Before and After study designs are used very frequently in injury research. This lecture introduces the concept of before and after study methods, the use of this method in injury studies, and the limitations that lie within it. Upon completing the lecture, the reader should be able to:

1. Understand the methods that underlie before and after studies
2. Describe the application of before and after studies in the injury field
3. Understand the limitations of this form of analysis
Aims

• Recognize the role that before and after studies play in injury research
• Recognize strengths and weaknesses of before and after studies

There are two primary objectives to this lecture. They include (1) having the ability to recognize how and why before and after studies are used in injury research, and (2) recognizing the advantages and disadvantages of this methodologic approach.
As Koepsell has illustrated in the book, “Injury Control”, injury studies may be descriptive in nature (describing the frequency or characteristics of injury events) or analytic (testing relationships between exposures and injury to identify risk factors). Differing forms of analytic studies exist.

Analytic studies include experimental designs (the randomized controlled trial) and observational designs (case-control studies, cohort studies, etc.). The before and after study design is one form of analytic study.
Before-and-After Studies

• A “quasi-experimental” design that surveys exposures and disease status before and after an intervention

A before and after study measures exposures and disease issues at two time points. The first time point is before the initiation of an intervention or treatment. The second time point is after the intervention has begun. The goal of the design is to examine if the exposure/injury link has changed over time. In theory, this would be due to the intervention.

The point in time when the first measure (“before”) and the second measure (“after”) are taken varies by study. There is no standard rule on when this time point should be. It is not uncommon, though, to see time points that are 6 months, to 1 year before and after an intervention.
Before-and-After Study Design

• A quasi-experimental design in which there is a pretest and posttest, but no comparison group.

• Instead of comparing subjects who received treatment to those who did not, we compare subjects before and after they got the treatment (or compare time periods before and after the intervention).

In the before and after study, there is no external comparison group. In the classic application of the before and after design, an individual is tested before the treatment (pre-test) and then again after the treatment (post-test). Changes in values are compared within the individual over time, not between the individual and a control.

In the injury field, we may be testing behaviors (e.g. seat belt use) before an intervention and after an intervention.
Background

- Traditionally most interventions have been evaluated using a pre-test post-test or before and after design.
- Participants are tested treated and then tested again any improvements are attributable to the intervention.
- Currently this is probably the most POPULAR evaluative method in most fields.

David Torgerson

Before and After Studies are very popular in research (though not in epidemiologic research). They are been used in many clinical studies to evaluate the impacts of treatments.
Before-and-After Study Design

• Advantage:
  – overcomes ethical concerns with randomized designs
  – Low cost, convenience, simplicity

• Disadvantage:
  – weaker than RCT with respect to establishing a cause and effect relationship between the exposure and the disease

The major reason for the popularity of before and after study designs is the low cost, convenience and simplicity in conducting the studies. In the injury area, another advantage of this design is its usefulness in addressing the ethical issues that may come up with randomized studies or prospective cohort designs. Consider the ethics of exposure to alcohol. Several studies in this area are not possible because the risk-benefit ratio in the studies are not acceptable.

The main disadvantage of before and after designs is the lack of a comparison or control group. This limits the value of information obtained on the exposure-injury link. Without a control group, it is difficult to establish the cause and effect relationship between the exposure and an injury. As we will outline later in the lecture, there are two major problems that arise in this light.
Before and After Studies

Two approaches are used in the literature

• Individual level data
  – Surveys of individual research subjects

• Group level data
  – A widely applied design for injury prevention policy evaluation

If you examine the literature, you will notice two approaches used in the application of before and after studies in injury. The first approach considers individual level data (information on specific individuals taken before and after an intervention). The second approach is an ecologic approach. It considers group level data and how this information changes before and after an intervention.

The classic example of the group level before and after design is the evaluation of the impact of many injury prevention policies. Changes in laws or regulations have been evaluated with this design.
Here is one example of data originating from a group-level before and after study. This study examined the impact of the change in drinking age policy requiring all states to have a legal drinking age of 21 years.

The green line examines the change in alcohol related fatalities over time. It illustrates that these fatalities (in absolute numbers) have declined by 56% from a period before the change (1982) to the period after the change (2002). In contrast, non-alcohol fatalities have increased.

