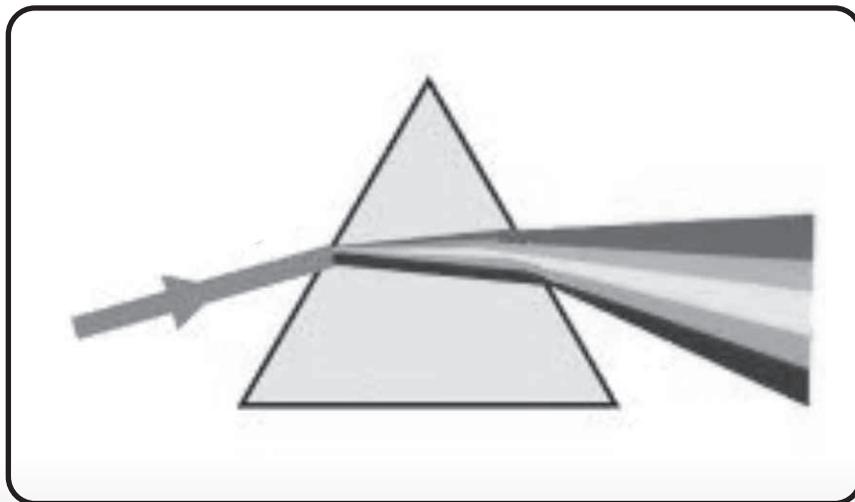




PRISM – A MEU Initiative
Evidence Generating Community Health Project
(EviGenCHIP)
HAND BOOK



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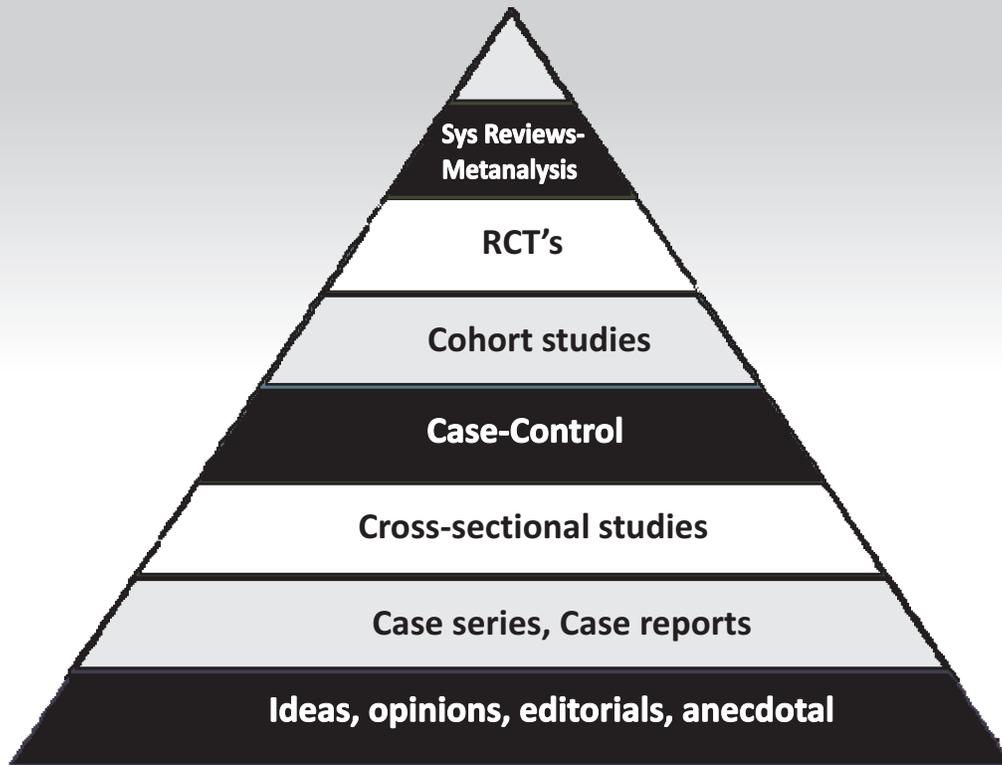
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Level of Evidence in Research



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EviGenCHIP (Evidence Generating Community Health Project)

Preamble:

“Health for all by 2000 A.D” This was a cherished goal evolved by the World Health Assembly and was universally accepted by all. However, as we can see in 2014, this goal is not fulfilled by any nation and has been reduced to a mere rhetoric. Yes, health for all may be a mission impossible, yet it is possible for us to provide better health to ever increasing number of people around us. The necessary ingredients for this are concern, commitment and innovativeness.

Greater participation by the people is an important requisite for improving their health. Health is not only one's right, it is also one's sacred duty and responsibility. People should make efforts to solve health problems at their own level. Innovative approaches to solving health problems through team efforts can lead to a great deal of achievements. One such initiative is Evidence Generating Community Health Project (EviGenCHIP)

A bit of history of PSBH:

- The Dreyfus Health Foundation, New York, pioneered the concept of PSBH.
- It was first tried in the West China Medical University, Chengdu in 1989.
- The philosophy soon gained momentum and the programme is now implemented in several countries of the world in hundreds of individual locations.
- Health Action by People (HAP), a nongovernmental organization based in Kerala, is the Indian partner of Dreyfus Health Foundation, New York since 1993. HAP has carried the message of PSBH to the country in a unique Indian way. By 2002, the programme had steadily grown and was implemented in 27 medical colleges of the country. This list was growing steadily.
- In Gujarat the PSBH programme was successfully launched in the N.H.L. Municipal Medical College, Ahmedabad and Pramukhswami Medical College, Karamsad.
- HAP works in close collaboration with the faculty and students of these colleges. It ropes them actively in this programme through participation and actual demonstration.

The PSBH Philosophy:

- PSBH believes that solutions to most health problems affecting our community are well within our reach.
- Every person can make a difference, be it small.
- Often the solutions to problems are simple & ingenious.

National and international efforts may be required to solve major health problems like outbreak of major epidemics i.e. H1N1 Influenza. But in most cases, culturally appropriate and cost-effective local solutions are possible e.g.

- universal immunization of all eligible children in an urban slum, prevention of vehicular accidents near a school or college, minimizing the infant mortality and maternal mortality due to tetanus etc.
- With this exercise the medical student learns to make detailed observations and generate scientific evidence. Evidence means the observation made with purpose or research outcome with purpose. These observations or researches may be part of animal studies, observational studies, analytic studies or clinical trials. All studies usually generate evidence, but all are not equally valid and relevant for health care practice.
- This Evidence Generating Community Health Project (EviGenCHIP) is the process of generating scientific evidence and use for finding the best solution. The philosophy of PSBH has helped to design EviGenCHIP.

