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IADVL SIG Dermatology Clinical Research Newsletter

RANDOM MUSINGS; 2020; Volume 3: Issue 1. Edited by Dr. Anupam Das

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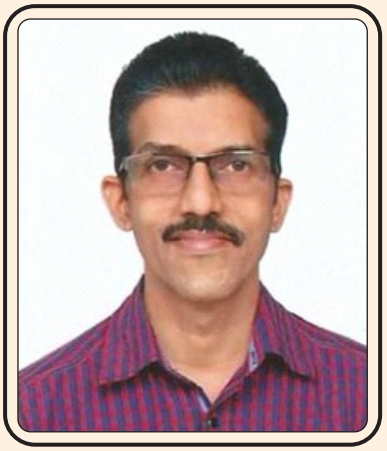

Dr. Asokan N

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Dr. Nayan Patel

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Welcome message

Dr. Ajith Kumar K

Dear Friends,

Welcome to the next edition of Random musings, the newsletter of the SIG Clinical research . This issue the first from the new team offers a mix of articles on clinical research. We tried to provide different flavors to make it interesting for the readers. These include introduction to areas like basics of research to examples of actual research happening in the various areas of the world. A special thanks to our authors. Dr Feroze Kaliyadan introduces us to few landmark clinical trials going on in Dermatology . Dr Anupam Das serves the recipe to make sure your manuscript is rejected. Dr Amrita Sil and Dr Nilay Kanti Das give us the gist of research ethics and regulatory requirements for research while Dr Nayan Patel discusses how to bridge the gap between private practitioners and research. There is an article on how to make journal club effective Dr Brijesh contribute a quiz for your delectation. We are sure you enjoy this issue by the new 'TEAM SIG-DCR' .

Keep musing!

Dr Ajith Kumar K
Convenor, IADVL SIG-DCR

Editorial

Dr. Brijesh Nair
Consultant Dermatologist, Military Hospital, Jaipur

Dear IADVLites,

It gives us immense pleasure to bring to you the ' IADVL SIG – Dermatological Clinical Research' newsletter, the first one of the year 2020. We in SIG-DCR will try to share information on various aspects of research. We will endeavour to provide end to end solution for all your research related queries. We, in the ensuing 'year of the CORONA VIRUS', shall put in all possible efforts to cover the entire gamut of research requirements for the dermatological clinical practitioners and post graduate students by conducting CMEs, Workshops, sessions at various IADVL events including PGCONs, newsletters, symposia in journals, a dedicated research e-helpline, research grant proposal embellishment, and FAQ sections, all at visible interfaces between IADVL and the IADVLite. We have tried to touch upon many facets of common lacunae in research knowhow in this edition of the newsletter to try and shed light on the myriad aspects of research. I will like to take the opportunity to thank the SIG members for taking time out of their busy schedule to help enrich us all with their knowledge. Looking forward to a fruitful intellectual kow tow with all IADVLites in the future! Au revoir for now!

Dr Brijesh Nair

Consultant Dermatologist

Military hospital Jaipur

Clinical trials in Dermatology- What's new and what's news?

Dr Feroze Kaliyadan
Assistant Professor, Department of Dermatology, King Faisal University, Saudi Arabia

For this issue of the newsletter we are focusing on childhood eczema, an area where there are a few interesting ongoing trials

TEST(Trial of Eczema allergy Screening Tests)

TEST (Trial of Eczema allergy Screening Tests) is an interesting feasibility study related to the use of routine allergy tests in children with eczema.

The research question for TEST is "What is the clinical (disease severity) and cost-effectiveness of routine food allergy testing plus advice compared to current standard practice for the management of eczema in children?" and the main outcome is to determine feasibility of a larger clinical trial.

Recruitment for the study is finished. The trial planned to include 80 children between 3 months and 5 years of age, having eczema, but no medically diagnosed food allergy. The test participants will be randomly allocated into an intervention group (where allergy testing will be done in addition to a detailed food allergy history) and the usual care group.

The study design will be a 'nested qualitative' design, based on inputs of the treating doctors and care givers regarding their views on the utility and value of allergy testing

You can get more details about the study at:

http://www.bristol.ac.uk/primaryhealthcare/researchthemes/test-study/

TREAT (The TREatment of Severe Atopic Eczema Trial)

A Randomised Controlled Trial Assessing the Effectiveness, Safety and Cost-effectiveness of Methotrexate versus Ciclosporin in the Treatment of Severe Atopic Eczema in Children: The TREatment of Severe Atopic Eczema Trial (TREAT)

TREAT is a multicenter RCT, lead by Carsten Flohr, Consultant Paediatric Dermatologist at St John's Institute of Dermatology, Guy's & St Thomas' NHS Foundation Trust. The trial, for which recruitment has finished, has a sample size of 102 patients aged between 2-16 years who require systemic treatment. Participants randomized to receive either methotrexate or ciclosporin for 9 months and then followed-up for another 6 months to assess short- and long-term effectiveness and the safety profile of both drugs. The study will also evaluate how the study medicines reduce skin inflammation and itch.

You can get more details about the study at:

http://treat-trial.org.uk/

BEE(Best Emollients for Eczema)

BEE (Best Emollients for Eczema) aims to finding out which emollients (moisturisers) are most acceptable and effective in the treatment of childhood eczema.The BEE study is funded by the NIHR Health Technology Assessment. Recruitment has closed for the study. BEE aims to answer the research question "Which is the best type of moisturiser to prescribe for treating the symptoms of childhood eczema – a lotion, cream, gel or ointment?". The sample size planned is 520 children between 6 months to 12 years of age, with eczema. The participants will be randomly allocated into four groups (1) Lotion, (2) Cream, (3) Gel, (4) Ointment, for a total duration of 16 weeks.The main outcomes will be patient-reported (Patient Orientated Eczema Measure, POEM) and researcher-collected (Eczema Area and Severity Index, EASI) measures of eczema severity.The qualitative component will also involve taking inputs from caregivers and the patients regarding experiences and acceptability of moisturisers.

You can get more details about the study at:

http://www.bristol.ac.uk/primaryhealthcare/researchthemes/bee-study/

The Barrier Enhancement for Eczema Prevention (BEEP) Study

The BEEP study was a multicentre, pragmatic, parallel-group, randomised controlled trial conducted in 12 hospitals and four primary care sites across the United Kingdom. The study attempted to evaluate if daily use of emollient in the first year could prevent eczema in high-risk children.

1394 newborns were randomly assigned to two groups; 693 to themollient group and 701 to the control group. The study outcome included incidence /relative risk of development of eczema in both the groups.

The study found no evidence that daily emollient use in high risk children, prevented development of eczema and based on the findings the authors recommended that children born to families with eczema, asthma or allergic rhinitis should not use daily emollients to prevent eczema.