Why did this study include fatalities that were not related to alcohol?
Before-and-After Group Data Example

- Evaluating a bicycle helmet law
  - A new law goes into effect in 2000. How do we evaluate it’s effect?
  - Could look at number of bicycle head injuries before and after the law

Here is another example. If a bicycle helmet law was introduced in the year 2000, how would you assess it’s impact. One method would be to pick a point in time before 2000 and compare this to a similar point after 2000. Another approach would be to pick a period of years before 2000 and compare this to a similar number of years after 2000. What differences would exist in these two approaches?

n.b. the data likely illustrate head injury numbers over time.
How do we know if the rate of bicycle head injuries would not have gone down anyway, even without the new law?

A key point that originates in every before and after study, is if the study is observing the impact of the intervention, or may simply be observing changes that would have taken place in any event (with or without the intervention).

This point illustrates one of the major issues in before and after studies. They do not take into account temporal changes. These are changes that are taking place independent of the intervention.
Problems with Before and After Designs

• Problems include:
  – Identifying individuals to test
  – Temporal changes;
  – Regression to the mean.

This slide highlights the major issues that affect most before and after studies. We have illustrated in the slides before the impact of temporal change. If alcohol consumption is declining in the population due to social changes, how can you determine how a change in the legal age of alcohol affects motor vehicle crashes?

Other problems in before and after studies include the individuals selected for study (most are not representative of the general population), and regression to the mean.
Questions to ask

• Did the study identify a representative sample of individuals to test at points before and after the intervention? Did they test the same persons before and after the intervention?

• Are there any identifiable time trends (apart from the intervention) which are likely to distort the results? Can these be measured and adjusted for?

When examining before and after studies, one should consider the following questions in assessing the strength of the study. In addition, you will want to examine the data sources used in the study and the measurement instruments. Solid data (collected with good methods) give rise to more confidence in the results of the study. Also, instruments will more exact measures of outcomes are preferred.
Temporal Change

- Self-learning occurs.
- Example: As children mature they will become better at learning.
- Any intervention or treatment is mixed up with these temporal changes. It is difficult to disentangle the two effects.

David Torgerson

How do you consider the impact of temporal change in a before and after study? One approach is to think about issues that are naturally occurring in the population. A primary issue in any study on changes in traffic crashes, for example, is the temporal change for a decline in crash rates over time. Think about existing data that highlight changes in behavior or the environment over time.

This slide illustrates another approach. Think about changes that occur in the individual over time. In children (and adults too!), learning changes over time. As a result, knowledge of a subject area may change before and after an intervention independently.
Regression to the Mean

• As well as temporal changes before and after studies are confounded by a statistical phenomenon known as ‘Regression to or towards the mean’

David Torgerson

Another issue in before and after studies is the statistical phenomenon of “regression to the mean”. Regression to the mean is a technical term in probability and statistics. It means that, left to themselves, things tend to return to normal, whatever that is (Thornley).

To understand regression to the mean, consider this example from David Thornley.

Suppose we are teaching a complicated task to someone, and our student has learned the basics but is still uncertain. He sometimes does well, and sometimes badly, because he knows what to do but does not yet have it ingrained.

When he does it well, this is partly because he was lucky, and therefore he will probably do less well the next time. When he does it poorly, this is partly because he was unlucky, and he will probably do better the next time. This is going to happen no matter what else happens, including what we do as teacher.

Other examples are available at: http://www.visi.com/~thornley/david/philosophy/thinking/mean.html

In before and after studies, the issue of interest is that the values measures in the pre-test (especially the extreme values) may change in the post-test because of regression to the mean, not due to the intervention.
Consider this example of the annual increase in firearm offenses (percentage increase) by year. An amnesty program began in 2002 in an effort to reduce firearms on the streets. Did this program influence firearm offence rates? The graph suggests that it does.

However….
Did the Amnesty work?

- Unclear, the year preceding the amnesty had a large, unexpected, increase in offences, we would expect through regression to the mean that in the following year the rate of increase would ‘regress’ back to towards the ‘average’ annual increase.

David Torgerson

It is not clear that the change in the increase in offenses was due to the amnesty alone. Because the year prior had an extremely high percentage increase, one might expect to see a smaller increase in the subsequent year (due to regression to the mean). Again, it is difficult to disentangle the effects of the intervention from the other external influences that exist that affect the data.
The following slides illustrate an example of a before and after study design. This approach was used in the evaluation of the California Child Passenger Safety Initiative.
CPSI Goals

1. To increase CPS use among families using selected public health care sites.

2. To decrease the rate of CPS misuse among these families.

3. To increase awareness of the then-new CA “booster seat” law.

The broad goal of the initiative was to increase child passenger safety. In this particular effort, it was centered around increasing the use of car seats for infants and toddlers and booster seats for children up to age 6 OR 60 lbs. The authors also examined how well the population was aware of a new booster seat use law.
CPSI Intervention

