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INTRODUCTION

A1

Indo-Swiss Symposium on Cohorts and Biobanks with special reference to chronic non-communicable diseases

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An indo-Swiss symposium on cohorts and biobanks with special reference to chronic non-communicable diseases was organized at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandum, India on 27-28 January 2012. The symposium was sponsored by the Department of Science and Technology (DST), Government of India in the frame work of the Indo-Swiss Joint Research Programme (ISSJRP) and organized in association with the Swiss Tropical and Public Health Institute, Basel, Switzerland. The objectives of the symposium were: (1) consider the value and priority of cohorts and bio-banks to explain vulnerability and risk factors, and to guide policy, (2) review Indian and Swiss experience and approaches to establishing and managing various cohorts, (3) clarify cross-cutting implications and prospects for cohort planning in India and Switzerland, and for particular chronic diseases and (4) examine ethical issues to be addressed in design and planning of cohort studies and biobanking.

ORAL PRESENTATIONS

O1

The Indian perspective

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The importance and usefulness of cohorts is evident from various studies involving the Framingham cohort in the United States. More recently a 50 year follow up study of 18 cohorts has announced a 50% risk of death among those with at least two of the risk factors of hypertension, diabetes, dyslipidemia and smoking. Even though such studies are important the Indian experience with cohorts is limited. This may be due to the relatively less importance of community medicine and public health in the medical education curriculum.

Notable among cohort studies in India were the South Indian BCG vaccination trials and a 15 year study in Chennai to test the efficacy of anti-leprosy vaccines. These studies gave us rich experiences in ensuring community participation. There were pockets of resistance as well as cooperation. There is a need to work and live with the community with sympathy and understanding in order to gain their confidence.

The Indian Council for Medical Research (ICMR) has identified Non-Communicable diseases as a priority area for research and interventions in India. Diabetes and pre-diabetes are rampant in India even affecting those in the 20s. Even though activities and programmes based on population based disease surveillance are going on in several states such as Tamil Nadu and Orissa, we still have a long way to go. Once we get proper surveillance data we can go forward. The ethical implications of establishing and managing biobanks have to be carefully thought out in a country like India with its rich, diverse and sensitive cultural heritage. The Department of Science & Technology has identified some priority areas for research and collaboration with developed countries such as Switzerland and include information & communication technology, materials & nanotechnology, human health sciences, sustainable development and renewable energy.

This symposium on cohorts and bio-banks with special reference to non-communicable diseases is part of the broader initiative to promote research and research based initiatives aimed at betterment of the society.

O2

Indo-Swiss partnership experience

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The Indo-Swiss partnership has been based on the principles enunciated by the Swiss Commission for Research Partnership with Developing Countries. It provides support for scientific research projects, exchange of scientists and building partnerships for science.

The 11 Principles of Research Partnership have been elaborated under the following headings:

1. Decide on the objectives together
2. Build up mutual trust
3. Share information; develop networks
4. Share responsibility
5. Create transparency
6. Monitor and evaluate the collaboration
7. Disseminate the results
8. Apply the results
9. Share profits equitably
10. Increase research capacity
11. Build on the achievements

The Swiss Tropical and Public Health (Swiss TPH) aims to improve the health of populations at the national and international levels with an extensive network of activities in Africa, India, and throughout the world. It collaborates and provides scientific support to the INDEPTH network (The International Network for the Demographic Evaluation of Populations and Their Health in Developing Countries), which comprises six sites in Asia, 12 sites in Africa and one site in Oceania. The INDEPTH network is involved in strengthening of Health and Demographic Surveillance Systems (HDSS). The Indo-Swiss symposium on cohorts and bio-banks with special reference to non-communicable diseases aims to consider and develop opportunities for Indo-Swiss partnership in research and to promote country and region-specific public health benefits.