You can get more details about the study at:

Chalmers JR, Haines RH, Bradshaw LE, Montgomery AA, Thomas KS, Brown SJ, Ridd MJ, Lawton S, Simpson EL, Cork MJ, Sach TH, Flohr C, Mitchell EJ, Swinden R, Tarr S, Davies-Jones S, Jay N, Kelleher MM, Perkin MR, Boyle RJ, Williams HC; BEEP study team.Daily emollient during infancy for prevention of eczema: the BEEP randomised controlled trial.Lancet. 2020 Feb 19. pii: S0140-6736(19)32984-8. doi: 10.1016/S0140-6736(19)32984-8. [Epub ahead of print]

Humour in Research

An IDIOT's guide on how to get your article rejected!

Dr. Anupam Das
Assistant Professor, Dermatology
KPC Medical College and Hospital, Kolkata, West Bengal

Dear readers, I shall come to the point straight away, without beating around the bush!

All of us have must have experienced the “pain” and “anger” following rejection of articles. We are not satisfied by the action of the editorial board members and reviewers for being less than sympathetic towards the hard work put in by the authors. However, I believe that the comments of the reviewers should be taken in positive spirit, and the article is only enhanced by the editorial and reviewer comments. You must have come across plenty of tips, tricks, guidelines etc on how to get your articles published in journals. This time, taking a contrarian view, I hereby endeavor to provide a list (albeit not comprehensive) of some of the easiest ways on how to get your article rejected. These are some of the commonest things which we come across, while reviewing articles from the editorial perspective; and to be honest, if the authors commit these mistakes, it becomes a cake-walk for the editors to reject the articles very easily.

So, here are some of the easiest ways to get your article rejected !! Let us catch the bull by the nail, not its horns.

1. You want a FAST REJECTION? Just ignore the author instructions, do not write the references as per the demand of the journal and exceed the word limit exorbitantly.
2. You want to make the editor REALLY UNHAPPY? Do not write a structured abstract.
3. Write an article on basic research related to interleukins, interferons, neutrophil-lymphocyte ratio in unintelligible language and confusing statistics (or with lack of statistical plan) and submit it to a clinically oriented journal, with abundant instances of non-correction for multiplicity of analysis. But when you think of “external validity” or “practical translatability” of the conclusion and its contribution to the general discourse, it is negligible. Such articles get rejected very easily, no matter how hi-fi molecules you have studied.
4. Think of an article pertaining to clinical dermatology, where good quality photographs form the backbone of the manuscript. But you have clicked the photographs with your mobile phone in a busy OPD, you did not manage to get it done using a digital camera. Please submit such images with all attendant distractors including your table cloth design, the upholstery color in background and even the occasional passerby attendant. And rest assured, your article takes a U-Turn!

5. Further to the assorted photographical shenanigans, you are advised to submit the lowest resolution image, with abundant pixelation, graininess due to high ISO, and indulge in anatomical subterfuge thereby preventing the reviewers to recognize the organ of involvement.. Rest assured that the article gets rejected pronto. Citing another example for you, say you are reporting a case of unilateral Schamberg's disease, but the photograph which you have submitted shows the affected limb ONLY (not both the limbs to prove that it is actually unilateral)! Don't you think you are giving a full toss ball to the batsman (editor I mean)
6. Talking of case reports and letters (for individual cases), I had come across an article which mentioned about “co-existence of scabies and tinea cruris in a middle aged lady”. Another worthy endeavor will be to study the incidence of lichen planus in conjunction with tinea in the Ramgarh taluka of Jhumri Talaiya district, and you get the recipe for prompt rejection. “Novelty” is the catch word, for individual cases. Dermatology has a plethora of diseases, and just the coexistence of two or more diseases in a single patient, does not make it unique. So, we as authors may be just wasting our precious time and energy, by penning down such reports.
7. You write an article which is 5% dermatology and 95% non-dermatology (say community health and too much basic sciences), and then you submit the article to a journal which deals with hardcore dermatology. Such submissions are pointless, because it actually is very unlikely to be accepted. Please do read the “aims” and “scope” of the journal before going ahead. Do not submit articles which touches dermatology tangentially, and the focus lies on something unrelated to dermatology unless it has a major influence on the prevalent dermatological discourse.
8. “What exactly are you trying to say?” Coming to a very important part of an article, the “language”. Of course, you don't need to pen down an article in “Shakespearean” language, studded with “flowery” words and sentences, but if you have sent us an article, whose language is so poor that the editors fail to understand what you want to convey, the chances of rejection becomes close to 100%. To add to the chances of rejection, use windy long sentences in which by the time reviewer deciphers what is the gist of the second part of the sentence, he has already forgotten what the first half of the sentence meant. Such linguistic depravity shall surely get your article tossed in the trash can.
9. Coming to the most difficult subset of articles, I mean these are some of the simplest ways to get your original articles rejected
    a. Make sure your study design is NOT suited to fulfill the aims of the study
    b. Make sure you have NOT chosen the correct statistical tests for analysis of your data (you did not include a statistician right from the beginning of your study, ab initio, when you were writing the protocol; and you

landed up inviting the statistician for a cameo appearance during post hoc analysis, after you have collected the data and finished recruiting samples). You may also formulate your thesis after the data has been crunched through by the statistician. That makes it even easier to be rejected. Better still, do not have a statistical plan.

c. You carried out your study, with too small or biased sample size. You did not bother to do a proper sample size calculation and just proceeded with the study with some arbitary number of patients and proved significance or insignificance! In such cases, it is best to kiss goodbye!

d. Evolve fantastic conclusions in a whimsical fashion, which have not been remotely touched by a bargepole by the materials and methods

e. Not doing sample size and then quoting in limitations low sample size, is a sure shot 'hasta la vista'.

10. Indulge in “salami publication” at your own peril or pleasure. What I mean to say is send an article, which is clearly part of a larger study which has been divided into gazillion nano-fragments to increase the count of publications! As the reviewers and editors are not quantum mechanists, they shall shred such nano-fragments with utmost alacrity.
11. Let me further guide you along the mechanistic path of rejection (the garden path). Do not answer to the reviewer's and editor's comments, just beat around the bush and make them irritated to a point, where they feel rejection is the easiest way than to understand the replies. Better is to be downright rude and condescending to editorial remarks.
12. May be this should have been the first point, but I have written this at last, purposely. The reviewers and editors are always busy. “Always cut to the chase”..make sure the title of your manuscript is NOT “well-thought, pointed, relevant and snappy” which reflects the matter covered by the article.

