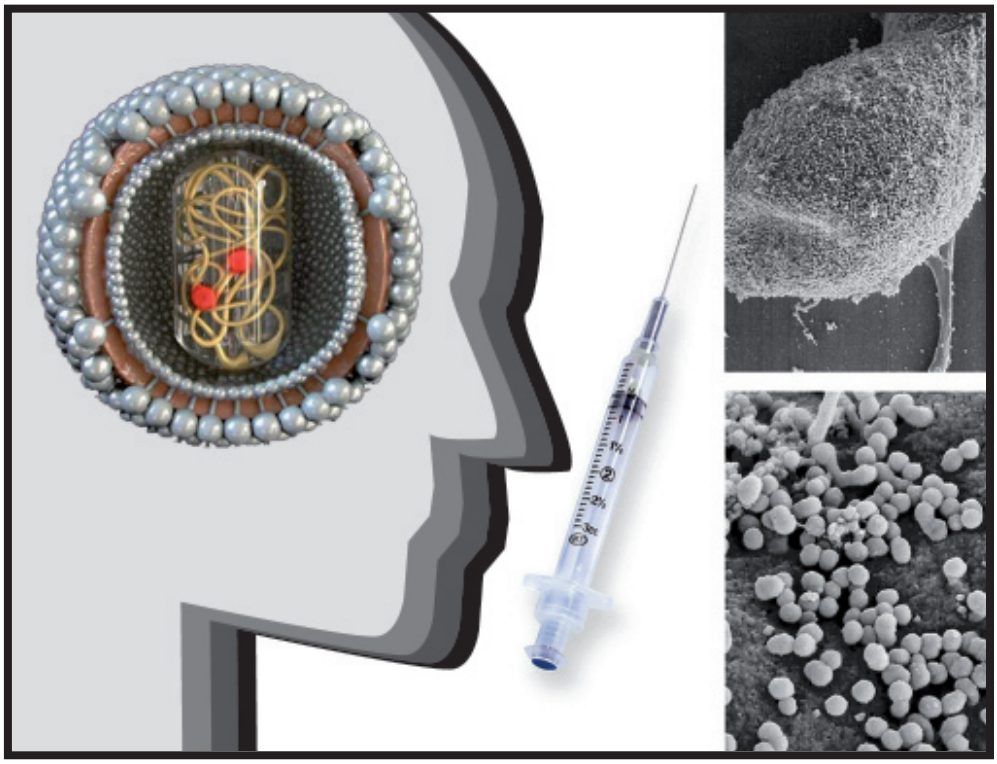
TuftScope

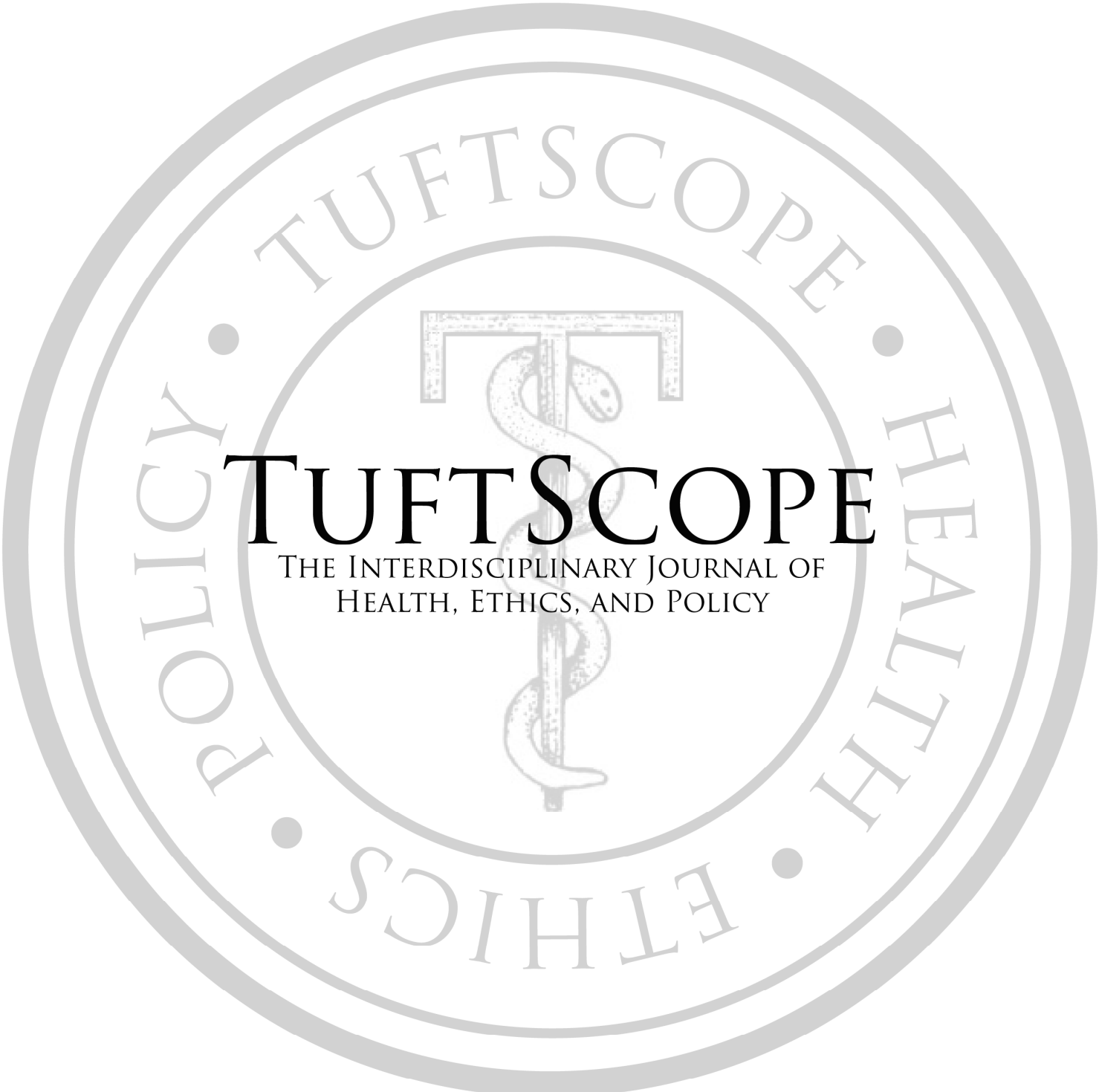
The Interdisciplinary Journal of Health, Ethics, and Policy

Winter 2007-2008 Volume 7



Featured Articles

A Publication of TuftScope,
a Student Organization of Tufts University



TuftScope

The Interdisciplinary Journal of Health, Ethics, and Policy

Inside this Issue

Featured Articles

A TuftScope Commentary

Original Articles

from the Editor

Dear Readers,

Thank you for picking up this brand new issue of TuftScope! You are about to embark upon a journey of incredible thought and query. For the last six years TuftScope has published original papers that have explored and challenged the topics of health, ethics, and policy in the United States and across the globe. Our goal has always been to present readers with papers that explore the very forefront of current health ethics. From healthcare to HIV and abortion, we have provided our readers with an insightful look into the ethical questions our society faces today and will continue to face in the future. Since the first publication of TuftScope, bioethical and health issues have only continued to grow and develop. Concerns about stem cells, abortion, genetic modifications, healthcare policy, and global health remain as salient today as they were a decade ago.

In our seventh volume we present five original articles covering a broad range of topics from HIV testing and psychiatric illness to the use of race in medicine and the influence of the pro-life lobby on pharmaceuticals. We hope that these articles will challenge your perceptions, encourage further inquiry, and perhaps even provide insight into an area of study you have not explored before. TuftScope has come a long way from our first issues and we continue to make structural and content-oriented changes to enhance the journal for its readers. We wish to thank our long time adviser Dr. Feldberg for his guidance in the past years and welcome Dr. Bernheim to our Editorial Board. As always, this issue would not have been possible without the submissions and efforts of the authors of the papers within this journal. We hope that you enjoy this issue and the journey upon which you are about to embark!

Sincerely,

David Kudlowitz , Hari Nandu
Michael Shusterman , Cole Archambault, Alice Tin

The TuftScope Editorial Board

Join TuftScope!

To become involved with the Interdisciplinary Journal of Heath, Ethics, and Policy, e-mail TuftScope@gmail.com, visit our website at http://ase.tufts.edu/tuftscope. If you are interested in submitting a paper to TuftScope, please see the Submissions Guidelines on page 22.

CHALLENGES TO TAXONOMIC SYSTEMS FOR MENTAL ILLNESSES

by Marc Bouffard

The field of psychiatric medicine is observed to lag far behind physical medicine. The notion of how mental illness ought to be defined is still debated. This confusion reflects serious problems in the system by which mental disorders are classified. The utilitiy derived from the DSM-IV is, in some ways, undermined by the lack of scientific validity seen in the criteria employed therein. This paper suggests the use of a dimensional taxonomic model, onto which categorical criteria might be selectively superimposed. With such a system in place, a guide that expresses both utility for the clinician and validity for the researcher might be found.

Several years ago British psychologist Richard Bentall submitted an article to the Journal of Medical Ethics. The purported subject of this article was to classify happiness as a mental disorder. Although it is highly doubtful that Bentall's work was not recognized in the psychiatric community for the satire that it was, one must wonder how well this satire was appreciated. Bentall applied contemporary standards used for classifying psychological disorders to happiness. Although his argument was not without flaw , he made an interesting case for supporting the absurd in a simple attempt to call attention to the fact that our definition of psychological disorders is quite vague. There is considerable controversy today over whether or not our system of categorical taxonomy for the organization of psychological disorders is appropriate. Part of this trouble reasonably stems from the fact that it is difficult to specify exactly what we mean by psychological disorder. The goal of this paper is therefore tripartite: to examine the controversy surrounding the current definition of psychological disorder, to scrutinize the reliability and validity of our current taxonomic system, and to consider alternatives to it.

The Etiology Enigma: What Is Mental Illness?

Defining what we mean when we say that an individual has a "psychological disorder" is a much more difficult task than it might seem at first blush. The root of this controversy may, in fact, come from the fact that modern psychiatry stems from physical medicine. Physical medicine (i.e. allopathic medicine outside the realm of psychiatry) has progressed to a point where the etiology of physical disorders can be identified with relative certainty. For example, one might be suffering from tuberculosis if one has impaired breathing and presents with a productive cough (including blood in the sputum). Although the signs and symptoms (syndrome) the patient presents might be shared by lung cancer, physical medicine has some relatively straight-forward ways of assessing the different etiologies and determining illness. The fact that modern psychiatry is based on physical medicine predisposes it to seeking the same kinds of hard answers when looking to define mental illness. Psychological disorders, however, are not currently understood well enough such that a certain physiological marker can be identified as out of a "normal" range, thus indicating disease. When one examines a patient suffering from mental disease, at best one can observe a coherent syndrome, oftentimes without the benefit of thoroughly understanding its etiology.

With an understanding of the considerable ambiguity surrounding the etiology of mental diseases, definitions of mental "illness" must be found without the benefits of the physiological markers employed by physical medicine. Multiple theories have been proposed, some of which will be briefly discussed here to illustrate an inherent difficulty underlying the taxonomic process. However, the complete arguing of this particular point would merit an entire paper in itself. Ossario (1985) proposed that the inability to complete intended tasks and participate normally under social circumstances characterized mental illnesses. While definitions like Ossario's are intended to be broadly inclusive, they also fall prey to being too broad, a point well illustrated by Bentall's aforementioned satire. More formally, Wakefield (1997) criticized Ossario for being overly inclusive and that none of the defining elements are necessary or sufficient for the classification of mental disorder.

