EVIDENCE-BASED MEDICINE

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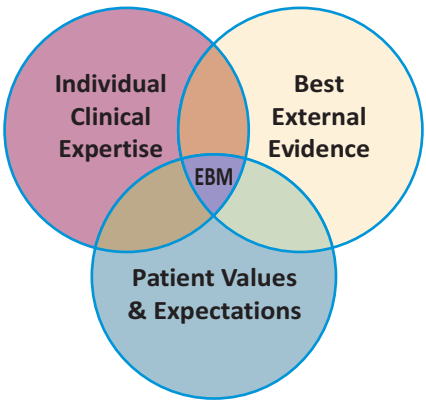
Chapter - 1

Introduction

Evidence-based healthcare is the conscientious use of current best evidence in making decisions about the care of individual patients or the delivery of health services. Evidence based clinical practice refers to the clinician's decision making based on the best evidence available, in consultation with the patient, to arrive upon the most suited option of management. Thus, evidence-based medicine is nothing but the explicit and judicious use of current best evidence in making decisions related to patient care. This is a method of implementing real life experience alongside documented and textbook versions together with patient expectations of disease and management.



Background

Since the early years, controlled trials were being used to assess the impact of medical interventions. However, in 1972, Prof. Archie Cochrane , the Director of Medical Research Council Epidemiology Research Unit at Cardiff, UK, enumerated some concepts in his book entitled 'Effectiveness and Efficiency: Random reflections on Health Services'. These were refined into practical methodology in the late 1980s and 1990s by working groups at Duke University, North Carolina USA and McMaster University at Toronto, Canada. The establishment of the Cochrane Centre with funding from the UK Government

occurred in 1992 with a view to facilitate the preparation of systematic reviews of randomized controlled trials of healthcare. This expanded to form an international collaboration of 13 centers across the globe with over 11500 researchers, forming the Cochrane Collaboration.

Logic behind using Evidence-based Medicine (EBM)

To encourage the use of Evidence-based Medicine, and to make it more acceptable to clinicians, the problem is turned into answerable questions related to:

1. The person or population in question
2. The intervention given
3. The comparison if appropriate
4. The outcomes considered

EBM encourages critical thinking and demands effectiveness of clinical interventions, accuracy and precision of diagnostic tests and scrutiny of the power of prognostic markers. This is a method of ensuring that clinicians remain open minded to look for and try out scientifically proven new effective methods and discard those which are harmful or ineffective. It is essential to check to see if there is evidence and information that relates to better practice as compared to the traditional and less rigorous sources of information. Common sources of evidence include:

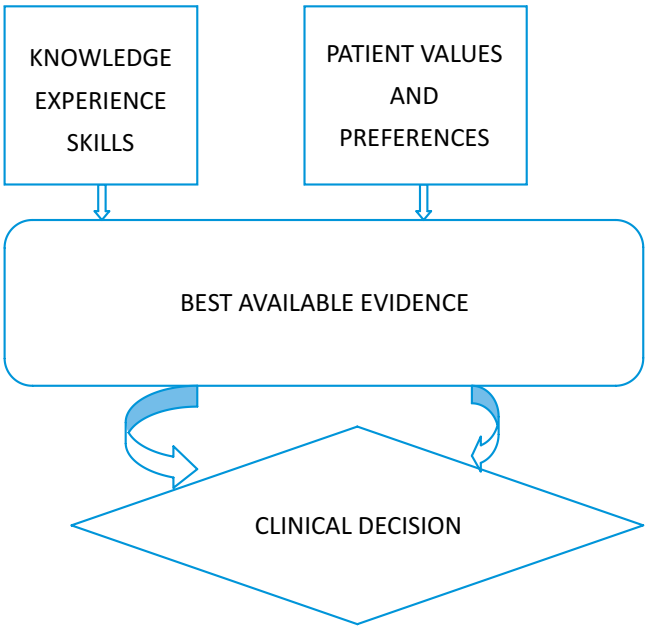
1. Personal experience- example, bad drug reactions
2. Reasoning and intuition
3. Experience of colleagues.

Five step EBM model

The practice of EBM involves five essential steps .These include

- Converting information needs into answerable questions
- Finding the best evidence with which to answer the questions
- Critically appraising the evidence for its validity and usefulness
- Applying the results of the appraisal into clinical practice
- Evaluating performance

Flow chart for evidence based medicine



Answerable questions

A good clinical question should have three to four essential components:

- the patient or problem in question
- the intervention, test or exposure of interest
- comparison interventions, if relevant
- the outcome / outcomes of interest.

An answerable clinical question should be structured according to the PICO (Patient/ problem, Intervention, Comparison, Outcome/s), or the PIO (Patient or problem, Intervention, Outcome/s) format.

An example could relate to a 4-month old baby with bronchiolitis , with worsening symptoms, and you wonder whether to give corticosteroids or not. The key components of the question would be:

Patient/problem: 4 month old baby with viral bronchiolitis

Intervention: corticosteroids

Comparison: no corticosteroids

Outcomes: clinical score, length of hospital stay.

Once the question is formulated, the next step is to seek clinical evidence to help answer the question. Traditional methods of textbooks or journals may be out of date. Consultation with a colleague may produce variable results. Online search of articles on PubMed etc, may bring forth evidence in the Medline database. A large number of articles may be found by this route. By typing the keywords, it may be possible to narrow down the search results. This evidence may be appraised based on validity, importance and applicability to the patient. Critical appraisal provides a simple method to assess the research evidence in all three areas.

Once it is decided, as to which piece of evidence is valid and important, we have to decide whether this information can be applied to our patient taking into consideration the patient and family's values and circumstances. The decision must then be discussed after weighing all the risks and efficacy and an informed decision must be taken.

Once the decision is taken, and the intervention is applied, it is essential to evaluate the outcome, and decide whether we can incorporate the EBM into our clinical practice.

The impact of EBM would be applicable at all levels of healthcare, ranging from the state supported healthcare systems, for example the National Health services (NHS) of UK. Guidelines issued periodically could guide the practitioners to adopt relevant and tested treatment protocols. The primary care organizations, hospitals and trusts could also issue guidelines based on assessments of prevailing evidence. At an individual level, the clinician can tailor the treatment based on the circumstance and after weighing the risk-benefit profile of the individual patient routine clinical practice.

Randomized Controlled trials

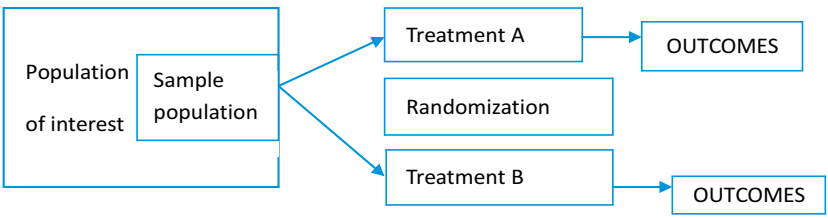
Some research designs are more powerful than others in their ability to answer questions on effectiveness and interventions, thus giving rise to a hierarchy of evidence.

Randomized controlled trials (RCT) are studies that randomly assign individuals to an intervention group or to a control group, in order to measure the effects of

the intervention. The RCT is considered to provide the most reliable evidence on the effectiveness of interventions because the processes used during the conduct of an RCT minimize the risk of confounding factors influencing the results.

The main purpose of random assignment is to prevent selection bias. This is done by distributing the characteristics of patients that may influence the outcome randomly between the groups, so that any difference in outcome is attributable to the treatment only . An RCT is regarded as the gold standard trial for evaluating the effectiveness of interventions.

Fig. - 1: The basic structure of a randomized controlled trial



While reading an RCT article, you need to decide whether you can trust the results of the study and whether you can apply the results to your patient population. Three important points must be considered while arriving at a decision:

- the validity of the trial methodology
- the magnitude and precision of the treatment effect. and
- the applicability of the results to your patient or population.

Table 1: Questions to consider while assessing an RCT :

1.	Did the study ask a clearly focused question?
2.	Was the study an RCT and was it appropriately so?
3.	Were the participants appropriately allocated to intervention and control groups?
4.	Were participants, staff and study personnel blind to participants' study groups?

5.	Were all participants who entered the trial accounted for at its conclusion?
6.	Were participants in all groups followed up and data collected in the same way?
7.	Did the study have enough participants to minimize the play of chance?
8.	How are the results presented and what are the main results?
9.	How precise are the results?
10.	Were all important outcomes considered and can the results be applied to your local population

An RCT is the most rigorous scientific method for evaluating the effectiveness of healthcare interventions. However, bias could arise when there are flaws in the design and management of the trial. Hence, it is important to employ skills of critical appraisal and assessment of the validity of trials, the methodology and precision of treatment effect and the applicability of results.

Systematic reviews

A systematic review is a form of research that provide a summary of medical reports on a specific clinical question, using explicit methods to search, critically appraise and synthesize the world literature systematically. It is extremely useful to bring together a number of separately conducted studies and synthesize their results.

Meta- Analysis

Data from individual studies may be pooled together in a quantitative manner and reanalyzed using established statistical methods. This technique is called meta-analysis. The rationale here is that by combining samples from individual studies, the overall sample size can be increased, thus improving the statistical power of the analysis, as well as the precision of the estimates of treatment.

There are two stages involved in a meta–analysis. The first stage involves the calculation of a measure of treatment effect with its 95% confidence intervals (CI) for each individual study. The summary statistics are used to measure

treatment effects including odds ratios (OR), relative risks (RR) and risk difference. In the second stage of meta-analysis, an overall treatment effect is calculated as a weighted average of the individual summary statistics. In meta-analysis, the data from individual studies are not just combined as if they were from a single study. Greater weightage is given for result from studies that provide more information, as they are likely to be closer to the "true effect" that is being estimated.

Table 2: Questions to consider while appraising a systematic review

1.	Did the review address a clearly focused question?
2.	Did the review include the right type of study?
3.	Did the reviewers try to identify all relevant studies?
4.	Did the reviewers assess the quality of all the studies included?
5.	If the results of the study have been combined, was it reasonable to do so?
6.	How are the results presented, and what are the main results?
7.	How precise are the results?
8.	Can the results be applied to your local population?
9.	Were all the important outcomes considered?
10.	Should practice or policy change as a result of the evidence contained in this review?

Odds ratio and Relative Risks

Odds Ratio (OR) is defined as the number of patients in the group who achieve the stated end point divided by the number of patients who do not. This is a ratio of two odds and could be considered as the ratio of the odds of the treatment group to the odds of the control group. For example, the odds of acne resolution during treatment with an antibiotic in a group of 10 patients may be 6 to 4, with 6 responders of acne divided by 4 non responders= 1.5. In the control group the odds may be 3 to 7, giving a ratio of 3 divided by 7= 0.43. Thus the odds ratio of treatment to control group is 3.5 (1.5 divided by 0.43).

Risk is calculated as the number of patients in the group who achieve a stated end point divided by the total number of patients in the group. The relative risk (RR) or the risk ratio is the ratio of two risks. In the above mentioned example, the risks would be 6 in 10 in the treatment group, that is 0.6, and 3 in 10 in the treatment group, that is 0.3, giving a risk ratio or relative risk of 2 (0.6 divided by 0.3).

Interpretation of odds ratios and relative risk

An odds ratio or relative risk greater than 1 indicates increased ~~like~~ likelihood of the stated outcome being achieved in the treatment group. If the odds ratio or relative risk is less than 1 then it indicates a decreased likelihood in the treatment group. A ratio of 1 indicates no difference, which means that the outcome is just as likely to occur in the control as in the treatment group.

Confidence Intervals

The results of any study are estimates of what might happen if the treatment were to be given to the entire population of interest. The 95% confidence interval (CI) of the estimate will be the range within which we are 95% certain that the true population treatment effect will lie. Commonly, the 95% CI is reported, but other intervals like 90% and 99% CI may also be calculated and estimated. If the CI for relative risk or odds ratio for an estimate includes 1, it indicates a statistically significant difference between the groups being compared. ~~The 95% CI of an estimate indicates the range within which we are 95% certain that the true population effect will lie.~~ The width of the CI indicates the precision of the estimate- the wider the interval, the less the precision. A very long interval interferes with the accuracy of the study in terms of prediction of the true effects.

