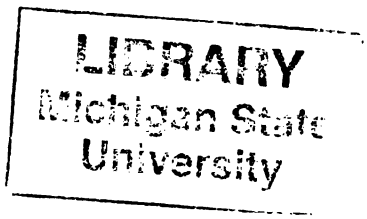

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Evaluation of Non-Response Bias
in a Study of Great Lakes Sport
Fish Consumption and Conception Failure

presented by

Eugene Michael Tay

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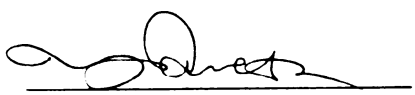
Master's degree in Epidemiology



Major professor

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EVALUATION OF NON-RESPONSE BIAS IN A STUDY OF GREAT LAKES SPORT FISH CONSUMPTION AND CONCEPTION FAILURE

By

Eugene Michael Tay

A THESIS

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ABSTRACT

EVALUATION OF NON-RESPONSE BIAS IN A STUDY OF GREAT LAKES SPORT FISH CONSUMPTION AND CONCEPTION FAILURE

By

Eugene Michael Tay

Research previously conducted by Courval et al.[1] has suggested a modest association in men of Great Lakes sport fish consumption with risk of conception delay. However, a low response rate raised concerns about non-response bias as an explanation for these findings. This study was performed to evaluate whether non-response bias could have occurred. Telephone interviews were conducted with 230 men and 38 women who did not respond to the original survey. Non-responders were compared to the original responders on key demographic, behavioral, and reproductive characteristics. Non-responders were approximately 1.5 years older at interview, were more likely to be Caucasian, and reported higher incomes than responders. No differences were found with respect to education level, marital status, or smoking. Non-responders fished fewer days in the past year and consumed fewer fish meals than responders. Compared with responders, non-responders were more likely to have had two or more children and were less likely to intend to have additional children within the next five years. However, among both non-responders and responders there was an increased prevalence of a period of conception failure among men who reported consuming greater quantities of Great Lakes sport fish. These results suggest that non-response bias is unlikely to have played a major role in the observed association of sport fish consumption and conception delay.

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[1] Courval JM, DeHoog JV, Stein AD, Tay EM, He JP, Humphrey HEB, Paneth N. Sport-caught fish consumption and conception failure in licensed Michigan anglers. Environ Res 1999;80:S183-S188.

To David Cameron
whose impending birth finally motivated me
to finish this thesis essay

To Laura Jane
who had to endure six years of
"Don't worry – I'm going to finish my thesis"

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I would first like to acknowledge Dr. Jeanne Courval and Dr. Aryeh Stein. Dr. Courval and Dr. Stein were instrumental in involving me with the Fisheaters Family Health Project and provided much guidance in the development, execution, and data analysis of this project.

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LIST OF ABBREVIATIONS

PCB ..... Polychlorinated biphenyl

FFHP ..... Fisheaters Family Health Project

INTRODUCTION

FISHING in the State of Michigan is big business. An estimated two million Michigan anglers along with 334,000 nonresident tourists fish Michigan waters annually. Collectively they contribute close to $1.4 billion to Michigan's economy in pursuit of sport-fishing (1).

Not only is fishing a great recreational activity for some, but eating Great Lakes sport fish is a healthy choice as well. Fish are a highly nutritious food – they are a good source of protein and are low in saturated fat, and they contain many valuable vitamins and minerals. Certain sport fish contain omega-3 polyunsaturated fatty acids, which can lower triglyceride and cholesterol levels in the blood (2, 3). Eating fish regularly can reduce mildly elevated blood pressure and prevent hardening of the arteries as well as heart disease (2, 4).

These benefits, however, are not without some potential drawbacks. Studies beginning in the early 1980's suggested potential developmental delay in children of sport fish-eating mothers (5-9). The concern has been about the chemicals found in sport fish of the Great Lakes basin. Organochlorine compounds such as polychlorinated biphenyls, or PCBs, do not degrade quickly or easily in the environment. Despite the banning of PCBs from production in 1976, it is estimated that only about five percent of the 3.4 billion pounds of PCBs made worldwide have been destroyed or degraded (10). Furthermore, PCBs accumulate in the fatty tissues of fish over their lifetimes in a process known as bioaccumulation. The resulting concentration of PCBs in fish can be millions of times greater than the concentration of the chemicals in the water in which they live.

In the Great Lakes region, consumption of contaminated fish has been identified as an important exposure route (11).

Because of these potential concerns, Michigan's fish advisory program was implemented in the 1970's and is updated annually. Women of child-bearing age and children under age 15 are advised to limit their intake or avoid certain types of sport fish altogether, depending on the species and size of fish and the location at which the fish were caught (12).

Recently, more intensive efforts at characterizing the potential health effects of sport fish on humans have been made. An emerging area of research has focused on the effect of sport fish consumption on reproductive and endocrine function. The Fisheaters Family Health Project at Michigan State University was established to pursue this research initiative.

Research conducted by Courval et al. (13) has suggested a modest association, in men only, of Great Lakes sport fish consumption with risk of conception delay. However, these results were not without their limitations. A low response rate in that study raised concerns about the validity of these findings. Responders may have differed from non-responders, and this difference, termed non-response bias (14), may have been a factor in the observed results. Therefore, the present study was conducted to evaluate whether non-response bias could explain these findings. The results of the present study are presented hereinafter and have also been published in the academic literature (15).

CHAPTER 1

BACKGROUND

Polychlorinated biphenyls

Polychlorinated biphenyls (PCBs) are a group of manufactured organic chemicals comprised of two covalently bonded benzene rings with chlorine substitution at any of the remaining carbons (Figure 1). They have the empirical formula of $C_{12}H_{10-n}Cl_n$, where n=1-10. However, due to steric hindrance and electrostatic factors, generally only four to eight of the available carbon atoms are chlorinated at one time. There are 209 possible PCB compounds, called congeners.

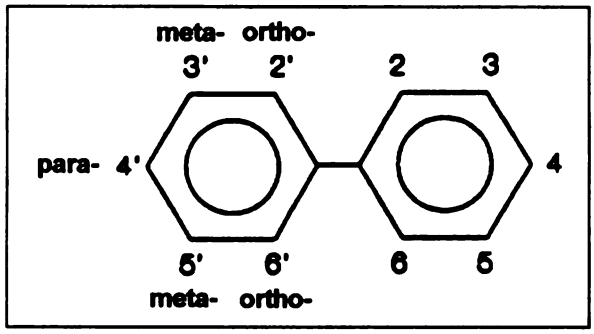

Figure 1: Basic structure of polychlorinated biphenyls.

PCBs were first synthesized in 1881 and manufactured commercially from 1929 until 1977 in the United States by the Monsanto Chemical Company, under the trade name Aroclor. Aroclors were designated by four digit numbers. The first two digits specify the number of carbon atoms in the biphenyl group (with the exception of Aroclor 1016), while the last two digits indicate the approximate percentage of chlorine content by weight in the compound, e.g., Aroclor 1254 contains 54% chlorine content by weight.

Commercial mixtures generally contained between 20 and 60 percent chlorine content by weight.

The amount of chlorination confers different chemical and physical properties to individual congeners. In general, however, PCBs are lipophilic and hydrophobic, resistant to acids, bases, and oxidation/reduction reactions, nonflammable, nonconducting, and heat-resistant. These properties made them well-suited to a variety of industrial applications, such as insulators in transformers and capacitors, lubricants and hydraulic fluids, plasticizers, as flame retardants, and in pesticides, paints, sealants, glues, and carbonless copy paper.

Unfortunately, these very properties that made PCBs ideal in industrial applications create problems for the environment. Their resistance to degradation causes PCBs to persist in the environment. Furthermore, their lipophilic nature causes PCBs to bioaccumulate in the food chain, with the amount of toxic chemicals increasing with each link up the food chain, a process known as biomagnification.

Toxicity of polychlorinated biphenyls

The toxicity of PCBs, like their chemical and physical properties, is a function of the structure of the individual congener, which in turn depends on its amount of chlorination. Individual congeners can assume a coplanar or non-planar conformation depending on the amount and position of the chlorine substitution. Chlorine atoms can be substituted at the ortho, meta, or para positions (Figure 1).

Safe (16) summarized that those congeners that assume a coplanar conformation, namely 3,3',4,4'-tetraCB, 3,3',4,4',5-pentaCB, and 3,3',4,4',5,5'-hexaCB, are

approximate stereoisomers of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) and elicit many of their toxicological effects through the same mechanism, hypothesized to be through the binding of the PCB compound to the Ah receptor to induce hepatic micosomal enzymes. The toxicity of such PCBs can be expressed in terms of TCDD-equivalency factors (TEFs), which is the potency of a particular congener to elicit a toxic effect relative to the potency of TCDD. In addition, there has been increasing focus on the toxic effects of non-coplanar, ortho substituted congeners that elicit their toxicity via unknown mechanisms (17).

Toxic responses to PCBs have been demonstrated in laboratory animals, observations in wildlife, and epidemiologic studies in humans. The literature on PCB toxicology is extraordinarily vast and many reviews have been published (16, 18-27).

In humans, toxicity as a result of PCB exposure came to prominence in 1968 when over 1,300 persons in Japan became ill from eating PCB-contaminated rice oil, in an incident later coined "Yosho" (28). A similar accidental poisoning occurred in Taiwan in 1979, called "Yu-cheng" (29). Consumption of PCB-contaminated rice oil resulted in a severe form of acne called chloracne and hyperpigmentation of the skin, as well as fatigue, nausea, and liver disorders (30).

Since then, researchers have studied the possible toxic effects of PCBs, which may include carcinogenicity (31-38), as well as hepatic (20, 32), dermatologic (32, 39-41), immune (42, 43), pulmonary (44), neurologic (45-48), developmental (5, 7, 8, 41, 48-54), endocrine (55), and reproductive (5, 41, 56-60) dysfunction.

Reproductive toxicity of polychlorinated biphenyls in humans

In several studies of reproductive toxicity of PCBs, women exposed to PCBs prenatally or occupationally gave birth to children who were slightly lighter in weight than those born to women less exposed (5, 56, 57), although this finding has not been consistently found (61, 62). In addition, women with higher serum PCB levels were more likely to have miscarriages than the general population (58), although these results may be confounded (63). More recently, women who ate more than one sport fish meal per month from Lake Ontario had shorter menstrual cycles compared to women who did not eat fish and a slight conception delay, although the latter finding was not statistically significant (59, 60).

In men, Bush et al. (64) found that the concentration of certain PCB congeners was inversely correlated with sperm motility index. Other studies (65, 66) which have reported a decline in semen quality and sperm count have heightened concern about possible reproductive effects of organochlorine compounds.

The Fisheaters Family Health Project

The Fisheaters Family Health Project (FFHP) at Michigan State University was established in order to further our understanding of the exposure to and potential adverse human health effects from environmental PCB exposure. Finding a suitable population to study these effects, however, can prove challenging. Few large populations are chronically exposed to detectable levels of PCBs. One group of individuals potentially at risk of PCB exposure is anglers of the Great Lakes who consume their catch.

Consumption of contaminated fish from the waters of the Great Lakes has been identified as an important exposure route (11).

For the FFHP, a postal questionnaire was developed to survey anglers and their partners about their demographic characteristics, behavioral and fish consumption habits, and reproductive histories (67). A source population of licensed anglers was selected from ten Michigan counties with Great Lakes shorelines. These anglers were identified using fishing license data obtained from the Michigan Department of Natural Resources. Surveys were mailed to 4,931 reproductive-age male and female licensed anglers aged 18-34 years between 1993 and 1995. Five hundred and five questionnaires were returned as undelivered; of the anglers who were presumed to have received the screening survey, 1,445 returned the questionnaire, giving an actual response rate of 1,445/(4,931-505) = 33%. Questionnaires were also received from 840 of their partners.

Data obtained from the original FFHP screening survey suggested a modest association, in men only, of Great Lakes sport fish consumption with risk of conception delay (13). However, these results were not without their limitations, as the low response rate and the simultaneous ascertainment of exposure and outcome raised concerns about bias as possible explanations for these findings.

In order to address some of these limitations, a prospective study was developed. From the previous postal survey, 375 couples and 1,030 individuals who were consumers of Great Lakes sport fish and who planned to have children in the near future were identified. These individuals were most suitable for a prospective study of reproduction and/or correlates of infertility in relation to PCB exposure. The methods and current progress of this prospective study have been described (68). Furthermore, a study of

potential non-response bias was also undertaken, the results of which are presented hereinafter and have also been published in the academic literature (15).

CHAPTER 2

NON-RESPONSE BIAS

The postal survey

The postal survey is a valuable epidemiological research tool. One of the primary reasons for its high prevalence in epidemiological research today is its cost and time effectiveness. Personal and telephone interviews demand significant time and human and financial resources. Multiple telephone calls are often required in order to contact individuals for interviewing or for setting up appointments for personal interviews. Personal interviews have the added cost of transportation of the interviewer to the interview site. If multiple interviewers are used, interviewer variability can become a concern.

In contrast, postal surveys do not require an interviewer and can be done with bulk mailings. Thus, data can be procured quicker, cheaper, and more abundantly with a postal survey. Questionnaires can be mailed to eligible participants, filled out at home at the participants' convenience, and returned by mail. In addition, postal surveys tend to be more valid than personal or telephone interviews because they enable respondents to check information by verifying their records or consulting with other members of the family, and because they permit more leisurely and thoughtful reply (69). Also, they often elicit responses from people too busy for personal interviews and avoids interviewer or respondent bias for topics that are potentially embarrassing in a personal interview situation (70). Enrollment of subjects into a prospective epidemiologic study, such as the

one carried out by us for the Fisheaters Family Health Project (67), is often accomplished using such a self-administered questionnaire.

