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SPECIAL REVIEWS

Core set of unfavorable events of shoulder arthroplasty: an international Delphi consensus process

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Background: Shoulder arthroplasty (SA) complications require standardization of definitions and are not limited to events leading to revision operations. We aimed to define an international consensus core set of clinically relevant unfavorable events of SA to be documented in clinical routine practice and studies.
Methods: A Delphi exercise was implemented with an international panel of experienced shoulder surgeons selected by nomination through professional societies. On the basis of a systematic review of terms and definitions and previous experience in establishing an arthroscopic rotator cuff repair core set, an organized list of SA events was developed and reviewed by panel members. After each survey, all comments and suggestions were considered to revise the proposed core set including local event groups, along with definitions, specifications, and timing of occurrence. Consensus was reached with at least two-thirds agreement.
Results: Two online surveys were required to reach consensus within a panel involving 96 surgeons. Between 88% and 100% agreement was achieved separately for local event groups including 3 intraoperative (device, osteochondral, and soft tissue) and 9 postoperative event groups. Experts agreed on a documentation period that ranged from 3 to 24 months after SA for 4 event groups (peripheral neurologic, vascular, surgical-site infection, and superficial soft tissue) and that was lifelong until implant revision for other groups (device, osteochondral, shoulder instability, pain, late hematogenous infection, and deep soft tissue).
Conclusion: A structured core set of local unfavorable events of SA was developed by international consensus to support the standardization of SA safety reporting. Clinical application and scientific evaluation are needed.
Level of evidence: Level V; Expert Opinion; Consensus Development

Keywords: Shoulder; arthroplasty; unfavorable events; complications; standardization; Delphi process; core event set

Institutional review board approval was not required for this consensus development project.

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The incidence of shoulder arthroplasty (SA) is increasing.[11,22,24] Although SA is associated with rapid and persistent recovery of shoulder function and quality of life for most patients, some experience local complications that may lead to revision surgery.[10,14,30,31] Among osteoarthritis patients, 4% require revision after primary total SA at a mean follow-up time of 3.3 years.[10] Monitoring implant survival, as well as establishing the reasons for revision,[29] is essential to identify inadequate or suboptimal implants or procedures.[9]

High-quality registries permit the assessment of implant survival. They also include relevant image-based, clinical, and patient-reported outcome data with sufficient granularity to allow in-depth and qualitative scientific evaluation of various procedures for all patients regardless of whether revision is necessary.[28] A recent international consensus process led to the development of a so-called core outcome set[8,15] for shoulder disorders,[25] which considers inner core domains of pain, physical function and activities, global perceived effect (personal assessment of recovery or degree of improvement), and adverse events (AEs).[6] From the consensus process, it was clear that clinically relevant AEs may not always lead to SA revision but could potentially harm affected patients and must be considered.

Valid and consistent reporting of AEs in SA is essential to foster adequate decision-making processes, but much of the quantitative information stems from reviews of published data[4,5,7,16,23,38] and retrospective series that are highly inconsistent.[20] Further reports of large administrative databases[13,21,36] only include events that were not defined by consensus and may not be considered unfavorable events relevant to surgeons and their patients. Mandated registration of device failures with health authorities more likely provides valid safety implant data[33] yet also excludes further relevant events. There is a clear need for consensus on which events should be documented according to outlined quality standards.

A core event set (CES) was recently developed for arthroscopic rotator cuff repair (ARCR) as a hierarchical and structured list of unfavorable events along with their terms and definitions.[1] The aim of this project was to extend the international consensus CES work for the common orthopedic procedure of SA. We hypothesized that by applying a Delphi process including a series of online surveys, we could achieve consensus within a large panel of experienced shoulder surgeons on a core set of local unfavorable events applicable to any type of prosthesis to support the standardization of SA safety reporting.

Materials and methods

General methodology

This study encompasses the development of a classification system for clinically relevant unfavorable events of SA. We applied a well-accepted methodologic process[37] for the development of the SA CES, which was similar to that for ARCR.[1] A systematic literature review was implemented comprising 495 original articles published between 2010 and 2014,[20] which gave rise to a total of 1399 event terms grouped according to 8 of 9 previously defined event groups: device, osteochondral, pain, surgical-site infection, peripheral neurologic, vascular, superficial soft tissue, and deep soft tissue.[1] Another group of terms related to impaired function was also established to examine the possibility of using a similar structured list. The majority of reported event definitions in 21.4% of the reviewed articles were related to periprosthetic radiolucency, as well as humeral or glenoid loosening. On the basis of this review and the previously published ARCR CES, we drafted an initial CES for SA.

