

2019-02-26 Agenda for Auckland University Research Presentation

1.30pm – 4pm

| Time (approx.) | Topic/research project |
|-----------------------|---|
| 1.30pm | <p>Biosimilars</p> <p>How does positive framing impact on patient willingness to switch to a biosimilar? – Prof Keith Petrie</p> <p>Reducing nocebo response in response to a biosimilar switch – education about nocebo as an intervention (a possible joint UK-NZ project)</p> |
| 2.15pm | <p>Gout</p> <p>Changing the name of gout - perception of Māori and Pacific groups – Prof Nicola Dalbeth</p> <p>Rural Māori patients with gout: medication use, disability and stigma etc - Prof Nicola Dalbeth</p> |
| 3pm | <p>Generics/ Venlafaxine/generic switch</p> <p>Does rebranding generics improve response? – Kate MacKrell</p> <p>What factors are associated with side effect reporting following switch to generic venlafaxine? Kate MacKrell</p> <p>The effect of print and TV media stories on nocebo response to venlafaxine switch - Kate MacKrell</p> <p>Does improving trust in pharmaceutical agencies improve acceptability and response to generics? – Prof Keith Petrie</p> |
| 4pm | <p>Finish/general questions</p> |



REQUEST TO FUNDER FOR CONTRACT VARIATION

Submitted for and on behalf of the University of Auckland by its authorised agent Auckland UniServices Limited, Level 10, 70 Symonds Street.

Email: contracts@auckland.ac.nz

| | | | |
|------------------------------|---|-----------------|---------|
| Funder Ref. | | UOA Project No. | 3704219 |
| Funder | PHARMAC | Funder Scheme | |
| Principal Investigator | Keith Petrie | | |
| Project Title | Psychological influences on the efficacy and side effects associated with generic medicines | | |
| Type of Variation Request | Budget change | | |
| Additional Funding Requested | N/A | | |
| New Requested End Date | N/A | | |

| | |
|-------------------|--|
| Variation Request | Please explain the variation that is being requested and the rationale for it. Explain how the variation will benefit the project |
| | <p>We wish to use unspent operating costs \$15,538 for a short term research assistance on this project. The current post-doc is finishing on the project in december and taking up an academic position at Otago University.</p> <p>A reseach fellow could be employed for approximately 2 months to work on finishing some other publications related to this grant. These are related specifically to the study on whether increasing trust in pharmaceutical agencies increases drug efficacy and reduces side effects.</p> |
| Project Progress | Please describe the work completed to date and any work not completed as a result of the change in circumstances leading to this request |
| | <p>Research work on Pharmac projects has included the following publications</p> <p>MacKrill, K., Kleinstauber, M., & Petrie, K.J. (in submission). The effect of rebranding generics on drug efficacy and side effects.</p> <p>Dalbeth, N., Douglas, M., MacKrill, K., Te Karu, L., Kleinstauber, M., Petrie, K.J. (in submission). The effect of renaming 'gout' to 'urate crystal arthritis' on illness and treatment perceptions in Māori (Indigenous New Zealanders).</p> <p>MacKrill, K., Gamble, G., Bean, D., Cundy, T., & Petrie, K.J. (in submission). Evidence of a media-induced nocebo response following a nation-wide antidepressant drug switch. Clinical Psychology in Europe.</p> <p>MacKrill, K., & Petrie, K.J. (2018). What is associated with increased side effects and lower perceived efficacy following switching to a generic medicine? A New Zealand cross-sectional patient survey. BMJ Open, 8:e023667. doi: 10.1136/bmjopen-2018-023667</p> <p>Kleinstäuber, M., MacKrill, K., & Petrie, K.J. (2018). What characterizes individuals who prefer branded innovator over generic medicines? A New Zealand general population survey. Drugs & Therapy Perspectives, 34, 478-483. doi:10.1007/s40267-018-0541-z</p> |
| | |
| | |

