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A Network of Doctors Treating with OMM

Adverse Events and Osteopathic Medicine: A Prospective Cohort Study

Osteopathic International Alliance
September 20, 2016
Brian F. Degenhardt, DO
Director, A.T. Still Research Institute

Learning Objectives

After attending, participants should be able to:

1. Summarize the current evidence on adverse events that may be due to OMT
2. Report on previous studies conducted by DO-Touch.NET regarding adverse events and OMT
3. Report on the current status of the Adverse Events Study being conducted by DO-Touch.NET

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Disclosure Information

Osteopathic International Alliance

Brian F. Degenhardt, DO

- I have no financial relationships to disclose
- I will not discuss off-label use or investigational use in my presentation

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Adverse Event Definition

Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure.

Reference: National Cancer Institute. (2006). Common terminology criteria for adverse events v3.0 (CTCAE) Retrieved May 6, 2014, from http://ctep.cancer.gov/protocolDevelopment /electronic_applications/ docs/ctcaev3.pdf

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Expert Opinion

AE Type	Duration	Severity	Descriptors
Major	Medium+	Moderate+	Unacceptable
Moderate	Medium+	Moderate	Requires further treatment; Serious; Distressing
Minor or Non-adverse	Short	Mild	Non-serious; Function remains intact; Transient/ reversible; No treatment alterations required; Short-term consequences only; Contained

Reference: Carnes, D., Mullinger, B., & Underwood, M. (2010). Defining adverse events in manual therapies: A modified Delphi consensus study. *Manual Therapy, 15*(1), 2-6. doi: 10.1016/j.math.2009.02.003

Patient Perspective

AE Type	Duration	Severity (on NRS)	Functional Impact
Major	>2 days	≥3	Loss of function; Complete inability to carry out activities
Moderate	>1-5 days	1-2	Activity modification necessary
Mild	≤2 days	0.5-2	No change in function

Note: Patients consider alternative causes when determining whether to attribute adverse event to manual therapy.

Carlesso, L. C., Cairney, J., Dolovich, L., & Hoogenes, J. (2011). Defining adverse events in manual therapy: An exploratory qualitative analysis of the patient perspective. *Manual Therapy, 16*(5), 440-446. doi: 10.1016/j.math.2011.02.001

Systematic Review – Manual Medicine Safety

- 8 prospective cohort studies
  - 42,451 treatments/22,833 patients
  - Primarily chiropractic treatments usually involving high velocity thrust techniques
  - Only 1 study identified major adverse events (14/4,712 treatments, 0.13%)
  - ~41% experienced minor or moderate transient adverse events

Reference: Carnes D, Mars TS, Mullinger B, et al. Adverse events and manual therapy: A systematic review. *Man Ther* 2010;15:355-363.

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Systematic Review – Manual Medicine Safety

- 31 randomized controlled trials
  - 2,281 participants in manual therapy arms
  - No reported major adverse events
  - 22% experienced minor or moderate transient adverse events

Reference: Carnes D, Mars TS, Mullinger B, et al. Adverse events and manual therapy: A systematic review. *Man Ther* 2010;15:355-363.

OMT Safety

- Standardized OMT protocol (HVLA, MVMA, soft tissue, MFR, counterstrain, muscle energy) for treating low back pain patients
  - 7% experienced an adverse event
  - 3% experienced a serious adverse event
  - 3% developed a contraindication
  - 1 participant discontinued study participation due to recurrent back spasticity following OMT

Reference: Licciardone JC, Minotti DE, Gatchel RJ, et al. Osteopathic manual treatment and ultrasound therapy for chronic low back pain: a randomized controlled trial. *Ann Fam Med.* 2013;11(2):122-129.

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OMT Safety

- Prospective surveys of 2,039 patients receiving OMT in the United Kingdom
  - 4% reported temporary disability attributed to OMT
  - 19% reported a clinically meaningful increase in symptoms at 1 day
  - 10% saw another healthcare practitioner due to worsening of or new symptoms attributed to OMT

Reference: Vogel S, Mars T, Keeping S, et al. (2013). Clinical risk osteopathy and management scientific report: The CROaM Study. Retrieved June 16, 2016, from http://www.osteopathy.org.uk/news-and-resources/document-library/research-and-surveys/the-croam-study-february-2013/

OMT Safety

- Retrospective surveys of 1,082 osteopaths in the United Kingdom
  - 12% reported having at least 1 patient with a serious adverse event during career
  - 4% reported having at least 1 patient with a serious adverse event during the last year
  - Most frequent serious adverse events were related to peripheral neurological symptoms
  - Estimated serious adverse event rate: 1 per 36,079 treatments

