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Psychology and the enhancement of medication adherence

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Abstract
This paper reports on a new approach to the enhancement of medication adherence - Medication Alliance. Medication Alliance was developed and piloted by a project team that includes Mitch Byrne as project leader, Frank Deane as research supervisor, and two consultants, Tim Coombs and Gordon Lambert. Because Medication Alliance borrows heavily from psychological principles such as functional analysis and cognitive therapy, this presentation is entitled 'Psychology and the Enhancement of Medication Adherence'. However, Medication Alliance is a non-discipline specific therapy approach that fits well within the purview of any clinician delivering psychosocial interventions. The theoretical underpinnings of the various Health Beliefs models and the importance of the Therapeutic Alliance in treatment outcomes shapes Medication Alliance as a contemporary intervention for an enduring problem in the effective delivery of mental health services.

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Psychology And The Enhancement Of Medication Adherence.

Introduction

This paper reports on a new approach to the enhancement of medication adherence - Medication Alliance. Medication Alliance was developed and piloted by a project team that includes Mitch Byrne as project leader, Frank Deane as research supervisor, and two consultants, Tim Coombs and Gordon Lambert. Because Medication Alliance borrows heavily from psychological principles such as functional analysis and cognitive therapy, this presentation is entitled 'Psychology and the Enhancement of Medication Adherence'. However, Medication Alliance is a non-discipline specific therapy approach that fits well within the purview of any clinician delivering psychosocial interventions. The theoretical underpinnings of the various Health Beliefs models and the importance of the Therapeutic Alliance in treatment outcomes shapes Medication Alliance as a contemporary intervention for an enduring problem in the effective delivery of mental health services.

The impact of non adherence

Severe mental health problems are a major cause of human misery for a substantial proportion of the population. In schizophrenia, for instance, the lifetime prevalence may be as high as 1.5% (Sue et al., 2000). Schizophrenia is a chronic relapsing condition, with 80% of those having one episode of illness going on to experience future mental ill health. Further to this, people who experience schizophrenic illnesses have on average significantly poorer physical health and a reduced life expectancy. In addition to the impact on the sufferer and their family, schizophrenia imposes a substantial economic impact upon the community.

Fortunately, the health system has responded to the challenge of schizophrenia and other psychotic disorders with the development of a range of effective treatment strategies. While non-pharmaceutical approaches to treatment and rehabilitation have proven promising over recent times, medication remains the primary tool in the clinician’s arsenal. Recently the so-called ‘atypical’ antipsychotic medications have been developed and the efficacy of these medications is well established. Not only do the atypical agents treat the positive symptoms of mental illness such as delusions and hallucinations, evidence is emerging that they may have additional benefits such as improving cognitive functioning and reducing negative symptoms and aggression. It is estimated that up to 80% of patients respond to these newer atypical medications and that relapse rates are significantly reduced.

In the face of such optimistic information, a major concern is the rate of what might be termed sub-optimal adherence with treatment prescriptions. Estimates vary; however it is conservatively estimated that approximately 50% of people with psychotic disorders do not use their medications as prescribed. This is alarming although not unusual, with similar figures cited for other chronic health problems (Sawyer and Aroni, 2003). None the less, the impact of poor treatment adherence in people who have mental health problems has been well documented. For instance, Weiden and Olfson (1995) observe that when discharged patients stop their medication, relapse rates increased from about 3.4% per month to about 12% per month. Weiden and Olfson modelled known non-compliance rates and relapse rates on and off medication, reporting that over a 24-month period, optimal medication use alone can slow or eliminate over 25% of relapses. However, there remains a significant proportion of people for whom medication alone is insufficient to prevent relapse, and it is here that the value of...
additional psychosocial interventions may be found. Weiden and Olfson estimate that medication non-compliance accounts for up to 40% of revolving door relapse and re-hospitalisations.

