**Research Methods in Health Promotion**

**Dr. Arista Lahiri**
**Dr. B.C. Roy Multi-Speciality Medical Research Centre,**
**Indian Institute of Technology Kharagpur**

**Week 12**

**Lecture 58: Report writing: quantitative research in health promotion (Part I)**

Hello. So in this week we were discussing regarding the different scientific writing techniques that we employ in our health promotion research. Till this point we have discussed how to write a good research proposal in health promotion and we also discussed in the last lecture regarding the different aspects of writing a good manuscript in health promotion. Now in this particular lecture we will be focusing on the report writing context that is writing your article or manuscript or in fact, the report of your research. We shall focus on the quantitative research methods only that means, the quantitative methodology that we employ in health promotion research we shall be focusing on those aspects, how to write a good report for a quantitative health promotion research. And in this particular lecture we shall cover the guidelines for reporting the observational studies and also we shall cover the stroke checklist and the different extensions it has.

So, mainly in this lecture we will be focusing on the observational studies in health promotion and basically how to write a good report on the observational studies. So, let us start our discussion with the reporting guidelines that we have for the observational studies. Now mostly the reporting guidelines that we have in health promotion research are you know taken from the core discipline of epidemiology. But the interesting part is the guidelines that we often employ in the study of epidemiology the same guidelines can be utilized when we are writing our health promotion research report.

So, this is the basic guideline that we have for the observational studies and see in even in health promotion research the observational studies that we perform they have the epidemiological bearing and they utilize the epidemiological study design. So, that is whenever we are writing the report for the health promotion research they should follow the basic epidemiological report writing guidelines and that is why we suggest that the reporting of observational studies in health promotion should follow the stroke checklist. Now what is stroke I have given the full form over here, stroke is strengthening the reporting of observational studies in epidemiology. This guideline is followed and we have different extensions of the stroke guideline as well let us first discuss the extensions because then it will be easier for us to understand how the original stroke guideline will help us in describing our own health promotion research. So, the stroke extensions these are like ME, ID, RDS like this.

So, what is ME? ME is whenever you are doing a molecular epidemiological study. So, again for observational studies you follow the stroke guidelines. So, whenever you are doing any

molecular epidemiological studies the guideline the extension is followed is called stroke ME it has certain extra points as compared to the normal stroke checklist. Then for infectious disease reporting you have ID, stroke ID. So, you can consider this as a bit of more of you know clinical study reporting format, but not case study please remember clinical epidemiological study.

So, RDS means where we are using respondent driven sampling we have discussed the different types of sampling and we also discussed about the respondent driven sampling during the discussion of selecting a good sample. So, whenever we have this kind of a study and it utilizes the stroke RDS format for reporting. Now apart from the many extensions these are some of the extensions that we have mentioned and these are perhaps the most prominent ones and this will give you an understanding that the stroke guideline even though it is used for a reporting of epidemiological studies they move way beyond the typical epidemiological designs and they move way beyond the typical concept of epidemiology. For example, you have the concept of molecular epidemiology built in you also have certain kinds of clinical epidemiological perspective when you are proposing certain infectious disease related article and even the stroke guideline can change when you have RDS respondent driven sampling. That means, based on your sample selection and some of the sample selection also depends on the study objective and the orientation of the study.

So, then again you have a whole different kind of a stroke extension. So, this this is the basic understanding of the stroke guideline that whenever we are utilizing any observational design we can utilize the stroke protocol or the stroke checklist right. We shall be discussing the combined checklist of the stroke in the subsequent slides. So, whenever we are utilizing this term combined. So, the natural question here is what do we really combine in this combined checklist.

Basically as we know that the observational study designs there are many types of designs like the simple simplest ones are the are the simple cross sectional designs it can be case control or it can be cohort even it can be case cohort like this we have discussed different designs in in the previous lectures. So, for each of those designs strobe has a different checklist. I would not say different because the difference in the in these checklist they are very minor and they depend on certain points. We shall get into the differences and the the different aspects when we discuss the stroke checklist subsequently. So, the basic understanding over here in this slide is that for our health promotion research whenever we are utilizing the observational design of enquiry we can utilize the strobe checklist for reporting our research.

