MODULE 3 – RESEARCH STUDY DESIGN

LEARNING OBJECTIVES:

1. To learn to choose a study design that matches both your research capacity and your research question. *(Sections A & B)*
2. To identify and understand the basic differences between some common study designs used in health and medical research. *(Section C)*
3. To understand the secondary use of data for research and identify some common types of secondary data *(Section D)*
4. To understand the various levels of evidence provided by different study designs. *(Section E)*

Section A: Choosing a Study Design: The Importance of Time & Resources

- Explain how time and resources (i.e. research capacity) might impact the choice of study design.
- Define and differentiate retrospective, cross-sectional and prospective study designs.
- Explain how sample size can impact feasibility of a study.
- Provide some relevant questions that should be asked when selecting a study design.

Section B: Choosing a Study Design: Matching Design to Objectives

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Review Questions – Part 1 (Sections A-B)

Section C: An Introduction to Some Common Research Study Designs

- Define and differentiate the two main categories of research design ("descriptive" and "analytical").
- Figure summarizing the common types of study design discussed in this section.
- Briefly describe the common types of study design as per the figure and discuss relevant differences, strength and weaknesses.
- Define important terms when and where relevant.

Section D: Secondary Use of Data for Research

- Define "secondary data usage".
- Briefly describe and discuss common types of secondary data research (chart reviews, case reports/series, administrative databases, registries).

Section E: The Hierarchy of Evidence

- Explain the hierarchy of evidence, including a summary figure (pyramid)
- Define "basic science" and contrast it with "clinical research"
- Define systematic reviews and meta-analyses and explain why they are considered the best evidence available.

Review Questions – Part 2 (Sections C-E)

INTRODUCTION

Designed in collaboration between Memorial University's Discipline of Pediatrics and Discipline of Obstetrics and Gynecology, this module is part of a series of teaching modules designed to augment residents' learning of the basic aspects of medical research and to prepare residents for conducting their own research projects.

This module is about ***research study design***. Once you have successfully formulated a research question and carried out a literature search, it is important to choose an appropriate study design for your project. There are many types and variations of study designs available, so it is important to choose a design that works best for you and your research question. The first two sections of this module will discuss some of the important factors that should be considered when selecting a design, while the last three sections will briefly describe some common study designs, the secondary use of data for research, and the levels of evidence provided by the various types of studies.

In this module, you will learn:

- How to select a study design that matches both your research capacity and your research question.
- To define and distinguish the most common types of study design used in health research.
- To understand the secondary uses of data for research.
- To understand the various levels of evidence provided by different study designs.

You will also start the process of choosing a study design for your own resident research project.

CASE STUDY

Ben is a pediatric resident at a mid-sized hospital that is also home to a large medical school and associated graduate programs. He has been working diligently with a faculty member and rheumatologist, Dr. Allair, to develop a research project involving their shared interest of childhood arthritis. Following some discussion with Dr. Allair and a broad literature review, they have refined their research question to the following:

How does having juvenile arthritis impact school-aged children's participation in extracurricular activities?

Ben knows that the hospital has a regular pediatric rheumatology clinic for children with arthritis and related diseases, which should prove instrumental in carrying out his research. But he is also keenly aware that he will have limited time to complete the research. He is expected to have his project finished within nine months, and he will be balancing a busy clinical schedule with obligations related to his young family.

Ben knows that his next step is to start planning his research study, but how does he go about choosing the right design?

SECTION A: CHOOSING A STUDY DESIGN – THE IMPORTANCE OF TIME & RESOURCES

As mentioned in the Introduction above, it is important to choose a study design that works best for you *and* your research question. To get started, you should consider your **research capacity** (how much research you can reasonably and effectively carry out) and how it might influence your choice of study design.

Two key components of your research capacity are the **time** and **resources** that you might have available to carry out your study. **"Time"** includes both the expected timeframe for your study to take place and/or how much time you (or other primary researchers) will have available to do the required work. (*As a busy resident, it is understandable that you may have limited time to commit to a research project, so a practical and appropriate study design should be used.*) **"Resources"** might include important factors such as funding, access to enough participants or existing data, and any equipment or outside expertise (e.g. lab analysis) that might be required.