EviGenCHIP for medical students:

- Modern medical education largely emphasizes on training young doctors to treat sickness on an individual basis.
- Technology of medical interventions and diagnosis take precedence over concerns for social and environmental origins of illness and the role of non-medical interventions in reducing the burden of illness.
- Modern medical training does not equip a young doctor to advise policy makers with confidence & competence.
- The EviGenCHIP process trains the young doctors to acquire these perspectives and address the above problems.
- It also enables them to gather skills in developing new and innovative approaches to solve health problems by generating evidences.
- The proposed method of implementing EviGenCHIP provides young medicos to experience the rewards of group discussion, learning from insight of other participants and developing collective wisdom. It also gives them opportunity to contribute generating evidence in the scientific community and also to make them problem solving.

In short, along with fellow learners and facilitators, it becomes a unique learning experience. Over two days the learners are guided gently through various stages of generating evidences for solving health problems. The exercise starts with the identification of a health problem and culminates in developing an action oriented plan to reach the solution of the problem by the participants.

EviGenCHIP in SBKS Medical Institute and Research Centre:

- This programme is carried out under aegis of Medical Education Unit (MEU) of the college.

- Several faculty of MEU have functioned earlier as facilitators or resource persons in PSBH training programmes. A few of them have been beneficiaries of such programmes during their student days. They are quiet familiar with process of PSBH and they are trained for the EviGenCHIP process in MEU
- It is now visualized to carry out this programme for students of III M.B.B.S - Part I starting from April 2014. This programme is fine tuned based on experience of first programme (2013) and it is renamed EviGenCHIP.
- Presently 25 teachers have been enrolled to execute the programme for nearly 110 students.

At The End:

- **The goal** of programme is to provide medical students with a new learning experience through an intensely participatory process. Participants will be encouraged to identify health problems of local importance and evolve innovative approaches of research to learn the quality evidence generation, not conventionally thought of otherwise, and suggest best solution to solve them. At the end of two days, the participants in the groups of 5 to 6 would have identified the problem, refined it, discussed and prepared an action plan of research for generating evidence which they will carry out in the subsequent 3 to 4 months. The end will be marked by preparing a report on project and its presentation / publication.
- **THE Mission** of EviGenCHIP for medical students of SBKS MI & RC is to sensitize them for importance of finding health problems of local relevance and to equip them with innovative skills of community based research thus the community based problem solving. The emphasis will be on quality evidence generation by good research methodology and suggest best solution for community health problem to make a difference, even if the numbers of the people who benefit out of them may be small. If found useful, the solutions may be replicated in subsequent studies involving larger number of beneficiaries. Equal emphasis will be on encouraging participants to generate information on health issues through cross-sectional surveys, or analysis of hospital records where such information is lacking. Subsequently this information may be used for identifying problems and devising their solutions.

So.....Let us get going and tread newer unknown paths of learning with joy.

Introduction to EBM and Process of EviGenCHIP-

Evidence Based Medicine (EBM) means the best use of current evidence in decision making in medicine to gether with experience of physician and keeping in mind patient values and expectations. The heart of EBM is the current best evidence. You learnt about PICO formation and literature search for scientific query. Here the learning objective is to develop community based evidence generating research project step by step.

What do you understand by Evidence?

Evidence means observation made with purpose or research out come with purpose. These observation or researche may be part of animal studies, observational studies, analytic studies or clinical trials. All studies generate evidences, but all are not equally valid and relevant for health care practice. EBM is the process of checking the validity and relevance of available evidences. Researchers need to ask that what are the evidences generated out of the research? This fully depends on the research methodology. Researchers should have knowledge of selecting best research method for best evidence generation. Such quality evidences will help for the health promotion of patient and community. For generating higher level of evidences through systematic review & meta analysis, there should be available mid level and lower level evidences. In present workshop the learner will learn the selection of best research method for research question, thus the researcher will generate best quality evidences for health promotion and protection of community.

Why do we generate evidences through research?

The ultimate goal of the health sciences is health promotion, protection, prevention and healthy community. There are continuous research going on to achieve this goal. Medical education is part of this process. Medical colleges are training the new Young Turks for upcoming challenges in medical sciences and health sciences. Thus medical students should learn to search available evidences, evaluation of available evidences and generate new evidences for healthy community. Resources like money, material, manpower and time are always scarce. So there must be judicious use of resources. There should not be duplication or wastage of resources.

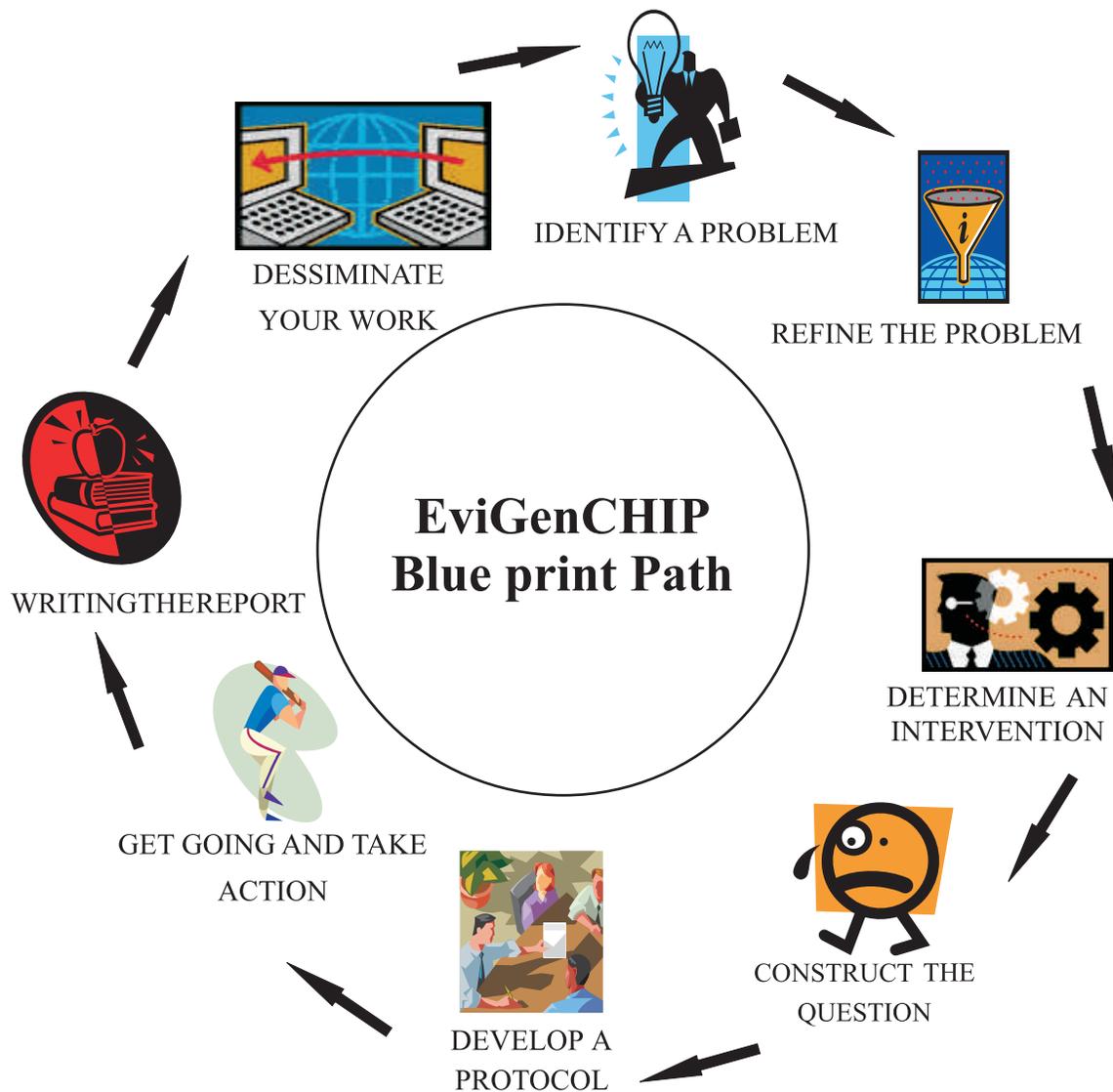
Thus whenever you think to generate evidence, the prime question one needs to ask is what more knowledge will this research add in existing knowledge? This is possible with extensive literature search. Searching available literature is also part of this module.

