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Optimization of critical care pharmacy clinical services: A gap analysis approach

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Optimization of critical care pharmacy clinical services: A gap analysis approach

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As Robert Sharma said, "What gets measured, gets improved." Every critically ill patient requires care by a critical care pharmacist (CCP) for best possible outcomes. Indeed, these highly trained professionals generate benefit through direct patient care (eg, pharmacist-driven protocols, medication monitoring, etc), participation on the intensive care unit (ICU) interprofessional team (eg, pharmacotherapy recommendations, team education, etc), and leadership in the development and implementation of quality improvement initiatives.[1] However, clinical CCP services are not provided for all ICU patients, and CCP staffing models often vary substantially across ICUs in a given hospital and among ICUs in the United States.[2-4] In this narrative review, we use a gap analysis approach to define current levels of clinical CCP services, identify barriers to reaching an optimal level of these services, and propose strategies focused on expanding clinical CCP services and justifying those that currently exist.

Current critical care pharmacy clinical services. The broad scope of beneficial activities performed by the CCP has been extensively reviewed and supported by a position statement from the American Society of Health-System Pharmacists (ASHP), the American College of Clinical Pharmacy (ACCP), and the Society of Critical Care Medicine (SCCM): the CCP is an essential member of the healthcare team for delivery of patient-centered care in the ICU.[1]

However, this recent position statement provides little guidance on how existing CCP resources can be optimized, how new CCP positions should be justified, and how the CCP, in their daily practice, can consistently reach the ICU practice goals the rest of the ICU interprofessional team, administrators, and patients expect from them.[1] Indeed, while the ASHP/ACCP/SCCM statement considers establishing appropriate ICU pharmacist-to-patient ratios as "foundational," it also states that "limited data are available to guide optimal [CCP] ratios" and "determinations regarding [CCP] coverage and service design should be based on patient acuity and complexity."[1] A CCP-to–ICU patient ratio of 1:15 has been proposed as the optimal ratio for clinical CCP services.

However, this ratio is not supported by rigorous research; ratios as low as 1:8 and as high as 1:30 have been proposed as being better.[5-9]

In the United States, 2,800 board-certified CCPs are currently available to provide care to the 100,000 ICU beds that are filled with 5 million patients per year. There is currently a substantial shortage of qualified CCPs to provide an optimal level of pharmacotherapeutic care to critically ill Americans.[10-12] When surveyed, 27% of CCPs self-reported working at a CCP-to–ICU patient ratio of 1:18, and another 25% reported working at a ratio greater than 1:30.[13] In a more recent survey of 441 US hospitals, a median ratio of 1:17 (interquartile range, 1:12 to 1:26) was reported.[2] In this same survey, only 70.8% of institutions had direct clinical CCP services in the ICU, CCP coverage was limited on nights and weekends, and CCPs frequently had nondirect patient care responsibilities.[2] Indeed, few institutions provide 24-7-365 clinical CCP coverage, despite the ever-increasing complexity of ICUs and calls for greater clinical CCP services during the current global pandemic.[14] As a result, general practice pharmacists, without formal CCP training, may be placed in the ICU despite evidence suggesting that a lack of ICU experience may be associated with fewer clinically important interventions and fewer optimal-level clinical CCP activities.[15-18]

Research surrounding the current staffing challenges faced by critical care physicians, advanced practice providers, and nurses, the risk for clinician burnout that may result from this, and the impact on care quality is informative for CCP staff justification.[19-25] Increased nursing workload as a result of reduced staffing is associated with greater patient mortality, particularly in those patients who are most seriously ill.[25] These reports have resulted in calls for federal mandates to standardize ICU nurse-to-patient care ratios.[26] Up to 60% of CCPs report experiencing burnout; increased roles and responsibilities are the most commonly reported factors.[15,27-29] However, few studies exist regarding CCP staffing ratios and burnout. Survey results suggest that CCPs perceive higher CCP-to–ICU patient ratios to be associated with worse quality of care.[13] This moral distress has previously been shown to be associated with clinician burnout.

Optimal CCP clinical services. The first step to addressing the current CCP staffing gap is to more clearly define what is meant by "optimal" with respect to CCP clinical services in ICUs. We propose the optimal staffing model to be a function of identifying a CCP-to–ICU patient ratio that maximizes a composite of 3 key domains: patient outcomes, healthcare costs, and CCP welfare (Figure 1). Within this model, individual pharmacist time is appropriately allocated among ICU responsibilities, including direct patient care, quality improvement, teaching, and outside (the ICU) leadership and service activities. Clearly delineated relationships between ICU census, patient need for CCP services, and the CCP staffing time required to deliver these services would allow for institutions to develop staffing models that fit their unique needs. Globally, as our knowledge of CCP-to–ICU patient ratio individualization continues to evolve and CCP staffing models improve, reduced medication-associated harm, healthcare waste, and CCP burnout will ideally ensue.

