National Library of Canada
Acquisitions and Bibliographic Services Branch
395 Wellington Street
Ottawa, Ontario
K1A 0N4

Bibliothèque nationale du Canada
Direction des acquisitions et des services bibliographiques
395, rue Wellington
Ottawa (Ontario)
K1A 0N4

Your file Votre référence

Our file Notre référence

NOTICE

The quality of this microform is heavily dependent upon the quality of the original thesis submitted for microfilming. Every effort has been made to ensure the highest quality of reproduction possible.

If pages are missing, contact the university which granted the degree.

Some pages may have indistinct print especially if the original pages were typed with a poor typewriter ribbon or if the university sent us an inferior photocopy.

AVIS

La qualité de cette microforme dépend grandement de la qualité de la thèse soumise au microfilmage. Nous avons tout fait pour assurer une qualité supérieure de reproduction.

S'il manque des pages, veuillez communiquer avec l'université qui a conféré le grade.

La qualité d'impression de certaines pages peut laisser à désirer, surtout si les pages originales ont été dactylographiées à l'aide d'un ruban usé ou si l'université nous a fait parvenir une photocopie de qualité inférieure.

Canada

ISSUES IN HEALTH PROMOTION SURVEY RESEARCH: THE EXAMPLE OF ANABOLIC STEROID USE AT THE HIGH SCHOOL LEVEL

by

ROBERT PAUL PLESS, B.Sc., M.D.

Thesis submitted to
the School of Graduate Studies and Research
in partial fulfilment of the requirements for the
M.Sc. degree in Epidemiology

University of Ottawa

August, 1994

ISBN 0-612-00594-1

UNIVERSITÉ D'OTTAWA
UNIVERSITY OF OTTAWA

ABSTRACT

Health promotion research can be an important adjunct to sound public health practice. Intervention programs designed to modify unhealthy behaviours require information in order to be properly targeted. In the absence of good data, these programs may be wasteful of increasingly scarce resources, or in some cases do more harm than good. However, designing sound research can be difficult. There are factors beyond pure research design issues that prospective investigators must take into account when planning their research. Scientific principles must be tuned to political constraints and practical reality. Most textbooks stress the science and ignore the "art" of survey research. Necessary compromises are not adequately dealt with, resulting in methodologically flawed research.

This thesis explores those issues. It begins by describing a partially successful survey to study anabolic steroid use by high school students that was intended to address some of the gaps in knowledge regarding those drugs in the adolescent population. The results, had the survey been completed, could have served in the design of an appropriate intervention strategy. In the end the actual study had to be aborted, but it gave rise to more general lessons and observations that are developed in the thesis. One major difficulty concerned obtaining parental permission for the students who were selected to take part. Consent forms were mailed to all households, but the results were poor: only 50.5% of parents gave written permission and more than 40% failed to return the consent

form. Other work had shown that non-response is not passive refusal.

In light of the difficulties conducting this study, three major themes were judged critical to the success of health promotion survey research: 1) the community being surveyed must consider the topic of sufficient importance to have an interest in participating in the research, 2) the design of the study and any data collection instrument must meet a set of guiding criteria: be applicable and acceptable to the study population, be feasible within the constraints of the community, produce good quality data and be of reasonable cost, and finally, 3) a method to ensure age appropriate consent that does not compromise data quality should be available for use. These themes are developed using the steroid survey as a case study. The public response to the topic is examined, the burden of ill health that may be caused by steroids is explored and the literature on the prevalence of use among adolescents is summarized. Finally, the ethics of consent requirements in survey research, with an emphasis on research involving children, are explored.

In the end, recommendations emerged. First, that strong linkages of a proactive nature be fostered between researchers, public health practitioners and interests within the community that would examine areas in need of study and encourage research on those issues determined to be important to study. Second that researchers, while maintaining attention to study quality, remain flexible in designing their protocols and be willing to stop research in progress if conditions arise that would lead to data of unacceptable quality. Finally, that education and public health authorities, along with stakeholders that include parent groups, work together to draft uniform consent guidelines for research

involving adolescents and their health. The purpose of such guidelines would be to outline situations in which alternatives to traditional requirements for parental permission, including no explicit requirement, are reasonable. This would overcome a major barrier to studying the adolescent high school population.

ACKNOWLEDGEMENTS

Teaching, wisdom and counsel are truly valuable gifts. During the development of this project, I received all three from the very special people who were my supervisors. Dr. Andrew Pipe, who was the spark; Dr. William Feldman who watched it grow while supporting and encouraging me in so many ways that I can never adequately give thanks, and Dr. Paula Stewart who steadily nurtured it to completion. To them I owe my learning - the greatest gift. Finally, when I was not sure I would be strong enough to finish, Dr. Ian McDowell did not let me give up.

Many others supported both the project and its author. At the Children's Hospital of Eastern Ontario the members of the research "tea party", and especially Mrs. Eva Feldman, watched the study unfold and offered gentle critique along the way. At the Ottawa Board of Education many doors were opened by many people, most of all Mr. Dan Wiseman whose energy was unfailing.

To the Ottawa Board of Education for accepting the project and to the Research Institute of the Children's Hospital of Eastern Ontario, without whose contribution this would not have been possible. They unlocked the door for me.

To the University of Ottawa, Department of Epidemiology and Community Medicine, and all others who helped who I have not mentioned, I owe more than a simple thank you.

CONTENTS

LIST OF TABLES

Part 1 INTRODUCTION

1.0 Research Climate

1.1 Health promotion research

Health promotion is defined as the process of enabling individuals to take control of, and improve their health [1]. It can involve the population as a whole in the context of their everyday lives, or it can focus on individuals or groups at risk and direct interventions geared towards specific risk factors for ill health. In order for those interventions to succeed, health professionals involved in health promotion efforts must strive to understand the influences that may maintain these risk factors. Thus health promotion practitioners must use the best available information to plan intervention activities, and research whose purpose is to gather this information is an important component of the practise of public health.

Descriptive studies are necessary to confirm the existence of a suspected problem and to delineate its scope. More analytic research can then attempt to determine ways to intervene. Such interventions, based on sound research, will then have a much better chance of achieving the desired impact. Evaluation studies will follow to ascertain this, and as a consequence may lead to changes in the intervention programs. The systems underlying these issues are complex, as are the roots of the behaviours that health promotion practitioners are trying to modify.

It therefore becomes important to maintain focus. The tasks faced by researchers in the area of health promotion may appear daunting, but they can be broken down into

broad areas. First, resources should be directed towards health issues and problems that contribute more significantly to a population's burden of ill health. Second, research should be of high quality in both study design and execution because the results may directly impact on entire populations and may in some cases be used to justify major expenditures for program planning and implementation. Should the program fail, not only does the population risk a bad outcome (or money is wasted), but the credibility of health promotion efforts may be called into question in future. Data are often disseminated from studies of poor quality, as a recent analysis has shown [2]. Third, researchers require timely access to a study population that must represent the one for whom intervention is planned. These populations may not be completely autonomous when it comes to informed consent, they may have "guardians". Thus attention to research ethics is needed to gain access to a study population. Increasingly, barriers are being erected by governments, public interest groups, and institutions concerned with the misuse of data and the maltreatment of subjects. Another example of exploitation of subjects occurs where research teams in the third world develop new treatments for disease, but leave behind nothing to follow up the care of the treated individuals when they depart with their data collection complete. All this contributes to public mistrust, and can defeat attempts to initiate even much needed studies. Further challenges arise when studies are needed to address difficult subjects such as drug use. Here, although the community may support the study, the burden of illness may be significant and access to the study population is granted, the study subjects themselves may either fail to participate or may subvert the study. Thus greater care in study design would need to be taken in order to minimize such

biases whenever they may arise.

An important lesson can be learned from a new initiative for research in the third world that is responding in part to the criticisms that were echoed above. A landmark document entitled Essential National Health Research (ENHR) [3] was produced by the Commission for Health Research for Development and is being promoted for adoption by developing countries [4] as well. ENHR seeks to promote research that is responsive to the needs of communities and targeted to the health problems of major importance to those communities. It urges collaboration and continuous communication between policy makers, educators and the public in designing research. Thus, as a concept it paves the way for optimized research designs because the population that is the object of the research has a vested interest in that research. It becomes a sort of "dance" between researchers and lay community members, working towards harmonizing both their agendas. By promoting communications and networking between the groups ultimately responsible for health promotion and education efforts, it strives to open dialogue and remove barriers to conducting research. The community would in essence directly influence research programs and in some cases manage the research, but as a benefit, the studies that are embraced should be easier to plan and execute.

All the measures alluded to in ENHR (although still in the discussion stage) are designed to facilitate research that can be important for public health. Unfortunately, the climate today erects more barriers than it removes. While protective on the surface and in the short term, such barriers to good studies may be detrimental in the long term. Intervention programs designed without research to assist in their planning and

implementation have the potential to do more harm than good [5]. Some drug abuse prevention strategies have been found to stimulate drug use, suggesting that effective program development requires basic information concerning knowledge, attitudes and behaviour [6]. Quality data are needed, otherwise programs may be devised based on invalid assumptions and would thus fail to achieve their objectives, or may even have an undesirable outcome.

1.2 Objectives of the present dissertation

The objective of this thesis is to describe and discuss the issues to consider in constructing and implementing a study among adolescents on a health promotion issue, and highlight the challenges that face researchers wishing to study this population. The general conclusions drawn are applicable to other areas of health promotion research.

The exploration of these research challenges arose from the lessons learned following a "failed" survey on anabolic steroid use at the high school level, which is described in Part 2 below. Although the study was only partially implemented for reasons beyond the control of the investigator, during the planning stages several issues arose that were generic to survey research in the adolescent population. The lessons learned are discussed as principles, developed into criteria, that may guide successful research in similar areas in the future. These are described in Part 3.

This thesis thus approaches the subject in two ways, combining the actual experience in planning and implementing a survey among high school students, with theoretical discussion. The survey itself, despite having had to be discontinued, is used as

a focus around which to consider options for study designs, explore the need for parental consent with education authorities, and prepare materials and protocols for its implementation. These materials and protocols illustrate the types of design compromises that emerged after planning a survey that took local "community" (in this case a school board) constraints into account. When these constraints compromise data quality, which may then impact on the planning of intervention programs, alternatives should be sought. The discussion in Part 3 rationalizes some compromises in design in order to improve study data. Part 4 then makes recommendations revolving around lowering barriers to studying health promotion issues in the adolescent population.

This thesis thus serves in part as a "post mortem" to the failed survey - first it reviews the procedural elements needed for study planning and implementation and sketching out the study design ultimately developed. Then it describes those design elements that could have been modified in order to improve data quality. Finally, it outlines important practical lessons learned that are applicable for other health promotion research projects involving adolescents.

Part 2 THE SURVEY OF STEROID USE

2.0 Study experience and background

The idea for a survey exploring the abuse of anabolic steroids grew from a concern regarding the lack of information about the use of these drugs in Canada. This concern was brought to the forefront by the publicity generated around the disqualification for steroid use of sprinter Ben Johnson at the 1988 Olympic Games and the creation of a federal inquiry to examine in greater detail steroid use among high performance athletes. Amateur sports and sports medicine authorities began to wonder about the extent of steroid use in Canada, especially among younger populations where aspirations towards competition begin. Their use in high performance athletes had been confirmed by sporadic disqualifications, but the prevalence of use among high school students had not been examined. The time seemed opportune to design an appropriate study to investigate this particular issue, and more specifically, to determine the prevalence and delineate some factors regarding the use of anabolic steroids. Given the anticipated resources available at the time, the only practical approach was a questionnaire survey, and given the interest of sports medicine authorities at the time, it was to be conducted in the adolescent population. Alternative design approaches will nevertheless be discussed in Part 3. Details of the study design will be provided in subsequent sections, but the following is a summary of the sequence of events that took place during the conceptualization, approval and implementation of the survey to illustrate the challenges faced.

The target population selected was high school students within school boards in

the regional municipality of Ottawa-Carleton. In order to conduct research in this population, several steps were required. First, studies of any kind had to be approved by research committees of the respective boards of education. Second, funding would be needed to defray any costs involved for the work. Third, each school chosen from within the board would have to agree to participate and fourth, parental permission may need to be obtained.

The approval phase was the first item on the agenda. A presentation was prepared for the regional School Health Liaison Committee (representing area boards of education, the local pediatric hospital and the public health department). The committee was approached through the hospital liaison member who had an interest in the study. There it received approval in principle with encouragement to take the necessary steps to make submissions to individual boards. This was done for three boards, and final approval was granted by two following scientific and ethical reviews of a draft protocol, which included a lay abstract that could be circulated (Appendix A). The second phase, securing the necessary funds (Appendix B), was also successful and $11,325 was provided by the research institute at the Children's Hospital of Eastern Ontario. This set the stage for fine tuning the research design with the boards of education selected. The draft protocol contained only a skeleton design for a questionnaire survey, but was prepared with consultation from the research committees of the boards who were able to provide advice on the general nature of survey research that is permitted. Final protocols would need to be negotiated with individual school principals.

A more comprehensive literature review was conducted, and discussions organized

with school officials and key informants and researchers in the field of amateur sports, substance abuse, social work and education. The purpose of these consultations included gathering further suggestions regarding survey methodology and gauging interest in the study from prospective schools and the feasibility of actually carrying it out. In the end, the key informant discussions, that were a part of the process from the time of the health committee meeting, also proved invaluable in helping gain approval for the survey. Using the information obtained, design options were narrowed and a final protocol developed to implement the selected design. It would still require last minute fine tuning after discussion with each participating school. These had not been selected up to that point. Ultimately, one of the two boards was selected for the survey in order to minimize the logistical difficulties of dealing with separate administrations and to reduce travel expenses, as the second board was more rural. In addition, the one board was of sufficient size to collect an adequate sample. The appendices contains the documents that were prepared to carry out the study. These include the budget, the timeframe, the survey questionnaire, a set of survey instructions for classes and students, as well as the consent form and cover letter. As indicated by the timeframe (Appendix C), the survey fits easily into one calendar school year.

From the original requirements of the school board granting permission, explicit parental permission was required for all students under the age of 18. The consent forms were mailed out, addressed to the parent or guardian of the students, and returns were collated. Section 2.5 describes in more detail the methodology and the results of this phase. After two rounds of mailings (the second being sent only to the households who

did not reply to the first mailing), just over 50% granted permission from a total return of 57%. Although the response rate was poor, a third mailing was not attempted as the school year was drawing to an end.

Unfortunately, on the eve of the final phase, a teachers strike was announced. School principals, although they had originally agreed to have the research conducted in their school, now felt uncomfortable proceeding due to the situation. The study had to be cancelled. The following academic year, because the consent forms were no longer valid and funding was not available to repeat the process (which had not been very successful in any case), alternatives were sought. As a first attempt, a request to have parental permission requirements modified was made to the board research committee. A submitted brief contained documented precedent from other research centres, and was supported by the department of social services of the board, who were ultimately responsible for a drug education curriculum. Nevertheless, the proposal was turned down. A second attempt was to "piggy-back" some questions about steroid use onto a general drug survey that the department of social services wished to conduct prior to beginning its new drug education curriculum. In the end, even the drug use survey was turned down. As all options had been exhausted, the project was abandoned and the balance of the research funds returned to the pediatric hospital.

The next sections describe my field research, beginning with the initial literature search. The sections to follow will describe the piecing together of the protocol and the steps taken to obtain parental consent for the adolescents to participate. Details serve

only to illustrate the planning of this particular survey, on this particular topic, in the chosen population. The presentation should not be viewed as a complete design thesis, but as a jumping off point for a discussion of broader issues involved in undertaking such research.

2.1 Literature review

Literature reviews regarding the prevalence of use, and the knowledge, attitudes and behaviour of anabolic steroid users were carried out on two computerized databases, 1) the MEDLARS system of the National Library of Medicine using Grateful Med search software [7] to access the main Medline file and its backfiles and 2) the SPORT database of the Sport Information Resource Centre (SIRC) in Ottawa. Selected articles were retrieved from journals available at the Canada Institute for Scientific and Technical Information on the campus of the National Research Council in Ottawa, as well as the library of the Canadian Fitness and Lifestyle Research Institute at SIRC.

The search was conducted through the Medline database from 1966 to the present under the keywords of "anabolic steroids", "doping in sports", "surveys" and "epidemiology". Keywords were selected through the Coach Metathesaurus Browser of the Unified Medical Language System [8] published on CD-ROM by the National Library of Medicine, a search tool that broadly maps concepts to the corresponding terminology of several databases, including Medline's MeSH headings. In addition, the SPORT database was searched for all "survey"s conducted on "doping in sports". Further material was gathered by picking up citations from the articles found in the search. All studies

specially related to the use of anabolic steroids in amateur sports at the high school or college level were reviewed. Further searches were carried out regarding the effectiveness of anabolic steroids in body building and the adverse effects of their use.

The results are presented in detail in Part 3 as they relate to the need for background information to support arguments overcoming challenges to conducting research in the adolescent population. For the basic needs to plan the study, however, the literature was useful in identifying survey results that estimated the prevalence of steroid use at between 5 and 10% in the population of interest but have not explored in any detail the factors surrounding such use. More specifically, knowledge and attitudes remained poorly documented. Other work had also delineated the harmful effects of anabolic steroids, and the preponderance of their use in athletic competition and bodybuilding.

2.2 Study Design

The two basic questions that the study would try to address were the extent of steroid use and whether there were any contributing factors to such use. These questions led to the elements necessary for the study: a survey instrument, a sample size, procedures for carrying out the work and an analysis plan. Each of these will be addressed in turn. The overall difficulty is reaching a compromise among these elements that will generate useful answers at the conclusion of the study eventually carried out - for example some study designs are impractical on a large sample.

