Prevention, diagnosis and management of medication overuse headache (MOH): quality improvement in the Australian primary clinical setting

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Full proposal

In Vivo Academy Limited

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This full proposal was prepared in response to Pfizer's office of Independent Grants for Learning & Change request for proposal on healthcare professional education and quality improvement in the clinical area of medication-overuse headache.

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Main section of the proposal

1. **Overall goal and objectives**

The World Health Organization reports that 50% of people with headache are primarily self-treating, without consulting a health professional. Educating patients effectively and efficiently, especially on the avoidance of MOH, is viewed as a public health concern. Neurologists on the other hand consider the lack of education of health professionals involved in the care of people with headaches to be the key issue that impedes better management of headache.[1] In light of these reports, we envision our program to be able to educate both GPs and pharmacists to be well equipped, not only to treat appropriately but also to opportunistically educate their patients with headache.

The overall goal of our proposed program is to identify and reduce gaps in knowledge, attitudes and systems in prevention, diagnosis and management of medication-overuse headache (MOH) in Australian primary care.

Our proposed program aims to:

1. Increase awareness and knowledge among Australian general practitioners (GPs) and pharmacists on the prevention, diagnosis and management of MOH based on guidelines set by the International Headache Society (IHS);
2. Train participating healthcare practitioners to implement individualistic and opportunistic health education and promotion during patient consultation, which in turn could impact their patient's knowledge, attitude and behaviours toward risks and avoidance of MOH;
3. Encourage healthcare practitioners to apply appropriate referral systems in their practice if needed; and
4. Show evidence of change in knowledge, attitude and systems among Australian GPs in the diagnosis and management of MOH by producing and publishing an outcomes paper at the end of the program.

2. **Technical approach**

a. Current assessment of need in target area

i. Quantitative baseline data and gap analysis

The Family Medicine Research Centre (FMRC) of the University of Sydney and the Australian Institute of Health and Welfare (AIHW) administer the Bettering the Evaluation and Care for Health (BEACH) program, which collects data on GP activities, their patients' reasons for seeking medical care, how problems are managed including medications prescribed and referrals to specialists. A BEACH report recording more than 600,000 patient encounters between April 1998 and March 2004 showed that patients with headache presented at a rate of 1.9 per 100 encounters, with undefined headache as the most common at 18.7%, followed by migraine at 14.0%. The medication rate for undefined headaches was 66.4 medications per 100 problems. Patients were referred elsewhere for undefined headache at a rate of 11.4

per 100 contacts. Primary care patients were mostly referred to neurologists (2.8 per 100 referrals).[2]

Migraine is frequently recognised in the Australian primary care setting, with about 12.3% of patients reporting three or more migraine episodes per month. As per published guidelines, most Australians use over-the-counter (OTC) analgesics for mild to moderate migraine; but for severe migraine, patients turn to combined analgesics (e.g. paracetamol and codeine), many of which are available OTC. Prophylactic medication is underutilised, with only a small proportion (8.3%) of migraine sufferers taking prophylactic medication.[3]

This shows that under-diagnosis of migraine is less in Australia compared to other countries, and Australian GPs appear to follow recommended guidelines in the use of acute medications, but there is still a risk of MOH as GPs seem to have limited knowledge and familiarity on the range of prophylactic therapies available for headaches that are well supported by published data and guidelines. Combined analgesics containing codeine are still being overused by their patients and GPs appear to limit their selections from a few acute agents (analgesics, triptans and ergotamines) as prophylaxis, despite the availability of prophylactic drugs for migraine in primary care.[3]

In a letter to the editor published in the *Australian Prescriber,* a pharmacist indicated that given the availability of OTC analgesics with codeine, the prevalence of MOH "in people who are unknowingly trapped in a vicious circle" is a cause for concern. Warning statements on many common OTC analgesics are scarce or absent. Consumer medication information materials have little information on the potential for developing MOH, the signs and symptoms to watch out for, and the importance of seeking medical attention should they become aware of this disorder.[4]

The above findings from published literature identify the gaps in current practice that we think can be addressed by education and skills improvement through training of healthcare professionals and changes in practice systems (or procedural structures) to improve patient safety and awareness. However, the literature may not reflect current practice and not specifically focused on MOH, and so to confirm these gaps, we intend to do an analysis of current needs and compare this with accepted guidelines in order to substantiate a genuine need for and design an education activity on MOH in primary care.

