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Title: Response to Mehuys et al. 'Self-medication of regular headache: a community pharmacy-based survey'

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Dear Sir,

We take note of the comments of Dr Haag on our cross-sectional descriptive observational study on self-medication of regular headache in the naturalistic setting of the community pharmacy. Dr Haag draws our attention to his publication on evidence-based recommendations for the self-medication of migraine and tension-type headache, “addressed to physicians engaged in primary care as well as pharmacists and patients” [1]. He concludes his comments by stating that “improved primary care management of headache in pharmacies... could be developed on the basis of the already existing data and would not have required this study...”.

We are puzzled as to what existing data Dr Haag is referring to. Indeed, a shortlist of drugs for self-medication of migraine and tension-type headache has been drafted by Dr Haag and co-authors, but there are some data to suggest that guidelines for the management of headache in primary care are seldom applied [2] and community pharmacists may represent an underused resource in the management of headaches in primary care [3]. We virtually have no data obtained directly in the community pharmacy setting.

We also respond to a number of specific remarks that were made in response to our article:

- 1) Our target population consisted of individuals presenting for self-medication at a community pharmacy and our goal was to formulate recommendations for improved community pharmacy management of headache complaints. We did not suggest the data were generalizable to self-medication in the general population. The random pharmacy selection and the consecutive patient recruitment however contributed to the generalizability of our results towards the entire population of pharmacy customers self-medicating regular headache, as the sale of OTC analgesics is limited to pharmacies in Belgium.
- 2) We believe the inclusion rate of 59 % in this study is acceptable. It is similar to response rates in other questionnaire studies in (headache) patients, such as the large HUNT-3 study [4]. Potential bias caused by those who refused participation could not be assessed as our Ethics Committee prohibits data collection in study refusers, but we have recorded reasons for refusal to participate (mainly ‘no time’ and ‘no interest’). We had pre-defined that patients for whom other people purchased the medication were not eligible for participation.

3) Due to the lack of other studies in pharmacy customers self-medicating headache, comparison of our sample to already published data was not possible. The only reference paper available in literature is a study in 22 pharmacy customers with headache [5].

4) We did not intend to assess the prevalence of medication overuse in the general headache population nor among pharmacy customers (and we also do not state this in the paper). The objective of our study is clearly stated in the paper: "The present observational community pharmacy-based study aimed to investigate the headache characteristics and the medication use of persons with regular headache, defined for this study as headache occurring at least once per month, presenting for self-medication." The ultimate goal was to formulate recommendations for improved pharmacy management of headache. As extra pharmacist follow-up is specifically warranted for those individuals with *regular* headache complaints, we only included patients with frequent headaches (defined for this study as headache $\geq 1x/month$). Pharmacy customers with occasional headaches were not within the scope of this study, because in most cases they self-treat successfully and are not at risk for developing medication overuse.

5) Dr Haag states that a substantial proportion of 'overusers' in our survey did not have any headaches at all, which is a misunderstanding. All participants suffered at least 1x/month from headache and used the reported medication for their headaches. However, a substantial proportion of medication overusers did not have *chronic* headache, indicating that they also used the analgesics for other pain conditions than headache. We are planning a follow-up study in which this aspect, which was unanticipated, will be included. Regarding the definition of medication overuse, we used the internationally accepted ICHD-IIR definition [6]. Medication overuse is a prerequisite for developing medication-overuse headache (MOH), and it has been suggested that MOH can develop in migraine patients using painkillers for another condition [7, 8].

6,7) An inherent limitation of a cross-sectional design is that causal relationships cannot be determined. Medication overuse does not necessarily lead to MOH, and we did not suggest patients suffered from MOH. From a community pharmacist's point of view, the conceptual difficulties in dealing with medication overuse and MOH are irrelevant. The pharmacist's role is to prevent overuse of acute headache medication, in order to avoid development of MOH or chronification of the underlying headache condition.

We hope to have clarified the issues raised by Dr Haag, and our observational data will be useful to achieve better implementation of existing guidelines on self-medication of headache into the community pharmacy setting .

Yours sincerely,

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