How to Develop and Validate Institutional ACS Protocols: Guidelines and Transitions of Care in ACS Management

Alpesh Amin · W. Frank Peacock · Scott Kaatz ·
Richard L. Summers · Charles V. Pollack Jr. ·
George Davatelis · Tomas Villanueva

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Abstract Clinical practice guidelines outline appropriate and evidence-based approaches for the management of medical conditions and performance of clinical procedures. Guidelines are typically developed with the goal of minimizing variations in clinical practice, improving quality of care, reducing litigation risk, optimizing health outcomes, and helping to control cost. The term “transitions of care” refers to specific interactions, communication, and planning that are required if patients are to move in a safe and orderly manner from one service or setting to another. Transitions occur between inpatient and outpatient settings and within hospitals, from initial presentation in the emergency department, through hospitalization, and back to the community or possibly to subacute care facilities. The objective of this article is to review processes for developing and validating institutional protocols that focus on management, communication, and transitions of care for ACS patients.

Keywords Acute coronary syndrome · ACS protocols · ACS management · Emergency and hospital medicine · Acute coronary syndrome protocols · Acute coronary syndrome management · ASC care and management

Introduction

Emergency physicians (EPs) and hospitalists are responsible for much of the early assessment and management of

patients with acute coronary syndrome. Their decisions have broad downstream ramifications, should be based on similar evidence, and should be consistently applied. In addition, hospitalists provide leadership to promote efficient, safe transitions of care that ensure patient safety, reduce loss of information, and maintain the continuum of care. Achieving timeliness and efficiency of care require that EPs, hospitalists, and specialists agree on management strategies, and practice guidelines serve as a tool to facilitate communication and agreement amongst them.

Practice Guidelines: What They Are and Why They Are Needed

Contemporary practice guidelines are the official statements or policies of major organizations and agencies that review appropriate indications for performing a given procedure, administering treatment, or appropriately managing specific clinical entities [1]. These guidelines are typically developed with the goals of minimizing variations in practice, improving quality of care, reducing litigation exposure, providing education, optimizing health outcomes, and helping control cost of care. See Fig. 1.

Practice guidelines/pathways enhance the knowledge, attitudes, and behavior of practitioners by converting science-based knowledge into clinical practice [2]. They also are intended to help identify research gaps and may improve patient and provider satisfaction. Current methods for developing practice guidelines predominately include informal and formal consensus development in which expert analysis of clinical data and opinion are the driving factors. Earlier guidelines were based on consensus development, but guidelines produced in this manner were sometimes poor in quality and lacked adequate documentation of methods and objective source materials. Contemporary evidence-based

A. Amin (✉) · W. F. Peacock · S. Kaatz ·
R. L. Summers · C. V. Pollack Jr. · G. Davatelis · T. Villanueva
Hospital Medicine, University of California-Irvine,
Orange, CA, USA
e-mail: anamin@uci.edu

Guideline topics are usually chosen for a variety of reasons:

- **High Risk**
- **High Benefit**
- **High Cost**
- **High Resource Utilization**
- **High Number of Affected Individuals**
- **High Variation in Clinical Practice**
- **Data are Available**

Fig. 1 Guidelines topics

guideline development links recommendations directly to scientific evidence of effectiveness, and the rules of evidence are emphasized over expert opinion.

Explicit guideline development clarifies rationales for recommendations by specifying the potential benefits, harms, and costs of available interventions, estimating the likelihood of specified outcomes, and comparing the desirability of outcomes on the basis of patient preferences [3]. For success, the development of clinically useful pathways requires credibility, clear writing, inclusion of derivative documentation, an element of flexibility and reproducibility, and a feedback and review process.

It is important to remember that guidelines recommendations reflect an optimal approach based on overall population performance, while any one individual patient may not necessarily be best served by strict adherence to this advice. However, the guidelines can serve as a general frame of reference from which to begin development of a management plan.

