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A Qualitative Evaluation of General Practitioners' perceptions regarding access to medicines in New Zealand

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Article Summary

Article Focus

- To evaluate GPs' perceptions regarding access to medicines in New Zealand
- To identify GPs' views and perceptions regarding the role of PHARMAC within the New Zealand healthcare system.

Key Messages

- GPs were of the view that the current range of medicines available in New Zealand was reasonable, however it was acknowledged that there were some drugs that patients were missing out on.
- When considering the range of subsidised medicines available in New Zealand some GPs felt that there had been an improvement over recent years.
- It was highlighted that unexpected funding changes could create financial barriers for some patients, and that administrative procedures and other complexities created barriers in receiving a subsidy for restricted medicines.

1) Strengths and Limitations.

Strengths

- This is the first independent objective study covering GPs' perceptions regarding access to medicines issues in New Zealand.
- Findings from this study will form an essential component of any future research which reviews New Zealand's current medicines policy.
- It will also help in developing strategies to better inform patients' access to medicines, with GPs being a large group of health professionals likely to positively affect patient knowledge and views.

Limitations

- All GPs were working in a large metropolitan city in New Zealand – it is not known whether their views and experiences differ from colleagues working and living in small towns and rural locales.
- Also, only 19 out of 150 were interested in participating so this could be another source of bias in the study.

ABSTRACT

Objective

The objective of this study was to evaluate general practitioners' (GPs') perceptions regarding access to medicines in New Zealand.

Design Qualitative

Setting Primary care

Participants GPs

Main outcome measures

GPs' views and perceptions

Results

GPs were of the view that the current range of medicines available in New Zealand was reasonable, however it was acknowledged that there were some drugs that patients were missing out on. When considering the range of subsidised medicines available in New Zealand some GPs felt that there had been an improvement over recent years. It was highlighted that unexpected funding changes could create financial barriers for some patients, and that administrative procedures and other complexities created barriers in receiving a subsidy for restricted medicines. GPs also reported problems with the availability and sole supply of certain medicines and claimed that switching from a branded medicine to its generic counterpart could be disruptive for patients.

Conclusions

The research concluded that although there were some issues with the availability of certain drugs, most GPs were satisfied with the broader access to medicines situation in New Zealand. This view is to contrary to the situation presented by the pharmaceutical industry. The issues around sole supply, the use of generic medicines and the administrative barriers regarding funding of medicines could be improved with better systems.

INTRODUCTION

One of the aims of New Zealand's medicines policy is to ensure that New Zealanders have access to affordable medicines[1]. New Zealand has been successful in containing pharmaceutical costs, primarily via the policies of the Pharmaceutical Management Agency of New Zealand (PHARMAC)[2]. PHARMAC is the New Zealand Government agency that decides which medicines are subsidised. It was created in 1993 to ensure that New Zealanders get the best possible health outcomes from money the Government spends on medicines[3]. PHARMAC manages drug costs by applying pharmacoeconomic techniques when selecting medicines, and by promoting the use of generic medicines[4, 5]. It uses a capped national medicines budget, along with a variety of contractual arrangements with companies that enables a company's medicine to be listed onto the schedule and therefore enables access to subsidies for consumers. These contractual arrangements include rebates on list prices from PHARMAC, tendering for off-patent drugs, and bundle agreements where PHARMAC may list expensive new drugs in its Pharmaceutical Schedule[6] in return for the manufacturer discounting the price of other products it supplies[7]. Most off-patent drugs listed in New Zealand's Pharmaceutical Schedule[6] are supplied from one supplier under contract to PHARMAC (sole supply) and large price discounts are provided in exchange for exclusivity[7].

In community settings, only drugs on the Pharmaceutical Schedule receive government subsidy[7]. The government subsidy means that consumers who are New Zealand citizens or who have Permanent Residence make a co-payment (NZ$3; US$2.20 per prescription item) for each medicine listed in the Schedule. If the subsidy level PHARMAC has set for a particular medicines is less than the price charged by the drug company, then patients pay an additional fee, known as 'manufacturers surcharge'. For the medicines which are not listed on the schedule consumers are required to pay the full price.

With an annual drug budget expenditure for subsidised medicines used in the community setting of NZ$599 million in 2007[8], over 78% of all consumed medications are publicly funded in New Zealand. Although PHARMAC has played an important role in containing the pharmaceutical budget in New Zealand, in 2009 medicines expenditure was recorded as $694 million a year and is expected to increase to 734 million NZ$ by 2012 [9-11]. Health care expenditure is a key concern for many countries and countries amend and form their policies on the basis of ongoing empirical research. General Practitioners (GPs) form a vital part in this research process because they are key stakeholders in the access to medicines process.

GPs are the main prescribers in New Zealand and prescribe over 44 million prescriptions annually[12]. They influence the "demand side" of the costs, and knowing what they think about "access to medicines" is important when exploring the impact of a country's medicines policy. Although very little independent research is available on GP views on access to medicines in New Zealand[13], some research has been conducted by the pharmaceutical industry. One industry study of a sample of 528 GPs in New Zealand revealed GPs' dissatisfaction over the current system, and it was observed that a large majority (75%) of GPs supported a general review of PHARMAC[14]. It was also reported that GPs felt that PHARMAC was "too budget oriented" rather than patient focused, its decision-making "lacks transparency" and New Zealand's access to medicines "lags behind other comparable countries".

Furthermore, the study also found that 71% of clinicians rated New Zealanders' access to medicines as "poor" when compared with Australia[14]. PHARMAC has undertaken its own research[15] exploring health professionals' perceptions about how it functions (n=23), but only investigated PHARMAC's operational abilities and did not assess issues of access, availability and affordability of medicines[13 16].

Whilst the New Zealand Government promotes affordable medicines[3,4] the media has portrayed New Zealanders as having problems regarding accessing medicines[17]. Furthermore, it has been argued that "newer" and "more effective" medicines available abroad, such as risedronate, atomoxetine, galantamine and montelukast are not available in NZ[17-19].

Hence in this context, the current study was undertaken. The key aims of the study were to evaluate GPs' perceptions regarding access to medicines in New Zealand and to identify GPs' views and perceptions regarding the role of PHARMAC within the New Zealand healthcare system.

METHODS

A qualitative approach was adopted for the study, which was undertaken in Nov 2008- Jan 2009 in Auckland, New Zealand. Auckland is New Zealand's largest city, with approximately 1.25 million people residing in the greater Auckland area (about one third of the population of the whole country[20]). The Auckland region is covered by three District Health Boards (DHBs), of which there are a total of 20 in New Zealand. DHBs are responsible for providing, or funding the provision of, health and disability services in their district[21]. A list of GPs practicing within the greater Auckland region was obtained from the Department of General Practice and Primary Health Care at the University of Auckland. GPs were stratified according to the DHB in which they were located (n=360 for Auckland DHB; n=393 for Counties Manukau DHB; n=482 for Waitemata DHB). Fifty GPs were randomly selected from each DHB list and were sent information regarding the study (n=150 in total). This included a participant information sheet which provided an overview of the research study and processes, and a research consent form (with a freepost envelope) that GPs could complete and return to the research team to indicate their interest in participating.

A series of face-to-face, semi-structured interviews was undertaken. Questions were developed following a review of the relevant literature and to gather GPs' perceptions regarding access to medicines in New Zealand, and views and perceptions of the role of PHARMAC in relation to medicines access in New Zealand (a detailed list of the questions is attached in Table 1). Demographic information, including age, gender, practice type, and length of time practicing, was also recorded for each GP at the time of the interview. The interview guide was piloted with two health professionals prior to the fieldwork commencing, and further reviewed (and amended) following the completion of the first two interviews. Interviews took place at the GP's workplace. Seventeen interviews were conducted, at which stage data saturation was reached. Most were around 35 minutes in duration (range: 23-41 minutes), and all were audio-taped. GPs who took part in the study were offered a $50 book voucher in recognition of their contribution to the research.

