THE IHS PRIMARY CARE PROVIDER

A journal for health professionals working with American Indians and Alaska Natives

July 2002 **Volume 27, Number 7**

The Diagnosis of Myocardial Infarction and Cardiac Troponins: An Expanding Role in IHS Facilities

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In the past, a general consensus had existed, based on World Health Organization (WHO) criteria, which required two out of three of the following for the diagnosis of acute myocardial infarction (MI): characteristic chest discomfort, electrocardiogram (ECG) changes, or a typical pattern of enzyme rise and fall. Now, however, a consensus document from the American College of Cardiology (ACC) and the European Society of Cardiology (ESC) has recently redefined the diagnostic criteria for acute MI.[1] This document underscored the variability of the definitions and diagnostic modalities previously used to document myocardial infarction in clinical settings, including the pathologic findings (both gross and microscopic), ECG criteria, as well as laboratory studies. Additionally, this consensus paper has expanded the definition of acute myocardial infarction to incorporate the use of the cardiac troponins.

Troponins are more sensitive markers of cellular necrosis, and identify a group of patients who have small areas of myocardial injury that might not result in elevation of creatine kinase (CK) or its myocardial isoenzyme (CK-MB). Identifying, and subsequently treating, this previously undiagnosed population is essential since there is a linear and direct relationship between troponin levels and cardiovascular mortality. Troponins have now become a fundamental component of the diagnosis and management of myocardial infarction; numerous tribal and IHS facilities have now appropriately supplemented or replaced their standard serologic assays for myocardial injury with quantitative or qualitative assays for cardiac specific troponins.

What are Troponins?

Cardiac troponins are structural proteins in myocytes. Following myocardial necrosis, they are released into the bloodstream in a characteristic, time-related fashion. While other markers of injury are found in abundance in skeletal muscle, smooth muscle and in some instances, other tissues, troponins I and T have a very high specificity for cardiac muscle. This increased specificity of troponins limits misdiagnosis from confounders such as muscle injury, stroke, or hypothyroidism as may be seen with other markers. Because of their increased sensitivity, troponins may be positive in

In this Issue…

141 The Diagnosis of Myocardial Infarction and Cardiac Troponins: An Expanding Role in IHS Facilities
145 ICD-9-CM Miscoding Involving Codes for Invasive Cervical Cancer
147 Using RPMS Data to Perform Population-based Analysis
152 Position Vacancies
155 Meetings of Interest
158 ACOG Meeting
159 ELDP Meeting

patients with myocardial infarction who have normal CK and CK-MB levels. In general, cardiac troponins should not be present in peripheral blood under normal circumstances. There are, however, a few cardiac and non-cardiac illnesses other than acute coronary syndromes (ACS) in which troponin elevations may be seen.

Patients with microscopic myocardial cell necrosis associated with pericarditis, myocarditis, non-ischemic cardiomyopathies, congestive heart failure, as well as sepsis and intracerebral hemorrhage in the absence of coronary artery disease may have troponin elevations.[2,3] Small leaks may also occur after cardioversion, electrical pathway ablation, and cardiac surgery. Earlier troponin assays demonstrated false positive results related to a circulating heterophile antibody that interfered with the assay; this has been remedied with later assays.

The question might arise, particularly in facilities not typically treating patients with acute coronary syndromes, whether the availability of troponins will benefit patients presenting with chest pain. Multiple studies have suggested that cardiac troponins clearly identify patients at higher risk for adverse cardiovascular outcomes, including death, in both short and long-term follow-up. These studies have looked at patients not only with acute coronary syndromes,[2,3] but following percutaneous coronary intervention (PCI) such as stent placement and before bypass surgery.[4,5] These studies suggest that troponin assays can identify high-risk patients with myocardial damage who are below the threshold of CK positivity. They further suggest that any patient with a cardiac presentation and positive troponin assay is at higher risk for complications including death and recurrent MI and, therefore, more likely to benefit from early evaluation and intervention by a cardiovascular specialist.

Troponins usually become positive six hours or more after symptom onset and peak within 24-48 hours following an acute coronary event. Perhaps most interesting (and useful) is the fact that troponins may remain positive for 7-10 days following a cardiac event. Thus, they are also useful for delayed presentation of acute myocardial infarction.

