

Volume 3, Chapter 10

Patient Compliance Committee Chapter

Manual of Operations Volume 3, Chapter 10

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10.2 Compliance Committee (CC) will prospectively track:

- 1 - Adherence to dietary protein prescription
- 2 - Alloisoleucine determinations
- 3 - Achievement of BP targets

Given our experience with Phase 2, following these 3 parameters alone could potentially involve this committee with up to 50% of the Diet L patients and up to 100% of the Diet K patients. In addition, as many as 60% of the patients in Phase 2 were outside the current BP target ranges at some point during follow-up. As a result, the committee elected to carefully assess compliance in areas that impact most directly on outcome.

Additional issues were suggested by other Steering Committee Members as areas that the CC might follow. These included but are not limited to items such as iron and calcium ingestions as assessed by pill counts or adherence to prescribed caloric intake. Given the potential enormity of the task in following the 3 primary measures (DPI, alloisoleucine, BP), we felt it necessary to prioritize, and thought that some of these other items might be more properly considered in committees assessing patient management in safety.

10.2 Methods by which CC will monitor compliance:

1. The DCC will provide CC members reports of the following, by center and by study-wide total, on a monthly basis:
 - a. Out of range reports for blood pressure, aminogram, and UNA. Included in these reports will be the number of patients and the degree to which values are discrepant in each area. (In the case of BP, the goal MAP and the patient MAP should be given. In the case of the UNA, the % deviation from target

should be given. In the case of the aminogram, just the patient data alone will suffice). Data will be grouped by diet assignment.

- b. Number of action items for blood pressure, UNA, and aminogram accruing each month.
- c. Number of persistently elevated BP, UNA, and aminogram accruing each month according to the criteria.
- d. Number of BP, UNA, and aminogram action items with unsuccessful resolution.

2. The NCC will provide CC members on a monthly basis:

- a. A report, by center, of the number of patients being followed by the NCC and the Dietitians' Compliance Committee for persistent UNA and aminogram out of range action items.
- b. The number of patients assigned for a CC review. The list will include: patient name code and ID number, reason for referral (e.g. % deviation from prescription), principal investigator, and name of assigned CC primary reviewer.

10.3. CC assessments for chronic UNA, aminogram or MAP out of range

1. When two consecutive discrepancy reports for UNA have been submitted, or if aminograms have been out of range for 2 out of 4 measurements in 2 consecutive 4 month compliance review periods, the CC becomes involved in the assessment and remediation of the problem.

a. The DCC will provide a patient file for the NCC Intervention Nutritionist and the primary reviewer. The patient file should include:

- Copies of Monthly and Four Month Compliance Flow Sheets
- Counseling Summary Form (Form 76)

This file should also include other relevant data such as:

- Quality of Life Assessments (symptom check list, physical activity assessment form, QWB if available and patient symptom list)

- Action Item Response Form (Form 23)
 - Biochemistry Flow Sheet
 - Aminogram reports for Diet K patients
 - Dietary Satisfaction Questionnaire (Form 74)
 - Dietary Information Summary Report
 - and, as needed: Pill Count Form (Form 73), Special Dietary Considerations Form (Form 72)
- b. The DCC will assign a CC primary reviewer on a rotating basis. Primary reviewer will discuss with local RD, PI and NCC nutritionist and act as a moderator during presentation of this patient to a CC conference call.
- c. Records of suggestions made during conference call will be kept by the NCC and the primary reviewer. Follow-up data will be provided to the primary reviewer by the NCC and DCC until the action item is resolved.
2. Persistent Hypertension - MAP out of range for 4 consecutive monthly BP measurements.
- a. DCC will prepare informational packet:
- Quality of life assessments (as above)
 - Medication flow sheets
 - Biochemistry flow sheets
 - Action item response form
- b. The DCC will assign a physician CC primary reviewer on a rotating basis. Review practices will proceed as described above for UNA or aminogram out of range. Modifications of these procedures may be required during Phase 3 once it becomes apparent how large the task will be, and how useful, the functions are. If useful, the number of committee members may have to be increased in proportion to the number of patients considered by the committee.