Optimizing Inpatient Pharmacotherapy Using a Single Clinical Policy Streamlining Pharmacy Protocols

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ABSTRACT

- **Objectives:** To describe the implementation of broadly scoped clinical pharmacy protocols positioned as a singular policy in a community hospital. These protocols were designed to expand the established benefits demonstrated using narrower, traditional protocols.
- **Methods:** A retrospective chart review of protocol interventions in the first year of the policy’s implementation was conducted to evaluate prescriber acceptance of protocol interventions. Interventions were identified from required email notifications. The frequency of use of each protocol was assessed, including evaluation of novel characteristics of specific protocols. Pharmacist utilization patterns were assessed for job classification, shift, and practice setting (ie, centralized or decentralized).
- **Results:** In the 1-year assessment period, 145 interventions were reported and 144 were accepted by the prescribing physicians. Interventions involved orders from hospitalists and intensivists most frequently, with the renal dosing and dose formulations protocols being the most commonly utilized. Staff pharmacists used the policy more frequently than clinical pharmacists, primarily during day shift from decentralized locations on the patient care units.
- **Conclusions:** The implementation of broadly scoped clinical pharmacy protocols for items our pharmacists routinely contact physicians about (and our physicians deemed were within the practice of pharmacy) instituted a cultural shift that expanded the elements considered to be part of routine pharmacy practice. As a result, pharmacists more seamlessly applied their expertise as pharmacotherapy specialists to optimize pharmacotherapy, which streamlined workflow for both pharmacists and physicians. This expanded the proven benefits of allowing professionals to work to their fullest extent, as established in the literature.

Allowing pharmacists to apply their expertise has been associated with improved outcomes in both pharmacotherapy quality (eg, reduction in mortality and length of stay [1]) and savings in healthcare dollars. Studies of focused protocols, including intravenous-to-oral (IV-to-PO) switch [2–20], renal dosing [21], stress ulcer prophylaxis [22] and anticoagulation management [1,23,24] demonstrate these benefits in a multitude of practice areas. While such protocols have become commonplace in the acute care setting [25–28], most continue to be singularly focused and impose patient population restrictions that preclude comprehensive patient evaluation. Many are administered as a task within the pharmacist workflow using a patient list generated by the limited protocol criteria, which are often restricted to agent or patient characteristics.

Better outcomes are associated with permitting professionals such as pharmacists to work to the fullest extent of their scope and expertise [29–31]. In specific cases, studies evaluating pharmacists’ impact within a multidisciplinary health care team have demonstrated improved outcomes in regard to both patient care and cost [29–31]. Recognizing this, accountable care organizations (ACOs) have developed practice models that are based on this benefit. Each team member is expected to robustly apply their training and expertise to achieve the best outcomes [32,33]. As health care moves toward a more integrative approach, it is paramount that pharmacists utilize the full scope of the skills in which they are trained.

This report describes the development, implementation, and outcomes of a singular policy outlining comprehensively scoped protocols allowing acute care hospital pharmacists within Princeton HealthCare System to...
optimize pharmacotherapy during the course of their usual clinical practice.

METHODS
Setting
The University Medical Center of Princeton at Plainsboro (UMCPP), part of the Princeton HealthCare System, is a 230-bed community acute care hospital located in central New Jersey. The hospital facility relocated in May 2012 from its previous location in Princeton to a new state-of-the-art facility in Plainsboro. As an affiliate of the Robert Wood Johnson Medical School and the Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey (ie, Rutgers), it is an academic teaching hospital with a mixed model for providing patient care. UMCPP employs both faculty physicians leading academic teams alongside hospitalists and private attendings.

Pharmacy services are provided on facility 24 hours a day, 365 days a year. The department of pharmacy services provides a full scope medication services from a centralized location with 3 full-time day pharmacists and 1 oncology satellite pharmacist. During weekdays, decentralized pharmacists provide medication review, patient education, and medication reconciliation on 2 to 3 inpatient care units. Centralized support decreases to 2 pharmacists in the evening and 1 overnight. Clinical pharmacists, both hospital-based and Rutgers faculty, work in conjunction with the staff pharmacists to ensure appropriate management of patients throughout different levels of care.

