Full title: A targeted intervention to improve monitoring of antipsychotic-induced weight gain and metabolic disturbance in first episode psychosis

Running title: Improving metabolic monitoring in early psychosis

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Abstract

Objective: International Guidelines recommend monitoring for weight gain and metabolic disturbance in patients prescribed second generation antipsychotics. We aimed to investigate whether a targeted intervention could improve levels of monitoring in a first episode psychosis clinic.

Method: A pre-intervention audit of both metabolic screening rates and specific monitoring of weight and metabolic indices following the initiation of antipsychotic medication was performed in our first episode psychosis clinic. This was repeated 18 months later following an intervention that included a number of targeted improvement strategies based on an analysis of barriers and enablers to performing monitoring within the clinic. The intervention included provision of monitoring equipment, interactive educational events, reminders and prompts and embedding processes for monitoring within team structure.

Results: There were significant improvements in both the screening of metabolic indices and the monitoring of indices following initiation of antipsychotic medications. There were also improvements in the number of active interventions offered to clients by clinicians. However, the level of guideline concordant monitoring remains low within our service.

Conclusions: A comprehensive program of implementation strategies can improve both screening and monitoring of the metabolic side-effects of antipsychotic medications. Further focused strategies are necessary to continue to improve monitoring to guideline concordant levels.

Keywords:

Antipsychotic medications; metabolic monitoring; implementation

Word count: 4931

Introduction

Individuals with schizophrenia have a 20% shorter life expectancy than the general population (1) with the majority of this excess mortality from physical causes such as cardiovascular disease rather than from suicide (2). Obesity and abnormalities in glucose and lipid metabolism are known to be risk factors for cardiovascular disease and are especially prevalent in those individuals with psychotic illnesses such as schizophrenia (3). Individuals with psychotic disorders such as schizophrenia also appear to have poor access to adequate physical health care and poorer treatment of physical health problems (4, 5). In addition to this, there is increasing recognition and concern about the metabolic side effects of second-generation antipsychotics (SGA's). Individuals with schizophrenia who take such medications have an increased risk of significant weight gain, diabetes mellitus, and an atherogenic lipid profile (6-9)

It appears that individuals experiencing their first episode of psychosis (FEP) could be particularly susceptible to weight gain and metabolic dysfunction when taking antipsychotics, especially SGA's (6, 10). Concern over weight gain interferes with medication adherence (11, 12), which may in turn increase relapse and impact negatively on quality of life, (13, 14) impacting on the early recovery process (15). Therefore addressing this concern is essential in terms of preventing long-term negative consequences. At the same time, there is evidence that various pharmacological (16) and non-pharmacological interventions can prevent and manage this weight gain and could benefit this population if offered early (17-19).

In response to these concerns a number of clinical guidelines have been produced recommending regular monitoring of weight gain and metabolic profiles in those prescribed antipsychotic medications (20). In Australia such a consensus based guideline was published in 2004 (21).

Despite these guidelines, the level of “metabolic monitoring” is invariably poor in most clinical services. Data from the UK report low rates of monitoring in assertive outreach teams; for example only 17% of individuals had a recorded measure of obesity and 28% a recording of blood glucose in the previous year (22). Similar low rates of monitoring are reported in the US and Australia (23, 24). The limited data on levels of monitoring in FEP suggests that this is also the case in this population (25)

Considerable evidence suggests that incorporation of evidence based guidelines into every day clinical care does not necessarily follow the dissemination of guidelines (26, 27). A range of strategies has been used to disseminate and implement guidelines into clinical practice. The evidence does not suggest any one single intervention as most useful but highlights the importance of using interventions that are specific to the setting and are theoretically driven (28). The importance of identifying and addressing specific barriers and enablers for behaviour change is consistently highlighted in this literature (26, 29, 30).

