

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

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DECLARATION

MPH (General) Mini-Dissertation

I, Fiona Gibson, Student No.GBSFIO002, declare that the work that I have submitted is my own and where the work of others has been used (whether quoted verbatim, paraphrased or referred to) it has been attributed and acknowledged.

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ABSTRACT

Unintentional overdose of over-the-counter (OTC) medications has become an increasing global public health concern due to the common and frequent use of painkillers among end users, to self-medicate and medicate others, without fully understanding the associated health risks. While many developed countries have started to implement measures in an attempt to reduce access to large quantities and raise awareness of the dangers of misuse of OTC medications, this is not the case in many middle and low income countries. Instead, many individuals are forced to rely on written information while faced with poor health literacy, inadequate information and limited verbal information from health professionals, all of which contribute to the increase in unsafe behaviours leading to overdosing.

In South Africa, most unintentional overdoses from OTC painkillers occur in children, which can often be attributed to incorrect dosing from caregivers. With the common practice of re-packaging medications at a distribution level, individuals are often not provided with adequate information about their medication, appropriate for their level of health literacy. This study explored whether caregivers are able to make informed decisions about the correct and safe administration of popular OTC painkillers (specifically paracetamol) to their children, based on information from labels, medication inserts and/or patient information leaflets (PILs).

The protocol (part A) provides a justification for the study and describes the methods used to collect and analyse the data. The literature review (part B) describes the extent of OTC medication overdose globally as well as the current regulations in South Africa around OTC medication and the difficulties with accessing health information. The factors which inform

decision making when using OTC medication are also discussed. The article (part C) presents research findings on whether caregivers in South Africa were able to make informed decisions about dosing, risk and use of paracetamol, specifically through the access to and comprehension of labels, medication inserts and/or PILs. The study found that caregivers do not have access to enough information to make informed decisions about administering medication to their children. Those who are provided with sufficient information are usually the end users who are already educated and have adequate levels of health literacy to make informed decisions with the information provided. Pictograms, clearer formatting and use of clear lay language appropriate for the health literacy of end users were found to be imperative for encouraging caregivers to make informed decisions about dosage and risks associated with OTC medication use.

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Abstract

Unintentional overdose of over-the-counter (OTC) medications has become an increasing global Public Health concern. While many developed countries have started to implement measures in an attempt to reduce access to large quantities and raise awareness of the dangers of misuse of OTC medications, this is not the case in many developing countries. Instead, many individuals are faced with poor health literacy, inadequate information and the ability to purchase large quantities of medication without much knowledge of the associated risks.

In South Africa, most unintentional overdoses from OTC painkillers occur in children, which can often be attributed to incorrect dosing from caregivers. With the common practice of re-packaging medications at a distribution level, individuals are often not provided with adequate information about their medication, which is against their constitutional right to information, and could have significant consequences for their health. The purpose of this research study is to determine whether caregivers are provided with adequate dosing and risk information about popular over-the-counter medications, thereby allowing them to make informed and risk reduction decisions about their own health as well as the health of their families. This will be done through the administration of a questionnaire to caregivers and pharmaceutical service providers in Cape Town, South Africa across socioeconomic groups. Recommendations as to how to improve health risk communication for OTC painkillers for these groups will be given after reviewing the results.

1. Justification

1.1 Introduction

The South African Patients' Rights Charter states that everyone has the right to access to healthcare in the form of health information (1). The World Health Organisation recommends that all essential medicines be available with assured quality and adequate information and the South African National Department of Health aims to ensure that all citizens have access to medicines, which are available and accessible for all people (2). The South African government also acknowledges that a crucial and often deficient element in curative services is the adequate supply and dispensing of appropriate medicines (2). The main objectives of the National Drug Policy are:

- To ensure the availability and accessibility of essential medicines to all citizens.
- To ensure the safety, efficacy and quality of drugs.
- To ensure good prescribing and dispensing practices.
- To promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information.
- To promote the concept of individual responsibility for health, preventive care and informed decision-making (2).

It is clear from the last objective of the National Drug Policy that the South African government aims to promote three specific concepts, specifically the concept of individuals being able to take responsibility for their own health, individuals being able to make use of, and practice preventive care and individuals being equipped to make informed decision-making about their own health (2). With the current practices relating to provision and

access to medication, one needs to determine whether these three concepts are being upheld in the South African context. Other than the state's responsibility to uphold the rights of its citizens, it is imperative that individuals are equipped to make informed decisions about their health to prevent or reduce the life threatening risks associated with incorrect use of medication such as co-morbid conditions or in some cases, death. Therefore, if the abovementioned concepts are not upheld, the barriers need to be identified. This research aims to determine whether caregivers are able to exercise their right to access to health information in order to make informed decisions about their and their families' use of popular OTC painkillers specifically, through the access to and use of medication inserts and/or patient education leaflets.

1.2. Access to medication information

In South Africa, there are three major means of communicating necessary medication information to end-users, (i.e. indications, contraindications, side effects, dosage, directions for use, warnings, etc). According to legislation, "all medicine intended for administration to humans shall have a label attached to it, with each package accompanied by a medication insert and Patient Information Leaflet (PIL) (3). Certain regulations regarding the standardisation of information are not clear and those that are available are not always implemented, with some medications being provided with only one or two means of communication, or in some cases, with no additional information. The written information provided with medication does not incorporate any Braille or other assistive technology, resulting in visually impaired consumers having limited or no access to this information.

1.2.1 Labels

The way in which medicines are dispensed in South Africa, varies from facility to facility. Certain brands of OTC medication (e.g. Panado™), will be sold in a box which contains a certain amount of tablets per box. In some public facilities and private pharmacies, medication is often dispensed into small packets (see Figure 1) or containers (usually generics). These boxes, packets and containers will usually have some form of label on them providing specific information, however information can be limited to the name of the medication and/ or its generic dosage. The legislation clearly states that the container of every medicine intended for human use must have a label clearly attached to it in English and one other official language (3). The container label should provide basic information about the medication such as the medication's name, patient's name, dosage, instructions indications, special instructions and general warnings and is created by the manufacturer of the medication (3). In certain South African settings it is not always possible to have a medication insert accompanying the medication, making the label incredibly important, as it is the consumer's only means of access to information.

Studies in the United States have found that readability of labels can be increased by having larger font, boldfacing, use of white space and aesthetically pleasing designs (4). However, the Act 101 does not have clear guidelines stipulating the font size or other instructions pertaining to the design of the label, allowing for a variety of labels being produced in South Africa (3). A study conducted in the United States found that those with low literacy were three times more likely to misinterpret warnings on labels than those with higher literacy levels, with some participants misinterpreting seven out of eight warnings on the label (5). The World Health Organisation (WHO) encourages the use of labelling to communicate the

risks associated with the substance being sold and has found pictograms to be particularly effective in attracting attention, reminding consumers of safety messages already known and aiding in conveying messages that are difficult to describe in text, especially for those who have limited health literacy (6). A study conducted in South Africa further highlights this, in that 72% of those who received a label including pictograms were found to have a high understanding (>90%) of the labels, compared to 15% of those who received a label without pictograms (Dowse & Ehlers, 2004). The use of pictograms in conveying health information on OTC medicine labels, however, is not currently common practice in South Africa.

Child resistant containers (containers which an adult can open but are not accessible to children under the age of 5 years) have been known to reduce the number of poisonings from medicines, and have the potential to make adults aware of the associated risks of the medication (6). However, as OTC medication is usually bought off a shelf or repackaged into smaller packets by health providers, child resistant containers and/or labels are not usually included with OTC medication, making the medication label or insert of particular importance for providing information about safe use of the medication.

1.2.2. Medication inserts

Medication inserts provide information about each medication, which is provided by the manufacturer of the medication, to health workers and patients about the technical and medical details of the product (8). In South Africa it is compulsory that every container of medication be provided with a medication insert, providing essential information about the medication to inform the consumer about correct use (3). This insert comes in the form of a

double sided printed piece of paper, each side printed in a different language, which in South Africa is English and Afrikaans. Regulation 9 of Act 101 provides an extensive description of the content that should be provided in the medication inserts (3). The inserts should include 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 publication date of the insert (3). All of these details should provide the consumer with accurate information about the contents of the medication, who manufactures the medication (and how they can be contacted) as well as instructions for safe use of the medication (including dosage, side effects and contra-indications). All information provided in the medication insert is produced by the pharmaceutical company or manufacturer and approved by the Medicines Control Council (3).

The medication leaflet is often the only resource available for accessing information about OTC medication in South Africa, making it an incredibly important source of information. It is a source of information that has the potential to empower patients through self-medication, aiding in improving compliance and allowing patients to make informed decisions about their health (9). For medication inserts to be effective, the information needs to be readable (appropriate font size, use of language, design, etc) as well as understandable (in one's first language) and culturally acceptable (10). However in South Africa, this is usually not the case, highlighted in a study found that on average, participants reported that the medication inserts are too difficult to understand for the average reader.

Many participants reported that the amount of information, the technical design and the type of language used in the insert was not acceptable and resulted in many participants not attempting to read the insert at all (9). In South Africa, there are guidelines referring to the content of medication inserts in the Regulation 9 of Act 101 as well as the font type and size (3). However, there are no guidelines referring to the size of the insert paper and insert design, which can result in a variety of designs between different medications. Information is often very technical and the language content is very difficult to understand correctly, even for those with adequate levels of health literacy, which could potentially be preventing many individuals from accessing information that is very important for their health and the health of their children.

1.2.3. Patient Information Leaflets (PIL)

The Patient Information Leaflet (PIL) is an information document, distributed with medication, which provides information about the accompanying medication in an easy to read format, making the information more accessible than the information provided in medication inserts, to the general public. PILs were formally introduced to South African legislation in 2003 in the Medicines and Related Substances Control Act 101 (3). A PIL usually includes key information on what the medication is to be used for, warnings or contraindications, how to take the medication, side effects, storage information and further information (with contact details) (11). Patient Information Leaflets have been found to reduce the gap between health professionals and patients, improve adherence to medication and reduce patient anxiety around administering of medication, however PILs are only effective if they match patients' level of education and are culturally sensitive (10). Patient information leaflets have been implemented throughout the developed world,

which has been found to improve patients' knowledge of medication, however the complete implementation of the PIL has often not occurred in developing countries (10).

Regulation 10 of Act 101 states that all medicines distributed in South Africa should be provided with PILs, which requires pharmaceutical companies to develop and distribute PILs with all medicines (3, 12). It also provides detail as to what content should be provided in each PIL and states that all PILs should be printed in English and one other official language (13). A study conducted in Grahamstown, South Africa, evaluating the effect of PIL use on patient knowledge and recall, found that those who received PILs with pictograms had a significantly higher level of knowledge and recall (76.3%), compared to those who were just given text-only PILs (50.9%) and no information at all (43.3%) (14). A related study found that when participants were provided with an easy to read PIL, they reported to understanding most words in the leaflet, with all participants approving the amount of information contained in each leaflet, compared to average medication inserts, which are scientifically based and difficult to read (15). However, there has been little evidence to suggest that South African public hospitals have received many PILs from pharmaceutical companies which causes questioning as to whether these leaflets are accessible and available to the general public (10).

Despite there being certain regulations regarding the level of information required on labels, medication inserts and PILs (i.e. font type and size), there are no guidelines included in the Act 101 which recommend how often the information found on medication inserts and PILs needs to be updated (3). This means that certain OTC medicines provide information that may not be up to date with current scientific findings. Despite regulations

set in place to promote the increased access to information through labelling, medication inserts and PILs, it would seem that there is little uniformity in South Africa, with regards to how these regulations and policies are implemented, resulting in discrepancies between policy and what consumers are experiencing on an individual basis. With regards to the availability of Patient Information Leaflets in South Africa, it would seem that many OTC medications are not provided with PILs, despite legislation requirements.

1.2.4. Other sources of information

Other sources of information regarding OTC medications which are available to the public include the internet, advertisements and health professionals (8). In South Africa, those who have access to the internet can access information regarding OTC medication. One website in particular has been created for the purpose of making South African medication inserts available in electronic format, providing generic and trade names (16). According to a technology research organisation, Wide World Worx, only one in nine South Africans had access to a computer or internet in 2008, with these individuals being in higher socioeconomic groups due to the expense of computers. However, with the increased availability of mobile phones with internet access, especially among those in lower socioeconomic groups, this number has increased since 2008 (17). Those living in urban areas who do not have access to the internet, usually have access to television which often advertises common OTC medications, as well as billboards, which are placed alongside busy roads or near communal centres, advertising OTC medications. Those who do not have access to these means of communication, specifically those in lower socioeconomic groups, often rely on information given from family or community members as well as health professionals. Accessing information from health professionals does prove to be difficult in a

South African context, as it has been found that many patients do not feel comfortable to ask questions or clarify information about their medication. The presence of language or cultural barriers also exacerbates these difficulties (12). Within many health facilities, health professionals often only fluently speak English and Afrikaans, without having sufficient communication skills in any African languages with limited access to interpreters. Even when health professionals who are able to speak the first language of patients or interpreters are available, these services are often restricted due to terminology difficulties and differences in meaning (18). Many of the participants in this study who have poor literacy skills will most probably rely on health professionals and people in their immediate context (such as family members) to provide information about the correct use of OTC medication. Due to increased workloads and reduced consultation time in public hospital settings, health professionals may not be able to provide adequate verbal information to knowledge regarding safe use of OTC medication. Those with higher socioeconomic groups will usually make use of the internet to find further information if the information is not provided or inadequate.

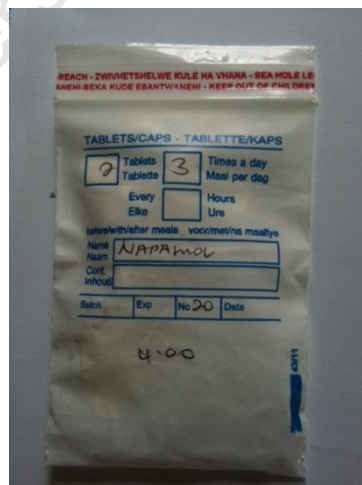
1.2.5. Repackaging of Medication

At certain private pharmacies in Cape Town, South Africa, the pharmacists reported that some OTC medications are distributed in packaging which has been re-packaged to reduce costs, with minimal information available (19) (see Figure 1). Policy also states that all generic medication needs to be repackaged on site where medication is administered (i.e. pharmacies) (3). The repackaging of medication is also described as a service that South African Pharmacists and Pharmacy assistants are able to perform, highlighting the fact that repackaging of medication is common procedure in South Africa (20). However, when

medication is repackaged, the information that is usually given is lacking, with just the dosage requirements, the time of day the medication should be taken, quantity of tablets provided and the name of the medication. Figure 1 shows a packet of medication given to the researcher at a private pharmacy in Cape Town after requesting generic paracetamol. No other information was provided with this packaging, and when it was queried whether other consumers ask for additional information, the employee distributing the medication responded, "It's just paracetamol, if people want something stronger they can request it", which seemed to imply that there was no need for further information due to the common use and perceived low risk of the product.

Figure 1

Repackaged paracetamol



The packet reads '2 tablets, 3 times a day'/'2 tablette, 2 maal per dag' (Afrikaans)

1.2.6. South African Pharmaceutical Providers

South Africans are able to obtain OTC medication from a variety of providers. The most common pharmaceutical providers include government public clinics and private chemists, however many individuals also purchase OTC medication, off the shelf, from commercial supermarkets such as Pick 'n Pay or Clicks stores. Other providers include 'Spaza' shops which are informal traders found in predominantly township areas, as well as small corner shops located in most areas of the country. The amount and level of information provided when purchasing OTC medication from these providers varies from provider to provider, with some providers (such as commercial stores) consistently providing medication inserts alongside the medication and other providers (such as a private chemist) providing medication in the packet seen in Figure 1.