Measuring the extent of use consists of calculating a prevalence measure. Prevalence in this case is defined as the number of study subjects reporting taking anabolic

steroids divided by the number of subjects in the study. There are several basic measures of prevalence defined epidemiologically that are of interest: point prevalence, period prevalence and lifetime prevalence. For this study, point and period prevalence would be considered together as steroids are taken in cycles and a subject may be on an "off week" at the time of the survey. They would be define current use. Lifetime prevalence would add all those who had used steroids but had stopped. A final measure would be the proportion who are not taking steroids but state they plan to in the future. Calculating any of these measures requires an adequately large and randomly selected sample.

Next, measuring the contributing factors to steroid use involves asking questions regarding a subject's knowledge of their effects, their availability, the reasons for considering their use, the existence of social support or peer pressure for using, and personal beliefs attached to use, among others. Although these questions can take the form of a knowledge, attitudes and behaviour survey, such studies are difficult to carry out as some of the concepts are difficult to accurately translate into measurable questions on a survey without considerable pre-testing and validation. The measurement of attitudes is problematic: one is trying to assess how a person feels about something, or what their views are about the desirability of an "attitude object". This contrasts with the more straightforward measurement of behaviours and beliefs. The former asks what a person has done, while the latter queries what the person thinks is true or false. Thus a belief is less value laden and more of an opinion or a perception of reality. Since attitudes bring a person's value system into play, it becomes a much more difficult construct to measure. Attitudes can change over time (whereas values tend to be static) and questions about

attitudes are much more sensitive to wording variations. At times investigators believing they were measuring one construct ended up measuring something else [9]. For these reasons attitude measurement was not formally attempted.

The next section discusses the construction of the instrument. For the purposes of the present survey, as alluded to it was unrealistic to try to build a questionnaire that measures all those aspects. Instead, the questions concentrate on determining the prevalence of past and present use as well as planned use, and will attempt to evaluate some of the important contributing factors surrounding use that were enumerated in the previous paragraph, rather than an attempt to capture attitudes around use.

2.2.1 Questionnaire

When available, surveys often make use of pre-existing questionnaires. Unfortunately, no suitable instrument had been developed for steroid use and none of the studies appraised from the literature search used an instrument that measured much beyond use of the drug. The challenge became to design a survey questionnaire whose implementation (suitable length, easily administered, etc.) would be acceptable to the subjects and to the school board.

In general, questionnaires should be designed to elicit four types of responses, as summarized by Woodward and Chambers [10]: what people say they want, their attitudes; what people think is true, their beliefs; what people do, their behaviour; and what people are, their attributes. The steroid use questionnaire was constructed mostly to gather information about the beliefs, behaviour and attributes of the subjects. Items would capture demographic data on students, their knowledge (awareness) of the effectiveness

and side effects of anabolic steroids, some basic feelings regarding the use of the drug to enhance athletic performance and finally whether or not they themselves use steroids. In essence, the study wished to determine the current prevalence of use and some of the factors that impact on such use.

Specific research questions were formulated from the general survey objectives (prevalence and factors involved in use), and "statements of justification" were developed to rationalize the final selection of questions. Specific survey items constructed from these questions would permit an exploration of factors surrounding use. These questions were as follows:

1. What do high school students in Ottawa know about anabolic steroids, their use, perceived effectiveness and adverse side effects?

   * If knowledge about anabolic steroids is inadequate, an education program should be developed and evaluated. If knowledge appears adequate but some students would risk them anyway, education will not be enough and other measures should be considered such as testing for steroid use or stronger enforcement to curb use.

2. What is the current prevalence and past use of anabolic steroids among high school students in Ottawa, both athlete and non athlete? Among non-users, are there students who are contemplating starting using steroids?

   * If the prevalence of the problem is very low, further action may not be necessary. If prevalence is high, interventions may be indicated. However if prevalence is increasing or students are contemplating future use, prevention may be needed to stop the increase.

3. For athlete and non athlete users, when did exposure to steroids occur and what were the motivating or situational factors?

   * If exposure occurred prior to high school or in extra-curricular activities, early preventive manoeuvres targeting outside the schools may be necessary. If body image constitutes a significant motivator, preventive programs could help deal with this.

4. For users in general, how are steroids being supplied and has the source changed over time? For non-users, do they perceive steroids as readily available if they wished to begin use?

   * Knowledge about ease of availability is necessary to bring about appropriate preventive policies.

5. To what extent has media attention to the problem affected the use of and knowledge about anabolic steroids? In general, where or from who are students acquiring their knowledge about steroid use?

   * If media attention has decreased prevalence and enhanced knowledge, repeated media attention should be considered. If the converse is the case, this should be brought to the media for their planning in responsible programming. An awareness of sources of information in general can also help target preventive or intervention efforts.

The prevalence estimate itself would be derived several ways by asking about duration of use and the history, or pattern of use. These items are consistent with research priorities set by the National Institute of Drug Abuse in the United States regarding behavioral

dimensions that most lead to adverse health outcomes: frequency, chronicity, pattern and age at onset of drug use [11].

The final questionnaire that was constructed is presented in the appendices. Depending on the time allotted by the schools for its completion, it could require some fine tuning. It would, however, be tailored to the school giving the least amount of time as all students must complete the same instrument. The questionnaire addresses the following issues: was early use encouraged by peers or by role models (coaches, teachers)? Was knowledge regarding steroids imparted by peers, the media or role models? Could it have been a combination, such that ultimate use of steroids was triggered by an event that awoke an immature awareness and knowledge of their existence? Clearly, it is unlikely that a single hypothesis could explain the prevalence of steroid use.

As a result of this need to explore alternative explanations, the questionnaire was developed to tactfully gather enough information to be able to reconstruct possible models of use. Questions would ask about the side effects of steroid use, the value placed on winning in athletic competition, and whether use would vary with the risk of being discovered. These questions hope to tease out some patterns. For example, would knowledge of "side effects" represent pure regurgitation of learned information or would an attitude be placed on it (if the side effect were not considered serious, the student might not label it as such and answer the question in the negative). Alternatively, would students only remember information consonant with their attitudes and filter out the rest, such that users would forget the side effects while non-users would focus on them. Any

interventions that followed analysis of the results could present appropriate facts in a way consonant with the factors thought responsible for steroid use.

A separate "lie scale" was not built in to the instrument to help verify validity. Rather, questions asked respondents about the ease of obtaining steroids if desired; potential sources of information about steroids; and sources of supply of steroids. Coherence or internal consistency among these questions would suggest that the student was answering truthfully and not just guessing. In addition, the questionnaire asks at the end whether there was any reason the student might not wish to answer truthfully. This technique was suggested by the WHO method for drug use questionnaire design [12].

Finally, a series of questions classified the students both by age and grade level, and assessed the students' level of participation in sports - both within and outside of school, and in activities that are either team based or personal. These distinctions were felt important as students may be in competition at several different levels, and physical education classes are not compulsory. The marked drop off in attendance between grade 9 and grade 12 in no way implies less participation in sports: students may simply be involved in more extracurricular activities. The particular level of physical activity would have been gauged by asking students to list only those activities they participated in more than once or twice a week, and by making the distinction between personal and competitive sports with allowances for both. The activities were selected based on a list of high school sports provided by a survey of sports activities conducted by the physical education division of the local board of education [13], as well as lists of intra and extra-mural sports activities in the same survey.

Because the survey would be completed in class, it was desirable to find a way to ensure that adolescents who were using steroids did not have to spend more time filling in the questionnaire because non-users could jump ahead on a skip pattern. The use of steroids is a sensitive issue, and although not as "illegal" as street drugs, remains a hidden behaviour. Any survey instrument should not place the subjects on the defensive, otherwise it would have encouraged them to hide behaviours. While completing the questionnaire, patterns of student responses should not give away to casual observers the behaviour engaged in by the students. Thus questions were designed in such a way as to always require a response, whether the student used steroids or not. In this way, students and survey invigilators would not have been able to identify users by their physical pattern of responding. This method was selected in combination with the anonymous nature of the survey to put students at ease about answering truthfully, rather than attempting to apply other techniques that are likely to increase the complexity of the survey and make the instrument more difficult to administer such as varying the ordering of questions on the questionnaires handed out.

Due to the fact that final approval to proceed (in each school) was not obtained because of the factors described earlier, final testing did not take place. However, the questionnaire was reviewed by an expert panel consisting of experienced researchers in the field of pediatrics. The group was able to assess face and content validity, and this phase resulted in the final instruments presented in the package of appendices. Further testing would have taken place in a few selected classrooms using a focus group of high school students, both athlete and non-athlete, who would have been asked to read it over and

provide comments regarding ease of use and clarity. Criterion validity would have been more difficult to test. Blood or urine sampling, which would be the gold standard would not have been feasible in the current setting. However, internal consistency was built in to the questionnaire in that several questions assessed similar factors and thus inconsistency of responses would suggest poor validity. In addition, the results could have been compared with studies that emerged from other centres. The more consistency in the prevalence figure between samples of high school students meeting the same demographic characteristics, the more valid the questionnaire was likely to be. An alternative to comparing with a gold standard would have been to pre-test the questionnaire on a group of athletes from sports known to have a high prevalence of steroid use, such as football players, weight lifters or members of a fitness club. A higher prevalence figure would be expected from questionnaire results among those groups, suggesting that the instrument is measuring prevalence with some degree of validity.

The questionnaire would also have needed to be assessed for test-retest reliability. This could have been accomplished on a small group of subjects given the questionnaire a few weeks apart. This step would also have served to anticipate some additional questions or problems students may have completing the form that were not identified by the focus group. Assessing inter-rater reliability is not required as the instrument is multiple choice, test instructions were pre-printed and test conditions were to be similar for all subjects.

2.2.2 Sample size

To determine a sample size required for the prevalence estimate portion of the

study, several elements are needed for the calculation. These include a rough estimate of the prevalence expected, a confidence interval for the prevalence and a level of significance. As there are only preliminary Canadian prevalence data among athletes and data from other sources that are either widely divergent or more likely poorly applicable to the current setting, the calculations below are of necessity very crude. Only a ballpark figure will be derived, and the results of the study will take into account this difficulty.

Previous studies have derived prevalence figures of between 2 and 11%. Most sources (albeit in predominantly athletic populations) placed the figure closer to 6%, with subgroups of athletes towards the higher end of the range. Considering that a general high school population would have been lower, but that recent attention to the problem might have increased the prevalence somewhat (a hypothesis that is suggested by some literature to be described below), the figure was set at 5% I wanted to place the prevalence at +/- 3% to allow for a reasonable sample for subgroup comparisons. Setting the alpha level at 0.05, at least 200 students were needed[1]. Without prior Canadian data, estimates for athletes is speculative so the 5% will suffice. However, for females, the prevalence is likely towards 1 or 2% and thus an accurate prevalence estimate for them will require potentially more subjects, at least 381 if 1% +/- 1% is used, or only 188 if 2% +/- %2 is selected. Finally, if students are dichotomized by athlete/non athlete status and by age group, such as 9/10 and 11/12, 2 'grades' X 2 sports groups X male/female would require a total of between 1552 and 2324 students. Allowing for a 70% response rate, which had

---

1 Table p.220 in: Hulley SB, Cummings SR, eds. Designing Clinical Research. Baltimore, Williams and Wilkins, 1988.

been achieved in some questionnaire studies described in the literature, a total of about 2200 to 3300 students would need to be approached. If a smaller sample is obtained, either because ultimately it was not feasible to sample so many students or the response rate fell short of expected, fewer groups would be compared or a wider confidence interval tolerated. However, with only two comparisons (eg: male vs. female) if the prevalence is very low it would still be detectable as the confidence interval drops to about +/- 1%. The large sample should also have yielded enough steroid users to be able to make some group comparisons between users and non-users. As discussed below, when the design was finalized, however, just under 2,000 students were available to take part in the study (prior to obtaining consent).

2.2.3 Survey design and data collection

The particular design of the survey ultimately arrived at should ensure that the required number of questionnaires (as defined by the sample size calculations) could be delivered as efficiently as possible to the study subjects using the available resources. In the school setting, it is obviously extremely disruptive to call individual students away from their classes. Therefore, the only practical method of questionnaire administration was considered to be by whole classroom. Indeed, the board of education agreed with this. Second, each school may have particular protocols for accessing classes for this purpose. Thus flexibility had to be maintained with a study planned in this population and the final survey procedures were negotiated and tailored to the particulars of each school. This was accomplished by approaching each school principal individually, and applying the guidelines described in the next paragraph. Given the selected sample size of 2,300, and

estimating about 25 to 30 students per class in each of the 12 schools available in the selected board of education, on average 8 to 10 classes per school were to be surveyed. These classes were chosen at random, stratified by grade such that an equal number were selected at each level.

A balance was struck between standardizing administration and tailoring it to each school. The objective was to disseminate the questionnaires to all students selected for the study in a uniform manner in order to minimise any bias that would have resulted from different testing conditions. I drew up some guidelines to facilitate discussion when balancing standardization and tailoring:

1. Classes selected had to be representative of the school population. This is not the case in some areas, such as physical education, where student enrollment at each grade level drops off considerably. At some schools, a bilingual program may exist, with similar self-selection of students into those classes. Efforts should therefore be made to select classes for sampling that involve required courses at each grade level. This way students within a particular class have not chosen to be in that class.
2. Testing "sites" (where students gather to fill out the questionnaire) should be uniform. Typically, this would be in their classroom and would avoid placing some groups of students in situations that are uncomfortable or unfamiliar for the completion of a questionnaire.
3. Survey instructions should be the same for all students. A prepared text would be read out by the monitor who administers the survey (such a text is illustrated in

Appendix F).

4. Students should be given adequate time to fill out the questionnaire. As some students will be faster than others completing the survey, ample time should be available to all.

5. Students should feel comfortable with the way in which confidentiality is maintained. Students should not feel that this might be violated in any way, such as under testing conditions that do not afford adequate privacy, or the possibility that their completed questionnaires are seen by others before they are batched for scoring, or the coding system does not ensure adequate anonymity.

6. The conduct of the survey should minimally disrupt the class and the teacher (other than requiring the time for completion). Otherwise, some teachers would not wish to allow their selected class to participate, or would follow haphazard techniques either in the delivery of instructions or by not allowing adequate completion time. This would also affect the outcome of the survey.

With these considerations required by the high school environment, and the need to randomly select classes in each school for the study, basic features of the school board were examined to determine the best way to proceed. At the Ottawa board, each day began with a "home-room" period where students gathered for 20 minutes to hear announcements and deal with attendance and other daily school business. Students were assigned home-rooms at random according to their grade level and not according to academic considerations. Thus home-room periods seemed an ideal choice and provided the required classroom setting to conduct the survey. The board also felt that home-room

periods would be the least disruptive time to conduct the survey, as did the school principals contacted. Most principals even volunteered to allot extra time (if necessary) for those students involved in the survey, a credit to the perceived interest in the study. Finally, survey instructions would have been read out by the teacher, who would also have supervised the students. Although ideally an independent invigilator would have been better, this was not practical from a resource point of view. The second best alternative would have been to have student leaders participate, but school officials were not keen on disrupting other students' activities. Having teachers administer the survey was a requirement.

Thus all the conditions in the guidelines described above were addressed. The questionnaire package would have been left in the selected teacher's mailbox for pickup on the day of the survey. The package included all the necessary materials (as listed in Appendix E) for carrying out the survey. The teacher would have read the introductory remarks provided and hand out a copy of the questionnaire to each student, who would then have completed it anonymously.

Maximizing response rates once the students with consent are participating revolved mainly around the assurance of confidentiality. The questions were written, as indicated earlier, in such a way as to provide a choice of response for all students (steroid users and non users). That way, one group could not have been identified by the length of time it took to finish the survey. On completion the forms were to be returned face down and placed in the numbered "return" envelope, which was to be sealed as soon as all the forms were collected. The number of students who responded, and the number absent or

without consent was to be recorded on the envelope. The purpose of this numbering system was to determine a response rate.

As indicated, only those students with signed consent forms, and who personally wished to participate, would have received a copy of the questionnaire. For those students who are of age, completion of the anonymous questionnaire would have been valid implied consent (MRC guidelines on Research involving Human Subjects, 1987 [14]). In practise, however, consent would have to be solicited for all students as age information was not available a-priori. Any student would of course have been free to withdraw from the survey at any time.

2.2.4 Analysis plan

Data entry for the questionnaires would be done using a template prepared for the Epi Info computer program [15], a software package specifically designed to work with survey data. The program would also be used for data analysis. An analysis plan was developed to address the objectives of the study.

The students would be described by age, grade, sex and athletic status. This latter measure would be derived from questions 4 to 16. Initially, students would be scored on whether they participate in gym class, extramural organized sports or extramural individual sports. Frequency of fitness activity is addressed in question 6. Finally, a list of sporting activities is presented that distinguishes between heavy sports (such as football and wrestling), strength sports (weightlifting), fitness sports (swimming, running, skiing, tennis) and team sports (basketball, soccer). Depending on the results of the survey, and what is known about the level of "risk" of steroid use among participants of these sports, a

scale would be constructed to classify subjects from non-athletes to serious athletes to "heavy sport" athletes. In summary, descriptive statistics would show:

1. Age and grade distribution of the sample (question 1 and 2)

2. Sex distribution (3)

3. Participation in sports:
   - None, gym class only, extracurricular sport, both (4)
   - Competitive sport or individual fitness (5)
   - Frequency (6)
   - Type of sports participation (7-16)

Regarding steroids, questions address their use by asking when it began and about length of time using. They also address impressions about risks and effects of use, impressions of the prevalence of use among peers, source of information and source of supply of steroids as well as reasons for use and reasons for discontinuing use. In summary:

4. Use of steroids:
   - Current use (24)
   - Past use (28)
   - Planned use (23)
   - Length of use (27)
   - Prevalence among peers (20,21)
   - Use if can't be caught (26)

5. Reasons around use:
   - Why started - sports, appearance (23)
   - Heard about from - friend, coach, doctor (17,22)
   - Sources of supply - friend, doctor, coach, "street" (29,30)

6. Knowledge of effects:
   - Whether steroids are harmful (19,25,28)
   - Whether steroids change appearance (18,23)
   - Whether steroids help performance (18,23)

The questions will be used to estimate the number using steroids at present, the

number who had tried steroids and stopped, and the number who are thinking of trying them. The first two would be combined into a lifetime prevalence estimate as well, the "ever users".