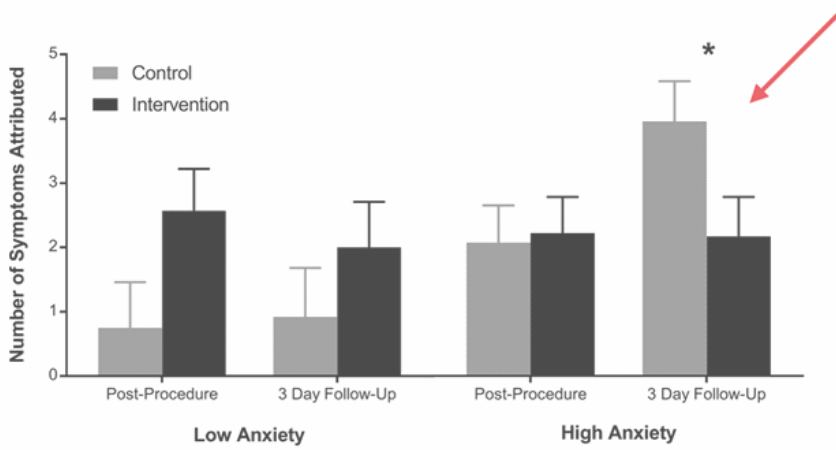
| | |
|------------------|---|
| | <p>Dalbeth, N., & Petrie, K.J. (2018). It's time to change the name of gout. BMJ. Feb 5.</p> <p>Petrie, K.J., MacKrill, K., Derksen, C., & Dalbeth, N. (2018). An illness by any other name: The effect of renaming gout on illness and treatment perceptions. Health Psychology, 37,37-41. doi: 10.1037/hea0000548</p> |
| Outcomes | Will this request change the intended outcomes or contracted objectives of the research project as a whole? If so, please provide some detail |
| | No |
| Budget Changes | If the variation request requires additional funding, changes in FTEs or shifting funds from one category to another, please detail the amounts and which categories the funds are moving between. |
| | \$15,538 from unspent operating to salaries. |
| Extensions | If the request is for a time extension please provide a revised timeline, particularly for major milestones. |
| | No |
| Advice to Funder | Has the proposed change or the circumstances leading to it previously been signalled to the funder via reporting or other communication? |
| | No |
| Ethics | Is ethics approval required for the proposed variation? If yes, please confirm the status of the ethics application. |
| | No |

From: Keith Petrie <[REDACTED]>
Sent: Friday, 5 October 2018 9:16 AM
To: Janet Mackay
Cc: Kate MacKrill
Subject: nocebo explanation intervention

Follow Up Flag: Follow up
Flag Status: Flagged

hi Janet - I wanted to sound out an idea with you. Over the past few years we have been investigating whether explaining the nocebo effect to the public or patients is an effective way of reducing side effect reports after the introduction of a new treatment or intervention.

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What we would like to do is to test whether this approach works in a drug switch to a generic. We were wondering if we could include such an approach with some up coming switch where one group (say pts in North Island) were given extra information about the nocebo effect along with the fact that their meds were going to change. We could then look at relative rates of adverse events reported to CARM in the 2 groups.

Here is the information we used in the recent colonoscopy study we could modify this to suit a drug switch.

Lay definition

Nocebo effect I want to tell you about what we call the *nocebo effect* as it is relevant to all the information I have given you about side effects. You may have heard about the placebo effect where people get positive benefit from a sugar pill just because they believe it is going to help them? Well the *nocebo effect* is the opposite.

Mechanisms

How it works The nocebo effect can occur when we are told we could get this or that side effect from a medical treatment or investigation, such as a nausea or stomach pain (like I have just done). When we are warned about possible side effects then we become more attuned to these particular side effects and focus more on possible changes in our body and this may cause us to notice those and other symptoms more.

Example

Examples It is a bit like when someone in your house suddenly gets sick after a meal and then you may start checking whether you feel sick and maybe noticing similar symptoms to what they may have.

Patient engagement

Have you ever had an experience like this? [let patient describe]

Summary

Summary and questions As part of good medical practice, we have to tell you about the side effects that can occur after colonoscopy but because of the *nocebo effect* sometimes just telling you about the side effects can cause you to focus on your notice symptoms more and naturally think the treatment may be causing the symptoms.

I look forward to hearing from you.

Best wishes, Keith

Keith J. Petrie

Professor of Health Psychology

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Department of Psychological Medicine

University of Auckland, New Zealand

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This **Variation to Research Funding Agreement** (“the **Variation**”) is made on _____

between (1) **Pharmaceutical Management Agency (Funder)**

and (2) **The University of Auckland (Researcher)**

and varies the **Research Funding Agreement** dated 23 May 2013 (signed 7 June 2013), the **Variation to Research Funding Agreement** dated 19 March 2015 (signed 25 March 2015) and the **Variation to Research Funding Agreement** dated 20 June 2017 (signed 20 June 2017) (together forming “the **Agreement**”)

Introduction

- A. The Researcher is currently undertaking a programme of Research in accordance with the Agreement as set out in the Proposals appended to the Agreement (the **2012 Proposal, the 2014 Proposal and the 2017 Proposal**).
- B. The Researcher wishes to carry out further Research in relation to a change in the funded brand of the pharmaceutical lamotrigine, which is being changed to a generic. A summary of the further Research request has been attached at Appendix 1 (**Request**).
- C. The objectives of the further Research shall for example identify factors associated with patient acceptance to this brand change and establish whether an internet delivered intervention can mitigate the issues associated with brand changes in comparison to a notification of the brand change.
- D. The substantive terms of the further Research shall be set out in a proposal, which will form part of the Agreement (the **2019 Proposal**) and the Funder agrees to fund this additional Research on the terms and conditions set out in the Agreement, the Variation and the 2019 Proposal.
- E. Unless varied by the Variation, the terms and conditions of the Agreement will continue to govern the ongoing Research (including those relating to reporting). Terms used in the Variation have the same meaning as in the Agreement unless the context otherwise requires.

