Pharmacist's Review and Outcomes: Treatment Enhancing Contributions Tallied, Evaluated and Documented (PROTECTED-UK)

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Title Page

Concise and informative title

Pharmacist's Review and Outcomes: Treatment Enhancing Contributions Tallied, Evaluated and Documented (PROTECTED-UK)

A short running title

PHARMACIST´S INTERVENTIONS IN THE CRITICAL CARE UNIT

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Conflict of interest

The authors declare that they have no conflict of interest

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PURPOSE. To describe clinical pharmacist interventions across a range of critical care units (CCUs) throughout the United Kingdom (UK). To identify CCU medication error rate, prescription optimisation and to identify the type and impact of each intervention in the prevention of harm and improvement of patient therapy.

MATERIALS AND METHODS. A prospective observational study was undertaken in 21 UK CCUs from 5-18th Nov 2012. A data collection web portal was designed where the specialist critical care pharmacist (SCCP) reported all interventions at their site. Each intervention was classified as either: medication error, optimisation or consult. In addition, a clinical impact scale was used to code the interventions. Interventions were scored as low, moderate, high impact and life saving. The final coding was moderated by blinded independent multidisciplinary trialists.

RESULTS. 20,517 prescriptions were reviewed with 3,294 interventions recorded during the weekdays. This resulted in an overall intervention rate of 16.1%: 6.8% were classified as medication errors, 8.3 % optimisations and 1.0% consults. The interventions were classified as: low impact (34.0%), moderate impact (46.7%) high impact (19.3%) and one case was life saving. Almost three-quarters of interventions were to optimise the effectiveness of and improve safety of pharmacotherapy.

CONCLUSIONS. This observational study demonstrated that both medication error resolution and pharmacist led optimisation rates were substantial. Almost 1 in 6 prescriptions required an intervention from the clinical pharmacist. The error rate was slightly lower than an earlier UK prescribing error study (EQUIP). Two thirds of the interventions were of moderate to high impact.

Key words

Critical care, interventions, specialist critical care pharmacist, medication errors, optimisations, impact coding

Introduction

The critically ill patient is at risk of medicines-related adverse events [1], drug interactions and on some occasions inadequate therapy [2]. This risk can be exacerbated by the presence of organ failure or by supportive therapies such as renal replacement therapy. Consequently, interventions to reduce medication errors and optimise therapy are an essential component of patient care. These include electronic prescribing, smart infusion pumps, medicines reconciliation, clinical guidelines and services normally led by a specialist critical care pharmacist (SCCP) [3]. Improving the safety and efficacy of medication therapy in critical care patients is the cornerstone of SCCP activity. Since the first reports of clinical pharmacist interventions in critical care in the mid-1980s [4], there has been a gradual progression from those focused on financial savings in medicine use, to reducing medication errors and more recently to the optimisation of medication therapy [5]. Clinical pharmacists have been reported to improve medicines-related patient outcomes in the use of sedation [6], antimicrobial therapy [7], therapeutic drug monitoring [8] and management of thromboembolism/ infarction [9]. Medicines optimisations by addition or adjustment of pharmacotherapy are becoming more dominant practices [10, 11].

Furthermore, proactive interventions, such as SCCP initiated recommendations made as part of their individual patient review or attendance in multidisciplinary ward rounds, now comprise the majority of medicines interventions made by SCCPs [11, 12].

Despite almost three decades of reports of clinical pharmacist in CCU activity, many important questions remain unanswered. Firstly, the current evidence-base is composed of mainly North American reports and focuses on single centres and often specific intervention types, *e.g.* drug-drug interactions [13] or adverse drug events [14]. As such, how transferable is the existing evidence-base to UK or indeed European practice, how do single site reports reflect wider practice and what is the scope of direct patient care delivered by clinical pharmacy teams ? Although European publications on SCCP in critical care are on the increase [8, 10, 11, 15, 16], variation in clinical pharmacy standards and services are pronounced [5, 17, 18]. The importance of SCCP services in critically ill patients are recognised in national UK intensive care standards [18]. These standards include recommendations for staff skill mix (pharmacist and pharmacy technicians) and recommends that clinical pharmacy services are best delivered using a team approach. More data is required to inform how these clinical pharmacy services should be configured and delivered to support resource decisions.

