Original Article

Parent-Directed use of Over-the-Counter Medications and Complementary and Alternative Medicine Therapies among Pediatric Patients: A Cross-Sectional Study

Shreyasi Seth[1], Ashok Kumar Dubey[2], Nidhi Maheshwari[1]

[1]Department of Pharmacology, School of Medical Science and Research, Sharda University, Greater Noida, Uttar Pradesh, India

[2]Department of Pharmacology, All India Institute of Medical Sciences, Bilaspur, Himachal Pradesh, India

Abstract

Objective: The use of over-the-counter (OTC) drugs and complementary and alternative medicines (CAM) as initial options by parents is common in the pediatric population. Despite the widespread use of parent-directed medication (PDM) among the pediatric population, we have scarce data in the Indian context. This study was done to assess the PDM practices and its determinants in the Indian population. **Methods:** It was a descriptive cross-sectional study assessing a representative sample of 284 parents of pediatric patients visiting the pediatrics department of a tertiary care hospital. **Findings:** Majority (64.08%; 182 out of 284) of the parents agreed to have used some form of PDM in the past 3 months. While higher socioeconomic status and having 2 or more children were associated with higher practice of PDM ($P < 0.05$), it was similar between educated or uneducated parents, rural or urban backgrounds, and nuclear or joint families ($P > 0.05$). CAM was the most commonly used option (58.12%; 161 out of 277), followed by OTC conventional allopathic medications (41.88%; 116 out of 277). Homeopathic medicines were the most preferred alternative therapy under the Alternative Medical System Category of National Centre for Complementary and Alternative Medicine. Majority of parents (71.43%; 130 out of 182) were confident that the treatment chosen could not harm the health of their children and they attributed time constraints or availability of prior prescriptions as reasons for such practice. **Conclusion:** PDM is a widespread phenomenon in the Indian pediatric population. The parents as well as the prescribers need to take a more balanced, practical, and judicious approach toward medications given to a child.

Keywords: *Alternative medicine, complementary medicine, over-the-counter medications, parents' socioeconomic status, pediatric, self-medication*

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Introduction

The use of over-the-counter (OTC) medications is a prevalent practice all over the world as a first-line approach for presumed minor ailments.[1] Self-medication with OTC medications is a double-edged sword with its own advantages and disadvantages. It provides benefits in terms of easy access to treatment, making an individual participate actively in the management of his or her health issues. Even though OTC medications are relatively safe with a wide therapeutic index and predictable adverse effects, their use is not free of risks. Improper treatment on generalized assumptions, without experience to understand illnesses and symptoms, can lead to disease progression, drug misuse, and even serious adverse effects.[2] The recent availability of Internet pharmacies has also added to the complexity of the practice.[3] Other than OTC medications from modern medicine, complementary and alternative medicines (CAMs)

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Address for correspondence:
Dr. Nidhi Maheshwari, E-mail: dr.nidhi2k3@gmail.com
Dr. Shreyasi Seth, E-mail: shreyasiseth22@gmail.com

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are also commonly used as initial therapeutic options in both developing and developed countries across the globe with wide variation in reported prevalence, ranging from 20% to 70% in different studies.[4-6] The general perception that CAM therapies are safer than modern medicines, further contributes to the high prevalence of CAM usage.[5]

For this study, the working definition of an OTC drug was taken as a drug that is available without a prescription. CAM therapy was defined as any health-care practice or product not considered a part of conventional modern medicine, which may include traditional practices, alternative medical systems, dietary supplements, herbal products, or any other so-called natural therapies.[2,5] According to the National Centre for Complementary and Alternative Medicine (NCCAM), CAM can be classified as biologically based practices, such as dietary supplements; energy medicine, such as electromagnetic radiation; manipulative and body-based therapies, such as chiropractic manipulation; and mind–body medicine, such as meditation.

