1. INTERNSHIP REPORT-

1.1 Introduction-

Internship is an integral part of course of PGDHHM. As a part of the curriculum students are required to undergo 3 months internship in any healthcare related organisation. The main purpose is to get an orientation towards healthcare and to complete the assigned task which includes the project and study.

I have done my internship at IIHMR (International Institute of Health Management research), New Delhi from 1st of February, 2010 to 30th April, 2010.

1.2 Establishment-

IIHMR, New Delhi is a part of Society for Indian Institute of Health Management Research (IIHMR) established on October 5, 1984 under Societies Registration Act 1958, with a mission to improve the standards of health of all people through better management of health. The first IIHMR was established in Jaipur. In order to cater to the growing needs of the country and Asia-Pacific region, IIHMR Delhi was established in 2008 with focus on national and international health.

1.3 Mission & Objectives of IIHMR Delhi-

Mission: IIHMR is an institution dedicated to improve the standards of health through better management of health care and related programmes. It seeks to accomplish this through management, research, training, consultation and institutional networking in a national and global perspective.

Objectives: The overall objective of IIHMR is to establish an excellent all-round academic environment for its students that can provide and disseminate the latest knowledge and management technology, through research, education, training and networking.

1.4 Core Activities at IIHMR, New Delhi-

Education-

IIHMR, New Delhi provides following full time or part time academic courses-

- AICTE approved Two-year full-time Postgraduate Programme with specialization in Hospital Management, Health Management and Healthcare IT Management
- Weekend course of Clinical Research and Pharmacovigilance
- Advance Diploma in Pharmacovigilance and Clinical Research
- Certificate in Health Insurance Management
- Certificate in Project Management (CIPM) – specialization in Healthcare (online course)

Training-

IIHMR, New Delhi conducts various Management Development Programmes or Short term training programmes in the field of healthcare. The MDPs are designed to respond to all healthcare challenges and help professionals in broadening their understanding and improving their skill set to face the newer challenges in their leadership roles

Research & Consultancy-

The Institute's focus is on health systems and health care research. It conducts and designs policy analysis and review and undertakes intervention research, evaluation studies and operation research studies. The key areas of research mainly include assessment surveys and studies in important health programmes, strengthening management of district health systems; involvement of PRIs and NGOs in reproductive and child health services; and alternative management approaches in implementing population programmes with district as the unit.

There has been an expansion in the nature and scope of projects and research studies. The interpretative research has been stressed upon thus influencing policy making at the state and central government levels. Some of the projects and studies specifically address the health research and population issues that have a direct impingement on clinical, health services research and other related industries. The Institute has also undertaken projects aiming at facilitating health sector reforms, developing implementation processes in decentralized district planning, implementing quality assurance in health care, strengthening information systems, and enhancing community participation. New research dimensions in health financing and human resource development have also been explored.

1.5 Industry/Community Linkages-

IIHMR, New Delhi has established a strong network in the health industry. It has signed MOUs with following organizations:

- MOU with Centre for Development of Advanced Computing (C- DAC), Mohali, Society of the Government of India in developing trained manpower, undertaking consultancies & research activities.
- MOU with National Health System Resource Centre, (Technical support unit) of NRHM for providing technical support in making District Health Action plan for the state of Haryana
- MOU with Project Management Associates (PMA) and Centre for Excellence in Project Management (CEPM) for online **c**ertificate course in Project Management (CIPM) – specialization in Healthcare
- MOU with Empower Manpower Solutions Private Limited short / long course on Pharmacovigilance & Clinical Research
- Association with TPAs, Health Insurance industry for Health insurance courses
- Association with Indian Association for Medical Informatics (IAMI) for Healthcare IT course

- Established a strong network with Public Health Institutes
- IIHMR is recognized as one of the Community Colleges of IGNOU

1.6 Other Achievements-

- **Training of Block Health Activists at Lucknow :** The training was organised by Rajiv Gandhi Foundation, Raibareilly, Uttar Pradesh with the support of ATRIMED Foundation and technical support of IIHMR, New Delhi from 23rd to 28th June 2009 at Sahbhagi Sikshan Kendra, Lucknow. Ms. Shabana Azami distributed the certificates to 38 participants.
- **Hospital Administration & Quality Management Training in Orissa:** 4 day training of hospital managers at Bhubaneswar, Orissa in collaboration with NHSRC.
- **Circulation of e-newsletters from IIHMR Delhi:** Dr.Sandeep Bhalla , Associate Professor and team of Synapse eNewsletter ensured circulation of IIHMR monthly newsletter to around 7000 health professionals wherein 11 issues have been released till date .
- Health Shield team lead by Mr. Harish Sihare, Assistant Professor have started bringing out newsletter on Health Insurance every month.

1.7 Research Experiences-

The research for two years at International Institute for Health Management Research (IIHMR), New Delhi has voyaged a series of projects, studies and development. The Institute has played a major responsibility in the promulgation of some of the sheer ground reality by undertaking surveys, health data generation to exploratory and impact studies of health services and health care programmes.

The Institute's focus is on health systems and health care research. It conducts and designs policy analysis and review and undertakes intervention research, evaluation studies and operation research studies. We do believe that while academic programme bring visibility, quality research brings credibility to the Institute. The key areas of research mainly include assessment surveys and studies in important health programmes, strengthening management of district health systems; involvement of PRIs and NGOs in reproductive and child health services; and alternative management approaches in implementing population programmes with district as the unit.

