OPEN ACCESS

Editorial

Biostatistics and Epidemiology International Journal

Statistics is an integral part of the scientific world

Manoj Kumar Yadav

IQVIA, India

Correspondence: Manoj Kumar Yadav, IQVIA, Mumbai Area, India, Tel +91-8237835306, Email manoj.bios@gmail.com

Received: February 05, 2018 | **Published:** February 20, 2018

Editorial

Dear readers, reviewers and editorial board members,

Greetings from Biostatistics and Epidemiology International Journal (BEIJ). In the modern era, the vital role of statistics is not only confined to medical research, but also is applicable in almost all disciplines of science. In this scenario, statisticians need to shoulder a bigger responsibility to contribute in scientific research by gaining expertise not only in statistics but also in the discipline they are deploying statistical principles. Statistics is not as straight forward asother disciplines, in which same principle is applicable in all circumstances (e.g. 'force is mass multiplied by acceleration' is always applicable). A biostatistician needs to first understand life science data well and then deploy appropriate statistical methods for the task (e.g. choosing parametric or non-parametric method). Due to vast expansions of medical research and epidemiology, biostatisticians have become an inherent part of health care research and this prestigious journal 'BEIJ' is dedicated to publishing research in this field. In this letter, I am trying to appeal to all reviewers and editorial board members to contribute to best of their efforts by selecting scientifically strong research material to be published in this journal, there by developing scientifically strong biostatistical talent across the globe. A request to all readers of this journal to not only read more and research material published in this journal but also create an awareness in the Biostatistics and Epidemiology society about the high standards of quality of research published here. We encourage all readers to submit their scientifically strong research material to be considered for publication. Let us contribute towards building a healthier world by performing high level of biostatistical research and showing it to the world by publishing in this prestigious journal. All the best!!!

On behalf of board members of BEIJ,

Dr. Manoj Kumar Yadav

Citation: Yadav MK. Statistics is an integral part of the scientific world. *Biostatistics Epidemiol Int J.* (2018);1(1): 1. DOI: 10.30881/beij.00002

OPEN ACCESS

Ology Press

Conceptual Paper

Biostatistics and Epidemiology International Journal

Processing of data and analysis

Dr Balkishan Sharma

Sri Aurobindo Medical College & PG Institute, India

Correspondence: Dr Balkishan Sharma, PhD, Associate Professor (Biostatistics), Department of Community Medicine, Sri Aurobindo Medical College & PG Institute, Indore (MP), India, Email bksnew@rediffmail.com and bksnew@gmail.com

Received: February 06, 2018 | **Published:** February 20, 2018

Introduction

Health research is essential in developing evidence-based interventions that will make a difference in mitigating health problems, promoting health and ultimately improving the quality of life. Data collected and compiled from experimental work, records and surveys should be accurate and complete. They must be checked for accuracy and adequacy before processing further. So far they lie in masses, are scattered in the records and in other words they are mixed and unsorted.

The processing of data and further analysis may be break up into three stages: (1) data management, (2) explanatory data analysis and (3) statistical analysis (testing and modeling). However, before proceeding for statistical analysis, researcher must consider the following raised points:

- ✓ Understand the process involved in data processing.
- ✓ Use computers to perform data processing.
- ✓ Distinguish between qualitative and quantitative data.
- ✓ Understand probabilities and their applications.
- ✓ Interpret summary statistics, graphical presentation and contingency tables.
- ✓ Commonly presented in the health literature.
- ✓ Carry out exploratory data analysis.
- ✓ Understand the process involved in estimations and hypothesis testing.
- ✓ Interpret the functions of confidence intervals and p-values.
- ✓ Understand statements in published articles relating to statistics.
- ✓ Use computers to perform some statistical analysis.

Exploratory data analysis involves examination of the data errors and describing data using summary statistics and graphical techniques (descriptive statistics). As data errors are often detected at this stage, the process of exploratory data analysis and data cleaning are typically iterative. The aim of this process is, for the researcher to gain familiarity with, and understanding of the data, in order to determine the approach to take, and methods to use in further statistical analyzes.

Data-processing techniques

Once the fieldwork has been completed, the information that has been gathered must be centralized and input to the computer. Data entry is tiresome work, but it isnecessary to accord it some attention because of inevitable errors in reading and entering the information, especially if it is not carried out by people accustomed to using a keyboard for data-entry. The computerized data can be stored in tabular form in a spreadsheet (e.g. Microsoft Excel, Lotus 123) or more compactly and efficiently in a relational database management system (e.g. Access, Oracle, dBase).

Methods of statistical processing

Statistics offers a range of methods, the choice of which will depend on four factors: (1) The type of variables: qualitative or quantitative; (2) The status of the variables: explanatory or dependent; (3) The number of variables: one, two or multiple and (4) the type of analysis: exploratory (descriptive) or confirmatory (inferential).

Scope and purpose

Data analysis is the process of developing answers to questions through the examination and interpretation of data. The basic steps in the analytic process consist of identifying issues, determining the availability of suitable data, deciding on which methods are appropriate for answering the questions of interest, applying the methods and evaluating, summarizing and communicating the results.

Analytical results underscore the usefulness of data sources by shedding light on relevant issues. Data analysis also plays a key role in data quality assessment by pointing to data quality problems in a given survey. Analysis can thus influence future improvements to the survey process.

Quality indicators

Main quality elements: relevance, interpretability, accuracy, accessibility. An analytical product is relevant if there is an audience who is (or will be) interested in the results of the study. For the interpretability of an analytical article to be high, the style of writing must suit the intended audience. Sufficient and relevant details must

Citation: Sharma B. Processing of data and analysis. *Biostatistics Epidemiol Int J.* (2018);1(1): 3-5.
DOI: 10.30881/beij.00003

be provided so that another person if allowed access to the data could replicate the results.

For an analytical product to be accurate, appropriate methods and tools need to be used to produce the results. For an analytical product to be accessible, it must be available to people for whom the research results would be useful.

Analysis of data

Data analysis converts data into information and knowledge, and explores the relationship between variables. Data Analysis is the process of systematically applying statistical and/or logical techniques to describe and illustrate, condense and recap, and evaluate data. According to Shamoo & Resnik[1] various analytic procedures "provide a way of drawing inductive inferences from data and distinguishing the signal (the phenomenon of interest) from the noise (statistical fluctuations) present in the data."

Understanding of the data analysis procedures will enable you to appreciate the meaning of the scientific method which includes testing of hypotheses and statistical significance in relation to research questions. There are a number of issues that researchers should be cognizant of with respect to data analysis. Some of the key considerations in analysis and selection of the right test of significance are as follows:

- ✓ Having the necessary skills to analyze.
- ✓ Distinguishing data types.
- ✓ Distinguishing different types of Statistical tests.
- ✓ Identify the selection of a right test.
- ✓ Determining statistical significance.
- ✓ Distinguishing between Parametric and Non-Parametric test with their applying criteria.
- ✓ Distinguishing between Correlation and Regression.
- ✓ Drawing unbiased inference.
- ✓ Inappropriate subgroup analysis.
- ✓ Lack of clearly defined and objective outcome measurements.
- ✓ Partitioning 'text' when analyzing qualitative data.
- ✓ Reliability and Validity.
- ✓ Extent of analysis.

Table 1 consists of common statistical tests. All tests which are described below are provided in the book titled *Intuitive Biostatistics* by Harvey Motulsky[2] and were performed by InStat, except for tests marked with asterisks. Tests labeled with a single asterisk are briefly mentioned in this book, and tests labeled with two asterisks were not mentioned at all.

Table 1 Common statistical tests

	Type of Data			
Goal	**Measurement (from Gaussian Population)**	**Rank, Score, or Measurement (from Non-Gaussian Population)**	**Binomial (Two Possible Outcomes)**	**Survival Time**
Describe one group	Mean, SD	Median, Interquartile range	Proportion	Kaplan Meier survival curve
Compare one group to a hypothetical value	One-sample *t* test	Wilcoxon test	Chi-square or Binomial test**	-
Compare two unpaired groups	Unpaired *t* test	Mann-Whitney test	Fisher's test (chi-square for large samples)	Log-rank test or Mantel-Haenszel*
Compare two paired groups	Paired *t* test	Wilcoxon test	McNemar's test	Conditional proportional hazards regression*
Compare three or more unmatched groups	One-way ANOVA	Kruskal-Wallis test	Chi-square test	Cox proportional hazard regression**
Compare three or more matched groups	Repeated-measures ANOVA	Friedman test	Cochrane Q**	Conditional proportional hazards regression**
Goal	**Measurement (from Gaussian Population)**	**Rank, Score, or Measurement (from Non-Gaussian Population)**	**Binomial (Two Possible Outcomes)**	**Survival Time**

Citation: Sharma B. Processing of data and analysis. *Biostatistics Epidemiol Int J.* (2018);1(1): 3-5. DOI: 10.30881/beij.00003

(Table 1 continuous..)

Quantify association between two variables	Pearson correlation	Spearman Correlation	Contingency Coefficients**	-
Predict value from another measured variable	Simple LR or Non LR	Nonparametric Regression**	Simple Logistic Regression*	Cox proportional hazard regression*
Predict value from several measured or binomial variables	Multiple LR* or Multiple Non LR**	-	Multiple Logistic Regression*	Cox proportional hazard regression*

*briefly mentioned in *Intuitive Biostatistics*[2]

**not mentioned in *Intuitive Biostatistics*[2]

Developments in the field of statistical data analysis often parallel or follow advancements in other fields to which statistical methods are fruitfully applied. Data is known to be crude information and not knowledge by itself. The sequence from data to knowledge is: *from Data to Information, from Information to Facts, and finally, from Facts to Verification of Truth*. Data becomes information, when it becomes relevant to your research problem. Information becomes fact, when the data can support it. Facts are what the data reveals. However, the decisive instrumental (i.e., applied) knowledge is expressed together with some statistical degree of confidence.

Lastly, I do hope that this in-depth knowledge will create an awareness to promote the use of statistical thinking and techniques to apply them to make educated decisions whenever there is variation in data.

References and further reading

1. Shamoo AE, Resnik DB. Responsible Conduct of Research. Third Edition. Oxford, New York: Oxford University Press. 2015;360p.
2. Motulsky H. Chapter 37: Choosing a test. In: Intuitive Biostatistics. *Oxford University Press Inc*. 1995.
3. Bland M. An Introduction to Medical Statistics. Fourth Edition. Oxford, New York: Oxford University Press. 2015;448p.
4. Daniel W. Biostatistics: A Foundation for Analysis in the Health Sciences. 4th ed. New York: Wiley. 1987.
5. http://www.emacpd.org/sites/default/files/resource_center/3.Data%20Processing%20Module.pdf
6. Korn EL, Graubard BI. Analysis of health surveys. *John Wiley & Sons*. 2011;323.
7. Lehtonen R, Pahkinen E. Practical methods for design and analysis of complex surveys. *John Wiley & Sons*. 2004.
8. Pagano M, Gauvreau K. Principles of Biostatistics. 2nd ed. *Duxbury Press*. 1990.
9. Sharma B. Right choice of a method for determination of cut-off values: A statistical tool for a diagnostic test. 2014.
10. Shamoo AE. Principles of research data audit. *Taylor & Francis*. 1989.
11. Sharma K. Chapter X. In: Nursing research and statistics. Haryana, India: Elsevier Health Sciences. 2011.
12. Shephard RJ. Ethics in exercise science research. Sports Medicine. 2002;32(3):169−183.
13. Silverman S, Manson M. Research on teaching in physical education doctoral dissertations: a detailed investigation of focus, method, and analysis. *Journal of Teaching in Physical Education*. 2003;22(3):280−297.
14. Smeeton N, Goda D. Conducting and Presenting Social Work Research: Some Basic Statistical Considerations. *The British Journal of Social Work*. 2003;33(4):567−573.
15. Thompson M. Theory of Sample Surveys. London: Chapman & Hall. 1997.

