerships for PMR researchers. Those that see the potential for change in funding note that public

health policies, industry partnerships, non-governmental organizations, and patient associations could increase the number of rehabilitation-related grant applications to improve the situation.

Question 7: Can you also identify changes to improve clinical research as short-term and long-term changes?

The participants note multiple short-term changes that will improve clinical research. Significant changes outlined by the group include improving the quality of publications, achieving better patient accessibility to trial sites, facilitating and providing institutional support for patient's recruitment, and providing researchers with more protected time. In general, those changes identified by the group as short-term are various forms of investment in clinical research. Multiple responses refer to the establishment of training programs that are higher in quality and more easily accessible to interested professionals. Specific changes within this overall effort include the development of research electives in medical school and of incentives for students to pursue research careers during residence and upon graduation. However, it has been reported that people must present a strong desire to pursue research before time and resources are devoted to their training. Careers in research are both time- and work-intensive, and thus require a high level of interest and devotion [11]. Responses also include investment in the development of the research area as a short-term change towards stronger PMR research. RMS 2005 includes in its improvement strategy the collaboration of PMR investigators to determine current research capacity and methods to expand the area in the future [1]. The same meeting also identifies the strengthening of old and the establishment of new PMR research programs as another venue for the development of

research [4]. In addition to committing to develop PMR research, another identified short-term change is increasing efforts to acquire greater financial investment. Acquiring more and stronger financial providers is another solution outlined by RMS 2005, as it allows for increased resource access [4]. Finally, the group cites the immediate creation of financial and political incentives to establish rehabilitation research within well-structured institutions as short-term changes towards the end goal of institutionalized research centers. Once again, the RMS 2005 similarly notes the need for political support for PMR research [1].

The participants identify numerous long-term changes towards improvement in clinical research in PMR as well. First, responses indicate the need to demonstrate the importance of PMR research consistently and for an extended period of time in order to acquire greater financial investment. Both group members and literature sources agree that a necessary long-term change is the acquirement of public support for PMR research, specifically in the form of funding [2]. Other papers record such findings as well, stating it is imperative to increase awareness about the fact that there is a high level of uncertainty in all fields of medicine, and thus pursuits in research must be supported [8]. The remaining long-term changes included in the group's response are the transformations that will occur if the short-term changes listed above are followed. One such example is the installation of courses in rehabilitation medicine in medical schools and of basic clinical research education in PMR residency programs. By investing in training now, as advised by the group as a short-term goal, such changes in medical education will be possible in the future. RMS 2005 recognizes the importance of educational improvements, calling for increased

training in rehabilitation medicine and research from the undergraduate level up [4]. Moreover, by investing in training on the short-term and altering medical school education in the future, PMR will be able to develop a body of research professionals of sufficient numbers and with the ability to compete for grants with other medical specialties. One source from the literature goes so far as to say that in order to recruit the necessary number of investigators as called for by the group members, increased awareness about research careers must start in high school [2]. Finally, one last identified long-term change dependent on investment in research in the short-term is the establishment of a Department of Medical Research Laboratories. This is very similar to one of the RMS 2005 solutions to challenges in PMR which calls for the creation of an independent institute in NIH (U.S.) for rehabilitation research [4].

Question 8: What have you done to improve research capacity recently?

Group members indicate various methods they have employed to improve research capacity. These mechanisms include resolving personal clinician-researcher dilemmas, preparing and applying projects to the pharmaceutical industry, and participating in multicenter trials with said industry. One participant notes he found a short-term solution to funding issues by acquiring an industry sponsorship, while another includes attending courses, lectures, and encouraging colleagues to publish reports as efforts taken to broaden research capacity. Interestingly, a potential bridge between these two participants' efforts is industry support for small projects designed for clinicians interested in dedicating more time to research. In addition, continuing education in clinical research was a topic chosen by some participants in order to deepen their knowledge of

clinical research and improve its practical execution and intellectual impact. Experienced researchers found a benefit in participating in an international course in clinical research as to improve their scientific performance, due to the fact of exchanging ideas and collaboration with other researchers of different fields, level of expertise and countries.

Question 9: How can the situation be improved?

