DO-Touch.NET
A Network of Doctors Treating with OMM

OMT Effectiveness and Safety Patient Registry (OESPRY)

2020 DO-Touch.NET Annual Meeting and Educational Seminar

March 10 and 11, 2020

Brian F. Degenhardt, DO, C-NMM/OMM

Disclosure Information

DO-Touch.NET Annual Meeting and Educational Seminar

Measuring the Impacts of OMM:

Patient-reported Outcomes in the Clinical Setting

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

- We have no financial relationships to disclose.
- We will not discuss off-label use or investigational use in our presentation.

Learning Objectives

After attending, participants should be able to:

1. develop strategies for implementing patient-reported outcomes into their clinical practice,
2. interpret patient-reported outcomes applicable to patients receiving osteopathic manipulative treatment, and
3. employ patient-reported outcomes in their clinical practice to improve clinician-patient communication.

WHAT HAVE HAS BEEN LEARNED BY MEMBERS OF THE NETWORK?

PATIENT CHARACTERISTICS

Representative of Population

Participants were:

- older
- more female
- more white; Less Black/African-American, Asian, Native Hawaiian/Other Pacific Islander
- less hispanic/latino
- more educated
- higher median income
- not different on percent on disability

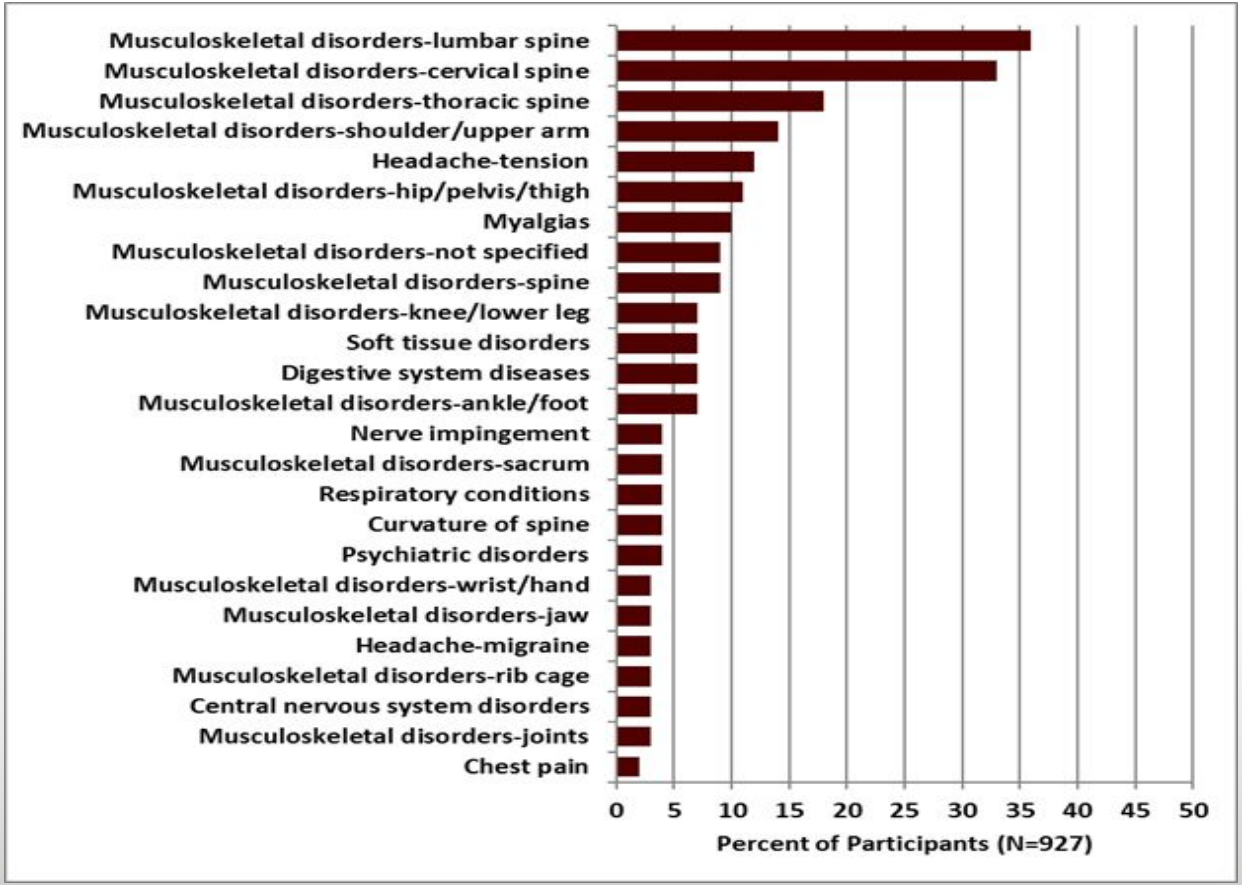
than population of county where clinic was located.

* 2 clinics with less than 10 participants were not included in the analysis.

Reference: US Census Bureau. QuickFacts. https://www.census.gov/quickfacts/fact/table/US/PST045217. Published 2017. Accessed January 5, 2018.

