ANNALS OF FAMILY MEDICINE

Online Supplementary Material

Westfall JM, Zittleman L, Staton EW, et al. Card studies for observational research in practice. *Ann Fam Med*. 2011;9(1):63-68.

http://www.annfammed.org/cgi/content/full/9/1/63/DC1

Supplemental Appendix 1. Linked Data in Card Studies

The first step in linking data is to obtain requested information from the practice and clinicians. We conduct regular surveys and observations about the practices in our networks. Important data will vary depending on the clinical question, but we attempt to collect demographic data about basic practice characteristics that includes practice type (rural/urban, private/community health center, residency or not), insurances accepted, number and type of clinicians, community size, and electronic health record (EHR) existence (Supplemental Figure 1). Occasionally, one practice member, typically the office manager, will complete a survey about the practice and community. We often ask the network clinicians to complete a basic demographic questionnaire at the outset of a study to include sex, age and years in practice, clinician type (medical doctor, osteopathic doctor, resident, nurse practitioner, etc) and beliefs or attitudes about the specific research subject. By various methods, these practice- and clinician-specific data can be anonymously linked to survey cards completed at individual visits.

At each level of linkage the complexity increases, as well as the need for anonymous coding and data management. We have used various coding schemes to identify practices and physicians. Each practice in our network is assigned a unique 3- to 5-digit code, and each clinician within that practice is also assigned a unique code. These codes are kept in a secure location with access limited to the necessary investigator and research staff and are usually blinded during data analysis. Each card for a particular practice is coded with that practice's code at the top of the card. Each practice is provided its specific stack of cards for completion. All cards are collected at the end of the data collection period so we are able to obtain a completion rate. It is important to cross-check the number of cards completed with the number of patients seen in the practice during the data collection period. Occasionally, staff may not give a card to a patient for various reasons—age, mental incapacity, severe illness. Because of clinician turnover, the individual clinician codes are often unique to a specific study and do not necessarily carry over from study to study.

When a patient's data must be linked to a clinician, the unique code for a particular clinician is also included at the top of the patient card (Supplemental Figure 2). Accordingly, each card would include an anonymous unique number, consisting of the practice-specific code, the clinician-specific code, and a patient-specific code. Each clinician must receive his/her specific stack of cards for completion, which requires the front office staff and/or nursing staff to place the correct card on the correct chart. As a substudy to one of our card studies, we conducted a validation of our linking methods. An onsite professional research assistant checked whether the physician who actually completed the card was the one officially linked to the study. We performed this study in 4 sites with 27 clinicians and 262 patient encounters. The linkage was accurate in 257 (98%) of cards with the inaccurate cards spread among several clinicians. It appears that this type of linkage is accurate and adds considerably to the analysis and results.

The most difficult level of linkage occurs when one wants information from the patient and the clinician for the same encounter (Supplemental Figure 3). We have attempted to obtain patient- and clinician-level data from linked surveys on several occasions. The complexity of this linkage creates a considerable burden on the practice and requires very high response rates from both the patient and the clinician to obtain a sample size sufficient for analysis. If the clinician sees 100 patients and completes 80% of his/her study cards, and the 80 patients complete only 60% of their cards, the final response rate is a mere 48% (48 cards from a total of 100 patients seen). In a pilot card study about colorectal cancer screening (CRC), we were interested in the agreement between clinician and patient understanding of the patient's screening status, as well as any conversations about CRC that occurred at the visit. Two study cards were placed on every patient chart visiting that day. The clinician was to complete a clinician card and hand the patient his or her card. The patient was to complete the card and return it to the designated secure box. We faced serious challenges in obtaining the responses necessary to provide for adequate analysis, especially relative to patient response rates. As a result, for the full study, we chose to link patient responses as a group to the clinician and practice.