BLUE PRINT

In the scientific process of finding workable solutions to known or unknown obstacles in the path of establishing or regaining individual or social health, it is advisable to accept every PROBLEM as a CHALLENGE posed to us. There is a simple, methodical system of dealing with such problems. The process starts from identifying a problem, and culminates in writing down your conclusions for authentication and sharing with peer group.

If it is not documented, it is a rumour!

In next few pages, we shall navigate through the basic components of the process of EviGenCHIP.



LEVEL 1: IDENTIFY A PROBLEM

Managing individual and social health is always going to remain a continuous process for healers. Though individual case management is the primary job of healthcare system, appreciating current lacunae in service and anticipating potential challenges in future, too, stays an alert responsibility.

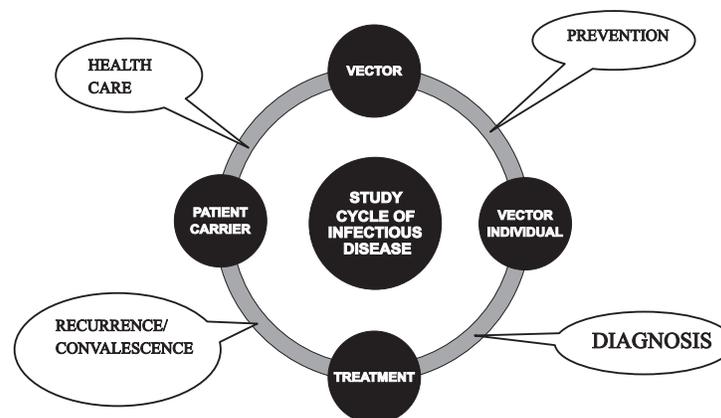
Problem identification has two action components. (A) Identify & (B) Validate

(A) IDENTIFY A PROBLEM. Problem can be identified using either of the two techniques.

- 1) Weak Link Method: Every disease has a disease cycle, comprising of cause-effect-correction-prevention. As long as all these links are well addressed to, no problems arise. However, one weak link in the cycle is capable of having a cascading ill effect on the following components. A problem can be earmarked by identifying the weak links in the study cycle of the disease of interest.
- 2) Personalization: For a beginner in the field of research, when the candidate is yet to be informed about various disease cycles of plethora of diseases, it is advised that he can start enquiries based on his personal experiences. Disease, either experienced by self or near and dear, or read about, or in news, or of personal curiosity may be zeroed upon. Learning about the disease cycle of disease such identified; and then identifying the weak link, reduces confusion; and has high chances of follow up due to personal interest of the investigator.

(B) VALIDATE THE PROBLEM. Once the problem is identified, it needs to be validated by asking following four questions.

- 1) Is the problem relevant to your situation?
- 2) Is it important?
- 3) Does it affect a large number of people?
- 4) Does it cause considerable mortality and/or morbidity?



LEVEL 2: REFINE THE PROBLEM

Once the weak link or problem area is grossly identified, the next natural step is to refine the enquiry. A problem can be refined by assessing it using following five parameters.

The SMART method!

S- Specific. Be specific. What, when, where, how – answer in details!

M- Measurable. Have definite parameters to evaluate process and results. TALL is a perception, 5'10" is height!

A- Affordable. Who is sponsoring the study? Are resources available and enough till completion?

R- Realistic. Is the study possible in given setup/expertise/population/resources/timeframe?

T- Time bound. Goal without timeframe is a Dream! Put dates on events.

Example:

To study the incidence (measurable) of malaria(specific) in patients of fever(specific) attending OPD at a tertiary care teaching hospital (affordable/realistic) over a period of three months (time bound).

LEVEL 3: DETERMINE AN INTERVENTION (OPTIONAL)

Now comes the action part. Every time action part may not possible. In such scenario you can suggest action at the end of study. If action component is feasible, do conduct in your study. – Deciding the solution to the problem you have identified and refined into a doable question. There are many ways of solving a problem:

(1) Direct medical intervention eg. Albendazole for worm infestation

(2) Health education eg. Hygiene education to prevent worm infestation

Economic – Getting funds for infrastructural development.

Legislative – Passing laws banning certain practices.

Logistic – Facilitating healthy practices.

There is no formula to apply which type of intervention for which problem. It all depends on the nature of problem and your approach towards it. A problem may be dealt with by various methods. Which one to adopt is your choice. For example: if you want to solve the problem of low rate of detection of tuberculosis in your community you could:

- (1) Go door to door, collect samples and diagnose the cases.
- (2) Educate the community by different means, increase awareness and compliance within it, thus increasing the turn up of people for diagnosis.
- (3) You could pass laws making it necessary for people to go for diagnosis of TB and make avoiding it punishable.

Each of the solutions in the above example might eventually lead to the solution of the problem. Which one is possible for you, which one will be the most effective, which one will give a lasting solution is what you have to decide.

LEVEL 4: CONSTRUCT THE QUESTION

A question is a form of communication which excites the human mind and keeps it alert to the situation. A question stimulates the human mind to a variety of reactions – something which a statement would not. Most of the goals of EviGenCHIP can be made systematic by putting it in the form of a question – a question whose answer you will find in the course of the project.

