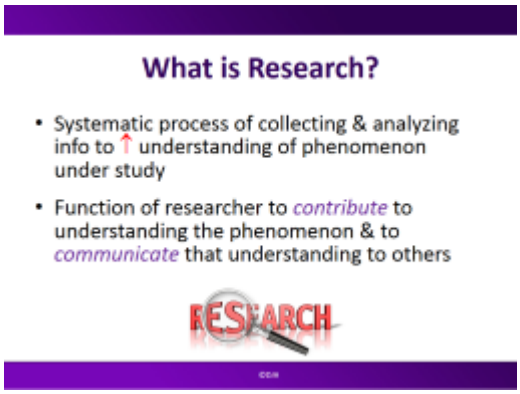
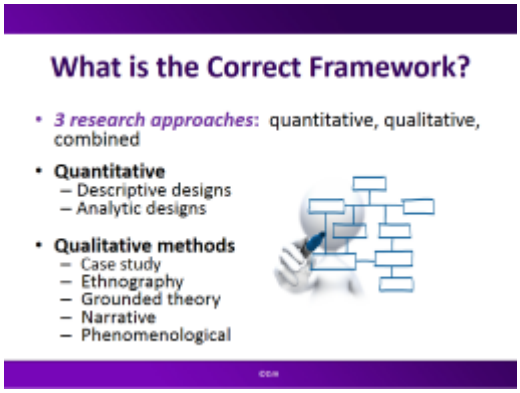
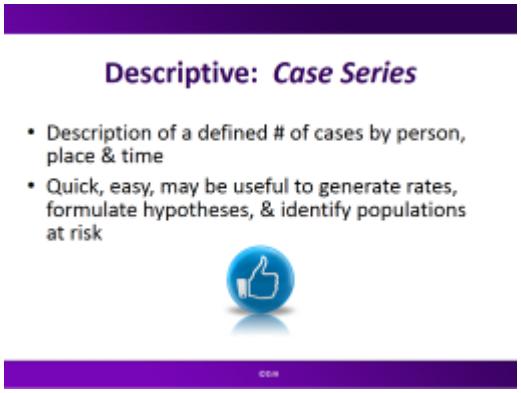
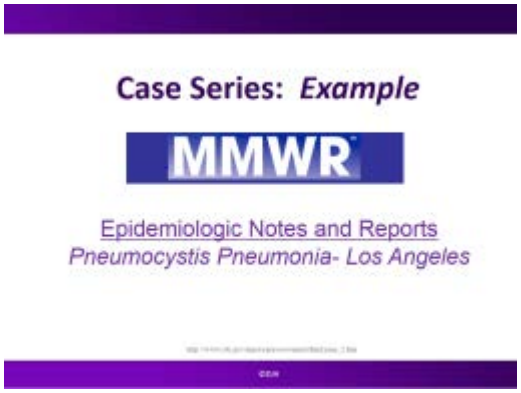
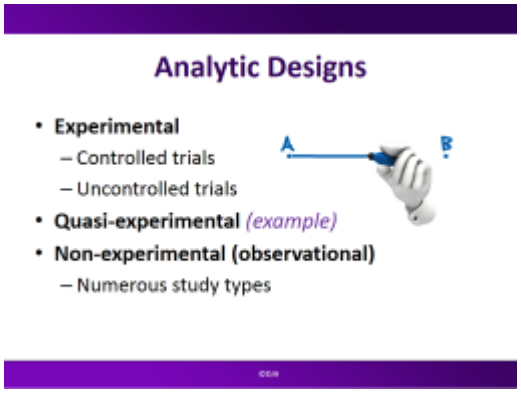
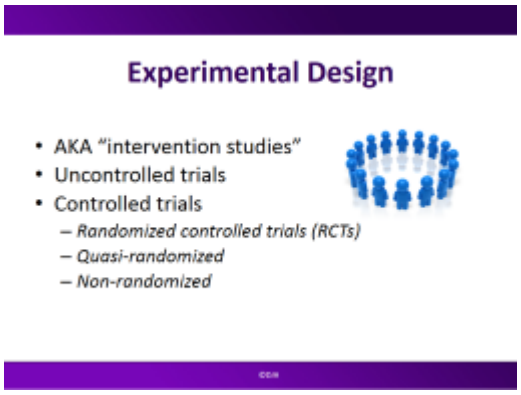
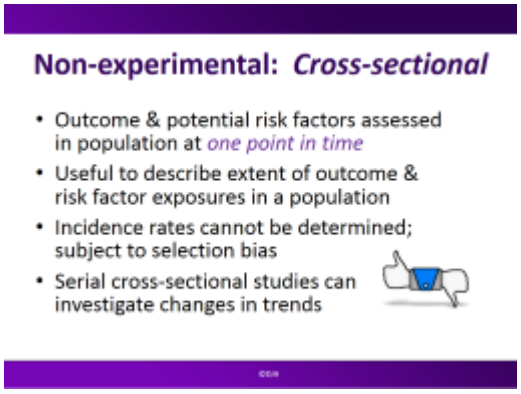
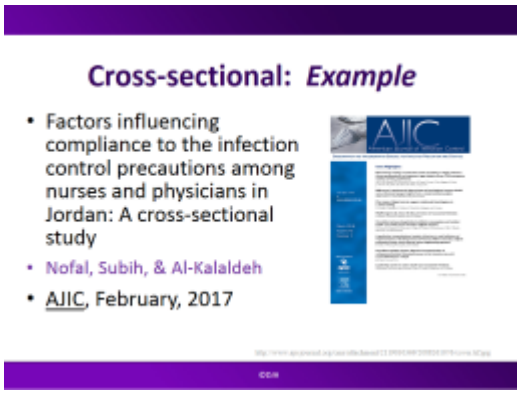
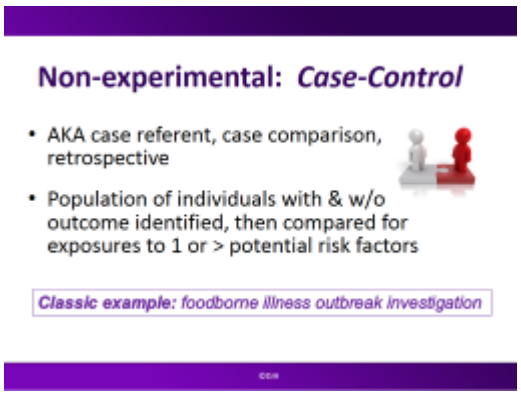
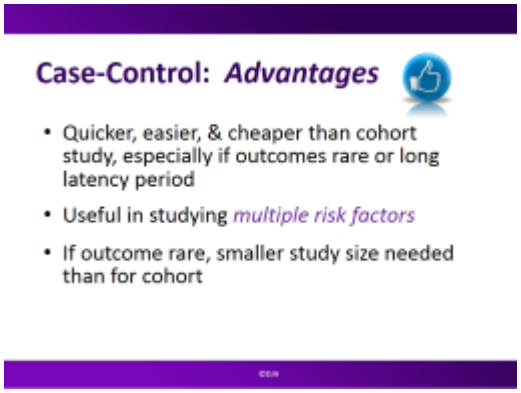
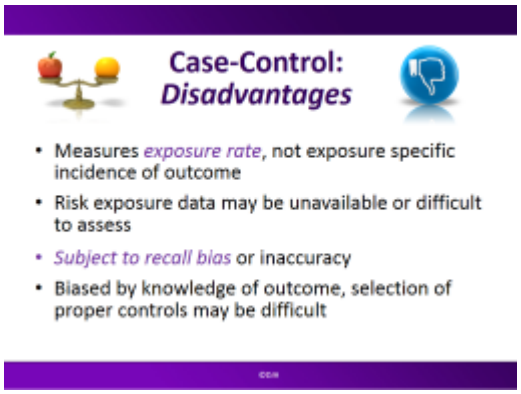
1		**Notes:** This is the lecture entitled “Research Study Designs". In this lecture, the different approaches of quantitative and qualitative research will be explained. This is not intended to be an intensive research discussion. The purpose is to provide a framework for understanding research study methods, designs and types designs. Selected study types will be outlined, along with advantages and disadvantages, and examples. Upon completion of this lecture, when provided a journal article, you should be able to identify the study method/design/type. In order for an Infection Preventionist or IP to effectively evaluate the literature on infection prevention and control, it is important to have a baseline knowledge of the different types of studies.