Guidelines are then subject to validation in practice. This was accomplished for the 2002 ACC/AHA NSTEMI ACS Guidelines. Peterson and colleagues used an observational analysis of the 350 participating centers and the 64,775 patients enrolled in the CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the ACC/AHA Guidelines) National Quality Improvement Initiative to demonstrate the benefit of adherence to guidelines. Overall, clinicians adhered to the nine ACC/AHA guideline-recommended treatments in 74 % of eligible instances. There was modest overall correlation in hospital performance with the individual ACS process metrics, but adherence performance varied widely among sites, from 63 % [59–66 %] to 82 % [80–84 %] (median [interquartile range]) in the lowest-performing and highest-performing hospital quartiles. The composite guideline adherence rate was significantly associated with in-hospital mortality, with mortality decreasing from 6.31 % for the lowest adherence quartile, to 4.15 % for the highest adherence quartile ($P < 0.001$). After risk adjustment, every 10 % increase in composite adherence at a hospital

was associated with a commensurate 10 % decrease in its patients' likelihood of in-hospital mortality. The investigators noted a significant association between care process and outcomes, which supports the use of broad, guideline-based performance metrics as a means of assessing and improving hospital quality.

Best Practices for Establishing Guidelines and Adherence

In the management of such diseases as ACS, sepsis, pneumonia, and others in which evidence-based guidelines have been promulgated, each hospital should initiate a process of quality improvement to identify target areas for optimizing medical care, and then to select a strategy that is most appropriate for its local needs [4]. Elements that enhance efficiency and reliability in implementing quality improvement efforts to close the gap between best practices and inpatient standards of care include: gaining institutional support; the formation of a multidisciplinary team; data collection and reliable metrics that, at a minimum, reflect the Centers for Medicare & Medicaid Services (CMS) core measures and relevant Physician Quality Reporting System (PQRI) measures; time-defined, measurable, and achievable specific goals; standardized order sets, clinical pathways, and discharge tools; institution-specific algorithms, policies, and protocols that support order sets; and comprehensive education programs for health care providers and patients to promote the safe, effective application of these measures [5•].

Institutional Support

Garnering institutional support is vital in this time of value base purchasing (VBP), in which there are core measures associated with, for example, the care of acute myocardial infarction. Engagement of representatives of hospital administrative personnel in the process is critical to insuring success. The institution has much to gain—or to lose—in facilitating this process, including prevention of loss of income from reimbursement withheld by CMS for VBP or from patient reselection due to poor results in data warehouse websites like Hospital Compare.

EPs and hospitalists should also expect their institutions to reach out to them to help lead this process, as well as a coordinated approach to other patient-facing and payment-determining quality programs such as Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scoring and the rate of 30-day readmissions for key diagnoses. Starting in October, 2011, a 30-day all-cause readmission penalty for ACS went into effect, and individual institutions that did not achieve predetermined CMS benchmark metrics

were subject to penalties of up to 1 % (FY 2013), 2 % (FY 2014), and 3 % (FY 2015) on total Medicare reimbursements (not just ACS patients). For many hospitals at which profit margins are no more than 1–3 %, this is a significant issue. Given their respective roles at the entry and disposition of the typical ACS patient, EPs and hospitalists will likely be consulted by their institutional leadership to develop systems of practice to avoid 30-day readmissions, especially given that these occurrences have quality, as well as financial, implications [6].

Multidisciplinary Teams

In the US, EPs and hospitalists are increasingly responsible for the management of inpatient care. Together they oversee decisions about the use of the most expensive care setting in medicine—the hospital. However, in most institutions there is little collaboration between emergency physicians and hospitalists, resulting in missed opportunities to improve the quality of care and reduce cost. Best practice guidelines developed by a multidisciplinary team of EPs, hospitalists, nurses, pharmacists, case managers, quality specialists and administrators could work toward achieving specified goals of patient care, education, and quality and safety outcomes to result in consistent, evidence-based, and expeditious care of patients [7•]. These teams' goals are to enhance quality and patient safety, improve outcomes, decrease length of stay, and reduce costs [5•]. The discussion that follows is generic in terms of diagnoses, though at times ACS is used as a specific example.

