

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	WHERE TO BUY OTC MEDICATIONS? A cross-sectional survey investigating consumers' confidence in over-the-counter (OTC) skills and their attitudes towards the availability of OTC analgesics.
<b>AUTHORS</b>	Brabers, Anne; van Dijk, Liset; Bouvy, Marcel; De Jong, Judith

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Hanna, Lezley-Anne School of Pharmacy, The Queen's University of Belfast
<b>REVIEW RETURNED</b>	11-Jul-2013

<b>THE STUDY</b>	<p>I have answered 'no' to two questions about patients and participants, however, the more appropriate answer is 'unsure'.</p> <p>The questionnaire was sent to the 'Dutch Health Care Consumer Panel'.</p> <p>As I have stated in the reviewer's comments, I think the reader would benefit from knowing more about the Dutch Health Care Consumer Panel (the respondents of the questionnaire).</p> <p>How representative are they of the population/could the fact that they are members of this panel mean they are more interested in healthcare and medicines than other members of the public? Is this a potential source of bias? Also, are some members of the panel healthcare professionals? This would affect how skilled they think they are (and others) at choosing medicines. If pharmacists have completed the questionnaire, they might prefer OTC medicines to be only available through pharmacies rather than supermarkets/petrol stations.</p> <p>In terms of the method, it is not clear whether a pilot study was conducted, whether definitions were provided as part of the questionnaire, and how they enhanced the validity and response rate of the questionnaire from the outset.</p>
<b>RESULTS &amp; CONCLUSIONS</b>	<p>Most of the interpretations and conclusions are appropriate. However, there is one statement which could be revised:</p> <p>"Consumers see pharmacists to be a reliable source of information because they prefer the analgesics to be available in pharmacies."</p> <p>I don't think this can be concluded (that they see pharmacists as a reliable source of advice) based on the data.</p>
<b>REPORTING &amp; ETHICS</b>	<p>The authors have stated that ethical approval was not necessary. They have provided details about data registering (with the Dutch Data Protection Authority).</p>

	<p>The authors need to expand on the 'Dutch Health care Consumer Panel' (the respondents who completed the questionnaire) and whether these people have a vested interest in healthcare and medicines, more so that a typical member of the public.</p> <p>The authors should expand on how they tried to increase the response rate from the outset (to reduce non-response bias) and how it was assessed for validity (for example, content/face validity and whether a pilot study was conducted and questions modified based on feedback)</p> <p>Also, they used mixed methods (postal and electronic questionnaires) to collect the data and then collated the results. Any implications of this approach should be mentioned.</p>
<b>GENERAL COMMENTS</b>	<p>Abstract:</p> <p>Design  Could rephrase the sentence to: Mixed methods (postal and electronic) self-administered questionnaire.</p> <p>Main outcome measures  The following sentences could be removed as they are not really main outcome measures:  “This is because, generally, people are roughly accurate when estimating peers’ attitudes and behaviours.”  “Respondents had to indicate which channel they prefer for each profile”</p> <p>Results  The response rate could be mentioned at the outset of this section and perhaps some other demographic data.</p> <p>Article summary:</p> <p>Another strength is that this study is novel and addresses an area where there is sparse information available and therefore it adds to the field.</p> <p>Other limitations are that the study only relates to one area of the over-the-counter medicines market (albeit a large area) and opinions gathered primarily relate to OTC analgesia that is available in the Netherlands.</p> <p>Manuscript:</p> <p>Background information</p> <p>This section could be further enhanced as outlined below:</p> <p>Include examples of recently deregulated medicines/over-the-counter medicines. You could tell readers how vast the area is/provide more information on the wide variety of conditions that can be treated over-the-counter. This would further emphasize the significance of these medicines and also your study.</p> <p>Mention the term ‘self-care’ which involves empowering people to take more control of their lives from a health perspective. Individuals must make informed choices so that they can select the right course of action.</p>

	<p>Outline a few other benefits of self-care (in addition to governments saving money). For example, in the UK, the Government has been promoting self-care on the basis that the public favour more control over their health and that it increases patient satisfaction.</p> <p>You discuss OTC availability increasing in various parts of the world such as USA, UK and Australia. It would be useful in the next paragraph to discuss the legal classifications of medicines in these places (alongside the Netherlands) so that readers can see how transferrable your findings are.</p> <p>You say that the Dutch government considered that consumers are well informed and know how to use OTC drugs appropriately. Perhaps you could mention problems with OTC medicines that have resulted in government regulatory bodies having to impose changes (for example, overdose/suicide risk with paracetamol meant restrictions were placed on pack size).</p> <p>You could expand on the theory around confidence/perception and also self-rating versus peer-rating.</p> <p>Methods</p> <p>The reader would benefit from knowing more about the Dutch Health Care Consumer Panel (the respondents of the questionnaire). How representative are they of the population/could the fact that they are members of this panel mean they are more interested in healthcare and medicines than other members of the public? Is this a potential source of bias? Also, are some members of the panel healthcare professionals? This would affect how skilled they think they are (and others) at choosing medicines. If pharmacists have completed the questionnaire, they might prefer OTC medicines to be only available through pharmacies rather than supermarkets/petrol stations</p> <p>You could mention that the questionnaires were self-completed/self-administered.</p> <p>Is the questionnaire available on request from the authors?</p> <p>Provide a brief overview of the number of sections/questions in total.</p> <p>State whether you collected any identifiable data (or whether it was anonymous).</p> <p>Did you provide any definitions/explanations/examples of over-the-counter medicines (for example, were vitamins, minerals and complementary and alternative medicines included in the umbrella-term of OTC medicines)?</p> <p>Did you define/explain what 'poor/bad'; 'good' and 'excellent/very good' health meant?</p> <p>How did you improve the validity of the questionnaire (piloting the questionnaire, content/face validity)?</p> <p>How did you try to maximise response rates from the outset with the postal and electronic questionnaires (to reduce non-response bias)? Edwards PJ, Roberts I, Clarke MJ, DiGiuseppi C, Wentz R, Kwan I, Cooper R, Felix LM, Pratap S. Methods to increase response to postal and electronic questionnaires. Cochrane Database of</p>
--	--

	<p>Systematic Reviews 2009, Issue 3. Art. No.: MR000008. DOI: 10.1002/14651858.MR000008.pub4.</p> <p>How did you ensure that all your data were entered accurately?</p> <p>The method section seems to contain some results - 972 members returned the questionnaire ; xx respondents failed to complete all profiles, the excluded respondents did not differ significantly from the respondents included.</p> <p>Question relating to the use of OTC drugs: This question might be affected by the time of year when the questionnaire was completed/there may also be recall bias. For example, if they completed the questionnaire in winter, you may get more cough, cold and sore throat medicines being mentioned because they were the most recent products used.</p> <p>Attitudes towards availability: In terms of transferability, it would be useful to know all analgesics that are available to purchase OTC in the Netherlands (and whether you mean oral/systemic analgesia only). For example, in the UK ibuprofen, diclofenac, naproxen, codeine, dihydrocodeine, paracetamol and aspirin are all available OTC in oral formulations. Ibuprofen and diclofenac are also available in topical preparations, flurbiprofen is available as a throat lozenge and choline salicylate is available in both eardrops and oromucosal form.</p> <p>With regard to analgesics/analgesia, did you use the word 'painkiller' or 'analgesic' in the questionnaire (i.e. was it a term that people would readily understand?).</p> <p>Were any reference sources used when developing the six safety profiles? "No side-effects when used as directed, but taking too many tablets can cause serious damage" implies oral formulations of analgesia, rather than topical.</p> <p>Results</p> <p>It would be useful to have population data in Table 1 so that the reader could easily see how the sample compared to the demographic profile of the population.</p> <p>The use of OTC drugs: 83% used OTC medications in the past year. As mentioned previously, did you define what was meant by an 'OTC medicine' from the outset?</p> <p>You mention that they had used analgesics, followed by medicines for coughs, colds and sore throat. I presume that these medicines also contain analgesia in many cases? In the question, did your pre-defined categories list types of medicines (analgesics, decongestants...) or rather medicines for specific conditions (headache products, cold products)? Do you have any data on % respondents who reported using analgesia, % who reported using cough medicines etc. It is unclear what the 76% relates to here.</p> <p>P8 'respondents felt clearly less confident.' is a bit confusing - perhaps rephrase to: 'Clearly, the respondents felt less confident...'</p> <p>P8 11% of them thought that others know how to apply OTC drugs safely. Perhaps reword 'apply' as this may make readers think of</p>
--	--

