



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

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Bone Innovation Summit
Lübeck 13-14 February 2019



Acknowledgements

Dr. H. Durchholz, Klinik Gut, St. Moritz, Switzerland

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Surgeons of ARCR and SA consensus groups, ISOC member clinics



Background

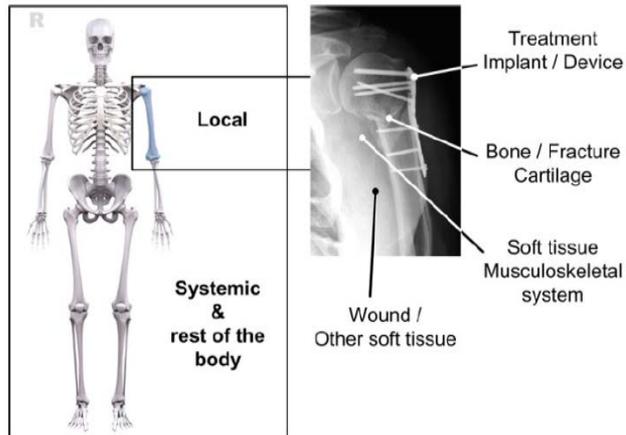
Inconsistent reporting of complications in orthopedics

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



Background

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Proposal for a structured descriptive system

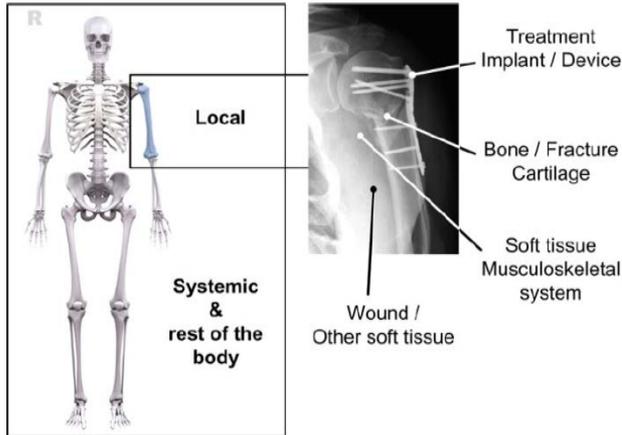


Table 4
List of reported complications.

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
↓ Heterogeneity of research results / Reporting bias

Increased development in orthopedics and trauma

Conceptual framework: OMERACT Filter 2.0

“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:

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



Williamson et al. J Health Serv Res Policy 2012

Clarke Trials 2007

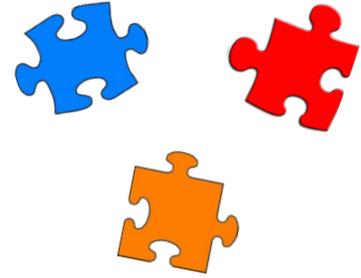
Gargon et al. PLOS one 2014

Boers et al. J Clin Epid 2014

Page et al. RMD Open. 2016 2:e000380

Disease categories
Cancer
Rheumatology
Neurology
Heart & circulation
Dentistry & oral health
Infectious disease
Orthopaedics & trauma

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

“any deviation from the normal postoperative course”

“... 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.”

“every unwanted development in the illness of the patient or in the treatment of the patient’s illness that occurs in the clinic”

“a complication, in any sphere of endeavor, is something out of the norm, and the product of extraneous and unexpected factors”

“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”

“any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure”

References

Clavien et al. Surgery 1992

Marang-van de Mheen et al, Qual Saf Health Care 2005

Veen et al. Eur J Surg 1999

Chapman A, in: Surgical complications, ICPress 2007

Sokol and Wilson, Surgery 2008

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

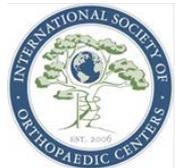
Dindo D and Clavien PA. World J Surg 2008;32(6):939-41

