9. Summary

The pharmacy practice is getting popular out of need in developed and developing countries. The current practice comprises of involvement of pharmacist in the therapeutics delivery in collaboration with doctors and nurses. The pharmaceutical care is delivered to patients in clinical, ambulatory and community settings. The model suggested by WHO – FIP seems to be appropriate for initiation in an existing healthcare system in India. This program comprises of evaluation of prescriptions and patients perceptions and practices in knowledge domains of drug, disease and lifestyle. Here, after receiving a prescription by doctors, Pharmacist interacts with the patient / patient party to learn and integrate the knowledge into practice model, customized to individual patient. Here, one to one interaction is the key factor which is supposed to bring in the possible lapses and mistakes which can be resolved by disease management approach. In our study, we have worked on patients who were treated for myocardial infarction in a tertiary care hospital, in collaboration with cardiologists and specialist nurses. The gap of service was adequately filled up by pharmacy practice.

The outcome of pharmaceutical care, need to be measured and establish its value in the existing healthcare delivery. Our study, has explored the ECHO model of health care delivery in which the economical, clinical and humanistic outcomes are compared in a RCT model. The ECHO model is an established model for comprehensive evaluations simultaneously of diverse outcomes. The outcomes are in terms of monetary benefits achievable, clinical superiority and the patient satisfaction. The control group received standard care without pharmaceutical care where as interventional group received the pharmaceutical care. PC comprised of patient education in areas of drug, disease and lifestyle. Patient education comprised of counseling regarding how to store and use medicines, observe and alert for any signals and symptoms of disease, healthy life style.
importance in the management of disease, importance of follow ups in identifying the
disease conditions.

The economic outcome are measured by Quality Adjusted Life Years, Clinical outcomes
are measured by lipid profile, body mass index and hospital readmissions and fasting
blood sugar for diabetic patients. Humanistic outcomes measured by quality of life
instruments - EQ 5D 5L (generic) and MacNew (disease specific).

9.1 Study highlights

In our study, we have a sample size of 105 patients in control group, and 108 patients in
intervention group. The patients were evaluated for 12 months at an interval of every 3
months. Repeated measures ANOVA and paired t test were applied to establish statistical
significance. Human ethics committee approval was obtained at the beginning of study by
Manipal University Ethics Committee. (UESC/11/2011 dated 27/01/2011) The study is
applied for registration in clinical trials registry of India, pending approval (CTRI-
2014/03/006557). All the patients in both groups were requested to participate by
obtaining the informed consent form.

During the study period, 2 persons were dead in control group and 7 people were unable
to trace. Whereas, 1 person was dead in intervention group and 5 people were unable to
trace. Hence, the final participants in control group were 96 and 102 in intervention
group. Attrition rate in our study is 8.57% and 5.55% for control and intervention groups
respectively.

Global Scores of MacNew questionnaire were calculated at different time intervals by
repeated measures ANOVA method. At baseline, both the groups have similar scores
(3.03 ± 1.29 & 2.89 ±1.12). Changes were observed during 9 months follow up was 2.58
± 1.14 and 5.54 ± 1.42 for control and intervention group respectively. At the end of the
study period (12 months), global score was 2.32 ± 0.91 and 5.47 ± 1.45 for control and intervention group respectively which is very significant (p<0.001).

EQ visual Analog Scale score at different time intervals were calculated by repeated measures ANOVA. At baseline, the VAS score was 59.97 ± 14.51 and 61.01 ± 13.3 for control and intervention group respectively. At the end of the study period (12 months), scores of 73.38 ± 5.19 and 85.13 ± 4.62 recorded for control and intervention group respectively which signifies the impact of pharmaceutical care (p<0.001).

EQ Utility values were calculated by repeated measures ANOVA method. The Utility values at baseline were similar (0.46 ± 0.17 and 0.47 ± 0.16). At 3rd follow up, 0.139 ± 0.25 and 0.72 ± 0.19 were observed for both control and intervention group respectively. At the end of the study period, the values were 0.11 ± 0.20 and 0.68 ± 0.23 for control and intervention group respectively.

In the present study, Death from cardiac problem was observed in one patient in Intervention Group (IG) and two patients in Control Group (CG). One patient underwent CABG in IG due to progression into triple vessel disease and one patient in CG underwent CABG due to in-stent Re-stenosis. One Patient in each group had chest pain due to in stent re-stenosis and advised PCI. Hospital readmissions due to non cardiac problems are – Inguinal hernia was documented in IG and weakness and fatigability, Iron deficiency anemia, and road traffic accident was documented in CG.