OPEN ACCESS

Ology Press

Conceptual Paper

Biostatistics and Epidemiology International Journal

Sample size calculation in cluster randomization clinical trials

Manoj Kumar Yadav

IQVIA, India

Correspondence: Manoj Kumar Yadav, IQVIA, Mumbai Area, India, Tel +91-8237835306, Email manoj.bios@gmail.com

Received: February 02, 2018 | **Published:** February 21, 2018

Abstract

The question of sample size is basic to the planning of any clinical study. When a survey is carried out using cluster sampling, between-cluster variation at each level of sampling contributes an additional source of variation, which must be allowed for in addition to between-subjects i.e. within cluster variation, to validly estimate parameters or to test their significance. The number of subjects needed for a cluster randomization trail is larger than for a study of the same power in which individual subjects are randomly sampled. In this paper, the illustrations are done to quantify the impact of increasing intraclass correlation on sample size.

Keywords: cluster randomized trials, intraclass correlation coefficient, variation inflation factor, sample size calculation, clinical research

Introduction

Cluster randomization trials (CRTs) are experiments in which entire social units or clusters of subjects rather than independent subjects are randomly allocated to intervention groups. For e.g. villages are selected as the randomization unit in clinical trials evaluating the efficacy of disease screening programs and schools are selected as the randomization unit in trials evaluating impact of nutritional pills on children's health. Randomizing individuals to treatments is not always feasible and cluster randomized trials are increasingly being utilized in the evaluation of health care interventions.[1] In school-based smoking intervention studies, randomization of schools rather than students to different treatment conditions is the usual approach to sampling.[2-3] CRTs are gaining popularity in health research to deal with large scale population surveys. There are few challenges in designing the CRTs, one, who may provide consent on behalf of a particular group and on what authority they may do so, another, in CRTs, the units of randomization and observation may not be the same, the group that receives the experimental treatment may not be the same as the group from which data are collected. For e.g. in trial assessing the surgical efficiency of two surgical instruments, surgeons are randomized to use surgical instruments by collecting post-operative pain scores on patients operated by surgeons. Weijer et al. have discussed these challenges in designing CRTs, the research community and regulators are persistently working on to conquer these challenges.[4] This research work is dedicated to address one of the challenge in calculating sample size for CRTs.

Intraclass correlation coefficient

The intraclass correlation coefficient ρ (ICC) measures the degree of similarity among responses within the same cluster. This parameter ρ may be interpreted as the standard Pearson's correlation coefficient between any two responses in the same cluster. In designing cluster-based randomized trials or intervention studies, accurate estimates of ICCs are required for sample size calculation to achieve desired power. In my earlier research, the ICCs at two and three levels have been illustrated in detail.[5-6]

Variation inflation factor

Variation inflation factor (VIF) is the ratio of the variance of an overall sample mean estimated from cluster means to the variance of an overall sample mean estimated from subjects within clusters. Generally VIF is a function of the average cluster size and the intraclass correlation coefficient (ICC) for the outcome variable under study i.e. $VIF = 1 + (\gamma - 1)\rho$ where γ is the average number of subjects per cluster and ρ is the ICC for the outcome variable. To estimate the required sample size, the design effect or variation inflation factor (VIF) must be incorporated into the sample-size calculation.[7] In my earlier research, the VIF at two and three levels have been illustrated in detail.[5-6]

Concepts

Consideration of units to be independent leads the situation of ignoring the variability at higher levels, thus having inferences with inflated power.[1,8-11] Nesting implies violation of the assumptions of independence of observations and ignoring this dependency in data yields inflated test statistics when observations are correlated.

Decisions have to be made first about the number of clusters which should be selected and second the number of units which should be selected from each cluster. Even very small ICC values may have a big impact on sample-size estimation. Several authors have discussed how to use ICC estimates in calculating the number of clusters needed per treatment to detect a treatment effect. It is illustrated below the

use of the ICC estimates for sample-size calculation in testing the hypothesis about the difference between means of two treatment groups. Type I error is fixed at α, and we want the test to have power $1-\beta$. If we were using simple random sampling (SRS), the sample size required would be:

$$N=\frac{2\sigma^2\left[Z_{1-\alpha/2}+Z_{1-\beta}\right]^2}{\delta^2}$$

Here, N is the number of subjects required per treatment group, $Z_{1-\alpha/2}$ and $Z_{1-\beta}$ are the values of standard normal variate for which the probability of smaller values is $1-\alpha/2$ and $1-\beta$ respectively, σ^2 is the variance (assumed common) in each treatment group, and δ is the difference in either direction in the treatment means which we would want to detect. If we fix the number of subjects per cluster at 'γ', the number of clusters 'n' required using SRS will be obtained from the above formula, by taking $N=n\gamma$. To take into account the intraclass correlation, we have to multiply the variance by a factor of VIF, the variation inflation factor. The number of clusters required using cluster sampling for each treatment group will be:

$$n=\frac{2\sigma^2\left[Z_{1-\alpha/2}+Z_{1-\beta}\right]^2 VIF}{\gamma\delta^2}$$

where $VIF=1+(\gamma-1)\rho$ and ρ is the intraclass correlation.[8-9]

Illustrations

This is the simulated case study to calculate sample size in a cluster randomization clinical trial to assess the effect of nutrients on height in infants completing 3 years. To detect the difference of 1.1 inches (34.5 and 33.4 inches in treatment and placebo groups respectively) with 6.2 inches of common standard deviation in both treatment groups with 5% type I error, Table 1 presents the total sample size per group with increasing ICC to achieve 80% power by considering 100 infants in each cluster, hence 100 is the average number of subjects per cluster.

Table 1 Sample size calculation with increasing ICC

Case	ICC	VIF	Total Sample Size per Group	% Increase in Sample Size as Compared to SRS
1	**0.000**	**1.000**	**500**	**SRS Case**
2	0.001	1.099	550	10
3	0.002	1.198	599	20
4	0.003	1.297	649	30
5	0.004	1.396	698	40
6	0.005	1.495	748	50
7	0.006	1.594	797	59
8	0.007	1.693	847	69
9	0.008	1.792	896	79
10	0.009	1.891	946	89
11	**0.010**	**1.990**	**996**	**99**
12	0.020	2.980	1491	198
13	0.030	3.970	1986	297
14	0.040	4.960	2481	396
15	0.05	5.950	2977	495
16	**0.100**	**10.900**	**5453**	**991**

Discussion and conclusion

By focusing on Table 1, case 1 with ICC=0 represents the SRS and total sample size per group is 500. Based on this SRS case, the sample size and % increase in sample size with respect to SRS is calculated with increasing ICC. In case 2, even a very small ICC=0.001, increases the sample size by 10%, almost same amount of increment in sample size is evident with an increase in sample size by 0.001. In case 11, ICC=0.01 increases total sample size by almost two fold. In case 16, ICC=0.1 increases the sample size by almost 10 fold. Figure 1 showing an increasing trend, depicts the impact of increasing ICC on sample size. Conclusively, role of even a very small ICC can't be ignored while designing the CRTs. To draw inferences from cluster randomized clinical trials, more sample size is required to produce the same power as compared to SRS schemes. The VIF and ICCs have to be supplemented into sample size calculations in order to furnish precise sample size to meet power requirement.

Citation: Yadav MK. Sample size calculation in cluster randomization clinical trials. *Biostatistics Epidemiol Int J.* (2018);1(1): 7-9. DOI: 10.30881/beij.00004

Acknowledgement

This research work is dedicated to my late grandfather Shudarshan Lal Yadav and his two brothers Kanhaiyaa Lal Yadav, Sardar Singh Yadav who created my endless interest in research. Special thanks goes to my PhD supervisor Prof. G. G. Agarwal. The suggestions and comments from two anonymous referees contributed greatly to improve the final manuscript.

References

1. Donner A, Klar N. Design and analysis of cluster randomization trials in health research. *London Arnold*. 2000.
2. Murray DM, Hannan PJ. Planning for the appropriate analysis in school-based drug-use prevention studies. *J Consult Clin Psychol*. 1990;58(4):458−468.
3. Donner A. A regression approach to the analysis of data arising from cluster randomization. *Int J Epidemiol*. 1985;14(2):322−326.
4. Weijer C. Ethical issues posed by cluster randomized trials in health research. *Trials*. 2011;12:100.
5. Yadav MK, Agarwal GG. On Estimation of standard error of intra-class correlation coefficient in unbalanced nested designs. *Commun Stat Theory Methods*. 2013;42:88−97.
6. Yadav MK. Estimating standard error of intra-class correlation coefficients up to three level unbalanced nested clinical trials. *Commun Stat Theory Methods*. 2016;44(22):6688−6699.
7. Kish L. Survey sampling. New York: John Wiley & Sons, Inc. 1965.
8. Snijders AB, Bosker RJ. Multilevel analysis: an introduction to basic and advance level multilevel modeling. London: Sage. 1999.
9. Agarwal GG, Awasthi S, Walter SD. Intra-class correlation estimates for assessment of vitamin A intake in children. *J Health Popul Nutr*. 2005;23(1):66−73.
10. Siddiqui O, Hedeker D, Flay BR, Hu FB. Intraclass correlation estimates in school-based smoking prevention study. *Am J Epidemiol*. 1996;144(4):425−433.
11. Gulliford MC, Ukoumunne OC, Chinn S. Components of variance and intraclass correlations for the design of community-based survey and intervention studies. *Am J Epidemiol*. 1999;149(9):876−883.

OPEN ACCESS

Review

Biostatistics and Epidemiology International Journal

Epidemiology and management of chronic renal failure: a global public health problem

Adekunle Sanyaolu,[1] Chuku Okorie,[2] Rochelle Annan,[3] Hanin Turkey,[3] Nofil Akhtar,[3] Fernanda Gray,[3] Kareem Hamdy,[3] Ainura Isina,[3] Gajendra Maharjan,[3] Watik Maghroudi,[3] Ifeanyi Chukwu Nwaduwa[3]

[1]Federal Ministry of Health, Abuja, Nigeria

[2]Essex County College, Newark, New Jersey, USA

[3]Saint James School of Medicine, Anguilla, BVI

Correspondence: Dr Adekunle Sanyaolu, Federal Ministry of Health, Abuja, Nigeria, Email sanyakunle@gmail.com

Received: February 02, 2018 | **Published:** February 26, 2018

Abstract

Chronic kidney disease is an emergent worldwide public health problem. The increasing incidence of chronic renal failure warrants a need for an epidemiological approach to better understand the disease and its prevention. While statistics have been identified concerning world demographics, there is not enough information on how to better prevent and screen for this disease. There is evidence on the global distribution suggesting that chronic renal failure is a growing issue in developed and developing countries. While screening and intervention can prevent chronic kidney disease, awareness of the disorder, however, remains low in many communities and among many healthcare workers hence, this paper explores the epidemiology, diagnosis, treatment and management of chronic kidney disease.

