Author's response to reviews

Title: An inevitable wave of prescription drug monitoring programs in the context of prescription opioids: pros, cons and tensions

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Author's response to reviews: see over
Dear Dr Capone,

Re: Manuscript submission: 3401281741279456 - An inevitable wave of prescription drug monitoring programs: pros, cons and tensions

Thank you for your advice and the provision of reviewers’ comments on our manuscript. We have found these comments very useful and they have allowed us to take a fresh look at our results and we have carefully edited the manuscript accordingly. Our response to the comments and specific changes are detailed below.

Thank you for considering our work for publication in the BMC Pharmacology and Toxicology. We look forward to hearing the outcome of your deliberations.

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Reviewer 1 comments

Discretionary Revisions

1. I suggest to authors to explain for what reason the physicians have fear of being controlled by the police, since it PDMP should be a tool to check the prescriptions and to increase the prescriptive appropriateness and not an instrument of repression for both physicians and patients.

Authors’ Response: We appreciate reviewer’s suggestion. We have now edited the concerned section and it now reads (last paragraph in page 8 of the manuscript):

However, in some settings with origins in law-enforcement, PDMPs are seen as a tool of the police rather than an important component of patient safety. With that police tool in mind many doctors see PDMP as a thinly veiled means of police looking over their shoulders and have fear of coming under scrutiny by law enforcement agencies [25]. Such a scrutiny to doctors, who for legitimate reasons need to prescribe large amount of opioids even if these are appropriate, is definitely a nuisance. The American Medical Association supports PDMP programmes being housed with a state agency whose primary purpose is health care quality and safety.

2. Also, I suggest to authors to devise a summary table that compares pros, cons and tensions and related studies.

Authors’ Response: We thank reviewer for this excellent suggestion. The following table has now been added (page 18 of the manuscript):
<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons and tensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>§ Informed and safe prescribing for patients.</td>
<td>§ Patient may not receive sufficient medications due to physicians’ fear of legal retribution (“chilling effect”).</td>
</tr>
<tr>
<td>§ An appropriately programed real-time PDMP is likely to reduce prescription drug diversion, doctor shopping, and related casualties.</td>
<td>§ Chilling effect may influence increased prescribing of inappropriate or inadequate alternate medications (substitution effect).</td>
</tr>
<tr>
<td>§ Reduction of overprescribing by the physicians.</td>
<td>§ May deter legitimate prescribing by creating confusion between the concepts of addiction and pseudo-addiction, and in treating patients with opioid dependence and pain.</td>
</tr>
<tr>
<td>§ Reduced risk of complications from polypharmacy.</td>
<td>§ Patients may fear of coming under scrutiny by law enforcement agencies and be deprived from medications.</td>
</tr>
<tr>
<td>§ Help avoiding awkward patient confrontation such as urine drug screening, and promote a more patient-centered approach to quality use of opioids.</td>
<td>§ PDMP-induced reduction of prescription opioids may increase crime particularly among illicit drug users, and push some pain patients into the illicit market.</td>
</tr>
<tr>
<td>§ Help monitor and detect forged prescription or stolen prescription pad/page.</td>
<td>§ Fear among the physicians of being categorised as fraudulent prescribers when they are actually prescribing in good faith but lack training.</td>
</tr>
<tr>
<td>§ Help reducing fraudulent prescribing and inform the professional licensing boards about inappropriate prescribing/dispensing.</td>
<td>§ May reveal changes in prescribing practices</td>
</tr>
</tbody>
</table>
and patterns, and spatial information in small geographical area may inform tailored intervention.

Privacy concern and data security.

May negatively impact on service rapport and trust.

Reviewer 2 comments

Minor Essential Revisions

The paper presents an undoubtedly interesting and actual item, the adoption of Prescription Drug Monitoring Programs, as an effective tool to control nonmedical use and/or medical abuse of prescription drugs. In its submitted form, the paper presents a discrepancy between the first ("Pros" and "Cons and tensions" sections) and the second part ("Discussion"). The Authors punctually present pros and cons of adopting PDMPs in the first part of the paper, but they do not exhaustively discuss all presented items in the second part.

