Staying in the Clinical Ballpark While Running the Evidence Bases

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CASE SCENARIO

Leimomi was a 16-year-old female of Asian Pacific Island descent born and raised on Oahu who was referred to the Department's Child and Adolescent Mental Health Division (CAMHD) by her public school student services coordinator for running away, chronic truancy, aggressiveness, and drug abuse. She had been diagnosed with systemic lupus erythematosus about 1 year before this referral and treated with prednisone 25 mg/day, Plaquinil 400 mg at bedtime, Plendil 2.5 mg twice daily, and Elavil 40 mg at bedtime for sleep. There was no relationship between her behavior, affective state, lupus, or her lupus treatment.

At the time of referral she had not been taking her medications, had been on the run for 2 months abusing methamphetamine, and was then living in the state detention home for violating probation. A child and adolescent psychiatrist with extensive experience using structured diagnostic interviews completed her evaluation. She reported a long history of oppositional and defiant behavior, willful disobedience, lying, stealing, fighting, gang involvement, running away from home, truancy, and suspensions and expulsions from school. She was on probation, but only because of truancy. Onset of her conduct and behavior problems was at age 5. The problems were mild in elementary school, and her grades were good at that time. Her behavior worsened at age 9, when a family friend repeatedly sexually abused her. Leimomi experienced subsequent nightmares, flashbacks, autonomic arousal, and avoidance from the abuse.

At age 10, she joined a native Hawaiian gang and began using drugs, being truant, and failing in school. At the age of 13, Child Protective Services removed her from the family home because of neglect and abuse by her mother. Her mother and entire family have an extensive history of drug addiction and criminality. Child Protective Services placed Leimomi in a permanent foster placement with a caring older sister. A year before the referral, Leimomi completed a chemical dependency treatment program but quickly relapsed when she recontacted her drug-using peers. At the time of evaluation, she was an overweight female adolescent of Asian/Pacific Island ancestry who met criteria for conduct disorder, amphetamine abuse, systemic lupus erythematosus, and posttraumatic stress disorder, chronic.

SETTING

Hawaii’s unique environment combines geographic isolation with a richness of cultural and economic diversity. The state is a veritable mosaic of interests, ethnicities, cultures, communities, and values. According to the Hawaii’s Vital Statistics 2001 Report (Hawaii Department of Health, 2002), 19.8% of the population identify themselves as white, 21.3% as Hawaiian, 21.6% as Japanese, 15.7% as Filipino, and 21.5% as other or mixed ethnicity. The CAMHD of the Hawaii Department of Health serves youths with intensive mental health needs from these diverse communities and in recent years has begun to implement and prioritize the use of evidence-based practices.
For example, a committee continually reviews relevant literature and summarizes the latest results regarding efficacy and effectiveness of interventions and makes the results available electronically to system stakeholders (Chorpita et al., 2002). Such summaries allow clinicians ready access to an extensive literature to guide clinical decision making.

**USING THE EVIDENCE BASE ON EFFICACY**

This case reflects the complexity faced in real-world service systems in that it is unlikely that there exists a series of controlled studies of psychosocial treatment or medication treatment for adolescent females with Leimomi’s complex and highly comorbid clinical profile. Because Leimomi did not endorse any current symptomatology of posttraumatic stress disorder or mood disorders, the treatment team chose to focus initially on her conduct disorder symptoms, which placed her at high risk of incarceration or additional assaults.

CAMHD uses the treatment outcome literature as a guide in selecting interventions by referring to both a detailed biennial report and an abbreviated quarterly summary relating disorders and problem areas to interventions (see http://hawaii.gov/health/mental-health/camhd/resources/index.html). The prevailing paradigm for using evidence-based approaches for selecting psychosocial treatments comes from the work of the American Psychological Association’s Task Force on Psychological Intervention Guidelines (1995) and the Task Force on Promotion and Dissemination of Psychological Procedures (1995). These guidelines rank evidence for interventions based on consideration of the quality of the efficacy studies conducted, with primary consideration being afforded to randomized clinical trials. An adaptation of these general guidelines for ranking treatments is used in the Hawaiian system (Chorpita et al., 2002, or see http://hawaii.gov/health/mental-health/camhd/resources/index.html) and places treatments into one of five levels (i.e., level 1: best support; level 2: good support; level 3: moderate support; level 4: minimal support; level 5: known risks).