The participants describe a range of improvements that can be made in PMR clinical research. As has been reiterated throughout responses to the questionnaire, improvement in research education is much needed. Four group members cite increased education in clinical research and the establishment of clinical research training as standard for all health profession students as vital to bettering the current situation. RMS 2005 calls for similar educational improvements as well [4]. A review examining the efficacy of Continuing Medical Education (CME) published helpful information in regard to how to best improve research training. According to the findings, those CME methods in current use are the least effective at educating physicians and eliciting change in their practices. CME must change to encompass “interactive education, audit and feedback, reminders, academic detailing, and other outreach programs” which have been found most-effective [23]. In addition, responses indicate the creation of a department devoted to the pursuit of PMR research will greatly improve the situation. Sources from the literature record similar opinions, arguing for the establishment of sites designed for RCTs that can provide researchers with the necessary internal support. Such sites will also convince outside agencies of the legitimacy of PMR research, and thus elicit them more likely to provide funding [7]. The creation of a department

of PMR research will enable various other improvements outlined by the group. For instance, participants identify the establishment of research as a full time career as a necessary improvement. Without this change, it will be impossible to solve the issue of a lack of protected time for research. Related to this, responses include an increase in researchers’ income as a much needed improvement, as presently there is very little financial incentive to pursue clinical trials. RMS 2005 also records the need for better funding for individuals in order to attract and retain researchers [4], as do other published sources [2].

According to the group, it is necessary not only to improve the financial resources for individual researchers, but also to acquire better funding for the field of PMR research in general. Some responses call for the creation of a fund specific to rehabilitation research, which is similar to one of the solutions outlined in the literature [5]. A participant from the U.S. urges the use of political pressure to increase federal resources, adding that “the whole NIH program behind rehabilitation (National Center for Medical Rehabilitation-NCMRR) has less money than a single program manager in other institutes.” Other experts in the field agree, stating NCMRR must collaborate with more research organizations to develop mechanisms to better promote productivity [7]. A final change in the financial realm outlined by the group is to demonstrate the cost-effectiveness of PMR research. DeLisa explains this necessity, writing that for health insurance to support a given treatment, it must be both clinically and cost effective. He adds that this is especially difficult to prove in PMR as multiple treatments are often involved, but if focus is placed on each treatment individually, proof of cost-effectiveness is possible [7].

Lastly, participants include improvements for the general field of PMR research in their responses as well. First, both the creation of a national or state database of patients with disabilities and the implementation of protocols specific to the treatment of principal syndromes seen in PMR have been identified as significant changes. It is important to note RMS 2005 similarly calls for the establishment of a model for rehabilitation research [4]. Second, one member of the group notes developing more creative study designs may be necessary to effectively assess those PMR treatments that do not fit the RCT model. Another change to improve PMR research is to create a database to facilitate the search for information/data from different rehabilitation research centers. As Wade argues in his paper, PMR investigators need to take full advantage of the research that has already been completed, as the answer to their research question may already exist [8]. Moreover, both participants and literature sources alike identify greater collaboration between different research centers and departments as vital to the improvement of PMR research [2,7]. Similarly, group responses and RMS 2005 indicate the necessity of expanding partnerships with the pharmaceutical industry [4]. Finally, the majority of the changes outlined above will lead to an increase in the number of studies and trials conducted, which is another area for improvement in PMR according to Johnston [5].

Question 10: Have you published all the results of your studies, if not, why?

Only two participants answered that they have published all the results of their studies. Of these two, one adds that the studies were published only in national journals due to difficulty in writing the articles properly for publication in international journals.

