Standardisation of complication assessment and reporting in orthopedics with focus on shoulder conditions

Prof Dr. Laurent Audigé, Schulthess Klinik, Zürich, Switzerland

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schulthess klinik

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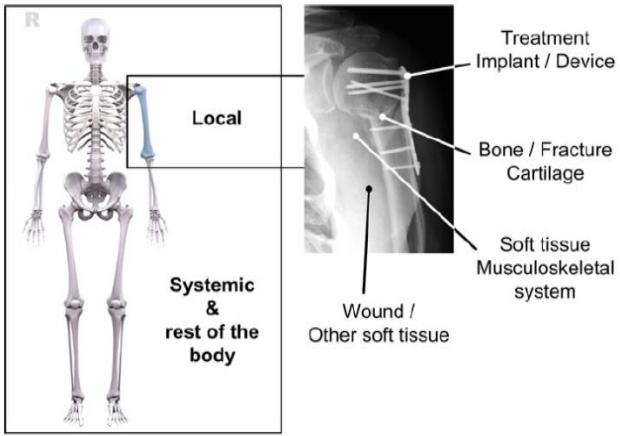
Background

Inconsistent reporting of complications in orthopedics

8 / 112 trials (7%) defined at least a complication *Goldhahn et al JBJS Am 2009; 91:1847-1853*

Proposal for a structured descriptive system *Audigé et al AOTS 2014; 134:269-275*



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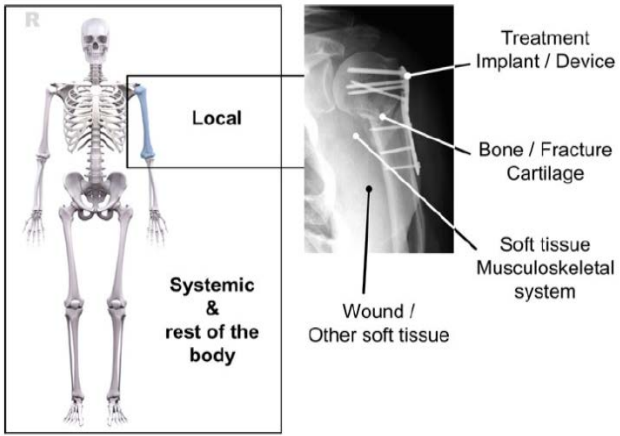


Table 4
List of reported complications.

Complications		
Soft tissue/wound	32	3
Infection	1	–
Healing problems	6	–
Carpal tunnel syndrome	5	–
Tendinitis	8	1
Tendon rupture	4	1
Other soft tissue problems	8	1
Implant/surgery	6	n.r.
Loss of reduction	2	–
Screw loosening	1	–
Plate/screw pull out	1	–
Other implant/surgery problems	2	–
Bone/fracture	4	n.r.
Loss of reduction	3	–
Healing problems	1	–
General	1	n.r.
Death	1	–
Total number of complications	43	3
Complication risk (%)[a]	15%	5%

n.r. = not reported.

Matschke et al Injury 2011; 42:385-392.

Table 4. Complications

Complication type	PHN 58* Number	Plate 153* Number
Intraoperative complications[†]	5	27
Primary screw perforation	3	23
Plate impingement	2	4
Nerve complication	1	2
Postoperative complications[‡]	12	28
Implant complications	10	19
Secondary screw perforation	3	13
Implant loosening	1	0
Screw backing out	5	2
Plate and/or screw pull-out	0	2
Implant breakage	0	3
Other implant/surgery	1	0
Bone/fracture complications	9	19
Loss of reduction	4	10
Secondary dislocation fragment	1	3
Impaction	4	7
Delayed union	0	5
Nonunion	0	0
Head necrosis	1	2
Impingement	0	1
Other bone/fracture	0	0
Soft tissue/wound complications	0	4
Superficial infection	0	2
Deep infection	0	2
Hematoma	0	0
Other soft tissue	0	0
Any local complication[§]	12	48
Complication risk (95% CI)[‖]	21% (11.2–33.4)	31% (24.1–39.4)

Konrad et al CORR 2012; 470:602-609.