Attempts to improve monitoring in other clinical services

It appears that legislative processes and practice recommendations such as the US Food and Drug Administration (FDA) department warnings and the American Psychiatric Association (APA) guidelines about metabolic effects of SGA's have had limited effect on practice (31). More specific implementation strategies to improve monitoring for metabolic syndrome have been described by an implementation research initiative in the UK. Barnes and colleagues describe an intervention consisting of audit and feedback as well as provision of educational tools and physical health and lifestyle information for patients. There were attempts to individualise interventions to services, and to address some pre-identified barriers to monitoring. They demonstrated a considerable improvement in monitoring but noted that even after the intervention only a minority of patients received screening in accordance with best practice recommendations (32). In Australia, others have attempted to outline potential barriers to improving practice (33) and have proposed the use of monitoring algorithms (34). However, we were unable to indentify any approaches to improving monitoring within a younger first episode psychosis population, a population that appears at particular risk for significant metabolic problems.

Concern about the incorporation of best practice regarding the management of side effects from second-generation antipsychotics arose in early 2006 at our first episode psychosis program the Early Psychosis Prevention and Intervention Centre (EPPIC) in Melbourne. Anecdotally clinicians reported that limited monitoring of weight gain and metabolic side effects was occurring. We therefore aimed to investigate the level of

monitoring in our service and whether an intervention, targeted at identified barriers and enablers to performing monitoring, could subsequently improve levels of monitoring.

The main aim of this study was to investigate whether a targeted implementation strategy could improve: 1) general "screening" of metabolic parameters in a first episode psychosis population and 2) clinical guideline concordant metabolic "monitoring" for those young people initiating antipsychotic medication. In addition, we also wanted to compare our current rates of screening for various indices with other services.

Materials and methods

Setting

Orygen Youth Health (OYH) is a comprehensive public youth mental health service for those aged 15-25 years old living in the Western Melbourne. The first point of contact with the service is the crisis and assessment team or in patient unit and then depending on presentation the patient is transferred to the appropriate continuing care team (CCT). EPPIC is a separate clinic within this service and accepts patients with FEP. Paients must have a diagnosed psychotic disorder. Patients receive a maximum of 2 years with the EPPIC CCT but might also be admitted to the service's inpatient unit. The EPPIC service has been described in detail elsewhere (Edwards et al, 2002). EPPIC receives around 300 new referrals a year. Patients accepted by EPPIC are assigned an individual "case manager" and a treating psychiatrist. There are 9 psychiatrists and 10 case managers (mixture of psychiatric nurses, social workers, psychologists and occupational therapists).

Trial design

The trial was a quasi experimental before and after study, with data collection taking place at baseline or pre-intervention and 2 ½ years later following the intervention (post intervention).

Eligibility and recruitment

Inclusion/exclusion criteria

The intervention was aimed at the entire cohort of clinicians (case managers and psychiatrists) currently working in the EPPIC clinic as well as those working on the inpatient unit and the crisis/assessment team during a 6 month period between January 2008 to July 2008. There were no exclusion criteria for clinicians as this was a service-wide intervention. The files of all consecutive clients first entering the EPPIC clinic during the pre-intervention and post-intervention time points were audited.

Assessment of monitoring practice

The audit of metabolic monitoring practice was performed using a predesigned standardized audit form. The audit items were derived from our guideline (see box 1).

The pre-intervention audit was undertaken on the files of all EPPIC patients presenting consecutively to the clinic for the first time between January 1 2006 and June 30 2006. Data on metabolic monitoring/screening in the preceding 18 months was extracted from these files. The results of this pre-intervention audit were also used to inform the intervention strategies (see below). A post-intervention audit was performed on patients

consecutively presenting to the EPPIC clinic between September 1 2008 and February 28 2009. The audit format differed slightly between baseline and post-intervention making some direct comparisons not possible.

Ethics

Ethical approval for the project was received from the local ethics and quality assurance committee.

Outcome measures

Guideline concordant metabolic monitoring:

This was defined as completion of all recommended monitoring indicated in box 1 at baseline, 1 month, 3 months and 6 months (post intervention data on the 12 month time point was not available due to time limitations). Our guideline recommendations were substantially stricter than those from other bodies (3, 21), for example, we specifically added a 1 month time period to monitor the early weight gain identified by studies in FEP populations (17). Therefore, we also defined additional minimum monitoring and screening standards as outcome measures.