Keywords: epidemiology, chronic kidney diseases, glomerular filtration rate, end-stage renal disease

Introduction

Disease morbidity and mortality patterns all over the world are changing, both in the developed and the emerging world. Throughout the 20th century, infectious diseases were the major cause of death and disability. Nonetheless in this century, non-communicable, noninfectious diseases have become the main cause of mortality and morbidity around the world.[1] This change is mirrored in the type of diseases causing chronic kidney failure and in their presentation and progression.[2]

Kidney disease is evaluated in terms of overall renal function (glomerular filtration rate, GFR) and the presence of kidney damage established by either kidney biopsy or other markers of kidney damage.[3] Chronic kidney disease (CKD) is a common condition in which there is a loss of kidney function over time. CKD is associated with increased risks of several co morbidities; not limited to but including cardiovascular disease and chronic renal failure.[4]

Chronic kidney disease is an emergent worldwide public health problem. In the United States, the prevalence of end-stage renal disease (ESRD) is increasing.[5] CKD is increasingly common in developed and developing nations.[2]

Screening and intervention can prevent chronic kidney disease, and where management strategies have been implemented the incidence of end-stage kidney disease has been reduced. Awareness of the disorder, however, remains low in many communities and among many physicians.[6]

There is a greater need in understanding of the mechanisms underlying renal scarring leading to ESRD to advise on current and future interventions as well as evidence relating to interventions to slow the progression of CKD. Strategies to reduce burden and costs related to chronic kidney disease need to be included in national programs for non-communicable diseases.[6] This paper aimed at exploring the epidemiology, diagnosis, treatment and management of chronic kidney disease.

Methodology

A literature search for chronic kidney diseases (CKD) and end stage renal diseases (ESRD) was carried out. Articles were retrieved by performing searches using online electronic databases (Pub Med, Medline plus, Mendeley, Google Scholar, Research Gate, Global Health and Scopus). Articles were streamlined to epidemiology and management of CKD and ESRD. Titles and abstracts of these results were reviewed and selected for inclusion based on relevancy to the research question. Overall, 30 articles and references were utilized for the study.

Epidemiology: incidence and prevalence of chronic renal failure

The growth of the population with ESRD is related to under recognition of earlier stages of Chronic Kidney Disease. The incidence of ESRD

being treated by dialysis varies enormously depending on the level of affluence of the country. The highly developed countries, such as North America, Europe and Japan have the highest incidence rate of ESRD (Figure 1).[7] There are over 1 million dialysis patients worldwide, with an incidence of about a quarter million per year. In the United States, the overall prevalence of CKD increased from 12 percent to 14 percent between 1988 and 1994 and from 1999 to 2004 but has remained relatively stable since 2004. The largest increase occurred in people with Stage 3 CKD, from 4.5 percent to 6.0 percent, since 1988.[8] Also in the United States, incidence of CKD is increasing most rapidly in people ages 65 and older which more than doubled between 2000 and 2008 (Figure 2).[9] The incidence among 20- to 64-year-olds is less than 0.5 percent. ESRD incident rates are more than three times higher for African Americans than for Caucasians (Figure 3).[9] The major cause of ESRD is diabetes and hypertension. Over the decades the United States Renal Data System (USRDS) figures demonstrates a progressive increase in the number of diabetics entering End Stage Renal Failure (ESRF) programs. About 44% of all incidence patients are diabetics. Glomerulonephritis and cystic kidney disease also remain relatively steady as a cause of ESRD.[7] Diabetes is the major cause of ESRD worldwide, in both developing and developed countries (Figure 4). In Australia the incidence of ESRD due to diabetes is about 25% (Figure 5) as well in European Union registry, the number of diabetics entering ESRF programs is about 15% - 33% while the number entering due to glomerulonephritis is about 9% - 20%.[10-11]

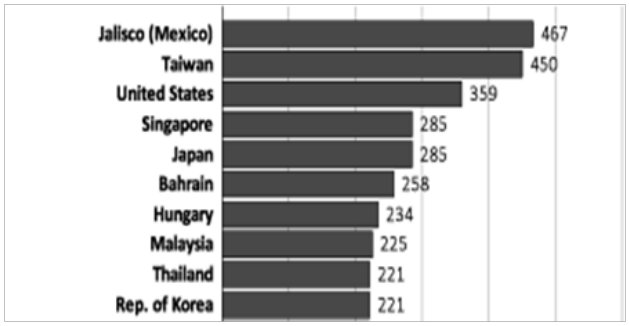

Figure 1 Incidence rate of ESRD (per million populations) for the top 10 countries in 2012 [7].

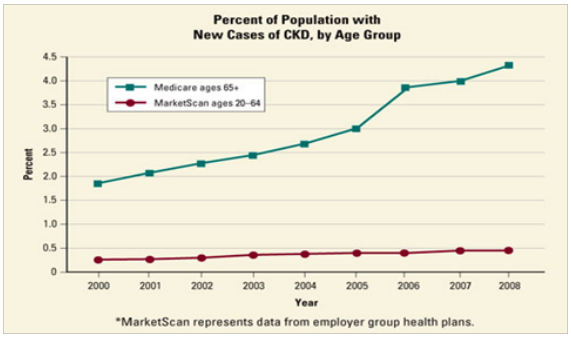

Figure 2 Percentage of population with new cases of CKD, by age group [9].

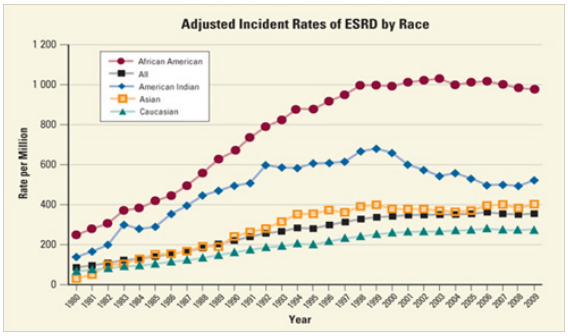

Figure 3 Adjusted incident rates of ESRD by race [9].

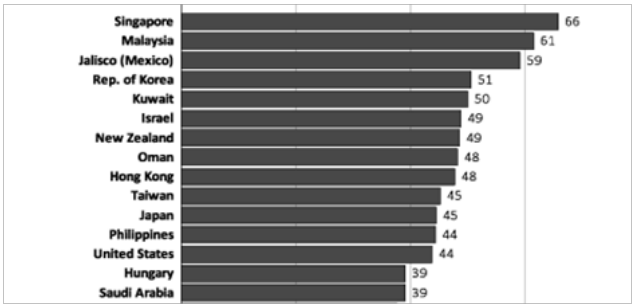

Figure 4 Percentage of incident ESRD patients with diabetes as the primary ESRD cause for the top 15 countries in 2012 [7].

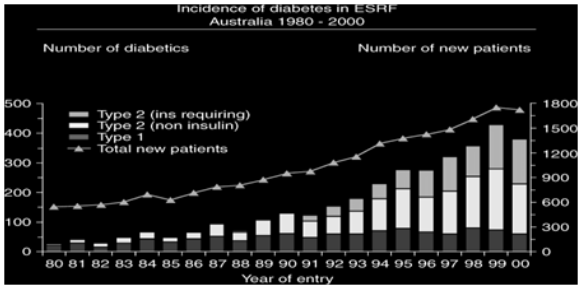

Figure 5 Incidence of diabetes in ESRF Australia 1980-2000 [2].

In developed countries, CKD is normally associated with old age, diabetes, hypertension, obesity, and cardiovascular disease; diabetic glomerulosclerosis and hypertensive nephrosclerosis are the presumed pathological finding; the exact diagnosis is however often difficult. In developing countries, common causes of CKD also include glomerular and tubule-interstitial diseases due to infections and exposure to drugs and toxins.[12] Sub-Saharan Africa is a vast heterogeneous region of roughly 47 countries and more than 900 million people. By 2030, more than 70% of patients with end-stage renal disease are estimated to be living in low-income countries, such as those in sub-Saharan Africa. There are many potential causes of CKD in sub-Saharan Africa, making kidney disease especially burdensome in the region. In addition to non-communicable diseases, communicable diseases such as infectious glomerulonephritis, schistosomiasis, leishmaniasis, and HIV infection are common and can cause CKD. Because more than 22 million people in sub-Saharan Africa have HIV, the potential for an overwhelming burden of CKD in the region is high.[13]

Citation: Sanyaolu A, Okorie C, Annan R, et al. Epidemiology and management of chronic renal failure: a global public health problem. *Biostatistics Epidemiol Int J.* (2018);1(1): 11-16. DOI: 10.30881/beij.00005

Among the general population in Africa (Figure 6), CKD prevalence was reported to range from 2% to 41% (pooled estimate: 16.5%) in the West/Central-West, in the Central region the prevalence ranged from 12% to 17% (pooled estimate: 16%), in the Southern region the CKD prevalence range was 6%–29% (pooled estimate: 12.2%), in the Eastern region, the prevalence ranged from 7% to 15% (pooled estimate: 11.0%), and in the North region, the prevalence ranged from 3% to 13% (pooled estimate: 4%). In sub-Saharan Africa, the prevalence ranged from 2% to 14% (pooled prevalence: 14.02%; 95% CI 13.5% to 14.5%).[14]

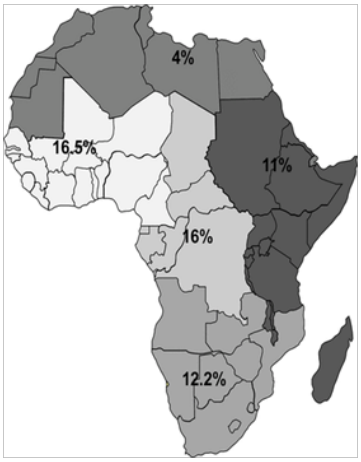

Figure 6 Prevalence of chronic kidney disease among the entire general population. Estimates from this figure should be presented with caution as it is bound to be imprecise and inaccurate due to its tentative way of estimation.[14]

