

Multicultural Aspects Affecting Patient-Doctor Interactions and the Conduct of Clinical Research

Examples Drawn from the Literature and First-Hand Knowledge

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Abstract—Interest in international multicenter clinical trials is increasing for a variety of reasons. Working with different cultures in clinical research creates its own unique set of problems. This paper focuses on these issues from multicenter and multicultural perspectives.

The influence of culture on patient-doctor communication is considered. Expectations and the use of outcomes measurements with different cultures are also explored. Details on the issue of pain and how it is expressed and measured in different cultures is also presented.

Having considered the patient-doctor dynamic, the paper concludes with an examination of the unique difficulties that international multicenter studies present. Multicultural differences manifest themselves in different forms in international clinical research. Although its impact is often ignored or minimized, this manuscript demonstrates that the impact of culture on a study's success is a very real issue.

In addition to secondary sources, examples from our own clinical investigations are outlined throughout this paper. A successful model to locate researchers in previously untapped countries is also outlined.

Keywords—Clinical research; multicultural; outcome measures; communication; international; patient expectations; surgeon expectations.

I. INTRODUCTION

Cultural awareness and sensitivity is a topic of relevance to medical professionals in general [1]. These issues have been addressed in a variety of forms. For example, through the development of a curriculum designed to sensitize physicians to the various issues involved in cross-cultural care [2]. An example is that doctors should be aware of the role that families play in medical decision making in some cultures [2].

Culture has been defined as the "beliefs and behaviors that are shared by members of a group [3]." In writing about the subject, it is also important to keep in mind that

we all have our own cultural background and baggage which may bias observations or interpretations of culture [3, 4]. In common with other papers on the topic, the observations presented here should not be viewed as stereotypes but generalizations from our experience which may or may not apply to someone from a particular culture or to a particular situation [5].

AO Clinical Investigation and Documentation (AOCID) is a not-for-profit Academic Research Organization (ARO) located in Switzerland and active in over 40 countries around the world. Dealing with multicultural issues in medical research is part of our daily work.

Cultural issues affect both patients and treating medical staff. For example, despite interest in their techniques and principles of operative fracture care, the AO found it difficult to gain a foothold in Japan until as late as the 1990s as a result of the hierarchical nature of the Japanese health system [6].

This article examines the role that culture plays in patient-doctor interactions and also how it affects international multicenter clinical research. The information presented is augmented by real-life examples that we at AOCID have experienced in the conduct of our clinical investigations worldwide.

II. PATIENT-DOCTOR INTERACTIONS

A. Patient-doctor communication

The paternalistic approach to patient care is changing, albeit at different speeds around the world [7, 8, 9]. The need to allow increased decision-making by patients is being increasingly recognized in the literature [10]. Empowered patients feel more confidence in the decision reached as it incorporates both their preferences and the doctor's expertise [11].

Differences in national cultures in 10 different European countries have been examined to see if they impact upon medical communication [12]. Using a framework originally developed by Hofstede, among the findings was that the wealthier a country is, the greater the amount of psychosocial issues discussed by both patient and doctor. The more individualistic a country is (e.g. the Netherlands and Belgium), the greater the amount of information given by a doctor. If a country has a large power distance (e.g. Romania and Poland), the roles played by doctor and patient are more fixed and there is less information given by the physician in shorter consultations.

The visits of Dutch patients compared to the United States were examined in one study and substantial differences between the two were found [13]. While there was no difference between the levels of patient participation, visits in the US were on average 6 minutes longer and the American physicians contributed more to the medical dialog than their Dutch counterparts. The Dutch patients disclosed less biomedical and psychosocial information, but were more concerned and optimistic than US patients. Both Dutch and American patients asked an average of 6 biomedical questions.

In another study of differences between countries, the focus was on the diagnosis and management of coronary heart disease [14]. The researchers found that American physicians had a routine consultation length of 18 minutes compared to a German average of 5.5 minutes. However, German doctors like to see their patients at shorter intervals. The same study also found that American and British doctors are more likely to ask the patient questions than German doctors.

Patient involvement in consultations is also a topic of interest. Research has been published on doctors who have raised concerns that increased cancer patient participation also excessively lengthens consultation visits [15]. This suggests that some doctors may prefer patient passivity to interaction for workload reasons alone. Other research shows that patients report higher satisfaction levels with longer consultations [16].

The impact of race on the patient-physician relationship in the United States has been studied [17]. Black (and to a lesser extent other minority) patients had significantly less participatory visits with their physicians than white patients.

B. Patient-doctor expectations and the use of outcome measurements

Patient expectations have been described as “beliefs or attitudes that interact with perceived occurrences to produce care-related evaluations [18].”

There are few studies focusing on patient expectations of orthopedic surgery [19]. One multicultural study examined what makes a good outcome in spine surgery from the perspective of both surgeons and patients throughout Europe [20]. Depending upon their condition, between 48.2% and 59% of patients surveyed expected

substantial pain relief as a result of surgery. All 30 of the spine surgeons interviewed viewed the initial expectations of their patients as being too high in general.