Minimum Metabolic Screening (MS): this was defined as the completion of full metabolic measures including obesity measures (BMI or weight and height or waist hip ratio); and metabolic blood tests (lipids and glucose) at some point within 6 months of being prescribed an antipsychotic

Minimum Metabolic Monitoring (MM): this was defined as the completion of full baseline measures including both obesity measure (BMI/waist hip ratio/ or weight) and metabolic blood tests plus the completion of full measures at between 1-6 months following initiation of antipsychotic medication (or 1 to 6 months after baseline).

Secondary outcome measure

Additionally, we aimed to compare our post intervention monitoring rates with that of other services. Therefore, we calculated monitoring/screening rates of 4 separate metabolic indices individually from the post intervention audit both at baseline and at some point in first 1-6 months following antipsychotic initiation. This enabled direct comparison of our results with those of previous studies from other services. These 4 metabolic indices were: 1) obesity measures (BMI/waist-hip circumference/weight) 2) Blood Pressure 3) Glucose measure (glucose or Hb1Ac, fasting or random) 4) Blood lipids (fasting or random). Such information was only available from the post-intervention audit.

Other outcomes

We compared the rates of documented interventions for metabolic/weight disturbance offered by clinicians pre and post intervention.

The intervention

Barrier and enabler analysis

The intervention was developed on the basis of interviews conducted with psychiatrists at EPPIC following the baseline audit. The interviews have been described in detail elsewhere (35). Interpretation of the interview data using thematic analysis allowed identification of barriers and enablers to implementing monitoring guidelines that were mapped to theoretical domains which help to understand and change behaviour.

Based on the barriers and enablers identified in the interviews by psychiatrists (35), a multifaceted intervention using a range of behaviour change strategies to target the identified constructs was adopted to implement routine monitoring. The choice of interventions were informed on the basis of evidence of effectiveness and expert opinion (28). The intervention was also informed by the pre-intervention audit; for example we were able to identify which parts of the service were better or worse at performing monitoring and therefore where to focus particular parts of our intervention.

Components of intervention

1) Development of local guidelines (see box 1)

We developed local consensus evidence based monitoring guidelines for the service, and distributed this to all clinicians, as a wall poster. This guideline is shown in box 1. These were based on a number of the guidelines including the Australian consensus statement (36). For further information regarding this see (35). The existing form that was being used to record metabolic measures was adapted to reflect the guidelines for monitoring. The form also served as a reminder of what and when to monitor and was designed as such. It was placed in all files by medical records staff.

2) Educational intervention

A series of didactic and interactive seminars were conducted, using persuasive communication to highlight the long term consequences of metabolic disturbance and weight gain in young people taking second generation antipsychotics. The seminars were also used to disseminate the recommendations from the locally developed guidelines. This format also adopted feedback about the service-wide levels of monitoring from the pre-intervention audit of current clinical practice.

3) Service/structural changes

Structural change was also part of the intervention. Prompts were provided in the form of the paper-based monitoring sheet being placed in every patient file. Regular reviews of a patients' metabolic status were built into the EPPIC regular clinical review process (which occurs on a 3 monthly basis for all clients) by allocating a metabolic "champion" to be responsible for reminding clinicians. This "champion" was a member of the research team and was a source for further consultation if there were difficulties in monitoring. A service policy on metabolic monitoring was also developed and distributed to all psychiatrists in the service.

4) Provision of monitoring equipment

We ensured the equipment required to undertake monitoring (e.g. scales, tape measures, blood pressure cuffs) were located in each psychiatrist's room. Stamps that indicated the

necessary blood tests for monitoring were placed in the psychiatrists' rooms to aid completion of the correct blood investigations.

This range of interventions was initiated over a 6 month time frame beginning in January 2008; the expectation was that they were subsequently to be integrated into the standard clinical infrastructure and pathways of the service.

Statistical analysis

We compared the monitoring at the two time points (pre and post-intervention) on the three main outcome measures of guideline concordant monitoring, minimum metabolic screening (MS) and minimum metabolic monitoring (MM) as well as the secondary outcome of number of interventions offered to clients. The data was analysed using SPSS version 18 (SPPS, Chicago, IL, USA). The differences in rates between pre and post-intervention were examined using t tests for continuous data and pearsons chi for categorical data.

