

# APPLICATIONS, ISSUES, AND EXAMPLES OF RESEARCH METHODS IN CLINICAL PSYCHOLOGY, PSYCHIATRY, AND THE MENTAL HEALTH PROFESSIONS

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# **1. ISSUES IN THE WORLD OF PSYCHIATRY**

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## **1.1. ISSUES IN THE HISTORY OF PSYCHIATRY**

Engstrom (2006) believed that the history of psychiatry had a "strong presentist orientation, that is to say, its narratives have tended to be framed from the perspective of today, not yesterday" (p595). Berrios (2004) talked of the "meta-space" which included the assumptions about the research in psychiatry ("research on research").

Psychiatry is not the same as other fields of medicine:

Physical abnormalities may be easy to see, and following the growth of laboratory science, many biochemical abnormalities are easy to measure. But diseases of the mind generally defy such "objective" assessments, while the point at which a behaviour becomes a morbidity may be hard to define (Berrios 2004 p33).

There are a number of contested areas in psychiatry and its history (Engstrom 2006):

i) Asylums (psychiatric institutions) as places of social control or protection and care.

The view of psychiatric institutions depends very much on which side of the fence (locked door?) an individual finds themselves. Jane Hedworth (2004) quoted from her own diary of April 2002 while being sectioned (detention without consent): "I managed to get my mobile today but they confiscated it in the middle of the night just as I was trying to phone my brother.. As usual they got quite nasty when I refused to take drugs" (p25).

Foucault (1965) has been most prominent in criticising mental institutions and asylums as not getting better over the last few centuries, but, in fact, getting worse in terms of social control.

Related to this is the attitude of family towards their deviant members. Were families quick to remove such members to institutions to hide them away or dump them as

unwanted? Work on Dutch asylums in the first half of the twentieth century has shown that there was interaction between families and institutions (Vijselaar 2005), and "that asylum walls" were in fact rather low and permeable" (Engstrom 2006).

ii) The power of psychiatry.

The idea that psychiatrists have a great deal of power to label and control is being challenged: "Increasingly.. sociological perspectives on the history of psychiatry are being written in relational terms as contests of jurisdiction between competing medical subdisciplines, service providers, regulatory agencies, third party payers, patient interest groups, and families" (Engstrom 2006 p597). In fact, now there are many "psy-experts" (Neve 2004).

iii) The place of psychoanalysis.

Did traditional psychoanalysis carry psychiatry in the early part of the twentieth century and aid in the first classification systems, or did it stop "real" (biological) psychiatry?

In Britain, for example, psychotherapy was viewed by psychiatrists as inadequate for long-term chronically ill patients in institutions. While, in Germany, it was seen more positively and "was built on the opportunities provided by the shameful of the bio-medical and social psychiatric past" (Neve 2004 p408) (ie: the use by National Socialism and Nazism).

Engstrom (2006) noted the "Freud Wars of the 1990s" within psychoanalysis which argued about the place of Sigmund Freud (raise a monument to him or smash it down).

iv) The development of classification systems.

This is related to the above issue, particularly in the major change that came in DSM-III (APA 1980). For many, this was the escape at last from the dominance of psychoanalysis in diagnosis and the terminology of psychiatry.

The Task Force within the American Psychiatric Association that produced DSM-III had, for the first time, a predominance of biological psychiatrists over psychoanalysts. The biological psychiatrists encouraged the field trials of the new categories before publication. Between 1977 and 1979, 500 psychiatrists were involved.

Gaines (1992) felt that a major change has occurred:

In terms of diagnosis, the identification of symptoms is transformed from an interpretation of symbols of distress into a reading of signs of disease. No longer would clinicians gaze upon symptoms as symbols of psychosocial, intrapsychic conflicts... (p9).

Mayes and Horwitz (2005) described the history of DSM-III in the context of conflicts between research psychiatrists, psychoanalysts, psychologists, and other parties like State regulatory agencies and medical insurance companies.

#### v) Treatments.

The second half of the twentieth century saw the development of the major treatment used by psychiatrists, namely psychoactive drugs. As well as their treatment benefits, such drugs have "cyclical career paths" (Pieters and Snelders 2005). Put simply, they are "medical commodities subject to the push and pull of market forces and patient demand" (Engstrom 2006 pp597-8).

David Healy, among his many criticisms of the pharmaceutical industry, has shown this path in the history of one particular antidepressant in "Let Them Eat Prozac" (Healy 2004) emphasising the power of these companies to "colonize the consciousness of citizens" among others.

An aspect of this process is "disease-mongering". Payer (1992) defined "disease mongering" as "trying to convince essentially well people that they are sick or slightly sick people that they are very ill". Payer listed ten strategies involved including "Taking a normal function and implying that there's something wrong with it and it should be treated" (p88), and "Taking a common symptom that could mean anything and making it sound as if it is a sign of a serious disease" (p98).

## 1.2. PARADIGMS AND APPROACHES

A paradigm (Kuhn 1962) <sup>1</sup> is a common set of assumptions within a discipline that direct how the world is viewed and tested. It attempts to bring together different theories, and specific observations and hypotheses in a discipline.

Ghaemi (2006) listed a number of the key issues that

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<sup>1</sup> A paradigm attracts "adherents away from competing modes of scientific activity" and is "sufficiently open-ended to leave all sorts of problems for the redefined group of practitioners to resolve" (Kuhn 1970 p10).

a paradigm in psychiatry must cover including:

- The nature of mental illness
- The structure of the mind
- The relationship of the mind to the brain
- The relationship of mental illness to physical illness
- The relationship of mental illness to society
- The nature of mental states and psychological concepts
- Definitions of specific mental pathologies
- The cause of those pathologies
- The course of those pathologies
- Treatments for those pathologies (p619).

These issues can be reduced to the most important questions of what is mental illness (if that term is used), what causes it, and how to treat it?

Historically, a number of approaches (paradigms) have appeared to answer these questions in psychiatry.

## 1. Medical Model

This is the dominant model in psychiatry, and is sometimes known as the biomedical model or the biological paradigm. The language and concepts of physical illness are applied to understanding mental illness.

Pincus et al (1993) found an increase in interest in, what they call, "clinical psychobiology" between 1970 and 1990 based upon an analysis of two psychiatric journals.

Moncrieff and Crawford (2001) argued that biological psychiatry is, in fact, not a new development but a "continuation of a long-standing inclination". They performed content analysis of the "British Journal of Psychiatry" over the twentieth century to highlight the concerns of British psychiatry. The study revealed that "there has been a continuous fascination with biological explanations for psychiatric disorders. Other systems of understanding and methods of treatment such as psychoanalysis and social psychiatry have generally received little attention" (p356) throughout the twentieth century.

A recent variation upon this approach is Darwinian (or evolutionary) psychiatry (McGuire and Troisi 1998; Stevens and Price 1996). Behaviour is viewed in the context of the "evolutionary environment of adaptation" (EEA) (Cartwright 2000) ie where humans first evolved. Thus it is possible that certain behaviour was adaptive then, but it is not so today being classed as pathological.

Nesse and Williams (1996) see the evolution of depression as a means to stop early humans from doing certain behaviours, and thereby increase their survival:

a) Low mood during bad weather discourages going out. The "if there is little chance of a payoff, it is best to sit tight rather than waste energy" strategy.

b) Depression at loss encourages the subordinate in a fight to withdraw without any further damage - a form of "damage limitation". Stevens and Price calls this the "rank theory of depression".

Under Popper's (1959) idea of refutation, evolutionary theory does not do well. Good science involves making predictions that can be disproved rather than fitted after the fact (Brewer 2003).

## 2. Biopsychosocial Model

Though the medical model dominates psychiatry, contemporary Western psychiatry is more pragmatic (Ghaemi 2006), and the biopsychosocial (BPS) model (Grinker 1969, 1976; Engel 1977, 1980) can be seen as the main paradigm. This focuses upon the interaction between the medical and the environment. For example, an individual inherits the potential traits of a mental disorder, but this may not show itself unless there is a certain amount or type of environmental stress.

This approach attempts to escape the reductionism of the medical model, and does allow for non-physical treatments, like therapy. Furthermore, psychosocial causes are viewed as important as the biological basis (Abbot and Spence 2006).

## 3. Psychoanalysis/Psychodynamics

Much of the early history of classification systems for mental disorders (DSMs in particular) were dominated by the principles of psychoanalysis. The key is this approach, whether it be Freud (psychoanalysis) or post-Freudians (psychodynamics), are early experiences, and the subsequent role of the unconscious throughout life.