Gaps to achieving optimal critical care pharmacy clinical services. No study has formally evaluated how the CCP-to–ICU patient ratio affects the number or quality of medication interventions, patient outcomes, healthcare costs, or pharmacist well-being. Indeed, the relationships that define the optimal CCP-to–ICU patient ratio, the quality of CCP care, the time required to deliver that care, and the resulting ICU patient–related outcomes remain poorly characterized, yet, a priori, these causative relationships are likely present. Among ICUs in the United Kingdom, research focused on pharmacist staffing resources, time spent by pharmacists in the ICU conducting direct patient activities, and the quality and impact of CCP interventions achieved support the hypothesis that the CCP-to–ICU patient ratio and quality of care are interrelated.[16,18,30,31] However, the application of this research to US CCPs is limited given that pharmacist practice models are different, healthcare reimbursement is distinct, and CCP training is more structured. While many before-and-after studies have clearly shown that the addition of a CCP to the ICU interprofessional team improves patient outcomes, the intensity at which clinical CCP services should be delivered to optimize patient care outcomes remains unclear.[32-39] In other words, while the presence of nearly any CCP service is better than the lack of a CCP presence altogether, the incremental relationship of workload to outcome is unknown. Key evidence gaps to address include the following:

- If a CCP has fewer ICU patients for whom to provide clinical care, does their effectiveness improve?
- If CCP clinical services are delivered on evenings and/or weekends, are ICU patient outcomes further optimized?
- What factors most influence the optimal clinical CCP-to–ICU patient ratio that should be delivered (eg, severity of illness, number and/or type of medications)?
- Are there additional CCP responsibilities with equally positive effects on patient outcomes that might influence this staffing ratio (eg, teaching, quality improvement, or medication order validation)?
- Does a synergistic relationship exist between the delivery of direct patient care activities, indirect patient care responsibilities, service roles (eg, institutional committees, supervisor roles, national organizations), and education of students, trainees, and colleagues? Indeed, while it has been established that clinician-scientists fill a vital translational gap with regard to scientific discovery owing to the nature of the "practice-oriented" questions they can ask, this concept is less formally established for clinicians but may have similar ramifications with regard to quality improvement.[40]

These knowledge gaps prevent pharmacy administrators from being able to individualize CCP scheduling to a specific ICU patient ratio goal that will maximize return on investment. Importantly, a failure to be able to fully optimize the efficiency of this expensive resource may serve as a barrier to CCP service expansion and have the unintended consequence of dictating CCP practice models by available resources as opposed to clinically oriented patient outcomes guiding the need for new resource allocation. This approach to CCP modeling precludes allowing desired ICU clinical outcomes to drive, refine, and optimize the CCP model best suited to a particular ICU. A backwards-design approach may be more optimal; one such approach is depicted in Figure 2.

Formalization of on- and off-service periods (as in many intensivist staffing models) may be beneficial to consider for CCPs. With many CCPs having multiple roles in the context of their primary direct ICU patient care role, a reasonable CCP-to-patient ratio would allow for both high-quality patient care and the completion of other nondirect care activities. Key knowledge gaps to optimizing CCP staff models and global resolution strategies are presented in Table 1.

Strategies to bridge knowledge gaps regarding clinical CCP optimization. *Metrics-based approach.* To effectively conduct a meaningful trial comparing clinical CCP practice models, outcome measures and covariates must be thoughtfully defined. A reliable metric able to define and incorporate the key domains and outcomes of CCP performance (eg, the institutional resources to hire and support CCPs and the influence of these pharmacists on patient outcome and medication-related healthcare costs) has a strong potential to nurture the development of robust CCP practice models. However, the tools and modes that have been developed to date each have notable limitations (Table 2).

