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Evidence-Based Medicine: Turning Residency Into Research

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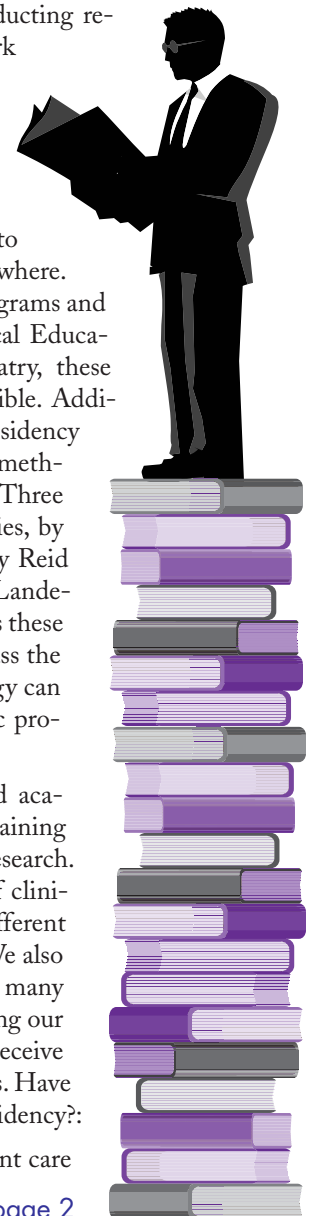
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Residency training poses significant challenges to conducting research. Lack of available time and control over our work schedule as well as lack of sleep are some of the central obstacles that interfere with academic productivity. Our professional responsibility to take care of our patients as best as possible can also come into conflict with academic research aspirations. There is only a limited amount of time in each day, and any time devoted to academic writing or research needs to come from somewhere. Given the current funding sources of most residency programs and the current Accreditation Council for Graduate Medical Education (ACGME) requirements for training in psychiatry, these obstacles are fairly ubiquitous and in most cases inflexible. Additional challenges to conducting academic research in residency include lack of experience in and knowledge of research methodology and lack of access to mentorship and funding. Three articles in this issue—on residency funding opportunities, by Joel Stoddard M.D.; on residency research meetings, by Reid Robison M.D., M.B.A.; and on mentorship, by Angeli Landeros-Weisenberger, M.D.—should help to further address these challenges. The purpose of the present article is to discuss the principles of evidence medicine and how its methodology can be used to enhance both clinical training and academic productivity in residency.

The aims of clinical training, quality patient care, and academic research are not mutually exclusive. Residency training provides significant advantages to conducting clinical research. Further, psychiatry residents work on the front lines of clinical care, with exposure to the care of a multitude of different types of patients in many different treatment settings. We also have the opportunity to work under the supervision of many different psychiatrists and, often, the advantage of viewing our field through fresh eyes. The quality of care patients receive presents a wealth of questions to their treating physicians. Have you ever had any of the following experiences during residency?:

- 1) Had two attendings who provided completely different care

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- plans or pharmacological treatment for the same type of patients;
- 2) Not known what might be the most effective treatment for a patient;
- 3) Not known if a particular treatment you were providing had any demonstrated efficacy; or
- 4) Observed a unique case from which you learned.

These situations are all opportunities for clinical research and often occur on a daily basis during residency.

Evidence-based psychiatry is a process wherein the goals are to 1) improve the care of patients by supporting solid data-driven decision making and 2) enhance care practices in psychiatry by facilitating the maximum benefit from scarce health-care resources (1). The core principles of evidence-based medicine have been proposed as a model to guide the reform and improvement of residency education as well as the clinical care of psychiatry patients (2). The core skills of evidence-based medicine involve the ability to formulate questions that arise in clinical situations as well as to locate, critically appraise, and apply evidence. Table 1

outlines the core steps in evidence-based medicine.

Not only is evidence-based medicine a powerful tool in improving clinical care and clinical competence, but it can also be a fruitful source of academic productivity during residency. When conducting an evidence-based medicine search on a clinical question, the answer usually falls into one of the following three categories: 1) no applicable evidence, 2) clear and convincing evidence, and 3) conflicting evidence. Worthwhile scholarly contributions can be derived from any of these situations.

Situation 1: No Applicable Evidence: A Traditional Case Report

As residents, we occasionally see a patient who has an extremely unusual presentation or an unusual side effect to well-established medication or who responds well to a novel form of treatment. Traditional case reports serve an important function in the medical literature. They are often the first line of evidence for new therapies but rarely are sufficient to establish treatment efficacy. Additionally, they tend to be the first, and sometimes major, source for detecting rare adverse events.

My most memorable case occurred when I was a third-year medical student at Yale, during my obstetrics/gynecology rotation. A 58-year-old woman presented with an epithelial ovarian tumor (diagnosed on a CT scan) and rapidly progressing memory loss. On the Mini-Mental State Examination she could not recall any of the three objects I had asked her to remember or even that I had asked her to remember the objects. She was unable to remember my name or if she had met me before, even though I had been rounding on her for the previous 2 weeks.

