Outcomes in Orthopaedic Trauma

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Outline

- History
- Types of Outcomes
  - Surgeon Reported vs. Patient Reported
  - Generic Quality of Life vs. Disease/Joint Specific
- How to evaluate an outcome tool
  - Validation, Reliability & Responsiveness
- Value & Policy
  - Bundled Payment, Complications and DRGs
- Sample PRO Protocol

History

- Ernest Codman
  - Radical concept of understanding the effect of medical and operative treatment on patient function
  - 1910 developed the idea of: “End Results”

“The common sense notion that every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire, ‘If not, why not?’ with a view to preventing similar failures in the future”

Dr. Codman 1869–1940
Portrait from The Boston Medical Library in the Francis A. Countway Library of Medicine

Brand, Richard A. "Ernest Amory Codman, MD, 1869–1940. CORR. 2009. 467.11: 2763-2765.

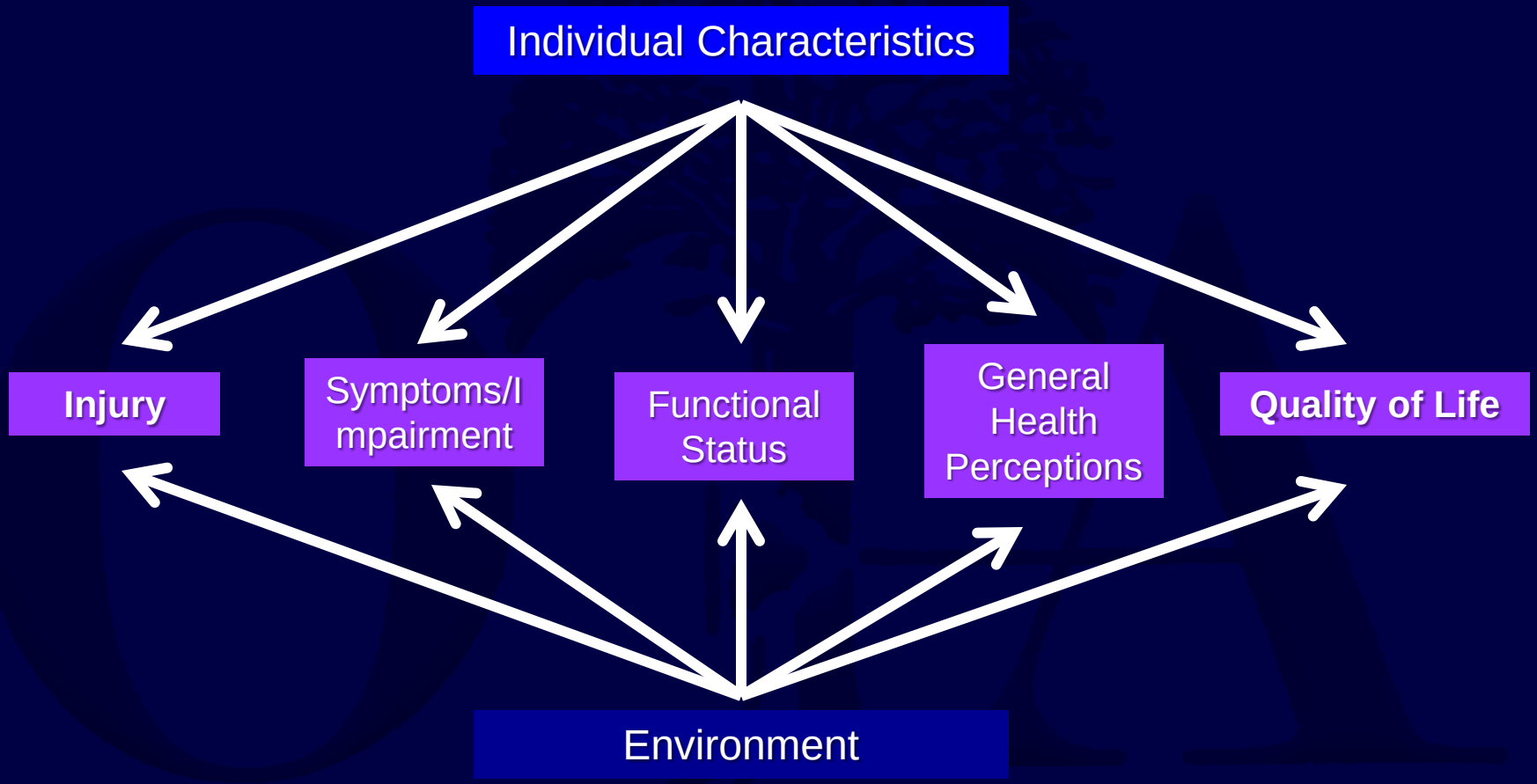
History

Wilson and Cleary

- Proposed a classification scheme for different measures of health outcomes
- They conceptualized five levels of outcomes:
  1) biological and physiological variables
  2) symptom status
  3) functional status
  4) general health perceptions
  5) overall quality of life
- Interest grows in PROs over the next 25 years.

Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life: A conceptual model of patient outcomes. JAMA. 1995;273:60
Bayley KB, London MR, Grunkemeier GL, Lansky DJ. Measuring the success of treatment in patient terms. Med Care 1995; 33: AS226-AS235

History



Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life: A conceptual model of patient outcomes. JAMA. 1995;273:60

History

Interest grows in the orthopaedic community

- Addressed the transition from clinical outcomes
  - Traditionally gold standard

  Examples: infection or dislocation rate, range of motion
- to functional outcomes
  - Validated questionnaires

  Examples: KOOS, SFMA, DASH

Two important papers highlight this transition

- *The outcomes movement in orthopaedic surgery: where we are and where we should go. JBJS. 1999.*
- *Outcome instruments: rationale for their use. JBJS. 2009.*

History

Symposium

The Outcomes Movement in Orthopaedic Surgery: Where We Are and Where We Should Go

"Clinical outcomes remain important as distinct measures of the success of orthopaedic interventions, however they should be accompanied by an assessment of functional outcomes"

Swiontkowski MF, Buckwalter JA, Keller RB, Haralson R. The outcomes movement in orthopaedic surgery: where we are and where we should go. JBJS Am. 1999;81:732-40.

History

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Outcome Instruments: Rationale for Their Use

By Rudolf W. Poolman, MD, PhD, Marc F. Swiontkowski, MD, Jeremy C.T. Fairbank, MD, FRCS, Emil H. Schemitsch, MD, FRCSC, Sheila Sprague, MSc, and Henrica C.W. de Vet, PhD

"Clinical outcomes can be subject to interrater disagreement and they often do not provide definitive answers about whether an intervention is useful from a patient's perspective….. Well-designed patient-reported instruments that have undergone rigorous testing and may be better validated and have greater reproducibility than the so-called objective or clinical outcomes."

Poolman, Swiontkowski, Fairbank, Schmeitsch, Sprague and de Vet. Outcome instruments: rationale for their use. JBJS Am. 2009. 91;3:41-49.

Outcome Measures

Clinical Outcomes

- Objective data from examination or clinical course
  - Example: infection or dislocation rate, range of motion, radiographic alignment.

Surgeon Reported

- Outcomes scored by surgeon based on validated set of clinical and/or radiographic criteria.
  - Example: Mayo Elbow Performance Score, Merle d'Aubigne

Patient Reported

- Outcomes reported by patient using a validated patient reported outcome (PRO) tool.
  - Example: DASH, SMFA, KOOS, AAOS Lower Extremity, PROMIS

Mixed

- Surgeon and Patient reported components
  - Example: ASES, AOFOS, Harris Hip Score

Patient Reported Outcomes

Patient-reported outcomes have several advantages vs. surgeon reported assessments:

1) Assessment of the patient's perception of their condition
2) Elimination of clinician observation bias
3) Ease of completion via telephone, mail, email
4) No physical examination
5) Can be completed outside the office
5) Cost-effectiveness
6) Less time required to administer

Patient Reported Outcomes

Disease or Joint specific

- Outcomes tool designed to evaluate a specific region or disease process.

  Example: ASES = shoulder and elbow injuries

  WOMAC = Osteoarthritis

General Quality of life

- Outcomes tool designed to evaluate the overall health and quality of life of the patient.

  Example: SF36, EQ5D, PROMIS, SIP

Disease Specific

- A disease-specific instrument is designed to focus on the concerns associated with a specific disease state.
- In orthopaedic trauma this represents an important component to specifically evaluate an area of interest and remove influence of other systems' pathology.
  - Example: Tibial plateau fracture treated with ORIF in a patient who also had pulmonary contusion, rib fractures and an exploratory laparotomy.
- Generic instruments take all of those injuries into account to provide an overall quality of life score.

PRO in Trauma

The impact of residual angulation on patient reported functional outcome scores after non-operative treatment for humeral shaft fractures

Edward Shields*, Leigh Sundem, Sean Childs, Michael Maceroli, Catherine Humphrey, John P. Ketz, Gillian Soles, John T. Gorczyca

- Does angular deformity effect PROs in non-op humeral shaft fractures.
- 32 patients completed DASH, Simple Shoulder Test (SST) and SF-12 physical component summary (SF-12 PCS) and mental component summary (SF-12 MCS). Healed angular deformity was measured.
- There was no correlation between residual sagittal or coronal plane deformity and outcome scores. Patients with >20° of healed coronal deformity had similar outcomes to those <20° .

Conclusion: Residual angular deformity had no correlation with patient reported DASH scores, SST scores, or patient satisfaction. Instead, overall physical and mental health status as measured by the SF-12 significantly correlated with patient reported outcomes.

Shields, Sundem, Childs, Maceroli, Humphrey, Ketz, Soles and Gorczyca. The impact of residual angulation on patient reported functional outcome scores after non-operative treatment for humeral shaft fractures. Injury. 2015 Dec 23.

PRO in Trauma

Patient-Reported Outcome Measures for Hand and Wrist Trauma: Is There Sufficient Evidence of Reliability, Validity, and Responsiveness?

Peter Jonathan Dacombe[1], Rouin Amirfeyz[1], and Tim Davis[2]

- Systematic review of the reliability, validity, and responsiveness of PROMs used in hand and wrist trauma patients.
- **Results:** The PROM used most often was the Disabilities of the Arm, Shoulder & Hand (DASH); the Patient-Rated Wrist Evaluation (PRWE), Gartland & Werley score, Michigan Hand Outcomes score, Mayo Wrist Score, and Short Form 36 were commonly used.
- Only the DASH & PRWE have evidence of reliability, validity, and responsiveness in patients with traumatic injuries to the hand and wrist

Conclusions: Only The DASH and PRWE have evidence of reliability, validity, and responsiveness in the hand and wrist trauma population.