Wakefield proposed his own definition for a mental disorder in 1992, and while it seems to be an improvement on Ossario's, it is not without its own faults. Wakefield's proposed definition of mental illness involves "harmful dysfunction." "Harmful" refers to impaired activity as compared to the norm. "Dysfunction" refers to the absence or dysfunction of a normal biological mechanism that is related to mental function. These biological mechanisms are described in further detail by Wakefield; he asserts that these have been shaped by evolution. Although Wakefield's lan-

guage does highlight the underlying difficulties at hand (as noted by Spitzer, 1997), it is far from universally accepted. Lilienfield & Marino (1995) have argued that psychological traits aren't the results of evolution – they are instead the by-products. They posit that natural selection often leads to a good deal of variability among individuals (rather than phenotypic uniformity) and that many disorders are simply positive adaptations that are overly expressed in the patient. For example, anxiety is a positive adaptation in the sense that organisms with a healthy anxiety mechanism avoid potentially life-threatening situations. Anxiety disorder is simply an over-amplification of a positive trait.

Other problems with such a definition certainly exist – the "harmful" effect of a disorder requires the diagnostician to make an assessment that is quite subjective, and might well vary considerably from clinician to clinician. This decreased reliability does not necessarily imply that the validity of the diagnosis or the resulting treatment will be substantially better or worse, but it is certainly a danger. Perhaps more troubling is the "dysfunction" in question. Wakefield refers to the dysfunction of the underlying biological correlates of illness, and this would be fine if we knew what those biological processes often were. However, as noted, many mental illnesses are understood rather poorly, if at all, in regard to their etiologies. Wakefield's definition of mental illness shows the penchant for the objective that harkens back to psychiatry's roots in physical medicine.

Given the problems inherent in accurately defining something as contentious as psychological disorders, the DSM-IV presents a set of guidelines to be considered in the determination of whether a mental illness is truly present. These guidelines include statistical abnormality, the violation of social norms, personal distress, and disability/dysfunction. These four points, each of which is necessary but not sufficient for diagnosis of illness, are meant to be coupled with the observation that they are unexpected in given circumstances – the idea being to provide the inclusiveness that Ossario sought without yielding inappropriate diagnoses. The DSM-IV guidelines also avoid basing a definition on unknown etiologies, as Wakefield's model does. However, the system is not perfect in its definition of illness, and an understanding of this fundamental instability is requisite to the exploration of the more complex topic of compiling the taxonomy of mental illnesses.

Partitioning the Continuum: Is Syndromal Taxonomy Valid?

Like the definition of mental illness itself, the taxonomy of such disorders cannot simply follow the format of physical medicine. Again, a large degree of uncertainty in regard to the etiology of mental illnesses prevents one from grouping disorders based on their underlying causes. Instead, we are presented with clinical signs and symptoms. The same (unknown) etiology may well lead to myriad manifestations. Conversely, the same clinical signs and symptoms may originate from very different etiologies. Without the luxury of a comprehensive understanding of etiology, the only reliable way of grouping disorders is on the grounds of symptomatology.

The current taxonomic system is an organization of discrete syndromes, and it has certainly increased the reliability with which mental illnesses are diagnosed. This should be seen as a crucial first step, for uniformly effective treatments or correlative factors for a disease can only follow reliable diagnosis. To demonstrate the increased reliability seen in modern classification, Hasin et al. (1996) performed a test/re-test of patients with dual diagnosis or substance abuse problems. Their test/re-test comparison revealed excellent reliability in the diagnosis of these patients for whom diagnostic reliability had been a problem before the advent of DSM-IV. Similarly, Fennig et al. (1994) used the DSM-III to assess 6-month stability in patients diagnosed with psychosis and schizophrenia, finding 87-89% of patients staying in the same broad category, with only 62-68% staying in the same sub-category. Additionally, Sartorius et al (1995) found that inter-rater reliability was high for the diagnosis of most categories, but at the sub-type level only half of the categories showed excellent agreement. From the aforementioned studies, one can gather that the syndromal taxonomy of mental illness has at least increased the reliability of diagnosis in general terms, although the diagnosis of sub-types may be more difficult as less research has been done in these more specific areas.

Less promising results regarding reliable diagnosis have been found with some Axis II (personality) disorders. A good illustration of this is the Nelson & Rice (1997) study in which they tested 1-year stability in patients originally diagnosed with obsessive-compulsive disorder (OCD) – only 19% of patients were re-diagnosed. This seems a far cry from the relatively heartening support of increased reliability seen above. But might this fluctuation be characteristic of the type of disorder seen here? One can only surmise that different etiologies exist for different types of mental illnesses. While schizophrenia, which research suggests is at least partially biological in origin, has a relatively reliable diagnosis, it is reasonable to give credence to the idea that personality disorders may only become evident when a particular stressor is applied to an individual who, through

personality disposition, is prone to crossing that ambiguous threshold into "disorder." Given a change in circumstances over year-long course of this study, what was a personality disorder might well fade into "normality" while the predisposition remains. The disorder could certainly recur at some point in the future, should the appropriate stressor(s) be applied. Support for this idea will be later mentioned in this paper under the topic of dimensions of personality and disease.

The validity of disorders under our current taxonomic scheme seems, unfortunately, to be as full of caveats as is the reliability. It is important here to distinguish between validity and utility. What the clinician means by "validity" may be quite different from what the researcher means in using the same term. In a discussion of scientific validity, a disease-entity is only (according to Kendall and Jablensky, 2003) valid if one of the following two categories is met:

1) If the defining characteristic of the category is a syndrome (group of symptoms), this syndrome must be demonstrated to be an entity, separated from neighboring syndromes and normality by a zone of rarity.

2) If the defining characteristics are more fundamental (defined by a physiological, anatomical, histological, chromosomal, or molecular abnormality), clear qualitative differences must exist between these defining characteristics and those of other conditions with a similar syndrome.

Two points must be made in regard to the above guidelines. The aforementioned "zone of rarity" refers to the lack of continuous variation between two similar syndromes. If one syndrome contains a certain set of symptoms, then a similar syndrome is said to be independent if and only if the prevalence of a middle ground, a syndrome composed of some symptoms shared with the first and some symptoms shared with the second, is very rare. This is often not found across the spectrum of mental illnesses (Kendall & Jablensky, 2003). The defining characteristics referred to in the second point are reflective of Andreasen's additions (molecular genetics & molecular biology, neurochemistry, neuroanatomy, neurophysiology, and cognitive neuroscience) to Robins and Guze's original validating criteria (clinical description, laboratory studies, delimitation from other disorders, follow-up studies, and family studies). Scientific progress is being made in elucidating the etiologies of numerous mental illnesses, albeit slowly. Faraone et al (1995) reviewed 30 studies of putative genetic indicators of schizophrenia, and found that only 6 turned up results that improved the notion of a genetic etiology. The aforementioned results call attention to the amount of difficulty encountered in trying to validate conceptions of mental illnesses in the scientific sense.

Some (or most) of the DSM-IV categories might not be valid in the scientific sense that they aren't discrete disease entities either separated from one another by zones of rarity or distinct etiologies. However, they do seem to be invaluable for clinicians; that is, they have great utility. The DSM-IV defines utility (cited in Spitzer, 2001) by the helpfulness of a category and the information provided about the disease in terms of diagnostic power, prognosis, treatment plans, and the like. We can therefore see where a problem might arise with the DSM-IV, commonly used by both researchers and practicing clinicians- two groups that often have very different needs in terms of "validity." For the diagnostician, the current DSM-IV is valid in a sense of utility, for many researchers, problems arise because the DSM assigns arbitrary cutoffs to what might better be described as a continuum of dysfunction. As this manual guides research to a degree, more pertinent research should be done on deciphering whether there are in fact some disorders that do have zones of rarity and distinct etiologies or whether they are, by and large, characterized by a continuum. Researching a disease that is accurately characterized as a continuum of dysfunction as if it were simply syndromal is inefficient. Herein one sees the benefit of having different versions of a reference for clinicians (where validity in a utility sense is important) and researchers (where validity in the scientific sense is paramount) – the ICD-10 is a good example of a reference that avoids some of the problems seen with the DSM-IV .

Dimension and Dysfunction: Alternatives to Syndromal Taxonomy

It is possible that, if the vast majority of disorders are best represented by dimensions of disease, illness should be classified dimensionally rather than by syndrome. Doing such would at least relieve the need for separate clinician/research manuals. But is this appropriate? Support for a dimensional system of classification, at least in terms of personality disorders, comes from work done by Hans Eysenck. Eysenck put forth a model of personality that consisted of three factors: introversion-extraversion, neuroticism, and psychoticism. Each individual falls somewhere along a continuum in relation to each of these three traits. Eysenck's work was based on Ivan Pavolov's, who noted differences in the excitability of the dogs he was training. Eysenck used this excitability difference in dogs to underpin his theory

that each individual has a different nervous system, and as a result some will possess nervous systems that are more easily excited while some possess nervous systems that are more easily inhibited. Eysenck posited that introverts have nervous systems that are more easily excited (via the reticular formation), while extraverts' nervous systems are more easily inhibited. This theory clearly lends itself to a dimensional range of excitability based on the relative strengths of the inhibitory/excitatory mechanisms in the brain. The importance of the introversion-extraversion range is underscored when taken in conjunction with the fact that Eysenck surmised it to be explanatory of variation within the fields of neuroticism and psychoticism (Claridge, Origins of Mentall Illness).

Eysenck's dimensional model of personality seems logical enough, and the biological underpinnings of his theory have been supported by evidence. But for a theory of this nature to have any influence on the taxonomic organization of mental illnesses, clinical observations are required in addition to organized laboratory experiments. These clinical observations have come in the form of high comorbidity rates among personality disorders . Personality disorders have an astoundingly high comorbidity rate that could easily be explained by Eysenck's three-dimensional model of personality. With each individual expressing a particular (x,y,z) coordinate in three dimensions of personality, it is rather straight-forward to surmise that if any one of these variables is sufficiently deviant from the average, multiple personality disorders (different manifestations of the same wayward variables) could occur. The shades of grey that result have been indicated clearly by clinical research. Minor differences in the definition of major depression, to provide one clinical example, greatly influenced its prevalence in study populations (Kendler, 1988; Regier, 1998).

With the advent of more complex scientific methods of exploring the neural underpinnings of mental illnesses, it seems clearer that not all of them are the result of aberrant personality traits – some do indeed have valid biological roots. This is not to say, however, that the cause of a given mental illness is either personality based or biologically based. It seems far more rational to examine mental illnesses in the context that each person has a certain personality, which may predispose one to a certain illness. Taken in hand with a possible biological predisposition and the presence of environmental stressors (should the biological and personality predispositions be mild enough to not cause dysfunction themselves), disease may manifest. As an example, Nathan (1993) found that alcohol abuse and dependence manifested differently based on differing personality traits. Given the idea that the causation of mental illnesses might be a more complex web than thought, it seems foolish to assign either a dimensional or a categorical designation exclusively to all illnesses.

Some illnesses, like schizophrenia, may in fact require both. Schizophrenia is categorically differentiated from affective disorders, although Kendall (1975, in Cooper & Cooper Adult Abnormal Psychology) has found that phenothiazines are the most effective treatment for both and that the same range and probability of outcomes exists for both disorders. This is highly indicative of the fact that schizophrenia and some affective disorders may just be different areas on one dimension. But schizophrenia should not necessarily be seen to be completely dimensional for we still do have some very useful categories in determining its sub-types. Different sub-types have different, all-or-none categories (e.g. one hears voices or one does not). The fact that the affective side may be best viewed as a dimension, on top of which one can super-impose further sub-categories is only further supported by the fact that those categories may differ in themselves (according to things like the frequency with which one hears voices, the severity of the statements they make, etc.). The best system may be one in which there are numerous categories and dimensions for more complex mental illnesses while others may be simply personality-based (Clark, 1998, suggests a complex hierarchy of categorical and dimensional classification).

