Research Article

Questionnaire-based Pan-India survey for impact assessment of National Formulary of India

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Abstract:

OBJECTIVES: The National Formulary of India (NFI), a ready reckoner for medicines among healthcare-professionals aims for promoting rational drug use. This needs periodic update based on evidence-based medicines and suggestions from end-users. This study assessed the level of awareness among health-care professionals and sought suggestions for enhancement of utility/content of NFI.

MATERIALS AND METHODS: This pan-India cross-sectional, questionnaire-based survey was conducted between November-2020 and March-2021. A Google-doc-based validated questionnaire (20 questions) was circulated through E-mail/social media groups and to 311 medical institutes/hospitals/clinics across India through the adverse drug reaction monitoring centers under the Pharmacovigilance Program of India.

RESULTS: A total of 461 participants (39-interns, 167-resident doctors, and the rest practicing physicians/doctors) affiliated to 224 institutes/hospitals/clinics had responded. About 46% respondents consulted NFI for drug-related information and 82.3% stated that NFI provides balanced unbiased information. About 95% respondents were aware of NFI's content and 76% mentioned usefulness of NFI in their clinical practice; however, 34.4% had misconceptions about NFI, 28.7% had a false belief that NFI is a legal document to safeguard health-care providers and 22.2% had never used it. Suggestions to enhance NFI's utility included digital accessibility, incorporation of information like drugs for basic medical emergencies (71.3%), disposal of expired-pharmaceutical products (38.7%), pharmaceutical price control policy (36.3%), and drug-procurement practices in hospitals (35.6%).

CONCLUSION: As per the survey findings, NFI is an effective tool for instant access to precise and unbiased drug-related information, and fostering rational use of drugs. Boosting its practical usefulness needs incorporation of suggested information, digital accessibility, and periodic update.

Keywords:

Healthcare professionals, national formulary of India, pan-India survey, practical usefulness, rational use of drugs

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Introduction

The information retrieval phenomenon in the current era has achieved great importance with an almost limitless library. However, the lack of control and ease of publication signifies that a fair proportion of the information and its sources are not reliable. Similar is the case for information about medicines and the health-care system. Internet search is a close and user-friendly aid for finding medicine information; however, it often breaches the reliability of findings.[1] The authenticity of medicine information has significant insinuations for the safety of the patient, betterment of health-care facility, roles of the state and drug regulators, established commercial

and noncommercial medical institutions as well as socially committed health-care personnel who have a track record of professional achievements. This necessitates having the right tools to know genuine information about drugs.

When searching for any information, it is of utmost importance to know the source of this or who takes the responsibility for the available information. Another important factor to look for when searching for medical information is whether the information has been reviewed by an editorial board/expert committee. The sound policy requires to have a source of information that is regularly updated.

Thus, there is a need for a database/source of information that is credible and has wealth of information on a wide range of topics related to drugs/medications, including treatment strategies, medications available for a particular disease condition, their characteristics such as dose, strengths available, indications and contraindications, adverse effects, precautions, and storage conditions. It should be in a comprehensive language for advanced search options, easy to read, and friendly to search specific content. Everything on this source should be evidence-based, time tested, and following current treatment guidelines and drug regulatory status.

Drug formulary provides an imperative guidance on proper use of the medications. It acts as a foundation of right information on essential medicines for drug regulators, policy-makers, and physicians prescribing medicines. A formulary is a compilation of facts related to each medicine's clinical indications, dose, formulations, adverse effects, contraindications and precautions, guidance on choosing the proper medicine for specific conditions like hepatorenal dysfunction, pediatric, and pregnant women.[2]

National Formulary of India (NFI) is a comprehensive document summarizing the therapeutic and pharmacological data about the listed drugs. Furthermore, this document has additional information about the handling of drugs from the manufacturer to the consumer level including storage, prescribing, and dispensing of drugs. The model of World Health Organization (WHO) formulary has been referenced while preparing and updating the content of NFI, especially keeping the prescribers, pharmacist, and consumers' role in India. Its main focus is on essential medicines. NFI has its first footprint in India in 1960 through the Ministry of Health, Government of India, followed by the 2nd and 3rd editions in 1966 and 1979. Since 2008, the responsibility of NFI is with the Indian Pharmacopoeia Commission (IPC), Ghaziabad.[3] Subsequently, its 4th and 5th editions are published in 2011 and 2016.[4] Currently, it is on the verge of revision for its 6th edition.