1.3. Literacy Issues

The United Nations Educational, Scientific, and Cultural Organization (UNESCO) Institute for Statistics, which defines the adult literacy rate as 'the percentage of people ages 15 and above who can, with understanding, read and write a short, simple statement on their everyday life,' states that in 2007, the South African adult literacy rate (males and females above the age of 15) was 88.72% (21). As South Africa has eleven official languages, a large majority of South Africans speak home languages other than English and for those who do attend schools, are often not taught in English (21). The 2001 census by Statistics South Africa reported that only 8.2% of South Africans were first language English speakers. The Pan South African Language Board (PanSALB) reported that in 2002, only 22% of South Africans were found to fully understand political, policy and administrative related speeches and statements made in English (22). As many official documents and forms of medical

information are produced in English and on most occasions Afrikaans as well, this presumes that those who are literate are not able to access many forms of information which are needed to make informed decisions about their health.

In developed countries, it is generally found that information provided with medication usually includes information at a higher level than the reading ability of the patient (10). It is important to acknowledge that individuals who have access to medication don't necessarily understand it. Therefore, it needs to be highlighted that providing access to information is not sufficient for informing the population about safe medication use, the information needs to be conveyed in a way that is effective and appropriate for the context. Low-literacy is associated with poor understanding of one's disease, poorer clinical outcomes as well as poor understanding of medication labels and instructions (23). When patients have an understanding of the benefits and potential risks of their medication, as well as an understanding of how to administer the medication, they are empowered to make appropriate decisions about using the medication safely. Patients should receive counselling and education in how to administer the medication, as well as the risks and benefits of the medication from their doctor and/ or pharmacists (24). Studies in the UK have found that in general, patients retain 20% of what they hear but this may increase up to 50% when accompanied by written information (25). Another study found that patients, who do receive education regarding their medication from pharmacists or physicians, struggle to remember this information and will rely on labels and other written information for further guidance (24). This, together with language and cultural barriers may result in a similar situation occurring in the South African context. However, many OTC medication inserts and written information contain a high volume of text filled information, which can be confusing

for those who have poor literacy skills. This has important implications as to what information should be included with medications in a South African context (23).

A study in Pretoria, South Africa, which looked specifically at the knowledge around aspirin use and use of medication inserts in the general public, found that most people have poor understanding or poor application of their knowledge with regards to indication, side effects and symptoms of overdose (8). A study conducted in the United Kingdom found that people often only read medication inserts or PIL's when they had experienced a side effect, the medicine was for a child or the medicine was not known to them. Many found the writing too small and struggled with dosages, especially concerning a child (26). Given the history of inequality in South African education and access to information, there is still a large discrepancy between the educated and uneducated, as a result of past injustices. Many South Africans are unable to converse in English or Afrikaans and many of those who are able to converse, struggle to read basic information. This means that a large proportion of the population are not able to access information as a result of illiteracy, which further exacerbates their poor health outcomes.

1.4. Misuse of OTC medication

The frequent and often everyday use of OTC medication for various indications has been common practice amongst adults. Almost half (42%) of adults in the United States take at least one form of OTC medication regularly (27). The ease, at which these medications are accessed, as well as the potential lack of any guidance from health professionals regarding the correct dosage and precautions, results in the public having to rely on their own level of health literacy to access the information provided with the medication. A South African

study which was carried out in 23 Cape Town specialist substance abuse treatment centres found that the second most frequently reported medicines which are abused or overused are OTC analgesics. OTC medicines as a primary and secondary substance of abuse accounted for 2.6% and 5.2% of all patients admitted, respectively (28). As this study was completed in substance abuse centres, the authors of the study suggest that the prevalence of OTC misuse in the general population is predicted to be more extensive than the misuse reported in the study.

There are significant risks associated with paracetamol overdose. Other than the known link between paracetamol toxicity and liver failure, recent studies in the UK have found a link between excessive use of common OTC painkillers (including paracetamol) and headaches (29). Despite these associated risks, paracetamol is known to be the most commonly used OTC medication in the United States, with approximately 19% of adults having admitted to using it on a weekly basis (27). Paracetamol overdose has resulted in more than 30 000 annual hospitalisations, and it has been suggested that the cause of overdose is due to reduced or limited understanding of medication labelling, as well as a lack of appropriate understanding of daily dosages (30). A Cape Town study carried out in specialist substance abuse treatment centres found that the most commonly used OTC medications were codeine based, which are easily available in paracetamol and codeine mixtures, commonly sold and dispensed at shops and dispensaries. Analgesics were the second most common OTC substances to be abused (28). However, in a study carried out by the poison centre in Tygerberg Hospital in Cape Town, South Africa, it was found that paracetamol (both intentional and unintentional abuse) was responsible for 14% of drugs reported to be involved in overdoses, followed by Benzodiazepines at 10.9% (31). A study conducted in a

poison centre in Durban, South Africa found similar findings, in that 11% of queries were related to paracetamol over dosage (32). The authors largely attribute these high figures of paracetamol overdosing to the lay public being unaware of the potential toxicity of the drug when taken in overdose, which is further exacerbated by the open display of drugs in shops contributing to the perception that these OTC medications are safe (31).

Due to overdosing and dependence on OTC medication becoming a common phenomenon, certain countries such as the United Kingdom and the United States have attempted to control the consumption of OTC medications by implementing limits on the daily consumption of certain products (33). Similar guidelines are followed in the USA and Canada. However, studies have found it difficult to determine whether this limitation has had any significant effect on the overuse of paracetamol amongst the population (34). Codeine by itself is a prescribed medication in the UK; however Codeine and paracetamol mixtures are sold as OTC medications in South Africa. Locally, there is no restriction on the number of tablets that can be sold at one time. Quantities of paracetamol tablets can range from 10 to 100 tablets, depending on the choice of the consumer. However, regulation does state that the maximum dose of paracetamol in each tablet is 500mg (35). Paracetamol is often distributed by public and private pharmacies in its generic form, often with little or no accompanying information (as seen above in Figure 1). As many forms of medication information have high volumes of text heavy information, which has been found to be confusing and difficult to follow for individuals with low-literacy skills, it is not clear in the literature if less intricate information accompanying medication will assist with the administering of medication to those with low-literacy skills (23). However, other than the considerable amount of information missing, what is concerning is that there are no contact

details available to contact the provider of the medication if the consumer requires more information regarding the information written or regarding the information not included on these packages shown in Figure 1, such as contact details for the poison centre in the case of emergency. Consumers are not provided with any information to make informed choices about the ingredients, how much is administered, when it should be administered and when it should not be administered as well as potential side effects. This is a significant infringement on the consumers' right to access to information and ability to make informed decisions through accessing the correct and acceptable information.

1.5. Over-the counter medication use in vulnerable groups

1.5.1. Foetuses

There is a significant focus on certain vulnerable groups and their susceptibility for overuse of OTC medications in the literature. Paracetamol is one of the most commonly used OTC medications during pregnancy worldwide (36). Although studies relating to overdose in pregnancy are still largely limited to small prospective and case studies, it has been found that paracetamol is the most common overdose drug, usually as a result of intentional overdose, although unintentional paracetamol overdose has also been documented (37). It has been found that paracetamol can cross the placenta, resulting in its metabolism by foetal hepatocytes. This can result in liver necrosis if the appropriate treatment is delayed or not given (36). There is evidence to suggest that the maternal use of paracetamol during pregnancy may be a risk factor for children in the development of asthma, and this increased use may have contributed to the increased prevalence of asthma, worldwide, over the last half century (38). Associations have been observed between the use of paracetamol in pregnancy and the risk of wheezing in children in infancy and early

childhood (38). These studies relating to the association between paracetamol and liver necrosis and childhood asthma highlight the potential risks for the unborn child when mothers use paracetamol in pregnancy. Therefore it is important to understand whether pregnant women are aware of the risks of paracetamol use for their unborn child, to provide recommendations on how to potentially raise awareness and reduce use during pregnancy.

1.5.2. Children

The safety and efficacy of paracetamol has been well documented, especially compared to Aspirin. In the United Kingdom, use of Aspirin is not encouraged in children below the age of 16, after associations have been found between childhood use of Aspirin and Reye's syndrome (39). In South Africa, health professionals advise administering paracetamol to babies over the age of three months, with the recommended dose of 10 to 15mg every four to six hours (40). Paracetamol toxicity remains a concern, due to its increased consumption in children (41). Due to the perceived low risk of cough and cold medicines, the Food and Drug Administration (FDA) in the US recommends medical supervision when providing medication for children below the age of two, however despite this, inappropriate administration of OTC medication still accounts for a large proportion of Emergency Room visits which are as a result of drug ingestion (42). Data collected from Poison centres across the United States in 1997 found that 25% of fatal child paracetamol overdoses were as a result of unintentional overdose, which was usually due to lack of understanding of correct dosing on the part of the caregiver (41). The UK's Medicines and Healthcare Regulatory Agency (MHRA) also administered guidelines recommending that OTC cough and cold medications, which can include paracetamol and/ or Ibuprofen, not be given to children

below the age of six, however it was found that 87% of parents still administered OTC medication to their children and 70% of the sample misunderstood the purpose of giving OTC medication to children (43). In the US, it has been found that unintentional overdoses of medication in children are especially common with parents of a lower socioeconomic status and limited English proficiency (23). It is important to determine whether this is the case in other contexts such as South Africa with lower socioeconomic groups who also have limited English proficiency.

The Tygerberg Poison Centre in Cape Town, South Africa, reported that varying levels of overdosing of OTC medication were common in children below the age of six, and this overdosing was usually unintentional (44). This is further highlighted in a study conducted at a children's hospital in Cape Town, which found that 60% of children admitted as outpatients for ingesting poisonous substances were as a result of drug ingestion, with 9% of those admittances due to the ingestion of analgesics (45). With regards to the amount of calls received at the same poison centre, almost half of the calls were regarding the ingestion of drugs. The large amount of queries involving children as opposed to adults may have been as a result of the association with the hospital being a children's hospital, however, it also demonstrates that unintentional poisoning is most common in children (45). A recent follow up study was conducted at the same Cape Town children's hospital, documenting poisoning statistics between 2003 and 2008. This study found that poisoning as a result of drug ingestion had decreased from the study conducted in 1987, however drug ingestion was still the most common toxin (34% of poisonings). This decrease in reported poisonings was thought to be as a result of the decentralisation of health services in the Western Cape, resulting in more poisonings being seen at Primary facilities. However, of the

drug ingestions reported, 8% were as a result of ingesting cold medicines and antihistamines, which are common OTC medications (46). An important finding from this study was the difference in the amount of child poisonings between different socioeconomic groups, with those in lower socioeconomic groups reporting more poisonings. This highlights the concern that unintentional poisoning from OTC medication is still occurring and varies between socioeconomic groups (46). These poison statistics from Cape Town hospitals and evidence from global and local studies highlight the detrimental overuse of OTC medication in children and therefore contribute to the main justification for choosing caregivers as the population group in this study.

1.6. Gaps in literature

The major body of literature focusing on OTC medication use and vulnerable groups focuses largely on the consumption habits and effects of overdose on unborn fetuses and children. However, there is limited research investigating the reasons as to why these unintentional overdoses occur and how these overdoses can be prevented. This means that further research needs to be done which focuses on potential reasons for overdose, such as limited access to appropriate information and limited health literacy needed to understand and apply the information provided, in order to reduce the risks when administering or taking medication.

There is a great body of knowledge being produced from developed countries regarding labelling of medication, health literacy and risk of overdose with OTC medications. However, these countries have very different health systems and regulations in place. These countries also have populations with vastly different socioeconomic and cultural factors as well as

levels of education and health literacy which effect choice and use of medications. The literature including studies from South Africa which includes health literacy, medication and informed decisions is largely dominated by HIV and factors affecting medication adherence. The literature available from South Africa which studies OTC medications in South Africa is outdated with only a few studies completed in the last 5-10 years and does not include certain groups such as pregnant women (and foetuses). Most of the literature on OTC medication misuse in South Africa is related to poisoning statistics, which is very relevant, given the severity of the problem but these statistics are not always accurate and are not up to date. However, from a public health perspective, it is important to look further upstream and investigate possible reasons as to why children are being treated for poisoning from unintentional overuse of OTC medications, and how these poisoning can be avoided. Therefore, there is a need for this topic to be researched in a South African context, which is unique to other contexts, so that appropriate recommendations and implementations can be made to contribute to improving the health of the public.

2. Aims and objectives

2.1. Research aim

The aim of this research is to determine whether caregivers are able to make informed decisions about the correct and safe administration of popular OTC painkillers to their children, based on information from labels, medication inserts and/or patient information leaflets and thereby exercising their right to access to adequate health information so as to reduce risks.

2.2. Specific objectives

To inform the research aim, this study has the following objectives:

- To determine what information and in what format (e.g. labels, medication inserts and PILs) this information is provided to caregivers when purchasing OTC painkillers from various providers.
- To explore the consumption habits (i.e. frequency of use and choice of products) of caregivers from various socioeconomic groups when providing OTC painkillers for their children.
- To determine whether the information provided with OTC painkillers provides sufficient information for dosing requirements of children in the caregiver population.
- To evaluate whether caregivers understand and use the information communicated to them on a label, a medication insert and Patient information leaflet (PIL) as scientifically intended.

- To determine which information (in the label, medication insert and PIL) is most effective and ineffective in encouraging informed decision making about use of OTC painkillers in the caregiver population.
- To identify how information provision could be improved upon in order to reduce over and inadequate dosing of children by caregivers

2.3. Research Question

Main Research Question:

- Are caregivers provided with sufficient and appropriate information to enable them to make informed risk reduction decisions when administering OTC painkillers to their children, thereby exercising their right to access to health information?

Sub Research Questions:

- What information is being provided to caregivers by pharmaceutical providers (i.e. public clinics, private pharmacies, NGOs and general stores) and is this information adequate for all consumers?
- In what form is this information commonly presented? (e.g. medication insert, label and/ or PIL)
- Where do individuals from respective socioeconomic groups obtain their OTC painkillers and why do they choose one product over another?
- Are caregivers able to understand the dosage requirements of OTC painkillers from the information provided?
- Do caregivers understand and use the risk (e.g., side effects) and safety information provided to them in the PILs and medication inserts, as scientifically intended?

- What information in the PILs and medication inserts is most effective and ineffective in communicating information to caregivers, and why is this information effective or ineffective?
- How can information for caregivers be improved upon in order to reduce over and inadequate dosing of children?

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3. Methods

3.1. Study design

A cross sectional study will be conducted over two months with two groups. The first group will include caregivers from different socioeconomic groups who are part of different mothers' groups. The second group will include pharmaceutical service providers in the private and public sectors of the health system in affluent and non-affluent areas of Cape Town, South Africa. The study will use a mixed method approach, in that both quantitative and qualitative research methods will be used to collect and analyse the data. The data to be used in this research project will be retrieved from two different descriptive cross sectional questionnaires, which will be administered face to face with caregivers of children and pharmaceutical service providers, respectively.

3.2. Study population and sampling

3.2.1. Sampling population

Jubilee Community Church in Observatory, Cape Town, has been chosen as the institution from which participants will be recruited to participate in the study. This is due to the diverse characteristics of individuals belonging to this institution, especially with regards to socioeconomic status. Jubilee Community Church runs a registered clinic (Non-Government Organisation), in which the investigator has been involved clinically, which allows for access to recruit participants within the rest of the institution.