Typically, **retrospective studies** (studies that examine the medical history of participants or existing data) require the least time and resources to complete. These types of studies often use existing data (e.g. chart reviews, databases or patient registries) or use surveys to determine the relevant history of participants. **Cross-sectional studies**, which collect data from a single sample of participants (e.g. from different stages of disease and/or treatment) at a single time point, can also be carried in a relatively short period of time. However, **prospective studies** that follow a group or participants for a period of time (e.g., throughout a course of treatment) generally require much longer periods of time and more resources to complete.

Some Questions To Ask …

- **What specific data or information will you need to collect in order to answer your research question?**
- **Does the data already exist somewhere or do you need to collect it directly from the patients/participants?**
- **What collection method(s) might be necessary (e.g., chart review, surveys, interviews, patient follow-up/tests)?**

The answer to these questions will help you determine which type of study design is required. Existing data or the ability to collect medical history may allow a retrospective design, while the need for patient follow-ups and tests may lead to a cross-sectional (one visit) or a prospective design (multiple visits or data collection points over time).

It is also important to keep in mind that some study designs require a much larger **sample size** than others, which also has a significant impact on the feasibility of your project. While there are specific statistical methods that can used to determine the necessary sample sizes for most study designs, a general rule of thumb is that prospective studies require a larger sample size than retrospective or cross-sectional studies. This is because the latter designs often allow the researcher to pre-select cases based on outcome, while the outcome of each case remains unknown at the onset of a prospective study.

Some Questions To Ask …

- **How many participants/cases (sample size) might you have to include?**

Some study designs, such as controlled trials, require much larger sample sizes than others, which is an issue to discuss with your supervisor or biostatistician.

- **How long might it take to collect the necessary data from this number of participants/cases?**

Some study designs allow for relatively quick data collection (e.g., chart reviews) while others require much longer (e.g., cohort studies or controlled trials).

- **How difficult will it be to recruit enough participants/find enough cases to meet the required sample size?**

The efficiency of doing the study may depend on a number of factors, such as the prevalence of the condition and/or treatment you are researching, access to a specialized clinic or health professional that can refer cases, or even an existing registry or database that might hold a list of cases or information you require.

SECTION B: CHOOSING A STUDY DESIGN – MATCHING DESIGN TO OBJECTIVES

In this section, we will briefly discuss choosing a study design that best fits your research question. In order to do so, it is often useful to develop specific **research objectives** that describe exactly what you aim to achieve and how you aim to do so. In other words, research objectives are statements about how this specific study is going to answer your research question. Depending on the scope of the research question, a study may have more than one specific objective.

Example of Research Objectives

Research Question: Do children under the age of 18 with type-1 diabetes mellitus (T1DM) access more general health care services than those without T1DM?

Research Objective 1: To survey general health service use (all doctor/hospital visits *not* related to routine T1DM care) of children included in the Newfoundland & Labrador T1DM registry and compare to control population.

Research Objective 2: To determine which, if any, specific types of health services are accessed more frequently by children with T1DM.

Note how the research objectives above describe what information will be collected (data), how (survey), from who (sample population) and any comparisons/analyses that will be made. This information is very useful in helping select an appropriate study design to answer the original research question. In this case, the researcher has determined that a registry of all T1DM patients in the province exists, providing an easily accessible patient population. However, since the required information (a history of all doctor and hospital visits) is not likely to be included in the registry itself, a survey will be required to collect that information from eligible patients in that database. In order to make valid comparisons, data will also be surveyed from a control group.

REVIEW QUESTIONS – PART 1

Refer to the Case Study at the beginning of this module in order to answer these review questions.