Limitations of postal surveys

Postal surveys, however, are not without their concerns. In the present society, an endless onslaught of bulk mailings and solicitations deluge individuals and make them reluctant to respond or even open before discarding. Furthermore, the rising prevalence of surveys, including those in the health professions field, may have created a "survey fatigue" in the population (71). The majority of Americans have participated in at least one survey and a substantial proportion are asked to do so again each year (72). In many cases, the experience of being a survey participant is a negative one, leading to an increased disinclination to participate in future surveys (73). Taken together, these factors have made it difficult to achieve high response rates.

Indeed, response rates since the 1950's have decreased markedly. Steeh (74) found that refusal rates in two ongoing trend surveys carried out by a major university survey research center increased from only 6-8 percent in the 1950's to 15-20 percent by the end of the 1970's. Refusal rates in one of these surveys that has continued to the present have leveled off in recent years at 18-20 percent (75). Other authors have found refusal rates as high as 30 percent in major academic surveys (73) and even higher in commercial surveys (76). Increasing concerns about privacy and confidentiality and how the data will be used are primary reasons why some individuals choose not to participate (77). Some authors have speculated that the decline in participation rates can be

attributed to a decline in people's sense of social responsibility and less belief in the legitimacy of social institutions (78).

This high refusal rate, or non-response, is a major limitation of survey research and can seriously challenge the external validity of survey results. Bias can occur when those who do not respond to a survey (the "non-responders") differ from those who do (the "responders"). This bias is termed "non-response bias" (14). When non-response bias occurs, the study population may not be representative of the total survey population. Results drawn from studies of this study population are not necessarily generalizable to the entire group invited to participate and incorrect conclusions may be drawn. Response that is correlated with exposure levels and disease outcome may artificially increase or decrease measures of association in cross-sectional, case-control, and cohort studies (79-83).

Non-response bias is most likely to occur when response rates are low. In this situation, survey estimates will become biased the more non-responders differ from responders. A low response rate, however, does not necessarily indicate that survey estimates are biased by non-response. When responders and non-responders do not differ, the response rate will have no effect on prevalence estimates. Conversely, high response rates does not necessarily protect against non-response bias, as this bias can still be important if the few remaining non-responders differ markedly from responders. For example, in a postal survey of almost 2,500 economically active and capably employable disabled persons, Sheikh and Mattingly (84) obtained an 84% response rate; nevertheless, non-responders were significantly different from responders with respect to employment status and training. Regardless, it has been suggested that in order to best minimize the

potential for non-response bias, response rates of at least 80 percent should be achieved (14, 85).

Handling non-response

There are multiple ways of dealing with non-response. Ideally, the best strategy to limit non-response bias is to maximize response rates. Several reviews and meta-analyses have been published (86-89), and the success of individual methods has been reported (69, 70, 90-101). These methods involve efforts revolving around the timing and techniques of survey administration. Some of the important factors include financial incentives, follow-ups, preliminary notification, questionnaire characteristics (length, color, subject matter), cover letter characteristics (length, type of appeal, format, status of signer), sponsoring institution, deadlines, time of posting, type and amount of outgoing and return postage, and respondent anonymity (102, 103). However, the particular details behind these methods are beyond the scope of this discussion. For the Fisheaters Family Health Project, several of these methods were employed to boost the response rate (67).

Given that increasing response rates often proves challenging, other strategies have been advocated in order to detect a possible bias. Most commonly, information is collected on a sample of non-responders. Non-responders can be contacted by telephone or in person and persuaded to complete a full or shortened survey. Then, a simple comparison of characteristics and responses of responders and non-responders can be made to determine if and how non-responders differ from the responders. However, it should be noted that similarity between responders and non-responders with regard to certain characteristics does not necessarily imply similarity with regard to exposure and

disease status, and the exact influence of any bias on survey variables cannot easily be determined.

Another strategy for detecting a possible bias is to compare the responses of "early" responders, or those who respond before a follow-up letter is sent, versus "late" responders, or those who respond after a follow-up letter is sent, to see if there are any trends operating. The assumption of this strategy is that responders are ordered on a continuum, and that non-responders are simply "super-late" responders. Considerable differences have often (104), but not always (105), been found between early and late respondents.

A final strategy for detecting a possible bias is to compare responders and non-responders on characteristics for which complete data are available, such as in the case of studies of veterans using military records. Seltzer et al. (106) was able to use military records in a postal questionnaire of smoking habits of U.S. veterans and found that only 67% of smokers returned their questionnaire within 30 days, in contrast to 85% of non-smokers.

If a significant difference between responders and non-responders or early versus late responders is detected, statistical methods for offsetting the bias can be employed. For example, weighting adjustments can also be employed. Adjustment using data from a sub-sample of non-responders followed-up intensively, weighted for the original proportion of non-responders, can be performed. However, weighting can sometimes produce disastrous results because weighting schemes assume that (1) the respondents represent a random sample of their subgroup, and (2) all relevant differences between responders and non-responders have been taken into consideration in defining subgroups,

both of which are tenuous assumptions (102). While weighting adjustments are easy to implement and often employed, they at best will attenuate, but not necessarily eliminate, non-response bias. For a more detailed discussion of data analysis strategies for taking non-response into account, see Kessler et al. (107).

Non-response bias in social science literature

The literature on survey response is enormous. Some of the first studies were published as early as the 1920's and 1930's, although the bulk of the literature did not begin to appear until the 1940's. The majority of the early research came out of the social sciences. Comprehensive bibliographies of these early studies have been published (108-110). An example of one such early study is that conducted by Finkler in 1946 (111) on commercial peach production by growers in the State of North Carolina. One of the survey questions asked how many trees the grower owned; the exact number of trees owned for each grower was previously known. The results are shown in Table 1.

Table 1: Responses to three mailings in a postal survey of North Carolina peach growers, 1946 (111).

	No. growers	Percent of population	Mean no. of fruit trees per grower
Response to first mailing	300	10	456
Response to second mailing	543	17	382
Response to third mailing	434	14	340
Non-responders after three mailings	1,839	59	290
Total population	3,116	100	329

The presence and direction of non-response are clear. Growers with a large number of fruit trees were more likely to respond and more likely to respond in an earlier

mailing than growers with fewer trees. Population estimates based solely on the sample obtained from the three mailings would have greatly overestimated the actual number fruit trees owned by each grower.

Attempting to summarize the socio-demographic determinants of response is a daunting task. This is due to the vast literature and the inconsistency within it. Bridge (102) and Goyder (78), however, have reviewed the literature and have attempted to summarize the existing evidence based on hundreds of early studies. Some of their main conclusions are presented in Table 2.

From Table 2, the primary socio-demographic variables that are related to survey response are education, income, and age. Education and income are positively correlated with response, while age is negatively correlated with response. Said another way, non-responders have historically tended to be less educated, have a lower income, and be of an older age.

It should be noted that the single most important factor in predicting response is interest in the topic of survey (102). If the topic interests the respondent, and s/he has something positive to report, then the respondent is very likely to complete the questionnaire. For example, in a 1939 study by Stanton (112), teachers who used radios in the classroom were more likely to respond to a survey about the educational use of the radio. In another study, Pace (113) found that alumni who had graduated from a university were more likely than dropouts to respond to a questionnaire from the university. Finally, Edgerton, Britt, and Norman (114) found that winners in a science fair contest were most likely to respond to a follow-up survey, honorable-mention recipients were next most likely to respond, and "others" were least likely to respond.

Table 2: Summary socio-demographic variables and their relationship with response status (abstracted from Bridge [102] and Goyder [78]).

Variable	Effect
Education	In general, education is positively correlated with response. However, in some studies, highly educated individuals have been difficult to contact.
Income	Income is positively correlated with response. However, as for education, in some studies, the wealthy have been difficult to contact.
Age	Age and response are negatively correlated for response once contacted (older individuals are less likely to respond once contacted). Some studies have reported that age and response are positively correlated for contact (older individuals are easier to contact than younger individuals, because of the frequent shifts in residence and active life style of the young), but this finding was not consistent.
Sex	No relationship exists between sex and response.
Marital status	Non-married individuals are more difficult to contact than married individuals, but this may be confounded by age, as non-married individuals tend to be younger. Once contacted, married and non-married individuals generally respond at similar rates.
Ethnicity	At least one study cited by Bridge (102) found that blacks had a lower response rate than whites, but this study also noted that ethnicity was highly correlated with income.
Others	Other variables were evaluated, such as work status, religion, country of birth, home ownership, dwelling type, family size, and urban vs. rural habitat, but none had convincing evidence of a relationship with response.

Non-response bias in epidemiological and health sciences literature

More recently, studies of non-response began to appear in epidemiological and health sciences research predominately in the 1970's and have grown in importance ever since. An early study was performed by Gordon et al. (115) in 1959. Using the Framingham cohort, the authors sampled 6,532 individuals for their study and were able to perform examinations on 4,494 persons, for a response rate of 68.8%. The authors found that more non-responders than responders died within the first five years of the study, as depicted in Table 3.

Table 3: Age-adjusted death rates for responders and non-responders for the first five years of the Framingham study, 1953-57 (adapted from Gordon et al. [115]).

	Annual age-adjusted death rate	
	Men	Women
Responders (n=4,494)	8.2	3.2
Non-responders (n=1,964)	10.4	6.9
Refused (n=1,464)	11.9	7.3
Moved (n=426)	4.6	3.6
Incapacitated/Ill (n=74)	14.8	11.9
Died during recruitment period (n=74)	-	-

For both males and females, non-responders had higher age-adjusted annual death rates compared with responders. In particular, those non-responders who had refused to participate, or those who "voluntarily" choose not to participate, had even higher age-adjusted annual death rates. This contrasts with those non-responders who had moved out of the study site, or those who were "involuntary" non-responders. As would be expected, those who were incapacitated or too ill to participate had the highest annual age-adjusted death rate within the first five years of the study. From these observations,

the authors suggested that non-responders were on average more likely to be seriously ill than the responders.

Other studies have reached similar conclusions. In a population-based study of cardiovascular disease in a planned suburban development in Southern California from 1972-1974, Criqui et al. (116) sampled 6,155 persons, of which 5,052 participated in the study, for a response rate of 82.1%. Analysis was restricted to those aged 30-79. The authors characterized the non-responders as less healthy than responders, at least in terms of past cardiovascular illness, based on the data presented in Table 4.

Table 4: Age-adjusted comparisons of responders and non-responders to responses on health status in a population-based study of cardiovascular disease (adapted from Criqui et al. [116]).

		Males			Females		
		Non-resonders	Res-ponders	p[a]	Non-resonders	Res-ponders	p[a]
Personal health history							
Hosp. for heart failure	%	4.2	1.1	0.0001	3.1	0.8	0.0001
Hosp. for heart attack	%	9.0	8.0	0.28	4.1	3.0	0.13
History of diabetes	%	4.9	5.7	0.31	6.0	3.0	0.0018
History of stroke	%	3.7	3.0	0.28	1.7	1.3	0.27
Family history (1st degree relatives)							
Family history heart attack	%	22.8	34.2	0.0001	25.1	40.5	0.0001
If previous question yes, was it at age 50 or under	%	12.9	15.1	0.32	17.8	18.9	0.4
Family history stroke	%	20.3	22.3	0.23	15.6	30.5	0.0001
Family history diabetes	%	12.7	15.7	0.10	14.8	17.8	0.09
Risk factors for disease							
History of hyperlipidemia	%	13.1	17.2	0.03	7.9	14.0	0.001
History of hypertension	%	23.4	23.8	0.44	24.4	24.7	0.46
No. eggs eaten weekly	#	4.0	4.2	0.25	3.0	3.2	0.08
Current cigarette smoker	%	26.9	22.4	0.05	31.6	26.6	0.03

[a] Z-test for differences between proportions.

Both male and female non-responders were significantly more likely than responders to have ever been hospitalized for a heart failure. Female but not male non-responders were significantly more likely to have a history of diabetes. Both male and

female non-responders were also significantly more likely than responders to be current cigarette smokers, a finding replicated in other studies (106, 117). Interestingly, both male and female responders were more likely than non-responders to have a history of hyperlipidemia or a first degree relative with a previous heart attack. The authors thus characterized the responders as the "worried well", or those who had lower prevalence of disease but had higher prevalence of risk factors for disease, as compared to non-responders.

Despite the differences found, however, Criqui et al. (116) believed that responders were generally representative of the target population. They based this conclusion for several reasons: the response rate was above 80%; subsets of the population had similar age-sex distributions; and the differences, while statistically significant, were generally small, suggesting that calculations of prevalence or relative risk would be relatively unbiased. For example, the variable with the largest percentage difference between responders and non-responders is the question of a family history of a heart attack for females, 40.5% vs. 25.1%, respectively. The authors claim that if all non-responders had participated, this percentage would have been reduced from 40.5% to 37.8%, and the effect of this bias on subsequent relative risk calculations would probably have been minor. However, the authors did note that the potential for significant non-response bias might increase in a study with larger differences between groups and/or a higher non-response rate. If the response rate had been only 50%, the true prevalence of a family history of a heart attack for females would have decreased from 40.5% to 32.8%.