We applied the modified Delphi technique[19] together with an international panel of experienced shoulder surgeons to review the proposed CES and reach consensus on appropriate modifications. In this process, participants were also invited to provide input regarding the development of a minimum set of parameters for postoperative monitoring of asymptomatic SA patients.[12] With the online electronic data capture system REDCap,[17] participants were asked to complete 3 successive surveys after personal invitation by e-mail, in which the CES was specifically addressed during the first and last surveys. We sent 2 automatic e-mail reminders and made individual personal contact to minimize the proportion of nonresponders. All participants remained unaware of the identities of the other panel members. We served as the adjudication committee and remained blinded to all respondent identities when reviewing the responses and proposing changes to the CES.

Nomination and selection of panel members

Our international expert panel included orthopedic surgeons and shoulder specialists with recognized experience in SA. The 84 shoulder surgeon members of the ARCR CES Consensus Panel were included and complemented by nominations from the following societies or professional groups: International Shoulder Arthroplasty Consortium[26]; International Society of Orthopedic Centers member clinics; European Society for Surgery of the Shoulder and the Elbow; Swiss Orthopaedics; German Association for Shoulder and Elbow Surgery; British Elbow and Shoulder Society; American Shoulder and Elbow Surgeons; Dutch Shoulder and Elbow Society; Italian Society of Shoulder and Elbow Surgery; steering committee of the Danish Shoulder Arthroplasty Registry; Swedish Orthopaedic Association; and Shoulder and Elbow Society of Australia. All nominated surgeons were invited to participate in the first and second Delphi surveys. Only respondents to 1 of these 2 surveys were invited to complete the third and final survey. Members of the SA Consensus Panel acknowledged in this work participated in at least 1 of the 2 surveys addressing the CES.

Development of initial core set and first online survey

The initial CES draft proposal was submitted for review and commentary by invited surgeons as part as the initial Delphi survey (Supplementary Appendix S1). Participants were asked about their level of experience in orthopedics and, more specifically, in performing SA, as well as their agreement on the CES development concept. We asked open questions regarding the suggestion to develop a set of imaging parameters for monitoring asymptomatic patients. Participants were asked if they agreed on the propositions made regarding the distinction between intraoperative and postoperative events, as well as the appropriate term definitions, specifications, and period of observation for each event group. For certain event groups (device, osteochondral, pain, peripheral neurologic, and deep soft tissue), alternative observation periods (eg, 12 months, 24 months, 5 years, 10 years, 15 years, and lifelong) were suggested. Open fields allowed participants to comment on any additions or corrections they believed were necessary. Consensus definitions of rotator cuff tear and shoulder stiffness that originated from the ARCR CES Delphi process[1]—and remained unpublished, particularly for the definition of shoulder stiffness—were proposed.

Second and third online surveys

On the basis of initial responses, a second survey was prepared to address only a core set of radiologic monitoring parameters, which was undertaken in parallel with this work on an SA CES. Proposed changes to the CES were presented for review, commentary, and agreement within the third and final survey (Supplementary Appendix S2). Intraoperative event groups were excluded from this survey because their definitions and specifications were fully agreed on in the first survey. Postoperative event definitions and specifications were amended for all initially proposed event groups; a ‘‘shoulder instability’’ event group was added as suggested by a panel member. In making the amendments, event specifications were tailored in line with the core set of radiologic parameters to ensure that these parameters could be defined and recorded in a similar manner regardless of whether the patient reported symptoms (ie, included in the CES) or not (ie, an observation independent of the CES).

Data analysis and final adjudication

Survey data were transferred to Intercooled Stata (version 14; StataCorp, College Station, TX, USA) for standard descriptive analyses. Consensus was achieved when agreement of at least two-thirds of the respondents was reached. The required observation period for specific event groups was proposed when at least two-thirds of the panel members suggested the same or a shortened period. All comments and suggestions made by panel members were listed and reviewed. Final amendments and adjudication of the CES were made by us for a few parameters to ensure simple, uniform, and pragmatic implementation of the core set.

Results

Consensus panel

Of 182 nominated surgeons invited to participate in the first survey, only 1 was excluded because this surgeon did not perform SAs. A total of 90 participants (50%) responded partly (n = 17) or completely (n = 73). The second survey sent to the same surgeons was answered by 72 participants (40%), including 64 who had responded to the first survey.

