“Sorting out Lemons and Oranges:”
Towards Better Quality of Reporting Clinical Trials in 

Senthil P Kumar MPT, (PhD)

ABSTRACT

The editorial aims to welcome the JPT readers to its first issue on a historical note of clinical trials in the field of Medicine and the Consolidated Standards Of Reporting Trials (CONSORT) statement’s reporting guidelines. History of research and randomized controlled trials (RCTs) in physiotherapy and the continuous growth in number of RCTs in physiotherapy evidence database (PEDro) necessitates better quality in reporting clinical trials by use of CONSORT checklist and flow diagram for clinical trials. Recently, the CONSORT statement was revised in 2010 and JPT became a journal endorser of the statement in its new version. The last section of the editorial envisions the aims of Journal of Physical Therapy in improving quality of reporting trials published by mandating the use of the statement.

Key words: clinical trial reporting, CONSORT 2010 statement, guidelines for reporting, randomized controlled trials.

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Clinical trials often involve studies performed on patients on effectiveness of interventions and/or their comparisons. Historically, the first “published” clinical trial was performed in 1747, on board the ship Salisbury by then Scottish Physician, Dr James Lind (1716-1794),...
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which he performed on his shipmen with Scurvy. In his own book, *A Treatise on the Scurvy* (figure-1) he described as follows, his first ever clinical experiment on the ship (figure-2).

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**Figure-1. Coverpage of the book, “A Treatise on the Scurvy” by Dr James Lind.**

"......Of the Prevention of the Scurvy
I shall conclude the precepts relating to the preservation of seamen with showing the best means of obviating many inconveniences which attend long voyages and of removing the several causes productive of this mischief. The following are the experiments...

......On the 20th May 1747, I took twelve patients in the scurvy, on board the Salisbury at sea. Their cases were as similar I could have them. They all in general had putrid gums, the spots and lassitude, with weakness of their knees. They lay together in one place, being a proper apartment for the sick in the fore-hold; and had one diet common to all, viz. water-gruel sweetened with sugar in the morning; fresh mutton broth often times for dinner; at other times puddings, boiled biscuit with sugar etc. And for supper, barley and raisins, rice and currants, sago and wine, or the like. Two of these were ordered each a quart of cider a day, upon an empty stomach; using a gargle strongly acidulated with it for their mouths. Two others took two spoonfuls of vinegar three times a day, upon an empty stomach: having their gruels and their food well acidulated with it, as also the gargle for their mouths. Two of the worst patients, with the tendons in the hamrigid (a symptom none of the rest had) were put under a course of sea-water. Of this they drank half a pint every day, and sometimes more or less as it operated, by way of a gentle physic. Two others had each two oranges and one lemon given them every day. These they eat with greediness, at different times, upon an empty stomach. They continued but six days under this course, having consumed the quantity that could be spared. The two remaining patients, took the bigness of a nutmeg three times a day of an electuary recommended by a hospital-surgeon, made of garlic, mustard-feed, rad. Raphan, balsam of Peru, and gum myrr; using for common drink barley water well acidulated with tamarinds; by a decoction of which, with the addition of cremor tartar, they were greatly purged three or four times during the course. The consequence was, that the most sudden and visible good effects were perceived from the use of the oranges and lemons; one of those who had taken them, being at the end of six days fit for duty. The spots were not indeed at that time quite off his body, nor his gums sound; but without any other medicine, than a gargle of vitriol, he
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became quite healthy before we came into Plymouth, which was on the 16th June. The other was the best recovered of any in his condition; and being now deemed pretty well, was appointed nurse to the rest of the sick.”

The above “story” clearly depicted the importance of use of oranges and lemons for treating scurvy. The following six important queries arise on reading the above information:

- How many Scurvy patients participated in “his” study?
- How many treatment groups were there in “his” study?
- What treatments were given for each of the groups?
- How many patients were there in each of the treatment groups?
- How many of “his” patients completed the study?
- How can we conclude “oranges and lemons” are the only effective remedy for Scurvy?

I hope our JPT readers would be able to answer these at the end of reading this paper. Historically however, Medical scientists were very skeptical in “his” findings. There was a growing controversy in the interpretation of “his” findings into either as rationally-derived experimentation or controlled empiricism. It took nearly forty-two years for the relevant authorities and The Navy Sick and Hurt Board to address the issue based on Dr. Lind’s study results. It should be recalled, however, that even Lind probably did not think of scurvy as primarily a nutritional disorder and the theory that antiscorbutics functioned by replacing a missing dietary component did not emerge until formulated by George Budd (1808-1882) over half a century later.

It took two centuries afterwards to implement this into routine clinical practice. It took less than a century for the scientists to find out that vitamin C was involved in the disease and another to find out that oranges and lemons had in them, greater content of vitamin C. It was finally in 1930s, that it was found the anti-scorbutic factor was Vitamin-C.

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**Table-1: Types of clinical trials**

<table>
<thead>
<tr>
<th>Purpose of clinical trial</th>
<th>Clinical trial methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>Tests new drugs, therapies, devices or surgeries.</td>
</tr>
<tr>
<td>Prevention</td>
<td>Tests new means to prevent disease: medicines, vaccines, lifestyle changes.</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>Tests new ways of diagnosing diseases or conditions.</td>
</tr>
<tr>
<td>Screening</td>
<td>Tests new ways of detecting diseases or conditions.</td>
</tr>
<tr>
<td>Quality of life</td>
<td>Tests new ways of improving quality of life for people with chronic illnesses.</td>
</tr>
</tbody>
</table>

**Table-2: Phases of clinical trials**

<table>
<thead>
<tr>
<th>Phase of clinical trial</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase-I</td>
<td>Initial testing of a new method (treatment) on a small group of human subjects to evaluate safety, as a certain dosage range and identify side effects.</td>
</tr>
<tr>
<td>Phase-II</td>
<td>The therapy (method) is tested on a larger group to determine its efficacy (i.e., whether it works under ideal circumstances).</td>
</tr>
<tr>
<td>Phase-III</td>
<td>Randomized controlled multicenter trials on even larger patient groups to confirm effectiveness, (whether the treatment or method does more good than harm under usual care conditions).</td>
</tr>
<tr>
<td>Phase-IV</td>
<td>Post-market studies gathering data on whether the new method affects population groups differently or whether there are side effects associated with its long-term use.</td>
</tr>
</tbody>
</table>

Source: U.S National Institutes of Health

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*CONSORT 2010 statement*

**Kumar SP**
Editorial

What is a clinical trial?

Meinert and Tonascia\(^6\) in their text- *Clinical Trials: Design, Conduct, and Analysis* explain the term “clinical trials” as follows:

“Trial is from the Anglo–French *trier*, meaning to try. Broadly, it refers to the action or process of putting something to a test or proof. Clinical is from clinic, from the French *clinique* and from the Greek *klinike*, and refers to the practice of caring for the sick at the bedside. Hence, narrowly, a clinical trial is the action or process of putting something to a test or proof at the bedside of the sick.”

Clinical trials are classified into five categories\(^7\) (table-1) depending upon their purpose; treatment, prevention, diagnostic, screening and quality of life. The interventional studies or treatment trials can further be divided into four phases\(^7\) (table-2) for conduct of the study at various levels to answer a research question valid enough to imply for a target population.

The objective of a clinical trial is to study the effects of a relatively less scientifically established intervention. The intervention to be studied is the experimental intervention and the patients in the group are termed as experimental group. The comparison group may be another intervention or a group either without any intervention (control), or a deceivably similar but no-effect intervention (sham) or a psycho-motivating intervention (placebo). Randomized controlled trials are for studying comparison between a control group and one or more experimental groups while randomized clinical trials are for comparison between two or more experimental groups. However, many authors use these terms interchangeably thus misleading the reading clinical community. This is explainable by the known fact that studying a group truly without administering any treatment for its effects, is deemed to be unethical in a clinical situation where the patient-centered treatment-decisions and payer’s policies influence on bio-ethical grounds.

Lind’s experiment in 1747 was a “controlled” clinical trial; the first use of sham procedure for comparison was done by Haygarth in 1799 and of placebo treatment as a comparison group was done by Gull in 1863.\(^6\) Historically, sham procedure was used much earlier than placebo treatments in randomized trials.

Sham-controlled trials are often used in studying treatment techniques which involve non-physiological effects like Manual Physical Therapy where it is widely believed that hands-on- touch of the therapist will eventually lead to subjective relief of symptoms more than actual biomechanical effects of the technique. Placebo-controlled trials are often used in studying interventions with probable psychological/perceptual effects. For example, comparing ultrasound with laser therapy is a randomized clinical trial; comparing ultrasound with no treatment is a randomized controlled trial; comparing ultrasound with detuned (switched-off) ultrasound is a sham-controlled trial; and, comparing ultrasound with verbally positively-reinforced supine-lying is a placebo-controlled trial.

Clinical trials are done on patients and hence clinical decision-making was supposed to be “informed” rather than being “driven” by evidence from such trial’s findings. Randomized controlled/ clinical trials (RCTs) are the single-most individual level of evidence for evidence-based practice (EBP) in applying study results for interventions. The rigorous methodology adopted in RCTs is sometimes argued to be impractical and does not mimic real-life clinical practice situations. The term “randomized” in RCT implies either random sampling of patients for recruitment into the study or random allocation of patients to receive either of the interventions studied.

History of Clinical trials in Physical Therapy:

Journals are acknowledged as crucial sources of evidence-based information relevant to physiotherapy practice.\(^8\) The first research about physical therapy in the United States was published in March 1921 in *The PT Review*.\(^9\)
On a historical note, the first ever randomized controlled trial in Physical Therapy evaluated Ultra-Violet radiation therapy and was published in 1929 by Dora Colebrook (figure-3) in Medical Research Council Special Report Series. Initially the RCTs were published in medical journals and not until 1967, for the first time an RCT evaluating physical therapy intervention was published in a physical therapy journal. This unique credit goes to author-Landen B whose study evaluated superficial heat vs. cold in LBP and was published in Physical Therapy journal.

Presently as was on March 2010, there were 15,920 records in Physiotherapy Evidence Database (PEDro) which includes 13,096 randomized controlled trials in physiotherapy alone. In April 2010, there are 13,189 RCTs (Figure-4). The last month thus witnessed an increase of 93 RCTs in a month- an average of 3 RCTs added to PEDro every day. This is the number for trials added to PEDro database alone. This number is the best example of “tip of an iceberg”

The actual number of trials in Physical Therapy will be a lot different considering...
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the actual number of trials performed and stay as unpublished trials or trials published but are not yet added to PEDro.

As true it is to interpret evidence from RCT, also is true that certain guidelines be followed for standardized reporting of trial findings for better accurate dissemination of trial findings and thus effective translation into clinical practice thus facilitating evidence-based healthcare. Thus the EBP paradigm demands reporting of evidence to be a single-most significant factor which influences evidence-informed clinical decision-making.

The need for trial reporting guidelines- history of CONSORT statement:

The work towards formation of reporting guidelines was begun in mid 1990s which then noticed The CONsolidated Standards Of Reporting Trials CONSORT group first publishing its original version in 1996 and later revising it in 2001. In 2004, the CONSORT statement was extended to include reporting of harms. In 2008, the statement was extended with explanation and elaboration with excellent examples of reporting for use in non-pharmacological studies. The updating and publication of latest revision of the statement was done this year 2010. The use of reporting guidelines for various levels in a RCT (CONSORT-2010) are schematically shown as CONSORT flow diagram in figure-4.