Apologies to the space induced restriction from the fount of my acquired knowledge. Most of these are issues, which I have faced over the last few years of writing articles, getting letters of rejection and trying to learn in the due course of rejection (most of the times) and acceptance (rarely). I am sure there are many other comments and remarks, which most of you have come across during rejection. We shall open out coffers about ensuring further ease in getting your articles rejected in the ensuing months. Till then, happy rejections

Acknowledgement : Dr. Saumya Panda, Dr. Brijesh Nair

Ethics in clinical research: Do's and Don't's

Dr. Amrita Sil,

Associate Professor, Dept. of Pharmacology, Rampurhat Government Medical College, Rampurhat, Birbhum, West Bengal

Medical science is a discipline where the advancement of knowledge is hugely guided by research and humankind has benefitted from many experiments. However, benefit and risk are the two faces of the same coin. If there is no loss there is no gain; but the risk/loss is assumed by individuals/participants of research, and benefit/gain is reaped by a population who did not have to bear that risk. The role of ethical guideline is to establish the balance between benefit and risk and to ensure all the participants gets fair treatment that he/she expects from his/her treating physician.

The ethics committee is strict regarding certain aspects of protocol and the following are the essential elements the investigator should be careful while submitting a proposal to the IEC.

a. ***Informed consent document:*** The informed consent is a process by which the physician sensitizes the patient about the nature of the study in a language that is nontechnical and understandable by the study participant. Informed consent document (ICD)has got two parts: the "subject information sheet" and the "informed consent form" (ICF), and they have to be approved by the Institutional Ethics Committee (IEC) before administration.

The DO's:

- The protocol must contain the vernacular version of the patient information sheet and the informed consent form along with its English counterpart.
- Both the parts, i.e., the "subject information sheet" and the "informed consent form" (ICF), should be present. The parts are not mutually exclusive.
- In case of a situation where a participant is not able to give informed consent (e.g., unconscious, minor, or those suffering from severe mental illness or disability), it has be obtained from a **legally acceptable representative (LAR)**. A LAR is an individual or a legal body authorized under applicable law to consent, on behalf of a prospective participant, to the individuals' participation in the clinical trial.
- If the participant or LAR is unable to read/write, then an **impartial witness** should be present during the entire informed consent process and must append his/her signatures to the consent form. An impartial witness is a person who is independent of the trial and cannot be unduly influenced by the people involved with the trial and who attends the informed consent process if the participant or the participant's LAR cannot read and who reads the ICF and any other written information supplied to the participant. Usually,

the patient party of the subsequent patient is taken as impartial witness. Staff nurse or technician is usually not regarded as impartial witness as they can be unduly influenced by the investigator.

- Every ICF should be signed by the participant and the investigator and dated at real time. A copy of the signed ICF is retained by the investigator and another copy is given to the participant.
- Any changes in the ICF after the trial commencement have to be re-approved by the IEC before it is administered
- The essential elements of the ICD that should be incorporated are:
  - That the trial **involves research.**
  - The purpose of the trial (**Study Objectives**)
  - The **trial treatment(s)** and the probability for random assignment to each treatment.
  - The **trial procedures** to be followed, including all invasive
  - The **subject's responsibilities.**
  - The reasonably **foreseeable risks or inconveniences** to the subject ± embryo, fetus, or nursing infant.
  - The reasonably **expected benefits**. When no intended clinical benefit subject should be made aware of this.
  - The **alternative procedure(s)**or course(s) of treatment that may be available to the subject,
  - The **compensation and/or treatment available** to the subject in the event of **trial-related injury.**
  - The anticipated **prorated payment**, if any, to the subject for participating in the trial.
  - The anticipated **expenses**, if any, to the subject for participating in the trial.
  - That the subject's participation in the trial is **voluntary** may **refuse to participate or withdraw** at any time, **withoutpenalty or loss of benefits** to which the subject is otherwise entitled.
  - **Confidentiality**
  - **Contact numbers of Principal investigator, Co-investigator, IEC**

The DON'T's

- Staff nurse or technician is usually not regarded as impartial witness as they can be unduly influenced by the investigator.
- Consent should be obtained without any coercion.

b. Audio-visual recording of the informed consent process: This is relevant when the research involves new molecular entity or vulnerable population according to fifth amendment of the Drug and Cosmetic Rules.

The DO's:

- The investigator should obtain audiovisual (AV) recording of the informed consent process for vulnerable participants **in clinical trials of new chemical entity or new molecular entity**.
- In cases where clinical trials are conducted on anti-human immunodeficiency virus **(HIV) and antileprosy drugs**, the investigator should **only obtain an audio recording** of the informed consent process.
- The place where the AV recording is performed should be conducive to recording of disturbance-free audio and video of the consent process.
- To identify the participant/LAR/impartial witness, his/her photo ID needs to be documented.
- Video camera for the AV recording needs to be of adequate enough to capture the facial details of study participant, LAR/impartial witness (if any), and investigator/authorized person present during the consent process.

The DON'T's:

- All research proposals do not require AV recording except the ones mentioned above

c. ***Vulnerable population:*** This subset of population have diminished autonomy and may have an increased likelihood of incurring additional harmas they may be relatively (or absolutely) incapable of protecting their own interest.

The DO's:

- Researchers must justify the inclusion of a vulnerable population in the research.
- The informed consent process should be well documented. Additional measures such as recording of assent and reconsent, when applicable, should be ensured.
- Take consent of the LAR when a prospective participant lacks the capacity to consent.
- Respect dissent from the participant.
- Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc
- Consent of the parent/LAR is required **when research involves children**.
    - A child's agreement to participate in research is called **assent.** If the child objects, this wish has to be respected. At the same time, mere failure to object should not be construed as assent.
    - There is no need to document assent for children below7 years of age.
    - For children between and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.
    - Forchildren between 12 and 18 years, written assent must be obtained.
    - This assent for malso has to be signed by the parents/LAR.

- Appropriate studies on **animals** and **non-pregnant individuals** should have been completed (if applicable)**when research is planned on pregnant women**.
    - When the purpose of the trial is to *meet the health needs of the mother or the foetus*, or the risk to the foetus is minimal.
    - Researchers **should not** participate in decision making regarding any termination of a pregnancy.
    - No procedural changes, *which will cause greater than minimal risk to the woman or foetus*, will be introduced into the procedure for terminating the pregnancy solely in the interest of the trial.
- Confidentiality should be strictly maintained and privacy protected

The DON'T's:

- Vulnerable population should not be included unless the research is essential to promote the health of the population represented, and this research cannot instead be performed on other participants.
- Researchers **should not** participate in decision making regarding any termination of a pregnancy.

d. Placebo-controlled trial:

The DO's:

When to do placebo controlled trial?

- When there is no established effective therapy
- Withholding an effective therapy would not expose the participant to harm
- Disease is self limited

Precautions in Placebo controlled trials?

- **Safeguard**: Clear-cut Withdrawal criteria + Intensive monitoring + Rescue medications
- Use an **Add-on trial design where the IP or placebo are added to standard of care.**
- Expose **fewer patients to placebo** groups *2:1 randomization (IP: Placebo)(unbalanced randomization).*
- Ensure **transition to *standard of care/active medicine*** *for study participants after research is completed*

e. Advertisements for recruitment of trial participants:

Need and greed for money interferes with autonomy.

The DO's:

- All advertisements for recruitment should be submitted to the Ethics committee for approval.

