

Joint
Orthopaedic
Initiative for
National Trials
of the Shoulder

OFF THE CUFF

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ABOUT THE GROUP...

JOINTS Canada is an organization of Canadian Orthopaedic surgeons dedicated to raising the standards of education assessment and care through multi-centre clinical trials, to improve the quality of life for patients with shoulder disorders.

NEXT JOINTS Canada MEETING

C.O.A. Meeting
June 18-21, 2004
The Telus Convention Centre
Calgary, Alberta

Meeting Time TBA
Watch your email for details!

WINNIPEG 2003: WARM WEATHER & WONDERFUL DISCUSSION

The JOINTS Canada group got lucky the weekend of its meeting in Winnipeg in conjunction with the rescheduled COA 2003. We enjoyed 20°C weather and a fantastic turnout despite many conflicting schedules. The meeting was held at the Winnipeg Convention Centre and ran from 10:00am to 1:00pm, following the Oratec Heat Probe Meeting.

12 Surgeons and 11 Research Coordinators were in attendance and we were able to cover many topics including ongoing trials, new studies which have recently begun recruitment or are in protocol development, potential study ideas and JOINTS group business.

Discussions regarding the issues of group authorship, grant competitions & applications within the group and the need for further infrastructure, in terms of official policies and procedures for the group, saw many interesting and salient points to be put forward.

Dr. Holtby and the membership committee have sent out the second round of invitation letters to potential members and there have been quite a few inquiries by new shoulder surgeons interested in joining the group. Katie & Trena are working on developing a membership package to follow-up. It was also decided that a general call for new members will be circulated through the COA distribution list in order to further extend the invitation to all potentially interested colleagues.

Despite the loaded agenda and press for time, it was great to have the opportunity to gather once again for the promotion of the group. Minutes for the Winnipeg meeting will be included via email with this newsletter. Thank you to all who were able to attend and we look forward to seeing



Photo Gallery

JOINT ORTHOPAEDIC INITIATIVE FOR NATIONAL TRIALS OF THE SHOULDER

FULL ACTIVE MEMBERS 2002-2003

John Antoniou— Montreal, QC
Robert Balyk— Edmonton, AB
Richard Boorman— Calgary, AB
Erin Boynton— Toronto, ON
Darren Drosdewech— London, ON
Ken Faber— London, ON
Robert Hawkins— Vancouver, BC
Laurie Hiemstra— Calgary, AB
Bob Hollinshead— Calgary, AB
Richard Holtby— Toronto, ON
Dianne Jackowski— Hamilton, ON
Jordan Leith— Vancouver, BC
Bob Litchfield— London, ON
Peter MacDonald— Winnipeg, MN
Scott Mandel— Hamilton, ON
Bob McCormack— New Westminster, BC
Joy MacDermid— London, ON
Mike McKee— Toronto, ON
Jaydeep Moro— Hamilton, ON
Nick Mohtadi— Calgary, AB
Bill Reagan— Vancouver, BC
Eric Renaud— Montreal, QC

And new members always welcome!

Congratulations!!

Congratulations to Dianne Jackowski and Steve Bryant on the birth of their beautiful new daughter Nicole Katherine!



CRA's DO BREAKFAST!

Bright and early on the Sunday morning the JOINTS Canada CRA's got together for a Breakfast meeting to catch up with each other and hash out some of the day to day issues of the clinical trials. Meetings go so much smoother over bacon & eggs!

Congratulations to Dr. Bob Hollinshead on his election to President of the Canadian Orthopaedic Association. Dr. Hollinshead took over the reigns officially at the 2003 meeting in Winnipeg!



Feature Member Section

Mauri Zomar, CRA - New Westminster, BC

Our feature member this month is Mauri Zomar who works with Dr. Bob McCormack and the Orthopaedic Surgery & Trauma team at Royal Columbian Hospital, New Westminster, British Columbia.

Born in Prince Albert, Saskatchewan. Mauri grew up in a little town called Ashcroft, in the interior of British Columbia. She now lives in Cloverdale, B.C. with her husband Tracy (yes, that's Tracy) and her 2 daughters, Bryn (13) and Addison (11). Outside of her research life, she is an avid Scrapbooker but admittedly spends most of her time chauffeuring her kids to all their activities!



FROM THE PHOTO ARCHIVES...

BOB
LITCHFIELD
WITH HAIR?
IT'S TRUE!



CIHR N.E.T. Grant Application for JOINTS

IMHA recognizes that many research communities are at varying levels of development and has launched three initiatives that will seed and temporarily support productive collaborations across the four CIHR pillars and across the six major IMHA disciplines (Arthritis, Bone, Skin, Muscle, Oral Health and Rehabilitation). This will lead to the eventual creation of successful New Emerging Teams (NETS) and IMHA supported Research Centres.

