BURNING ISSUES

TRDRP Newsletter

Volume 5, Number 2, July 2002

Women with COPD: The Tip of the Iceberg?

by M.F. Bowen

Are women more susceptible than men to smoking-related pulmonary disease? We know that heart disease annually kills more women than men[1] and that female smokers are more likely than male smokers to develop lung cancer at the same level of exposure.[2] Some researchers are beginning to suspect that sex and gender[i] also matter when it comes to the induction and etiology of pulmonary conditions such as chronic bronchitis and emphysema and that the prevalence of these diseases in women represents the mere tip of a looming iceberg.

What is COPD?

Emphysema and chronic bronchitis are both diseases of the lungs that result from cigarette smoking. Both conditions have similar clinical manifestations (airflow obstruction and breathing difficulties) and frequently occur together; as a result, they are often referred to collectively as chronic obstructive pulmonary disease (COPD).[ii] They are, nonetheless, distinct diseases with distinct etiologies and pathologies. Emphysema is characterized by the destruction of lung tissue, enlarge-

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ALSO IN THIS ISSUE

$20.4 Million Awarded to 58 Grantees

by Susanne Hildebrand-Zanki

In the 11th annual funding cycle, TRDRP awarded a total of $20.4 million for 58 grants to individual investigators at 26 California institutions. The number of applications was slightly lower this year compared to the 10th cycle (225 versus 273). Funds available were also less, $20.4 million versus $23.4 million. The result was a 'slight' increase in the overall funding pay line to 26.2% (from 24.5%). This increase was due to the lower number of applications as well as the hard budget cap TRDRP introduced for this cycle. Despite the slightly higher funding rate, excellent proposals still fell below the pay line. The funding rate for full research, community-academic, and school-academic proposals was only 21.7%. Funding levels varied due to the different number of applications received for various mechanisms and the different number of applications reviewed in the different study sections. Funding levels by award mechanism and area are listed on page 6.

A complete list of all grant recipients and the abstracts describing their research projects will be published in the 2002 Compendium of Awards, which is now available (both in hard copy and online). All currently funded investigators and 11th cycle applicants will receive a copy; others interested may obtain copies upon request from TRDRP or via our website in pdf format (www.ucop.edu/srphome/trdrp).

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ment of the alveolar spaces and, eventually, loss of elastic lung recoil. Chronic bronchitis results from inflammatory processes that result in cellular proliferation, mucus hypersecretion, and narrowing of the airways. Presently, there are no treatments that can prevent the progression of these conditions except for smoking cessation.

COPD and Smoking

Cigarette smoking is the leading risk factor for the development of COPD and risk increases with the amount and duration of smoking. Abstaining from smoking and minimizing exposure to environmental tobacco smoke are the only effective ways to prevent COPD and the only avenue for alleviating its debilitating symptoms. Unfortunately, for those individuals diagnosed with COPD who have moderate to severe pulmonary dysfunction, the symptoms are essentially irreversible even if the patient quits smoking.

Women in the US are currently "in the throes of an epidemic of tobacco-related diseases" [2] and COPD is a major contributor to the onslaught, accounting for an annual average of 64,735 of the 178,311 smoking-related deaths in women between 1995 and 1999.[3] Because most COPD deaths occur in people older than 55 years of age,[4] there is no doubt that the increase in current cases of COPD in women stems from the tremendous increase in the number of women smokers that occurred in the mid 20th century. Tragically, these women have "come a long way" only to suffer the debilitating and life-threatening health consequences of smoking. Given current smoking trends among younger women and girls, as well as tobacco companies' continued targeting of this market segment not only in the US but worldwide,[2] we can expect COPD to continue to be a women's health issue for years to come and to exact an increasing toll globally on women's health.

The Influence of Sex and Gender on COPD

Women who smoke may be more susceptible to developing COPD than men who smoke. Edwin K. Silverman, M.D., Ph.D., of Brigham and Women's Hospital in Boston spoke on this intriguing topic at a symposium entitled "Gender Differences in Lung Disease." Dr. Silverman's ongoing epidemiological and genetic studies in early-onset COPD suggests that females may have a genetic susceptibility to early-onset COPD that is independent of a proven genetic cause (alpha-1 antitrypsin deficiency). Dr. Silverman's work confirms and extends previous studies suggesting that females are more susceptible to the effects of smoking than males: Lung function declines more acutely in female smokers as compared to male smokers given the same smoking exposure;[5] airway hyper-responsiveness is higher in women who smoke and such women experience a more rapid decline in lung function than men if they continue to smoke.[6] Women smokers are also at greater risk of hospitalization for COPD.[7]

Women do not even have to smoke themselves in order to be affected by cigarette smoke: Exposure to environmental tobacco smoke is associated with decreased lung function in women, a response that is not observed in nonsmoking men.[8] Dr. Silverman's work suggests that it may be possible to identify a sex-based genetic mechanism for COPD. This would not only contribute to our understanding of the cellular and molecular mechanisms underlying this condition but, like alpha-1 antitrypsin deficiency, offers the hope that a pharmaco-genetic approach to this intractable disease can eventually be developed.

