



DENIS MEE-LEE:

• Director & Principal Investigator, Hawaii Clinical Research Center (since 1989)

• Chief, Department of Psychiatry, Castle Medical Center (since 2000)

• Director of Clinical Research, Kahi Mohala (Since 2000)

• Clinical Professor of Psychiatry, University of Hawaii

• Practice of Psychiatry, Consultant, Speaker, Trainer, Honolulu, HI

Every day, patients ask me about their medications; how do they work? what are the likely good and bad effects? are there any alternatives? anything new on the horizon? etc. Each month, right here in "Better Meds", I will answer some of those questions. Write to me at denis.meelee@hawaiiclinicalresearch.com if you have a question.

Q. I am 29 years old, have Bipolar Disorder, and have been hospitalized for both manic and depressed episodes. My doctor has me on three different medications and I would like to take none. Do I need so many different pills?

- J.D.

A. Actually, bipolar patients, as a whole, average closer to four different medications at any one time. This is because the discomforts and symptoms of bipolar disorder are often multiple and varied. Different medications target and help different aspects of the illness. We have often used a mood stabilizer, with an antidepressant, and an anti-anxiety agent, and something for sleep. Fortunately, new medications are being found to help combinations of these symptoms so that we can manage with fewer pills. For example, Seroquel (quetiapine) was recently approved by the FDA for depression as well as mania in bipolar disorder. Some of our studies are directed towards this purpose.

Q. Are there any medications that can help me with my abuse of cigarettes and alcohol? I have tried many other forms of treatment but never been offered any medications. - S.T.

A. We have learnt much about treating addictions in recent years. We know now that our focus on past treatments like psychotherapy, educational programs, and even 12-step approaches have helped the conscious, thinking, decision-making aspects of these addiction illnesses but have not helped the less conscious, urge/pleasure reinforcement forces that often drive the dependency cycle. This depends more upon the dopamine releasing areas of the meso-limbic areas of the brain. New medications like Chantix (varenicline) for nicotine dependency and Vivitrol (intramuscular injections of naltrexone) for alcoholism block the relevant receptors in these areas of the brain and reduce the urge and pleasure of these addictive substances. These were exciting studies to do.

Q. My 14-year-old son displays some very strange moods and says some quite off-the-wall things at times. He is much more withdrawn. What can I do? -B.Y.

A. Bipolar disorder and schizophrenia are being diagnosed earlier and earlier in recent years. We used to think of these disorders only appearing in late teens or early twenties but more clear-cut cases are being recognized in early teens and younger. Up to now, medications have not been tested or approved for children and teens but studies are under way to evaluate some of the newer atypicals for these disorders. It is definitely worthwhile having your son evaluated by a child psychiatrist. HCRC is conducting some of these studies at this time.

Key Hawaii Clinical Research Center Staff

Dr. Denis Mee-Lee

Director and Principal Investigator

Karen Garcia

Site Manager

Mitzi Kamau

Trials Manager

Margaret Bell

Research Coordinator

Craig Jobb

Research Coordinator

Shauna Clen

Research Coordinator and Editor of Better Meds

Micah Tong

Research Coordinator

Akemi Fukutomi

Research Associate

Lana Eltagonde

Research Coordinator

Denis B. Mee-Lee

Residential Manager

Phone

(808)949-4977

Office Hours

Monday - Friday
9:00am - 5:00pm



Hawaii Clinical Research Center

1750 Kalakaua Ave.
Honolulu, HI 96826

HCRC BETTER MEDS

A Newsletter By

Hawaii Clinical Research Center



ALOHA FROM HCRC



pharmaceutical, biotechnology and contract research organizations to conduct these research studies.

Dr. Denis Mee-Lee and Dr. Walter Nunokawa established the Hawaii Clinical Research Center in 1989 to conduct specialized research within the diverse ethnic population of Hawaii. Since its onset, the Center has conducted more than 200 Phase I-IV clinical trials. Volunteers receive investigational medication aimed at addressing certain symptoms. They are reimbursed for time and travel expenses. HCRC conducts both outpatient studies (the individual meets with us to receive medication) and inpatient studies (the individual stays with us at Hale Ekahi through the duration of the study). Hale Ekahi (ha-lay-eh-ka-he) is a modern 30-bed residential unit, designed with the comforts of home, for the conduct of inpatient trials. HCRC is dedicated to safety, efficiency and the highest quality of patient care.

