Restructuring supervision and reconfiguration of skill mix in community pharmacy: classification of perceived safety and risk

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Abstract

Background

Broadening the range of services provided through community pharmacy increases workloads for pharmacists that could be alleviated by reconfiguring roles within the pharmacy team.

Objectives

To examine pharmacists' and pharmacy technicians (PTs)' perceptions of how safe it would be for support staff to undertake a range of pharmacy activities during a pharmacist's absence. Views on supervision, support staff roles, competency and responsibility were also sought.

Methods

Informed by nominal group discussions, a questionnaire was developed and distributed to a random sample of 1,500 pharmacists and 1,500 PTs registered in England. Whilst focussed on community pharmacy practice, hospital pharmacy respondents were included, as more advanced skill mix models may provide valuable insights. Respondents were asked to rank a list of 22 pharmacy activities in terms of perceived risk and safety of these activities being performed by support staff during a pharmacist's absence. Descriptive and comparative statistics were performed using SPSS16.

Results

Six-hundred-and-forty-two pharmacists (43.2%) and 854 PTs (57.3%) responded; the majority worked in community pharmacy. Dependent on agreement levels with perceived safety, from community pharmacists and PTs, and hospital pharmacists and PTs, the 22 activities were grouped into 'safe' (n=7), 'borderline' (n=9) and 'unsafe' (n=6). Activities such as assembly and labelling were considered 'safe', clinical activities were considered 'unsafe.' There were clear differences between pharmacists and PTs, and sectors (community pharmacy vs. hospital). Community pharmacists were most cautious (particularly mobile and portfolio pharmacists) about which activities they felt support staff could safely perform; PTs in both sectors felt significantly more confident performing particularly technical activities than pharmacists.

Conclusion

This paper,, presents novel empirical evidence informing the categorisation of activities into 'safe,' 'borderline' or 'unsafe.' 'Borderline' activities will deserve particular attention, especially where they are part of processes, e.g. dispensing. This categorisation could help inform reconfiguration of

skill mix in community pharmacy and thus make an important contribution to the rebalancing medicines legislation agenda and pharmacist supervision.

Key words: community pharmacy; role delegation; scope of practice; role substitution; supervision; pharmacy technician; professional accountability

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BACKGROUND

Community pharmacists internationally now offer increasing levels and ranges of clinical, diagnostic and public health services, in keeping with the profession's growing involvement in patient-focused activities. There is evidence that as a consequence of the delivery of these new services pharmacists may experience substantial increases in workload, high levels of work pressure,[1,2] and conflicting priorities, all factors which may have patient safety implications.[3-8]

To manage this growing workload and enable further service development, it is becoming paramount that the pharmacy team are used at maximum professional capacity. Besides pharmacists, the pharmacy team include medicines counter assistants (in community/retail pharmacy), pharmacy assistants, and pharmacy technicians (PTs),[9] the latter being the highest qualified member of pharmacy support staff. While certification, regulation and registration have been called for for some time, implementation and specific requirements differs across the United States (US).[10,11] In Great Britain, PTs have been required to register with the pharmacy regulator, the General Pharmaceutical Council (GPhC), since 2011, and now form a second group of regulated pharmacy professionals, alongside pharmacists. Concerns have been raised, however, about the level of competence of support staff and the extent to which this might limit safe and effective skill mix and role reconfiguration, with pharmacists in particular voicing unease.[12-19] Addressing these concerns is of paramount importance if service delivery is to be redesigned around the needs of patients in such a way as to not add to the workload of highly pressurised pharmacy teams.

Internationally there is surprising diversity in the operation of community pharmacies. In some countries, such as the United Kingdom (UK) and United States (US), all pharmaceutical services are required to be undertaken or supervised by the pharmacist in charge (therefore requiring the pharmacist to be on the pharmacy premises all or most of the time). In some European countries, there is much more flexibility in pharmacists exercising their responsibility and delegating to pharmacy staff. [20] In Denmark and the Netherlands, for example, qualified pharmacy technicians, or their equivalent, routinely undertake the dispensing of prescription medicines in community pharmacy, without direct pharmacist supervision. In these countries there is effective professional collaboration between physicians and pharmacists practising in primary care, often supported by integrated patient databases. Electronic transfer of prescriptions and original pack dispensing with barcode reconciliation are normal practice.

In the UK the Responsible Pharmacist (RP) regulations make it a requirement that a RP is appointed in each community pharmacy. A legal duty is placed on the RP "to ensure the safe and effective

running of the pharmacy in relation to the retail sale and supply of all medicines" (not other services, such as diagnostics).[21] However, the RP regulations also allow the named 'responsible pharmacist' to be absent from the pharmacy for a maximum of two hours per day, with the intention of enabling pharmacists to provide clinical services to patients and other healthcare professionals away from the registered pharmacy premises. Medicines available for general sale (also known as general sales list, GSL), i.e. those which are also available through retail outlets other than pharmacies, can be sold during this absence. However, the longstanding requirement for sales of Pharmacy (P) medicines, i.e. medicines whose sales are legally restricted to pharmacies, and the dispensing of all prescription-only medicines (POM) to be supervised by a pharmacist who is physically present remains unchanged. Ultimately, this means that during the absence of a RP, and without another, second, pharmacist present, most core pharmacy functions still cannot be performed legally.

