Applying a Continual Quality Improvement Model to Make Data-Based Clinical Decisions

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Continual quality improvement is essential to the provision of excellent services for people with intellectual disability. When helping individuals who have behavioral or psychiatric problems, it is often necessary to use data analysis to track symptoms and improvement. Simple frequency charts are often inadequate, and analytic procedures differentiating patterns of variation in key performance indicators will provide superior information. A case report illustrating the need for such data analysis is presented.

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Continual quality improvement in human services has been described as “the systematic analysis of service quality indicators for the purpose of optimizing service delivery programs and procedures.”²²⁵ (p. 115) This is accomplished by applying certain data analytic procedures and problem solving strategies (process behavior charts, cause and effect diagrams, Pareto charts, etc.) to differentiate between the patterns of variation present in key performance indicators of the process targeted for improvement. Interventions can then be developed, implemented, and continually adjusted based on an ongoing analysis of the resulting outcomes to continuously improve the system’s level of functioning.¹⁵ Although there have been many detailed illustrations of how the principles of continual quality improvement have been applied at the organizational level to optimize outcomes in human services,⁷,¹¹,²⁸ there have been few descriptions of how these principles can be employed to improve the functioning of an individual or consumer of health care services. This article presents a framework for data-based clinical decision making, together with an example of how these principles were applied in the pharmacological treatment of a man with developmental disabilities and bipolar disorder.

Description of the Continual Quality Improvement Model

This article describes a three-step model of continual quality improvement that has been documented to be effective in manufacturing,³⁰ business,³¹ and human services settings¹⁶ and which can be used to make data-based clinical decisions. Our model builds upon the diagnostic and treatment formulation approach described earlier in this Special Issue²¹ by more formally elaborating the role that outcome data can play in modifying on-going treatment decisions for a specific individual. Stripped to its essential characteristics, our continual quality improvement model involves reiterative answers to the following three interrelated questions:

1. What objectives does the proposed treatment intend to accomplish?
2. What methods or interventions will be used to accomplish these objectives?
3. What criteria will be used to determine if and when these objectives have been accomplished?

We will describe how answers to each of these interlocking questions can be used to provide a framework for hypothesis-driven, data-based treatment for people with developmental disabilities and psychiatric impairments. We will also present a case study of how the model was applied to make decisions regarding pharmacological treatment for a man with developmental disabilities and bipolar disorder. The discussion below focuses on pharmacological treatment but the decision making model can be applied to any type of intervention that utilizes empirical data to systematically monitor treatment outcomes.
1. What are the intended accomplishments?

The diagnostic and treatment formulation article by Sovner and Hurley identifies three different approaches to psychopharmacological treatment which parallel similar distinctions made by Gardner and Cole regarding behavioral interventions: 1) **Behavioral control** strategies seek to suppress the occurrence of discrete target behaviors without necessarily identifying the underlying biopsychosocial processes or mechanisms which might be responsible for the presenting problems (aggression, self-injury, or property destruction); 2) **Behavior management** approaches, on the other hand, seek to stabilize the person's functioning at an optimal level by identifying and modulating the underlying conditions which are responsible for the expression of the presenting problems. Depending on the practitioner's theoretical orientation, these underlying conditions are typically either conceptualized in behavioral terms as environmental contingencies (antecedent, behavior, environmental consequence interrelationships) or psychiatrically as medication-responsive symptom complexes (over-arousal, chronic irritability) which can be modulated by a particular psychotropic medication regimen; and 3) In contrast to the above, **behavioral treatment** approaches seek to normalize the person's functioning by achieving a complete remission of the presenting problems.