## 4. Reactions Against Traditional Psychiatry

In the 1960s, most particularly, "anti-psychiatry" developed (eg: Laing 1969; Szasz 1970) as critics of the power and misuse of medical psychiatry.

Modern reactions against traditional psychiatry tend not to completely reject mental illness as did Thomas

Szasz in "The Myth of Mental Illness" (1962), rather to be critical of the role of pharmaceutical companies, for example, in "corporate psychiatry" (eg: Healy 2006) and "neo-liberalism" (Moncrieff 2006).

Market forces are viewed as the correct way to control everything, even the health service, and the consequent profits for private companies as normal. "Therefore the guilt that would normally arise from excessive consumption or profiteering is suppressed" (Moncrieff 2006 p301).

The phrase "postpsychiatry" (Bracken and Thomas 2001) has appeared among critical psychiatries. This approach "argues that the voices of service users and survivors should be centre stage" (p707), and:

- Emphasises social and cultural contexts;
- Puts ethics above techniques;
- Minimises medical control of coercive interventions.

From the patient viewpoint, the recovery movement" and "survivors groups" have developed.

## 5. Combination of approaches

The idea that one approach has all the answers (dogmatism) has declined in psychology and psychiatry in the last quarter of a century. An interest in using "what works" to help patients irrelevant of the philosophical origins (pragmatism, eclecticism, integrationism, pluralism). Each of these terms can mean something slightly different.

Recent examples of integrationism included Kandel (1998), who emphasises the two-way relationship between brain and environment (from his work of many years on conditioning in aplysia), and "neuropsychanalysis" (combination of neuroscience and psychoanalysis, and moves away from Freud's distinction between mind and brain)(Whitehead 2005).

Pluralism is more the idea of different approaches for different situations in a "pick and choose from a menu" sort of way. For example, schizophrenia is treated by the medical model, while depression among individuals living in poverty is better addressed by a social or political approach to mental illness. Pluralism requires being "flexible about methods in general" (Ghaemi 2006).

Unfortunately, these types of approaches can be "excessively loose, seeking to combine methods used on individual whims and preferences" (Ghaemi 2006).



Table 1.1 summarises the main approaches in psychiatry on the key issues of the cause and treatment of mental illness.

<u>APPROACH</u>	<u>CAUSES OF MENTAL PROBLEMS</u>	<u>TREATMENT OF MENTAL PROBLEMS</u>
Medical model	Physical; eg: genes, neurochemistry	Physical; eg: drugs
Biopsychosocial model	Combination of physical and environment	Physical and therapy
Psychoanalysis	Unresolved issues in unconscious mind, usually from early childhood	Analysis
Critical psychiatries	Political and social explanations	Dealing with social and political issues; eg: homelessness
Combination	Depends/multiple	Choose as appropriate

Table 1.1 - Five approaches and causes and treatment of mental illness.

### 1.3. DIAGNOSIS ISSUES

The diagnosis of a mental disorder is made from the overt symptoms shown. The combination of symptoms that make up a particular mental disorder are listed in classification systems like DSM-IV (APA 1994). As with any measuring instrument in psychology and psychiatry, there are concerns about reliability and validity (table 1.2)(Brewer 2001).

Debates exist within psychiatry about the diagnosis process. These include the case of "new" disorders that appear, and how they relate to already existing ones. van Staden (2006) took the example of undifferentiated somatoform disorder (USD)<sup>2</sup> and the new disorder, chronic fatigue syndrome (CFS).

In DSM-IV (APA 1994), USD is characterised by one or more physical problems where no known medical condition exists, or, where there is a medical condition, the physical problems are in excess of what is expected. It must last for at least six months (table 1.3).

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<sup>2</sup> USD was introduced into DSM-III-R (APA 1987) "based on the concern that the high symptom count then required for Somatization Disorder would result in inadequate coverage for many individuals who present with clinically significant somatoform complaints" (First et al 2004 p271).

RELIABILITY	Consistency of diagnosis of mental disorder from same symptoms over time (test-retest reliability) or between psychiatrists (inter-judge reliability).
VALIDITY	Combination of symptoms accurately reflects an underlying illness or reality. This is established through historical antecedents (the cause is the same for all sufferers)(aetiological validity), common characteristics among sufferers of the same disorder (concurrent validity) but differences between sub-categories of the disorder (descriptive validity), and prediction of future outcomes of the illness (predictive validity). Face validity is where the categories fit well with clinical experience (Gelder et al 2001).

Table 1.2 - Reliability and validity of classification systems for mental disorders.

But such characteristics could also be symptoms of depression and anxiety, where somatization occurs. The psychological distress is "converted" into physical complaints. Henningsen et al (2005) reported a high level of overlap between USD and depression and anxiety in cases studied (as much as 80%). In other words, the same symptoms could be diagnosed in different ways depending upon the psychiatrist. This is a question of reliability.

CFS is not included in DSM-IV <sup>3</sup>, but an "official" definition comes from the US Centers for Disease Control and Prevention in 1994. The persistence or relapse of unexplained chronic fatigue for at least six months, not alleviated by rest, and showing at least four of the following: impaired memory or concentration, sore throat, tender cervical or axillary lymph nodes, muscle pain, pain in several joints, headaches, poor quality sleep, and tiredness after exertion (van Staden 2006).

Both conditions are situated in a difficult area for the medical profession, particularly in relation to the key symptom of fatigue. As to "whether the fatigue is mental or physical, 'functional' or 'organic', real or unreal, and even whether the patient is really ill" (van Staden 2006 p615).

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<sup>3</sup> CFS can be coded as "neurasthenia" in ICD-10 (WHO 1992) (Gelder et al 2001).

A. One or more physical complaints (eg: fatigue, loss of appetite, gastrointestinal or urinary complaints).
B. Either (1) or (2):  (1) After appropriate investigation, the symptoms cannot be fully explained by a known general medical condition or the direct effects of a substance (eg a drug of abuse, a medication);  (2) When there is a related general medical condition, the physical complaints or resulting social or occupational impairment is in excess of what would be expected from the history, physical environment, or laboratory findings.
C. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
D. The duration of the disturbance is at least six months.
E. The disturbance is not better accounted for by another mental disorder (eg: another Somatoform Disorder, Sexual Dysfunction, Mood Disorder, Anxiety Disorder, Sleep Disorder, or Psychotic Disorder).
F. The symptom is not intentionally produced or feigned (as in Factitious Disorder or Malingering).

Table 1.3 - Symptoms of USD in DSM-IV-TR (APA 2000 p492).

USD can be assumed by the medical profession as imagined physical problems caused by the mind. But this appears to belittle the reality of the experience.

While individuals with CFS can emphasise their fatigue as physical, and not caused or related to the mind ("mindless fatigue" van Staden 2006), including preferring the label "ME" (myalgic encephalomyelitis) (Ong et al 2005).

A CFS sufferer, Daphne Evans, reported her frustration at being labelled "psychological problem" when "so many parts of my body were malfunctioning. I was angry and frightened at symptoms being dismissed, like people saying 'pull yourself together' and 'there is nothing the matter with you'" (Ong et al 2005 p649).

van Staden (2006) talked of a reductionism in the medical profession that needs to see fatigue as only mental or as only physical. Patients with CFS do not want their fatigue to be the mental kind because, sadly, it will be dismissed, if not by the medical profession, by society as shown by the phrase "yuppie flu" used in the media. Furthermore, there is a desire to avoid the stigma of mental illness. So individuals with fatigue symptoms

sent to psychiatrists feel dismissed (Lamberg 2005).

Of course, if a condition is physical it does not mean that it is not psychological: "many psychiatric disorders have physical aetiological factors and the mere presence thereof does not render the condition non-psychiatric/mental" (van Staden 2006 p616).

While there are also medical conditions, like idiopathic hypertension, which are accepted although the exact physical cause is unknown. But not fatigue here. So both individuals and the medical profession are making sense of reported/experienced symptoms in a social context.

Sufferer and medical professional need to negotiate a shared narrative in order to help the former: "I've learnt a lot about ME, and Andrew [GP] has taught me about managing chronic illness - and I've taught him all I know about the disease" (Daphne Evans in Ong et al 2005 p649).

CFS is more popular in diagnosis because USD suggests that the physical symptoms are made up, or at least a sign of mental weakness, and who wants that. The need is to take the psychological seriously. Biological psychiatry, seeking physical explanations for all mental disorders, does not help here.

