Topical Review

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World Health Organization essential medicines lists: where are the drugs to treat neuropathic pain?

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1. Introduction

Neuropathic pain has been deemed a priority health issue[5] and is the topic of the 2014 to 2015 Global Year Against Neuropathic Pain campaign of the International Association for the Study of Pain (http://www.iasp-pain.org/GlobalYear/NeuropathicPain). Between 6% and 10% of adults are affected by chronic pain with neuropathic features,[6,24,26] and this prevalence is significantly greater among individuals with specific conditions. For example, neuropathic pain is a common comorbidity in infectious diseases such as HIV, leprosy, and herpes zoster, and in noninfectious conditions such as diabetes mellitus, stroke, multiple sclerosis, and traumatic limb and spinal cord injury.[7,13,15,18,20] The pain is associated with significant decreases in quality of life and socioeconomic well-being, even more so than nonneuropathic chronic pain.[9,19,21] Developing and emerging countries share the greatest burden of conditions that are associated with the development of neuropathic pain[5,10] and can ill afford the negative consequences of this pain.

There are medicines with proven efficacy in the treatment of neuropathic pain.[11,12] Nevertheless, the pain can be difficult to treat, with significant interindividual variation in efficacy within and between drug classes, independent of the underlying peripheral or central nervous system lesion or disease.[2,4] Effective management of neuropathic pain within a population therefore requires access to a small, but crucial, group of drug classes with proven efficacy.

The World Health Organization's (WHO) model list of essential medicines (http://www.who.int/selection_medicines/list/en/) presents medicines deemed necessary to meet priority health needs, and local implementation of essential medicines policies is associated with improved quality use of medicines.[14,17] However, none of the analgesic medicines included in the WHO model list is recommended as first-line treatments for neuropathic pain.[11] Thus, the WHO model list is not a good framework from which national policies on managing neuropathic pain can be structured, but countries do adapt the model list according to local needs and resources.[17] To estimate the nominal availability of medicines recommended for the treatment of neuropathic pain in developing and emerging countries, we assessed national essential medicines lists (NEMLs) for the inclusion of recommended treatments. We also assessed whether the coverage of recommended drugs classes on these NEMLs was dependent on countries' economic status.

2. Methods

2.1. National essential medicines list selection

We confined our analysis to the 117 NEMLs accessible through the WHO Web site (http://www.who.int/selection_medicines/country_lists/en/). Updated editions of the 117 NEMLs were sought on public, crawler-based search engines using country names, and titles of the downloaded documents as search terms; 14 newer editions were identified.

2.2. Data extraction

Each NEML was independently reviewed by 2 authors. The NEMLs were assessed for drugs recently recommended as first or second-line treatments for neuropathic pain after a meta-analysis and grading of the evidence.[11] Drug classes and drugs assessed included the following: (1) tricyclic antidepressants (TCA)—amitriptyline, nortriptyline, clomipramine, desipramine, and imipramine; (2) serotonin and noradrenaline reuptake inhibitors—duloxetine and venlafaxine; (3) anticonvulsants—gabapentin and pregabalin; (4) opioids—tramadol; and (5) topical agents—capsaicin and lidocaine. Drugs were recorded as being listed if they appeared anywhere on an NEML, irrespective of therapeutic class classification or treatment indications. Lidocaine was only recorded as being listed if it was specified as a topical formulation and at a concentration of at least 5%, or was a eutectic mix of 2.5% lidocaine: 2.5% prilocaine. Capsaicin was only recorded as being listed if the concentration was specified to be at least 8%.

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Information was also extracted on the strong opioids morphine, methadone, and oxycodone, which are listed in the WHO model list and are recommended as second or third-line therapy for neuropathic pain.[3,11] Anticonvulsants that are listed on the WHO model list, but for which the data on their efficacy in treating neuropathic pain are inconclusive (carbamazepine and oxcarbazepine) or against their use (sodium valproate), were also assessed.[11]

2.3. Data analysis

Only countries and territories classified as developing or emerging by the International Monetary Fund (IMF) were included in the analysis, which resulted in the exclusion of NEMLs from Sweden, Malta, Slovenia, and Slovakia.[16] The NEML of the Democratic People's Republic of Korea also was excluded because the list was generated by the WHO, and not by the country itself. The NEMLs of the remaining 112 countries were then categorised according to the World Bank system of low, lower-middle, higher-middle, and high income.[22] Data from 8 countries (Bahrain, Barbados, Chile, Croatia, Oman, Poland, Trinidad and Tobago, Uruguay), which are classified as developing or emerging by the IMF, but as high income by the World Bank, were included in the analyses. Basic descriptive statistics were generated on whether the selected drugs were listed, and the number of recommended first-line drug classes included on each NEML. The χ^2 test for trend was used to assess whether country income category predicted which of the drugs assessed were listed, and the number of first and second-line drug classes listed. The Holm method was used to correct P values for multiple comparisons.

