## General Introduction

Please note these recommendations contain a survey of the available Anti Epileptic Drug (usual spelling is Antiepileptic Drug) (AED) Adverse Event collection tools. The tools should be considered as supplemental. The primary tool for a prospective study should be spontaneous report, using the adverse event tracking log.

All instruments below can be used to assess adverse event burden in a cross-sectional study, or an ongoing prospective assessment, except for the VA scale, which is intended for used after an intervention to assess the impact of that intervention.

Some types of adverse events are not assessed on these forms, particularly AEs associated with newer or emerging AEDs that are not central nervous system side effects.

Please note the date of the reference for each scale, indicating when it was validated. Drugs introduced after these dates were not included in the validation sample.

Appropriately designed comparisons of the psychometric characteristics of the four instruments reviewed have not been carried out. The instruments are sufficiently different in scope and length, the AE domains assessed, and the published evidence for validity and responsiveness that no single instrument can be preferred for all studies. Rather, instrument selection should be based on carefully matching the study’s design, population and hypotheses to the strengths and weaknesses of each instrument, as described below.

It is not clear that any of these scales allow a comparison of side effect burden from one patient to the next based on an aggregate score. It may be more appropriate to use the scales to identify specific side effects for a given intervention, or a change over time. For example, it is not clear if moderate irritability and moderate rash, which would produce the same score, are equivalent in their side effect burden.

## Pediatric Instruments

Instrument: The Side Effects Scale (Hague)

Instrument***:*** Pediatric EpilepsySide Effects Scale (Cincinnati Side Effects Scale)

## Adult Instruments

Instrument: VA Toxicity Rating Scale

Instrument: Adverse Events Profile