



Implementing and using a systematic risk assessment scheme to increase  
patient safety on a risk management unit for individuals with severe  
mental illness: A demonstration project

**Prepared by**

**Anne, G. Crocker, Ph.D.**

Assistant professor, dep. of psychiatry, McGill University  
CIHR-New Investigator, Douglas Mental Health University Institute

**Amparo Garcia, M.A.**

Clinical-Administrative Director of Clinical Activities,  
Knowledge Transfer and Teaching, Douglas Mental Health University Institute

**Mimi Israël, MD, FRCPC**

Psychiatrist-in-Chief, Douglas Mental Health University Institute  
Interim Chair, Associate Professor Dep. of Psychiatry, McGill University

**Yvonne Hindle, RN**

Clinical Administrator, Douglas Mental Health University Institute

**Danny Gagnon, Ph.D.**

Psychologist, Douglas Mental Health University Institute

**Carlos Venegas, RN**

Nurse clinician, Douglas Mental Health University Institute

**Erika Braithwaite, B.Sc.**

Research Assistant, Douglas Mental Health University Institute

**Marie-Ève Roy, M.Sc.**

Project coordinator, Douglas Mental Health University Institute

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## ACRONYMS & ABBREVIATIONS

<b>IIP</b>	Individual intervention plan
<b>HCR-20</b>	Historical-Clinical-Risk -20 scale
<b>NCRMD</b>	Not criminally responsible on account of mental disorder
<b>PCL-R</b>	Psychopathy Checklist-Revised
<b>REHAB-scale</b>	Rehabilitation evaluation Hall and Baker scale
<b>RMRU</b>	Risk management and rehabilitation unit
<b>SD</b>	Standard deviation
<b>SMI</b>	Severe mental illness (usually includes schizophrenia spectrum disorders, bipolar disorder and major depression)
<b>START</b>	Short Term Assessment of Risk and Treatability

## OVERVIEW

Assessment and management of risk for violence which were traditionally the responsibility of specialized forensic institutions are now requested in various mental health services. The Short Term Assessment of Risk and Treatability (START) is a patient-centered scheme informing multiple risk domains through a comprehensive assessment of dynamic risk factors and strengths based on a set of definitions. However, there is a dearth of literature on the implementation of such tools in real life mental health settings, their correlates with future behaviour and their perceived usefulness in clinical settings.

The objective of the current demonstration is two-fold: 1) Is the START associated with actual short-term challenging behaviour outcomes on an acute psychiatric unit? 2) How could START be thoroughly implemented in taking account typical barriers to dissemination of evidence practices?

START risk scores were predictive of physical aggression as well as aggression against objects in the month, 6 and 12 months following the assessment and were not statistically predictive of the other challenging behaviours measured. START strength scores were also predictive of physical as well as aggression against objects at one-month, 3, 6 and 12 months. Overall, the START was well integrated the team's clinical and administrative activities. However, a number of challenges need to be overcome in order to improve START implementation in the medium to long term.

This type of demonstration project is essential for clinicians, researchers and administrators to better understand what would be the best strategies to adopt for implementing and studying the implementation of risk assessment and management programs in a variety of mental health settings.

## EXECUTIVE SUMMARY

Changes to Civil and Criminal Codes as well as to mental health policies have resulted in clientele movements of individuals with a mental illness who display aggressive behaviour. In fact, there is an internationally observed tendency to allot an increasing number of inpatient beds to those most severely disordered individuals, who are likely to be acutely dangerous to self or others. Assessment and management of risk for violence which were traditionally the responsibility of specialized forensic institutions are now requested in various mental health services. Research conducted over the past 20 years has circumscribed risk factors and developed assessment instruments in order to target interventions. The Short Term Assessment of Risk and Treatability (START) is a patient-centered scheme informing multiple risk domains. The aim of the START is to encourage a comprehensive assessment of dynamic risk factors and strengths based on a set of definitions. However, there is a dearth of literature on the implementation of such tools in real life mental health settings, their correlates with future behaviour and their perceived usefulness in clinical settings.

**Questions:** There were two main questions associated with the current demonstration project on using and implementing the START: 1) Is the START associated with actual short-term challenging behaviour outcomes on an acute psychiatric unit? 2) How could START be thoroughly implemented in taking account typical barriers to dissemination of evidence practices? To do so, the demonstration project set out to: 1) Test the relation between the START and various challenging behaviours on the unit; 2) Monitor the actual use and frequency of START assessments; 3) Support the implementation process with (promotion of the active engagement of key resources, line-level staff education); 4) Integrate the START with other ward activities and rehabilitation components of the inpatient program; 5) Document the

implementation process to promote the further dissemination of the scheme in different inpatient and outpatient contexts.

## **Methods**

This is a longitudinal prospective mixed-method (qualitative and quantitative) design. The quantitative component of the project included: 1) a Unit-level data collection; 2) a validation sample data collection of patients who authorized full medical file access for comprehensive chart review of challenging behaviours. The study followed participants on the unit from May 1, 2006 to August 31, 2007. The qualitative component involved semi-structured focus group discussions at three time points (at the beginning of the study, 9 and 18 months post-implementation) involving each of the core treatment teams.

## **Results**

*1) Relation between START assessments and challenging behaviours.* START risk scores were predictive of physical aggression as well as aggression against objects in the month, 6 and 12 months following the assessment and were not statistically predictive of the other challenging behaviours measured. START strength scores were also predictive of physical as well as aggression against objects at one-month, 3, 6 and 12-months. Thus individuals displaying physical and property aggression had higher risk and lower strength scores on the START. There was a general tendency for physical and object aggression to decrease over time, this decrease was also observed for seclusion measures as well as calls to emergency services to have decreased over time. However, further analyses are needed with longer time periods and with control variables.

*2) Implementation of the START on a clinical unit.* Overall, the START was well integrated the team's clinical and administrative activities as demonstrated by: 1) the high rate at which staff

was able to assess their patients on a regular basis, i.e. once a month for each patient; 2) the integration of the START assessment into the general clinical pathway of the client's intervention program; 3) improved awareness of risk factors and strength associated with various challenging behaviours (physical, verbal property aggression, self-harm, suicide, substance abuse, unauthorized leave self-neglect & victimization); 4) perceived utility of the START in daily practice; 5) improved structure of team meetings; 6) improved communication. However, a number of challenges need to be overcome in order to improve START implementation in the medium to long term, some of which include: 1) additional trainings and inter-rater reliability checks to avoid rating drifts; 2) improving time-appropriate monitoring of behaviours; 3) developing specific intervention strategies for specific items; 4) involving a larger number of team members in the clinical operationalization of the START assessment.

## **Conclusion**

In these times of financial restraints, particularly scarcity of human resource in the mental health services, as well as the increased pressure of mental health services to manage a wide variety of challenging behaviours, risk management tools can provide some help in improving patient care and empowering staff to better understand violence and other challenging behaviours. The type of initiative described in the current report and other pilot or demonstration projects are essential for clinicians, researchers and administrators to better understand what would be the best strategies to adopt for implementing risk assessment and management programs in a variety of mental health settings. This type of research is certainly in its infancy for risk management. The results of the current project are an essential tool for planning the next steps in the programs of the Douglas Institute, but it is hoped that they can be helpful to other organizations in planning risk assessment and management strategies.

