

Monitoring Adherence to Evidence-Based Practices

A Method to Utilize HL7 Messages from Hospital Information Systems

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Keywords

HL7, inpatient care, workflow, monitoring, surveillance, clinical decision support

Summary

Background: Clinical pathways are evidence-based recommendations for treating a diagnosis. Although implementations of clinical pathways have reduced medical errors, lowered costs, and improved patient outcomes, monitoring whether a patient is following the intended pathway is problematic. Implementing a variance reporting program is impeded by the lack of a reliable source of electronic data and automatic retrieval methods.

Objectives: Our objective is to develop an automated method of measuring and reporting patient variance from a clinical pathway.

Methods: We identify a viable and ubiquitous data source for establishing the realized patient's path- Health Level Seven (HL7) formatted message exchanges between Hospital Information Systems. This is in contrast to current practices in most hospitals where data for clinical pathway variance reporting is obtained from multiple data sources, often retrospectively. This paper develops a method to use message exchanges to automatically establish and compare a patient's path against a clinical pathway. Our method not only considers pathway activities as is common practice, but also extracts patient outcomes from HL7 messages and reports this in addition to the variance.

Results: Using data from our partner hospital, we illustrate our clinical pathway variance analysis tool using major joint replacement patients. We validate our method by comparing audit results for a random sample of HL7 constructed pathways with data extracted from patient charts. We report several variances such as omitted laboratory tests or additional activities such as blood transfusions. Our method successfully identifies variances and reports them in a quantified way to support decisions related to quality control.

Conclusions: Our approach differs from previous studies in that a quantitative measure is established over three dimensions: (1) omissions from the pathway, (2) additions to the pathway, and (3) patient outcomes. By examining variances providers can evaluate clinical decisions, and support quality feedback and training mechanisms.

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Applied Clinical Informatics 2013; 4: 126–143

DOI: 10.4338/ACI-2012-06-RA-0026

received: June 27, 2012

accepted: January 10, 2013

published: March 20, 2013

Citation: Konrad R, Tulu B, Lawley M. Monitoring adherence to evidence based practices – a method to utilize HL7 messages from hospital information systems. *Appl Clin Inf* 2013; 4: 126–143
<http://dx.doi.org/10.4338/ACI-2012-06-RA-0026>

1. Introduction

A clinical pathway is a collection of evidence-based recommendations on the sequence and timing of care interventions for a diagnosis [1]. These recommendations, also referred to as care maps or care paths, are intended to improve patient outcomes and care delivery [2-3]. The benefits of clinical pathways are well documented and include increased hospital efficiency [4-5], decreased operations costs [6-7], reduced length of stay [8] and decreased mortality rates [9].

Clinical pathways differ from other information provision systems in that they support variance reporting [2]. Variances are discrepancies between recommended and actual care events, outcomes that differ from those anticipated, and deviations from projected timelines [1, 10]. By examining variances, providers can evaluate clinical decisions and identify appropriate treatment changes [11]. Thus, variance analysis provides significant potential for continuing quality improvement [12].

Unfortunately most hospitals face major impediments in implementing variance reporting programs, the most significant being a reliable, electronic source of data [13-14]. Patient charts often contain little data in useable electronic format [15], and workflow data must be gathered from many sources, which introduces interoperability and compatibility issues [13, 14, 16]. Although technologies for integrating clinical pathways into hospital workflows are beginning to emerge [17], many organizations have abandoned variance reporting because the process is too difficult [18]. Indeed, several recent authors report the need for automated variance reporting [1, 19]. To the best of our knowledge, methods to automatically track and report variances are not reported in the literature, although techniques for automatically detecting and modeling patient flow paths are being developed [20-22].

In this paper, we outline our objectives present our methodology to establish a patient's trajectory using transactional Hospital Information Systems (HIS) data, and describe our variance measurement approach using a patient's trajectory. We then demonstrate our method through a joint replacement case study based on clinical data collected from a hospital. We present a discussion of our approach and conclude with a summary of our contributions.

2. Objectives

Our objective is to develop an automated method of measuring and reporting variance throughout a patient's journey. Our method contributes to existing variance reporting mechanisms by (1) explicitly considering patient outcomes, and (2) by quantifying both the additions to, and omissions, from a clinical pathway. Presenting patient outcomes with quantified variance allows for immediate corrective action for the individual patient. Since the measurement method is automated, it also enables rapid retrospective study for quality assessment purposes. In the absence of a reliable electronic source of data, our innovative approach utilizes existing Health Level Seven (HL7) formatted messages from HIS that are routinely created as part of the hospital workflow. We automatically extract workflow and outcomes data from these messages, use that data to reconstruct the patient's care path to date, compare the patient's care path with that prescribed, and compute measures of pathway deviation and outcomes that can be reported to care providers during the patient's stay. A significant advantage of this method is that it uses HIS infrastructure currently existing in every hospital.

3. Methods

3.1 Data Source: Electronic Message Exchanges

The most significant impediment to a systematic variance reporting is accessing a reliable, electronic source of data [13, 14]. While electronic medical records systems would provide the best solution, these systems are not yet widely adopted by the healthcare organizations. In contrast, messaging standards such as HL7 enable interoperability among HIS components and are widely adopted. Modern hospitals use HL7 formatted messages to drive the care process and support billing. How-

ever, they are rarely used to structure and summarize the patient's care pathway in an organized electronic report of what happened to the patient during the hospital stay. This is unfortunate as hospitals struggling to collect data for flow-type analyses already have much of the required data in electronic form. Our hypothesis is that these messages can be used to construct a detailed flow path for a patient during his/her hospital stay. This constructed path can then be compared against a clinical pathway to measure variance.