The use of the CONSORT statement was associated with improvements in the quality of reporting RCTs when the authors compared journals which required CONSORT as mandatory versus the ones which did not. Hywel Williams added, “The benefits of CONSORT are manifest right from trial conception to the application of evidence to patients in the clinic. A trial that is “CONSORTED” gives a signal to the reader that they can find what they want to find. CONSORT 2010 is not a tool to catch out well intentioned researchers with a straitjacket of prescriptive reporting formats – it is simply an aid to ensure that a trial report contains key information. Whether you are buying a car or a trial report, you need essential information to help you decide whether it is a good one. CONSORT 2010 helps you to do that. Use CONSORT 2010 if you are a generator of research. Insist on it if you are a user of research”.

CONSORT 2010 and history revisited:

The historical "controlled" clinical trial by James Lind is depicted in the new CONSORT 2010 flowchart in figure- 5. It is now evident how a different style of reporting (description in text versus CONSORT flowchart) makes interpretation clearer for our readers.

The lack of standards of reporting (illustrated below) often undermines the value of the scientific findings which always is true. Atleast half-a
CONSORT 2010 Flowchart of the historical Dr James Lind’s “first controlled clinical trial” in 1753. (U*: unexplained or unreported by the author).

Figure-5. CONSORT 2010 Flowchart of the historical Dr James Lind’s “first controlled clinical trial” in 1753. (U*: unexplained or unreported by the author).

century before Dr Lind’s report of his findings on “oranges and lemons” for Scurvy, an European traveler, John Flyer (1650-1733) noticed the “proven” value of citrus fruits (oranges and fresh limes) for Scurvy in sailors at a place less well developed when compared to Western countries, India, during his travel from 1672 to 1681, which he wrote;

“. . . when half the fleet were disabled by distempers acquired by salt meats, and a long voyage without refreshments. . . . The first care then was to send the sick men ashore, which it is incredible to relate how strangely they revivified in so short a time by feeding on oranges and fresh limes. . . .”

Dominik Wujastik described the importance of John Flyer’s observations in India in his paper, as follows;

“Amongst the many narrative and descriptive accounts of India written by European travelers in the seventeenth century... that of John Fryer (1650–1733) stands out for its attention to daily life and the Indian environment, and especially for its many comments on the medical situation in India. Among scientifically important observations made on arrival in India, Fryer noted the value of citrus fruits in curing sailors of scurvy, predating Lind’s famous observations by half a century. Fryer travelled in India for nine years, between 1672 and 1681.”

Past is past indeed.

Presently, the 20th May 2010 marks in the pages of History, another event of highly relevant importance, The International Clinical Trials Day, at Stockholm, Sweden, organized by European Clinical Research Infrastructures Network (ECRIN) to mark the 264th anniversary of James Lind’s first controlled clinical trial in 1747.
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Role of Journal of Physical Therapy:

It is a mutual responsibility on reporting authors and endorsing journals alike, in not only including the CONSORT for reporting clinical trials but to mandate such standards both in conduct of research and in instructions to authors respectively. JPT promises to ensure quality in reporting standards as recommended by CONSORT 2010, and this was evident when JPT became the fourth among the physiotherapy journals to endorse the new statement and the JPT instructions to authors (Altman, 2005) provide the prospective authors with link to CONSORT website and direct download citation link for the published reference.

“It is not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change.”

- Charles Darwin.

According to National Library of Medicine, there are four broad categories of journals- research, clinical/practice, review and general. Whilst research journals publish scholarly articles, practice journals publish practice-oriented discussions and case reports. JPT aims to strike a balance between the two in an effort to bridge the gap between academicians, clinicians and researchers for the betterment of Physical Therapy globally. We, the global editorial board of Journal of Physical Therapy assure you, our reader just that, of being responsive to change. We welcome articles that would bring a change, to move Physical Therapy forward, in lines of World Physical Therapy 2011 (WCPT).

Every article in JPT will have a key points tab where past-information what already exist on the topic; present-information provided by this article; future- what implication the article has towards moving Physical Therapy forward. JPT editorial policy makes it mandatory for all submitted clinical trials to follow CONSORT 2010 statement- the CONSORT checklist for abstract and report, and flow diagram for trial procedure. JPT will also ensure unbiased publication of well-reported trials irrespective of their findings and direction of treatment-effect.

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Date of acceptance- 10th May 2010.
Reviewer- R. Selvam
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WFIN: JPT-2010-ERN-107-1(1)-1-10.

REFERENCES


Editorial


Key points:

**Past**- The first clinical trial was performed by Dr James Lind on sailors with Scurvy and he found lemons and oranges were effective in curing the disorder. The CONSolidated Standards Of Reporting Trials (CONSORT) statement was formed in 1996, and was revised in 2001 and then extended to non-pharmacologic interventions.

**Present**- The CONSORT statement is revised this year 2010 with updated reporting guidelines. The randomized controlled trials (RCTs) in physical therapy are increasing at the rate of 3 studies getting added to physiotherapy evidence database (PEDro) everyday.

**Future**- To improve evidence-based healthcare and evidence-informed decision-making in physical therapy, the *Journal of Physical Therapy* (JPT) endorsed the CONSORT 2010 statement and mandated the statement and its flow diagram for future intervention studies submitted to JPT.
Appendix 1 - CONSORT 2010 Checklist for randomized trials.

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item No</th>
<th>Checklist item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title and abstract</td>
<td>1a</td>
<td>Identification as a randomized trial in the title</td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
</tr>
<tr>
<td>Introduction</td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
</tr>
<tr>
<td>Background and</td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
</tr>
<tr>
<td>objectives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td>3a</td>
<td>Description of trial design (such as parallel, factorial) including allocation ratio</td>
</tr>
<tr>
<td>Trial design</td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
</tr>
<tr>
<td>Participants</td>
<td>4a</td>
<td>Eligibility criteria for participants</td>
</tr>
<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
</tr>
<tr>
<td>Interventions</td>
<td>5</td>
<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
</tr>
<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed</td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
</tr>
<tr>
<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
</tr>
<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
</tr>
<tr>
<td>Randomisation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sequence generation</td>
<td>8a</td>
<td>Method used to generate the random allocation sequence</td>
</tr>
<tr>
<td></td>
<td>8b</td>
<td>Type of randomisation; details of any restriction (such as blocking and block size)</td>
</tr>
<tr>
<td>Allocation</td>
<td>9</td>
<td>Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned</td>
</tr>
<tr>
<td>concealment mechanism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implementation</td>
<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
</tr>
<tr>
<td>Blinding</td>
<td>11a</td>
<td>If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how</td>
</tr>
<tr>
<td></td>
<td>11b</td>
<td>If relevant, description of the similarity of interventions</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>12a</td>
<td>Statistical methods used to compare groups for primary and secondary outcomes</td>
</tr>
<tr>
<td></td>
<td>12b</td>
<td>Methods for additional analyses, such as subgroup analyses and adjusted analyses</td>
</tr>
<tr>
<td>Results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant flow</td>
<td>13a</td>
<td>For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome</td>
</tr>
<tr>
<td>(a diagram is strongly</td>
<td>13b</td>
<td>For each group, losses and exclusions after randomisation, together with reasons</td>
</tr>
<tr>
<td>recommended)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recruitment</td>
<td>14a</td>
<td>Dates defining the periods of recruitment and follow-up</td>
</tr>
<tr>
<td></td>
<td>14b</td>
<td>Why the trial ended or was stopped</td>
</tr>
<tr>
<td>Baseline data</td>
<td>15</td>
<td>A table showing baseline demographic and clinical characteristics for each group</td>
</tr>
<tr>
<td>Numbers analysed</td>
<td>16</td>
<td>For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups</td>
</tr>
<tr>
<td>Outcomes and estimation</td>
<td>17a</td>
<td>For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</td>
</tr>
<tr>
<td></td>
<td>17b</td>
<td>For binary outcomes, presentation of both absolute and relative effect sizes is recommended</td>
</tr>
<tr>
<td>Ancillary analyses</td>
<td>18</td>
<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory</td>
</tr>
<tr>
<td>Harms</td>
<td>19</td>
<td>All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)</td>
</tr>
<tr>
<td>Discussion</td>
<td>20</td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
</tr>
<tr>
<td>Limitations</td>
<td>21</td>
<td>Generalisability (external validity, applicability) of the trial findings</td>
</tr>
<tr>
<td>Generalisability</td>
<td>22</td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
</tr>
<tr>
<td>Interpretation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other information</td>
<td>23</td>
<td>Registration number and name of trial registry</td>
</tr>
<tr>
<td>Registration</td>
<td>24</td>
<td>Where the full trial protocol can be accessed, if available</td>
</tr>
<tr>
<td>Protocol</td>
<td>25</td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
</tr>
</tbody>
</table>

CONSORT 2010 statement

Kumar SP
Orthopaedic Manual Physical Therapy- 
History, Development and Future Opportunities

Peter A. Huijbregts, PT, MSc, MHSc, DPT, OCS, FAAOMPT, FCAMT

Abstract

Manual therapy is among the oldest interventions in medicine with records of its use dating back over 4,000 years. Although currently manual therapy is a well-established part of physiotherapy practice around the world, few therapists are aware that it has been a continuous and inextricable part of the physiotherapy scope of practice dating back at least as far as 1813 AD, with noted contributions to the field by our professional colleagues for now almost two centuries. This paper intends to acquaint the reader with the definition, history and development of orthopaedic manual physical therapy (OMPT) with specific attention to the paradigm shift within OMPT from an authority-based to an evidence-based and now an evidence-informed paradigm. This historical paper concludes with suggestions for the role the Journal of Physical Therapy might play in the ongoing development of OMPT.

Key words: Orthopaedic Manual Physical Therapy, History, Evidence-Informed Practice

Definition of Orthopaedic Manual Physical Therapy

Both as an entry-level skill set and as a postgraduate specialization, OMPT is a well-established part of physiotherapy practice around the world, although perhaps more so in Europe, Australia and New Zealand, and North America. Whereas many of our patients and health care colleagues from other professions may equate OMPT exclusively with the high-velocity, low-amplitude thrust maneuver, it, of course, also encompasses a great variety of other techniques. The American Physical Therapy Association has defined manual therapy techniques as “…skilled hand movements intended to improve tissue extensibility, increase range of motion, induce relaxation, mobilize or manipulate soft tissue and joints, modulate pain, and reduce soft tissue swelling, inflammation or restriction…”. Techniques include massage, manual lymphatic drainage, manual traction, mobilization/manipulation, neural mobilization, joint stabilization, self-mobilization exercises, and

Key points and pre-publication history of this article are available at the end of the paper.