2. What methods or interventions will be employed to accomplish these objectives?

The choice of a particular intervention strategy is typically linked, either implicitly or explicitly, to the objectives the practitioner is trying to accomplish. If the focus is on **behavioral control**, the methods employed are usually chosen to rapidly suppress the presenting problems. Reactive, restrictive behavior control strategies like exclusionary time out or response-contingent physical punishment involving the use of aversive stimuli like electric shock, may be quite effective in immediately suppressing the occurrence of discrete target behaviors like aggression, self-injury, or property destruction (as they were in the case study described below). However, apart from ethical objections and regulatory obstacles that restrict their application, use of such restrictive interventions (including the use of psychotropic medications as a form of chemical restraint) has typically been associated with poor long-term maintenance of any immediate treatment gains. There has been an unfortunate tendency in the field of developmental disabilities to regard psychotropic medications as effective control strategies that can suppress the occurrence of specific behavioral problems which are identified as the targets for treatment. This is not only reflected in the professional literature but also in the language caregivers typically use when referring someone for a psychiatric evaluation ("His behavior has escalated out of control, he needs something to control his aggression."). The perception that psychotropic medications are being used to control specific behavior problems has led regulatory agencies to classify them together with the use of mechanical restraints and seclusion as interventions which "pose an untoward risk to the protection of basic human rights." Considered as such, they are subject to review by human rights committees in accordance with strict regulatory standards. This has caused regret on the part of many psychiatrists who object to what they perceive as the intrusion of lay people into their zone of professional competence. However, this is the logical consequence of talking about the use of psychotropic medications as if they were an effective form of "chemical restraint." Using the language of "behavioral control" also reinforces the notion that medications should be reduced to the lowest possible dose and that drug holidays should be attempted whenever there have been no behavior problems for a period of time. While these may be legitimate strategies when psychotropic medications are used as a form of chemical restraint, adhering to them is counterproductive when treating a person's psychiatric disorder. Kalachnik et al. provide guidelines for establishing the lowest optimal effective dose of psychotropic medication in cases where it is being used to treat a psychiatric disorder.

**Behavior management** approaches typically produce more durable treatment gains by developing interventions which are tailored to the biopsychosocial mechanisms which have been determined by a comprehensive functional analysis to underline the expression of the person's presenting problems. Even though it has become increasingly clear that challenging behaviors are rarely the result of single causes (either environmentally-based or medically-related), it is still customary to describe
interventions as either pharmacological or behavioral, although there have been some notable exceptions. Consider, for example, the case described below where one factor contributing to self-injurious behavior was hypothesized to be the reinforcement provided by activation of the endogenous opiate system. This does not preclude the possibility that the person has learned to terminate what are perceived as aversive, task-related demands by engaging in self-injurious behavior, particularly if the person has an unusually high pain threshold also associated with dysregulation of the endogenous opiate system. By formulating the presenting problems in this manner, naltrexone would be prescribed to manage self-injury by regulating the production of endogenous opiates so that the pain threshold is lowered and the person does not experience the euphoric "high" associated with the release of endogenous opiates. To some, this may be just a semantic distinction, since the intended outcome is the same reduction in the frequency and/or intensity of self-injury sought by prescribing a neuroleptic medication as a form of chemical restraint. However, the process of matching the medication to the presenting problem is different in both cases. The "behavior control" mentality focuses on the typology of the behavior in question—promoting selection of medications that are effective in treating self-injury, aggression, property destruction, etc. However, one person's self-injury may be mediated by the same biopsychosocial mechanisms that control another person's aggression, as illustrated by the abundant literature documenting the importance of developing interventions based on a functional analysis of the presenting problems. Regarding the use of psychotropic medications, this behavior management strategy attempts to match the medication prescribed with a corresponding biological mechanism (dysregulation of the endogenous opiate system, as described above) that has been empirically determined to be effective in managing the expression of the presenting problems.

In cases where it is possible to identify a psychiatric disorder which underlies the expression of the presenting problems, then treatment can proceed according to the guidelines described by Sovner and Hurley reprinted in this Special Issue. This represents a distinctly different approach to the use of psychotropic medications to suppress or control specific target behaviors, as noted above. It is beyond the scope of this article to consider the conceptual pitfalls and practical difficulties encountered when attempting to make an accurate psychiatric diagnosis in persons with intellectual disability. The interested reader can consult the chapter in The International Consensus Handbook, as well as a recent article in this journal which provides useful guidelines. The National Association for Dually Diagnosed recently published an entire volume on the topic of mood disorders in people with intellectual disability and is also preparing a classification manual that adapts DSM-IV criteria for use with people who have intellectual disability. A specific application of this strategy for diagnosing bipolar disorder in people with development disabilities was previously published in this journal and is also illustrated in the article by King in this Special Issue. The general utility of this approach to treating psychiatric disorders underlying challenging behaviors was documented by Tsiouris and colleagues, who described how self-injurious behaviors that were not controlled by behavioral interventions or the use of neuroleptic medications as a form of chemical restraint were significantly decreased or eliminated in 26 individuals with severe to profound intellectual disability when the use of psychotropic medication was matched to the corresponding psychiatric diagnosis (depression, anxiety, impulse control disorder).

