This lecture addresses, in more detail, the process that injury epidemiologists undertake to understand the risk factors involved in injuries. It builds upon the injury surveillance lecture and discusses the distinction between descriptive types of studies and analytic studies.
Learning objective

- To differentiate between various study designs used in injury epidemiology
Background

- Epidemiology looks to control or prevent disease
- In this endeavor, epidemiology seeks to
  - describe the frequency of disease and its distribution
    - consider person, place, time factors
  - assess determinants of disease
    - consider host, agent, environment

To provide context to the understanding of study designs used in injury research, it is important to take a step back to review what the studies are intended to accomplish. The broad goal of injury epidemiology is the same as that in epidemiology in general; to reduce the frequency and burden of injuries. This is done by first gaining an understanding of the frequency of the injury and its distribution in the population by person, place and time factors. Investigations into the determinants of injury, then, focus on the inter-relationships between the host, agent (energy transfer), and the environment.
Types of primary studies

- Descriptive studies
  - describe occurrence of outcome

- Analytic studies
  - describe association between exposure and outcome

Epidemiologic studies have two forms; descriptive and analytic. They serve different purposes as outlined here. Also, descriptive studies generally precede analytic studies in the logical order of understanding.
Basic Question in Analytic Epidemiology

Are exposure and disease linked?

Analytic studies test the relationship between exposure and disease, or in this course, between exposure and injury.
Big Picture

- To prevent and control disease
- In a coordinated plan, look to
  - identify hypotheses on what is related to disease and may be causing it
  - formally test these hypotheses
- Study designs direct how the investigation is conducted

In epidemiology, the coordinated plan is to first identify the frequency of disease and its distribution in the population. This information comes from descriptive studies. This information also highlights potential hypotheses to explore in future analytic studies.

Analytic studies formally test these hypotheses.
Thus, the basis for this lecture is to highlight the distinction between descriptive epidemiology and analytic epidemiology in the field of injuries. Descriptive epidemiology seeks to measure the frequency in which injuries occur or collect descriptive data on possible causal factors. Analytic epidemiology “attempts to specify in more detail the causes of injury” (Robertson, 1992).

Studies in both areas are necessary for the development of appropriate injury control programs. The public health model outlined here illustrates how the two disciplines work together for controlling injuries. Injury control comes about from a good understanding of both the frequency in which the events occur (through surveillance), but also the risk factors that lie behind their occurrence (through analytic epidemiologic studies).

One caution, however, is that the success of several previous injury control measures have led many individuals to espouse control measures in areas where we do not have appropriate measures for incidence or the causal factors behind the injury occurrence.
What designs exist to identify and investigate factors in injuries?
As Koepsell has illustrated in the book, “Injury Control”, several types of study designs may be applied in injury research. Injury studies may be descriptive in nature (describing the frequency or characteristics of injury events) or analytic (testing relationships between common traits and injury). Differing forms of descriptive studies exist. These designs are outlined in the next slide.

Analytic studies include experimental designs (the randomized controlled trial) and observational designs (case-control studies, cohort studies, etc.). The case-crossover study design has received a lot of attention in the injury field in the last five years.
Our understanding of the causes of disease generally evolves over time. Successive studies answer research questions that were not answered previously.

This slide illustrates how epidemiologic knowledge progresses through repeated and successive studies of the same outcome. These studies take advantage of the temporal nature of the cause-effect relation (i.e., Causes precede Effects). As one moves from left to right on the x-axis, our knowledge about the causes for a disease or injury increases.

Case Series report new diseases or injuries. They may provide some descriptive data on exposures to potential causal factors. Sentinel event surveillance systems fall here.

Cross-Sectional Studies measure existing disease and current exposure levels. They provide some indication of the relationship between injury and exposure or non-exposure.

Case-Control Studies identify existing injuries and look back in previous years to identify previous exposures to causal factors. Cases are those who are injured. Controls are those with no injuries. Analyses examine if exposure levels are different between the groups.

Cohort Studies identify existing exposure levels and track disease as it occurs over time. Analyses examine if persons who are exposed to a possible causal factor are injured more frequently than those who are not exposed.
To further illustrate, if one seeks to identify the etiologic factors (e.g. causal factors) behind an outcome (e.g. an injury), then each step in the epidemiologic framework provides new and important information.