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## **2. ISSUES IN CLINICAL TRIALS: EXAMPLE OF PHARMACEUTICAL TREATMENTS FOR NON-ALZHEIMER DEMENTIAS**

- 2.1. Introduction
- 2.2. Example of a Clinical Trial
- 2.3. Issues
- 2.4. Conclusion
- 2.5. References

### **2.1. INTRODUCTION**

Clinical trials are used to assess the efficacy <sup>4</sup> of treatment by comparison with no treatment or a placebo group. They use scientific principles based around the experimental method which emphasise control of the variables and replicability.

The National Institutes of Health in the USA distinguished four types of clinical trial, each with a different focus (<http://clinicaltrials.gov>; accessed 11/12/07). The first three types are usually before the drug is made publicly available or marketed:

- Phase I trials - First study of the drug on a small number of people (20-80) to identify dosage range and side effects;
- Phase II trials - Larger study (100-300 people) to test effectiveness of the drug;
- Phase III trials - Full scale study of the drug (1000-3000 people);
- Phase IV trials - Post marketing study to confirm previous information about the drug.

Matthews (2000) listed five biases with clinical trials:

i) Selection bias - selecting patients for particular groups rather than randomly allocating them to treatment or not;

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<sup>4</sup> Efficacy and effectiveness can be interchangeable. However, Truax and Thomas (2003) saw them as distinct: efficacy research emphasises control and effectiveness research is concerned with generalisability ("how well does this treatment work in the real world?").

Efficacy of the drug means the outcomes under ideal conditions, while effectiveness is how well it works under practice conditions (Zito and Provenzano 1995). The former involves controlled environments, and compliant and homogeneous patients. For the latter, it can be the complete opposite.

ii) Allocation bias - random allocation to groups could produce groups that are not comparable in terms of pre-study characteristics (eg: severity of disorder);

iii) Assessment bias - open trials that use measures with elements of subjectivity;

iv) Publication bias - tendency to publish positive findings only;

v) Stopping rules - not having a clear date to stop the study (ie: keeping going until have results wanted).

This article highlights a number of issues involved in clinical trials and draws examples from the assessment of drugs <sup>5</sup> for non-Alzheimer's dementias (eg: vascular dementia) <sup>6</sup>.

## **2.2. EXAMPLE OF A CLINICAL TRIAL**

de Tommaso et al (2004)

Twenty-one patients known to have genetically confirmed Huntington's disease <sup>7</sup>, who were outpatients at the neurological clinic of the University of Bari, Italy, were divided into two groups. Two patients were allocated to the treatment group to receive rivastigmine for eight months (on top of existing drugs) to every one in the control group. Patients with cardiovascular and general medical diseases were excluded.

Baseline measures of cognitive impairment were taken using the Mini-Mental State Examination (MMSE) as well as measures of movement problems, and then every two months during the study. The examiners were blind to the treatment, though this was an open-label study.

Four patients did not finish the study, of which one was from the control group.

This is a typical clinical trial for this area of study with strengths and weaknesses (table 2.1).

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<sup>5</sup> Donepezil (trade name "Aricept"), rivastigmine ("Exelon" in the USA, "Prometax" in the UK), and galantamine ("Reminyl") are cholinesterase inhibitors (ChEIs) which inhibit the breakdown of the neurotransmitter, Acetylcholine (Ach) (ie increase amount of Ach available).

<sup>6</sup> Vascular dementia is a general name for a number of forms of dementia after cerebrovascular disease (stroke).

<sup>7</sup> Huntington's disease is a genetic disease characterised by involuntary movements and neurodegeneration including attention deficits, loss of concentration, and memory failure (de Tommaso et al 2004).



<u>STRENGTHS</u>	<u>WEAKNESSES</u>
<p>1. Patients from same clinic, so no problem of differences in procedure as in multi-centre studies.</p> <p>2. Reasonable length of the study - 8 months.</p> <p>3. Similarity of demographic characteristics of two groups - age (53.0 years for treatment group vs 53.8 years), disease duration (8.9 vs 7.4 years), and age of onset (45.5 vs 46.4 years).</p> <p>4. Examiners blind to treatment or control.</p> <p>5. Genetically confirmed Huntington's disease.</p>	<p>1. Open-label meant that patients knew which group they belonged (ie: no placebo in control group, simply not given drug).</p> <p>2. Small sample size.</p> <p>3. Drop-out was large with such a small sample (19%).</p> <p>4. More females (9) than males (3) in treatment group.</p> <p>5. Rivastigmine given as well as other drugs that varied between individuals: eg: five patients had pimozide, two had risperidone; eleven members of the treatment group were taking three or more other drugs.</p>

Table 2.1 - Strengths and weaknesses of de Tommaso et al (2004) study <sup>8</sup>.

### 2.3. ISSUES

#### 1. Length of study.

How long should the study be? Less than three months, for example, or longer than six months? There will be issues in either case (table 2.2).

A brain scan technique known as magnetic resonance spectroscopy (MRS) has shown that it takes six months of steady use of fluoxetine (anti-depressant) to reach the maximum concentration in the brain. This is twenty times the serum concentration (level in blood) which is the usual measure of the drug in the body (Sadock and Sadock 2003).

The Donepezil 307 Vascular Dementia Study group (Black et al 2003) trial lasted twenty-four weeks which is a common length for clinical studies of this type.

Measures were taken at baseline, 6, 12, 18, and 24 weeks. There is a question of how often to take measurements from the patients (table 2.3).

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<sup>8</sup> Pimozide and risperidone are antipsychotic drugs.

<u>SHORT CLINICAL TRIALS</u> eg: 10 weeks or less	<u>LONG CLINICAL TRIALS</u> eg: 6 months or more
<p>STRENGTHS</p> <ol style="list-style-type: none"> <li>1. Relatively quick results.</li> <li>2. Easier to control.</li> <li>3. Less fear of drop-out through death.</li> </ol> <p>WEAKNESSES</p> <ol style="list-style-type: none"> <li>1. Little time for full effect of the drug in the body to be assessed.</li> <li>2. No assessment of long-term effects.</li> <li>3. Can have feeling of being rushed.</li> </ol>	<p>STRENGTHS</p> <ol style="list-style-type: none"> <li>1. Able to see long-term effects of drugs.</li> <li>2. Able to study progress of patients as well over time.</li> <li>3. Allows for full crossover design including washout period.</li> </ol> <p>WEAKNESSES</p> <ol style="list-style-type: none"> <li>1. Expensive and time-consuming.</li> <li>2. Risk of drop-out from death.</li> <li>3. Non-compliance could decline with time, particularly if patients feel there are no improvements with the drug.</li> </ol>

Table 2.2 - Strengths and weaknesses of short and long clinical trials.

## 2. Length of follow-up.

As well as the length of the study, there is the length of the follow-up time after the study. This is the time between the study ending (ie: treatment stops) and the next measurement taken. It could be weeks or years (table 2.4).

For example, the Prospective Study of Pravastatin<sup>9</sup> in the Elderly at Risk (PROSPER) (Shepherd et al 2002) had a mean follow-up of 3.2 years (range 2.8 - 4.0 years) for risk of vascular dementia in a group of 70 year-olds. But, with older adults, the longer the follow-up time, the greater the chance of drop-out through death. This limits any studies, unless death is a measurement being used.

The longer the study, the greater risk also of losing contact with patients; eg: eight patients moved and were lost during a 24-week study (Black et al 2003).

## 3. Type of participants.

This relates to who is recruited by the researchers:

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<sup>9</sup> Pravastatin is used to reduce cholesterol levels.

<u>FREQUENT MEASURES</u> eg: weekly	<u>INFREQUENT MEASURES</u> eg: monthly
<p>STRENGTHS</p> <ol style="list-style-type: none"> <li>1. Regular progress of patients.</li> <li>2. Spot any short-term changes.</li> <li>3. Make patients feel part of something and motivated to comply.</li> </ol> <p>WEAKNESSES</p> <ol style="list-style-type: none"> <li>1. Expensive and time-consuming.</li> <li>2. Difficult for patients; eg: travelling to clinic regularly.</li> <li>3. Reaction of patients to being studied so often.</li> </ol>	<p>STRENGTHS</p> <ol style="list-style-type: none"> <li>1. Less expensive.</li> <li>2. Able to see longer term patterns, particularly in long-term studies.</li> <li>3. Not overwhelmed by too much data.</li> </ol> <p>WEAKNESSES</p> <ol style="list-style-type: none"> <li>1. Misses short-term changes.</li> <li>2. Patients may feel forgotten if not contacted regularly, and possible increased risk of non-compliance.</li> <li>3. Staff may change between check-ups and this could confuse patients.</li> </ol>

Table 2.3 - Strengths and weaknesses of frequent and infrequent measures of behaviour.