Conclusions

There are numerous implications of the taxonomic system on treatment. Rachman & Philips have argued that it is detrimental for patients to be labeled with a mental illness because of the associated societal stigma (Rachman & Philips, 1978; Rachman & Wilson, 1980, in Cooper & Cooper Adult Abnormal Psychology). No doubt this stigma comes from a poor understanding of what causes mental illnesses, and should the etiologies of psychological disorders come to be more fully understood, these stigma may recede considerably. Until that time and in spite of stigma, so long as identification is conducive to treatment, clinicians are ethically bound to denote full record of a patient's illness (kept confidential, of course). Yet other practical problems regarding treatment exist as well. Rosenham's 1973 study, where he and a number of colleagues voluntarily faked mental illness so as to be committed, reveals a rather unsavory state of the facilities for the treatment of the mentally ill. The isolation and prison-like environment to which the mentally ill are subjected is no doubt pathological in and of itself. Might this denote the need to return to facilities such as the

moral hospitals of the nineteenth century, in which patients were treated as normal people with temporarily illnesses? Housing patients in a more comfortable setting where they can be intellectually stimulated may be highly helpful in their recovery. Even the medieval practice of circulating the mentally ill among relatives and members of their close communities had its merits – we can certainly assume that today's institutions are stressors in and of themselves, and given the aforementioned personality predispositions, being in a comfortable environment might well help quell forceful manifestations of wayward personality traits.

To conclude, we find ourselves at a nexus in the field of psychiatry; a place where the possibility, rooted in empirical evidence, exists for overhauling our current syndromal taxonomic system of mental illnesses to include dimensions where appropriate. This effort has long been confounded by questions of theory (what is a "mental illness" after all?) as well as by questions of laboratory science. Nevertheless, demonstrable advances have been made in increasing the reliability of diagnoses, without which further advances would certainly be hampered. The bearing of etiology on true validity cannot be underestimated, and is not fully appreciated by our current syndromal taxonomic system. For example, McNally (1991) has shown that single incident stressors lead PTSD patients to relive their experiences while prolonged stressors lead PTSD patients to display dissociative symptoms. Conversely, we currently denote different diagnostic categories (GAD and major depression) for illnesses that have extremely similar, if not indistinguishable, neural correlates (Kendler, 1996).

The optimal taxonomy is clearly one, like physical medicine, that is based on classification by etiology. The most effective and efficient treatments only come from being able to remedy the underlying cause of disease, mental or physical, and so long as we are unable to group disorders based on etiology, these treatments will not be realized. We are currently unable to do this because of vast gaps in our understanding of mental illnesses, and research needs to be targeted to parse personality causes from biological ones, as well as in the further refinement of functional models for each group. We can conclude that alternatives to our current system might be preferable; in the temporary sense an integration of dimensions and categories would be beneficial, and in the long-term, a thorough development in our understanding of etiology is imperative.

References (Note: Parenthetical citation)

1. Andreasen, NC. (1995) The validation of psychiatric diagnosis: new models and approaches (editorial). Am J Psychiatry, 152, 161-162.
2. Bentall, R. (1992). A proposal to classify happiness as a psychiatric disorder. Journal of Medical Ethics, 18, 94-98.
3. Claridge G. Origins of Mental Illness. Oxford, UK, Blackwood Press, 1985. Chapters 1 and 2.
4. Clark LA (1998) Dimensional approaches to personality disorder assessment and diagnosis. Personality and Psychopathology (ed. Cloninger). Washington , DC: Am. Psychiatr. Press. (In Press)
5. Clark, Watson & Reynolds. (1995) Diagnosis and Classification of Psychopathology. Annu. Rev. Psych. 46 : 121-153.
6. Cooper, Z. & Cooper, P.J. Classification and diagnosis p. 6-25. In Adult Abnormal Psychology.
7. Faraone et al. (1997) Diagnostic accuracy and linkage analysis: How useful are schizophrenia-spectrum phenotypes? American Journal of Psychiatry, 152, 1286-1290.
8. Fennig et al (1994) Six month stability of psychiatric diagnoses in first-admission patients with psychosis. American Journal of Psychiatry, 151, 1200-1208.
9. Harris, J., Birley, J. L., & Fulford, K. W. A proposal to classify happiness as a psychiatric disorder. British Journal of Psychiatry, 162, 539-542.
10. Hasin, Trautman, Miele, Samet, Smith, Endicott. (1996) Psychiatric Research Interview for Substance and Mental Disorders (PRISM): reliability for substance abusers. American Journal of Psychiatry, 153, 1195-1201.
11. Kendall & Jablensky. (2003) Distinguishing Between the Validity and Utility of Psychiatric Diagnoses. American Journal of Psychiatry, 160, 4-12.
12. Kendler, KS. (1988). The impact of diagnostic hierarchies on prevalence estimates for psychiatric disorders. Compr Psychiatry, 29, 218-227.
13. Kendler, KS (1996). Major Depression and generalized anxiety disorder: same genes, (partly) different environments – revisited. British Journal of Psychiatry Supplement, 30, 68-75.
14. Lilienfield SO, Marino L (1995) Mental disorders as a Roschianconcept: a critique of Wakefield's harmful dysfunction analysis. Journal of Abnormal Psychology, 104: 411-420.
15. McNally, R.J. (1991) Assessment of Post-traumatic Stress Disorder in Children. Psychol. Assess. 3 : 531-537.
16. Nathan, PE. (1993) Can alcohol abuse and dependence be dimensionalized – and should they be? Psychol Inq. 4 : 113-115.
17. Nathan & Langenbucher. (1999) Psychopathology: Description and Classification. Annu. Rev. Psychol., 50, 79-107.
18. Nelson & Rice (1997) Stability of diagnosis of obsessive-compulsive disorder in the Epidemiological Catchment Area study. American Journal of Psychiatry, 154, 826-831.
19. Regier et al. (1998) Limitations of diagnostic and assessment instruments for mental disorders. Arch Gen Psychiatry, 55, 109-115.
20. Regier, Kaelbert, Roper, Rae, Sartorius. (1994) The ICD-10 Clinical Field Trial for mental and behavioral disorders: Results in Canada and the United States. American Journal of Psychiatry, 151, 1340-1350.
21. Robins & Guze. (1970) Establishment of diagnostic validity in psychiatric illness: its application to schizophrenia. Am J Psychiatry, 126, 983-987.
22. Rosenhan, D. L. (1973). On being sane in unsane places. Science, 179, 250-258.
23. Spitzer (2001) Values and assumptions in the development of DSM-III and DSM-III-R: an insider's perspective and a belated response to Sadler, Hulgus, and Agich's "On values in recent American psychiatric classification." J Nerv Ment Dis, 189, 351-359.
24. Zimmerman, Pfohl, Coryell, Corhenthal, Stangl. (1991) Major depression and personality disorder. J Affective Disorders. 22 : 199-210.

RISK PERCEPTION AND THE STIGMA OF HIV/AIDS: WHY ROUTINE TESTING WILL CHANGE HOW AMERICANS VIEW THE DISEASE

by Vanessa Lynskey

The Centers for Disease Control and Prevention (CDC) recently introduced new guidelines which will make HIV testing a routine part of a thorough medical evaluation. Given the high rates of incidence and transmission of the disease, and the startling number of people who are unknowingly infected, the number of people who seek testing on their own is unacceptably low. As this low testing rate can be attributed in many instances to an incorrect assessment of risk based on the common stigmas associated with HIV, routine testing will help to break down these barriers by normalizing the process and bringing to light the common misperceptions about risk factors. As a result, routine testing should lead to a better-informed public with lower rates of HIV transmission.[1]

Since first diagnosed nearly three decades ago, HIV/AIDS has received widespread attention both in the media and the general public, with events such as the annual World AIDS Day designed to increase awareness of the disease and ways in which it may be prevented. Despite the large emphasis placed on HIV prevention, however, a recent study by the Centers for Disease Control and Prevention (CDC) reported that approximately 50 percent of individuals between the ages of 15 and 44 had never been tested for HIV,[2] thus explaining why such a large percentage of those infected (roughly one quarter of the estimated 1 million infections[3]) remain unaware of their HIV status. If HIV is such a widely prevalent disease, and knowledge about one's infection status can prevent transmission and drastically improve the length and quality of life, why do so few people seek testing?

The answer to this question lies tangled within the social history of the disease and the way in which it was represented to the public upon first diagnosis. A highly stigmatized disease from the outset, this has created a host of misconceptions about the disease, and has consequently led people to miscalculate their own level of risk of contraction. When people feel that they do not fall into one of the groups typically affected by HIV, they fail to view themselves as vulnerable to it and hence do not get tested. For this reason, the introduction of routine testing will significantly alter the public's perception of the disease, as well as their own susceptibility to it, by elucidating the true patterns of the disease and shifting the focus away from only those groups of people most commonly associated with HIV.

A Changing Demographic

Twenty-five years after the first diagnosis of HIV, an estimated 40,000 people become infected with the virus annually,[4] for a combined U.S. prevalence of roughly 1 million cases.[3] Of these 1 million infected individuals, approximately one quarter (164,000-264,000) are unaware of their HIV status,[3] thus creating major personal and public health concerns as these individuals are responsible for nearly 65% of all new infections[5]. In order to reduce this high level of transmission by unknowingly infected individuals, it is crucial that more people undergo testing and become aware of their HIV status early.

Lack of accurate knowledge about the trends of HIV in the population and the changing face of the demographic affected by the disease strongly influence peoples' perception of risk. When it first arose in the population, HIV immediately became associated with homosexual males, as it was first diagnosed among members of this population.[6] As more information became available about the disease, however, scientists determined that in fact three main modes of transmission existed: "sexual contact with an infected person, exposure to infected blood or blood products (mainly through needle-sharing among IV-drug users), and perinatal transmission from an infected woman to her fetus or infant."[7] These three defined modes of transmission, along with summary statistics of those initially infected with the disease, quickly led to the development of risk categories referred to as the "4 H's": homosexuals, Haitians, hemophiliacs, and heroin addicts.[8] These 4 H's, though intended to define generic risk categories based on actual incidence data, actually played a major role in producing the stigma associated with HIV. Although only a minority of people from each of these groups was infected with HIV, their distinction as "risk factors" led people to falsely stereotype anyone in each of these

categories as dangerous based on their apparently inherent risk for contracting the disease. While these categories may have been a fairly accurate representation of the population of infected individuals at the time, they quickly became insufficient descriptors of risk factors as the demographic of those infected began to change.

Historical Trends

In the years immediately following its diagnosis in the human population, HIV remained somewhat contained among the adult male homosexual population. The first reports by the CDC that linked certain opportunistic infections to the HIV virus found in a late 1981 survey that "over 95% [of those infected] were men 25-49 years of age," and furthermore, "ninety-four percent (95/101) of the men for whom sexual preference was known were homosexual or bisexual."[6] By 1988 this demographic had already begun to change as the incidence began rising in females. However, a comparison between the 1988 statistics and those from 2005 tells much more, as it reveals how drastically the affected demographic has changed over the past twenty years (Table 1). This comparison reveals that although homosexual males and males in general do still account for a significant fraction of HIV cases, the number of infected women and the number of infections attributed to heterosexual contact have increased dramatically.

