Pharmacogenomics and Cultural Issues in Psychopharmacology

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Ethnopharmacology

- Ethnic pharmacology, cross-cultural pharmacology, translational pharmacology, transethnic pharmacology
- Differences in drug metabolism

Ethnicity
- Genetic constitution
- Culture

- How ethnicity affects drug response
- Culturally competent healthcare

Objectives

- Know the effect of genetics on psychotropic disposition and response
- Identify cultural factors that influence
  - Recognition and diagnosis of mental illnesses
  - Health seeking
  - Medication use
- Understand the scope of cultural competency
Culture versus Ethnicity

“Ethnicity represents the common heritage shared by a group of people.”

“Culture is the complex whole which includes knowledge, beliefs, art, morals, law, custom etc”

Edward Tyler 1874

Categories and rules that different people interpret their world and act within it.

Culture, Ethnicity, Medications

♦ Transcultural communication
  - Language barrier
  - Perception imposed by different cultural values

♦ Culture and mental health
  - Normal vs. abnormal behavior
  - Pattern of presentation
  - Response to treatment

♦ Cultural implications of treatment
  - Understand a client’s cultural beliefs and proper use of psychotherapy / counseling

Ethnicity and Pharmacological Management

♦ Few information on transethnic pharmacology
  - Study result and dosage recommendations extrapolated from homogenous Caucasians to other populations??
    - JAMA 1998;279:1049,1051
    - J NIMH Res 1998;2:37

♦ Differential dose requirement / response to psychotropics among different ethnic groups
  - Well known
  - Biological basis: genetic differences in
    - drug metabolism
    - drug transport
    - drug targets

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**Schema of ADME**

Liver Metabolizing Enzymes

- CYP3A4
- CYP2D6
- CYP2C19
- CYP2C9
- CYP1A2

Cytchrome P450: CYP

Enzyme Family: 2

Enzyme Subfamily: D

Isoenzyme: 6

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Polymorphisms: Mutations (structural alterations) in DNA code that occur in ≥1% of population

- 2 distinct groups with different activities of the same drug metabolizing enzyme

Adapted from: Science 1999;286:487-91

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Pharmacological Implications of CYP Genotypes

CYP2D Polymorphism and Antidepressants

Clinical Example
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Ethnic Distribution of CYP2D6 Genotypes

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>CYP2D6 Genotype</th>
<th>Genotype Distribution (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasians</td>
<td>IM (CYP2D6*10)</td>
<td>30%</td>
</tr>
<tr>
<td></td>
<td>PM (CYP2D6*17)</td>
<td>70%</td>
</tr>
<tr>
<td>Asians</td>
<td>*1/*1</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>*1/*2</td>
<td>100%</td>
</tr>
<tr>
<td>Africans</td>
<td>*1/*5</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>*1/*9</td>
<td>100%</td>
</tr>
</tbody>
</table>

Venlafaxine

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Cmax</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYP2D6*10</td>
<td>184%</td>
<td>484%</td>
</tr>
<tr>
<td>CYP2D6*15</td>
<td>101%</td>
<td>383%</td>
</tr>
</tbody>
</table>

Japanese subjects, PK values w.r.t. subjects with *1/*1 and *1/*2


PM (CYP2D6*10)

Ethnicity and Tricyclic Antidepressants

♦ Asians most extensively studied
  - Lower doses prescribed in 10 Asian countries
    Psychopharmacol Bull 1979;15:29-31
  - Belief of smaller physical size
    - Biological basis of slower metabolism
  - Less tolerant to clompramine side effects

Tendency for African Americans to have higher TCA conc., faster response, and more S/E

Psychopharmacol Bull 1991;27:441-8
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CYP2D6 and Ethnic Groups in the U.S.
- Less data for major ethnic minority groups (Native Americans, Mexican Americans)
  - Extensive interracial marriage
  - Definition of cultural / ethnic groups
- CYP2D6 and acetylation phenotyping in Mexican Americans
  - Questionnaire modified from those used in the San Antonio Heart Study
  - 4% PM and 45% slow acetylator (SA)

Ethnicity and Antidepressants
- Hispanics required ↓ TCA dosage and have ↑ sensitivity to anticholinergic S/E's

<table>
<thead>
<tr>
<th></th>
<th>Hispanics</th>
<th>Caucasians</th>
</tr>
</thead>
<tbody>
<tr>
<td>41F</td>
<td>66 mg</td>
<td>131 mg</td>
</tr>
<tr>
<td>21F</td>
<td>76.5%</td>
<td>71.4%</td>
</tr>
<tr>
<td>TCA dosage</td>
<td>78%</td>
<td>33%</td>
</tr>
<tr>
<td>D/C TCA</td>
<td>17%</td>
<td>4.8%</td>
</tr>
<tr>
<td>S/E complaints</td>
<td>78%</td>
<td>33%</td>
</tr>
</tbody>
</table>