The speciality of critical care and patient-related factors affect the types of interventions clinical pharmacist make [15]. In addition, the knowledge, skills and level of practice of the clinical pharmacist [19] is another important factor likely to affect the clinical impact of the direct patient care provided. Data on the clinical significance of these SCCP-led direct care activities need to be better described if we are to ascertain the true patient value of the services provided.

In order to begin to answer some of these questions, we conducted a prospective multicentre service evaluation of clinical pharmacist interventions across UK intensive care units (ICU). The aim of the study was to describe, quantify and assess the clinical importance of direct patient care activities of critical care clinical pharmacy teams.

Materials and methods

Design

This prospective observational study was conducted in 21 adult critical care units across the UK over a 14 day period from 5-18th November 2012. A pilot test run was undertaken prior to this to test the data collection web portal and to support SCCP familiarity with the categories and methodology. All SCCP were members of the United Kingdom Clinical Pharmacy Association (UKCPA) Critical Care Group Expert Group. These members were the site co-ordinators of their base hospital's pharmacy team. The study was deemed a clinical audit at University College London (UCL) and need for ethics committee approval was waived. It was consequently registered as a clinical audit at each participating site.

Data collection

At each CCU, every SCCP and pharmacy team member recorded their recommendations/interventions, which they provided as part of their existing role. Intervention episodes were recorded on the specifically created, password-protected web portal. All patient identifiable data was anonymised. The details recorded included a short description of the intervention, type of intervention, severity as decided by reporting pharmacist, whether the intervention was acted on (acceptance), method of communication back to CCU multidisciplinary team and whether the intervention lead to a positive or negative patient outcome. The primary medication that underpinned the intervention was classified by associated body-system, as defined by the British National Formulary .

Activity data including time spent on clinical activities, number of patients seen and medication orders that were reviewed, was also entered on the portal

Interventions

To explore the nature of the interventions made by clinical pharmacists, the number of interventions was quantified. To assess relevant denominators, the following data sets were recorded: the number of new prescriptions reviewed each day (on day 1, all prescriptions were regarded as new) and the number of patients drug charts reviewed. The type of intervention was characterised according to a previously used classification [20] . The CCU team would either accept' or 'reject' the intervention or in some cases the changes would be self-prescribed by 'independent prescribing pharmacists'. The incidence of these were recorded.

Each intervention was categorised by the clinical pharmacist into one of three groups: [1] medication error, [2] optimisation or [3] consult. 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 [21]. Optimisation was defined as a proactive contribution that sought to enhance patient care. A consult was defined as a reactive intervention in response to a request from member of the multidisciplinary team (MDT) for a SCCP review.

Clinical pharmacists

In the UK, a SCCP describes a practitioner who is working at advanced or mastery level, as defined by Royal Pharmaceutical Society Faculty of Advanced Practice [22]. Accreditation by the Faculty is based upon competency, skills and knowledge specific to the speciality of critical care. Certain teams were led by a consultant pharmacist which describes a practitioner working at mastery level with a consultant job plan.

A 'junior pharmacist' is working at or below foundation level in critical care and would typically be working within a team lead by a SCCP.

A number of pharmacists were accredited 'independent pharmacy prescribers' which allows them to prescribe within their sphere of competence, without co-signature by a medical practitioner.

Clinical impact coding

Each intervention was coded for clinical impact/importance to the patient. An established scale was used to code medication errors [21]. A bespoke optimisation and consult scale was created because a validated scale to cover this aspect of pharmaceutical care was not available. The new scale was based on the principles of categorised severity of drug related problems described in the literature [23, 24]. Participants were provided with examples of coding for typical interventions. The error coding was applied on the premise of what the potential consequence would be if the error had not been prevented by the pharmacist's intervention. The optimisation and consult coding was ascribed on the basis of its potential clinical significance to the patient's care.

The individual clinical pharmacist recorded their own impact code. All the interventions were blind-coded by one of the principal investigators (SCCP RS) for the purposes of consistency. Where the codings matched, this was considered the final code. If there was a difference, the intervention was blind-coded by one of two investigators (consultant pharmacists RB and MT). Where two of the codes matched, this was considered the final code. If all three codes disagreed, then a critical care consultant physician (AJ) blind-coded the intervention and the final code was where two codes matched. This was deemed a pragmatic method to deal with the high number of interventions.

Analysis

The data from the web portal was downloaded and analysed using SPSS version 22 (IBM).