Table 1. Modes of Transmission

Demographic/ Mode of Transmission	% of infections in 1988[7]	% of infection in 2005[9]
Men who have sex with men (MSM)	63%	49%
Heterosexual contact	4.8%	32%
Males	91%	74%

As a reflection of this demographic shift, new risk factors have been defined that more thoroughly address the risky behaviors which have led to an increase in incidence outside of the initially affected populations. Whereas the 4 H's dealt only with sexual risk resulting from homosexual contact, six newly defined categories outline current risks related to sexual behavior in the past year, only two of which deal with homosexual contact:

1. Five or more opposite sex partners
2. Men having sex with other men
3. Sex with an injecting drug user (IDU)
4. Sex with an HIV-infected person
5. Exchange of sex for money or drugs
6. Having been treated for an STD
7. For females, sex with a man who has sex with a man[2]

This comprehensive set of risks reflects the changing demographic of those infected so as to allow people to more accurately assess their own risk of contracting HIV. Unfortunately, these risk factors, used mainly as a tool for research and data purposes, are unknown to a large percentage of the general population and therefore people remain in the dark about their exposure status. Were everyone aware of these risks, however, there would still be no guarantee that they would pay attention to the warnings and seek testing on their own.

As the demographic affected by HIV/AIDS continues to evolve, ignorance of the disease trends continues to prevent individuals from accurately assessing their own risk of contraction, thus leading to lower rates of testing and higher levels of incidence. In an effort to increase testing and detection rates, the CDC has recently released a report calling for the routine testing of all individuals, regardless of their perceived risk status. Through these revised testing practices, they aim to overcome risk perception barriers and break down the social stigma associated with HIV and HIV testing.

The Goals and Procedures of Routine Testing

With regards to adults and adolescents, the CDC defines their objectives for routine testing as follows:

"…to increase HIV screening of patients, including pregnant women, in health-care settings; foster earlier detection of HIV infection; identify and counsel persons with unrecognized HIV infection and link them to clinical and prevention services; and further reduce perinatal transmission of HIV in the United States."[10]

In order to achieve these objectives, the revision of current testing recommendations was crucial. The revisions outlined in the CDC's September 2006 report entitled "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-

Care Settings" differ from previously published guidelines in the following ways:

- HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening)
- Persons at high risk for HIV infection should be screened for HIV at least annually.
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.[10]

The most notable change in these recommendations is that HIV screening would now adopt an opt-out model; rather than leaving it up to an individual to realize his or her own risk and actively seek out testing, or be referred for testing at the recommendation of a physician, the HIV test would now become standard for all individuals seen in health-care settings. This routine process eliminates the potential for bias and human error with regards to risk assessment.

Overcoming Risk Perception and Breaking Down Stigma

The fact that HIV testing guidelines differ from those of other medical tests provides evidence of the social stigma attached to it. Written consent and counseling are not required for blood tests that could reveal cancer or for urine tests that could reveal kidney disease; such routine tests have been accepted as necessary components of a thorough medical examination. However, when it comes to HIV, many people warn about the dangers of eliminating such practices, as they fear that patients may not be as thoroughly prepared for a positive diagnosis. This logic seems faulty as patients would likely find themselves equally unprepared for a diagnosis of cancer or kidney disease, and yet no debate exists about requiring counseling under these conditions. Especially because a diagnosis of HIV no longer implies imminent death thanks to advances in medicine over the past two decades, pre-test counseling has much less to do with preparing someone for the medical realities of a positive diagnosis than with preparing them for the social realities of such an outcome. Ironically, however, requiring counseling and written consent before testing actually helps to perpetuate the stigma associated with the disease by implying that something about HIV makes it more delicate and worthy of special attention.

What about HIV makes it different from other infectious diseases? It can be prevented easily. Because contraction of HIV usually results from involvement in so-termed "risky activities", those who contract HIV can be seen as irresponsible and even deserving of their condition as a result of their "reckless" behavior. In order to eliminate this judgmental perception and avoid placing blame on infected individuals, HIV must be treated like other communicable diseases which do not require pre-test counseling or written consent.

Peoples' levels of risk are directly correlated to the evolving demographics of those affected, leaving many susceptible to contraction that would not normally recognize this vulnerability. Just as individuals may miscalculate their own risk, so too can physicians miscalculate the risk of their patients. Physicians are not always above the influence of society's biases, and they therefore may fail to recognize a patient's risk if he or she does not fit into the supposed "typical demographic" of an HIV patient. Although exposure to HIV may have been associated with social factors such as race, class, and sexual orientation in the past, those ties do not hold as strong now and therefore these social markers should no longer be given such heavy weight when assessing a patient's risk.

In addition to those who remain unaware of their risks, many people who do recognize their vulnerability are unwilling to disclose this important information to their physicians[10], reflecting again the power of social stigma. The fact that individuals would go untested and therefore potentially untreated rather than disclose to their physicians their risk for HIV indicates that there still exists great fear of discrimination based on risky behaviors. While routine testing cannot address outside discrimination resulting from a positive test, it will allow these individuals to receive the medical care they need without having to "incriminate" themselves to their physician by requesting the test.

For each of the aforementioned reasons and certainly many more, routine testing will help to break down the social stigma associated with HIV and HIV testing.

Skepticism and Opposition

Despite the numerous personal and public health

advantages afforded by routine testing, many people remain skeptical of the revised testing practices. Sources of concern include the elimination of pre-test counseling and the lack of sufficient resources to ensure that treatment is available to all who test positive, as well as patient privacy rights and informed consent.[5, 11-15]

Because the new recommendations eliminate the currently mandated pre-test counseling, a fear exists that people would be unprepared for a positive test result and that they would not receive accurate knowledge about HIV, HIV risk reduction, and HIV testing; however, in their article "HIV Counseling and Testing: Less Targeting, More Testing", Koo et.al. report that "there are no studies establishing the additive value of pretest counseling in counseling and testing services."[16] On the contrary, making testing routine and involving every patient in the screening process will open the door to more honest communication between physicians and patients. Such dialogue will allow doctors to discuss HIV and HIV prevention with patients early, hopefully leading to more widespread adoption of prevention strategies.

Lack of access to treatment is also a major concern when it comes to HIV. According to Thomas Coates, director of the Program in Global Health at the University of California, Los Angeles, "The people most likely to get HIV are the least likely to have access to healthcare."[5] Citing this claim as an argument against routine testing does not provide constructive solutions to overcome the various barriers to health care access. If people who lack sufficient resources test positive for HIV, it is possible that they will be unable to obtain treatment; however, if they are never given the test it is certain that they will not receive treatment. A rise in the number of identified infections as a result of routine testing could even put pressure on the government and other private sources to allocate more funds for treatment of individuals who cannot afford it. Additionally, an increase in the number of early detections should decrease the transmission rate as people will become aware of their need to take extra precautions. This would in effect reduce the amount of people needing treatment and therefore in the long run reduce the amount of money being spent on HIV treatment. For this reason, all parties with a financial stake in the care of HIV-infected individuals should support routine testing.

Issues of privacy, while a valid concern when dealing with HIV, do not differ when discussing opt-out or opt-in testing. Whether a person requests a test or simply does not opt-out of the test, there exists an inherent risk of his or her medical status and sexual history becoming public, and therefore this argument should not be taken into account in discussions of routine testing. People also worry that eliminating the need for written consent could lead to some patients being tested without their consent or knowledge, "whether due to vulnerability, lack of initiative, lax hospital procedures, or cultural differences."[13] This concern is a valid one, and therefore it will be crucial for physicians to thoroughly explain to their patients these new procedures, especially during the first few years of their use. Media campaigns and the availability of more literature regarding the topic could also help to inform the public so that people are aware of the new practices and their rights with regards to refusing a test.

While these concerns do raise some interesting scenarios that deserve careful consideration, the benefits of routine testing are great enough that any potential sources of conflict can be dealt with and adjusted so as to ensure that every patient receives optimal care.

Conclusions

While certain individuals and activists remain skeptical of routine testing, this new process offers enormous benefits not only with regards to individual and public health but also in dealing with the social stigma of HIV and individuals' perception of risk. Routine testing conquers stigma in a simple way: there can be no stigma associated with testing if everyone is being tested. When only certain individuals or groups regularly seek out testing, it becomes easy for society to associate these groups with the disease and discriminate against them as a result. However, when there ceases to be a division among "those who get tested and those who don't" or "those who are at risk and those aren't," there ceases to be a basis for exclusion or discrimination. This latter distinction is especially irrelevant in light of recent trends, which indicate that while some individuals are decidedly more at risk than others, every sexually active or injection-drug-using individual faces a risk for contracting HIV, regardless of sexual orientation. Therefore, routine testing represents a crucial step in the process of breaking down the social stigma of HIV and HIV testing, and in effectively detecting and preventing the transmission of HIV in the population.

References

1. Scott, J. Blake. Risky Rhetoric :AIDS and the Cultural Practices of HIV Testing. Carbondale: Southern Illinois University Press, 2003.
2. Anderson, John E., William D. Mosher, and Anjani Chandra. Measuring HIV Risk in the U.S. Population Aged 15-44: Results from Cycle 6 of the National Survey of Family Growth. Vol. 377. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2006.
3. Glynn, M., and P. Rhodes. "Estimated HIV Prevalence in the United States at the End of 2003 (Abstract)." National HIV Preventon Conference. Atlanta, Georgia, June 12-15, 2005.
4. ---. CDC Media Facts: HIV and AIDS in the United States: A Picture of Today's Epidemic., November 2006b. 3 December 2006 <http://www.cdc.gov/hiv/resources/factsheets/PDF/GeneralHIVFact%20SheetFINAL-Nov%202006.pdf>.
5. Reilly, Michael, and Andy Coghlan. "To Know Or Not to Know ... would Routine HIV Testing Help Stem the Epidemic, Or Spell Big Trouble for Vulnerable Individuals?" New Scientist 191.2561 (2006): 8(2).
6. Centers for Disease Control and Prevention. "Follow-Up on Kaposi's Sarcoma and Pneumocystis Pneumonia." Morbidity and Mortality Weekly Report 30 (1981): 409.
7. Centers for Disease Control and Prevention. "AIDS and Human Immunodeficiency Virus Infection in the United States: 1988 Update." Morbidity and Mortality Weekly Report 38 (1988a)
8. Gallo, Robert C. "A Reflection on HIV/AIDS Research After 25 Years." Retrovirology 3.72 (2006) <http://www.retrovirology.com/content/3/1/72>.
9. Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report, 2005. Vol. 17. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2006.
10. Centers for Disease Control and Prevention. "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings." Morbidity and Mortality Weekly Report 55.RR-14 (2006)
11. "Winners and Losers: Routine HIV Testing is on the Cards. Who Will it really Help?(Editorial)." New Scientist 191.2561 (2006): 5(1).
12. Opar, Alisa. "US Plan for Routine HIV Testing Alarms Privacy Advocates." Nature medicine 12.8 (2006): 866-.
13. Gostin, Lawrence O. "HIV Screening in Health Care Settings: Public Health and Civil Liberties in Conflict?" JAMA, The Journal of the American Medical Association 296.16 (2006): 2023(3).
14. Hollander, Dore. "Aids Testing Plan Stirs Controversy.(Brief Article)." Perspectives on Sexual and Reproductive Health 38.3 (2006): 125(1).
15. "Plans to Expand AIDS Testing Alarm Activists. (Acquired Immunodeficiency Syndrome)." The AIDS Reader 16.8 (2006): 388.
16. Koo, Douglas J., et al. "HIV Counseling and Testing: Less Targeting, More Testing." American Journal of Public Health 96.6 (2006)

-A TuftScope Commentary-

THE RIGHT TO REFUSE

by Kathryn Reiser

The rights and duties of the patient and the physician regarding the option of life-sustaining treatment is a hotly contested issue in American healthcare. When a patient suffers from severe disability or terminal illness, the patient's quality of life may be so far reduced as to drive him or her to decide against such treatment. This scenario is not uncommon and it presents an ethical dilemma to the physician, who may be torn between his sympathy for the patient, his moral obligations as a healthcare professional, and his own personal beliefs. In this article, Kathryn Reiser explores arguments for and against the patient's autonomy in this mater, arguing that with very few exceptions, the patient is entitled to refuse life-sustaining medical treatment and is not obligated to justify his or her decision.