One innovative method we are developing to link clinician and patient data involves a single card with 2 overlapping pages (Supplemental Figure 4). The top page contains questions for the clinician and is one inch narrower than the bottom page. The clinician places his or her coded answers (A, B, etc) along the right edge of the card, which is actually the bottom page. The clinician then tears off the first page and hands the card to the patient. The patient completes the card on the bottom page and places the completed card in the secured box in the practice lobby or mails it to the research office in the envelope provided. A recent study in the American Academy of Family Physicians National Research Network used this method and obtained complete data from both the patient and clinician on 90% of the nearly 2,000 enrolled patients.

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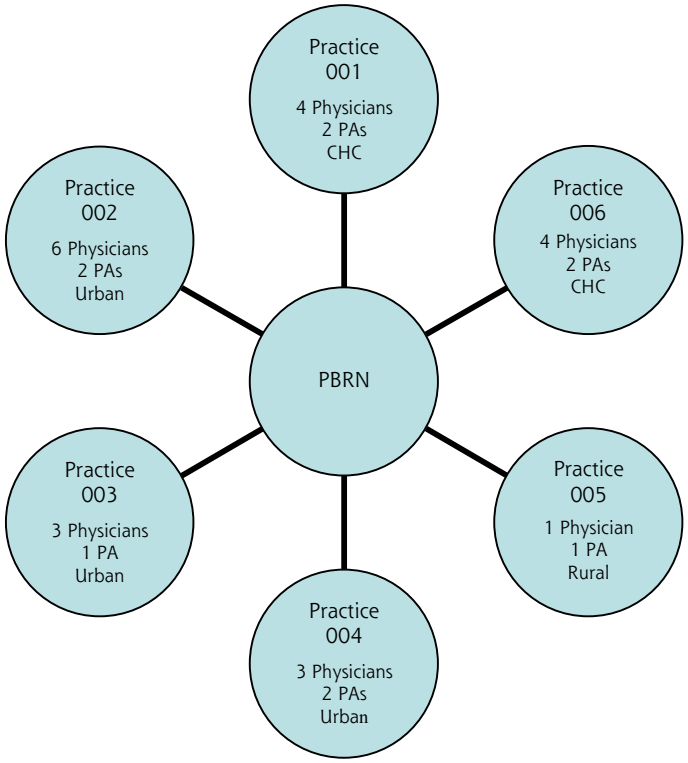
Supplemental Figure 1. Practice-level data in a PBRN.



CHC = community health center; PA = physician assistant; PBRN = practice-based research network.

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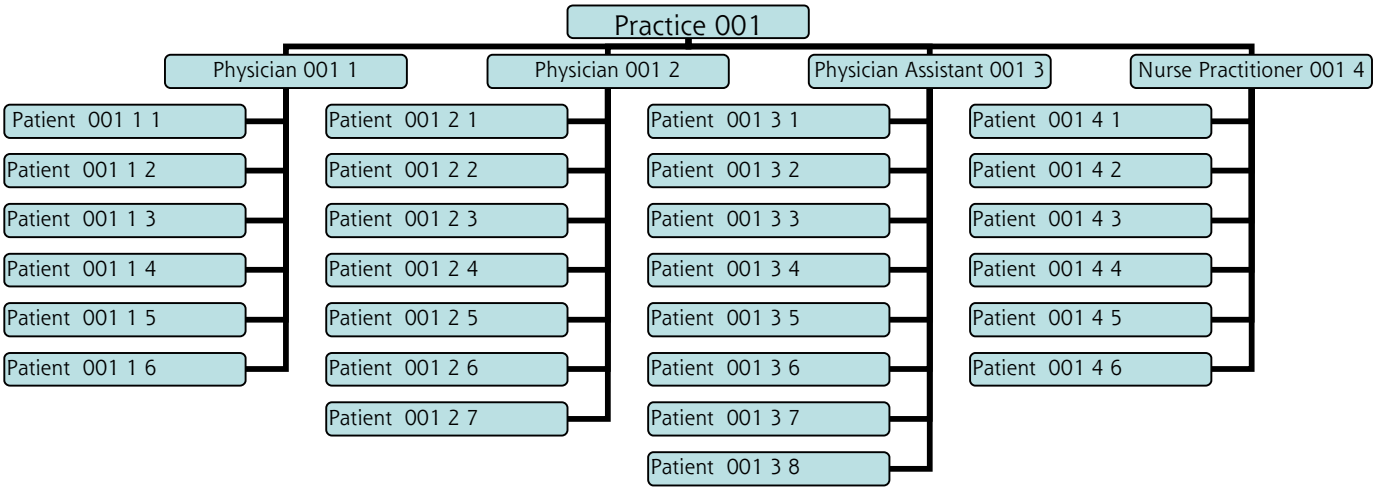
Supplemental Figure 2. Linking practice, clinician, and patient data in observational survey research.