3. What criteria will be employed to determine if and when the interventions accomplished their intended objectives?

Unfortunately, little has changed since 1992 when the Sovner and Hurley paper was first published to negate their impression that treatment outcomes are too frequently based on subjective impressions derived from a cursory review of the person's presenting problems "without forethought about the expected outcome, and no prospective outcome criteria are developed that define an adequate therapeutic trial." (p. 81) Even when treatment is evaluated against objective measurements of the frequency or intensity of operationally defined target behaviors obtained during an adequate period of baseline observation (a "gold standard" rarely achieved in routine clinical practice), the criticisms leveled by Barnhill against
unidimensional data management systems still apply. Unidimensional measurements often contain so much “noise” due to day to day variability across time and within day variability across measures that it is difficult (if not impossible) to clearly discern long-term changes that are associated with treatment. Even when multiple data sets are combined, as recommended by Barnhill and illustrated in the King et al. article, the absence of explicit criteria for distinguishing “statistically significant changes” from “clinically significant improvements” represents a significant obstacle to determining if and when the person has benefitted from the interventions he/she has received to remediate the presenting problems. The case study described below demonstrates how it is possible to develop explicit outcome criteria for determining if and when interventions have accomplished their intended objectives by using baseline measures of key outcome indicators to evaluate treatment effectiveness and to make data-based, clinical decisions.

**Clinical Application of the Continual Quality Improvement Model**

**Background Information**

At the time of this study, Mr. A was a 25-year-old man with autistic disorder who functioned in the severe range of intellectual disability. He was blind from birth, possibly as a result of his mother’s exposure to rubella when she was pregnant with him, although an older brother is also congenitally blind and is intellectually gifted. Self-injurious behavior first emerged during Mr. A’s infancy and has persisted throughout his life. Periods of stable functioning have been interrupted by dramatic relapses, sometimes due to known factors (serious medical problems) but for unknown reasons on other occasions. In a previous residential placement a number of highly controversial forms of aversive treatment were attempted, using interventions no longer permitted (physical punishments such as spanking him and using painful electric shocks), in a desperate attempt to eliminate his self-injurious behaviors. None of these aversive consequences produced any lasting changes in Mr. A’s behavior. Short term treatment gains were immediately followed by a return to dangerously high rates of self-injury. Furthermore, punishing one type of self-injury (e.g., head banging) led to the emergence of other problems (attempting to bite himself or aggression towards others) which then led to the use of even more aversive forms of treatment. When his parents refused to authorize the continued use of painful forms of electric shock, Mr. A was put in physical restraints to prevent him from harming himself. Restraints were used 24 hours a day, 7 days a week for nearly 18 months until Mr. A came to us for treatment.

When we first attempted to remove the restraints that Mr. A wore to prevent him from injuring himself (which included devices resembling handcuffs that tethered his wrists to a belt worn around his waist, as well as a helmet to prevent him from injuring his head on sharp or hard objects), he became extremely agitated and attempted to injure himself so violently that it was necessary to restore them again immediately to protect him from harm. This indicated that these devices functioned as a form of self-restraint that is frequently encountered among individuals who engage in self-destructive behavior. \(^1\) This conceptualization formed the basis for the behavioral component of our treatment plan for Mr. A. Since restraints clearly functioned as a form of self-control that Mr. A used to prevent self-injury, we would not attempt to prohibit their use. Rather, we gradually attempted to develop his tolerance for having them removed periodically for short intervals (as required by statutory regulation). At the same time, we gradually increased the level of task demands (requirements that he perform certain routines spelled out in his treatment plan to increase his functional independence, such as teaching him to brush his teeth). In the past, Mr. A’s self-injury appeared to function as a strategy for manipulating staff to terminate these sources of frustration. Staff were instructed to make realistic demands on him that did not exceed his capacity to respond in the desired manner and to allow him to terminate training sessions when it was appropriate to do so if he communicated this request appropriately.

