PROTECTED-UK - Clinical pharmacist interventions in the UK critical care unit: exploration of relationship between intervention, service characteristics and experience level

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Introduction

Critical care is a high risk medication area where vulnerable, acutely unwell patients are treated with intense therapies in a complex environment. As well as critical illness, patients are often older and with multiple co-morbidities [1]. The presence of multiple organ failure adds to the complexity of medication regimes in the individual patient. There is both a high rate of parenterally administered medication and a high risk of prescribing error. The frequent lack of mental capacity of patients, prevents them contributing to medication reviews or taking responsibility for medicines administration, and increases their vulnerability to erroneous or suboptimal medication therapy.

There is much evidence to support the need for clinical pharmacists (CPs) in the care of critically ill patients. CPs have been demonstrated as essential to improving medicines safety both at an individual and a broader critical care organisational level [2-5]. There is also a wealth of evidence existing to demonstrate the value of CPs in critical care, showing a significant positive impact on patient care, particularly in relation to improved safety, medicines optimisation, reduced expenditure and reduced length of stay [6-9].

Pharmacist interventions include identification of 'errors' (rectification of incorrect prescribing, including omissions), 'optimisation' (the enhancement of a patient's medication to improve efficacy of therapy) or a 'consult' (reactive provision of advice to a healthcare professional regarding a specific issue) [10]. Whilst, anecdotally, many hospitals collect intervention data from their pharmacy teams, this is rarely analysed in depth and, to our knowledge, there has been no larger scale multi-site study collecting and reviewing CP interventions in critical care. The Expert Practice Development Group (EPDG) of the United Kingdom Clinical Pharmacy Association (UKCPA) is composed of pharmacists with expertise in critical care (including consultant pharmacists, regional representation and extensive experience in critical care pharmacy). In 2011, the EPDG undertook to collaborate on the first multi-site study relating to CP activity. In 2012, this study became known as PROTECTED-UK (Pharmacist's Review and Outcomes: Treatment Enhancing Contributions Tallied, Evaluated and Documented), with the first paper published in 2015 [11]. The results of PROTECTED-UK demonstrated that CP interventions were made in nearly one in six of all prescriptions reviewed, and that two thirds of these interventions were of moderate or high clinical impact. A prescription is defined as a single item prescribed; therefore, review of a

patient may include multiple prescriptions. Of these interventions, 2,953 (87.1%) were proactive, where the intervention was identified by the CP without prior involvement of a healthcare professional. The breakdown of intervention type was 6.8% error, 8.3% optimisation and 1% consultation, of all prescriptions reviewed. The great majority of interventions - 2,967 (87.5%) - were accepted by the inter-professional team.
What was not shared in the earlier manuscript was the nature of the CP intervention and characteristics of the clinical pharmacy service and how these contribute to patient care.

The recent Faculty of Intensive Medicine (FICM) and Intensive Care Society (ICS) standards on staffing, specifies daily input of the pharmacist on the interprofessional ward round, ideally provided seven days a week [12]. Despite these standards, earlier national surveys have demonstrated that provision of pharmacy services varies amongst hospitals in the UK, both in terms of pharmacist-to-patient bed ratio, and level of expertise of the CP providing the service [13]. The FICM/ICS standards state that sole pharmacist practitioners on critical care should be of an Advanced Stage II standard, with a broad range of clinical expertise. If the practitioners work as a team, there should be a range of CPs (from Foundation to Mastery), including the support of clinical pharmacy technicians. These levels of expertise correlate to the recently introduced (UK) Royal Pharmaceutical Society's Faculty accreditation system for post-Foundation training [14] which provides a quality assured credentialing system. Pharmacists are now able to provide evidence to support a credential at advance practice Stage I (established, experienced practitioners), Stage II (expert practitioners) or Stage III (Fellowship, consultant or exceptional practice). Prior to this national initiative (and during the study period) - which continues to be rolled out to the workforce – defining level of practice remains a challenge. Consequently, pharmacist grade, according to National Health Service (NHS) Agenda for Change banding, is often used as a surrogate indicator of level of practice, despite clear limitations (Table 3). Whilst the expectation might be that the greater the expertise of the pharmacist, the higher the impact of the intervention, there is a lack of corroborating evidence to date.