	<p>topical formulations.</p> <p>P8 'Supermarkets or petrol stations were hardly mentioned.' Perhaps rephrase and consider making more exact. Only x% chose supermarkets or petrol stations as their preferred option.</p> <p>You could write your results in the past-tense: "Women felt slightly more confident..." rather than "Women feel slightly more confident...."</p> <p>Figure 1: I am/others are able to make a choice. Perhaps the word 'appropriate' could have been included in the question. I am/others are able to make an appropriate choice.</p> <p>Discussion</p> <p>Acknowledge that data were collected in two different ways (postal versus electronic) and any implications a mixed-methods approach may have on the findings.</p> <p>Question relating to use of OTC medicines: you could acknowledge that the question might be affected by the time of year when the questionnaire was completed/there may also be recall bias. For example, if they completed the questionnaire in winter, you may get more cough, cold and sore throat medicines being mentioned because they were the most recent products used.</p> <p>Question relating to availability: perhaps opinions would be different if the question had included information on pack sizes/quantity available. Someone might think it is okay to be able to buy a small quantity of an analgesic in the supermarket/petrol station, but not large quantities. Furthermore, it would have been interesting to get opinions/views on the actual analgesics that are available to buy. I would posit that if you asked the question again (but this time named specific medications instead of providing the safety profile) you would get different results. If you are familiar with a name, and have used a medication before with little/no adverse effects, you may not consider that it needs to be restricted to pharmacies only.</p> <p>Also, in the UK, the General Pharmaceutical Council outline the possibility of non-prescription medicines moving to self-selection (no 'pharmacy' medicine category). For more details, please see: <a href="http://www.pharmacyregulation.org/standards/standards-registered-pharmacies/self-selection-p-medicines-related-documents">http://www.pharmacyregulation.org/standards/standards-registered-pharmacies/self-selection-p-medicines-related-documents</a></p> <p>Some recent deregulations have been criticized by the medical profession because of concerns that serious underlying conditions will be masked or that their availability OTC will delay patients making an appointment.</p> <p>Implications</p> <p>Consumers see pharmacists to be a reliable source of information because they prefer the analgesics to be available in pharmacies. Not sure you can conclude this (that they see pharmacists as a reliable source of advice) - it certainly seems that they consider a pharmacy to be a 'safer/more controlled' environment.</p> <p>Also, see the recent Which? report entitled Can you trust your local pharmacy's advice?</p>
--	---

	<a href="http://www.which.co.uk/news/2013/05/can-you-trust-your-local-pharmacys-advice-319886/">http://www.which.co.uk/news/2013/05/can-you-trust-your-local-pharmacys-advice-319886/</a>
--	---

<b>REVIEWER</b>	Mackridge, Adam Liverpool John Moores University, Pharmacy & Biomolecular Science
<b>REVIEW RETURNED</b>	15-Jul-2013

<b>THE STUDY</b>	<p>Regarding the patients being representative, the use of the Dutch Health Care Consumer Panel seems to be a reasonable approach for gaining a wide sample of the public, but I wondered if the authors could include some comment regarding their representativeness of the wider Dutch population. In particular, that their interest in being involved in the panel may mean that their opinions regarding health may differ to the wider population. This may account for their perceived above-average OTC skills.</p> <p>Although I consider that the study is well written, the following points might be usefully considered prior to publication:</p> <ol style="list-style-type: none"> <li>1. Regarding the description of the methods, the following points needs clarifying: On page 8, line 41, the authors state that "Supermarkets and petrol stations were hardly mentioned as a preferred channel". However, in the methods (Page 6, line 39), the authors suggest that a closed question was used to evaluate respondent preferences for availability and supermarkets/petrol stations were not listed options.</li> <li>2. Page 6, lines 39-57 &amp; Page 7, lines 1-4: Please clarify how the score was calculated for availability - 1=GS, 4=POM - this is not clear from the text as two numbered lists are used, with different numbers for the different responses</li> </ol>
<b>GENERAL COMMENTS</b>	<p>Thank you for the opportunity to read this well written study exploring links between consumer confidence in OTC skills and availability of OTC analgesics in the Netherlands. I found the study interesting and well designed, with appropriate analysis and good presentation of the data. I do have a couple of minor points which I think may be helpful in improving the current version of the paper and these are listed below.</p> <ol style="list-style-type: none"> <li>1. Parts of the discussion may benefit from some revision to make them easier to follow - at present many of the points are not connected and the text does not flow as a consequence</li> <li>2. In the limitations section, it may be helpful for the authors to discuss the impact of culture arising from no general sales availability until shortly before the study and the possible social acceptability bias that this may cause. For example, if this study were to be performed in a country where general sales of medicines is well established, the public confidence in such availability may be considerably different - this is an important point for applicability of the findings beyond the Netherlands</li> <li>3. I also noted a small number of typographical/grammatical errors, for example: on page 8, line 13 'apply' seems incorrect here, 'use' would be more appropriate</li> </ol>

<b>REVIEWER</b>	Cooper, Richard University of Sheffield, SchARR
<b>REVIEW RETURNED</b>	24-Jul-2013

## THE STUDY

The main concern in the study is the operationalisation of what is meant by consumers' skills. This is more than the use of a synonym (and elsewhere the term 'confidence' is used but so too is 'appropriate' and is related to the more fundamental attempts to measure this concept. 3 questions are used: 1) does consumer feel they can make a choice between medicines, 2) do they know exactly how to use them, and 3) when they try to get advice, do they get it. I am not sure that 1) captures this, as it simply asks if they have in effect the capacity to choose. I would have thought a more telling or probing question would be to ask them to rate their self-reported knowledge about medicines and use a 5 point Likert from 'very good' to 'very poor'. If I substitute this for, say, my current need to buy block paving for a drive, if asked this question about that I would say 'yes' but because I have the choice, and I can exercise it, and to SOME extent I am aware of different colours, shapes and porosity BUT I do not feel expert and would want further advice. By analogy, I feel that consumers could answer 'yes' to this question yet it not capture quite what the authors intend. Regarding 2) this feels more acceptable save for the use of the word 'exactly' which seems odd and introduces a degree of certainty that is too demanding. 3) I feel is not appropriate since it is actually asking more of the ability of the provider of the information rather than the 'skill' of the consumer and how easy this is. Are the authors asking if the consumer is skilled in looking for information? If so, then asking about their confidence in where to find information would have been a better phrase. But to ask about ease of obtaining and of whether the 'right' information is provided, then this is manifestly the domain of the provider of the information (pharmacist, druggist, manufacturer etc).

Regarding the second main aim, to solicit consumers' views of others, this is worthy in one sense and does, as the authors indicate, link to obvious psychological literature around self and other and knowledge/control BUT again this is limited by asking the same questions above that I have concerns with. These obviously only represent self-report and are clearly limited as such but in theory are of value in understanding if individuals over-estimate their own ability.

It does not appear that the survey instrument was piloted and I felt, given my concerns above, that this would have benefited from this, or an expert panel OR a mixed methods study to use a qualitative initial stage to explore and identify themes for these concepts (ie to increase validity).

The third aim I felt was more successful, in seeking views on the most appropriate supply route/location for the hypothetical medicines with different profiles. This DOES work and is of use. However, I am very surprised at the omission of internet supplies, as this is now a very significant market and one with considerable concerns over quality/safety etc and would have been an excellent and obvious 5th category.

I have indicated no for the sample, as this is clearly a useful group who by my understanding of the demographics presented, reflect a different group to the general population. Comparisons do help but the authors do indicate the limitations but this I suspect reflects a very atypical group. I am assuming they are, like other such groups, rather experienced and sensitised to being involved in 'consumer' work and their motivations for participating may be different from the public. Sampling from pharmacies is notoriously hard in terms of response rates but perhaps even 'general public' sampling would

	<p>have been better (random address etc).</p> <p>I was curious if the word 'analgesic' was used (obviously in Dutch) and not a more common phrase like 'pain killer', as in the UK it would be extremely rare for a customer/patient to ask for an analgesic and again might this have affected the study. I did however like the reflection on the difference between brand and generic and the authors recognise this from previous data.</p>
<b>GENERAL COMMENTS</b>	<p>The comments I have provided are sadly negative and do have an impact on the fundamental concepts and methods of the study which I feel make it unsuitable for revision. However, the one part which appeared valid and would be of interest concerned the attitudes to where the hypothetical medicines would be available. However, even this I felt was limited by not considering all the possible supply routes and the internet being an important one.</p>

### VERSION 1 – AUTHOR RESPONSE

Reviewer 1 – Dr. Lezley-Anne Hanna

General comments

Comment 1:

The questionnaire was sent to the 'Dutch Health Care Consumer Panel'. As I have stated in the reviewer's comments, I think the reader would benefit from knowing more about the Dutch Health Care Consumer Panel (the respondents of the questionnaire).

Response to comment 1:

We included more information (see hereafter for the exact information) about the Dutch Health Care Consumer Panel in the paragraph Setting in the Methods.

In addition, more information about the Consumer Panel is available in The Dutch Health Care Consumer Panel in Brabers et al. (2012) (see reference 18 in the manuscript), and on <http://www.nivel.nl/dossier/about-panel>

Comment 2:

The first reviewer has several comments regarding the representativeness of the respondents:

- 1) How representative are they of the population/could the fact that they are members of this panel mean they are more interested in healthcare and medicines than other members of the public? Is this a potential source of bias? Also, are some members of the panel healthcare professionals? This would affect how skilled they think they are (and others) at choosing medicines. If pharmacists have completed the questionnaire, they might prefer OTC medicines to be only available through pharmacies rather than supermarkets/petrol stations.
- 2) As previously mentioned the authors need to expand on the 'Dutch Health care Consumer Panel' (the respondents who completed the questionnaire) and whether these people have a vested interest in healthcare and medicines, more so than a typical member of the public.
- 3) The reader would benefit from knowing more about the Dutch Health Care Consumer Panel (the respondents of the questionnaire). How representative are they of the population/could the fact that they are members of this panel mean they are more interested in healthcare and medicines than other members of the public? Is this a potential source of bias? Also, are some members of the panel healthcare professionals? This would affect how skilled they think they are (and others) at choosing medicines. If pharmacists have completed the questionnaire, they might prefer OTC medicines to be only available through pharmacies rather than supermarkets/petrol stations.

