



Neurological Devices Advisory Panel Meeting

Aversive Conditioning Devices

April 24, 2014



Description of Judge Rotenberg Educational Center, Inc.

Glenda P. Crookes, Executive Director

Judge Rotenberg Educational Center

- The Judge Rotenberg Educational Center is a special education school and treatment facility that was founded in 1971 for children and adults.
- Located in Canton, Massachusetts
- 241 patients enrolled and living in one of 40 group homes
- Aversive conditioning devices have been in use at Center since 1989 in conjunction with comprehensive behavior modification techniques
- 60 of the 241 current patients have an aversive conditioning device as one component of a comprehensive behavior modification plan

State approvals, licenses and certifications

- Licensed by the Massachusetts Department of Elementary and Secondary Education
- Approved by the New York State Education Department
- Approved by the State of Illinois Department of Education
- Adult day program is licensed by the Massachusetts Department of Developmental Services
- Groups homes are licensed by the Massachusetts Department of Early Education and Care or the Massachusetts Department of Developmental Services
- Certified to use aversive procedures by the Massachusetts Department of Developmental Services

JRC Currently Treats Patients from 11 States

These states fund the placement of their citizens at JRC:

- Massachusetts
- New York
- California
- Connecticut
- Delaware
- Maine
- New Hampshire
- New Jersey
- Pennsylvania
- Rhode Island
- Virginia



One computer per student, individualized educational program designed for each student

Comfortable, happy, and upbeat environment



All Patients Receive State of the Art Behavioral Programming

- Evaluations of all incoming patients
 - Assessment of behavior function
 - Objective measurement of problem behaviors
- Therapies and education
 - Reinforcement of positive behaviors
 - Teaching of positive behaviors to replace harmful behaviors
 - Additional treatments such as psychotropic medications and psychotherapy, if indicated
 - Vocational training
 - Programmed Instruction and Precision Teaching

Certain JRC Patients Treated with Aversive Conditioning

- Patients with extraordinary behavior disorders
 - Typically have been treated ineffectively with wide range of therapeutic interventions over long periods of time
 - Head banging, biting and scratching self, throwing objects, attacking others, eye gouging, tearing their own flesh, pulling out their own adult teeth, hair and toe nails
 - Behaviors have results in hospitalizations and other permanent injuries
- Patients expelled from or refused admission to 12-15 placements, on average, before admission to JRC
- Patients have not improved with comprehensive behavioral programming alone



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Many of our students arrive heavily sedated and restrained

Friendly's



This same student developed the necessary behaviors and skills to be able to obtain a competitive job at a local business

