

**Appendix II. Data Extraction Form for Review and meta-analysis**

<b>Study Details</b>	
<b>General information</b>	
• Title	
• First author	
• Year of publication	
• Journal	
• Country	
• Foundation	
• Study duration	
<b>PICOs information</b>	
• Study design (RCT, case-control, cohort)	
• Participants	
Sample size	
Day-age	
Gestational age	
Birth weight	
Delivery route	
Diagnosis criteria	
Inclusion criteria	
• Intervention	
Type of AED	
Dose (Loading dose/ maintenance dose)	
Duration	
Frequency	
• Comparison	
• Main outcome	
Primary outcome	
<i>Cessation of seizure</i>	
<i>Long-term neurodevelopmental outcome</i>	
Second outcome	
<i>Mortality</i>	
<b>Exclusion criteria</b>	

**Risk of bias assessment (For RCT)**

Domain	Description	Risk of bias
Election	1) Random sequence generation	a) High risk: Selection bias (biased allocation to interventions) due to inadequate generation of a randomize b) Low risk: Random sequence generation method should produce comparable groups c) Unclear risk: Not described in adequate detail
	2) Allocation concealment	a) High risk: Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment. b) Low risk: Intervention allocations likely could not have been foreseen in advance of, or during, enrollment c) Unclear risk: Not described in adequate detail
Reporting	1) Selective reporting	a) High risk: Reporting bias due to selective outcome reporting b) Low risk: Selective outcome reporting bias not detected c) Unclear risk: Insufficient information to permit judgement (It is likely that the majority of studies will fall into this category.)
Blindness	1) participants and personnel	a) High risk: Performance bias due to knowledge of the allocated interventions by participants and personnel during the study b) Low risk: Blinding was likely effective. c) Not described in adequate detail
	2) outcome assessment	a) High risk: Detection bias due to knowledge of the allocated interventions by outcome assessors. b) Low risk: Blinding was likely effective. c) Unclear risk: Not described in adequate detail
Attrition bias	1) Incomplete outcome data	a) High risk: Attrition bias due to amount, nature or handling of incomplete outcome data. b) Low risk : Handling of incomplete outcome data was complete and unlikely to have produced bias c) Unclear risk : Insufficient reporting of attrition/exclusions to permit judgment of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided)
Other bias	1) Other sources of bias	a) High risk: Bias due to problems not covered elsewhere in the table. b) Low risk: No other bias detected c) Unclear risk: There may be a risk of bias, but there is either insufficient information to assess whether an important risk of bias exists; or insufficient rationale or evidence that an identified problem will introduce bias.

Domain	Item	Score
Selection	1) Representativeness of the exposed cohort	a) truly representative of the average ___ (describe) in the community * b) somewhat representative of the average ___ in the community c) selected group of users eg nurses, volunteers * d) no description of the derivation of the cohort
	2) Representativeness of the non-exposed cohort	a) drawn from the same community as the exposed cohort * b) drawn from a different source <sup>[SEP]</sup> c) no description of the derivation of the non-exposed cohort
	3) Ascertainment of exposure	a) secure record (eg: surgical records) * b) structured interview * c) written self-report d) no description
	4) Demonstration the outcome of interest was not present at start of study	a) yes * b) no
Comparability	1) Comparability of cohort on the bases of the design or analysis	a) study controls for ___ (select the most important factor) <sup>[SEP]</sup> * b) study controls for any additional factor * (These criteria could be modified to indicate specific control for a second important factor.)
Outcome	1) Assessment of outcome	a) independent blind assessment * b) record linkage <sup>[SEP]</sup> * c) self-report <sup>[SEP]</sup> d) no description
	2) Was follow-up long enough for outcomes to occur	a) yes (select an adequate follow up period for outcome of interest) * b) no
	3) Adequacy of follow up of cohort	a) complete follow up - all subjects accounted for <sup>[SEP]</sup> * b) subjects lost to follow up unlikely to introduce bias - small number lost - > ___ % (select an adequate %) follow up, or description provided of those lost <sup>[SEP]</sup> * c) follow up rate < ___ % (select an adequate %) and no description of those lost d) no statement
Quality scores		