## **1. CONTEXT**

### **Violence in institutional settings**

Although the majority of individuals with a mental illness do not display violent behaviour (1), violence and other challenging behaviours can often lead to psychiatric hospitalization. It is therefore not surprising to observe that psychiatric inpatients are more likely than non hospitalized mentally ill individuals to commit violent acts (2, 3). Many studies have been conducted on violence among individuals with severe mental illness (SMI) prior to, during and after hospitalization (4-8). Between 10% and 40% of persons in psychiatric hospitals had committed violent acts in the weeks preceding their admission (9). Being discharged from the hospital is often associated with improvement of clinical symptoms, including a reduction of aggressive behaviour. Krakowski et al. (6) note that the most common diagnosis related to violence during hospital stay is paranoid schizophrenia followed by personality disorders. Furthermore, a strong percentage of SMI also suffer from a substance use disorder (10), which is an important factor in violence risk (9).

### **Deinstitutionalization**

The psychiatric deinstitutionalization movement which started in the 60s was in part attributable to the discovery of antipsychotic medications as well as the emergence of a consensus on an approach to treatment with the least restrictive of liberty. The objective was to create and maintain community tenure of individuals receiving mental health services. In the 30 years that followed, the number of patients in psychiatric hospitals decreased by 80%. However, mental health services only partly followed patients into the community (11). Furthermore, changes brought to civil legislations, again in the movement towards self-determination of individuals with a mental illness had the effect of rendering involuntary treatment and

hospitalization more difficult. With the increasing number of individuals suffering from a mental illness living in the community and these civil code changes, the risk of individuals coming into contact with the criminal justice system increases; whether it be for disturbing behaviour, survival crimes or violent behaviour. The criminal justice system thus becomes, for many individuals with SMI, the back door access to mental health services.

### **Changes to the Criminal Code**

A certain number of individuals who suffer from SMI who are in contact with the criminal justice system are declared not criminally responsible on account of mental disorder (NCRMD). The Canadian Criminal code has also been the object of significant changes over the past two decades, again with the objective of the least restrictive environment possible while maintaining public safety. Some of the changes included: 1) the creation of provincial Review Boards, quasi-judicial entities who decide of dispositions for individuals found NCRMD; 2) the possibility of different modalities of dispositions: detention, conditional release or unconditional release; 3) the application of the principal of least restrictive disposition, taking into account public safety, the mental state and the possible social reintegration of the individual; 4) the abolition of indeterminate detention of individuals found NCRMD; 5) an annual review of dispositions process. Immediately following these changes, many studies were carried out in Canada to assess implementation and effects (12-21) and revealed a significant increases in the annual number of individuals found NCRMD (22). Just in the province of Québec, there were twice as many individuals found NCRMD in 2001 (n=360) than in 1992 (n=177). Not all these individuals are detained or followed in specialized forensic psychiatric settings. In fact, there has been increased pressure in the generic mental health system to deal with this population. This continues to generate a certain level of anxiety on the part of non-specialized mental health

services regarding their own capacity to address the clinical specificities and risk management of this clientele for which they have no special training. Just at the Douglas Institute, over 90 NCRMD hearings are held every year. A study mandated by the Health and Social Services ministry of Quebec (23) reveals that psychiatrists of civil psychiatric hospitals do not feel as comfortable as do clinicians from forensic psychiatric hospitals in presenting their cases to the annual review board hearings and in managing this clientele, the latter having more expertise and more risk assessment instrument training. This poses significant problems as the new international tendency is to increase first line mental health services to the detriment of second and third line specialized services. In Quebec at least, it can be expected that a larger number of individuals declared NCRMD will tend to be managed through first line services (24).

Thus, changes in civil commitment laws and criminal code legislation have led to the allotment of inpatient beds to those most severely disordered individuals, who are likely to be acutely dangerous to self or others (25, 26). In fact there seems to be not only a national but an internationally observed tendency to increased number of beds dedicated to individuals coined “forensic” that is individuals with a mental illness who have contact with the criminal justice system and/or who display violent behaviour (27-29).

## **2. IMPLICATIONS**

In this context, psychiatric inpatient services are called upon every day to safely and effectively treat those patients demonstrating risk for violence to themselves or to others. For these services, the challenge is two-fold : 1) a need to limit the incidents during the inpatient stay. Specifically, this means ensuring that acute treatment in inpatient’s setting is performed in a way that minimizes risk from aggressive and violent patient behaviour, as well as from staff

attempts to control these behaviours on the units (26); 2) services must provide the patient with skills, attitudes and resources in preparation for a safe return to the community (30).

### **Assessing and Managing risk**

Over the past 20 years, research in the field of risk, safety and SMI progressed in a way that currently sets the stage for the implementation and dissemination of best practices that could meet the above challenges. First, with regards to the safe treatment of patients during their stay on the units, the use of confinement strategies (e.g., restraints and seclusion) has been identified as problematic and in some instances even painful (31-33) and the opportunity to develop, implement and evaluate alternative options has been emphasized (26, 34, 35). Second, it has been proposed that using a rehabilitative and recovery oriented approach in itself – including making patients active participants in their treatment plan - represents a critical means to improve patients safety on the units and in the community (36, 37). Third, a major progression in the domain has been the movement from the ‘dangerousness assessment’ approach (i.e., prediction of dangerous behaviour) to ‘risk assessment and management’, which means taking a proactive approach to risk prevention (38). In this approach, the task is to assess risk in order to manage the behaviour of individuals thought to be at risk for violent/aggressive acts. In doing so, this ensures the protection of both other individuals on the unit or in the community, as well as the at-risk patients themselves (30). Specifically, assessment and management means developing case conceptualization approaches that integrate historical, dispositional, clinical, contextual factors and their interactions (39-41). With this approach, clinicians engage in functional analysis of behaviour that allows for the identification of contextual and other treatable variables (38). In essence, functional analyses approaches contribute to informing public mental health systems to make real life decisions about whether, when and how to release SMI patients at risk (39, 42).

Studies had historically shown that clinical judgment alone was not particularly useful for predicting future violence (43) and efforts to standardize risk assessment and management approaches to promote ‘structured clinical judgement’(44) have been very successful. This means defining guidelines that structure the functional analysis approach in the collection of relevant and valid evidence (45-47). Such an effort is based on recent research developments where substantial progress has been realised in the empirical identification of risk and protective factors associated with injury, violence, aggression and safety (e.g., 48). This progress has yielded the development of systematic assessment guidelines and tools that incorporate the relevant empirical information into specific assessment protocols (30, 49, 50).