Aloha from the Staff of Hawaii Clinical Research Center

This newsletter is designed to share practical information with consumers, families and friends about psychiatric and other medications, and the latest clinical research studies that are testing new treatments. Our staff would love to speak to you concerning how HCRC

wants to partner with you in supporting and contributing to the development of better medications.

Hawaii Clinical Research Center is a research facility devoted to the development of new medications for a variety of physical and mental health needs. HCRC interfaces with

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Craig Jobb
Clinical Research Coordinator

Craig's List

Some of the research studies we do involve children and adolescents with mental health issues. I am currently running studies on children and adolescents with bipolar disorder or schizophrenia. In terms of seeing a real turnaround, one of my participants, a young boy named "Matt", suffered from behavioral problems before his parents sought out a research study here at Hawaii Clinical Research Center. Matt had limited success with previous medications and his ADHD was adversely affecting his life. Matt had been placed in special education courses in school. His mother was told he was developmentally disabled. Matt's family found a resource at Hawaii Clinical Research Center. They received information about ADHD and different treatment options open to them. Matt was enrolled in an outpatient study concerning a new drug trial for the treatment of ADHD. Upon recent completion of the study, two years after its onset, Matt is back in public school. Matt's grades improved and he has begun to seek out extracurricular activities. He became involved in sports and began to evolve socially. He even has a girlfriend now. HCRC is a great resource for the public. When individuals contact us, regardless of what happens, they are taking the first step in the problem solving process.



Margaret's Memos

I am currently running studies concerning adult bipolar mania, adult schizophrenia and have an upcoming bipolar depression study as well. Out of these studies, I find schizophrenia to be the most interesting. Schizophrenia can be a very debilitating disorder and I enjoy the challenge that is inherent in trying to alleviate schizophrenia symptoms. One person in particular stands out in my mind. "Steve" has been an active participant in a schizophrenia study at HCRC for the past two years. He participated in an 8-week inpatient study (a study in which the individual stays at our facility for the duration of the study). When Steve first came in, he was taking Haldol (an oral medication), which just wasn't addressing his symptoms. Steve had a lot of EPS (extra-pyramidal symptoms) that included drooling, involuntary movements and a general lethargic and zombie-like demeanor. He heard about medication trials at HCRC through a word-of-mouth referral. We try to create a very friendly and warm atmosphere here so word-of-mouth referrals are not uncommon. Steve had great success with the study medication. He has now held a job that allows him to travel to different islands in Hawaii. He is more active socially and was even able to assist on his father's campaign for political office. Different medications work for different people, and HCRC's goal is to pursue new medications so that the right prescription is available for the right person.

HCRC's Current Studies

The research process is rewarding in both its human and science facets. Hawaii Clinical Research Center is currently conducting outpatient studies involving: Adult Schizophrenia, Adult Bipolar, Adolescent Schizophrenia, Child/Adolescent Bipolar, Sleep disruptions in Alzheimer's Disease and Insomnia. Inpatient studies are being conducted involving medications for dry eye, jet lag and a new pain medication delivery system.

HCRC is now accepting healthy volunteers for research studies as well as those with certain mental health conditions.

To volunteer: call 808-949-4977

For More Information: visit us on the web at www.hawaiiclinicalresearch.com
"The discovery of new medications depends upon volunteers for medical research."

BETTER MEDS HCRC

Karen Garcia
Site Manager



Karen's Corner

Aloha, I am the site manager at HCRC and have worked here since 1995. Among other functions, I help to assess pharmaceutical company proposals for new studies. We currently have accepted several mental health studies including studies involving schizophrenia and bipolar disorder. When we receive a study proposal for a medication, we evaluate the proposal in terms of whether the research is safe, meaningful and efficient. In terms of future research pursuits, pharmaceutical research needs to focus on adolescents and children with mental health issues. Currently, there are medications designed for adults to address mental health concerns.

