Chapter 7

Alerts

INTRODUCTION

Alerts: An "alert" is identified as a situation in which specific responses to questions, signs, or symptoms exist that should result in a medical follow-up or referral after discussion with principal investigator or designee.

Alerts may appear during the following four parts of the exam:

- Blood Pressure
- CES-D
- Laboratory Analysis
- Living Conditions

Definitions:

Immediate referral – Discuss with supervisor and/or PI within 24 hours. The designated staff member should make a phone call or send letter to participant's physician at the direction of the PI (provided the participant has consented to release of the information to MD). Document in participant's chart.

Urgent referral – Discuss with supervisor and/or PI within 2 weeks of receipt of the information. The designated staff member should make a phone call or send letter to participant's physician at the direction of the PI (provided the participant has consented to release of the information to MD). Document in participant's chart.

Elective reporting – Normal or borderline results can be provided to the participant and/or reported to the participant's physician (with signed participant's consent) at the discretion of the field center PI.

Blood Pressure Alerts: Blood Pressure Alert levels requiring IMMEDIATE (within 24 hrs) referral are:

Diastolic BP ≥ 120
Systolic BP ≥ 210

Systolic BP < 80 with symptoms of lightheadedness, severe weakness or fatigue.

URGENT alert levels requiring referral within two weeks are:

Diastolic BP = 110-119
Systolic BP = 180-209

Alert levels requiring ELECTIVE REPORTING physician notification are:

BP ≥ 140/90 requires follow-up within two months time, and therefore we recommend physician notification for systolic or diastolic BP above these levels.

CES-D Alerts: A CES-D alert is identified as a score of greater than or equal to 14 on the modified 30 point CES-D (Depression) scale. In addition, any mention or indication during the clinic exam of suicidal tendencies is also to be considered an alert. If this occurs, the interviewer should let the participant know that it is possible to obtain help in dealing with such feelings. If the interviewer is uncomfortable with doing this, a supervisor may discuss this with the participant. The participant should be asked if he/she has a physician that could be consulted regarding depression. If the participant indicates he/she has no outside resource, the interviewer may provide a professional referral which has been selected by the site's Principal Investigator.

Laboratory Alerts:

Upon receipt of these lab values, the study coordinator should evaluate them for urgent referral.

Cholesterol >360 mg/dL
Cholesterol <100 mg/dL

HDL – cholesterol <20 mg/dL

LDL-cholesterol >260 mg/dL
LDL-cholesterol <60 mg/dL

Triglycerides >1000 mg/dL

Creatinine >2.0 mg/dL

Glucose >200 mg/dL
Glucose <60 mg/dL

Hemoglobin >19 g/dL
Hemoglobin <8 g/dL

WBC >25 x 10^9/L
WBC <2 x 10^9/L

Platelets >1000 x 10^9/L
Platelets <50 x 10^9/L

Living Condition Alerts: During a home visit staff may encounter living conditions that are unsafe or unhealthy. Clinics should develop a local resource list of social services that may be able to address problems of cleanliness or lack of basic services such as heat or water. Any unsafe or unhealthy conditions including suspected abuse should be discussed with the clinic coordinator and principle investigator for follow-up based on local statutes.

Study Documents Referred to in this Chapter:

- BP, Weight, Height and Waist Circumference Data Collection Form
- Mood and Personality Data Collection Form
- Spirometry Data Collection Form

Sample – MD Alert Letter

[DATE]

[PHYSICIAN NAME]
[ADDRESS]
[CITY, STATE, ZIP CODE]

Dear Dr. [INSERT NAME]:

Your patient is participating in the LONG LIFE Family Study, an observational study of exceptional survival in families. As part of this research study several tests were performed on [Insert Date]. [Because of abnormal findings, a copy of the results is attached for your review.]

[PI may insert narrative here, if needed.]

All tests were performed for research purposes only and will be used to describe the health status of men and women who are taking part in this study.

These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest specific diagnosis or treatment, we hope this information is useful to you and your patient. If you have any questions, please feel free to contact us at [Insert name, phone number of site-specific study clinical coordinator here].

Thank you for your support.

Sincerely,

[Insert site-specific PI Name Here]
Principal Investigator
LONG LIFE Family Study

Sample – Participant Alert Letter

[DATE]

[PARTICIPANT'S NAME]
[ADDRESS]
[CITY, STATE, ZIP CODE]

Dear [INSERT PARTICIPANT'S NAME]:

On [Insert Date] we performed a research interview and examination as part of your participation in the LONG LIFE Family Study, an observational study of exceptional survival in families. As part of this research study several tests were performed. [Enclosed are results from your visit.] As we discussed on the telephone, several of the results are abnormal.

[PI may insert narrative here, if needed.]

All tests were performed for research purposes only and will be used to describe the health status of families who are taking part in this study.

These tests are not intended to replace any tests that your doctor may order for a specific reason, but do provide information about your health. Although we do not suggest specific diagnosis or treatment, we hope this information is useful to you and your patient. If you have any questions, please feel free to contact us at [Insert name, phone number of site-specific study clinical coordinator here].

Thank you for your support.

Sincerely,

[Insert site-specific PI Name Here]
Principal Investigator
LONG LIFE Family Study