

Parents' decision following the Food and Drug Administration recommendation: the case of over-the-counter cough and cold medication

Y. Hanoch,* M. Gummerum,* T. Miron-Shatz†‡ and M. Himmelstein§

*University of Plymouth, School of Psychology, Drake Circus, Plymouth, UK

†Center for Health and Wellbeing, Princeton University, Princeton, NJ, USA

‡Marketing Department, Ono Academic College, Kiryat Ono, Israel, and

§Center for Research on Child Wellbeing, Princeton University, Princeton, NJ, USA

Accepted for publication 2 January 2010

Abstract

Background In 2007, the Food and Drug Administration (FDA) recommended against parents administering over-the-counter cough and cold medications (OTC-CCM) to children under 2 years of age because serious and potentially life-threatening side effects can occur. This study examined the impact of FDA's recommendations against giving children under 2 years old OTC-CCM.

Methods We asked parents ($n = 377$) whether they knew of and trusted the FDA recommendations, as well as whether they intended to follow them. We also examined parents' knowledge, perceptions and behaviours with respect to OTC-CCM.

Results About 33% of our sample had never heard of the FDA recommendations. Of those who were aware, 32.9% intended to continue administering OTC-CCM, and another 36.7% were not sure what to do. Our results indicate that parents who trust the FDA recommendations are significantly more likely to stop giving OTC-CCM to their children. However, almost half did not trust the FDA recommendations or were not sure whether to trust them. Our results indicate that parents who trust the FDA recommendation are significantly more likely to discontinue using OTC-CCM. Our data also reveal that many parents give more than one drug simultaneously (32.9%), cannot identify the active ingredient(s) (28.9%) or fail to store the medications in a safe place (86.1%).

Conclusion Parents' confidence in the FDA recommendations predicted whether they would continue or stop administering OTC-CCM to their children. Our findings illustrate the urgent need for widespread public education about OTC-CCM products to ensure children's safety.

Keywords

decision making,
over-the-counter cough
and cold medication,
parents, trust

Correspondence:

Yaniv Hanoch, School of
Psychology, University of
Plymouth, Drake Circus,
Plymouth PL4 8AA, UK
E-mail: yaniv.hanoch@
plymouth.ac.uk

After an expert panel reviewed the safety of over-the-counter cough and cold medications (OTC-CCM), the Food and Drug Administration (FDA) recommended that 'these drugs not be used to treat infants and children under 2 years of age because serious and potentially life-threatening side effects can occur' (Food and Drug Administration Public Health Advisory 2008). Because earlier studies have shown that people treat OTC medications as if they carry little risk (Glasziou 2002;

Roumie & Griffin 2004), it is important to evaluate parents' beliefs regarding OTC-CCM for children and their response to the FDA recommendations. In this study, we analysed parents' knowledge, perceptions and behaviours with respect to OTC-CCM, in addition to their perceptions of the FDA and awareness of the agency's recent actions. Our results demonstrate a link between these factors and adherence to the FDA warning.

OTC-CCM: risks and parental misuse

Colds are one of the most common illnesses among children (Heikkinen & Järvinen 2003) and parents administer OTC-CCM to alleviate symptoms (Kogan *et al.* 1994; Kaufman *et al.* 2002). OTC-CCMs are considered safe when used properly and have low absolute risk, package labels clearly advise medical supervision for use in children under 2 years. Despite the availability of instructions on the label, unsupervised OTC-CCM consumption by children 2–5 years of age and caretakers' inappropriate administration (e.g. giving more than recommended) account for most ER visits because of an adverse drug event (Schaefer *et al.* 2008; see also Dart *et al.* 2009). The FDA panel and the American Academy of Pediatrics' Committee on Drugs (Ward *et al.* 2001) have in fact indicated failure to follow label instructions, use of incorrect measuring devices and inappropriate storage as the main causes of unintentional overdosing. Based on these concerns, we explored parental knowledge, perceptions and behaviours with respect to OTC-CCM in the first section of our study.

OTC-CCM: the FDA warning and parental intended behaviour

The FDA warning about OTC-CCM has received much attention in the media, yet it is unclear whether parents are aware of the warning, whether they trusted the FDA recommendations, and whether they intend to obey. As the cases of genetic technology (Barnet *et al.* 2007) and child vaccinations have previously proven, trust and confidence in governmental health agencies are pivotal. In UK, for example, parents' decisions of not to vaccinate against measles, mumps and rubella – despite assurances and campaigns by the UK government – stemmed largely from lack of trust in messages about the safety of these vaccines (Casiday 2006; Casiday *et al.* 2006; Hobson-West 2007). Indeed, a growing corpus of data (Williams & Noyes 2007) illustrates the role of trust as a key moderator between risk perception and decision making. Thus, we examined trust as a prerequisite of adherence to the FDA warning.

