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Medical Decision Making

"But it's just paracetamol": Caregivers' ability to administer over-the-counter painkillers to children with the information provided

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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.

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

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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 painkillers 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

older and one of the primary caregivers of a child (i.e., under the age of 18). Participants also needed to be able to understand and converse in English or Afrikaans, as these are the common languages used by manufacturers of OTC medications. However these languages needed not be their first language.

The study sample also included seven pharmaceutical service providers in the private ($n = 3$), public ($n = 3$) and NGO ($n = 1$) sectors of the health system, who were recruited using convenience sampling. These represented the providers used by the study participants (and greater South African public) chosen according to where the caregivers reported to obtaining their OTC medication. It was important to determine pharmacists' role in information provision to caregivers, as the South African 2008 Code of Conduct for Pharmacists [27] clearly states all patients should receive advice (predominately through counselling) on the safe use of medicine. As this study was for fulfilment of degree purposes, the sample size was calculated according to the time frame and budget restrictions.

2.3. Study design

A cross sectional face to face questionnaire (Table 2) was designed by the researchers. Ethical approval was granted by the University of Cape Town's Health Sciences Faculty Research Ethics Committee (HREC REF: 560/2012). The questionnaire, piloted and revised accordingly, was administered to caregivers ($N = 59$) in higher ($n = 30$) and lower ($n = 29$) socioeconomic groups as well as representatives from pharmaceutical service providers ($n = 7$). Questionnaires comprised of open and close ended questions (the majority of questions being dichotomous and filter questions). Caregiver questionnaires contained 87 key questions and pharmaceutical service provider questionnaires contained 50 key questions. Each caregiver's socioeconomic status was determined by their self reported level of education and income. For the purpose of this study, those in a higher socioeconomic status group had a tertiary education and/or earned higher than R50,000/annum. Those in a lower socioeconomic status group had not completed secondary education or they had completed secondary education but had an annual income of below R50,000. Qualitative and quantitative data were collected and analysed using mixed techniques.

2.4. Data collection

The questionnaires were administered at the church by the researcher or by the researcher trained field worker. Each mothers' group was approached via a contact person known to the researcher or suggested by other participating caregivers. A representative working for the seven pharmaceutical service providers was selected in terms of who was on duty that day and invited to participate in the study.

Table 2
Examples of questions of caregiver questionnaire (available from authors upon request).

General questions
Where do you usually get painkillers for your children and why?
Do the painkillers that you buy come with a label, insert and/or PIL?
Medication insert questions
What is the maximum amount of Panado™ (paracetamol) a child (age 6–12 years) is allowed in one day?
What do you think about the size of the writing on the page?
Patient information leaflet questions
Is it safe to take this medication when you are breastfeeding?
What does the term 'side effect' mean?
Medication label questions
Is it safe to give this medication to a child under the age of 6 years?
Do you think there is any information missing from this label?
Previous poisonings
Has your child ever taken too much medication?
Improving information provision
Which form of information (PIL, insert or label) do you find easiest to read?
Would you find the information easier to understand if it was written in another language other than English/Afrikaans?
Do you think over-the-counter medications are dangerous?

The questionnaire was structured so that each caregiver first answered general questions about their use of OTC medications. The respondents were then provided with a label, insert and PIL (one at a time), and asked a set of questions immediately after reading each form of information. This was for determining self reported levels of literacy and to answer questions about general use, knowledge and perceptions of OTC medication when dosing children (Table 2). One participant did not administer OTC painkillers to her children, resulting in the questionnaire being discontinued. The remaining 59 participants were asked to read a Panado™ (a commonly sold OTC paracetamol in South Africa) insert and label (present on the box), as well as a paracetamol PIL. This PIL was sourced from the United Kingdom since the authors were unable to locate a South African PIL (Fig. 1b). It was important to include and assess comprehension of this PIL as South African law requires inclusion with OTC medication and generally all PILs comply with an internationally accepted format. The questionnaire for the pharmaceutical service providers inquired about the information they provide and their common practices when