Descriptive studies are useful for identifying hypotheses to test in analytic studies. Case-control studies are then usually applied to evaluate if the hypothesized factor is related to the outcome of interest. Subsequently, cohort or longitudinal studies are applied to further define the importance of exposure to the causal agent for the development of the outcome.
Descriptive Studies
Most descriptive studies in the injury field are centered around the information available from injury surveillance systems. These systems are generally designed to identify the frequency of existing injuries through a systematic review. They may also provide some information on the possible causes for the injury, but they are not designed to measure exposure information. By design, they identify persons who are injured. An adequate assessment of risk factors, though, requires the use of a control group (those who are not injured).
This paper on fireworks injuries is based upon a review of injuries identified in an emergency department from 1972-1993. It concluded that injuries from fireworks were a meaningful burden; affecting 316 children. It also found common traits to those who presented with injuries from these devices. These traits included the time of the event (primarily from June 22 to July 14), male gender, and injuries to the eyes from bottle rockets. These findings provide an indication of hypotheses to explore in future studies, such as the association between type of explosive and the site of the injury. An analytic study is necessary to investigate this in more detail.
Whether you are undertaking a descriptive study or an analytic study, it is important to recognize that injuries can be identified from a number of data sources. Several of these sites are outlined here.

The most appropriate data source(s) to use to identify or study a specific injury will depend upon several factors, such as the type of injury that you want to study, its relative level of severity, and the amount of resources that you have available. Generally, an investigator will want to have a comprehensive assessment of injuries. That is, the investigator will want to capture as many of the injury events as possible. A study of injury deaths, for example, may want to review hospital records, coroner’s office records, and death certificates to identify events. Reviewing only one of the sources may exclude a number of events.

Most injury studies are based upon events identified from medical records. They depend, to a large degree, upon the presence of E-codes for their injury ascertainment.
Data Sources and Injury Severity

<table>
<thead>
<tr>
<th>No injury</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Fatal</th>
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<td>Survey</td>
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<td>Doctor visit</td>
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<td>Trauma center</td>
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<td>Death certificate</td>
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Rogams, 1995

The most appropriate source to identify and study injuries may also depend to some extent upon the severity of injury that you want to identify. If you want to evaluate or study injury deaths, appropriate surveillance or study designs would be based upon a review of death certificates and coroner’s records, and not surveys. On the other hand if you want to identify or study self-treated injuries, then surveys are more appropriate, and a review of hospital records would be inappropriate.

Consider also that surveys provide information on people who have not been injured. Thus, giving you some assessment of exposure data. This is an important component of analytic designs.
Descriptive study designs include case reports, case series, incidence studies, and ecologic studies. The case report is the most elementary study design in the literature. It generally describes an injury or injuries to one or two individuals that have been identified in a medical setting. There is also usually a unique feature to the noted injury (by cause, by nature of injury, etc.). The case series design is an extension of the case report. In a case series, a number of events are described. These events usually have been observed over a set period of time (such as one year) and are identified from one reporting source (e.g. a hospital).

The descriptive epidemiology study is noted by the collection of injuries over a defined population base and by the use of denominator data to determine rates. The most frequent information generated from these designs are incidence rates for injuries.
Causes of Death in Travelers

- Cardiovascular
- Injury
- Cancer
- Suicide/Homicide
- Medical
- Other

An example of an injury study based upon death certificate evaluation is shown here. A review of deaths among overseas travelers by Hargarten found that unintentional injuries (22%) and intentional injuries (suicide/homicide) represent nearly one quarter of the total deaths.

Here is an example of a descriptive epidemiology study.

Scooters are one in a series of fads in the United States. What injury risks do they carry? This paper examines scooter-related injuries from 1998-2000 to highlight this issue. It provides an estimate of all injuries in the United States. The study design is of a descriptive epidemiology format. However, no population estimates are gathered. In other words, the authors have gathered numerator data, but not denominator data. No measures of exposure have been gathered. Thus, an assessment of injury is not possible.

The study examines data in the NEISS and IPII files of the Consumer Product Safety Commission. This allows for the determination of whether a scooter was involved or not. All of the other injury surveillance systems do not gather this type of information. It would be very difficult to obtain from a medical records system. The definition of injury used in the study is not stated. In NEISS methods, though, injury visits to emergency departments are abstracted. As NEISS is based upon ED visits, the severity of injury assigned is moderate to severe. Scrapes and cuts from scooter crashes are not going to be included here. The NEISS methods also sample hospitals throughout the U.S. to allow for population estimates.