We shall discuss the combined checklist, but whenever you are reporting your own research be very sure on what design you have used and use the checklist accordingly right. For example, if you use the cross sectional studies then utilize the stroke cross sectional study checklist for you know case control use the case control checklist and this extension for case cohort study if you have utilized the case cohort study you can utilize this extension, but

basically these are the four core strobe checklist that we use. Now that you have a clear understanding of what basically strobe checklist allows us to do and how it helps us in reporting our observational study let us start our discussion regarding the combined checklist that I have mentioned in the previous slide. In the last lecture we discussed about the different parts or different aspects or components of a good research manuscript. We discussed that often the research manuscripts are structured are structured in a way that first you mention a title then you move on to the abstract or summary section then you have a background or introduction next you have a methods then results then discussion and depending on the journal guidelines the conclusion can be a separate section or it can form just the last paragraph of the discussion and after that you mention the references of your article and then again the references will depend on the journal guidelines as well.

So, the strobe checklist or as a matter of fact, any of the checklist that will be discussing in this lecture and also in the next lecture they develop the guidelines for reporting of your article based on this structure of the manuscript. So, the first one is the title and also the abstract because based on the title and the abstract a reader will overall understand what research they are actually going to read. So, that is why in the checklist they have mentioned title and abstract together this is the first item in the checklist. What is the recommendation? Recommendation is indicate the studies design with a commonly used term in the title or the abstract. Now, the strobe checklist the or the strobe guidelines suggest that it is better to utilize the study design or state the study design either in the title or in the abstract, but in fact, it is always a good practice to mention this the study design in the title itself.

Particularly whenever you are utilizing the interventional design then it is better to mention the particular design in the title in the title of the study. But in this case in strobe we are studying the observational ones. So, you have a relaxation of mentioning the study design in the abstract of your article because in some instances the research hypothesis that you get or the research question that you are trying to answer through your object or through your research it is it forms the whole of the title and you do not get any space or any word left to mention the research design or as in some instances it happens that if you mention the research design in the title itself the title does not look engaging enough. So, these are the considerations when you can utilize this mention the study design in the abstract instead of the title. And obviously, if you mention the study design both in the title and also in the abstract it is always a good practice.

Another recommendation over here is that always try to mention always try to mention remember always the study design in the abstract. So, there is a choice for you to not mention the study design in the title, but in the abstract you obviously, have to mention the study design it is same for the observational studies and also for the interventional studies. So, it will be same for in the case of the strobe and also for the consort that will be discussing in the next lecture. Next is that provide in the abstract an informative and balanced summary of what was done and what was found. This is the aspect we were discussing in the last lecture that the abstract should provide an outline of your article and it should be a balanced summary.

That means, you should not write for example, if you have a 250 word limitation for your abstract then you should distribute the background methods results and the conclusion segment of your abstract in such a way that they appear similar I mean equitably distributed in nature. That means, you mention only the key points in the background what are the gaps, why you did the study in a line or two then in the methods you briefly mention how you did the study and if you have any newer method employed then you can detail the newer method a bit, but only in a line or two then you mention the key results not all the results that you have described in your research article. In the conclusion you just mention in again in a line or two the basic finding of your study and what you are proposing through this study. So, that is a balanced summary and it also provides sufficient information for the reader to understand what exactly to expect from this article. So, this is the guideline for the title and the abstract of your article.

Next we come to the major section of your of the of the manuscript that is the introduction. Now an introduction they have the guidelines for background or rational of the study. See we discussed regarding background rational again and again in the last two lectures when we discussed how to develop a research proposal and then how to develop a manuscript. This is the same thing in the manuscript the stroke guideline says that explain the scientific background why actually the study is required and what are the chain of research that led you to conduct your own research and the rational or justification for the investigation that you have reported. So, basically we usually form two or three paragraphs in the background section or the introduction section where we mention the background also include some of a bit of review of literature that highlights the gap in the existing literature and then we justify the study topic.

In our last lecture we mentioned that it depends on the journal guidelines also it depends on the on the nature of article that you are presenting where you put your objectives. We mentioned that it is better to mention the research hypothesis or research question then just to specify the objectives at the end of your introduction section. So, that is what the stroke guideline says although there is no typical guideline regarding the research question part, but under the objectives it says that state specific objectives including any pre specified hypothesis. So, they are more focused on the hypothesis aspect and in a way if you if you do not mention the research question it is always a good practice to clearly state the hypothesis because again the analytical techniques that you have used that should focus on the hypothesis and also the specified pre specified hypothesis will help the reader understand the objectives through which you have designed the study and conducted it. Now, the next question is how do we describe the methods? The stroke guideline says you divide the methods in these segments ok.