**Risk of Bias assessment (For cohort studies)**

Domain	Item	Score
Selection	1) Representativeness of the exposed cohort	a) truly representative of the average ___ (describe) in the community * b) somewhat representative of the average ___ in the community c) selected group of users eg nurses, volunteers * d) no description of the derivation of the cohort
	2) Representativeness of the non-exposed cohort	a) drawn from the same community as the exposed cohort * b) drawn from a different source <sup>[SEP]</sup> c) no description of the derivation of the non-exposed cohort
	3) Ascertainment of exposure	a) secure record (eg surgical records) * b) structured interview * c) written self-report d) no description
	4) Demonstration the outcome of interest was not present at start of study	a) yes * b) no
Comparability	1) Comparability of cohort on the bases of the design or analysis	a) study controls for ___ (select the most important factor) <sup>[SEP]</sup> * b) study controls for any additional factor * (These criteria could be modified to indicate specific control for a second important factor.)
Outcome	1) Assessment of outcome	a) independent blind assessment * b) record linkage <sup>[SEP]</sup> * c) self-report <sup>[SEP]</sup> d) no description
	2) Was follow-up long enough for outcomes to occur	a) yes (select an adequate follow up period for outcome of interest) * b) no
	3) Adequacy of follow up of cohort	a) complete follow up - all subjects accounted for <sup>[SEP]</sup> * b) subjects lost to follow up unlikely to introduce bias - small number lost - > ___ % (select an adequate %) follow up, or description provided of those lost <sup>[SEP]</sup> * c) follow up rate < ___ % (select an adequate %) and no description of those lost d) no statement
Quality scores		

**Risk of Bias assessment (For case control studies)**

Domain	Item	Score
Selection	1) Is the case definition adequate	a) yes, with independent validation* b) yes, eg record linkage or based on self-reports c) no description
	2) Representativeness of the cases	a) consecutive or obviously representative series of cases* b) potential for selection biases or not stated
	3) Selection of Controls	a) community controls * b) hospital controls c) no description
	4) Definition of Controls	a) no history of disease (endpoint) * b) no description of source
Comparability	1) Comparability of cases and controls on the bases of the design or analysis	a) study controls for ____ (Select the most important factor.)* b) study controls for any additional factor * (These criteria could be modified to indicate specific control for a second important factor.)
Exposure	1) Ascertainment of exposure	a) secure record (eg surgical records) * b) structured interview where blind to case/control status * c) interview not blinded to case/control status d) written self-report or medical record only e) no description
	2) Same method of ascertainment for cases and controls	a) yes * b) no
	3) Non-Response rate	a) same rate for both groups * b) non respondents described c) rate different and no designation
Quality scores		

**Risk of Bias assessment (For case series studies)**

<b>Domain 1: Study design</b>
1. Is the hypothesis/aim/objective of the study stated clearly in the abstract, introduction, or methods section?
<b>Domain 2: Study population</b>
2. Are the characteristics of the participants included in the study described?
3. Were the cases collected in more than one center?
4. Are the eligibility criteria (inclusion and exclusion criteria) for entry into the study explicit and appropriate?
5. Were participants recruited consecutively?
6. Did participants enter the study at a similar point in the disease?
<b>Domain 3: Intervention and co-intervention</b>
7. Was the intervention clearly described in the study?
8. Were additional interventions (co-interventions) clearly reported in the study?
<b>Domain 4: Outcome measure</b>
9. Are the outcome measures clearly defined in the introduction or methods section?
10. Were relevant outcomes appropriately measured with objective and/or subjective methods?
11. Were outcomes measured before and after intervention?
<b>Domain 5: Statistical analysis</b>
12. Were the statistical tests used to assess the relevant outcomes appropriate?
<b>Domain 6: Results and conclusions</b>
13. Was the length of follow-up reported?
14. Was the loss to follow-up reported?
15. Does the study provide estimates of the random variability in the data analysis of relevant outcomes?
16. Are adverse events reported?
17. Are the conclusions of the study supported by results?
<b>Domain 7: Competing interests and sources of support</b>
18. Are both competing interests and sources of support for the study reported?

**Other information**

	Description as stated in report/paper
Key conclusions	
Study funding sources	
Conflicts of interest	
References to other relevant studies	
Correspondence required for further study information	