



A.T. STILL

RESEARCH INSTITUTE

A.T. Still Research Institute

Consistent with the tenets of osteopathic medicine, the purpose of the A.T. Still Research Institute is to advance whole person healthcare and wellness through development and support of premier clinical and translational research.



Residency Mentorship Program

- Unifying Postgraduate Education
- ACGME
- New era for osteopathic training and research
- A new era for osteopathic practitioners
- Reimbursement models



Background and Context

- Distinct philosophy and diagnostic/treatment paradigm developed over 120 years
- Expansion of profession partially based on clinical observations and patient reported outcomes
- Research lacking - extremely narrow evidence base
- No systematic objective evaluation of clinical findings, treatment approaches and outcomes
- Efficient use of science is based on astute observations indicating trends or patterns from which hypothesis driven research is created



Clinician – Scientist/Researcher

- Provider of care consistent with the knowledge – current evidence
- Technician



Clinician – Scientist/Researcher

- Provider of care consistent with the knowledge – current evidence
- Discoverer of new knowledge
- Technician



Scientific Process

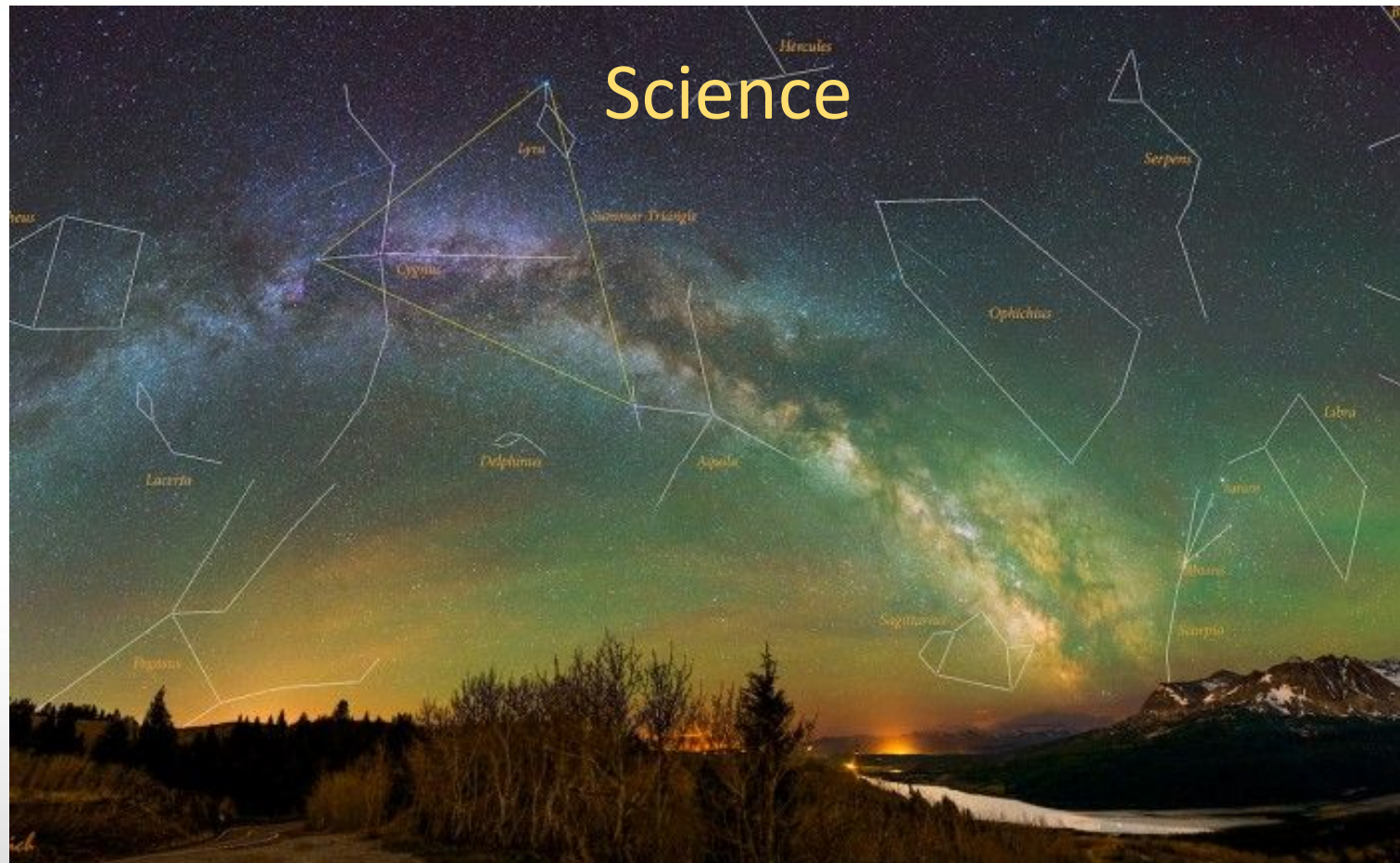


- Organized search of natural phenomena that **continually ... moves carefully along progressive stages** until a level of certainty is reached.

