Researching the Appropriateness of Care in the Complementary and Integrative Health Professions Part 5: Using Patient Records: Selection, Protection, and Abstraction

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ABSTRACT

Objectives: The purpose of this paper is to describe the 4-step process (consent, selection, protection, and abstraction) of acquiring a large sample of chiropractic patient records from multiple practices and subsequent data abstraction.

Methods: From April 2017 to December 2017, RAND acquired patient records from 99 chiropractic practices across the United States. The records included patients enrolled in a survey e-study (prospective sample) and a random sample of all clinic patients (retrospective sample) with chronic back or neck pain. Clinic staff were trained to collect the sample, scan, and transfer the records. We designed an online data collection tool for abstraction. Protocols were instituted to protect patient confidentiality. Doctors of chiropractic were selected and trained as abstractors, and a system was established to monitor data collection.

Results: In compliance with data protection protocols, 3603 patient records were scanned, including 1475 in the prospective sample and 2128 in the random sample. A total of 1716 patients (prospective sample) consented to having their records scanned, but only 1475 could be retrieved. Of records scanned, 19% were unusable owing to illegibility, no care during the period of interest, or poor scanning. The abstractor interrater reliability for appropriateness of care decisions was fair to moderate (κ .38-.48).

Conclusion: The acquisition, handling, and abstraction of a large sample of chiropractic records was a complex task with challenges that necessitated adapting planned approaches. Of the records abstracted, many revealed incomplete provider documentation regarding the details of and rationale for care. Better documentation and more standardized record keeping would facilitate future research using patient records. (J Manipulative Physiol Ther 2019;42:327-334)

Key Indexing Terms: *Chiropractic; Complementary Therapies; Patient Generated Health Data; Medical Records*

INTRODUCTION

The National Center for Complementary and Integrative Health funded RAND Corporation to advance the methodology of determining the appropriateness of care in complementary and integrative health. The treatments studied were chiropractic spinal manipulation and mobilization, and the target conditions were chronic low back pain (CLBP) and chronic cervical pain (CCP). To accomplish that, we needed to access patient files to be able to calculate a rate of appropriate care and to determine how much chronic back and neck pain is being treated in chiropractic offices. In addition to collecting data from the patient record, the overall project involved input from 2 expert panels and collection of data through a series of online patient surveys described elsewhere.[1] In this article, we review the process of acquiring and abstracting 2 samples of chiropractic patient records to evaluate appropriateness of mobilization and manipulation for CLBP and CCP. The data collection from patient records for this project, the challenges it presented, and how we addressed them are the focuses of this paper. Four major steps were involved in acquiring the patient record data: obtaining consent for record review, identification and transfer of the records, record protection, and record abstraction.

Problems

The collection of a large amount of patient data from records is challenging. Files can be in various forms (electronic and nonelectronic), the data can be entered in a variety of ways, some highly personalized, and relevant data may not be entered at all. Furthermore, the data collection must be done in a manner that ensures that data are acquired, handled, and abstracted in a fashion that is not only methodologically correct but also meets regulations and laws related to handling protected health information (PHI).

The tasks included selecting the most appropriate source of data, obtaining consent for chiropractic patient record review, obtaining records, maintaining patient confidentiality, creating a reliable and comprehensive patient record abstraction tool, selecting and training abstractors, and maintaining quality during data collection. The choices made are driven by the project's needs but must take into consideration other factors, such as timeline, budget, and addressing unexpected issues that arise during implementation.

Patient records provide a readily available data source but are highly dependent on what is recorded in them. The medical record may be considered the gold standard of information about patient care owing to its comprehensiveness. However, other sources of data (eg, patient interviews, administrative documents) may be more feasible. Comparisons of administrative and medical record data have revealed that certain aspects of care (eg, surgery, radiation treatments) are reliably accessed from either source.[2,3] But other data elements (eg, time of symptom onset, contraindications, patient refusals of offered care) are less likely found in the medical record.[4,5,6] Data such as current symptoms and counseling received may be better elicited from patient interviews.[7] The source of data used can also affect the results of quality-of-care measures.[8]