In another health survey carried out by Macera et al. (118), all persons who visited a free health clinic in Dallas, TX at least once from 1972-1981 were surveyed in

1982 to obtain health outcome information, including questions on physical activity, demographics, and health conditions that had developed since their last visit. Of the 18,806 questionnaires mailed, 3,224 were returned for bad addresses and an additional 142 were not deliverable because of that person's death. Of the 15,440 persons who received the questionnaire, 11,972 responded (77.5%). To assess any potential non-response bias, the authors compared data from the first clinic visit for the responders and non-responders. This data is presented in Table 5.

Among men, responders were more likely to be older, thinner, and able to perform on the treadmill longer than non-responders. Women responders were similarly able to perform on the treadmill longer than non-responders. Both male and female responders were more likely to exercise more and smoke less than non-responders. Responders reported higher percentages of all family history of illness than non-responders (except for women having a father having died of CHD, which was equal). The differences were statistically significant for a family history of cardiovascular disease and stroke in both men and women, and additionally for a family history of hypertension in males only. However, the responders and non-responders did not differ statistically on personal medical history characteristics or clinical measurements, except for male responders having significantly lower uric acid levels than male non-responders.

Table 5: Comparison of baseline characteristics of non-responders and responders to a mailed follow-up survey of 15,440 persons who attended a preventive medicine center in Dallas, TX at least once from 1972-81 (adapted from Macera et al. [118]).

	Men %		Female %	
	Non-responders (n=2,624)	Responders (n=9,409)	Non-responders (n=844)	Responders (n=2563)
Physical characteristics				
Age[a]	20	25*	22	26
Waist girth[b]	7	8	5	8
Body Mass Index[c]	23	19*	20	18
Treadmill test[d]	36	27*	36	28*
Lifestyle behaviors				
Current non-exerciser	50	37*	54	38*
Current smoker	23	19*	20	12*
Current or past smoker	50	51	44	39
Alcohol usage ≥ 14 drinks/wk	21	19	7	8
Egg consumption ≥ 4 eggs/wk	41	38	26	30
Fried food consumption ≥ 4 times/wk	24	23	10	7
Family medical history				
Cardiovascular disease (CVD)	35	40*	35	42
Father died of CVD	19	21	19	19
Hypertension	30	34*	37	44
Obesity	31	34	35	40
Diabetes	20	21	24	27
Stroke	14	18*	15	22*
Personal medical history				
Hypertension	16	16	10	11
Hyperlipidemia	6	6	4	3
Diabetes	4	4	2	2
Asthma	6	6	6	6
Chest pain	17	18	21	19
Thyroid problems	3	3	13	16
Clinical measurements				
Total serum cholesterol > 220 ml	42	38	33	28
Serum glucose > 110 ml	16	15	9	6
Uric acid < 3 or > 7	36	31*	7	6
Diastolic blood pressure ≥ 90 mm	14	12	6	5
Systolic blood pressure ≥ 140 mm	10	9	6	5

[a] Percent of men ≥ 50 years or women ≥ 49 years

[b] Percent of men with waist girth ≥ 97 cm or women ≥ 75 cm

[c] Percent of men with BMI ≥ 27.7 or women ≥ 30.5 cm

[d] Percent of men with treadmill test ≤ 780 sec or women ≤ 495 sec

* $p<0.001$

Macera et al. (118) thus concluded that responders tend to have better health practices, such as regular exercise and non-smoking, and also tend to have a family history of disease of cardiovascular disease, hypertension, and stroke. Therefore they reasoned that using data to the mail survey to make estimates about the underlying population of the clinic would introduce bias into their results, insofar as estimates of prevalence of current non-exercise or smoking habits would be spuriously low and estimates of prevalence of physical fitness and family history of cardiovascular disease, hypertension, and stroke would be spuriously high.

These studies are just a few examples of studies conducted to assess the role of non-response bias in the epidemiological and health sciences literature. A more complete review of this literature is presented in Table 6.

Table 6: Summary of studies of non-response bias in the epidemiological and health sciences literature.

Author	Study design	Study population	n	Response rate	Method of ascertaining response bias	Major Study Variables	effect size among responders	effect size among non-responders	p-value
Gorton et al., 1959 (115)	Population-based, prospective cohort study of cardiovascular disease	Sample of adult Framingham, Mass. population aged 30-59 years, 1948-52	6,532	68.8%	Mortality data from 1953-57	Annual age-adjusted all-cause mortality rate per 1,000 population during first 5 years of study			
						Men	8.2	10.4	no p given
						Women	3.2	6.9	no p given
Paul et al., 1963 (119)		Random sample of men aged 40-55 employed at a Chicago, IL utility for ≥ 2 years in 1957	3,102	67%		Annual all-cause mortality rate per 1,000 population during 4 years and 5 months of study	4.9	4.7	no p given
Doll et al., 1964 (117)	Cross-sectional survey, with 10 year longitudinal follow-up	Men and women whose names were on the British Medical Register and who were then resident in the UK in 1951	59,600	68.2%	Survey, details not elucidated	Smoking status in 1961			
						Non-smokers	21%	6%	no p given
						Heavy smokers (≥ 15 cigarettes/day)	15%	28%	
Oakes et al., 1973 (120)	Cross-sectional postal survey	Random sample of Kaiser-Permanente members aged 20 years and older living in Oakland or Berkeley, CA in 1971	3,827	66.8%	Telephone or personal interview of non-responders	Smoking status			p=0.02
						Smoker	35.4%	43.1%	
						Non-smoker	46.9%	44.8%	
						Ex-smoker	17.6%	12.1%	
						Did not feel well at time of survey	9.7%	4.5%	p=0.01
						Unable to perform work due to health reasons at time of survey	17.1%	16.5%	p=0.80
Seltzer et al., 1974 (106)	Cross-sectional postal survey	Adult white male veterans participating in the Normative Aging Study of the VA Outpatient Clinic in Boston, MA in 1973	1,987	96%	Prior interview data	Cigarette smoker Also: 85% of nonsmokers responded within 30 days vs 67% of non-responders	27.7%	53.2%	p<0.00001

Table 6 (Continued): Summary of studies of non-response bias in the epidemiological and health sciences literature.

Author	Study design	Study population	n	Response rate	Method of ascertaining response bias	Major Study Variables	effect size among responders	effect size among non-responders	p-value
Criqui et al., 1978 (116)	Population-based, cross-sectional survey via personal interview, for study of cardiovascular disease	Suburban neighborhood in Southern California, aged 30-79, 1972-74	6,155	82.1%	Telephone interview with non-responders	*Questions on illness*			
						Men			
						Hosp. for heart failure	1.1%	4.2%	p=0.0001
						Hosp. for heart attack	8.0%	9.0%	p=0.28
						History of diabetes	5.7%	4.9%	p=0.31
						History of stroke	3.0%	3.7%	p=0.28
						Women			
						Hosp. for heart failure	0.8%	3.1%	p=0.0001
						Hosp. for heart attack	3.0%	4.1%	p=0.13
						History of diabetes	3.0%	6.0%	p=0.0018
						History of stroke	1.3%	1.7%	p=0.27
						Family history (1st degree)			
						Men			
						Family. hx. heart attack	34.2%	22.8%	p=0.0001
						If previous question yes, was it at age ≤50	5.1%	12.9%	p=0.32
						Family history stroke	22.3%	20.3%	p=0.23
						Family history diabetes	15.7%	12.7%	p=0.10
						Women			
						Family. hx. heart attack	40.5%	25.1%	p=0.0001
						If previous question yes, was it at age ≤50	18.9%	17.8%	p=0.4
						Family history stroke	30.5%	15.6%	p=0.0001
						Family history diabetes	17.8%	14.8%	p=0.09
						Personal risk factors			
						Men			
						Hx. of hyperlipidemia	17.2%	13.1%	p=0.03
						Hx. of hypertension	23.8%	23.4%	p=0.44
						No. eggs eaten weekly	4.2%	4.0%	p=0.25
						Current cigarette smoker	22.4%	26.9%	p=0.05
						Women			
						Hx. of hyperlipidemia	14.0%	7.9%	p=0.001
						Hx. of hypertension	24.7%	24.4%	p=0.46
						No. eggs eaten weekly	3.2	3.0	p=0.08
						Current cigarette smoker	26.6%	31.6%	p=0.03

Table 6 (Continued): Summary of studies of non-response bias in the epidemiological and health sciences literature.

Author	Study design	Study population	n	Response rate	Method of ascertaining response bias	Major Study Variables	effect size among responders	effect size among non-responders	p-value
Brambilla et al., 1987 (121)	Cross-sectional postal survey	Mass. women aged 45-55 years in 1981-82	10,455	56.7%	Telephone interview of non-responders	Self-assessed health compared to peers			p<0.0001
						Worse	6.9%	9.9%	
						Same	51.8%	58.7%	
						Better	41.3%	31.4%	
						No. of physical symptoms experienced in prior 2 weeks			p<0.0001
						0	23.2%	43.1%	
						1	26.1%	25.7%	
						≥ 2	50.7%	31.2%	
						No. of current chronic conditions			p>0.10
						0	52.2%	50.1%	
						1	31.6%	32.7%	
						≥ 2	16.3%	17.2%	
						Recently sought professional consultation			p=0.053
						No	75.9%	77.9%	
						Yes	24.2%	22.1%	
						Number of lifetime surgeries			p<0.001
						0	54.6%	57.4%	
						1	35.0%	35.5%	
						≥ 2	10.4%	7.1%	
Walker et al., 1987 (122)	Prospective study of cardiovascular disease in men	Randomly selected men aged 40-59 years, stratified by age, among 24 towns in the UK, 1978-80	10,412	65.4%	Death registry, NHS Central Resisters in Southport and Edinburgh	All-cause mortality in mean 7.2 years of follow-up	5.4%	6.7%	p=0.02
						Cardiovascular-related mortality in mean 7.2 years of follow-up	2.8%	3.1%	NS
						Annual all-cause mortality rate by year for 6 years of follow-up			
						Year 1	0.49%	0.82%	p<0.05
						Year 2	0.69%	1.02%	p<0.05
						Year 3	0.63%	1.06%	p<0.05
						Year 4	0.84%	1.04%	NS
						Year 5	0.99%	1.17%	NS
						Year 6	1.10%	1.18%	NS

Table 6 (Continued): Summary of studies of non-response bias in the epidemiological and health sciences literature.

Author	Study design	Study population	n	Response rate	Method of ascertaining response bias	Major Study Variables	effect size among responders	effect size among non-responders	p-value
Jacobsen et al., 1988 (123)	Postal survey of individuals who had attended a coronary heart disease screening	Men aged 20-54 and women aged 20-49 living in Tromso, Norway in 1979-80	16,621	88.2%	Baseline data that had already been collected	*Men*			
						Daily smoker	49.1%	59.8%	p<0.001
						Morning coughing	12.6%	14.9%	p<0.05
						Morning phlegm	9.3%	9.6%	NS
						On sick leave	3.8%	2.7%	NS
						Women			
						Daily smoker	46.2%	57.2%	p<0.001
						Morning coughing	7.0%	10.3%	p<0.001
						Morning phlegm	4.8%	6.4%	p<0.05
						On sick leave	2.5%	4.4%	p<0.001
Macera et al., 1990 (118)	Cross-sectional postal survey in 1982, with analysis of first clinic visit data only	All persons who attended a preventive medicine center in Dallas, TX at least once from 1972-81	18,806	77.5%	First clinic visit data	Waist girth (≥75th percentile)			
						Men ≥ 97 cm	8%	7%	NS
						Women ≥ 30.5 cm	8%	5%	NS
						Body Mass Index (≥ 75th percentile)			
						Men ≥ 27.7	19%	23%	p<0.05
						Women ≥ 30.5 cm	18%	20%	p<0.05
						Treadmill test (≥75th percentile)			
						Men ≤ 780 sec	27%	36%	p<0.05
						Women ≤ 495 sec	28%	36%	p<0.05
						Current non-exerciser			
						Men	37%	50%	p<0.05
						Women	38%	54%	p<0.05
						Current smoker			
						Men	19%	23%	p<0.05
						Women	12%	20%	p<0.05
						Alcohol usage ≥ 14 drinks/wk			
						Men	19%	21%	NS
						Women	8%	7%	NS

Table 6 (Continued): Summary of studies of non-response bias in the epidemiological and health sciences literature.

Author	Study design	Study population	n	Response rate	Method of ascertaining response bias	Major Study Variables	effect size among responders	effect size among non-responders	p-value
Macera et al., 1990 (118) (Continued)						*Family history of disease: Men*			
						Cardiovascular disease	40	35	p<0.05
						Hypertension	34	30	p<0.05
						Obesity	34	31	NS
						Diabetes	21	20	NS
						Stroke	18	14	p<0.05
						Family history of disease: Women			
						Cardiovascular disease	42	35	p<0.05
						Hypertension	44	37	NS
						Obesity	40	35	NS
						Diabetes	27	24	NS
						Stroke	22	15	p<0.05
						Personal medical history: Men			
						Hypertension	16	16	NS
						Hyperlipidema	6	6	NS
						Diabetes	4	4	NS
						Asthma	6	6	NS
						Angina	18	17	NS
						Personal medical history: Women			
						Hypertension	11	10	NS
						Hyperlipidema	3	4	NS
						Diabetes	2	2	NS
						Asthma	6	6	NS
						Angina	19	21	NS
						Clinical measurements: Men			
						Tot. serum chol > 220 ml	38	42	NS
						Serum glucose > 110 ml	15	16	NS
						Uric acid < 3 or > 7	31	36	p<0.05
						Diastolic BP ≥ 90 mm	12	14	NS
						Systolic BP ≥ 140 mm	9	10	NS
						Clinical measurements: Women			
						Tot. serum chol > 220 ml	28	33	NS
						Serum glucose > 110 ml	6	9	NS
						Uric acid < 3 or > 7	6	7	NS
						Diastolic BP ≥ 90 mm	5	6	NS
						Systolic BP ≥ 140 mm	5	6	NS

Table 6 (Continued): Summary of studies of non-response bias in the epidemiological and health sciences literature.