<u>STRENGTHS</u>	<u>WEAKNESSES</u>
<ol style="list-style-type: none"> <li>1. Able to see long-term benefits of treatment.</li> <li>2. Able to check for long-term problems from treatment.</li> <li>3. Can see what happens after treatment withdrawn and how disease progresses.</li> </ol>	<ol style="list-style-type: none"> <li>1. Greater chance of loss of participants through death.</li> <li>2. Risk of losing contact as participants move.</li> <li>3. May involve different staff if follow-up is very long time after study.</li> </ol>

Table 2.4 - Strengths and weaknesses of long-term follow-ups.

same or different disease, and severity of disease.

Many studies prefer mild or moderate sufferers because they are easier to handle, and it is felt that there is a better chance of gaining positive results than with severe cases (table 2.5). Malouf and Birks (2004), concluded their review of the efficacy of donepezil for vascular dementia, with the plea to test the drug with patients in the advanced stages of the condition.

<u>STRENGTHS</u>	<u>WEAKNESSES</u>
1. Better chance of gaining positive results because less likely to have complications. 2. Easier to handle as, for example, outpatients. 3. Can use in short-term studies. 4. Able to give full informed consent themselves rather than from relatives.	1. Ignores severe sufferers. 2. Some drugs may work better with severe cases. 3. Severe sufferers may be inpatients and thus in more controllable environment. 4. Mild sufferers may be highly motivated to improve and so the benefits of the drugs cannot be isolated from other factors, like diet and exercise.

Table 2.5 - Strengths and weaknesses of using mild sufferers of the disease.

4. Side effects and drop-outs.

All drugs have side effects, the question is whether they are so adverse as to cause drop-out from the study. In assessing this problem, two concepts are used (Brewer 2003):

- Therapeutic index - Difference between the concentration of the drug that produces the desired effects and the concentration that produces adverse effects;
- Therapeutic range - Difference between "minimum useful effect" (where dosage of drug first has a positive effect) and the "maximum tolerated effect" (where side-effects become greater than the positive effects).

Black et al (2003) reported 67 drop-outs due to "adverse event" on donepezil (table 2.6).

How to assess the death rate in studies - as a severe side effect?

During a phase III twenty-four week clinical trial of a type of donepezil, Eisai Co Ltd recorded a death rate of eleven of 650 patients with vascular dementia in the treatment condition and zero out of 326 in the placebo group (reported in Arlt and Jahn 2006). That death rate of 1.7% for the treatment group is unexpectedly high, is it a side effect of the drug? When working with older adults with health problems, the risks of death are higher than in other clinical trials with younger adults.

<u>REASON</u>	<u>TREATMENT GROUP</u>	<u>CONTROL GROUP</u>
Adverse event	67	22
Patient or carer request, withdrew consent	14	4
Protocol violation	2	1
Medicine non-compliance	2	-
Placed in nursing home	3	1
Lost, no longer available	7	2
TOTAL	95	30

Table 2.6 - Reasons for drop-out in Black et al (2003) study.

Arlt and Jahn (2006) felt that the "finding is likely an artefact, as the death rate in the placebo group is lower than one should expect, and in other trials an increased death rate was never observed" (p643).

##### 5. Inclusion and exclusion criteria for studies.

Ideally all participants should have the same condition (and the same level of severity) to make comparison between the treatment and placebo groups straightforward. But often studies have mixed groups because of convenience or availability of participants: eg Erkinjuntti et al (2002) had mixed dementia in their study of galantamine.

While a good example was the study by Moretti et al (2003) who concentrated on patients with a specific type of subcortical vascular dementia (small vessel disease)(n = 208) with rivastigmine over twelve months.

Black et al (2003) made the following exclusions from their study:

- Dementia other than vascular dementia
- MMSE score >26 and <10
- New stroke within 28 days before study began
- Major depressive disorder
- Pregnancy
- History of alcohol/drug abuse
- Known hypersensitivity to donepezil

The Vaspect study (an open-label trial of donepezil in vascular and mixed dementia) sponsored by Pfizer began recruiting in November 2007 with the following general criteria (<http://clinicaltrials.gov> accessed 11/12/07).

Inclusion - 50 years and older; DSM-IV-TR<sup>10</sup> criteria for vascular dementia or clinical diagnosis of "dementia due to multiple etiologies"; "a reliable caregiver or family member who agrees to accompany the subject to all scheduled visits, provide information about the subject as required".

Exclusion - Current primary diagnosis other than dementia of Alzheimer's type or vascular dementia.

## 6. Interaction of drugs.

Many patients are taking other drugs before and during the study, and it may not be possible to isolate the effects of the studied drug if there are interactions between the different drugs. Practically, however, it is not possible to get participants to stop taking other drugs during the study especially where there are health problems as well as the dementia.

## 7. Open versus blinded studies.

There is the problem of the knowledge of who is in the treatment or placebo group by the researchers or the participants. Knowing who is receiving the treatment introduces expectations (placebo effect) to the study. Researchers unconsciously response differently to those who are known to be taking the drug compared to the placebo, and patients themselves behave differently with that knowledge<sup>11</sup>.

This problem is addressed by the use of "blinding". In an "open" trial (or open-label), both researchers and participants know which group they belong to.

With "blind-at-randomisation", participants are divided into the conditions with no prior knowledge of the condition, but they may soon learn as the trial develops. For example, the presence of side effects with the drug condition, and not with the placebo condition.

"Single-blind" design is where the participants cannot tell which condition, but the researchers know.

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<sup>10</sup> DSM-IV-TR (APA 2000) is the diagnostic classification systems of mental disorders devised by the American Psychiatric Association.

<sup>11</sup> Generally the placebo effect accounts for some part of drug improvements; eg: 30-40% (Brown 1998).

But, best of all, is "double-blind" design, where neither the researcher nor the participants know which condition is which (Cohen and Posner 1995)(table 2.7).

<u>STRENGTHS</u>	<u>WEAKNESSES</u>
1. Removes any influence of researcher expectations. 2. Removes role of expectations by patients. 3. Most scientific type of clinical trial.	1. Not necessary where outcome measure is outside control of researcher (eg: still alive at end of study). 2. Safety of patients is risked if doctors do not know if medication was taken or not should an emergency arise. 3. Some studies cannot be blinded.

Table 2.7 - Strengths and weaknesses of double-blind clinical trials.

Thomas et al (2005) performed an open-label study of donepezil with forty Parkinson's disease dementia (PDD) sufferers and thirty Dementia with Lewy bodies (DLB) sufferers. The treatment condition showed improvements at week 20, but side effects were common for all (69%). However, it was known who was receiving the treatment and the placebo.

#### 8. Size of dosage.

Studies vary in the level of dosage given to the treatment group (table 2.8). Many studies vary dosage over the study, usually increasing it (table 2.9), and others involve a crossover design.

Dosage is important because not all of the active ingredients of the drug gets to the site of action. The amount that gets into the bloodstream and thus the site of action is known as bioavailability. When drugs are taken orally, stomach acid can reduce bioavailability as the drug passes through the stomach, for example (Brewer 2003).

In crossover design participants are randomly allocated to treatment or no treatment/placebo group for the first part of the trial, then the groups are changed over for the second part (known as AB/BA design; Matthews 2000)(table 2.10; figure 2.1).

<u>STUDY</u>	<u>DRUG</u>	<u>DOSAGE</u>
Black et al (2003)	Donepezil	5mg daily OR 5mg for 1-4 weeks, then 10mg daily weeks 5-24
Deakin et al (2004)	Paroxetine	20mg per day for 1 week, then 30mg in week 2, and 40mg weeks 3-8, back to 30mg in week 9
de Tommaso et al (2004)	Rivastigmine	1.5mg twice daily for 0-2 months, than 3mg twice for 6 months

Table 2.8 - Three examples of dosage size <sup>12</sup>.

<u>STRENGTHS</u>	<u>WEAKNESSES</u>
<ol style="list-style-type: none"> <li>1. Starting or stopping drug with large dosage can cause problems.</li> <li>2. Allows the researchers to assess tolerance and side effects before varying the dosage.</li> </ol>	<ol style="list-style-type: none"> <li>1. Varying the dosage in the middle of the study is a confounding variable.</li> <li>2. Dosage may not be altered equally for all participants.</li> </ol>

Table 2.9 - Strengths and weaknesses of varying the dosage during a study <sup>13</sup>.