The principal objective of NFI is the promotion of rational use of medicines. Health professionals are supposed to refer this document during practice along with their professional experience, judgment, etc., while prescribing medicines or adopting treatment regimes. The references to statutory provisions/requirements, etc., in NFI are based on the status of such provisions at the time of compilation of this document. In the event of any dispute in any of the content of these documents and the statutes, the statutory provisions shall prevail.[4]

The primary objective of NFI is to provide physicians a ready reckoner for medicines. It is also aimed to provide information about other medicines not commonly available from other sources. It also intends to promote the rational use of medicines. NFI contains comprehensive monographs of selected drugs with priority being assigned to the drugs mentioned in the National List of Essential Medicines (NLEM), National health programs, Indian Pharmacopoeia, and drugs recommended by a panel of experts. Harmonization with global standards is one of the objectives of NFI and for which its revision is corroborated through collaboration with other formularies available in the world. Revision of NFI along with its drug monographs is conducted periodically; the obsolete and undesirable drugs are excluded, the new drugs with sound evidence are included and information about existing drugs requiring up-gradation/revision are amended.[4]

In spite of this broad mission and periodic update through expert committee, the NFI has assumed limited utility among health-care professionals. According to a previous study by Sharma *et al*. 2010, assessing attitude and opinion toward essential medicine formulary through a questionnaire-based survey, it has been found that 45% responded to the questionnaire and nearly 74% consulted formulary during clinical practice for obtaining medicine-related information.[5] To fulfil the basic aim of NFI, i.e. updating medical practitioners and other health-care professionals, there is a need for introspection of the methods adopted for its proposed use and access. Programs related to information, education and communication, and research activities are needed for establishing and circulating the scope and utility of NFI-based drug information among stakeholders.

The stakeholders of NFI includes prescribers or interns (medical and dental), pharmacist or interns, nurses, and other health-care professionals, personnel involved in the supply chain management of medicaments (basic reference on drug information), and government and individual hospitals. Hence, this study assessed the

level of awareness among prescribers/doctors, resident doctors, or interns (medical and dental) regarding the use of NFI, its practical information/content, and to seek suggestions to enhance practical usefulness/popularity of NFI through a questionnaire-based pan-India survey.

Materials and Methods

Study design
This was a pan-India, cross-sectional, questionnaire-based survey among health-care professionals (prescribers or interns) (medical and dental) conducted between November 2020 and March 2021.

Study participants
The study population consisted of health-care professionals (prescribers/doctors, resident doctors, or interns [medical and dental]) who can read, write, and understand the English language, has access to E-mail. The participants were recruited/contacted by E-mail. Prospective participants were identified for participation based on their location (North, North-central, Central, West, South, East, and North-east) and affiliation (government and private) from all over the country. The study was initiated after obtaining Ethical approval (IEC-1075/06-11-2020).

Sample size
According to a previous study by Sharma *et al.*, 2010 assessing attitude and opinion toward essential medicine formulary through a questionnaire-based survey, it has been found that 45% responded to the questionnaire and nearly 74% consulted formulary during clinical practice for obtaining medicine-related information.[5] Considering the precision as 5% and the level of the confidence interval as 95%, sample size for this prevalence survey was estimated to be 296. Expecting 65% response (as compared to 45% of the previous study), the sample size for this survey was kept at 455.

Data collection
The questionnaire was sent through E-mail as Google Doc. format explaining the purpose of the study to medical institutes across India through the adverse drug reaction monitoring centres enrolled under the Pharmacovigilance Programme of India (PvPI). It was also circulated through E-mail/social media groups individually by the investigators. The E-mail mentioned that it is voluntary to participate in this survey and there was no undue coercion or financial interest. The questionnaire had the initial page to fill up the name, designation, affiliation, and E-mail of the participant which served as the consent for participating in this study. The participants were given sufficient time (within 15 days) to answer the questions by striking out the most appropriate option(s)

against each item and sent back the answered document by clicking submit button in the Google Doc. They were given the alternative to leave any question unanswered if desired. The collected responses in form of a filled questionnaire had undergone final analysis as Google doc. format. A completeness check and quality analysis of all the questionnaires received was carried out. The questionnaires received in an incomplete form, i.e. not having the designation, affiliation, or E-mail address of the participants were removed from the final analysis. About 10% of respondents to the questionnaires were randomly selected and contacted to check the authenticity of participation in the study.