Response to comment 2:

Hereafter, we would like to give an overall response to these comments.

The potential bias is expected to be low. First, there is no possibility for consumers who are interested in healthcare and medicines to sign up for the panel on their own initiative. Second, to recruit new panel members an address file is bought from an address supplier. As a result, possible new

members are sampled at random from the general population in the Netherlands. Third, the panel is renewed on regular base to make sure that members do not develop specific knowledge of, and attention for, health care issues, and that no questionnaire-fatigue occurs.

We added the following sentences in the paragraph Setting in the Methods:

“There is no possibility for consumers to sign up for the panel on their own initiative. The panel is renewed on regular base. Renewal is necessary to make sure that members do not develop specific knowledge of, and attention for, health care issues, and that no questionnaire-fatigue occurs. Moreover, renewal compensates for panel members who, for example, have died or moved without informing us about the new address. To recruit new panel members an address file is bought from an address supplier. As a result, possible new members are sampled at random from the general population in the Netherlands. Sampled people receive an information letter about the panel and are called within a week after receiving that letter. If they are interested, they receive a questionnaire on their background characteristics. When that questionnaire is returned, they are considered members of the panel.”

Moreover, the reviewer wonders whether some members of the panel are healthcare professionals. The aim of the Dutch Health Care Consumer Panel is to be a cross-section of the Dutch population aged 18 years and older. As such, we also aim that people being a healthcare professional or working in the healthcare sector are members of the panel, since a considerable part of the Dutch population is working in healthcare (see report Statistics Netherlands, 2011).

We know from our panel members whether they work(ed) or never worked in healthcare, however, we do not know what kind of work they do or did in the healthcare sector. We therefore did some additional t-test analyses, and we included the variable “working in healthcare” in our regression analyses. The additional analyses show that respondents who work or worked in healthcare were significantly, but modest, more confident than respondents that have never worked in healthcare. No difference was observed between both groups with regards to their attitudes towards availability. We added the results of the additional analyses in the Results section of the manuscript, as well as in table 3 (results regression model).

Report Statistics Netherlands (2011) (in Dutch): <http://www.cbs.nl/NR/rdonlyres/935FE963-90F9-4439-8E1A-54A92D20CE78/0/2011c156pub.pdf>

Comment 3:

In terms of the method, it is not clear whether a pilot study was conducted, whether definitions were provided as part of the questionnaire, and how they enhanced the validity and response rate of the questionnaire from the outset. Most of the interpretations and conclusions are appropriate. However, there is one statement which could be revised: “Consumers see pharmacists to be a reliable source of information because they prefer the analgesics to be available in pharmacies.” I don't think this can be concluded (that they see pharmacists as a reliable source of advice) based on the data.

Response to comment 3:

We provided definitions in our questionnaire. At the beginning of the questionnaire we defined OTC medications as: “OTC medications are medicines that you can buy at pharmacies and chemists without a doctors' prescription. In addition, you can buy some of these medicines at supermarkets and petrol stations. Examples of OTC medications are painkillers, such as paracetamol or ibuprofen. Homeopathic medicines, nutritional supplements and contraceptives are not considered to be OTC medications.”

We added this definition in the paragraph Use of OTC drugs in the Methods.

There were no validated scales available to measure our concepts. Face and content validity were assessed by two senior researchers of this study (LVD and MB). MB is an expert in the field of OTC medications. He is author of a Dutch handbook of self-medication published by the Dutch Consumers Organisation. Furthermore, the concept questionnaire was discussed with senior staff members of the Medicines Department of the Dutch Ministry of Health, Welfare and Sport. In addition, the questionnaire was commented upon by the program committee of the Dutch Health Care Consumer Panel, consisting of representatives of different actors in the healthcare sector, e.g. the Dutch Ministry

of Health, Welfare and Sport, the Federation of Patients and Consumer Organizations in the Netherlands, the Health Care Inspectorate and the Dutch Consumers Association. No pilot study was conducted due to lack of time within the project.

The response rate of surveys within the Dutch Health Care Consumer Panel is generally high, usually above 65%. We have a standard procedure to improve the response rates, we send two electronic and one postal reminder. The following sentence has been added in the paragraph Questionnaire in the Methods: "To increase the response from the onset, two electronic reminders and one postal reminder were sent to panel members who had not responded yet."

We revised the statement in the Discussion in the following sentence: "What seems clear is that consumers consider pharmacies as a safe environment, since most of them prefer the painkillers described to be available in pharmacies exclusively." Nevertheless, based on earlier research, we think that Dutch consumers consider pharmacists as a reliable source of information regarding OTC medications. We added some additional sentences in the paragraph Implications in the Discussion to support this: "This is confirmed in an earlier study where was found that Dutch consumers consider pharmacists as the most reliable source of information regarding OTC medication (Brinkman et al., 2008). Although Dutch consumers expect to be provided with reliable information from pharmacies, it is possible that there are differences between pharmacies with regards to the quality of their advice. Furthermore, in 2010, 88% of the Dutch adult population put much or very much trust in pharmacists."

Comment 4:

The authors should expand on how they tried to increase the response rate from the outset (to reduce non-response bias) and how it was assessed for validity (for example, content/face validity and whether a pilot study was conducted and questions modified based on feedback)

Response to comment 4:

See our reaction on comment 3.

Comment 5:

Also, they used mixed methods (postal and electronic questionnaires) to collect the data and then collated the results. Any implications of this approach should be mentioned.

Response to comment 5:

As previously mentioned, the aim of the Dutch Health Care Consumer Panel is to be a cross-section of the Dutch population. A large part of them using the internet. When consumers become member of the panel, they can indicate whether they prefer to receive questionnaires by post or through the internet. Providing panel members with this option is also meant to increase the response rate from the onset. The implication of using mixed methods is that we do not exclude certain groups that are not reached by using one of the methods, postal or electronic questionnaires.

Abstract & abstract summary

Comment 6:

Design: Could rephrase the sentence to: Mixed methods (postal and electronic) self-administered questionnaire.

Response to comment 6:

Has been changed in the following sentence: "Mixed methods (postal and electronic) self-administered questionnaire."

Comment 7:

Main outcome measures: The following sentences could be removed as they are not really main outcome measures: "This is because, generally, people are roughly accurate when estimating peers' attitudes and behaviours." "Respondents had to indicate which channel they prefer for each profile"

Response to comment 7:

The first sentence "This is because, generally, people are roughly accurate when estimating peers' attitudes and behaviours" has been removed.

The second sentence has been combined with the sentence before, resulting in the following sentence: "Consumers' attitudes towards availability were assessed using six safety profiles, by asking which channel consumers prefer for each profile".

Comment 8:

Results: The response rate could be mentioned at the outset of this section and perhaps some other demographic data.

Response to comment 8:

We added the following sentence at the outset of the Results section: "The response rate was 68% (N=972)." Due to the word limit of the abstract there was unfortunately no space to add other demographic data.

Comment 9:

Article summary: Another strength is that this study is novel and addresses an area where there is sparse information available and therefore it adds to the field. Other limitations are that the study only relates to one area of the over-the-counter medicines market (albeit a large area) and opinions gathered primarily relate to OTC analgesia that is available in the Netherlands.

Response to comment 9:

The mentioned strength has been added in the article summary as well as in the paragraph The strengths and limitations of the study in the Discussion: "Another strength is that this study addresses a relatively unexplored area." The first limitation has been added in the article summary as well as in the paragraph The strengths and limitations of the study in the Discussion: "In addition, the study only relates to painkillers, the most used OTCs in the Netherlands." Regarding the second mentioned limitation, we recognize that there are some cultural differences between countries. In the discussion of the revised manuscript we tried to reflect more on the international context.

Manuscript

Comment 10:

Background: Background information: This section could be further enhanced as outlined below: Include examples of recently deregulated medicines/over-the-counter medicines. You could tell readers how vast the area is/provide more information on the wide variety of conditions that can be treated over-the-counter. This would further emphasize the significance of these medicines and also your study.

Mention the term 'self-care' which involves empowering people to take more control of their lives from a health perspective. Individuals must make informed choices so that they can select the right course of action. Outline a few other benefits of self-care (in addition to governments saving money). For example, in the UK, the Government has been promoting self-care on the basis that the public favour more control over their health and that it increases patient satisfaction. You discuss OTC availability increasing in various parts of the world such as USA, UK and Australia. It would be useful in the next paragraph to discuss the legal classifications of medicines in these places (alongside the Netherlands) so that readers can see how transferrable your findings are. You say that the Dutch government considered that consumers are well informed and know how to use OTC drugs appropriately. Perhaps you could mention problems with OTC medicines that have resulted in government regulatory bodies having to impose changes (for example, overdose/suicide risk with paracetamol meant restrictions were placed on pack size). You could expand on the theory around confidence/perception and also self-rating versus peer-rating.

