

# From compliance to concordance in diabetes

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Compliance is a key concept in health care and affects all areas of health care including diabetes. Non-compliance has previously been a label attached to many patients without much thought having been given to the causes of poor compliance. Over the last few decades there has been a large volume of research focusing on compliance that has exposed the multitude of factors affecting compliance. Even the definition is not clear cut and so comparability between studies is not without difficulties. A better understanding of the factors affecting compliance, including the doctor/patient relationship, has allowed the evolution of “concordance”. Concordance views the patient as being the equal of the healthcare provider and as having a right to make informed decisions. In a condition such as diabetes, which has many potential long term complications, it is vital that concordance is embraced in the healthcare system in order to improve care.

diabetic complications.<sup>4</sup> Non-compliance imposes an immense financial burden on modern healthcare systems such as the National Health Service (NHS), as well as imposing personal costs on the individual patient.<sup>1</sup> Low compliance can have detrimental effects on medical research trials, reducing the value and the usefulness of studies.<sup>3</sup>

## Compliance: definition

Compliance research has focused on the extent and the determinants of non-compliance and on strategies to improve compliance. In order for comparative assessment there would need to be a single definition for the term “compliance”. Unfortunately, there are different definitions and many authors do not define the term. One definition is the extent to which the patient’s actual history of drug administration corresponds to the prescribed regimen.<sup>2</sup> Another definition is the extent to which a patient’s behaviour in terms of taking medication, following diets, or implementing lifestyle changes coincides with medical or health advice.<sup>6</sup> However, neither of these definitions address how much non-compliance matters in relation to clinical outcome. Compliance can also be assessed in terms of process orientated and outcome orientated definitions, the latter being more relevant to clinical outcome. Gordis defines non-compliance as: “the point below which the desired preventative or therapeutic result is unlikely to be achieved”.<sup>7</sup> Although this addresses non-compliance in terms of clinical outcome, it fails to address economics and wasted resources.

## Research

In terms of research and day to day patient care, detecting non-compliance is a requirement for adequate treatment.<sup>8</sup> Before determinants of non-compliance can be investigated, accurate detection is necessary. Variability in the rates of non-compliance reported in different studies may be influenced by differing study design, patient group, and methods of measurement. The most sensitive and specific measure of compliance would be direct observation at the time of taking medicine (insulin), adhering to a lifestyle change (diet), or changing dressings in the case of a wound. For obvious reasons this is impractical.

Non-compliance can be divided into categories.<sup>1</sup> Primary non-compliance occurs when the patient fails to have the medication dispensed; secondary non-compliance occurs when it is not taken as instructed. Further categories relate to intentionality.<sup>9</sup> Intentional non-compliance may occur when the doctor’s diagnosis or treatment is rejected by the patient. Unintentional non-compliance can be related to

Compliance has been the focus of significant research and clinical interest in the past two decades. At a basic level, compliance is the term used for following a recommended treatment regimen.<sup>1</sup> It is important in terms of health care, economics, and research. Compliance to treatment is a key factor between process and outcome in medical care.<sup>2</sup> It is relevant to all aspects of medical care, including diabetes and consequently wound care. This review studies the concept of compliance in relation to the diabetic patient and the evolution of the concept of concordance in medical practice.

Low compliance to treatment regimens is a complex problem, particularly for those with chronic illness, and is significantly undermining the benefits of medical care.<sup>3</sup> Diabetes is a chronic condition and treatment is complex, life long, and requires behaviour changes on the part of the patient. These include glycaemic control (taking medication and testing blood sugar), urine testing, diet, exercise, and foot care. Complications from poorly controlled diabetes include infection, vascular disease, and neuropathy—these being significant factors in the development of diabetic foot disease. Hence the holistic approach to the care of the control of diabetes is vital and will actually have a direct impact on the prevention of complications including diabetic foot disease. Rates of non-compliance vary, with estimates ranging from 50% to 80%.<sup>14</sup> Greater compliance may be associated with a decreased probability of

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social, demographic, psychological, and clinical variables. One example of unintentional non-compliance might be the diabetic patient with retinopathy and neuropathy who is unable to see or feel a developing foot ulcer and therefore does not comply to seek medical attention. Most studies do not indicate clearly the different types of non-compliance being studied, and therefore comparability between studies is problematic.