The DON'T's:

- Try to avoid advertisements

f. Serious adverse events:

Any unwanted and noxious effect of a drug when used in recommended doses is an adverse drug reaction (ADR) whereas if causal association is not yet established it is termed adverse event (AE). An AE or ADR that is associated with death, in-patient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, a congenital anomaly, or is otherwise life threatening is termed as a serious adverse events (SAE).

The DO's:

- The protocol must elaborate the timeline for reporting of serious adverse events to the ethics committee, regulatory body (DCGI), sponsors (if relevant) and head of institution; and also management protocol of SAEs.
- The principal investigator reports the event to the licensing authority (DCGI), sponsor and Chairperson of the Ethics Committee (EC) within 24 hours of occurrence of the SAE. (DCR-6th Ammendment)
- If the investigator comes to know about the AE after 24 hours of occurrence, then "occurrence of SAE" is interpreted as "within 24 h of a Principal Investigator (PI) getting to know of the SAE"
- The investigator is responsible to further send a detailed report after due analysis to the DCGI, the EC Chairman, and the head of the institution where the trial is being conducted within 14 calendar days of the occurrence of SAE.

g. Compensation in serious adverse events:

Research participants who have suffered physical injury as a result of their participation in a clinical trial are entitled to financial compensation commensurate with their temporary or permanent impairment or disability subject to confirmation from EC. In case of death, their dependents are entitled to material compensation. The quantum of compensation is decided by the regulatory authority (Drug Controller General of India or DCGI) who gives a final decision on the amount of compensation to be given by the sponsor or the sponsor's representative to the grieving partyafter consideration of reports available from Ethics committee and the expert committee constituted by DCGI.

The DO's:

- Provide standard care where the drug under investigation failed to provide desired effect
- Timely reporting of ADRs
- A compensation policy must be established at the beginning of the trial to provide a cover for this contingency or issues related to trial, usually third-party insurance. Always check the expiry date of the insurance policy prior to initiating a trial.

- For investigator-initiated trials, financial arrangements must be made by the institution/investigator for the conduct of the study as well as to pay for free management of research-related injury and compensation, if applicable. Funds should be made available or appropriate mechanisms be established.

The DON'T's:

- Avoid violation from approved protocol, scientific misconduct or negligence

h. Compensation for participation in trial:

The DO's:

- Compensate for wage loss, travel allowance and food.
- The compensation amount should be approved by the Ethics committee

The DON'T's:

- The compensation should not amount to inducement

i. Regulatory clearance of a new drug trial:

For conduct of clinical trials for academic/ research purposes that are non-regulatory in nature, permission of the regulatory body or DCGI is not required, provided that the Ethics Committee had approved the proposal. Non-regulatory trials are those which do not claim permission of 'New Drug' for marketing purpose. (CDSCO circular on 10.11.2015)

The Ethics committee could inform the DCGI in some cases. In case, no objection was received from DCGI was received within 30 days, the clearance of DCGI can be presumed.

j. Don't forget to submit amendment and progression report to the Ethics Committee and Sponsor.

k. Registration of clinical trial:

Clinical trial registry at Clinical trial registry, India (CTRI) should be done for all clinical trials prior to commencement of the trial. Nowadays, even observational studies can be registered. Further information about registration of a clinical trial is to discussed in the subsequent newsletters.

Suggested reading:

1. ICMR Ethics Guidelines, 2017
2. ICMR Ethics Guidelines on children, 2017

Ethics Committee Clearance in Clinical Research

Dr. Nilay Kanti Das
Professor, Dermatology, Bankura Sammilani Medical College and Hospital, West Bengal

1. If the study involves just interview, would it require ethics committee clearance?
2. If a survey is being conducted, should is go through ethical review process?
3. If the study on a topic which is an existing indication or a small modification should it also require ethics clearance?

To understand this scenario, one needs to understand the basic principal of ethics which stands on 4 pillars of

1. Autonomy

2. Beneficience

3. Non-maleficience

4. Justice

Recently two more pillars are added to it, namely:

5. Honesty

6. Confidentiality

So with this understanding if we review the following research settings, we would understand there is any possibility of *unscrupulous investigators* taking *advantage of the situation and breaching the principles of ethics to their benefit:*

1. Survey of *jail inmates* regarding their *satisfaction* with heath care provisions with the new administrative policy in health care reforms.

Perspective of Ethics committee:

The *welfare of the responder (jail inmates) may be at stake if he responds adversely* since the new administration might not take criticism in the right kind of spirit.

Thus, here among the principles of ethics, the ***Autonomy*** is breached.

This population is also known as "***Vulnerable Population***" and its the responsibility of ethics committee to see the study (even though observational) does not compromise their rights.

Way to safeguard: Anonymity of the responder. The ethics committee will approve the situation if the protocol ensures that the ***Confidentiality*** and ***Anonymity*** of the responder will be properly secured.

In addition to it, even if the confidentiality and anonymity of the individuals are protected, they can be adversely affected as a group. Thus, ethics committee should also make sure that the results of the study should not be revealed to immediate supervisors in the jail/ school and should be used only by policy makers (like prison department/ controller of examinations etc).

2. Survey of *2nd professional MBBS* students in their *experience with newly developed exam policy of OSPE* against the orthodox patter in their semester exams.

Perspective of Ethics committee: Similar to above mentioned scenario, the 2nd Prof MBBS *relation with his/her teacher might not go well if he/she adversely comments on the newly exam policy (OSPE) developed by his teacher*.

Here too, the responder is "***Vulnerable***".

Way to safeguard: As in the above case, the protocol must ensure that ***Anonymity*** is strictly ensured.

3. Survey of *knowledge, attitude, practice of cosmetic use i*n persons in their teens with respect to *usefulness and safety.*

Perspective of ethics committee: The survey could send out *biased data* if:

1. Name of cosmetic company and brands are revealed

2. The responders are given compensation for their favorable responses.

In this case the pillar of ethics at stake is "***Honesty***". Also *compensation (more than travel expense or wage loss due to participation in the study) may undermine the "**Autonomy**"* to express free and fair opinion.

Way to safeguard: The ethics committee will ensure that the *protocol mentions that the **name and brand** of the cosmetics are not captured i*n the CRF.

It will also insist on ensuring that favorable response is not favored with rewards. Thus the ***compensation for participation*** *should not be more than travel expense of wage loss due to participation.*

4 Effectiveness and safety of *treatment X vs. treatment Y* in the management of melasma. (Where *treatment X is the standard care* and *treatment Y is a minor modification of X.)*

Perspective of Ethics committee: If the hypothesis states that *treatment Y is better then why half of study population are not given the opportunity of better treatment* ***(Beneficience*** is in question)

If the new *treatment Y can result in some complication, then why half of the study population are made to suffer* (***Non-maleficience*** is in question)

Perspective of Investigator: ***Clinical trial registry won't be possible*** without ethics committee approval and thus publication in high indexed journal would suffer since they required the registry number.