The relationship between patient and healthcare professional is often defined by the common goal of sustaining the life of the patient. However, this may not be the case when a patient suffers severe disability or terminal illness and requires life-sustaining treatment to live. In this situation, the patient's quality of life may be so far reduced as to drive him or her to decide against further treatment. This scenario is not uncommon and it presents an ethical dilemma to the physician, who may be torn between his sympathy for the patient, his moral obligations as a healthcare professional, and his own personal beliefs. Here I argue that with very few exceptions, the patient is entitled to refuse life-sustaining medical treatment and is not obligated to justify his or her decision in order to have and exercise that right.

Refusal of treatment on the part of a severely ill or disabled person is not unreasonable because many complicated and deeply personal issues may factor into the patient's decision; this decision should be respected regardless of his or her personal grounds for reaching it. Some reasons for refusal of life-sustaining medical treatment are decay in quality of life, both for the patient and other involved parties; the artificiality of medically sustained life; and the value of patient autonomy both during and after a decision regarding treatment. I will explore these three reasons in detail, but first I will address two arguments against the right to refuse, and show that they are inadequate grounds for forbidding a severely disabled or terminally ill patient to refuse life-sustaining treatment.

Many have argued against the patient's right to refuse treatment, but these arguments are not strong enough to force the patient to justify his or her refusal. First, Ackerman[1] makes the case that the duty of the physician should be to restore autonomy to the patient, which may be compromised during times of acute disability or illness. He suggests that the "transforming effects of illness" cloud the judgment of the patient and prevent him or her from making a truly informed and rational decision about pursuing further treatment. According to this argument, the patient may be unable to make the choice he or she would make under less compromising conditions. Ackerman seems to view the severely disabled or ill patient as incompetent. I argue, however, that neither the desire to refuse treatment nor the illness or disability itself should serve as grounds for classifying a patient as incompetent. Powell and Lowenstein[4] agree that "the competence of patients with recent traumatic injuries may be questioned," but they endorse careful evaluations of capacity before overriding the patient's wishes. If, after competency has been proven and options for rehabilitation discussed, the patient still wishes to refuse treatment, it is his or her right to do so. The patient is not obligated to justify this decision.

Second, Michel[3] objects to the notion that refusal of treatment by severely handicapped, but otherwise competent, people amounts to suicide. For this reason, she argues that the Court should not readily grant disabled persons the right to refuse life-sustaining treatment, and that "it is not the disability itself that makes life so unbearable that suicide seems a reasonable solution, but rather the conditions that people with disabilities have to contend with".[3] Disabled persons unquestionably deserve equal respect in court, but it is simply unreasonable to treat such persons as ordinary patients in every regard; their situations constitute a special case. Michel's call for the "eradication of social barriers"[2] for handicapped people is unfortunately a very idealistic goal, as there is little hope that most patients on life support will return to normal, independent, or autonomous lives if they remain on treatment. For this reason, refusing treatment cannot be considered suicide in the same sense as other suicide cases. Michel's argument against the right to refuse life-sustaining treatment cannot override the motives for permitting it.

The basis for a patient's right to refuse life-sustaining medical treatment outweighs Ackerman's and Michel's arguments. The patient does not have to justify his or her refusal because there are many reasons for arriving at such a

decision, the nature of which may be deeply personal. I will consider the quality, artificiality, and autonomy of life during life-sustaining medical treatment as reasons for refusal, and then give an example of a rare exception to the right to refuse.

First and foremost, the quality of life of an individual is dramatically reduced following the incurrence of sickness or injury. The patient may become depressed, suffer physical as well as emotional and psychological trauma, or develop a feeling of worthlessness. Additionally, a patient on life support places great burdens on family members or other caretakers, causing their qualities of life to decrease as well. Both the patient and family members may wish to remember the patient's healthy days and forgo the pain and suffering that further treatment entails. The patient may even feel embarrassed and ashamed of his or her last days, carrying the sentiment that "I don't want them to see me like this." When quality of life is thus compromised, it is the patient's right to refuse further life-sustaining treatment. Neither the physician nor the law has the authority to impose treatment or to require justification for refusal of treatment, even in an effort to prolong life. The goal should not always be to preserve life, but rather to preserve happiness, comfort, quality of life, and the interests of the patient and his or her family.

Second, the life of a patient who is dependent on life-sustaining treatment is artificial to a certain degree. Some patients may find this state depressing or unacceptable. Cancer patients have the right to refuse chemotherapy; Powell and Lowenstein explain, "We accept this refusal more readily [than refusal of life-sustaining treatment] because we can say that the illness kills the patient, who has merely let nature take its course." It seems that refusal of life-sustaining treatment certainly allows nature to take its course. Dependence on life support is, in fact, quite unnatural from this point of view. Although a large number of patients are unbothered in this regard and choose to remain on life-support, others may find the artificiality of this type of life undesirable; it is the right of the patient to choose between these two options. As we have seen, dependence on life-sustaining treatment may cause great suffering, much in the same way as chemotherapy. Patients with severe disabilities should be given the same rights as cancer patients in this respect.

Finally, the value of patient autonomy confers his or her right to refuse life-sustaining treatment. If the patient is competent and understands the ramifications of potential treatment as well as the prospect of death without treatment, he or she should not be required to justify a decision whether or not to accept that treatment. It is also worth noting that if the patient does decide to remain on life support, his or her autonomy will be diminished simply due to reliance on constant care and technology. To some, this constitutes a loss of individuality and dignity and may serve as a reason to forgo treatment. Additionally, religious and cultural beliefs may serve as grounds for refusing treatment. Whatever the reason for a patient's decision to refuse life-sustaining treatment, the decision should be respected and carried out regardless of the personal reasons for reaching it.

Thus far we have considered severely disabled or ill patients whose lives would be significantly shortened if they were to refuse further treatment, and it has been argued that they always deserve the autonomy to make decisions regarding their continued dependence on life-sustaining treatment. Michel raises one case that nicely illustrates an exception to this rule when she introduces Howard Andrews[3], who sustained paralyzing injuries when he attempted to commit suicide. In this unusual case, the patient acquired the need for life-sustaining treatment as a direct result of intentional action, leading the refusal of treatment to equate itself with the fruition of his suicide attempt. Here, the Court can rationally treat the patient as if he were non-handicapped and suicidal. Other patients who sustain injuries via illness or debilitating accidents do not fall into this very specific category, and should be able to refuse medical treatment without providing justification.

Life-sustaining treatments may prove to be the best solution for many patients with severe handicaps or illnesses. For others, such treatment may lead to depression, misery, feelings of worthlessness or artificiality, and undermined autonomy. It is the right of the patient to decide whether or not to pursue medical treatment, and he or she should not be required to justify that decision due to its deeply personal nature. This is not to say that all patients will withhold their reasons for refusing treatment; to the contrary, many patients will want to discuss the possible options with their doctors and families. The right to choose, however, and the right to choose for whatever reasons the patient sees fit, should be inalienable except in very rare and specific circumstances.

References

1. Ackerman, Terrence F. "Why Doctors Should Intervene." Biomedical Ethics. Comp. Thomas A. Mappes and David Degrazia. New York: McGraw Hill, 1982. 85-89.

2. Mappes, Thomas A., and David Degrazia, eds. Biomedical Ethics. New York: McGraw Hill, 2006.

3. Michel, Vicki. "Suicide by Persons with Disabilities Disguised as the Refusal of Life-Sustaining Treatment." Biomedical Ethics. Comp. Thomas A. Mappes and David Degrazia. New York: McGraw Hill, 1995. 335-340.

4. Powell, Tia, and Bruce Lowenstein. "Refusing Life-Sustaining Treatment After Catastrophic Injury: Ethical Implications." Biomedical Ethics. Comp. Thomas H. Mappes and David Degrazia. New York: McGraw Hill, 1996. 330-334.

RACE AS A LIFESAVER

by Erica Lee

The topic of race has long been controversial and misused, but does it have a role to play in medicine? In the past, corrupt and immoral reigns have often hid behind a veil of science to define the superiority and inferiority of different races. Now, the existence of the concept of race itself is in question, and the most common point of contention remains focused on the question of how to define various ethnicities or races. The use of geographical gradients, or 'clines', has been proposed as a solution to this problem. Many biological differences among racial groups have been shown, ranging from increased risks of genetic diseases to increased risk of dangerous drug side effects. The potential for preventative measures that would compensate for these risks and therefore save lives is drastic. As history has shown, the social implications that could potentially result from legitimizing the existence of racial differences cannot be ignored. However, this past exploitation should not have the result of excluding the potential role of ethnicity in identifying risk variation among different ethnic groups, and personalizing medicine in order to address and overcome these risks and differences.

Discrimination by the majority against the minority has been a defining feature throughout history. Some of the major factors that in the past have divided – and still divide – mankind are religion, class, and race. The concept of race has been, and most likely always will be, a topic of contention. However, modern society now questions the very existence of race and whether it should be a topic of discussion at all. This debate plays a significant role in the development of laws, social policy, and scientific research. In essence, discovering whether biological differences with regards to race or ethnicity do exist is an important field of research whose investigation should not be impeded to satisify ideas about political correctness.

A race can be defined as a subset within a species that has come to differ in the frequencies of alleles in the population. It is commonly believed that these differences arose after dispersed settlements about 40,000 years ago underwent natural selection when isolated in different environments. However, this belief is contested by the discovery that for most of those years there were continuous migrations between groups, leading to a continuous gene flow, and very few if any groups remained completely isolated.[1] Ethnic groups, in contrast to racial groups, are considered to share a common origin, and exhibit a continuity in time; that is, a past and a future as a people. There can be clear external differences between people of various races or ethnicities, whether a lighter or darker pigment of skin, a different shape to certain facial features, or a lack of variability in hair color and texture. Some argue that the next logical conclusion is that these differences cannot be only skin deep; that races or ethnicities may differ in deeper physiological and even psychological ways as well.

This debate has reached the point where recent research has led to epidemiological statistics and subsequent drug development and marketing that report the existence of variability between certain disease rates or drug effectiveness in different groups of people. Some are of the opinion that any differences between 'races' have no basis in biology and "instruction in medical genetics should emphasize the fallacy of race as a scientific concept and the dangers inherent in practicing race-based medicine."[2] The opposing argument is that although other factors may be involved as well, race or ethnicity should play a role in medicine and in treatment; therefore, "current available methods of individualizing care should not be overlooked."[3] Since epidemiological differences do exist, we have a moral obligation to study this difference and determine its cause, in order to provide a benefit to a future society of all ethnic or racial groups. All of this begs the question as to whether or not these differences should be acknowledged or considered when making medical decisions, if they do indeed exist.

The use of race as a category when making medical decisions has important social implications and the major issues should include how to define different groups, whether distinct races even exist in the modern world after, future uses of this knowledge, and, what some believe to be the most important – distinguishing which differences are due to biological factors and which are due to environmental factors, and whether that would lead to a neglect of social disparities in health.

