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M. Himmelstein ^a, T. Miron-Shatz ^b, Y. Hanoch ^c & M. Gummerum ^c

^a Center for Research on Child Wellbeing, Princeton University, Princeton, USA

^b Center for Medical Decision Making, Ono Academic College, Kiryat Ono, Israel

^c School of Psychology, University of Plymouth, UK

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Over-the-counter cough and cold medicines for children: A comparison of UK and US parents' parental usage, perception and trust in governmental health organisation

M. Himmelstein^a, T. Miron-Shatz^b, Y. Hanoch^{c*} and M. Gummerum^c

^aCenter for Research on Child Wellbeing, Princeton University Princeton, USA; ^bCenter for Medical Decision Making, Ono Academic College, Kiryat Ono, Israel; ^cSchool of Psychology, University of Plymouth, UK

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In 2008, the Medicines and Healthcare products Regulatory Agency (MHRA) issued guidelines discouraging use of over-the-counter cough and cold medications in children under six. In light of these recommendations, this study assessed whether parents had heard of the MHRA recommendations and whether they trusted those recommendations. It also examined parental knowledge, perception and behaviours associated with over-the-counter cough and cold medication use in children. In a sample ($N = 941$) of UK parents, one-third (36.5%) had not heard about the MHRA recommendations. Half (54.4%) of parents who were aware of the recommendations did not trust them or were unsure what to believe. UK parents with children under six showed widespread (86.9% of sample) use of over-the-counter cough and cold medications with children. Many parents were able to identify one active ingredient in the over-the-counter cough and cold medication they reported using with their children yet few were able to identify all of the active ingredients. Despite ubiquitous use of over-the-counter cough and cold medication with children, only 29.6% of parents rated the medication as very effective, and just half (50.3%) rated the medication as very safe. In a subsample of UK parents ($N = 424$), 70% misunderstood the purpose of using over-the-counter cough and cold medication with children.

Keywords: risk; risk communication; public health; risk perception; over-the-counter medicines

Introduction

In 2008 the Medicines and Healthcare products Regulatory Agency (MHRA) issued a statement, suggesting the treatment of coughs and colds with paracetamol or ibuprofen in children under six, and simple cough remedies (glycerol, honey, lemon) and saline drops in children under two.¹ The MHRA advised parents to discontinue use of certain cough and cold medicines in young children. The pharmaceutical industry in the UK subsequently responded by pulling medications from the market and instituting label changes for use of these medicines with children under six (MHRA 2008a). The recommendations were widely publicised in their respective countries.

*Corresponding author. Email: yaniv.hanoch@plymouth.ac.uk

Three studies (NPR 2008, Hanoch *et al.* 2010, Miron-Shatz *et al.* 2010) have examined the reactions and adherence to similar recommendation put forth by the Food and Drug Administration (FDA) in the United States. They found that parents rely heavily on the use of over-the-counter cough and cold medication to treat coughs and colds in their children and, more importantly, that parents intend to continue treating their children with over-the-counter cough and cold medication despite the health warning. To date, there have been no similar studies in the UK, and it is unknown what the parental reactions to the MHRA warning were, and how those compare to reactions in the US. After all, the two countries differ on important aspects like health care coverage (Laugesen and Rice 2003), access to health care professionals, and possibly trust in governmental health agencies. This paper examines parents' trust of the medical system and its representatives as an indicator of adherence to the MHRA warning. In addition, we map UK parental usage patterns of over-the-counter cough and cold medication: parents' knowledge of active ingredients, whether they use more than one drug with their children, side effects of over-the-counter cough and cold medication usage, and perceived safety.

On trust and adherence

Trust is a crucial aspect of health-related decision making (O'Neill 2002, Mechanic 2004, Hanoch *et al.* 2010). Trust in governmental health agencies is especially important, as the cases of genetic research (Barnett *et al.* 2007) and child vaccination have previously illustrated. In the UK, parents' decision not to vaccinate against measles, mumps, and rubella (MMR), despite assurances and campaigns by the UK government, stemmed largely from parents' lack of trust in messages about the safety of these vaccinations (Casiday 2006, Casiday *et al.* 2006, Hobson-West 2007). A growing corpus of data (e.g., Williams and Noyes 2007) has shown that trust is a key moderating variable between risk perception and decision making.

Studies on trust have largely focused on patients' attitudes toward their general practitioner or primary care physician and less about their trust in governmental health agencies. Mechanic (2004) suggests trust in large organisations is equivalent to trust in government and business, which tends to be low. Walls *et al.* (2004) cite various studies indicating that as the level of abstraction of the institution goes up so trust falls (e.g. 'government scientists' or 'local authorities' vs. 'department of health'). Walls and his colleagues further elaborate on the notion of trust, suggesting that various agencies elicit not only different degrees of trust, but also different trust patterns, as evident by critical trust, which marks the extent to which the agency is considered effective.