Dacombe, Amirfeyz and Davis. Patient-Reported Outcome Measures for Hand and Wrist Trauma Is There Sufficient Evidence of Reliability, Validity, and Responsiveness?. Hand. 2016. 11:1; ***11-21***

PRO in Trauma

What Outcomes Are Important for Patients After Pelvic Trauma? Subjective Responses and Psychometric Analysis of Three Published Pelvic-Specific Outcome Instruments

Kelly A. Lefaivre, MD, MSc, FRCSC, Gerard P. Slobogean, MD, MPH, FRCSC, Jacqueline T. Ngai, MD, MSc, PhD, Henry M. Broekhuyse, MD, FRCSC, and Peter J. O'Brien, MD, FRCSC

- Evaluate pelvic PRO to test the construct validity, respondent burden, floor & ceiling effects, and patient perception of previously published pelvic outcome questionnaires.
- Majeed Pelvic Score, Orlando Pelvic Score, Iowa Pelvis Score, Short Form-36 & SMFA.
- 38 surgically treated OTA type B and C pelvic ring disruption at 12 months follow up

Conclusion: All 3 PRO instruments have strong construct validity based on correlation with the Physical Component Score of the SF-36 and SMFA. Subjects identified mental and emotional outcomes as important consequences of their injury; however all PROs correlated poorly with the Mental Component Score of the SF-36. Ceiling effects limit the utility of the all 3 current instruments, and their reliability and responsiveness over time remain unknown.

LeFaivre, et al. What outcomes are important for patients after pelvic trauma? Subjective responses and psychometric analysis of three published pelvic –specific outcomes instruments. J Orthop Trauma 2014 Jan: 28(1): 23-7

Generic Quality of Life

- Health-related quality of life (HRQOL):
  - the value assigned to duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy
- Generic instruments provide a composite measure of all positive and negative effects of an intervention on quality of life.
- Allow “apples to apples” comparisons

Shearer and Morshed. Common generic measures of health related quality of life in injured patientsInjury, Int. J. Care Injured 42 (2011) 241–247

PROMIS


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Dynamic Tools to Measure Health Outcomes from the Patient Perspective
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Patient Reported Outcomes Measurement Information System (PROMIS), funded by the National Institutes of Health (NIH), is a system of highly reliable, valid, flexible, precise, and responsive assessment tools that measure patient–reported health status.
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What Patient Reported Outcomes (PROs) Are
PROMIS Measures

PROMIS

Mission

- PROMIS® uses measurement science to create a state-of-the-art assessment system for self–reported health.

Vision

- The Patient–Reported Outcome Measurement Information System (PROMIS®), funded by the National Institutes of Health, aims to provide clinicians and researchers access to efficient, precise, valid, and responsive adult– and child–reported measures of health and well–being.

PROMIS

Item response theory (IRT):

- IRT is a psychometric method commonly used in educational testing, but more recently adopted by the field of health outcomes. Statistical models based on IRT produce scores associated with answers to questions.

Computer Adaptive Testing (CAT):

- CAT is an algorithm that utilizes the IRT calibrations to select the most informative follow-up question to an initial question. The content of the assessment, that is the questions that are asked, adapts to the patient based on his or her responses to the previous question. Allows faster administration of question sets.

PROMIS

OTA Highlight Paper

Computerized Adaptive Testing Using the PROMIS Physical Function Item Bank Reduces Test Burden With Less Ceiling Effects Compared With the Short Musculoskeletal Function Assessment in Orthopaedic Trauma Patients

Man Hung, PhD, Ami R. Stuart, PhD, Thomas F. Higgins, MD, Charles L. Saltzman, MD, and Erik N. Kubiak, MD

- Study, we compared the SMFA versus the PROMIS PF CAT for 153 trauma patients.
- Mean administration time for PROMIS PF CAT was 44 vs. 599 seconds for sMFA
  - ($P < 0.05$).
- SMFA revealed 14.4% ceiling effect while thePROMIS PF CAT did not.

Conclusions: PROMIS PF CAT required less than one-tenth the amount of time for patients to complete than the sMFA while achieving equally high reliability and less ceiling effects. The PROMIS PF CAT is a very attractive and innovative method for assessing patient-reported outcomes with minimal burden to patients.

Hung M, Stuart AR, Higgins TF, Saltzman CL, Kubiak EN. Computerized Adaptive Testing Using the PROMIS Physical Function Item Bank Reduces Test Burden With Less Ceiling Effects Compared With the Short Musculoskeletal Function Assessment in Orthopaedic Trauma Patients. Journal of orthopaedic trauma. 2014 Aug 1;28(8):439-43.

