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# A Qualitative Study to Assess the Need of Home Medication Review to Improve the Quality of Life in General Population in a District Head Quarters

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#### **ABSTRACT**

**Objective:** Home Medication Review (HMR) is a structured and collaborative health care service provided to consumers in the community to ensure optimal use and understanding of medicine to promote its quality use and assist in continuity of care. The objective of the study was to assess the need of HMR in preventing adverse events and improvement in medication adherence.

**Study Design:** A community based observational study was carried out for a period of 6 months to assess the need of HMR with the help of NO TEARS tool by World Health Organization (WHO) which assess the need, indication and adverse events related with the therapy which was given to the patient.

**Method:** Subjects above 18 years and able to understand English/ Hindi/ Kannada/ Malayalam and living in Mangalore Taluk were included for the study. After obtaining the information, HMR was provided including counselling, life style modification, intervention on Drug Therapy Problems (DTPs) and the importance of adherence. They were requested to consult their physicians for taking appropriate measures for the same. After 2 months, follow-up was done and analysed whether any DTPs are still prevailing and what the benefit was after providing HMR, whether the adherence were improved or not or they have modified their lifestyle.

**Result:** Among 135 subjects, 74 DTPs including drug interaction 43.24%, inappropriate drug therapy 29.72% and Adverse Drug Reaction (ADR) with 27.02% were found. Among the 74 DTPs identified, 50(67.56%) were accepted by the physician and appropriate decisions were made. Considering adherence, initially 28 subjects were not adherent to the therapy. After providing HMR, 75% improvement in adherence was found.

**Conclusion:** Hence it clearly shows that pharmacists led medication reviews could reduce the adverse events as well as improve the adherence.

**Keywords:** Home medication review, Patient safety, Drug therapy problems, Medication adherence.

- Importance of Home Medication Review in public population.
- Effectiveness in monitoring Drug Therapy Problems by Pharmacist.
- Attitude of Physicians towards the interventions made by the Pharmacist.
- Effectiveness of Patient counselling as well as HMR by Pharmacist.

### **INTRODUCTION**

Home Medicines Review (HMR) also known as Domiciliary Medication Management Review is a patient oriented, scrupulous and collaborative health care service which is provided to the consumers in the community to ensure that their medicine use is optimal and fully understood as well as to promote quality use of medicines<sup>1</sup>. The HMR was introduced

into the Medical Benefits Scheme (MBS) (item 900) in October 2001 as support for the National Medicines Policy 2000 in Australia<sup>2</sup>. The aims of HMR are to improve health outcomes for consumers and to promote the quality use of medicines. These aims are best achieved through the collaboration between all health care providers involved in the service and the consumers. The HMR should be conducted in the consumer's home by an accredited pharmacist<sup>3</sup>. HMR process is capable of accessing wide range of potential drug related problems in the community and also maximize an individual patient's benefited from his/her medication regimen<sup>1</sup>. All pharmacists involved in the HMR service should collaborate with all members in the HMR service including consumers, community pharmacists, General practitioners (GPs), medical specialists, practice nurses, community health workers, allied health professionals, carers and family member<sup>3</sup>.

There are many reasons why a consumer may be identified for an HMR based on their clinical need. Some examples include:

- Taking more than five regular medicines, 12 doses of medicine per day or being treated for three medical conditions;
- Discharged from hospital in last four weeks;
- Significant changes to their medication regimen in past 3 months;;
- Taking a medicine with narrow therapeutic index or requiring therapeutic drug monitoring;
- Symptoms suggestive of adverse drug reaction (ADR);
- Sub-therapeutic response to treatment;
- Suspected non-compliance/problems managing medication-related therapeutic devices<sup>3</sup>.