However, the need to free pharmacists and allow them to focus on the delivery of clinical, patient-centred services has been widely recognised, and pharmacy technicians may be most suited to support this.[22,23] The UK Department of Health launched a "Rebalancing Medicines Legislation and Pharmacy Regulation" programme in 2012,[24] which re-examines the legal and regulatory framework underpinning supervision requirements for the sale and supply of medicines in registered pharmacies, and whether supervision always requires a pharmacist's physical presence. The reaction of pharmacists to potential changes to supervision (such as remote supervision, the supervision and supply of medicines by a pharmacist who is not physically present) in the pharmacy press has been guarded. This suggests that any future changes need to clarify both the extent to which an individual pharmacist's liability is likely to increase, and the training and competency requirements of support staff needed for them to safely extend their scope of practice.[25]

What is missing from the literature is an analysis of what this uneasiness relates to. It may be about changes in pharmacy supervision as a concept because it is viewed as allowing for the substitution of pharmacists with lower unit cost workers who are less qualified and hence less safe.[18,26] It may also be that particular pharmacy activities are perceived as inherently more or less risky to patient safety in terms of remote supervision and hence might be more or less suited to being undertaken within an enhanced non-pharmacist's scope of practice. Certain pharmacy activities may be more suited to remote supervision and to being safely reconfigured within the pharmacy team structure, whilst others may be too risk-prone. By identifying this variation, potential risks associated with any future changes in supervision could be reduced and acceptability of broadening the scope of practice of support staff could be increased. Whilst previous, mostly US, studies have identified duties, tasks or functions that are or could be performed by pharmacy technicians,[27,28] these studies assumed

pharmacist presence. The present study aimed to examine pharmacy staff perceptions of how safe it would be for support staff to conduct a range of activities during a pharmacist's absence from the community pharmacy premises. As perceptions of risk may vary according to team/ professional role[29,30] the views of both pharmacists and PTs were sought and compared. Due to more advanced skill mix models in hospital pharmacy, responses from this sector were also sought.

METHOD

Questionnaire design

To inform questionnaire design, 4 nominal group discussions (NGDs) were undertaken with pharmacists and pharmacy support staff from community and hospital pharmacy settings, the detailed methods and findings of which have been published elsewhere.[31] The questionnaire was piloted with 5 pharmacists and 3 PTs identified through the authors' own network of contacts. Two versions of the same questionnaire were designed, one for pharmacists, the other for pharmacy technicians (PTs). The main section of the questionnaire, presented respondents with a list of 22 activities; these activities were derived from the NGD findings[31] and were grouped into a list of medicine related activities and service related activities (listed in Table 1). Medicines related activities are those activities mainly associated with the dispensing process that currently require pharmacist supervision, apart from the sale of medication available for general sale, i.e. through pharmacies and other retail outlets. Service related activities are those activities that community pharmacies may provide in addition to their dispensing service. Some services can only be provided by a pharmacist, such as a medicines use review (MUR – a consultation in which the pharmacist ensures that the patient knows how to use their medicines appropriately), new medicines service (NMS – a pharmacist consultation and follow-up with patients who have been prescribed medication that they have not taken before) and minor ailments service (pharmacists can provide patients with P and prescription-only medication for common conditions from a limited formulary, without the need for a prescription). Other service-related activities can be provided by trained pharmacy support staff, such as the provision of health checks, signposting to other services and smoking cessation consultations.

Respondents were posed two questions. Firstly, "If a pharmacist was not physically present on the pharmacy premises for up to 2 hours (but contactable to advise and intervene), it would be safe for suitably trained and competent support staff to… (followed by the list of 22 activities)". The definition of the pharmacist's absence being 'up to 2 hours' was added in order to ground the

question in current practice under the RP regulations. To examine the strength of agreement (or disagreement), a four-point Likert type scale was presented to respondents (1=strongly agree, 2=agree, 3=disagree, 4=strongly disagree). A 'don't know/not relevant' option was also included specifically to allow those working in hospital pharmacy to still respond to items and avoid problems of missing data. Respondents were asked to assume that support staff were suitably trained and competent, as past research has highlighted pharmacists' concerns over support staff training and competence affecting their decision to delegate.[31]

The second question presented the same list of 22 activities and asked "If a pharmacist was not physically present on the pharmacy premises for up to 2 hours (but contactable to advise and intervene), and support staff were to carry out these tasks, the risk to patient safety would be…". A 4 point perceived risk scale (1=no risk, 2=low risk, 3=moderate risk, 4=high risk) was presented to respondents for this question as well as a separate 'don't know' option. The aim of this question was to examine how respondents rated the risks of these activities and to examine the extent to which those activities viewed as safe for support staff to perform were also perceived as being of relatively low risk.

For both questions, support staff were defined as those in possession of National Vocational Qualification (NVQ) level 2 or 3 (or equivalent). An NVQ is a post-secondary school, competency-based qualification usually completed in the workplace. Initially, the research team considered limiting this definition to PTs only (and thus level 3 NVQ and GPhC registered only). However it was apparent from the NGDs and previous studies[9] that not all pharmacies employ PTs and thus some pharmacist respondents may not have any experience of working with PTs.

These questions were followed by a series of statements designed to capture respondents' perceptions about changes to supervision requirements and extending scope of practice of suitably qualified support staff, and were intended to explore attitudes to reconfiguring skill mix. These were based on a previous study[25] and developed following the NGDs. The same four point likert-type scale of agreement was used (1=strongly agree, 2=agree, 3=disagree, 4=strongly disagree).