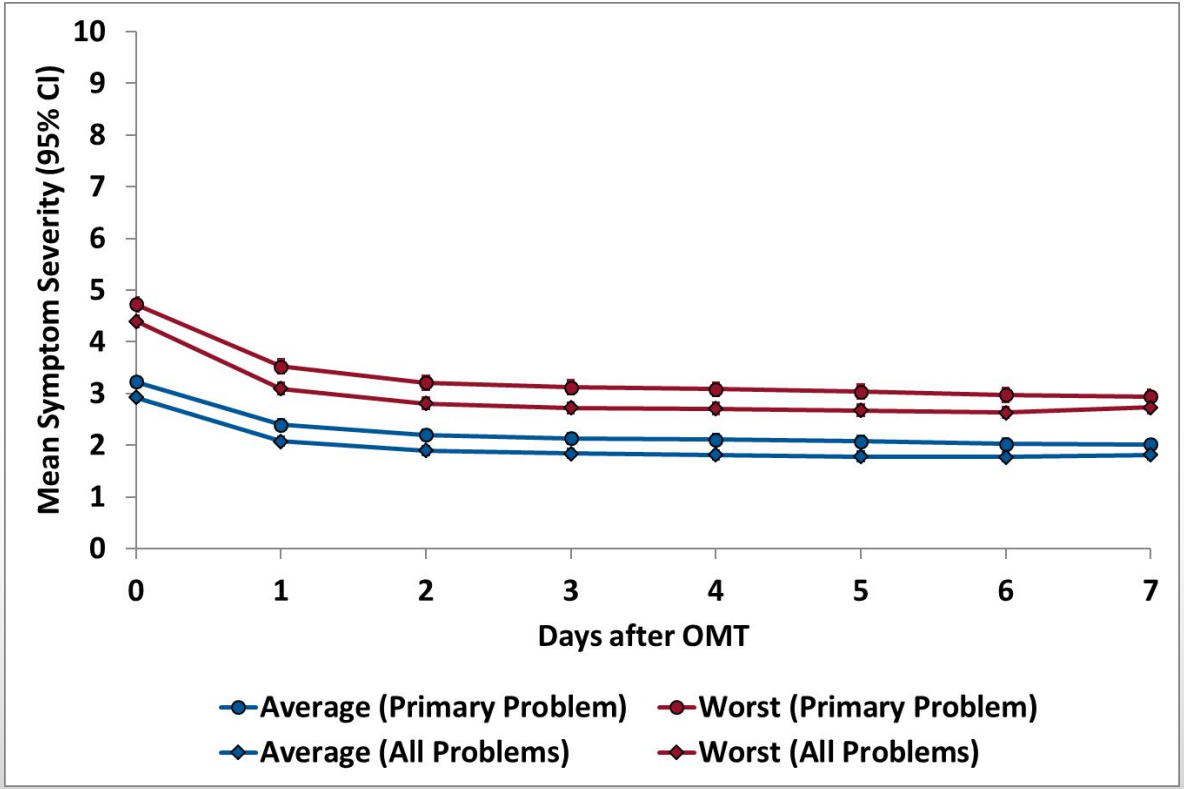
CONDITIONS TREATED WITH OMT

Diagnoses

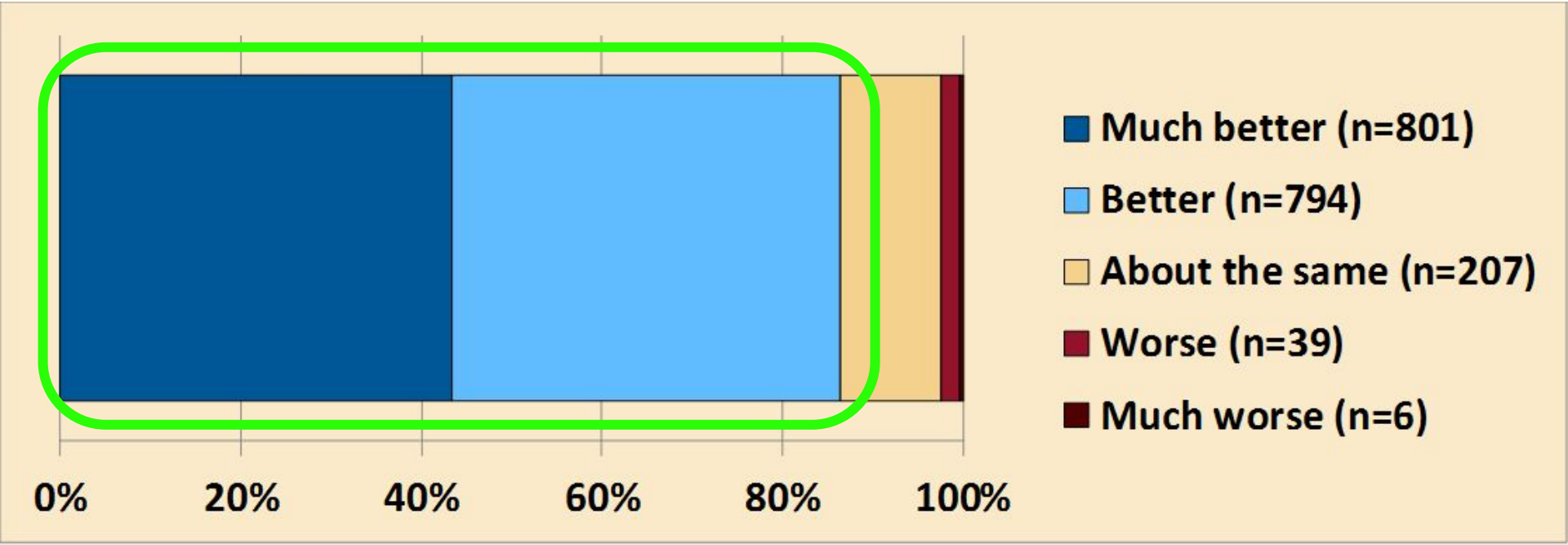

Musculoskeletal disorders-lumbar spine
Musculoskeletal disorders-cervical spine
Musculoskeletal disorders-thoracic spine
Musculoskeletal disorders-shoulder/upper arm
Headache-tension
Musculoskeletal disorders-hip/pelvis/thigh
Myalgias
Musculoskeletal disorders-not specified
Musculoskeletal disorders-spine
Musculoskeletal disorders-knee/lower leg
Soft tissue disorders
Digestive system diseases
Musculoskeletal disorders-ankle/foot
Nerve impingement
Musculoskeletal disorders-sacrum
Respiratory conditions
Curvature of spine
Psychiatric disorders
Musculoskeletal disorders-wrist/hand
Musculoskeletal disorders-jaw
Headache-migraine
Musculoskeletal disorders-rib cage
Central nervous system disorders
Musculoskeletal disorders-joints
Chest pain
0 5 10 15 20 25 30 35 40 45 50
Percent of Participants (N=927)

EFFECTIVENESS

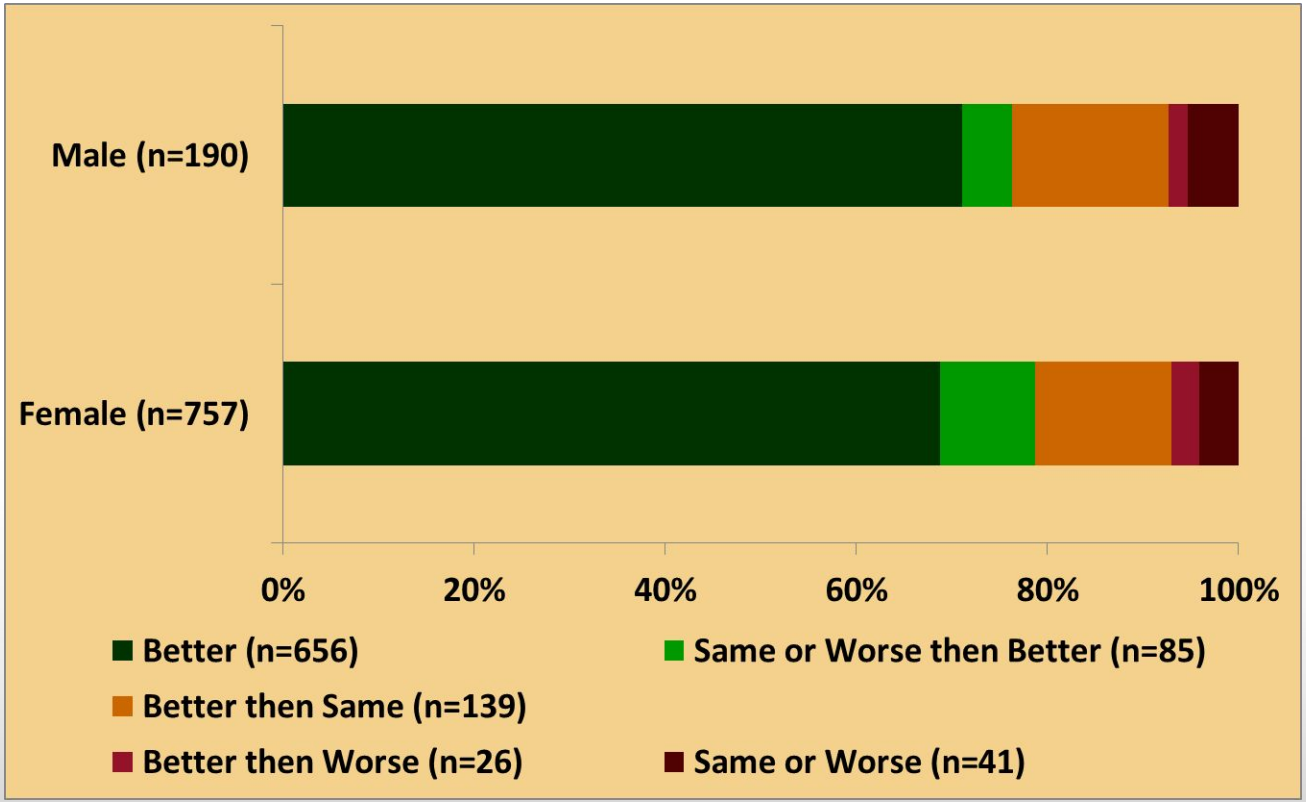
Symptoms Over 1-week Follow-up



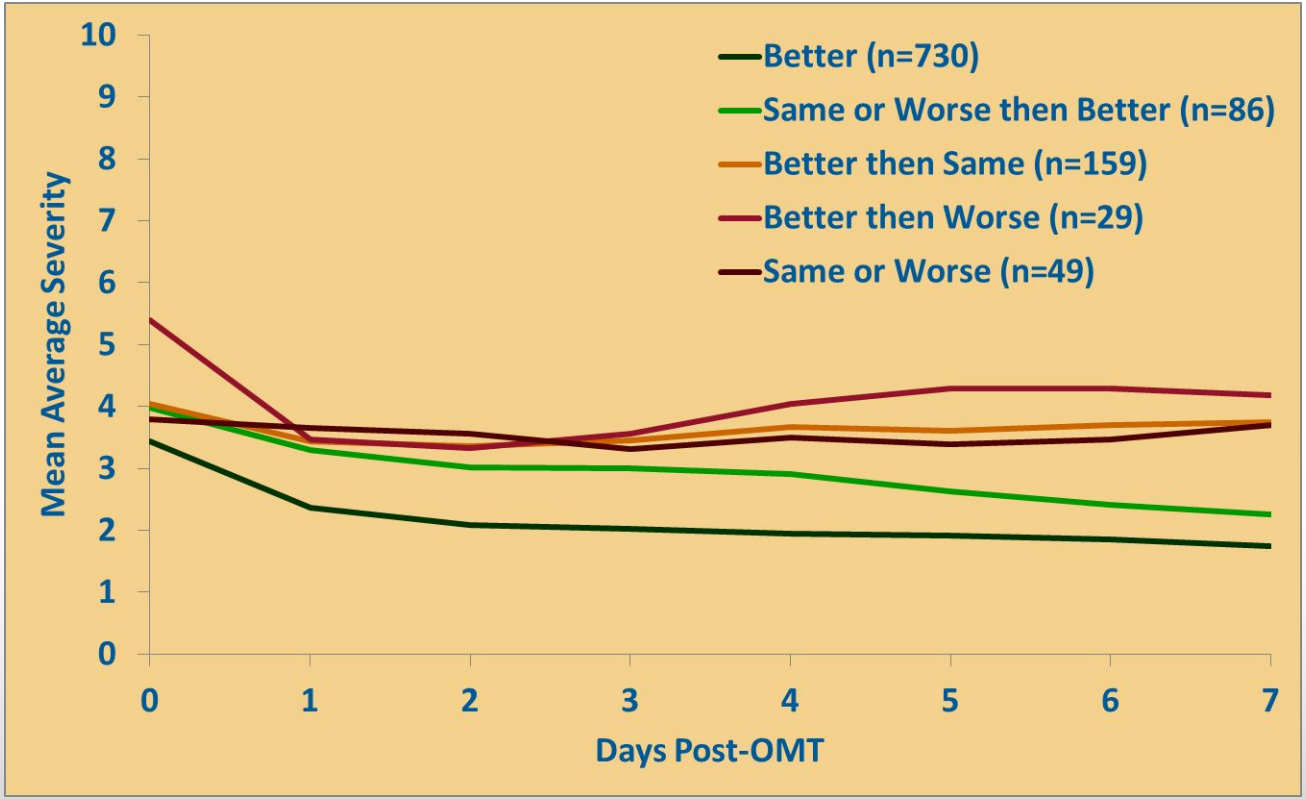
Patient Reported Response - Immediate AE