1. Ben has been informed that staff from the pediatric rheumatology clinic are willing to help him any way they can – from referring patients to providing access to charts and records (provided the necessary permissions are granted, of course). However, given the limited time that Ben has to work on this project, which type of study might be most practical?
    a. Prospective – following a select group of children/patients to determine the impact of arthritis on extracurricular activities in the coming school year.
    This would be a poor choice of study design for Ben's project. While he may have access to current patients through the clinic, prospective studies tend to require a lot of time – both in the long- and short-term – and Ben does not have that luxury.
    b. Retrospective – determining the impact of arthritis on the extracurricular activities during the past school year(s).
    This would be a better choice for Ben. A retrospective study can usually be carried out much more quickly as the data may be already available, and Ben should be able to collect data about current and/or previous patients in the clinic using one of several methods.

2. Considering Ben's research question, the resources available to him through the pediatric rheumatology clinic, and your answer to the question above - which of the following statements best describe the data he will need to collect?
    a. All of the information he requires will be contained in the health records of clinical patients.
    No. We know that Ben will need to collect some data about the children's extracurricular activities – information that would not be contained in their health records.
    b. Some of the information he requires will not be available in the health records and must be collected directly from the patients.
    Yes. While Ben may be interested in some of the basic health and/or patient information that would be available through health records (e.g. child's current age, age at diagnosis, severity of disease), other important information about extracurricular activities must be collected directly from the patients/families.
    c. Some of the information he requires will necessitate follow-up visits to the clinic and/or medical tests.
    We have already determined above that a retrospective study design is best suited to Ben's project and timeline. Based on his research question, there does not appear to be any reason to include follow-up visits to the clinic or medical tests.

3. Which of the following represents a good research objective for Ben's upcoming study? Why?
    a. To examine the extracurricular activities of children with juvenile arthritis.
    No. This statement is very broad and does not specify anything about the research question or how it will be addressed.
    b. To determine how juvenile arthritis affects extracurricular activities.

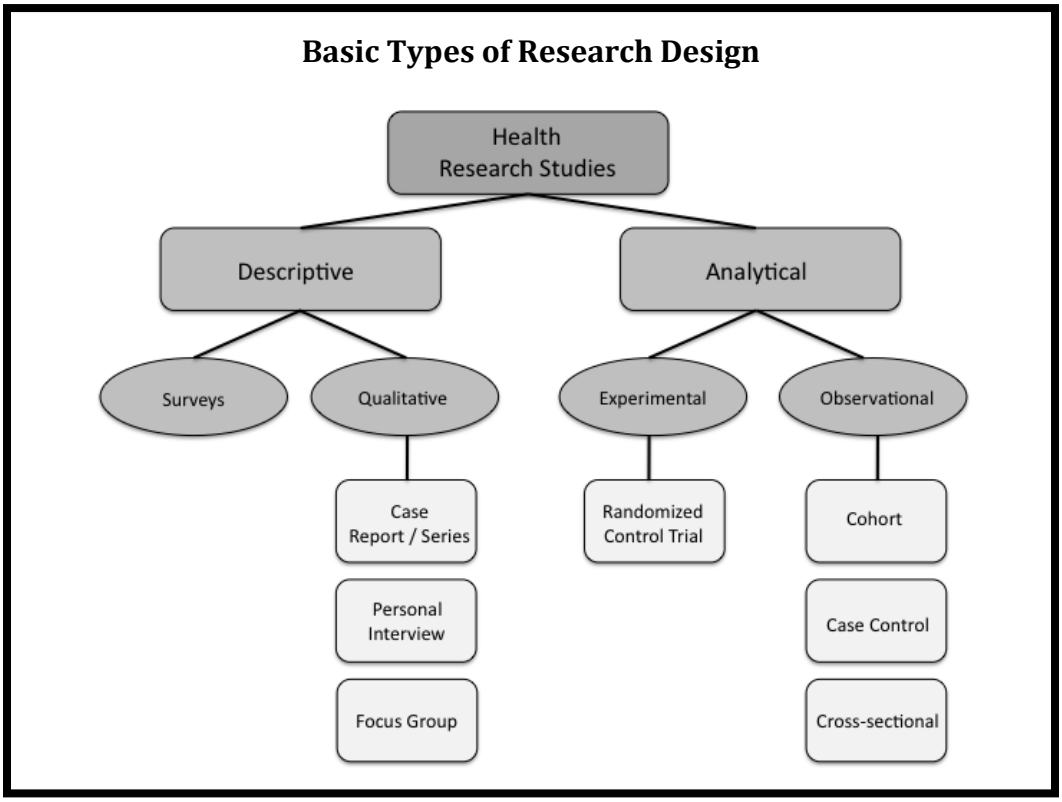
No. This statement does better describe the study's purpose than the one above, but does not specify who the target population is or how the data might be collected.