Perspective of scientific committee: The negative results are sometimes not published but all *enrolled trials in clinical trial registry* need to update their findings upon completion. Thus the *scientific world comes to know about the outcome of treatment Y.*

Way to safeguard: Participations enrolled after signing the "***informed consent***" which details the two methods (X and Y) about their *pros and cons and chance of each participant to get assigned to each treatment arm.*

The above mentioned situations are real-life instances; and in all these situations every investigator questioned "why should the ethics committee raise question on the integrity of the investigator and thinks investigators are unscrupulous in their practice?"

The fact is a *few such immoral researchers led to the environment of mistrust* and its the duty of ethics committee to lift the air of mistrust in the mind of common (non-medical) people by *ensuring that "no harm" is done to the participant* in the name of research.

Thus, it is imperative that study protocol should be submitted to ethics committee and if the investigator feels that the protocol has no element of ethical issues please ask for *exemption from review*. The chairperson or Member secretary can exempt review and issue approval.

Investigator may also request *expedited review* if you are working on any emergency situation or epidemic, which will pass-off if you have to wait for full-house review. It should be highlighted the decision to exempt from review or expedite a review is a prerogative of the ethics committee not a decision of the investigator.

A. **Exemption from review by ethics committee** (Table 4.2, National ethical guidelines for biomedical and health research involving human participants. New Delhi: Indian Council of Medical Research; 2017)

At times an *Investigator can request the chairperson to exempt the proposal to be reviewed by the full house* but that DOES NOT mean that the proposal won't be submitted to ethics committee. The committee would give its permission without review if:

Research conducted on data available in the public domain for systematic reviews or meta-analysis;

Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;

Quality control and quality assurance audits in the institution;

Comparison of instructional techniques, curricula, or classroom management methods;

Consumer acceptance studies related to taste and food quality; and

Public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

B. **Waiver of Informed consent document** (Table 5.2, National ethical guidelines for biomedical and health research involving human participants. New Delhi: Indian Council of Medical Research; 2017)

The list is holistic and self explanatory

Research cannot practically be carried out without the waiver and the waiver is scientifically justified;

Retrospective studies, where the participants are de-identified or cannot be contacted;

Research on anonymized biological samples/data;

Certain types of public health studies/surveillance programmes/programme evaluation studies;

Research on data available in the public domain; or

Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

Suggested Reading

1. Das NK, Sil A. Evolution of Ethics in Clinical Research and Ethics Committee. Indian J Dermatol. 2017; 62: 373-79.
2. Sil A, Das NK. Informed Consent Process: Foundation of the Researcher-participant Bond. Indian J Dermatol. 2017; 62: 380-86.
3. National ethical guidelines for biomedical and health research involving human participants. New Delhi: Indian Council of Medical Research; 2017.

Journal club : what when why and How

Ajithkumar Kidangazhiyathmana
Additional Professor, Department of Dermatology and Venereology, Govt Medical College Thrissur, Kerala.

Asokan Neelakandan
Professor Department of Dermatology and Venereology, Govt Medical College Thrissur, Kerala

What is a journal club?

A journal club is a regular meeting of experts in the field to critically evaluate recent articles in the academic literature. Though in Indian scenario, it is used usually to enable members to keep abreast of the current medical literature, actually it is meant to critically evaluate the article. Thus it becomes an important forum for learning research methodology, clinical epidemiology, statistics, and critical appraisal.

Traditionally a journal club involves one person (generally a trainee) picking up a journal article which he/she chances upon to read and present it while others discuss or even criticize it. It generally leads to the transmission of only superficial information. But in the era of evidence-based practice, the journal clubs have transformed into an exercise that critically appraises a recently published article and evaluate its usefulness in a given situation.

Why a journal club?

It is always better to have regular journal clubs in an academic department. Regular clinical clubs will facilitate team members to imbibe critical appraisal skills along with various other skills like evidence-informed clinical decision making, research methodology, and literature search. The current postgraduate curriculum proposes a weekly journal club for residents. In this era of evidence-informed patient care and information explosion, it is important to learn to critically evaluate available information and use it appropriately

When?

Considering the enormous increase in knowledge happening around the world, it is preferable to have a journal club at least once a week, The time of the event in a day should be convenient to most of the participants.

How?

What to read in a journal club? Generally, one of the latest studies is selected randomly by the presenter with the help of the mentor. But it is much better if we select a paper relevant to a clinical problem you face currently. Once the Journal is selected it should be sent to all members adequately early so that all can read the article before attending the meeting. Generally, the discussion is done in a classroom with projection facilities as a powerpoint presentation. But one should take care not to overload the slides with information cut and pasted from the article and the presenter ending up reading from the slides. That would divert the attention from discussion to the PowerPoint. Journal club presentation is often compared to clinical case presentations. In both, the aim is to convey the essential information in a concise manner using a standardized structure. It is good to organize the presentation in a constant format. A format we use regularly at Government Medical College, Thrissur is given in the box. (Table 1).

The following steps can be followed.

Start with why the article was chosen and capture everyone's interest. If the article was located based on a purposeful literature search, it would be better to explain the search engine and the search terms. You may follow the following steps.

1. Mention who wrote the paper? Where was it published? Any background of the authors? What is the Iimpact factor of the Journal?
2. Explain What was the study setting? e.g. if it was a service hospital, academic institute, multicentre study, population or community-based study.
3. State and explain the research question and hypothesis

It may be explained if the question is addressing mainly a diagnostic, prognostic, etiologic, economic, quality of life or therapeutic problem. Also, it may be commented if it is reflected in the objectives.

Explain PICO/PECO (population, intervention/exposure, control/comparison, the outcome of interest).

4. Appraise the evidence base: what is the background knowledge? What are the references?
5. Discuss the Methodology: e.g. randomized controlled trial, case-control, meta-analysis, cross-sectional, descriptive, etc Are Possible biases addressed in the design and/ or analysis plan?
6. Is the study design adopted appropriate to answer the research question? See table no 3 and 4 for different study designs
7. Is the Inclusion and exclusion criteria stated appropriately? Do you think they are appropriate for the study? Check whether the sample size, sampling, randomization are appropriate?
8. Check the variables assessed? What are the measurements done? Who did it? How was it done? Were variables selected measured, tabulated and analyzed appropriately to address the research question? For clinical trials, use the questions mentioned in table 6

9. Results: Are the result stated clearly? Is the Primary outcome mentioned? Is the secondary outcome mentioned, if relevant? Do the data add up?
10. Have any results been ignored and if so why? Are the baseline characteristics of cases and controls comparable? Are the tables and results consistent? Is the result statistically significant, i.e. is the P value less than 0.05?
11. Statistical analysis: Did the researchers select appropriate statistical methods? How did they address chance and bias?
12. Is the study adequately powered? (see table 6 for details)
13. Discussion: Did the authors discuss consistency/deviation from previous studies? Did they explain postulation to explain these? Did they discuss the limitations and strengths of the study? Do they suggest future studies?
14. Conclusions: Are the conclusions supported by the results? Are the significance of the study clinically relevant?
15. Conflict of Interest: Are conflicts of interest declared?
16. What is the external validity of the study? Is the study relevant to our clinical scenario? Do you think it is directly applicable to us?