For our needs assessment, a total of 4500 GPs will be invited to join an online survey to assess their present clinical practice in terms of their knowledge on headaches and appropriate medications as well as their perception of patient behaviour and attitudes towards headaches and medications. Approximately 1000 headache and migraine patients will be invited to complete a

knowledge, attitude and perception survey, which can later be compared with the GP survey. A third online survey involving around 3000 pharmacists will also be conducted to assess their knowledge and attitude, especially when communicating to patients about headache medications. A conservative 1–2% participation for each of these surveys is anticipated.

ii. Primary audience

The primary audience of our program will be GPs who are the first points of patient contact, and pharmacists who play a role in the treatment of headaches among patients who self-medicate. GPs, their patients (and if applicable, their families and carers), and pharmacists will benefit from the program outcomes.

b. Intervention design and methods

Our proposed intervention is to develop and deliver a Category 1 Quality Improvement & Continuing Professional Development (QI&CPD) 6-hour Active Learning Module (ALM) that will be accredited by the Royal Australian College of General Practitioners (RACGP) and the Australian College of Rural and Remote Medicine (ACRRM).

The ALM in general is designed "to provide structured, quality education opportunities directed to achieving demonstrable changes in the performance, knowledge, skills, behaviours, and attitudes of GPs" by covering one or more of the domains of general practice. The ALM takes the adult learner through a learning cycle that involves: self-reflection, planning, action, review, and again, planning, and as such consists of: (1) a predisposing activity, which gives the opportunity for participants to reflect on their current clinical practice; (2) a structured learning activity (SLA) of at least 6 hours, covering both "person approach" to enhance professional competence (behaviour, attitude, skills and knowledge) and "system approach" that focuses on team and procedural processes to safeguard patient safety; and (3) a reinforcing activity that consolidates learning.[5]

Following the results of the online needs assessment involving GPs, patients and pharmacists, the next step of our intervention is to work with a Steering Committee consisting of general practitioners, pharmacists, pyschologists and specialists to discuss how the content will be shaped, designed and delivered, underpinning each of the learning objectives and according to current best practice guidelines.

For the predisposing activity, we anticipate asking participants to recall a patient who presented with a headache, his or her presenting symptoms, the medication or list of medications prescribed, whether the headache was cured, and if not, what could have been done to change the outcome. The predisposing activity will also include questions to collect baseline data for the program evaluation. (*See 2c. Evaluation Design*)

The SLA, which will be a combination of face-to-face and online activities, is expected to revolve around case studies with reflective questioning to encourage participants to ponder on their own knowledge and skills, as well as discussions on the ICHD-II diagnostic criteria of MOH, most common causes, and how to identify patients who are susceptible to MOH. ALMs previously produced by In Vivo Academy (IVA) show that a combination of face-to-face meetings and online activities attracts more participation as it allows time-poor GPs to attend only one evening meeting while completing some parts of their education on their own free time.

The reinforcing activity will ask the GPs to go back to their practice, apply what they have learned and write their insights on the changes in their practice. All components of the ALM will be fine tuned based on the results of the needs assessment and upon consultation with the Steering Committee.