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Historical paper

passive range of motion.\textsuperscript{1,2} Within physiotherapy in the United States defined synonymously as “a manual therapy technique comprised of a continuum of skilled passive movements to joints and/or related soft tissues that are applied at varying speeds and amplitudes, including a small amplitude/high velocity therapeutic movement”, in most other parts of the world the term manipulation is used to describe a thrust technique performed at a pathological endrange of a joint, whereas mobilization describes a non-thrust, sustained or oscillatory, low-velocity movement within or at the end of range of joint motion.\textsuperscript{1}

Adding an emphasis beyond the purely technical and thereby also reflecting the recent paradigm shift we will discuss later from an authority-based to an evidence-based and now evidence-informed paradigm, in 2004 the International Federation of Orthopaedic Manipulative Physical Therapy (IFOMPT) defined OMPT as “...a specialized area of physiotherapy/physical therapy for the management of neuromusculoskeletal conditions, based on clinical reasoning, using highly specific treatment approaches including manual techniques and therapeutic exercises. OMPT also encompasses, and is driven by, the available scientific and clinical evidence and the biopsychosocial framework of each individual patient...”.\textsuperscript{3}

Early Manual Therapy

Manual therapy is among the oldest recorded influential interventions in medicine. Documentation of its practice dates back over 4,000 years to Egyptian scrolls (Edwin Smith papyrus) and its use is also depicted in ancient Thai sculptures.\textsuperscript{4} The first mention of massage appears in 2598 BCE in the oldest existing medical work, the Nei Ching dedicated to the Chinese Emperor Huang Ti. Ancient Indian and Greek texts, including the work of Hippocrates, describe massage as an effective therapy for treating injuries resulting due to war or sports.\textsuperscript{5} Hippocrates (460-385 BCE) (Figure-1) described a combination of traction and manipulation on the back of a patient lying prone on a wooden bed in his treatise, On Setting Joints by Leverage.\textsuperscript{6} Whether Hippocrates solely attempted by this method to reposition traumatically displaced vertebrae or if he intended to manipulate slightly luxated vertebrae for a variety of indications to this day remains a matter of debate.\textsuperscript{7} The Roman physician Galen (131-202 CE) (Figure-2) commented on Hippocrates’ manipulative techniques in 18 of his 97 surviving treatises, as did the Arabic physician Abu Ali ibn Sina, also known as Avicenna (980-1037 CE) (Figure 3). Hippocrates’ manipulative procedures were again included in the 16th century writing of Guido Guidi and Ambrose Pare (Figure 4). Pare (1506-1590), a military surgeon who served four French kings, in 1580 advised the use of manipulation in the treatment of spinal curvature. In 1656, Friar Thomas described manipulative techniques for the extremities in his book, The Complete Bone Setter, and in as late as 1674 Johannes Scultetus still included descriptions of Hippocrates’ manipulative methods in his text, The Surgeon’s Storehouse.\textsuperscript{8}

Manipulation fell out of favor in medicine when Sir Percival Pott (1714-1788) described tuberculosis of the spine and condemned traction and manipulation as not only useless but dangerous.\textsuperscript{6-8} However, manipulation in the form of bone-setting continued to be practised with some of its lay practitioners attaining great notoriety including Sarah Mapp in 18th century and Sir Albert Baker in 20th century England, who both counted royalty among their patients. In the United States, the male
members of the Rhode Island Sweet family were reputed to possess hereditary skills in bone setting. One of them, Waterman Sweet, in 1829 even published a text called, *An Essay on the Science of Bone Setting*. Bone-setting continues to be practiced today in large parts of the world by lay practitioners as a form of folk medicine.  

During this time, manual therapy in medicine was relegated to a number of fringe clinicians, foremost among them the 1784 Edinburgh University graduate Edward Harrison. Harrison published in the *London Medical and Physical Journal* on a proposed pathophysiological connection between spinal subluxations and visceral disease and adjusted vertebrae by pressing on the spinous or transverse processes with his thumbs or with a device. In 1828, Glasgow physician Thomas Brown popularized in the medical community the concept of “spinal irritation”. Brown proposed that a shared nerve supply could implicate the spine in visceral disease and nervous conditions, which led him to target the spine with non-manipulative heroic medicine interventions including local blistering, application of leeches, and cautery. Dr. Isaac Parrish of Philadelphia introduced the concept of spinal irritation in North America with an article on the topic in *The American Journal of Medical Sciences*. Riadore, a prominent London physician practising manipulation, stated in 1842, “if an organ is insufficiently supplied with nervous energy or blood, its function is decreased and sooner or later its structure becomes endangered.” With at least their theories acceptable even to many eminent 19th century medical physicians, it is easy to understand how first osteopathy after 1874 and then chiropractic after 1895 and its offshoots, naturopathy after 1902 and naprapathy after 1905, rapidly gained widespread acceptance among at least the American general population.

**Early Physiotherapy**

Examples of renewed medical interest included an 1867 paper in the *British Medical Journal* that reported on a lecture by Dr. James Paget, *On the Cases that Bonesetters Cure*. In 1871, Dr. Wharton Hood wrote a series of papers for the *Lancet* complementary to bonesetting based on his experiences with a bonesetter by the name of Hutton and in 1882 there was a discussion of bonesetting at the 50th annual meeting of the *British Medical Association*. The successful establishment of thriving practices by the earliest Swedish-educated physiotherapists in various countries, including the United Kingdom, may have brought about this renewed interest. Physiotherapy as a government-sanctioned, university-educated profession began when in 1813 in Stockholm Pehr Hendrik Ling (1776 -1839) founded the Kungliga Gymnastiska Centralinstitutet or Royal Central Institute for Gymnastics (RCIG) in Stockholm. Students at the RCIG were either noblemen or belonged to the upper echelons of society; most were also army officers. They were instructed in physical education, military gymnastics (mainly fencing, which was not surprising considering Ling’s background as a fencing master and his personal experience with its effects on physical wellbeing), and physiotherapy (medical gymnastics). The RCIG education included a strong

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**Figure-5**

Thoracic traction ad modum Ling (Reproduced with kind permission from Dr. Ottoson, [http://www.chronomedica.se/](http://www.chronomedica.se/))

**Figure-6.**
manual therapy component, leading medical historian Dr. Anders Ottoson to describe physiotherapy as the world’s oldest manual therapy profession easily predating osteopathy and chiropractic (Figures 6 and 7). Although by today’s standards the OMPT techniques instructed can hardly be called sophisticated, RCIG-educated clinicians further developed and published on more specific manipulative interventions.

Physiotherapy education in Sweden and eventually world-wide was restructured to a technical education producing allied health technicians. In English-language countries physiotherapy was often practised by nurses with additional course work in massage and exercise therapy. In other Western European countries, physical education teachers with additional course work in rehabilitative exercise, often begrudgingly gave up their previous professional independence for support from the medical profession in their search for societal recognition.

In rapid succession these physiotherapy technicians established national associations. In 1889 in the Netherlands, physiotherapists founded the world’s first professional association, the Society for Practising Heilgymnastics in the Netherlands. In 1894 in Great Britain, the Society of Trained Masseuses was founded and in 1906 in Australia the Australasian Massage Association.

Physiotherapy in the United States had a relatively late start with the founding of the American Women’s Physical Therapeutic Association in 1921. When the US entered World War I, it did not, in contrast to its European allies, have a military with an established division of physiotherapy. By command of the Surgeon General, a number of university physical education programs, instituted “War Emergency Courses” to train women who could physically rehabilitate returning soldiers. As a result, 90% of World War I physical therapists came from schools of physical education; in fact, the physician then in charge of the Army Physiotherapy Division stipulated that all therapists have 4-year university degrees in physical education in addition to their physiotherapy training. When in 1922 the military reduced therapy services as a result of government cutbacks many therapists previously employed by the military were forced into the private sector. This led to conflicts with other manual medicine practitioners including nurses, osteopaths, and chiropractors all claiming to practice physiotherapy. It was this early conflict with especially the chiropractic profession that caused therapists to align themselves more closely with medical physicians. To garner physician support, US physiotherapists in 1930...
voluntarily relinquished their right to see patients without physician referral.\textsuperscript{18}

In the US, this close alliance with the medical profession and the adversarial relationship between physicians and especially chiropractors also had physiotherapists in their communication with physicians de-emphasize the use of manual therapy in their clinical practice, although these interventions continued to be used and further developed within the profession with various publications during this period on this topic in the US physiotherapy literature.\textsuperscript{19} In Western Europe and Scandinavia, this adversarial stance never developed. Instead, medical physicians embraced osteopathy, chiropractic, and the various manual medicine approaches indigenous to Europe. Through-out Europe, postgraduate manual medicine training institutes were well attended by physicians and even academic chairs in manual medicine were established.\textsuperscript{20}

These European physicians also educated their physiotherapy technicians in manual therapy. Dr. James Mennell (1880-1957), the medical officer at St. Thomas Hospital in London, taught manipulation to therapists as of 1916. His son, Dr. John McMillan Mennell (1916-1992) (Figure 8), educated both physicians and therapists worldwide in manipulation and with Dr. Janet Travell co-founded the North American Academy of Manipulative Medicine.

Dr. James Henry Cyriax (1904-1985) (Figure 9), Mennell’s successor at St. Thomas, stated that physiotherapists were the most apt professionals to learn manipulative techniques. He is most known for developing and instructing to therapists and physicians worldwide his system of orthopaedic medicine emphasizing clinical diagnosis and conservative management by way of friction massage, exercise, manipulation, and infiltration. Less well-known is his link to early Swedish physiotherapy though his father Dr. Edgar Cyriax (1874-1955) and his maternal grandfather Jonas Henrik Kellgren (1837-1916), both RCIG graduates. Another influential person teaching manipulation to therapists at this time at the London School of Osteopathy was Dr. Allan Stoddard, qualified both in medicine and osteopathy. Therapists and physicians were also educated in manual therapy at the British School of Osteopathy as of 1920.\textsuperscript{8}

\textbf{Orthopaedic Manual Physical Therapy Approaches}

Without a doubt the most influential person to again increase the emphasis on manual therapy within the profession of physiotherapy and arguably “the father of manual therapy” was Norwegian-born Freddy Kaltenborn (1928-). Already trained as a physical education teacher in 1948 he was admitted as the first male student to the Norwegian program in physiotherapy. Educated in London in orthopaedic medicine by Dr. James Cyriax from 1952-1954 and qualifying in chiropractic in Germany in 1958 and in osteopathy at the London School of Osteopathy with Dr. Stoddard in 1962, Kaltenborn –from 1968 on associated with physical therapist Olav Evjenth (Figure 10)– developed an eclectic manual therapy system known as the Kaltenborn-Evjenth approach.\textsuperscript{15}

With Kaltenborn the first to apply the new science of arthrokinematics to manual therapy,\textsuperscript{8} central to the Kaltenborn-Evjenth approach is the emphasis on restoration of the gliding component of a normal joint roll-gliding movement. Also central is the concept of a treatment plane defined as the plane across the concave joint surface. With manual translatoric techniques

\textbf{Orthopaedic Manual Physical Therapy}

\textbf{Figure-8}

\textbf{Figure-9}

\textbf{Figure-10}

(From left- Evjenth, Kalternborn)
defined in this system as encompassing traction, compression, and gliding techniques, traction and compression are performed perpendicular to this treatment plane, whereas gliding techniques induce movement parallel to this plane. Mobilization and manipulation techniques are used to reduce pain and increase range of motion. Joint restrictions are classified as peri-articular, articular, intra-articular, or combined in etiology. Peri-articular restrictions due to adaptive shortening of neuromuscular and inert structures (including skin, retinacula, and scar tissue) and articular structures (capsule and ligaments) are treated with sustained mobilization techniques, whereas peri-articular restriction due to arthrogenic muscle hypertonicity is managed with neurophysiological inhibitory techniques including thrust techniques. Intra-articular restrictions are treated with (traction) manipulation initiated from the actual resting position.

In Australia, physiotherapist Geoff Maitland (1924-2010) (Figure 11), after studying abroad with Cyriax and Stoddard and physiotherapists Gregory Grieve and Jennifer Hickling developed his own approach and started teaching this OMPT system at the University of Adelaide in the entry-level physical therapy program. The world’s first 3-month postgraduate certificate was offered in 1965. In 1974, 12-month postgraduate diploma courses in manipulative therapy were offered at physiotherapy programs in Australia. This approach to manual therapy is now referred to as the Maitland or Australian approach.

Although often associated with variations of the non-thrust postero-anterior pressure technique, the Maitland system uses a whole spectrum of thrust and non-thrust techniques. Perhaps its greatest contribution is its emphasis on structured clinical reasoning. History taking is used to gather information that is used in the subsequent physical examination to establish the patient’s concordant or comparable signs. A concordant sign consists of pain or other symptoms reproduced upon physical examinations that are indicated by the patient as his or her chief complaint or reason to seek out therapy.