Participants from the Jubilee Community Church sample live in Observatory, Salt River and the Southern Suburbs of Cape Town. Observatory and Salt River are suburbs with residents representing all races, genders and ages. Residents range in socioeconomic status, in that

there is a mix of low, middle and high socioeconomic status groups; however Salt River residents usually come from lower socioeconomic contexts. Residents in these suburbs speak a variety of languages; however, English, Afrikaans, Xhosa and French are most common. The Southern suburbs (e.g. Rondebosch, Claremont and Constantia) in which other residents in the sample live, generally come from a higher socioeconomic background. As a result of previous Apartheid laws, these areas have a very high proportion of white, affluent residents, however all other races are found to be represented, albeit in smaller proportions compared to other areas of Cape Town.

Participants in the group of pharmaceutical service providers will come from a variety of locations across the area of Cape Town, according to where the caregiver participants are found to purchase their medication. At this stage it is unknown where the respondents obtain their OTC medication from, however it is assumed that they will obtain their OTC medication from a public clinic (such as Woodstock CHC), an NGO clinic which is run from Jubilee Community Church, from private pharmacists and/ or from general stores such as Pick 'n Pay or Clicks.

3.2.2. Sampling strategy

Convenience sampling will be used, in that participants will be chosen as a result of being part of respective caregiver groups at Jubilee Community Church which are easily accessible to the investigator. The investigator has access to these groups by personally knowing one member (or leader) of each group, who will recruit the other members of the group to participate in the study. The researcher aims to have an equal representation of socioeconomic groups, ages, races and first language speakers (specifically an equal

representation of English, Afrikaans and Xhosa first language speakers as these are the predominant languages spoken in the Western Cape).

Jubilee Community Church runs weekly groups for mothers with small children, and participants will be selected from a number of these groups that are held at the church. Examples of these groups include a support group for mothers living in the community, a health promotion group to aid development of children and a group that is run for caregivers who need to access the clinic to attend to the health needs of their children. There are a number of small support groups which will include the majority of the higher socioeconomic participants, with approximately six or seven members in each group. The contact person for each group will explain the study process and seek informal approval from the group members. The investigator will then attend each group, explain the study, and administer the questionnaire at a time which is appropriate for each group. The health promotion group has approximately 15 members in the group, who are mostly in a lower socioeconomic status group. The investigator will attend this group to explain the study and process, and will then return the next week to administer the questionnaire to each group member. The group attending the clinic comprises of approximately 40 members, most of which are in a lower socioeconomic status group. Each group member is seen by a health professional on a specific day. On the day of the appointment, after each member has been seen by the clinician, the investigator will schedule an appropriate time to administer the questionnaire with each participant.

There are various ways of measuring socioeconomic status in the literature, such as assessing an individual's level of education, income as well as their occupation according to

a scale, such as the Kuppuswamy socioeconomic scale, commonly used in India (47). Socioeconomic status can also be determined using the Living Standards Measure (LSM), however this requires knowledge of the individuals assets, according to the measure, which is beyond the scope of this study. For the purpose of this study, the socioeconomic status of participants will be defined as those in a higher socioeconomic status group having a tertiary education or who have completed secondary education and have an annual income above R50 000. Those in a lower socioeconomic status group will be defined as not having completed secondary education, or will have completed secondary education but their annual income is below R50 000. Participants in the sample could potentially be English, French, Xhosa and/ or Afrikaans first language speakers, but all are able to communicate in English as the group is run in English. Half (fifty) of the selected participants will be from higher socioeconomic status groups and half (fifty) will be from lower socioeconomic status groups.

The sample of private pharmacies, NGO and/ or clinic pharmacies used will be chosen according to the data collected from the caregivers in the questionnaire. These providers will be chosen based on the facilities from which the participants identify as where they primarily and regularly purchase their medication. However, it is assumed that this sample will comprise of a mix of public and private providers (and the registered NGO which is based at Jubilee Community Church) as well as larger corporate providers such as supermarkets and Clicks stores. A representative of each provider (e.g. pharmacist) will be asked to participate in filling in the questionnaire on behalf of the facility. Participants in the lower socioeconomic group will presumably obtain their painkillers from government clinics (for example, Woodstock Clinic) and at the Jubilee Clinic (registered NGO) although it may

be found that some may buy in bulk from supermarkets such as Pick 'n Pay or private chemists if they have the funds to purchase medication. It is presumed that participants in the higher socioeconomic group will purchase their painkillers from private chemists and corporate providers such as Clicks stores. The researcher will apply for permission from the Western Cape Provincial Department of Health to conduct research in a government health facility with consenting pharmacists. Questionnaires will only be administered once approval has been obtained from the Department of Health. The information provided with common products purchased by participants at supermarkets will be obtained by the researcher, which will then be analysed and included in the discussion of the study, however no individuals in these stores will answer questionnaires face to face as it is assumed that these personnel are not trained to provide further health literacy information to the public.

3.2.3. Sample size

Based on international and South African studies (14, 24), to calculate a sample size, it is assumed that the caregivers will understand 50% of the information provided in OTC labels, medication inserts and PILs. According to the formula used to determine a sample size in a prevalence study ($n = \frac{p(1-p)z^2}{d^2}$) where the anticipated proportion (p) is equal to 0.5 and assuming a precision of 10%, it was calculated that 96 participants would be needed, which was then rounded up to 100. Therefore, with an underlying proportion of 50%, a sample of 100 will provide a 95% confidence interval of 40 to 60% which is narrow enough for the purpose of this study. The investigator aims to include 20 individuals within pharmaceutical facilities distributed within each study location. This number was decided by the investigator to be the maximum amount of pharmaceutical providers that could be feasibly included in the study, due to budget and time constraints of a study conducted at a masters' mini

dissertation level. Therefore, the sample will consist of 100 caregiver participants and 20 pharmaceutical provider participants.

3.2.4. Inclusion and exclusion criteria

Individuals who have given informed consent will need to be 18 years or older to participate in the survey and therefore all individuals younger than 18 years will be excluded from participating in the research study. All participants need to be one of the primary caregivers of a child (below the age of 18) at the time of the research. Participants need to be able to understand and converse in English or Afrikaans, as these are the languages used to convey information on labels, medication inserts and PILs of OTC painkillers; however these languages do not need to be their first language.

3.2.5. Fieldworkers

Because most medication inserts and patient information leaflets are provided in English or Afrikaans and the aim of the research is to determine whether the information provided allows for caregivers to make informed decisions about their families' health, the questionnaires will be provided in English and Afrikaans. However, some participants from the lower socioeconomic group may be able to converse in English but struggle to understand certain terminology. Therefore, a fieldworker will assist with administering the questionnaires when collecting data from these participants. The fieldworker, who has experience in administering questionnaires in research, will be internally recruited through UCT.

3.3. Data collection

Data will be collected in the form of two questionnaires which will be administered by the researcher to all participants in the caregiver and pharmaceutical service provider samples. All questionnaires will be administered face to face, so as to ensure validity and equality amongst those who are not literate or have limited literacy. The questionnaire will be provided in either English or Afrikaans, according to whichever language each participant is more comfortable conversing.

A small pilot study will be done before the study begins to determine whether the questions in the questionnaire are appropriate for collecting the relevant data. The pilot study will be conducted as soon as the investigator has received ethics approval, and will then re-submit the updated questionnaire if required. The pilot study will consist of two caregivers from a higher socioeconomic status group, two caregivers from a lower socioeconomic status group and one pharmacist. The caregivers in the higher socioeconomic group and pharmacist are fellow Masters of Public Health students. The caregivers in the lower socioeconomic group are employees of two of the researcher's colleagues. Each participant in the pilot study will complete an informed consent form before participating in the pilot study.

Each questionnaire will have the participant's respondent number and date of interview. The questionnaire administered to the caregivers will contain questions determining demographic and background information as well as questions that aim to answer the specific objectives of the research study. Each questionnaire will require the participant to answer questions about their general use of OTC medication for their children, as well as

their knowledge regarding OTC medication. They will then be asked to read a medication insert and Patient Information leaflet from a common OTC medication (Panado™) to determine whether they are able to understand the information being communicated to them. The questionnaire for the pharmaceutical service providers will include demographic information and questions relating to the availability and accessibility of information, their understanding of information provided with OTC medication, alongside the common practices regarding distribution of OTC painkillers to the general public.

3.4. Data management and analysis

The data will be locked in a safe location, with password computer access which only the researcher will be able to access and will be kept confidential at all times. All data will be stored in individual folders, containing the surveys, handwritten and transcribed notes of each participant. The researcher's personal thoughts and observations about the caregiver and pharmacists' responses given in the surveys will be recorded at the end of each day and if feasible, after completion of each survey. This will be done to provide clarity and richness to the data by documenting phenomena e.g. emotion which cannot be captured in the questionnaire. If the investigator is unable to continue with the research, all questionnaires and collected data will be destroyed.

All data will be entered into the latest version of Statistical Package for the Social Sciences (SPSS) software and will be cleaned where necessary. The first step will be to define the variables used. Each respondent will have a row in the data sheet with each question having one column. Responses will be stored as numbers. Questions which have definite answers will be categorised as either correct or incorrect i.e. correct answers will be assigned a

numerical value of 1, incorrect answers will be assigned a numerical value of 0. Answers from the questionnaires will be coded and organised into categories to be analysed. SPSS will be used to analyse the data as it provides flexibility in carrying out a variety of data analysis tasks, and therefore, is suitable for a mixed method approach (48). Variables will be compared using appropriate graphs and descriptive statistics will be cross tabulated using the information entered from each questionnaire.

The qualitative data will be analysed using thematic networks analysis. The text is dissected and arranged into meaningful segments which are then coded. Themes are then generated once all the material has been coded. Similar themes are then placed into groups, which will eventually become thematic networks. Themes are summarized and patterns are then interpreted by returning to the original question and addressing the arguments that have arisen from the text (49). The investigator has undergraduate experience in analysing qualitative data and has acquired skills in quantitative data analysis through the MPH course. The investigator’s UCT supervisor has vast experience in use of SPSS software and analysis of both qualitative and quantitative data.

3.5. Logistics and time schedule

Timetable

	Jul 2012	Aug 2012	Sep 2012	Oct 2012	Nov 2012	Dec 2012	Jan 2013	Feb 2013	March 2013	April 2013	May 2013	June 2013	July 2013
Research Protocol													
Literature review													
Develop questionnaire													
Ethics review													
Data collection													

Data Analysis													
write up													
Hand in													

Budget

All costs except fieldworker salary are to be covered by the investigator. The fieldworker salary is to be funded by the researcher’s supervisor from existing research funds.

Description	Cost
Transport	R1000
Telecommunications	R500
Stationery/ Printing	R500
Dissertation fee/ ethics	R0
Internet & computer	R0 (Use of personal and/or UCT facilities)
Analysis software	R0 (available from UCT)
Remuneration	R250 (R50 x 50)
Fieldworker Salary	R1000
Total	R3250

As the questionnaires will be administered at a group that the caregivers already attend and at the pharmaceutical service providers’ work premises, participants will not need to be reimbursed for transport costs.

3.6. Limitations

There are certain limitations of the study that may affect the rigour of the research, of which the researcher is aware. It should be acknowledged before the research process has started that the researcher has no affiliations or competing interests with the subject being studied. The major limitation in using a cross sectional study design is the difficulty in collecting data and drawing conclusions that are representative of the whole population,

which could potentially be a limitation in this study. Other limitations include budget and time constraints, which limit the size of the study and again possibly the external validity. Certain phenomena such as the effect of the researcher being present when answering questions may result in certain biases which cannot be controlled. Although there may be methodological triangulation in the mixed methods of the study, due to the nature of the study, there is a lack of researcher triangulation, which may also have an effect on the rigour of the findings.

4. Ethical and Legal Considerations

The participants will be fully informed of the research process, including methodology, analysis etc. and what is expected of them during the process. Each participant will be required to sign a letter of written informed consent which will be fully explained to them in each participant's first language by the investigator (with the assistance of a translator who is familiar with the research process), however informed consent forms will be provided in English and Afrikaans as these are the primary languages spoken by the participants. This will be done just before the questionnaire is administered in a private room to reduce distractions. Participants will be encouraged to clarify information that is unclear to them throughout the research process, and are encouraged to ask questions whenever requiring more information or feeling unsure of the situation. All the information retrieved in the study will be treated as confidential and will only be used for the purposes of this study. All names and personal information will be discarded as soon as the study is complete. All participants will remain anonymous throughout the study to allow for confidentiality. Participants will be informed that they can withdraw from the study at any time, without penalty.

Participants attending the caregiver groups will be provided with remuneration according to the needs of the respective groups and average socioeconomic status of the group members. For example, those attending the developmental stimulation group (lower socioeconomic status) will be provided with a session, run by the researcher (a registered Occupational Therapist), which will provide simple home activities to aid in gross and fine motor development. A donation will be made to the clinic for their service provision. All participants will also be given further information with guidelines on safe administration of medication with children, although those in higher socioeconomic status groups will only be provided with the information, and no other monetary remuneration. This will be provided in the form of a paper hand out and will be developed by combining existing material on safe administration of medication, together with pictograms and simple instructions developed by the investigator. Participants from pharmaceutical service providers will be provided with the findings of the study and recommendations for future practice regarding provision of adequate information to caregivers administering OTC medication to their children. The study promotes the concept of justice as it may be used to provide more information which is rightfully due to the population. There are no overt risks for individuals who participate in the study. This study complies with the latest version of the Declaration of Helsinki (2008) as well as the Department of Health: Ethics in Health Research: Principles Structures and Processes (2004).

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PART B: LITERATURE REVIEW

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1. Introduction and objectives of literature review

Unintentional overdosing with over-the-counter (OTC) medications has become an increasing global public health concern, due to the common and frequent use of these (especially painkillers) and end users' perceptions of these being low risk drugs. Almost half (42%) of adults in the United States take at least one form of OTC medication regularly (1). As a result, some higher income countries have attempted to address this concern by reducing the quantity of medication available to the consumer and providing greater access to health information (2). However, despite the increase in use of OTC medication, many consumers in middle and low income countries still do not have access to enough information when obtaining their OTC medicines, hindering their ability to make informed decisions about OTC medication use.

In South Africa, a large proportion of unintentional overdoses from OTC painkillers occur among children, which can often be attributed to incorrect dosing from caregivers (3). Recent studies from poison centres in South Africa have found that medications are the most common toxins ingested by children, with analgesics, specifically paracetamol, accounting for a large proportion (10-15%) of these overdoses (3). With the common practice of re-packaging medications at a distribution level, detailed risk and dosage information is often not included with the medication. When information is provided, only a small minority of caregivers receive information in their first language, with even fewer accessing information which is appropriate for their levels of literacy.

The purpose of this research study was to determine whether caregivers are provided with adequate dosing and risk information about popular OTC medications, specifically paracetamol, thereby allowing them to make informed risk reduction decisions about their own health and their families' health.

To inform this research, the objectives of this literature review included:

- To determine the current regulations, policies and guidelines concerning provision of information with OTC painkillers in South Africa which guide and keep service providers accountable when providing health information.
- To determine the extent of overdosing of OTC painkillers internationally and in South Africa, specifically in children with paracetamol.
- To determine the barriers which prevent OTC painkiller users from making informed decisions, internationally and in South Africa.
- To determine the factors which encourage informed decision making in consumers using OTC painkillers.