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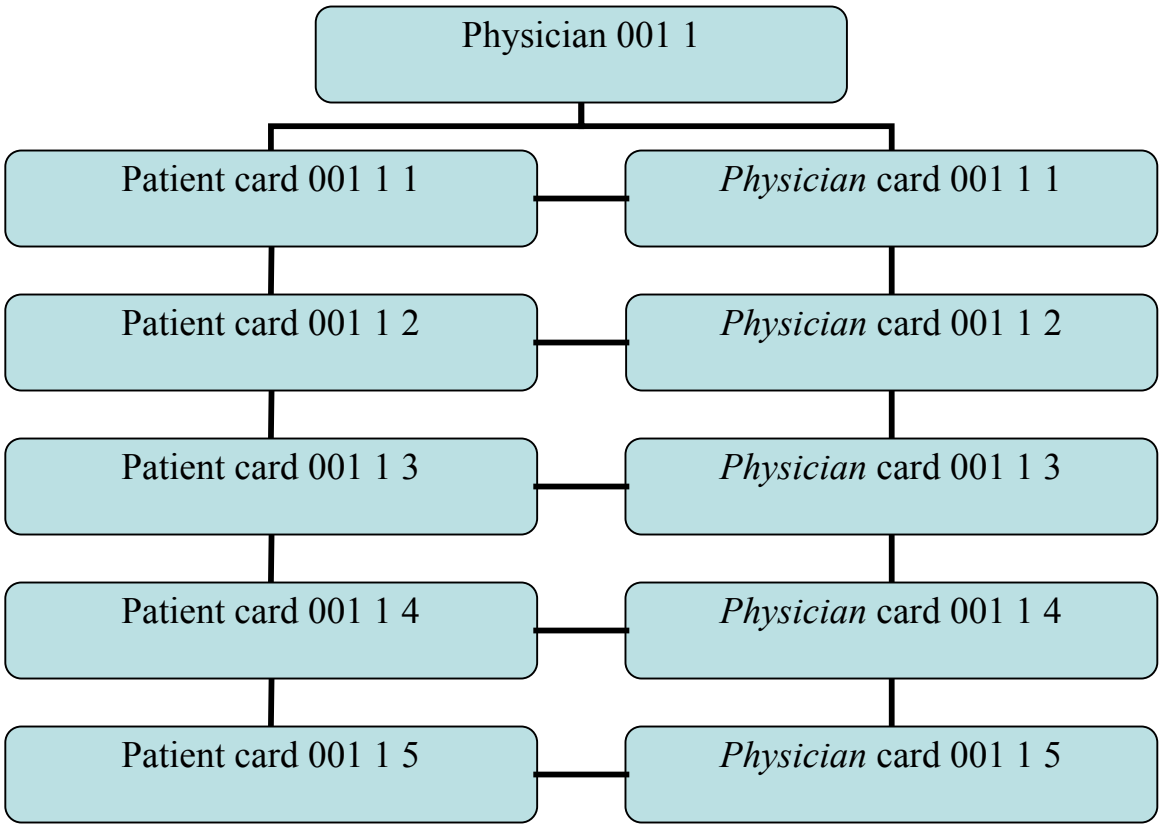
Supplemental Figure 3. Linking physician and patient study cards.