2		**Notes:** If we are going to discuss research study design, let’s start by defining “research”. Research is the systematic process of collecting & analyzing information to increase understanding of the phenomenon under study. It is the function of the researcher to contribute to understanding of the phenomenon & to communicate that understanding to others. (Source: Leedy, PD & Ormrod, JE. Practical Research: Planning and Design, 8th Edition, March 7, 2004.)
3		**Notes:** Depending upon the source of your inquiry, you may find classification schema for research designs, methods and types to differ depending upon the discipline and source of the information. In addition, the terms design, method, type, and approach may be inconsistently used. In general, there are 3 approaches for research-quantitative, qualitative and combinations of the two. To prepare this section, I reviewed at least 20 different sources and there was no consistent framework among the sources reviewed. I have adapted a graphic of quantitative design from a university in Canada as well as incorporated qualitative study types from several other sources into an algorithm provided as one of your readings this week. Therefore, for purposes of this course, the framework on this graphic lists 3 approaches but mostly breaks research designs, methods, types, etc. into two approaches: 1) quantitative and 2) qualitative. Obviously, if the approaches use one or more of the quantitative designs and qualitative methods, then it is considered a combined approach, which is the third approach. Within the quantitative approach, there are 2 designs: 1) descriptive, and 2) analytic. In descriptive designs, exposures or risk factors are not influenced by study design. In contrast, in analytic designs such as in quasi or experimental studies, certain factors or treatments that may influence the disease process or outcome are controlled as part of the study design. All study designs can be used to investigate the relationship between an outcome (e.g., infection, disease progression) and one or more factors (exposures or treatment). However, they differ in the conclusions that can be drawn. Within the qualitative approach, there is no division of designs, but there are different “types” which we will include in this lecture: case study, ethnography, grounded theory, narrative, and phenomenological.

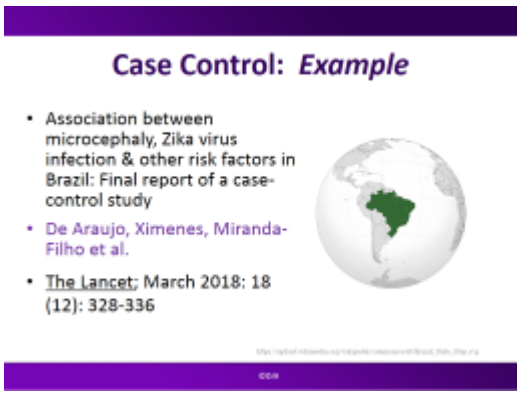
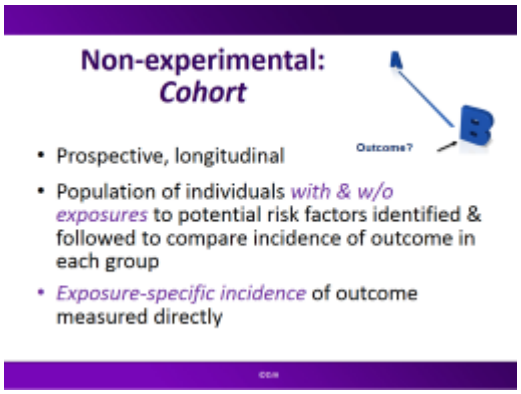
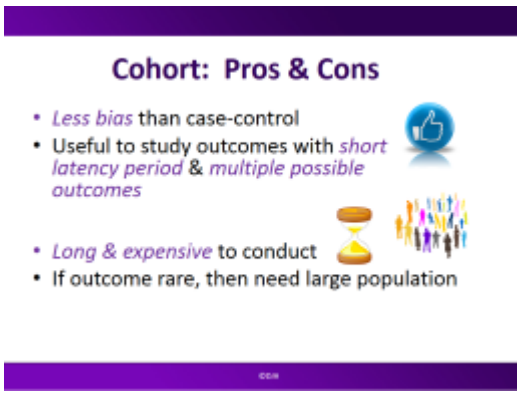
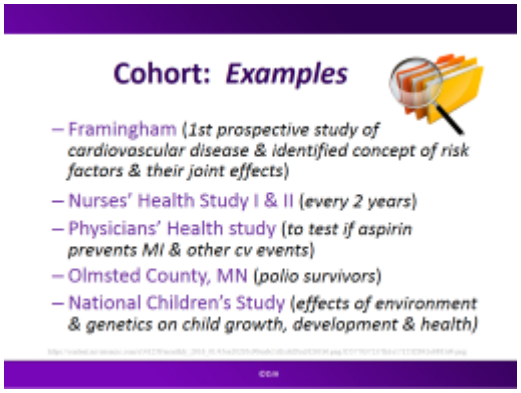
		Additional methods include field research and historical.