Response to comment 10:

Thank you very much for the suggestions.

We added a sentence in the introduction to indicate that a wide variety of conditions can be treated with OTC medications. In addition, we added some examples of classes of OTC medications to the text: "Today, a wide range of conditions can be treated using medications that are available OTC. Some examples of categories of medicines that have been reclassified to non-prescription medication

in many countries are NSAIDs, anti fungal creams and laxatives.”

We now mention the term self-care in the introduction, in the following sentence: “The need to save on health care spending and the trend to enhance self care have led to more emphasis on patients taking their own responsibility for the management of minor ailments, including the use of medication that is available without a prescription.”

We provided some additional information about the Dutch Medicines Act. The idea of the Health Department was that increasing the availability of OTC medications fits better with the idea of the independent and critical consumer who wants to choose a particular drug themselves. We included the following sentence: “The Dutch healthcare policy is based on ideas that independent and critical consumers require an increased availability of OTC medication in order to select a particular drug themselves.”

We agree with the reviewer that adding an overview of the legal classifications of several countries to the text is of value, however, we think that giving such an overview is beyond the scope of our study. We therefore decided to only include that there is an increasing availability in various parts of the world. “Nevertheless, in many countries, increasingly more drugs that were previously only available on prescription are being switched to OTC status.”

Our study is part of a larger policy evaluation of the Dutch Medicines Act of 2007. Based on this overall policy evaluation, it has been decided to restrict the package size of some OTC medicines in 2011 after this study was performed. We therefore decided not to include this in the introduction. Moreover, it has been observed that in the last decade there had been an increase in requests on paracetamol poisoning to the National Poisons Information Center. This is included in the paragraph Implications of the Discussion.

Regarding the reviewers’ comment to expand on the theory around confidence/perception and also self-rating versus peer-rating, we acknowledge that this would be interesting. However, we think that expanding on this theory is beyond the scope of our descriptive study.

Comment 11:

Methods: You could mention that the questionnaires were self-completed/self-administered.

Response to comment 11:

We added this in the following sentence in the paragraph Questionnaire in the Methods: “In June 2010, a self-administered questionnaire was sent to 1,422 panel members and returned by 972 members.

Comment 12:

Methods: Is the questionnaire available on request from the authors?

Response to comment 12:

The questionnaire (in Dutch) is available on request from the authors. We added the following sentence in the paragraph Data Sharing in the Footnotes: “The questionnaire (in Dutch) is available on request from the authors.”

Comment 13:

Methods: Provide a brief overview of the number of sections/questions in total.

Response to comment 13:

We added the following sentence in the paragraph Questionnaire in the Methods: “In total, the questionnaire included 36 questions focusing on different aspects of OTC medications.”

Comment 14:

Methods: State whether you collected any identifiable data (or whether it was anonymous).

Response to comment 14:

Data are anonymously processed. We added this in the following sentence in the paragraph Setting in the Methods: “Data are anonymously processed, and the protection of the data collected is registered with the Dutch Data Protection Authority (nr. 1262949).”

Comment 15:

Methods: Did you provide any definitions/explanations/examples of over-the-counter medicines (for example, were vitamins, minerals and complementary and alternative medicines included in the umbrella-term of OTC medicines)?

Response to comment 15:

We provided a definition of OTC medicines at the beginning of the questionnaire (see comment 3 for the definition).

Comment 16:

Methods: Did you define/explain what 'poor/bad'; 'good' and 'excellent/very good' health meant?

Response to comment 16:

To measure self-reported general health we used one question from the SF-36, which is a commonly used scale to measure quality of life. In the SF-36, the answer categories are not defined so we also did not provide an explanation.

Comment 17:

Methods: How did you improve the validity of the questionnaire (piloting the questionnaire, content/face validity)?

Response to comment 17:

See our reaction on comment 3.

Comment 18:

Methods: How did you try to maximise response rates from the outset with the postal and electronic questionnaires (to reduce non-response bias)? Edwards PJ, Roberts I, Clarke MJ, DiGiuseppi C, Wentz R, Kwan I, Cooper R, Felix LM, Pratap S. Methods to increase response to postal and electronic questionnaires. *Cochrane Database of Systematic Reviews* 2009, Issue 3. Art. No.: MR000008. DOI: 10.1002/14651858.MR000008.pub4.

Response to comment 18:

Thank you for pointing at the interesting publication of Edwards et al. (2009). Some of the methods mentioned in this article are also used in the Dutch Health Care Consumer Panel. The response rate of the Dutch Health Care Consumer Panel is generally high. To maximize our response rate, we sent two electronic and one postal reminder. The following sentence has been added in the paragraph Questionnaire in the Methods: "To increase the response from the onset, two electronic reminders and one postal reminder were sent to panel members who had not responded yet." (see also our reaction on comment 3).

Comment 19:

Methods: How did you ensure that all your data were entered accurately?

Response to comment 19:

NIVEL holds a full ISO-9001 accreditation to assure the quality of the products. We have extensive procedures regarding, for example, data collection.

For this study, the answers of the online respondents are directly extracted from the website/system the respondents use to fill in the questionnaire. To ensure the data from the postal questionnaires were entered accurately, 100 postal questionnaires were re-entered by another research employer of our institute. The difference between both times the data were entered should be less than 1%. This was the case.

Comment 20:

Methods: The method section seems to contain some results - 972 members returned the questionnaire ; xx respondents failed to complete all profiles, the excluded respondents did not differ significantly from the respondents included.

Response to comment 20:

We agree with the reviewer that some of the results are already mentioned in the Methods. However, we decided to include these results in the Methods, since we require these results for the operationalization of our outcome measures confidence and attitudes towards availability.

Comment 21:

Methods: Question relating to the use of OTC drugs: This question might be affected by the time of year when the questionnaire was completed/there may also be recall bias. For example, if they completed the questionnaire in winter, you may get more cough, cold and sore throat medicines being mentioned because they were the most recent products used.

Response to comment 21:

We acknowledge that there might be some recall bias, since the questionnaire was conducted in the summer (June/July) of 2010. However, by asking respondents about the use of OTC medications in the past year and by pre-defining some categories of OTC medicines, we tried to overcome the problem that respondents possibly only remember products they recently used. Furthermore, we only used this information to get a first insight in the OTC medications used by the respondents.

Comment 22:

Methods: Attitudes towards availability: In terms of transferability, it would be useful to know all analgesics that are available to purchase OTC in the Netherlands (and whether you mean oral/systemic analgesia only). For example, in the UK ibuprofen, diclofenac, naproxen, codeine, dihydrocodeine, paracetamol and aspirin are all available OTC in oral formulations. Ibuprofen and diclofenac are also available in topical preparations, flurbiprofen is available as a throat lozenge and choline salicylate is available in both eardrops and oromucosol form.

Response to comment 22:

In The Netherlands, paracetamol (500 mg) is the most frequently used painkiller, followed by ibuprofen (200 mg) (Van Dijk et al, 2010; see reference 11 of the manuscript).

Comment 23:

Methods: With regard to analgesics/analgesia, did you use the word 'painkiller' or 'analgesic' in the questionnaire (i.e. was it a term that people would readily understand?).

Response to comment 23:

We used the word painkiller in the questionnaire. We changed this in the manuscript.

Comment 24:

Methods: Were any reference sources used when developing the six safety profiles? "No side-effects when used as directed, but taking too many tablets can cause serious damage" implies oral formulations of analgesia, rather than topical.

Response to comment 24:

Information reflected in the Patient Information Leaflets and in the Summaries of Product Characteristics were used to develop the six safety profiles. This information is reflected in the following sentence in the paragraph Attitudes towards availability in the Methods: "The profiles were descriptions of possible adverse effects of their use, inappropriately or not, and were based on information reflected in patient information leaflets and summaries of product characteristics."

Moreover, the six profiles were constructed by one of the research members (MB), who is a pharmacist with special interest in OTC medication and author of a Dutch handbook of self-medication. We indeed assumed oral formulations of painkillers, since paracetamol 500 mg is the most used painkiller in The Netherlands, followed by ibuprofen 200 mg.

Comment 25:

Results: It would be useful to have population data in Table 1 so that the reader could easily see how the sample compared to the demographic profile of the population.

Response to comment 25:

If applicable, we added population data in Table 1 based on data from Statistics Netherlands.

Comment 26:

Results: The use of OTC drugs: 83% used OTC medications in the past year. As mentioned previously, did you define what was meant by an 'OTC medicine' from the outset?

Response to comment 26:

We provided a definition of OTC medicines at the beginning of the questionnaire. See comment 3 for the used definition.

Comment 27:

Results: You mention that they had used analgesics, followed by medicines for coughs, colds and sore throat. I presume that these medicines also contain analgesia in many cases? In the question, did your pre-defined categories list types of medicines (analgesics, decongestants...) or rather medicines for specific conditions (headache products, cold products)? Do you have any data on % respondents who reported using analgesia, % who reported using cough medicines etc. It is unclear what the 76% relates to here.