All interviews were transcribed verbatim with the full transcripts utilised in the subsequent analysis process. Analysis of the data was undertaken by the research

team via a staged process. In the first instance, transcripts were read and notes were taken regarding key themes and issues. Following this, a basic coding framework was developed, and interview data were coded, with the assistance of the NVIVO software programme. Lastly, a series of group analysis sessions involving the senior members of the research team were conducted, whereby further refinement of the themes was undertaken. Each 'quote' from within each theme was read by a member of the research team, and a brief interpretation of the quote written on a 'post-it' note. These were then placed on a board, and moved around into sub themes.

Ethical approval for the study was gained from the University of Auckland Human Participants' Ethics Committee (Reference: 2008/445).

RESULTS

A total of 19 GPs returned a research consent form and 17 of those were interviewed. Over half of participants (n=10) had been practicing as a GP for more than 20 years, and 13 were male. GPs were recruited from each of the DHBs, although the majority were based within Counties Manukau DHB (n=10). An overview of the demographic characteristics of the sample is provided in Table 2. Key findings from the research are presented below.

General perceptions of access to medicine in New Zealand

When considering the range of (subsidised) medicines available in New Zealand, some GPs felt that there had been an improvement over recent years, and that – for the most part - sufficient drugs were subsidised and able to meet the needs of most patients.

> *95% I'm happy with what we have got. There are a small number of things which I would like more direct access to as a general practitioner. But I'm not aware of, and that may just be ignorance, of any major drugs or drug classes that we have zero access to. Most of the things that I'm aware of that are of any genuine value we have at least some access to.* [GP3]

Some comments were made, however, about the range being fairly basic or limited – particularly in relation to there being few options available, in terms of the number of brands subsidised within certain classes of drugs. This included medicines such as statins and ACE inhibitors. While some GPs were accepting of this, particularly in light of the country's limited drug budget, other reported that it could become an issue in certain circumstances (e.g. where a specific medication was not effective for a patient):

> *I would say that I have to struggle sometimes if one is not working. What can I do more to get it? What else can I try? So there are very limited options?* [GP1]

One GP noted that whilst they felt the current range of medicines available in New Zealand was *'reasonable',* they highlighted that it was likely there were some drugs that patients were missing out on. However, they also indicated that it was not always possible to know what these were:

> *For most GPs I think it is 30 drugs that cover 90% of your patients or something. So you kind of concentrate on those and the other ones you worry about but you don't actually worry about what you can't prescribe.* [GP7]

GPs were asked their views on the pharmaceutical industry's opinion that access to medicines is poor. There was limited agreement with this claim. Some GPs were dismissive of it, citing the self-serving nature of the statement and the fact that the pharmaceutical industry would have much to gain from promoting such a scenario:

> *Of course they would* [say that]. *They've got a vested interest ... I wouldn't listen to them* [laughter].... *A company has only got profit in mind, yeah. ...I mean they're playing a devil's advocate to PHARMAC so obviously they need to be there and they need to, they need to advertise their products to PHARMAC, but you know, they're only there for profit.* [GP9]

Others reported that, whilst it may be an issue in relation to some medicines, it was not a widespread occurrence. One GP noted that, due to the restrictive nature of New Zealand's pharmaceutical market, drug companies could see limited opportunities for marketing and reimbursement for their products and were subsequently withdrawing. Whilst this was viewed as a potential problem, it was also seen to be inevitable given the small size of the country (and associated drug budget).

Affordability of medicines

Patients in New Zealand are often required to pay a co-payment fee which ranges from 3 to 15 NZ$ per item for subsidised medicines. However, from 1st Sep 2008[22] (shortly before the research was conducted) the eligibility criteria for the lower co-payment of 3 NZ$ was expanded. In some cases, however, patients still have to pay up to a maximum pharmaceutical co-payment of $15NZ$ per item[22]. These are when the patients are not enrolled in a Primary Health Organisation[a] (PHO), if the prescription is from a private specialist (who is not part of the publicly funded system) or the patient does not have a Community Services Card or a Prescription Subsidy Card (PSC)[b].

It was acknowledged by GPs who took part in the study that the widening of the 3NZ$ co-payment had improved access to medicines for patients, given the lower fee structure. In particular, GPs felt that the 3NZ$ per item fee was at a level that most people would be able to afford, with some indicating that some level of fee was appropriate:

> *I think that by and large we have in New Zealand a good number of subsidised medications to use. So, the subsidy level such that the patients pay 3NZ$ I think is appropriate. I think that's, you know, I think sometimes if a thing's*

[a] Primary Health Organisations in New Zealand are health providers that are funded on a capitation basis by the New Zealand Government via District Health Boards.

[b] Community services card are issued for the patients with lower socioeconomic status while the PSC is for a family unit that has received 20 initial dispensing of single supplies of subsidised pharmaceuticals in the year commencing 1Feb to 31 Jan. People entitled for PSC are entitled for a reduce co-payment charges of 2NZ$ per prescription item.22. DHBNZ. Pharmacy Procedures Manual, 2010.

made completely free it's wasted. Its value is degraded. So, and yet that's a fine line between that and preventing access. [GP12]

Some GPs, however, were of the view that cost remained a barrier to accessing medicines for some people. This included people not registered with a PHO, those on limited incomes (including teenagers and the elderly) and patients with an extensive medicine regime:

I think the people who are on a large number of medications and I've got some here on 12 or 13 different pills..... Most of those people don't work, they are on a benefit so they are actually a little bit limited. Once they pay for 30 items[sic- 20 items] then they are fine but that is still $100 so for them, it is quite a cost or can become a cost. [GP7]

For some, the PHO enrolment system was seen as somewhat arbitrary, with one GP commenting that it was a *'ridiculous'* system, as *'essentially everyone is either registered* [with a PHO] *or should be'*. Other GPs, however, highlighted that the system encouraged patients to access their healthcare from one provider only, which was likely to have greater benefits than visiting a number of different general practices. Comments were also made regarding the complexity of the system, resulting in confusion for some patients:

Obviously encouraging patients to see their own doctor is a good thing, but there seems to be some inconsistencies between $3 and $15, whether they're funded or non-funded, enrolled or un-enrolled patient. You know, there's the question of waiting for three months before they become funded and enrolled and it becomes so, such confusion to patients. [GP8]

Affordability of non-subsidised medicines was discussed by GPs during interviews, with comments made about these being very expensive and only being accessible to the *"rich"*. Particularly for those GPs working in lower socio-economic areas, the cost to the patient was a key consideration when deciding which medicines to prescribe:

I work in South Auckland at the moment and I'll be choosing subsidised medications and I know that, in the large majority, if it is non-subsidised medication it will be a significant financial strain for people. [GP4]

Cost to a patient has a major influence on me. And in that I routinely prescribe generics and I tend to pre-warn people if something is going to cost an additional, or is not subsidised. Or sometimes ring the chemist to see what's cheaper and what it will cost. [GP3]

Changes regarding medicines subsidy and access to medicines

GPs talked about amendments in drug subsidy which could affect patients. This meant that prices sometimes fluctuated, with reports that the changing costs sometimes angered patients. As evident in the interview extract below, unexpected funding

changes could create financial barriers for some patients, and ultimately result in medicines not being accessed:

> *Those are snags that all of a sudden the rules change and you don't know about it and you have written a prescription for a child to have a medicine which normally would have been funded fully, no price whatsoever – and all of a sudden there is a change and now the parent goes to go and pick up* [name of medicine] *and now there is a partial charge to it. ...and the pharmacy calls me up in the middle of my next consultation and the parents have gone away because they couldn't afford the $7 or whatever the part charge was.* [GP6]

Another GP reported that keeping up to date with the subsidy changes was challenging, and also sometimes resulted in medication regimes needing to be amended:

> *I suppose my main comment would be about the things changing which cause us major problems having to rethink a medication regime that me may have just got really fine tuned. That's the major problem. The other major thing I suppose is keeping up with the continuous changes of what is subsidised and what isn't.* [GP4]

GPs reported that, for patients, the system was also confusing, particularly with regard to what medicines were funded and when (e.g. if accessed 'out of hours' higher charges are incurred). One research participant noted that informing patients about these issues sometimes dominated patient-GP discussions, at the expense of other important health-related issues.