A set of HIS message exchanges represents much of what happens to the patient during his/her hospital stay. These message exchanges are extremely rich in information, providing time-stamped details such as order status, ordering physician, and results for labs and diagnostic testing. ▶ Figure 1 illustrates the wealth of information found in a set of message exchanges in HL7 format. The HL7 standard defines specific information that each message field should contain. Using these definitions we can determine relevant message fields and extract message information. We refer the reader to the HL7 standard which is available at www.HL7.org for specific information contained in each field.

For instance, using the HL7 standard we can read the message in ▶ Figure 1a. The message tells us that patient William A. Jones, III was admitted on August 18, 2008 at 11:23 a.m. by Dr. Sidney J. Lebauer (#004777) for surgery (SUR). He has been assigned to room 2012, bed 01 on nursing unit 2000. His next of kin is his wife Barbara. The message was sent from system ADT (Admission) at the MCM site to system LABADT (Lab) also at the MCM site three minutes after the admission. In addition to clinical information, messages sent between HIS can record admission and discharge information, bed transfers, patient location, vital signs, nutrition and medication orders, and a plethora of other information. For example, as an example ▶ Figure 1b contains information about the patient's blood pressure (98/62) as of August 19, 10:15 AM, while ▶ Figure 1c tells us that at 12:06 PM on the same day, the patient was prescribed one tablet of warfarin sodium to be administered at 4:00PM. The content of these messages was deciphered using the HL7 standard and is discussed in greater detail in the next section.

At this point, we should acknowledge that the information we extract from HL7 messages are stored in various HIS, such as billing, administrative and clinical systems. However, these systems do not share a standardized format for storing data. Each system is designed to store data in a way that best satisfies the requirements for its own purpose. Therefore, extracting the same data from HIS directly to summarize a patient's pathway requires significant consolidation efforts. On the other hand, HL7 logs represent a single and standardized source of data. As hospitals implement Electronic Medical Records (EMRs) that can capture all relevant patient information in a single system, EMRs can become the new source of data for our analysis. However, the current practices and slow adoption rates show that converging into a single system will take a long time especially in the hospital settings where multiple specialized HIS are used by various departments.

3.2 Data Collection

For this study we obtained trace logs of message exchanges for ten diagnoses. The average file size for a single patient stay was approximately 1.3 megabytes of data containing 1,270 messages. ▶ Table 1 summarizes message types, segments, and fields accessed. Administrative messages prefaced by ADT contain information on patient transfer, admission, registration, and discharge activities. Order messages, prefaced by ORM or ORU, contain information on medical or clinical procedures the patient underwent during his/her stay, including (a) the time the order was placed, (b) when it was scheduled to occur, (c) when it was completed, and (d) observational results. Pharmaceutical messages, prefaced by RAS and RDE contain dosage and timing information. ▶ Table 1 contains information about each segment and field used. For example, the third field of the PVI segment always contains the assigned patient location. This segment appears in multiple message types. We refer the reader to www.HL7.org for more details regarding the HL7 standard and message fields.

Parsing functions were developed to extract relevant administrative and clinical data and to generate a sequential table listing all the activities a patient underwent during his/her stay using the message fields and message types determined to be relevant for our study. ▶ Table 2 contains sample entities obtained from the parsing functions including the activity, when the activity occurred, the order status (e.g. SC - Scheduled, IP - In Process, CM - Completed) when applicable, and patient location.

3.3 Data Validation: Chart Audit

Literature on the concordance and accuracy of computer-based health records suggests that validity be established by comparing to a “gold standard” [23-25]. Although the obvious choice for this standard is the patient chart [26-27] some researchers report that the chart, whether paper-based or electronic, fails to provide complete information [23]. Thus, it would be naïve to accept the patient chart as a “gold standard”. Rather, we identify and interpret the differences between information obtained from patient charts and message exchanges, forearmed with the knowledge that the two sources are very likely to contain complementary information.

We randomly selected two types of patients, heart-stent (8 patients) and joint-replacement (6 patients), for chart audit to validate the data we constructed using HL7 messages. The scope of the chart audit was constrained by the two-day electronic access granted to us for this study. Patient charts contained scanned hand-written orders and progress notes, as well as surgery log reports, medications, imaging, and lab tests, which were fed from the respective departmental information system directly into the patient chart. Charts were not electronically searchable. We prepared a chart review process with guidance from two experienced reviewers from an associated nursing school. A single reviewer was responsible for all the chart audits. The review focused on comparing two aspects between the patient chart and the patient sequence reconstructed from the HL7 messages: (1) agreement in the occurrence of an event, and (2) agreement in the timing of the event.

The patient sequence reconstructed from HL7 messages was first compared against patient charts with respect to the occurrence of an event such as a procedure, lab work, imaging, or an administrative event such as patient discharge. A quantitative measure of disagreement between the two sources was developed. A score of zero indicates perfect agreement between patient chart and HL7 message exchanges, while a score greater than 0 indicates missing information in the patient chart or some disagreement between the data stored in the two sources. A score of 1 indicates complete disagreement. This scoring technique was used to assess the extent that a patient’s pathway can be reasonably constructed from HL7 logs.