The type and range of information gathered should include:

- Demographic and/or personal information (e.g. consumer name, Medicare/concession details, address, date of birth, gender, weight, height, body mass index);
- Relevant social history (e.g. previous occupation, lifestyle, cultural factors, family and/or social support systems, attitudes to health, illness and treatment, understanding general situation, health status, expectations); medical history (surgical and/or specialist history, current conditions or co-morbidities, pathology and/or radiology investigations and results determining renal, hepatic and cardiovascular function and allergies,
- Previous adverse drug reactions, nicotine, alcohol and caffeine consumption;
- Consumer assessment (status regarding vision, hearing, falls risk, balance, cognition, memory, mood, gait, mobility and dexterity, psychological status)<sup>3</sup>.

In 2011, changes to the HMR program were introduced to allow for referrals directly to accredited pharmacists in addition to the community pharmacy model. These changes were introduced to improve efficiency of the process<sup>4</sup>. Studies indicate that drug reviews conducted by clinical pharmacists identification valuable for the of prescription alterations in the community<sup>5</sup>. Inappropriate medication use community and institutional settings has been reported to be a common continuing problem, particularly in patients taking multiple medications. One means of addressing inappropriate medication use is to conduct medication reviews and related interventions as part of multidisciplinary team process<sup>6</sup>. HMR for the older people will reduce the medicine related problems through continuous monitoring of patient's health status<sup>7</sup>. The pharmacy profession has significantly improved in the past years in the professional services delivered and now has been accepted as a significant profession Anika A et.al. A qualitative study to assess the need of home medication review to improve the quality of life in general population in a district head quarters.

in the multidimensional provision of healthcare<sup>8</sup>.

#### **METHODS**

**Study Design:** A community based observational study to assess the need of HMR with the help of NO TEARS tool by WHO.

**Study Site:** The study was conducted in the community of Mangalore Taluk (Jeppu and Valencia).

**Study Duration:** Study was conducted for duration of 6 months from September 2018 to February 2019.

**Sample Size:** The study was limited for a sample of 135 along with their follow-up based on the time schedule allotted for the project including other circumstances.

**Ethical Clearance:** The study protocol was approved by the Institutional Ethics Committee (IEC) of Srinivas Institute of Medical Science and Research Centre (SIMS & RC), Mukka, Mangaluru. (Ref. No: EC/0014/18-19)

#### **Study Criteria:**

Inclusion criteria: Patients selected were both sex above 18 years of age and able to understand English/ Hindi/ Kannada/ Malayalam and living in Mangalore Taluk.

Exclusion criteria: Patients who are less than 18 years of age and unable to understand English/ Hindi/ Kannada/ Malayalam and/ or not living in Mangalore Taluk.

**Source of Data:** Data were collected from the study population during our visit to their homes. Validated questionnaire were filled by 135 subjects.

### STUDY METHOD

Preparation of Inform Consent Form: Inform consent was already preoccupied (English) in the questionnaire by NO TEARS tool. Before getting the consent of the subjects, the consent form was orally explained to the subject or their caregiver in their own language and made them understood. Only those participants who fill the Informed Consent Form were included for the study.

Data Collection: Data were collected using NO TEARS tool with the help of medical reports, prescriptions and discharge summary from the patients or their caregiver. Data collected include patient name, age, gender, social history, previous vaccination, screenings done, past and current medical condition and treatment regimen, Over the Counter (OTC) medications. adverse drug reactions. medication adherence as well as other dug related problems. The data collected were analysed for the drug related adverse events based on WHO probability scale. The results were obtained after completing the analysis with the help of Microsoft excel and SPSS software. All the data were kept confidential.

Data Analysis: All the data were entered in IBM-SPSS data sheets and results were analysed using the SPSS version 20.0, for descriptive statistical analysis.