Program Overview and Implementation
To enhance protocols allowing pharmacists to more holistically and robustly optimize pharmacotherapy, UMCPP implemented the Clinical Pharmacy Services policy in February 2012. The policy outlined 8 protocols through which registered pharmacists within the acute care hospital could implement outlined medication order adjustments for adults of inpatient status. Pediatric patients or those treated outside of the acute care hospital (eg, in the psychiatric hospital, surgical center or outpatient facilities) were excluded. While the hospital had existing traditional programs such as IV-to-PO conversions, the programs were restricted to specific agents or conditions. As such, pharmacists were assigned to review queues in the clinical computer system to which orders for the agents outlined by the specific program would flow. Review would occur at set intervals and focus on that detail of the patient’s care as opposed to broadly encompassing an evaluation of the patient’s comprehensive pharmacotherapy. The goal of the new policy was to better utilize the pharmacists’ expertise by broadening these assessments to all applicable agents, refine workflow (by allowing protocol management instead of requiring individual prescriber calls for each issue) and integrate holistic refinement of pharmacotherapy regimens during the usual course of the pharmacist’s clinical care.

In the state of New Jersey, the Pharmacy Practice Act (updated on 14 January 2004) formally recognizes pharmacists as health care professionals and permits for collaborative practice in the community setting [34]. However, pharmacist management by protocol in the acute care hospital setting is defined separately, requiring only medical approvals within the system [35]. In accordance, the policy and associated protocols were approved by the institution’s multidisciplinary pharmacy and therapeutics (P&T) and medical executive committee processes.

The protocols included in this singular practice policy were designed to allow pharmacists to apply their professional expertise in the areas in which calls to physicians with recommendations for adjusting pharmacotherapy were routinely accepted and/or for which the literature strongly supported improved outcomes with pharmacist involvement. Some protocols evolved from existing programs (Table 1). The renal dosing protocol expanded the existing program by supporting dose and/or interval adjustments for all medications instead of a handful of selected agents across all levels of renal function, both stable and fluctuating. The protocol set standards for assessment of renal function (as approved by the hospital’s section of nephrology) and referred pharmacists to formal and universally accepted drug information sources for specific dosing recommendations. A dose formulation protocol expanded the existing IV-to-PO program to permit for adjustment of prescribed agents to the most appropriate formulation to facilitate administration based on the pharmacist’s assessment of need and appropriateness or as requested by the nurse. Thus, unlike its traditional IV-to-PO counterpart, the goal of the evolved protocol was not simply to save cost by converting IV to oral products but to assure the most appropriate method of administration to enhance pharmacotherapy response by optimizing pharmacokinetic and pharmacodynamic characteristics. Expanded beyond products of 100% bioavailability, this protocol also allows for dose adjustments to account for differences in bioavailability between formulations to assure dose equivalency to that originally prescribed. Like
the renal dosing protocol, there was no defined list of agents for which adjustments were permitted. A third protocol expanded the pharmacist’s authority to order laboratory tests for any pharmacotherapy monitoring purpose.

Several new protocols additionally targeted pharmacotherapy optimization (Table 2). For example, the stress ulcer prophylaxis protocol promotes appropriate use by permitting for initiation, discontinuation, or dose adjustment of both histamine-receptor antagonists and proton pump inhibitors consistent with nationally accepted, evidence-based guidelines [36]. Other refinement of existing therapy allowed for adjustment of parenteral formulations, pain management orders, and administration times based on age and fall risk. Protocol interventions could be initiated by the pharmacist during order review, during clinical rounds, or by request of the nurse, patient/family or other practitioner. Use of the protocols for these intervention types was not mandatory thus did not preclude discussion with the prescriber if the pharmacist felt it warranted.