**Mental health clinician skills in managing non-adherence**

If optimal use of medication can reduce vulnerability to mental ill health, have community mental health workers been trained in skills to support medication use? The answer appears to be no. Coombs et al. (2003) recently undertook a study of the role of community mental health workers in supporting medication adherence. Primarily nurses, Coombs and colleagues found that 84% of respondents had received no formal training in medication adherence strategies. Of those who said that they had received training, they indicated that this had consisted of viewing lectures on pharmacology (an ineffective strategy given that enhanced clinician knowledge of psychopharmacology has been found not to predict improved patient medication adherence - Gray, 2001). Significantly, over 40% of Coombs sample reported they ‘often’ or ‘always’ had problems with issues such as discussing medication side effects, discussing the link between ceasing medication and becoming unwell, and undertaking education with the patient and family members about medication. Coombs also reported that the majority of his sample viewed the development of a therapeutic alliance as a ‘low priority’. Clearly there is a need for both the enhancement of clinician skills and modification of therapeutic attitude as it relates to medication adherence.

**What skills to train for: strategies to enhance medication adherence**

Research into adherence interventions can be broadly divided into three categories: educational interventions; behavioural interventions; and cognitive behavioural interventions. Results suggest that only the cognitive behavioural approaches have demonstrated consistent improvements in adherence, with the seminal research conducted by Kemp and her colleagues (Kemp et al., 1996/97/98). Kemp, a psychiatrist, developed an inpatient intervention termed ‘Compliance Therapy’.

Compliance Therapy is a manualised treatment program that incorporates motivational interviewing techniques and aspects of cognitive behavioural therapy. It introduced taking a therapeutic approach to solving difficulties with medication-taking by working collaboratively with the patient, emphasizing their choices and responsibilities, and focusing on their concerns about treatment.

Most successful treatments that have followed, including *Medication Alliance*, have been modifications and enhancements of Kemp’s original work. Kemp’s study involved a randomized control trial with two inpatient groups - the Compliance Therapy group and a non-directive counselling group. Forty seven patients were seen by a psychiatrist and a psychologist for four to six sessions, each of an average of 40 minutes, and measures were taken at several time points. Kemp observed enhanced medication taking behaviour, and patients in the compliance therapy group took longer to relapse than the comparison group.

However there were difficulties with Kemp’s study. Kemp reported a minimal effect on levels of patient psychopathology (measured with the GAF) and there were methodological issues in the early phase of the study, with the assessor not blind to treatment condition. Given that her sample was an inpatient sample, there was also the potential for floor and ceiling effects, magnifying the clinical impact of her intervention but, more importantly, bringing into question the applicability of compliance therapy to a community setting. Finally, Kemp’s intervention relied upon highly trained experts to deliver the therapy, limiting dissemination potential.

In an effort to overcome the limitations of Kemp’s compliance therapy, Gray and colleagues (2003) developed ‘medication management’. Gray sought to demonstrate that the techniques of compliance therapy could be taught to ‘coal face’ clinicians in community mental health settings. Gray and colleagues describe a 10-day (80 hour) teaching program delivered across 10 weeks. The program involved training in assessment of medication adherence issues (such as patient attitudes to treatment,
insight into illness and medication side effects), cognitive and compliance therapy skills, psychopharmacology and ongoing (weekly) clinical supervision of the trainees' implementation of 'medication management' (Gray et al., 2003). It was Gray's contention that if the briefer 'medication management' training could effect significant changes in clinician skills and knowledge, then a more comprehensive clinical outcome trial would be justified. Gray found that his program was effective in enhancing both clinician skills and knowledge, demonstrating that at the very least, the techniques of compliance therapy were not restricted to experts in an inpatient setting.

Training needs in Australia: the development of Medication Alliance

It seems clear that optimal medication use is important, that mental health consumers commonly do not optimally use psychotropic medications and that, in Australia, community mental health workers are not trained in specific skills to enhance medication adherence. There also appears to be an established training program in Gray's 'medication management' that might meet that need. The question is, can medication management be imported into Australia?

There are a number of challenges to the importation of Gray's program, as it stands, into an Australian context. Key among these are practical issues. Can the Australian mental health care system meet the costs associated with work release (80 hours) provided in the UK study? What are the implications for the dissemination of training to rural and remote sites and across different jurisdictions (and States)? There are also issues with respect to potential differences between populations. In the UK study, 50% of clients were receiving depot medication and only 20% of clients were prescribed atypical medication. In Australia some sites report up to 80% of clients are treated using atypicals (eg. Barwon Mental Health Service). Finally, Gray and colleagues failed to report on any attempt to manage or measure discrepant clinician attitudes, such as the low priority applied to the therapeutic alliance, as reported by Coombs et al., (2003).