Table I Skill of clinician consensus panel

Average annual SAs*	Years of experience, n†				Total, n
	1-5	6-10	11-20	>20	
1-20	—	4	5	3	12
21-50	1	6	14	15	36
51-100	—	3	16	15	34
>100	—	1	7	6	14
Total	1	14	42	39	96

SA, shoulder arthroplasty.
* Panelists were asked, “On average, how many SAs do you perform annually?”
† Panelists were asked, “How many years of surgical experience do you have in orthopedics?”

The third survey was sent to 98 surgeons, to which almost three-quarters (n = 73) responded. There were 96 members who responded to either the first or third survey, with 83 reporting either having more than 5 years’ orthopedic surgical experience and performing at least 20 SAs annually (Table I). Of these members, 74 (76%) originated from Europe (Germany, 14; Switzerland, 15; United Kingdom, 14; The Netherlands, 8; others, 23), with 12 from North America (United States, 11; Canada, 1) and 10 from elsewhere (Chile, 2; Brazil, 2; Israel, 1; Australia, 5).

Initial survey

The development framework for the CES was highly supported with 99% agreement (89 of 90) among the first survey participants. Of respondents, 89% (72 of 81) supported a clear distinction between intraoperative and postoperative events. In addition, consensus was reached with 93% agreement (71 of 76) to organize intraoperative events into 3 distinct event groups (device, osteochondral, or soft tissue) with specific consideration for the field of SA (Table II). Respondents were rather (44%) or definitively (47%) in agreement to adopt a structure comprising 8 event groups and definitions gained from the ARCR CES with rotator cuff events being considered within the deep soft-tissue event group (implant [device], osteochondral, persisting or worsening pain, peripheral neurologic, vascular, surgical-site infection, superficial soft tissue, or deep soft tissue). Percentages of agreement for each event group definition and specification ranged from 89% to 99%. Nevertheless, numerous comments and suggestions were made, including the option to add a separate shoulder instability event group (Supplementary Appendix S3); this event group would comprise those relevant events that do not fit as a new specification within any of the previously defined event groups.

Final survey

As a result of this last process, the shoulder instability event group was added. The event group of surgical-site infection

Table II Definitions and specifications of intraoperative event groups* in core set

Event group	Definition and specification
Device events	Events affecting any *component* of the implanted device or material or the instrumentation used for their implantation
	Instrument problem (breakage, failure)
	Implant (breakage, malpositioning, *separation*)
	Cementation problems
Osteochondral events	Events affecting the osteochondral tissue of the proximal humerus, clavicle, and/or scapula
	Articular cartilage damage
	Fracture†
	Humeral metaphyseal (above the surgical neck)
	Humeral diaphyseal
	Scapula
Soft-tissue events	Events involving only the soft tissue in the treated shoulder
	Skin, muscle, tendon, joint capsule, ligament, labrum
	Blood vessels (bleeding): bleeding at the surgical site that requires *additional intervention or leads to a stop of the operation*
	Nerves: recognized damage of a neurologic structure that needs additional surgical intervention‡

* Intraoperative events were organized into 3 distinct event groups as previously presented[1] and adapted to focus on the field of shoulder arthroplasty. Adaptations are italicized. Consensus was already reached for these definitions and specifications with 93% agreement (71 of 76 participants) achieved during the first Delphi survey.
† Fracture includes hairline fracture.
‡ A standard list of potentially affected nerves is only presented for postoperative neurologic events.

was renamed the infection event group to incorporate late hematogenous infections in the core set. The adjustments of postoperative event terms and definitions organized into 9 groups were approved with 88% to 100% agreement (Table III). The period of documentation ranged from 3 to 24 months after SA for 4 event groups and subgroups (peripheral neurologic, vascular, surgical-site infection, or superficial soft tissue) and was lifelong until implant revision for the following: device, osteochondral, shoulder instability, pain, late hematogenous infection, and deep soft tissue.