Study questionnaire
This questionnaire-based survey used a standard and validated questionnaire. The questionnaire was developed by a group of experts and after detailed revision by the group, it was finalized. Initial validation was through its application in about 10 participants as a pilot survey. After the analysis of the pilot data, it was further modified. The final set comprised 20 questions (multiple choice type including 4 open-ended questions) about overall awareness/background regarding the use of the NFI, practical information/content of NFI, and the suggestions to enhance practical usefulness/popularity of NFI among general practitioners and the medical fraternity. The questionnaire was prepared by keeping in view the suggestions of Jayakaran, 2011.[6]

Statistical analysis
All the questionnaires fulfilling the inclusion criteria were taken for the final analysis. The items not attempted by the respondents were removed from the final count. However, other marked items of that questionnaire were taken up in the final analysis. For the items, where multiple options are marked by the respondents against only one applicable option, all the chosen options were considered toward the final analysis. For analyzing item responses of the questionnaire, descriptive statistics were applied. The percentage of responses for each question was judged based upon the total number of responses for that question. The data were analyzed using Excel in Microsoft office and Statistical Package for the Social Sciences (SPSS, Chicago, Illinois, USA) version 23 for Windows. Data were presented as frequency (percentage).

Results

The questionnaire has been circulated in Google-doc format to the doctors and interns in about 311 medical colleges and private hospitals/clinics. A total of 461 doctors/interns affiliated with more than 224 hospitals/institutes across the country (the affiliation of 39 respondents could not be localized) had completed

the questionnaire. These include 39 interns, 167 resident doctors, and the rest as practicing physicians or doctors.

Out of the 461 respondents, 452 have mentioned consulting some database or book for ready information about medicines. Maximum ($n = 251$, 54.4%) have consulted Current Index of Medical Specialities alone or in combination with others while practicing for ready information about medicines. A significant number ($n = 214$, 46.4%) have mentioned regarding consultation of NFI alone ($n = 55$, 11.9%) or in combination with other resources for drug-related information [Question 1 and Table 1].

Maximum respondents ($n = 376$, 82.3%) have opined that NFI provides balanced unbiased information about medicines, whereas 15.1% did not provide any comment. Similarly, 68.5% have opined that NFI promotes rational use of the drug, whereas 24.5% suggested that it needs to be assessed [Question 2 and 3, Table 1].

Most of the respondents (92.9%) were aware that NFI is published by the IPC, Ghaziabad. Regarding access to NFI, there were varying opinions. About 56.6% opined for its free downloadable App and 45.5% preferred a printed version of NFI. Even practitioners are willing (20.5%) to subscribe to an upgradable version of the NFI app [Question 4 and 5 and Table 1].

About 76.7% have mentioned that NFI is useful (very useful or useful to some extent) in their clinical practice, though 22.2% have never used it [Question 6 and Table 1]. About 90.8% have information that NFI can be used as a reference document during practice for medical professionals. Although it is not under the purview of NFI, about 20.6%–33.3% have mentioned that it is a document with the chemical formula of drugs, treatment regimens for common diseases, and information about newly launched drugs in India. This is also noted down that 28.7% of respondents have a false belief that NFI is a legal document for safeguard of health care provider, whereas, actually it has no legal binding as mentioned in the NFI document [Question 7 and 8 and Table 1].

Most of the practitioners are aware of the content of NFI and rightly indicated that NFI contains monographs of the medicines (95.3%) and provides information regarding drugs commonly used and their indications (96%). Although 91.5% have marked that NFI has information about dose, dosage forms, and strengths, only 25.4% have rightly mentioned that NFI contains a combination of drug information such as clinical indications, dose, dosage forms and strengths, contraindications, and precautions. However, about 34.4% have given wrong reply that NFI contains information regarding brands of drugs available in the market [Question 13, 9, and 10 and Table 1].

The purpose of NFI has been rightly identified as rational use of drugs by 92.3%. A few participants (6.6%) have pointed that NFI promotes more popular drugs. Except for a few participants (2.4%), all others have the right information that medicines mentioned in NFI are aligned with the Essential Medicines List of WHO, NLEM of India, and Standard treatment workflow [Question 11 and 12 and Table 1].