**START.** A newly developed structured clinical judgement approach, the Short Term Assessment of Risk and Treatability (START: 30) is a patient-centered, comprehensive scheme informing multiple risk domains and guides toward organizing clinical interventions. Furthermore, START also provides a means to index possible improvement due to therapeutic interventions (decrease in psychiatric symptomatology, increase in functioning, etc.) and may be used as a guideline to initial and iterative treatment planning. It includes 20 anchored items representing domains of functioning shown empirically related to patients’ risk, and each of these domains are rated for both their strength and risk value in predicting seven categories of behaviours that pose a direct threat to patient’s safety (violence towards others, self-harm, suicide, unauthorised leave, substance abuse, self-neglect, and victimization). The START was developed to be used in multidisciplinary clinical teams in order to provide the best coverage possible of all functional domains of an individual. This multidisciplinary approach also allows clinicians to share the intervention strategies according to profession. Moreover, as the START represents a comprehensive psychosocial assessment of the patient, its use leads to the

identification and promotion of coping strategies that are alternatives to confinement techniques conventionally associated with agitated inpatient behaviour. To date, no studies have reported on the implementation of the START in actual clinical practice.

### **Implementation issues**

At Douglas Mental Health University Institute, the START was identified as a needed best practice to be introduced on the Risk management and rehabilitation unit (RMRU). However, efficient use of good practices in real-world mental health settings is associated with significant implementation challenges (51, 52) as well as methodological difficulties. This probably partly explains the dearth of literature on the actual use and implementation of risk assessment and management tools. With regards to the characteristics of clinical team, there appears to be two main sets of barriers related to dissemination and implementation of best practices (53). First, services providers' lack of basic knowledge and skills required to assimilate evidence-based practices into their regular approach to treatment. In this regard, three categories of competencies have been identified: a) a 'recovery attitude' characterised by perceiving services not as custodial, but as adjuncts to helping people regain a place in the community; b) knowledge about the nature of severe mental illness and its impacts, and knowledge about pharmacological and psychosocial interventions and assessments; c) skills and basic behavioural tools common to most psychosocial interventions (52, 54, 55). The second set of barriers to dissemination associated with the characteristics of the clinical team is the provider team's cohesion. This lack of cohesion has been linked to four categories of causes : 1) staff burnout; 2) the belief that innovations and training initiatives reflect the interests of the administrators rather than representing what level services believe to be the key needs and concerns of their clients; 3) bureaucratic constraints including the paper work and other documentation needed to

track the implementation and impact of services; 4) 'passive management by exception' leadership and 'laissez-faire' leadership (56, 57).

Different implementation strategies have been shown useful to deal effectively with these barriers : 1) making the innovation user friendly to line-level staff by translating jargon and principles in guidelines and manuals; 2) educating and training line-level staff on discreet rehabilitation skills; 3) pairing training with ongoing regular consultation; 4) insuring the active commitment of medium level managers; 5) training leaders in transactional leadership skills including goal setting, feedback, self-monitoring and reinforcement strategies; 6) consulting line-level staff in the identification of implementation needs; 7) relying on data rather than opinion to identify program needs and client's progress; 8) conducting development efforts for a significant length of time (51, 53, 58, 59).

### **Aim of the demonstration project**

The current project aims at improving the safety and well being of the patients suffering from severe mental illness by implementing and using the START (30) clinical guide in the context of the RMRU of the Douglas Mental Health University Institute. There were two main questions associated with using and implementing the START: 1) Is the START associated with actual challenging behaviour outcomes on an acute psychiatric ward? 2) How could the START be thoroughly implemented in taking into account typical barriers to the dissemination of good practices? To do so, the demonstration project set out to 1) Describe the prevalence and types of challenging behaviours occurring on the RMRU unit; 2) Test the relation between the START and various challenging behaviour outcomes and other measures used on the unit; 3) Monitor the actual use and frequency of START assessments; 4) Support the implementation process (with promotion of the active engagement of key resources, line-level staff education); 5) Integrate the

START with other ward activities and rehabilitation components of the inpatient program;

6) Document the implementation process to promote the further dissemination of the scheme in different inpatient and outpatient contexts.

### **3. METHODS**

***Study design.*** The implementation project is based on a longitudinal prospective mixed-method design in that it relies on both qualitative and quantitative data collection. The quantitative component of the project included: 1) a Unit-level data collection (information obtained from computerized administrative files) to describe client movements, general trends in the use of the START and patient characteristics; 2) a validation sample data collection of patients who authorized full medical file access for comprehensive chart review. This interrupted time series design was planned to cover 6 months prior to START (November 2005-May 2006) implementation and 15 months following implementation (May 2006-August 2007). However, the implementation coincided with significant changes to the unit's vocation, admission criteria and program, as well as an administrative instruction requiring the staff to increase reporting of significant incidents (incident reports). The initial pre-post design of measuring the actual effect of the START could therefore not be assessed with any significance. The project therefore shifted towards an implementation study and correlating START scores with observed challenging behaviours. The qualitative component involved semi-structured focus group discussions at three time points involving each of the core treatment teams of the unit.

***Context of the transformation of care on the study unit.*** The implementation of the START coincided with a major shift in care and admission criteria to the RMRU identified for the demonstration project. The transformation resulted in a significant reduction of the number of patients to be treated on the inpatient unit from 31 (prior to the study) to 16 patients. Two

residences in the community afforded the extension of the rehabilitation program in the community reinforcing the generalization of behaviours learned in house. The patients in these outpatient programs were not included in the current demonstration project. These changes occurring at the same time as the START implementation project resulted in a better environmental milieu by reducing crowding, increasing space for patients and staff. In addition to decreased crowding, the changes also involved environmental modifications to the actual physical unit, such as renovations, improvement of privacy for patients and new furniture. The patients' rooms can now also all be seen at the same time by the staff which is a clear advantage for patient and staff safety. The transformation also meant a concentration on the work of a clearly defined risk management mandate and the improvement of tools and interventions to best address the changing needs of the patient population on this unit. Safety became a major focus of concern as staff faced a significant increase in the proportion of male patients found NCRMD from 25% to 75%. Another 15% are on treatment orders. In the year prior to START implementation, a training curriculum had been put in place for the use of standardized measures such as the REHAB scale, the completion of Individualised intervention plans (IIP) and Behaviour modification programs that target knowledge on the nature and impact of SMI, the recovery model, and pharmacological and psychosocial interventions and assessments.

***Mandate of the Risk Management/Rehabilitation Unit.*** “To provide our adult patients with a Risk Management/Rehabilitation Program that reflects their severe and persistent mental disorder within the confines of any legal restrictions that may be present and that cannot be managed in a less restrictive environment. To elevate our patients' behavioural and psychosocial functioning to a maximum level possible and assist in their recovery to eventual community reintegration.” (60).