When using these guidelines, we discriminate between “efficacy” and “effectiveness.” A treatment is said to possess efficacy if it shows a statistically significant effect in a controlled experimental study (Task Force on Psychological Intervention Guidelines, 1995). A treatment is considered effective if it shows a clinically significant effect in “real life,” that is, with a representative clinical population served by practicing clinicians in a true service setting.

Decisions are thus made based on both reviews of a treatment’s efficacy and its effectiveness. On the one hand, clinicians selecting interventions based on their efficacy may give particular consideration to manual-based interventions that have been replicated by independent investigator teams in multiple randomized clinical trials. On the other hand, clinicians may choose to examine the “effectiveness” evidence base, focusing on evaluations whose designs may have less internal validity but involve tests with those patients and contexts most similar to the situation in question. Balancing these two evidence bases is not easy, given that in many circumstances they do not entirely align. Our recommendation is typically to start with consideration of the efficacy findings and then to consider other aspects of evidence next (see Daleiden and Chorpita [2005], for a detailed description of balancing multiple sources of evidence in decision making).

When medication and psychosocial treatment must be integrated, CAMHD-generated summaries of the evidence are considered as well. Although there is a growing research examining separate and combined effects of psychosocial and medication (e.g., Multimodal Treatment Study of Children With ADHD Cooperative Group, 1999; Pediatric OCD Treatment Study [POTS] Team, 2004; Treatment of Adolescent Depression Study [TADS] Team, 2004), CAMHD currently considers psychosocial and medication treatments separately until there is a greater accumulation of research on combined treatments. By following the principle of *primum non nocere* (first, do no harm), best practices, and recommended treatment algorithms, we suggest nonpsychopharmacological treatments be tried first for Leimomi (e.g., Pappadopulos et al., 2003; Schur et al., 2003).

If medications were to be considered, then we would suggest that medications with the best evidence for efficacy be tried first. For example, in this scenario, the psychiatrist on Leimomi’s treatment team may consider atypical neuroleptics based on the TRAAY recommendations (e.g., Pappadopulos et al., 2003; Schur et al., 2003) or a mood stabilizer for suspected mood
disorder. Because her aggression was thoughtful and willful and not reactive (e.g., Pappadopulos et al., 2003; Schur et al., 2003) and her irritability was the result of plans that failed and not getting her own way, her treatment team decided that neuroleptics and mood stabilizers were not indicated and would put her at risk of serious side effects. Recent CAMHD summaries of the psychosocial treatment literature demonstrate that the level 1 treatments (those with the highest level of support for their efficacy) include various forms of parent training for conduct and oppositional disorders. It would seem then, with a strict application of the efficacy guidelines, that our choice for this youth may involve a parent training approach. However, Leimomi’s age, her lack of a supportive parent figure, and the predominance of willful misconduct raised the question of whether the type of trial and number of replications were the only variables to consider when using evidence to select a treatment for her.

USING THE EVIDENCE BASE ON EFFECTIVENESS

CAMHD decision support tools summarize much of the information that clinicians may use to match patients to treatments, including such parameters from the research trials as age, sex, ethnicity, therapist background, effect size, acceptability of treatment, and so forth. The literature is reviewed regularly to contribute to the CAMHD decision support tools (see http://hawaii.gov/health/mental-health/camhd/resources/index.html for examples). Careful examination of CAMHD reports showed that parent training approaches with empirical support apply only to youths ages 2–12 and that few if any of these youths demonstrated true delinquency. Based on Leimomi’s age and clinical profile, CAMHD decision support tools showed that multisystemic therapy (MST; Borduin et al., 1995; Henggeler et al., 1986, 1992) was a better fit regarding age and clinical profile. MST services were introduced in 1999 in Hawaii as part of a larger effort to implement evidence-based practice for the state’s most challenging youths. Training and implementation was supported by MST services in partnership with the state department of health. By the time of Leimomi’s registration into our system, CAMHD had 10 MST treatment teams distributed across the state, each with appropriate certification and training, and several years of experience in their communities.

