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Subject Mortality: Is It Inevitable?

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Subject mortality, which is the differential loss of subjects from a study, is a problem that plagues nurse researchers in all clinical areas. Mortality not only is a frustrating problem, but more importantly, is a threat to the internal validity of a study. When mortality occurs in experimental, control, or both groups, the differences in the study outcomes may be attributed to this differential dropout of subjects and not to the independent variable. Textbooks on research are all quick to note the danger of subject mortality as a threat to internal validity; however, the solutions to this problem are not addressed. What can a nurse researcher do to combat this serious problem of subject dropout? The causes of mortality can be grouped into two main categories: those the researcher has control, and those over which he/she has no control. Possible solutions to subject mortality will be explored with the help of examples from an obstetrical time perception study.

This obstetrical study investigated whether there was a difference in the temporal experiences reported by women during latent and active labor. Verbal estimation was used to research 60 laboring women's temporal experiences. The experimenter first demonstrated a specific interval of time (through the use of a stop watch) then the subject was asked to verbally estimate the duration of that preceding interval in seconds and/or minutes. Between her contractions each laboring woman was asked to verbally estimate a 40 second interval once during the latent phase of labor (1-4 centimeters), and again during the active phase, specifically during transition (7-10 centimeters). If a woman over-estimated the 40 second interval of time, this was indicative of objective time passing relatively slowly, while an under-estimation indicated time was passing swiftly. The researcher remained on the labor floor between the latent and active phase verbal estimates to insure she was present when the women reached transition.

During the five month data collection period the researcher frequently encountered subject mortality in her quest of obtaining a sample size of 60. In addition to the final sample of 60 women, latent phase verbal estimates were obtained from an additional 21 women, but due to the following reasons these

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subjects did not complete the study: (1) nine women underwent Caesarean deliveries due to a failure to progress; (2) three women had Caesarean deliveries due to breech presentations; (3) five women were sent home after their contractions had stopped; and (4) four women refused to verbally estimate the time interval during transition.

The researcher had no control over the subject mortality due to Caesarean deliveries or labor ceasing. Nurse researchers in other clinical areas also lose subjects due to reasons they have no control over; i.e., subjects dying or moving away. Nevertheless, it is an extremely frustrating reality of clinical research. An example of such a discouraging data collection day in the obstetrical study began when the researcher obtained a primigravida's first verbal estimate at 7:45 A.M. The researcher followed this woman until 2:30 P.M., only to have her undergo a Caesarean delivery for failure to progress beyond 3 centimeters. A multigravida had also been admitted that same day at 1:30 P.M. The researcher obtained the woman's first verbal estimate at 2:00 P.M. and followed her until 9:15 P.M., when she too had a Caesarean delivery for failure to progress. After having spent fourteen hours that day in the labor and delivery unit, the researcher left without having obtained any subjects for her sample.

There are reasons, however, for subject mortality that nurse researchers can take an active role in preventing. Subjects' lack of cooperation or outright refusal in completing the study procedures are two such reasons. Establishing trust between a nurse researcher and the study participant is vital if subject mortality is to be prevented. When a nurse researcher collects data during a particularly stressful event, he/she first needs to establish a trusting relationship. This is vital to have any success at all in obtaining subjects' cooperation. For example, in the obstetrical study the researcher quickly learned that if she wanted the women to cooperate and complete the study procedures she had to first gain their trust by supporting them through their labor. This researcher's participation in the nursing care of the laboring women enhanced the women's cooperation during transition. This benefit is not possible, however, in all types of clinical research. If, for example, a research design necessitates that a nurse researcher be a nonparticipant observer, this solution to subject mortality is not a viable option. In the obstetrical study the benefits of the nurse researcher's supporting the women during labor were enormous. Only four women out of 64 refused to estimate the second time interval during transition. Two of the women who refused had not received supportive care from the researcher. One woman stated that she only needed her husband to coach her. The second woman did not receive support from the researcher due to lack of time. This woman dilated from 4 centimeters to fully dilated in less than 30 minutes.

Nurse researchers in all clinical areas need to be aware of two potential problems in using participation in subjects' care to decrease subject dropout rate. First, there is the potential of creating a conflict with the nursing staff. This problem never occurred in the obstetrical time perception study. The nurse researcher's nursing care of the laboring women was strictly supportive. She did not perform any technical tasks, such as giving medications. The nursing staff on the labor and delivery unit were grateful for the researcher's assistance in supporting the laboring women, especially on hectic days when the staff nurses did not have the time to devote as much attention to the women as they would have liked. If a nurse researcher is planning on using this technique for decreasing subject mortality, it is essential that the nursing staff first be met

with to explore their feelings about the researcher participating in the subjects' care and to set up guidelines to be used during data collection.