Results

Of the 119 patients presenting to EPPIC for the pre-intervention audit, 118 files could be obtained for audit as one file was missing. There was metabolic data available from 106 of these files. For the post-intervention audit there were 106 patients presenting to EPPIC at this time. The files on two of these patients could not be located. Data on metabolic monitoring was available on 86 of these patients. There were a number of files where patients were not prescribed antipsychotic medication during their period of care. These

patients were therefore not included in the audit and this accounts for the attrition from the original samples. There were no differences in entry criteria into the service between at the two audit time points. There were also no differences in mean age or gender distribution of the samples at the two time points.

Difference in guideline concordant metabolic monitoring, metabolic screening (MS) and metabolic monitoring (MM) pre and post intervention

No patients had all the strict guideline concordant metabolic monitoring completed for the 6 months following starting antipsychotic medication at either time points. Based on our defined criteria, minimum metabolic screening (MS) (or completion of full metabolic measures at some point within 6 months of being prescribed an antipsychotic) was completed on 22.2% (n=24) of patients at pre-intervention. A significant improvement to 81.4% (n=70) was found post intervention (Mantel-Haenszel Chi = 8.171, p=<0.001). The rate of minimum metabolic monitoring (MM) (completion of full baseline measures plus the completion of full measures at between 1-6 months following initiation of antipsychotic medication) was low at both time points but did improve significantly from 1.7% (n=2) to 39.5% (n=34) post-intervention (Mantel-Haenszel Chi = 6.897, p=<0.001). The rates pre and post intervention are shown in figure 1.

Insert figure 1

Post intervention rates of monitoring/screening for the 4 separate metabolic indices

The monitoring and screening rates (as previously described) for the individual metabolic indices of obesity measures, blood pressure, glucose measure and blood lipids are shown in table 1. The individual rates were higher for the screening outcomes (74.4% to 84.9%) than for the monitoring outcomes, which ranged between 17.4% for blood lipids to 34.9% for obesity measures.

Insert table 1

Rates of preventative interventions

Finally, with a view to implementing service wide targeted preventative interventions, the number of clinicians intervening to prevent patients' potential weight gain and metabolic side effects, was analysed. Overall, there were only 8 (7.2%) instances where clinicians were noted to have intervened with their patients in the pre-intervention sample. Post intervention the number of patients where clinicians' had documented interventions was 22 (29.3%). This was significantly higher than pre-intervention (Mantel-Haenszel Chi = 4.069, p=<0.001).

Discussion

Summary of results

Following the implementation of a focused implementation strategy that addressed barriers and enablers, there was a significant improvement in both the overall screening and initial monitoring of metabolic indices. There was also an improvement in number of

interventions for metabolic problems offered by clinicians. The rates of screening for the 4 specific areas of metabolic problems (weight, blood pressure, glucose and lipids) were relatively high post intervention. However, despite the implementation strategy, the rates of monitoring metabolic disturbances following initiation of second generation antipsychotic medications were still far from concordant with current clinical guidelines.

Comparison of screening rates

The screening rates in the post-intervention audit presented here (table 1) are considerably higher than a recent UK audit of a FEP service in the UK (25). Rates are also higher than those given for screening from adult psychiatry services in the UK (32, 37). The results we present in table 1 are derived from very similar variables to the two UK studies of Barnes and colleagues (22, 32), the main difference being that the screening rates from our study are taken over a 6 month period as opposed to a 12 month period in these studies (and therefore our results may be higher than if we looked at a 12 month period). Despite this, screening rates remain over twice as high in our post-intervention sample than in this study, as shown in this table. Direct comparisons with previous research for metabolic monitoring following initiation of antipsychotic medication are more difficult to make. However, our rates of baseline testing on initiation of medication compare favourably to those for baseline testing in relation to new prescriptions for antipsychotics in the US (23).

