Report on One Day Workshop on Research and Publication thought process for Faculty

Program Organized By:	Date:	Venue:
Pharmacy Education Unit	17.01.2018	Seminar Hall
Center for Continuous Learning & Professional Experience		JSSCoP, Ooty
JSS College of Pharmacy		
Ooty		

Report Submitted By:
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Dr S Ponnusankar, Co-ordinator, Pharmacy Education Unit of JSS College of Pharmacy, Ooty welcomed the staff members and resource persons of the workshop for the program with the note to "ignite the young minds to do more research and publication" at our campus. He made the introductory note during the workshop regarding the importance of this workshop and how this workshop is going to benefit the participants. This workshop is organized to detail the academic publication, research integrity, funding opportunities, and publication of review article etc.

Scientific writing and publication marks the endpoint of research that has been performed, completed, peer reviewed and accepted, and complements teaching and training, clinical service and patient care. Writing has numerous benefits, one of the most important ones being the inherent training undertaken to better appreciate and evaluate the published work of others. Effective scientific writing is an important component of a pharmacy teacher, and should be cultivated at an early stage of the career.

Lecture 1:
Topic: "Somebody watching you" – Research Integrity and Academic misconduct
Speaker: Dr Suresh Kumar, Research Director, JSS College of Pharmacy, Ooty

Research integrity may be defined as active adherence to the ethical principles and professional standards essential for the responsible practice of research. By active adherence, the individual researcher may adopt the principles and practices as a personal credo, not simply accepting them as impositions by rule makers. By ethical principles such as honesty, the golden rule, trustworthiness, and high regard for the scientific record each individual should conduct the research.

NAS report definition: "For individuals research integrity is an aspect of moral character and experience. It involves above all a commitment to intellectual honesty and personal responsibility for ones actions and to a range of practices that characterize responsible research conduct."

These practices include:

- Honesty and fairness in proposing, performing, and reporting research;
- Accuracy and fairness in representing contributions to research proposals and reports;
- Proficiency and fairness in peer review;
- Collegiality in scientific interactions, communications and sharing of resources;

- Disclosure of conflicts of interest;
- Protection of human subjects in the conduct of research;
- Humane care of animals in the conduct of research;
- Adherence to the mutual responsibilities of mentors and trainees."

While science encourages (not requires) vigorous defense of one's ideas and work, ultimately research integrity means examining the data with objectivity and being guided by the results rather than by preconceived notions.

Academic misconduct is any action or attempted action that may result in creating an unfair academic advantage for oneself or an unfair academic advantage or disadvantage for any other member or members of the academic community. This includes a wide variety of behaviors such as cheating, plagiarism, altering academic documents or transcripts, gaining access to materials before they are intended to be available, and helping a friend to gain an unfair academic advantage.

Further, the speaker showed various examples of academic misconduct and explained how the same was pointed by the scientific community.

Lecture: 02
Topic: Institutional Ethical Committee and Protocol Review
Speaker: Dr PR Anand Vijayakumar, Professor, Dept. of Pharmacy Practice, JSS College of Pharmacy, Ooty

Institutional Ethics Committee (IEC) is the committee formed of a group of people who go through the research protocol / proposal and state whether or not it is ethically acceptable. As per the WHO definition, a clinical trial is any research study that prospectively assigns human participants to one or more health related interventions to evaluate the effects on health outcome. Ethics are concerned with the distinction between Right and Wrong, with moral choices, duties and obligations.

The four main principles of Biomedical Ethics are:

1. AUTONOMY
2. NON-MALEFICENCE
3. BENEFICENCE
4. JUSTICE

Institutional Head constitutes an IEC and it is independent, competent and multidisciplinary unit. The number of persons are fairly small between 8 – 12. The IEC appoints from among its members a chairperson who should be from outside the Institution and not head of the same Institution, and the Member Secretary from the same Institution who conducts the business of the committee. Members of IEC are:

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

The members work to safeguard the interests and welfare of all sections of the community. If required, subject experts could be invited to offer their views like a pediatrician for pediatric conditions, a cardiologist for cardiac disorders etc. Responsibilities of IEC are to protect the dignity, rights and well-being of the potential research participants, to ensure that universal ethical values and international scientific standards are expressed and to assist in the development and the education of a research community responsive to local health care requirements. The IEC's member-secretary screens the research proposals for their completeness and depending on the risk involved categorize them into 3 types:

1) Exemption from review for proposals that involve less than minimal risk
2) Expedited review for more than minimal risk proposals, minor protocol amendments, research on disaster management, and research on material collected during routine patient care like CT scans
3) Full review for more than minimal risk and that involve vulnerable subjects

The ethical review should be done in formal meetings by all primary reviewers and decision is made only when quorum complete. The committee should meet at regular intervals and should not keep a decision pending for more than 3 – 6 months. Periodic reviews are done as per the SOPs. All the decisions are communicated in writing to the principal investigator (PI). Members should be encouraged to attend trainings so that they are aware of all new guidelines and developments.

Elements of review are:

- Scientific design, conduct of the study and approval of review committees
- Examination of predictable risks and potential benefits
- Procedure for selection of subjects including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details
- Management of research related injuries, adverse events and compensation
- Justification for placebo and availability of products after the study
- Patient information sheet and informed consent form in local language
- Protection of privacy and confidentiality
- Plans for data analysis and reporting
- Adherence to all regulatory requirements and applicable guidelines
- Competence of investigators, research and supporting staff, and facilities
- Criteria for withdrawal of patients, suspending or terminating the study

Lecture: 03
Topic: Systematic Review and Meta-analysis
Speaker: Ms. BS Roopa, Dept. of Pharmacy Practice, JSS College of Pharmacy, Ooty

A systematic review answers a defined research question by collecting and summarizing all empirical evidence that fits pre-specified eligibility criteria. A meta-analysis is the use of statistical methods to summarize the results of these studies.

Systematic reviews can be of varying quality. They are a significant piece of work and to be useful to other researchers and practitioners they should have:

- clearly stated objectives with pre-defined eligibility criteria for studies

- explicit, reproducible methodology
- a systematic search that attempts to identify all studies
- assessment of the validity of the findings of the included studies (e.g. risk of bias)
- systematic presentation, and synthesis, of the characteristics and findings of the included studies

Systematic reviews differ from traditional narrative reviews in several ways. Narrative reviews tend to be mainly descriptive, do not involve a systematic search of the literature, and thereby often focus on a subset of studies in an area chosen based on availability or author selection. Thus narrative reviews while informative, can often include an element of selection bias. They can also be confusing at times, particularly if similar studies have diverging results and conclusions.

Systematic reviews, as the name implies, typically involve a detailed and comprehensive plan and search strategy derived a priori, with the goal of reducing bias by identifying, appraising, and synthesizing all relevant studies on a particular topic. Often, systematic reviews include a meta-analysis component which involves using statistical techniques to synthesize the data from several studies into a single quantitative estimate or summary effect size.

In contrast to traditional hypothesis testing which can give us information about statistical significance (i.e., did the intervention group differ from the control group) but not necessarily clinical significance (i.e., was this difference clinically meaningful or large), effect sizes measure the strength of the relationship between two variables, thereby providing information about the magnitude of the intervention effect (i.e., small, medium, or large). The type of effect size calculated generally depends on the type of outcome and intervention being examined as well as the data available from the published trials; however, some common examples include odds ratios (OR), weighted/standardized mean differences (WMD, SMD), and relative risk or risk ratios (RR). Although systematic reviews are published in academic forums, there are also organizations and databases specifically developed to promote and disseminate them. For example, the Cochrane Collaboration (www.cochrane.org) is a widely recognized and respected international and not-for-profit organization that promotes, supports, and disseminates systematic reviews and meta-analyses on the efficacy of interventions in the health care field.

8 Stages of a Systematic Review and Meta-Analysis

1. Formulate the review question
2. Define inclusion and exclusion criteria
3. Develop search strategy and locate studies
4. Select studies
5. Extract data
6. Assess study quality
7. Analyze and interpret results
8. Disseminate findings

The above stages of the systematic review and meta-analyses were discussed in details with specific examples.

