

## 15. Practical aspects of epidemiologic research

*Epidemiology in the "real world": the practice of epidemiology and its institutional environment -- funding, logistics, collaborations, peers, publication, publicity, politics and policy, study conduct, data management.*

### **Natural history of a study**

1. Develop an idea for a study, see an RFA, be invited to work on a proposal, . . .
2. Explore the literature, talk with others, brainstorm
3. Develop the rationale and specific aims/questions
4. Design the study - architecture, setting, study population, eligibility criteria, measures, analysis
5. Arrange collaborations, secure access to needed resources
6. Prepare proposal and submit for review (human subjects and scientific) / approval / funding
7. Obtain resources - funds, release time, space, personnel, equipment, subcontracts, consultation, advice, and assistance
8. Create a management structure, timetable, workplan, communication infrastructure, quick reference resources, documentation procedures, filing systems
9. Identify measurement instruments, analytic procedures, etc.
10. Develop data collection protocol, forms, confidentiality, training
11. Obtain human subjects (IRB) approval for data collection instruments and procedures
12. Pretest questionnaires and data collection forms, and revise
13. Create tracking system(s) for subjects and forms
14. Develop data filing systems - manual and electronic
15. Design a system for data linkage (ID and numbers)
16. Arrange contemporaneous monitoring of process and output, with feedback to data collectors, including quality control measures
17. Pilot test questionnaires, data collection forms, and procedures
18. Modify instruments and procedures
19. Obtain IRB approval for revised data collection instruments and procedures
20. Schedule and train data collection personnel
21. Collect data, monitor the activity with frequent written reports
22. Review completed forms for completeness, consistency, and accuracy
23. Make modifications and provide feedback to get back on track

24. Submit manuscript from previous study
25. Develop formal edit specifications and coding rules, pilot test them, and implement
26. Computerize data
27. Compile Data Management Manual
28. Explore the data
29. Create data files for each data stream, create analysis files
30. Prepare an accounting for all data, check the N's very carefully!
31. Carry out preliminary analyses to inform planning and to look for big surprises
32. Write next grant proposal
33. Clean and summarize data
34. Create analysis variables and scales
35. Write a descriptive report
36. Address the research questions
37. Control for potential confounders, effect modifiers, other extraneous factors
38. Bring documentation up-to-date
39. Write up results of analyses
40. Write conclusion and introduction
41. Submit request for no cost extension
42. Fill in missing analyses
43. Complete manuscript and/or report
44. Arrange for storage for data, analyses, and documentation and/or make data and documentation available for use by others
45. Write and submit final report to funding agency

### ***Funding an epidemiologic study***

Most epidemiologic studies of any size (e.g., costing \$20,000 or more) conducted by independent agencies (e.g. universities, research institutes) are funded through research grants or contracts. The large majority of these are awarded by federal agencies, particularly institutes within the National Institutes of Health (NIH).

Major NIH agencies that fund epidemiologic research include the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Disease (NIAID), the National Institute of Environmental Health Sciences (NIEHS, located in Research Triangle Park), the National Institute of Child and Human Development (NICHD), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH). Other agencies of particular interest to epidemiologists seeking funding are the Centers for Disease Control

(CDC, which includes the National Institute of Occupational Safety and Health [NIOSH] and the Agency for Toxic Substances and Disease Registry [ATSDR]), the Environmental Protection Agency (EPA), and the Agency for Health Care Policy and Research (AHCPR).

### ***Types of federal funding mechanisms***

Grant applications to NIH are submitted through several funding mechanisms. The first mechanism is unsolicited investigator-initiated proposals (often called "R01's", since the application and grant, if awarded, will be assigned a number that begins R01-). Here the investigators develop a proposal on their own initiative and submit it on the hope (preferably with some informed judgment and informal advice) that an institute will have some interest in the proposed research.