Device events included radiolucency around the implant and implant loosening, as well as implant migration, breakage, disassembly, and malpositioning (Table III). Specific osteochondral events were listed as bone formation or resorption, fracture around the implant, and the presence of loose bodies. Several definitions were formulated and agreed on in the context of radiologic SA monitoring, particularly regarding subluxation and dislocation in the shoulder instability event group; dynamic instability was also considered in the CES. Persisting or worsening pain events were similar to those outlined by the ARCR CES and defined as occurring at night or during the day while at rest or during everyday activities. Peripheral neurologic events were reorganized by distinguishing sensory and/or motor disturbance from autonomic disturbance (complex regional pain syndrome). Vascular events included hematoma requiring evacuation, as well as thrombosis and ischemia of the involved extremity. Periprosthetic late hematogenous infections considered for lifelong observation in SA until implant revision were added to the CES, along with the surgical-site infections, in a global infection event group. Superficial soft-tissue events included early events over a period of 30 days and late hypertrophic scar and keloid events over a period of 6 months. Finally, the deep soft-tissue event group was extended to include metallosis and rotator cuff events; 94% of respondents (67 of 71) approved the proposed consensus definition of rotator cuff tear as a loss of tendon integrity with Sugaya classification[34] type IV or V diagnosed by appropriate diagnostic imaging including arthrographic computed tomography and ultrasound examination (Table IV). The consensus definition of shoulder stiffness was also approved with the following consideration: Motion restriction in passive external rotation in 0° of abduction was defined for anatomic SA only as glenohumeral motion no more than 50% of the contralateral-side value. In addition, the observation time frame for stiffness following SA was extended to 12 months.

Discussion

This project focused on the development of a consensus core set of unfavorable local events for SA. We used a modified Delphi process and reached widespread consensus after only 2 online surveys with between 88% and 100% agreement for specific event groups within an international panel of 96 experienced shoulder surgeons. The period of

Table III Definitions and specifications of postoperative event groups* in core set

Event group	Definitions and specifications	Period	Agreement, % (n)
Implant (device)	Events affecting the implanted device(s) (prosthesis) that is (are) shown on adequate postoperative imaging (eg, radiographs, ultrasound, CT) and associated with clinical symptoms Migration (subsidence, tilt, shift): noticeable change in the position of an implant component relative to the bone to which it is supposedly fixed Radiolucency around the implant or implant loosening Wear of the implant articular surfaces: damage, erosion or loss of the articular surface material over time, which is identified by reduction of joint space observed on serial plain radiographs Breakage Disassembly: noticeable change in the relative position of the various parts of an implant humeral or glenoid component Malpositioning†: implant not in its expected position	Lifelong until implant revision	100 (64 of 64)
Osteochondral	Events affecting the osteochondral tissue of the proximal humerus, clavicle, and/or scapula Bone formation or resorption (including scapular notching in reverse shoulder arthroplasty, osteochondral erosion in hemiarthroplasty, and bone cyst) Fracture around the implant Loose body	Lifelong until implant revision	92 (59 of 64)
Persisting or worsening pain	Shoulder pain reported by the patient that is not associated with another identified local event (idiopathic) and is either persisting (compared with preoperative status) beyond 6 mo postoperatively or worsening any time postoperatively Night pain: shoulder pain that awakens the patient at night or interferes with sleep Daily pain while at rest Daily pain during everyday activities (household, work, sport, leisure, and so on)	Lifelong until implant revision	95 (62 of 65)
Shoulder instability	Symptomatic shoulder associated with loss of alignment of the articulating surface of the humeral component with the articulating surface of its joint partner Subluxation: non–arm position–dependent eccentric misalignment with residual contact Dislocation: non–arm position–dependent complete loss of contact of the articulating surfaces Dynamic instability: arm position–dependent loss of contact of the articulating surfaces apparent on physical examination and/or visible on functional radiographs (horizontal flexion/extension view in 90° of abduction and true AP view in 60° of abduction) The direction of instability is noted from clinical examination as well as the AP view (superior/inferior) and from the axillary view or Y-view (anterior/posterior)	Lifelong until implant revision	91 (59 of 65)
Peripheral neurologic	Events resulting from peripheral neurologic injury at the surgical site, which was not present prior to surgery (including worsening of preoperatively known neurologic lesion) and which is associated with sensory and/or motor and/or autonomic disturbance Sensory and/or motor disturbance: affected nerve(s) Cervical or brachial plexus Branch neuropathy (suprascapular, musculocutaneous, median, ulnar, radial, axillary, dorsal scapular, long thoracic, spinal accessory, thoracodorsal, cutaneous nerves of arm and forearm) Autonomic disturbance: CRPS Neurologic injury may be classified by a neurologist according to	3 mo	91 (58 of 64)

(*continued on next page*)

Table III Definitions and specifications of postoperative event groups[*] in core set (*continued*)