It is notable that 76% (23) of the spine surgeons viewed a good outcome as achieving patient expectations. There was little regional variation with the exception that Southern European patients placed more value on a return to work, possibly attributable to shorter periods of disability pay in that region compared to the rest of Europe.

Other researchers point out that using sick leave as a parameter to measure musculoskeletal illness may produce distorted results, because countries differ in the amount of compensation a worker on sick leave may receive. In countries where compensation levels are high (e.g. in Scandinavian countries), a higher level of sick leave may therefore be expected [21].

It is of course also possible to learn from practices in other countries. One paper notes three spine surgeons from Northern Europe who suggest a preoperative contract between surgeon and patient which includes both of their expectations regarding the planned surgery [20]. This may be a novel way of aligning expectations in a measured way.

Other research focused on the country specific difference in patient expectations regarding total knee arthroplasty in results from a large multicenter cohort comprised of different countries [22]. They found that patient demographics were associated with patient expectations. For example, Australian patients were more likely to expect better function 12 months postoperatively than patients in the United States or United Kingdom. Patients from the United Kingdom were more likely than the other nationalities to expect to be using a walking aid by the same point in time.

One study of knee and hip arthroplasty patients examined the influence of preoperative educational classes on expectations [23]. Two randomized controlled trials were conducted and baseline expectation scores were high in both. Many patients at follow-up had expectations in line with surgeon’s general recommendations and the proportion of such patients was higher in the group who had undergone classes. This was more pronounced for the knee patients than it was for the hip patients.

Patients and doctors who are not aligned in expectations are likely to interpret the results of an outcome measurement differently. For clinical researchers, the two main issues with outcome measures in international multicenter trials are measuring the same data at each site and obtaining the same data [24].

AOCID conducted the Pan-American TEFTOM (Trauma Expectation Factor Trauma Outcome Measure) study which examined the role of patient expectations in traumatic orthopedic outcomes [25]. Marked cultural differences in patients’ expectations were observed. The results were so interesting that the study was replicated in

a Eurasian population and a final publication is currently in preparation.

Using outcome measurement instruments in clinical studies conducted among different cultures is fraught with difficulty. There is a need to cross-culturally adapt outcome measurements developed elsewhere. For example, a team in the Netherlands translated and cross-culturally adapted the PROMIS physical function item bank to the Dutch language. Since Dutch streets are irregularly shaped, unlike in the US, the question, "Are you able to walk a block on flat ground?" was changed to "Can you walk 150 meters on flat ground?" to make it more understandable to Dutch people [26].

Validating outcome measurements is a difficult but necessary task. It may be the case in international multicenter trials that instruments are not available in the local language of one or more of the clinics. This means either forgoing this element of the study in those clinics or developing a local language version. However, the problems of using these instruments to clinically assess patient progress may well extend beyond simple translation.

Patient-reported outcomes can be a confounding factor if they have been translated but not undergone a process of cross-cultural adaptation and testing. This involves forward and back translating as well as synthesis and expert review [27]. The importance of scrupulously checking translations and back translations in multicultural studies has been previously noted [28]. AOCID has cross-culturally adapted outcome measures as part of our studies [29, 30] and we are aware how time intensive it is to do so.

C. *Multicultural differences in pain and pain measurement*

Researchers have shown that Hispanic patients with an isolated long bone fracture who were treated in an emergency department were twice as likely as non-Hispanic white patients to receive no pain medication [31]. Interestingly, a follow-up study at the same trauma center found no difference in the physician's ability to assess pain severity in Hispanic and non-Hispanic white patients [32].

An examination of the satisfaction levels of Slovenian patients compared to other ex-Yugoslavians in the country, found lower satisfaction levels from the non-Slovenians in regard to general practitioner's ability to relieve pain quickly, thoroughness and explanations of the illness [33].

The pain element of an outcomes measure may differ from culture to culture. Filipino [34], Japanese [29], and Irish patients [5] have a tendency to minimize expressions of pain compared to other patient groups.

Doctors also vary in their levels of interest in a patient's pain. One study found that American doctors (62%) are almost twice as likely to ask questions about pain as German doctors (32%) are [14].

Indeed, there appears to be cultural differences in the classification of pain. For example, most Australian lower back pain classification systems use a treatment-based model compared to the diagnostic-based models typically used in Europe [35]. The same paper notes that non-inclusion of cultural factors other than language in classification systems is widespread.

Cultural differences affecting rehabilitation also appear in a study which examined cross-cultural differences in spinal cord injury rehabilitation professionals. A marked discrepancy between the US panel and both the Italian and Canadian panels was found on the issue of mobility [36]. The study authors speculate that the differing healthcare systems have an impact upon rehabilitation strategy.