Lack of trust in health care institutions may result from decreases in public satisfaction with healthcare reform (Taylor-Gooby *et al.* 2003, Taylor-Gooby 2006). Rather, patients place their trust in their doctor because they have a personal relationship with their doctor and view them as their ally (Mechanic 2004). That is, trust in doctors over health care institutions stems from the direct interaction between patients and doctors as opposed to intangible interaction with removed institutions (Brown 2009).

The discrepancy between caretaker and institution is also apparent across professions. A study by Calnan and Sanford (2004) compared trust in health service managers to trust in the general practitioner/primary care physician. They found trust in the general practitioner/primary care physician to be relatively high

compared to low trust in health service managers (see also Calnan and Rowe 2004), which Calnan and Sanford (2004) equate with trust in the overall healthcare system. Similarly, Brown and Calnan (2010) suggest that patients have little trust in broad systems or institutions (i.e. pharmaceutical companies, FDA, MHRA), in part, because those institutions are faceless to them. Rather, patients rely on recommendations from their general practitioner/primary care physicians about messages from these broad institutions and thereby rely only indirectly on the institutions. Given that the new guidelines regarding over-the-counter cough and cold medication consumption have been issued by governmental agencies rather than by general practitioners/primary care physicians, it is important to determine the degree to which parents trust the MHRA message and intend to adhere to the new guidelines. Indeed, adherence to the MRHA over-the-counter cough and cold medications guidelines might depend on parents' trust of the agency.

A study by Jackson, Putnam & Twohig (2004) revealed that even doctors sometimes express lack of trust in treatment recommendations (especially if they stem from pharmaceutical companies) because of the perceived vested interests of the organisations from which the recommendations come. This could prove important, as the MHRA recommendations were reinforced by pharmaceutical companies who either withdrew their products from the market or changed their package labels. As such, it is possible that the public trust in the MRHA recommendation was eroded due to its perceived affiliation with pharmaceutical companies.

Over-the-counter cough and cold medication: Information search and risk perception

Colds are one of the most common illnesses experienced by children (Heikkinen and Järvinen 2003), and parents frequently use over-the-counter cough and cold medications, with millions of packages sold each year, to alleviate their children's symptoms (Kogan *et al.* 1994, Kaufman *et al.* 2002). Prior to the FDA and MHRA warnings, over-the-counter cough and cold medications were considered safe when used properly and to have low absolute risk. Additionally, package labels clearly advised parents to use over-the-counter cough and cold medications only in children under two years old under medical supervision. On the other hand, little clinical evidence exists to support their efficacy (Taylor *et al.* 1993, Clemens *et al.* 1997), nor have they been extensively tested among paediatric populations (Smith and Feldman 1993).

Despite label instructions about storage and administration, Schaefer *et al.* (2008) found that both unsupervised over-the-counter cough and cold medication consumption by children two to five years of age and caretakers' inappropriate administration (e.g., giving a higher dosage than recommended) accounted for most visits to the hospital emergency department due to an adverse drug event. In another comprehensive study (Dart *et al.* 2009), a panel of experts assessed (using medical literature, manufacturer adverse event reports, National Poison Database system of the American Association of Poison Control Centers, FDA briefing materials, and citizens' petitions to the FDA) the possible involvement of over-the-counter cough and cold medication in child deaths. Based on data from over 30 years, the panel identified a total of 118 cases, with 82 of them that could possibly relate to over-the-counter cough and cold medication. Their results also showed that the majority of cases were among children under the age of 2 (75%), that 17% of the cases could be attributed to self administration by the children and to parents' failure to follow

instructions (e.g., giving two products that contain similar ingredients and incorrect measuring).

Others have reported that between 2004 and 2005, 1500 children under two were admitted to emergency rooms due to adverse reactions from over-the-counter cough and cold medication (Centers for Disease Control and Prevention 2007, Brown 2008). In 2007, the FDA completed a review that uncovered a total of 54 reported child deaths from decongestants and 69 from antihistamines between 1969 and 2006; most of these involved children under two (Akhayan-Toysekani *et al.* 2007). Surprisingly, little data exist regarding children in the UK. Despite ubiquitous usage of over-the-counter cough and cold medication in the UK (an estimated 77 million packages are sold each year), relatively few side effects have been reported to the MRHA (2008b). Brown and Calnan (2010) suggest that consumers maintain confidence in the drugs they use, based on repeated positive experiences with those drugs. High confidence in over-the-counter cough and cold medications may be a particular problem for UK parents in light of the MHRA regulations, given the low incidence of reported side effects, which suggests repeated positive experiences and few negative experiences.

The primary aim in our study was to assess parental awareness of the MHRA recommendations and the extent to which they trust them. We were also interested in parents' behavioural tendencies with regard to over-the-counter cough and cold medications: whether they give more than one drug, their ability to reduce the risk of adverse drug events (e.g., knowing the active ingredients in their child's medication), their risk perception (e.g., how safe they consider over-the-counter cough and cold medications, how often side effects are experienced), and their comprehension of the purpose of over-the-counter cough and cold medications.

