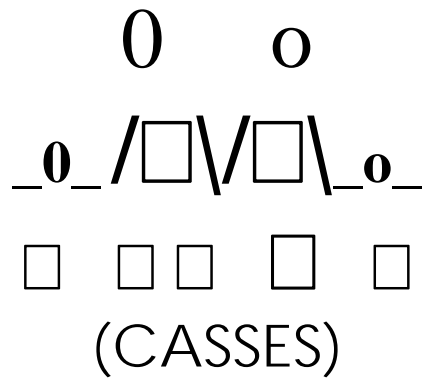
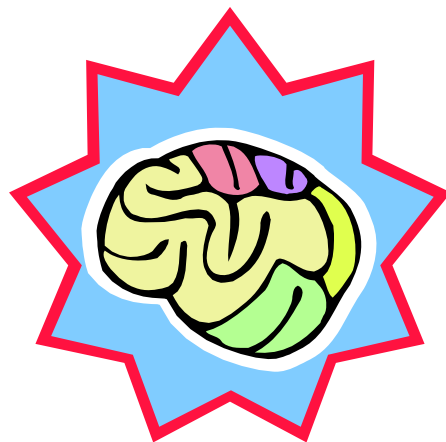


CASSES Child and Adolescent Special
Studies Evaluation Service Research
Programs,
Research Clinic and Child/Adolescent
Psychiatry Specialty Clinics



at Louisiana State University Health Science
Center at New Orleans



CLINICAL DIRECTOR OF RESEARCH

H. Quintana, M.D.

Child and Adolescent Psychopharmacology Research Group at Louisiana State University Health Science Center at New Orleans:

CASSES Child and Adolescent Special Studies Evaluation Service:

Dr. Quintana is the Director of the Child and Adolescent Psychiatry Special Studies Evaluation Service (CASSES). This program initially started in July 1989, as a group of child/adolescent psychiatrist and psychology faculty who came together to discuss current research issues and methodology. This research group eventually expanded to the current service-CASSES, which has been in existence for three years. The Child & Adolescent Psychiatry Special Studies and Evaluation Service--CASSES, focus on Child/Adolescent Psychiatry and Psychopharmacology Research.

The CASSES program offers comprehensive evaluations to Children and Adolescents in New Orleans and the metropolitan area, as well to any child or family that is able to travel to our program. Often the CASSES program has research programs that meet the needs of the patients and their family. Involvement in any research program is involuntary and must serve the best interest of the patient and family. All research studies undertaken by the CASSES program have been approved by the Louisiana State University Health Sciences and LSU Medical Center Institutional Review Committee. Special care is taken in the case of studies undertaken by our CASSES program to assure that they meet the highest level of established ethical standards and good clinical practice guidelines.

The CASSES staff consist of highly trained and experience professionals who form a multidisciplinary team that works to provide the highest standards of care. The CASSES team consist of Dr. Quintana, the Director of CASSES Clinical and Research programs and Primary Investigator, Dr. Purnell, Associate Director of the ABLE Clinic and Research Co-Investigator, Mrs. Janis Sita, R.N., the Program Manager and Senior Clinical Coordinator, who also coordinates laboratory services and the Preschool and QEEG studies, Mrs. Josefina Duran, Pharmacy Consultant, Research Associate, Fiscal Officer, and Insurance Services, and several other research assistants.

The CASSES program recognizes the importance of research for the advancement of our field and the importance of research literacy and research training in general and child and adolescent psychiatry. Therefore, general psychiatry residents and child and adolescent psychiatrist in training are given an opportunity to observe and engage in some activities in the CASSES program. All trainees are under the supervision of a trained faculty member or experienced and specially trained member of the CASSES team.

CASSES program engages in variety of research activities, for example, in some cases the CASSES group is investigating the safety and efficacy of medications that have been shown to be effective in adults to determine there safety and efficacy in children and adolescents.

In some cases, the group is investigating new medications that have not been previously released in children and adolescents. This new medications have specific or special applications to certain child and adolescent psychiatric disorders. In addition, the group is examining new and innovative methods of diagnosing childhood psychiatric disorders and alternative treatments for existing childhood and adolescent psychiatric disorders.

CASSES encourages its doctors and staff to develop independent initiated trials on new medications and new treatment approaches. Approximately 25%-30% of the CASSES research activities are involved in this area. Twenty percent of the CASSES time is devoted to exploring new treatments and approaches, and 50%-60% of it time is spent investigating and involved in pharmaceutically sponsored multi-enter medication/treatment studies.