Sample

The questionnaire survey aimed to gather views from a representative sample of pharmacists and PTs in England so that the findings would be generalisable to the wider population. Following submission and approval of a request for the release of data for research purposes, and instructions on how to select a random sample, the GPhC provided a register extract of 1,500 pharmacists and

1,500 PTs based in England. The database contained the respondents' encrypted names, addresses and email addresses (where available). Although this study focused on changes in community pharmacy supervision, sampling by sector was not possible as the GPhC register does not contain sector information. A filter question was employed at the start of the questionnaire asking only those working in community and hospital pharmacy to complete the full questionnaire; pharmacists working in other sectors (e.g. industry and academia) were asked to indicate their sector and return the rest of the questionnaire blank. Hospital pharmacists' views were sought, as team structures have already been reconfigured in this sector,[18] with PTs safely adopting an enhanced scope of practice (defined as what a healthcare professional is educated, competent and authorised to perform[32]) that allows pharmacists to work at their maximum, clinical capacity, delivering services away from the dispensary. Thus, whilst clinical checks are still performed by pharmacists in the hospital setting, other functions, may be performed by support staff without direct pharmacist supervision. One such function is accuracy checking, which is separate from a clinical check and involves checking of the selected medication including dosage and labelling against what is prescribed. Qualified 'accuracy checkers' can check a prescription that has been assembled by another member of pharmacy staff (but not one they have assembled themselves). This can free up time for pharmacists, who would traditionally perform an accuracy check alongside their clinical and legal checks, for other (more clinical) tasks. It was felt that such experiences in the hospital setting of working outside of traditional job demarcations and established divides between who does what could help to inform the future evolution of supervision and service delivery in community pharmacy. It was therefore decided to aim this questionnaire at 4 professional groups: community pharmacists and PTs, and hospital pharmacists and PTs. Acknowledging that some activities may not be relevant to all and to ensure that respondents, particularly those from hospital, were not forced to express views on community pharmacy activities they were less familiar with, a category of 'don't know/ not relevant' was included in the questionnaire design.

Questionnaire distribution

Prior to postal distribution of the questionnaire, an email notification was sent to those in the sample whose email addresses were available (n=2786. 93%). Paper questionnaires were distributed to potential respondents with a covering letter, information sheet and freepost return envelope at the beginning of August 2012. Each individual was assigned an ID number to enable reminders to be sent to non-responders. In an effort to boost response rates, online versions of the questionnaire were also developed using selectsurvey.net. Non-responders received a reminder letter including another copy of the questionnaire and an email reminder containing a link to the

online version approximately 4 weeks later. Two weeks following this, a second email reminder was sent.

Analysis

Mean agreement and risk levels were calculated using the 4-point Likert-type scale for each professional subgroup (community pharmacists, community PTs, hospital pharmacists and hospital PTs) and activity. The fifth response option, the 'don't know/not relevant' category, was separate from the likert-type scale and thus these responses were excluded from the analyses. This also served to strengthen the validity of the analysis, as not all activities may be relevant to all professional groups. The Mann-Whitney U test was also used to examine significant differences in response between profession/sector groups. Statistical significance was defined as $\rho \leq 0.05$. SPSS (Statistical Package for the Social Sciences) v16 was used to perform the analysis. Microsoft Excel was used to create graphs and figures. The study received ethical approval from the University of Manchester Research Ethics Committee 1 (ref 11375).

RESULTS

The survey achieved an overall response rate of 50% (57.3% for pharmacy technicians (PTs) and 43.2% for pharmacists). As sector information was not included in the sample provided by the GPhC, it was not possible to calculate response rates by sector.

Categorisation of activities

Figure 1 shows the mean agreement score (strongly agree=1; strongly disagree=4) in response to "if a pharmacist was not physically present on the pharmacy premises for up to 2 hours (but contactable to advise and intervene), it would be safe for suitably trained and competent support staff to… " for each activity, and in relation to each professional subgroup (community pharmacists, community PTs, hospital pharmacists and hospital PTs). The black horizontal line shows the cut-off point for agreement, i.e. where the mean ≤2 [agree].

Based on these mean scores, the 22 activities were categorised into three groupings: those that were 'safe'; 'borderline'; and 'unsafe' (Table 2). 'Safe' activities achieved a mean of ≤2 for each professional subgroup . 'Borderline' activities did not achieve a mean of ≤2 from every professional subgroup, but did achieve this from at least one. 'Unsafe' activities did not achieve a mean of ≤2 from any of the professional subgroups, i.e. all groups disagreed that these activities could be safely performed during a pharmacist's absence (mean > 2).

Figure 2 shows the mean perceived risk (1=no risk through to 4=high risk) for the 22 activities for each profession. The activities are ordered by the same categorisation as in Figure 1.

'Safe' activities

On average, all groups perceived the risk of the 7 'safe' activities to be either no or low risk[1] (mean of ≤2), except for community pharmacists in relation to the labelling of prescription items (mean = 2.07). Moreover, for all 7 'safe' activities, community PTs tended to be more strongly agreed that these activities were safe to perform than the other subgroups (Figure 1). Similarly, community PTs on average perceived the risk of these seven activities to be lower than the other professional subgroups (Figure 2). Generally, community pharmacists were less likely to have agreed that these activities could be performed safely than the other three subgroups. There was a tendency for hospital PTs to be less strongly agreed about the safety of certain activities which are not usually performed in hospital pharmacy, such as the sale of GSLs and healthy living advice.

Mann Whitney U tests indicated significant differences in agreement levels between community (C) PTs and community pharmacists (CPs) for all 7 safe activities (all $\rho < 0.001$); CPTs were most likely to agree that the 7 activities were safe. Differences in agreement between hospital pharmacists (HPs) and HPTs were only significant for 4 of the 7 activities, with HPTs being more in agreement about the safety of taking in prescriptions, signing for deliveries, assembling and labelling prescriptions than hospital pharmacists (all $\rho < 0.001$). Between community and hospital PTs there were significant differences in agreement levels for the sale of GSL ($\rho < 0.001$), labelling ($\rho = 0.017$), signposting ($\rho < 0.001$) and providing healthy living advice ($\rho = 0.002$), with CPTs expressing more agreement that these activities were safe. There were no significant differences detected between the agreement levels of community and hospital pharmacists indicating an alignment of view for these activities by profession regardless of sector.