An appropriate PubMed search revealed only five previous case reports of amnesia associated with ovarian tumors (all with ovarian teratomas and none with epithelial tumors), each involving paraneoplastic autoimmune syndromes. The patient eventually made a complete recovery (5 years cancer free and short-term memory regained) with surgical resection, plasmapheresis, and chemotherapy. The five previous case reports were instrumental in determining the appropriate treatment. (This situation is often the case when there is little available evidence in an area.) We decided

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Table 1: Steps of Evidence-Based Medicine (3)

Step	Example
1. ASK a focused clinical question. A clinical question involves: <ul style="list-style-type: none"> • Patient population • Intervention or Exposure • Comparison Group • Outcome 	"Is treatment with a SSRI more effective than placebo for adulthood trichotillomania?"
2. ACCESS the evidence.	Search PubMed for randomized controlled trials using the MeSH terms "trichotillomania" and "serotonin reuptake inhibitors" and limit the search results to "meta-analysis" or "randomized controlled trials."
3. APPRAISE the evidence.	There exists one meta-analysis that examines four randomized controlled clinical trials of SSRI treatment for adulthood trichotillomania. Neither the meta-analysis nor the four clinical trials demonstrated efficacy of SSRI on measures of hair pulling severity (4). Please see www.fmhs.auckland.ac.nz/soph/depts/epi/epiq/ebp.aspx for interactive applications for appraising the scientific literature.
4. APPLY the evidence.	We instead offered our patient clomipramine or habit reversal therapy, both of which have demonstrated some efficacy for trichotillomania.
5. ASSESS the outcome in the patient.	Our patient declined to take clomipramine due to concerns about side effects and elected to engage in habit reversal therapy. She did not improve with habit reversal therapy and eventually agreed to take a selective-norepinephrine reuptake inhibitor that has no proven efficacy, but a biological rationale for working similar to clomipramine.

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to publish our case report in an effort to help guide further treatment of this condition (5). Since publishing our case report, an unrelated group of investigators (6) have 1) reported on a case series of 12 treatment-responsive patients with ovarian tumors, 2) demonstrated the autoimmune process, and 3) proposed a diagnostic test for paraneoplastic autoimmune syndromes.

Situation 2: Clear and Convincing Evidence: An Evidence-Based Medicine Case Report

Clinicians are encouraged to use current scientific research to guide data-driven evidence-based care of patients. However, this exercise is very difficult in practice. If available at all, the relevant academic publications are often difficult to locate and poorly oriented to clinical practice (7). The evidence-based case report is a special type of case report designed to model the principles of evidence-based medicine and apply its steps (see Table 1) as they pertain to specific clinical questions that arise in the everyday care of individual patients (8). Another article in this issue, by Alexander Westphal, M.D., et al., presents an example of this process, involving the risks of psychostimulant-induced psychosis in young adults. Such case reports can serve as an excellent method to teach, model, and enhance clinical skills in evidence-based practice. Several journals, such as the *Journal of Evidence-Based Medicine*, *Evidence-Based Mental Health*, and, occasionally, the *British Medical Journal* and *British Journal of Psychiatry*, publish articles in this format.

Situation 3: Conflicting Evidence: Systematic Review and Meta-Analysis

Sometimes, when searching the scientific literature, one will come across conflicting clinical recommendations or conflicting clinical trial results. These areas of clinical uncertainty are perfect situations to conduct systematic reviews and/or meta-analyses. A meta-analysis is a statistical method of quantitatively analyzing the results of previous studies. Systematic reviewers utilize a particular methodology in order to conduct scientific reviews, such that methodology for conducting the review is transparent, reproducible,

and specified prior to completing the review in order to minimize bias.

During my second year of residency, while working on an inpatient unit at Yale, a 57-year-old man with a 32-year history of obsessive-compulsive disorder (OCD) presented with severe refractory symptoms. The patient had numerous checking compulsions and obsessions involving fear of accidentally causing harm to other people. He had significant OCD symptoms despite treatment with multiple serotonin reuptake inhibitors of adequate dose and duration. My attending suggested adding a low-dose antipsychotic agent to the patient's regimen. I thought those medications were only supposed to be used for psychosis. Atypical antipsychotics are not without significant side effects, and I began to wonder about the evidence that antipsychotics worked for treatment-refractory OCD. In conducting a PubMed search, we found nine previous randomized, double-blind, placebo-controlled trials involving antipsychotic augmentation for OCD. Among these, five were positive trials and four were negative trials. This information by itself did not answer the question of whether antipsychotics were effective. We decided to conduct a systematic review and meta-analysis of these available trials and determined that antipsychotics were marginally effective for treatment-refractory OCD, with a number needed to treat equal to 5. (The number needed to treat is the number of patients who need to be treated with a given intervention in order for one patient to improve, who would not have improved if given the control condition.) Antipsychotics seemed to be particularly effective in patients with comorbid tics and only after subjects had received 12 weeks of previous selective serotonin reuptake inhibitor (SSRI) treatment. We were able to publish the results of our research in an academic journal and add more insight into the use of antipsychotic agents for the treatment of OCD (9). I have since had the opportunity to publish additional meta-analyses of OCD (10-12), trichotillomania (4), and Tourette's syndrome based entirely on questions raised during the clinical care of my patients.

My training in evidence-based medicine and epidemiology has proved to be extremely useful in improving my clinical skills and in starting an academic research career. Perhaps the most important skill I have learned in my evidence-based medicine training is to keep a notebook handy to write down the questions that arise in the everyday care of patients. These questions have been a fruitful source for research and inevitably reoccur in the future care of patients. Research in evidence-based medicine, in terms of case reports, evidence-based medicine case reports, and meta-analyses, are quite adaptable to the challenges posed to conducting research during residency. Since evidence-based medicine typically relies on the existing scientific literature, the funding requirements are minimal. Additionally, many of the tools needed for meta-analyses are free. PubMed literature searches are free at www.pubmed.gov. RevMan, a useful software package for meta-analyses, can be downloaded without charge from the Cochrane Collaboration website (www.cc-ims.net/revman/download). Affordable conferences on evidence-based medicine and meta-analyses are organized through McMaster University in Canada (hiru.mcmaster.ca/epc/) and the Center for Evidence-Based Medicine at Oxford University (www.cebm.net) as well as many universities throughout the United States. In addition, *JAMA* has a series of articles that make up an evidence-based medicine user's guide, which is available without charge at jamaevidence.com. More psychiatric-focused, evidenced-based mental health information, including PowerPoint lectures, is also available without charge from the website for the Center of Evidence-Based Mental Health (www.cebmh.com).