There has been an expansion in the nature and scope of projects and research studies. The interpretative research has been stressed upon thus influencing policy making at the state and central government levels. Some of the projects and studies specifically address the health research and population issues that have a direct impingement on clinical, health services research and other related industries. The Institute has also undertaken projects aiming at facilitating health sector reforms, developing implementation processes in decentralized district planning, implementing quality assurance in health care, strengthening information systems, and enhancing community participation. New research dimensions in health financing and human resource development have also been explored.

Therefore, we strongly believe that given the past history and experience of the Institute we are most suitable and capable of undertaking the assignment and the financial proof of the Institution can be judged for your kind perusal.

1.8 A documentation of the process of work, project done & lessons learnt-

During the period of my Internship I was placed with the Research Department on the project **"To Study the Quality of IUCD Services for Promoting the Spacing Between Children in Madhya Pradesh"** .The project was funded by JSK (Jansankhya Sthirita Kosh), MoHFW, Govt. of India. The main aim of this study is to support population stabilization efforts, particularly in the major northern states (Uttar Pradesh, Bihar, Madhya Pradesh and Rajasthan) where the

challenges are high. Madhya Pradesh is one of the state which requires special attention in order to check its fertility trend (3.1 in 2005-06 compared to 3.4 in 1998-99 (NFHS-3)).The Objective of the project was to study the quality of IUCD services so as to promote the spacing between children and to examine and assess retention/ discontinuation rate and various factors responsible for its discontinuation and after analyzing and assessing provides the solution so that its acceptance can be increased. The study was based on some secondary and primary data collection. For primary data collection 3 districts (1 highest, 1 Medium and 1 Lowest IUCD acceptors/ IUCD performance districts) were selected randomly through simple random sampling (SRS) among the districts with 1,000 IUCD acceptors per 10,000 unsterilized couples. The study tools involved data collection, both quantitative and qualitative data. For quantitative, data were taken from secondary and primary study. For primary study, the structured questionnaire (household and individual) was prepared. For qualitative data collection, some Focused Group Discussions (FGDs) and in-depth interviews was conducted among ANMs, health care provider and other stakeholders. After conducting and analyzing the survey we will be able to identify the gaps in implementation of IUCD Services, reasons for the retention and discontinuation of IUCD use, knowledge and practice of other methods rather than IUCD, and document guidelines for Policy Makers/Programme Managers to strengthen IUCD services.

1.9 Responsibilities allotted-

I worked as a Research Associate in this project. We started our work from proposal writing and till date we have completed our field study. During this period I have assigned following task/ responsibilities-

Literature Review: Literature review for this project has be done for proposal writing and to assess and find out the scenario in India & states also.

Questionnaire Design: Both Quantitative and Qualitative Questionnaires has been prepared for primary data collection. Then these questionnaires have been translated in Hindi also.

Recruitment of investigators & supervisors: Telephonic interviews were conducted for the selection of investigators and supervisors required for field study.

Training of investigators & supervisors: W have organized two days trainings for Investigators and Supervisors in Bhopal.

Field study: I have been allotted Datiya district of Madhya Pradesh for field survey. The target sample was 500 Quantitative Questionnaire & 30 Qualitative Questionnaire. Within the district we have selected two blocks randomly and from each block a sample of 250 questionnaires was collected. During field survey, I had to coordinate/ supervise with district, block, Sub Centre (SC) level's health providers and my team.

CHAPTER 1- INTRODUCTION-

1.1 HIV/ AIDS-

"AIDS (Acquired immune deficiency syndrome) is the disease caused by the retrovirus human immunodeficiency virus (HIV) and characterized by profound immune suppression that leads to opportunistic infections, secondary neoplasms and neurologic manifestations."

AIDS have now been reported from more than 193 countries around the world and the pool of HIV infected persons in Africa and Asia is large and expanding. Because of the magnitude of the AIDS problem, there has been an explosion of research aimed at understanding HIV and its remarkable ability to cripple host defenses. [1]

India is one of the largest and most populated countries in the world, with over one billion inhabitants. Of this number, it's estimated that around 2.3 million people are currently living with HIV. HIV emerged later in India than it did in many other countries. Infection rates soared throughout the 1990s, and today the epidemic affects *all* sectors of Indian society, not just the groups – such as sex workers and truck drivers – with which it was originally associated. In a country where poverty, illiteracy and poor health are rife, the spread of HIV presents a daunting challenge. [2]

1.1.1 The Global HIV/ AIDS Timeline History

Table1- History of HIV/ AIDS at a glance

S. No.	Year	Events
1.	Pre 1981	Although HIV/ AIDS epidemic came in picture in 1981 but Scientists believe that HIV was present years before 1981.
2.	1981	First case of HIV/ AIDS was detected officially in US.
3.	1982	First case of HIV was reported in Africa region

4.	1985	First International AIDS Conference held in Atlanta. First case was detected in China. First HIV test licensed by USFDA (US Food & Drug Administration)
5.	1986	First HIV case was detected in Russia & India.
6.	1990	USFDA approved use of zidovudine for pediatric AIDS
7.	1991	Red ribbon was introduced as the symbol of AIDS awareness
8.	1992	AIDS becomes number one cause of death for US middle age group
9.	1995	First guidelines were issued for prevention of Opportunistic Infections (OI) in patients infected with HIV.
10.	1996	USFDA approved 1st non nucleoside reverse transcriptase inhibitor (NNRTI), Nevirapine. USFDA also approved viral load test and HIV urine test.
11.	2000	Global AIDS Programme was formed by US CDC (Centre for Disease Control). HIV/ AIDS became a part of MDG (Millenium Development Goal)
12.	2002	HIV was leading cause of death worldwide, among those aged 15-59.
13.	2005	Ranbaxy became 1st Indian drug manufacturer to gain USFDA approval to produce generic antiretroviral.
14.	2006	US CDC revised HIV testing recommendations.