For this intervention, we plan to invite around 425 GPs and 75 pharmacist participants from major cities nationally. These figures factor in the uneven distribution of medical workforce between states and territories due to the vastness of Australia, the overall per capita rate of GPs to population[6], the RACGP rule of limiting each face-to-face meeting to 25 participants per facilitator to ensure interactivity, together with the total budget for this project. With more doctors working in major urban and regional cities, prioritizing these doctors for this educational activity will bring about more impact and measurable outcomes.

c. Evaluation design

IVA and AXDEV Group propose a comprehensive strategy (Figure 1) designed to measure outcomes at levels 1 , 2, 3, and 4.[7] This initiative will be evaluated through a mixed-methods approach: data will be collected across three points in time (pre, immediate-post, and 5–7 weeks post) using both quantitative and qualitative methods. Approval from an Institutional Review Board will be obtained for the AXDEV led-qualitative 5–7 weeks post assessment (only). Control will be obtained by a within-subject design wherein immediate post, and 5–7-week post change data will be contrasted to the pre-assessment findings.

Pre-assessment - lead by IVA, in consultation with AXDEV. To be completed by all registered participants 4 weeks to 2 days prior to commencement of the SLA: Baseline data from registered GPs and pharmacists will be collected quantitatively prior to their participation in the SLA. Data from the pre-assessment will ensure that program attendees report the same practice gaps, as those sampled in the needs assessment, thereby ensuring alignment of the ALM content, learning objectives, and activities with the participant needs.

Immediate-Post Assessment - lead by IVA, in consultation with AXDEV Group. To be completed by all participants immediately after completing the SLA**:**
After completing the SLA, participants will respond to a quantitative survey assessing satisfaction with the program, procedural and declarative knowledge change related to the program content, as well as assessment of key questions

required by the RACGP and ACRRM to measure the degree by which the learning objectives, the GPs' own learning needs, and the activity's relevance to practice were met. Questions will be Likert–type scales, and content-specific multiple choice questions.

5–6 Weeks Post Assessment - lead by IVA; in consultation with AXDEV Group. To be completed by all participants 5–6 weeks post SLA, and 1 week post reinforcing activity:
Participants will be invited to take part in a post-assessment which will include a quantitative survey assessing maintenance of knowledge, attitudinal change, changes implemented in clinical practice and barriers to implementation of change in the month following program participation.

5–6 Weeks Post Qualitative Assessment - independently designed and conducted by AXDEV Group, 5–6 weeks post SLA and 1 week post reinforcing activity:
A subset of participants (n=25; 5 pharmacists and 20 GPs) will be recruited for independent, IRB-approved qualitative interviews to obtain an in-depth understanding of changes implemented into clinical practice, and of facilitators/ barriers to clinical changes. Associated causes regarding application of change to clinical practice will also be investigated.

Learning Objectives	Evaluation	Evaluation
Define MOH and state the ICHD-II diagnostic criteria	• Change in knowledge of diagnostic criteria • Maintenance of knowledge of diagnostic criteria	• Δ from Pre to Post of 70% accuracy • Δ from Post to 5-6 week post SLA of 50% accuracy
List the most common causes of MOH	• Change in knowledge of causes of MOH • Maintenance of knowledge of MOH	• Δ from Pre to Post of 70% accuracy • Δ from Post to 5-6 week post SLA of 50% accuracy
Identify patients susceptible to MOH	• Change in knowledge of patients susceptible to MOH • Maintenance of knowledge of patients susceptible to MOH • Change in skill identifying patients susceptible to MOH • Change in behavior in identifying patients susceptible to MOH • Change in confidence identifying patients susceptible to MOH	• Δ from Pre to Post of 70% accuracy • Δ from Post to 5-6 week post SLA of 50% accuracy • Δ from Pre to Post of 50% accuracy • Qualitative assessment including changes made in clinical practice • Δ from Pre to 5-6 week post SLA to 75%

Develop a checklist and implement a system that will let the patient, clinician, and pharmacist identify when a patient is at risk of MOH and know whether a specialist referral is required	• Change in Behavior (implementing standard operating approaches to identify at risk patients, referring to specialists etc.)	• Δ from Pre to Post of 50% accuracy • Qualitative assessment including changes made in clinical practice