c. **To determine how having juvenile arthritis impacts participation in extracurricular activities in a sample of children aged 6-15 years who attend a regular clinic and have been diagnosed for at least two years.**
Yes. This statement is much more specific than those above, outlining both the relationship that will be examined and who the target/sample populations are. Choosing a study design that matches this objective will help Ben determine his next steps and how he will collect the data.

SECTION C. AN INTRODUCTION TO SOME COMMON RESEARCH STUDY DESIGNS

Study designs used in health research can be divided into two broad categories – ***descriptive*** and ***analytical***, as shown in the figure below. **Descriptive** studies provide information about the characteristics of a population, their experiences or a specific health outcome. While descriptive studies generally do not answer questions of how/when/why, they can be very useful in helping form hypotheses for further research. **Analytical** studies use numerical data and/or statistical methods to quantify relationships between health outcomes (e.g., disease incidence or recovery) and various factors (e.g., genetic/environmental or interventions). The terms "analytical" and "quantitative" research are sometimes used interchangeably, although some descriptive studies may also include quantitative data and/or methods.

This section will provide you with a *brief introduction* to the common types of study design summarized below. We strongly recommend that you learn more about the type(s) of study design that you consider using in your own research projects. You may start by discussing them with your supervisor and/or referring to the References / Further Resources section below. It is also important to realize that this list is not exhaustive and there are other types of study design that you may encounter and even find useful in your own projects. Some studies may utilize methods or aspects from more than one type of design – often referred to as a "**mixed methods**" approach.



Descriptive Research Design

Surveys are commonly used tools in health and many other fields of research. Surveys are used to collect data from a population sample in order to make inferences about the population as a whole. In order to make such inferences meaningful, an appropriate *sample size* should be calculated using statistical methods – generally, a larger population of interest will require a larger the number of respondents. Survey sampling should also aim to collect data from a *representative sample,* meaning that all other demographic factors are (e.g., age, gender, etc.) included in ratios similar to those that would be found in the entire population. There are number of methods available to ensure these criteria are met.

Surveys may be completed either in written (e.g., mail-out or online surveys) or oral (e.g., telephone or in-person interview) formats. Depending on the questions included in the survey, the data collected may be qualitative (e.g. open-ended questions), quantitative (e.g. yes/no or numerical responses), or a combination of both. Hence, while we discuss surveys as a type of descriptive research design, it is possible that a given survey may also include analytical methods. The choice of questions included in a survey, the order they are asked in, and the ultimate interpretation of those questions should be planned very carefully when designing a survey-based study.

Since the participants complete the survey or provide the information themselves, this type of data collection is referred to as "self-reported data". Self-reported data is somewhat limited in its validity and should be interpreted cautiously.

Qualitative research encompasses a number of designs and methods that aim to describe a population or explain a health outcome using subjective and/or non-numeric data. A **case report** is a detailed summary of the symptoms, diagnosis, treatment and/or follow-up of an individual patient, often to document an unusual or novel observation. Similarly, a **case series** describes a set of patients that have the same diagnosis and/or were exposed to the same treatment. The number of patients included in a case series is generally small and as such only provide anecdotal findings, however they may reveal trends that can then be tested in larger controlled studies.

A commonly used type of qualitative research is the **personal interview,** in which a series of one-on-one interviews are used to gather information regarding experiences and/or opinions regarding the research topic. While the basic premise of this study design is simple, various methods exist that differ in aspects such as how the participants are selected (e.g., criteria-based patient referrals, key informant interviews, snow-ball sampling), which questions are asked during the interview (e.g. structured/semi-structured/unstructured interviews) and how the information gathered might be organized and interpreted (e.g. thematic analysis, grounded theory). Careful consideration should be given to these aspects when planning a qualitative interview study. While detailed summaries of these methods are beyond the scope of this teaching module, we recommended that you take the time to learn about them if you choose this type of research design.