3. Results

3.1. Coverage of developing and emerging countries

The 112 documents analysed covered 24/34 (71%) developing or emerging countries and territories classified as low income by The World Bank, 40/50 (80%) countries classified as lower-middle income, 37/55 (67%) countries classified as higher-middle income, and 8/38 (21%) developing or emerging countries and territories classified as high income.[22] Thirty-nine countries were in Africa, 23 in the Americas, 30 in Asia (including the Middle East), 8 in Europe, and 12 in Oceania. The median NEML publication date was 2009 (range, 2002 to 2014). Additional information on the 112 NEMLs is provided in Supplemental Digital Content 1, available online at http://links.lww.com/PAIN/A51.

3.2. Listing of individual drugs

Table 1 summarizes the listing of individual drugs. Tricyclic antidepressants were almost universally listed, with amitriptyline being the most commonly listed agent. Only the NEMLs of Angola, Bulgaria, and Cambodia did not list any of the assessed TCAs. There was a positive association between country income and listing of imipramine (corrected $P = 0.037$), but not of the other TCAs. Serotonin and noradrenaline reuptake inhibitors duloxetine and venlafaxine were infrequently listed, and no association was detected between drug listing and country income. The majority of NEMLs did not include an $\alpha 2\delta$ calcium channel antagonist, but when they did, it was more likely to be gabapentin than pregabalin, and the NEML was more likely to be from an upper-middle income or high-income country than a country from a lower-income category (corrected $P = 0.005$).

Approximately half the NEMLs listed tramadol, and no association was detected between the income category and drug listing. Only one-fifth of the countries' lists included topical lidocaine (no association between income and drug listing was detected), and none of the NEMLs included high-dose capsaicin.

Morphine and the anticonvulsants carbamazepine and sodium valproate were almost universally listed (Supplemental Digital Content 2 for countries that did not list morphine, available online at http://links.lww.com/PAIN/A52), and no associations between income and drug listings were detected. There were low rates of inclusion for other strong opioids, oxycodone and methadone, and the anticonvulsant oxcarbazepine. Inclusion of methadone and oxcarbazepine was positively associated with the country's income status (corrected $P < 0.05$ for both drugs).

Very few NEMLs indicated that the assessed drugs were for the treatment of neuropathic pain, with amitriptyline (9% of NEMLs) and carbamazepine (14% of NEMLs) receiving the most indications for treating neuropathic pain (Supplemental Digital Content 3, available online at http://links.lww.com/PAIN/A53).

3.3. Listing of drug classes

Figure 1 shows the percentage of NEMLs that included 0, 1, 2, or 3 drug classes recommended for the treatment of neuropathic pain. Approximately two-thirds of countries had only 1 class of first-line agent (typically TCAs), and approximately half had only 1 second-line agent (typically tramadol), included on their NEMLs. Two countries (Angola and Cambodia) had no first-line treatment classes listed, and almost 40% of countries had no second-line therapies listed. There was an association between the income category and number of drug classes listed for first (corrected $P < 0.001$) and second-line (corrected $P < 0.001$) therapies. No low-income countries had all 3 first-line drug classes listed, compared with half of all high-income countries. Only 1 low-income country (Tanzania) had 2 first-line classes listed (TCA and $\alpha 2\delta$ calcium channel antagonists), compared with one-quarter of high-income countries.

4. Discussion

Our analysis shows gross deficiencies in the scope of drugs recommended for the treatment of neuropathic pain on the NEMLs of developing and emerging countries. The poor selection of recommended treatments means that should a patient fail to respond to initial therapy (number needed to treat for 50% pain relief is typically ≥4 for neuropathic pain[11]), have significant side effects, or have contraindications to a drug's use, there are no or limited alternative therapies available. Furthermore, even when recommended drugs are listed, the drugs generally are not indicated, or are inappropriately indicated, for the treatment of neuropathic pain.

Management of pain is a priority issue that has been codified in the WHO model list since 1977.[30,32] Indeed, the WHO[31] recently urged member states to ensure, "the availability of essential medicines for the management of symptoms, including pain," and "(the) education and training of healthcare professionals, in order to ensure adequate responses to palliative care needs." Yet for neuropathic pain, the WHO model list fails on both accounts, being deficient in drugs with proven efficacy in treating neuropathic pain, and it provides no guidance on appropriate medications to use for treating neuropathic pain. These deficiencies are echoed in the NEMLs of developing and emerging countries. Although the WHO model list informs the development of NEMLs, countries tailor their lists according to local needs. For example, tramadol was included on approximately half the NEMLs we assessed, but it is not on the WHO model list. Thus, the dearth of recommended medications for

Table 1

Drug listings on the national essential medicines lists of 112 developing countries.