#### **Program announcement**

Agencies often issue program announcements (PA's) describing particular interest areas and/or types of application the agency would like to receive. These announcements may or may not designate an amount of funding available. They usually do not involve a special review process, but they may request a Letter of Intent prior to the submission of the application.

The recipient of a grant award made in response to a program announcement has a considerable degree of latitude in carrying out the research, subject to overall responsibility for the general scientific conduct of the study and the accurate accounting for all monies expended within the budgeted categories. Funds can generally be shifted between budget categories and other adjustments made, and research objectives can be modified (in consultation with the granting agency project officer) if necessary.

#### **Request for applications**

A second funding mechanism is proposals submitted in response to a Request for Applications (RFA). RFA's describe a specific research area in which the agency wants to generate research. The difference between RFA's and program announcements is that an RFA usually identifies specific funds for the successful applications. In addition, applications in response to the RFA may be reviewed by a special review group, chosen to be knowledgeable or sympathetic to the kinds of research solicited.

The RFA may include special requirements for applying or for eligibility for funding. For example, a Letter of Intent may be requested or required; a certain number or types of components may be required to be present in the proposed study. The RFA may specify a special deadline other than the usual review dates.

Within these guidelines, however, the investigator has complete freedom in the type of study and study population he/she proposes, the specific hypotheses to be tested, the manner of carrying out the investigation, and so forth. Should a grant be awarded, the investigator has the same latitude as for other investigator-initiated research proposals. There is somewhat less freedom than in the first mechanism in that the agency has defined explicit goals and guidelines for the research proposals. But some of the guessing-game of what research would the agency like to fund has been eliminated

## Cooperative agreement

A cooperative agreement is a grant where it is anticipated that there will be considerable interaction between the grantee and the funding agency, and often with other grantees who are part of the same cooperative agreement. This mechanism can provide considerable flexibility for both the grantee and the granting agency. The level of involvement of the granting agency can vary considerably, but often includes measures designed to achieve greater uniformity across multiple studies (e.g., common questionnaire items, uniform procedures for data collection, joint analyses).

An important feature of a cooperative agreement is that the funding agency may be able to redefine the goals and objectives, and other major aspects of the activity, in midstream, even terminating the agreement if it decides that other needs are of higher priority. Often a steering or executive committee is created from among principal investigators and NIH representatives to make decisions concerning the direction of a funding program.

## Request for proposals

A request for proposals (RFP) differs substantially from the above mechanisms. An RFP is a solicitation for contract research rather than simply for the purpose of encouraging research in a particular area.

In issuing an RFP, the agency has decided that a particular study or studies are needed and has already decided the general framework of the study design. The investigators still have latitude in proposing how they would do the requested study or project, but much of this latitude will be directed toward interpreting and designing an approach to meet the specific objectives and criteria that have already been set out in the RFP.

A specific amount of money or other indication of resources available is usually given. If the agency likes your proposal but thinks it can persuade you to do it for less money, the agency may negotiate with you to reduce your budget.

If you receive an award under this mechanism, you will need to sign a contract specifying in some detail what you will provide to the sponsoring agency and when (a schedule of "deliverables"), and certain other conditions from the RFP. If you do not meet those conditions, or if the reports and "deliverables" you provide are not regarded as acceptable, your contract may be terminated.

RFP's are for the procurement of research. The data may belong to the funding agency.

Obviously, investigators generally prefer grants to cooperative agreements and contracts. There is much sentiment in favor of increasing the amount of government funding going to research project grants, which provide the greatest opportunity for investigators to pursue research of their own choosing.

Contracts need not be undesirable, however, particularly if the investigators are already interested in or would like to gain experience in an area of activity. Moreover, much of the major research in the

cardiovascular area -- notably the large collaborative randomized trials (HDFP, MRFIT, CPPT) and the ARIC study -- has been conducted through contract mechanisms.

Contract officers are generally understanding of difficulties that may arise in carrying out a project, and can be strong allies of the researchers. The contract officer's responsibility is to represent the interest of the agency in seeing the results of the project completed and of high quality. If you are working toward that end, you can generally expect a cordial relationship.