Focus groups bring together a group(s) of participants to discuss their experiences, perceptions, thoughts, and opinions about the research topic. While this type of research originated in the field of marketing research, a variety of approaches and methods are now

used commonly in a range of fields, including health. Focus groups have advantages over individual interviews in that they allow the researcher to gather information from a group of people quickly and allow participants to discuss the questions together, deliberating on the topics. However, effective use and moderation of a focus group requires some skill and experience, so appropriate measures (e.g., training/practice) should be taken when choosing this design.

Analytical Research Design

Analytical research designs can also be divided into categories that differ primarily on how exposure to the treatment or intervention is determined. In **experimental** studies, the investigator actively assigns a treatment or intervention to subjects and then observes the effects. In **observational** studies, the investigator observes or measures outcomes in groups of subjects without assigning treatments (although subjects may be selected or categorized accordingly).

Experimental research includes **randomized control trials (RCTs)**, which are considered the "gold standard" for evaluating the effects of therapeutic or preventative interventions. As its name suggests, a key features of an RCT is **randomization**, which aims to make treatment groups similar in all aspects (e.g. demographics, disease state) except for exposure to the intervention. There may be two (e.g. treatment/no treatment) or more (e.g. multiple treatments or various dosages) comparison groups in a study. Another important feature in most RCTs is **blinding**, which means that the participants and/or researcher(s) are not aware which treatment group each individual is assigned to during the trial. This may be accomplished in a number of ways, such as using unique identifying numbers rather than names to label all results and/or samples, and using placebos in non-treated groups. Ideally, both the researcher and the participant are blinded (referred to as a **double-blind** experiment). While the strict control and high quality of evidence provided are major advantages of this design, RCTs are also time consuming, require a large sample size, and can be very costly. As such, RCTs are rarely employed in conduct resident research projects.

Three main types of **observational** studies are routinely used in health research. **Cohort studies** are longitudinal studies that follow a group of participants (referred to as a *cohort* since they share a similar characteristic or set of characteristics) for a period of time and evaluate the occurrence or risk of a specific health outcome. For example, a study may follow a large group of cognitively healthy people aged 70+ for the remainder of their lives and attempt to correlate the occurrence of dementia with various lifestyle factors within that group. Since these studies are longitudinal, they are not well suited for the study of rare diseases (very large sample sizes would be required to ensure enough cases) or those with long latencies. Because of the long length of time required to complete, cohort studies are rarely used in resident research projects.

Case control studies involve selecting and comparing two existing groups that differ in their diagnosis (i.e. disease/no disease) or exposure to a treatment (e.g. treatment/no treatment or treatment X/treatment Y). By virtue of this design, most case control studies are retrospective (although some may continue to follow the groups for a period of time, adding a prospective component). These studies are generally less time consuming or expensive compared to cohort studies, and are better suited for the study of rare diseases or those with long latencies.

Cross-sectional studies are a study of a population at a single point in time, and are often used to determine the prevalence of a specific health condition or known risk factors within that population. Since the data is collected at one time point, these studies are relatively quick and easy to carry out but are limited in their ability to determine temporal relationships between risk factors and disease or the effect of any treatments. Surveys can be considered a type of cross-sectional study design since they collect data from a representative sample at one point in time.

SECTION D: SECONDARY USE OF DATA FOR RESEARCH

Some studies are carried out using data that has been collected for some reason other than this research. This is known as "**secondary data usage**" or "secondary data analysis", since the information is being used for something other than its original (primary) purpose.

This type of approach is especially common in the fields of health research since patients leave a great deal of information about themselves, their families, their interactions with the health care system, and their outcomes with different treatment regimes, while they are seeking and receiving care. Four common types of secondary data research using this form of patient information are described below. Since these studies use personal information about patients, there are unique privacy concerns and ethical regulations which must be considered at all stages of planning and research.