Probability Values (p values)

This is a measure of statistical significance. The p value refers to the probability that the observed difference between two treatment groups might have occurred by chance. Many researchers use a p- value of 0.05 as a cut off for significance. This indicates that if the p value is < 0.05, the observed difference between the groups is so unlikely to have occurred by chance alone that we reject the null hypothesis and accept the alternative hypothesis that there is a

real difference between the treatment groups. When the p- value is below the chosen cut off, eg 0.05, the result is referred to be statistically significant. If the p value is greater than 0.05, the observed difference might have happened by chance and we fail to reject the null hypothesis. Here we are unable to demonstrate a difference between the groups and the result is usually referred to as not statistically significant.

Levels of evidence:

Evidence is presented in many forms and it is important to understand the basis on which it is stated. The classification of evidence is varied and of different levels with varying degrees of impact.

The levels of evidence vary with the types of studies and the date that is looked at.

The levels of evidence for therapeutic studies differ from levels of evidence for prognostic studies.

Table 2: Levels of evidence for therapeutic studies

Level	Type of evidence
1A	Systematic review (with homogeneity) of random controlled studies (RCT's)
1B	Individual RCT(with narrow confidence intervals)
1C	All or none study
2A	Systematic review(with homogeneity) of cohort studies
2B	Individual Cohort study(including low quality RCT, eg < 80% follow up)
2C	"Outcomes" research; ecological studies
3A	Systematic review(with homogeneity) of case-control studies
3B	Individual case control study
4	Case series(and poor quality cohort and case- control study)
5	Expert opinion without explicit critical appraisal or based on physiology bench research or " first principle"

Ref: Plast Reconstr Surg 2011;128(1): 305-10

Fig 2: Levels of evidence for prognostic studies

Level	Type of evidence
I	High quality prospective cohort study with adequate power or systematic review of these studies; testing of previously developed diagnostic criteria on consecutive patients; sensible costs and alternatives; values obtained from many studies with multi way sensitivity analyses; systematic review of Level I RCT's and Level I studies
II	Lesser quality prospective cohort, retrospective cohort study, untreated controls from an RCT or systematic review of these studies. Lesser quality prospective study; development of diagnostic criteria on consecutive patients; sensible costs and alternatives; values obtained from limited studies; with multi-way sensitivity analyses; systematic review of Level II studies or Level I studies with inconsistent results
III	Case control study or systematic review of these studies, retrospective comparative study: study of nonconsecutive patients without consistently applied reference “gold“ standard: analyses based on limited alternatives and costs and poor estimates; systematic review of Level III studies.
IV	Case studies, case series: poor reference standard: analyses with no sensitivity analyses.
V	Expert opinion, case report or clinical example, or evidence based on physiology, bench research or “ first principles”

Ref: Ref: Plast Reconstr Surg 2011;128(1): 305-10

Grade Practice recommendations

Grade	Description	Qualifying Evidence	Implications for Practice
A	Strong recommendation	Level I evidence or consistent findings from multiple studies of levels II, III or IV	Clinicians should follow a strong recommendation unless clear and compelling rationale for alternative approach is present

Grade	Description	Qualifying Evidence	Implications for Practice
B	Recommendation	Levels II, III or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences
C	Option	Level II, III or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role
D	Option	Level V evidence: little or no systematic empirical evidence	Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role

Ref: Ref: Plast Reconstr Surg 2011;128(1): 305-10

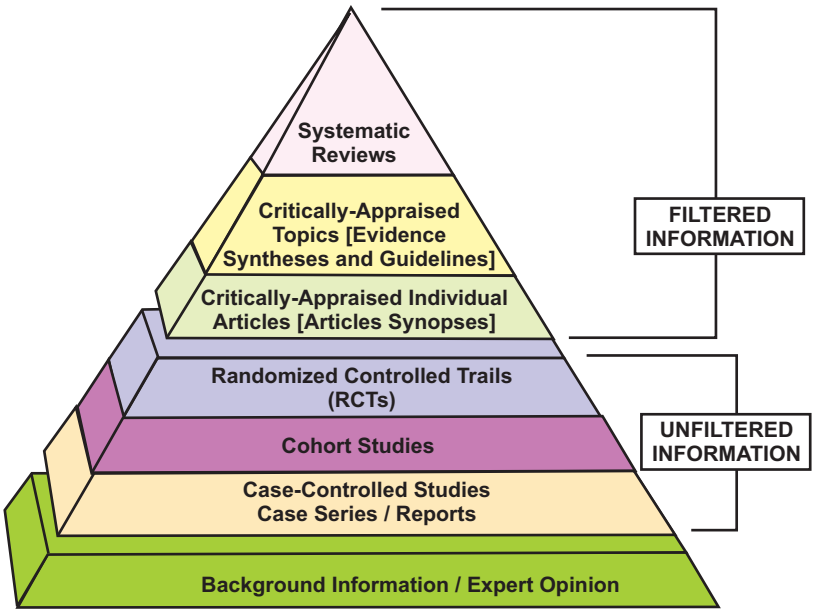
Interpretation of Levels of Evidence

Level 1 Evidence: Likely, reliable evidence. Represents research results addressing clinical outcomes and meeting an extensive set of quality criteria which minimize bias.

Level 2 Evidence: Mid level evidence. Represents research results addressing clinical outcomes and some method of scientific investigation, but not meeting the quality criteria to achieve level 1 evidence labeling.

Level 3 Evidence: Lacking direct evidence represents reports that are not based on scientific analysis of clinical outcomes. Eg. case series, case reports, expert opinion and conclusions extrapolated indirectly from scientific studies.

Evidence pyramid



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MEDICOLEGAL MANUAL FOR CASUALTY

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Chapter - 2

Medico legal evidence is critical to the success of investigation of crimes against persons. It is therefore imperative to develop standard protocols and guidelines for medico legal examination and update them from time to time. This ~~Manual~~ is prepared with inputs from different state forensic Experts. All medicolegal examinations in the Casualty shall be governed by this ~~Manual~~.

Medico-legal cases could fall into any of the categories mentioned below,-

1. The following category of cases admitted in the hospital is to be treated amongst others as medico legal cases-
   - All cases sent by the Police / Magistrate
   - All Cases of Burns / Poisoning / Hanging / Drowning / Fall from tree/ Injury / animal bites / Unknown bites/sexual offenses / Tetanus /Electric shock or lightening, Natural disaster / Criminal abortion etc.
   - All unconscious patients with injury of any nature.
   - All patients brought to the hospital under suspicious circumstances.
   - Person in police custody or judicial custody.
   - Cases which at time of admission are purely medical/surgical but later they may assume medico- legal importance.
2. **Whenever a medico legal case** is brought in the casualty, it shall be the duty of the CMO on duty to register it as an MLC and send the information to the police station, in the prescribed police intimation letter [form I (a)] in duplicate. This information shall be sent to the police by the quickest possible means (telephonically) and recorded by the casualty staff nurse. Acknowledgement from the police officer receiving the information will be kept in the file of the patient for further reference by the casualty staff nurse.
3. **The CMO** will make a note in the file of the patient and the MLC register as to the time and date of informing the police. He will then make an entry in the MLC register.The name and addresses of the attendants who brought the patient should also be recorded in the file and MLC register.

4. The CMO will also instruct the staff nurse to put the stamp **"Medicolegal case"** on the top of the first page of the file of the patient. The stamp should be kept with the staff nurse on duty in the casualty.

5. **Consent -** CMO will always take the consent of the patient on the MLC Register. If the patient is less than 12 years/ insane, the consent of the guardian/accompanying person should be taken and his signature/thumb impression must also follow; consent is not required in case of an accused person u/s 53 and 53A of Cr.PC. Even reasonable force can be used for his examination at the request of the police official not below the rank of a Sub Inspector.

   If an unconscious/ semiconscious/ intoxicated patient is brought in an emergency along with family/guardian, the consent shall be taken from them. In unknown patients, unconscious/ semiconscious/ intoxicated patient without relatives and in case of refusal by the family/guardian, the CMO shall mention in the medico-legal report that the consent could not be recorded (write brief reasons).

6. The preliminary entries like name of the patient with complete address, age/sex, religion/occupation, name of the accompanied person and his / her relation, MLC No. with date, name of the doctor with full designation and registration No., exact date and time of examination, name and designation of police (B.No. of the constable/HC) with police station must be entered before the medicolegal examination of the patient is started. If admitted, write the ward name/number with the date of admission.

7. **Identification marks -** Two identification marks preferably on the exposed parts of the body should be recorded for comparing the same for identification in the court while giving the evidence.

8. Brief history of the incident should be recorded as stated by the patient/accompanying person regarding time, manner (accidental/ intentional) with weapon/ means caused and place of event of injury/poisoning, and the time sequence of symptoms/ incapacitation etc.

9. **General condition** of the person like pulse, BP, respiration, temperature, pupils, level of consciousness, orientation, posture, gait, speech, bleeding through natural orifices like ear, nose, mouth, rectum, vagina, etc., paralysis, urinary/faecal retention/incontinence, smell etc. to be recorded as per the case.

10. The condition of the clothes should be recorded regarding their disorder, buttons (intact, undone, or torn), rents, tears, cuts whether coinciding with a particular injury, presence of stains like blood, mud/sand, weeds, fecal, seminal etc., foreign matter, stippling, burns etc.

11. **Particulars of injuries** - The person should be examined in a systematic way from the front as well as back aspect from head to toe. Always depict the site of the injury and presence of stains and foreign material on the diagram. All the injuries should be recorded in a way as if you are giving a statement to the court. The following particulars of each and every injury must be recorded.

- **Type of injury** like abrasion, bruise, wounds (lacerated, incised, punctured, etc.), fracture dislocation or burns etc.
- **Size -** Exact dimensions (in centimeters) of each injury should be noted down in respect of its length, breadth and depth where ever possible.
- **Shape** that is circular, oval, spindle, triangular, elliptical, crescentric, satellite, etc., margins/edges of wounds should be examined (by hands/lenses where ever necessary), regular or irregular having bruise on its vicinity, the floor must be examined by just retracting the edges for seeing the tissue in it. Foreign matter like grease, dirt, gravel, straw, coal, paint, glass, weed, metal, palettes, bullets, wads, clothes, hair etc. should be reported and must be preserved for further analysis.
- **Location** of injuries.
- **Age of injury** (Colour changes and healing process)
- **Direction** of the injuries
- **Nature of injuries** like simple or grievous.

  CMO shall specify the sub-section of the Section 320 IPC for declaring the injury to be grievious.

Section 320 - The following kinds of hurt only are designated as "Grievous" :-

1. Emasculation
2. Permanent privation of the sight of either eye.
3. Permanent privation of the hearing of either ear.

4. Privation of any member or a joint.
5. Destruction or permanent impairing of powers of any member or joint.
6. Permanent disfiguration of the head or face.
7. Fracture or dislocation of a bone or tooth.
8. Any hurt which endangers life or which causes the sufferer to be, during the space of twenty days, in severe body pain or unable to follow his ordinary pursuits.

12. **The medico legal report (MLR) - CMO** should prepare the MLR in all cases brought into the emergency by the police, those coming of their own for medico legal examination or any other case in which foul play is suspected. The medico-legal report of different cases like Injury, Sexual offense (victim/accused), Impotency, Drunkenness, Age, etc. are to be prepared in the different prescribed formats only. Further, the CMO on duty shall himself / herself write the medico-legal reporting his / her own handwriting.

However, in difficult cases, the CMO should take the guidance of the Faculty of Forensic Medicine for conducting the medico legal examination or for preparing the medico legal report.

