

Retention in Prospective Studies: Cohort Studies and RCTs

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Losses to Follow-up (LFU)

- ◆ LFU materialize as perhaps the most vexing of the proffered reasons for exclusions after randomisation
 - Participants may move or refuse to continue participating



Losses to Follow-up (LFU) (cont.)

- ◆ Participants lost to follow-up could still be included in the analysis if outcome information could be obtained from another source, such as a national death registry
 - Those opportunities rarely happen, however



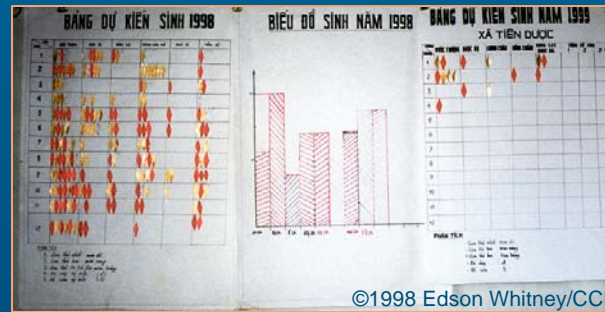
The screenshot shows the 'Citizen Services' page for Birth/Death Registration. The page features a navigation breadcrumb: 'You are here: [Home](#) > [Citizen Services](#) > [Birth/Death Registration](#) > [Death Registration](#)'. The main content is divided into two sections: 'Birth/Death Registration' and 'Death Registration'. The 'Birth/Death Registration' section includes links for 'Birth Registration', 'Birth Extract Application', 'Death Registration' (with a sub-link for 'Frequently Asked Questions'), and 'Death Extract Application'. The 'Death Registration' section includes links for 'Procedure', 'Documents Required', 'Fees', 'Processing Time', and 'Statistics on Deaths in Singapore'.

Exclusions of LFU Damage Internal Validity

- ◇ Without outcomes from those lost to follow-up, investigators have little choice but to exclude them from the analysis
- ◇ Any losses damage internal validity
 - However, differential rates of loss among comparison groups cause major damage
- ◇ Investigators must minimize their losses to follow-up

Exclusions of LFU Damage Internal Validity (Cont.)

◆ Consider outcomes to the point of loss



◆ Analyze losses by group for differential rates of loss

- Unpleasantness
- Toxicity
- Efficacy
- Anything that may affect loss

Pragmatic, Procedural Hint to Minimize Exclusions

- ◇ Minimizing exclusions after randomisation usually involves **randomising at the last possible moment**
- ◇ **If randomisation occurs when the participant is first identified and before treatment is initiated, then any exclusions occurring before treatment still become exclusions after randomisation**
- ◇ Investigators can address this potential problem by delaying randomisation until immediately before the treatment begins

Retention of Trial Participants

- ◇ **Minimizing losses in some trials exudes difficulties**
- ◇ **Eliminating losses may be impossible**
 - **But investigators too frequently profess insurmountable difficulties**
- ◇ **Many investigators should work harder to obtain higher follow-up rates**
 - **Must commit adequate attention and resources to develop and implement procedures**
 - **Diligent and clever**



Innovative Twists That Cultivate High Follow-up Rates (1)

- ◆ **Establish many convenient follow-up clinics**
 - **Follow-up venues should cater to the participants rather than to the investigators and trial implementers**
 - **Too often investigators expect participants to visit a single, inconvenient location**
 - **More locations than just the central hospital, close to where participants live, with convenient access**



Innovative Twists That Cultivate High Follow-up Rates (2)

- ◆ **Shorten the data collection instrument to a manageable size**
 - **Caters to the participants' wishes and needs**
 - **Fosters follow-up by not overburdening participants**
 - **Also may engender higher quality data on the main items of interest**



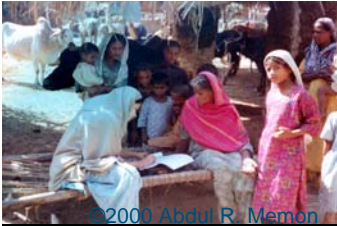
Enhancing Retention

- ◇ **Streamline trial procedures to move participants quickly through a follow-up visit**
 - **Sensitive to wait-time**
- ◇ **Provide excellent and free medical care**
- ◇ **Provide monetary subsidies, primarily for time and travel costs incurred by participants**



Enhancing Retention

- ◆ Hire an additional person to manage and encourage follow-up
- ◆ Hire additional personnel to call or visit participants at their homes or place of work, if participants are not returning for follow-up
- ◆ Exclude before randomisation those likely to be unwilling to return
- ◆ Exclude before randomisation those likely to move



Enhancing Retention

- ◆ **Obtain contact information to prompt participants to return for follow-up and to facilitate locating participants if they do not return (e.g. mail, telephone, and email)**
 - **For enrolled participants**
 - **For close friends or relatives who do not live with the participant**
 - **For their primary physician**
- ◆ **Obtain an identification number, such as a national health care number**

Summary for Retention

- ◇ Randomize at last possible moment
- ◇ Be innovative
 - E.g., many convenient FU facilities
 - E.G., shorten data collection instrument
- ◇ Devote appropriate time and resources
- ◇ Set goals high for retention
 - E.g., LFU rate not to exceed the outcome event rate

End