Administrative issues

Despite a general level of support expressed by GPs regarding the range and accessibility of subsidised medicines, the research identified perceptions of the New Zealand system as being somewhat *'complex'*. GPs spoke about this being an issue both for themselves as health professionals – as well as for patients. Some GPs claimed that they did not always understand all the codes utilised (including 'section 29'[c]), and that the eligibility criteria for subsidies were inconsistent. Research participants also spoke about the system being based on controlling costs rather than patient care, with examples provided of drugs that - at the time of the research - were unable to be prescribed by GPs (e.g. initially only specialist could prescribe Isotretinoin, however later on GPs were allowed to prescribe with subsidy from 1 March 2009 [23]). With no apparent clinical-related reasons for this, it was therefore assumed that these were budget-related decisions.

GPs spoke about having to undertake '*a lot of paper work'* in order to receive a subsidy for medicines which are not listed for subsidy on the Pharmaceutical Schedule. This mostly related to processes for medicines requiring Special Authority.

[c] Section 29 is law that permits an unregistered medicine in NZ to be procured and supplied to patients.

"Special Authority" means that the medicine is only eligible for subsidy for a particular person if an application meeting the criteria specified in the PHARMAC Schedule has been approved.[20] Once approved, the prescriber is provided with a Special Authority number which can provide access to subsidy for a specified medicine. Applications can be made electronically via the Internet, although a paper-based system was also still in operation at the time of the research. It should be noted that one research participant, at least, was still using the old system, and another reported that they did not have access to the electronic system at their practice. This process was felt to not only be time-consuming, and add to an already heavy workload, but also burdensome:

> *We have a lot of medication in here, but then there's a lot of loopholes that we have to jump through to get those medications, you know, just like a lot of those special authority regulated medications… it creates so much more work for us before we can actually get the medication and so I guess a lot of those special authority medication if they can be available without special authority that would be quite good.* [GP8]

Having to reapply for Special Authority was also raised as an issue, particularly where medication was required for a long-term condition. Other comments made by research participants included the fact that *"too many"* medicines still required Special Authority approval (one GP noted that many of these were *"freely available"* overseas), and that the system and policy remained complex. Some GPs stated a desire for GPs to gain greater control of Special Authority medicines – in terms of being able to prescribe those that had been around for a longer period. It was also suggested that barriers in accessing Special Authority medicines should be removed for GPs who have been vocationally trained or who have special prescriber designation.

Despite some dissatisfaction with the system, it was acknowledged that the number of medicines requiring Special Authority had reduced over time. In addition, it was reported that the introduction of an electronic process for making applications had improved things considerably. There were also comments made about the protection that limited/restricted access affords GPs, in cases where patients are requesting a particular medicine that they do not feel comfortable prescribing (e.g. methylphenidate).

It was also acknowledged by GPs that a system that placed some restrictions on access to medicines was appropriate – and that patients should not have open access to any medicine they requested, nor that GPs should have the right to prescribe whatever they wanted, unrestricted. Findings from the research suggest that GPs considered the limitations appropriate, due to the need to improve rational use of medicines, to control costs, as well as safeguard against potential harm to patients:

> *I think that if their* [special authority restrictions] *aim is to reduce waste, I think sometimes an application and then a reapplication process is sensible, because many times I see in primary care a person's started on an agent and it's just continued without thought and conscious review of whether that agent's still needed and that can be an instance that causes harm* [GP12]

> *Well of course originally everything was totally free, and there was a much small, there was much smaller number of drugs provided back in the old days.*

And there really were no cost incentives for patients to comply…. I think it's changed, it's a little bit more rational now in terms of that …I think, there's probably for some people there probably is a price barrier whereas thirty years ago there were not, there was not. But again as I said I'm not unhappy having that signal there. [GP11]

Sole supply

As part of their cost containment system, PHARMAC issues requests for proposals from pharmaceutical companies to bid for the sole supply of specific medicines, with the contract awarded to the cheapest supplier[9]. Whilst the financial savings are a clear benefit of the sole supply system, negatives such as the risk of drug shortages due to a dependence on only one supplier were mentioned by GPs:

I think the sole supply thing from time to time has found to be wonky....I mean as soon as you have got sole supply you are heading for disaster because it is only one shipment away from either don't have any or something goes wrong like what happened with adrenaline....It seems like a crazy business model which has repeatedly failed in the past and I can't see why it is not going to fail in the future. [GP7]

As highlighted above, historical examples such as an adrenaline shortage in 2007, and other incidents such as problems with the supply of the flu vaccine were cited.

Brand switching/generic medicines

In New Zealand PHARMAC manages the drug budget by negotiating with drug companies; competition between suppliers is also encouraged.[6] Switches from a branded medicine to a generic version (and between different brands as a means of cost-saving) are commonplace.[20] At the time of writing, the Pharmaceutical Schedule listed 2000 funded medicines, the majority of which are generics. [20]

GPs reported that the switching from a branded medicine to its generic counterpart could be disruptive for patients. For example, issues such as the medicine being a different colour, or of a different name, could upset patients who sometimes needed added reassurance from their GP that the newly introduced medication was essentially the same medicine and would do the same job. It was also commented that patients sometimes viewed the replacement medicine as being inferior:

Each time the colour or something is changed, it is tough. Just recently I had a tough time explaining to a patient that it was the same medicine at the same strength and it just had a different colour. He still isn't convinced. I don't know what to do. [GP1]

Changes could be particularly disruptive for patients who were taking a wide range of medicines, and expressed frustration that GPs – as health professionals working at the 'frontline' – were not consulted before changes were introduced:

> *Every so often there is a major problem with the change of generic formulation. … Those sorts of changes occur without sort of any face talk from us and they are to do with widely prescribed medications ….. I think if something is broadly prescribed then widespread changes are inadvisable without you know asking GPs' opinion about it because we often have the front line appreciation of how differences in medicines do affect patients differently.* [GP4]

Another GP highlighted that a recent switch from a branded paracetamol to a generic formulation had created difficulties for some patients, and that reactions to a replacement for Ritalin™ had varied across different individuals:

> *I also don't agree with the information written in it saying that generics are as good as the original drugs. A lot of cases that has been proved not to be the case either in presentation, formulation. I mean the example would be the cheap Panadol™ [sic-paracetamol] they have got which dissolves before people can swallow. The problem with clogging of Salamol™ [salbutamol] pills [*sic - *inhaler]. The change in the effectiveness of Ritalin™ for example. I think it is about 40% of people reacted quite differently to it and to say that new drug is as good is absolute rubbish. So I think that's why I refuse to hand out PHARMAC's stuff. I just won't do it.* [GP7]

DISCUSSION

This study set out to explore the views of GPs in relation to access to medicines in New Zealand. GPs were generally satisfied with the range of medicines available and noted that there had been a recent improvement, but raised some issues in relation to specific drug availability and a narrow range within some classes. There were concerns about financial barriers for some patients. In some respects, the findings from our research seem to be at odds with those in relation to pharmaceutical industry research on GP views, in which GPs seem to be generally not satisfied with the range of medicines available, in terms of meeting the needs of their patients [13] and also the industry point of viewpoint which claims issues with access [17].

Whilst in this study the range of subsided prescribed medicines available was broadly supported, GPs highlighted that the cost of prescriptions could act as a barrier for some patients. This is similar to another New Zealand study[24] which stated that out of a total of 18,320 respondents, 6.4% reported that they had deferred collecting a prescription at least once during the preceding 12 months because they could not afford the cost of collecting the prescription. Younger adults aged 15-24, females, smokers, Māori and Pacific patients, and those with the lowest income status, were more likely not to obtain or buy prescription drugs because of cost barriers[24]. However, it is important to note that since September 2008 the co-payment for prescribed medicines have been decreased from 15 NZ$ to 3NZ$ for many people. It was acknowledged by the GPs in this study that the widening of the 3NZ$ co-payment had improved access to medicines for patients, given the affordability of the lower fee structure.