The medico legal report should be handed over to the police through the record section within 24 hours ~~immediately~~ after the examination on the departmental working day (excluding 2nd & 4th Saturdays, Sundays and holidays). If there is any injury kept under observation, the same may be recorded as such and the result there of must be communicated to the police at the earliest. The CMO issuing the medicolegal report will be held responsible if any complication that arises for not submitting the report to the department within 24 hours after the examination has been conducted.

The police, however, can ask for any specific information which may be supplied to them from the record of the case. The CMO supplying the information should write on top of such report that the same has been noted from the file of the case. Such report should never be back dated.

Medicolegal report (MLR) should not be written in the presence of a police officer, patient's relatives or any other interested party. If a medicolegal report has already been issued elsewhere, it is not permissible to issue a

second MLR unless specifically requested by the police in writing or by the order of the Court.

A medico legal report given by an expert is confidential and not a public document as held in state V/S Gyan Singh (1981 CRL. L.J 538) of the Delhi High court. Hence, a copy of the medico legal report should not be issued to individuals other than the patient and the police officer investigating the case.

13. Examining female patients in the presence of the female attendant

A female patient, medicolegal case or non-medicolegal case should not be examined without the presence of a female attendant. The CMO in his own interest should refrain from acting otherwise.

14. Statement and dying declaration

If a patient is likely to expire as a result of injuries (including burns) or alleged criminal act, immediate arrangement should be made to get the his/her dying declaration recorded. The CMO will immediately inform the police in writing to call a magistrate or if there is no time to call a magistrate, the CMO will himself record the dying declaration keeping in view the legal provisions in this regard.

The dying declaration should be recorded in the presence of another doctor or staff member who will witnesses~~xx~~ the statement and will append his signatures at the bottom of the declaration. The CMO – Medicolegal recording the statement (either in question /answer form or narrative) should also certify that the patient was conscious and in a sound state of mind when the statement was recorded and remained so till the statement was completed.

If possible the signature or thumb impression of the patient is obtained on the dying declaration after the same has been read over to him/her. Police officers or relatives of the patient should not be present at the time of recording of the dying declaration.

In case of a patient who is not fit to make a statement, the reason should be noted and duly explained in the file. A careful watch is kept and police are informed as soon as the patient becomes fit to make the statement.

15. Discharging a medico legal case.

As far as possible, no medico legal case shall be discharged or send against medical advice (AMA) without informing the police in Form – I(a) in

duplicate however it should be recorded accordingly in the police information form. CMO should take the signature of the patient/ relative in case of AMA discharge in the treatment case papers.

16. **Death of the Medico legal case.**

Whenever a medicolegal case dies, the police officer I/C of the police station should be informed immediately in the prescribed police intimation letter [Form – I (b, c & d)] and a note to the effect be recorded on the file of the deceased.

The dead body of ~~MLC~~ should be kept in mortuary through RMO. While sending the body of a medicolegal case to the mortuary, clear instructions should be given to the mortuary attendant, not to hand over the body to the relatives. Complete chain of custody of the dead body shall be maintained at all times beforethe body is finally hand over to the relatives of the deceased.

The body shall be transported to the mortuary. The name of the ward attendant or any other employee/police staff transporting the dead body shall be recorded in the dead body register. Medical Certification of Cause of Death (MCCD) should not be issued in Medico-Legal cases by the doctor to the relative. The dead body and MCCD shall be handed over to the relatives of the deceased only through police.

17. **Cases of poisoning**

In poisoning cases,samples from stomach wash, vomitus, urine, blood etc. must be collected and preserved in bottles which should be properly sealed, labeled and made into a parcel. The sealed parcel along with a letter [form no. 2] is sent through the police official concerned to the chemical examiner for detection of suspected poison. The letter should give particulars of the case, details of the bottles, sample impression of the seal placed on the bottle and the poison suspected

18. **Rape/Sexual assault cases.**

Detailed guidelines for examination of Rape/sexual assault cases are annexed in the Manual, and the same must be followed in letter and spirit, provided that in case of an examination of an accused person, consent is not required as per section 53 A of the code of Criminal Procedure, 1973. Medico legal examination of Rape/sexual assault cases of female victims is to be conducted by the on call duty doctor (preferably female) of OBGY department.

The opinion of a Gynecologist, dental Surgeon and Radiologist is obtained wherever required in the above cases in prescribed formats. CMO will issue the final report and will also attend the court when summoned.

19. **Examination of the accused at the request of the police officer.**

The consent of the arrested accused person is NOT required in such cases.

Whenever a request for medical examination of an arrested accused is received from a police officer, not below the rank of a Sub-Inspector, in accordance with section 53 or 53A of the Code of Criminal Procedure 1973, it shall be lawful for the registered medical practitioner to make such an examination of the arrested person and to use such force as is reasonably necessary for that purpose.

20. **Collection of parcel by the police officer.**

The Police officer, who sends the request for medical examination will collect the parcel containing the samples and duly filled forms (for transmission to the chemical examiner/FSL) immediately after the examination.

If the police officer refused to collect the samples, it must be informed to his higher authority and Medical Superintendent. The parcel must be kept under lock & key in the casualty by the staff nurse till further instructions are issued by the CMO.

21. **Suspecting foul play in cases admitted as ordinary non-medicolegal patients.**

Cases which are admitted as a non medico-legal case initially, but later the treating doctor suspects foul play should be immediately brought to the notice of the CMO.

To take necessary action in this matter the police will be informed in writing by the CMO. In the event of death of such a case, a written report should be sent to the police so that a medicolegal post mortem could be arranged.

22. **No dues**

The staff nurse in emergency ward should see that all charges have been paid by the relatives of the patient/deceased. In case of difficulty, she should inform CMO/ RMO/MS.

23. **Hospital record**

The file including the X-ray, investigation reports, forms and letters shall be kept in the record section. However, if there is a holiday, the file shall be kept with the staff Nurse in charge till it is sent to the record keeper. Under no circumstances, the CMO shall take the file to his/her home.

Original hospital record / file of the medicolegal case should not be handed over to the police authorities. If the police requests the MS/RMO for the original record of a case, they should be given a photocopy instead of original documents. A receipt of acknowledgement must be obtained from the concerned police.

The In-charge MRD shall be maintaining & keeping the record for future reference. In ML cases, the records have to be maintained for 20 yrs.

At times, the courts ask for the original record. In such cases, duplicate/Photo copy shall be retained for record. The original file/X-ray films/ CT films are then submitted to the court under a sealed cover and obtain receipt of acknowledgement.

MLC register and Medicolegal reports will be maintained and kept in the Record section.

24. **Clothes in medico legal cases**

Details of clothing, including color, condition, size etc. should be written in the MLR. Torn/damaged/stained portions should be encircled and asignature affixed. Clothes in medico legal cases involved in rape, stab injuries, firearm injuries, burns, unidentified dead body etc. should be made into a parcel, sealed and handed over to the police. Clothes of accident victims are not to be preserved unless asked for by the police.

25. **Foreign body, such as bullets, lead shots etc. recovered from the wounds/clothes.**

Foreign body, such as bullets, lead shots etc. recovered from the wounds or body in firearm injury cases should be collected in a gauze piece and then placed in a container(s). The container must be sealed, labeled and handed over to the police along with duly filled form under proper acknowledgement for sending to the Forensic Science Lab for expert opinion.

Details of all such recovered material should be mentioned in the MLR. If the parcel is not collected by the police, the Medical Superintendent/RMO and also the district SP/DSP/PI are to be informed about the same.

26. **Criminal abortion**

Cases of attempted abortions performed by un-authorized persons or against the indications/rules of the MTP act (for details, see M.T.P. act of 1971 and relevant rules framed under the said act) are to be considered as medico legal cases and reported to the police.

The treating gynecologist should take care of the medicolegal issues in case of criminal abortion.

27. **Medicolegal cases brought dead and death on arrival to the Institution**

In the first instance, vigorous attempts by CMO must be made to resuscitate the patient.

After all attempts have failed to revive the patient and he/she is declared dead, then the CMO will record the MLC details. If possible, the name and address of the persons who brought the deceased may also be noted.

The body is then sent to the mortuary and the police is informed (Form No. I (b & c).

28. **Consent/Permission from relatives for autopsy**

Consent or permission of the relatives is not required for conducting a medico legal postmortem examination.

In case of clinical (Pathological) autopsy, the consent of two persons (kith and kin/ close relatives) is mandatory.

The treating doctor can even advise partial clinical autopsy and the pathologist on call will conduct the autopsy.

29. **Belongings of the patient.**

In unconscious / intoxicated patients the belongings shall be handed over to the relatives of the patient by the staff nurse in the presence of the doctors treating and this fact shall be recorded in the register.

In medicolegal cases, if no relative is accompanying the patient, a list of important articles of the person shall be prepared by the Staff Nurse, whosoever is on duty, in duplicate, and articles handed over to the police officer for custody. In all such cases, a proper receipt must be obtained.

In medicolegal cases which are brought dead, the belongings of the deceased shall be handed over to the relatives attending to the patient, if available (after verifying the nature of the relationship) or to the police officer dealing with the case. A proper receipt must be obtained in each case.

30. **Referral cases**

If the patient is serious and required advanced facilities are not available, then it should be referred to higher centers for treatment with full detailed referral note by the CMO.

If MLC could not be prepared due to the seriousness of the patient, the same should be reflected in the referral note.

31. **In case of an unconscious patient (Non MLC) not accompanied by an attendant**

The CMO has to inform about the non availability of an attendant with the patient to MS/RMO for further necessary steps to be taken.

32. **Emergency Surgery**

When emergency surgery is required and no attendant is available to give the consent, the surgeon and RMO/MS, will decide and may conduct an emergency surgery on the patient. Please note that the surgeon treating the case will be held responsible if such a patient dies for want of operative treatment because of the non- availability of attendant to give consent for surgery.

33. **Taking away a patient/ dead body of a medicolegal case forcibly by the attendant.**

- The CMO cannot act as a security staff or a police officer. He cannot forcibly detain a medico-legal case or his body.
- In case the attendants want to take away a medicolegal case/body, the implication of their action should be explained to them politely.
- If they still insist, the CMO should get it in writing from the attendants that they are taking away the patient/body against medical advice.
- If they refuse to write anything and take away the patient/body, the CMO should record the same in the file of the patient.
- Police intimation in such cases is mandatory.

- In such cases, the doctor in-charge of the case, Medical Superintendent / RMO, Police and security staff be informed immediately.

34. **Treating the patients v/s information to the police**

- The first and foremost duty of the CMO is to treat and save the life of the patient. Everything else is secondary.
- The CMO will inform the police as soon as possible.
- The treatment should not be delayed because of non arrival of the police in any circumstances by the CMO.

35. **Summons**

Summons from the courts should always be accepted by the concerned CMO.

In case particulars of the case i.e. name of the patient, date of admission, MLC No. etc. are not mentioned, in the summons and the CMO is not able to trace the case file,such summons may be returned to the court, requesting the court to supply the relevant particulars.

(A very polite language should be used if the summons is not accepted e.g. "The particulars of the case, i.e. name of the patient / deceased and date of admission/death, MLC/MLR No. have not been given. No useful purpose will be served by attending the Court on_____. Kindly provide the necessary particulars so that the relevant papers are brought at the time of the next hearing.")

Utmost care should be taken if the summons is received from the Session Court or High Court. In case the doctor is busy withsome urgent work or an operation/consultation is already fixed and the notice is too short, information to this effect may be supplied to the Court and request be made for adjournment.

To avoid unpleasantness, the doctors must attend the court when summoned. In case, one cannot attend the court because of unavoidable circumstances, an official communication should be sent to the Court well in time.

The CMO islikely to receive a bailable warrant in case he/she doesnot attend the court. This requires furnishing security for the amount ordered by the court. In case a CMO is not still attending the court, the security

amount will be forfeited and a non bailable warrant will be issued by the court. This will be very embarrassing for the CMO officer concerned.

In case a CMO does not attend the Court and also fails to inform the Court, the Court may prosecute him/her u/s 174 IPC

36. **TA/DA**

TA/DA will be paid as per Govt. Rules of the court which has summoned the concerned CMO.