Comparison with other quality improvement programs

Other similar quality improvement programs have managed to change practice in this area. However, these have often had a less targeted approach to the implementation strategies used, not pre-identified local barriers and enablers and have been in older populations (32, 38). Researchers in the area of metabolic disturbance in relation to antipsychotic therapy have specifically advocated for the investigation of barriers and enablers to change as a prerequisite to any implementation efforts (33, 38). It also appears that the first episode population, given the relatively younger age than general adult psychiatry, may suffer from particular difficulties with regard to accessing and prioritising physical health care compared to those in adult mental health services. For example, at least 60% of the clients in our service are unable to identify a regular General Practitioner (GP). Some monitoring, such as blood tests, were not routinely done on site and relied on a young person accessing a local pathology service or a GP. Low monitoring of baseline metabolic blood levels have been reported in other first episode psychosis populations (25). One of the particular difficulties in youth populations in general is accessing appropriate physical healthcare. This may be compounded in young people suffering from mental illness. It is therefore not unexpected that these rates are relatively low, but calls for more creative strategies to address this particular problem such as the headspace initiative (39).

Limitations

This was a naturalistic study examining the effects of a series of implementation strategies on current practice. Given the non randomized nature of the trial we cannot be

sure that the change was not simply an effect of time and an increase in profile of metabolic problems in this population. There was also some acknowledged turnover of staff and the clinicians whose behaviour was subject to the first audit were not exactly the same as the follow-up. However, the majority of the senior staff and "culture carriers" were the same at the two time points; rotation of junior psychiatrists is an inevitable consequence of psychiatric training in public hospitals. There were a small number of files in both audits we were unable to locate. We do not feel that this amount of missing data biased our results.

Future directions

We are encouraged that the interventions were able to change practice in a number of areas. However, practice is still far from concordant with our guideline or even our less stringent minimum guidelines. We were aware, both early in the study, and from our final results, that our recommended guidelines were particularly strict for clinicians to follow (especially the 1 month time point) in relation to other guidelines. Despite this, further intervention approaches are obviously needed to improve level of monitoring in our service. Audit and feedback has been shown to be effective when baseline concordance with recommendations is low and when the audit and feedback is continuous (40). We plan to make more continuous audit and feedback possible by a specifically designed electronic database to capture routine metabolic monitoring data for each client. This will be available to all psychiatrists and will show changes over time in metabolic status and weight for each of their clients. The database will also serve as a reminder system or prompt to complete monitoring. We aim to evaluate the impact of such an innovation.

One identified barrier we were unable to address in our reported implementation strategy was the lack of knowledge or skills that clinicians had about how to intervene with a young person who gains weight or develops metabolic complications. We have recently developed a local evidence based protocol for identification and management of abnormal results and are currently attempting to develop a comprehensive program of interventions to reduce weight gain and address metabolic disturbance.

We are also investigating the effectiveness of changes to service delivery, we are considering trialling the use of an on site phlebotomist and/or the possibility of a sessional General Practitioner or physical health nurse being available for physical consultation in the same building. Other researchers have highlighted success in monitoring when using a dedicated physical health nurse to co-ordinate and administer monitoring (41). However, both approaches have financial implications and would need evaluation of their cost benefit.

Conclusions

Using a targeted implementation strategy we were able to substantially improve the routine screening and monitoring of weight and metabolic indices in a first episode psychosis service. Implementing guideline-concordant routine monitoring is essential to ensure better outcomes for clients. Services should endeavour to use such targeted implementation strategies in other areas where practice does not conform to guideline standards.

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Conflicts of Interest:

Dr Thompson has investigator initiated grants with AstraZeneca and Janssen-Cilag Pty limited. He has also been awarded a Pfizer Neurosciences Research (NSR) grant. Professor McGorry has investigator initiated grants with AstraZeneca and Janssen Cilag Pty limited. He has also received honoraria from AstraZeneca, Janssen-Cilag, Pfizer and Eli Lilly.

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Box 1: Guideline for monitoring of weight and metabolic side-effects developed at the service

Box 1.