## **Quantitative component**

*Unit-level data.* Summary computerized file review was carried out for all individuals who were on the unit or had been admitted to the unit between May 2006 and August 2007. This included START assessments, incident reports as well as sociodemographic, diagnostic and patient movement. From the beginning of the START implementation to the end of data gathering, 48 men and 20 women were admitted on the unit at one point or another (the maximum capacity of the unit is 16 patients, although it has reached up to 19 on some days). The mean age was 39.96 years of age (SD=13.12), 69.1% had a diagnosis of schizophrenia, 10.3% of schizoaffective disorder, 10.3% of bipolar disorder and 7.7% of intellectual disability. Nearly 85% of the patients were of Canadian origin, 82.4% were never married, 17.6% had completed high school, 44% were under some form of guardianship or representative payeeship and 74.5% had no paid employment prior to have been hospitalized. Between May 1, 2006 and August 31, 2007, patients were on average 138.25 days on the unit, but there was substantial variability (SD=122.42) and had on average 4.96 (SD=3.63) prior admissions and 12.46 (SD=11.04) previous emergency visits to the Douglas hospital. However, only 42 of these individuals remained on the unit for a long enough time for clinical staff to conduct one or more STARTS.

*Validation sample.* A validation sample was used because only a proportion of the challenging behaviours are actually reported to hospital authorities through incident reports (see Figure 4). Comprehensive file reviews were carried out for all clients who consented to participate. Participants were recruited between May 2006 and May 2007 as they were admitted to the unit and chart reviews followed up to August 2007. This means that the minimum possible follow-up time was 3 months (unless discharged earlier) and the maximum was 15 months follow-up for those who were present when the study started. Of the 42 patients who could be

approached for participation, 12 refused and 29 (70%) consented to full medical file reviews. For those who were under some form of legal guardianship, permission to consult files was obtained from the public or private guardian and assent was obtained from the patient. Of the 20 men and nine women who authorized the research team to consult their full medical file, 24 (82.8%) had a diagnosis of schizophrenia, three (10.3%) schizoaffective disorder, two (6.9%) a bipolar disorder and five participants (17.2%) also had a diagnosis of intellectual disability. Participants were on average, 43.48 years of age (SD=13.66), over half were under some form of guardianship or representative payeeship, 72.4% had never married, 25% had completed high school, 69% had had no paid employment prior to psychiatric admission, half were English speaking, 45% French-speaking and 72.4% were of Canadian origin. One-third had been declared not criminally responsible on account of mental disorder and 25% were certified (involuntarily committed). Participants stayed on average 179.45 days (SD=128.71) on the unit between May 1, 2006 and August 31, 2007. Participants had on average 5.6 (SD=4.8) previous admissions and 11.45 (SD=11.17) previous emergency visits to the Douglas hospital in addition to an average of 6.7 (SD=8.04) hospitalizations in other psychiatric institutions.

### **Measures and instruments**

As described above, *sociodemographic and legal status information* included gender, age, legal status, language, ethnicity, civil status, level of education, protection settlement (guardianship and representative payeeship), previous employment and date of admission to the unit. *Psychopathological information* included psychiatric diagnosis and number of previous psychiatric admissions and emergency visits at the Douglas Institute and at other hospitals for the validation sample.

**START.** As was briefly mentioned above, the START (30), which is now available in French (61) is a clinical guide for the assessment and management of risk. Evaluators rate 20 dynamic items ranging from social adjustment, physical and mental health to treatment adherence in order to set up an intervention plan for a particular client (see Appendix A and J). Each of the 20 items are scored both as risks and as strengths, each on a three point scale (no evident strength or risk to high risk, high strength) in order to then assess seven types of behaviours as Low, Medium or High Risk (risk to others, self-harm, suicide, unauthorized leave, self-neglect, substance abuse and victimization by others). For the purpose of the current project, total risk and total strength scores were calculated. Furthermore, risk to others was disaggregated into physical aggression, aggression against property and verbal aggression; stalking was also added as a possible challenging behaviour. Initial studies on the START's psychometric properties indicate good inter-rater reliability (Cronbach's alpha of .87<sup>1</sup>) across professions, and predictive validity (AUC of .65 to .77) of challenging behaviours (62) . In addition, clinical staff found it to be an easy and useful instrument to work with (30).

Staff of the RMRU was trained to use the START by the head psychologist of the unit, a former Ph.D. student and the nurse program coordinator who all had previously received training by the one of the developers of the START and the researcher. A first training of the full staff took place at the end of April 2006 and a booster training session took place in February 2007. The nurse program coordinator and psychologist were then in charge of conducting the START meetings on a regular basis with the core teams for each client fore the duration of the project.

The START coding sheets (see Appendix A) for all patients on the unit were sent on to the research team for data entry. A random inter-rater reliability check was carried out six

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<sup>1</sup> A coefficient of 1 indicates perfect agreement and a coefficient of 0 indicates no agreement.

months following the last booster training sessions with five anonymous staff members regarding six different patients in order to identify the necessity of providing additional booster or coding feedback sessions. The results indicated low inter-rater reliability for total risk score (.38) measured by Chronbach's alpha and a high agreement on total strength scores (.81). The risk items with most agreement were relationships, substance use and insight; the lowest were attitudes, conduct and coping. For strength the items yielding the most consensus were social skills, substance use and conduct and the least were coping, treatability and self-care. These results should be taken with caution, as they have limited statistical power and even a few additional ratings could change some of the values. Despite these limitations, they do underline the need to continue booster training and feedback sessions on a regular basis focused on specific items. Furthermore, the check should have been carried out following a team meeting because all cases on the unit are discussed in team meetings which are designed to obtain group agreement on final ratings. The results described below are thus based on these team consensus ratings.

*START-Pilot questionnaire.* The Doyle & Brown (63) questionnaire (see Appendix E) was filled out following just before focus group sessions 2 and 3 by participating staff who agreed to give feedback. This short questionnaire was developed by colleagues in the U.K. to assess the usefulness of the START and identify potential improvements on the START guide.

*Challenging behaviours* were defined according to the START outcome categories. They were operationalized using what is now known as the START-Outcomes Scale (64) (see Appendix B). This scale was constructed using the Modified Overt Aggression Scale (MOAS, 65, 66) as a template. The MOAS assesses physical, verbal, property, and self-aggression. Each of the four aggressive behaviour categories includes 5 items (0= no such behaviour to 4= highest level of such behaviour). A fifth category of sexual aggression was added and developed in the

same format as the MOAS (67) as it is considered aggressive behaviour from both the societal and judicial perspectives. Using equivalent severity levels, the MOAS was again modified to include self-neglect, substance use, unauthorized absence and victimization. All these items now comprise the START Outcomes Scale (64). In the present study, each item of each category outcome was scored as either present or absent for each incident. Unlike the START and the REHAB scales which were rated by the clinical team as part of ongoing interventions, the challenging behaviours using the START-outcomes scale were rated by the research assistant, blind to the START ratings, through extensive case-file reviews as well as accident/incident reports. Unit-level coding of challenging behaviour was based exclusively on incident reports submitted to the quality assurance department of the hospital. For the validation sample (n=29), challenging behaviour was based on coding both incident reports as well as all nursing and staff notes found in the participant's unit files. The incident reports are thus an underestimation of all incidents. As can be observed in the Figure 4, our results indicate that only 17% of all incidents of challenging behaviour actually get officially reported. Only severe challenging behaviours get reported, as such, physical aggression is more likely to get reported.