The dichotomy between ever users and non-users would form the basis of exploring the factors surrounding use as described earlier. Using the chi-squared statistic, users and non-users would be compared on their having information about steroids, their perceptions of the effectiveness and risks of using them and their knowledge of availability and estimates of peer use. Mantel-Haenszel stratification would be used to control for age and sex where appropriate and for athletic status. Finally, logistic regression techniques (with use/non-use as the dependent variable) would be applied to determine which factors are independently responsible for contributing to steroid use. The independent variables would include age, sex, athletic status, awareness of supply, awareness of risks, desire to benefit from their effect and belief that peers also use.

The final analysis plan can be determined only after the data are collected. Only with final frequency counts on the variables would it be possible to ascertain the number of subjects in each of the groups of interest and whether they are of sufficient number to give power to the calculations.

2.3 Obtaining Parental Permission

The need for consent can become a problematic issue when conducting research on certain subjects. Obtaining permission to study a population from proxies other than the study population itself (ie. parents on behalf of their children) has the potential to lead

to sampling bias and methodological difficulties. This was borne out in the present study: described below are the results of gathering parental permission using mailed consent forms. This exercise illustrated the impact such a requirement can have on a study sample. Mailed consent was used because the school board felt it too disruptive to have teachers distribute forms in class, urge students to bring them back, and keep track of the outcome. In consultation with other board researchers, this was also echoed. Mailing the requests was also selected as the method of choice because the number of schools and classes made it impractical to hand deliver the forms.

2.3.1 Introduction

The following sections describe the results of the mailed out request to obtain parental permission to carry out the study on anabolic steroid use at the high school level. As discussed later in section 6, such requests have yielded mixed results. Previous work on the topic of suicide was only able to achieve a 50% response rate [16]. As it was felt the subject of anabolic steroids did not carry the same stigma and had piqued public interest, parents were expected to be more willing to have their children participate.

2.3.2 Methods

High school students under the age of 18 were required to have parental permission to participate in the steroid use survey. Birthdates, however, were not available on mailing lists. Therefore all parents whose children were selected for the survey, from all schools in the study, were approached. The procedure for soliciting consent broadly followed the method of Dillman [9]. A letter and consent form were developed (Appendix G) and sent out by mail. The funding obtained was sufficient to

cover the cost of 2 full mailings, with stamped, self-addressed envelopes included. The cover letter and consent form asked parents to give permission for their son or daughter to fill out a short questionnaire during a pre-determined class period. Two copies of mailing labels and a printed list of all students attending the selected list of home-room classes were obtained directly from the board of education, sorted by class and surname. The address labels included the student's home room class (a proxy for their grade level), but no other demographic indicators. When sent in a windowed #10 envelope, the labels were strategically placed on the folded consent form such that they remained part of the return portion when sent back in the self-addressed envelope. This made it easy to match up the respondents with the class lists. The consent forms were duplicated, stapled and folded by a printing service who also prepared covering envelopes with the investigators return address. Self-addressed #8 "business reply" envelopes were obtained to include with the consent form in the larger windowed envelope. Using these business reply envelopes, although about 20% more costly than a regular stamped envelope, would in the long run be less expensive if the response rate was less than 80%, since charges would obviously only be incurred if they are actually used (sent back). A mailing service was contracted to collate the envelopes, apply the labels and send them out. Two mailings were carried out in the following manner. The first batch of responses was tracked for the first 2 weeks, and as the number of returns declined, a second mailing list was readied. Because over 40% of the letters were returned, it was felt both less costly and more "polite" to only carry out a second mailing to those who did not return the first letter, rather than a mailing to the entire original sample. Those who responded simply had their mailing labels

removed from the second set of prepared labels, a second cover letter was prepared and the mailing service again contracted to carry out the mailing. The automated machinery easily dealt with the label sheets despite the missing addresses. This mailing took place 3 weeks after the first round.

2.3.3 Results

A total of 1958 letters were sent out. The results of the consent gathering exercise are presented below:

Table 1: Results of consent form mailings in the steroid use survey

Round 1	Total mailed	1958	
	Returned	825	(42%) of mailed
	YES	760	(92.1%) of returned
	NO	66	(7.9%)
Round 2	Total mailed	1168	
	Returned	299	(25.2%)
	YES	228	(76.3%)
	NO	71	(23.7%)
Summary	Total mailed	1958	
	Total received	1124	(57.4%)
	YES	988	(87.9%)
	NO	136	(12.1%)
Sample granted permission: 988/1958 = 50.5%			

Each mailing round is shown separately and the total response is indicated at the end. Of the number received, "YES" indicates that the parent granted permission for their son or daughter to participate in the survey. Less than 2% were returned because of an incorrect address or because the family had moved.

The results show that 42% responded to the first mailing, with 92% agreeing to participate and 8% refusing participation. The response rate for the survey after this

mailing would have been only 39%. The second mailing obtained a 25% response rate with 76% agreeing to participate. However, negative returns were much higher - 23% of respondents.

The overall response rate to the mailing was 57.4%, with 50.5% granting permission, 12.1% refusing and approximately 40% not responding. At this point (as discussed earlier), the survey had to be abandoned for the current school year. To repeat it for the following year would have required soliciting consent from parents all over again as the classroom structure would have changed. Nevertheless, the poor response rate raised a number of issues that called into question the utility of pursuing the survey even if it had been possible to proceed. These are discussed further in the next section, culminating in the challenge to pursue a change in the consent requirements.

2.3.4 Discussion, conclusions and implications

Of the close to 2,000 letters sent, only 50% returned a positive response. This occurred despite two mailings that included a simple form and a self-addressed return envelope and involved a topic that had extremely high visibility at the time (the Dubin inquiry [17] was just concluding its work and had received much media attention). One would have expected more enthusiasm to participate in a survey of this nature. However, no attempt was made to compare respondents with non-respondents. The only variables that were available were grade and school. Gender could only have been determined by the name.

Reasons for such a poor response rate can only be surmised. The envelopes were addressed "to the parent or guardian of..." and there is a possibility that some students

may have intercepted the letter and not passed it on - though again there is no way to verify this. The increasing refusals with the second mailing indicated less willingness to participate among the few who did respond. Again, whether the poor response reflected apathy or passive refusal cannot be determined. Even the refusals to the second mailing may have been due to irritation at having received a reminder. It obviously cannot be determined how a third mailing would have been accepted, but the diminished return to the second mailing made it more likely that the parents who continued to refuse passively or who were apathetic would have become irritated and complain to the education authorities. As school boards are concerned about this possibility, and resources were limited anyway, a third mailing was not considered.

As discussed earlier, the proposal arrived at with the board of education indicated that sampling was to take place by class and that on average only 10 to 12 classes per school would be surveyed. Since their review requirements are strict and procedures for consent lengthy and complex, there was no possibility of increasing the sample size. Further, the response of 50% did not take into account the number of students who themselves might refuse participation, or the number who might be absent on the day of the survey. Thus the actual participation would likely have been even lower. Other studies that did not use parental consent still had response rates as low as 50% [18], but some had response rates over 90% [19,20] . Thus a further 10 to 50 percent may not have participated in the final survey. These consent gathering results had serious implications on data analysis. For the crude prevalence estimates this sample size would at least double the width of the confidence interval. For the stratified groups, it would have

eliminated many of the possible groupings and severely compromise the quantity of information gained from the study. More importantly, the sample that is left was more than likely no longer representative of the population. There was no way to ascertain why some parents refused to give permission unless yet another questionnaire was sent requesting exactly that information. There was no demographic information on the non respondents other than that which was indicated above. Whereas earlier, it was felt that the high school population reasonably represented adolescents within the geographic area of the board of education, and perhaps even similar metropolitan areas, the sample that remained might no longer have even represented high school students.

The question that remained was simple: was the study still worth carrying out? This question was never answered: the strike that put an end to the project arose at the very time this question came up. In its absence, the study would have proceeded, but its failure contributed to an exploration of this very issue, presented in part below and carried on in section 6.

Would it have been more fruitful (even if the study was allowed to proceed under the conditions of a 50% response rate) to address the serious concern raised by the potential of a biased sample and instead explore more fully with the board the possibility to relax consent requirements? The study could then be re-initiated. This would have recognized up front the limitations imposed by poor response rates, and would suggest that the most responsible course of action in such cases could be to actually hold back or cancel studies that do not meet minimum consent requirements. Too few researchers seem to do this, and instead publish studies whose results are questionable. Developing

criteria for halting a study should response rates from third party consent be inadequate is a worthwhile issue to explore in the future.

Part 3 ISSUES IN CONDUCTING HEALTH PROMOTION SURVEYS AMONG ADOLESCENTS

The study presented above illustrated some of the challenges facing the investigator wishing to study health promotion issues among youth by conducting surveys. These challenges, unless overcome, may reduce the feasibility and damage the quality of other studies in future. The remainder of this thesis will describe these challenges in more detail, and illustrate them from the example of the survey of anabolic steroid use just presented.

These challenges are derived from three major lessons, presented here and elaborated upon below:

First, the topic must be perceived as relevant by the population being studied such that the subjects will more readily accept to participate. The concepts of Essential National Health Research [3] are a beginning, that of achieving community participation, but some topics such as drug use and abuse may be sufficiently daunting to scare away participants. In addition there is an expectation that the study results will be useful for health promotion intervention planning. Is the community prepared for and does it desire intervention?

Second, there must be a study design and data collection instrument that produces reliable and valid data and is minimally disruptive. This includes a design that may be simple to carry out, at reasonable cost. This may seem like a "motherhood statement", but is important to highlight nevertheless and

work towards achieving.

Third, the selection of an acceptable method to ensure age appropriate consent must be considered. It must be free of coercion and should be as simple as allowable. The issues involved here impact on the quality of the sample that would ultimately participate in the study and thus impact in part on the generalizability of the results.

The following sections discuss the critical components in turn using the practical example of the questionnaire described above which assesses the knowledge, attitudes and use of anabolic steroids at the high school level.

3.0 Selecting a relevant health issue

3.1 Criteria for selecting health issues to be studied

Criteria should be applied to select a topic on which research would have a better chance of succeeding. These take into consideration realities of the research "climate". Studies of poor relevance to the subject population or their guardians have a greater chance of either being turned down, or failing altogether.

Using the simple concepts from the ENHR document [3], and the Measurement Iterative Loop [21], I developed four criteria that are important to consider when deciding whether to study a health issue. Essential National Health Research stresses the importance of doing research on issues of community importance. The iterative loop is a tool used to assess the significance of a disease by considering its burden in the population and the availability of therapies to modify this burden. Both stress evaluation as a tool for

measuring the impact of any intervention carried out. The iterative loop also specifically considers the prevalence of the issue being studied (which in the present case study would be both the actual prevalence of steroid use as well as the perceived level of importance (perceived burden) to the community.

The preliminary classification is outlined here, and the next section applies them more thoroughly to the specific example of steroid use.

1) Is the issue of importance to the public?

Does the public share the same concern that health practitioners, educators and researchers do, and is there interest in intervening as appropriate?

This criterion is important to determine whether the public would have enough interest to take part in a study of the issue. Despite possible objective evidence of the existence of a problem, subjectively is the public really concerned?

2) Is the issue a serious or potentially serious health problem?

Do we know the health risks taken and problems incurred by (in this case) steroid users? The literature needs to be evaluated regarding the burden of illness or the burden to health.

If significant enough, there should be a desire to invest resources (human and financial) in studying the issue on the part of policy makers, and the public would also more likely want to participate in an examination of the issue.

3) Is there interest in developing programs to deal with the issue?

If a study is undertaken, there must be the desire to make use of the results. Does this interest exist on the part of practitioners, policy makers and community

groups.

The public should want to see an intervention program in place to modify the health risk, and policy makers would then be interested in investing the necessary resources.

4) Is more information needed to plan or evaluate programs?

Has the population at risk been identified? Have knowledge and attitudes been evaluated in the target population? Have programs of intervention been planned with adequate data to suggest their potential effectiveness, or is there a need to carry out more work?

3.2 Steroid use as a health issue: should it be studied?

This section applies the criteria laid out above to the issue of anabolic steroids.

1) Is the public concerned about steroid use?

This issue has received much attention in the lay press. As one example, not only was Ben Johnson's disqualification for steroid use at the time of the survey very prominent in local Ottawa newspapers, but the generic issue of anabolic steroid use was covered in follow-up with at least 3 major articles, one concentrating exclusively on their use among adolescents. Even the medical press began targeting steroid use [22]. The issue has become a concern to the public as well as to educators and health professionals ever since that day in Seoul, Korea in the summer of 1988. The following paragraphs summarizes this event and a brief chronology of steroids and sport.

Many people are familiar with the story of Ben Johnson. A Jamaican-born

Canadian, Ben was coached to several world championships in the 100 meter sprint. He soon broke the world record in that event and earned the coveted status as the world's fastest human. Defeat came much quicker. After shattering his own world record at the summer Olympics in Seoul, he was stripped of his medal and his record the following day when it was discovered that he had been taking the banned substance Stanozolol - an anabolic steroid. The issue of steroid abuse in sports vaulted into the minds of Canadians and the consciousness of the international community, and unfortunately may have piqued the interest of youth as an easy way to improved body image.

Until then, little was known about steroid use, and any concerns were mere suspicions that were rarely investigated at the high school level. Historically athletes had always sought ways of getting an "edge", be it with special diets, herbal prescriptions, or the use of alcohol or caffeine. Unfortunately, when modern pharmacology entered the picture, sports literature began to recount fatalities. Little could be done however until science had caught up enough to enable systematic testing for drugs - only then was there merit in drawing up a list of banned substances. It took slightly longer for anabolic steroids to be considered a drug of abuse in sports. Despite their discovery in 1935 and use by athletes since the 1950's, they only joined the IOC's list of banned drugs in 1975. Press reports of athletes being disqualified for drug use have been around a long time. But steroids quickly took over the limelight. In the late 1980's, accounts began to surface that use among adolescents may be prevalent.

After the summer of 1988, the issue had drawn enough public attention in Canada to warrant further study. Therefore this first criterion is met - the public is concerned or at

least very interested in the topic.

2) What is the burden or potential burden of illness caused by steroids?

Anabolic steroids can lead to serious health problems. At least three major literature review articles concluded that steroids can impair liver function and lead to hepatic tumours, alter lipid profiles increasing the risk of cardiovascular disease, affect both male and female reproductive systems, and alter personality [23,24,25]. Other side effects include acne, hairline recession, virilization in young women and gynaecomastia in males. The pre-pubertal age group also risks premature epiphysial closure. Finally, given that many steroids require administration by injection, one indirect risk of use is HIV or Hepatitis B infection from sharing needles [26]. The practise of "coupling", whereby athletes give each other injections (often with the same needle), is common.

Although some health professionals doubt their effectiveness, athletes certainly believe that steroids enhance performance [27] and appear to be more than willing to risk side effects to take them. This degree of use, despite the health concerns, betrays a need to artificially improve athletic performance or enhance body image. The issue broadens to become one of honesty in competition and a lack of self esteem through concern over body image [28]. Until more data are available, some physicians are facing a major dilemma: should they refuse to treat steroid users in their practise, should they do everything in their power to encourage them to stop taking steroids (and risk losing them as patients), should they ignore that behaviour in their patient or should they monitor their steroid use, provide clean needles for injection but otherwise look the other way [29,30]. We do not know which dimension around steroid use by adolescents is important: denial

of the effects or ignorance. The story of Ben Johnson illustrates either a "hero" who was misguided by his coaches, or an athlete in denial. There is likely an element of both: to the elite athlete, the coach reigns supreme.

Thus steroids are an important health issue, and therefore the second criterion is met - the potential burden of illness is high.

3) Is there interest among policy makers and practitioners to develop countermeasures?

Many are trying to control the use of steroids and are concerned about drug abuse in sport. Olympic committees are demanding that attention be paid to the issue [17]. Athletic federations have responded by considering various methods to keep drugs away from sports. Educators are considering adding steroids to the list of drugs of abuse about which to teach students. As will be shown, however, little is known about the prevalence of use and we need information for such policy discussions and education-intervention programs. It was not until 1989 that the Addiction Research Foundation in Ontario added performance enhancing drugs to their biennial drug use survey among high school students [31]. This move was in fact prompted by the Ben Johnson affair. The solution that is currently receiving the most attention for athletes is random drug testing. It is based on the premise that if the risk of getting caught is high, the prevalence of use will decline. This has been born out in some studies of use before and after the implementation of testing programs [32]. Some epidemiologists predict, however, that steroid use will continue to rise despite these efforts [33]. The ethical issues surrounding random tests (ie. right to privacy) have not all been resolved in everyone's mind [34,35,36]. At the very least, testing will focus attention on the problem and it is interesting to note that at the

high school level, there is growing support for such testing. Two school districts have initiated random drug testing in the United States [37]. Students wishing to participate in sports must sign a consent form waiving any right to refuse random urinalysis. The programs were given strong support from parents groups and the administration. But this does nothing to change the root causes of steroid use. Given this seemingly constant battle between athletes trying to get away with drug use and sports bodies trying to detect abuse, it is becoming clear that the eradication of the use of drugs in sports likely won't be accomplished by the biochemists and policy writers. There is still a need for education to change use. Though the issues of why athletes use steroids despite the risks not only to health but of being caught are complex [38,39], it may very well be that education and the promotion of a desire in young people to compete clean in the pursuit of excellence will play a role in decreasing future drug abuse in sports [40].

