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**Title:** Development of the Epilepsy Risk Awareness scale (ERA scale) for people with epilepsy

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### Abstract

**Purpose:** Quality of life in people with epilepsy depends on balancing protection from risks and avoiding unnecessary restrictions. The Epilepsy Risk Awareness Checklist (ERAC) was developed to summarise an individual's safety, health care and quality of life and to facilitate communication between professionals. Although effective, the existing Checklist required quantification and shortening to increase its utility, particularly as a longitudinal tool for measuring and communicating changes over time.

**Methods:** 5 clinical experts, 3 people with epilepsy and 5 carers assessed the importance of each item on the ERAC questionnaire in a two-round Delphi survey. The refined Epilepsy Risk Awareness scale (ERA scale) was piloted in 30 patients to obtain an overall and sub-scale score for personal safety, health care, and quality of life domains, and was compared with the validated Seizure Severity Scale and Epilepsy Self-Management Scale.

**Results:** ERAC was shortened from 69 to 48 items to take 15-20 minutes for completion. Pilot results showed good internal consistency for the overall ERA scale, for the Personal Safety and Health Care subscales, but less for the Quality of Life subscale. There was strong association between ERA scale and the Epilepsy Self-Management Scale, but little relationship with Seizure Severity Scale scores, which focus on individual seizures. User ratings were high.

**Conclusions:** The ERA scale has been shortened and quantified. It shows potential for quantifying the risks and safety profile in people with epilepsy. These pilot results will be further tested for intra-rater variability and utility.

**Keywords:** Epilepsy, Risk, Checklist, Seizure, Scale, Personal Safety, Health Care, Quality of Life

## Introduction

Epilepsy, one of the most common neurological disorders, with a lifetime prevalence of 2 - 5% [1], has major medical and psychosocial consequences [2]. It carries a significant risk of injury and is sometimes fatal, most commonly through sudden unexpected death in epilepsy (SUDEP) [3-6]. The fear of having a seizure can isolate the patient and limit both work and leisure activities [7-9].

Maximising quality of life depends on reducing seizure frequency, and appropriate personalised safety advice without undue restriction [4,9-11]. Scales are an important and established tool in neurological practice, for example the Glasgow Coma scale [12], the FAST score for stroke [13] and the Waterlow score for pressure areas [14]. Formal risk assessment is recommended for those with epilepsy, including during daily activities (such as washing, preparing food), assessment of the social situation, and degree of independence [1]. Healthcare professionals, particularly epilepsy nurses [15], have had limited evidence-based standardised measures of risk despite their recognised importance [16-18]. To fill this need, the Epilepsy Risk Awareness Checklist (ERAC) was developed by the authors as an evidence based tool recording personal safety, health care and quality of life related to epilepsy. Face and content validity of the ERAC has been established in the pre-pilot work [19].

The aim of this study was to streamline and quantify the ERAC. Specifically, the study examined whether any of the questions on the ERAC tool were redundant, to shorten the Checklist, and to provide a weighted numerical score for each item and a total risk score for adults with epilepsy.

## Methodology

The study incorporates a Public Patient Involvement component (four carers and one patient with epilepsy) who reviewed the study protocol, the participant information sheet (PIS), consent form and the Delphi and pilot questionnaires. Patient involvement [20] allowed the study team to review the significance of risk management from a patient and carer perspective, to examine ease of use of the Checklist. The user consensus was that the ERAC checklist needed to be shorter and easier to complete.

A mixed methods [21] approach to tool development was used for the Delphi and pilot stages, drawing on established techniques of confirming items, validating that each item is a measure of risk and undertaking reliability and construct validity testing. The study was carried out within the following two stages:

- Stage 1: Delphi Questionnaire

Clinical experts, adults with epilepsy and carers of people with epilepsy were recruited via clinical networks and epilepsy organisations to assess each item on the ERAC questionnaire. The objective was to reduce the number of items by one third to around 50 so that the questionnaire could be completed in about 15 minutes. The Delphi survey approach was used to reach consensus on health related issues [22]. The survey was conducted in two rounds. The first round investigated the perceived usefulness of the items in the ERAC questionnaire. Panel members were asked to rate the usefulness of each item to the concept of risk in epilepsy on a Likert scale [23] from 1 (unimportant)

to 5 (essential). Participants could also rate an item as completely redundant (0) and suggest new items that they thought might be important.