Many studies have established a difference between the rate of certain genetic diseases, drug metabolism, allele frequency, or the prevalence of certain mutations between various racial or ethnic groups. A classic example involves variations in blood types. For example, many studies have concluded that the B allele of the ABO gene for blood type varies in frequency among different racial groups, the highest frequencies concentrating around central Asia, decreasing into Western Europe, and virtually absent from Native Americans and Aboriginal Australians.[4] An example where the difference between two races may affect the preferred course of treatment is the fact that African Americans tend to have a higher rate of salt retention, which can often lead to high blood pressure. Since this condition is more prevalent in them than in Caucasians, African American

patients may tend to benefit more from the use of diuretics to treat high blood pressure than white patients.[5]

The first step in assessing whether differences actually exist between groups is undoubtedly to create clear and accurate definitions of these groups. Because of human migration, it is very hard to define race and to assign individuals to a specific racial group. The fact that humans, by nature, have migrated and interbred over thousands of years means that there are virtually no "pure" races left to study. There are two main factions that come into play when developing racial or ethnic categories. One is known as the "lumpers," who tend to place people into relatively few classes (generally about three to five). The other group, the "splitters," recognizes that there are a great many different races that are all distinct in their own ways.[6] A solution to this issue could be to acknowledge a large number of groups based on their geographic origin. The use of "clines" – geographical gradients in certain biological traits – as a method of classification has been proposed as a more meaningful identification. The key reasoning behind the concept of clines is the fact that a gradient exists, and that there are generally no "all-or-none" characteristics.[7] In order to attempt to accurately categorize people, it must be recognized that a great number of people will fall into more than one category and that these classifications are not static. As society shifts and scientific knowledge increases, it should be expected that these ethnic or racial categories shift as well.

Some studies confront the problem of racial classification by asking subjects to self-categorize themselves. However, some people classify themselves as being of a certain group if they were born in what is generally considered that group's country of origin, even if both of their parents were born elsewhere. Others have a similar identification problem if their parents are of different races or ethnicities. Although interracial marriage rates vary between racial groups, "the number of… 'mixed race' births has grown 26 times faster than all U.S. births."[8] Due to the incredible variability of individual situations, "racial" categories as we know them today are most likely arbitrary and useless.

Another major issue arises when considering group variations. Countless statistical studies have found that groups do not differ as much as it is commonly believed. That is, the amount of variability found within a group of people always far exceeds the differences found between different groups of people. For example, in a 1970 study that measured the heights of Japanese and American young adult male populations, the variability within each group is over 40 cm, but the difference between the average height of each group is a mere 10 cm.[9] This is an extremely important issue because two individuals of different races can easily have the same height, blood type, or salt retention rate. However, using race in medicine would certainly not be the sole reason for a physician's diagnosis or selected course of treatment; it would simply be used as an aid with which to acquire as much information about the patient as possible, in order to achieve the most individualized care.

As racial issues have been the cause of a great number of catastrophic social events, a substantial fear is that, given our past and the tendency of humans to find others inferior, investigating differences between racial groups would legitimize racism. This is not a far-fetched concept, and is clearly demonstrated by the actions of Nazi-Germany. There, 'scientific' articles and publications were often just propaganda that supported the government's political agenda. Prestigious professors and scientists routinely advocated eugenics, compulsory sterilization, or limited reproductive rights to 'inferior' races in order to create a better society. Using these supportive works to promote his ideas, Hitler opposed abortion for healthy German women yet advocated it for "those of 'inferior' races or in cases where the infant would likely have a congenital illness."[10] Due to the terrible misuse of scientific acknowledgement of race differences in the past, it is reasonable to have certain reservations about misuse in the future. Frequently, a political agenda holds influence over some studies in this field and, regardless of governmental legitimization or scientific investigation, racism and racial discrimination does exist. Avoiding research into this field will by no means eliminate racism. However, I believe that the positive implications of individualized healthcare outweighs the the past misuse of science in the racial arena.

Another very important possible negative implication of potential research conclusions in this field is that in finding racial differences, the tendency might arise to blame social discrepancies on these differences. For example, if diabetes rates are found to be higher in African Americans, it might be generally assumed that this is due to a physiological difference. However, diabetes could result from diet or the environment. By attributing this disease to biological differences between races, social and environmental differences will be overlooked. African Americans routinely get worse health care than white Americans and tend to have a lower socioeconomic status, which could lead to poorer nutrition, and poorer education about better nutritional options.[11] If the health care system were to reach out to African Americans to make them aware of better food choices or help them to afford better food, perhaps the diabetes rate would not show such a discrepancy.

Socioeconomic factors could, and undoubtedly do, lead to varied disease prevalence among certain ethnic groups. If the cause is placed solely on biological differences, a result could be a loss of interest or funding for programs that would better serve those parts of society through education, health care

reform, or social outreach. Therefore, it is very important that even though medical research may find the existence of differences between ethnic groups, the possible social contributions to these differences cannot be ignored.

A major question with regards to researching differences between ethnicities is how would it benefit society if major biological differences were found? One answer is that results from this research would provide additional information that would aid in diagnosis. It is doubtful that any reasonable physician would diagnose a patient solely based on his or her race or ethnicity. Rather, statistical information on tendencies of certain groups could act as the family history information acts now. It would provide background information that would aid the doctor in arriving at a more informed decision on the patient's case, whether a diagnostic or a prescription decision. Individualized medical care is a future goal of medical research, and race or ethnicity could serve as one consideration in determing which medication, or even which dosage to prescribe.

Certain side-effects of some pharmaceuticals are more common in particular ethnic groups. For example, a side effect of clozapine, a drug used to treat schizophrenia, is agranulocytosis, a potentially life threatening blood disorder. This disorder is significantly more common in Ashkenazi Jews who take the drug; the genes associated with this increased susceptibility are found in 10-12% of Israeli Jews, but only in 1% of Caucasian Americans.[12,13] To ignore ethnicity when prescribing this drug could result in a patient with this life threatening side effect, but if the information about his or her heritage were used, this increased risk would be avoided. Thus, "ignoring race and ethnic background would be detrimental to the very populations and persons that this approach allegedly seeks to protect."[14]

The consideration of race would also have beneficial effects for other diseases, as is the case with rickets, a debilitating bone disease caused by a lack of Vitamin D and calcium. Rickets in the U.S. is almost exclusively found in darker-skinned children, and the occurrence is rising. Though these darker-skinned children do not produce vitamin D when their skin is exposed to UV light, rickets is being attributed solely to lack of nutrition. This is an indication of how "public health policies underestimated biological differences among races."[15] If darker skinned families were educated about the fact that their children have an increased susceptibility to this disease and how to prevent it, perhaps there would not be this greater prevalence at all. Rickets would be able to be prevented by acknowledging the fact that racial differences do occur, and then by educating those who are affected about the effects of these differences and how to prevent them.

Despite the limitations and possible drawbacks to the study of racial differences, it remains a curious, tempting and potentially beneficial field. The concept of biological race may prove to have significant value in improved, personalized healthcare for individuals. By avoiding research on this topic and its use in medicines and diagnostics, and by completely disregarding the theory, society would lose out on this potentially lifesaving opportunity. If we let fear of past exploitation or political correctness stand in the way of progress, society would miss out on vital research and developments that humankind has been striving for since the beginning of civilization. Human societies set themselves apart by their continual quest for advancement, knowledge, and explanation of their surroundings and the world as they see it. With the caveats understood, advancements in this field have the potential to save lives and greatly increase the effectiveness and personalization of medical care.

References

1. Genetics: Human Aspects. Mange, A and Mange, E, pub. Philadelphia (1980) pp510.
2. Schwartz, R. A. (2001) "Racial Profiling in Medical Research" New England Journal of Medicine 344:1392-1393.
3. Bourroughs, V.J., Waxey, R.W. and Levy, R.A. (2002) "Racial and Ethnic Differences in Response to Medicine: Towards Individualized Treatment" Supplement to the Journal of the National Medical Association.
4. Genetics: Human Aspects. . Mange, A and Mange, E, pub. Philadelphia (1980) pp513.
5. Bourroughs, V.J., Waxey, R.W. and Levy, R.A. (2002) "Racial and Ethnic Differences in Response to Medicine: Towards Individualized Treatment" Supplement to the Journal of the National Medical Association.
6. Genetics: Human Aspects. . Mange, A and Mange, E, pub. Philadelphia (1980) pp511.
7. Racial and Ethnic Differences in Disease. Polednak, A.P, pub. Oxford (1989) pp4.
8. From Black to Biracial. Korgen, K.O, pub. London (1998) pp1.
9. Genetics: Human Aspects. . Mange, A and Mange, E, pub. Philadelphia (1980) pp515.
10. From Darwin to Hitler: Evolutionary Ethics, Eugenics, and Racism in Germany. Weikart, R, pub. New York (2004) pp213.
11. Race and Health Policy. McNaught, A, pub. New York (1988) pp50-54
12. Bourroughs, V.J., Waxey, R.W. and Levy, R.A. (2002) "Racial and Ethnic Differences in Response to Medicine: Towards Individualized Treatment" Supplement to the Journal of the National Medical Association.
13. Amar, A., Segman, R.H., Shtrussberg, S. Sherman, L., Safirman C., Lerer, B., and Brautbar, C. (1998) "An Association Between Clozapine-Induced Agranulocytosis and HLA-DQB1*0201" International Journal of Neuropsychopharmacology 1: 41-44.
14. Burchard, E.G., Ziv, E., Coyle, N., Gomez, S.L., Tang, H., Karter, A., Mountain, J., Perez-Stable, E. Sheppard, D., Risch, N. (2003) "The Importance of Race and Ethnic Background in Biomedical Research and Clinical Practice" New England Journal of Medicine 348: 1170-1175.
15. Sanhavi, D. (2005) "Rickets sheds light on how racial disparities happen" Nov. 7, 2005. Boston Globe. ppC1 & C3.

THE BROAD-REACHING INFLUENCE OF AMERICAN ANTI-ABORTION INTEREST GROUPS: FROM THE UNITED STATES TO FRANCE

by Erica Popovsky

Approval of the "abortion pill", RU-486, in the United States occurred twelve years after France's Ministry of Health approved the pill for medical abortions. For over a decade, a combination of conservative presidents and the mobilization of pro-life groups kept the pill off the market. These interest groups framed the debate surrounding the pill in the abortion arena, effectively hinging its approval on morals rather than the drug's safety and efficacy. Anti-abortion groups wielded a variety of tactics to delay the drug's approval including lobbying U.S. Congressmen, threatening a boycott of Hoescht products, publicly decrying the drug based on moral grounds and, in an interesting twist, framing the issue under women's rights. RU-486 was eventually approved for use in the United States, demonstrating that interest groups' influence is not omnipotent and political currents can often override vocal minorities. However, the case study of RU-486 provides substantial evidence that when safe scientific advances clash against powerful interest groups, these groups can significantly hinder the process of approval.

Introduction

The arrival and legalization of RU-486 or the "abortion pill" in the United States was a long and arduous process during which mobilized many interest groups. The debate continued from the time of the drug's introduction in France in 1988, until the Food and Drug Administration's approval of RU-486 on September 28, 2000. The drug was strongly contested by anti-abortion groups who actively rallied to try to prevent its availability in the United States. Opponents of RU-486 employed multiple tactics and framed the issue in various arenas, ranging from abortion to women's rights. Pro-life interest groups significantly influenced Roussel Uclaf, RU-486's manufacturer, to prevent the drug from arriving in the United States, and at one point forced RU-486 off the French market. The primary focus of this paper is assessing the influence that pro-life interest groups in the United States had on the international distribution of RU-486 and their attempts to delay RU-486 from coming to market in the United States. This paper argues that despite the positive scientific results of the RU-486 clinical trials, the significant period of time between the approval of the drug in France and in the United States demonstrated that the antiabortionists' outcry over the nature of RU-486 constituted a more significant political challenge in the United States than the actual safety of the drug itself.