37. **Signature of the CMO**

The name of the CMO should be written in capital letters (Preferably stamp contain name, designation, address, registration number) below the signature on all MLRs.

38. **Dealing with the police**

The CMO is advised to render all possible help to the police investigating a case. The CMO is advised to be polite to the police. Any rudeness on the part of the police should be brought to the notice of the RMO/M.S.

39. **Medical Secrecy**

According to Declaration of Geneva as adopted by the World Medical Association (1948), every member of the Medical Profession has solemnly pledged that he will maintain the secrets of the patient confided in him even after the patient has died.

40. **Record of the Medicolegal cases**

a. A Record of the medicolegal case should not be divulged to any unauthorized person. Cases have occurred when the culprits have posed themselves as relatives and have taken away the record of the case and produced the same in the court after making changes therein to suit their purpose..

b. **Secrecy of the patient's illness in non-medicolegal case.**

Even in non-medicolegal cases, secrecy of the patient's illness has to be maintained except in such case where “public interest” is involved.

c. **Examination of the record (file) in non medicolegal cases.**

Relatives wanting to see the file of a non –medico-legal case, should be sent to the concerned treating doctor or Medical Superintendent for getting necessary permission. The patient's file is a secret

document and as such should not be divulged to any un- authorized person.

d. **Examination of the record (file) by L.I.C. or other investigation agencies.**

All records (file) related to Medicolegal cases/Post-mortem cases are not open to any person, including the L.I.C. or other investigation agencies. In case of Non-Medicolegal cases, such agencies should be asked to make an application to the Medical Superintendent /RMO, who may permit inspection of the record when considered necessary, keeping in view the secrecy of the illness of the patient

e. **Inspection of records by lawyers**

Under no circumstances, the record of the case will be allowed to be inspected by a lawyer. In case a lawyer gets a court order in this regard, the matter will be referred to the Medical Superintendent for guidance as the court orders cannot be defied.

41. **Re-examination of Medicolegal cases**

Re-examination of Medicolegal cases shall not be conducted except on written request of the Executive Magistrate or by the orders of the Judicial Magistrate. Re-examination should be done after obtaining permission from the HOD Forensic Medicine dept.

42. **Age Estimation**

A Board of three members namely dental Surgeon, Radiologist and CMO will be constituted to estimate the age of a patient. In case the examination of a Female is required thenthe Fourth member shall be a lady doctor from OBGY department.

The CMO will register as a ML case and then refer to the dental surgeon for his opinion on dental examination regarding age. Also refer to radiologist for his opinion or age on X-ray examination.

Finally, the age estimation certificate must be drafted and issued by the CMO on the basis of physical examinations (in female cases lady doctor from OBGY department records the finding of physical examination), dental and radiological findings. In case of any doubt, the opinion of a forensic expert (faculty of FM department) must be obtained.

CASUALTY

_____ Hospital

_____

Form No. I (a)

Police Intimation in Medico-Legal Case

MLC No:_____ Date:_____

From

Dr._____
CMO
_____
_____.

To

The Inspector of Police
Police Station
_____.

Sir,

I write to inform you that a patient by name_____ _ _____aged about ____ years, resident of _____ _____ _____ has been brought into the casualty of _____ at_____AM/PM on_____is alleged to have been _____ _____ at AM/PM at (place) _____ _____ He/She is being treated in Casualty/ Ward No _____

Please do the needful.

Yours faithfully,

Signature & Seal

Date:
Time:

CASUALTY

_____ Hospital

_____

Form No. I (b)

Police Intimation in Unnatural Death Case

MLC No:_____ Date:_____

From

Dr._____
CMO
_____
_____.

To

The Inspector of Police
Police Station
_____.

Sir,

This is to inform you that Mr./Ms./Mrs. _____ aged _____ years, resident of_____ _____admitted here on_____ at _____AM/PM with history of consuming an unknown poison / attempted suicide by hanging / alleged accidental drowning / alleged to be a victim of assault / road traffic accident/ fall from height/ burn/snake bite/ _____ expired on _____ at _____AM/PM while on treatment.

Identification marks/left thumb impression of the deceased is given below:

(i) _____

(ii) _____

The dead body is preserved in the mortuary cold chamber.

Please do the needful.

Yours faithfully,

Date:

Time: Signature & Seal

CASUALTY

_____ Hospital

_____

Form No. I (c)

Police Intimation in Dead on Arrival Case

MLC No:_____ Date:_____

From

Dr._____
CMO
_____
_____.

To

The Inspector of Police
Police Station
_____.

Sir,

This is to inform you that Mr. /Ms /Mrs_____ aged _____ years, resident of_____ _____ brought here to the casualty of this hospital on_____ at_____AM/PM with history of _____ _____ _____, expired on arrival at_____AM/PM.

Identification marks/left thumb impression of the deceased is given below:

(i) _____

(ii) _____

Dead body is kept in the mortuary. Please do the needful.

Yours faithfully,

Date:
Time:

Signature & Seal

Copy to: Mortuary file

CASUALTY

_____ Hospital

_____

Form No. I (d)

Police Intimation in Brought Dead Case

MLC No:_____ Date:_____

From

Dr._____

CMO

_____

_____.

To

The Inspector of Police

Police Station

_____.

Sir,

This to inform you that the below mentioned has been brought dead to the casualty of this Hospital on _____ at _____AM/PM from_____\

Name: _____ Age: _____ Sex: _____

Address: _____

_____

Identification marks/left thumb impression of the deceased is given below:

(i) _____

(ii) _____

Dead body is kept in the mortuary. Please do the needful.

Yours faithfully,

Date:

Time:

Signature & Seal

Copy to: Mortuary file

CASUALTY

_____ Hospital

_____

INJURY / WOUND CERTIFICATE

MLC No:_____ Date:_____

Name:_____
Address:_____
_____

Brought and Identified by:
Name:_____
Constable B No_____ of police station _____

Marks of identification:
1. _____
2. _____

Brief History:
_____
_____
Clinical finding:

a) General examination: Conscious / Unconscious
GCS:_____

Oriented / Not oriented
Co-operative / Non co-operative
T -
P -
R -
BP –

b) Systemic examination:

CNS:

CVS:

RS:

P/A:

c) Local Examination: Details of injuries / Clinical features.

Sl. No	Type	Size	Location	Shape	Colour	Other finding (if any)	Simple/ Grievous	Causative agent	Age of injury

I.P.No_____

X-ray report no_____

Opinion:

Date:

Time:

Signature & Seal

WHAT CAN INVESTIGATORS EXPECT FROM THE ETHICS COMMITTEE?

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WHAT CAN INVESTIGATORS EXPECT FROM THE ETHICS COMMITTEE?

Chapter - 3

Introduction

In the late forties, the first randomized trials were conducted in the world. The Patulin trial in 1943 and the Streptomycin treatment of Pulmonary Tuberculosis in 1948 were the earliest trials conducted in the world. Both the trials were conducted by Medical Research Council (MRC). Sir Austin Bradford Hill is credited for organizing the Streptomycin trial. He used the Hippocratic Oath as the basis for conducting the study. There were no ethics committees at that time. He obtained consent from the participants. When the participants were interviewed they participated in the trial because they believed that they were helping to discover a treatment for Tuberculosis and they trusted their doctors.

The early part of clinical trials was dominated with altruism and trust between the investigators and the subjects of research. The patients believed that their participation will contribute to improved health for others and that researchers will minimize risks to participants. As the randomized clinical trial (RCT) became the golden standard for the use of drugs, the simple relationship between the doctor and patient changed.

In the same year(1948) the atrocities of the Nazi rulers led to the Nuremberg Declaration. In 1964 the Helsinki declaration was published. In the sixties, Beecher published unethical trials that were being conducted in the United States. The Tuskegee study in 1970 brought out the vulnerabilities of the research subjects. All these events lead to development of the Belmont report in 1974. It was essential to protect the subject. Hence, ethics committees (ECs) were set up protect the subjects.

Doctor – Patient relationships

The patient suffers from his disease. The physician has the technical knowledge and specialized knowledge to help the patient from his ailment. The relationship between the doctor and the patient is an unequal relationship. The physician has an upper hand in this relationship and he can exploit the patient. In a research setting the subject may get the best care. He may benefit from the new treatment. At the same time he is exposed to risk associated with the side effects of the drugs. The physician gains by adding knowledge and the fame that goes

with the scientific activities. He may also benefit financially. He does not undertake any risk. An unscrupulous physician can exploit the patients to his advantage. The interest of the subject has to be protected. This is achieved if there is a mechanism to protect the interest of the research subjects. Hence, there is a need for ethics committees.

Ethics committee Work

The Ethics committees (ECs) have tremendous responsibilities. They have to examine the protocol to see whether the proposed methodology is scientific and if it can answer the question that it has raised. The proposal should be scientifically sound and clinically meaningful. The Ethics committees have to see that there is clinical equipoise before the study is started. Clinical equipoise means that there is no difference in the outcomes between two groups of patients at the start of the study. As data accumulates, there may be a difference between two groups and if it is significant then the trial is stopped.

Apart from the scientific review the ethics committee also has a duty to protect the trial participants. It has to make sure that there is no exploitation of the patient; proper consent is obtained as well as the risks are equally distributed.

The ethics committee is mandated to supervise the research and to see that it is conducted according to the protocol. It has a right to examine the data and results. It also has to advise the researcher on different aspects of the trial, so that the investigation becomes scientifically and ethically sound. Scientific review precedes the ethical review. For proper review, the ethics committee can request experts in the field to review the scientific part of the proposal.

Composition of Ethics committee

The hallmarks of the ethics committee are its independence and it should be competent. The ethics committees should be constituted by the authority of the institution or board. The ECs should specify in writing the authority under which the Committee was established. The composition of the ethics committee should be multidisciplinary and multi-sectorial. The number of persons in an ethics committee should be kept fairly small (8 - 12 members).A minimum of five persons is required to form the quorum without which a decision regarding the research should not be taken.

The board that constitutes the ethics committee has to appoint members to the ethics committee. The appointment must be for a specified period. The term of appointment of members can be extended for another term. A defined percentage of the members have to be changed on regular basis. The members should undergo regular training in ethics. The EC can nominate a substitute member only when a regular member does not attend the specified number of meetings continuously due to some unforeseen circumstance.

The ethics committee must have a standard operating procedure(SOP) that is written down even before the committee starts functioning. The SOP must include all the details of the members.

The composition- members

1. One - two persons from basic medical science arena
2. One - two clinicians from various institutes
3. One legal expert or retired judge
4. One social scientist/ representative of non-governmental voluntary agency
5. One philosopher/ ethicist/ theologian
6. One lay person from the community

The chairperson of the committee should be appointed by the appointing authority. He/She should not be from the institution. The head of the institution should not be the chairperson. These precautions are taken to ensure the independence of the committee. The Member Secretary of the committee should be from the institution so that the business of the committee can be conducted smoothly.

The ethics committee should be constituted by an appropriate authority i.e. the management of the hospital. The terms of reference should include the names of the members and the duration of their terms.

Each ethics committee must have standard operating procedures that states how it will function. It should have a policy for removal/replacement of members and the resignation procedures if the members want to resign. It should state the frequency of meetings. The charges that are levied for review should be specified. The honorarium that will be paid for the consultants/ experts and members must be mentioned.

Review Procedures

The proposals have to be submitted to the member secretary or to ethics committee office. The last date for submission should be at least one week before the scheduled meeting of the EC. The EC's member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types,

1. Exemption from review
2. Expedited review
3. Full review

Accordingly the review will be undertaken by the ethics committee.

The risk of the study to the participants in the research has to be decided by the chairperson/ member secretary of the committee. The studies that involve minimal risk are defined as 'An intervention which may be anticipated as harm or **discomfort not greater than that encountered in routine daily life activities** of general population or during the performance of routine physical or psychological examinations or tests.'