	Overall listing, n (%)	Listing by World Bank income category, n (% countries within a category)				
		Low (n = 24)	Lower middle (n = 40)	Upper middle (n = 37)	High (n = 8)	Other* (n = 3)
First-line medications						
TCA						
Amitriptyline	105 (94)	23 (96)	38 (95)	33 (89)	8 (100)	3 (100)
Clomipramine	53 (47)	11 (46)	21 (52)	16 (43)	5 (62)	0 (0)
Desipramine	2 (2)	0 (0)	1 (2)	1 (3)	0 (0)	0 (0)
Imipramine†	46 (41)	3 (12)	17 (42)	20 (54)	6 (75)	0 (0)
Nortriptyline	10 (9)	1 (4)	2 (5)	6 (16)	1 (12)	0 (0)
SNRI						
Duloxetine	5 (5)	0 (0)	3 (8)	1 (3)	1 (12)	0 (0)
Venlafaxine	19 (17)	0 (0)	7 (18)	8 (22)	4 (50)	0 (0)
$\alpha 2\delta$ antagonist						
Gabapentin†	33 (30)	1 (4)	10 (25)	16 (43)	6 (75)	0 (0)
Pregabalin	11 (10)	0 (0)	3 (8)	6 (16)	1 (12)	1 (33)
Second-line medications						
Opioid						
Tramadol	61 (55)	8 (33)	19 (48)	26 (70)	7 (88)	1 (33)
Topical						
8% capsaicin	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
5% lidocaine	22 (20)	3 (12)	6 (15)	9 (24)	3 (38)	1 (33)
Strong opioid medications						
Methadone†	34 (30)	4 (17)	8 (20)	16 (43)	6 (75)	0 (0)
Morphine	106 (95)	22 (92)	40 (100)	33 (89)	8 (100)	3 (100)
Oxycodone	15 (13)	0 (0)	4 (10)	9 (24)	2 (25)	0 (0)
Other anticonvulsant medications						
Carbamazepine	109 (97)	22 (92)	40 (100)	36 (97)	8 (100)	3 (100)
Oxcarbazepine†	15 (13)	0 (0)	3 (8)	8 (22)	4 (50)	0 (0)
Sodium valproate	107 (95)	22 (92)	40 (100)	35 (95)	7 (88)	3 (100)

* Countries not included on the World Bank income list: Cook Islands, Nauru, Niue.

† $P < 0.05$ for χ^2 test for trend (listing vs income category).

$\alpha 2\delta$ antagonist, $\alpha 2\delta$ calcium channel antagonists; SNRI, serotonin and noradrenaline reuptake inhibitors; TCA, tricyclic antidepressants.

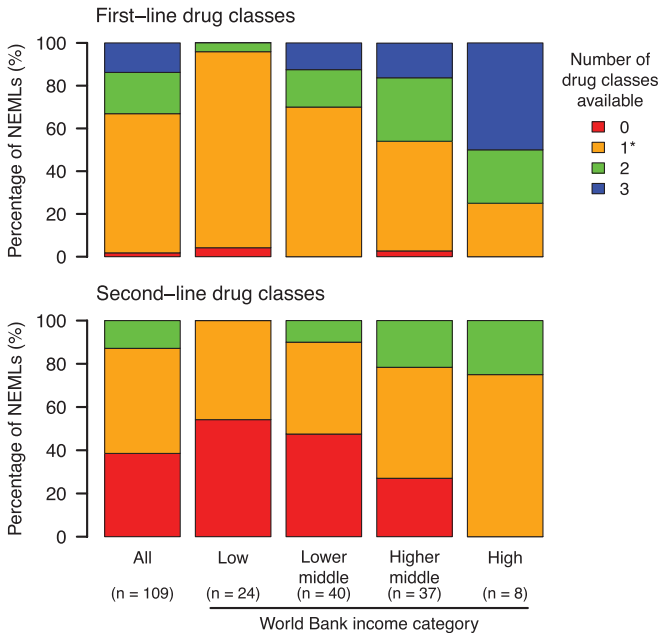

Figure 1. Percentage of national essential medicine lists (NEMLs) that included 0, 1, 2, or 3 drug classes recommended for the treatment of neuropathic pain. Data are shown grouped according to World Bank income category and for all countries (n = 109, data from the Cook Islands, Nauru, and Niue were not included because the World Bank does not index them). The top panel shows drug-classes recommended as first-line treatment, and the bottom panel shows second-line drug classes. First-line drug classes include: tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors, and a2d calcium channel antagonists. Second-line drug classes include: opioids (tramadol) and topical agents (5% lidocaine). There was a positive association between income category and the number of first-line and second-line drug classes listed on NEMLs (corrected $P < 0.001$). *The tricyclic antidepressant amitriptyline was the only first-line drug listed on the NEMLs of 32% of low income countries, 36% of lower-middle income countries, 28% of higher-middle income countries and 4% of high income countries.

treating neuropathic pain reflects deficiencies at the international and national level.