### **Access to data collected with federal funding**

In October 1998, the U.S. Congress passed a law providing for access under the Freedom of Information Act (FOIA) to data collected with federal funds. The legislation stimulated considerable unease in the scientific community, and the Office of Management and the Budget (OMB) received numerous comments in response to the draft regulations for implementing the law. OMB published a reviewed draft in August 1999 and in October issued final regulations, so that from this point forward (it is not clear whether or not the requirement applies retroactively) any investigator who receives federal funding to collect data (even if the federal funds represent only a portion of the total cost) can be required to provide that data under FOIA (FOIA contains certain provisions for the protection of privacy and proprietary material, though whether investigators will be regarded as having a proprietary interest research data they have been collected is an open question).

### **Research supplements for underrepresented minorities and for disabled scientists**

Another advantage of a grant or cooperative agreement is the opportunity to apply for supplements. Competitive supplements, where additional funds are requested through a proposal that goes through peer review, are generally difficult to obtain. Administrative supplements (generally below a certain dollar limit) can be awarded by the agency.

Most supplements are made in response to individual, ad hoc requests. However, there are also two supplement programs. In order to increase the number of underrepresented minorities in biomedical research and also the number of scientists with disabilities, the National Institutes of Health has for a number of years funded a program of supplements whereby an investigator who has a grant or cooperative agreement with at least two years of funding remaining can apply for an administrative supplement (i.e., rapid review within the funding agency) to obtain additional funds to support a minority or disabled graduate student, postdoctoral fellow, or junior faculty member to work on the study or a closely related investigation. There are also programs for high school and undergraduate students.

### **Information about grants**

One good source for learning about opportunities to apply for grants and contracts is the NIH Guide for Grants and Contracts, published by the NIH. The Guide appears approximately weekly and is available on the World Wide Web at <http://www.nih.gov> from where you can view institute program descriptions and access funding and other information.

## Assurances by the applicant and her/his institution

In the British colonies in what is now the United States, the "power of the purse" was a primary strategy by which the colonial legislatures could influence the conduct of government. In more recent times (I would guess since about the 1960's), the U.S. federal government has used the awarding of funds as a mechanism to achieve various governmental objectives. In some cases this strategy has enabled the federal government to enforce behaviors in areas of authority outside those assigned to it by the U.S. constitution (and therefore reserved by the Tenth Amendment to the states or the people). But even where the federal authority is clear, tying requirements for desired behaviors to funding gives a more detailed and powerful means of achieving compliance than that available through overburdened law enforcement and judicial systems. Thus, the applicant institution for a grant from the Public Health Service (of which NIH is a part) must provide assurances related to: Age Discrimination, Civil Rights, Debarment and Suspension, Delinquent Federal Debt, Financial Conflict of Interest, Handicapped Individuals, Human Subjects, Lobbying, Research Misconduct, Sex Discrimination, Vertebrate Animals. These assurances primarily relate to the presence of institutional practices and policies (with which individual researchers must, of course, comply). One area, though, risk to human subjects, often demands specific attention from researchers, such as epidemiologists, who study people (scientists who study non-human animals have a corresponding concern regarding vertebrate animals).

Before an investigator can collect data from or on human subjects, s/he must obtain permission from a human subjects protection review committee. In the United States, these are designated by NIH as Institutional Review Boards (IRB), though they may have other names as well (e.g., "Committee for the Protection of Human Subjects in Research"). The IRB mechanism was created in 1973, following a public outcry and Congressional hearings in response to media publicity about the now-infamous Tuskegee Syphilis Study (the history is presented in James Jones, *Bad Blood: The Tuskegee Syphilis Experiment – a tragedy of race and medicine*, NY: Free Press, 1981; the following synopsis comes from Stephen B. Thomas and Sandra Crouse Quinn, *The Tuskegee Syphilis Study, 1932 to 1972: implications for HIV education and AIDS risk education programs in the Black community*, *AJPH*, 1991; 81:1498-1504). In that study, carried out by the U.S. Public Health Service (PHS) in collaboration with the Tuskegee Institute, Alabama State Board of Health, the Macon County Medical Society and Board of Health, and the Milbank Memorial Fund, poor, African American men in rural Alabama who had been found to be infected with syphilis were studied over four decades to resolve questions about the longterm sequelae of syphilis.