Suggestions have been provided to include drugs for basic medical emergencies (71.3%), disposal of expired pharmaceutical products (38.7%), pharmaceutical price control policy (36.3%), and drug procurement practices in hospitals (35.6%) in NFI [Question 14 and Table 1].

To make NFI more useful about 446 of total 461 have suggested including one or other of the following: drugs used for doping (22.0%), common drug interactions (88.6%), normal values of electrolytes (17.5%), nomogram for drug titration in poor liver function test (LFT) and Karl Fischer titration (KFT) (58.1%), and drugs with potential teratogenicity (59%) [Question 15 and Table 1]. About 24.8% have suggested including the common brand name of drugs available in the market, 22.5% suggested for price range of available drug brands in the market, and 47% suggested both for increasing utility of drug monographs in NFI [Question 17 and Table 1]. Other topics suggested by more than one persons for inclusion are antidotes, nomogram/guidance for drug dosing in specific population i.e. pediatric, geriatric, pregnant, and lactating women, approximate cost and maximum price of drugs under National Pharmaceutical Pricing Authority, source/places of availability of generic medicines, off label use of drugs, biologics and biosimilars, nutraceuticals, and drugs with abusive potentials [Table 2].

About 63% are fully agreed and 30.1% agree to some extent that NFI would enrich the quality of care within a health-care facility in India, though 6.6% did not comment upon it [Question 16 and Table 1]. The majority (97.3%) of the respondents were willing to recommend/suggest their colleagues use NFI in their clinical practice because it will promote the safe use of medicines. Similarly, about 90.2% of the practitioners/resident doctors/interns were willing to attend 1 day CME organized on NFI [Question 18 and 19 and Table 1].

Regarding the last question in the questionnaire seeking any other comments, it has been found that the majority have mentioned it as a very useful document and need a soft copy (App based) for its use.

Table 1: Participants' response to the questions in the survey regarding enhancement of utility of NFI

	Total response (*n*=461), *n* (%)
1. While practicing, which of the following source you consult for ready information about medicines.*	452 (98.0)
a. CIMS alone or with other sources (MIMS, IDR, WHO formulary, NFI, BNF)	251 (55.5)
b. NFI alone or with other sources	214 (47.3)
c. NFI alone	55 (12.2)
2. Do you think NFI will give balanced unbiased information about medicines?	457 (99.1)
a. Yes	376 (82.3)
b. No	12 (2.6)
c. No comment	69 (15.1)
3. In your opinion, use of NFI promotes rational use of drug	457 (99.1)
a. Yes, it does	313 (68.5)
b. No, it does not	5 (1.1)
c. Need to be assessed	112 (24.5)
d. No comment	27 (5.9)
4. NFI is published by	45197.8)
a. IPA	20 (4.4)
b. IPC	419 (92.9)
c. OPPI	8 (1.8)
d. MCI	4 (0.9)
5. How would you like to access NFI?	459 (99.6)
a. Have a personal printed version of NFI (alone)	122 (26.6)
b. Have a personal printed version of NFI (alone or with other)	209 (45.5)
c. Will consult NFI printed version in library (alone)	21 (4.6)
d. Will consult NFI printed version in library (alone or with other)	47 (10.2)
e. Will prefer free downloadable App (alone)	154 (33.5)
f. Will prefer free downloadable App (alone or with other)	260 (56.6)
g. Will like to subscribe upgradable version of NFI App (alone)	36 (7.8)
h. Will like to subscribe upgradable version of NFI App (alone or with other)	94 (20.5)
6. To what extent NFI is helpful in your clinical practice?	459 (99.6)
a. Very useful	207 (45.1)
b. Useful to some extent	145 (31.6)
c. Not useful	2 (0.4)
d. Never used NFI	102 (22.2)
7. National formulary of India is	457 (99.1)
a. A reference document for clinical practice	315 (68.9)
b. A book mentioning the chemical formula of drugs	102 (22.3)
c. A document with treatment regimens for common diseases	152 (33.3)
d. A document about the newly launched drugs in India	94 (20.6)
8. NFI can be used for the following purposes	455 (98.7)
a. Legal document for safeguard of health care provider	131 (28.7)
b. Promoting material by pharmaceutical company	29 (6.37)
c. Reference document during practice for medical professionals	413 (90.8)
d. Reference material for consumer/patients for self-medication	36 (7.9)
9. NFI provide information about the following	456 (98.9)
a. Drugs commonly used and their indications	438 (96.0)
b. Common disease symptomatology	31 (6.8)
c. Diagnostic investigation procedures for common diseases	25 (5.5)
d. Guidance for conducting clinical research	33 (7.2)
10. Practitioner can find following information about medicines in NFI	457 (99.1)
a. Clinical indications	279 (61.0)
b. Dose, dosage forms and strengths	418 (91.5)
c. Brands of drugs available in market	156 (34.4)
d. Contraindications and precautions	261 (57.1)
e. Right options (clinical indications; dose, dosage forms and strengths; contraindications and precautions)	116 (25.4)