Method

Participants

Prior to data collection we obtained approval for the research protocol from the appropriate Institutional Review Boards. Participants included 941 parents with children under the age of six, residing in the UK. The rate of survey attrition was 25.1% ($n = 217$) over the course of the survey. No patterns of attrition were noted within the data. In terms of gender (total gender $n = 665$), 81.5% of participants were female and 18.5% were male. We opted not to compare men and women given the oversample of women. Additional demographic information may be found in Table 1.

The MHRA recommendations appeared in March 2008. Participants were recruited in several waves over a period of six months (June–November 2008) through an online advertisement on the popular social networking website Facebook, which described an opportunity to win a £25 gift certificate to Amazon.co.uk by completing a survey for parents with children under six. The online advertisements targeted men and women 24 years of age or older, with children. All participants indicated they had at least one child. Participants collected in separate waves did not exhibit any differences.

Materials and procedure

Participants completed an online survey that included open-ended questions, multiple-choice questions (some allowed multiple answers), and demographic

Table 1. Sample demographics.

| | <i>N</i> | <i>M (SD)</i> |
|----------------------|------------------|---------------|
| Age | 580 ^a | 33.32 (5.80) |
| Number of children | 785 | 2.02 (1.08) |
| | <i>N</i> | <i>%</i> |
| Income | | |
| <£10,000 | 82 | 11.9% |
| £10,001–20,000 | 137 | 19.9% |
| £20,001–30,000 | 163 | 23.7% |
| £30,001–40,000 | 117 | 17.0% |
| >£40,000 | 189 | 27.5% |
| Education | | |
| O level ^b | 159 | 22.9% |
| A level ^c | 78 | 11.3% |
| Diploma/certificate | 104 | 15.0% |
| University degree | 181 | 26.1% |
| Professional | 120 | 17.3% |
| | 51 | 7.4% |

^aAge was an optional question, 361 participants declined to answer.

^bO level (or ordinary level) refers to exam taken at age 16 (known now as GCSE).

^cA level (or advance level) refers to an exam taken at age 18.

questions about themselves and their children (see Appendix 1). Questions regarding behaviours associated with over-the-counter cough and cold medication use in children were specifically asked about the parent's youngest child. The questions were based on those from an earlier survey by Hanoch *et al.* (2007, 2010) and modified to fit the current study. As our study had two related but separate aims, the survey was designed to tap into these two domains. The first segment of the survey was geared to study parents' knowledge, perception and behaviour with respect to over-the-counter cough and cold medication medications. The second part dealt with awareness of and trust in the MHRA recommendations.

Medication actions and identification of active ingredients

To avoid parents' misidentification of over-the-counter cough and cold medication with other drugs (e.g., pain killers, allergy medication), we provided the names of 12 drugs that modified packaging after the MHRA regulation was released. Parents were asked to check off all drugs they administered to their youngest child when the child was sick.²

Since accidental drug overdose (giving two different drugs that contain the same active ingredient) has been identified as a cause of adverse drug events, we assessed participants' awareness of active ingredient(s). Participants were provided the names of 18 different active ingredients (see Appendix 1), though we did not explain what active ingredients mean, and asked to identify ones in the over-the-counter cough and cold medication(s) they checked off in the preceding question. The names of the 18 active ingredients were taken from MHRA report (2008b) as they represented the main pharmacologically active ingredients used over-the-counter cough and cold medication in the UK, and possibly implicated in causing harm.

We also applied more stringent criteria for knowledge (participants had to identify all active ingredients in the over-the-counter cough and cold medication(s) without including incorrect ingredients) for two reasons. The first is that the likelihood of identifying at least one active ingredient in any over-the-counter cough and cold medication increases as the number of over-the-counter cough and cold medications administered increases. The second is that parents must know all of the active ingredients in the multiple medications they use, if they are to prevent accidental overdose and other adverse side effects.

Effectiveness, perceived safety, and side effects of over-the-counter cough and cold medication

Parents indicated how effective the over-the-counter cough and cold medications were for treating their child's cough or cold on a Likert scale ranging from 1 (*not effective at all*) to 5 (*very effective*). Parents similarly indicated how safe they considered over-the-counter cough and cold medications on a Likert scale ranging from 1 (*not safe at all*) to 5 (*very safe*). Finally, parents indicated the frequency of side effects experienced by the child after administration of over-the-counter cough and cold medications, measured on a Likert scale ranging from 1 (*never*) to 5 (*always*).

Comprehension

A subset of participants (recruited in November 2008: $n = 424$) indicated what they believed over-the-counter cough and cold medications were supposed to do for their child. Response options were: 'cure and shorten illness', 'shorten illness', 'cure illness', and 'neither cure nor shorten illness'.