In response to these issues, a team of clinicians and academics at the Illawarra Institute for Mental Health developed Medication Alliance (Byrne et al., 2003). The development of Medication Alliance involved wide consultation with clinicians, patients, carers, and other researchers (including Gray and colleagues). Our review of the literature indicated that far from being of low importance, the development of the therapeutic alliance was a key strategic target in the provision of adherence interventions, a finding supported by patients and carers. Guided also by Health Behaviour theories, Medication Alliance surveyed the key features of successful adherence interventions (such as medication management and compliance therapy) and built upon these with a greater focus on the development of skills in the individualised assessment of patient need. Importantly, Medication Alliance was developed with the needs of Australian dissemination issues in mind, and the duration of the training was kept to a minimum.

The final Medication Alliance ‘therapy’ approach integrated components of an adherence intervention into a standard evidence-based therapy approach. This included a process of engagement with the consumer, psychometric, clinical and functional analytic assessment of medication-taking behaviour, the delivery of targeted therapy for identified needs (such as motivational interviewing, CBT and problem solving), and evaluation of treatment outcomes. Added to this, Medication Alliance provides an opportunity to reflect upon duty of care obligations as they relate to assisting the patient to resolve medication issues and, where required, the use of more directive intervention strategies.

Does it work? Outcomes of a Medication Alliance pilot study

Following Gray et al., (2003), we undertook a trial to determine to what extent Medication Alliance enhanced clinician skills and knowledge. In keeping with earlier observations, we added to our evaluation two measures of clinician attitudes as they relate to working with people who do not make optimum use of their medications. Training was provided to two groups of Tasmanian mental health workers (total 23 participants), with the duration of training being four days. Included in this time were
all data collection points. Total actual training time equated to a little over three days. The demographic characteristics of the health workers (Slide 19) indicated that our sample was mature and experienced, with relatively average caseloads. Furthermore the training was pertinent to their needs, with 70% of their caseload experiencing psychotic disorders and 35% reported as variable or unreliable in their use of medication.

Outcome measures fell within three domains: knowledge, attitudes and skills (Slide 20). There were two knowledge measures. The first, the Medication Alliance Clinician Knowledge Questionnaire, is a 15 item multiple-choice questionnaire that was developed by the Medication Alliance team to assess participant knowledge of material taught in the training program. The second knowledge measure, referred to as the Functional Analytic Case Formulation, is a case vignette detailing information for a person who has become unreliable in their medication use. The task is for the participant to identify the range of possible reasons for the change in adherence, and in particular, to identify the reasons that appear to be functionally related to the changed behaviour.

Attitude scales included the Elsom Therapeutic Optimism Scale (ETOS) and the Medication Alliance Beliefs Questionnaire (MABQ). The ETOS was developed by Stephen Elsom at Monash University, initially for the Medication Alliance program. The ETOS measures the extent to which the participant feels optimistic about treatment outcomes for the people on their caseload. The MABQ surveys five constructs in relation to the participant’s work with people whose adherence to medication is variable: motivation to work with them; adequacy of knowledge to work in the area; degree of expected work satisfaction when working with this type of patient; sense of self esteem as a result of this type of work; and perceived legitimacy to work in this area.

Skills were measured via a blind rating of videotaped role-plays. The rating device, the Medication Alliance Cognitive Therapy Scale for Psychosis (MACTS-Psy) was an adapted version of the Cognitive Therapy Scale for Psychosis (Haddock et al., 2001). The MACTS-Psy was specifically focused on a subset of behaviours taught and rehearsed in the training program. These were the participants’ attempts at setting a therapy agenda, their ability to undertake an assessment of the ‘patient’s’ problem, their use of one or more therapy skills to resolve the problem, how well they supported the therapy with homework tasks, and the overall quality of the intervention. The quality of the intervention was rated according to evidence of engagement, assessment, therapy, evaluation of the session, proactive therapy approaches and demonstration of empathy.

Our main analysis of the findings was by way of a series of paired samples t-tests. Although we had specific directional hypotheses, we chose 2-tailed p values with Bonferroni corrections to reduce the potential for Type 1 error. Analysis was conducted using SPSS Version 11.0.

At the very least, we expected to find that by attending the workshop, participants’ knowledge would be enhanced. This is precisely what we found ($t = 4.27, p < .000$), indicating that the participants’ ‘factual’ knowledge about adherence issues had been enhanced. However, we were more interested in how well the participants were able to apply that knowledge in order to understand an individual’s reasons for non-adherence. This was measured by the functional analytic case formulation. We found that participants improved in their ability to identify both possible reasons for non adherence ($t = 3.32, p < .003$) as well as the specific causal variables ($t = 2.73, p < .013$).