The aim of this paper was to determine factors affecting the interventions made, specifically examining the relationships between:

- Intervention and grade of pharmacy staff
- Number of prescriptions reviewed and demographics of the service provided within the hospital, including number of patient beds, ward round attendance, pharmacist prescribers
- Day the interventions were made.

Method

PROTECTED-UK was a prospective descriptive study of self-reported clinical interventions undertaken by pharmacy staff, conducted in 21 adult critical care units across the UK over a 14 day period from 5-18th November 2012, capturing all interventions reported by the critical care pharmacy team. The trial period of 14 days was chosen as a balance of pragmatism, with the inclusion of at least two weekends and within a calendar period, where annual leave or calendar events were least likely to influence the data capture.
An online survey was developed to record pharmacist and pharmacy service demographics of the study site. All members of the EPDG were encouraged to participate in this study. A

detailed description of the methodology and site demographics can be found in the first paper [11].

Interventions

Interventions were defined as contributions to care aimed at improving patient care, and classed as 'error' (A medication error was defined as an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicine advice, regardless of whether harm has occurred [2, 15], 'optimisation' (defined as a proactive contribution that sought to enhance patient care) or a 'consult' (reactive intervention in response to a request from a member of the MDT for an CP review). At each site, each critical care pharmacy team member recorded their interventions, which they provided as part of their routine clinical service. All intervention data were recorded on a bespoke password-protected web portal database in real time, with all identifiable patient specific data anonymised. The details recorded included a short description of the intervention, medication involved, type of intervention, grade of clinical impact as decided by reporting pharmacist, acceptance rate and patient outcome (positive or negative). Each intervention included the grade of pharmacy staff involved. This data was exported into SPSS version 22 (IBM) from an SQL file. SPSS data file was examined for variable correspondence with the SQL file. Coding of the data, investigating missing data and clarification of ambiguous data was undertaken.

The activity data of the clinical pharmacy team were also recorded in the web-portal, daily, in terms of time involved in clinical activity, and numbers of patients and prescriptions reviewed. Practitioners were provided with definitions and supporting 'help files' on the web-portal. To address data consistency, data entry fields were format locked to reduce typographical entries or field input errors. The web-portal itself, the field entry formats and the on-screen form layout were piloted before start of the study period.

To assess relevant denominators, the following data sets were recorded: the number of medication orders (new prescriptions) reviewed each day (on day one, all medication orders were regarded as new) and the number of patients reviewed. The type of intervention was characterised according to a previously used classification [16]. The proportion of interventions accepted by the team (or self-prescribed by independent prescriber pharmacists) was also recorded.

Clinical impact coding

Each intervention was graded for potential clinical impact to patient care. The ordinal scale utilised is well established to grade medication errors [2]. The optimisation and consult scale were specifically developed for PROTECTED-UK, to mirror the errors scale i.e.low, moderate, high and life-saving impact.

All collated interventions were blind-graded by one of the principal investigators, a CP, for the purposes of consistency. Where the grading was the same as the recording pharmacist, this was considered the final grade. If there was a difference, the intervention was blind-graded by one of two consultant pharmacist investigators. Where these two grades agreed, this was considered the final grade. If all three grades disagreed, then a critical care consultant physician blind-graded the intervention and the final grade was where two grades agreed.

Pharmacy and Critical Care Service Survey

An online survey was designed using www.surveymonkey.co.uk in order to record the demographics of each of the participating units and clinical pharmacy teams. The number, grade of clinical pharmacist, and whether a consultant pharmacist led the team were recorded. Further data included: type of unit (general or specialist); utilisation of electronic prescribing; 'developed' (defined as more than one practitioner in the team) or 'undeveloped' pharmacy service; the presence, scope and grade of independent prescriber; presence of a weekend clinical pharmacy service, and finally the method of communication back to the interprofessional team (team meeting, self-prescribed interventions, individual feedback to junior doctors, bedside ward round or 'other').