Sole supply and the perceived risk of drug shortages were raised as an issue by GPs in this research. Other problems with sole supply have previously been reported, including the poor quality of slow release morphine and a brand of felodipine with questionable pharmacokinetics and bioequivalence[25]. In addition, the flu vaccine chosen for sole supply in 2005 was under-strength in one of the three component flu strains, and another company had to step in to supply the vaccine[25]. However, PHARMAC reiterates that reference pricing and sole supply occurs only where it is clear that a loss of choice between one equivalent brand of drug and another is not considered critical[26]. It has been suggested that it may be possible to manage some of the problems around sole supply through contingency and indemnity clauses in tendering contracts[7].

The GPs in this study also discussed many administrative barriers regarding accessing medicines, including Special Authority, restrictions on prescribing certain medicines and a fair amount of paper work. However, since the research was conducted many of these administrative issues may have been solved by instituting a system of electronic Special Authority application[27, 28]. In addition, whilst issues were evident regarding Special Authority applications, it should be noted that, only a small proportion of people are taking medicines that require a Special Authority in order to access the subsidy for a specified medicine (for example it was found that less than 1% of patients require statin through special authority[29, 30]). Furthermore, many restrictions to medicines have clinical dimensions, and are not simply in place because of issues related to cost containment. For example, prior to March 2009, isotretinoin (Roaccutane®) was only available on "specialist only prescription medicines"[31]. Recently the specialist prescribing requirement was removed, however the decision has been criticised by the New Zealand Dermatological Society stating that Isotretinoin is prone to misuse.[32]. Moreover, these restrictions are not something which are specific to the New Zealand scenario, and are quite common in Canada[33], Australia[34],[41] and the United Kingdom[35]. Nevertheless, there remain issues around sole supply and administrative barriers regarding funding of medicines, which could be perhaps improved with better systems.

Concerns were raised by research participants regarding brand switching, and with respect to generics, which were viewed by some GPs as being of lower quality. Similar findings were observed in a New Zealand report which evaluated stakeholders' views regarding generic substitution. The report found that although PHARMAC and pharmacists agreed with generic substitution, physicians and opposed the proposal for voluntary generic substitution citing concerns which included reduced patient compliance, patient confusion and quality and bioavailability[36]. However, on the one hand, research indicates that most generic medicines provide the same quality, safety, and efficacy as the original brand name product, and are typically 20-90% less expensive than the brand name original[37]. Whilst generic medicines are associated with large cost reductions, findings from a study evaluating consumer perceptions in Auckland suggest that older patients and patients with chronic conditions needed more information about generic medicines. Less than half of survey participants viewed generic medicines "to be as safe, effective and equivalent in quality" than branded medication[38]. In addition, in a PHARMAC discussion, it was noted while the term ''generic'' is well understood by PHARMAC, the public may simply regard them as ''cheap'' [39]. Moreover, it has been shown the physician views can strongly influence those of their patients [38-39]. With

Medicines New Zealand, the New Zealand's medicines policy promoting the use of generic drugs and stating that consideration must be given to 'cost-effective treatment options'[1], it is vital that apart from assuring the quality of generic medicines, programmes that educate prescribers and patient about brand switching are required.

Limitations of the study

All GPs were working in a large metropolitan city in New Zealand – it is not known whether their views and experiences differ from colleagues working and living in small towns and rural locales. Also, only 19 out of 150 were interested in participating so this could be another source of bias in the study.

CONCLUSION

Whilst GPs in this study had some issues with the availability of certain drugs, they were generally satisfied with the access to medicines in New Zealand in primary care. The issues around sole supply, the use of generic medicines and the administrative barriers regarding funding of medicines could be improved with better systems. Findings from this study will form an essential component of any future research which reviews New Zealand's current medicines policy. It will also help in developing strategies to better inform patients' access to medicines, with GPs being a large group of health professionals likely to positively affect patient knowledge and views.

Competing interest statement
Piyush Grover was given a summer student scholarship by the University of Auckland to do initial work on the project. Lynne Bye and Rachael Butler worked as paid researcher from the grant received from New Zealand Pharmacy and Education and Research Foundation (NZPERF). Zaheer Babar and Janie Sheridan did not receive any personal funding or benefits from the grant. All authors have filled up competing interest forms (and have declared competing interest, if there are any) and are available upon request.

Authors' contribution

ZB was the principal investigator and designed the study with the input from JS, LB, and PG. PG did the field study. PG and LB entered, checked and validated the data. The data was analysed by LB, PG, JS, ZB and RB. ZB and RB wrote the paper with significant contribution from JS. All authors participated in editing the article and approved the text for final submission.

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Table 1: List of questions utilised in interviews with GPs

Domain 1 – General Practitioners' perceptions regarding access to medicines and high cost drugs in New Zealand.	
A	What is your understanding of the "access to medicines" in New Zealand?
B	In your opinion what is the current state of access to medicines and high cost drugs in New Zealand and why?
C	If and how has this access changed in the past few years?
D	What role do GPs play in determining the access to medicines in New Zealand?
E	How do you compare the access to medicines and high cost drugs in New Zealand with that of other developed countries?
F	The current notion by drug industries is that access to medicines in New Zealand is inadequate. What is your opinion?
G	Do you believe high costing medicines are readily accessible in New Zealand? Are there any examples you would like to mention?
H	Are there examples of medicines you would like to see being available in New Zealand?
Domain 2 - Views and perceptions regarding the role of Pharmac (Pharmaceutical Management Agency of New Zealand) to access of medicines in New Zealand.	
A	What is your understanding of the role of Pharmac in New Zealand healthcare system?
B	Do you think New Zealand needs an agency like Pharmac? Why?
C	Pharmac has been under immense public scrutiny. Is it justified?
D	How successful has Pharmac been in achieving its aims?
E	How does Pharmac influence the access to medicines for New Zealanders?
F	How do you find the decision making process undertaken by Pharmac?
G	Does Pharmac have sufficient representation from various health professionals and consumer groups?
H	What are your views on communication between Pharmac and GPs?

Table 2: Overview of GP sample

N	Number of participants (GPs)
District Health Board (DHBs)	
Auckland	5
Counties Manukau	10
Waitemata	2
Gender	
Male	13
Female	4
Age of participants (yrs)	
<40	4
40 – 60	10
60 +	3
Experience (yrs)	
<10	3
10 – 20	4
20 +	10

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A Qualitative Evaluation of General Practitioners' perceptions regarding access to medicines in New Zealand

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A Qualitative Evaluation of General Practitioners' perceptions regarding access to medicines in New Zealand

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Article Summary

Article Focus

- To evaluate GPs' perceptions regarding access to medicines in New Zealand
- To identify GPs' views and perceptions regarding the role of PHARMAC within the New Zealand healthcare system.

Key Messages

- GPs were of the view that the current range of medicines available in New Zealand was reasonable, however it was acknowledged that there were some drugs that patients were missing out on.
- When considering the range of subsidised medicines available in New Zealand some GPs felt that there had been an improvement over recent years.
- It was highlighted that unexpected funding changes could create financial barriers for some patients, and that administrative procedures and other complexities created barriers in receiving a subsidy for restricted medicines.

1) Strengths and Limitations.

Strengths

- This is the first independent objective study covering GPs' perceptions regarding access to medicines issues in New Zealand.
- Findings from this study will form an essential component of any future research which reviews New Zealand's current medicines policy.
- It will also help in developing strategies to better inform patients' access to medicines, with GPs being a large group of health professionals likely to positively affect patient knowledge and views.

Limitations

- All GPs were working in a large metropolitan city in New Zealand – it is not known whether their views and experiences differ from colleagues working and living in small towns and rural locales.
- Also, only 19 out of 150 were interested in participating so this could be another source of bias in the study.