Contd...

Table 1: Contd...

	Total response (*n*=461), *n* (%)
11. NFI serves the following purpose	456 (98.9)
a. Promoting more popular drugs	30 (6.6)
b. Rational use of drugs	421 (92.3)
c. Guideline for disease management	109 (23.9)
d. Regulatory approval status of drugs	126 (27.6)
12. Medicines mentioned in NFI are aligned with	454 (98.5)
a. Essential medicines list of WHO	179 (39.4)
b. National list of essential medicines of India	379 (83.5)
c. Standard treatment workflow	72 (15.9)
d. High selling drugs in the market	11 (2.4)
13. NFI contain monographs for the following	452 (98.0)
a. Medicines	431 (95.3)
b. Diagnostic agents	50 (11.1)
c. Health and hygienic product	57 (12.6)
d. Medical devices	46 (10.2)
14. NFI should also provide information on the following	449 (97.4)
a. Disposal of expired pharmaceutical products	174 (38.7)
b. Drugs for basic medical emergencies	320 (71.3)
c. Drug procurement practices in hospitals	160 (35.6)
d. Pharmaceutical price control policy	163 (36.3)
15. Following information will make NFI more useful*	446 (96.7)
a. Drugs used for doping	98 (22.0)
b. Common drug interactions	395 (88.6)
c. Normal values of electrolytes	78 (17.5)
d. Nomogram for drug titration in poor LFT and KFT	259 (58.1)
e. Drugs with potential teratogenicity	263 (59.0)
16. National Formulary of India would improve the quality of care within the health care delivery system	452 (98.0)
a. Fully agree	285 (63.0)
b. Agree to some extent	136 (30.1)
c. Not agree at all	1 (0.2)
d. Cannot comment	30 (6.6)
17. Following can be added to drug monograph to increase utility of NFI?*	444 (96.3)
a. Common brand name of drugs available in market	110 (24.8)
b. Price range of available drug brands in the market	100 (22.5)
18. Will you suggest/recommend your colleagues to use NFI in their clinical practice?	444 (96.3)
a. Yes, because it will promote safe use of medicines	432 (97.3)
b. Yes, because it will improve the income of doctor	6 (1.3)
c. No, it is very cumbersome to use it	6 (1.3)
19. Will you like to attend 1 day CME organized by NFI?	449 (97.4)
a. Yes	405 (90.2)
b. No	44 (9.8)

*Open-ended questions along with choices. CIMS=Current index of medical specialties, MIMS=Monthly index of medical specialties, IDR=Indian drug review, KFT=Kidney function test, LFT=Liver function test, CME=Continuing medical education, WHO=World Health Organization, NFI=National formulary of India, BNF=British national formulary, IPA=Indian pharmaceutical alliance, IPC=Indian pharmacopoeia commission, OPPI=Organization of pharmaceutical producer of India, MCI=Medical council of India

Discussion

As per a recent decadal survey (2007–2017) by WHO, about a quarter of the world population (2 billion) lacks access to essential medicines leading to a cascade of health hazards including chronic pain, sustained illness, disabilities, and poor quality of life, increased morbidity and mortality.[7] NLEM aims to improve medicine use rationally ensuring access, and availability of well-established and cost-effective medicines mentioned in this list.[8,9]

Despite the availability of NLEM, access to affordable medicines/devices is an unmet need in low- and middle-income countries including India.[10] According to previous studies, the prevalence of potentially inappropriate medicines use worldwide ranges from 21% to 84% and some of the factors associated with this are prolonged illness, polypharmacy, gender bias i.e. female subjects, self-medication, and skewed access to the health-care facility.[11] The high incidence of potentially inappropriate medicines not only potentiates inefficacy and safety concerns/adverse effects of medicines but