A comprehensive literature review of existing guidelines and disease protocols can allow a team to package that knowledge to align with the scope and goals of a protocol that will be established, with the specific capabilities (and limitations) of the institution in mind. An understanding of major guidelines and core measures provides the cornerstone of the patient management project, along with broad understanding of the etiology, treatment options, risk stratification, and discharge planning/transitions relevant to a given medical condition [5•]. Information gathering and evaluation begins in the ED and continues after admission, when the hospitalist may need to seek additional medical and medication history to inform risk assessment.

Risk assessment and balance of therapy with risk should continue throughout the hospital stay as additional diagnostic information becomes available and consultations occur. Changes in therapy must be recorded carefully as part of the medication reconciliation (“med rec”) process. Med rec begun during pre-hospitalization can be complicated by lack of a reliable source of medication history and should be reevaluated 24 h after admission, with the inclusion of the patient's home caregiver. It is appropriate for a hospitalist to contact a patient's PCP during the hospital stay to provide

updates about diagnoses, interventions, and major clinical events during hospitalization. A PCP may also offer valuable insight about issues that can be relevant to discharge planning [8]. Med rec is a vital component of evidence-based care, as risk-driven treatment decisions must be promulgated through each transition of care for the patient. During the admission process the hospitalist should reconcile the patient's outpatient medications with that of the hospital's formulary, taking into account the patient's risk for untoward effects. Within 24 h of admission, the hospital team should already be exploring patient's potential access to new medications as an outpatient and begin planning contingencies. At the time of discharge, efforts should be made to reconcile the patients' home medications with their new therapeutic regimen, which should be checked against the patients' insurance formulary.

Communication among stakeholders around such issues as med rec is a vital element of an institutional pathway. Use of an electronic medical record (EMR) should facilitate this process, allowing all stakeholders to view and update the patient's medications and status in real time. Such a system also supports the delivery of transitional information to the patient's post-hospitalization providers. One key component of this process is to assure that discharge summaries are produced and sent to the outpatient care provider in a contemporaneous fashion.

Data Collection and Reliable Metrics

Even if the data around management of a specific diagnosis within an institution are not perfect, one must start from someplace; one cannot fix what one cannot measure. How and what type of data the team chooses should be predetermined and the availability of the resources needed to obtain them should be verified. Data that require chart review tend to be more accurate, but are also prone to be subjective and the process is time consuming. The authors recommend that automated methods of data collection and compliance be undertaken whenever possible.

One should also prioritize what is collected, avoiding being “data rich, info poor” (a DRIP). To guide the performance improvement process, it is essential that an ACS team track performance longitudinally using a standard set of metrics. Findings from the data analysis should also be shared with all relevant parties and benchmarked against past performance and the metrics from similar hospitals or systems. At a minimum, adherence to the CMS core measures [9] should be measured: aspirin at arrival and at discharge, prescription of an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) for patients with left ventricular systolic dysfunction, smoking cessation advice/counseling, beta blocker prescription at discharge, reperfusion management of STEMI with fibrinolysis (within

30 min of ED arrival or percutaneous coronary intervention (PCI, within 90 min), and statin prescribed at discharge.

Time-Defined Goals

Once the protocol process is initiated, it is important not to lose momentum. The data-gathering process should result in quick feedback on performance indicators to ACS care stakeholders. It is also important to define overall goals for the team and to set realistic times for achieving these goals. A performance “dashboard” that is continuously updated can be a highly impressionable tool. Transparency is essential in any form of measure and its feedback.