### **Operational Modality**

The study protocol was submitted to the Ethical Committee of SIMS & RC. After obtaining the Ethical Committee approval, community visits were carried out in the areas of Jeppu and Valencia. Visit was done in individual's house. At first self introduction and objectives of the project were explained to the subject or their care-giver. Later the inclusion and exclusion criteria were analyzed. If the criteria were satisfied they were ensured that the information provided by them will be highly confidential. If they agreed, their consent was obtained. They were interviewed regarding their medical conditions as well as the medications they were taking. By considering these aspects HMR was provided which included patient monitoring counselling, **DTPs** importance of medication adherence. All the data were analysed and intervention was provided. They were asked to re-visit their

physician with respect to the intervention provided. After 2 months, follow-up was done in which improvement of medication adherence and reduction of DTP were assessed. Those subjects who were not willing to sign the consent and those who did not meet the criteria were excluded from the study.

## RESULTS

# DEMOGRAPHIC DETAILS OF THE STUDY POPULATION

A total of 135 subjects were enrolled in the study. From the collected data it was observed that 68 (50.4%) were male and 67 (49.6%) were female. The subjects enrolled for the study were above 18 years of age. Among the observed data, predominance were seen in the age group of 41-60 years with 61 (45.2%) subjects, while 56 (41.5%) subjects were of 61-80 years, 8 (5.9%) subjects were of 26-40 years, 5 (3.7%) subjects were of both 18-20 and more than 80 years.

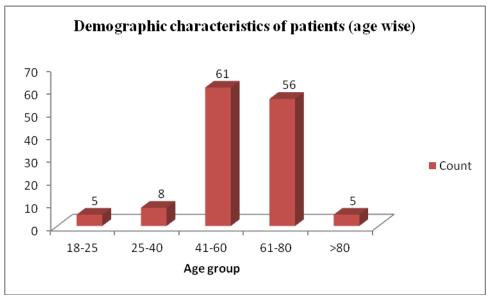


Figure 1: Demographic Characteristics (Age Wise)

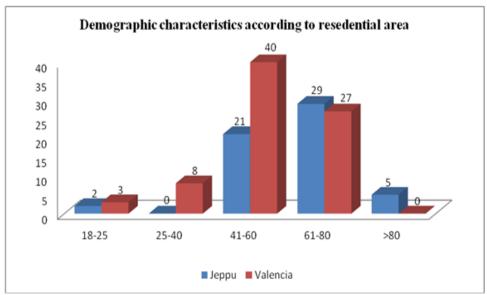


Figure 2: Demographic Characteristics According to Residential Areas

# DISTRIBUTION OF BMI IN AGE GROUP

Out of 135 subjects, 64 were found to be overweight. The highest number of subjects in overweight category belonged to 61-80 years accounting for 31 (48.4%) subjects and the least were in the age group

above 80 years accounting for 2 (3.1%) subjects. It was also found out that only 1 subject was found to be underweight in the age group of 41-60 years. One of the major risk factor for HTN and DM is overweight and all the subjects with lifestyle disease were found to be overweight.

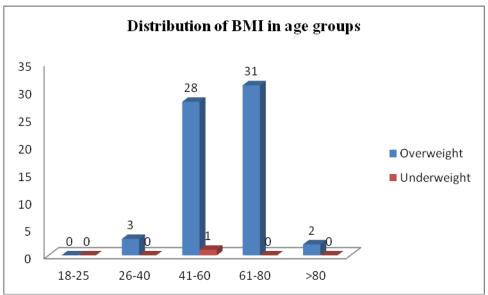


Figure 3: Distribution of BMI in Age Groups

# DISTRIBUTION OF DISEASE CONDITION Vs AREA

The most predominant disease conditions were found to be Hypertension and Diabetes Mellitus in both the areas of Jeppu and Valencia followed by Kidney disease, Ischemic Heart Disease and Bronchial Asthma. Without any lifestyle modifications or the revisit to their physicians they were continuing their old medications. Most of the subjects were unaware about the adverse reactions caused by their medications.

