Complications associated with arthroscopic rotator cuff tear repair: definition of a core event set by Delphi consensus process

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Background: The literature does not consistently report on complications associated with arthroscopic rotator cuff repair (ARCR). Valid comparison of the occurrence of complications between ARCR interventions requires standardization. This project was implemented to define a core set of negative (untoward) events associated with ARCR along with their terms and definitions, which should be systematically documented and reported in routine care and clinical research.

Materials and methods: A Delphi consensus process was applied. An international panel of experienced shoulder surgeons was nominated through professional societies and personal contacts. On the basis of a systematic review of terms and definitions, an organized list of relevant events associated with ARCR was developed and reviewed by panel members. Between 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 defined as at least two-thirds agreement.

Results: Three successive online surveys were implemented involving 84 surgeons. Consensus with over 86% agreement was reached for a core list of local events including 3 intraoperative event groups (device, osteochondral, and soft tissue) and 9 postoperative event groups (device, osteochondral, pain, rotator cuff, surgical-site infection, peripheral neurologic, vascular, superficial soft tissue, and deep soft tissue). Experts agreed on a period for documentation of each event or group of events ranging from 3 to 24 months after ARCR.

Conclusion: A structured core set of local events associated with ARCR has been developed by international consensus. Further evaluation and validation in the context of clinical studies are required.

Level of evidence: Development of Classification System

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Keywords: Shoulder; rotator cuff; complications; standardization; Delphi process; core event set

Institutional Review Board/Ethics Committee approval was not required.

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Valid reporting of surgical complications is essential to support quality control,\textsuperscript{4,21} as well as to foster adequate decision-making processes. Unfortunately, a lack of consensus on what comprises a surgical complication and which adverse events (AEs) should be documented contributes to inconsistent reporting.\textsuperscript{11,21,27} Consensus is therefore required on which clinical parameters and outcome instruments should be used\textsuperscript{8} in the evaluation of surgical interventions, including AEs.

This may be particularly true for arthroscopic rotator cuff repair (ARCR) because complication rates vary substantially between studies. Shoulder stiffness and rotator cuff rerupture are commonly reported complications, with rates ranging from 1.5\% to 11.1\% and from 11.4\% to 94\%, respectively.\textsuperscript{25} Strauss et al\textsuperscript{29} reported postoperative complication rates ranging from 2.5\% to 11.9\%. There are several reasons for this heterogeneity. Some events (eg, shoulder stiffness) may occur naturally after ARCR but may be perceived as a complication if they persist. Yet time limits to differentiate between a naturally occurring event and a complication are rather based on subjective judgment. Moreover, some events (eg, absence of tendon healing) may be regarded as complications depending on the surgeon’s or patient’s perspective. Finally, without appropriate training and monitoring, the reporting of complications is likely to be incomplete.\textsuperscript{7,31} Without an agreed list of events, investigators and clinicians will continue to determine for themselves if an event should be reported as a surgical complication, considered part of the normal treatment and recovery course, or simply ignored because of its apparent irrelevance with the applied procedure.

In addition to trial registration,\textsuperscript{22} the standardization of outcome measurement in ARCR should help resolve these problems.\textsuperscript{5} A core outcome set (COS) represents an agreed minimum set of parameters to be assessed within the context of clinical studies and registers of health-related interventions.\textsuperscript{5,32,6} The number of published reports on COSs increased over recent years\textsuperscript{9} but was limited in orthopedics.\textsuperscript{2,11} Available COSs, however, do not always clearly define AEs. In general, there is a clear need for structure in documenting complications in orthopedics,\textsuperscript{5,11} which should be complemented by the specification of context-specific core event sets (CESs). Preliminary work was implemented regarding distal radius fractures\textsuperscript{23} and total knee replacement.\textsuperscript{15}

The aims of this project were to highlight the lack of standardized documentation of ARCR and to develop an internationally accepted CES. Our hypothesis was that by using Delphi methodology, we could achieve consensus on a clearly structured and defined list of complications associated with ARCR, which may be used for systematic reporting in routine care and clinical research.

\section*{Materials and methods}

For CES (hereafter referred to as core set) development, we applied a methodology process\textsuperscript{32} used for COS development that included a literature review, panel consensus process, and field evaluation (Fig. 1).