'Borderline' activities

Nine activities were categorised as 'borderline' (Table 2) – that is, they did not achieve a mean score of ≤2 from every professional subgroup, but did achieve this from at least one professional subgroup (Figure 1). CPs were least likely to agree that these activities could be performed safely and most likely to rate activities as risky compared with other subgroups in the sample. For the activities 'accuracy checking' and 'dispensing established repeat prescriptions', CPs were the only group not in overall agreement that these activities could be safely performed. The 'handing out of checked and

[1] 'Healthy living advice' received a mean risk rating of 2.01 from hospital pharmacists.

bagged prescriptions' achieved almost near overall agreement from all groups except CPs as well (HP mean rating = 2.03). HPTs, on average tended to be most strongly agreed that the 'borderline' activities were safe to perform, apart from smoking cessation consultations and health checks, which received higher levels of agreement from CPTs. Again, this finding may be related to the types of tasks that those based in different sectors are most familiar with.

While CPs' perceptions of safety and risk tended to correspond, this was not the case for the other subgroups (see Figures 1 and 2). For example, HPs on average rated the risk of dispensing established repeat medications to be more than moderate (mean = 2.37), but were still on average agreed that this activity was safe for support staff to perform (mean = 1.99). For both HPTs and CPTs, the selling of P medicines and accuracy checking achieved an average risk rating of above 'moderate', but both groups, on average, still considered these activities to be safe for them to perform during a pharmacist's absence, perhaps indicating that this is an area where PTs might safely extended their scope of practice.

For all 9 borderline activities, CPTs were significantly more likely than CPs to agree that they could safely be undertaken by suitably trained support staff (all $\rho < 0.001$. Similarly, there were also significant differences in agreement levels between HPTs and HPs (all $\rho \leq 0.023$) for 7 of the borderline activities, with HPTs expressing higher safety agreement levels than HPs. No significant differences were found for the provision of health checks and smoking cessation services. For the majority of the borderline activities, HPTs expressed significantly higher levels of safety agreement than CPTs, except for the provision of health checks and smoking cessation services, which attracted higher levels of agreement from CPTs than HPTs. No significant differences were found between these groups for 'handing out checked and bagged prescriptions' and 'selling P medication.' Comparing between CPs and HPs, for 7 of the borderline activities, HPs had significantly higher safety agreement levels than CPs (all ≤ 0.012). Again, no significant differences were present for the provision of health checks and smoking cessation services.

'Unsafe' activities

The remaining 6 pharmacy activities achieved a mean agreement level greater than 2 from each of the 4 professional groups, and are thus the activities which attracted the strongest disagreement from the respondents. Overall, these activities can be considered to be the most clinical and least technical of the 22 activities and thus more firmly situated in the domain of the pharmacist in terms of appropriate knowledge and skill.

Generally, risk perceptions for all professional groups were highest for these activities. There was consensus between the groups that 'advising patients about POMs,' 'providing clinical advice to patients,' 'providing NMS' and 'conducting MURs' were the 4 activities perceived as most risky for support staff to perform. However, both CPTs and HPTs tended to rate these activities as lower risk than pharmacists from both sectors.

Although on average all groups felt that these 6 activities were unsafe for support staff to perform during a pharmacist's absence, a similar pattern between subgroups was observed in terms of the extent to which they were likely to agree/disagree. Thus CPTs were significantly more likely to agree than CPs that support staff were safe to perform these activities (all $\rho < 0.001$). Similarly HPTs were more likely than HPs to agree that these could safely be performed (all $\rho \leq 0.032$); and HPTs were more likely to agreed than CPTs. Between HPTs and CPTs there were significant differences observed for the provision of medication under Patient Group Directions (PGDs[2]), POM advice, NMS and MUR, with HPTs expressing higher agreement levels. Following the pattern of the borderline activities, the unsafe activities also demonstrated further divergence in opinion levels between CPs and HPs, with significant differences found for all 6 unsafe activities, with HPs expressing higher safety agreement levels than CPs (all $\rho \leq 0.034$).

Perceptions on supervision and attitudes to reconfiguring skills mix

The series of statements shown in Figure 3 give an indication of each professional group's overall readiness to change. Community PTs were more in favour of legislation being changed to enable PTs to perform more activities when the responsible pharmacist was absent than the other subgroups. A similar but subtly different statement that 'pharmacy technicians should be able to perform more tasks when there is no pharmacist present' attracted greater agreement from CPTs, but lower disagreement from the other three subgroups than the legislation change statement. For both these statements, responses differed significantly when comparing between CPTs and CPs (both $\rho < 0.001$) and HPTs and HPs (both $\rho \leq 0.005$). There were also significant differences between CPTs and HPTs for these statements, with CPTs more likely to support legislation change ($\rho < 0.001$) and performing more tasks during a pharmacist's absence ($\rho = 0.021$).

On average, the statement 'now that PTs are registered professionals, they should be more accountable for the tasks they perform' achieved agreement from all professional groups (mean of ≤ 2).[3] However, despite this, significant differences were found between the responses of CPTs and

[2] PGDs allow pharmacists to supply prescription-only medicines under strict protocols.
[3] This statement achieved a mean of 2.01 from CPTs

CPs, with CPs being more in agreement than CPTs ($\rho < 0.001$), and similarly between HPs and HPTs ($\rho = 0.022$). No significant differences were found for this statement between HPs and CPs, and HPTs and CPTs.

