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Enhanced clinical pharmacy practice in the emergency department: what is it, and what does it mean for patient care?

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Background

This project is timely in its focus on the UK emergency department (ED). In March 2018, ED performance as measured by the 4-hour target reached a record low, continuing a downward trend that began in summer 2009 (1). There are many reasons for continuous poor performance, not least a shortage of healthcare professionals – particularly doctors – to staff these departments (2). Health Education England and other stakeholders have looked to and invested in non-medical professions to supplement these shortages and meet patient demand. For example, in 2015, Health Education North West commissioned the Division of Pharmacy and Optometry at the University of Manchester to provide advanced clinical skills training to clinical pharmacists (3). Tailored to an emergency care setting, the ‘Advanced Clinical Skills’ (ACS) course delivered training in how to clinically examine patients, produce a management plan and provide treatment. Similar courses also became available at other institutions, although these were not specific to pharmacists. Graduates began to work in an ‘enhanced clinical role’ in the ED.

To gain some understanding of their roles, visits were undertaken to observe the practice of these ACS qualified pharmacists. They appeared to use both their traditional clinical pharmacy skills and newly acquired skills side-by-side, something previously described in the *Pharmaceutical Journal* (4). For example, they would take a traditional drug history from a patient but then also progress this to a full medical history and maybe also perform a clinical examination.

At a similar time, the findings of a Health Education England (HEE) study concluded with the hypothesis that pharmacists with additional clinical skills training could manage 36% of ED patients as part of a multidisciplinary team (5). This created further interest and likely increased role implementation, but also led to further questions; what were these pharmacists *actually* doing, and how can we evaluate whether they add value to existing emergency care provision? This project sought to answer these questions and has been structured in two parts:

Stage A

Study title: An investigation of Emergency Department Pharmacist Practitioners in the United Kingdom (ENDPAPER study)

Aim: to define and describe the Emergency Department Pharmacist Practitioner (EDPP) role

Specific objectives investigated EDPPs:

- Contribution to direct patient care (“treatment performed through interaction with the patient(s), direct social actions and counselling”) (6)
- Contribution to the wider ED, including indirect patient care (“actions performed away from the patient, but on his/her behalf or on behalf of a group of patients,

where these actions support the overall effectiveness of direct care interventions”) (6)

Research question: what is the work of EDPPs?

Stage B

Aim: to develop the methods required to evaluate the impact of EDPPs on quality of care

Specific objectives were to:

1. Develop an EDPP quality evaluation framework of structures, processes, outcomes and outcome indicators
2. Identify a priority outcome and begin development of methods to evaluate associated indicators
3. Develop process standards (a service specification)

Research question: what are the methods required to evaluate the impact of EDPPs on quality of care?

Informed by observation visits, wider anecdotal evidence and preliminary investigation by HEE, the following hypothesis was developed to guide all aspects of the research, ensuring all possible aspects of the EDPP role would be considered:

“EDPPs undertake both traditional clinical pharmacy work and new ‘practitioner’ work”

Methods

Stage A

The study had EDPPs report their activities in the ED over 10 work days using a purpose developed two-part questionnaire (ENDPAPER-Q). Hosted on the iPad application Form², Part 1 focused on patient care activities and Part 2 their contribution to the wider ED. On days of their choosing, EDPPs were asked to complete Part 1 every time they contributed to a patient’s care, and Part 2 twice a day.

Inclusion and exclusion criteria

Eligible participants:

- Were a pharmacist registered with the General Pharmaceutical Council or the Pharmaceutical Society of Northern Ireland
- Worked in a UK ED (part-time or full-time) including Type-3 EDs (walk-in centres, urgent care centres and minor injuries units)
- Had completed additional clinical skills training (short or comprehensive courses)

Ineligible participants:

- Had only completed a post-graduate diploma in clinical pharmacy (typically a two-year level 7 qualification with no prescribing component)

Recruitment

Past and current students of the ACS course were forwarded a study flyer, and UK Chief Pharmaceutical Officers were asked to forward this to hospital chief pharmacists. The flyer was also posted to social media platforms and the 'Emergency Care' discussion group of the UK Clinical Pharmacy Association web-forum. Those who responded to the advertisement and consented were forwarded a pre-study questionnaire (Appendix 1) which confirmed eligibility and collected participant information.

