Reviewer's report

Title: Impact of different pack sizes of paracetamol in the United Kingdom and Ireland on intentional overdoses: a comparative study

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Reviewer: Leonard Hawkins

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Major Compulsory Revisions

1. The title of the manuscript reads ‘impact of different pack sizes of paracetamol in the United Kingdom and Ireland on intentional overdoses: a comparative study’ – however, with respect to the United Kingdom, the authors only consider data from England – therefore, the title of the study may require revision.

2. Related to the above point, since the UK legislation also covers Scotland, Wales and Northern Ireland (and previous studies show that rates of self-harm may vary across the UK), it may be useful to broaden the comparison. It would be interesting to see comparisons between Scottish / Welsh / Northern Irish data and that for the Republic of Ireland. Is there any regional variation within the Republic of Ireland?

Minor Essential Revisions

1. As a comparative study, I feel that there could be a greater depth of analysis; mortality, hepataotoxicity, hospital admissions and sales data are all valid measures of assessment of the success of the legislation(s). Are these data available for the Republic of Ireland?

2. The study the authors cite in reference to breaching of the legislation in the UK (ref 26) is itself based on an incorrect assumption that 16 tablets is the maximum number that may be purchased over the counter in the UK.

3. The study data is restricted to non-fatal intentional self-poisoning, assumedly because (as the author states), data on deaths involving paracetamol in Ireland have not been published. This is unfortunate as mortality is the most prominent measure of severity – are the authors concerned that the absence of mortality data may cause a false positive bias in the data?

Discretionary Revisions

1. I am not sure that 4 tablets taken at any one time would constitute an overdose in the clinical sense – up to 4 g (8 tablets) of paracetamol may be taken daily. Overdose must really be defined by intent and/or circumstance. Accidental overdose (e.g. for dental pain) is not considered but is intentional.
2. The authors also do not consider the wider implications of the UK legislation. There is no legal restriction on the number of packs that can be purchased in a single transaction provided the total amount does not exceed 100 tablets (at which point the medicine becomes subject to prescription control). Although some retailers have introduced in store measures such as till bars that restrict sale of analgesics to a maximum of 2 packs of 16 tablets/capsules, this is an area of voluntary action only.

3. Is there any scope for the use of data from UK poisons centres? The authors mention data from the Irish poison centre but do not provide the figures.

4. Many patients will have residual stocks of analgesics in the home so may take 5 or 6 tablets from an old pack and then all 16 from a new pack. Also, how often do patients actually report the number of packs taken as opposed to the number of tablets – I suspect that the latter is significantly more frequent (although I can only judge this via the data available at my own poisons centre and from my own experience). In the data analysed by the authors, what proportion of patients reported the number of packets ingested as opposed to the number of tablets?

Also, it is impossible to know whether the patient has taken tablets from a pharmacy / non-pharmacy pack. Why do the authors feel that extrapolating the number of tablets consumed into the equivalent number of packets is more useful than analyzing the size of overdose purely by looking at the number of tablets ingested? (Is it to account for the smaller pack sizes in Ireland compared to England, and so therefore is it being used to standardize the data in order to compare the 2 countries?).

5. The UK legislation was introduced in 1998 and the Irish one in 2001; the data assessed by the authors ranges from 2002 – 2007. To determine whether the legislation has resulted in smaller overdoses, should there be at least some comparison with overdose data pre-introduction of the legislation(s)?

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.