Medication regimen complexity has been proposed as a quantifiable metric designed to connect all components of the optimal CCP practice model, including ICU patient outcomes, healthcare costs, pharmacist welfare, and pharmacist resources.[3,68-75] The MRC-ICU scoring tool is the first validated, objective method to measure medication regimen complexity solely in critically ill adult patients.[71,76] Adapted from methods used for the medication regimen complexity index (MRCI), the MRC-ICU scoring tool was developed and validated in a single-center study of medical ICU patients and demonstrated an appropriate construct, a convergent, discriminant, and internal validity.[71] Subsequently, a prospective study in both medical and surgical ICU populations was conducted at an academic medical center and a community teaching hospital to confirm initial external validity.[75] The MRC-ICU score has also been evaluated in a multicenter study of 4,052 patients and 28 institutions, and preliminary analysis from the published abstract showed promise, with each increase of 1 point in MRC-ICU demonstrating 2% increased risk of mortality following Cox regression.[70] An abbreviated version of MRC-ICU, with 17 (vs 39) line items was then validated in an effort to simplify future information technology (IT) builds.[68]

To objectively quantify pharmacist activity, MRC-ICU at 24 hours has also been correlated with CCP interventions at 24 hours and cumulative interventions at discharge.[74] Drug-drug interactions (DDIs) correlated with both the MRC-ICU score at 24 hours.[27] Notably, correlation with potential DDIs was an expected finding as the rate of DDIs is known to increase as the total number of medications increases, thus serving as another validity confirmation but also suggesting a potential clinical use to identify high-risk patients.[77,78] For a construct such as medication regimen complexity to be effective, evaluation of the relationship with "real-time" events in which a CCP can intervene is necessary. In a multicenter, retrospective study, linear regression controlling for gender, age, and weight demonstrated that the MRC-ICU scoring tool has an association with fluid overload (as defined as a positive cumulative fluid balance that would be expected to produce weight gain of over 10% from baseline).[73] This finding is promising as fluid overload is a common adverse drug event in ICU patients associated with poor outcomes but also has a documented role for CCP intervention and benefit.[41,79,80]

Potential roles for a metric like MRC-ICU include providing resource predictions from a hospital administrative perspective for clinical CCP position justification, real-time guidance to establish optimal CCP-to–ICU patient ratios, and clinician-oriented information for prioritization of those critically ill adults who are at greatest risk for unfavorable medication-related outcomes (eg, fluid overload). Ideally, by applying this tool in a wide variety of institution types and ICU settings without losing translatability, a common language to investigate and establish best pharmacy practice models can be established. A potential construct for applying such a metric may be where resources are objectively predicted by an algorithm and patient outcomes are evaluated as a result of this staffing model, allowing for future site-specific modifications. In such a construct, patient-specific data and a pharmacy-based metric would be fed into a predictive model that provides both predictions for patient outcomes (eg, mortality, fluid overload) and pharmacist resources per patient (eg, number of interventions, time per intervention, etc). At this juncture, institution-specific needs (eg, unit census, non–patient care responsibilities of the pharmacist) would be incorporated to identify a reasonable pharmacist-to-patient ratio and associated staffing model. This staffing model would then be evaluated by comparing actual patient outcomes and pharmacist activities against the tool's original predictions to allow for further optimization (Figure 3).

A proof-of-concept model was developed using machine learning (ML) methods to validate the MRC-ICU score, and, despite a small dataset, the results suggest that prediction of patient outcomes can be improved with inclusion of medication regimen complexity data and the MRC-ICU score in comparison to the traditional predictor of acute physiology and chronic health evaluation (APACHE) III.[72] ML methods have shown promise in the domains of both critical care and pharmacy, but full application of a pharmacy-based metric for critical care pharmacy model optimization within a clinical decision support system (CDSS) requires rigorous prevalidation utilizing real-time scenarios.[81,82] Indeed, use of artificial intelligence and ML predictive algorithms facilitates the interpretation and application of complex information to real-time data and may be the future of predicting CCP resource needs. ML tools have transformed healthcare data to predict, diagnose, and treat disease. Recently, CDSS improvements have begun to support complex decision-making with the assistance of IT, data mining, and ML methods. These methods have been developed and used to predict severe sepsis and septic shock, early warning of sepsis,[83,84] unplanned transfer to the ICU,[85] ICU discharge,[86] acute injury risk,[87] complications in the critical care setting,[88] and hospital mortality.[89] While prediction model interpretation provided by CDSS requires substantial testing and validation, including integration of expert knowledge, to improve its overall accuracy, application of CDSS utilizing pharmacy-based metrics has the potential to provide much-needed insight as an alternative analytic approach to handle complex interactions and may elucidate hidden patterns that generate clinically justified predictions.[90,91]

Quality improvement approach. Institution-based evaluation and quality improvement efforts focused on potential clinical CCP staffing gaps are important. Available resources to justify additional CCP resources are reviewed elsewhere.[3] In the only study of its kind, one institution employed a mixed methods approach to justify the addition of a second full-time CCP in a medical ICU.[92] While the complexity of interventions (as defined by a perceived quality ranking) was not observed to increase, the absolute number of desirable and optimal clinical activities increased from baseline and a multiprofessional focus group of medical ICU team members qualitatively described the additional coverage as beneficial. Figure 4 provides recommendations for institution-based evaluation of current CCP services.

