4. METHODOLOGY

4.1 Study site: The study was conducted at seven different health care facilities near Anand town in Gujarat state of India using Prescription Quality Index (PQI) tool. They include four Primary Health Centers (PHC), two Secondary Health Center (SHC) facilities - one Community Health Center and one Civil Hospital and one Tertiary Health Center (THC).

Primary Health care facilities include primary health centers of villages Changa, Dabhov, Karamsad and Bandhani. Community health center at Mehlav and civil hospital at Petlad town of Anand district were included as secondary health care facilities. Shree Krishna Hospital affiliated to Pramukhswami Medical College at Karamsad was selected as Tertiary care health facility of Anand District in Gujarat state.

4.2 Study design: A cross sectional prospective multicentre study

4.3 Study Duration: April 2012 to June 2013- spread over 15 months

4.4 Pilot study: To test the suitability and feasibility of the study, a pilot study was conducted over 30 days at a primary health center. Total 18 prescriptions were collected and quality of prescribing was analyzed. Based on the experience of this preliminary study the design of the study and the case record form (CRF) were suitably modified and finalized. The final CRF, as depicted in Annexure 9.1 was used in study.

4.5 Study Population: Patients attending the outpatient department (OPD) of selected health care facilities-four Primary Health Centers (PHC), two Secondary Health Center (SHC) facilities - one Community Health Center and one Civil Hospital and one Tertiary Health Center (THC). Prescriptions of patients were collected and recorded as per study criteria.
4.6 Study criteria:
The following inclusion criteria were considered for selecting the suitable patients for the study.

4.6.1 Inclusion criteria: (For chronic illnesses)

- Patients of either sex and of all ages suffering from following chronic illnesses e.g. Hypertension and/or bronchial asthma with or without co-morbidities.
- Patients attending to outpatient department (OPD) for at least three months or longer at primary, secondary and tertiary health care facilities.
- Patients who consented for study.
- Consent given by parents or guardian attending the child.

4.6.2 Inclusion criteria: (For elderly)

- Patient of either sex and aged 65 years and above.
- Patients attending the outpatient department (OPD) for at least three months or longer at primary, secondary and tertiary health care facilities.
- Patient suffering from hypertension and/or bronchial asthma with or without co-morbidities.
- Patients who consented for study.

4.7 Ethical considerations

The study was approved by the Institutional Human Ethics Committee. Formal permission of Chief Medical Officer of each health centers was obtained. Each participant’s informed consent was obtained before collecting his/her data and any other relevant information.

4.8 Data Collection

Data was collected for a period of 4 weeks (Three days in a week) at each facility. After obtaining consent from the patient meeting inclusion criteria, his/her complete medical history was obtained by personal interview and other relevant information including prescription details was recorded in Case Record Form (Annexure 9.1). Compliance of patient for medicines was evaluated using patient’s self report. Total 66 prescriptions were collected from all PHCs; out of which, 51 prescriptions were of Hypertension and Asthma. Rests of the prescriptions were of other chronic conditions.
4.9 Data collection flow chart

![Data Collection Flow Chart]

Figure 2: Data Collection Flow Chart

4.10 Evaluation for PQI score

The quality of prescribing was evaluated using the Prescription Quality Index tool. The quality of prescription was examined using 22 criteria—indication, dosage, effectiveness, evidence-base, correct and practical administration, drug-drug interaction, drug-disease interaction, adverse drug reaction, unnecessary duplication, duration of therapy, cost minimization, use of generic name, selection from hospital drug list, compliance, medication name, legibility, prescriber’s name and information, patient information, diagnosis, requirement for drug therapy and patient’s improvement. Each criterion carried a specific maximum score depending on its importance (8).

Prescriptions may contain a single drug or multiple drugs. If prescriptions consisted of more than one drug, each drug was rated individually. Similarly, if patients suffered
from more than one disease, each disease state was rated separately. PQI manual obtained from Dr. Hassan, the corresponding author of the reference publication (8) was used as a guide for assessment of scores for each item. The minimum score was then selected for the PQI summation. If a drug was not indicated, criterion 1 was scored as ‘0’ (zero). Subsequently, criterion 2 (dosage), criterion 11 (duration) and criterion 12 (cost minimization) were all scored as ‘0’. The PQI total score was obtained by summing up all the minimum scores for the 22 criteria for all drugs in a prescription. The possible maximum score of the PQI was ‘43’. Prescription with the PQI total score of £31 was interpreted as poor quality, scores 32 and 33 as medium quality and scores 34 to 43 as high quality as described in PQI tool (8). Assessment form for the Prescription Quality Index is depicted as Annexure 9.2.

To evaluate different items in the questionnaire, standard references or publications were used. The primary references were PQI manual, pharmaceutical/pharmacological texts or credible medical journals or established online websites. Examples are A to Z Drug Facts (136), USPDI, Evidence Based Medical Reviews (EBMR), Martindale’s Complete Drug Reference (137), WHO essential drug list 2011(53), National list of Essential medicines of India 2011(73), National Formulary of India 2011 (138) British National Formulary (BNF) 2011 (139) and articles on Medline and Pub MED. For the cost of the therapy current issues of commercial sources like Current Index of Medical Specialties (CIMS) (140), Monthly Index of Medical Specialties (MIMS) (141) and Indian Drug Review (IDR) (142) were reviewed. Hospital formularies were used if available.

In this study, one additional parameter- use of Potentially Inappropriate Medicines was reviewed in elderly participants- those with age ≥65 years. I evaluated prescribing quality with PQI tool and reviewed use of potentially inappropriate medicines with the help of updated Beers Criteria (102) using a comprehensive, systematic review and grading of the evidence on drug-related problems and adverse drug events (ADEs) in older adults.

Potentially inappropriate medications (PIMs) continue to be prescribed and used as first-line treatment for the most vulnerable of older adults, despite evidence of poor outcomes from the use of PIMs in older adults. PIMs now form an integral part of policy and practice and are incorporated into several quality measures.
4.11 Statistical analyses
Data was analyzed using Statistical Package for Social Science 20. Descriptive statistics were used to describe the samples. Mean and standard deviation (SD) were used to describe numerical and variables and frequency (%) was used for categorical variables. Normality was checked using appropriate tests like Kolmogrov – Smirnov and Shapiro Wilks test. Non Parametric tests were applied due to skewed distribution of our data. To validate the PQI, item analysis and internal consistency were performed. Floor effects (percentage of prescriptions with minimum possible score) and ceiling effects (percentage of prescriptions with maximum possible score) were also assessed. Item analyses were performed to examine the relationship between the PQI scores and each criterion on the index. Factor analysis (143) was performed to explore common dimensions between the PQI criteria. P<0.05 was considered significant.