To compound the problem, women with COPD are often mis-diagnosed, resulting in an underestimate of the prevalence of COPD in the female population. When primary care physicians were presented with hypothetical patients of both genders with airflow obstruction and asked to diagnose these individuals based on medical history and physical exam, a statistically significant number of female cases of COPD were misdiagnosed as asthma.[9] This example of gender bias suggests that there may be many women who are being treated for asthma when they should more appropriately be treated for COPD. Misdiagnosis leads to a complication that is particularly damaging to women. Although asthma is effectively treated with corticosteroids, such drugs are contraindicated in postmenopausal women because they tend to increase the rate of bone loss, thus exacerbating estrogen-depletion-associated osteoporosis.[10] Since most women with COPD are postmenopausal, misdiagnosed women may be needlessly subjected to a treatment that has particularly debilitating side effects for them.

Sex and Gender Matter

Dr. Silverman suspects that COPD incidence in women may only be the "tip of the iceberg." Not only may existing cases of COPD in females be misdiagnosed, but the incidence of COPD will likely rise as increasing numbers of current and past women smokers reach middle age.

More white women than African-American women die from complications of this disease: In 1992, mortality due to COPD was 44% higher in white women than in African American women.[2] The underlying cause of this disparity is uncertain although differences in the number of women who smoke within each group[2] may offer a partial explanation. However, age-adjusted mortality due to COPD increased at a comparable rate in African American women

I. "Sex" is a classification based on chromosomal complement and the reproductive organs and functions that derive from it. "Gender" refers to a person's self-representation as male or female and how society responds to that individual based on his or her self representation.[11] Differences in disease incidence between men and women are likely due to an interaction between sex and gender.

II. Asthma, as well as other obstructive lung diseases, are sometimes included under the general rubric of "COPD."

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(78%) and white women (75%) between 1980 and 1992, suggesting that the rise in COPD incidence in women that we expect to see in the future will likely cut across racial and ethnic lines.

The Institute of Medicine report "Exploring the Biological Contributions to Human Health: Does Sex Matter?"[11] comes to the incontrovertible conclusion that, with respect to disorders like heart disease and lung cancer, sex and gender do matter. It now appears likely that sex and gender also matter when it comes to COPD.

Acknowledgements

The author thanks Dr. Edwin K. Silverman, of Brigham and Women's Hospital, Boston for sharing his research and expertise on sex and gender-based differences in COPD and for his helpful comments and suggestions on this article.

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Do You HIPAA?

A primer on the New Federal Regulation's Effect on Human Subject Research

by Francisco Buchting

What is HIPAA? Will HIPAA affect the way research is funded and conducted? How do we comply with HIPAA? How will TRDRP address the HIPAA requirement? The following is a short overview of the impact HIPAA may have on research.

What is HIPAA?

HIPAA is the Health Insurance Portability and Accountability Act of 1996. It represents federal efforts to standardize and protect the privacy of individual's medical records and other personal health information (PHI). HIPAA is in part a response to concerns about an individual's health care information being accessed without that individual's consent, knowledge, or control over his/her own medical data. It provides rules and regulations on how PHI should be treated by *covered entities*. For HIPAA, covered entities are defined as health plans, health care clearinghouses, health care providers, and researchers that recruit subjects in these venues. The HIPAA rules and regulations published thus far by DHHS call for all covered entities to comply with HIPAA regulations. Any covered entity that misuses or fails to comply with HIPAA regulations is subject to significant civil and criminal penalties. Thus, HIPAA will significantly limit or regulate who can access an individual's PHI and how the information can be used. What this means for research is that access to any patient data will be restricted and only allowed after certain criteria have been met as set forth by HIPAA rules or standards, in particular the Privacy Rule (or "Standards for Privacy of Individually Identifiable Health Information").

The Privacy Rule

The Privacy Rule establishes conditions for when and how a covered entity can use and disclose PHI. The Privacy Rule will affect research because it deals with what kind of information can be released for research purposes. The effective date for the Privacy Rule is April 14, 2001 and the compliance date for all covered entities is April 14, 2003 (small health plans have an extra year to comply, April 14, 2004). The full impact that the Privacy Rule will have on research can only be speculated on due to the fact that the "final" Privacy Rule is scheduled to be published by DHHS late summer or early fall 2002. The reason for the delay is that Secretary Thompson has reopened the original Privacy Rule, published by DHHS in December 28, 2000, for further public comments and proposed

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revisions. Nevertheless, there seems to be agreement at this point as to what scientists will have to do to comply with HIPAA in order to gain access to PHI for research purposes.

Following is what you will need to know about what is expected to be the "final" Privacy Rule and its impact on research.

Is there a grandfather clause?

Yes, an ongoing study will be grandfathered-in if the legal permission or informed consent for the research or an IRB waiver of informed consent under the Common Rule was obtained prior to the compliance date of April 14, 2003. It is expected that no distinction will be made between research that involves treatment (clinical) and research that does not when it comes to different grandfathering provisions of the Privacy Rule.

What type of information falls outside Privacy Rule?

De-identified information (data that has been stripped of 18 information fields—see box page 5) and human biological tissue not linked to a specific donor's medical information seem to fall outside the domain of the Privacy Rule.