Reference: Vogel S, Mars T, Keeping S, et al. (2013). Clinical risk osteopathy and management scientific report: The CROaM Study. Retrieved June 16, 2016, from http://www.osteopathy.org.uk/news-and-resources/document-library/research-and-surveys/the-croam-study-february-2013/

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Use and Effectiveness of OMM in the Clinical Setting

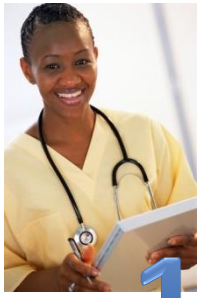
Brian F. Degenhardt, DO; Jane C. Johnson, MA; William J. Brooks, DO; and Daniel Freeland, DO

Funded by the American Osteopathic Association and A.T. Still University

Specific Aims

- Identify conditions that are being treated with OMT in the 21st century.
- Identify conditions that appear to be responsive to OMT.
- Determine characteristics of patients who are more responsive to OMT.
- Determine characteristics of clinicians who most consistently demonstrate positive outcomes from OMT.
- Identify and accurately describe techniques that are most beneficial in treating conditions responsive to OMT.

Study Flowchart



1

New patient recruited, consented, and completes the Office Visit Questionnaire

Treatment

2

Physical Examination and Treatment Form

3

4

Patient Post-treatment Questionnaire

7

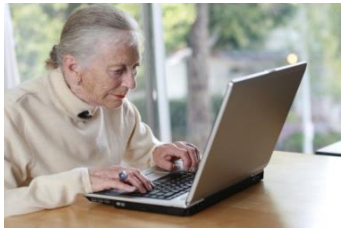
5

Daily Follow-up Questionnaire for 7 days

6

One-week follow-up Questionnaire

Established patient completes the Office Visit Questionnaire



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Results

- 936 participants
- 1,929 office visits
- 1,483 office visits (77%) with complete follow-up data

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Two ways of demonstrating Effectiveness