Self-medication with OTC medications and CAM therapies is not just limited to the adult population but holds true for pediatric patients as well, as many parents begin initial treatment of their children at home, either taking decisions themselves or on advice from different sources, without consulting any qualified physician (17%).[1] Such practice may have its role in taking care of minor ailments such as fever, cough, cold, and diarrhea, but inadequate knowledge and wrong perceptions may sometimes result in therapeutic failures, adverse effects, and even fatal outcomes, as the pharmacokinetics (absorption, distribution, metabolism, and excretion) and pharmacodynamics (responses to the drug) in the pediatric age group are different from those in adults.[7]

Despite the widespread practice of parent-directed medication (PDM) among the pediatric population, there is not enough data to help us analyze and understand the same. Although there have been some studies in western countries, the determinants of these practices, to the best of our knowledge, have not yet been scientifically evaluated among the parents of the pediatric age group of Indian patients. This study was conducted to help evaluate the usage of OTC medications, CAMs, and traditional home remedies specifically directed by parents in the pediatric population. This article was previously presented as an oral presentation at the 67th Annual National Conference of APPICON (Association of Physiologists and Pharmacologists of India) on April 16, 2022.

Methods

It was a descriptive cross-sectional study assessing a representative sample of parents of pediatric patients visiting a tertiary care hospital in Greater Noida, Uttar Pradesh, India. Prior approval for the study was taken from the Institutional Ethics Committee (see IEC letter Ref. No.SU/SMSandR/76-A/2021/75 dated May 2, 2021). Participation in the study was voluntary, and written informed consent was obtained from all the subjects before participation in the study. Parents with children visiting the pediatrics outpatient department between May 2021 and July 2021 for the first time for any illness and who were willing to participate in the research were recruited and interviewed. Those parents who themselves were health-care professionals were excluded from the study.

Data collection was done through a face-to-face interview-based survey conducted on a semi-structured questionnaire. The questionnaire was pretested among 10 parents to assess the applicability and quality of the questions. Experienced faculty members from pharmacology and pediatrics interpreted the transparency and accuracy of these completed questionnaires, and then, the interview questionnaire was finalized after incorporating, deleting, or modifying the suggested changes. The questionnaire was also approved by the Institutional Ethics Committee.

For this study, "pediatric" population included any patient below 18 years of age.[8] PDM referred to any form of medication given by a parent in the last 3 months without consulting a registered medical practitioner for the child's ailment.

The first part of the questionnaire [Annexure 1] was to assess the sociodemographic profile of the participants. The next part of the questionnaire was to evaluate whether the parents had used OTC medications or CAM therapies for their children on their own. Those who responded positively were further explored for the determinants of usage, such as the type of CAM (classified as per NCCAM) and/or OTC medicine used, the trigger symptoms, the types of therapies, routes of administration, frequency, reasons, sources of information, communication with their doctors, and their experiences and perceptions regarding the same. The datasets generated during and/or analyzed during the current study can be made available from the corresponding author on reasonable request. Based on related studies, on an assumed prevalence of 20% (±5) for OTC medications and CAM usage in the pediatric population, sample size calculations showed that 246 participants would have been required to provide a 95%

confidence interval with ±5% variation.[1,9] The following formula was used to calculate the sample size:

Sample size = $(z^2 \times p[1 - p])/e^2$

z = z-score; e = margin of error; p = standard of deviation

Evaluation and interpretation of data were done after appropriate statistical analysis for the descriptive studies. All categorical data were expressed as proportions and percentages. The Chi-squared test was used to compare PDM usage in demographic parameters. P <0.05 was considered statistically significant. The data collected were evaluated and interpreted using the Microsoft Excel 2019 version.

Results

A total of 284 parents participated in the study. Sociodemographic details of all the respondents as recorded are shown in Table 1. Of the total respondents, 64.08% (182 out of 284 parents) admitted to having given some form of medication to their children [Table 1]. Parents with more than one child (68.13%; 124/182; $P < 0.05$) and parents belonging to upper/middle socioeconomic classes were more likely to practice PDM (74.55%; 82 had given PDM out of 110 upper-class families interviewed $P < 0.05$). Educational qualifications of the parent, type of family (nuclear/joint), area of residence (rural/urban), and gender of the parent did not show significant statistical differences toward PDM usage [Table 1].