The study had its origins in a series of programs to demonstrate that Black persons in the rural South could be tested and treated for syphilis, whose prevalence had been found to be as high as 40%. A combination of financial shortfall (the loss of the treatment funding that was being provided by the Julius Rosenwald Fund until the stock market crash of 1929) and a 1929 Norwegian study whose findings conflicted with prevailing theories concerning racial differences in the natural history of syphilis led the PHS to launch the study as an "unparalleled opportunity for the study of the effect of untreated syphilis" (p94 in Jones J, quoted on p1500 of Thomas and Quinn). The study was by no means a secret enterprise. While it was continuing, study investigators presented the study at medical/scientific conferences and published their findings in major medical/scientific journals. In order not to lose this "never-again-to-be-repeated opportunity" (p179 in Jones, quoted at p1501 in Thomas and Quinn), the PHS arranged with county, state, and other federal agencies to exclude study participants from treatment, even after penicillin became the standard treatment for syphilis in 1951. Indeed, as late as February 1969 a blue-ribbon panel convened by the Centers for

Disease Control (CDC) decided against treating the men in the study in order to harvest all of the scientific information it could provide.

National publicity caused the termination of the study several years later, though, and stimulated initiatives to attempt to prevent future research projects with inadequate protection of human subjects. Among these initiatives in the U.S. was a set of guidelines issued in 1971 by the U.S. Department of Health, Education, and Welfare (now DHHS) and the National Research Act (Pub. L. 93-348, enacted July 12, 1974), which created National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges of the Commission was to “identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles” (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>). The Belmont Report, a summary of four years of deliberations by the Commission, is the basic statement of DHHS policy regarding research on human subjects. The report proposes three principles intended to “provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects” (Belmont Report): 1) **Respect for persons** (the requirements to acknowledge the autonomy of individuals and to protect those with diminished autonomy); 2) **Beneficence** (maximizing benefits to people and minimizing harm); 3) **Justice** (fairness in the apportionment of the risks and burdens of research and its benefits). These principles are applied through three requirements: 1) **informed consent** (comprising sufficient information, comprehension, and voluntariness, 2) **risk/benefit assessment**, and 3) **selection of research subjects**.

Before collecting any data from human subjects, an investigator must provide a description of the study objectives, potential risks to participants, and procedures for data collection, participant enrollment, and informed consent to an IRB and obtain their approval. Changes to the study procedures must receive IRB approval, and the IRB must be informed of any harm that occurs to participants. Over the years the requirements related to human subjects protection, including training about use of human subjects and other ethical issues in research, have continued to expand. The U.S. Department of Health and Human Services now requires that all personnel involved in the conduct of DHHS-funded research must have documented training in the requirements concerning human subjects protection.

In their mandate to protect human subjects, IRB's have also begun to consider investigators' freedom from financial conflicts of interests in the research (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html>), another topic that since 1995 has been linked to funding of health research. The NIH web site contains links to a great deal of information on research ethics and human subjects protection. The information on human subjects research can be found by starting at the page for Bioethics Resources ([www.nih.gov/sigs/bioethics/](http://www.nih.gov/sigs/bioethics/)).

In response to Congressional action, NIH has also instituted and recently expanded requirements that minorities, women, and children be included in studies unless that would conflict with the scientific objectives of the research. The expanded guidelines may be found at: [grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html).

## **Study management**

Definition of study management: Accomplishing the aims of the research.