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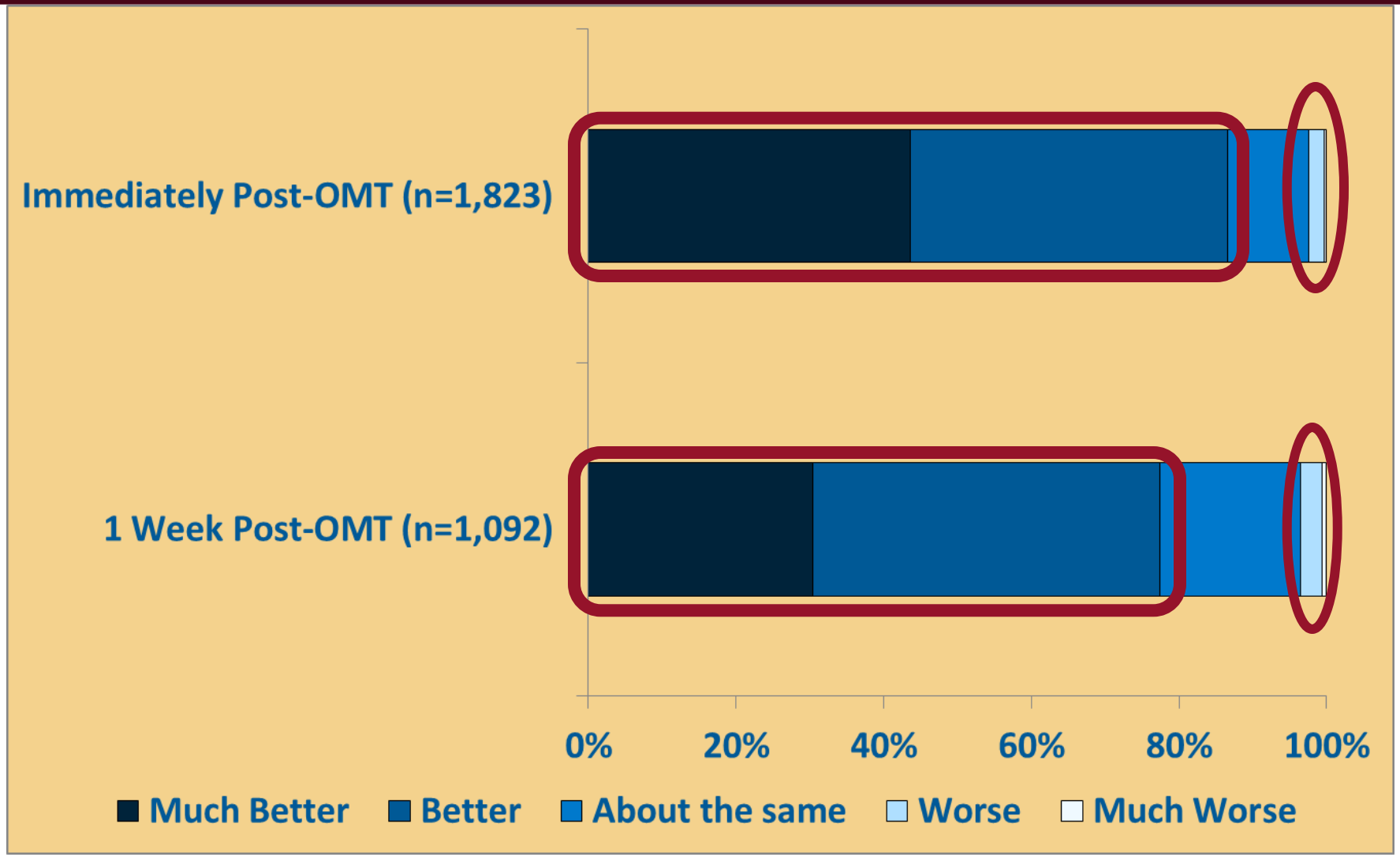
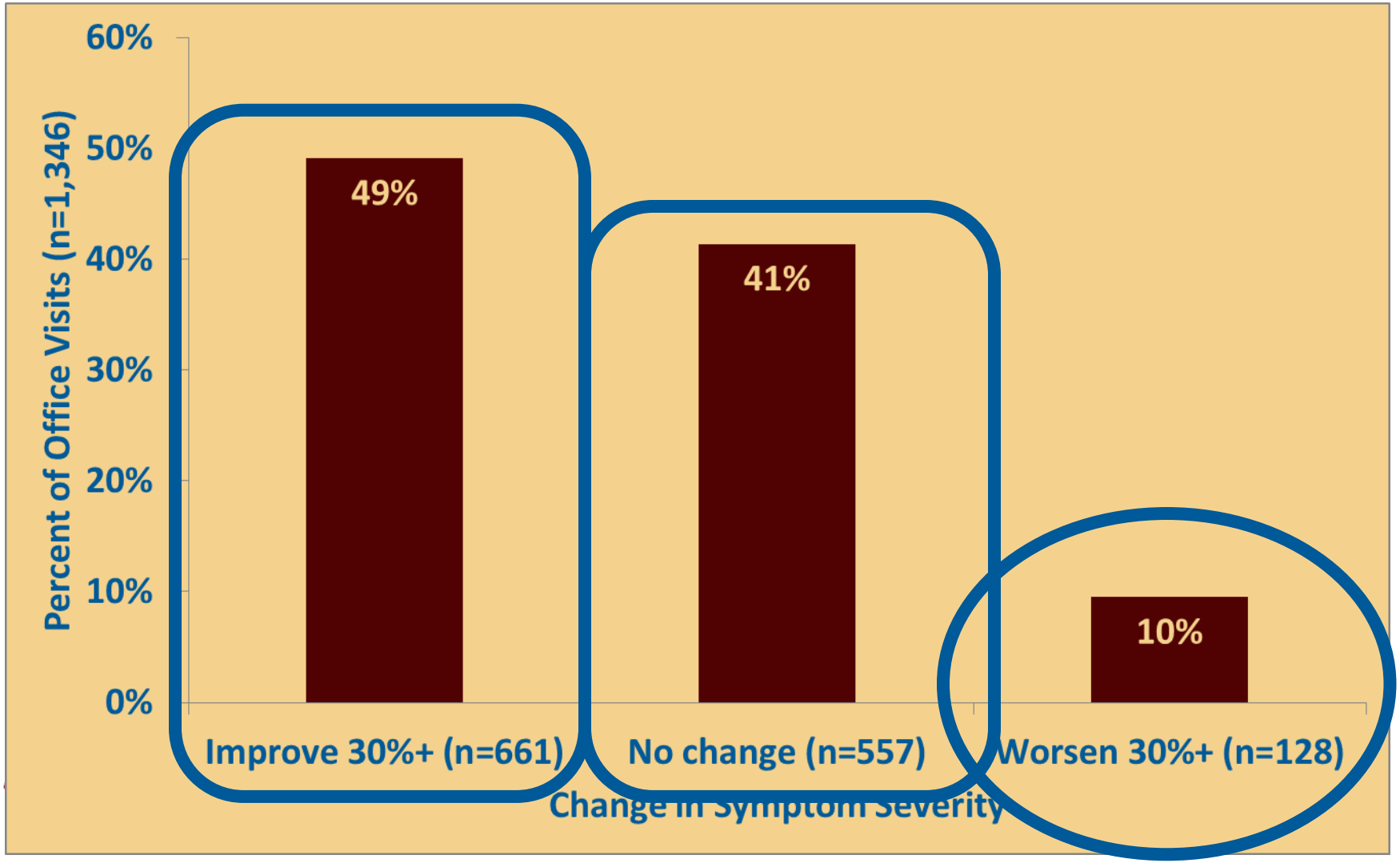
Patient Perceived Response



