The prescribing of specialist medicines: what factors influence GPs' decision making?

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Background. As Governments worldwide strive to integrate efficient health care delivery across the primary–secondary care divide, particular significance has been placed on the need to understand GPs' prescribing of specialist drugs.

Objective. To explore the factors which influence GPs' decision-making process when requested to prescribe specialist drugs.

Methods. A qualitative approach was used to explore the perspectives of a wide range of practice-, primary care trust-, strategic health authority-level staff and other relevant stakeholders in the North-West of England. All semi-structured interviews ($n = 47$) were analysed comprehensively using the five-stage ‘framework’ approach.

Results. Six diverse factors were identified as having a crucial bearing on how GPs evaluate initial requests and subsequently decide whether or not to prescribe. These include GPs' lack of knowledge and expertise in using specialist drugs, the shared care arrangement, the influence of a locally agreed advisory list, financial and resource considerations, patient convenience and understanding and GPs' specific areas of interest.

Conclusion. This exploration of GPs' decision-making process is needed to support future integrated health care delivery.

Keywords. Decision making, GP, prescribing, primary care, qualitative research.

Background

In 2008, the National Prescribing Centre highlighted the importance of patient medicines management activities between primary and secondary care. Like the Department of Health’s White Paper ‘Our health, our care, our say’, it also encouraged the enhancement of primary care’s role in the routine management of patients with chronic conditions. Over the last number of years, GPs have accepted this increasing role by responding to the evident need, and ever growing demand, for a wider range of community services. The General Medical Services (GMS) contract has assisted the reshaping of NHS services by providing clearer definition for GPs and specification on the financial gains obtainable. By allowing more care to be delivered outside the acute care setting, patients in turn have benefited from a reduction in the number of outpatient visits and an enhancement in the quality of care provided by their primary care team. Popular among diabetic patients, integrated care schemes were also shown to be cost-effective, and of financial and clinical benefit to asthma patients. GPs have been facilitated in developing specialist interests and able to monitor and prescribe more specialist drugs as specified in shared care arrangements.

Specialist medicines have been defined as ‘medicines, usually of high-cost, that are initiated only by a hospital doctor and require complex prescribing and/or therapeutic monitoring arrangements not normally undertaken in general practice’. Horne et al. examined GPs’ perceptions of shared care arrangements that involved the prescribing of specialist drugs and found that such arrangements caused them considerable concern. The study showed how GPs did not perceive the prescribing of specialist medicines in general practice to be jointly managed and highlighted difficulties with the communication process. This contrasted with previously published guidance which advised that when ‘prescribing responsibility for a patient is transferred from...
hospital to GP it is of utmost importance that the GP has full confidence to prescribe the necessary drugs. Although Horne et al. also highlighted how the medico-legal aspects of prescribing were of particular concern to GPs, recent development of ‘traffic light systems’ by primary care trusts (PCTs) and regional groups across the UK may help address their unease. These advisory lists provide recommendation on prescribing responsibilities through the classification of drugs as ‘Red’ (for hospital prescribing only), ‘Amber’ (appropriate for shared care arrangements subject to clinical agreement) or ‘Green’ (appropriate for primary and secondary care prescribing). While Horne et al. highlighted how such GP requirements should be considered in future, shared care arrangements, limited information is available on what factors influence GPs’ initial decision to participate in such arrangements and/or prescribe specialist drugs. This study aims to address this knowledge gap.

Methods

Participants
This study involved three sequential stages. Stage 1 sought the perspectives of a wide range of practice staff [GPs (n = 14), practice managers (n = 9), nurses (n = 6) and administrative staff (n = 7)] from nine general practices in three North-West PCTs. These practices were purposively selected to include one or more GPs willing to participate in a face-to-face semi-structured interview. Additional information and further explanation were sought from the pharmaceutical adviser/prescribing lead in each PCT (Stage 2, n = 3) and stakeholders with a vested interest in the primary–secondary care interface (Stage 3, n = 8). These stakeholders included the hospital chief pharmacist, medical director and members of various interface groups like the strategic health authority (SHA) Interface Prescribing Group (a group specifically set up to address interface prescribing issues). Recruitment for all stages involved the distribution of letters of invitation. This iterative process enabled a holistic and in-depth picture of the multifaceted primary–secondary care issues to be built; only data about GPs’ decision-making processes when requested to prescribe specialist drugs are presented in this paper. Ethical approval was obtained, with individual and institutional confidentiality assured.

