

KG MU ICMR STS Guide for Undergraduate Medical/Dental Students

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What is the STS program?

Every year, the Indian Council of Medical Research (ICMR) offers a Short-Term Studentship (STS) program **for undergraduate medical and dental students** with a prime goal to make them familiar with the research methodologies, scientific writing, and research ethics. Under this program, each student has to undertake a research project, which may be an independent project or an ongoing project of their seniors or faculties, of which, they can be a part.

Why STS program?

- A golden opportunity to learn how to conduct a research in health sciences domain.
- The selection of your own idea (proposal) among thousands of applicants by ICMR is like a self-rewarding endeavor which motivates you to conduct further research studies in upcoming years of medical school.
- It adds to your CV and hence boosts your career profile.
- A stipend of INR 20,000 is awarded for two months.

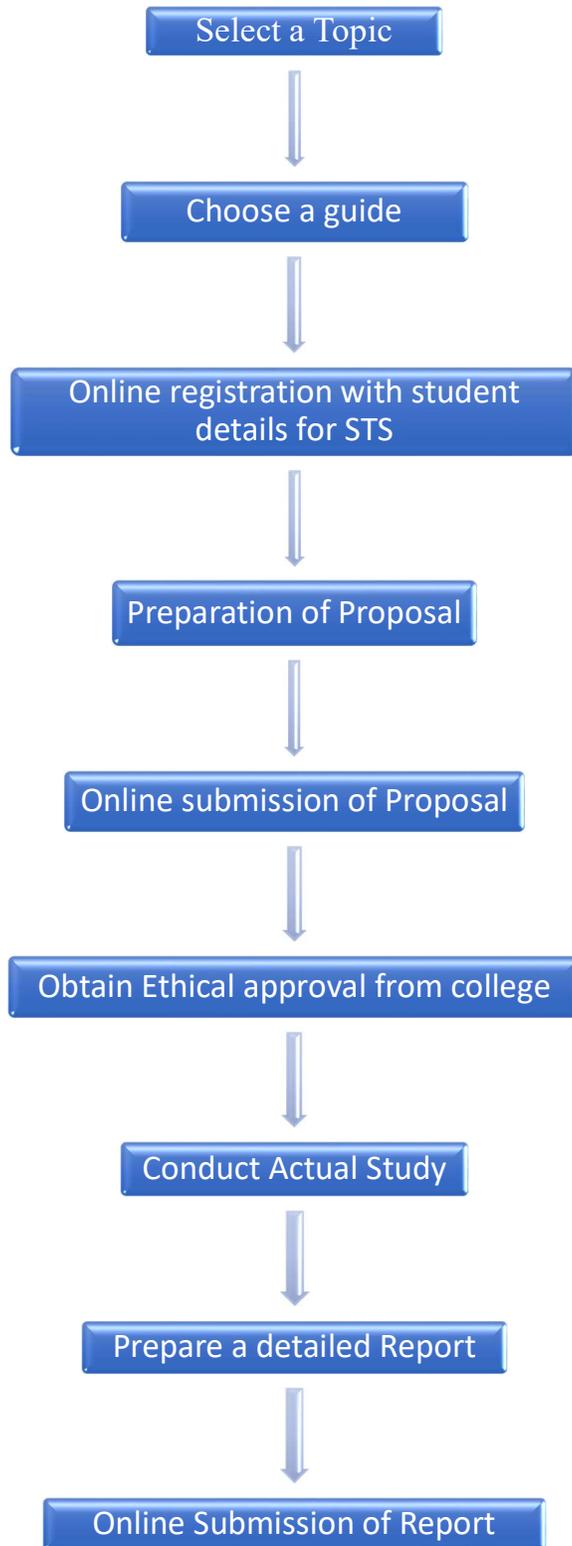
Why research at such an early stage?

THERE IS A LACK OF RESEARCH

Apart from giving direction to your curiosities, research at the undergraduate level has umpteen number of gains.

