CHAPTER III

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Plan and Design

The major objective of this study was to find out the impact of Health Communication between the doctors and the patients with primary HTN on their Adherence and Prognosis of the disease.

To meet this objective the study was planned in two phases. In Phase I the Quality of Health Communication was measured based on the initial doctor-patient communication during the consultation. Therapeutic Adherence of the patients with primary HTN was also measured during consultation. In addition to this BP readings were also recorded as baseline for evaluation of Prognosis. Six weeks after the first phase, the patients visited the doctors for review. Phase II of the study was this consultation. During Phase II the patients were assessed by the doctors on prognosis based on the reported clinical symptoms (as reported by patients). BP readings were also recorded during this phase. Thus, while Phase I of the study involved assessment of Quality of Communication, Phase II consisted of evaluation of Prognosis.

The study primarily adopted correlational design involving Quality of Communication as predictor of Adherence and Prognosis. Then, Adherence was also taken as predictor of Prognosis. The study also included between-subjects design to find out the effect of Quality of Communication (High, Medium and Low) on the level of Adherence, Prognosis (as measured by doctors’ ratings) in patients with primary HTN, and also to determine the effect of level of Adherence (High, Medium and Low) on prognosis. In addition to this a 3X2 Simple Mixed Factorial design was
adopted to find out the effect of Quality of Communication (between-subjects) on Prognosis by studying the difference in BP readings between the pre and post Adherence Phase. The same design was adopted to study the effect of level of Adherence (High, Medium and Low) on Prognosis measured by BP readings.

In the present study, Health Communication i.e. the communication between the doctor and patient has been defined as the explanation from the doctor about the present condition of the patient vis-à-vis the norm, need and schedule of medication, diet and exercise, hazards of not following them, follow-up schedule and the alarm signals warranting the patient to visit the doctor, and the patient’s extent of comprehension of the same. The match between the doctor’s explanation and the patient’s comprehension determined the Quality of Communication.

Patient Adherence has been operationally defined as the regularity, with which the patient takes the prescribed medication, sticks to the restrictions of diet and duration and type of exercise and the punctuality with which the review visits to the doctor are made.

Prognosis was operationally defined as the relative condition of the patient compared to that of pre-Adherence Phase in terms of BP readings and doctor’s ratings on the reported clinical symptoms such as palpitation, breathlessness, headaches, heaviness in the head, swelling in the foot and free urination, etc.

Participants

The sample for this study was initially organized as 30 nests. By applying survey method, 30 groups were taken into the study, each group consisting of one doctor and 10 patients with primary HTN. The term ‘nest’ implies that each group is a
unit where the ten patients were attended by a single doctor who is expected to cater to their health needs.

Sampling of hospitals, doctors and the patients were done in multiple stages. The first unit of sample is the hospital and the last units of sample are the doctors and their patients. The hospitals were selected through the method of convenience sampling technique. The study was conducted in the hospitals in Bhubaneswar, Odisha because the investigator is well versed with the native language Odia. A list of all hospitals in Bhubaneswar was obtained. Out of them the hospitals which had minimum of ten General Physicians and Cardiologists were identified. The hospitals which met the following inclusion criteria were selected to be included in the sample.

_Inclusion Criteria of Hospitals_

1. The hospital must have a total of at least 10 or more General Physicians/Cardiologists who provide consultation to outdoor patients.

2. There must be a cardiology unit where there must be a minimum of four cardiologists offering consultations.

Out of the four hospitals that met the above inclusion criteria, the authorities representing of two particular hospitals expressed interest and were willing to let the hospitals be included in the study. Out of these two hospitals, one hospital consisted of 15 General Physicians and four Cardiologists who held consultation for the patients in the morning and evening, while the other had six General Physicians and five Cardiologists who held consultations in the morning and evening. On an average, the doctors provided consultation to 40 patients per day.
The following inclusion criteria were used to recruit the doctors and patients in the sample.