• Focus on health care providers:
  – ~10,000 restraints distributed to low-income families
  – >6,600 low-income parents shown how to fit children into restraints
  – 11,000 parents/caregivers educated about CPS
  – >Almost 200 CPS check-ups held

• Focus on parents/guardians:
  – >700 public health and children’s workers trained in CPS

The intervention in the initiative was multi-factorial. The major objectives are highlighted here. They focused on distributing car and booster seats, education on how to seat children in automobiles, and how to place the seats in the cars appropriately (trained observers provided technical assistance to parents about correct installation of child safety seats in vehicles).
CPSI Evaluation

- Quasi-Experimental Design with cross-sectional data collection before/after the interventions at sites to measure any changes in use, misuse and parental knowledge of law

- Interview and observational component

The impact of the intervention was assessed with a before and after design. It had two components, a self-report survey, and an observational survey of car and booster seat use.
Observations

• Collected for parents/guardians who had traveled by private vehicle to the hospital or clinic on the day of the interview and who had children with them.

• Observers accompanied families to their vehicles and documented:
  – vehicle types
  – presence of air bags in the front passenger seats
  – children’s ages and weights
  – restraint types and location in vehicle and position of children in restraints and vehicle.

Details on the observational component are highlighted in this slides.

CPS Coordinators, public health nurses, social workers, and outreach workers conducted the observations. CPS Coordinators were all CPS-certified technicians, as were most, but not all, of the other observers. When not certified technicians, they were trained to conduct the observations. The objective of the survey was to obtain information on the use of child restraints and the misuse of car and booster seats.
Observational Study Locations

• Should be consistent with study purpose

• Data collectors must not influence subjects under observation

• Factors that influence behavior
  – Physical conditions
  – Environment
  – Heavy traffic
  – Enforcement activity

Observational surveys are a common approach used to identify changes in traffic safety. Observations may be taken to identify seat belt use, helmet use, and vehicle speeds. The selection of sites to observe these behaviors is an important issue in this approach. The sites selected should be consistent with the study purposes.

For example, in seat belt studies, locations where people are just getting into or out of vehicles may present a problem (e.g. parking lots), as persons are taking their belts off early or putting them on late. The location selected should allow for typical driving and belt behavior. In spot studies of vehicle speeds, locations where vehicles are accelerating or decelerating (in the vicinity of STOP- or signal controlled intersections) should be avoided.

The data collector and data collection equipment should be inconspicuous. They should not influence the behaviors of the subjects under study. Observers should not pose a threat to motorists.

The observers should also select locations that do not have other characteristics that influence behavior. For example, speed is affected by:

• Physical - alignment, sight distance, access control, …
• Environment - area, posted speed limit, weather, time of day, …
• Traffic - volume, classification, pedestrians, …
• Enforcement – unusually heavy enforcement activity on the road or in the vicinity may create bias in the study results
Knowledge of Booster Seat Law

- 79.4% of adults in “before” sample reported they knew about the new law.

- In “after” interviews, 75% reported they knew about the law. (p<0.05)

The results of the before and after interview regarding awareness of the booster seat law as shown here. The decline in awareness is unusual.

A explanation for this decrease might be that at the time of the pre-tests, there was significant media attention given to the law, and media attention subsequently declined in the period between the pre- and post-tests. This is an example of a temporal change and it’s influence on the results of a before and after study.
Care Seat Use: Self-reported vs. Observed

• Self-reported use did not change much between before and after (not statistically significant)
  – Car seat use stayed at 83%; booster seat use dipped from 57-56%.

• However, observed use of car seats increased from 89-94% (p<0.05).

Data on the use of car and booster seats are highlighted here. In the assessment by interview, not much change in CPS was reported. As in general population, use of car seats is greater than use of booster seats.

Observed use noted a change in use after the intervention. There was also more use of care seats in the observational study than by self-report. This could be higher because the observations were conducted only for those families that traveled to the medical appt. by private vehicle that day and also could have been more mindful about healthy behaviors. Parents and guardians who either did not travel by vehicle or who do not own car seats or who do not regularly use car seats would have been included in the self-reported data, but not in the observational data.
Key Lecture Points

• Before and After analysis is another research technique in the injury field.
• It is advocated in situations where controlled trials may not be ethical. It is widely applied in ecologic policy analyses.
• The analytic approaches in before and after studies can be influenced by temporal change and regression to the mean.