

VAMHCS Office of Research Compliance
Guidelines for Narrative Notes

(These Guidelines were written in 1998 for a BVAMC Inpatient Unit. They are somewhat dated but may still be helpful as ideas for study-specific SOPs.)

There are three places where narrative notes are recorded: VA (CPRS) progress note, Unit Comments Sheet, AE Comments Sheet.

1. VA Progress Notes: admission note, progress notes at least q shift and prn, note discharge. Focus on physical condition of subject as opposed to study events. Should include physical assessment, description of and follow-up of adverse events (AE's), short mention of study events and how well the subject tolerated the study events.

This is the main place where there is a detailed description of the subject's condition.

2. Unit Comments Sheet: study events, problems, protocol deviations, record of verbal communications from Principle Investigator (P.I.), P.I.'s staff, VA staff, CRU staff, etc., issues with subject's conduct/visitors' conduct, etc.

This is an internal document within the CRU that is mainly focused on the conduct of the study protocol (as opposed to the subject's clinical status which is mainly addressed in the VA Progress Note). Its main purpose is to keep staff informed of study events (especially unexpected ones) and to serve as a record of why things were done the way they were especially if there were protocol deviations.

Remember that questions frequently arise weeks or months after a subject has completed a study, long after staff can possibly recall details of an event. In this case, Comments Sheets are *incredibly* valuable and their presence or absence may often be the deciding factor in whether or not to believe or retrieve certain data.

Comments Sheets must be charted at least q shift. The note may be as simple as:

“Subject now in Washout Day 1. No c/o. No problems in study events. See Progress Notes for details”

OR

“Subject c/o headache. See AE Comment Sheet”.

Don't double-chart. If you've already described an event or condition in the AE Comment Sheet or in the VA Progress Note, just write “see ____ for further details” in the Unit Comments Sheet instead of rewriting the whole thing. (There's nothing terribly wrong with rewriting notes in different places except that it's extra time and unnecessary effort.) You must at least make reference as to where details are charted.

3. AE Comment Sheet: the second page of the “Adverse Event/Intercurrent Illness Form“. Focuses on the specifics of an adverse event (AE) as opposed to the subject's general physical condition (which is charted in the VA Progress Notes) or study events (which are charted in the Unit Comments Sheet). Must be charted q shift and prn, *even if no AE has occurred*.

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If no AE has occurred on your shift, you must at least write:

“No AE’s or c/o” on the AE Comment Sheet with date, time and signature.

If an AE or illness occurs-even minor ones-it must be described on the AE Comment Sheet (specific data must be entered on the AE form. See “Adverse Event Form“ section of manual for details). Describe the S/S, the context, onset, resolution (if it resolves on your shift), patient comments, your actions, therapeutic measures, who was notified (if necessary), other pertinent info. If the AE has not resolved, you must state that it continues as of the end of your shift.

If an AE continues from a previous shift, you must continue to chart on its follow-up. It might be as simple as: “headache continues” but needs to be detailed if there are changes in intensity, character, etc. or if there are any therapeutic interventions.

If an AE resolves all details MUST be recorded, including time and date of resolution.