Interviews
Stage 1 interviews were conducted between January and July 2005, Stage 2 between July and August 2005 and Stage 3 between October 2005 and January 2006. All interviews took place at a location of the interviewee’s choice and lasted for ~25–150 minutes. Interview schedules for practice staff elicited information on a range of topics including existing shared care arrangements, prescribing responsibility issues, GPs’ own knowledge and expertise regarding specialist drugs and the quality and quantity of supplied information. Throughout the interviewing process, the researcher refined questions, pursued ideas and investigated further areas in depth. Interviews with PCT staff and stakeholders sought further knowledge and increased understanding about their perception of GPs’ attitudes to prescribing responsibility, specialist drug requests, licensing and classification within the relatively new Red–Amber–Green list (a locally agreed advisory list). The authors judged that thematic saturation had been successfully achieved when subsequent participants’ interviews yielded no new themes. All interviews were audiotaped with permission and transcribed verbatim.

Data analysis
A robust and complete analysis was carried out using the five-stage ‘framework’ approach. This involved developing a workable list of main and subthemes and applying it systematically to the whole data set using computerized software QSR N-Vivo version 2.0. This index was continually refined and reapplied to ensure consistency. The close proximity of important themes was noted, and apparent ‘negative cases’ were examined. The ‘constant comparison’ technique was used to move backwards and forwards between the data and evolving explanations for the recurring patterns and associations. A research diary was kept to help overcome threats to validity and promote the author’s ‘reflectivity’. Words in parenthesis have been added by the authors to clarify meaning, and ellipses (...) have been used to indicate the removal of unrelated text. The following key identified Stage 1 participants—DR: Doctor, PM: Practice Manager and NU: Nurse; Stage 2 participants—PA: Pharmaceutical Adviser or PL: Prescribing lead; Stage 3 participants—ST: Stakeholders. As the data from the administrative staff were not relevant to the focus of this paper, those interviews are not included. An identification code was assigned to reflect the order of interviews.

Results
Six factors impacted on GPs’ decision-making process when requested to prescribe specialist drugs. These included: ‘The Specialist Medicine, The Quality and Quantity of Information, The Shared Care Arrangement, The Financial Arrangement, The Patient, The Practice Decision and GPs’ Specific Areas of Interest’. The importance of each of these factors was dependent on the beliefs and behaviours of each individual GP and/or others within the practice.

The specialist medicine
GPs’ decision making was influenced by the type of medicine. This incorporated three main themes: GPs’
own knowledge and expertise, the drug’s licence (marketing authorization from a national regulatory body) and classification within the Red–Amber–Green list.

GPs’ own knowledge and expertise significantly impacted on their decision to prescribe, with one GP emphasizing his discontent in making such a decision about drugs for ‘cancer and neurological diseases … things which we have no experience of prescribing’ (DR1). This view was also shared by another GP who expressed her apprehension about prescribing a requested ‘mega cytotoxic drug’ which she was keen to point out ‘wasn’t even on the (hospital’s) formulary’ (DR2). Her struggle to make a decision acquired particular significance when ‘the patient ended up leaving the list to go to another practice’ (DR3). An outcome which caused her particular unease as she ‘was genuinely trying to do the best for the patient’ (DR4). In her account, she reflected on her actions as legitimate, explaining how she was faced with no alternative but to refuse to prescribe. Stakeholders displayed understanding for her situation, with one perceiving GPs as ‘a bit nervous about accepting prescribing responsibility (for) something that is new or they are not familiar with’ (ST4).

Whether the specialist medicine was licensed or requested to be used outside the terms of the licence (off-label/off-licence) was of varying importance to GPs. One GP recounted frequently being asked to prescribe such drugs, emphasizing the practice’s willingness to prescribe.

By and large as a practice we have taken the line with melatonin, Ritalin® … certainly unlicensed use that’s quite common. Off-licence use, I guess you would have to say that that is not an unusual thing to do both in general practice and secondary care … I wouldn’t have a great issue with that (DR9).

Another GP reflected on how some colleagues would contact specialists for supporting evidence when presented with unlicensed recommendations.

