

Study	AE definition (direct quotes with eventual comments)	Severity rating (direct quotes with eventual comments)
Chung 2015	"Participants were asked the acupuncture AEs by acupuncturists using an open-ended question first, then the AcupAE. The open ended question asked if they had any discomfort during treatment and after the last few treatments."	"...mild AE required no treatment or resolved within 1 day, moderate AE lasted more than 1 day or relieved by non-prescription medication, severe AE required medical treatment."
Da Silva 2014	"Adverse effects were defined as 'any unusual, inconvenient or ill-effect, no matter how small, that is unintended and non-therapeutic', Examples were given to patients"; "We did not include 'aggravation of symptoms' because of the difficulty in judging whether the event was associated with acupuncture, was serious or not, and also because some practitioners believe that transient worsening is part of treatment."	"A 'serious event' was considered as one which needed further specific medical intervention or had interfered with the patient's normal life for at least the remainder of the day"
Endres 2004	"The ICH definition of an adverse event (AEs) is any untoward medical occurrence experienced by patients, temporally but not necessarily causally associated with the use of a drug or medical treatment..."	"... serious adverse event (SAEs) identified, according to the ICH, as an adverse event that results in a life-threatening condition or death, requires hospitalization or prolongation of existing hospitalization, or results in persistent or significant disability or incapacity, including congenital anomaly/birth defects"
Ernst 2003	"A checklist was provided which mentioned haemorrhage, haematoma, infections, neurological abnormalities, fainting, vestibular symptoms, nausea, prolonged DeQi effect and increase of pain. Free space was provided to record other observed adverse effects. All therapists asked their patients with standardised open questions: during therapy, "How do you feel now?"; and before every subsequent therapy, "How did you feel after the last acupuncture therapy?". The therapists were asked to document 'possible septic syndrome' if fever and/or hypotension were observed in combination with local infection at one or more points that had been needed."	SAE not defined
Furose 2017	"...any untoward medical occurrence in a patient who underwent acupuncture therapy and which does not necessarily have a causal relationship with this treatment." In line with ICH but only selection list with AE likely related to acupuncture applied	"...serious AE (pneumothorax, other organ injury, central nerve injury, peripheral nerve injury, suppurative arthritis, suppurative myositis, cellulitis, hepatitis B, hepatitis C, needle breakage and/or needle migration, accidental insertion, and other symptoms that practitioners regarded as serious)..."
Leung 2009	"A list of possible complications and adverse effects was used to check the events thoroughly. The list consisted of bleeding, obvious tissue/ organ damage, fainting, syncope, persistent needle pain, post-puncture tiredness, palpitation, exacerbation of symptoms nausea, dyspnea, convulsion, psychological symptoms, etc."	SAE not defined "no harmful complication was encountered"
List 1992	"In this paper, adverse event refers to any reaction to a treatment besides the intended treatment effect irrespective of any correlation between the treatment and the reaction."	SAE not defined
Mac Pherson 2001	"Practitioners were asked to record mild transient reactions to treatment, within one or more of three categories (systemic, aggravation, local)"	"... 'significant adverse event' was defined as any event that was 'unusual, novel, dangerous, significantly inconvenient, or requiring further information'..."
Mac Pherson 2004	"For the purposes of this survey we did not define an adverse event but, instead, provided patients with a checklist of possible events. This and the overall questionnaire, while not formally validated, were developed from two practitioner surveys."	"In contrast, "serious adverse events" were predefined as those resulting in admission to hospital or being permanently disabling or life threatening"
Mac Pherson 2005	"Patients were asked to report short term reactions, by answering the question: "Thinking about the visit at which you were given this form, did you experience during or immediately after your acupuncture any of the following?" We provided a checklist of possible short term reactions drawn from the results of two recently published practitioner surveys."	SAE not defined
Melchart 1998	„Der Fragebogen sollte, der Erfahrung der behandelnden Ärzte entsprechend vergleichsweise häufige Ereignisse erfassen, die aus Patientensicht im Allgemeinen als unangenehm oder unerwünscht beurteilt werden“ English translation: The questionnaire was designed to reflect relatively frequent events that are, according to the physicians' experience, often experienced as unpleasant or adverse by the patient.	SAE not defined
Melchart 2004	"...physicians had to report whether an adverse effect (defined as any adverse event possibly related to acupuncture) occurred. If this was the case, the adverse effect had to be specified. Predefined categories were bleeding, needling pain, hematoma, infection orthostatic problems, forgotten needles, and any other events."	"Serious adverse effects (defined as any adverse effects possibly related to acupuncture making treatment necessary or severely interfering with the patient's wellbeing, eg a pneumothorax or a nerve injury)..."
Odsberg 2001	"Negative side effect – a non-intended effect of the acupuncture treatment that the patient experiences as negative, i.e. haematoma and fainting."	"Complication – a non-intended effect of the acupuncture treatment that may threaten the patient's life, i.e. pneumothorax."
Park 2009	"Therefore, this study has surveyed to report on short-term reactions as well as de qi, side-effects, and the satisfaction of patients following acupuncture treatment.", "After explaining the purpose of the survey to the patients, we had them fill out a survey form querying their reactions..."	SAE not defined