2. Search strategies

The following strategy was followed to search for literature which informed this study:

Strategy: Relevant search engines were used to search for terms relating to the topic. Once relevant articles were found, the journals in which these articles were published were searched further using the same criteria. Journal article titles relating to the search terms, which were found in the reference list of journal articles, were also read. Information from

informal material, such as newspaper articles, were also considered. Only peer reviewed articles which were published in online journals were reviewed.

Search engines: Primo UCT, Academic Search Premier, Google Scholar, Pubmed, EBSCOhost, Science Direct, Swetswise.

Inclusion criteria: Studies which included OTC painkillers, health literacy, information and medication use, child dosing, poisoning, and informed decision making.

Exclusion criteria: Studies not written in English and studies published before 1985. Articles not peer reviewed.

Search terms (categorised by search area):

- *Overuse of OTC medication:* children and painkiller poisoning or overdosing, paracetamol and overdose and children, OTC poisoning and children.
- *OTC regulations in South Africa:* OTC medication and information or Patient information leaflet or medication insert or label and South Africa, OTC medication and legislation
- *Health literacy and health communication:* health literacy and OTC medication, informed decisions and medication, literacy and access to health information, health literacy and painkillers, health and communication and medication, labels and literacy, comprehension or understanding and medication or information, readability and labels and OTC medication, risk communication, risk perception and OTC medication

3. Summary of literature review

3.1 Extent of OTC medication overdose

The common overuse of OTC medication, both intentional and unintentional, amongst adults and children, has been frequently described in international and South African literature over the last fifteen years (1, 4-7). In terms of overdosing with OTC pain medication, the literature suggests that paracetamol is responsible for a large proportion of these overdoses (4, 5, 8, 9). The increased availability and lack of awareness of the effects of overuse are both factors which contribute to end users overdosing on the drug. Paracetamol overdose leads to more than 300,000 hospitalisations in the United States each year (6). In South Africa, the findings have been similar. In two studies carried out by the poison centre in Tygerberg Hospital in Cape Town, South Africa, paracetamol was found to be the most common exposure in analgesic poisoning (3, 10). These findings are further supported by a study conducted in a poison centre in Durban, South Africa which found that 11% of queries were related to paracetamol over dosage (9). These studies indicate that paracetamol plays a significant role in OTC drug overdoses in South Africa, which warrants research on consumers' perceptions and use of paracetamol, as well as their access to important health information about the painkiller.

Most overdosing cases documented in recent local and international literature are related to vulnerable groups, specifically children, pregnant women and their foetuses (11, 12). Paracetamol is one of the most commonly used and overused OTC medications during pregnancy worldwide. Despite studies relating to overdose during pregnancy being limited to small prospective and case studies, paracetamol was indicated as the most common overdose drug. This is usually as a result of intentional overdose, although unintentional

paracetamol overdosing has also been documented (8). Although a Nigerian study determining the extent of paracetamol overdose in children found that only 1.7% of caregivers overused paracetamol, other studies have found greater proportions of child overdosing (13). For example, at a children's hospital in Cape Town, 60% of children admitted as outpatients for ingesting poisonous substances were from drug ingestion, with 9% of those admittances due to the ingestion of analgesics (14). A recent follow up study, documenting poisoning statistics between 2003 and 2008 found that drug ingestion (including analgesics) poisoning had decreased (due to a decentralisation of health services) from the study conducted in 1987, however drug ingestion was still the most common toxin (34% of poisonings) with analgesics, making up 15.8% of analgesic overdose cases (10). Despite the differences in prevalence of paracetamol overuse, the literature still highlights the common overdosing of children with paracetamol. This significant problem of paracetamol overdosing in children led to caregivers being the main focus group in this study.

There are several potential reasons for the increased prevalence of paracetamol overdosing in South Africa. Currently, there is no limit in the amount of paracetamol that can be bought from shops or pharmacies, and if information is provided with paracetamol, warnings are often not clear enough to convey the risks associated with excessive paracetamol use. As children are reliant on caregivers for the provision of medication and treatment, it is important to determine whether caregivers are provided with risk information and whether this information is appropriate, particularly for dosage and side effects. This information is provided through mechanisms, including labels, medication inserts and Patient Information Leaflets (PILs), which are regulated by the South African government.

3.2. Current regulations and difficulties with access to medication information

In South Africa, Act 101 of the Medicines and Related Substances guidelines clearly states that medication information should be communicated by means of labels, medication inserts and PILs). According to legislation, “all medicine intended for administration to humans shall have a label attached to it, with each package accompanied by a medication insert and (PIL) (11). These three mechanisms of communication are important as they are the primary means of communicating risk and health information to consumers. According to the Act, all three mechanisms of information should be provided in English and another official language (11), however many end users are still not able to access this information in their first language. It is therefore important to determine whether end users have access to information in a language that they can understand and furthermore, if they are able to understand the specific language being used in the text.

Medication insert

The medication insert has the potential to empower patients self-medicating by aiding in improving dosage compliance. (15) The insert comes in the form of a double sided printed piece of paper, each side printed in a different language, which in South Africa is English and Afrikaans. The 2001 census by Statistics South Africa reported that only 9.6% and 13.5% of South Africans were first language English and Afrikaans speakers, respectively, with a large proportion of the population speaking isiZulu and isiXhosa (22.7% and 16%, respectively) (12). This means that only 23.1% of the population have the potential to access health information in their first language (assuming they read the information), while those from the other official language groups do not. The literature is not clear about how often medication inserts are distributed with OTC medication in South Africa, and therefore it is

not known how many consumers actually have access to inserts. However, for those who do have access to these inserts, it is estimated that less than 23% of the South African population is able to fully access health information due to difficulties with health literacy (discussed later in this paper).

Patient information leaflet

The Patient Information Leaflet (PIL) is an information document, distributed with medication, which includes simple non-scientific, everyday language with a clear format, to provide risk and dosage information to consumers with a variety of health literacy levels. PILs have been implemented throughout the developed world, which has been found to improve patients' knowledge of medication. However, PILs are still not being provided with medication in middle and low income countries (16). Act 101 states that all medicines distributed in South Africa should be provided with PILs (11). It also states that all PILs should be printed in English and one other official language, which has potential for greater access to information than the medication insert which is only printed in English and Afrikaans (8). However, there has been little evidence to suggest that South African public hospitals have received many PILs from pharmaceutical companies which leads to the question as to whether these leaflets are accessible and available to the general public (16).

Label

Act 101 states that the container of every medicine intended for human use must have a label clearly attached to it in English and one of South Africa's other eleven official languages (11). However, labels are predominantly written in English, resulting in many consumers attempting to understand information written in their second or third language.

The container label should provide basic information about the medication such as the medication's name, patient's name, dosage, instructions, indications, special instructions and general warnings and is created by the manufacturer of the medication (11). Despite labels being the primary source of information for OTC medication users in more developed countries (17), the literature is not clear about the extent to which labels are currently being used and distributed with OTC medication in South Africa.

Regulations regarding risk communication outlined in Act 101 of the Medicines and Related Substances guidelines are in place to protect consumers; however, if they are not implemented correctly, consumers are at risk of causing significant harm to themselves and their families. In certain South African settings, medication inserts often do not accompany the medication, making the label incredibly important, as it is the consumer's only means of access to information. However, in South Africa, warnings are often missing on labels distributed with OTC medication and labels are predominantly produced in English, which is not the first language of the majority of users. The literature clearly highlights the importance of the label, medication insert and PIL and that there is sufficient South African legislation in place to encourage access to this information. However, further investigation needs to be done to determine whether end users have access to this information and/or why end users are not able to understand and use the provided information appropriately.

3.3. Factors influencing informed decision making

The literature is clear about what factors influence informed decision making, specifically relating to the use of labels, medication inserts and PILs. These include the format of the information, the parent-physician relationship, effective health and risk communication as

well as one of the most important factors - the end users' ability to comprehend the information.

Format of information:

The United States Pharmacopeia (USP) recently released universal standards for medication labels in containers dispensed by pharmacists (18). The standards emphasize the use of high contrast print, large font size, prudent use of white space and prominent placement of important information (18). This is supported by other studies in the United States, which have found that readability of labels and inserts can be increased by having larger font, boldfacing, use of white spacing between words and aesthetically pleasing designs (19, 15, 16). The World Health Organisation, on the other hand, does not focus on the use of words at all and has found pictograms (for example, a picture of the number of spoons of medicine to administer to a child) to be particularly effective in attracting attention, reminding consumers of safety messages already known and aiding in conveying messages that are difficult to describe in text, especially for those who have limited health literacy (20). A study conducted in South Africa further highlights this, in that 72% of those who received a label including pictograms were found to have a high understanding (>90%) of the labels, compared to 15% of those who received a label without pictograms (16, 21). Currently, information accompanying paracetamol in South Africa (both generic and brands) do not have pictograms.

Parent-physician communication:

International studies have found that a combination of parent –physician (or pharmacist) communication and appropriate labelling have been effective in encouraging parents to

make informed decisions about their children's medication (22, 19). Studies in the UK have found that in general, patients retain 20% of what they hear but this may increase up to 50% when accompanied by written information (23). However, a study by Shrank and Avorn found that patients, who receive education regarding their medication from pharmacists or physicians, struggle to remember this information and will rely on labels and other written information for further guidance (24). Culture also tends to mould health beliefs such as, what is deemed to be appropriate behaviour of the health provider and effective treatment for certain conditions/ illnesses. Other cross-cultural difficulties include problems with certain words not existing in some languages, or having a different meaning. Accessing information from health professionals does prove to be difficult in a South African context, as it has been found that many patients do not feel comfortable to ask questions or clarify information about their medication and the presence of the previously mentioned language or cultural barriers also exacerbates these difficulties (25, 26). This study seeks to determine whether pharmacists consider verbal counselling to be as, or more important than written information, as this will determine how much verbal counselling is provided by respective pharmacists. It is important to determine whether South African caregivers are provided with verbal instructions from health professionals when obtaining their OTC medication or whether users need to rely purely on written information.

Health and risk communication:

It is widely accepted that information and communication together, are imperative in determining whether people make decisions to engage in suggested health behaviours and whether these behaviours have positive outcomes (27). The way in which risks are communicated is an important factor to consider when encouraging decision making

according to the known risks and benefits of OTC medication. However, for risk to be communicated effectively, it is important to determine what motivates individuals to change their health behaviour. There are a number of models and theories (Health Behaviour Model, Health Action Process Approach, Protection Motivation Theory and Expectancy Value Theory) which highlight perception of risk as one of the core reasons for individuals adopting certain health behaviours (28, 29, 30). These theories suggest that most health behaviour is motivated by the perceived benefits and barriers to adopting certain behaviours as well as the perceived magnitude of a threat, if certain behaviour is not adopted. The way in which individuals perceive the benefits, barriers and threats of behaviour change is largely affected by the effectiveness of how risk is communicated. Glik (2007) highlighted several guidelines for effective risk communication. These guidelines stressed the importance of the following:

- Consistency of the message
- Accuracy of messages, as past errors result in people not responding to subsequent risk information
- Information being specific, so that the end users are provided with precise details on 'what', 'how', 'when' and 'how long'.
- Adapting information to the diverse audiences they intend to reach, specifically considering their cultural, social and economic norms. (31)

Effective risk communication should meet the specific needs of all populations, especially those at greatest risk (most vulnerable) and most likely to experience difficulties with communication (32). One of the most important factors when communicating risk is the ability to establish trust with the public. If the public does not trust the providers of information, they will not consider any messages given to them by that authority (31, 33,

34). This trust is largely linked to social and culture values within the public groups and has a large effect on how risk messages are accepted and utilised. The social constructionist approach suggests that risks cannot be studied in isolation, but rather within a larger socio-cultural environment highlights how different groups perceive and value risks differently (32). These are important concepts to consider when determining what information is provided to OTC end users and whether this information is effective in conveying messages to end users in a variety of social, cultural and economic groups. This is especially important in the South African context where risk needs to be communicated to a variety of socio-cultural groups, with differing perceptions and values placed on risk.

Comprehension of information:

The link between literacy levels and comprehension of information has been well documented in the literature. Health literacy has been defined as 'the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health' (35). Health literacy plays a large role in understanding the name, dosage, side effects and indications of medication, with there being a large association between educational background and level of understanding of medication information (36). A study conducted in Nigeria found that those who were educated up to secondary and tertiary level provided correct doses of paracetamol to their children (13). However, in the US it has been found that many of those groups perceived to be 'educated' and able to understand verbal health information and instructions, are not necessarily able to fully understand written health information. These individuals may have highly functional literacy levels, but have low health literacy levels, which results in them being able to read and understand everyday language and

information, but struggle to understand language used in health information. These are the individuals who are often overlooked or unaccounted for, as they are perceived to be able to understand health information provided to them, yet in reality, they are covertly being denied access to important risk and dosage information (37). The 2003 National Assessment of Adult Literacy focusing on Americans' ability to understand health-related information found that only 15% of the participants had proficient health literacy skills needed to prevent disease by managing their medication appropriately and understanding their respective health conditions (38). The same study found that low parent health literacy was an independent predictor for having difficulty understanding OTC medication labels (38). Another study conducted in the US found that caregivers with inadequate health literacy were more likely to use non-standardized dosing instruments when providing liquid medication to their children, compared to caregivers with adequate health literacy. These caregivers with lower health literacy levels were also less likely to have adequate knowledge about weight-based dosing, compared to the caregivers with adequate health literacy (38). The international literature highlights caregivers' difficulty with comprehending health information, as a result of limited health literacy. Similar difficulties are also prevalent in South Africa. The United Nations Educational, Scientific, and Cultural Organization (UNESCO) Institute for Statistics, reported that in 2007, the South African adult literacy rate was 88.7%, which is considered to be relatively high, compared to other middle income countries (39). However, a study in Pretoria, South Africa, which looked specifically at the knowledge around the use of aspirin and medication inserts in the general public, found that most people have poor understanding or poor application of their knowledge with regards to indication, side effects and symptoms of overdose (40). With many South Africans not able to access information in their first language, it is important to determine if

these factors further exacerbate their potential difficulties in accessing information so that the appropriate recommendations for policy planning and implementation can be put forth.

4. Gaps in literature

The major body of literature focusing on OTC medication use and vulnerable groups focuses largely on the consumption habits and effects of overdose on unborn fetuses and children. However, there is limited research investigating the reasons why these unintentional overdoses occur and how these overdoses can be prevented. There is a great body of knowledge being produced from developed countries regarding this subject, yet very little being produced in developing countries such as South Africa. This could be due to limited funding as well as a lack of clear legislation regarding information provision. Further research needs to focus on potential reasons for overdose, such as limited access to appropriate information and limited health literacy needed to understand and apply the information provided.

5. Need for further research

The majority of OTC medication literature regarding labelling of medication, health literacy and risk of overdose focuses on developed countries such as the United States and United Kingdom. However, these countries have very different health systems and regulations in place, which means that these studies may not be valid in a middle income country. The literature from South Africa which includes studies on medication, health literacy and informed decision-making is largely dominated by HIV and factors affecting medication adherence. This is understandable, due to the high prevalence of HIV in South Africa, however, this literature is very specific to HIV and does not often translate to other

contexts. The OTC medication literature available from South Africa is outdated with only a few studies completed in the last 5-10 years and does not include certain groups such as pregnant women (and foetuses). Most of the literature on OTC medication misuse in South Africa is related to poisoning statistics, which is very relevant, given the severity of the problem, but these statistics do not capture those individuals who do not end up being considered overdose cases. From a public health perspective, it is important to look further upstream and investigate possible reasons as to why children are being treated for poisoning from unintentional overuse of OTC medications, for example, paracetamol, and how these poisoning can be avoided. Being in a lower socioeconomic group is a risk factor for exposure due to decreased supervision of children, lack of education and small homes with limited storage facilities (41). However, it is unknown whether the information provided, or lack thereof, further exacerbates the misuse of OTC medication among certain groups. Therefore, there is a need for this topic to be researched in a South African context, so that appropriate recommendations and policy can contribute to preventing overdosing in children.