Some procedures are inherently a great risk, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life

1. Exemption from review

The EC can exempt proposals that present less than minimal risk from full review of the EC. This usually involves research on educational practices. Exemption is granted if the research participants cannot be identified and private papers of the individual are not examined.

2. Expedited Review

Sometimes the Member- Secretary and the Chairperson of the institutional ethical committee (IEC) or designated member of the Committee or Subcommittee of the IEC may do expedited review. These are proposals presenting no more than minimal risk to research participants ~~may be subjected to expedited review.~~ Protocols that can merit expedited review are minor deviations from originally approved research during the period of approval. Revised proposal previously approved through full review by the IEC. Research involving clinical materials that have been collected for non-research (clinical) purpose can

also qualify for expedited review. When a drug has already been approved for therapy expedited review can be granted. If the same drug is used to study drug interactions or for conducting trials on vulnerable population, an Expedited review can be given for a minor adverse event or a drug reaction.

Expedited review in emergency situations requires prior written permission of IEC. It must be taken before the use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study

3. Full Review

All research presenting with more than minimal risk, which do not qualify for exempted or expedited review and involve vulnerable population and special groups must be subjected to full review by all the members.

Decision making process

The decision must be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps. A brief summary of the project with informed consent and patient information sheet, advertisements or brochures, should be circulated to all the other members. The ethical review should be done in formal meetings and EC should not take decisions through circulation of proposals. The committee should meet at regular intervals. It should not keep a decision pending for more than 3 - 6 months.

The Member- Secretary should communicate the decision in writing to the principal investigator (PI).All the discussions of the EC should be documented. A negative decision should always be supported by clearly defined reason and conveyed to the PI. EC can reverse its decision.

If a member has conflict-of-interest (COI) involving a project or has an own proposal, it must be conveyed to the chairperson in writing before the meeting takes place. The member should withdraw from the meeting when the proposal is being discussed. This should be recorded in the minutes of the meeting.

EC can order discontinuation of a trial any time during the trial. It can be done if the goals of the trial have already been achieved midway or unequivocal results

are obtained. In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.

The EC can invite the applicant/ investigator, representative of the patient groups or interest groups and Subject experts to assist in clarifying the doubts that they have about the proposal.

Duties of the principal investigator to the ethics board

The PI has a duty to inform the EC if there are any amendments to the protocol from the originally approved protocol along with proper justification. Serious and unexpected adverse events and remedial steps should be taken to tackle them or any new information that may influence the conduct of the study must be informed.

Review process

The EC also has a duty to review the research that is being carried by the PI. The EC has the responsibility to continue reviewing approved projects for continuation, new information, adverse event monitoring, follow-up and later after completion if need be. The method of review should be stated in the SOP. The review should be done by all reviewers or by primary reviewer(s).Different types of reviews are done. When on-going research is reviewed at regular intervals of six months to one year, it is known as periodic review. Apart from periodic review, EC can have an interim review. Each IEC should decide the special circumstances and the mechanism when an interim review can be resorted to by a sub-committee instead of waiting for the scheduled time of the meeting. Decisions taken should be brought to the notice of the main committee.

Monitoring

Apart from reviewing, IEC has a responsibility to monitor the study. It also has to monitor adverse reactions. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the **DSMB** may also be sought.

Record keeping

All documentation and communication of an IEC are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval of the documents. It is recommended that all records must be safely maintained after the completion/termination of the study for a period of 3 years

Records to be maintained by IEC

1. The Constitution and composition of the IEC
2. Signed and dated copies of the latest the curriculum vitae of all IEC members with records of training, if any
3. Standard operating procedures of the EC
4. National and International guidelines
5. Copies of protocols submitted for review
6. Correspondence with EC members and investigators regarding application, decision and follow up
7. Agenda of all EC meetings
8. Minutes of all EC meetings with signature of the Chairperson
9. Copies of decisions communicated to the applicants
10. Record of all notification issued for premature termination of a study with a summary of the reasons
11. Final report of the study including microfilms, CDs and Video recordings

Ethical principles that have to be applied by the ethics committees in deciding about the ethical validity of the study have been enunciated by the ICMR guidelines of 2007. EC have to follow these guidelines meticulously while evaluating the proposals. There are 12 guidelines. They are

1. Essentiality

The need for using human subjects to answer the research question must be considered as **absolutely essential.**

The ethics committee should come to this conclusion after a due consideration of all alternatives in the light of the existing knowledge in the proposed area of research.

2. Principles of voluntariness, informed consent and community agreement

The principles of informed consent and voluntariness are cardinal principles to be observed throughout the research or experiment.

3. Non-exploitation

Human subjects should be selected so that the burdens and benefits of the research are distributed without arbitrariness, discrimination or caprice.

4. Privacy and confidentiality

The identity and records of the human subjects of the research or experiment are as far as possible kept confidential; and that no details about identity of said human subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions.

5. Precaution and risk minimization

Due care and caution is taken at all stages of the research and experiment to ensure that the research participant and those affected by it including community are put to the minimum risk. They should not suffer from any known irreversible adverse effects. The experiment must generally benefit the research participant.

6. Professional competence

The research is conducted at all times by competent and qualified persons who act with total integrity and impartiality and who are aware the ethical considerations to be borne in mind in respect of such research or experiment.

7. Accountability and transparency

The research or experiment will be conducted in a fair, honest, impartial and transparent manner. Full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research. It is necessary to disclose any conflict of interest that may exist. Full and complete records of the research inclusive of data and notes are retained for such reasonable period as may be prescribed or considered necessary for the purposes of post-research monitoring, evaluation, make such records available for scrutiny by the appropriate legal and administrative authority.

8. Maximization of the public interest and of distributive justice

The research or experiment and its subsequent applicative use are conducted and used to benefit all human kind and not just those who are socially better off but also the least advantaged; and in particular, the research subject themselves.

9. Institutional arrangements

There shall be a duty on all persons connected with the research to ensure that all the procedures required to be complied with and all institutional arrangements required to be made in respect of the research and its subsequent use or application are duly made in a bonafide and transparent manner. To take all appropriate steps to ensure that research reports, materials and data connected with the research are duly preserved and archived.

10. Public domain

The research is brought into the public domain so that its results are generally made known through scientific and other publications.

11. Totality of responsibility

The professional and moral responsibility, for the due observance of all the principles, guidelines or prescriptions laid down generally or in respect of

the research or experiment in question must be observed by the researcher, Funding agency, and the institution where the research is conducted.

12. Compliance

There is a general and positive duty on all persons, conducting any research entailing the use of a human participant to ensure that both the letter and the spirit of these guidelines are scrupulously observed and duly complied with.

Protocol and its relevance to the guiding principles

The protocol that is submitted to the ethics committee should answer the ethical principles that have been outlined above. Introduction and review of the literature section of the protocol helps the EC to determine if the research is essential. The aims and objectives of the study help to clarify this issue. Informed consent form that is submitted to the EC will help the EC to decide if the principles of informed consent and voluntariness are followed.

The materials and method section will help the EC to decide if the research question is being answered. The subject selection, inclusion and exclusion criteria will help the EC to determine if the research is non-exploitative. The material methods section must mention the ways and means of protecting confidentiality of the subjects. The protocol must clearly the ways and duration the records will be preserved. This will ensure that privacy and confidentiality will be preserved. The methods section must also indicate how public interest and distributive justice will be carried out. Methods section will also indicate the precautions that the investigator will adopt to reduce the risks.

The Curriculum Vitae of the principal investigator and of the co-investigators will help the EC to decide if the investigators are competent to conduct research. Similarly disclosure of conflict of interest is essential.

It is essential that all institutional and financial arrangements are informed in the protocol. The protocol must clarify the responsibility and role of the funding agency, the institution and the research so that the accountability can be identified. The protocol must indicate a section on how the results will be disseminated. This will help the EC to determine if the material will be available in the public domain.

By regularly monitoring the research by interim reports regular reviews, audit and with the final report, the EC will be able to monitor that the researcher is compliant with the protocol that has been approved.

Conclusion

Ethics committee has a great responsibility to protect the research participant and ~~the~~ science. EC has a primary obligation to protect the patient. The PI has a duty to supply all the necessary details to the EC, so that the EC can make a correct decision. EC also has a duty to help the PI to improve the study so that together they can contribute to development of knowledge.

Consent for research

Introduction

Since the era of the seventies, the conduct of clinical research has changed. The Belmont Report in 1974 highlighted the need for informed consent. The Indian guidelines have endorsed it. Over the years the consent for research has evolved from a simple consent to a complex process. Hence, it is necessary to understand consent in all its details. Consent is not a single one time event. It is a process that has to be followed throughout the research.

What does consent mean?

It is a process of communication between a subject and researcher/clinician that results in the subject's authorization or agreement to undergo a specific medical intervention.

Doctrine of informed consent

Informed consent is a fundamental principle that has marked the emergence of modern medical ethics based on personal autonomy. In 1914 the Supreme Court of America held that every person has the right to determine what happens to his/her body. This ruling was based on the concept of autonomy of the individual. The doctrine of informed consent goes beyond the question of whether consent was given. It focuses on the content and process of consent. Informed consent is essential from legal and ethical considerations. It is a way to

minimize potential harm. It avoids unfairness and exploitation. It protects the subjects rights.

Advantages of informed consent

Obtaining informed consent from the patients builds the trust between the subject and the investigator. It sets the limits that an investigator can take. Informed consent protects the individual's freedom of choice. It gives ample respect for individual's autonomy. In a research setting it is the permission that is given by the participant to voluntarily ~~to~~ participate in research or ~~not~~.

Informed Consent of Participants

For all bio-medical research involving human participants it is essential to obtain the informed consent of the prospective participant or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. To obtain informed consent patient must be instructed orally as well receive written information. This written instruction is known as patient information sheet. Patients go through the ~~oral instructions,~~ information sheet and then decide on participation in the trial.

Informed Consent Form with Participant/ Patient Information Sheet

Document that provides adequate information about the research to the subject of research is known as consent form. It must be in a simple and easily understandable unambiguous language.

Components of informed consent form

The informed consent form should carry all these details. It should mention the

1. Nature and purpose of study. It must also state that it is a research study.
2. Duration of participation with number of participants must be mentioned.
3. The document should describe in brief the procedures that will be followed in research.
4. Mention all the investigations that may be done.

5. Foreseeable risks and discomforts adequately described and whether the project involves more than minimal risk must be stated.
6. Benefits to participant, community or medical profession as may be applicable must be clearly explained to the subject.
7. Policy on compensation should be clearly mentioned
8. In case of injuries or risk the availability of medical treatment for such injuries or risk management must be mentioned.
9. Alternative treatments if available must be mentioned. Subjects have the right to be aware of alternate treatments that are available.
10. Steps taken for ensuring confidentiality of the subject must be mentioned.
11. The subject should be assured that there will be no loss of care and benefits on withdrawal from the study.
12. In case of any commercialization of the research findings, the subject must be made aware of the sharing of benefit between the researcher and the subject.
13. The investigator must ensure that there is voluntary participation.
14. If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines.
15. Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results.
16. Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same is needed.
17. Risk of discovery of biologically sensitive information and provision to safeguard confidentiality.
18. Publication, if any, including photographs and pedigree charts.
19. Contact details of principal investigator (PI) or local PI/Co-PI in multi-centric studies must be mentioned so that the participant can ask for more information related to the research or in case of injury he/she may contact the PI.

20. Contact details of Chairman of the IEC so that the patient can complain against violation of rights.

Witnessing consent

Signature

If the participant cannot sign then the thumb impression needs to be obtained. It has to be documented by an unrelated independent witness. This is applicable more so with drug trials.

Verbal consent

Sometimes the participants may not give written consent. It may be because of the sensitive nature of the topic or to preserve their anonymity and confidentiality. They may be reluctant to sign and may prefer to give oral consent. Verbal consent can be obtained. It must be video graphed and an independent witness must be present.