CASSES, as explained previously, engages in both Independent Investigator Studies and Multicenter Studies. CASSES Primary Investigator, Dr. Quintana has completed the following studies:

- (1) Attention Deficit Hyperactivity Disorder (ADHD) (at least 5 studies over a three year period with one long term study in this area still in progress);
- (2) ADHD, pharmacokinetic studies on new medication for this disorder;
- (3) ADHD and co-morbid disorders (anxiety and mood disorders) (at least two studies in this area);
- (4) Pediatric Depression Study (at least two studies in this area);
- (5) New use for existing medication for Panic Attacks in children;
- (6) Use of Psychotropic Medication in Children with Psychotic Disorder;
- (7) Obsessive-Compulsive Disorder in children and adolescents (acute and long term study); *
- (8) Tourettes Disorder with ADHD; Tourettes Disorder with Anxiety Disorder; *
- (9) Autistic Disorder; *
- (10) Independent studies on Risperidone, Clozapine and Ziprasidone; *
- (11) Study on prevalence and effectiveness of medication treatment and hospitalization on children in the US vs. children in Finland.

Dr. Quintana and/or the CASSES Program and Research Team over the past six years have received grants/funding for its participation and completion of psychopharmacological studies in children and adolescents (*) in the following

areas:

- Attention Deficit Hyperactivity Disorder
- Attention Deficit Hyperactivity Disorder and Co-morbid Anxiety and Depression
- Attention Deficit Hyperactivity Disorder—Long Term Treatment Outcome
- Comparison of Atomoxetine HCL to Concerta
- Major Depression in Children and Adolescents
- Panic Attacks
- Posttraumatic Stress Disorder
- Bipolar Disorder and Depakote treatment
- Schizophrenia in adolescents—new medication
- Bipolar Disorder and new medications
- Schizophrenia in adolescents—new medications
- Bipolar Disorder and new medications
- Diagnostic Assessment of ADHD using QEEG
- Treatment of Preschool Children with ADHD
- Medication Treatment Evaluation using QEEG
- Use of Atomoxetine HCL in Adults with ADHD

Dr. Quintana and/or the CASSES Program and Research Team have over the past six years received grants/funding for its participation and completion of psychopharmacological studies from the following pharmaceutical companies:

- (1) Eli Lilly (four multicenter studies);
- (2) Eli Lilly (2 independent investigator studies);
- (3) Pfizer (2 multicenter studies);
- (4) Pfizer (1 independent investigator study);
- (5) Smith-Kline and Beechum (1 multicenter study);
- (6) Wyeth (1 multicenter study);
- (7) Glaxo-Wellcome (1 multicenter study);

Interview rooms, examination rooms, and full laboratory with EKG services are available at our site; also, we utilized our campus University Lab located at the Lions Center. Our core staff group has been together for four years; therefore, they are an experienced team in all aspects of child and in dealing with sponsors and monitoring visits. All visits are by appointment only, and the patient's family must call for information or for appointments (504)-568-7901.

CASSES Research Group has Independent ownership and use of the following equipment:

- (1) Three computers and software with internet connection, palm pilot(s), TV-VCR, Camera filming equipment (video camera), e-mail access, two Fax machines, two copiers, scanner, Lab Setup with EKG equipment and blood drawing and shipping capacity, and administrative/financial and secretarial support.

- (2) Secure double-locked Medication and File Storage Area.
- (3) Easy Access to Licensed Full Service Lab.
EKG technician and EKG interpretation.

New Orleans Population: 1, 312,890.00

Population by Age and Sex

<u>Age</u>	<u>Total</u>	<u>Female</u>	<u>Male</u>
Children under 5 years	106,229	52,141	54,088
5 to 9 years.....	111,717	54,726	56,991
10 to 14 years.....	107,281	52,617	54,664
15 to 19 years.....	104,162	52,073	54,664

Therefore since our studies are generally for children between the ages 7 to 18, we have approximately 500, 000 children available in the Metro New Orleans Area. Including the North Shore population, we have an additional 100,000 children.