ABSTRACT

Objective

The objective of this study was to evaluate general practitioners' (GPs') perceptions regarding access to medicines in New Zealand.

Design Qualitative

Setting Primary care

Participants GPs

Main outcome measures

GPs' views and perceptions

Results

GPs were of the view that the current range of medicines available in New Zealand was reasonable, however it was acknowledged that there were some drugs that patients were missing out on. When considering the range of subsidised medicines available in New Zealand some GPs felt that there had been an improvement over recent years. It was highlighted that unexpected funding changes could create financial barriers for some patients, and that administrative procedures and other complexities created barriers in receiving a subsidy for restricted medicines. GPs also reported problems with the availability and sole supply of certain medicines and claimed that switching from a branded medicine to its generic counterpart could be disruptive for patients.

Conclusions

The research concluded that although there were some issues with the availability of certain drugs, most GPs were satisfied with the broader access to medicines situation in New Zealand. This view is to contrary to the situation presented by the pharmaceutical industry. The issues around sole supply, the use of generic medicines and the administrative barriers regarding funding of medicines could be improved with better systems. The current work provides a solid account of what GPs see as the advantages and disadvantages of the current system and how they balance these demands in practice.

INTRODUCTION

One of the aims of New Zealand's medicines policy is to ensure that New Zealanders have access to affordable medicines[1]. New Zealand has been successful in containing pharmaceutical costs, primarily via the policies of the Pharmaceutical Management Agency of New Zealand (PHARMAC)[2]. PHARMAC is the New Zealand Government agency that decides which medicines are subsidised. It was created in 1993 to ensure that New Zealanders get the best possible health outcomes from money the Government spends on medicines[3]. PHARMAC manages drug costs by applying pharmacoeconomic techniques when selecting medicines, and by promoting the use of generic medicines[4, 5]. It uses a capped national medicines budget, along with a variety of contractual arrangements with pharmaceutical companies that enables a company's medicine to be listed onto the schedule and therefore enables access to subsidies for consumers. These contractual arrangements include rebates on list prices from PHARMAC, tendering for off-patent drugs, and bundle agreements where PHARMAC may list expensive new drugs in its Pharmaceutical Schedule[6] in return for the manufacturer discounting the price of other products it supplies[7]. Most off-patent drugs listed in New Zealand's Pharmaceutical Schedule[6] are supplied from one supplier under contract to PHARMAC (sole supply) and large price discounts are provided in exchange for exclusivity[7].

In community settings, only drugs on the Pharmaceutical Schedule receive government subsidy[7]. The government subsidy means that consumers who are New Zealand citizens or who have Permanent Residence make a co-payment (NZ$3; US$2.20 per prescription item) for each medicine listed in the Schedule. If the subsidy level PHARMAC has set for a particular medicines is less than the price charged by the drug company, then patients pay an additional fee, known as 'manufacturers surcharge'. For the medicines which are not listed on the schedule consumers are required to pay the full price.

With an annual drug budget expenditure for subsidised medicines used in the community setting of NZ$599 million in 2007[8], over 78% of all consumed medications are publicly funded in New Zealand. Although PHARMAC has played an important role in containing the pharmaceutical budget in New Zealand, in 2009 medicines expenditure was recorded as $694 million a year and is expected to increase to 734 million NZ$ by 2012 [9-11]. Health care expenditure is a key concern for many countries and countries amend and form their policies on the basis of ongoing empirical research. General Practitioners (GPs) form a vital part in this research process because they are key stakeholders in the access to medicines process.

GPs are the main prescribers in New Zealand and prescribe over 44 million prescriptions annually[12]. They influence the "demand side" of the costs, and knowing what they think about "access to medicines" is important when exploring the impact of a country's medicines policy. Although very little independent research is available on GP views on access to medicines in New Zealand[13], some research has been conducted by the pharmaceutical industry. One industry study of a sample of 528 GPs in New Zealand revealed GPs' dissatisfaction over the current system, and it was observed that a large majority (75%) of GPs supported a general review of PHARMAC[14]. It was also reported that GPs felt that PHARMAC was "too budget oriented" rather than patient focused, its decision-making "lacks transparency" and New Zealand's access to medicines "lags behind other comparable countries". Furthermore, the study also found that 71% of clinicians rated New Zealanders'

access to medicines as "poor" when compared with Australia[14]. PHARMAC has undertaken its own research[15] exploring health professionals' perceptions about how it functions (n=23), but only investigated PHARMAC's operational abilities and did not assess issues of access, availability and affordability of medicines[13 16].

Whilst the New Zealand Government promotes affordable medicines[3,4] the media has portrayed New Zealanders as having problems regarding accessing medicines[17]. Furthermore, it has been argued that "newer" and "more effective" medicines available abroad, such as risedronate, atomoxetine, galantamine and montelukast are not available in NZ[17-19].

Hence in this context, the current study was undertaken. The key aims of the study were to evaluate GPs' perceptions regarding access to medicines in New Zealand and to identify GPs' views and perceptions regarding the role of PHARMAC within the New Zealand healthcare system.

METHODS

A qualitative approach was adopted for the study, which was undertaken in Nov 2008- Jan 2009 in Auckland, New Zealand. Auckland is New Zealand's largest city, with approximately 1.25 million people residing in the greater Auckland area (about one third of the population of the whole country[20]). The Auckland region is covered by three District Health Boards (DHBs), of which there are a total of 20 in New Zealand. DHBs are responsible for providing, or funding the provision of, health and disability services in their district[21]. A list of GPs practicing within the greater Auckland region was obtained from the Department of General Practice and Primary Health Care at the University of Auckland. GPs were stratified according to the DHB in which they were located (n=360 for Auckland DHB; n=393 for Counties Manukau DHB; n=482 for Waitemata DHB). Fifty GPs were randomly selected from each DHB list and were sent information regarding the study (n=150 in total). This included a participant information sheet which provided an overview of the research study and processes, and a research consent form (with a freepost envelope) that GPs could complete and return to the research team to indicate their interest in participating.

A series of face-to-face, semi-structured interviews was undertaken. Questions were developed following a review of the relevant literature and to gather GPs' perceptions regarding access to medicines in New Zealand, and views and perceptions of the role of PHARMAC in relation to medicines access in New Zealand (a detailed list of the questions is attached in Table 1). Demographic information, including age, gender, practice type, and length of time practicing, was also recorded for each GP at the time of the interview. The interview guide was piloted with two health professionals prior to the fieldwork commencing, and further reviewed (and amended) following the completion of the first two interviews. Interviews took place at the GP's workplace. Seventeen interviews were conducted, at which stage data saturation was reached. Most were around 35 minutes in duration (range: 23-41 minutes), and all were audio-taped. GPs who took part in the study were offered a $50 book voucher in recognition of their contribution to the research.

All interviews were transcribed verbatim with the full transcripts utilised in the subsequent analysis process. Analysis of the data was undertaken by the research team via a staged process. In the first instance, transcripts were read and notes were

taken regarding key themes and issues. Following this, a basic coding framework was developed, and interview data were coded, with the assistance of the NVIVO software programme. Lastly, a series of group analysis sessions involving the senior members of the research team were conducted, whereby further refinement of the themes was undertaken. Each 'quote' from within each theme was read by a member of the research team, and a brief interpretation of the quote written on a 'post-it' note. These were then placed on a board, and moved around into sub themes.

Ethical approval for the study was gained from the University of Auckland Human Participants' Ethics Committee (Reference: 2008/445).

RESULTS

A total of 19 GPs returned a research consent form and 17 of those were interviewed. Over half of participants (n=10) had been practicing as a GP for more than 20 years, and 13 were male. GPs were recruited from each of the DHBs, although the majority were based within Counties Manukau DHB (n=10). An overview of the demographic characteristics of the sample is provided in Table 2. Key findings from the research are presented below.