When the data source is the patient record, the complexity of data can be challenging for abstractors to interpret in a standardized manner. Therefore, a comprehensive abstraction guide is essential, including priorities of source for data elements, standardization of terminology, definitions for unstructured data elements, and a process for guideline revision during data collection.[9,10] The utility of the abstraction tool used is maximized by logically organizing the content to be user friendly and approximate the organization of the medical record. However, even if content is organized in a logical order, patient records in the field may not reflect that order.[11] Pilot testing of the tool during the design phase provides an opportunity to gauge ease of use and content adequacy.[12]

Clinical knowledge and experience are key to abstractors' ability to interpret documentation in patient records and should guide abstractor selection. Selected abstractors must be trained to follow prescribed study protocols. Use of a standardized medical record for training is an additional tool for evaluating abstractors' level of guideline adherence and abstracting accuracy.[12,13] Selection of appropriate abstractors and provision of comprehensive training are vital for successful data collection.

Medical record content may be structured and poses challenges to interpreting and collecting data in a uniform fashion across all abstractors. In addition to training, abstractors are monitored during data collection by assessing interrater reliability (IRR).[14,15] Two abstractors abstract the same record to evaluate whether abstraction guidelines are implemented consistently and to identify problems for ongoing quality improvement.

In summary, patient records present 5 major challenges: first, getting consent; second, selecting the physical records themselves, which includes their format (eg electronic), their location, and their age; third, the content of the records, that is, what is and what is not included, and lack of standardized record keeping; fourth, protecting the data, that is, preserving confidentiality; and fifth, abstracting the data from the record, which includes developing a protocol, training abstractors, abstracting the data, and interpreting the data.

THE SOLUTION

The following describes the choices we made for this study regarding the acquisition, housing, and protection of patient records; selection and training of abstractors; and data abstraction.

Obtaining Consent

The project was reviewed and approved by RAND's Human Subject Protection Committee and was registered as an observational study on ClinicalTrials.gov (ID: NCT03162952). Two forms of written consent from participants were required: consent from the chiropractor to collect data in his or her clinic and consent from patients enrolled in the prospective sample of the study to obtain their records. For the first, the chiropractor received a consent form to sign before RAND staff visited the office. For the second, the prospective patients were recruited for the survey data collection portion of the overall study through an iPad in the clinic. If recruited patients agreed to participate, they signed a consent form. Patients could consent to be in the survey study but not consent to allowing access to their treatment records. Even with patient consent, some providers declined to provide patient records, usually because of the extra work involved for the clinic staff.

An additional challenge was related to acquiring a random (retrospective) sample of patient records for patients not in the study's online survey sample (ie, prospective sample). Because who would be in the

randomized sample was not known in advance, it was not possible to elicit prior patient consent. Under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, researchers can obtain and use individually identifiable health information if they follow stipulations set forth in the legislation. These are described in part 2 of this *Journal of Manipulative and Physiological Therapeutics* series.[16] For the institutional review board or privacy board to approve a waiver of authorization under the privacy rules, 3 criteria must be satisfied: (1) there must be minimal risk to patient privacy, which means records must be securely protected and deidentified, and links to identifiers destroyed as soon as possible; (2) the research could not be adequately conducted without a waiver of consent; and (3) the study could not be done without access to the patient data.

We provided a copy of the Human Subject Protection Committee approval letter to participating clinics. For clinics that expressed concern about HIPAA compliance, we also provided a document explaining, in clear and nonlegal language, our justification for not obtaining informed consent from the randomly sampled patients. In addition, we made the project data safeguarding plan available to clinic staff who wished to view it. All project staff were trained in HIPAA requirements and had certificates to show HIPAA compliance. The project staff were also required to complete the research ethics certificate program offered by the Collaborative Institutional Training Initiative.

Selecting Records

The selection of records is fully described in part 4 of this *Journal of Manipulative and Physiological Therapeutics* series.[17] It involved 2 samples: prospective (patients in the survey part of the study) and retrospective (patients in a randomly drawn sample from each clinic). For the prospective sample, the iPad Recruitment Form screened out ineligible patients (younger than 21 years old, workers' compensation or personal injury cases, patients with no CLBP or CCP) and gathered contact information (emails and phone numbers) of those who qualified and agreed to participate.