Data collection instrument and tool

Both Parts 1 and 2 of ENDPAPER-Q (Appendix 2) were developed according to the same literature recommended process. First, 3 EDPPs who each worked in a different ED were each observed for one day and their activities recorded. Questions that captured these activities were then developed. The questionnaire was pre and pilot tested with 3 EDPPs, the latter for up to 3 days with changes made to some aspects of the structure and question wording.

Part 1 was structured according to the patient management process, as questions about both traditional and practitioner care could be mapped to this. The Emergency Care Data Set, used in the ED to record patient information, further informed the structure and question development. Specific data collected concerned: patient characteristics; patient history; vital signs, clinical examinations and investigations, tests and procedures; diagnosis; management planning; treatment; monitoring treatment; and discharge or admission to hospital. Key features of Part 1 include that it is highly user-responsive; a minimum of 31 questions were required and additional fields appeared if certain answers are chosen (a maximum of 978 fields were possible). Sections and subsections supported efficient navigation and data reporting.

Part 2 was a single section of 8 focused questions and 1 open question for EDPPs to report any unanticipated work. Form² enabled data to be recorded in the hospital and received electronically and quickly by researchers on a password protected website, without additional data entry.

Study pack

Participants were posted an iPad or iPad mini, a data collection diary and return pre-paid postage bag. Detailed printed instructions about use of the iPad and ENDPAPER were also included. These instructions were supported by 13 short training videos on YouTube (accessed via QR code at Appendix 3).

Data processing and analysis

Received forms (Part 1=682; Part 2=148) were exported to Microsoft Excel for data management. Free-text answers were coded to new or existing variables. First,

patients cared for have been described. Second, through creation of a Clinical Pharmacy Care Typology (Appendix 4), EDPP activities were defined as either traditional or practitioner and used to describe and compare the overall roles of EDPPs. Specifically, the ratio of traditional to practitioner activities undertaken for each patient were calculated and averaged for each EDPP. Third, using SPSS, data for each stage of the patient management pathway was analysed for EDPPs collectively. Finally, Part 2 data was analysed thematically.

To define the role, key attributes were identified through consideration of inclusion criteria and all study findings. These attributes were then used to produce a definition, with particular attention given to those attributes more novel to hospital pharmacy practice.

Ethics

Health Research Authority was obtained. IRAS project ID: 221114. Research and ethics committee reference: 17/YH/0275.

Stage B

Objectives 1 and 2

The EDPP quality evaluation framework was developed through a systematic review of the literature, an expert panel meeting with EDPPs, and a multidisciplinary expert panel meeting with other ED healthcare professionals. To support comprehensive evaluation of quality, Donabedian's 'Structure, Process, Outcome' construct was chosen to structure the framework (7). Outcomes and their associated indicators were categorised by the Institute of Medicine's 6-domain definition of 'Quality of Care' and related to structures and processes (8).

Systematic review

Question: "What are the structures, processes, outcomes and outcome indicators required to evaluate and understand the quality of care provided by EDPPs?"

Five databases commonly used in Health Services Research were searched (no publication date limits) using the strategy given in Appendix 5. The 'Preferred Reporting Items for Systematic Reviews and Meta-Analysis' (PRISMA) guidelines were used for the review, with the flowchart of literature handling from identification through to inclusion given in Appendix 6. Briefly, 432 unique search results were identified; 130 papers underwent full-text eligibility screening; and data was extracted from 33 papers. See Appendix 7 for inclusion/exclusion criteria.

Three different categories of study design were identified and defined. Whether the type of study has been included and the rationale for doing so is given in brackets:

1. Direct outcome studies where a pharmacist provided direct patient care and the consequence of this was measured using outcome indicators (*included*; outcome of EDPP process measured in simple linear fashion)

2. Surrogate outcome studies where the direct outcomes of pharmacist care were presumed through inference and reference to other studies (*excluded*; outcome of EDPP process presumed; processes of UK studies extracted and included due to high-relevance)
3. Indirect outcome studies of 2 sub-categories:
 - a) Presuming an outcome from pharmacist's influence on other professionals i.e. studies which evaluate how an EDPP influences other professional's processes and use the resultant findings to presume an eventual outcome on quality (*included*; the outcome of EDPP process – albeit their impact on the process of others – has been evaluated)
 - b) Concluding an outcome from pharmacist's influence on other professionals i.e. studies which evaluate how an EDPP influences another professional's processes and then conclude the impact of this process change on quality (*included*; outcome of EDPP process on patient care has been evaluated, albeit indirectly)

Extraction of structures, processes and outcomes was guided by Campbell's definitions of each component (9). The highest available level of granularity was extracted from the papers e.g. the process 'recommendation to change dosage frequency' was extracted rather than the generic 'recommended interventions to doctors'.