Symptom Severity



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Patient-reported Adverse Events from Osteopathic Manipulative Treatment

Brian F. Degenhardt, DO; Jane C. Johnson, MA

Funded by the American Academy of Osteopathy and the ATSU Strategic Research Fund

Research Questions

- What types and incidence of adverse events occur following osteopathic manipulative treatment?
- Are there individual osteopathic techniques in particular body regions that have higher incidences of adverse events than other techniques or body regions?
- Is the incidence of adverse events higher for some patient conditions than others?

Goals

- Develop a monitoring system that
  - Is easily incorporated into clinical practice
  - Can be tested and refined for long term surveillance of adverse events
  - Build a research culture within the osteopathic clinician community
  - Can combine with a refined system for assessing long term the utilization and effectiveness of OMT

Study Flowchart

1

Patient reviews informational poster and brochure in waiting room.

TREATMENT

2

OMT patient receives coded study packet from office staff.

3

Participant consents and completes surveys at home on paper or online.

4

Clinician fills out OMT Documentation Form.

5

Participant and clinician's office are reimbursed for participation.

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Informational Material

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RESEARCH OPPORTUNITY

In conjunction with A.T. Still University in Kirksville, Mo., we are conducting a research study entitled "Patient-reported Adverse Events from Osteopathic Manipulative Treatment (OMT)," and we are seeking research volunteers. If you receive OMT at this office visit, you may be eligible to participate. If you agree to participate and complete the required surveys, you will receive $10 in compensation (in the form of a gift card or money order) for your time. If you would like more information, please take one of the brochures below, talk to the office staff, or contact the DO-Touch.NET network manager, Lisa Norman, at lnorman@atsu.edu or 660.626.2443.

Thank you for your interest!

Brochure or flyer in pocket

A.T. Still University ATSU

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Please review this brochure to learn more information about an exciting research study. Your participation will help lead the way to improving healthcare and advancing the future of medical education.

Thank you for your interest!

Patient-reported Adverse Events from Osteopathic Manipulative Treatment (OMT) study

Study design

This study is being conducted at the clinics of participating members of DO-Touch.NET, the only practice-based research network focused on research related to osteopathic manual medicine. If you consent to participate, you will be asked to complete a brief paper or online survey regarding any side effects you may experience within 24 hours, 72 hours, and one week after your OMT. Copies of the surveys are available in your clinician's office if you would like to review them. Additionally, information regarding your treatment will be obtained from your clinician.

Who can participate?

Patients who

- are adults, 18 years or older,
- received OMT by a participating provider,
- give informed consent, and
- are able to communicate in English and have the ability to provide accurate information.

Time duration

Your initial office visit will take the same amount of time as if you were not in the study. The 24-hour, mid-week, and one-week survey will take approximately 5-10 minutes each to complete.

Voluntary participation

Participation in this research study is voluntary and you may withdraw at any time. Withdrawing from this study or refusing to participate will in no way affect your care or access to medical services.

Potential benefits

Information gained from this research may lead to improved understanding of various osteopathic techniques and side effects associated with each individual treatment. This may eventually lead to improved medical interventions for multiple common conditions.

Research opportunity

In conjunction with A.T. Still University in Kirksville, Mo., we are conducting a research study entitled "**Patient-reported Adverse Events from Osteopathic Manipulative Treatment (OMT)**" and are seeking research volunteers. If you receive OMT at this office, you may be eligible to participate. For more information, review this brochure, talk to office staff, or contact the DO-Touch.NET Coordinating Center at the number/email address below.