Author	Study design	Study population	n	Response rate	Method of ascertaining response bias	Major Study Variables	effect size among responders	effect size among non-responders	p-value
Heilbrun et al., 1991 (124)	Prospective cohort study of cancer, 15 year follow-up	Japanese men born from 1900-19, residing on Oahu, Hawaii in 1965	11,136	71.9%	Mortality surveillance, via review of death certificates filed	Annual all-cause mortality rate per 1,000 population	12.3	16.8	p<0.0001
						Annual cancer mortality rate per 1,000 population			
Follow-up to Heilbrun et al., 1982 (125) and Benfante et al., 1989 (126)					State Health Dept.	All-cause	4.2	5.1	p=0.03
						Lung	1.2	1.3	p=0.80
						Stomach	1.1	1.5	p=0.06
						Colon	1.3	1.4	p=0.52
						Rectal	0.6	0.5	p=0.31
						Prostate	1.3	0.9	p=0.02
						Any health impairment at enlistment among Vets serving in Vietnam	32.6%	29.5%	NS
						Rel. risk of lung cancer for smokers vs. nonsmokers	9.77 (4.95-19.3)	6.73 (1.58-28.7)	NS
						Rel. risk of colon cancer for those in highest BMI tertile vs. others	1.37 (0.82-2.29)	1.60 (0.59-4.31)	NS
Vestbo et al., 1992 (127)	Postal survey of an established prospective cohort of 11 years	Sample of male cement workers aged 46-69 in Denmark, 1974-75	1,404	87%	Data from baseline survey of the cohort (1974)	Heavy smoker	46.1%	52.8%	NS
						Cough	26.5%	31.7%	NS
						Phlegm	20.4%	21.1%	NS
						Dyspnea grade 3 or worse	13.0%	15.1%	NS
						Chronic bronchitis	9.2%	8.5%	NS
						Mean FEV_1	3.06L	2.95L	NS
						Mean FVC	4.22L	4.13L	NS
					Nationwide register of all hospital admissions during follow-up period	Hospital admissions due to respiratory disease	1.0 (ref)	2.0 (1.1-3.8)	
						Hospital admissions due to COPD	1.0 (ref)	2.2 (1.0-4.9)	
Boström et al., 1993 (128)	Cross-sectional postal survey	Adult inhabitants living in fourteen district healthcare team's catchment areas in Sweden, aged 18-64 years, 1984-85	5,199	63.2%	Telephone interview of non-responders	Daily smoker	36.1%	49.6%	p<0.001

Table 6 (Continued): Summary of studies of non-response bias in the epidemiological and health sciences literature.

Author	Study design	Study population	n	Response rate	Method of ascertaining response bias	Major Study Variables	effect size among responders	effect size among non-responders	p-value
Locker, 1993 (129)	Personal interview of persons having already completed a telephone survey	Adults aged 50 years and older living in Ontario, Canada	3,033	29.9%	Baseline data that had already been collected during the telephone survey	One or more chronic med. cond.	66.8%	62.1%	p<0.001
						Limitations in ADL's	22.2%	18.2%	p<0.05
						Problem chewing	22.8%	22.0%	NS
						Oral pain in previous 4 weeks	35.3%	27.1%	p<0.0001
						Self-rating of oral health			p<0.05
						Excellent	27.3%	28.2%	
						Good	44.8%	48.9%	
						Fair	20.2%	17.8%	
						Poor	7.7%	5.0%	
						Self-perceived need for dental treatment	31.3%	22.2%	p<0.0001
						Regular source of dental care	75.4%	73.9%	NS
						Dental treatment within last year	65.8%	62.3%	NS
Melton et al., 1993 (130)	Prospective cohort study of diabetic complications	All Rochester, Minn. residents meeting criteria for diabetes mellitus on 1/1/86	870	43.7%	Medical records were available for all residents	Presence of any macro-vascular disease (MI, stroke, PVD)	19.7%	29.7%	p<0.001
						Presence of any micro-vascular disease (retinopathy, glomerulo-sclerosis or nephrosclerosis, ESRD)	15.0%	19.3%	NS
						Any neuropathy (neuropathy, radiculopathy, carpal tunnel)	18.7%	17.8%	NS
						Congestive heart failure	1.9%	9.4%	p<0.001
						Hypertension	16.1%	12.4%	NS
Bisgard et al., 1994 (131)	Cross-sectional postal survey with 5 year follow-up surveillance for occurrence of cancer or death	50% random sample of Iowa women aged 55-69 years on January 1, 1986	98,029	42.7%	Department of Transportation license information and cancer and mortality data from State Health Registry of Iowa	Body Mass Index (kg/m^2), quintiles			
						≤ 21.16	20.1%	19.9%	*Responders were on average 0.38 kg/m^2 lighter than non-responders*
						21.17-22.86	21.6%	19.1%	
						22.87-24.78	20.5%	18.8%	
						24.79-27.44	20.6%	21.2%	
						≥ 27.45	17.1%	21.0%	
						Five-year age-adjusted rate per 1,000 person-years for:			RR (NR:R)
						All-cause mortality	7.89	12.32	1.58 (1.49-1.68)
						Myocardial infarction mortality	0.93	1.47	1.63 (1.36-1.95)
						All-site cancer	10.89	11.86	1.09 (1.03-1.16)
						Breast cancer	3.57	3.63	1.01 (0.92-1.12)
						Lung cancer	1.10	1.45	1.40 (1.18-1.66)
						Endometrial cancer	0.89	0.92	1.03 (0.84-1.25)
						Colon cancer	1.27	1.24	1.00 (0.85-1.18)

Table 6 (Continued): Summary of studies of non-response bias in the epidemiological and health sciences literature.

Author	Study design	Study population	n	Response rate	Method of ascertaining response bias	Major Study Variables	effect size among responders	effect size among non-responders	p-value
Panser et al., 1994 (132)	Cross-sectional postal survey with home interview	Random sample of male residents age 40-79 years, age and geographic region stratified, Olmsted County, MN, 1989-91	5,135	55%	Postal survey of non-responders	Age-adjusted prevalence rates			
						Benign prostatic hypertrophy	9.56 (8.08-11.03)	5.26 (3.57-6.94)	no p given
						Prostatitis	1.95 (1.35-2.55)	1.45 (0.66-2.24)	no p given
						Renal/ureteral stones	5.52 (4.49-6.55)	2.60 (1.53-3.67)	no p given
						Urinary tract infection	5.33 (4.29-6.36)	2.61 (1.57-3.65)	no p given
						Infectious pneumonia	4.55 (3.61-5.49)	5.45 (3.88-7.02)	no p given
						Diabetes mellitus	7.46 (6.20-8.72)	8.24 (6.24-10.24)	no p given
						Malignancy (non-urologic)	1.98 (1.32-2.64)	1.71 (0.84-2.58)	no p given
						Myocardial infarction	3.69 (2.80-4.57)	3.53 (2.28-4.77)	no p given
						Stroke	2.15 (1.45-2.86)	2.71 (1.54-3.89)	no p given
						Transient ischemic attack	1.79 (1.15-2.43)	1.94 (0.94-2.94)	no p given
Papageorgiou et al., 1995 (133)	Population-based cross-sectional postal survey	Adults aged 18-75 years registered with two family practices in Manchester, UK	7,699	59%	Computerized diagnostic recording system	Annual age-adjusted consultation rate for low back pain			
						Males	6.5%	4.5%	no p given
						Females	7.5%	6.5%	no p given
						Total	7.1%	5.5%	no p given
Jackson et al., 1996 (134)	Population-based cross-sectional home interview and clinical exam study	Random sample of adults aged 45-64, permanent residents of one of four U.S. counties, stratified by race, 1986-90	26,427	60%	Baseline data that had already been collected	Among white males:			
						Reported general health			p<0.001
						Excellent	38%	26%	
						Good/fair	60%	68%	
						Poor	2%	6%	
						Hospitalized last year	10%	12%	p<0.05
						Self-reported cardiovascular risk factors			
						Current smoker	25%	44%	p<0.001
						Hypertension	32%	37%	NS
						Hypercholesterolemia	24%	17%	p<0.001
						MI, stroke, or diabetes	13%	17%	p<0.01

The results of Table 6 display some remarkably consistent results. Overwhelmingly, non-responders compared to responders tended to be smokers (106, 116-118, 120, 123, 127, 128, 134), with increased cough and phlegm production (123) and requiring more frequent hospitalization for respiratory disease and COPD (127). Most studies that examined differences in mortality between responders and non-responders found a higher all-cause mortality among the non-responders (115, 122, 124, 131), with increased mortality due to myocardial infarction and all cancers (131), although one study (119) did not find such an association.

More conflicting results arose when looking at chronic disease. Some authors found an increased prevalence of congestive heart failure, diabetes mellitus, hyperlipidemia, and/or previous myocardial infarction and stroke among non-responders compared to responders (116, 130, 134). Other authors, however, found no increased prevalence for such conditions (118, 132).

Criqui et al. (116) discussed the "worried-well" phenomena, as discussed previously, in which non-responders tended to have lower prevalence of disease but had higher prevalence of risk factors for disease. Macera et al. (118), however, found somewhat divergent results. Although the authors did find an increased prevalence of risk factors for disease (increased family history of cardiovascular disease, hypertension, and stroke), much like Criqui et al., they found that in their study population non-responders were not as healthy as responders, as evidenced by an increased BMI and decreased exercise tolerance. Bisgard et al. (131) also found that non-responders tended to have higher BMI when compared to responders. Furthermore, other authors have

determined that non-responders tended to self-report poorer general health (121, 134) and required more frequent hospitalizations than responders (134).

Interest in the study subject also tended to attract responders. Persons who did not feel well at the time of survey or were experiencing problems related to the study topic were more likely to respond (120, 129, 133), a finding consistent with previous literature (102).

The data presented by the above studies seem to suggest that in general, non-responders can and do differ from responders with respect to certain morbidity and mortality endpoints. However, the data are far from consistent. Differences in study design, study population, and study topic likely play a sizable role in the discrepancies encountered within the literature. Furthermore, data from non-responder studies are presently limited, and no study to date has examined the role of non-response bias in reproductive epidemiology studies.

CHAPTER 3

METHODS

Population and setting

The design of the Fisheaters Family Health Project (FFHP) has been described (67). Briefly, between 1993 and 1995 a questionnaire was mailed to 4,931 licensed anglers between 17 and 34 years of age and resident in one of 10 Michigan counties bordering a Great Lake (Figure 2). These counties were selected because of the high PCB burden in the sport fish of the surrounding waters due to localized industrial contamination, thereby maximizing the PCB exposure among the study population. Usable responses were received from 1,445 anglers, who form the study base for the results reported previously (13,67). Eligible participants for this study of non-response consisted of the 2,937 individuals (2,371 men, 566 women) who did not respond to the original FFHP screening survey and whose original survey had not been returned as undeliverable by the U.S. Postal Service.

Due to the potential for differences in responses between men and women, the population was first stratified on gender. In addition, because individuals from different parts of the State are quite diverse and distinct from one another in terms of demographic, socio-economic, and behavioral characteristics, the population was stratified based on geographic region as well. Region 1 includes the counties of West Michigan: Allegan, Muskegon, and Ottawa counties. Region 2 includes the Bay Area counties: Bay, Midland, and Saginaw counties. Region 3 includes counties of Southeast Michigan: Macomb, Monroe, St. Claire, and Wayne counties.

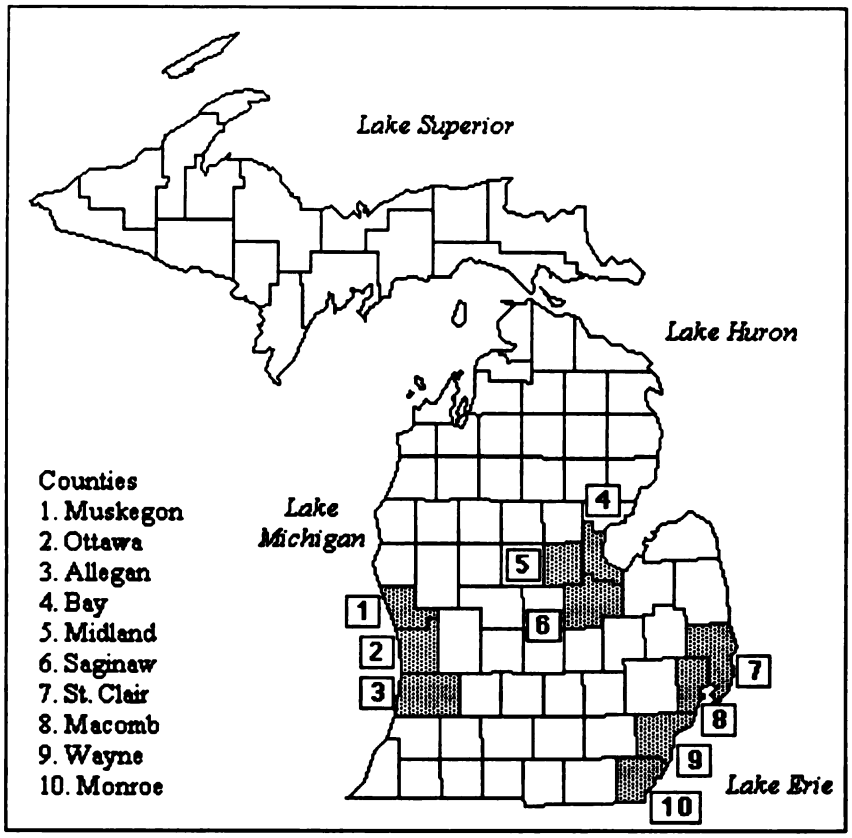

Figure 2: Target counties for the Fisheaters Family Health Project, Michigan.