Response to comment 27:

In the questionnaire we used six pre-defined categories that were a combination of both types of medicines and medicines for specific conditions, namely: 1) medicines for coughs, colds, flu and a sore throat; 2) laxatives (for stool); 3) medicines for stomach and intestinal problems; 4) medicines for the skin (acne, eczema, itching, dandruff, wounds); 5) pain and antipyretic medicines (such as paracetamol, ibuprofen or diclofenac) and 6) other drugs. In the article, we only presented the two categories that were most often used. We changed some sentences in the paragraph Use of OTC drugs in the section Results to make more clear where the 76% relates to.

Comment 28:

Results: P8 'respondents felt clearly less confident.' is a bit confusing - perhaps rephrase to: 'Clearly, the respondents felt less confident...'

Response to comment 28:

Has been changed in the following sentence: "Clearly, the respondents felt less confident about the OTC skills of others (mean score 2.92 and 95% CI: 2.88 to 2.96)."

Comment 29:

Results: P8 11% of them thought that others know how to apply OTC drugs safely. Perhaps reword 'apply' as this may make readers think of topical formulations.

Response to comment 29:

'Apply' has been changed in 'use'.

Comment 30:

Results: P8 'Supermarkets or petrol stations were hardly mentioned.' Perhaps rephrase and consider making more exact. Only x% chose supermarkets or petrol stations as their preferred option.

Response to comment 30:

Has been changed in: "Only 1% to 8% chose supermarkets or petrol stations as their preferred option."

Comment 31:

Results: You could write your results in the past-tense: "Women felt slightly more confident..." rather than "Women feel slightly more confident...."

Response to comment 31:

We revised the results section, and write it more in the past-tense.

Comment 32:

Figure 1: I am/others are able to make a choice. Perhaps the word 'appropriate' could have been included in the question. I am/others are able to make an appropriate choice.

Response to comment 32:

Has been changed in "I am/others are able to make an appropriate choice."

Comment 33:

Discussion: Acknowledge that data were collected in two different ways (postal versus electronic) and any implications a mixed-methods approach may have on the findings.

Response to comment 33:

See our reaction on comment 5.

Comment 34:

Discussion: Question relating to use of OTC medicines: you could acknowledge that the question might be affected by the time of year when the questionnaire was completed/there may also be recall bias. For example, if they completed the questionnaire in winter, you may get more cough, cold and sore throat medicines being mentioned because they were the most recent products used.

Response to comment 34:

See reaction on comment 21.

Comment 35:

Discussion: Question relating to availability: perhaps opinions would be different if the question had included information on pack sizes/quantity available. Someone might think it is okay to be able to buy a small quantity of an analgesic in the supermarket/petrol station, but not large quantities.

Furthermore, it would have been interesting to get opinions/views on the actual analgesics that are available to buy. I would posit that if you asked the question again (but this time named specific medications instead of providing the safety profile) you would get different results. If you are familiar with a name, and have used a medication before with little/no adverse effects, you may not consider that it needs to be restricted to pharmacies only.

Response to comment 35:

We acknowledge that the reviewer has a good point with regards to the information on pack sizes/quantity. We added this in the paragraph The strengths and limitations of the study in the Discussion. With respect to the reviewers' second point, we already addressed this point in the paragraph The strengths and limitations of the study. Earlier research in the Netherlands demonstrated that when trade names (e.g. paracetamol) of painkillers are presented to consumers, they judge them as safe or very safe. Further research is therefore recommended to include both indirect and direct measurements, to be able to compare the results.

Comment 36:

Discussion: Also, in the UK, the General Pharmaceutical Council outline the possibility of non-prescription medicines moving to self-selection (no 'pharmacy' medicine category). For more details, please see: <http://www.pharmacyregulation.org/standards/standards-registered-pharmacies/self-selection-p-medicines-related-documents>

Response to comment 36:

Thank you for the interesting information. We acknowledge that also other countries are outlining the possibility of moving medicines to non-prescription status, and we refer to this in the discussion and the introduction of the manuscript: "Nevertheless, in many countries an increasing number of drugs that were previously only available on prescription have been switched to OTC status."

Comment 37:

Discussion: Some recent deregulations have been criticized by the medical profession because of concerns that serious underlying conditions will be masked or that their availability OTC will delay

patients making an appointment.

Response to comment 37:

We acknowledge that recent deregulations have been criticized. We added the following sentence to the paragraph Implications in the Discussion: "There also have been some concerns regarding switching the status of prescription drugs to OTC availability. Examples of such concerns are an inaccurate diagnosis by patients and delay in obtaining medical assistance."

We also recommended in our manuscript that it is important for further research to examine the actual self-medication behaviour of consumers to be able to monitor what they buy and do (e.g. is there a delay in making an appointment, do they buy the right products).

Comment 38:

Implications: Consumers see pharmacists to be a reliable source of information because they prefer the analgesics to be available in pharmacies. Not sure you can conclude this (that they see pharmacists as a reliable source of advice) - it certainly seems that they consider a pharmacy to be a 'safer/more controlled' environment.

Response to comment 38:

See our reaction on comment 3.

Comment 39:

Implications: Also, see the recent Which? report entitled Can you trust your local pharmacy's advice? <http://www.which.co.uk/news/2013/05/can-you-trust-your-local-pharmacys-advice-319886/>

Response to comment 39:

Thank you for the interesting information. Interesting to read that there are such big variations in the quality of advice given by different companies in the UK. It is important that consumers can be confident that they get the right advice from pharmacies, since, for example, Dutch consumers see them as the most reliable source for information regarding OTC medications (see also our reaction on comment 3). We added a sentence about this in the discussion: "Although Dutch consumers expect to be provided with reliable information from pharmacies, it is possible that there are differences between pharmacies with regards to the quality of their advice."

Reviewer 2 – Dr. Adam J Mackridge

Comment 40:

Regarding the patients being representative, the use of the Dutch Health Care Consumer Panel seems to be a reasonable approach for gaining a wide sample of the public, but I wondered if the authors could include some comment regarding their representativeness of the wider Dutch population. In particular, that their interest in being involved in the panel may mean that their opinions regarding health may differ to the wider population. This may account for their perceived above-average OTC skills.

Response to comment 40:

First, there is no possibility for consumers who are interested in healthcare and medicines to sign up for the panel on their own initiative. Second, to recruit new panel members an address file is bought from an address supplier. As a result, possible new members are sampled at random from the general population in the Netherlands. Third, the panel is renewed on regular base to make sure that members do not develop specific knowledge of, and attention for, health care issues, and that no questionnaire-fatigue occurs.

So, we expect that the potential bias is low.

We added the following sentences in the paragraph Setting in the Methods:

"There is no possibility for consumers to sign up for the panel on their own initiative. The panel is renewed on regular base. Renewal is necessary to make sure that members do not develop specific knowledge of, and attention for, health care issues, and that no questionnaire-fatigue occurs.

Moreover, renewal compensates for panel members who, for example, have died or moved without

informing us about the new address. To recruit new panel members an address file is bought from an address supplier. As a result, possible new members are sampled at random from the general population in the Netherlands. Sampled people receive an information letter about the panel and are called within a week after receiving that letter. If they are interested, they receive a questionnaire on their background characteristics. When that questionnaire is returned, they are considered members of the panel.”

Comment 41:

Regarding the description of the methods, the following points need clarifying: 1. On page 8, line 41, the authors state that "Supermarkets and petrol stations were hardly mentioned as a preferred channel". However, in the methods (Page 6, line 39), the authors suggest that a closed question was used to evaluate respondent preferences for availability and supermarkets/petrol stations were not listed options. 2. Page 6, lines 39-57 & Page 7, lines 1-4: Please clarify how the score was calculated for availability - 1=GS, 4=POM - this is not clear from the text as two numbered lists are used, with different numbers for the different responses.

Response to comment 41:

1. We understand that this might not be clear. We used supermarkets / petrol stations as an operationalization of the category general sales, since we expected that consumers are not familiar with the term general sales as such. We added this in the paragraph Attitudes towards availability in the Methods in the following sentence: "..., with the following options: general sales (defined in the questionnaire as supermarket / petrol station); chemist; pharmacy only; and prescription only."
2. We again understand that this might not be clear. We revised some sentences, and give only one number for each answer category to avoid possible ambiguities: "We asked respondents to indicate their preferences for the availability of painkillers with the above described profiles, with the following options: general sales (defined in the questionnaire as supermarket / petrol station); chemist; pharmacy only; and prescription only. It should be noted that in the questionnaire the options were used in a different order, namely: pharmacy only; chemist; general sales; and prescription only. The answer options were based on the Dutch Medicines Act. The options were scored as 1 general sales; 2 chemist; 3 pharmacy only; and 4 prescription only. In addition, items scored as 'I don't know', were recoded as missing (in total 115 times, 16 to 25 per profile)."

Comment 42:

Parts of the discussion may benefit from some revision to make them easier to follow - at present many of the points are not connected and the text does not flow as a consequence.

Response to comment 42:

Based on the comments of the reviewers, we revised parts of the discussion. We hope that the discussion is now more easier to follow.