O3 Experiences and prospects for cohorts and biobanks
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There has been a complete turnaround in scientific thinking about malnutrition as a protective factor to that of a major determinant of diabetes. Development of Type 2 diabetes is attributed to a combination of genetic susceptibility and precipitation factors in adult or early adult life. Current trials and preventive interventions are based on this gene-obesity model causing glucose intolerance necessitating food restriction for management. However when we compare the burden of low birth weight and intrauterine growth restriction with that of type 2 diabetes it can be hypothesised that good nutrition during intrauterine development and early childhood is more important. Foetal programming due to under nutrition can result in intergenerational transfer of long latency disorders. This hypothesis led to the establishment of the Pune maternal nutrition study and Pune children study involving cohorts. The Pune children study involving 400 children has completed 21 years of follow up and has shown an inverse relationship between birth weight and risk of diabetes mellitus measured by high glucose and high insulin levels. The maternal nutrition study which started with 2675 pregnant women in six villages has now completed 17 years. Both the mothers and children are being followed with very good follow up rates. The study involved consensus building among village leaders, consultation of experts, focus group discussions and training of local girls as Auxiliary Nurse Midwives (ANMs). The study involves assessment of weight and haemoglobin of young women, nutritional intake during pregnancy, foetal growth monitoring, biochemical assessments, storage of maternal and cord blood samples, detailed anthropology at birth and continuing monitoring for cardiovascular disease risk markers. A steering committee of all stakeholders was constituted to oversee the study. The observations have shown that the intra abdominal fat content of Indian babies is higher. Low vitamin B12 levels, folate levels and high homocysteine levels are shown to be associated with low birth weight and insulin resistance in offspring. This demonstrates that maternal micro nutrient status influences risk of diabetes in the offspring and birth weight is a marker of intrauterine environment. Policy implications include ensuring the health of the young girl and addition of vitamin B12 along with folate for pregnant women. The biochemical estimation was made possible by storage of samples in biobanks which is a most useful resource for subsequent measurements, but there are ethical concerns and issues of subject approval.

O4 Establishing community based cohorts: approaches, methods and challenges
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BMC Proceedings 2013, 7(Suppl 5):O4

India with a population of 1.2 billion is changing rapidly with increasing literacy, declining sex ratio, huge urban growth, high population density and a rising proportion of young people. Some communicable diseases show a declining trend while others show an upward trend. The proportion of deaths and burden of disease due to chronic disease risk factors are on the rise. Resource limited countries like India face several practical problems, the most prominent being the difficulty to convince policy makers that non-communicable diseases are silent killers. The size and diversity of the population necessitates large cohorts resulting in significant cost escalation. In addition infrastructure, manpower and resource limitations preclude the availability of quality data. The operational and management challenges include consistency of data capture across diverse regions, building and sustaining clinical infrastructure, long term data storage and ethical issues. The scientific requirements in undertaking population based cohort studies in India include identification of susceptible individuals, tracking of migrants and qualitative studies to supplement quantitative data. Mechanisms to ensure community participation like need based benefits for the community, proper feedback and networking with non-governmental organizations and private health care providers are also important.

In addition to the information available from routine surveillance, medical records and national programmes, a well planned cohort study can provide incidence rates, predictors of diseases, sub-clinical infections, individual, family and community parameters, in-migration and out-migration, early indications of impending outbreaks, health and treatment seeking behaviour and impact of individual or community level clinical or behavioural interventions. Senior level health managers and experts have identified non-communicable diseases as a public health research priority next only to maternal and child health and it is necessary to initiate population based cohort studies and plan interventions accordingly.