Acute Coronary Syndromes: Diagnosis in the Era of Cardiac Troponins

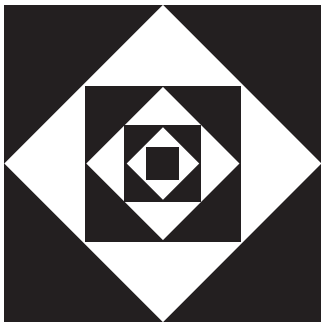
Clinical evaluation remains the foundation for diagnosis and provides the basis for the optimal therapy for ACS despite the advent of these powerful new diagnostic tools. This evaluation must include a focused history, physical examination, and ECG within 10 minutes of patient presentation with acute chest pain, dyspnea, chest pressure, or symptoms of acute heart failure. The presence of known coronary artery disease or cardiac risk factors such as diabetes, older age, smoking, hypertension, dyslipidemia, and positive family history increase the likelihood of acute coronary syndromes and should prompt an even more aggressive evaluation. Classic ischemic chest pain most commonly presents with non-pleuritic, substernal chest pressure, often radiating to the neck, arms, or jaw, and is often associated with shortness of breath, diaphoresis, and/or nausea. However, patients with diabetes as well as women may have atypical (or even silent) symptoms. A high level of suspicion and a probing history are therefore required for our diabetic and female patients presenting with shortness of breath, indigestion, or chest or upper abdominal complaints.

In a patient with a stuttering course, it is important to ascertain if there was a point in time at which the pain became more intense or continuous, since this will help to determine the benefits of acute interventions (e.g., thrombolytic therapy). Thrombolytic therapy is indicated in patients with ST-segment elevation MI presenting within the first 12 hours of symptom onset. Establishing the time that symptoms were initially noted to be continuous is vital for determining eligibility for this potentially life-saving treatment.

Baseline laboratory evaluation should include a complete blood count (CBC) including platelets, a renal panel (SMAC-7), troponin I or T, CK with MB fraction, and a protime (PT) and partial thromboplastin time (PTT). Patients presenting with suspected ACS during the first six hours of symptom

onset require serial measurements of serum markers, including CK and troponin (again, usually not positive until at least six hours after symptom onset). ECG remains an essential component of the diagnostic evaluation and risk stratification in acute coronary syndromes. If the initial ECG is unremarkable but the patient continues to have pain, it is important to repeat the ECG, as the yield in diagnosing MI is improved by the performance of serial ECGs. Patients with ST-segment depression are another high-risk group with increased mortality. It is also helpful to remember that some areas of ischemia or infarction, particularly in the circumflex artery distribution, can be silent; a normal ECG does not rule out ischemia or even acute MI.

Clinical presentation and cardiac markers determine therapeutic interventions including hospital admission. Patients with a worrisome history, physical exam, and/or ECG findings must be admitted to a telemetry unit for further observation and testing, regardless of laboratory findings. In addition, patients with positive serum markers must be strongly considered for admission or transfer to a tertiary care center for further evaluation, even in the setting of an atypical presentation.



Therapy of Acute Coronary Syndromes

History, physical examination, and ECG along with serum markers remain the standards for triage of patients with potential acute coronary syndromes. The decision to discharge a patient from the Emergency Department cannot be made on the basis of enzymatic markers alone. Again, since patients with diabetes and women often have atypical ischemic symptoms, a high level of suspicion is necessary in these patient populations.

As discussed in a prior article in the *IHS Provider* ("Management of ST-Segment Elevation Myocardial Infarction: Thrombolytic Guidelines," Volume 27, Number 4, pages 69-75), patients presenting with ST-segment elevation of at least 1 millimeter or left bundle branch block along with chest discomfort consistent with an acute myocardial infarction should receive 325 mg aspirin immediately. If there is no response to sublingual nitroglycerin, thrombolytic therapy (in the absence of contraindications) should be administered within 30 minutes of presentation, regardless of serum markers. Strong consideration should be given to adjunctive beta-blocker administration as well, unless contraindicated.

Chest pain patients at moderate or high risk for acute coronary syndromes should be admitted to an intensive care unit (ICU) or transferred to a facility with a higher level of care. All patients with chest pain and a suspicion of unstable coronary syndromes should be treated with aspirin, sublingual nitroglycerin, heparin (unfractionated or low molecular weight), and oral/intravenous beta-blocker therapy in the absence of contraindications. Higher risk patients (those with a history of definite coronary artery disease (CAD), ECG changes, positive troponins, or hemodynamic instability) should generally be cared for in facilities with the availability of ICU monitoring and acute coronary intervention. Recent data have shown that the increased mortality associated with troponin elevations is optimally reduced by an invasive approach as compared with conservative medical therapy. Therefore, patients with positive troponins (even with a normal CK) in the setting of acute coronary syndromes should be transferred to institutions with the availability of cardiac catheterization, coronary angiography, and acute intervention unless other co-morbidities (such as dementia, terminal illness, severe debility, etc.) mandate a more conservative approach.

