PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Identifying priority medicines policy issues for New Zealand; a general inductive study.
AUTHORS	Babar, Zaheer-Ud-Din; Francis, Susan

VERSION 1 - REVIEW

REVIEWER	Michael Wonder Director Wonder Drug Consulting Pty Ltd Sydney, Australia I am a consultant on market access issues. I have worked on various market access projects commissioned by the pharmaceutical companies around the world, pharmaceutical industry associations in Australia and New Zealand and with a PBAC member (in an academic institutional setting) in Australia.
REVIEW RETURNED	16-Dec-2013

GENERAL COMMENTS	The manuscript provides scant details on some major issues such as the New Zealand's medicines policy, High Cost Medicines and the Trans Pacific Partnership Agreement (TPPA). Notwithstanding the fact the manuscript is already rather long, further background on the medicines policy is required for an international audience. Notwithstanding the fact the the TPPA is currently a big issue in New Zealand, it is still under active negotiation so it is unclear to me what it impact it WILL have. On page 10 it is stated that "very few participants were familiar with the TPPA; some referred to speculation and no facts." Given the TPPA still under active negotiation, other than the fact that it is under negotiation, the rest is pure speculation and hence I question its role in the paper at this time. It might be better to include this as a relevant issue in a follow-up study when the TPPA has been signed by New Zealand. The authors need to check/confirm the following: 1. Whether or not median values can have a range ("The median length of interview ranged from 53-56 minutes" on page 5). 2. The definition to utilitarianism ("The greatest good for the greatest number which also means you get what you need: not what you want" on page 9). The 'Discussion' section cites many references but is unclear if all are from New Zealand and hence are directly applicable/relevant. It is interesting to note that the manuscript discusses the problems of the Maori and Pacific Island people in some detail yet the authors did not interview any of these people. The paragraph in the 'Discussion' section on new immigrants seems odd given there is

	little discussion on them in the 'Results' section and the authors did not seek to interview somebody from this demographic group. The inclusion of some text in the 'Discussion' section seem odd, such as the paragraph on PHARMAC's role expansion (page 14) and the issue of treating large and small patient populations (page 15). The inclusion of a paragraph on the results of the study by Vitry et al makes has no sense to me as it has no relevance to the study (page 16). Some of the stated strengths of the study are results rather than actual strengths (page 3). I found the manuscript very hard to read; this was compounded by an excessive use of semi-colons and the incorrect use of colons. It could also do with some further editing to ensure consistency of expression (e.g. PHARMAC/Pharmac, health care/healthcare, 4th line/first line, etc.) The use of capital letters for certain terms is also questionable (e.g. Stakeholders). The manuscript needs a major overhaul (especially the discussion and cited references) before it could be published in the BMJOpen. Whilst I am sympathetic to the publication of the results of original research from NZ, the manuscript falls below what I think is an acceptable standard for the BMJ Open.

REVIEWER	Jo-anne Brien University of Sydney Australia
REVIEW RETURNED	25-Jan-2014

GENERAL COMMENTS	"Conclusion: The results suggest equitable ability for the general population to have funded medicines prescribed. However, vulnerable groups and some procedures still continue to have issues, not necessarily as a direct result of Medicines Policy or PHARMAC." I think this is not a helpful conclusion, in that the first sentence awkwardly worded and to "have issues" does not communicate the important findings that the authors wish to convey. This is qualitative paper- so does not need to be representative nor a large sample size, nonetheless I think the paper should comment further on the recruitment and selection of these participants in order to draw conclusions around policy. It is stated that participants signed a confidentiality agreement but unclear if the study required institutional IRB/HREC approval.

VERSION 1 – AUTHOR RESPONSE

Reviewer Name Michael Wonder
Institution and Country Director
Wonder Drug Consulting Pty Ltd
Sydney, Australia
Please state any competing interests or state ‘None declared’: I am a consultant on market access

issues. I have worked on various market access projects commissioned by the pharmaceutical companies around the world, pharmaceutical industry associations in Australia and New Zealand and with a PBAC member (in an academic institutional setting) in Australia.