It is agreed

1. Amendment to Term of Agreement

Clause 2 of the Agreement is amended by deleting the end date “30 June 2019” and replacing it with 30 September 2020.

2. Additional Services

Clause 3.2 of the Agreement is amended by the addition of the following further services:

- (j) carry out the Research in accordance with the 2019 Proposal.

3. **Amendment to Financial Terms and Conditions**

Clause 8.1 shall be amended by adding the following text immediately following the existing text:

Following execution of the Variation and subject to the Funder's approval in writing of the 2019 Proposal, the Funder will pay the Researcher a total of \$72,683 plus GST on receipt of a valid tax invoice from the Researcher.

For the avoidance of doubt no invoice shall be issued by the Researcher to the Funder and no payment shall be made by the Funder to the Researcher under the terms of the Variation until the 2019 Proposal has been approved by the Funder in writing.

4. **Additional Proposal**

The 2019 Proposal shall be deemed to form part of the Agreement. The Funder and Researcher shall negotiate in good faith the terms of the 2019 Proposal.

5. **Entire Agreement**

For the avoidance of doubt the Request has been attached to the Variation to provide a summary to the Funder and the Researcher and shall not constitute any agreement between the Funder and the Researcher.

The agreement between the Funder and the Researcher shall be the terms set out in the Agreement, the Variation and the 2019 Proposal (**Contract Documents**).

The Contract Documents shall be the entire agreement between the parties regarding its subject matter, and supersedes and extinguishes all prior agreements, understandings and negotiations between the parties regarding its subject matter.

Execution

Executed as an agreement

On behalf of **Pharmaceutical Management Agency** by:

Sarah Fitt
Chief Executive

Date:

On behalf of the **University of Auckland** by:

Name:

Position:

Date:

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Appendix 1 – Request to Funder for Contract Variation

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From: Adam McRae <[REDACTED]>
Sent: Monday, 20 May 2019 8:38 AM
To: Tegan Evans <[REDACTED]>
Cc: Keith Petrie <[REDACTED]>
Subject: RE: Contract variation request - Psychological influences on the efficacy and side effects associated with generic medicines (3704219)

Dear Tegan

Just wanted to briefly introduce myself. I have recently joined the Implementation Programmes team here at PHARMAC and will have responsibility for this piece of work. To close the loop, the research proposal has been agreed (copy attached for your records). Accordingly UniServices are able raise an invoice in line with the contract variation.

Please let me know if you have any questions.

Kind regards
Adam

Adam McRae | Senior Implementation Lead

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From: Tegan Evans <[REDACTED]>
Sent: Friday, 12 April 2019 10:11 AM
To: Janet Mackay <[REDACTED]>
Cc: Keith Petrie <[REDACTED]>
Subject: RE: Contract variation request - Psychological influences on the efficacy and side effects associated with generic medicines (3704219)

Hi Janet,

Thank you for the update, we look forward to hearing from you next week.

Let me know if you need any further information.

Hope you have a lovely weekend as well.

Kind regards,
Tegan

From: Janet Mackay <[REDACTED]>
Sent: Friday, 12 April 2019 9:45 AM
To: Tegan Evans <[REDACTED]>
Cc: Keith Petrie <[REDACTED]>
Subject: RE: Contract variation request - Psychological influences on the efficacy and side effects associated with generic medicines (3704219)

Kia ora Tegan,

Just an update from us on this contract variation. We are just following the internal processes for signing this off and, given the total value of the contract (based on the original grant with this amendment) it will need to be approved by our Chief Executive.

We don't anticipate this will be an issue, but just adds another step to the process. We will be aiming for this to be all approved from our end before Easter, i.e. Thursday next week, but will keep you updated if this is delayed.

Have a great weekend.

Ngā mihi,

Janet

Janet Mackay | Manager, Implementation Programmes

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DOI: [REDACTED] P: +64 4 460 4990 | F: +64 4 460 4995 | [REDACTED] www.pharmac.govt.nz

(This is a computer generated letter. No signature required.)

UAHPEC Administrators
University of Auckland Human Participants Ethics Committee

c.c. Head of Department / School, Psychological Medicine
Kate MacKrill

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REQUEST TO FUNDER FOR CONTRACT VARIATION

Submitted for and on behalf of the University of Auckland by its authorised agent Auckland UniServices Limited, Level 10, 70 Symonds Street.