Medical Usage of RU-486

RU-486 is an abortofacient that was created as an alternative to surgical abortion to terminate unwanted or dangerous pregnancies. Almost twelve years after RU-486 was made available to French women, American women gained access to the drug. On September 28, 2000, the FDA approved RU-486 (generic name mifepristone) for terminating intrauterine pregnancies through the forty-ninth day of pregnancy.[1] The drug is distributed by Danco Laboratories, a single product company created for the sole purpose of distributing RU-486 (Mifeprex in the United States).[2]

RU-486 is a synthetic steroid, an antiprogesterone that interferes with a woman's pregnancy. The drug causes the endometrial lining of the pregnant woman's uterus to soften and break down.[3] Alone, RU-486 is only 64-85% percent effective in aborting the fetus and expelling it from the uterus[3], and is clinically ineffective. To increase the effectiveness of the drug (defined by the FDA as "the complete expulsion of products of conception without the need for surgical intervention"[4])the woman must also take misoprostol, a prostaglandin analogue, two days after ingesting RU-486.44 The prostaglandin causes myometrial contractions and, according to clinical trials conducted in the United States and France, results in complete medical abortion at least 92% of the time.[5,6]

In a memo to the Population Council, the group that owns the U.S. rights to RU-486[7] , the FDA stipulated the following qualifications for any physician who could provide mifepristone:

- Ability to assess the duration of pregnancy accurately
- Ability to diagnose ectopic pregnancies

- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
- Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, given her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well
- Must report any hospitalization, transfusion or other serious events to the sponsor or its designate[8]

Because of the possible side effects of mifepristone and misoprostol, including excessive bleeding (sometimes to the point of requiring blood transfusion or surgery)[9], the FDA imposed the above requirements to ensure the safety of patients taking RU-486 and misoprostol. To guarantee that a woman is fully informed about the abortion process via RU-486, the physician is required to council her regarding the procedure and guarantee that she has access to any medical services (such as surgery) that could possibly be necessary.

Although medical abortions are less invasive than surgical abortions, they actually require more medical visits than the latter technique. Unlike surgical abortions that require only one visit to physician or clinic, RU-486 abortions require three visits to a physician. On the first visit, the physician counsels the patient about RU-486 and if the patient decides to continue with the abortion, three tablets (200mg each) of mifepristone are then administered to be taken orally.[10] The second visit occurs two days later and the physician checks to see if the pregnancy has been terminated. If not, the patient must take two misoprostol tablets (a total of 40μg) and stay under physician observation for four hours.[10,11] The patient then returns approximately two weeks after the initial visit to ensure that the pregnancy has been effectively terminated. If the pregnancy is not terminated, the physician must discuss and present alternative options. [12]

Interest Group Politics and Framing

Abortion is legal in the United States and has been since the Roe v. Wade decision by the Supreme Court in 1973. Abortion's legal status, however, has done nothing to quell the debate that surrounds it. The company Roussel Uclaf, owned by the German corporation Hoescht, developed RU-486 in France and the World Health Organization (WHO) announced the success of its clinical trials in 1988. Roussel Uclaf reported that clinical trials in Great Britain, China, France, and Sweden demonstrated that a combination of RU-486 and prostaglandin therapy resulted in abortion 95% of the time, without many serious complications. [13] Immediately, following the results of the studies anti-abortion activists in the United States prepared to combat the growing popularity of the drug.[14]

The opponents of RU-486 employed many political tactics to block the approval of RU-486. They framed the issue in the abortion arena, attracting pro-life groups to their cause; the women's rights arena, utilizing rhetoric of the women's rights movement by arguing that the drug could harm women in addition to their unborn fetuses; and threatened to boycott the drug's manufacturer (Roussel Uclaf) and its parent company's (Hoescht) products. [15,16]

Framing

One of the major tactics of antiabortionist groups was to frame RU-486 in the abortion arena. Richard Glasow, the education director for the National Right to Life Committee (NRLC), a prominent pro-life interest group in the United States, voiced the fear of many pro-life groups. He worried that RU-486 would trivialize abortion by "bolster[ing] the comparison between taking the drug and swallowing an aspirin."[17] The pro-life groups frequently employed rhetoric emphasizing that RU-486 would further devalue human life due to the decreased intensity of the medical abortion. [18]

Medical abortions using RU-486 take place within a doctor's private office, as opposed to an abortion clinic. This posed a threat to pro-life groups because many of their protests occurred outside abortion clinics and they worried that RU-486 would signal an end to the effectiveness of using these locales to garner media attention.[19] In 1982, over 75% of abortions in the U.S. occurred in abortion clinics, providing pro-life activists with easily accessible protest sites that generated media coverage – sites they did not want to lose. [19] The pro-life interest groups' fears were not, however, grounded in fact. RU-486 is only effective until the 49th day of pregnancy, and any abortion after this period would have to be performed surgically. [20] This, however, did not quell the antiabortionists' campaign against RU-486.

In an ironic twist, pro-life groups decided to adopt rhetoric from the women's rights movement, a movement that had argued for contraception and the legalization of

abortion.[21] The issue was framed in terms of concern for the safety of women through a number of tactics. In 1988, the National Right to Life Committee together with women's groups and consumer advocates opposed particular provisions in a U.S. bill that decreased the liability of manufacturers who produced defective products. (22) NRLC opposed the bill specifically because it would decrease the liability of any drug manufacturer that produced RU-486 in the United States if women encountered problems during the abortion. (23) Women's groups, although they too believed that this bill would diminish protection of women who had been hurt by contraceptive use, did not want to align themselves with the NRLC, and framed their opposition under the auspices of consumers' rights. [23]

In an attempt to ensure that RU-486 would be excluded from the new liability laws if the bill were to pass, "NRLC supported an amendment, sponsored by Congressman Gerry Sikorsky (D-Minn.), that would have removed all drugs or medical devices used as contraceptives or to facilitate abortions from the broad protections of the bill." [23] If passed, this amendment would have presented a significant obstacle for any pharmaceutical company willing to manufacture RU-486. As RU-486 was only 95% effective when used in conjunction with misoprostol during clinical trials, a 5% possibility existed that the fetus would not be aborted. If any of these children were born with birth defects or problems, unrestricted liability for the company meant that women could sue if the birth defect was linked to RU-486. [24] In part because of the large mobilization of interest groups against the bill, it was defeated in Congress and drug companies (among other industries) remained liable for defective products. [25] This was a large blow to the prospect of RU-486 production in the United States, as any company that produced it would remain in danger of severe lawsuits.

Boycotts

The most effective threat that interest groups wielded over Roussel Uclaf and Hoescht was the threat of an economic boycott of both companies' products. [26] The night before Roussel Uclaf's annual meeting in June 1988, NRLC's executive director, David O'Steen publicized a letter the group had written to the French ambassador.

"…We are especially incensed that the abortion pill's proponents have announced that they intend to make women of Third World countries a special target for the death drug's use… If Roussel Uclaf or any other pharmaceutical company attempts to manufacture or market RU-486, [the] National Right to Life Committee would seriously consider joining with other pro-life groups around the world to initiate a boycott of the products of Roussel Uclaf and firms affiliated with it through the parent company Hoescht." [27]

The French government was a minority shareholder in Roussel Uclaf [28], and NRLC seized on this to associate them with the company's perceived immorality. They hoped that the publicized threat of a boycott would place pressure on both Roussel Uclaf and Hoescht to cease their development of RU-486. By citing the safety of women in developing countries, NRLC again borrowed framed the issue in the context of the women's rights movement. [28]

The major benefit of RU-486 is its oral administration, which eliminates the need for an invasive surgical procedure. This was touted as a significant advance for the safety of pregnant women in third world countries where sterile surgical environments are rare.[29] NRLC, however, turned the issue on its head. In addition to claiming that the distributors would market the drug to uninformed women in developing countries, they also cited safety concern for women taking the drug.[30] Yet, even as the group advocated this version of women's rights, women's rights groups themselves actually supported RU-486. [31]

The threat of a boycott demonstrated the effect of a vocal minority in the United States on an internationally based company. Although the French Minister of Health, Claude Evin, approved the drug for marketing in September of 1988, Hoescht pressured Roussel Uclaf to stop marketing the pill. [32] "Hoescht… feared that the boycott threats by the American anti-abortion movement could cripple [its] $6-billion-a-year American subsidiary." [33] Despite the fact that 59% of Americans favored introducing RU-486 to the U.S. (according to an October 1988 poll[34]), the vocal anti-abortionist minority's threat of a boycott caused Hoescht to lean on Edouard Sakiz, the chairman of Roussel Uclaf, to halt the drug's production.[35]

Eventually Sakiz succumbed to corporate pressure. He had assumed that the political outcry from pro-life interest groups would drop after the government approved RU-486 for marketing, but protests and threats from NRLC and other pro-life interest groups (mainly based in the United States, but some in France) escalated after the approval.[36] On October 21, less than one month after the drug's approval, Sakiz and the Roussel Uclaf board voted to take it off the market.[36] Pierre de Rible, Roussel's deputy financial leader assessed the influence of American pro-life groups. "The pressure groups from the United States are very powerful, maybe even more so than in France."[37] The U.S. groups framing and threats significantly influenced

Roussel Uclaf's decision, despite the fact that the drug was legalized only for French and not U.S. use.

The Counter-Protest: the influence of proponents of RU-486

Interest group politics are not a one-way street. Both opponents and proponents of RU-486 were capable of influencing the international distribution of the abortion pill. Roussel Uclaf's announcement regarding the withdrawal of RU-486 was well timed to illicit an outcry from supporters of RU-486. The decision was announced during the meeting of the World Congress of Gynecology and Obstetrics, where physicians, professors, and other pro-choice groups immediately mobilized to protest the company's decision.[38] They compiled a list of Roussel Uclaf's other products, and physicians stated that they would boycott them to show that, according to one professor, "Medical groups and family planning clinics… …have a voice, not only right-to-life groups."[39] Other groups such as the National Abortion Rights Action League (NARAL), Planned Parenthood, and even the French Minister of Women's Rights, Michèle Andrè, all denounced the decision and framed their dissent in the same general context: Roussel Uclaf was conceding to a small minority and consequently ignoring the potential benefits to many women worldwide.[40]

The protest of these pro-choice groups did not go unheard, but once again, the distributors of RU-486 made their decision based on economics. The French government accepted the legality of abortion and did not want to rekindle the debate,[40] and decided to use its power as a minority shareholder of Roussel Uclaf to bring RU-486 back to market by threatening to give the patent rights of the drug to a company willing to market it.[41] Evin, the French Minister of Health, "feared that if the antiabortion movement was triumphant in its crusade against Roussel, it would begin fighting for a repeal of the 1975 French law legalizing abortion."[41] Roussel Uclaf did not want to lose its patent rights for a likely profitable drug (even in the currently hostile political environment), and put RU-486 back on the market on October 28, 1988, only one week after it had been withdrawn.[42]

The Delayed Arrival in the United States: the influence of interest groups

Although RU-486 was distributed throughout France, dealing a blow to the antiabortionist groups, the debate over the drug did not subside. In February 1989, Congressman Robert Dornan (R-CA), sponsored H.R. 619, a bill that specifically banned funding for RU-486 in the United States.[43] A federal ban on funds for abortion research was already in effect, but because RU-486 also had other potential clinical uses, such as treating Cushing's disease, breast cancer and endometriosis, the bill never came to a vote.[43] The government, however, was in the midst of a series of pro-life administrations, and during the Reagan and Bush administrations, RU-486 was classified as "a banned drug," and no research was undertaken with Federal funding.[44]

Furthermore, U.S. interest groups gained a major victory in their attempt to delay the arrival of RU-486 to the U.S. when Hoescht decided not to distribute RU-486 outside of France.[45] Although the company claimed that it was a company policy not to market abortofacients, "… in the case of RU-486, it [was] the commercial and public relations consequences of the antiabortion groups' moral outrage that seem[ed] to underlie the decision of so many pharmaceutical companies to avoid the drug and of Roussel to limit its distribution and licensing."[45] Roussel Uclaf explicitly stated that if they were to market RU-486 outside of the country, they would only do so if a foreign government demanded it.[46] Due to the conservative political environment in the United States in the late 1980s and early 90s, this effectively ensured that the product would not come to the United States.