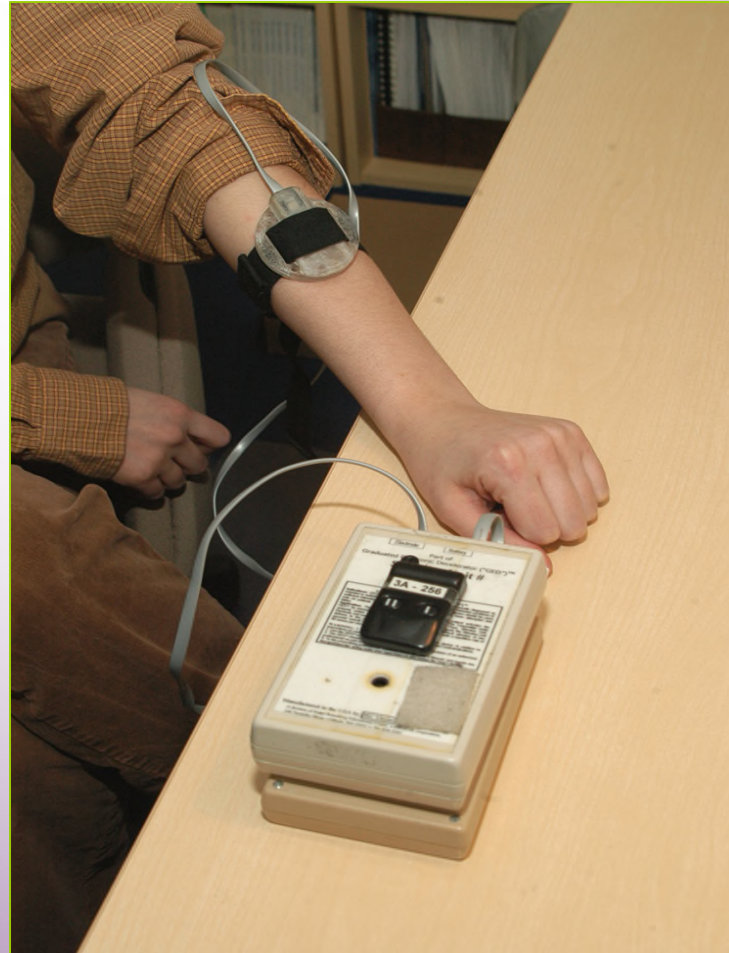
Aversive Conditioning Devices

- Data demonstrate clinical need for such devices
 - Patients utilizing this therapy have failed all other treatment options
 - Data demonstrate effectiveness in reducing harmful behaviors
 - Patients no longer a threat to themselves or others
- Data clearly demonstrate that aversive therapy is safe and does not present a substantial and unreasonable risk of injury
- Risk/benefit ratio supports continued availability

Device Description

- The Graduated Electronic Decelerator (GED) is an aversive conditioning device developed by JRC
- GED provides a harmless cutaneous electrical stimulation contingent on extreme aggressive, disruptive, or self-injurious behaviors to reduce or eliminate the behavior
- Produced at and used only for patients enrolled at JRC
 - GED devices are not distributed or marketed for sale

Electrode



Battery

Regulatory History

- 510(k) cleared on December 5, 1994 (K911820)
- In 2000, FDA sent letter to JRC stating that the GED devices were not subject to FDA's 510(k) requirements
 - “After discussions with NEW-DO compliance branch and CDRH, it was determined that the firm is exempt from 510(k) notices, and the device is considered to be within the practice of medicine.”
- In 2011, FDA changed its position and issued an Untitled Letter and 2012 Warning Letter stating that a new 510(k) notice for the GED devices is required
- JRC believes use of devices is still within the scope of the practice of medicine exemption (21 U.S.C. § 396)

Regulatory History, cont.

- JRC has worked interactively with FDA since 2011 to address the 510(k) issue
- JRC offered to conduct a clinical study under FDA's IDE regulations
- In response to FDA request, JRC filed a pre-submission prior to submitting a 510(k) notice
- FDA postponed pre-submission meeting, failed to reschedule, and never finalized pre-submission process
- Next communication from FDA was notice of this panel meeting to ban aversive conditioning devices

Device Specifications

- GED is remotely activated to deliver an electrical stimulation to patient
 - Administered by trained staff who directly observe the behavior that has been identified for treatment by a Doctoral level clinician
- 2 second pulsed stimulation to skin surface
- GED device delivers DC current
 - Thermal injury not possible with GED output parameters
 - Low output parameters avoid sequelae associated with electrical stimulation (e.g., severe muscular contraction, burns, seizures, and ventricular fibrillation)

Device Components

- Stimulus Generator for creating the stimulation
 - GED-3A delivers 15 mA stimulation
 - GED-4 delivers 41 mA stimulation
- A skin contact Electrode which delivers the stimulation to the patient
 - Typically place on arm or leg
 - Never placed on spine; chest or breasts, genitals; head; top of hand or foot; lower quadrant on the buttocks; any sensitive area of skin
- A Remote Activator for activating the Stimulus Generator

When are Aversive Conditioning Devices Considered as a Treatment Option

- Small subgroup of patients who exhibit self-injurious, harmful, aggressive behaviors
 - Danger to themselves and/or others
- Medications and other therapies at other institutions and JRC have failed to safely and effectively treat behaviors
- Positive behavior support techniques at JRC and other institutions have failed to treat behaviors
 - Patients currently treated approximately 12 months at JRC prior to using the GED devices

Requirements Prior to GED Therapy

1. Other therapies used to treat the patient have failed;
2. The parent/guardian must provide written informed consent which can be withdrawn at any time;
3. A Ph.D.-level licensed psychologist or a Ph.D.-level Board Certified Behavior Analyst must prepare an appropriate treatment plan for the patient;

Requirements Prior to GED Therapy, cont.