The study reports that scooter related injuries increased from a few hundred in 1998 and 1999 to 27,600 in 2000. Potential bias might exist in the form of under-reporting of scooter events in the medical system.

Source: Anonymous. Unpowered Scooter-Related Injuries-United States, 1998-
2000. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4949a2.htm
To fully understand the causal factors behind injuries, it is important to move beyond descriptive studies and develop analytic studies.
A beautiful illustration of the reason for undertaking analytic studies is available in Chapter 1 of the book, “Epidemiology for the Uninitiated”. The authors provide the following example, “A study, based on a survey of hang gliding accidents, recommended that flying should be banned between 11 am and 3 pm, because this was the time when 73% of the accidents occurred.”

Conclusions from studies based upon descriptive data face an common epidemiologic problem. Namely, they only provide information on the numerator (the number of injuries) and little information on the denominator (the population at risk). In the example above, it is not correct to assume crashes are a problem from 11 am to 3 pm without first understanding the times and frequency in which all pilots (including those who do not crash) operate hang gliders. The number of hang glider accident cases was not related to the appropriate "at risk" population. Analytic epidemiologic studies focus on identifying causal factors for injuries from the population at risk. The population at risk includes persons who are injured and persons who are not injured.

What is Epidemiology?

Epidemiology for the Uninitiated
Case-Control Studies

Cases: injured
Controls: not injured

Case-Control studies represent one form of analytic study that provides information on the relationship between causal factors and injuries. In a case-control study, subjects who have been injured are identified and their past exposure to suspected causal factors is compared with that of controls (persons who have not been injured).

Many case-control studies ascertain exposure from personal recall, using either a self administered questionnaire or an interview. The validity of such information will depend in part on the subject matter. People may be able to remember recent events quite well. On the other hand, long term recall is generally less reliable.

Source: Chapter 8: Case-control and cross-sectional studies, Epidemiology for the Uninitiated
An example of a case-control study investigating blood alcohol concentration and the risk of fatal pedestrian injury is shown here. The research question underlying the study design is, “How do exposures to alcohol among cases compare with the exposures to alcohol in the population?”

The table shows with numbers and percentages the simplest way to express the difference in exposure between cases and controls. The controls in this study were chosen by selecting pedestrians similar in age and gender to the cases. The controls were also similar to the cases in that they were walking near the same intersection in Manhattan, and at the same time of day as the cases were when they were struck by a motor vehicle.

The data show a clear association between blood alcohol concentration and fatal pedestrian injury. One may collapse the categories above and say that the odds of a fatal injury are about four times higher with 50 mg% or more BAC compared with a BAC of less than 50 mg%, with a 95% confidence interval of 1.5 to 12.8.

Source: Haddon, 1961
Cohort or longitudinal studies represent another form of analytic study that provides information on the relationship between causal factors and injuries. In a cohort study, subjects with an exposure to a causal factor are identified and the incidence of injury over time is compared with that of controls (persons who do not have the exposure). In a longitudinal study, subjects are followed over time with continuous or repeated monitoring of risk factors or health outcomes, or both.

One issue to consider in cohort studies is the frequency in which the outcome occurs. Cohort studies are usually not appropriate when the outcome is a rare event. The study subjects would have to be followed up for long periods before sufficient cases accrue to give statistically meaningful results.

Source: Chapter 7: Longitudinal Studies, Epidemiology for the Uninitiated
An example of a cohort study investigating the risk factors for sports-related injuries is shown on the next few slides. Exercise and sports participation is a leading cause of injury, particularly among adolescents. The aim of this study were to determine the incidence and risk of sports injuries in adolescents and to determine the risk associated with exposure to physical activity.
Limitations of Existing Studies

- Do not take into account the injury risk among non-participants, cannot determine the relative risk of sports participation
- Do not quantify the “exposure” or the “dose” of activity, do not know the risk of injury per “activity hour”

There are relatively few research studies investigating the link between physical activity and injury. In previous reports, investigators have focused on the incidence of injuries among specific athletes, such as runners or football players. This approach does not examine the injury risk among non-participants. Therefore, we know little concerning the relative risk of sports participation.