6. Contribution of research to literature

The legislation which guides how and what information should be provided with OTC medication is available, however various factors hinder end users from being able to appropriately use and understand the information provided. This research aims to investigate what the missing factors could be, so as to provide recommendations to policy makers and encourage more effective risk communication. The limited research that has been conducted around this topic in South Africa has looked at whether people are able to understand specific forms of information (such as PILs or pictograms which have been

specifically designed for the purposes of their study, for example, a PIL created to determine whether use of the pictogram improved adherence to Anti-Retroviral treatment) and what factors have an effect on this understanding. This research aims to determine what information is being provided to caregivers and whether this information fosters informed decision-making. As most of the research has focused on adults and the effect of literacy and informed decision making on their own health, this research aims to provide further insight into whether caregivers are able to provide appropriate treatment to their children, with the information given to them.

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PART C: ARTICLE

“But it’s just paracetamol”: Caregivers’ ability to administer over-the-counter painkillers to their children with the information provided.¹

Abstract

Objective: To determine whether South African caregivers are able to make informed decisions about their families’ use of over-the-counter (OTC) painkillers, through access to and use of labels, medication inserts and/or patient information leaflets (PILs). *Methods:* A cross sectional, face-to-face questionnaire was administered to sixty caregivers and seven pharmacists in Cape Town, South Africa. Caregivers were requested to answer questions related to paracetamol labels, inserts and PILs provided. *Results:* Most caregivers receive labels with their painkillers with few respondents having received or ever seen PILs. The majority of respondents who received inserts were from a higher socioeconomic group. Caregivers found it difficult to understand the scientific terms in all three mechanisms of information provision. Eighty percent of respondents found the study PIL easiest to understand, yet PILs are largely unavailable in South Africa. 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, due to limited provision of information and health literacy, potentially placing their children at risk of being overdosed with OTC painkillers. Policy makers need to consider end users’ levels of health literacy when creating and implementing health information policies.

Keywords: Overdose, children, South Africa, health literacy, OTC drugs

¹Patient Education and Counseling suggest that Tables and Figures should be uploaded as separate table files and separate figure files. For readability, figures and tables have been included.

1. Introduction

The increase in self-medication with over-the-counter (OTC) medicines in middle and low income countries has resulted in consumers using OTC medicines to medicate themselves and their children without fully understanding the associated health risks. As OTC medication (for example, painkillers and cough medicine) in South Africa, and other low and middle income countries, can be purchased without any verbal information provided by a health professional, end users rely predominantly on written information accompanying the medication about how to self-medicate and medicate others. International studies have found that those who use written sources of information have increased knowledge about the medication, however less than half of end users can fully understand this written information (1). The worldwide increase in overuse and distribution of OTC medication over the last 15 years (2-7), together with limited verbal information from health professionals, has contributed to the increase in unsafe behaviours (such as overdosing) due to users not being aware of the risks and having a decreased understanding of the accompanying information (1). Thus it is important to determine whether end users have access to adequate information, equipping them to administer OTC painkillers safely themselves and to their families, while understanding the associated risks of the medication.

In South Africa, OTC medication can be obtained from government clinics, private pharmacies, general stores and 'spaza' shops (informal convenience shops, usually run from home), all of which will provide different, and often limited, information with the medication. There are three major and legally required health communication mechanisms for providing end-users access to dose and health risk information, namely a label, medication insert and Patient Information Leaflet (label, insert, PIL; Table 1) (8). All three

are created by the manufacturer and approved by the Medicines Control Council (8). The label provides basic information about the medication, while the medication insert contains scientific information appropriate for use by health professionals. The PIL is written in lay language to provide simple but sufficient information to the end user. In many developed countries, most OTC medicines are only accompanied by a label and PIL. Common practice in South Africa, however, is that OTC medication is provided without any of these three, especially when the medication is repackaged by government clinics or pharmacists, when none are provided. Despite the existence of three different and quite thorough mechanisms for providing medical and risk information to consumers, overdosing and overuse, especially of children, continues.

Table 1

SA Legislated Information Provision Requirements for OTC Medication (8)

Information Provision Mechanism	Information Required
Label	The label, stuck to 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	The 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. 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 publication date of the insert.

Patient Information Leaflet (PIL)

The Patient Information Leaflet (PIL), given to consumers by the manufacturer of the medication, provides information about the accompanying medication in an easy to read format, making the information more accessible than the information provided in medication inserts or labels, to the general public. It is to be printed in English and one other official language and includes key information on what the medication is to be used for, warnings or contraindications, how to take the medication, side effects, storage information and further information (with contact details).

Low-literacy has been found to be associated with poor understanding of one's disease, poorer clinical outcomes as well as poor understanding of medication labels and inserts (9 - 12). A study conducted in Italy found that functional health literacy (that is 'the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health') (13), was directly associated with education level, with those educated having higher health literacy levels than those who were less/ not educated (1). An individual's level of health literacy plays a key role in understanding the dosage, side effects and indications of medication, with there being a significant association between educational background and level of understanding of medication information (1, 14, 15). In 2007, the South African adult literacy rate was 88.7%, (16) however; due to the low health literacy levels of many South Africans, even those with high literacy levels are not able to fully comprehend

medication information , even if they are provided with all forms (written and verbal) of information (17). This places many South African medication users at risk of overdosing on prescribed and OTC medicines such as paracetamol.

Despite its documented safety and efficacy, paracetamol toxicity remains a public health concern, especially due to its increased consumption by children (18-21). Paracetamol overuse and overdosing has been linked to liver failure, headaches and development of asthma in children (22, 23). In studies conducted in South Africa, one study found that paracetamol was responsible for between 10-14% of drug overdoses and another study that paracetamol was the most common drug in analgesic poisoning amongst children (24, 25, 26). However, despite the health risks associated with paracetamol overdose, the lay public are often unaware of the potential toxicity (24). Perceptions that this is a low risk drug are highlighted in the response of an employee at a South African pharmacy, who when asked for more information to accompany a repackaged packet of paracetamol responded; “but it’s just paracetamol...”. As many consumers rely on pharmacists for verbal counselling regarding their OTC medication, this response could further exacerbate the lack of perceived danger in using paracetamol with children.

The literature attributes the overuse of paracetamol in South Africa to its accessibility as a non-prescription drug (25, 26). However, it is unclear whether it is merely the accessibility of the drug or lack of appropriate information accompanying it, which contributes to this overuse, or both. There are a number of models and theories (Health Behaviour Model, Health Action Process Approach, Protection Motivation Theory and Expectancy Value Theory) which highlight perception of risk as one of the core influences on individuals’

health behaviours (27-29). That is, 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 (e.g., lack of pain relief) if certain behaviour is not adopted. 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 (27-29). The literature also suggests that 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. This begs the question as to whether the three written forms of risk information available for paracetamol in South Africa are appropriate for all users. Effectiveness is also reliant on the end users' ability to trust the information provider (30, 31). Clamusa and colleagues found that 10-65% of OTC medication users in Italy were not fully aware of several risk areas including drug interactions and misuse. It is important to know whether similar results would be found amongst South Africans. (1) That is, particularly to explore caregiver perceptions of risk and understanding of medical information so as to prevent overdose 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, medication inserts and/or PILs.

2. Methods

2.1. Study area

This study was conducted between December 2012 and January 2013 in a Christian Church in Cape Town, South Africa. The Church runs a Non-Governmental Organisation health clinic

from its premises and is home to approximately 10-20 informal mothers' groups. This site was chosen due to the diversity of the individuals taking part in these groups to provide a varied perspective. 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 fifty nine caregivers from different socioeconomic groups and nationalities who were part of five mothers' groups. The Church has a number of informal 'mothers' groups' which provide support for mothers with children ranging from newborn to approximately eight years old. Study participants needed to be 18 years or older and one of the primary caregivers of a child. Participants also needed to be able to understand and converse in English or Afrikaans, as these are the current languages used to convey information provided with OTC painkillers; however these languages did not need to 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. These represent the providers used by the study participants (and greater South African public) chosen according to where the caregivers reported to obtaining their OTC medication. As the code of conduct for Pharmacists (2008) clearly states that all patients should receive advice (often through means of further counselling) on the safe use of medicine, it was important to determine the role of pharmacists in the provision of information to caregivers (32). As this study was conducted for fulfilment of degree purposes, the sample number was calculated according to the time frame and budget restrictions associated with the study.

2.3. Study design

A cross sectional face to face questionnaire (Figure 1) was designed by the researchers and approved by the University of Cape Town's Health Sciences Faculty Research Ethics Committee. The questionnaire, piloted and revised accordingly, was administered to caregivers (N=59) in higher (n=30) and lower (n=29) socioeconomic groups. 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 , specifically a 'complementarity' mixed method approach, where the qualitative and quantitative methods measured the different and overlapping aspects of the same phenomenon. This resulted in a richer, more in depth understanding of the phenomenon being studied, which in this study is whether caregivers were provided with enough information to make informed decisions (33). This approach aimed to seek clarification and elaboration of results from the qualitative data with the results from the quantitative data. In this study, the quantitative data was used to quantify where caregivers received their information, how often they received it, how well they understood the information, etc. The qualitative data served to elaborate further and contributed to the understanding of the quantitative results to determine for example, the reasoning behind the caregivers' choices or perceptions of types of information which motivated their actions when administering OTC medication to their children (33).

Figure 1

Examples of questions provided in each section of caregiver questionnaire (available upon request from authors)

General Questions:

Where do you usually get painkillers for your children and why?

Do the painkillers that you buy come with a label, medication insert and/ or PIL?

Medication Insert Example 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 Example Questions

Is it safe to take this medication when you are breastfeeding?

What does the term 'side effect' mean?

Medication Label Example 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, medication 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 medicines are dangerous?

2.4. Data collection

The interviews took place at a church (with a clinic) in Cape Town, South Africa. This location was chosen due to the socioeconomic, racial and linguistic diversity of the sample. Each

mothers group was approached via a contact person who was either known to the researcher or suggested by other caregivers participating in the study. Each questionnaire was written in English and was administered by the researcher or trained field worker. Each questionnaire incorporated quantitative methods e.g. quantifying how often caregivers received respective pieces of medication information, as well as qualitative methods (in the form of open ended questions) to gather data. The interviews were approximately 45 – 60 minutes long with each participant only being interviewed once. A representative working for the seven pharmaceutical service providers was randomly approached by the researcher when entering the facility (the representative was usually the first pharmacist to make contact with the researcher) and invited to participate in the study. The questionnaire was verbally administered to each caregiver and pharmacist after written consent was given. Each caregiver participant was provided with informal feedback after each questionnaire was completed.

Each questionnaire required the caregiver to read the medicine information provided (to determine level of literacy) and answer questions about their general use, knowledge and perceptions of OTC medication when administering to their children (Figure 1). One participant did not administer OTC painkillers to her children, resulting in that questionnaire being discontinued. The remaining 59 participants were asked to read a Panado™ (i.e., paracetamol) medication insert and label (on an actual box), as well as a paracetamol PIL produced in the UK (this was due to the researcher being unable to find a PIL accompanying South African paracetamol medication) (Figure 2). The questionnaire for the pharmaceutical service providers included questions relating to the information they provide, alongside the common practices regarding distribution of OTC painkillers to the general public.

Figure 2

Photographic description of Paracetamol medication insert and PIL

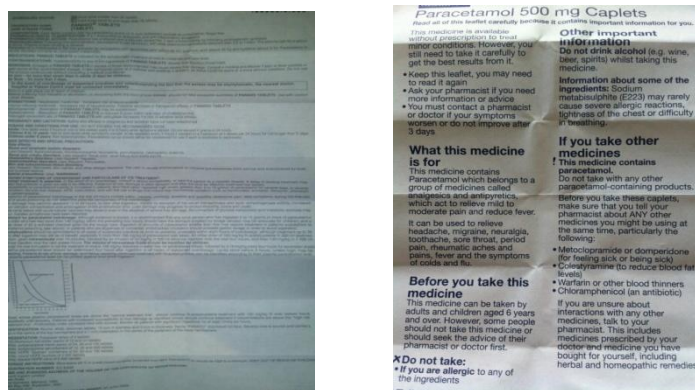


Fig 2.1 Product Medication insert

Fig 2.2 Product PIL

2.5. Analysis

The data was captured using SPSS21 to calculate the results and analyse emerging themes from the qualitative data. The researcher documented relevant themes based on the literature which emerged as data was captured. 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. Questions which had definite answers were categorised as either correct with a numerical value of 1 or incorrect with a numerical value of 0. Descriptive statistics were used to determine the frequency of variables and the chi squared test was used to determine the significance of specific associations.

2.5.6 Research quality

From a qualitative perspective, the strategies to ensure confirmability and dependability included the use of theory and literature as well as a careful protocol to guide the formation of the questionnaire. Researcher triangulation was encouraged by having three different sources (student, supervisor and assistant fieldworker) involved in the project. The study aimed to have a sufficient degree of generality by providing theoretical insights which arose from the study that could be projected to other contexts, thus encouraging transferability of findings.

From a quantitative perspective, there were a number of strategies used to ensure reliability and validity (external & internal). Information bias was reduced by using the same measure (questionnaire) for all participants and having one prominent researcher which meant that the questionnaire was asked in a consistent way throughout the study (encouraging internal validity). Selection bias was minimized by having limited non-responses or loss to follow up, which also allowed for greater internal validity. Reliability of the questionnaire was increased by conducting a pilot study.

From a mixed method perspective, legitimation was encouraged in a number of ways. Sample integration legitimation was ensured by having the same group of caregivers answering both the quantitative and qualitative aspects of the questionnaire, so that inferences could accurately be drawn from the data. Sequential legitimation was ensured, as the quantitative and qualitative questions were mixed together, which meant that the interpretations of the data were not affected by the sequence in which the qualitative and quantitative data was collected (35).

3. Results

Table 2 describes the demographics of the sample. The majority of caregivers were literate, South African and English speaking.

Table 2

Demographics of caregivers

	n (%)
Literacy (N=59)	
Literate	55 (93.2)
Illiterate	4 (6.8)
Nationality (N=59)	
South African	40 (67.8)
Other	19 (32.2)
Primary language (N =59)	
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 (N=59)	
1 child	17 (28.8)
2 children	19 (32.2)
3 children	17 (28.8)
4-6 children	6 (10.2)

3.1. Information provided to caregivers

All seven of the pharmacists reported that labels are *always* included with OTC painkillers, with 90% of caregiver respondents reporting to *always* receiving labels with their OTC painkillers. Two of the pharmacists reported that medication inserts were *never* included with OTC painkillers given to patients (both of these pharmacists worked at government facilities which repackage tablet medication into small plastic packets (Figure 3), while five pharmacists reported that medication inserts were *sometimes* included with OTC painkillers.