*Measures following incidents* included: 1) Code White calls made to an emergency team for support to the unit staff when needed during an incident; 2) restraint and seclusion measures; 3) other outcomes included medication and behavioral interventions (these are not included in the present report as they need further analyses).

*REHAB scale.* As was mentioned above, the staff had been trained, in the year prior to START implementation, to the use of the REHAB scale (Rehabilitation evaluation Hall and Baker: 68, 69). This scale is a 23-item behaviour rating scale containing a 7-item deviant behaviour subscale and a 16-item general behaviour subscale which can be subdivided into 5

factors. The scale was designed to be used with people with a chronic or disabling psychiatric disorder who are in institutional settings. Previous research had shown inter-rater reliability correlations ranging from .62 to .92 for the independent items (68). Ratings made by the clinical team using the deviant behaviour subscale were correlated with the START assessments.

### **Qualitative component**

Six focus group discussions three in English and three in French were carried out at three distinct points in time over the course of the study. The first was carried out at the beginning of the implementation of the START project on the unit in early May 2006. The second focus group session immediately proceeded the START booster session 9 months into the implementation process and a final focus group session took place at 18 months into implementation. Each focus group session ran from 60 to 90 minutes and followed a semi-structured guide that a former student had developed for the program (See Appendix D). Initial group sessions focused on program implementation in general and concerns surrounding the management of violence and other challenging behaviours. These questions were used to generate a list of issues brought forth by a moderator in order for the group to rate the importance of the practical issues surrounding risk management. Additionally, perceived barriers to implementation were also discussed. More specifically, the four following theme were addressed: 1) Have frontline staff been exposed to the implementation of mental health programs? 2) What were some of barriers encountered? 3) What factors would ensure active participation of frontline workers in the implementation and maintenance of a mental health program? 4) What are the issues encountered in attempting to manage challenging behaviours? The second (9 months) and third sessions (18 months), focused on how these issues relate to the START based on concerns expressed in the initial focus group session and the front line staff's level of satisfaction with START and its implementation,

whether initial concerns were addressed and the clinical benefits/disadvantages of the START. More specifically, the following themes were addressed: 1) Impact of the START on the working environment; 2) Factors associated with START implementation; 3) Changes to be made; 4) Improvements based on last focus group discussions; 5) Appropriateness of using START for all patients; 6) Change in perceptions of risk management or challenging behaviours; 7) Would they recommend using the START and why?; 8) General comments.

Staff invited to participate in these focus groups signed consent forms to allow us to record and transcribe the focus group discussions. Administrators were not included in the focus groups in order to allow the staff to speak freely about concerns and issues that they thought needed to be addressed. Staff quotes that are presented remain anonymous.

***Ethical considerations.*** Permission was obtained from the Director of professional services of the hospital to consult computerized unit-level data. The research protocol, consent form for the validation sample and procedures were approved by the Douglas Hospital Research Ethics Board. All data are analyzed anonymously.

***Analytic strategy.*** In this longitudinal study, the START was measured at different points in time for different individuals, but at monthly intervals for each participant. Some participants had measures on multiple time periods and others had few. The presence of incidents was measured on a given period, after the START calculation. Our objective was to evaluate whether START risk scores and strength scores were correlated with challenging behaviour incidents at one month, 3, 6 and 12 months post-START assessment for each individual. To do so, we carried out a mixed linear model using PROC MIXED procedure from the SAS statistical package (70). The model used allowed to take into account the fact that many measures were taken for the same individuals at different points in time (repeated measures) and that individuals

do not have measures at all points in time. It thus takes into account the between-subject factor of presence or absence of incidents as well as the within-subject factor which is the period referred to as it refers to many measures taken for the same individuals at different time-points. This allowed the evaluation of the immediate prospective predictive utility of START risk and strength scores for various challenging behaviours. All levels of severity of the challenging behaviour are collapsed (see Appendix B for a description of severity levels by type of behaviour), i.e. the outcome is the presence or absence of an incident involving the behaviour.

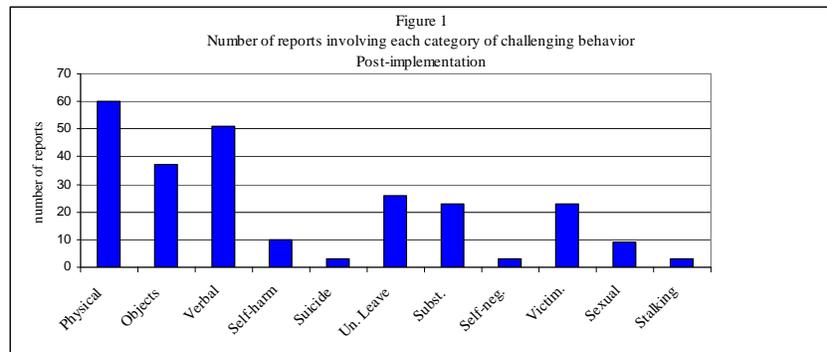
#### 4. SUMMARY OF RESULTS

##### 1) Is the START associated with actual challenging behaviours on the inpatient unit?

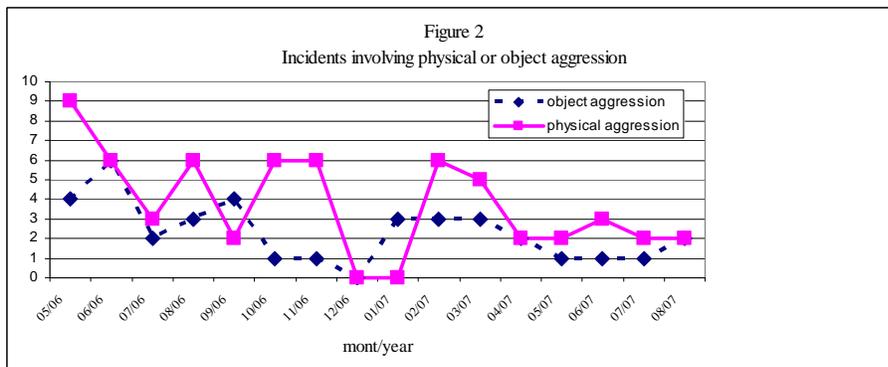
###### 1.1 Unit-level analyses

###### *Challenging behaviours.*

A total of 187 incident reports were filled between May 2006 and August 2007



involving 238 challenging behaviours of 68 patients. As can be observed in Figure 1, outward oriented aggression was the most frequent reason for writing up an incident report (many



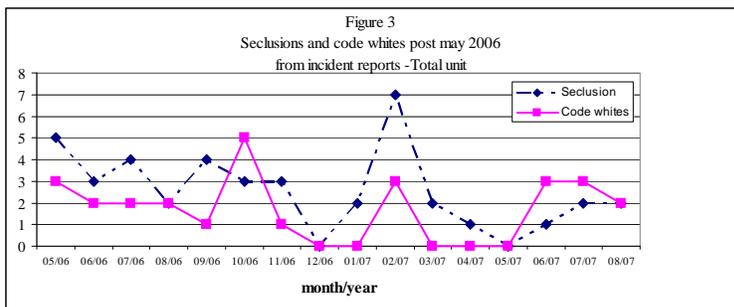
behaviours can be observed within one incident). Figure 2 indicates a general decrease in the frequency of incident

reports involving physical aggression and object aggression over the course of the

implementation study. However, this trend must be taken with caution as further statistical analyses need to take into account days at risk (i.e. number of individuals on the unit at any point in time).