The second potential problem of a nurse researcher's participating in the subjects' care is the effect the dual role as nurse and researcher may have on the subjects. The subjects may not be able to separate these two distinct roles of the nurse researcher. A subject might be so grateful to the nurse researcher for the care given that the subject may be "coerced" into cooperating in the study procedures. The nurse researcher must emphasize to subjects that they should not feel an obligation to complete the study procedures just because the researcher has given them nursing care. For example, in the obstetrical study the researcher vividly remembers one multigravida who happened to be the oldest woman in the sample. Her husband, who believed having babies was women's work, dropped his wife off at the hospital entrance and told her to call him when she had delivered. Consequently she was alone during labor. The researcher supported her throughout labor and during transition. When the researcher asked her if she minded estimating one more time interval she replied, "I'm so grateful to you for staying with me during my labor that I'd do anything you asked me to do!" After hearing this, the researcher stressed to this multigravida that the nurse researchers supporting her throughout labor did not necessitate the woman's estimating the second time interval during transition, it was further emphasized that it was perfectly all right if she refused to complete her participation in the study.

Lack of motivation may be another factor in subject dropout rates. In order to help prevent mortality due to lack of motivation, nurse researchers should make certain they include in their informed consent sheets a paragraph alerting the potential subjects to the benefits of the study for future patients. After the potential subjects have read the informed consent sheets, the nurse researcher should take a few minutes to reinforce the benefits the knowledge obtained from his/her study will have for patients in the future. Hopefully these explanations will be an incentive to subjects to remain in a study and complete all the study procedures.

In summary, the following are three suggested solutions to subject mortality: (1) Explanation of the benefits of the study. (2) Establishment of a trusting relationship. (3) Participation in nursing care when permissible by the research design. By no means foolproof, but certainly is well worth the effort is the time a nurse researcher expends in order to decrease his/her subject dropout rate.

Commentaries

A number of important points are made about causes of subject mortality and ways to prevent mortality. I would take a broader perspective in considering approaches to decrease the mortality: Prior to testing:

(1) Sixty women in the sample obtained in five months seems low according to what one would expect for a researcher in the hospital five days a week. Could the researcher select a labor and delivery area offering a chance to obtain the required sample size in a shorter period of time? Perhaps this could decrease the researcher's frustration and discouragement.

(2) Could the researcher establish contact with potential subjects prior to the time subjects come to the hospital to deliver? Here the researcher could establish trust with the women and have the consent form signed. This may allow more time for the trust to become firm within the subjects and thereby decrease risks of subject mortality once the study has begun.

(3) Could the researcher have included only mitigravidas in the study who had no history of complications? This may decrease the chance of subject mortality.

(4) It is not known what number of subjects refused to sign the consent form to initiate the study. I suspect the number who did refuse was high and that the reasons for refusal were not immediately under the control of the researcher. These reasons are related to (1) the lack of sufficient status of a *nurse* (researcher) in many health care facilities. The patient, then, feels no contagion of status if she/he does participate and may even take advantage of an "easy" opportunity of establishing control over others by refusing to participate in the study and (b) the uninterested manner in which many researchers are given access to patients in the hospital. Paving the road for the nurse researcher and having enthusiasm expressed for the study once it is underway is a task just begun by many nursing administrators. The hospital is still the doctor's workshop, not the nurse's.

Factors (a) and (b) influence the willingness of subjects to cooperate throughout the research process. The operation of these factors occurs through behavior of persons in the milieu which in turn affect the patient, rather than the effect operating from researcher to patient (though the nurse him/herself may act as one without status). While the staff may have liked the researcher giving care to patients, this does not mean that in other behaviors visible to the patients they indicated support for the nurse or the research.

Prior to and During Testing:

Subject mortality was one factor leading to the researcher's discouragement and frustration. How did the researcher and her frustration affect subject mortality? I question the ability of the researcher to do accurate data collection and to have a neutral effect on the subject after thirteen hours of data collecting. Here one needs to research the researcher as advocated by Garfinkel (1967).

To overcome the problems mentioned the researcher could join or start a peer group of nurse researchers to obtain ideas and support.

This group could take place in the hospital with attendance or leadership by nursing administration so as to provide a networking system to ease the barriers to the nurse researcher.

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Is subject mortality inevitable? Of course it is. It is the bane of a researcher's existence. There will always be those who refuse to participate, who cannot follow directions, who move, or who die. What, then, can the researcher do? They can plan for attrition and use it to benefit their research.