Classification and staging

The Kidney Disease Outcomes Quality Initiative (KDOQI) of the National Kidney Foundation (NKF) defines chronic kidney disease (CKD) as kidney damage (structural or functional) or a decreased glomerular filtration rate (GFR) of less than 60 mL/min/1.73 m^2 for 3 or more months.[15] KDOQI has also established a five-stage classification system of CKD, which is based mainly on glomerular filtration rate (GFR) (Table 1). New equations that show enhanced precision and accuracy of GFR have been developed, such as the Chronic Kidney Disease Epidemiology Collaboration equation. GFR can be estimated using creatinine and cystatin C. Estimating GFR using creatinine alone has been shown to over diagnose CKD and it has been proposed that combination creatinine-cystatin C equation performed better than either of these markers alone.[15] Risks of complications at any given GFR are modified by the amount of proteinuria and KDOQI has implemented the inclusion of both estimated GFR and albuminuria. In stage 1, the kidney function is normal with other evidence of kidney disease, in stage 2, the function is mildly reduced and in stage 3 eGFR is approximately 30-60%. In stages 1 to 3 CKD should be confirmed with other diagnostic evidence proteinuria or hematuria, a genetic diagnosis of kidney disease (polycystic kidney disease) or evidence of structurally abnormal kidneys (reflux nephropathy), medication review (nephrotoxic drugs) and imaging to exclude obstruction. Patients in stages 1 to 3 can be managed in primary care with aim in reduction of associated risks, such as cardiovascular events, the risk of which is increased with CKD. The risk of cardiovascular death is much higher than the risk of the patient needing dialysis or a renal transplant. Patients should be advised on smoking and lifestyle changes and cholesterol lowering therapy should be considered if there is already a presence of macrovascular disease. In stages 4 and 5 clinical manifestations of CKD are apparent due to low kidney function and patients should be promptly seen by kidney specialist with very low GFR (<15 mL/min/1.73 m^2) or very high albuminuria (>300 mg/24 hours).[15–17]

Table 1 Stages of chronic kidney disease according to Kidney Disease Outcomes Quality Initiative (KDOQI)[17]

Stage	Description	GFR (mL/min/1.73 m^2)
1	Kidney damage with normal or increased GFR	>90
2	Mild reduction in GFR	60-89
3	Moderate reduction in GFR	30-59
4	Severe reduction in GFR	15-29
5	Kidney Failure	<15

Signs and symptoms

Signs and symptoms of CKD develop over time if kidney damage progresses slowly. Both signs and symptoms of kidney disease are often nonspecific, and can be caused by other illnesses. Due to the kidneys high adaptability to compensate for lost function; signs and symptoms may not appear until irreversible damage has occurred. The early symptoms and CKD are the same for many other illnesses.[18] The signs and symptoms of kidney disease can be seen in Table 2.

Table 2 Signs and symptoms of kidney disease

Early stages of renal failure	Kidney function worsening	End stage renal failure
Appetite loss	Abnormally light or dark skin	Anemia (may begin earlier)
Fatigue and weakness	Drowsiness	Difficulty breathing (fluid in lungs)
Pruritis and dry skin	Numbness	Nocturia
Nausea	Breath odor	Swelling and puffiness of feet and ankles
Weight loss without trying to lose weight	Frequent hiccups	High blood pressure
Decreased mental sharpness	Blood in stool	Changes in menstrual cycle
Muscle twitching, cramps	Problems sleeping	Poor digestion

Differential diagnosis

The differential diagnosis with CKD is a challenge owing to the overlapping clinical features. Making the distinction between CKD can be very difficult. A history of chronic kidney disease is usually silent. Therefore, differential diagnosis relies heavily on laboratory evaluation and diagnostic imaging. Nonetheless, a careful history and examination will often reveal clues to the correct diagnosis. Differential diagnosis includes acute kidney injury, diabetic neuropathy, glomerulonephritis, nephritic syndrome and systemic lupus erythematosus.[19]

Citation: Sanyaolu A, Okorie C, Annan R, et al. Epidemiology and management of chronic renal failure: a global public health problem. *Biostatistics Epidemiol Int J*. (2018);1(1): 11-16. DOI: 10.30881/beij.00005

Pathophysiology

Briefly, chronic renal failure is characterized by a gradual loss of kidneys function. The kidneys function as the body main excretory organs eliminating the body's metabolic waste products by filtering blood. Substances that are unneeded or present in excess are filtered out of the blood and forming the urine. By adjusting the blood composition, the kidneys are able to maintain blood volume and pressure, ensuring a balance of Sodium (Na^+), Chloride (Cl^-), Potassium (K^+), Calcium (Ca^{2+}), Hydrogen (H^+) and pH and eliminating urea, uric acid and creatinine.[12]

Treatment and management

Once there is diagnosis of chronic renal failure, there is an attempt to determine the cause and put into practice a specific treatment plans. Nonspecific plans can be implemented to delay or possibly arrest the progressive loss of kidney function.

Non-specific treatment plans

Control hypertension: Controlling hypertension is important to slow the progression of kidney damage. ACE inhibitor class of antihypertensive drugs is preferably used because of its protective effect on kidney. The main target of the treatment is to bring the blood pressure down to the range of systolic 120 to 135 mm of Hg and diastolic pressure of 70 to 80 mm of Hg. Two meta-analyses have looked at the effect of adding ARB treatment to ACE inhibitors in patients with CKD. These show that combination treatment reduces proteinuria (≥0.5 g/day, approximately equivalent to a protein/creatinine ratio of 50 mg/mmol) more than ACE inhibitor alone in both patients with diabetic and non-diabetic kidney disease.[20]

Restrict dietary protein: Dietary protein is broken down into amino acids and absorbed from the stomach into blood. Our body use amino acid to build muscle and perform other essential functions. Excess amino acids are broken down into carbohydrate and nitrogen-containing waste that is eliminated by the kidneys. More intake of dietary protein intake means more jobs for the kidney eliminating the more waste products. This process may further damage kidney and speed up the Progression of CRF.[20]

Manage pre-end-stage renal disease (pre-ESRD): Treatment of pre-ESRD should begin once the GFR drops below 30 ml/min. Anemia often develops because the kidneys produce an inadequate amount of erythropoietin (EPO). Erythropoiesis stimulating agents should be considered in all patients with anemia of CRF to improve their quality of life. In patients with chronic kidney disease treated with erythropoiesis stimulating agents (epoetins) the hemoglobin should normally be kept between 100 g/l and 120g/l with a warning not to exceed a concentration of 120g/l.[20]

Identify and treat secondary hyperparathyroidism: Secondary hyperparathyroidism can occur when the parathyroid glands over produce parathyroid hormone in an attempt to help the body to increase the amount of calcium in the blood.[19] The patient cannot absorb enough calcium in their diet and there is loss of control of calcium and phosphorus. Patients with secondary hyperthyroidism should restrict dietary phosphorus intake when phosphate or parathyroid hormone levels begin to rise.[20] Most patients require a potent vitamin D supplement, which will help suppress excess PTH production. Cinacalcet hydrochloride may be used alone or in combination with vitamin D supplements or phosphate-binders to treat patients with secondary hyperparathyroidism who are on dialysis.[21-22]

Relieve swelling: Retention of fluids is common in chronic renal failure. This can lead to swelling in the legs and ankles. When the kidneys cannot keep up with waste and fluid clearance on their own, they may fail near completely or completely. Different procedures involved in Renal Replacement Therapy (RRT) include:

Specific treatment plans

Hemodialysis: Removal of toxic elements from the blood by filtering blood through a membrane while circulated outside of the body.

Peritoneal dialysis: A catheter is inserted into the abdomen, fills the peritoneal cavity with a dialysis solution that absorbs waste and excess fluids. Waste products are filtered through the lining membrane of the abdominal cavity. After a period of time, the dialysis solution drains from the body carrying the waste materials.

Kidney transplantation: Kidney transplants involve surgically replacing a healthy kidney from a donor and removing damaged kidney of the CRF patient. Transplanted kidneys can come from deceased or living donors. Patients will require medication for the duration of life to prevent the new kidney from being rejected.[20–22] At 85.5 %, the 5-year survival rate for transplant patients is more than twice the 35% survival rate for dialysis patient (Figure 7). In the United States, it is estimated that perhaps 6,000 persons whose life spans could be appreciably prolonged through treatments already known, die every year from chronic renal disease. Majority of these people are 15-54 years old. Currently, it is estimated that approximately 1,000 - 1,100 receive available treatment, 850 are on dialysis and 150-200 receive kidney transplants annually.[9]

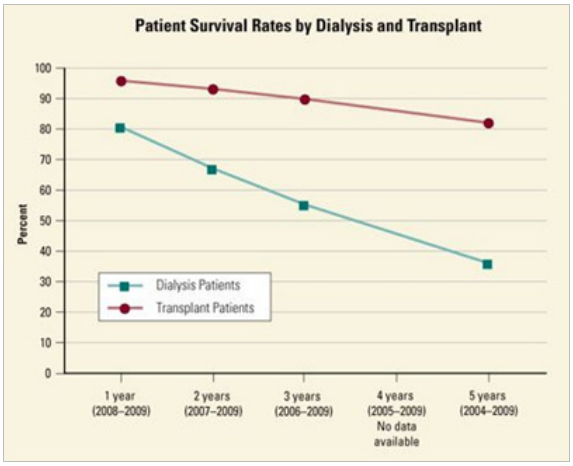

Figure 7 Patient survival rates by dialysis and transplant graph [9].

Current and future research in disease prevention and management of CKD

When attempting to treat chronic kidney failure, many efforts are used to help diagnose and treat the underlying cause(s). However, when the kidneys are failing due to some of the previously mentioned causes,

Citation: Sanyaolu A, Okorie C, Annan R, et al. Epidemiology and management of chronic renal failure: a global public health problem. *Biostatistics Epidemiol Int J.* (2018);1(1): 11-16. DOI: 10.30881/beij.00005

laboratory tests can help determine kidney function and allow for early diagnosis and prevention, and reversal of complications before progression to chronic renal failure.

Many researchers are focusing on identifying genetic markers that may help predict those who may be at risk of developing kidney damage by observing key biochemical pathways.[23] This mechanism can be valuable element in allowing for early detection and diagnosis of the disease process. If the disease is caught in its early stages, this will permit effective treatment plans with improved outcomes and increased prevention of the disease. One of the ways researchers are looking to provide additional years without dialysis for CKD patients is to treat and manage the diabetes and hypertension from a very early stage.[24]

Lifestyle modifications for individuals that are at risk and management programs for patients currently suffering from disease, can then lead to a decreased number of individuals progressing to the advanced/chronic and irreversible stage. Programs are available to screen individuals based on factors such as race, family history of chronic renal failure, as well as individuals aged older than 60.[25] Current research in regards to better strategies being used to prevent scarring includes using immunosuppressive therapy.[25] Overall there are many ways to diagnose and treat patients who may acquire chronic kidney failure. Current researches with various drugs are in the beta testing stage. Researchers are now looking at these drugs in order to help minimize fibrosis of the kidneys which contributes to the failing of the kidneys.[24] Researchers are looking into whether or not more frequent dialysis treatments improve function of kidneys, as well as the cardiovascular system long term. For patients undergoing hemodialysis regularly, there are many ways in which scientists are looking to use a fistula in order for the body to have access to a constant pool of blood. Kidney transplantation always remains an option, however chronic regeneration often comes into play and the patient often ends up losing the transplant.[26] On the public health approach, there is the need for more research efforts aimed at measuring and tracking the CKD burden, identifying at risk populations, as well as targeting program efforts.[27]

Discussion and conclusion

Incidence of ESRD is on the increase worldwide at an annual growth rate of 8%, far more than the population growth rate of 1.3%. Only about 15% of the world populations are receiving hemodialysis worldwide, with about 80% being treated in Europe, North America, and Japan. Only about twenty percent receive treatment in 100 developing countries which make up over 50% of world population, with some proportion of those living in the poorest countries dying of uremia due mainly to absence of renal replacement therapy.[28] CKD issues extends beyond a clinical problem that can be addressed only by health care providers to a major public health issue that demands multilevel efforts because CKD is not being diagnosed early enough to initiate treatment regimens and reduce death and disability; also several interventions are being delivered too late to improve population-based outcomes and most individuals with the disease are unaware of having this disorder; hence, there is the need to make health care providers and the general population more aware of the seriousness of the disease, its risk factors, and opportunities for screening. Those identified with the diseases should be provided with appropriate education that explains the treatment regimens and the benefits of undertaking therapy.[27]

Other early intervention includes reducing obesity, hypertension, diabetes and indiscriminate use of non-steroidal anti-inflammatory drugs. At the primary health care level, a proactive approach is required that will help in early detection of the disease. Hence providing adequate nephrology services as well as taking measures to achieve a quantum leap in cadaver kidney donation is essential for affected population.[29] The burden of CKD, as measured by human suffering and economic costs, is on the rise; thus a comprehensive public health approach is required.[30]

Chronic renal failure is a global issue. While there is still no cure, it is evident that further funding and research is needed to understand the disease, create enhanced screening tools and methods, and education so more can be learned in hopes of better prevention and an ultimate cure.

