



A Validation Study of Homeopathic Prescribing and Patient Care Indicators

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ABSTRACT

A preliminary version of the homeopathic prescribing and patient care indicators was available. The instrument was modified further in this study with an intention to address formally its validity and reliability, audit prescriptions, identify areas of sub-optimal prescribing, and highlight target areas for improving the quality of practices. A cross-sectional study with record analysis was conducted on systematically sampled 377 patients of Mahesh Bhattacharyya Homeopathic Medical College and Hospital (MBHMC and H), Howrah, West Bengal, India. The outcome measures were homeopathic prescribing indicators (6 items) and patient care indicators (5 items). Individualized homeopathic prescriptions predominated in the encounters. Areas demanding immediate attention were extremely poor labeling of drugs dispensed from the hospital pharmacy, improper record of case history and disease diagnosis, ongoing therapies, and investigational findings in the prescriptions. Internal consistency of the overall instrument was estimated to be good (Cronbach's alpha: Prescribing indicators 0.752 and patient care indicators 0.791). The prescribing indicators, except items 1 and 3, reflected acceptable item-corrected total correlations – Pearson's *r* from 0.58 (95% CI: 0.52-0.65) to 0.74 (95% CI: 0.69-0.78). The patient care indicators, except item 2, showed acceptable correlations – Pearson's *r* from 0.40 (95% CI: 0.31-0.48) to 0.82 (95% CI: 0.78-0.85). The instrument also showed high discriminant validity (prescribing indicators $P < 0.0001$ and patient care indicators $P < 0.0001$). Improper prescribing practice was quite rampant and corrective measures are warranted. The developed indicators appeared to be validated and reliable; however, they are amendable for further development.

Key words: Homeopathy, Patient care indicators, Prescribing indicators, Reliability, Validity

INTRODUCTION

As medical practice has become more complex, the scope of the term "prescription" has been broadened to include clinical

outcome assessments, disease diagnosis, and reporting of investigations performed relevant to optimizing the safety or efficacy of medical treatment.^[1] In a prescription audit study, these parameters may be evaluated for their presence or absence; the

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number of absent parameters directly correlates to the inconsistencies in the prescriptions and raises medico-legal concern. The indicators may be used to measure the impact of the interventions undertaken and problems in performance. They can help health planners, managers, and researchers to make basic comparisons between healthcare and prescribing practices in different areas or at different time periods.^[2]

A preliminary version of the indicator instrument was developed which was pilot-tested and implemented on 600 samples as well.^[3] The instrument was modified further in this study. This study shall address formally the validity and reliability of this newly developed instrument, audit prescriptions, and intend to identify sub-optimal levels of prescribing and highlight target areas for improving the quality of prescribing and patient care practices.

MATERIALS AND METHODS

Setting and design

A cross-sectional, prospective, institutional, observational, prescription and record analysis study was conducted in January 2014 on 377 patients visiting different outpatient clinics of Mahesh Bhattacharyya Homeopathic Medical College and Hospital (MBHMC and H), Howrah, West Bengal, India.

Participation criteria

Inclusion criteria were patients 18 years and above, completing their physician's and pharmacist's consultation, giving written informed consent, and being ready to share their prescription information. Exclusion criteria were patients who were too sick for consultation, unable to read patient information sheets, unwilling to stay after the doctor's visit, and not giving consent to join the survey.

Sample size

The sample size was determined as 377 [margin of error 5%, confidence level 95%, population size 13,500 (monthly average patient turnover of the hospital in 2013), and response distribution estimated to be 50%.] Systematic sampling method was used for recruitment of the patients. Sampling fraction was estimated (and approximated) to be $5/6$ (n/N ; n = required sample size of 377; N = average number of out-patient patients every day, i.e. 450); 5 was decided as the sampling unit by simple random sampling, and thus every 5th patient was interviewed.

Study instrument

The prescribing indicators consisted of six items – a single item (single individualized medicine per encounter) provided with “yes”/“no” options and five items provided with a 5-point agreement Likert scale (strongly agree: 5; agree: 4; uncertain: 3; disagree: 2; strongly disagree: 1; does not apply: 0), which were proper record of case history and disease diagnosis, proper record of patient identification, good legibility of prescription, proper record of ongoing therapy (if any), and proper record of investigations (if any). There were five patient care indicators – drugs properly dispensed as per prescription, drugs adequately labeled, patient understands the directions given in prescription and has a

knowledge of correct dosage and follow-up, patient understands what to do in adverse events, and patients satisfied with the care they received – all ascribed with similar 5-point Likert scale to assess agreement. Agreement ratings were arrived at by a consensus among the six research assistants. Maximum obtainable score for prescribing indicators was either 26 or 16 and that of patient care indicators was 25.

Methodology

The audit involved documentation of current drug regimens and analysis of case notes. No identifiable information of the patients was required, ensuring anonymized protection of patient's privacy. The modified version of the instrument was pilot-tested on 10 randomly selected patients for length, clarity, language, relevance, overall adequacy, and whether the content reflected what it purports to assess. The instrument appeared to be satisfactory and ready for field-testing.

The study protocol was approved by the Institutional Ethics Committee of MBHMC and H. Patient information sheets were provided to the participants to achieve full cooperation. Though the survey did not intend to intervene anyway with the treatment being provided by the institutional doctors, written consent was obtained from all the participants. The survey matter was also explained verbally to all the participants by the research assistants. The filled-in questionnaires by the research assistants were concealed by putting those inside opaque envelopes, which were sealed at the survey site. All these were subjected to data analysis.

Statistical analysis

Different computational websites were used for the purpose. Descriptive analysis was presented in the form of absolute values, percentages, and mean values. *P* values less than 0.05 for a two-tailed test were considered as statistically significant. The instrument was tested for item-corrected total correlations (Pearson's *r*), internal consistency or reliability (Cronbach's alpha coefficient), and discriminant validity [by comparing the mean scores obtained by the different indicators of the instrument using one-way analysis of variance (ANOVA)].

RESULTS

Survey participants mostly spanned the age group of 41-55 years ($n = 132$, 35%). Most of the participants were females ($n = 220$, 58.4%), had a level of education of 10th-12th standard ($n = 163$, 43.2%), were urban residents ($n = 278$, 73.7%), married ($n = 231$, 61.3%), had a monthly family income of less than 10,000 Indian rupees (INR) ($n = 234$, 62.1%), and were dependent ($n = 160$, 42.4%). Self-reported health status was good in most of the respondents ($n = 136$, 36.1%), and rheumatologic complaints were the most frequently encountered conditions ($n = 57$, 15.1%) [Table 1].

Majority of the homeopathic encounters were individualized (97.4%), and record of patients' identification in the prescription (83.8%) was quite satisfactory. Legibility of the prescriptions was moderate (57%). Proper records of case history and disease diagnosis (46.7%), ongoing therapies (39%), and laboratory in-

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