Analysis

Bivariate analysis was conducted using SPSS version 22 (IBM). The data were analysed for central tendency. Multiple regression was not feasible as many of the factors were not independent factors. A p value <0.05 was considered statistically significant, and the correlation coefficients (r values) were reported as an indication of the strength and direction of the relationship between the factors analysed. Chi test was used for explore the relationship between pharmacy staff grading and intervention rate.

The intervention rate was defined as the number of interventions divided by the number of prescriptions reviewed. The same calculation was applied to error rate, optimisation rate and consult rate. The rate of each intervention type was then checked for correlation against the pharmacy and critical care service factors.

Ethical Considerations

The study was deemed a clinical audit after with discussion with Research and Development (R&D) at University College London (UCL), the lead site, and the need for ethics approval was waived. It was consequently registered as a clinical audit at each participating site, in line with local requirements.

Results

The majority of results were analysed solely on the weekday data. The weekend intervention numbers were relatively low and reported separately. A breakdown of individual unit activity is provided (table 1).

Table 1.

Time Spent on Prescription Review

The mean time spent on the ward per pharmacist was 3.5 hours per day (±SD 1.7). Each pharmacist reviewed a mean of 10.3 patients per day (±SD 4.2), and spent 22.5 (±SD 9.5) minutes per patient review. A mean of 1.2 (±SD 0.6) interventions were made per patient seen. The intervention rate had a moderate inverse correlation with both the number of prescriptions reviewed and the total number of patients reviewed daily (p = 0.02, r=-0.5 and p=0.02, r=-0.5 respectively. The length of time the pharmacist spent on the ward also had a moderate inverse correlation with the intervention rate (p = 0.05, r=-0.4). There was a strong inverse correlation between the optimisation rate and daily prescriptions reviewed (p

= 0.001, r=-0.7) and a moderate inverse association with the total number of patients reviewed daily (p = 0.02, r=-0.5).

Weekday and Weekend Service Provision

When weekdays were broken down into individual days, Monday had the highest intervention rate (24.1%) and Friday the lowest (17.0%). The greatest number of patients were reviewed on a Monday, as well as a statistically significantly greater number of new drug orders reviewed (p = 0.038). The total pharmacy time spent reviewing patients on the ward was similar across all weekdays with a mean of 5.7 hours (±SD = 0.19).

Of the 21 units with a proactive clinical pharmacy service, only two provided a specialist service at weekends (Saturdays only, at the time of the study), with the other units predominantly providing an on-call, reactive service for emergencies, or a dispensary-based service. A greater intervention rate was seen on weekends compared with weekdays (Table 2); 33.6% and 16.1% respectively (p <0.0001). Of the weekend interventions, the majority (89%) were optimisations, with 83.9% of moderate, or high clinical impact. Five of the units without a specialist weekend service also recorded interventions; 15 in total. These were from dispensary or on-call shifts. At weekends, there is a lower than expected frequency of errors (4.2% at weekends against 42.3% on weekdays, χ^2 = 56.59 p<0.0001) and a peak in error reporting on Mondays. This could imply that errors are being missed or less frequently identified at weekends, and may represent a period of increased patient risk.

The initial data entry for 'impact' was made by the practitioner. Subsequently, an independent clinician provided a blinded impact assessment of the case entry. Cases with disagreement between the impact scores were subsequently blindly reviewed by a third independent clinician. Any cases where there was disagreement between all three scores prompted a fourth blinded assessment and a majority decision. In all, there was disagreement in 1655 (49.0%) of cases after the first independent impact scoring, which resolved to 110 (3.3%) of cases of disagreement following a second round assessment before consensus.

Table 2.