Following the FDA statements, concerns grew over parents' awareness and understanding of the new recommendations, their perceptions of OTC-CCMs' safety and their intentions to adhere to the new recommendations. Shortly after the FDA announcement, a survey by the NPR/Kaiser Family Foundation/Harvard School of Public Health (2008, henceforth NPR *et al.*)¹ investigated parents' knowledge, perceptions and

intentions regarding use of OTC-CCM. Their results, explained further in the discussion section, showed that the FDA message did not reach all of its target audience – about one-fifth of the surveyed parents planned to continue giving OTC-CCM to their children despite the FDA recommendations. The study also highlighted the fact that parents consult friends and fellow parents more often than their paediatricians about OTC-CCM. At the same time, many parents rated their paediatricians as the most trusted source of information, more so than the FDA.

Our study, then, overlaps with the NPR *et al.* (2008) investigation. However, as data collection for both studies took place during the same time period, we were unaware of the NPR *et al.* (2008) research until their results became public. Hence, it was impossible for us to incorporate some of NPR *et al.*'s survey questions into our inquiry. While we surveyed separate populations and collected data differently (telephone vs. online), our results share some important findings with those of NPR *et al.*

The NPR *et al.* (2008) investigation, despite its focus on the FDA recommendations, neglected to examine the broader relationship between perceived safety and parental misuse of OTC-CCM. For example, two major factors contributing to adverse drug reaction and death – storage conditions and simultaneous use of more than one OTC-CCM – were left unaddressed (Dart *et al.* 2009). In contrast, our study had two general aims. First, we aimed to examine parents' behavioural tendencies with regard to OTC-CCM (e.g. giving more than one drug simultaneously), whom they consulted regarding OTC-CCM (e.g. package label) and their risk perceptions (e.g. how risky they thought OTC-CCMs are); these aspects of OTC-CCM use were absent in the NPR *et al.* study. Our second aim, which closely mirrors that of the NPR *et al.* study, was to evaluate whether parents knew of the recommendations, whether they trusted them and, most importantly, whether they intended to obey. This question has major practical implications, as the FDA's efforts to inform parents and the impact of its recommendations have yet to be thoroughly studied.

Methods

Participants

Before data collection, we obtained approval for the research protocol from the appropriate Institutional Review Boards. A total of 377 parents participated in this study (although there were between 6 and 47 missing responses for each specific question), of which 280 were female ($M = 31.68$, $SD = 5.20$), and 53 were male ($M = 33.96$, $SD = 4.61$), with 44 participants who did not specify their gender. We opted not to compare men and

¹ No information was provided about the survey's development or its external and internal validity.

Table 1. Demographics

| | Child ≤2 years old | | Child >2 years old | | US population estimates* |
|--------------------------------|--------------------|--------------|--------------------|--------------|--------------------------|
| | <i>n</i> | M (SD) | <i>n</i> | M (SD) | |
| Parent's age | 180 | 30.91 (2.01) | 135 | 33.54 (5.82) | |
| Number of children | 189 | 2.01 (1.09) | 141 | 2.23 (1.06) | |
| | <i>n</i> | % | <i>n</i> | % | % |
| Income | 186 | | 135 | | |
| Under \$15 000 | 6 | 3.2 | 3 | 2.2 | 9.1 |
| \$15 001–30 000 | 16 | 8.6 | 11 | 8.1 | 15.2 |
| \$30 001–45 000 | 30 | 16.1 | 20 | 14.8 | 13.7 |
| \$45 001–60 000 | 35 | 18.8 | 21 | 15.6 | 12.1 |
| \$60 001–75 000 | 32 | 17.2 | 21 | 15.6 | 11.1 |
| \$75 001–100 000 | 27 | 14.5 | 31 | 23.0 | 14.5 |
| More than 100 000 | 40 | 21.5 | 28 | 20.7 | 26.0 |
| Education | 189 | | 139 | | |
| Less than high school | 1 | 0.5 | 1 | 0.7 | 11 |
| High school grad | 12 | 6.3 | 16 | 11.5 | 28 |
| Some college | 51 | 27.0 | 38 | 27.3 | 27 |
| Bachelors degree or equivalent | 77 | 40.7 | 47 | 33.8 | 22 |
| Graduate degree | 48 | 25.4 | 37 | 26.6 | 13 |

*US Census Bureau, Current Population Survey, 2009 Annual Social and Economic Supplement.

women, given the small number of males in our sample. Additional descriptions may be found in Table 1.

Participants were recruited through a Facebook ad that announced a chance for parents with children under 6 to win a \$50.00 gift certificate to Amazon.com upon completion of a parenting survey. Thus, while we recognize the limitations of online-based studies (e.g. sample selection), using the Internet has important advantages like low cost, the ability to reach a diverse and large audience and quick data collection. Furthermore, because the FDA recommendations were meant for the general population, we purposely avoided recruiting parents in the clinical setting (e.g. hospitals).