Clearly, the majority of the group members respond that they have not published all the results of their studies. However, the reasons for this lack of publication vary. One key issue confronted by the investigators is a lack of time to analyze the data and write the reports. This is due to the fact that each step of research is very time-intensive and they are unable to make research their top priority. Another major problem is having either insignificant data or strong doubts about the importance of the research and data at the conclusion of the study. Four of the participants note their inability to publish is due to the poor quality of their methods and their studies in general. Finally, an over-arching issue inhibiting the publication of group members' study results is a lack of knowledge in clinical research, despite their participation in such work. Interestingly, investigators are conducting clinical trials, but lack of proper training may result in unpublished data. In fact, responses indicate poor understanding of study types, statistical analysis, and the process of writing and submitting a paper is a major challenge to publication. According to a panel made up of the editors-in-chief of four prominent PMR journals and convened at the Fourth World Congress of the International Society of Physical and Rehabilitation Medicine in Seoul, Korea in 2007, publishing in peer-reviewed journals is vital to the careers of clinical investigators. Not only is publishing a personal and professional achievement, the researcher may also be better regarded for promotions and grants as a result. Moreover, the review process itself is very beneficial to researchers, as it identifies points of weakness or error in each aspect of the study, such as methodology, data analysis, and results. Finally, publishing results is an obligation of investigators to disseminate their findings to the scientific and public community [20]. Thus, the state of

publication of PMR research must be improved as soon as possible.

Question 11: How to measure improvement in clinical research capacity?

The group identifies numerous methods to measure improvement in clinical research capacity. First, one idea for such a method would be to account for all of the current rehabilitation instruments in use worldwide, and then to record any developments in terms of new instruments. To do so, first, a system would have to be devised to identify instruments and to perform the necessary translations across languages and cultures to create a valid list of devices. This idea found mutual consensus among the participants, but has not been translated into action yet. Another mechanism for the measurement of improvements is the use of mathematical models to evaluate the efficacy of specific treatments for different diseases; therefore measuring outcomes improvement. Such models could also be used to estimate the individual importance of different aspects of the disease on overall recovery, thereby pinpointing to investigators those symptoms or issues that deserve the bulk of their attention. The group also indicates the need to measure capacity improvement on both an individual and institutional level. In terms of individual investigators, the participants include various measurements that could be combined to judge improvement. Such measures include data quality, writing quality, number of congresses attended, and number of publications and projects in progress. Similarly, various factors such as, number of grants acquired, ratio of projects submitted to the IRB that have been approved, number of PhDs within the department, and structural evaluations are good measures of institutional improvement in research capacity. In his paper, DeLisa also includes measures to judge

research productivity based on his personal experience in the field. He advises against basing productivity solely on the number of NIH grants (U.S.), as most PMR grants are not from the NIH. In terms of individuals, DeLisa argues improvement should be based on time devoted to research, and the number and quality of publications [7]. The creation of valid assessment methods to measure improvement in clinical research capacity is essential to achieving change. The establishment of such evaluations for rehabilitation research is both a short- and long-term goal of RMS 2005 [4], and thus is universally recognized as a necessary effort to undertake.

Discussion

A meeting of Brazilian, American and Canadian PMR clinician researchers examined 11 questions regarding problems and challenges of clinical research in PMR. In the following paragraph we shortly summarize the findings and discuss what has been changed in 2013.

1. How does clinical research change your decision making in the clinical practice?

The researchers state that they consider treatments which are well-supported by research evidence and are published in respected journals. One difficulty is to keep up with new publications and treatments. Good sources are meta-analyses, and studies of prognosis and cost-effectiveness. Overall, in the last years the number of those articles and publications has increased allowing to state that there is a good trend in a positive direction.

2. What are the challenges you face to perform clinical research in general?

Some of the most important points raised were challenges due to a lack of a solid infrastructure, a supportive chair, well-defined processes, and time. Looking at the current state, complex and time-consuming challenges such as infrastructure and well-defined processes cannot be changed quickly. Thus, those challenges are still remaining. Given challenges such as a supportive chair are not to change easily as well. However, personal challenges such as time dedicated to research even got worse in the current time comparing some years before. Reasons for that worsening are increased economic burden and widespread attitude to demand assistances so that one person need to fulfill more work in the same time (e.g. students training, publishing papers and clinical duties).

3. What are the specific challenges to perform clinical research in PMR?

Specific challenges include recruiting, difficulty blinding subjects, transportation of patients, and working with patients under multiple treatments/interventions. Since those challenges are relatively specific for the field of PMR, there are not much changes in 2013. The only issue which can be tried to minimize is recruiting since patients and the general population are increasingly educated what research is about which secondarily lowers the fear of being a subject.