Table 1: Distribution of Disease Condition Vs Area

Disease	Place	
	Jeppu	Valencia
Hypertension	39	55
Diabetes Mellitus	40	45
Kidney Disease	11	21
Ischemic Heart Disease	11	10
Hyperlipidemia	9	3
Chronic Kidney Disease	7	15
COPD	6	2
Stroke	4	2
Bronchial asthma	3	11
AKI	2	6
LRTI	0	5
Liddle's syndrome	0	3

# DISRTIBUTON OF DISEASE CONDITION Vs AGE

In the current study, a total of 23 medical conditions were found among 135 participants in the study. Among these 10 lifestyle diseases including were Hypertension, Type 2 Diabetes Mellitus, Liver disease, Cardio-vascular complications and Respiratory diseases which can further lead to chronic conditions if not controlled. In this study, the most prevalent health conditions were found to be Hypertension which constituted 26% (94) of total disease count, Type 2 Diabetes Mellitus constituting 24%.(85), Kidney disease constituting 17% (62), while 10% were constituted by other Cardiovascular complications. Considering the geriatric population (above 60 years), Hypertension and Diabetes Mellitus were the most prevalent diseases.

Table 2: Distribution of Disease Condition Vs Age

Disease	Count					
Disease	18-25	26-40	41-60	61-80	>80	Total
Kidney Disease	0	0	16	16	0	32
Liver Disease	0	1	0	0	0	1
Hypertension	0	1	50	38	5	94
Diabetes Mellitus	2	3	44	31	5	85
Bronchial Asthma	0	2	5	6	1	14
Hyperlipidemia	0	0	5	7	0	12
Chronic Obstructive Pulmonary Disease	0	0	6	2	0	8
Ischemic Heart Disease	0	0	6	12	3	21
Chronic Kidney Disease	0	0	16	6	0	22
Stroke	0	0	5	2	0	7
Hypokalemia	0	0	9	1	0	10
Congestive Cardiac Failure	0	0	0	2	0	2
Anaemia	1	1	2	3	0	7
Gastritis	0	0	4	6	0	10
Urinary Tract Infection	0	0	0	2	0	2
Acute Kidney Injury	0	0	1	7	0	8
Hyponatremia	0	0	0	2	0	2
Pedal oedema	0	0	6	2	0	8
Breathlessness	1	0	0	3	0	4
Liddle's Syndrome	0	0	3	0	0	3
Alzheimer's Disease	0	0	2	1	0	3
Coronary Artery Disease	0	0	0	1	0	1
Lower Respiratory Tract Infection	0	1	1	3	0	5

## IMPROVEMENT OF NON ADHERENCE AFTER HMR VISIT

Table 3: Improvement of Non Adherence after HMR Visit

Age	Number of subjects			
	Non adherence	Improvement in		
	before HMR	adherence after HMR		
18-25	2	1		
26-40	0	0		
41-60	12	10		
61-80	14	11		
>80	4	2		
Total	32	24		

An improvement in number of skipped medicines were seen in the age group of 61-80 years accounting for 11 (45.8%) subjects, 10 (41.7%) subjects improved their adherence in the age group of 41-60 years, while 2 (8.3%) subjects improved their adherence in the age group above 80 years and only 1 (4.2%) subject improved adherence in the age group of 18-25 years. 75% improvement in the

medication adherence were found after providing HMR.

# EFFECT OF HMR ON TREATMENT INTERVENTION

While analyzing the data, it was observed that after follow up some medications had been stopped for some patients according to the improvement of their disease or some other reasons. In 11 subjects medications were stopped after follow-up. For 10 (7.4%) subjects only a single drug was stopped. Among them more number of people belonged to the age group of 61-80 (50%) years, then in 41-60 (40%) years and the least was seen in the age group of 18-25 (10%). The most common stopped medications include those like antibiotics, proton pump inhibitors and pain killers.