MHRA recommendation: Knowledge and trust

Participants first indicated whether or not they heard of the MHRA's recommendation that non-prescription cough and cold preparations should not be used in children under two years of age ('yes, I have heard' or 'no, I have not heard'). We opted to ask about knowledge of the MHRA recommendations in children under two, as opposed to children under six, because the strictest MHRA recommendations were issued for children under two. That is, the MHRA recommended that paracetamol and ibuprofen may be used in children under six, and that children under two should only receive treatment for coughs and colds in the form of glycerol, honey, lemon and saline drops. Participants then indicated the degree to which they trusted the recommendation on a Likert scale ranging from 1 (*highly doubt the recommendation*) to 5 (*highly trust the recommendation*). The middle point (3) was '*I am unsure about the recommendation*'.

Findings

We organised the results section into four parts: First, refers to the section on awareness of the MHRA recommendations and trust (MHRA recommendation: Knowledge and trust) and the remaining three sections deal with parental knowledge, perception and behaviors related to the use of OTC-CCM in children: Medication actions and identification of active ingredients, effectiveness, perceived safety, and side effects of over-the-counter cough and cold medication, and comprehension.

MHRA recommendation: Knowledge and trust

A large portion of the sample ($n = 343$, 36.5%) had not heard of the MHRA recommendations; an additional 217 (25.1%) quit the survey before reaching this section. In order to detect differences between parents who knew about the recommendations and parents who did not, we conducted t tests on education, age, income, belief in effectiveness of over-the-counter cough and cold medication, comprehension of over-the-counter cough and cold medications' purpose, number of children, and gender of youngest child. None of these tests yielded significant results. In the following analyses, we included only participants who were aware of the MHRA recommendations and who indicated giving over-the-counter cough and cold medications to their children in the survey ($n = 349$), unless otherwise indicated. Of these participants, 54.4% ($n = 190$) reported not trusting the MHRA recommendations or were not sure whether to trust them.

A linear regression predicting trust in the recommendations by belief in over-the-counter cough and cold medication effectiveness, age, income, education, number of children, number of over-the-counter cough and cold medications administered, gender of child, comprehension of the purpose of over-the-counter cough and cold medication, and possession of private health insurance did not yield any statistically significant predictors.

Medication actions and identification of active ingredients

The vast majority of parents (86.9%, $n = 818$) administered at least one over-the-counter cough and cold medication to their children, and 61.5% ($n = 579$) gave two or more over-the-counter cough and cold medications; only 13.1% ($n = 123$) reported not giving over-the-counter cough and cold medications to their children. A series of t tests and one-way ANOVAs revealed no demographic (income, age, education) differences among parents who administer only one over-the-counter cough and cold medication, two or more over-the-counter cough and cold medications, or no over-the-counter cough and cold medications.

Most parents ($n = 582$ of 818, 71.1%) who administered at least one over-the-counter cough and cold medication to their child were able to correctly identify at least one active ingredient in that medication, but only 29% ($n = 237$ of 818) were able to identify all active ingredients. The most common active ingredients identified were ibuprofen ($n = 328$) and paracetamol ($n = 526$). Of the parents who gave multiple (two or more) over-the-counter cough and cold medications to their children (61.5%, $n = 579$, of our sample reported doing so), 77.7% ($n = 450$) correctly identified at least one active ingredient, but only 22.3% ($n = 129$) were able to identify all the active ingredients in all medications.

We conducted two chi-square tests on correct identification of active ingredient(s) between parents administering only one over-the-counter cough and cold medication ($n = 239$) and parents administering two or more ($n = 579$). The first test indicated that parents who administered two or more over-the-counter cough and cold medications ($n = 450$ of 579) were more likely to recognise at least one active ingredient in any over-the-counter cough and cold medications administered to their children than parents who administered only one over-the-counter cough and cold medication, ($n = 132$ of 239), χ^2 (1, $n = 818$) = 41.69, $p < .0001$. This finding may be due to the increased probability of choosing one

correct ingredient when giving more than one medication. As for correct identification of *all* ingredients, parents administering only one over-the-counter cough and cold medication fared better ($n = 108$ of 239) than parents administering more than one ($n = 129$ of 579), χ^2 (1, $n = 818$) = 43.14, $p < .0001$.

Effectiveness, perceived safety, and side effects of over-the-counter cough and cold medication

Despite the ubiquitous usage of over-the-counter cough and cold medications, only about a third of parents who administered one or more over-the-counter cough and cold medications (29.6%, $n = 242$) considered the medication extremely or very effective, whereas approximately half of the parents indicated that over-the-counter cough and cold medications were somewhat (38.1%, $n = 312$), slightly (13.0%, $n = 106$), or not at all (1.5%, $n = 12$) effective. This analysis does not include parents who did not use over-the-counter cough and cold medication ($n = 123$) or attrited before arriving at this question ($n = 146$). When asked about the safety of over-the-counter cough and cold medications, half of the parents (50.13%, $n = 372$) considered them 'very safe' and 37.87% ($n = 281$) responded 'somewhat safe', while 9.43% ($n = 70$) thought they were neither safe nor unsafe, and only 2.56% ($n = 19$) judged them as somewhat unsafe or not safe at all. Fewer parents (1.89%, $n = 14$) reported that their child experienced side effects.