*Inclusion Criteria for Doctors*

1. Doctors handling outdoor patients on a regular basis.

2. Doctors willing to allow the investigator in the consultation room when the patients consulted the doctor.

3. Doctors willing to sign the informed consent form.

Specialists from other departments were excluded from the study. The recruited sample of doctors included a total of 30 General Physicians and Cardiologists. Out of these nine were Cardiologists and 21 were General Physicians. The following inclusion and exclusion criteria were used to recruit patients.

*Inclusion Criteria for Patients*

1. Out patients who are diagnosed with primary hypertension.

2. Hypertensive patients between the age group of 20-65 years.

3. Patients willing to sign the informed consent form.

*Exclusion Criteria for Patients*

1. Patients with secondary hypertension.

2. Patients with a history of psychiatric problem.

3. Patients under treatment for any other medical complications.

4. Patients below 20 years and above 65 years.
A total of 30 groups constituted the sample. Every group is also called a nest. Each nest consisted of one doctor and ten patients diagnosed with primary HTN. This totaled to 30 doctors and 300 patients. The sample characteristics are presented in Table 3.1.

Table 3.1
Sample Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Doctors (n = 30)</th>
<th>Patients (n = 300)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age range (in years)</strong></td>
<td>38-65</td>
<td>28-63</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>56.73 (6.51)</td>
<td>47.07 (7.32)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>30 (100)</td>
<td>265 (85)</td>
</tr>
<tr>
<td>Female</td>
<td>Nil</td>
<td>35 (15)</td>
</tr>
<tr>
<td><strong>Qualification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-graduate &amp; above</td>
<td>9 (30)</td>
<td>36 (12)</td>
</tr>
<tr>
<td>Graduate</td>
<td>21 (70)</td>
<td>222 (74)</td>
</tr>
<tr>
<td>Higher secondary/High School</td>
<td>NA</td>
<td>42 (14)</td>
</tr>
<tr>
<td><strong>Type of Doctor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Physicians</td>
<td>21 (70)</td>
<td>NA</td>
</tr>
<tr>
<td>Cardiologists</td>
<td>9 (30)</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Type of Patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Old</td>
<td>NA</td>
<td>242 (80.67)</td>
</tr>
<tr>
<td>New</td>
<td>NA</td>
<td>58 (19.33)</td>
</tr>
</tbody>
</table>

*Note. Figure in parentheses represent percentage.*

The age range of the doctors varied from 38-65 years ($M = 56.73, \ SD = 6.51$). All the doctors were male. There were 21 General Physicians, comprising 70% and nine Cardiologists, forming 30% of the doctors’ sample. The age group of the patients ranged between 28-63 years ($M = 47.07, \ SD = 7.32$). Out of the 300 patients, 85% were men and 15% were women. The patients’ educational level varied from Higher secondary to Post-graduation and above. As presented in Table 3.1, 12% of the patients had a qualification of post-graduate and above, 74% were graduates while 14% had a high school level qualification. The table indicates that a large proportion of patients had a qualification of graduation. Out of the 300 patients, the old and new patients formed 80.67% and 19.33% respectively of the sample.
Instruments

The instruments used for the study included were Health Communication Checklist (HCC), Hypertension Compliance Scale (HYCOMPS), and Doctor’s Disease Prognosis Rating Scale (DoDPRS). All the instruments are enclosed in Appendix Ia – Id. The instruments were initially constructed in English. The instruments that were administered on the patients were translated into the local languages of Odia, Telugu, and Hindi. This was done to help the patient understand the instrument. For this purpose, the scales were given to language experts (for Odia, Hindi and Telugu), for translation. The translated versions of scales were then back translated into English with the help of an English language expert to ensure that the meaning of the contents remained the same and was not lost in the process of translation. It was ascertained that there was no discrepancy in the meaning of any of the items. The instruments used for the study are described below in detail.

In addition to these, demographic details such age, gender, qualifications of both, the doctors and the patients were collected in a separate sheet.