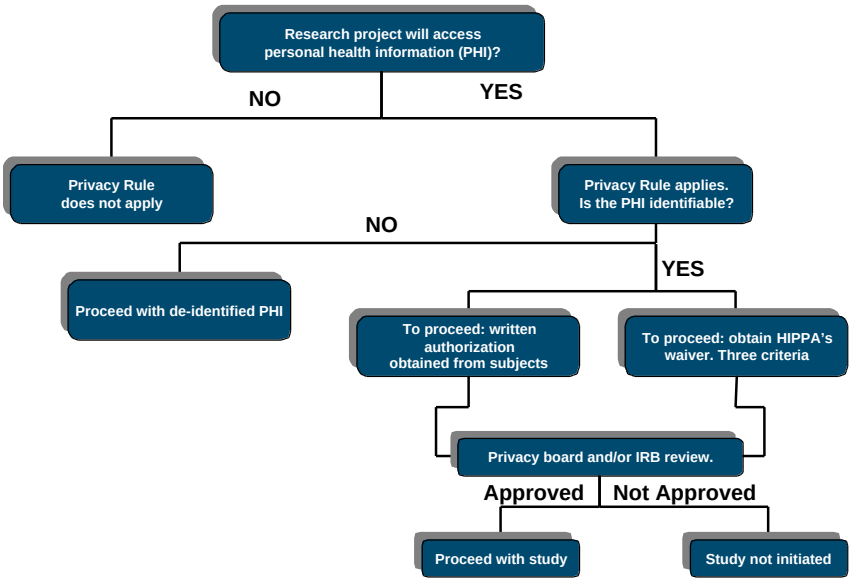
So, does my study fall under the Privacy Rule?

If a study uses de-identified data, the Privacy Rule will not apply. A possible obstacle may be if the PHI that is planned to be used for the study has not been de-identified by the covered entity. In this case, the researcher will have to negotiate for the PHI to be de-identified. Who covers the expense of de-identifying the data and whether the covered agency is willing to dedicate resources to de-identifying data may vary depending on the institution.

The type of research that will be affected by HIPAA are studies that will need to use existing PHI that has identifiers (e.g., health service research, epidemiological research) and research that includes treatment of research participants (e.g., clinical trials). In addition, researchers may also need access to PHI to develop research protocols or to collect data from a clinical record.

At this point, studies that will create new health information that is not linked to the records of a covered entity (i.e., the information will not originate from, be stored in, or be associated with the existing records of a covered entity) appear to outside of HIPAA's Privacy Rule.

Privacy Rule Decision Tree



My study does fall under the Privacy Rule, what now?

If a study will use PHI, the researcher will have to comply with the Privacy Rule through a new review process. This new review process, conducted by a privacy board, will need to be put into place in order to provide documentation so covered entities know that the requirements to release or provide access to PHI as set forth by the Privacy Rule have been satisfied by a researcher. Keep in mind that it will be up to the discretion of covered entities to use and disclose PHI for research purposes.

Due to the cost of maintaining review boards, it is expected that most institutions will not set up a separate privacy board, but will review compliance to the Privacy Rule concurrently with human subjects compliance within one IRB. Nevertheless, some institutions may choose to have two separate review boards. The training of IRBs and privacy boards on reviewing requirements set forth by the Privacy Rule more than likely will be carried out by the Office of Human Research Protection.

The question still remains how covered entities without an IRB, e.g., an independent physician's office or a small clinic or hospital, will meet the requirement set forth by the Privacy Rule given the expense associated with setting and maintaining a privacy board. Once again it is expected that certification of compliance by an IRB or privacy board from the researcher's institution (e.g., university) may be enough. This has not been decided or it is not clear if further guidance will be provided as to whether a covered institution can consider certification of compliance from an IRB from another institution as satisfying the Privacy

2. The Common Rule, Title 45 of Federal Regulations - Part 46, are the rules governing research at all federally funded organizations and mandate IRB approval and empower local authorities to make key judgments about research protocols.

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Rule's requirements.

The IRBs and privacy boards may use normal review procedures or expedited review procedures when reviewing and approving research proposals for compliance with HIPAA. A researcher can satisfy the Privacy Rule's requirements by demonstrating to a privacy board or IRB: (1) a plan to obtain individual authorization from each research participant to access their PHI, or (2) satisfy the conditions to obtain a waiver, under limited circumstances, in order to access PHI without individual authorization.

I will be obtaining individual written consent from research subjects in order to satisfy human subjects requirements, isn't this the same? Am I not also satisfying the authorization requirement set forth by the Privacy Rule?

No, it is not the same and no, you are not! The Privacy Rule does not override the Common Rule[2] (IRB) or FDA's human subjects regulations. In fact, both Privacy Rule and human subjects regulations, when applicable, will need to be approved by an IRB board and/or privacy board. The reason for the difference is *authorization vs. consent*. The Privacy Rule requires that an individual provides authorization for the use of his/her PHI for research whereas the Common Rule requires that an individual provide *informed consent* to participate in research. Depending on the type of study, sometimes one, both, or no authorization and consent may be required, but a review board(s) will have to give its approval in most scenarios.

It is expected that the use of a compound authorization form may be approved in the soon-to-be-released "final" Privacy Rule. The compound authorization form would require only a single authorization form for all uses and disclosures of PHI. The authorization form will be required to include the following elements in detail: a listing of each information item to be used, who may use or disclose the information, who may receive the information, the purpose of the use or disclosure, the expiration date of event (unless for a research database or repository), individual's signature and date, right to revoke authorization, inability to condition treatment, payment, enrollment or eligibility for benefits (except for research-related treatment), and notification that re-disclosure may no longer be protected. In addition, the compound authorization form may be combined with the informed consent form, thus eliminating the need for a separate authorization form and a consent form.