Comprehension

Of the subsample who answered about the purpose of over-the-counter cough and cold medications, 25.7% ($n = 112$) believed they were meant to shorten and cure illness, 39.9% ($n = 174$) believed they were meant to only shorten the illness, 3.7% ($n = 16$) believed over-the-counter cough and cold medications were meant to only cure the illness, and 134 (30.7%) believed over-the-counter cough and cold medication did not shorten or cure the illness.

Discussion

Following the FDA recommendation to avoid the misuse of over-the-counter cough and cold medication in children under six, the MHRA announced similar guidelines in the UK. One important question is whether parents trust the MRHA recommendations about cough and cold medication. An additional issue that this study addressed is parents' knowledge, perception, and behaviour with respect to over-the-counter cough and cold medication.

Do parents trust the MRHA recommendation, given that the recommendations were made by a national health organisation? There was widespread publicity surrounding the MHRA recommendations, but one-third of the sample remained unaware. This is particularly alarming, given no detectable demographic differences between parents who were aware and those who were not. Of further concern is that more than half of participants who knew about the recommendations either did not trust them or were not sure what to believe. This notable lack of trust in the medical regulatory body corresponds to earlier results by Hanoch and colleagues (2010) and to MMR vaccination trends in the UK. It is also interesting to note that we found no differences between UK and US parents on their degree of trust in the FDA/MHRA

recommendations, despite inherent differences in the health coverage structure. This suggests that the important issue of trust in risk regulators could benefit from a qualitative approach, such as the one utilised by Walls *et al.* (2004).

Taylor-Gooby (2006, Taylor-Gooby *et al.* 2003, Mechanic 2004) has argued that trust is associated with the public acceptance of health care reforms and their willingness to vote for agent advocating these reforms. Others (Brown 2009) have argued that knowledge gained via mass media is the weakest form of knowledge. Our study nicely captures both lines of research, as it illustrates the lack of trust in public institutions and the poor effectiveness of mass media message. As such, to gain public trust in the MHRA cold and cough medication recommendation, the new guidelines should have also been communicated directly by doctors to patients. Finally, it is possible that the involvement of pharmaceutical companies has negatively affected public trust even further.

As in previous studies (Ames *et al.* 1982, Kogan *et al.* 1994), the majority of parents (over 85% in this sample) used over-the-counter cough and cold medications to treat cough and cold symptoms in their children, and well over half used more than one over-the-counter cough and cold medication. Usage prevailed in the months following release of the MHRA (and FDA) recommendations despite the fact that only one-third of this sample considered the medication(s) very/extremely effective.

Hanoch and colleagues (2010) and Miron-Shatz and colleagues (2010) examined US parents' reactions and adherence to the over-the-counter cough and cold medication guidelines put forth by the FDA. Compared to US parents assessed in these previous studies, parents in the UK were more likely to administer more than one medication to their children as well as to consider over-the-counter cough and cold medications safe. In contrast, parents in the UK reported less side effects compared with US parents (Hanoch *et al.* 2010), most UK parents succeeded in identifying at least one active ingredient, and parents who reported using multiple over-the-counter cough and cold medications were more likely to identify the correct active ingredient(s) than parents administering only one. It is important to note that only one-third of this sample could correctly identify all of the ingredients in the medication administered to their children. Regardless, the fact that UK parents were better able to identify active ingredients is commendable and may explain the different rates of adverse side effects associated with over-the-counter cough and cold medication usage in the US and the UK.

While over-the-counter cough and cold medications might help relieve symptoms, they are not designed to shorten or cure illness. Yet most parents (about 66%) assumed that over-the-counter cough and cold medications were meant to do just that: shorten the illness, cure the illness, or both. Furthermore, parental knowledge of the active ingredients is not necessarily a good reflection of their knowledge of the risk of a medicine. Indeed, knowing the active ingredient could serve as a possible protective barrier only in cases where parents might intend to use more than one product. While in this study we did not present parents over-the-counter cough and cold medication package labels and evaluate their understanding, Lokker *et al.* (2009) found that caregivers misinterpreted over-the-counter cough and cold medication labels and wrongly assumed that these products were suitable for children under the age of two. Likewise, Dart *et al.* (2009) reported that the main factor involved in children deaths was due to parents' misuse of over-the-counter cough and cold medication.