4. Has the situation changed in the past 5 years? Why?

There is common agreement that the situation of PMR research continuously changes. There are more incentives for medical school graduates and those in residence programs to pursue clinical research. Moreover, there is also increased access to information via the internet,

open access journals and the NIH policy of open access to research sponsored by federal grants. Altogether, this has contributed to better conditions for clinical research in PMR.

5. What are the opportunities (or facilitators) you identify to perform clinical research in PMR?

The same facilitators as they were present in 2005 are applicable in 2013. There is continuously growing development of relationships and professional networking which makes it easier to exchange research ideas and questions in order to improve quality of PMR research. PMR is collaborative and supports the creation of multidisciplinary teams. Furthermore, there is much to investigate and study within the field of PMR, and therefore the area for research is expansive, ranging from the assessment of new interventions to the development of new techniques and devices.

6. Can you identify the difficulties and separate in the ones that can potentially be changed and the ones that will hardly be changed?

Focusing on the difficulties with the potential to be changed, the current development is clearly positive. There is an increasing connection to scientific institutions which strengthens the stimulus for clinical research, and which protects time for research pursuits. In addition, also the number of researchers and their respective levels of qualification and education are growing. Also of note is that there is a larger number of PMR residency programs.

7. Can you also identify changes to improve clinical research as short-term and long-term changes?

Short-term changes to improve clinical research were mostly named with investing more money to PMR research. In fact, in 2002 NIH funded grants totaling US\$15,431,590 for the department of PMR which represents just 0.17% of the funds allocated by the NIH to medical school departments that year (7). In comparison, in 2009 the situation became worse; the department of PMR only received US\$12,812,938 which is 0.12% of the NIH funds of that year (9). However, in 2012, a total of US\$20,532,294 was given to fund PMR research which reflects 0.17% of all funds that year (9). Still this is not a positive development, but the funding situation at least got back to where it was about 10 years ago.

8. What have you done to improve research capacity recently?

Group members mentioned resolving personal clinician-researcher dilemmas, preparing and applying projects to the pharmaceutical industry, participating in multicenter trials, attending courses, lectures, and encouraging colleagues to publish reports. These personal efforts to improve PMR research are also current in 2013.

9. How can the situation be improved?

The situation was improved by the creation of a national and state database of patients with disabilities and the implementation of protocols specific to the treatment of principal syndromes seen in PMR. Another improvement has been suggested. The creation of a database to facilitate the search for information/data from different rehabilitation research centers. However, this suggestion has still not become present. One issue here is the increased awareness of data security and secrecy which makes it difficult to fulfill such an idea.

10. Have you published all the results of your studies, if not, why?

The reasons for the lack of publication varied. One key issue mentioned by the investigators is a lack of time to analyze the data and write the reports. Moreover, poor understanding of study types, statistical analysis, and the process of writing and submitting a paper are more challenges to publication. To date, some of these issues have been overcome since the offer of education in clinical research is great and has increased in the past years. However, one key issue still remaining unchanged is time. This can only be changed by personal priority setting.

11. How to measure improvement in clinical research capacity?

It has been suggested that recording any developments of new instruments could help to measure improvement in clinical research capacity. A system has been suggested that is devised to identify instruments and to perform the necessary translations across languages and cultures to create a valid list of devices. This idea has currently not been translated into action. In addition, diverse factors such as number of grants acquired, ratio of projects submitted to the IRB that have been approved, number of PhDs within the department, and structural evaluations have been identified to be a good measure of institutional improvement in research capacity. In fact, there are institutions that yearly create such statistics.

Conclusion

To conclude, clear challenges face the pursuit of clinical research in the field of PMR in some countries – Brazil, US and Canada – according to a panel of PMR experts. The same might be true for other countries, in which the

situation of PMR is similar, for instance in other developing and developed countries. These problems have been outlined by both the participants in this study and by sources from the literature. The problems identified by these experts encompass a wide range of issues, from financial to institutional to political. Thus, sweeping changes are needed to improve the current situation and to allow for these challenges to be overcome. Although there is a general optimism from the members and initial steps towards change have been made, it is currently still not enough as the situation remains similar 5 years after RMS 2005. Therefore it is vital that change is initiated as soon as possible in order for PMR to reach its full potential and to address global medical needs in the near future.

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