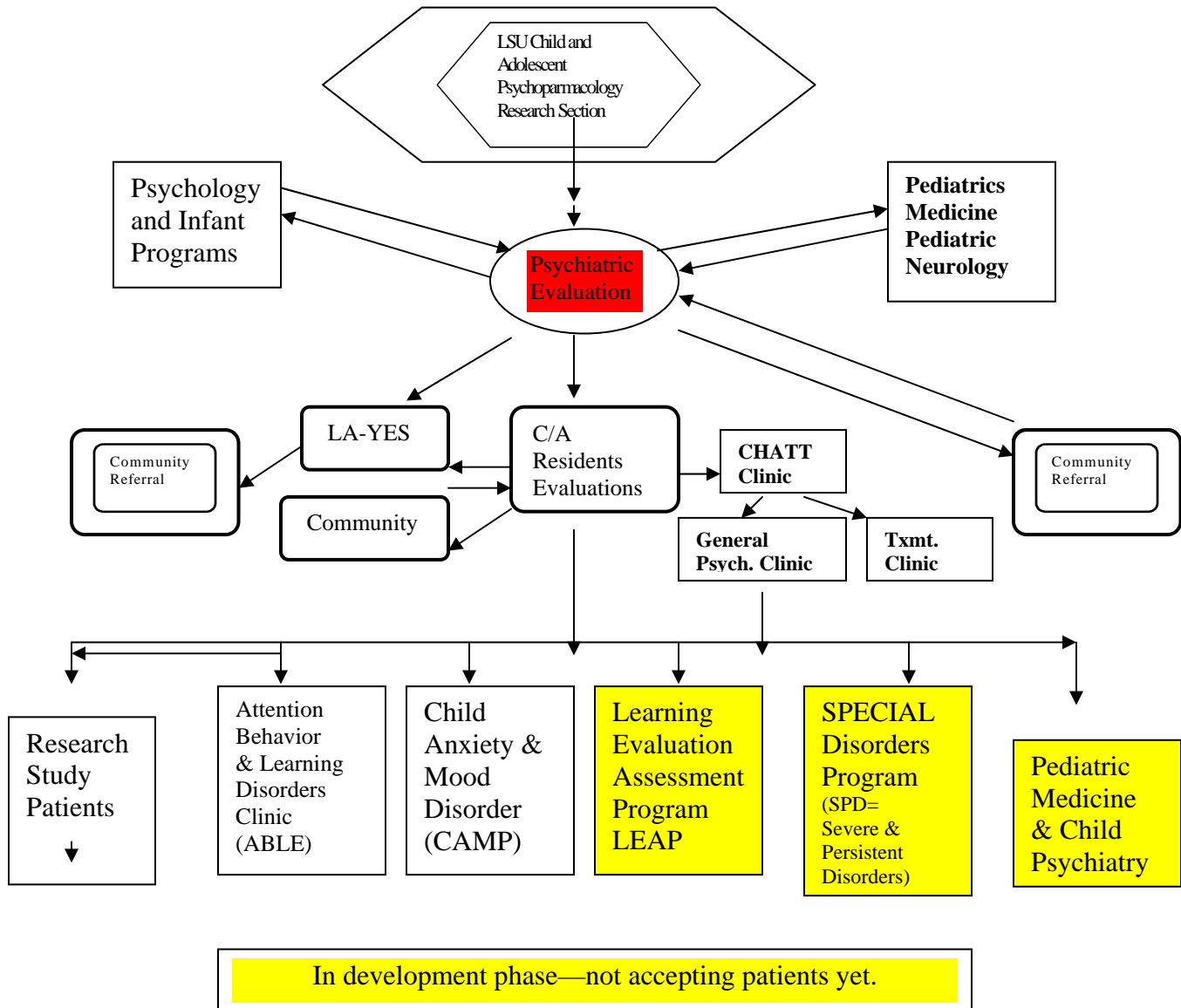
New Orleans Metropolitan Area-summary of participating patient's ethnicity:

Caucasian.....52%
 African-American.....35%
 Hispanic.....08%
 Other.....05%

Male to Female Sex Ration.....60% / 40%

Note: over the last 2 years the CASSES research group has seen 200 subjects who have taken part in various research studies. CASSES associated with the LSU Child and Outpatient Clinic, which affiliated with 5 Child and Adolescent Community Mental Health Centers--- LSU sees over 150 active patients, the 5 C/A CMHC see approximately 900 patients per month.