Event group	Definitions and specifications	Period	Agreement, % (n)
	Seddon[32] (ie, neurapraxia, axonotmesis, or neurotmesis) and/or Birch[3] (degenerative, short conduction block, prolonged condition block)		
Vascular	Events involving laceration, avulsion, contusion, puncture, or crush injury to an artery, vein, or microvascularity at the surgical site Hematoma that requires evacuation by needle puncture or surgery Superficial and deep thrombosis at the involved extremity Ischemia of the involved extremity that requires additional intervention	30 d	91 (59 of 65)
Infections	SSI: definition and specifications adapted from the 2008 Centers for Disease Control and Prevention definition[18] Superficial incisional SSIs: infections involving only the skin and subcutaneous tissue of the incision: early (<3 mo) Deep SSIs (incisional and organ or space): infections involving any part of the anatomy (eg, fascia, muscle, organs, and spaces) other than the skin and subcutaneous tissue of the incision: early (<3 mo) and low grade (3-24 mo)[35]	3-24 mo	88 (57 of 65)
	Late hematogenous infections: periprosthetic infections defined according to international consensus[27]	>24 mo until implant revision	
Superficial soft tissue	Events affecting the superficial soft tissues (ie, skin and subcutaneous tissue) at and around the surgical site and/or wound that do not affect deep soft tissues (ie, fascia, muscle, or articular capsule) and that require additional treatment Early events within 30 d: edema, emphysema, burn, delayed wound healing, hypersensitivity reaction, skin necrosis, and skin bulla Late events within the first 6 mo: hypertrophic scar and keloid (except if known history of development)	30 d to 6 mo	97 (62 of 64)
Deep soft tissue	Events affecting the deep soft tissues (ie, fascia, muscle, or articular capsule), except infections Affecting the subacromial/subcoracoid space (impingement, adhesion, and so on) Affecting the biceps Affecting the capsule (shoulder stiffness,[‡] metallosis) Affecting the rotator cuff[‡] Affecting the deltoid	Lifelong until implant revision	94 (59 of 63)

CT, computed tomography; *AP*, anteroposterior; *CRPS*, complex regional pain syndrome; *SSI*, surgical-site infection.

* Postoperative events were organized into distinct event groups as previously presented[1] and adapted for the field of shoulder arthroplasty. The rotator cuff event group was moved into the deep soft-tissue event group. A new event group related to shoulder instability was included. The infection event group includes late hematogenous infections. Most specifications within the implant, osteochondral, and peripheral neurologic event groups were adapted.

† A malpositioned implant may result from intraoperative malpositioning and/or postoperative implant displacement. The time of occurrence may be determined by immediate postoperative assessment of the implant position.

‡ Consensus definitions of shoulder stiffness and rotator cuff tear were also agreed on, together with the deep soft-tissue event group, as presented in Table IV.

documentation after SA was limited to between 3 and 24 months for only 4 event groups and should otherwise remain a lifelong process. There is a lack of general agreement in the literature about how "consensus" should be defined, although reaching a threshold percentage for certain responses is most often applied.[19] Our decision to consider a threshold of two-thirds agreement was determined a priori to include relevant items that should not be excluded from further evaluation in field testing; the reporting of actual percentages of agreement well above 80% shows the robustness of our achievement.

The development framework for this project was highly supported among participants of the first survey. The fact that the CES achieved large consensus after only 2 survey rounds shows that our concept appeals to the vast majority of clinicians. Adaptation of the previous ARCR CES was

Table IV Consensus definitions of rotator cuff tear and shoulder stiffness in shoulder arthroplasty

Event	Definition*
Rotator cuff tear†	A rotator cuff event affects the anatomic and functional integrity of the rotator cuff including one of the following muscles and tendons: subscapularis, supraspinatus, infraspinatus, or teres minor A rotator cuff tear (imaging definition) is a loss of rotator cuff tendon integrity (full-thickness tear defined as either type IV or V based on the Sugaya classification[34] and diagnosed on appropriate imaging (*arthro-CT*, ultrasound)
Shoulder stiffness‡	Postoperative restriction in passive shoulder motion diagnosed in ≥2 of the motion planes of flexion, abduction, and external fixation in 0° of abduction Motion restriction is assessed separately for each plane according to the following criteria: Flexion: total motion ≤ 90° or glenohumeral motion (fixed scapula) ≤ 80° Abduction: total motion ≤ 80° or glenohumeral motion (fixed scapula) ≤ 60° External rotation in 0° of abduction: glenohumeral (fixed scapula) motion ≤ 20° *(or, for anatomic shoulder arthroplasty only, no more than 50% of the contralateral-side value)* For the core set, only shoulder stiffness occurring *within 12 mo* after shoulder arthroplasty is considered

arthro-CT, arthrographic computed tomography.
* These definitions were agreed on by the consensus panel together with the deep soft-tissue event group, as described in Table III.
† This definition was adapted from a previous proposal[1] with 1 change highlighted in italics.
‡ This definition was previously developed by members of the Arthroscopic Rotator Cuff Repair Core Event Set Consensus Group[1] and adapted for the context of shoulder arthroplasty.[12] Modifications are shown in italics. The observation time frame of 6 months following arthroscopic rotator cuff repair was extended to 12 months for shoulder arthroplasty.