O5 The SAPALDIA cohort: design and results in the field of respiratory and cardio-vascular diseases
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The SAPALDIA (Swiss Study on Air Pollution and Lung Disease in Adults) cohort involving eight geographical areas of Switzerland was initiated in 1991 for studying the effects of air pollution on the respiratory and cardiovascular health in adults. The study was initiated with a cross-sectional interview of 9631 subjects aged 18 to 60 years and more than 90% of them underwent lung function and atopy testing. More than 7000 of the subjects had bronchial reactivity tested by a methacholine challenge. The address histories of the participants were carefully followed up and a follow up assessment was done in 2002 (SAPALDIA 2). A second follow-up was done in 2010-11. In the 2002 follow-up, 8047 (83%) provided health information, 6528 persons underwent physical re-examination, and 6345 provided blood samples to establish an extensive blood, plasma, serum and DNA bank. In addition, 1813 subjects aged 50 or older participated in 24h-ECG Holter monitoring to provide detailed data on parameters of heart rate variability as an early marker of cardiac response to the environment. With the inclusion of cardiovascular endpoints, SAPALDIA is one of the first studies examining effects from long-term exposure to air pollution on cardiovascular health parameters as well as mutual influence between the respiratory and the cardiovascular system. A paper validating the prediction model for individual exposure to PM10 particles was published and another paper published in the New England Journal of Medicine demonstrates that outdoor air pollution is associated with the evolution of individual lung function in adults. The SAPALDIA biobank has allowed scientific publications on the association between gene polymorphisms and the propensity to develop asthma, allergic diseases, or accelerated lung function decline with age. Ongoing studies are focusing on gene-environment interactions a crucial question to understand why some persons suffer more from the effect of air pollution than others.
The recent publications by the SAPALDIA team have addressed the key questions of the project: i) the impact of air pollution on respiratory and cardiovascular health in a longitudinal perspective; ii) the role of genetic factors in modifying health effects from the environment, and iii) the complex interactions between respiratory and cardiovascular health. Further studies and refinements are necessary to address many unresolved issues. These require extensive collaborations, particularly in the fields of exposure assessment and genetic associations.

**06 Setting up the CoLaus study**

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The CoLaus study is a large population based cross sectional study in over 6000 subjects aged 35-75 years living in Lausanne, Switzerland. Its main goals are to obtain information on (1) The prevalence of cardiovascular risk factors and diseases in the population of Lausanne, (2) New biologic and genetic determinants of isolated and clusters of cardiovascular risk factors. Recruitment was done from 2003 to 2006 to obtain a representative sample of subjects. The participation rate was 42%. The participants were extensively phenotyped by administering a questionnaire on personal and family history of cardiovascular risk factors & personal medical history, a basic physical exam for cardiovascular risk factors, mental status examination and biological markers in blood and urine. Plasma, serum, whole blood and urine were stored at -80°C and all Caucasian subjects were genotyped with database in Lausanne. Starting in 2004, over 3600 CoLaus participants underwent an extensive psychiatric phenotyping (PsyCoLaus). This extensive phenotype should allow us to better understand the known association between cardiovascular diseases and mental health. In May 2009 follow-up of the entire CoLaus population was started to prospectively assess the association between cardiovascular diseases, cardiovascular risk factors and mental disorders. Data were collected to know the course of the conditions related to cardiovascular diseases or mental disorders observed at baseline, the incidence of such conditions during the follow-up and the evaluation of candidate variables which could be either mediators of a causal relationship or shared factors underlying the association between mental disorders and cardiovascular diseases.

Several sub-studies were also started like:  
(1) AngioLaus – a case control study in which 500 participants underwent detailed cardiovascular pheno-typing including intima-media thickness in the carotid arteries, pulse-wave velocity, central arterial pressure and endothelial function before and during reactive hyperaemia.  
(2) HERCULES - to study the prevalence of hypertension using 24-hour ambulatory blood pressure measurement, to assess renal function using 24-hour urine collection (creatinine clearance, micro-albuminuria) and to expand understanding of genetic variants associated with hypertension and renal function within the CoLaus study.  
(3) OsteoLaus - to compare risk models to discriminate osteoporotic fractures, to better understand the association of osteoporosis, cardiovascular diseases & mental health and to determine the genetic determinants of osteoporosis.  
(4) HypnoLaus - to determine the prevalence of sleep disorders in the general population, to assess the genetic basis of sleep and its disorders and for better characterization of a potential link between cardiovascular disease risk factors and mental health. Each subject had reversible anonymised unique identification barcode and samples in the bio-bank were identified with barcodes. The data are stored in an Oracle database updated with Epi-data software. A scientific advisory board consisting of external experts evaluated the progression of the project. The participant motivation is being sustained with regular newsletters and interactive website. The project had received funding from GlaxoSmithKline initially and is currently supported by the Swiss National Science Foundation. There have been over 100 publications with more than 3000 citations so far from the project.