Based upon the population size in each region by gender cell, initial estimates called for a randomly selected sample of 40 men and 40 women from each region, for a total of 240 participants. These numbers were determined based on power calculations performed in Epi Info 6.02 (135). This sample size would provide adequate power to detect, at the 95% confidence level, a 10% difference in proportions between responders and non-responders within each region (n=80) as well as within each gender separately (n=120). Given the much larger numbers of participants that would be required to survey in order to increase our power, and considering the financial and time constraints of this project, it was felt to be impractical to attempt to detect a smaller difference or to attempt to detect within-region differences among men and women separately. For example, in

order to detect a 9% difference in proportions at the 95% confidence level, at least 100 participants per region would have been required, and in order to detect a 5% difference a sample in excess of 240 participants per region would be needed.

Sampling

Names and addresses of non-responders were imported into a Microsoft Excel (136) spreadsheet. After being sorted into their respective gender and region strata, non-responders were assigned random numbers using the RAND function and sorted by this number. Non-responders were then selected sequentially from each stratum for recruitment into this study until either the target sample size for each stratum was reached or until the population of non-responders for that stratum was exhausted.

Identification of telephone numbers

The original database of angler license applications from the Michigan Department of Natural Resources was previously obtained. This database, however, did not provide telephone numbers. Since the names and addresses of licensed anglers listed in the database were obtained in 1992 and 1993, at the start of the original FFHP survey, it was felt that a telephone number for the angler would best be located by using a telephone database from those years rather than using a database current at the time of this non-response study. It was expected that many would have changed residences during this intervening time interval, given the young age and relative mobility of the study population. Furthermore, many women might have married and hence changed their family names. Use of a 1992 database would, at a minimum, provide a telephone

number which could be used to initiate a tracing of the individual, whereas a 1996 database might have no number at all listed for that individual. A 1992 CD-ROM database of listed telephone numbers (137) was used to obtain anglers' telephone numbers.

Some licensed anglers would not be expected to be listed in the telephone directory, because they may have been children, spouses, partners, or friends of the telephone subscriber. In addition, because people often move within a city, it was thought that anglers who moved between 1991 and 1992, and who consequently had outdated listings and might not match on address, might still live in that city with the same telephone number. Therefore anglers were matched to a listing if they matched in either of the following ways: last name and street address; or first and last name and city, with no other matching name in that city. For example, an angler with a unique name in a city would be matched to a unique listing of that name in that city, regardless of street address. However, there was no way to match a common name in a community with a particular listing without the exact street address.

Interview

The instrument used for this telephone survey was based on the original FFHP screening survey. In order to increase participant compliance and response rates, the survey was adapted so that it could be administered by telephone in a five-minute period. Key questions regarding reproductive history and future productive plans, Great Lakes sport fish consumption and fishing habits, and demographic, socio-economic, and

behavioral characteristics were included. A copy of the survey instrument used is included in Appendix A.

The administration of the telephone survey took place between November 1995 and April 1996. A protocol on how to handle situations such as encountering wrong numbers, busy signals, answering machines, and no answers was developed, based on a protocol developed for the Behavioral Risk Factor Surveillance System (138). In such situations, effort was made to reach the angler on five separate occasions during different periods of the day (morning, afternoon, or evening) and on both weekdays and weekends before replacement. This protocol was established in order to minimize non-contact with those individuals who are employed during non-traditional hours. In general, however, most attempts at reaching eligible anglers occurred weeknights between the hours of 6:00 and 9:00 PM. All attempts were logged for proper book-keeping and tracking. The complete protocol is included in Appendix B.

At the beginning of each telephone call, identification was made by the interviewer and the purpose of the call explained. The subjects were informed that their responses would remain confidential. A copy of the script used is included in Appendix C. If the subject agreed to participate, responses to the interview were recorded on a paper form with only the identification number attached in order to ensure confidentiality.

Data entry

Data were entered into a Microsoft Access (136) database concurrently to its collection and subsequently exported to SPSS for Windows 6.1.3 (139) for analysis. Participants were identified in the database only by their identification number. This

database was separate and distinct from the database matching identification number to study participant. Both databases were password-protected. These measures were all undertaken to ensure confidentiality.

Statistical methods

Initial analyses examined the distribution of all variables between non-responders and responders as a whole using the Pearson χ^2 test for dichotomous variables and independent samples t-test for continuous variables. Stratified analyses were also performed in order to examine the distribution of variables within each gender group and among the three regions for men.

Previous research by Courval et al. (13) suggested a modest association, in men only, of Great Lakes sport fish consumption with risk of conception failure, defined as ever having failed to conceive after 12 months of trying. An attempt to replicate these results by performing logistic regression analyses on both the responder and the non-responder population was performed, recognizing that this study was under-powered to detect modest differences between the two groups. For these analyses, Great Lakes sport fish consumption was defined as the number of average-sized meals of fish caught from the Great Lakes or its tributary system in the past year by the angler himself or by someone that angler knew personally. Sport fish consumption was categorized first as a dichotomous variable (none vs. any), and second as a categorical variable with four levels (none, 1-12 meals, 13-24 meals, or $\geq$ 25 meals per year). In order to increase comparability, analyses were restricted to currently-married and ever-married males. It

was felt that these individuals were most likely to have attempted to conceive a child and thus most likely to have experienced conception delay. As in the main study, both unadjusted analyses and analyses adjusted for age, race, geographic region of residence, income, education, tobacco use, and alcohol consumption were performed. Individuals with missing covariate data were included in the adjusted models, with a 'missing' code applied in such cases, in order to maximize our sample sizes. All data analyses were performed with SPSS for Windows 6.1.3 (139).

CHAPTER 4

RESULTS

The final disposition of all eligible study participants is provided in Table 7. Target cell sizes for men in Region 3 (Southeast Michigan) or for women in any region were not reached. The primary reason for failure to conduct an interview was the inability to identify a telephone number in our CD-ROM telephone database for the angler. This was particularly true in the regions in which target cell sizes were not reached, where 78% of the anglers were not listed, compared to only 56% of the men in Regions 1 and 2. Overall, 72% were not listed. Significantly, an additional 10% of the anglers had telephone numbers that were incorrect or disconnected at the time of this survey. Smaller percentages of anglers did not return phone messages left with family members or on the answering machine, and there were a few anglers who did not answer the phone on successive attempts, were deaf and could not communicate, or had passed away. Of the 364 anglers reached, 230 men and 38 women completed the telephone interview, for a response rate of 74%. A complete tracking flowchart is shown in Figure 3. Because of the inability to reach target cell sizes for women, the three regions of women were combined into one for further analyses.

Table 7: Participation status in a survey of Michigan licensed anglers, by gender and region.

	Males				
	Region 1[a]	Region 2[b]	Region 3[c]	Females	Total
Eligible for non-response study	543	597	1,207	566	2,937
No contact attempted	68	52	0	0	120
No telephone number listed	261	312	945	439	2,030
Listed telephone number incorrect	54	48	68	46	216
Listed telephone number disconnected	10	13	33	8	64
Did not return phone calls	17	26	47	9	99
Answering machine 5x	3	8	6	5	22
Ring no answer 5x	7	2	8	2	19
Unable to communicate (deaf)	0	1	0	0	1
Deceased	0	0	2	0	2
Refused Interview	26	20	31	19	96
Completed Interview	82	83	65	38	268

[a] Region 1: Allegan, Muskegon, and Ottawa counties.
[b] Region 2: Bay, Midland, and Saginaw counties.
[c] Region 3: Macomb, Monroe, St. Claire, and Wayne counties.

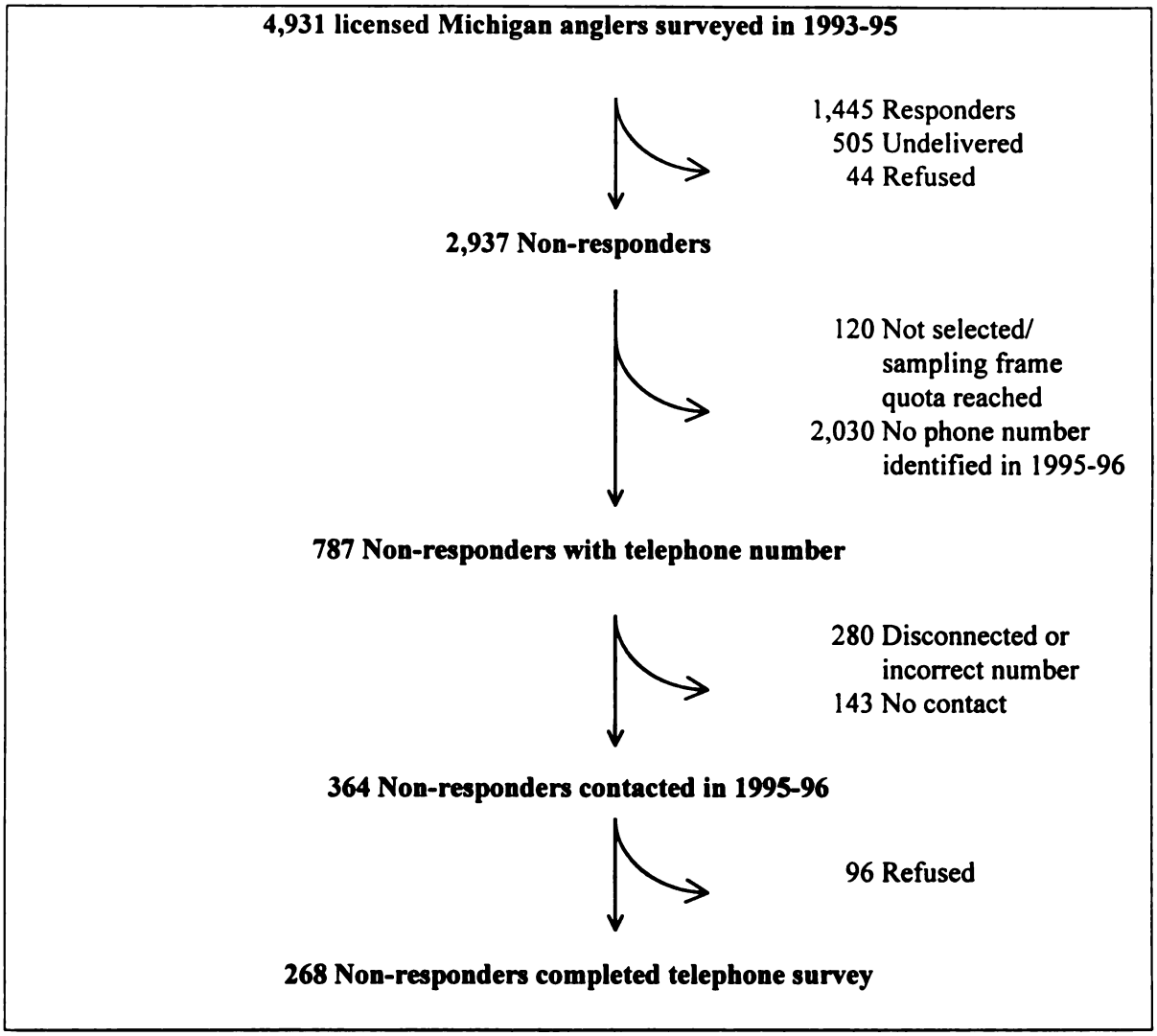

Figure 3: Tracking flowchart of study participants.

Demographic characteristics of men

Demographic, socio-economic, and behavioral characteristics among male responders and non-responders are presented in Table 8. Region-specific analyses of these characteristics for men are presented in Table 9. Although the largest percentage (42%) of male responders resided in Region 3, male non-responders from the same region comprise the smallest percentage (28%) of non-responders. This is consistent with our inability to contact eligible participants from and to reach our target cell size for this region.

On average, male non-responders were approximately 1.5 years older at interview than were responders, 30.9 years vs. 29.5 years. This, however, may reflect the time interval between the two studies. The median year of birth for male non-responders was actually one year later than that for responders, suggesting that, if interviewed at the same time, male non-responders on average would have in fact been younger than responders. These trends were consistent within all three regions. Interestingly, male non-responders tended to be both older and younger than their responder counterparts: higher percentages of male non-responders were found at ages 21-26 years and at ages 35 years and older, with lower percentages in the age groups in between. There were virtually no male non-responders 20 years of age or younger, a finding consistent with the fact that non-responders were interviewed at a significantly later date.

