

The Relationship Between Health Status Perceptions & Compliance with Antihypertensive Therapy - Market Research as a Pilot Study (& Beyond)

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Introduction

This paper summarises the design, analysis and results of an international study to improve knowledge of the reasons for non-compliance with drug therapy for hypertension (Saul, Stafford & Brice, 1999). Market research methods were chosen in order to assess the viability and value of investing in a more expensive and time-consuming definitive longitudinal clinical study. It also led to important conclusions in its own right.

Background

Mild to moderate essential hypertension is a major risk factor for stroke, cardiovascular and renal morbidity and mortality (MacMahon et al 1990, Collins et al, 1990). Clinical and epidemiological research has shown that control of high blood pressure (BP) reduces the incidence of most related complications. Yet, inadequate blood pressure control still occurs in up to 73% of the hypertensive population (JNC-VI Report 1997), with inadequate treatment adherence by patients being a major factor (Sclar et al 1991). It has also been reported, on a number of occasions, that physicians' ability to identify (and certainly to do so ahead of the event) which patients do not take medicine is limited (e.g. Norell 1981).

The research of compliance in hypertension management has found the problem to be multi-factorial and has approached it through a number of different directions, including clinical and socio-demographic perspectives to health psychology models and patient education and communication theories. A number of health status parameters have been identified in exploring this. These include cognitive attributes such as dizziness and anxiety (Cantillon et al; Pennebaker & Watson 1988), physical symptoms (Pennebaker & Watson 1988) and perceived health status (Meyer, Levanthal & Guttman 1985). However, a better understanding of the relationship between patient perceptions and hypertension treatment compliance is warranted in identifying factors that are addressable. Ideally, addressing this problem should be through the treating physician being able to identify, in advance, a patient's likelihood of not complying with therapy, together with the drivers of this, enabling an individually tailored compliance strategy to be devised.

The ideal method to study this would be to conduct a carefully designed prospective observational study (Brice 1997). However this approach involves both significant cost and time: a 7-figure sum would have to be budgeted and up to three years allowed for data collection and analysis. It was decided that a feasibility study was required and that market research would be the appropriate approach. It was with this goal and also with the expectation of, in itself, adding to the understanding of non-compliance and how to effect it that the current research was conducted.

Objectives

The quantitative research reported here follows from two earlier qualitative studies, comprising in-depth individual interviews and focus groups with mild to moderate hypertensive patients, their partners, and treating physicians. These were conducted to explore potential influences of hypertension treatment itself on compliance. Based on this work, a conceptual model was constructed describing patients' experiential pathways in hypertension treatment Figure 1.