Email: contracts@auckland.ac.nz

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|------------------------------|---|-----------------|-----------------|
| Funder Ref. | AWD-3704219 | UOA Project No. | 3704219 |
| Funder | Pharmac NZ | Funder Scheme | Pharmac Project |
| Principal Investigator | Prof Keith J Petrie | | |
| Project Title | Psychological influences on the efficacy and side effects associated with generic medicines | | |
| Type of Variation Request | Extension of time and funding | | |
| Additional Funding Requested | Yes – additional \$72,683 | | |
| New Requested End Date | Yes – extension until 30/09/2020 | | |



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|------------------|--|
| Project Progress | Please describe the work completed to date and any work not completed as a result of the change in circumstances leading to this request |
| | This project has already achieved a number of important findings and this has resulted in several publications and has been disseminated in several academic conferences and to Pharmac NZ audiences. |
| | MacKrill, K., Gamble, G., Bean, D., Cundy, T., & Petrie, K.J. (2019). Evidence of a media-induced nocebo response following a nation-wide antidepressant drug switch. <i>Clinical Psychology in Europe</i> , 1(1), e29642, doi: 10.32872/cpe.v1i1.29642 |
| | Gasteiger, C., Jones, A.S.K., Kleinstaubler, M., Lobo, M., Horne, R., Dalbeth, N., & Petrie, K.J. (in submission). The effects of message framing on patients' perceptions and willingness to switch to a biosimilar. <i>Arthritis Care & Research</i> . |
| | MacKrill, K., & Petrie, K.J. (2018). What is associated with increased side effects and |

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|---|---|
| | <p>lower perceived efficacy following switching to a generic medicine? A New Zealand cross-sectional patient survey. <i>BMJ Open</i>, 8:e023667. doi: 10.1136/bmjopen-2018-023667</p> <p>Kleinstäuber, M., MacKrell, K., & Petrie, K.J. (2018). What characterizes individuals who prefer branded innovator over generic medicines? A New Zealand general population survey. <i>Drugs & Therapy Perspectives</i>, 34, 478-483. doi:10.1007/s40267-018-0541-z</p> <p>Hemmington, A., Dalbeth, N., Jarrett, P., Fraser, A.G., Broom, R., Browett, P., & Petrie, K.J. (2017). Medical specialists' attitudes to prescribing biosimilars. <i>Pharmacoepidemiology and Drug Safety</i>, 26, 570-577. doi: 10.1002/pds.4186</p> |
| <p style="text-align: center; opacity: 0.5; font-size: 2em;">OFFICIAL INFORMATION ACT</p> | |
| Budget Changes | <p>If the variation request requires additional funding, changes in FTEs or shifting funds from one category to another, please detail the amounts and which categories the funds are moving between.</p> |
| | <p>The change only has additional funds and does not alter existing categories</p> |
| Extensions | <p>If the request is for a time extension please provide a revised timeline, particularly for major milestones.</p> |
| | <p>Current studies are completed or almost complete. This extension to focus on this upcoming drug switch will be finished and written up for publication and final report by 30/09/2020.</p> |
| Advice to Funder | <p>Has the proposed change or the circumstances leading to it previously been signalled to the funder via reporting or other communication?</p> |
| | <p>Yes – The University has discussed the budget change and extension with Pharmac (Janet MacKay, Senior Manager Implementation)</p> |
| Ethics | <p>Is ethics approval required for the proposed variation? If yes, please confirm the status of the ethics application.</p> |
| | <p>Ethics is approved.</p> |



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From: Keith Petrie <[REDACTED]>
Sent: Monday, 15 April 2019 5:52 PM
To: Janet Mackay; Hamish Franklin
Cc: Kate MacKrell
Subject: Fwd: [REDACTED] Ethics Application
Attachments: Approved(eform).pdf; ATT00001.htm

Approved!

Keith J. Petrie

Professor of Health Psychology

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[REDACTED]

Department of Psychological Medicine

University of Auckland, New Zealand

[REDACTED]

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Study 1: Lamotrigine Patient Survey

Lamictal, Arrow-Lamotrigine and Logem are three brands of the same medication lamotrigine and have been approved by Medsafe NZ as being bioequivalent. However, changing medicine brands, regardless of bioequivalence, can be a problematic process. Patients often prefer their original brand and can hold negative expectations of the new medication, resulting in perceptions that the drug does not as well and has more side effects than the original (Faasse, Cundy, Gamble, & Petrie, 2013), although pharmacologically that is unlikely to be the case (MacKrill & Petrie, 2019).

Research has also shown that patients being treated for psychological conditions are more likely to experience a nocebo effect following a medicine brand change (Weissenfeld, Stock, Lungen, & Gerber, 2010).