### **Elaboration**

1. Working out the details of the study design and implementation, often incompletely specified in the proposal - developing the protocol.
2. Garnering and managing the resources to carry out the study:

Funding

Space

Equipment and infrastructure

Supplies

Staff

Subjects

Time (from one's other responsibilities)

The new element is the grant award. But grant funding isn't everything. The grant may not bring enough money. And money can't buy everything - space, telephones, secretarial assistance, time.

3. Meeting legal, ethical, institutional, and professional requirements.
4. Obtaining quality data (see Chapter 8 in Szklo and Nieto, 2000)
5. Publishing the study results and possibly other forms of dissemination.
6. Solo versus team

Even a study carried out by a single person research team involves study management in terms of the above. Typically, though, epidemiologic studies involve multiple investigators and staff. Larger and more complex (e.g., multidisciplinary) research teams bring in issues of collaboration, communication, personnel management, and greater needs for formal project management.

### **Study management tends not to be taught**

Study management is somewhat neglected in teaching, for several important reasons, including:

1. Faculty teach what they have been taught. Since study management isn't taught, it is harder to teach.
2. Study management may be better learned "on the job", for example, in a research apprenticeship. That is undoubtedly true for various aspects, but it is also likely that much could be taught systematically.



3. Designing the study (more "intellectual") and securing the funding (money talks) have higher status than getting the work done. Doing the work takes longer, entails more tedium, and involves more mundane tasks. In industry, there is more glory for sales than for production. Consider the fascination of sex versus the reality of raising children.
4. Teaching study management is akin to teaching other aspects of methods - most often the teaching does not flow out of nor feed into the faculty member's research. Therefore the time demands of teaching are felt more strongly.

### ***Natural history of study conduct***

(on analogy to William Haddon's pre-crash, crash, post-crash for motor vehicle injury prevention)

### ***Preaward***

The principal investigator's role in study management begins with the proposal development activity. Production of the proposal is a foretaste of what production of the study will involve, only on a smaller scale. Developing and elaborating a vision, maintaining interest of a team, delegating responsibilities, communicating, supervising staff, negotiating, distributing rewards, organizing work, projecting costs and completion times, etc. Key considerations: are the right people being involved, is the concept sound, is there sufficient time set aside for quality thinking and review, is the budget realistic (in both directions)?

After submission but before the award, the PI may be the only study staff person as well as the PI. That means (if funding appears likely):

- Writing job descriptions
- Requesting space
- Interviewing and hiring
- Negotiating subcontracts
- Developing instruments
- Working out communications infrastructure
- Clarifying uncertainties in the proposal
- Publicity and media relations (news release)
- Planning preaward expenditures? (equipment, personnel)

Problem: How to motivate before the award is official?

### ***Award***

Once the award arrives, there is often the painful necessity to reduce the budget: the study may have been underbudgeted (because of faulty projections or in an attempt to fit under a ceiling or to

avoid or respond to criticism) or the award may be for less than the amount requested. Should the scope of the project be narrowed?

Startup tasks come next - many of the things that ideally would have been done before the award began likely remain to do - for example, staffing, space, equipment, subcontracts. All of these issues take time, and the PI will want the best staff, the most suitable space, the best type of equipment affordable, and the most desirable subcontract. She/he will probably feel lacking in expertise in some or all of these areas. And each has the potential to take much more time than appears to be available. In the meantime, various people (reporters, university administrators, community people, politicians, students) may want information about the study, whereas all that is available are the grant proposal and the PI!

With core staff and infrastructure in place, the PI is ready to confront the reality of the work that has been proposed and to find out how well have the production aspects of the research been anticipated? At this time, more conventional project management needs come into play:

1. Managing time
2. Managing people
3. Managing money

The basics of these three dimensions can be stated as follows:

A. Create a workplan

1. What needs to be done?
2. How long will it take?
3. When will it happen?
4. Who is responsible?
5. How much does it cost?