Mean difference of Total Cholesterol in IG, **36.93** is higher than **16.95** of CG. Mean differences of HDL value in IG and CG are **-6.14** and **-4.62** respectively. Paired mean differences of LDL value in IG and CG are **24.43** and **14** respectively. Paired mean differences of Triglycerides values in IG and CG are **21.46** and **3.08** respectively. Hence, we can conclude that, even the changes were occurred at CG which is due to drugs, which the participants were consumed. However, the changes were more prominent in IG,
which is due to along with drugs, pharmaceutical care was provided. Hence, we can conclude that, even the changes were occurred at CG which is due to drugs, which the participants were consumed. However, the changes were more prominent in IG, which is due to along with drugs; pharmaceutical care was provided by RP.

We have evaluated the Fasting Blood Sugar (FBS) values of the Diabetes Mellitus patients in both the groups. In the CG, mean FBS values are 187.09 ± 54.61 mg/dl and 154.51 ± 38.73 mg/dl at baseline and at 12 months respectively with the paired mean differences of 32.57 mg/dl (p<0.05). In the IG, mean FBS values are 175.64 ± 49.41 mg/dl and 132.80 ± 20.28 mg/dl at baseline and at 12 months respectively with the paired mean difference of 42.83 mg/dl (p<0.001).

In the CG, mean BMI was 23.69 ± 3.87 kg/m² at Baseline and 24.17 ± 3.87 kg/m² at 12 months follow up was recorded with the paired mean difference of -0.486 kg/m². This indicates that, BMI has increased in the CG. In the IG, mean BMI was 24.94 ± 3.63 kg/m² at baseline and 22.84 kg/m² at 12 months with the paired mean difference of 2.10 kg/m². It signifies that, pharmaceutical care provided by RP has shown reduction in the BMI which is very much essential parameter of the clinical outcome.

We calculated the QALY; 0.7114 and 0.8582 were for control and intervention groups respectively at the end of study period (12 months).Incremental QALY 0.1468 was observed in favour of IG. Hence, we can conclude that, Pharmaceutical care intervention had an incremental cost effectiveness ratio of Rs. 5,688.21 per QALY gained when compared with standard care.

9.2 Conclusion
Pharmaceutical care provided by trained pharmacist will improve and stabilize the quality of life of the participants, improves the medication adherence which results into improved lipid profile parameters, decrease in body mass index and fasting blood sugars values in
Summary

118 diabetics. However, there was no significant changes were observed in mortality rates and hospital re admission rates between the groups. Quality adjusted life years were significantly higher and with an additional cost of ` 5,688/- will provide a gain of a QALY which would surely help to consolidate the position of pharmacist in healthcare system. This study emphasized the fact; pharmaceutical care provides the holistic approach to manage the patients who underwent angioplasty procedure, will improve the overall economical, clinical and humanistic outcomes. We hope this type of pharmaceutical care model will be implemented in India in larger scale, which will surely catches the attention of policy makers and different stake holders and make the provision of pharmaceutical care by pharmacist mandatory by law.

9.3 Future prospective

The pharmaceutical care has been established to be effective in clinical, economic and humanistic outcomes in Indian settings. The trained, skilled pharmacists are available in India as post graduates of pharmacy practice, Pharm. D and Pharm. D (post Baccalaureate). The time is ripe to introduce the pharmaceutical care services to improve the therapeutic outcomes and patient centric healthcare. This would act as a preventive healthcare approach as many patients with chronic conditions are reporting to hospital in critical conditions of diabetes, hypertension and cardiovascular diseases which are preventable. The cost of service is mainly for intellectual inputs of pharmacy knowledge by a trained, skilled pharmacist. However, there will be positive increments in reductions of cost by lesser admissions to hospitals, saving on costs due to adherence and rational use of drugs.
9.4 Limitations of the study

This randomized control trial was designed and implemented to improve the overall outcomes of the study participants. Since the study period was 12 months, we could not be able to assess the long term outcomes and complications. We are unable to perform economic outcomes from society and payer perspective due to difficulty in getting the indirect costs like patient attendee cost, traveling cost of patient parties etc., as family members and many relatives will come and meet the patient during the crisis period of myocardial infarction. We faced the problem of getting the information of smaller ailment, which they may consult, locally available physicians. We could not be able to perform the sensitivity analysis of economic analysis, because of non availability of resource person who could guide on this parameter. We are unable to evaluate the Glycolated hemoglobin values for the diabetic patients in the follow up visits due to high cost of the test.