\subsection*{Systematic review}

A systematic review of the literature was implemented to search for terms and definitions related to the occurrence of negative (unfavorable) events associated with ARCR as described in detail elsewhere.\textsuperscript{1} In short, the PubMed, Embase, Cochrane Library, and Scopus databases were searched on November 2013 for English or German reviews, clinical studies, and reports of complications involving human subjects with ARCR published after 2007. Reference lists of selected articles were screened for additional relevant publications. The terminology of complications and their definitions were extracted from 233 original articles resulting in 242 terms used to describe local events with no standardized and consistent reporting. We made a preliminary list by grouping all terms according to similarity of events to support the development of an initial core set proposal and survey (Appendix S1).

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{Development process for consensus core event set.}
\end{figure}
Consensus development

We implemented a consensus process with an international panel of experienced clinicians using the modified Delphi technique. Three successive online surveys were completed using the electronic data-capture system REDCap. Participants were invited by email and were made aware of all members’ identities after the second survey, though not of the individual survey responses. Individual reminders were sent to encourage participation. Each survey was prepared by the main and senior authors, who remained blinded to respondent identities when reviewing responses. All authors served as the adjudication committee for the core set.

Nomination and selection of panel members

Panel members were selected among orthopedic surgeons and shoulder specialists with recognized experience in ARCR after being nominated by their peers. The project was initiated within the International Society of Orthopaedic Centers, and International Society of Orthopaedic Centers member clinics were invited to participate through their respective shoulder specialists. The project coordinating team (and authors) made a preliminary short list of potential participants to generate a panel with worldwide representation, yet most nominations stemmed from the following societies and their respective shoulder committees: Swiss Orthopaedics, British Orthopaedic Association, European Society for Surgery of the Shoulder and the Elbow, Society for Arthroscopy and Joint Surgery, German Association for Shoulder and Elbow Surgery, and American Shoulder and Elbow Surgeons. All nominated shoulder specialists were invited to participate in the first and second Delphi surveys. Respondents to either of these 2 surveys were considered panel members and were invited to complete the final, third Delphi survey.

Development of initial core set and first online survey

An initial core set proposal was drafted on the basis of personal surgical expertise as well as results from the systematic review. Event terms were grouped and assigned to higher-level categories (event groups) with a distinction between local and systemic (nonlocal) events. Local pain and surgical-site infection events were considered as individual groups, which could not be related to a specific tissue location like other event groups. In addition, rotator cuff events were considered within a single group given the importance of tendon healing and integrity in ARCR. In the initial survey (Appendix S2), participants were asked to rate the inclusion of each event group in the core set on a 5-point Likert scale. Participants responding positively or undecided about a local event group (device event, extravasation, bone event, rotator cuff event, peripheral neurologic event, vascular event, surgical-site infection, superficial soft-tissue event, deep soft-tissue event, or persisting or worsening pain) completed another survey page including suggested specifications and definitions. For each event group, they were asked if they agreed on the propositions made and to make any suggestions if they believed additions or corrections regarding completeness and/or clarity of terms were required. Participants were also asked to indicate during which observation period (30 days, 3 months, 6 months, 12 months, 24 months, or other period) any of the respective event groups should be documented.

In a similar manner, a preliminary list of nonlocal event groups (event occurring in the post-anesthesia care unit, anaphylactic/allergic reaction, neuro-psychiatric event, cardiovascular event, pulmonary event, urinary tract event, gastrointestinal event, event affecting the musculoskeletal system, or other events) was presented for consideration as part of the core set, along with suggested observation periods (30 days, 3 months, 6 months, or other period). Finally, participants were asked if there should be a clear distinction between intraoperative and postoperative complications, if intraoperative complications should include only those events leading to a change in the operative procedure, and if the core set should include only those events that can be related to the operative procedure.

The development of a general definition of surgical complication, as well as that of a classification system for complication severity, remains beyond the scope of this report, although they were briefly addressed during the initial survey.