4		**Notes:** On this slide is a diagram that I created, adapted from several sources listed in the transcript. You can use this for visualizing the research designs. Remember that depending upon where you look, you will find differing versions, but this is what you will use for this course. Note: Adapted from Pai & Filion (Classification of Study Designs, Version 8, http://www.teachepi.org/documents/courses/Classification%20Design.pdf]), 5 Types of Qualitative Methods by Jeff Sauro (https://measuring.com/qual-methods/), & Qualitative Research Designs (http://www.umsl.edu/~lindquists/qualdsgn.html)
5		**Notes:** Let's start with the quantitative approach, descriptive design. Descriptive designs aim to communicate the occurrence of disease by time, place and person. Within the descriptive design are numerous study types: prevalence surveys, case series, surveillance data, and descriptive analyses of collected data. Let's use a case-series study type from the descriptive design, as an example. A case series is a description of a defined number of cases by person, place and time. This type of study is quick and easy to conduct. Additional advantages are that this may be useful for formulating hypotheses and identifying important populations at risk of the particular disease or condition. Disadvantages of this study type are that it does not use controls for comparison and it cannot be used to estimate risk factors. The first time a case-series is recognized, it will often result in a publication. Thus, identification of a new disease might first be recognized in a case-series..
6		**Notes:** A classis example of a case series is presented on this slide. On June 5, 1981, MMWR published a report of cases of Pneumocystis carinii pneumonia among previously healthy young men in Los Angeles. The editorial note that accompanied this report suggested a “cellular immune dysfunction related to a common exposure”. This prompted additional reports from New York, San Francisco and other cities. The Centers for Disease Control & Prevention (CDC) then developed an investigative team to identify risk factors and to develop a case definition for HIV/AIDS.

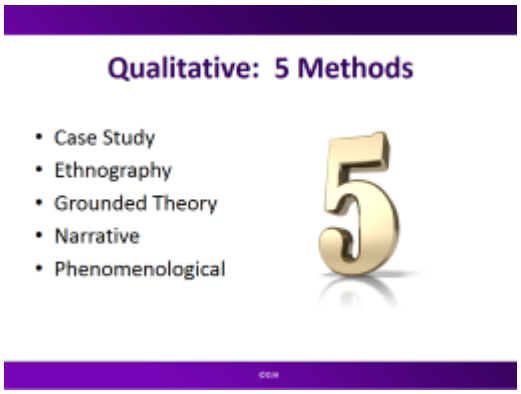
7		**Notes:** Analytic designs are intended to examine etiology and causal associations. Under analytic designs are experimental, quasi-experimental and non-experimental (also known as observational design) categories. Under experimental designs are uncontrolled and controlled trials. Under non-experimental or observational, there are numerous study types, which we will cover shortly. In quasi-experimental studies, the investigator lacks full control over the intervention but conducts the study as if it were an experiment. This type of study is often used when it is not logistically feasible or ethical to conduct a randomized controlled trial. These are often referred to as "before-after" or "pre-post" study designs. Let's use an IPC example. Suppose there is a new guideline on how to monitor central line infections. The nurses need to be educated on this guideline. Using a "before and after" design, the baseline central line infection rate is measured, then the nurses are provided an educational session on the new guidelines. A month later, the central line rates are measured again. In this quasi-experimental design, the investigators cannot monitor all factors that may affect a rise, decline or static rate of central lines infections. Perhaps there are some float nurses or agency nurses who have not had the educational session. Perhaps the acuity level of the patients monitored during this specific period have higher or lower risk factors for this type of infection. Perhaps "extinction" of the learned guidelines has occurred, resulting in less compliance with the new monitoring procedures.