The negatively phrased statement eliciting views on confidence in the competence of support staff achieved consistent disagreement from all groups, indicating that overall all groups were confident that pharmacy support staff were competent enough to perform more tasks when the responsible pharmacist was absent. However, significant differences were detected between groups for this statement. CPTs were significantly more likely to disagree with this statement than CPs ($\rho < 0.001$), as were HPTs in comparison with HPs ($\rho = 0.005$). HPs were also more likely to disagree, indicating greater confidence in support staff than CPs ($\rho = 0.027$). There were no significant differences between CPTs and HPTs for this statement.

Similar mean levels (range 2.46-2.60) were seen across all professional groups concerning whether or not the role of PTs had changed since becoming registered professionals, suggesting overall disagreement that their role had changed.

DISCUSSION

Against the background of potential changes to supervision requirements in the UK to enable pharmacists to take on more clinical roles, this paper has examined the perceived safety of pharmacy support staff extending their scope of practice to perform different activities during a pharmacist's absence. This is the first study to categorise 22 medicines and service related activities as 'safe', 'borderline' and 'unsafe' according to the perceptions of community pharmacists, hospital pharmacists, community pharmacy technicians (PTs), and hospital PTs. These findings thus provide valuable and detailed insights which can inform policy formation around supervision requirements and effective skill mix in community pharmacy, with or without a pharmacist's presence.

Seven activities were on average considered 'safe' by each professional group and the perceived risk for the majority of these activities was either no or low risk amongst each professional subgroup. The largest difference in opinion was between community pharmacists and community PTs, where PTs were more likely to view activities as appropriate for them to perform.[33] Differences between hospital and community PTs were also found and may be explained by the level of familiarity those in different sectors have with individual activities. Community pharmacist and hospital pharmacists' perceptions of safety appeared to be aligned for these activities. Findings suggest that if supervision changes were made to enhance the role or skills of support staff and extend their scope of practice

during a pharmacist's absence, then these 7 activities could be adopted into a revised model of supervision.

Nine activities were classified as 'borderline' due to variation in perceived safety and risk between the professional groups surveyed. These can be viewed as the activities likely to cause most controversy and debate if they were to be included in any proposed supervision reforms. Overwhelmingly, community pharmacists expressed the highest levels of disagreement that these 'borderline' activities could be performed by support staff during their absence and were the most cautious group in relation to their perception of risk.

One group of medicines which deserve attention are those available to buy over-the-counter (OTC), without a prescription (GSL and P medicines) as they are considered an important aspect of community pharmacy practice. Whilst GSL medicines can already be sold in non-pharmacy outlets and during a pharmacist's absence, P medicines currently require pharmacist supervision. Although PTs in both sectors agreed that the sale of P medicines within standard operating procedures (SOPs) was safe, in particular community pharmacists were less agreed. Nominal Group discussions had revealed that some community pharmacists thought the selling of other P-medicines could only be considered if certain high-risk P-medicines (e.g. those with the potential risk of abuse or misuse) were excluded and strict protocols implemented.[23,31] Sufficient reassurance would also need to be provided that support staff are appropriately trained and competent, recognise their own limitations and thus know when referral to the pharmacist is required.

Three further activities deserve particular attention, 'handing out checked and bagged prescriptions,' 'dispensing established repeat prescriptions,' and 'accuracy checking,' as the only respondent group not in agreement that these activities could be safely performed during a pharmacist's absence were community pharmacists. As shown in Figure 4, these 3 activities form a crucial part of the dispensing process. Without them the dispensing process comes to a halt, effectively nullifying any potential gain from performing the other 'safe' activities in a pharmacist's absence. Given these 3 activities also align with the medicines supplier identity of community pharmacists[34,35] attempts to reconfigure skill mix to include them are likely to challenge pharmacists' sense of 'who they are', or self-concept, in relation to their work.

On average, hospital PTs appeared to be the most comfortable and least cautious about performing these 'borderline' activities and there was greater divergence in opinion between hospital and community pharmacists for these activities, with hospital pharmacists perceiving them as relatively less of a risk to safety. These findings suggest that hospital PTs may have more experience of

carrying out these activities, and that hospital pharmacists may have greater experience observing PTs conducting these tasks, and hence of PTs safely operating within an extended scope to their practice which is underpinned by an alternative skill mix model.[18] These findings indicate that there may indeed be lessons that community pharmacy could learn from the supervision arrangements in hospital pharmacy, which confirms the value of adding these groups in this study.

The remaining 6 activities were classified as 'unsafe' and attracted some of the highest levels of disagreement and highest risk ratings from all professional groups. Differences between the professionals groups were still seen, with PTs from both sectors tending to express more agreement that these activities could be safely performed. However, given the overall perceived risk associated with these activities it may be inappropriate for support staff to perform them during a pharmacist's absence. Those activities categorised as 'unsafe' all involve clinical skills which only a pharmacist is qualified in and therefore are not appropriate for PTs to take on within any model proposing an extension to their scope of practice, as it would involve the 'substitution' of pharmacists with PTs – that is, expanding the breadth of PTs' jobs in such a way that they are involved in working across professional divides, effectively exchanging PTs for pharmacists. Such substitution is likely to be perceived as both a risk and a threat to the pharmacist profession and to patient safety,[26] with activities requiring clinical knowledge remaining reserved for pharmacists.[23,28] Therefore, it is unlikely that activities, such as clinical checks, providing clinical advice to patients (regardless of whether this is with regards to prescription or OTC (P) sales or POMs, providing minor ailment services, MURs or NMS), should be performed by support staff in a pharmacist's absence. For the dispensing process shown in Figure 4 this means that a clinical check by a pharmacist would have to have been incorporated (for non-repeat prescriptions) at some point during the dispensing process (before the pharmacist leaves the premises), or through utilisation of remote technology. If clinical advice is required, then a reliable system needs to be established to ensure the patient receives this promptly.

