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Pharmacists' Perceptions and Communication of Risk for Alertness Impairing Medications

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Article Synopsis: This article describes a qualitative study using semi-structured interviews to explore pharmacists' perceptions and communication strategies of the risks related to alertness impairing medications. Interviews were analysed using Framework Analysis and unveiled three key themes: *Safety and Consequences of AIMs',* '*Factors that Influence Risk Communication'* and '*Refining Risk Communication'*. Risk communication was perceived to be an important part of clinical practice but a number of factors influence

Abstract

Background: A core role of the pharmacist is to ensure safe and effective medication use. Therapeutic classes that impair alertness (e.g. sedatives or hypnotics) can pose safety concerns for the consumer when undertaking activities requiring psychomotor vigilance (e.g. driving).

Objective: To explore pharmacists' perceptions and communication strategy of the risks related to alertness impairing medications in clinical practice.

Methods: In-depth semi-structured interviews explored community pharmacists' perceptions of medication-related risks, current medication provision and the feasibility of new practice tools. Interviews were digitally recorded, transcribed verbatim and analysed using Framework Analysis to identify emergent themes. A Psychometric Risk Perception Questionnaire was also used to evaluate pharmacists' perceptions across 7 common psychotropic drug classes.

Results: Synthesis of the qualitative dataset of 30 pharmacist interviews revealed three key themes: *'Safety and Consequences of AIMs',* '*Factors that Influence Risk Communication'* and '*Refining Risk Communication'*. Participating pharmacists were generally aware of the therapeutic classes associated with medication-related risks but were concerned about patients' level of understanding. Counselling approaches were largely dictated by perceived patient interest/experience with a medication. Concerns were centred on inter-individual pharmacokinetic differences, which could make the precise risk assignment difficult. Pharmacists also highlighted workflow limitations and the need to bring patients' attention to these resources during the clinical interaction to maximise impact.

Conclusions*:* Medication-related risk communication is a complex clinical phenomenon dictated by patients' prior experiences and the pharmacists' practice environment. Extending the evidence base in this therapeutic area and refining clinical resources are key steps towards optimising patient medication safety.

Keywords: Risk Communication, Sedatives, Consumer, Medication Safety

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Abbreviations[1]

Introduction

[1] AIMs: Alertness Impairing Medications
DRUID: Driving Under the Influence of Drugs, Alcohol and Medicines in Europe
EPPM: Extended Parallel Process Model
TAC: Transport and Accident Commission
TGA: Therapeutic Goods Administration

Attentional deficit, which involves deficits in concentration, alertness or vigilance, is a serious adverse effect that results directly from medications that affect the central nervous system such as psychotropic medications (e.g. hypnotics) or *indirectly* from the blood-pressure/glucose lowering effects of anti-hypertensive and anti-diabetic agents respectively. The latter group is especially problematic as health professionals or consumers alike may be indifferent to the impairing effect of the medication. [1] These medications may be referred to as Alertness Impairing Medicines (AIMs).

Undertaking any activity relying on psychomotor vigilance whilst using a medication that may impair alertness can have important safety implications for the patient. Worldwide, road traffic authorities warn against the use of medications causing impaired psychomotor vigilance whilst driving. The impact of AIMs on driving (e.g. slow reaction time and decreased motor coordination) is highlighted through reports of traffic accidents and simulated driving experiments. For example, in the US, a 2010 nationwide study found that 46.5% of drivers who tested positive for drugs after a fatal accident had used a prescription medication, with benzodiazepines or opiates most implicated;[2] similar findings have been reported from Europe, Canada, and Australia. [3-5] Driving impairment is only one example of the detrimental effects of AIMS. Particular classes of AIMs medications, such as sedatives antidepressants and antipsychotics have been implicated in falls and fractures.[6] Sedatives such as benzodiazepines have been linked with an increased mortality.[7] Although as yet inconclusive, recent research studies have also investigated the link between benzodiazepines and cancer,[7] dementia development,[8] as well as nosocomial infection [9]in critically patients. Newer sedatives such as the Z-drugs have also been linked to serious neuropsychiatric consequences such as parasomnias e.g.

sleepwalking.[10, 11] Many AIMs are also often implicated in cases of accidental poisoning. [12] Much research in the area of risk management (e.g. drugs and driving)focuses either on medication misuse rather than use or on de-prescribing interventions. Given the increasing burden of chronic disease and ageing populations in the developed world, legitimate use of AIMs is a palpable concern.