In planning for subject attrition, a decision must be made regarding the required "N" for the study. This will depend upon the type of study, the type of data, and the number of variables studied, then one must look for a setting that can potentially provide the appropriate sample. After estimating the potential sample size obtainable, one must then consider the effect of attrition. I tell master's students to estimate how many subjects they *think* they can obtain, then cut that number in half. If 50 percent of the estimated sample is not sufficient to conduct the research, they must decrease the number of variables or count on doubling their data collection time. There are also other ways to decreasing subject mortality or attrition.

The researcher can do cross-sectional data collection rather than long-term follow up. More subjects are likely to be lost over time than in a one-time only data collection (this is especially important for student projects in which time is a critical factor).

Data collection should cause as little disruption and effort on the subjects' part as possible. This includes questionnaires that are readable, not too long, clearly worded, and as inoffensive as possible. Cultural appropriateness is also important. For example, in my experience, adolescents do not respond well to forced choice Likertlike scales when dealing with sensitive issues.

One can provide some benefit to the subject if feasible. There is clear precedent in research for monetary compensation. If not possible, other forms of compensation are permissible. However, one must be careful that the benefit received by the subject does not influence his/her perception of the variables being tested. For instance, I would question in the study reported whether the nursing intervention provided might not have significantly influenced time perception in labor. Pain, combined with loneliness and fear, could make the hours interminable.

However, many analyses require "x" number of subjects per variable. If a study has too many variables, the researcher will end up requiring an enormous sample size or having too few subjects to make the analyses valid. Moreover, so many statistical tests will be done that some will come out significant just by chance.

Planning for subject attrition is fairly straightforward; however, it is often difficult to see how attrition can actually be used to benefit research. When subjects are lost, one should question why. Perhaps the questionnaire was too long or unreadable. Perhaps data was collected in the wrong setting—a setting where there was no privacy, or subjects were in a hurry. Perhaps subjects were approached incorrectly and did not understand the study or what they were supposed to do. Attrition may also related not only to the data collection method, but to the actual variables being tested. It would be significant, for instance, if only members of a certain ethnic group dropped out or if only women declined to participate. In this reported study it would be interesting to see if those who were dropped because of Caesarean birth differed in any other way from the rest of the sample. There is evidence that a woman's emotional state may significantly effect progress and complications of labor. Perhaps in early labor these women evidenced longer latent phases (a potential sign of uterine dysfunction). Their time perspective, then, could differ from

the rest of the group even earlier in labor. Time perspective could be viewed not only as a reflection of the stage of labor but the woman's general emotional state as well.

When subject attrition is high, the researcher should attempt to find out as much as possible about the subjects lost. That data should then be scrutinized as carefully as that from the remaining subjects. The researcher may then learn something significant about the study design or instruments, or perhaps even the variables themselves.

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Subject loss is a dreaded problem for all researchers engaged in longitudinal studies. The author has addressed the problems of expense and the challenge to internal validity. If internal validity is established, external validity may then become a problem. A careful study of characteristics of the dropouts is an important part of a longitudinal or time-phase study. Initial scores and characteristics of those who remain in a study may be compared with those who dropped out. For example, did the 21 subjects who were lost differ during the latent phase of labor from remaining subjects in estimating the passage of time. If so, were demographic or other variables also different? In our recent project we interviewed subjects over a one-year period. We quickly learned that those persons initially hesitant in deciding to participate were also most often those who dropped out later. We had a 17.4% subject loss. Dropouts were more often single and had a less integrated personality. Within the total sample, we studied three age groups. Younger women who also were single more often and had a significantly lower personality integration score were more likely to drop out (39.4% of the 15-19 year olds, 17.4% of the 20-29 year olds, and 2.2% of the 30-42 year olds dropped out). Within age groups there were no differences between those who dropped out and those who continued for marital status, ethnicity, total positive self-concept, and personality integration. In the 20-29 year old group, only those who dropped out had significantly less education. The dropouts from the total sample appeared more attributable to age than to other variables. We found that among other differences, the teenager is less likely to continue in a longitudinal study than the older woman.

The author raises the question of whether coercement may occur if nursing care is given to subjects by the researcher. The same question may be addressed in situations where subjects are paid to participate in a project. One may view the agreement between the researcher and subject as the establishment of a contract (trust) with trade-offs. In exchange for time or intrusion into privacy, the patient receives a valuable (and expensive) service when the nurse investigator also provides supportive care. Small monetary awards help

offset the expense of time spent as a research subject. We are then faced with the problem of the Hawthorne effect. For example, in the author's time study, those patients who received her expert emotional support during labor could be expected to be more in control at transition, and thus perceive time more accurately. Similarly, a paid participant might tend to respond in a way perceived as helpful to the researcher.