Case studies represent a type of secondary data research since most or all of the information used to create the summary may have been collected during the course of patient care and not for the original purpose of research. Case studies are valuable in highlighting interesting or unusual cases (e.g., a rare disorder or the outcome of a novel treatment approach), but are not always representative of a larger population.

Chart reviews collect information from the health records of multiple patients. A set of criteria is developed to determine which patient records are selected for the study, and a set list of variables is retrieved from each chart. This research design is popular due to its inexpensive costs, easily accessible information (especially as health records are becoming increasingly digitized), and the ability to include a relatively large number of cases in a short period of time. However, this approach also has several weaknesses, including its retrospective nature (unable to determine cause-effect relationships), the inconsistent way that the information may have been originally collected and recorded (usually by any number of health professionals), and the inability to account for missing or inaccurate information within the charts. However, chart reviews often reveal important findings that can be used to develop new hypotheses and inform future research.

Administrative databases are compiled by governments and/or health authorities using the vast amount of information collected during the routine administration of health care programs. These databases are often used by those entities to answer questions regarding service usage and provide basic health care statistics, but are also available for other research. An example of such an administrative database available in this province is the Perinatal Database which is a collection of health and perinatal records data, contains demographic variables, procedures, interventions, maternal and newborn diagnoses, morbidity and mortality information for all pregnancies and births occurring within three of four Regional Health Authorities.

Other large, powerful research tools are **patient/disease registries** that compile information about individuals that have been diagnosed with a particular disease or condition. These registries are often geographically or hospital-based . A major advantage of these databases is that they deal with one specific disease or condition, often allowing for more precise data to be collected and for more direct interpretation and application of research results. However the set up and maintenance of these databases require a lot of effort and coordination, especially when dealing with large geographical regions or relatively large numbers of patients. Variations in data collection and clinical practice may

also be problematic, especially in large regions, so care should be taken to verify data quality when possible.

Section E: Research on Existing Research Studies

Some studies are research studies that focus on other research studies as their data. Because of the amount of available evidence, these summative studies can be quite useful to directing clinical decision making. **Systematic reviews** provide an exhaustive summary of all the available literature relevant to a specific research question or topic. They are comprehensive (include all studies and papers), use explicit search strategies, assess the studies for methodological quality, and synthesize the findings to make important conclusions and recommendations. While superficially similar, a **meta-analysis** extracts data from the body of literature, analyzes it collectively, and presents a "new" overall result or findings. Meta-analyses provide a broader determination of treatment effects and are therefore considered the best type of evidence available.

REVIEW QUESTIONS – PART 2

You should have already ascertained (from previous review questions) that a retrospective study collecting data directly from patients/families is best suited for Ben's upcoming study. The following two questions will help you narrow down the study design options.

4. Using the information you have determined about Ben's research question and objectives, would you categorize this study as **descriptive** or **analytical**? Provide a brief rationale for your decision.

    a. *Analytical. Incorrect, it aims to describe the nature of a relationship (between juvenile arthritis and participation in extracurricular activities), but is unlikely to quantify the relationship in any way or explain exactly how or why the relationship exists.*
    b. *Descriptive. This study would be considered descriptive since it aims to describe the nature of a relationship (between juvenile arthritis and participation in extracurricular activities), but is unlikely to quantify the relationship in any way or explain exactly how or why the relationship exists.*

5. It is often possible that more than one study design can be used to answer a research question. However, each design has strengths and weaknesses that may influence a specific choice. Referring to the figure in Section C, list three basic study designs that Ben *could* use. Provide one strength *or* weakness about each that might impact on his ultimate choice.
   Since it is a descriptive study, Ben could use either of the study designs below (Case reports/series would not be appropriate in this case):
   - Survey
   - Strengths: Surveys are both time- and cost-effective, allowing for data collection from a large sample size fairly quickly; Standardized questions allow for consistent data collection across the sample (i.e. all participants answer the same questions)
   - Weaknesses: The use of standardized questions may limit the potential for new or unique ideas/information from participants.
   - Personal Interview
   - Strengths: Personal interviews are effective ways to gather information, thoughts and opinions about the topic from participants; New and interesting ideas or findings may arise from a less structured interview (compared to structured surveys, for example).
   - Weaknesses: It may be time consuming to carry out enough interviews to include a reasonable number of participants (sample size); Transcription and/or interpretation of the discussion may be challenging and require some training.
   - Focus Group
   - Strengths: Given Ben's limited time, this may be a practical way to gather data from a number of participants at one time; Focus group discussions often lead to "richer" data as participants converse, exchange ideas and build on each others comments.
   - Weaknesses: Ben may have to learn to effectively moderate a focus group or find an experienced moderator to do so, since it requires a specific set of skills; Transcription and/or interpretation of the discussion may also be challenging.
   **** Note that other strengths and weaknesses may be provided.***