General perceptions of access to medicine in New Zealand

When considering the range of (subsidised) medicines available in New Zealand, some GPs felt that there had been an improvement over recent years, and that – for the most part - sufficient drugs were subsidised and able to meet the needs of most patients.

> *95% I'm happy with what we have got. There are a small number of things which I would like more direct access to as a general practitioner. But I'm not aware of, and that may just be ignorance, of any major drugs or drug classes that we have zero access to. Most of the things that I'm aware of that are of any genuine value we have at least some access to.* [GP3]

Some comments were made, however, about the range being fairly basic or limited – particularly in relation to there being few options available, in terms of the number of brands subsidised within certain classes of drugs. This included medicines such as statins and ACE inhibitors. While some GPs were accepting of this, particularly in light of the country's limited drug budget, other reported that it could become an issue in certain circumstances (e.g. where a specific medication was not effective for a patient):

> *I would say that I have to struggle sometimes if one is not working. What can I do more to get it? What else can I try? So there are very limited options?* [GP1]

One GP noted that whilst they felt the current range of medicines available in New Zealand was *'reasonable',* they highlighted that it was likely there were some drugs that patients were missing out on. However, they also indicated that it was not always possible to know what these were:

> *For most GPs I think it is 30 drugs that cover 90% of your patients or something. So you kind of concentrate on those and the other ones you worry about but you don't actually worry about what you can't prescribe.* [GP7]

GPs were asked their views on the pharmaceutical industry's opinion that access to medicines is poor. There was limited agreement with this claim. Some GPs were dismissive of it, citing the self-serving nature of the statement and the fact that the pharmaceutical industry would have much to gain from promoting such a scenario:

> *Of course they would* [say that]. *They've got a vested interest ... I wouldn't listen to them* [laughter].... *A company has only got profit in mind, yeah. ...I mean they're playing a devil's advocate to PHARMAC so obviously they need to be there and they need to, they need to advertise their products to PHARMAC, but you know, they're only there for profit.* [GP9]

Others reported that, whilst it may be an issue in relation to some medicines, it was not a widespread occurrence. One GP noted that, due to the restrictive nature of New Zealand's pharmaceutical market, drug companies could see limited opportunities for marketing and reimbursement for their products and were subsequently withdrawing. Whilst this was viewed as a potential problem, it was also seen to be inevitable given the small size of the country (and associated drug budget).

Affordability of medicines

Patients in New Zealand are often required to pay a co-payment fee which ranges from 3 to 15 NZ$ per item for subsidised medicines. However, from 1st Sep 2008[22] (shortly before the research was conducted) the eligibility criteria for the lower co-payment of 3 NZ$ was expanded. In some cases, however, patients still have to pay up to a maximum pharmaceutical co-payment of $15NZ$ per item[22]. These are when the patients are not enrolled in a Primary Health Organisation[a] (PHO), if the prescription is from a private specialist (who is not part of the publicly funded system) or the patient does not have a Community Services Card or a Prescription Subsidy Card (PSC)[b].

It was acknowledged by GPs who took part in the study that the widening of the 3NZ$ co-payment had improved access to medicines for patients, given the lower fee structure. In particular, GPs felt that the 3NZ$ per item fee was at a level that most people would be able to afford, with some indicating that some level of fee was appropriate:

> *I think that by and large we have in New Zealand a good number of subsidised medications to use. So, the subsidy level such that the patients pay 3NZ$ I think is appropriate. I think that's, you know, I think sometimes if a thing's made completely free it's wasted. Its value is degraded. So, and yet that's a fine line between that and preventing access.* [GP12]

[a] Primary Health Organisations in New Zealand are health providers that are funded on a capitation basis by the New Zealand Government via District Health Boards.

[b] Community services card are issued for the patients with lower socioeconomic status while the PSC is for a family unit that has received 20 initial dispensing of single supplies of subsidised pharmaceuticals in the year commencing 1Feb to 31 Jan. People entitled for PSC are entitled for a reduce co-payment charges of 2NZ$ per prescription item.22. DHBNZ. Pharmacy Procedures Manual, 2010.

Some GPs, however, were of the view that cost remained a barrier to accessing medicines for some people. This included people not registered with a PHO, those on limited incomes (including teenagers and the elderly) and patients with an extensive medicine regime:

> *I think the people who are on a large number of medications and I've got some here on 12 or 13 different pills..... Most of those people don't work, they are on a benefit so they are actually a little bit limited. Once they pay for 30 items[sic- 20 items] then they are fine but that is still $100 so for them, it is quite a cost or can become a cost.* [GP7]

For some, the PHO enrolment system was seen as somewhat arbitrary, with one GP commenting that it was a *'ridiculous'* system, as *'essentially everyone is either registered* [with a PHO] *or should be'*. Other GPs, however, highlighted that the system encouraged patients to access their healthcare from one provider only, which was likely to have greater benefits than visiting a number of different general practices. Comments were also made regarding the complexity of the system, resulting in confusion for some patients:

> *Obviously encouraging patients to see their own doctor is a good thing, but there seems to be some inconsistencies between $3 and $15, whether they're funded or non-funded, enrolled or un-enrolled patient. You know, there's the question of waiting for three months before they become funded and enrolled and it becomes so, such confusion to patients.* [GP8]

Affordability of non-subsidised medicines was discussed by GPs during interviews, with comments made about these being very expensive and only being accessible to the *"rich"*. Particularly for those GPs working in lower socio-economic areas, the cost to the patient was a key consideration when deciding which medicines to prescribe:

> *I work in South Auckland at the moment and I'll be choosing subsidised medications and I know that, in the large majority, if it is non-subsidised medication it will be a significant financial strain for people.* [GP4]

> *Cost to a patient has a major influence on me. And in that I routinely prescribe generics and I tend to pre-warn people if something is going to cost an additional, or is not subsidised. Or sometimes ring the chemist to see what's cheaper and what it will cost.* [GP3]

Changes regarding medicines subsidy and access to medicines

GPs talked about amendments in drug subsidy which could affect patients. This meant that prices sometimes fluctuated, with reports that the changing costs sometimes angered patients. As evident in the interview extract below, unexpected funding changes could create financial barriers for some patients, and ultimately result in medicines not being accessed:

> *Those are snags that all of a sudden the rules change and you don't know about it and you have written a prescription for a child to have a medicine which normally would have been funded fully, no price whatsoever – and all*

> *of a sudden there is a change and now the parent goes to go and pick up* [name of medicine] *and now there is a partial charge to it. ...and the pharmacy calls me up in the middle of my next consultation and the parents have gone away because they couldn't afford the $7 or whatever the part charge was.* [GP6]

Another GP reported that keeping up to date with the subsidy changes was challenging, and also sometimes resulted in medication regimes needing to be amended:

> *I suppose my main comment would be about the things changing which cause us major problems having to rethink a medication regime that me may have just got really fine tuned. That's the major problem. The other major thing I suppose is keeping up with the continuous changes of what is subsidised and what isn't.* [GP4]

GPs reported that, for patients, the system was also confusing, particularly with regard to what medicines were funded and when (e.g. if accessed 'out of hours' higher charges are incurred). One research participant noted that informing patients about these issues sometimes dominated patient-GP discussions, at the expense of other important health-related issues.

Administrative issues

Despite a general level of support expressed by GPs regarding the range and accessibility of subsidised medicines, the research identified perceptions of the New Zealand system as being somewhat *'complex'*. GPs spoke about this being an issue both for themselves as health professionals – as well as for patients. Some GPs claimed that they did not always understand all the codes utilised (including 'section 29'[c]), and that the eligibility criteria for subsidies were inconsistent. Research participants also spoke about the system being based on controlling costs rather than patient care, with examples provided of drugs that - at the time of the research - were unable to be prescribed by GPs (e.g. initially only specialist could prescribe Isotretinoin, however later on GPs were allowed to prescribe with subsidy from 1 March 2009 [23]). With no apparent clinical-related reasons for this, it was therefore assumed that these were budget-related decisions.