Conflict of interest

The authors wish to declare no conflicts of interest.

References

1. Yach D, Hawkes C, Gould CL, et al. The global burden of chronic diseases: overcoming impediments to prevention and control. *JAMA*. 2004;291(21):2616−2622.
2. Atkins RC. The epidemiology of chronic kidney disease. *Kidney Int Suppl.* 2005;67:S14−S18.
3. Couser WG, Remuzzi G, Mendis S, et al. The contribution of chronic kidney disease to the global burden of major noncommunicable diseases. *Kidney Int*. 2011;80(12):1258−1270.
4. https://emedicine.medscape.com/article/238798-clinical
5. Obrador GT, Pereira BJ, Kausz AT. Chronic kidney disease in the United States: an underrecognized problem. In: Semin Nephrol. *Elsevier.* 2002;441−448.
6. Jha V, Garcia-Garcia G, Iseki K, et al. Chronic kidney disease: global dimension and perspectives. *Lancet*. 2013;382(9888):260−272.
7. https://www.usrds.org/2014/view/img_v2_10.html
8. National Institutes of Health. Kidney disease statistics for the United States. Washington, DC. 2016.
9. National Institutes of Health. Kidney Disease Statistics for the United States. Washington, DC. 2012.
10. McDonald SP. Australia and New Zealand dialysis and transplant registry. *Kidney Int Suppl*. 2015;5(1):39−44.
11. Stel VS, Kramer A, Zoccali C, et al. The 2007 ERA-EDTA registry annual report—a precis. *NDT Plus*. 2009;2(6):514−521.
12. Levey AS, Coresh J. Chronic kidney disease. *Lancet*. 2012;379(9811):165−180.
13. Stanifer JW, Jing B, Tolan S, et al. The epidemiology of chronic kidney disease in sub-Saharan Africa: a systematic review and meta-analysis. *Lancet Glob Health*. 2014;2(3):e174−e181.
14. ElHafeez SA, Bolignano D, D'Arrigo G, et al. Prevalence and burden of chronic kidney disease among the general population and high-risk groups in Africa: a systematic review. *BMJ Open*. 2018;8(1):e015069.
15. Levey AS, Eckardt K-U, Tsukamoto Y, et al. Definition and classification of chronic kidney disease: a position statement from Kidney Disease: Improving Global Outcomes (KDIGO). *Kidney Int.* 2005;67(6):2089−2100.

Citation: Sanyaolu A, Okorie C, Annan R, et al. Epidemiology and management of chronic renal failure: a global public health problem. *Biostatistics Epidemiol Int J*. (2018);1(1): 11-16. DOI: 10.30881/beij.00005

16. Levey AS, Eckardt K-U, Tsukamoto Y, et al. Definition and classification of chronic kidney disease: a position statement from Kidney Disease: Improving Global Outcomes (KDIGO). *Kidney international*. 2005;67(6):2089−2100.

17. Inker LA, Schmid CH, Tighiouart H, et al. Estimating glomerular filtration rate from serum creatinine and cystatin C. *N Engl J Med*. 2012;367(1):20−29.

18. http://www2.kidney.org/professionals/KDOQI/guidelines_ckd/p9_approach.htm

19. http://www.mayoclinic.org/diseases-conditions/chronic-kidney-disease/symptoms-causes/syc-20354521

20. Rolfo A, Attini R, Nuzzo AM, et al. Chronic kidney disease may be differentially diagnosed from preeclampsia by serum biomarkers. *Kidney Int*. 2013;83(1):177−181.

21. Stevens PE, O'Donoghue DJ, de Lusignan S, et al. Chronic kidney disease management in the United Kingdom: NEOERICA project results. *Kidney Int.* 2007;72(1):92−99.

22. http://www.sign.ac.uk/assets/sign103.pdf

23. Ramage IJ, Durkan AM. Principles of management in chronic renal failure. *Paediatr Child Health*. 2003;13(7):496−501.

24. Klarman HE, Rosenthal GD. Cost effectiveness analysis applied to the treatment of chronic renal disease. *Med Care*. 1968;6(1):48−54.

25. Coca SG, Singanamala S, Parikh CR. Chronic kidney disease after acute kidney injury: a systematic review and meta-analysis. *Kidney Int*. 2012;81(5):442−448.

26. Bucaloiu ID, Kirchner HL, Norfolk ER, et al. Increased risk of death and de novo chronic kidney disease following reversible acute kidney injury. *Kidney Int.* 2012;81(5):477−485.

27. Hallan SI, Stevens P. Screening for chronic kidney disease: which strategy? *J Nephrol.* 2010;23(2):147–155.

28. Jacobson S. Chronic kidney disease--a public health problem? *Lakartidningen*. 2013;22;110(21):1018−1020.

29. Schieppati A, Remuzzi G. Chronic renal diseases as a public health problem: epidemiology, social, and economic implications. *Kidney Int.* 2005;68:S7−S10.

30. Bhowmik D, Pandav CS, Tiwari SC. Public health strategies to stem the tide of chronic kidney disease in India. *Indian J Public Health*. 2008;52:224−229.

31. Schoolwerth AC, Engelgau MM, Hostetter TH. A public health action plan is needed for chronic kidney disease. *Adv Chronic Kidney Dis*. 2005;12(4):418−423.

OPEN ACCESS

Ology Press

Review Article

Biostatistics and Epidemiology International Journal

Data analysis and documentation of statistics in biomedical research papers in Albania

Eliana Ibrahimi

Department of Biology, University of Tirana, Albania

Correspondence: Eliana Ibrahimi, Department of Biology, University of Tirana, Faculty of Natural Science, Albania,
Email eliana.ibrahimi@fshn.edu.al

Received: January 31, 2018 | **Published:** February 27, 2018

Summary

The statistical part is an essential ingredient of any research study. The research methodology and application of statistical methods have developed rapidly over the years and have significantly improved the research activities in every field of study. In this paper, is presented an evaluation of statistical methods used in 49 scientific papers, published in biomedical sciences journals in Albania from 2012 to 2016. Based on this review, 31 papers (63.3% of 49) presented numerical results and aimed significance with no statistical analysis performed. Majority of studies which performed statistical analysis (83.3 % of 18 papers) failed to prove test assumptions. In 38.9% of cases there was no explicit statement of the tested Null-Hypotheses. Multivariable techniques to adjust for confounding factors were absent in all papers in which the multivariate analysis was necessary to arrive to conclusions. In many papers (61.1% of cases) the statistical tests used were not specified and defined correctly. Failure to state degrees of freedom was also very common. In these circumstances there is high evidence that the statistical reviewing of biomedical sciences journals has strong deficiencies and must be improved as much as possible.

Keywords: data analysis, documentation of statistics, biomedical research

Introduction

Statistical methods are an inseparable part of the biomedical research with a significant increase in the use of statistics which has been documented for a wide range of biomedical journals over the past decades.[1] However, there is wide consensus that standards are generally low, statistical errors are alarmingly common in published research, according to statisticians at least half of the published papers in biology and medicine contain serious statistical mistakes.[2-3]

Unfortunately, even simple and basic statistical methods such as t-tests or chi-square tests are constantly misused in biomedical research, because test assumptions are not assessed before application.[4]

The misuse of statistics in biomedical research has been discussed repeatedly, and it has been indicated that it is dishonest and at times can have serious consequences.[4-5] The inappropriate use of statistical analysis may lead to inaccurate conclusions and false research conclusions. Therefore, valuable efforts have been made by many journal editors to improve the quality of statistics by strengthen the statistical peer reviewing of incoming manuscripts.[6-7] Apart from these efforts, there is low indication that standards have improved over time, for as much as recent studies refer a continuance of major problems.[8-9]

In this paper we present a comprehensive evaluation of data analysis and documentation of statistical methods in biomedical research papers in Albania.

Methods

We reviewed 49 scientific papers which presented numerical results, published in Biomedical Journals in Albania from 2012 to 2016. We evaluated the process of data analysis and documentation of statistical methods. The review was based on earlier studies,[10] which showed the most common statistical errors occurring in biomedical research.

Results

Based on the review, 31 papers (63.3% of 49) presented numerical results with no statistical analysis performed (Figure 1). All this studies claimed significance without data analysis or statistical test mentioned.

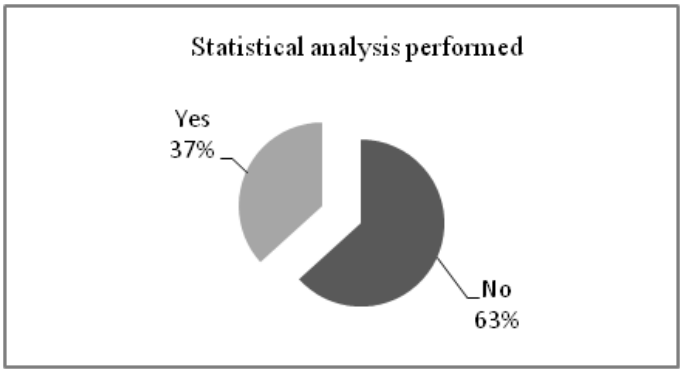

Figure 1 Statistical analysis in papers with numerical results.

Eighteen papers (36.7% of 49) performed statistical analysis. Many of them contained statistical errors related to data analysis and documentation of statistical methods performed. Some errors were not serious in nature, but many were serious enough to cast doubt on conclusions.

Citation: Ibrahimi E. Data analysis and documentation of statistics in biomedical research papers in Albania. *Biostatistics Epidemiol Int J.* (2018);1(1): 18-20. DOI: 10.30881/beij.00006

The most frequent deficiency related to data analysis was failure to prove test assumptions. Majority of studies (83.3 % of papers which performed statistical analysis) failed to prove test assumptions. In 38.9% of cases there was no explicit statement of the tested Null-Hypotheses. Multivariable techniques to adjust for confounding factors were absent in all papers in which the multivariable analysis was necessary to arrive to conclusions. In (Table 1) is a summary of several statistical errors related to data analysis and their frequency.