Child/Adolescent Special Studies Evaluation Service-(CASSES)



Child and Adolescent Special Studies Evaluation Service Staff

CASSES STAFF MEMBERS	
Dr. H. Quintana	Director of CASSES and Primary Investigator
Mrs. Janis Sita, R.N.	Program Manager & Administrator Senior Coordinator, Head of Lab/Environmental Safety
Mrs. Josefina R. Duran	Fiscal Officer and Research Associate
Dr. Kris Kaleibe	Co-Director of CASSES in New Orleans
Dr. William Purnell	Sub-investigator and Co-Director of Baton Rouge CASSES Clinic
Dr. Jessica Hof	Research Fellow 07,08
Dr. Lakisha Williams	Research Fellow 07,08
Mrs. Dee Bonvillian	Secretarial and Supportive Services
Research Assistants	
Child Psychiatry Residents (1 st year)	
Child Psychiatry Residents (2 nd year)	
Psychology Intern (Graduate School)	
Nursing Student(s)	
MSW students	
Work Study Student (HS)	
Therapy Section	

Integration of the LSU Clinical Child/Adolescent Outpatient Psychiatry Rotations (through CHATT) with the Outpatient Clinical Research Programs (through the Child/Adolescent Special Studies Evaluation Service- Research and Specialty Clinics at LSU:

The Child Adolescent Treatment Training (CHATT) Clinic is a clinic that accepts referrals predominantly from the community at-large and private practice clinicians (family Practice, Pediatricians, and Neurologist) in the Community. The child and adolescent psychiatry residents and other mental health trainees

(social work externs and psychology interns) provide diagnostic evaluations and mainly psychotherapy/behavioral and family oriented therapy through this clinic. Therefore, it functions as the LSU Infant, Child and Adolescent Psychiatry Division as an Evaluation and Therapy Clinic where various forms of therapy are taught and practiced. The clinic especially focuses on individual psychodynamically influenced psychotherapy and family therapy. The child and adolescent psychiatry residents spend 1 hour per week in the CHATT Team Meeting and typically spends 2-3 hours doing evaluations in this clinic and spends an additional 4-6 hours providing direct treatment services through this clinic (for approximately a total of 6-10 hours per week). Assigned supervisors, therapy and psychopharmacotherapy, provide direct supervision for all patient care activities that the residents provided through this clinic.

This clinic provides psychiatric diagnostic evaluation/assessment component and small psychotherapy (Therapy Component) and psychopharmacology (General Psychopharmacology Clinic). This clinic provides therapy and psychopharmacotherapy in an integrative treatment approach—this is a multidisciplinary clinic in philosophy and practice.

Many of the patients seen in this clinic have been treated at NOAH, the child and adolescent mental health center clinics, or the Crisis Intervention Center or from Community Referrals. In many cases the patients are patients that the residents have had contact with in other clinical settings and clinical rotations, thus leading to a continuity of care across settings. Supervision of these cases is by full time and clinical faculty. Each resident is assigned three hours of individualized supervision for this clinic's case load. Enhanced levels of supervision are available on demand, including with child analysts.

In summary, the CHATT-Child/Adolescent Treatment Training Clinic is a multidisciplinary clinic that screens and assigns outpatients to the residents for psychotherapy and psychopharmacotherapy. The residents' work with other trainees in psychology and social service in assessing and treating patients in this program and often share patients or work together as a team.

Child/Adolescent Special Studies Evaluation Service (CASSES):

Research Program: the CASSES Program is very active in executing clinical research studies on child and psychiatric disorders. The CASSES Program carries out investigation on the safety and effectiveness of various psychopharmacology treatments for psychiatric disorders. In addition, the program investigates new diagnostic methods and techniques and examines emerging and alternative treatment approaches.

<p>Psychiatry Research Experience/Psychopharmacology Research Experience: Experiences in pediatric psychopharmacology are provided with Dr. Bert Quintana as part of psychopharmacologic services provided by the LSU General Child/Adolescent Psychopharmacology Clinic as part of the CHATT Clinic. There</p>
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is the ability for residents to work along side Dr. Quintana doing pediatric psychopharmacologic research and see patients with him.

Dr. Quintana is the Director of the Child and Adolescent Psychiatry Special Studies Evaluation Service (CASSES). This program initially started as a group of child/ adolescent psychiatrist and psychology faculty who come together to discuss current research issues and methodology. The Child & Adolescent Psychiatry Special Studies Service – CASSES, focuses on Child/ Adolescent Psychopharmacology Research. Currently CASSES's is involved in several psychopharmacological studies – independent investigator studies and larger and lengthier multicenter studies. The senior coordinator for this program is Mrs. Ann K. Layman who is an experienced researcher and oversees the administrative and support staff management for the CASSES program.