Results

Clinical pharmacy teams from twenty one critical care units participated. The demographics of the units and pharmacy teams are described in Table 1. The critical care units comprised of general or specialist intensive care

units (ICUs), high dependency units (HDUs including single organ support and post-operative care) and mixed ICU/HDUs. There were differences in the composition of the pharmacy teams in terms of pharmacist to patient ratio, pharmacist experience, independent prescriber status, team-members role and grading. There were 13 independent pharmacist prescribers and 24 non-prescribing pharmacists in total. Some teams had a clinical pharmacy technician or a student on attachment and their role was focussed on medicine reconciliation. Only two of the units had any weekend proactive clinical pharmacy service, both of which were on Saturdays. Hence the vast majority of the interventions were made on weekdays.

In total there were 3,390 interventions recorded in the 925 patients reviewed by the pharmacy teams, of whom at least one intervention was made in 774 patients (83.7%). Since 97% of these interventions occurred on weekdays, the following results concentrate on the weekdays when a full service was in place. There were 3,294 interventions recorded in of 20,517 medication orders reviewed, equating to a rate of 1 intervention per 6 (16.1%) medication orders reviewed. Of these 1393 (6.8%) were medication errors, 1693 (8.3%) were optimisations and 208 (1.0%) were consults. 2889 (87.7%) interventions were agreed with and actioned by the doctor or self-prescribed by the pharmacist. 6% of interventions were not accepted, whilst the remaining data was lost to follow-up (1.4%) or missing (5.1%). Over half (1956, 59.4%) of the interventions were discussed with the critical care team by the clinical pharmacist attending the bedside multidisciplinary ward round. In other cases the intervention were discussed with individual doctors, in a multidisciplinary handover meeting or were self-prescribed by independent pharmacist prescribers. The impact coding of the interventions made at weekdays are shown in Table 2. Of the medication errors, 19.0% were designated as 'high' impact had they been administered as prescribed and 42.6% were of 'moderate' impact. A similar pattern was seen with the optimisations with 19.0% 'high' and 48.3% of 'moderate' impact. Of the consults, 24.0% were 'high', 60.6% of 'moderate' impact and 0.5% potentially averted a fatal consequence.

The impact scores of the interventions of different types of pharmacy team members are shown in Figure 1. The interventions of the specialist, more experienced team members were of a higher impact score than the more junior pharmacy team members (Kruskal Wallis Test=154.9; $p<0.0001$).

The reasons for the interventions are described in Figure 2. The dominant two categories were to optimise the effectiveness of, and to improve safety of the pharmacotherapy, accounting for 2,432 (73.8%) of all the interventions. The less frequent categories were: medicine reconciliation; conformity to guidelines, communication flow within the critical care team and primary teams and infection control.

Figure 3 describes the problem that the interventions addressed. The most common problem was adding or refining pharmacotherapy to optimally treat the patient. Approximately 15% of the interventions were to stop prescribed drug therapy that was no longer considered necessary. Other frequent interventions related to drug administration, medicines reconciliation, supra or sub-therapeutic drug doses, non-conformity to guidelines, monitoring of drug therapy, instigating supply alternatives to medicines that were unavailable, identifying and investigating adverse drug events, issues of intravenous compatibility and drug interactions.

There was a statistically significant increased proportion of interventions on Mondays (24.1%) versus any other weekdays (range 17.0 to 21.0%) (CHI squared test $p=0.01$)

More than 75% of the interventions were related broadly to central nervous system, cardiovascular, infection, gastrointestinal, nutrition and blood systems. Only a small proportion involved the respiratory system which contrasts to the general focus of medicine in critical care.

Discussion

To our knowledge, this is the first multi-centred study describing clinical pharmacist contribution to the care of the critically ill patient. Overall clinical pharmacists made interventions in almost 1 in 6 prescribed medications (16.1% of prescribed items) and more than 60% of the interventions were of at least moderate impact. Medication errors were found in 6.8% of all prescribed items, which is slightly lower than the 8.9% rate identified by the EQUIP study [25] which specifically examined prescribing error rates by medical staff in multi-site acute hospitals in the UK.

Unlike EQUIP; this study also uncovered a further 8.3% of prescriptions where clinical pharmacists made an optimisation intervention and another 1% of orders where a specific consult occurred, shedding more light on the extent of a pharmacists clinical interactions within this environment in the UK.