There are certain necessary characteristics of a question which can be put into the acronym FINER

F – Feasibility

Do you have the time, resources and man power to solve the problem? Would the number of cases be substantial enough to make the intervention significant? Or you think the observational study will give adequate information in line of generation of quality evidences.

I – Interesting

Everyone would be interested if the problem is significant enough for them. No one would be interested if you talk of yellow fever in India; but you talk of malaria – people will be interested.

N – Novelty

Novelty has a very broad definition. However it is necessary because there is no meaning in repeating things which have already been done – successfully or otherwise.

E – Ethical

As we are dealing with human beings and that too in a scientific format, ethicality of your actions is paramount.

R – Relevance

The problem and the solution should be relevant according to time, place and person.

Let us take an example:

On the problem of worm infestation, a question can be asked: *Will education on personal hygiene and food habits lead to a decrease in the load of worm infestation in the paediatric population in the target village?*

Though the whole idea of PSBH is to solve the problem, EviGenCHIP projects includes on identifying the magnitude of the problem which could eventually help in deciding the priority of solution. Such magnitude measuring problem will generate evidences in scientific knowledge pool. Thus this is helping you to generate community based evidence which you can verify with the available evidences in literature. Sometime you may generate new evidences in existing knowledge. For the beginner, this exercise is helpful to understand the scientific way of learning evidence generation. For example: *What is the prevalence of anaemia in female students of a rural government school in the target village?* If the answer turns out to be of a very low prevalence, just routine health education to the students would suffice. Also this will raise the new question that why this village female students have low incidence of anaemia? Searching answer will help the scientific community to learn new evidences for prevention of anaemia. If the answer turned out to be in the range of 40% - 50%, then it would probably require including the parents and their teachers too in the education target group. And if the answer turned out to be all the students it would require institution of treatment of the children first.

In the present format, searching solution and testing the solution in community is very difficult as the project needs to finished in six to eight months. So the students will find out the problem and search the possible causating factors and suggest best solution. Thus the students will learn descriptive and analytic epidemiology and what level of evidences they are generating with this EviGenCHIP project.

LEVEL 5: DEVELOP A PROTOCOL

Once the whole problem and its attempted solution are clear in your minds, the next step is to put it all on paper in a systematic manner. This systematic representation of the

definition of the problem, its background, what you aim to do about it, how you propose to do it and how to evaluate outcome is known as a protocol. It has the following sections:

Title page

Background of the problem and the rationale of the intervention

Objectives

Design of the study

Materials and methods

Resources

Time line

Evaluation

TITLE

This should be a brief and precise phrase describing your study. Eg Screening for prevalence of anaemia in female students of a rural government school. Will Educational intervention to increase the awareness of sexually transmitted diseases in college students reduce the STD among them?

BACKGROUND/RATIONALE

This section gives a short description of why the problem is important and what is the reasoning behind using the solution you are planning to implement. Here you give a brief overview of what is already known about the problem, its magnitude etc.; what solutions have been attempted in different places and what were the outcome.

OBJECTIVES

This section enlists what you actually intend to do during the course of the study. Small precise sentences, breaking down the whole gamut of your study is preferable. Eg
To study the prevalence of haemoglobin levels in female students of a rural government school
To find out whether anaemia is more common in females than in males
To study whether health education can solve the problem

DESIGN

There are two main categories in design: Qualitative and quantitative. Finding out the perceptions of people regarding different health problems falls within the confines of a

qualitative study. However EviGenCHIP type studies are more likely to be quantitative. The type of study design you choose has to be mentioned in brief in the next section on materials and methods. In fact the materials and methods are more or less decided based on the study design.

MATERIALS AND METHODS

This section describes actually how you are going to go about the study in a systematic manner. All minute details have to be covered and nothing can be left out open for interpretation. Each step has to be properly defined. Certain points which need to be covered include:

Study design

Target population

Study site

Selection Criteria

How many subjects are planned?

What are the different activities planned?

What will be the exact method of executing them?

As such there is no end to detailing but the more details you can work into your protocol the more scientific and convincing it will look.

RESOURCES

This is a very important section and is more of administrative importance than scientific. However the availability of resources can make or break your study. Hence it is of paramount importance to plan out the needed resources and the timing of its use. It is also necessary to monetise the resources you are planning to use so that an estimate can be made regarding the expenses involved in conducting the study, in short, making budget.

TIME LINE

By now it is clear to you that your study involves various steps and it also has to be completed within the deadlines set by the institute. Hence together with budgeting for conventional resources, you should budget for your most important resource i.e. time. This budgeting has to be presented in a graphic manner in the form of a time line.

Undergraduate research activity will provide you an opportunity to get to know about the basics of it. There is a different level of understanding that comes from doing things yourself rather than just sitting back and listening to someone tell you about it Your commitment will

allow you to look at the work with a fresh perspective and you will find very often that you possess very insightful ideas for EviGenCHIP

During the tenure many unexpected obstacle may come threatening delay in completion. You remain determined and patient they will vanish slowly. It is always good to keep in touch with your facilitator who will guide, facilitate and sooth you whenever needed.It's never wrong to ask for help. We can save you a lot of time and frustration by getting you on the right track to finding the resources you need.

“The project you have just finished must have a proposal, and the proposal has to be your own”

LEVEL 7: REPORT WRITING

By now you have acted on your plan guided by the protocol you have established beforehand. So far what you have done can be concluded broadly into two ways. One, you achieved what you had expected and the second possibility; you did not achieve the expected success. It is never disheartening as most of us fee because while engaged into the project you have practically experienced it which surely would have filled energy and confidence in you.

It's time to document your work as this will help others know your experience all the way of PSBH activity. Scientific research demands precision. Scientific writing should reflect this precision in the form of clarity. It has to be concise, informative and orderly rather than vague and general.

The Scientific work is generally documented with these elements: Title, Abstract, Introduction, Methods, Results, Discussion, and Literature Cited. The actual words "Introduction", "Methods," etc. are used to head the sections of your paper. Begin a new page for each section. Tables and Figures are placed at the end of the text.

Hereby we lay down an outline of a model project report. Do not consider the following outline as unchangeable convention. A particular format and style is adopted for a given paper depending upon both the nature of the report and the journal or other publication in which the paper is thought to be published.

| | | |
|--------------|---|---------------------------------|
| Opening Page | Title of the Project | It has to be clear and precise. |
| | Name of the Author with current affiliation and Designation | |
| | Name of the Facilitator | |
| | Year | |

Page 2 Contents (list the sections and corresponding page numbers)

Page 3 Abstract

The abstract should be a self-contained unit capable of being understood without the benefit of the text.

It should contain four elements:

1. The purpose of the study (the central question);
2. A brief statement of what was done (Methods);
3. A brief statement of what was found (Results);
4. A brief statement of what was concluded (Discussion, in part).