<u>STRENGTHS</u>	<u>WEAKNESSES</u>
<ol style="list-style-type: none"> <li>1. Controls for spontaneous remission.</li> <li>2. Controls for expectations of improvement.</li> <li>3. Each participant is both treatment and control group which has all the advantages of the repeated measures design experiment.</li> </ol>	<ol style="list-style-type: none"> <li>1. Ethics of giving and removing treatment.</li> <li>2. Participants can guess when they are taking the drug or the placebo.</li> <li>3. Participants may drop-out in the second half if they know they will be the placebo group.</li> </ol>

Table 2.10 - Strengths and weaknesses of crossover design.

<sup>12</sup> Paroxetine (trade name "Seroxat") is a type of anti-depressant known as selective serotonin reuptake inhibitors (SSRI).

<sup>13</sup> Often a larger dose is given at the beginning of the treatment ("loading dose") to gain an immediate response, then less for the maintenance of the effect (Brewer 2003).



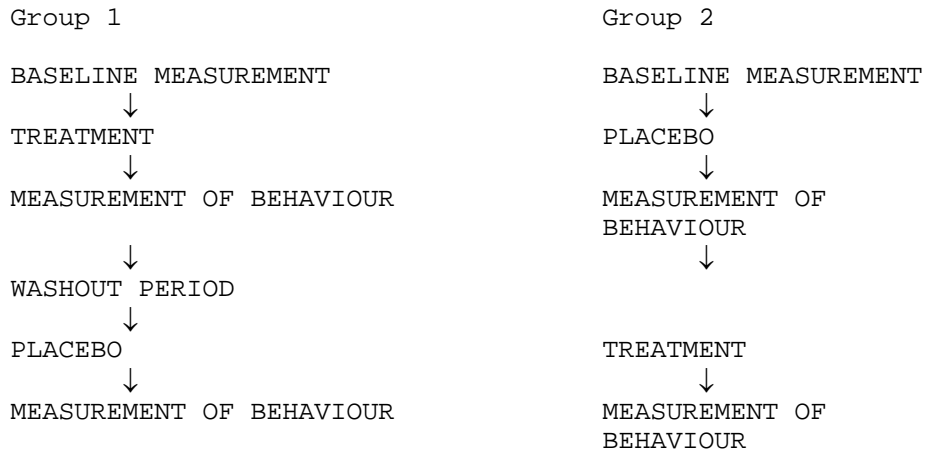


Figure 2.1 - Crossover design.

There has to be a "washout" period for the drug to leave the body. This is the period of drug elimination; ie: the complete removal of the drug from the body (which is also influenced by the size of the dosage). It is important to avoid confounding the conditions of the drug trial.

#### 9. Sample size.

It is assumed that the larger the sample studied the better (table 2.11). Black et al's study, for example, started with 603 patients and 478 finished the trial.

Many diseases are rare and so the number of those available for study will be limited. For example, Deakin et al (2004) studied only ten patients with frontal variant frontotemporal dementia (FvFTD)(right frontal lobe degeneration, formerly known as Morbus Pick; Arlt and Jahn 2006) using international agreed criteria and confirmed local guidelines at the Memory and Early Onset Dementia Clinic at Addenbrooke's Hospital, Cambridge.

#### 10. Measurement of improvement criteria.

Studies should have a clear set of criteria for improvement or success of the treatment.

But what is success when diseases cannot be cured? For example, with Huntington's disease a fatal genetic disease, which often includes dementia. de Tommaso et al (2004) used the criteria of a slowing in decline of cognitive performance based on the Mini-Mental State Examination (MMSE) in Italian (Measso et al 1993) in their small Italian study of rivastigmine.

<u>STRENGTHS</u>	<u>WEAKNESSES</u>
<ol style="list-style-type: none"> <li>1. Allows for good statistical analysis.</li> <li>2. Less likely to have sampling bias.</li> <li>3. Overcomes individual variations which can distort small studies.</li> <li>4. Not distorted by inevitable drop-out.</li> <li>5. Too small sample may leave research question unanswered.</li> </ol>	<ol style="list-style-type: none"> <li>1. Expensive and time-consuming.</li> <li>2. Large samples may disguise weaknesses in design or relevant participant variables.</li> <li>3. Often at multi-centres, and risk of variation in procedure.</li> <li>4. Patients may feel unimportant.</li> <li>5. Unethical to recruit many more patients than needed.</li> </ol>

Table 2.11 - Strengths and weaknesses of studying a large sample.

In a situation where drugs can only hope to slow the decline, it is not surprising that finance for such research and development of drugs is limited.

But it does mean that the focus of drug research can change from neurotransmitters (the usual focus of psychoactive drugs). For example, the development of substances that inhibit the formation of the harmful prion protein in Creutzfeldt-Jakob disease (Arlt and Jahn 2006).

#### 2.4. CONCLUSION

Producing drugs to treat dementias lags behind other fields in psychiatry, including Alzheimer's disease. Arlt and Jahn (2006) are saddened:

For many patients, we still have nothing but words. At the same time, probably with regard to cost constraints, some actors like health insurances and legislators are inclined to nurture therapeutic nihilism and cultivate ethical questions and demurs instead of supporting clinical trials or at least not blocking them with bureaucratic handcuffs, whereas pharmaceutical companies contemplate naturally over questions like return of investment (pp642).

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### **3. SCREENING INSTRUMENTS IN THE DIAGNOSIS OF MENTAL DISORDERS: THE CUT-OFF POINT**

- 3.1. Introduction
- 3.2. Setting the Cut-Off Point
- 3.3. Cut-Off Points of Different Screening Instruments: Example from Autistic-Spectrum Disorders
- 3.4. References

#### **3.1. INTRODUCTION**

The diagnosis of mental disorders can be aided by the use of psychometric screening instruments. These are standardised measures of the behaviour of interest with a cut-off point as to when the individual shows a mental disorder or abnormal behaviour. Table 3.1 lists five common examples used.

<u>SCREENING INSTRUMENT</u>	<u>DETAILS</u>
Hamilton Anxiety Scale (HAS) (Hamilton 1959)	13 items about anxiety; each scored 0-4 by interviewer for last week
Hamilton Rating Scale for Depression (HRSD) (Hamilton 1967)	21 items about severity of depression; used in unstructured interview
General Health Questionnaire (GHQ) (Goldberg 1972)	16 self-administered questions with 4 point scale; used to detect non-psychotic disorders
Rating Scale for Mania (Young et al 1978)	11 items to assess severity of mania
Impact of Event Scale (IES) (Horowitz et al 1979)	15 items scoring 0-4 on frequency and intensity of post-traumatic stress disorder

Table 3.1 - Five commonly used screening instruments for mental disorders.

Good screening instruments will show reliability, validity, discrimination and standardisation (table 3.2). There are strengths and weaknesses to the use of psychometric screening instruments (table 3.3).

CRITERION

RELIABILITY - consistent both within itself (internal reliability) and over time (external reliability).

Internal reliability established by the split-half method, Kuder-Richardson method, or Cronbach's alpha. External reliability by test-retest or parallel forms method.

VALIDITY - measure the behaviour that it claims to measure. The main types of validity are face, content, criterion (made up of concurrent, and predictive validity), and construct validity.

STANDARDISATION - when the test is first constructed, it must be adjusted to approximate to a normal distribution of scores. Most tests have norms ("normal scores") for the majority of the population.

DISCRIMINATION - individual items and the test as a whole discriminate between high and low scorers: eg individual with severe depression should answer items different to individual not depressed. Item analysis is the main technique used here.

Table 3.2 - Criteria for good psychometric screening instrument.

STRENGTHS	WEAKNESSES
<ol style="list-style-type: none"> <li>1. Compare scores to other people.</li> <li>2. Compare scores to norms.</li> <li>3. Clear cut-off point for normal and abnormal behaviour.</li> <li>4. Psychometric test criteria established; ie: reliability, validity, discrimination, and standardisation.</li> <li>5. Removes concerns about subjectivity in diagnosis.</li> </ol>	<ol style="list-style-type: none"> <li>1. Depends upon accuracy of instrument construction.</li> <li>2. Can be reliable without being valid and vice versa.</li> <li>3. Cut-off point can be arbitrary decision and this can be a subjective decision.</li> <li>4. Ratings either need co-operation of test-taker or depends upon accuracy of observer (eg parents).</li> <li>5. It is not completely objective, and subjectivity can occur in a number of places including design of instrument, and interpretation of behaviour observed.</li> </ol>

Table 3.3 - Strengths and weaknesses of psychometric screening instruments in diagnosis of mental disorders.