866.626.2878 ext. 2443
or lnorman@atsu.edu

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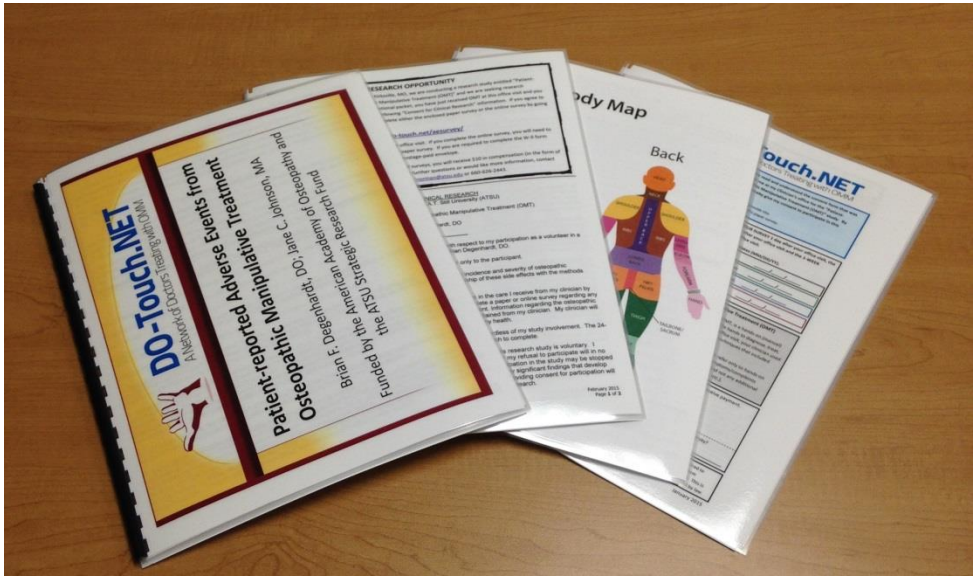
Brian F. Degenhardt, DO, director
Jane C. Johnson, MA, associate director
Lisa Norman, project manager

A.T. Still University | ATSU



Study Flowchart

1

Patient reviews informational poster and brochure in waiting room.

TREATMENT

2

OMT patient receives coded study packet from office staff.

3

Participant consents and completes surveys at home on paper or online.

4

Clinician fills out OMT Documentation Form.

5

Participant and clinician's office are reimbursed for participation.

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Eligibility Criteria

Adult Patient Receives OMT from Participating DO-Touch.NET Clinician

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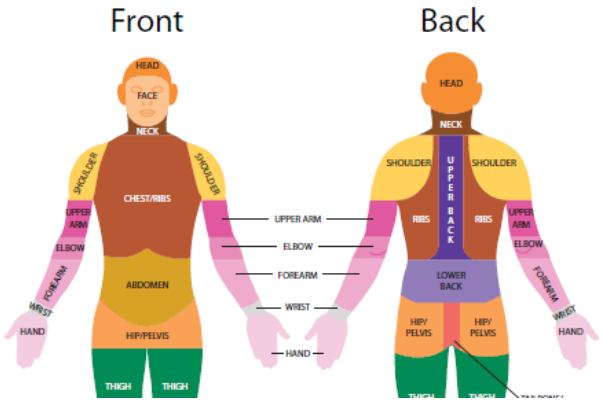
Patient Packet Contents

- Informed Consent Information
- Body Map
- Paper Surveys
- Envelope



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Must Check To Participate

☐ **By checking here, I verify that I have read and understood the consent form that was enclosed with the study packet given to me at my Clinician's office for the "Patient-reported Adverse Events from Osteopathic Manipulative Treatment (OMT)" study. By completing and returning this survey, I hereby give my consent to participate in this research study.**

If you are completing the surveys online, please provide the following **STUDY CODE** when asked. **D016**

24-HOUR SURVEY
(Please complete this page **the day after** your office visit.)

For any of the following symptoms/complaints you have had **since your OMT (the hands-on treatment you received from your clinician)**, please indicate:
1. the **worst severity** since your OMT;
2. whether you feel these symptoms/complaints were **related to your OMT**; and
3. if you had this same symptom/complaint in the **6 weeks** before your OMT, what was the **worst severity during the week before OMT.**

Symptom/Complaint (+See Body Map included in packet)	1. Worst severity since your OMT				2. Related to OMT					3. Worst severity during week before OMT				
☐ Please check here if you have **not** had any of the following symptoms/complaints since your OMT.	Mild	Moderate	Severe	Very Severe	Definitely	Probably	Not Sure	Unlikely	No	No Problem	Mild	Moderate	Severe	Very Severe
Pain/Discomfort in Head/Face (including Jaw, not including Headache)+	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pain/Discomfort in Neck+	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pain/Discomfort in Upper Back+	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pain/Discomfort in Chest/Ribs+	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Patient Surveys