Health Communication Checklist (HCC). The HCC consisted of 12 items related to five dimensions on communication between the patient and the doctor (Appendix I-a, I-b). This has a parallel form, one to be responded by the doctor and the other by the patient. Out of the 12 items, there were two items under the dimension of Medication (item 4 and 10). The next dimension on Diet had two items (item 5 and 11). The dimension on Exercise and Emergency signals comprised of two items each. Item numbers 6 and 12 covered the Exercise dimension while item numbers 8 and 9 covered the dimension of Emergency. The fifth dimension on Present status and Cautions encompassed four items (item no. 1, 2, 3, and 7). The doctors were required
to tick (√) those items which they claimed to have communicated to the patients. In
the parallel form, the patients were required to tick (√) those items which they had to
confirm that they were explained to their satisfaction on those aspects by the doctor.

The two parallel forms of the checklist were scored independently. A score of
1 was assigned to those items ticked (√) by the doctor. Similarly a score of 1 was
assigned to those items ticked (√) by the patients.

The score of the quality of communication was evolved on the basis of the
similarity of response between the doctor and the patients i.e. match between the
doctor’s and patient’s response. When the patient’s score is 1 and doctor’s score is 1,
the communication is said to be highly matching. In cases where only either the
doctor or the patient had checked the item the scores are 1 and 0. The quality of
communication was measured by evolving similarity index by matching the responses
of the doctor and the patient. The similarity indices of quality of communication on
each item ranged between 0 and 1. The process of arrival at similarity index is
appended (Appendix II). The HCC was run through the pilot testing and it was found
to have a strong internal consistency, Cronbach’s α = .75

**Hypertension Compliance Scale (HYCOMPS).** The Hypertension Compliance Scale
(HYCOMPS) was a 5-point scale ranging in frequency of behavior (Appendix I-c).
The scale consisted of positive and negative statements related to compliance with the
clinical prescription. The patients were required to read each item and indicate the
frequency of the non-adherent behavior on his/her part (None of the time = 4, some of
the time = 3, Most of the time = 2, All the time = 1, Do not know/ Not applicable = 0).
For the positive items the scores are reversed. Thus higher scores indicated higher
compliance. The scale was developed taking Hill-Bone Compliance to High Blood
Pressure Therapy Scale (Kim, Hill, Bone & Levine, 2000) as the base. HYCOMPS had four domains, namely – Medication (items 1,2,7,8,9,10,11), Diet (item 3,4,5), Exercise (item 13,14,15) and Self-monitoring (item 6,12). For the dimension of Medication, the score ranged from 0 to 28. For the domain of Diet, the score ranged between 0 to12. On the dimension of Exercise, the score ranged from 0 to 12. With two items under the dimension of Self-monitoring, the scores ranged from 0 to 8. The total score on the scale ranged from 0 to 60. For the total score as well as the dimensions, higher score indicated better compliance. The internal consistency of the scale was established and the Cronbach’s α was found to be .67.

**Doctor’s Disease Prognosis Rating Scale (DoDPRS).** The DoDPRS (Appendix I-d) was a single-item scale where the doctor rated the overall prognosis after six weeks (Adherence Phase) post the first consultation when the investigator collected the data on doctor-patient communication. This scale represented the overall evaluation of the doctor on the patient’s prognosis of primary hypertension. Here the doctor examining the patient, as per his clinical assessment on patient reported clinical symptoms such as palpitation, breathlessness, headaches, heaviness in the head, swelling in the foot and free urination, etc. rated the prognosis on a 3-point scale having the options – Bad Prognosis (1), Status Quo (2), and Good Prognosis (3).

In addition to this the BP readings were recorded in the first consultation and also six weeks later i.e. post-Adherence Phase.

**Participant Demographic Details.** The demographic details of the participants viz. age, gender, and educational qualification were taken. The demographic details were noted in the instruments itself. For the doctors, it was also recorded whether the doctor was General Physician or a Cardiologist. Apart from these details, it was also
noted whether the patient was a new patient or an old patient of the doctor and also the order of the entry of the patient i.e. whether the patient was among the first five of the patients to consult that particular doctor or among the last five.