For the retrospective sample, the clinic staff (with or without assistance from RAND staff) were asked to pull records according to a randomization process provided by RAND until 10 CLBP patient records and 12 CCP patient records were identified. The clinic staff determined whether the low back pain or cervical pain was chronic. If the patient had both CLBP and CCP, we included them in the CCP sample based on the expectation that the numbers of CCP would be considerably lower than CLBP.

The random sampling process started with a patient list. If any part of the clinic's record system (including billing) was electronic, we asked the clinic staff to generate a list of all patients seen between January 1, 2014, and December 31, 2016 (most current patients), or if not, a list of all patients ever seen in the clinic. The generated patient list was then randomized by RAND, and the resulting patient list was used by the clinic for the record pull. If randomly pulled patients were also part of the prospective sample, they were included in both parts of the study. A random sample patient log was created to document a limited dataset for every randomly pulled patient record (Fig 1). The same exclusion criteria used on the iPad enrollment applied to the random record selection: patients under 21 years old, workers' compensation or personal injury cases, or those without CLBP or CCP. The log also documented the reason for care if other than low back pain or cervical pain.

The manner of record scanning was driven by the record format (paper vs electronic health record [EHR] vs a combination) and the practices' record storage arrangements. The clinics were asked to create a separate Word file or portable document format for each patient record labeled in "Last Name, First Name" format. Patient record files and completed random sample patient logs were uploaded to prelabeled "prospective" and "random sample" folders on an encrypted hard drive or on Kiteworks, a secure platform by Accellion that provides file sharing and lockdown and governs the exchange of confidential information. RAND supplied the encrypted hard drive, laptop, scanner, and mouse for this process. The scanner did not have data storage capacity to reduce any data leakage vulnerabilities. Clinics were instructed not to fax or email any patient data to RAND. RAND provided a heavy-duty scanner with an automatic feed that was "smart" and scanned both sides or 1 side as needed for easy and rapid scanning.

Protection of Records

Protection of both patient records and abstracted data is crucial under HIPAA regulations for abstracting data without patient permission. For this project, the protection occurred both in the clinic and at RAND. Patient names for the prospective sample were sent to clinics on Kiteworks (internet) or on an encrypted independent drive. Kiteworks had a unique clinic folder that only clinic staff and RAND staff could access or, if the site had no internet access, we sent the file on an encrypted hard drive. We used a Federal Information Processing Standard 140-2 compliant encrypted hard drive, which satisfied all US government data storage and transportation requirements.

For the random sample, clinics with internet access put their patient list for randomization on Kiteworks or if they had no internet access, on the encrypted hard drive, where we recovered it, randomized it, and then resorted it. The randomized list was put on the encrypted hard drive and sent by FedEx (certified mail) back to the clinic. Other clinic staff who preferred to do the randomization

RANDOM SAMPLE LOG

Instructions: Answer the questions for each file pulled. Pull patient files until you get **10 chronic back pain** and **12 chronic neck pain** patients.

Patient Name (Last Name, First Name)	Able to locate medical record?	Patient currently at least 21 years old?	Patient case currently WC or litigation related?	Patient seen at clinic between 01/01/2014 and 12/31/2016?	Is the patient currently being seen for low back or neck pain?		Was the patient seen for low back or neck pain that had a duration ≥3 months or was described as chronic?		If NOT a patient with current low back or neck issues, please note the current problem areas for the patient (mark all that apply):					
	If NO, mark cell and STOP	If NO, mark cell and STOP	If YES, mark cell and STOP	If NO, mark cell and STOP	Low Back If YES, mark LBP and CONTINUE	Neck If YES, mark NP and CONTINUE	IF YES or MAYBE, mark Chronic and SCAN FILE	If NO, mark cell and STOP	Head	Shoulder or arm	Leg or foot	Non-musculo-skeletal	Stress/wellness	Other reason only, (please specify):
Example: Doe, John					LBP	NP	Chronic							