If there is a drug that’s not licensed for that purpose, what they’ll do then is phone up and just say ‘you have given this’ and just ask ‘why?’ or ‘what evidence is there behind it?’ … they might refuse if it’s dangerous (DR11).

GPs’ hesitation in prescribing may be partly related to the likely ‘Red’ classification of such unlicensed drugs. Although this GP admitted not having ‘come across it that much to know’, she still portrayed a willingness to authorize such recommendations, explaining how ‘most of the time I’d probably be happy to say well, it is what this specialist recommended’ (DR11).

The Red–Amber–Green list was perceived by two practice managers as influencing GPs’ decision making, one of whom explained how such a list provided clarification and support to those who refused to take on prescribing responsibility.

So like the Red-Amber-Green thing for instance and now that certainly clarifies the position on a lot of drugs and you have got back-up to say “No, we don’t do this because it has been agreed” … So it is making things clearer and making your areas of responsibility probably clearer as well (PM).

This manager also highlighted the importance of distributing such a list among practice staff, perceiving his GPs as knowledgeable about its contents: ‘they have all got a copy of it and we have discussed it, so it is something that we are aware of’ (PM). However, GPs’ accounts in the same practice seemed to refute this, with one stating ‘I haven’t come across that (List)’ (PM). A GP in a different practice also recounted: ‘They have this Red–Amber–Green don’t they in the PCT but I don’t know what’s on it or not on it’ (PM). The manager of this practice was completely unaware of the document’s existence, with a fellow GP regarding it as appropriate to ‘just ignore’ its contents. One stakeholder also acknowledged how: ‘awareness of it is fairly low … I am absolutely convinced … There are a lot of GPs out there that still do not understand what the concept of Red-Amber-Green is. Does it exist? What is it? What does it do? Who has done it?’ (ST).

The inadequacies of the dissemination process were brought into focus, with one pharmaceutical adviser acknowledging the ‘poor communication, poor dissemination’ (PA) within her PCT. She accepted that the PCT was responsible for GPs’ lack of awareness of this SHA document, explaining how ‘it’s not their fault. It’s very much our (PCT’s) fault. Very much’ (PA).

Alternatively, some GPs may have ‘contact(ed) the(ir) pharmaceutical adviser’ upon receiving such requests previously and became aware of the Red–Amber–Green list at that point: ‘He is very good and usually says go ahead or not. That’s hospital only and you don’t do that’ (PM).

One stakeholder highlighted ‘the danger of the Red–Amber–Green list’ emphasizing how adherence ‘can stifle’ patients’ ability to ‘be treated where they are best treated’ (PM). GPs were presented in his account as having the necessary competencies and confidence to undertake such specialist drug prescribing and he appeared unsupportive of any proposed changes to already established practice (which the Red–Amber–Green list was perceived to have encouraged). A second stakeholder was also eager to emphasize how the Red–Amber–Green list should not interfere with already established practice between individual PCTs and hospitals.
where a local hospital (and) PCT have got an agreement on something and that agreement works to the satisfaction of both organisations, if that happens to be different to what has been agreed in the Red-Amber-Green we are not going to dictate to them you have to fall in line. If it works for them they can get on with it (ST45).

The quality and quantity of information
The quality and quantity of secondary care information supplied also influenced GPs’ decision making. This encapsulated two main areas: the existence of shared care protocols for the ‘Amber’ classified drugs and GPs’ acceptance of these protocols.

GPs showed appreciation for specialist drug requests which were supported by evidence-based recommendations. One recounted the ‘thoughtfulness’ exhibited by a specialist who provided ‘the paper on it’ and ‘the thinking behind’ (DR34) his drug choice. This specialist was presented as being attentive to GPs’ needs, explaining what to do in an untoward event.

we started to prescribe metformin for polycystic ovaries . . . I love it when the consultant does a bit of explanation about . . . “This is what I have done now. This is what should happen. If you need more do this and do that”. . . I appreciate the teaching that comes with it sometimes (DR34).

However, the majority of specialist drug requests appeared to be supplied with less supporting information, one prescribing adviser recounting ‘a lot of times that they (GPs) get written out to, very little information comes with that request’ (PL39). This was supported by a stakeholder who portrayed ‘consultant staff’ as ‘not particularly good at transferring the information when they are asking GPs to prescribe’ (ST45).

