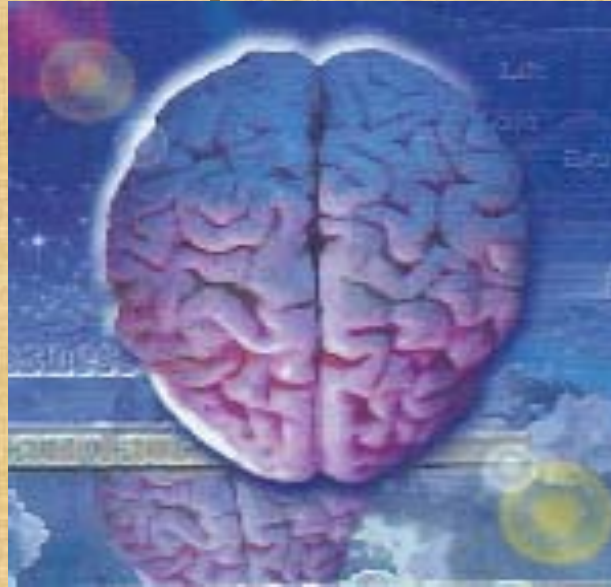


Transformation of the Laboratory Science Emergence of the Discipline of Laboratory Medicine



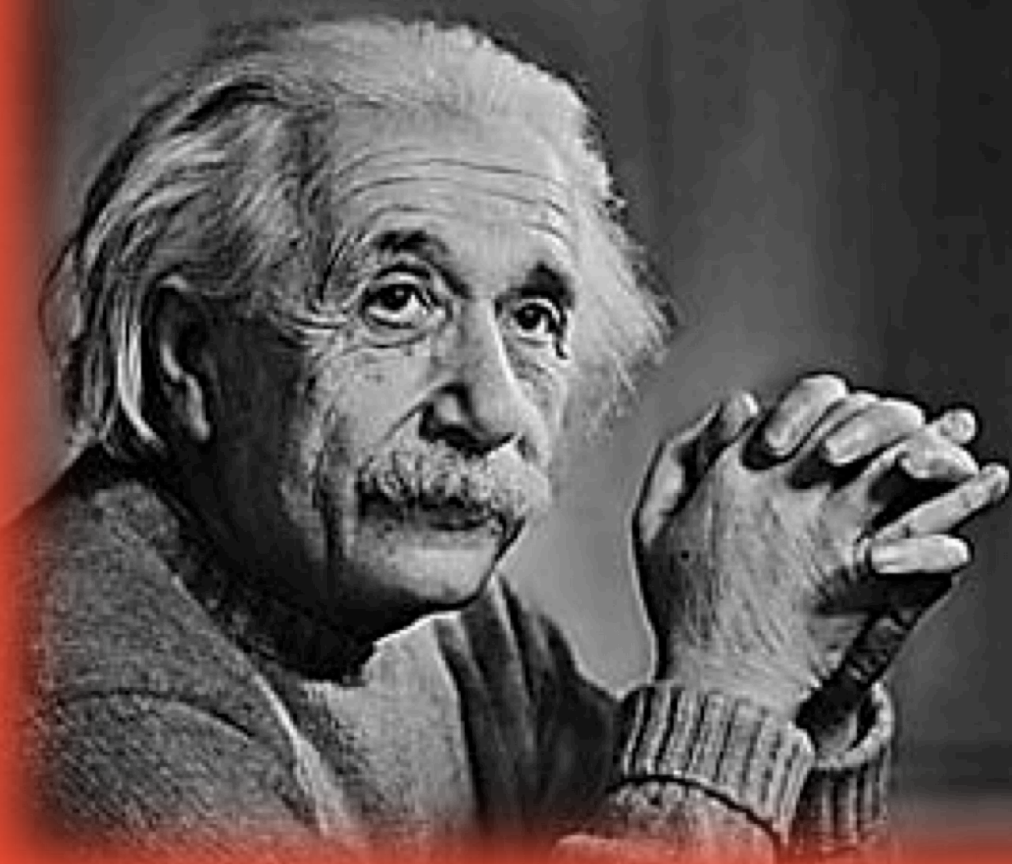
**Third National Conference,
Society of Clinical Pathologists, Dhaka, Bangladesh
17th December, 2016**



**Dr. A. K. Mukhopadhyay, MD.
All India Institute of Medical Sciences, New Delhi**

If you can't explain it **simply**, you
don't understand it well enough.