New Emerging Team (NET) grants are intended to support the creation or development of teams of investigators undertaking collaborative multidisciplinary research. The Workshops Program is considered "phase one" of early stage New Emerging Team development and IMHA will provide up to \$25,000 to a group of researchers to hold significant planning meetings and conferences to network and to exchange ideas. Identification of key research questions and action plans of how the team will subsequently address those key questions is the goal. We feel that the annual JOINTS meetings fit perfectly into this category

The JOINTS group has talked about applying for one of the CIHR's New Emerging Team (NET) program grants on numerous occasions. We have decided to enter the competition for February 2004 and a sub-committee of JOINTS members are currently working on the a draft of the Workshop Support proposal.

FYI on Research Info:

The ISAKOS Scientific Committee has put out an excellent set of publications on Research Methodology in the October, November and December issues of Arthroscopy. This was an idea spearheaded by Sandy Kirkley when she was Chairperson of the Committee and they have worked hard to see it come to fruition in her honour. Check it out, it's a great resource!

Newest Studies on the go!

- Randomized Arthroscopic Anterior Instability (with Bankart) Shoulder Study (RAAIB)
- *Peter MacDonald et al*
- Arthroscopic vs. Open Rotator Cuff Repair
- *Richard Holtby et al*
- Intra-Rater Reliability of Diagnostic Shoulder Arthroscopy: Video Analysis
- *Treny Sasyniuk et al*
- Pilot Study for Restore/ S.I.S. Pig Mucosa Patch for Rotator Cuff Repairs
- *Dianne Jackowski et al*

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compliments and
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regarding this publication
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**GOOD CLINICAL PRACTICE:
MORE THAN JUST A GOOD IDEA**

Katie Dainty, M.Sc., C.R.P.C.

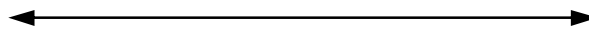
Over the years, you may or may not have heard the words “GCP guidelines” or “Guidelines of Good Clinical Practice” used in research circles or by your Ethics Office. Until recently, surgical/orthopaedic researchers have not been tuned in to many of the same regulations as our sister pharmaceutical researchers must abide by. Fortunately for the good of clinical research, the tide is changing and these guidelines are becoming a force to be reckoned with.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. It involves areas such as roles and responsibilities of trial staff and primary investigators, informed consent, randomization, data handling and record keeping, reporting of adverse events, monitoring procedures and many other very important trial issues.

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Canada, Japan and the United States to facilitate the mutual acceptance of clinical data in these jurisdictions. The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO).

This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities or for publication. The ICH harmonized tripartite guideline: "Good Clinical Practice: Consolidated Guideline" has been developed by an ICH Expert Working Group and has been subject to consultation, in accordance with the ICH process, by regulatory parties which include Canada. The Therapeutic Products Directorate of Health Canada has adopted this international guideline in order to ensure that (a) the roles and responsibilities of the Investigator and Sponsor are clearly and uniformly defined, (b) the Investigator's Brochure and Clinical Trial Protocols are prepared according to international standards. While it is anticipated that the principles outlined, such as those dealing with the responsibilities and functions of the Institutional Review Board/Independent Ethics Committee, will generally be respected, it is recognized that provincial/regional policies and laws may supersede them.

As of January 2001, the Therapeutic Products Directorate and Health Canada have the legal authority to audit/inspect all clinical trials, including those which are investigator initiated and recognizes that other jurisdictions may conduct audit(s)/inspection(s) in Canada. Although not officially law, compliance with GCP guidelines is a win-win situation for those of us involved in running clinical trials and should be in the forefront of all of our minds as we strive to do solid research.



Recent Shoulder Publications By Members of The Group

Kirkley A, Litchfield R, Thain L, Spouge A. Agreement between magnetic resonance imaging and arthroscopic evaluation of the shoulder joint in primary anterior dislocation of the shoulder. *Clin J Sport Med.* 2003 May;13(3):148-51.

Andrews G, Forster B, Cheong Y, Sidhu G, Hawkins R, Leith J. Shoulder magnetic resonance arthrography in the sagittal oblique plane: pictorial essay. *Can Assoc Radiol J.* 2003 Jun;54(3):169-73.

Hasan SS, Leith JM, Smith KL, Matsen FA 3rd. The distribution of shoulder replacement among surgeons and hospitals is significantly different than that of hip or knee replacement. *J Shoulder Elbow Surg.* 2003 Mar-Apr;12(2):164-9.