Often the final interface between an AIM user and a health professional is the pharmacist, who has an ethical, clinical and legal responsibility to ensure consumers are well informed about the effects of AIMs and take appropriate measures to minimise risk. However, effective risk communication is influenced by various factors, key amongst them, are effective tools that assist in the communication process. These tools include 1) specific product information (PI)/consumer medicines information (CMI) provided to patients 2) the use of ancillary warning labels affixed on the product container 3) Risk related counselling and communication. Specific knowledge about medications and their extent or type of alertness impairment would be a factor that can enhance risk related counselling. In Europe, this has been realised through the Driving Under the Influence of Drugs, Alcohol and Medicines (DRUID) project. One arm of this project relates to categorising individual medications into different levels of driving impairment i.e. Category I, II & III (minor, moderate & severe) and detailing specific information to facilitate individualised counselling about the medications' effect on driving for users.[13] In Australia, the Transport Accident Commission (TAC) utilises similar categories proposed by the International Council on Alcohol, Drugs and Traffic Safety (ICADTS),[14] but this classification is not widely disseminated/integrated within pharmacy dispensing programs.

Other key factors that may affect the risk communication by pharmacists to AIM users may be the risk perceptions and perceived efficacy of recommended risk limiting actions by the recipients of the communication (e.g. AIM users). Several frameworks to understand how individuals perceive risk and respond to risk communication have been developed and used understand risk perception, so as to develop effective messaging about risk mitigation to consumers. One such framework is the Extended Parallel Process Model (EPPM). The Extended Parallel Process Model (EPPM), [15, 16] suggests that when individuals are faced with risk prevention messages, they consider whether the threat is serious/real and whether they are susceptible to its potential impact. If the threat is perceived as real and the individual perceives susceptibility (i.*e. the medication will affect my alertness, and can impair my driving skills*), then a further assessment of efficacy is undertaken, specifically, whether the risk prevention message contains information that can help the individual to avoid the threat (i.e. *if I avoid driving for 24 hours after taking this medicine, I will be safe*). This latter appraisal is twofold, with an assessment of the usefulness of the information (response efficacy) and one's self-efficacy (ability, capability, and access).[15]

The response following the appraisal can be either 'fear control' or 'danger control'. Fear control is an emotional response by which the individual seeks to eliminate fear, without eliminating the causative risk; this response is more likely if the threat or susceptibility associated with the risk is higher than impressions about self or response efficacy (i.e. *I will not drive at all but will continue to use this medication*).[16] Danger control is a more rational response, where the individual seeks to eliminate the cause of the risk, this response is more likely if the perceived threat or susceptibility about the risk are assessed to be lower than self or response efficacy by an

individual (i.e., *I will use this medication only if needed, and time my driving carefully to be in periods where my driving will not be affected by the medicine*).[15]

Patel, Barnett [17] (2011) describe how the EPPM can be used by pharmacists. In their study, they trained pharmacists on strategies such as the use of universal statements and open ended questioning which was used with a view to counsel male patients about health risk factors. [17] These strategies allowed participating pharmacists in their study to minimise 'fear' whilst controlling feelings of 'vulnerability' whilst motivating patients about their self and response efficacies.[17] Whilst much of the EPPM focusses on the recipients of the risk communication, it may be posed that providers are perhaps also subject to the same processes. For example, their level of risk perception and perception about the usefulness of the message they communicate and beliefs about their own ability to convey a message effectively can affect uptake of the risk minimisation strategies conveyed.

Australian pharmacists currently draw on a set of generic, albeit well established, counselling protocols, reference texts and mandatory labelling requirements (Fig.1) during the provision of AIMs. However, little is known about the perceived usefulness of these clinical resources or how pharmacists might delineate and communicate AIM related risks to the consumer. Therefore, the aim of this study is to explore pharmacists' perceptions of risk and safety with regards to the provision of AIMs in routine clinical practice and to explore the feasibility of implementing new clinical resources for refining risk communication.

