

Improving specialist drug prescribing in primary care using task and error analysis:

an observational study

Abstract

Background

Electronic prescribing has benefited from computerised clinical decision support systems (CDSSs); however, no published studies have evaluated the potential for a CDSS to support GPs in prescribing specialist drugs.

Aim

To identify potential weaknesses and errors in the existing process of prescribing specialist drugs that could be addressed in the development of a CDSS.

Design and setting

Semi-structured interviews with key informants followed by an observational study involving GPs in the UK.

Method

Twelve key informants were interviewed to investigate the use of CDSSs in the UK. Nine GPs were observed while performing case scenarios depicting requests from hospitals or patients to prescribe a specialist drug. Activity diagrams, hierarchical task analysis, and systematic human error reduction and prediction approach analyses were performed.

Results

The current process of prescribing specialist drugs by GPs is prone to error. Errors of omission due to lack of information were the most common errors, which could potentially result in a GP prescribing a specialist drug that should only be prescribed in hospitals, or prescribing a specialist drug without reference to a shared care protocol. Half of all possible errors in the prescribing process had a high probability of occurrence.

Conclusion

A CDSS supporting GPs during the process of prescribing specialist drugs is needed. This could, first, support the decision making of whether or not to undertake prescribing, and, second, provide drug-specific parameters linked to shared care protocols, which could reduce the errors identified and increase patient safety.

Keywords

clinical decision support system; drug prescribing; general practice; primary health care; specialist drugs.

INTRODUCTION

In the UK, initiatives such as practice-based commissioning have encouraged the development of GPs with special interests to deliver specialist services in the community.¹ The introduction of GP commissioning and transfer of the NHS primary care budget to GP consortia² has been seen as an opportunity to change the arrangements for prescribing specialist drugs and providing new services in primary care to avoid patients attending hospital clinics.³ Specialist drugs are those that have significant pharmacological complexity and/or rarity of use, making prescribing in primary care relatively uncommon.⁴ In 1991, the NHS Management Executive outlined core principles and clinical responsibilities associated with prescribing at the primary and secondary care interface, including the use of protocols to support GPs prescribing specialist drugs under shared care agreements.¹ Local advisory lists were made available to support GPs in managing shifts in prescribing from secondary care to primary care, with medicines grouped as hospital only (red), appropriate for shared care or restricted use (amber), and for GP use and initiation (green).⁵

NHS Prescription Services provides prescribing, financial, and drug information to managing organisations in the NHS in England. In 2006–2007, 1.3 million prescriptions for specialist drugs were

issued by GPs,⁶ rising to 1.7 million in 2014–2015,⁷ with the most frequently prescribed specialist drugs (29.3%) being the immunosuppressant drugs ciclosporin, mycophenolate, sirolimus, and tacrolimus. Between 2005 and 2010 these four drugs were involved in 1103 reported safety incidents, with 282 (25.5%) directly related to prescribing, and with 11 occurring in primary care (National Patient Safety Agency, personal communication, 2 March 2011). From April 2013, changes in NHS commissioning arrangements for specialist drugs and services have allowed hospitals to repatriate the prescribing of immunosuppressant drugs from primary care to secondary care.⁸

The specialist drugs list maintained by NHS Prescription Services is not exhaustive and does not specify which drugs should be classed as red or amber. This responsibility rests with local organisations such as area prescribing committees, which can lead to regional variation in which specialist drugs are recommended for use only in secondary care or those suitable to be prescribed by GPs under shared care arrangements (in the form of local advisory lists). In 2014–2015, 41.89% of prescriptions for specialist drugs issued by GPs in England were classified as red, that is, hospital only based on the traffic light classification used across northwest London.⁹

Shared care protocols are developed

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How this fits in

In this study, software engineering and human factor methodologies were used to identify and analyse GPs' current workflow and tasks. Better use of information technology and clinical decision support systems provides a solution to the current risks associated with prescribing specialist drugs, addressing current concerns of GPs and making the process more efficient and less error prone.

and approved by local area prescribing committees such as the Midlands Therapeutic Advisory Committee.¹⁰ Shared care protocols must be patient specific and clarify individual roles and responsibilities, medicine details, patient monitoring, and circumstances where treatment should be modified or stopped.¹ One UK survey has reported on the production of 321 shared care protocols that have described 99 different drugs or treatments.¹¹ A range of factors influence GP decision making in prescribing specialist drugs, including shared care arrangements and the recommendations of local advisory lists.¹² GP dissatisfaction with arrangements for prescribing specialist drugs¹³ and a lack of GP involvement in the development of shared care protocols have been reported.^{11,14} Barriers to GP acceptance of shared care protocols have included cost shifting,^{11,13} training,¹⁵ staffing, and time constraints.¹⁶ Shared care protocols have been described as variable in standard, lacking formal evaluation, distributed erratically, and with unclear benefits to patients.¹¹ Suggested improvements to shared care protocols have included joint agreement between primary care and secondary care,¹⁵ a clearer definition of roles and responsibilities, and dissecting barriers such as risk management and clinical competence.¹⁶ One potential solution lies in computerised clinical decision support systems (CDSSs).