This study aims to understand patients' perceptions of their new brand Logem, experiences of the lamotrigine brand change and whether this is different for those taking the medicine to treat epilepsy compared to bipolar disorder.

AIM & HYPOTHESIS

The aim of this research is to understand patient's perceptions and experiences following a change in the funded brand of lamotrigine. The study also aims to examine whether there are any differences in the experience of patients taking this medication to treat epilepsy compared to a mood disorder. Based on previous research, it is hypothesised that patients prescribed lamotrigine for a mood disorder will experience a greater nocebo effect, characterised by lower efficacy beliefs and greater side effect reporting, compared to those taking the medicine to treat epilepsy.

We also wish to examine the role of social media in influencing patient responses to the switch. We hypothesise that patients who have read about problems with the medication on social media will be more susceptible to the nocebo effect following the drug switch.

METHOD

The study will consist of a one-off anonymous internet-based survey. The survey will be hosted on the Pharmac website on the "Lamotrigine: my medicine has changed" webpage. Patients who navigate to this page will be able to click a link to complete a brief survey about their perception and experience with the change. To be eligible to complete the survey, respondents must be 16 years or age or older and prescribed Lamictal or Arrow-Lamotrigine before the brand change. The first page of the survey will comprise the participant

information sheet, which will outline the purpose of the study, that it's being conducted by researchers at the University of Auckland, how anonymity is preserved and participant rights. Completing and submitting the survey will be taken as a participant's informed consent to participant.

The survey will take approximately 20 minutes to complete and will assess a number of areas. Firstly, participants will be asked about their previous brand of lamotrigine (dose, indication, how long they have been taking it), and whether they have changed to the new brand. A section on information sources will assess how they found out about the change, how they would have liked to, how much they trust various information sources and whether they have been exposed to anything in the traditional or social media about the lamotrigine brand change. There are questions to gauge how effective participants think the old and new lamotrigine brand is, and any side effects experienced. Finally, there are general questions about a person's experience and sensitivity to medicines and demographic information.

The results of the survey will provide information on how patients found out about the switch, their level of concern and trust in the sources of this information. The survey will also provide information on the role of social media in influencing transition to the new generic medication and how background factors relate to exposure to social media stories about the switch.

Study 2: Generic Switch Information Study

There is preliminary evidence that explaining the nocebo effect can reduce side effect reporting. Studies have shown that explaining the association between health problems and wind-turbine induced infrasound from a nocebo perceptible reduces side effect reporting compared to a biological explanation (Crichton & Petrie, 2015). Further, discussing the nocebo effect with patients before they receive a colonoscopy reduces subsequent side effects in those who are highly anxious (Burton et al., 2019). Recent evidence shows that media stories following a medicine switch can generate a widespread nocebo effect across patient groups and this may be attenuated by providing additional information about the nocebo effect (MacKrell, Gamble, Bean, Cundy, & Petrie, 2019). However, this has yet to be evaluated in an actual drug switch. In fact, there is no previous studies on the value of just notifying patients there will be a switch to their medication on side effect and adjustment to the new medication. There are two aims of this study: (1) to investigate the value of a text message notification on adjustment to a new medication compared to not getting any notification (2) to investigate whether a brief nocebo explanation before patients change lamotrigine brands will reduce subsequent side effect reporting compared to the group getting notification but no information on the nocebo response.

AIM & HYPOTHESIS

- (1) To investigate whether providing a providing a text message notification about an upcoming medication change reduces side effects and medication problems compared to not getting any notification.
- (2) To investigate whether giving patients a brief explanation of the nocebo effect will reduce the reporting of side effects following a switch in lamotrigine brands. It is hypothesised that patients who receive additional nocebo information will report fewer side effects after the switch compared to a group who are just notified that their medicine brand is going to change and the control group who does not receive any additional information about a drug switch.

METHOD

Green Cross Health, a New Zealand provider of primary health care services, will be used to recruit participants. Patients in the Green Cross database who are taking either Lamictal or Arrow-Lamotrigine and have a mobile phone will be eligible to participate in the study. It is estimated that around 4,500 patients in the Green Cross database are prescribed lamotrigine, of which approximately 60% have a phone number listed in the Green Cross database. We anticipate that approximately 1,500-2,000 participants will agree to participate.

Prior to study enrolment, patients will be randomly assigned to one of three groups based on the last two digits of their NHI number. Patients allocated to the 'notification only' group and 'notification plus nocebo explanation' group will be sent a text message by Green Cross inviting them to take part in a study being conducted by researchers at the University of Auckland, which is looking at improving medicine switch information. The message will be sent two weeks before patients are going to pick up their first prescription of Logem and will contain a brief description of the study with a link to the complete Participant Information Sheet if they would like more information.