To ensure appropriate oversight, the policy required that the pharmacist making changes submit notification of protocol intervention to the patient’s attending physician, the physician who generated the original order (if other than the attending) and a designated clinical pharmacist (for auditing purposes). All notifications were made via email within the clinical computer system in “interrupt” status to ensure active recognition by the prescriber(s).

**Program Evaluation**

An evaluation of the first year’s interventions was conducted to validate the program, describe its utility, and

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<th>Protocol</th>
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| Formulation adjustments               | Allows for conversion of a prescribed agent to any available formulation at an equivalent dose to that prescribed | • Formerly referred to as “IV-to-PO switch,” as changes were restricted to IV formulations converted to oral formulations for a defined list of agents with 1:1 bioavailability.  
• The revision permitted for any formulation adjustment, including adjusting between available oral formulations (ie, liquids, tablets, capsules, powders) based on swallowing capability/gastric tube compatibility or between oral & IV formulations to meet needs |
| Laboratory tests                      | Pharmacists may:                                                            | • Specific existing policies identified limited laboratory tests that could be ordered under certain conditions. For example, the anticoagulation program allowed for pharmacists to order PTT/INRs and CBCs at defined points in time.  
• The revision expanded these niche applications to any test required to monitor any medication during the course of the patient’s care |
| Renal dose adjustments                | Allows for adjustment of prescribed agents for renal function based on standardized assessments | • Exclusions: chemotherapeutic and biologic agents  
• CrCl calculations per Cockcroft-Gault if renal function is stable (defined at ± 25% increase in SCr in last 24 hours)  
• Adjustment were made per recommendations of the product’s labeling or Micromedex’s DrugDex monograph  
• Weight applied in the Cockcroft-Gault equations is defined as:  
  - Actual body weight (ABW) when ABW < ideal body weight (IBW)  
  - IBW when ABW 100–134% of IBW  
  - Adjusted body weight when ABW ≥135% IBW  
• For unstable/fluctuating renal function, the following apply:  
  - Consider CrCl < 10 mL/min if SCr double within 24 hours or urine output (UOP) < 0.5 mL/kg/hour  
  - Do not use Cockcroft-Gault; consider relative trends in SCr and UOP as well as clinical status |
provide a basis for re-evaluation and continued evolution. The aim was to evaluate the institution’s experience with the program, focusing on both specific physician and pharmacist elements. One of the primary goals was to evaluate which physician’s orders were associated with interventions as well as the rate of physician acceptance of protocol interventions, as their acceptance clearly validates the pharmacist’s ability to appropriately apply the protocols in patient-specific contexts.

To evaluate the pharmacist’s experience, trends in pharmacist utilization were captured, including which pharmacist by job classification (ie, staff or clinical pharmacist) implemented interventions, during which shift, and in what operational capacity (ie, centralized or decentralized) the pharmacist was practicing. Lastly, the study sought to characterize the frequency to which each protocol was applied. Based on the existing experiences described in the literature as well as with consideration of institutional culture and operation, we hypothesized that all pharmacists would apply protocols with equal efficacy with more interventions likely generated by staff pharmacists due to their role in primary order review and that the types of interventions would vary based on shift and location.

A retrospective review of cases throughout the first year of the policy’s implementation was conducted, including interventions made between 1 February 2012 and 31 January 2013. Cases were identified through the