These findings raise important questions about the readiness of the community pharmacy profession for change[36] and for reconfiguring skill mix in order to support this change.[37] The four professional groups examined in this paper appear to be at different stages in terms of their readiness for a reorganisation of the supervision model. Those appearing to be least ready for change are community pharmacists, the one group whose buy-in is most required for any revised model to work, where effective skill mix is essential in order to free up pharmacists for more clinical, patient-focussed activities. However, in terms of the readiness for change explored in our questionnaire, there was general agreement across professional groups that pharmacy support staff

were competent to perform further activities when the responsible pharmacist was absent. Although community pharmacists were the most reserved in terms of their views, they agreed that 'now that PTs are registered professionals, they should be more accountable for the tasks they perform,' as did hospital pharmacists. The reverse was observed for community PTs, who were most confident to perform more activities during a pharmacist's absence, yet less sure about having increased accountability for these. It will therefore be imperative that clarity be provided, possibly by the professional regulator and/or the UK government's Department of Health rebalancing programme,[24] on pharmacists' and PTs' roles (scope of practice), responsibilities and accountability, so that greater acceptability of changes to the supervision model by community pharmacists can be achieved.

Strengths and limitations

One potential limitation of this research is that questionnaire respondents were asked to consider support staff generally (both NVQ level 2 and 3 staff) when making their assessments of safety and risk, but it is recognised that the competencies and knowledge of PTs (NVQ level 3) may be more advanced than those of pharmacy/dispensing assistants (NVQ level 2).[38,39] PT respondents may have been likely to base their answers on their own level of competencies as PTs, whereas pharmacists may have based their answers on staff with a lower level of competency, which may have contributed to their lower agreement scores.

It is recognised that the scales used in this analysis are ordinal and not strictly interval data. Although commonly used, there is considerable debate as to whether it is appropriate to use a measure of the mean for these types of data. The authors have chosen to follow the convention of viewing Likert-type scales as interval data, but acknowledge this as a potential limitation.[40-42] The purpose of this analysis was to enable categorisation of activities, in terms of consensus amongst the respondents, as to which activities were considered safe or not and which were considered high/low risk. Taking a mean level of agreement was considered the most appropriate measure for this. Measures of central tendency considered appropriate for ordinal data, such as the median or mode were decided against as they resulted in a loss of detail and the more subtle variation in opinion between the groups. The results/categorisations were checked against the percentage level of agreement (which involved binarising the Likert-type scale into 'agree'/'disagree'). Using an agreement level of 75% or above provided an identical categorisation of activities.

This paper provides valuable evidence to inform and underpin current developments and consultations into the requirements for pharmacist supervision, which are being reviewed by the Department of Health in England and the UK Medicines and Healthcare Products Regulatory Agency

(MHRA),[24] but have received mixed press amongst the pharmacist profession.[43-50] Besides involving participants working in community pharmacy (the sector of focus for any potential changes to future supervision arrangements), hospital pharmacy staff were also included in this study, allowing valuable comparisons between the sectors, with some insights potentially informing further developments in community pharmacy.

Conclusion

This paper provides an evidence base for any future potential changes to the pharmacy supervision model in the UK. It also provides important insights into effective use of skill mix to free up pharmacists for more clinical, patient-centred services. It demonstrates that those truly clinical skills still sit firmly in the domain of the pharmacist without threat of boundary encroachment from pharmacy support staff. More technical tasks could 'safely' be incorporated with an enhanced scope of practice of support staff, to allow the pharmacist freedom and time to provide other services in or away from the pharmacy. Disagreement, especially from community pharmacists, about the safety of a number of 'borderline' activities which form a crucial part of the dispensing process, highlight a potential sticking point in the future development of the supervision model, which will require careful consideration and navigation. In a revised model of supervision, pharmacy technicians appear to be the most obvious choice for taking on extended roles, being the most qualified and registered professionals themselves. Providing clarity on roles, responsibilities and professional accountability of pharmacists and pharmacy technicians may go some way to appease community pharmacists and increase acceptability of future supervision changes.

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Table 1: List of the 22 pharmacy activities included in questionnaire

Medicines related	Service related
Sell General Sales List (GSL) medication	Conduct a smoking cessation consultation
Sell Pharmacy (P) medication following standard operating procedures (if no need for referral /intervention)	Provide health checks (e.g. blood pressure, weight check)
Take in prescriptions	Signposting to other services
Sign for controlled drug (CD) deliveries	Provide healthy living advice to patients
Sign for deliveries of medicines (not CDs)	Provide a minor ailments service
Assemble (without labelling) prescriptions (not CDs)	Provide New Medicine Service (NMS)
Label prescription items (not CDs)	Conduct Medicine Use Reviews (MURs)
Accuracy check items, if dispensed by someone else (not CDs)	
Hand out checked and bagged prescriptions (which do not require pharmacist advice or intervention)	
Have access to the CD cupboard to put away items	
Give patients advice about Prescription Only Medicines (POMs)	
Carry out extemporaneous preparation	
Give clinical advice to patients	
Dispense established repeat prescriptions (which have already had a previous clinical check)	
Provide medicines under Patient Group Direction (PGD)* (e.g. chloramphenicol, not Emergency Hormonal Contraception). **PGDs are a legal framework which allows health care professionals to supply POMs without prescription, within a written group protocol or guideline.*	