Figure 3

Photo of repackaged paracetamol in small plastic packet



The majority of the caregiver respondents (69.5%) reported to *always* receiving inserts (when buying painkillers packaged in a box) with 27% indicating *sometimes* receiving them and the remainder (3.4 %) reported to *never* receiving inserts with OTC painkillers. Four pharmacists reported to *never* providing PILs while three reported to *sometimes* providing PILs with OTC painkillers. Over half (61.0%) of the caregivers reported to *never* receiving PILs, with 24% reporting to *sometimes* receiving them and 15% reporting that they *always*

receive PILs with OTC painkillers. Table 3 describes the information provided to caregivers by socioeconomic group. The majority of respondents receive labels, while those in the high socioeconomic group receive inserts more often than those in the low socioeconomic group. There was a significant association between socioeconomic group and how often caregivers received medication inserts ($p=0.000264$) and PILs ($p=0.006679$). As expected, there was no significant association between socioeconomic status and how often caregivers received labels ($p=0.663729$).

Table 3

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)

When asked whether the current verbal and written forms of information provided with OTC medication to caregivers were effective, 57% of the pharmacists felt that it was effective, while 43% felt it was ineffective. Table 4 illustrates the reasons provided for their perceived effectiveness or ineffectiveness. Based on their responses, pharmacists were divided in their opinions, with some suggesting that the information was effective as there is a large emphasis on providing counseling and parents can generally understand the information. Conversely, others felt it is ineffective as there is not enough time for counseling and the information is not sufficient for parents to understand.

Table 4

Pharmacists' perceived effectiveness/ ineffectiveness of current verbal and written 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 counselling 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”

3.2. Consumption habits of different socioeconomic groups

Most (95%) of respondents 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™ (Paracetamol) was only found in the higher socioeconomic group, as these are more expensive painkillers than paracetamol. Table 5 describes where individuals from each socioeconomic group obtain their OTC painkillers.

Table 5

Facilities where caregivers choose to obtain or purchase OTC medication by socioeconomic status group (N=59)

	Chemist (n=45) n (%)	Shop (n=11) n(%)	Clinic/ Physician (n=18) n(%)	Spaza Shop*(n=2) 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)

*Informal convenience shop business, usually run from home

Some caregivers obtain painkillers from more than one facility

3.3. Sufficiency of information provided for dosing children

Nearly half (48%) of the caregiver respondents did not have English or Afrikaans as their first language, but all respondents who were literate could read English. All of those who did not have English as their first language were in the lower socioeconomic status group. A small number (7%) were illiterate and unable to read the forms of information. Some (10%) of the respondents were unable to read the medication insert or the label (6.8%) because the print was too small for them to read (not because of language difficulties). All literate respondents could read the PIL. A few respondents (10%) were unable to determine at what age a child could be given the paracetamol. When asked to provide the dosage, 10% gave an incorrect dosage when reading the medication insert and label, respectively, and

3.4% reported an incorrect dosage (when reading the PIL). Three of the respondents reported that their child had become sick when taking OTC medication, specifically from paracetamol, however, according to the respondents, this was as a result of an allergic response to the paracetamol, as opposed to overdose.

3.4. Ability of caregivers to use information 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 38.8% answered one or more of the scientific terms incorrectly. A few caregivers (10%) acknowledged that they did not understand one or more specific scientific terms found in the label and on average, 11.9% answered the scientific terms incorrectly. Some (20%) acknowledged that they did not understand one or more specific scientific terms found in the PIL and on average, 16.4% answered the scientific terms incorrectly. More respondents found the insert difficult to understand with 32.2% answering the insert scientific terms incorrectly. Examples of scientific words in the PIL which were reported as difficult to understand or incorrectly interpreted included, 'contraindication', 'side effect', 'ingredients' and 'exceed'. 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'. 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.

3.5. Effectiveness of information in promoting informed decision making

Caregiver respondents reported that the size of the text on the medication insert (70%), label (54.7%) and PIL (3.7%), respectively, were too small to read. When asked which of the

three forms of information was the easiest to read, 87% of the caregivers identified the PIL, 7% the label and 6% the medication insert. Many (60%) of the respondents thought that all three mechanisms of information together provided adequate information to safely administer it to their children. Reasons as to why caregivers felt the information usually provided to them with OTC painkillers is sufficient or insufficient are described in table 6. Reasons as to why the information is effective were not directly related to the information provided but were attributed to other reasons such as trusting a health professional or knowing it has worked in the past. Reasons as to why it was insufficient related more to the actual information, as caregivers found it difficult to understand.

Table 6

Caregivers' reasons why the information provided by all three mechanisms of information is sufficient/ insufficient

Reasons why information is sufficient

"Because I know",
 "It has worked in the past" and
 "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.

3.6. Respondent recommendations for improvement of information

Caregivers suggested that the important sections, for example dosage, be printed in larger font, in bold, near the top of the label, insert and PIL, in order to assist caregivers in 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 suggested that simpler words be used or that a glossary of scientific terms could be provided for those who wish to use them as a reference. Most caregivers would like information about dosage for children to be more explicit (as the dosage is often 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 overdose as well as contact details for the closest Poison Centre.

4. Discussion & Conclusion

4.1. Discussion

In order for individuals to make informed decisions about dosage and risk, it is imperative that the information is written at the correct literacy level for readers with varied levels of health literacy. In a United States study, half of adults were not able to understand basic health information, despite having adequate levels of literacy (35). This was highlighted in this study, in that many of the caregivers were able to read the information provided, but were not able to understand it enough to make decisions about dosage requirements for their children, which was also found in the Clamusa et al. study among Italian OTC medication users (1). An interesting finding was that respondents found the scientific words in the label easier to understand than the PIL, yet the purpose of the PIL is to provide information which the end user can easily understand. This could be due to the label using fewer words than the PIL, resulting in the respondents needing to understand fewer terms. Specific difficulties included misunderstanding of 'contraindication' and 'side effect' as well

as understanding the interactions of the drug, which again, were also found in the Italian study (1). As highlighted in the factors needed for effective risk communication (30), many caregivers found the inconsistency of the dosage between the three pieces of information confusing (explicit dosage instructions for children were found on the PIL and insert but not the label, which just mentioned adult dosage). This made them question the intensity of the drug, as an inconsistent dosage did not communicate a high risk of danger if overdosed. This highlights how the content of the information is much more important than the quantity of information, as those who are most in need of information, will not necessarily read or understand all of the information provided, unless it is appropriate for their level of understanding.

It is important to note that the majority of the respondents found the PIL easiest to understand and calculate dosages correctly, making it the most effective mechanism of information in this study, but that this same majority had never even seen or heard of a PIL before. PILs are not commonly provided with OTC medications in South Africa, however if they were, more end users could effectively access health information. This is despite a large proportion of caregivers obtaining their OTC painkillers from private pharmacists, who should be providing PILs with the medication. This is further highlighted by the researcher not being able to find a PIL in packaged paracetamol to collect data for this study. Lack of provision of PILs is due to the pharmaceutical companies not providing them in the packaging, or due to pharmacists having limited capacity to make copies of them for distribution with repackaged medication. However, legislation states that all medicines distributed in South Africa should be provided with PILs, which requires pharmaceutical companies to develop and distribute PILs with all medicines (36). Therefore, apart from

checking the content of PILs, the Medicine Council should also be ensuring more compliance with legislation by checking that PILs are actually being distributed. Most of the pharmacist respondents reported that according to their knowledge, the purpose of the medication insert is for use by health professionals, whereas the PIL is intended for the public. Perhaps it would then be more beneficial to the OTC users (and cost effective for the provider) if companies provided a label and simple PIL instead of a medication insert, with references provided to health professionals if further scientific information is needed.

All seven pharmacists interviewed emphasized the importance of providing verbal information or 'counselling' to each patient. However, accessing information from health professionals does prove to be difficult in a South African context, due to the presence of language barriers and patients not feeling comfortable to ask questions or clarify information about their medication (36). Within many health facilities, health professionals often only fluently speak English and Afrikaans, without having sufficient communication skills in any of the other nine official African languages or with limited access to interpreters. In this study, there was a significant discrepancy between socioeconomic groups, as those in the lower socioeconomic group generally had less access to written mechanisms of information accompanying their OTC medication. However, it was found that some caregivers in the lower socioeconomic status group were unaware that they even had a right to receive more information, reporting that they were content with the amount of information given. Reasons for this included, '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 the information is enough'. This further emphasizes the importance of verbal counselling as many patients will base their actions on what is said by a health

professional that they seem to inherently trust, which according to risk communication theory, is effective in conveying risk (30). However, conversely, it is difficult to in control the content and consistency of verbal information provided to users in different settings, leaving potential for inconsistencies and ineffective communication of important health information.

Although information is provided for free with all OTC painkillers, there was a difference in what information was provided in different locations. The reality is that those obtaining OTC medication (and information) from public institutions will usually only be provided with a label (as seen in the results of this study) or plastic bag with limited written instructions, and are usually provided with less verbal counselling due to limited time and increased pressures to tend to many patients. Those obtaining OTC medication from private pharmacies or general stores will usually be provided with some information (such as the insert) along with the label, and may be able to ask more questions to the pharmacist on duty. As the majority of those with basic literacy levels (according to level of education) were in the lower socioeconomic status group, they would tend to be the group obtaining their OTC medication from government facilities. As pharmacists tended to suggest that the information was effective because most patients have sufficient 'intellect' or ineffective due to their being limited time, this also shows that the information being provided to those in the lower socioeconomic groups is also less effective. This is something which is also seen in the rest of the South African health system, where the educated who have resources to afford quality health care, do receive it, while the less educated continue to have poor health outcomes as they cannot afford quality health care which is only available for the select few.

4.2. Strengths and Limitations

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. Selection biases include the potential for the Hawthorne effect, sample bias and participation bias. Recall bias could also be a specific form of information bias present in the study. Using a cross sectional study design could result in difficulties with drawing conclusions that are 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.

4.3. Conclusion

This study highlights some of the major challenges for health providers and policy makers to prevent caregivers from overdosing their children with common painkillers. Firstly, many people do not have access to enough information to make informed decisions about administering medication to their children. Those who are provided with sufficient information are usually the patients who are educated and also have adequate levels of health literacy to make informed decisions with the information provided. It is, therefore, imperative that packages have at least one of the three legislated mechanisms of information (preferably the PIL) in order to increase information provision to lower-socioeconomic populations. Secondly, even when those in need of information are provided with this information, this information is usually limited, not appropriate or not understood. The findings in this study suggest that although the respondents had not had experience of

overdosing on OTC painkillers with children, their lack of understanding and low perceived risk of this medication potentially places their children at risk of being overdosed with OTC painkillers, and that overdosing may not be understood.

4.4. Practice Implications

Suggestions for improved practice include providing pictograms to convey important concepts such as dosage and warnings, and use of a glossary to provide further explanation of scientific terms in simpler words, in a variety of languages. Pharmaceutical companies and government need to acknowledge the growing refugee communities in low and middle income countries such as South Africa and therefore the need for information in French, for example, PILs. According to legislation, the actual information itself should be reviewed the Medicines Control Council to adequately address the health literacy levels of end users, with there being more emphasis on providing PILs. This includes simple terms or pictures which are easily understood by the lay person, with a clear, simple design. Spot checks of pharmaceutical providers could be done to ensure compliance of PIL provision. The responsibility lies with pharmacists to provide as much verbal counselling as possible, and with the adult caregiver, to make use of their right to access to information to avoid overdosing of children with painkiller OTC medication. As this study focused on paracetamol, which comes with a label and insert, more research is needed focusing on other OTC painkillers. Especially those OTC painkillers provided through more informal means, for example, by pharmacists who provide repackaged medication in small plastic bags or containers with generics, spaza shops and informal markets.

Conflict of interests

No conflict of interest has been declared by the authors in this study.

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University of Cape Town

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PART D: APPENDICES

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University of Cape Town

1. Questionnaire (Caregiver)

Respondent No: _____

Date of interview: _____

Place of interview: _____

Date of Birth: _____

Gender (please tick): Male _____ Female _____

Home language: _____

Home address: _____

Highest level of education: _____

Occupation (if applicable): _____

Partner's occupation (if applicable): _____

Annual income: _____

Number of children: _____

Ages of children: child 1 _____

child 2 _____

child 3 _____

child 4 _____

A. 1) If your child has a headache and fever, would you give him/ her medication?

yes	no
-----	----

A. 2) If yes, what medication would you give your child?

A. 3) Do you give any of the following medicines to your children?

Ponstel	Yes	no
Stopayne	Yes	no
Stilpane	Yes	no
Paracetamol	Yes	no
Disprin	Yes	no
Other (please state)	Yes	no

B. 1) Where do you usually get painkillers for your children?

B.2) Why do you get them there?

B. 3) Do you have to pay for these painkillers?

always	sometimes	never
--------	-----------	-------

B. 4) Does the medication come with packaging (e.g. in a box) or in a packet provided by the pharmacy/ store?

sometimes	never	always
-----------	-------	--------

B. 5) If you got your painkillers from a private pharmacist/ chemist in the last year, did the pharmacist tell you verbally how to correctly give the medication to children? (choose one)

yes	no	N/A	Can't remember
-----	----	-----	----------------

B.6) If yes, what did he/ she tell you about the medication?

	Can't remember	Did not give info	N/A
--	----------------	-------------------	-----

B. 7) Did the pharmacist give you any written information about the correct use of medication with children? (choose one)

yes	no	N/A	Can't remember
-----	----	-----	----------------

B. 8) If yes, did you read the information given?

yes	no	Did not give information	N/A	Can't remember
-----	----	--------------------------	-----	----------------

B. 9) If you did read it, what information can you remember most?

	Can't remember	Did not read info	N/A
--	----------------	-------------------	-----

B. 10) If you got your painkillers from a clinic in the last year, did the pharmacist tell you verbally how to correctly give the medication to children? (choose one)

yes	no	N/A	Can't remember
-----	----	-----	----------------

B. 11) If yes, what did he/ she tell you about the medication?

	Can't remember	Did not give info	N/A
--	----------------	-------------------	-----

B. 12) Did the pharmacist at the clinic give you any written information about the correct use of medication with children? (choose one)

yes	no	N/A	Can't remember
-----	----	-----	----------------

B. 13) If yes, did you read the information given?

yes	no	Did not give information	N/A	Can't remember
-----	----	--------------------------	-----	----------------

B. 14) If you did read it, what was included in the information?

	Can't remember	Did not read info	N/A
--	----------------	-------------------	-----

B. 15) If you have purchased painkillers from a shop e.g. Pick n' Pay/ Clicks or Spaza shop, did you ask anyone for more information about the safe use of painkillers with children?

yes	no
-----	----

B. 16) If you did ask for more information, who did you ask? (please tick)

The employee working at the till	
The shop's information desk	
A family member	
A friend	
The internet	
I did not ask anyone for more information	

B. 17) Do the painkillers that you buy come with the following? (show documents)

	sometimes	never	always
A label			
A medication insert			
A Patient Information leaflet			

C. 1) You reported that you give _____ (A.2 answer) when your child has pain or fever. What were your reasons for choosing this medication?

C. 2) Did you hear about the medication from any of the following sources?

Friend	Family	Billboard/ Sign	Television	Health Professional
--------	--------	-----------------	------------	---------------------

C. 3) How much of the medication do you buy at one time?

C. 4) Where do you store your over-the-counter medication at home?

C. 5) At what age do you let your children help themselves to this medication when they are sick?

C.6) Would you allow the following people to give medication to your child if you are not able to give it to them? (Please tick)

Your partner	yes	no	Why?
Your other children	yes	no	Why?
A neighbour	yes	no	Why?
A friend	yes	no	Why?
Your child's teacher	yes	no	Why?