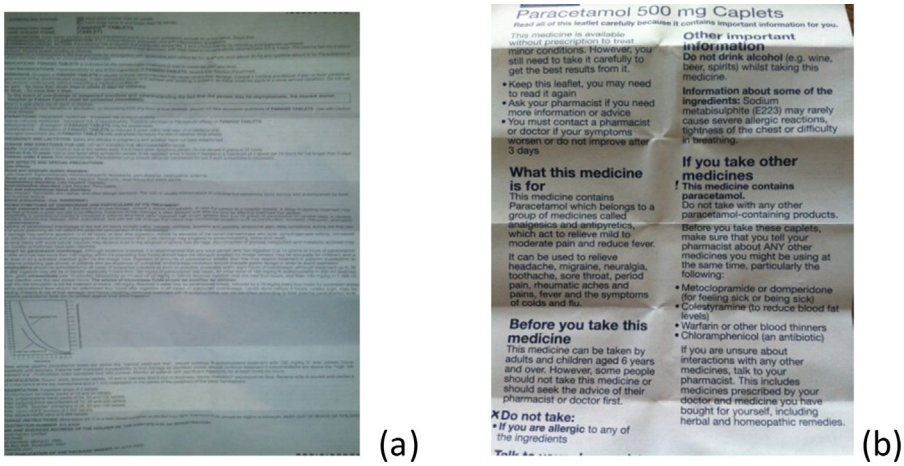

Fig. 1. Pictures of Paracetamol medication insert (a) and PIL (b).

Fig. 2. Photo of repackaged paracetamol in small plastic packet. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

distributing OTC painkillers to the general public. The questionnaire was verbally administered in English to each caregiver and pharmacist after written consent was given. Participants were not provided with monetary compensation. Instead, compensation was provided in kind by the primary researcher who is a trained Occupational Therapist. This was through the provision of volunteer services at the clinic, and through providing developmental stimulation groups for the study mothers and their children.

2.5. Analysis

The data was captured and analysed using SPSS21. The relevant themes were documented based on the literature. Answers from questions determining the caregivers understanding of each form of information were either classified as correct or incorrect to determine their level of information comprehension. Descriptive statistics were used to determine the frequency of variables and the chi-squared test was used to determine the significance of specific associations.

3. Results

All responses, except for questions related to consumption habits of OTC medication (not included due to limited relevance to study), are presented in this section.

3.1. Study demographics

The majority of caregivers were self- reported as literate (93.2%) and South African (67.8%). Of all the primary languages spoken by the study respondents, English was the language with the highest first language proportion (47.4%; Table 3). Of the 59 caregiver respondents, two were males. The number of children per caregiver varied, with 61% having two to three children.

Nearly half (46.8%) of the caregiver respondents did not have English or Afrikaans as their first language, but all respondents

Table 3
Demographics of caregivers ($N = 59$).

	n (%)
Gender	
Female	57 (96.6)
Male	2 (3.4)
Literacy	
Literate	55 (93.2)
Illiterate	4 (6.8)
Nationality	
South African	40 (67.8)
Other	19 (32.2)
Primary language	
English	28 (47.4)
French	11 (18.6)
Xhosa	9 (15.3)
Afrikaans	3 (5.1)
Shona	3 (5.1)
French/KiSwahili	1 (1.7)
Ndebele	1 (1.7)
KiSwahili	1 (1.7)
Chichewa	1 (1.7)
German	1 (1.7)
Number of children below 18	
1 child	17 (28.8)
2 children	19 (32.2)
3 children	17 (28.8)
4–6 children	6 (10.2)

self-reported as literate, could read English. A small number (6.8%) were illiterate and unable to read any forms of information. Some respondents were unable to read the insert (10.0%) or the label (6.8%) because they indicated that the print was too small for them to read and not because of language difficulties. All literate respondents (93.2%) could read the PIL.

3.2. Information provided to caregivers

All seven pharmacists reported that labels are *always* included with OTC painkillers and this was confirmed with 90% of caregivers reporting *always* receiving labels. Two pharmacists reported that inserts were *never* included with OTC painkillers (both of these pharmacists worked at government facilities which repackaged tablet medication into small plastic packets; Fig. 2). In the case of inserts, five pharmacists reported they were *sometimes* included with OTC painkillers.