Need to 1) better understand “complications”

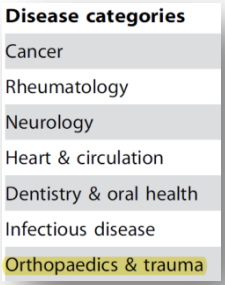
2) identify and define relevant events

Core outcome sets (COS)

Development and application of agreed standardized COS — *Williamson et al.* J Health Serv Res Policy *2012*

↓ Heterogeneity of research results / Reporting bias — *Clarke Trials 2007*

Increased development in orthopedics and trauma — *Gargon et al. PLOS one 2014*



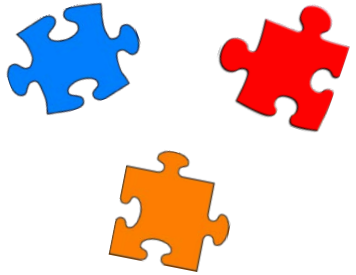
Conceptual framework: OMERACT Filter 2.0 — *Boers et al. J Clin Epid 2014*

"Developers must decide whether specific adverse events need to be monitored as part of the core set."

COS for shoulder disorders with inner core domains: — *Page et al. RMD Open. 2016 2:e000380*

pain physical function and activities,
global perceived effect and …… adverse events !

Project objectives



Development of a universal standard for
documentation and reporting of
orthopaedic adverse events / complications

Phase 1

Definition and classification of surgical complications

Catalogue of complication terms and definitions for specific body locations / indications / treatments

→ Core Event Set (CES)

Phase 2

Documentation / data management process / analysis / presentation

Utilization (conference, quality control, prediction, prevention)

Multiple definitions of surgical complications

Definitions	References
"any deviation from the normal postoperative course"	*Clavien et al. Surgery 1992*
"… an unintended and unwanted event or state occurring during or following medical care, that is so harmful to a patient's health that (adjustment of) treatment is required or that permanent damage results."	*Marang-van de Mheen et al, Qual Saf Health Care 2005*
"every unwanted development in the illness of the patient or in the treatment of the patient's illness that occurs in the clinic"	*Veen et al. Eur J Surg 1999*
"a complication, in any sphere of endeavor, is something out of the norm, and the product of extraneous and unexpected factors"	*Chapman A, in: Surgical complications, ICPress 2007*
"an undesirable, unintended, and direct result of an operation affecting the patient which would not have occurred had the operation gone as well as could reasonably be hoped"	*Sokol and Wilson, Surgery 2008*
"any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure"	*Dindo and Clavien, Surgery 2008*

Definition of surgical complications

"Any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure"

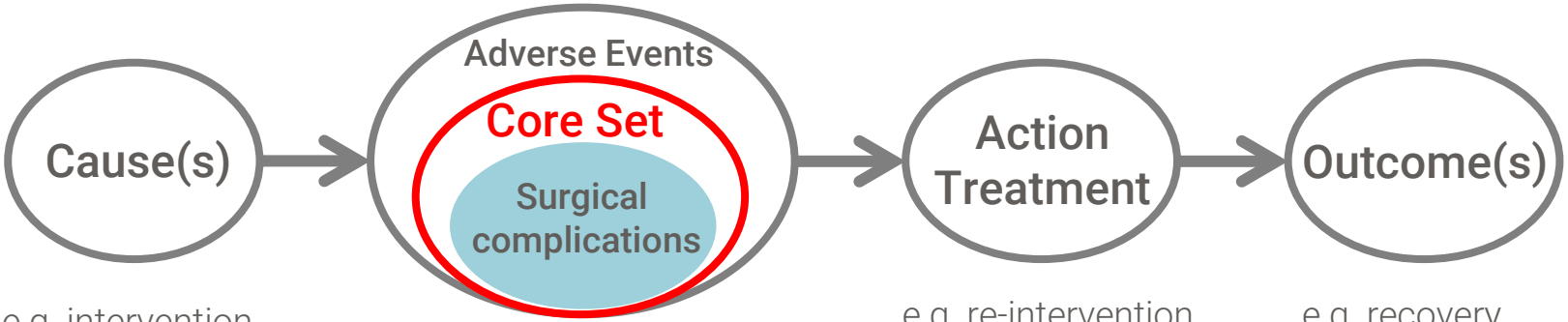
Three type of negative events / outcomes :