Second online survey

After initial responses were reviewed, a second survey was prepared considering only local events (Appendix S3) with a distinction between intraoperative and postoperative events based on previous work in thoracic surgery (Fig. 2). Intraoperative event groups included device, bone, and soft-tissue events for which feedback was requested regarding proposed definitions and specifications. Postoperative event definitions and specifications were amended for all initially proposed event groups, except the event “extravasation,” which was excluded. The shortest required observation period for each event group or specific events within groups was reconsidered because of widely divergent panel member opinions. Finally, we suggested that postoperative nonlocal events become the focus of a separate research agenda involving the whole orthopedic field.

Third online survey

In view of consensus gained after the second survey, only minor amendments were made to the proposed core set, yet they were presented to panel members in a third survey to reach final agreement (Appendix S4). This survey also questioned panel members about attributes to consider in formulating a definition for shoulder stiffness; however, this part requires further development and will be reported elsewhere.

Data analysis and final adjudication

Survey data were transferred to Intercooled Stata (version 14; StataCorp, College Station, TX, USA) for standard descriptive analyses. For the inclusion of event groups in the core set, we combined the 2 highest Likert scale scores. Consensus was achieved for a categorical response when it involved at least two-thirds of respondents. The required observation period for specific events or event groups was proposed when at least two-thirds of panel members suggested the same period or a shortened period (eg, if 6 months, 12 months, and 24 months were approved for an event by 30%, 50%, and 20% of respondents, respectively, the shortest required period for that event was defined as 12 months). Final adjudication after the third survey was made by the authors for a few parameters that
did not lead to clear consensus, as well as to ensure simple, uniform, and pragmatic implementation of the core set.

Results

Consensus panel

Of 121 nominated surgeons invited to participate in the first survey, 56 (46%) responded partly (n = 8) or completely (n = 48). The second survey was sent to 132 surgeons, of whom 69 (52%) participated; of these 69 surgeons, 10 only partly responded. The third survey was sent to the ARCR CES Consensus Panel consisting of 84 surgeons: 64 (76%) from Europe (Germany, 15; Switzerland, 14; United Kingdom, 7; Netherlands, 5; and ten other countries, 23), 16 from North America (United States, 15; Canada, 1), and 4 other members from elsewhere (Chile, 2; Australia, 2). The third-survey response rate was 75% (63 of 84). The majority of the 61 respondents who reported on their level of clinical experience either had more than 5 years of orthopedic surgical experience and/or performed at least 50 ARCRs annually (Table I).

Initial survey

Nine proposed event groups were supported for inclusion in the core set by the first survey panel with 71% to 97% agreement, with the exception of “extravasation,” which was supported by 24% of respondents (Fig. 3, A). No additional event groups were suggested. Detailed results and comments related to the initially proposed definitions and specifications for each agreed local event group were presented as feedback to panel members during the second survey (Appendix S5). Nonlocal event groups achieved between 27% and 70% support for inclusion into the core set (Fig. 3, B) with 58% to 81% agreement between groups that the period of observation should be limited to 30 days after surgery. No additional or alternative event group was suggested.

Ninety-four percent of respondents supported a clear distinction between intraoperative and postoperative events. In addition, 67% and 74% agreed that intraoperative events should not only include events leading to a change of the operative procedure and events that can be related to the operative procedure, respectively.

Table I Description of panel of clinicians* who responded to third survey

<table>
<thead>
<tr>
<th>Average annual ARCRs†</th>
<th>Length of experience‡</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1-5 y</td>
<td>&gt;5-10 y</td>
</tr>
<tr>
<td>1-20</td>
<td>0</td>
<td>1</td>
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<td>&gt;20-50</td>
<td>0</td>
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<td>&gt;50-100</td>
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<td>2</td>
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<tr>
<td>&gt;100</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>8</td>
</tr>
</tbody>
</table>

ARCR, arthroscopic rotator cuff repairs.
* Two clinicians did not report their level of experience.
† Clinicians were asked, “On average, how many arthroscopic rotator cuff repairs do you perform annually?”
‡ Clinicians were asked, “How many years of surgical experience do you have in orthopedics?”
Second survey

In the second survey, 95% of panel members supported previous thoracic surgery definitions for the intraoperative and postoperative periods,\(^\text{20}\) with the former extending from the time of patient entry into the operating room (OR) and the time of OR patient exit. The 3 intraoperative event groups (device, bone, and soft tissue) were approved with 93% to 98% agreement. Postoperative event groups and their revised specifications were further supported with 93% to 98% agreement, along with more variability in proposed observation periods. Although the surgical-site infection event group reached final consensus with 97% agreement (only a minor change to the final version was made), other event groups did not reach agreement and required further amendments (Appendix S6).