Materials and procedure

Data collection took place between November and December 2007, ending 45 days after the FDA first announced its recommendations (in comparison, the NPR *et al.* survey took place from November 15–25, 2007, with a break during the Thanksgiving holiday). We used SurveyMonkey (see <http://www.surveymonkey.com/>) to create our online survey and to collect data. Participants completed an online survey that included open-ended questions, multiple-choice questions (some of which allowed multiple answers) and demographic questions about themselves and their children. The questions were based on an earlier survey by Hanoch and colleagues (2007) that was

modified to fit the current study and our two basic aims.² The first segment of the survey, containing 27 questions, was designed to assess parents' knowledge, perceptions and behaviours with respect to OTC-CCMs. To avoid confusion with other drugs (e.g. analgesics/antipyretics) that were not included in the FDA recommendations, we provided the names of 16 drugs that were voluntarily removed from the market and asked participants to indicate which one(s) they gave their children. Questions asked included how often parents read package labels, how safe OTC-CCMs were in their opinion and whether they worried about giving their child too much OTC-CCMs. The second part of the survey asked parents whether they knew about the FDA recommendations, their trust in the recommendations and whether they intended to continue giving their child OTC-CCMs. Finally, to avoid misunderstandings regarding the drugs of interest, all relevant questions started with the following sentence: 'Think of the over-the-counter cough and cold medicine that you have checked in question 2.'

² The original survey by Hanoch and colleagues (2007) was designed to evaluate participants' risk perception and behaviour with regard to OTC painkillers. In the current study, we altered or removed questions about painkillers and replaced them with questions about cough and cough medications as appropriate. In addition, the original survey by Hanoch *et al.* asked participants about their own behaviour, while in this study we asked about administration of OTC-CCM to participants' children. We did not validate the revised survey, a fact that could represent one limitation of the current study.

Question 2 requested parents to identify the type of OTC-CCM administered in the past 3 months. The complete questionnaire can be found in Appendix S1.

Safety, effectiveness and side effects of OTC-CCM

Parents indicated how safe they thought the OTC-CCMs were for their child. Safety was rated on a Likert scale ranging from 1 (not safe at all) to 5 (very safe). Similarly, parents indicated how effective the OTC-CCMs were for their child's cough or cold on a Likert scale ranging from 1 (not effective at all) to 5 (very effective). Parents also noted the frequency with which they consulted a medical professional before administering OTC-CCM on a Likert scale ranging from 1 (never) to 5 (always). Finally, parents indicated the frequency of side effects experienced by the child after administration of OTC-CCMs on a Likert scale ranging from 1 (never) to 5 (always).

FDA trust

Participants evaluated their faith in the FDA recommendations on a Likert scale ranging from 1 (highly doubt the recommendation) to 5 (highly trust the recommendation). The middle point (3) indicated 'I am unsure about the recommendation.'

Adherence

Participants indicated their future actions in the case that their child develops a cough or cold, given the FDA recommendations. Possible responses were 0 (stop giving my child OTC-CCM) and 1 (continue giving my child OTC-CCM). An additional point was, 'I am unsure what I will do.' ($n = 88$).

Results

We organized this section into two main parts, consistent with our two main objectives: first, we report on parents' information search, knowledge, perceptions and behaviours with respect to OTC-CCM; second, we outline parents' awareness and trust with regard to the FDA recommendations as well as intended behaviour.

The on-line advertisements targeted men and women aged 24 years or older. All participants indicated they had at least one child. Our sample is, on average, more educated than the general population (DeNavas-Walt *et al.* 2008; Crissey 2009). The median income for our sample (60 001–70 000) is approxi-

mately equal to that for the general population (DeNavas-Walt *et al.* 2008) (see Table 1 for further comparisons).³

Medications, actions, knowledge and perceived effectiveness

Most parents (281, 82.5%) had administered one or more OTC-CCM to their child, and 110 (32.9%) had given two or more. Despite the ubiquity of OTC-CCM, only 110 (38.9%) of the parents who had administered one or more OTC-CCMs thought the medication was extremely or very effective; many more parents indicated that the OTC-CCM used was somewhat effective (113, 40.3%), slightly effective (52, 18.4%) or not effective at all (6, 2.4%). This analysis does not include parents who had not used OTC-CCM.

Because accidental drug overdose (giving two different drugs that contain the same active ingredient) has been identified as a cause of adverse drug events, we asked parents whether they gave OTC-CCMs in conjunction with other medications (e.g. pain and fever reliever) and, if they did, we asked them to identify the active ingredient(s) in the OTC-CCM given to their child. Parents were provided the names of every active ingredient in OTC-CCMs and asked to check all the ingredients the OTC-CCM they had used contained; if the participant identified at least one active ingredient correctly, he or she received a score of 1 (correct) versus 0 (incorrect). About one-third of parents (28.9%) were unable to correctly identify the active ingredient(s) in the OTC-CCM they reported giving their child. Of the parents who gave their child more than one drug simultaneously (32.9% of our sample reported doing so), only 18 (16.1%) were unable to correctly identify at least one active ingredient. A chi-squared test for independence showed that parents who administered multiple OTC-CCMs ($n = 104$) were more likely to identify at least one active ingredient in the medications they used than parents who administered just one OTC-CCM [$n = 66$, $\chi^2(1, n = 239) = 20.37$, $P < 0.0001$]. Finally, despite clear instructions on the labels, only 37 (13.2%) of the parents who use OTC-CCM for their children reported placing the OTC-CCMs in a locked or a childproof cupboard – thus, over 223 (80%) stored them inappropriately.