The types of PDM chosen are shown in Figure 1. The reasons that made the parents consider self-directed use of medicines are summarized in Figure 2. The various sources on which the parents depend for self-directed medicine use are shown in Figure 3. The perceptions and attitudes of parents toward prescriptions are displayed in Figure 4.

Out of the 182 parents who were further asked about the types of therapies they give to their child (multiple

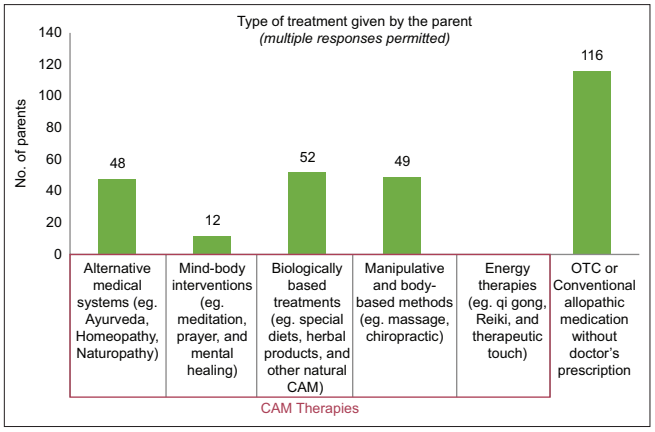

Figure 1: Types of parent-directed medication chosen. OTC: Over-the-counter, CAM: Complementary and alternative medicines, PDM: Parent-directed medication

Table 1: Demographic details of respondents mapped with the usage of parent-directed medication

	Parent-directed medication given (n=182), n (%)	Parent-directed medication not given (n=102), n (%)	Grand total (n=284), n (%)	P*
Relationship with the child				
Father	61 (63)	36 (37)	97	0.76
Mother	121 (65)	66 (35)	187	
Number of children of the respondent				
One	58 (54)	50 (46)	108	0.004*
Two or more	124 (70)	52 (30)	176	
Residence				
Rural	68 (62)	42 (38)	110	0.53
Urban	114 (66)	60 (34)	174	
Educational qualification of the parent				
Illiterate	4 (40)	6 (60)	10	0.55
School up to 12th	92 (67)	46 (33)	138	
Graduate and above	86 (63)	50 (37)	136	
Type of family				
Nuclear	82 (66)	42 (34)	124	0.4
Joint/3-generation	100 (62)	60 (38)	160	
Socioeconomic status of family^				
Upper	82 (75)	28 (25)	110	0.007*
Middle	74 (54)	64 (46)	138	
Lower	12 (86)	2 (14)	14	
Details not available	14 (64)	8 (36)	22	