**Table 4: Effect of HMR on Treatment Intervention** 

Age Number of Medicine stopped after follow-up								
	0		1		2		Total	
	Count	N%	Count	N%	Count	N%	Count	N%
18-25	4	3.2%	1	10.0%	0	0.0%	5	3.7%
26-40	7	5.6%	0	0.0%	1	100.0%	8	5.9%
41-60	57	46.0%	4	40.0%	0	0.0%	61	45.2%
61-80	51	41.1%	5	50.0%	0	0.0%	56	41.5%
>80	5	4.0%	0	0.0%	0	0.0%	5	3.7%
Total (N)	124	100.0%	10	100.0%	1	100.0%	135	100.0%

# TYPE OF DRUG THERAPY PROBLEM

Among 135 subjects, 74 had drug therapy problems (DTPs) including drug interaction which accounted for (43.24%),inappropriate drug therapy including 22 (29.72%) and ADR with 20 (27.02%). Among the 74 DTPs found, 50 (67.56%) were accepted by the 3physician and appropriate decision was made. Among 74 drug therapy problems identified, 34 were found in geriatrics population above 60 years, in which 8 accounted for ADR, 18 were drug interaction and 8 inappropriate drug therapy. This clearly shows that there is a positive attitude of physician towards the interventions made by the pharmacist. One of the common ADR found during the study was Calcium Channel Blockers (CCBs) induced pedal oedema.

Table 5: Type of Drug Therapy problem

Type of DTP	Category	Total	
	Accepted	Not Accepted	
ADR	8	12	20
Drug interaction	24	8	32
Inappropriate drug therapy	18	4	22
Total	50	24	74

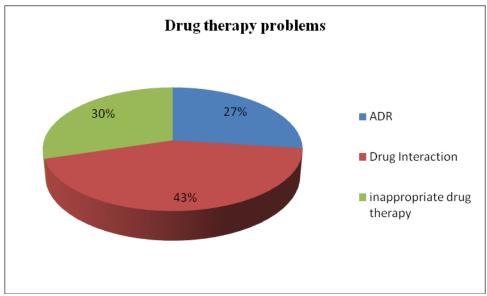


Figure 4: Type of Drug Therapy Problems

### DRUG COST REDUCTION

Cost analysis was carried out for the entire drugs which were recorded during the survey and a significant reduction of cost was found. Up to 20% cost reduction was seen in 65 drugs while more than 80% reduction was seen with 55 drugs.

**Table 6: Drug Cost Reduction** 

Percentage cost reduction category	Number of drugs	Percentage of drug cost reduction
0-20%	65	27.31%
21-40%	33	13.86%
41-60%	36	15.12%
61-80%	49	20.59%
81-100%	55	25.11%

### **DISCUSSION**

In the current scenario the importance of Home Medication Review (HMR) can be assessed by the increasing drug related issues among the patient of vulnerable population, patient with chronic illness and patient on poly-pharmacy. HMR

can assess a patient's use of medicines to promote its qualitative use and lead to reduction in drug-related problems like adverse drug effects (ADEs) or drug interactions. The present study was done in a population of 135 subjects in which 50.4% were male and 49.6% were female. In the

total population 45.1% accounts for geriatric population. Among the 135 subjects 6 were not taking any kind of medication.

After visiting the homes of 135 subjects, 74 drug therapy problems were identified. These problems varied in clinical significance, in which 43.24% accounted for drug interaction, 29.72% accounted for inappropriate drug therapy and 27.02% of adverse drug reaction. HMR programs are emerging as one of the extended roles of community pharmacists in developed countries such as Australia, the USA, Canada, and various European countries<sup>9</sup>. Unfortunately, such programs have not been launched in most developing countries, such as India, for diverse reasons including the reluctance of general practitioners to follow recommendations made by pharmacists, a lack of awareness regarding HMR services among the public, patients' conflicts of interest and privacy issues that affect their willingness to disclose their disease status and medication use, and linguistic and cultural diversity<sup>10</sup>. The current study implies the importance of pharmacist role in reducing the DTPs as well as improving the compliance towards their medication.

The study by Elaine Lau et al., found that the mean number of drug-related problems (DRPs) identified per patient was 3.2 and the mean number recommendations made per patient was 3.3. The most common DRP identified during the home visit was not taking a prescribed drug appropriately (35.2%, range 4.7– 49.3%). The most common recommendations made involved patient education (37.2%,range 4.6–48.2%). Implementation rates were generally high for all types of recommendations, with the highest being for provision of patient education  $(81.6\%)^{11}$ .