The following example illustrates how this measure is calculated. Assume that a patient had *four instances* of a complete blood count (CBC) in the HL7 messages and *three instances* in the patient chart. To compute the level of disagreement, we subtract the quotient resulting from the division of the concordance (the three instances show agreement) by the maximum number of instances (four instances) from one. In this example the level of disagreement is 0.25, obtained from $1 - (3/4)$.

Next, patient charts and sequences derived from HL7 messages were compared with regards to the timing of an activity. In some cases, there was full agreement. For example, the HL7 messages indicated that a patient began an EKG at 12:11, and the patient chart contained the same time stamp. There were also differences. First, while all HL7 messages had time stamps, not all entries in the patient chart included an associated time. For example, transfers and discharge times did not have time stamps in the patient chart but were documented with simple notes such as “discharge patient later today.” In other instances, the chart and the HL7 messages had different time stamps. For example, one patient’s chart indicated that surgery began at 11:22, while the corresponding time stamp from the HL7 messages recorded it as 11:52. To quantify the level of disagreement between the two sources, we took the normalized difference, with a zero indicating perfect agreement and a score of one indicating missing information or complete disagreement. For the surgery time example, the difference of 30 minutes corresponds to 0.02 when normalized over a 24 hour period and hence indicates a close to perfect agreement. If the timing difference was greater than 24 hours, the activity received a score of 1 indicating perfect disagreement. The validated data is now used to measure compliance to an actual clinical pathway.

3.4 Measuring Compliance to Prescribed Pathway Activities

It is important to measure variance from prescribed clinical pathways because deviations could either constitute improvement in care delivery or indicate errors and sub-optimal care. Both of these conditions could provide an opportunity for improvement in care delivery if recognized in a timely manner. In the ► Appendix we present a formulism to measure pathway compliance that we briefly describe here.

We define the term *activity* as a unit of care delivered to the patient. *Activity* is executable and can be recorded. Examples of *activity* are a patient neurological consult, an echocardiogram, or a patient education session. We assume that a patient's length of stay is divided into T time intervals with index variable t , that is, $t = 1, 2, \dots, T$. These intervals are not necessarily uniform and are selected to correspond to a logical pattern of care. A set $S_t = \{s_1, \dots, s_m\}$ of *activities* occurring in time interval t is called a *parallel activity*; for example $S_1 = \{\text{CT Scan, MRI, and Complete Blood Count}\}$ is a set of *activities* occurring in time period 1. Thus a *clinical pathway* is the prescribed sequence of *parallel activity* sets over the course of care, and likewise *patient trajectory* is the sequence of realized *parallel activity* sets occurring during the patient's care period. The ► Appendix further develops these definitions.

Non-adherence occurs when the care a patient received is not exactly what was prescribed in the pathway. For example, consider the case in which an activity (e.g. Fasting Lipid Profile) is omitted from the prescribed clinical pathway. A simplified clinical pathway for $t = 1$ is {Fasting Homocysteine Level, PTT, Fasting Lipid Profile} while the patient trajectory for the same time interval is {Fasting Homocysteine Level, PTT}. This means that one of three lab activities listed on the clinical pathway was omitted from the patient's care. We consider this to be an *omission deviation*. Next, consider the case of non-adherence resulting from the addition, rather than omission, of an activity to the patient trajectory. To illustrate this case, a simplified clinical pathway could be {Fasting Homocysteine Level, PTT, Fasting Lipid Profile} while the patient trajectory for the same time interval is {Fasting Homocysteine Level, PTT, Fasting Lipid Profile, MRI} which contains the additional MRI activity. We consider this to be an *addition deviation*. Both omission and addition deviations could arise from a variety of reasons. Non-adherence could be justifiable arising from pre-existing medical conditions or new-found practices. Deviations could also inadvertently arise from erroneously delivered care, or be unavoidable due to resource or operational constraints. We constructed a measure to capture both deviations and adherence for a patient (► Appendix for details of measure construction).

In addition to information about the *activities*, HIS messages contain a vast amount of information regarding a patient's condition including lab results, vital signs, medication changes, diet, and so forth. Including such clinical information in variance analysis can be useful for monitoring quality and patient safety issues. We construct another measure that computes if a particular outcome falls within a prescribed range normalized over time. Should multiple outcomes be of interest (e.g. glucose levels, blood pressure), a weight is assigned to each outcome indicating its significance. We refer the reader to the ► Appendix for details.

To compare clinical pathways and patient trajectories with respect to activity adherence and patient outcomes, we developed a Visual Basic for Applications (VBA) user-interface. This application required the following user-input: HL7 trace logs in a text format, clinical pathway activities for each time interval t , and weights designating the importance of various outcomes and activities. The application generated the deviation and outcome measures described above which are formulized for completeness in the ► Appendix.

3.5 Case Study Description: Major Joint Replacement

We apply our method to major joint replacement patients as this particular group of patients is of interest to our clinical partner. From the audit data set, we expanded the initial set of joint replacement patients to seventeen. Given an ageing population and the related prevalence of osteoarthritis, the number of joint replacement cases is steadily increasing [28, 29]. Joint replacement surgery is the most common surgical treatment of persons with osteoarthritis and is considered a highly cost-effective intervention resulting in pain relief, enhanced function, and improved quality of life [4, 30, 31]. We note an earlier study [32] that conducted a prospective (manual) variance analysis of pathway adherence for joint replacement patients over a 12-month period. The authors found high rates of serious variance, which highlights the need for instant variance notification for joint replacement surgery.