4. A peer review committee must review the plan and deem it appropriate;
5. The school district or agency that referred the patient to JRC also must approve the treatment plan and incorporate it into the patient's Individualized Education or Service Plan;
6. A physician must certify the absence of medical contraindications to the use of the GED devices for each patient;

Requirements Prior to GED Therapy, cont.

7. A human rights committee must approve the treatment plan; and
8. Treatment plan must be authorized by a Massachusetts Probate and Family Court.
 - The patient must be assigned his or her own court-appointed independent counsel
 - May hire court-funded experts, as appropriate, to evaluate the patient and oppose the treatment in court
 - Court must review and reapprove treatment plan on yearly basis

Procedures for Use *Patient Monitoring*

- Stimulus delivered contingent upon harmful behaviors designated by the attending clinician
- Staff must observe behavior directly
- Staff must observe the patient prior to and during the activation
- Before any administration of an application, the behavior and the transmitter have to be verified by two staff members

Procedures for Use *Patient Monitoring*

- Each patient is evaluated by a nurse within 24 hours of receiving stimulation
- Staff member must visibly check the skin area where the electrode was placed immediately after GED stimulation
- GED electrodes must be moved to different body location every hour and also immediately after an application of GED

Procedures for Use *Patient Monitoring*

- All patients receive at least weekly evaluations by the attending clinician to evaluate efficacy and side effects
 - Each patient is generally seen numerous times / week
- Each activation of the GED device is documented in a behavior tracking sheet and database
 - 24 hour video monitoring to ensure proper implementation
- Any misapplication or spontaneous application of the GED device is rare
 - Error rate is less than 0.01%
 - JRC personnel are terminated automatically for any confirmed misapplication

Clinical Data Demonstrating Safety and Efficacy of Aversive Conditioning Devices

Nathan Blenkush Ph.D., BCBA-D

Available Treatment Options

- Clinicians must consider both safety and efficacy of treatments
 - Function Based Behavioral Intervention (Applied Behavior Analysis, Positive Behavior Support)
 - Psychotropic Medications
 - Psychotherapy
 - Restraint
 - Seclusion
 - Electroconvulsive Therapy (ECT)
 - Psychosurgery
 - Aversive conditioning therapy

Clinical Data for Current Patients

- 241 patients enrolled at JRC
- 83 of these patients have used the GED devices
- 71 patients currently indicated and approved for treatment with aversive conditioning devices
- Only 60 patients currently receiving therapy with GED devices

Clinical Data for Current Patients

- Currently, on average, patients receive treatment at JRC for 12 months prior to use of aversive conditioning devices
- Of the 60 patients receiving GED therapy:
 - Average of less than 2 applications / week over the past 6 months
 - Less than 4 seconds of stimulation / week
 - 6 patients have not received any applications in past 6 months

Safety of GED Devices

- No long-term side effects have been noted
- No mental health side-effects such as PTSD
- Positive side-effects consistently noted
- Patients have demonstrated an improved quality of life
 - Generally free of restraint and psychotropic medications and free of injuries
 - Actively learning educational, vocational and habilitative skills

Safety of GED Devices

- In rare cases, mild erythema of the skin that disappears within an hour to a few days
- Less than 1% of applications result in <1mm lesion
 - Resolves in 1-2 days with no scarring
- Brief, temporary anxiety just prior to the delivery of the application
- Occasional harmless avoidance responses (tensing of the body, removing the electrode in some cases)
 - These responses are brief (seconds in duration) and minimized by the remote control application
 - Shorter in duration than avoidance responses associated with restraint and time out