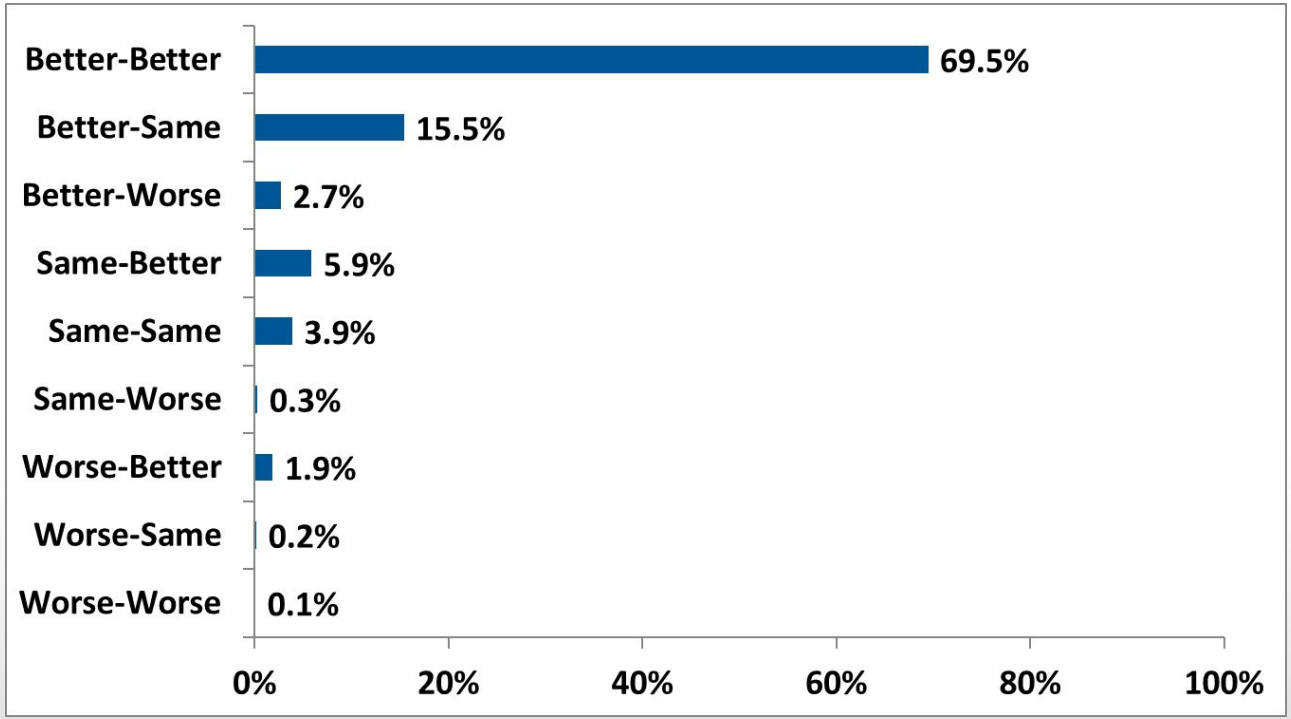
Sub group analysis - sex



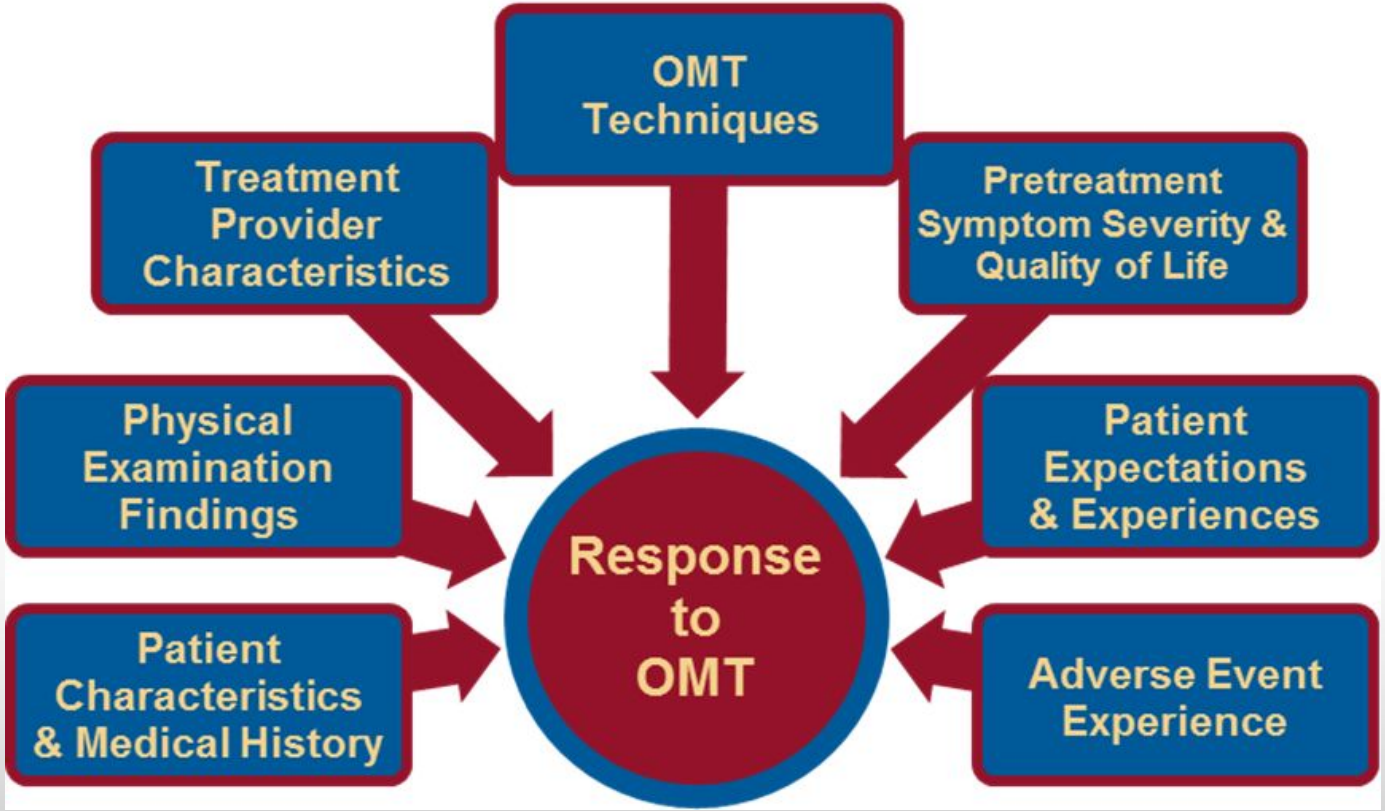
Symptoms Over 1-week Follow-up



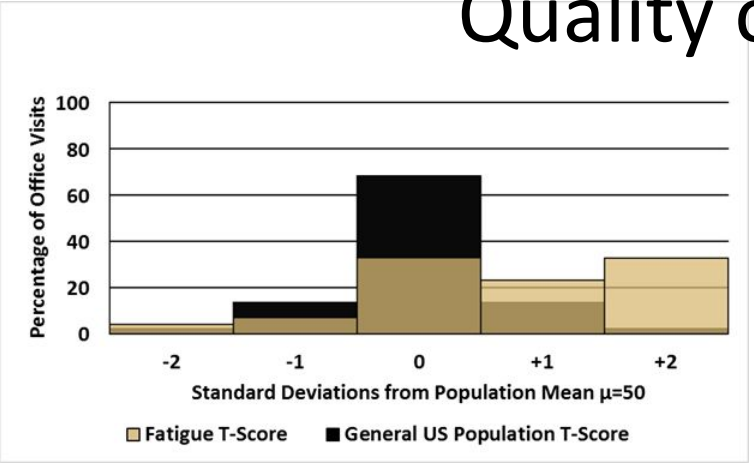
Symptoms Over 1-week Follow-up

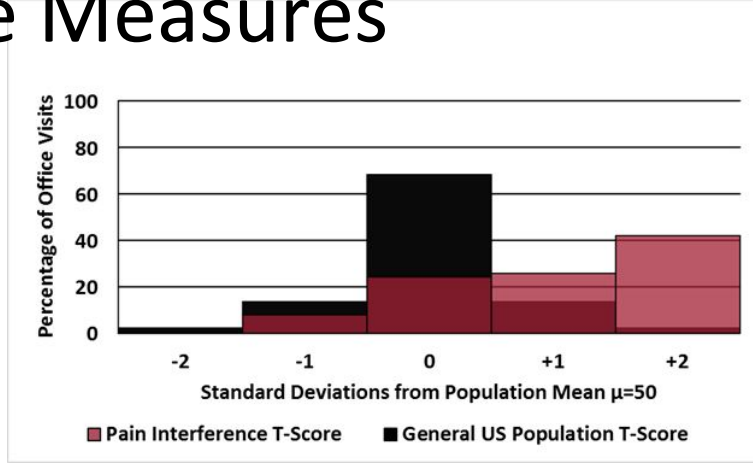


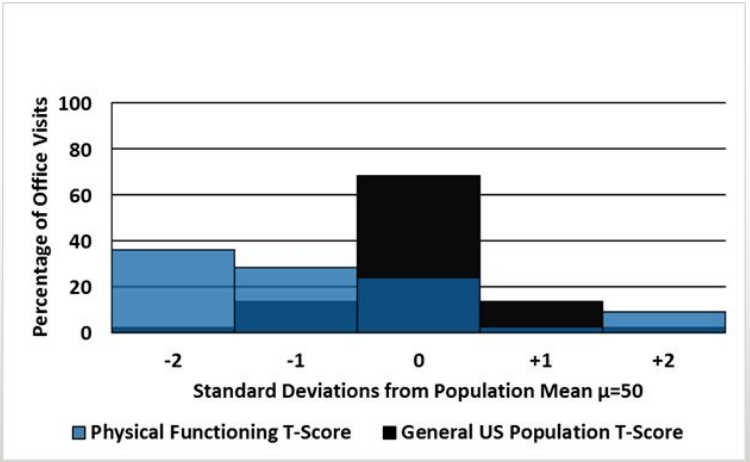
Information – Connecting Dots