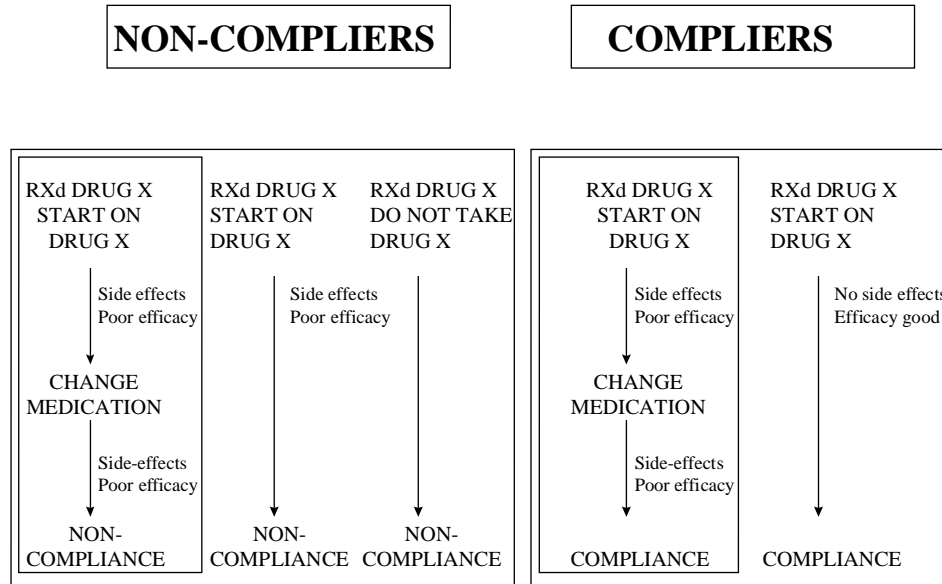


Figure 1: Conceptual model of hypertension therapy experiences and compliance

This early research raised the issue that while treatment experiences can be similar, individual reactions to treatment and varying understanding of hypertension control will result in differing compliance behaviours. Moreover, a particular group of hypertensives was observed who were essentially asymptomatic or whose symptoms (of whatever nature) had been recently relieved; this group was likely to perceive themselves as being cured of hypertension. This observation drove the notion that patient reactions to functional experiences, as well as therapy experiences and interactions with the healthcare system, play an important role in compliance decisions.

Hence, the present study explored the role of self-reported health status among other key hypothesised factors in influencing compliance behaviour in mild to moderate, essential hypertension. Self-reported health status was assumed to be a proxy measure of patients' perceptions of their clinical condition. Through this parameter, whether patients reporting better functioning (among other factors) are likely to be non-compliant (or sub-compliant) with therapy, based on their misunderstanding that continued pharmacotherapy is unnecessary, was examined.

Methods

Subjects

In the interests of time and economy, respondents were identified through a number of different sources such as general practice records, responses to newspaper advertisements, and within leisure, retirement, or unemployment centres. Following a screening exercise (conducted either by telephone or face-to-face interview), candidates meeting the recruitment criteria and providing consent for participation were then interviewed in person by trained interviewers. The interview included both patient-completed and interviewer-administered questions.

A sample of 730 hypertensive patients was recruited from France, Germany, Italy, Canada and the United States. These recruited individuals comprised newly treated (within 3-18 months) patients diagnosed with mild to moderate hypertension, lacking other acute/symptomatic cardiovascular conditions and at least 18 years of age. Quotas were specified for the representation of 3 broad compliance categories: non-compliers, sub-compliers and compliers. Additional quotas were also set for country, gender and age group.

Identification of compliance was based on patient self-reports, through responses to the question, *“Which of the following statements best describes you?”* The response choices presented were as follows Figure 2 with items #1 and #2 being combined to define non-compliers:

1. I have been prescribed medications for my high blood pressure, but I have never taken it.
2. I have taken medication for my high blood pressure in the past, but I am not taking the medications now.
3. I am currently taking medication for my high blood pressure, but I am not taking it exactly as instructed by my doctor (e.g. I could be taking less of the drug or not taking it regularly, among other things).
4. I am currently taking medication for my high blood pressure, and I am taking medication exactly as the doctor instructed.

Figure 2: Self-reported compliance question response options

Data

Questionnaire

After being developed in English, the questionnaire was translated into the relevant languages of each of the study countries. While the main questionnaire translation checking followed a simple forward and backward translation methodology, the health status items had previously been adapted into French, German, Italian, Canadian English and UK English through the linguistic adaptation projects sponsored by the instrument developers (Ware et al 1995).

Compliance measurement

In addition to the main compliance status question, an additional question on compliance, *“How often have you taken hypertension medications in the last 4 weeks?”*, was included to serve as a response consistency check prior to further analysis. The response choices to the question are given below (Figure 3). This item originated from the Medical Outcomes Study (MOS) the published, landmark research that also explored antecedents of compliance (Sherbourne et al 1992).