– Albert Einstein



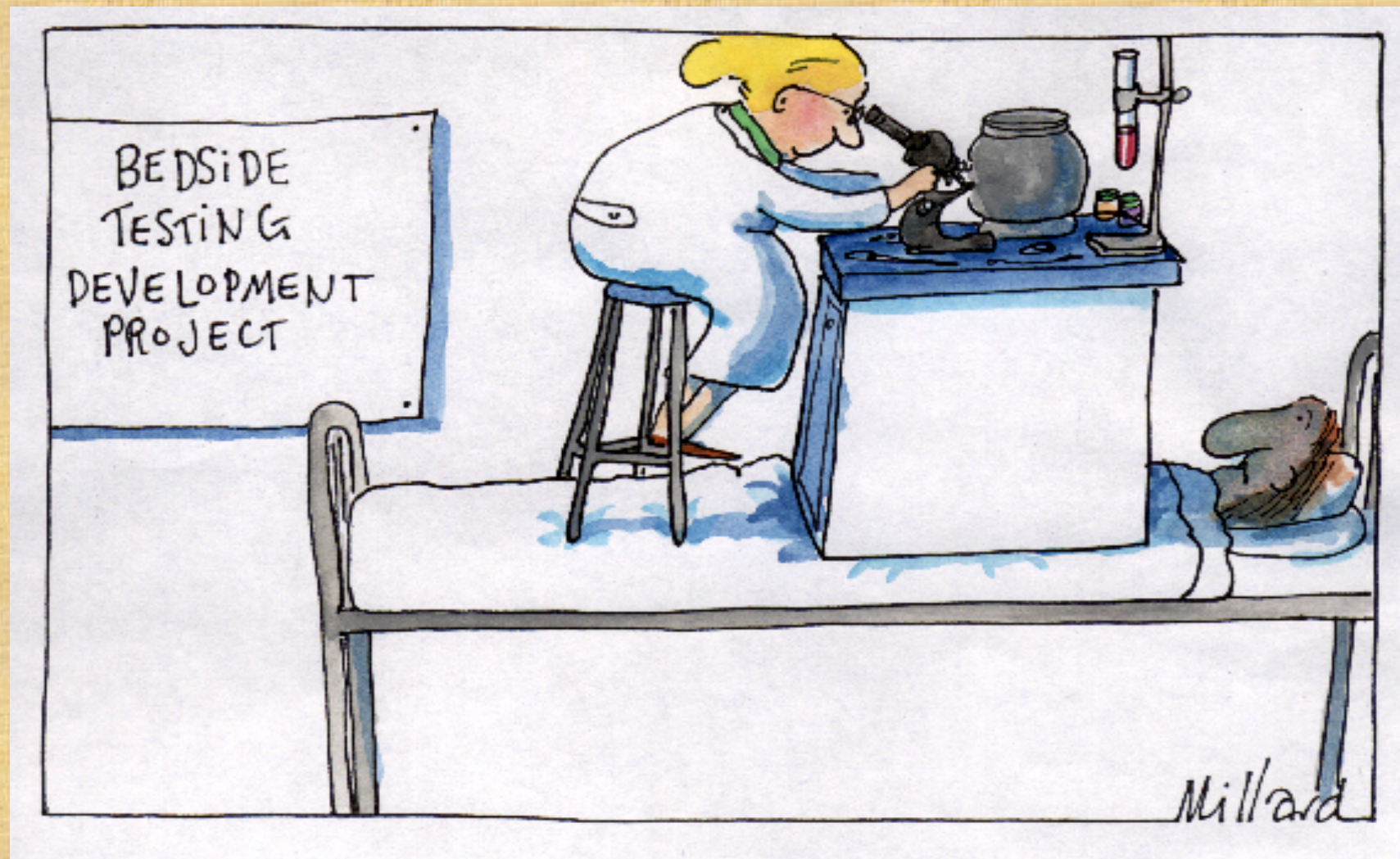
www.hellomasti.com

A healthy Hospital

begins with a

healthier laboratory





It started about 800-1000 years ago

Clinical Pathology

Pathology had been the 'generic' name for any Diagnostic

Clinical Microscopy

Hematology

Chemical Pathology

Microbial Pathology



EVIDENCED-BASED MEDICINE

Diploma in Clinical Pathology (DCP)

Disintegration(?) of 'Pathology'

Information Overload

Pathology

Microbiology

Cl. Biochemistry

Virology

Parasitology

Mycology

Infectious Disease

Surgical
Pathology

Hematology

Transfusion Medicine

Autopsy
Pathology

Cytology

Struggling to "integrate" Laboratory Medicine

ACBICON-2014

Much water has flown down the River



- 1. Shift of Laboratory investigations from Research Lab to Diagnostic lab. Thanks to the contribution of scientists. Information overload**
- 2. Automation**
 - Pre-Phlebotomy**
 - Post-phlebotomy**
 - Pre analytical**
 - Analytical**
 - Post analytical**
- 3. Specific measures on Quality Assurance**
- 4. LIS & HIS**

Emergence of new disciplines

1. Molecular Biology

2. Immunology

3. Biotechnology

4. Transplantation Biology

'Diploma' course is not sufficient enough.

Also, 'diploma' holder cannot compete with Degree holder like MD in Pathology/Biochemistry/Microbiology

What is the way forward?

ORGANISATIONAL REFORM

ACADEMIC REFORM

Any discipline in Medical Science has three components

I. Service to Patients

II. Service to Students: Education,
Creation of Human Resource for the Nation,
Capacity building

III. Service to Science: Research

I. Service towards Patients

Current Status

- Multiple windows

Different Times & Location for

Sample collection

Report retrieval

- Chance of report getting lost
- Patient's discomfort; Long queue in multiple locations and on multiple times

Mushrooming of Laboratories

- I. Govt. Institutions and Medical Colleges
Teaching Hospitals
- II. Govt. Non-teaching Hospitals