The CASSES program-Specialty Clinics: In addition to the Research Studies Program, there are four Specialty Clinics that are part of the CASSES program. These Specialty Clinics provide specific diagnostic evaluations and the latest treatment interventions for children and adolescents with certain psychiatric diagnosis. The currently existing specialty clinics that are staffed with experienced professionals who are experienced and trained to recognize and treat psychiatric specialty areas include:

1. **Attention, Behavior and Learning Disorder (ABLE) Clinic.** The ABLE clinic evaluates and provides treatments for children/adolescents with disruptive disorders including a primary diagnosis of Attention Deficit Hyperactivity Disorder (AD/HD), Oppositional Defiant (ODD), and Conduct Disorders (CD). Also, patients with associated co-morbid such as anxiety, depression, and learning disorders will be treated in this clinic.
2. **Child/Adolescent Anxiety and Adolescent Disorder (CAAMP).** The CAAMP clinic evaluates and provides treatments for children and adolescents with disruptive disorders including a primary diagnosis of Attention Deficit Hyperactivity Disorder (AD/HD), Oppositional Defiant (ODD), and Conduct Disorders (CD). Also, patients with associated co-morbid disorders such as anxiety, depression, and learning will be treated in this clinic.
3. **Special Disorders Program (SDP).** The Special Disorders Program has two major clinical component programs: an Autistic Spectrum Disorders Clinic (SDP-ASD) and a Severe and Persistent Disorders Clinic (SDP-PDSD) (this includes Psychotic Disorders and Schizophrenia).
 - A. **SDP-ASD:** the Special Disorders Program (SDP)-Autistic Spectrum Disorders (ASD) clinic or SDP-ASD evaluates and treats patients with Pervasive Developmental such as *Pervasive Developmental Disorders, Autistic Disorder, Asperger's Disorder, Rett's Disorder and Childhood Disintegrative Disorder*

- B. **SDP-PDS:** the Special Disorders Program (SDP)-Psychotic Disorders and Schizophrenia (PDS) Clinic evaluates and treats patients with delusions and hallucinations and that are suspected of having schizophreniform and schizophrenia or other psychotic Disorders.
4. **Learning Evaluation and Assessment Program (LEAP).** The LEAP program focuses on providing screening, assessment, and comprehensive evaluations of children and adolescents suspected of having specific learning disorder. The patients accepted into this program may or may not have associated psychiatric disorders. However, a significant number do have co-morbid psychiatric diagnosis that includes ADHD, Anxiety, Depression or other psychiatric disorders.

Additional Components of the CHATT-CASSES Integrative Program and Services:

Clinical Evaluation and Treatment Program: The resident attends CHATT clinic where they complete psychiatric evaluations and medication evaluations and treatment. As stated previous this clinic functions as a general clinic that screens all patients referred to it from the community and from community physicians and mental health professionals. Residents are assigned two-three psychiatric evaluations per month and also follow patients that require medication treatment. Both first year and second year residents participate in this program during the whole year. During this experience, the first year resident receives instruction in interviewing techniques and methods, psychodiagnostics, psychopathology and writing evaluations and reports to social agencies. The residents provide written reports to the courts and other mental/health providers.

Referral Sources to the LSU Child/Adolescent Psychiatry Outpatient Services and CHATT-CASSES programs:

Community and Physician Referrals: New Orleans Metropolitan Area referrals from the community, community agencies, family practitioners, pediatricians, neurologist and other physicians.

Louisiana Youth Enhancement Program (LA-YES): this is a NIMH Funded program that provides psychiatric services to Children and Adolescents involved with various state agencies—office of child services, child protective services, juvenile and family court services, alcohol and substance abuse services. Many children in Louisiana who cannot afford psychiatric services are admitted and provided services through this program.

Louisiana Office of Child Protective Services (OCS): Children and adolescents in Louisiana that are state custody and who are in various types of out of home placements are evaluated and treated.

Pediatric Medicine and Behavioral Pediatrics Clinic: The LSU Pediatrics Department's general pediatrics and Behavioral Pediatric Clinics routinely refer patients to the LSU Child and Adolescent Psychiatric programs. Patients referred from this clinic are evaluated and treated by the CHATT-CASSES program and the Child and Adolescent Psychiatry first and second year residents.

Pediatric Medicine Subspecialty Clinics: The LSU pediatric subspecialty clinics routinely request consults and evaluation/treatment of pediatric patients that attend their specialty clinics. Referrals most commonly come from Pulmonary, Endocrinology, cardiology and gastrointestinal subspecialties.

Pediatric Neurology: the LSU pediatric neurology subspecialty clinics routinely request consults and evaluation/treatment of pediatric patients that attend their subspecialty clinics—Seizure & Movement Disorders Clinic, etc.