Similarly, very few studies have attempted to quantify the “exposure” or the level of activity that a subject participates in. Thus, we know little about the injury risk per unit of exposure. In addition to the issue of “exposure”, other factors have not been addressed in sport injury research, such as How do we define a “serious injury”? What is the role of recreational sports participation? And what is the best surveillance system for less severe sports injuries?
The Adolescent Injury study was a population-based longitudinal study conducted in a single school district in Western Pennsylvania. The school district that participated in the study was chosen based upon the similarities of its demographics to that of Allegheny County for racial, economic, and educational categories. Recruitment efforts targeted the population of junior high students (grades 7th-9th) in the school district. 89% agreed to participate in the project.

Baseline measures were collected by survey and testing at the beginning of the study to quantify the level of exposure to selected characteristics. These included the student’s medical history, socioeconomic indicators, physical fitness, physical activity, risk behavior assessment, and fine motor skills.
A surveillance system was established to record new injury events over the following 3 years. In this system, students were surveyed every 3 months for injuries during physical education class. Validation of all reported injuries was done by follow-up phone calls to a parent. The parents verified 92% of the injuries. Following parental verification, medical records were examined in a 25% random sample of injuries to assess the reliability of the information reported. Overall, the students reported the circumstances surrounding an injury with a very good degree of accuracy.
In any study, it is vitally important to have a standard definition for the selected endpoints of interest. In this study, an injury was defined as an event that resulted in bodily damage and required medical treatment by a general physician or a specialist, or treatment at an urgent care facility or emergency department, or required hospitalization. A severe injury was defined as an injury that required care at an emergency department or by a specialist within 24 hours of symptoms, and resulted in restricted physical activity.
Overall, about 13-15% of the young men and women survey reported medically-treated injuries in the 3 year period. The non-sport injury rate was similar for all 4 race-gender subgroups of our population. Sports-related injuries were notably higher in the males and accounted for most of the significant ethnic differences observed in our cohort. Both male and female African Americans had significantly lower sports related injury rates compared to their white counterparts.

WM: White Male
NWM: Non-White Male
WF: White Female
NWF: Non-White Female
A strong dose response relationship was evident for male competitive sports participation. The greatest incidence of injuries occurred in those participating in competitive sports year round (3 or more sports). One could make the argument that it is not necessarily the participation in sports that is risky but rather the students who are engaged in sports year round may represent a unique group that is more susceptible to injury. If this were the case, one would have expected these students to also have higher rates of non-sport injuries. This was not true. Non-sport injury incidence remained fairly equal regardless of competitive sports participation.
An even stronger dose response relationship was seen for females, with those participating in sports year round having twice the risk for a sports injury than females involved in one sport a year. The injury risk for competitive females (year-round sports) was four times the risk of those not participating in any competitive sport. Further, females participating in sports year round had a similar sports injury rate as the males participating in sports year round, suggesting that when exposure balances out between genders, the risk of injury is similar. As in males, the non-sport injury incidence was nearly equal for all females.

This study was one of the first reports to highlight the magnitude of sports related injuries relative to non-sports related injuries. Competitive athletics carries with it, a rather large injury burden.

The authors of the study argue that current approaches to sports injury prevention (which focus on pre-sport screening, better training, and equipment improvements) ignore the strong influence of exposure (increased activity) on injuries.
If you are writing a grant to conduct a cohort study of injuries, you will need to demonstrate that you have sufficient sample size and statistical power to detect a difference between the alternatives in your hypothesis. This graph shows that the sample size needed for a cohort study depends upon, among other things, the percent of the cohort having the outcome of interest. If the injury under study occurs frequently, you will need fewer study participants. If the injury is rare, then you will need larger samples. For example, injury studies with people who do heavy manual materials handling (lots of low back pain) may need a smaller number of subjects than a study of office workers (relatively little low back pain). Where the outcome is very frequent, such as 30% of an elderly cohort falling over a six-month period, cohort studies become easier and less expensive to conduct.
I conclude the discussion of analytic studies with an emerging study design in the literature. The Case-Crossover epidemiologic design has just recently been applied to injury. This design is used to ask the following question: What unusual and transient exposure may have happened just before the occurrence of injury? It uses injured persons as their own controls, by comparing events that happen just prior to the injury to events that occurred in a previous time. The control period may be recent in time (minutes) or longer in time (months). The point is to look for events that occur just prior to the injury and compare these circumstances to what normally occurs. Since the controls in this design are “the cases”, this design limits the influence of confounding by factors that are different between people, such as age, gender, occupation, and perceptual motor skills.
Conclusions

- Descriptive studies are the most common approaches used today in injury research.
- Analytic designs are often difficult to conduct, but the yield in terms of new information can be great.