We decided to evaluate the results of our interventions by having each work shift in the treatment unit record the number of minutes that Mr. A spent free of any form of restraint. This variable was chosen as an outcome measure for the following reasons. First, it reflected Mr. A’s clinical status at the time of admission and provided a focus for our treatment plan, as explained above. This measure was also objective and was readily obtained with the use of a simple
A timing device that could be set and re-set by staff when restraints were removed and placed back on again. Furthermore, it reflected a practical necessity that did not require additional paperwork. New York State Mental Hygiene Law prohibits the use of mechanical restraints unless certain conditions are met, one of which involves the documentation that restraints are removed every two hours so that a safety check can be carried out. These measurements, therefore, provided staff in the treatment unit with the means of complying with a regulation while providing us with a useful indicator of clinical status. This outcome measure also avoided problems associated with using multiple measurements of discrete target behaviors (self-injury, aggression towards other, property destruction) to evaluate the effectiveness of multi-component treatment plans, noted by Barnhill in this Special Issue.

Initially, good periods were more predictable during the night shift than at any other time during the day, as Mr. A learned to sleep through the night without the need for restraints. The severity of his behavioral outbursts necessitated the assignment of two staff to protect him from harm on each work shift. This was accomplished within the unit by means of a rotational assignment of overtime duty that brought virtually the entire roster in the building into contact with him during the course of his treatment. Some staff worked with Mr. A more effectively than others, and we learned to identify their presence (or absence) by carefully inspecting changes in a graph of his behavioral data. Other “unexpected” changes also became predictable over time, such as the effect that parental visits had on Mr. A’s behavior, particularly when they didn’t occur on weekends as he had come to expect.

A placebo was introduced during the second week of treatment in anticipation of the introduction of naltrexone in combination with the other medication (Tegretol) that Mr. A was taking when he entered the treatment unit. This was done to minimize the possibility that an expectation of improvement might confound the interpretation of results due to the planned introduction of this new (and somewhat experimental at the time) medication at a later date. After Mr. A had been taking the placebo for five weeks, it was discontinued for one month before the dosage of his original medication (Tegretol) was increased during week 9 to determine if it was possible to help Mr. A control his self-injury by using only a single medication. Figure 1 summarizes the results of the first three months of Mr. A’s treatment in terms of the weekly average of our key performance indicator, the number of minutes each work shift recorded that Mr. A was able to engage in his daily activity schedule without use of restraints to protect him from harming himself. It is clear from inspecting the results presented in Figure 1 that Mr. A made considerable progress during the first twelve weeks of treatment. Restraints were used less than two hours per shift, mostly during the evening and on those weekends when his parents didn’t visit and there were fewer opportunities for him to participate in structured activities. Furthermore, he learned to tolerate task-related demands in his day program and to ask for restraints when he felt overwhelmed by these demands. Nevertheless, Mr. A occasionally engaged in SIB that was so intense that it required the use of restraints to prevent him from injuring himself. Clearly it was necessary to revise his treatment plan in order to accomplish more optimal outcomes.
Up to this point, treatment outcomes were evaluated retrospectively by looking backwards in time, to determine if any significant changes had already occurred (as illustrated above). Retrospective decision making is like trying to steer your car by looking in the rear view mirror—you can tell if you have made any major mistakes but it isn’t clear where you are headed. We decided to implement a trial with naltrexone and to evaluate the results prospectively by more formally applying the principles of continual quality improvement described above, including statistical process control to develop explicit outcome criteria that could be used in “real time” to determine if and when significant changes occurred.