There were several limitations in this study. First, using an ad on a popular website (e.g., Facebook) precludes us from verifying that all participants were actually caregivers. It could also lead to a sampling bias. While Facebook has over 500 million users, they may still be more affluent and educated than the general population. They might also have greater interest in health issues and more health knowledge in general, and about over-the-counter cough and cold medication in particular. Furthermore, we are unable to tell how many people viewed the ad and thus to calculate response rate. It is possible that using a certificate for Amazon.co.uk may have attracted specific parental population, even though it is a general commerce website. In addition, it is possible that parents' knowledge of active ingredients may not reflect their knowledge of the risk of a medicine. Furthermore, asking parents to state the active ingredients without showing them the package may be an unrealistic way to assess parental knowledge, as most parents have the ability to examine the package prior to deciding whether to administer the medicine to their children. Finally, in this research we have focused on how parental perceptions of over-the-counter cough and cold medication are affected by regulatory agencies (the MHRA or FDA), and primary care providers. Parental attitudes, needless to say, could also be formed and influenced by the pharmaceutical industry. This is a considerable omission, as a number of researchers have shown the importance of the pharmaceutical industry in shaping parental attitude and behaviour, for example with regard to HPV vaccination (Friedman and Shepeard 2007).

While we recognise the limitations of online-based (e.g., through sample selection) studies, using the Internet has important advantages like low cost, the ability to reach a diverse and large audience, and quick data collection. Second, as the MHRA recommendations intended to reach the general population, we purposely avoided recruiting parents in a clinical setting. Finally, as our sample may have been more educated or better informed than the general population, our results might in fact be conservative by nature regarding actual rates of misuse and mishandling of over-the-counter cough and cold medication by parents. As a number of studies (e.g., Lokker *et al.* 2009) reported greater prevalence of misunderstanding, it is possible that having a more representative population would have yielded an even more worrisome result. It would be of great importance to examine whether caregivers from low socioeconomic status have heard of the MHRA recommendation and whether they intend to follow them.

Conclusion

Limitations aside, our results raise a number of important issues that need to be addressed in future risk regulation efforts. First, despite the publicity efforts, one-third of our sample remained unaware of the MHRA recommendations. In addition, the lack of trust in the MHRA recommendations raises concern about the efficacy of their message. As Brown and Calnan (2010) suggest, it may be particularly important for such messages to be conveyed to parents through general practitioners and primary care physicians, given that physicians mediate interactions between patients and messages from institutions like the MHRA. In addition, there is a need to increase efforts to notify parents of changes in medication recommendation and to facilitate a trust relationship between agencies like the MHRA and patients.

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Notes

1. To view the MHRA recommendation, see: <http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON038908s>.
2. Our survey design does not allow us to tell whether they gave more than one OTC-CCM at the same time or on different occasions.

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Appendix 1. UK Survey

- (1) Do you have children under 6?
- Yes
 - No (*skip to end of survey*)

PLEASE ANSWER THE FOLLOWING QUESTIONS ABOUT YOUR YOUNGEST YOUNGEST CHILD

- (2) Think of the last three months. Can you tell us how many times your child had a cough or a cold?
- 0
 - 1–3 times
 - 4–6 times
 - 6–10 times
 - More than 10 times

- (3) Think of the times that your child had a cough or a cold. Can you tell us the names of any over-the-counter cough or cold medicine that you gave them (please tick off as many as needed)?
- Aspirin
 - Chesty Coughs
 - Nurofen
 - Calprofen
 - Medised for Children
 - Tixylix Chesty Cough
 - Calcold
 - Benylin: Children's Cough and Cold
 - Calpol Night
 - Calpol
 - Robitussin Chesty Cough Medicine
 - Tixylix: Cough and Cold
 - None
 - Other (Please specify) _____.
- (4) Think of the coughs or colds medicine you have mentioned in question 3. Can you tell us what is the active ingredient in that over-the-counter medicine (please tick off as many ingredients as needed)?
- Hydrochloride Phenylephrine
 - Dextromethorphan Hydrobromide
 - Triprolidine Hydrochloride
 - Pholcodine
 - Brompheniramine
 - Ibuprofen
 - Maltitol Liquid
 - Ephedrine
 - Diphenhydramine
 - Paracetamol
 - Guaifenesin
 - Chlorphenamine Maleate
 - Aspirin
 - Ipecacuanha
 - Oxymetazoline
 - Phenylephrine
 - Xylometazoline
 - I don't remember
- (5) Please list the ages of ALL of your children
(Leave the extra boxes blank if you have fewer than 8 children; if you have more than 8 children, please list the ages of the 8 YOUNGEST)
- Youngest Child: _____
- 2nd Youngest Child: _____
- 3rd Youngest Child: _____
- 4th Youngest Child: _____
- 5th Youngest Child: _____
- 6th Youngest Child: _____
- 7th Youngest Child: _____
- 8th Youngest Child: _____
- (6) What is the gender of your youngest child (the one that your responses referred to)?
- Male
 - Female