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Research Grants for Psychiatry Residents

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While physicians usually do not have training in the grant application process, understanding this process is crucial for anyone who wishes to conduct psychiatry research. For those who go on to become academic independent investigators, it is arguably the most important skill because it will sustain their research program as well as guarantee their paycheck! The present article aims to introduce the psychiatry resident to grant opportunities as well as the grant application process.

Initially, a resident will usually apply for an intramural grant. Intramural grants are given to a resident by his or her home institution. Most residents start with a freebie: an educational fund from their department or a funded research elective. However, a research training fellowship would be more prestigious. If a resident has a research system and mentor already in place, he or she may be competitive for an endowed institutional grant. These grants are usually named after a professor emeritus, such as the John A. Smith, M.D. Award. As a psychiatry resident becomes more advanced and committed to transitioning to further research training, he or she may be eligible for a National Institutes of Health (NIH) institutionally-administered training grant, such as the "T32" or "K30" awards or coveted "K12" award. It is important to apply for intramural grants, since the process establishes name recognition within an institution and notifies institutional research program directors of a resident's plans for research.

Any grant administered outside a resident's home institution is referred to as extramural. Often, residents will begin by applying for travel awards from the APA or from their preferred psychiatry subspecialty. If a resident receives such an award, he or she can include it on a curriculum vitae, establishing credibility. A resident can also make the most of the award by presenting a poster. In addition to travel

awards, psychiatry subspecialties and the American Psychiatric Institute for Research and Education (APIRE) sponsor mentored grants at all levels. Once a psychiatry resident has established a mentor and a research plan, he or she should consider applying for an APIRE mentoring award. APIRE maintains a comprehensive list of research training opportunities for PGY-IV residents considering an academic career in research (<http://www.psych.org/MainMenu/Research/ResearchTrainingandFunding/ResearchTrainingOpportunities.aspx>). Outside of professional society support, foundations, such as NARSAD, often provide awards. Foundation grants are numerous but are field or technique specific and vary widely in application requirements and award size. These grants can be very substantial, such as the Doris Duke Foundation Medical Research Grant, and are a viable supplement or an alternative to government support early in a resident's research career. A resident should seek advice from his or her mentor about relevant opportunities. Finally, for those working with drugs, new medical devices, or new applications of medical devices, industry-sponsored investigator-initiated grants are often necessary. However, these grants are complicated by legal issues surrounding conflict of interest and intellectual property.

Government grants confer universally-recognized prestige and offer scheduled awards and mentorship structure. Additionally, these grants usually pay for expenses. A resident researcher will generally apply for an institutionally-administered award (as previously discussed) or research fellowship. While not directly funding research activities, the NIH Loan Repayment Program (LRP) is substantial (up to \$70,000 over a 2-year period) and can supplement a resident as he or she continues training to pursue research. Residents in a strong research program and mentorship may be competitive for

the NIH mentored training grants (K-series) as they approach the junior faculty level. Government extramural grants offer the advantage of bringing funds as well as distinction to a resident and his or her department, making departmental chairpersons very happy. These grants also give a resident name recognition outside his or her institution.

Although there are several types of grant sources (see Table 1), there are some elements of the grant application process that are consistent. First, a psychiatry resident will almost exclusively apply for awards that require an identified mentor and mentorship plan. Obviously, mentors cannot be listed on an application if they have not been notified by the applicant. A mentor should be involved in the entire application process, from the high-level direction to mundane editing. Second, grants are repetitive and structured around one to three specific aims, with associated testable hypotheses, and are best written in direct language, avoiding passive clauses. Third, applicants must follow instructions assiduously, since minor errors could lead to an application being disqualified or rejected. Fourth, prior successful grant applications to a funding body are excellent models for future applications to that body. Previously funded grants are often available from residents' mentors and their home institutions as well as through the funding body itself or by contacting previous award recipients. Finally, a grant applicant should review the Computer Retrieval of Information on Scientific Projects (CRISP) database for any research funded by NIH that has not been published. The CRISP database is available online at <http://crisp.cit.nih.gov/>. In addition to contacting peer scientists, reviewing CRISP allows the applicant to more accurately assess the status of his or her field as well as to plan methods.

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In addition, grant applications should demonstrate sound study design, including rationale, subject selection, and methods. The plan for analysis should always include a statistical framework. Grant applications are usually required to specifically address vulnerable population concerns and explicitly discuss any possible discriminatory inclusion/exclusion criteria as well as participant safety. Each element of the grant application process requires careful thought, especially with regard to participant safety and a statistical plan, since these are often poorly communicated.

There are a few caveats to the grant process for applicants. Unfortunately, failure is common. The good news is that a high-quality grant application never goes bad. An application can be reused with a bit of reformatting and rewording. It can also provide text for an internal review board application, and the background research may help produce a review article. Recycling grant applications can help residents and junior faculty stay abreast of relevant literature. This is especially important for physician researchers who have never been vetted through a dissertation defense. Despite high failure rates, a good application will usually succeed over time if the applicant is persistent.