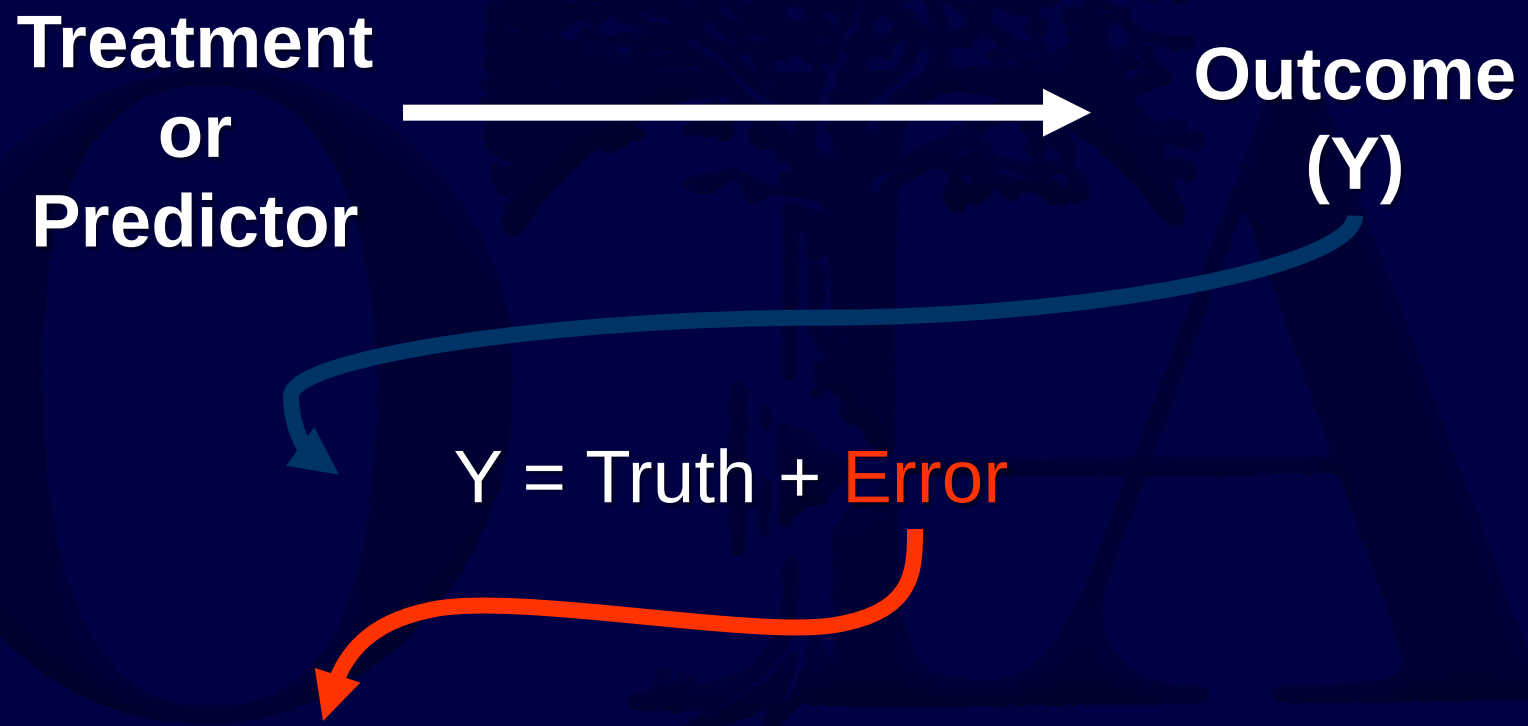
How to evaluate an outcome tool

1. **Validity** (i.e. it measures what it says it does)
   - A function of ***systematic error***.

2. **Reliability** (i.e. it will reveal the same result consistently)
   - A function of ***random error***.

3. **Responsiveness** (i.e. it can detect meaningful increments of change)

Measurement



Validation is one of those words that is constantly used and seldom defined. . .

- Alvin Feinstein, Yale University

Validity

Is the scale measuring what it is intended to measure?

Three main types of validity testing:

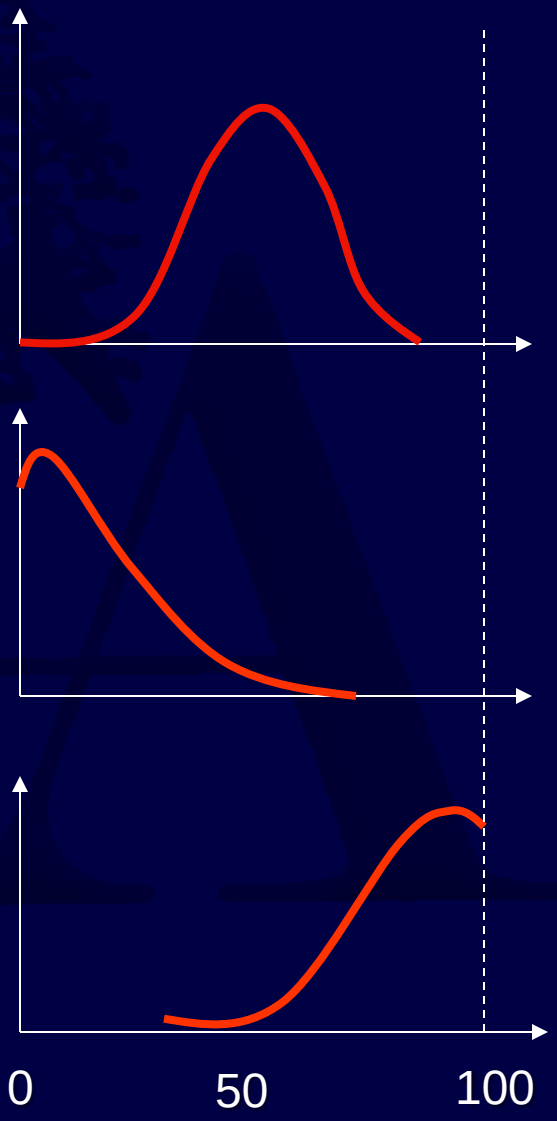
- Content validity
- Criterion-related validity
- Construct validity

Content validity

How well does the measure cover the domain of interest ?

Example: MFA

- Adequacy and completeness reviewed by academic experts and community based orthopaedic physicians
- “Floor” or “ceiling” effects were assessed



*Martin et al. J Orthop Res **14**:173-181*

Criterion Validity

How well does the measure of interest correlate with a gold standard or well-established measure of the characteristic?