- (7) When your child shows the first signs of coughs or colds, which of the following actions do you take first (please tick one answer)?
- I first give them over-the-counter coughs and colds medicine (such as Calpol).
 - I first seek help from a doctor or a nurse.
 - I first call the NHS helpline or use information from the internet.
 - I wait and see if they get better.
 - Other (please specify) _____.
- (8) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. Did you discuss giving it to your child with your doctor or nurse?

| | | | | |
|-------|--------|-----------|-------|--------|
| Never | Rarely | Sometimes | Often | Always |
|-------|--------|-----------|-------|--------|

- (9) Think of the over-the counter cough and cold medicine that you have ticked in question 3. Which of the following topics did you discuss with your doctor or nurse (please tick more than one topic if needed)?
- How much medication to give.
 - How many times a day you should give the medication.
 - How many days you should give the medication.
 - Specific strengths and formulation.
 - What risks or side effects the medication has.
 - Other (please specify) _____.
 - None of the above.
- (10) Think of the over-the counter cough and cold medicine that you have ticked in question 3. How many times have you consulted the internet before giving your child the medicine?

| | | | | |
|----------------------------------|------|-------|-------------|------------------|
| I haven't consulted the internet | Once | Twice | Three times | Over three times |
|----------------------------------|------|-------|-------------|------------------|

- (11) Think of the non-prescribed coughs and colds medicine that you have ticked in question 3. How many times have you consulted a health book before giving your child cough and cold medicine?

| | | | | |
|-----------------------------------|------|-------|-------------|------------------|
| I haven't consulted a health book | Once | Twice | Three times | Over three times |
|-----------------------------------|------|-------|-------------|------------------|

- (12) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. Do you think giving your child a **higher** amount than recommend on the package is?

| | | | | |
|-----------------------|---------------------|------------|-----------------|----------------------|
| Not beneficial at all | Slightly beneficial | Beneficial | Very beneficial | Extremely beneficial |
|-----------------------|---------------------|------------|-----------------|----------------------|

- (13) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. Do you think giving your child a **lower** amount than recommend on the package is?

| | | | | |
|-----------------------|---------------------|------------|-----------------|----------------------|
| Not beneficial at all | Slightly beneficial | Beneficial | Very beneficial | Extremely beneficial |
|-----------------------|---------------------|------------|-----------------|----------------------|

- (14) Think of the times that you gave your child an over-the-counter cough and cold medicine. Did you ever give them other medications (such as pain and fever reliever) at the same time?

| | | | | |
|-------|--------|-----------|-------|--------|
| Never | Rarely | Sometimes | Often | Always |
|-------|--------|-----------|-------|--------|

- (15) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. Do you worry about giving your child too much coughs and colds medicine?

| | | | | |
|-------|--------|-----------|-------|--------|
| Never | Rarely | Sometimes | Often | Always |
|-------|--------|-----------|-------|--------|

- (16) In your opinion, how safe are the cough and cold medicines that you have ticked in question 3?

| | | | | |
|-----------------|---------------|-------------------------|------|-----------|
| Not safe at all | Somewhat safe | Neither safe nor unsafe | Safe | Very safe |
|-----------------|---------------|-------------------------|------|-----------|

- (17) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. Has your child ever experienced any side effects after taking the medication?

| | | | | |
|-------|--------|-----------|-------|--------|
| Never | Rarely | Sometimes | Often | Always |
|-------|--------|-----------|-------|--------|

- (18) Can you tell us where you buy cough and colds medicine for your child (please tick more than one answer if needed)?

- Pharmacy/Chemist
- Supermarket
- Convenience store
- Petrol station
- Other place (please write) _____.

- (19) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. How did you decide how much medicine to give to your child (please tick more than one answer if needed)?

- I ask my child for his or her preference.
- It depends on my child's weight.
- I consider whether it is a girl or a boy.
- It depends on how old my child is.
- It depends on how ill my child is.

- (20) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. How important was it for you to give the precise amount (dosage) written on the package?

| | | | | |
|----------------------|----------------------|-----------------------------------|--------------------|----------------|
| Not important at all | Somewhat unimportant | Neither important nor unimportant | Somewhat important | Very important |
|----------------------|----------------------|-----------------------------------|--------------------|----------------|

- (21) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. How important was it for you to follow the correct intervals between doses written on the package?

| | | | | |
|----------------------|----------------------|-----------------------------------|--------------------|----------------|
| Not important at all | Somewhat unimportant | Neither important nor unimportant | Somewhat important | Very important |
|----------------------|----------------------|-----------------------------------|--------------------|----------------|

- (22) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. How important was it for you to give the medicine for no more than the number of days written on the package?

| | | | | |
|----------------------|----------------------|-----------------------------------|--------------------|----------------|
| Not important at all | Somewhat unimportant | Neither important nor unimportant | Somewhat important | Very important |
|----------------------|----------------------|-----------------------------------|--------------------|----------------|

- (23) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. How did you measure how much medicine to give to your child (please tick more than one answer if needed)?

