

## **RPA POSITION ON THE USE OF CLINICAL CARE ALGORITHMS OR PATHWAYS IN THE DELIVERY OF QUALITY RENAL PATIENT CARE**

### **Purpose**

Protocols are used throughout health care and take the form of standing instructions, regulations, procedure manuals, policies, and orders. The RPA herein establishes its position on the use of algorithms or protocol pathways when stated as an order for patient care. In this paper, a protocol order is intended to mean any order that authorizes the administration of a medication on an "as needed" basis or the adjustment of the dose of a medication based on the regular scheduled testing of one or more variables to attain, maintain, or optimize a certain hematological, biochemical or physiological variable. The terms, "algorithm", "protocol", and "pathway", - often preceded by "clinical" - all have been used to describe the instrument addressed in this paper.

### **Background**

In its monograph, To Err is Human: Building a Safer Health System<sup>i</sup>, the Institute of Medicine (IOM) focused on the morbidity, mortality, and costs – measurable and unmeasurable - of medical errors. The monograph urges a comprehensive approach to improving patient safety in which a multifaceted response by health care professionals is envisioned and prevention is the cornerstone. Several recommendations were forthcoming in that report at the many tiers that impact on health care. As noted in the monograph, the implementation of safe practices at the delivery level is the “ultimate target of all of (their) recommendations”.

Among these recommendations, the IOM called on professional societies to – among other things – “recognize patient safety considerations in practice guidelines and standards related to the introduction and diffusion of new technologies, therapies, and drugs” and “incorporate well-understood safety principles, such as standardizing and simplifying equipment, supplies, and processes”.

Subsequently, the IOM published the second report of this committee, Crossing the Quality Chasm that focused on quality-related issues and provided a strategic direction for redesigning the health care delivery system.<sup>ii</sup> In their recommendations, they addressed several points, two of which are excerpted here:

1. Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.
2. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

In achieving these goals, the IOM urged the health care industry to identify, adapt, and implement state-of-the-art approaches to redesign care processes based on best practices, and to use information technologies to improve access to clinical information and support clinical decision-making. Such efforts are in keeping with the basic principle that striving for improvement in patient care is a fundamental aspect of medical ethics.

This paper will discuss the implementation of processes based on clinical care algorithms in renal care, outline some concerns and benefits emanating from the use of these protocols, and offer recommendations regarding their use in renal care.

## **Discussion**

Present advocates of process improvement (many by way of protocol-driven care) include the Agency for Healthcare Research and Quality (AHRQ), many major universities, and a variety of departments of social and health services responsible for Medicaid in several states (see below). In research supported by the AHRQ, Alan Morris, M.D., an expert in the use of medical informatics, observed that one way to improve treatment, reduce errors, and increase quality of care is using computerized protocols at the point of care. He concluded that when explicit computerized protocols are driven by patient data, the output is a patient-specific protocol that preserves individualized treatment while standardizing clinical decisions. The expected decrease in clinical practice variation and the increase in compliance with evidence-based recommendations should lower the error rate and enhance patient safety.<sup>iii</sup>

This has been articulated further in an address to the 2002 meeting of Dialysis Clinic, Inc. by James Conway, Chief Operating Officer of the Dana-Farber Cancer Institute, who emphasized the importance of protocols. He pointed out that, after forcing functions – e.g., the interlock on an auto transmission that prevents you from putting the lever in reverse when the car is moving forward, (1) automation and computerization and (2) protocols and preprinted orders are most effective in effecting change and preventing errors.<sup>iv</sup>

Among the techniques employed by clinicians to achieve these goals, protocol orders have been used to improve safety and efficacy of drug therapies. Perhaps the simplest and most widely employed of these is the familiar “sliding scale” insulin-dosing regimen in which the patient takes or is administered insulin at variable doses depending upon the result of a test of blood glucose concentration. This approach is used both in hospital and at home where the patient executes the physician's instructions. Such a protocol has the net effect (as do all care algorithms) of diminishing variability, thus lessening the potential for committing errors. Furthermore, if an evidence-based practice is known, protocol or algorithm-driven care may be marshaled to enhance its implementation. Hospital intensive care and post-operative recovery units use a wide variety of protocol orders to optimize care, as do physician offices, disease management organizations, and many contractors with Medicaid in a variety of states.

Currently, dialysis providers of all sizes, from the largest for-profit corporations to single independent units, use computer-based information systems for a multitude of purposes, among which are the collection, collation, and dissemination of clinical laboratory data. The availability of clinical data in this format has facilitated the development of protocols (“clinical pathways”, “standing orders”) to standardize the administration of medications administered in dialysis units, with the goal of meeting optimum clinical performance standards for all patients--precisely the goals recommended by the IOM.

As a part of this trend, computer-based data systems have also allowed for the on-line implementation of algorithms for the execution of protocols for the administration of drugs, easing the burden of executing more complex protocols than the simple example above for “sliding scale” insulin.

Protocol orders by their nature usually require periodic iteration based on the receipt of new data. For the administration of insulin, this may occur several times a day. In dialysis units, the administration of erythropoietin (rHuEPO) – for example - by protocol order usually requires revision of dosage every two to four weeks. Such an order is designed to ensure that the change in dosage occurs promptly and in a uniform manner based on objective, easily measured variables.

Recently, concerns have arisen from a variety of sources (state health care organizations, regulators, financial intermediaries, and other payers) regarding the use of such orders in treating renal osteodystrophy, maintaining adequate iron stores, and regulation of erythropoietin therapy. These have centered in two areas. First, there are the concerns of pharmacists, nurses, regulators, and payers regarding the nature/validity of “standing orders” and whether these directives are in fact bona fide orders. Second, there is a question surrounding the necessity of physicians signing off on their use in the treatment of their patients.