A thorough history-taking allows the clinician to distinguish between concordant and discordant signs. Discordant signs are findings on physical examination seemingly implicating a source of symptoms that are, however, in no way related to the chief complaint. Unique to the Maitland approach are also the frequent immediate post-intervention re-evaluations of the deemed most relevant concordant or so-called asterisk signs to guide further management.

In 1960, New Zealand physiotherapist Stanley Paris (Figure 12) received a scholarship from the New Zealand Workers Compensation Board to study with Freddy Kaltenborn and Allan Stoddard. Upon his return to New Zealand he organized courses and introduced –among others– physiotherapists Robin McKenzie and Brian Mulligan to manual therapy before leaving to teach and practice in the US. Once there, Paris became the voice of manual therapy as a specialization within orthopaedic physiotherapy both within the US and worldwide. Denied access as a non-physician to the North American Academy of Manipulative Medicine by Dr. Janet Travell, he founded the North American Academy of Manipulative Therapy in 1968, which was disbanded in 1974 to become the Manual Therapy Special Interest Group in Canada and the North American Academy of Orthopaedic Physical Therapy.
Orthopaedic Section of the APTA in the US. Together with among others physiotherapists Grieve, Kaltenborn, Lamb, and Maitland, Paris also founded in Montreal in 1974 the International Federation of Orthopaedic Manipulative Therapists (recently renamed to IFOMPT), the first recognized subgroup of the World Confederation of Physical Therapy. At the urging of Kaltenborn, Paris was again involved in 1991 in organizing the American Academy of Orthopaedic Manual Therapy. He also developed an eclectic OMPT system with a unique diagnostic classification system and an emphasis not on addressing pain but on treating dysfunction defined as a state of altered mechanics, either an increase or decrease from the expected normal, or the presence of an aberrant motion. New Zealand physiotherapist Robin McKenzie (Figure 13) developed a strongly research-based approach to management of spinal and extremity conditions called the Mechanical Diagnosis and Therapy (MDT) approach that incorporates examination and treatment by way of sustained and repeated active patient-generated movements and, if required, mostly non-thrust manual therapy interventions. Classification into postural, dysfunction, or derangement syndromes is guided by patient report of pain during repeated movement examination occurring within range or at endrange and by the possible occurrence of centralization and peripheralization.

Unique to the MDT concept and indicative of the derangement syndrome—strongly associated in the spine with discogenic dysfunction—centralization is defined as “the situation in which pain arising from the spine and felt laterally from the midline or distally is reduced and transferred to a more central or near midline position when certain movements are performed”. Peripheralization describes the opposite condition whereby movements cause pain to be felt more distally or laterally from the midline.

New Zealand physiotherapist Brian Mulligan (Figure 14) suggested minor positional faults as an etiology for joint dysfunction thought to respond to a unique manual therapy intervention called mobilizations with movement (MWM). With an MWM the therapist applies a sustained accessory glide, long axis rotation, or combination while the patient actively performs a previously but now no longer painful movement.

The Mulligan approach shares with the Kaltenborn approach an emphasis on restoration of the gliding component of the normal joint roll-gliding movement. Central to both is also the concept of the treatment plane but whereas Kaltenborn emphasizes gliding techniques in the direction normally associated with the restricted physiological motion, Mulligan often starts with a sustained glide at a right angle to this physiological glide. An iterative process then tests glides in different directions or long axis rotation before settling on the most effective direction allowing for pain-free active range of motion or isometric muscle contraction, together constituting the MWM. Mulligan’s NAGs or natural apophyseal glides are mid to endrange facet joint mobilizations applied anterosuperiorly along the treatment plane. Sustained natural apophyseal glides or SNAGs combine active movement with therapist-applied mobilization. The techniques are supported by a home program of self-mobilization and corrective taping.

Based to a large extent on pioneering work by Breig, Australian physiotherapists Robert Elvey,
David Butler (Figure 15), and Michael Shacklock (Figure 16) have contributed greatly to our understanding of the possible role of impaired neural mobility in the etiology of neuromusculoskeletal dysfunction.32,33

Also used in diagnosis, interventional neural mobilization techniques attempt to restore normal neural mobility or neurodynamic function in relation to the structures surrounding the nerve by inducing stretch or tension in the effected nerves or by mobilizing the surrounding tissues.2

Butler has more recently expanded on this approach by integrating new insights with regard to pain physiology and this emerging knowledge on pain physiology has the potential to complement and at times replace the previously dominant mechanical hypotheses in determining the indications and content of manual therapy management.34

Other manual therapy systems include eclectic systems such as the Grimsby, Canadian, and Dutch manual therapy approaches. The Grimsby approach developed by Norwegian physiotherapist Ola Grimsby and the Canadian approach initially developed by Canadian and English physiotherapists David Lamb, Erl Pettman, Cliff Fowler, Jim Meadows, Ann Hoke, and Diane Lee are derived mainly from the Kaltenborn-Evjenth approach but continue to be developed into progressively more distinct systems of diagnosis and management.35-40 Most characteristic of the Grimsby approach is its emphasis on very specific exercise progressions. The Canadian approach emphasizes the use of screening examinations to guide further examination and diagnosis. The Dutch manual therapy system41 combines various manual therapy approaches developed within medicine, physiotherapy, chiropractic, and osteopathy and bases diagnosis and management on assumptions with regard to three-dimensional joint motion behavior and on extrapolations related to somato-somatic and somato-autonomic neuro-anatomical connections.

Although often erroneously associated with Pehr Hendrik Ling, Swedish massage was popularized in the late 19th century as a viable medical treatment by Dr. Johan Georg Mezger (1838-1909), a Dutch physical education teacher turned physician.16 Traditional or - when applied to athletes-sports massage incorporates effleurage or rhythmic stroking hand movements, petrissage or kneading, tapotement or manual percussive massage, friction or deep penetrating pressure delivered through the finger tips, and vibration or shaking.5 James Cyriax promoted deep friction massage transverse to the fiber direction for the treatment of ligament and tendon injuries4 and from this various instrumented-assisted versions have developed including most prominently Graston technique and ASTM (assisted soft tissue mobilization).

Physiotherapists also use soft-tissue mobilization, which includes techniques intended to affect muscles and connective tissues such as stretching, myofascial release, trigger point techniques, and deep tissue techniques.2 Active release technique (ART) is a form of deep tissue technique developed by the chiropractor P. Michael Leahy.

In ART, protocols based on symptom patterns are linked to manual treatment of specific anatomic sites. Specific techniques are then used for release of proposed soft tissue adhesions that consist of applying deep digital tension usually with the thumb or two fingers combined with both active and passive passage of the tissue through this area of deep tension. An active home stretching
Manual therapy interventions include both static and facilitated stretching. In the 1950s, physiotherapists Margaret Knott & Dorothy Voss developed proprioceptive neuromuscular facilitation (PNF) that by way of a combination of isometric contractions and mid through endrange movements in three-dimensional naturally occurring spiral and diagonal patterns used reflexogenic activation and relaxation for specific stretching, strengthening, and stabilization. Post-isometric relaxation is a European manual medicine technique similar to a PNF hold-relax-stretch technique in that the patient is asked to gently contract a muscle from a slightly lengthened position followed by a further gentle stretch upon relaxation.

In the late 1930s, Dr. Janet Travell (Figure 17), at that time a cardiologist and medical researcher, became interested in muscle pain.

In the early 1960s, physiatrist Dr. David Simons (Figure 18) and his wife, physiotherapist Lois Simons, started collaborating with Travell, which eventually resulted in the "Trigger Point Manuals", consisting of two volumes on the upper and the lower half of the body. Although initially in addition to spray-and-stretch techniques heavy ischaemic pressure was advocated as a manual technique for treatment of myofascial trigger points, the updated second edition of the first volume instead suggested the use of gentle digital pressure or manual trigger point pressure release.

Paradigm Shift

The above approaches to OMPT were all developed in a time when the traditional medical paradigm was still the predominant paradigm guiding clinical practice. Kuhn first adopted the term paradigm to refer to a set of practices that together defined a scientific discipline in a given historical period. The defining set of practices of the traditional medical paradigm was that patient management was guided mainly by a pathophysiologic rationale or extrapolation from basic science and by knowledge provided by respected authorities in the field. With its emphasis on expert opinion this traditional medical paradigm has also been called the authority-based paradigm. Associated with this paradigm, diagnostic classification models used within OMPT at that time (and still to this day) were an amalgam of patho-anatomical and mechanism-based classification models. The patho-anatomical classification assumes a direct correlation between underlying pathology and signs and symptoms, whereas the mechanism-based classification system is based on the premise that dysfunctions identified during examination are the cause of pain and decreased function. The intent of this amalgam of patho-anatomical and mechanism-based OMPT diagnosis is to identify the joint(s) and/or soft tissues implicated, the extent of damage to the tissue, the possible neuro-reflexive extension of the local impairment, and the levels of reactivity and ability for a targeted or selective response to intervention within the nervous system.

Kuhn described how scientific revolutions come about by way of paradigm shifts, whereby a change occurs in the basic assumptions within the predominant or central theory of a specific scientific discipline. Although Kuhn reserved his observations for the hard sciences, the term paradigm shift has since also been applied to other fields of study and practice including medicine and the other health sciences, specifically to describe the shift from the traditional medical paradigm to the evidence-based practice (EBP) paradigm.

The EBP paradigm can be traced back to the late 1970s, when a group of clinical epidemiologists at McMaster University in Hamilton, Ontario in Canada led by David Sackett published a series of articles in the "Canadian Medical Association Journal" for practicing physicians on critical appraisal of research information found in professional journals.
In 1990, Dr. Gordon Guyatt, an internal medicine specialist and residency director of internal medicine at McMaster University, then proposed plans for restructuring the residency program to one based less on authority-based knowledge and more on knowledge and understanding of the relevant medical research literature. His first choice for the name of this new paradigm, scientific medicine, understandably met with more than a little resentment and resistance from his colleagues and the university administrators but a second try by Guyatt at renaming this new paradigm to evidence-based medicine, proved more fortuitous and this new method of teaching medicine gained acceptance at initially McMaster University and in rapid succession at increasing numbers of medical programs worldwide. Acknowledging the broad application of this new paradigm also in areas of health care clinical practice other than solely medicine, the terms evidence-based health care or EBP have since been widely adopted.

Evidence-based practice has since also rapidly been embraced by other health care professions including physiotherapy. Within current-day OMPT the EBP paradigm is most closely associated with the treatment-based diagnostic classification system in which a cluster of signs and symptoms from the patient history and physical examination ideally derived from clinical prediction rule (CPR) or other relevant research is used to classify patients into subgroups with specific implications for management. Clinical prediction rules (CPR) are decision-making tools that contain predictor variables obtained from patient history, examination, and simple diagnostic tests; they can assist in making a diagnosis, establishing prognosis, or determining appropriate management.55

Within the OMPT community, this paradigm shift from the authority-based to the EBP paradigm has met and continues to meet with noted resistance. For many, their perception of an overreliance in this paradigm on strictly defined types of research evidence in the decision-making process seemed mirrored in the early definition of EBP as the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."56 Of course, the often unwarranted and extravagant claims made in the early days by EBP proponents, the perceived disregard for established clinical practice, and a social context that involved clinicians trying to maintain their autonomy in the face of increased managerial influence within the health care system, increasing financial constraints on clinical practice, and the need for increased risk management strategies have not helped to diminish the resistance to the paradigm shift.57,58 Other justified criticisms have been related to the fact that the emphasis of EBP was (at least initially) placed on solely medical practice, that its evidence concerned single clinical interventions rather than the more pragmatic multi-intervention approaches common in areas of health care other than medicine, and that there was an overemphasis within the paradigm on evidence produced by randomized controlled trials (and meta-analyses of such trials), a study design modeled after pharmacological research and considered less appropriate for producing evidence relevant to these other health care professions.59 An even more powerful philosophical criticism against the adoption of EBP as the predominant paradigm in OMPT but also in physiotherapy in general is that the evidence-based rational model of decision-making does not reflect the reality of the individualized and contextualized clinical practice. This holds true especially in non-medical practice such as OMPT clinical practice in which the health problems with which patients present are often multifactorial and less well defined than in medical practice.60

However, in the face of all this resistance and criticism it should be recognized that EBP is not a static concept. Although at first the paradigm undeniably placed the randomized controlled trial on an undeserved pedestal as the only truly relevant form of evidence to guide clinical practice, EBP has evolved to where it now adopts a more inclusive view of evidence that recognizes not only the value
Historical paper

of different research designs but also of clinical expertise, patient values, and preferences, and even contextual factors in the clinical decision-making process. As such it more closely mirrors the extended diagnostic process relevant to rehabilitation professionals proposed by the World Health organization in the International Classification of Functioning, Disability and Health (Figure 19). Sackett et al. also de-emphasized the perceived pre-eminence of research evidence in favor of an EBP paradigm supported equally by three pillars when they defined the paradigm as the process of integrating the best research evidence available with both clinical expertise and patients’ values.