GPs spoke about having to undertake '*a lot of paper work'* in order to receive a subsidy for medicines which are not listed for subsidy on the Pharmaceutical Schedule. This mostly related to processes for medicines requiring Special Authority. "Special Authority" means that the medicine is only eligible for subsidy for a particular person if an application meeting the criteria specified in the PHARMAC Schedule has been approved.[20] Once approved, the prescriber is provided with a Special Authority number which can provide access to subsidy for a specified medicine. Applications can be made electronically via the Internet, although a paper-

[c] Section 29 is law that permits an unregistered medicine in NZ to be procured and supplied to patients.

based system was also still in operation at the time of the research. It should be noted that one research participant, at least, was still using the old system, and another reported that they did not have access to the electronic system at their practice. This process was felt to not only be time-consuming, and add to an already heavy workload, but also burdensome:

> *We have a lot of medication in here, but then there's a lot of loopholes that we have to jump through to get those medications, you know, just like a lot of those special authority regulated medications… it creates so much more work for us before we can actually get the medication and so I guess a lot of those special authority medication if they can be available without special authority that would be quite good.* [GP8]

Having to reapply for Special Authority was also raised as an issue, particularly where medication was required for a long-term condition. Other comments made by research participants included the fact that *"too many"* medicines still required Special Authority approval (one GP noted that many of these were *"freely available"* overseas), and that the system and policy remained complex. Some GPs stated a desire for GPs to gain greater control of Special Authority medicines – in terms of being able to prescribe those that had been around for a longer period. It was also suggested that barriers in accessing Special Authority medicines should be removed for GPs who have been vocationally trained or who have special prescriber designation.

Despite some dissatisfaction with the system, it was acknowledged that the number of medicines requiring Special Authority had reduced over time. In addition, it was reported that the introduction of an electronic process for making applications had improved things considerably. There were also comments made about the protection that limited/restricted access affords GPs, in cases where patients are requesting a particular medicine that they do not feel comfortable prescribing (e.g. methylphenidate).

It was also acknowledged by GPs that a system that placed some restrictions on access to medicines was appropriate – and that patients should not have open access to any medicine they requested, nor that GPs should have the right to prescribe whatever they wanted, unrestricted. Findings from the research suggest that GPs considered the limitations appropriate, due to the need to improve rational use of medicines, to control costs, as well as safeguard against potential harm to patients:

> *I think that if their* [special authority restrictions] *aim is to reduce waste, I think sometimes an application and then a reapplication process is sensible, because many times I see in primary care a person's started on an agent and it's just continued without thought and conscious review of whether that agent's still needed and that can be an instance that causes harm* [GP12]

> *Well of course originally everything was totally free, and there was a much small, there was much smaller number of drugs provided back in the old days. And there really were no cost incentives for patients to comply…. I think it's changed, it's a little bit more rational now in terms of that …I think, there's probably for some people there probably is a price barrier whereas thirty years ago there were not, there was not. But again as I said I'm not unhappy having that signal there. [GP11]*

Sole supply

As part of their cost containment system, PHARMAC issues requests for proposals from pharmaceutical companies to bid for the sole supply of specific medicines, with the contract awarded to the cheapest supplier[9]. Whilst the financial savings are a clear benefit of the sole supply system, negatives such as the risk of drug shortages due to a dependence on only one supplier were mentioned by GPs:

> *I think the sole supply thing from time to time has found to be wonky....I mean as soon as you have got sole supply you are heading for disaster because it is only one shipment away from either don't have any or something goes wrong like what happened with adrenaline....It seems like a crazy business model which has repeatedly failed in the past and I can't see why it is not going to fail in the future.* [GP7]

As highlighted above, historical examples such as an adrenaline shortage in 2007, and other incidents such as problems with the supply of the flu vaccine were cited.

Brand switching/generic medicines

In New Zealand PHARMAC manages the drug budget by negotiating with drug companies; competition between suppliers is also encouraged.[6] Switches from a branded medicine to a generic version (and between different brands as a means of cost-saving) are commonplace.[20] At the time of writing, the Pharmaceutical Schedule listed 2000 funded medicines, the majority of which are generics. [20]

GPs reported that the switching from a branded medicine to its generic counterpart could be disruptive for patients. For example, issues such as the medicine being a different colour, or of a different name, could upset patients who sometimes needed added reassurance from their GP that the newly introduced medication was essentially the same medicine and would do the same job. It was also commented that patients sometimes viewed the replacement medicine as being inferior:

> *Each time the colour or something is changed, it is tough. Just recently I had a tough time explaining to a patient that it was the same medicine at the same strength and it just had a different colour. He still isn't convinced. I don't know what to do.* [GP1]

Changes could be particularly disruptive for patients who were taking a wide range of medicines, and expressed frustration that GPs – as health professionals working at the 'frontline' – were not consulted before changes were introduced:

> *Every so often there is a major problem with the change of generic formulation. … Those sorts of changes occur without sort of any face talk from us and they are to do with widely prescribed medications ….. I think if something is broadly prescribed then widespread changes are inadvisable without you know asking GPs' opinion about it because we often have the front line appreciation of how differences in medicines do affect patients differently.* [GP4]

Another GP highlighted that a recent switch from a branded paracetamol to a generic formulation had created difficulties for some patients, and that reactions to a replacement for Ritalin™ had varied across different individuals:

> *I also don't agree with the information written in it saying that generics are as good as the original drugs. A lot of cases that has been proved not to be the case either in presentation, formulation. I mean the example would be the cheap Panadol™ [sic-paracetamol] they have got which dissolves before people can swallow. The problem with clogging of Salamol™ [salbutamol] pills [*sic - *inhaler]. The change in the effectiveness of Ritalin™ for example. I think it is about 40% of people reacted quite differently to it and to say that new drug is as good is absolute rubbish. So I think that's why I refuse to hand out PHARMAC's stuff. I just won't do it.* [GP7]

DISCUSSION

This study set out to explore the views of GPs in relation to access to medicines in New Zealand. GPs were generally satisfied with the range of medicines available and noted that there had been a recent improvement, but raised some issues in relation to specific drug availability and a narrow range within some classes. There were concerns about financial barriers for some patients. In some respects, the findings from our research seem to be at odds with those in relation to pharmaceutical industry research on GP views, in which GPs seem to be generally not satisfied with the range of medicines available, in terms of meeting the needs of their patients [13] and also the industry point of viewpoint which claims issues with access [17].

Whilst in this study the range of subsided prescribed medicines available was broadly supported, GPs highlighted that the cost of prescriptions could act as a barrier for some patients. This is similar to another New Zealand study[24] which stated that out of a total of 18,320 respondents, 6.4% reported that they had deferred collecting a prescription at least once during the preceding 12 months because they could not afford the cost of collecting the prescription. Younger adults aged 15-24, females, smokers, Māori and Pacific patients, and those with the lowest income status, were more likely not to obtain or buy prescription drugs because of cost barriers[24]. However, it is important to note that since September 2008 the co-payment for prescribed medicines have been decreased from 15 NZ$ to 3NZ$ for many people. It was acknowledged by the GPs in this study that the widening of the 3NZ$ co-payment had improved access to medicines for patients, given the affordability of the lower fee structure.

Sole supply and the perceived risk of drug shortages were raised as an issue by GPs in this research. Other problems with sole supply have previously been reported, including the poor quality of slow release morphine and a brand of felodipine with questionable pharmacokinetics and bioequivalence[25]. In addition, the flu vaccine chosen for sole supply in 2005 was under-strength in one of the three component flu strains, and another company had to step in to supply the vaccine[25]. However, PHARMAC reiterates that reference pricing and sole supply occurs only where it is

clear that a loss of choice between one equivalent brand of drug and another is not considered critical[26]. It has been suggested that it may be possible to manage some of the problems around sole supply through contingency and indemnity clauses in tendering contracts[7].