Two issues are important in relation to the cut-off point of screening instruments. Firstly, the cut-off point of an individual screening instrument, and secondly, cut-off points of different screening instruments.

### 3.2. SETTING THE CUT-OFF POINT

The cut-off point of a screening instrument is usually based on the theoretical assumption of the normal distribution. This presents the data of any population as distributed in a certain way around the mean (table 3.4)(Coolican 1990).

MEAN to +1 SD	34.13%	MEAN to -1 SD	34.13%
+1 SD to +2 SD	13.59%	-1 SD to -2 SD	13.59%
+2 SD to +3 SD	2.15%	-2 SD to -3 SD	2.15%
> +3 SD	0.13%	> -3 SD	0.13%

(SD = standard deviation)

Table 3.4 - Percentages of the population around the mean in a normal distribution of scores.

So, for example, using an IQ test with a mean of 100 and a standard deviation of 15, 68.26% of the population will score between 85 and 115 (-1 SD to +1 SD), and 95.44% will score between 70 and 130 (-2 SD to +2 SD). This leaves 2.28% of individuals scoring an IQ of less than 70 (< -2 SD) and 2.28% above 130 (> +2 SD).

Cut-off points will be based on such assumed distribution of scores. But behaviours in relation to mental disorders may not have a normal distribution.

The cut-off point chosen produces four possibilities (table 3.5).

	<u>HAS MENTAL DISORDER</u>	<u>DOES NOT HAVE MENTAL DISORDER</u>
<u>SCREENING INSTRUMENT SAYS YES</u>	"True positive" - correct diagnosis	"False positive" - misdiagnosis of disorder present
<u>SCREENING INSTRUMENT SAYS NO</u>	"False negative" - missed	"True negative" - correct diagnosis

Table 3.5 - Four possibilities of diagnosis.

<u>SCORES</u>	<u>NUMBER OF CASES WITH DISORDER</u>	<u>NUMBER OF CASES WITHOUT DISORDER</u>
50	10	0
40	8	5
30	6	10
20	1	15
10	0	20

Table 3.6 - Hypothetical distribution of scores for a screening instrument.

Using the hypothetical data in table 3.6, the differences can be seen between three cut-off points. If a high cut-off point of 50 is chosen, all 10 cases diagnosed will have the disorder ("true positive"), but 15 cases are missed ("false negative"). This is acceptable if the consequences of wrong diagnosis are massive and of missed diagnosis are small.

Using a cut-off point of 40 and above, 18 cases are "true positive", 7 "false negative" and 5 cases "false positive" (diagnosed with disorder when do not have it). This is acceptable if the consequences of "false positive" are small.

A low cut-off point of 30 and above only misses one real cases of the disorder, but produces 15 "false positive". A "false positive" can produce anxiety for the individual. Thus it is important that the cut-off point is carefully calculated for any screening instrument (table 3.7).

HIGH CUT-OFF POINT	LOW CUT-OFF POINT
- less risk of "false positive"	- less risk of "false negative"
- more risk of "false negative"	- more risk of "false positive"

Table 3.7 - High and low cut-off points.

### **3.3. CUT-OFF POINTS OF DIFFERENT SCREENING INSTRUMENTS: EXAMPLE FROM AUTISTIC-SPECTRUM DISORDERS**

Charman et al (2007) compared three screening instruments for identifying individuals with autistic-spectrum disorders (ASD) in the Special Needs and Autism Project (SNAP) cohort of 9-13 year olds in the UK. These individuals were born between 1st July 1990 and 31st December 1991 (Baird et al 2006).

i) Social Communication Questionnaire (SCQ)(Rutter et al 2003)

A 40 item questionnaire of symptoms of autistic behaviour which parents rate as 0 or 1 for each item. Nineteen items are current behaviour and the others are when the child was 4-5 years old. The cut-off score for ASD is 15 or more.

ii) Social Responsiveness Scale (SRS)(Constantino and Gruber 2005)

This is a 65 item questionnaire rated 0 ("never

true") to 3 ("almost always true") for each item for ASD over the last six months by the parents or teachers. The cut-off score is 75 or greater.

iii) Children's Communication Checklist (CCC; CCC-2)(Bishop 1998; 2003)

This instrument measures language and communication impairments generally with 70 items. Such impairments are seen as symptomatic of ASD. Each item is scored as 0 ("does not apply") to 2 ("definitely applies") by the parents. The cut-off point is a composite score of 130 or less.

Comparing the three questionnaires, the SCQ was rated as performing best followed by the SRS and the CCC-2. This means that fewer "false positives" and "false negatives" occurred (table 3.8).

	<u>SCQ</u>	<u>SRS</u>	<u>CCC-2</u>
"True positive" - 100 individuals with ASD diagnosed as ASD	86	78	93
"False negative" - 100 individuals with ASD diagnosed as non-ASD	14	22	7
"True negative" - 150 individuals non-ASD diagnosed as non-ASD	117	100.5	69
"False positive" - 150 individuals non-ASD diagnosed as ASD	33	49.5	81

Table 3.8 - Accuracy of diagnosis of 100 hypothetical cases of ASD and 150 non-cases.

Using the figures in table 3.8, the prevalence of ASD will vary depending on the instrument used. The SCQ gives a rate of 47.6% ("true positives" and "false positives" out of 250), SRS 51%, and CCC-2 69.1%. The CCC-2 overestimates the prevalence of ASD markedly, but this could be because it is not a screening instrument specific to ASD. The SCQ and the SRS showed similar rates, but, in a large population, this will lead to a number of misdiagnoses, either "false negatives" or "false positives", for ASD.

Charman et al (2007) noted that in the case of expensive treatment, minimising "false positive" would be crucial. They pointed out that "false positives tend to cost services, whereas false negatives tend to cost the



child and parent" (p558).

The authors also referred to the fact that a screening instrument should not be a diagnosis, and full interviews are required for this.

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## **4. BIOCHEMICAL MEASURES TO STUDY BEHAVIOUR: SOME EXAMPLES**

- 4.1. Introduction
- 4.2. Measurement of Body Fluids
- 4.3. Infusion of Substances
- 4.4. Detailed Example
- 4.5. References

### **4.1. INTRODUCTION**

Biochemistry refers to the chemical processes in the body that are involved in physiological processes, and underlie behaviour.

Biochemical measures are based around two main techniques:

- i) The measurement of body fluids;
- ii) The infusion of substances.

### **4.2. MEASUREMENT OF BODY FLUIDS**

- i) Detection of the presence of drugs.

It is possible to detect the presence of drugs in the urine and/or blood. Miller (1995) noted two main methods used here: chromatographic techniques, which separate molecules, and competitive binding/immunoreactive techniques, which employ antibodies against specific drugs.

While alcohol levels can be assessed by estimations of gamma-glutamyl-transpeptidase (GGT) (liver enzyme) in blood, mean corpuscular volume (MCV), or blood alcohol concentration (Gelder et al 1996).

- ii) To show physiological changes.

For example, plasma hormone levels can be used to measure hormone secretions, like corticosteroids and stress, and neurotransmitters (eg: pituitary gland secretion controlled by neurotransmitters).

In terms of differences in behaviour, Lidberg et al (1978) used a sample of 24 arrested men, aged 18-29 years old, who gave urinary samples in two different situations. The samples were analysed for the excretion of adrenaline and noradrenaline, which are signs of a physiological stress response.

The group were divided into high or low psychopathy based on three scales: Gough Delinquency, Solidarity, and

Stability Scales.

The two situations were a mildly stressful lab experiment two weeks before the individual's trial, and immediately before court appearance. The "high psychopathy" group did not produce increased adrenaline and noradrenaline in either stressful situation.

iii) To look for biochemical causes of behaviour.

Some behaviours may have clear biochemical causes, particularly if there are biochemical abnormalities. For example, blood glucose levels are relatively stable in most individuals, and normal changes are linked to food intake. But, for some individuals, variations in these levels may account for problem behaviour.

Using glucose tolerance testing methods <sup>14</sup> with Finnish participants, Virkunen and Huttunen (1982) found that hypoglycaemia <sup>15</sup> was present more often in violent individuals with a diagnosis of Anti-Social Personality Disorder as compared to violent offenders, and non-violent Anti-Social Personality Disorder diagnoses.