EDPP expert panel 1

To obtain framework components of a more recent context, a panel of 6 EDPPs was convened. Individually, participants were first asked to consider each Institute of Medicine (IoM) quality domain and suggest outcomes that may result from traditional or practitioner activities. All suggestions were then collated and grouped by similarity. In pairs, EDPPs were allocated two domains and asked to record any potentially causative processes. After the meeting, participants were forwarded all processes and outcomes collated in the meeting (divided into traditional and practitioner) and asked to suggest indicators that could be used to measure the outcomes. Data sources that could be used to support outcome indicator measurement, and participants 'top-5 outcomes' for evaluation, were also sought. Outcomes ranked in 1st place were allocated 5 points, those in 2nd place 4 points et cetera, with points summed for each outcome and priority outcomes identified.

Processing framework data

Findings of the systematic review and EDPP expert panel were collated to produce a draft framework which was refined to ensure usability e.g. language modified to ensure relevance to a UK setting and excessive detail reduced through combination of categories.

Multidisciplinary expert panel 1

Finally, a multidisciplinary panel of ED healthcare professionals (2 staff nurses; 1 nurse practitioner; 1 physiotherapist and 1 occupational therapist) was convened to further develop the framework. Although invited, no physicians were available for the meeting, but some did show interest in the research. As the meeting focused on general ED function and environment, a lack of physician input would have limited impact on data collected. Indeed, the participation of 4 different professional roles was thought sufficient. Following an introductory presentation, the panel were asked to suggest indicators for each outcome. After the meeting, panel members were forwarded a complete list of outcome indicators and asked to record any potential data sources that could be used in future evaluation studies.

Objective 3

An EDPP service specification has been developed with input from EDPPs, other healthcare professionals, experts in quality and standards, and patients, as recommended in the literature. The specification would define what a service should provide to be deemed of high quality, and how this should be provided. Again, development was guided by the IoM quality domains.

EDPP expert panel 2

The panel meeting aimed to develop and agree themes which would be used to draft service criteria of the specification. For the meeting, which was audio recorded, a variation of the Nominal Group Technique was used with 4 stages:

- Stage 1 – Silent generation: for each IoM domain, EDPPs were asked to make notes about what they thought constituted high quality EDPP care.
- Stages 2 and 3 – Round robin and clarification: in deviation from the classic NGT, EDPPs each put forward their ideas for the first domain which were discussed by the group before moving to the next idea. These are normally 2 distinct stages but, to capture thoughts as they emerged (which may not have re-emerged), concurrent discussion was permitted.
- Stage 4 – Voting: in the meeting, participants individually rated themes on a 9-point Likert scale as to whether they should be taken forward to standard development (1=theme should *definitely not* be used for standard development, and 9=theme should *definitely* be used). Participants were forwarded a personalised survey after the meeting to re-rate themes. Each survey included the EDPPs own initial rating, and the initial mean group rating, for each theme.

Analysis first involved calculations to identify which themes achieved consensus (defined as *both* strong group support and a high level of agreement). Appendix 8 provides detailed explanation of these calculations. To draft specific criteria, the audio recording of the meeting was transcribed and this transcription reviewed for those themes which achieved consensus. Dialogue associated with these themes was coded in NVivo 11, and from these codes, specific service criteria related to the theme and its parent IoM domain were drafted.

Patient interviews

EDPPs distributed study advertisement flyers to their patients, but due to no success, patients in 2 London EDs were also directly approached by the study Principal Investigator, after identification by the EDPP. After consent was obtained, semi-structured audio recorded telephone interviews were held with 8 patients up to 2 weeks after their ED visit to learn of their expectations of an EDPP service (see Appendix 9 for interview schedule). Interview recordings were then transcribed and transcripts analysed using template analysis, whereby dialogue from all interviews related to each IoM domain was identified, coded and analysed thematically.