8		**Notes:** Let's discuss the experimental design in more detail. Experimental studies are also known as intervention studies. In this category, the investigator/s intentionally alter one or more factors to study the effects of these factors. Under experimental are uncontrolled trials and controlled trials. In uncontrolled trials-there are no control or comparison groups. Examples would be a phase 1 and II clinical trial. In a phase I trial, using drug testing as an example, the testing of the drug is conducted on healthy volunteers to determine acceptable dose-ranging. In phase 2 trials, the testing of the drug is inducted on patients to assess efficacy and side effects. Controlled trials are conducted with control groups (e.g., phase III clinical trials). Using the previous example of drug testing, in phase III trials, the safety and effectiveness of the new drug is tested against the current standard treatment, thus there is one croup who receives the standard treatment and one who receives the new treatment. Controlled trials use randomization, where the unit of randomization is an individual in a clinical trial or a community/field trial where the unit of randomization is a community or cluster from that community. There are 3 subtypes under controlled trials: randomized controlled trials (or RCTs), quasi-randomized trials, and non-randomized trials. In non-randomized trials, the allocation of subjects to different groups is conducted arbitrarily and not randomly. In quasi-experimental trials, the allocation of subjects may be conducted using schemes such as date or birth (odd or even), number on the hospital record, date of invitation into the study, or alternatively allocating into the different study groups. This leaves the RCTs, which we will discuss next.

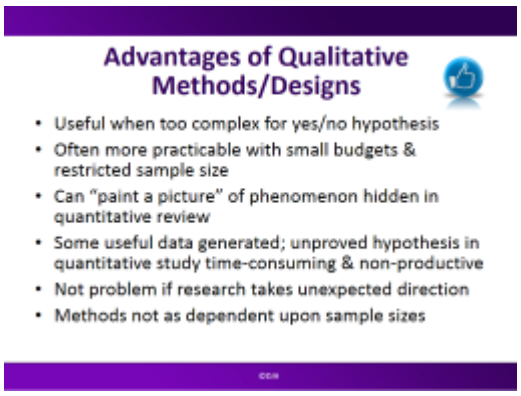
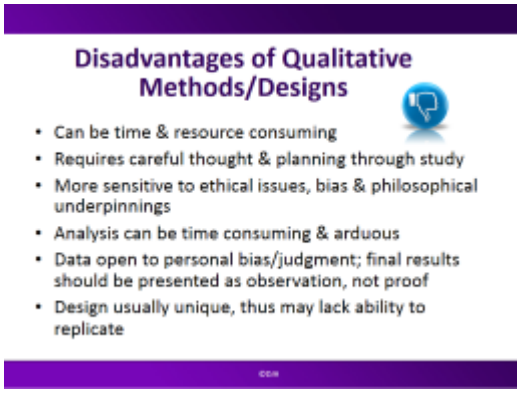
9	**Experimental: *RCTs*** • Compare experiment (intervention) to control *(placebo, standard care, or no treatment)* • Strongest study design, gold standard, is "randomized controlled clinical trial"(RCT) • Why?  	**Notes:** The randomized controlled trial (RCT) is the gold standard of research design, which is why we will cover it in more detail. This is often the type of study you will be asked to review for infection prevention and control issues. RCTs are prospective studies designed to compare outcomes in individuals who are assigned to an experimental (intervention) or control (placebo or standard care) group. The intervention may be a procedure, drug, or other treatment, and the comparison group usually receives a placebo, the previously accepted treatment, or, if appropriate, no treatment. With the experimental design, the researcher assigns interventions to an experimental (or "treated" group) and to a control (placebo, standard care, or no treatment). The strongest study design, or the "gold standard" experiment is one where there is control of as many variables as possible. That is because a "tighter" design controls as may factors as possible to avoid confounding the results. The study type with the tightest control possible is a "blinded randomized controlled clinical trial". In this type of study, there is random allocation of subjects to either the experimental or control group, and the investigators are "blinded" to either the drug or intervention. In that way, there can be no bias of results that could occur when the investigators know whether the subject has received the placebo or the treatment. An example of a randomized controlled clinical trial could be illustrated with a clinical trial of a hand hygiene agent. One unit would use a new hand hygiene agent while the other would use a different agent. The persons assigned to evaluate the condition of healthcare workers' hands would be "blinded" to which of the agents was used. Another example would be if investigators wanted to test the efficacy of a new vaccine versus an older one, they would randomly assign persons who had not been vaccinated against a particular disease into two groups: one to receive the traditional (or standard) vaccine and one to receive the new one.