Patients with symptoms but who are felt to be at low risk (due to clearly atypical symptoms, normal ECG, young age, and no history of coronary artery disease) should be considered for admission to facilities with telemetric monitoring. The use of troponins in this setting may assist in this decision. Troponins should be ordered on arrival and confirmed with repeat study 6-12 hours later. We continue to suggest that CK should be evaluated in all patients presenting with symptoms compatible with acute coronary syndromes. If admitted, serial CK with MB isoenzymes should be drawn at initial evaluation and every eight hours for the first 24 hours.

Introducing Troponins in a New Clinical Setting

The reliability of troponin assays must be adequately proven in individual laboratories before practitioners can develop confidence in these new diagnostic tools. Obviously,

important clinical decisions rest upon their appropriate implementation and interpretation. For this reason, we strongly suggest the continued use of both CK isoenzymes and troponins when the new assays are introduced in a clinical practice. Once adequate clinical follow-up has established the utility of the new troponin assays and their accuracy, consideration of discontinuation of CK-MB assays may be given. This may benefit facilities by offsetting the added expense of the troponin assays. In most circumstances, the continued use of CK-MB will be unnecessary once experience with the troponin assay has been obtained.

Conclusions

Cardiac troponins are highly sensitive and specific assays for the detection of minimal amounts of myocardial damage. They have now been designated the preferred serum marker of myocardial damage and, thus, are the new standard of care for the diagnosis of ACS. Evaluation of patients with acute coronary syndromes should include risk assessment by history and physical examination, ECG, and serial cardiac markers. High risk patients, such as those with troponin elevations, ischemic ECG changes, hemodynamic compromise, or known CAD, should be transferred to facilities where high quality interventional cardiovascular procedures are available.□

Recommended Reading

1. ACC/AHA Guideline Update for the Management of Patients with Unstable Angina and Non–ST-Segment Elevation Myocardial Infarction. The full text and be found in the *Journal of the American College of Cardiology* 2000;36:970-1056. An executive summary can be found in *Circulation* 2000;102:1193-1209. It is also available at *http://www.acc.org/clinical/guidelines/unstable/unstable.pdf.*
2. ACC/AHA Guidelines for the Management of Patients with Acute Myocardial Infarction. *Circulation* Vol. 100, No. 9, August 1999; 1016-30. The full text can be found at *http://www.acc.org/clinical/guidelines/nov96/edits/dirindex.htm*. An executive Summary can be found at *http://www.acc.org/clinical/guidelines/nov96/1999/execIndex.htm.*

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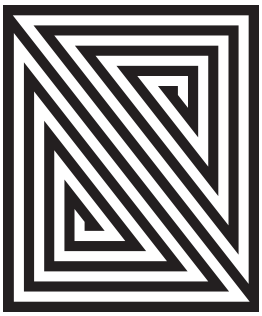

ICD-9-CM Miscoding Involving Codes for Invasive Cervical Cancer

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The IHS National Epidemiology Program recently completed an evaluation of invasive cervical cancer incidence and mortality among American Indians and Alaska Natives (AI/ANs) in one of the IHS Areas. As part of this study, the accuracy of diagnostic codes included in the clinical component, the Patient Care Component (PCC), of the IHS healthcare information system, the Resource and Patient Management System (RPMS), was evaluated.

Methods

Cases were initially identified through a search of International Classification of Disease, Ninth Edition, Clinical Modification (ICD-9-CM) codes performed by the Area office. ICD-9-CM codes used included 180.0 (invasive cancer of the endocervix), 180.1 (invasive cancer of the exocervix), 180.8 (invasive cervical cancer, other specified sites), and 180.9 (invasive cervical cancer, site not specified). All patients with these diagnoses entered into RPMS from 1993 through 2000 were sought. We then conducted chart reviews for all people identified through the ICD-9-CM code-based search, plus seven additional persons identified through review of Contract Health Service (CHS) referrals to confirm the diagnosis, to identify any miscoding, and to assess for systematic patterns in miscoding if present.