In the last 30 years, CDSSs have emerged to aid diagnosis, disease management, calculations, and, more recently, supporting electronic prescribing via alerts on drug interactions, allergies, and contraindications.¹⁷ Systematic reviews of controlled trials of CDSSs in primary care settings have demonstrated positive effects linked to the adherence to clinical guidelines,^{18,19} improved prescribing,²⁰ clinician performance,²¹ and drug dosing and therapeutic response.²² However, limitations include a lack of evidence in

improving safety measured by medical errors or adverse events,¹⁹ patient outcomes,^{23,24} and in the understanding of the impact of CDSSs on specific aspects of the prescribing process.²⁵ Poor usability has been cited as a core barrier to CDSS adoption, with system designers encouraged to apply common standards based on human-computer interaction methods and user-centred design.²⁶

In the UK, commercial CDSSs that support cost-effective prescribing are widely available to GPs.^{27,28} In a recent development CDSSs have become available to support GPs in implementing medicines optimisation.²⁹ Such systems are able to provide locally authored messaging platforms to provide drug information and safety alerts to prescribers, including links to local advisory lists known as traffic light classifications and shared care protocols. However, in a recent review,³⁰ the impact of one of these systems²⁸ has been described as limited compared with other existing cost-effective prescribing initiatives, with drawbacks including alert content and a lack of GP control. No published study has evaluated the potential for a CDSS to support GPs prescribing specialist drugs. In the current study, software engineering and human factors methods were used to identify a potential operating model for a CDSS to support GPs in the safety and quality of specialist drug prescribing.

METHOD

Study design

A review of the published literature of CDSSs in the UK identified four stakeholder groups who would provide insight into the requirements of a potential CDSS that could support GPs during the process of prescribing specialist drugs. An exploratory study was initially undertaken using face-to-face interviews with 12 key informants, which were all conducted by the lead trained research pharmacist. The key informants were GPs ($n=2$), NHS IT managers ($n=2$), secondary care clinicians ($n=4$), and representatives from the CDSS industry or GP clinical system suppliers ($n=4$). Secondary care clinicians with a specific knowledge of specialist drugs and immunosuppression in renal transplantation were invited to participate. UK-based commercial CDSS and GP clinical system suppliers were approached while London-based IT managers and GPs were invited. These interviews were used to gain an understanding of current usage and characteristics of CDSSs available in primary care and to explore the feasibility

of incorporating a CDSS to support GPs in the prescribing of specialist drugs. Interview schedules were designed for each stakeholder group and used as a topic guide. During each interview emerging themes were used to formulate further questions. Interviews were recorded, transcribed verbatim, and analysed using framework analysis,³¹ supported by NVivo (version 10). The resulting data were reviewed by two members of the research team, and analysed for emerging key themes across the interviews.

In order to further understand the actual needs and requirements of GPs as end users of a potential CDSS, an observational study with GPs was conducted. In total, nine GPs who were users of the three major UK GP clinical systems (EMIS, Vision, and SystmOne) were purposively³² selected to participate. The selection took into account the results from the key informant interviews and factors such as GP availability, willingness to participate, and demographic characteristics. Six of the GPs were partners and three were salaried

GPs. The GPs qualified between 2001 and 2013. All of the GPs described themselves as having either a medium or high IT aptitude. In this observational study the lead researcher discussed and observed the participants perform predefined case studies and took written notes. A research guide was designed to include specific predetermined questions about computer use including CDSSs both during and outside patient consultation, with emerging themes used to formulate further questions. Case scenarios were developed from the results of the key informant interviews with particular emphasis on the use, quality, and availability of shared care protocols. The case scenarios were observed and discussed with each GP, and depicted situations where patients presented prescriptions for specialist drugs (for example, tacrolimus), or these were requested by the hospital, identifying the steps taken by each GP to accept or decline prescribing.

Data analysis

Data from the observations and discussions were used to develop activity diagrams representing how GPs conducted their work, used their computers both during and outside patient consultation, and how they dealt with the specialist drug prescribing case scenarios. Activity diagrams are often organised as swim lanes to identify who or what is responsible for a specific task or activity,³³ and have been used to model workflow patterns involved in prescription writing and management in primary care settings.³⁴ A hierarchical task analysis (HTA) was performed to describe in detail the process GPs used to prescribe specialist drugs. HTA models tasks as hierarchies of goals and sub-goals, with plans showing how sub-goals should be undertaken.³⁵ Error analysis based on systematic human error reduction and prediction approach (SHERPA)³⁶ was applied to the HTA sub-tasks, identifying possible errors, consequence, recovery, probability of occurrence, and remedial action or design solution.