- Working on an idea (your research question) requires you to reflect on, analyse, and write whatever you do and think, doing so improves your critical thinking skills.
- Critical appraisal of the existing literature on any topic is a prerequisite to practice evidence-based medicine. Exposure to medical research at this level may prove helpful in inculcating these skills.
- Students' involvement in research contributes to the research output of their institution and stimulates their interest in academics as well.
- Moreover, it helps you to explore future opportunities, enhance network, and build better relations with your seniors and guide.

Overview of ICMR-STS Program



Step by Step Guide to the ICMR STS Program

1. Selecting a topic and framing the study design:

- Choose the domain of your research (a list of various domains is available on the STS website, for example- Biochemistry, Human Genetics, Physiology, etc). **It is not mandatory to choose a topic related only to your current year subjects**, say for example – A first-year student can do a research project in psychiatry or SPM.
- Once you have identified your topic in any subject, do a preliminary search (**literature review**) to know what work has been done on the topic in the past and what gaps have remained yet. Afterwards, start developing the research questions (objectives).
- Based on the facilities available in the department/ institute, you can do a laboratory-based as well as survey-based research.
- At the undergraduate level, survey-based studies are comparatively easy to perform.
- Don't proceed further if your study objective(s) is/are not novel and related to done-to-death topics, for example, the effect of mobile addiction on students, the prevalence of hypertension or prevalence of diabetes.
- You will have a maximum of 2 months to complete your project, so be careful while selecting your topic, objectives, and study design.
- In case you don't get any idea of the topic on your own, you can directly approach any faculty (may or may not be related to your current year subjects). They will surely suggest something to work upon.

Note: Preliminary Literature review:

- The whole study is built based on existing data. Moreover, it helps to create a new study design. So, make sure the base is strong.
- **Background information** of the work done over your topic can be found in published materials such as relevant textbooks, articles from medical research databases (e.g., Medline/PubMed- searched with the help of **MeSH** which shorts 'Medical Subjects Headings'), reliable non-predatory research journals, internet search engines, and Wikipedia.
- While **going through the existing literature**, make sure to **write down the information** that can be useful for your study (e.g., lacunae in the existing knowledge, gaps in previous study designs, methodology or scientific writing).
- If similar studies have been done in the past, whether they were able to achieve their objectives. If not, you can repeat the study with a new approach (different study design, sample size, and location).
- Simultaneously, start **collecting the references** as well. This will be needed later when citing the references.
- **Pre-writing phase:** Finally, **organize** the existing information on the topic and make a **rough draft exactly in the same format as the proposal** before you actually start writing the proposal.

2. Comprehensive Literature search on PubMed:

- Gather keywords for your search from the relevant content on Wikipedia and reliable websites (.gov,.edu,.org).
- Efficient searching on PubMed can be done by combining MeSH terms with the BOOLEAN operators.
- **Searching a database by BOOLEAN operators:** Simple BOOLEAN operators include- ‘AND’ ‘OR’ ‘NOT’, which are used to broaden or narrow your search.

For instance,

Typing ‘Lungs AND infections’ in the PubMed search bar will show articles that have both the terms/concepts, ‘Lungs OR infections’ will show articles that have either terms/concepts and ‘Lungs NOT infections’ will show articles that focus on lungs, not infections.

3. Choosing a mentor for your project:

- Good mentorship is the key to avoid any discontentment with research methodologies and scientific writing.
- Choosing a guide may involve evaluation based on various criteria like their availability, previous research experience, publication record, relevancy to your topic domain, approachability, etc.
- After evaluation, approach any of your faculty. Explain to them the ‘rough draft’ you have made about your project.
- Your guide can also help you with sample size calculation for your study.
- **Not to forget, any resident or a senior can’t be your guide** though it is always a good option to involve any experienced senior in your project.
- The research project can be done individually as well as teamwork (with you as the principal investigator).