Park 2010	<p>"According to the World Health Organization (WHO), an AE is described as "any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment."</p> <p>"In the AE section, the reporter was asked to describe when the AEs appeared and disappeared, the type and details of the AE, and the treatment for the AE. Two (2) types of AE were identified: local AEs and systemic AEs..." "Local AEs included a broken or forgotten needle, hemorrhage, needle allergy, needle-site pain, hematoma, and a stuck or bent needle. Systemic AEs included drowsiness, fainting, fever, hypotension, nausea, vomiting, diarrhea, sweating, headache, discomfort, dizziness, anxiety and panic, seizure, insensibility, mental disturbance, pain, temporary paresthesia, pneumothorax, organ or tissue injury, hepatitis B/C, otitis externa, sepsis, central nerve injury, skin infection, or symptom aggravation."</p>	<p>"The International Conference on Harmonization guidelines define a serious AE as any untoward medical occurrence that, at any dose, results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.¹⁸ There were no serious AEs related to acupuncture in this study."</p>
Weidenhammer 2008	<p>„Außerdem wurde gefragt: „Welche unerwünschten Wirkungen oder Komplikationen der Akupunktur sind aufgetreten?“ Antwortoptionen waren hier: „Blutung“, „Nadelschmerz“, „Hämatom“, „Infektionen“, „Kreislaufprobleme“, „vergessene Nadeln“ und „andere“ (mit Freitextfeld zur Beschreibung des Ereignisses).“</p> <p>English translation: Furthermore it was asked „Which adverse effects or complications occurred through acupuncture?“ Response options were: 'bleeding', 'needling pain', 'haematoma', 'infections', 'circulatory problems', 'forgotten needles' and 'others' (with free text for a description of the event)</p>	<p>"Als schwerwiegende unerwünschte Therapiewirkungen waren alle Ereignisse zu bewerten, die a) möglicherweise in einem kausalen Zusammenhang mit der Akupunkturbehandlung standen und b) behandlungspflichtig waren oder/und den Patienten gravierend beeinträchtigten oder gefährdeten (z. B. Pneumothorax, Nervenläsion).“</p> <p>English translation: Serious adverse treatment effects were defined as events that a) had a possibly causal relationship with the acupuncture treatment and b) required treatment and/or compromised or threatened the patient seriously (e.g. pneumothorax, nerve lesion).</p>
Wen 2017	<p>"Adverse events, including pain, hematoma, perforation, bleeding, fainting, local infection, abscess, or breakage or retention of the needle after treatment, were recorded after every session."</p>	<p>SAE not defined</p>
White 2001	<p>"We defined an adverse event as 'any ill-effect, no matter how small, that is unintended and nontherapeutic'. This definition was used both in order to identify events that occurred through error but were not reactions to acupuncture, and in order to include minor events such as bleeding, not just serious events, even when these may have been an expected consequence of needling. We decided not to record unintended beneficial or pleasant events." "...number of adverse events classified under specific headings..." "Some practitioners regard aggravation or drowsiness as a part of the response to treatment (the 'healing crisis'), and not as unintended 'adverse' events. Therefore, if a patient later improved substantially, respondents were instructed to convert the relevant mark in the box to an asterisk."</p>	<p>"Significant Event Report...to record any event that was 'unusual, novel, dangerous, significantly inconvenient or requiring further information'. Examples were provided, which included needling problems (broken or forgotten needle, moxa burns), systemic effects (faint, convulsion, drowsiness causing hazard e.g. on the road, severe nausea) and symptoms (unexpected or prolonged aggravation)."</p>
Witt 2009	<p>"At the end of each treatment cycle, all patients were asked to complete a standardised questionnaire and to document adverse events they associated with acupuncture (defined as adverse effects) in free text and, if necessary, the kind of treatment they had needed (self-treatment, medication/physician treatment, treatment in hospital). Adverse events without association to the acupuncture treatment were not documented."</p>	<p>"Patients who reported adverse effects which needed treatment, received from the study office an additional, more detailed standardised questionnaire concerning their most important adverse effect."</p>
Yamashita 1999	<p>"We defined AE as an unfavorable medical event that occurred during or after the treatment regardless of causal relationships [Beam 1992]"</p>	<p>"...no serious or severe cases of negligence such as pneumothorax or spinal cord injury were reported in the TCT Clinic But 2 cases identified from reports that required hospitalization / likely to have caused disability."</p>
Yamashita 2000	<p>"The acupuncturists meticulously observed the punctured region and general condition of the patients during and immediately after treatment. The patients were asked to report any pain or discomfort caused by needle insertion. In the interview after each treatment session, the acupuncturists asked the patients, "Did you feel any discomfort during today's treatment session, or do you have now such a feeling that did not exist before the treatment session? Please tell me every slight discomfort even if you don't think it is a problem." A similar question was asked at the patient's next visit, "Did you feel any discomfort that may have had something to do with the previous treatment, after you left our clinic?"</p>	<p>"Details recorded on the report form included ... severity or magnitude of symptom, and treatment for the reaction." "All reactions were mild and transient." "No medical care was required for any of these reactions."</p>
Zhao 2011	<p>"AE is defined as an unfavourable medical event that occurs during or after the treatment regardless of causal relationship", "AE and SAE were defined a priori from the literature and the State Food and Drug Administration (SFDA) in China."</p>	<p>"Serious adverse effects (SAEs) refers to those that caused hospitalisation, extended duration of hospitalisation, disability, impaired ability to work, death or were life threatening, resulting in events such as congenital malformations in the process of the clinical trials."</p>

Online supplementary appendix S4: Definition of adverse events with respective severity ratings as direct quotes from the included manuscripts