Using the method of Paschoal [24], each item was scored by calculating the mean rating (redundant items were taken to be zero), and these scores used to rank the items based on their perceived usefulness. Items in the lowest third of the scores were removed; new items suggested by more than 20% of the participants were added to the list. Items rated as borderline by the Delphi panel were discussed by the clinical members of the team and removed if regarded as unhelpful.

In Round 2 of the Delphi questionnaire, the same participants were asked to rank each of the remaining original items from the ERAC questionnaire along with any new suggested items using a Likert scale of 1 to 4. The ranked items were divided into quartile bands based on the sum of the Likert scores given by the participants. In the calculation of the ERAC totals, items in the highest quartile were assigned a weight of 4, those in the third quartile a weight of 3, those in the second quartile a weight of 2, with items in the lowest quartile having a weight of 1.

- Stage 2: Reliability and construct validity - Piloting

Following the Delphi phase, the refined ERAC questionnaire (ERA scale) was piloted with 30 patients, using sample size calculation methodology of Lancaster [25]. The weights were used to score each item. A positive response, indicating good risk assessment, received the item weight and a negative response scored zero. These values were used to calculate an overall ERA scale score and a total for each subscale (personal safety, health care, and quality of life), high scores indicating low risk. The pilot study questionnaire also contained the Seizure Severity Scale (SSS) [26], the Epilepsy Self-Management Scale (ESMS) [27] and questions on age, gender, marital status, religion, current employment, education, and number of antiepileptic medicines currently prescribed. Participants were asked to rate the questionnaire (on a scale from 0 to 10) in terms of its usefulness and how easy it was to complete.

ERA scale total scores were tested for internal reliability using Cronbach's alpha coefficient ( $\alpha$ ) [28]. Construct validity for the ERA scale questionnaire was assessed by comparing total scores with those from the validated SSS and ESMS using the Spearman rank correlation coefficient ( $r_s$ ). In addition, the level of internal consistency was calculated for each subscale of the ERA scale. Internal consistency was considered to be satisfactory with a Cronbach's alpha coefficient of at least 0.7 [29]. The SSS and ESMS were selected as appropriate comparators for construct validity as the concept of risk is inherent in both. Seizure severity is related to the risk of seizure and its sequelae. Self-management is related to risk management through the person's ability to manage their epilepsy without unnecessary medical attention. The ERA scale aims to quantify epilepsy risk and is therefore a different construct that is theoretically related to these measures but not the same.

For the ERA scale items, "not applicable" and missing responses were scored as zero, a cautionary approach being taken so that a high score depended on positive data. For SSS data with missing information, the total score was estimated as the mean of the highest and lowest possible values, unless the range of possible totals was greater than 10. Totals that were too uncertain to be estimated were recorded as missing. With the ESMS, each of the five subscales (management of medication, information, safety, seizures, and lifestyle) was checked for missing values. If a subscale

contained only one missing value, this was estimated by the median of the other subscale observations. Using this method, the ESMS total could be estimated in cases where all subscales contained no more than one missing value. Analyses were performed using SPSS Version 20 [30].

### Ethics Approval

Ethics approval was through the NHS REC on 10/07/2015 (ID:15/NW/0607). The study was conducted in accordance with the guidelines of Good Clinical Practice, and data handling was in accord with the Data Protection Act 1998 [31].

## Results

- Delphi

The panels recruited for the Delphi exercise consisted of 3 patients, 5 carers and 5 professionals. Average age was 46 years and 9 (82%) were female.

In Round 1 of the Delphi exercise, averaged usefulness scores across the 69 ERAC items ranged from 2.77 (for “Are injuries unlikely to occur while protective devices are in place?”) to 4.85 (for “Is neurological (epilepsy) consultation or management obtained when seizures are not well controlled or when significant drug side effects are present?”). The number was reduced to 51 by retaining only the items with a score of greater than 3.6. Seven of the 8 items on the theme of social activities of the patient with family/ carers were removed at this stage. Each of the new items suggested by panel members were proposed by less than 20% (3) of those surveyed so none were included.