4. Registration with student details on the STS website

- The link to register for the STS program is usually activated in mid-December and remains till the first week of January (for STS 2020, it was available from 10th December till 9th January).
- Once you have registered with your personal details, ICMR provides you with a Reference ID and password (via e-mail) that you have to use for all future purposes.
- Though the registrations start in December, you don’t need to wait for it to start. Start thinking about your topic and research questions as early as possible, because it is a time-taking process.

5. Preparing the proposal

- Make a ‘proposal’ as per STS guidelines on ‘**Preparation of Proposal.**’ Every year this is made available on the STS website.
- As far as the word limit is concerned, the provided guidelines are flexible, but the rest of the guidelines should be followed strictly.

- Doing a few courses on research methodologies and scientific writing will help you to prepare the proposal/report better.
Free online courses on research methodologies and scientific writing are available:
 1. **‘Writing in the Sciences,’** an online course on scientific writing offered by Stanford University.
<http://online.stanford.edu/courses/som-ysciwrite-writing-sciences>
 2. A short-term online course on basic biomedical research methodology: **‘Health Research Fundamentals,’** offered by NPTEL.
https://swayam.gov.in/nd1_noc20_hs20/preview
The NPTEL certificate course is offered twice a year at specific times. However, the video lectures are available for free on YouTube channel - **‘Health Research Fundamentals.’**
 3. **‘Introduction to Clinical Research,’** a short online course offered by Global Health Training Centre.
<https://globalhealthtrainingcentre.tghn.org/introduction-clinical-research/>
 4. **Introduction to Principles and Practice of Clinical Research –** By National Institutes of Health, US. Possibly the single best and most comprehensive free course.
<https://ocr.od.nih.gov/courses/ippcr.html>
 5. Other free courses offered by Global Health Training Centre.
<https://globalhealthtrainingcentre.tghn.org/elearning/short-courses/>
- Once you have prepared your proposal, check for plagiarism using **‘iThenticate’**- ask your guide or department about this application.
- Also, check for any errors in spelling, grammar, and punctuation using **‘Grammarly.’**
<https://www.grammarly.com/>
- Make sure you have written your references properly (must be in Standard Vancouver format). References should preferably be taken from recently published research papers.
<https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/library/public/vancouver.pdf>
- Now, get it reviewed by your colleagues, seniors, and guide.

Note: A brief overview of what to write in your proposal:

- Critical appraisal of the existing medical literature on the topic plays an important role here. To write, you need to read the existing literature thoroughly.
- Write a short **introduction** about your topic (includes a brief writeup about the magnitude of the problem e.g. its incidence and prevalence, what’s known about the topic, what are the gaps, clear statement of the problem, and about your approach).
- Define your **aims and objectives**. Objectives (Not more than 2-3) should be clear, specific, and achievable.
- Write about **methodology** in short (study setting, design, duration, sample size and population, inclusion and exclusion criteria, ethical approval, **methods to achieve each objective** i.e. there should be synchronization b/w objectives and methodology, and statistical analysis).

- The **implications** section makes up an essential part of your proposal. This section includes the benefits expected from your study.
- **References.** The standard style is ICMJE style also known by the following names: Vancouver style, NLM style, MEDLINE style or Index Medicus style. Please read more about how to reference in this style here: <https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/library/public/vancouver.pdf>

6. Submission of proposal

- The proposal made as per the STS guidelines has to be submitted online (in pdf format) on the STS website.
- Mandatory attachments with a proposal include ‘Application Attestation Form (AAF)’ while the consent form, study questionnaire (if any), and ethical approval submission are generally submitted at the time of report submission.
- The AAF takes time to get signed by all i.e. your guide, Head of Department of the guide, and Dean of Medical Sciences. So, plan accordingly.
- **“Application will not be accepted unless accompanied by AAF.”** The blank format of AAF can be downloaded from the STS website and must be signed by the guide and attested and forwarded by the Head of Department and Dean of Medical Sciences for KGMU. Once the AAF is signed by all (guide, HOD, and Dean), scan and save it as a pdf file. This must be uploaded at the time of online proposal submission.
- Do not merge pdf file of the proposal and AAF. Both files are to be uploaded separately.