On receiving consent to participate, participants in these two groups will be sent their allocated text message. The notification only group will be informed that they have been changed to another brand of lamotrigine and when they pick up their next prescription, they will receive Logem. The intervention group will receive this message as well as a link to a brief information video explaining the nocebo effect and how this could be relevant to their upcoming switch by 1) becoming more aware of physical symptoms and 2) inappropriately misattributing them to the effects of a new medicine brand.

Three weeks after participants have changed lamotrigine brands, the two notification groups and a control group will receive a text message asking them to complete a brief online survey on their experience with the switch. The control group will be invited to complete a University of Auckland survey about their recent experience with Logem. The survey is the same for all three groups and will investigate the side effects they may have experienced and their perceived efficacy of Logem.

IMPLICATIONS

The purpose of this study is to examine whether nocebo responding can be reduced following a medicine brand change by simple notification or a nocebo explanation. If notification or a brief explanation of the nocebo effect are shown to have a positive effect on adjustment to the new medication, they could be incorporated into the activities that support future medication switches. The potential outcomes of this intervention could be quite significant for reducing the nocebo effect, particularly for patient groups where anxiety about the switch is likely to be increased. This could ultimately reduce healthcare expenditure, aid adherence and improve health outcomes.

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REFERENCES

- Burton, D., Perera, A., MacKrell, K., Kleinstaubler, M., Wolf, L., Menchavez, M., ... Petrie, K. J. (2019). Can a nocebo explanation reduce symptom reporting following colonoscopy? A randomized controlled trial. [Manuscript in preparation].
- Colgan, S., Faasse, K., Martin, L. R., Stephens, M. H., Grey, A., & Petrie, K. J. (2015). Perceptions of generic medication in the general population, doctors and pharmacists: A systematic review. *BMJ Open*, 5, e008915.
- Crichton, F., & Petrie, K. J. (2015). Health complaints and wind turbines: The efficacy of explaining the nocebo response to reduce symptom reporting. *Environmental Research*, 140, 449-455.
- Faasse, K., Cundy, T., Gamble, G., & Petrie, K. J. (2013). The effect of an apparent change to a branded or generic medication on drug effectiveness and side effects. *Psychosomatic Medicine*, 75, 90-96.
- Howland, R. H. (2009). What makes a generic medication generic? *Journal of Psychosocial Nursing and Mental Health Services*, 47, 17-20.
- MacKrell, K., Gamble, G. D., Bean, D. J., Cundy, T., & Petrie, K. J. (2019). Evidence of a media-induced nocebo response following a nationwide antidepressant drug switch. *Clinical Psychology in Europe*, 1, e29642.
- MacKrell, K., & Petrie, K. J. (2018). What is associated with increased side effects and lower perceived efficacy following switching to a generic medicine? A New Zealand cross-sectional patient survey. *BMJ Open*, 8, e023667.
- Petrie, K. J., & Rief, W. (2019). Psychobiological mechanisms of placebo and nocebo effects: Pathways to improve treatments and reduce side effects. *Annual Review of Psychology*, 70, 599-625
- Weissenfeld, J., Stock, S., Lungen, M., & Gerber, A. (2010). The nocebo effect: A reason for patients' non-adherence to generic substitution?. *Die Pharmazie-An International Journal of Pharmaceutical Sciences*, 65, 451-456.

From: Janet Mackay
Sent: Wednesday, 27 March 2019 4:46 PM
To: Sonja Woodall
Cc: 'Keith Petrie'
Subject: RE: Patient survey and Intervention study Lamotrigine

Kia ora Sonja,

As indicated by Keith, we are happy to extend the current grant (*Psychological influences on the efficacy and side effects of generic medicines*) to incorporate this further research. However, happy if you would prefer to have another grant rather than an extension if that would be better for your processes.

Are you happy to frame something up, or would you like us to do that from our end?

In principle we are happy with the costings as outlined below, but as it is outside my delegation, this will need to be approved by others within PHARMAC before it can fully be confirmed. I don't foresee any major issues in that, but best to be nice and clear.

Ngā mihi,

Janet

Janet Mackay | Manager, Implementation Programmes

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From: Keith Petrie <[REDACTED]>
Sent: Wednesday, March 27, 2019 3:37 PM
To: Janet Mackay <[REDACTED]>
Cc: Sonja Woodall <[REDACTED]>
Subject: Patient survey and Intervention study Lamotrigine

Hi Janet - would you be able to send an email to Sonja indicating that you are (1) happy to extend the Psychological influences on the efficacy and side effects of generic medicines grant for a year to 30/9/20 and (2) also approve the budget attached. They have added some extra for ACC, holiday pay etc and \$5k for dissemination on top of what I originally sent you as a draft. Total now \$72,683.