The manuscript provides scant details on some major issues such as the New Zealand's medicines policy, High Cost Medicines and the Trans Pacific Partnership Agreement (TPPA). Notwithstanding the fact the manuscript is already rather long, further background on the medicines policy is required for an international audience.
Though we feel that there is sufficient introduction, however some further background on medicines policy has been added in the introduction section of the paper.

Notwithstanding the fact the TPPA is currently a big issue in New Zealand, it is still under active negotiation so it is unclear to me what it impact it WILL have. On page 10 it is stated that "very few participants were familiar with the TPPA; some referred to speculation and no facts." Given the TPPA still under active negotiation, other than the fact that it is under negotiation, the rest is pure speculation and hence I question its role in the paper at this time.. It might be better to include this as a relevant issue in a follow-up study when the TPPA has been signed by New Zealand.

We still feel it's pertinent to have some discussion on TPPA in the paper. Trade ministers of the 12 TPPA nations are currently meeting in Singapore, where it is said that the talks are said to be nearing completion. A recent article in Inside U.S. Trade suggested that the current version of the TPPA 'medicines annex' may be modelled on provisions in the Australia-US Free Trade Agreement (AUSFTA), which may limit PHARMAC's ability to purchase the most affordable medicines. "There are a number of clauses in transparency chapter annex based on AUSFTA (Annex 2-C) that New Zealand may want to discuss in detail.

The authors need to check/confirm the following:
1. Whether or not median values can have a range ("The median length of interview ranged from 53-56 minutes" on page 5).
Changed as suggested by the reviewer

2. The definition to utilitarianism ("The greatest good for the greatest number which also means you get what you need: not what you want" on page 9).
What reviewer is referring to, is a summation that medicines provision has a utilitarian focus, supported by a quote from a participant. To follow, is further information from an academic: Although forms of utilitarianism have been put forward and debated since ancient times, the modern theory is most often associated with the British philosopher John Stuart Mill (1806- 1873) who developed the theory from a plain hedonistic version put forward by his mentor Jeremy Bentham (1748- 1832). As most clearly stated by Mill, the basic principle of utilitarianism is:
Actions are right to the degree that they tend to promote the greatest good for the greatest number.
(Professor Charles D. Kay, Wofford College, Spartanburg, South Carolina, USA)

The 'Discussion' section cites many references but is unclear if all are from New Zealand and hence are directly applicable/relevant.

This has been amended now.

It is interesting to note that the manuscript discusses the problems of the Maori and Pacific Island people in some detail yet the authors did not interview any of these people.

Kindly refer to the Participant selection section: 4 participants were of the ethnicities in question. : 2

were Māori, 1 Indian and 1 Asian. Three are practicing general practitioners with high percentages of patients belonging to these ethnicities. The Indian doctor's previous practice had been in a Pacifica area, where he practiced for some time. All 4 of these participants are/or have been very active members for their respective ethnic medical interest group and community . One of the patient group representative, represents a group of patients with a chronic condition, who are large in number and where Māori, Pacifica and increasingly Indian are disproportionately represented.

The paragraph in the 'Discussion' section on new immigrants seems odd given there is little discussion on them in the 'Results' section and the authors did not seek to interview somebody from this demographic group.

Some amendments have been made. New immigrants are considered at risk of reduced access to health services, especially in consideration that New Zealand has a significant migrant population (approximately 1/5 of the population were not born in New Zealand) Currently most new immigrants are from Asian countries.That's a lot of people potentially at risk of diminished access.

The inclusion of some text in the 'Discussion' section seem odd, such as the paragraph on PHARMAC's role expansion (page 14) and the issue of treating large and small patient populations (page 15).

PHARMAC are currently the decision makers for whether a medicine is subsidised or not, expanding their scope of decision for provision does make them a powerful stakeholder in medicines access and healthcare.
The trend for medicines research is considered to be in the direction of identifying sub-types/genomics of a condition, where clinical treatment and resultant effect may be targeted and maximised because we will know more accurately which groups respond to treatment and which don't. The concern is that the future may not find treatments for some sub-groups. Currently we tend to treat large populations with a condition the same and with the same variety of drugs, where medically appropriate with varying results but never-the-less being treated. The future may mean this is no longer the case. How do we then deal with those left in need without an identified treatment?