4. Results

We first discuss the results of the chart audits and validation process and then describe how this validated data was used for adherence calculations.

4.1 Data Preparation and Audit Results

► Table 3 compares the sequences of activities derived from message exchanges against the patient chart for the two patient diagnoses considered.

Both clinical partners and researchers concurred that a score below 0.4 constituted reasonable agreement between the two data sources, which represents disagreement in roughly 1 out of 3 instances. The number of instances per category considered (e.g. procedures, lab tests) ranged from 14 admissions to over 250 lab tests. Based on this threshold, there is reasonable agreement between the two sources of patient flow information in terms of labs, radiology, EKGs, hematology, bed transfer events, discharges and the admission event itself. The areas of disagreement between the two sources of data were procedures, consults, transfers and admission times. At our collaborating hospital, the surgery information system is a stand-alone system that does not communicate with HIS regarding procedure details. As a result, procedure orders and post-operative reports are issued and communicated amongst other hospital systems independently of surgery. Provider consults in the patient charts were not always captured. The patient chart contained progress notes and observations from providers although the specialty has to be inferred from the content of the note. Transfer times for patients moving from one unit to another were generally not recorded in the patient chart, but had to be inferred from physician or nursing notes, as were admission times.

4.2 Measuring Adherence for Joint Replacement Patients

► Table 4 reports the degree of adherence between the patient's trajectory and the clinical pathway for seventeen joint replacement patients. The first set of columns in the table describe activity adherence. As described previously both the addition and omission of activities to the clinical pathway are considered. A score of 0 indicates perfect adherence to the pathway, while a score of 1 indicates complete non-adherence (the reader is referred to the ► Appendix for calculation details). We used a 24-hour period care interval, which corresponds to the structure of the clinical pathway at our partner institution.

The second set of columns in ► Table 4 reports outcomes of interest to our clinical partner: glucose levels, morphine administration, and patient length of stay. The results are displayed for each patient, where desired levels for blood glucose level, morphine use, and length of stay respectively are 80 to 120 mg/dL, no dosage (meaning patient is able to tolerate existing pain without medication), and less than 96 hours. These levels were set by our clinical partners who provided us with their organization's best practices as a guideline for the analysis. Each outcome reading has an associated weight stressing the importance of early detection of non-compliance with expected outcomes. For example a patient's abnormal glucose levels on the first day post-surgery received a higher weight than those on the subsequent days post-surgery. These weights are customizable to the implementation site; we merely present them as a proof of concept. Our clinical partner requested that weights for both glucose level and morphine use be set at 0.5, 0.4, 0.1 and 0 for subsequent days respectively. The outcome values were normalized as described in the ► Appendix.

5. Discussion and Conclusion

5.1 Findings

Despite the HIS not being fully integrated at our study site, the HL7 generated patient flow sequences provided an accurate representation of a reconstructed patient trajectory for the purposes of variance reporting. Activities that needed to be monitored for variance reporting such as labs and radiology were accurately captured in the HL7 messages.

Patients with high omission scores tended to have longer lengths of stay (e.g. over 100 hours), for example Patients 3, 14, 16 and 17. Subsequent investigation revealed that causes of omission generally consisted of excluded lab tests such as hematocrit or hemoglobin. From a manager's point of view, this would warrant investigation as to why these tests are not administered.

Similarly, patients with higher addition scores, indicating additional activities not on the clinical pathway were added to their care, had longer lengths of stay for the most part. For example, Patients 3 and 16 incurred high addition scores early in their stay, indicating that these patients underwent laboratory and diagnostic tests not on the clinical pathway. Such addition scores could potentially signal complications or pre-existing medical conditions. Upon further investigation we discovered that both patients required a blood transfusion, and Patient 3 had an EKG. We note that while Patient 13 had a high addition score of 0.45, he/she had an average length of stay. It is beyond the scope of this paper to establish the clinical reasons why a joint replacement patient may have a longer than expected length of stay. Rather, our intent is to illustrate how message exchanges can be used for automated variance reporting in clinical pathways. Our method can be used as an alarm to warrant further investigation for quality control. Using our method, a clinical team can screen patient charts that should undergo an extensive review to investigate the reasons for deviations from the pathway and the effects of deviations on patient outcomes. For example, clinical teams can determine why certain patients had longer stays than average or, as in the case of Patient 3, why a patient who had activities added to the clinical pathway was discharged on time.

Patients with poor glucose measures tended to have longer lengths of stay as well. However, the same cannot be said for morphine use. Patients who used morphine did not necessarily have longer lengths of stay as in the case of Patient 4. This finding is likely related to a patient's personal pain tolerance. Although our data set is too small to draw statistically meaningful results, our intent is to illustrate the application of our method.

One of the interesting findings from ► Table 4 is the need to jointly consider both deviations and patient outcomes. For example, if the hospital strictly considered activity deviation, Patient 4 may not have been flagged for further investigation. His/her compliance to the clinical pathway was generally good; however, the patient had a poor outcome and slightly longer than average stay. On the other hand, if a hospital solely monitored outcomes, patients such as Patient 16 may have been overlooked. A third example is that of Patient 13 who incurred a high addition score, but a relatively low length of stay. Despite additional activities this patient underwent (in this case oxygen usage) the patient's health status enabled him/her to be discharged at a reasonable time. Although these examples are somewhat simplistic, we believe they are effective in demonstrating the importance of monitoring both clinical pathway variance and patient outcomes.