1.1.2 HIV/ AIDS History in India-

At the beginning of 1986, despite over 20,000 reported AIDS cases worldwide, India had no reported cases of HIV/ AIDS. Later in the year, India's first case of HIV was diagnosed among sex workers in Chennai, Tamil Nadu. It was noted that contact with foreign visitors had played a role in initial infections among sex workers and as HIV screening centres were set up across the country there were calls for visitors to be screened for HIV. Gradually, these calls subsided as more attention was paid to ensuring that HIV screening was carried out in blood banks.[3, 4]

In 1987 a National AIDS Control Programme was launched to co-ordinate national responses. Its activities covered surveillance, blood screening and health education. [5, 6]

Initial cases had occurred mostly through heterosexual sex but at the end of the 1980s a rapid spread of HIV was observed among injecting drug users (IDUs) in Manipur, Mizoram and Nagaland - three north-eastern states of India bordering Myanmar (Burma).[7,8]

At the beginning of the 1990s, as infection rates continued to rise, responses were strengthened. In 1992 the government set up NACO (the National AIDS Control Organisation), to oversee the formulation of policies, prevention work and control programmes relating to HIV and AIDS. In the same year, the government launched a Strategic Plan for HIV prevention. This plan established the administrative and technical basis for programme management and also set up State AIDS bodies in 25 states and 7 union territories. It was able to make a number of important improvements in HIV prevention such as improving blood safety. [9]

By this stage, cases of HIV infection had been reported in every state of the country. Throughout the 1990s, it was clear that although individual states and cities had separate epidemics, HIV had spread to the general population. Increasingly, cases of infection

were observed among people that had previously been seen as *'low-risk'*, such as housewives and richer members of society. **[**10**]**

1.1.3 Epidemiology of HIV/ AIDS-

Epidemiologic studies have found 5 groups of adults at risk for developing AIDS. The case distribution is as follows-

- Homosexual or Bisexual men
- Intravenous Drug Users
- Hemophiliacs (especially those who received large amounts of factor 8^{th} or factor 9^{th})
- Recipients of blood & blood component
- Hetrosexual contacts of members of other high risk groups.

Transmission of HIV/ AIDS occurs under conditions that facilitate exchange of blood or body fluids containin g the virus or virus infected cells. Hence, three major routes of transmission are sexual contact, parenteral inoculation & passage of virus through infected mothers to their new born. [11]

1.1.4 Pathogenesis of HIV infection & AIDS-

While HIV can infect many tissues, there are two major targets of HIV infection: the immune system and the central nervous system.

Profound immunosupression, primarily affecting cell mediated immunity, is the hallmark of AIDS. This results chiefly from infection of and severe loss of CD4+ T cells as well as impairment in the function of surviving helper T cells. Macrophases and dendritic cells are also targets of HIV infection. HIV enters the body through mucosal tissues and blood and first infects T cells as well as dendritic cells and macrophases. The infection becomes established in lymphoid tissues, where the virus may remain latent for long periods.

Active replication is associated with more infection of cells and progression to AIDS. [11]

1.1.5 The global AIDS epidemic-

"The global HIV epidemic continues to remain a serious public health problem. An estimated 33.4million (31.1million–35.8million) people are currently living with HIV. In 2008, an estimated 2.7 million (2.4 million–3.0 million) people were newly infected with HIV. The majority of new infections were in low- and middle-income countries. The global HIV prevalence has remained stable and the number of new HIV infections decreased by approximately 15% from 2001 to 2008. In 2008, an estimated 2 million (1.7 million–2.4 million) people died due to AIDS related illnesses." [12]

Women account for 50% of people living with HIV, although this proportion varies from 27% in the Region of the Americas to 58% in the African Region. An estimated 2.1 million (1.2 million–2.9 million) children under 15 years are currently living with HIV. There were 430 000 (240000–610 000) new infections and 280 000 (150 000– 410 000) AIDS related deaths among children in 2008.[12]

Globally, 0.8% of the adult population is infected with HIV, however, region-wise differentials. The epidemic appears to have stabilized in most WHO regions, except eastern Europe and centralAsia where HIV prevalence remains on the rise. Sub-SaharanAfrica continues to bear the brunt of the global epidemic accounting for two-thirds of all people living with HIV/AIDS and 70% of global AIDS deaths. The epicentre of the global HIV epidemic is in southern Africa, where nine countries have HIV prevalence above 10% and three countries (Swaziland, Botswana, Lesotho) have an adult HIV prevalence above 20%. [12]

Table-2. The latest statistics for the global HIV/AIDS

	Estimate	**Range**
People living with HIV/AIDS in 2008	33.4 million	31.1-35.8 million
Adults living with HIV/AIDS in 2008	31.3 million	29.2-33.7 million
Women living with HIV/AIDS in 2008	15.7 million	14.2-17.2 million
Children living with HIV/AIDS in 2008	2.1 million	1.2-2.9 million
People newly infected with HIV in 2008	2.7 million	2.4-3.0 million
Children newly infected with HIV in 2008	0.43 million	0.24-0.61 million
AIDS deaths in 2008	2.0 million	1.7-2.4 million
Child AIDS deaths in 2008	0.28 million	0.15-0.41 million

(source- published by UNAIDS in November 2009, and refer to the end of 2008)

1.1.6 Current Scenario in India-

In 2006 UNAIDS estimated that there were 5.6 million people living with HIV in India, which indicated that there were more people with HIV in India than in any other country in the world. In 2007, following the first survey of HIV among the general population, UNAIDS and NACO agreed on a new estimate – between 2 million and 3.1 million people living with HIV.