Conclusion. ICU workload for CCPs providing ICU clinical services has not been optimized, which exposes critically ill patients to worse outcomes and increased healthcare costs. Regardless of an institution's current status, incremental improvements to optimize current and future resources are possible. Use of a quantifiable and externally validated metric that allows for cross-institution and cross–patient population evaluation of patient outcomes, healthcare costs, pharmacist welfare, and pharmacist resources has strong potential for optimizing CCP clinical services. While closing the gap between current and optimal CCP clinical services will require deliberate action and a coordinated effort, CCP-delivered care for every critically ill patient is a deeply worthwhile vision.

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Figure 1. Visualization of an optimal pharmacist staffing model. This theoretical construct incorporates the 3 stakeholders: institutions, pharmacists, and patients. Evaluation of how to optimize productivity or finding the "tipping point" before healthcare costs increase and return on investment is diminished is warranted. Performance sections indicate optimal time allocation for critical care pharmacist direct patient care and indirect patient care activities during a daily shift.

Figure 2. Begin with the end in mind: evaluation of the ideal vs current model creation process. Following the dictum "begin with the end in mind," pharmacy practice models would be dictated by clinically oriented patient needs; however, the ability to predict these needs with regard to critical care pharmacist resources is a vital knowledge gap.

Figure 3. Construct for metrics-driven staffing model optimization. The ability to compare predictions to actual outcomes through a metric has powerful ramifications for position justification and patient outcome optimization. This figure demonstrates a possible application cycle for such a metric.

Figure 4. A proposed quality improvement evaluation approach to critical care pharmacist ratios. ICU indicates intensive care unit.

Table 1. Key Knowledge Gaps to Critical Care Pharmacist Staffing Model Optimization and Strategies to Overcome Them

Rationale	Potential Resolution Strategies
Mechanism(s) of how CCP activities improve patient outcomes are not clear	
• Unknown relationship of CCP activities to incremental improvements in patient outcomes (eg, renal dose adjustment in the ICU is counted via intervention tracking, but the effect on patient outcome is unknown)	• Increased research focus on measurement of ICU patient outcomes and evaluation of CCP impact in 2 distinct areas: direct patient care and indirect quality improvement activities[37,41]
No standard/efficient method to characterize day-to-day CCP productivity	
• Cannot reliably predict the amount of CCP time spent per intervention, how many interventions a particular ICU patient will require, or whether an intervention with a potential clinical benefit (eg, preventing drug-drug interaction) will actually contribute to beneficial outcomes • Productivity tracking is dependent on the CCP's efforts to individually record and appropriately classify each intervention.[42-44]	• Internal and external benchmarking across institutions • Investigating the relationship of CCP responsibilities to quality of interventions to predict what type of responsibilities are reasonable within a shift
Current methods to track CCP value are limited	
• Intervention tracking captures direct patient care activities but does not capture other indirect activities (eg, protocols, education) that likely prevent the need for direct "interventions."	• Real-time documentation of CCP interventions that occurs concurrently with patient care and includes both direct and indirect interventions
• Value tracking supports the value of pharmacist services, but substantial limitations are present, notably the difference between cost avoidance and cost savings and low-quality data.[45-48] The metric of "cost avoidance to pharmacist salary" may have more quickly diminishing ROI than using patient-centered outcomes (eg, length of stay).	• While tracking the value of CCPs is essential for staffing justification, more robust foundational data and not "widget counting" are needed to lay the groundwork for more comprehensive and reliable evaluations of the holistic nature of clinical pharmacy services.
The potential for CCP workload to result in pharmacist burnout not considered	
• Practice models do not account for the high practice standards set by guidelines and may contribute to CCP BOS, which has higher prevalence across the whole critical care discipline and contributes to worse patient safety outcomes.[29,49-52]	• Investigation of factors associated with CCP BOS (eg, lack of off-service time, vacation coverage, patient volume)[50,53] • The link between CCP practice models, CCP-to–ICU patient ratios, ICU patient outcomes, and BOS requires exploration.
Limited ability to compare CCP practice models among institutions	

