

# A New Psychosocial Tool for Gaining Patient Understanding and Acceptance of Long-acting Injectable Antipsychotic Therapy

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## ABSTRACT

Nonadherence to antipsychotic medications in serious, persistent mental illness remains a significant clinical challenge. Long-acting therapy was developed to help improve adherence to schizophrenia therapy and provide an effective means for ameliorating symptoms and preventing relapse. The Agency for Health Care Policy and Research/National Institute of Mental Health Schizophrenia Patient Outcomes Research Team recommends that antipsychotic long-acting therapy be strongly considered for patients who have difficulty adhering to an oral medication regimen or who prefer long-acting therapy. Depot conventional formulations have long been available; for clinicians and patients who would rather use an atypical antipsychotic, studies with risperidone long-acting therapy suggest that it is efficacious and well tolerated. A common concern of clinicians who elect to initiate long-acting therapy is how to introduce the possibility of changing from the current oral antipsychotic to a long-acting therapy injection.



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As with other aspects of patient care, having an established therapeutic relationship with the patient is advantageous for recommending changes in care, but the way in which the idea is approached may improve the likelihood of its acceptance. To help clinicians broach a recommendation of long-acting therapy with their patients, the GAIN approach was designed as a standard interview process for presenting this option. It encompasses (and is an acronym for) goal setting, action planning, initiating treatment, and nurturing motivation. This novel clinical tool is based on the principles of motivational enhancement therapy, a patient-centered approach that seeks to evoke the patient's own motivation for change, to consolidate the decision to change, and to plan for change. This tool is also based on the Listen-Empathize-Agree-Partner, or LEAP, communication strategy. Motivational enhancement therapy, which is typically brief, has been found effective in several chronic illnesses in both outpatient and inpatient settings. GAIN may be a practical tool for aligning clinician-patient expectations and enhancing long-term maintenance of therapy.

## INTRODUCTION

Nonadherence to oral antipsychotic medications is one of the most significant clinical challenges in the treatment of schizophrenia. Reviews indicate that nonadherence rates are as high as 50 percent in the first year of treatment, and almost 75 percent in the first two years of treatment.<sup>1,2</sup>

Despite evidence that continuous antipsychotic treatment is more effective than interrupted treatment,<sup>3,4</sup> and the fact that long-acting therapy (LAT) is strongly recommended,<sup>5</sup> LAT use in the United States remains low. Concern with this low rate of LAT use has been heightened by recent studies demonstrating that partial adherence to a prescribed medication regimen is common

among patients with schizophrenia and detrimental to treatment outcomes.<sup>6</sup> In an effectiveness study gauging the clinical experience of antipsychotic treatment in a naturalistic setting, Docherty et al<sup>6</sup> found that 9 of 10 patients taking oral antipsychotic medication for one year were only partially adherent. The degree of their adherence was linked to outcome; lower adherence was significantly associated with higher (worse) symptom ratings. Another analysis found that patients who stopped taking their medication for as little as 10 days incurred a significantly increased risk of hospitalization.<sup>7</sup> Other studies have demonstrated a direct relationship between reduced adherence, rehospitalization, and hospitalization costs.<sup>8,9</sup>

## LONG-ACTING INJECTABLE ATYPICAL ANTIPSYCHOTICS: WHAT HAVE WE LEARNED SO FAR?

Until recently, the only LAT options in the United States were formulations of the conventional antipsychotics haloperidol and fluphenazine (i.e., haloperidol decanoate and fluphenazine decanoate). A newer alternative is currently available with an atypical antipsychotic, risperidone long-acting therapy (RLAT). Initial studies in clinically stable patients with schizophrenia or schizoaffective disorder have established the safety and efficacy of RLAT.<sup>10-20</sup> demonstrating significant improvements in overall symptoms and quality of life, low rates of relapse and rehospitalization and high patient satisfaction with treatment.<sup>10,13,14,16,21</sup> Of note, these short- and long-term studies found that RLAT was well tolerated, with low rates of discontinuation due to adverse events and reportedly little pain from injections.<sup>10,13-16</sup>