In 2008 the figure was confirmed to be 2.31 million, which equates to a prevalence of 0.3%. While this may seem a low rate, because India's population is so large, it is third in the world in terms of greatest number of people living with HIV. With a population of around a billion, a mere 0.1% increase in HIV prevalence would increase the estimated number of people living with HIV by over half a million.[13]

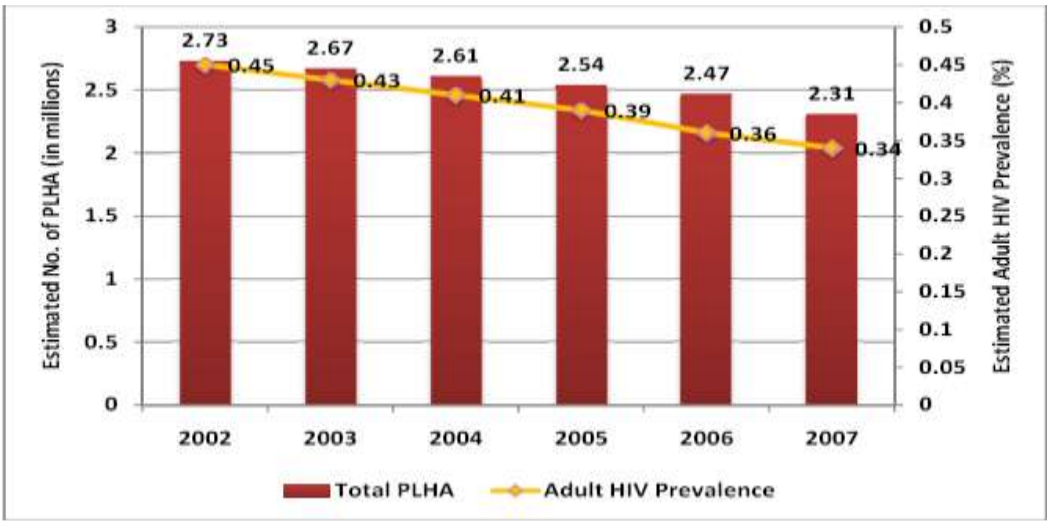


Fig1.- HIV prevalence in India

The national HIV prevalence rose dramatically in the early years of the epidemic, but a study released at the beginning of 2006 suggests that the HIV infection rate has recently fallen in southern India, the region that has been hit hardest by AIDS. In addition, NACO released figures in 2008 suggesting that the number of people living with HIV has declined from 2.73 million in 2002 to 2.31 million 2007.

1.1.7 HIV Prevention-

"Educating people about HIV/AIDS and how it can be prevented is complicated in India, as a number of major languages and hundreds of different dialects are spoken within its population. This means that, although some HIV/AIDS prevention and education can be done at the national level, many of the efforts are best carried out at the state and local level.

The third stage of the National AIDS Control Programme (NACP-III), was launched in July 2007 and runs until 2012. The programme has a budget of around $2.6 billion, two thirds of which is for prevention and one sixth for treatment. Aside from the government, this money will come from non-governmental organisations, companies, and

international agencies, such as the World Bank and the Bill and Melinda Gates Foundation.

The government has announced that prevention campaign will place a strong focus on condom promotion. It has already supported the installation of over 11,000 condom vending machines in colleges, road-side restaurants, stations, gas stations and hospitals. With support from the United States Agency for International Development (USAID), the government has also initiated a campaign called ‘Condom Bindas Bol!’ (Condom-Just say it!), which involves advertising, public events and celebrity endorsements. It aims to break the taboo that currently surrounds condom use in India, and to persuade people that they should not be embarrassed to buy them.

The government has however funded a small number of national campaigns to spread awareness about HIV/AIDS to complement the local level initiatives. On World AIDS Day 2007 India flagged off its largest national campaign to date, in the form of a seven-coach train called the 'Red Ribbon Express.' A year later the train journey was completed, having travelled to 180 stations in 24 states and reaching around 6.2 million people with HIV/AIDS education and awareness.” [14]

1.1.8 Treatment for people living with HIV-

“Antiretroviral drugs (ARVs), which can significantly delay the progression from HIV to AIDS – have been available in developed countries since 1996. Unfortunately, as in many resource-poor areas, access to this treatment is severely limited in India; an estimated 218,000 people were receiving ARVs by the end of March 2009. According to NACO, under India’s Paediatric HIV/AIDS initiative launched in 2006, 14,303 (out of an estimated 70,000) children living with HIV or AIDS received free ART as of March 2009. Some people manage to access the drugs through private health facilities, which dominate India’s healthcare sector, but the vast majority of people cannot afford to buy treatment privately.” [14]

1.1.9 The future of HIV and AIDS in India

Various groups have made predictions about the effect that AIDS will have on India and the rest of Asia in the future, and there has been a lot of dispute about the accuracy of these estimates. For instance, a 2002 report by the CIA's National Intelligence Council predicted 20 million to 25 million AIDS cases in India by 2010 - more than any other country in the world. India's government responded by calling these figures completely inaccurate, and accused those who cited them of spreading panic. The government has also disputed predictions that India's epidemic is on an African trajectory, although it claims to acknowledge the seriousness of the crisis.

Indeed, recent surveys do suggest that national HIV prevalence has probably fallen slightly in recent years. This trend is mainly due to a drop in infections in southern states; in other areas there has been no significant decline.