Lecture: 04
Topic: Developing Protocol for Cochrane Systematic Review
Speaker: Dr D Raja, Asst. Professor, Dept. of Pharmacy Practice, JSS College of Pharmacy, Ooty

The Cochrane Database of Systematic Reviews (CDSR) is the leading resource for systematic reviews in health care. The CDSR includes Cochrane Reviews (the systematic reviews) and protocols for Cochrane Reviews as well as editorials. The CDSR also has occasional supplements. Cochrane Reviews are prepared by review author teams, working with CRGs, which are led by one or more Co-ordinating Editors.

The Cochrane editorial process follows a consistent and structured path. It is unique in two ways:

- CRGs monitor the process of review development throughout the editorial life cycle, beginning with registration of a title, through preparation and publication of the protocol and completed review;
- Cochrane Reviews are updated to take account of emerging evidence, to provide the best and most current evidence to guide decision-making

Editorials aim to stimulate discussion and ideas around the development of evidence synthesis to promote good decision-making in clinical care and health policy.

Cochrane Reviews and Protocols

Cochrane Reviews are systematic reviews of primary research in human health care and health policy, and are internationally recognized as the highest standard in evidence-based health care. They may either investigate the effects of interventions for prevention, treatment, and rehabilitation, or alternatively may assess the accuracy of a diagnostic test for a given condition in a specific patient group and setting. A unique feature of Cochrane Reviews is that they are living documents in that they are updated with new evidence that emerges. They were conceived as electronic publications from the outset, and designed to take advantage of features unique to electronic publishing.

Each systematic review addresses a clearly formulated question; for example: Can antibiotics help in alleviating the symptoms of a sore throat? All the existing primary research on a topic that meets certain pre-determined criteria is searched for and collated, and then assessed using stringent guidelines, to establish whether or not there is conclusive evidence about a specific treatment.

Each Cochrane Review is a peer reviewed systematic review that has been prepared by a team of authors and supported by a Cochrane Review Group editorial team in the Collaboration. Cochrane Reviews are prepared using Review Manager (RevMan) software provided by the Collaboration, and adhere to a structured methodological approach and format. Protocols for Cochrane Reviews are peer reviewed articles that describe the rationale for the review, the objectives, and the methods that will be used to locate, select, and critically appraise studies, and to collect and analyses data from the included studies.

Lecture: 05
Topic: Funding opportunities with national agencies
Speaker: Dr MJN Chandrasekar, Professor, Dept. of Pharm. Chemistry, JSS College of Pharmacy, Ooty

Grant writing is time-consuming, tedious and the success rates are depressing. Winning funding for your research ideas is tough, and there is growing pressure in all disciplines to get grants. While there's no easy way to write a successful application, there are some steps you can take to make the process less stressful. Identify your field of work and apply the same with broader perspective and inform the funding agencies that your idea is an emerging idea incorporating more technology and outcome based

research. It is very important that you should know your competitor and their approach in the proposed area of research. Further, check the funding agencies priority areas and does your proposal fit these.

He also added the various national funding agencies who are supporting the quality research proposal. He further added the skills needed to prepare the funding applications. The session was concluded with the question and answer sessions.

Lecture: 06
Topic: Implementation of internal grant review process at JSS CoP, Ooty
Moderator: Dr Suresh Kumar, Research Director, JSS College of Pharmacy, Ooty

The aim and objective of the internal grant review process is to increase the success of grant applications submitted by members of the department. Ultimately, this process will save applicants time and increase their satisfaction and rewards in research.

In order to begin the pre-submission peer review process, the grant applicants would submit the application title and abstract (proposal summary) along with the names of their suggested internal faculty reviewers to the Office of Research no later than 60 days before the application deadlines. It is recommended that applicants try to find three internal peer reviewers. The applicant would be responsible for securing their reviewers and providing them with the peer review forms. The Office of Research recognizes that for some researchers it may be difficult to recruit suitable internal peer reviewers on campus and may need to seek out external peer reviewers. Applicants are encouraged to contact the external peer reviewers on their own, but if the need arises, the Office of Research would organize the peer review activities by contacting the external reviewers and forwarding the research proposals in 2 electronic format to them for review. Peer reviewers (whether internal or external) should have expertise in the area of the applicant's research proposal.