**07 Cohorts in chronic disease research: experiences from the PRO-LIFE cohort, Varkala, South India**

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This study demonstrates the setting up of a cohort study in a resource poor setting. The study began as an initial survey in 2001 conducted at Varkala, Kerala by Health Action by People, a non-profit research group. It was a cross sectional study of all households in seven Panchayaths and an urban segment coming under the ICDS (Integrated Child Development Scheme) block. Eventually with multiple funding sources, the study was extended as a cohort study, in the form of a registry for births, deaths and major health events in the community from 2002-2006. The cohort was named PRO-LIFE (Population registry of lifestyle diseases) with the objectives of setting up a community registry for coronary disease, hypertension, stroke, COPD & type 2 diabetes and to initiate community level action for prevention of these diseases. The study was conducted by trained grass root level workers of the ICDS programme and the comprehensive survey included socio-demographic characteristics, food frequency information, detailed lifestyle attributes and information on births and deaths. A cause of death analysis was also conducted during the period 2002-2006 which showed a similarity with USA except neoplasms. However the age standardized death rates were much higher than USA. Other findings include a high suicide rate among the young population, higher prevalence of diabetes in the affluent group and a reduced relative risk for mortality from coronary heart disease in more physically active men and women. The follow up was stopped after 2006 due to lack of funds and unreliable collection of information. It is currently proposed to resurvey the project population including anthropometry and biochemical profile with periodic follow up and fool proof system of reporting births, deaths and major events. The experience showed that full support of the local self government and political units is very important. Existing health workers need to be carefully selected for long term follow up. Discussion points included the reasons for high suicide rate among young females and the social gradient of non-communicable diseases. The high rate of suicide among youngsters may be due to their high aspirations and pressures such as entrance examinations. The higher prevalence of non-communicable diseases in the affluent classes may be due to their lifestyle, however it may change very soon as we move from a situation of food scarcity to plenty of food.

**08 Experience of cohort studies in Trivandrum**

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This is the results of Trivandrum Oral Cancer Screening study (TOCS) initiated in 1996 and the Trivandrum Breast Cancer Screening study (TBCS) initiated in 2006. The objective of TOC study is to evaluate the efficacy of oral cancer screening by visual inspection of the oral cavity in detecting early stages of oral cancer and in reducing mortality. Control and intervention groups have been followed up for over 16 years. Visual screening for oral cancer was found to have acceptable sensitivity and specificity, associated with detection in early stages, associated with 34% reduction in oral cancer mortality, highly cost-effective and can be readily integrated into routine care. The TBCS study had the objective of evaluating the efficacy of breast cancer screening to reduce incidence of advanced breast cancer, increase survival and reduce mortality due to breast cancer. The intervention group received health education, regular clinical breast examination and early access to diagnostic procedures. Early stage cases, node negative cases and those who underwent conservative surgery were more among the intervention group.
Cohorts are an excellent method to study the role of environmental factors in causing chronic diseases, but usually takes decades of data collection. Further studying environmental causes of diseases requires assessment of environmental exposures. However many environmental exposures can be assessed independently from study subjects by retrospective characterization using existing monitoring data and modeling. Therefore it is tempting to add retrospective and prospective environmental exposure assessment to existing cohorts for studying the role of such factors in causation of chronic diseases.