**Procedure**

The procedure is discussed in two parts viz. pilot study and the main study. It is important to mention here that prior to the initiation of the study clearance was sought from the Institutional Ethics Committee (IEC), University of Hyderabad. The pilot study was carried out after the study was cleared by the IEC. Permissions were sought from the administrative departments of the hospital prior to the initiation of the study (*Appendix III*).

**Pilot Study**

The tools developed were pilot tested in four hospitals in Hyderabad. A total of five doctors and 50 patients were taken for the pilot study. After obtaining the administrative clearance and informed consent of the doctors (*Appendix IV*) and the patients (*Appendix V*) the investigator sat in the consultation room of the doctors during the consultation of the patients. After completion of the interaction, the doctor advised the patients to come for a review consultation after six weeks.

The doctors were given the HCC to be filled regarding their communication with the patient, following which the investigator accompanied the patient out of the consultation room and administered the HCC on the patient. Prior to this rapport was established with the patient. In addition to the written instructions, the doctors and the patients were orally explained about the criteria of filling the checklist. The patient was then administered the HYCOMPS. On an average each consultation took 10
minutes. It took two to three minutes for the doctor to respond to the checklist. The patients took approximately 20 minutes to respond to HCC and HYCOMPS.

The pilot study helped in establishing the suitability of the instruments and the method. The analysis of the results of the pilot study was used to determine the internal consistency of the instruments. It was found that the Health Communication Checklist has a strong internal consistency where the alpha was .75. The HYCOMPS was found to have the internal consistency with the alpha .67. The item analysis did not suggest deletion of any item. The results of the analysis of HCC and HYCOMPS are appended (Appendix VI and VII).

The method followed in observing the doctor-patient communication was found to be acceptable for the doctor and the patients. The only problem that the investigator encountered in the pilot study was the language used between the doctors and the patients. Since the investigator had no knowledge of the local language Telugu, she had to drop all those patients who could not converse in any language except Telugu. This led to the decision of conducting the main study in Bhubaneswar so that the inclusion of sample will be unbiased and scientific.

**Main Study**

The study was conducted in four stages. In the first stage, a survey was taken up on the hospitals in Bhubaneswar and the hospitals meeting the inclusion criteria were shortlisted, the hospital managements were approached and consent was sought from the hospital authorities to conduct the study. In the second stage the physicians and cardiologists were contacted and explained about the study. Those willing to participate in the study were given Informed Consent Form and a schedule was drawn for the investigator’s visit. In the third stage, the investigator visited the doctors
concerned on the scheduled day. The list of patients, who had appointment with the doctor, was scrutinized and the patients consulting for primary hypertension were identified. These patients were contacted in the waiting lounge and explained about the study. Those patients meeting the inclusion criteria were requested to participate in it on voluntary basis and rapport was established accordingly. Those willing to participate were given Informed Consent Form to sign. The investigator accompanied them to the consultation room whenever their turn came. The consultation ended with the doctor advising the patients to come for a review consultation after six weeks. At the end of the consultation, the investigator handed over the HCC to the doctor and requested to complete it. Before the consultation was terminated, the BP reading was taken by the doctor and noted down by the investigator.

The investigator accompanied the patient out of the consultation room and administered the HCC. In addition to the written instructions, the doctors and the patients were orally explained about the criteria of filling the checklist. Followed by the administration of the HCC, the HYCOMPS was administered on the patient. At the end of six weeks the patient’s prognosis was rated by the doctor. The BP reading was taken by the doctor and noted by the investigator as a record of BP was required for the follow-up visit six weeks later.

This procedure was followed until 10 patients with primary hypertension from the identified doctors were recruited into the sample. In case of drop-out patients, more patients were recruited to fulfill the desired sample size. On an average it required four visits to each doctor for Phase I of data collection and three visits for collecting data on follow up visit i.e. Phase II. At the end of the assessment, the doctors as well as the patients were debriefed.