RESULTS

Exploratory study

The primary themes that emerged from the exploratory interviews were safety, IT systems, and cost, which are shown in Box 1 with secondary themes and key criteria. In total, 25 CDSSs were identified, of which nine were active systems (provide patient-specific advice), and 16 passive (clinicians need to request the information, not patient-

Box 1. Summary of primary and secondary themes from key informant interviews

Primary theme	Secondary theme	Key criteria
Safety	Prescribing, monitoring, specialist drugs, shared care protocols, commissioning of services (secondary care)	<ul style="list-style-type: none"> • Communication: problems specifically between primary care and secondary care (interface) • Clinical responsibility: for GPs when prescribing specialist drugs • Monitoring of patients receiving specialist drugs • Experiences of specialist drugs (adverse experiences such as drug interactions, generic prescribing, repatriation of prescribing to secondary care) • Experiences of shared care protocols
IT systems	Operational features of IT systems (primary care)	<p>General usage of computers in general practice and key characteristics of IT systems</p> <ul style="list-style-type: none"> • Regulation (current NHS management systems, GP clinical system suppliers, and shifting to hosted systems) • Data quality (Read coding, accuracy, accreditation) • Integration of systems • Implementation of systems • CDSS and experience in general practice (current profiles, usage, and characteristics) • Current and future developments in CDSS • CDSS and specialist drugs (views and attitudes, enablers, barriers)
Cost	Drug costs, service costs, IT funding (general practice), CDSS funding models	<ul style="list-style-type: none"> • Prescribing budgets (primary care) • NHS service costs and use of home care • GP System of Choice Framework (licence fees), CDSS funding streams • CDSS and specialist drugs: funding models

CDSS = clinical decision support system.

Box 2. Key informants' views on the use of specialist drugs and shared care protocols, and the concept of developing a clinical decision support system to support GPs prescribing specialist drugs

Specialist drugs and shared care protocols

'I never had any awareness of shared care protocols, I think they are universally pretty useless and I think they are a significant area of potential danger.' (GP 1)

'I think it's something that we frequently get letters from the hospital consultants ... you know or this is the drug they are taking, it's not made clear to us if we're expected to take on prescribing, it's not made clear to us if there is a shared care protocol in place, it's certainly not clear that they have any idea if there are shared care protocols in place.' (GP 1)

'My normal first response is no, we won't take this on until we get the protocol and when it is sent it is not written in my perspective ... in the sense that it's often written from how it's initiated ... not terribly helpful or easy to use.' (GP 2)

'I have written quite a lot of them [shared care protocols] ... usually renal drugs ... once I have written it I send it to our formulary pharmacist ... and then she goes to meetings with the local PCTs ... rather than the individual PCTs now we deal with the sector.' (Secondary care clinician 2)

'I think drug interactions are one of the major headaches that we have with immunosuppressant drugs, you know mainly penicillin-allergic patients come in with a fever and a chest infection and they get clarithromycin and then the next thing you know their tacrolimus levels have doubled.' (Secondary care clinician 3)

'There is a huge variation in bioequivalence, we had one patient who had the wrong brand of tacrolimus and came in and rejected due to lower levels of tacrolimus ... we had another patient who came in who had a recurrence of herpes zoster because she had received a different brand and had been over-immunosuppressed.' (Secondary care clinician 3)

Developing a CDSS to support GPs prescribing specialist drugs

'I think the priority for me would be to have ... you know, for example, if the shared care protocol is presented to me at the time of prescribing, at the point of prescribing, it's no good having some dim and distant website, somewhere having to trawl through for every drug, every indication, that is useless.' (GP 1)

'It has to be intuitive ... it has to be minimally intrusive unless where it needs to be intrusive, so it shouldn't take me 15 minutes for me to do something where previously I would do it in 2 minutes.' (CDSS industry/GP clinical system supplier representative 4)

'The barriers would be there from the big players the clinical applications out there in the practices, EMIS, Vision, SystemOne ... the barriers would be for them for allowing these new guys, this company coming along with this product to talk to them and say yes we can make it work with our product.' (NHS IT manager 1)

'So then it can be an extension of the system the GP already has ... which depending on the exact complexity of what you want it is not going to be that expensive ... if you wanted a stand-alone system that was used by the GP for these drugs and by hospital clinicians that initiated the drug it becomes a different cost model altogether, particularly if the hospital records are still paper.' (CDSS industry/GP clinical system supplier representative 2)

'And there are substantive costs, not just development but ongoing maintenance of the product and the NHS has not always been able to do that particularly well ... and I think it is very telling ... that the NHS has not chosen to be one of the GP Systems of Choice.' (CDSS industry/GP clinical system supplier representative 4)