Eighty-one percent of respondents agreed that a core list of nonlocal events be developed to encompass all orthopedic interventions.

Third survey

Final core set definitions for the 3 intraoperative event groups (device, osteochondral, and soft tissue), as well as their specifications, were approved by 97% of respondents (Table II). Intraoperative events include those affecting any part of the implant (the term *implant* should be understood as any foreign body placed locally as part of the surgical procedure, excluding skin sutures) or its instrumentation. Other events may be caused by the surgical intervention, yet do not involve an implant. Ninety-eight percent of respondents agreed with our suggestion, on the basis of the study by Rosenthal et al,\(^\text{26}\) that

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Figure 3  Inclusion of event groups within the core set collated from the first survey responses of 59 panel members. (A) Local events. As indicated by the asterisk, the term “Bone” was replaced by the term “Osteochondral” after the second survey. (B) Nonlocal events. The red line indicates the limit of two-thirds agreement for consensus achievement. “Rather yes” and “Yes, definitely” responses were combined to evaluate approval for inclusion.
intraoperative events in the core set would occur during the operative procedure defined from skin incision to skin closure.

Postoperative event terms and definitions organized into 9 groups (device, osteochondral, pain, rotator cuff, surgical-site infection, peripheral neurologic, vascular, superficial soft tissue, and deep soft tissue) were approved with 89% to 98% agreement (Table III). The postoperative observation period spans from OR exit to time limits that were specifically defined for each event or group of events, ranging from 30 days to a maximum of 24 months.

Device events focus on implant positioning and displacement, which should become symptomatic within 24 months after primary implantation. Ten specific osteochondral events were listed because they may affect the clavicle and/or scapula around the shoulder, as well as the proximal humerus, with an observation period of 24 months. The panel distinguished 3 types of pain within 12 months after surgery, comprising pain at night, daily pain at rest, and daily pain during everyday activities, which should be further characterized as persisting or worsening. Soft-tissue events were categorized into 5 groups. The panel agreed that magnetic resonance imaging arthrography, plain magnetic resonance imaging, ultrasound, and arthro–computed tomography are appropriate tools for rotator cuff events, which can be specified within 12 months after repair as new tears or recurrent defects (failure of repair, retear, medial cuff failure). Peripheral neurologic events include local neurologic injuries that do not result in additional surgical intervention during the primary surgical procedure; the outcome is postoperative sensory and/or motor disturbance occurring within 3 months after initial repair. Although most panel members supported a 30-day period for the occurrence of symptoms associated with single nerve lesions, this was believed too short for complex regional pain syndrome. Relevant vascular events for the core set were limited to hematoma and thrombosis at the involved extremity. Superficial and deep soft-tissue events complete the remainder of the core set; the former includes early events over a period of 30 days and late hypertrophic scar and keloid events over a period of 6 months. Events of the deep soft-tissue group were limited to the subacromial space, biceps, capsule, and deltoid; their observation period was defined as 12 months.

Some explanations and rationales regarding the event groups and specifications resulting from panel members’ comments and suggestions are presented in Appendix S7.

**Discussion**

This project focused on the development of a core set of negative events associated with ARCR. By use of modified Delphi methodology, we achieved consensus among a panel of experienced specialist shoulder surgeons after completion of 3 successive online surveys.