Initially, the visit date associated with the invasive cervical cancer code was not available to the chart reviewers, a significant limitation which made it difficult to link a specific chart entry with the diagnostic code. Probable indications for assignment of the invasive cervical cancer code were determined based on a review of progress notes, laboratory results, and records received from pathologists and gynecology and oncology consultants. In cases where a diagnostic narrative read simply "cervical cancer" or "history of cervical cancer," a common finding in older records, and where there was no documentation of tissue pathology to the contrary, we assumed that the entry had been correctly coded as invasive.

To further clarify the reason for assignment of cervical cancer-associated codes, we conducted a search of electronic records for two of the service units in the study. We reviewed the provider narrative ("purpose of visit") that prompted assignment of each cervical cancer-associated code, and compared the findings with those from the chart review to determine if the conclusions using the two methods were consistent.

Results

In all, 233 patient records, representing 228 individuals, were identified through the initial database search and review of CHS referrals. Five individuals were identified by database searches at two different clinic sites. Each chart was reviewed, since coding at the different sites was presumed to have occurred independently. Thirty-one records were either not available at the time of review, or were felt not to be sufficiently complete to permit determination of the basis for the assignment of the invasive cervical cancer code.

Chart review of the remaining 202 records revealed that 75 (37%) had been correctly coded as invasive cervical cancer. Forty-three (21%) were found to have cervical carcinoma-in-situ (ICD-9-CM code 233.1). Fifty-six (28%) had cervical dysplasia. Seven (3%) had cervical polyps. Four (2%) had uterine cancer, three (1.5%) had vaginal dysplasia or cancer, and three (1.5%) had undergone hysterectomies for benign causes. One (0.5%) had gestational trophoblastic neoplasia, while nine (4%) appear to have had the code assigned secondary to non-dysplastic pap results (benign cellular changes, infection/inflammation, atypical squamous cells of uncertain significance, or a class I pap). In one case the code was apparently linked to cervical spine disease. Miscodes occurred throughout the study period, with multiple miscodes noted in 1999 and 2000.

When the seven people identified through CHS referrals were considered separately, two (29%) were correctly identified with invasive cervical cancer, two (29%) had cervical carcinoma in situ, one (14%) had a hysterectomy without evidence of cervical cancer, one (14%) had cervical dysplasia, and one person (14%) had a non-dysplastic pap.

The electronic evaluation of provider narratives associated with invasive cervical cancer codes encompassed 93 (40%) of those in the study. Correct coding for invasive cervical cancer could be confirmed in 24 (26%) persons. "Cervical carci-

noma-in-situ" from the provider narrative was coded as invasive cancer in ten (11%) of the records, and "cervical intraepithelial neoplasia" was the narrative on 21 (22%) of the records. Three (3%) had narratives describing cervical polyps, three (3%) had narratives denoting diagnostic procedures such as "colposcopy" or "endocervical curettage," one (1%) had "vaginal dysplasia," one (1%) had "myoma," and one had simply "endocervical" listed in the narrative.

"Cervical cancer" or a history of it was included in the narrative for 29 (31%) of those without evidence of invasive cervical cancer on chart review. Of these, 23 had cervical dysplasia or carcinoma-in-situ documented in the chart. Four had no evidence of cervical dysplasia on chart review; of these, two had a history of uterine cancer, one had undergone hysterectomy for endometriosis, and one had undergone hysterectomy related to gestational trophoblastic disease. Two had charts not felt to be sufficiently complete to allow assessment for the presence or absence of cervical dysplasia.

Conclusions

This investigation involved a very specific set of ICD-9-CM codes denoting a (happily) rare condition. We recommend caution in drawing conclusions based on these findings about the general utility of ICD-9-CM code-based searches in identifying patients with specific medical conditions. However, the study does shed light on two primary reasons for incorrect coding in RPMS and other electronic medical record systems:

1. The electronic review of provider narratives revealed that the ambiguous and misleading term "cervical cancer" was used in almost one-third of narratives in which invasive cervical cancer was incorrectly coded as the diagnosis. Even the most skilled coder is likely to consider entry of an incorrect code in this situation, or when "rule out cancer" is written in the provider narrative. The bottom line for the health care provider: Avoid ambiguity or inaccuracy in recording a "purpose of visit."
2. The study also demonstrated that miscoding most commonly occurred when closely related conditions (e.g., cervical carcinoma-in-situ or cervical dysplasia) were described in the provider narrative. Less commonly, miscoding occurred when diagnostic procedures (e.g., colposcopy) were mentioned, and more rarely still, miscoding was triggered by description of essentially unrelated medical conditions in the same anatomic region or with a similar-sounding name. Correct assignment of codes for "cervical carcinoma-in-situ" and "cervical intraepithelial neoplasia" would eliminate 100 cases or 79% of the miscoding found through chart review. The bottom line for coding personnel: Review and correct assignment of distinct codes for closely related medical conditions could eliminate the majority of incorrect coding in this setting. It could affect billing and reimbursement, improve the accuracy of the electronic medical record, and make it easier to track disease trends at IHS facilities.

By addressing these two potential causes of incorrect ICD-9-CM coding, we can increase the utility of PCC data to track disease trends in IHS service populations and to identify individuals with specific medical conditions.

Acknowledgements

The authors would like to thank our colleagues in the local facilities and in the Area office for their help in this study, and Stan Griffith of the IHS Information Technology Support Center for his helpful comments on the manuscript.□

Using RPMS Data to Perform Population-based Analysis

A Conversation with a Colleague

Stanley P. Griffith, MD, Medical Informaticist, Information Technology Support Center, IHS; Albuquerque, New Mexico

Over the last several years a number of us have spent a fair amount of time analyzing the quality of the data in our healthcare information systems and using the derived information to perform various population-based analyses. Increasingly many of us are using data in the Resource and Patient Management System (RPMS) and its primary clinical component, the Patient Care Component (PCC), and other information systems to perform analyses needed for quality improvement, performance measurements, public health care, epidemiology, and research. All of us who have been doing this work have learned a great deal, some of which was not intuitively obvious to us when we first began.

Back in the early 1990s, David M. Eddy, MD, PhD wrote a wonderful series of articles on Clinical Decision Making that were published in *The Journal of the American Medical Association (JAMA)*. Several of those articles were organized as a series of conversations with his father. I spend a fair amount of time advising and assisting others as they plan and then perform population-based analyses at the local, Area, or national levels. Therefore it seemed appropriate to similarly organize this article as a fictitious conversation with a colleague who is planning such a project. I hope this proves to be an effective way to share with you what we have learned.

Erica P. Investigator, MD, MPH Okay, I read a bunch of those articles and reports you suggested on using RPMS data for various purposes.[1-13] I see lots of information, but those articles did not focus on the subjects I need to investigate. What about the data I want to look at? Is it any good?

Stan I think that analyses or performance measures based on data within RPMS generally fall within one of three categories. First are analyses that can be performed with sufficient accuracy today. An example of this is BP control in individuals with diabetes. A second larger group are those that have some value right now, but can become much more complete and accurate if a few specific steps are taken. An example of this is that data on Papanicolaou (Pap) smear rates can be greatly improved if sites implement the RPMS Lab Package and enter tests sent to outside labs into that package. Finally there are a large group of measures where data comprehensiveness and/or quality are just not sufficient yet, and major long-term efforts will be required. So an honest answer is, "It depends."

Erica Now you are sounding like a politician. I already know that we don't gather all the data and the data are not perfect. How do I determine whether or not the data are sufficient for my analysis?

Stan We have learned a lot about assessing whether or not the data are likely to be sufficient for a particular analysis. Although it may at first sound overly simplistic, to start with you should ask three basic questions.

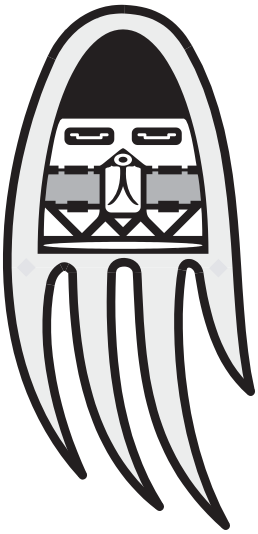
1. Are there data fields in RPMS to store those data elements that are required for your analysis? It is important to realize that RPMS is not a complete computer-based record. RPMS only stores a subset of the information that is contained in the written chart.

2. Do some(?), many(?), most(?) sites collect and enter data into those fields? Even if RPMS can store the data in which you are interested, not all data that could be entered are actually entered at each and every site.