Mixed model analyses were carried out in order to test whether the START total risk and total strength scores were predictive of future challenging behaviour at one month, 3, 6 and 12 months, indicating whether or not risk scores are useful for short-term violence. START total Risk scores were significantly predictive of physical aggression in the immediate short term (one and 3 months) but not in the long term (6 and 12 months). In other words, individuals who had committed a physically aggressive act in the month and in the 3 months following a team START assessment had a statistically significantly higher total risk score than individuals who did not display physically aggressive behaviour at those time-points. The START Risk scores were also predictive of aggression against objects at one month. START risk scores were statistically unrelated the other types of challenging behaviour (some of which had very low incidence rates). START total strength scores were predictive of physically aggressive behaviour at 1 month, 3 and 12 months, indicating that individuals who displayed aggressive behaviour at these time-points following the START assessment had statistically significantly higher strength scores on the than did those without the behaviour.

**Post-incident measures.** Figure 3 indicates a general trend towards decreased use of

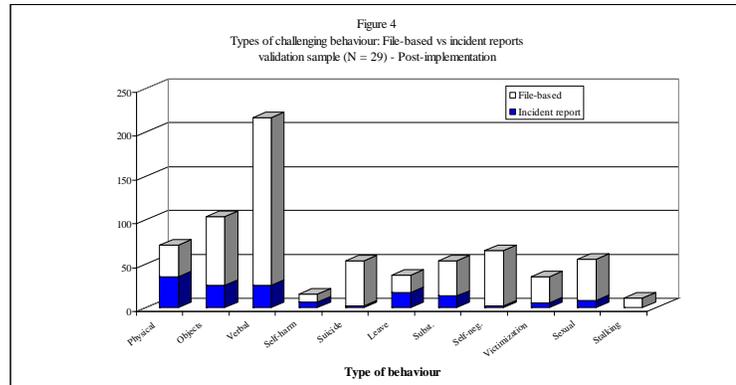


seclusion measures over time as a decreased number of emergency calls made the code white team. This may be indicative of better containment of behaviour with non

coercive methods by the staff of the unit. However, further analyses are necessary to correlate with types of behaviours and to take into account the individuals involved.

## 1.2 Validation sample

**Challenging behaviour.** Between May 1, 2006 and August 31, 2007, a total of 102 incidents reports were filed by the staff involving 138 different types of challenging behaviours for the validation sample of 29 individuals. In addition, 498 milder incidents were identified from medical files



that were not the object of incident reports involving 578 different types of behaviours. Figure 4 displays the number of challenging behaviours involved in all incidents by type of behaviour and source of information (incident report or file review). As can be observed, physical aggression is the most likely behaviour to be reported officially. Among all the incidents, only 71 (14.3%) involved some form of physical aggression and 104 (17%) involved aggression against objects. Fully 30% (n=217) of incidents involved some form of verbal aggression, most of which were mild in nature (55%: levels 1 and 2, see Appendix B). Among incidents involving physical aggression, 6 (8%) caused major injuries, 31 (43%) caused minor injury and 34 (47%) were minor physical incidents. Among property related aggression, only 12 (12%) actually caused significant damage.

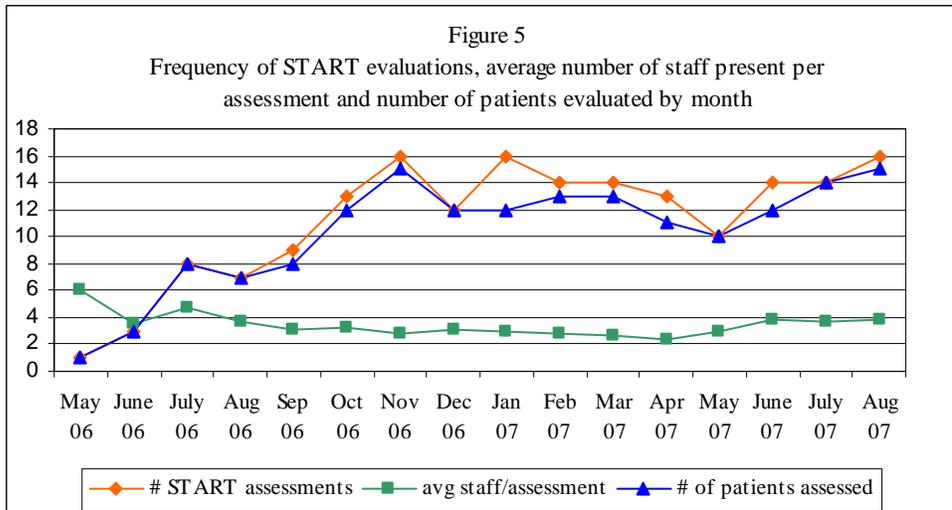
Again, a mixed model design was carried out and START risk scores were predictive of physical aggression as well as aggression against objects in the month, 6 and 12 months following the assessment and were not statistically predictive of the other challenging behaviours

measured. START strength scores were also predictive of physical as well as aggression against objects at one-month, 3, 6 and 12 months. Thus individuals displaying physical and property aggression had higher risk and lower strength scores on the START.

*Association between the START and REHAB scale.* Small but statistically significant correlations in the expected directions were observed between total strength scores ( $r=-.31$ ,  $p<.05$ ) well as the total risk score ( $r=.21$ ,  $p<.05$ ) on the START and the deviant subscale of the REHAB in the month following the START. Individuals with higher delinquency scores had lower strength scores and higher risk scores than individuals with lower delinquency scores.

## **2) Can the START be thoroughly implemented despite previous implementation barriers for other programs?**

As can be seen in Figure 5, 180 START assessments were completed by the clinical team regarding a total of 42 patients who were on the unit at one time or another for a long enough period of time to conduct one or more START assessments over the course of the study, representing approximately one START assessment/patient/month. The clinical staff began by conducting a few assessments in the first few months of implementation to finally conducting one assessment/patient/month at the end of the study period.



The START is now integrated into the standard assessment and treatment procedures (IIP and clinical pathway, see Appendix I) on the unit and continues to be used despite the end of the research component of the implementation. It is completed for each patient upon arrival on the unit and monthly for the duration of their stay. Participation of staff at START assessment meetings decreased from 6 in the initial meetings to a stable number of three to four staff over the course of the study. This seems to be the ideal number of individuals involved in the core treatment meeting to maximize the probability of START assessments being conducted for each patient each month. Having a larger number of individuals was found to increase time spent on the assessment and redundant content. These results also seem to indicate that a 6-month period was necessary to attain a stable level of risk assessments to be done on the unit. To facilitate the implementation of monthly assessments, two meetings are scheduled weekly and during each meeting, two risk assessments are completed.