Male non-responders were more likely to be Caucasian than responders. Almost 99% of male non-responders were Caucasian, compared to 92% of responders. This trend was consistent within all three regions, and particularly for Region 3, in which this difference reached significance. In Region 3, no non-Caucasian males were recruited for

our non-responder population, despite the fact that this region contained the highest percentage of non-Caucasians in our responder population.

No significant differences of marital status were found between male non-responders and responders. Overall, approximately 50-53% of both groups reported being currently married, 40-43% of both groups reported having never married, and about 7% of both groups reported being divorced, separated, or widowed. Significantly, a higher percentage of male responders residing in Region 1 (West Michigan) reported being currently married compared to non-responders of the same region as well as responders from the other regions.

Non-responders reported higher incomes than responders. Almost 90% of non-responders reported annual incomes of $20,000 or more, and 40% reported annual incomes in excess of $40,000. This compares with approximately 75% and 32% of responders, respectively. These trends were consistent within all three regions.

With respect to education, similar percentages of male non-responders and responders had earned a high school degree or less. Of those who attended college, male non-responders were slightly more likely than responders to have obtained a college degree. Twenty-two percent of male non-responders compared to 18% of responders had attained a college degree, although this finding was not statistically significance. These trends were similar among the three regions.

Table 8: Demographic, socio-economic, and behavioral characteristics among male non-responders and responders to a survey of Michigan licensed anglers.

		Non-responders (n=230)	95% CI[b]	Responders (n=1,129)	95% CI[b]	p[a]
Region of Residence						<0.001
West Michigan	%	35.7	(29.6, 42.3)	28.3	(25.7, 31.0)	
Bay Area	%	36.1	(30.0, 42.7)	29.7	(27.1, 32.5)	
Southeast Michigan	%	28.3	(22.7, 34.7)	42.1	(39.2, 45.1)	
Year of birth (median)	year	1965		1964		
Age at time of survey (mean)	years	30.9	(30.0, 31.9)	29.5	(29.1, 29.8)	<0.01[c]
Age at time of survey						<0.001
≤20 years	%	0.4	(0.0, 2.7)	5.6	(4.4, 7.2)	
21-26 years	%	32.7	(26.8, 39.2)	22.4	(20.0, 25.0)	
27-32 years	%	21.7	(16.7, 27.7)	42.2	(39.3, 45.2)	
33-34 years	%	11.9	(8.2, 17.0)	18.8	(16.6, 21.2)	
≥35 years	%	33.2	(27.2, 39.7)	11.0	(9.3, 13.0)	
Ethnic distribution						<0.001
Caucasian	%	98.7	(95.9, 99.7)	91.9	(90.1, 93.4)	
Other	%	1.3	(0.3, 4.1)	8.1	(6.6, 9.9)	
Marital status						0.66
Never married	%	43.2	(36.8, 49.9)	40.0	(37.1, 42.9)	
Married	%	49.8	(43.2, 56.4)	53.0	(50.0, 55.9)	
Divorced, separated, widowed	%	7.0	(4.2, 11.3)	7.1	(5.7, 8.8)	
Annual income						<0.001
<20,000	%	10.4	(6.9, 15.3)	24.9	(22.4, 27.6)	
$20,000 - $39,999	%	49.6	(43.0, 56.2)	43.2	(40.3, 46.2)	
>= $40,000	%	40.1	(33.8, 46.8)	31.9	(29.2, 34.7)	
Highest education level						0.09
High school degree or less	%	47.1	(40.5, 53.8)	44.2	(41.3, 47.2)	
Some college, no degree	%	30.8	(25.0, 37.3)	38.0	(35.2, 40.9)	
College degree or higher	%	22.0	(16.9, 28.0)	17.8	(15.6, 20.2)	
Tobacco use						0.10
Current smoker	%	31.1	(25.3, 37.6)	38.6	(35.8, 41.5)	
Prior smoker	%	20.2	(15.3, 26.1)	18.8	(16.6, 21.2)	
Non-smoker	%	48.7	(42.1, 55.3)	42.6	(39.7, 45.6)	
Alcohol use in past year						0.001
None	%	16.4	(12.0, 22.0)	9.1	(7.5, 11.0)	
< 1 drink/wk	%	38.7	(32.4, 45.4)	48.2	(45.3, 51.2)	
≥ 1 drink/wk	%	44.9	(38.4, 51.6)	42.7	(39.8, 45.7)	

[a] Significance of chi-square test for differences in the distribution of the characteristic between response groups, unless otherwise noted.

[b] 95% confidence interval.

[c] Significance of independent-samples t-test for the difference in the mean age at time of survey between response groups.

Table 9: Demographic, socio-economic, and behavioral characteristics among male non-responders and responders to a survey of Michigan licensed anglers, by geographic region.

		Region 1[a]			Region 2[b]			Region 3[c]		
		Non-responders (n=82)	Responders (n=319)	p[d]	Non-responders (n=83)	Responders (n=336)	p[d]	Non-responders (n=65)	Responders (n=475)	p[d]
Year of birth (median)		1964	1964		1965	1964		1965	1963	
Age at time of survey (mean)	years	31.2	29.3	0.04[e]	30.4	28.8	0.02[e]	31.3	30.1	0.23[e]
Age at Interview				<0.001			<0.001			<0.001
≤ 20 years	%	1.2	7.4		0.0	6.7		0.0	3.6	
21-26 years	%	32.1	22.5		33.8	24.8		32.3	20.6	
27-32 years	%	17.3	39.5		23.8	44.5		24.6	42.5	
33-34 years	%	9.9	20.3		13.8	14.4		12.3	20.8	
≥ 35 years	%	39.5	10.3		28.8	9.5		30.8	12.5	
Ethnic distribution				0.11			0.14			0.01
Caucasian	%	98.8	94.7		97.6	93.2		100.0	89.2	
Other	%	1.2	5.3		2.4	6.8		0.0	10.8	
Marital status				0.03			0.73			0.91
Never married	%	43.2	28.1		41.5	45.0		45.3	44.5	
Married	%	53.4	65.5		50.0	48.6		45.3	47.5	
Divorced, separated, widowed	%	3.7	6.4		8.5	6.4		9.4	8.0	
Annual income				0.02			0.01			0.03
< $20,000	%	8.5	20.9		15.1	34.1		6.9	21.1	
$20,000 - $39,999	%	47.9	48.3		52.1	38.4		48.3	43.1	
≥ $40,000	%	43.7	30.8		32.9	27.5		44.8	35.8	
Highest education level				0.38			0.83			0.14
High school degree or less	%	55.6	50.3		42.7	42.1		42.2	41.6	
Some college, no degree	%	27.2	35.3		35.4	38.4		29.7	39.6	
College degree or higher	%	17.3	14.4		22.0	19.5		28.1	18.8	

Table 9 (Continued): Demographic, socio-economic, and behavioral characteristics among male non-responders and responders to a survey of Michigan licensed anglers, by geographic region.

		Region 1[a]			Region 2[b]			Region 3[c]		
		Non-responders (n=82)	Responders (n=319)	p[d]	Non-responders (n=83)	Responders (n=336)	p[d]	Non-responders (n=65)	Responders (n=475)	p[d]
Tobacco use				0.70			0.29			0.36
Current smoker	%	34.6	37.3		26.8	35.9		32.3	41.3	
Prior smoker	%	17.3	19.6		22.0	20.4		21.5	17.1	
Non-smoker	%	48.1	43.0		51.2	43.7		46.2	41.5	
Alcohol use in past year				0.14			0.03			0.15
None	%	15.0	9.5		18.8	8.8		15.4	9.1	
< 1 drink/wk	%	42.5	53.8		38.8	48.8		33.8	43.9	
≥ 1 drink/wk	%	42.5	36.7		42.5	42.4		50.8	47.0	

[a] Region 1: Allegan, Muskegon, and Ottawa counties.
[b] Region 2: Bay, Midland, and Saginaw counties.
[c] Region 3: Macomb, Monroe, St. Claire, and Wayne counties.
[d] Significance of chi-square test for differences in the distribution of the characteristic between response groups, within region, unless otherwise noted.
[e] Significance of independent-samples t-test for the difference in the mean age at time of survey between response groups, within region.

Behavioral characteristics of men

There was little difference between male non-responders and responders in their smoking patterns. Approximately 43-49% of both groups reported themselves as non-smokers and 31-39% of both groups as current smokers. A higher proportion of non-responders, however, reported drinking no alcohol in the past year, 16% compared to 9%. These trends were relatively similar within the three regions.

Demographic and behavioral characteristics of women

On the whole, these trends for most of the characteristics described above in males were similar for females as well. These data are presented in Table 10. Female non-responders were on average two years older at time of interview than responders, 31.4 years vs. 29.4 years, and a significantly larger percentage of female non-responders were 35 years of age or older, 32.4% vs. 12.6%. Female non-responders were also more likely to be Caucasian, be currently married, have higher annual incomes, have a college degree, and report no alcohol consumption in the past year than their responder counterparts, although because of the small sample size, only the income and alcohol consumption characteristics reached statistical significance.

Table 10: Demographic, socio-economic, and behavioral characteristics among female non-responders and responders to a survey of Michigan licensed anglers.

		Non-responders (n=38)	95% CI[b]	Responders (n=316)	95% CI[b]	p[a]
Region of Residence						<0.01
West Michigan	%	42.1	(26.7, 59.1)	19.9	(15.7, 24.8)	
Bay Area	%	13.2	(5.0, 28.9)	29.4	(24.5, 34.8)	
Southeast Michigan	%	44.7	(29.0, 61.5)	50.6	(45.0, 56.2)	
Year of birth (median)	year	1963		1964		
Age at time of survey (mean)	years	31.4	(29.9, 33.0)	29.4	(28.9, 29.9)	0.02[c]
Age at time of survey						0.02
≤20 years	%	0.0	(0.0, 11.4)	2.9	(1.4, 5.6)	
21-26 years	%	18.9	(8.7, 35.4)	23.5	(19.0, 28.6)	
27-32 years	%	32.4	(18.7, 49.6)	43.9	(38.4, 49.6)	
33-34 years	%	16.2	(6.9, 32.4)	17.1	(13.2, 21.8)	
≥35 years	%	32.4	(18.7, 49.6)	12.6	(9.3, 16.9)	
Ethnic distribution						0.14
Caucasian	%	97.3	(84.5, 99.9)	89.7	(85.7, 92.7)	
Other	%	2.7	(0.2, 15.5)	10.3	(7.3, 14.3)	
Marital status						0.31
Never married	%	24.3	(12.5, 41.3)	27.3	(22.5, 32.6)	
Married	%	70.3	(53.1, 83.4)	59.5	(53.9, 64.9)	
Divorced, separated, widowed	%	5.4	(1.0, 19.3)	13.2	(9.8, 17.6)	
Annual income						0.04
<20,000	%	6.3	(1.3, 20.4)	26.7	(22.0, 32.0)	
$20,000 - $39,999	%	46.9	(30.9, 63.5)	38.0	(32.7, 43.6)	
>= $40,000	%	46.9	(30.9, 63.5)	35.3	(30.1, 40.9)	
Highest education level						0.07
High school degree or less	%	43.2	(29.7, 60.1)	37.3	(32.0, 42.9)	
Some college, no degree	%	27.0	(14.5, 44.1)	45.0	(39.5, 50.7)	
College degree or higher	%	29.7	(16.6, 46.9)	17.7	(13.8, 22.5)	
Tobacco use						0.48
Current smoker	%	42.1	(26.7, 59.1)	35.7	(30.5, 41.3)	
Prior smoker	%	13.2	(5.0, 28.90	21.2	(16.9, 26.2)	
Non-smoker	%	44.7	(29.0, 61.5)	43.1	(37.6, 48.8)	
Alcohol use in past year						0.01
None	%	26.3	(14.0, 43.4)	10.3	(7.3, 14.3)	
< 1 drink/wk	%	55.3	(38.5, 71.0)	70.8	(65.4, 75.7)	
≥ 1 drink/wk	%	18.4	(8.3, 34.9)	18.9	(14.8, 23.8)	

[a] Significance of chi-square test for differences in the distribution of the characteristic between response groups, unless otherwise noted.

[b] 95% confidence interval.

[c] Significance of independent-samples t-test for the difference in the mean age at time of survey between response groups.

Fishing habits and fish consumption

Table 11 presents data on fishing habits and fish consumption for both men and women. Region-specific analyses of these characteristics for men are presented in Table 12. Among men, non-responders as a whole fished significantly fewer days than did responders. Non-responder men fished in the Great Lakes on average 26.3 days in the past year, compared with 33.5 days for responders. In addition, 12.2% of non-responder men reported no fishing at all during the past year, compared to 4.3% of responders. Approximately 40% of non-responders and 50% of responders claimed to have fished 25 or more days in the past year. These trends generally hold for men when examined regionally, particularly for men in Regions 2 and 3. In Region 1, although there were a higher proportion of non-responder men who reported no fishing during the past year compared to responders, 12.3% vs. 3.3%, the non-responder men on average fished about the same number of days as did their responder counterparts, 34.2 and 36.8 days, respectively. Interestingly, non-responder men from Region 1 fished more days than the non-responder men from the other regions (22.1 and 21.8 days for non-responder men in Regions 2 and 3), although this was not statistically significant by the Kruskal-Wallis one-way ANOVA nonparametric test ($p=0.11$).