- Complications
- Failure to cure
  - Conditions that remain unchanged after surgery,
    e.g. rotator cuff re-tear / defect, lack of restoration of function, fracture nonunion, …
- Sequelae
  - Conditions that are inevitably associated with the intervention,
    e.g. scar formation, …

Clavien et al. Surgery 1992;111(5):518-26
Dindo D and Clavien PA. World J Surg 2008;32(6):939-41

International survey International Society of Orthopedic Centers (ISOC)
385 clinicians and researchers from 20 clinics
70%-80% agreement : relates at least partly to medical management
and to the expected course of both surgical intervention and patient recovery.
60% believed a complication affects patient outcomes.

Adverse Event versus Complication



e.g. intervention, accident, …

Deviations from the ideal postoperative course

≠

Failure to cure & Sequelae

Dindo and Clavien World J Surg 2008

e.g. re-intervention, medical, physio, nothing, …

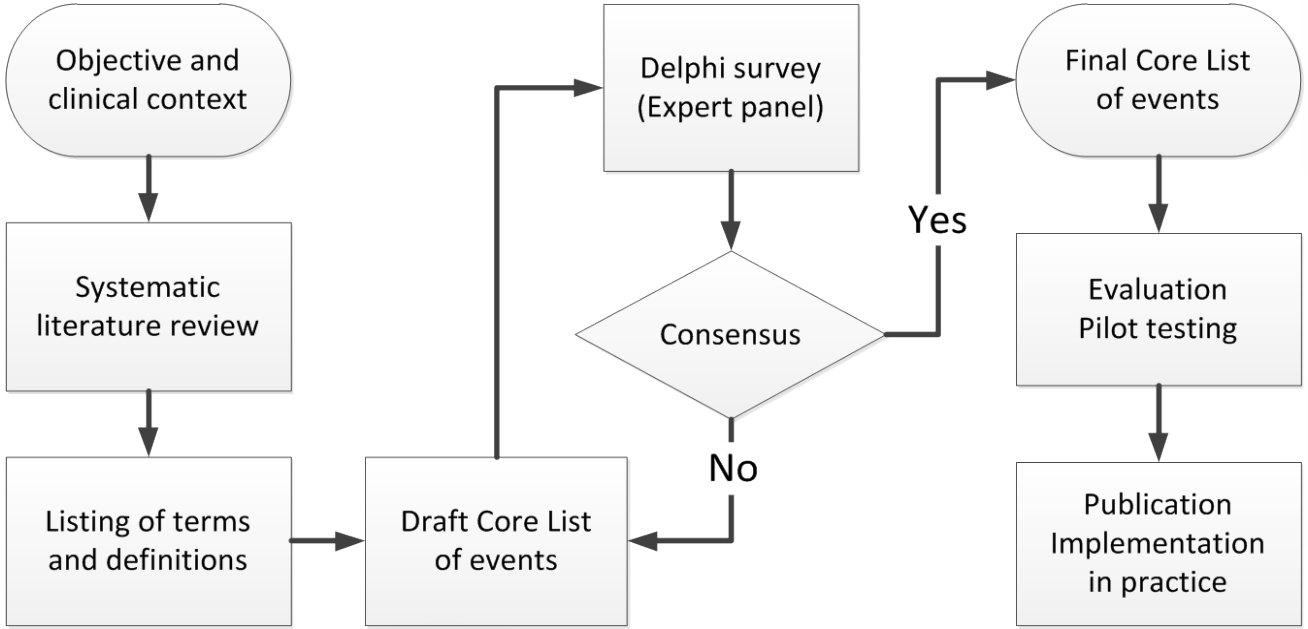
e.g. recovery, disabilities, death, …

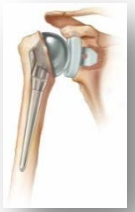
Severity grading of surgical complications