Three items that received a mean score of less than 3.8 from the Delphi panel were thought to be either unnecessary or irrelevant by the team and were removed. These were: “Is the seizure type classified according to the International Classification of Epileptic Seizures?” (too technical for routine assessment) (panel mean 3.77); “Does the client/ patient attend paediatrician?” (irrelevant for adult patients) (panel mean 3.62); “Does individual and family/ carers use public transport?” (panel mean 3.62). The shortened version of the ERAC questionnaire consisted of 48 items, 14 from the Personal Safety section, 25 from the Health Care section, and 9 on Quality of Life. The goal of a reduction in the number of ERAC items to around 50 was therefore achieved.

For Round 2 of the Delphi exercise, the quartile bands were derived from the completed questionnaires of the 10 original respondents who participated at this stage (3 patients, 3 carers, 4 professionals). The total weighting scores were restricted to whole numbers so exact quartiles could not be derived. However, similarly sized bands were obtained. Of the 48 items, 11 received the lowest weight of 1, 12 received a weight of 2, 11 received a weight of 3, and the remaining 14 items the highest weight of 4. The maximum possible ERA scale total score for these bands (124) was close to that for exact quartiles (120) indicating that the inequality of the band sizes would have little impact on the participant ERA scale totals.

- Pilot

For the 30 participants recruited in the pilot study, average age was 37 years and 20 (67%) were female. Most patients (17, 59%) were single, with 6 (21%) married and 4 (13%) in a partnership. Half (15, 52%) were in employment and 11 (55%) had either a university degree or a diploma. The number of anti-epileptic drugs prescribed had a median of two. For half (50%) of the participants (15) a seizure usually lasted 1-10 minutes, and for 11 patients 10 seconds to 1 minute (37%).

There were relatively few missing observations. Data for the Seizure Severity Scale were complete and an ERA scale score could be calculated for each participant. For the Epilepsy Self-Management Scale, the total score was missing for only 2 (7%) of the patients.

Internal consistency was acceptable for the ERA scale questionnaire as a whole ( $\alpha = 0.795$ ), the Personal Safety subscale ( $\alpha = 0.708$ ) and Health Care ( $\alpha = 0.705$ ). However, for the Quality of Life subscale, internal consistency was low ( $\alpha = 0.259$ ).

Construct validity was high for the ERA scale overall (Fig.1) when compared to the ESMS total scores ( $r_s = 0.781$ ) but was non-existent (Fig.2) in a comparison of the ERA scale with the Seizure Severity Scale ( $r_s = -0.100$ ).

Feedback regarding the questionnaire was good. Participants gave it a mean score of 7.5 for usefulness and a mean score of 7.9 for how easy the questionnaire was to understand.