It is the intent of the Office of Research to expedite the pre-submission peer review process in a congenial and timely manner, therefore applicants are encouraged to interact with their reviewers on a regular basis to get the maximum benefit of the pre-submission peer review process and are encouraged to give serious consideration to the reviewer's comments. All internal and external peer reviews should be completed 20 days before the application deadlines set by the funding agencies. This will give applicants ample time to complete any necessary revisions and formalities.

Finalized grant applications along with the completed peer review comment forms are to be submitted to the Office of Research no later than 15 days. The final outcomes of the pre-submission peer review process should be tracked and feedback collected from both researchers and reviewers as to their experience with the entire procedural aspect of the process. Based on the feedback information, regular and timely improvements or adjustments to the pre-submission peer review process can be implemented.

The purpose of the internal grant review process was explained by the moderator and the views of the participants were moderated by him.

Dr S Ponnusankar, Coordinator, thanked all the resource persons and participants for their wonderful support for the day long program. He also requested all the participants to provide the feedback through online feedback form.

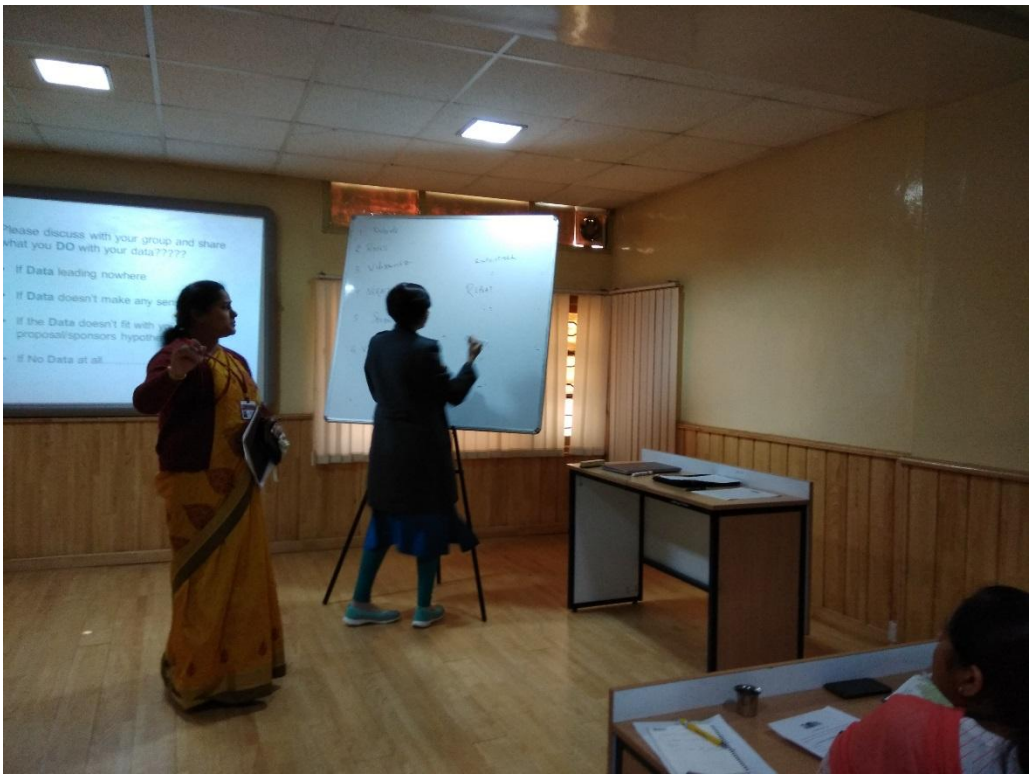
DR S Ponnusankar
Pharmacy Education Unit – Coordinator

Glimpses of the events

Dr Sureshkumar, Research Director presenting on "Somebody is watching You"

Dr PR Anand Vijayakumar, Professor presenting his lecture on "Institutional Ethical Committee and protocol review"

Dr MJN Chandrasekar presenting his lecture on "National Funding Agencies"



Activity of our staff Dr Khayati and Dr Gomathi during the one day workshop

Dr GK Sadagoban is in action……..may I have your attention please… this is clinical research problem…

Group 1: is in active participation during the workshop

Group 3: in action…. During the workshop

Sir…. I have a question… this is my problem.. how can I solve….