Another caveat is that submitting a poorly written, poorly thought out grant is worse than submitting no grant at all. This becomes especially important later in one's research career. Bad grant applications are tedious to the reader and are often remembered with distaste, which is precarious in the small world of science. A bad grant application can easily be avoided by soliciting review and assistance from others throughout the entire

Table 1: Specific Research Grant Opportunities for Psychiatry Residents

Type	Examples	Description
Travel Grants	APA, APIRE, AACAP, AAGP, AAAP, AAPL, APM, SBP, ACNP	Stipends to travel to a professional meeting. Some have well established mentored programs. Hidden travel grants may be available for committee service of members in training.
Pilot Grants	APIRE Janssen Resident Psychiatric Research Scholars, AACAP Pilot Grant, institutional awards	Larger awards (\$5,000 to \$10,000) that may sustain a small project for about 1 or 2 years to generate data for a larger training award. Most suitable for residents with a research plan.
Research Training Awards	NARSAD Young Investigator Award, Klingenstein Third Generation Foundation Award, American Federation for Aging Research Award, professional society awards, e.g. APIRE, NIH series: F32, T32, K-series	Generally \$30,000 to \$100,000 per year. Most appropriate for those at the PGY-V level arranging a junior faculty position or a research track resident with substantial protected research time.

American Academy of Child and Adolescent Psychiatry (AACAP), American Academy of Geriatric Psychiatry (AAGP), American Academy of Psychiatry and The Law (AAPL), Academy of Psychosomatic Medicine (APM), Society of Biological Psychiatry (SBP), American College of Neuropsychopharmacology (ACNP).

application process. A resident should seek review of his or her application from as many people as possible. A good resource is the grant review office at one's institution. Some institutions have policies that mandate office review for larger grants.

Although difficult to obtain, grants are important for psychiatry residents pursuing research careers. Early in a research career, grants provide funds, name recognition, and enforce a clear research training plan. Later, they become integral to advancement. There are some encouraging changes to the grant process that have been spearheaded by NIH. Specifically, NIH is encouraging younger applicants, creating new avenues for team

science, and simplifying the application process. These changes are spelled out clearly by the National Institute of Allergy and Infectious Diseases in the first three articles of their December 17, 2008 newsletter (<http://www.niaid.nih.gov/ncn/newsletters/2008/1217.htm>, accessed 6/1/2009). These changes will affect all psychiatry residents who wish to progress to an independent research career.

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Early Career Development in Psychiatry

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From grantsmanship to K-series awards and from fellowships to tenure track, embarking on a research career can be an overwhelming endeavor. There is a critical need for new researchers in psychiatry, and psychiatry residents interested in such a career path have a number of options available to assist them along the way (1). Mentoring plays a tremendous role in the success of young investigators, and residents should seek opportunities to interact with more senior and successful individuals in their chosen field. The present article describes a number of meetings designed to enhance the career development of young investigators in psychiatry.

Career Development Institute (CDI) for Psychiatry

CDI for Psychiatry is a 4-day intensive meeting for junior investigators interested in a research career, with continuing communication among mentors and peers (2). The institute is led by Drs. David Kupfer and Alan Schatzberg and is supported by a competitive grant from the National Institutes of Health (NIH).

The goals of CDI (as stated on their website) are as follows (2):

- To increase the number of new researchers from diverse institutions and disciplines who will promote scientific excellence and provide academic leadership;
- To shorten the time between their research training period and initial extramural grant support;
- To foster their relationships with established researchers who can serve as mentors or consultants; and
- To facilitate peer support and collaborative research among their cohort group of developing investigators.

The CDI for Psychiatry 2010 meeting will be held April 10-14 in Pittsburgh. Meetings generally alternate annually

between Palo Alto, Calif., and Pittsburgh. Participants must be less than 5 years in a mental health research career trajectory and are generally senior residents, research fellows, and junior

faculty from psychiatry and related disciplines. The application process is competitive, and applications usually open in October (with a due date of early January) for the following spring. The CDI for Psychiatry meeting is limited to 15 to 20 young investigators, and participants are chosen based on their commitment to a research career and their academic accomplishments as reflected in their peer-reviewed publications, personal statement, and letters of recommendation from mentors. The selection committee also considers diversity on the basis of ethnicity, race, gender, scientific interests, geographic location, and institution affiliation.

Another unique aspect of CDI for Psychiatry is its extensive website, which provides a number of valuable resources for participants (even after the meeting), including a discussion forum and an archive of video presentations from the current year's meeting. CDI has contracted with the 3-C Institute for Social Development to maintain the website, film the presentation, and store the video footage of presentations online for participants to review (3). The website also contains contact information for participants and faculty as well as surveys, agendas, maps, and other information needed before the meeting begins. All travel expenses are covered for those selected to participate.

The meeting typically begins with a dinner reception, which is a chance for participants and faculty to get acquainted.

Table 1: Early Career Development Meetings in Psychiatry

Type	Date	Application Deadline
CDI For Psychiatry	April	January
CDI for Bipolar Disorder	May	January
Junior Investigator Research Colloquium	May	November
SRI in Geriatric Psychiatry	July	March

After formal introductions and an overview of the meeting by Drs. Kupfer and Schatzberg, participants are asked to give an oral platform presentation about their area of research. There is also time scheduled for several one-on-one mentoring sessions, and participants can volunteer their K-series award application draft for a mock NIH review session. Other presentations encompass a wide variety of topics, including negotiation, project management and budgeting, CV writing, conflict of interest, institutional review board issues, and biostatistics. A tremendous amount of forethought is put into the agenda, and the days are filled with valuable presentations and workshops.