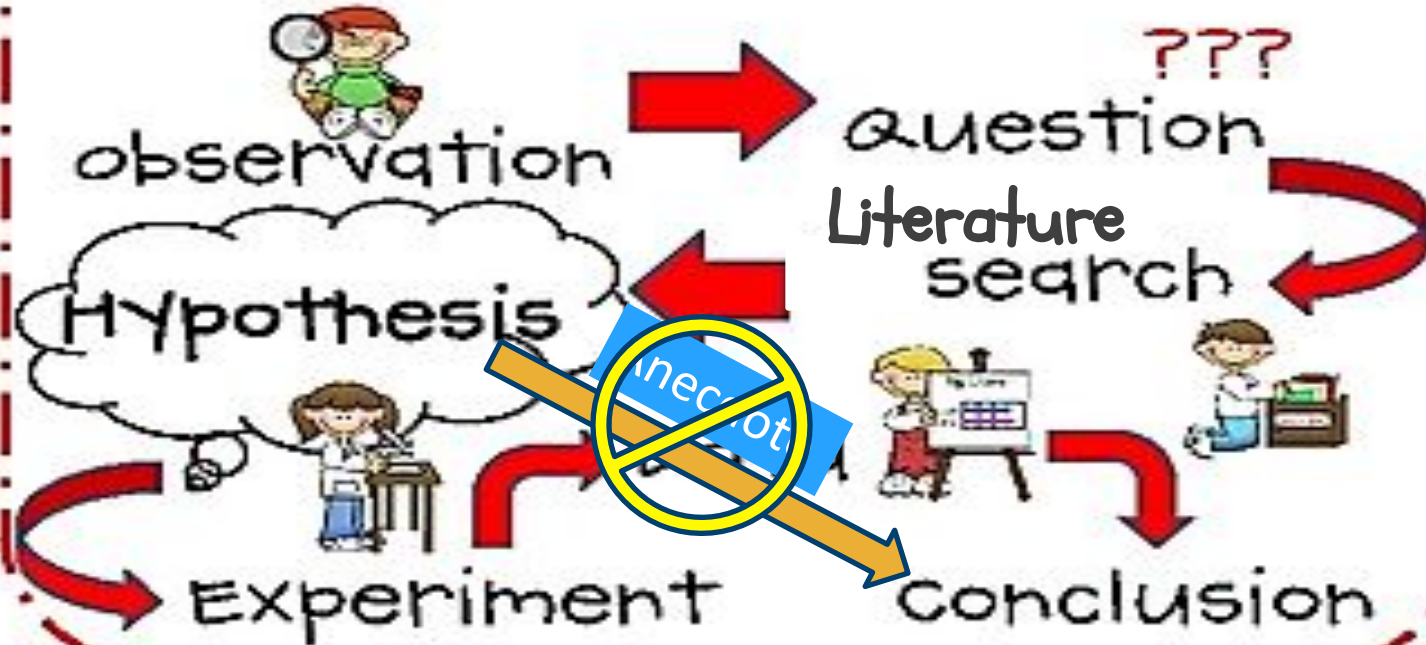
Sir Francis Bacon, 1620 Novum Organum



Science






The Scientific Method



The Scientific Method

observation 

question 
Literature 
search 

Hypothesis 

Experiment 


Data 

conclusion 


21st Century
Clinician Scientist 

DO-Touch.NET 



Caring for Patients – Historical Considerations

- James Mackenzie, Will Pickles, John Fry, F. J. A. Huygen, and Curtis G. Hames, William Johnston.
- Pioneers demonstrated that important new knowledge can be discovered by practicing family physicians.
- All wondered about their patients' problems, and developed a systematic means of gathering, recording, and aggregating data on their patients.



Common Physician Perspective

- of practitioners who study their patients' conditions with rigor
 - “I had not been long in the practice when I discovered how defective was my knowledge. I left college under the impression that every patient's condition could be diagnosed. For some years I thought that this inability to diagnose my patients' complaints was due to personal defects. But gradually, through consultations and other ways, I came to recognize that the kind of information I wanted did not exist.”

James Mackenzie, MD



Practice-Based Research Networks

- Expanding the impact of clinicians who are astute observers with a critical attention to clinical details.
- Provides an environment for important new knowledge, not otherwise accessible, to be discovered by practicing physicians
- Creates an infrastructure for acquiring, analyzing and interpreting data as a by-product of basic clinical operations.