Once the START is completed, the treatment teams discuss how any specific risk estimates (e.g. risk to others, suicide, substance abuse) that have been identified as critical to treatment can be managed and ultimately decreased so that the patient can be safely returned to the community. Treatment components to decrease specific risk estimates are integrated into the

patient's IIP which is reviewed on a monthly basis. Examples of common interventions include: changes in medication, behavioural modification plans, various group therapy programs (e.g. anger management, legal reasons for hospitalization), and individual meetings with staff members. The START also helped identify needs that the unit in order to offer the best available program. Specific policies and procedures were thus developed following a few months of START implementation: room search policy for objects that could pose a threat to self or others; procedure for collecting urine specimens for substance abuse. These policies and procedures have been integrated into the structure of the unit to maximize safety of both patients and staff.

### **Staff perceptions**

Results of the first focus group indicate that the following factors had acted as roadblocks to implementation in the past, i.e. before START implementation:

1) the lack of strong leaders, at both the frontline and administrative levels; 2) financial constraints related to program monitoring and staffing (e.g., staff time allotment for training, ensuring continual funding to promote program success); 3) barriers to knowledge transfer as a result of insufficient training and communication of evidence; 4) complicated and non-user-friendly manuals; 5) absence of team cohesiveness and; 6) lack of monitoring and feedback to detect and address relevant concerns. Regarding violence and other challenging behaviors, staff indicated factors such: 1) some patients not fitting the behavioral program operating on the unit (e.g., personality disorders); 2) treatment that is "partial" (e.g., staff expertise has not kept pace with more difficult caseload and lack of knowledge about new programs); 3) lack of consistency in responding to violent patients; 4) need for a better accounting system for dealing with violence and other behaviors; 5) better communication needed between administrators and teams; 6) and an overall lack of leadership.

Many of the factors underlined during these focus groups were then addressed over the course of the study. And in order to gain continuous feedback on the monitoring and

maintenance of the START, two other focus groups were carried out specifically addressing the implementation of the START in light of discussions from the initial focus group. For the purpose of the current report, the mid and end-point focus group conclusions were merged.

1) Impact of the START on the work environment

a) Increased knowledge regarding factors associated with risk; b) Usefulness of the START in individualizing the treatment plan, needs and symptom assessments and usefulness in developing the IIPs as well as allows to monitor progress; c) Increased structure in assessments and broadened perspective on way patients are evaluated when using the START; d) Identification of clearer objectives in the treatment of patients; e) START represents a positive force for the team; f) “Now we try to make interventions before something happens, have gone from reactive to attempting to prevent.”

2) Factors (positive and negative) associated with START implementation

a) Problem that arose during implementation: need to make sure to integrate the START in the intervention plan and really use it; b) Problem that arose during implementation: not always the whole team that is up to date; c) There were times when the psychologist had to remind staff of the definitions of certain factors; d) “Time was a big issue in the early START assessments, each took from 45 to 60 minutes, but with practice and regular use, the time has been reduced to 20 to 30 minutes/assessment”; e) “Having the START scheduled in team meeting is crucial to getting it done”; f) Success of the implementation is largely due to the support of the administration, pushing to getting it done; g) Having a clinical go-to resource person for START assessments and clinical operationalization; h) At the beginning of the study, there were worries of how START would fit on the unit’s activities and if it the START implementation would die out as did other projects.

3) Changes that could be made to the START instrument or its implementation

a) Include a mechanism for monitoring month to month variation on the START items; b) Develop more precise definitions of scores 0, 1, 2, in line with the HCR-20 and PCL-R instruments where the scoring is more precise; c) The THREAT section is not useful; d) Have the research present at more clinical staff meetings; e) START should be

implemented during night shift work and weekends; f) Develop a standardized mechanism to share information regarding patients between shifts; g) Give more background information, historical background of risk and violence during trainings; h) More information on how to orient interventions; i) Develop more examples and demonstrations of how to use the information provided by the START.

4) Changes that were made since last discussion for improvement

a) Addition of treatment coordinators in START assessment meetings, who were primary nurses in contact with the patients; b) Additional training was provided every 6 months to ensure that staff remembered everything”; c) “START was something that should have been used a long time ago”; d) “Staffing will never be ideal!”; e) Someone in charge who can keep everything on track (Go-To person), answer front line staff’s questions and link with experts at the research center.

5) Appropriateness of using START for all patients

a) Not ideal with individuals with intellectual disabilities as their behavior is not always comparable to those with schizophrenia; b) Questionable use with psychopathic patients; c) Patients in which physical trauma is the cause of the behavioural problem might not be ideal for the tool.

6) Changes in perception of risk management or challenging behaviour

a) Help staff recognize that while patients can have several factors that contribute to levels of risk, patients can also have strengths that can be targeted to reduce risk; b) Recognition that there not just one profile that leads to a person being aggressive or dangerous; c) Increased general knowledge on risk, structured staff conversations, feedback and data collection; d) Everyone uses the same language and definitions; e) Certain expertise developed within the staff; f) START implementation has been good for the evolution of the unit, solidify unit’s mandate.

7) Recommend the use of the START to other mental health services and for what reasons?

a) Would recommend using the START to other colleagues in the hopes of using a uniform tool in all adult psychiatric services; b) The fact that the staff continues to use it; c) Can bring the START to provincial Review Board hearings to show some of the work that the team has

been doing and to structure the hearings with the knowledge that the START has provided the staff on risk factors; d) “All the factors included in the START are related to risk. Once we know all the factors, we can make intervention plans to reduce challenging behaviour”; e) Allows for “better communication of information, and the other elements of risk identified by other professionals”; f) Allows to prevent rather than react; g) Argument against the use: Need to free up staff and hiring new persons to take their place costs money.

8) General comments

a) Will continue to use the START, brings together the key players working with the patient and gives the opportunity to have in-depth discussions and share ideas about patients during clinical meetings; b) Would like to see how other groups use the START; c) Very impressed and encouraged when met people from Europe, Canada and Australia who were all using the START. Felt like part of something larger and extremely significant; d) Could be a universal tool; e) “START marked the beginning of research being integrated onto the unit”.

Following the focus group sessions, 10 staff at focus group 2 and 4 staff at focus group 3 accepted to give some feedback on the actual construction and possible improvements of the tool with the START-Pilot questionnaire (see Appendix E). Years of experience on the unit varied from less than a year to 35 years. At focus group 2, staff had conducted an average of 50 START assessments each (SD=19.6) and it took them on average 32 minutes (SD=12.06) to complete each assessments. At focus group 3, staff carried out on average 100 START assessments (SD=43.21) and stated that it took them on average 22.5 minutes (SD=5) to complete an assessment. At both times, 90-100% of staff indicated that the information necessary to fill out the START assessments, were readily available. In 70% to 75% of cases, the START was being used for reviews and in 25% of the time for new referrals. In 70% to 75% of cases, more than one source of information was used to fill out START (interview, record review and observation). At focus group 2, 50% of staff indicated that some items were difficult to rate whereas at focus group 3, this rate dropped by half. Overall, staff were moderately to fairly

confident in their ratings. Some of the main comments about what is less useful about the START include: a) not using the results of the START assessments enough in daily practice; b) the section on low-medium-high risk estimates are too vague and need anchors; c) section on THREAT and medical tests were not useful. Comments on how to improve the use of the START included: a) reviewing the IIP right after START assessments to ensure it is a real reflection of the points that stand out in the START; b) need for more coaching; c) add a second sheet on the START summary specifically to detail interventions and provide guidelines in the manual for intervention strategies.