Fig 1. *Recording log for randomly chosen sample.* LBP, *low back pain;* NP, *neck pain;* WC, *workers compensation.*

themselves were guided by project staff in the process. Clinic staff were counseled that if they were interrupted mid-process, they were to password-protect the records or lock their computer if left unattended. These precautions were used whether the records contained patient names or just unique identifiers. Upon completing randomization, clinics were instructed to delete their local list copy and empty their trash file. For data on encrypted hard drives, we asked clinics to work with the hard drive and not pull a local copy. If RAND staff randomized lists in the clinic using RAND laptops, their laptops had all information security requirements of 2-level encryption with no network capabilities and were sanitized after each visit.

To protect PHI at RAND, we created a secured cold room to house the electronic patient records and provide work space for abstraction. The cold room was a separate room with 4 computers on an isolated network that was locked, and only abstractors and selected staff had access. Upon arrival in-house, patient data files were stored on Kiteworks as a backup and were copied to the cold room computers via an encrypted hard drive. Kiteworks provided a secondary backup in the event of network failure.

In summary, the confidentiality of PHI was protected by keeping acquired patient records encrypted on an isolated computer network, limiting access to selected project staff, and abstracting data within the restricted environment. Technical, physical, and administrative measures were employed.[16] Abstractors completed a certified online HIPAA course, and further discussion about protection of PHI was incorporated into abstractor training.

Abstraction

The evaluation of appropriateness of spinal mobilization or manipulation for CLBP or CCP is based on the patient's clinical data known at the initiation of chiropractic care. The required data elements to assess appropriateness include patient history, symptoms, physical exam, and imaging findings. The patient record was selected as the source for these data because no other source could provide all required data elements.

Abstraction Tool. The abstraction tool created for this study was a computer-based instrument that guided data collection and provided direct data entry. The tool included the discrete data elements required to place the patients in the clinical scenarios detailed in the CLBP and CCP reports published previously.[18,19] The data elements included presenting symptoms, pain history, past and current treatments for CLBP and CCP, medical history, physical exam findings, recent lab results, imaging findings, and potential contraindications to treatment. We created standardized definitions for key concepts, such as "chronic pain," "psychosocial stress," and "joint dysfunction." Two of the authors (E.L.H. and H.V.) were the primary content consultants in creating these definitions. The data elements within the abstraction tool were organized to approximate the logical flow of clinical evaluation during a patient visit and subsequent treatment knowing, however, that it would not approximate all variations in the study practices. Deidentified patient records provided by 4 local chiropractic offices were used to pilot test the abstraction tool. Based on the pilot test, organization of content and definitions were modified.

Abstractors. Abstractors were required to understand chiropractic care documentation and terminology, so we selected chiropractors for the task. Abstractors were recruited through a local chiropractic college, and 4 chiropractors were chosen: 3 recent graduates and 1 highly experienced chiropractor with 40 years in practice and work as an educator and medical-legal consultant. All participated in a training program and completed the Collaborative Institutional Training Initiative research ethics certificate program.

We developed detailed clinical guidelines for abstraction with the understanding that these would be edited and

supplemented during actual data collection. Exercises were created that focused on the more complex abstraction items (eg, evaluation of pain chronicity, identifying an episode of care). Five deidentified records from local chiropractic offices were selected for abstraction during training. The training records covered a range of issues, including diverse types of pain presentations and treatments and varying provider documentation formats. Two of the authors (C.P.R. and E.L.H.) conducted abstractor training over a period of 3 days. During training, abstractors completed focused exercises and abstracted 5 training records as individuals and participated in group discussion and review of their work. An additional 2 days were spent in the cold room in group abstraction and discussion of actual study records.

Project staff were available for abstractor questions during data collection, and any revisions to guidelines were distributed to all abstractors. A 10% sample of records was drawn to evaluate abstractor IRR. Research staff also audited selected abstracted results (eg, positive medical history findings, unusual pain presentations) by reviewing chart documentation to validate collected data. We focused on medical data that were outside of the traditional scope of chiropractic care and with which the abstractors might be less familiar. Data validity was adjudicated by one of the authors (C.P.R.) and, in some cases, in consultation with the chiropractors (H.V. and E.L.H.) on the project staff.