These trends were similar for women, although both non-responder and responder women fished on significantly fewer days than the their male counterparts. Non-responder women on average fished in the Great Lakes on slightly fewer days in the past year than did responder women, 12.9 vs. 15.9 days, respectively, and a higher percentage of non-responder women reported no fishing at all during the past year, 28.9% compared

to 14.1%. Neither of these findings were statistically significant, however, due to the small sample size of non-responder women.

For men, there was no clear pattern in consumption of Great Lakes sport fish. Over 40% of both non-responders and responders reported eating 1-12 Great Lakes sport fish meals in the past year. A higher percentage of non-responders, however, did not eat any Great Lakes sport fish in the past year compared to responders, 20.5% vs. 13.7%. For women, significantly more non-responders did not eat any Great Lakes sport fish meals in the past year compared to responders: about 45% vs. 25%, respectively.

Table 11: Fishing habits and Great Lakes sport fish consumption in past year among non-responders and responders to a survey of Michigan licensed anglers, by sex.

		Male non-responders (n=230)		Male responders (n=1,129)		p[a]
			95% CI[b]		95% CI[b]	
Days fished in waters of State of Michigan in past year (mean)	days	26.3	(22.2, 30.4)	33.5	(31.2, 35.8)	<0.01[c]
Days fished in waters of State of Michigan in past year						<0.001
None	%	12.2	(8.4, 17.3)	4.3	(3.2, 5.7)	
1 – 12 days	%	33.2	(27.2, 39.7)	28.9	(26.3, 31.7)	
13 – 24 days	%	14.4	(10.3, 19.8)	18.1	(15.9, 20.5)	
≥ 25 days	%	40.2	(33.9, 46.9)	48.7	(45.8, 51.7)	
Great Lakes sport fish meals eaten in past year						0.02
None	%	20.5	(15.6, 26.4)	13.7	(11.8, 15.9)	
1 – 12 meals	%	40.6	(34.2, 47.3)	45.6	(42.7, 48.6)	
13 – 24 meals	%	20.1	(15.2, 26.0)	25.4	(22.9, 28.1)	
≥ 25 meals	%	18.8	(14.1, 24.6)	15.3	(13.3, 17.6)	

		Female non-responders (n=38)		Female responders (n=316)		p[a]
			95% CI[b]		95% CI[b]	
Days fished in waters of State of Michigan in past year (mean)	days	12.9	(5.8, 20.1)	15.9	(13.3, 18.5)	0.46[c]
Days fished in waters of State of Michigan in past year						0.13
None	%	28.9	(15.9, 46.1)	14.1	(10.6, 18.5)	
1 – 12 days	%	42.1	(26.7, 59.1)	50.3	(44.7, 55.9)	
13 – 24 days	%	13.2	(5.0, 28.9)	17.3	(13.4, 22.0)	
≥ 25 days	%	15.8	(6.6, 31.9)	18.3	(14.3, 23.1)	
Great Lakes sport fish meals eaten in past year						0.05
None	%	44.7	(29.0, 61.5)	24.6	(20.0, 29.8)	
1 – 12 meals	%	28.9	(15.9, 46.1)	48.4	(42.8, 54.1)	
13 – 24 meals	%	15.8	(6.6, 31.9)	16.3	(12.5, 20.9)	
≥ 25 meals	%	10.5	(3.4, 25.7)	10.7	(7.6, 14.8)	

[a] Significance of chi-square test for differences in the distribution of the characteristic between response groups, unless otherwise noted.

[b] 95% confidence interval.

[c] Significance of independent-samples t-test for the difference in the mean number of days fished between response groups.

Table 12: Fishing habits and Great Lakes sport fish consumption in past year among male non-responders and responders to a survey of Michigan licensed anglers, by geographic region.

		Region 1[a]			Region 2[b]			Region 3[c]		
		Non-responders (n=82)	Responders (n=319)	p[d]	Non-responders (n=83)	Responders (n=336)	p[d]	Non-responders (n=65)	Responders (n=475)	p[d]
Days fished in waters of State of Michigan in past year (mean)	days	34.2	36.8	0.59[e]	22.1	28.8	0.07[e]	21.8	34.5	0.02[e]
Days fished in waters of State of Michigan in past year				0.01			0.001			0.001
None	%	12.3	3.3		14.5	3.2		9.2	5.8	
1 – 12 days	%	24.7	25.2		27.7	33.1		50.8	28.3	
13 – 24 days	%	14.8	19.5		19.3	20.1		7.7	15.8	
≥ 25 days	%	48.1	52.0		38.6	43.6		32.3	50.0	
Great Lakes sport fish meals eaten in past year				0.15			0.44			0.03
None	%	17.3	12.6		16.9	11.1		29.2	16.3	
1 – 12 meals	%	39.5	45.7		47.0	45.2		33.8	45.7	
13 – 24 meals	%	21.0	27.6		21.7	27.2		16.9	22.5	
≥ 25 meals	%	22.2	14.0		14.5	16.4		20.0	15.4	

[a] Region 1: Allegan, Muskegon, and Ottawa counties.
[b] Region 2: Bay, Midland, and Saginaw counties.
[c] Region 3: Macomb, Monroe, St. Claire, and Wayne counties.
[d] Significance of chi-square test for differences in the distribution of the characteristic between response groups, within region, unless otherwise noted.
[e] Significance of independent-samples t-test for the difference in the mean number of days fished between response groups, within region.

Reproductive characteristics

Table 13 provides data on reproductive characteristics of the two populations. Table 14 provides region-specific analyses of reproductive characteristics for males. Among men, similar percentages of non-responders and responders reported having fathered at least one child, but non-responders were more likely than responders to have fathered two or more children, 40.5% vs. 28.1%, respectively. Consistently, non-responders were significantly less likely to intend to have at least one child in the next five years, 27.2% compared with 40.4% of responders. These trends were consistent among the regions. Similar trends persisted for women as well, but statistical significance was lost due to smaller cell sizes.

A key component in analysis of response bias is the potential for selective response by those who have experienced the study outcome event. As shown in Table 13, among men, a small excess of responders (8.5% compared to 5.7% for non-responders) reported a period of conception failure, defined as trying to conceive and not succeeding for twelve months or more. This difference, however, was not significant. There was no difference in the proportion who reported a medically diagnosed reproductive problem with fathering a child; for both groups only 2.2% reported a medically diagnosed reproductive difficulty.

For women, both non-responders and responders were several times more likely to report difficulty conceiving or having a medically diagnosed reproductive problem than men. However, the non-responders did not differ significantly from the responders for either characteristic. Indeed, female non-responders even reported a higher

prevalence of a period of conception failure (15.8%) than did female responders (11.6%). Thus, there was no suggestion of this response bias.

Table 13: Reproductive history among non-responders and responders to a survey of Michigan licensed anglers.

	Male non-responders (n=230)		Male responders (n=1,129)		p[a]
	%	95% CI[b]	%	95% CI[b]	
Fathered ≥ 1 pregnancy	54.4	(47.7, 60.9)	51.4	(48.4, 54.4)	0.55
Fathered ≥ 1 live birth	52.4	(45.7, 59.0)	46.3	(43.4, 49.3)	0.09
Number of previous live births					<0.001
None	47.6	(41.0, 54.3)	53.7	(50.7, 56.6)	
1	11.9	(8.2, 17.0)	18.2	(16.0, 20.6)	
≥ 2	40.5	(34.2, 47.2)	28.1	(25.5, 30.8)	
Intends to have ≥ 1 child within the next 5 years	27.2	(21.7, 33.5)	40.4	(37.5, 43.3)	<0.001
Has tried, unsuccessfully, to father/conceive a child for > 1 year	5.7	(3.2, 9.8)	8.5	(7.0, 10.3)	0.16
Doctor has said that s/he would have difficulty having children	2.2	(0.8, 5.3)	2.2	(1.5, 3.3)	0.98

	Female non-responders (n=38)		Female responders (n=316)		p[a]
	%	95% CI[b]	%	95% CI[b]	
Experienced ≥ 1 pregnancy	65.8	(48.6, 79.9)	63.7	(58.1, 69.0)	0.80
Experienced ≥ 1 live birth	65.8	(48.6, 79.9)	55.1	(49.4, 60.6)	0.21
Number of previous live births					0.11
None	34.2	(20.1, 51.4)	44.9	(39.4, 50.6)	
1	13.2	(5.0, 28.9)	19.9	(15.7, 24.8)	
≥ 2	52.6	(36.0, 68.7)	35.3	(30.1, 40.9)	
Intends to have ≥ 1 child within the next 5 years	31.6	(18.1, 48.8)	50.2	(44.6, 55.8)	0.03
Has tried, unsuccessfully, to father/conceive a child for > 1 year	15.8	(6.6, 31.9)	11.6	(8.4, 15.8)	0.45
Doctor has said that s/he would have difficulty having children	10.8	(3.6, 26.1)	11.9	(8.4, 16.1)	0.85

[a] Significance of chi-square test for differences in the distribution of the characteristic between response groups, within sex.

[b] 95% confidence interval.

Table 14: Reproductive history among non-responders and responders to a survey of Michigan licensed anglers, by geographic region.

		Region 1[a]			Region 2[b]			Region 3[c]		
		Non-responders (n=82)	Responders (n=319)	p[d]	Non-responders (n=83)	Responders (n=336)	p[d]	Non-responders (n=65)	Responders (n=475)	p[d]
Fathered ≥ 1 pregnancy	%	61.3	60.3	0.88	53.7	50.3	0.59	46.9	46.0	0.90
Fathered ≥ 1 live birth	%	58.8	58.4	0.96	51.2	45.3	0.34	46.2	38.7	0.25
Number of previous live births				0.30			0.04			0.06
None	%	41.3	41.6		48.8	54.7		53.8	61.3	
1	%	13.8	20.6		11.0	18.3		10.8	16.5	
≥ 2	%	45.0	37.8		40.2	27.0		35.4	22.3	
Intends to have ≥ 1 child within the next 5 years	%	32.1	39.0	0.26	24.4	35.4	0.06	25.0	44.8	<0.01
Has tried, unsuccessfully, to father a child for > 1 year	%	5.0	9.4	0.21	7.3	5.3	0.49	4.6	10.1	0.15
Doctor has said that he would have difficulty having children	%	1.3	2.9	0.41	3.7	2.1	0.43	1.5	1.7	0.90

[a] Region 1: Allegan, Muskegon, and Ottawa counties.
[b] Region 2: Bay, Midland, and Saginaw counties.
[c] Region 3: Macomb, Monroe, St. Claire, and Wayne counties.
[d] Significance of chi-square test for differences in the distribution of the characteristic between response groups, within region.

Logistic regression analyses

Table 15 shows the results of the logistic regression models relating fish consumption in the past 12 months to the prevalence of a period of conception failure among both ever-married and currently-married male anglers. Among both responders and non-responders, there is an increased prevalence of a period of conception failure among those men who reported consuming any Great Lakes sport fish in the past year. The unadjusted odds ratio for conception failure among ever-married non-responders was 0.96 for any Great Lakes sport fish consumption in the previous year compared to non-consumers. Among ever-married responders, the odds ratio was 1.47. After adjusting for age, race, region of residence, household income, education, tobacco use, and alcohol consumption, the odds ratios were 2.24 and 1.52, respectively. It should be noted that these odds ratios differ from those presented by Courval et al. (13) because Great Lakes sport fish consumption of non-responders was recorded only for that within the previous year and not for lifetime consumption. Analysis for this study was restricted to Great Lakes sport fish consumption within the past year.

A dose-response relationship between fish consumption and conception failure was found among ever-married responder men. This relationship was not evident among the non-responder men; however, the non-responders represent a small sample, and estimates are inevitably imprecise. On the whole, these trends were similar for currently-married male anglers as well.

Table 15: Associations between Great Lakes sport fish consumption and prevalence of a period of conception failure among male responders and non-responders to a survey of Michigan licensed anglers.

	Ever-married			
	Non-responders (n=129)	Responders (n=806)	Non-responders (n=129)	Responders (n=806)
Great Lakes sport fish meals consumed in past year	unadjusted odds ratio		adjusted odds ratio [a]	
Model 1				
None	(-)	(-)	(-)	(-)
Any	0.96	1.47	2.24	1.52
Model 2				
None	(-)	(-)	(-)	(-)
1 – 12 meals	1.13	1.35	2.89	1.39
13 – 24 meals	0.72	1.61	1.98	1.63
≥ 25 meals	0.87	1.71	1.11	1.97

	Currently married			
	Non-responders (n=113)	Responders (n=721)	Non-responders (n=113)	Responders (n=721)
Great Lakes sport fish meals consumed in past year	unadjusted odds ratio		adjusted odds ratio [a]	
Model 1				
None	(-)	(-)	(-)	(-)
Any	1.56	1.89	2.81	1.95
Model 2				
None	(-)	(-)	(-)	(-)
1 – 12 meals	1.76	1.68	3.21	1.71
13 – 24 meals	1.20	2.15	2.67	2.21
≥ 25 meals	1.50	2.40	1.71	2.88

[a] Adjusted for region, age, race, education, income, tobacco use, and alcohol consumption.

CHAPTER 5

DISCUSSION

In this study, non-responders were approximately 1.5 years older at interview, were more likely to be Caucasian, and reported higher incomes than responders. No differences, however, were found with respect to education level, marital status, or smoking. Non-responders had fished fewer days in the past year and consumed fewer fish meals than responders. Compared with responders, non-responders were more likely to have had two or more children and were less likely to intend to have additional children in the next five years.