Material and methods

Design

Individual semi-structured interviews were conducted either face-to-face or via telephone by the first and second authors. The interviews were guided by a schedule of questions that was informed by a review of the relevant literature on the attentional deficits of medication use and on risk communication frameworks (Table 1). The key focus of the interview explore pharmacists' provision of AIMs, their perception of consumer risk awareness associated with AIMs, the perceived effectiveness of their risk communication messages and the need/feasibility of integrating new resources into clinical practice. To stimulate discussion of the latter, a new warning label design based on previous research in France was used as a discussion prompt. [18] Data collection proceeded until thematic saturation was achieved (i.e. ensuing interviews did not provide additional themes/concepts around AIMs provision). Interviews were digitally recorded, transcribed verbatim and analysed for emergent themes. In addition, a psychometric risk perception scale adapted from a patient-focused study by Slovic, Peters, Grana, Berger, Dieck [19] was used to quantify the perceived risks across the different therapeutic classes of AIMs among pharmacists.

The scale is based on the psychometric paradigm, originally proposed by Slovic, Peters, Grana, Berger, Dieck [19] which posits that risk perception can be quantified by asking people to make quantitative judgments about the relative riskiness of various hazards.[19] The original instrument assessed consumer perceptions around 53 medical risk items (including pharmaceutical products both prescription or over the counter, as well as medical tests, procedures and devices) across 5 key characteristics of risk. These characteristics include: 1) risk 2) benefits 3) seriousness of harm in an accidental exposure 4) the extent to which risks are known to those exposed and 5)

whether serious problems if occurring in those exposed would serve as warning signs. For the purpose of the current study, the item on 'warning signs' was omitted, given that all pharmacists are trained on pharmacovigilance and reporting adverse events is a part of their professional role, which fact may have biased their responses on this item. Further, each item was framed around pharmacists' perceived consumer awareness of the respective dimensions, rather than their own perceptions. The scope of the current study also focused on medication classes where pharmacists would normally need to warn patients about sedation and potential attentional deficits. An additional class of complementary sleep aids were also included to broaden the scope of the study (Appendix 1). It may be noted that the main intent of the study was the qualitative exploration of pharmacists risk perceptions. The psychometric risk perception scale was used merely to clarify in our qualitative method paradigm whether quantified risk perception could offer any explanation of variable responses in the participant's interview data. The study protocols and materials were approved by the University of Sydney Human Research Ethics Committee (HREC Protocol #2014/1020).

Participants and Settings

A convenience sample of community pharmacists known to the researchers were initially recruited throughout metropolitan Sydney, New South Wales and Perth, Western Australia. Following this initial recruitment, a passive snowballing technique was used whereby initial participants were asked to discuss the study within their professional networks and interested colleagues were encouraged to contact the researchers directly. Participants were offered $30 gift vouchers for their involvement in the study.

Data Analysis

Interview transcripts were subjected to Framework Analysis (FA) as described by Ritchie, Spencer [20] using QSR NVivo 10 software. FA evolved out of applied social policy research and allows for the incorporation of diverse perspectives on a given phenomenon and involves five key stages (consisting of *familiarization* where interview transcripts and field notes were iteratively to identify emergent concepts. These emerging concepts were combined with the a priori issues outlined in the interview guide to form the basis of the preliminary *thematic framework.* Three researchers independently read and coded initial transcripts (n=5) against the preliminary thematic framework. New thematic categories or discrepancies were discussed at subsequent research meetings to further develop the thematic framework. The next stage involved indexing where the final thematic framework is systematically applied to each transcript to identify relevant units of text that were *indexed* corresponded to a particular theme. Indexed data were further abstracted and *charted* into thematic matrices containing the related thematic categories. In the final stage, *mapping and interpretation*, cross-case and within-case relationships were identified and discussed with the research team for abstraction into a set of emergent themes. [21, 22]