Am J Psychiatry 1982;36:505-12

Identify PM to prevent adverse drug effects
Differentiate UM from patients who are non-adherent to Rx

Measure CYP2D6, 2C19
Should we use it??? How and when to use it?
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Case Report
Fluoxetine-Related Death in a Child with Cytochrome P-450 2D6 Genetic Deficiency

Genetic Variabilities in Drug Targets

Depressed patients treated with SSRIs

Responders

Non-responders

Serotonin transporter gene polymorphism:

l/l, l/s, s/s

32%, 49%, 19%

l = higher activity allele
s = lower activity allele

Paroxetine Efficacy and 5-HTTLPR

- Major depression, no psychosis
  - Placebo run in phase excluded 4 responders
  - n = 60, HAM-D > 20
- Paroxetine 40 mg/d x 4 weeks
  - Paroxetine Cp at end of week 4
  - HAM-D rating @ baseline, q week
  - 5-HTTLPR genotypes
    - Lab personnel blinded to clinical course
    - Raters blinded to lab result

J Clin Psychopharmacol 2000;20:105-7
Paroxetine Efficacy and 5-HTTLPR

<table>
<thead>
<tr>
<th></th>
<th>II</th>
<th>I/II</th>
<th>II/II</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (M / F)</td>
<td>10 (7 / 3)</td>
<td>20 (9 / 11)</td>
<td>16 (4 / 12)</td>
</tr>
<tr>
<td>HAM-D Wk 0</td>
<td>21.1 ± 3.3</td>
<td>20.9 ± 4.4</td>
<td>27.7 ± 3.4</td>
</tr>
<tr>
<td>HAM-D Wk 1</td>
<td>16.6 ± 6.6</td>
<td>20.0 ± 4.5</td>
<td>23.4 ± 2.2</td>
</tr>
<tr>
<td>HAM-D Wk 2</td>
<td>11.1 ± 7.0</td>
<td>15.3 ± 4.8</td>
<td>22.2 ± 6.3</td>
</tr>
<tr>
<td>HAM-D Wk 3</td>
<td>7.4 ± 8.0</td>
<td>10.3 ± 7.9</td>
<td>26.8 ± 7.6</td>
</tr>
<tr>
<td>[Paroxetine] 67.6 ± 36.4</td>
<td>71.1 ± 29.3</td>
<td>58.4 ± 21.8</td>
<td></td>
</tr>
</tbody>
</table>

- Significant effect for genotype (p = 0.001), time (p < 0.0001), and genotype x time interaction (p < 0.0001)
- No significant effect for paroxetine conc.

Augmentation therapy (paroxetine (5-HT_1A antagonist) + beta-adrenergic antagonist) 2.5-5 mg/4 h

Fluoxetine alone (n=53)

Fluoxetine plus pindolol (n=40)

- Genotype I/I
- Genotype I/S
- Genotype S/S

Mol Psychiatry 1998;3:508-11

What Are the Potential Benefits?

- All SSRIs are equally effective
- Reduce trial and error prescribing
- Each ineffective drug trial
  - 4 - 12 weeks of continued symptoms, illness, impaired QOF
  - Potential for significant ADRs
  - Affects medication adherence
  - Direct and indirect health care costs

SERT polymorphism: l/l, I/I, I/S

Efficiency with I/I genotypes in 7/9 studies
Efficiency with I/S genotypes in 3/2 studies

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Antidepressants Discontinuance Due to ADR

FDA ALERT (12/12/2007) — Dangerously or even fatal skin reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis), that can be caused by carbamazepine therapy, are significantly more common in patients with a particular human leukocyte antigen (HLA) allele, HLA-B*1502. The risk appears almost exclusively in patients with specific HLA alleles seen more often in some Asian populations, including South, East, and Southeast Asia. Patients at risk include those with the HLA-B*1502 allele present before starting treatment with carbamazepine. If they test positive, carbamazepine should not be started unless the expected benefit clearly outweighs the increased risk of serious skin reactions. Patients who have been taking carbamazepine for more than a few months without developing skin reactions are at low risk of these events even developing from carbamazepine. This is true for patients of any ethnicity or phenotype, including patients positive for HLA-B*1502. This new safety information will be reflected in updated product labeling. More information