Likewise, we were able to demonstrate significant attitudinal change among participants. Given that clinician optimism has been associated with positive outcome expectancies by the patient, and following a Health Beliefs model in relation to adherence behaviour, we were keen to effect an improvement in participant optimism. This was achieved ($t = 3.15, p < .005$), with the greatest change occurring among those participants who were least optimistic to start with. However, results on the MABQ were less comprehensive, with improvements only observed in the participants’ sense of adequacy of their knowledge in working with people who have medication non-adherence issues ($t = 4.43, p < .000$) and the extent to which trainees expect to derive work satisfaction from engaging with
people who have medication non-adherence issues ($t = 3.31, p < .003$).

The clinical domain assessed the extent to which participant skills were enhanced as a result of attending training. This represented a good point of comparison with the work of Gray et al., (2003), given that their program was a 10 day program (versus the equivalent of 3 days in *Medication Alliance*) and that the Gray program was conducted over 10 weeks with weekly supervision and practice of skills. If we were able to demonstrate skills enhancements, even across a limited array of skills variables, then we might conclude that the *Medication Alliance* program is a valid adherence-training program for the Australian health system.

In an improvement on Gray’s design, pre-training/post-training video role-plays were blind rated by two experienced therapists, enabling the determination of inter-rater reliabilities (Pearson $r$). Of the five skills, four were significantly enhanced. Agenda setting is an important skill in developing a collaborative framework with patients and in managing limited time. Participants significantly improved in their use of an agenda ($t = 4.04, p < .001, r = .71$). *Medication Alliance* provided skills based training in motivational interviewing, CBT techniques and problem solving skills, which were assessed in combined form as Total Intervention Skills. There was a significant improvement in total intervention skills ($t = 5.23, p < .000, r = .72$). The effective use of homework has been shown to be associated with enhanced treatment gain (Kazantzis and Deane, 1999) and was a specific focus of training in *Medication Alliance*. Participants demonstrated a significant improvement in their use of homework as a result of training ($t = 4.19, p < .000, r = .56$). Finally, the overall quality of the participants’ intervention strategy was enhanced following training ($t = 5.87, p < .000, r = .60$).

A limitation of the present study is the modest inter-rater reliability coefficients. One of the raters had to be replaced at short notice and the extent of rater training was unavoidably affected. For that reason the fifth skill, Problem Assessment, was deemed non-significant ($t = 2.65, p < .015$) with a Pearson’s $r$ of -.01. However, given that *Medication Alliance* training is significantly shorter than comparable (eg. Gray et al., 2003) programs and that inter-rater reliabilities were calculated, we contend that these results are quite encouraging.

Also encouraging were the positive ratings provided to the program by participants. The workshop evaluation questionnaire involved ten questions rated on a 1 - 7 Likert scale, with 7 indicating the most positive rating. There was also an opportunity for participants to make specific narrative comments on the training program. There was one participant outlier who consistently rated items negatively. We included the data of this person in all analyses, including the workshop evaluation. Not withstanding the relatively small sample size in this study, *Medication Alliance* was rated at about 5/7 and above across evaluation items (Slide 34). Given that the sample included experienced and well qualified clinicians, we contend that this is a clear endorsement from the field. Of particular note was the rating of 6.48 on the critical item ‘I would recommend *Medication Alliance* training to other clinicians’, providing a clear statement of the perceived utility of *Medication Alliance* training.

**Summary**

*Medication Alliance* training improves clinician skills, knowledge and attitudes in relation to working with patients who do not effectively use their medications. It represents an improvement upon previous similar programs in that it is focused on ‘coal face’ clinicians; it enhances attitudes and beliefs; and it is relatively brief. One key question remains however: does *Medication Alliance* training for clinicians result in clinical improvement for patients? Answering this question constitutes the next phase in the development of a *Medication Alliance* with consumers of mental health services.

Postscript: Mental health services who may wish to participate in the clinical trial of *Medication Alliance* are invited to contact Mitch Byrne (mbyrne@uow.edu.au or + 61 2 4221 5310). This is a staggered trial and sites will be included up to and including 2005.
References