10	**Non-experimental (Observational)** Numerous types: Cross-sectional Case-control Cohort Case-case or case only Ecological Hybrid designs *(see examples)* 	**Notes:** Also under Analytical Designs are the non-experimental (or observational) study types. There are numerous types: Cross-sectional Case-control Cohort Case-case or case only Ecological Hybrid designs (e.g.,, nested case-control, case-cohort, case-crossover, serial cross-sectional), to name a few examples. We will now cover 3 types of studies in the analytical (or non-experimental) design category: cross-sectional, case-control and cohort.

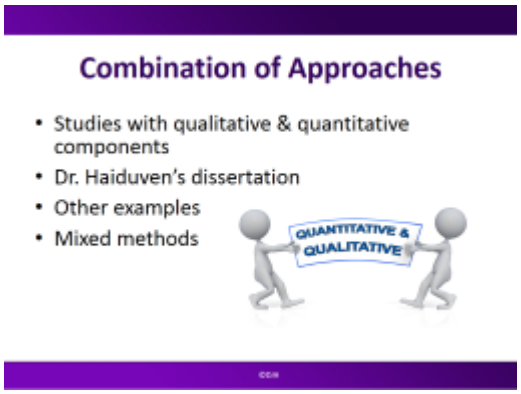
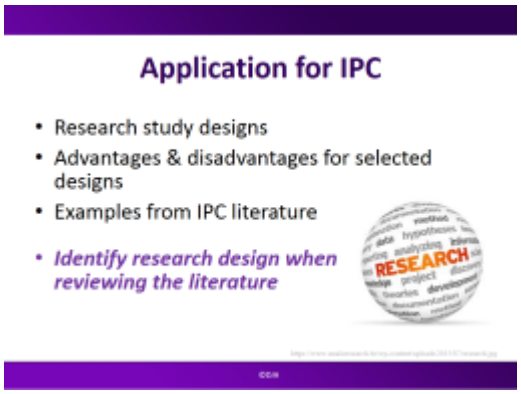
11		**Notes:** In cross-sectional studies (either prevalence, correlational, or survey), the outcome (disease, condition, infection, etc.) and risk factors (age, exposure, location, etc.) are assessed at one point in time (either a single time point or a specific time period). Advantages include that it is quicker, easier and less expensive to conduct than cohort studies. An example of a cross-sectional study would be a survey administered to a group of construction workers on their work practices and accident history to assess hearing loss risk or risk of falls. To assess adverse events following immunization, military recruits could be surveyed to determine vaccines that had been received and any adverse physical events that were prevalent. Cross-sectional studies are important because many questions can be efficiently answered and sometimes, it is the only method available. In medical research and social science, a cross-sectional study (also known as a cross-sectional analysis, transverse study, prevalence study) is a type of observational study that analyzes data from a population, or a representative subset, at a specific point in time-that is, cross-sectional data. This type of study collects data to make inferences about a population of interest at one point in time. The cross-sectional design is useful to describe the extent of an outcome and risk factors for exposure to that outcome in a single population. Because prevalent outcomes (both old and new) are measured at one point in time, incidence rates cannot be determined in such correlational studies. However, a series of correlational studies can be used to estimate prevalence trends. It is important to realize, with cross-sectional studies, that a temporal sequence of cause and effect for risk factors and outcome cannot be determined. Another disadvantage of this study design is that it carries a risk of selection bias. Those who choose to participate may differ in some way, and it could be in a significant way, thus clouding the true results.
12		**Notes:** On this slide is an example of a cross-sectional survey conducted among nurses and physicians regarding their compliance with universal precautions, in Jordan. It was published in the February 2017 issue of the American Journal of Infection Control (AJIC). A link to this paper is provided in the transcript: http://journals.sagepub.com/doi/pdf/10.1177/1757177417693676

13		**Notes:** A second type of study under the analytical design is the case-control study. This type has also been referred to as “case referent”, “case comparison” and “retrospective”. Case-control studies begin with the identification of persons that have the outcome of interest. Then a control group of individuals without the outcome is selected for comparison. A classic example of a case-control study would be that which occurs after an outbreak of a foodborne illness, such a hepatitis A. Once cases have been identified, a case-control study is undertaken to determine what risk factors were present in those who got hepatitis A versus those who did not. If it is suspected that patrons of a particular restaurant were affected, then food histories would be given to those who ate at that restaurant. This would help to narrow down what foods were eaten by the “cases” who ate at the restaurant and came down with hepatitis A versus the “controls”, or those who ate at the restaurant but did not get hepatitis A.