The existence of a shared care protocol. The classification of drugs as ‘Amber’ enabled prescribing responsibility to be transferred from secondary to primary care once the patient has been stabilized and an agreed shared care arrangement established. Such arrangements require a shared care protocol to be drawn up, following joint discussion and agreement. However, this study suggests that specialists’ drug requests were often not accompanied by such protocols thus creating difficulties for GPs:

There are no shared care protocols for a lot of the Amber drugs sometimes or if it is a new drug, so consequently the GP doesn’t know exactly what they are taking on. Consultant doesn’t give the full list of information so there is an impasse in communication (PA38).

A second stakeholder, offering similar evidence, believed the perceived shortcomings started during the
classification of specialist drugs into the Red–Amber–Green list.

when it (Red-Amber-Green List) first started off, drugs were arbitrarily being slotted into the Amber list and there were no shared care arrangements behind them so suddenly because there were no shared care arrangements in effect they were Red drugs. GPs would turn around and say “Well, we have no shared care (arrangements). We won’t prescribe these drugs” (ST40).

This view was supported by GPs across each of the PCTs, as exemplified by the actions of staff in one practice.

as a practice we would refuse to prescribe something that we weren’t comfortable with, and we have done so in the past, but I think most of the common areas are covered with these shared protocols (DR15).

Another GP was unable to think of any specialist drugs that were prescribed without a protocol and recalled how ‘blood tests and the follow-up for methotrexate, azathioprine, gold’ (classified as ‘Amber’ drugs for the conditions being treated) were ‘all done to protocol’ (DR9).

A second explanation for the lack of protocols is related to the beliefs and behaviours of requesting consultants. From one stakeholder’s perspective, consultants in the past have chosen to overlook the SHA interface group’s recommendations and requested GPs to prescribe ‘Amber’ drugs without shared care protocols. Despite informing them of their obligations, one stakeholder was met with what he perceived as a lack of consultant understanding of the importance of supplying such documents.

often if you tell the consultant “Oh yes, fine. You can use the drug and it is Amber etc. but only when we got the shared care protocol”. The shared care protocol gets binned. “We will forget that. I have got more things to do with my time” and they will start. So in some cases they will try to get the GPs to prescribe it without a shared care protocol (ST45).

Acceptance of the shared care protocol. Shared care protocols accompanying ‘Amber’ drug requests were not always accepted by GPs. This was exemplified in one stakeholder’s account who recalled how various authoritative groups had approved the ‘use of a growth hormone’ and its associated ‘shared care protocol’ (ST45) prior to distribution to GPs. Despite gaining such formal approval, he felt that individual GPs’ acceptance was not guaranteed.

So the shared care protocol was approved by the SHA prescribing group, was approved by the local hospital Medicines Management Group, was
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approved by the Primary Care Trust Medicines Management Group with GP and PCT representatives on both groups and then when we tried to roll it out, we have GPs saying “Oh, no, we are not taking on the responsibility for that”. So it is still mostly very much a mess (ST45).

The development process was perceived to influence GPs’ acceptance: ‘the majority of GPs will be asked to accept a shared care protocol which they have had no say in developing’ (ST45). Although this stakeholder felt it was inappropriate and unfeasible to gain the input of ‘thousands of GPs across SHA’ (ST45) for the process, he emphasized that shared care protocols were ‘never developed and agreed without (some) GP input’ (ST45). He also considered the adaptation of existing protocols from other organizations to be another influencing factor and felt GPs were justified in not accepting them if they were ‘out-of-date’ or ‘had simply been adopted from another health authority without any kind of amendment’ (ST45).

The shared care arrangement

A third factor which impacted on GPs’ decision making was the shared care arrangement. This consisted of two elements: the monitoring arrangements and follow-up arrangements. Four interrelated subthemes central to understanding the former were the nature of the patient group, sharing of test results, complying with the shared care arrangement and response to requests for specialist advice. The importance of the latter element was illustrated by one GP who felt that as long as ‘they (patients) are under follow-up then I am not bothered’ (DR30). However, the routine follow-up of rheumatology and neurology patients was considered inadequate by another, who explained how ‘I would think the biggest problem we have probably in disease monitoring these days is cancellation of appointments in the follow-up process particularly’ (DR9). Despite this, she accepted that ‘patients are generally stable’ (DR9) and cancelled appointments were usually rescheduled.