In our study, 'high impact' interventions were made in 3.1% of prescriptions, compared with the reported rate of 1.74% in EQUIP (which does not include optimisations and consults), whilst moderate impact interventions were made in 7.7% of prescriptions compared with 5.48% in EQUIP. Many recommendations were made in EQUIP including improving the work environment, the use of standard medication charts and improving the undergraduate education of medical students, whilst acknowledging that the existing systems in place meant that many errors were intercepted by pharmacist before reaching the patient. These recommendations were made on the basis that errors were being predominantly made by junior doctors. Critical care is generally staffed by more experienced caregivers from the multi-disciplinary team (MDT) and whilst the EQUIP recommendation are still valid, we believe that further measures could be made to strengthen the existing systems for error detection and medication optimisation within critical care.

The clinical pharmacists were closely integrated within the clinical teams, with nearly 60% participating on the MDT ward round and approximately 88% of interventions were accepted by the clinical team. The senior or consultant SCCP made interventions with a higher impact than non-specialist pharmacists. This confirms that the UK clinical pharmacist is a vital component of the critical care unit; senior (and consultant) SCCPs should be available to clinically review the more complex patient and train the MDT and junior colleague(s) [18].

The avoidance of unnecessary iatrogenic harm is a key objective of patient safety measures in the acute patient setting [26]. Over a 2 week period, there were 1,393 reported medication errors in 395 patients at weekdays (result not shown). This corresponds with earlier studies confirming that the presence of a clinical pharmacist is an effective method for identifying and rectifying of medication errors. Only 2 of 21 units reported a weekend (Saturday service). The higher proportion of interventions made on Mondays could be attributed to a lack of a clinical pharmacy service from the preceding weekend. The intervention rate was higher at the weekend with rate of 1 in 3 prescriptions [27]. Such data implies that clinical pharmacy services should be reviewed to ensure that every critically ill patient receives pharmaceutical care when needed; 7 days per week and perhaps ultimately 24/7; though the cost-effectiveness of this coverage would need to be explored. It seems counter intuitive to provide an intervention that improves prescribing safety or optimises therapy only on specific days of the week whilst the rest of critical care is delivered continuously.

In Europe, many critical care units do not routinely receive clinical pharmacy services [5]. This is despite evidence that corroborates the important medication safety role of clinical pharmacists in European critical cares [8, 10]. In May 2014, new hospital pharmacy practice standards for Europe were agreed at an international summit in Brussels [28]. These standards were developed to ensure safe and effective medicine use is applied across European health systems. Whilst this study was undertaken in the UK where clinical pharmacy is fully integrated within the National Health Service (NHS). We believe this multi-site study of existing practice contributes to existing evidence and further supports the development of a European standard for the provision of clinical pharmacy services (including specialist services by SCCPs). In 2006, MacLaren et al, [12] reported on the clinical services provided by US critical care pharmacists at the time. The results of our study demonstrate further developments in the fundamental and desirable direct patient care clinical activities delivered by clinical pharmacy teams including SCCPs.

The dominant two categories of clinical pharmacy intervention were to optimise the effectiveness and to improve safety of pharmacotherapy. This accounted for 73.8% of all reported interventions. Alongside prevention of iatrogenic harm; patient safety is paramount in critical care. A gravely ill patient cannot actively participate in decisions on their pharmacotherapy. Thus it is essential that the MDT (nurse, pharmacist and doctor) ensures that the patient is safe and that their therapy is optimised for their needs (including taking account of their pharmacokinetic reserve). The investigators believe that the data from this study are an important addition to the existing literature and affirm the major role the clinical pharmacists and especially SCCPs have in delivering this goal.

It is generally accepted that patients are at greater risk of harm on 'step-down' or transfer of care [29-31]. Medicine reconciliation is a recognised method of reducing the medication related harm [32, 33]. This study confirmed that medicines reconciliation was undertaken by the clinical pharmacist at all participating sites and which is recognised as core in the recently published UK critical care national standard.

There a number of limitations of this study: critical care units were not standardised and the study included all the patients on each CCU, which could include ICU, HDU and a number patients were ready for ward care. Some of the hospitals were treated as though they were one discrete ICU whereas others reported each critical care unit within a hospital group separately. The clinical interventions were self-reported by the SCCP which could introduce bias and potentially those interventions not accepted may have been less likely to be reported. Although this did not appear to be the case at the regular study meetings. The study was solely conducted in the UK, where clinical pharmacists are well established and integrated into critical care team. This may not be the case elsewhere. It is not known how many patients were admitted during the study period and were not seen by the pharmacy teams, e.g overnight and at weekends. Lastly, the impact coding was allocated on the basis of what may have happened if the intervention did not occur, introducing some subjectivity to the coding. We assert that this was partially offset by a series of blinded multi-disciplinary assessors.