Approved EPPIC guidelines for standard clinical practice for weight and metabolic monitoring (developed on the basis of guidelines and in consultation with multi-site experts in the field and clinical team and approval from clinical management group)

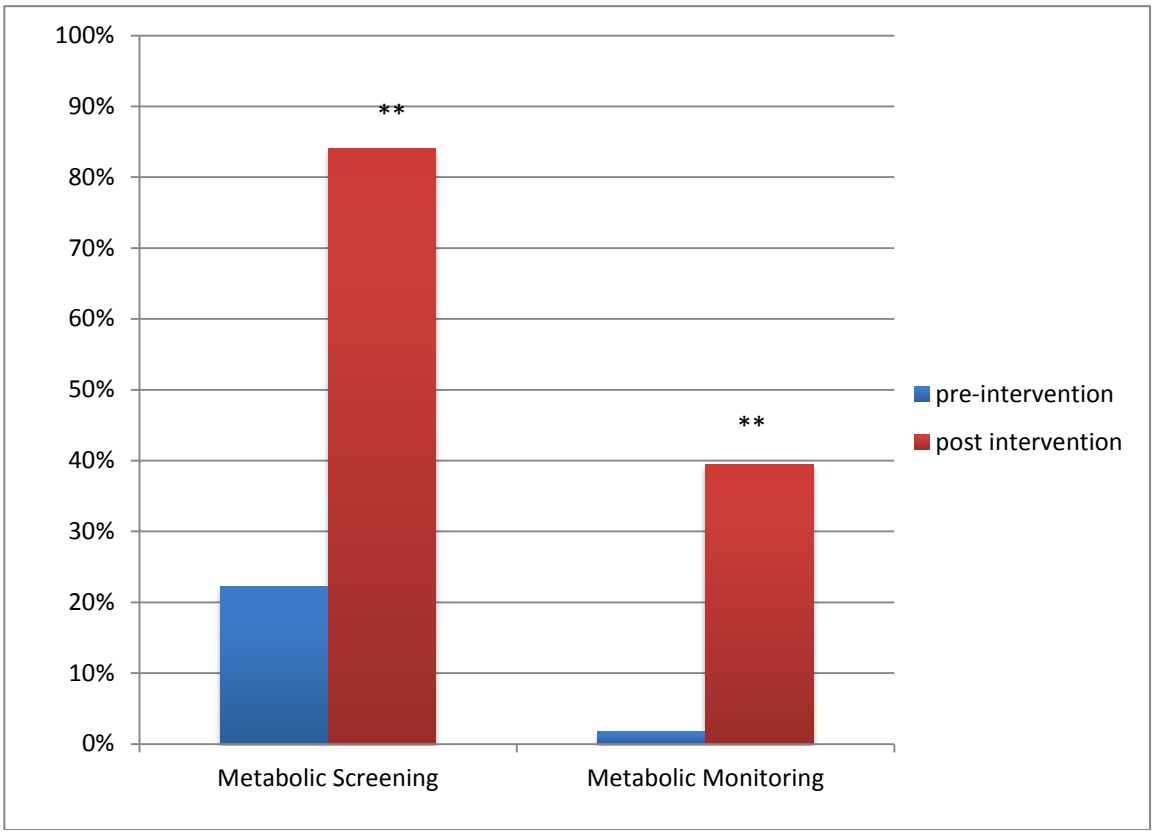
Indices to be assessed:

- Height and weight to estimate BMI
- Systolic and diastolic blood pressure
- Waist and hip circumference (to obtain waist-hip ratio)
- Blood glucose (fasting)
- Total cholesterol
- Low and high density lipoprotein
- Triglycerides
- Number of cigarettes smoked daily
- Level of daily exercise
- Fasting blood sample to measure insulin resistance if fasting blood glucose level abnormal

Assessment time points:

- Baseline, (or as close to)
- 1 month (We seek to collect)
- 3 months
- 6 months
- 12 months
- 18 months

Figure 1. Percentage of clients with Minimum Screening (MS) and minimum monitoring (MM) at pre (n=106) and post intervention (n=86) time points



** p<0.001

Table 1: Rates of metabolic screening and metabolic monitoring (following antipsychotic initiation) over a 6 months period for 4 separate metabolic indices at the post-intervention time point and comparison with a UK audit over a 12 month period (32)

	Metabolic Screening (MS) N=86	Metabolic Monitoring (MM) N=86	UK audit of metabolic screening (32) N=1516
Number with obesity measures recorded (%)	73 (84.9)	35 (40.7)	655 (43)
Number with blood pressure recorded (%)	70 (81.4)	36 (41.6)	511 (34)
Glucose level recorded (%)	64 (74.4)	21 (24.4)	571 (38)
Blood lipids recorded (%)	65 (75.6)	23 (26.7)	532 (35)

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