Our study is also supported by the study done by Stafford A C *et al.*, reveals the ability of the pharmacist to identify the drug related problems with the help of medication review. From 234 medication reviews done, a total of 1038 DTPs were identified. The study was carried out in both

home dwelling patients and care facility patients. **DTPs** related to oral hypoglycaemic antipyretics/ agents. analgesics were significantly associated with home dwelling patients<sup>12</sup>. In our study DTPs were identified in the first visit and gave counselling for the same. During the second visit it was noticed that there were reduction in the number of DTPs that were identified in the first visit.

This study is also supported by the study done by John Papastergiou et al. in the home bound patients among Ontario residents in Canada, which implicate that in 43 home visits done by pharmacist out of which 41 subjects involved patient more than 65 years or older who were taking a mean of 11.7 (range, 3-23) medications. Pharmacists identified a total of 62 drug therapy problems, like medications being incorrectly transferred into pill vials, patients decreasing doses or discontinuing prescribed medications without the physician's approval and patients knowing the reasons that they were on certain drugs. Patient confusion commonly implicated as the underlying cause for drug therapy problems and nonadherence. The top 3 types of problems identified were noncompliance (40.3%), (20.9%)adverse drug reactions additional therapy required (19.4%)<sup>3</sup>. While analyzing the current study it was found that the main drug therapy problems identified were adverse drug reaction (27.02%), drug interaction (43.24%) and inappropriate drug therapy (29.72%).

Sorensen L et al., conducted a study on medication review in the community and the results showed that there was a high level of satisfaction among the participants. Even though the study and follow up was carried out within a short period of time evidence of medication there were misadventure risk reduction and a trend towards positive patient outcomes<sup>6</sup>. In this study follow up was carried out 2 months after the first visit. During the follow up there was a reduction in the DTPs that were identified during the first visit.

The study done by Amrith Kaur Dhillon et al., showed that most GPs had positive attitude towards the HMR service. Main perceived benefits of the service were poly-pharmacy reduction and education for both the GPs and patient. A number of participants stressed that HMR improved pharmaceutical knowledge, their commenting that after receiving HMR report they were more informed about OTC and prescription medication. Participants highlighted that HMR provided insight into potentially harmful combinations medicines that patients take without GPs' knowledge. This allowed for concerns regarding potentially harmful combinations to be addressed. Additionally, issues pertaining to duplication of therapy due to generic substitution were also addressed<sup>4</sup>. In the present study, during the follow up it was found that interventions or suggestions given for the drug related problem were significantly accepted by the patients and physicians. We found that interventions or suggestions for 8 among the 20 adverse drug reaction, 24 among 32 interaction, 18 among the 22 inappropriate drug therapy were accepted and implemented by the general physician or treating doctors. This shows 67.5% of the suggestions made after HMR visits were implemented by the physician. This implies a positive attitude of most of the physicians towards HMR.

The study done by Basheti et al., to assess the prevalence of DTPs and their types among chronic disease patients as well as geriatric population demonstrated the importance of role of pharmacist in identifying DTPs in Jordanian outpatients with chronic diseases mainly in geriatric population visiting community pharmacies. The mean number of chronic disease conditions and number of medications per patient were found to be 4.1  $\pm$  1.7 and 8.1  $\pm$ 2.7, respectively. The mean number of DTPs identified per patient through the HMR was  $7.4 \pm 2.8$ ; Among the DTPs identified, 125 (74.9%) were incomplete drug therapy problems, 114 (68.3%) were untreated conditions, 101 (60.5%) were

non-adherence to non-pharmacological therapy, 84 (50.3%) were inappropriate dosage regimens, 40 (23.9%) were adverse drug effects, and the fewest were potential drug interactions<sup>13</sup>. In this study 72 DTPs were found. Among them 34 were found in the geriatric population which constituted 45% of the total population participated in the study. Study carried out by Willis J et al., implicated that for the elder population the need of HMR is very important to reduce major drug interactions. the duplication in therapy and other adverse drug events<sup>14</sup>. In this current study after conducting HMR, DTPs were identified and the subjects reported the same to their respective physicians and appropriate measures were taken for the same. Thus it shows HMR is an excellent work to increase the quality of life as well as to improve overall health care for elderly patients.