Another family member	yes	no	Why?
-----------------------	-----	----	------

D. 1) How often do you read the information on the Medication Insert (if given) before giving the medication to your child?

sometimes	always	never	not given
-----------	--------	-------	-----------

D. 2) If not, why not?

	N/A
--	-----

D. 3) Are there specific sections that you always read? Please state

	N/A
--	-----

D. 4) Are there any sections that you ignore? Please state

	N/A
--	-----

Please read the Panado™ medication insert and answer the following questions:

Participant is unable to read information insert due to:

inadequate literacy levels	Insert not written in language participant reads (language _____)	N/A
----------------------------	---	-----

D. 5) At what age is it safe to give a child this medication?

D. 6) How much can the child be given at one time?

D. 7) After giving a child Panado™, do you have to wait before you give more Panado™?

yes	no
-----	----

D. 8) If yes, how long do you have to wait?

D. 9) How many times in one day can you give this medication to a child ?

D. 10) What is the maximum amount of Panado™ a child is allowed in one day?

D. 11) Do you think your child could be poisoned from taking too much of the medication?

yes	no
-----	----

D. 12) Is it safe to take the medication when you are pregnant?

yes	no
-----	----

D. 13) After how many days of taking this medication should you call a doctor if your child's health is not improving?

D. 14) Can this medication cause your child to have:

Skin rashes	Yes	No
Vomiting	Yes	No
Diarrhoea	Yes	No

D. 15) List one more side effect that this medication could cause your child to have.

D. 16) What does the word 'contraindication' mean?

D. 17) What does the word 'overdosage' mean?

D. 18) What does the word 'hypersensitivity' mean?

D. 19) What is this medication for?

sore throat	Yes	No
allergies	Yes	No
vomiting	Yes	No
headache	Yes	No

D. 20) Indicate which part of the medication insert you find most difficult to understand

D.21) What do you think about the size of the writing on the page?

Too big	Too small	Correct size
---------	-----------	--------------

D. 22) Do you think there is any information missing from this medication insert?

Yes	no
-----	----

D. 23) If yes, what do you think should be added to the information already given?

	N/A
--	-----

E. 1) How often do you read the information on the Medication label (if given) before giving the medication to your child?

sometimes	always	never	not given
-----------	--------	-------	-----------

E. 2) If not, why not?

	N/A
--	-----

Please read the Panado™ label (on the box) and answer the following questions:

Participant is unable to read label due to:

inadequate literacy levels	Label not written in language participant reads (language_____)	N/A
----------------------------	---	-----

E. 3) Is it safe to give this medication to a child under the age of 6 years?

yes	no
-----	----

E. 4) How much can a child (age 6-12 years) be given at one time?

E. 5) After giving a child Panado™, do you have to wait before you give more Panado™?

yes	no
-----	----

E.6) If yes, how long do you have to wait?

E. 7) How many times in one day can you give this medication to a child (age 6-12 years)?

E. 8) What is the maximum amount of Panado™ a child (age 6-12 years) is allowed in one day?

E.9) After how many days of taking this medication should you call a doctor if your child's health is not improving?

E.10) What does the word 'mild' mean?

E.11) What does the word 'continuously' mean?

E. 12) Indicate which part of the medication label (on the box) you find most difficult to understand

E. 13) What do you think about the size of the writing on the box?

Too big	Too small	Correct size
---------	-----------	--------------

E. 14) Do you think there is any information missing from the label?

yes	no
-----	----

E. 15) If yes, what do you think should be added to the information already given?

	N/A
--	-----

F. 1) How often do you read the information on the Patient Information leaflet (if given) before giving the medication to your child?

sometimes	always	never	Medicines not given with PIL
-----------	--------	-------	------------------------------

F. 2) If not, why not?

	N/A
--	-----

Please read the Paracetamol Patient Information Leaflet and answer the following questions:

Participant is unable to read PIL due to:

inadequate literacy levels	PIL not written in language participant reads (language _____)	N/A
----------------------------	--	-----

F. 3) At what age is it safe to give this medication to a child?

F. 4) How much can the child be given at one time?

F. 5) After giving a child Panado™, do you have to wait before you give more Panado™?

yes	no
-----	----

F. 6) If yes, how long do you have to wait?

F. 7) How many times in one day can you give this medication to a child?

F. 8) What is the most amount of Panado™ a child can take in one day?

F. 9) Is it safe to take the medication when you are breastfeeding?

yes	no
-----	----

F. 10) After how many days of taking this medication should you call a doctor if your child's health is not improving?

F. 11) Can this medication cause your child to have:

Skin rashes	Yes	No
Vomiting	Yes	No
Tiredness	yes	No

F.12) List one more side effect that this medication could cause your child to have.

F. 13) What does the word 'exceed' mean?

F. 14) What does the term 'side effect' mean?

F. 15) What the word 'allergic' mean?

F. 16) What is this medication for?

headache	Yes	No
Tooth ache	Yes	No
dizziness	Yes	No
body pain	yes	No

F. 17) Indicate which part of the PIL you find most difficult to understand

F. 18) What do you think about the size of the writing on the page?

Too big	Too small	Correct size
---------	-----------	--------------

F. 19) Do you think there is any information missing from the PIL?

yes	no
-----	----

F. 20) If yes, what do you think should be added to the information already given?

	N/A
--	-----

G. 1) Have you ever had to take your child to the doctor/ clinic/ hospital because your child became sick after taking the medication you gave him/ her?

yes	no
-----	----

G. 2) If yes, what medication did he/she take?

	N/A
--	-----

H. 1) Which form of information (PIL, medication insert or label) do you find easiest to read?

label	PIL	Medication insert
-------	-----	-------------------

H. 2) Do you think that the current information provided with medication gives you enough information about the health risks of the medication and dosing requirements for children?

yes	no
-----	----

H.3) Why?

H. 4) From which sources would you like more information about the dosage requirements and risks of over-the-counter medication?

Written information with medication	yes	no
Pharmacist	yes	no
advertising	yes	no
Friends and family	yes	no

H. 5) Would you find the information easier to understand if it was written in another language other than English/ Afrikaans?

Yes	No
-----	----

H. 6) If your child developed an allergic reaction after taking the medication what would you do?

H. 7) Do you think over-the-counter medicines are dangerous?

yes	no
-----	----

H. 8) Why?

Thank you for taking the time to complete this questionnaire.

2. Questionnaire (Pharmacist)

Respondent No:

Date of interview:

Place of interview:

Demographic Information:

A.1) Date of Birth:

A.2) Gender (please tick):

Male	Female
------	--------

A.3) Home language:

A.4) Type of Facility (please tick)

Public	Private	General store
--------	---------	---------------

A.5) Degree/ highest level of training:

A.6) Position (e.g. Pharmacist, Head of Dept, etc)

A.7) Pharmacy location

A. 8) How long have you worked at this pharmacy?

Questions:

COMMON PAINKILLERS

B.1) What are the most common over-the-counter painkiller medications sold/ administered in your dispensary to those in higher socioeconomic groups? (please list top 3)

B. 2) What are the most common over-the-counter painkiller medications sold/ administered in your dispensary to those in lower socioeconomic groups? (please list top 3)

B. 3) What is the most common over-the-counter medication that you recommend for people from a higher socio-economic group:

Children with a fever?

Children with a headache?

B. 4) What is the most common over-the-counter medication that you recommend for people from a lower socio-economic group:

Children with a fever?

Children with a headache?

B.5) If there is a difference between socioeconomic groups, why is there a difference?

	N/A
--	-----

GENERICIS

C.1) Are the following generics sold in re-packaged containers/ packets to the general public from this pharmacy? (please tick)

Paracetamol	Yes	No
Aspirin	Yes	No
Ibuprofen	Yes	No

If you answered yes please answer the following questions:

C.2) Why are these over-the-counter medications re-packaged?

Paracetamol		N/A
Aspirin		N/A
Ibuprofen		N/A

C.3) How many tablets are sold in each container/ packet?

Paracetamol		N/A
Aspirin		N/A
Ibuprofen		N/A

C. 4) Are medical medication inserts included with the re-packaged medication? (please tick)

Paracetamol	Yes	No
Aspirin	Yes	No
Ibuprofen	Yes	No

C.5) Which socioeconomic group commonly buys re-packaged generics?

Higher socioeconomic	Lower socioeconomic	Both groups
----------------------	---------------------	-------------

C.6) Are Patient Information Leaflets included with the re-packaged medication? (please tick)

yes	no
-----	----

C.7) How are they included?

C.8) What do you do if a person asks for more information regarding medication?

INFORMATION PROVISION

D.1) What information do you believe is required to be included with all over-the-counter medication when sold to the public in order to prevent overdosing and side effects?

D.2) Do you provide different information to women who are pregnant compared to other groups of consumers?

Yes	no
-----	----

D.3) Why?

D. 4) Do you provide different information to clients buying/ obtaining medication for their children compared to the information given to other groups of consumers?

Yes	no
-----	----

D.5) Why?

D. 6) Please describe what you understand the following forms of information to be:

Medication label	
Medication insert	
Patient information leaflet	

D.7) When distributing to clients/ consumers, are labels provided with all OTC medicines?

Always	never	sometimes
--------	-------	-----------

D.8) When distributing to clients/ consumers, are medication inserts provided with all OTC medicines?

Always	never	sometimes
--------	-------	-----------

D.9) When distributing to clients/ consumers, are Patient information leaflets provided with all OTC medicines?

Always	never	sometimes
--------	-------	-----------

D.10) Do you think the following forms of information are effective in communicating health risks and dosage requirements to clients?

Medication labels	yes	no
-------------------	-----	----

D.11) Why?

D.12)

Medication inserts	yes	no
--------------------	-----	----

D.13) Why?

D.14)

Patient information leaflets	yes	no
------------------------------	-----	----

D.15) Why?

D.16) Do pharmacy assistants provide information to clients when selling/ providing OTC medicines?

Yes	no
-----	----

D.17) When are they expected to provide information to clients regarding OTC medicines?

D.18) Do pharmacy assistants and pharmacists provide the same information with OTC medication?

Yes	no
-----	----

D.19) If no, how does it differ?

	N/A
--	-----

D.20) What do you consider to be common problems experienced by clients when they administer OTC medication?

D.21) Do you think there is sufficient information provided with OTC medication to assist with these problems?

D.22) Do you think that overdosing of children with OTC medication is a problem?

Yes	no
-----	----

D.23) Why?

D.24) Do certain groups tend to ask for more information about OTC medicines than other groups?

Always	sometimes	never
--------	-----------	-------

D. 25) If yes, which groups tend to ask for more information?

MEDICATION INFORMATION

Please read the accompanying medication insert and answer the following questions:

E.1) Is it safe to give pain medication to children of the following ages?

0 – 3 months	yes	no
3 months – 1 year	yes	no

1 year – 6 years	yes	no
------------------	-----	----

E.2) If yes, how much can the child be given at one time?

0 – 3 months		N/A
3 months – 1 year		N/A
1 year – 6 years		N/A
6 years – 12years		N/A

E.3) How many times in one day can one give the medication to a child (aged 6-12 years)?

E.4) What is the maximum amount of pain medication a child (aged 6-12 years) is allowed in one day?

E.5) What does the word 'contraindication' mean?

E. 6) What does the term 'hepatic function' mean?

E. 7) What does the word 'cardiovascular' mean?

E.8) Are the following reported to be side effects of this medication?:

Skin rashes	Yes	No
Vomiting	Yes	No
Diarrhoea	yes	No

E.9) How often have customers reported to you in the last year that their child experienced side effects from the OTC medication they administered to their child?

Never	Less than 5 times	More than 5 times
-------	-------------------	-------------------

E.10) If they do report side effects, what are the side effects reported?

E.11) What is your opinion of the size of the writing in medication inserts?

E. 12) What is your opinion of the design of medication inserts?

LANGUAGE

F.1) How do you communicate information regarding safe use of over-the-counter medication to your customers/ patients if they speak a different language to you?

F.2) Do you think your current method of communication with those who speak another language is effective?

Yes	no
-----	----

F.3) Why?

F.4) Do you find it difficult to explain any definitions or terms found on medication labels or leaflets to patients/ customers?

Yes	no
-----	----

F.5) If yes, please describe which definitions or terms you find difficult to explain

F.6) From your experience, do you think that the general population is fully informed and aware of the risks regarding over-the-counter painkiller use? (please tick)

yes	no
-----	----

F.7) Why do you think that they are/ are not fully informed or aware of the risks regarding over-the-counter medication use?

F.8) Do you think the current way of communicating risks to caregivers is adequate enough to enable safe administration of OTC medication in children?

Yes	no
-----	----

F.9) Can you elaborate why or why not?

RECOMMENDATIONS

G.1) What recommendations do you suggest for making medication users more aware of the risks of over-the-counter medication, especially for low literate populations and populations who do not speak/read English and Afrikaans?

G. 2) What recommendations do you suggest for making medication users more aware of the dosing requirements of over-the-counter medication, especially for low literate populations and populations who do not speak/read English and Afrikaans?

G.3) Are there forms of communication other than labels, medication inserts or PIL's that you would recommend using for making medication users more aware of the risks of OTC medication?

Yes	no
-----	----

G.4) If yes, what are they?

	N/A
--	-----

G.5) Do you have any suggestions for improving the layout and design of the PILs, inserts and labels?

Yes	no
-----	----

G.6) If yes, what are they?

	N/A
--	-----

G.7) Is there any information that should be omitted from the medication inserts to encourage safer use of OTC medication?

Yes	no
-----	----

G.8) If yes, what should be omitted?

	N/A
--	-----

G.9) Is there any information that should be added to the medication inserts to encourage safer use of OTC medication?

Yes	no
-----	----

G.10) If yes, what should be added?

	N/A
--	-----

G.11) Where did you receive your training on how to explain to customers the information for OTC medication for:

PIL	
Medication insert	
Medication label	

G.12) Do you feel this training is sufficient?

Yes	no
-----	----

G.13) If no, how do you suggest it could be improved?

	N/A
--	-----

Thank you for taking the time to complete this questionnaire.

3. Informed consent (Caregiver)

Research Title

“But it’s just Paracetamol”: Caregivers’ ability to make informed decisions about administering over-the-counter painkillers to their children with the information provided

Introduction

My name is Fiona Gibson and I am a Masters of Public Health student at the University of Cape Town Working on my thesis. You are kindly invited to take part in our research study and we would like to ask for your permission to be included in the study. Please read the information below and let me know if you need any clarifications or have any concerns.

Background and reason for the study:

The purpose of this study is to find out if you have been given enough information about common painkillers when you have gotten them from the clinic or the shop, and if this information helps you to safely give the right amount of medication to your child, at the right times. We would also like to find out how well you understand the instructions given to you and if there is anything we can recommend to the pharmaceutical companies to make the information easier to understand. Your participation in the study will therefore assist us in improving the information provided with medicines.

What will be required of you should you choose to be a part of the study?

You have been chosen to participate in the study because you are a caregiver who attends a group or clinic at Jubilee Community Church. If you choose to take part in the study, you will be asked to answer a few questions in a questionnaire, which will include details such as where you live and your level of schooling, as well as other questions such as what kind of medication do you give your child or whether you are aware of the risks of the medication. The questionnaire should take approximately 15 minutes to complete.

What are the benefits of participating in the study?

There are no major individual benefits of participating in the study; however, an information leaflet about how to safely use over-the-counter medication will be given to you, which could be beneficial for the health of your child in the future.

The group that you attend will be given a gift to thank you for your time given to participate in the study. On a larger scale, the researcher is hoping to publish the findings so that others in the medical profession can understand more about what information is needed for caregivers when they are providing medication to their children.

What are the risks of participating in the study?

The investigator is not aware of any risks of participating in the study.