Other Pages Introduction

Introduction is meant to introduce the reader to

your research. It should contain the description of the nature of the problem and current state of knowledge about it. A statement of the purpose, scope, and general method of investigation in your study and hypothesis/hypotheses and predictions.

Aim

A brief statement what exactly you were aiming to find out or achieve.

Methodology (Material & Methods)

Already described in previous section

Result

Discussion

Conclusion

References

Annexure (if any)

Working tools (eg questionnaire, lab diary);
Summary of raw data (in tally or table form)

Key notes:

It is important to understand that scientific writing is not the same as essay writing. The Style and language of a scientific report is different. It should be written in past tense; in passive voice and pronouns should be avoided. However the objection of using pronouns is receding and use of 'I' and 'we' is

LEVEL 8. DISSEMINATE YOUR WORK

Your journey with a valuable, however little research project might be thrilling. Conceptualizing a road map to do something for the society you live in; start working on it with high spirit and all noble thoughts; moving onwards, overcoming all the hurdles which finally gets completed yielding a well written report. May be inhabitants of your work area are going to be benefited because of this in different ways.

Something more and important is in line. Don't you feel to present your work before others? Don't you want it to get published? You may ask why? The simple reason is, many are desperate to see why, how and what you have done. Remember what inspired you to get involved into this Project? Instill that same sense of wonder in others by sharing your research with the broader world. They want to listen carefully and discuss every finer details of your work. Many want to be guided and inspired by your experience. And would it not be nice if your work is available for the whole world to read and comment?

Obviously you would like to share your work with other for all good reasons. Also remember that a series of notable publications can drive a young scientist to the next academic stage, whereas an inadequate publication record can overturn a career. Publications are the main way scientists publicize their work, and ultimately, it is by their papers that they will be judged. In recent years with advancement in electronics, manuscript could be circulated widely and are relatively cheap. There are few websites dedicated to these small projects and are ready to host manuscripts in order to provide global reach. Otherwise nicely written manuscripts can also be sent to peer reviewed journals for consideration of publication.

Aiming your paper at the most appropriate journal can save much effort and reveal your results to the world sooner. The so-called top journals value novelty and unexpected findings, but other journals may be more interested in careful, extensive analyses of critical processes. Survey the various journals and see where your work would fit best. Seek advice from teachers, fellow colleagues and others in the field who has experience as authors, reviewers, and journal editors. You may be tempted to send your paper to a top journal even if your results are not of the highest originality or broadest interest. But you can save time and reduce your frustration if you send it to the appropriate journal first instead of waiting until it's rejected by a top journal.

We have planned to provide a platform to you young problem solvers to share your experience with your fellow colleagues, juniors and seniors.

Share your experience and inspire others

Annexure 1. Model Action Plan

Screening for Refractive Errors in School Children: An EviGenCHIP Protocol

X Yzzzz

Background

Refractive errors are fairly common in the general population. The prevalence increases as age advances. It is estimated that the prevalence of refractive errors range between 5-7 percent among school children⁽¹⁾. Only a few children are lucky to have these errors detected early. Children with uncorrected refractive errors have learning disabilities and their poor performance is generally attributed to laziness or dullness. Early detection and correction of the disability will restore proper eyesight to these children and help them perform better in school. Detection of refractive errors is simple, inexpensive and can be carried out by trained, educated nonprofessionals. Teachers in schools can be used at the first level for screening and detection of refractive errors.

Research Question

Will a screening programme for detection of refractive errors, using teachers at the first level, administered to 1200 school children, aged 5-15 years, in a school in Vadodara result in detection of new cases of refractive errors and subsequent adoption of spectacles?

Objectives

The principal objectives of the research project are

- To detect children with refractive errors using school teachers trained to use Snellan's chart.
- To confirm the diagnosis with the help of professional ophthalmologists
- To encourage parents to provide spectacles to the affected children.

Materials and Methods

Design of the study: Cross-sectional survey

Subjects: 1200 children in the age group 5-15 years studying in high school located Vadodara city.

Inclusion criteria: Children not wearing glasses and in whom refractive error has not been detected

Exclusion criteria: Children wearing glasses

Implementation of Screening Programme

After taking permission of institutional ethics committee the project will be started. A pamphlet explaining the purpose of the screening programme will be printed and distributed to all parents and their signed consent obtained. Six teachers will be selected on a volunteer basis and the principles of use of Snellan's Chart demonstrated to them. Each teacher will be given the opportunity to test their skills on a batch of 60 children under the watchful eyes of an ophthalmologist for fine tuning their skills. The teachers will be allotted children in such a way that each teacher gets about 200 children for screening. The test result will be recorded in a printed form for each child.

After the initial screening is over, a list will be prepared of all children who have been identified to have defective vision. The parents will be informed and they will be requested to bring their children for detailed evaluation by a professional ophthalmologist on appointed days. All children, short-listed initially, will be examined by the ophthalmologist. The final list will be prepared on the basis of the diagnosis made by the ophthalmologist. The ophthalmologist will also prescribe glasses for affected children.

Health Education

On the day of the screening by the ophthalmologist, health education sessions will be conducted by the investigator to the parents for giving motivation to buy glasses for their children. Health education will also focus on helping the child to cope with the spectacles in the initial few weeks. The schools will be visited one month after the ophthalmological examination and the number of children wearing spectacles estimated.

Prevalence of undetected refractive errors will be calculated using the following formula:

$$\text{Prevalence} = \frac{\text{Number of children ucwly detected}}{\text{Total number of children screened}} \times 100$$

$$\text{Spectacle adoption rate} = \frac{\text{Number of children started wearing spectacles}}{\text{Nubber of children who were given prescription for glasses}} \times 100$$

Annexure 2: Common Research Design in Quality Evidence Generating Research (EviGenCHIP)

The principal goal of a research design is to develop good protocol for data collection, analysis and outcome within community. They may be observational or interventional. Examples are- Knowledge on HIV and AIDS, with or without educational intervention, levels of plasma HDL before and after a programme of exercise, the incidence of lung cancer in smokers and nonsmokers and blood pressure lowering effect of a new drug.

Types of design

The principle designs are

Observational designs

- Designs aimed at generating hypothesis
- Designs aimed at testing hypothesis

Experimental designs

- Designs for testing hypothesis with intervention

In experimental studies, the intervention is under the control of the researcher, whereas in observational studies, the researcher observes patients at a point in time (cross-sectional studies) or over time (longitudinal studies). If the observations are made by looking forward and gathering new data, the study is prospective; if the data already exist (for instance, in records or as census data), the studies are retrospective.