However, these drugs are not approved in children. In order to get proper medication available for children medical research trials are needed. Herein lies the Catch-22. Many people have negative opinions about children and adolescents participating in research studies for medications. However, everyone wants effective medications to be available for children and adolescents. Of course, there is no way to ensure proper medication without research trials. As a result, mental health medications for children and adolescents are lagging. There is nothing more important to us than patient safety. Our studies go through a rigorous screening process before we even consent to do the study. Our staff is very patient-focused, and of course we reimburse participants for their time and travel. We need more education about medical research to address a lot of the unfounded negative biases and misperceptions that are out there.

Mitzi Kamau
Clinical Trials Manager



Mitzi's Minutes

Aloha! As clinical trials manager, I primarily focus on Phase 1 studies. These Phase I studies, which are normally run on healthy individuals, sometimes require individuals to reside here in our Hale Ekahi unit during the study. Although we are a clinic, appearance-wise our facility looks like a home or a condo. Participants watch TV, use the computers and have their meals together in the dining room. In addition to contributing to medical research and being compensated for their time, many participants benefit socially from the atmosphere. There is generally a lot of camaraderie and many times volunteers make new friends amongst themselves.

Many of our participants are Japanese and relatively new to Hawaii. We try to expose them to the culture here. We encourage the Japanese students to speak English with our staff and ask frequent questions. Light exercise and a healthy diet are promoted. The individuals are able to make contact with fellow Japanese participants from other studies as well. A few of our study subjects that no longer qualified for future studies have come back to work here with us because they enjoyed their experience so much. Our cook is a former study subject. Another study subject, "Mark", who had been a volunteer in several studies decided to go into medicine and came back to work with us to get experience from a staff member's perspective. Our healthy volunteers come from all walks of life: office, construction, nursing, students, housewives, and even visitors. E komo mai!



Are you suffering from Schizophrenia?

Doctors in your area are comparing the effects of olanzapine taken orally with olanzapine given by injection for Schizophrenia. Review the list below to determine if you should call: You have experienced, at anytime in your life, 2 or more of the following:

- Delusions (false beliefs)
- Hallucinations (seeing things or hearing voices)
- Disorganized speech
- Disorganized or abnormal movements
- Emotional withdrawal
- You had a worsening of any of the symptoms above in the past 24 months
- You want to change your current treatment for these symptoms

If you qualify and are enrolled, you will receive one of the medications and regular medical evaluation at no cost to you.

To learn more, call:

Margaret Bell, Research Coordinator
Hawaii Clinical Research Center
808-949-4977

JAPANESE Volunteers Needed

- Japanese Ethnicity
- 1st Generation (born in Japan and living outside Japan - 5 years) Ages 18 - 50 years old
- In generally good health

Hawaii Clinical Research Center is conducting a clinical research study. Qualified participant will receive investigation medication and all study related procedures at no cost. Compensation for time and travel up to \$7,000.

To see if you qualify or for more information, please call 949-4977.

Denis Mee-Lee, M.D.,
Principal Investigator

ACCEPTING APPLICATIONS FOR NEW RESEARCH

Hawaii Clinical Research Center, conducting medical research in Hawaii since 1989, is accepting volunteers for the following study. Medical care and study drug provided at no cost. Compensation for time, travel and study participation is available. Patients with mild to moderate Alzheimer's disease who reside with a primary caregiver may be eligible for a study being conducted that is investigating sleep disturbances associated with this disease. Medication, doctor visits and study medication are provided at no cost.

Alzheimer's disease touches many lives in addition to the person afflicted. It affects the day-to-day lives of family members who devote much time, effort and energy to minimizing the negative consequences of this disease. It's not just a daytime illness affecting memory, the symptoms occur at night as well. Some people with Alzheimer's experience difficulty falling asleep or may awaken during the night or very early in the morning. Excessive daytime napping can be problematic if it prevents the Alzheimer's victim from sleeping well at night.

Compensation of \$600 as reimbursement for time and effort for this study may be available to qualified study participants.

If you believe your loved one might be eligible for this study, please call Hawaii Clinical Research Center at 808-949-4977.