14		**Notes:** Case-control studies may be undertaken in a timelier and less expensive manner than prospective cohort studies, because cases may be identified retrospectively, and at least some exposure data are often available through medical record review. Case-control studies are particularly well suited for studying relatively rare outcomes or outcomes that develop over a long time after exposure. For example, if a particular infectious disease has a long incubation period or time from exposure to symptoms (e.g., hepatitis C, Creutzfeldt-Jakob disease), a case-control study would be appropriate.
15		**Notes:** There are some potential disadvantages of case-control studies. First, these measure exposure rates, NOT exposure-specific incidence. The exposure risk may be unavailable or difficult to assess. In addition, because the determination of exposure is usually made retrospectively, a problem known as “recall bias” may occur. This can happen when subjects have difficulty in remembering (or “recalling”) exposures OR if the medical record from which the study is being conducted, contains inaccurate or incomplete information. Thus, with this study type, the selection of an appropriate control group is essential. That control group must not only have the outcome of interest, but it should also be similar to the cases in the potential exposure period that the risks are being evaluated.

16		**Notes:** There are numerous examples of case control studies in the literature. In the March 2018 issue of the Lancet, is a report of a case-control study related to the association between microcephaly, Zika virus infection and other risk factors in Brazil. A link to this paper is provided in the transcript: http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(17)30727-2/fulltext
17		**Notes:** The third type of non-experimental or observational study design we will cover is the cohort study. Cohort studies are also called prospective or longitudinal studies. Cohort studies assess individuals with and without exposure to a potential risk factor who did not have the outcome of interest at the time they enrolled in the study. Both groups are then followed to determine the incidence of the outcome in each group. With this study type, it is possible to directly measure the exposure-specific incidence of the outcome.
18		**Notes:** Additional advantages include the existence of less bias in both subject selection and in determining exposure information than in case-control studies. The cohort study is useful in studying outcomes with short latency periods and multiple possible effects. As you can probably foresee, the cohort study takes longer and because of that, is more expensive to conduct, especially if there is a long latency period from exposure to outcome. If that outcome is rare, then a very large study sample may be needed.
19		**Notes:** There are several famous examples of cohort studies. Five are listed on this slide: 1) The Framingham- the first prospective study of cardiovascular disease & identified the concept of risk factors & their joint effects 2) Nurses' Health Study I was established in 1976 by Dr. Frank Speizer. Nurses Health Study II was established in 1989 by Dr. Walter Willet. These are among the largest prospective studies regarding risk factors for major chronic diseases in women. In this study, registered nurses have been selected to be followed prospectively. Every 2 years, the cohort receives a follow-up questionnaire with questions regarding diseases, and health-related topics (e.g., smoking, hormone use and menopausal status). 3) Physicians' Health study- (to test, among one of the goals, if aspirin prevents myocardial infarctions & other cardiovascular

		events) 4) The Olmsted County, Minnesota study of polio survivors 5) The National Children's Study - to study the effects of environment and genetics on children's growth, development, and health in the U.S.
20		**Notes:** The qualitative approach is a general way of thinking about conducting qualitative research. Qualitative research strives to define human behavior and explain the reasons behind that behavior. Like with the quantitative study methods, designs and types, there is variety among resources for qualitative methods. The 5 types of qualitative methods on this slide are from several resources. Let's briefly describe each of these. The purpose of a case-study is to describe in depth, the experience of one person, family, group, community or institution. It results from direct observation and interaction with the subject/s. The processes involved in preparing a case-study are interdisciplinary, so a variety of different theories and concepts may emerge when interpreting a case-study. The focus of the case-study can be individual, event, entity or organization. With ethnography, the researcher immerses him or her self into the target participant's environment to understand the goals, cultures, challenges, motivations and themes that emerge. This method has its roots in cultural anthropology where researchers immerse themselves within a culture, and this can last for periods up to a year or more. Rather than relying on interviews or surveys, the researcher experiences the environment first hand, often as a participant-observer. The focus is on a culture or context. Grounded theory was initially developed in the 1960's. With this method, the aim is to provide an explanation or theory behind the phenomena being studied. Interviews and existing documents are used to build a theory based on the data, with the use of coding techniques. Often this method uses lager samples sizes, e.g., 20-60 to facilitate establishment of a theory. With the narrative method, a sequence of events, usually from just a few individuals, are weaved into a cohesive story, using in-depth interviews and documents. The final narrative does not necessarily require being in chronological order, but it is presented as a story with themes, reconciling of conflicting stories and may highlight tensions and challenges which present as opportunities for innovation. The goal of the phenomenological method is to understand how others view the world and how this view may vary from commonly held views. This is accomplished by focusing on a person's subjective interpretations of what he or she experiences. Thus the focus is on persons who have experienced a phenomenon. A combination of tools, including interviews, reading documents, watching videos, or visiting places and events are used.