Over time, EBP has changed its focus from a consistent use of best available research evidence to an approach that acknowledges that clinical decision-making requires a judicious mixture of many forms of knowledge other than research evidence including once again clinician experience and expertise. In effect, the paradigm has changed from being evidence-driven to one that is evidence-informed. Practicing under the evidence-informed paradigm, the clinician takes the evidence from research into account when making his or her clinical decision with regard to patient management but evidence does not dictate this

Decision. However, adopting the evidence-informed paradigm does not represent a solely semantic difference in that the term is more palatable to many clinicians. The evidence-informed paradigm has not redefined EBP to simply include clinician experience but rather acknowledges that as clinicians we recognize the importance of and are learning to combine the various types of knowledge in addition to research evidence that form the basis of real-life clinical decision-making.

Future Developments and a Role for the Journal of Physical Therapy

In discussing the history and development of manual therapy, this paper should serve to highlight to the reader not only the contribution made by physiotherapists to technique and concept development and research within manual therapy but also that manual therapy has been a continuous and inextricable part of the physiotherapy scope of practice dating back at least as far as 1813. With the increasing integration of research evidence into clinical practice and the associated paradigm shift from an authority-based to an evidence-based and now an evidence-informed paradigm, as also stressed by IFOMPT in their definition of OMPT, we find ourselves as a profession learning to integrate various diagnostic classification models relevant to OMPT and various rationales for determining indications, contra-indications, and precautions for use of diverse manual therapy interventions. Perhaps most important in this regard is the emerging knowledge with regard to pain physiology and implications on the integration of OMPT interventions within a
comprehensive and multidisciplinary approach to management of especially patients with chronic pain syndromes.

It is my hope that the Journal of Physical Therapy will serve as a medium for exchange of information between clinicians, educators and researchers. Specific to my interest area of OMPT, I would hope to see a respectful and constructive discussion that values and acknowledges the importance of clinical experience and expertise, basic and applied research evidence, but also contextual factors relevant to patient management, integrating art and science of OMPT in the form of case reports and case series, narrative and systematic literature reviews and meta-analyses, research studies, commentaries, historical papers and any other form of communication relevant and committed to optimal, patient-centered and evidence-informed clinical care for our patients.

Ethical approval
Exempted.

Acknowledgments
None.

Conflicts of interest
None declared.

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Historical paper


Key points:

Past- The techniques used in orthopaedic manual physical therapy (OMPT) were used well before the name “Physical Therapy (PT)” came into existence. History is filled with moments of milestones and of pride and glory.

Present- The recent developments are owed mainly to international collaborations especially in education and research, and its dissemination through evidence-based practice (EBP).

Future- Studies on further paradigm-shifts will improve the perception and levels of professionalism among physical therapists not only in the field of OMPT but in PT as well. Impact analysis of such paradigm shift is thus warranted.
Reporting of Ethical Issues in Indian Physiotherapy Journals

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INTRODUCTION

Reporting of ethics related issues during publication not only gives credibility to the study but also increases the confidence of the readers and public. The first guideline of the Nuremberg code makes it clear that voluntary consent of the human subject is absolutely essential for research.1 Principle B-15 of the Helsinki Declaration (2008) emphasizes that a research study should be submitted for consideration, comment, guidance and approval of an ethics committee. Principle B-30 of the Helsinki Declaration (2008) also mentions that the author is responsible for the completeness of the report. It also mentions that studies which have not been conducted in accordance with the Helsinki Declaration should not be accepted for publication.2 Editors have a large responsibility ensuring that only research conducted in the most ethical manner is published.

ABSTRACT

Background: Reporting of ethical issues in published articles not only improves the credibility of the journal and its published articles but also increases the confidence of the readers and general public.

Purpose: The current study aimed to determine the current prevalence of reporting ethical issues in Indian Physiotherapy journals.

Materials and methods: Two physiotherapy journals, the Journal of Indian Association of Physiotherapists (JIAP) and Indian Journal of Physiotherapy and Occupational Therapy (IJPOT) were searched for articles on human participants. The ethical issues expected to be reported were; ethical committee clearance, informed consent, assent in 3/6 studies (50%), picture consent in 1/5 studies (20%), parent/guardian consent in 4/8 studies (50%) and acknowledgements in 8/73 studies (10.95%).

Results: Ethical committee clearance was mentioned in 14/73 studies (19.17%); informed consent in 38/68 studies, assent in 3/6 studies (50%), picture consent in 1/5 studies (20%), parent/guardian consent in 4/8 studies (50%) and acknowledgements in 8/73 studies (10.95%).

Conclusion: The poor status of ethical reporting and lack of proper guidelines were evident in our findings. There is an immediate need for improving the situation considering the international reporting guidelines for research ethics.

Key words: Physiotherapy, Publication, Ethical issues, Reporting.

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The International Committee of Medical Journal Editors (ICMJE), in their “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication”, have mentioned that when informed consent has been taken, it has to be reported in the published article. The same can be applicable for ethics committee clearance. The guidelines also go on to mention that anyone who has assisted in the study design, data collection, analysis of data and manuscript preparation but have not qualified for authorship, should be acknowledged in the publication. The ethical guidelines for biomedical research on human participants published by the Indian Council of Medical Research (ICMR) in 2006 mentions that if photographs are used in published articles, appropriate consent should have been obtained.

The ethical guidelines for social science research in health published by the Center for Enquiry into Health and Allied Themes (CEHAT), Mumbai, India also mention that the publication should mention how ethical guidelines were followed.

In other studies considering whether these standards have been met, we found variable results. Olsen et al. reviewed 43 articles related to interventional research in human cardiopulmonary resuscitation and reported that 51% mentioned ethical committee approval and 26% addressed subjects’ consent. Miguel Ruiz-Canela et al. studied 767 clinical trials and found that the proportions of not reporting informed consent and ethics committee clearance was 19.8% and 29.2% respectively. Another study by Bauchner et al. reviewed articles related to child health research from five leading journals and reported that 340 articles out of 560 (61%) reported ethics committee approval. Veronica Yank et al. reviewed 300 articles published before 1997 and 300 articles published after 1999. They found that informed consent was not mentioned in 26% of articles published before 1997 and in 18% published after 1997. In the same study, ethics committee clearance was not mentioned in 31% before 1997 and 18% published after 1997. Meschia et al. found that out of 41 articles related to genetics studies of stroke, 29% did not report informed consent and 37% did not report ethics committee clearance. A study by S. Schroter et al. conducted in March 2003 found that only 31% of the manuscripts mentioned ethics committee approval and only 47% mentioned consent. A previous study by Henley et al. reviewed 806 articles in six physiotherapy journals published between 1996 and 2001 and found that only 48% documented ethics committee approval and informed consent. Bavdekar et al. studied 132 manuscripts in two Indian pediatric journals and found that only 29.53% reported ethics committee clearance and only 8% reported informed consent and assent. Chaturvedi et al. reviewed 157 articles from the Indian Journal of Psychiatry and reported that 64% mentioned obtaining informed consent and only 15% mentioned ethics committee permission.

The Indian Journal of Physiotherapy and Occupational Therapy started publishing physiotherapy research from 2007 onwards in its quarterly journal. The Journal of the Indian Association of Physiotherapists has been publishing physiotherapy research since 2005 and is a biannual journal. Whether the ethical issues are reported in the Indian physiotherapy journals is not clear and to date, there is no research, study or documentation available in this regard. Hence, this study aims to determine the incidence of reporting of ethical issues in Indian physiotherapy journals and discover if editorial policies mandate the submission and publication of ethics related information.

METHODOLOGY

This study protocol was submitted for ethics committee review and was exempted from review since human participants were not involved and the published articles were in the public domain.

A total of 73 articles were reviewed from both the IJPOT and IAP journal. Articles were included if they involved human participants.
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and their information in the form of case records or databases. Reviews and studies that did not involve human participants were excluded from the study. All types of study designs were included in the study.

The authors distributed the articles among themselves and reviewed them against a check list which included the mention of ethics committee clearance, informed consent or parent/guardian consent, assent, picture consent and acknowledgements. Reporting for the above ethical issues was accepted if it was mentioned anywhere in the article.

Reporting Ethics Committee Clearance
This was accepted as reported if the words “ethics committees” were mentioned.

Reporting Informed Consent
Informed consent was understood to have been reported if it was mentioned in the article.

Reporting Assent
Studies which involved participation of children were expected to report if “assent” had been taken from the children or not.

Reporting Parental/Guardian Consent
Studies which involved research on infants and others who were not in a position to give consent or assent were expected to have reported “consent from parents or guardians”.

Reporting Photograph Consent
Covering the eyes of the participant was not accepted as that does not satisfy the confidentiality of the participant. Informed consent should have been taken from the participants and it should be mentioned in the article. The manuscript should have been shown to the participant before sending for publication.

Reporting Acknowledgement
It is the opinion of all the authors of this study that it is not possible to conduct research without the assistance of other research personnel and technical staff and this contribution should be acknowledged even if these contributors do not qualify for authorship. Many study participants suffer loss of time and work hours while participating in research. We felt that it would always be worthwhile to acknowledge all the study participants.

RESULTS (figure-1)
Excluding reviews and studies that did not involve human participants, 53 articles, published during the years 2007 and 2008, were reviewed. All 53 studies involved human participants and required reporting of ethics committee clearance. However, only 11 (20.75%) of the articles mentioned that they obtained ethics committee clearance. The study involving animals required mentioning animal ethics committee clearance but it was not reported.

From the 19 studies that required informed consent, it was reported in only five (26.4%) of the studies. There were two studies where children were research participants and neither of these studies reported obtaining this assent. Four studies were conducted on infants and required parental consent but none of these mentioned that parental consent was obtained. Photographs of study participants appeared in one study and that study did not report obtaining photograph consent. Out of the 20 studies reviewed, only four (16%) mentioned acknowledgement of any kind (Table-2).

DISCUSSION
The results of this study are similar to other studies of similar nature conducted in the past. Of the 73 articles included in this study, which needed ethics committee approval, only 19.17% of the articles reported approval. Informed consent was required in 68 of these studies.
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Table-1. Comparison of reporting ethical issues between the two Indian Physiotherapy journals

<table>
<thead>
<tr>
<th>Ethical issues</th>
<th>Indian Journal of Physiotherapy and Occupational Therapy N = 53</th>
<th>Journal of Indian Association of Physiotherapists N = 20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Required</td>
<td>Mentioned</td>
</tr>
<tr>
<td>Institutional ethics committee</td>
<td>53</td>
<td>11</td>
</tr>
<tr>
<td>Informed consent</td>
<td>49</td>
<td>33</td>
</tr>
<tr>
<td>Assent</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Picture consent</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Parent/guardian consent</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Acknowledgement</td>
<td>53</td>
<td>4</td>
</tr>
</tbody>
</table>

Table-2. Reporting of ethical issues in the both Indian journals (combined).