- I used a medicine spoon.
- I used a teaspoon.
- I used an oral syringe.
- I used a plastic medicine cup.
- I used tablets.
- Other method (please specify) _____.

- (24) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. How did you decide how many times a day you can give the medication to your child?

- I read the instruction on the package.
- I asked a pharmacist.
- I asked a doctor.
- I asked my friends or family members.
- I did not need to consult anyone.
- Other (please specify) _____.

- (25) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. How did you decide what is the maximum amount your child should receive a day?

- I read the instruction on the package.
- I asked a pharmacist.
- I asked a doctor.
- I asked my friends or family members.
- I did not need to consult anyone.
- Other (please specify) _____.

- (26) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. How did you decide for how many days you can give your child the medication?

- I read the instruction on the package.
- I asked a pharmacist.
- I asked a doctor.
- I asked my friends or family members.
- I did not need to consult anyone.
- Other (please specify) _____.

- (27) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. When did you read the instructions written on the box?
- When I bought the medication.
 - Before the first time I used the medication.
 - Every time I used the medication.
 - I never read them.

- (28) Do you consider the instructions written on the box before buying cough and cold medicine?

| Never | Rarely | Sometimes | Often | Always |
|-------|--------|-----------|-------|--------|
|-------|--------|-----------|-------|--------|

- (29) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. At home, where do you keep your children's medicine?
- Locked or in a childproof cupboards.
 - In cupboards, bathroom cabinets, or high shelf.
 - In a refrigerator, pantry, airing cupboard, or under the sink.
 - Medicine box.
 - Kitchen, bathroom, parent's bedroom.
 - Other (please specify) _____.

- (30) Think of the over-the-counter cough and cold medicine that you have ticked in question 3. How effective was the medicine for helping your child's cough or cold?

| Not effective at all | Slightly effective | Effective | Very effective | Extremely effective |
|----------------------|--------------------|-----------|----------------|---------------------|
|----------------------|--------------------|-----------|----------------|---------------------|

- (31) Have you heard that Medicine and Healthcare products Regulatory Agency (MHRA) recommended that non-prescription cough and cold preparations should not be used in children under 2 years?
- Yes, I have heard
 - No, I have not heard

- (32) If you have heard about the Medicine and Healthcare products Regulatory Agency (MHRA) recommendation, what do you intend to do when your child has a cough or cold in the future?
- I intend to keep giving my child over-the-counter coughs and colds medicine
 - I am not sure what I will do
 - I intend to stop giving my child over-the-counter coughs and colds medicine

- (33) How much do you trust the MHRA recommendation?

| Highly doubt it | Slightly doubt it | Not sure | Trust it | Highly trust it |
|-----------------|-------------------|----------|----------|-----------------|
|-----------------|-------------------|----------|----------|-----------------|

- (34) What is your age, please? _____.

- (35) What is your gender?

- Male
- Female

- (36) What is your family yearly income before taxes:

- Less than £10,000
- Between £10,000 and £20,000
- Between £20,000 and £30,000
- Between £30,000 and £40,000
- Higher than £40,000

- (37) What is the highest level of education that you have completed? (Please mark one response only):
- GSCE O levels
 - A levels
 - Diploma or certificate
 - University or college degree
 - Professional qualification
 - Other (please specify) _____.
- (38) How many children do you have: _____
- (39) Do you have health insurance:
- Yes
 - No

Questions 40–43 were only asked of participants recruited in November 2008 (n = 424)

- (40) Think of over-the-counter (OTC) cough and cold medicine that you selected in question 3. In your opinion, the over-the-counter cough and cold medicine is supposed to:
- Cure the illness and shorten the length of the illness
 - Not cure the illness but shorten the length of the illness
 - Cure the illness but not shorten the length of the illness
 - Not cure the illness and not shorten the length of the illness
- (41) To the best of your knowledge, the Medicine and Healthcare products Regulatory Agency (MHRA) has recommended that:
- No OTC cough and cold medicines should be used in children under the age of 2
 - No OTC cough and cold medicines should be used in children under the age of 6
 - Some OTC cough and cold medicines should not be used in children under the age of 2
 - All OTC cough and cold medicines can be used in children under age of 6
- (42) To the best of your knowledge, the Medicine and Healthcare products Regulatory Agency (MHRA) has recommended that parents of children under 2 years of age could use which of the following courses of treatment: Use Ibuprofen or paracetamol to lower the child's temperature
- Use simple cough mixtures (honey, lemon)
 - Use vapour rubs
 - Use all of the above
- (43) After you heard about Medicine and Healthcare products Regulatory Agency (MHRA) recommendation, did you seek help or advice from any of the following sources?:
- Pharmacists
 - Health visitor
 - Nurses
 - Doctor
 - Other (please specify) _____.