1. None of the time
2. A little of the time
3. Some of the time
4. A good bit of the time
5. Most of the time
6. All of the time

Figure 3: Additional compliance question response options

Health status measure

Health status was measured through physical and mental component scores of the SF-12 Health Survey (Ware et al 1995). The SF-12 Health Survey is a self-report of physical and mental functioning. The Physical Component Score (PCS) comprises two physical functioning items, two items on role limitations related to physical functioning, one item about bodily pain and a final item about general health. The Mental Component Score (MCS) comprises two mental health items, two items on role limitations related to mental health, an item on vitality and a final item about social functioning. Details on scoring and measurement properties can be found elsewhere (Ware et al 1995).

Hypothesized 'explanatory' variables

The variables included in the final model were specified following univariate and sequential multivariate analyses, and also hypotheses around their association with compliance from the qualitative research. These variables are described below together with the unit of measure (Figure 4).

Risk factors:
Smoking (yes/no)
Level of alcohol consumption (units of alcohol per week)
Relatives who have or had hypertension (yes/no)
Clinical health status:
Diastolic BP (mm/Hg)
Socio-economic parameters:
Employment status (employed/not employed)
Children less than age 10 live in household (yes/no)
Age
Marital status: married or living with partner (yes/no)
Higher education: educated beyond high school or technical school (yes/no)
Full insurance coverage for prescriptions (yes/no)
Healthcare satisfaction and expectations:
Satisfaction with assistance from healthcare providers (0-10 rating scale)
Desire for physician expertise and clinical judgement to inspire trust (0-10 rating scale)

Figure 4: Summary of questionnaire items included in analysis

Methods

Three objectives were specified for the analysis of the data: (1) to conduct a quality assurance exercise to assess the consistency of self-reported compliance; (2) to assess the univariate and bivariate properties of the variables; and (3) to develop the quantitative compliance model.

Consistency confirmation

A cross-tabulation of responses to the MOS and screening compliance items was performed to assess the consistency of self-reported compliance. Subjects who provided inconsistent responses to these questions were excluded from further analysis.

Univariate and bivariate analyses

Standard tests (Pearson parametric coefficients, χ^2 and Student's *t* tests) were used.

Multivariate analyses

The multivariate analyses comprised the development of two types of probability models, facilitating analysis through two different perspectives. First, an ordered logit model was constructed to obtain an indication of how each level of compliance is relatively associated to each hypothesized explanatory variable. This model provides information on the marginal impact of each of the explanatory variables to each element of the ordinal, dependent variable. The emphasis of interpretation following the exercise was then placed on examining the general direction of the impact rather than the magnitude of the impact.

The aim of the binomial logit analysis was to independently examine the subgroup of patients who responded as being fully compliant (i.e. taking medication exactly as the doctor instructed) to the subgroups of completely non-compliant patients. Once the logistic function was estimated, the marginal effect of each explanatory variable on the odds of full compliance was examined. The odds were estimated through the formula e^{β} (where β represents the parameter estimate). Two-tailed significance values (at $p < .05$) judged whether the odds were significantly different from unity (i.e. the explanatory variable had no marginal effect on compliance).

Results

Following the consistency assessment, 106 (24%) of the records were found to include inconsistencies in compliance recall and they were excluded from the analysis.

The analysis results detailed here summarise the results of the ordered logit (Table 1) and binomial logit (Table 2) models. For clarity, only significant variables are presented. More detailed results are included in the full paper (Saul, Stafford & Brice, 1999).

Compliance category	Have never taken hypertension medication	Have taken hypertension medication in the past, but not now	Taking hypertension medication but not as directed	Taking hypertension medication exactly as prescribed
PCS (physical functioning)	0.3%	0.2%	0.0%	-0.5%
Satisfaction assistance from healthcare providers	-2.5%	-1.8%	-0.3%	4.6%
Desire for physician's expertise and clinical judgement to inspire trust	-1.6%	-1.1%	-0.2%	2.9%

Variables listed are statistically significant at $p < .05$

Table 1 Marginal Effects of Explanatory Variables on the Probabilities of Compliance*

The results of the ordinal logit analysis are presented as percentage changes. It is notable that the trends for the variables 'satisfaction with assistance from healthcare providers' (scored 1-10) and 'desire for physician to inspire trust' (scored 1-10) are positive. A negative trend was observed for PCS; i.e. an increase in reported physical status is associated with a decline in compliance. PCS is scored such that 50 = the total population norm. A typical figure for a "healthy" group is 55. The scale is sensitive to small changes and, therefore, the differences found of 0.8% and 0.7% between the complier group and the two non-complier groups respectively can be anticipated to be clinically significant.