There is also a Career Development Institute for Bipolar Disorder, tailored to junior investigators with a specific interest in bipolar disorder research. The CDI for Bipolar Disorder mirrors the format of the CDI for Psychiatry, and the 2010 workshop will take place May 1-4 in Pittsburgh (4).

Research Colloquium for Junior Investigators

The Research Colloquium for Junior Investigators is a one-day meeting organized by the American Psychiatric Institute for Research and Education (APIRE) in conjunction with a research training advisory committee (5). The colloquium takes place at the beginning of the APA Annual Meeting in the same

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city. The purpose of the colloquium is to provide mentorship to young investigators in the early phases of their training. Eligible applicants are senior residents, fellows, and junior faculty as well as those who have an interest in and potential for developing research careers. A stipend is issued in order to help defray travel expenses. Participants receive feedback about their research and career plans from experienced mentors in related fields. The 2008 meeting took place on May 17th in San Francisco and began at 8:30 a.m., with an introduction to psychiatric research, along with some useful information about grant writing and research careers. Participants were then assigned to small groups, which included two mentors in their field of research. Each participant was allowed the opportunity to give a 1-hour oral presentation about his or her research, which included time for feedback from peers and mentors. Another plenary session took place in the late afternoon and included talks from established researchers focused on the needs of young investigators.

Other Career Development Meetings and Opportunities

Residents interested in geriatric psychiatry may wish to participate in the Summer

Research Institute (SRI) in Geriatric Psychiatry (6). SRI in Geriatric Psychiatry convenes annually each July, with 25 to 30 junior faculty and/or postdoctoral fellows. The objectives are to teach young investigators how to successfully compete for career development awards, such as NIH K-series awards (7).

In addition, there are specific events at society meetings that cater to residents and early career researchers. For example, at the annual APA meeting, there is an Early Career Breakfast meeting in which residents and junior investigators have the opportunity to speak with different mentors whose role will be to provide advice on starting a research career. The meeting room is divided into tables based on specific areas of interest, with two or more mentors at each table. More information about the Early Career Breakfast can be found on APA's website (<http://www.psych.org>).

A research career in psychiatry can be both rewarding and challenging, and residents planning to embark on this journey should seek the advice of peers and mentors to learn from their experiences. Career development meetings for psychiatry residents and junior investigators, such as those described in the present article (see Table 1), can provide an invaluable opportunity to network, receive feedback, and learn what is necessary to succeed in a research career.

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Evidence-Based Case Report: Prescribing for a Young Adult With Inattention and Probable Stimulant-Induced Psychosis

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“Mr. PB” was a 21-year-old man with a 2-year history of attention-deficit/hyperactivity disorder (ADHD). He had been receiving treatment with amphetamine-dextroamphetamine mixed salts and was referred to our clinic following hospitalization for new-onset paranoia and hallucinations after taking “extra” of this stimulant. He was diagnosed with ADHD during his freshman year of college when he began to fall behind academically while experiencing difficulty with concentration and organization. During this period, he withdrew socially, spending time alone in his room in order “to get work done.” Prior to college, he was an excellent student with many friends and had no substance abuse history. The patient was eventually placed on academic probation and ultimately withdrew from the college. He then enrolled at a community college near his parents’ home but continued to experience academic and social diffi-

culties. Several days prior to the final exams of his sophomore year and after taking “extra” amphetamine-dextroamphetamine mixed salts to improve his exam performance, he became convinced that he was “under surveillance” and repeatedly saw insects crawling behind the screen of his computer monitor. He was hospitalized, the stimulant treatment was discontinued, and risperidone was started. His symptoms resolved within 1 week. Neuropsychological testing demonstrated significant defects in attention and memory, with normal cognitive functioning in other areas. Upon discharge, he was referred to our clinic. During the next 6 months, he remained free of psychotic symptoms, started work at a children’s camp, and began making arrangements to return to college. He worried that he would not be able to finish college without his stimulant treatment regimen and asked to resume this medication.

Asking A Question

We were concerned that restarting the stimulant treatment might trigger another psychotic episode in the patient. Furthermore, we were not convinced of the previous ADHD diagnosis, since adult-onset ADHD is rare (1), and our patient’s difficulties may have represented prodromal psychotic symptoms instead. However, there were reasons to consider our patient’s request to resume treatment. Data support the benefit of stimulants in adults with ADHD (2, 3), and the rapid onset and resolution of the patient’s symptoms suggested stimulant intoxication. Thus, to respond to his request, we needed answers to the following questions:

- 1) What is the risk of psychotic exacerbation with stimulants when used as prescribed?
- 2) Are there pharmacotherapeutic alternatives that would lower this risk?

In the present article, we describe our process (as an example) of a search for an

evidence-based answer to typical clinical questions.

Accessing the Evidence

We searched the literature using an evidence-based hierarchy of resources (Appendix 1). The case reports generated by this search yielded descriptions of stimulant-induced psychosis but did not quantify the risks. We found two Food and Drug Administration (FDA) reports (4, 5), referenced by a case report (6) and summarized by Mosholder et al. (7), in a meta-analysis published after completion of our patient’s care (8). Our search of MedWatch (a drug safety monitoring system maintained by the FDA) did not reveal these reports—only the following warning: “Clinical experience suggests that, in psychotic patients, administration of amphetamines may exacerbate symptoms of behavioral disturbance and thought disorder.”