Some have requested individual physician signoff on each decision step in clinical subroutines outlined by standing protocols, such as dose adjustment, ‘hold times” for IV infusions, and lab draws required to resolve dilemmas in decision making. Although the advent of electronic signatures has partially allayed this concern without undue convenience to physicians, in some quarters electronic signatures are not deemed acceptable, and in others, are not available. Further, these concerns are often expressed by the local Medicare fiscal intermediaries (FI), and are therefore not consistently seen as national issues.

An important result and objective of protocol orders is the ability to assess subsequently the effectiveness of a particular regimen to achieve a specific desirable therapeutic goal. Doses as well as dose intervals are essential features of such protocols, and the interpretation of their result. In a dialysis unit, for example, strict adherence to a protocol for the administration of erythropoietin in a biweekly iteration in a large group of patients allows the medical director and the attending physicians to examine the success or failure of such a protocol in meeting the goal(s) of the treatment.

Because physicians are not continually present in dialysis units and care for an ever-increasing number of patients, any rule or regulation that would mandate individual signatures prior to obtaining a scheduled test or changing a dose of medication that is part of a protocol order based on an algorithm is contrary to the goals of excellent patient care.

Some have regarded standing protocols with skepticism as substituting efficiency for thought (i.e., bonafide physician care). The utilization of algorithms may potentially result in less physician attention to deviant laboratory values, or other overall trends in care (e.g.: drifting towards marginal dialytic adequacy or nutritional status, tendencies towards depletion of iron stores, and slowness in response to needed changes in estimated dry weight). Such a view ignores the development of these protocols by physicians with the explicit goal of diminishing variability in treatment.

Some would countenance only a specific drug dose equated to a particular patient-specific laboratory datum, e.g. a specific number of units of insulin given for a specific plasma glucose concentration but not a percent increase in dose. The argument here is that the precise dose is specified. However, the increasing body of evidence gleaned from studies of applied molecular genetics shows that response to drugs varies from patient to patient and thus relative or percent changes in dose are likely to be more rational than a fixed relationship between drug dose and the biological response<sup>v vi vii</sup>.

The benefits of such protocols significantly outweigh these concerns. First, given the leadership of the nephrology community in pioneering evidence-based practice, the employment of programmatic care provides unique opportunities in both implementing and realizing evidence-based goals for treatment. Second, use of such pathways will provide measurement tools for assessing performance of care over any one of a variety of denominators (organization-wide performance, physician self-assessment, and inter-physician comparisons). Thus, the value of protocol-driven care as a tool of continuous quality improvement (CQI) cannot be overstated. In most instances, rather than distancing physicians from care, standardized treatment tools may enhance detection of physiological outliers/exceptions to care, promote improved physician efficiency, and thereby enhance physician performance in care delivery. Additionally, as payers scrutinize increasingly the relationship between care optimization and cost, treatment paradigms that optimize care and minimize its variability will be viewed in an ever-increasingly favorable light.

## **Recommendations**

- 1. RPA unequivocally supports the use of algorithm orders to achieve excellence in patient care, to implement the goals of evidence-based guidelines thereby enhancing quality, and to promote patient safety by avoidance of medical errors.**
- 2. RPA believes that individual nephrologists must decide whether a protocol order is appropriate for each patient and, if so, to authorize the use of the protocol for that patient.**
- 3. RPA believes that an order for regular periodic laboratory tests generated by a protocol should be executed without further authorization or signature.**
- 4. RPA believes that a change in dose generated by iteration of a protocol algorithm should be instituted promptly without prior signature by the physician.**
- 5. RPA believes that all changes in dose should subsequently be signed to confirm awareness and approval of the changes in accordance with individual facility/organization policy or within a reasonable period.**
- 6. RPA believes that the principles of continuous quality improvement should be applied to the direct outcome of treatment algorithms. Individual nephrologists and medical directors of dialysis facilities should regularly review outcomes not only to assess patient progress, but to making appropriate changes to existing protocols to incorporate new recommendations from published studies. Failure to achieve desired clinical practice goal should result in protocol reexamination and revision.**
- 7. RPA believes that protocols should be reviewed and updated as needed, at least yearly.**

## References

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<sup>i</sup> Committee on Quality of Health Care in America, Institute of Medicine: To Err is Human: Building a Safer Health System. Kohn L, Corrigan J, Donaldson M, ed. National Academy Press, Washington DC, 1999.

<sup>ii</sup> Committee on Quality of Health Care in America, Institute of Medicine: Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century. National Academy Press, Washington DC, 2001.

<sup>iii</sup> Morris AH: Decision support and safety of clinical environments. *Quality and Safety in Health Care* 2002, 11: 69-75.

<sup>iv</sup> Conway, J: Creating a Culture of Safety, presented at DCI Annual Meeting, St Petersburg FL, 2002.

<sup>v</sup> Wood AJJ: Racial differences in the response to drugs – pointers to genetic differences. *N Engl J Med* 2001; 344: 1393-6.

<sup>vi</sup> Weinshilboum R: Genomic medicine: Inheritance and drug response. *N Engl J Med* 2003, 348: 529-37.

<sup>vii</sup> Evans WE, McLeod HL: Pharmacogenomics – drug disposition, drug targets, and side effects. *N Engl J Med* 2003; 348: 538-49.