*P<0.05 on Chi square test, ^As per Modified BG Prasad Scale 2020

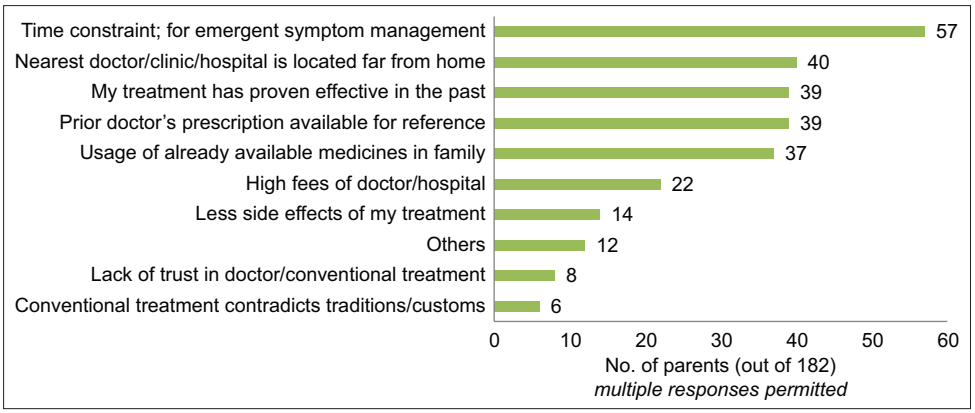

Figure 2: Reasons for considering parent-directed medication

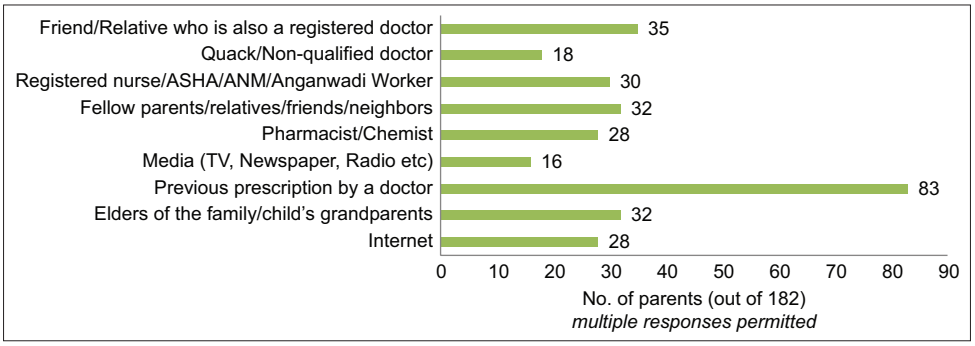

Figure 3: Sources of information for the parents practicing parent-directed medication. ASHA: Accredited social health activist, ANM: Auxiliary nurse and midwife, TV: Television

responses permitted), various CAM therapies together had the maximum overall popularity (58.12%; 161 out of the 277 responses) as compared to OTC conventional allopathic medications (41.88%; 116 out of the 277 responses). Alternative medical systems were used by 26.37% (48 out of 182) of the parents giving medications, and homeopathic medicines were the most commonly preferred alternatives [Figure 1]. Most parents (31.32%; 57 out of 182) attributed time constraints to giving PDM over any other reason [Figure 2]. The most common indications for such practices were fever and upper respiratory tract infections (52%; 185 out of 354 responses) followed by pain (16%), gastrointestinal problems (16%), skin ailments (6%), ear ailments (2%), eye ailments (1%), and other conditions (7%).

Previous prescriptions of adults, other children, or the same child for a similar ailment in the past were a popular source and reason for giving PDM in our study [Figure 3]. The oral route was the most common route by which parents administered PDM (72.57%; 164 out of 226 responses), followed by topical application (20%; 46 out of 226 responses), nasal (4.42%), and others (0.88%). Four parents (about 2%; 4 out of 226 responses) had used the parenteral route for their children; they had procured injections without consulting doctors and administered the medicines with the help of quacks or village health-care workers.

Although 85.71% (156 out of 182) of parents agreed that the dosages for children were different from those for adults, 71.43% (130 out of 182) were confident that the treatment given by them could not harm the health of their child [Figures 5 and 6]. 85.7% (12 out of 14) parents in lower socio-economic group agreed to have practiced PDM. Despite this, the expense of a hospital or doctor was not the main reason for parents to self-medicate their children. Seventy-two percentage of the interviewed parents reported that the doctors asked them about any other type of self-medication used, and the majority of them confirmed that they had informed their doctor (82.42%; 150 out of 182) about PDM used. Around 26.92% (49 out of 182) of the interviewed parents reported that their treating physician guided them on how to begin PDM for any future milder episodes of illness [Figure 7].

Discussion

The overall prevalence of 64.08% in our study was close to that found in another Romanian study (70%).[10] While in previous reported studies, mothers have been the medicine administrators and decision-makers, our