I do not want to obtain individual authorization to access research subjects' PHI. What do I have to do to obtain a waiver?

This will require that a researcher obtain documentation from a privacy board and/or IRB that the Privacy Rule's criteria to obtain a waiver were satisfied in order for a covered entity to provide access to PHI without individual authorization. According to the Privacy Rule, there are three possible criteria under which one may obtain a waiver of authorization from a privacy board and/or IRB.

1) Obtain representation that the use or disclosure is necessary to prepare a research protocol or for similar purpose preparatory to research. It is still not clear whether the new "final" Privacy Rule will retain the condition that no PHI may leave the covered entity.
2) Obtain representation that the use or disclosure is solely for research on a decedent's protected health information. The researcher may still need to provide proof of death.
3) Use or disclose only *indirect identifiers* (e.g., zip codes, age) for research, public health, or health care operations. It will require a data-use agreement from the recipient agreeing to use only for purpose provided and not to re-identify or contact individuals.

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HIPAA De-identified PHI

According to the Privacy Rule, PHI is considered de-identified if a covered entity has removed the following 18 information fields from a data set.

1) Names
2) All geographical subdivisions smaller that a state (includes street address, city, county, precinct, zip code, and equivalent geo codes—except the first three digits of zip codes unless the population density is under 20,000)
3) All elements of dates except year (e.g., birth date, admission date, discharge date, date of death). If an individual is older than 90 years old, birth year can't be used.
4) Telephone numbers
5) Fax numbers
6) Electronic mail addresses
7) Social security numbers
8) Medical record numbers
9) Health plan beneficiary number
10) Account numbers
11) Certificate/license numbers
12) Vehicle identifiers and serial numbers (includes license plate numbers)
13) Device identifiers and serial numbers
14) Web universal resource locators (URLs)
15) Internet Protocol (IP) address numbers
16) Biometric identifiers (including finger or voice prints)
17) Full face photographs or comparable images
18) Any unique identifying number, characteristics, or code; and the covered entity does not have knowledge that information could be used alone or in combination to identify an individual

2003 TRDRP Grant Awards

Award Mechanism	Percent Funded	
Research Project	20.3	(29/143)
IDEA	22.2	(4/18)
Community-Academic	36.4	(4/11)
School-Academic	25.0	(1/4)
New Investigator	19.0	(4/21)
Postdoctoral Fellowship	55.6	(10/18)
Dissertation	66.7	(6/9)

Area	# Awards		$Funded	(%)
Health Effects	32	(55)	11,745,369	(58)
Nicotine Dependence	9	(16)	2,541,497	(12)
Interventions/Policy	17	(29)	6,095,850	(30)
Total	58	(100)	20,382,716	(100)

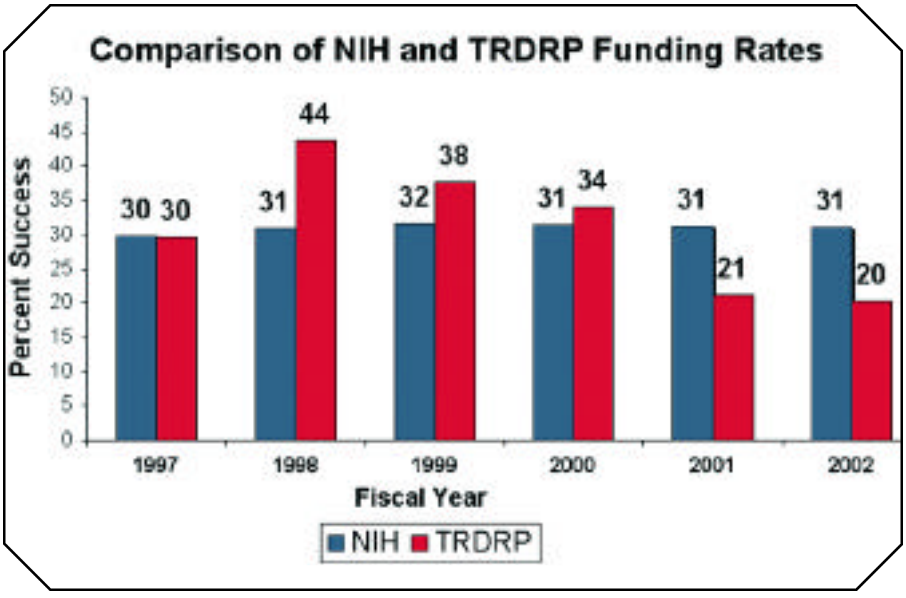
The Realities of Fiscal Constraint

It looks like TRDRP will fortunately not be directly affected this year by the severe state budget cuts being made to cover the projected $24 billion deficit. As a result, TRDRP's appropriation for the 2002–2003 fiscal year will be the same as it was for 2001–2002: $19.434 million. Shortfalls in revenues are being covered from the last remaining reserve in the Prop. 99 Research Account. However, unless revenues for the next year exceed expectations, TRDRP will see a budget reduction in the next fiscal year and the years to come. The redirection of funds ($5 million in FY 2003) to the California Cancer Registry is also a continuing issue that looms larger as the Prop.99 revenues continue to decline. As we have indicated in the past, TRDRP will constantly monitor the budget situation and reassess how to position itself for the future.