5.2 Study Limitations

Our study had some limitations. The quality of some of the message exchange data depends on manual entry of orders and order completion. For example, a lab technician needs to enter the results of a lab test into a computer. Thus, data inaccuracies may result from delays or mistakes in entry. Furthermore, while the HL7 standard specifies where data should be located within a message and the format, not all fields are required and exact message content is site specific. Thus, the types of data available and the quality of data could vary greatly between facilities. We note that the requirements of a sound variance reporting system need to be considered when IT professionals configure their organizations use of the HL7 protocol. Feedback is required to continually improve both the configuration of the data source and the quality of the data it contains. This has in fact happened with our clinical partner, the method has been improved since the initial results were presented to our clinical partner. Finally, the assumptions made in this study should be explored further using sensitivity analysis, particularly the definition of time intervals. In order to mirror the preferences of healthcare organizations in implementing clinical guidelines, these assumptions should be adjusted to reflect actual implementation preferences.

5.3 Contributions and Managerial Implications

The lack of automated variance reporting has hindered implementation of clinical pathways. Our approach is an attempt to overcome this challenge and should provide a basis for future variance reporting mechanisms. Our contributions can be summarized as follows. We identified a single, viable, and ubiquitous data source for establishing a patient's path, HL7 formatted message exchanges between HIS. This is in contrast to current practices in most hospitals where data for variance reporting is obtained from multiple data sources, often prospectively. As reported in a previous prospective longitudinal cohort study [33], IT-supported clinical pathways lead to higher staff satisfaction. Our comparison of HL7 messages and paper charts (► Table 3) showed variations between paper-based and IT-based data sources. However, as healthcare organizations move towards electronic data representations, the overlap between different data sources will become greater. Given the current emphasis on health information technology, more patient information is expected to become available in electronic format. The movement towards greater system interoperability will enable our method to be applied more effectively in a greater number of clinical contexts.

Our method can be used by case managers as a quality feedback mechanism and a learning tool. For example in ► Table 4 some patients, despite having activities added to their stay, had a lower than average length of stay (e.g. Patients 7,8,10,15). Each of these patients could be flagged for further investigation as to possible reasons why he/she was discharged earlier than others. While the specific outcomes of interest may vary from one hospital to the next, the salient factor is that our method is automatic and customizable. Care teams could analyze hundreds of patient visits, consider different types of indicators, and conduct analysis either in real time or prospectively. Such a feedback mechanism presents significant enhancements to clinical pathway implementations and potentially impacts the quality of care.

Finally we created a mechanism to track patient outcomes; a feature though not typically captured in variance reporting is highly advantageous. The insight gained here is that desirable indicators can be achieved with little or no additional effort. This is especially relevant given the current push towards implementing evidence-based medicine. The ability to provide more meaningful measures may enhance learning and compliance.

A clinical pathway recommends an evidence-based sequence of care interventions. In reality patients often veer from this prescribed course. Care providers need to be notified of these deviations and adjust care accordingly. Unfortunately a systematic mechanism to identify, record, and quantify variations between a patient's path and the clinical pathway does not exist in practice. Clinical pathway variance reporting has been challenged by the availability of real-time electronic data. The method developed in this paper enables the measurement of clinical pathway variance using electronic data sources and computational algorithms. These algorithms can be used not only to measure clinical pathway adherence of past events, but also to conduct real time analysis of activities and pathway adherence. Real time analysis could provide valuable information to clinical decision makers as the patients move along a clinical pathway. Instant alerts of variations can be generated to inform clinical processes and help prevent errors.

5.4 Future Research

There are a number of interesting directions worthy of future research. First, research that evaluates and gives guidance to care managers concerning appropriate clinical indicators could be valuable. Such a study would explore the relationship between patient demographics, or co-morbidities and pathway adherence and recommend customized indicators. This would be an important study for the newly emerging field of "personalized medicine," which seeks to use an individual patient's characteristics to tailor strategies for patient-specific treatment. Second, resource allocation decisions, such as the composition of the nurse workforce, would also be of interest using our approach. Our study focused on adherence measurement without including the involvement of the workforce. As discussed, the message exchanges contain a wealth of data. It would be possible to obtain workforce data and incorporate this information into the measures we developed to study the impact of staffing levels on clinical pathway adherence. Third examining the cause of non-adherence is worthy of further investigation. We recognize that non-adherence to a clinical pathway may be (1) justifiable –

for medical reasons, new-found practices, or pharmaceutical substitution, providers may diverge from a pathway; (2) inadvertent – care could be erroneously delivered, thus the pathway could have been followed, but was not, and (3) unavoidable – resource and operations constraints are such that a pathway cannot be followed. Such non-adherence of clinical pathways can have positive or negative implications on care delivery. In certain cases, deviations from clinical pathways could be due to quality improvement in patient outcomes or operational efficiency. On the other hand certain deviations could indicate patient safety breaches, poor operational processes, and sub-optimal care. Finally, another interesting study would account for stricter precedence relationships between activities. Generally, many clinical pathway activities are not specified; however activity order is critical for certain patient types. For example, in suspected stroke cases, the precedence of activities in the Emergency Room is of concern. With this type of precedence, techniques akin to sequence alignment algorithms could be used to consider precedence. Each of these studies, as well as many others, is needed in light of a health care environment that continues to change and bring new challenges.