USING THE LOCAL EVIDENCE BASE

In this case, as the treatment team considered whether the ethnicity of the youth fit with MST, it was noted that few Asian/Pacific Island youths have participated in published trials involving MST. Furthermore, efforts to disseminate or “export” MST from its South Carolina base have not been universally successful. Leimomi’s treatment team thus questioned whether her ethnicity warranted an alternative intervention from within our array of services, in this case intensive in-home (IIH) therapy. Two significant limitations of IIH therapy, however, are that the level and quality of supervision do not match that provided by MST and that far less is known about the efficacy of IIH.

Rather than addressing this concern with routine clinical judgment, her clinical team next asked whether the clinical decision could be additionally supported with local evidence. CAMHD regularly evaluates the quality of its mental health services as part of its own quality review process (Daleiden and Chorpita, 2005). Measurement includes standardized measures of functioning and psychopathology and also includes MST’s strategy of outlining “overarching goals” and determining the percentage met at posttreatment (Henggeler and Schoenwald, 1999). Using CAMHD reports, the treatment team could examine the comparative outcomes of MST and IIH services, albeit in an uncontrolled manner (Daleiden, 2003). In addition, CAMHD also funded an independent evaluation of MST services in Hawaii to evaluate whether these services were functioning as expected. Although the data were not controlled, both reports suggested that MST was efficacious in the CAMHD system at a level that is consistent with published clinical trials. For example, roughly 70% of CAMHD adolescents treated with MST met the majority of their overarching goals after treatment, and outcomes did not correlate with ethnicity (Daleiden, 2003; Rosenblatt et al., 2001).

RUNNING THE EVIDENCE BASES

Table 1 outlines the multiple sources of information considered to inform the selection of an intervention for
this youth. When the multiple evidence bases corroborate each other, then clinical decisions can be simple. For example, if MST were a level 1 intervention (evidence of efficacy), matching youth, system, and provider context (evidence of effectiveness), and enjoying unequivocal support within our system (local evidence), there would be no doubt about how to proceed. However, in our “Leimomi” scenario, none of these evidence bases aligned completely. Nevertheless, the efficacy data were strong enough (level 2), the effectiveness data matched on most characteristics (e.g., sex, age, acceptability of treatment, duration of treatment, training requirements), and our local data provided some assurance regarding any remaining gaps (e.g., ethnicity). At the time of this writing, the case is still under way, so any review of outcome must wait several more months. As always, a final source of evidence is being gathered as part of routine service delivery: client-specific outcome information. Ultimately, it is this information that will or will not confirm the validity of our choice.

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REFERENCES


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TABLE 1

Sources of Evidence Used to Inform the Selection of a Clinical Intervention

<table>
<thead>
<tr>
<th>Category</th>
<th>Sources of Information</th>
<th>Example(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>Randomized clinical trials; summaries of study parameters (e.g., replications) that inform the reliability of the inference that the treatment has had a positive effect in outcome trials</td>
<td>CAMHD Tabular Summary (<a href="http://hawaii.gov/health/mental-health/camhd/resources/index.html">http://hawaii.gov/health/mental-health/camhd/resources/index.html</a>); Henggeler et al. (1992)</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Randomized clinical trials; summaries of study parameters (e.g., feasibility, generalizability, and cost/benefit information) that speak to likelihood of real-world success</td>
<td>CAMHD Biennial Report (<a href="http://hawaii.gov/health/mental-health/camhd/resources/index.html">http://hawaii.gov/health/mental-health/camhd/resources/index.html</a>); Chorpita et al. (2002)</td>
</tr>
<tr>
<td>Local data</td>
<td>Aggregated information (controlled or otherwise) regarding the effects of an intervention within the system itself</td>
<td>CAMHD Annual Evaluation (Daleiden, 2003); MST Independent Evaluation (Rosenblatt et al., 2001)</td>
</tr>
<tr>
<td>Client-specific data</td>
<td>Outcome measures on this specific youth, used to monitor clinical progress over time</td>
<td>Number of overarching goals met, scores on measures of clinical functioning</td>
</tr>
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</table>

Note: CAMHD = Child and Adolescent Mental Health Division; MST = multisystemic therapy.