

CHAPTER 1

1.0 INTRODUCTION

1.1 Description and Definition of non Compliance

Medical non-compliance has been identified as a major public health problem, perhaps one of the most serious problems facing health care today. (Langer, 1999; Trick, 1993; Camargo, Zanini and Leital, 1991; Kelloway, Wyatt and Adlis, 1994;). It imposes a considerable financial burden upon modern health care systems (Donovan, 1995). It also has serious implications for the efficacy of research on certain drugs which could be deemed ineffective when in actual fact they were never taken as prescribed. (Urquhart, 1994b). New and more reliable techniques to assess patients' compliance with their prescribed drug regimen have shown that the problem of poor and partial compliance is much greater than was originally anticipated (Urquhart, 1994b). Despite an explosion of research into the effect of medical advice on patient behaviour, only about 50% of patients comply with long-term drug regimens (Wright 1993), and when it comes to changes in lifestyle, the percentage of patients who comply with medical advice often falls to single figures (Donovan, 1995; Butler, Rollnick, & Stott, 1996;).

It was observed by Wright (1993) that it seems that one-third of patients comply adequately, one-third more-or-less, and one-third are non-compliant, so that compliance rates hover around 50%. Berger, Braverman, Sohn and Morrow (1988) stated that patient compliance with

prescribed therapeutic regimens for benign diseases has been studied extensively over the past 20 years and treatment non-compliance is reported to vary from 15% to 93%. However, they feel that few reliable predictors of non-compliance have been identified in these studies. According to Sclar, Tartaglione and Fine (1994), reported rates of non-compliance with taking all types of prescribed drugs range from 13% to 93% among adults and from 25% to 82% among children. Kravitz, Hayes, Sherbourne, Dimatteo, Rogers, Ordway and Greenfield (1993) found that the majority of chronically ill patients failed to recall elements of potentially important medical advice and did not always adhere to advice that was recalled. In fact, Kessel's (2003) research found that between half and four fifths of all medical information delivered during an average consultation was forgotten instantly by the patient. Conway, Pond, Hamnet and Watson (1996) went as far as to conclude that non-compliance is universal and should be recognised as normal behaviour. Earl (1991), comments that medical non-compliance remains one of the least understood of health related behaviours.

As early as 1938, Menninger, in his book, *Man Against himself*, was writing about the extraordinary propensity of the human being to join hands with external forces in an attack upon his own existence which he saw as one of the most remarkable of biological phenomena. He writes about the idealistic doctor who puts all his energy into curing his patients, believing completely that all his patients wanted to be cured. Suddenly, or perhaps gradually, he is disillusioned. He discovers that the patients often do not want to get well as much as they say they do. He discovers that their hovering and solicitous relatives often do not want them to get well either.

He discovers that his efforts are combated not alone by nature, bacteria and toxins, but by some imp of the perverse in the patient himself.

Centuries ago, Hippocrates stated that the physician should keep aware of the fact that patients often lie when they state that they have taken certain medicines (Tebbi, 1993; Haynes, Taylor & Sackett, 1979). Today compliance is a well recognized but still unresolved health problem (van Berge Henegouwen, van Driel & Kasteleijn-Nolst Trenite, 1999).

Freud (1920/1962) postulates an irreconcilable conflict between Eros, (the Life Instinct - seeking to preserve and enrich life) and Thanatos (the Death Instinct - seeking to return life to the peace of death).

Compliance is generally defined as a patient's behaviour in terms of taking prescribed medication, following diets, or executing medically recommended lifestyle changes.

Furthermore, compliance measures the extent to which a person's behaviour coincides with medical or health advice (Blackwell, 1976; Hasford, 1992; Horwitz & Horwitz, 1993; Sanson-Fisher & Clover, 1995).

Simply put, compliance can be said to exist when the patient carries out the doctor's orders with regard to the medical regimen (Bille, 1981). The terminology of compliance studies has come under scrutiny as it seems to stress the subordinate position of the patient in relation to the health expert (Bakker & Kastermans, 1994)

The list of medical subjects headings (MESH) compiled by the National Library of Medicine has included the term patient compliance only since 1975. Before then the major descriptive term was, "patient drop-out". In America the coercive connotation of the word compliance has led to increased use of adherence as an alternative (Blackwell, 1976).