Clavien and Strasberg Ann Surg 2009
Kaafarani et J Am Coll Surg 2014

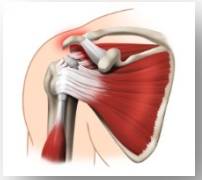
→ Core Set of Unfavorable Events (CES)

Development of core event set (CES)





Shoulder Arthroplasty (SA)



Arthroscopic Rotator Cuff Repair (ARCR)

Proximal Humerus Fracture (PHFx)

Adapted from COS development - Williamson et al. Trials 2012

ARCR Core Event Set – Delphi exercise

Surgeon panel:

121 nominations via ISOC, SECEC, SGOT, AGA, DVSE, BESS, ASES

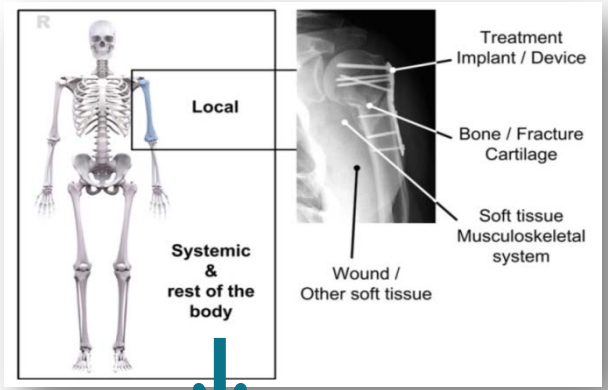
84 participants - 3 Delphi on-line surveys (REDCap)

Conceptual framework

Jacobs et al. The Annals of Thoracic Surgery 2007
Rosenthal et al. World Journal of Surgery 2015

98% panel agreement !

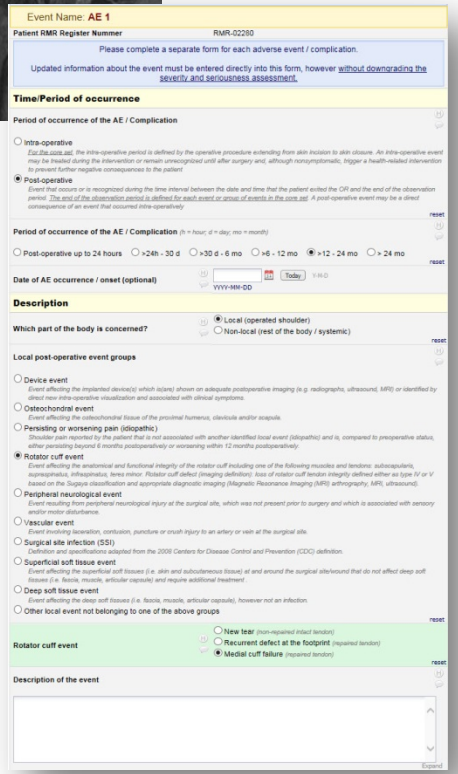
Audigé et al. AOTS 2014



81% agreed that non-local events be considered globally in orthopedics

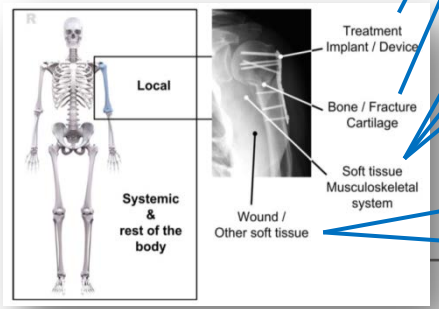
ARCR Core Event Set (CES 1.0)