International survey International Society of Orthopedic Centers (ISOC)

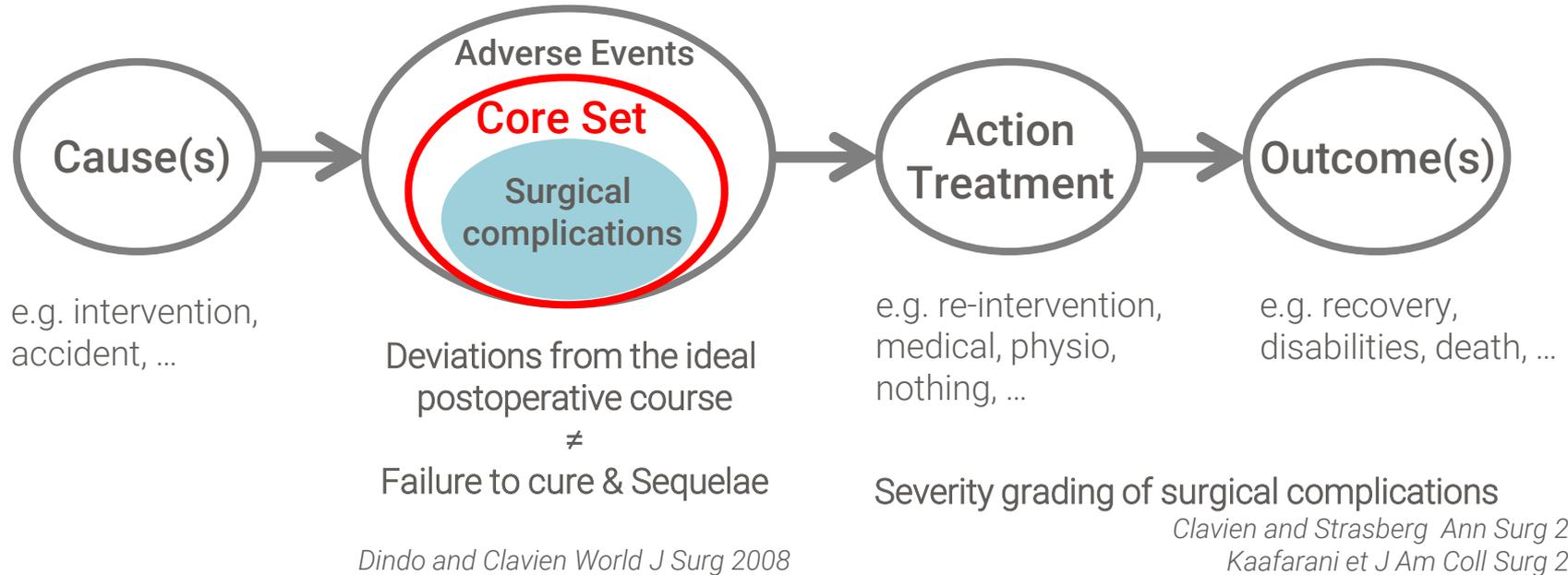
385 clinicians and researchers from 20 clinics

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.