Conclusion

We have described a multi-centre study undertaken over a number of critical care units in the UK which identified the high frequency and clinical importance of medication interventions made by clinical pharmacists. These results underline the importance of the direct patient care clinical pharmacists, including SCCPs. The study also informs our understanding on the difference between levels of clinical pharmacist, from junior to consultant SCCP and the likely clinical impact of their practice in improving patient safety and care. The medicines optimisations activities of clinical pharmacist further emphasise that clinical pharmacy is a fundamental component of critical care medicine across the UK and the wider healthcare community.

Conflict of interest

The authors declare that they have no conflict of interest

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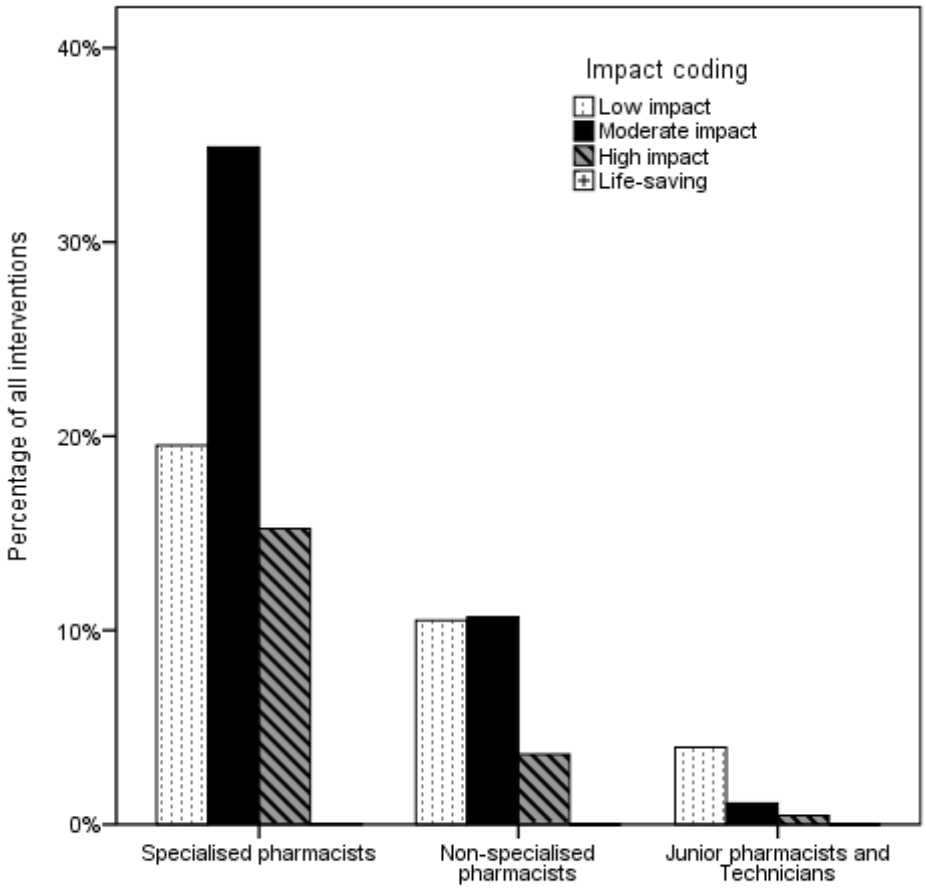

Fig. 1 Impact coding of interventions in relation to critical care practitioner's specialisation