DiMatteo and DiNicola (1982, p. 2) describe the phenomenon:

"Patients with heart disease, once, sure to die in early middle age, are now offered treatments that prolong their lives and restore in some measure their health and vigour. Diabetic patients can now enjoy essentially normal and productive lives by faithfully taking insulin and regulating their diet and exercise. Patients with acute infections are quickly and easily cured by merely adhering to a ten-day course of medication. Typically, patients who receive these sound medical recommendations have come in search of them and have invested considerable time, money, energy, and emotion. They have withstood detailed questioning and sometimes obnoxious physical examination in the process of seeking help. Their practitioners have in turn puzzled through elaborate and sometimes complicated differential diagnoses. At the end of the medical visit a specific treatment recommendation is usually formulated, but despite the considerable investment of both parties and the serious health consequences that might result, the chances are really quite good that the patient will fail to follow the hard-earned medical advice. Deliberately or not, many patients ignore, totally forget, or erroneously implement their treatment recommendations."

Is this instant forgetting (Kessels, 2003) or is it due to something much deeper within the

patient? In fact, as Kessels (2003) seems to suggest, is the instant forgetting due to something deeper within the patient?

Slonim (1994) gives, "You can lead a horse to water...(but you can't make him drink)" as a title for an article on non-compliance. In other words, a patient can be given every opportunity for medical treatment but may just refuse or not comply with it. Awad (2004) makes the salient point that the best medicines are of little value unless they are taken.

1.2 Implications for Research

Non-compliance also has very serious implications for research and the interpretation of the results of drug trials. It poses a threat to the accuracy of clinical research efforts, as the measurement of the effectiveness of a new drug or treatment is based upon the assumption that patients have followed the conditions of administration (Urquhart, 1994b; DiMatteo and DiNicola, 1982).

For this reason, Steiner and Vetter (1994), in discussing compliance with migraine prophylactics, point out that it is possible that all evaluations of efficacy and tolerance of the medication reported so far have been unsoundly based.

Researchers conducting clinical trials of medical interventions must evaluate compliance in the population studied and consider the potential impact of noncompliance on trial results and their generalizability (Melnikow and Kiefe, 1994).

Ramsay (1982) studying participants in non-compliance research, poses a further problem: Patients have the option to participate in many investigations of non-compliance for medical recommendations, and he raises the question about whether a tendency to volunteer for medical research is consistent with a tendency to comply with other medical treatment requests. The results of his study suggested that investigations of non-compliance have used samples that are select for compliant behaviour, a factor that could have been operational even in the present research.

Whitney and Dworkin (1997) also make this point about research in general: Randomized clinical trials are recognized as providing the most rigorous evidence of treatment efficacy. However, if a tendency to volunteer is more common among the compliant patients, the treatment efficacy is based on the compliant subjects, subjects who may no longer represent randomized groups or yield the desired "fair" estimate of treatment efficacy.

In the area of oncology, a large percentage of paediatric cancer patients are treated according to research protocols. In a research setting, noncompliance can result in erroneous or inconsistent findings, potentially affecting investigational results. With the availability of venous access ports and sophisticated, yet easy-to-operate pumps, increasingly, it is possible to administer parental medications at home. This adds a new dimension to the self-administration of medication that previously concerned mainly oral therapy. Because a significant number of determinants are involved, it is often not possible, with any degree of certainty, to identify non-compliers or to predict the level of patient adherence to the treatment (Tebbi, 1993).

1.3 The Inability of Doctors to Consistently Detect Compliance

Urquhart (1994a) writes about the concept of "white coat compliance", referring to the tendency of patients to take their medicine correctly only a day or two prior to their appointment with the doctor. This was especially true, he felt, before the late eighties. He feels that compliance is now shown as a great deal poorer in clinical trials than has been revealed by the older methods due to the fact that the measurement of compliance has become increasingly more scientific and accurate. Dekker, Dieleman, Kaptein and Mulder (1993) note that non-compliance with medication may well provide an alternative explanation for the discrepancy between prescribed medication and medical outcome, which has been labelled in the literature as "under treatment". In clinical practice, non-compliance is an often unrecognised or frustrating reality, which physicians find difficult to accept or deal with (Alvin, Rey and Frappier, 1995).