Best wishes, Keith

Keith J. Petrie
Professor of Health Psychology

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Department of Psychological Medicine
University of Auckland, New Zealand

Begin forwarded message:

From: Keith Petrie <[REDACTED]>
Subject: Re: Rough Budget - Patient survey and Intervention study Lamotrigine
Date: 27 March 2019 at 1:34:34 PM NZDT
To: Sonja Woodall <[REDACTED]>
Cc: Janet Mackay <[REDACTED]>

Hi Sonja - thank you that is so helpful. I am guessing that [REDACTED] are a contract for services.

I will complete the RO-90 and send this to you shortly. Still probably quicker and easier to do this than create a new project.

Sorry Janet's email should be [REDACTED]

Many thanks, Keith

Keith J. Petrie
Professor of Health Psychology

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Department of Psychological Medicine
University of Auckland, New Zealand

From: Keith Petrie <[REDACTED]>
Sent: Saturday, 18 May 2019 2:08 PM
To: Adam McRae
Cc: Kate MacKrill
Subject: Re: Research Proposal

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Adam - its all good from our end. Thanks for the feedback on the [REDACTED] All the best, Keith

Keith J. Petrie

Professor of Health Psychology

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[REDACTED]

Department of Psychological Medicine

University of Auckland, New Zealand

[REDACTED]

On 17/05/2019, at 1:05 PM, Adam McRae <[REDACTED]> wrote:

Hi Keith

Just wanting to close the loop on the research proposal, we are all good from this end. Can you confirm you are happy with the proposal and I will let the team at UniServices know for invoicing.

By the way [REDACTED] is fantastic. Keen to investigate if we can repurpose it following the study.

Cheers

Adam

Adam McRae | Senior Implementation Lead

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: [REDACTED] | P: +64 4 460 4990 | F: +64 4 460 4995 | M: [REDACTED] www.pharmac.govt.nz

.....

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<PHARMAC Lamotrigine Studies Proposal University of Auckland.docx>

RELEASED UNDER THE
OFFICIAL INFORMATION ACT

From: Kate MacKriill <[REDACTED]>
Sent: Wednesday, 10 April 2019 1:44 PM
To: Janet Mackay
Cc: Keith Petrie
Subject: Re: Survey link

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Janet,
Here's the link to the lamotrigine survey, it's active and ready for responses. It's anonymous however I've made it so it can only be answered once per person (unless people clear their cache or use a different computer).

https://auckland.au1.qualtrics.com/jfe/form/SV_eeMsviiUNYol3FP

Cheers,
Kate

Kate MacKriill | BSc MHealthPsych
PhD Candidate, Health Psychology
Department of Psychological Medicine, University of Auckland
A Level 12, Auckland Hospital Support Building, Grafton
[REDACTED] M [REDACTED]

From: Janet Mackay <[REDACTED]>
Sent: 10 April 2019 12:14
To: Kate MacKriill; Keith Petrie
Subject: Survey link

Hi there – great to spend time with you both last week.

Just checking re the lamotrigine survey link and whether that's all complete? No worries if it's not quite ready, but if it is we might be able to include it in any notification we make over the next little while.

Ngā mihi,

Janet

Janet Mackay | Manager, Implementation Programmes

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DDI: [REDACTED] | P: +64 4 460 4990 | F: +64 4 460 4995 | M: [REDACTED] www.pharmac.govt.nz

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From: Adam McRae
Sent: Friday, 17 May 2019 1:06 PM
To: 'Keith Petrie'
Cc: Kate MacKrell
Subject: Research Proposal
Attachments: PHARMAC Lamotrigine Studies Proposal University of Auckland.docx

Hi Keith

Just wanting to close the loop on the research proposal, we are all good from this end. Can you confirm you are happy with the proposal and I will let the team at UniServices know for invoicing.

By the way the little video is fantastic. Keen to investigate if we can repurpose it following the study.

Cheers

Adam

Adam McRae | Senior Implementation Lead

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DDI: [REDACTED] | P: +64 4 460 4990 | F: +64 4 460 4995 | M: [REDACTED] www.pharmac.govt.nz

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From: Keith Petrie <[REDACTED]>
Sent: Thursday, 14 March 2019 9:45 AM
To: Janet Mackay
Subject: Rough Budget - Patient survey and Intervention study Lamotrigine

Hi Jane how does this look? I haven't including anything for my time but can make it work

Contract research assistance (\$25 x 800 hours) = \$20,000

[REDACTED]

2 summer students \$12,000

Travel costs \$2,000

Publishing costs \$11000

Total \$65,000

Keith

Keith J. Petrie

Professor of Health Psychology

[Webpage and download NEW publications](#)

[REDACTED]

Department of Psychological Medicine

University of Auckland, New Zealand

[REDACTED]

On 13/03/2019, at 10:59 AM, Janet Mackay <[REDACTED]> wrote:

Thanks Keith, that's looking great.