Information search and risk perception by age of child

Package labels advise parents to seek medical advice before usage on children under 2 years. An independent-samples *t*-test

³ We are unable to compare our sample with that of the NPR *et al.* study, as no demographic information (e.g. age and income) was provided. Additionally, it is impossible to compare the mean age of sample with the national average; the US Census Bureau only outlines age group proportions as opposed to average age (e.g. xx% of the US is between the ages of 18 and 65 years).

Table 2. OTC-CCM behaviour, information search and intention to use by parents with children under 2 years old and children over 2 years old

| | Experience | | Total | χ^2 (d.f.) |
|---|---------------------|--------------------|-------|-----------------|
| | Child under 2 years | Child over 2 years | | |
| FDA report | | | | 2.40 (1) |
| Heard | 142 | 95 | 237 | |
| Has not heard | 47 | 46 | 93 | |
| Total | 189 | 141 | 330 | |
| Number of OTC-CCM | | | | 5.05† (2) |
| None | 30 | 19 | 49 | |
| 1 | 88 | 83 | 171 | |
| 2 or more | 71 | 39 | 110 | |
| Total | 189 | 141 | 330 | |
| Consulted doctor about number of times per day | | | | 16.75** (1) |
| No | 94 | 99 | 193 | |
| Yes | 86 | 33 | 119 | |
| Total | 180 | 132 | 312 | |
| Consulted doctor about maximum dose | | | | 18.44* (1) |
| No | 96 | 101 | 197 | |
| Yes | 84 | 30 | 114 | |
| Total | 180 | 131 | 311 | |
| Consulted doctor about number of days to give OTC-CCM | | | | 11.65* (1) |
| No | 101 | 97 | 198 | |
| Yes | 82 | 34 | 116 | |
| Total | 183 | 131 | 314 | |

* $P < 0.001$, ** $P < 0.0001$.

†Number of OTC was marginal: $P < 0.08$.

FDA, Food and Drug Administration; OTC-CCM, over-the-counter cough and cold medications.

showed that parents with children of 2 years old or younger who used OTC-CCM ($M = 3.00$, $SD = 1.24$) were significantly more likely to seek medical guidance before giving OTC-CCM than parents with children over 2 years old who used OTC-CCM ($M = 2.56$, $SD = 1.00$), $t(278.34) = -3.32$, $P = 0.001$. Chi-squared tests for independence revealed that parents with children under 2 years were also more likely to consult a doctor about the frequency of administration [$\chi^2(1, n = 312) = 16.75$, $P < 0.001$], maximum dosage [$\chi^2(1, n = 311) = 18.44$, $P < 0.001$] and duration of usage in days [$\chi^2(1, n = 314) = 11.65$, $P < 0.001$]. Additional information on these tests may be found in Table 2.

We also sought to tap into parents' risk perceptions. When asked how safe they thought OTC-CCMs were, 124 (28.5%) answered 'very safe', and 144 (32.3%) responded with 'somewhat safe', while 32 (7.2%) thought they were neither safe nor unsafe, 38 (8.5%) judged them as somewhat unsafe, and 11 (2.5%) answered, 'not safe at all.' Additionally, 66 (18.9%) reported side effects experienced by their child after taking OTC-CCM (about 5% of these parents reported their child 'sometimes', 'often' or 'always' experienced side effects). However, the Pearson correlation between perceived safety and experience of side effects was small, $r(299) = 0.15$, $P = 0.01$. An ordinary least squares linear regression analysis on safety

yielded apparent effectiveness and side effects as significant predictors of perceived safety [$R^2 = 0.18$, $F(2, 330) = 35.60$, $P < 0.0001$]. Side effects had a negative association with perceptions of safety [B (SE = 0.09) = -0.19, $P = 0.05$], while effectiveness had a positive association [B (SE = 0.06) = 0.46, $P < 0.0001$].

FDA recommendation: knowledge, trust and intended behaviour

Because the FDA recommendations have specifically targeted children under 2 years, we inspected the effect of the child's age (under 2 years or over 2 years) on parental knowledge, trust and intended behaviour with respect to OTC-CCM. In the following analyses, we excluded participants who had not heard of the FDA recommendations ($n = 95$). Despite the wide publicity of the FDA's warning, 47 (25%) parents with children under 2 years were unaware of the FDA recommendations. Of those who had heard, 46 (32.4%) intended to continue giving their children OTC-CCM and 43 (30.3%) were not sure what to do. Of those who had heard and had a child under 2, 70 (49.6%) reported not trusting the FDA recommendations or were not sure whether to trust them.