REDCap



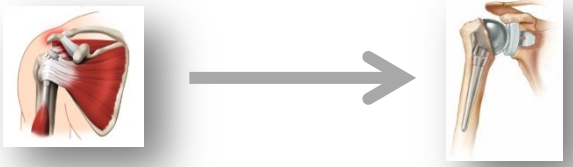
Local (regional) events : 89%-98% agreement
(terms, definitions, specifications and periods)

Intra-operative Event groups	Post-operative Event groups	Period
Device	Implant (device)	24 months
Osteochondral	Osteochondral	24 months
Soft tissue	Persisting or worsening pain	12 months
	Rotator cuff	12 months
	Peripheral neurological	3 months
	Vascular	30 days
	Surgical site infection	30 days (no implant) 12 months (implant)
	Superficial soft tissue	30 days to 6 months
	Deep soft tissue	12 months



Audige et al. JSES 2016 25; 1907–1917

Shoulder Arthroplasty CES 1.0



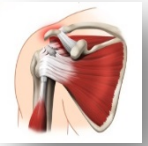
182 nominations - 90 participants

Local (regional) events : 88%-100% agreement
(terms, definitions, specifications and periods)

Intra-operative	Post-operative		
Event groups	Event groups	Period	
Device	Implant (device)	~~24 months~~	Lifelong until revision
Osteochondral	Osteochondral	~~24 months~~	Lifelong until revision
Soft tissue	Persisting or worsening pain	~~12 months~~	Lifelong until revision
	~~Rotator cuff~~ Shoulder instability	~~12 months~~	Lifelong until revision
	Peripheral neurological	3 months	
	Vascular	30 days	
	Surgical site infection	30 days (no implant)	
	+ Late hematogenous infection	12 months (implant)	Lifelong until revision
	Superficial soft tissue	30 days to 6 months	
	Deep soft tissue	~~12 months~~	Lifelong until revision

Audige et al. JSES 2016 25; 1907–1917

Pilot field testing ARCR CES 1.0



Retrospective single-center, registry-based study (N = 1661)
4 independent clinicians - 6 months follow-up & severity classification

Risk (%) of events per group according to tear severity

			Full-thickness tears		
	All tears (N=1661)	Partial tears (N=349)	Single tendon (N=688)	Two tendons (N=499)	Three tendons (N=125)
Event groups	%	%	%	%	%
At least one local event (AE)	18.5	21.8	15.8	18.0	25.6
Device	0.7	1.1	0.4	0.8	0.8
Osteochondral	0.4	0.9	0.3	0.4	-
Persisting or worsening pain	**3.4**	**4.3**	**2.8**	**3.6**	**3.2**
Rotator cuff – failure to repair	**3.1**	**0.9**	**2.3**	**4.8**	**6.4**
Peripheral neurological	**1.7**	**1.4**	**1.5**	**1.8**	**4.0**
Vascular	0.1	-	0.1	-	-
Surgical site infection	0.8	0.3	0.6	1.0	2.4
Superficial soft tissue	0.2	0.3	0.1	0.2	-
Deep soft tissue	**9.4**	**13.8**	**8.6**	**7.4**	**9.6**
Capsule (stiffness)	7.6	11.2	6.7	6.0	9.6

Summary and outlook

General framework supported

- Better understanding of complications, but **international consensus definition still missing**
- **Local** vs **non-local** events
- **Intra**-operative vs **post-operative** events
- Involvement of **international consensus panels** using Delphi exercises
- Need to consider **severity classifications**

First Core Event Sets defined (ARCR and SA)

- Practical **hierarchical systems**
- Need for **prospective evaluations** in routine clinical settings
- Need for consideration of the **patients' perspective**
- **Promotion as a standard** for AE documentation in clinical studies (e.g. using REDCap eForm)
- Adaptation in many **other indications** in orthopedics (e.g. PHFx)

Contribution towards the standardization of complication reporting in orthopedics

Thank you