8% INDIA
5 to 20% 14%
18% 1%
12 to 15% 5 to 12%
10% 36%
<1% <1%
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Antipsychotics Utilization Patterns and Genotype

No clinically relevant predictor of efficacy to-date

Ethnicity and Antipsychotic Therapy

- Lin and Finder observations
  - Mean max. antipsychotic dose (converted to chlorpromazine equivalent units): 849 mg/d in Asians vs. 2061 mg/d in Caucasians (p < 0.05)
  - Mean stabilized dose: 652 mg/d in Asians vs. 1456 mg/d in Caucasians
  - Patients all matched for age, diagnosis, duration of illness, past antipsychotic usage

Polymorphism and Haloperidol Therapy

- Mean dosage in Chinese patients < Caucasians
- PKs and PDs after po and IM

<table>
<thead>
<tr>
<th></th>
<th>Chinese</th>
<th>Foreign born</th>
<th>US born</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO Cmax</td>
<td>1.4 ng/ml</td>
<td>1.2</td>
<td>0.8</td>
</tr>
<tr>
<td>IM Cmax</td>
<td>2.0 ng/ml</td>
<td>1.6</td>
<td>1.2</td>
</tr>
</tbody>
</table>

- Most likely genetic / metabolic differences
- ↑ sensitivity to haloperidol in Chinese

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RHHL Ratio in Different Ethnic Groups
A determinant of therapeutic response to haloperidol

<table>
<thead>
<tr>
<th>Low ratio</th>
<th>High ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chinese</td>
<td>0.20 ± 0.01</td>
</tr>
<tr>
<td>(n=60)</td>
<td>(n=20)</td>
</tr>
<tr>
<td>Mexican Am.</td>
<td>0.46 ± 0.03</td>
</tr>
<tr>
<td>(n=36)</td>
<td>(n=27)</td>
</tr>
<tr>
<td>Blacks</td>
<td>0.33 ± 0.03</td>
</tr>
<tr>
<td>(n=16)</td>
<td>(n=23)</td>
</tr>
<tr>
<td>Caucasians</td>
<td>0.36 ± 0.03</td>
</tr>
<tr>
<td>(n=28)</td>
<td>(n=38)</td>
</tr>
</tbody>
</table>

↓ 2D6-mediated elimination related to ↓ metabolic capacity


Ethnicity and Antipsychotics

Asians: ↑ Cp of typical antipsychotics, ↑EPS
- Atypicals better? Few comparative data
- African Americans reported to be more sensitive to antipsychotic medications
Psychopharmacol Bull 1991;27:441-8

↑ risk of tardive dyskinesia (in African Americans)
- Higher antipsychotic dose
- Longer treatment duration
Arch Gen Psychiatry 1993;50:723-33

Hispanics    Asians    Caucasians
Mean CPZ eq. dose 211 mg 212 mg 339 mg
Movement disorder 4% 4% 1.6%
Antiparkinsonian Rx 42% 88% 52%

Ethnopharmacology and Pharmacogenetics

Ethnic Variations of CYP2D6 and CYP2C19
Metabolic Phenotypes (Approximated Frequencies, %)

<table>
<thead>
<tr>
<th>Phenotypes</th>
<th>Caucasians</th>
<th>East Asians</th>
<th>African Americans</th>
<th>North Africa &amp; Middle East</th>
<th>Mexican Americans</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYP2D6 PM</td>
<td>5 to 10</td>
<td>0 to 1</td>
<td>1 to 2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>IM</td>
<td>1 to 10</td>
<td>0.2</td>
<td>2</td>
<td>10 to 29</td>
<td>1</td>
</tr>
<tr>
<td>CYP2C19 PM</td>
<td>2 to 4</td>
<td>10 to 25</td>
<td>1 to 5</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>PM for both</td>
<td>0.1 – 0.4</td>
<td>0.1 – 0.25</td>
<td>0.01 – 0.1</td>
<td>0.04</td>
<td>0.12</td>
</tr>
</tbody>
</table>

Diversity Within Ethnic Groups

- Chinese (55 minorities in different regions)
  - CYP2C19 overall PM% = 20%
  - 20% PM in Han (n=101) vs. 13% in Bai (n=202)
  - CYP2D6 overall PM% = 1%
  - Zang (1.8%), Han (1.1%), Mongolian (0.6%), Wei (0.7%)

- Ethnic heterogeneity in Africa
  - 0 - 19% CYP2D6 PM in African populations
  - 0-4 % in West, central and southern Africans

Implications of ethnic heterogeneity

- Whites
  - Caucasians
  - Non-Hispanic Whites
- Blacks
  - Africans
  - Jamaicans
- Hispanics
  - Mexicans
  - Cubans
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Response to Medications

- Pharmacokinetics and pharmacodynamics
  - Individual PM treated with high doses → ↑ S/Es, noncompliance
  - Ethnic variations in PM and IM prevalence
  - Japanese regulatory agency insists on PK data in Japanese
- Ethnicity and pharmacology
  - Homogenous drug therapy NOT ideal for heterogeneous populations

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Why Does Culture Matter?