Safety of GED Device

- No evidence of burns
 - JRC has found no evidence of burns
 - DC current cannot produce thermal injury at these outputs
 - Canton police have responded to outside anonymous calls reporting patient burns and have found no evidence upon inspection. Call reported as false police report
 - Massachusetts Disabled Persons Protection Commission has thoroughly investigated the use of the device

Safety Profile of Aversive Conditioning Devices Generally

- JRC's data on the GED is consistent with information regarding aversive conditioning devices in medical literature
- Literature addresses minor temporary side effects of aversive conditioning devices
 - Slight local tremor during activation
 - No tissue damage
 - Brief anxiety

Efficacy of GED Devices

- Patients undergoing therapy with the GED devices have experienced a meaningful decrease in their aggressive, self-injurious, or other harmful behaviors

Efficacy of GED Devices

- Benefits include clinical, physical, and mental improvements
 - Dramatic improvement in affect
 - Have been able to undergo necessary medical procedures
 - Can receive and benefit from educational and training opportunities
 - Enjoy time with family and leisure time
 - Community integration (ADA Requirement)
- Often eliminates the need for psychotropic medications
- Generally eliminates the need for restraint and protective equipment

Efficacy of GED Devices

Current Patient Population

- 12 of the 83 patients no longer require therapy with GED devices
- 11 additional patients who have stopped using devices but devices are still indicated if needed
- 6 additional patients have not received any applications in past 6 months
- Other patients who now only use devices during certain hours of the day

“Treatment of Aggression with Behavioral Programming that Includes Supplementary Contingent Skin-Shock”

Israel MA, Blenkush NA, von Heyn RE, Rivera PM

JOBA-OVTP Volume 1, Number 4 2008

- Participants: 60 participants (assigned a wide range of diagnoses)
- Methods: 3-year retrospective analysis of aggressive behavior frequency before and after the introduction of contingent skin shock
- Results:
 - All patients experienced 90% reduction of behaviors from baseline at the end of the 3-year period
 - Side effects included temporary discoloration of skin under electrode, temporary emotional behaviors, temporary tensing of the body, attempt to remove device

“Seven Case Studies of Individuals Expelled from Positive Only Programs”

Israel ML, Blenkush NA, von Heyn RE, Sands CC
JOBA-OVTP Volume 2, Number 1, 2010

- Participants: 7 patients who were all expelled from well regarded residential programs and treatment settings
- Methods: Retrospective analysis of all behaviors for which the GED was arranged as a consequence
- Results: All 7 patients experienced:
 - Significant reductions in problem behavior frequency
 - Elimination of psychotropic medication
 - Significant reduction or elimination in restraint
 - Improved skill and academic achievement

Efficacy of Aversive Conditioning Devices

Positive Side Effects

- Findings of reduction in harmful, self-injurious, and aggressive behaviors supported by the literature
- Literature also reports positive side effects
 - Reduction in other problem behaviors (bites, hair pulls, hits)
 - Increases in behaviors suggestive of relaxation and decreased distressed vocalizations
 - Increasing in smiles, laughs, self-initiated communication, self-initiated socialization, decreases in pinching
 - Less distressed when upset, more responsive to reinforcement, emission of more appropriate behaviors
 - Heart rate and breaths per minute **INCREASED** when device was removed

Linschied et al. (1990), Linschied et al. (2002), Salvy et al. (2004), Barrera et al. (2007), Duker et al. (2007), Williams et al. (1993)