Randomized controlled trials provide the highest internal validity for questions regarding the effects of treatment inter-

ventions (9). The ideal evidence for our questions would thus come from a large randomized placebo-controlled trial assessing the risk of psychosis in young adults being treated for ADHD with stimulants. However, randomized controlled trials usually do not enroll enough subjects to measure rare risks adequately. A systematic review of several randomized controlled trials would mitigate this limitation. Observational studies, such as those that follow a large cohort of subjects and assess rates of psychosis, may provide important evidence, especially because these studies can be conducted over longer follow-up periods than randomized controlled trials. However, data from observational studies are often gathered through postmarketing surveillance (mandated by the FDA) conducted by pharmaceutical companies and are of varying quality.

We did not find a systematic review, randomized controlled trial, or observational cohort study that included young

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adults (only case-reports), but we did find these data for children. Thus, to answer our questions, we had to generalize from the pediatric literature. We evaluated the reports using a critical appraisal template adapted from Sackett et al. (9) (Table 1), which involved assessment of the following three broad domains: the internal validity or extent of freedom from common sources of bias; the size and precision of the estimates of risk; and the external validity or applicability to our patient.

Appraising the Evidence

We found two case reports of children who experienced psychotic episodes while taking amphetamine-dextroamphetamine mixed salts that resolved shortly after discontinuation of treatment (10, 11). Parasitotic visual hallucinations similar to those experienced by our patient were also reported (10). A case series reported psychotic symptoms in six adult patients after they received treatment with stimulants (12). Among these, five experienced improvement within days of discontinuation of the stimulant and the addition of antipsychotic medication.

One FDA report described 92 cases of new-onset psychosis during treatment with amphetamine-dextroamphetamine mixed salts. There were 77 cases of psychosis associated with prescribed amphetamine or dextroamphetamine reported to the FDA (Table 1). In short, these case reports suggest that stimulants increase the risk for a psychosis that generally resolves with discontinuation of the medication. However, these reports do not quantify risk and are not robust enough to exclude spurious associations.

A retrospective cohort study found that six out of 98 children treated with methylphenidate for ADHD developed psychotic symptoms relative to none of the 94 children in the treatment-naïve comparison group (Table 1), supporting an association (13). However, observational studies are prone to selection bias. Furthermore, retrospective studies may overestimate the actual population risk by reporting on the unrepresentative samples seen in mental health clinics.

The FDA systematically reviewed the side effects reported in 42 open-label trials of the following eight medications used to treat ADHD: amphetamine-dextroamphetamine mixed salts, dexamethylphenidate hydrochloride, dexamethylphenidate hydrochloride extended release, methylphenidate hydrochloride extended release capsules, methylphenidate transdermal system, methylphenidate hydrochloride long-acting, atomoxetine hydrochloride, and modafinil (5). These studies followed 15,999 children for a total of 9,393.22 patient years and reported 45 psychotic/manic events, yielding a risk of psychosis of 0.4% per patient year.

The FDA also systematically reviewed 49 double-blind placebo-controlled trials of stimulants in the treatment of ADHD. These studies ranged from 1 to 9 weeks in duration. Among the 5,717 children treated with stimulants, there were 43 psychotic/manic events, compared with none in the 3,990 children treated with placebo, suggesting an absolute risk of 1.5% per patient year.

Between the observational and randomized trials, the risk of stimulant-induced psychosis is 0.4%-1.6% per patient year in the pediatric population. However, many of the trials required a history of response to stimulant medication and thus enriched the samples for individuals who may have been less likely to have adverse events than treatment-naïve individuals, thereby leading to an underestimation of risk.

Although there were no trials directly comparing the risk of psychosis between stimulant medications, an alternative approach examined the risk of psychosis among stimulant medications across clinical trials. However, the following caution is warranted with this approach: Any finding may reflect differences in the populations studied (i.e., different inclusion or exclusion criteria) rather than differences in the actual risk of psychosis. In double-blind trials, subjects treated with amphetamine-dextroamphetamine mixed salts had a lower risk of psychosis (0 events in 59 patient years) relative to methylphenidate derivatives (dexamethylphenidate hydrochloride, dex-

methylphenidate hydrochloride extended release, methylphenidate hydrochloride extended-release capsules, methylphenidate transdermal, methylphenidate hydrochloride long-acting [4.4% per patient year]) and nonstimulant ADHD medications (modafinil [0.3% per patient year] and atomoxetine [0.2% per patient year]). In longer-duration open-label studies, the risk of psychosis was similar across agents. The lower bound was for nonstimulant ADHD medications (0.2% per patient year), and the upper bound was for methylphenidate derivatives (0.4% per patient year). Amphetamine-dextroamphetamine mixed salts had an intermediate risk of psychosis at 0.3% per patient year.

Applying the Evidence

These findings suggest a clinically meaningful risk of stimulant-induced psychosis. Uncontrolled retrospective long-term observational studies have suggested a risk as high as 3.5% per patient year in children, whereas a systematic review of randomized controlled clinical trials suggested a risk between 0.4% and 1.6% per patient year. A preliminary search for alternative interventions in an evidence-based summary (www.clinicalevidence.org) led us to consider clonidine, which is an agent with evidence for efficacy for the treatment of ADHD in randomized controlled trials of children (14). Other agents that have demonstrated efficacy for treating ADHD in adults are desipramine (15), bupropion (16), and guanfacine (17). However, the risk of psychosis is unclear with these medications.

We explained to our patient that we had not found definite answers to our questions pertaining to how to address his requests. However, we could confidently state that—even with appropriate dosing—he could expect an increased risk of psychosis with resumption of any of the medications typically used to treat ADHD. We discussed nonpharmacological options, including cognitive remediation training, and pharmacological alternatives to the typical ADHD agents. Ultimately, our patient agreed

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to return to school while being treated with risperidone (without amphetamine-dextroamphetamine mixed salts) and to revisit the issue of pharmacological treatment of ADHD if, in a school context, he continued to experience difficulties with concentration and organization.