Subsequently, we examined the relationship between adherence to the recommendations and trust of the FDA. Although

Table 3. Adherence and trust

| | Adherence | | | Total | χ^2 (d.f.) |
|----------------|-----------|----------|----------|-------|-----------------|
| | Stop | Not sure | Continue | | |
| FDA trust | | | | | 103.2* (8) |
| Highly doubt | 9 | 2 | 0 | 11 | |
| Slightly doubt | 22 | 6 | 5 | 33 | |
| Not sure | 34 | 9 | 33 | 76 | |
| Slightly trust | 15 | 8 | 34 | 97 | |
| Highly trust | 0 | 23 | 0 | 23 | |
| Total | 80 | 88 | 72 | 240 | |

* $P < 0.0001$.

FDA, Food and Drug Administration.

we included participants who were not sure whether to follow the recommendation ($n = 76$) in analyses involving chi-squares, we excluded these participants in regressions to allow interpretation of trust in the FDA recommendation. Thus, the variable 'FDA Trust' involves all participants who had heard of the FDA recommendation and who had responded to the question on faith in the FDA ($n = 242$). A second variable, 'Absolute FDA Trust', excluded participants who were unsure about their belief in the FDA recommendation ($n = 166$). A chi-squared test for independence comparing adherence and trust in the FDA (both variables included the 'not sure' responses) yielded a significant difference between distributions, χ^2 (8, $n = 240$) = 103.1, $P < 0.0001$ (see Table 3). Parents who highly doubted or slightly doubted the recommendation ($n = 44$) were more likely to continue giving the OTC-CCM (31 continue, 8 unsure, 5 stop). Parents who were unsure about the FDA recommendation were equally likely to continue or stop, but less likely to be unsure of what to do (continue = 34, stop = 33, not sure what to do = 6). Parents who trusted or highly trusted the recommendation ($n = 120$) were most likely to indicate uncertainty with regard to adherence or stop use of OTC-CCM (continue = 15, stop = 34, not sure what to do = 71).

As with trust in the FDA, we analysed adherence in two ways. First, 'Adherence' included all participants who answered this particular question ($n = 240$). Second, 'Binary Adherence' excluded people who did not know what to do in the future, in order to produce interpretable regressions ($n = 152$). Because the dependent variable was dichotomous, we conducted a logistic regression on binary adherence (excludes 'not sure what to do in future') by absolute trust (excludes 'not sure about the recommendation'), side effects, OTC-CCM effectiveness and safety. Greater trust in the FDA recommendations was associated with lower likelihood of continuing OTC-CCM use by a factor of 0.09 [B (SE = 0.58) = -2.37, $P < 0.001$]. Greater perceived effectiveness was associated with increased likelihood of

continuing OTC-CCM use despite recommendations [B (SE = 0.49) = 1.39, $P < 0.001$]. Perceived safety and side effects were not significantly associated with adherence.

Discussion

Our study had two main aims: first, we were interested in parental information search, knowledge, perceptions and behaviour with respect to OTC-CCM. Second, we evaluated whether parents were aware of, trusted or intended to follow the new FDA recommendations.

In line with earlier studies (Ames *et al.* 1982; Kogan *et al.* 1994), most parents relied on OTC-CCMs to treat cold/cough symptoms in their children. Despite FDA's warnings and perceptions of low effectiveness for OTC-CCMs, parents chose to continue use. The NPR *et al.* (2008) study revealed similar results: 37% of parents with children under 6 years reported confusion about the safety/effectiveness of OTC-CCM. Unlike that of the NPR *et al.*, our survey also investigated whether parents give multiple OTC-CCMs at a time, a factor that Dart and colleagues (2009) identified as a major factor of death because of accidental overdose in children. Our results show that over one-third gave more than one OTC-CCM, and parents of children under 2 years were even more likely to do so.

This finding is important for a number of reasons. Children under 2 years are more likely to experience adverse drug effects; a smaller body mass increases the likelihood of an overdose, and OTC-CCM package labels do not typically provide dose information for children younger than 2 years but instead advise parents to contact their physicians (which many parents fail to do). Providing clearer instructions and warnings, as well as educating parents about the potential dangers associated with administering multiple OTC-CCMs, could ameliorate the situation.

In our study, a majority of the parents were unable to correctly identify the active ingredient(s) in the OTC-CCMs they reported using. Given the wide assortment of drugs that contain acetaminophen, parents may be unaware of the risks of giving different drugs containing the same active ingredient (Webster *et al.* 1996). Indeed, in our study, Tylenol Concentrated Infants' Drops Plus Cold and Tylenol Concentrated Infants' Drops Plus Cold & Cough – both containing acetaminophen, an active ingredient – were the most frequently mentioned OTC-CCMs. These trends are worrisome, as acetaminophen may lead to acute liver failure in children (Squires *et al.* 2006), and inappropriate administration of OTC-CCMs gives rise to ER visits.

As in earlier findings (Conroy *et al.* 2003), only a minority of parents stored their OTC-CCM in a childproof place (Kuehn 2007). As identified by the FDA panel of experts (Food and Drug Administration Public Health Advisory 2008), inappropriate storage of OTC-CCM has been linked to unintentional overdoses among children. Parents' storage habits could reflect their failure to read or understand the package instructions (Orr *et al.* 2006) and might also indicate perceived safety of these products, as argued by the American Academy of Pediatrics Committee on Drugs (Ward *et al.* 2001).