The financial arrangement

The financial and resource implications of participating in shared care arrangements and/or prescribing specialist drugs also appeared to influence GPs’ decision making. This was particularly evident in PCT staff accounts, with ‘extra payment’ sought by GPs ‘to take on this prescribing’ (PL39). The importance of financial reimbursement was also recognized by another stakeholder, who felt that practices were obligated in the past to ‘absorb’ the extra costs associated with taking on rheumatology patients. However, with a perceived rise in patient numbers, he believed practices were now faced with no alternative but to seek extra payments.

One GP also emphasized how the size of their practice and limited resources had hindered their ability to participate in shared care arrangements. Although recognizing the potential benefits of providing a local anti-coagulant service, she highlighted the need for additional support:

it is a lot of work just to say “You do it”. You have to give us some sort of backup to do it. It is an enhanced service so it’s good if people can access it in the area . . . You have to balance it out with what you can do in the practice I mean it is a small practice here you cannot do that much (DR34).

The patient

Patient convenience and understanding also influenced GPs’ decision-making process. According to one practice manager, GPs considered the patients’ circumstances when asked to prescribe the ‘Red’ drug goserelin (Zoladex®). She explained how one GP felt it was ‘not fair to ask them to go all the way to the other side of the city (to the hospital) just for her to be given an injection so we now do it here’ (PM35). Her account was also confirmed by the GP who, although reluctant, helped the patient by participating in this ‘very off-the-wall prescribing’ (DR34). Another GP recounted how a specialist medicine was prescribed for ‘a young girl who has got some kind of haematological thing’ because it was ‘not convenient for her to get everything from the hospital’ (DR24). The pharmaceutical adviser also shared this view, recognizing how it was ‘totally inconvenient’ to have a patient ‘coming back to the hospital to get the drug every month, every week’ (PA38). Some GPs were assured by the fact that patients had been made ‘aware of the pit falls or hazards’ (DR25) before prescribing. Another GP offered similar evidence by explaining that if it has been initiated and the patient understands it and we understand it we probably have taken the line that if the patient needs it, we will prescribe it’ (DR9).

The practice decision and GPs’ specific areas of interest

The sixth factor suggests that GPs’ decision making to participate in shared care arrangements and/or prescribe
specialist drugs was influenced by discussions within the practice. According to one nurse, the decision to ‘take all the monitoring on for ... patients with rheumatoid arthritis’ was made ‘as a practice’ (NU7), following lengthy discussions about the feasibility and practicalities. Another GP explained how ‘we might mention it at a practice meeting and we meet every week so yes I might say “Oh, you won’t believe what I have had a demand for ... or have you ever heard of this?”’. (DR24). The practice’s decision was influenced by whether a GP within the practice had a special area of interest.

Dr Y has got a real interest (in Dermatology) so anyone that has got a funny skin condition is on some really wild and wonderful drugs has automatically gravitated to her already even prior to her been referred to secondary care (DR23).

His colleague supported this view, explaining how GPs tended to ‘have little fields of expertise’ like ‘Dr Y is our dermatology special interest person (so) most of those patients go back to see (her) until they become better’ (DR25). This GP felt it was appropriate to trust her experience and issued repeat supplies of medication based on her recommendations.

Another GP described her unease about ‘sign(ing) a prescription that has been generated (for) a patient that I didn’t refer’ (DR24). In her account, she expressed her dislike for checking and signing repeat prescriptions generated at the patient’s request (a process that enables patients to obtain further medication supplies without having to routinely see the doctor). As this process requires the prescriber to make an informed decision about whether to change or stop medication, she highlighted her aversion towards accepting responsibility as ‘named signatory’ for specialist drugs she knew nothing about.

Let’s say one of my colleagues referred a patient to the paediatrician with hyperactivity. Doctor put them on Ritalin® and I had to sign the prescription and I don’t know anything about ... I don’t want to prescribe Ritalin®. Not my patient, not my problem, not my referral. Bit of a problem. Because the prescription was generated in our reception area on the request form and I am the one that is signing prescriptions today (DR24).

Discussion

This study has identified six factors shown to have a crucial bearing on how GPs’ evaluate initial requests and subsequently decide whether or not to prescribe specialist drugs.