Table 1 illustrates the funding crunch faced by TRDRP. We compared funding rates of the National Institutes of Health for full research projects with those of TRDRP. The data clearly show that the funding rate for TRDRP has steadily decreased and is now ten percentage points lower than that of NIH. The data for 2002 is actual TRDRP data, and assumes that the NIH funding rate stays at 31%. With the increased NIH budget, it is possible that their funding rate will increase, making the gap even larger. To fund to the 31% level, TRDRP would need another $7.4 million to fund an additional 13 awards. The $5 million going to the California Cancer Registry would have paid for nine of those awards and would have gone a long way to narrow this widening gap.

We'd like to thank those of you who have contacted your legislators about the redirection of Research Account funds to the California Cancer Registry. We have heard back from legislators wanting to know more about the problem. While there likely will be no resolution of this issue this year, the fact that it is on lawmakers' radar screen is helpful.

Table 1



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Cornelius Hopper Diversity Award Supplements

This year marked the third year of funding for the Cornelius Hopper Diversity Award Supplements (CHDAS). The aim of the CHDAS is to encourage TRDRP-funded principal investigators to mentor individuals who want to pursue careers in research on tobacco use and tobacco-related disease. Qualified applicants for the CHDAS are individuals from groups that are underrepresented among researchers who investigate tobacco use or tobacco-related disease and/or individuals who will work directly with underrepresented groups who are disproportionately affected by tobacco use. We are pleased to announce that five of our currently funded investigators will receive supplements to their TRDRP grants for support of new personnel on their projects.

CHDAS Trainee	Education	Principal Investigator	Institution
Andrea Casillas	Post-baccalaureate	*Randolph Hastings*	Veterans Medical Research Foundation of San Diego
Spring Faller	Post-masters	*Richard Hofstetter*	San Diego State University Foundation
Catherine Domier	Graduate student	*Edythe London*	University of California, Los Angeles
Kim Jinsook	Graduate student	*William McCarthy*	University of California, Los Angeles
Pina Maricela	Undergraduate student	*Ricardo Munoz*	University of California, San Francisco

Other News

TRDRP's 7th Annual Investigator Meeting (AIM 2002)

Focus: Women and Smoking

Mark your calendar for this year's annual meeting, which will be held at the Fairmont Hotel in San Jose on Wednesday and Thursday, December 4 and 5, 2002. Several of the workshops on Wednesday and the plenary session on Thursday morning will focus on the impact of tobacco use on women. The purpose is to provide information on all of the unique issues related to tobacco use by women from marketing to disease, and to identify research needs in this area. Based on feedback received from attendees of previous meetings, we have moved the meeting to Wednesday and Thursday. We are also putting more emphasis on the first day, with workshops in both the morning and afternoon. Additionally, the poster sessions will be held on both Wednesday and Thursday.

The workshops will be followed by a town hall meeting on harm reduction. This is a hot topic in tobacco research and control, spurred on in part by the emergence of new, "less toxic" tobacco products.

The reception on Wednesday evening will be held at the San Jose Modern Art Museum, right across from the hotel.

On the second day, in addition to the plenary session, there will be a luncheon speaker. In the afternoon we will hold a public forum for our attendees. This is an important meeting for TRDRP and our stakeholders to discuss future research priorities and programmatic direction of TRDRP to maximize our effectiveness as a tobacco-related research program. We value your feedback and encourage you to participate.

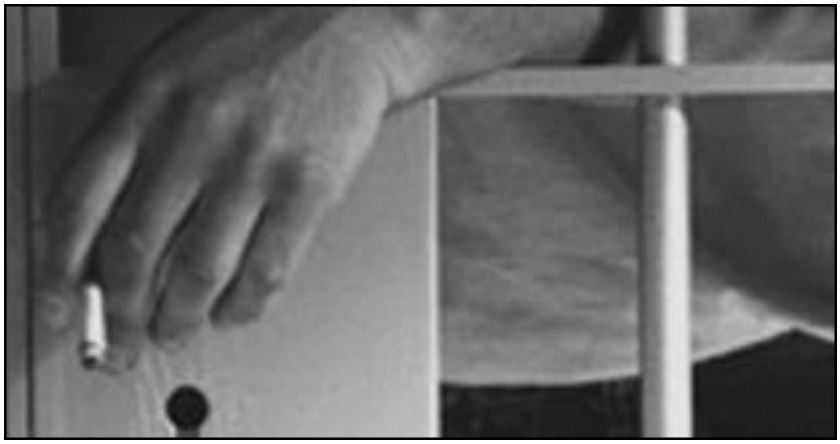
In August, TRDRP will issue a Call for Abstracts to investigators. We encourage all of our investigators and especially the career awardees to take this opportunity to present their findings during the poster sessions. **The abstract submission deadline is October 15, 2002**.

National Conference on Tobacco or Health

The largest US tobacco-control conference is coming to California this year. The **National Conference on Tobacco or Health** will be held in San Francisco on November 19–21, 2002 under the theme *Everyone Counts: Achieving Parity Through Tobacco Control.* Focusing on prevention, cessation, and policy issues, this conference will be of special interest to TRDRP investigators conducting research on behavioral, policy, and economic issues. Researchers focusing on tobacco-related diseases may also find this conference valuable as a way to stay current on the politics and practice of tobacco control at the national, state, and local levels.

TRDRP investigators will be presenting at sessions throughout the conference, among them three TRDRP-sponsored sessions:

- Participatory Research: Breaking down the barriers.
- Tobacco Use and the LGBT Community: From Knowledge to action.
- New Tobacco Products: What do we know? What do we need to know?