III. MULTICULTURAL ISSUES IN CLINICAL RESEARCH

Clinical trials are increasingly conducted in more diverse locations [37]. This expansion in orthopedics and trauma can be attributed to many factors, not least the low numbers of specific fracture types in patients who present at hospitals, leading to an expansion in the search for more patients to be recruited on studies [38, 39, 40]. The extra work associated with multicenter trials is generally worthwhile, because although studies may take longer to get started, they tend to finish earlier [37, 41].

However, despite the advantages, international multicenter collaboration is not that common in orthopedic observational research [41]. The number of high quality Randomized Controlled Trials published in the orthopedic literature is also low [38, 42].

This is regrettable because large global trials in orthopedics have the potential to change practice among surgeons in a way that small case studies do not. For example, a survey of 796 surgeons indicated that they were willing to adopt alternative surgical approaches to hip fractures if the evidence to do so was compelling and sound [43].

There are also negative aspects to conducting international trials. Research organizations which operate in different countries are beset with a variety of challenges that these trials bring [3, 28, 41]. Some of these issues include informed consent, patient recruitment, human rights, and data collection [44] along with the challenge of standardization of protocols and procedures and communication difficulties due to language barriers [41].

The impact of culture on research is not to be underestimated. We at AOCID have discovered that something as simple as phoning up a patient to remind them of their follow-up visit can also be culturally loaded. At a site investigators meeting held for a study we ran in India, we learned that although for most people this phone call is not a problem, in parts of the country some patients may feel threatened. Receiving an unexpected telephone call from the hospital is upsetting for these patients

because they then believe that there is something wrong with the implant.

AOCID's experiences in conducting medical device trials in China also provide some nice illustrations of the types of multicultural issues that can arise in international multicenter studies.

Despite meticulous planning, we once encountered real recruitment problems on an implant-related study. We were at a loss as to why this was so because we were offering the patients free implants which they ordinarily would have to pay for. In fact, so concerned was the study sponsor about the state of events that we traveled to China to conduct some field research ourselves. It transpired that the free implants were the problem. In Chinese culture, the patient's family all chip in to pay for care. By offering free implants we were removing the family's involvement and creating dissonance. The solution to this problem proved to be charging the patient a token fee for the implant which meant their relatives could cover this cost and feel satisfied that they had fulfilled their familial obligations.

As these examples show, there are many factors to consider in the conduct of international multicenter trials. Overcoming the challenges that these multicultural differences present in order to become culturally competent [45] is a skill that AOCID, like any successful internationally active research organization, has had to learn.

A. *Finding capable new researchers around the globe*

The AO Foundation has a long history of conducting clinical research. However, the world of research has changed immensely since the AO's founding in 1958, both in terms of focus and location. The need to include the next generation of surgeons within the organization means reaching out to new clinical researchers in countries where there have not previously been strong links to. How can these previously untapped researchers be best reached? The answer we have found is through open calls for clinical research sites for planned studies.

An open call is made among the membership of the AO clinical division in question – e.g. Trauma or Spine. In this way, interested sites with motivated researchers can be identified and their capacity to conduct research checked through the use of feasibility questionnaires.

The following main elements are examined in the assessment of each applicant: completeness of the application, infrastructure (a clinical trial unit is preferred), geographical location (to ensure an appropriate spread of centers), and how representative is the treating clinic for the indication in question. These criteria all lead to a certain ranking. However, the final decision on which sites will participate in the trial rests with the study funder.

The open call model has successfully been used for studies examining double mandibular fractures, geriatric fracture treatment and fracture treatment within China. Up

to ten percent of members of a clinical division will respond to an open call to take part on the study. However, in the end there are only approximately ten slots to be filled for each clinical trial and, given that membership may run into the tens of thousands, many applicants will inevitably be disappointed.

AOCID has once again seen the benefit of including smaller clinics from around the world as opposed to large trauma centers based in big cities. Smaller clinics may see and treat certain types of patients who do not tend to present at larger clinics. For certain studies, this means that big is not always beautiful when it comes to patient recruitment. Given the very good experience with this model so far, it has become the preferred model for studies sponsored by the AO Foundation's clinical divisions. For future studies it is not unthinkable that the open calls will be truly 'open' with the removal of the current AO membership criteria.

IV. CONCLUSIONS

This article has provided an overview of cultural issues which may manifest themselves between doctors and patients as well as in the conduct of international clinical trials.

The literature reviewed in this manuscript, along with AOCID's real-life experience, indicates that CROs and others engaged in international studies should be sensitive to the multicultural challenges and potential barriers they may encounter. Methods to successfully locate new clinics in previously untapped countries do exist.

We would also like to repeat the caveat that the opinions contained in this manuscript reflect our own personal experience from conducting clinical research in over 40 different countries and may not reflect the experience of others.

To summarize, there is no panacea to the cultural problems that will arise in international clinical research. Identification of cultural difficulties is necessary before they can be solved on an individual basis. Avoidance of such cultural problems in the first place is preferable to attempting to fix them during the course of a clinical trial. Cultural competency is an essential skill that doctors and clinical researchers should strive to possess.

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