Standardized Pathways, Order Sets, and Discharge Tools

It is tempting, because of individual or institutional pride, to devote time and resources to developing one’s own tools when developing a protocol. In the interest of efficiency, the authors suggest consulting various society resources that provide customizable order sets, discharge tools, etc. These include the Society for Hospital Medicine [10–13].

It is also important for institutions to benchmark their performance against evidence-based guidelines, against their own goals, and against that of peer institutions through such national quality improvement programs as the National Cardiovascular Data Registry ACTION–get with the guidelines (NCDR ACTION-GWTG). Participation in such initiatives also provides access to standardized order sets, protocols, etc.

Educational Programs; Gaining Buy-In, Avoidance of Pitfalls, and Opportunities for Success

Some hospitals fall short of complying with basic recommendations for many of their patients. Adherence to some guidelines is high (over 50 % of physicians would follow a third of the recommended actions), yet there is low adherence to others (less than 20 % would follow another third) [14]. A series of challenges to implementation of guidelines includes the current payment system, access to information technology, the existing physician culture, and the guidelines development process itself. The New England Healthcare Institute (NEHI) explores the gaps between standards of care and the actual care provided. Its research has identified barriers to guideline adherence and to strategies for change.

Payment

The present payment system for physicians’ services disincentivizes guideline adherence by being based on volume rather than on outcomes. Most existing pay-for-performance

(P4P) programs do not provide financial incentives sufficient to change behavior, and lack of uniformity in payer policies diffuses whatever effect remains. The NEHI survey data show that significant increases in P4P incentives may accelerate the adoption of guidelines. A decision by hospital leadership to include emergency physicians and hospitalists in the rewards reaped from such programs could have dramatic impact, considering the proportion of inpatients managed by these providers.

IT Systems

At current adoption levels, most physicians have insufficient access to guidelines at the point of care, sacrificing an opportunity to reinforce consistent practice in clinical decision-making. To support guideline adoption, IT systems should provide useful data and guidance to providers as they enter orders, offer feedback loops so physicians can measure their practice patterns against other colleagues, and supply institution-specific algorithms that enable physicians to exercise autonomy and clinical judgment, while responding to the needs and preferences of the individual patient.

Physician Culture

Physicians’ perception of their work is often misaligned with objective measures because many providers receive little or no comparative feedback on their performance. Measures of adherence to evidence-based clinical practice guidelines would offer benchmarking opportunities.

Guideline Development Process

The lack of transparency in guideline development often leads to a lack of trust among physicians, while guidelines themselves often lack sufficient flexibility and relevance for efficiency in clinical practice. Many guidelines do not reflect the complexity and context in which real clinical decisions must be made. To assure physician “buy-in” to guidelines, physicians need to be engaged in the guideline development and review process.

Transition of Care: Communicating Among Stakeholders

Institutional

The term “transitions of care” refers to specific interactions, communication, and planning required for patients to move safely from one service or setting to another, and comprises a set of actions designed to ensure coordination and continuity. Sound transitions are based on a comprehensive care plan and the availability of well-trained practitioners who have

current information about a patient's treatment goals, preferences, and health or clinical status. Transitions of care also incorporate logistical arrangements and patient and family education, as well as coordination among the health professionals who are involved in the transition [15].

Transitions occur all along the continuum of ACS care, from out-of-hospital to the ED, from ED to hospital admission, among hospitalists and specialists after a patient has been admitted, and extend through discharge to outpatient care. Communication among providers is essential to promoting efficient, safe transitions of care to ensure patient safety, reduce loss of information, and maintain the continuum of care [16]. Patients benefit from clear communication across other information interfaces, including primary care physician (PCP)/nursing facility to ED during (or in advance of) ED care, hospitalist to PCP/nursing facility at the conclusion of inpatient care, and communication to facilitate care coordination outside the hospital. Systematic transfer of information across these interfaces is critical to good continuity of care and helps to reduce the likelihood of near-term rehospitalization. Emergency physicians and hospitalists should work more closely together with information services and hospital administration to maximize the efficiency of such information transfers, to identify and strengthen weak links in the communication chain, and improve patient care across the continuum.⁷

In 2007, the Step Up to The Plate Alliance (SUTTP), convened by the American Board of Internal Medicine Foundation (ABIMF), noted that transitions of care often involve interactions among unrelated parts of the health care delivery system, and that transitions occur “in the ‘white space’ between individuals and organizations that is neither owned nor claimed by anyone.” This crosscutting nature of transitions of care necessitates focused attention in developing measures that the work group has considered, including: [15].

