The following articles appeared in the print edition of O&P NEWS.

Table of Contents

COMMENTARY
Research Trials in O&P: Turn Enthusiasm into Engagement
Michael Wininger, PhD

5 QUESTIONS WITH O&P NEWS
A Conversation With Robin Burton

BUSINESS NEWS
Health care leaders recommend restructuring US health care system

CLINICAL NEWS
Increasing employment of physicians in hospitals not associated with improved quality of care

COVER STORY
Lean Manufacturing: A Sustainable Approach for O&P Practices

HEALTH CARE UPDATES
Mindfulness, stress management reduce physician burnout

Researchers convert body heat into electricity for wearable electronics

Standing desks in schools linked to decrease in BMI percentile

BMI linked to high costs of workers' compensation claims

Primary care interventions aimed at obesity not effective, new strategies needed

IN THE FIELD
UTSW students host OPAF First Dance, First Swim Clinics
Paceline Inc. announces expansion and relocation of its office

Clinical Education Concepts recognized with all star award

New analyses support blocking Anthem-Cigna and Aetna-Humana mergers

MARKETING WITH MANSFIELD
Saying Thank You
Elizabeth Mansfield

MEETING HIGHLIGHTS
White House Event Celebrating Inclusive Design, Assistive Technology and Prosthetics

O&P Practices ‘Think Pink’ for Breast Cancer Awareness Month

PIONEERS
Museum Tells Story of Early Prostheses
Berry Craig

RESEARCH TRIALS IN O&P
Home Study of an Advanced Upper Limb Prosthesis
Research Trials in O&P: Turn Enthusiasm into Engagement

Michael Wininger, PhD, discusses the importance of engagement in clinical trials, a new era of O&P research.

O&P News, November 2016

Michael Wininger, PhD

Clinical trials are considered the pinnacle of evidence in medicine.

O&P clinicians and researchers have recognized the importance of these trials in advancing the profession.

With an ever-increasing interest in evidence-based practice and the ever-advancing threat of estrangement between payer and practitioner, enthusiasm is growing into engagement.

Getting out the word

I was delighted to see the debut of “Research Trials in O&P” in the Fall issue of O&P News. It is about time we leverage popular publications to showcase opportunities for patients to participate in clinical trials.

This level of dissemination will prove to be a watershed for several reasons, including improved recruitment and feasibility of the featured studies; greater awareness of ongoing studies in anticipation of publication of future results; and visibility of the investigators, their research agendas and their sponsors. Moreover, advertising studies in a national or international platform improves study generalizability.

By starting the conversation on our research trials, we are stepping into the arena of scrutable empiricism that is the bedrock of both evidence-based practice and advancement of the field. For example, the precipitous decline in mortality rates in some of our more extensively researched disease conditions is a direct consequence of thousands of clinical trials introduced during the span of decades.

Keyword searches on clinicaltrials.gov yield more than 56,000, 29,000 and 14,000 results for “cancer,” “AIDS” and “diabetes,” respectively. By comparison, there are less than 1,200 results for “prosthesis or prosthetics” and less than 250 results for “orthosis or orthotics.” It seems the preponderance of prosthetics trials are in prosthetic dentistry.
We have every reason to believe that when a groundswell of investigators participate in the thoughtful design, operation and publication of results of clinical trials, O&P will gain a further hold with the medical community at large.

**Turn ideas into trials**

I would like to identify a hidden opportunity within the *O&P News* “Research Trials in O&P” section: This forum could provide a venue where O&P clinical trials can be conceived and shaped. The earliest and most critical stage of clinical trial design is the specification of the research questions and the selection of study parameters. What is the true target population? What is the target effect size? Which historical studies should be referred to in drawing assumptions for the future study? This is an inherently conversational process and requires input from all stakeholders. Top medical journals place a premium on impact and relevance. Studies that are scientifically sound still risk obscurity without substantiation. The *O&P News* “Research Trials in O&P” column could serve as the crucial nexus for critical mass and consensus.

**Looking ahead**

The clinical trials landscape in O&P is beginning to take shape, and there are venues for trials at every scale — from exploratory phase 1 trials operated adjunctly, to the graduate-level practitioner training programs, to phase 3 and phase 4 trials supported through structured clinical research programs, such as the U.S. Department of Veterans Affairs Office of Research and Development. Let’s recognize the potential of the “Research Trials in O&P” column not only as a menu of current clinical trials in O&P, but as a “test kitchen” where new recipes can be developed.

To read more about ongoing research trials in O&P, turn to page 24. The complete listing can be found at OandPNews.com/Research.

**For more information:**

Michael Wininger, PhD, is a statistician of clinical trials with the Department of Veterans Affairs Cooperative Studies Program, assistant professor in the University of Hartford’s Prosthetics and Orthotics Program, and assistant clinical professor in the Department of Biostatistics, Yale School of Public Health. He is a member of the O&P News 175. Wininger is the author of a “Formulating Clinical Trials in P&O and Allied Health Fields,” which will appear in the January 2017 issue of the *Journal of Prosthetics & Orthotics*.

Disclosure: Wininger reports no relevant financial disclosures.

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**More in Orthotics Prosthetics**

AGING MATTERS | CORRESPONDENCE | FEATURE ARTICLE
<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caring for Depression in Older Home Health Patients</td>
<td>Findings indicate need for reform in EU medical device regulation</td>
</tr>
<tr>
<td>Laboratory-Measured MTF of IOLs and Clinical Performance</td>
<td>Stem cell therapy may hold potential for patients with severe burns</td>
</tr>
<tr>
<td>Current Concepts, Classification, and Results in Short Stem Hip Arthroplasty</td>
<td>Simple recreational activities may be as effective as virtual reality games for stroke rehab</td>
</tr>
</tbody>
</table>

**HEALTH CARE UPDATES**

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**VIDEO**

- **VIDEO: Unity among O&P professionals** can bring success
- **VIDEO: Allied health professionals** come together to discuss pediatric O&P
- **VIDEO: Positive relationships needed between O&P, allied health professions**