'In order for it to be fair to a GP you would have to build in a very high level of supervision in terms of checking ... basically calling the patients back to have their renal function checked and their levels checked after dose changes ... you are basically asking the GP to run a transplant clinic and I think that would be a lot to ask ... clearly transplants are about life-sustaining organs ... livers, hearts, and lungs — if you get that wrong then it's good night Vienna.' (Secondary care clinician 4)

CDSS = clinical decision support system. PCT = primary care trust.

specific). The CDSSs supported a wide range of areas including prescribing, drug information, and disease management. All of the GP clinical systems provided active CDSSs to support prescribing via drug alerts or warnings and reminders or prompts to support the Quality and

Outcomes Framework component of the national General Medical Services contract. In terms of specialist drugs and shared care protocols, mixed experiences were described by the GPs and secondary care clinicians, with specific concerns from a GP perspective in relation to safety, clinical responsibility to prescribe, and in the availability and quality of shared care protocols (Box 2). The concept of developing a CDSS to support GPs prescribe specialist drugs was acknowledged as beneficial by all 12 key informants. Enablers and barriers to CDSS development were identified, including a number of potential operating and funding models (Box 2). Key enablers included multiuser access, active alerting, ease of use, joint development and implementation, patient involvement, data quality and functionality, and the use of existing systems and frameworks. Key barriers included security and regulation, implementation, integration and data quality, and addressing the needs of end users.

Activity diagram and hierarchical task analysis

GPs described their actions in the case scenarios, deciding whether or not to accept clinical responsibility for prescribing a specialist drug. Figure 1 displays the activity diagram representing their decision-making process. The GPs described limited functionality within each GP clinical system to support the prescribing of specialist drugs. All GPs highlighted the importance of adding simple alerts or reminders to the patient's electronic health record (EHR) to indicate that the patient was treated with a specialist drug or that a shared care protocol should be followed. Additional needs included restricting drug quantities and creating tasks, such as recall, to ensure patients were seen on a regular basis. Where shared care protocols were available, all GPs reported they should be scanned and added to the patient's EHR. An additional problem identified was the reliability of administrative staff to scan letters or communications from hospitals. Although the GPs found the use of the clinical systems quick and simple, navigating the systems to locate a shared care protocol was not straightforward (for example, if the scanned letters were not filed by specialty they were difficult to locate). HTA was applied to the actual task of prescribing specialist drugs and is shown in Box 3. Key steps undertaken were to open the patient's EHR and to familiarise themselves with the patient's clinical history before reviewing the