Cigarette Smoking In Prisons

by Phillip Gardiner

Tobacco control in prisons today is a conglomeration of varying rules, penalties, and regulations. Some states have banned tobacco products altogether, as in Oregon.[1] Conversely, smoking remains unrestricted in many jails and prisons.[2] Still, smoking in prisons is greatly reduced, compared to the image of old Hollywood movies, where smoking was allowed everywhere and tobacco served as currency within the prison. Yet, California has the largest (and growing) prison population in the United States with over 160,000 as of 1998.[3] The composition of California's prison population is mainly made up of African American and Latino males.[4] Thus, given the size and demographics of the California prison population, tobacco use and tobacco-related disease in prisons should be a major part of epidemiological studies, policies initiatives, and tobacco-control interventions for the 21st century.

Off the Radar Screen?

Smoking inside prison buildings has been outlawed in most states.[4] However, the number of inmates who smoke, the amount of disease related to tobacco smoking, the number of guards and other prison personnel who smoke, and the new natural history of tobacco use in prisons has not been researched in any depth. With the rampant spread of HIV/AIDS, the continuing scourge of tuberculosis and the constant insults to one's mental health, caused or exacerbated by confinement, scholars have, more often then not, focused their attention on these maladies while neglecting tobacco related diseases and smoking in prisons.[5] While there are over 1600 citations in the PubMed data base on prison health, only 25 articles were directly related to tobacco use and smoking.[5] The last articles on smoking in prisons that I was able to identify in PubMed were written by Skolnick in 1990, well before the curtailing of smoking in US prisons.[6, 7] It should also be noted that none of the 25 mentioned citations are review articles; rather, they are short news stories.

Off the radar screen may be too harsh, since the United States Supreme Court upheld the right of the federal government to prohibit smoking on all federal properties in 1997.[8] This national law, coupled with California's 1995 law that outlawed indoor smoking in all state and local buildings, effectively drove smoking outside (and in some cases into the closet) in California's prison system.[9] Despite these restrictions, the majority of California prison commissaries continue to sell cigarettes and loose tobacco to prisoners.[4] Just like Indian reservations and military base commissaries, tobacco products in prisons aren't federally taxed, thus making them more accessible to their captive audiences.[10, 11] In 1995 over $60 million dollars passed through the accounts of California inmates, with most of that money going for food, snacks, toiletries and of course cigarettes and other tobacco products.[12]

Policies Vary State to State

To truly comprehend the complexity of tobacco use and smoking policies and regulations, one must keep in mind that local jails, county lock-ups, state prisons, federal detention centers, and private prisons all may be located in one state and yet, all may have different regulations governing tobacco use. For example, during November 1991, the Wisconsin Department of Health and Social Services and the Centers for Disease Control and Prevention conducted a statewide survey of all 72 jails about smoking and tobacco use. Of the 64 jails that responded to the questionnaire, 21 (33%) had policies that banned smoking for inmates; 15 (23%) had smoking restriction policies; and 28 (44%) had no policies to restrict smoking.[2]

In Massachusetts in 1997, smoking was banned in all Department of Corrections facilities in the Commonwealth.[13] Since the ban left it up to each warden's discretion whether smoking would be permitted outside or banned altogether, some prisons in Massachusetts are under a complete tobacco ban.[13] The Maryland penal system has gone a few steps further. As of May 2001, all 25 prisons, nearly 24,000 inmates and about 8,000 employees were not allowed to smoke inside or in the prison yard.[14] Moreover, the first phase of this sweeping policy was the prohibition of tobacco sales in prison commissaries.[14]

It should be noted that restrictions on smoking practices are not only state or federally mandated, prisoners have more often then not led the way for tobacco control in

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prisons.[8] It was the inmates in Massachusetts and Maryland's prison system who initiated the fight against tobacco use. In Maryland, five former and current inmates filed a lawsuit that sought an order requiring the state to either enforce its 1995 law banning indoor smoking in prisons or offer smoke-free housing. It was the order to ban smoking in Maryland's prisons by the Department of Public Safety and Correctional Services that partially settled the seven year lasuit.[14] Andrew Freeman, the attorney of the inmates that sued Maryland's corrections department, stated that inmates "are supposed to be sentenced to a period of incarceration, not death by lung cancer or heart attacks."[14] The new policy states that employees caught bringing tobacco products into prison will be subject to penalties ranging from a reprimand to dismissal.[14] Maryland has even gone so far as to make matches and lighters contraband![14]

In 1990 Oregon banned smoking in all new prisons and by 1996 older prisons were brought into line. The Oregon Department of Corrections reasoned that it was too expensive to treat inmates for smoking-related diseases. Perrin Damon, Oregon Department of Corrections spokeswoman stated: "Taxpayers have to pay for all their [the inmates] health and upkeep ... we'll see people coming in with those diseases, but we don't need to contribute to the problem and the cost."[1] The downside to Oregon's ban is that tobacco has become the contraband of choice, successfully competing with other illegal drugs.[1]

It should be noted that starting in June 2002, the Men's Colony at San Luis Obispo, California adopted a policy banning all tobacco products for inmates but not for guards.[15] It is too early to comment of the success or failure of this experiment. Recently, Nebraska banned all smoking and use of tobacco products on all state property, including prisons; inmate's lawsuits prompted the state's action.[16]