Figure 1: ERA scale vs. Epilepsy Self-Management Scale

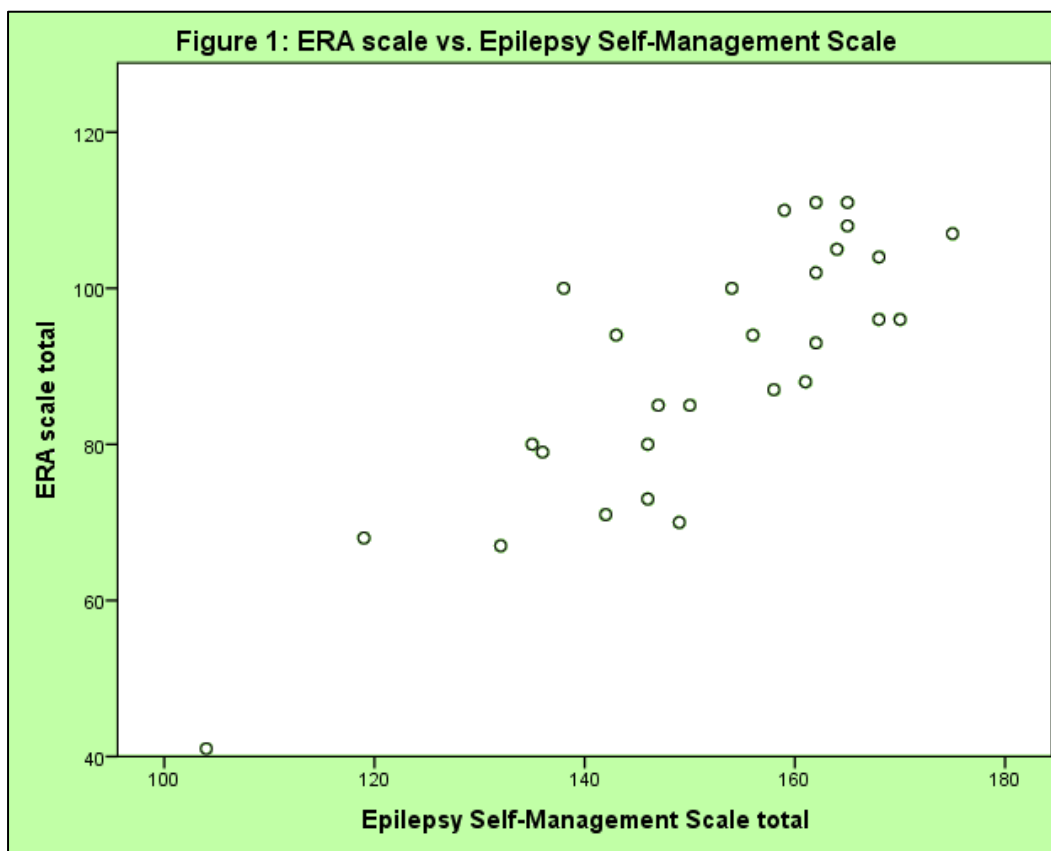
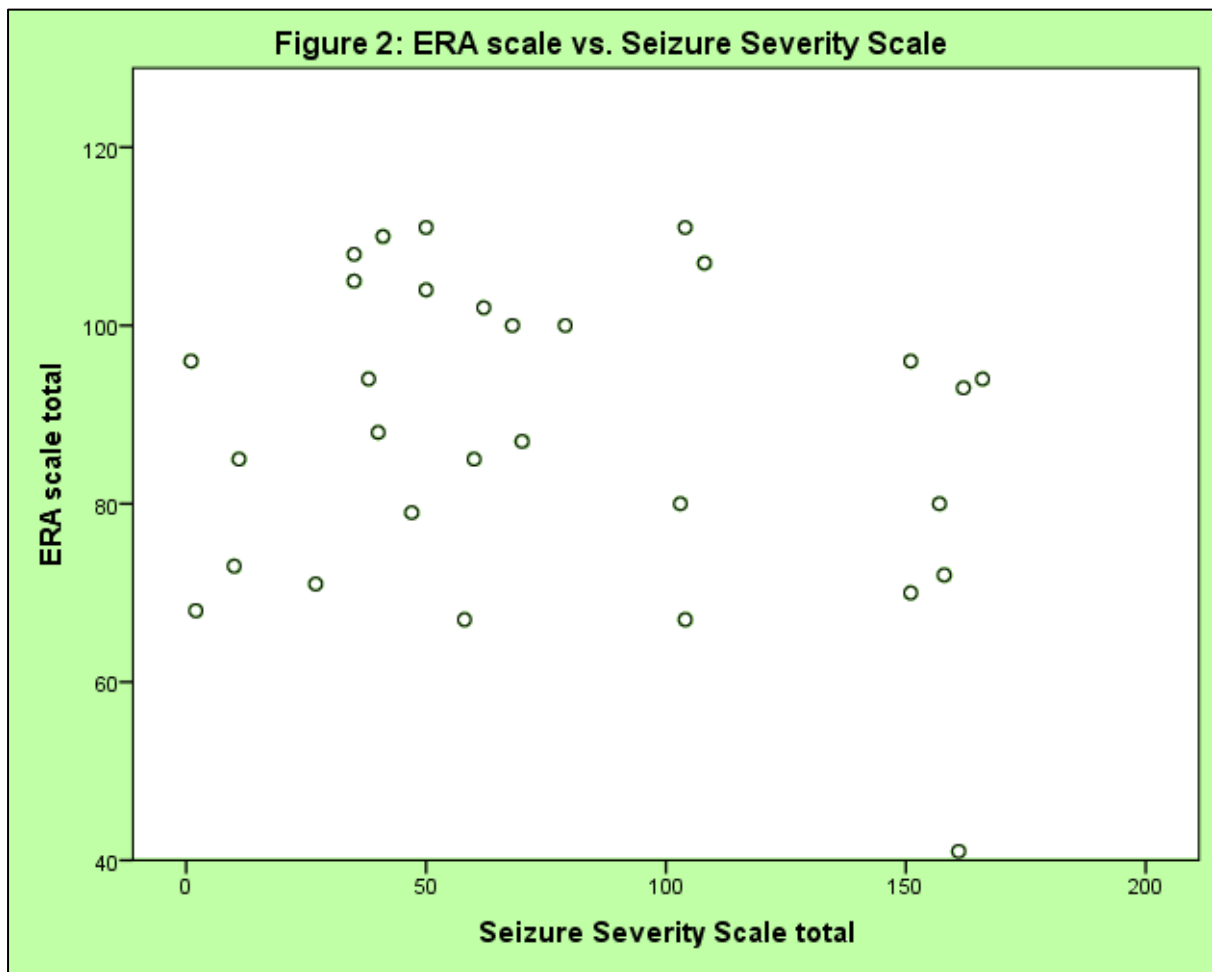