3. How accurately are those data entered? There are inevitable problems in how data are recorded in the written chart and then entered into RPMS. And this varies from site to site. Of course, some data elements are more problematic than others.

Erica Yes, I have noticed that there is a big difference in the accuracy of data, even when it is supposed to be there. Some types of data seem to get into RPMS accurately and reliably and other types do not, even when the data in the written chart are accurate.

Stan That's right. It is not just a matter of having adequate numbers of well-trained data entry staff, although that is a very important concern. Adequate, well-trained data entry staff are seriously lacking at too many sites. Sometimes it is a matter of poor provider training. Some providers have never been shown how to properly record data on a PCC form. This is especially true at sites with high turnover, or sites with lots of



short-term, contract staff. Sometimes providers record data in ways they should not, for example writing "Rule out breast cancer" instead of "Right breast nodule," which the data entry clerk then incorrectly codes as "breast cancer." It can be a problem of a lack of precision, writing "diabetes" for a child, but not specifying whether it is Type 1 or 2. It can be writing the abbreviation "OM" instead of "Otitis Media" which a data entry clerk misreads as "DM" and then enters as "Diabetes Mellitus." Sometimes it is because the same data can be or is required to be entered in more than one place in the written chart. A good example of this is the recording of immunization data on the "blue forms" and not on the PCC form where it can be picked up by data entry staff. And some data, like cause and location of injury, do not get reliably entered even though there is one specific location on a standard PCC for this information. Right or wrong, in the crush of a busy clinic, recording injury information is sometimes not among a provider's highest priorities.

All in all, and despite all of the above, I have been pleasantly surprised with how accurate much of the data are and how accurately we can perform many analyses.

Erica I have heard that there is a new RPMS project called "PCC Plus" that will help us improve getting data accurately into our system.

Stan Yes, we are moving ahead with "PCC Plus." It is a wonderful and exciting application that has great potential for improving the recording of data on the written form and then the entry of those data into PCC as well as the display of PCC data to service providers. But that is a subject for another day and another author.

Erica Hmmm . . .. So, if I understand you right, if the data elements in which I am interested have fields in RPMS, if the sites with whom I am working all assure me they reliably enter those data, and if the data I am looking at are data that can be entered simply – data that don't require special skills such as ICD-9 coding – my data should be highly accurate and I won't have any problems?

Stan Whoa, hold on a moment! Things aren't that simple. You still need to consider a number of other things.

- Are you looking at measurements or events performed by our system (direct care) or by outside providers (contract care, private care, community health fair, etc.)? We have had problems accurately measuring influenza vaccination rates at sites where individuals can get flu shots at Wal-Mart.

- Are the data in which you are interested entered as standard codes (something the computer can "understand" so that it can group and sort data in a meaningful and automated manner) or is it "free-text" (something you will have to look at yourself and group or sort by hand)? RPMS can use its search tools to easily select and aggregate records by ICD code; however, if you want to search and aggregate provider narratives, you will likely have to do that manually, looking at each individual record yourself.

- Are you searching for a low prevalence condition amidst much more frequent, related conditions? In this case, even with very accurate data entry, you should be concerned that you are likely to find a high rate of false positives. For example, using ICD codes to search for individuals with HIV infection will result in some false positives, individuals who just had HIV testing but were miscoded as HIV infected. This is analogous to the well-described tendency for even highly sensitive and specific screening tests to have high false positive rates when used in low-prevalence populations. Fortunately looking at the provider's written narrative, also in the electronic record, almost always distinguishes between the two.

- Are the data only sufficiently accurate at sites with certain specific characteristics? For example dental access for patients with diabetes can be measured accurately at sites that have on-site dental clinics that use an inte-

grated dental information system. Similarly, Pap rates can be more accurately determined at sites that use the RPMS Lab Package and which enter data on tests sent out to contract labs into that system.

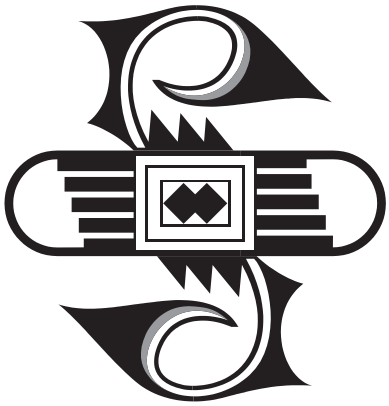
Erica This is getting complicated! I expected challenges with using the data, but are they going to make my project impossible?