<p><i>Taking hypertension medication exactly as prescribed ($y_i=1$)</i></p> <p>Vs</p> <p><i>Have taken hypertension medication in the past, but not taking now</i></p> <p><i>($y_i=0$)</i></p>		
Parameter and odds estimates for x_i :	Parameter	Odds
PCS (physical functioning)	-0.04	1.04
Diastolic BP		
Male		
Children less than age 10 live in household	1.55	0.21
Satisfaction with healthcare	0.22	0.80
Desire for physician's expertise and clinical judgement to inspire trust	0.13	0.88

Variables listed with associated parameters and odds values are statistically significant at $p < 0.05$

Table 2 Parameter (β) and Odds Ratio (e^β) Estimates for Binomial Logit Models for Compliant Sub-group vs. Each Non-compliant or Sub-compliant Sub-group

The results shown for the binomial logit analysis are both parameter and odds estimates of each explanatory variable on the equation's dependent variable (y_i). The variable PCS resulted in statistical significance. With an odds estimate of -1.04, the PCS-to-compliance relationship is negative, with a decreasing odds of compliance per unit increase in physical functioning. Other significant variables in this model include the variables representing 'children less than age 10 living in household', 'satisfaction with assistance from healthcare providers', and 'desire for physician to inspire trust'.

Conclusions

The analysis of the data supported the hypothesis that health status notably, physical functioning as measured through the physical component score (PCS) of the SF-12 Health Survey is associated with compliance. First, a decreasing pattern of compliance associated with increased scores of physical functioning (PCS) was noted through bivariate analysis and multivariate examination of the ordinal compliance variable. Similar results were obtained in the binomial compliance equation comparing patients who stopped taking their medications versus those who took medications exactly as the doctor directed. Here, we observed decreasing odds of compliance with every unit increase of PCS. While such consequences can be viewed as being clinically significant, further research is required to substantiate this hypothesis.

The non-compliers in the sample also reported a lack of satisfaction with assistance from healthcare providers and a desire for the physician to inspire trust. It is tempting to interpret these results as indicating a causative mechanism and that a lack of satisfaction with the healthcare delivery is a predictor of non-compliance. Such interpretation from cross-sectional data is dangerous and potentially misleading. This has been recognized in earlier discussion (Brice 1997) where the possibility of a lack of satisfaction being a post-event (i.e. after the decision not to comply) rationalisation was identified.

A greater understanding of the factors influencing compliance behaviour will assist the healthcare provider to improve the effectiveness (which requires long term adherence to therapy) of their patient management strategies. It is clear that these factors go beyond the side effects of medication so often attributed as the cause of non-compliance and that, for many patients, these are not the prime cause.

The use of market research techniques meant that the study timeline and costs were acceptable and the exercise judged to be a success. The study results demonstrate that there is an urgency to recognise patient perceptions in compliance and confirm the viability and potential value of a definitive longitudinal study. They also clearly demonstrate that physicians need to measure their own success beyond the short term lowering of blood pressure. Should this lead to a patient perception of success, this very “success” with treatment may, in itself, lead to non-compliance with drug therapy necessary for the (necessarily long term) goals of hypertension treatment. It can be argued, therefore, that physicians need to be extra vigilant in these situations and that the implied necessary extra time would be more efficiently allocated if the more likely non-compliers could be identified.