RESULTS

A total of 3603 records were scanned and delivered to RAND, including 2128 in the random sample and 1475 in the prospective sample. A total of 1702 or 84% of the 2018 prospective study participants consented to record review, but only 1475 of those records (87%) were accessed. This was due to 27 clinics that did not complete this part of the study and to participating clinics that were unable to locate some of the requested files.

The random sample patient log that was to be completed for every randomly pulled record proved challenging for the sites to complete. Among the clinics that sent retrospective records, 23% did not complete the log beyond indicating if the patient was a candidate for the study or not. Based on an initial review of all the records obtained from the practices, 19% were unusable owing to illegibility, no documented care during the period of interest, or poor scanning. Receipt of incomplete records was sometimes related to practices' not having adequate record storage space or records stored in varying locations. Another problem involved long-term patients, where initial years of care, including the new patient visit, were often missing from the record and no longer retained or stored off site. If the practice moved from one EHR system to another, records did not always migrate to the new system.

Of the 99 providers who submitted patient records, 19% documented care entirely in EHRs, 35% used paper records, and 45% used a combination of electronic notes and paper. Usable records (paper and electronic) had varying formats, from minimal documentation to multiple pages of narrative, demonstrating a lack of standardized content across providers. The variable record formats resulted in record scanning that was not consistent across clinics. Files were sent with variable formats and organization, including multiple electronic files per patient. This presented a challenge for abstractors who needed additional time to navigate complete patient records. The project would have benefited from better planning with the sites regarding consistent file labeling and organization before submission. Although we sought to obtain consistent files, project staff were also sensitive to the burden the scanning task placed on the clinics. However, at a minimum, checking for consistency in the name labels for patients with multiple files would have helped. In 8 instances during record acquisition, sites breached protocol by emailing PHI to RAND. The RAND Human Subject Protection Committee was notified in each instance, and measures to correct the sites' procedures were put into place.

We found much variation among providers in the content and level of detail documented in their records. For example, providers disagreed about what treatments were categorized as "mobilization," and some providers indicated to project staff that they did not routinely document mobilization even if performed. Therefore, our mobilization cases likely under-represent the actual number of those treatments. A surprising number of records did not include physical exam or detailed treatment data. Rationale for treatment and patient outcome data (eg, pain scale or standardized outcomes measures) were also often lacking. This was particularly true for paper records, but even EHR notes were not always comprehensive. This finding highlighted a potential opportunity for practices to more consistently document a complete record of patient care and the clinical rationale guiding that care.

Records also revealed that a high number of patients were not treated episodically, that is, did not have episodes of care but rather converted directly from care for a chronic pain exacerbation to "maintenance care" with a schedule of regular visits. This complicated the evaluation of appropriateness, which focuses on the initiation of care, because there was, in these cases, no effective break in care. This reduced the number of cases eligible for appropriateness of care assessment if we were unable to identify an initial visit or start to care.

The complexity of some abstracted data elements (eg, psychosocial stress) and those outside the usual realm of chiropractic care increased the possibility for inconsistent abstractor interpretation.[18-20] Therefore, we audited selected data elements by comparing the abstractor's data to the patient record. This audit revealed that abstractors were

more consistent with using standardized definitions (requiring less interpretation) but were less accurate in interpreting patient medical histories. Abstracted elements of the patient's medical history were used to place each patient in an appropriateness indication cell. To audit the abstractor's performance, we chose significant items in the abstracted data, such as history of abdominal aortic aneurysm or patient presentation of unexplained vertigo. The auditor accessed the patient record and compared the abstractor's data with the chiropractor's documentation and determined whether the abstracted data matched what the chiropractor documented. In cases of abstract or data mismatch, we corrected the abstracted data to reflect the chiropractic record documentation. The extreme brevity of documentation in some records also contributed to variable abstractor interpretations. The abstractor IRR for determination of appropriateness of care for mobilization and manipulation was fair to moderate (κ .38-.48) with better agreement for CLBP-related documentation than that for CCP.