### DETECTION AND MEASUREMENT

Detection methods have been broadly divided into indirect and direct methods. Self reporting and interviews are commonly used indirect detection methods. A study by Morisky *et al*, to assess the concurrent and predictive validity of self reporting, involved a self reported scale of medication taking behaviour and the subsequent measurement of blood pressure.<sup>10</sup> The study demonstrated reliability of the measurement tool, and concurrent and predictive validity for those scoring high on the adherence scale compared to those scoring low. However, a large proportion of patients had mid-range scores (between high and low) demonstrating an inefficiency in prediction of blood pressure control. In fact, when analysed for positive and negative predictive value, the sensitivity was 0.81 and the specificity 0.44, which from a practical point of view is rather poor. The actual use of the scale in predicting an individual patient's adherence or blood pressure control level cannot be based entirely on statistical validity.<sup>10</sup> Despite this, Haynes *et al* have shown that self reports have greater sensitivity and specificity than other techniques.<sup>11</sup>

Pill counts are another indirect method of measuring patient non-compliance but pill dumping can cause over-estimation of compliance.<sup>12</sup>

The achievement of treatment goals has often been used as a measure of compliance. When a particular therapy is associated with a successful outcome—for example, normal blood pressure or glucose level, satisfactory compliance with the regimen may be inferred.<sup>8</sup> However, a patient may be non-compliant but have a successful outcome either because of partial compliance or the “toothbrush effect” (taking medication just before follow up or brushing teeth just before dental appointment). Additionally, a patient may be compliant but resistant to treatment and therefore have an unsuccessful outcome, which is not uncommon in diabetic patients. Therefore outcome measurement may tell us little about compliance.

Direct methods tend to be more expensive, invasive, and more difficult to perform, but they tend to have a higher sensitivity and specificity, making them more reliable in the assessment of compliance. Direct methods of measurement of compliance include the measurement of markers in the blood. Some of these, such as glycosylated haemoglobin, used to indicate glycaemic control in diabetics, reflect compliance over a period of time. However, poor glycaemic control may not necessarily be due to poor compliance. The use of drug concentrations in the blood is another direct method that has been used, but it has limitations. Individual patients vary in their absorption, metabolism, and excretion of drugs, and consequently a compliant patient may have low levels on measurement or a non-compliant patient may have high levels. Furthermore, concentration levels do not assess whether the patient adhered to the prescribed timing of administration. Although many methods have been used, there are problems with each method for producing valid and reliable data to give an accurate estimate of the extent of compliance.

### Predictors

The determinants of non-compliance have been the subject of many studies, with a view to implementing strategies to

improve patient compliance. Demographics such as age, gender, sex, intelligence, and economic status have been analysed in a number of studies. Although sociodemographic variables have been found to be predictive of entry into the healthcare system, they have not been predictive of compliance levels once treatment has been commenced.<sup>13</sup> With specific regard to patients with diabetes mellitus, Bloom, Cerkoney and Hart showed no significant difference in compliance levels when patients were grouped according to demographic variables.<sup>14</sup> Clinical variables such as symptoms, duration, diseases, classes of drugs, and regimens have also been assessed. Most of these have shown poor correlation with the way in which medicines are taken.<sup>1</sup>

In the extensive study area of frequency of dosing, Pullar has shown that once or twice daily regimens have better compliance rates than three or four times a day regimens.<sup>15</sup> Therefore longer acting medication, which allows reduced frequency to achieve glycaemic control, may be beneficial for diabetic patients. Although this may be possible to achieve in type 2 diabetes, those with type 1 (insulin dependent) diabetes often require frequent subcutaneous injections in order to maintain adequate control.

