The National Formulary of India 2010: Thorough and extensive revision of the preprint version needed

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"Experience is the name everyone gives to their mistakes" - Oscar Wilde

The National Formulary of India (NFI), 4th edition, 2010 (pre-print version) was published amidst a lot of advance publicity by the Indian Pharmacopoeia Commission (IPC). The book was released by Shri K. Chandramouli, Secretary, Ministry of Health and Family Welfare, Govt. of India and Chairman, IPC on 16th December 2010, at Nirman Bhawan, New Delhi, in the presence of officials.[1] Coming after a gap of three decades, the NFI will be a much sought after document for health care providers all over India. The need for unbiased, quality information on medicines is felt all over the country and the NFI 2010 may have been the answer which health professionals were waiting for. However, a quick look at the preprint version of the NFI shows that much work has to be done before the final version is printed.

WHAT IS RIGHT ABOUT THE NFI 2010?

The pre-print version (for review) looks visually appealing, is compact in size, is light and is printed on good-quality paper.[2] The font size is easily readable with a lot of free space in the wide margins and between paragraphs. The cover is aesthetically designed and gives information that it is an official document. The preface also lists the large number of people associated with the preparation of the document and the impressive process by which it was revised.

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WHAT IS WRONG WITH THE NFI 2010?

Though the cover states that it is the pre-print version for review, and forms are attached at the end of the book to fill up and send comments, the name of person to whom the comments should be sent or his/her address is not given. The back cover gives the address of the IPC - should we send it there for some "babu" to throw into a dustbin? If the IPC were serious about getting comments they should have sent out copies to pharmacologists/pharmacists all over the country and asked them to send in their comments. I was given a hard copy from a friend in the World Health Organization, Geneva. Why cannot the IPC put it on their website for people to download, comment and post their comments? Surely a wider circle of people giving their comments will be better for the formulary?

LACK OF COMPLETE INFORMATION

Appendix 8 of the NFI lists the national health programs (NHP). Unfortunately, it is not a complete list. Some of the NHPs such as National Programme for Control and Treatment of Occupational Diseases, National Diarrhoeal Diseases Control Programme, Reproductive and Child Health Programme, National Polio Surveillance Project, and others have been left out.[3] It is difficult to believe that such a large group of experts did not know that the list of national health programs was incomplete. The source of reference given is the Ministry of Health and Family Welfare website. Anyone who has accessed government websites in India will know that these are notorious for their incomplete and out of date information.

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ERRORS

One of the main functions of the formulary is to give correct information. This makes the proof-reading a very critical and crucial part of the preparation process. The NFI fails in this aspect. Even the composition of the Oral Rehydration Salt is wrong. The quantity of glucose is given as 3.5 g/l of water when it should read 13.5 g/l. Though the availability is listed as 5 and 37.5 g, information is given only for the one litre solution. There is no information as to what should be the volume of water in which the 5 g packet of ORS should be dissolved in. There is also no information as to what should be the dose in children. Only the dose for adults is mentioned. The above mentioned are the errors I could spot for just one of the listed medicines - ORS.

The number of spelling mistakes and grammatical errors is far too numerous to list in this editorial. The IPC should spend sufficient money on employing good technical oversight of the NFI and get the whole document properly proof read. It is far too important a document to be left to a group of amateurs.

LACK OF CRITICAL APPRAISAL

The worrisome part is the lack of critical appraisal and use of unsatisfactory evidence in including information in the NFI 2010. Appendix 10 is on "pharmacogenetics." Though there is quite a body of work being done in India on this subject, it is hardly sufficient to extrapolate to a 1.2 billion population. The appendix in the NFI mostly describes what happens in Caucasians, African Americans, the population of the United States of America, and so on. There is hardly anything on the population of India. Is this information relevant to health care providers in India? The one study that has been cited on phenytoin is on just 27 healthy volunteers and in which the results were not statistically significant.[4] By including this information in the appendix, the advisory group implies that this is important. By no stretch of imagination should we expect some work on 27 Indians (that too from a sample that was not randomly selected) to be extrapolated to 1.2 billion people.

This appendix should be removed because the evidence is not adequate and the information not relevant to India. Drugs such as rasburicase, niridazole, stibophen, and moxifloxacin are listed in this appendix only. These drugs are not in the formulary – so why should they appear in the appendix? Including information in the National Formulary for which there is inadequate and unsatisfactory evidence should be carefully looked at, as it may lead to some decisions which can be against public health interests. It is not sufficient for evidence to be available – the quality and quantity of evidence must be weighed carefully before deciding to include such information in a national formulary.

Unintentional humor

Sildenafil is listed for the indication of erectile dysfunction. The precautions (on the same page) state "pregnancy" and it is stated that the drug is "pregnancy Category B!". Had pulmonaryarterial hypertension been one of the indications, as in the British National Formulary,[5] this would have been acceptable.

DANGEROUS STATEMENTS

Appendix 12 describes principles of dose calculation in special conditions. When describing dosage calculations in children, the NFI states "The above mentioned rules are helpful in situations requiring the use of a drug that is unlicensed in children and for which no pediatric prescribing information is available." Does this mean that the NFI supports the use of medicines which are not licensed for use in children? Does it say (by default) you can use a drug for which no pediatric prescribing information is available? This is a rather dangerous and outrageous statement to be included in a formulary. One of the uses of a formulary is to support the professional growth and development of a "safe" doctor, i.e., one who prescribes medicines that are licensed, for approved indications and at the permitted dosages. It can and should never be otherwise.

To conclude I would say that there is a statement on the front inside cover of the NFI, in a box which states, "The pre-print version of NFI is being distributed for review only. Reasonable precautions have been taken by the Indian Pharmacopoeia Commission to verify the information contained in this Pre-print version of the NFI…." I am afraid that the members of the apex body, the core-group, and the subject review committee have not done justice to their positions. The book contains 675 pages. If each person of the 30 odd member team read just 22 pages of the NFI, the mistakes may get corrected. But that would be asking too much.

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