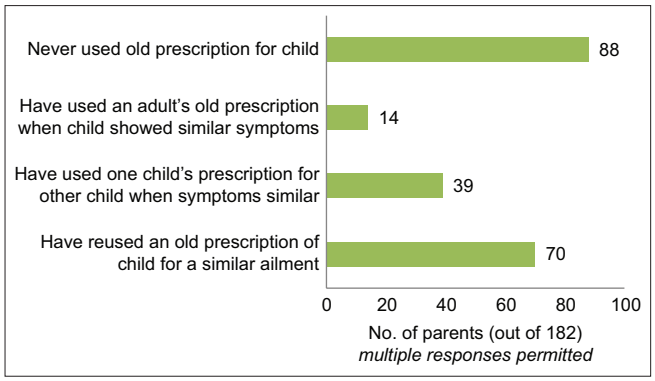

Figure 4: Attitudes of parents toward prescriptions

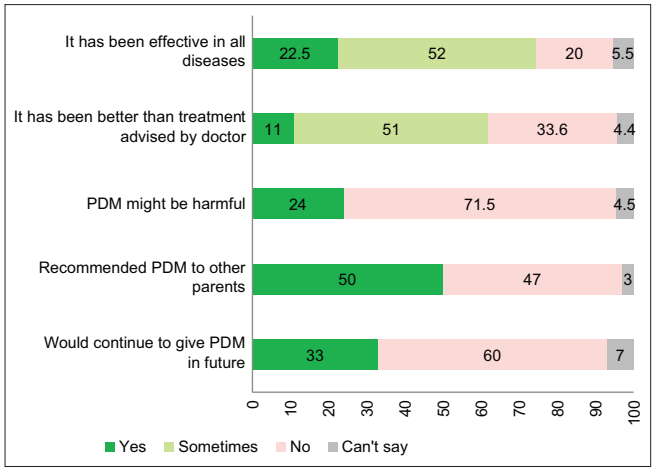

Figure 6: Attitude of parents toward interventions done by them

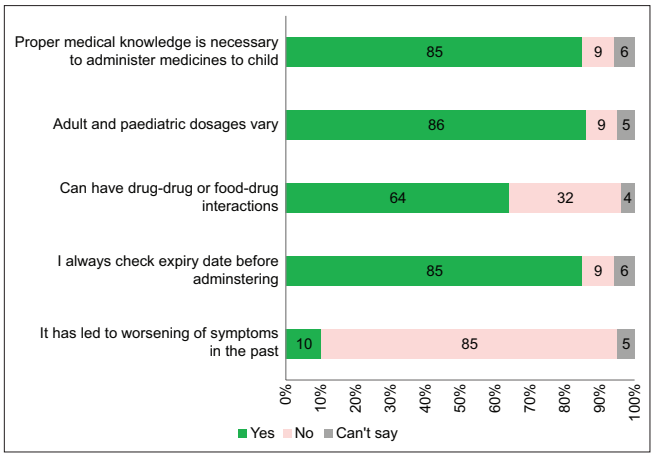

Figure 5: Perceptions of parents about the complementary and alternative medicines/OTC medications given by them

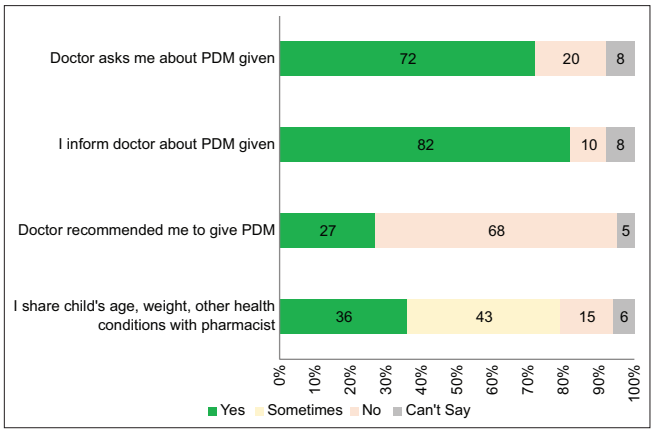

Figure 7: Parent–doctor and parent–pharmacist communication about parent-directed medication. PDM: Parent-directed medication

study included the representation of both parents.[11,12] The involvement of fathers reflects a changing primary caregiver dynamic over the past few decades. However, there was no significant difference in the prevalence of PDM between parents in our study.

