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Pharmacists' perceptions and communication of risk for alertness impairing medications

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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.

1. Introduction

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

Abbreviations: 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.

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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 deprescribing 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 h 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.

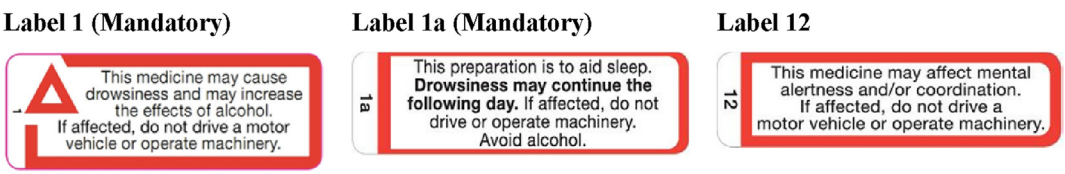

Fig. 1. Existing Warning Labels in Australia (Warning borders and triangle are red). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)