Your presentation on this line can surely generate further discussion. The chair of the meeting should be able to moderate the discussion and lead to a conclusion. Think if you can contribute to the outcome of the clinical journal club as a letter to the editor/opinion to the journal and boost the knowledge and your CV? Can it lead to a better study by your team?

Suggested readings:

1. Phillips RP, Glasziou P. ACP Journal Club. 2004;140:A11-12.
2. Mark D. Schwartz, Deborah Dowell, Jaclyn Aperi, Adina Kalet, ACP Journal Club 2007:147 .A8-9
3. Bowles P, Marena K, Rickets D, Rogers DA How to prepare for and present at a journal club British Journal of Hospital Medicine, October 2013, Vol 74, No 10
4. Afifi Y, Davis J, Khan K, Gee H, Publicover M. The journal club: a modern model for better service and training. The Obstetrician & Gynaecologist 2006;8:186–189.
5. ERIC - EJ988868 - A Journal Club Workshop that Teaches Undergraduates a Systematic Method for Reading, Interpreting, and Presenting Primary Literature, Journal of College Science Teaching, 2012-Jul [Internet]. [cited 2020 Mar 8]. Available from: https://eric.ed.gov/?id=EJ988868

Deenadayalan Y, Grimmer-Somers K, Prior M, Kumar S. How to run an effective journal club: a systematic review. *J Eval Clin Pract*. 2008;14(5):898–911. doi:10.1111/j.1365-2753.2008.01050.x

Table 1-- How to conduct a Journal club-Summary

Clnical scenario---Do literature search using key words —identify relevant article--- check internal validity---disseminate ----check methodology--- check results ---check external validity--- conclusions—Discuss—conclude the critical appraisal

Table 2 Components of the research question

- Population – who was studied?
- Intervention/Exposure – what was the intervention tested?
- Control – what was the alternative that the intervention was compared to?
- Outcome – what was the nature of the outcome measured?

Table 3 Research designs

Descriptive (No comparison group)

1. Case report/ series
2. Survey
3. Cross sectional - prevalence
4. Longitudinal (single cohort) – incidence
5. Diagnostic test evaluation
6. Sensitivity/ specificity/ predictive value
7. Open drug trials

Analytical (Comparison group present)

1. Cross sectional
2. Case control
3. Cohort
4. Controlled Trial
5. Non randomized
6. Randomized
7. Ecologic study
8. Mixed design
9. Systematic review/ Meta-analysis

Table 4 Research designs and Objectives

Case series --- Describing clinical features , Prognosis, disease pattern
Cross sectional studies—Burden of the disease/ prevalence
Cohort study—Incidence/ Prognosis
Cross sectional—Association between exposure and outcome
Case control study – casual relationship/ to identify risk factors
Randomized control study—Efficiency/ effectiveness of an intervention

Table 5 Questions to be asked when you read a clinical trial

For a clinical trial , use these questions:

a) Did the experimental and control groups have a similar

Prognosis till the end of the study?

b) Were patients randomized and was it concealed ?

c) Were patients analyzed in the groups to which they were

randomized?

d) Were groups similar regarding known prognostic factors?

e) Were patients, clinicians, and outcome assessors were blinded regarding allocation?

f) Was follow-up complete?

Table 6 Few statistical terms explained

P-value :

Measure of the strength of evidence against the null hypothesis (usually $P<0.05$,

P <. 05indicate that the chance of reproducing the result obtained in the study will only be 5/100 if ther truly was no difference between the two groups tested)

Type 1 (α) error: a false positive result; It is decreased by lowering the acceptable P-value

Type 2 (β) error:a false negative result; usually it results from small sample size and can be avoided by performing a power analysis

Power of study : Assuming there is a true underlying difference, how certain do you want to be of detecting this – usually power is set as set at ≥80%

It determines the number of subjects needed in a study in order to analysis have a reasonable chance of showing a difference if one exists

Effect size : is the magnitude of the difference between groups. The absolute effect size is the difference between the average, or mean, outcomes in two different intervention groups.Table 6 Few statistical terms explained

Private practitioners and research : how to abridge the gap?

Dr. Nayan Patel

Evidence based practice and shared decision making in accordance with current best evidence is a felt need in the current academic scenario, where it is difficult for practitioners to keep up with the ever increasing knowledge turnover. It is a felt need that private practitioners who are at the cutting edge of the Indian doctor-patient interface need to be the trailblazers of patient oriented real world research. According to study published by *Indian Institute of Ahmedabad (IIM-A) in Health policy and planning journal* in 1999, about 57% of hospitals and 37% hospital beds are in private practice. Similarly 80% of all registered allopathic medical practitioners registered with Medical Council of India work in private sector. At the same time, if we look at the published manuscripts in leading medical journals, share of private sector authorship is sub-optimal. Academic institutes lead when it comes to biomedical research. Perception among private practitioners is that medical research is a time consuming, administratively and legally complex process. Hence there exists a prevalent fallacious perception that it is difficult to achieve tangible advancements in medical research in private practice. Few perceptions among private practitioners during my interactions with them regarding their interest in research can be summarized as follows.

Most of the dermatologists once in full time private practice lose interest in research; many who still have zest for research find it difficult due to following perceived reasons.

1. Insufficient patient load to conduct research.

2. My patients are from 'well to do' back ground and they are not interested or cannot be convinced to participate in biomedical research.

3. Lack of access to registered institutional ethics committees, where they can acquire ethical clearance of research which is imperative and a big obstacle in practitioner initiated research.

4. Documentation process is very complex and time intensive and lots of paperwork are required for research.

5. Adverse patient events during research endeavours can adversely affect their reputation in practice and can put them in legal entanglements.

6. Research in private practice is not financially rewarding.

Facts:

Practically all rules and regulations for biomedical research are same for academic institute and private practice. If one

takes out little time to understand guidelines from authorities like ICMR or CDSCO, then it is well worth the added effort. Physicians with high patient load can have enough patients to carry out research.