<table>
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<th>Table 2. New Clinical Protocols</th>
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<td><strong>Protocol</strong></td>
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| Adjustment of administration times of prescribed agents | Adjustment to minimize sedation:  
- Allows for a change in time of medication administration time to 2100 for once daily medications known to cause sedation  
Adjustments to minimize wakefulness:  
- Allows a change in time of medication administration to 0900 for once daily medications known to cause wakefulness  
Diuretic therapy:  
- Allows for adjustment of evening diuretic dose administration time to avoid administration between 1900 and 0500 to modify associated fall risk | Protocol for patients >85 years ONLY  
Exclusions criteria for diuretic therapy applied to one-time order, orders given more frequently than q12h and patients with a urinary catheter |
| Adjustment of base solution and/or concentration for parenteral products | Allows for modification of ordered parenteral products through adjustment of base solution to meet the patient's clinical goals | Applied to meet fluid restriction requirements or as part of a glycemic management strategy (by limiting dextrose solutions) |
| Differentiation of PRN pain management orders | Pharmacist may amend pain management PRN conditions as follows:  
- For orders of the same agent with overlapping pain scale ranges: adjust the lowest dose to be administered for the lower pain scale range and the higher dose for the higher pain scale or  
- For orders for IV and PO agents within the same pain scale range: (1) use oral agent first if patient is able to tolerate oral and (2) use IV if patient is NPO or fails to respond to oral dose. | |
| PRN order discontinuation | Pharmacist may discontinue PRN orders that have not been used in > 72 hours (excluding the behavioral health unit) | Exclusions: patients at the behavioral health hospital |
| Stress ulcer prophylaxis | Allows for addition, discontinuation or adjustment of stress ulcer prophylaxis based on the American Society of Health System Pharmacists guidelines [36] | Permits for preferential use of H$_2$RAs (famotidine) over PPI (pantoprazole), including adjustment from PPIs to H$_2$RAs |
required email notification of the auditing clinical pharmacist. The patient’s electronic medical record for that defined visit was reviewed. To assess pharmacist utilization patterns, data captured included the agent involved in the intervention, date, day of week and shift, whether the pharmacist was centralized or decentralized, and whether that pharmacist was classified as staff or clinical. Decentralized pharmacists were defined as a pharmacist working on the patient care unit with direct access to other practitioners and patients, rather than those performing their functions from within the confines of the pharmacy department.

Prescribers were described both by status (ie, attending or resident/training) and specialty. Physician acceptance was assessed through evaluation of order trends as the electronic medical record allows for all changes to an order to be audited and tracked; a review of progress notes to capture any commentary or rationale regarding interventions or the surrounding circumstances; as well as a review of any associated laboratory or diagnostic reports and nursing notes. If the order was not altered by the physician within 24 hours (ie, the time frame in which orders must be reviewed by the prescriber per institutional standards) of the pharmacist’s protocol change it was deemed accepted by the physician. Changes made within 24 hours for clinical reasons unrelated to the protocol change as verified by documentation in the progress notes were considered as accepted. These included, for example, the discontinuation of empiric antibiotics that had been dose adjusted by the pharmacist for patients in whom infection had been ruled out or a change from the adjusted agent to one of another class (such as might occur during de-escalation of antibi-otic therapy). Interventions were excluded if there were insufficient patient and/or intervention details to allow complete assessment.

For protocol evaluation, details concerning the nature of the adjustment were collected. For formulation changes, agents were classified by their bioavailability. Renal dose adjustments were classified by the patient’s estimated creatinine clearance range since interventions were not restricted to ranges or agents. Stress ulcer prophylaxis adjustments were classified as those involving initiation, changes or discontinuation of therapy. For parenteral product adjustments, the initial and final base solution and/or the change in concentration was captured. Pain management order adjustments were classified as those involving the same agent with overlapping indications or those with oral and intravenous orders for the same pain scale range. When laboratory tests were ordered, the type of test was captured.

The study was approved by the institutional review boards of Princeton HealthCare System and Rutgers.

RESULTS

There were 145 interventions occurring between 1 February 2012 and 31 January 2013, with 144 (99.3%) of those being accepted by the prescriber. The 1 intervention that was not accepted involved an IV to oral conversion of levothyroxine. The pharmacist performed the conversion appropriately as the patient was tolerating other oral medications. However, on the day of the change, the patient refused all oral medications despite having the ability to accept them and, as a result, all medications were converted back to parenteral formulations.