The majority of the caregiver respondents (69.5%) reported *always* receiving inserts when buying painkillers packaged in a box, with 27% indicating *sometimes* receiving them. The remainder (3.4%) reported *never* receiving inserts. In terms of providing PILs, 57% of pharmacists reported *never* providing PILs, while 43% indicated *sometimes* providing PILs with OTC painkillers. In terms of the caregivers, over half (61.0%) reported *never* receiving PILs, 24% reporting *sometimes* receiving them and 15% reporting *always* receiving PILs.

In assessing socioeconomic status as an indicator of access to health risk information, Table 4 presents the findings of types of information provided to caregivers when purchasing paracetamol by socioeconomic group. Interestingly, the majority of respondents indicated receiving labels, while those in the high socioeconomic group received inserts more often than those in the low socioeconomic group. There was a significant association between socioeconomic group and how often caregivers received inserts ($p = 0.000$) and PILs ($p = 0.007$). As expected, there was no significant association between socioeconomic status and how often caregivers received labels ($p = 0.664$).

In regard to effectiveness of current verbal and written forms of information provided with OTC medication, 57% of the

Table 4
Caregivers access to OTC medication information by mechanism and socioeconomic group ($N = 59$).

	Always *n* (%)	Sometimes *n* (%)	Never *n* (%)
Label			
High SE group	28 (47.5)	2 (3.4)	0 (0)
Low SE group	25 (42.4)	4 (6.8)	0 (0)
Medication insert			
High SE group	28 (47.5)	2 (3.4)	0 (0)
Low SE group	13 (22.0)	14(23.7)	2 (3.4)
Patient information leaflet			
High SE group	5 (8.5)	2 (3.4)	23 (40.0)
Low SE group	4 (6.8)	12 (20.3)	13 (22.0)

pharmacists felt they are, while 43% indicated ineffectiveness to prevent over dosing. Table 5 lists pharmacists' reasons for effectiveness or ineffectiveness.

3.3. Dosing habits by socioeconomic status

Most respondents (95.0%) administered paracetamol to their children for a headache and/or fever. Both socioeconomic groups chose paracetamol/Panado™ as their primary painkiller for children, however the use of Ponstel™ (Mefenamic Acid (MA)), Ponstan™ (MA) and Calpol™ (infant suspension paracetamol) was only found in the higher socioeconomic group, as these are more expensive. Table 6 describes where individuals from each socioeconomic group obtained their OTC painkillers as this impacted access to type of health information.

3.4. Sufficiency of information provided for dosing children

Of concern was that some respondents (10%) were unable to determine at what age a child could be given paracetamol. When asked to provide the dosage, 10% gave an incorrect dosage after reading the insert and label, respectively, and 3% reported an incorrect dosage after reading the PIL. Only three respondents reported children becoming sick after taking OTC medications, specifically from paracetamol. According to the respondents, however, this was as a result of an allergic response to the paracetamol, as opposed to overdose.

Table 5
Pharmacists' perceived effectiveness or ineffectiveness of OTC information.

Reasons methods of communication are effective:
"Most patients have a degree of responsible and rational intellect"
"We take more time with parents and mothers"
"Now a days there is more and more emphasis on counseling and right outcome"
"Parents might not listen, but it is still up to the parent"
Reasons methods of communication are ineffective:
"Need lots of verbal communication between caregivers and patients in relationship of trust"
"Not enough info stuck on the actual bottle"
"Not enough time with them"

3.5. Caregivers information comprehension as scientifically intended

In testing respondents' understanding of specific scientific terms found on all three mechanisms of information, 35% of caregivers indicated a lack of understanding and 39% answered one or more of the scientific terms incorrectly.

In relation to the paracetamol label, 10% of caregivers acknowledged that they did not understand one or more specific scientific terms while on average, 12% answered the scientific terms incorrectly. The majority of respondents seemed to understand the label's dosage information while 17% reported to finding the dosage instructions for children difficult to understand.

More respondents found the medication insert difficult to understand as evidenced by 32% defining the scientific terms incorrectly. The caregiver respondents found the following scientific words in the insert most difficult to understand (in descending order of difficulty): 'overdosage', 'side effects', 'interactions', 'pharmacological classification', 'composition', 'presentation' and 'dosage'.

With the study PIL, 20% acknowledged that they did not understand one or more scientific terms and on average, 16% answered the scientific terms incorrectly. Common examples of scientific words in the PIL which were reported as difficult to understand or incorrectly interpreted included, 'contraindication', 'side effect', 'ingredients' and 'exceed'.