Grade of Pharmacist

The relationship between the grade of pharmacist and interventions made was also investigated, however the correlation between impact of intervention and grade of pharmacist was not. The presence of a consultant pharmacist had a moderate inverse correlation with the error rate detection of the unit (p=0.008, r=-0.6). An explanation of UK pharmacist gradings can be found in Table 3. Consultant pharmacists made the most interventions per prescription reviewed (22.6%), followed by pharmacy technicians (17.6%) whose interventions were in relation to medicines reconciliation (Table 3). Consultant pharmacists were also more likely to intervene in the form of a consult. Junior pharmacists made the lowest number of interventions per prescription reviewed (11.1%). Band 8a pharmacists reviewed the most prescriptions, with a total of 7825 items, and had an intervention rate of 15.0% (p <0.0001, χ^2 = 37.7).

Table 3.

Other Factors

There was no correlation between the presence of electronic prescribing on the critical care unit and any of the intervention rates. This was also found for 'developed/undeveloped pharmacy team' and specialised versus general units. However, moderate positive associations were found for the presence of non-medical prescribing (excluding pharmacist prescribers) and overall intervention rate and optimisation rate (p=0.04, r=0.5 and p=0.02, r=0.5 respectively).

Discussion

The study results demonstrate the clinical impact clinical pharmacists routinely have on patient care in critical care units. As described in the earlier paper, there was a mean intervention rate of one intervention per six prescriptions reviewed [11]. None of the sites that participated in PROTECTED-UK had an intervention rate of zero. This could imply that hospitals in the UK that do not provide a clinical pharmacy service to their critical care units could be compromising patient care by not facilitating daily CP review.

Intervention rates were inversely correlated with the number of prescriptions and patients the pharmacist reviewed. As far as we are aware, this is the first piece of work to demonstrate that CP review takes time, and that to achieve full effect from a clinical pharmacy service providers must ensure that units are adequately staffed.

Error rates also inversely correlated with the presence of a consultant pharmacist, which could suggest the presence of a consultant pharmacist leads to more effective prescribing error reduction, although given the low numbers of these posts within UK critical care, results are hard to extrapolate conclusively. A recent review found that pharmacists had no significant impact on general medication error reduction, however they were more likely to reduce preventable errors [17]. An accompanying editorial suggests that CP impact on patient care is related to experience and clinical training, supporting the results found in our study [18].

In terms of pharmacist grade, as a pharmacist's knowledge and skills increase it is expected that their role in critical care will change in a more proactive way, with more consultations, optimisations and overall higher impact intervention, which is demonstrated in the reported data. A lower intervention rate was observed with junior pharmacists. This could be attributed to their limited specialist knowledge. Contrary to this was the observation that pharmacy technicians had the second highest intervention rate after consultant pharmacists, 88.2% of these were in medicines reconciliation. This clearly demonstrates their review of medication on admission and the meticulous attention to detail they take in getting the medicines reconciliation right.

These data also supports the ICS staffing recommendations that sole practitioners should be of at least an 8a level and pharmacists working in teams should reflect a skill mix, preferably led by a consultant pharmacist in larger centres [19].

The data suggest that for a nine-bedded critical care unit, a CP needs at least three hours of clinical time to effectively review all patients, producing an intervention rate of 1.16

interventions per patient reviewed. This is in line with ICS standards which recommend 0.1 whole time equivalent (WTE) of a CP for level 3 patients, and 0.05WTE for level 2 patients. Importantly, the data do not distinguish differences between the length of time needed to review a level 3 patient, and level 2 patient. One would anticipate a longer review time would be needed for sicker patients, due to their complexity, both in terms of medication and co-morbidities.
In addition, increased time is needed at both admission and discharge; admission, in order to fully review the patient and undertake medicines reconciliation and discharge, to ensure that medications have been reviewed and appropriately discontinued or reinitiated [19]. In units currently understaffed with CPs, consideration should be given to increase staffing to national ICS standards, which would be expected to increase time available for appropriate patient review as well as increase the intervention rate with patient safety benefits [4, 5]. Importantly, the clinical pharmacy workforce should also be considered and essential supporting clinical technicians included wherever feasible.