Fresh or re-consent

As the research progress new knowledge may be generated. This knowledge may change the perceived risks. Participants need to know this information so that they can take an informed choice. It calls for fresh or re- consent. Fresh or re-consent should be obtained in the following situations:

1. Availability of new information which would necessitate deviation of protocol.
2. When a research participant regains consciousness from unconscious state or is mentally competent to understand the study. If such an event is expected then procedures to address it should be spelt out in the informed consent form.
3. When long term follow-up or study extension is planned later.
4. When there is change in treatment modality, procedures, site visits.
5. Before publication if there is possibility of disclosure of identity through data presentation or photographs (this should be camouflaged adequately).

Waiver of consent

Sometimes the consent cannot be obtained eg. Retrospective studies. In such situations the IEC can waive the consent. It can be waived, if it is justified that the research involves not more than minimal risk or when the participant and the researcher do not come into contact or when it is necessitated in emergency situations. Studies must have protections in place for privacy and confidentiality and do not violate the rights of the participants.

Situations when wavier can be granted.

a. When it is impractical to conduct research

There may be situations when research is essential and it may be difficult to obtain consent. Research in cardiac arrest management is a good example. The patient is unable to give consent and there is no time to ask the family hence research is done without obtaining consent. Even in these situations confidentiality of personally identifiable information has to be maintained throughout research as may be required by the sensitivity of the research objective.

b. Research on Information in the public domain

Consent can be waived if the information is available in a public domain. Publicly available information, documents, records, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.

c. Research on anonymousbiological samples

Biological samples may be obtained from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc. In these situations it is not practical to obtain consent.

If these situations are anticipated by the researcher, it needs to be mentioned in the protocol that is submitted to the IEC. It is the ethics committee that will decide the wavier of consent.

Obligations of investigators regarding informed consent

1. Provide all the information necessary for informed consent.
2. Exclude the possibility of unjustified deception, undue influence and intimidation.
3. Seek consent only after the prospective participant is adequately informed.
4. Written consent has to be obtained from each prospective participant in a signed form as an evidence of informed consent. This consent must be witnessed by a person not related to the trial in case the participant is not competent to do so, a legal representative can give consent.
5. Verbal consent, when the participant refuses to sign or give thumb impression or cannot do so. This can then be documented through audio or video means.
6. If a person is incompetent then consent may be obtained from a surrogate. A surrogate may be an authorized relative or legal custodian or the institutional head in the case of abandoned institutionalized individuals or wards under judicial custody.
7. The investigator has to renew or take fresh informed consent of each participant if necessary.
8. If participant loses consciousness or competence to consent during the research period, surrogate consent may be taken from the authorized person or legal custodian.
9. The investigator must assure prospective participants that their decision to participate or not will not affect the patient - clinician relationship or any other benefits to which they are entitled.

Recent Supreme Court orders

The procedures of obtaining consent were described in the ICMR guidelines on bio-medical research. Recently it was brought to the notice of the Supreme Court of India that researchers were violating the provisions of informed consent. On 21/10/2013 the Supreme Court in the Swasthya Adhikar Manch, Indore & ANR. *Vs* Union of India & ors case ordered that the Government should issue administrative directions to ensure that consent must include audio visual(A-V) recording. This is in addition to written consent.

Drugs Controller Government of India (DCGI) order

The DCGI issued orders to implement the same from 19/11/2013. CDSCO vide F. No. GCT/20/SC/Clin./2013 DCG1. In addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject must be recorded. It should include the procedure of providing information to the subject and his/her understanding on such consent. The principles of confidentiality must be adhered. Such audio-visual recording and related documentation must be preserved. This is applicable to all the new subjects to be enrolled in all clinical trials including Global Clinical Trials. When a participants not able to give informed consent the information must be given to the surrogate and it should be recorded. If the subject or a surrogate cannot read or sign, then an impartial witness must be present during the A-V recording. The whole process must be video graphed. Even the doubts and questions that a participant may ask during the process must be recorded.

During the audio-visual recording of informed consent process, the identity and records of the trial subjects are as far as possible kept confidential. It can only be revealed if there is a valid scientific and legal reason. The subject should authorize the release of the identity.

In order to maintain the confidentiality, the videographer should be engaged as part of the study team. Prior to initiation of the study, the Investigator should define and allocate the activities of audio-video recording of informed consent process to the respective identified person as videographer. The Investigator has to maintain the details of the person to whom he has delegated the duties of audio video recording.

Prior consent of the subject must be taken for audio-visual recording of the informed consent process and the same must be documented by the investigator. Such consent may be taken orally. Only those subjects who give the consent for the AV recording must be included in the clinical trial. The DCGI has laid down the procedure for obtaining consent.

Procedure of audiovisual recording

At the beginning of the video recording process, the Investigator will identify the protocol, the subject/surrogate and the language understood by the subject/surrogate. If the Investigator does not know the language of the subject/surrogate member of the study team who understands the language, has to be used as an interpreter.

In order to identify the subject/surrogate his/her photo ID may be documented. The video camera for the audio-visual recording should be of adequate capability to simultaneously capture the facial details of subject/surrogate /Impartial Witness (if any) ant the Investigator/authorized person present during the consent process. The audio-visual recording should be conducted in a room conducive to recording of disturbance-free audio and video of the consent process. During the videography process, care should also be taken not to include unrelated persons/patients at the hospital within the field of vision.

During this process of obtaining A-V consent the PI must ensure that the quality of recording of both audio and the visual components is good. The DCGI mandates that the recordings are preserved safely for a period of five years after completion of the study. It urges that if possible the recording should be preserved permanently.

Conclusion

Obtaining consent for research is of paramount importance. With the recent Supreme Court ruling and DCGI directions, it has become a herculean task for the investigators. In future this will bring up new problems and solutions. Whatever maybe the problems, without informed consent no clinical research will be allowed to take place.

LIFESTYLE IN DISEASE

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Chapter - 4

Introduction

Lifestyle is a term used to describe the way individuals, family circles, and societies live and thebehavior that they manifest whilecoping with their physical, psychological, social, and economic environments on a day-to-day basis. It is closely related with the concept of risk, with multiple and complex interferences. Developing countries suffer most or all of the burden due to many of the leading risks. Strategies that target these known risks can provide substantial and still underestimated public-health gains.

Lifestyle is expressed by daily work and leisure profiles, including activities, attitudes, interests, opinions, values, and allocation of income. From a psychological point of view lifestyle derives from people's self image or self concept (the way they see themselves and believe they are seen by the others), including self esteem and self-efficacy. Lifestyle is a composite of motivations, needs, and wants and is influenced by factors such as culture, family, reference groups, and social class.

Lifestyle diseases

Lifestyle diseases are diseases that appear to increase in frequency as countries become more industrialized and people live longer. Lifestyle diseases share risk factors similar to prolonged exposure to three main modifiable lifestyle behaviors such as smoking, unhealthy diet (including alcohol abuse), and physical inactivity all of whichresult in the development of non-communicable and chronic diseases, substantially degenerative diseases like heart disease, stroke, diabetes, obesity, metabolic syndrome, chronic obstructive pulmonary disease, and some types of cancer, all of which can actually be considered a consequence of “contagious” behaviors. These conditions imply loss of independence, years of disability, or death, and impose a considerable economic burden on health services.

However, despite the well known benefits of a healthy lifestyle, only a small number of adults follow changes toward attaining a healthier lifestyles.; nonetheless, through other factors,especially pharmacological,the prevalence of disease is declining and the development and consequence of unhealthy lifestyles is delayed.

Lifestyle medicine

Lifestyle medicine is defined as the application of environmental, behavioral, medical and motivational principles to the management of lifestyle-related health problems in a clinical setting. It is an established branch of medicine where we discuss the contribution of lifestyle to health in addition to non-pharmacological interventions, in the treatment and management of lifestyle diseases such as exercise and weight management.

Hippocrates can be seen as the father of lifestyle medicine. He often used lifestyle modifications such as diet and exercise to treat diseases such as diabetes.. He is often quoted as saying"Let food be your medicine, and medicine be your food" and "Walking is man's best medicine".

Lifestyle medicine is often prescribed in conjunction with a typical medicine approach of pharmacotherapy. For example, diabetic patients who may be on medication to help control the blood glucose levels in the short term might also be prescribed a lifestyle intervention of a healthy diet and exercise to assist in the long term management of their pathology. In some cases lifestyle interventions are more effective when augmented with appropriate pharmacotherapy, as with tobacco use where medications such as bupropion may be prescribed to assist the patient to quit smoking and adopt a healthy lifestyle change.

A cultural framework of competences and skills by which doctors can personally manage the need of prediction (early diagnosis), prevention (intervention on healthy persons) and tailored therapy and follow-up for patients is the basisfor reasonable guidelines that are aimed at more effective clinical practice and favorable cost-benefit balance.

The doctor can be trained not onlyas currently done, to become an improbable medical-financial manager but, as intuitive for anybody, to manage the psychological and nutritional assessment of patients, to extend the power of physical examination by non-invasive, quick and almost inexpensive procedures and to prescribe what is needed, including drugs or other therapies within the scheme of a reasonable follow-up strategy.

Therapeutic Lifestyle Changes (TLC)

Overweight and obesity are complex health problems that affect adults causing an increased risk of chronic disease. There are many health conditions associated with being overweight and obeseincluding hypertension, coronary

artery disease (CAD) and type 2 diabetes mellitus (T2DM). Therefore, it is likely that health care practitioners will be advising overweight or obese individuals who also have additional health conditions. The challenge for many practitioners is choosing an appropriate weight management therapy that will simultaneously address these multiple health conditions. Fortunately, lifestyle changes including healthy eating patterns, increased physical activity, and weight management all together often decrease the risk factors associated with obesity. One such lifestyle approach, Therapeutic Lifestyle Changes (TLC) is recommended by various health organizations.

Overweight (BMI 25–29.9 kg/m2) and obesity (BMI $\geq$30 kg/m2) are independent risk factors for several chronic disease conditions including coronary artery disease, hypertension, elevated cholesterol, and diabetes. The prevalence of these conditions increases as BMI increases. The risk for developing diabetes also increases with increasing weight. Compared to a healthy weight person, an overweight individual is 3 times more likely to develop diabetes within 10 years. This risk rises dramatically to 23 times the risk at higher BMI levels (BMI $\geq$35 kg/m2).Individuals with diabetes are also at an increased risk of developing coronary heart diseas

The metabolic syndrome—a clustering of multiple risk factors associated with overweight and obesity .It is now known that when certain chronic disease risk factors co-exist (abdominal obesity, low level of high density lipoprotein (HDL) cholesterol, elevated fasting glucose, and elevated triglycerides), there is an increased risk for cardiovascular disease and diabetes. The metabolic syndrome is a defined cluster of three or more of these chronic disease risk factors that are often accompanied by insulin resistance.

TLC is the lifestyle component of the Third Report of the NCEP Adult Treatment Panel (ATP) III guidelines that focuses on diet, weight management, and increased physical activity. The ATP III guidelines specifically target low-density lipoprotein (LDL) cholesterol because of its strong, positive correlation with coronary artery disease risk. Although drug therapy may also be used, ATP III places a major emphasis on TLC as an essential therapy for persons at risk for coronary heart disease. The cumulative effect of the TLC diet components can reduce LDL by 25-30% similar to the effect of drug therapy.

TLC components

- Diet
- Weight management
- Increased regular physical activity

Dietary Recommendations for TLC

Total fat	25-35% of total calories
Saturated fat	<7% total calories
Polyunsaturated fat	Up to 10% of total calories
Monounsaturated fat	Up to 20% of total calories
Trans *fat*	Lower intake
Carbohydrate	50-60% of total calories
Dietary fiber	20-30 grams per day
Protein	15-25% of total calories
Cholesterol	<200 mg/day
Sodium	<2,300 mg/day
Dietary options	
Plant sterols/stanols	Add up to 2 grams per day
Soluble fiber	Increase 5-10 grams per day
Fish (fatty fish)	Include in weekly eating plan

Reduced-Calorie TLC Diet for Weight Loss Because an overweight status and physical inactivity are highly correlated with the metabolic syndrome; weight reduction and increased physical activity using TLC are recommended for those who are overweight or obese and at risk for type 2 diabetes and/or coronary heart disease. Lifestyle interventions are effective therapies in promoting weight loss and improving coronary heart disease and diabetes risk factors. Specifically, TLC-like interventions have been shown to promote weight loss while improving coronary heart disease and diabetes risk factors.