Themes were used to further develop existing criteria developed from EDPP expert panel data and to produce new criteria from scratch.

Multidisciplinary expert panel 2

Finally, the specification was reviewed by a panel of academics, health services researchers and policy workers, consultant doctors and EDPPs. After an introduction, participants were asked to individually review the specification with respect to face validity of the specific criteria and any content oversights. Participants were then invited to each share their comments with the panel who then discussed these, and if necessary, changes were made and agreed.

Ethics

Health Research Authority was obtained for patient interviews. IRAS project ID: 221114. Research and ethics committee reference: 17/YH/0275.

Patient and public involvement

A research advisory group of was formed to provide input into the design and analysis of the project. Comprised of patient representatives, hospital pharmacists, academics and policy makers, the group met quarterly. Patient representatives were particularly involved in the development of the patient interview schedule and methods to recruit patients for interview.

Results

Stage A

Participants

Twenty EDPPs from 15 different NHS Trusts across the UK were recruited who worked an average of 8 sessions a week (range 2 to 12) over 4 days (range 2 to 5). On average, EDPPs had been a registered pharmacist for 13 years (range 4 to 30 years) and had 4 years of ED experience (range 1 to 15 years). A total of 26 different types of qualification/course had been completed by participants (see Appendix 10). Independent prescribing was most common (16 EDPPs) followed by phlebotomy and cannulation courses (=5 EDPPs).

A total of 682 Part 1 and 148 Part 2 forms were received from all EDPPs; individually, EDPPs each submitted Part 1 an average of 34 times (range 10 to 89) and Part 2 an average of 8 times (range 1 to 12) over an average of 8 work days (range 3 to 10 days).

Patients

Data were collected on 682 patients cared for by EDPPs; 346 (50.7%) were female. The most common age group EDPPs cared for were 80-89 years (112, 16.4%), with those aged 6-12 years least likely to have been cared for (13, 1.9%). Children made up 9.7% (n=66) of patients.

Two indicators of patient acuity were collected: triage category and arrival mode. For 472 patients for whom triage category data was reported, most were of the 'Green' (standard) triage category (180, 38.1%). All other categories were reported, including those of the most serious 'Red' (immediate) category (28, 5.9%). Arrival mode was reported for 658 patients; nearly half of these (325, 49.4%) arrived by road ambulance, with the second most common arrival mode being 'Self-presentation' (310, 47.1%).

The largest group of patients who EDPPs helped to care for were those diagnosed with medical conditions (254/682, 37.2%). This was most commonly cardiac related (62/254, 24.4%) and specifically an Acute Coronary Syndrome (13/254, 5.1%). The second most common diagnosis category was infectious disease (174/682, 23.5%) with respiratory infections being most common (86/174, 49.4%) and specifically a Lower Respiratory Tract infection (59/174, 33.9%).

Role comparison

EDPPs overall median ratios (the middle ratio value of traditional to practitioner work undertaken for a patient) ranged from 1.11 to 5.50. From comparison of these overall ratios, and the ratios of traditional and practitioner care provided by each EDPP to individual patients (see Appendix 11), it can be concluded that:

- All EDPPs undertook both types of work
- All EDPPs provided more traditional than practitioner care to more patients
- 9/20 EDPPs did sometimes provide more practitioner than traditional care to individual patients
- EDPPs who provided a greater proportion of practitioner care did so more consistently i.e. from Appendix 11, the range of ratios (box plot tails) for those EDPPs who carried out more practitioner care for patients (median ratios closer to 1) were less (shorter tails)
- EDPPs who provided a greater proportion of traditional care did so less consistently i.e. from Appendix 11, the range of ratios (box plot tails) for those EDPPs who carried out more traditional care for patients (median ratios much greater than 1) were larger (longer tails)

Direct patient care

EDPPs were the 'designated care provider' of 262/682 patients (34.0%). Due to the large number of different activities undertaken, only those more novel to pharmacists are presented below. All activities undertaken at each stage of the patient management pathway given in Appendix 12.