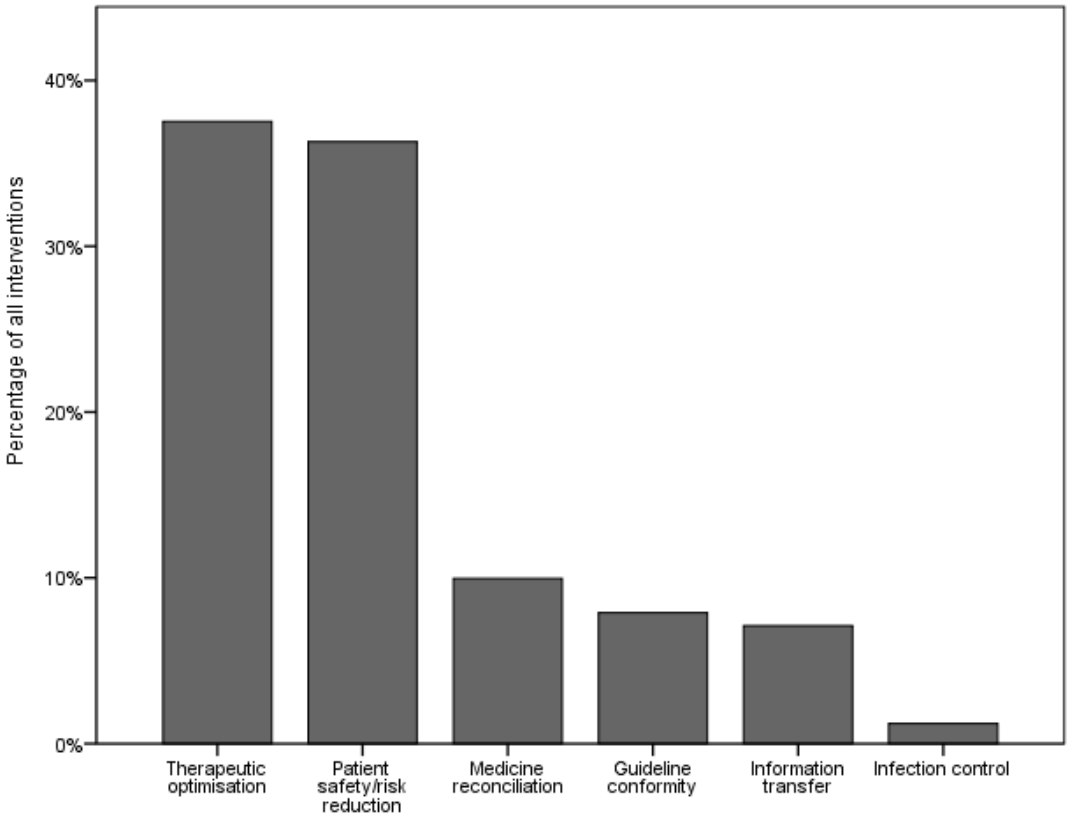

Fig. 2 Underlying reason for intervention

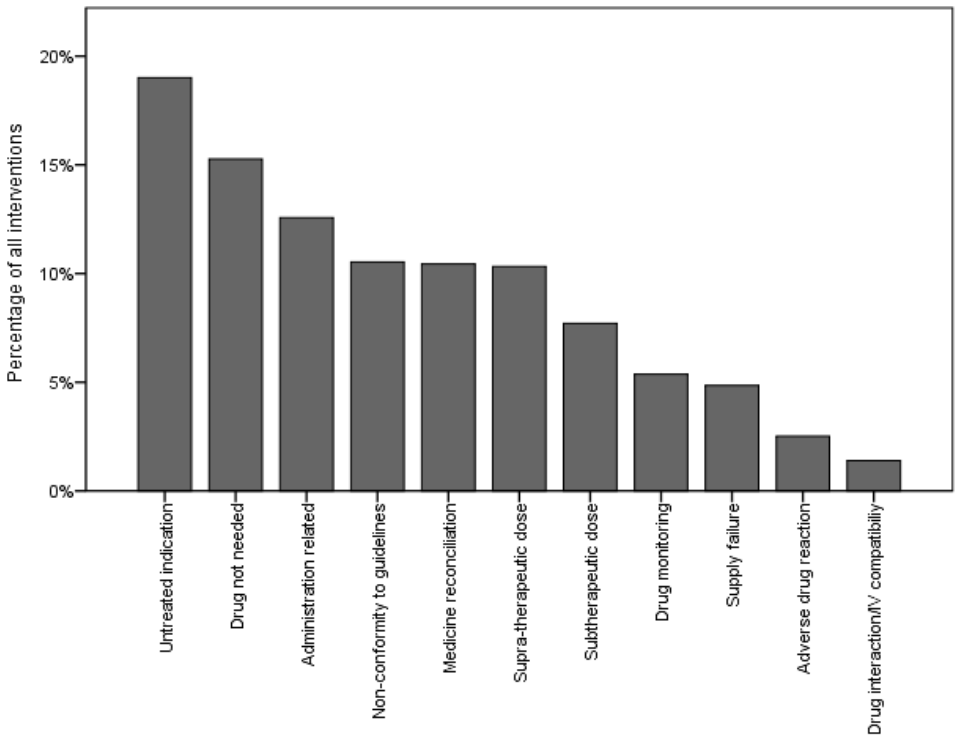

Fig. 3 Problem addressed by intervention

Table 1. Demographics

Hospital	General/specialised unit?	Medical/surgical unit?	Number of beds	Developed team[a]?	Electronic prescribing?	Consultant pharmacist?	Accredited teaching unit?	Weekend service?	How do pharmacists address interventions?
Addenbrooke's Hospital	General	Mixed	20	Yes	No	Yes	Yes	No	Self-prescribed
FIFE Hospital	General	Mixed	9	No	No	No	Yes	No	Bedside ward round
Guy's and St Thomas' NHS Foundation Trust	General	Mixed	80	Yes	Yes	Yes	Yes	Yes	Other
Newcastle Upon Tyne Hospital - Freeman Hospital	Specialised	Mixed	18	Yes	Yes	No	Yes	No	Other
Newcastle Upon Tyne Hospital - Royal Victoria Infirmary	General	Mixed	20	Yes	Yes	No	Yes	No	Other
Oxford University Hospitals	General	Mixed	18	Yes	Yes	Yes	Yes	No	Individual feedback to junior doctors
Portsmouth Hospitals	General	Mixed	22	Yes	Yes	No	Yes	No	Bedside ward round
Royal Free Hospital	General	Mixed	31	Yes	No	No	Yes	No	Bedside ward round
Salford Royal Hospital	Specialised	Mixed	16	No	Yes	No	Yes	No	Bedside ward round
Sandwell and West Birmingham Hospital	General	Mixed	10	No	No	Yes	Yes	No	Bedside ward round
Northern General Hospital - General ICU	General	Mixed	16	Yes	Yes	Yes	Yes	Yes	Multidisciplinary team meeting
Northern General Hospital General HDU	General	Mixed	16	Yes	Yes	Yes	No	Yes	Multidisciplinary team meeting

Royal Hallamshire Hospital General ICU/HDU	General	Mixed	8	Yes	Yes	Yes	No	Yes	Multidisciplinary team meeting