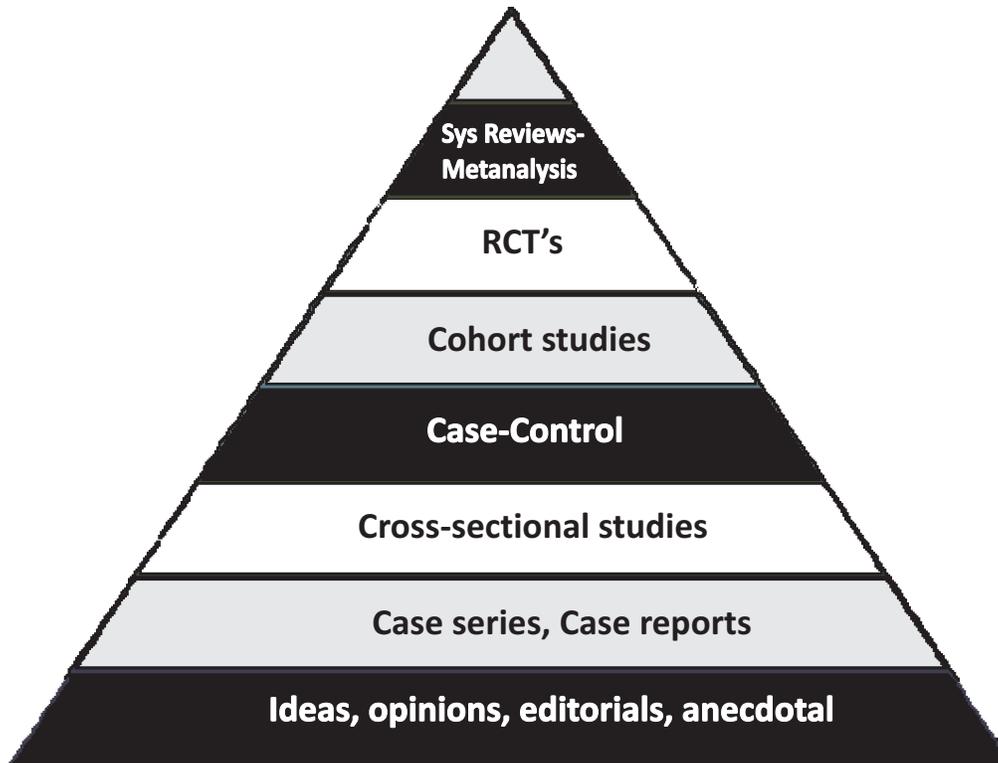
These study designs will produce the primary data. These primary data will develop low and middle level of evidence. With the help of large number of primary data and their analysis, scientists are generating secondary data which are the readymade answer to clinical questions. Various study design and level of evidence generation can be understood by level of evidence pyramid or table.

Levels of Evidence from Sackett*

| Level | Type of evidence |
|-------|---|
| I | Large RCTs with clear cut results |
| II | Small RCTs with unclear results |
| III | Cohort and case-control studies |
| IV | Historical cohort or case-control studies |
| V | Case series, studies with no controls |

Adapted from Sackett DL. Rules of evidence and clinical recommendations on the use of antithrombotic agents. Chest 1989;95:2S-4S

Level of Evidence in Research



Observational design aimed at generating hypothesis

Cross sectional survey

A cross sectional survey is a survey of a population at a given time. Examples are- surveys carried out to estimate the prevalence of diseases like type 2 diabetes, hypertension and obesity or behavioural attributes like smoking. Both interview techniques and screening tests can be used.

Advantages - The chief advantages of a cross sectional survey are:

- These are fairly quick and easy to perform
- These are useful for determining the prevalence of risk factors and the frequency of prevalent diseases
- These are useful in assessing current health status of a population.
- These are particularly useful in infectious disease epidemiology for establishing antibody levels indicative of past exposures and the degree of population immunity

Disadvantages- The principle disadvantages are:

The temporal relationship between exposure and outcome remains uncertain because information on both is collected simultaneously

- Indolent and chronic cases of illness are preferentially detected

Cross sectional ecologic studies

These studies relate the frequency with which some characteristic (e.g. smoking) and some outcome of interest (e.g. lung cancer) occur in the same geographically defined population.

Advantages:

- These are quick to perform
- These are inexpensive
- Information about individual exposure need not to be obtained
- Information about individual outcome need not to be obtained

Disadvantages:

- Inferences on the causal nature of the factors on any individual will be fallacious
- All other disadvantages of cross sectional surveys.

Longitudinal ecological studies

These studies use ongoing surveillance studies or frequent cross sectional studies to measure trends in disease rates over years in a defined population,

Advantages

- These may reveal important associations between determinant and outcomes over an extended period of time such as the relationship between smoking and lung cancer.

Disadvantages

- As with all ecological studies, no information is provided between outcome and exposure in individuals
- Other factors may change over time may confound associations of interest.

Observational studies for generating or testing hypothesis

Cohort studies

A cohort study, the investigator assembles a group people in the present time on the basis of certain attributes, collects baseline data on them and continues to collect data over time.

Advantages -

- Data collection is controlled by the investigator, so that outcome events may be confirmed
- True estimates of absolute risk may be obtained
- Different disease outcomes may be studied

Disadvantages-

- The costs are high
- There is a long wait for the results
- Only risk factors that have been defined and measured at the beginning of the study can be assessed.

Retrospective cohort study

Here the investigator goes back into history to define a risk group and follows the group members up to the present to see what outcomes have occurred

Advantages

- These are less costly than prospective cohort studies
- Results are available quickly

Disadvantages

- The investigator loses the ability to control the criteria used in the determination of the outcome

Case control studies

Here the groups are defined on the basis of outcome and the assessed for differences in past exposures to possible risk factors. These studies are essentially designed to compare the “risk of having the risk factor” in the two groups.

Advantages

- These are easy and quick to perform
- These are relatively inexpensive to perform
- These are useful when the outcome in question is rare
- The actual risk of the outcome cannot be determined but is estimated by the odds ratio.

Disadvantages-

- There is risk of recall bias and other types of bias
- The selection of proper control group may be difficult
- The actual risk of the outcome cannot be determined but is estimated by the odds ratio

Experimental design for testing hypothesis with intervention

Randomized control clinical trials

In randomized control trials (RCT) subjects are randomly assigned to one of the following groups. (1) intervention group (2) control group. The intervention group will receive the experimental treatment while the control, group will receive the placebo (inert substance) or the standard treatment.

If neither the subject nor investigator aware of the treatment assignment until the end of the trial, the trial is a double blind study or double blind trial

Advantages

- They are the GOLD STANDARD for studying interventions
- Bias is minimized, if not completely eliminated
- Generate high level of evidence in evidence pyramid

Disadvantages

- The studies are lengthy and expensive to perform
- Ethical concerns arise regarding the allocation of subjects to inactive or placebo groups
- Drop out and changes in treatment may contaminate the original design
- External validity may be limited if the subjects who agree to participate differ in some way from the general population.