<table>
<thead>
<tr>
<th>Ethical issues</th>
<th>Both Indian Physiotherapy Journals (Combined) N = 73</th>
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<tr>
<td></td>
<td>Required</td>
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<td>Institutional ethics committee</td>
<td>73</td>
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<tr>
<td>Informed consent</td>
<td>68</td>
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<tr>
<td>Assent</td>
<td>6</td>
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<tr>
<td>Picture consent</td>
<td>5</td>
</tr>
<tr>
<td>Parent/guardian consent</td>
<td>8</td>
</tr>
<tr>
<td>Acknowledgement</td>
<td>73</td>
</tr>
</tbody>
</table>
but was reported only in 55.88% of articles; assent was required in six studies and reported in 50% of studies; picture consent was required in five studies and reported in 20% of articles; parental or guardian consent was required in eight studies and only 50% reported it; and acknowledgements of any kind were mentioned in only 10.95% of the 73 articles. The results of this study are similar to other studies of similar nature conducted in the past.6-13

One article analysed in our study mentioned that permission was obtained from a “University Committee” and another mentioned that the “research committee” approved the study. Both these studies were assumed not to have reported ethics committee review since it is not known if the review process involved ethics related issues.

Some terminologies that were reported in the articles and that were considered as having not reported obtaining informed consent are: (a) Willing to give consent; (b) Volunteers participated in the study; (c) Volunteered to participate; (d) Subjects option to participate or not; and (e) If they could not give informed consent they were excluded from the study. The abovementioned reporting methods do not state clearly if informed consent was obtained or not and were included in the analysis as not having reported obtaining informed consent. A patient may volunteer to be a study participant for fear of being denied care, under duress or due to coercion. It is also not clear from these statements if participants were fully informed about the study and consent was obtained. Another study reported “Blanket consent” which was not acceptable by the authors as equivalent to informed consent as we felt that informed consent should have been taken from the parents or guardians. Some published studies had photographs of study participants but did not mention obtaining consent for using the photographs in the manuscript.

A large number of the articles published did not mention ethics related issues. Instructions to authors and editorial guidelines play an

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![Figure 1. Comparison of reporting ethical issues between the two Indian Physiotherapy journals- Indian Journal of Physiotherapy and Occupational Therapy (Indian Jr PT and OT) and Journal of Indian Association of Physiotherapists (Jr Indian Assc PT)](image_url)
important role in authors reporting ethics related issues. When the authors started the study in December 2008, IJPOT had an “instruction to authors section” in which there was clear mention that no study would be published without ethics committee clearance. However, the instructions have been removed from the website and an attempt was made, by emailing the Executive Editor, to obtain the latest copy of instructions to authors. The Executive Editor responded that they no longer have a set of guidelines as it obstructs creativity.

The Journal of the Indian Association of Physiotherapy has published a proposed editorial draft in the April 2006 issue which states that if informed consent is taken, it should be reported in the published article. It also mentions that when reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human research. This guideline could be assumed as the study should have been subjected to ethics review and the same should be reported.

Apart from the responsibility on the part of authors to report ethics related issues, the onus also lies with editors and the editorial policy to ensure that such issues are reported in their journals and discourage articles which have not mentioned them. The argument that the researchers might have obtained ethics committee clearances, informed consent and other ethics related issues but did not mention this because the journal did not require stating so in the body of the article that ethic committee approval is required, is weak. Some publication guidelines clearly require these statements. If there was uniformity of instructions to authors and authors’ guidelines, it would be apparent that studies have been conducted in an ethical manner. Such decisions by editors would create a ripple effect where researchers would be careful and honest in reporting and institutions, presently without ethics committees, would be motivated to create such functioning bodies. Instructions to authors should also mention that where there are institutional ethics committees, these should be identified by name and authors should mention clearly if written informed consent or assent was obtained.

CONCLUSION

It can be concluded from the current study that despite the presence of international and specific journal publication guidelines, a large number of articles did not report ethical issues related to their research. We also found that one journal did not have any editorial guidelines requiring reporting of ethical issues.

We also conclude that ethical issues related to research are not considered important issues for publication by these two Indian physiotherapy journals and do not necessitate formulation of stringent editorial guidelines. The authors of this study are disturbed by this lack of interest and feel that it would be important for research if they changed their position and mandated strict reporting of ethical issues.

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REFERENCES


Key points:

Past- The Uniform requirements for manuscripts submitted to biomedical journals were proposed by International Committee of Medical Journal Editors (ICMJE) and the standards of ethical reporting were given by Nuremberg code and Declaration of Helsinki.

Present- The standards of reporting ethical issues in two Indian physiotherapy journals were too low to warrant interpretation of ethical conduct and ethical reporting of research. Indian journals did not have mandatory instructions for authors towards ethical reporting.

Future- The International Society of Physiotherapy Journal Editors (ISPJE) and World Confederation of Physical Therapy (WCPT) should ensure thorough quality check on physiotherapy journals on a periodical basis if we realize our dearth to improve research in Physical Therapy. Training on medical writing for the authors may also provide some assistance in this aspect.

INTRODUCTION

Recent advances in health science and technology have dramatically changed the teaching and learning in the health professional course programs owing to the change in trends of health seeking behavior that the prospective professionals would face during their practice. There is increasing concern of morbidity related to lack of physical activity. Physical therapists are increasingly becoming the practitioners of first contact. The Post Graduate Physical therapy curriculum can be considered as the stem cells which have the capability of differentiation that enables post graduate Physical therapist to differentiate as academicians, reflective clinical practitioner and researchers. The validity of professional clinical practice should be based on sound scientific evidence that would contribute to professional development. There are not much research studies that scientifically validate the physiotherapy treatment modalities owing to academic inadequacies. Presently in India, the Graduate level entry in to Physical therapy education programs with broadened areas of clinical specialties provides scope for widening the horizon of knowledge base of Physical therapy.

ABSTRACT

The post graduate programs serves as the precursor for graduate level entry professionals to undertake diverse professional roles. Despite pedagogical innovation in post graduate physical therapy programs in India, there is dearth of professional expertise in academic, research and evidence based clinical practice. The objective of this article is to identify, describe and evaluate curriculum development and review curricular issues. There exist diversity in the curricula development, design, content, delivery, assessment, evaluation and review process among all the Government and Deemed universities offering postgraduate physical therapy programs in India. The review focuses on those issues in relation to the requirements of new areas in physical therapy education, which include multidisciplinary practice, broadening of specialty areas and information and communications technology keeping in mind the realistic learning outcomes. In order to streamline the curriculum processes in physical therapy, the article outlines the need for a national council for physical therapists that has significant implications for curriculum development at the national level. The article emphasizes for a dynamic & common Physical therapy curriculum across India as well as the need for a regulatory council that licenses Physical therapy practice so that physical therapy postgraduates are increasingly likely to begin professional life as practitioners of first contact, academicians as well as researchers in the field of physical therapy. In this review, the role of learning outcomes in Physical therapy pedagogy and curricula is critically appraised. The review suggests for the need of comprehensive, articulated & complimentary learning outcomes and objectives in post graduate Physical therapy pedagogic and curricula.

Key words: Curriculum development, Pedagogy, Learning objectives & Outcomes, Regulatory council.

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Professional discussion

The academic post graduate physical therapy curriculum which is primarily intended to provide skills and expertise in academic, research and evidence-based clinical practice has failed that is evident with lack of specific knowledge outcomes. The professional education is influenced by several factors that would affect the professional outcomes. In order to cope with the changing trends of the health care needs there is a need for the continuous evaluation of curricula of Post Graduate Physical therapy education programs and to update with recent advances in health care needs, knowledge base of Physical therapy and also with changes in cultural trends. The updating of curriculum should take in to consideration not only the present trends but also prospects in the future.

The objective of this article is to throw light on crucial issues prevailing in post graduate physical therapy education program in India. As Indian Association of Physiotherapists (IAP) is not a council, it is facing challenges in improving the standards of Physical therapy education and practice. The role of IAP, in the context of lack of council status, is overseen by educational institutions and do not comply with guidelines and recommendations prescribed by IAP to run post graduate physical therapy programs. To rope in more education institutions accreditation and thereby increasing the professional membership, the Indian Association of Physiotherapists has virtually compromised the process of accreditation that is affecting the quality of learning experiences of prospective professionals. The physical therapy post graduates feel that there is no much difference in KAP (Knowledge, Attitude & Practices) on completion of post graduate physical therapy program. Time has come to critically review the process of accreditation and to evolve a dynamic curriculum that contemplates with the learning objectives and outcomes. Persistent efforts of IAP has resulted in the proposal of council bill for allied health professions that was ratified by the standing committee of the Indian parliament and pending for resolution in the Lok Sabha.

**Figure 1: Conceptual framework representing the factors affecting professional education.**

The Physical therapy education in India has undergone multitude of changes. As the post graduate physical therapy curriculum determines the prospective physical therapy academicians, clinicians and researchers, there is a need to derive an ideal curriculum that affects all domains of learning experiences specific to the areas of interest. Presently there are numerous Government and Deemed universities offering physical therapy education programs. Ironically, in India we don’t have such an autonomous body to regulate educational institutions offering Physical therapy education programs.

**Current Status of Physiotherapy Post-Graduate Curriculum:**

1. **Entry level knowledge of learner:**

   The knowledge of the entry level graduate for a post graduate physical therapy program should be evaluated on standard protocols and objective measures. The evaluation should be done at the

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Institutes at regular intervals to accredits and monitor accredited therapy educational programs that empowered to regulate physical field of health education should be care professionals, experts in the of Government bodies, other health academicians, curriculum development, the views areas. Selected candidates called for counseling have less option in choosing specialty (usually candidates who appear for counseling at last). Certain institutions have reservations or quotas. In institutes where entrance examination is not held, entry to PG program is not based on merit. Clinical Experience is not taken in to account for entry to Master programs.

2. PROCESS OF CURRICULUM DEVELOPMENT:

Ideal Curriculum: National body for physical therapy education should involve with other health care professionals and Government bodies in the process of curriculum development. In the process of curriculum development, the views of physical therapy academicians, clinicians, researchers, authorities of Government bodies, other health care professionals, experts in the field of health education should be included. National body should be empowered to regulate physical therapy educational programs that accredits and monitor accredited institutes at regular intervals to check for compliance.

Issues: There is no national statutory body governing the process of curriculum development for Physiotherapy educational programs and do not involve the stakeholders. There is lack of coordinated curriculum committee in the IAP. There is no documented philosophical statement and curriculum design. There is much variability of course duration, curriculum design, content and sequence. The educational institutions offering post graduate physical therapy programs does not provides the detailed curriculum in their websites. The institutes and colleges accredited by Indian Association of Physiotherapists do not have the common PG curriculum.

3. FACILITIES & INFRASTRUCTURE: Ideal curriculum: The institution that offers post graduate educational programs should fulfill the unique needs of such a program by providing appropriate facilities and infrastructure that enhances the learning experiences of prospective candidates. The nature of such fulfillment shall include recruiting and retaining core faculties duly qualified to administer the academic program. The institutions should involve in faculty development program that enables the faculties to update the knowledge and clinical skills. The institutions that offer PG Physical therapy education should have facilities for research activities. The Core faculty should be encouraged to involve in research activities and should be provided funds for conducting such research activities.

Issues: Many Colleges offering post graduate physical therapy programs do not have a teaching hospital. Even if there is a teaching hospital, it is located in a remote place distant from the educational institution. Basic amenities of teaching and learning are not provided (Audio Visual aids, Libraries without Scanner, Photocopier, journals, books etc).