We're happy with that as a summary of the proposal and look forward to continuing to work/with you around the next steps for making this happen.

Ngā mihi,

Janet

From: Keith Petrie <[REDACTED]>
Sent: Tuesday, March 12, 2019 12:56 PM
To: Janet Mackay <[REDACTED]>
Subject: Research proposal

Hi Janet - This is to follow on from our phone discussion yesterday. We propose two studies of the upcoming Lamotrigine generic switch:

Study 1 Patient survey

This would be accessed from a link on the Pharmac website and be an anonymous patients survey on patients experiences and perceptions around this switch. Respondents would complete questions on demographic background, perceived sensitivity, information on length of time on branded med and side effects from new medication. In a change from previous venlafaxine survey we would also include information on exposure to media stories (including social media) on switch, questions patients have about the switch and personal ideas or theories (if any) about why new medication may not be working as well and differences between the groups prescribed for mood disorder versus as an anticonvulsant.

[REDACTED]

[REDACTED]

Best wishes, Keith

Keith J. Petrie
Professor of Health Psychology

[Webpage and download NEW publications](#)

[REDACTED]

Department of Psychological Medicine
University of Auckland, New Zealand

[REDACTED]

.....

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OFFICIAL INFORMATION ACT

Subject: FW: PHARMAC - OIA for your feedback

From: Keith Petrie <[REDACTED]>
Sent: Monday, January 21, 2019 2:47 PM
To: Janet Mackay <[REDACTED]>
Subject: Re: PHARMAC - OIA for your feedback

Hi Janet - This looks fine to me. Interesting to see how much there is.

All the best, Keith

On 17/01/2019, at 11:54 AM, Janet Mackay <[REDACTED]> wrote:

Hi Keith,

Happy New Year – hope the start of the year has been good for you.

Find attached a letter and key documents for your feedback/review. It would be great if you could get back to us by next Wednesday, 23 January, 2019.

Ngā mihi,

Janet

Janet Mackay | Manager, Implementation Programmes

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DDt: +[REDACTED] | P: +64 4 460 4990 | F: +64 4 460 4995 | Mt: +[REDACTED] www.pharmac.govt.nz

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<2019-01-17 Consultation Letter to Keith Petrie re venlafaxine OIA.pdf><Keith Petrie - OIA combined - correspondence - print and scan.pdf><Keith Petrie OIA - summary of phone calls and meetings.xlsx>

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Janet Mackay | Manager, Implementation Programmes

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Sent: Thursday, 17 January 2019 11:54 AM
To: 'Keith Petrie'
Subject: PHARMAC - OIA for your feedback
Attachments: 2019-01-17 Consultation Letter to Keith Petrie re venlafaxine OIA.pdf; Keith Petrie - OIA combined - correspondence - print and scan.pdf; Keith Petrie OIA - summary of phone calls and meetings.xlsx

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Janet

Janet Mackay | Manager, Implementation Programmes

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17 January 2019

Level 9, 40 Mercer Street, Wellington 6011
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Phone 64-4-460-4990

Fax 64-4-460-4995

Information line 0800 66 00 50

enquiry@pharmac.govt.nz

www.pharmac.govt.nz

Keith Petrie
Auckland University

Via email: [REDACTED]

Dear Keith,

PHARMAC has received two further OIA requests from Trudi Webber for information under the Official Information Act 1982 (OIA).

One of the questions in the requests includes all communication between yourself and PHARMAC and between Kate MacKrill and PHARMAC.

The attached information appears to be in-scope of this question. We have marked (in red) the information with our proposed redactions. The information we propose to redact is personal contact information and information we believe to be out of scope.

In addition, we have included in the attached information the signed Research Funding Agreement between PHARMAC and the University of Auckland dated 23 May 2013, which includes the associated proposal. We would appreciate your view as to whether there would be any issues from your perspective if PHARMAC were to release the Agreement and proposal to the requester.

If you have any specific concerns about releasing this information, please let us know by Wednesday 23 January 2019.

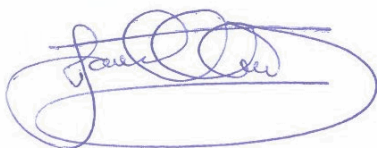
If you are interested, you can find practice guidelines on the Official Information legislation on the following link:

<http://www.ombudsman.parliament.nz/resources-and-publications/guides/official-information-legislation-guides>

Please note that we are only able to withhold information to the extent permissible under the OIA and other relevant laws and requirements.

Please feel free to contact us if you have any questions or require further information.

Yours sincerely,



Janet Mackay
Manager, Implementation Programmes