Achieving energy balance (calories consumed = calories expended) is the key to maintaining a healthy weight. Weight loss occurs when calories expended exceed calories consumed. Optimally, this is achieved by reducing caloric intake while increasing daily physical activity levels. The diet should be planned to provide the appropriate balance of nutrients at the lower calorie levels. For example, a particular diet may provide the proper balance of carbohydrates, protein, fats, and other nutrients at a 2,000 calorie level, but not provide adequate amounts of fat, protein, and/or other nutrients when the daily calories are reduced to 1,200 calories.

Overall, the TLC diet is low in saturated fats, dietary cholesterol, and sodium, while emphasizing adequate levels of monounsaturated and polyunsaturated fats. These nutrient levels remain constant at the reduced calorie levels, making it a high quality/balanced diet for weight reduction. In addition, along with providing the recommended amounts and types of dietary fats, a reduced-calorie TLC diet plan also maintains a healthy balance between carbohydrate, protein, and total fat intake.

Increasing Physical Activity

Weight reduction that incorporates increased physical activity has beneficial effects on several metabolic risk factors including insulin resistance, blood pressure, serum triglycerides, LDL, and HDL cholesterol levels. In a recent weight loss study of overweight and obese women with metabolic syndrome, the addition of physical activity to a reduced-calorie diet improved metabolic syndrome risk factors approximately 3.5-fold as compared to diet alone.

Thus, because of its positive effects on coronary heart disease, diabetes, and metabolic syndrome risk factors, physical activity provides the following benefits:

- To reduce the risk of chronic disease in adulthood: Engage in at least 30 minutes of moderate-intensity physical activity, above usual activity, at work or home on most days of the week.
- For most people, greater health benefits can be obtained by engaging in physical activity of more vigorous intensity or longer duration.
- To help manage body weight and prevent gradual, unhealthy body weight gain in adulthood: Engage in approximately 60 minutes of

moderate- to vigorous-intensity activity on most days of the week while not exceeding caloric intake requirements.

- To sustain weight loss in adulthood: Participate in at least 60 to 90 minutes of daily moderate-intensity physical activity while not exceeding caloric intake requirements. Some people may need to consult with a healthcare provider before participating in this level of activity.

Lifestyle changes in cardiovascular disease

Cardiovascular diseases (CVD) continue to be the major cause of mortality representing about 30 per cent of all deaths worldwide. Lifestyle diseases like hypertension, diabetes mellitus, dyslipidaemia and overweight/obesity are the major risk factors for the development of CVD. With rapid economic development and increasing westernization in the past few decades, the prevalence of these diseases has reached alarming proportions among Indians lately.. There is a strong linear relationship between high blood pressure (BP) levels and the risk of CVD. The terminology "prehypertension" (systolic blood pressure 120-139 mm Hg and/ or diastolic blood pressure 80-89 mm Hg) is associated with two fold higher risk of mortality with stroke and coronary artery disease when compared with normotensives (individuals with BP less than 120/80 mm Hg). In addition, prehypertensives are at higher risk of developing hypertension and CVD in their later lives. Without lifestyle or pharmacological intervention these individuals were found to have more than two times higher risk (prehypertensives vs. normotensives - 37 vs. 17%) of progression to overt hypertension within four years of diagnosis.

Co-existent CVD risk factors like dyslipidaemia, raised blood sugar levels and higher body weight are common among prehypertensives. Hence, the individuals with prehypertension are expected to have higher cardiovascular mortality risk.

Lifestyle modification in cardiovascular disease

Regular physical activity

Advise all patients to become physically active, as part of a comprehensive plan to control hypertension, regardless of drug treatment. Aim for 30 minutes of moderate-intensity physical activity on most, if not all, days of the week.

- There is strong evidence that regular physical activity has an independent cardioprotective effect.
- Regular aerobic exercise can lower systolic BP by an average of 4 mmHg and diastolic BP by an average of 2.5 mmHg.

The daily dose can be accumulated in shorter bouts (e.g. three 10-minute walks). Moderate-intensity physical activity (e.g. brisk walking, lawn mowing, low-paced swimming, cycling, gentle aerobics) will cause a slight increase in breathing and heart rate, and may cause light sweating. Advise against isometric exercise routines that may raise BP (e.g. weight lifting), except within professionally supervised programs.

Smoking cessation

Smoking cessation may not directly reduce BP, but markedly reduces overall cardiovascular risk. The risk of myocardial infarction is 2–6 times higher and the risk of stroke is 3 times higher in people who smoke than in non-smokers.

Advice from health professionals may be effective in increasing the quit rates. Even 3–5 minutes taken to encourage smokers to attempt to quit can increase the success rates.

Pharmacotherapy (nicotine replacement therapy, bupropion, varenicline) is effective in aiding cessation of smoking. The risk of adverse effects is small and is generally outweighed by the significant risk of continuing to smoke.

Dietary modification

There is strong evidence that salt restriction can reduce systolic BP by approximately 4–5 mmHg in hypertensive individuals and 2 mmHg in normotensives individuals.

- Suitable for patients with normal renal function only: Increasing dietary potassium can reduce systolic BP by 4–8 mmHg in hypertensive individuals and 2 mmHg in normotensives individuals.

Limit salt intake to ≤4 g/day (65 mmol/day sodium) by:

- choosing foods processed without salt, foods labeled 'no added salt' or 'low salt' (or 'reduced salt' products when other options are unavailable)

- avoiding high-salt processed foods, salty snacks, takeaway foods high in salt, salt added during cooking or at the table

Patients with normal renal function only: increase potassium intake by eating a wide variety of fruits and vegetables, plain unsalted nuts (limit quantity and frequency to avoid excess kilojoules), and legumes (e.g. beans, lentils, dried peas).

Patients taking potassium-sparing diuretics must limit potassium intake to avoid severe hyperkalaemia.

A healthy eating pattern includes mainly plant-based foods e.g. fruits, vegetables, pulses and a wide selection of wholegrain foods, moderate amounts of low-fat or reduced-fat dairy products, moderate amounts of lean unprocessed meats, poultry and fish, moderate amounts of polyunsaturated and monounsaturated fats (e.g. olive oil, canola oil, reduced-salt margarines).

Weight reduction

Every 1% reduction in body weight lowers systolic BP by an average of 1 mmHg. Weight reduction by as little as 4.5 kg reduces BP and/or prevents hypertension in a large proportion of overweight people. Weight loss of 10 kg can reduce systolic BP by 6–10 mm Hg.

Assess waist circumference and BMI. Targets are:

- Waist circumference < 94 cm (males); < 80 cm (females)
- BMI < 25 kg/m^2

Advise patients on how to reduce kilo joule intake as well as increase their physical activity. Explain that energy input (kilojoules) from food and drinks must be less than the kilojoules expended in daily activities and have some planned regular physical activity in order to lose weight. In order to lose weight, most people will need to do more physical activity than the 30 minutes of moderate-intensity physical activity per day recommended for general health benefits.

Limiting alcohol intake

Moderate drinking may increase BP and binge drinking may increase the risk of hypertension. Reducing alcohol consumption can substantially lower BP in some patients. Advise patients with hypertension to limit their intake to: a maximum

of two standard drinks per day for men, a maximum of one standard drink per day for women. Advise at least two alcohol-free days per week.

Lifestyle modifications in diabetes

Diabetes mellitus is a chronic condition, but people with diabetes can lead a full life while keeping their diabetes under control. Lifestyle modifications (changes in day-to-day habits) are an essential component of any diabetes management plan .Lifestyle modifications can be a very effective way to keep diabetes under control. Improved blood sugar control can slow the progression of long-term complications. Multiple small changes can lead to improvements in diabetes control, including a decreased need for medication. Diabetes requires a lifelong management plan.. Therefore, it is important to learn as much as possible about diabetes and to take an active role in making decisions about healthcare and treatment.

Alcohol and type2 diabetes mellitus: Drinking a moderate amount of alcohol (up to one serving per day for women, up to two servings per day for men) with food does not affect blood sugar levels significantly. People who take oral diabetes medications do not usually need to adjust their medication, as long as the alcohol is consumed in moderation and with food. Alcohol may cause a slight rise in blood sugar, followed hours later by a decrease in the blood sugar level.

Fruit juice or regular cola can increase blood sugar levels and increase the number of calories consumed in a day. Also, calories from alcohol have little nutritional value and may interfere with efforts to lose weight or contribute to weight gain.

Exercise and Diabetes For diabetics, exercise promotes cardiovascular fitness and weight loss, lowers high blood pressure, improves lipid profiles, improves blood sugar control in some cases, and leads to an overall sense of well-being. When combined with dietary lifestyle intervention it will even help prevent type 2 diabetes in some people. General exercise precautions — It is important to balance enthusiasm and common sense when beginning an exercise program. These precautions encourage patients to stay safe and ensure that exercise is productive.

- Wear well-fitting, protective footwear.

- Drink adequate amounts of liquids before, during, and after exercise to prevent dehydration, which can upset blood sugar levels.
- Measure blood sugar before, during, and after exercise to determine the body's typical response to exercise. If the pre-exercise blood sugar reading is 250 mg/dL or higher, exercise should be postponed until the level is under control.
- Consider a decrease in insulin dose by about 30 percent during exercise.
- Choose an insulin injection site away from exercising muscles (for example, avoid the legs if running).
- Keep rapidly absorbed carbohydrates on hand (glucose tablets, hard candies, or juice).
- Eat a snack 15 to 30 minutes before exercise, and again every 30 minutes during exercise.
- Eat a source of slowly absorbed carbohydrates (dried fruit, fruit jerky, granola bars, or trail mix) immediately after exercise. This will counter a post-exercise drop in blood sugar levels

Type of exercise — Gentle aerobic exercises, which increase the heart rate for a sustained period of time, are often the best choice for diabetics. Examples of aerobic exercise include walking, cycling, swimming, or rowing. Diabetics with well-controlled blood sugar levels and no complications can usually participate in different types of exercise without any hesitation. People with diabetic eye complications (proliferative retinopathy) may be advised to avoid high-impact activities and strenuous weight-lifting, which can increase blood pressure and cause bleeding in the eye. People with neurologic complications (peripheral neuropathy) are usually advised to avoid traumatic weight-bearing exercises such as running, which can lead to foot ulcers and stress fractures although this depends on the severity of the nerve damage.

Duration — A reasonable exercise session consists of 10 minutes of stretching and warm-up, followed by 20 minutes of gentle aerobic exercise. Eventually, you may wish to exercise for more than 30 minutes at a time. Timing — People who take insulin should try to exercise at the same time of the day. This practice can help to maintain predictable blood sugar levels. Frequency — Most of the benefits of exercise for people with diabetes require a regular, long-term exercise program. Patients should commit to exercising 30 minutes a day most days of the week.

Diet and Diabetics: Changing the type and amount of food eaten can help people with diabetes to lose weight, improve blood sugar control, and lower blood cholesterol levels and blood pressure.

Weight loss — Many people with type 2 diabetes are overweight. Losing even a small amount of weight (5 to 10 percent of total body weight) can help the body to produce and use insulin more efficiently. In fact, eating fewer calories can reduce blood sugar levels even before the first pound is lost. Recommended calorie intake — The number of calories needed to maintain weight depends upon your age, sex, height, weight, and activity level. In general:

- Men, active women – 3.3 cal/kg
- Most women, sedentary men, and adults over 55 years - 29 cal/kg
- Sedentary women, obese adults - 22 cal/kg
- Pregnant, lactating women - 33 to 37 cal/kg

To lose 1 kg per week (a safe rate of weight loss), subtract 500 to 1000 calories from the total number of calories needed to maintain weight.