3.6. Information effectiveness in promoting informed decision-making

Caregiver respondents reported that the text size was too small to read on the insert (70.0%), label (54.7%) and PIL (3.7%). When asked which of the three forms of information was the easiest to read, 87% indicated the PIL, 7% the label and 6% the insert. The majority (60.0%) of respondents felt all three information mechanisms presented together, provided adequate information to safely administer paracetamol to their children. Table 7 presents caregivers' reasons why the information usually provided with OTC painkillers is sufficient or insufficient. Explanations as to why the information is effective were not directly related to the information provided but were more attributed to other factors such as trusting a health professional or experience with medication efficacy. Reasons as to why it was insufficient related more to the actual information, as caregivers found this information generally difficult to understand.

3.7. Recommendations for improvement of information

Study caregivers suggested that the important sections, for example dosage, be printed in larger font, in bold, near the top of the label, insert or PIL. This was seen as assisting with finding the important information quickly. Both caregivers and pharmacists suggested the use of pictograms or diagrams to assist those who are unable to read or understand the information. Both groups also suggested using simpler words or providing a glossary of scientific terms as a reference. Most caregivers requested information about dosage for children to be more explicit (as the dosage is often

Table 6
Facilities where caregivers obtained OTC medication by socioeconomic status (SES).

Chemist/Pharmacy	($N = 45$)	Shop ($N = 11$)	Clinic/Physician ($N = 18$)	Spaza shop* ($N = 2$)
	n (%)	*n* (%)	*n* (%)	*n* (%)
High SES	23 (40.0)	8 (13.6)	6 (10.2)	0 (0)
Low SES	12 (20.3)	3 (5.1)	12 (20.3)	2 (3.4)

Some caregivers obtained painkillers from more than one facility.
* Informal convenience shop business, usually run from home in townships.

Table 7
Caregivers' reasons of information sufficiency or insufficiency.

Reasons why information is sufficient
"Because I know."
"It has worked in the past."
"I trust health professionals giving it to me."
Reasons why information is insufficient
"It doesn't tell you what the medication does in the body, but sometimes it does, but it's scientific so I don't understand it. And if there are warnings, they are in small writing or in the last section of the page. . .there are never clear warning signs."
"It is ambiguous and difficult to read, not in lay man's terms. . .the writing is so small so I just tend to glance over it."

clearer for adults than children), as well as potential side effects to be written in layman's language on the label. Some caregivers suggested that there be more information about what to do in the event of an overdose as well as contact details for the closest Poison Centre.

4. Discussion and recommendations

4.1. Discussion

This research highlighted that there are two key issues that need to be addressed for South African consumers to adequately medicate their children with OTC medications. That is, (1) the need for health risk information provided with medications in an accessible format (i.e. readable and understandable) which is appropriate for populations with low health literacy at risk of medication overdosing and (2) the need for provision of more than one form of information with all OTC medications in order to effectively reach these high risk consumers.

Accessibility was firstly impacted by whether the OTC medication was accompanied by a label, insert and/or PIL as legislated in SA. It is important to note that the label is the most accessible source of information to consumers purchasing from shops, yet the label did not have explicit dosage instructions for children. This should, at a minimum, be a requirement for all labels on OTC medications. Of significance is that most pharmacists believed the medication insert was only for health professionals to use and the PIL for the public. This highlights the complexity of the information being provided to consumers as many with low literacy levels found it difficult to comprehend the information provided on the label.

Importantly, 87% of respondents found the PIL easiest to understand and calculate dosages correctly, making it the most effective mechanism of information, and yet this same majority had never even seen or heard of a PIL before this study. Although the purpose of PILs is to provide simplified health risk information, these are not commonly accessible in SA irrespective of socioeconomic status. This is despite a large proportion of caregivers obtaining their OTC painkillers from private pharmacists who are legislated to provide PILs [28]. Ironically, study participants' recommendation was for the provision of simplified information. The participants' and researchers' inability to easily obtain PILs in South Africa reconfirms the importance of access to information as the first step to promote health literacy. Further research is needed to evaluate how PILs distribution is monitored and to identify ways of improving dissemination.