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Appendix: Searching for the Evidence

Step 1: Search secondary resources for relevant controlled trials.

- Clinic Evidence www.clinicalevidence.org
- Evidence Based Mental Health <http://ebmh.bmj.com/>
- Cochrane Library <http://www.cochrane.org/> (Focused on the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects and Cochrane Central Register of Controlled Trials)

Search terms “psychosis” and “ADHD” and “psychostimulants”

These resources led to only one somewhat relevant systematic review that reported stimulants were more effective than placebo in the treatment of the negative symptoms of schizophrenia based on a randomized controlled trial of 16 patients (25).

Step 2: Search a primary database (Medline) for observational studies and case reports using the PubMed Clinical Query search tool: <http://www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml>

Search strategy (Methylphenidate (MeSH) OR Dextroamphetamine (MeSH)) and (Psychotic Disorders (MeSH) or hallucinosis) and limited to English language and human studies.

This search yielded 8 manuscripts studying the association between psychostimulant medications and psychosis. These manuscripts included 7 case reports or case series and 1 observational study linking psychostimulant medications and psychosis. These data are reviewed in the evaluating the evidence section of this manuscript.

Step 3: Scanning the bibliographies of relevant articles for further references.

This led to two very useful FDA reports (7, 8) referenced by the author of a single case report (9). All the FDA data presented later in this article was a result of finding these FDA reports in this case report's reference list.

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Table 1. Appraisal Template of Studies

Level of Evidence	Clinical Observations		Observational Studies		Randomized Controlled Trials (RCTs)
Study	Gelperin (4)	Gelperin (4)	Cherland (13)	Mosholder (5)	Mosholder (5)
Type of study	FDA Adverse Event Reports	Shire Adverse Event Reports	Cohort Study	Systematic Review of Open-Label Studies	Systematic Review of randomized control trials
Description of studies	FDA Summary of 77 adverse event reports of psychosis or mania in patients treated with amphetamine or dextroamphetamine derivatives.	Summary of 92 adverse event reports of psychosis or mania in patients treated with amphetamine-dextroamphetamine mixed salts made directly to their pharmaceutical manufacturer.	Retrospective chart review of 192 children treated for ADHD at an outpatient mental health clinic. 98 children treated with methylphenidate were compared with 94 children who received no medications.	Systematic Review of 42 open-label studies involving 8 different medications requesting FDA approval for treatment of ADHD.	Systematic Review of 62 double-blind placebo controlled trials involving 8 different medications requesting FDA approval for treatment of ADHD.
Are the results valid?					
Are the patients and controls similar?	N/A	N/A	No. There may be selection bias as to which children were prescribed methylphenidate vs. no medications.	N/A	N/A
Were the outcomes and exposures measured in the same way?	N/A	N/A	Yes	N/A	Yes
Was the follow-up long enough and complete?	No, adverse event reports have inconsistent follow-up	No, adverse event reports have inconsistent follow-up	Yes, average follow-up length was 21 months.	Maybe, open trials followed subjects for an average length of over 7 months.	No. Trials ranged from 1-9 weeks in duration
Is the temporal relationship correct?	Yes	Yes	Yes	Yes	Yes
Is there a dose-response gradient?	Unknown	Unknown	Unknown	Unknown	Unknown
What are the results?					
How strong is the association between exposure and outcome?	Unable to calculate from adverse event reporting, which likely represents a small proportion of actual cases	Unable to calculate from adverse event reporting, which likely represents a small proportion of actual cases	The risk of psychosis was 6.1% in the methylphenidate treated group and 0% in the medication-naïve group. The calculated risk of methylphenidate-induced psychosis was 3.5% per patient year.	The risk of psychosis was 0.4% per patient year in the medication treated group.	The risk of medication induced psychosis is 1.6% per patient year compared to 0 in the placebo group.
How precise is the estimate of risk?	N/A	N/A	The authors do not report confidence intervals for risk.		
Will the results help the patient care?					
Are the results applicable to my patient?	Yes, 40% of adverse event reports occurred in patients older than 20 years-old.	Yes, 8% of adverse event reports involved drug abuse and 40% involved patients older than 20.	Limited applicability. Our patient is a young adult whereas this study describes children	Limited applicability. Our patient is a young adult whereas this systematic review describes children. Also, some non-stimulant ADHD medications are included in this review.	
What is the magnitude of risk to my patient?	Unknown; but appears greater than 0.	Unknown; but appears greater than 0.	Difficult to extrapolate to our patient from child data, but highest reported risk of 3.5% per patient year in longest followed cohort (13) is clinically significant.		
What are the patient preferences?	To discontinue antipsychotics and restart stimulants				
What alternatives are available?	Continue antipsychotics. Pursue alternative ADHD therapies such as bupropion, clonidine or desipramine				

Tailor-Made Mentoring

Angeli Landeros-Weisenberger, M.D.
Yale Child Study Center, Yale University School of Medicine

“As teachers and doctors, we offer ourselves to be metabolized by students and patients, and we enjoy seeing our thoughts and attitudes become internalized and thus immortalized. We do not know which student will carry what part of us into the future...and make our work and beliefs a part of him or herself. We know that only through risking ourselves in true encounters—in family and in our teaching—is there any hope for surviving, at least in part.”