Defective communication between the doctor and the patient is often at the heart of the problems that lead to non-compliance.<sup>16</sup> One commonly used measurement of poor communication has been the patient's inability to recall the doctor's instructions: failure rates of between one third and one half of the statements made by doctors have been recorded.<sup>17</sup> However, using methods of measuring recall that rely on direct recall do not take account of the patient's understanding of the statements made to them by the doctor. Additionally, this type of measurement fails to incorporate the patients' intentions. Patients' understanding, recall, and satisfaction have been linked with compliance.<sup>18</sup> Satisfied patients are more likely to comply.<sup>19</sup> Patients' understanding of information received from healthcare professionals has also been shown to correlate with satisfaction with communication.<sup>20</sup> Brody showed that the amount recalled by patients correlates with the degree of satisfaction with the doctor and with the communications made by the doctor.<sup>21</sup> The cognitive hypothesis claims that a significant proportion of the variance in both patient satisfaction and compliance can be accounted for by comprehension and memory variables.<sup>18</sup> However, Sackett *et al* have shown evidence to the contrary in which improvement of comprehension and memory has not led to the predicted drop in non-compliance.<sup>22</sup>

The problems encountered during communication are not solely the fault of the physician. Korsch *et al* found that 76% of the patients' main worries were not mentioned to the doctor.<sup>23</sup>

Individuals who do manage to adhere to their regimens may succeed because of determinants not associated with the regimen itself. Some of these variables may be explained by the “health belief” model. This model sees the adoption of a health promoting behaviour as being determined by (1) a cue to action; (2) perceived vulnerability to the health problem; (3) the perceived seriousness of the illness; (4) the perceived effectiveness of the treatment of advocated action, and (5) the perceived costs of adopting the treatment or action. Bloom, Cerkoney and Hart conducted an interview survey to determine the health belief model's association with the compliance levels of chronic diabetics.<sup>14</sup> This study looked at the relationship between the compliance levels of diabetics regarding specific aspects of their medical regimen (insulin administration, diet, hypoglycaemia management, foot care, and urine testing) and the health belief model and its specific aspects numerically outlined above. Results showed that more than half of the patients were compliant with at least

70% of the items measured. Less than seven per cent were considered totally compliant with essential behaviours. The results showed that patients who perceived diabetes to be serious and responded to cues tended to be more compliant, particularly with insulin administration and foot care. In regard to the perceived effectiveness, although a high percentage of patients believed that treatment would control their diabetes, most of these understood “treatment” as being insulin administration only. Hence, there appeared to be a gap in patient knowledge. The overall relationship between health beliefs and compliance was too low to be able to use these health belief variables as predictors of compliance in diabetic patients.

Harris and Linn studied diabetics in relation to their health beliefs, compliance, and glycaemic control.<sup>4</sup> Interview and biochemical analysis of blood and urine were used to assess these three areas. Interestingly, as in the study by Bloom, Cerkoney and Hart, perceived severity was the health belief that accounted for most of the variance in compliance.<sup>14</sup> However, the overall results suggested that health beliefs were minimally associated with compliance but strongly associated with metabolic control.<sup>4</sup> Although, as discussed earlier, poor glycaemic control may not necessarily be due to poor compliance; the reasons for the lack of direct relationship between compliance and control in this study are not fully explained. Both of these studies suggest that perceived severity as an individual health belief may be associated with increased compliance in diabetics. If, as Harris and Linn have demonstrated,<sup>4</sup> health beliefs and therefore attitudes correlate to control in the diabetic patient, it may be valuable for the medical profession to understand more about patients’ health beliefs and what influences them in order to optimise attitudes with a view to providing better diabetic control. This would ultimately directly impact on the complications of diabetes, including diabetic foot disease.