An example of such studies is the ESCAPE (European Study of Air Pollution Effects) which is a large inter-disciplinary collaboration of 25 European partners in 17 countries linking 32 existing cohorts including the SAPALDIA cohort in Switzerland. It aims to characterize long term exposure to traffic related pollution and its association with chronic pathologies with particular reference to pregnancy & birth outcomes, respiratory diseases, cardiovascular diseases and cancer. The work package for respiratory health in adults aims to investigate the effect of ambient air pollution on the level and change of lung function (FVC and FEV1), prevalence and incidence of COPD, prevalence of chronic bronchitis symptoms and incidence of asthma. Such studies using existing cohorts are faster, cheaper and efficient due to availability of long term health information including early life time covariates, socio-economic information, past changes in health and known co-factors. Availability of different phenotypes and biobanks are also advantageous. If environmental monitoring data are available it is easy to link with existing cohort data. However the major disadvantage will be the heterogeneity of study designs with respect to population selection, sampling, age structure etc. Large heterogeneity can occur with the questionnaires used, the health assessment methods, phenotype definitions, biobank markers, and quality of retrospective exposure assessment. Therefore "other-purpose" existing cohorts are complementary but not an alternative to establishing fully standardized cohorts, biobanks and enviro-banks. Large scale new mega cohorts with biobanks and enviro-banks have major scientific advantages that cannot be accomplished with uncoordinated smaller cohorts.
Stigma is less intense, but people reject health workers (other than doctors) as healers. There is also poor follow up and lack of continuity in care from hospital to community. Special programmes included the district-based suicide prevention programme in Thrissur and the Ponnani initiative which included a school mental health programme, old age care, suicide prevention and palliative care. Decentralisation of administration, political will of the local leadership and availability of a committed young psychiatrist in the community were the success formula behind the Ponnani initiative. There is an urgent need to include various aspects of mental health in medical education and to promote research in the area.

**O13**
Evidence based politics: knowing and acting today to shape tomorrow
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BMC Proceedings 2013, 7(Suppl 5):O13

The role of scientific evidence in influencing political decisions that affect the future and the importance of research in generating such evidence is highlighted in the context of the Swiss federation. Within the Swiss federation the responsibilities are balanced between the confederation and the cantons. Currently Switzerland faces several challenges such as epidemiological transition, increase in chronic non-communicable diseases, increasing social costs, increasing health care costs, need for more medical professionals and health inequalities. Therefore we need more scientific knowledge to tackle these problems. Considerable investment in research infrastructure is needed in the form of cohorts and biobanks. Two new federal laws have been enacted which pertain to prevention, health promotion, managed care and disease management. However such laws need scientific support and collaboration across political, economic, academic and social forces.

**O14**
The role of cohort studies for NCD prevention and health promotion – the example of physical activity
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BMC Proceedings 2013, 7(Suppl 5):O14

There has been transition in the profile of health risks from traditional risks such as under nutrition and low sanitation towards modern risks such as obesity and overweight. This has resulted in a high burden of non-communicable diseases such as diabetes, cardiovascular diseases, cancers and chronic respiratory diseases. Cross sectional studies, case-control studies and randomised controlled trials have significant challenges in exposure assessments and studying their long-term effects with respect to non-communicable diseases. Cohort studies are ideal for the study of long term effects on NCD outcomes, to study temporal sequence of exposure and potential outcomes, to study changes in exposure and may allow nested case-control studies with prospective exposure assessment.

Physical activity plays an important role in non-communicable diseases and despite the initial success, more evidence based advocacy is necessary. There are concerns whether the resolutions of the UN NCD summit can be implemented speedly and physical inactivity is not included in the first set of targets currently under discussion for WHO’s monitoring framework. Better methods for quantification of levels of physical activity and assessment of different domains of physical activity are now available and more trans-cultural research in physical activity and health is necessary. Indo-Swiss partnership in this area assumes importance in the above context.

**O15**
Biobanks: understanding chronic diseases in their complexity
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The concept of biobanks can well be explained through the example of SAPALDIA cohort study which involves multicentric collection and central storage of blood, plasma, serum, buffy coat and DNA extracts. Personalized medicine through genomic sequencing and genetic risk profiling is very much a possibility with the publication of genome-wide associations. Even though access to complete genome sequencing is technically feasible the clinical utility and relevance of DNA sequencing is still very poorly understood and it should not be assumed that research will provide answers quickly. Genomics helps in the study of gene-environment interactions thus contribution to insights in genetic epidemiology. But genetic testing can also be a motivating factor for behavioural change.