Example: MFA

- Instrument was tested against physicians' ratings (11-point scale of dysfunction) and clinical measures (grip strength, walking speed, etc). Adequate correlations were reported (Spearman's rho >0.4 and $p<0.001$).

*Martin et al. J Orthop Res **14**:173-181*

Construct Validity

How well does the measure quantify some unobservable construct or hypothesis?

Examples: MFA

- Hypotheses that patients with worse clinical presentation would score higher on MFA (correlations and ANOVA reported)
- Convergent and discriminant validity against other health status measures were assessed (i.e.: SF-36, WOMAC)

*Martin et al J Orthop Res **14**:173-181, 1996*
Martin et al J Bone Joint Surg 79: 1323-35, 1997

Reliability

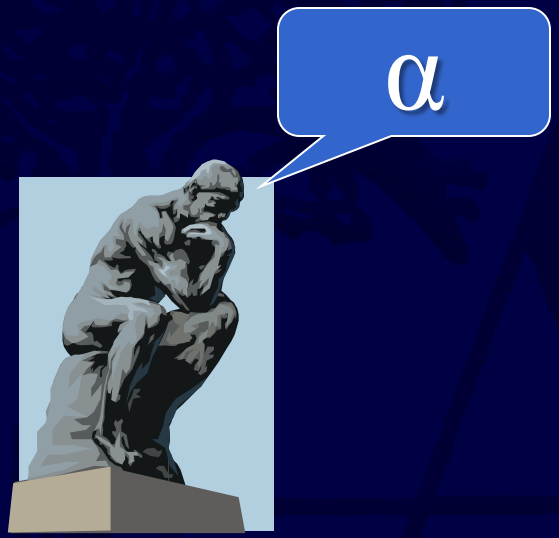
Is the measure consistent or stable across time, patients or observers?

Three main types of reliability testing:

- Internal consistency
- Test-retest reliability
- Inter-rater reliability

Internal Consistency

Are the items in the scale homogenous?



Example: MFA

- Cronbach's alpha analysis used to assess internal consistency for the total survey (100 questions) and for 10 categories across all disease groups.

*Martin et al. J Orthop Res **14**:173-181*

Test-retest Reliability

Does the same test given at different time points yield similar results?

Example: MFA

- A sample of patients repeated the same instrument 5-8 days after initial administration. Percentage agreement, Spearman's rho and intra-class correlation were calculated.

*Martin et al. J Orthop Res **14**:173-181, 1996*

Martin et al J Bone Joint Surg 79: 1323-35, 1997

Inter-rater Agreement

To what degree is there agreement between observers taking into account the proportion of responses that are expected by chance?

		Observer A	
		Healed	**Not Healed**
Observer B	**Healed**	**+/+**	**+/-**
	Not Healed	**-/+**	**-/-**

Kappa

Responsiveness

- How well are meaningful clinical changes detected?

Example: MFA

- Compare categories of SF-36 and MFA with similar items using standardized response means and relative efficiency statistic.

Martin et al. J Bone Joint Surg 79: 1323-35, 1997

Outcomes in Healthcare Policy

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

DECEMBER 23, 2010

What Is Value in Health Care?

Michael E. Porter, Ph.D.

Michael Porter. What Is Value in Health Care? New England Journal of Medicine. 2010

Value in Healthcare

Value in healthcare = $\frac{\text{Outcomes}}{\text{Dollar Spent}}$

Michael Porter. What Is Value in Health Care? New England Journal of Medicine. 2010

Bundle Payment

Relationship between the Charlson Comorbidity Index and cost of treating hip fractures: implications for bundled payment

Daniel J. Johnson · Sarah E. Greenberg · Vasanth Sathiyakumar · Rachel Thakore · Jesse M. Ehrenfeld · William T. Obremskey · Manish K. Sethi

- The aim of this study is to investigate how the Charlson Comorbidity Index (CCI) scores effects length of stay (LOS) and healthcare costs in hip fracture patients.
- 615 operatively treated hip fracture patient were evaluated for CCI, LOS & cost.
- Each unit increase in the CCI score corresponded to an increase in length of hospital stay and hospital costs. Patients with a CCI score of 2 (compared to a baseline CCI score of 0), on average, stayed 1.92 extra days in the hospital, and incurred $8,697.60 extra costs.

Conclusion: The CCI score is associated with length of stay and hospital costs incurred following treatment for hip fracture. The CCI score may be a useful tool for risk assessment that can be applied to bundled payment plans.

Johnson et al. Relationship between the Charlson Comorbidity Index and cost of treating hip fractures: implications for bundled payment. Journal of Orthopaedics and Traumatology. 2015 Sep 1;16(3):209-13.

Outcomes and Policy

Variation in Resource Utilization for Patients With Hip and Pelvic Fractures Despite Equal Medicare Reimbursement

Andre M. Samuel BBA, Matthew L. Webb AB, Adam M. Lukasiewicz MSc, Bryce A. Basques MD, MHS, Daniel D. Bohl MD, MPH, Arya G. Varthi MD, Joseph M. Lane MD, Jonathan N. Grauer MD

- DRG 536 (fractures of the hip and pelvis) includes a broad spectrum of patients. The purposes of the study were to determine whether (1) inpatient length of stay; (2) ICU stay; and (3) ventilator time differ among subpopulations
- A total of 56,683 patients, 65 years or older, with fractures of the hip or pelvis were identified inpatient length of stay, intensive care unit (ICU) stay, and ventilator time were compared
- After controlling for patient and hospital factors, large differences in inpatient length of stay, ICU stay and ventilation days were present between patients with non-operative pelvis fractures, hip fractures, acetabulum fractures and operative pelvic fractures

Conclusion: Hospitals are reimbursed equally for these subgroups of Medicare DRG 536 despite widely variable financial margins and trauma volume therefore re-evaluation of this Medicare Prospective Payment System DRG is warranted.