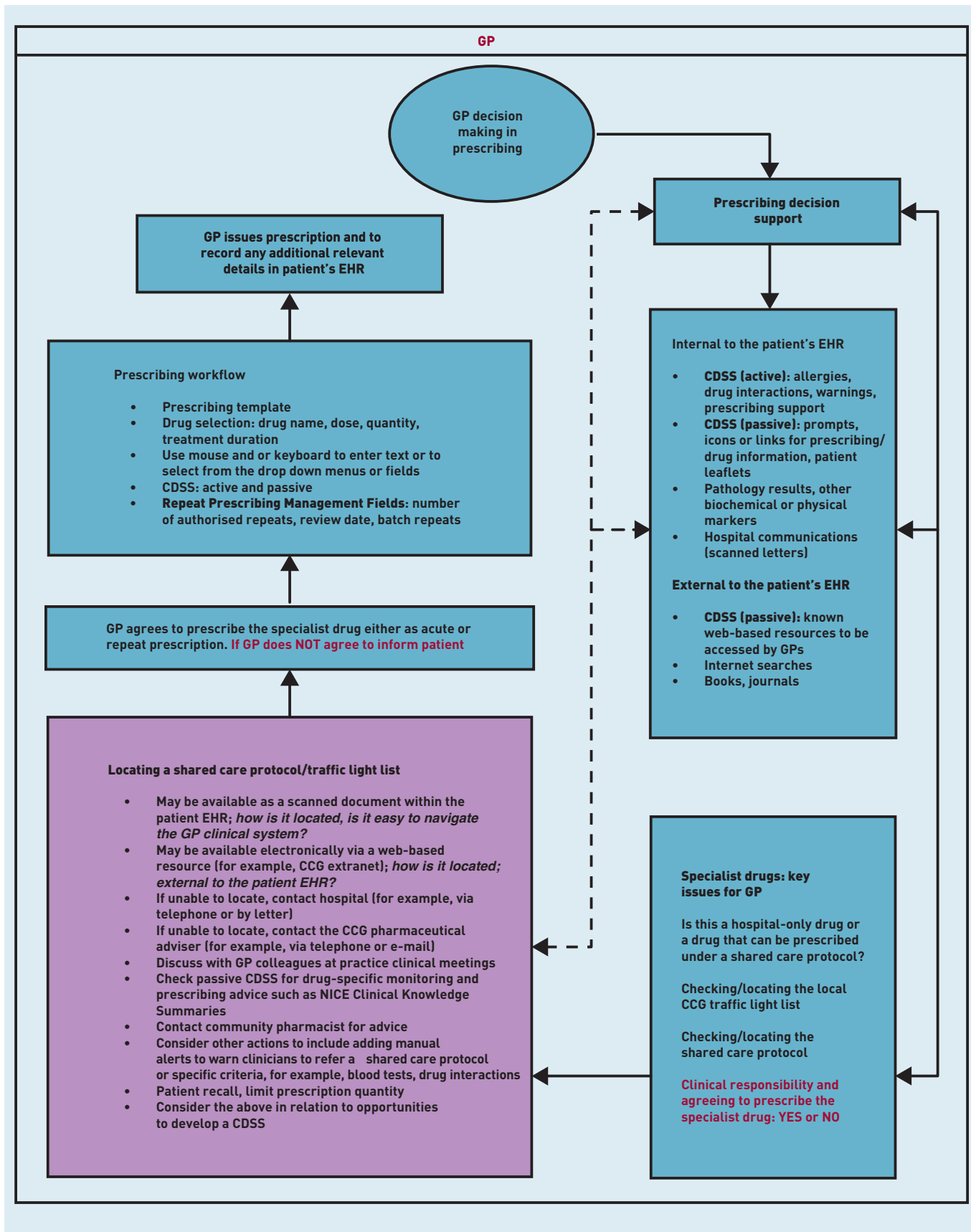


Figure 1. Activity diagram representing GPs' decision making in managing requests to prescribe specialist drugs. CCG = clinical commissioning group. CDSS = clinical decision support system. EHR = electronic health record.

Box 3. Hierarchical task analysis of the prescribing of specialist drugs by GPs (current tasks)

Prescribing a specialist drug

PLAN 0: Either during or outside a patient consultation do 1, 2, and 3 in order.

1. Open patient's electronic health record
2. Get familiar with patient's clinical history
3. Review a request to prescribe a specialist drug

PLAN 3:

Do 3.1 to 3.8 in order according to instructions

- 3.1. Check traffic light list if drug is 'hospital only'. If 'Yes' go to 3.8. If 'No' go to 3.2
- 3.2. Check if drug can be prescribed under a shared care protocol. If 'Yes' go to 3.3, if 'No' go to 3.5 or 3.7
- 3.3. Locate the shared protocol
- 3.4. Read shared care protocol. If agree to accept clinical responsibility, go to 3.5, if decline, go to 3.7
- 3.5. Accept clinical responsibility for prescribing the specialist drug
- 3.6. Prescribe specialist drug
- 3.7. Decline clinical responsibility for prescribing the specialist drug, go to 3.8
- 3.8. DO NOT prescribe drug. Refer back to the hospital clinic and inform the patient

request to prescribe a specialist drug. GPs checked if the specialist drug was 'hospital only' or whether it could be prescribed by using a shared care protocol. These

checks were made by locating and referring to a traffic light classification of specialist drugs. Although CDSS providing support at the point of prescribing was available, for example, ScriptSwitch®, none of the GPs referred to this specific functionality during the decision-making process.

Errors involved in prescribing specialist drugs

The SHERPA analysis demonstrated that although the specific task of prescribing was relatively simple in terms of the number of steps required to complete the task, the potential for error was considerable (Boxes 4 and 5). The potential errors that could occur were either cited by the individual GP (GP1 to GP9) or identified by the research team during data analysis. The underlying problem faced by the GPs was dealing with a paper-based communication system with secondary care. The risk of prescribing specialist drugs in an unsafe manner was increased due to lack of functionality within all of the GP clinical systems and time constraints, particularly where a decision needed to be made during a consultation. To resolve these issues GPs relied on other staff to provide advice and information. In many cases the next opportunity to resolve such problems was when a further prescription was requested by the patient. The predominant theme that emerged from the SHERPA analysis was the high frequency of error mode R1 ('Information not obtained') because information required by the GP was not readily available. The potential adverse outcome was that a GP could inadvertently prescribe a specialist drug classified as hospital only, or prescribe one without reference to an appropriate shared care protocol. In addition, in 11 of the 20 task steps an error rated as a high probability of occurrence could occur. The fundamental problems described by the GPs related to lack of awareness or availability of either the traffic light list or shared care protocols. In addition, where shared care protocols were required, a major obstacle was locating them in either a paper or electronic format, particularly during patient consultations.