Doctors often do not realise that their patients are non compliant. Davis (1966) pointed out that one of the basic problems in the relationship between a doctor and a patient was the expectation that each has for the other is rarely congruent. A patient will not always accept everything a doctor recommends and he suggests that doctors become aware of this and consider and interpret the motivations of their patients or part of their role. He found that in comparison with the findings in empirical studies, that more than one third of patients do not fully comply, nearly half of the doctors in his study claimed that almost 100% of their patients complied. Congruent with this overestimation, there was little recognition that certain types of patient were more compliant. When faced with non compliance, the doctors in this study

failed to understand it. Their attitude in general was that if there was non-compliance, it was due to the patient's lack of understanding or simply that he/she was an uncooperative personality.

Though some physicians may cherish the illusion that they can intuitively detect drug defaulters, the evidence indicates otherwise. Skilled psychiatrists have been shown to err in up to 20% of their predictions concerning which out-patients are taking their drugs, though it is interesting that 71% of mistakes were in the direction of believing that patients were not taking their drugs when in fact they were (McClellan & Cowan, 1970). Valenstein, Barry, Blow, Copeland and Ullman (1998) found that seriously mentally ill patients and their clinicians showed little agreement about medication use beyond that expected by chance.

Gross, Bilker, Friedman, Coyne and Strom, (2002) examined the ability of health service providers to predict and estimate patient adherence to newly initiated highly active antiretroviral therapy (HAART). Widespread inaccuracy was found in providers' adherence predictions and estimates.

Hasford (1992) points out that the traditional physicians' non-perception of patients' partial compliance is no longer acceptable, as partial compliance has a negative impact on the benefit to risk ratio and disappointing therapeutic performance (Mancia, 1995). Sackett and Snow (1979) comment that the gap between the regimen recommended by the clinician and that adhered to by the patient is distressingly wide. They feel that it is one of the paradoxes of compliance that the former partner (the doctor) in this relationship is frequently the last to

know.

Donovan (1995) feels that for today's patients, particularly those with chronic illnesses, compliance is not an issue. They make their own reasoned decisions about treatments based on their own beliefs, personal circumstances, and the information available to them. He feels that the traditional concept of compliance is thus outmoded in modern health care systems, where chronic illness and questioning patients predominate. While it may be reasoned that adults need to take responsibility for their own healthcare, children and adolescents always pose an ethical dilemma.

van Es, le-Coq, Brouwer, Mesters, Nagelkerke and Colland (1998) in dealing with adolescent asthma found that this group of patients were not always frank in telling their pediatrician how they managed their asthma. Non-compliance in adolescence is notorious because of the developmental stage. Rebellion against compliance becomes part of dealing with identity and autonomy with opposition to adult instruction, as will be discussed later.

1.4 Financial Implications

Apart from the considerable financial loss of ineffective drug trials or treatment, there are other serious financial implications. Improvement of compliance to treatment would increase cost-effectiveness (van Berge Henegouwen et. al., 1999). The lack of (or poor) response to drugs has very important medical, social and economic consequences. An unsatisfactory response to treatment implies not only a worsening or prolongation of the pathological state,

but also prolonged hospitalization, longer withdrawal from social and active life, and waste of community resources (Lacombe, Vicente, Pages and Morselli, 1996; Sclar et.al., 1994).

Meredith (1996) notes that it has been suggested that hospitalization due to non-compliance accounts for 11.7% of all healthcare expenditure in the U.S.A. In Riyadh, Saudi Arabia, al-Shammari , Khoja and al-Yamani (1995) found that admissions due to non-compliance had been estimated to account for up to 10.5% of all admissions to hospital.

Given the importance and far reaching effects of non-compliance on the health and even the life of patients, research efficacy and the financial implications for services, resources and quality of life, and the fact (as we shall see later) that numerous interventions have only partially succeeded in reducing or eliminating it, it is clear that non-compliance requires further investigation to clarify the causes and to suggest further effective interventions.