In addition, RLAT has been shown to be efficacious and well tolerated in elderly patients, in those with illness diagnosed within three years, and in newly diagnosed

patients.<sup>17,18</sup> RLAT has also been evaluated in a prospective naturalistic study in patients with psychotic disorders and poor antipsychotic adherence, tolerability problems, or lack of effectiveness. Even in this difficult-to-treat population, approximately 50 percent completed the six-month study, with two-thirds of patients experiencing improvement in Clinical Global Impression (CGI) score.<sup>19,20</sup> Taken together, these studies suggest that RLAT provides clinical benefits for a range of patients extending beyond those who are persistently nonadherent.

## RATIONALE FOR THE GAIN APPROACH

Although antipsychotic LAT has advantages over daily oral formulations, injectable medications have been reserved for only the most refractory cases of recurrent nonadherence and relapse. Use of LAT has also been limited by reluctance of many psychiatrists to administer injectable medications, confusing reimbursement procedures, and the belief that patients would invariably reject an offer of this treatment modality.<sup>22,23</sup>

In the relatively near future, as many as four new atypical antipsychotic LAT formulations may become available. To utilize these new therapeutic options effectively, however, several barriers associated with their use must be addressed. One of these barriers, patient acceptance, may be overcome by the use of structured psychosocial interventions. We have, therefore, developed a structured approach for gaining patient acceptance of treatment and to address the need for increased comfort on the part of clinicians in discussing LAT with patients with this goal in mind. Our approach encompasses goal setting, action planning, initiating treatment and nurturing motivation (GAIN).

## DEVELOPMENT OF THE GAIN APPROACH

GAIN was developed in the absence of a structured approach for

**TABLE 1.** The GAIN approach for long-acting therapy (LAT): stepwise objectives and structured interview considerations

STEP	OBJECTIVE
<b>GOAL SETTING</b>	Identify patient-based reasons for using antipsychotic LATs to help patients achieve long-term goals; discuss personal life, treatment goals and realistic goal selection with patient.
1. Establish clinical need for improvement	a. Help patients recognize the disparity between where they are and where they would like to be.
	b. Ask about the patient's hopes and expectations from treatment.
	c. Talk about current treatment and any issues associated with it (compliance, etc.).
	d. Work together on a list of medication and psychosocial treatment "pros and cons" and show how continuous treatment can help the patient to achieve goals.
	e. Frame the discussion in patient-specific, personal terms. If relevant, raise the patient's awareness of some of the difficult issues that he/she has had (e.g., "You've had two hospitalizations in the last year.").
2. Provide sensitive feedback	a. Seriously consider the patient's point of view.
	b. Identify differences between your perceptions and the patient's perceptions of current status and needs.
	c. Link identified goals with the barriers posed by potential relapse of illness.
	d. Agree to disagree and focus on areas of agreement.
3. Create a written goal plan with the patient	a. Ask the patient which specific life goals are most important (eg, desire to have a job, be more independent, etc).
	i. Pay as much attention to unrealistic goals as to the attainable ones.
	ii. Provide respectful "grounding" to support realistic expectations of life goals and therapy.
	b. Ask the patient to focus on one or two small goals that are the most important; focusing on too many goals or goals that are too big may be overwhelming.
4. Collaborate with the patient on a plan of action to achieve goal. <sup>26</sup>	a. Listen actively and reflectively to the patient's possibilities for action.
	b. Empathize with the patient's fears, frustrations, desires and discomforts.
	c. Partner; work with the patient on a plan of action and be willing to compromise.
<b>ACTION PLANNING</b>	With the patient and family, assess and consider actions necessary to achieve goals and discuss how LAT may specifically enable patients to attain the goals.
1. Show the patient that you, as a clinician, believe that treatment with an LAT may be an overall positive step.	a. Explore both the positive and negative aspects of treatment with LATs with the patient.
	b. Describe why you think that treatment with an antipsychotic LAT will help your patient to better achieve the life goals established previously.
	c. Allow the patient to express fears and concerns.
	d. If the patient has concerns about injection, clarify the history of prior treatment with an antipsychotic injection (either a short-acting agent in the emergency room [ER] or an older depot). Stress that a long-acting atypical injectable medication is not the same as the short-acting injectable given to "control" patients in the ER and that it differs from older depot medications.
2. Review the potential benefits and risks of LAT and explain how it works.	a. Long-acting injectable atypical antipsychotics need to be taken only periodically.
	i. It may be easier to receive periodic injections than to remember to take pills every day.
	ii. Steadier blood levels (no sharp peaks)
	iii. Other patients have improved significantly. <sup>10,13,14,16,21</sup>
b. Stress that coming in for a periodic injection allows the patient more opportunity to interact with the treatment team and discuss any problems or concerns about the long-acting nature of the medication.	
3. Re-link the specific goals potentially achievable with the help of an LAT.	a. Explain that taking medication regularly is crucial to staying well and making progress toward goals.
	i. Discuss specific changes of importance to the patient that may be expected with this new treatment and tie them to personal life goals.
	ii. Engage the patient's family or significant others to support the new treatment.