To support diagnosis: clinical examinations, tests and procedures performed

EDPPs examined 264/682 patients (38.7%). Excluding general examination of appearance and the external body, the most common types of clinical examination performed were: respiratory (145 patients, 21.3%), cardiovascular (131, 19.2%) and abdominal (123, 18.0%). Tests and procedures to inform diagnosis were performed for 48/682 patients (7.0%), most commonly: urinalysis (21 patients, 3.1%); arterial blood gas analysis (10, 1.5%); and venepuncture to withdraw a blood sample (9, 1.3%).

Diagnosis by EDPPs

EDPPs diagnosed 238/682 patients (34.9%); 79/238 (33.2%) were diagnosed entirely independent of any support, 106 (44.5%) independently and then reviewed by another healthcare professional, and 53 (22.3%) with the support of another healthcare professional. Categories of diagnoses made by EDPPs, and the level of support provided, are given in Table 1. For each category of diagnosis made by EDPPs (any level of support), the most common diagnosis sub-category and specific diagnoses are given in Table 2.

Table 1: Categories of diagnoses made by EDPPs and level of support provided

| Diagnosis category | Total patients | Independently diagnosed | Independently diagnosed and then reviewed | Diagnosed with support |
|-------------------------------------|----------------|-------------------------|---|------------------------|
| Medical | 73 | 25 | 21 | 27 |
| Infectious disease | 67 | 19 | 40 | 8 |
| Surgical | 27 | 8 | 12 | 7 |
| Soft tissue injury/wound | 19 | 6 | 12 | 1 |
| No abnormality detected | 10 | 2 | 7 | 1 |
| Toxicology | 8 | 5 | 3 | 0 |
| Musculoskeletal | 7 | 2 | 3 | 2 |
| Fracture/dislocation | 5 | 4 | 0 | 1 |
| Childhood condition | 4 | 0 | 3 | 1 |
| Obstetrics/gynaecology | 4 | 2 | 2 | 0 |
| Psychiatric | 4 | 0 | 1 | 3 |
| Drug/alcohol related | 3 | 2 | 0 | 1 |
| Environmental/social/not applicable | 3 | 3 | 0 | 0 |
| Foreign body | 2 | 1 | 1 | 0 |
| Trauma | 2 | 0 | 1 | 1 |

Table 2: Most common diagnosis sub-categories and specific diagnoses

| Diagnosis category | Total patients | Most common diagnosis sub-category (n) | Most common diagnosis (n) |
|-------------------------------------|----------------|--|---|
| Medical | 73 | Gastroenterology (14) | Constipation (4) |
| | | Respiratory (14) | Chronic Obstructive Pulmonary Disease (8) |
| Infectious disease | 67 | Respiratory (26) | Lower Respiratory Tract Infection (12) |
| Surgical | 27 | General surgery (9) | Abscess: perianal/anal (2) |
| | | | Acute pancreatitis (2) |
| | | | Bowel obstruction (2) |
| | | | Gallstones with cholecystitis (2) |
| Soft tissue injury/wound | 19 | Muscle injury (7) | Lower back (3) |
| No abnormality detected | 10 | - | - |
| Toxicology | 8 | - | Paracetamol overdose (4) |
| Musculoskeletal | 7 | Orthopaedics (3) | Sciatica (2) |
| | | | Cervical spine (1) |
| Fracture/dislocation | 5 | Closed fracture (4) | Facial bones/mandible (1) |
| | | | Hip (NoF) (1) |
| | | | Radius (1) |
| | | | |
| Obstetrics/gynaecology | 4 | Gynaecology (2) | Abscess of labia/vulva (1) |
| | | | Dysmenorrhoea (1) |
| Psychiatric | 4 | - | Anxiety (2) |
| | | | Delirium (acute confusion) (2) |
| Childhood condition | 4 | Medical (4) | Croup (2) |
| Drug/alcohol related | 3 | - | Alcohol dependence syndrome (1) |
| | | | Alcohol withdrawal syndrome (1) |
| | | | Recreational drug use (1) |
| Environmental/social/not applicable | 3 | - | Prescription request (2) |
| Foreign body | 2 | - | Alimentary tract (1) |
| | | - | Ear canal (1) |
| Trauma | 2 | Head injury (1) | Post-concussion syndrome (1) |
| | | Neck injury (1) | Vascular injury (1) |

Treatment: prescribing and de-prescribing

EDPPs prescribed medicines as treatment to be administered in the ED for 266/682 patients (39.0%). Detail about 603 prescriptions (a sample of all prescriptions) was obtained which consisted of 191 unique drugs. The most common drugs prescribed were paracetamol (40 times), salbutamol (24) and prednisolone (14). Examples of those least prescribed include etanercept (biologic) and digoxin. Of 5 possible reasons for prescribing, re-prescribing of a patient's regular medicine was most common (291, 48.8%), closely followed by prescribing a new medicine (273, 45.8%).