—Donald J. Cohen, M.D. (1940-2001)

Five years ago, I could not have imagined the place where I am now. I began my journey at the Hospital Español, in Mexico City, as a psychiatric resident engrossed in learning the clinical art of my profession. I am currently a postdoctoral research fellow conducting repetitive transcranial magnetic stimulation (rTMS) treatments in a clinical trial of Tourette’s syndrome. Much has changed in my professional life during this journey as I strive to be a collage of the mentors I have had along the way.

Listening and Caring

Mentor: Enrique Suárez, M.D.

I met Dr. Suárez during my internship at the Hospital Español. He taught me about ECT and fueled my passion for brain stimulation techniques, but most of all he instilled in me the importance of truly listening and having a deep dedication to my patients. There were many instances in which Dr. Suárez was quite unorthodox and went above and beyond the standard of care for his patients. However, what I remember best was what he did for his aging dog Herman. Herman was a 15-year-old schnauzer who was diabetic, had kidney failure, and couldn’t walk. Near the end of Herman’s life, Dr. Suárez could be seen on the streets of Polanco, in Mexico City, carrying Herman around (who was dressed in a T-shirt because of skin problems) on their daily walk. He would place Herman down at all the local attractions so he could do his “doggy duties” and then pick him up to complete the circuit. I have no doubt that Dr. Suárez demonstrated a similar devotion to his patients as well as his residents.

Molding, Mentoring, and Teaching the Next Generation

Mentor: Andrés Martín, M.D., M.P.H.

I first met Andrés when he came to the Hospital Español to give talks on “The Consequences of Serotonin Reuptake Inhibitor (SRI) Use in Young Children” and “Autism Spectrum Disorders.” I was assigned to give him a tour of the hospital, during which time I got the opportunity to pick his mind about psychiatry. At the end of the tour, one of the attendings asked me to “fetch” a cup of coffee. I felt belittled and nullified. Besides, Andrés does not drink coffee. He likes caffeine-free tea with cream and no sugar. Recognizing the situation, Andrés made the joke that if in the United States he were to ask a resident to “fetch” a cup of coffee, he would either get reprimanded or get the coffee thrown at him. The joke put me at ease and ended my humiliation. After our meeting, he invited me to Yale to do a fourth-year residency rotation in child psychiatry.

While at Yale, I recognized that my experiences with Andrés were hardly unique. Despite editing for a major psychiatric journal, being Medical Director of a large child inpatient psychiatric unit, and attending a consult service part-time, he still finds time to be a stellar teacher and mentor for his students. He currently runs the Klingenstein/Donald J. Cohen Medical Student Fellowship in child psychiatry at Yale, where medical students are exposed to child psychiatry. He also oversees a mentorship program for early trainees at the American Academy of

Child and Adolescent Psychiatry and turned his child psychiatry unit into one of the great teaching rotations for medical students at Yale.

In me, Andrés saw that I had an interest in teaching, and he fostered this passion of mine. When I returned to Yale as a postdoctoral research fellow, he enabled me to start teaching medical students as an Interview Tutor, which allowed me to continue in an area I enjoyed. It is a constant joy for me to be able to view the wonder and horror of psychiatric illness through naïve eyes and impart some of my clinical skills to my trainees.

Listening, Scientific Rigor, and the Program for Minority Research Training in Psychiatry (PMRTP)

Mentor: James F. Leckman, M.D.

I met Dr. Leckman at Yale and formally started working with him at the beginning of my postdoctoral research training through PMRTP. PMRTP is a program that provides support and mentorship for minorities interested in psychiatric research and offers funding for both summer and year-long research fellowships. Jim is a caring and dedicated physician as well as a wonderful teacher and researcher. He is also a great listener and resilient person. He has spent hours listening to me, not only to help me find a research project in which I would be successful, but also in helping me to make the transition needed to live in a new country and engage in a new line of work. Through his help, I have become profi-

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cient in rTMS and oversee the treatments in a sham-controlled trial of Tourette's syndrome (a collaboration with Columbia University), which we will hopefully finish and publish next year.

Warmth, Enthusiasm, Success of Women in Research, and Passion for Research

Mentor: Uma Rao, M.D.

I met Dr. Rao at an American College of Neuropsychopharmacology (ACNP) meeting, and she was my assigned mentor

(through PMRTP). For those of you who do not know, the ACNP meeting can be very intimidating for junior investigators. The meeting is exclusive and invitation-only, and psychiatrists whose names appear in journal articles and textbooks are usually in attendance. My husband calls ACNP the cool place to be for nerds in academic research. Dr. Rao was assigned as a mentor to help me network and navigate the meeting. She invited me to dinner every night. She is not only personable but energetic and a true example of a female success in academia. Moreover, she has the ability to make an individual feel special, recognized, and

capable of successful research. I know whenever I travel away from home I have a friend and mentor waiting in her.

These are only a few of the people who have touched me. Each one of them has given me a part of themselves, as their mentors did with them. There is no such thing as a "one-size-fits-all" mentor. Usually, the best mentors are "tailor-made" from many people they met along their way.

Dr. Landeros-Weisenberger thanks APIRE and PMRTP for funding her research training.

Committee of Residents and Fellows

The Committee of Residents and Fellows (CORF) is a permanent standing committee of APA. The Committee is composed of seven psychiatry residents, each representing one of the seven geographic areas into which APA divides the United States and Canada. Additionally, representatives from APA's three fellowship programs participate as active members. Each member is nominated by his/her residency training program and serves a 3-year term.

Since 1971, the Committee has represented resident opinions and issues within the Association and has established effective and meaningful liaisons with many components of APA, as well as with many other organizations that are involved in training and the profession.

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