7. Applying for ethical approval:

- Just after you have submitted your proposal, make sure to apply for ethical approval from the Institutional Ethics Committee of KGMU.
- Ethical Approval takes upto 3 months if properly submitted in the first attempt. If poorly done, the IEC can ask you to revise, which can extend the process upto 5-6 months.
- There is a separate guide available on the official website of KGMU on applying for ethical approval to the Institutional Ethics Committee. Kindly go through the same. <http://www.kgmU.org/download/Ethical-Approval.pdf>

8. Conducting the actual study:

- After obtaining the ethical approval, start conducting your study with the help of available facilities in the institute and guidance from your mentor.
- This includes stages-
 1. **Sampling process** which includes access to the target population and sample size calculation.
 2. **Ethical considerations (e.g.** voluntary participation, informed consent, conflict of interest).

3. **Systemic data collection** can be done by using both online as well as offline data collection techniques. Data collection demands both time and patience, so plan your study accordingly.

- **Set the inclusion and exclusion criteria.**
- **Framing of the questionnaire (if any).** This includes important instructions to the participants and the body of the questionnaire.
 - Identifying information should not be asked in the questionnaire. If asked, assign them unique code IDs to ensure the confidentiality of the data.
 - Your response rate depends on your questionnaire as well. So, make sure it's in an easy format and preferably in the local language.
- **Store the data in a spreadsheet.**

4. Once you have obtained the data, **group and recode** your data for analysis purpose.

5. Do the **data analysis** with the help of statistical software.

6. **Write up your conclusions and formulate recommendations.**

- ICMR provides you two months to conduct your study and write a detailed report on it. No extension of duration is given.

9. Applying the statistics:

- You may need a biostatistician, but if you have done courses related to statistics in medical research, you can apply statistics on your own.
- Some most commonly used statistical tests in medical research are student's t-test, ANOVA, Chi-square test.
- KGMU provides 'SPSS version 24.0 software' for free to its residents and faculties who are involved in research work. More details can be obtained from your guide or IT Cell, KGMU in PHI Bhawan.

10. Preparing a detailed report:

- Once you have finished your actual study, start writing a **detailed** report as per the STS guidelines on 'Preparation of Report.'
- Represent your results well with the help of figures and flowcharts. Discuss both expected as well as unexpected findings in your report.
- The effect sizes/confidence intervals should be mentioned in your proposal along with the p-values. Only p-values are never sufficient to interpret your findings.
- Give references properly. No references are given in the conclusion/summary.
- Once finished, check for plagiarism and any errors in spelling, grammar, and punctuation.
- Now, get it reviewed by your guide as well as seniors who have been involved in research work.

11. Submission of the report:

- Ideally, the report is prepared as a single file with consent forms and the questionnaire (if any) compiled in it. As ICMR guidelines say- “There is no separate provision for separate submission for these forms/tools.”
- Along with the pdf file of the report, you will need to upload the Report Attestation Form (RAF), which can be downloaded from the STS website. RAF should also be signed and attested similarly to AAF.

12. After STS report submission:

- If the report is selected, you will be awarded the stipend and certificate from ICMR. Till then, target a relevant journal and publish your study.
- Once your report has been selected, you can't re-apply to the STS program.
- If not selected, you can still publish your study in medical research journals. Though, you will not get the stipend and certificate from ICMR. You can re-apply to the STS program next year. Till then, consider doing independent research projects or you can apply for KG MU intramural seed research grant.
- In both cases, you will have to write a paper to get it published in a journal. **ICMR has nothing to do with the publication process.** ICMR STS does not guarantee you the publication of your article.