Table 2: Categorisation of the 22 pharmacy activities

'Safe' activities	'Borderline' activities	'Unsafe' activities
Take in prescriptions	Conduct a smoking cessation consultation	Provide a minor ailments service
Sell General Sales List (GSL) medication	Provide health checks (e.g. blood pressure, weight check)	Provide medicines under Patient Group Direction (PGD) (e.g. chloramphenicol, not Emergency Hormonal Contraception)
Sign for deliveries of medicines (not CDs)	Hand out checked and bagged prescriptions (which do not require pharmacist advice or intervention)	Give patients advice about Prescription Only Medicines (POMs)
Assemble (without labelling) prescriptions (not CDs)	Dispense established repeat prescriptions (which have already had a previous clinical check)	Give clinical advice to patients
Label prescription items (not CDs)	Sell Pharmacy (P) medication following standard operating procedures (if no need for referral /intervention)	Provide New Medicine Service (NMS)
Signposting to other services	Accuracy check items, if dispensed by someone else (not CDs)	Conduct Medicine Use Reviews (MURs)
Provide healthy living advice to patients	Sign for controlled drug (CD) deliveries	
	Have access to the CD cupboard to put away items	
	Carry out extemporaneous preparation	

Figure 1 : Mean agreement levels for pharmacy activities Scale of 1=strongly agree 2=agree 3=disagree 4=strongly disagree

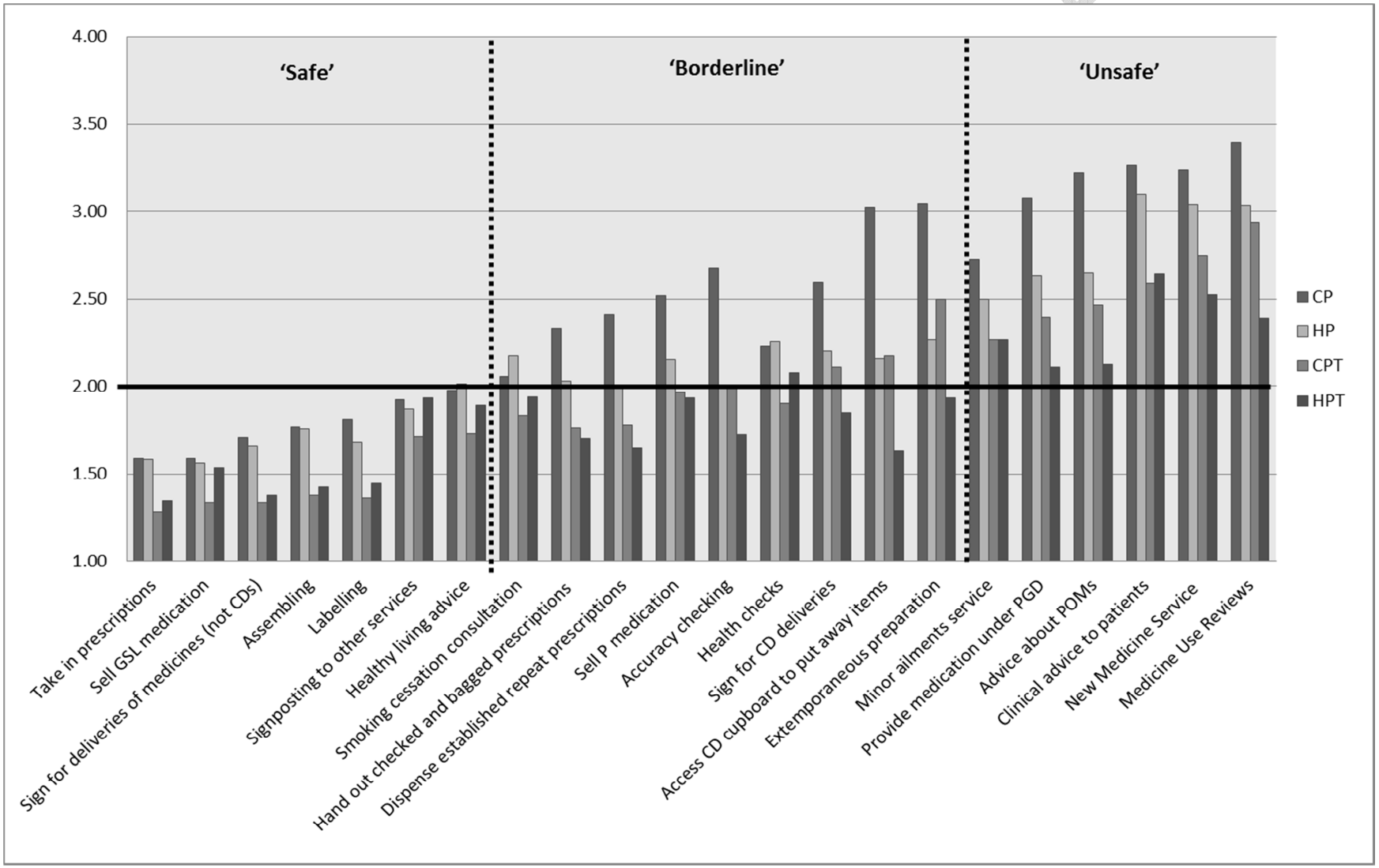


Figure 2: Mean risk rating levels for activities Scale of 1=no risk 2=low risk 3=moderate risk 4=high risk