• No universal ICU pharmacy practice model can exist given the unique nature of each ICU and each institution (ie, there is no "one size fits all") • Although scores like APACHE III and case-mix indices can provide general comparisons, the nature of the ICU patient population, specialty or focus area of the institution, geographic region, institution size, and other factors can lead to comparisons "between apples and oranges" when discussing the correct CCP-to–ICU patient ratio.[54,55]	• Development of pharmacy-specific metrics to "match" ICUs for more direct comparisons • Development of general standards regarding pharmacist-to–ICU patient ratio and staffing models (eg, evenings, weekends)[4,56,57]
Lack of validated predictive metrics to define CCP resources	
• Tools have been derived to help predict workload for central pharmacy staffing but do not address the complexities of ICU patients and have significant limitations for objective measurement of pharmacy personnel allocation (Table 2).[58-61]	• Development of a universally accepted and validated metric for productivity

Abbreviations: APACHE, acute physiology and chronic health evaluation; BOS, burnout syndrome; CCP, critical care pharmacist; ICU, intensive care unit; ROI, return on investment.

Table 2. Clinical Pharmacy Resource Prediction Tools

Development	**Limitations**
pCATCH: uses 5 key components to identify areas of highest requirement for pharmacists	
• Developed at the University of North Carolina Medical Center to determine the number of CPSs by various medical services[62] • The task force reached a consensus on 5 key components upon which to base CPS allocation. • After applying this methodology to each medical service, the service receives a score from 1 to 5, with 5 indicating the highest need for a CPS, at which time pharmacists were reallocated.	• While a broad staffing model for a large academic medical center with an associated school of pharmacy, it is not specific to a critical care population. • Not linked to patient outcomes • Bases patient acuity on DRG • Limited external validity due to its design oriented toward a single academic medical center • Not specific to CCPs
PIS: resource-based relative value intensity grouping system that utilizes pharmaceutical resource consumption data to allocate pharmacy personnel	
• Calculated by multiplying the number of patients with a specific DRG by a specific PIW, giving insight into pharmacy cost and patient acuity • PIW is calculated by comparing the median pharmacy cost for a given DRG with the median pharmacy cost for all DRGs to determine the "intensity" of pharmacy resource use in relation to other diagnoses. • Gives insight into medication expense at an institution and potentially patient acuity at that site[63]	• Assumes patient acuity is correlated with DRG, which has been shown to not always hold true[64,65] • Has only been used to predict expenditure on resources and has not been shown to improve patient outcomes or determine optimal pharmacist-to-patient ratio • Not specific to CCPs
MRCI: measure of patient-level MRC through 3 key components: dosage form, dosage frequency, and additional medication directions[66]	
• Developed from the MCI from 134 chronic obstructive pulmonary disorder patient regimens by using an expert panel of 5 researchers scoring 6 regimens to demonstrate construct- and content-related validity • Two researchers scored the same 6 regimens to determine interrater and test-retest reliability	• Is a patient-oriented outpatient tool intended to screen for community pharmacist clinical services (vs those in the ICU) • Not intended to be related to patient acuity or patient outcomes[67]

Abbreviations: CCP, critical care pharmacist; CPS, clinical pharmacy specialist; DRG, diagnosis-related group; ICU, intensive care unit; MCI, medication complexity index; MRCI, medication regimen complexity index; pCATCH, census, patient acuity, teaching services, medication cost, and use of high-priority medications; PIS, pharmacy intensity score; PIW, pharmacy intensity weight.