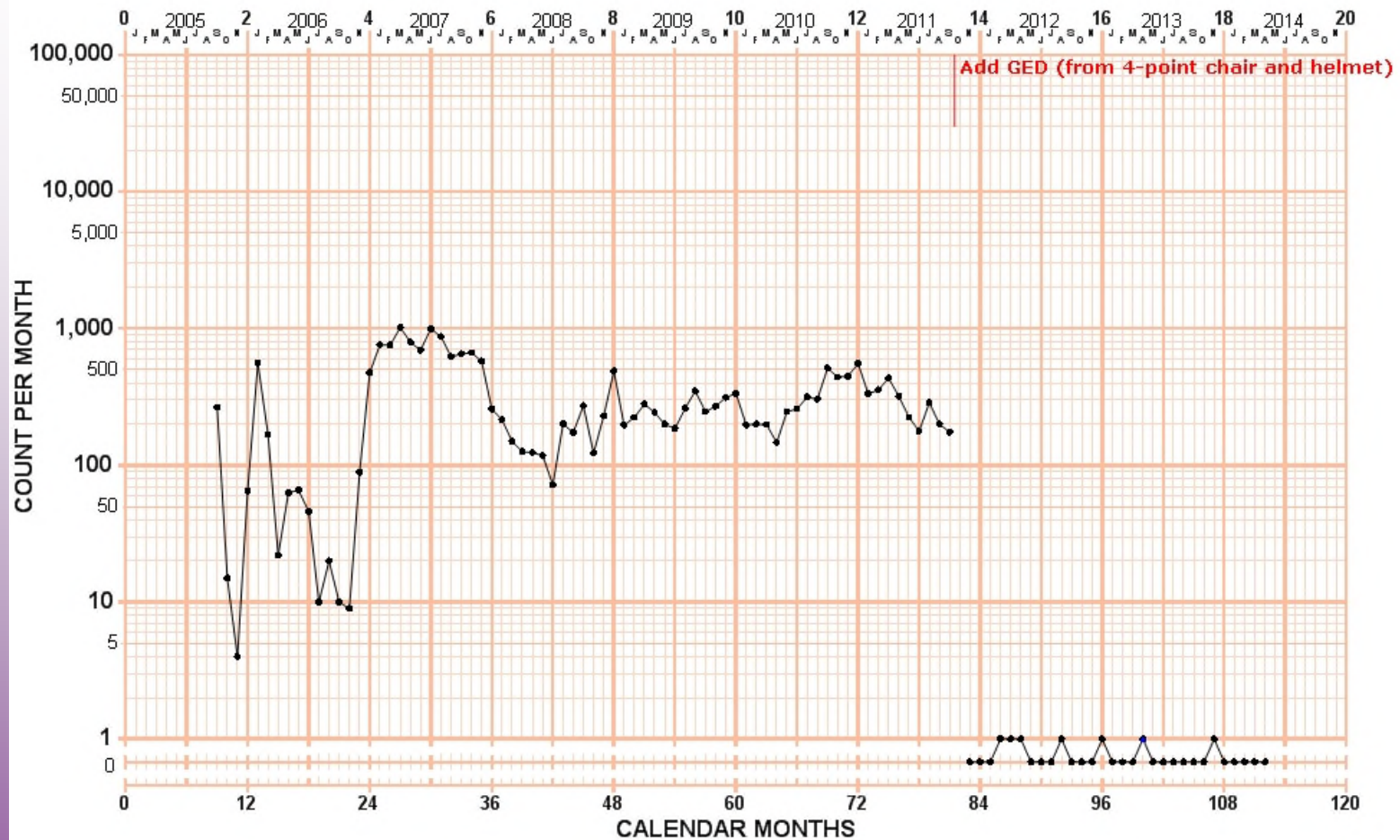
Andrew

- Early autism intervention
- Well regarded private day school
- Wide range of medication trials
- Obese from antipsychotic medication at age 13
- From 2007 to 2011, required emergency restraint on 1945 occasions (748 hours)
- Caused severe injuries to himself (concussions, lacerations, bites, broken bones)
- Cause severe injuries to others (bites, broken bones, concussions)
- Was unable to enter the community or attend home visits