#### **4.3. INFUSION OF SUBSTANCES**

i) To see the effect of pharmacological substances.

The infusion of substances can be used with humans or more often done on non-human animals if there are risks of harm.

In an example with humans, Balon et al (1988) got a group of volunteers with panic disorder, and a control group who agreed to receive an infusion of sodium lactate of 0.5m intravenously over 20 minutes. The researchers were interested in how many of the participants reported symptoms similar to panic disorder.

They found that 25% of the control group and 85% of the panic disorder group reported such symptoms.

It has been argued that lactate sensitivity is the cause of panic disorder.

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<sup>14</sup> The most common method used is the oral glucose tolerance test (OGTT). After an overnight fast, the participant drinks 75g of glucose dissolved in water, and blood glucose levels are measured before and two hours after drinking. The results are compared to normal values (Wilding and Williams 1997).

<sup>15</sup> Severe change in blood glucose levels due to too much insulin or not enough food.

ii) To eliminate physical causes of behaviour.

It is also important to use these techniques to eliminate physical causes for behaviour when searching for the cause of a disorder, say.

For example, psychiatrists need to rule out potential physiological causes of dementia in the process of diagnosis. The main areas are (Flynn and Mueller 2000):

- Blood, plasma or serum levels - eg: white blood cell count, vitamin B12 level, folic acid, lactic acid;
- Antigen and antibody test - eg: fluorescent treponemal antibody absorption (FTA-ABS) for syphilis;
- Lumbar puncture (LP) to detect haemorrhaging in the central nervous system. This involves an examination of a sample of the cerebrospinal fluid.

Using biochemical measures to understand behaviour has both strengths and weaknesses (table 4.1).

#### **4.4. DETAILED EXAMPLE**

Otte et al (2005) looked at levels of stress among police academy recruits in relation to childhood trauma experienced. Seventy-six recruits, all but ten male, to eight police departments in California took part in the repeated measure experiment.

The level of stress was measured using salivary cortisol and MHPG (3-methoxy-4-hydroxy-phenylglycol<sup>16</sup>). Measures were taken at three points in the experiment. Childhood trauma, before the age of fourteen years, was measured by the Life Stressor Checklist-Revised (LSC-R; Wolfe et al 1996), which asks respondents to record their experience of twenty-one stressful life events. Events include experiencing or witnessing a serious accident, illness, or physical assault. Other measures of mental health were also taken.

The experiment revolved around a specially made video that the participants had to watch together. The video was divided into three segments:

i) 10 minutes of "innocuous travelogue". (The first saliva measures taken before it started to serve as baseline);

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<sup>16</sup> Major metabolite of noradrenaline. A metabolite is produced when a biochemical has been active (ie broken down), so it used as a measure of that biochemical's presence.

<u>STRENGTHS</u>	<u>WEAKNESSES</u>
<p>1. Gives objective measures of biochemical changes in the body before, during, and after certain behaviour.</p> <p>2. Multiple and detailed measures can be taken in controlled situations.</p> <p>3. Biochemical measures can be correlated with observed behaviour.</p> <p>4. Infusion of substances can be used to test hypotheses about the cause of behaviour.</p> <p>5. Can be used with humans and non-human animals.</p>	<p>1. The findings are only correlations between biochemical changes and particular behaviour.</p> <p>2. These methods are indirect and not always easy to interpret the results.</p> <p>3. The presence of confounding factors; eg: the measurement of biochemicals in urine affected by diet.</p> <p>4. Practical difficulties of measuring the fluids, like cerebrospinal fluid which contains neurotransmitter metabolites.</p> <p>5. Ethical difficulties in invasive techniques: eg blood sample by injection of syringe.</p>

Table 4.1 - Strengths and weaknesses of biochemical measures to understand behaviour.

ii) 20 minutes of "critical incidents" containing real-life footage of fourteen incidents involving police officers, like a homicide, an autopsy, and an officer being killed by a detonated bomb. (the second saliva measures taken at end of this segment);

iii) 20 minutes of more travelogue. (The third saliva measures were taken at the end of this segment as research had found that cortisol response to a stressor peaks at 20-40 minutes after its onset; Dickerson and Kemeny 2004).

There was no food intake, exercise, or smoking by the participants for two hours before the study (and obviously during it). The participants also recorded their level of subjective distress to the video.

The childhood trauma group contained sixteen police recruits. The "critical incidents" segment of the video produced a significant increase in salivary cortisol and MHPG in both groups of recruits compared to their baseline measures, but the childhood trauma group had a significant higher level of MHPG than the non-trauma group. There was no difference for cortisol levels. The childhood trauma group also reported significantly greater subjective distress about the video.

The study confirmed other work that individuals with childhood trauma experience greater stress reactions to events as adults.

Table 4.2 details the strengths and weaknesses of this study.

<u>STRENGTHS</u>	<u>WEAKNESSES</u>
<p>1. Good level of control over variables by using participants who could be kept from eating, smoking, and exercise. Easier to control police recruits in academy than other participants.</p> <p>2. Appropriate measures of saliva using nylon swabs placed individually in Salivetta tubes and stored at correct temperature until analysis.</p> <p>3. Use of real-life police incidents as stressor.</p> <p>4. Full informed consent gained before study began.</p>	<p>1. Childhood trauma was only measured by participants' own recall with no verification of fact. Participants may have forgotten events or not wanted to admit to them.</p> <p>2. Limited sample in terms of total numbers, few females, and police academy recruits in a particular state and country. This does limit the generalisability of the findings to the whole population (police officers) and other populations (eg general public).</p> <p>3. Longer term measures of cortisol and MHPG not taken, and other stress-related substances, like ACTH, not measured.</p> <p>4. Ethical concerns about distress from using disturbing images in video.</p>

Table 4.2 - Strengths and weaknesses of Otte et al (2005) study.

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## **5. ETHICS OF PSYCHIATRY IN A DIRTY WORLD: SOME REFLECTIONS**

- 5.1. Introduction
- 5.2. Issues
- 5.3. References

### **5.1. INTRODUCTION**

The traditional view presented by psychiatrists is of medical specialists working for the good of their patients or clients. This fits with the general approach of medicine "to do good for the patients" (Arboleda-Florez 2006). There are those who would despite the motives of psychiatrists, and take an anti-psychiatry or critical standpoint (eg: Szasz 1960 or views of "survivors of the mental system" - [www.asylumonline.net](http://www.asylumonline.net)).

Leaving aside these criticisms at the moment, when psychiatrists are involved in the legal system (eg: forensic psychiatry), their ability "to do good for the patients" is challenged, and ethical concerns arise. The next section looks at four situations which produce such ethical concerns (eg: confidentiality, coercion).

### **5.2. ISSUES**

#### 1. Assessment of offenders for a third party.

Psychiatrists (or psychologists or therapists) can be asked to interview individuals in the legal system, usually offenders or defendants, for a third party, like the police or courts.

In this situation anything that the interviewee (evaluatee) says that is relevant to the assessment (or diagnosis) will probably be repeated to the third party. There is no guarantee of confidentiality which is usually an ethical principle of psychiatry. Furthermore, some information can go beyond the third party and into the public domain.

The interviewee may understand such lack of confidentiality, and refuse to engage in the assessment. But if the assessment has been ordered by the court, refusal to proceed could be an offence: "hence a clear element of coercion enters into play by the mere handshake as the evaluatee enters the office of the expert" (Arboleda-Florez 2006 p545).

Put simply, coercion is the absence of consent. In psychiatry generally, coercion is accepted as protection of the patient from injuring themselves or others. Sadly



the concerns of society are more about injuring others, though it is so much rarer than self-injury. Coercion varies from "sectioning" (compulsory admission to a psychiatric ward) to forced drug administration for patients. These events are justified by psychiatrists, if not supported by patients, as ultimately for the goal of the patient.

But what about forced psychiatric assessments as requested by an insurance company or an employer before authorisation of benefits or payment of a claim? Are these for the good of the patient? It could be argued that they are if the interviewee receives the appropriate benefit or recognition of their mental health problem. On the other hand, it can look like psychiatrists as the instrument of social control (again).

## 2. Involvement with intelligence interrogations.

Interrogations by intelligence services in the atmosphere of the world today (eg: "War on Terror") are concerned with gaining information (or what they believe to be truth). How this is done depends on the ethics of the individuals, intelligence services, and countries involved. In other words, whether torture (physical or mental) is used <sup>17</sup> (and even how torture is defined).