CP interventions undertaken to correct a medication error accounted for only around 40% of all interventions recorded in this study. This is a similar proportion to those found in other studies [20, 21]. The majority of interventions were optimisations or consults. The importance of these data is that it clearly demonstrates a progression in CP practice, from one historically regarded as primarily focused on detecting errors in prescribing, to one that includes consideration of evidence and individual patient variability in terms of medicines optimisation.

Several studies conducted in critically ill populations have largely demonstrated higher mortality rates associated with admission during weekends and out of hours [22-28]. The intervention rate in this study was substantially higher at weekends, with an intervention made every three prescriptions. Of these interventions, the high proportion (83.9%) of moderate or high impact graded interventions suggest that CP input at weekends is essential to reduce harm from medication errors, and optimise pharmacotherapy. This data could also demonstrate that the quality of patient care is currently diminished at the weekend in units that do not provide a clinical pharmacy service.

Despite an intervention rate of more than double the weekday rate, a lower percentage of these interventions were accepted by the team. This could be attributed to a number of factors, including on-call medical staff being less familiar with patients and less confident to make changes in their medication, reduced availability of prescribers or lastly, that the CP did not always have time to complete the intervention process. Whatever the reason, developments in the number of independent pharmacist prescribers in this speciality will be expected to improve pharmacy and medical staff efficiency in this aspect [29]. Extension of critical care pharmacy services to full weekend provision, as recommended by the ICS, should be considered so that all critical care patients have access to clinical pharmacy review. This is now a future directive for both the pharmacy profession and the UK deliverers of critical care [30].

Limitations
The units involved in the study were heterogeneous, with a wide range of pharmacy expertise, pharmacist-to-patient-bed ratios, patient illness severities and different types of

pharmacy service provided. A number of hospitals were treated as a single unit whilst others, with multiple sites, reported each separately. Interventions were reported and graded by the individual pharmacists on the units, which may cause variation in data collection and bias due to self-reporting. However, the moderation process should have addressed some of the variation. There is a potential for under-reporting and recall bias, although the majority of interventions were recorded close to the time of intervention and should have minimised this. Units self-defined as 'developed/undeveloped' and may represent a simplistic assessment of the resources available which may reduce medication errors in practice.

Conclusions

These results demonstrate that every patient cared for in the ICU should have daily prescription review by a clinical pharmacist. We have demonstrated that CPs reduce medication errors and optimise pharmacotherapy, with a high intervention rate per number of prescriptions reviewed. However, intervention rate is proportional to time spent reviewing a patient and thus appropriate pharmacy workforce (number and practitioner levels) levels are essential. On weekdays, optimisations and consults accounted for the majority of all interventions, with the remaining interventions involving medication error correction, demonstrating a shift in the role of the CP over the last two decades. Lastly, the higher intervention rate on the units that provided a weekend service highlights the need for clinical pharmacy services in critical care seven days a week. In summary, this study demonstrates the need for specialist pharmacists, in sufficient numbers, to be integral to the provision of high quality critical care in the United Kingdom (UK).

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Table 1: Interventions and Charts Reviewed Per Critical Care Unit During the Weekday