B. Revise the plan (so keep it easy to change)

(Adapted from Alan Gump, The basics of project management, *Symantec Newsletter*, Summer 1991, 30-31:)

Of course, managing means more than just making and revising a plan. Staff need to be found, oriented, trained, motivated, guided, supervised, and sometimes disciplined. Involving staff with a democratic management style can help staff to become invested in the study goals and its accomplishments. But there are costs to democracy (time, persuasion energy) and not everyone may want to participate in that way.

Two problems:

1. Since research almost by definition involves unfamiliar terrain, one typically doesn't know all that one needs to know to make the plan and carry it out.
2. Information (e.g., about what is going on in data collection, about spending) is often less available than would be helpful.

Some other issues that arise are:

- Data management - like study management, this is a major but largely unrewarded activity, especially documentation. Generating adequate, timely documentation is a constant challenge, and a balance must also be struck between documenting and doing.
- Monitoring - in principle, all activities should be monitored, so that adjustments can be made in time to meet study goals.
- E.g., a doctoral student found that after 4 months of his study, only 25% of WIC mothers recruited in the first 2 months had filled out their 2nd visit survey (because they missed the scheduled appointment and there was no other mechanism in place). So he changed the protocol to have the resurvey completed at any time the subject came for a WIC visit). He also revised his entry criteria when the number of eligible women was smaller than expected.
- All data should be reviewed as close to the time of its collection as possible, so that corrective action can be taken. For example, are all forms present and completed consistently? However, who will do this? PI? Project coordinator? Research assistant? Graduate assistant? Crucial but unpopular and always a "second" priority.
- Data analyses, especially those that will be published, require extra scrutiny. Ideally, analyses for publication should be replicated independently from the original work. It does not feel good to have to submit a letter like "We regretfully report that we have discovered an error in computer programming and that our previous results are incorrect." (New England Journal of Medicine, Jan 14, 1999, p148). It is much, much easier to make programming errors than to find them.
- Professional meetings (formal presentations and works in progress) are both opportunities and challenges - opportunities to gain the insight and perspectives of outsiders and a stimulus to thinking through the study data and their interpretation; challenges because they typically take precedence over other important tasks and draw upon data that have not been fully cleaned.
- Getting time to write - the daily needs of the study tend to absorb all the time available for it, and so often it seems that the data are never ready until the study is over.
- How to manage authorship so that opportunities are appropriately shared, enough writing gets done, and the architects of the study get a reasonable share of articles. Increasingly, written policies are being developed to guide investigators and would-be authors.

Some other predictable and unpredictable challenges:

- Staff turnover - possible detours
- Continuation applications and progress reports
- Human subjects permission renewal
- Site visits
- Managing time and money so one comes out ahead but not too far

- Figuring out - beforehand - what data will need to be collected, entered (e.g., dates), analyzed
- Low response rates (NCM SHS & QFL)
- Low exposure rates (Irva)
- Missing data
- Fraudulent data (NCM, Russ Harris)
- Competition from other investigators
- Controversy (animal rights activism, safety hazards (lab, fieldwork), ethics attacks)
- Changing priorities of the funding agency
- Initiating new proposals - new research, funding for self and staff
- Staying in touch with the science

Industrial quality control technique (per King Holmes) - Identify the 5 ways this project can fail. Then try to reduce their likelihood.