**Intraoperative versus postoperative**

Ninety-eight percent of the panel agreed on intraoperative and postoperative period definitions. Whereas all intraoperative events occur between OR entry and exit, relevant surgical events considered in the core set were thought to occur only during the operative time. This is consistent with recent developments in surgery. The postoperative observation period for negative events was defined as 24 months after primary ARCR, and specific time limits were determined for each event or group of events. In this way, the expert panel recognized that beyond the defined time limits, events may still occur but may not be considered surgical complications. For instance, a recurrent rotator cuff defect on a healed tendon occurring more than 24 months after initial repair may be clinically relevant for the patient, but the event is considered a part of the natural history and not associated with the primary repair.
<table>
<thead>
<tr>
<th>Event group</th>
<th>Definition and specifications</th>
<th>Period</th>
<th>Agreement</th>
</tr>
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</table>
| **Device**         | Events affecting the implanted device that are shown on adequate postoperative imaging (eg, radiographs, ultrasound, MRI) or identified by direct new intraoperative visualization and associated with clinical symptoms:  
  • Displacement (anchor migration, anchor pullout, and so on): change in the position of an implant compared with a previously documented position  
  • Malpositioning*: implant not in its ideal position | 24 mo (34/62) | 95% (59/62) |
| **Osteochondral**  | Events affecting the osteochondral tissue of the proximal humerus, clavicula, and/or scapula:  
  • Glenohumeral arthritis  
  • Cuff tear arthropathy  
  • Osteonecrosis  
  • Chondrolysis (or articular cartilage damage)  
  • Symptomatic acromioclavicular arthritis  
  • Fracture  
  • Loose body  
  • Bone cyst  
  • Osteolysis/loosening  
  • Chondromalacia | 24 mo* (44/63) | 89% (56/63) |
| **Persisting or worsening pain** | Shoulder pain reported by the patient that is not associated with another identified local event (idiopathic) and is, compared with preoperative status, either persisting beyond 6 mo postoperatively or worsening within 12 mo postoperatively†:  
  • Night pain: shoulder pain that awakens the patient at night or interferes with sleep‡  
  • Daily pain at rest  
  • Daily pain during everyday activities (household, work, sport, leisure, and so on) | 12 mo | 97% (59/61) |
| **Rotator cuff**    | Events affecting the anatomic and functional integrity of the rotator cuff including one of the following muscles and tendons: subscapularis, supraspinatus, infraspinatus, teres minor  
  Rotator cuff defect (imaging definition): loss of rotator cuff tendon integrity defined as either type IV or type V based on the Sugaya classification30†† and appropriate diagnostic imaging (MRI arthrography, MRI, ultrasound)  
  • New tear (affecting non-reconstructed intact tendons)  
  • Recurrent defect (affecting reconstructed ruptured tendons)  
    1. Failure of repair: defect at the footprint/suture site diagnosed up to 6 mo postoperatively  
    2. Retear: defect at the footprint/suture site occurring after 6 mo postoperatively provided that healing‡‡ was shown previously on appropriate imaging  
    3. Medial cuff failure: defect between the medial suture row and the muscle mass | 12 mo | 95% (59/62) |
| **Peripheral neurologic** | Events resulting from peripheral neurologic injury at the surgical site, which were not present before surgery and which are associated with sensory and/or motor disturbance:  
  • Affected nerve or nerves (radial, ulnar, median, axillary, suprascapular, long thoracic, plexus brachialis, musculocutaneous, cervical plexus; eg, greater auricular/occipital nerves) AND injury classification according to Seddon28 (ie, neurapraxia, axonotmesis, neurotmesis)  
  • Complex regional pain syndrome | 3 mo | 98% (61/62) |

(Continued on next page)
Event groups

For the core set, a group of negative events in a hierarchical system was adapted from the publication of Audigé et al² and received broad approval from the panel. We believe it provided a clear overview of all considered events and also, possibly through its structured and stepwise development, facilitated the consensus process. In orthopedics, McKay et al²³