About half of our sample reported consulting a doctor or a nurse before giving their children OTC-CCMs, although parents of children under 2 years were less likely to do so. This group of parents, however, was more likely to consult their doctor about dose, frequency and duration. Parents who consulted physicians or other health professionals after the FDA announcement may have been advised to stop giving their children OTC-CCM. This may be a potential limitation, as our study did not ask parents who they consulted after the FDA recommendation. However, the NPR *et al.* study did evaluate this issue, only to find that the majority of parents preferred to consult their friends or fellow parents (47%) over paediatricians (28%).

In our study, a larger proportion of participants reported consulting the package labels. As earlier studies have shown that individuals have difficulties understanding and following package instructions (Goldman & Scolnik 2004; Lokker *et al.* 2009), this finding might help explain why not all parents with children under 2 years sought medical advice before giving their child OTC-CCMs. Thus, our data further stress the importance of designing appropriate package labels, the main source of information for consumers (Brass 2001).

Despite the widespread usage of OTC-CCM, only a minority of parents judged them as very safe. Moreover, even parents who did not consider OTC-CCM very safe and who reported experience of side effects due to OTC-CCMs reported intentions to continue giving OTC-CCMs to their child. The majority of participants in the NPR *et al.* study, in contrast, viewed children's OTC-CCMs as very safe or somewhat safe (17% and 47%, respectively). However, participants were not asked whether their children had experienced side effects, so that differences in perceptions of safety may stem from the fact that many in our study reported adverse reactions in their children because of OTC-CCMs. Finally, it should be noted that our regression analysis indicated that perceived effectiveness and experience of side effects predicted 18% of the variance regarding parents' perceived safety of OTC-CCM. Other variables – such as recommendations by friends and family

members, in addition to one's own experiences with OTC-CCM – could also account for parents' safety perceptions. As such views are important to parents' usage of OTC-CCMs, an exploration of other factors contributing to perceptions of safety is necessary.

Finally, it is unclear why parents who considered OTC-CCMs as 'not safe at all' would nevertheless continue using them.⁴ Another mystery is why parents would continue use after their child experiences side effects. Indeed, these puzzling findings were also reflected in the lack of correlation between parents' perception of safety and their child's experience of side effects (as well as between report of side effects and number of OTC-CCMs given), when one would expect an inverse relationship. In addition, while parents with only one child considered OTC-CCM less safe than parents with more than one child, the former administered as many OTC-CCMs as parents with multiple children. Finally, we found across the study that demographic variables – for instance, income and education – had little to no effect on parents' knowledge, perception or behaviour (see, Norton 2000). The notable exceptions, however, were parents with one child who were more cautious and worried about the safety of OTC-CCMs.

Our discussion thus far touched on the first objective of our study. Our second aim was to study parents' awareness, trust and intended behaviour following the FDA recommendations. Despite wide publicity (the story was covered by newspapers, TV news programmes and numerous websites), about one-third of our sample had not heard of the new guidelines. Relatively few parents displayed high levels of trust in the FDA recommendations, and over half were either unsure or doubted them. Our results with regard to awareness, trust and intentions to continue use closely match those reported by the NPR *et al.* study. For example, in the NPR *et al.* survey, 32% of the parents reported hearing either nothing at all or not much about the recent FDA recommendations. In addition, close to 40% reported confusion over the safety and effectiveness of OTC-CCM. Similarly, only 29% indicated that they trust the FDA, while doctors were rated as the most trustworthy sources, followed by pharmacists, national paediatrics organizations and only then the FDA. While a number of factors could explain the low levels of trust in the FDA recommendations, one reason may be the negative publicity suffered by the agency over its handling of the approval and subsequent removal of Vioxx from the drug market (Harris 2005).

⁴ As the NPR *et al.* (2008) study only reported descriptive statistics, it is impossible to tell whether their results would have revealed similar trends.

The relatively low levels of parental trust in the FDA recommendation are of keen concern. Even more troubling, however, are the intentions of parents with children under 2 years to continue using OTC-CCM. Indeed, our results show that about one-third of our sample intended to continue giving OTC-CCM to their children, and another third are unsure what to do. Essentially, only one-third indicated that they will follow the FDA recommendation. In the NPR *et al.* study, only about 15% reported that they will stop using OTC-CCM for their children. In contrast, 20% of parents with children under 2 years and 30% of parents with children under 6 years intended to continue giving OTC-CCM to their children; an additional 26% and 28% (respectively) were undecided; and 15% had not heard about the discussion. Our results, in fact, are even more alarming than the ones obtained by the NPR *et al.* (2008) survey. First, our sample was more educated than the one used in the NPR sample, so that one would expect them to be more aware and more compliant with the FDA recommendations. Second, our sample was predominantly composed of educated women, a group that tends to be more likely to read package instructions and to administer OTC-CCM to their children (Kogan *et al.* 1994; Allotey *et al.* 2004). Thus, although the NPR *et al.* study may include a more representative sample, our study has the advantage of being more closely aligned with the group that is heavily involved in the administration of OTC-CCM to their children.