However, attempts at control in the absence of information may be detrimental. Some experts feel that improperly delivered, education may even lead to increased use [41]. When a steroid hotline was put in place in the United States following the 1988 Olympics, the majority of calls were not to learn about the harmful effects of steroids, but where one can buy them. This is similar to the response to an information session given to high school students [42] by a well meaning group of medical students. Despite showing graphic slides of the potential harm steroids can cause, the audience was intrigued by their body building potential. The recently published Report of the Task Force on Illegal Drug Use in Ontario [43] made five recommendations on education programming for primary and secondary schools. But the Task Force recommended first analyzing the evidence on

drug use in the province. That information is not available for steroids. There is a recognition that any program put into place needs to be evaluated in order to ensure that it does no harm [42]. At least in the United States, a number of prevalence surveys (discussed below) are providing information to those designing programs [44,45].

From the material above, the third criterion is met, that policy makers and educators want to plan interventions. Reliable data is one element with which to accomplish this.

4) Is the prevalence of steroid use, and the knowledge and attitudes of users adequately known?

Do we know enough about the issue to begin intervention programs, or do we need to learn more. Steroids may be widely used among competitive athletes and among those who body build at local health clubs [46], as well as among students in the United States. But as will be shown, their use in Canada had not been adequately studied when this project was initiated. Recent work has looked at prevalence, but research has not yet delineated more than basic factors regarding knowledge and attitudes. Thus discussion of those issues remains speculative. Prevalence has often been estimated, but no standards exist to measure uniformly. What is known in these areas is presented below.

The attitude of athletes is not too surprising. Few successes are more rewarding than victory in athletic competition. Years of hard work for little recognition may or may not lead to major competition and the hope of a win. At these top levels, this is a reward enjoyed by comparatively few who undertake the training and discipline required. Is it really such a surprise to hear that some athletes have been taking performance enhancing substances? Indeed, the Dubin inquiry [17] seems to have uncovered somewhat more use

than was expected and the problem may be much more widespread than anyone had imagined.

There is also concern over steroid use by non-athletes. At issue is the use of anabolic steroids by non-athletic boys for the purposes of enhancing self image [28] through gains in muscle bulk. Recent surveys have found that more than one third of adolescents who take steroids do so for this reason [18]. Some experts in the field have compared this behaviour in young men to the intense pre-occupation with body self-image that may lead to anorexia nervosa in young women. The tragedy emerges from two angles. Not only are teenagers risking the side effects, but the drugs are often purchased from illicit sources. The same survey reported that 80% of the drugs were bought from the black market [18]. Thus "criminal" behaviour is an indirect consequence.

At the time the story of Ben Johnson emerged, very little was known about the prevalence of anabolic steroid use below the top athlete level. Some educators and coaches believed that steroid use may be prevalent in Canada, but this information is anecdotal [47]. During the Dubin enquiry, one newspaper reporter doing a story on anabolic steroid use among adolescents had no trouble finding students who were taking the drugs, but only 3 would agree to be interviewed [48].

The majority of published material on steroid use comprised informal interview surveys or the gathering of general impressions of coaches, officials and researchers. Recent reports have included a poll of high school coaches who were simply asked how bad they thought the problem was at their school [49]. Twelve percent overall believed steroids were used by at least one of their athletes. A survey of 6 Arkansas high schools

found that 11% of athlete and non-athlete boys and 0.5% of girls used steroids [19]. Another study in the same setting 3 years later found a prevalence of 7.6% among boys and 1.5% of girls [28]. The figures seem elevated in comparison to other reports. A usage rate of only 1% overall was found in a survey of athletes presenting for pre-participation examinations [50]. No explicit mention was made about whether the questioning was anonymous, but responses to other questions leads the reader to suspect it was not. Various surveys of college athletes in the United States both on and off season showed overall steroid use between 4 and 9%, while the prevalence among the top schools, where pressure to win is highest, was reported to be up to 20 to 30% [51]. A questionnaire mailed to male college athletes and non-athletes in 3 eastern US schools reported a 2% usage rate of anabolic steroids [52]. The response rate, however, was only 31%. A large study of US high school seniors recently found that 6.6% had used anabolic steroids [18]. However, schools were included in the sampling frame by virtue of having an athletic trainer on staff, only 69% of the schools contacted agreed to participate, and only 50% of seniors eligible to complete the survey volunteered. It is impossible to tease out whether this led to under or over-estimation. Schools where it was genuinely felt there was no problem may not have participated, raising the prevalence, while students who took steroids may have declined to participate, leading to a lowering of the prevalence estimate. In West Virginia, a 46% response rate from 8400 questionnaires (n=3900) sent to male high school students found 5.3% used steroids [53]. In Chicago, 8.5% of male adolescents surveyed used either anabolic steroids, growth hormone or both [54]. An earlier study found a prevalence of 6.5% among males and 2.5% among females

for anabolic steroids [20].

The first Canadian data were presented in Banff at the Academy of Sport Medicine meetings by Dr. Gary Greenberg from the University of Ottawa who had conducted a survey of university football players during the summer of 1988 [47]. Of the 14 (out of 23) teams responding, self disclosed use was 6.2%. However, when respondents were then asked to estimate what they thought the prevalence was among their fellow players, a majority believed that up to 25% took steroids and one quarter of respondents felt the prevalence could be as high as 50%. The first studies of adolescents were completed by the Addiction Research Foundation [31] and a group in London, Ontario [55]. The ARF survey included questions on steroid use for the first time and found a prevalence of 2.1% among males and 0.2% among females. In London, the prevalence among males and females was 5.3% and 0.6% respectively. This prevalence was similar to a study in Texas, with prevalence estimates of 5.0 and 1.4% [56].

However, more work on the prevalence of use needs to be done. Although there are some Canadian data, prevalence estimates from repeated and larger surveys will add more relevant work. Response rates in many studies were poor, leading to difficulty interpreting the results. In addition, comprehensive survey work is missing. More information is needed regarding knowledge and attitudes towards use to round out the information required for planning interventions.

3.3 Conclusion: the need for a study

Based on the above discussion, with prevalence estimates varying between 5 and

10 percent or more (from US data) and public concern, anabolic steroid use among adolescents is an issue worthy of study. Despite the tremendous publicity surrounding steroids in recent years brought out by events in athletic competition, they remain poorly explored. The lack of knowledge about the prevalence and attitudes regarding drug use among Canadian adolescents at their early stages of training, let alone among non-athletic teenagers, makes the magnitude of risk in this country speculative. With public interest, there is thus an urgent need to better delineate the prevalence and also examine the knowledge and attitudes of users. In the absence of information about how young people learn about drugs, we cannot design or target educational programs. Further complicating matters, even the effectiveness of education programs to deal with issues already identified remains speculative. And control measures cannot be planned without an understanding of the reasons for steroid use. To target these intervention efforts appropriately, we need facts: how many adolescents are taking steroids, what are their reasons for taking them, when did they start, and (for athlete users) in what sports are students most "at risk". Once the data are known, we will be in a much better position to construct and evaluate effective education programs and start dealing with an emerging and evolving health problem.

The majority of the work conducted regarding prevalence were surveys, either informal interviews or anonymous or confidential questionnaires. Invasive tests such as blood and urine sampling had not been used to date. Given the climate in Canada - with less emphasis on sports programs in the schools compared with the United States - and the need to study more than just athletics, the use of a general anonymous survey appears the

most useful methodology to be employed. However, the specific techniques will be reviewed below before one is selected and developed into a study protocol.

4.0 Selecting the study population

This section and the following one describing data collection techniques are intimately linked. Given the necessity of exploring a prevalence measure, the size and selection of the study population become crucial issues. The following discussion will outline options to find a population to target for sampling and methods to recruit subjects (such as random and snowball sampling), while the next section will then concentrate on various methods to measure variables of interest within the selected sample (such as the novel randomized response technique used in some face to face interviews).

Three criteria that are derived from the measurement iterative loop [21] can be applied to selecting a population to study:

1. Does the population experience a significant portion of the "burden of illness", or will it in the future? This question applies whether we are measuring quantitatively (high prevalence) or qualitatively (the morbidity or mortality experienced by the study cohort is high).
2. Do interventions exist that can modify the burden of illness if it is found to be high enough (from criteria #1) to warrant such effort?
3. Is the population accessible enough to both study and to later apply and evaluate any interventions that emerge from studies?

There was discussion earlier about the need to investigate the adolescent population.

During adolescence, experimentation with drug use begins or has just begun and adolescents taking anabolic steroids place themselves at risk of developing health problems. It is during the peri-pubertal phase that anabolic steroids have the greatest potential to do harm. Although specific intervention programs have not been developed to address steroid use among adolescents, education programs do look for teaching points and have already bought into the need for teaching strategies to counter drug abuse in general [43]. Without evaluation, intervention efforts cannot be assessed to determine whether they do more harm than good. Finally, there is the potential for easier access to the subjects through the schools. These points all fit the criteria described from the measurement iterative loop above, reinforcing the need to study adolescents.

The question is, where is the best sample found and how are they best approached. The study described in Part 2 of this thesis was designed in large part to estimate prevalence. However, as we are dealing with a potentially rare behaviour, locating users might require considering various different techniques other than more traditional random sampling [57,58]. The following pages and Table 2 summarize various options, and discussion will then follow regarding which one would ultimately fit best with the topic at hand. The options include sampling people (numbers 1, 3 and 6), sampling from lists of people (2, 4) or using consumption data rather than people (5) to estimate the behaviour of people. Sampling can also be random, where a known universe is selected and its members are selected from, or targeted, where the investigator selects subjects wherever they can be found (by necessity or convenience), using specific locations [59] or obtaining specific lists of subjects [60]. Finally, sampling can target either a particular group of

interest, such as steroid users, or capture both users and non-users. The options are as follows:

(1) Random sampling: If a universe can be located for the purposes of delivering a survey instrument or selecting a sample, then that universe can be sampled on a random basis (simple, stratified or cluster). For adolescents in school, this is possible. However, for adolescents not in school, a two stage process would be needed: for example in a telephone survey, a screening question would consist of "are there any members of the household between the ages of 10 and 19?" before soliciting participation. The advantage of random sampling is the existence of a built-in denominator to calculate prevalence from the numerator of steroid users.

(2) Capture-Recapture: An estimate of prevalence can be calculated if independent lists of steroid users can be located. A simple mathematical formula making use of the size of each list and the number of cases that overlap both lists can be used to derive a prevalence estimate [61]. This technique applies to disease prevalence when case lists or registries exist [60]. No such list is available identifying steroid users.

(3) Snowball sampling: To identify steroid users this way, an investigator need only find one user who can identify another. Then each of these can help locate others, and so on until a sufficient number have been located for the purposes of the study. If this "network" is large enough, then a crude estimate of prevalence can be found if the population denominators are known [62]. This is somewhat inefficient however, so the purpose of snowball sampling is mainly to build up a large enough

sample of hard to locate subjects for the purpose of collecting information about them, most often by interview, rather than counting to measure prevalence [63].

(4) Jelinek formula: Uses data from the outcome of an activity (for example a particular disease state) to estimate the prevalence of the activity in a population [64]. Jelinek in his work assumed that a predictable proportion of persons with alcoholism die of hepatic cirrhosis. Thus one can calculate the prevalence of alcoholism by the prevalence of cirrhosis. The formula is unsuitable for use with anabolic steroid consumption for the same reason that it had not become popular: there is no specific outcome for steroid of use just as hepatic cirrhosis is not just caused by addiction to alcohol.

(5) Ledermann formula: Using an assumption that the distribution of alcohol consumption in a population is log-normal, and that the definition of alcoholism has a cut point on the graph (for example having more than a certain number of drinks per day), Ledermann [65] considered it possible to calculate the prevalence of alcoholism based on that population's consumption data for alcoholic beverages. For anabolic steroid use, no such graphs have been derived and neither are accurate sales data available (users often obtain the drug from illicit sources). Therefore this formula cannot be applied.

(6) Case series: Here, a convenient sample of adolescents is surveyed such as a group at a fitness club, on a sports team or at a youth club. Some of the settings (such as the sports club) may have a higher than expected prevalence of steroid users. This technique does not allow for an estimate of prevalence, but can capture

information about the use of the drug. It cannot capture an accurate numerator nor denominator for steroid use in a general population of adolescents.

Table 2: Sampling options

Sample	Selection	Target	Technique	Purpose/Requirement
Large	Random	Both	1. Random sampling	*Prevalence or information >Requires known group to sample
	Targeted	Both	2. Capture - Recapture	*Prevalence >Requires defined "lists" of users
		Users	3. Snowball	*Information (sometimes prevalence if network large enough)
Variable	Targeted	Both	4. Jelinek formula	*Prevalence using a proxy measure
		Users	5. Ledermann formula	*Prevalence using consumption data
Small	Targeted	Both	6. Case series	*Information only
		Users	3. Snowball	*Information

Given the options above, which one would suit a survey of steroid use that wishes to capture enough data for a prevalence estimate as well as obtain some basic information about current users and non-users? Clearly, a large random sample technique is preferable as a means of obtaining both a numerator and denominator. The requirements of capture-recapture (a list of users - such a list being non existent) and the resource intensive nature of snowball sampling (to obtain the necessary exhaustive numerator) make those methods unsuitable. Fortunately, for the random sampling technique, a population of adolescents does exist that could lend itself to being sampled. That population is in the school system.

All adolescents should be in school until at least the age of 16 (grade 10 or 11) when attendance is compulsory, and a majority do stay on to completion at age 18 or Other gathering places include clubs and athletic facilities. In sports clubs there is likely a higher prevalence of steroid use but the population is less representative of adolescents in

general because personal choice is a greater factor in attendance. In addition, it is much more difficult to obtain a large sample. The trade off is clear: sample size and representativeness in order to obtain an unbiased prevalence figure, versus high prevalence to permit more probing of reasons for steroid use. Although a study wants to capture both, because the work is preliminary, obtaining a prevalence estimate is a more important consideration in order to delineate the magnitude of the problem. In addition, some questioning of non-users can determine if adolescents are thinking about steroids, if they know anything about them and whether they feel that steroids are easy to obtain in the school setting should they wish to use them. We already know from repeated anecdotal accounts that steroids are easy to obtain in the sports club setting. Thus the schools appear to be the best choice for a sampling frame. The generalizability of a sample taken from within the school system is greater, as mentioned because it represents most adolescents, and the structure of classes and grades makes selecting a random sample easier, and accessing the population easier.

Does the school system capture most adolescents and is this a real concern? First, as mentioned earlier, school attendance is generally considered mandatory. Thus the majority of this age group are attending school at least for the first few years. Second, as the questions will address the most relevant issues surrounding steroid use - namely their function to enhance athletic competitiveness versus their use to enhance body image, results from these questions can be incorporated into prevention programs. These programs will be delivered mainly in the schools where most adolescents can be targeted. Thus the school population will both generate the data and benefit from the intervention.

Other studies can address those teens who do not attend school. They should be surveyed separately for data to plan their own targeted intervention.

Both elementary and high schools cover the adolescent population, as do the first few years of university. The majority, however, are within the high school age range. In order to simplify data collection, the high school age population was selected for the study. This population consists of male and female students in grades 9 through 12 (covering students taking credits which used to be part of grade 13). Only one board of education was selected, again for simplicity. It allows dealing with one administration and one uniform group of schools with minimization of travelling time. There are 12 high schools meeting those criteria in the Ottawa Board of Education. Vocational schools were excluded to avoid difficulties with comprehension because the survey instrument, discussed in section 2.2, is somewhat complex. As well, translation costs would have been prohibitive and would have introduced an additional confounder for this study. Thus it was restricted to English. The survey was to be administered to entire classes, as discussed earlier, with a random sample of 10 to 12 classes stratified by home-room grade from each school. This was accomplished by obtaining a list of all classes in the schools to be sampled, numbering them and randomly selecting a pre-determined number from each grade level. As described, selection by whole class was the simplest technique and the least disruptive to the schools, both important considerations.

The sampling frame includes non-athletes to determine the extent to which students are using steroids to improve personal appearance, and females as there is no data from that group at all. All grades will be surveyed in order to assess patterns of use across

the high school years.

Students who train competitively may be under-represented if they often take time off school for extracurricular events. A morning survey would still capture students who leave early for extracurricular events, and any students late for morning home-room because of an early practise would have their absence documented. Thus it would be possible to quantify missed responses. The probability that students are absent because of long term activities is small, and tends to be concentrated in schools on the semester system which is better geared for taking blocks of time off because its programs are condensed. A check with each school on such a system will reveal the number of students absent long term.

5.0 Selecting the data collection method

Having selected the topic and the study population of interest, the next step is to select the data collection method. The one ultimately chosen will best be able to balance certain factors. These factors include:

1. Quality of data - is the method able to collect the type of data desired to achieve the goals of the study (such that an intervention can be planned from the result)? In other words, can it collect the type of data needed to estimate prevalence and/or can it collect the type of data necessary to learn some details about factors surrounding steroid use.
2. Applicability to the selected population - does the method fit with the ability/capacity of the intended study population to participate? In other words, it

is more advantageous if subjects are familiar with the testing procedure (such as filling out questionnaires), or the procedures are interesting, than if they are foreign to them.

3. Acceptability - is it deemed acceptable to conduct the study on the selected population (does it follow basic ethical guidelines for conducting studies), and is the method acceptable as well to the community (which in the present case would be the school board)?

4. Feasibility - can the study be carried out? Is access to the study population granted in such a way as to facilitate the data collection?

5. Cost - the more reasonable the cost for the information gathered, the more likely the study is to be funded.

Careful balance must be maintained between accuracy of data and cost. The prime objective is quality data (poor data even cheaply obtained are useless). Clearly, some aspects of each of these criteria must be followed. With reasonable cost, the study may be funded. With a good study design, the target population will accept participation and be able to complete the study. With a good data collection method, data quality will be maximized. The key is simplicity. A simple method would be of lower cost, applicable and acceptable and more likely feasible to carry out.

When selecting a study design for investigating the use of steroids in an adolescent (as well as in other subjects), one of the most important considerations is assuring confidentiality of the data during and after testing has taken place. This addresses part of point three above, acceptability to the study population, without which no study can take

place. There are several data confidentiality options that can be selected from here, and are discussed below.