<table>
<thead>
<tr>
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<th>Definition and specifications</th>
<th>Period</th>
<th>Agreement</th>
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| Vascular                     | Events involving laceration, contusion, puncture, or crush injury to an artery or vein at the surgical site:  
• Hematoma that requires evacuation (puncture, aspiration, operative intervention, and so on)  
• Thrombosis at the involved extremity | 30 d         | 98% (61/62)   |
| Surgical-site infection      | Definition and specifications adapted from the 2008 Centers for Disease Control and Prevention definition⁶⁹⁷:  
• Superficial incisional surgical-site infections: infections involving only the skin and subcutaneous tissue of the incision  
• Deep surgical-site infections (incisional AND organ/space): infections involving any part of the anatomy (eg, fascia, muscle, organs, and spaces) other than the skin and subcutaneous tissue of the incision | 30 d (no implant) 12 mo (implanted material in place; eg, anchor, suture, patch) | 97% (57/59)*** |
| Superficial soft tissue      | Events affecting the superficial soft tissues (ie, skin and subcutaneous tissue) at and around the surgical site/wound that do not affect the deep soft tissues (ie, fascia, muscle, or articular capsule) and require additional treatment:  
• Early events over 30 d: edema, emphysema, burn, delayed wound healing, hypersensitivity reaction, skin necrosis, skin bulla, others  
• Late events over 6 mo: hypertrophic scar and keloid | 30 d to 6 mo  | 98% (59/60)   |
| Deep soft tissue             | Events affecting the deep soft tissues (ie, fascia, muscle, or articular capsule), except for infections affecting the following:  
• Subacromial space (impingement, adhesion, and so on)  
• Biceps  
• Capsule (shoulder stiffness)  
• Deltoid | 12 mo        | 98% (61/62)   |

MRI, magnetic resonance imaging.
* The definition of postoperative events is presented in Figure 2.
† 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.
‡ The proposed timelines for osteochondral events were very heterogeneous between surgeons. We believe, however, that the vast majority of these events, depending on the implant and material used, will occur within 24 months after implantation. This means that after 24 months of observation, these events are considered part of the natural history.
§ For clarification, persisting pain means that the patient does not have any pain reduction within at least 6 months after surgery compared with his or her preoperative level of pain. This event cannot occur before 6 months and cannot occur twice. Worsening pain means that the patient has increasing pain within 12 months after surgery, whether the pain had previously been reduced or not. This event can occur at any time within 12 months.
** Having pain on changing positions at night, having pain while sleeping on the operated shoulder, and waking up sore are expected and considered sequelae of the intervention.
†† The Sugaya classification³⁰ is as follows: type I, repaired cuff appears to have sufficient thickness compared with normal cuff with homogeneously low intensity on each image; type II, sufficient thickness compared with normal cuff associated with partial high intensity area; type III, insufficient thickness with less than half the thickness when compared with normal cuff, but without discontinuity, suggesting a partial-thickness delaminated tear; type IV, presence of a minor discontinuity in only 1 or 2 slices on both oblique coronal and sagittal images, suggesting a small full-thickness tear; and type V, presence of a major discontinuity observed in more than 2 slices on both oblique coronal and sagittal images, suggesting a medium or large full-thickness tear.
‡‡ Healing is defined by tendon integrity type I, II, or III according to the Sugaya classification. If no imaging is performed at 6 months postoperatively, a recurrent defect at the footprint/suture site cannot be differentiated into failure of healing or retear.
§§ The distinction between early infection, low-grade infection and late infection is a classification that is not considered in the definition. Late hematogenous implant-associated infections are not considered in the core set; however, they may be documented as relevant negative events inherent to the procedure.
*** Agreement was achieved after the second Delphi survey for surgical-site infection definition and specifications.
identified 3 event groups including nerve, bone/joint, and tendon complications of distal radius fractures. A standardized list of complications related to total knee replacement, however, was not organized into logical groups. In spine surgery, Mirza et al. provided operational definitions for 176 (mostly nonlocal) events (termed “adverse occurrences”) in 17 groups. There were 2 groups of multiple technical device and injury events with limited structure and 1 group related to wound healing and infection. We believe a logical hierarchical system offers flexibility in development (because it is always possible to add more detailed specifications at a later stage) and should facilitate the evaluation of events most likely to influence outcome in ARCR. In defining negative events, the main difficulty arose as to how much detail was required; a balance between being sufficiently detailed and clinically meaningful and keeping the system easy to use was important.

**Application of core set in practice**

We are not aware of any similar system for documenting negative events or complications in shoulder surgery. The present core set has been included into a standard electronic event form for systematic documentation as part of our ARCR register using a REDCap database. At the time of writing this report, we were updating complication data retrospectively from the clinic patient information system regarding already documented patients as well as prospectively for new operations and follow-up examinations. Shoulder surgeons were trained about the core set and were required to use the new form for any occurring complications they considered clinically relevant. As reported in a surgical department, definition criteria are presented on the documentation form as a reminder to the users.