4. PHYSICAL THERAPY PEDAGOGY: Ideal curriculum: The core faculty should provide the learner with enhanced learning experiences using different teaching methodologies. The core faculty should keep pace with the advancing educational technology that has revolutionized the process of thinking and learning of the learner. The core faculty should establish academic, clinical and professional ethical standards throughout the educational program. The core faculty should play a role model in continuing professional development and also to encourage prospective candidates in updating the recent advances in specialty areas. Should engage the candidates in different context to play specific roles that are inherent objectives of the curriculum like micro teaching sessions, group discussions that moulds as a clinician and to collect, document, analyze and to make inferences from the data of the research subjects that moulds as a researcher. The regulating body should conduct a national level examination for the post graduate Physical therapist who wishes to pursue his career as academician.

Indian Post-graduate PT Curriculum
This will help set standard in teaching methodologies and better learning outcomes in educational programs. Imparting of knowledge shall include identification, selection and utilization of appropriate teaching modality to maximize the understanding of concepts in specific areas.

**Issues:**
An inconsistency exists in teaching methodology either due to lack of infrastructure or due to lack of skills. No involvement of core faculty in research and professional activities either because of lack of funds or due to lack of demand from the regulating body to involve in such activities. The academic skills of the post graduate Physical therapist are doubtful that attributes to inadequate learning experiences. Most of the core faculty has got dependency on audio visual aids and are not using other forms of teaching modalities.

5. **EVALUATION:**

**Ideal curriculum:**
The universities conducting examination should have a uniform pattern of evaluation. The number of subjects included in a question paper and number of question papers included in each year should be the same. The blue print of the question paper should give equal importance to all subjects that are present in that question paper especially in the basic sciences paper where there are four or more subjects included in the first year of post graduate study. Changes in the evaluation pattern especially the number of subjects included in a question paper and number of question papers included in each year should be based on the continuous evaluation of the process of curriculum development.

**Issues:**
Examination question pattern is different in different universities.

Number of question papers included in each year differs from universities to universities. The blue print of the question paper does not include questions from few subjects that are part of curriculum content especially in the Basic Sciences paper. This makes the candidates learn implicitly that those subjects are not important. Numerous regulations in number of subjects included in a question paper are in existence and essentially it is not the outcome of continuing evaluation process of the curriculum. Ironically the changes are attributed to administrative reasons. The internal mark awarded is subjective and usually decided by one evaluator and is not disclosed before the university examinations. There is a difference in eligibility to appear for Theory & Practical exams if a candidate fails in either of the two besides difference in evaluation of dissertation.

6. **CURRICULUM DESIGN:**

6.1. **Course Content:**

**Ideal curriculum:**
The course content should cover all domains specific to the area of interest. The core domain, supportive domain, interdisciplinary domain and elective content should be framed. The sequence of the course content presented should be generic in the first year of study and in the second year it should be very specific to the area of interest. Importance should be given to pedagogic innovations in physical therapy education so that best academicians are produced as one of the learning outcomes of the post graduate program.

**Issues:**
Imbalance exists in the domains of course content included. Importance is seldom given to Educational technology and pedagogic innovations in Physical therapy education. At the end of the program the candidates submits the thesis of his research work which is always pertaining to the elective area which he has chosen. The core faculty never accepts the thesis work on pedagogic innovations in Physical therapy education.

6.2. **Course Duration:**

**Ideal curriculum:**
The duration allocated for the course content and program as a whole should be optimal. The duration should specify number of hours that should be spent for different domains of course content. The duration thus allocated should specify number of hours spent for theory, practical and demonstrations. The specialty training in the third year should lead to a transitional degree for higher studies.

**Issues:**
The duration of the post graduate Physical therapy program varies from university to university and it changes owing to administrative reasons. While few universities offer post graduate program for three years, other universities offer such post graduate program for two years only. Additional learning and training in area of elective requires the 3rd year of training leading to a specialty in that area equivalent to M. Phil or Doctorate in physiotherapy as suggested by IAP is contradictory.

7. **EVALUATION OF ACCREDITATION:**

**Ideal Curriculum:**
The regulating body should evaluate the performance of the candidates who have successfully completed the PG Physical therapy education program. Based on the evaluation and input from various
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societies such as core faculties of different institution, university authorities, Education department of the Government of India the regulating body should bring about changes in the curriculum keeping in mind the projected health care needs in the future. The regulating body should monitor the facilities and infrastructure provided by the education institutions offering such education programs formally and informally. The post graduate Physical therapists who pursue their career as academicians should get enrolled with the education committee of Indian Association of Physiotherapists or the regulating body of Physical therapy education.

Issues:
The changes in the post graduate Physical therapy curriculum are mostly attributed to administrative reasons rather than actual learning outcomes. The cyclic process of curriculum development is seldom followed. The present curriculum doesn't address the future health care needs. Presently the monitoring and evaluation of accreditation of educational institutions offering PG Physical therapy education programs are done formally and notice for the same is issued well in advance to such institutions. This makes the institution prepared for such an evaluation by hiring facilities, infrastructure and core faculties. As the academic Physical therapists are not enrolled with the regulating body, there are more chances of playing the role of core faculty in more than one institution. The institutions impeding accreditation with IAP hires core faculty who are full time worker in other educational institutions.

8. LEARNING EXPERIENCES:

Ideal curriculum:

Learning experiences in the due course of the post graduate Physical therapy education program should mould the prospective candidates as academicians, reflective clinical practitioner and researcher upholding professional ethical standards. The curriculum should not only specify the course content but also specify the appropriate teaching methodology that has to be chosen for teaching that course content so that learning becomes comprehensive. The learning environs should provide and enhance learning experiences in form of facilities, infrastructure and core faculties who will facilitate such process of learning experiences to occur. The core faculty should enhance learning experiences using multitude of teaching methodologies according to their effectiveness in communicating ideas. It enables the prospective candidates acquire intuitive knowledge in specific areas of interest. The ideal curriculum should enhance learning experiences in such a way that actual learning outcomes are closely associated with expected learning outcomes. Learning experiences should be both formal and informal.

Issues:
The curriculum does not specify the teaching methodology specific to the course content. The curriculum does not define the requisite academic skills of the core faculty. There is no evaluation by the regulating body on the academic physical therapist to establish or to determine such requisite academic skills. The learning environs are more often so formal and there is no encouragement of problem based learning. This hinders the prospective candidates to acquire the intuitive knowledge on specific areas of interest. More often the core faculty has difficulty in choosing appropriate teaching modality specific to the course content.

PROSPECTIVE CURRICULUM:

Professional education is the process of preparation for exacting, responsible service in the professional spirit that requires well-informed and disciplined insight and skill of a high order. The Responsibilities of Professional Education is to develop over-all principles and philosophy by which professional men should live and work. Fundamentals of Professional Education is that the foundation of professional education should be not only technical skill, but also a sense of social responsibility, an appreciation of social and human values and relationships, and disciplined power to see realities without prejudice or blind commitment. An increased sense of social responsibility requires a changing of professional education in method and spirit. In the present day, the Physical therapists are increasingly becoming as practitioners of first contact. The Physical therapists are increasingly recruited as consultants in fitness centers and in industrial setups for ergonomic advices apart from the demand in the hospital settings. The Physical therapists are included in the multidisciplinary team in national level health programs and disaster management. For physical therapy to continue to provide high-quality and effective health care services, physical therapists must initiate and participate in the research needed to substantiate current and future practices in the field.

Defining professionalism in Physical therapy:

Over the years the perceptions of being physical therapy professional has changed and the prospective curriculum should incorporate dimensions of specific knowledge and skills that attribute to changing perceptions.

- Worthingham, 1965 Ethics, communication, self-control
- Daniels, 1974 Problem solving
Carlin, 1977 Relevant knowledge, ongoing evaluation
Moore, 1978 Clinical-educational integration
Blood, 1979 Consumer advocacy
Purtlilo, 2000 Institutional advocacy
Pinkston, 1986 Need to understand fundamentals.
Bartlett, 1991 Unique knowledge and skills.
Rothstein, 2001 Unique and essential identity.

Even though the knowledge base of Physical therapy profession has broadened, the role of Physical therapist in providing health care services is not well appreciated in India and the Physical therapist is regarded posing skills of technical knowledge, no matter the Physical therapist is a graduate or post graduate.

This is very evident from the fact that the eligibility criteria for the recruitment of Physical therapists in Government Hospitals in India are still at Diploma level and having a bachelor degree is desirable. The post graduate Clinical Physical therapist doesn’t have any scope in Government hospitals. The Private hospitals and the corporate sectors have recognized the need and knowledge of Physical therapists in the area of rehabilitation and are increasingly recruiting the Physical therapists.

Why is this scenario prevalent?
The reason for this adversity may be attributed to the lack of apex body regulating Physical therapy education and practice. Lack of documentation of clinical and research works has imposed the perception that Physical therapists have technical knowledge. To strengthen the Physical therapy profession, there is an acute necessity to revitalize the curriculum of post graduate Physical therapy education. As stated in the prologue, the post graduate Physical therapy curriculum are the stem cells that enables prospective post graduates to differentiate as academicians, clinicians and researchers.

Curricular Plasticity:
The knowledge base of Physical therapy stems from the process of education. To strengthen the knowledge base the curriculum that determines the prospective Physical therapists should be comprehensive and should be dynamic. In other words, the curriculum should be plastic. The process of curriculum development should be a cyclic process and should adapt to the changing health needs of the society. The process of curriculum development should set stage for developing professional ethical standards in academic, clinical and research areas.

Apex body to regulate curriculum of post graduate Physical therapy education:
The fact that Indian Association of Physiotherapists is not a council is overseen by the educational institutions offering post graduate Physical therapy programs. Presently the IAP provides recommendations and guidelines for accreditation of educational institutions offering post graduate Physical therapy programs and it cannot make it mandatory. The Government Universities and cropping of Deemed Universities offering such programs without basic facilities and infrastructure add to the adversity of the system of Physical therapy education. The outcome of such an education program is quantitative Physical therapist rather than qualitative Physical therapist. To weed this adversity, there should be an apex body regulating the Physical therapy education. The Indian Association of Physiotherapists should have a curriculum committee and in association with Government agencies and experts in health education should form the Central Board of Physical therapy Education (CBPTE) that should monitor the process of curriculum development and also accredit the educational institutions offering post graduate Physical therapy education programs.

CONCLUSION:
The present post graduate physical therapy curricula in India is diversified and is disarticulated with learning objectives and outcomes. There is an acute necessity to improve the skills and expertise of prospective post graduate students as academicians, reflective clinicians and researchers.

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My sincere thanks to Prof. P.G. Shivananda, Former Dean & Chairman, Department of Medical Education and to Prof. S.K. Saxena, Prof. In charge of Department of Medical Education, Sikkim Manipal Institute of Medical Sciences who have inspired me to get involved in activities of professional education and have always encouraged professional and faculty development programs.

CONFLICTS OF INTEREST
None declared.

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WFN-JPT-2010-ERN-104.
Professional discussion

REFERENCES:


Chief Editor's note:

The article throws light on the most important aspect of issues in evaluation, planning and development of post-graduate physical therapy curriculum. Though the issues reported were for India, the professional community would for sure agree that similar scenario if not in total but in parts do exist in countries around the world.

Key points:

**Past:** The post graduate physical therapy program serves as the precursor for graduate level entry professionals to undertake diverse professional roles. In India, the program had seen expansion with diverse specialty and elective subjects.

**Present:** In India, owing to the lack of regulatory body, there exists diversity in post graduate physical therapy curriculum that adversely affects learning outcomes.

