

M E M O R A N D U M

Corresp. Gatewood
A GOOD CONSULTATION!
RB

DATE: 9 February 1990

FROM: Laëll Gatewood *Laëll Gatewood*

TO: Wayne Rosamond

COPIES: R. Luepker, G. Burke, H. Blackburn ✓

SUBJECT: Acute MI Registry Manual

Thank you for sharing a copy of the newly developed manual for the registry with me. These comments pertain to the draft dated January 1990. Since registration data will be collected either by hospital or research staff members, it is important to have a protocol and directions that are clearly understood by everyone coming in contact with the patients and/or the data collection process. The following comments indicate potential problems with the draft that I received.

There is no detailed list nor explanation of eligibility criteria for selecting these patients. Questions such as age limits, acceptable diagnostic categories, ward location, counties of residence, time of residence, etc. are not answered clearly. There should be a specific discussion of these categories in a section of the manual, with definitions and examples given for each item. Are there any exclusions to the registry? If so, this requires discussion also. This may be a good place to describe data collection in case of refusals and/or early death or disability.

Little thought has been paid to transfer patients. All admission dates and times seem to refer to the current hospitalization, but there's no indication of when the initial myocardial event may have occurred. In addition it's not clear whether you are going to accept patients who were admitted to the hospital for another reason and suffered a heart attack thereafter. All types of transfer patients may require special tracking in order to verify their records. It may be necessary to add a special code to the form to indicate transfers.

Since Dr. Burke will be leaving Epidemiology shortly, I'd omit his name from the manual and consent form. The consent form, in particular, forms the contract between the patient/family and the study, and a copy should be given to the respondent. It's not appropriate to list Greg as an investigator for further contact.

In other studies, it has been useful to provide example dialogues for the interviewer. You provide one for requesting consent, but it would be good to have one describing the study and the patient's role in it. This is especially helpful to non-research staff.

It's not clear how much of the form will be filled out in case of refusal or inability to complete for whatever reason. There should be an indicated set of core items which are collected under all circumstances for enumeration and event characterization. This basic data set should include the person's Social Security Number, which is not being obtained at the present time. This will be very important for survival studies using the National Death Index.

The initial registration form has a number of inconsistencies between its items and/or the Instructions in Section 4. I have listed these problems below. In most cases clarification will be important to aid the hospital staff concerned with registration and documentation of the event. I appreciate your efforts to keep this form and manual short and simple, but missing definitions can hinder collecting the high quality data envisioned for this registry.

1. Case ID should have space for a computer-generated label, unless each form will be pre-printed before use.
2. Question 1. Today's date and time may not be the "date when case was identified initially" for transfer patients within or between hospitals.
3. Question 3. The rest of the form refers to Patient, but this question refers to Participant. If this means Patient or Relative/Guardian, then it should state this.
4. Question 4. The middle name should be obtained in full, if possible. Minnesota has many people with very similar names. Death record linkage has sometimes depended on knowing middle names, when people of similar ages and names die during the year.
5. Question 7. Social Security Number should be obtained in addition to the Medical Record Number. This is also important for future record linkage.
6. Question 9. Gender types should be capitalized to match format of other items.
7. Question 10. Admission Date and Time are meant to track "first measurement of vital signs in hospital". This may not be relevant information for a transfer patient. If an Event date/time is desired, it should be asked for specifically.
8. Question 13. The phrases describing education can be rearranged and grouped more efficiently by leaving out the word "Graduate" under "Less than High School".
9. Question 19. It's not clear what "this" previous heart attack refers to, especially in case of transfer patient.
10. Question 21. There should be a permission code (Question 22) for every hospital in the list.
11. Question 23. Has this question been checked by Dr. Lando? Many smoking investigators are now concerned about length of smoking exposures.
12. Question 28. Are you only interested in family history before age 55? Only siblings and parents are referred to; what about children?
13. Some of the later questions 23-29 could be grouped more effectively, i.e. place all questions related to hospitalization before those concerning disease risk factors.