- Online or paper versions available
- 24 hours, 72 hours, and 1 week after OMT

www.do-touch.net/aesurveytraining/

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Symptom/Complaint [+]See Body Map included in packet	1. Worst severity since your OMT				2. Related to OMT					3. Worst severity during week before OMT				
☐ Please check here if you have **not** had any of the following symptoms/complaints since your OMT.	Mild	Moderate	Severe	Very Severe	Definitely	Probably	Not Sure	Unlikely	No	No Problem	Mild	Moderate	Severe	Very Severe
Pain/Discomfort in Head/Face (including Jaw, not including Headache)[+]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pain/Discomfort in Neck[+]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pain/Discomfort in Upper Back[+]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pain/Discomfort in Chest/Ribs[+]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

MID-WEEK SURVEY
(Please complete this section **3 days after** your office visit.)

For any of the following symptoms/complaints you have had **in the past 2 days**, please indicate:
1. the **worst severity** in the past 2 days;
2. whether you feel these symptoms/complaints were **related to your OMT**; and
3. if you had this same symptom/complaint in the **6 weeks** before your OMT, what was the **worst severity during the week before OMT.**

1-WEEK SURVEY

Worst severity on day 7 for any **symptom/ complaint listed on the MID-WEEK SURVEY.**

Symptom/Complaint [+]See Body Map included in packet	1. Worst severity in the past 2 days				2. Related to OMT					3. Worst severity during week before OMT					Worst severity at 1 week				
☐ Please check here if you have **not** had any of the following symptoms/ complaints in the past 2 days.	Mild	Moderate	Severe	Very Severe	Definitely	Probably	Not Sure	Unlikely	No	No Problem	Mild	Moderate	Severe	Very Severe	Not Present	Mild	Moderate	Severe	Very Severe
Pain/Discomfort in Head/Face (including Jaw, not including Headache)[+]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pain/Discomfort in Neck[+]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pain/Discomfort in Upper Back[+]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pain/Discomfort in Chest/Ribs[+]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Study Flowchart

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Patient reviews informational poster and brochure in waiting room.

TREATMENT

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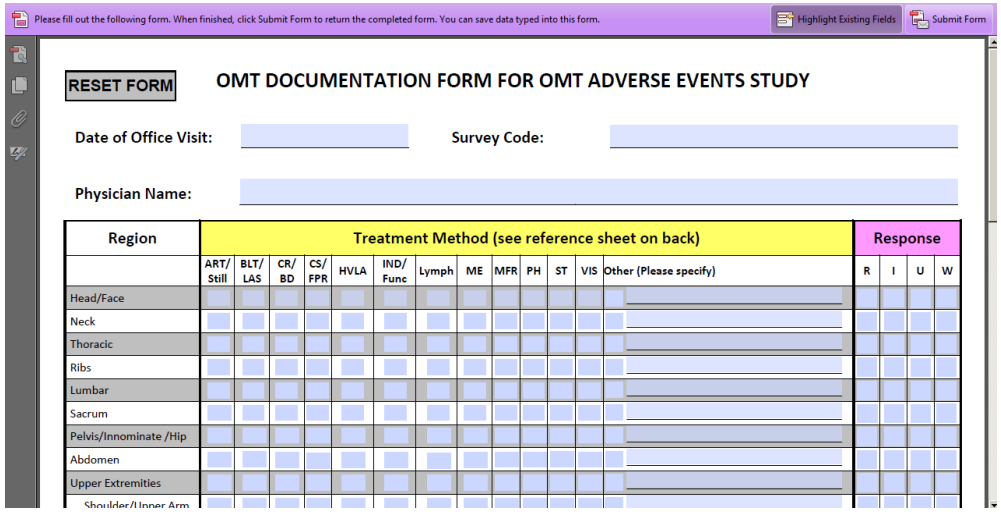
OMT Documentation

- Treatment
  - Techniques used
  - Regions treated
  - Patient response
- Diagnoses
  - Regions with somatic dysfunction
  - Medical diagnoses
- Additional interventions/procedures



Please fill out the following form. When finished, click Submit Form to return the completed form. You can save data typed into this form. Highlight Existing Fields Submit Form

RESET FORM

OMT DOCUMENTATION FORM FOR OMT ADVERSE EVENTS STUDY

Date of Office Visit: Survey Code:

Physician Name:

Region	Treatment Method (see reference sheet on back)												Response			
	ART/ Still	BLT/ LAS	CR/ BD	CS/ FPR	HVLA	IND/ Func	Lymph	ME	MFR	PH	ST	VIS	Other (Please specify)	R	I	U	W
Head/Face																	
Neck																	
Thoracic																	
Ribs																	
Lumbar																	
Sacrum																	
Pelvis/Innominate /Hip																	
Abdomen																	
Upper Extremities																	
Shoulder/Upper Arm																	