21		**Notes:** Rather than focus on specific qualitative methods, the next 2 slides will present the advantages and disadvantages of the various qualitative methods as a whole. On this slide, the advantages of qualitative methods/designs are listed and described. • Qualitative techniques are extremely useful when a subject is too complex be encapsulated by a simple yes or no hypothesis. While quantitative data reveals simple linear relationships between discrete variables, qualitative techniques yield data that are richer and more insightful into underlying reasons and patterns within phenomena. • Qualitative research is often more practicable when budgets are small and sample sizes are restricted. If a large number of participants cannot be secured for a quantitative study, the few available participants can be better understood with in-depth interviews. For example, if there are only three people in a clinic who qualify as subjects for a study, it might make more sense to conduct comprehensive interviews with them, i.e. opting for quality over quantity. • The benefit of qualitative research is that is can "paint a picture" of a phenomenon that might be hidden within a quantitative review. For example: Surveys can show that HIV incidence among men who have sex with men is up, but only interviews with cases could reveal personal motivations and reasons behind why that is the case. • The nature of qualitative research designs means that some useful data are very frequently generated, whereas an unproved hypothesis in a quantitative experiment can be a time-consuming and non-productive endeavor. • In qualitative research, it is not a problem if the research develops in an unexpected direction. In fact, the researchers are usually pleased with whatever they discover, and deliberately try to avoid going in with any expectations. • Finally, qualitative research methods are not as dependent upon sample sizes as quantitative methods; case studies, for example, can generate meaningful results with just a small sample group.
22		**Notes:** On this slide, the disadvantage of qualitative methods/designs are listed and described. • Qualitative research experiments can be time- and resource-consuming compared to quantitative experiments. A researcher may need to be present for hundreds of hours of interviews, whereas a quantitative study using a questionnaire can be completed in an afternoon. • Qualitative methods also require careful thought and planning throughout the study. • Researchers may have to be sensitive to ethical issues, bias and the philosophical underpinnings of their research question in comparison to those undertaking quantitative studies. • Qualitative data cannot be mathematically analyzed in the same way as quantitative results. Their analysis and interpretation may be time-consuming and arduous. • Qualitative data are more open to personal bias and

		judgment, and therefore care must be taken to present the final results appropriately: as observation and not proof. • Lastly, qualitative research design is usually unique and may lack the ability to be replicated.
23		**Notes:** As previously mentioned, if a study uses quantitative designs or study types and qualitative methods, then it is considered a combined approach. My dissertation is an example. My dissertation was entitled "Circumstances Surrounding Blood Exposures and Needle Safety Practices in Home Health Care Nurses." The quantitative component of my research consisted of a cross-sectional prevalence study of needlestick and blood exposure information from the three home care agencies included in the study. The information from this study was used to formulate focus group questions among the nurses from these 3 agencies to explore circumstances surrounding these exposures. The resultant qualitative component consisted of 2 phases of focus groups. The first phase was to build upon data obtained in the quantitative component and generate themes to explore in phase 2. In phase 2, the emphasis was on exploring nurses' perceptions of barriers and facilitating conditions for safe needle use and practices in the home care setting that were formulated in phase 1. Both the quantitative and qualitative approaches complemented each other and the research was richer from this combination of approaches. There are numerous examples in the literature of studies using qualitative and quantitative approaches. This is also known as a "mixed-methods" approach.
24		**Notes:** Up to this point, we have defined research, provided a framework for identifying and describing research approaches, designs, types and classification, and provided advantages, disadvantages and examples of selected study types. This is not intended to be a comprehensive research class. If you are interested in other types of studies or more extensive details, please consult other more in-depth resources. For those in the field of infection prevention and control, the information provided can facilitate review and critique of the scientific literature, which will be covered in the next lecture. This lecture has provided the background for this next step of critique. This concludes the lecture on Research Study Designs.