- Sets of beliefs, norms, values, meanings
- Influences actions and expectations
  - Symptom expression (what, how, meanings)
  - Health-seeking behavior
  - When, how and from whom the medical support is sought
- Impacts perception and expectation of others
  - Communication and understanding of health information
  - Reaction to recommendation for lifestyle changes and treatments
- Influences therapeutic outcome, herbal use

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By 2050 cultural minorities may account for as much as 90% of the population growth in the U.S.

<table>
<thead>
<tr>
<th>Race or ethnic group in Texas</th>
<th>2000</th>
<th>2008</th>
<th>Growth</th>
<th>% increase</th>
<th>% growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>2,349,641</td>
<td>2,748,323</td>
<td>398,682</td>
<td>17.0</td>
<td>11.5</td>
</tr>
<tr>
<td>Anglo</td>
<td>10,927,538</td>
<td>11,525,623</td>
<td>598,085</td>
<td>5.5</td>
<td>17.2</td>
</tr>
<tr>
<td>Latino</td>
<td>8,670,122</td>
<td>8,870,475</td>
<td>200,353</td>
<td>33.0</td>
<td>63.3</td>
</tr>
<tr>
<td>Asian</td>
<td>549,054</td>
<td>810,967</td>
<td>261,913</td>
<td>47.7</td>
<td>7.5</td>
</tr>
<tr>
<td>Other/Two</td>
<td>355,465</td>
<td>371,586</td>
<td>16,121</td>
<td>4.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Total</td>
<td>20,853,820</td>
<td>24,328,982</td>
<td>3,475,154</td>
<td>16.7</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Source: U.S. Census Bureau, 2000 and 2008
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Culture and Mental Health in Asian Americans

- Cross-cultural diagnosis - A challenge
  - Normal vs. abnormal behavior
  - Witchcraft and possession states misinterpreted as paranoid disorder
- Modes of presentation
  - Depression in clients from S.E. Asian countries likely present as somatic symptoms, e.g. lethargy, joint pains
  - Misinterpreted as reflection of language difficulties

Ethnic Diversity in Patient Care: Cultural Considerations for Asian Americans

- 75 Mien patients from Laos
  - HA (93%): generalized, worsened by excessive worry
  - Burning epigastric pain (89%)
  - Most refused invasive w/u, 3 documented PUD
  - Extremity pain (85%), chronic low back pain (81%)
  - Dizziness (71%), Negative w/u for vertigo
- Consider culture from which a patient derives
  - The mind AND the body
  - Profound stigmatization of mental illness
  - Presentation of somatic symptoms

Ethnic Diversity in Patient Care: Cultural Considerations for Asian Americans

- Depression + PTSD common in IndoChinese
  - No desire for hospitalization
  - No suicidal intention
  - Not socially acceptable
- Enlist help from family members (key decision makers) and friends
  - Defining nature and extent of problem
  - Counter-balance stigmatism
  - ↑ utilization
Ethnic Diversity in Patient Care:Cultural Considerations for Asian Americans

- Explain medical treatment and drug therapy
  - Incorporate the patient's own explanatory model of the illness
  - Social and religious factors vs. stress, psychological factors, life events
  - Culture-bound syndrome:
    - "Kh Pathfinder" in Cambodia: tendency to worry over past events, thinking too much
    - "Hwa-byung" in Koreans: suppressed anger syndrome
    - "Neurasthenia" in Chinese — exhaustion of CNS's energy reserve

Blood Levels of Imipramine + Desipramine

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>None</th>
<th>25 - 180 ng/ml</th>
<th>≥ 180 ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodian</td>
<td>39%</td>
<td>39%</td>
<td>22%</td>
</tr>
<tr>
<td>Vietnamese</td>
<td>81%</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Mien</td>
<td>75%</td>
<td>17%</td>
<td>8%</td>
</tr>
<tr>
<td>Total</td>
<td>61%</td>
<td>24%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Intolerance and ineffective communication hampered by saving face and desire to protect the doctor's honor.