Samuel AM, Webb ML, Lukasiewicz AM, Basques BA, Bohl DD, Varthi AG, Lane JM, Grauer JN. Variation in Resource Utilization for Patients With Hip and Pelvic Fractures Despite Equal Medicare Reimbursement. CORR. 2016 Feb 25:1-9.

Outcomes and Policy

Adverse Events in Orthopaedics: Is Trauma More Risky? An Analysis of the NSQIP Data

Vasanth Sathiyakumar, BA, Rachel V. Thakore, BS, Sarah E. Greenberg, BA, Paul S. Whiting, MD, Cesar S. Molina, MD, William T. Obremskey, MD, MPH, MMHC, and Manish K. Sethi, MD

- Determine financial risks of bundled payments by identifying adverse event rates for (1) orthopaedic trauma patients vs. general orthopaedic patients (2) compare anatomic region
- A total of 146,773 orthopaedic patients (22,361 trauma) from 2005 to 2011 NSQIP data
- The complication rate in the trauma group was 11.4% vs 4.1% in the general orthopaedic group (P = 0.001). Controlling for all variables, trauma was a risk factor for developing
- Hip and pelvis patients were 4x & lower extremity patients are 3x more likely to develop any complication vs. upper extremity patients

Conclusion: Orthopaedic trauma patients are 2x more likely vs. general orthopaedic patients to sustain complications. Complication rates vary among anatomic regions. Orthopaedic trauma surgeons face increased financial risk with bundled payments.

Sathiyakumar V, Thakore RV, Greenberg SE, Whiting PS, Molina CS, Obremskey WT, Sethi MK. Adverse Events in Orthopaedics: Is Trauma More Risky? An Analysis of the NSQIP Data. Journal of orthopaedic trauma. 2015 Jul 1;29(7):337-41.