The doctor/patient relationship, communication, and disparity between the health beliefs of doctors and patients appear to be important in predicting compliance, and the study of these three factors has exposed and undermined the very ideology of compliance. It has been suggested that compliance is a function of the doctor/patient relationship.<sup>24</sup> Sackett’s definition of compliance is somewhat paternalistic.<sup>6</sup> A patient who does not do as advised by the doctor is viewed as non-compliant and the roles of doctor and patient in this relationship could be compared to parent and child. Much of the research in patient compliance has shared this stance, with patients being seen as passive and powerless.<sup>9</sup> Even the term compliance has certain connotations, such as submitting to and obeying instructions. There has been an assumption in health care that patients should comply and that non-compliance is often the fault of the patient. This school of thought portrays non-compliance as deviant behaviour and ensures that the blame is largely directed toward the patient.<sup>9</sup> The very suggestion of patient obedience implies that the empowered doctor enforces a treatment on a patient. This is a somewhat out of date approach to patient care and flawed in many respects. There may be legitimate reasons why a patient may not comply with a treatment, and it may be sensible, safe, and in the interest of the patient to be non-compliant. For example a reaction to a drug may lead to the patient refraining from taking that medicine again.

### Adherence

The term “adherence” has been used as an alternative to compliance. It comes closer to describing and emphasising patient and clinician *collaboration* in decisions, rather than conveying the idea of obedience to a medical prescription but “is not an optimal description for diabetic self management behaviour”.<sup>25</sup> Unfortunately many authors have used the

term adherence interchangeably with compliance, failing to distinguish the two and therefore the term adherence will not be mentioned again in this discussion.<sup>26</sup>

### Concordance

In the mid 1990s, the UK Department of Health and the Royal Pharmaceutical Society of Great Britain started a collaborative project that aimed to understand why patients did not take their medication, and to develop solutions to this problem. The resulting report, *From Compliance to Concordance*, was significant in the development of the concept of “concordance”.<sup>1</sup> Concordance encompasses the idea that the doctor and the patient are equals, and that the patient makes informed decisions. The doctor/patient relationship should be a partnership, in which time is taken to explain the illness in question—such as diabetes—and to explore what the patient understands and believes about the condition. Different treatment options available to the patient should be explained in such a way that the patient can understand them. According to the model of concordance there should be an open exchange of beliefs about medicines upon which both prescribing and medicine taking decisions may then be based.<sup>1</sup> The key difference between compliance and concordance is that the former generally focuses on the behaviour of one person, the patient, whereas the latter requires the participation of at least two people.<sup>27</sup> Modernisation of diabetic care provides patients with tools, such as blood glucose monitors, in order to tailor their treatment for optimal glycaemic control. Such self treatment gives responsibility and choice back to the patient, while enhancing their knowledge and awareness of the condition.

There are, however, potential problems with the concordance model. Where will the doctor stand ethically and legally if a patient makes an informed decision not to take medication as directed? Failure to take diabetic medication properly could lead to uncontrolled diabetes, long term diabetic complications, coma, or even death. Additionally, concordance relies on the patient being the decision maker. However, certain patients may expect the doctor to tell them what to do, as Bissell *et al* found in a study of type 2 diabetics.<sup>28</sup> These problematic areas need to be explored in more depth.

### CONCLUSION

Although the concept of compliance is outdated, the work that has evolved from its study has been most valuable in helping to increase our understanding of the problems encountered by the patient and the doctor, particularly when involving complex conditions such as diabetes. It is clear that the patient’s attitudes have a significant impact on the control of diabetes. Openness between the doctor and the patient during consultations will ultimately lead to clearer understanding, both in terms of the patient’s understanding of the disease and treatment options, and in terms of the doctor’s understanding of the patient’s attitudes. The concordance model is a relative ideal that will take many years to be fully incorporated into medical practice. Currently the Department of Health is supporting a task force on medicines partnership. This initiative involves the implementation of concordance into medical education and practice.<sup>29</sup>

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