We Need Answers

The above cursory overview of smoking policies of some prisons is in no way meant to be exhaustive of the myriad of policies governing tobacco use and smoking in prisons. On the other hand, with the prison industry becoming big business in the United States through housing and employing literally millions of people, the use and burden of tobacco smoking can not be lost sight of. While California adult and teen smoking and tobacco use rates of the nonincarcerated are on the decline, we can't say with any certainty that the smoking and tobacco use rates for inmates are following the same pattern. For example, African American teens not in prison have the lowest tobacco use rates both in California and throughout the nation.[17] On the other hand, it is plausible that African American teens who are incarcerated smoke more often then their nonincarcerated counterparts.[18] This is just one example highlighting the need for a better picture of smoking in California's prisons.

The complexity of the situation does not end here. There appear to be conflicting and contradictory interests that must be sorted out. Do prisoners and guards have the same rights to tobacco products in prisons? Will a policy that favors one group over the other benefit tobacco control? What is the health care cost associated with smoking in prisons? Is it the same in prison, as it is on the outside, where tobacco-related diseases dominate health care expenditures?

The states reviewed above that have banned all tobacco use in prisons, only offered limited cessation programs for inmates and employees.[1, 13, 14, 16] It seems reasonable that in the multibillion-dollar-a-year California Department of Corrections budget, a line item for cessation programs be adopted; not just fliers and brochures, but tailored programs that address the needs of California's multiracial and multiethnic prison population. If California is to succeed in reducing the costs of tobacco use in prisons, it must offer effective tobacco-use cessation services to all prisoners and employees.

The Tobacco-Related Disease Research Program is interested in shedding some light on prisons and tobacco use. Why? In 1980 there were 22,500 prisoners in California.[12] By 1996, there were more than 140,000.[12] Today, this figure is well over 160,000.[12] Given these growing numbers, it behooves us to know the status of smoking and tobacco use in California prisons and to develop effective policies and programs to combat it.

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UCSF Faculty to Consider Policy Refusing Tobacco Industry Funding

by Margaret Shield

Members of the UC community, especially researchers examining tobacco use and tobacco-related diseases, should pay attention to a growing controversy at UCSF about UC's position that campuses may not create policies placing restrictions on any particular source of research funding. The controversy hinges on a May 2002 recommendation from the UC Council of Vice Chancellors that is being protested by a number of UCSF researchers, with an upcoming poll of UCSF faculty on the topic scheduled for the fall. At issue is also the ability of UC researchers to accept research grants from funders that require their grantees to forego tobacco industry funding.

In May, the UC Council of Vice Chancellors submitted an opinion to President Atkinson that a university policy singling out a particular industry, such as tobacco companies, for funding restrictions would violate academic freedom and therefore could not be adopted by any UC campus or even by individual faculty members. In response, two UCSF researchers — Dr. Neal Benowitz, Professor of Medicine, Psychiatry and Biopharmaceutical Sciences, and Dr. Stanton Glantz, Professor of Medicine —delivered a letter to UCSF's Chancellor J. Michael Bishop urging UCSF to enact such a policy despite the Council's opinion. At the time the Vice Chancellors expressed their opinion, Dr. Benowitz and Dr. Glantz had been collecting faculty signatures on a petition stating in part "In recognition of the fact that the goals of UCSF and the tobacco industry are fundamentally opposed, we the faculty encourage the University of California, San Francisco to adopt a policy that will reject any financial support from the tobacco industry." Signatures of 200 UCSF faculty in support of this petition were presented along with the letter. Chancellor Bishop has referred the matter to the UCSF Academic Senate which will sponsor an open forum discussion on this issue in the fall. A formal poll of UCSF Senate members on this issue will then be conducted. Currently, UCSF does not receive any funding from tobacco companies.

In the letter to their Chancellor, Dr. Benowitz and Dr. Glantz rejected the argument by the Council of Vice Chancellors that a policy of refusing tobacco industry funding violates academic freedom or the policies of the Regents. Drawing the distinction that restrictions on sources of funding are not the same as restrictions on freedoms of speech or publication, they argued that such a policy would not in any way reduce a UCSF faculty member's ability to publish or advocate positions supporting the tobacco industry. In addition, the UC Regents have already distinguished tobacco companies from other industries by excluding tobacco stocks from the University of California's investment portfolio. The aggressive behavior of the tobacco industry towards UC tobacco researchers—through actions such as lawsuits and subpoenas to block or hamper UC research projects —were cited as further reasons that UC should forego funding from this particular industry. The most recent example of such tactics was an extremely broad set of subpoenas received by four UC campuses (UCB, UCLA, UCSD, and UCSF) and six other universities to turn over all documents—including notes, rough drafts, personal records, letters, telegrams, e-mails, and daily schedules—relating to government-funded tobacco research performed since the 1940s![1]

> *Faculty discussions about this topic have resulted in bans on accepting tobacco funds at a number of prominent US research institutions.*

Faculty discussions about this topic have resulted in bans on accepting tobacco funds at a number of prominent U.S. research institutions, including the M.D. Anderson Cancer Center in Houston, the Roswell Park Cancer Center in Buffalo, the University of Arizona College of Public Health, University of Iowa College of Public Health, Massachusetts General Hospital and Brigham and Women's Hospital. Perhaps the most recent addition to this list was the Harvard School of Public Health whose faculty voted in January of 2002 to refuse tobacco money. An even larger number of public and private universities have divested their investment portfolios of tobacco stock, finding that association politically embarrassing.