Table 2: Recommendations by the respondents regarding enhancement of utility of National formulary of India

Reference question	Responses mentioned in question	Other responses	Number of respondents
Question 1: While practicing, which of the following source you consult for ready information about medicines	CIMS, MIMS, IDR, WHO formulary, NFI, BNF	Internet (1 mg.com, centerwatch.com, drugs.com, Medscape, UpToDate, Google, Lexicomp, Micromedex, Docguide, PubMed)	44
		Textbooks	13
		Senior doctors	2
Question 15: Following information will make NFI more useful	Drugs used for doping, common drug interactions, normal values of electrolytes, nomogram for drug titration in poor LFT and KFT, Drugs with potential teratogenicity	Antidotes	2
		Drugs dosing in specific population-pediatric, pregnancy, lactation	4
		Approximate cost, maximum price of drugs under NPPA	2
		Drugs with abusive potentials	2
		Suitable substitute drugs in case of ADR	1
		Off label use of drugs	1
		Orphan drugs	1
		Drug alerts, labels	1
		Standard treatment guidelines	1
		Treatment regimen for common diseases	1
		Biologics and biosimilars, nutraceuticals	1
Question 17: Following can be added to drug monograph to increase utility of NFI?	Common brand name of drugs available in market, price range of available drug brands in the market	Source/places of availability of generic medicines	3
		Pharmaceutical price control policy, maximum price under NPPA	2
		Most cost effective brands	1
		Disposal of expired drugs	1
		Off label use of drugs	1
		Newer drugs approved and drugs in clinical trial	1
		Synopsis of clinical trials	1
Question 20: Any other comment on national formulary of India		It should be freely available/easily accessible/available as mobile app/offline app/PDF/soft copy	29
		A copy should be made available in all hospitals for reference purpose	1
		Precautions in special groups like geriatric	1
		CME on NFI should be online and to occur every year with topics like new drugs approval, drug resistance, rational use of drugs, drug interaction	1
		Drug resistance and drug interactions in Indian population	1
		Awareness for its use is needed	1
		Updated at fixed interval	1
		Step wise treatment algorithm for common diseases	1
		Management of common and emergency conditions	1
		New drugs information to be available in NFI	1
		Types of poison and their treatment	1
		Inclusion in MBBS curriculum is a must	1

CIMS=Current index of medical specialties, MIMS=Monthly index of medical specialties, IDR=Indian drug review, KFT=Kidney function test, LFT=Liver function test, NPPA=National pharmaceutical pricing authority, ADR=Adverse drug reaction, CME=Continuing medical education, WHO=World Health Organization

also raises the health-care cost which emphasizes the need for actions to reduce their use.[8,12]

There has been considerable development toward rational use of medicines in India in recent years from government initiatives including PvPI, Free Drugs Service Initiative under National Health Mission, Pharma Jan Samadhan initiative under the aegis of Digital India program of Government of India, New Drugs and Clinical Trials Rules 2019, revised NLEM, India-2015, Pradhan Mantri Bhartiya Janaushadhi Pariyojana', Drugs (Prices Control) Order-2013, Pharmaceutical Promotion Development Scheme, Cluster Development Programme for Pharma Sector-2014, and NFI.

The drug formulary is a desk-reference manual describing the concise facts about clinical and pharmacological information of selected medicines. In addition, the information related to safe handling of medicines, storage, disposal, regulatory matters, and other facts concerned with prescribing and dispensing of drugs may also be included in this formulary. Aligning with NLEM, a national drug formulary focuses on the drugs which are required for the treatment of diseases prevalent in the country or satisfy the essentiality concept. Drug formularies can be prepared at different levels of the health system or can be at the level of individual institution/hospital/clinic specific; however, they should be aligned with NFI.