In total, EDPPs de-prescribed (stopped) at least 1 medicine for 86/682 patients (12.6%). Detail was given about 113 medicines de-prescribed which included 71 unique drugs. Those drugs most likely to be stopped were simvastatin (6 times), aspirin (5) and ramipril (4).

Discharge: developing and enacting discharge plans

Of 271 patients discharged, 145 had a discharge plan in place (53.5%). EDPPs developed at least part of 58 of these (40.0%); specifically, they most often put plans in place for: a medication review (27, 46.6%), an outpatient review (8, 13.8%), and the patient's transport out of the ED (4, 6.9%). EDPPs enacted (i.e. put into action) at least part of 40 plans (27.6%). For the 24 plans where further detail was provided, action related to only medication review (22, 55.0%) and outpatient review (2, 5.0%).

Contribution to the wider ED

From 138 forms, activities undertaken to support the wider ED were of 6 categories with some more common than others: education of individuals / groups (61 forms); risk management (35); guideline development and review (33); ward-round participation (24); financial tasks (20); and other activities (55). All contribution made to the wider ED is presented in Appendix 13.

Role definition

Key role attributes were identified. EDPPs:

- Have completed additional hands-on clinical skills training
- Provide medical and/or pharmaceutical care, and sometimes arrange social care
- Work in any area of the ED
- Support patients with medical complaints and injuries of any severity and at any stage of their visit
- Are sometimes the designated care provider of patients
- Care for patients as part of a multidisciplinary team and learn from and educate this team;
- Undertake indirect patient care activities e.g. develop guidelines and other activities e.g. governance and management.

Based on this, the proposed definition of the EDPP role is:

“Emergency Department Pharmacist Practitioners are hospital pharmacists who have completed additional clinical skills training and who provide medical and pharmaceutical care to patients with medical complaints or injuries, in any area of the ED and at any stage of their visit. They may take overall responsibility as the patient's designated care provider, and work as a member of a multidisciplinary team, supporting and being supported by others.”

Stage B

Quality evaluation framework

The final quality evaluation framework which is made up of 12 tables is presented in Appendix 14. Tables 1 and 2 present structures with Tables 3 and 4 focused on processes. Tables 5 through 10 concern outcomes for each IoM domain, with outcome indicators also given. Finally, Tables 11 and 12 present Category 3a indirect outcome studies. Data extracted from these studies have been collated separately from the main framework as, unlike all other types of study included which conclude EDPPs impact on quality, they presume an outcome from EDPPs influence on other professionals. A diagram explaining the contents of each table has been added at the beginning to support navigation.

In total, 72 outcomes were identified (27 from the literature and 45 from the EDPP expert panel). For all outcomes, 399 indicators were identified (54 from the literature, 181 from the EDPP expert panel, and 164 from the multidisciplinary expert panel). The relationships between structures, processes and outcomes are given through use of reference numbers. For expert panel data, these relationships are given through reference to the IoM domain i.e. 'EPEFFECT7' which means the component originates from the expert panel and relates to the 'effectiveness' domain. The number at the end is a unique identifier for the outcome across all domains. Similarly, outcome indicators developed through multidisciplinary expert panel are labelled 'MTDEP'.

To support future evaluation, outcome indicators have been included and categorised as: quantitative, qualitative, quantitative and/or qualitative. Those which lack specificity and require further development have been categorised as 'lacks specificity'. These are primarily from the EDPP expert panel and more closely resemble themes or ideas rather than an indicator that could be measured. They have been included as they could be further developed/defined for future evaluation purposes. Data sources which could be used to measure outcome indicators are also listed.