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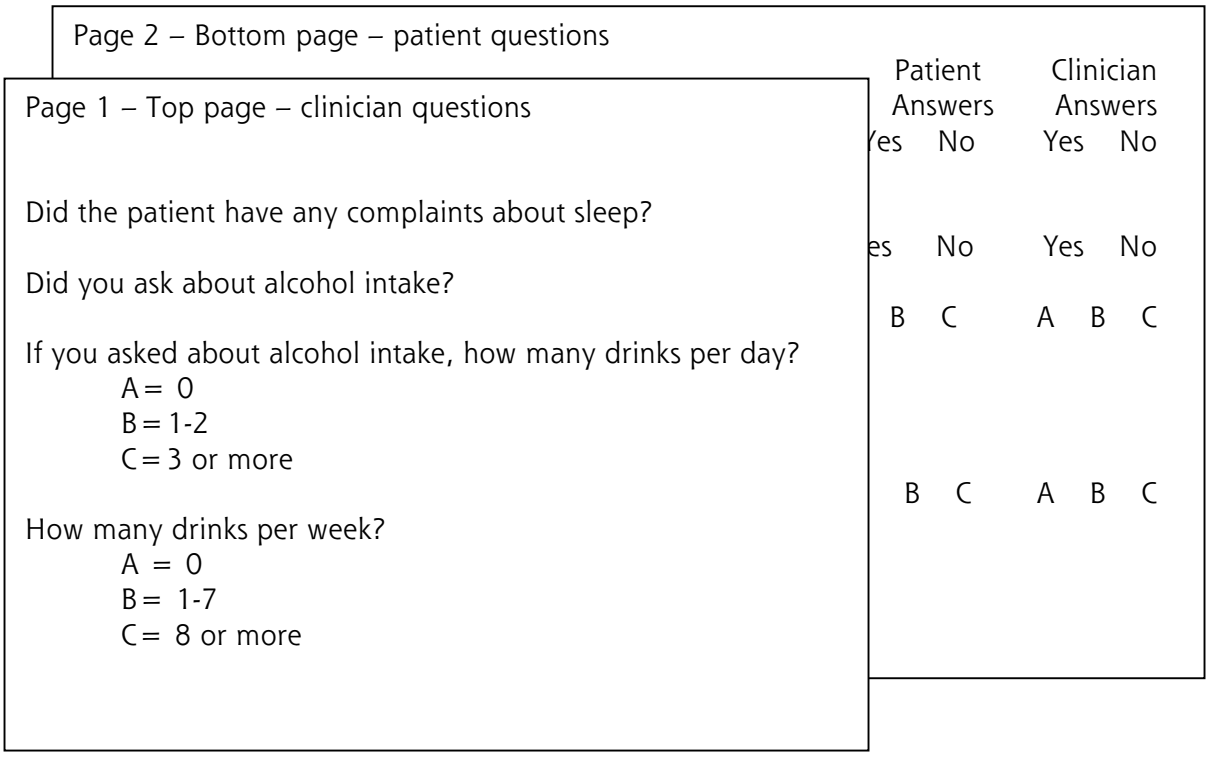
Supplemental Figure 4. A novel approach to link patient and clinician data.



This is an excellent method for obtaining data from both the clinician and the patient about a single visit. The study card consists of 2 pages. The bottom page includes the patient questions and 2 columns for answers. The first column is for the patient's answers. The second column is for the clinician's answers. The top page of the card is narrower so the clinicians' answers are visible on the bottom page. This allows for the clinician to answer the questions at the time of the visit, tear off the top sheet and give the bottom page to the patient, who then completes the questions and returns the card. For each returned card, there is both clinician and patient data about the same visit. It is not necessary that the questions be the same for the clinician and the patient.