fairly straightforward and required minimal changes, which further demonstrates the relevance of the current proposal for SA, as well as any future CES development for other indications or treatments in orthopedics.

Previous reports on complications after SA were largely based on retrospective case series, and about one-fifth of examined articles in our previous literature review[20] were narrative reviews. Without international consensus, the authors of these reports were left to judge which events were most relevant to them or their patients. Other reports using large administrative databases[13,21,33,36] targeted specific events that were not primarily documented for assessing comprehensively unfavorable events and patient safety in SA. Therefore, our CES provides a more specific and comprehensive system for events localized to the affected shoulder; this system can then be complemented by a more generic system for events affecting other body structures.[2] The CES should be considered the minimum documentation requirement for assessing AEs in the context of clinical studies.[6] We believe the CES will also allow for a more in-depth and transparent assessment of patient outcomes in clinical registries. The use of a standardized structure to record these events should facilitate the ability to combine data from multiple assessment sites as well as compare outcomes between implants, clinical settings, and surgeons. Consistent with the need to document long-term implant survival in SA registries, all events that may lead to the deterioration of shoulder function and implant revision should be documented over the patient's lifetime.

Our proposed hierarchical system organized into event groups offers flexibility in its application and development so that detailed specifications can be added to the CES at any time point. Although definitions of rotator cuff tear and shoulder stiffness were approved in the context of SA, we foresee that further development and adjustment will be required after a period of application and evaluation in real-life settings. It should be noted that the CES from this project focuses on symptomatic events that may trigger additional examinations or treatments for affected patients; the events may be captured passively when patients consult the surgeon of their own accord, as well as actively by asking patients about the occurrence of unfavorable events at regular postoperative intervals. We recommend the documentation of symptomatic events in parallel with a proposed systematic SA monitoring schedule in all patients.

The strengths and limitations of this consensus project are similar to those previously outlined.[1] We applied the term "unfavorable event" because the term "surgical complication" remained undefined. Comprehensive documentation in clinical registries and studies should outline how recorded events relate to SA, harm patients, or influence outcomes. We used cost-effective methodologic standards for consensus development using a modified Delphi exercise. Participation was very high within the large international panel of experienced shoulder surgeons, with a 74% response rate for the final survey; although the consensus reflects their opinions well, the perspective of SA patients remains to be captured during the evaluation phase of the current proposal. Only 2 surveys were required to complete the CES, partly because our initial proposal was based on adapting the existing CES in ARCR. We believe that there was no justification to start the development process without consideration of the previous consensus and that there is value in harmonizing the framework and structure of the approved systems for documenting unfavorable events across various indications or treatments in shoulder surgery. Finally, our own judgment was applied to assess individual opinions and ensure applicability of the final CES in practice.

The present core set has been included in a standard electronic complication form for systematic documentation as part of our local SA registry using a REDCap database.[17] The use of branching logic facilitates the documentation and evaluation of any unfavorable events in the defined structure. To foster availability and wide uniform field application, we created an electronic and paper form for our ''SA core event set 1.0'' to be used in any documentation system, as well as clinical studies (Supplementary Appendix S4). Some unfavorable events may occur simultaneously in any patient, which can result in an overall assessment and management process. We suggest that only the leading event should be recorded, although contrary to Somerson et al,[33] we did not predefine a hierarchy of events for anatomic and reverse SA. Treating surgeons should rely on their own professional judgment. Finally, our paper form remains limited with respect to the space offered to adequately document the events. Our electronic form, on the other hand, offers more detailed options for recording, for example, grading of radiolucency, scapular notching, and fracture classification, which are addressed in the context of a parallel project on radiologic monitoring.[12] This information can be captured in the descriptive field of the paper form if not recorded electronically.

Conclusion

This international Delphi consensus process contributes to the standardization of reporting unfavorable events of SA for safety evaluation. The proposed SA CES in its first version should be applied in practice and assessed regarding its comprehensiveness and relevance for patients.

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Supplementary data

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