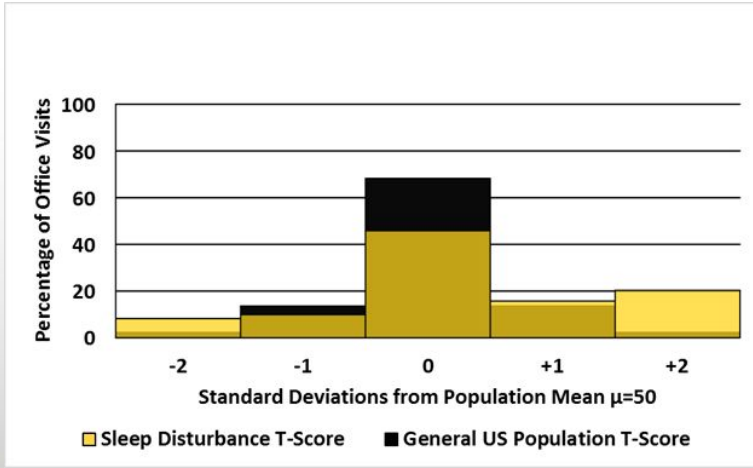


Quality of Life Measures

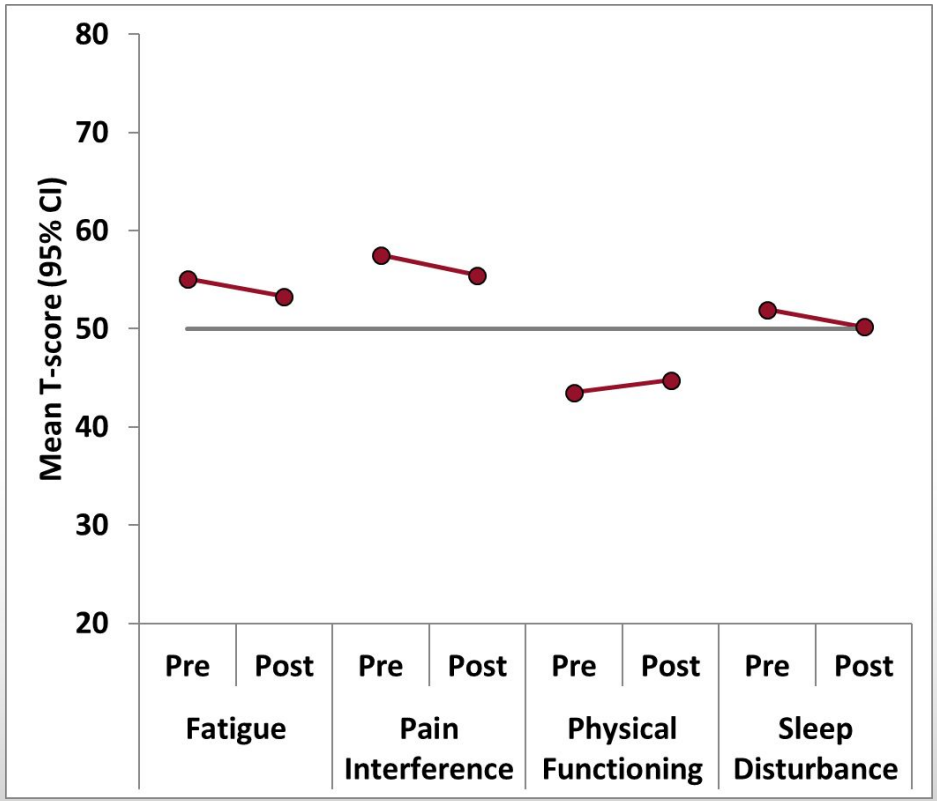








OMT Effect of Quality of Life Questionnaires



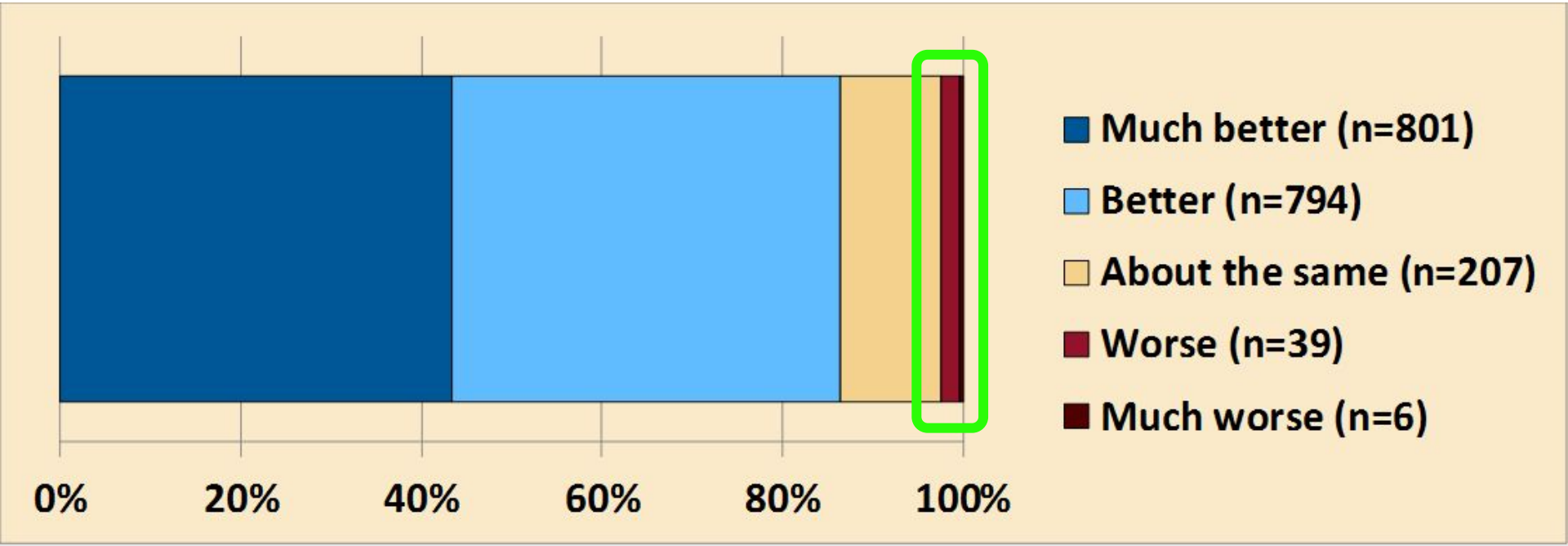
Aim of Medicine

- To provide safe, effective, timely, patient centered, efficient and equitable care