Access was further impacted by where the caregiver bought their medication. Those obtaining OTC medications from public institutions, predominately caregivers in the lower socioeconomic group, were provided with plastic bags with minimal instructions, and little verbal counselling. Those purchasing from private pharmacies were provided with more information and the opportunity to ask questions. Pharmacists felt that the current information was effective as long as patients had sufficient 'intellect' and sufficient time for verbal counselling. Caregivers in the lower socioeconomic group, furthermore, were unaware that they had a right to receive more information; reporting that they were content with the amount of information given as the assumption was that current information provision must be adequate. This was reflected in some of the reasons listed including, 'it is given by a doctor who knows the medication and problem' and 'if somebody gives you the tablets they will give you all the information and that information is enough'. All seven pharmacists interviewed emphasised the importance of providing verbal information or 'counselling' to each patient for promoting health literacy and comprehension of medication information. These results further emphasise the importance of verbal counselling and highlight a health disparity for consumers in lower socioeconomic groups who are not provided with sufficient or effective information and verbal support.

Comprehension was dependent on being able to read the information, as well as understand and apply it as scientifically intended as other studies have highlighted [29,30]. The participants in this study were unable to provide the correct dosage when treating their children for fever or pain based on the information accompanying the OTC medication. The participants were not required to calculate dosages according to weight, as weight is generally not included in the dosage instructions. Many of the participants, however, struggled to calculate the correct dosage, according to age as per the instructions. Although, many of the caregivers were able to read the medication information provided during the research, they were unable to apply this information to dosage requirements for their children.

An interesting finding was that respondents found the label scientific words easier to understand than those in the PIL, despite the intention that PILs provide simplified information. This could result from respondents required to read and understand less text on labels. Despite this, technical words still impeded understanding, such as 'contraindication', 'side effect' and 'medication interactions'. As highlighted in the factors needed for effective risk communication (e.g., accurate, consistent, specific and appropriate information; trust of messenger) [26,27], many caregivers found the inconsistency of the dosage between the three pieces of information confusing. For example, explicit dosage instructions for children were found on the PIL and insert but not the label, which just mentioned adult dosage. The lack of clear dosage amounts for both children and adults on all three pieces of information resulted in respondents questioning the intensity of the medication. The perception was that if there is a danger of overdosing, the manufacturers would make sure all dosages were clearly provided to prevent overdosing. This highlights that quality and comprehensibility of the information provided is more important than provision of too much information.

There were a number of limitations in this study. Due to the nature of the study design, there was potential for both selection and information biases during the data collection process. Specifically, there was potential for selection bias as recruitment of participants was largely reliant on who was approached by the researcher and/or who was suggested by other participating caregivers. Using a cross sectional study design presents difficulties in drawing conclusions representative of the whole population. Budget and time constraints limited the size, and therefore could affect the precision of the quantitative findings. A strength of the study included having caregivers from a variety of backgrounds and investigator triangulation in the analysis of the findings. Having one researcher and one measure (questionnaire) in the study ensured internal validity of the findings.

4.2. Conclusion

The health risks associated with the increasing dosage and over-dosing of children with paracetamol are a growing concern, as is the limiting effect of current health risk communication measures to mitigate these risks. This study highlighted that access to, and comprehension and applicability of health information are key challenges impacting caregivers' ability to prevent overdosing their children with OTC painkillers. Despite legislated requirements, South African consumers, and particularly lower socioeconomic populations, are not being provided with adequate and understandable dosing information. This lack of provision to assist consumers with understanding health risk information is increasing health disparities for low-literate populations. It is, therefore, imperative that policy and future research address improving access to and comprehension OTC medication risk information.

4.3. Practice implications

The clinical implications of caregivers not receiving adequate or appropriate risk and dosage information is the potential increase and/or overdosing with OTC medications, especially for children. Monitoring and enforcement of legislation requiring the provision of information with OTC is needed to increase access to this information. This includes the consistent provision of PILs which include simple terms or pictures easily understood by the lay person with a clear and simple design as well as a glossary, to provide further explanation of scientific terms. The responsibility also lies with pharmacists to provide regular and standardised verbal counselling. This preliminary study had a small sample size. Further extensive studies, including other OTC medications, are recommended.

We confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

Competing interests

None declared.

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