## **5. SUMMARY OF CONCLUSIONS**

To our knowledge this is the first reported demonstration project regarding the actual implementation of the START on an actual inpatient unit. The researchers were involved in terms of support to the clinical staff and for training on the issue of risk and risk assessment. The clinicians and administrative staff and leaders were at the center of the implementation process. This decision was made from the outset in order to avoid the replication of an outcome that is all too often observed when looking at evidence-based practices: once the research project has terminated and the funding that goes with it, the actual clinical programs tend to be abandoned. In this case, the true commitment of the institution in the project is believed to be a central reason why the START continues to be at the center of the unit's clinical activities, despite the "official" end of the research project. It is also a shared belief in the team (administration, clinical and research) that the fact that the administrators and clinicians were the leaders in the organization of the implementation strategy and played the lead roles at go-to persons for the program significantly increased the probability of success. It is believed that this is a reason why the team was able to attain a level of one START assessment per month per patient on the unit.

Prior to the implementation of the START on the unit, there was no standardized tool used by any of the clinical staff to evaluate the potential risk to self or others for individual patients. As a result, there were no systematized risk management plans nor were there any specific challenging behaviour treatment goals included in the individualized intervention plans. The START and the use of a structured professional approach are instrumental in developing the risk management and psychosocial rehabilitation mandate of the unit. The quantitative results indicate that the START has significant potential for predicting short term physical aggression towards others as well as destruction of property. Results also showed that the START was not statistically predictive of the other types of challenging behaviours. Overall, START risk scores tended to be higher for individuals who did have challenging behaviours in the short term than those who didn't and their strength scores tended to be lower. With the exception of unauthorized leave, the levels of severity of all other behaviours were relatively minor and may not pose clinically significant problems to staff. Also, some behaviours such as stalking, self-harm and suicidal indicators were of such low frequency that statistical power is significantly limited. A next analytic step would be to assess how the START risks and strengths can be helpful in predicting the most severe levels of behaviours within each subtype of behaviour. However, larger sample sizes are needed. At this stage, it clearly predicts the most severe behaviour such as such as physical aggression and property damage, making it a useful tool for front line staff. There was a trend towards a decrease in the number of incidents involving physical and object aggression on the whole unit over the course of the study; this trend was also observed for calls to emergency teams and seclusion measures following incidents. These trends however, need further statistical analyses over a longer time period and controlling for other variables such as time at risk.

Future implementation efforts of the START should integrate regular START booster sessions (every six months) in order to avoid coding drifts and conduct frequent inter-rater observer checks. However, this type of procedure is time-consuming for the clinical staff as it requires that each staff rates the same client and then have someone compile the results and discuss disagreements. This was actually a significant obstacle in the current demonstration project. Arrangements should be made to allow a certain number of these audits to be made in an efficient manner. In addition, it is essential to focus the trainings on using the anchors provided for the items in the context of the definition of the item. In addition, allowing a period of adjustment at the beginning of implementation is believed to have been a key factor in the staff being able to arrive at conducting one assessment per month per patient (see Figure 5).

***Limitations.*** The current project has a number of limitations that need to be taken into account. First, the main limitation is related to the small number of individuals actually assessed using the START and the variable number of assessments conducted per individual because of the high turnover rate of patients on the unit. The results are thus to be interpreted in terms of tendencies as the statistical power was limited. Future studies should aim at following-up a larger number of participants. The second main limitation of the current project is that the implementation of the START coincided with such a large number of changes on the unit, the initial pre-post design of looking at the change of aggressive behaviour outcomes before and after the implementation of the START is limited. The characteristics of the patients on the unit changed, as did the physical environment, the systematic manner of reporting incidents, and the mandate of the unit. However, the fact that the START assessments have now become an integral part of ongoing inpatient assessments will enable future research to be conducted. Finally, inter-rater reliability

checks were not carried out regularly by the clinical staff, thereby limiting the possibility of adjusting trainings more regularly.

Despite these limitations, the most important advantage of the current project is its ecological validity, in that it was an observation of the true functioning of a unit around the implementation of a new tool. In this sense the results obtained from both the quantitative and qualitative components can be used to improve future implementation efforts as well as ongoing work on the unit. If one had to qualify the stage of START implementation on the RMRU, it would probably be fair to say that it is in childhood going into adolescence. At this stage, the language used is now common among team members and relatively well understood, the START is integrated into the initial assessment and follow-up clinical pathway of the unit and there are indications of its predictive utility particularly for aggressive behaviour. Work now needs to be done in terms of precisions on certain item definitions, linking the risk estimates with specific strategies of interventions and developing more precise monitoring techniques.

***Future directions.*** There is a need for more research into the implementation of such risk assessment and management tools in real life settings. In terms of actual implementation strategies, the next steps in risk management on the psychiatric unit will be the following: 1) the research and clinical teams will be working towards the development of a more time-appropriate data feedback and monitoring of challenging behaviours to the clinical staff. Part of this will be carried out through the testing of the computerized START program (see Appendix F); 2) the use of the START-Outcomes scale (SOS, see Appendix B), which to date has been coded by the research team based on nursing and clinical notes, but will be integrated into the unit's monitoring protocols and thus carried out by the clinical teams themselves; 3) the clinical team will begin to refine intervention strategies specifically addressing the strengths and risks

identified using the START guide; 4) in line with the recovery movement, having patients themselves be involved in their own assessments and the identification of their key risk factors for challenging behaviours could be explored.

The hospital administration and other inpatient and outpatient services have requested START training. This is highly encouraging and the researcher and psychologist on the START implementation study will be working together over the next few months to enhance the current training protocol by integrating the results and experience yielded from the current demonstration project (see Appendix H). Training and implementation have also been requested from other mental health services in the Québec mental health network as well as from the correctional system. The increasing interest in the possible use of the START and the results of the current demonstration project indicate the necessity to promote the empowerment of clinical staff to gain knowledge and confidence in the realm of risk assessment and management and eventually reduce unnecessary coercive interventions with individuals who display challenging behaviours.

There is still much research needed into the effects of implementing risk management programs in multiple types of settings as well as to the psychometric properties of the START and how to assess those properties in uncontrolled clinical settings. In fact, we are planning on developing a multi-site grant proposal with the authors of the START to be submitted to the Canadian Institutes of Health Research. This would allow the assessment of a more heterogeneous population of severely mentally ill individuals in various contexts and with various base-rates of challenging behaviours. The current project should provide valuable pilot data to this effect.

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