



Medical Decision Making

“But it’s just paracetamol”: Caregivers’ ability to administer over-the-counter painkillers to children with the information provided



Fiona Bennin, Hanna-Andrea Rother*

School of Public Health and Family Medicine, University of Cape Town, Cape Town, South Africa

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ABSTRACT

Objective: To determine whether caregivers are able to make informed decisions about their families' use of over-the-counter (OTC) painkillers through access to and use of three mechanisms of information provision.

Methods: A cross sectional, face-to-face questionnaire was administered to 60 caregivers and seven pharmacists in Cape Town, South Africa. Caregivers answered questions related to paracetamol (acetaminophen) labels, inserts and Patient Information Leaflets (PIL).

Results: Most study caregivers received labels with the painkillers they purchased. Many pharmacists (43%) felt that the information provided was ineffective in preventing overdosing. Study caregivers found it difficult to understand the scientific terms in all three mechanisms of information provision. Most respondents (80%) found the PIL easiest to understand, yet few had received PILs with their purchase. Ten percent of literate respondents were unable to understand the dosage requirements for children.

Conclusion: Most caregivers are not able to make informed decisions from the information provided with OTC painkillers. This is mostly attributable to limited provision of information and low health literacy.

Practice implications: Written information with OTC medications in simple language and verbal counselling at dispensaries would play a significant role in increasing the health literacy of especially at risk populations of over-dosing their children.

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1. Introduction

The increase of self-medication with over-the-counter (OTC) medications (for example, painkillers and cough medicine) has resulted in consumers medicating themselves and their children without advice from health professionals; often without fully understanding the associated health risks and implications of overdosing. Consumers rely predominantly on written information accompanying OTC medication for dosage information and potential side-effects. Studies have found that those who use written sources of information have increased knowledge about the medication, and yet less than half of the consumers can fully understand this information [1]. The worldwide increase over the last 15 years in the use and overuse of OTC medication [2–7] has

resulted in a critical need to assess the current process of informing OTC medication users of the correct dosage and potential health risks. Specifically, there is a need to identify whether consumers' health literacy can be improved upon, to reduce risks from self-medicating or medicating children in contradiction to the label instructions. We hence present findings from a South African case study.

In South Africa, OTC medication can be obtained from government clinics, private pharmacies, general stores and 'spaza' shops (informal convenience shops, usually run from township homes); all of which will provide different, and often limited, information with the medication. There are three major and legally required mechanisms for providing end-users access to dosage instructions and health risk information. These are, a container label, medication insert and Patient Information Leaflet (referred to respectively as a label, insert and PIL; Table 1) [8]. All three are produced by the manufacturer and approved by the South African Medicines Control Council [8]. The label provides basic information about the medication, while the insert contains scientific information for health professionals. The PIL is a simplified insert

* Corresponding author at: School of Public Health and Family Medicine, University of Cape Town, Anzio Rd., Observatory 7925, South Africa. Tel.: +27 21 406 6721.

E-mail address: andrea.rother@uct.ac.za (H.-A. Rother).

Table 1
SA legislated information provision requirements for OTC medication [8].

Information provision mechanism	Information required
Label	Stuck on the container, provides basic information about a medication such as the product name, patient's name, dosage instructions, indications, special instructions, general warnings, ingredient list and date on which the medication is dispensed.
Medication insert	Comes in the form of a double sided printed piece of paper in the box holding the container, each side printed in English and one other official language (usually Afrikaans) respectively and uses scientific/technical language. The insert includes the following: Proprietary name and dosage form, scheduling status, pharmacological classification, composition, dosage and direction of use, contra-indications, pharmacological action, indication, warnings, pregnancy information, interactions, side effects and precautions, over dosage information, information for certain categories/ingredients, presentation, storage, contact details of certificate holder, registration name and insert publication date.
Patient information leaflet (PIL)	Provided to consumers and produced by the manufacturer. Presents medication information to consumers in an easy to read format to be more accessible than the information provided in inserts or on labels. Generally printed in English and one other official language. Includes key information on medication uses, warnings or contraindications, how to take the medication, side effects, storage information and manufacturer contact details.