HIV spending has been steadily increasing in India in recent years. In 2006-2007 $171 million was spent to contain and prevent the growth of HIV, which represented an increase of 28% from the previous year. Currently, India spends about 5% of its health budget on HIV and AIDS. However, the World Bank has warned that India will have to scale up prevention efforts in order to avoid spending more of its health budget in the future. According to the World Bank's report, by 2020 India will have to spend 7% of its health budget on AIDS if the rising tide of the AIDS epidemic in New Delhi, Mumbai, the north and the north east is not halted. This would put further strain on a struggling health sector which, on top of HIV and AIDS, faces a growing multitude of health challenges including malaria, diabetes, heart disease and cancer.

Even if the country's epidemic does not match the severity of those in southern Africa, it is clear that HIV and AIDS will have a devastating effect on the lives of millions of Indians for many years to come. It is essential that effective action is taken to minimise this impact. [15, 16]

1.2 CLINICAL TRIALS-

1.2.1 Defination-

"A systematic study of pharmaceutical products on human subjects – (whether patients or non-patient volunteers) – in order to discover or verify the clinical, pharmacological (including pharmacodynamics / pharmacokinetics), and / or adverse effects, with the object of determining their safety and / or efficacy."[17]

1.2.2 Types of Clinical Trials-

1. **Treatment trials-**

Test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

2. **Prevention trials-**

Prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.

3. **Diagnostic trials-**

These are conducted to find better tests or procedures for diagnosing a particular disease or condition.

4. **Screening trials-**

Test the best way to detect certain diseases or health conditions.

5. **Quality of Life trials (or Supportive Care trials)-**

Explore ways to improve comfort and the quality of life for individuals with a chronic illness.[18]

1.2.3 Phases of Clinical Trials-

1. **Human/Clinical Pharmacology trials (Phase I)**

The objective of phase I of trials is to determine the maximum tolerated dose in humans; pharmacodynamic effect, adverse reactions, if any, with their nature and intensity; and pharmacokinetic behaviour of the drug as far as possible. These studies are often carried out in healthy adult volunteers using clinical, physiological and biochemical observations. At least 2 subjects should be used on each dose.

Phase I trials are usually carried out by investigators trained in clinical pharmacology and having the necessary facilities to closely observe and monitor the subjects. These may be carried out at one or two centres.

2. **Exploratory trials (Phase II)**

In phase II trials a limited number of patients are studied carefully to determine possible therapeutic uses, effective dose range and further evaluation of safety and pharmacokinetics. Normally 10-12 patients should be studied at each dose level. These studies are usually limited to 3-4 centres and carried out by clinicians specialized on the concerned therapeutic areas and having adequate facilities to perform the necessary investigations for efficacy and safety.

3. **Confirmatory trials (Phase III)**

The purpose of these trials is to obtain sufficient evidence about the efficacy and safety of the drug in a larger number of patients, generally in comparison with a standard drug and/or a placebo as appropriate. These trials may be carried out by clinicians in the concerned therapeutic areas, having facilities appropriate to the protocol. If the drug is

already approved/marketed in other countries, phase III data should generally be obtained on at least 100 patients distributed over 3-4 centres primarily to confirm the efficacy and safety of the drug, in Indian patients when used as recommended in the product monograph for the claims made.

Data on ADRs observed during clinical use of the drug should be reported along with a report on its efficacy in the prescribed format. The selection of clinicians for such monitoring and supply of drug to them will need approval of the licensing authority under Rule 21 of the Act.

4. **Phase IV**

Studies performed after marketing of the pharmaceutical product. Trials in phase IV are carried out on the basis of the product characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, assessment of therapeutic value, treatment strategies used and safety profile. Phase IV studies should use the same scientific and ethical standards as applied in pre-marketing studies.

After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc. are normally considered as trials for new pharmaceutical products. [19]

1.2.4 Good Clinical Practices (GCP)

Clinical research is the key to the discovery of latest diagnostic methods and to develop modern drugs for treatment of diseases. Good Clinical Practices (GCP) is an ethical and scientific quality standard for designing, conducting and recording trials that involve the participation of human subjects. Compliance with this standard provides assurance to public that the rights, safety and well being of trial subjects are protected, consistent with

the principles enshrined in the Declaration of Helsinki and ensures that clinical trial data are credible.

1.2.5 Need of GCP-

A need was, however, felt to develop our own Indian Guidelines to ensure uniform quality of clinical research throughout the country and to generate data for registration for new drugs before use in the Indian population. An Expert Committee set up by Central Drugs Standard Control Organisation (CDSCO) in consultation with clinical expert has formulated this GCP guideline for generation of clinical data on drugs.

The Drug Technical Advisory Board (DTAB), the highest technical body under D&C, Act, has endorsed adoption of this GCP guideline for streamlining the clinical studies in India.

Good Clinical Practice is a set of guidelines for biomedical studies which encompasses the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects. The fundamental tenet of GCP is that in research on man, the interest of science and society should never take precedence over considerations related to the well being of the study subject. It aims to ensure that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical substances under investigation are properly documented. The guidelines seek to establish two cardinal principles: protection of the rights of human subjects and authenticity of biomedical data generated.

These guidelines have been evolved with consideration of WHO, ICH, USFDA and European GCP guidelines as well as the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research. They should be followed for carrying out all biomedical research in India at all stages of drug development, whether prior or subsequent to product registration in India. [20]

1.3 HIV/AIDS Research-

The Federal government has supported HIV/AIDS research since the earliest days of the epidemic. Today, Federal funds make up the largest public investment in HIV/AIDS research—totaling $2.8 billion in 2009.