Take-home messages:

- Do a proper literature review before you start the research.
- Always write in your own words. Never copy verbatim.
- Never fake data.
- Avoid the dredging of data.
- Give references wherever needed.
- Do not misinterpret the findings of your study.
- Visit the ICMR-STS website frequently throughout the program.
- **Undergraduates can do research.**

End of ICMR STS Guide

Prior ICMR-STs proposal acceptance from KGMU:

ICMR-STs 2020

- **Nishanth R Subash** (MBBS Batch of 2019) for “Effect of Stress and Workload on the empathy of medical residents- A cross-sectional study.” | nishanthsubash@gmail.com |
- **Shubhajeet Roy** (MBBS Batch of 2019) for “Effects of Diet Components on the sleep quality of first-year medical students.” | shubhajeet5944.19@kgmcindia.edu |
- **Girjanand Mishra** (MBBS Batch of 2019) for “Serum uric acid measurement by using traditional wet chemistry versus dry chemistry fully autoanalyzer.” | girjanandmishra98@gmail.com |
- **Zareen Akhtar** (MBBS Batch of 2018) for “Cross-sectional study to assess knowledge and practices of medical students regarding the evidence-based learning strategies.” | akhtar.zareen@outlook.com |
- **Saurabh Singh** (MBBS Batch of 2018) for “Neuroprotective role of berberine against ROS generation in diabetic mice models.” | ssaurav279@gmail.com |

ICMR-STs 2019:

- **Kaushal Kishor Singh** (MBBS, Batch of 2018) for “Comparative study of loss of empathy in undergraduates of different medical colleges.” | kaushal2018@kgmcindia.edu |
- **Shubham Tripathi** (MBBS, Batch of 2018) for “Effect of internet-based electronic gadgets on sleep-wake cycle and dietary pattern of medical students.” | shubhamtripathi@kgmcindia.edu |
- **Prince Rai** (MBBS, Batch of 2018) for “Cross-sectional survey on new patients of arthritis attending Rheumatology OPD to ascertain the pattern of Hydroxychloroquine (HCQ) prescription by the doctors in periphery.” | princerai2018@kgmcindia.edu |

ICMR-STs 2018:

- **Ahmad Ozair** (MBBS, Batch of 2016) for “Retrospective clinico-serological analysis of chikungunya cases in a tertiary care referral centre in northern India.” | ahmadozair@kgmcindia.edu

ICMR-STs 2017:

- **Shubham Verma** (MBBS, Batch of 2015) for “An observational study to record Adverse Drug Reactions (ADRs) in patients co-infected with tuberculosis and HIV.”
- **Priya Singh** (MBBS, Batch of 2015).

Note: The pages that follow provide an ICMR STS proposal that was accepted. It is meant to be a rough example of how to write a proposal, and not one to modelled after with exactness.

Exemplar ICMR Proposal

Student: Ahmad Ozair

Mentor: Prof Amita Jain, MD, PhD

Department of Microbiology, King George's
Medical University, Lucknow, India

Reference ID – 2018-02187

Title

Retrospective clinico-serological analysis of chikungunya cases in a tertiary care referral centre in northern India.

Introduction

Chikungunya is an arboviral disease, caused by chikungunya virus (CHIKV) and transmitted by female mosquitoes.¹ The name comes from a word in Makonde language of southeast Tanzania, meaning ‘that which bends up’, as the disease classically causes severe joint pain resulting in a contorted posture of the acutely infected patient.^{2,3} First recognized in an epidemic form in Africa in 1952,¹ numerous outbreaks have been documented in both Africa and Asia since then.⁴

CHIKV is an alphavirus, member of the Togaviridae family, part of the Semliki Forest Antigen complex.⁵ A positive sense, single-stranded RNA virus of 11.8 kb, CHIKV has three distinct lineages: the West African, the Asian and the East Central South African (ECSA) phylogroup.⁶ These lineages have distinct genotypic and antigenic characteristics.⁷ The virus is usually diagnosed by enzyme-linked immune sorbent assay (ELISA) using anti-CHIKV IgM antibody, indicating active infection or by polymerase chain reaction (PCR).⁸ The virus is currently a global re-emerging virus, not just restricted to the tropics but also affecting subtropical areas of Europe and North America.⁹⁻¹³