Stan Actually, data do not have to be perfect in RPMS for it to be useful. If I am providing care for an individual patient, even 99% accuracy may not be sufficient. But if I am assessing something about a large group of individuals, generating a measure that is accurate within several percentage points may be more than sufficient. For example, knowing that a community's Pap smear rate is in the 20-30% range rather than 70-80% may be adequate to make me want to investigate the situation further.

Similarly, we have empirically shown that if you are performing an analysis that is looking for at least one of multiple events it can still be accurate even if your system has "lost" one or more of those events. This is especially true for measures that perform a calculation (e.g., mean or median) on several values. Even if one or more of the values is "lost," as long as the values are not lost in an obviously "biased" fashion (the data entry clerk just forgets to enter some values or random encounter sheets are "misplaced," rather than the clerk is more likely not to enter specific abnormal values or selectively loses encounters from one type of clinic) or the values tend to remain consistent over the short-term, the measurement may remain accurate. Examples of this include BP control, a measurement that typically is based on a derived calculation using multiple values, and obesity that, except with crash diets, does not typically come and go in the short-term.

Furthermore, if I wanted to investigate individuals in a population with diagnosed HIV, I could do an ICD search for HIV. Based on results from a previous study, I would expect that a number of the individuals who would be identified in this manner would be "false positives," e.g., individuals who had undergone HIV testing but had been miscoded as having HIV disease. Even if I had to manually look at the electronic or written chart information on all 100 individuals identified through the ICD search so as to correctly identify the 85 who really had HIV disease, that is still an incredible time savings. Imagine my having to manually review all of the 50,000 charts of the patients looked at in that ICD search!

For all these and many other reasons, if you are planning a data project such as yours, it really makes good sense to talk with someone who is familiar with the data and who has previous experience analyzing it, before you finalize any project plans.



Erica All right, I can see that. But your last example worries me. Unless I look at the 50,000 charts, how do I know that I did not miss individuals with HIV disease, individuals whose HIV diagnoses were miscoded as something else?

Stan Ultimately, you don't, anymore than you can be assured that an individual really does not have HIV disease just because you can't find "HIV disease" written in his or her chart. But you can mitigate your risk a bit with other strategies. If you were trying to identify all individuals in a population with invasive cervical cancer, you could just do a search for individuals with any of the ICD codes representing invasive cervical cancer. Alternatively you could broaden your search and do it on all codes representing invasive cervical cancer as well as those codes for frequently miscoded, related conditions, e.g., carcinoma-in-situ of the cervix, cervical dysplasias, cervical polyps, and other GU cancers. You would then need to do a secondary manual review of the electronic or written chart records, not an insignificant task, but far easier than doing a manual review of all the records of the entire population or, worse yet, going out and interviewing all in the population, searching all other healthcare system charts, etc.!

Erica Several times now you have mentioned doing a manual review of the electronic record rather than the written chart. What do you mean by that?

Stan Most people have heard about QMan, PGen, and VGen, powerful tools that allow you to search, sort, and display information from PCC. But PCC also has tools that allow you to display almost all of the data it contains for a patient – all the visits, all the medications, all the laboratory tests, all the measurements, and so forth. Looking at these data for a patient is the electronic equivalent of doing a written chart review. I

would remind you, though, that PCC still only contains a subset of the most important information in the written chart, not all of it. But I would also remind you that this "electronic chart review" can be performed remotely – you don't have to travel to where the chart is stored or have it copied and sent to you.

Erica Neat! My service unit has a central facility and six outlying, satellite clinics, each of which maintains its own charts. Information from all seven facilities is entered into the one RPMS computer at the central facility. You are saying that I could gather information about a given patient from all the facilities by manually looking at the electronic record from the central facility? I don't have to travel to each of the outlying clinics to look at the written charts? That really would save time!

Stan Exactly!

Erica I am also interested in doing a study that would involve several service units in my Area. To do this, would I have to "dial-in" to each service unit or can I look at data in one regional or national repository?

Stan Dialing-in is one way to do that. Many times you have to dial-in because not all of the data in PCC are exported to our national repositories – NPIRS and ORYX. The local PCC repository has a more complete spectrum of information than our national databases. Because dialing-in is the only way to do certain analyses, ITSC has been working on a tool, originally proposed by Roger Gollub, that would allow an individual with appropriate permissions to broadcast certain QMan, PGen, and VGen search logics, or requests for certain PCC Patient Management Reports, to multiple facilities in one, unified process. But, of course, if the data elements in which you are interested are exported to the national repositories, then you could potentially get those data from a national repository like the NPIRS or ORYX databases.