Addition of GED Eliminated Aggression

MONTHLY CHART



Cort, Reynaldine
CASE MANAGER

Blenkush, Ph. D., BCBA-D, Nathan
CLINICIAN

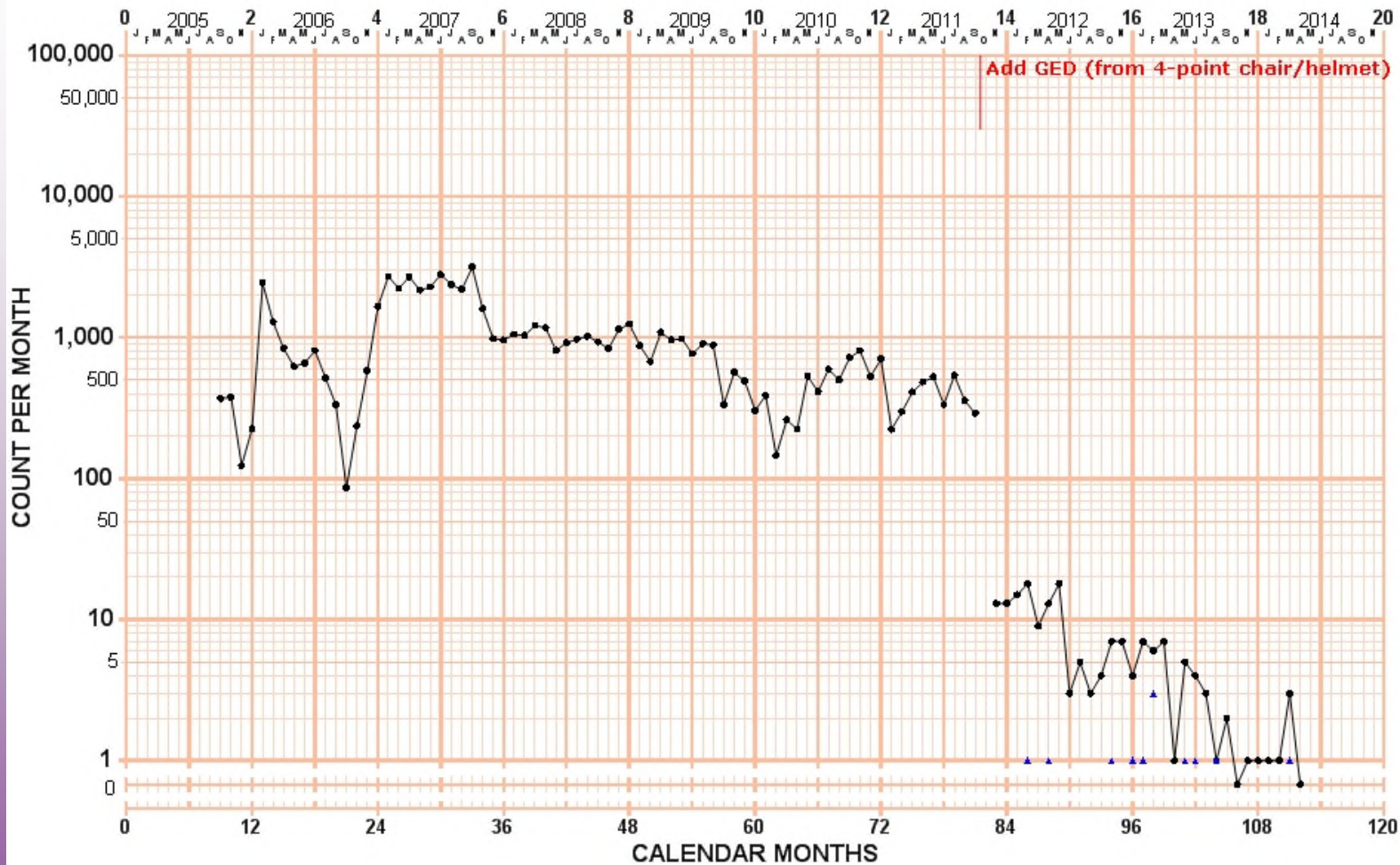
Engle, Melody
TEACHER

Aggression 1
ITEM MEASURED

hit others, scratch others, kick others, spit at others, push others, pull others hair, head-butt others, bite others; including attempts.
COMPONENTS

Addition of GED Nearly Eliminated Self-Injury

MONTHLY CHART



Cort, Reynaldine
CASE MANAGER

Blenkush, Ph. D., BCBA-D, Nathan
CLINICIAN

Engle, Melody
TEACHER

Health Dangerous 1
ITEM MEASURED

bite self, bang head, hit self (e.g. punching, slapping self), scratch self, pinch self, slam body parts together (e.g., slam/bang legs or knees together with force), slam body parts against objects (e.g., hitting wall with hand, hitting chair with knee); including attempts.
COMPONENTS



- Andrew experienced significant reduction in aggressive and self-injurious behavior
- Andrew is now free from restraint and medication. He can now enjoy his weekly outings with his family.