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6. Which of the following studies is <u>not</u> an example of secondary data research?
    a. In order to determine if the type or severity of respiratory symptoms at admission are related to length of hospital stay in young children, pediatric resident Gillian examines the charts of all children aged 2-12 who were admitted to a large hospital with respiratory distress in the past five years. *This is an example of a chart review – a type of secondary data research.*
    b. Dylan is a psychology research nurse in a region with one of the highest rates of autism in North America. He has been tasked with using information in the Provincial Autism Registry to determine if there is a relationship between the child's age at diagnosis and his/her gestational age at birth. *This is an example of a disease registry – a type of secondary data research.*
    c. Jeff, a graduate student in the faculty of medicine, designs a survey to gauge the pre-pregnancy diet and physical activity of mothers with children who have been diagnosed with type-1 diabetes. The survey is distributed to families listed in a large diabetes registry and have indicated their consent to be contacted for research purposes. *This is <u>not</u> an example of secondary data research. Although the participants may be recruited from an existing database/registry, the data collected is novel and for the purpose of Jeff's specific study.*
    d. Dr. Turner, a neurologist at a large hospital, recently examined and cared for a man who had suffered an unusual head injury that produced an even more unusual set of symptoms – some that abated over the following weeks and others that did not. After a year of care and follow-up examinations, Dr. Turner published this patient's account in a clinical neurology journal. *This is an example of case report – a type of secondary data research.*

SUMMARY / RESIDENT WORKSHEET

Choosing the right study design for your project is an integral step in the research process. In this module, we have examined how your research capacity (time & resources) and research objectives might influence your choice of study design, described and compared a number of common study designs used in health research, discussed the role of secondary data research, and considered the various levels of evidence provided by different study designs in the literature. Now is a good time to put what you have learned into practice by determining which study design might best suit your own research project.

1. Consider how your own **research capacity** might impact your choice of study design by asking yourself the questions outlined in Section A. For example: What is your timeframe for carrying out this research project? How much time are you and/or your colleagues able to commit to research during that time? What resources will you have available that might influence your decision? Will you be able to find/recruit a large enough sample size (cases and/or participants) using the resources available?

2. Using the research question that you formulated in the previous modules, develop one or more **research objectives** that specify (as much as possible) what you aim to achieve and how (refer to Section B). The objective(s) should reflect the resources considered in the questions above (e.g. declaring a sample population and/or database that you would use), specific outcomes you might measure, and comparisons you would make.

3. Determine whether your study is **descriptive** or **analytical** in nature (refer to Section C). How does this influence the study design options that are available to you?

4. Consider potential **strengths, weaknesses and limitations** of each study design option in the context of your project. Do one or two stand out as obvious choices? *At this stage it would be a good idea to chat about your options and ideas with a supervisor or experienced researcher – before making a final decision.*

5. Once you have chosen a study design (and received the support/approval of your supervisor(s)), you can start planning your **next steps**. For example: How will you select cases or recruit participants? What sample size might be required (*see Module # for more details*)? Do you need a control/comparison group and, if so, how will you select it? How will you collect the data? What data collection tools (e.g. surveys, interview guide, chart review forms, etc) will you need and how will you prepare them to make sure you are collecting all the necessary data? **It may be helpful to develop a timeline to guide the various stages of your research project (e.g. participant selection, data collection, data analysis, writing) in order to keep things on track.**