How to bridge the gap

- We can divide clinical research in two parts. 'Clinical trials' funded by pharmaceutical companies and 'Investigator initiated studies'. One will be surprised to know that at any given time or in any multicentric randomized clinical trial (RCT) funded by pharmaceutical companies, almost fifty percent of selected centers belong to “private practitioner” category.
- Any private practitioner who has sufficient patient load for given indication and attached to at least 50 bed hospital can participate in clinical trials. Practitioner who is attached to corporate hospitals or having group practice with other specialties can initiate these trials. All you need is clear understanding of Good Clinical Practice (GCP) guidelines and need to be certified for same. *National Institute on Drug Abuse* (NIDA) *Center for Clinical Trials* (CCTN) *Clinical Trials Network* (CTN) is one such institute which offers this course online, which requires not more than 10 hours of learning online module and undergoing online test for acquiring certificate.
- Secondly, it is imperative to study recent guidelines for conducting clinical trials in a particular country issued by competent authorities. For India it is Central **Drugs** Standard **Control** Organization (CDSCO) under Ministry of Health and Family Welfare CDSO and Indian council of Medical research (ICMR).
- If you are working with corporate or multispecialty hospital, you can persuade your hospital administration to set up Institutional Ethics committee (IEC) based on guidelines issued by CDSCO. It is very important to register this IEC with CDSCO before it starts evaluating institutional trial protocols. Alternatively one can approach independent ethics committee available within 50 km of site where research is proposed to be conducted. One institute can also utilize IEC of other institute by signing memorandum of understanding (MoU) with host institute. Fees for EC review is usually borne by the sponsor of the study.
- Regarding documentation, these type of trials have sufficient investigator grant which enables Practitioner Investigator to hire qualified site coordinator who can look after all documentation and communication with CRO/sponsor and CDSCO.
- Another category of research is “Investigator initiated study” where investigator conducts study for evaluating research question without intention of using the result for commercial use. This is the category where, at present, majority research is coming from academic institutes only.
- If we look at the hierarchy of evidence, lowest level of evidence is 'letter to editor'. Any private practitioner can write letters to editor sharing practically any interesting observation in their practice, may it be interesting clinical

presentation, critical comments on research published, case series which can add on to published studies, novel therapeutic effects of already available medicines, etc. Most of the reputed journals do not insist for IEC or IRB approval for same, only thing required is endorsement of properly signed informed consent from patient for sharing their particulars and details for publication. Keeping such standard Informed consent forms handy in clinic will be of great help. Practitioners can design their own patient consent forms for publication or take help of their academic colleagues who are using similar forms in other departments in their institute. IADVL has periodically circulated standard consent forms which can be utilized post-customization by the practitioners. Most of the reputed biomedical journals too have their standard patient consent forms available for download on their website.

- Next important research item in biomedical journals is 'Research letter'. If a private practitioner is using multiple antifungals for treating dermatophytosis and he/she observes palpable difference in their comparative effectiveness, or two different parameters of any LASER machine delivering incremental results over other. Often, practitioners share these findings in conferences and panel discussions. It will be a good idea to convert this into script which can be submitted as research letter to editor. Journals can forgo requirement of EC approval for such communication as only established therapeutic modalities have been manipulated without incremental harm to study subjects.
- In the hierarchy of 'Case report' and 'Case series', the private practitioner finds himself/herself at par with academic institutes. Only USP for such research is sharp clinical observation and determined case investigation and chart documentation post proper patient consent. Developing good photography skill and collaboration with a pathologist friend will help in writing a good case report. Emphasis has to be laid to complete the chain of evidence and act as your own devil's advocate/critic prior to revision and submission to journal. Compiling your observation of series of rare case of any conditions, forms a good case series.
- Practitioner with good interest in literature search can always pen down narrative reviews about available evidence on any burning issues in practice (narrative review article). Practitioners with in depth knowledge of statistical analysis and interest in literature search can also initiate a meta-analysis or systematic review.
- There is a perception among most of the physicians, that original research has to be technology-heavy, which is not true. Original ideas can be as simple as cause and effect analysis of variables like diet, anthropometry or occupation in a particular dermatosis which has previously not been delved into. For example, effect of diet on pruritus of dermatophytosis, cumulative exposure to topical steroid in its effect on outcome of treatment of dermatophytosis are some lines into which the clinical practitioner researcher can plunge into. Any physician with

sufficient patient load for the said condition can think of testing his/her original research idea.

- First step to start any original research is to plan a pilot study where idea is tested on a small sample size. For your original research to be authentic, proper understanding of how to formulate research question, selecting proper study design, calculating proper sample size and applying appropriate statistical tests are important steps. Proper understanding of these aspects are of paramount importance, otherwise even the most honest original research idea may not find place in a reputed journal.
- Clearance from ethics committee is mandatory for all original research. For practitioner working in multispecialty or corporate hospital, he/she can access their IEC or have MoU with IEC of 'host institute'. Practitioner can also approach independent ethics committee which can review their proposal albeit with some pecuniary implication in the form of fees.
- Practitioner must also keep in mind registering their study protocol with Clinical Trial Registry of India (CTRI) which is slowly emerging as mandatory requirement for interventional research and might also be of relevance to descriptive, analytic and other trial methods. Attending a short course on 'how to write a protocol' will help in big way in structuring good study protocol.

Conclusion

Private practitioners are exposed to research during their post graduate training in the form of thesis or participation as co- investigator in departmental research projects. Many of us who decide to choose private practice as career do not consider carrying forward these research efforts. Pressure to generate sustainable income in early years of practice and later desire to expand practice leaves the practitioner with very little time to research or write. Research is always about keeping your inquisitiveness alive, allotting dedicated time (say, 1-2 hrs) for reading good quality journal and critically appraising the literature and writing styles. One can start with simple things and gradually build on more complex research.

TEN COMMANDMENTS FOR PRIVATE PRACTITIONERS TO BRIDGE THE RESEARCH GAP

1. Read, Read, Read Keep abreast with What is New and read for at least an hour based on cases seen in daily practice
2. Learn the habit of critically appraising any literature that you read
3. Write 'Letters to Editor' based on such critical appraisal
4. Publish your interesting cases as case reports
5. Submit your dermoscopy vignettes for publication and publish interesting images as 'Clinical Images'
6. Note down your original research ideas on a scrap pad and evolve your thought process over time after checking feasibility of the project

7. Collaborate with colleague dermatologists, academic dermatologists, pathologists, other specialists, and even young enthusiastic MBBS doctors. Collaboration ensures fruitful evolution and can reduce research load on individual practitioner.
8. Convert your PG thesis into one or two literary pieces. Further your thesis efforts by delving into the subject incrementally
9. Attend CMEs which are the fountain heads of knowledge and speak at all given opportunities (FREE PAPERS)
10. Always think 'YOU CAN' and eschew negative thoughts

Resources and references for further reading:

- Vijayananthan A, Nawawi O. The importance of Good Clinical Practice guidelines and its role in clinical trials. Biomed Imaging Interv J. 2008 Jan;4(1):e5. doi: 10.2349/biij.4.1.e5. Epub 2008 Jan 1.
- Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, Robson R, Thabane M, Giangregorio L, Goldsmith CH. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010 Jan 6;10:1. doi: 10.1186/1471-2288-10-1.

https://gcp.nidatraining.org/

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https://www.pharmalessons.com/free-courses/gcptraining/

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https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

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https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

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Quiz

Dr. Brijesh Nair
Consultant Dermatologist, Military Hospital, Jaipur

The itinerant quiz aims at sensitising and breeding general interest regarding the field of evidence based dermatology (medicine) and biostatistics, which is presumed, eclectic. The aim of this and subsequent iterations is to convert a seemingly esoteric field into an exoteric area of understanding. So here goes!