Railway Hospital, City Hospital, Distt. Hospital,
Sub-divisional Hospital, CGHS lab, Army Hospital
- III. Private Referral/Non referral Hospitals
- IV. Hub & Spoke Network Hospitals
- V. Private Hospital Laboratories with Teaching Facility
- VI. Hub & Spoke Network Lab
- VII. Private Public Partnership Lab

MIND-SET SOLUTION

Outsourcing

Outsourcing:

1. Whether done in-house, or outsourced, like any part of the Medical service, the laboratory service is expected to generate report of a **defined quality** to save life of millions of suffering patients.
2. A part of medical service, in this context laboratory investigations, is often outsourced because the said organization lacks **minimum essential infrastructure and qualified human resource** to generate trustable reports for management of ailing patients.
3. Even the organization to which the service is outsourced, certainly merits to have the essential minimum infrastructure and **academically qualified human resource, here a laboratory physician**, for a quality and trustable outcome.
4. **Medical Council of the country** is the highest regulatory body to ensure quality health care, here laboratory services, in terms of **minimum essential infrastructure, qualified teacher and academically qualified health personnel**.

Scenario I

No Central Laboratory in the Hospital

Scenario II

Central Laboratory in the Hospital

24x7 hour service

Looked after by respective consultant, three faculty on Duty

?Centralized Sample collection Center

Multiple windows for patients, both for sample collection and report

Delivery

Reform the Service towards Patients

**Bring all laboratories under one roof.
If,
not under one Head.**

**Emergence of “Central
Laboratory” Concept**



Collection centre



One-Lab Concept:

There has been evolving an “One-Lab Concept” with pre-analytical automation and several automated analyzers connected in series and in parallel including knowledge-partnership with manufacturer.