It was evident throughout the whole process that GP clinical systems and CDSSs were not able to provide full solutions to the problems described by the GPs. One remedial solution was to manually add simple alerts or reminders to the patient's EHR. These alerts allowed free text to be added to a pop-up box informing each user of key messages related to prescribing of specialist drugs, for example, checking

Box 4. SHERPA error modes

Error type	Code	Error mode
Action errors	A1	Operation too long/short
	A2	Operation mistimed
	A3	Operation in wrong direction
	A4	Operation too little/much
	A5	Misalign
	A6	Right operation on wrong object
	A7	Wrong operation on right object
	A8	Operation omitted
	A9	Operation incomplete
	A10	Wrong operation on wrong object
Checking errors	C1	Check omitted
	C2	Check incomplete
	C3	Right check on wrong object
	C4	Wrong check on right object
	C5	Check mistimed
	C6	Wrong check on wrong object
Retrieval errors	R1	Information not obtained
	R2	Wrong information obtained
	R3	Information retrieval incomplete
Communication errors	I1	Information not communicated
	I2	Wrong information communicated
	I3	Information communication incomplete
Selection errors	S1	Selection omitted
	S2	Wrong selection made

SHERPA = systematic human error reduction and prediction approach.

Box 5. Application of SHERPA to the prescribing of specialist drugs by GPs

Task step	Error mode	Description	Consequence	Recovery	Probability of occurrence	Remedial strategy/design solution
3.1 To check if the specialist drug is a 'hospital only' drug	C1	Failure by GP to check the traffic light list (GP1, GP3, GP4, GP7)	A hospital-only specialist drug is prescribed by the GP	At next request for prescription (3.1) Community pharmacist informs GP that a hospital-only drug has been prescribed	Medium	Screen alert when prescribing Design solution: The GP clinical system to automatically alert the GP that this is a hospital-only drug, not to prescribe and to automatically refer back to the hospital, that is, a hard stop Design solution: The GP clinical system to enable a search of a drug and see its attributes, that is, 'hospital only' Design solution: The pharmacy computer system to automatically alert the pharmacist that this is a hospital-only drug and not to be issued in primary care and to refer back to the GP
	R1	Traffic light list is not available at the practice (paper list) (GP1)	A hospital-only specialist drug is prescribed by the GP	At next request for prescription (3.1)	High	Screen alert when prescribing (same design solutions as above) Practice to ensure paper list is available to all GPs including locums
	R1	Traffic light list is available at the practice (paper list), but is out of date	A hospital-only specialist drug is prescribed by the GP	At next request for prescription (3.1)	Low	Screen alert when prescribing (same design solutions as above) Practice to ensure updated/current paper list is available to all GPs including locums
3.2 To check if a shared care protocol is required to support the prescribing of a specialist drug	R1	Traffic light list is available at the practice (via local extranet) but lack of GP awareness (GP1)	A hospital-only specialist drug is prescribed by the GP	At next request for prescription (3.1)	High	Screen alert when prescribing (same design solutions as above)
	R1	Traffic light list is available at the practice (via local extranet) but lack of GP access rights (GP1)	A hospital-only specialist drug is prescribed by the GP	At next request for prescription (3.1)	High	To make a link available to local extranet webpage. Practice to ensure all GPs and locums have a user name and password, and an easy way to retrieve them
	C1	Failure by GP to check the traffic light list (GP1, GP3, GP7)	A specialist drug prescribed without reference to the shared care protocol	At next request for prescription (3.2)	Medium	Screen alert when prescribing Design solution: The GP clinical system to enable a search of a drug and see its attributes; that is, if a shared care protocol is required
3.2 To check if a shared care protocol is required to support the prescribing of a specialist drug	R1	Traffic light list is not available at the practice (paper list)	A specialist drug may be prescribed without reference to the shared care protocol	At next request for prescription (3.2)	High	Screen alert when prescribing Practice to ensure paper list is available to all GPs including locums
	R1	Traffic light list is available at the practice (paper list), but is out of date	A specialist drug may be prescribed without reference to the shared care protocol	At next request for prescription (3.2)	Low	Screen alert when prescribing Practice to ensure updated/current paper list is available to all GPs including locums
	R1	Traffic light list is available at the practice (via local extranet) but lack of GP awareness (GP1, GP8)	A specialist drug may be prescribed without reference to the shared care protocol	At next request for prescription (3.2)	High	Screen alert when prescribing Practice to ensure all GPs and locums have a user name and password, and an easy way to retrieve them

... continued

Box 5 continued. Application of SHERPA to the prescribing of specialist drugs by GPs