Although these pilot data will be presented elsewhere, we acknowledge that some level of detail in the core set may not be documented in practice depending on routinely performed examinations including imaging. For instance, intraoperative implant malpositioning may only be noted during the procedure. Postoperatively, it may not be possible to distinguish between primary implantation malpositioning and implant migration depending on the imaging performed. We do not advocate performing imaging examinations that are not part of routine practice in any clinical setting. In addition, because final 6-month follow-up clinical examinations with ultrasound are performed in our clinic, only failure of rotator cuff repair can be documented. Between 6 and 24 months, only symptomatic events can be documented (a patient questionnaire completed at 24 months may help identify events treated elsewhere) in the absence of additional systematic imaging. It is therefore essential to clearly describe clinical settings and routine practices when reporting ARCR complications. Full documentation of the core set would require the implementation of appropriately designed clinical studies.

Having reached consensus about a CES will foster scientific comparability and transparency of reporting only if widely and appropriately applied, as shown in other surgical areas such as pancreatic surgery. One issue is availability. We believe this work should be made available to all orthopedic shoulder specialists and researchers involved in ARCR, and the core set should become required minimum documentation of complications in any clinical studies. Another issue is uniform application. Core set development projects such as ours should be registered (eg, within the COMET [Core Outcome Measures in Effectiveness Trials] initiative database) to avoid duplication of work, which would be counterproductive in achieving standardization. In addition, future developments should lead not to different parallel systems but to an update of the present core set.

**Strengths and limitations**

We did not define the term _surgical complication_ in this study, yet our motivation to include specific events in the core set was derived from their perceived clinical relevance and potential indicator of surgical quality. Large prospective studies are required to assess how far these agreed local events are related to the surgical procedure and/or harm patients and influence outcome.

Clear methods and standards should be applied in COS development. Our use of modified Delphi consensus methodology was very cost-effective; the core set was generated by an international panel within a period of about 18 months. Each survey required about 15 to 20 minutes for completion, and personal reminders were sent to encourage participation; on the basis of these factors, we achieved a high response rate of 75% for the third survey. In a traditional Delphi process, the initial survey is based on open-ended questions, but we were already able to make some suggestions after a comprehensive literature review. This initial proposal may have introduced bias into the core set. Moreover, some definitions may have been formulated differently if the related issues had been discussed openly during a consensus meeting, as applied for the development of some COSs in orthopedics. However, this is more resource intensive and difficult to achieve when a large international panel is involved. Although we believed that all comments and suggestions were addressed with equal weight (by remaining blinded to the respondents’ identities when evaluating responses), we were also guided by our own knowledge, experience, and beliefs. Our own judgment was required to assess individual opinions and, notably, to ensure that the final core set could essentially be applied in practice.

For the agreed core set, some local events may have been wrongly excluded or forgotten or, alternately, some included events may have no true relevance. In any case, the exclusion of an event from the core set does not mean that it is not relevant for the affected patient. In this context, it will be important to consider the patient’s perspective.
which may be better captured by patients themselves in the context of a prospective register. The panel was uncertain about including nonlocal events and agreed that they should ideally be documented uniformly across orthopedic specialties; hence, this development requires a broader scope than only surveying specialist shoulder surgeons. Finally, we recognize that some definitions are still missing, although diagnosis criteria for some events should not represent specific difficulties for any trained shoulder surgeon. Further consensus work is required for shoulder stiffness (ie, an event affecting the capsule), despite an existing consensus definition of “frozen shoulder.” Therefore, the present core set may be labeled “ARCR core event set 1.0” to reflect that future revision after field application is likely. Any feedback on potential amendment of this core set is encouraged.

Conclusion
This international Delphi consensus process supports the establishment of a new standard in documenting and evaluating surgical complications associated with ARCR. At this stage of development, this core set has face validity, that is, it is perceived as appropriate by the panel. Further practical evaluation is certainly required to assess its comprehensiveness and the potential need for more specific definitions and detailed specifications.

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Appendix
Supplementary data
Supplementary data related to this article can be found online at doi:10.1016/j.jse.2016.04.036.

References