Confidential versus Anonymous: refers to whether the identity of the subject is available to those who conduct the testing. If anonymous, identity should remain unknown unless the tester personally recognizes a subject (rare). In this case no individual follow-up can be achieved. If the testing is confidential, then the tester knows the subject's name, but mechanisms to protect privacy are in place. However the subject can be traced for follow-up purposes.

Linked versus Unlinked (usually of anonymous testing): refers to whether the subject and the test result can be linked together. If unlinked, neither tester nor the subject can know the results of the testing that took place. Confidential testing is linked, otherwise there would be no need to record specific identifiers and the study would be done anonymously.

Nominal versus Non-nominal: refers to whether names are used on the sampling. In non-nominal testing, only codes identify the sample so a result without the "key" to link it to a study subject is anonymous.

The following table highlights these options with examples of possible study designs for anabolic steroid use. Some of these designs will be elaborated on in the next sections.

Table 2: Range of study confidentiality "options" and examples.

CATEGORY		EXAMPLE
Confidential	**Nominal**	Testing for steroids during a "medical checkup", subject's files are held confidential.
	Non-nominal	A code is used on the sample but the subject can be contacted.
Anonymous	**Linked**	The subject is tested for steroids and the sample's identifying code is given to the subject but not recorded. Later, the subject calls with the code to obtain results.
	Unlinked	Leftover samples of blood or urine are stripped of all identifiers, pooled with others and tested.

Although several options for an unlinked, anonymous survey are available; other designs in addition to those will be reviewed below with special attention paid to criteria defined above regarding cost, applicability, acceptability, feasibility and data quality. The method selected will be compared to what had been used in the study described at the outset.

5.1 Medical examinations

Blood and urine tests for steroids can reveal present use. It is questionable, however, whether adolescents taking steroids would volunteer for such a study even if it were performed anonymously. Further, information on reasons for use and history of past and present use would not be available unless a questionnaire or face to face interview accompanies the testing. This complicates the assurance of confidentiality. The only reasonable strategy would be to conduct a survey as part of some pre-school or pre-participation physical examination that included routine urine or blood testing. Aliquots of the sample could be sent off for steroid screening. But consent would have to be obtained

for the tests, and test results would have to be linked to the questionnaire. Even if the data from the questionnaire were stripped of identifiers and linked by code to the urine or blood test, assurance of confidentiality would be difficult to make to the study sample and participation may not be optimal. Finally, the issue of test sensitivity would also come into play. For example, in a study of drug use during pregnancy [66], although only 41% of users who screened positive admitted to drug use, 50% who claimed they used drugs screened clean. Although steroid testing is more sensitive and specific, it is very costly.

Medical examinations are therefore not a viable alternative unless the only piece of information sought is use, in which case the methodology presented below in anonymous unlinked testing may be considered instead. As will be shown, it has its own further set of limitations.

5.2 Anonymous unlinked prevalence surveys

To avoid the concern over confidentiality that using sports participation or other routine medical examinations (with blood or urine testing) create, methods exist to test blood or urine for steroids without the knowledge of participants. These designs meet ethical guidelines and are known as anonymous unlinked prevalence surveys. They are more commonly used for population studies of HIV infection [67] and involve analyzing a portion of blood samples that were drawn for other reasons. These can include routine medical exams, but also emergency room visits or testing from participation in other studies. A key feature is that no extra blood is collected than would have been done for the stated purpose and the subject does not know that his or her sample was used for the

seroprevalence survey. The data are completely anonymous (with perhaps very minimal demographic data) and cannot be linked to the subject in any way because the sample is disconnected completely from its donor. Guidelines exist for the ethical conduct of such work [68]. They were developed by a panel of experts representing medicine, law, ethics and the general public and are listed here.

1. Institutional ethics review would still be required to ensure that record keeping is truly anonymous and unlinked.
2. The specimens originally collected for the other purpose must be sufficient (no extra samples taken).
3. The public would still be made aware of the existence of the study in the community, by both general publicity and with information letters sent to physicians potentially caring for subjects.
4. No sample size small enough to identify individuals or groups would be analyzed (for example if a positive sample came from a small hospital with few visits it may be possible to identify the individual).

In essence, the rationale is that patients do not need to give explicit consent for participation, thus permitting a truly random and representative sample. The unlinking of the sample from the patient and provisions for coding data only when a large enough sample is obtained from any given area help guarantee anonymity. Finally, the provisions for publicity regarding the survey still allow for opting out by patients (a "passive consent" technique that will be elaborated on in a later section).

However, there are major drawbacks to this methodology. Some are similar to the

concerns raised by medical tests combined with interviews described above. First the sample does not represent the general population of adolescents, only those seeking health care for some reason. Second, little or no demographic information would be available to supplement the tests. Third, the only estimate would be prevalence of use within the preceding weeks - steroids clear the body after discontinuation thus missing current users on an off cycle. Fourth, testing for steroids is expensive, and sensitive screening techniques must be used. To achieve the required sample size given the estimated prevalence of use would be prohibitively costly. Finally, the lack of data regarding knowledge and attitudes towards use would make it difficult to plan intervention programs regardless of the prevalence uncovered. It could therefore only be a first step at best and does not meet the criteria set out above as an acceptable option in this case.

5.3 Unobtrusive measures

A slight extension of the theme of anonymous surveys is that of unobtrusive measures. These options are observational: information is collected on individual subjects, or sometimes on groups, but without their knowledge. Usually no direct evidence of steroid use is obtained on individuals. Instead, other evidence that suggests steroid use is collected. This evidence may include:

1. Sales figures of anabolic steroids obtained from pharmaceutical companies. As anabolic steroids have limited and likely stable legitimate use in humans, any increases over time or use of larger than expected quantities could represent illegal use. Section 4.0 discussed the Ledermann formula [65] which has been applied to

alcohol consumption data. Unfortunately, the data needed for the formula do not exist for steroids.

2. Size of students over time as observed by an investigator. A trained observer may be able to keep a log of students using gym facilities and be able to estimate abnormal growth patterns that may suggest steroid use. This could take place in the school gym, but would require longitudinal sampling over several months.
3. If steroid dealers are identified, their "sales" figures could be estimated as well as any increasing demand over time. Further, their clients could be characterised in a limited way through interviews regarding their demographics.
4. Environmental sampling from washrooms (urinals) at the high school for traces of steroids. A simple two point scale would indicate either some evidence of use, or none.

Although these techniques are covert, the data collected are too crude and in some cases may not be acceptable to the school boards (observing in a locker room or washroom would be trespassing, and even if sanctioned, would appear very strange indeed). It would be unacceptable to students if they were aware it was being considered. In addition, none of these techniques can offer an accurate prevalence figure: lack of sensitivity and specificity of observations, and lack of accuracy of any sales figures are coupled with denominator data which is either not available or impossible to estimate given that none of the techniques can "survey" the entire population. Further, none can collect data relevant to planning intervention programs as no actual users would be interviewed. The only purpose of these measures would be to identify likely target groups

for a more in depth study. However we already have a target group in mind for the present work. Therefore these options are not worth pursuing beyond the theoretical.

5.4 Personal Data Collection Methods

The use of specially constructed survey instruments can be used several ways in several different settings. These include personal interviews with subjects, telephone interviews, and self completed questionnaires (either mailed to the subjects with a self-addressed envelope, handed out for self-completion and return, or self completed in a group setting and collected immediately upon completion). The differences between these methods have to do with how resource intensive they are to carry out, how easy it is to access the study population and how comfortable the subjects feel about responding to the survey. Each is discussed in turn below. In most cases they can measure attitudes, as well as prevalence.

5.4.1 Face to face interviews

In the adolescent population, this may not be viable as there is no explicit guarantee of confidentiality. Experience with steroids as a topic has shown how difficult it is to even interview a small handful of users. For a lead story in a local paper [48] the author spent a great deal of time trying to find even one user who was willing to speak with him even with assurances of anonymity. There is uncertainty whether steroid users would volunteer for the study even if special techniques are applied such as randomized response [69]. In randomized response, the student can answer truthfully without the interviewer knowing whether or not they actually uses steroids. It works by providing

each student with two questions, the sensitive one ("Do you take steroids?") and an innocuous one (such as "Was your mother born in May?"), along with a coin to toss covertly to select which question to answer. In this way, the true behaviour of the individual subject cannot be known to the interviewer, but by knowing the distribution of responses to the non-threatening question in the population (in this case the proportion of live female births in the month of May), it is possible to mathematically derive the actual response to the threatening question. Another possible variant is to structure the face to face interview in such a way as to ask the subject not whether he or she uses steroids, but from their knowledge of others who may be users, what the prevalence might be and what they think the reasons for use are, and what interventions could be applied to curb use. The alternative measures, however, may still not provide sufficient reassurance (especially if they are perceived as odd or complicated by the students) to avoid biased self selection for participation. Moreover, in the case of randomized response the sample size required for a prevalence measure of the same precision as a regular response study would be much higher [70] and the survey would not be able to compare users and non-users, further limiting its usefulness.

A further difficulty is the labour intensive nature of personal interviews, making it very expensive to use with a large sample. Rather, this technique may serve well to complement the use of a large prevalence survey by adding to the detailed information that could not be collected by the larger study.

Finally, when the face to face interview was compared to other interview techniques such as telephone surveys, it was not any better at gathering health

information[71,72,73].

5.4.2 Telephone interviews

These can be conducted either with prepared lists of individuals to contact, or using a random digit dialling system. Both ways of preparing lists have unique difficulties in addition to the labour intensive nature of the telephone interview that also makes it an expensive survey technique. Although, when conducted by a large polling company, the telephone interview can yield a prevalence estimate, costs can reach $30,000 for a sample of 400 obtained by random digit dialling [74], with completion of a 10 minute questionnaire. Assuming easier recruitment of subjects (the quoted study sought a very narrow age range), the same amount of money would still be needed for the sample size desired in the present study.

To circumvent some of the labour intensiveness of random digit dialling, prepared lists may be used if they are available. In the present situation, they are available: however they belong to the school board. Making calls from lists provided by the education system is expected to anger many parents as this information is supposed to be confidential. School boards do not want to alienate their constituents and would justifiable refuse to allow this method.

Random digit dialling as indicated is the other way to obtain a sample within the age group. The constraints there are the number of attempts required to find a respondent within the age range sought would inflate the costs to those of the survey described above. The only advantage would be the possibility of a nationwide sample. But the low prevalence estimates would not permit regional comparisons in any case.

Finally, given the deteriorating climate with polling companies and the sensitive nature of the survey, once again users are probably less likely to participate. Even with the relatively benign nature of the telephone survey described in this section, close to 20% of respondents refused to be interviewed.

5.4.3 Questionnaires

The self-administered questionnaire has several advantages: 1) the method is relatively inexpensive for a large sample, 2) the length of the instrument adds little to the difficulty of conducting the study and 3) it is often used for subjects that are sensitive because confidentiality can better be assured. The questionnaire can capture attitudes and knowledge as well as measure prevalence, unlike the use of drug testing alone. However, can drug use be reliably measured by a questionnaire? Exaggeration of use and minimization of use lead to over or underestimation of prevalence. Studies have found, however, that the assurance of anonymity and the use of well constructed measures can minimize these deviations from the truth [12,75]. The authors of the second paper [75] had reviewed numerous studies of validity in self-report surveys among high school students. Most validity assessments were conducted using lie scores, and self reported use was accompanied by low scores indicating honest reporting. In addition, the WHO has developed a methodology for student drug use questionnaires that has been tested in several countries including Canada. It includes a question asking students whether they would answer truthfully if they had used drugs.

Two formats can be used. The first is a mail survey. The second a questionnaire administered "in person" (though distinct from the face to face interview which uses an

instrument completed by the researcher). The mail survey requires respondents to fill out the questionnaire that is sent out and reply using a self-addressed envelope provided. This is the simplest method to use in surveys of adults, but for the adolescent population requiring parental consent (see below), it would add a degree of complexity that would make assurances of confidentiality difficult.

The second method relies on the fact that the adolescent population is "captive". If school time can be obtained, the survey can be administered relatively easily during a pre-determined period of time and collected with the greatest assurance of confidentiality because parental permission would be easy to verify yet also easily dissociated from the survey questionnaire. The latter can then be completed anonymously.

One drawback of the questionnaire method is the lack of a validated tool that covers steroid use. The literature review conducted when the survey was planned had not uncovered any comprehensive knowledge and attitude measures. An instrument would need to be developed from the beginning.

5.5 Recommendation: a questionnaire survey

For survey research on steroid use, a sensitive topic, anonymous unlinked data collection techniques would offer the most reassurance to subjects.

Drug testing and medical examinations are not feasible as the subjects would have serious concerns about confidentiality and the process is prohibitively expensive on a large scale. Unobtrusive measures are too blunt an instrument to provide any useful data in this situation. Face to face interviews are time consuming and unreliable and telephone

interviews impractical. Thus self-administered questionnaires remain our best tool to assess this problem, and the only way to measure knowledge, attitudes and prevalence. Of the available techniques, one stands out as meeting the requirements of the present study: the self administered, handout questionnaire. Once completed, it could also be readily reproduced by other jurisdictions who would like to collect local data for their own use. This would also add to the knowledge base regarding steroid use in Canada. The most difficult portion of any survey in the adolescent population within the high schools is obtaining parental consent. Section 6 below discusses in detail the ethical and philosophical issues involved.

The main challenge to be overcome is obtaining a good response rate from a properly selected random sample of the population under study with the constraints of parental consent requirements. In the end, a variety of studies may need to be completed to round out the necessary information for program planning, such as (after all), more intensive interviews to capture detailed reasons for use in addition to the prevalence surveys capturing superficial data.

In conclusion, then, the type of instrument would not be changed from the one that had been selected for the steroid use survey described in Part 2 of this thesis. However, the requirement for parental permission before proceeding would have been brought forward for discussion much sooner than it was.

6.0 Consent and the Adolescent Population

Until adolescents reach a certain age, some activities are prohibited (obtaining a

driver's license, buying alcohol) while others require parental permission. Until that age, which can vary from province to province, adolescents are "minors" under the law. A similar situation exists for research, except that age limits are not legally set. Whether parental consent is required or not is entirely at the discretion of the study sponsors.

The concern is that the more layers of permission there are between the survey instrument and the subjects, the more attrition can take place. One group must give their permission (ie. the parents), and a second group must still consent to participate, and actually fill out the survey (the students). This compounds the effect of any refusals: the response rate to the consent letters must be multiplied by the response rate of the students.

Melton [76] stated that deference to parental wishes in most situations is based on a presumption that parents will act in the best interests of their children. In most research no direct benefits are anticipated for participants, so the usual presumption is inapplicable and parental judgements may be less authoritative. Thus is there any valid reason why adolescents cannot consent to participate in research without a parent or guardian's permission? The following section looks at this issue more closely.

6.1 The ethics of epidemiologic investigations

Consent forms are only one aspect of the broader questions that address ethical issues in epidemiology.

Loosely defined as the study of epidemics, the goals of epidemiological investigation in the past were fairly obvious to the subjects: by their participation, they played a part in helping stop the spread of disease that they were at risk themselves of

acquiring. Today, epidemiology is much more than the study of acute disease, although investigating drug use such as steroids has as the ultimate goal the curbing of its use ("spread"). While traditional epidemics may be beyond the victims' control, drug use is generally a matter of choice. Thus investigating the issue can be construed as paternalistic, an attempt to control "choice". This evolution has led to a much closer examination of the ethical issues in epidemiology, and the publication of guidelines to deal with them [77]. The guidelines are based on three principles that are widely quoted [78]:

1. Autonomy.

   Also referred to as respect for persons, dictates that subjects "capable of deliberation about their goals be treated with respect for their capacity for self-determination". This includes protection of persons with diminished autonomy from harm or abuse. In the present context, it amounts to obtaining informed consent from the study subjects, without dismissing out of hand the permission their parents may need to provide, but taking into account whether this need conflicts with an adolescent's capacity for self-determination. Essentially it amounts to protecting from harm while respecting self-determination.

2. Beneficence and non-maleficence.

   These are the ethical obligations to maximize benefits and minimize harms. These require that the research be worthwhile to conduct as it will be of benefit, requires that the researchers be competent and able to use a sound design that ensures the well-being of the subjects. These issues are built into the study question and the study design, and must be passed by ethics review committees.

3. Justice.

Justice dictates that the subjects be treated with equality. Thus they may also derive the benefits of the study, or at the very least other individuals similar to themselves can derive the benefit. Conversely, it also dictates that the persons (or group) who derive benefit from the study results should bear their share of the burden of participating in the research. In the present context, it is adolescents who will benefit from the research, and adolescents who will participate.

When conducting research on human subjects the most important principle is the first one, that of ensuring autonomy [79]. This can only be achieved by soliciting voluntary participation and disclosing as much as ethically necessary about the study being undertaken - in other words obtaining full informed consent. Added to this, subjects must also be informed of their right to withdraw from the study at any time even after giving consent. Although consent is usually obtained in writing, in cases where the research is in the form of a survey questionnaire separate consent is usually not required. It is implied by the act of participating. The Medical Research Council (MRC) Guidelines on Research Involving Human Subjects (1987) [14] state that completing the questionnaire itself is implied consent, as long as no coercion is used. What about parental consent requirements for survey research? The parent is obviously not completing the questionnaire. The question that will now be explored is whether adolescents truly need parental permission to protect their involvement in such research.

6.2 Consent and children/adolescents

The concept of the "age of consent", before which a parent or guardian's permission is required for a child to take part in some activities, is a difficult one. It is usually considered either 16 or 18 years depending on the purpose or institution defining it. The age of majority, on the other hand, is set by provincial law and is usually at the higher end, around 18 years. Often this age of majority is also used as the age of consent. However there is an important distinction: in common law a minor (a person under the age of majority) can consent to medical treatment without a parent or guardian's permission as long as they can fully appreciate the nature and consequences of the procedures performed [80]. Therefore in clinical medicine physicians can treat without parental consent patients under 16 years of age if the patient appears to have the intellectual capacity to make an informed decision. This arises most often when teenagers seek birth control or other sensitive treatment, and do not wish to tell their parents. Because it is difficult to define the concept of "mature enough" and make a proper determination, most treatment of minors is done nevertheless with parental permission. In recent times the chronological set point has become even more fuzzy and is even less of a useful marker for maturity. There are obvious paradoxes: to be given the responsibility of driving a motor vehicle or quitting school and leaving home to go on social assistance only "requires" 16 years of maturation. Yet to buy alcohol and to vote requires reaching the age of 18 (19 in Ontario), the age of majority.