However, these differences, while real, did not impact on the previously observed association between sport fish consumption and conception failure as published by Courval et al. (13). Among both non-responders and responders there was an increased prevalence of a period of conception failure among men who reported consuming greater quantities of Great Lakes sport fish. These results suggest that non-response bias is unlikely to have played a major role in the observed association.

There are several limitations of this study. The first limitation was an inability to recruit a sufficient number of female non-responders. The total of 38 females out of a desired 120 provides very little statistical power. Indeed, on a number of study variables, similar trends were observed for both males and females. For example, 28.9% of female non-responders reported having not fished in the Great Lakes within the past year, as compared to 14.1% for female responders. For men, these percentages were 12.2% and 4.3%, respectively. While clearly females in general were more likely than males to have

not fished within the past year, the trend is similar. While this difference reached statistical significance for men, it did not for women. This lack of power was also most notable on the number of previous live births, with both male and female non-responders reported having more children, being only significant for males.

The second limitation of this study was the roughly two year delay in interviewing the non-responders. While the data for the original FFHP study was collected between 1993 and 1995, the data for this non-response study was collected in 1996. This two year delay correlates remarkably well with the non-responders mean age, which was 1.5 to two years older at the time of interview. They had, however, similar median years of birth. In fact, for males, median year of birth was 1965 for non-responders and 1964 for responders; if the non-responders and responders were assessed simultaneously, the non-responders may have been on average younger than the responders.

This delay in assessment can predictably produce spurious results. Being on average two years older, non-responders could have been expected to have higher incomes, to have completed schooling and college, to have had a child, and to have completed their planned family. Many of the differences found between non-responders and responders are likely to be confounded by this delay. The differences of many socio-demographic and behavioral characteristics found in this study are not easily comparable to those found in the literature due to this critical delay in non-responder assessment. Ideally, this limitation could have been avoided had the non-responder study been conducted simultaneously with the main Fisheaters study.

The third limitation of this study is the possibility that the results could be invalid due to the differences in interview method. The responders were surveyed by a postal

survey. In contrast, the non-responders were surveyed by telephone interview. This raises the possibility of differential response between non-responders and responders.

According to Dillman et al. (140), there are several major differences between mail and telephone survey. First, telephone interviews require the presence of an interviewer to read questions and record responses, whereas mail surveys can be done privately, directly, and virtually anonymously. The necessary social interaction of a telephone interview may effect answers from respondents. Respondents may be looking for the most socially acceptable response or not want to divulge personal and sensitive information to a total stranger.

Second, telephone interviews require dependence on visual or aural communication, whereas mail surveys depend solely on written directions and cues. Dillman et al. (140) suggested that memory limitations and cognitive processes may effect responses during a telephone interview. Lengthy questions and the interviewer's pace, which is frequently pressured, could make responding to the telephone questions more difficult. In contrast, mail questionnaire respondents can look back and forth at the question and answer choices as needed and answer at their own pace.

Third, the context for responding differs between the two modalities. In telephone interviews, respondents answer one question at a time. In contrast, during mail surveys respondents can see individual questions as part of a larger set of questions; they can look ahead and preview questions and answer them in a different order.

Despite the potential differences between mail and telephone surveys, few studies have directly compared data collected by the two methods. Of the handful of studies performed, there are conflicting results. In a study by McHorney et al. (141), mail

respondents were more likely than telephone respondents to skip questions, report a less favorable health status, and have a chronic medical condition. However, other studies have found little or no systematic differences in responses from mail and telephone respondents (105, 142-144). Mixed results have been reported across survey modes for tests of reliability and response validity (see McHorney et al. (141) for a brief review). In short, few generalizations can be gleaned about differential score reliability or response validity.

A major limitation of this study was an inability to interview a true random sample of the non-responders to the original survey. Telephone numbers were unable to be found in a CD-ROM telephone database (137) for 72% of those eligible for this non-response study, and an additional 10% had disconnected or incorrect telephone numbers. The latter can be attributed primarily to the time interval between the two studies. Given our young, mobile population, it is not unreasonable to expect a significant percentage to have changed residences in this time interval.

The former, however, cannot as easily be explained. A telephone database from 1992 was explicitly used to obtain names and addresses of licensed anglers, rather than one from a current one, in hopes of identifying more eligible anglers. It was felt that this would give the best chance of locating an individual, particularly if that individual had moved between then and the current non-response sub-study. If that individual had moved, a current telephone database would result in no listing; a previous database would, at a minimum, provide a telephone number that could be used to attempt a tracing. In addition, "soft" matching criteria of either a last name and street address, or unique name and city, was used, without regard to address, in hopes of increasing sensitivity.

However, while these techniques did result in a tangible number of completed interviews, neither was notably successful in significantly increasing the low telephone number identification percentage. Furthermore, while a certain percentage of eligible anglers could be expected to have unlisted numbers, as well as to cohabit with an unrelated individual who was the telephone subscriber and therefore not be listed, these factors alone would not be expected to account for all of our difficulty.

Regardless of the causes, the inability to interview a true random sample of the non-responders may have resulted in a study that continues to be biased, as interviewees represent the responders among a study of non-responders. Nevertheless, it is felt that the sample is reasonably valid, as the primary reason for non-participation was not related to the study population's awareness of the hypothesis, but to the above-mentioned inability to identify telephone numbers for a large proportion of the population using publicly available information. Once an individual was personally reached, participation was 74%.

Finally, this study cannot address the more critical aspect of the main study, which is the cross-sectional nature of the observed relationship. A time order to the association can not be assigned: indeed, it is likely that the period of conception failure was in the more remote past than the past 12 months for which fish consumption was estimated. Resolution of this limitation requires prospective data, which is currently being accrued (68).

Despite these limitations, this study has a number of strengths. This study adds to the growing literature on non-response bias. Several socio-demographic and behavioral characteristics were assessed. Similarities and differences in results of different variables

provides for further intellectual thought and debate. In addition, this study is the first study to our knowledge to assess non-response bias in a reproductive epidemiological study. Furthermore, it provides validation to the findings of the relationship between sport-caught fish consumption and conception delay.

While this study provides useful information, as with any study it could be improved upon. Future studies should give consideration to alternative recruitment methods. While in 1996 world wide web telephone directories were rather primitive, today they are quite advanced, and their use in searching for persons is suggested. Given that anglers are required to purchase annual fishing licenses, it may be possible to cross-reference names from previous databases to names on the current license database. Finally, the use of credit histories and banking information to locate individuals is a possible, albeit costly, method at locating individuals.

Future studies should also consider the application of more advanced statistical analyses. The analyses conducted here consisted mainly of Pearson χ^2 test for dichotomous variables and independent samples t-test for continuous variables. Multivariate logistic regression modeling could be done in order to ascertain independent predictors of response.

Finally, as mentioned above, ideally the non-responder sub-study should have been conducted simultaneously with the main Fisheaters study. Future studies should allow for non-response considerations in its planning stages.

APPENDICES

APPENDIX A

TELEPHONE CALLING RULES OF REPLACEMENT

CODE		EXPLANATION/RULE
01	Completed interview	Do not replace.
02	Wrong number	Angler does not live at this residence. Replace.
03	Non-working number	Usually recognized by a recording or fast-busy signal. Replace.
04	Ring no answer (five rings)	Normal telephone ring which no one answers. Replace after five (5) calling occasions, each consisting of three (3) attempts, and occurring at varying periods of the day and on different days (weekday, weeknight, weekend).
05	Answering machine -- left message	Answering machine picks up. Leave name, message (script), and 1-800#. Replace after five (5) calling occasions, occurring at varying periods of the day and on different days (weekday, weeknight, weekend)
06	Line busy	Replace only after five (5) calling occasions, each consisting of three (3) attempts at ≥ 10 minute intervals, and occurring at varying periods of the day and on different days (weekday, weeknight, weekend).
07	Language barrier	Angler does not speak English well enough to be interviewed and there are no interviewers who speak his/her language. Replace.
08	Refused interview	Replace.
09	Correct number but angler not home	Other family member answers telephone, but angler him/herself is not home. Attempt to determine when angler will be home and schedule an appointment.
10	Angler home but bad time -- appointment made	Angler home, but bad time for interview. Appointment scheduled.

CODE		EXPLANATION/RULE
11	Terminated within interview	A hang-up or refusal to continue at some point after the first question has been asked (this does not mean the respondent refused a particular question). If disconnection was accidental, phone again and attempt to complete interview; otherwise, consider completed.
12	Respondent unable to communicate	Physical/mental impairment. Example: respondent is deaf. Replace.
13	Angler no longer resides at this residence -- left 1-800#	Family (e.g., parents) resides at residence, but angler has moved. Give 1-800#.

APPENDIX B

QUESTIONNAIRE

I would first like to ask you some questions about your fishing and fish eating habits.

1. In this past fishing year, from April 1, 1994 to March 31, 1995, how many days did you go fishing in waters in the State of Michigan? _____ days

2. In April, May, and June of this past fishing year (1994), how many meals of Great Lakes sport fish that were caught by you personally or by someone you know did you eat? _____ meals

3. In July, August, and September of this past fishing year, how many meals of Great Lakes sport fish that were caught by you personally or by someone you know did you eat? _____ meals

4. In October, November, and December of this past fishing year, how many meals of Great Lakes sport fish that were caught by you personally or by someone you know did you eat? _____ meals

5. In January, February, and March of this year (1995), how many meals of Great Lakes sport fish that were caught by you personally or by someone you know did you eat? _____ meals

6. How do these amounts of fish that you eat during this past fishing year compare with previous years? Would you say you ate about the same, more than usual, or less than usual?
   _____ same
   _____ more
   _____ less

Now I would like to ask you some general questions about your health.

7. Have you smoked more than 100 cigarettes during your entire life?
   NO: GOTO QUESTION 9.
   _____ yes
   _____ no

8. Do you currently smoke cigarettes? _____ yes
_____ no

9. How often have you drunk alcoholic beverages over the past 12 months?

1	Never	5	4-6 days/week
2	Once a month or less	6	About once a day
3	> 1/mo. but < 1/wk	7	More than once a day
4	≥ 1/wk but < 4 days/wk		

code _____

10. How many times have you and any partner conceived a child together? _____ preg.
NONE: GOTO 12.

11. How many of these have resulted in a live birth? _____ births

Have you ever had a child with a birth defect? _____ yes
_____ no

12. How many children do you intend to have within the next five years (not including any child if currently pregnant)? _____ kids

13. Did you and any partner ever try for more than one year to conceive a child without being able to do so? _____ yes
_____ no

14. Has a doctor told you that it would be difficult or impossible for you to have children? _____ yes
_____ no
NO: GOTO 15.

15. What was the reason?

_____

Now I would like to ask you some questions about yourself.

16. In what year were you born? 19 _____

17. What is your main racial background?

1	African-American	4	Caucasian
2	American Indian	5	Hispanic
3	Asian/Pacific Islander		

code _____

18. What is the highest level of school you have completed?

1	No high school degree	3	Some college	
2	High school degree	4	College degree or higher	code _____

19. What is your present marital status?

1	Never married	4	Separated	
2	Married	5	Widowed	
3	Divorced			code _____

20. Which category best describes your total family income for 1994?

1	< $20,000	3	$40,000 or more	
2	$20,000 to $39,999			code _____

21. Do you have a spouse or partner? _____ yes
NO: GOTO END. _____ no
YES: May I ask some questions of him/her?

END:
Thank you very much for taking the time to answer these questions. Like I said before, your responses will be very helpful in the analysis of our data and will be kept strictly confidential. I greatly appreciate your help. Do you have any questions or comments?

Would you like to receive any information about our study?
NO: Well, thank you, again. Goodbye.
YES: Can I confirm your address? My records indicate that you live at...

☐ 1. Wants information about study

☐ 2. Does not want information about study

☐ 1. Correct Address

☐ 2. New Address:

COMMENTS/QUESTIONS:

APPENDIX C

QUESTIONNAIRE SCRIPT AND LOG

Name:

Address:

Hello, may I speak with (First and last name)? Hi, my name is Gene Tay. I am a graduate student at Michigan State University, and I'm working with the Fisheaters Family Health Project, which is a project that is looking at people's eating habits of Great Lakes fish. Within the past year or two, we mailed a questionnaire to you on this topic, but we did not receive it back. At this time, I am not asking you to participate in our study, but I would like to ask you a few questions about your fish eating habits and your family background so that we can learn whether those who responded to our questionnaire are different from those who did not. Your responses will be critical in the analysis of our data and will also be helpful for me for my master's thesis project. I want to let you know that your participation in this telephone survey is voluntary, but if you do, your responses will be kept strictly confidential. In addition, you may refuse to answer any question you do not wish to answer, and you may stop this interview at any time. Is this a good time for you to spend about five minutes to answer my questions?

NO: Is there a better time I could call back? Like I said, your responses are very important to us.
NO AGAIN: Okay. Thank you for your time and I'm sorry to have inconvenienced you. Goodbye.
YES: Continue.

LOG

CALL #1 DATE	TIME	RESULT	CALL #2 DATE	TIME	RESULT	CALL #3 DATE	TIME	RESULT
_____	_____	_____	_____	_____	_____	_____	_____	_____
	_____	_____		_____	_____		_____	_____
	_____	_____		_____	_____		_____	_____
CALL #4 DATE	**TIME**	**RESULT**	**CALL #5 DATE**	**TIME**	**RESULT**			
_____	_____	_____	_____	_____	_____			
	_____	_____		_____	_____			
	_____	_____		_____	_____			

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