1. Patients: all or only those identified as high risk.
2. Applicability to all health care settings and providers or to a defined subset.
3. Types of measures: structure, process, outcome, patient experience, efficiency, effectiveness.
4. Focus of measures: patients' or providers' perspective or experience.
5. Feasibility of data sources and data collection.
6. Unit of measurement: organization/facility/practice, individual health care professionals, multidisciplinary teams, system level, communities, population.

Inpatient to Outpatient

Timely and accurate communication between the hospitalist and the PCP is a vital component of safe transition

from inpatient to primary care. This communication directly affects continuity of care, patient outcomes, patient and caregiver satisfaction, and use of healthcare resources. Although the role of hospitalists continues to evolve, these hospital-based professionals will continue to have pivotal roles in transitions of care, and exert direct impact on the quality of ACS patients' transitions at discharge and outcomes. Hospitalists should be aware of gaps in care that result from the ways information is generated, recorded, and shared between the inpatient setting and outpatient primary care and should be proactive in identifying barriers and facilitating solutions. A hospitalist's responsibility to a patient does not end at patient discharge but, rather, extends until a patient's PCP assumes responsibility for post-hospital care. Every reasonable effort should be made to ensure that patients and their outpatient providers and caregivers receive all the information and tools they need to deliver appropriate care [8].

Emphasizing the importance of accurate and efficient transitions of care, a study of Medicare claims data from 2003–2004 described patterns of rehospitalization and the relationships among rehospitalization and patient demographics and hospital characteristics. Almost one-fifth (19.6 %) of the 11,855,702 Medicare beneficiaries who had been discharged from a hospital were rehospitalized within 30 days, and 34 % were rehospitalized within 90 days. Furthermore, two-thirds of those who had been discharged with medical conditions and 51.5 % of those who had been discharged after surgical procedures were rehospitalized or died within the first year after discharge.

For fully half of the patients who were rehospitalized within 30 days after medical discharge to the community, there was no evidence that they visited a physician's office between the time of discharge and rehospitalization. Among patients who were rehospitalized within 30 days after a surgical discharge, 70.5 % were rehospitalized for a medical condition. While the authors estimated that about 10 % of rehospitalizations were likely to have been planned, the average stay of rehospitalized patients was 0.6 day longer than that of patients in the same diagnosis-related group whose most recent hospitalization had been at least six months previously. The authors also estimated that the cost to Medicare of unplanned rehospitalizations in 2004 was \$17.4 billion.

Efforts to mitigate adverse events that occur post-discharge have been developed. Project BOOST (Better Outcomes by Optimizing Safe Transitions) is a national initiative led by the Society of Hospital Medicine to improve the care of patients as they transition from hospital to home. The components of Project BOOST are exemplary of the components necessary in appropriately transitioning patients among different levels of care and eventually through discharge.