In an attempt to better define the common law, the province of Ontario has passed legislation on consent to treatment [81] that sets out clear criteria for obtaining informed

consent as well as the discretion to treat patients in both emergency and other situations when no parental consent is available. It goes even further in denying parents and guardians the right to refuse treatment for a minor (as in the case of Jehovah's Witnesses who would refuse a transfusion for their critically ill child) if that treatment were deemed medically necessary to protect life. Apprehending the child by court order is no longer required *a priori*. Although as mentioned there is no defined age of consent in common law either, this legislation now specifically prohibits discrimination on the basis of age. Therefore, anyone will be able to seek treatment as long as they appear capable of giving full informed consent. This recognition of capacity for consent among individuals who traditionally have been encouraged to get permission from a guardian reflects the changing direction of autonomy for children.

One aspect of obtaining consent in research that may make it different from consent considerations in treatment is that participation rarely brings direct benefits to the subjects themselves. In fact, the Ontario Consent to Treatment Act specifically excludes consent that is obtained for research purposes. Therefore the ethical principles of autonomy, non-maleficence and justice described above must be carefully considered. However, there is no reason to doubt that altruistic behaviour cannot operate among children and adolescents. Therefore, they may also be fully prepared to participate in research for the benefit of others and I propose to argue that the same principles should apply as for consent to treatment.

At the present time in survey research, parents may be asked to return a signed form giving (or denying) their child's consent to participate in the study. This additional

step has yielded poor results, even with the expenditure of considerable effort on the part of the researchers ([82] and the exercise described above). Forms sent home with the students get lost (in either direction), and mailed forms get ignored [83], as had occurred in the present study described above with 40% of parents not returning the consent forms. One study noted that the problem did not appear to be that parents refuse consent, but that too much effort was required to return the forms: each perceived their contribution to the research as small [82]. In that study parents had to return a consent form only if they refused consent. Few did, suggesting that non-response is not passive refusal. This is the essence of the dilemma: an intervening step in assembling a sample may destroy the validity of the study results by eroding the response rate and the randomness of the sample. Is this step always justified or can it be re-evaluated?

The purpose of requiring parental consent may be because: (1) the child does not understand the nature of the study, (2) because in some way they feel coerced into taking part or (3) because without parental assistance (and by implication explicit parental consent), the child cannot give accurate information. Among adolescents, in a study of personal behaviour, the third concern cannot apply. The second concern only peripherally involves issues of explicit parental consent and can be dealt with by careful attention to study design and ethics: getting approval from an ethics committee as well as school authorities with parental input that could ensure that individual students would be able to give their consent and participate or not without feeling coercion. However, the first concern, lack of understanding, is the very issue that consent to treatment legislation deals with: assessing the capacity of a minor to provide full informed consent while not

discriminating on the basis of age. As will be described in section 6.4.4, even young children can understand basic concepts of research and their participation in it.

6.3 Striking a balance: the need for optimal data

As will become clear in the next sections, there is no consistency in consent requirements among centres where research is conducted. This situation needlessly perpetuates a climate of biased research in many fields of inquiry. The difficulty addressing this issue is that nowhere in the discussion of guidelines and recommendations regarding ethics, is data quality described as an important consideration. The conflict between consent procedures and data quality is a conflict between social and individual rights. Society needs good data in order to plan. Individuals should feel some responsibility to help provide that data in certain cases, and policy makers should facilitate this process.

In the present context, it is difficult to conduct good research when restrictive parental consent policies are in place. It also suggests that in view of the lack of consistency across jurisdictions, and the need for good data, restrictive policies may not be justified and the ultimate benefits from well conducted research should outweigh them.

6.4 Consent options

Consent must be revisited: the next section will examine guidelines in place surrounding "age of consent". It will also review the options for obtaining parental consent and describe these in the context of the procedures used by different centres for

conducting survey research among the high school students in their jurisdiction. This overview will clearly illustrate the diversity of procedures that local boards of education actually accept.

Several authors reviewing the involvement of children in research [84,85,86,87] acknowledge the existence of legal limits and requirements (usually set at age 18). However, some ask whether this is based on any information that younger adolescents are incapable of giving their own consent [84]. The answer tends to be "no".

6.4.1 Current research consent guidelines

To begin the discussion, it is useful to review research guidelines put forward by established agencies. These guidelines form the emergent thinking on the ethical issues of research and although they do not supersede any legal requirements that are in place, the issue of consent is not inherently a legal matter. Thus guidelines can be thought of as documents recognizing and describing the capacity of various subject populations to make decisions on their own behalf in order to suggest to researchers and policy makers the appropriate consent procedures to apply. The current climate does not contain legislation to guide the policies of different Boards of Education and this has resulted in widely varying practises.

The first sets are from the Medical Research Council and the Social Sciences and Humanities Research Council [14,88]. Both groups discuss consent issues involving children and adolescents but more within the context of general research involving human subjects. The National Council on Bioethics in Human Research (NCBHR), established in part by the Medical Research Council, published guidelines specifically dealing with

research involving children. Recommendations on that subject were revised following a workshop held in December of 1992 [89]. The salient points regarding consent are outlined below. Finally, although The International Guidelines for Ethical Review of Epidemiological Studies [77], published in 1991, did not address children's participation in research in particular they did mention principles to follow regarding research on vulnerable groups. A later conference addressed children while discussing the issue of research involving human subjects in 1993 [90]. Both of these will also be discussed below.

a. The Medical Research Council

The MRC takes a general view of research, including that which uses questionnaires. Its guidelines state, in part:

> "In very minor cases, consent may be implied by the subjects freely entering into the research project; a subject voluntarily completing an anonymous questionnaire would be an example.
>
> "A relevant measure is that society and parents should not expose children to greater risks, for the sake of pure medical research, than the children take in their everyday lives. Parents control this level of exposure now. . .Much centres upon the level of development of the individual child and the surrounding circumstances. A child's agreement may be mere toleration without comprehending, or it may come close to informed consent as conventionally understood.
>
> "A concept has developed that a child incapable of giving legally and ethically acceptable consent may give an 'assent' which is significant in respecting a level of autonomy.
>
> "Regarding older children and adolescents, it may be appropriate to initiate discussion with them, and, if they appear to favour participation, to say that their parents' approval will be necessary." However, the guidelines go on to say that, "A mature adolescent willing to participate in a study has a claim to respect for privacy and to freedom of participation, under vigilance of a research ethics board.
>
> "The legal capacity of children to consent must be adjusted, of course, to relevant provincial legislation or regulation on the age of consent to medical treatment and, when this gives no guidance, to the maturity of

the individual child."

Thus the Medical Research Council considered all types of research and allowed that the maturity of the child and the nature of the research can be taken into account. It clearly felt that it is ethical to give autonomy to older children in some cases.

b. The Social Sciences and Humanities Research Council

The SSHRC restricted its comments to experimental research involving human subjects. It is a too narrow a view to apply to the general innocuity of survey research.

> "...where practical, informed consent of both parents and children should always be obtained in respect of research involving children.
>
> "Research on captive populations must be free of any possibility of coercion.
>
> "The informed consent of parents should always be obtained before experimenting with minors."

The SSHRC failed to define "minor", and therefore did not make any allowance for the level of maturity of the subjects. This diminishes the applicability of these guidelines to the present situation.

c. National Council on Bioethics in Human Research

The Report recommended several levels of authorization.

1. For children up to the age of 7 years, a parent or guardian must give informed and voluntary authorization.
2. For the older child, ages 7 to 14, the parent should authorize but the child must assent or provide voluntary consent.
3. For children and adolescents 14 years and older, informed and voluntary consent is required of them.

Thus, one can infer that by age 14, parental permission was no longer considered

necessary for adolescents to participate in research. Although some members of the workshop did not agree with setting the age at 14, the definition of research was very broad. Questionnaire surveys are considered among the least harmful to study subjects.

d. International Guidelines for Ethical Review of Epidemiological Studies.

The Guidelines discuss obtaining informed consent where feasible and acknowledges situations where consent may be waived as long as there are valid reasons to do so, and these reasons are agreed upon by an ethics review committee. These committees can also act for vulnerable groups (which include children, although no age limits are stated), but need to be particularly vigilant.

In addition, the guidelines mention alternatives to individual consent known as "community agreement". In this situation a representative of a group gives informed consent so that each individual member of the group need not.

Although these guidelines did not specifically address the issue of parental permission, they did stress the need to be conscientious, accepting the possibility that consent is not always explicitly necessary. Subjects still remain free to withdraw from any study at any time.

The guidelines also highlighted the need to assure scientific soundness, recognizing that one purpose of ethics review could be to facilitate the conduct of beneficial studies. The guidelines fail, however, to address the issue of chronological age or to define maturity.

e. International Ethical Guidelines for Biomedical Research Involving Human Subjects.

Informed consent regarding children is mentioned in guideline 5. It states that:

"the parent or legal guardian of each child (should give) proxy consent". However it goes on to say that "It may be assumed that children over the age of 13 are usually capable of giving informed consent", but parents should usually also provide proxy consent unless local law does not require it.

These guidelines thus make two relevant comments regarding the present situation. First that children over the age of 13 may be competent to give consent, and second that although parental permission should still be sought, it is not crucial. However, as with other guidelines, the impact of proxy consent on data quality was not addressed.

f. Summary of the lessons learned from research guidelines

Unfortunately, no two organizations deal with the issue in quite the same way. As national or international bodies, however, they share in the desire to maintain high standards of research ethics in all epidemiologic work. Thus their recommendations can play a valuable role in guiding the setting of policy and protocols at the local level and offer some options for latitude.

In general, guidelines that addressed level of maturity allowed for the child's consent to be valid without need for parental permission. Further, some considered children old enough by age 13 or 14 to give consent. The climate among these organisations setting ethics guidelines is towards granting autonomy to adolescents.

6.4.2 Options for obtaining informed consent

Despite the direction taken by the recommendations of the National Council on Bioethics in Human Research to permit adolescents by age 14 to provide their own informed consent, the requirement by many bodies is still to obtain parental permission.

Given this necessity, are there options that could alleviate the burden of traditional written parental consent?

The following sections review these options using examples of studies that have been conducted. Contrasts are made between studies that were required to use traditional consent methods and those in which no consent was needed.

a. Mail-in consent forms:

Using this method of obtaining parental permission, consent forms are mailed out to the home address, and a parent or guardian is asked to grant or refuse consent by returning the form in a self-addressed envelope. Only those students for whom a positive response was received may participate. Children of parents who do not return a form may not participate.

Response rates to mailed consent forms vary depending on the survey and the population to whom the mailing is conducted. A response rate of 50% was achieved following multiple mailings and reminders to parents during a questionnaire study by researchers at the Children's Hospital of Eastern Ontario [16]. On the other hand, a greater than 70% response rate was obtained on a general health status survey mailed directly to adolescents, without parental involvement [91], conducted by the same institution. Had the adolescents been accessible only after their parents had granted permission, the overall response rate for the health status survey would undoubtedly have been worse. Although the two studies were not entirely comparable, the results suggest that adolescents show more enthusiasm for participation than the parents in those cases, or welcome the opportunity to demonstrate maturity. Anther possible explanation for the

difference may be that envelopes addressed to parents inevitably are marked "To the parent or guardian of..." and some may get intercepted by the curious adolescent!

b. Carry-home consent forms:

This approach is similar to the process above, except that the forms are given to students to carry home to their parents. This technique is used with primary school children, where, with careful prompting by public health nurses, one Health Department achieved a 70% response rate [92]. When teachers alone were involved, the rate was only 50%. Large studies with a high profile can achieve similar results with handed out consent forms, as was the case with the Canada Youth and AIDS Study reaching 77% [93] among their sample of primary and secondary school students. These rates reflect very high cooperation by the schools involved and the high profile of the survey, and are similar to results obtained by the Addiction Research Foundation in Ontario when they are required to obtain parental consent [31]. Experience with other studies have yielded more consistently low response rates of 50-53% [94,95]. Although it is difficult to compare high school and elementary school students, there is a suspicion that younger students may in fact be more responsible with bringing papers home than adolescents. Further, it depends as well on the level of cooperation ("prompting") by teachers to return the forms after handing them out. Due to the extensive cooperation required by school staff to recover consent forms using this method, it was not a permitted option in the steroid use survey described in this thesis.

c. Passive consent:

With this technique, consent forms are mailed to parents with a self-addressed,

stamped envelope enclosed, but the parent only returns the form if they *do not* want their child to participate. Otherwise, it is assumed that permission for the child to participate is granted. Sufficient lead time and careful mailing will ensure that parents receive the letters. General publicity about the survey can also in some cases alert parents who may not receive a letter. These parents could then request one should they wish to refuse permission. Despite great care in alerting parents, some will inevitably miss the publicity. Since only a minority of parents will be in this situation, the benefits of using this technique more than likely outweighs the "risk".

In studies cited in the literature [82], this method has yielded a larger and much less biased sample, with response rates increasing from 40% to 97% in one study described, and 68% to 87% in another, when passive consent replaced the explicit requirement for parental permission. The authors note that parents did not object to the use of passive consent.

In Canada, precedent has already been set for this consent procedure. One Board of Education in Manitoba was asked by a research group to adopt this method and has approved it for a survey on anabolic steroid use [96].

6.4.3 Options for obtaining adolescent consent

Regardless of how parental permission is obtained, and even if it is not, two other issues need to be addressed. The school setting creates a "captive" population and therefore the issue of coercion must be dealt with all the more rigorously. Students may feel that they must take part, either to fit in with their peers if it appears that the majority will be taking part, or to please school administration. Steps can, however, be taken to

eliminate coercion by ensuring that students are fully reassured that participation is voluntary, that the teachers not be present while the survey is administered, and that the student is given the option of "missing" the period during which the survey is to be conducted without penalty or simply handed a "placebo" questionnaire or other document to read while other students are filling out the forms.

As well, informed consent from the students themselves should not be compromised - in fact, this is a given. Using the MRC guidelines, surveys must be fully explained and students notified of it in advance with the option to withdraw at any time (ie, by using one of the procedures just mentioned).

6.4.4 Conclusions

In the study described at the outset of the thesis, 42% of parents failed to return the consent form despite two mailings requesting that it be returned whether or not consent was granted. It is impossible to tell whether failure to return is really passive refusal or apathy. Nevertheless, this result was consistent with some of the other studies described. Was the use of "active consent" really necessary? For the school board surveyed, it was a strict requirement. However, the section above has highlighted the absence of consistency in the area of high school consent among other boards of education, and highlighted some of the difficulties achieving unbiased sampling inherent in a two-stage consent process. Thus at the very least, passive consent should be more readily approved for use.

Can consent be waived altogether? Studies have shown that children as young as age 9 can ask appropriate questions with regards to proposed research studies, and

certainly by age 14 can give full informed consent [97,98]. Further, in an unusual departure, the first reported survey of steroid use at the high school level was conducted in southern Ontario without parental consent [55]. The questionnaires were filled out by a large number of students, anonymously, during classes. It is notable that after the survey had taken place, not one parent complained to the School Board about the study. As another example, the biennial Addiction Research Foundation surveys in Ontario [31] are conducted this way whenever acceptable to the schools. Consent forms are made available, but are not always used. The researchers have calculated that on average across the province, only 34% of students are required to get parental consent, yet the majority of students surveyed are of an age requiring consent. Finally, a survey was conducted in 1981 as part of one school's drug awareness week at the same board of education as the present study [99]. The anonymous questionnaires were delivered to all period 2 classes without parental consent. Yet today, on a similar topic, parental permission is required.

Despite glaring inconsistencies, many boards do in fact waive the requirement for explicit parental consent, and thus precedent at many levels has been set for using "no parental consent". Recognizing nevertheless that this expectation may not be realistic for some jurisdictions, the use of "passive consent" techniques deserves careful consideration instead. To this end, guidelines should be in place to assist setting this up as a viable alternative [82]. First, quite obviously, parents must be informed of the survey with a letter and are given the option of denying permission for their child to participate if they felt strongly enough. Sufficient lead time and publicity surrounding the survey ought to ensure that the vast majority of parents are informed. Of the few who for some reason do

not receive a letter, given that few parents complain, it can be inferred that most would still not object to the survey provided it has been fully approved by their child's school board. For the rare case remaining, the importance of unbiased, quality, cost-effective data may overshadow it. The risks of inappropriately targeted interventions due to biased data are felt to be greater.

If a consistent policy can be adopted by a large number of centres, "between school board" difficulties can be minimized. Much of the reticence to relax very rigid policies stems from fear of losing public support in a difficult fiscal climate. Consent requirements can (and in some cases should) be relaxed in order to maximize the quality of a potentially important study by helping to optimize the quality of its data.

Part 4 CONCLUSIONS AND RECOMMENDATIONS

When a topic is identified as important for further study, research is planned. This was the case with the present work - the issue of anabolic steroids was a hot topic, and information regarding its use was lacking. Thus began the planning and implementation of the study described in the opening sections. Although there was a great deal of interest in the project by school boards, principals and individuals, unforseen circumstances led to the ultimate failure of the project. Attempts at altering requirements for explicit parental permission in order to complete the study were not successful. Much of this thesis suggested that such requirements may not be necessary, and in fact may be damaging to collecting quality data.

As there are many important health promotion areas that need to be studied in the adolescent population, and given the challenges described in this paper relating to topic, design and consent issues, I would make the following recommendations regarding designing and carrying out health promotion research among that group.