Cultural and Pharmacological Considerations

- Explain drug therapy
  - Time for full benefit and need of daily dosing
  - Incorporate patient's response expectation
  - Southeast Asian patients may feel prescribed medication is too strong
  - Exemplary compliance
  - Western medicines are too strong!
    - Biological basis, food- or herb-drug interaction
  - Polypharmacy is a no no no concept
  - Educate, enhance trust and improve adherence
  - Symptoms, Rx therapeutic and side-effects, effects of herbs, diet
### Blood Levels of Imipramine + Desipramine

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>25 - 180 ng/ml</th>
<th>≥ 180 ng/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodian</td>
<td>22%</td>
<td>33%</td>
<td>44%</td>
</tr>
<tr>
<td>Vietnamese</td>
<td>27%</td>
<td>36%</td>
<td>36%</td>
</tr>
<tr>
<td>Mien</td>
<td>67%</td>
<td>25%</td>
<td>8%</td>
</tr>
<tr>
<td>Total</td>
<td>37%</td>
<td>34%</td>
<td>31%</td>
</tr>
</tbody>
</table>

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### The Case of CYP3A4 Inhibition

- Female patient with panic disorder <4 yr, alprazolam 4 mg/d.
- Developed depression, nefazodone Rx, tolerated combination. After 4 weeks, indicated sedation but “felt good.”
- After another 3 weeks, MVA due to oversedation.

Herbal medications (SJW’s) induction effect on CYP3A4 and/or P-gp.

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### Cultural Dietary Practices

- Grapefruit juice (↓ expression of CYP3A4 and P-glycoprotein)
  - Highest consumption in Eastern Asia, followed by Japan
  - Americas and European Union nations
- Cruciferous vegetables (cabbage, broccoli)
  - Precursor of a P-glycoprotein inhibitor
  - Koreans – world’s largest cabbage consumer
    - Kimchi (fermented, spicy cabbage dish)

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Cultural Heterogeneity
Within “Asian Americans”

- Mien vs. Hmong (Laotian immigrants)
  - Sensitive to TCA S/Es
  - Better success with
    - fluoxetine (78%)
    - bupropion (15%)
- Single ethnic definition masks variations
  - Social customs
  - Culture
  - Language

Cultural competency
is NOT
the same as
Speaking the language
or
Having an interpreter

Culturally sensitive psychiatric care
What are the necessary elements?
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Knowledge and skills AND Attitudes (awareness, respect, desire)

Communication
Institutional Staff
Family Involvement
Education
Advocacy Groups

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Culturally Sensitive Psychiatric Care

♦ Communication
  - Interview with interpreters or staff with relevant language skills
    - Bilingual patients tend to gravitate towards native language
    - Especially important during hospitalization and discharge
  - Treat patients with respect
  - Encourage patients to explain their viewpoints and vice versa

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Culturally Sensitive Psychiatric Care
What Are the Necessary Elements?

♦ Institutional bilingual staff
  - Staff ratio reflective of local ethnic needs
  - Trained in cross-cultural health care delivery
  - Understand issues of ethnicity and stigma related to mental health
  - Aware of cultural norms and religious beliefs, traditional healing methods
  - Attempt to understand different explanatory models of mental health problems
  - Encourage family involvement
    - ↑ acceptance, coping, ↓ length of stay

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Culturally Sensitive Psychiatric Care
What Are the Necessary Elements?

- Mental health education
  - Western concept of mental health and treatments
- Advocacy groups
  - Available at local level for patient support
  - Consulted and involved in developing and delivering service
- Flexible, patient-oriented treatment packages
  - Home environment vs. inpatient ward setting

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Culturally Sensitive Psychiatric Care
What Are the Necessary Elements?

Develop services according to the needs, and not just based on clinical diagnosis.

Ideally identify the needs of the local community before setting up services. Modify existing services with regular feedback.

Understand local explanatory models of illness and local epidemiological data of various illness to help prioritize and provide appropriate service.

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Culture, Ethnicity, Mental Health Management

- No single model can account for the interplay among social, environmental, and biological factors that determine the nature and extent of mental illness
  - Patient's interpretation of illness "shapes" the illness, the symptoms, and care-seeking behavior
    - Variable among different ethnic groups with diverse cultural backgrounds
  - Likewise, the same factors can affect medication compliance, use of herbal medicine, therapeutic response

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Ethnicity and Pharmacology

Homogeneous health care and drug therapy
NOT ideal for heterogeneous populations

Ethnicity and Culture

Cultural Genotypes
- Shared values
- Norms
- Beliefs

Cultural Phenotypes
- Language
- Practice
- Presentation

Client care
Health work environment