### ***Postaward***

- Final report
- What to do with all of the data, files, equipment, etc.
- Finishing the papers
- Secondary analyses

### ***Data management***

#### **Develop protocols and forms for data collection**

- What data to collect
- How will data be transmitted
- Data processing, editing, coding
- Quality control - accuracy, completeness, consistency

#### **Computerize data**

- Design screens
- Field separators
- Range checks during data entry
- Double entry with verification

- Quality control - error rate

### **Compile Data Management Manual**

- Study summary
- Brief description of all data streams
- Instrumentation, original sources, and modifications made
- Data collection protocols and (dated) forms
- Account of the data collection process, with dates and numbers
- Correction procedures (audit trail)
- Directory structure / Paths
- File identification - names, labels, computer runs, directory
- Variable identification - names, labels, formats, techniques for long labels, cross-references to forms and instruments

### **Explore the data**

- Look at data (raw)
- Perform "quick and dirty" analyses

### **Create data files for each data stream, create analysis files**

- Check for missing, bad, or duplicate IDs
- Check order of records
- Check for missing forms
- Define special missing values for skip patterns, special situations
- Make sure that all the numbers add up

### **Prepare an accounting for all data**

- Check the N's - tabulations, tracking, records, and resolve
- Eligibility, consents, dispositions for all

### **Carry out preliminary analyses to inform planning**

### **Clean and summarize data**

- Variable distributions (SAS PROC UNIVARIATE FREQ), range checks, outliers, consistency

## Create analysis variables and scales

- Derived variables, scales, coefficient alpha, indexes

(For further information, see chapter on Data management and data analysis.)

## **Typical problems that need to be caught**

It is very important to review forms quickly in order to catch irregularities promptly -- when there may be a chance of correcting them. For example, towards the end of a study of partner notification for HIV exposure, it was discovered that partners who were located and notified, but refused to be interviewed, were not being systematically recorded anywhere. The data collection system had been designed to capture partner information on a partner interview questionnaire, but because of the refusal the interview questionnaire was not completed. But the fact of location / notification and who initiated it were important to log.

It is essential to:

1. log all forms in a computer file to be able to account for all data and quickly search for who is in the database.
2. maintain close supervision of the coding operation, to ensure that coding standards are being maintained but at least as important, to apply expert judgment in resolving irregularities detected (the coder's judgment is often not what the investigator would want) and finding out about the reality of the data.
3. pursue systematic data cleaning - subject ID's, linkage of forms, key variables, remaining variables.

## **Designing a questionnaire**

The Inter-university Consortium for Political and Social Research (ICPSR) located within the Institute for Social Research at the University of Michigan provides Internet access to the world's largest archive of computerized social sciences data (<http://www.icpsr.umich.edu>). In most cases, an abstract and codebook are freely available over the Internet. Persons at institutions that belong to ICPSR can also obtain access to the data themselves.

## **Writing a paper (courtesy of Barbara Hulka, M.D., M.P.H.)**

INTRODUCTION	From literature review
METHODS	Cull from more thorough version written for internal use
RESULTS	Make tables as go along, then cull, highlight and display
INTRODUCTION	Rewrite after doing Results Section

## DISCUSSION

1. Repeat - simply - the key results.

2. Review possible biases and other limitations, and indicate how handled or how not. Don't be superficial. Consider counterweighting factors.
3. Refer to recent major studies addressing the same issue and try to identify reasons for differences
4. Depth and breadth:
  - implications for theory (from other disciplines)
  - implications for practice (for other disciplines)
  - the "breadth aspect of EPID" — the ability to get enough grasp of another field's literature to use it.

TITLE - simple, informative, and accurate

ABSTRACT -- that's all many people will read:

1. Why - what's the issue, problem, research hypothesis (1 sentence)
2. What did you do (methods) - study design, N, length of follow-up (2-3 sentences)
3. What did you find (e.g. from first paragraph of discussion)
4. What do you conclude? -- so what?

Recently, standardization has come to abstract writing, in the form of "structured abstracts". Their use is now required by a number of journals.

The text by Szklo and Nieto (2000) includes a helpful chapter on "Communicating the results of epidemiologic studies", which includes a detailed outline of what to report taken from Kahn and Sempos (1989). Szklo and Nieto also include suggestions for writing style (e.g., avoiding scientific arrogance, and jargon), drawing appropriate inferences (including differentiating between association and causality and between statistical significance and strength of association), and preparation of tables and figures.

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