QUESTIONS

1. The term PROSPERO designates:

(a) A causality score in adverse drug reactions

(b) A registry for systematic reviews

(c) Patient reported outcome measure

(d) A Pityriasis Rubra Pilaris severity score

2. Recently, in an observational study, sunscreens were controversially implicated to a clinical entity, which led to lots of controversy regarding the study design of the trial and the consequent outcomes

(a) Psoriasis

(b) Seborrheic dermatitis

(c) Rosacea

(d) Lupus miliaris disseminate faciei

(e) Frontal fibrosing alopecia

3. X is commonly used to quantify the degree to which individuals with a fixed degree of relatedness (e.g. full siblings) resemble each other in terms of a quantitative trait. But nowadays it is also used to measure the level of agreement between observers in measuring quantitative parameters or two or more raters scoring the same set of subjects. What is X?

4. This concept in pharmacoeconomics can be summed up as below. An individual will be presented with a set of directions such as:

Imagine that you are told that you have 10 years left to live. In connection with this you are also told that you can choose to live these 10 years in your current health state or that you can choose to give up some life years to live for a shorter period

in full health. Indicate with a cross on the line the number of years in full health that you think is of equal value to 10 years in your current health state.

What is this concept called?

5. Image below is a real life representation a graphical representation method of data. Name it.

6. A clinical search engine, its primary function is to help clinicians identify the best available evidence with which to answer clinical questions. The site was created in 1997 as a search tool to answer queries of Welsh GPs regarding clinical medicine. Name this extremely useful open access search engine.

7. X is an epidemiological measure used in communicating the effectiveness of a health-care intervention, typically a treatment with medication. It is defined as the **reciprocal of the absolute risk reduction or risk difference [1/(*p*1 –*p*2)].**It was described in 1988 by Laupacis, Sackett and Roberts. It gives an easily comprehensible metric to determine effectiveness of medications. Name X

8. Benjamini and Hochberg and Benjamini and Yekutieli are two among many methods used for:

(a) Sample size calculation

(b) Power analysis of trials

(c) Post hoc testing

(d) Journal impact factor measurement

(e) Correction for multiplicity of analysis

9. The ideal trial design for a prognostic study is

(a) Randomized controlled trials

(b) N of 1 study

(c) Case control design

(d) Cohort study

(e) Descriptive study

10. The STRATOS collaboration was initiated to help researchers cope with the methodological complexity arising from the broad range of issues potentially thrown up by_____'.

(a) Observational study

(b) Qualitative study

(c) Equivalence trials

(d) Non inferiority trials

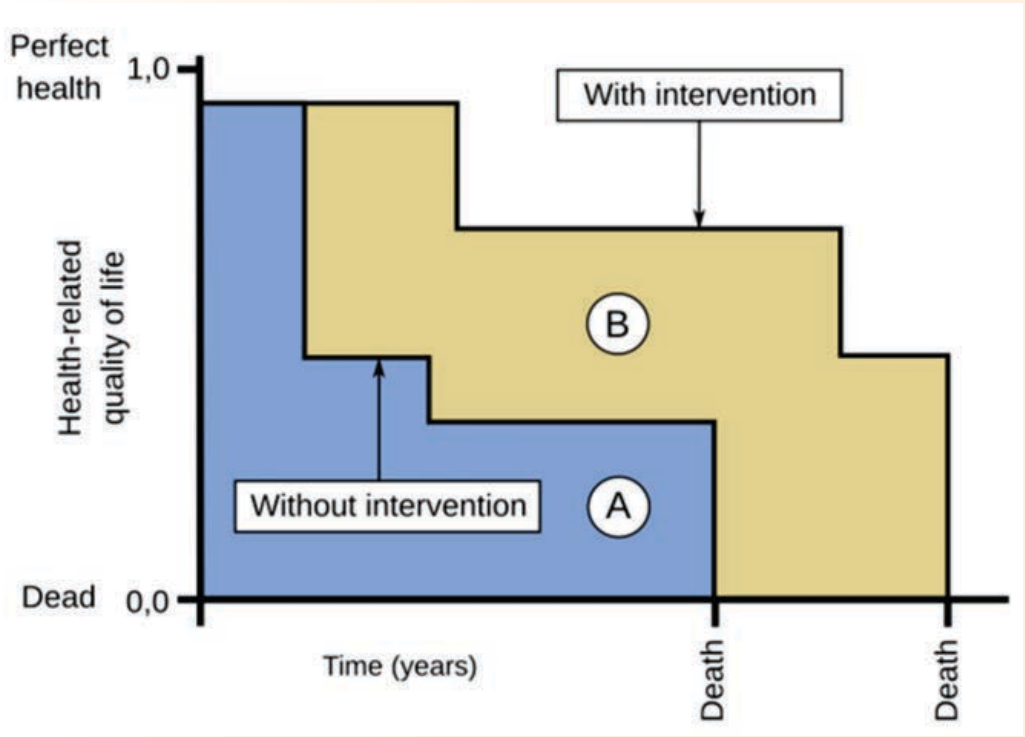
(e) N of 1 trials

11. This 'father of pragmatism' (image below)and philosopher, logician, mathematician, and scientist all rolled into one introduced concepts of randomized controlled studies in psychology well before it was used in medicine trials.

12. *Drapers' Company Research Memoirs Biometric Series I* published in 1904termed the concept first in an article by Karl Pearson. Kempthorne noted that they are the most elemental data structures leading to ideas of association. What are we talking about here?

13. X is used wrongly by many triallists as a measure of data dispersion. It is calculated by dividing the standard deviation by the square root of N (number of observations aka sample size); This corroborates with the fact that the larger the sample (N), the more closer the sample mean of the observed study group approximates the whole population mean. What is X?

14. Which parameter is being compared between 2 subjects in the graphical representation below?



15. A state of genuine uncertainty about the benefits or harms that may result from different exposures or interventions. A state of _____ is an indication for arandomized controlled trial, because there are no ethical concerns about oneregimen being better for a particular patient. This is a basic foundation for conducting an ethical RCT. Fill in the blanks

ANSWERS

1. b
2. e
3. Intraclass Correlation Coefficient (ICC)
4. Time trade off
5. Stem and leaf plot or STEMPLOT
6. TRIP (Turning Research into Practice) database
7. Numbers needed to treat (NNT)
8. e
9. d
10. a
11. Charles Sanders Pierce
12. Contingency tables
13. Standard Error of Mean (SEM); The correct measure of dispersal of data around a mean is standard deviation (SD)
14. Quality Adjusted Life Years (QALY)
15. Equipoise

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