Clinical Relevance Statement

The methods developed in this paper can be used by physicians and case managers as a quality feedback mechanism and a learning tool. Using message exchanges between HIS, both past and real-time analysis of a patient's adherence to a clinical pathway can generate alerts to inform clinical processes and help prevent errors.

Conflicts of Interest

The authors declare that they have no conflicts of interest in the research.

Protection of Human and Animal Subjects

Human subjects were not included in the project. All data was de-identified prior to analysis.

Acknowledgment

We would like to acknowledge Dr. Patricia Franklin at : University of Massachusetts Medical School for the guidance she provided during the development of this paper.

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MSH|^~\&|ADT|MCM|LABADT|MCM|200808181126|SECURITY|ADT^A01|MSG00001|
P|2.3|
EVN|A01|200808181123||
PID|||PATID1234^5^M11||JONES^WILLIAM^A^III||19610615|M||C|1200 N
ELM STREET^^GREENSBORO^NC^27401-1020|GL|(919)379-1212|(919)271-
3434||S||PATID12345001^2^M10|123456789|987654^NC|
NK1|JONES^BARBARA^K|WIFE||||NK^NEXT OF KIN
PV1|1|I|2000^2012^01||||004777^LEBAUER^SIDNEY^J.||||SUR||||ADM|A0|
    
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Figure 1a: Admission message

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MSH|^~\&|PCM|N7|HIS|N7|200808191015||ORU^R01|67185|P|2.3|
...
OBR|1||276002109^CC|18688^Vital Signs^L||2008191015|
OBX|1|ST|688I^BP^CC|1|98/62||
    
```

Figure 1b: Partial message containing vital sign data

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MSH|^~\&|MED|N7|HCM|N7|200808191206|RDE^O01|MM05071|P|2.3|
...
ORC|RE|RX4193612^MEDS|4193612^^14|||^Q1600^^200808191206^^|...
RXE|1.00^^^200808191206|^WARFARINSODIUM^^^00056017275||TAB| |||||
||14.....
    
```

Figure 1c: Partial message containing medication administration data

Fig. 1 Three sample HL7 messages

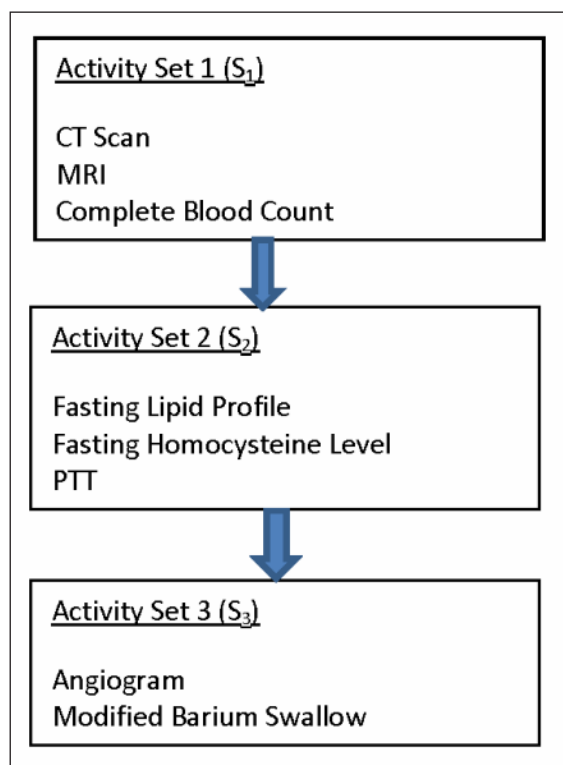


Fig. 2 A Sample Clinical Pathway (C) for stroke patients

Message Types	Description	
ADT^A01	Admit	
ADT^A02	Transfer patient location	
ADT^A03	Discharge	
ADT^A04	Register	
ADT^A06	Transfer patient status from outpatient to inpatient	
ORM^O01	General order message	
ORU^R01	Observation result	
RAS^O01	Pharmacy administration	
RDE^O01	Pharmacy encoded message	
Segment	Field	Description
EVN (Event type)	2	Recorded date/time when transaction entered
MSH (Message header)	7	Date/time of message
	9	Message type
PVI (Patient visit)	3	Assigned patient location
ORC (Common order)	2	Placer order number
	5	Order status
	7	Order quantity/timing
	9	Date/time of transaction
OBR (Order detail)	15	Order effective date/time
	4	Universal service ID
	22	Results report/status change: date/time
OBX (Observation/result)	25	Result state
	5	Observation result
RXE (Pharmacy/treatment encoded order segment)	14	Date/Time of the Observation
	2	Medication

Table 1
HL7 messages, segments, and fields used

Activity	Hours since admission	Order status	Patient location
PX Hip 1V Unilateral	7.88	IP (in process)	SRM5
Complete Blood Count, Auto w/Diff	9.15	CM (completed)	SRM5
Hemoglobin	13.17	SC (scheduled)	SRM5
Basic metabolic profile	23.34	IP (in process)	SRM5

Table 2
Sample of the data preparation step for a joint replacement patient

Table 3 Comparison between activities in the patient chart and information system messages for joint- replacement and heart-stent patients. A score of zero indicates perfect agreement between patient chart and HL7 message exchanges, while a score greater than 0 indicates missing information in the patient chart or some disagreement between the data stored in the two sources. A score of 1 indicates complete disagreement.

