

The authors reply

Os autores respondem

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We are very grateful for the comments on our paper, *Adverse Drug Events Identified in Hospitalized Patients in Brazil, by International Classification of Diseases (ICD-10) Code Listings* ¹. The article reports on a study in which a list previously selected codes from ICD-10 (10th revision of the International Classification of Diseases) was applied to the Hospital Information Systems of the Brazilian Unified National Health System (SIH-SUS) database of Brazil's public health system. The comments stressed adverse reactions to psychoactive drugs, which are conspicuous for their high incidence. Accordingly, we have attempted to address them to some degree in the paper.

The irrational and unsafe use of medicines is causing concern to health personnel, wherever they work. In recent years, several countries and the World Health Organization (WHO) have taken measures based on three pillars: the alarming statistics for adverse events; the importance of pharmaco-epidemiological studies; and the need to develop measures on a supra-national scale to help prevent harm caused by medicines. Two of these initiatives – publication of the *To Err Is Human* report by the U.S. Institute of Medicine ² and the other, the creation of the World Alliance for Patient Safety ³ network – deserve special mention due to their range and being so widely welcomed. Prompted by both, the Brazilian government presented a patient safety program ⁴, which was launched by the Ministry of Health in 2013.

In addition to the general considerations on safety in prescribing and using medicines in general, there are substantial gaps in how health personnel are trained to deal with psychoactive drugs (as observed by the commentators). One of the results is that health personnel and patients easily fall prey to unprescribed use, a strategy that benefits the pharmaceutical products industry and trade. Sales grow and, with them, the number of adverse reactions. Strictly speaking, the therapeutic approach should be technically informed and involve the following aspects: non-drug and non-medical therapeutic alternatives; formation of therapy groups and workshops; and bonding between health system personnel and users. Currently, such bonding is being undermined by increasingly precarious employment relations and by inadequate supply to meet demand – particularly in the public health service.

Given these issues, the Brazilian government has set up psychosocial care centers (*Centros de Atenção Psicossocial* – CAPS), where multidisciplinary teams provide care for patients with mental disorders, substance dependence and psychoactive drug abuse. Although this strategy is broadly supported by society and patients, it is being threatened by budget cuts. Accordingly, we face the growing

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challenge of not only securing, but extending, the gains made in the field of pharmacovigilance. This will demand efforts by society, regulatory agencies and researchers.

Studies on the harmful effects of medicines based on available Brazilian databases have huge potential. Such studies are still incipient in Brazil. In addition to the vast potential of the SIH-SUS, which contains information on all hospital admissions, there is a national controlled products management system (*Sistema Nacional de Gerenciamento de Produtos Controlados – SNGPC*), an information database on purchases of controlled medicines in pharmacies. The SNGPC, available at the Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária – ANVISA*), enables statistics to be calculated and hypotheses to be raised. A recent study using SNGPC data indicated that consumption of clonazepam in Rio de Janeiro State rose between 2009 and 2013. The data suggested that approximately 2% of the state's adult population used clonazepam⁵. The high frequency of consumption is an alert to the need for measures involving health personnel with a view to restricting the prescribing of products that act on the central nervous system. The estimates raise concerns of abuse and suggest a need to review diagnostic and therapeutic criteria in the mental health field.

Contributors

All authors contributed in designing and writing the response to comment, critical review, and review version approval.

Additional informations

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References

1. Martins AC, Giordani F, Guaraldo L, Tognoni G, Rozenfeld S. Adverse drug events identified in hospitalized patients in Brazil by International Classification of Diseases (ICD-10) code listings. *Cad Saúde Pública* 2018; 34:e00222417.
2. Kohn LT, Corrigan JM, Donaldson MS. *To err is human: building a safer health system*. Washington DC: National Academy Press; 2000.
3. World Health Organization. World Alliance for Patient Safety. <https://www.who.int/patientsafety/worldalliance/alliance/en/> (accessed on 14/Feb/2019).
4. Ministério da Saúde. Portaria nº 529, de 1º de abril de 2013. Institui o Programa Nacional de Segurança do Paciente (PNSP). *Diário Oficial da União* 2013; 2 apr.
5. Zorzaneli RT, Giordani F, Guaraldo L, Oliveira MG, Mota R, Souza RM, et al. Consumo do benzodiazepínico clonazepam (Rivotril®) no Estado do Rio de Janeiro, 2009-2013: estudo ecológico. *Ciênc Saúde Colet* 2018. <http://www.cienciaesaudecoletiva.com.br/artigos/consumo-do-benzodiazepinico-clonazepam-rivotril-no-estado-do-rio-de-janeiro-20092013-estudo-ecologico/16563>.

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