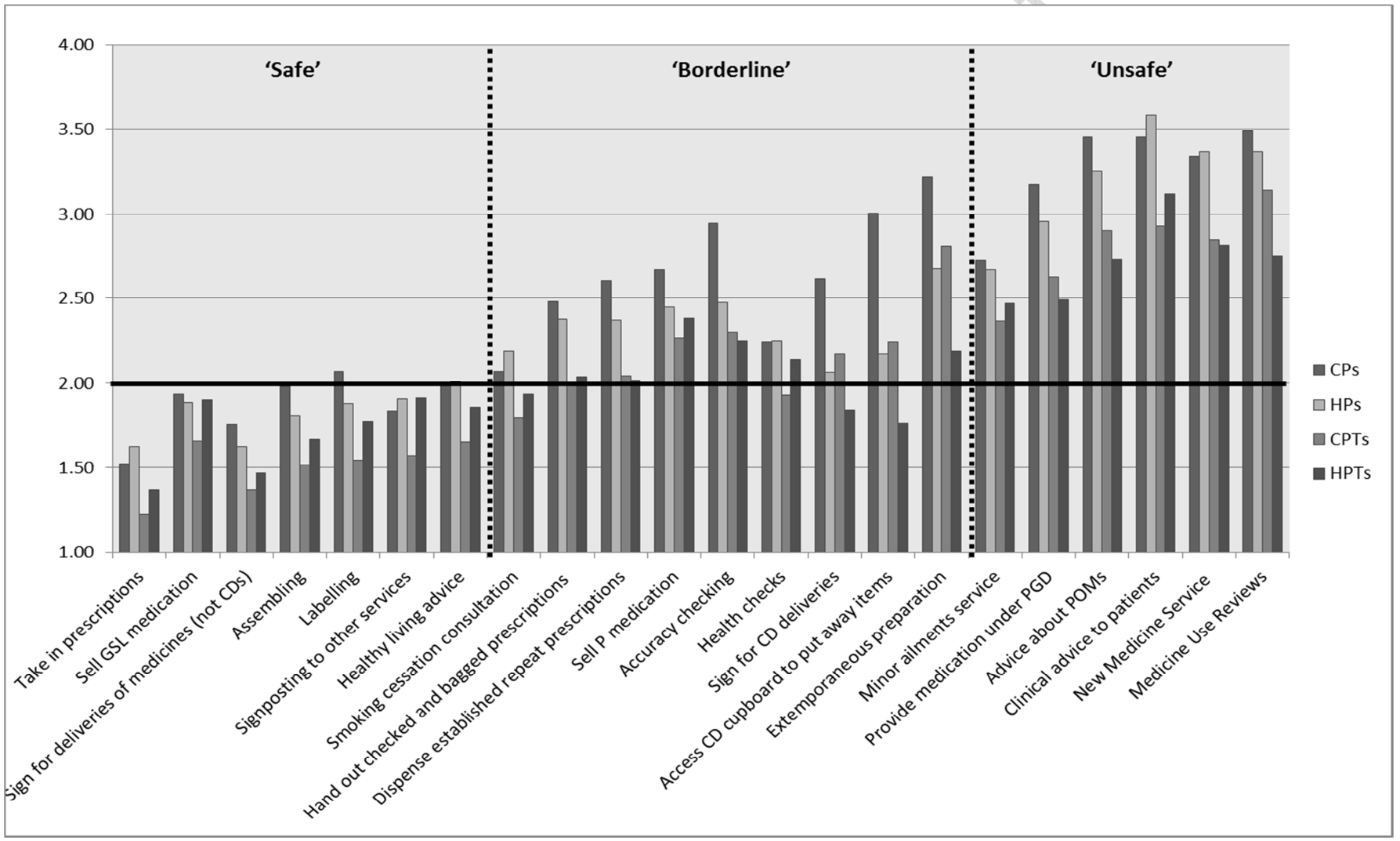
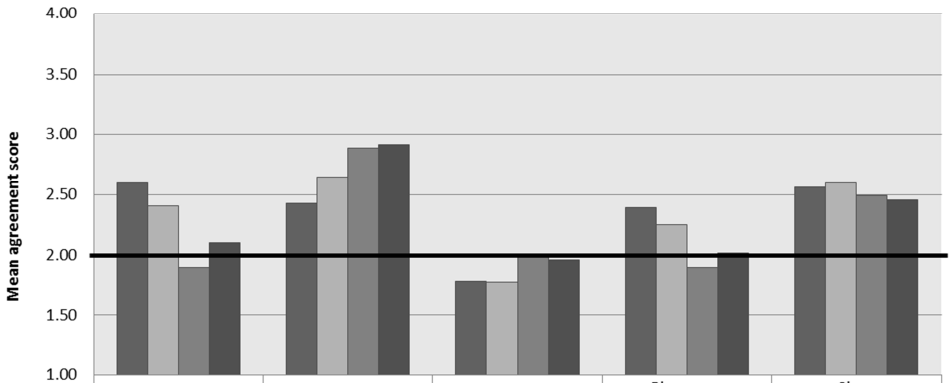


Figure 3: Mean agreement levels for perceptions of supervision and attitudes to skill mix reconfiguration (scale of 1=strongly agree, 2=agree, 3=disagree, 4=strongly disagree)



	Legislation change - support staff to perform more tasks when RP absent	I am not confident that support staff are competent enough	Pharmacy technicians should be more accountable	Pharmacy technicians should be able to perform more tasks when no pharmacist present	Since registration, the role of pharmacy technicians has changed
CPs	2.60	2.43	1.78	2.39	2.56
HPs	2.41	2.65	1.77	2.25	2.60
CPTs	1.89	2.89	2.01	1.89	2.49
HPTs	2.10	2.92	1.96	2.02	2.46

Figure 4: The dispensing process and categorisation of activities (a-d 'safe'; e-g 'borderline'; h and I 'unsafe')