In India, the initial versions of NFI were available in 1960, 1966, and 1979 as the first, second, and third editions, respectively by the Ministry of Health, Government of India. In the later period, the responsibility of NFI publication was bestowed upon the IPC, Ghaziabad. Considering the huge expansion in the pharmaceutical sector and availability of marketed drugs in the last few decades, there is an immense need for frequent updating of this formulary. The NFI has adopted the fundamental principles of the WHO Model Formulary and being thoroughly updated keeping in view the Indian context for its content based on evidence. The recent version of NFI (5th edition, 2016) was published by IPC with 521 drug monographs and many value added Appendices.[4] To make this formulary more user-friendly, the views of the end-users like physicians and other health-care professionals in India are of utmost importance.

The WHO has recognized Pharmaceutical and Therapeutics Committees (PTCs) in several countries for the promotion of rational use of medicines; these are also referred to as Drugs and Therapeutics Committees. One of the primary responsibilities of PTCs is formulary development and management.[13] Enlisting medicines in formularies considers several key factors about clinical practice, ethical concerns, legal and social aspects,

philosophical views, quality-of-life, safety, and economic perspectives. Decisions for inclusion and deletion of medicines should also focus on accessibility and procurement practice of drugs. Besides, periodic update of the formulary is indispensable which should consider the views of users, current changes in health-care practice, and the unmet need of the society about the use of drugs, although decisions should be based on scientific rationality.

This study was designed to congregate data regarding some of the above key influencing factors because of the forthcoming update of NFI. A questionnaire (Google-doc based) was circulated to doctors/interns across the country to learn about their practice experience and opinion toward the NFI. Among the representative sample of the doctor population, i.e., 461 participants, >95% have responded to all the questions of this questionnaire.

A significant number 46.4% have consulted NFI during clinical practice, which is one of the main objectives of NFI. As per a previous study, the survey regarding Delhi State Essential Medicines Formulary, 74% referred to this in their practice.[5] In the current era, doctors prefer the digital version of the reference document like a mobile app or soft copy. Most of the responders are aware that NFI is published by IPC; about 56% have preferred the availability and access of NFI as a soft copy/downloadable application. This will improve the usability of NFI.

In the opinion of responders, NFI disseminates unbiased and useful information about medicines used in current health-care practice. More than 90% have opined that NFI is to promote rational use of drugs and considered it as a reference document during clinical practice. Most of them are aware of the contents of NFI, though about one-third (28.7%–34%) have the wrong information that NFI is a legal document for the safeguard of health-care workers and it contains brand name of drugs.

Several doctors have suggested that NFI should provide information about drugs for basic medical emergencies, disposal of expired pharmaceutical products, pharmaceutical price control policy, and drug procurement practices in hospitals. Similarly to enhance the utility of NFI, it has been suggested to include information such as drugs used for doping, common drug interactions, normal values of electrolytes, nomogram for drug titration in poor LFT and KFT, and drugs with potential teratogenicity. Consequently, this broad information will serve as a guide for the rational use of prescribed medicines. Commendation for prescribed medicines should only be based on evidence and simultaneously, there should be a rigorous process

to optimize the use of available resources.[14] However, limitations pertain to the ambit of recently approved medicines and recent advances of already marketed medicines for which substantial information on efficacy and safety are lacking.

The increasing health care cost vis-à-vis drug prices leads to an increment in the challenges to industry sustainability, consumers, and health-care providers, and this compels for options with value for money.[15] Cost-effectiveness analysis is gradually evolving and will be more focused in future healthcare, especially for chronic diseases.[16] The information of pharmaceutical pricing is a gray area for the doctor fraternity, and as per a previous study, doctors have expressed that cost information would improve their prescribing.[17] These data favor the inclusion of pricing policy information, price range, and median value of the cost of marketed preparations of the concerned drug in the NFI, and some responders have opined in favor of this. However, it is far from feasibility to provide the price information of all medicine brands in the formulary since generic medicines are continuously being added to the market-leading to the dynamic nature of medicine brands' availability and their pricing, also the constraints of expected periodic revision of NFI. It will be worthy of providing the information about drugs price control policy, the median price with a range of commonly prescribed medicines with mention of the period of its assessment.

Limitations

Although this questionnaire was circulated to most of the health-care facilities across the country including medical institutes, private hospitals, and clinics, only 461 practitioners/resident doctors/interns have responded. It may be because others were reluctant to contribute due to time constraints, work pressure, or not following the NFI which is available as hard copy in the current digital era.