Institute of Medicine, Crossing the Quality Chiasm, 2001

SAFETY

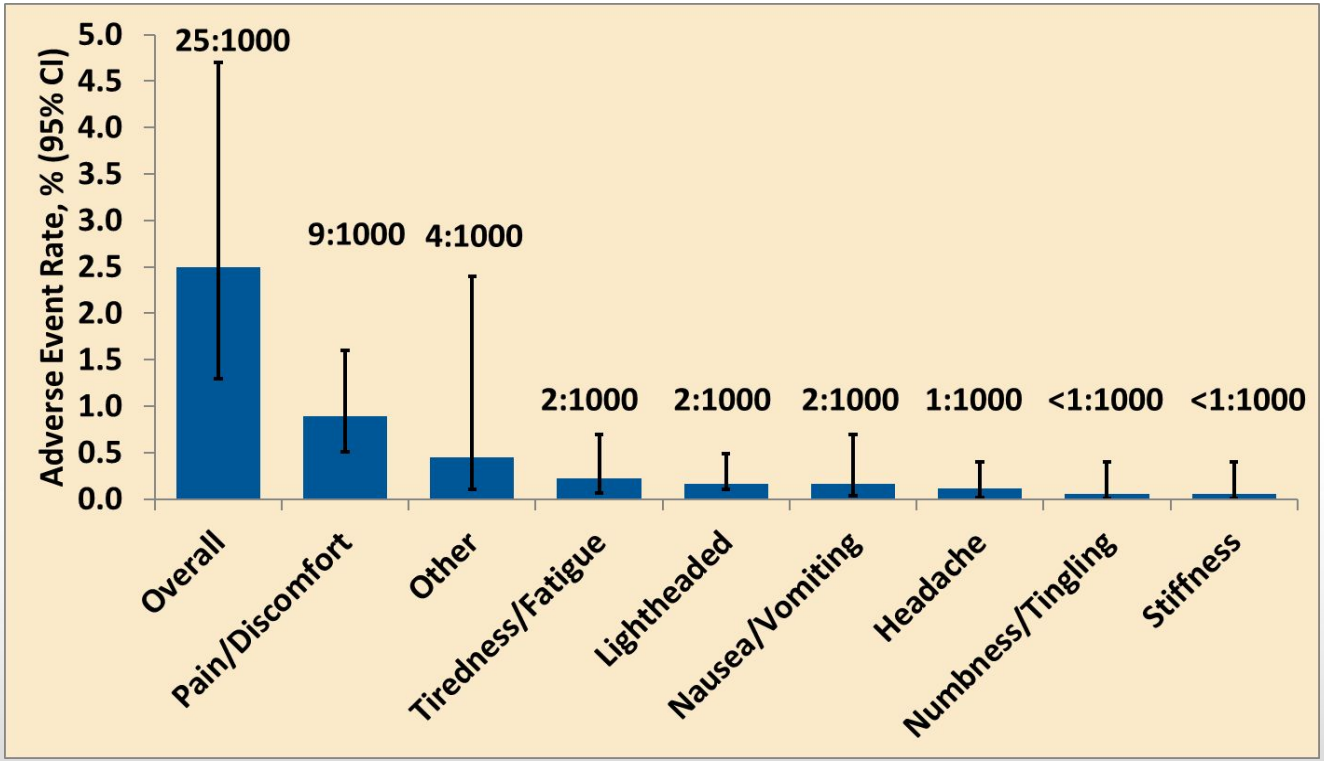
Patient Reported Response - Immediate AE



Adverse Events

- Number of Participants: 27/864
- Number of Office Visits: 44/1,817
- Number of Clinicians: 14/43
- Gender: 26 (96%) female, 1 (4%) male
- Age: mean (SD) 52.6 (15.7) years, range 21-90
- Ethnicity: 26 (96%) Not Hispanic/Latino or not specified
- Race: 26 (96%) White

Patient Reported Response - Immediate AE



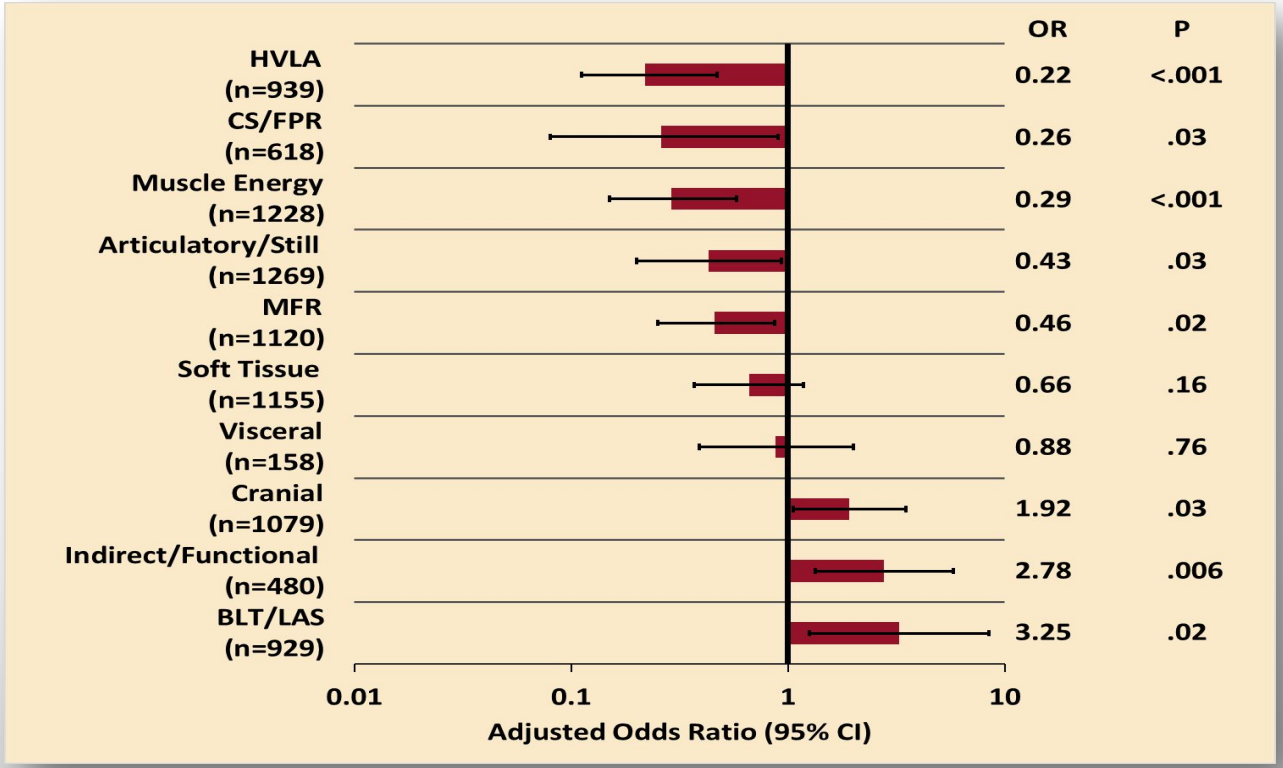
Adverse Event Rate (Immediate): 2.5% (1.3%-4.7%)

Table.
Association of Demographic Characteristics and Incidence of Adverse Events Reported Immediately After Osteopathic Manipulative Treatment (N=1847 office visits)

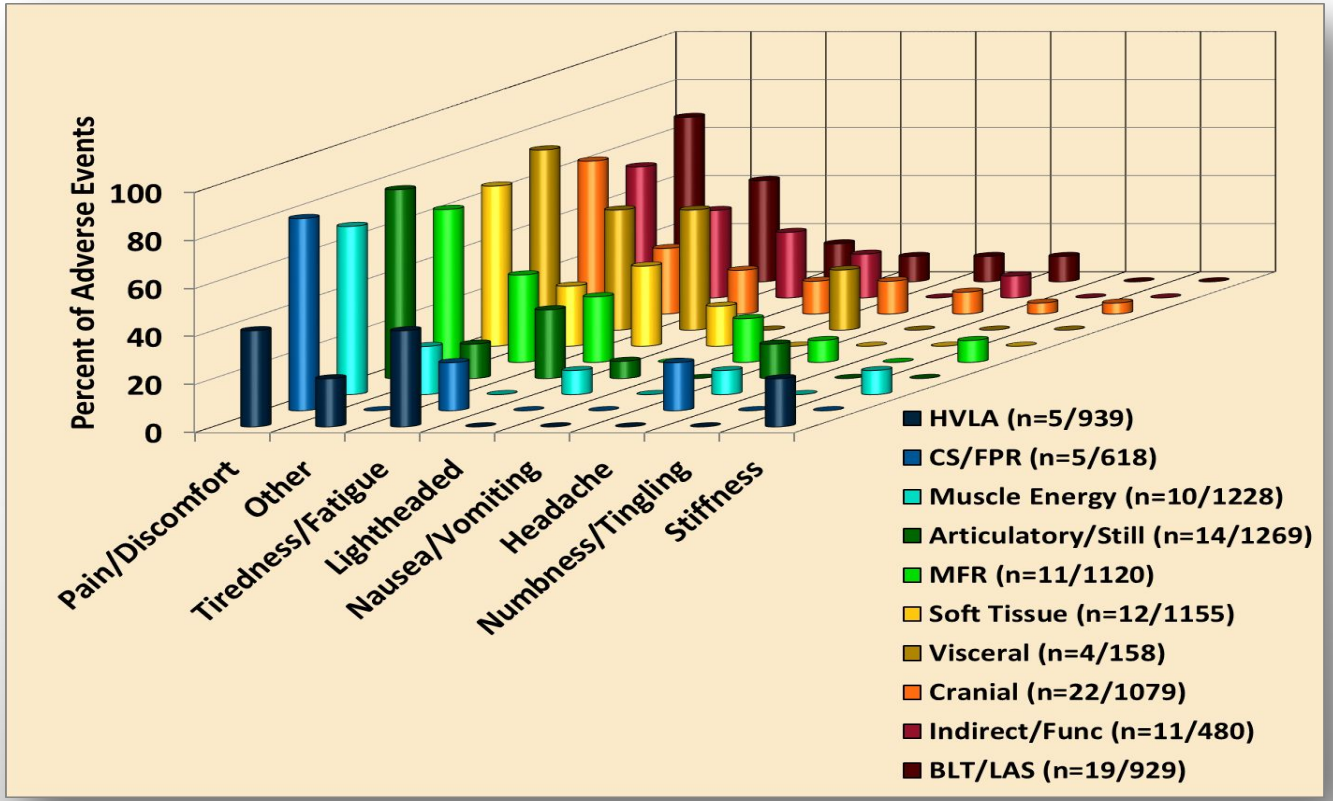
Demographic Variable	Adverse Event (n=45)	No Adverse Event (n=1802)	OR (95% CI)	*P* Value
Gender, No. (%) female[a]	44 (97.8)	1380 (76.9)	13.9 (1.7-115.6)[b]	.01
Race/ethnicity, No. (%)[c] other	2 (4.4)	144 (8.1)	0.6 (0.1-4.8)[d]	.61
Age, y, mean (SD)[e]	46.8 (16.3)	51.2 (14.5)	0.8 (0.5-1.3)[f]	.35

[a] Seven participants chose not to provide their gender; none had an adverse event.
[b] OR comparing female with male patients.
[c] Twenty-four participants chose not to provide their race and/or ethnicity; none had an adverse event.
[d] OR comparing other race/ethnicity patients with white patients.
[e] Twenty-two participants chose not to provide their age; none had an adverse event.
[f] OR comparing the change in odds for a 10-year increase in age.