Outcomes and Policy

AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

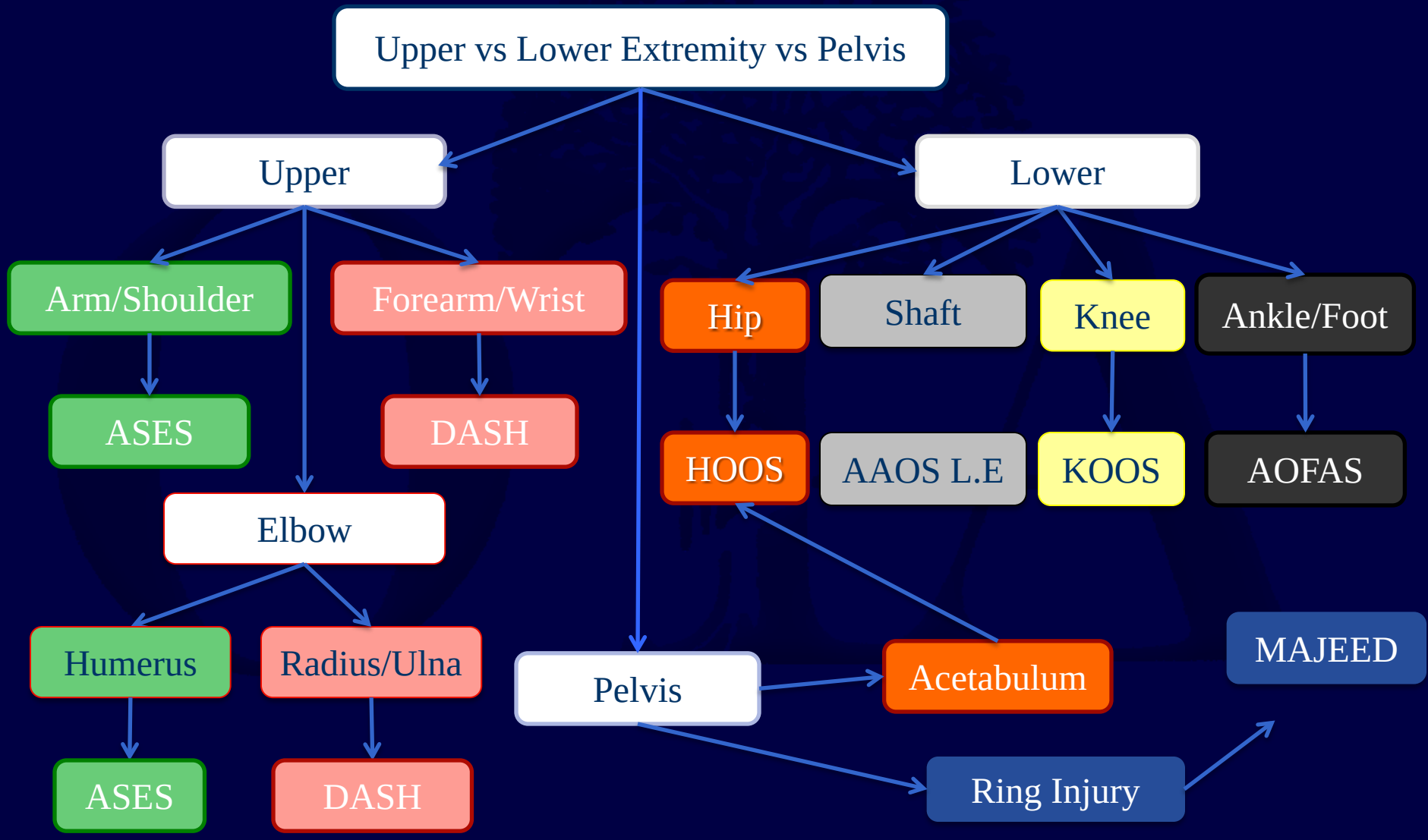
Information Statement

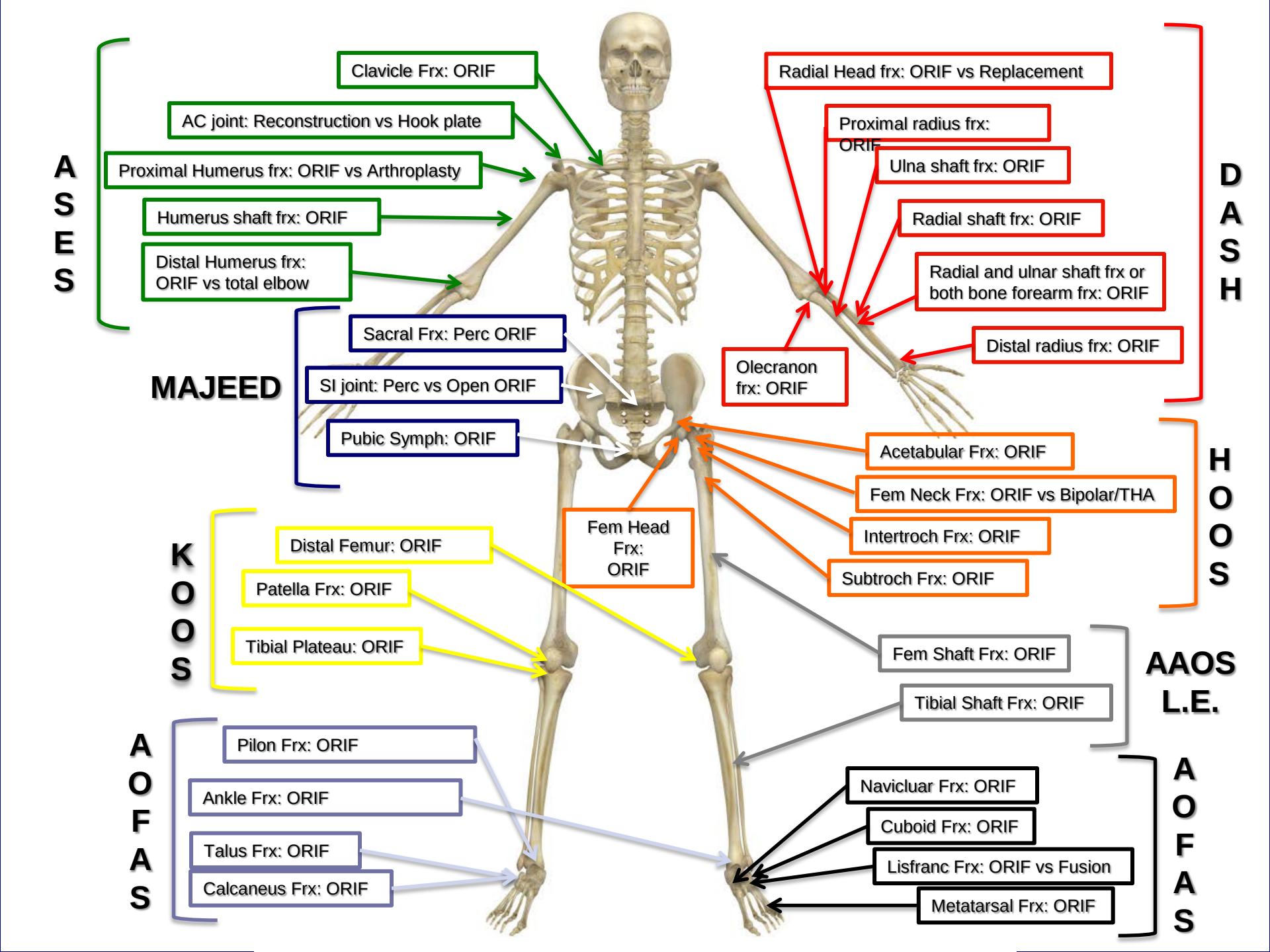
Principles of Patient Reported Outcome Measures (PROMs) Reporting

Highlights:

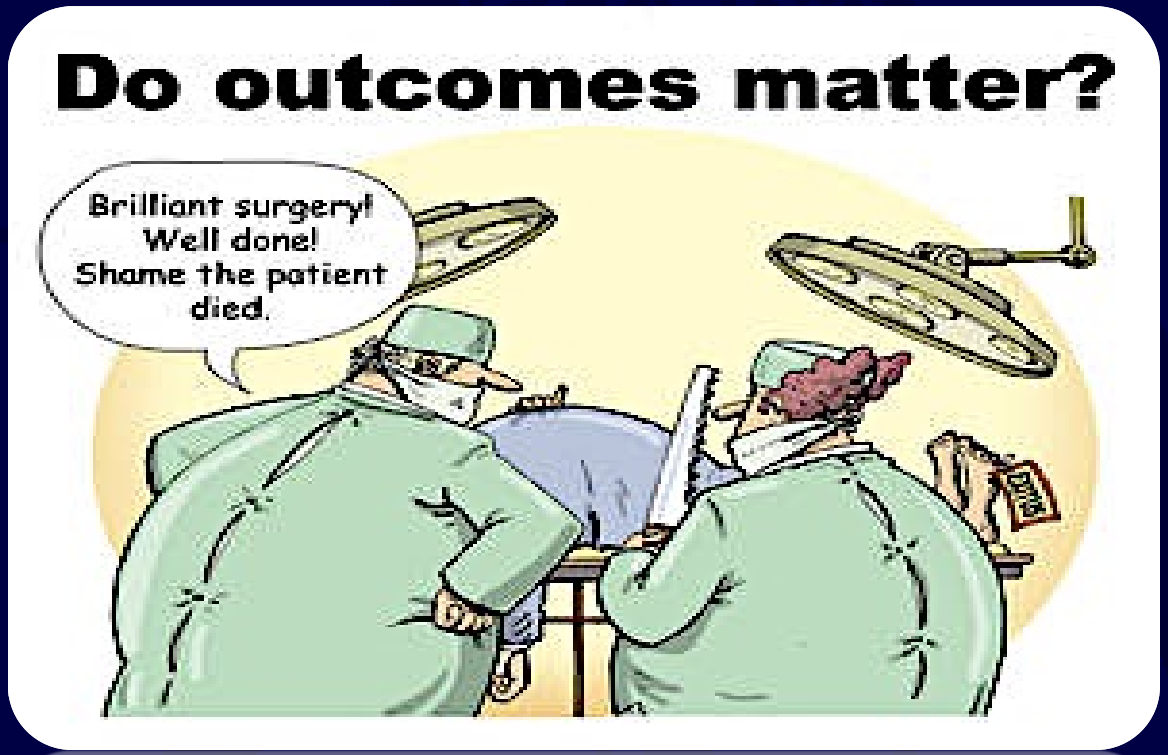
- "Change in patient reported outcome is arguably the best measure of the 'success' of an orthopaedic procedure "
- "This is not a research effort, but one aimed at practice improvement."
- "Both generic and condition-specific measures of health-related quality of life should be used."
- PRO tools should be easily administered, validated, and free to use without licensing.

Sample Protocol




ASES
Clavicle Frx: ORIF
AC joint: Reconstruction vs Hook plate
Proximal Humerus frx: ORIF vs Arthroplasty
Humerus shaft frx: ORIF
Distal Humerus frx: ORIF vs total elbow
MAJEED
Sacral Frx: Perc ORIF
SI joint: Perc vs Open ORIF
Pubic Symph: ORIF
KOOS
Distal Femur: ORIF
Patella Frx: ORIF
Tibial Plateau: ORIF
AOFAS
Pilon Frx: ORIF
Ankle Frx: ORIF
Talus Frx: ORIF
Calcaneus Frx: ORIF
Radial Head frx: ORIF vs Replacement
Proximal radius frx: ORIF
Ulna shaft frx: ORIF
Radial shaft frx: ORIF
Radial and ulnar shaft frx or both bone forearm frx: ORIF
Distal radius frx: ORIF
Olecranon frx: ORIF
DASH
Acetabular Frx: ORIF
Fem Neck Frx: ORIF vs Bipolar/THA
Intertroch Frx: ORIF
Subtroch Frx: ORIF
Fem Head Frx: ORIF
HOOS
Fem Shaft Frx: ORIF
Tibial Shaft Frx: ORIF
AAOS L.E.
Navicluar Frx: ORIF
Cuboid Frx: ORIF
Lisfranc Frx: ORIF vs Fusion
Metatarsal Frx: ORIF
AOFAS

Thank You



If you would like to volunteer as an author for the Resident Slide Project or recommend updates to any of the following slides, please send an e-mail to ota@aaos.org

E-mail OTA about Questions/Comments

Return to Lower Extremity Index

OTA Return to index

Appendix PRO tools

ASES: Association of Shoulder and Elbow Surgeons Score (http://www.ncbi.nlm.nih.gov/pubmed/12469084)

WOMAC: Western Ontario and McMaster Universities Arthritis Index (http://www.ncbi.nlm.nih.gov/pubmed/12880577)

KOOS: Knee disability and Osteoarthritis Outcome Score (http://www.koos.nu)

HOOS: Hip disability and Osteoarthritis Outcome Score (http://www.koos.nu)

Majeed: Majeed Pelvis Score (http://www.bjj.boneandjoint.org.uk/content/jbjsbr/71-B/2/304.full.pdf)

MFA/SMFA: Musculoskeletal Functional Assessment/Short Musculoskeletal Functional Assessment (http://www.ortho.umn.edu/research/mfa-smfa-resources)

DASH: The Disabilities of the Arm, Shoulder and Hand Score (http://www.dash.iwh.on.ca/scoring)

AOFAS: American Orthopaedic Foot and Ankle Society score (http://www.ncbi.nlm.nih.gov/pubmed/17331864)

AAOS Lower Extremity: America Academy of Orthopaedic Surgeons Lower Extremity Score (http://www.aaos.org/CustomTemplates/Content.aspx?id=22833)

PROMIS: Patient Reported Outcomes Measurement Information System (http://www.nihpromis.org/about/overview)

EQ5D: EuroQol 5 Dimension Questionnaire (www.euroqol.org)

SIP: Sickness Impact Profile (http://www.jstor.org/stable/3764241)

SF-36: Short Form 36 (http://www.sf-36.org/tools/sf36.shtml)

- For questions or comments, please send to ota@ota.org