**Clinical Decision Making Using Statistical Process Control**

Statistical process control (SPC) can be described as a way of thinking with some tools attached, although some practitioners become preoccupied with describing the formal properties of the tools to the exclusion of a consideration of their utility. The case study presented here was originally published in a technical newsletter and later reprinted in a handbook for practitioners interested in learning how to make sense of data gathered in service settings. There are seven basic tools of SPC commonly used to detect patterns of variation in measurements of performance that need to be corrected in order to ensure that quality control standards are achieved and to implement a plan leading to continual quality improvement: 1) the construction of histograms (e.g., bar charts or stem and leaf plots), 2) running records that provide a graphic presentation of the production process, 3) use of process behavior charts [described below] and 4) procedures for setting the process aim that provide for a more in-depth analysis of the quantitative information used to monitor productivity and to evaluate the quality of the outcomes accomplished. In addition, three organizational tools for problem solving, 5) flowcharts, 6) Pareto charts and 7) cause and effect diagrams, are useful in tracking down the sources of variability that result in special causes of variation. These are considered exceptions to the manner in which the system normally functions. A fundamental objective in using SPC tools is to distinguish patterns of variation due to these special (assignable) causes of exceptional variation from patterns of routine variation due to common causes, which are regarded as inherent features of how the process typically functions.

SPC offers an approach to evaluating the significance of changes associated with planned interventions or with the spontaneous occurrence of uncontrolled variables. It combines the rigor and objectivity of a statistical analysis of data with the sensitivity of clinical judgment developed by the behavior analytic tradition that favors visual inspection of characteristics in the time series of scores from an individual subject. This is accomplished by constructing a process behavior chart, in which the average values obtained during a trial period are used to compute a measure of location (the mean of the measurements) and process limits, based on a measure of dispersion or variability in the scores obtained. The running record serves as a graphic representation of the process being studied. Use of process behavior charts provides objective criteria (i.e., scaling factors) for “eyeballing the data” to assist in the visual interpretation of quantitative information. Accordingly, use of these procedures allows the investigator to avoid choosing between either a statistical analysis or a visual inspection of time series data. Using control charts, it is possible to do both types of analysis without aggregating data from a group of heterogeneous subjects in a manner that obscures meaningful and unique patterns of variation displayed by an individual.

The upper and lower limits of a process behavior chart are established by converting measurements of a key performance indicator into sigma units. Sigma units reflect the distribution of scores that can be expected to lie on either side of the mean of the measurements, in terms of standard deviation units. Process behavior limits are used to establish the extent of routine variation. These limits specify a range of values to be expected if only those factors intrinsic to the individual’s normal functioning affect the results obtained in a clinical setting. A prediction is made about how the process should continue to function if only common causes of routine variation are operative. The process limits are extended and subsequent measurements of the person’s functioning are monitored by applying certain objective guidelines to determine if and when the assumption of chance variation has been violated and the effects of special causes of exceptional variation are apparent. In the
context of our continual quality improvement model, these guidelines are used to determine if and when a particular intervention has been effective, as illustrated.

**Using the Continual Quality Improvement Model to Evaluate the Naltrexone Trial**

**What Objectives Did We Attempt to Accomplish by Using Naltrexone?**

The decision to introduce naltrexone as part of Mr. A's medication regimen was made on the basis of the diagnostic rationale discussed previously. He displayed a pattern of self-injury that was consistent with the hypothesis that his behavior was reinforced by the consequences it produced (i.e., self-administered reinforcement associated with activation of the endogenous opiate system). This hypothesis provided the framework for identifying the outcome we intended to accomplish. We would attempt to block the release of endorphins triggered by Mr. A's self-injury and thereby extinguish this behavior by preventing him from obtaining the secondary reinforcement it produced. Evidence to support this hypothesis would be provided by the absence of self-injury requiring the use of restraints.

**What Methods Did We Employ to Accomplish this Objective?**

Naltrexone was administered as part of a comprehensive treatment plan previously described. We obtained approval to use of a maximum dose of 100mg of naltrexone based on guidelines available at that time. Treatment was started at 25mg daily with dosage adjustments made on the basis of the outcomes we obtained.