Randomized control field trials

Advantages

- These are similar to RCTs but are designed to test preventive interventions such as vaccines

Disadvantages

- Same as for RCTs

Annexure 3: Searching the medical literature

Research is all about filling gaps in knowledge. If new knowledge is to be acquired, you need to have some surrounding knowledge at your finger tips. You have to make sure that you know all that should be known. You should have a strategy for picking up any relevant new knowledge that is published, right up to the end of your research. A well organised literature review using all available tools at your disposal is an integral part of research methodology. It will constitute a firm foundation for your research. Given below is a summary of the most pertinent tools for searching the literature

Why Search Medical Literature?

A literature search helps you to

- Clarify your research ideal and sharpen your research question
- Establish a theoretical framework for your study
- Find investigation similar to the one you are contemplating
- Learn from similar study designs
- Define your variables and terms clearly
- Identify useful methodologies and instruments
- To locate data sources
- Appreciate historical perspective
- To identify authorities or important contributors in the field

Sources of Medical Literature

Sources of medical literature are broadly classified in to primary and secondary sources.

You are advised to start your search with secondary sources

- Primary sources: Journal articles that report original work
 - Print
 - Electronic
- Secondary sources
 - Textbooks
 - Monographs
 - Review articles

- Alternative sources
- Government publications
- Doctoral dissertations
- Unpublished data

Textbooks and review articles are good place to knowing about a topic. Textbooks are useful when you are just venturing in to an area you know little about. They are however limited by the fact that they represent the viewpoint of only one or few persons, and hence be incomplete or even biased. Also, the information is a bit dated (generally at least 2 years old). Review articles in good journals are written by people specializing in a narrow area of study. References provided in reviews are good sources of more reading material. But eventually, an organized search for journal articles of original research pertaining to topic is a must.

Searching Medical Literature

Every year tens of thousands of original research get published in journals. It is not very easy for any one person to keep track of even a small number of such publications. Index journals and year-books come to your aid. Till the advent of the InfoTech revolution index journals in print were the first source of reference.

Traditional methods of literature search are by

Index medicus
Year books
Excerptamedica

National library of Medicine (NLM), USA and its predecessor, the Surgeon-General's office of the U.S. Army, have been indexing medical literature review since 1879, when the predecessor to today's Index Medicus was first produced. Cumulative IndexMedicus consists of several volumes published each year indexed according to the Medical Subject Headings (MeSH).

Print indexes mentioned above are now practically extinct, with the advent of electronic indexes. Electronic indexes are simply computer-searchable versions of the print index.

However, research by information science professionals does indicate that some print indexes are actually more efficient than the electronic counterpart for some types of searches.

The World Wide Web and Electronic Data Bases

Electronic indexes and databases searchable through the World Wide Web (WWW) have virtually revolutionized medical literature search. Even a person working in a remote area with no access to a good library can do it provided there is a telephone connection and a computer.

How do we go about getting information from the books in a library? We use library resources, such as catalogs, indexes and databases that share certain characteristics. We go around browsing the shelves and look at the catalogues or index cards, these are prepared by information professionals who assign subject and may include abstracts. Books have unique identity (ISBN) and are part of the permanent written record.

The World Wide Web is very different. It is now estimated to contain more than two billion pages of publicly accessible information and it continues to grow at an exponential rate; tripling in size over the past two years, according to one estimate. At the same time, it lacks the bibliographic control standards we take for granted in the print world: There is no equivalent ISBN to uniquely identify a document; no standard system; analogous to those developed by Library of Congress, of cataloguing or classification; no central catalogue including the Web's holdings. In fact many, if not most, Web documents lack even the name of the author and the date of publication.

Obviously traditional information retrieval methods will not work in case of the Internet. The most popular means of searching the web for information are the 'Search engines'

Search Engines

What is a search engines?

They are huge Databases – Which are repository of indexed web documents. They hold information on: Location (site), keyword found on page, language used (international), content rating (adult/child), hyper-linked in document etc.

Benefits of using search engines

- Quicker access to vast amounts of information
- Can perform searches on any keyword or subject combination – Sort of like a library!
- Searches almost always return many HITS for each search!! – Not always a good thing!
- Access is totally FREE!!

Problems with using Search Engines

- Do not always return what you are looking for
- Things you are after are not always at the top of the results page. Many hits to same page are returned so you have to filter manually (can take many hours/days)
- A page may only return 20 items at a time from a total of 1000!
- May take time to connect to them as they are servicing thousands of users
- Bombarded with advertising – this is why the service is free!

How do Engines Index the Web? – Two main ways:

- People submit a starting URL to a search engine in order for it to be indexed.
 - May take few days as many other submit theirs
 - Slow links affect performance of indexing
- Engine automatically indexes your site/pages
- Engines automatically examine new sites and re-index stale indexes
 - Performed using either Crawlers/Spiders or Bots

Search Strategies

Search logic refers to the way in which you and the search engine you are using combine your search terms. For example, the search – HEALTH ACTION BY PEOPLE – could be interpreted as a search for any of the four search terms, all of the search terms, or the exact phrase. Depending on the logic applied, the results of each of the three searches would differ greatly. All search engines have some default method of combining terms but their documentation does not always make it easy to ascertain which method is in use. Reading online help and experimenting with different combinations of words can both help in this regard. Most search engines also allow the searcher to modify the default search logic, either with the use of pull-down menus or special operators, such as the + sign to require that a search term be present and the – sign to exclude a term from a search.

Boolean logic is the term used to describe certain logical operations that are used to combine search terms in many databases. The basic Boolean operators are represented by the words AND, OR and NOT. Whether or not a search engine supports Boolean logic, and the way in which it implements it, is another important consideration when selecting a search tool.

A Six-Step Search Strategy

Step 1: State what you want to find

First, in one or two sentences, state what you want to find on the Internet. For example

- I want to find information on ocular complication of diabetes
- I want to find notes in pathology on inflammation
- I want articles on histopathology of Medullary Carcinoma of thyroid

Step 2: Identify Keywords

Next, underline the main concept in the statement

- I want to find information on ocular complication of diabetes
- I want to find notes in pathology on inflammation
- I want articles on histopathology of Medullary Carcinoma of thyroid

Step 3: Select synonyms and variant word forms

List synonyms, alternate spellings and variant forms of each keyword

- Ocular ophthalmic eye
- Lecture notes tutorial

Step 4: Combine synonyms, keywords and variant word forms

Combine synonyms with Boolean OR. (NOTE: place parentheses around OR statements).