Activity Category	Occurrence Disagreement	Timing Disagreement	Notes
Admission	0	0.43	For certain patient diagnoses, such as joint replacement, the procedure is considered an 'outpatient event' and the patient is only admitted post procedure. In these cases the admit times between the patient chart and information system messages did not agree.
Procedure	0.43	0.47	Depending on whether the procedure was considered an outpatient, the procedure would not have been captured in the information exchange.
Labs	0	0	Full agreement
EKG	0	0.03	Almost full agreement
Hematology	0.25	0.37	Not all blood transfusions were captured in the information system messages.
Radiology	0.06	0.03	Unclear why one instance of an X-ray was found in a patient chart but not in the information system messages.
Bed Transfers	0.17	0.66	Bed transfers were generally not recorded in the patient charts. Some transfers were noted, but this was not consistent. Transfers from the ED were the same.
Specialist Consults	See note	See note	Consults were usually not captured in the information system messages. In the patient chart, orders and notes were written, but the specialty was unclear.
Discharge	0.17	0.17	For all patients, a 'time of discharge' was not present in the patient chart, but rather had to be inferred from other entries.

Table 4 A comparison of joint replacement patients' trajectories against the clinical pathway. These scores are normalized such that values close to 0 do not warrant alarm, where as a value close to 1 indicates an extremely undesirable state such as all activities on the clinical pathway were omitted, or every glucose measurement was beyond the specified range.

Patient Number	Adherence Measure		Patient Outcomes		Length of Stay (hours)
	Addition	Omission	Poor Glucose Measure	Morphine Use	
1	0.3	0.25	0.5	0	97
2	0.18	0.14	0	0.5	97
3	0.33	0.32	0.5	0.9	138
4	0.18	0.11	0.9	0.5	100
5	0.23	0.14	0	0	99
6	0.29	0.11	0.3	0.9	97
7	0	0.11	0	1	72
8	0.21	0.11	0	0.9	69
9	0	0.25	0.3	0.5	96
10	0	0.25	0	0.5	75
11	0.23	0.21	0	0.5	97
12	0.07	0.11	0.17	0.5	97
13	0.45	0.11	0	0	94
14	0.25	0.32	0	0.5	100
15	0.19	0.04	0	0.5	72
16	0.58	0.32	0	0	120
17	0.25	0.39	0	0.5	100
	Addition	Omission	Poor Glucose Measure	Morphine Use	Length of Stay (hours)
Mean	0.22	0.19	0.16	0.48	95.16
Median	0.23	0.14	0	0.5	96.7
Minimum/ Maximum	0/ 0.58	0.04/ 0.39	0/ 0.9	0/ 1	69/ 138

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Appendix

In the following, we formalize the concept of pathway compliance measurement consistent with existing practice. Definitions 1 and 2 and the concept to unordered activities within a set are similar to Definitions 1 and 2 in [11]. We build on [11] by considering patient outcomes and streamlining the matching concept.

We first assume that a patient's length of stay is divided into T time intervals with index variable t , that is, $t = 1, 2, \dots, T$. These intervals are not necessarily uniform and are selected to correspond to a logical pattern of care. The design and content of clinical pathways vary but often contain a set of activities (ranging from interventions to communication) which have to be performed on a daily basis [28]. The order in which these activities must be performed is not always explicitly stated [11].

Definition 1

An activity is a unit of care delivered to the patient which is executable and can be recorded.

Examples of activities are a patient neurological consult, an echocardiogram, or a patient education session. Sometimes a set of activities must be executed in a fixed order. For example, an echocardiogram (activity x) must be taken before its outcomes can be discussed with the patient in a consult (activity y). We denote such precedence relationships by $x \rightarrow y$ and say x precedes y , or y succeeds x .

Before further developing precedence relationships, we first define sets of activities between which such relationships will and will not exist:

Definition 2

A set $S_t = \{s_1, \dots, s_m\}$ of activities occurring in interval t is called a parallel activity set if for $s_u \in S_t$ and $s_v \in S_t$ such that $u \neq v$, neither $s_u \rightarrow s_v$ or $s_v \rightarrow s_u$. Parallel activities will be denoted as $s_u \leftrightarrow s_v$.

When a patient receives care, precedence relationships between activities might or might not exist, they might be unspecified, or the execution of some activities may overlap. Because of this ambiguity, we will assume that activities occurring during a time interval are parallel activities, whereas those occurring in different intervals have precedence relations. This is formalized as follows.

Definition 3

A clinical pathway C is the sequence $\langle S_1, \dots, S_T \rangle$ of parallel activity sets. For $S_i \in C$ and $s_u, s_v \in S_i$ ($u \neq v$), we have $s_u \leftrightarrow s_v$. For S_i and $S_j \in C$ ($i < j$), $s_m \in S_i$, $s_n \in S_j$, we have $s_m \rightarrow s_n$. We denote this as $S_i \rightarrow S_j$.