1. As an example: # no mention and/or comment or proposal about the lack of knowledge about drug addiction symptoms evidenced in some physicians, who are consequently unable to recognize addicted patients, is discussed; # no mention about the opportunity of performing a correct information among patients and physicians themselves, about aims and scopes and related benefits of adopting PDMPs, is present;

Authors’ Response: We thank the reviewer for raising this gap. We agree that we have not discussed all aspects of pros, cons and tensions into the discussion. We have now carefully read the manuscript and identified the major aspects that warrant a discussion, and accordingly we have added the following two paragraphs (first and second paragraphs at page 11). With addition of these two paragraphs and some other small editing, we believe, the discussion has now got a consistent shape with a nice flow.
Clearly, abuse of prescription opioids is a multidimensional problem. While there are no simple solutions for effective prevention, some measures could be taken immediately. One such measure is to offer up-to-date information to that section of providers who have insufficient knowledge about PDMP and prescription drug addiction. This issue can be addressed through medical education curriculum and continuing programs for the physicians and pharmacists. Physicians’ willingness to fill their knowledge-gap about prescription opioids and PDMP are well recorded in the literature [20, 33, 34]. Another measure is to educate patients about prescription opioids, their appropriate use, potential risks and proper disposal techniques, and the necessity and importance of PDMP in prescribing opioids. Physicians are better placed to do that comfortably.

Improving the existing PDMPs to real-time programs is another highly recommended measure. Physicians and pharmacists who currently use PDMP or are willing to use this program often report its lack of real-time data provision. Unfortunately only in few settings authorities could ensure a real-time data transmission at the point of dispensing. Currently, the most common time frame for data transmission is ranging from monthly to daily [30]. In fact, as demonstrated in British Columbia, the usefulness of a PDMP, to a large extent, is attributable to the speed of its data collection [35].

2. The Authors just state (and redundantly repeat throughout the paper) that since we are in an era of information technology…”PDMP will remain and probably expand over time”, and it seems that it is a fact and we have just to passively accept it.

Authors’ Response: We appreciate the reviewer’s concern about that. We agree that this point has been reflected several times. To reflect the reviewer’s point and to tone down that statement we have now edited the respective paragraphs. These now read:
Given the international trends amidst an increasing concern about abuse of prescription opioids, PDMPs are likely to gain more ground and expand, and the current reluctance among a portion of physicians/pharmacists to PDMP use is likely to disappear over time. We have evidence from similar events. When the supervised dispensing of methadone was introduced in 1996 in the UK some practitioners regarded it as an intrusion upon their clinical autonomy, but in the decades since then prescribers have followed the treatment guidelines [44]. (First paragraph at page 12)

In the discourse on PDMP, one thing often overlooked is the information and communication technology breakthroughs, networking and internet that enable work to be separated from time and space. The information technology improvement is running so fast, people are being so much habituated to it that, despite its problems, PDMP will continue. However, this does not mean that one will have to accept it passively. PDMP needs to be shaped appropriately so that it caters the needs of providers and patients. The sooner the prescribers and dispensers shape the PDMP the way they want and embrace it, the better the outcomes will be for their patients. (Second paragraph at page 12)

3. Only in the Conclusion paragraph such crucial items are synthetically listed. So, in my opinion the Discussion section should be revised and improved.

Authors’ Response: We thank the reviewer for raising this point. We have checked the latest version of the manuscript and found that through our aforementioned and other editing all the crucial items reflected in the conclusion have now been well discussed in the main body of the manuscript.
4. Moreover, since in the last sentence of the “Background” paragraph, the Authors state that “…the paper will focus on opioids”, the title should be modified accordingly.

Authors’ Response: We agree with the reviewer and accordingly inserted the following phrase: “in the context of prescription opioids”. Thus the title now reads:

An inevitable wave of prescription drug monitoring programs in the context of prescription opioids: pros, cons and tensions