DO-Touch.NET

A Network of Doctors Treating with OMM

- **D**octors of **O**steopathy
Treating with **O**MM - **U**sefulness in
Current **H**ealthcare

Precision/Personalized Medicine

- “an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.”
- tailoring **medical** treatment to the individual characteristics of each patient ...
- **personalized medicine** is sometimes misinterpreted as completely individualized treatments are available for every unique patient



What are Patient-reported Outcomes and Patient-reported Outcome Measures?

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. distinguish between patient-reported outcomes and clinical outcomes,
2. describe how patient-reported outcome measures are developed, and
3. identify patient-reported outcomes which could be useful in their clinical practice.



Clinical Outcomes

- Objective (relatively)
- Examples
 - mortality
 - biomarkers
 - blood pressure
 - number of infarcts
 - work days missed
 - somatic dysfunction diagnosis



Osteopathic Research

“[Research d]esigns are required that assess the effect of treatment not merely on the presenting complaint, dysfunction, or disease, but the impact of treatment on the total person and the person's ability to carry on, with adequate reserve, the functions that are important to him or her.” - Korr (1991)



Patient-reported Outcome (PRO)

“Any information on the outcomes of health care obtained directly from patients without modification by clinicians or other health care professionals. ... we use this term broadly to include any patient input, whether or not it is standardized or gathered with a structured questionnaire.” - Cella et al (2015)



PRO Measure (PROM)

“Any standardized or structured questionnaire regarding the status of a patient’s health condition, health behavior, or experience with health care that comes directly from the patient (i.e., a PRO). The use of a structured, standardized tool such as a PROM will yield quantitative data that enables comparison of patient groups or providers.” - Cella et al (2015)



Measuring PROs

- Source of report
 - Self
 - Proxy



Measuring PROs

- Mode of Administration
 - Self
 - Interview



Measuring PROs

- Setting of Administration
 - Clinic
 - Home
 - Other



Measuring PROs

- Method of Administration
 - Paper-and-pencil
 - Electronic



Measuring PROs

- Administration Format and Scoring
 - Classical
 - Short-form
 - Computerized Adaptive Testing (CAT)



Development of a PROM

1. Generate a list of relevant issues
2. Convert list of issues into questions
3. Pre-test
4. Field-test
5. Psychometric testing



Types of PROs

- Health-related quality of life
- Functional status
- Symptoms and symptom burden
- Health behaviors
- Patient experience



Health-related Quality of Life

- Multidimensional
 - physical, social, emotional well-being
- Examples
 - Generic (eg, SF-36, Sickness Impact Profile)
 - Health utility/preference measures (eg,)
 - Chronic illness (eg, Neuro-QOL)
 - Specific disease or treatment (eg, EORTC QLQ-C30)



Functional Status

- Ability to perform basic and advanced activities of daily life
 - physical function, cognitive function, sexual function
- Examples
 - Specific type of function (eg, Upper Limb Functional Index)
 - Specific disease population (eg, PAQLQ)
 - Chronic conditions (eg,)



Symptoms and Symptom Burden

- Presence and intensity of symptoms
- Examples
 - Severity (eg, pain intensity Visual Analogue Scale)
 - Impact (eg, PROMIS Pain Interference)
 - Burden (eg, Functional Assessment of Chronic Illness Therapy - Fatigue scale)



Health Behaviors

- Monitor risk behaviors and assess response to health promotion interventions
- Examples
 - Health risk assessment (eg, Personal Wellness Profile, Insight Health Risk Appraisal Survey)
 - Large-scale (eg, BRFSS, NHANES)
 - Health-promotion behaviors (eg, SHAPES, Morisky Medication Adherence Scale)



Patient Experience of Care

- Related to perceived needs, expectations of care, and experience of care
- Examples
 - Satisfaction (eg,)
 - Motivation and activation (eg, PAM)
 - Reports of experiences (eg, CAHPS project)



Exercise

What types of patient-reported outcomes could be useful in your clinical practice?

- Patient population
- Health issues you address
- Information you need outside of physical examination and lab tests



Discussion



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>
- Cella DF, Hahn EA, Jensen SE, Butt Z, Nowinski CJ, Rothrock N, & Lohr KN. (2015). *Patient-reported outcomes in performance measurement* (Vol. 97). RTI Press Research Triangle Park, NC.
- Fayers PM & Machin D. (2016). *Quality of life: The assessment, analysis and reporting of patient-reported outcomes*. John Wiley & Sons.
- Korr IM. (1991). Osteopathic research: the needed paradigm shift. *The Journal of the American Osteopathic Association*, 91(2), 156, 161–168, 170–171.
- Refolo P, Minacori R, Mele V, Sacchini D, & Spagnolo AG. (2012). Patient-reported outcomes (PROs): the significance of using humanistic measures in clinical trial and clinical practice. *European Review for Medical and Pharmacological Sciences*, 16(10), 1319–1323.