engaging patients in discussions of LAT and tested to support treatment initiation and maintenance. Motivational enhancement therapy (MET), which has been successful in motivating change in patients with alcohol and/or substance dependence,<sup>24,25</sup> served as the platform for the GAIN approach. GAIN is based in particular on the

LEAP (Listen-Empathize-Agree-Partner) communication strategy.<sup>26,27</sup>

LEAP focuses first and foremost on strengthening the therapeutic alliance so that the therapist/prescriber is more trusted and ultimately more persuasive in his or her recommendations to patients. LEAP was recently found to improve insight into illness, positive attitudes

about treatment, adherence with long-acting injectable medication, and motivation to change in patients with schizophrenia.<sup>27</sup>

As a MET-based instrument, GAIN is a structured clinical discussion tool to support clinicians and patients in considering LAT and to maintain patients' motivation to continue treatment. This tool also

**TABLE 1, CONTINUED.** The GAIN approach for long-acting therapy (LAT); stepwise objectives and structured interview considerations

INITIATE TREATMENT	Begin the new treatment plan, review practical aspects of treatment and which issues could interfere with treatment, and confirm the recognition and acceptance that use of an LAT can help reduce the risk of relapse.
1. Manage patient perceptions and experience.	a. Maintain a positive feeling within the medication administration setting (i.e., engage the patient and offer positive reinforcement).
	b. Explain in detail the mechanics and logistics of medication administration.
	i. Show the patient the planned injection location.
	ii. Minimize anxiety; make efforts to reduce waiting time to receive the injection.
	iii. Explain who will administer the medication and exactly how it will be done.
	iv. Be sensitive to the patient's dignity—ask about concerns about exposing this.
	v. Identify any perceptions the patient may have about injections.
	vi. Address any negative perceptions about injections.
	vii. Normalize the patient's dislikes about injections; compare these injections with other medical illness approaches (flu shot, insulin injections).
	viii. Explain that injections with newer LATs are much less painful than depot LATs.
	c. Consider data on pain (e.g., only 2% report injection pain, rated as mild).
	i. Seek patient feedback on the injection experience.
	d. Discuss with the patient the need for oral medications that should be continued.
	e. Remind patients that you look forward to seeing them again for the next injection and more feedback.
NURTURING MOTIVATION	Undertake proactive discussions around of the use of LATs with the patient, family and treatment team; assess progress toward goals.
1. Engage the patient in dialogue and listen carefully.	a. Ask how the patient is experiencing treatment.
	b. Be prepared to talk through all aspects (positive and negative) of treatment.
	c. Proactively ask the patient about any side effects, changes in medication, trouble getting to the appointment, etc.
	d. If the patient has ongoing known psychotic symptoms, check whether he/she has any fears of the new therapy.
2. After a few months of therapy, discuss the long-term treatment plan.	a. Explain to the patient that taking the medication is only one part of the larger overall treatment plan.
	b. Determine whether there are any additional interventions that may help your patient make greater progress toward goals.
	a. Ask the patient about life goals frequently and on an ongoing basis (e.g., at every visit or at minimum, every six months). Revisit the written plan from the goal-setting period regularly.