3.3 To locate the shared care protocol to support the GP in prescribing the specialist drug	R1	Shared care protocol not available to GP (paper copy) as not sent by hospital clinic. GP unable to contact clinic due to time constraints (GP1, GP2, GP6, GP7)	A specialist drug may be prescribed without reference to the shared care protocol	At next request for prescription (3.3)	High	Screen alert when prescribing Ensure hospitals send copies of shared care protocols to GPs (action for medicines management team) ^a
	R1	Shared care protocol not available to GP (paper copy) as filed in patient's paper notes and NOT scanned into patient's EHR (GP1)	A specialist drug may be prescribed without reference to the shared care protocol	At next request for prescription (3.3)	Low	Ensure paper copy of shared care protocol is scanned into patient's EHR (for practice staff). Need to highlight in practice policy handling of communications from hospitals, that is, scanning in appropriately. Screen alert when prescribing
	R1	Shared care protocol has been scanned into patient's EHR, but not easily available or difficult to locate (that is, difficulty in navigating the clinical system)	A specialist drug may be prescribed without reference to the shared care protocol	At next request for prescription (3.3)	Medium	Design solution: The GP clinical system to make the protocol easily available and/or identifiable in the patient's EHR Training for GP on the use of the clinical system
	R1	Shared care protocol is not available via the local extranet (GP6, GP8)	A specialist drug may be prescribed without reference to the shared care protocol	At next request for prescription (3.3)	High	To ensure that the shared care protocol is available on local extranet (action for medicines management team) ^a
	R1	Shared care protocol is available on local extranet but lack of GP awareness	A specialist drug may be prescribed without reference to the shared care protocol	At next request for prescription (3.3)	High	Screen alert when prescribing
	R1	Shared care protocol is available via local extranet but lack of GP access rights	A specialist drug may be prescribed without reference to the shared care protocol	At next request for prescription (3.3)	High	To make a link available to local extranet webpage (will need user name and password). Practice to ensure all GPs and locums have a user name and password, and an easy way to retrieve them
	R1	Shared care protocol is available via local extranet but out of date	A specialist drug may be prescribed without reference to the current shared care protocol	At next request for prescription (3.3)	Low	To ensure that the current shared care protocol is available on local extranet (action for medicines management team) ^a
	R1	Lack of GP awareness of availability of shared care protocols from other external web-based NHS resources (GP1, GP2)	A specialist drug may be prescribed without reference to the shared care protocol	At next request for prescription (3.3)	Medium	Screen alert when prescribing with names of external web-based NHS resources

... continued

Box 5 continued. Application of SHERPA to the prescribing of specialist drugs by GPs

R1	Lack of GP awareness of prescribing support from other electronic or manual resources (drug specific, for example, drug interactions, monitoring) [GP1, GP3, GP9]	A specialist drug may be prescribed without reference to the shared care protocol	Following issue of prescription, end of surgery (3.3) At next request for prescription (3.3)	High	Screen alert when prescribing; checks to be made before next prescription due date
R1	GP unaware of local CCG pharmaceutical adviser contact details (GP1, GP2, GP3, GP4, GP5, GP8, GP9)	A specialist drug may be prescribed without reference to the shared care protocol	Following issue of prescription, end of surgery (3.3). At next request for prescription (3.3)	Medium	Details of local CCG pharmaceutical adviser to be made available either at the GP practice and/or in the GP clinical system

**Medicines management team refers to the primary care NHS pharmacist-led management framework that supports and advises local NHS CCGs, GPs, and other stakeholder groups, although actual arrangements may differ locally. CCG = clinical commissioning group. EHR = electronic health record. SHERPA = systematic human error reduction and prediction approach.*

the shared care protocol or requirements for regular blood tests. Other interventions described were manual tasks to contact and liaise with a range of individuals, such as other GPs, primary care pharmacists, and clinical teams in secondary care. Application of both HTA and SHERPA identified a potential operating model for a CDSS to support GPs in prescribing specialist drugs. Box 6 describes an HTA of this proposed model, which demonstrates how GPs could potentially safely prescribe a specialist drug in primary care.

DISCUSSION

Summary

Previous studies have identified concerns from GPs in prescribing specialist drugs and in the use of shared care protocols,^{11–13} Difficulties have included lack of awareness or access to either local traffic light classification lists or shared care protocols.¹¹ Furthermore, CDSSs have been reported to appear too late during patient consultations, by which time GPs had already made a decision around treatment options.³⁷ In the current study it was identified that the lack of specific functionality in GP clinical systems (EMIS, Vision, SystemOne), including CDSSs, adversely affected the GPs' ability to resolve problems associated with prescribing of specialist drugs. To the authors' knowledge, this is the first study to perform a detailed analysis of the tasks and potential errors (HTA and SHERPA) during the prescribing process in the three major GP clinical systems available in the UK. This detailed analysis enabled the identification of specific weaknesses and potential errors with current systems that have not been previously identified, and the proposal of possible solutions in the form of a potential operating model for a CDSS to support GPs in prescribing specialist drugs.