providing only information appropriate for the end-user and written in simple lay-man's language. In many developed countries, most OTC medications are only accompanied by a label and PIL. In the South African public health sector, which serves the majority of South Africans, OTC medications are predominantly provided without any of these three information sources. This is because they are often repackaged for cost effectiveness in plastic bags with only limited dosage information on the packet (Fig. 2). OTC medications are repackaged in government health facilities as well as many pharmacies, whereas, convenience stores provide medications in their original packaging. These repackaged medications are provided for free at government health facilities, but are also sold cheaply and often in bulk to consumers at pharmacies. Despite the law requiring all manufacturers to provide all three forms of information with the medication, none of these forms of information tend to be replicated and distributed when OTC medications are repackaged. This practice of redistribution without provision of information is a major impediment for improving consumers' health literacy. That is, the degree to which consumers have the capacity to obtain, process and understand basic health information to make appropriate use and dosing decisions [9], as well as having the baseline literacy skills (which include reading, writing and simple calculation skills) that enable people to understand and apply medical information [1]. An individual's level of health literacy plays a key role in their ability to understand health and dosing information as scientifically intended since there is a significant association between health literacy, level of understanding of medication information and health outcomes [1,10,11].

Paracetamol (acetaminophen) use is a good example of consumers' tendency to overdose with an OTC medication. Despite its documented safety and efficacy, paracetamol toxicity remains a key public health concern, especially due to its increased consumption by children [12–16]. Paracetamol overuse and overdosing has been linked to liver failure, headaches and development of asthma in children [17,18]. Studies conducted in South Africa have found that paracetamol was responsible for 10–14% of medication overdoses and was the most common medication in analgesic poisoning amongst children [19–21]. However, despite the health risks associated with paracetamol overdose, consumers are often unaware of the potential toxicity [19]. For example, many parents use more than one medication at one time on a sick child without knowing what active ingredients (including paracetamol) are in each medication, increasing the risk of overdosing [22]. Perceptions that this is a low risk medication are highlighted in the response of an assistant at a South African pharmacy, who when asked for more information to accompany a repackaged packet of paracetamol responded; “but it's just paracetamol. ...”.

The literature attributes the overuse of paracetamol in South Africa to its accessibility as a non-prescription medication [20,21].

However, it is unclear whether it is merely the accessibility of the medication or lack of appropriate risk and dosage information accompanying it, which contributes to this overuse, or both. There are a number of models and theories which suggest that health behaviour is motivated by the perceived benefits (e.g., pain relief) and barriers (e.g., monetary expense) to adopting certain behaviours, as well as the perceived magnitude of a threat if certain behaviours are not adopted (e.g., lack of pain relief) [23]. The way in which individuals perceive the benefits, barriers and threats of behaviour change is largely affected by the effectiveness of how potential risks are communicated [23–25]. In order for risk communication to be effective, information needs to be accurate, consistent, specific and appropriate for the diverse audience it intends to reach [26,27].

This begs the question as to whether the three written forms of risk information available for paracetamol in South Africa are appropriate particularly for vulnerable populations at risk of medication overdosing—that is, consumers with low health literacy. It is particularly important to explore caregiver perceptions of risk and understanding of medical information so as to prevent overdosing and overuse especially from common pain-killers such as paracetamol. This article, therefore, presents research findings on determining whether caregivers in South Africa were able to make informed decisions about dosing and use of paracetamol, specifically through the access to and comprehension of labels, inserts and/or PILs.

2. Methods

2.1. Study area

This study was conducted between December 2012 and January 2013 with mothers' groups in a Christian church and with pharmacists in Cape Town, South Africa. The church runs a Non-Governmental Organisation (NGO) health clinic from its premises and is home to approximately 10–20 informal mothers' groups. These groups, organised by the mothers themselves and not the NGO, meet weekly for a common purpose, for example, to provide emotional support, for income generation activities, or to receive developmental and play advice for their children. This site was chosen due to the socioeconomic, racial and linguistic diversity of the mothers. The pharmaceutical service providers, from where the caregivers purchased their OTC medication, were situated in close proximity to the church.

2.2. Study population

Convenience sampling was used to recruit 60 caregivers from different socioeconomic groups and nationalities who were part of five mothers' groups. Study participants needed to be 18 years or

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