When Bill Clinton was elected in 1992, the pro-choice interest groups' finally gained a chance to be heard. The Clinton Administration pressured Roussel-Uclaf to donate the U.S. rights of RU-486 to the Population Council, a nonprofit organization for advancing reproductive health, and finally in 1994, the administration succeeded.[47] The Population Council applied for approval of RU-486 from the FDA in 1996, and the FDA deemed mifepristone "approvable" according to clinical trial data from France, but noted that the Council needed to find a manufacturer in the United States willing to produce the drug, properly label of the drug, and deal with other concerns.[48,49]

Despite this triumph for pro-choice advocates, antiabortionist interest groups still attempted to prevent the appearance of the drug on the market. Pharmaceutical companies were wary of entering the political fray, and pro-life interest groups focused their efforts on keeping RU-486 from being manufactured.[49] As a result, Teva, Merck, Abbot Laboratories, Johnson & Johnson and Phamarmacia & Upjohn all refused to manufacture the drug.[49]Finally, Danco Laboratories proved to be the answer for allowing the production of RU-486 in the United States. Danco was created specifically to market RU-486[49], leaving it immune to threats of a boycott because there were simply no other

products to boycott. The Population Council subsequently reapplied for approval of RU-486 in both 1999 and 2000 and the FDA deemed the drug clinically effective and ready for market on September 28, 2000.[50] The FDA prohibited RU-486 distribution by pharmacists, instead giving the sole privilege to certified physicians.[51]

Conclusion

Scientific work is supposed to be factual and unbiased. But, what happens though when a scientific advance clashes with moral values? The case of RU-486 demonstrated the power of American antiabortionist interest groups in dictating the fate of the controversial drug's legalization in the United States. Despite the positive results of the RU-486 clinical trials, antiabortionist groups framed the issue in the abortion arena, derailing the debate from centering on the safety of the drug. Their most powerful tool, however, in the fight against RU-486 was the threat of a boycott against Roussel Uclaf and its parent company, Hoescht's products. Because of Hoescht's significant business in the United States, the company decided that protecting its international image was a higher priority than allowing the distribution of the revolutionary drug.

Women in the United States, however, now have access to RU-486. Despite the twelve-year lapse between the initial distribution of medical abortions in France and the United States, the legalization of RU-486 showed that interest groups are not invincible. Although they can wield significant power and make credible threats, other forces are also at work in the political arena. The French Minister of Health's request for Roussel Uclaf to put RU-486 back on the market in 1988 and Clinton's request for Hoescht to allow the Population Council to obtain the rights to the drug if they refused to market it in the United States, were followed by compliance of the companies.

During the first eighteen months mifepristone was available in the United States, over 18,000 medical abortions were performed.[53] However, it has not revolutionarily changed the abortion landscape as pro-life activists feared. The debate surrounding abortion is far from over, as South Dakota proved when it banned abortions in 2006.[54] RU-486 has not ended the abortion wars nor eliminated the need for abortion clinics. The approval process, however, gave pro-life and pro-choice activists a forum to renew the debate over the morality of abortion, and demonstrated the wide-reaching influence of U.S. pro-life interest groups.

References

1. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Drug Evaluation and Research. 2000. Memorandum to NDA 20-687 MIFEPREX (mifepristone) Population Council. p. 1-8, 1.
2. Talbot, Margaret. 1999. "The Little White Bombshell." New York Times Magazine. July 11, 1999, Section 6; 39.
3. Susan J. Mackenzie and Seonae Yeo. 1997. "Pregnancy interruption using mifepristone (RU-486). A new choice for women in the USA." Journal of Nurse-Midwifery. March-April 42(2): 86-90, p. 86.
4. Dept. for Health and Human Services, op. cit., p. 1
5. Mackenzie and Yeo, op. cit., p. 86
6. Dept. for Health and Human Services, op. cit., p. 1
7. Talbot, op. cit., p. 39.
8. Dept. for Health and Human Services, op. cit., p. 6
9. R. Alta Charo. 1991. "A Political History of RU-486." Biomedical Politics. Ed. Kathi E. Hanna. Washington D.C.: National Academy Press, 43-87, p. 44.
10. FDA/Center for Drug Evaluation and Researc. 2001. "Mifepristone Medication Guide." http://www.fda.gov/cder/drug/infopage/mifepristone/medguide.htm March 8, 2001.
11. Mackenzie and Yeo, op. cit., p. 87
12. FDA/Center for Drug Evaluation and Research, op. cit.
13. R. Steinbrook. 1988. Wide use of non-surgical abortions is called likely. Los Angeles Times, February 4, at part 1, p. 3, column 1. Quoted in R. Alta Charo. 1991. "A Political History of RU-486." Biomedical Politics. Ed. Kathi E. Hanna. Washington D.C.: National Academy Press, 43-87, p. 54.
14. Charo, op. cit., p. 54.
15. Adele Clarke and Theresa Montini. 1993. "The Many Faces of RU486: Tales of Situated Knowledges and Technological Contestations." Science, Technology, & Human Values, Vol. 18, No. 1, Theme Issue: Technological Choices. (Winter 1993): 42-78, p. 67.
16. Charo, op. cit. p. 43, 54, 56
17. R. Glasow. 1990. RU 486: The prostaglandin connection. National Right to Life News, December 13, p. 7. Quoted in R. Alta Charo. 1991. "A Political History of RU-486." Biomedical Politics. Ed. Kathi E. Hanna. Washington D.C.: National Academy Press, 43-87, p. 43.
18. Charo, op. cit., p. 44.
19. Clarke and Montini, op. cit., p. 56.
20. Ibid., p. 46.
21. Ibid., p. 57
22. Charo, op. cit., p. 55
23. Ibid., p. 55.
24. M. Gladwell. 1988b. Birth control makers weary of controversy. Los Angeles Times, May 3, at part 4, p. 15, col. 1. Quoted in R. Alta Charo. 1991. "A Political History of RU-486." Biomedical Politics. Ed. Kathi E. Hanna. Washington D.C.: National Academy Press, 43-87, p. 55.
25. Charo, op. cit., p. 56
26. Charo, op. cit., p. 54
27. PR Newswire. 1988. Planned Parenthood gives Margaret Sanger Award. October 17. Quoted in R. Alta Charo. 1991. "A Political History of RU-486." Biomedical Politics. Ed. Kathi E. Hanna. Washington D.C.: National Academy Press, 43-87, p. 57.
28. Charo, op. cit, p. 57.
29. Clarke and Montini, op. cit., p. 48
30. Ibid., p. 56
31. Ibid., p. 57.
32. Ibid., p. 58.
33. S. Greenhouse.1989. A new pill, a new battle. New York Times Magazine, February 12, at sec. 6, p. 1, col. 6. Quoted in R. Alta Charo. 1991. "A Political History of RU-486." Biomedical Politics. Ed. Kathi E. Hanna. Washington D.C.: National Academy Press, 43-87, p. 58.
34. PR Newswire. 1988. Planned Parenthood statement on RU 486 pill decision. October 26. Quoted in R. Alta Charo. 1991. "A Political His-

tory of RU-486." Biomedical Politics. Ed. Kathi E. Hanna. Washington D.C.: National Academy Press, 43-87, p. 58.
35. Charo, op. cit., p. 58.
36. Ibid., p. 61.
37. Ibid., p. 62.
38. Charo, op. cit, p. 63.
39. M. Simons. 1988. Doctors protest company's action on abortion pill. New York Times, October 28, at sec. A, p. 12. Quoted in R. Alta Charo. 1991. "A Political History of RU-486." Biomedical Politics. Ed. Kathi E. Hanna. Washington D.C.: National Academy Press, 43-87, p. 64.
40. Charo, op. cit., p. 64.
41. Ibid., p. 65.
42. Ibid., p. 66.
43. Ibid., p. 70
44. Talbot, op. cit.
45. Charo, op. cit., p. 75
46. Ibid., p. 76
47. Talbot, op. cit.
48. Dept. for Health and Human Services, op. cit., p. 1
49. Talbot, op. cit.
50. Dept. for Health and Human Services, op. cit., p. 1
51. Ibid., p. 6.
52. Charo, op. cit., p. 63.
53. R. Hausknecht. Mifepristone and misoprostol for early medical abortion: 18 months experience in the United States. Contraception, Volume 67, Issue 6, Pages 463-465
54. Evelyn Nieves. 2006. S.D. Abortion Bill Takes Aim at 'Roe.' The Washington Post. February 23. Page A01.

TuftScope Submission Information

TuftScope's Mission

With many of the recent advances in biotechnology and advanced medical techniques comes a multitude of ethical and philosophical questions, and a need for policy review. The mission of TuftScope is to promote a well-rounded discussion of bioethical and health issues in today's society with an emphasis on active citizenship. TuftScope accepts original essays, opinion/editorial pieces, and research papers on topics including public & community health, government policy, health economics, bioethics, education, and the influence of technology. TuftScope's main goal is to achieve a thorough discussion of these issues in the context of understanding these problems and creating effective policies.

Guidelines for Authors

These guidelines are a basic overview of publication requirements, for a complete set of guidelines please visit the Tuftscope website (http://ase.tufts.edu/tuftscope) or email us at TuftScope@gmail.com.

Original articles, editorials, and research papers are eligible for publication in TuftScope provided that they have not been published elsewhere, either in whole or in part. Submissions must be submitted electronically in a word processing program. Files must be Microsoft Word with *.doc extension or .rtf file extensions. Hard copies may be mailed to TuftScope, but electronic copies are required as well. Papers should be 2000-3000 words in length, include an abstract, and a title page. Editorials should be 1000 - 1500 words in length and do not require an abstract. Please include a title page with title, author(s) name, affiliation, lead author's mailing and e-mail addresses with all submissions.

It is recommended that submissions for the Spring 2008 issue include the *Consent of Publication* form. All submissions for the Fall 2008 issue onwards must include the form. TuftScope reserves the right to edit submissions for length.

References

Please use numeric notation for citations, and include the reference list on an attached page. An example would be:
1. Norton RA. The ethics of voluntarily stopping eating and drinking: A survey of Massachusetts physicians. TuftScope. 2002; 2:2-5

How To Submit

To submit your manuscript, please e-mail your submission to TuftScope@gmail.com. Please email us if you have any additional comments, questions, or concerns.

TuftScope
Mayer Campus Center
Tufts University
Medford, Massachusetts 02155
Website: http://ase.tufts.edu/tuftscope
Email: TuftScope@gmail.com