1) Research should not be conducted in a vacuum. By embodying the principles of ENHR, the selection of a topic of study must be made with care and should ideally be a partnership between the health promotion researchers, the community and any organization involved in the study. With a greater interest in the topic, the community should be more willing to help out and take part. This was almost successful in the present situation with the support of the department of social services of the board who had recognized the importance of the topic and were

eager to conduct their own drug use survey and add questions relating to steroid use.

When the topic of anabolic steroids was brought before the school health liaison committee, there was already some interest in studying the issue. The letter of approval to undertake the study, sent by the director of research of the Ottawa Board of Education, noted the high level of interest shown by the committee members regarding the topic. Broad consultations had been made with school board officials while refining the study topic and design, prior to the submission of a formal proposal to conduct research.

I would therefore recommend strong linkages of a proactive nature between researchers, public health practitioners and interests within the community that would examine areas in need of study and encourage research on important topics, and facilitate their completion. This could take the form of a meeting of stakeholders comprising academic researchers, health care practitioners from pediatrics, parents, school board officials, the medical officer of health, youth groups, and youth workers. Others with an interest in children's and adolescent's health would also be identified and invited to participate. The purpose of this stakeholder forum would be several-fold. The outputs are discussed below but the overall purpose would be to set a community research agenda and facilitate the process of conducting the research. It would not be a static process but would re-evaluate its progress and the relevance of the agenda on a regular basis.

2) The design of a study can only be selected after careful consideration of certain relevant factors. These include the particulars of the topic itself, the population sampled and the setting in which the study will take place. Standard methodologies are available to guide study designs. However investigators conducting health promotion research face the additional challenge of remaining flexible to accommodate the particular requirements of the local situation in which they plan to carry out the study. Nevertheless, every attempt should be made not to compromise the integrity of the study. This was not possible in the present setting - resulting in the final survey never taking place.

The initial requirement for parental consent necessitated a major undertaking of gathering letters of permission. Formal requests were made to have this policy waived for the study, without success. Thus the resulting poor starting sample (had the study proceeded) would likely have resulted in virtually unusable data. "Remaining flexible" means a willingness to cancel the study before sending out the questionnaires, recognizing the likelihood of an invalid sample.

I would therefore further recommend that researchers remain flexible in designing protocols, yet set specific criteria for proceeding with a study in advance. Such criteria would include setting an acceptable response rate for any preliminary work, without which the study would not be allowed to continue, and obtaining adequate cooperation from school officials that would prevent sampling bias and interviewer bias (through uneven testing conditions). Thus researchers must also be willing to stop a study in progress if conditions arise that would lead

to unacceptable data, and attempted compromises cannot be reached.

I would also recommend that the stakeholder forum described above discuss the nature of research and develop recommendations to maximize the quality of the research. Specifically,

1. the need to investigate health issues in children and adolescents.
2. the importance of quality data to intervention program planning.
3. the importance of well conducted studies in providing this quality data.
4. the individual elements of research studies that impact the most on study quality and how to facilitate the selection of elements that result in the highest data quality (for example allowing the use of a random sample rather than a convenience sample in a school-based study).
5. the options for obtaining informed consent from adolescents.

3) Researchers must be able to obtain informed consent directly from adolescents without the need to obtain parental permission. This recognizes both the autonomy of participants and the difficulty obtaining a representative sample with each additional consent layer that is present. Simplifying this step will yield a much better sample and one easier to approach.

It is expected that the stakeholder forum described above will recognize that requirement for parental permission for studies involving adolescents is not absolute. From the literature, it is obvious that the majority of jurisdictions do not require it. Medical authorities already recognize the ability of adolescents to take

an increasingly responsible role for decisions regarding their health and recognize their ability to provide valid informed consent. This has even been entrenched in new Ontario legislation that prohibits discrimination on the basis of age for the ability to make informed choices for treatment.

I would therefore finally recommend that the stakeholders brought together to discuss the conduct of research also turn their attention to the issue of parental permission requirements. In addition to the research agenda, the group should also draft special consent procedures for their jurisdiction. These procedures would follow accepted ethics principles and the precedents learned from research in other jurisdictions where more relaxed methods (such as passive consent or no parental permission requirements) have been acceptable. This recognition of the autonomy of adolescents takes into account the spirit of the new Ontario Consent to Treatment legislation.

Survey research on important health issues should be conducted with a view to being of benefit to the population. At the same time, funding agencies are demanding that intervention programs prove their effectiveness. Thus research should be sound, and barriers to obtaining quality data should be minimized whenever possible. The responsibility must be two-fold: researchers should be flexible in study design, and those responsible for allowing access to study populations should make a commitment to assist as much as possible if all parties agree that the topic is important to investigate.

REFERENCES

1. Last J. Dictionary of Epidemiology. Oxford University Press 1988.

2. Feldman W, Feldman E, Goodman J, McGrath P, Pless R, Corsini L, Bennett S. Is childhood sexual abuse really increasing in prevalence? an analysis of the evidence. Pediatrics 1991; 88(1):29-33.

3. Task Force on Health Research for Development. Essential National Health Research: A strategy for action in health and human development. UNDP 1991.

4. Pless R, Labrosse J, O'Connor A, Tugwell P, Spasoff R., Haynes B, Heyland D, Neufeld V. Essential health research: perceptions, precedents, progress, plans and proposals - Action and research for community participation. Working document from the Universities of Ottawa and McMaster 1993.

5. Cowart V. Blunting "steroid epidemic" requires alternatives,innovative education. JAMA 1990; 264(13):1641.

6. Society for Adolescent Medicine. AIDS prevention and education: recommendations of the working group. Journal of Adolescent Health Care 1989; 10:45S-47S.

7. National Library of Medicine. Grateful Med (A software tool for searching MEDLARS). U.S. Department of Health and Human Services 1993; Version 6.0.

8. National Library of Medicine. UMLS Knowledge Sources. U.S. Department of Health and Human Services 1993; 4th Experimental Edition.

9 Dillman A. Mail and telephone surveys: the total design method. New York, John Wiley and Sons, 1978.

10. Woodward C, Chambers L. Guide to questionnaire construction and question writing. Ottawa, Canadian Public Health Association 1986; 3rd Edition.

11. Blanken A. Measuring use of alcohol and other drugs among adolescents. Public Health Reports 1993; 108(S1):25-30.

12.. Smart RG, Blair NL. Test-retest reliability and validity information for a high school drug use questionnaire. Drug Alcohol Depend 1978; 3:265-71.

13. Zacour B, Campbell M. A survey of grades 9 and 10 girls' preferences and attitudes for selected activities in physical education programs, Ottawa Board of Education 1985-86. OBE Department of Physical Education, April 1986.

14. Medical Research Council. Guidelines on research involving human subjects. Supply and Services Canada 1987.

15. Dean A, Dean J, Burton A, Dicker R. Epi Info 5.01b: Public Domain Software for Epidemiology and Disease Surveillance. Centres for Disease Control, Atlanta, GA.

16. Davidson S. Study on adolescent suicide. Children's Hospital of Eastern Ontario, personal communication.

17. Dubin CL. Commission of inquiry into the use of drugs and banned practices intended to increase athletic performance. Supply and Services Canada 1990.

18. Buckley WE, Yesalis CE, Friedl KE. Estimated prevalence of anabolic steroid use among male high school seniors. JAMA Dec 16 1988; 260(3):3441-45.

19. Johnson M, Jay S, Shoup B, Rickert V. Anabolic steroid use by male adolescents. Pediatrics 1989; 83(6):921-924.

20. Terney R, McLain LG. The use of anabolic steroids in high school students. Am J Dis Child 1990; 144(1):99-103.

21. Tugwell P, Bennett KJ, Sackett DL, Haynes RB. The measurement iterative loop. Journal of Chronic Disease 1985; 38:339-351.

22. Swales W. FP's should be aware of anabolic abuse. Family Practise 1991; April 6:7.

23. Ryan AJ. Anabolic steroids are fool's gold. Fed Proc 1981 Oct; 40(12):2682-8.

24. Haupt HA, Rovere GD. Anabolic steroids: a review of the literature. Am J Sports Med 1984; 12(6):469-84.

25. American college of Sports Medicine Position stand on the use of anabolic-androgenic steroids in sports. Med Sci Sports Exerc 1987 Oct; 19(5):534-9.

26. Amsel Z, Genser S, Haverkos H. Anabolic steroid use among male high school seniors. JAMA 1989; 261(18):2639.

27. Holden S, Calvo R, Sterling J. Anabolic steroids in athletics. Texas Medicine 1990; 86(3):32-36.

28. Komoroski EM, Rickert VI. Adolescent body image and attitudes to anabolic steroid use. Am J Dis Child 1992 Jul;146(7):823-8.

29. Crawshaw JP. The young athlete: recognizing anabolic steroid abuse. Patient Care 1985; Aug15:28-42.

30. Bagley G. Steroids. Current Therapy 1989; 2(7):4-5.

31. Smart R, Adlaf E. The Ontario student drug use survey: trends between 1977 - 1989. Addiction Research Foundation 1989.

32. van der Merwe PJ, Hundt HK, Muller FO, van Velden DP. Drugs in sport. The first 5 years of testing in South Africa. S Afr Med J 1988 Aug 20; 74(4):161-2.

33. Cowart V. Some predict increased steroid use in sports despite drug testing, crackdown on suppliers [news JAMA 1987 Jun 12; 257(22):3025, 3029.

34. Murray TH. The coercive power of drugs in sports. Hastings Center Report 1983 Aug; 13(4):24-30.

35. Fost N. Banning drugs in sports: a sceptical view. Hastings Center Report 1986 Aug; 16(4):5-10.

36. Ryan AJ. Drug tests for athletes - pro and con. Physician and Sportsmedicine Aug 83; 11(8):131-140.

37. NCAA News Dec 21 1988; 25(45):11

38. Fuller JR, LaFountain MJ. Performance-enhancing drugs in sport: a different form of drug abuse. Adolescence 1987 Winter; 22(88):969-76.

39. Clarke KS. Drugs, sports and doping. J Maine Med Assoc 1970 Mar; 61(3):55-8.

40. Cowart V. Physician-competitor's advice to colleagues: steroid users respond to education, rehabilitation [news] JAMA 1987; 257(4):427-8.

41. Cowart V. Issues of drugs and sports gain attention as Olympic games open in South Korea [news JAMA 1988 Sep 16; 260(11):1513, 1517-8.

42. Cowart VS. Blunting 'steroid epidemic' requires alternatives, innovative education [news]. JAMA 1990; 264(13):1641.

43. Black K. Report of the task force on illegal drug use in Ontario. Government of Ontario, 1988.

44. Goldberg L, Bents R, Bosworht E, Trevisan L, Elliot D. Anabolic steroid education and adolescents: do scare tactics work? Pediatrics 1991; 87(3):283-86.

45. Goldberg L Bosworth E, Bents R, Trevisan L. Effect of an anabolic steroid education program on knowledge and attitudes of high school football players. J Adolesc Health Care 1990; 11:210-14.

46. Perry HM, Wright D, Littlepage BN. Dying to be big: a review of anabolic steroid use. Br J Sports Med 1992; 26(4):259-61.

47. Greenberg G. Anabolic steroids in canadian university football: The player's perspective. (preliminary report and personal communication, 1989).

48. Hardie G. Pumping steroids. The Ottawa Citizen 1991; July 3:B4-B5. (and personal communication)

49. Swenson EJ, McKeag DB, Hough DO. Anabolic steroids: statewide survey of high school football coaches. Med Sci Sports Exercise 1988; 20(2):S24.

50. Krowchuk D. High school athletes and use of drugs to enhance performance. Am J Dis Child 1988; 142(4):385-86.

51. Duda M. Only 4% of athletes use steroids. Physician and Sportsmedicine Aug 85; 13(8):30.

52. Pope HG, Katz DL, Champoux R. Anabolic-androgenic steroid use among 1,010 college men. Physician and Sportsmedicine Jul 88; 16(7):75-81.

53. Whitehead R, Chillag S, Elliott D. Anabolic steroid use among adolescents in a rural state. J Fam Pract 1992 Oct;35(4):401-5.

54. Rickert VI, Pawlak-Morello C, Sheppard V, Jay SM. Human growth hormone: a new substance of abuse among adolescents? Clinical Pediatrics 1992; 31(12):723-26.

55. Killip SM, Stennett RG. Use of performance enhancing substances by London secondary school students. Board of Education for the City of London 1990.

56. Windsor R, Dumitru D. Prevalence of anabolic steroid use by male and female adolescents. Med Sci Sports Exerc 1989; 21(5):494-497.

57. Sudman S, Sirken MG, Cowan CD. Sampling rare and elusive populations. Science 1988; 240(20 May): 991-995.

58. Laporte RE. Assessing the human condition: capture-recapture techniques. British Medical Journal 1994; 308:5-6.

59. Watters JK, Biernacki P. Targeted sampling: options for the study of hidden populations. Social Problems 1989; 36(4): 416-430.

60. Bruno G, Laporte RE, Merletti F, Biggeri A, McCarty D, Pagano G. National diabetes programs: application of capture-recapture to count diabetes? Diabetes Care 1994; 17(6): 548-556.

61. Laporte RE, McCarty DJ, Tull ES, Tajima N. Counting birds, bees and NCD's. Lancet 1992; 339:494-95.

62. Biernacki P, Waldorf D. Snowball sampling: prblems and techniques of chain referral sampling. Sociological Methods and Research 1981; 10(2): 141-163.

63. Kaplan CD, Bieleman B, TenHouten WD. Are there "casual users" of cocaine? In: Cocaine: scientific and social dimensions. Ciba Foundation Symposium 1992; 166: 57-80.

64. Jelinek formula. In: Last J.(ed.) A Dictionary of Epidemiology. Oxford University Press 1983.

65. Miller GH, Agnew N. The Ledermann model of alcohol consumption. Description, implications and assessment. Q J Stud Alcohol 1974; 35(3): 877-98.

66. Christmas JT, Knisely JS, Dawson KS, Dinsmoor MJ, Weber SE, Schnoll SH. Comparison of questionnaire screening and urine toxicology for detection of pregnancy complicated by substance use. Obstet Gynecol 1992 Nov;80(5):750-4.

67. Dondero TJ, Pappaioanou M, Curran JW. Monitoring the levels and trends of HIV infection: the Public Health Services HIV surveillance program. Public Health Reports 1988; 103:213-220.

68. Federal Centre for AIDS Working Group on Anonymous Unlinked HIV Seroprevalence. Guidelines on ethical and legal considerations in anonymous unlinked HIV seroprevalence research. CMAJ 1990; 143(7):625-27.

69. Shimizu IM, Bonham GS. Randomized response technique in a national survey. Journal of the American Statistical Association 1978; 73(361):35-39.

70. Warner SL. Randomized response: a survey technique for eliminating evasive answer bias. Journal of the American Statistical Association 1965; 60(309):63-69.

71. Aquilino WS. Telephone versus face-to-face interviewing for household drug use surveys. Int J Addict 1992; 27(1):71-91.

72. Weeks M, Kulka R, Lessler J, Whitmore R. Personal versus telephone surveys for collecting household health data at the local level. AJPH 1983; 73(12):1389-1394.

73. Aneshensel C, Frerichs R, Clark V, Yokopenic P. Telephone versus in-person surveys of community health status. AJPH 1982; 72(9):1017-1021.

74. Pless R, Glavin V. Immunization coverage of children by age two, and attitudes towards immunization of parents in Canada, 1993. Division of Childhood Immunization, Laboratory Centre for Disease Control, Health Canada 1993.

75. Williams C, Eng A, Botvin G, Hill P, Wynder E. Validation of students' self-reported cigarette smoking status with plasma cotinine levels. AJPH 1979; 69(12):1272-1274.

76. Melton G. Ethical and legal issues in research and intervention. Journal of Adolescent Health Care 1989; 10:36S-44S.

77. Bankowski Z, Bryant JH, Last JM. Ethics and epidemiology: international guidelines. Proceedings of the XXVth CIOMS Conference, Geneva, Switzerland. World Health Organization 1991; Geneva.

78 Beauchamp TL, Childress JF. Principles of biomedical ethics, Second Edition. Oxford University Press, New York, 1983.

79. Last J. An ethical framework for epidemiology. Paper presented at the Third International Congress on Ethics in Medicine, Stockholm, Sweden, September 15, 1989.

80. Sharpe G. The Law and Medicine in Canada. Butterworths, Toronto, 1987

81. Ministry of Health, Ontario. Consent to Treatment: A guide to the Act. Queen's Printer for Canada, August 1994.

82. Severson H, Biglan A. Rationale for the use of passive consent in smoking prevention research: politics, policy, and pragmatics. Preventive Medicine 1989; 18:267-279.

83. Siemiatycki J. A comparison of mail, telephone and home interview strategies for household health surveys. AJPH 1979; 69(3):238-245.

84. Broome ME, Stieglitz KA. The consent process and children. Res Nurs Health 1992 Apr;15(2):147-52.

85. Porter JP. Regulatory considerations when children are involved as subjects in research. J Sch Health 1985 May;55(5):175-8.

86. Working Party on Ethics of Research in Children. Guidelines to aid ethical committees considering research involving children. Archives of Disease in Childhood 1980; 55:75-77.

87. Janofsky J, Starfield B. Assessment of risk in research on children. Journal of Pediatrics 1981; 98(5):842-846.

88. Social Sciences and Humanities Research Council. Ethics guidelines - research with human subjects. Annex H in Research grants guide for applicants. Ottawa: July 1986.

89. Task Force on Research Involving Children. Report on research involving children. NCBHR Communiqué 1993; 4(1):8-11.

90. Council for International Organizations of Medical Sciences. International Ethical Guidelines for Biomedical Research Involving Human Subjects. CIOMS, Geneva, 1993.

91. Feldman W, Hodgson C, Corber S, Quinn A. Health concerns and health-related behaviours of adolescents. CMAJ 1987; 134:489-93.