Conclusion

In terms of responses, the majority of respondents considered NFI an effective tool for instant access to drug-related information such as therapeutic indications, dosage and availability of formulations, strengths, and safety aspects of commonly prescribed medicines. The information provided in the NFI is considered precise, unbiased, and simple, making it reader-friendly and handy. Several key suggestions were assimilated for improvement and enhanced practical usefulness of the NFI. In general, the view was to make the NFI digitally accessible which will reduce the time spent in choosing medicine with optimal efficacy and safety. As this document is considered by the majority of respondents to be a key source of medicines information, so its periodic update, introspection, and collating users notions akin to this pan-India survey is vital for achieving the goal of NFI.

Highlights

- To achieve the goal of promoting rational drug use, National formulary of India (NFI) needs periodic update and feed back from end-users like physicians and other health-care professionals.
- This pan-India questionnaire-based survey reflected that 95% respondents were aware of NFI's content and 46.4% used this in clinical practice
- Also there are misconceptions about NFI (34.4%) and even 22.2% had never used it
- Boosting its practical usefulness needs incorporation of suggested information, digital accessibility, periodic update, and creating more awareness among health professionals.

Conflicts of interest
There are no conflicts of interest.

References

1. How to Search for Health Information Online. Available from: https://www.hss.edu/conditions_techniques-patients-search-health-websites.asp. [Last accessed on 2021 Apr 27].
2. WHO Model List of Essential Medicines. Available from: https://www.who.int/selection_medicines/list/en/. [Last accessed on 2021 Apr 27].
3. National Formulary of India. Available from: https://www.nhp.gov.in/national-formulary-of-india_mtl. [Last accessed on 2021 Apr 27].
4. NFI. National Formulary of India. Indian Pharmacopoeia Commission, Government of India. 5th ed; 2016. p. XIII-XVII.
5. Sharma S, Reeta K, Chaudhury RR. Attitude and opinion towards essential medicine formulary. Indian J Pharmacol 2010;42:150-2.
6. Jaykaran. How to increase the response rate to a questionnaire study?. Indian J Pharmacol 2011;43:93-4.
7. World Health Organization. Ten Years in Public Health, 2007–2017: Report by Dr. Margaret Chan, Director-General, World Health Organization; 2017.
8. Sarangi SC, Kaur N, Tripathi M, Gupta YK. Cost analysis study of neuropsychiatric drugs: Role of National List of Essential Medicines, India. Neurol India 2018;66:1427-33.
9. Report of the Core-Committee for Revision of National LIST of Essential Medicines. November 2015. Available from: https://main.mohfw.gov.in/sites/default/files/Recommendations.pdf. [Last accessed on 2021 Jan 30].
10. Chigome AK, Matlala M, Godman B, Meyer JC. Availability and use of therapeutic interchange policies in managing antimicrobial shortages among South African Public Sector Hospitals; Findings and Implications. Antibiotics (Basel) 2019;9:4.
11. de Araújo NC, Silveira EA, Mota BG, Neves Mota JP, de Camargo Silva AE, Alves Guimarães R, *et al.* Potentially inappropriate medications for the elderly: Incidence and impact on mortality in a cohort ten-year follow-up. PLoS One 2020;15:e0240104.
12. Kumar S, Sarangi SC, Tripathi M, Gupta YK. Evaluation of adverse

drug reaction profile of antiepileptic drugs in persons with epilepsy: A cross-sectional study. Epilepsy Behav 2020;105:106947.

13. Matlala M, Gous AG, Meyer JC, Godman B. Formulary management activities and practice implications among public sector hospital pharmaceutical and therapeutics committees in a South African province. Front Pharmacol 2020;11:1267.

14. Meyer JC, Schellack N, Stokes J, Lancaster R, Zeeman H, Defty D, *et al*. Ongoing initiatives to improve the quality and efficiency of medicine use within the public healthcare system in South Africa;

A preliminary study. Front Pharmacol 2017;8:751.

15. Garrison LP Jr. Cost-effectiveness and clinical practice guidelines: Have we reached a tipping point?-An overview. Value Health 2016;19:512-5.

16. Sarangi SC, Kaur N, Tripathi M. Need for pharmacoeconomic consideration of antiepileptic drugs monotherapy treatment in persons with epilepsy. Saudi Pharm J 2020;28:1228-37.

17. Allan GM, Lexchin J, Wiebe N. Physician awareness of drug cost: A systematic review. PLoS Med 2007;4:e283.