Pharmacist Evaluation

Decentralized pharmacists performed 81% (n = 118) of interventions. Fifty-two percent (n = 76) were made during day shift between 0700 and 1500, 15% (n = 21) on evenings between 1500 and 2300, and 33% (n = 48) on nights between 2300 and 0700. The types of interventions made by each shift differed (Figure 1). Staff pharma-cists performed 71% (n = 103) of all interventions compared to 29% by clinical pharmacists (n = 42) (Figure 2). Some intervention categories were performed by only one pharmacist type. Differentiation of pain management orders were performed only by staff pharmacists while stress ulcer prophylaxis was performed only by the critical care clinical pharmacist. No pattern existed in regard to day of week on which interventions were made.

Prescriber Evaluation

An evaluation of prescribers revealed that the primary physician groups (ie, order generators) involved were hospitalists (n = 32) and critical care attendings (n = 24) at 22% and 17% of all orders, respectively. The remaining 89 interventions were distributed across other attending types (including general medicine physicians, specialty physicians and surgeons) and trainees (residents and fellows) with no more than eight orders for any individual physician category.

Protocol Evaluation

The renal dosing protocol was the most commonly used, representing 39.3% (n = 57) of all changes, followed by dose formulation changes at 21.3% (n = 31).
Enoxaparin, levofloxacin, and vancomycin were involved in 80% of all renal dose adjustments made with the most common creatinine clearance range involved being 11–30 mL/min (Table 3). Gastrointestinal agents (ie, docusate, famotidine, pantoprazole, senna) and antimicrobials (ie, levofloxacin, fluconazole, metronidazole) were involved most commonly in formulation adjustments.

The total number of laboratory tests ordered accounted for 14% (n = 21) of all interventions. Studies related
to the management of anti-infective agents and blood formation, coagulation, and thrombosis agents consisted of the majority of the lab tests ordered; INR/PTT and vancomycin levels were the most commonly ordered. Thirteen percent \((n = 19)\) of all interventions include pain management adjustments with an even distribution between pain medications.

Several protocols were less frequently used, specifically the stress ulcer prophylaxis protocol (representing 3% of all interventions or \(n=5\)), base solution changes (< 1% of all interventions or \(n = 1\)), and adjustment of administration time (7.6% of all interventions, \(n = 11\)). Of the time adjustments, more than 50% \((n = 6)\) involved furosemide.

**DISCUSSION**

While the literature has many studies describing pharmacists improving outcomes through successful provision of clinical programs by protocol in the acute care hospital setting, the majority of studies are limited to single or focused protocols [2–24,27,37,38]. This approach fails to recognize or limits application of a pharmacist’s expertise in pharmacotherapy, as intervention is permitted only on defined agents under specific circumstances. This is the only report we are aware of that addresses a broader approach in permitting pharmacists to optimize pharmacotherapy during the course of their usual practice through a single policy. As better outcomes are associated with allowing professionals to work to the fullest extent of their expertise, a broad range of protocols identified as pharmacy clinical services were selected and integrated into a singular policy that would be the foundation for instituting cultural change in regard to the elements considered to be routine pharmacy practice. Thus, the protocols applied here did not specify agents that could be adjusted for renal function or classes for which formulation conversion were permissible. This is also the case for dose formulation adjustments, where the protocol allowed for the pharmacist to apply their expertise beyond 1:1 conversions using standardized drug information references (Table 1 and Table 2). As such, the protocols allowed for the full application of the pharmacist’s expertise as a pharmacotherapy consultant within these intervention categories to assure that therapies are optimized. Additionally, eliminating phone calls streamlined the workflow for both the pharmacist and physicians, thus minimizing interruptions that distract from the other functions in which they are engaged.

During the approval process, physicians inquired whether all pharmacists were equally capable of making the clinical judgments involved with the protocols as described and, thusly, whether protocol management should be limited to clinical pharmacists who have less traditional dispensing roles and more experience and time at the bedside. During those discussions we contended that the nature of these protocols were fundamental and applicable to all practicing pharmacists and, if limited, would result in missed opportunities as the clinical pharmacists are focused in specialized areas during weekdays only at UMCPP. For example, a single, centralized night-shift pharmacist could make routine dose or formulation adjustments without the need to awaken a physician as the UMCPP electronic medical record makes available all progress notes, laboratory results, and diagnostics crucial to clinical decision making. All pharmacists, regardless of job title, meet the same requirements for licensure. Post-doctoral residency or fellowship training and advanced certifications in specialty areas of practice exist among both groups as well. The study results support the validity of this argument. The majority of interventions were successfully performed by staff pharmacists with involvement from all shifts, including a third that occurred overnight. This is important because, like at most hospitals, the UMCPP staffing ratio decreases throughout the course of the day presenting changing workflow challenges throughout different shifts.