Table 1 Statistical errors and deficiencies related to data analysis

Data analysis error	N*	% **
Inappropriate use of parametric methods	2	11.1
Use of an inappropriate test for the hypothesis	2	11.1
Failure to include a multiple-comparison correction	5	27.8
Using unpaired instead of paired t-test	3	16.7
Failure to prove test assumptions	15	83.3
Use of chi-square when expected numbers are less than 5	5	27.8
No explicit statement of the tested Null-Hypotheses	7	38.9

* Number of papers which performed statistical analysis and contained the error. Note that one type of error occurred in more than one paper. **The percent for each error shows the frequency of the error within 18 papers who performed statistical analysis.

Documentation of applied statistical methods was generally poor and insufficient. In a large number of studies (61.1% of cases) the statistical tests used were not specified and defined correctly. Failure to state if the test was one or two sided was very common. In 66.7 % of papers failed to state if the test was one or two tailed, while in 44.4 % of cases there was no statement for using paired or unpaired t-test. Table 2 summaries important statistical errors related to documentation of statistical methods.

Table 2 Statistical errors related to documentation of data analysis

Documentation error	N *	% **
Failure to specify/define all tests used correctly	11	61.1
Failure to state if the test was one or two tailed	12	66.7
Failure to state if test was paired or unpaired	8	44.4
Wrong names for statistical tests	1	5.6

* Number of papers which performed statistical analysis and contained the error. Note that one type of error occurred in more than one paper. **The percent for each error shows the frequency of the error within 18 papers who performed statistical analysis.

Discussion

When performing statistical data analysis or estimation techniques, it should be clear that each method is based on several underlying assumptions, which have to be fulfilled in order to ensure correct and significant results.

The type of the statistical test applied for a particular data should be clearly explained.[11] Every evasive statement, related to the application of different statistical tests should always be avoided.[5,11]

Furthermore, when applying t-tests or chi-square tests, researchers have to be aware of choosing the accurate version of the test, since they have various forms.[4] If expected counts in a cell are less than 5, than chi-square tests should not be used, as their result under this condition is no longer credible.[11]

It is essential, that all statistical methods applied are described appropriately and with enough detail, to enable a literate reader, to recalculate all results, in case he has access to the data.[8] In addition, a subsection where all techniques and methods used are explained correctly, is obligatory in every research paper.

For statistical tests, which has paired and unpaired versions (eg, t-test, Wilcoxon test), it is obligatory to specify which form of the test was performed and the degrees of freedom has to be declared. In any case, randomly used tests do not need to be explained in detail, while any new test applied should be summarized or referenced.[10,12]

However, it is very difficult for a researcher or academician to study all statistical tests for his or her research. Consequently, still majority of researchers are unaware to which statistical tests they should perform to the data they have collected.[13] One possible solution to improve statistics in papers published might be adding a statistical review stage to allow the statisticians to have a deeper look at the various statistical observations.

Conclusion

The statistical error level is high in papers published in biomedical research in Albania. Journal editors should seriously consider improvement of quality by enhancing the statistical reviewing of incoming manuscripts, as there is also evidence, that the statistical reviewing of biomedical journals has strong deficiencies. In these circumstances statistical reviewers should at least be given the opportunity to see the revised manuscripts before final publication.

References

1. Altman DG. Statistics in medical journals. *Stat Med*. 1982;1(1):59–71.
2. Gore SM, Jones IG, Rytter EC. Misuse of statistical methods: critical assessment of articles in BMJ from January to March 1976. *Br Med J*. 1977;1:85–87.
3. Gardner MJ, Bond J. An exploratory study of statistical assessment of papers published in the British Medical Journal. *JAMA*. 1990;263:1355–1357.
4. Olsen CH. Review of the use of statistics in infection and immunity. *Infect Immun*. 2003;71(12):6689–6692.
5. Welch GE 2nd, Gabbe SG. Review of statistics usage in the American Journal of Obstetrics and Gynecology. *Am J Obstet Gynecol*. 1996;175(5):1138–1141.
6. Goodman SN, Altman DG, George SL. Statistical reviewing policies of medical journals. *J Gen Intern Med*. 1998;13(11):753–756.
7. Murray GD. Statistical guidelines for the British Journal of Surgery. *Br J Surg*. 1991;78(7):782–784.
8. Bajwa SS. Basics, common errors and essentials of statistical tools and techniques in anesthesiology research. *J Anaesthesiol Clin Pharmacol*. 2015;31(4):547–553.
9. Marshall SW. Testing with confidence: the use (and misuse) of confidence intervals in biomedical research. *J Sci Med Sport*. 2004;7(2):135–137.
10. Strasak AM, Zaman Q, Pfeiffer KP, et al. Statistical errors in medical research – a review of common pitfalls. *Swiss Med Wkly*. 2007;137(3-4):44–49.

11. Goodman NW, Hughes AO. Statistical awareness of research workers in British anaesthesia. *Br J Anaesth*. 1992;68(3):321–324.

12. Altman DG. Statistics in medical journals: some recent trends. *Stat Med*. 2000;19(23):3275–3289.

13. Altman DG, Goodman SN, Schroter S. How statistical expertise is used in medical research. *JAMA*. 2002;287(21):2817–2820.

OPEN ACCESS

Ology Press

Editorial

Biostatistics and Epidemiology International Journal

A letter from the Editor-in-Chief

Brian P Mangum

Fiji National University, Suva, Fiji

Correspondence: Brian P Mangum, Fiji National University, Suva, Fiji, Tel 6913202480, Email epidemiology.doc@gmail.com

Received: March 15, 2018 | **Published:** April 06, 2018

Dear Colleagues and Readers:

It is my great pleasure to welcome you to this issue of *Biostatistics and Epidemiology International Journal*. I am particularly excited to be writing this introduction on 15 March 2018 – the 205th birthday of the founder of our noble discipline, Dr John Snow. No more fitting tribute to our profession could be made than to celebrate the launching of this exciting new journal during the same month of Dr Snow's birthday, as we remember his countless contributions to our profession stemming from the 1854 Broad Street pump investigation.

Herald forward in time 164 years from the birth of modern epidemiology, and you see a profession that is growing rapidly as it adapts to the changing demands of the world around us, as well as advances in scientific knowledge. No other field of basic science enquiry is as adaptable as that of epidemiology and biostatistics; our methodologies allow us to undertake research in all areas of medicine, public health, the social sciences, genetics, psychology, and more. We have the necessary tools, and continue to grow and refine our methods in such a way as to make epidemiological enquiry applicable to all disciplines, and all questions faced by humanity. Taken in total, all of this makes it an incredibly exciting time to be an epidemiologist, biostatistician, or associated researcher.

We are very much a thriving, exciting, and cutting-edge field, as is evidenced by our expansion into areas such as genetic epidemiology, which holds the promise of understanding, predicting, and preventing disease based upon personalised genetic profiles of individuals as we fight diseases such as type 2 diabetes, alcoholism, and more. Or the use of big data applications in association with computer science professionals to better harness the power of existing databases to understand risk and disease on a global level.

Of course, as we embrace new technologies and frontiers of enquiry, there is ample opportunity to remain true to our roots of traditional epidemiological methods as we continue to address pressing issues in both developed and developing setting globally. It is here at the grassroots level where we continue to form the scientific backbone of decision making by physicians, whether practicing as a solo practitioner on an isolated island in the Pacific, or in a university medical centre in London; public health practitioners, who rely on our data to develop targeted and efficacious intervention for health issues such as tobacco use among teens; health planners, who look to us for the information needed to prepare for future threats to the health security of the communities they serve; national and local leaders, who use epidemiological data and analysis to determine how to prioritise spending related to health; and many others.

While we look to the future of epidemiology, and embrace new technologies, we must also remember our commitment to these traditional settings for the application of epidemiological data, where the knowledge we create has the largest impact at the community level.

Technology has forever changed the face of epidemiology. Whether we are talking about cutting edge investigations to identify linkages between specific genes responsible for myocardial infarcts as independent risk factors separate from lifestyle choices; or locally-relevant descriptive studies, such as risk factor analysis between betel nut use and oral cancers in Asia and the Pacific region, technology has forever altered the way in which we communicate, collaborate, and disseminate our findings. Egalitarian access to cutting-edge epidemiological research and data is key to both researchers as well as practitioners from around the globe.

Yet, the divide between developed and developing nations in terms of access to opportunities to share knowledge, as well as opportunities to learn from others while at the same time continuing to grow the efforts of researchers from around the globe, is significant. Traditional routes of knowledge dissemination, including conferences and the customary publications, are increasingly beyond the reach of researchers and practitioners. Many researchers working in smaller universities, community settings, or developing nations perform stellar research which has the potential for impact on practice at the community level; yet, they are handicapped in disseminating this information through traditional routes.

This is where journals, such as *Biostatistics and Epidemiology International Journal*, come into their own. At *Biostatistics and Epidemiology International Journal*, we celebrate and embrace both the past, present, and future contributions of epidemiology; while at the same time providing an open-access platform for the dissemination of impactful research which may otherwise have been only available at the local level where it is produced, and thus lost to the global audience of researchers and practitioners who rely upon epidemiology data and best practices from smaller, often times overlooked settings, to further the goal of evidence-based practice in the myriad of settings they serve.

Citation: Mangum BP.A letter from the Editor-in-Chief. *Biostatistics Epidemiol Int J*. (2018);1(1): 22-23. DOI: 10.30881/beij.00007

For me, this is why I am so thrilled to serve as Editor-in-Chief of *Biostatistics and Epidemiology International Journal*, or that it provides an egalitarian opportunity to share high-quality research done at the local level with a global audience. In so doing, I believe the future of both epidemiology as well as this journal can be summed up in one sentence: world class science, real world impact.

Warmest regards,

Dr Brian P Mangum
Editor-in-Chief

Citation: Mangum BP. A letter from the Editor-in-Chief. *Biostatistics Epidemiol Int J*. (2018);1(1): 22-23.
DOI: 10.30881/beij.00007

OPEN ACCESS

Monography

Biostatistics and Epidemiology International Journal

The social epidemiology and construction of risk for Fetal Alcohol Syndrome in Native American communities

Brian P Mangum

Fiji National University, Suva, Fiji

Correspondence: Brian P Mangum, Fiji National University, Suva, Fiji, Tel 6913202480, Email epidemiology.doc@gmail.com

Received: April 19, 2018 | **Published:** April 20, 2018

Abstract

Fetal alcohol syndrome (FAS) is characterized by craniofacial dysmorphology, growth deficiencies, and central nervous system dysfunction. The results of FAS are generally mild to moderate retardation, as well as social dysfunction andlack of social attainment. FAS is entirely preventable by not consuming alcohol during pregnancy. Despite this, FAS remains a factor within the general population, with abnormally high rates among Native Americans. This monograph explores the ways in which sociocultural factors play a role in the construction of FAS as a threat in the Native American community, through an examination of FAS as a public health intervention. By examining the determinants of FAS as cultural factors from the standpoint of social epidemiology, including those underlying economic and political factors that place certain ethnic and cultural groups in a state of disenfranchisement, we are able to see how public health interventions that examine such factors can meet immediate clinical demand as well as address long-term cultural stigma and disenfranchisement. Programs that wish to address FAS in Native American communities must address the lack of community resources, such as alcohol abuse counseling, needed to support educational efforts. In addition to this, long-term studies must address how to effectively implement such programs, as well as addressing underlying economic needs that have been shown to be related to alcohol abuse.