Results

Data saturation was achieved at 30 interviews. Participant demographic data are highlighted in Table 2. Analysis of the qualitative data identified three main themes: Safety and Consequences of AIMs, Factors Influencing Risk Communication and Refining Risk Communication. After completing the analysis, the thematic structure was qualitatively analysed for any patterns explainable by demographic or psychometric risk score variation; this was done by reading each

transcript again with the framework and demographic characteristics of that participant imposed on the transcript. This subjective analysis did not result in the identification of any discernible difference in responses between genders or various pharmacy roles (e.g. manager vs. locum). Relevant participant quotes have been included for the respective themes and sub-themes to support our findings. Quotes have been assigned codes to indicate gender (denoted by M and F), participant's unique number and years of practice (F#Y# or M#Y#). Participant responses on the Psychometric Perception Questionnaire are highlighted in Figure. 2.

Theme 1: Safety and Consequences of AIMs

Subtheme 1.1: AIMS Risk and Harm

The majority of participants identified AIMs as medications perceived to pose a serious safety risk to consumers, stressing on the possibility of side effects (particularly in terms of drowsiness) and expressing a strong concern for the likelihood of tolerance and dependency. The participants mainly conveyed their concerns in relation to the risks associated with driving a motor vehicle under the influence of AIMs and they often did not elaborate upon other activities that may be compromised (e.g. working with machinery/tools or leisure activities such as swimming etc.)

> *"Definitely, I think drugs can affect a person's ability to drive, in some people it can have very severe consequences and it needs to be a lot more recognised and it needs to be in the same category as alcohol when we talk about driving." (M8Y6)*

Subtheme 1.2: Consumer and Medication variability

Participants recurrently emphasised that AIM related risks are complicated by the varying extent to which these agents inherently influence psychomotor vigilance, the nature of the activity undertaken by the patient, inter-individual patient differences and concomitant medication use/history. They noted how variations in pharmacogenomics and pharmacokinetics such as

faster or slower medication metabolism could lead to individuals reacting differently to medications. Therefore they considered that some could experience side effects of 'profound drowsiness' whilst on these medications and others could maintain 'normal' motor function. This led to uncertainty when counselling. Certain drug classes were perceived to pose greater risks, particularly sedatives, hypnotics and analgesics. It was evident that non-prescription Over-the-Counter (OTC) AIMs were key concerns for participants, particularly codeine-containing and/or sedating antihistamines (e.g. doxylamine succinate) due to the high prevalence of consumer requests. Interestingly, despite this expression, participants' mean ratings of the risk for OTC categories were scored lower than that for prescription medications (Figure 2).

> *"People tolerate things differently to other people, certain medications can be tolerated by certain people and some can't and again there are certain medications that we know you can build tolerance to sedation or even pain tolerance, so they would need increased doses to get the same effects." (M14Y10)*

Theme 2: Factors that Influence Risk Communication

Subtheme 2.1: Perceived Consumer Beliefs and Actions

Successful risk communication was seen as contingent on consumers' health literacy levels, whereby they were perceived to have little awareness towards the risks associated with AIM use. Participants considered that consumers were influenced into taking AIMs from a number of sources including friends, family and from the Internet. These sources were viewed to skew the expectations of consumers when requesting an AIM. They suggested that consumers believe that these medications 'solve' a number of their ailments, whilst underestimating possible risks, specifically regarding non-prescription/OTC products. However our participants also indicated that beliefs differ and that some consumers were perhaps more concerned for their health and

therefore questioned more about their medications than others and their decisions to use AIMs were based on reasonable estimates of benefits versus risks.

Participants expressed that the role they play is often limited by external factors, suggesting that counselling does not necessarily correlate with consumers' actions (e.g. driving under the influence of an AIM). Chronic AIM users were mainly portrayed as those dependent and tolerant to most effects of the medication; therefore they were considered more likely to ignore pharmacists' concerns. They also indicated that it is often difficult to warn consumers about the risks associated with their medication, particularly due to the fear of decreased adherence or abrupt withdrawals.