- (Ocular OR ophthalmic OR eye)
- (Lecture OR notes OR tutorial)

Use truncation with an asterisk symbol (*) to combine variant word forms (not supported in Google)

- (diabet*)
- (Lecture OR note* OR tutorial)

Combine keyword with Boolean AND. (note that the phrase medullary carcinoma is put in parenthesis)

- (Ocular OR ophthalmic OR eye) AND (diabet*) AND complication
- (Lecture OR note* OR tutorial) AND pathology AND inflammation
- Histopathology AND “medullary carcinoma” AND thyroid

Step 5: Check your spelling

Search engines return websites with words that match your keywords. If you misspell a keyword, your result will contain website where that word is also misspelled.

Step 6: Add additional key words to enlarge the concept if necessary

Think of some of the words that are bound to be present in a document that you expect. Exclude pages you do not want with - and include those you want with +

“Medullary carcinoma” +thyroid – breast AND amyloid AND plasmacytoid

Some popular search engines

META SEARCH Google (<http://www.google.com/>)

- Largest database
 - § Best for ranking results, based on number of other web pages linked from it
 - § Saves web pages. Even expired pages available in cache
 - § PDF files indexed
- AllThe Web (<http://www.alltheweb.com/>)
 - § Fastest, good relevancy
- AltaVista (<http://www.altavista.com/>)
- Northern light (<http://www.northernlight.com/>)
- HotBot (<http://www.hotbot.lycos.com/>)
- Excite (<http://www.excite.com/search>)

Specialty databases

Sometimes a specialty database will be more effective at finding what you need than a general search engine, specialty databases are dedicated to collecting relevant sites for a particular subject. For example, Findlaw targets legal resources and Achoo! Collects health and medical sites.

Beaucoup lists more than 1,200 engines, directories and indices from around the world.

Price's Direct Search links to a wide variety of business, government, humanitites, legal news and science databases.

At search.com, search more than 100 specialised databases.

If you can't find it at any of the sites above, try Internets – another comprehensive specialty database directory

Some special medical databases

- MEDLINE: database of NLM searchable by NLM's pubmed and several other search engines
- CDC WONDER (<http://www.wonder.cdc.com/>) provides a single point access to a variety of CDC reports, guidelines and numeric public health data
- Index of food and nutrition Internet Resources
- MDchoice.com: Peer reviewed content, medical information, interactive education, online textbooks and journals
- Medical matrix:
- Medmark: Medical Bookmarks
- Mednets: Professional search engines and databases
- Medweb plus:
- National Institute of Health Web Search Engine
- OMIM: Online Medical Inheritance in Man; The most comprehensive database on genetic diseases.
- OMNI: The UK gateway to quality biomedical and health information on the Internet
- PDQ: (<http://cancernet.nci.nih.gov/pdq.html>): Physicians Data Query. By National Cancer Institute. The best and current database on cancer prevention screening and treatment.
- The Cochrane library (<http://www.update-software.com/cochrane/>): for evidence based medicine
- National Guideline
Clearinghouse(http://www.guideline.gov/body_home_nf.asp?view=home): for guidelines on various diseases
- WebMedLit: View latest medical literature on the Web

More on Medline

MEDLINE (Medical Literature Analysis and Retrieval System Online) is the electronic version of the Index Medicus. It consists of over 10 million articles published in 4300 journals in 40 different language fro 75 countries. There are several software online for searching MEDLINE. PubMed is a

search interface from National Library of Medline (NLM). It is free and is available at (<http://www.ncbi.nlm.nih.gov/PubMed/>)

NLM has designed a “concept-based” search methodology using medical Subject heading (MeSH). Over 19,000 standardised medical terms constitute the thesaurus of MeSH. The arrangement of the MeSH is in the form of tree where subject headings are arranged under one another with increasing specificity. It also contains a group of 83 subheadings. Trained indexers scan published articles and assign 10-12 MeSH terms and subheadings to each article.

When you type a word or phrase in the search box, it is automatically matched for a MeSH term and also simultaneously searched in all fields as a text word. For e.g. typing in 'olfactory neuroblastoma' results in search for

[“esthesioneuroblastoma, olfactory”(MeSH terms) OR olfactory neuroblastoma (text word)]. Sometimes search as a text word results in articles you do not want. If you type in 'ulcerative colitis' it returns 17707 articles, some of them may be those about other conditions in which the word ulcerative colitis is merely mentioned in some context. You can use MeSH browser (by clicking MeSH browser on the left of the screen) to limit the search to subheadings of the MeSH term. For e.g. by checking in the box 'pathology', you limit the search to articles coded as ulcerative colitis/pathology. This results in 2267 articles

The limits feature helps you to limit the search to specific age group, gender or human or animal studies. Limits also allows you to restrict to articles published in a specific language and to specific types of articles such as review articles, you can limit by either Entrez or Publication Date and lastly you may limit your retrieval to a specific subset of citation within PubMed, such as AIDS-related citations or nursing journals.

You can use Boolean operators OR, AND and NOT which must be entered in upper case, e.g. vitamin c OR zinc, PubMed processes all Boolean connectors in a left-to-right sequence. You can change the order that PubMed processes a search statement by enclosing individual concepts in parenthesis will be processes as a unit and then incorporated in to the overall strategy, e.g. common cold AND (vitamin c OR zinc) .

Searches can be limited to particular fields by using tags. Each search field tag is abbreviated into few characters and can be typed in brackets, e.g. [au] for author's name or [ti] for title words. Use of these tags directs the search in the specified field alone.

Some examples are:

(AB) Abstract; (AD) Affiliation; (AU) Author; (EDAT) Publication Date; (MH) MeSH Terms; (TI) Title; (TA) Journal Title Abbreviation

The *Clipboard* gives you a place to collect selected citations from one search or several searches. After you add citations to the Clipboard you can save or print them. The maximum numbers of items that can be placed in the Clipboard is 500. Once you have added to the Clipboard, you can click on Clipboard from the Features bar to view your selections.

Related PubMed Articles Link will retrieve a pre-calculated set of PubMed citations that are closely related to selected article, Click on Related Articles to the right of each citation to display the related set of articles, PubMed creates this set by comparing words from the title, abstract and MeSH terms using a powerful word-weighted algorithm, citations are displayed in rank order from most to least relevant with the linked from citation displayed first.

Citation Matcher options allow you to find the citation or the PubMed ID of any article in the PubMed database using bibliographic information. The Single Citation Matcher is a fill-in-the-blanks form that allows you to enter partial journal citation information to locate a record for a specific article, or items indexed from a particular volume or issue of a journal to look for a single citation.

Images and Sound

General search engines have multimedia search capabilities. Images can be specifically searched at Google, Alltheweb and Altavista. Sound files can be located by altavista and alltheweb.

Specialised medical images and sound can be searched in special databases. Examples are Medical history images at the nlm website (<http://www.ncbi.nlm.nih.gov/>) and sounds at (<http://www.wilkes.med.ucla.edu/index.html>)