Comment 43:

In the limitations section, it may be helpful for the authors to discuss the impact of culture arising from no general sales availability until shortly before the study and the possible social acceptability bias that this may cause. For example, if this study were to be performed in a country where general sales of medicines is well established, the public confidence in such availability may be considerably different - this is an important point for applicability of the findings beyond the Netherlands

Response to comment 43:

Before the introduction of the new legislation in 2007, OTC medicines were only available in supermarkets with an incorporated chemist. With the introduction of the legislation, some medicines became also available for general sales in supermarkets and petrol stations. Nevertheless, there is still a limited number of OTC medications that are available on general sale in The Netherlands. Furthermore, supermarkets appear to be not a big sales channel in The Netherlands for OTC medicines that are available for general sales. As such, we think there is a low possible social acceptability bias, since not much differed for consumers. The most important difference between pre-

2007 and after 2007 was the availability of OTC medications in supermarkets. Yet, supermarkets are not an important sales channel in The Netherlands. Moreover, this study has been performed three years after the introduction of the Medicines Act. We therefore think consumers are familiar with the increased availability.

Comment 44:

I also noted a small number of typographical/grammatical errors, for example: on page 8, line 13 'apply' seems incorrect here, 'use' would be more appropriate.

Response to comment 44:

Has been changed from 'apply' in 'use'.

Reviewer 3 – Dr. Richard Cooper

Comment 45:

The main concern in the study is the operationalisation of what is meant by consumers' skills. This is more than the use of a synonym (and elsewhere the term 'confidence' is used but so too is 'appropriate' and is related to the more fundamental attempts to measure this concept. 3 questions are used: 1) does consumer feel they can make a choice between medicines, 2) do they know exactly how to use them, and 3) when they try to get advice, do they get it. I am not sure that 1) captures this, as it simply asks if they have in effect the capacity to choose. I would have thought a more telling or probing question would be to ask them to rate their self-reported knowledge about medicines and use a 5 point Likert from 'very good' to 'very poor'. If I substitute this for, say, my current need to buy block paving for a drive, if asked this question about that I would say 'yes' but because I have the choice, and I can exercise it, and to SOME extent I am aware of different colours, shapes and porosity BUT I do not feel expert and would want further advice. By analogy, I feel that consumers could answer 'yes' to this question yet it not capture quite what the authors intend. Regarding 2) this feels more acceptable save for the use of the word 'exactly' which seems odd and introduces a degree of certainty that is too demanding. 3) I feel is not appropriate since it is actually asking more of the ability of the provider of the information rather than the 'skill' of the consumer and how easy this is. Are the authors asking if the consumer is skilled in looking for information? If so, then asking about their confidence in where to find information would have been a better phrase. But to ask about easy of obtaining and of whether the 'right' information is provided, then this is manifestly the domain of the provider of the information (pharmacist, druggist, manufacturer etc).

Regarding the second main aim, to solicit consumers' views of others, this is worthy in one sense and does, as the authors indicate, link to obvious psychological literature around self and other and knowledge/control BUT again this is limited by asking the same questions above that I have concerns with. These obviously only represent self-report and are clearly limited as such but in theory are of value in understanding if individuals over-estimate their own ability.

Response to comment 45:

The reviewer has concerns with regards to the operationalisation of consumers' skills. Within our study, we did not aim to measure the knowledge of consumers with regards to OTC medication. This has already been done by several other studies, as mentioned in the introduction and discussion of our manuscript. In sum, literature shows that consumers seem to be unaware of how to use OTC medications appropriately. We therefore aimed to measure their own confidence in their OTC skills, because based on the self-estimation of their skills consumers chose and use OTC medications. Even consumers who have the right knowledge can have little confidence in their skills, but also consumers with limited knowledge can have high confidence in their own skills. There appears to be a discrepancy between our findings on the public perception about their own OTC skills and earlier research on the public awareness, perception and knowledge of OTC medication. While previous studies show that consumers seem to be unaware of how to use OTC medications appropriately, our study shows that consumers are convinced they know how to use OTC medications appropriately. Also regarding the view of others, we were interested in the perception of consumers regarding the skills of others, and not in the actual knowledge of consumers. Therefore, it would not be better to

operationalise our concepts in another way as the reviewer suggests.

Comment 46:

It does not appear that the survey instrument was piloted and I felt, given my concerns above, that this would have benefited from this, or an expert panel OR a mixed methods study to use a qualitative initial stage to explore and identify themes for these concepts (ie to increase validity).

Response to comment 46:

There were no validated scales available to measure our concepts. Face and content validity were assessed by two senior researchers of this study (LVD and MB). MB is an expert in the field of OTC medications. He is author of a Dutch handbook of self-medication published by the Dutch Consumers Organisation. Furthermore, the concept questionnaire was discussed with senior staff members of the Medicines Department of the Dutch Ministry of Health, Welfare and Sport. In addition, the questionnaire was commented upon by the program committee of the Dutch Health Care Consumer Panel, consisting of representatives of different actors in the health care sector, e.g. the Dutch Ministry of Health, Welfare and Sport, the Federation of Patients and Consumer Organizations in the Netherlands, the Health Care Inspectorate and the Dutch Consumers Association. No pilot study was conducted due to lack of time within the project.

Comment 47:

The third aim I felt was more successful, in seeking views on the most appropriate supply route/location for the hypothetical medicines with different profiles. This DOES work and is of use. However, I am very surprised at the omission of internet supplies, as this is now a very significant market and one with considerable concerns over quality/safety etc and would have been an excellent and obvious 5th category.

Response to comment 47:

This study was part of a policy evaluation regarding the Dutch Medicines Act of 2007. Within this policy evaluation only the official Dutch sales channels were evaluated. Internet is, however, not an official sales channel and as such not included in the analysis. Yet, we think this did not influence our results to a large extent. We recognize that the internet is an interesting category to examine in future and we added the following sentence in the paragraph The strengths and limitations of the study in the Discussion: "Furthermore, we did not include internet as a channel in our questionnaire, because this study was part of a policy evaluation in which only the official Dutch sales channels were evaluated. With the increasing growth of internet pharmacy, it would be interested to include this category in further research."

In The Netherlands the market share of internet pharmacy is limited. A Dutch report of Nyfer (2006) showed that, at that moment, internet pharmacy had a market share of less than 1%. The report expected that this will increase to at least 5% in the upcoming ten years. Consequently, we expected that at the time of our study (June 2010) the market share of internet pharmacy was still limited in The Netherlands. Moreover, our results show that people indicate pharmacies as preferred channel for the described painkillers. If we included internet as a fifth category, we expect that a very low percentage of the consumers indicate that channel, since this is less restrictive than supermarkets and petrol stations. And in our study, only 1% to 8% indicated supermarkets or petrol stations as preferred option.

Link to the Nyfer report:

<http://www.nyfer.nl/documents/Maatschappelijkeeffectenvaninternetfarmacie.pdf>

Comment 48:

I have indicated no for the sample, as this is clearly a useful group who by my understanding of the demographics presented, reflect a different group to the general population. Comparisons do help but the authors do indicate the limitations but this I suspect reflects a very atypical group. I am assuming they are, like other such groups, rather experienced and sensitised to being involved in 'consumer' work and their motivations for participating may be different from the public. Sampling from

pharmacies is notoriously hard in terms of response rates but perhaps even 'general public' sampling would have been better (random address etc)

Response to comment 48:

First, there is no possibility for consumers who are interested in healthcare and medicines to sign up for the panel on their own initiative. Second, to recruit new panel members an address file is bought from an address supplier. As a result, possible new members are sampled at random from the general population in the Netherlands. Third, the panel is renewed on regular base to make sure that members do not develop specific knowledge of, and attention for, health care issues, and that no questionnaire-fatigue occurs.

So, we expect that the potential bias is low.

We added the following sentences in the paragraph Setting in the Methods:

“There is no possibility for consumers to sign up for the panel on their own initiative. The panel is renewed on regular base. Renewal is necessary to make sure that members do not develop specific knowledge of, and attention for, health care issues, and that no questionnaire-fatigue occurs. Moreover, renewal compensates for panel members who, for example, have died or moved without informing us about the new address. To recruit new panel members an address file is bought from an address supplier. As a result, possible new members are sampled at random from the general population in the Netherlands. Sampled people receive an information letter about the panel and are called within a week after receiving that letter. If they are interested, they receive a questionnaire on their background characteristics. When that questionnaire is returned, they are considered members of the panel.”

Comment 49:

I was curious if the word 'analgesic' was used (obviously in Dutch) and not a more common phrase like 'pain killer', as in the UK it would be extremely rare for a customer/patient to ask for an analgesic and again might this have affected the study. I did however like the reflection on the difference between brand and generic and the authors recognise this from previous data.

Response to comment 49:

Painkiller was used in the questionnaire, this has been changed in the manuscript.