Keywords: Fetal Alcohol Syndrome, FAS, Native Americans, social epidemiology, risk

Introduction

Fetal alcohol syndrome (FAS) is a health concern across all socioeconomic and cultural/ethnic groups.[1]However, among certain ethnic and cultural groups, FAS, with the concurrent costs to both the individual and society, is considered a greater problem. This is particularly true among the Native American population, which has FAS rates 33% higher than the Caucasian population.[1]FAS is a condition that is entirely preventable by not drinking during pregnancy.[1] Given the preventable nature of FAS, the question arises of what are the underlying reasons that Native American women continue to drink during pregnancy, given the life-altering detriments of FAS to the unborn child. Clearly, there are factors at work more complicated than simply stating that FAS can be prevented by not drinking during pregnancy.

That is what this monograph seeks to address, or what are the underlying sociocultural reasons that Native American women drink during pregnancy, thus exposing their unborn child to the risks of FAS. In so doing, this monograph will explore FAS among Native Americans from the perspective of a public health intervention based on the social epidemiology of the disease. In this way, not only will the monograph be able to explore the sociocultural construction of FAS in the Native American community through a discussion of the various determinants of FAS, and the social construction of risk perception of such, but will also be able to develop a practical framework for addressing such problems that is culturally appropriate. In so doing, the following points will be discussed: (a) what is FAS, including the long-term effects of such; (b) what is the epidemiology of FAS in the general population, as well as the Native American population (c) what are the sociocultural and behavioral determinants of FAS in the Native American community, and how can these determinants be addressed through a culturally appropriate public health intervention; (d) this monograph will conclude with recommendations for further study of FAS in the Native American community as well as recommendations for implementing prevention programs.

Etiology of fetal alcohol syndrome

To begin the discussion of the sociocultural construction of FAS in Native American Communities, the monograph will first discuss what FAS is, and what the long-term effects of the disorder are. FAS is a neurodevelopmental and physical syndrome that is characterized by a triad of symptoms, including "…craniofacial dysmorphology, growth deficiencies, and central nervous system dysfunction".[2]This triad of symptoms is used to make the diagnosis of FAS, although reliance upon morphology and phenotype among infants is the prime diagnostic feature,[3] particularly among newborns. Later in life, FAS may be diagnosed using other factors such as cognitive ability as well as craniofacial features.[4] Regardless of diagnosis, FAS is the result of exposure of the fetus to alcohol in utero, and results in lifelong morbidity, particularly characterized by developmental delay as well

as physical malformation.[2]Studies indicate that FAS can be caused by as little as 1-ounce of absolute alcohol per day in utero; however, most cases of FAS are linked to much greater intake of alcohol, usually around 60-75 ml of absolute alcohol consumption per day during the pregnancy.[1,2]Accordingly, the CDC states that there is no determined safe level of alcohol consumption during pregnancy,[1] with the Royal College of Obstetrician and Gynaecologists stating that women should limit consumption of alcohol to one standard drink per day.[5]

In terms of diagnosis, it is interesting to note that the degree to which the child with FAS is developmentally delayed is related to the degree of craniofacial abnormalities.[2]That is to say, that the greater the craniofacial abnormalities, the greater the developmental and neurocognitive delays the child will possess. Developmental specialists often use the degree of craniofacial abnormalities to determine the level of intervention needed, as well as to estimate the degree to which the child's neurocognitive abilities can be trained.[3,4] Still, there is caution in the overuse of such phenotypical diagnosis to the detriment of other testing, as FAS can mimic other alcohol related syndromes. Particularly, it should be noted that FAS is different from fetal alcohol effect (FAE), in which a child who has been exposed to alcohol during pregnancy suffers the craniofacial abnormalities but not the cognitive deficits.[2] The phenotypical expression of FAS is characterized by microcephaly, a flat mid face, thin upper lip, short nose, minor ear abnormalities, low nasal bridge and others.[6,7]In addition to the underlying neurodevelopmental delays that such physical manifestations represent, such physical malformations also represent a stigmatized view of both the patient of himself as well as the world to the patient, resulting in a cycle of both physical, intellectual, and emotional difficulty which the patient must bear throughout their lives.

The long-term effects of FAS are related primarily to physical and developmental abnormalities. The greatest developmental disability related to FAS is mild to moderate retardation, including difficulty with arithmetic, inattention, poor concentration, memory deficit, and poor judgment.Other problems include those related to motor deficits, such as fine motor skills, and behavioral problems, including attention-deficit hyperactivity disorder (ADHD) and maladaptive behavior as adults.[2] There are also problems related to growth, including deficiencies in head circumference, as well as microcephaly, and sub-standard height and weight both as infants, adults and children.[2,8] In addition to this, children diagnosed with FAS may also suffer from cardiac murmurs, heart vessel abnormalities, skeletal abnormalities and hernias of the diaphragm, groin and umbilicus.[2]

Given such, the long-term prognosis of the child diagnosed with FAS is not positive. Growth and craniofacial abnormalities do become less obvious over time, and the weight to height proportion may improve as the child grows older,[2]thus improving the sociocultural conditions under which the patient with FAS may learn to survive if not thrive in contemporary culture. However, other physical malformations, such as short stature and microcephaly are persistent conditions that do not generally improve.[8] Neurodevelopmental handicaps do not generally improve with time, and most individuals with FAS will have lifelong cognitive handicaps preventing them form obtaining educational and social attainment with most "…failing to achieve independent income or housing",[2] thus depriving them of the traditional paths to social status attainment within the larger culture. However, and while there have been no studies done to examine such, it would be interesting to examine self and community conceptualizations of the individual with FAS among Native American communities to determine of differences exist between such and mainstream American culture.

Descriptive epidemiology of fetal alcohol syndrome:native americans versus the general population

Having discussed what FAS is, including the long-term effects of such, this monograph will now turn to a brief discussion of the epidemiology of FAS among the general and Native Americans populations. The rates of FAS in the general population vary widely according to various demographic factors, such as ethnicity and geography. This is true among the general population of the United States, as well as ethnic groups, such as Native Americans, where there are varying rates of FAS present among different tribal groups. This highlights a specific point, in that it is difficult when engaging in a cultural study such as this to determine the extent of a health problem, given that contemporary statistics tend to differentiate little with regard to such factors as sub-groups within ethnic categories such as Native Americans. According to the CDC, the rates of FAS range from 0.2 to 1.5 per 1,000 births in the general population.[9] Demographically, Asian Americans have the lowest rates of FAS at 0.3 per 10,000 births, with Hispanics having a rate of 0.8, Caucasians 0.8, African Americans 6.0, and Native Americans the highest demographic rate at 29.9 cases per 10,000 births.[10]

The rate of FAS among different tribal groups varies widely as well, ranging from 13 to 103 per 10,000 births in the American Southwest.[11] Among the Navajo and Pueblo tribes, the rate of FAS is more similar to the overall rate for the United States, while among the Southwest Plains Native Americans there is a much higher rate of one per every 102 live births.[12]

Social epidemiology of the determinants and risk constructs of fetal alcohol syndrome

Thus, it can be seen that among the Native American there is a varying rate of FAS present in the population, that might be understood better from a sociocultural standpoint, and include issues related to economics, education, access to healthcare and so forth. For instance, among the Navajo tribes, where there is greater economic development, there are also fewer reported cases of FAS than other tribes.[12] Given this, we can turn to an understanding of such sociocultural and economic factors as determinants of health as related to FAS, and thus examine them from the model of a public health intervention based in the social epidemiology of such. Public health interventions are based upon understanding the underlying lying causes of a health problem in terms of direct and indirect determinants. Such determinants can be seen as the risk factors that influence the level of health problems.[13]

For instance, when considering the health problem of high blood pressure, one could state that obesity, diet, and cigarette smoking are all determinants of the problem, as well as being behavioral in nature. Determinants are further impacted by direct contributing and indirect contributing factors that influence the level of the determinant. Indirect contributing factors are those that affect the determinant by affecting the direct contributing factor. Returning to our example of high blood pressure, a direct contributing factor of the determinant of obesity would be sedentary lifestyle or lack of activity,

Citation: Mangum BP. The social epidemiology and construction of risk for Fetal Alcohol Syndrome in Native American communities. *Biostatistics Epidemiol Int J*. (2018);1(1): 25-29. DOI: 10.30881/beij.00008

with an indirect contributing factor being the amount of television that Americans view. In so doing, public health interventions rely upon a series of steps with the ultimate goal in mind of addressing or lowering the risk factor. Public health programs designed to address health issues do so by addressing these determinants and contributing factors, thus addressing the underlying issues that have resulted in the health problem. These steps are activities, process objectives, impact objectives and outcome objectives.[13]

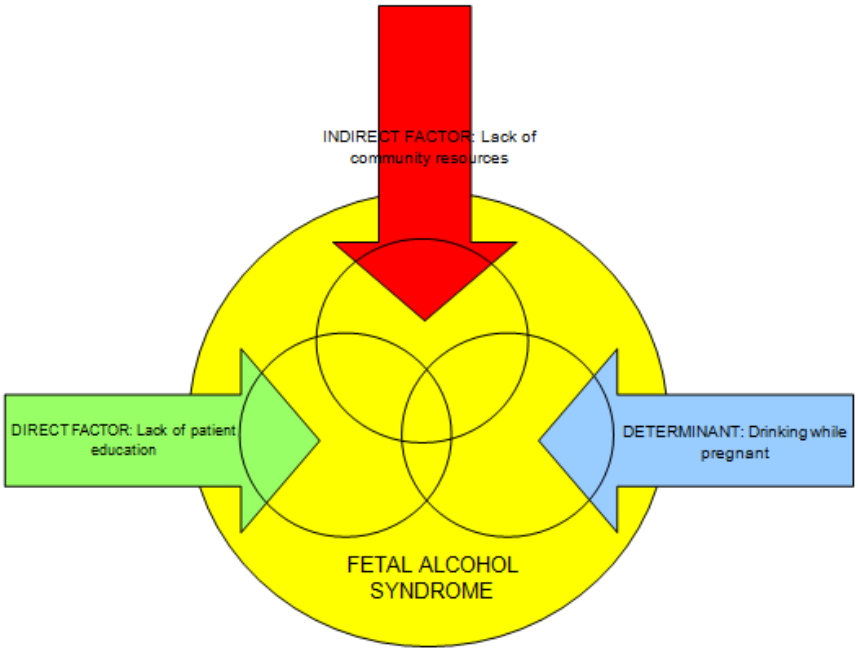

Figure 1 Graphical representation of the sociocultural construction of FAS in Native American communities.