addresses barriers, such as needle phobia, stigma associated with injectable antipsychotics, and concerns about adverse effects (Table 1).<sup>10,13,14,16,21,26</sup>

The GAIN approach was developed via collaborative consensus by an eight-member steering committee of psychiatrists, psychologists, and nurses (see Acknowledgments) and designed for implementation with relative ease by any member of a clinical treatment team during a single or multiple clinical visit(s). As a patient-centered approach, GAIN focuses on engagement with patients to optimize the opportunity for success. Table 2 includes

examples of the clinical strategies that may be useful to clinicians who implement GAIN.

### INITIAL APPLICATIONS OF THE GAIN APPROACH

The Schizophrenia Treatment Acceptance Response Trial (START) evaluated the effectiveness of GAIN versus approach as usual (AAU) in acceptance of RLAT at clinical centers randomized to implement either option. The study consisted of a six-week “approach” phase, during which patients were exposed to GAIN or AAU over three visits, and a 12-week “treatment” phase, during which patients received

RLAT every two weeks. Rates of patient acceptance and adherence to treatment were high (and indistinguishable) in the GAIN and AAU sites. Possible reasons for these high rates include the positive effects of more frequent contact between patients and their treatment teams in this study than is typical in clinical practice, or because clinicians who participated in the trial were already motivated to encourage patients to accept LAT. Nonetheless, clinicians who used GAIN found it easy to implement, and almost all indicated that they would use this tool with their current and future patients (Janssen, data on file).

**TABLE 2.** Clinical strategies in using GAIN

- Consistency and continuity are advantageous: Identify and introduce the provider on the treatment team who will have the most interaction with the patient.
- Build a collaborative relationship with the patient to achieve trust and understanding.
- Understand the patient's perception of the advantages and disadvantages of treatment. Revisit these routinely, as weighing pros and cons is the basis of all decision making.
- Active or reflective listening is important—listen to your patient first, learn his or her point of view, and let the patient know that you have heard and understand what was said.
- Convey empathy concerning the patient's fears, frustration, and discomfort while normalizing these experiences.
- Avoid direct disagreement or arguments, as it usually increases resistance to acceptance of new recommendation.
- Refrain from offering unsolicited opinions; your opinions have more value when the patient asks for them.
- Make sure that all communications are recapped at the end of each session and then documented in the event that another treatment team member sees the patient at the next visit.

## FUTURE DIRECTIONS

START represents the first application of the GAIN approach, and the results suggest that it may be helpful in patient care. Further evaluation of its efficacy in a clinical setting is recommended to determine whether GAIN might also be useful for other pharmacologic approaches. Indeed, with adaptation, GAIN could be valuable for all patients with schizophrenia in the quest to enhance their acceptance of and adherence to antipsychotic therapy in general. The ultimate goal is to help the individual patient achieve the full benefits of therapy by encouraging adherence to treatment as prescribed.

## CONCLUSIONS

Clinicians can utilize GAIN for enhancing patient acceptance of and adherence to LAT by changing patients' perception of LAT as a punitive measure to that of a team-based action for long-term success. This structured approach also may be helpful for expanding the benefits of LAT to patients other than those in the START study, who were at high likelihood of acceptance before

this intervention. Our stepwise approach of discussing possible actions to reach therapeutic goals and then working collaboratively with patients to achieve those self-defined goals provides a team-based action for long-term success.

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