Federal agencies, including the U.S. Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), are leaders in the field of HIV/AIDS research

It has been widely recognized that India offers unique opportunities for conducting clinical trials in view of the large patient pool, well- trained and enthusiastic investigators and premiere medical institutes available in the country along with considerable low per patient trial cost, as compared to developed countries.

India is spending 5% of its health budget on HIV/AIDS. Only 1/3rd of this 5% health budget is spending on HIV/AIDS research & development part. According to a report India have to increase its health spending by 7% by 2020.

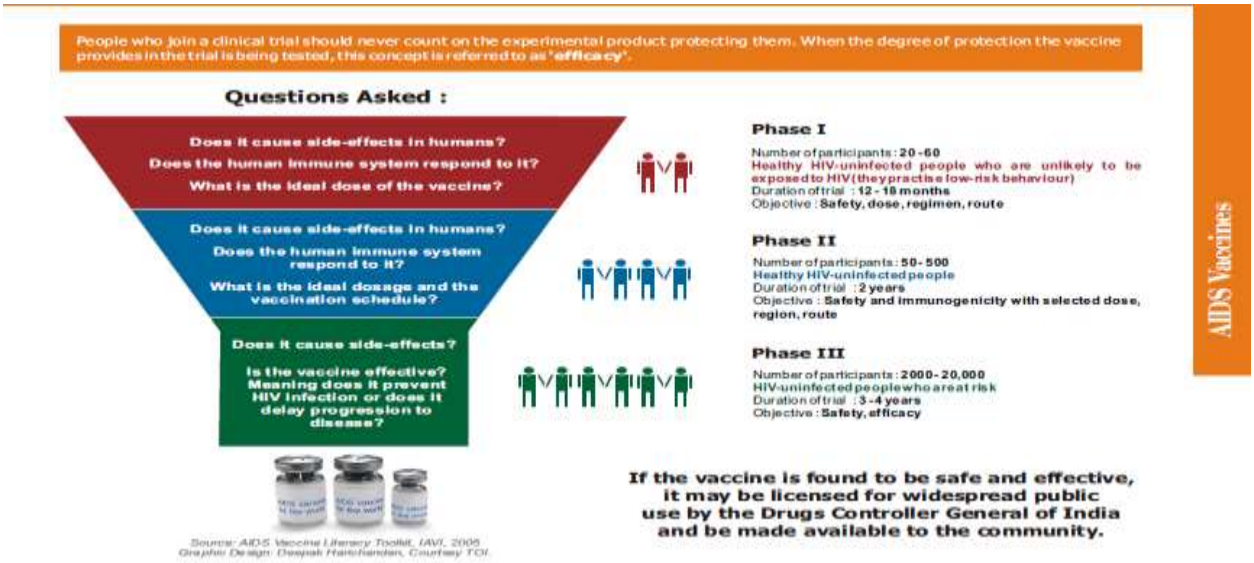


Fig.2- Phases of HIV/ AIDS clinical trials

1.4 Problem Formulation-

Although a lots of research completed and many are still going on for HIV/ AIDS drug trials in India but very few researches are published or registered anywhere. By doing this Systematic analysis we will try to compile all this HIV/ AIDS drug trials. By the end of our report we will also able to delineate different type of HIV/ Drug trials.

1.5 OBJECTIVE-

The main objective of this study is to compile HIV/ AIDS drug trials in India.

The secondary objectives of this study are

- To find out the proportion of drug trials related to HIV in India
- To delineate the different types of trials for HIV drugs in India.

CHAPTER2. METHODOLOGY-

2.1 Design of study- Systematic Review

2.2 Data Source-

We searched the CDSCO (Central Drug Standard Controller of India) and USFDA for collecting the HIV/ AIDS drug list so that we can find drug trials individually for each drug in the list. We have also searched PubMed via the NCBI, INDMED for published drug trials individually for each drug. For ongoing and completed but not published trials we searched www.clinicaltrials.gov of US for drug trials carried out globally and in which India was one of the centre for these multicentric studies and www.ctri.in for drug trials carried out exclusively in India.

2.3 Data Review & Analysis-

Review and Analysis was done under the supervision of two independent investigators. Studies will be grouped under prior category.

Search strategy & terms used to identify studies on HIV/ AIDS Drug Trials-

Pub Med term Search:

1. Drug's name HIV/ AIDS India

Direct Keyword Search:

1. HIV/ AIDS
2. Clinical Trials
3. Good Clinical Practices

Fig.3- Search strategy & terms used to identify studies

Search Results from PubMed-

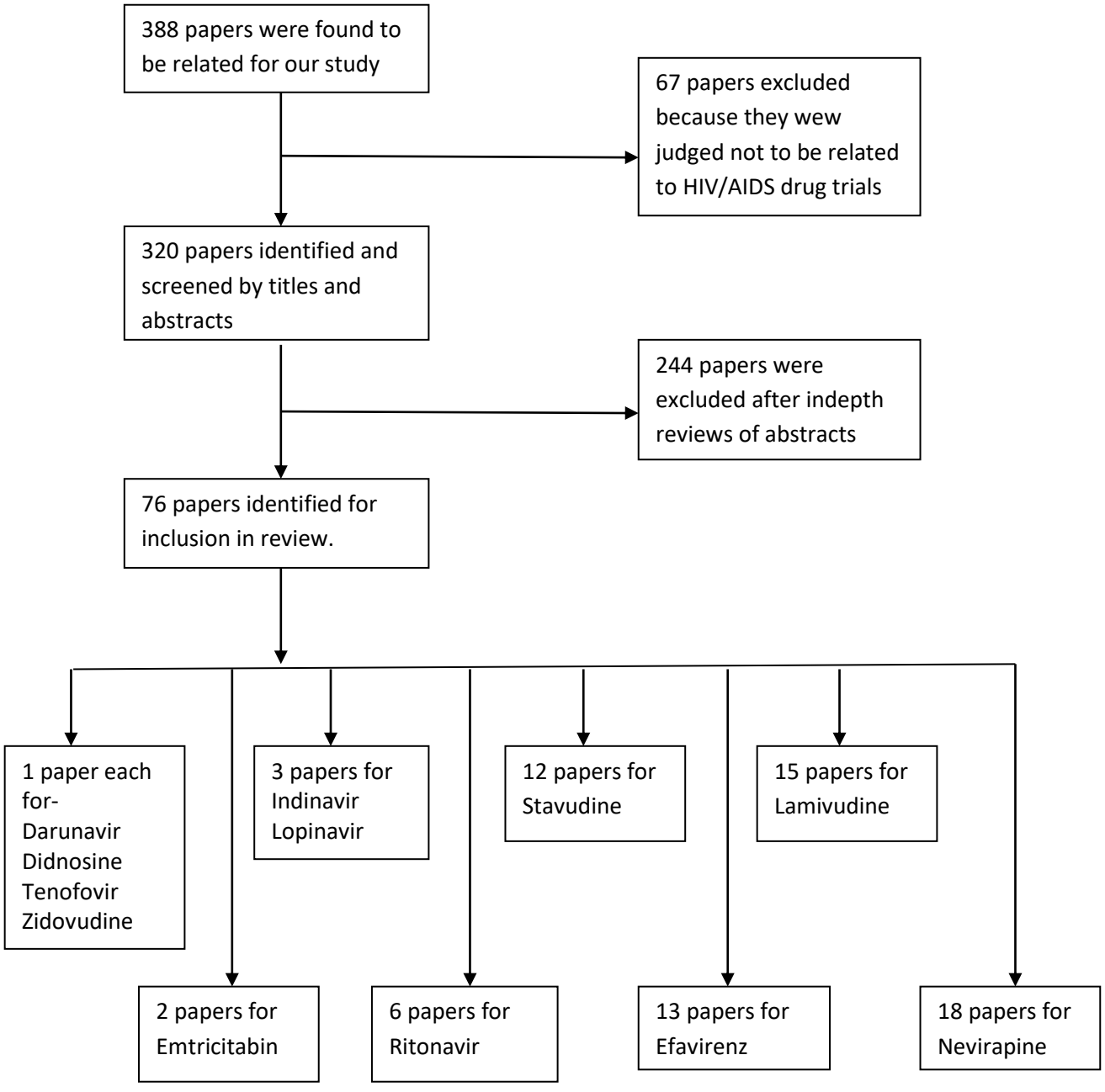


Fig.4- Flow Diagram of Study Steps for pub med search

Search Results from www.clinicaltrials.gov-

Key words for search- Drug name and HIV/AIDS and India

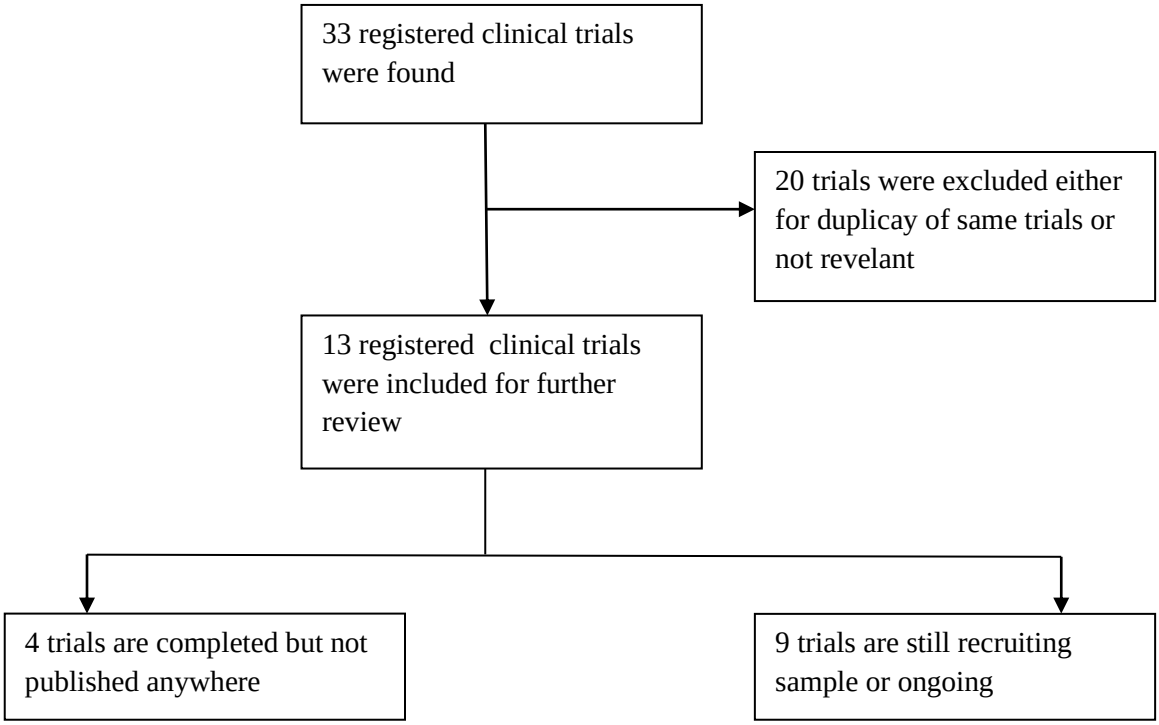


Fig.5- Flow Diagram of Study Steps for www.clinicaltrials.gov search

Search Results from www.ctri.in-

Key words for search- Drug name and HIV/AIDS and India

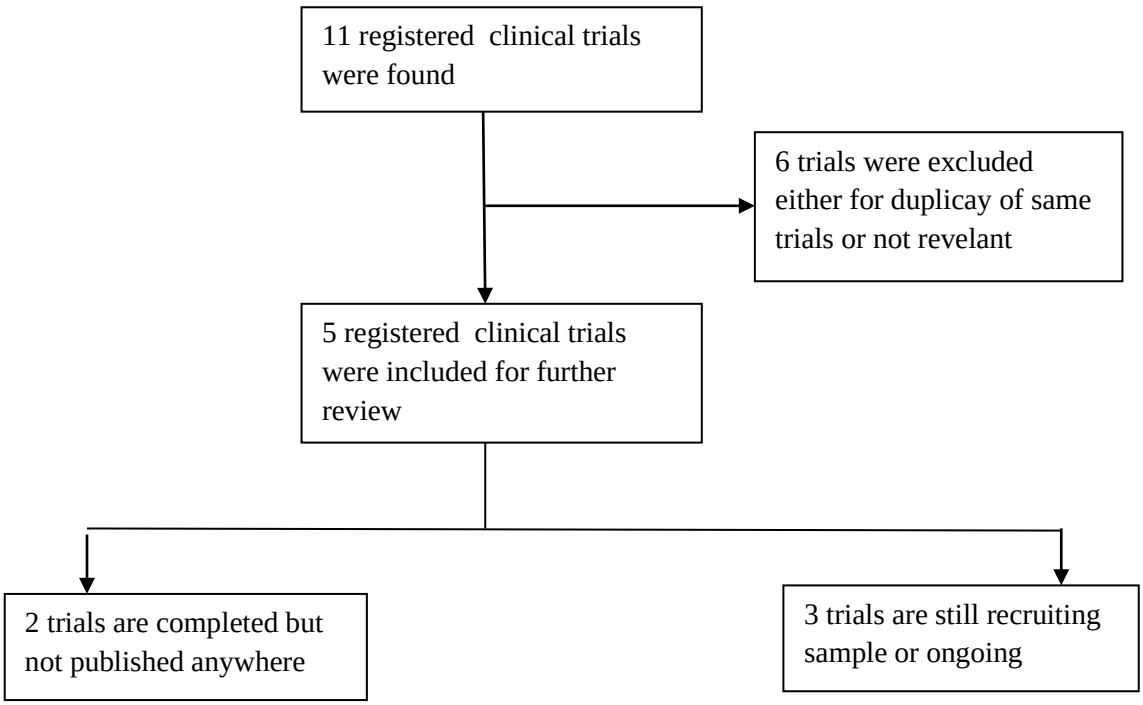


Fig.6- Flow Diagram of Study Steps for www.ctri.in search

CHAPTER3. RESULTS & DISCUSSION-

We identified and screened 388 papers by titles and abstracts for published trials for HIV/ AIDS drug trials. We excluded 67 papers because they were judged not to be related to drug trials. The remaining 321 articles were obtained for detailed assessment; 238 papers were excluded further because the same studies were published in different journals and in few cases same paper was selected by searching for more than one drug, because of combination study drug trials. 76 papers were included in the final analysis. Figure 1 delineates the exclusion process and Table 1 summarizes the studies that were included in the final analysis.

Table3- Categorization of HIV/ AIDS drug trials

Type of Trials	Total included in study
Completed & Published Trials	76
Completed but not Published	6
Ongoing HIV/ AIDS drug trials	12
Total	**94**

We have found 33 HIV/ AIDS drug trials registered at www.clinicaltrials.gov (A service of the US national institute of helath). These were the multicentric HIV/ AIDS drug trials in which India was one of the centres. We excluded 20 trials after screening. The remaining 13 trials were included in the study from which 4 were completed and rest 9 trials are still recruiting/ ongoing trails.