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Supplemental Appendix 2. IRB and HIPAA for Card Studies

In terms of human subjects protections and privacy concerns, card studies have two advantages over other studies:

1. Data are typically collected by those in the practice who already have a relationship with a patient

2. They are observational studies that often ask questions clinicians would routinely ask their patients when delivering care.

Human subjects protections and privacy concerns, however, must be considered when developing a card study. Because card studies often take place across multiple settings, investigators often face challenges of working with multiple institutions.[1,2] Unfortunately, there is no institutional review board (IRB) standard for reviewing card studies. Each IRB has its own sense of a study's risk.[3] To effectively address IRB and privacy concerns, an investigator must be able to explain the risks in terms familiar to IRBs and HIPAA (Health Insurance Portability and Accountability Act) privacy boards.

Collecting Personally Identifying Information

Because card studies themselves are not therapeutic interventions, the primary risk to patients is disclosure of potentially harmful information about their health. Think strategically about the need to obtain identifying information. If patient-level identifiers can be avoided, most IRBs will not require full board reviews and will often consider a study exempt from further IRB review. If your data require linking information, consider whether the linking information can be maintained only at the practice. If identifiable information is needed, limit it as much as possible and be clear about how those data will be used and if they can be stored separately from the analytical data. Also consider the potential risk or harm if someone outside the research team or practice discovered the information. In many cases, such disclosure is likely to pose no greater than minimal risk to a patient.

Speak Their language

Having each patient review and sign a formal consent document is simply not practical for the card study method. To avoid this step, carefully consider the risk to patients and then submit a protocol that explains how the risk is minimized.

First, remind reviewers that the card study is an observational study with no intervention and that data are collected in the practice by the practice. Second, if you are not collecting identifiable information then state that early and often in your protocol. Third, if you are collecting some identifiable information, then be clear how the information is going to be used, whether the practice collects it but does not send it, and how the risk to patients will be minimized or is no greater than normal. In the United States, collecting identifiable information does not automatically disqualify a study from exempt or expedited review. Review the language in the federal code carefully (eg, 45 CFR 46.110, 45 CFR 46.101) and use it to help formulate the description of the card study's risks.[4] Finally, describe the method accurately and openly, but use words and terminology that IRBs already know to convey the appropriate level of risk they should consider, such as:

"no individually/personally identifiable information"

"no protected health information (PHI)"

"anonymous"

"secure location"

"minimal risk" or "no greater than normal risk"

"routine medical practice"

"voluntary"

"the participant can stop any time"

"no treatment or evaluation of patients other than usual clinical care"

"no examinations, blood tests, X-Rays, or other special tests on patients will be used"

"no drugs, devices, or instruments will be used"

"data are collected by the practice, not outside research staff"

"no control group" and "subjects are not randomized"

"tracking information will be maintained by the practice, not researchers"

On the card or questionnaire itself remember to include important phrases and terms (if they apply to your research), such as:

"Do not write your name on this survey"

"voluntary"

"anonymous"

"you can stop participating at any time"

In some cases, it is worth the time to talk directly to the IRB director or panel chairs to help them understand this study method and what the risks are relative to how they consider risks.

References

1. Pace WD, Staton EW, Holcomb S. Practice-based research network studies in the age of HIPAA. *Ann Fam Med.* 2005;3(Suppl 1):s38-s45.
2. Wolf LE, Walden JF, Lo B. Human subjects issues and IRB review in practice-based research. *Ann Fam Med.* 2005;3(Suppl 1):s30-s37.
3. Green LA, Lowery JC, Kowalski CP, Wyszewianski L. Impact of institutional review board practice variation on observational health services research. *Health Serv Res.* 2006;41(1):214-230.
4. US Department of Health and Human Services. Office for Human Research Protections (OHRP). Protection of Human Subjects – Title 45, Code of Federal Regulations, Part 46. Available at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm. Accessed May 10, 2010.