So, under study design what you can do is you have to present the key elements of the study design early in your paper. That means, whenever the method section or the methodology as per the journal guideline if the section starts you have to present the key elements of your study design. That means, what kind of study you have actually performed whether it is a quiz control study or a cross sectional study or a cohort study or any of the derivatives of the cohort study

like this you have to clearly state the design of your study and also you have to mention how the design was actually achieved. For example, in a in the study design if in in some case you have utilized the cross sectional design first and then after the cross sectional design you have utilized the case control design in such situations you have to mention the sequence of utilization of the designs. Again since the whole study is still the observational study you can utilize this stroke checklist for for reporting this complex kind of study.

Still you have to mention the study design in a bit detail in the beginning of your research or actually in the beginning of the method section. Next is the setting where you have conducted your study the stroke checklist says describe the setting locations and the relevant dates. That means, the timeline when you conducted your study typically the reviewers and the journals they are interested in how old the data you are presenting. That means, when you collected the data that is the matter of importance in this case. So, relevant dates should always include when you conducted your research or when you collected your data.

For example, here they have mentioned that including the periods of recruitment, exposure, follow up and data collection. See the periods of recruitment, exposure, follow up these are applicable I mean regarding the particular term follow up this is applicable when you are reporting a cohort study. But when you are reporting simply a cross sectional study it is believed that only mentioning the period of recruitment when you recruited all the participants whom you have studied that is sufficient to mention as part of the timeline of your study. And also you have to mention that we have discussed the duration of data collection when the data was collected. For example, you may recruit your participants say in 2022 and you start your data collection in 2023.

Now this has certain drawbacks of it. So, to make the reviewers to make the readers understand what could have transpired I mean between recruitment and your actual data collection you have to mention the timelines and if there are certain huge duration gaps it is better to mention the reason for such gap in this case. So, in setting we not only describe the locations or the preferred places I mean actual places where the study was done we also mention the timelines the relevant ones. Now regarding the participants see over here you know they have mentioned based on the study designs. For participants if you are reporting a cohort study you have to give the eligibility criteria the sources and methods of selection of the participants and also describe the methods of follow up.

So, that means, here methods it not necessarily means the measurement techniques or the questionnaire that you are utilizing. Here the methods of follow up and methods of selection of participant means what are the criteria that you used while you selected the participants, when you recruited and you decided that you should follow these participants for further suppose one year or two year or certain duration. Now, here there is a very interesting concept in cohort study or as a matter of fact, in survivor analysis we utilize the term or we use the

term censoring. That means, where we are stopping or where we are stopping to follow up a particular participant. So, after that point we call it a censored.

So, in cohort study you should mention if there is any censoring criteria or not. That means, after say development of a disease if a participant is developing a disease we are not following that participant anymore. So, that may be a criteria. So, that you have to mention and if a person suppose develops some other terminal illness then also we are not following up that participant. If this kind of criteria you have utilized in your research then you have to clearly state in this section and the participants.

For case control study you have to provide again the eligibility criteria who are eligible to be part of your of your study. Again the sources from where you are taking the participants the methods of case assignment how do you detect or how do you select the participant who will be a case and who will be a control. Typically in this case I mean in in in the situation of a case control study you have a set criteria like a case definition for in in the situation. You utilize that case definition to identify a recruited participant to be either in the case or in the control group. That means, here in the participant section for case control study you have to mention the criteria for calling a person as a case or we typically call it as a case description.

Next you have to give the rational for the choice of cases and control. Like why you have you have chosen the cases and control in this way if the case definition is not a standard one for example, if it is an operational definition that you have devised for the purpose of the study then you have to clearly justify why you have you have devised the case definition in this way. Again if it is a standard definition then it is always a good practice to use the reference of of that particular case definition. Now for the simplest form of observational research that is the cross sectional study you have to give the eligibility criteria and the sources and the methods of selection of participants. Similarly, here since you do not have any case assignment or assignment of exposure or any follow up it is quite simpler.

You have to simply put the eligibility criteria you have to put the resources I mean sorry the sources from where you have selected the participants. This part is same in all the types of the study and also the methods of selection of participants inclusion exclusion criteria like this these are all the same. Now another thing I would like to highlight over here is that for case control studies what you can have or even in in cohort studies what you can have you can have certain differing criteria inclusion and exclusion criteria for cases and controls or exposed and unexposed groups. Now if you have such differing criteria for inclusion and exclusion in the two study groups then again you have to mention it in this participant section and it is always a good practice again to mention why the difference in inclusion exclusion criteria was there for the different study groups. Next for again for cohort study if you have performed matching for match studies give matching criteria and the number of cases number of sorry exposed and unexposed.