The policies of two relatively new national funders of tobacco research, the American Legacy Foundation (ALF; www.americanlegacy.org) and the Flight Attendant Medical Research Institute (FAMRI; www.famri.org), are part of the reason that UC's position on tobacco industry dollars is in the spotlight now. American Legacy, a public health foundation created by the 1998 Master Settlement Agreement (MSA), offers grant funding for research on prevention, cessation, secondhand smoke education, and other areas relating to reduction of tobacco use. FAMRI, a non-profit $300 million

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endowment fund, was established as part of the settlement of a class action lawsuit brought against the tobacco industry in 1991 by flight attendants suffering health disorders and early deaths due to exposure to secondhand smoke in airplanes. Currently, FAMRI offers Young Clinical Scientist Awards, Clinical Innovator Awards, as well as Centers of Excellence awards. As conditions of these awards, both funders require that grantees refuse any financial or in-kind compensation from a tobacco or tobacco-related company. FAMRI, in addition, requires that the recipient institution as a whole refuse any tobacco industry funds. Thus, a UC policy preventing individual campuses, or even individual researchers, from signing statements promising to reject tobacco industry funding could take monies from these funders off the table.

Several UC researchers have qualified for grants from ALF and FAMRI, but initiation of the awards, which are worth million's of dollars, has been complicated by the possibility that UC campuses may accept tobacco industry money. A compromise was reached recently between FAMRI and UCSF on one major award. UCSF allowed the principal investigator to agree to forego all sources of tobacco industry funding, and FAMRI waived the requirement that the entire institution make the same promise.

The debate over how the research community should deal with tobacco company research dollars has been discussed several times in the pages of *Burning Issues* and was also the topic of TRDRP's Town Hall Meeting at AIM 2001. It is clear that the controversy over this issue is not going away. In fact, for UCSF faculty the decision has come to the fore. TRDRP encourages UC researchers to get involved in the debate.

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HIPAA

Continued from page 5

How about if I want to obtain a waiver under criterion three –obtain PHI with indirect identifiers? What will the privacy board or IRB require to grant the waiver?

It is expected that the soon to be released "final" Privacy Rule will modify the provisions that need to be met to obtain a waiver under criterion three. The new proposed provisions to obtain a waiver under criterion three are:

A) The use or disclosure of protected health information involves no more that a minimal risk to the privacy of individuals, based on, at least, the presence of an adequate plan to protect the information, an adequate plan to destroy the identifiers at the earliest opportunity, and assurance that PHI will not be reused or disclose.

B) The research could not practicably be conducted without the alteration or waiver.

C) The research could not practicably be conducted without access to and use of the protected health information.

What will TRDRP do about HIPAA?

TRDRP is following the developments of HIPAA and its Privacy Rule very closely due to the impact it may have on questions of the feasibility of particular research projects. At this point, there may be more questions than answers for everyone concerned, i.e., funders, researchers, universities, and IRB boards. TRDRP historically has patterned itself closely to NIH and thus it will monitor what NIH is doing in regards to HIPAA. The goal is not to burden researchers with different requirements from NIH and TRDRP around HIPAA. That said, two key issues, among others, that TRDRP will be looking into is in what way, if any, will HIPAA be taken into account in the peer review process of applications (e.g. project's feasibility), and will HIPAA assurances be required as a condition to release funding. TRDRP welcomes comments or suggestions on this issue.

Since the HIPAA regulations were still being revised at the time this article was written, the reader is encouraged to visit the following websites for the latest developments:
http://www.hhs.gov/ocr/hipaa

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Tobacco-Related Disease Research Program
University of California—Office of the President
300 Lakeside Drive, 6th Floor
Oakland, CA 94612-3550
1672

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Research Program
Office of Health Affairs
University of California
Office of the President
300 Lakeside, 6th Floor
Oakland, CA 94612-3550
Phone: (510) 987-9870
Fax: (510) 835-4740
e-mail: trdrp@ucop.edu
www.ucop.edu/srphome/trdrp/

JULY 2002 Newsletter

The Tobacco-Related Disease Research Program (TRDRP) supports innovative and creative research that will reduce the human and economic cost of tobacco-related diseases in California and elsewhere.

HOLD THESE DATES

December 4–5, 2002
TRDRP—AIM 2002
San Jose, California

November 10–14, 2002
American Public Health Association
Philadelphia, Pennsylvania
www.apha.org/

November 18, 2002
Lesbian Gay Bisexual Transgender Intersex Tobacco Control & Research Summit
San Francisco, California

November 19–21, 2002
National Conference on Tobacco or Health
San Francisco, California
Registration deadline—October 28, 2002
Early Bird registration by August 26, 2002
www.tobaccocontrolconference.org

February 19–23, 2003
Society for Research on Nicotine and Tobacco
New Orleans, LA
Abstracts deadline—Sept. 20, 2002
www.srnt.org

August 10–14, 2003
10th World Conference on Lung Cancer
Vancouver, British Columbia
Call for Abstracts—September 2002
Abstract deadline—January 31, 2003
www.2003worldlungcancer.org
Note: Although this conference is just across the U.S. border, TRDRPscientific meeting travel funds can be used to attend this conference.