The GPs in this study also discussed many administrative barriers regarding accessing medicines, including Special Authority, restrictions on prescribing certain medicines and a fair amount of paper work. However, since the research was conducted many of these administrative issues may have been solved by instituting a system of electronic Special Authority application[27, 28]. In addition, whilst issues were evident regarding Special Authority applications, it should be noted that, only a small proportion of people are taking medicines that require a Special Authority in order to access the subsidy for a specified medicine (for example it was found that less than 1% of patients require statin through special authority[29, 30]). Furthermore, many restrictions to medicines have clinical dimensions, and are not simply in place because of issues related to cost containment. For example, prior to March 2009, isotretinoin (Roaccutane®) was only available on "specialist only prescription medicines"[31]. Recently the specialist prescribing requirement was removed, however the decision has been criticised by the New Zealand Dermatological Society stating that Isotretinoin is prone to misuse.[32]. Moreover, these restrictions are not something which are specific to the New Zealand scenario, and are quite common in Canada[33], Australia[34,41] and the United Kingdom[35]. Nevertheless, there remain issues around sole supply and administrative barriers regarding funding of medicines, which could be perhaps improved with better systems.

Concerns were also raised by research participants regarding brand switching, and with respect to generics, which were viewed by some GPs as being of lower quality. Similar findings were observed in a New Zealand report which evaluated stakeholders' views regarding generic substitution. The report found that although PHARMAC and pharmacists agreed with generic substitution, physicians and opposed the proposal for voluntary generic substitution citing concerns which included reduced patient compliance, patient confusion and quality and bioavailability[36]. However, on the one hand, research indicates that most generic medicines provide the same quality, safety, and efficacy as the original brand name product, and are typically 20-90% less expensive than the brand name original[37]. Whilst generic medicines are associated with large cost reductions, findings from a study evaluating consumer perceptions in Auckland suggest that older patients and patients with chronic conditions needed more information about generic medicines. Less than half of survey participants viewed generic medicines "to be as safe, effective and equivalent in quality" than branded medication[38]. In addition, in a PHARMAC discussion, it was noted while the term ''generic'' is well understood by PHARMAC, the public may simply regard them as ''cheap'' [39]. Moreover, it has been shown the physician views can strongly influence those of their patients [38-39]. With Medicines New Zealand, the New Zealand's medicines policy promoting the use of generic drugs and stating that consideration must be given to 'cost-effective treatment options'[1], it is vital that apart from assuring the quality of generic medicines, programmes that educate prescribers and patient about brand switching are required.

The above mentioned is a key account of what GPs see as the advantages and disadvantages of the current system and how they balance these demands in practice. Though there are matters related to affordability of medicines and the decisions doctors face clinically and administratively, these issues are not specific to New Zealand. Doctors and general physicians all the over the world face similar issues related to cost containment and the clinical prescribing. For example, in a study of GPs in UK, it was found that almost all GPs believed that costs should be taken into account; however, conflict was observed regarding policy related to cost-containment and GPs' resistance to cost-cutting[40]. In Singapore, costs related to differential subsidies in the consultation fees and the availability of medicines at public polyclinics and GP clinics were key factors in influencing the family physicians' asthma drug treatment decisions[41]. Also, in a Canadian study, it was reported that ' most physicians mentioned that drug reimbursement guidelines complicated their prescribing process and can require lengthy interpretation and advocacy for patients who require medication that is subject to reimbursement restrictions[42].

Limitations of the study

All GPs were working in a large metropolitan city in New Zealand – it is not known whether their views and experiences differ from colleagues working and living in small towns and rural locales. Also, only 19 out of 150 were interested in participating so this could be another source of bias in the study.

CONCLUSION

Whilst GPs in this study had some issues with the availability of certain drugs, they were generally satisfied with the access to medicines in New Zealand in primary care. The issues around sole supply, the use of generic medicines and the administrative barriers regarding funding of medicines could be improved with better systems. The work provides a solid account of what GPs see as the advantages and disadvantages of the current system and how they balance these demands in practice. Findings from this study will form an essential component of any future research which reviews New Zealand's current medicines policy.

Competing interest statement

Piyush Grover was given a summer student scholarship by the University of Auckland to do initial work on the project. Lynne Bye and Rachael Butler worked as paid researcher from the grant received from New Zealand Pharmacy and Education and Research Foundation (NZPERF). Zaheer Babar and Janie Sheridan did not receive any personal funding or benefits from the grant. All authors have filled up competing interest forms (and have declared competing interest, if there are any) and are available upon request.

Authors' contribution

ZB was the principal investigator and designed the study with the input from JS, LB, and PG. PG did the field study. PG and LB entered, checked and validated the data. The data was analysed by LB, PG, JS, ZB and RB. ZB and RB wrote the paper with significant contribution from JS. All authors participated in editing the article and approved the text for final submission.

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Data Sharing
The original data is available from the principal author (ZB)

Table 1: List of questions utilised in interviews with GPs

Domain 1 – General Practitioners' perceptions regarding access to medicines and high cost drugs in New Zealand.	
A	What is your understanding of the "access to medicines" in New Zealand?
B	In your opinion what is the current state of access to medicines and high cost drugs in New Zealand and why?
C	If and how has this access changed in the past few years?
D	What role do GPs play in determining the access to medicines in New Zealand?
E	How do you compare the access to medicines and high cost drugs in New Zealand with that of other developed countries?
F	The current notion by drug industries is that access to medicines in New Zealand is inadequate. What is your opinion?
G	Do you believe high costing medicines are readily accessible in New Zealand? Are there any examples you would like to mention?
H	Are there examples of medicines you would like to see being available in New Zealand?
Domain 2 - Views and perceptions regarding the role of Pharmac (Pharmaceutical Management Agency of New Zealand) to access of medicines in New Zealand.	
A	What is your understanding of the role of Pharmac in New Zealand healthcare system?
B	Do you think New Zealand needs an agency like Pharmac? Why?
C	Pharmac has been under immense public scrutiny. Is it justified?
D	How successful has Pharmac been in achieving its aims?
E	How does Pharmac influence the access to medicines for New Zealanders?
F	How do you find the decision making process undertaken by Pharmac?
G	Does Pharmac have sufficient representation from various health professionals and consumer groups?
H	What are your views on communication between Pharmac and GPs?

Table 2: Overview of GP sample

N	Number of participants (GPs)
District Health Board (DHBs)	
Auckland	5
Counties Manukau	10
Waitemata	2
Gender	
Male	13
Female	4
Age of participants (yrs)	
<40	4
40 – 60	10
60 +	3
Experience (yrs)	
<10	3
10 – 20	4
20 +	10

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the inter view or focus group?	Piyush Grover
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	One was a Bachelor of Pharmacy final year student Two researchers having PhD While two have Masters
3. Occupation	What was their occupation at the time of the study?	Student Lecturers Researchers
4. Gender	Was the researcher male or female?	Male
5. Experience and training	What experience or training did the researcher have?	Formal Qualitative NVivO traning
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	No special relationship Just introduced
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Participant Information Sheet and the Study Guide describes the process and reasons for doing this research
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	No specific bias was reported
Domain 2: study design		

Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Content analysis
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Probability sampling
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	mail
12. Sample size	How many participants were in the study?	17
13. Non-participation	How many people refused to participate or dropped out? Reasons?	2 were refused as data saturation was reached
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Clinic/workplace
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	GPs within the greater Auckland region; November 2008
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Yes Yes
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Yes – interviews were recorded with consent
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Yes
21. Duration	What was the duration of the inter views or focus group?	40 minutes
22. Data saturation	Was data saturation discussed?	Yes
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No but was checked within the research team for accuracy
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	2
25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes
26. Derivation of themes	Were themes identified in advance or derived from the data?	Derived from the data

27. Software	What software, if applicable, was used to manage the data?	NVivo
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

Once you have completed this checklist, please save a copy and upload it as part of your submission. When requested to do so as part of the upload process, please select the file type: *Checklist*. You will NOT be able to proceed with submission unless the checklist has been uploaded. Please DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.