Samantha

- Early autism intervention
- Well regarded private day school
- Expelled from a well regarded Residential Treatment Program
- Wide range of medication trials
- Slapped head thousands of times per day
- Detached her retinas due to self-injury
- Was unable to enter the community or attend home visits





- Samantha experienced significant reduction in self-injurious behavior
- Was able to undergo surgeries to correct damage caused by self-injurious behaviors

Conclusions

- Clinical need for aversive conditioning devices for a limited subset of patients
- Recent literature recognizes failure of pharmaceutical and typical behavioral interventions for some patients with self-injurious behaviors (e.g., Symons 2011, Wachtel et al. 2009)

Conclusions

- All other therapies have previously failed to safely control harmful behaviors
 - There are no other treatment options
- Consequences of banning device
 - Behaviors that cause extraordinary harm and threaten the lives of some patients will likely re-emerge
 - Educational and vocation progress may be lost
 - Patients may return to a life of mechanical restraint and seclusion and lose access to the community and their family
 - Patients who require the treatment and are currently seeking it will lose the opportunity to access it

Conclusions

- Safety and efficacy of GED devices have been demonstrated
- 24 years of use of GED at JRC and literature on aversive conditioning devices establish:
 - Limited temporary minor side effects
 - Consistent reduction of harmful, aggressive, self-injurious behaviors
 - Increase in positive behaviors
 - Only treatment able to stop harmful behaviors without chemical sedation and give the patient an opportunity to recover and improve

Conclusions

- Devices do not present substantial deception
 - Multi-step process to initiate therapy with GED
 - Safety and efficacy data of GED device consistent with literature
 - Every aspect of the use of the device is transparent and court monitored
- Therapy does not present unreasonable and substantial risk of harm
 - Risk/benefit calculation
 - Patients present a more significant danger to themselves than the potential risks of aversive conditioning devices
- Any safety risks are immaterial in comparison to the public health benefits for individuals who have failed all other treatment options

Anthony B. Joseph, M.D.

CV Highlights

Education

- University of Cambridge, Medicine and Surgery
- Chief Resident and Teaching Fellow (Psychiatry), St. Elizabeth's Hospital, Tufts University School of Medicine

Board Certifications and Licenses

- Massachusetts Medical License
- Certification in Psychiatry, American Board of Psychiatry and Neurology

Selected Professional Experience and Appointments

- 1995-present: Associate Clinical Professor of Psychiatry, Harvard Medical School
- 1997-present: Attending Psychiatrist, McLean Hospital
- 1998-2002: Member, Restraint Working Group, Executive Office of Health and Human Services, Commonwealth of Massachusetts
- 2002-2004: Member, Workgroup on Restraint Safety. Child Welfare League of America

Edward A. Sassaman, M.D.

CV Highlights

Education

- Harvard Medical School, MD
- Residency, Children's Hospital Medical Center, Boston, MA
- Fellowship (Developmental Disabilities), Children's Hospital Medical Center, Boston, MA

Board Certifications and Licenses

- Diplomate, American Board of Pediatrics
- Massachusetts Medical License
- New York Medical License

Selected Professional Experience and Appointments

- 1994-present: Clinical Instructor, Pediatrics, University of Rochester School of Medicine
- 2000-present: Regional Medical Director, Excellus BlueCross BlueShield
 - Development of practice guidelines and management programs for individuals with Autism Spectrum Disorder
 - Implementation of community-wide Pediatric Preventive Health Guidelines
- Appointment: Expert Reviewer in Pediatrics, Office of Professional Medical Conduct, New York Department of Health

Thank You