Like any research study, this study had inherent limitations. It was undertaken within a single SHA in England and, as such, it was difficult to assess the representativeness of participants’ attitudes in relation to general practice as a whole. Common themes did emerge and thematic saturation was satisfactorily achieved; yet caution should still be taken in generalizing the findings. A further limitation of this study was the focus placed on primary care perspectives; Patients, hospital clinicians and discharge liaison nurses may have offered alternative viewpoints. Notwithstanding these limitations, the findings have important implications as one of the main strengths of this study was the breadth of participants interviewed, some of whom had recent or current experience in secondary care. The sequential approach also enhanced the entire study by allowing the results obtained in one stage informing that of the next.

Internationally, general practice plays an important role in providing co-ordination and continuity for patients across episodes of specialist care. The seamless movement of patients between settings is facilitated by the effective delivery of information between primary and secondary care physicians. In the USA, primary care physicians visit and communicate with their hospitalized patients and respective specialists to check on progress. According to Wachter and Pantilat, this approach helps mitigate the risks associated with discontinuity in care between settings, considered the greatest liability of the increasingly prevalent hospitalist model. This model, in which ‘a separate inpatient physician manages patients during a hospital stay, returning the patient to the primary care physician at discharge’, has similar inpatient–outpatient discontinuity to the European system, although it differs in other respects. Primary care physicians worldwide rely on the quality and quantity of hospital information for decision making; our study shows the many other factors that influence their decision making when asked to prescribe specialist drugs.

Of particular concern to GPs was their lack of knowledge and expertise in using specialist drugs. This age-old problem was a significant factor in their decision making with several accounts, suggesting that the lack of supporting evidence may have accentuated this. As Horne et al. observed, GPs were more likely to participate in shared prescribing if they felt that hospital doctors were ‘supportive, informative and understanding’ of their position. Whether the specialist medicine was licensed or requested to be used off-licence was also found to influencing. This emphasized the varying importance that some GPs placed on their prescribing responsibility and consequent accountability for adverse effects which may occur. The possibility of GPs being held negligent may have discouraged some from accepting responsibility and encouraged those who did to inform their patients of adverse effects before prescribing. This may explain the importance which some GPs and PCTs/communities, respectively, placed on...
‘patient understanding’ and GP awareness of their prescribing responsibilities. Such findings reinforce the need for good communication and sufficient information to accompany specialists’ prescribing requests.

Although the existence of shared care protocols may go some way towards addressing GPs’ concerns, this study also revealed significant obstacles to the availability and acceptability of shared care protocols for specialist drugs. The emerging message is that these protocols may not exist when initial requests are made; for those that do exist, their dissemination and subsequent acceptance was not always guaranteed. This study therefore challenges the local discussion and agreement of shared care protocols between relevant parties, i.e. the individual specialist and GP. Rather, it is the SHA or PCT in association with local consultants. The work of Gerada and Tighe supports this finding, by confirming how few SHAs involved GPs in the development of their shared care protocols. Although impractical to involve all GPs in the process, one might suggest that this influenced GPs’ acceptance of a document that they had little input in developing.

This study supports the work of Sibbald et al., Illife et al. and McCrone et al. by highlighting the practice resources needed to participate in shared care arrangements. The introduction of the new GMS contract has ensured that national pricing is used as the basis for commissioning services and enabled practice activities such as monitoring of anti-rheumatic drugs to be paid for. Patient convenience and understanding also influenced GPs’ decision-making process. Although the patient’s situation was reportedly taken into account, this factor was mentioned less frequently when compared to others, and no evidence was presented to suggest that these decisions were made in partnership with patients. Variations in the quality and quantity of information received, including the lack of shared care protocols accompanying specialists’ drug requests, raise concerns about the quality of care patients receive. The need to continuously improve the quality of care provided to patients was a guiding principle of Lord Darzi’s recently published NHS Next Stage Review. According to this report, delivering this vision will mean tackling head on those variations in the quality of care and giving patients more information and choice. This study helps shed light on the improvements which need to made, if this vision is to become a reality. In conclusion, this study had a seamless care emphasis identifying factors which influence GPs’ acceptance and prescribing of specialist drugs. It also underlines the importance of increased understanding of GPs’ decision-making process for future integration of health care delivery across the primary-secondary care interface.

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