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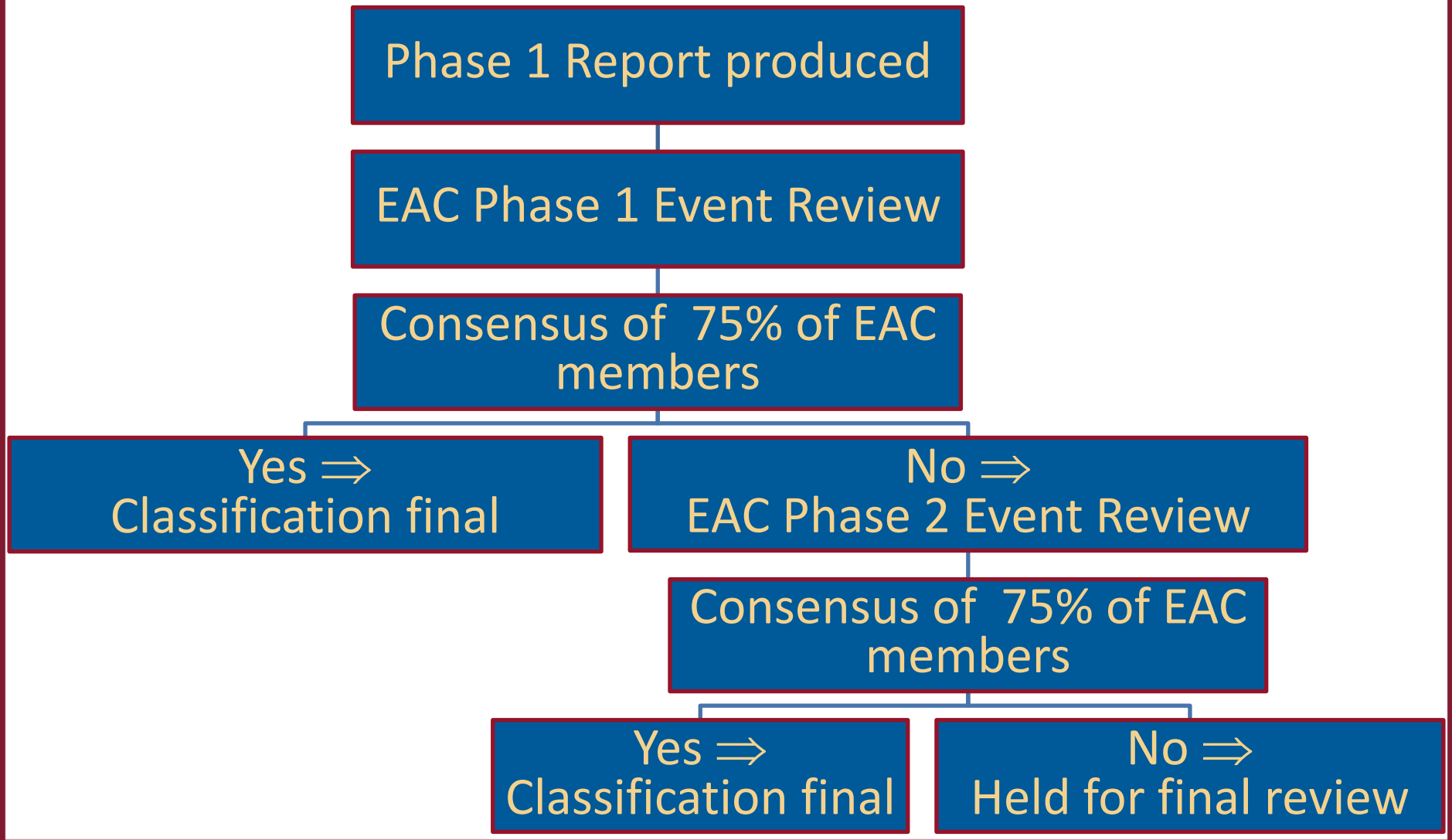
Event Adjudication Committee

EAC responsible for classifying patient-reported symptoms and healthcare utilization:

- Whether adverse event or not
- If adverse event,
  - Presence at 24 hours, 72 hours, and 1 week
  - Intensity
  - Degree related to the OMT received

EAC Review Process



Current Status – United States

- 11 clinicians completed enrollment
- 15 clinicians currently enrolling
- 25 clinicians in final stages of preparation

- 390 patients completed surveys (53% response)

- Goals:
  - 50 clinicians participating (achieved)
  - 1,000 patients completing surveys

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Current Status – Germany

- 6 clinicians completed enrollment
- 8 clinicians currently enrolling

- 220 patients completed surveys (61% response)

- Goals
  - 20 clinicians participating
  - 400 patients completing surveys

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Expectations

Research Questions

- What are the incidence and types of adverse events occur following osteopathic manipulative treatment?
- Are there individual osteopathic techniques in particular body regions that have higher incidences of adverse events than other techniques or body regions?
- Is the incidence of adverse events higher for some patient conditions than others?