Limitations in environmental epidemiology of chronic diseases has left several gaps in understanding the causality of risk factors, etiological pathways and shared pathways. The environment and lifestyle varies over time, exposures are difficult to measure and susceptibilities have been ignored in the past. Biobanking and genomic studies are important in understanding the pathways by which risk factors and behaviours result in chronic diseases in a particular environmental context. The exposome concept refers to the exposures of an individual over a lifetime and the relation of these exposures to health. The exposome changes throughout life as our bodies, diets and lifestyles change. Measurement of exposures and their effects are important in describing the exposome and understanding the interaction between environmental exposures and genetic and epigenetic mechanisms. The use of biomarkers to determine exposures, effect of exposures, disease progression and susceptibility factors are common to the “omics” technologies of genomics, transcriptomics, proteomics and metabolomics. A blood or urine sample taken from an individual could provide a snapshot of what that person has been exposed to. The metabolic profile thus potentially reflects the interactions between the exosome and genome with the ability to provide insights into causal pathways of complex, chronic diseases.

Metabonomics refers to the study of metabolic responses to environmental changes, drugs, genetic modifications and it involves measurement of small molecular weight compounds which may act as regulatory signals in the biological system. Examples of metabolomic studies include the INTERMAP study which is a multi-centric investigation into the role of dietary factors in development of hypertension in adults. Study populations differ by ethnicity, diet, diet-related major cardiovascular risk factors and prevalence of hypertension/coronary heart disease/stroke. Another study involving identification of urinary metabolites suggests well differentiated metabolic phenotypes. Most discriminatory metabolites are of dietary origin or gut microbial co-metabolites. Candidate biomarkers emerging from other studies include formate for blood pressure, proline-betaine as a marker for citrus consumption and C-Reactive protein as a marker in the pathway of coronary heart disease. In addition several genetically determined metabolic phenotypes are also being identified. The expected benefits from studying exposomes and biomarkers include decreased exposure misclassification, identification of early disease markers , assigning causality, identification of determinants of susceptibility and the understanding of biological mechanisms. Complex chronic diseases can be studied through biomarkers of susceptibility, exposure and disease. Understanding the differential burden of chronic diseases and risk factors across different ethnic, cultural and geographic settings through biomarkers can improve the causal understanding. Establishing mega cohorts and international cohorts can help better understanding of lifestyle, environment, biomarkers and diseases through proper networking. They provide important policy inputs, maintain and strengthen competitive research, help scientific and technological advancement in addition to funding and job opportunities.

**O16**
Establishing and maintaining biobanks: experience of Rajiv Gandhi Centre for Biotechnology, (RGCB) Trivandrum
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A biobank is a depository for biomaterials from a representative portion of a human population and acts as a vault with intricate detailed information pertaining to the individuals from whom biological materials have been
collected. Biobanks can be classified into population biobanks, biobanks for molecular epidemiology and biobanks for disease biology. RGCBB has been involved in biobanking with respect to three large studies in India namely (i) Molecular Epidemiology of HPV in India, (ii) A Randomized 2 versus 3 dose HPV Vaccination Clinical trial and (iii) HPV AHEAD- Role of Human Papilloma Virus Infection and other co-factors in the aetiology of Head & Neck Cancer.

A cervical cytology biobank has been established at the centre which is an almost inexhaustible resource for fundamental and applied biological research. It helps to understand the natural history of HPV infection and HPV induced lesions and cancers, screening effectiveness, exploration of new biomarkers, surveillance of the short- and long-term effects of the introduction of HPV vaccination. However legal and ethical principles concerning personal integrity and data safety must be respected strictly and biobank based studies require approval of ethical review boards.

The HPV vaccination study involves 10 different sites & different collaborating institutes across the country and all samples are shipped to RGCB, Trivandrum, which acts as a Central storage facility/ biobank. Sample shipment was an important procedure involving communication between base laboratory and biobank, import of registration database, strict temperature control, tracking of shipment and ready storage freezers on arrival. The sample verification process involves a temperature logger, freeze control tubes and bar code verification. The amount of clinical data linked to the samples determines the availability and biological value of the sample. Thus acquiring the background information of each sample and cataloguing the available information systematically and meticulously is a must.