Now matching is again a technique that we often utilize to get rid of certain confounding factors and also to make certain robust analysis. So for cohort study it is always better to mention based on which criteria you have matched. Again also for the case control study you have to mention based on which criteria you have matched the cases and controls. Usually the matching criteria are age, gender like this the simpler demographic variables which otherwise might have an effect of confounding when we are performing the statistical analysis. So in order to to omit that effect of confounding what we usually do is you may we match and it is always better to mention the matching criteria under the participant section.

For cohort study you mention the number of ultimate number of exposed and unexposed persons you have selected and for case control study mention the number of controls per case like like I will give you an example. What happens is typically we do a 1 is to 1 case control study that means, 1 is to 1 matching means you take one person in the case arm and you match another person in the control arm. That means, the number of cases will be equal to the number of controls in a case control study. See if you have a 1 is to 2 ratio of cases to control in that scenario what you have to do is you have to match 2 controls for 1 case. Now this can also become more complicated like among these 2 controls you can match one control based on age and another control based on gender.

For example, I am taking the issue of age and gender or among these 2 controls you can match one control based on age and gender of the case and one control based on simply the age. These are the different variations that can happen when we are employing matching and that is why under participant section you have to mention all of these issues. So that the reader or the reviewer gets a fair bit of idea about how the participants were selected, who are really the participants, where you are actually generalizing your study on among which population and why the differences in the selection criteria or selection mechanism if there is any. So, this is make this makes the participants section complete.

Next is the variables. So, the variables are perhaps the most important segment of the method section why because based on the variables you will be able to define the data analysis and based on the data analysis you will be able to make certain inferences. So, variables are perhaps the most important part of your study. So, we define the outcomes what are the outcome variables, what are your exposures exposures are typically utilized for the cohort study. The predictor variables if you have any hypothesis that these variables are predicting the outcome then if the predictor variables you have already selected or if you are just exploring what variables are associated or predicting the the outcome typically as we do it in a cross sectional study. You also mention that we are simply exploring and these variables can be the predictor again here also you are using the hypothesis that you have mentioned at the end of the introduction section and based on the hypothesis and the objectives you are specifying all these variables.

Also mention the potential confounders that you think may affect the result and the effect modifiers. Now, regarding the confounders and the effect modifiers we will be discussing very briefly when we discuss we discuss the the the analytical methods. So, I hope that part when where we discuss the effect modifiers how they are modifying the effect the mediators and also the confounders is clear till this point. Just remember that whatever we discussed the relationship you can put in a diagram of the interaction between the variables also what you can do is you can mention the the variables that you think are having these sort of effects that can actually change the relationship between predictors and outcomes. Then you have to mention the data sources or measurement how you have actually measured the variables for each variable of interest give sources of data and details of methods of assessment like you can directly collect data from the participants or you can collect data through a certain secondary secondary sources.

And you just simply have to mention how you have collected these data and how you have measured those variables. For example, with the help of any questionnaire or any other study tool and again you have to mention the the reliability and validity of those tools. Here you also mention about the bias although we usually do not make a separate segment of bias, but if we think certain bias might have been there we typically mention about the bias during the course of mention of the methods. For example, typically we we state about the bias when we are specifying you know the the variables. You have to mention the study size ideally wherever you are mentioning about the participants you can include the study size or the sample size as a matter of fact, what was the final sample size that you conducted your study.

And I mean you can use also a prior calculation that we calculated the sample size to be say 100, but ultimately we conducted the study on 90 participants. Then again you have to mention why the lower sample size was there or then you have to mention in statistical methods by appropriate power analysis that the the sample size that you have achieved is sufficient for the conclusions that you are providing. Now, the quantitative variables explain how the quantitative variables were handled in the analysis and if applicable describe which groupings were chosen and why. So, again this is about measuring the variables and in the statistical analysis what the stroke guidelines says is describe all the statistical methods. In the previous lecture also we mentioned that you have to mention all the statistical methods that you have used in the method section.

So, it is also explains that and specifically the methods that are used for control of confounding. Usually we control for confounding statistically you with the use of multivariate techniques, use of simple regression techniques like this you have to mention whether they those were utilized for control of confounding or not. Now also describe any methods that are used to examine any subgroups or in interactions these are the different concepts that basically changes the actual relationship between the predictor and the outcome. So, if there are any such method used you have to mention explain how missing data were addressed this is very important because in real in real life situation you will have you will encounter certain missing

data. So, either you can omit the data as a whole or you can simply omit the cells where where you find the missing data.