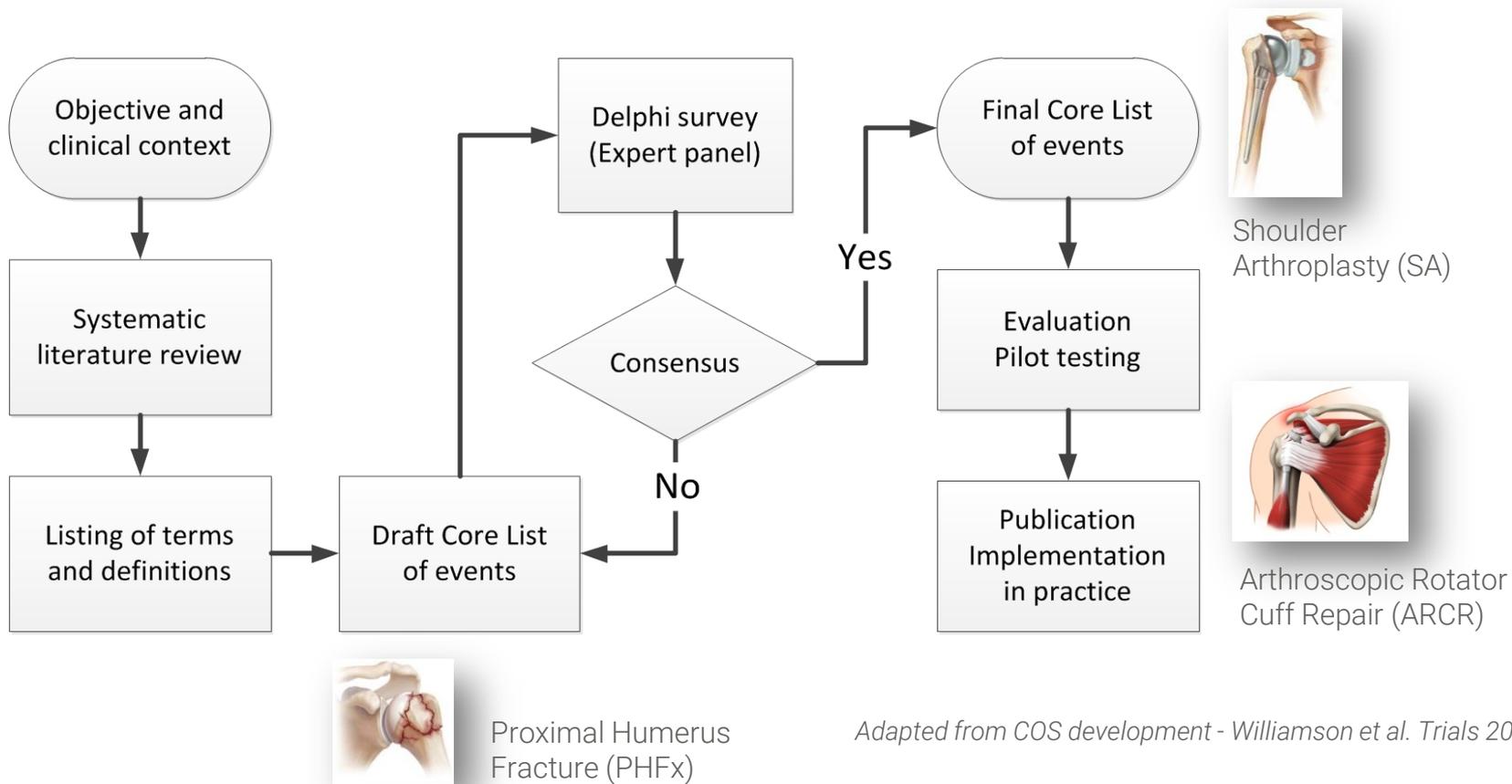


Adverse Event versus Complication



→ **Core Set of Unfavorable Events (CES)**

Development of core event set (CES)



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

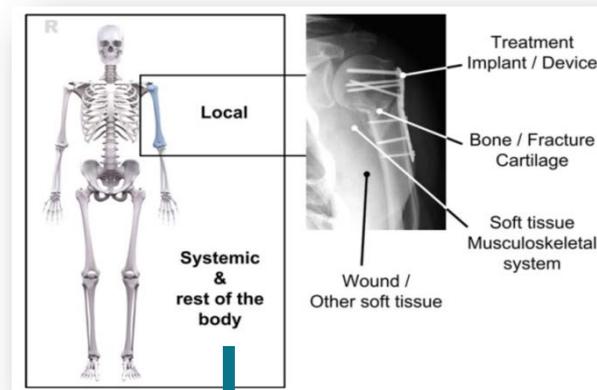


Jacobs et al. The Annals of Thoracic Surgery 2007

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)

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



Event Name: AE 1
Patient RMR Register Number: RMR-02200

Please complete a separate form for each adverse event / complication.
Updated information about the event must be entered directly into this form, however without downgrading the severity and seriousness assessment.