Immediate AE



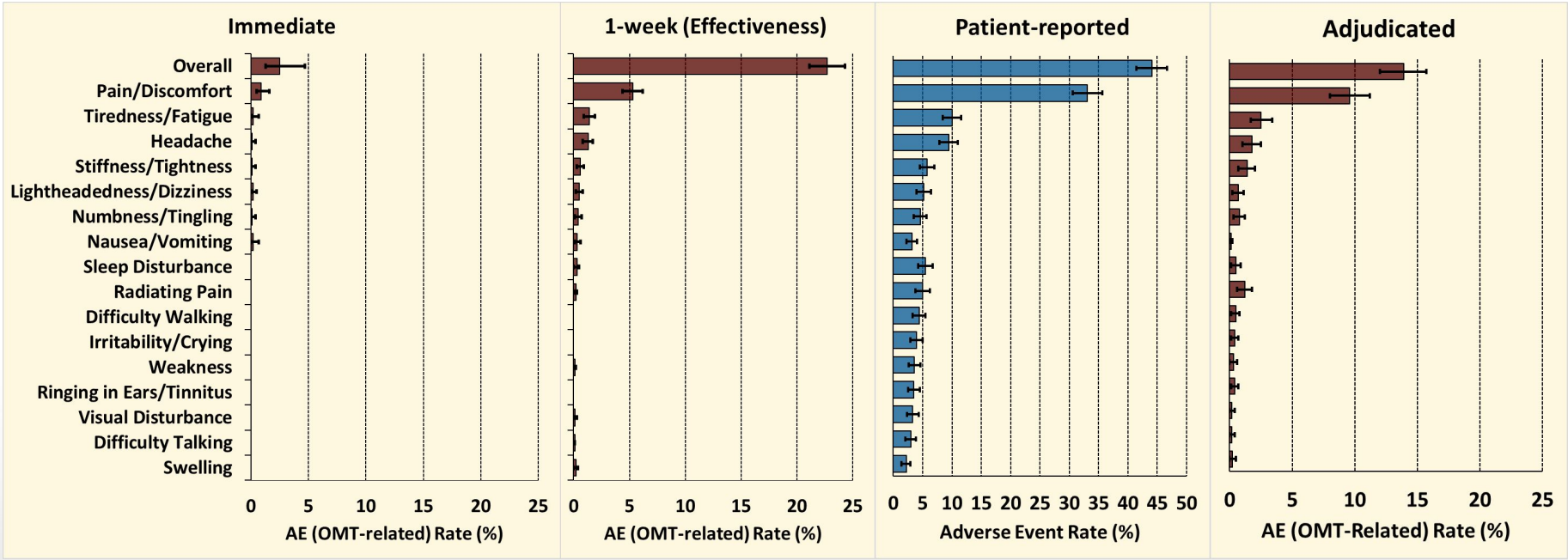
Immediate AE - *Techniques and Types of AEs*



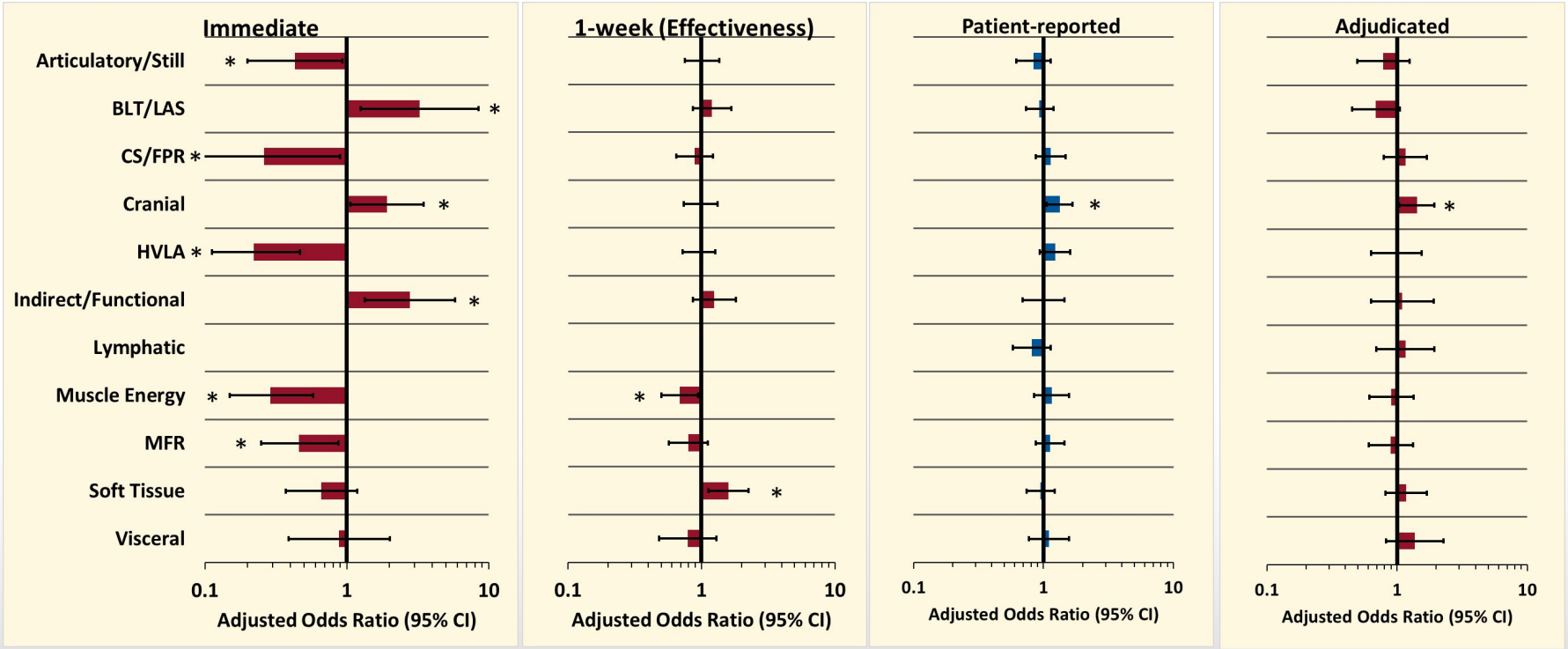
Adjudicated AE

- 1303 patients participated, 899 from the US and 404 from Germany
- 541 (42%) patients had 1 or more AEs during week after OMT
- Adverse Event Rate: 41.5% (38.9%-44.2%)
- Adverse Event (OMT-Related) Rate: 13.9% (12.0%-15.7%)
  - Only 1 patient report of healthcare usage (a return visit to the treating clinician in the office) was an adverse event that was judged to be related to OMT.
- Adverse Event (OMT-Related or Undetermined) Rate: 29.9% (27.4%-32.3%)

Comparison on Adverse Event Rates



Comparison on Effect of Techniques



AE Severity Grading Scale (NCI)

- Common Terminology Criteria for Adverse Events (CTCAE) used for oncology drugs, generally not appropriate for otherwise healthy subjects.
- Grade refers to the severity of the AE
  - **Grade 1** Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; no intervention indicated
  - **Grade 2** Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL
  - **Grade 3** Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL
  - **Grade 4** Life-threatening consequences; urgent intervention indicated.
  - **Grade 5** Death related to AE.

FDA

http://evs.nci.nih.gov/ftp1/CTCAE/About.html

https://www.fda.gov/downloads/training/clinicalinvestigatortrainingcourse/ucm337224.pdf