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Expectations

Research Questions

- What are the incidence and types of adverse events occur following osteopathic manipulative treatment?
- Are there individual osteopathic techniques in particular body regions that have higher incidences of adverse events than other techniques or body regions?
- Is the incidence of adverse events higher for some patient conditions than others?

Outcomes

- Build an infrastructure capable of easily monitoring the utilization, effectiveness and safety of OMT from both patient and clinician report

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Expectations

Research Questions

- What are the incidence and types of adverse events occur following osteopathic manipulative treatment?
- Are there individual osteopathic techniques in particular body regions that have higher incidences of adverse events than other techniques or body regions?
- Is the incidence of adverse events higher for some patient conditions than others?

Outcomes

- Build an infrastructure capable of easily monitoring the utilization, effectiveness and safety of OMT from both patient and clinician report
- When this system is established, assessment of serious adverse events can be determined

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Expectations

Research Questions

- What are the incidence and types of adverse events occur following osteopathic manipulative treatment?
- Are there individual osteopathic techniques in particular body regions that have higher incidences of adverse events than other techniques or body regions?
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Outcomes

- Build an infrastructure capable of easily monitoring the utilization, effectiveness and safety of OMT from both patient and clinician report
- When this system is established, assessment of serious adverse events can be determined
- Refine recommendations of when OMT should be used

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Expectations

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- What are the incidence and types of adverse events occur following osteopathic manipulative treatment?
- Are there individual osteopathic techniques in particular body regions that have higher incidences of adverse events than other techniques or body regions?
- Is the incidence of adverse events higher for some patient conditions than others?

Outcomes

- Build an infrastructure capable of easily monitoring the utilization, effectiveness and safety of OMT from both patient and clinician report
- When this system is established, assessment of serious adverse events can be determined
- Refine recommendations of when OMT should be used
- Establish evidence that may help in building mechanistic studies

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Conclusion

Healthcare needs to be:

- Safe,
- Effective,
- Efficient,
- Timely,
- Patient-centered, and
- Equitable.

Reference: Institute of Medicine. Committee on Quality of Health Care in America. *Crossing the quality chasm: A new health system for the 21st century*. Washington, DC: National Academy Press; 2001.

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Conclusion

- This type of healthcare can not be achieved without an accurate, consistently used monitoring system assessing safety, effectiveness, patient-centered, etc.
- The power of this type of research is in preparation and participation

Evidence-based References

1. Carlesso LC, Cairney J, Dolovich L, & Hoogenes J. (2011). Defining adverse events in manual therapy: An exploratory qualitative analysis of the patient perspective. *Manual Therapy, 16*(5), 440-446. doi: 10.1016/j.math.2011.02.001
2. Carnes D, Mars TS, Mullinger B, et al. (2010). Adverse events and manual therapy: A systematic review. *Manual Therapy, 15*, 355-363.
3. Carnes D, Mullinger B, & Underwood M. (2010). Defining adverse events in manual therapies: A modified Delphi consensus study. *Manual Therapy, 15*(1), 2-6. doi: 10.1016/j.math.2009.02.003
4. Institute of Medicine. Committee on Quality of Health Care in America. *Crossing the quality chasm: A new health system for the 21st century*. Washington, DC: National Academy Press; 2001.
5. Licciardone JC, Minotti DE, Gatchel RJ, et al. (2013). Osteopathic manual treatment and ultrasound therapy for chronic low back pain: a randomized controlled trial. *Annals of Family Medicine, 11*(2), 122-129.
6. National Cancer Institute. (2006). Common terminology criteria for adverse events v3.0 (CTCAE). Retrieved May 6, 2014, from http://ctep.cancer.gov/protocolDevelopment /electronic_applications/ docs/ctcaev3.pdf
7. Vogel S, Mars T, Keeping S, et al. (2013). Clinical risk osteopathy and management scientific report: The CROaM Study. Retrieved June 16, 2016, from http://www.osteopathy.org.uk/news-and-resources/document-library/research-and-surveys/the-croam-study-february-2013/