Unit	Total Time (hrs) Spent on Unit During Study[a]	Total number of patients reviewed (Mean)	Interventions Per Day (Mean)	Prescriptions reviewed (Total)	Errors	Optimisations	Consult	Interventions Made (Total)	Intervention Rate	Prescriptions Reviewed Per Intervention
1	81.0	23.8	30.5	1415	141 *10.0%*	121 *8.5%*	43 *3.0%*	305	21.6%	4.6
2	142.5	33.3	31.0	2480	162 *6.5%*	147 *5.9%*	1 *0.0%*	310	12.5%	8.0
3	194.5	57.2	32.9	4206	99 *2.4%*	197 *4.7%*	33 *0.8%*	329	7.8%	12.8
4	64.0	17.1	14.4	911	112 *12.3%*	29 *3.2%*	3 *0.3%*	144	15.8%	6.3
5	35.0	7.5	11.0	356	50 *14.0%*	53 *14.9%*	7 *2.0%*	110	30.9%	3.2
6	12.0	4.1	9.5	250	42 *16.8%*	52 *20.8%*	1 *0.4%*	95	38.0%	2.6
7	23.8	6.1	9.5	337	23 *6.8%*	56 *16.6%*	16 *4.7%*	95	28.2%	3.5
8	33.5	15.5	26.3	845	147 *17.4%*	112 *13.3%*	4 *0.5%*	263	31.1%	3.2
9	24.0	13.6	9.3	779	20 *2.6%*	44 *5.6%*	29 *3.7%*	93	11.9%	8.4
10	56.8	14.4	20.6	1268	95 *7.5%*	84 *6.6%*	27 *2.1%*	206	16.2%	6.2
11	22.0	10.6	8.9	521	15 *2.9%*	59 *11.3%*	15 *2.9%*	89	17.1%	5.9
12	40.5	6.8	11.3	328	46 *14.0%*	67 *20.4%*	0 *0.0%*	113	34.5%	2.9
13	48.0	15.3	8.6	730	8 *1.1%*	65 *8.9%*	13 *1.8%*	86	11.8%	8.5
14	19.5	5.7	4.2	166	25 *15.1%*	14 *8.4%*	3 *1.8%*	42	25.3%	4.0
15	58.8	17.2	15.9	1309	74 *5.7%*	78 *6.0%*	7 *0.5%*	159	12.1%	8.2
16	19.0	10.4	4.2	853	21 *2.5%*	20 *2.3%*	1 *0.1%*	42	4.9%	20.3
17	93.0	14.6	14.3	605	12 *2.0%*	131 *21.7%*	0 *0.0%*	143	23.6%	4.2
18	85.5	14.0	16.4	1343	9 *0.7%*	152 *11.3&*	3 *0.2%*	164	12.2%	8.2
19	37.5	5.0	7.5	301	2 *0.7%*	73 *24.3%*	0 *0.0%*	75	24.9%	4.0
20	43.0	18.1	6.8	504	6 *1.2%*	60 *11.9%*	2 *0.4%*	68	13.5%	7.4
21	36.5	15.5	36.3	1010	284 *28.1%*	79 *7.8%*	0 *0.0%*	363	35.9%	2.8
	55.7 (mean)	**15.5 (mean)**	**15.7 (mean)**	**20517 (total)**	**1393** ***6.8%***	**1693** ***8.3%***	**208** ***1.0%***	**3294 (total)**	**16.1% (mean)**	**6.2 (mean)**

[a]Total time all pharmacy team members spent on unit over study period

Table 2: Interventions by Weekdays and Weekends

	Weekdays (Average Day)	**Weekends (Saturdays)**
Number of hospitals with proactive clinical pharmacy service	21	2
Number of interventions addressed by pharmacy team	3294	81
Prescriptions reviewed by pharmacy team	20517	241
Intervention rate[a]	16.1%	33.6%
Proactive interventions[b]	2865 (87.0%)	78 (96.0%)
Interventions accepted by interprofessional team	2887 (87.6%)	67 (82.7%)

[a]Number of prescriptions intervened on by pharmacy team divided by the prescriptions reviewed
[b]Problem identified by intervening pharmacy team member without being approached by another healthcare professional

Table 3: Intervention Rate By Grade of Pharmacy Team Member During the Weekdays

Band	**Description of Grade**	**Number of Interventions**	**Prescriptions Reviewed**	**Intervention Rate (%)**
4 & 5	Clinical pharmacy technician	102	580	17.6
6	Newly qualified pharmacist	80	715	11.1
7	Foundation level pharmacist *RPS Advanced Practice I*	817	4974	16.4
8a	Excellence level pharmacist *RPS Advanced Practice II*	1177	7825	15.0
8b	Excellence/Mastery level pharmacist**	896	5317	16.9
8c	Mastery level (consultant) pharmacist** *RPS Mastery*	222	983	22.6
Total		3294	20,394*	16.6%

**The total number of prescriptions reviewed was 20,517, however some entries have missing bandings*

***The consultant pharmacists were graded at bands 8b and 8c*