### VERSION 2 – REVIEW

<b>REVIEWER</b>	Hanna, Lezley-Anne School of Pharmacy, The Queen’s University of Belfast
<b>REVIEW RETURNED</b>	22-Aug-2013

<b>THE STUDY</b>	No - there are no questions raised about the work.  The standard of English is okay, although some statements could be rephrased as outlined in my comments below.
<b>REPORTING &amp; ETHICS</b>	The authors have declared that ethical approval was not deemed necessary to conduct this work.
<b>GENERAL COMMENTS</b>	General comment: the majority of queries have now been satisfactorily addressed. There are some additional comments arising from the 2nd review process.  Previous comments 1-2: the reader can now appreciate how representative the respondents were of the Dutch population and understand more about the Dutch Health Care Consumer Panel. Furthermore, thank you for doing additional t-tests and regression analyses in relation to those working in healthcare. It was interesting to note that those who work or worked in healthcare were significantly more confident than respondents that have never worked in healthcare, but that there was no difference between both groups with regard to their attitudes towards availability.

	<p>Previous comment 3: thank you for including the definition of an OTC medicine. Perhaps you could clarify that 'we defined it as...' or include the reference that the definition was taken from. For example, in the UK, the OTC medicines market data encompasses vitamins, minerals, slimming aids and emergency contraception, whereas your definition excludes nutritional supplements and contraception.</p> <p>Previous comment 4: I think it would be useful to add in a few sentences about questionnaire development, pilot, and validity to the Methods section under the sub-heading 'Questionnaire'. Additionally, I would remove the 'and returned by 972' since this is part of the results/already mentioned at the start of the Results section.</p> <p><b>Questionnaire</b>  The questionnaire was developed based on... (discussions within the research team and the wider literature?) and included 36 questions (with largely pre-defined categories of responses?) focusing on different aspects of OTC medication. While a pilot study was not conducted due to time constraints, face and content validity of the questionnaire were assessed by two senior researchers (LVD and MB). In June 2010, the self-administered questionnaire was sent to 1,422 panel members. According to their previously stated preference, 671 members received the questionnaire by post and 751 received an electronic version via the internet. Using a mixed methods approach helped ensure that certain groups were not excluded from the study and may also have increased the response rate. Other methods used to increase the response rate included sending two electronic reminders and one postal reminder to panel members who had not yet responded. The cut-off date for return of questionnaires was xxx.</p> <p>Previous comment 5: I think a comment about the mixed methods (postal and electronic questionnaires) could be included under the sub-heading 'Questionnaire' within the Methods section. Please see my suggestion above: "Using a mixed methods approach helped ensure that certain groups were not excluded from the study and may also have increased the response rate."</p> <p>Previous comments 6-9: thank you for addressing these comments</p> <p>Previous comment 10: thank you for further expanding upon the background information. The only remaining suggestion (since your study focuses largely on OTC analgesia) is that you outline the analgesics that are available OTC in the Netherlands so that the reader can transfer the findings of your study to their particular setting. For example, in the UK ibuprofen, diclofenac, naproxen, codeine, dihydrocodeine, paracetamol and aspirin are all available OTC in oral formulations. Ibuprofen and diclofenac are also available in topical preparations, flurbiprofen is available as a throat lozenge and choline salicylate is available in both eardrops and oromucosal form.</p> <p>Previous comment 11-15: thank you for addressing these comments</p> <p>Previous comment 16: The information which you have provided below could be added under the sub-heading 'Questionnaire' within the Methods section.</p>
--	--

	<p>“To measure self-reported general health one question from the SF-36 was used since this is a commonly used scale to measure quality of life (ref). In the SF-36 the answer categories (bad/poor; good; excellent/very good) are not defined, therefore we did not provide any explanation of these terms either.”</p> <p>Previous comment 17-21: thank you for addressing these comments</p> <p>Previous comment 22: In terms of transferability, it would be useful to know all analgesics that are available to purchase OTC in the Netherlands (and whether you mean oral/systemic analgesia only). Please provide this information either as part of the background information or in the discussion. This is a separate point from providing data on the most frequently used OTC painkillers.</p> <p>Previous comment 23: Thank you for clarifying that you used painkiller rather than analgesia in the questionnaire. I did not intend for you to remove all occurrences of the word analgesia/analgesic from the manuscript, but rather that you clarified what term was used in the actual questionnaire.</p> <p>Previous comment 24: Perhaps it would have been useful to clarify in the questionnaire that you were seeking views on oral painkillers, if this is indeed what you specifically wanted the focus to be (rather than topical).</p> <p>Previous comment 25-30: thank you for addressing these comments</p> <p>Previous comment 31: more of the results could be written in the past-tense, for example: “consumers felt confident about their own OTC skills but had less confidence in the skills of others.” However this is just a difference in opinion over how to report the findings.</p> <p>Previous comment 32: in my previous review, I commented on the wording of one of the questions: “I am/others are able to make a choice.” I suggested that the word ‘appropriate’ could have been included in the question i.e. “I am/others are able to make an appropriate choice”.</p> <p>I see this has now been added throughout the manuscript and figure – however, if this wasn’t actually in the original version of the questionnaire, please remove it and consider including this point as a limitation/suggestion as to how the question could have been more suitably worded.</p> <p>Previous comment 33-38: thank you for addressing these comments</p> <p>Additional comment 1: in the Background section, the sentence: “Pharmacies are run by a pharmacist and able to sell all prescription and non-prescription drugs...” is potentially confusing and misleading. It almost implies that a person could purchase any type of medicine (prescription-only or non-prescription) from a pharmacy.</p> <p>Additional comment 2: in the Background section, the ‘A study of the US Government Accountability Office conducted in the UK...’. This could be rephrased: the United States of America Government Accountability Office studied five countries (Australia, Italy, the Netherlands, the UK and the USA) and determined how medicines were classified in each. They found that....</p> <p>Additional comment 3: In the Background section, please expand</p>
--	--

	<p>the abbreviation NSAIDs.</p> <p>Additional comment 4: In the Methods section, typo: 'can quite at any time'</p> <p>Additional comment 5: Attitudes towards availability. Word missing: Only 1% to 8% chose supermarkets or petrol stations as [xxx] preferred option</p> <p>Additional comment 6: In the discussion section, within 'Comparisons with other studies'. I think 'your study shows' should be 'our study shows'.</p> <p>Additional comment 7: "This is confirmed by an earlier study." Perhaps consider rephrasing/softening this statement (since the two studies are not making exactly the same point): "This is similar to the findings of an earlier study..."</p> <p>Additional comment 8: I consider that a lack of a pilot study was another limitation that you could add to the strengths and limitations section. Perhaps a pilot study would have enabled some of the issues raised to be flagged up and addressed from the outset.</p>
--	---

## VERSION 2 – AUTHOR RESPONSE

Reviewer 1 – Dr. Lezley-Anne Hanna

General comment:

The majority of queries have now been satisfactorily addressed. There are some additional comments arising from the 2nd review process.

Response to general comment:

We are very glad to hear that according to the reviewer the majority of the queries have been satisfactorily addressed. Hereafter, we give a point by point response to the (additional) comments that have arisen from the 2nd review process.

Previous comment 3:

Thank you for including the definition of an OTC medicine. Perhaps you could clarify that 'we defined it as...' or include the reference that the definition was taken from. For example, in the UK, the OTC medicines market data encompasses vitamins, minerals, slimming aids and emergency contraception, whereas your definition excludes nutritional supplements and contraception.

Reaction to previous comment 3:

We rephrased the sentence to make more clear that the used definition was our own definition, based on the Dutch Medicines Act. "We defined OTC medications in the questionnaire as follows: "OTC medications are medicines that you can buy at pharmacies and chemists without a doctors' prescription. In addition, you can buy some of these medicines at supermarkets and petrol stations. Examples of OTC medications are painkillers, such as paracetamol or ibuprofen. Homeopathic medicines, nutritional supplements and contraceptives are not considered to be OTC medications"".

Previous comment 4:

I think it would be useful to add in a few sentences about questionnaire development, pilot, and validity to the Methods section under the sub-heading 'Questionnaire'. Additionally, I would remove the 'and returned by 972' since this is part of the results/already mentioned at the start of the Results section. Please see my suggestion below:

Questionnaire

The questionnaire was developed based on... (discussions within the research team and the wider literature?) and included 36 questions (with largely pre-defined categories of responses?) focusing on

different aspects of OTC medication. While a pilot study was not conducted due to time constraints, face and content validity of the questionnaire were assessed by two senior researchers (LVD and MB). In June 2010, the self-administered questionnaire was sent to 1,422 panel members. According to their previously stated preference, 671 members received the questionnaire by post and 751 received an electronic version via the internet. Using a mixed methods approach helped ensure that certain groups were not excluded from the study and may also have increased the response rate. Other methods used to increase the response rate included sending two electronic reminders and one postal reminder to panel members who had not yet responded. The cut-off date for return of questionnaires was xxx.

Response to previous comment 4:

Thank you very much for the suggestions. We added some additional information with regards to the questionnaire development, pilot and validation in the Methods section under the sub-heading Questionnaire: "The questionnaire was developed based on the wider literature and experiences of the research team. In total, the questionnaire included 36 questions (with largely pre-defined answer categories of responses) focusing on different aspects of OTC medications. While a pilot study was not conducted due to time constraints, face and content validity of the questionnaire were assessed by two senior researchers (LVD and MB). In June 2010, the self-administered questionnaire was sent to 1,422 panel members. According to their previously stated preference, 671 members received a questionnaire by post and 751 through the internet. Using a mixed methods approach helped to ensure that certain groups were not excluded from the study and may also have increased the response rate. Other methods used to increase the response rate included sending two electronic reminders and one postal reminder to panel members who had not responded yet. The closing date of the questionnaire was late July 2010." In addition, we removed "and returned by 972".