4.1 Limitations

Our assessment was limited to 112 developing or emerging countries, and the median publication date of the NEML assessed was 2009. Nevertheless, we believe that our assessment provides an accurate appraisal of the current situation. First, our sample included the majority of countries classified as low, lower-middle, and higher-middle income. Second, no medications relevant to treatment of neuropathic pain have been added to the WHO model list in over a decade.[27,28] Finally, since 2009, only approximately 5% of countries have transitioned to a higher World Bank income category.

Indeed, NEMLs only indicate nominal drug availability, whereas actual drug availability tends to be low in developing countries because of poor policy implementation, lack of infrastructure and logistical support, drug cost, availability of reimbursement, and knowledge of health care professionals.[23,25,29] Low availability of oral formulations of drugs such as the opioids also may limit the use of these medications to the clinic setting; although our analysis indicates that most of the opioids are nominally available in oral and parenteral formulations (Supplemental Digital Content 4, available online at http://links.lww.com/PAIN/A54). Furthermore, most of the medications to treat neuropathic pain are included on NEMLs as treatments for depression or epilepsy. Stigma toward these conditions by communities and health care providers may be an important barrier to inclusion on NEMLs and their use by health care providers and patients.[1,8] Thus, even when a drug is physically available, a combination of attitudes, health care professional knowledge, and prescription policies could mean that a drug is not prescribed. We therefore believe that our analysis probably overestimates the actual availability of neuropathic pain medications in these countries.

4.2. Recommendations

As a first step in improving the management of neuropathic pain, we believe that there is a strong enough therapeutic need and a sufficient evidence base to warrant applying for inclusion of additional recommended treatments for neuropathic pain in the 19th edition of the WHO model NEML. Indeed, the need to expand the scope of essential medicines lists is one of the subjects of a commission on essential medicine policies recently established by The Lancet (http://www.bu.edu/lancet-commission-essential-medicines-policies/). To facilitate the appropriate use of new and existing medications on the WHO model list, the medicines should be listed under a neuropathic pain subsection of the "pain and palliative care" section of the model list. In addition, we also motivate for research into the actual cost and availability of these medications in rural and urban settings, and to identify the knowledge, attitudes, beliefs, and training needs of prescribers that are required to improve access to care for neuropathic pain treatments worldwide.

Conflict of interest statement

A. Hietaharju received honoraria or consultancy fees from AbbVie, Glaxo Smith Kline, Lilly, Mundipharma, Pfizer, and Sanofi in the past 36 months. P. R. Kamerman declared consultancy fees from Reckitt Benckiser, lecture fees from Pfizer and Novartis, and travel support from Janssen. A. Kopf received consultancy fees from Grunenthal and Mundipharma, lecture fees from Grunenthal, Janssen, Pfizer, and Mundipharma, developed educational material for Grunenthal, and was on the advisory board of Astellas. A. C. Meyer declared receiving research support from the US National Institutes of Health, World Federation of Neurology, a drug donation from Valeant Pharmaceuticals, and travel support from Abbott Pharmaceuticals. A. S. C. Rice undertakes consulting for Imperial College Consultants, and in the past 36 months received fees from Spinifex Pharmaceuticals, Astellas, Servier, Abide, Relmada, Allergan, Asahi Kasei, and Medivir. ASCR's laboratory received research funding from Pfizer and Astellas. S. N. Raja received research funding from Medtronic and was a member of an advisory board for Mistsibushi Tanabe and QRx Pharma. B. H. Smith declared receiving occasional lecture and consultancy fees in the past 36 months, on behalf of his institution, from Pfizer, Napp, and Grunenthal. R. D. Treede received research support or honoraria from AbbVie, Allergan, Astellas, AWD, Bauerfeind, Boehringer Ingelheim, Bundesministerium für Bildung und Forschung, Deutsche Forschungsgemeinschaft, European Union, Glaxo Smith Kline, Grünenthal, Kade, Lily, Merz, Mundipharma, Nycomed, Pfizer, Sanofi, StarMedTec, Schwarz, US National Institutes of Health. The other authors have no conflicts of interest to declare.

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Appendices. Supplemental Digital Content

Supplemental Digital Content associated with this article can be found online at http://links.lww.com/PAIN/A51, http://links.lww.com/PAIN/A52, http://links.lww.com/PAIN/A53, http://links.lww.com/PAIN/A54.

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