Thus, while all activities within a parallel activity set can be carried out in any order or at the same time, activities between parallel activity sets will be strictly ordered, that is, for $i < j$, all activities in S_i must be completed before any of those in S_j can begin. A hypothetical pathway is depicted in ► Figure 2. In this figure, the precedence relationships between the parallel activity sets are depicted using arcs, and parallel activity sets are depicted as rectangles. For example, S_1 precedes S_2 , and S_2 precedes S_3 . The activities within a parallel activity set do not have a precedence relationship. For example, in the parallel activity set S_1 , an MRI can be the first, second, or third activity to occur. However, all three activities (CT Scan, MRI, and Complete Blood Count) must happen before the activities in S_2 can begin.

Definition 4

Let S_t be the parallel activity set for period t . Then S_t can be partitioned into care categories (k), S_{t1} , S_{t2} , ..., S_{tk} , such that S_{tk} is the subset for all activities associated with a particular aspect of care.

Typically, clinical pathways categorize different aspects of care. For example, a clinical could have the following categories: laboratory/diagnostic tests, assessments/nursing interventions, mediations/treatments, consults, patient activity, nutrition, and patient/family education. This definition could be applied to a clinical pathway as follows:

- $S_{11} \subset S_t$ is the subset of activities of S_t associated with laboratory/diagnostic tests;
- $S_{12} \subset S_t$ is the subset of activities of S_t associated with assessments/ nursing interventions;
- $S_{13} \subset S_t$ is the subset of activities of S_t associated with mediations/treatments;
- $S_{14} \subset S_t$ is the subset of activities of S_t associated with consults;
- $S_{15} \subset S_t$ is the subset of activities of S_t associated with patient activity;
- $S_{16} \subset S_t$ is the subset of activities of S_t associated with nutrition;
- $S_{17} \subset S_t$ is the subset of activities of S_t associated with patient/family education.

Definition 5

A patient trajectory, P , is the sequence of realized activity sets $\langle A_1, \dots, A_T \rangle$ occurring during the patient’s care period, where A_t is the set of care activities occurring during the t^{th} care interval.

Definition 6

Trajectory, P , adheres to Pathway, C , if $A_t = S_t$ for $A_t \in P$ and $S_t \in C$ and $t = 1 \dots T$.

Definition 7

Trajectory, P , deviates from Pathway, C , if for some t , if $A_t \neq S_t$.

Deviation occurs when the care a patient received is not exactly what was prescribed in the pathway. For example, consider the case when $S_1 = \{\text{Fasting Homocysteine Level, PTT, Fasting Lipid Profile}\}$ and $A_1 = \{\text{Fasting Homocysteine Level, PTT}\}$. In this example, the parallel activity set for the patient path deviated from the clinical pathway during the first care interval. Further, consider a second case in which $S_1 = \{\text{Fasting Homocysteine Level, PTT, Fasting Lipid Profile}\}$ and $A_1 = \{\text{Fasting Homocysteine Level, PTT, Fasting Lipid Profile, MRI}\}$. Again, the patient trajectory deviates from the clinical pathway.

Note that, in general, we have the cases:

1. $A_t = S_t$
2. $A_t \supseteq S_t$
3. $A_t \subseteq S_t$
4. $A_t \not\subseteq S_t$ and $S_t \not\subseteq A_t$

Case 1 represents perfect compliance during the t^{th} interval, while cases 2-4 represent deviations. More specifically, case 2 represents the addition of activities beyond those specified by the prescribed pathway, case 3 represents omission of activities specified by the prescribed pathway, and case 4 represents both addition and omission of activities. We note that for cases of activity addition, patients receive care activities beyond those specified in the prescribed pathway, while for cases of omission, patients are receive less care than is prescribed.

We propose measuring patient’s deviation from a clinical pathway on a numerical scale. To quantify the degree of adherence, the following calculations are done for each patient:

$$\text{addition of activities: } \sum_{t=1}^T \frac{|A_t \setminus S_t|}{|A_t|} \quad (1)$$

$$\text{ommission of activities: } \sum_{t=1}^T \frac{|S_t \setminus A_t|}{|S_t|} \quad (2)$$

where $A_t \setminus S_t$ and $S_t \setminus A_t$ represent set difference, that is, the elements of A_t not in S_t and vice versa, and the vertical bars $|\cdot|$ represent set cardinality. Thus, the numerator measure counts the number of instances of activity addition and omission, while the denominator provided normalizes the count to the unit interval.

Finally, we note that HIS messages often contain a vast amount of information regarding a patient’s condition including lab results, vital signs, medication changes, diet, and so forth. Including such clinical information in variance analysis can be useful for monitoring quality and patient safety issues. To do this, define $O = \{O_1, O_2 \dots O_n\}$ be the set of outcomes to be monitored and let

$$M(O_k) = \frac{\sum_{t=1}^T w_t G_{kt}}{\sum_{t=1}^T w_t} \quad (3)$$

where $G_{kt} = \begin{cases} 1 & \text{if } O_k \text{ outside normal range in interval } t \\ 0 & \text{otherwise} \end{cases}$

and $w_t \in [0,1]$ is a weight assigned to the time period, $t = \{1..T\}$. Weights were set with the help of physicians at the clinical site indicating that an outcome for a specific time interval is more significant than others. For example, abnormal glucose levels immediately after surgery would receive a higher weight than abnormal glucose levels later in the patients stay.

Note that this measure falls in the unit interval. Values close 1 reflect undesirable outcomes warranting investigation, whereas values close to 0 do not warrant an alarm.