Figure 2: ERA scale vs. Seizure Severity Scale



## Discussion

The ERA scale is a quantified tool (Appendix) for determining individual safety and risk in people with epilepsy. The scale had good overall internal consistency and acceptable consistency for personal safety and healthcare sub scales. Internal consistency for quality of life was poor, possibly because the questions are too diverse; and further refinement of this section will be needed. User satisfaction was high.

### *Association with other scales*

The construct validity between the ERA scale and the Epilepsy Self-Management Scale was high. The ERA scale showed little correlation with the Seizure Severity Scale, despite the SSS being validated. This lack of association is probably because the Seizure Severity Scale places a very high weighting on the time to complete recovery from a seizure (which is not necessarily related to safety or risk). Additionally, the Seizure Severity Scale places weighting on automatisms, which may or may not correlate with risk. Automatisms include potentially risky behaviour (such as running onto the road or utilising nearby dangerous objects) and benign motor activity (such as orobuccal automatisms).

### *Limitations*

The limitations of the study include the inherent difficulties of quantifying subjective experience particularly in terms of quality of life, a crucial but difficult concept to measure. A larger sample may have generated a wider range of statements from patients and carers with different types of epilepsy. We did not include carers of people with epilepsy who had lost a relative with SUDEP or from other causes of mortality that may have had some specific impact on risk.

### *Future developments*

The ERA scale provides rapid assessment of immediate risk, and longitudinal assessment of changes, essential for improving epilepsy management in patients, in particular, those with refractory epilepsy. It also facilitates communication between services. This is particularly important when a patient faces an acute change in their health (such as infection, operations, new co-morbidities), care provider or responsible healthcare professional. A strength of the ERA scale is that patient centred methods were used to ensure patient involvement in research and management at all stages, not only at the final stage of their treatment [32]. Use of the Delphi method also ensured that the ERA scale is pragmatically acceptable as well as statistically valid.

Future development of the ERA scale is planned with a test re-test investigation involving 100-200 patients who will complete the ERA scale with their nurse or carer at baseline and at two months of follow-up. Scores will be analysed for repeatability using intra-class correlation coefficients. The final stage of the research will be to assess the utility of the ERA scale in measuring long-term outcomes of risk management interventions for people with epilepsy.

### **Conclusions**

Through an iterative process that involved the Delphi technique a pragmatically acceptable and valid risk assessment scale, the ERA scale, has been developed for use with patients with epilepsy. Whilst the scale needs a test re-test assessment, it has potential to estimate current risk. This will enable clinicians to stratify risk and prioritise those most in need of intervention. To our knowledge, the ERA scale is the only valid scale available for this purpose and it could, in the future, be an invaluable tool in the reduction of risk with direct cost savings to the NHS and indirect cost reductions to patients and carers. This would require further cost-effectiveness analysis. Nonetheless, the ERA scale should be considered as part of the toolkit of the clinician in assessing the daily lives of people with epilepsy.

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### **Conflicts Of Interest**

The authors declare no conflicts of interest.



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