Erica So, if the data I need are exported to the national repository, I can just as accurately run this analysis on national as local data? That would save me a lot of time.

Stan Yes, many times you can. But once again, it is not always quite that simple. There are other considerations. For example, if the data in which you are interested are collected and stored at the local site by a set of codes that are unique to that local site, but the set of codes varies from site to site, then those data at the national level are not uniform and become the equivalent of "free-text." Even though the content of those data elements is standardized at the local site, at the national level they are not, and so your analysis of those data may have to be manual. We try to get around that by asking local sites to set up "local taxonomies," as for the PCC Diabetes Audit, but these require a fair amount of work and diligence to set up and maintain. Examples of data affected by this problem include medications and laboratory tests.

I would note that this is not a problem caused by some "deficiency" within RPMS. It has arisen because the healthcare industry as a whole had not previously developed a uniformly accepted, standard terminology, a sort of "set of codes" for either of these subject areas. On the good side, the healthcare industry and the Federal government have begun to cooperate to correct this situation.[14] Our Agency now has several active initiatives to implement code sets that would promote standardization of laboratory test names and medications at the national level.

Erica You know, the more I think about doing this electronically, though, I just don't know. I am used to doing chart reviews and I think they are just more accurate than looking at computer data. If I am willing to spend the time to be more accurate, why don't I just do the chart review?

Stan You are right, there are much more data available in the written chart than there are in RPMS, so in many situations they will be more complete. But our work has shown us that they are not always more complete. In a number of our studies we were able to gather information on individuals whose written chart was missing or had been sent to the archives. In other cases, as we just discussed, we were easily able to obtain information about an individual's care at an outlying clinic that maintained its own separate charts. Also some important data are not in the written chart and are only available in the electronic system. For example, at many sites, referral information is stored in the RPMS Referred Care Information System and not in the written chart, except on the PCC's printed Health Summary. Data about contract health cares, e.g., diagnoses, procedures, payments, etc., are passed electronical-

ly and automatically back to RPMS from the Fiscal Intermediary. Often consultation letters and discharge notes just never get back to the written chart.

Erica Oh. I hadn't thought of that. So in some situations there are important data in RPMS that are not in the written chart?

Stan Yes, although you may find much of them if you print a current PCC Health Summary. Because of this I often advise that it is most prudent to look at both sources, not just one, for the most complete information.

Erica Okay, you are convincing me. Do these issues only affect GPRA or ORYX reports or my ability to do a population-based investigation?

Stan No, not at all. GRPA and ORYX, and other population-based analyses are critical to our Agency and various health-care delivery systems. But I am, at heart, a clinician. I like to look at these measures, at least in part, as miners' canaries. For example, if we cannot accurately measure how many of our patients have had influenza vaccinations because we don't get the shots provided at Wal-Mart into our system, that means a physician caring for that patient likely doesn't have that information either and it certainly cannot be displayed on the patient's Health Summary.

Similarly, if we aren't getting data into our systems in some kind of a coded manner that the computer can "read," then we also can't as easily and effectively generate the automated alerts and prompts. A provider could not get a real-time special alert that tells her that the patient for whom she is prescribing a thiazide had a life-threatening anaphylactic reaction to trimethoprim/sulfamethoxazole a few years back. As Professor Larry Weed has said, developing information systems that can process these types of information will allow providers to focus on the "art of medicine" rather than "memorizing airline schedules."

Erica Okay, this seems to make sense. I guess I now pretty much know all I need to know about data in our information systems?

Stan I am not sure I would go that far. I sure don't "know it all," and I don't know anyone who does. And there are a whole bunch of subtleties we haven't even begun to discuss. For example, if you are looking at data collected over time, you need to be aware of the exact when and where of some of the historical changes in the fields, code-sets, exports, and so forth, because data that are accurate and complete now may not have been so a year ago. The only thing I can guarantee you about data is that the more we gather and learn, the more questions we will have!

I hope you come back to me with many more questions and even some answers. Will you let me know how your analysis goes and share with all of us what you learn?

Acknowledgements

I thank Amy Groom and Bill Mason for their careful reviews and excellent suggestions that significantly improved this article.

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