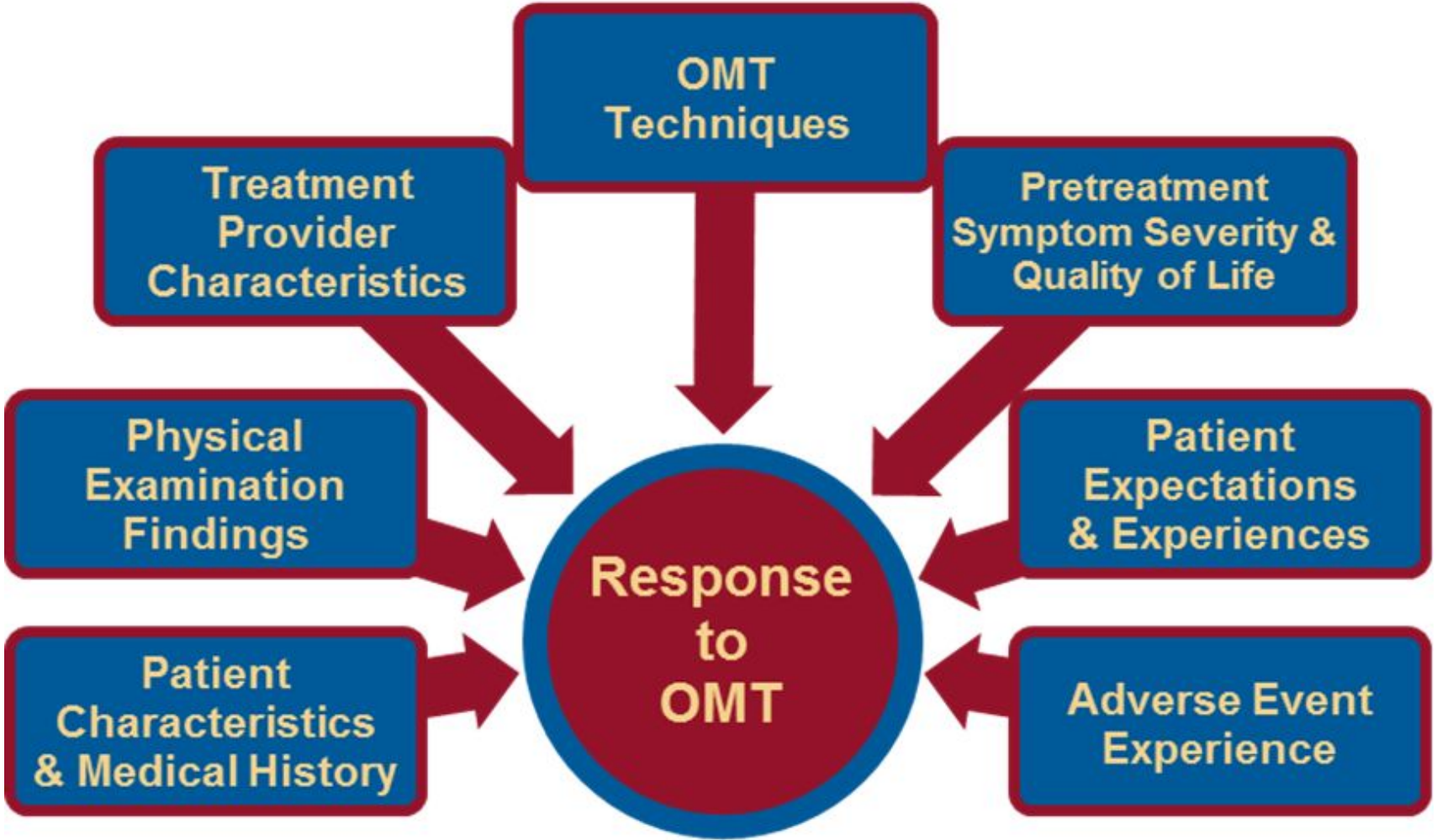
Conclusion

- Consent parameters
- Adverse events occur with all OMTs
- Most common immediate AE tend to fall into one of seven categories
- Immediate AE are infrequent and mild (2.5% rate)
- >80% report feeling better or much better
- Large numbers of office visits are needed to best estimate the incidence of AE following OMT
- Longitudinal data is needed to assess the true impact of OMT

Osteopathic Manipulative Treatment Effectiveness and Safety Patient Registry

Long-term Objective

To help patients and healthcare providers make informed decisions regarding whether OMT would be a beneficial treatment to address patients' healthcare needs.


OMT Techniques
Treatment Provider Characteristics
Pretreatment Symptom Severity & Quality of Life
Physical Examination Findings
Patient Expectations & Experiences
Response to OMT
Patient Characteristics & Medical History
Adverse Event Experience

Response to OMT = PROs

- Change in Problem Severity
- Change in Quality of Life
- Side Effects/Adverse Events
  - Occurrence
  - Severity

Patient-reported Outcomes

Background and Appointment	Pre-OMT (Day -1)	Post-OMT (Day +1)	Post-OMT (Day +3)	Post-OMT (Day +7)

OMT
Effectiveness & Safety
Patient Registry
OESPRY

Exercise

Hands-on experience with OESPRY as a patient

Patient-reported Outcomes

Background and Appointment	Pre-OMT (Day -1)	Post-OMT (Day +1)	Post-OMT (Day +3)	Post-OMT (Day +7)
• Demographics • Reason(s) for Appointment • Patient Expectations	Baseline • Problem Severity • Side Effect Symptom Severity • Quality of Life	Post-treatment • Problem Severity • Side Effect Symptom Severity • Side Effect Cause	Post-treatment • Problem Severity • Side Effect Symptom Severity • Side Effect Cause	Post-treatment • Problem Severity • Side Effect Symptom Severity • Side Effect Cause • Quality of Life

OMT
Effectiveness & Safety
Patient Registry
OESPRY

Implementing PROs

Discussion

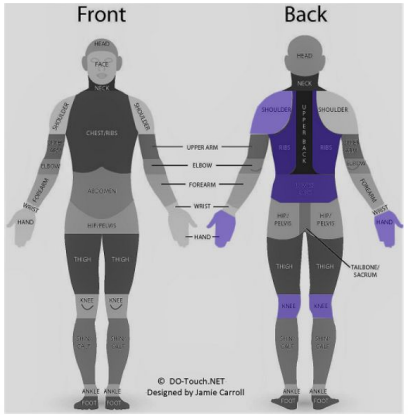
How would you introduce OESPRY into your clinical practice?

Interpreting PROs

- General guidelines
- Cut-off score/levels of severity
- Reference scores
- Follow-up structured interview
- Link to management guidelines
- Comparison to previous scores
- Minimally clinically important difference

Source: Aaronson et al (2015)

PRO Reporting



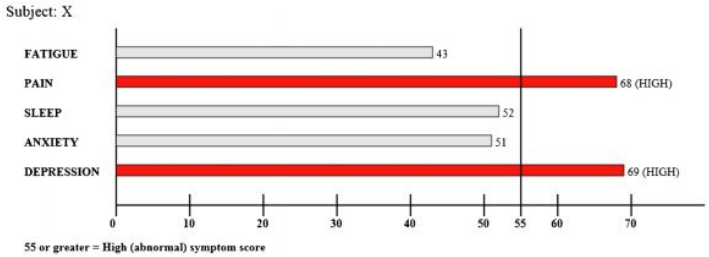
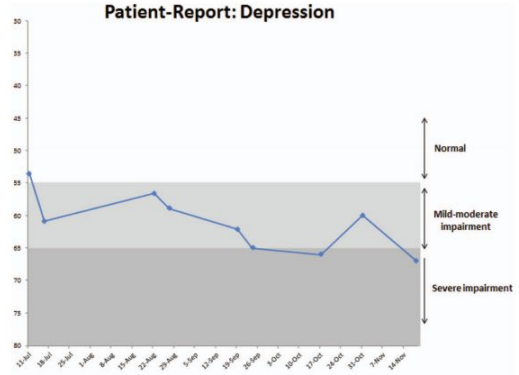
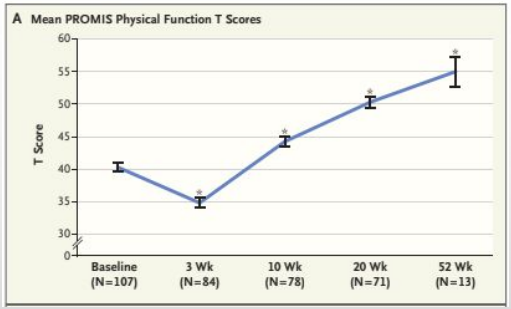
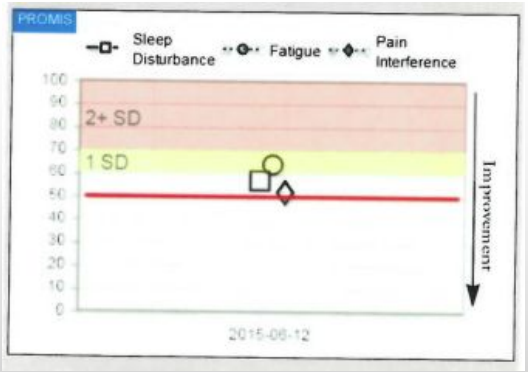


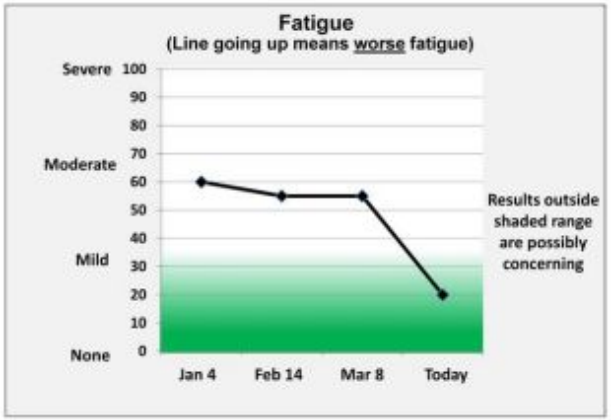
Fig. 1 Visual display of PROMIS symptom scores provided to physicians in feedback group.