> *"Some people have strong beliefs of medication… I would say one of the hard points is that we actually need to change the perception of the patient." (F17Y5)*

Subtheme 2.2: Professional Practice and Regulation

Participants identified their role as being responsible for educating consumers about the risks of AIMs and signified the importance of this task from a moral and ethical viewpoint to ensure consumer safety, and also from a legal viewpoint to protect the pharmacist from possible liability or indemnity. Most participants exhibited a strong faith in the current regulations and practice standards surrounding the provision of AIMs, however application was considered difficult suggesting that certain aspects of community practice make them incommodious. The main issues raised were related to time and the busy work environment that prevented them from providing consumers with the necessary information required to ensure the safe use of medications.

"Most pharmacists find it difficult because they are restricted by time to go through [information] in more details…" (F12Y18)

Subtheme 2.3: Tools and Resources

Participants indicated that the main tools available to communicate risks with regards to AIMs were cautionary advisory labels and Consumer Medicines Information (CMI) printouts. The main label mentioned was the ancillary warning label 1 (L1), which is a mandatory component for the supply of medications that may cause sedation or drowsiness in Australia. According to participants, other labels (L1a and L12 (Figure 1)) were less often used and considered difficult to differentiate from L1. A major limitation perceived by participants regarding labels was the perception that consumers do not read or notice these labels, most likely negating any possible benefits.

When probed about which resources they use to determine the risks of medications, participants indicated that they prefer what is easily accessible and available, with the majority using eMIMs (Monthly Index of Medical Specialities) as their main or sole source of information. Current tools and resources were considered lacking in details that may contribute to risk communication, such as duration of effect or severity of risk.

"No one has ever asked me about the L1 label, no one has ever asked me about the L12 label, no one has ever brought labels to me. No one reads boxes from all my experience. It is me delivering it, as I am giving it out and talking about it." (M18Y8)

Theme 3: Refining Risk Communication

Subtheme 3.1: Government and Organisation

Most participants were content with the current practice/legislations in pharmacy and considered them sufficient, however a need for improved resources or tools that could improve risk communication was emphasised. When juxtaposed with the media and government focus on driving under the influence of alcohol, participants considered that similar efforts should be enacted regarding the effects of AIMs on driving. The majority stressed the importance of government and organisational intervention via the use of campaigns or media in order to increase the consumers awareness of the possible risks associated with AIMs and to warn that misuse can result in consequences. The majority opposed increased regulations within the community pharmacy setting but suggested that the involvement of law enforcement in the public setting could possibly deter potential abusers or misusers of such medications.

> *"I think it's pretty clear that the authority has made it quite clear about the low tolerance with drinking and driving. You need to be under a certain threshold to be able to drive, I think the same should apply to medications so they are known to have an effect on peoples concentration and their ability to maintain alertness" (F4Y5)*

Subtheme 3.2: Counselling

Participants indicated that although consumers vary in their response to AIMs, it is often difficult to tailor counselling to this fact. However they generally concluded that it falls upon a pharmacist's judgement and relationship with the consumer to identify whether brief counselling or an extended consultation is necessary. A large emphasis was placed on the importance of verbal communication. Written materials (e.g. labels, leaflets) were also mentioned as being

important because they can be used to reinforce certain points and act as reminders to the consumer.

> *"The role of the pharmacist would be to verbally reinforce what has already been depicted on the label and offcourse the labels would form a reminder and particularly with S3 products the pharmacist must always provide counselling and when they take it home all they see is what is on the box, they may not remember what the pharmacist said... It's my message that is going to make a difference, the way I deliver the message is going to make a difference, my body language is going to make a difference and my connection to you is going to make a difference. The way I talk as a human and the way I deliver my message, the way I interact with you on a personal level is everything. (**F10Y4**)*

At an explicit level, participants' portrayed confidence in their skills and abilities. However, uncertainty was a distinctly resounding theme that participants unconsciously echoed throughout the interviews. It was evident in most aspects discussed with participants, ranging from their ability to individualise, assess and communicate AIMs related risk to the effectiveness of current tools and resources.

> *Whether **what consumers actually take from what we say** and whether **what we are saying is actually enough** or whether we need to do more, its currently **unknown** and I think it should be **investigated**. **(M5Y3)***

Subtheme 3.3: Labelling

Regarding labelling, participants unanimously stressed on the importance of drawing the consumers attention to the warning labels whilst counselling, as the labels are often lost among the busy medication packaging. There were two main opposing opinions, which were to either

make the contents of the labels more detailed, or to simplify the labels into a more succinct and comprehensible message. Suggestions for the current label included: increased font size, the addition of graphics and highlighting/bolding certain words to emphasise their importance. Some participants considered the current labels efficient but others even recommended customised labels for certain medications to accommodate for the variability in drug side effects between classes. A summary of the labelling preferences among participants are also presented in Table 2.