Table 1. Proposed Plan for Outcomes Evaluation

Qualitative data will be analyzed using thematic analysis method, N-Vivo 7.0 software (QSR International, Cambridge, MA). Quantitative data will be analyzed using frequencies and cross-tabulations using SPSS 22.0 software (SPSS, Chicago, IL). Aggregate data collected through the two methods will be triangulated ensuring a more reliable, comprehensive and trustworthy report on the outcomes achieved by this program. Results from previous ALMs in other fields will be used in order to quantify the amount of expected change and will also be adjusted in relation to the program participants' baseline assessments. Findings from the needs assessment will be used to refine the amount of change expected. Expected change is not homogenous throughout the sample and therefore analyses will include comparisons by years of clinical practice experience, practice setting (rural vs urban) and profession.

A report of the program evaluation and outcomes assessment will be developed for the collaborators (and made available to the funding source). A summary of the findings will be disseminated to the program participants and the population of GPs and pharmacists via the RACGP. The program effectiveness and impact would also be further disseminated through submission of abstracts to key conferences (e.g. the RACGP Conference for General Practice and the Australian Pain Society Annual Scientific Meeting) and manuscript submission to peer-review journals (e.g. Australian Family Physician).

3. Detailed work plan and deliverables schedule

Activity	J F M A M J J A S O N D / J F M A M J J A S O N D
Needs assessment (Jan -Feb 2014)	X-X
Planning (Feb 2014)	X
Develop content (Feb–Jun 2014)	X----------X
Enlist facilitators (Mar 2014–May 2015)	X----------X
Register GPs (Jun 2014–Mar 2015)	X----------X
Baseline survey (Jun 2014–Mar 2015)	X----------X
Conduct SLA of ALM (Jul 2014–May 2015)	X----------X
Immediate post-assessment (Jul 2014–May 2015)	X----------X
Reinforcing activity (Aug 2014–Jun 2015)	X----------X
5–6 weeks post assessment (Sep 2014–Jun 2015)	X----------X
Admin duties (Sep 2014–Jul 2015)	X----------X
Outcomes analysis (Jul 2015)	X
Outcomes report (Jul–Oct 2015)	X-----X
Writing of paper for peer review (Oct–Dec 2015)	X----X

Task 1. Needs assessment. The project will start with the writing of online surveys for the needs analyses, one each for GPs, patients and pharmacists. Each survey, built using SurveyMonkey, will be short and not take more than 7 minutes. We will run the survey for 2–3 weeks before a report is generated in preparation for the inaugural Steering Committee planning meeting.

Task 2. Planning. With the help of our Steering Committee members, we will:

- set specific achievable and measurable learning objectives based on the needs assessment
- outline a thorough agenda for the complete ALM, outlining the themes and formats to be used and decide on how the education will be delivered
- agree on action points, key people and timelines

The IVA event management team will also start identifying locations for the structured learning face-to-face meetings and begin scheduling meetings.

Task 3. Development of content and materials. Based on agreements from the Steering Committee members, medical writers from IVA will conduct their research and start outlining the content manuscripts for the online modules, the face-to-face meeting presentations slides, the participants' and facilitator's guides for the face-to-face meetings, predisposing and reinforcing activities, and evaluation forms.

All content outlines will be approved by the Steering Committee before writers start developing full manuscripts. The full manuscripts will undergo in-house editorials checks and full reviews from the committee. Once these are approved by the committee, the activity will be submitted to the RACGP, ACRRM and the Australian College of Pharmacists (ACP) for accreditation. Final manuscripts will then be built as online modules or laid out as print materials.

Medical writers will also write the invitations with agenda, website content, and other associated materials.

Task 4. **Enlisting and briefing of facilitators**. By March 2014, while materials are being developed and finalised, we will start short-listing and briefing facilitators about their roles and ensure commitment. This task will continue around May 2015 until we have enlisted and briefed the facilitator for the last meeting.