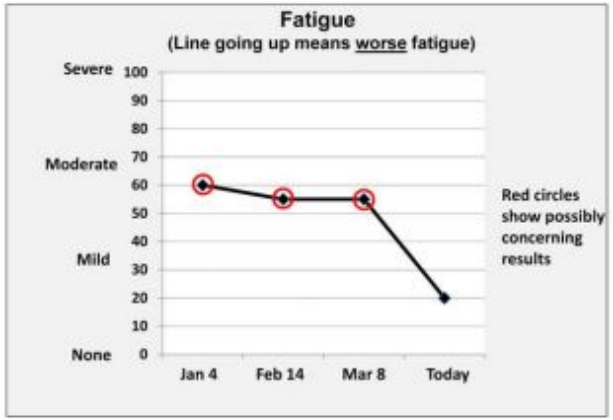






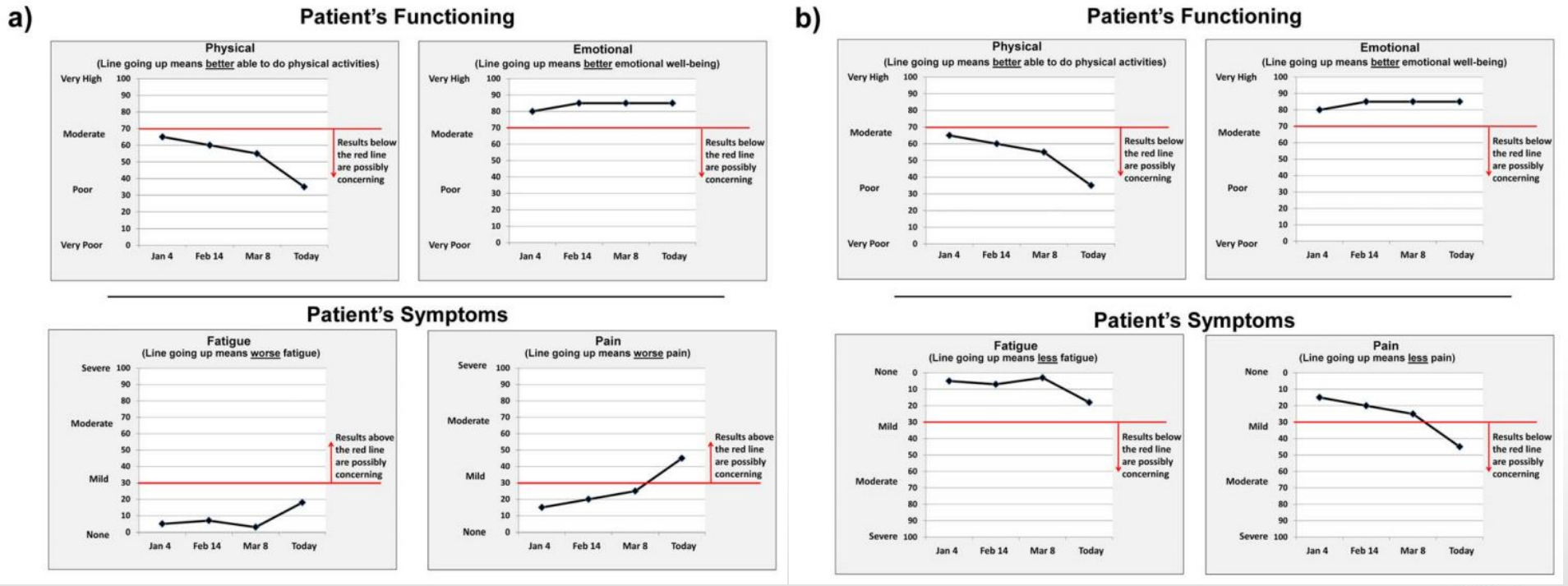
PRO Report Formats





Source: Snyder et al (2017)

PRO Report Formats



Source: Snyder et al (2017)

Discussion

- How can you use PROs to improve two-way communication with your patients?
- How will you respond if your patient's PROs indicate there may be some issue?

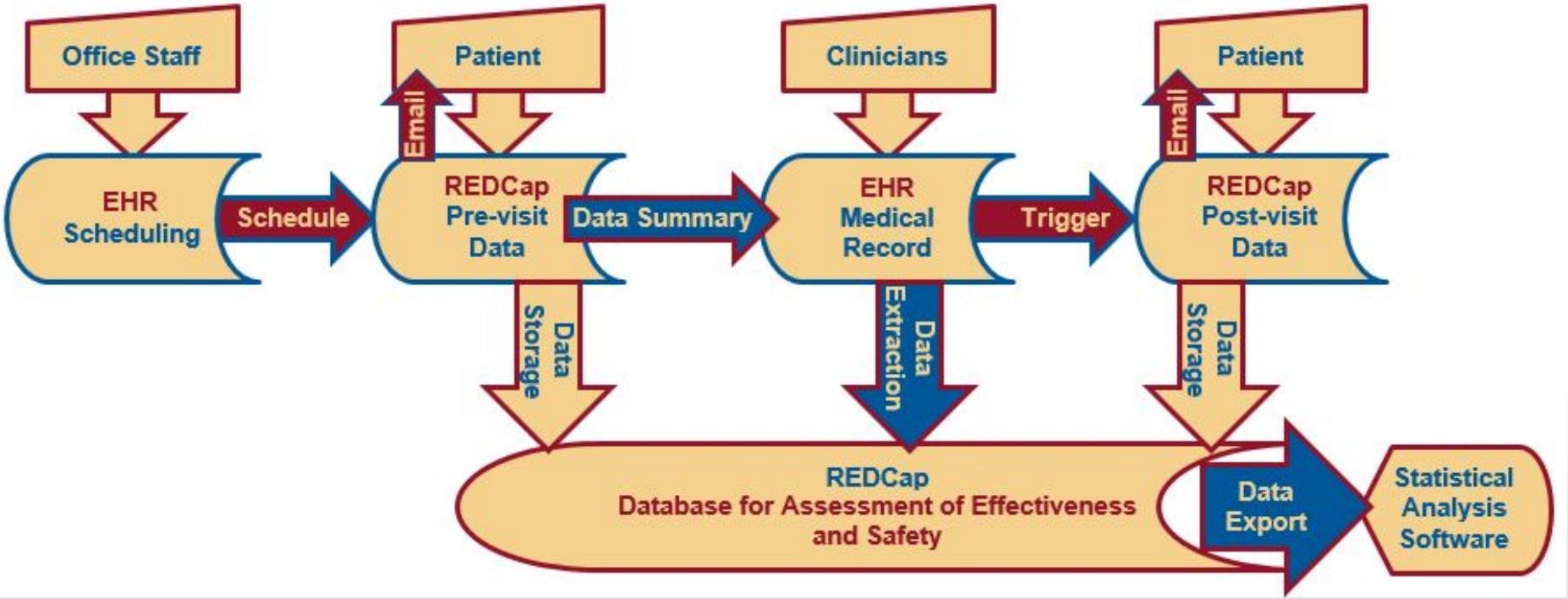
Discussion

- How can you integrate collection of PROs into your clinic workflow?
- What challenges will you need to address?

Future Steps

1. Patient-reported Outcomes report for single appointment available for clinicians
2. Spanish translation and release in USA
3. Adverse event alert/notification to clinician
4. International releases (Germany, Brazil, …)
5. Longitudinal Patient-reported Outcomes report available for clinicians
6. Manual entry of physical examination and treatment data
7. Link with EHRs for:
    a. scheduling
    b. importing PRO report
    c. download physical examination and treatment data
8. Coordinating with researchers on studies including clinical outcomes (eg, biomarkers, functional measures like balance)

The Future of OESPRY



Evidence-based References

- Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, & Snyder C. (2015). *User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice* (Version 2). International Society for Quality of Life Research. https://www.isoqol.org/wp-content/uploads/2019/09/2015UsersGuide-Version2.pdf
- Degenhardt BF, Johnson JC, Brooks WJ, & Norman L. (2018). Characterizing Adverse Events Reported Immediately After Osteopathic Manipulative Treatment. *The Journal of the American Osteopathic Association*, *118*(3), 141–149.
- Degenhardt BF, Johnson JC, Gross SR, Hagan C, Lund G, & Curry WJ. (2014). Preliminary findings on the use of osteopathic manipulative treatment: outcomes during the formation of the practice-based research network, DO-Touch.NET. *The Journal of the American Osteopathic Association*, *114*(3), 154–170.
- Johnson JC & Degenhardt BF. (2019). Who Uses Osteopathic Manipulative Treatment? A Prospective, Observational Study Conducted by DO-Touch.NET. *The Journal of the American Osteopathic Association*, *119*(12), 802–812.
- Korr IM. (1991). Osteopathic research: the needed paradigm shift. The Journal of the American Osteopathic Association, 91(2), 156, 161–168, 170–171.
- Snyder CF, Smith KC, Bantug ET, Tolbert EE, Blackford AL, Brundage MD, & PRO Data Presentation Stakeholder Advisory Board (2017). What do these scores mean? Presenting patient-reported outcomes data to patients and clinicians to improve interpretability. Cancer, 123(10), 1848–1859.
- Snyder C, Smith K, Holzner B, Rivera YM, Bantug E, Brundage M, & PRO Data Presentation Delphi Panel. (2019). Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation*, 28(2), 345–356.
- Tolbert E, Brundage M, Bantug E, Blackford AL, Smith K, Snyder C, & PRO Data Presentation Stakeholder Advisory Board. (2018). Picture This: Presenting Longitudinal Patient-Reported Outcome Research Study Results to Patients. *Medical Decision Making: An International Journal of the Society for Medical Decision Making*, 38(8), 994–1005.