The major problems faced in the management of cervical cytology biobanks have been reclassification of smears before entry into database, failure of temperature logger, bar codes slipping off and maintaining uninterrupted power supply.

Publicly funded biobanks aim to promote the development of new knowledge by giving the research community access to data and samples. The most efficient way to acquire these benefits is to first maximize the use of biobanks in research and, second, to maximize the dissemination of knowledge developed by the research projects that used the biobanks. However there are issues with regard to the use of such stored materials especially when the demand occurs from the private sector. The decision is finally made by a scientific management committee consisting of members of World Health Organization (WHO) and the international agency for research on cancer (IARC).

### O19

**Mental health: an Indian perspective**

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In the Indian scenario, research in mental health is notably deficient, but available clinical and epidemiological data suggest a significant co-morbidity between mental diseases and cardiovascular diseases. Mental health problems do not have the precision of other biological sciences due to the complex phenotypes. In India the effects of culture and the transition in symptomatology of psychiatric patients are also important. Equally important are the family influences, traditional Indian herbal ethnomedicine and the community care perspective. The Indian systems of medicine give a lot of attention to visceral functioning and psychiatric research look into the metabolic substrate.

### O20

**Mental illness: a political perspective**

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**BMC Proceedings** 2013, 7(Suppl 5):O20

I Cassis, a member of the Swiss National council presented the political perspective regarding mental illnesses. What is the role of drug companies and new definitions in creating a scenario wherein majority of the population are mentally ill? We do not know for sure and whether epidemiology can help in the matter. The responsibility of providing solutions is another vague area. We are not sure whether we improved with the current strategy. These may be the result of a lack of clear institutional framework, lack of financial need assessment and a lack of a common culture in mental health.
The codes and practices of professional morality had been enunciated centuries ago in the traditional Indian systems of medicine. The modern code of medical and research ethics has its origin in the Nuremberg Code, Universal Declaration of Human Rights, Code of Medical Ethics by Medical Council of India, World Health Assembly Helsinki Declaration, Belmont report and the Revised Council for International Organizations of Medical Sciences (CIOMS) guidelines. The revised Indian Council of Medical Research (ICMR) guidelines have been adopted in 2006. The ethical principles of autonomy, justice, non-maleficence and beneficence are applicable to any research undertaken. Careful attention has to be given to the processes of taking consent, consent from minors, re-consent, community engagement, risk-benefit assessment, interventions, data management and follow up. Special concerns for cohorts include the difficulty in conveying results due to the absence of immediate benefits and unpredictable susceptibility due to genetic variations. There are issues of confidentiality and stigmatization due to the allotment of unique identification. There is a need for translational research in cohort studies to understand the priorities, validity and applicability in different cultural settings and the role of community based participatory research. There are concerns in research methodology due to shifting from acute paradigm to chronic paradigm, involvement of special population groups.

Bio-banks have advantages such as advancement of scientific knowledge, present and future medical benefits for the individual, improved pharmacogenomic understanding and commercial benefits through patents. The major ethical concerns revolve around collection, storage and management of samples. Human dignity, right to share benefits, assent from minors, re-consent, community engagement, risk-benefit assessment, interventions, data management and follow up. Special concerns for cohorts include the difficulty in conveying results due to the absence of immediate benefits and unpredictable susceptibility due to genetic variations. There are issues of confidentiality and stigmatization due to the allotment of unique identification. There is a need for translational research in cohort studies to understand the priorities, validity and applicability in different cultural settings and the role of community based participatory research.

The ICMR has issued guidelines for DNA banking in 2006 for primary and secondary use of samples. A draft DNA Profiling Bill, 2007 is under the consideration of the Indian Parliament which looks to legalize the collection and analysis of DNA samples and to create a balance between the constitutional rights of an individual and the public interest along with accountability and transparency in the practice of DNA collection and testing. It will be essential to establish standards for laboratories, staff qualifications, training, proficiency testing, collection of body substances, custody trail from collection to reporting and a data Bank with policies of use and access to information therein, its retention and deletion. Thus genetic technology faces ethical challenges in the clinical, social, economic, scientific, legal and political domains.