> *"If we can tailor it, and be a bit more specific that would be nice. For example how long are the effects likely to last or something like that. That would be very beneficial, to put a time, a quantitative figure." (F22Y32)*

Subtheme 3.4: Resources and Training

Most participants suggested a need for additional novel resources to help communicate risk, however some indicated that the current issue is one of ineffective (rather than a lack of) resources. While most considered themselves sufficiently trained in handling the provision of AIMs, there was some acceptability for increased training, particularly to improve their skills in communication with consumers. Support options such as a Call-Up information service dedicated to provide detailed and individually contextualised information received mixed responses with some recommending this potential resource yet others stating that time constraints, privacy issues and other factors would make it ineffective. Participants indicated the need for more research on AIMs and supported the idea to implement something similar to the DRUID project in Australia. They suggested that it would be successful as long as it was government/organisation supported and for such changes to be integrated into current tools and resources (e.g. dispensing software).

"It [DRUID] would be beneficial for the health professionals, such as the pharmacist who has to make the decision, so I think it would be more beneficial for the pharmacist to properly and clearly communicate their thoughts and if they ask why, then we can state that this is based on the parameters that we have here and it is self-explanatory." (F20Y2)

Discussion

To our knowledge this is the first study to explore the factors influencing the provision and safe use of Alertness Impairing Medications (AIMs) by pharmacists. It extends on the current literature on medication safety and pharmacy practice with broader public health implications. To date, research on AIMs has been limited to economic and health related consequences (e.g. road traffic injury) and few studies focus on the point of medication supply (i.e. the pharmacist-patient interaction). A recent report stresses the importance of the role that pharmacists play in the safe and effective use of AIMs and indicates the need for pharmacists to "reconsider how they are counselling patients on medication impairment", [1] further supporting the importance of our approach.

A salient message that reverberated throughout our participant interviews is that medication risk communication is a complex clinical phenomenon dictated by consumers' prior experiences and the pharmacists' practice environment. That risk communication is a complex process is well known; in the sociological literature, much research focusses on communication about general side effects in balance with benefits (e.g. for new or trial/investigational drugs). There is a paucity of drugs on the specific risk communication/counselling for drugs impairing alertness. In our study, participant concerns revolved around the possibility of traffic related accidents and the

overuse/misuse of non-prescription/OTC codeine-containing products. Participant frustration also stemmed from the dilemma between being aware of the misuse of AIMs and consumer misbeliefs about the risks of such medications. The issues, concerns and needs reported by our participants provide new insight for shaping potential novel strategies to facilitate Australian pharmacists in providing targeted and effective counselling to consumers using AIMs, ultimately enhancing public safety.

A key issue highlighted in the study was the need for consumer engagement to improve risk awareness of AIMs. Perceptions of consumers ignoring warning labels is consistent with published literature related to Australian consumers [23] and globally.[24, 25] To counter this, several studies have tested ways to enhance the noticeability of warning labels through depicting organ specific damage, [26] black-box warnings and the addition of text and colour [13]. One study comparing warning labels used in Australia and France concluded that participants were more readily able to delineate risk levels from the French labelling system due to the inclusion of medication risk categorisation and the effective use of colour and graphics. [18] Drawing form the patient-centred work of McCarthy, Davis, King, Mullen, Bailey, Serper, Jacobson, Parker, Wolf [27] instruction labels containing action-terms (e.g. Take-Wait-Stop) as a means to 'frame' important behavioural precautions while using AIMs might be another approach for enhancing consumer engagement in a meaningful way. [27]