Task 5. **GP registration**. Starting June 2014, the program website will be completed to handle GP registrations.

Task 6. **Predisposing activity and pre-assessment (baseline) survey**. Also by June, GPs will be able to start accessing the predisposing activity and pre-assessment survey before attending the SLA face-to-face meetings.

Task 7. **Conducting the SLA component of the ALM**. From July 2014 to May 2015, evening face-to-face meetings will be held in major cities (both urban and provincial) across Australia. GPs will also be able to access online modules as part of the 6-hour SLA.

Task 8. **Immediate-post assessment**. Immediately following completion of the SLA, GPs will be asked to respond to the evaluation and immediate-post assessment forms.

Task 9. **Reinforcing activity**. Beginning August, those GPs who have completed the SLA and the immediate-post assessment will be able to commence accessing the requirements for the reinforcing activity.

Task 10. **5–6 weeks post assessment**. From September 2014 or 5-6 weeks after the face-to-face meeting, GPs will be asked to participate in a quantitative and qualitative post assessment survey.

Task 11. **Administrative duties**. Also by September, IVA will start fulfilling its administrative duties to the RACGP, ACRRM and ACP by sending attendance certificates to those GPs and pharmacists who have completed the ALM and also submitting their names to the Colleges for accounting of points.

Task 12. **Outcomes analysis**. By July 2015, when GPs have completed the ALM, AXDEV will start collating the data collected from the pre-assessment, immediate-post, and 5-6 weeks post quantitative and qualitative assessments, and start analysis.

Task 13. **Outcomes report**. Between July and October, AXDEV will prepare the outcomes report.

Task 14. **Outcomes paper**. Between October and December 2015, IVA and AXDEV will work together to produce an outcomes paper to be submitted for peer review and published as an abstract and full paper.

Deliverables Table

High Level Activities/Milestones	Responsible Parties	Month/s from Start year 2014: Schedule of Deliverables
TASK 1. Needs assessment Conduct a needs assessment among GPs, patients and pharmacists using online survey's	IVA/Brain Foundation	Months 1–2: January – February 2014
TASK 2. Planning Sub-Task A. Organise a Steering Committee planning meeting	IVA/Steering Committee	Month 2: February 2014
Sub-Task B. Identify locations of face-to-face meetings to optimise attendance	IVA	Months 2–4 February–April 2014
TASK 3. Development of content and materials		
Sub-Task A. Research and writing of modules	IVA	Months 2–6: February–June 2014
Sub-Task B. Expert review	SC members	Months 4–6: April–June 2014
Sub-Task C. Submit activity to the RACGP QI&CPD program and to ACRRM CPD program and ACP for accreditation	IVA	Month 6: May 2014
Sub-Task D. Final print out and publishing of materials/content	IVA	Month 6: June 2014
TASK 4. Enlist and brief facilitators	IVA	Months 3–17: March 2014–May 2015
TASK 5. Register GPs	IVA	Months 6–15: June 2014–March 2015

TASK 6. Predisposing activity and pre-assessment survey (baseline data for the outcomes paper)	IVA/AXDEV	Months 6–15: June 2014–March 2015 (4 weeks–2 days prior to attending the SLA)
TASK 7. SLA (total of 6 hours of learning) **Sub-Task A**. Conduct face-to-face meetings **Sub-Task B**. Provide GPs access to the online modules	IVA	Months 7–17: July 2014–May 2015
TASK 8. Immediate-post assessment and meeting evaluation	IVA/AXDEV	Months 7–17: July 2014–May 2015
TASK 9. Implement reinforcing activity	IVA	Months 8–18: August 2014–June 2015 (2-4 weeks following completion of SLA and evaluation form)
TASK 10. 5–6 weeks post-assessment **Sub-Task A**. Quantitative survey assessing maintenance of knowledge, attitudinal change, changes implemented in clinical practice and barriers to implementation of change **Sub-Task B**. Qualitative interviews with a subset of participants to obtain understanding of changes implemented and barriers	AXDEV	Months 9–18: September 2014–June 2015 (5–6 weeks post SLA and 1 week post reinforcing activity)