Since late 2002, psychiatrists and psychologists have been involved at Guantanamo Bay as part of the Behavioural Science Consultation Team to make "interrogation more productive". Psychiatrists and psychologists prepare psychological profiles of detainees for use by interrogators, and observe the interrogations and give feedback to the interrogators (Bloche and Marks 2005). The profile can include tailoring stressors or rewards to individual detainees (eg: fears, beliefs). In other words, helping to find the vulnerabilities of individuals.

The services of psychiatry can be just another set of tools for intelligence officers in achieving their aims. For example, the use of techniques that can "guarantee" to spot liars.

For example, "Brain fingerprinting" is based on this assumption. Developed by Lawrence Farwell (Farwell and Smith 2001), it measures P300 waves by EEG in response to knowledge of facts about a crime.

The P300 wave response to crime-related words flashed on a screen are classed as "guilty knowledge"

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<sup>17</sup> Bloche and Marks (2005) reported the increasing examples of techniques being used at Guantanamo Bay including sleep deprivation, painful body positions, feigned suffocation, and beatings.

which the offender cannot hide. The key is that there will be information that is only known to the offender and the "guilty knowledge test" will find it among hundreds of questions asked. The technology is being used in the US legal system (eg: murder conviction reversal in Iowa; Fuchs 2006).

One major problem stands out with "brain fingerprinting". It measures recognition, and this recognition may be from elsewhere than the "guilty knowledge" of the offender (Innovation 2004).

Neuroimaging has also been used to detect deception by showing the physiological correlates of intentional deception (eg: in anterior cingulate cortex in functional magnetic resonance imaging; Langleben et al 2002).

Leaving aside privacy and confidentiality with the use of such techniques, there is the issue of the ethics of claims that liars can be detected with such techniques. Buller (2005) questions whether neuroimaging is able to tell if a person is lying because, among other reasons, there are many different types of lies.

### 3. Assessment of inmates in countries with capital punishment.

Professional organisations within the medical professions have tended to denounce participation in capital punishment (eg: Royal College of Psychiatrists in the UK; World Psychiatric Association), while others see such involvement as part of the job that just needs ethical guidelines. American Law Professor, Bonnie (1990), for example, sees "no qualitative differences between sentencing evaluations in capital cases and non-capital cases; or capital sentencing evaluations and execution competency evaluations" (quoted in Matthews and Wendler 2006 p519).

In the USA, one task for psychiatrists relates to execution competency. This is an assessment of the individual's mental state because individuals who are "mentally incompetent" cannot be legally executed" (Matthews and Wendler 2006). if the individual is found to be "mentally competent" then the psychiatrist has confirmed that the execution can go ahead. On the other hand, finding the individual as "mentally incompetent" saves them, at least in the short term. But individuals usually facing capital punishment have committed serious crimes. What does the psychiatrist or assessor do?

This situation is worsened by the observation that professionals who oppose capital punishment self-select not to involve themselves in such work (Deitchman et al 1991).

Another issues is whether to prescribe the prisoner medication to make them "mentally competent" so that execution can take place. This can also be against the prisoner's choice (ie: they do not want medication - for obvious reasons). Commutation of the sentence to life imprisonment could be a solution (American Psychiatric Association Board of Trustees 2005 in Matthews and Wendler 2006).

In relation to a non-capital punishment situation, Cornwall (2003) quoted the case of Charles.T.Sell who was arrested for fraud. He subsequently developed a psychotic illness before the trial. Should he be given medication to render him competent for the trial? But he must be "mentally competent" to give consent to medication, but if he is "mentally competent" he does not need the drug.

#### 4. Making predictions about future risks and dangerousness.

The holy grail of psychiatry (and psychology) is the ability to predict the future. This is most relevant in the case of future dangerousness of offenders. Certainly in the case of the release of individuals from institutions, this has important implications.

There are four possibilities related to these decisions (table 5.1), and situations 2 and 3 are the key ones.

PREDICTION:	FUTURE BEHAVIOUR:	
	DANGEROUS	NOT DANGEROUS
DANGEROUS	1. Remain in institution - risk controlled	2. Individual remains confined unnecessarily
NOT DANGEROUS	3. Potential harm to innocent party	4. Return into society with no risk

Table 5.1 - Four possibilities for predicting future dangerousness.

In situation 2, an individual is not released and suffers the consequences of continued confinement when they will not be dangerous in the future. While situation 3 produces the scenario highlighted by the media after an individual re-offends - "why did they let him (her) out?".

Actuarial risk assessment using statistical probabilities and producing generalisations is one way to deal with the uncertainty of prediction. Though it may

feel more secure than guesswork, any generalisation is like an average which makes it liable to be right with some individuals and not others.

Having a number of risk factors does help, and the more of the risk factors that an individual has the more likely they are to be a definite predictable future danger (eg: violence among individuals with mental disorders; table 5.2).

- 1. Active psychotic symptoms and substance abuse and history of violence or current hostile attitudes
- 2. "Threat/control override" (TCO) symptoms - delusions of being threatened or controlled by outside forces
- 3. Delusional beliefs about significant others - for example, that they are imposters
- 4. Hallucinations to commit violence or self harm
- 5. Erotomania with multiple delusional objects (ie: focus of obsession as in stalking behaviour) and history of serious anti-social behaviour unrelated to delusions
- 6. Narcissistic injury (self harm), isolation of affect (lack of appropriate emotional responses in situations), threatening behaviour, and availability of weapon

(After Litwack and Schlesinger 1999)

Table 5.2 - A number of different risk factors for violence among individuals with mental illness.

Soothill et al (2005) applied the risk assessment tool, Static-99, to data on sexual offences against children in Lancashire, England. Static-99 (Hanson and Thornton 1999) is based around ten measures relating to previous convictions for sexual and non-sexual offences, and relationship to the victim. High risk offenders for recidivism have a score of six or more on the measures.

The researchers found that over 70% of the high risk group had a subsequent conviction for a sexual offence compared to between 10-15% for the other risk groups (low, medium). As risk assessment tools go, that is a fair degree of accuracy, but, of course, there is nearly one-third who did not re-offend.

To some degree, the accuracy of prediction of risk is not the issue, rather it is the context in which the prediction is made. This context is that every negative event can be prevented. So when, for example, a low risk individual released from an institution re-offends, the "authorities" are criticised because "they should have known".

This response is partly due to the workings of the

hindsight effect/bias (Fischhoff 1975) or the "knew-it-all-along effect" (Wood 1978). This is the use of information known after the event in attributing the understanding of decision-makers before the event. One example of this process at work is in the form of "obvious signs". After the event a list is made of these signs that should have been heeded, but the "inevitable failings of authority" meant that they were not. In reality, some of these signs may have been missed, but many of them are only easy to see when looking backwards with the knowledge of today.

Brewer (2002) looked at the case of a man with a personality disorder who died after falling from the ninth floor of a tower block. The local newspaper reported emphasised the many "obvious signs" that he was intending to kill himself after release from hospital (table 5.3). And the "authorities" were oblivious to them.

"OBVIOUS" WARNING SIGNS

OFFICIALS OBLIVIOUS

- "...housed.. on 9th floor of a tower - despite being warned he could jump.." (lines 2-5)

- "...coroner.. said she was not convinced 'beyond reasonable doubt' that.. intended to kill himself.." (lines 22-27)

- "...even though his consultant psychiatrist feared he would attempt suicide.." (lines 10-12)

- "...there was no indication ..was considered at risk of committing suicide.." (official of council) (lines 104-106)

- "...after being involved in previous incidents.." (lines 17-18)

- "...despite his consultant psychiatrist sending two faxes to ..housing department.." (lines 45-49)

- "A note written by.. was found by police at his home following the incident.." (lines 58-61)

- "...cocktail of drink and drugs in his blood.." (lines 63-65)

- "...would drink to relieve pains in his head.." (lines 74-75)

- "...comments he had made in the past about not wanting to be here.." (lines 80-83)

- warnings "omitted from relevant housing forms through lack of room.." (lines 52-54)

Table 5.3 - Examples of "obvious signs" in the case of a man with a personality disorder who fell to his death from a tower block.

However, the need to blame someone is also a construction of this society. There is a contradiction between the need to find someone to blame ("blame culture") and the "individualism without responsibility". For example, after a rail crash, there is the search for who caused it. Yet if certain advice is given beforehand, individuals would reject it as to "Nanny-State". Individuals are free to choose their destiny, not the State, but when it goes wrong, the State is responsible.

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