Our results further highlight the relationship between trust and behaviour, as the case of measles, mumps and rubella vaccination in the UK has shown. In accordance with our predictions, parents who trusted the FDA recommendations were more likely to stop giving OTC-CCM to their children than parents who were not sure or did not trust the FDA. Indeed, one of the advantages of the current study over the NPR *et al.*'s (2008) is our analysis of the relationship between trust in the FDA and intentions to continue using OTC-CCM, thus highlighting the importance of trust in governmental health institutions to people's decisions to adhere to or ignore health-related recommendations. Finally, following the statement of the American Academy of Pediatrics' Committee on Drugs (Ward *et al.* 2001) on the connection between perceived safety and inappropriate behaviour, our analysis shows that parents who intend to stop giving OTC-CCM to their children following the FDA recommendations also judged these drugs to be less safe.

We acknowledge a number of limitations to our study. First, our sample was of convenience and did not necessarily represent the general population. It is possible that parents who have access to the Internet are different from those who lack

access. However, we believe that in our case, this might be less of a problem, as our results follow similar trends to those found by the NPR *et al.* (2008) survey (which used a representative sample of the population of the USA). Second, the majority of participants and their children had health insurance (over 90%), which could explain the high rate of doctor consultations among participants. Third, we had not validated our survey and therefore cannot exclude potential biases. For example, few parents reported overdosing their children. While there is little absolute risk when used as directed, overdosing has been one of the main factors underlying the FDA recommendation. Unfortunately, our study design does not allow us to draw causal relationships between the variables. Again, although, the similarities between our results and those of NPR *et al.* provide further validation of our data. Furthermore, as our sample may have been more educated or better informed than the general population, and as social desirability may have reduced the proportion of parents reporting misuse and mishandling of OTC-CCM, our results might in fact under-represented actual rates of misuse and mishandling of OTC-CCM by parents.

Limitations aside, our results raise a number of important issues. First, despite the publicity efforts, about a quarter of parents with children under 2 years did not know of the FDA recommendations. In addition, the lack of trust in FDA's recommendations raised concern over the efficacy of their message. On the other hand, the high levels of trust in the paediatricians and pharmacists, as well as the fact that many parents reported buying their OTC-CCMs in pharmacies, suggest that both doctors and pharmacists could take a more active role in raising awareness among parents and advise them on the merits of the FDA's expert panel. Finally, our results illustrate the need for widespread public education about the use of OTC-CCMs.

Key messages

- The FDA needs to ensure that parents are aware of its recommendation to stop using over-the-counter cold and cough medication for children under 2 years.
- Parents' decisions to administer over-the-counter cold and cough medications depend, at least partially, on how much they trust the FDA.
- Widespread public education on the use of OTC-CCMs is necessary.

Acknowledgements

We would like to thank the Center for Health and Wellbeing, Princeton University, for providing financial support, the members of the health psychology group at University of Plymouth for comments on an earlier version of the survey and Eric Brass for comments on earlier version of the manuscript.