Priority outcome and methods to measure associated indicators

Only 3 EDPPs prioritised outcomes, and only 1 prioritised outcomes for both traditional and practitioner work. Overall, the outcome EDPPs prioritised for future evaluation was 'Prescribing errors' which attracted 10 points (see Appendix 15 for complete EDPP rankings). Table 3 presents 8 indicators from the quality evaluation framework which could be used to measure this outcome. As suggested by EDPPs, incident reports, near miss records, medical notes, and pharmacist intervention logs are also possible data sources which could support indicator measurement.

Table 3: Potential outcome indicators to measure the outcome 'Prescribing errors'

| Outcome indicator | Category |
|---|-------------------|
| Number of adverse incidents due to prescribing errors for pharmacist prescription | Quantitative |
| Number of interventions made for pharmacist prescriptions | Quantitative |
| Review local incident reports that concern prescribing errors | Lacks specificity |
| Evaluate types of prescribing error | Qualitative |
| Number of prescribing errors | Quantitative |
| When prescribing errors are made | Qualitative |
| How prescribing errors were resolved | Qualitative |
| Extent to which pharmacists prevent errors from reaching the patient | Qualitative |

Whilst this project initially set out to develop data collection and analysis methods for measurement of an outcome for prescribing errors, measurement of prescribing errors is complex and was beyond the time and financial resources available (10-12). To develop the methods required, the existence of methods which could be adapted for this project would first need to be investigated. Next, specific data available (e.g. the content of data sources suggested such as incident reports) would need to be determined, outcome indicators validated, and expected standard of measurement defined. As described later, further development of methods will be a priority going forward.

Service specification

The final service specification is presented at Appendix 16. This evidence-based document is the product of patient, EDPP and multidisciplinary input. All themes developed by EDPPs and results of consensus calculations are given in Appendix 17. Patient quotes used to develop specific criteria are presented in Appendix 18.

Prior to review by the multidisciplinary expert panel, the specification was restructured from 6 IoM domains – which often had overlapping criteria – into 4 categories: direct patient care; other activities (including indirect patient care);

service structures (likely beyond EDPP control); and general approach (including communication and behaviours). This reduced duplication and increased usability. Multidisciplinary review involved rewording criteria and restructuring categories. The new sub-category 1a 'Approach to clinical activities' was created to collate criteria which experts felt were general underpinning principles that should always apply to direct patient care. New criteria were also added e.g. those which pertain to mentorship and appraisal which was added to sub-category 2a. One criterion which advised that patients be given a choice of which practitioner they see was removed as it was thought unfeasible in practice.

Discussion and conclusions

This project has been novel and innovative in its aim of defining the EDPP role. To our knowledge, this is the first ever study – globally – to define and describe the role of a pharmacist who has overall clinical responsibility for patients in an emergency care setting. As well as investigate EDPP care provision, methods to support evaluation of the impact of these pharmacists have been developed. The quality evaluation framework will support structured and comprehensive evaluation of EDPP quality impact. The service specification will also support quality evaluation in that it can be compared with existing EDPP service structures and processes; however, it also sets out expectations for hospitals wishing to launch the service.

Stage A

A niche role

EDPPs provide both traditional and practitioner care. Unlike nurse practitioners who seemingly withdraw from their traditional nursing activities, EDPPs continue to carry out drug focused activities to support both patients and the wider ED which includes educating other staff (13). The combined nature of the EDPP role supports HEE's efforts to develop a flexible workforce which can respond to ever-changing patient demand (14). Further, through introduction of an EDPP service, those EDs who have limited – if any – pharmacy service could gain 2 types of role from 1 employee; a pharmacist who can both undertake more general pharmaceutical activities and also provide direct patient care when needed.

Pharmacists as patient managers

EDPPs were the designated care provider/manager of 232 patients (34.0%) of those included. Whilst the 682 patients cared is somewhat a selective sample, it is interesting that this proportion is similar to HEE's suggestion that 36% of ED patients would be suitable for management by a pharmacist (5). Due to differences in the clinical groupings, it has not been possible to compare diagnoses of patients managed.

Medicines prescribed

EDPPs prescribed medicines for 39.0% of patients. Medicines prescribed were typical for an emergency care setting which cares for acutely unwell patients e.g.

analgesics, inhalers, antibiotics and steroids. However, there were some unexpected prescriptions e.g. for the biologic medicine etanercept.