1. General assessment of preparedness (GAP) assessment completed with issues addressed. The GAP is a document list largely derived from a study of patient preferences of common logistical and psychological areas that, when not addressed, may act as barriers to a patient's ability to receive or obtain the care the patient needs [17].
2. Medications reconciled with preadmission list. It is important that a patient's pre-hospital medications are reviewed at admission, during transfers in the hospital, and at discharge and that changes to the medication list are reconciled.
3. Medication use/side effects reviewed using teach-back with patients/caregivers. Medication-associated complications, so-called adverse drug events (ADEs), are the most common type of adverse event after discharge [18–20]. The use of the teach-back technique [21], ensuring that patients and their caregivers understand how, when, and why to use their medications, what key side effects they should look out for, and what to do if they arise, can reduce the incidence of ADEs.
4. Teach-back used to confirm patient/caregiver understanding of diagnosis, prognosis, self-care requirements, and symptoms of complications requiring immediate medical attention. Such symptoms are commonly referred to as "red flags," and patients/caregivers should be able to recite them and the appropriate response to them prior to discharge.
5. Action plan for management of symptoms/side effects/complications requiring medical attention established and shared with patient/caregiver using teach-back. Patients are more likely to be adherent to prescribed therapy if they understand these potential issues and react accordingly, should they occur.
6. Documented receipt of discharge information from principal care providers. Recommended by the National Quality Forum's Safe Practice on Discharge, there should be objective confirmation that the patient's principal outpatient provider receives the discharge summary. This should also require a tracking mechanism and may be in any format viable within the organizational structure, from a phone call (documented in the record) to a secure e-mail or a return fax.
7. Direct communication with principal outpatient provider at discharge. Communications between inpatient and outpatient providers often occurs via mailed or faxed materials.
8. Telephone contact arranged within 72 h of discharge in order to assess the patient's condition and adherence and to reinforce follow-up. Such contact can be used not only to reinforce compliance but can also augment the institution's patient satisfaction efforts.

Developing an ACS Protocol

Acute coronary syndrome (ACS) defines a spectrum of ischemic heart disease that may include non-ST-segment elevation myocardial infarction (NSTEMI) and ST-elevation myocardial infarction (STEMI). The American Heart Association (AHA) estimates that 942,000 people with ACS were discharged from acute care hospitals in 2002. ACS treatment pathways and protocols facilitate the diagnosis, risk stratification, and initiation of early management tactics in patients with suspected ACS. EPs and hospitalists provide leadership for multidisciplinary teams that optimize the quality of inpatient care, maximize opportunities for patient education, and efficiently utilize resources. In addition, hospitalists initiate secondary preventive measures, which increase compliance with outpatient medical regimens [5].

While developing evidenced-based treatment protocols that can be validated, it must first be determined which stakeholders should be at the table. Representation on the part of interested parties can facilitate their buy-in. A probable list of stakeholders includes emergency department physicians and nurses, hospitalists, primary care, cardiology, the pharmacy department, and possibly social workers and risk management as well.

After the development team has been established, the next order of business is to determine what the team plans to measure and how such a protocol could benefit patients and the institution. A review of major guidelines and core measures for inpatient management of ACS can form effective cornerstones of an ACS management project, along with understanding of the etiology of ACS, interventions and medical treatments, risk stratification, and discharge planning/transitions [22]. The benefits of such a protocol can help to result in improved outcomes, reduction in guesswork by all parties and departments involved, more consistent treatment within and among departments, and reduction in errors.

From a practical standpoint, as the team gathers, they may want to distribute a variety of materials to the group, including:

1. Data or national guidelines on which protocols will be based.
2. A spreadsheet that depicts current management of such patients, and use that as a baseline to show improvement over time.
3. Articles such as the CRUSADE analysis referenced above, which show a clear relationship between consistent, guidelines-based care and clinical outcomes.
4. Starting points for protocols, such as those posted on the SHM or ICI websites.

Conclusion

The establishment of cross-disciplinary, evidence-based protocols is the key to success in reaching the goal of improving quality and efficiency, while decreasing cost and inconsistency of care and improving patient satisfaction. Acute coronary syndrome—a high-impact area with large volumes, great patient risk, and for which outcomes are closely monitored and publicly reported—is an ideal target for institutional guideline development. Detailed specialty society guidelines for the evaluation and management of ACS are readily available and provide an evidence-based starting point.

Compliance with Ethics Guidelines

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