Several limitations of this study should be noted. Due to its retrospective nature, it is likely that not all interventions were captured. Some decentralized pharmacists reported not emailing interventions as they had verbally communicated the adjustments prior to having the opportunity to send the email. Four interventions could not be assessed as the email notification did not contain all the required patient identifiers or intervention information to permit for appropriate evaluation. The hospital also moved to a newly built facility in the fourth month.

### Table 3. Renal Dosing by Creatinine Clearance (CrCl) Range

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<th>Range</th>
<th>Number of Adjustments</th>
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<td>CrCl &gt; 50 mL/min</td>
<td>5</td>
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<tr>
<td>CrCl 31–50 mL/min</td>
<td>10</td>
</tr>
<tr>
<td>CrCl 11–30 mL/min</td>
<td>40</td>
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<tr>
<td>CrCl &lt; 10 mL/min</td>
<td>2</td>
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of protocol implementation, which required significant changes in drug distribution methods, and this could have contributed to the small sample size of interventions. The move temporarily shifted departmental resources to support operational needs.

Another important factor is the voluntary nature of the policy; while it was within the pharmacist’s professional judgment to apply the protocols, pharmacists were encouraged to contact prescribers if there was any ambiguity. Therefore, while one might have expected more resident physicians to be involved with orders that were adjusted, the UMCPP practice philosophy supports contacting training physicians about changes so that they may learn from the discussion to support developing stronger prescribing habits. Future development should therefore support more universal protocol application to all eligible patients to optimize the benefits described here. Lastly, data measuring the clinical outcomes and time savings or increased productivity secondary to the elimination of physician phone calls was not directly measured. We thus sought to first demonstrate to the physician base that pharmacists could successfully apply a variety of protocols that were broader than those formally studied with equal accuracy. With that effectiveness established, future studies should explore if broader protocol application produces a greater optimization of outcomes.

After the study was completed, a survey was conducted of the pharmacists to assess perceptions and guide further policy development. We received a 63.6% response rate (14 of 22 possible respondents) with a strong majority of the respondents expressing a favorable perception of the protocols. A few respondents indicated some protocols were infrequently utilized and there was limited familiarity with others. We anticipate this is largely based on various shift and unit assignments that would make some protocols more applicable than others to the populations serviced. One of the survey questions polled the respondents on the necessity of the email notification to the prescriber given that this practice is of a higher level of notification than other established hospital protocols which only requires a notation of the change within the medication order. Seventy-one percent (n = 10) of respondents favored removing the email notification, citing primarily that it would be consistent with physician comments regarding the existing notifications. Pharmacists also identified further areas of protocol development including electrocardiogram ordering for QTc monitoring, implementation of a standardized vancomycin dosing protocol, discontinuation of duplicate orders, product substitution for nonformulary items and addition of a protocol for pharmacists to order over-the-counter or nonprescription products as they would in a community setting. This input will shape the revision of the policy and its protocols.

CONCLUSION
Consistent with the published literature, pharmacists effectively performed pharmacotherapy interventions in a multitude of practice categories for adult inpatients of an acute care community-teaching hospital using a single, comprehensive clinical policy. Providing these broadly scoped protocols in a singular policy allowed pharmacists to increase the autonomy with which they applied their pharmacotherapy expertise during the course of their routine, prospective care and expanded the established benefit of allowing professionals to work to their fullest extent. Pharmacist protocol intervention was met with a high physician acceptance rate.

Acknowledgment: We thank all the pharmacists at UMCPP for supporting our efforts to refine pharmacy practice for our patients.

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