**Future:** The Government of India has contemplated National Council for Higher Education and Research (NCHER) and National Council for Human Resource in Health (NCHRH) for accreditation and professional licensing respectively. It is expected that the councils once empowered, would evolve a dynamic and articulated post graduate physical therapy curriculum.
Critically Appraised Paper: Zusman M. There’s something about passive movements,...Medical Hypotheses; 2010 (In press)

Israel Zvulun MApSc,

Appraised paper:
Zusman M- There’s something about passive movements,...Medical Hypotheses

Title ABSTRACT (of the appraised paper) + EXTRACT

Perhaps a more suitable title would be: "From the cell to the body: possible biological mechanisms for passive (therapeutic? see below) movements." (?). There is surely something in passive movements as we all know as clinicians and as previous research has shown. The current title may imply that before we discovered cellular mechanics, there was nothing in (or about) passive movements...

Introduction

"It would be a sad state of affairs for the physical therapy profession if, a decade into the 21st Century, it still needed to fall back on the evasion that ‘absence of evidence is not necessarily evidence of absence’ in order to justify the use of its passive movement procedures as Hurley and Bearne suggest."

I believe that because there seems to be a lack of clarity amongst

The recognised (funded) stand-alone clinical status for therapeutic methods of passive movement has become increasingly threatened in recent times as the preference for active treatment (specific exercise) gains hold. This is in part due to the equivocal results for clinical trials of passive movement, queries regarding its cost-benefit and negative findings for many of the fundamental claims and recommendations of its clinical process. Linked to these issues has been the profession’s difficulty in demonstrating plausible science-based mechanisms for anything more than transient effects. The present proposal is that the manual application of graduated oscillatory tensile loading to healing (or unhealed) soft tissues in the form of passive movement could facilitate optimal repair and tissue integrity (and so protection against subsequent ‘stress’). The mechanism depends on the intrinsic ability for non-excitable connective tissue cells to ‘sense’ mechanical stimuli and to transduce mechanical into chemical signals. This leads to gene transcription and subsequent adaptive remodelling of the extracellular matrix (ECM). An outline of these events is given, emphasising their dependence on the effective interplay between internally (cellular) and externally (matrix) generated mechanical forces. In principle, it ought to be possible to investigate the proposal and other clinical passive movement issues using modern soft tissue imaging and biological techniques with suitable human subjects and animal models.

The author provides a constructive critique of the published paper by Zusman, adding valuable opinions from his experiences and published works.

Key words: passive movements, critical appraisal, journal club, critical reading.

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Key points and pre-publication history of this article is available at the end of the paper.

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Cr it icall y a p p r o a c he d p a p e r

Physiotherapists all over the world regarding what is defined or considered as 'passive movement' or 'mobilization' that it should be defined from the start. Are we talking of the traditional 'accessory' movements of the peripheral joints or the spine? Physiological movements? Are we dealing with soft tissue mobilization techniques? Any form of massage which is considered by some as 'movement' or 'mobilization'? Or neurodynamics? And so on. Needs to be defined clearly.

There are also other relevant questions to the contents of this article: Are passive movements really passive? Perhaps, but only when a patient is anaesthetized. If they are not (and there is always some EMG activity of the muscles even at rest), then the paper should refer to 'therapeutic movements' performed by the therapist (while taking into account that the patient is somewhat 'active') or movement performed solely by the patients without any assistance by the therapist and so on.

The words "progressive tensile loading or gradual stretch" are used in many occasions in the text. It should be noted that 'passive' movements can also be performed in 'mid-range' where no resistance is present and therefore no stretching occurs. Again, a definition of what is meant by passive movements would help to clarify things.

Donald Ingber mentioned in one of his papers\(^1\) that the concept of cellular mechanics and mechanotransduction refers to any kind of movement including physical activity. Therefore, my opinion is that the paper deals with any kind of movement not just passive movements. Perhaps (and probably likely), the response of the cell, nervous system or the entire organism might be (very) different in passive vs. active movements as it has been shown in imaging studies of the brain.\(^2\)

"Nowadays justification for the use of passive procedures appears to be where this is intended to pave the way for currently favoured ('evidence-based') active therapeutic strategies."

I would add to the (blind) emphasis on evidence-based procedures (and also pressure from the part of stakeholders and funders of health care), the neglect of clinical reasoning in favor of, for example, 'clinical prediction rules' (as the author stated). I believe this is an important issue in the light of "the notable return to earlier dogma". This "currently favoured evidence-based active strategies" would not have happened if a clinician would use sound clinical reasoning with knowledge from basic sciences (of course, with knowledge from many domains). Passive movement would have been included in treatment because the clinical situation requires it (for example, a stiff joint following a healing fracture or as a result of osteoarthritis).

"In the case of 'mobilisation', its founders simply adapted a well known and naturally utilised physiological phenomenon, progressive tensile loading or graduated stretch."

Again, not completely true. There some types of mobilization that do not include stretching, for example grade I in the Maitland concept. A broad and general definition would help.

"The present discussion focuses on one such mechanism: the intrinsic sensitivity and response of 'apparently' non-excitable (connective tissue) cells to mechanical stimuli such as stretch, pressure and shear/glide.

Science vs. empiricism

Ref 37 is Maitland's vertebral manipulation. Just to make justice with Maitland. "In many cases any mention of possible mechanisms, therapeutic and to a large extent pathological, was strictly avoided" is not accurate. Maitland's permeable brick wall suggests using medical and scientific knowledge in order to explain clinical phenomena where it is possible. A good example is the "slump test" and the article by Maitland on "positive canal signs" where he tried to find a ('evidence-based') patho-mechanical rationale behind the Slump test.\(^4\)
Physiological mechanism

The reader who does not remember cell biology/architecture and mechanics will simply leave out the article. I think that (unfortunately) not many professionals remember what ECM, microfilaments is and so on. There are a lot of terms that are probably new to many readers. Therefore, I believe that a very brief description or better a schematic drawing of the cell and the components that are relevant to the discussion would be of assistance to the reader. And perhaps drawings that explain the concepts presented in the article would also help.

Conclusions

"In the context of successful cost-effective physical rehabilitation, passive movement could never replace active movement."

This sentence is somehow problematic. There is a significant (perhaps not convincingly based on evidence yet but based on clinical experience and inference from pathobiology) role for both passive and active movements in rehabilitation. For example, for a quadriplegic patient the only way to gain and later preserve the ROM is by using passive movements. A patient with ankylosing spondylitis: preserving the existing ROM – passive movements and active movements and so on.

Where this is not feasible e.g. the spine, specific active movements may be substituted. Either could be expected to deliver regular therapeutic mechanical stimulation/tensile loading to repairing and strengthening connective tissue”.

Self-mobilization of the spine using passive movements may be applied by the patient using devices such as ‘bakballs’ (www.bakballs.com).

References


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CONFLICTS OF INTEREST

None declared.
Osteopathy and Physical Therapy- a Gap Bridging Between Two Professions.

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ABSTRACT

Numerous treatment approaches exist within manual and manipulative therapy for the management of a variety of musculoskeletal and non-musculoskeletal conditions. Most of the techniques such as manipulation, muscle energy techniques, positional release techniques, myofascial release techniques and craniosacral therapy, which are also commonly used in manual therapy. Traditionally osteopathy developed both the “art” and the “science” of these techniques but most of the research supporting their use in clinical practice is now published by physical therapists. Orthopaedic Manual Physical Therapy encompasses the so-called bridge for the plausible gap between the two professions. While osteopaths work under the somatic dysfunction model and physical therapists under the pain and movement model, the recent International Association for the Study of Pain (IASP) global year against musculoskeletal pain emphasized the “biopsychosocial model.” The biopsychosocial model demands both the professions to work hand-in-hand and to understand mutual responsibilities and roles. Such an inter-professional teamwork would henceforth facilitate better patient recovery and care.

Key words: manual therapy, biopsychosocial model, inter-professional teamwork, somatic dysfunction.

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As an osteopath, trained and experienced in the management of patients with neuromusculoskeletal pain disorders for 13 years, I would like to take this opportunity to share my views and thoughts on the plausible yet perceptible relation between the two professions- Osteopathy and Physical Therapy.

Numerous treatment approaches exist within manual and manipulative therapy for the management of a variety of musculoskeletal and non-musculoskeletal conditions. Osteopathic medicine is an approach to healthcare that emphasizes the role of the musculoskeletal system in health and disease; its philosophy is based on four key principles: (1) the body is a unit, (2) the body possesses self-regulatory mechanisms, (3) structure and function are reciprocally interrelated and (4) rational therapy is based on the previous tenets.

A key identifiable feature of osteopathic medicine is the concept of somatic dysfunction defined as a functional disturbance of the tissues of the musculoskeletal system and related vascular and neurological components, which can be treated by manipulation. Clinical symptoms associated with somatic dysfunction are commonly represented by the acronym “TART” (Tenderness, Asymmetry, Restriction and Tissue texture change). According to its commonly used neurophysiological model and depending on the patient’s condition, the somatic dysfunction may be causative, reflexive, reactive, or perpetuating, or a combination. The evaluation of the patient’s capability for a homeostatic response and the interpretation of theoretical underlying physiopathological processes with the palpation of components of the somatic dysfunction guide the osteopath for treatment strategies. A wide range of manual techniques described in the Official Osteopathic Thesaurus are used for the treatment of somatic dysfunctions by the two categories of osteopathic practitioners, the osteopaths...
who provide only osteopathic manipulative treatments (OMT) and the osteopathic physicians who are fully licensed to practice medicine and provide OMT, as they are defined by the World Health Organization's (WHO) draft report Guidelines on Basic Training and Safety in Osteopathy. These practitioners have a first contact status in every country where osteopathy has been recognized and regulated by Law.

The challenge for both patients and manual practitioners is to determine the therapeutic approach that would be most appropriate and effective for a specific condition. Differences of concepts or techniques claimed by practitioners are not so evident for “naïve” patients seeking relief for their symptoms; the only thing they are sure about is that they will be treated with manual therapy. If a therapy is preferable in terms of efficacy, cost-effectiveness or less side-effects for specific clinical conditions, research should be pursued in this direction in order to provide more evidence for appropriate referral.

There is a current trend in osteopathic research toward evaluation of the relevance of somatic dysfunctions in the incidence and the maintenance of symptoms, not only in the evaluation of OMT. The techniques in osteopathy include but are not limited to manipulation, muscle energy techniques, positional release techniques, myofascial release techniques and craniosacral therapy, which are also commonly used in Orthopaedic Manual Physical Therapy (OMPT) techniques. Physical therapies are indeed perceived as effective for neuro-musculoskeletal conditions (pain and movement) but treating the musculoskeletal system may also significantly influence the individual’s ability to restore one’s inherent capacity for the maintaining general health and also towards recovery from disease and thereby to resist further disease processes.

The use of the said techniques into OMPT and Physical Therapy has indeed added some value of “science” to the “art” of their origin- Osteopathy. There is a growing body of evidence to support the shift from technique-based approaches for musculoskeletal conditions to patient-centered approaches, especially with the use of the biopsychosocial model.

Comprehensive multidisciplinary care is indicated in current healthcare delivery systems and payer’s policies in order that we, as part of global healthcare professional team work together in addressing not only the biological processes but also the psychological and social outcomes as well. Further research in this direction would benefit all manual practitioners irrespective of their professions.

REFERENCES
Point of view

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CONFLICTS OF INTEREST

None declared.

Key points:

Past- Osteopathy and Physical Therapy had huge overlap in their knowledge base and were thus considered as conflicting professions- the gap.

Present- the somatic dysfunction model of osteopathy and pain-movement model of physical therapy is integrated in biopsychosocial model of pain.

Future- Interprofessional teamwork of combining and comparing the two professions should be studied for its effectiveness in a multidisciplinary patient care model.

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