Time/Period of occurrence

Period of occurrence of the AE / Complication

Intra-operative
Ends the same day as the intra-operative period is defined by the operative procedure extending from skin incision to skin closure. An intra-operative event may be treated during the observation or research surveillance period until after surgery and, although nonoperative, trigger a health-related intervention to prevent further negative consequences to the patient.

Post-operative
Event that occurs or is recognized during the time interval between the date and time that the patient exited the OR and the end of the observation period. The end of the observation period is defined for each event or class of events in the same set. A post-operative event may be a direct consequence of an event that occurred intra-operatively.

Period of occurrence of the AE / Complication (h = hour; d = day; m = month)

Post-operative up to 24 hours >24 h - 30 d >30 d - 6 mo >6 - 12 mo >12 - 24 mo > 24 mo

Date of AE occurrence / onset (optional) Today

Description

Which part of the body is concerned? Local (operated shoulder) Non-local (rest of the body / systemic)

Local post-operative event groups

Device event
Event affecting the implanted device(s) which occurs on adequate postoperative imaging (e.g. radiographs, ultrasound, MRI) or identified by direct non-intra-operative visualization and associated with clinical symptoms.

Osteochondral event
Event affecting the osteochondral status of the proximal humerus, clavicle and/or acromion.

Persisting or worsening pain (diopathic)
Shoulder pain reported by the patient that is not associated with another identified local event (diopathic) and is, compared to preoperative status, either persistently located 6 months postoperatively or worsening within 12 months postoperatively.

Rotator cuff event
Event affecting the anatomical and functional integrity of the rotator cuff including one of the following muscles and tendons: supraspinatus, infraspinatus, teres minor, Rotator cuff tendon (imaging deficiency), loss of rotator cuff tendon integrity defined as tear II or IV based on the Sugaya classification and appropriate diagnostic imaging (Magnetic Resonance Imaging (MRI), arthrography, MR, ultrasound).

Peripheral neurological event
Event resulting from peripheral neurological injury at the surgical site, which was not present prior to surgery and which is associated with sensory and/or motor deficits.

Vascular event
Event involving laceration, contusion, puncture or crush injury to an artery or vein at the surgical site.

Surgical site infection (SSI)
Definition and specification adapted from the 2008 Centers for Disease Control and Prevention (CDC) definition.

Superficial soft tissue event
Event affecting the superficial soft tissues (i.e. skin and subcutaneous tissue) at and around the surgical site/tears that do not affect deep soft tissues (i.e. fascia, muscle, articular capsule) and require additional treatment.

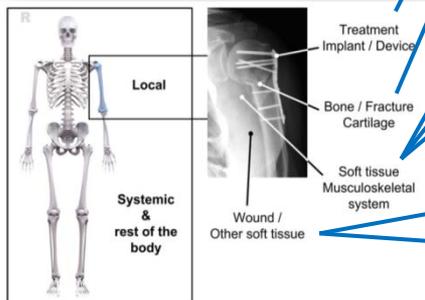
Deep soft tissue event
Event affecting the deep soft tissues (i.e. fascia, muscle, articular capsule), however not an infection.

Other local event not belonging to one of the above groups

New tear (non-repaired intact tendon)
 Recurrent defect at the footprint (repaired tendon)
 Distal cuff failure (repaired tendon)

Description of the event

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	Period	
Event groups	Event groups		
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	<u>12 months (implant)</u>	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

Event groups	All tears (N=1661) %	Partial tears (N=349) %	Full-thickness tears		
			Single tendon (N=688) %	Two tendons (N=499) %	Three tendons (N=125) %
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