The inclusion of a paragraph on the results of the study by Vitry et al makes has no sense to me as it has no relevance to the study (page 16).
Yes this has been removed now

Some of the stated strengths of the study are results rather than actual strengths (page 3). Amended.

I found the manuscript very hard to read; this was compounded by an excessive use of semi-colons and the incorrect use of colons. It could also do with some further editing to ensure consistency of expression (e.g. PHARMAC/Pharmac, health care/healthcare, 4th line/first line, etc.) The use of capital letters for certain terms is also questionable (e.g. Stakeholders).
Amended

The manuscript needs a major overhaul (especially the discussion and cited references) before it could be published in the BMJOpen. Whilst I am sympathetic to the publication of the results of original research from NZ, the manuscript falls below what I think is an acceptable standard for the BMJ Open.

Reviewer Name Jo-anne Brien
Institution and Country University of Sydney

Australia
Please state any competing interests or state ‘None declared’: none declared

My comment on the abstract relates to the conclusion:
"Conclusion: The results suggest equitable ability for the general population to have funded medicines prescribed.
However, vulnerable groups and some procedures still continue to have issues, not necessarily as a direct result of Medicines Policy or PHARMAC."
I think this is not a helpful conclusion, in that the first sentence awkwardly worded and to "have issues" does not communicate the important findings that the authors wish to convey.
Amended.

This is qualitative paper- so does not need to be representative nor a large sample size, nonetheless I think the paper should comment further on the recruitment and selection of these participants in order to draw conclusions around policy.
Kindly refer to the Study design and participant selection section. We have clarified the ethnicity representatives further in a response to Reviewer 1(kindly see above)

It is stated that participants signed a confidentiality agreement but unclear if the study required institutional IRB/HREC approval.
Kindly refer to the Ethics section in this manuscript: (This has also been mentioned in the earlier draft of the manuscripts)

Ethics: Ethics approval was obtained from The University of Auckland, Ethics Committee. Approval number; 8367

VERSION 2 – REVIEW

REVIEWER	Michael Wonder Wonder Drug Consulting Pty Ltd, Australia
REVIEW RETURNED	19-Mar-2014

GENERAL COMMENTS	I have not bothered to read the whole paper; after reading the first five pages of the revised manuscript it is clear that the authors have not addressed the concerns I expressed on the original manuscript late last year. The standard of written English is not acceptable; the revised manuscript is incredibly hard to read to due the excessive and inappropriate use of colons and semi-colons. The authors need to pay greater attention to detail with regard to consistency of expression; 'socio economic' versus 'socioeconomic' etc, etc. The authors should note whether the 2007 national medicines policy of NZ sets out priorities to put their research in a full and proper context. Insofar as the 2007 policy does have stated objectives/goals, it is unclear whether their research was to identify (new) priorities or to review/update/confirm existing priorities. The inclusion of the TPPA in the paper is highly questionable insofar as no agreement has been reached so is it unclear as to how it may impact on national health priorities.

REVIEWER	Jo-anne Brien University of Sydney Australia

REVIEW RETURNED	21-Mar-2014

GENERAL COMMENTS	The initial review comments have been addressed.

VERSION 2 – AUTHOR RESPONSE

1. The paper has been further reviewed for language clarity and structure and the use of semi colon and colons have been revised.

2. We find it's difficult to remove the discussion around Transpacific Partnership Agreement (TPPA) because this is something which is part of the original questions being asked from the participants. Also, currently negotiations are in place and these negotiations are central for the future of funding and provision of medicines in NZ. Also both (differing) views have been presented in the paper. (The people who are supporting and opposing a TPPA with Pharmac). It's difficult to understand that why the reviewer is so opposed to include TPPA discussion when a balanced view has been presented.

3. This research was not attempt to systematically evaluate the goals of medicines NZ (The National Medicines Policy of NZ). The current paper is an independent research and it is an effort to cover the following:
1) To identify the current NZ Medicines policy issues
2) What would be future issues NZ medicines policy issues (specifically with regards to funding, access and affordability of medicines)