The acute form of chikungunya is usually characterised by high-grade fever, headache, myalgia, arthralgia and rash. Crippling arthritis symmetrically involving small joints of hands, wrist, elbow, shoulder, knee and ankle joints is seen, evident in the bent or stooped posture of the patient.¹⁴ Fatal haemorrhagic or encephalitic manifestations can also be seen in a subset of patients.¹⁵ The chronic form presents with relapses including fever, inflammatory polyarthritis, stiffness and exacerbation of arthralgia. Neurological, ocular and mucocutaneous manifestations may also be present.¹⁶ Rarely, chikungunya may prove fatal, especially in the elderly, neonates and individuals with co-morbidities or coinfection with dengue, another arboviral disease spread by the same vector as chikungunya.^{17,18,19} Clinical diagnosis of the disease may sometimes prove difficult since it shares many features with dengue and Japanese encephalitis (JE).²⁰⁻²²

Chikungunya, which earlier had its human spread mainly by female *Aedes aegypti* i.e. the tiger mosquito, gained a new vector in the re-emergence of 2004 in the form of *Aedes albopictus* after a genetic mutation in a membrane fusion glycoprotein considerably increased its efficiency of transmission via the latter.^{23,24} In India, after an epidemic in 1973, the disease had been silent for 32 years, when it re-emerged in October 2005.²⁵⁻²⁸ Since then, the epidemic has been ongoing, with numerous reports documenting the significant affliction of the populace by the re-emergent virus^{25,29-31} and the resultant impact.^{32,33} Phylogenetic analysis showed that the current epidemic has been caused by CHIKV belonging to the ECSA phylogroup while earlier isolates from India (1963 to 1973) were of the Asian genotype.^{34,35}

Currently, chikungunya has neither any safe and effective vaccination nor any targeted therapeutics available.³⁶ Prevention and supportive care are the mainstays of tackling the disease outbreaks.³⁷

The proposed study will retrospectively evaluate serological data of chikungunya patients tested at Microbiology department of King George's Medical University (KGMU), Lucknow, which is the major referral centre for the entire state of Uttar Pradesh. The study will analyse data in different subgroupings of age, sex, clinical manifestations, district etc. and chart the trends. It is the primary prevention that the study aims to bolster by highlighting the epidemiological patterns in the seropositivity of Chikungunya, which may be helpful in guiding the focus of vector control programmes, especially in resource-scarce settings, by concentrating on the most affected of subgroups.

The National Vector Borne Disease Control Programme (NBVDCP) of the Government of India is the nodal agency for national monitoring and surveillance of chikungunya, along with other vector-borne diseases such as dengue and malaria. NBVDCP reports a total of 64057 and 62268 cases of clinically suspected chikungunya cases for the year 2016 and 2017, respectively, lending weight to the impact of chikungunya on the Indian population.³⁸ However, NBVDCP data indicates a significant gap in the reporting of chikungunya from Uttar Pradesh (UP) in the last 8 years with less than 100 cases per year except in 2016, when 2458 cases were reported. The present study also aims to fill in this gap, by providing a report for all patients tested serologically for chikungunya in a tertiary care institute catering to the entire UP. Furthermore, because chikungunya may have encephalitic manifestations, the study will also serve to illustrate whether or not CHKV is an important etiological diagnosis of acute viral encephalitis, a perspective grossly underrepresented in the literature.³⁹⁻⁴² The study is well-equipped to demonstrate this since the hospital caters to the encephalitis afflicted belt of UP.

Primary Objectives

- To analyse serological and clinical data in different subgroups of age, sex, clinical manifestations, region etc. and chart the trends.
- To derive meaningful epidemiological conclusions from the patterns emerging post-analysis.