TASK 11. Administrative duties **Sub-Task A**. Send certificates of attendance to GPs **Sub-Task B**. Submit records of GP participation to the RACGP, ACRRM and ACP	IVA	Months 9–19 September 2014–July 2015
TASK 12. Outcomes analysis	AXDEV	Month 19: July 2015
TASK 13. Development of outcomes report	AXDEV	Months 19–22: July–October 2015
TASK 14. Writing of paper for peer review	IVA/AXDEV	Months 22–24: October–December 2015

Organizational detail

1. **Leadership and organizational capability**
   a. In Vivo Communications (IVC), the lead organisation for the proposed intervention is a long-established provider of quality medical education and a registered provider of QI&CPD with the RACGP. IVC has extensive experience in providing well-researched, focused medical education in Australia, via a variety of platforms to a range of target audiences including GPs, specialists, nurses, pharmacists and patients. The leadership of IVC is managed by Lisa Sullivan, Group Managing Director who has over 30 years experience in medical education with more than 15 of those years working closely with accredited programs across Australia and beyond.
   b. In Vivo Academy is the not-for-profit company that will be responsible for all financial grant management including payment of honoraria and all expenses together with the final requisitions for Pfizer's grant process. Although In Vivo Academy does not employ staff directly the In Vivo Communications writing and management staff work across both companies for accredited education programs. In Vivo Academy is also an accredited provider to the RACGP.
   c. The Brain Foundation is a registered Australian charity dedicated to funding world-class research into neurological disorders, brain disease and brain injuries. Headache Australia is an initiative of the Brain Foundation and is the only organization in Australia that aims to support the more than 5 million Australians affected by headache and migraine, and provides information on headache, including migraine at www.headacheaustralia.org.au. The Brain Foundation will

provide access to their extensive patient database for needs analysis purposes.

d. AXDEV (www.axdevgroup.com) has an evidence-based record of identifying the issues and challenges undermining optimal performance, diagnosing the cause, and evaluating the impact of solutions targeted to overcome those challenges. AXDEV's proven performance assessment methodologies provide clear direction for decision makers. The key AXDEV staff who will be responsible for working with In Vivo Academy on this program are Sean Hayes and Marilyn Powers, both of whom have extensive experience in the field of psychological research and outcomes analysis for accredited programs globally (*see Biosketches for more detail about both*).
e. Associate Professor Richard Stark is a Neurologist at the Alfred Hospital, Melbourne who has published widely on headache and migraine, including educational programs for GPs[6,7] and epidemiology and current management of chronic migraine and chronic daily headache,[4,8,9] including MOH. It is proposed that Associate Professor Stark will lead the expert review of the proposed ALM content both within the Steering Committee planning meetings and at the point of materials approval.
f. Professor Deborah Turnbull is a Professor of Psychology at the University of Adelaide. She has made major contributions in the area of behaviour and attitudes affecting participation in screening, and it is anticipated that her input into this ALM will be in relation to behavioural and attitudinal change.
g. University of Queensland (UQ) Discipline of General Practice and School of Pharmacy are involved in teaching, clinical and research activities and consist of multidisciplinary teams of GPs, Public Health and Primary Care Professionals dedicated to improving the quality of care provided to patients in the community. UQ is in the top 100 universities worldwide in terms of academic and performance ranking. Professor Mieke Van Driel, head of the department of general practice with an academic track record in evidence-based practice and implementing evidence in clinical practice will lead her team of GPs and Pharmacists to assist us in content development and review of our proposed program. The UQ team will also assist in the facilitation of the Queensland based face-to-face meetings as this is a requirement of the QI&CPD program.

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