Royal Hallamshire Hospital Neurosciences ICU/HDU	Specialised	Mixed	20	Yes	No	Yes	Yes	No	Multidisciplinary team meeting
St Helen's and Knowsley Teaching Hospital	General	Mixed	14	No	No	No	Yes	No	Other
University College London Hospitals	General	Mixed	35	Yes	Yes	No	Yes	No	Multidisciplinary team meeting
University Hospital Birmingham	General	Mixed	18	No	yes	No	Yes	No	Individual feedback to junior doctors
University Hospitals Southampton	General	Mixed	21	Yes	No	Yes	Yes	No	Bedside ward round
Western Infirmary Glasgow	General	Mixed	9	No	Yes	No	Yes	No	Bedside ward round
West Suffolk Hospitals	General	Mixed	9	No	Yes	No	Yes	No	Bedside ward round
Wrightington Wigan and Leigh Hospital	General	Mixed	11	Yes	No	No	Yes	No	Bedside ward round

[a]Developed team= defined as more than one pharmacist per team

Table 2. Impact coding of the interventions

	Impact coding of the interventions				
Type of intervention	**Low impact**	**Moderate impact**	**High impact**	**Life-saving**	**Total**
Error	536 (16.3%, 38.5%)	593 (18.0%, 42.6%)	264 (8.0%, 19.0%)	0 (0.0%, 0.0%)	1,393 (42.3%)
Optimisation	553 (16.8%, 32.7%)	818 (24.8%, 48.3%)	322 (9.8%, 19.0%)	0 (0.0%, 0.0%)	1,693 (51.4%)
Consult	31 (0.9%, 14.9%)	126 (3.8%, 60.6%)	50 (1.5%, 24.0%)	1 (0.0%, 0.5%)	208 (6.3%)
Total	1120 (34.0%)	1537 (46.7%)	636 (19.3%)	1 (0.0%)	3,294 (100%)

In each case the first percentage is the percentage of total interventions
The second percentage is the percentage of the type of intervention i.e. error, optmisation or consult.