Contrary to our study, Tobi *et al.* and Du and Knopf reported higher OTC drug usage for children of educated parents.[1,13] Findings of significantly higher PDM practice in higher SES, as per the modified BG Prasad socioeconomic scale 2020 (74.55%), are similar to those in another study with more mother-initiated medication practice in higher socioeconomic groups, almost twice as common as in lower SES.[14,15]

In our study, PDM usage was significantly more common among parents of more than one child, which could be due to previous experience with similar symptoms in the first child. This can be corroborated with the fact that 21.43% (39 out of 182 parents) agreed to have used the other child's prescription at some point [Figure 4]. The usage of PDM in the present study was more common in the 5–12 year and the adolescent age groups, which is the school-going age, and parents tend to become more confident in taking steps for minor redressal as compared to the infant age group when the clear communication of symptoms by the child and drug dosage are points of concern. Similar ailments in other children of the family, the influence of other parent couples in the family while choosing treatment, etc., could be reasons for a higher prevalence of PDM in joint and three-generation family set-ups (62.50%; 100 out of 160 joint and three-generation families) in our study. Moreover, if grandparents also lived with the child, it was found that PDM was more often than not influenced by their choices and practices. Traditional home remedies, practiced and passed on over generations, dominated as one of the main reasons why parents from such families agreed to give some kind of medicine or alternative treatment to their children. However, in our study, 66.13% (82/124) of those living in nuclear families also sought PDM, which could be due to the inability of working parents to visit the doctor for their child's illness, especially if they felt that the symptoms were minor and could be resolved by OTC medicines, easily available at any nearby chemist.

Overall, CAM usage (58.12%) was more prevalent in our study compared to OTC medicines (41.88%). Among the OTC medicines, paracetamol was used most commonly, followed by multivitamins and supplements. Earlier studies have also reported a similar trend.[16] Similar to the findings of our study, Vlieger *et al*. reported a 30% prevalence of CAM in pediatric patients, with the highest prevalence for homeopathy (48%).[17] Similar to that reported in other studies, parents in this study also believed that homeopathic medicines could have a slower onset of action, but the effects were prolonged and sustained without any risk of adverse effects, with better compliance due to the sweet and easy-to-administrate formulations.[17,18]

The use of CAMs among the pediatric age group should be discussed with parents when prescribing medicines or recommending self-medication to avoid the risks of drug interactions because CAMs are also used by many in conjunction with conventional care. CAM may be sold in pharmacies as well, and this blurs the boundary between CAMs and OTC medicine for many parents. This needs to be considered by both health-care professionals and pharmacists.[19]

In our study, it was seen that indigenous herbal products were also used by parents, especially those from rural backgrounds. "Guti" or "Baal Guti" was a popularly used herbal product consisting of Kakadshringi (also called Karkalshrungi), or leaf galls, of the herbal medicinal plant Pistacia integerrima, which is claimed to have anti-diarrheal effects.[20] It was a popular choice (29%) for infants and toddlers, including even those who were following "exclusive breastfeeding". A few parents had used it on the advice of their doctors. Many traditional home remedies, such as the application of asafetida with salt on the child's stomach for stomach ache and the intake of milk with honey syrup for constipation, were recommended to the parents by the child's grandparents or other elders in the family. One of the respondents had applied juice from the freshly plucked leaves of *Cynodon dactylon* (Bermuda grass or Dūrvā grass) at the site of a presumed nappy rash in an infant. The safety issue concerning the risks of CAM modalities, especially herbal remedies and nutritional supplements, and the prevention of interactions with conventional medications may be an issue of concern for pediatricians. Earlier studies have shown that parents who prefer CAM for their children believe that it is "safe" because it is a relatively "natural" therapy.[21]

The reasons for PDM in this study [Figure 4] are similar to an Italian study, which had reported that the majority of the parents engaged in the practice because they felt that the illnesses of their children could be treated by themselves or because of the availability of old prescribed medication at home (32.9%) and getting the medicines from a pharmacist without a prescription (29%).[22] Using antibiotics (either "leftover" from an incomplete course in the past or those bought OTC) could also be contributing to the growing antimicrobial resistance in pediatric health care and needs to be addressed.

The majority of the parents agreed to have been inquired about prior self-directed treatment and have communicated its use to the treating pediatrician. This finding is in contrast to adult or elderly patients, where most of the doctors usually miss asking about self-medication practices, and even the patients do not share the information unless asked specifically.[23] In our study, as reported by parents, some of the doctors (27%) actually guided them on how to begin PDM for any future milder episodes of illness.