**What Criteria Were Used to Determine If and When These Objectives Were Accomplished?**

Results of measurements for the naltrexone trial were obtained by constructing a process behavior chart (specifically a chart for individual values and a moving range) based on measurements obtained during the four week period shown in Figure 1 when the higher dose of Tegretol was administered. In order to obtain upper and lower process limits, these four weekly averages were used to obtain three moving ranges, and limits for the process behavior chart shown in Figure 2 were calculated according to procedures described elsewhere. Figure 2 shows that an increase in time out of restraints from the baseline average of 378 minutes to the upper process limit of 448 minutes would be necessary to indicate that significant improvements occurred while taking naltrexone. Likewise, a decrease in average weekly time spent out of restraints to less than 308 minutes (the lower process limit) would indicate that Mr. A was doing significantly worse while taking naltrexone. Four weekly values and three moving ranges are certainly a minimal amount of data for computing control limits, all values are approximate. Nevertheless, process limits have been proven to "fail safe" under these conditions, meaning that any changes detected will not be false positives and will represent significant departures from baseline functioning.

Results presented in Figure 3 indicated that Mr. A suffered a regression in clinical status as the dosages of naltrexone were raised from 25mg to 100mg. When the dose of naltrexone was raised to 75mg, the average time out of restraints for week 17 dropped below the lower process limit of 308 minutes. Additionally, all of the values
obtained during the four week period when the 100mg dose of naltrexone was administered were at or below the lower process limit. Decreasing the dose of naltrexone and discontinuing it brought the weekly averages of time out of restraint back within the range of chance variation associated with measurements obtained when the higher dose of Tegretol was administrated, as shown in Figure 4. This quantitative, data-based analysis was borne out by the subjective impressions of staff and other objective indicators. During this time Mr. A inflicted some injuries to his face that required medical interventions (sutures and use of antibiotics to treat an infected wound). A reduction in dosage and eventual discontinuation of naltrexone confirmed this impression and led to a reformulation of the presenting problems. The day to day and week to week variability that we previously regarded as “noise” could now be seen as signs of mood instability, particularly in the context of other symptoms of bipolar disorder that Mr. A displayed (sleep and appetite disturbances, sudden shifts in mood from euphoric to sullen and withdrawn, with periods of sadness and crying). Lithium was introduced as an additional mood stabilizer in combination with Tegretol during week 30 of Mr. A's treatment. This produced a dramatic improvement in clinical status, measured objectively by the outcome data shown in Figure 4 and subjectively by the reports of staff and Mr. A's parents, as noted below. After week 33, use of restraints was virtually eliminated except for several instances associated with recurring medical problems. Prospective use of the objective criteria for identifying clinically significant changes in functioning that were provided by process limits permitted us to quickly determine that naltrexone was not accomplishing its intended objectives. This was important because treatment with naltrexone had considerable face validity and we believed that it would be successful. When our outcome measurements broke through these process limits, it represented a clear warning signal that our hypothesis was wrong. This served as an incentive to try a different approach and prevented Mr. A's continued exposure to a counter-therapeutic medication regimen.

Mr. A's parents wrote the following commentary regarding the use of this continual quality improvement model to make data-based decisions regarding his treatment:

"The statistical process of measuring our son's behavior has enabled those who have interpreted the graphs to have a clearer picture of what underlying factors influence the exhibited behaviors. The precise recording and interpretation of the daily processes have pinpointed the incidents that our son is unable to verbalize or relate to his caregivers. Through the years it has been difficult to identify and understand those factors that may have contributed to his complex behavior that is manifested by severe battering of his face and biting of his hands."

"Many behavior altering programs have been tried with varying responses in improved or worsening behavior. It has always been difficult, in a retrospective approach, to try to sort out those treatment techniques that were effective. This sorting was usually left to subjective analysis and
interpretive impressions by observers and involved staff interacted with our son in his daily management and treatment regimen. It appears that with the mode of precise recording and analysis using the continuous graph formats which was used with our son in this program one could relate his specific behavior at a given point in time to any factor in his daily life that would affect his behavior pattern. This has permitted us to correlate changes in behavior and response to treatment as a total interaction of all the factors, e.g., starting, changing, or terminating medication, parental visits as related to program days and non-program days, different interactions with specific members of staff, etc. A major triggering factor had always been the undetectable onset of illness, e.g., earache, sore throat, or viral infection, which would now be evident on analysis of his behavior chart.

“We feel that this is a far more appropriate approach toward the trials of medication in attempts to control the self-injurious behavior. In all the years of our son’s behaviors, since the age of three, we have never felt that a treatment program and staff were as totally involved with him as has been the case during the past year.”

References


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