However, such program must be certain that the issues they are addressing truly are the underlying sociocultural determinants of the problem, and not merely symptoms of a larger systemic problem. For instance, programs that provide condoms to sex workers in Africa do not address the underlying sociocultural inequity that does not grant sex workers the ability to demand condom use, as well as the economic reasons why women must turn to the sex trade to support themselves while being placed at greater risk for sexually transmitted infections (STI) such as HIV/AIDS. It is important to understand, that properly done, the choice of determinants, which are generally behaviorally-based, will expose the underlying sociocultural basis of a healthcare problem, including cultural bias, stigma, and other undesirable attributes of any culture which results in the disenfranchisement of cultural and social groups. Given this, well-designed public health interventions go beyond simply addressing health needs within a specific population, to targeting and alleviating social and cultural injustice in the form of health disparities, and thus meet the larger goals of the growing and influential field of social epidemiology. Such health disparities are generally not defacto, in that they are the product of social and legislative policies designed to result in such, but do represent underlying economic and cultural bias. For instance, while programs that cut Medicaid funding for uninsured individuals and families are not targeted with a specific malignancy towards such groups, and rather may be economically based in times of deficits and decreased tax revenue, they do have the impact of placing such groups at risk in relation to their socioeconomic status within the larger cultural system.

Given such, addressing the determinants of FAS among the Native American population, must take the form of direct contributing factors, but also indirect contributing factors. Indeed, if the determinant can be seen as the underlying causative factor of the health problem, then the direct and indirect determinants can be seen as the true sociocultural stigma and bias that have resulted in such.

Therefore, in terms of the health problem of FAS in general, including Native American women, there can be only one determinant, or that of drinking while pregnant, leaving us to question why women in Native American communities have such a higher prevalence of drinking while pregnant, or the direct and indirect contributing factors. In terms of direct and indirect contributing factors, this monograph will identify one of each, which will be discussed in further detail, including objectives to deal with such. These include the direct contributing factor of a lack of education on the part of patients as to what FAS is and how it can be prevented, with the indirect factor being a lack of community resources.

Patient education models of FAS prevention in Native American communities have been shown to be effective when combined with other methods, particularly assistance in accessing community service agencies to gain access to alcohol abuse programs,[14] thus underpinning the issue that FAS education can be a useful tool if it is combined with programs to address underlying socioeconomic issues related to risk. Thus, it is theoretically possible that if short term access to resources, such as adequate counseling, are the key components to health education models addressing FAS, then long-term models that address

Citation: Mangum BP. The social epidemiology and construction of risk for Fetal Alcohol Syndrome in Native American communities. *Biostatistics Epidemiol Int J.* (2018);1(1): 25-29. DOI: 10.30881/beij.00008

educational and employment opportunities in the community could be seen as a way of directly affecting FAS on a community-wide basis. Such short-term assistance could be seen as meeting the process objectives of a health intervention. Process objectives are those activities that change the contributing factor, or in this case, a lack of patient education. However, as stated above, patient education must be coupled with addressing underlying economic issues, which from a behavioral standpoint have been shown to have a direct corollary between alcohol abuse and socioeconomic status.[5] Therefore, in order to meet the needs of patient education in the community, several steps must be taken. These include educating providers about the need to not only provide culturally appropriate counseling regarding the risks of FAS, but also helping at risk patients access the services they need which will allow the patient education model to be most effective. This would include educating providers about the services available in Native American communities, including drug and alcohol counseling, access to government sponsored housing for pregnant and at-risk women, as well as food assistance, and in the long term the possibility of job training and other educational opportunities. Such services would allow a program to meet its impact objectives, which is a measure of the reduction of the determinant in a specific amount of time.[13] In this case, the determinant to be reduced is the consumption of alcohol by Native American women who are pregnant or are planning to become pregnant.

However, such process and impact objectives cannot address the direct determinants if there is a lack of community resources to assist with such, particularly in regard to drug an alcohol counseling programs that address the needs of women. Tragically, despite Indian Health Services (IHS), this is often the case in Native American communities, where the true underlying social problem is not a lack of patient education, but a lack of those services that allow patient education to be successful. According to Thomason[14], the problem is not in a total lack of resources, but rather in a lack of culturally appropriate resources for dealing with alcohol counseling that are directed at women. While IHS does offer alcohol counseling programs, such are generally directed towards men, who have represented the traditional burden of alcohol abuse in native communities in terms of recognition, if not actual practice.[2]This includes a lack of female counselors, or counseling methods directed at women and their unique place within the Native American community. Furthermore, such is compounded by a lack of recognition for referral by providers,[2,15] as well as a low rate of referral acceptance by patients.[16]In such an atmosphere where providers fail to recognize the need for referral for alcohol counseling among Native American women at risk for FAS, and where counseling services are not available that are culturally acceptable in terms of being directed towards women as well as an understanding of FAS, it is clear that patient education alone will not allow women to successfully stop drinking during pregnancy to reduce the risk of FAS.

While such is not a physical lack of resources within the community to help women successfully combat alcohol dependence during pregnancy or for those considering becoming pregnant, there is in fact a psychological absence or barrier between these resources and the women who need them. Therefore, any program designed to intervene in the cycle of FAS in the Native American community will be able to meet the patient education process objective (e.g. lack of patient education) within the framework of the provider, however, in terms of the ultimate goals or the impact and outcome objectives, the program will fail, as the community resources that will allow patient education to be effective are not present.[14]Therefore, the determinant of drinking while pregnant and the outcome objective of reducing FAS in the Native American community cannot be met.

Conclusions and recommendations

FAS is an entirely preventable disorder.[1]Yet despite this, the percentage of children born with FAS in Native American communities remains disturbingly high. Given this, public health interventions must be designed that take into account the needs of both the community and the individual when assessing how best to intervene. Programs designed to educate patients regarding the risks of FAS and how to prevent such must be predicated upon community resources, including appropriate alcohol abuse and dependence treatment programs. While IHS has such programs in place, they are primarily geared towards men, who represent the traditional burden of alcohol abuse in Native American communities. Studies have shown that if patient education models are to be successful, then such programs must be in place to provide access to community resources such as alcohol abuse counseling.

Further studies are needed to assess how best to implement patient education models that are integrated with community resources that include not only drug and alcohol abuse counseling, but also resources to address underlying socioeconomic disparities that lead to alcohol abuse in the first place. Such programs that combine not only short-term interventions for those who are at risk for FAS, but also address long term disparities in terms of the availability of economic and educational opportunities for Native American communities are needed. Such studies would help provide one of the key components of public health interventions, or that of evidence based practice.

References and further reading

1. https://www.cdc.gov/ncbddd/fasd/documents/fas_guidelines_accessible.pdf
2. Entin E. Fetal alcohol syndrome. In: *Saunders Manual of Medical Practice*. W.B. Saunders; 2000.
3. Astley SJ, Clarren SK. A fetal alcohol syndrome screening tool. *Alcohol Clin Exp Res*. 1995;19(6):1565–1571.
4. Bagheri MM, Burd L, Martsolf JT, Klug MG. Fetal alcohol syndrome: maternal and neonatal characteristics. *J Perinat Med-Off J WAPM*. 1998;26(4):263–269.
5. Wilkie S. Global overview of drinking recommendations and guidelines. *AIM Dig*. 1997;2(Supplement):4.
6. Hagerman RJ. *Neurodevelopmental Disorders: Diagnosis and Treatment*. Oxford University Press; 1999.
7. Pytkowicz Streissguth A, LaDue RA, Randels SP. A manual on adolescents and adults with fetal alcohol syndrome with special reference to American Indians. 1986.
8. Hay W, Levin M, Sondheimer J, Hayward A. *Current Pediatric Diagnosis & Treatment*. 15th ed. New York: McGraw-Hill; 2001.
9. Centers for Disease Control. Alcohol consumption among women who are pregnant or who might become pregnant–United States, 2002. *MMWR Morb Mortal Wkly Rep*. 2004;53(50):1178.
10. Chavez GF, Cordero JF, Becerra JE. Leading major congenital malformations among minority groups in the United States, 1981-1986. *MMWR CDC Surveill Summ Morb Mortal Wkly Rep CDC Surveill Summ*. 1988;37(3):17.

11. US Department of Health and Human Services. *Report of the Secretary's Task Force on Black & Minority Health: Crosscutting Issues in Minority Health.* 1985.
12. May PA, Hymbaugh KJ, Aase JM, Samet JM. Epidemiology of fetal alcohol syndrome among American Indians of the Southwest. *Soc Biol*. 1983;30(4):374–387.
13. Turnock BJ. *Public Health: What It Is and How It Works*. 3rd ed. Sandbury, MA: Jones & Bartlett; 2004.
14. Thomason TC. Issues in the treatment of Native Americans with alcohol problems. *J Multicult Couns Dev*. 2000;28(4):243–252.
15. Cummings NA, Cummings JL, Johnson JN. Behavioral health in primary care: A guide for clinical integration. 1997.
16. Gatchel RJ, Oordt MS. *Clinical Health Psychology and Primary Care: Practical Advice and Clinical Guidance for Successful Collaboration.* Washington, DC: American Psychological Association; 2003.
17. Abel EL, Sokol RJ. Incidence of fetal alcohol syndrome and economic impact of FAS-related anomalies. *Drug Alcohol Depend*. 1987;19(1):51–70.
18. Abel EL, Sokol RJ. A revised conservative estimate of the incidence of FAS and its economic impact. *Alcohol Clin Exp Res*. 1991;15(3):514–524.
19. Barr HM, Streissguth AP. Identifying maternal self-reported alcohol use associated with fetal alcohol spectrum disorders. *Alcohol Clin Exp Res*. 2001;25(2):283–287.
20. Farmer P. *Pathologies of Power: Health, Human Rights, and the New War on the Poor*. Berkeley, CA: University of California Press; 2003.
21. Frank RG, McDaniel SH, Bray JH, Heldring M, eds. *Primary Care Psychology*. Washington, DC: American Psychological Association; 2003.
22. House JS, Umberson D, Landis KR. Structures and processes of social support. *Annu Rev Sociol*. 1988;14(1):293–318.
23. Klerman LV, Ramey SL, Goldenberg RL, Marbury S, Hou J, Cliver SP. A randomized trial of augmented prenatal care for multiple-risk, Medicaid-eligible African American women. *Am J Public Health*. 2001;91(1):105.
24. Klug MG, Burd L. Fetal alcohol syndrome prevention: annual and cumulative cost savings. *Neurotoxicol Teratol*. 2003;25(6):763–765.
25. Mattison DR, Damus K, Fiore E, Petrini J, Alter C. Preterm delivery: a public health perspective. *Paediatr Perinat Epidemiol*. 2001;15(s2):7–16.
26. Schneiderman NE, Speers MA, Silva JM, Tomes HE, Gentry JH. *Integrating Behavioral and Social Sciences with Public Health.* American Psychological Association; 2001.
27. Streissguth AP, O'Malley K. Neuropsychiatric implications and long-term consequences of fetal alcohol spectrum disorders. In: *Seminars in Clinical Neuropsychiatry*. Vol 5; 2000:177–190.

Citation: Mangum BP. The social epidemiology and construction of risk for Fetal Alcohol Syndrome in Native American communities. *Biostatistics Epidemiol Int J*. (2018);1(1): 25-29. DOI: 10.30881/beij.00008