DISCUSSION

There is increasing interest in the traditional field of medicine in the integrated use of chiropractic care, particularly for low back and neck pain, and chiropractic care is also increasingly being included in research studies.[21-24] This interest may subject chiropractic records to increased scrutiny, and, as a result, chiropractic leaders have urged for more complete chiropractic documentation, including rationale for treatment modalities, procedures, and monitored patient outcomes.[25-28] Many of these documentation needs may be facilitated with the use of an EHR. However, an EHR requires significant provider buy-in, financial investment, and upkeep and requires intensive staff training and redevelopment of practice work flow for successful implementation.[29-31] Regardless of the form of record documentation, paper or electronic, a provider can maximize documentation by comprehensively describing the care provided, the rationale for that care, and the results of tracked patient outcomes. Better documentation would also facilitate internal practice audits for those clinics that may want to self-evaluate their care as a basis for quality improvement. For this research project, better record documentation and increased involvement of trained clinic staff would have potentially increased the quality of data collected and allow for a more valid generalization of the results. Three results from this type of study are of paramount importance to the profession: (1) how much chronic back pain is being treated in chiropractic clinics, (2) how appropriate is the treatment being rendered, and (3) does appropriate care lead to better patient outcomes. These outcomes cannot be determined without adequate record keeping.

Limitations

This study used a convenience sample, thus persons who were available therefore may not be representative of all chiropractors treating patients with CLBP and CCP. However, this was a methods study, so the purpose was not to generalize to the total population being treated in chiropractic clinics. We did end up with a large patient sample from 6 regions across the United States, so it is likely we are capturing the variability in chiropractic care in the United States. Furthermore, the imperfections in some submitted patient records meant that we could not determine the actual care rendered and therefore could not judge its appropriateness or link it to patient outcomes.

Documentation in some records was missing essential treatment data or was only minimally documented. Also, record documentation may be partly determined by what care can be billed for reimbursement. If mobilization cannot be billed for, for example, it is less likely to be noted in the record even if it done in conjunction with manipulation. Also, clinics that do not bill insurance may be less incentivized to maintain more detailed documentation. All these factors affect what is recorded in the patient file and therefore determine the files' usefulness in research.

CONCLUSION

The chiropractic record data collection for this project focused on evaluating the appropriateness of mobilization and manipulation for CLBP and CCP. Additional data were collected to summarize the duration of care, frequency of visits, and nature of treatments provided. For this study, the chiropractic record provided the most comprehensive data to assess appropriateness of chiropractic care. Records of care were successfully obtained from most study sites.

This paper set out to provide an overview of the 4-step process (consent, selection, protection, and abstraction) of acquiring a large sample of chiropractic patient records from multiple practices and subsequent data abstraction. As we noted, each step poses challenges, and in each step, we documented the solutions we implemented. For future research based on chiropractic clinics, it is clear that improved record keeping and easier access to files would greatly simplify the task of abstracting data from a patient file.

Use of an EHR may improve clinical content, but even paper-based records could benefit from improved and better use of templates to document patient history, examinations, treatment, and outcome measurements. Consistent documentation would ease ongoing research efforts and support providers in case of legal questions or a reimbursement audit. As chiropractic care becomes more accepted in medical settings that may require more provider collaboration, maintenance of complete treatment documentation will become even more important.

CONTRIBUTORSHIP INFORMATION

Concept development (provided idea for the research): I.D.C., E.L.H., H.V., P.G.S., P.M.H.

Design (planned the methods to generate the results): C.P.R., I.D.C., L.S.K., G.W.R., J.S.M., E.L.H., H.V., P.M.H.

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Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): C.P.R., I.D.C., J.S.M.

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Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): C.P.R., I.D.C., L.S.K., G.W.R., G.J., J.S.M., E.L.H., H.V., P.G.S., P.M.H.

Practical Applications

- This study describes the selection, protection, and abstraction of chiropractic patient records for determining appropriateness of care.
- This approach was successfully applied in a national study of chiropractic patients with chronic pain.
- The findings will be of interest to researchers and clinicians in the complementary and integrative health professions who want to collect data about patient care and outcomes from patient records.

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