Figure 1

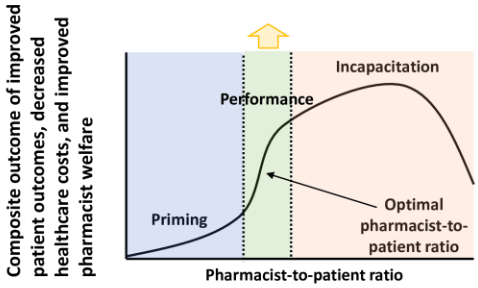
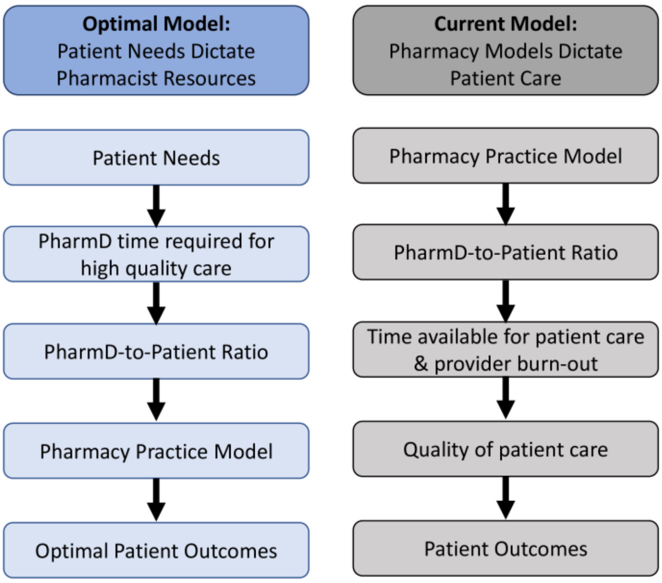
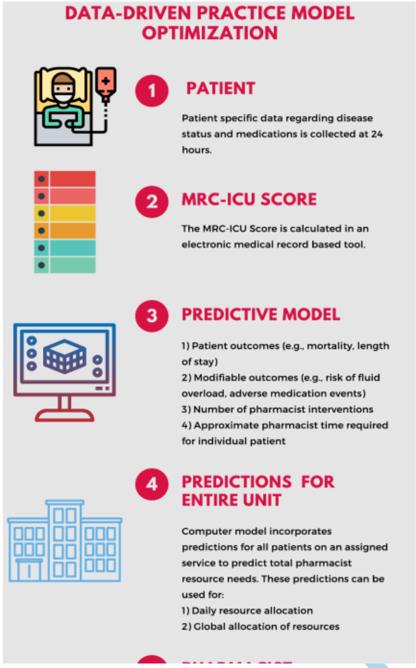

Composite outcome of improved patient outcomes, decreased healthcare costs, and improved pharmacist welfare
Performance
Incapacitation
Priming
Optimal pharmacist-to-patient ratio
Pharmacist-to-patient ratio

Figure 2



Optimal Model:
Patient Needs Dictate
Pharmacist Resources
Patient Needs
PharmD time required for high quality care
PharmD-to-Patient Ratio
Pharmacy Practice Model
Optimal Patient Outcomes
Current Model:
Pharmacy Models Dictate
Patient Care
Pharmacy Practice Model
PharmD-to-Patient Ratio
Time available for patient care & provider burn-out
Quality of patient care
Patient Outcomes

Figure 3



DATA-DRIVEN PRACTICE MODEL OPTIMIZATION
1
PATIENT
Patient specific data regarding disease status and medications is collected at 24 hours.
2
MRC-ICU SCORE
The MRC-ICU Score is calculated in an electronic medical record based tool.
3
PREDICTIVE MODEL
1) Patient outcomes (e.g., mortality, length of stay)
2) Modifiable outcomes (e.g., risk of fluid overload, adverse medication events)
3) Number of pharmacist interventions
4) Approximate pharmacist time required for individual patient
4
PREDICTIONS FOR ENTIRE UNIT
Computer model incorporates predictions for all patients on an assigned service to predict total pharmacist resource needs. These predictions can be used for:
1) Daily resource allocation
2) Global allocation of resources

Figure 4

Study Objective			
To explore the benefit of reduced CCP-to–ICU patient ratios at a single institution			
Intervention			
Institution-specific change in service coverage (eg, plan to go from 1 to 2 CCPs in a unit, addition of evening services, etc)			
Primary Outcome Options			
Workload	**Quality**	**Patient Outcomes**	**Satisfaction**
• Intervention quantity • Intervention quality	• Adverse drug events • Institution-specific protocol adherence	• Hospital mortality • Length of stay • Acute kidney injury • Duration of mechanical ventilation • Fluid overload	• Provider burnout • Employee satisfaction ratings
Secondary Outcomes			
Recommended to include outcomes from multiple categories to allow for exploratory relationships between workload, care quality, patient outcomes, and wellness			
Parameters			
• Patient demographics (eg, age, sex, admission diagnosis) • Patient acuity measures (eg, sequential organ failure assessment) • Primary and secondary outcomes as noted above • Institution-specific metrics (eg, medication regimen complexity) • Pharmacist staffing (eg, patients cared for per shift, on- and off-service patients, ICU vs non-ICU responsibilities, shift type)			
Data Analysis			
• Descriptive statistics and basic inferential statistics (eg, χ^2) • Recommended to include multivariate modeling to be able to adjust for noted confounders such as patient acuity or length of stay			