Strengths and limitations

The strength of this work resides in its use of human factors methods (HTA and SHERPA) for analysing the GPs' tasks and workflows in prescribing specialist drugs. Using human factors techniques and risk assessment methods are encouraged for designing healthcare interventions.^{38,39} Nevertheless, this is the first study that has analysed the prescribing of specialist drugs by GPs using these methods. Participants used the three major GP clinical systems available in the UK. This ensures that the findings are relevant to most GP practices. However, the recruitment process of the participants was not optimal as two of the GPs (GP1, GP2) participated in both

Box 6. Hierarchical task analysis for prescribing specialist drugs by GPs (potential operating model supported by CDSS)

Prescribing a specialist drug

PLAN 0: Either during or outside a patient consultation do 1, 2, and 3 in order.

1. Open patient's electronic health record
2. Get familiar with patient's clinical history
3. Review a request to prescribe a specialist drug

PLAN 3:

Do 3.1 to 3.10 in order and according to instructions

- 3.1. Enter the 'Management of Specialist Drugs Module' integrated within the electronic health record
- 3.2. Enter drug name and check drug attributes
- 3.3. If drug is 'hospital only' go to 3.10
- 3.4. If drug requires a shared care protocol go to 3.5
- 3.5. Module will automatically update fields for monitoring requirements according to the information in the patient's electronic health record
- 3.6. If data are not available in patient's electronic health record, module will automatically prompt action or task, for example, full blood count
- 3.7. Decide whether to accept clinical responsibility for prescribing the specialist drug. If agree to accept clinical responsibility go to 3.8, if decline, go to 3.9
- 3.8. Follow the prescribing workflow and issue prescription (consider repeat or acute prescription)
- 3.9. Decline clinical responsibility for prescribing the specialist drug, go to 3.10
- 3.10. Exit module, system will automatically refer to hospital clinic, inform the patient
- 3.11. Module will save all recorded information with relevant Read codes in the health record on exit and automatically update the prescribing authorisation and/or review date
- 3.12. If GP does not enter the 'Management of Specialist Drugs Module' and prescribes a 'hospital only' drug or prescribes a drug without reference to the shared care protocol, the GP clinical system will automatically alert the GP

CDSS = clinical decision support system.

the early stages of technology development, before more detailed processes of interface design are undertaken. Furthermore, although HTA was chosen as the preferred research method in this study, the results from the SHERPA analysis identified that further exploration of the decision-making processes used by GPs is required. This could be undertaken by adopting a cognitive approach to task analysis to inform further research in this area. It is also common that repeat prescribing and tasks relating to hospital correspondence are undertaken separately from the patient consultation.

Comparison with existing literature

Although health care has increased the awareness of retrospective safety assessment techniques such as root cause analysis, the use of predictive safety assessment techniques (such as SHERPA or failure modes and effects analysis) is limited and there is a need to adopt more proactive and rigorous approaches.^{40,41} This work is novel as no previous study has applied HTA and SHERPA to inform a CDSS for prescribing specialist drugs. Previously reported use of HTA with or without SHERPA in the UK has been primarily limited to the study of endoscopic surgery,⁴² diagnosis,⁴³ drug administration,⁴⁴ and anaesthesia use.⁴⁵

Implications for research and practice

The results from this study have highlighted that, despite the availability of CDSSs and other functionality in GP clinical systems, safety concerns remain with the use of specialist drugs prescribed by GPs in primary care. Designing a CDSS that considers the needs of GPs, their current workflow, and their decision-making process has the potential to both facilitate the prescribing of specialist drugs and decrease the associated risks with prescribing errors. Designing and evaluating with GPs a CDSS prototype, based on the authors' operating model, could be a meaningful step in improving the current prescribing process. In addition, further research could investigate how GP clinical systems and community pharmacy systems could incorporate active hard stops to alert users when hospital-only drugs are prescribed.

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Ethical approval

Ethical approval for the key informant interviews (Reference BDM/11/12-82) was granted by King's College London Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee on 28 May 2012. A modification of this application to include the observational study and interviews with GPs was granted on 9 May 2014.

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the exploratory study and the main study, whereas GP3 was involved in the piloting of the exploratory study and also participated in the main study. All of the GPs worked in a single clinical commissioning group, were purposively selected, and were known to the lead researcher, which may have introduced bias. All of the GPs described themselves as having either good or high IT aptitude, and this may have introduced bias linked to competencies in the use of computers, GP clinical systems, and CDSSs. Therefore participants who were less computer literate could have found the prescribing process even more challenging. A limitation of this research is the focus of the HTA on the process of prescribing at the exclusion of other tasks GPs routinely perform, such as history taking or patient examination. Future work to develop a fully functional CDSS will need to consider how prescribing interacts with other consultation tasks. However, this approach is common during

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