92. McMillan S. Study on AIDS and elementary school children. Ottawa-Carleton Health Department, personal communication.

93. King A, Beazley R, Warren W, Hankins C, Robertson A, Radford J. Canada youth and AIDS study. Queen's University Press 1988.

94. Severson H, Ary D. Sampling bias due to consent procedures with adolescents. Addictive Behaviors 1983; 8:433-437.

95. Kearney K, Hopkins R, Mauss A, Weisheit R. Sample bias resulting from a requirement for written parental consent. Public Opinion Quarterly 1983; 47:96-102.

96. Hildahl W. Proposed study of anabolic steroids at the high school level. Board of Education, City of Winnipeg, personal communication.

97. Lewis C, Lewis M, Ifekwunigue M. Informed consent by children and participation in an influenza vaccine trial. AJPH 1978; 68(11):1079-1082.

98. Weithorn L, Campbell S. The competency of children and adolescents to make informed treatment decisions. Child Development 1982; 53:1589-1598.

99. Bonyun R. Survey of drug use in an Ottawa Board high school, January 1981. Ottawa Board of Education, Research Centre 1981; Report 81-11.

APPENDICES:

MATERIALS SUPPORTING THE SURVEY

Appendix A LAY ABSTRACT

A Survey of Anabolic Steroid Use: Project Objectives

Anabolic steroids are synthetic versions of the male hormone testosterone, which is responsible for the development of male sex characteristics during puberty and also plays a part in building proteins like those found in muscle tissues. Doctors rarely prescribe anabolic steroids, their medical use is limited to some rare hormone disorders and sometimes to help recovery after starvation.

They have gained notoriety in recent months as drugs of abuse in athletic competition, particularly since Ben Johnson was disqualified during the Olympic Games in Seoul when he tested positive for a banned steroid after finishing first in the 100m run. Surveys of college athletes are finding that the use of steroids in that age group lies around 5-10%, with a suspicion that the figure is much higher. This "non-medical" use of anabolic steroids carries with it potentially serious side effects. These side effects can be worse in the young athlete, but paradoxically we know much less about their use among teenagers.

The purpose of this study is to quantify anabolic steroid use at the high school level by surveying students in selected schools in the four boards of education in Ottawa/Carleton regarding their knowledge, attitudes and use of anabolic steroids. The students will be asked to complete a questionnaire anonymously using a computer coding form accompanying it.

Determining the extent of steroid use and the accompanying level of knowledge about their side effects is crucial in order to properly target intervention efforts and start dealing with what seems to be growing as a major health problem among our young people.

Appendix B **BUDGET (from an original proposal for 3500 subjects)**

Personnel Services			
	/hr	#hrs	Total
Principal investigator	$0.00		
Co-investigators	$0.00		
Consultations	$0.00		
Research Assistant (includes benefits at 15%)	$14.00	120	$1,932.00
Fieldwork and Travel			
	/event	#events	Total
School visits	$8.00	12	$96.00
Conference travel			$750.00
Visits to other centres			$500.00
Presentation supplies			$250.00
Telecommunications			$150.00
Survey supplies			
	/set	#sets	Total
Questionnaires	$0.35	3500	$1,225.00
Envelopes + instructions	$0.17	150	$25.50
Machine coding forms	$0.10	3500	$350.00
Consent forms	$0.18	7000	$1,260.00
Mailing of forms	$0.38	2x7000	$5,320.00
Pencils	$0.02	3500	$70.00
Reprints			$350.00
Data Analysis			
Computer time			$0.00
Consultations			$0.00
			=========
			$12,278.50

BUDGET JUSTIFICATION

The bulk of the cost will be for reproduction of the questionnaires and consent forms, and the scoring sheets, and mailing of the consent forms. No consultation fees will be incurred as one of the co-investigators (RP) is externally funded and has informal consult privileges within his department.

Similarly, there is access to mainframe computer time at no cost. However, due to the planned sample size and breadth of school visits, a research assistant will likely be required to assist with questionnaire packaging, delivery and coding of response rates following the survey. It is estimated that total involvement with each school will be approximately 5 hours.

Costs for visits to other centres and telecommunications will be required as collaboration on the survey design is being undertaken with a group doing a similar study in Winnipeg.

As one of the co-investigators and/or the research assistant will be visiting each school, travel and parking costs have been estimated at $8.00 per visit on average, based on mileage to the schools in the Ottawa/Carleton region.

Presentation supplies are needed to prepare talks to student and teacher groups concerning the survey when soliciting their assistance.

Appendix C PROPOSED TIME FRAME

Planned to cover a school year, with funding proposal and approvals in the fall, consent mailings during the winter, and the survey conducted in the late spring.

3 MONTHS:	Application for funding by CHEO Research Institute. Approval from school principals and preliminary discussions about the survey methodology.
5 MONTHS:	Reproduction and packaging of survey forms, preparation of seminars and talks for students and teachers about the survey.
	Presentations to teachers, recruitment of students (class representatives) and final planning and implementation of the survey in schools.
	Data coding and preliminary analysis. Follow-up discussions with the School Board and principals about the completed survey and presentation of preliminary results.

Appendix D **SURVEY INSTRUMENT**

SURVEY OF ANABOLIC STEROID KNOWLEDGE, ATTITUDES AND PREVALENCE.

(COVER SHEET)

SURVEY ON ANABOLIC STEROIDS

MARK ONE ANSWER FOR EACH QUESTION ON THE COMPUTER CARD.

PLEASE READ THROUGH EACH POSSIBLE ANSWER BEFORE CHOOSING ONE -THERE SHOULD BE A POSSIBLE ANSWER FOR EVERYONE. IF YOU ARE UNSURE OF WHICH ANSWER TO PICK, CHOOSE THE BEST ONE YOU CAN.

PLEASE DON'T LEAVE ANY QUESTION BLANK, AND REMEMBER, THIS SURVEY IS ANONYMOUS SO DON'T PUT YOUR NAME ON THE ANSWER CARD OR ON THE QUESTIONNAIRE.

1. I am now in grade...
   A. 9
   B. 10
   C. 11
   D. 12

2. My age right now is...
   A. 14 or younger
   B. 15
   C. 16
   D. 17
   E. 18 or older

3. I am...
   A. Male
   B. Female

4. Which one of the following best describes the kind of SCHOOL sports you are doing during this year?
   A. I take gym (Phys Ed) class only.
   B. I take part in a school sport (eg. intramural, varsity).
   C. I take gym AND participate in a school sport.
   D. I'm not taking gym class and don't play a school sport.

5. Which one of the following best describes the kind of regular sports you do OUTSIDE of school?
   A. I do a sport for recreation (not competition).
   B. I am involved with a sport on a team or with a coach.
   C. I am involved with both types of sports.
   D. I am NOT involved with any sport outside school.

6. How often do you participate in some form of sports or physical activity?
   A. Very little or not at all.
   B. A few times a month.
   C. About once a week.
   D. About twice a week.
   E. More than twice a week.

------- IN THE NEXT SECTION, DESCRIBE THE SPECIFIC SPORT ACTIVITY YOU ARE MOST INVOLVED WITH, IN OR OUT OF SCHOOL.

For each sport or sports listed below, mark:

A. I do one of these sports competitively (I train for it).
B. I do one of these sports for recreation regularly (at least once a week).
C. I do one of these sports occasionally (less than once a week).
or D. I don't participate in one of these sports.

7. football or rugby
8. soccer or field hockey or ice hockey
9. a field event (high jump, discus, vault, shot put,...)
10. basketball or volleyball
11. swimming and/or water polo
12. racquet sports (tennis, squash, badminton,...)
13. gymnastics, figure skating
14. downhill or cross country skiing
15. jogging/running, aerobics or dance, speed skating
16. weights (lifting, bodybuilding or for general fitness)

---------- END OF SECTION

17. Whether or not you use them, where did you first hear about anabolic steroids and their use in sports...
    A. I've never heard of steroids before
    B. From my doctor
    C. From a friend, family or someone at the gym club.
    D. From my sports coach or teacher.
    E. From newspapers/radio/TV/a magazine

18. I think that if someone takes steroids, he or she...
    A. will for sure become stronger and look more muscular
    B. has a good chance of becoming stronger or more muscular
    C. might get stronger and more muscular.
    D. won't change much, steroids really don't work.
    E. I'm not sure what would happen.

19. I think that if someone takes steroids, he or she...
    A. is taking medical risks and will probably get sick either when they start taking them or later on.
    B. might get sick when they start or later on.
    C. Is not likely to have side effects (get sick from them).
    D. I'm not sure what would happen.

20. I think the number of high school students who are taking steroids is about...
    A. less than 5%
    B. 5 to 10%
    C. 10 to 25%
    D. more than 25%
    E. I really don't know

21. Among my friends, at my school, or at my sports club,
    A. I know someone who I think might be using steroids.
    B. I know someone who definitely uses steroids.
    C. I know many who are using steroids.
    D. I don't know anyone who uses or might be using steroids.

22. Whether or not you use steroids, did you get the urge to take or think of taking any MAINLY...
   A. Because a friend told you about them.
   B. Because you got some from a doctor
   C. Because a coach told you to take some for sports.
   D. Because you heard or read something good about steroids.
   E. You never got the urge to take any.

23. I am taking steroids (or I used to take them), or I'm thinking of starting to use them because..
   A. I want them to help me with my sports training.
   B. I want them to make me look more muscular.
   C. I want to look more muscular AND help with my training.
   D. I don't plan to take steroids.
   E. I want to learn more about them before I decide whether to start taking them or not.

24. I tried steroids for the FIRST time...
   A. within the past 6 months.
   B. about a year ago.
   C. about 2 years ago.
   D. more than 2 years ago.
   E. I never took steroids before.

25. Whether or not you take steroids, do you think the advantages of taking them (for example if they could help you win in sports or look better) outweigh the disadvantages (for example getting caught, maybe feeling sick)...
   A. The advantages strongly outweigh the disadvantages.
   B. The advantages do outweigh the disadvantages.
   C. The advantages do not outweigh the disadvantages.
   D. There are no advantages, they don't work or should not be used.
   E. I don't know.

26. If no one could find out that you took steroids, you would...
   A. think about taking steroids.
   B. definitely take steroids.
   C. continue taking steroids.
   D. still not take steroids.
   E. I'm not sure what I would do.

27. I've been using anabolic steroids regularly for ABOUT...
   A. a few weeks
   B. a few months
   C. a year
   D. 2 years
   E. I don't use steroids.

28. I quit taking steroids or don't want to take any MOSTLY because
   A. I heard they can be bad for you.
   B. I don't think they work (or they didn't work for me).
   C. Taking steroids is not natural.
   D. None of the above (or I plan to start or I don't plan to stop using them)

29. I got my steroids mostly from
   A. A friend or someone at a gym or sports club.
   B. A coach or teacher.
   C. A pharmacist, veterinarian or doctor
   D. By mail order or "off the street"
   E. A source not listed (or I never got any steroids).

30. If you wanted to take anabolic steroids, would you know where to get some?
   A. Yes, easily
   B. I'd have to ask around but it should not be a problem.
   C. I would not know how to get some.

31. Whether or not you take steroids, do you drink alcohol?
   A. once in awhile or rarely
   B. almost every week, usually on weekends
   C. almost every week, both weekends and weekdays
   D. almost every day.
   E. I don't drink alcohol

32. Even though you have been assured that your answers concerning your use of steroids cannot be traced back to you, are you concerned that they might be?
   A. No
   B. Yes
   C. I don't know.

33. Whether or not you have ever taken steroids, is there a reason you might not be able tell the truth about it.
   A. No
   B. Yes
   C. I don't know

THANKS FOR TAKING PART !

Appendix E LIST OF SUPPLIES FOR THE SURVEY

	Number of copies
1. School coordinator cover letter	10
2. Coordinator instructions	10
3. Class teacher letter	80
4. Teacher instructions	80
5. Questionnaires	80x20
6. Coding forms (?)	80x20
7. Questionnaire/coding form return envelope	80
8. Outer envelope for class package	80
9. Outer envelope for school package	10

Appendix F SURVEY INSTRUCTIONS

SURVEY ABOUT ANABOLIC STEROIDS
SCHOOL COORDINATOR INSTRUCTIONS

A number of classes in your school have been randomly selected to participate in an anonymous survey on anabolic steroids. The survey is to be administered the week of June 4, 1990 at the beginning of each of the selected classes.

Please review the instructions below, as well as the teacher instructions. If you have any questions, please contact Dr. Robert Pless, Pediatric Research, Children's Hospital of Eastern Ontario (737-2510) for clarification.

(A) The package should contain:

(1) A set of envelopes, labelled with a period 1 class and teacher. Each envelope contains questionnaires for the class and an instruction sheet for the teacher, as well as a class list with the names of participating students highlighted.

(2) A copy of the teacher instruction sheet for your reference.

(3) A list of classes to be surveyed

(B) Please distribute the packages to the appropriate teachers on the week of June 4, 1990, and contact them to ensure that all is in order for administration.

(C) Please arrange with the main office to accept delivery of the sealed return envelopes which will contain the completed surveys.

(D) Please check to ensure that the main office received a sealed envelope from each of the participating classes and bundle them together into one package.

(E) The complete package of returns will be picked up from the main office on the afternoon of June 8 by one of the project organizers.

SURVEY ABOUT ANABOLIC STEROIDS
TEACHER INSTRUCTIONS

Your class has been randomly selected to participate in a survey on anabolic steroids. The questionnaires are to be administered at your convenience on the week of June 4, 1990 during your first period class.

Prior to the administration of this survey, please read the complete instructions below. If you have any questions, please contact the person coordinating the survey in your school or Dr. Robert Pless, Pediatric Research, Children's Hospital of Eastern Ontario (737-2510).
To administer this survey, please follow these guidelines:

(A) The questionnaires should be administered ONLY to those students whose names are highlighted on the class list. They have been given written permission by their parents to participate.

(B) The survey will take approximately 15 minutes to complete. Please try to ensure that students have as much quiet and privacy as possible when completing the survey and that no discussion occurs.

(C) Students may use pen or pencil to record their responses directly onto the survey. The enclosed envelope is provided so that surveys can be returned in it.

(D) Please read the comments on the "Instructions to students" as they appear without additional comment.

(E) Distribute the surveys to the students highlighted on the list.

(F) If a student has difficulty with the meaning of a word you may define it for him/her. However, do not answer questions for them or suggest responses. When in doubt ask students to complete the item in the best way he/she can.

(G) When all students have completed the survey, have the students pass the envelope from student to student and deposit their own survey inside.

(H) When all surveys are deposited, appoint a student to seal the envelope and deliver it to the main office. The office should be expecting it.

(I) Please thank the students.

SURVEY ABOUT ANABOLIC STEROIDS
INSTRUCTIONS TO STUDENTS

I'm going to be handing out a survey questionnaire about steroid drugs, the kind of drug that Ben Johnson and other athletes took. Since this survey is being run in many classes at this school, and in most of the high schools around Ottawa, these instructions were prepared so that everyone will have the same information before starting.

Remember that your answers to the survey are anonymous and confidential so don't write your name on the questionnaire.

Wait until everyone has a copy before getting started and carefully read the directions at the top of the first page.

When you are finished, turn over your questionnaire so no one can see it and wait for me to pick them up. I'll keep them face down and put them back in the large envelope. When I've got them all, I'll seal it.

Answer all questions as best you can. Even if you think the question does not apply to you, there will be an answer you can mark down. This way, everyone should finish at about the same time. If you do not have consent from your parent or guardian to complete this survey, or do not wish to participate, then leave the questionnaire blank.

Thanks for taking part!

Appendix G CONSENT FORM AND LETTER TO PARENTS

March 1, 1990

Dear parent or guardian,

In recent months there has been a growing concern about the use of anabolic steroids in athletic competition. They have been in the news especially since Ben Johnson was disqualified at the Olympics for using them. Most of the attention so far has been centred around world class athletes.

More recently, studies are showing that even teenagers who do not participate in sports are using steroids just to help them look better because of the drug's ability to help build muscle tissue. The use of steroids carries side effects. A lot of effort is going into devising testing methods to catch the steroid users, but very little effort is being spent to prevent their use in the first place.

The problem is that nobody really knows when steroid use starts, so nobody knows when to start taking preventive action. The Advisory Research Committee of the Board of Education has approved a survey of steroid use among high school students to determine the extent of the problem, if any, among Ottawa area teenagers.

With your approval, your son or daughter may be asked along with his or her classmates to anonymously complete a short questionnaire about his or her knowledge and attitudes towards steroid drug use. The answers to the questionnaire will be kept strictly confidential. No information will be obtained from any school records. The survey forms will be distributed by one of your son or daughter's teachers or a designated student during a class period and should only take about 10 minutes to complete with very little interference with classroom activities.

Because we require your consent for your child to participate, we ask that you fill out the permission slip on the next page and return it. Your reply will have no bearing whatsoever on your child's education.

The results of this survey are very important to us. By asking high school students what they know about steroids, where they get information about them and what they do with the information, we can get an idea of the extent and nature of the problem of steroid use among teenagers. Only then will we be closer to finding ways of reducing this emerging health risk to our children.

Thank you in advance for your assistance with this survey. If you have any questions at all about it, please do not hesitate to call me during the day at the University of Ottawa, department of Community Medicine (tel: 737-6480). If I am not immediately available, please leave a message and I will be pleased to return your call.

Sincerely,

Robert Pless, M.D.
University of Ottawa
Department of Epidemiology and Community Medicine

PLEASE COMPLETE AND RETURN THIS SECTION TO THE SCHOOL:

CONSENT FOR HIGH SCHOOL STEROID SURVEY

I have read and understood the request for my child to participate in the survey of steroid use among Ottawa teenagers. I understand that he or she may or may not be asked to fill out a questionnaire but that my signing this form requesting consent should my child be asked to participate is important for the research.

____ I give permission for my child to participate.

____ I do not give permission for my child to participate.

NAME OF STUDENT:

_____

SIGNATURE OF
PARENT OR GUARDIAN: _____

DATE: _____