What if you agree to participate in the study and then decide that you do not want to continue being a part of it?

You are completely free to stop participating in the study at any time. This means that if you are in the middle of completing the questionnaire, you will not be forced to answer any questions that you are not comfortable to finish or if you have completed the questionnaire and wish for your answers to be taken out of the study, please feel free to contact the investigator. For any questions or comments, you can contact the investigator on the following number or email address:

Name: Fiona Gibson

Tel: 0741714014

Email: gibson.fa@gmail.com

If you would like to contact the board of ethics with any questions or concerns please feel free to contact them. Their contact details are available here:

Research Office at the University of Cape Town Faculty of Health Sciences

Tel: 021 650 4015

Confidentiality and anonymity

All questionnaires will be kept in a secure area and all information will remain confidential i.e. the investigator will not discuss or reveal any of your personal information or answers with anyone in the group or anyone else not involved with the study. All questionnaires will be completely anonymous i.e. the identity of who filled in each questionnaire will not be known by the investigator or the public. I will also not mention that the study was done in Jubilee Church so that no one knows that the study was done here.

If you are willing to participate in the study, please continue to the informed consent section below.

Informed consent

Participant

This consent form has been clearly explained to me, all of my questions have been clearly answered and I understand all of its contents. I understand that my participation in the study is voluntary. I understand that I do not have to answer any question that I feel uncomfortable answering and am free to withdraw from the study at any time, without anyone asking my reasons for leaving. I know that I can contact the researchers if I have any questions about the study, or if I would like to withdraw from the study. I understand that all information will remain confidential and anonymous.

I give consent to participate in this study.

Name and Signature (Participant):

Date:

Investigator

I declare that this document was thoroughly explained to the participant and all questions were answered in full.

Name and Signature (Investigator):

Date:

4. Informed consent (Pharmacist)

Research Title

“But it’s just Paracetamol”: Caregivers’ ability to make informed decisions about administering over-the-counter painkillers to their children with the information provided

Introduction

My name is Fiona Gibson and I am a Masters of Public Health student at the University of Cape Town Working on my thesis. You are kindly invited to take part in our research study and we would like to ask for your permission to be included in the study. Please read the information below and let me know if you need any clarifications or have any concerns.

Background and reason for the study:

The purpose of this study is to find out where caregivers obtain their medication from and what type of medication they commonly use. We would also like to determine whether caregivers have enough information about common painkillers when they have obtained them from the clinic or the shop, and if this information helps them to safely give the right amount of medication to their child, at the right times. We would also like to find out how well they understand the instructions given to them and if there is anything we can recommend to the pharmaceutical companies to make the information easier to understand. Your participation in the study will therefore assist us in improving the information provided with medicines.

What will be required of you should you choose to be a part of the study?

You have been chosen to participate in the study because you are a representative of a pharmaceutical service provider commonly used by caregivers in our study. If you choose to take part in the study, you will be asked to answer a few questions in a questionnaire, which will include details such as your position and level of training, as well as other questions such as what kind of medication do you provide to caregivers and what type of information is given with over-the-counter medication. The questionnaire should take approximately 15 minutes to complete.

What are the benefits of participating in the study?

There are no major individual benefits of participating in the study; however, a journal article detailing the findings of the study as well as any further recommendations for pharmacists will be sent to you via post. On a larger scale, the investigator is attempting to provide more research on this topic which can potentially be used to inform policy makers of what information is needed for caregivers when they are providing medication to their children.

What are the risks of participating in the study?

The investigator is not aware of any risks of participating in the study. The questionnaire may require you to be away from work tasks for approximately 15 minutes, however your work schedule will be accommodated and the investigator will only administer the questionnaire at your convenience.

What if you agree to participate in the study and then decide that you do not want to continue being a part of it?

You are completely free to discontinue participating in the study at any time. This means that if you are in the middle of completing the questionnaire, you are also not obligated to answer any questions that you are not comfortable to finish or if you have completed the questionnaire and wish for your answers to be taken out of the study, please feel free to contact the investigator. For any questions or comments, you can contact the investigator on the following number or email address:

Name: Fiona Gibson

Tel: 0741714014

Email: gibson.fa@gmail.com

If you would like to contact the board of ethics with any questions or concerns please feel free to contact them. These are their contact details: Research Office at the University of Cape Town Faculty of Health Sciences

Tel: 021 650 4015

Confidentiality and anonymity

All questionnaires will be kept in a secure area and all information will remain confidential i.e. the investigator will not discuss or reveal any of your personal information or answers with anyone not working on the study. All questionnaires will be completely anonymous i.e. the identity of who filled in each questionnaire will not be known by the investigator, your employer or the public, and your facility will also remain unnamed. Individuals outside of the study will only know whether your facility is in the private or public sector. Participating in this study will not influence your work in any way and no information given in the questionnaire will be given to your employer or employees.

If you are willing to participate in the study, please continue to the informed consent section below.

Informed consent

Participant

This consent form has been clearly explained to me, all of my questions have been answered and I understand all of its contents. I understand that my participation in the study is voluntary. I understand that I do not have to answer any question that I feel uncomfortable answering and am free to withdraw from the study throughout the whole research process. I know that I can contact the researchers if I have any questions about the study, or if I would like to withdraw from the study. I understand that all information will remain confidential and anonymous.

I give consent to participate in this study.

Name and Signature (Participant):

Date:

Investigator

I declare that this document was thoroughly explained to the participant and all questions were answered in full.

Name and Signature (Investigator):

Date:

5. Letters of Approval from Research Ethics Committee



UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Faculty of Health Sciences Human Research Ethics Committee
Room 852 24 Grootte-Straat Hospital Old Main Building
Observatory 7925
Telephone (021) 406 6238 • Facsimile (021) 406 6411
e-mail: approval_erie@uct.ac.za

22 November 2012

HREC REF: 500/2012

Ms F Gibson
Public Health & Family Medicine
Falmouth Building
FHS

Dear Ms Gibson

PROJECT TITLE: "BUT IT'S JUST PARACETAMOL": CARERS' ABILITY TO ADMINISTER OVER-THE-COUNTER PAINKILLERS TO THEIR CHILDREN WITH THE INFORMATION PROVIDED

Thank you for addressing the issues raised by the Human Research Ethics Committee.

It is a pleasure to inform you that the Ethics Committee has formally approved your collaboration in the above mentioned study.

Approval is granted for one year till the 28 November 2013.

Please submit a progress form, using the standardised Annual Report form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC REF in all your correspondence.

Yours sincerely

Signature removed

PROFESSOR M. BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: TWAG0031637
Institutional Review Board (IRB) number: BUC0001038
Date: 2012



STRATEGY & HEALTH SUPPORT

Western Cape Government
PO Box 12021, 8012, Cape Town, South Africa
111 Putney, Newlands, 7800, Cape Town, 8021
www.westerncape.gov.za

REFERENCE: RF 156/2012
TO: QUINCY Mx Co-facilitator

2 Faure Clouse
Dop River
Cape Town
7800

For attention: Miss Tanya Glover and Dr. Maria-Andreia Fuller

Re: But It's Just Paracetamol? Caregivers' ability to administer over-the-counter painkillers in their children with the information provided

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the decision has been made in your favour for your research.

Please contact the following people to discuss any and further enquiries in following the following steps:

Gugulethu CHC	Katy Maurie	021- 632 0020
Dr. Abdurhman	S. BV Julius	021-637 9071

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities are requested to be suspended if needed.
2. Researchers, in accessing provincial health facilities, are expressing concern to provincial health department with an electronic copy of the final report within 6 months of completion of research. This can be submitted to the provincial Research Co-ordinator (hr@mms2@wcg.gov.za).
3. The reference number above should be quoted in all future correspondence.

Yours sincerely

Signature removed

DR NE Naledi
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE: 17/12/2012
CC DR G PEREZ

ACTING DIRECTOR: ALPH ONTEIN V, MITCHELLS PLAIN

Page 1 of 1

6. Submission instructions for author for Patient Education and Counseling

Source: <http://www.elsevier.com/journals/patient-education-and-counseling/0738-3991/guide-for-authors>

Invitation to contributors

Patient Education and Counseling is an interdisciplinary, international journal for patient education and health promotion researchers, managers, physicians, nurses and other health care providers. The journal seeks to explore and elucidate educational, counseling and communication models in health care. Its aim is to provide a forum for fundamental as well as applied research, and to promote the study of the delivery of patient education, counseling, and health promotion services, including training models and organizational issues in improving communication between providers and patients.

Patient Education and Counseling is the official journal of the European Association for Communication in Healthcare (EACH) and the American Academy on Communication in Healthcare (AACH).

Definitions

Patient education is defined as a planned learning experience using a combination of methods such as teaching, counseling, and behavior modification techniques which influence patients' knowledge and health and illness behavior. Patient counseling is an individualized process involving guidance and collaborative problem-solving to help the patient to better manage the health problem. Patient education and counseling involve an interactive process which assists patients to participate actively in their health care. Clinical health promotion is a part of the patient education and counseling defined as that which predisposes, enables, and reinforces patients to take greater control of the non-medical determinants of their own health.

Submission of Manuscripts

The journal welcomes unsolicited manuscripts related to the field of patient education, counseling, clinical health promotion and communication in health care.

Patient Education and Counseling uses an online, electronic submission system. By accessing the website <http://ees.elsevier.com/pec> you will be guided stepwise through the creation and uploading of the various files. When submitting a manuscript to Elsevier Editorial

System, authors need to provide an electronic version of their manuscript. Authors may send queries concerning the submission process, manuscript status, or journal procedures to the Editorial Office. Once the uploading is done, the system automatically generates an electronic (PDF) proof, which is then used for reviewing. All correspondence, including the Editor's decision and request for revisions, will be by e-mail.

Manuscript Categories

During online submission, the author can select a category from the following list: Review, Original Article, Educational or Counseling Model, Short Communication, Book Review or Letter to the Editor, Reflective practice or Medical Education. The type of manuscript should be indicated in the cover letter.

Original Articles - Preference is given to empirical research which examines such topics as adherence to therapeutic regimens, provider-patient communication, patient participation in health care, degree of social support, decision-making skills, anxiety, physiological changes, or health/functional status (maximum 4000 words not including references and tables). Both descriptive and intervention studies are acceptable.

Review Articles (Current Perspectives) - In-depth reviews of the empirical research in one facet of the patient education and counseling including an analytical discussion of contemporary issues and controversies in patient education and counseling (maximum 5000 words not including references and tables).

Educational Model of Health Care - Case studies of innovative programs which exemplify the educational model of health care, for example, self-care groups, patient advocacy efforts, medication self administration programs and co-operative care units (maximum 2000 words not including references and tables).

Short Communications in any of the above categories will also be considered (maximum 1500 words not including references and tables).

Reflective practice - The Reflective Practice section includes papers about personal or professional experiences that provide a lesson applicable to caring, humanism, and relationship in health care. We welcome unsolicited manuscripts. No abstract is needed. No (section) headings, no numbering. Maximum 1500 words. First name and surname of the author and his/her institution affiliation address, telephone and fax number and e-mail

address where the corresponding author can be contacted, title of the papers and text.

Submissions will be peer-reviewed by two reviewers.

All authors must include *one* of these two statements at the end of their manuscript:

(1) " I 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."

OR

(2) " I confirm that the patient/person(s) have read this manuscript and given their permission for it to be published in *PEC*".

For further information on the Reflective Practice section see: Hatem D, Rider EA. Sharing stories: narrative medicine in an evidence-based world. *Patient Education and Counseling* 2004; 54:251-253.

Medical Education - Articles on medical education focus on educational efforts that target experiences, programmes and educational research on the teaching/training and evaluation of interpersonal/communication skills of health care providers and their attitudes and skills needed for optimal communication.

Manuscript Organization

Manuscripts should be organized as follows:

Title page, Abstract, 1. Introduction, 2. Methods, 3. Results, 4. Discussion and Conclusion, References, Legends.

Keep text, graphics and tables as separate files - do not import the figures and tables into the text file. Tables and Figures should be uploaded as separate table files and separate figure files. Acknowledgments for technical assistance should be indicated on the title page.

Financial Support and any conflict of interest should be indicated in the acknowledgments.

All articles and reviews must have a structured abstract not exceeding 150-200 words and appropriate keywords. Abstracts should adhere to the following format: **Objective,**

Methods, Results, Conclusion, Practice Implications.

Articles must be in electronic format (double-spaced).

The title page should include a concise and **informative title, first name and surname of the first author and his/her institution affiliation address. Please also provide an address, telephone and fax number and e-mail address where the corresponding author can be contacted. For co-authors, mention only first name and surname of their institution affiliation, but no address.**

Footnotes to the text should be avoided.

Discussion and Conclusion should be headed as one section and divided into three parts.

Example: 4. Discussion and Conclusion, 4.1. Discussion, 4.2. Conclusion. 4.3 Practice Implications

Practice Implications

Articles should include a paragraph or paragraphs entitled 'Practice Implications' as part of the discussion and conclusion, which outlines the implications for practice suggested by the study. Authors should take care that these implications follow closely from the data presented, rather than from other literature. In the event that an article presents very preliminary data or conclusions, these paragraphs may be omitted.

References

Reference citations should be numbered consecutively throughout using Arabic numerals in parentheses or square brackets (not superscripts). References should be double-spaced and start on a separate page. References should conform to the system used in Uniform Requirements for Manuscripts Submitted to Biomedical Journals (Brit Med J 1991;302:338-41; N Engl J Med 1991;324:424-8), using standard abbreviations of the journal titles cited in Current Contents.

[1] Rosenberg SG. Patient education leads to better care for heart patients. HWA Health Rep 1971;86:793-802.

[2] Worden JW. Grief counseling and grief therapy: a handbook for the mental health practitioner. New York City: Springer, 1982.

[3] Greenfield S, Kaplan S, Ware JE. Expanding patient involvement in care: effects on patient outcomes. Ann Intern Med 1985;102:520-8.

[4] Schwarzer R. Self-efficacy in the adoption and maintenance of health behaviors:

theoretical approaches and a new model. In: Schwarzer R, ed. Self efficacy: thought control of action. Washington, DC: Hemisphere, 1992;217-42.

Note All authors' names should be listed. Issue numbers should not be included.

Headings

Headings should be arranged in hierarchically manner according to the following plan:

- first level, numbered 1., 2., etc., first letter capitalized, all other letters lower case;
- second level, numbered 1.1., 1.2., 2.1., etc., first letter capitalized, all other letters lower case;
- third level, numbered 1.1.1., 1.1.2., 2.1.1., etc., first letter capitalized, all other letters lower case;
- fourth level (if really necessary), not numbered, paragraph indent, runs onto text.

Figures

Research articles may include a figure, which outlines the sequence of recruitment, measurements, and interventions, indicating the number of subjects at each stage, etc. **Figures of good quality should be submitted online as a separate file.** The lettering should be large enough to permit photographic reduction. Legends should be typed together on a separate page in the electronic manuscript. If a figure cannot be submitted online, a hardcopy may be sent to:

Elsevier Ireland Ltd., Brookvale Plaza, East Plaza, Shannon, Co. Clare, Ireland, Fax: +353 61 709250, PEC@elsevier.com. This address should also be used to submit multimedia files

Tables

Tables should be submitted **online as a separate file** and should bear a short descriptive title. Legends for each table should appear on the same page as the table.

Policy and Ethics

For work described in your article involving human experimental investigations of any kind, must have been carried out in accordance with The Code of Ethics of the Declaration of Helsinki; <http://www.wma.net/e/policy/b3.htm>