Shilpa Palaksha et al., conducted a study on the impact of HMR services on medication adherence in geriatrics and found out that a statistically significant overall increase in medication adherence was observed in the patients enrolled in the study (in the first follow up only 4.6% adherence was seen but in the second and third follow up it got increased to 7.24% and 7.83% respectively)<sup>15</sup>. This clearly showed that the pharmacist-led HMR service approach was better in increasing the medication adherence, which can be correlated with the present study, which implicates a significant improvement in medication adherence among the patients and a positive attitude of public towards home medication review.

Castelino RL et al., conducted a Retrospective evaluation of home medicines review by pharmacists in older Australian patients using the Medication Appropriateness Index (MAI) and found that the number of patients with a cumulative medication adherence score ≤ 15 increased to 216 after the HMR service, compared to 116 at baseline. Pharmacists' recommendations documented in the HMR reports and uptake of these recommendations by the GP resulted in a statistically significant decrease in the MAI scores. The study demonstrates that the provision of medication reviews accredited pharmacists can improve the appropriateness prescribing of demonstrated by the change in Medication Appropriateness Index score and hence, has the potential to improve patient outcomes <sup>16</sup>. The current study also shows improvement in the medication adherence.

According to the study by Hassan SS et al., pharmacist-led medication reviews confirm many benefits such as attainment of biomarker targets for improved clinical outcomes, and other clinical parameters, as well as depict concrete financial advantages in terms of decrement in total medication costs and associated cost saving<sup>17</sup>. This study can be positively correlated with the present study, in which HMR contributes for a significant reduction in cost of the drugs which are recorded during the survey. Up to 20% cost reduction was seen in 65 drugs while more than 80% reduction was seen with 55 drugs, and can be attributed to the cost effective treatment plan.

Srinivas B et al., conducted a study on Betterment of Patient to Get Optimal Health Outcomes through Home Medicines Review and found that HMR has emerged as an important tool of pharmacist to provide pharmaceutical care of the patient. HMR improves rational use of medicines improves patient healthcare and also outcomes. HMR has not yet been implemented in India, but efforts can be taken up to bring up HMR in India. It is possible when pharmaceutical industry appoints pharmacist as HMR specialist or government of India can implement rules or guidelines for bringing up HMR in India<sup>1</sup>. This study clearly shows that HMR is an inevitable tool for improving the pharmacotherapy issues as well medication adherence of the patient and it can be established world-wide to enhance the health care of the public.

#### **CONCLUSION**

The Home Medication Review was successfully done with participants reporting moderately high levels satisfaction. Even in the relatively short period of follow-up, there was evidence of risk reduction and a trend towards positive patient outcomes. During the study it was found that more number of patients was satisfied with the need of reviewing their medications at home, considering the number of medications and co-morbidities present. Pharmacists are among the most accessible front-line primary practitioners and are well positioned to affect the care of homebound patients. Pharmacist-directed Home Medication Reviews offer an effective mechanism to address the pharmacotherapy issues of those members of the community who are most in need but may otherwise lack access to general pharmacy services. As the population ages, the demand for such services will undoubtedly increase. Pharmacist-directed home medication reviews could serve to minimize inappropriate use of medication, maximize health care cost savings and expand the scope of pharmacy practice. By that, we can improve total health outcome of the patients.

#### **Authors' Statement**

Ethical approval was obtained from Srinivas Institute of Medical Science and Research Centre (SIMS & RC), Mukka, Mangaluru, Karnataka, India (Ref. No: EC/0014/18-19). There is no funding source and competing interest.

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