We have found 11 HIV/ AIDS drug trials registered at www.ctri.in (set up by ICMR's National Institute of Medical Statistics). We excluded 6 trials after screening. The remaining 5 trials were included in the study from which 2 were completed and rest 3 trials are still recruiting/ ongoing trails.

CHAPTER4. CONCLUSION-

From the above literature review it has been found out that total 3138 drug trials are registered on clinical trials registry of India from which total HIV/ AIDS drug trials are only 11 and in our study we included only 5. It means India is spending more of its Health Budget sectioned for HIV/ AIDS on prevention part not on Research or development part of new HIV drugs.

4.1 Limitations-

1. Due to time constraint we focused our search only on HIV/ AIDS drug trials. We didn't include vaccine trials in our study.

2. We limited our search only for pubmed and clinical trials registry of US and India. We should also find literature from other sources like Cochrane library, Popline etc.

3. We should also collect literature of unregistered trials, it could be helpful to compare both of these findings.

4.2 Recommendations-

Although it has not been revealed from this study but from inclusive literature review it has been revealed that Government, various policymakers & Drug manufacturer especially those which are involved in HIV/AIDS clinical research need to focus on following recommendations-

1. Government should also focus on HIV/AIDS research along with prevention part.
2. Proper budget should be provided for clinical research of HIV/ AIDS's drugs.
3. Compilation of these type of HIV/AIDS research studies should be done regularly so that proper knowledge/ information should be collected from one authorized source.

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