General recommendations — To help manage the ABCs (**A**1C, **B**lood pressure, and **C**holesterol) and promote good health, the American Diabetes Association (ADA) recommends decreased calorie intake, increased physical activity to promote weight reduction, and monitoring of carbohydrate intake as primary considerations.

- A diet that includes carbohydrates from fruits, vegetables, whole grains, legumes, and low-fat milk is encouraged.

  However, monitoring carbohydrate intake (carbohydrate counting or experience-based estimation) is important in patients with diabetes, as carbohydrate intake directly determines postprandial blood sugar, and appropriate insulin adjustment for identified quantities of carbohydrate is one of the most important factors that can improve glycemic control. When considered in addition to total carbohydrates, the use of lower glycemic index and glycemic load meals may provide a modest additional benefit for glycemic control.
- A variety of eating patterns (low fat, low carbohydrate, Mediterranean, vegetarian) are acceptable.
- Fat quality is more important than fat quantity. Saturated fat and trans fat contribute to coronary artery disease, while

monounsaturated and polyunsaturated fats are relatively protective. Saturated and trans fats are found in solid fats like cheese, red meats, butter, margarine, and shortening. Saturated fats can be replaced with monounsaturated and polyunsaturated fatty acids (e.g., in fish, olive oil, nuts). Transfatty acid consumption should be kept as low as possible. People with diabetes are at increased risk for heart disease and stroke, and eating a diet low in saturated and transfats and cholesterol can help to reduce cholesterol levels and decrease these risks.

- Total cholesterol should be less than 300 mg daily. The main sources of cholesterol in the diet are foods such as organ meats and egg yolks.
- The role of dietary protein restriction is uncertain, particularly in view of problems with compliance in patients already being treated with saturated fat and simple carbohydrate restriction. Furthermore, it is uncertain if a low protein diet is significantly additive to other measures aimed at reducing cardiovascular risk and preserving renal function, such as ACE inhibition and aggressive control of blood pressure and blood glucose. Thus, protein intake goals should be individualized. An automatic reduction of dietary protein intake (e.g., 15 to 19 percent of calories) below usual protein intake in patients who develop diabetic kidney disease is not recommended. The usual intake of dietary protein should be approximately 10 to 25 percent of total caloric intake. Patients should be encouraged to substitute lean meats, fish, eggs, beans, peas, soy products, and nuts and seeds for red meat.
- A diet that is high in fiber (25 to 30 grams per day) may help to control blood glucose levels and hemoglobin A1C.
- A diet that is low in sodium (less than 2300 mg per day) and that is high in fruits, vegetables, and low fat dairy products, is recommended and can help manage blood pressure. For people with diabetes and heart failure, further reduction in sodium may be necessary to reduce symptoms.
- Artificial sweeteners do not affect blood glucose levels and may be consumed in moderation. The US Food and Drug Administration (FDA) has tested and approved five artificial sweeteners such as aspartame (Equal, NutraSweet), saccharin (Sweet'N Low, Sweet Twin), acesulfame-K (Sunnet, Sweet One), neotame, and sucralose

(Splenda). Stevia (sometimes called Rebaudioside A or rebiana) and they are generally recognized as safe by the FDA as a food additive and table top sweetener. Sugar alcohols (sorbitol, xylitol, lactitol, mannitol, and maltitol) are often used to sweeten sugar-free candies and gum, and increase blood glucose levels slightly. When calculating the carbohydrate content of foods, one-half of the sugar alcohol content should be counted in the total carbohydrate content of the food. Eating too much sugar alcohol at one time can cause cramping, gas, and diarrhea.

- Previously, people with diabetes were told to avoid all foods with added sugar. This is no longer recommended, but sugar should be eaten in moderation. If one is taking insulin, one should calculate the dose based upon the total number of carbohydrates in the food, which includes the sugar content, as described above.
- Products that are "sugar-free" or "fat-free" do not necessarily have a reduced number of calories or carbohydrates. Read the nutrition label carefully and compare it to other similar products that are not sugar- or fat-free to determine which has the best balance of serving size and number of calories, carbohydrates, fat, and fiber.

Lifestyle modification and malignancy

Research suggests that only 5% of cancers are hereditary. That means that most are due to the non inherited causes of cancer-our lifestyle, the foods we eat and our physical activity levels , all of which have a direct impact on our overall cancer risk. People should be encouraged to take charge of their lives by making smart lifestyle nutrition choice, seeing their doctors for regular screening, monitoring their bodies for any changes and seeking attention at right times. Cancers such as lung, prostate, breast, cervical, oral testicular, colorectal can be prevented through lifestyle changes and early screening and detection.

Smoking cessation- When you quit smoking, you lower your chances of getting many types of cancer. Smoking makes you more likely to get cancers of the lung, bladder, kidneys, pancreas, cervix, mouth, esophagus, and throat .Quitting is hard, but you can do it with the right amount of information and support. There are several medicines that work well to help people quit for good.

Diet- Eating a variety of vegetables, fruits, legumes (for example, peas and beans), fish, poultry, and whole grains helps prevent cancer. Limit the amount of fat in your diet, especially animal fat. Some scientists think certain supplements might help prevent cancer, but there isn't enough research yet to prove that. If you want to take supplements to prevent cancer, talk to your doctor about what is safe for you to take. Eating healthy foods is still the best way to get the vitamins and minerals your body needs.

Weight management- If you are very overweight, your chances of getting some forms of cancer are higher. And people whose extra fat is in the waist area may be at higher risk than people whose extra fat is in the hips or thighs. Eating a healthy diet and being more active can help you reach a healthy weight. It can be hard to change habits around eating and being active. But you can do it by taking one step at a time.

Physical activity- Being active every day may prevent a number of cancers. Regular activity can help you get to and stay at a healthy weight.Being physically active and getting enough sleep may work together to lower your cancer risk even more than activity alone, especially for women

Skin Protection- Most skin cancers are caused by too much sun. Follow these steps to help prevent skin cancer:

- Stay out of the sun when you can, especially from 10 a.m. to 4 p.m., the hours of peak ultraviolet (UV) exposure.
- If you must go out in the sun, wear protective clothing, like a wide-brimmed hat, a long-sleeved shirt, and pants.
- On skin that isn't covered by clothing, use a sunscreen that has a skin protection factor (SPF) of at least 15. Use it every day, all year, even when it is cloudy. Sunscreens that say "broad-spectrum" can protect the skin from ultraviolet A and B rays.
- Wear sunglasses that block UV rays.
- Use lip balm or cream that has sun protection factor (SPF) to protect your lips from getting sunburnt or developing cold sores.
- Avoid tanning booths and sunlamps, which emit UV radiation and can cause skin damage.

Safe sex - Practicing safe sex helps keep you from getting HPV, a sexually transmitted disease that can cause cervical cancer in women. Safe sex includes using condoms and talking to every potential sex partner about his or her sexual history.

Regular checkups and screening- Visiting your doctor and dentist for regular checkups is good for your health. Your doctor can schedule regular screenings for various types of cancer, such as mammograms for breast cancer and colonoscopy for colon cancer. Most screenings and checkups are to find cancer early, when it's easier to treat and may even be curable. But there are some things your doctor may recommend that can actually prevent the occurrence of certain cancers.. Although there are several types of screening tests for colon cancer,only two of them can actually help to prevent cancer: colonoscopy and sigmoidoscopy These tests can find and remove polyps in the colon before they turn

Vaccination- If you area female below the age of 45 years, you can get the HPV shot to protect against the virus that can cause cervical cancer. Three shots are given over a period of 6 months in a 0,1,6 0r a 0,2,6 schedule, depending on which vaccine is used.. Males age 9 through 26 may also get the HPV shot (Gardasil) which may prevent anal cancer, but this is not licensed for use in India as yet.

Avoid toxins and other poisons at work and at home- Living or working in unhealthy places can make you sick. Stay away from certain chemicals and other things in the environment that can increase your chances of getting cancer.

- Asbestos, an insulating material found in some older buildings, can cause tumors, lung cancer, and other diseases.
- Unsafe drinking water from a rural well polluted with pesticides or other poisons from a nearby industrial plant could cause allergies, cancer, or other problems.
- Take care when using cleaning products, paints, solvents, and pesticides. Be aware that paint can release trace gases for months after you apply it. Try to use paint without volatile organic compounds.
- Avoid being exposed to benzene, which can cause cancer. Benzene is found in tobacco smoke, stored fuels, paint supplies, and vehicle exhaust inside garages.
- Radon is a radioactive gas that causes cancer. Radon is found in rock, soil, water, some building materials, and natural gas.

Lifestyle changes and gastrointestinal diseases

Lifestyle changes mean modifying the things that we have control over. It involves factors that may bring on symptoms or make them worse, such as dietary changes or changes in daily routine. While diet perse does not cause gastroesophageal reflux disease (GERD), reflux and its most frequent complaint of heartburn can be aggravated by foods. Certain medications can aggravate these symptoms.

Position - Gravity plays an important role in controlling reflux. Those of us who have a less than perfect lower esophageal sphincter (LES) find that if we lie down after a large meal, food comes back into the esophagus and heartburn occurs Maintaining an upright posture until the meal is digested may prevent the heartburn. If heartburn occurs regularly at night, consider raising the head of the bed or inserting a triangular wedge to keep your esophagus above the stomach. Avoid exertion after a meal. Don't lie down within 3 hours of eating, which is the time when acid production is at its peak, so plan early dinners and avoid bedtime snacks.

Eating Habits - How you eat is perhaps more important than what you eat. A large meal will empty slowly from the stomach and exert pressure on the LES. A snack at bedtime is well positioned to reflux when you lie down. It is best to eat early in the evening so that the meal is digested at bedtime. You might try having the main meal at noon and a lighter one at dinnertime. All meals should be eaten in a relaxed stress-free surroundings. Smaller meals and an upright, relaxed posture should help minimize reflux. Avoid large meals, especially late in the day.

Certain foods compromise the sphincter's ability to prevent reflux, and are best avoided before lying down or exertion. These differ from person to person. Many persons find that fats, onions, and chocolate are particularly troublesome. Alcohol often provokes heartburn, by compromising the LES, irritating the esophagus, and by stimulating stomach acid production. Common beverages such as coffee (both caffeinated and decaffeinated), tea, cola, tomato juice, and citrus juice may aggravate symptoms by irritating the esophagus or stimulating stomach acid production.

Irritable bowel syndrome (IBS) - Diet and lifestyle changes are important in decreasing the frequency and severity of IBS symptoms. The first thing you must suggest is to keep a food diary. This will help to figure out the foods that trigger the symptoms.

- Limit foods that contain ingredients that can stimulate the intestines and cause diarrhea, such as: Caffeine, Alcohol, Dairy products ,Fatty foods, Foods high in sugar, Artificial sweeteners
- Some vegetables (cauliflower, broccoli, cabbage, Brussels sprouts) and legumes (beans) may worsen bloating and gassiness and should be avoided.
- Dietary fiber may lessen symptoms of constipation.
- Drink plenty of water, and avoid carbonated drinks such as soda, which may cause gas and discomfort.
- Eat smaller meals and eat slowly to help reduce cramping and diarrhea.
- Low fat, high carbohydrate meals such as pasta, rice, and whole-grain breads may help (unless you have celiac disease).

Conclusion

Overall, the encouragement of healthy lifestyles in the population should help to reduce the high burden of lifestyle diseases in India. Governmental and non-governmental agencies of the country should work together to achieve this goal. Lifestyle interventions have shown definite benefit in the management and prevention of these diseases in large scale studies.

Implementation of widespread non-invasive diagnostic procedures will be effective in early detection of many life style diseases. A favorable cost-benefit ratio along with adequate professional knowledge will go a long way in decreasing these diseases.. Knowledge and skills in health psychology, nutritional and physical activity assessment and prescribing can be enhanced through appropriate funding of Continuous Medical Education (CME) and by professionally targeted e-learning courses.