The need for more concerted efforts that triangulate public health action and increased informational support for health professionals were cited among our participants as key strategies for enhancing consumer awareness/engagement. The DRUID project exemplifies the latter

through refining information on risk categorisation of AIMs with respect to driving risks in all labelling and resources. Similar programs could be adopted in Australia, and may be beneficial in pharmacists' counselling and decreasing the intrinsic possibility of consumers inaccurately assigning risks to different medication classes. Evidence-based information could also allay some of the uncertainty participating pharmacists exhibited regarding risk communication around AIMs. For example, a Belgian research group recently developed and tested detailed dispensing support electronically integrated with dispensing software for pharmacists and reported positive outcomes (i.e. increased frequency of pharmacist counselling and targeted information gathering concerning AIMs use).[28] The successful legislative limits that have been introduced over the years to manage driving under the influence of alcohol can similarly be proposed for AIMs as suggested by our participants and recently implemented in Norway. [29]

In order to suggest new risk communication strategies or propose new educational processes, it is often important to investigate public health behavioural change theories. The results from this study of pharmacist perceptions directly align with the constructs of the Extended Parallel Process Model (EPPM) described in the introduction.[15] In the case of pharmacists, they indicated that they consider their capability of communicating the risks of AIMs (efficacy), weighing it against the risks associated with the medication (perceived risk) and the additional fear of variable consumer response (e.g. disapproval or decreased adherence to medications) - all acting as strong motivators that influence the extent to which they use resources and/or spend time counselling. Pharmacists' uncertainty about how a medication may affect the consumer may have also unconsciously affected the communication process. Furthermore, it is evident that the pharmacists' perception of consumers follows a similar process, whereby consumers were

perceived to incorrectly assign the benefits and harms of AIMs (perceived risk), denying the need to receive more counselling due to 'fear' of being asked to stop a medication that they were reliant/dependent on and considering themselves capable of managing the risk (efficacy).

In order to introduce new strategies to communicate AIMs risks, it is important to first understand how people form a meaningful understanding of risk in order to eventually implement evidence based methods that result in safe medication use. The EPPM has been used previously in attempts to warn consumers of other risks, using the notion of 'fear' through graphics and health promotion campaigns to effectively target issues such as smoking harm and even driving related risks (e.g. fatigue); it would be pertinent to explore the utility of this model in future research around pharmacists' risk communication regarding alertness impairing medicines.[30] Figure 3 outlines some suggested strategies to enhance the effectiveness of AIM related risk communication by pharmacists by applying the EPPM model constructs.

Furthermore, the findings of this study resonate closely with the recent Australian regulatory proposal to reassign codeine-containing over the counter products to 'prescription only' by the Therapeutic Goods Administration (TGA) to address issues of misuse/abuse. Most of the participants observed that misuse of non-prescription/OTC codeine-containing analgesics was still a frequent problem despite previous regulatory changes, which mandated compulsory pharmacist involvement in the provision of such products. [31-33] Based on this experience, our participants unanimously rejected the need for new scheduling and indicated that this will not necessarily solve the overarching issue in the long term. There were suggestions of mandatory recording/reporting similar to that of pseudoephedrine, which has proven effective, [34] and the

need for more collaboration between General Practitioners and pharmacists in educating consumers on possible risks/harms.

AIMs are indicated for the management of a range of conditions and this study investigated pharmacist perceptions of the processes involved in risk communication and opportunities for possible improvement. Given our sampling frame, the transferability of our findings is limited, warranting the need to extend our approach on a national (e.g. rural vs metropolitan) and international level (e.g. Canada and Europe due to similar healthcare systems). Furthermore, since the data analysed was obtained solely from the pharmacist viewpoint, there is a clear need for additional research involving the consultation of consumers. This would act as additional confimation and would help to accurately ascertain their level of awareness and to understand how they associate AIMs with risk. Another key area that would thoroughly assist future research is good instrumentation. For example, the psychometric perception questionnare utlised in this study is not a validated tool; currently a validated instrument that explores specific domains of medication risk is not available as validated tools utilised in similar research studies explore more generalised issues with respect to beliefs about medication use.

Conclusion

The themes identified from our participants indicate that in the context of AIMs, risk communication is a complex clinical phenomenon dictated by patients' prior experiences and the pharmacists' practice environment. Extending the evidence base in this therapeutic area and refining clinical resources are key steps towards optimising safe medication use in patients.

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