Although the study sample taken in this study was demographically diverse, this study was conducted in a small geographical area; hence, it is difficult to generalize the findings to a country as diverse as India. The study site, a tertiary care center, caters majorly to the health-care needs of urban populations; hence, the sample representation from illiterate and lower-income groups was comparatively lower in our study. Another limitation of the study was that since it was a questionnaire-based study, the responses received from the parents during the interviews relied on their memory.

The widespread prevalence of self-medicating practices requires the need for educational and awareness programs for parents regarding the practice and its risks.[10] Detailed history taking and counseling of parents regarding PDM should be an important and integral part of pediatric health care. It is important that all parties – the physician, the pharmacist, and the parent(s), as well as peer parents, family members, and other members of society – who influence the choice of treatment for the child should forgo their biases and do what is ultimately in the best interest of the child on the basis of evidence-based information.

In conclusion, our study revealed that PDM is a common and widespread phenomenon in Indian pediatric patients. It encompasses various treatment modalities that a parent seeks without consulting a registered medical practitioner, ranging from CAM to allopathic medications administered without prescription and traditional home remedies given in the best interests of the child's health. Instead of an opinion against or for the usage of PDM, the parents as well as the prescribers of modern medicine should take note of these prevalent

practices and have a balanced, practical, and judicious approach toward medications given to a child.

Authors' Contribution

We certify that all authors hereby named deserve authorship, agree to be so listed, and have read and approved the manuscript and its submission. Dubey AK was primarily involved with the concept and design of the work; Seth S was chiefly in charge of primary data collection and report writing; and Maheshwari N was substantially involved in data analysis and interpretation.

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Conflicts of interest

There are no conflicts of interest.

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Annexure 1

Questionnaire

Date:

Form number:

Project title: Parent-directed use of over-the-counter medications and complementary and alternative medicine therapies among pediatric patients: A cross-sectional study

Part I: Demographic profile of the respondent (parent)

1. **Sex of parent:**
   a. Mother b. Father
2. **Number of living children (up to 18 years) of the parent:**
   a. 1 b. 2 c. 3 d. 4 or more
3. **Age group of child (tick multiple if more than one child and in different age groups):**
   a. <1 year (infant)
   b. 1–3 years (toddler)
   c. 3–5 years (preschool child)
   d. 5–12 years (school-age child)
   e. 12–18 years (adolescent)
4. **Residence:**
   a. Rural b. Urban
5. **Educational qualifications of the parent:**
   a. Illiterate
   b. Primary School
   c. Secondary/Matriculation (Class 10th)
   d. Higher secondary/Senior Secondary (Class 12th)
   e. Graduate
   f. Postgraduate
6. **Type of family:**
   a. Nuclear (only parents live with their children)
   b. Joint (wherein 2 or more couples live with their dependent children)
   c. 3-generation family (wherein grandparents also live with the child)
7. **Total Family Income per month (Approximate in rupees)** _____
8. **Total number of members in family** _____
9. **Per capita monthly income: Socioeconomic class according to BG Prasad Scale 2020** ***(as calculated by the investigator)***

I	7533 and above
II	3766-7532
III	2260-3765
IV	1130-2259
V	1129 Below

Part II:

10. **Have you given any medicines without prescription or any alternative treatment to your child for any disease (without consulting a doctor or without approval of a doctor) in the last 3 months?**
    a. Yes
    b. No
11. **If yes, for which of the following? (You can select multiple responses)**
    a. Runny Nose/Cold
    b. Cough
    c. Fever
    d. Headache
    e. Vomiting

f. Body pain e.g., stomach ache, joint pain
g. Diarrhea
h. Acidity
i. Genital/Urinary tract symptoms
j. Ear ailments
k. Eye ailments
l. Dental Pain
m. Skin ailments
n. Others (Please specify if any other medical condition/disease)

12. Which type of alternative medicines have you given to your child:

a. **Alternative medical systems e.g.** Ayurvedic medicine, Homeopathy, and Naturopathy.
b. **Mind-body interventions, e.g.** meditation, prayer, and mental healing.
c. **Biologically based treatments, e.g.** specialized diets, herbal products, and other natural products such as minerals, hormones, and biologicals.
d. **Manipulative and body-based methods e.g.** massage, chiropractic
e. **Energy therapies. e.g.** qi gong, Reiki, and therapeutic touch.
f. **None of the above** (I give conventional **allopathic medication** without doctor's prescription e.g. Crocin, Vitamins, ORS, Antibiotics, Volini analgesic gel, etc.)