How you the missing data was handled you have to specifically mention it and how you get how the missing data was handled typically from the software outputs they mention how missing data they handled during the course of the analysis. So, this also you have to mention. Again for cohort study see you you will have loss to follow up you have to mention how you the loss to follow up was handled for case control study explain how the matching of cases were addressed. So, that means, after matching how you are proposing the analysis to go like this in cross sectional study only if applicable describe the analytical methods taking into account the sampling strategy. That means, if for in some cases you have utilized multiple levels of sampling then the multilevel model or multilevel quantitative technique may be appropriate.

So, in the in that situation only you have to mention like that and as we have mentioned finally, describing a sensitivity analysis or power analysis to showcase that your results that you gained are valid and reliable. And the results section you have to mention about the participants again in the method section how you have chosen the participants what are the number of participants who are the people in different groups what are the different criteria for follow up censoring etcetera you have mentioned. And results you report the number of individuals at each stage of the study for typically for the cohort study and for the case control and cross sectional study you define your study groups for case control you can compare the case and control based on certain simple demographic criteria. This is particularly important whenever you have employed matching based on certain criteria to showcase that because of matching the age groups in the two study groups they are not differing. So, these are the things that you have to mention this is simply the descriptive part and for typically where you have multiple stages of recruitment it is better to consider use of a flow diagram.

If you have sufficient information on non participation then it is always better to include the reasons that you have for non participation at each of the stages. Then the descriptive data you simply characterize the participants usually based on the demographic or the clinical or in this situation the different health behavioral or health behavior practice related aspects you have to just simply describe the participants. Now again you have to indicate the missing data for each variable usually we represent the missing data in the tables when where we represent our analysis and cohort summarize the follow up time for cohort study only. Regarding the outcome data this is the description of part where you have described all those issues the different variables and also the outcomes. Now regarding the outcome data in cohort study report the number of outcome events or the summary measures over time.

For example, you may have to report the incidence in this situation incidence of a new behavior or incidence or sustenance of a new behavior that may be a very important outcome data for our health promotion research. For case control report the numbers in each exposure

category or the summary measures of the exposure it is similar to you know understanding the outcome versus predictor relationship. So, similarly here the exposure may be certain health behaviors here you have to specify the numbers in terms of those health behaviors in a comparative way and simply for the cross sectional studies just report the number of outcomes events or simply the summary measures. The main results give the unadjusted estimate that means, here you are you are developing the hypothesis through a cross sectional study or you are testing the hypothesis in your case control or cohort study you are proposing something new. So, first you give the unadjusted estimates the crude multivariate results that you get and then you adjust for the different confounders or other factors.

Next report the category boundaries highest lowest like this and if relevant consider translating the estimates of risk into absolute risk for a meaningful time period that means, the the the relative risk means as we have discussed compared to say control cases have this much higher risk. It is always better if you can provide the during this duration this much amount of risk in a crude sense was observed more in the exposed route than in the unexposed say or in the control group like this. So, this makes the reader understand exactly what is the crude nature of the risk. Also if you have performed any other analysis that is not directly related to the objectives of your study, but a supplement to those you have to mention. The discussions part again you summarize the key results then you mention the limitations and you provide a cautious interpretation of ah the findings in your study also you compare with the existing literature and report it.

So, these are almost the similar things that we discussed and as a general measure in the previous lecture. For observational studies typically in the epidemiological study generalizability is a very important issue and also for large scale observational studies in health promotion as well we have to discuss regarding the generalizability of the result whether they are generalizable to a larger audience or not. And finally, you have to provide some other information typically the funding information is important. You have to mention whether any funding was received from any other sources and also you have to mention ah like whether there are any conflict of interest because of the funding or because of any other issue of the different authors with the results that you have presented. So, in conclusion I would like to emphasize that the strobe checklist is the checklist for the observational studies and you can utilize the strobe checklist for health promotion research as well.

There are different extensions, but we discussed the combined checklist and we showed how the checklist varies between cohort, case control and simple cross sectional study. I would again suggest you that whenever you are reporting your own research for health promotion research also utilize the particular checklist that is there for ah for ah say case control or cohort or cross sectional study. So, the checklists can be observed or can be downloaded, you know, from equator network website So, that is again a very useful resource for you. So, see equator network this is where you will get all the checklist. So, I suggest you go through the equator network website ah at least once after this lecture that is all for this lecture. Thank you.