Previous comment 5:

I think a comment about the mixed methods (postal and electronic questionnaires) could be included under the sub-heading 'Questionnaire' within the Methods section. Please see my suggestion above: "Using a mixed methods approach helped ensure that certain groups were not excluded from the study and may also have increased the response rate."

Response to previous comment 5:

Thank you very much for the suggestion. We added a sentence regarding the implications of a mixed methods approach under the sub-heading Questionnaire in the Methods section: "Using a mixed methods approach helped to ensure that certain groups were not excluded from the study and may also have increased the response rate."

Previous comment 10:

Thank you for further expanding upon the background information. The only remaining suggestion (since your study focuses largely on OTC analgesia) is that you outline the analgesics that are available OTC in the Netherlands so that the reader can transfer the findings of your study to their particular setting. For example, in the UK ibuprofen, diclofenac, naproxen, codeine, dihydrocodeine, paracetamol and aspirin are all available OTC in oral formulations. Ibuprofen and diclofenac are also available in topical preparations, flurbiprofen is available as a throat lozenge and choline salicylate is available in both eardrops and oromucosol form.

Response to previous comment 10:

In the Netherlands the following analgesics are available OTC: paracetamol 500 mg (package size 20 general sales, package size 20-50 also in pharmacies and chemists); several combinations of paracetamol 500 mg with caffeine and/or vitamin C (in both pharmacies and chemists); several combinations of paracetamol 250 mg with propyphenazone 250 mg or acetylsalicylic acid 250 mg (in both pharmacies and chemists); ibuprofen 200 mg (package size 10 general sales and package size until 50 also in pharmacies); ibuprofen 400 mg (pharmacies and chemists only) (other strengths of ibuprofen only on prescription); naproxen 220 and 275 mg (pharmacies and chemists only) (other strengths of naproxen only on prescription); diclofenac 12,5 mg (pharmacies and chemists only)

(other strengths of diclofenac only on prescription); ketoprofen 25 mg (16 tables in pharmacies and chemists only) (other strengths of ketoprofen only on prescription); acetylsalicylic acid 500 mg (pharmacies and chemists only); and carbasalate calcium 600 mg (pharmacies and chemists only). In addition, diclofenac gel is registered OTC as topical preparation, however, only for pain due to arthrosis of fingers and knees.

We included the following sentences in the Methods section under the sub-heading Attitudes towards availability, since we mean that this is a more logical place to include this information compared to the Background section and/or the Discussion section. "In the Netherlands, paracetamol 500 mg; several combinations of paracetamol 500 mg with caffeine and/or vitamin C; several combinations of paracetamol 250 mg with propyphenazone 250 mg or acetylsalicylic acid 250 mg; ibuprofen 200 mg and 400 mg; naproxen 220 and 275 mg; diclofenac 12,5 mg; ketoprofen 25 mg; acetylsalicylic acid 500 mg; and carbasalate calcium 600 mg are all available OTC in oral formulations. In addition, diclofenac gel is registered OTC as topical preparation, however, only for pain due to arthrosis of finger and knees."

Previous comment 16:

The information which you have provided below could be added under the sub-heading 'Questionnaire' within the Methods section. "To measure self-reported general health one question from the SF-36 was used since this is a commonly used scale to measure quality of life (ref). In the SF-36 the answer categories (bad/poor; good; excellent/very good) are not defined, therefore we did not provide any explanation of these terms either."

Response to previous comment 16:

We included an additional paragraph "Demographic characteristics" in the Methods section. In this paragraph we also included the following sentences with regards to the variable self-reported general health: "To measure self-reported general health one question from the SF-36 was used. In the SF-36 the answer categories (bad; fair; good; very good; excellent) are not defined, therefore we did not provide any explanation of these terms either."

Previous comment 22:

In terms of transferability, it would be useful to know all analgesics that are available to purchase OTC in the Netherlands (and whether you mean oral/systemic analgesia only). Please provide this information either as part of the background information or in the discussion. This is a separate point from providing data on the most frequently used OTC painkillers.

Response to previous comment 22:

See our response to previous comment 10, where we give an overview of the analgesics that are available OTC.

Previous comment 23:

Thank you for clarifying that you used painkiller rather than analgesia in the questionnaire. I did not intend for you to remove all occurrences of the word analgesia/analgesic from the manuscript, but rather that you clarified what term was used in the actual questionnaire.

Response to previous comment 23:

To be consistent throughout the manuscript, we decided to use painkillers instead of analgesics.

Previous comment 24:

Perhaps it would have been useful to clarify in the questionnaire that you were seeking views on oral painkillers, if this is indeed what you specifically wanted the focus to be (rather than topical).

Response to previous comment 24:

Since in the Netherlands mainly oral painkillers are available OTC (see our reaction on previous comment 10), we expect that consumers based their answers on oral painkillers.

Previous comment 31:

More of the results could be written in the past-tense, for example: “consumers felt confident about their own OTC skills but had less confidence in the skills of others.” However this is just a difference in opinion over how to report the findings.

Response to previous comment 31:

As this is indeed a difference in opinion over how to report the findings, we decided not to write more of the results in the past-tense.

Previous comment 32:

In my previous review, I commented on the wording of one of the questions: “I am/others are able to make a choice.” I suggested that the word ‘appropriate’ could have been included in the question i.e. “I am/others are able to make an appropriate choice”.

I see this has now been added throughout the manuscript and figure – however, if this wasn’t actually in the original version of the questionnaire, please remove it and consider including this point as a limitation/suggestion as to how the question could have been more suitably worded.

Response to previous comment 32:

Also in the original question of the questionnaire the word “appropriate” was included. Therefore, we added this throughout the manuscript.

Additional comment 1:

In the Background section, the sentence: “Pharmacies are run by a pharmacist and able to sell all prescription and non-prescription drugs...” is potentially confusing and misleading. It almost implies that a person could purchase any type of medicine (prescription-only or non-prescription) from a pharmacy.

Response to additional comment 1:

To avoid potential confusions we rephrased the sentence: “Pharmacies are run by a pharmacist and able to sell all prescription (when a prescription is given) and non-prescription drugs, while chemists are run by a druggist, who requires less training than a pharmacist and is able to sell many but not all non-prescription drugs.”

Additional comment 2:

In the Background section, the ‘A study of the US Government Accountability Office conducted in the UK...’. This could be rephrased: the United States of America Government Accountability Office studied five countries (Australia, Italy, the Netherlands, the UK and the USA) and determined how medicines were classified in each. They found that....

Response to additional comment 2:

We rephrased this sentence in the following sentences: “The United States Government Accountability Office studied five countries (the UK, the USA, the Netherlands, Italy and Australia) and determined how medicines were classified in each. They found that since 1995 all these countries have increased OTC availability. This is due either to changes in the classification of non-prescription drugs or to the reclassification of medications into less restrictive classes.”

Additional comment 3:

In the Background section, please expand the abbreviation NSAIDs.

Response to additional comment 3:

We expand the abbreviation NSAIDs in the sentence: “Some examples of categories of medicines that have been reclassified to non-prescription medication in many countries are nonsteroidal anti-inflammatory drugs (NSAIDs), anti fungal creams and laxatives.”

Additional comment 4:

In the Methods section, typo: ‘can quite at any time’

Response to additional comment 4:

We rephrased the sentence in: “Each individual member of the panel receives a questionnaire

approximately three times a year and can quit the panel at any time.”

Additional comment 5:

Attitudes towards availability. Word missing: Only 1% to 8% chose supermarkets or petrol stations as [xxx] preferred option

Response to additional comment 5:

We added the missing word in the sentence: “Only 1% to 8% chose supermarkets or petrol stations as their preferred option.”

Additional comment 6:

In the discussion section, within ‘Comparisons with other studies’. I think ‘your study shows’ should be ‘our study shows’.

Response to additional comment 6:

We were not able to find our mistype of “your study shows” in the paragraph Comparison with other studies.

Additional comment 7:

“This is confirmed by an earlier study.” Perhaps consider rephrasing/softening this statement (since the two studies are not making exactly the same point): “This is similar to the findings of an earlier study...”

Response to additional comment 7:

Thank you for your suggestion. We rephrased the sentence in: “This is similar to findings of an earlier study where was found that Dutch consumers consider pharmacists as the most reliable source of information regarding OTC medication.”

Additional comment 8:

I consider that a lack of a pilot study was another limitation that you could add to the strengths and limitations section. Perhaps a pilot study would have enabled some of the issues raised to be flagged up and addressed from the outset.

Response to additional comment 8:

We added the lack of a pilot study as another limitation in the paragraph strengths and limitations.

“Finally, a possible limitation is that we were not able to conduct a pilot study due to time constraints. By performing a pilot study some issues could have been identified and addressed from the onset to improve the questionnaire.”