13. Please name and discuss briefly such treatment given by you-

_____

_____

_____

14. What was the most common way of giving these medicines?

a. Orally through the mouth (syrup, tablet, etc.)
b. Parenteral (injections)
c. Application on skin (massage etc.)
d. Nasal
e. Others (Please specify) _____

15. What was/were the reasons?

a. Nearest doctor/clinic/hospital is far from home
b. Saves time
c. Availability of an old prescription for reference
d. High fees of doctors/hospital
e. Lack of trust in doctor/conventional treatment
f. Usage of already available medicines of family members
g. My treatment has proven effective in the past
h. Less side effects
i. Conventional treatment contradicts our family traditions and customs
j. Others (Please specify) _____

16. What are your sources of information while choosing the treatment for your child's disease?

a. Internet
b. Elders of the family/child's grandparents
c. Previous prescription by a doctor
d. Media (TV, Newspaper, Radio, etc)
e. Pharmacist/Chemist
f. Fellow parents/relatives/friends/neighbors
g. Village health care worker/nurse/ASHA/ANM/Anganwadi Worker
h. Quack/Nonqualified doctor (any doctor whose registration status cannot be established)
i. Friend/relative who is also a registered doctor
j. Others (Please specify) _____

17. Has a doctor ever advised you to use over-the-counter drugs or alternative medicines for your child? Please specify.

a. No, never
b. Yes_____

18. Do you tell the pharmacist about other health ailments/weight/age of your child before buying medications on your own for him/her?
a. Yes, always
b. Yes, sometimes
c. No, never

19. Do you think your type of medication can ever harm the health of your child?
a. No
b. Yes

20. Do you think your type of treatment is better than that offered by the doctor?
a. Yes
b. No
c. Sometimes

21. Is it effective in all diseases/medical conditions of your child?
a. Yes, always
b. Yes, sometimes
c. No

22. Do you advise other parents also about the treatment given by you?
a. Yes
b. No

23. Are you aware about "completing the course" of allopathic medicines?
a. No never heard of it
b. Yes

24. Do you check the expiry date/any health hazards associated with the treatment before giving it to your child?
a. Yes
b. No

25. Tick on all that are applicable-
a. I have reused an old prescription of my child for a similar ailment in the past
b. I have used one child's prescription for my other child when symptoms were similar
c. I have used an adult's old prescription when my child showed similar symptoms d) None of the above
d. None of the above

26. Do you think dosage in children is different from adults?
a. No
b. Yes

27. Are you aware that certain medications can interact with other medicines and food?
a. Yes ____ (e.g. reason why some medicines are taken empty stomach and some after a meal)
b. No. I do not know.

28. Has your child experienced worsening of symptoms/any health hazards after any treatment given by you? {If yes, please specify}
a. Yes _____
b. No

29. If yes, what did you do then?
a. Stopped treatment and consulted the doctor
b. Continued treatment and waited for symptom relief
c. Continued treatment with increased dose and frequency

30. Are you aware about hazards of over dosage of allopathic medicines in children?
a. No, not aware
b. Yes, I am aware

31. Do you consider that medical knowledge is necessary for administration of medicine to a child?
a. Yes
b. No

32. Do you inform your child's doctor about such medication/treatment given by you to your child whenever you visit the doctor next?
a. Yes
b. No

33. Do the doctors at the tertiary care hospital ask you about any treatment you have given to child in past?
a. Yes
b. No

34. Would you like to continue giving medications to your child without prescription/practicing alternative therapy for your child's illness in the future as well?
a. Yes
b. No
c. Only after consulting the doctor about the same