

# WHO SAMPLE SIZE CALCULATOR FOR VALIDATION STUDIES IN RADIOLOGY : FEW OBSERVATIONS AND SUGGESTIONS

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Respected Sir,

Through your journal we wish to draw the attention of CPSP towards an important issue that requires to be urgently addressed.

The practice of synopsis and dissertation writing by CPSP as a prerequisite to FCPS degree is a commendable step. It introduces the residents to the art of research, which is so essential for future academic growth of an individual.

However the recent introduction of WHO sample size calculator for calculating sample size, although an authentic method, is posing problems for majority of residents in particular radiology due to the following reasons:

In radiology newer techniques and machines are increasingly common and validation studies regarding their sensitivity and specificity of a given modality/technique form a significant portion of all radiology journals. Unfortunately with the recent introduction of sample size calculator it is becoming increasingly difficult to do these studies in radiology because of the large sample size that comes through WHO sample size calculator.

We present 3 recent examples to explain the problem: One of our residents submitted "VALIDITY OF NON-ENHANCED 320-SLICE CT-SCAN (NECT) BRAIN IN THE EVALUATION OF ACUTE ISCHEMIC STROKE WITH MR-DWI AS GOLD STANDARD."

The sensitivity and specificity of spiral NECT from previous studies was found to be 71% and 100% using appropriate window width and centre level settings. The prevalence of stroke was reported as 5%. Keeping an absolute precision of 2.5 %, her sample size was calculated to be 25,000 patients by the CPSP regional research officer. Since this was impossible in the time

available she was asked to choose another topic unless she could find an article with prevalence of stroke rating at about 20-30%. After much research she found another article which reported a prevalence of 21.8%. Keeping a precision of 10% in this case, her sample size was reduced to 370 patients, which despite being much less than the initial number is still a very difficult target to achieve in the time available considering the work load in the department. It may be noted that studies on similar topic have been published in international literature with sample sizes of 100 patients in the 'Journal of neurology, neurosurgery and psychiatry' titled "Imaging of the brain in acute ischaemic stroke: comparison of computed tomography and magnetic resonance diffusion weighted imaging" in 2005.<sup>1</sup> A sample size of 200 patients was selected in another study titled "Comparison of MRI and CT for detection of acute intracerebral hemorrhage" in The Journal of American Medical Association<sup>2</sup> published in 2004 and 190 patients in the Archives of Internal Medicine under the title "Sensitivity of the neuroimaging techniques in ischemic stroke."<sup>3</sup>

Another resident submitted "VALIDITY OF RESISTIVE INDEX IN ULTRASOUND TO DIFFERENTIATE BENIGN AND MALIGNANT BREAST LESIONS".

In literature its sensitivity was 96%, specificity was 89.5% and prevalence of malignant breast masses was reported 2.62%. Her sample size as calculated by the CPSP regional research officer using WHO sample calculator was 25,000. In contrast a study on similar topic have been published in international literature with sample sizes of 104 in journal of clinical imaging titled "Significance of resistive index in color Doppler ultrasonogram: Differentiation with benign and malignant breast masses" in 2000 in Elsevier.<sup>4</sup> Since this sample was impossible to achieve she had give it up and she changed the topic to the following

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## one. "ACCURACY OF MAGNETIC RESONANCE IMAGING IN PREOPERATIVE EVALUATION OF PERI ANAL FISTULA".

It is a relatively newer technique in Pakistan and very limited local data is available for it. In literature its sensitivity was 97%, specificity was 100% and prevalence of 0.01% was reported. Her sample size according to CPSP regional research officer using WHO sample calculator was too large to calculate.

This is in contrast to studies published internationally on similar topic i.e. a similar study published in international literature used sample size of 56 patients in journal "Radiology" titled "Preoperative MR imaging of anal fistula: does it really help the surgeon".<sup>3</sup> Another study published in 'RadioGraphics' used a sample size of 178 patients in the study titled "MR imaging evaluation of perianal fistulas; spectrum of imaging features".

These impracticable figures calculated by the WHO sample size calculator have led to significant frustration in the radiology residency programs particularly when residents are unable to complete the sample size during their residency and then are either forced to delay delayed their give exams by a year or may consider resorting to the use of unfair means such as using retrospective data or fabrication of data. This builds in them an aversion from research and they think of it as an unnecessary burden, which is the opposite of what is the desired intention of CPSP.

Besides the large sample sizes calculated by the WHO sample size calculator the difficulty in attaining the required sample size also increases in our particular setup because of the following reasons:

- a. Retrospective data is not allowed by CPSP in dissertation writing.
- b. Time restriction of around 1 year to 18 months as usually in a 4 year radiology residency programme a synopsis at the earliest is submitted at the end of year one and gets approved by the end of year 2, leaving around one and a half year to complete the sample size, write the dissertation and submit it 6 months before the end of residency to be able to sit in the FCPS II exam at the end of 4 years.
- c. Most hospitals do not have enough patient load to complete the sample size.

This has led to significant frustration in the residents particularly when they are unable to complete the sample size during their residency and then are either delayed to give exams by upto 1 year or more or use unfair means such as retrospective data or fabrication of data. Also it builds in them an aversion from research

and they think of it as an unnecessary burden, which is the opposite of what is the desired intention of CPSP. To solve this problem in a way that is both acceptable scientifically world wide and is more practical for the residents, we suggest another sampling technique that is commonly used in validation studies in radiology literature in both national and international journals commonly termed as CONVENIENCE SAMPLING. This method requires the researcher to conduct a literature survey and find 3 to 5 similar studies published in indexed journals on similar topics. The sample size is taken roughly as average sample size used in these studies. This method is much more practical in our setup considering the short time available for research and non allowance of using retrospective data.

It may also be emphasized here that dissertation writing is supposed to be just an exercise to orient residents to research and many of these dissertations are not published anywhere.

We sincerely appreciate the endeavors that CPSP is doing for the betterment of residents and this step would further strengthen the prestige of CPSP.

## References

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