When planning research projects, some subject loss can be predicted by studying available statistics. How many subjects have been available in the comparable period of time preceding the research (or at the same time of year if the variable under study is seasonal)? Much of the author's loss could have been predicted prior to data collection. Of 81 who completed time estimations during the latent phase of labor, 12 or 15 percent had a Caesarean birth. This rate is within the range of Caesarean births reported in hospitals across the country (rates include repeat Caesareans and vary). Another 5 (6 percent) had false labor and were sent home. Most importantly, only 4 of 81 (5 percent) refused to estimate the time interval during transition, and one of these progressed from 4 to 10 centimeters in 30 minutes. With the ego constriction that occurs as labor progresses (Rich 1973) mental gaps occur (Affonso 1977), and the author is to be commended for her low attribution rate. However, commendation and empathy do not reduce the expense to the researcher in travel, time or loss of employment (giving up work days for research days) which may not be reimbursed.

There are no easy answers to the philosophical questions raised here. Those who have time constraints are duly forewarned of some of the hazards in conducting time-phase studies by the author.

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Response by the Author

In her commentary Mercer stressed the importance of studying the characteristics of the dropouts in a longitudinal study. She raised the question as to whether the 21 women who were lost from the obstetrical time study differed in

their latent phase verbal estimate of a 40 second interval from the remaining 60 subjects. The mean latent phase verbal estimate of the 21 dropouts was 113 seconds which is strikingly similar to the mean latent phase verbal estimate, 118 seconds, for all 60 women who completed the study.

Both Mercer and Howe proposed that the nursing intervention provided by myself might have influenced the subjects' time perception in labor. I agree with both Mercer and Howe that my nursing support was an intervening variable which might have affected the parturients' temporal experiences. Just how the nursing support affected time perception is unclear. Mercer purported that it may have resulted in the women being more in control during transition. My own thoughts are that the intense nursing support provided a distraction for the women and prevented them from attending to the passage of time. The effect of nursing intervention on temporal experiences in labor needs to be addressed in future research.

In Birckhead's commentary she enumerated four approaches to decreasing subject mortality, but for the following reasons I was not able to carry out her suggestions. Due to geographic location and the inundation of research requests at the larger teaching hospitals, it became necessary for me to collect data at two smaller community hospitals, thus requiring a longer data collection period. I chose not to approach women prior to their admittance to labor and delivery for two reasons: a time constraint and I would have to be on-call for the deliveries. Some of the women would have delivered during the night, and I had excluded night deliveries from my sample since time of day might effect time perception. Both multigravidas and primigravidas were included in this study since a literature review revealed a lack of obstetrical time-perception studies, and I wanted to explore whether gravida had any effect on women's temporal experiences durig labor.

(Birckhead stated she suspected that a high number of subjects in the obstetrical time study had refused to sign the consent form.) Contrary to Birckhead's belief, not one women who was approached to participate in this study refused to sign the consent form. This success rate is attributable to the fact that the women were invited to participate in the study during early labor (before the women were beyond 4 centimeters). While their contractions were still mild, the women were excited that their labor had finally begun and were eager to talk.

In response to Birckhead's question: "How did the researcher and her frustration affect subject mortality?", I believe my frustration level did not affect the dropout rate of my sample because either Caesarean birth or labor ceasing were the reasons why 17 out of the 21 women had to withdraw from my study. Both of these reasons were beyond my control as a researcher.

Birckhead also questioned my ability to accurately collect data after thirteen hours of data collecting. With each parturient, no matter how long I had been data collecting, I had a list of precautions which I faithfully carried out prior to asking the woman to estimate the 40 second interval. These precautions included the following: covering the wall clocks, removing wristwatches, turning off the television and the volume of the fetal monitor, and standing at least 4 feet from the women so they could not hear the ticking of the stopwatch.

The last point that I would like to address was brought up in Dr. Howe's commentary. She questioned whether the women who had been dropped from the study because of Caesarean births had a longer latent phase and, if so, would this have resulted in these women having a different time perspective

than the remaining women in the study. The reason nine out of the twelve dropouts had Caesarean births was because of a failure to progress. These nine women did have a longer latent phase than most of the remaining women in the sample. However, the mean latent phase verbal estimate for the dropouts due to Caesarean births was 114 seconds which does not differ significantly from either the mean latent phase verbal estimate of all 21 dropouts (113 seconds), nor from the 60 subjects (118 seconds) who had completed the study.