References

- Allotey, P., Reidpath, D. D. & Elisha, D. (2004) Social medication' and the control of children: a qualitative study of over-the-counter medication among Australian children. *Paediatrics*, **114**, 378–383.
- Ames, J. T., Hayden, G. F., Campbell, R. E. & Lohr, J. A. (1982) Parents' conception of their use of over-the-counter medicines. *Clinical Paediatrics*, **21**, 298–301.
- Barnet, J., Cooper, H. & Senior, V. (2007) Belief in public efficacy, trust, and attitude toward modern genetic science. *Risk Analysis*, **27**, 921–933.
- Brass, E. P. (2001) Changing the status of drugs from prescription to over-the-counter availability. *New England Journal of Medicine*, **345**, 810–816.
- Casiday, R. E. (2006) Children's health and the social theory of risk: insights from the British measles, mumps, and rubella (MMR) controversy. *Social Science & Medicine*, **65**, 1059–1070.
- Casiday, R., Cresswell, T., Wilson, D. & Panter-Brick, C. (2006) A survey of UK parental attitudes to the MMR vaccine and trust in medical authority. *Vaccine*, **24**, 177–184.
- Conroy, S., Collier, J., Birchley, N., Neil, K., Rodgers, S., McIntyre, J., Choonara, I. & Avery, A. (2003) An examination of the risk management issues in the handling at home of over-the-counter medicines purchased for children. *The Pharmaceutical Journal*, **271**, 209–213.
- Crissey, S. R. (2009) Educational attainment in the United States: 2007. *Current Population Reports*, pp. 20–560.
- Dart, R. C., Paul, I. M., Bond, R. G., Winston, D. C., Manoguerra, A. S., Palmer, R. B., Kauffman, R. E., Banner, W., Green, J. L. & Rumack, B. H. (2009) Pediatric fatalities associated with over the counter (Nonprescription) Cough and Cold Medications. *Annals of Emergency Medicine*, **53**, 411–417.
- DeNavas-Walt, C., Proctor, B. D. & Smith, J. (2008) Income, poverty and health insurance coverage in the United States: 2007. *Current Population Reports*, pp. 60–235.
- Food and Drug Administration Public Health Advisory (2008) *FDA Recommends that over-the-counter (OTC) cough and cold products not be used for infants and children under 2 years of age*. Available at: <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm051137.html> (last accessed 6 June 2009).
- Glasziou, P. P. (2002) Analgesia and public health: what are the challenges? *American Journal of Therapeutics*, **9**, 207–213.
- Goldman, R. & Scolnik, D. (2004) Underdosing of acetaminophen by parents and emergency department utilization. *Pediatric Emergency Care*, **20**, 89–93.
- Hanoch, Y., Katsikopoulos, K. V., Gummerum, M. & Brass, E. P. (2007) American and German students' knowledge, perceptions, and behaviors with respect to over-the-counter pain relievers. *Health Psychology*, **26**, 802–806.
- Harris, G. (2005, March 5) *F.D.A. official admits 'Lapses' on vioxxx*. *New York Times*. Available at: <http://www.nytimes.com/2005/03/02/politics/02fda.html> (last accessed 9 June 2008).
- Heikkinen, T. & Järvinen, A. (2003) The common cold. *The Lancet*, **361**, 51–59.
- Hobson-West, P. (2007) Trusting blindly can be the biggest risk of all: organized resistance to childhood vaccination in the UK. *Sociology of Health & Illness*, **29**, 198–215.
- Kaufman, D. W., Kelly, J. P., Rosenberg, L., Anderson, T. E. & Mitchell, A. A. (2002) Recent patterns of medication use in the ambulatory adult population of the United States: the Slone survey. *JAMA: Journal of the American Medical Association*, **287**, 37–344.
- Kogan, M. D., Pappas, G., Yu, S. M. & Kotelchuck, M. (1994) Over-the-counter medication use among U.S. preschool-age children. *JAMA: Journal of the American Medical Association*, **272**, 1025–1030.
- Kuehn, B. M. (2007) FDA: cold medications risky for young children. *JAMA: Journal of the American Medical Association*, **12**, 1151.
- Lokker, N., Sanders, L., Perrin, M. E., Kumar, D., Finkle, J., France, V., Choi, L., Johnston, P. E. & Rothman, R. L. (2009) Parental misinterpretations of over-the-counter pediatric cough and cold medication labels. *Pediatrics*, **123**, 1464–1471.
- Norton, B. (2000) Parental knowledge of different acetaminophen concentrations for infants and children. *Academic Emergency Medicine*, **7**, 718–721.
- NPR/Kaiser Family Foundation/Harvard School of Public Health (2008) *Children's OTC cold medication: the public, and parents, weigh in*. Available at: <http://www.kff.org/kaiserpolls/pomr121307pkg.cfm> (last accessed 10 May 2009).
- Orr, K. K., Matson, K. L. & Cowles, B. (2006) Nonprescription medication use by infants and children: product labeling versus evidence-based medicine. *Journal of Pharmacy Practice*, **19**, 286–294.
- Roumie, C. L. & Griffin, M. R. (2004) Over-the-counter analgesics in older adults. *Drugs and Aging*, **21**, 485–498.
- Schaefer, M. K., Shehab, N., Cohen, A. L. & Budnitz, D. S. (2008) Adverse events from cough and cold medications in children. *Pediatrics*, **1221**, 783–787.
- Squires, R. H., Shneider, B. L., Bucuvalas, J., Alonso, E., Sokol, R. J., Narkewicz, M. R., Dhawan, A., Rosenthal, P., Rodriguez-Baze, N., Murray, K. F., Horslen, S., Martin, M. G., Lopez, J. M., Soriano, H., McGuire, B. M., Jonas, M. M., Yazigi, N., Shepherd, R. W., Schwarz, K., Lobritto, S., Thomas, D. W., Lavine, J. E., Karpen, S., Ng, V., Kelly, D., Simonds, N. & Hynan, L. S. (2006) Acute liver failure in children: the first 348 patients in the pediatric acute liver failure study group. *Journal of Pediatrics*, **148**, 652–658.
- Ward, R. M., Bates, B. A., Benitz, W. E., Burchfield, D. J., Ring, J. C., Walls, R. P. & Walson, P. D. (2001) Acetaminophen toxicity in children. *Pediatrics*, **108**, 1020–1024.

- Webster, P. A., Roberts, D. W., Benson, R. W. & Kearns, G. L. (1996) Acetaminophen toxicity in children: diagnostic confirmation using a specific antigenic biomarker. *Journal of Clinical Pharmacology*, **36**, 397–402.
- Williams, D. J. & Noyes, J. M. (2007) How does our perception of risk influence decision-making? Implications for the design of risk information. *Theoretical Issues in Ergonomics Science*, **8**, 1–35.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. OTC-CCM Survey.

Please note: Blackwell Publishing are not responsible for the content or functionality of any supporting materials supplied by the authors. Any queries (other than missing material) should be directed to the corresponding author for the article.