Pharmacists as prescribers of new medicines

In 2014, Baqir and colleagues found that only 184/1415 medication orders (13.0%) prescribed by pharmacists across were for a newly initiated medicine and 799/1415 (56.5%) for regular medicines that had been missed (15). In this study, these figures were 273/596 (45.8%) for new medicines prescribed and 291/596 (48.8%) for regular medicines re-prescribed. Whilst this difference could be due to the nature of the clinical setting studied, it does suggest pharmacist independent prescribers are not just repeat authorisers of treatment initiated by others.

Clinical examinations and procedures

Traditionally, the clinical examination of patients has been the remit of doctors. In this study, EDPPs examined over a third of all patients (38.7%), with types of examination performed primarily of the major systems e.g. respiratory, cardiovascular and abdominal. This demonstrates a change in pharmacists towards provision of hands-on patient care. Similarly, EDPPs also physically carried out many tests and procedures to both inform patient diagnosis and treat them.

Stage B

Quality Evaluation Framework

The framework is purposely independent of any particular study design and therefore can be used to evaluate the role of any pharmacist working in the ED and using any method e.g. randomised control trial or cohort comparison. The inclusion of structures and processes will enable evaluation of outcomes which relate to specific activities in a particular setting.

Outcome indicators

Whilst few EDPPs ranked outcomes according to priority for evaluation, outcomes ranked most highly e.g. prescribing errors agree with discussion groups held prior to this project. For example, in 2015 when the first cohort of the ACS course were asked what evaluation of the EDPP role their managers would like to see, most suggestions related to prescribing errors followed by impact on finances, wait times and patient flow through ED (16). In this study, EDPPs did not prioritise financial outcomes, although few of these were identified given the studies focus on patient quality of care in the NHS which is free at the point of use.

Service specification

The specification can be used to develop any type of new and existing EDPP services and guide training. The inclusive wording of criteria and the designation of criteria as dependent on local service agreements ensured a single specification could be produced. An alternative would have been to draft two specifications, one each for traditional and practitioner work; however, this would potentially have been divisive and caused conflict between traditional and 'practitioner' pharmacists. This

occurred with the advent of advanced nursing practice, where jealousy and conflict were observed between staff nurses and nurse practitioners (17).

Next steps and future outcomes

Moving forward, plans are to develop and conduct a study that will conclude the quality impact of EDPPs. This will focus on prescribing errors but also other priority outcomes such as length of ED stay. In addition to evaluation of EDPP impact, other pertinent research themes were identified such as EDPP care pathways. As providers of both traditional and practitioner care, it is important to explore how both types of care can be provided efficiently side-by-side, to the same and different patients, and alongside other healthcare professionals. Further, as the ED workforce continues to diversify, it will also be necessary to improve our understanding of multidisciplinary working in emergency care. Finally, as more pharmacists acquire additional clinical skills and move into new practice settings e.g. general practice and other urgent care settings such as NHS 111 call centres, this research provides a basis for evaluation of these new roles. Indeed, it is vital that we understand *how* and *how well* pharmacists in emerging roles care for patients to ensure quality and value for the NHS.

The study acronym ENDPAPER was chosen as it captures this projects efforts to progress clinical pharmacy practice as we currently know it; indeed, it bridges existing 'traditional' and more novel hands-on practice.

ENDPAPER – “a leaf of paper at the beginning or end of a book”

Appendices

Appendix 1: ENDPAPER participant pre-study questionnaire

Appendix 2: ENDPAPER-Q

Appendix 3: Accessing ENDPAPER-Q training videos

Appendix 4: The clinical pharmacy care typology and its development

Appendix 5: Systematic review search strategy

Appendix 6: PRISMA flow chart

Appendix 7: Systematic review inclusion and exclusion criteria

Appendix 8: Consensus calculations (themes for service specification)

Appendix 9: Patient interview schedule

Appendix 10: EDPP qualifications

Appendix 11: Role comparison

Appendix 12: Direct patient care activities

Appendix 13: Contribution to the wider ED

Appendix 14: Quality evaluation framework

Appendix 15: Priority outcome rankings

Appendix 16: EDPP service specification

Appendix 17: EDPP expert panel themes and consensus calculations

Appendix 18: Patient interview quotes

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