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Studies Using Verbal Autopsy Data Collection Procedures

Definition: “Verbal Autopsy” is the collection of post-mortem information about a deceased individual through questionnaire or interview of household members, friends and others (including health care workers) who cared for the person at home or are familiar with the circumstances of the death.

Verbal autopsy methods are most often used in locales where formal medical care is difficult to access. In such locales, deaths often occur at home and official records are inconsistently available. Verbal autopsies may provide important public health information about factors related to deaths and actions taken to address the medical problems and prevent the death.

Investigators must adhere to cultural norms and sensitivities when approaching and asking for information from family members and other informal caregivers of the deceased person. Study teams, especially research interviewers who will conduct these interactions, require training in local customs about these issues, particularly regarding awareness of the pressures on respondents to portray situations in a particular manner, sensitivity to the distress respondents may feel related to the interview/questionnaire, and approaches for handling high levels of distress.

Very rarely, verbal autopsies may indicate that unnatural causes have contributed to a death, whether accidental or intentional. The legal and ethical issues associated with such a suspicion are challenging for Principal Investigators and IRBs. When there is a legal mandate to report suspicions of intentional injury or death, PIs must follow the law. A well known example is the statutory requirement to report suspicion of past or current abuse of children in all states in the U.S.

Even when there is no legal mandate to report, a PI understandably may feel that s/he ought to inform authorities about a suspected harm in order to redress a potential wrong. However, such a report may cause harm to the family of the deceased, to the reporting party, or to the research enterprise. A primary problem is that it is impossible for the PI to determine the veracity of the reports that give rise to suspicions of intentional injury or death. A report would clearly cause a harm if the PI were to make an erroneous suggestion to authorities that a death was intentional. Other problems include the risk of retribution against the reporter, the violation of promises of confidentiality made by the PI to the reporter, disincentives for honest reporting in the future, and the variable or unknown integrity of police and judicial infrastructures, with consequent uncertainty about whether the responsible person would be appropriately identified and prosecuted.

As a rule, in the absence of a legal mandate to report suspicions of intentional death, the PI should not report to local authorities about suspicious deaths based on information from verbal



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autopsy. Nor, as a rule, should the PI report such suspicions to local IRBs, which are unlikely to be equipped to do anything with the information to address the ethical or justice issues.

The most substantive protection a PI may provide a reporter is thorough and extensive context-specific training of the interviewers who conduct the verbal autopsy. The interviewer should be prepared to handle reports of actual or suspected intentional death, and reports of concern about the safety (self-harm or harm from others) of other household members, primarily by referring reporters or other household members to resources that are appropriate and available to address safely the need expressed.

Additionally, information about suspicious deaths may be useful in the aggregate to indicate prevalence of suspected intentional harming behaviors in the population, and to reflect trends, such as prevalence of suspected intimate partner violence, or of harm to female infants. PI monitoring of reports of suspicious deaths, and report of aggregate information to the JHSPH IRB, could provide adequate oversight of the local situation. This report could either be through timely interim analyses, or through regular Progress Report submission.

Specific Information Required for Submissions to the IRB

- The consent document should be silent on reports to authorities, unless there is a legal mandate in place. The IRB has the authority to see reports, and is listed on the consent document; the question of whether to include a reference to the IRB in the confidentiality section may be handled on a case by case basis. If the IRB will only see aggregate, de-identified data in the PI reports, there is no reason to specifically mention the IRB in the consent document.
- The research plan should explain what the legally mandated reporting requirements are in a particular research site. It should also include a description of the PI's plans for training interviewers, and for reporting to the JHSPH IRB on information obtained about actual or suspected intentional deaths.
- The research plan should identify what local referral opportunities are available in the event that a reporter or other household member requires additional help.
- The Progress Report should include aggregate information about reports of suspicious deaths learned from verbal autopsy.

Information for Guidance obtained through discussions with the following participants: IRB X members and staff, Jon Links, Joan Pettit, Abdullah Baqui, Linda Bartlett, Peter Winch, (and by teleconference), Henry Kalter and Harshad Sanghvi.

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