Secondary Objectives

- To sort and organize medical records in microbiology related to all patients tested for chikungunya in Microbiology department of KGMU from 2012 to 2017.

Methodology

Type of Study

Epidemiological investigation.

Study Design

The study will be a retrospective observational study conducted at Microbiology department of the King George's Medical University, Lucknow.

Inclusion Criteria

1. All patients, with clinical suspicion of chikungunya who were tested for chikungunya by ELISA (Anti CHKV IgM antibody) or both ELISA and PCR, from 2012 to 2017, both years included.
2. Patients from whom informed consent had been obtained at the time of testing for the use of their serological and clinical data for any current or future research purposes.

Exclusion Criteria

1. Data missing regarding the patient.

Sample size

All patients fulfilling the inclusion criteria will be included, which a preliminary review indicates are more than 3000.

Data Collection Procedures

Testing of patients for chikungunya, for which the current analysis is proposed, has been already done in the department of Microbiology as follows.

Patients who presented with signs and symptoms of chikungunya were asked by various departments of the hospital to get tested serologically. ELISA has been the method of diagnosis, with Anti CHKV IgM antibody kit issued by the National Institute of Virology, Pune being used, with a sensitivity of 95% and specificity of 98%. After getting informed consent for testing and research purposes, ELISA was done, which came out as either positive, negative or equivocal. Patients who were ELISA equivocal were then asked to get tested by conventional PCR. A subset of patients was tested for both ELISA and PCR simultaneously.

Using the provisional diagnosis of the patient, made before serological testing, different manifestations of chikungunya will then be used to group patients into four clinical categories. The manifestations used for classification will be as follows: classical arthralgia, Viral Haemorrhagic Fever (VHF), Pyrexia of Unknown Origin (PUO) and Acute Encephalitis Syndrome (AES).

Patients would be considered positive for chikungunya in the analysis if the ELISA is positive or if ELISA is equivocal/negative but PCR is positive.

Statistical Analysis

Data will first be tabulated in Microsoft Excel and documented clearly. Seropositivity will be calculated for different subgroups of age, sex etc with groups being compared across different manifestations of chikungunya.

Using the data obtained above, further statistical analysis would be done in IBM Statistical Package for Social Sciences (IBM SPSS, version 24), for which institutional access is available . Pearson's chi-square test will be applied for determining whether significant difference exists between observed and expected seropositivity in different corresponding subgroups. Logistic regression with multivariate analysis will be applied to independent variables being age, sex, district to which patient belongs etc. and dependent outcomes being different clinical manifestations and seropositivity.

Meaningful conclusions regarding epidemiology of chikungunya henceforth would be derived.

Ethical Considerations

All patients sent to the Microbiology department of the hospital from various other departments have already given informed consent for use of their test data for any research in the future, records of which have been maintained meticulously.

Implications

The present study, on completion, will contribute to filling the gap in the literature pertaining to the epidemiology of Chikungunya in the state, thus revealing trends in the manner of involvement of the general population. This would be a step further in the epidemiological studies of viral diseases prevalent in the area concerned.

As a disease causing significant morbidity and some mortality, but still lacking effective vaccination and therapeutics, chikungunya's epidemiological data, post analysis, will be beneficial to the public health officials in better tackling the menace by ensuring preventive measures to those groups of population who have the highest seropositivity or the most severe of manifestations.

Furthermore, the study will serve to illustrate whether the 2005 re-emergence of chikungunya virus and subsequent epidemic has continued unabated, especially in Uttar Pradesh, or has started declining. The study will also help to contribute to the literature whether chikungunya as an etiological diagnosis should be considered or not in the evaluation of acute viral encephalitis. The analysis will also be useful in filling the void in the reporting of chikungunya cases in the state of Uttar Pradesh to the National Vector Borne Disease Control Programme (NBVCDP).

Conduct of the proposed study will also help the student investigator to better understand research methodology and to do better investigational work in the future, especially during his clinical years as a resident.

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