POCT

- 1. Q.A. is responsibility of Laboratory Medicine
NABL guidelines**
- 2. Not for diagnosis
But for monitoring at local level**
- 3. How does one integrate POCT with lab report within LIS?**
- 4. Not to be encouraged in Hospital but may be used for home-
monitoring, Monitoring in the field**

Certain Equipments have dissolved the division of Laboratory:

(i) Chemiluminiscence Analyzer: One can do serum chemistry, as well as viral makers and hormones, also Vit. B₁₂ and Folate for Hematology



(ii) Flowcytometer: Used for hematological, microbiological and biochemical (molecular) diagnosis.



(iii) Gene-Sequencer and Micro-array technology: Required as common instrument for all four sub-disciplines.



II. Service towards Students

Education

Human Resource Development

Capacity Building

The Current Status

The Disciplines related to Medical laboratory

Department of Pathology, Dept. of Biochemistry, Dept. of Microbiology.

No specialty exclusively for Mol. Biology or Immunology, Oncology, taught with Pathology, Microbiology, Biochemistry.

Hematology in some places has come out separately as a Department, combining clinical (Patients management) aspects too

Transfusion Medicine, in many places comes under pathology. In some places this has become a separate department.

Present Educational Scenario

- No undergraduate sensitization on how laboratory works!
- MD Degree
 - Pathology
 - Microbiology
 - Biochemistry
 - Transfusion Medicine

Diploma / degree in

Transfusion Medicine

Clinical Pathology

New Post Graduate Courses:

DM in Hematology

DM in Histopathology

DM in Neuropathology

DM in Infectious Disease

Alternative Scenario

Certified fellowship course

in Laboratory Medicine

**following MD Pathology/ Microbiology /
Biochemistry**

(Recognized by National Board of Examination)

RESULT

INCOMPLETE LABORATORY PHYSICIAN

The Vision

As in the discipline of Medicine, three year residency leading to MD degree in general Medicine has become a *basic postgraduate degree* followed by super specialty three year residency leading to *DM degree* in Cardiology, Neurology, Nephrology, Gastroenterology, Geriatric, Pulmonary Medicine etc., as in the discipline of Surgery, three yr. residency leading to a *basic postgraduate degree* MS, followed by super specialty three year residency leading to M.Ch. Degree in Pediatric Surgery, Neurosurgery, Cardiac surgery, Uro surgery, GI Surgery etc., so also in *laboratory Medicine three year residency leading to MD degree is envisaged to be the basic postgraduate degree in Laboratory discipline followed by three year residency leading to DM degree in Hematology, Transfusion Medicine, Virology, Histopathology etc.*

**Is Discipline of Laboratory Medicine
a Threat
to
Any of the Lab-related existing discipline like
Pathology, Microbiology and Biochemistry?**

No! Never! Can't be thought of!

It is an Alternative option for the students

It is to produce Human Resource, a Laboratory Physician,
who can take care of a multidisciplinary Central Diagnostic Laboratory

What is the issue?

1. Overlapping and Gaps!

2. Every discipline has its own specifics

Overlapping and Gaps

Overlapping of the syllabus always exist in the disciplines of Medicine. However, the gaps in the syllabus of old disciplines are taken care of by emerging new discipline

Example:

The Discipline of PMR has emerged as felt need out of Orthopedics, Neurology and Rheumatology and that too on the top of existing Physiotherapy

Dept. Specifics

1. Pathology, Microbiology and Biochemistry have specific role in teaching undergraduates and concept building in the respective areas. They have their specific and core service area too. They have their respective MD degree.

2. Further, the disciplines of Pathology, Microbiology and Biochemistry have expanded enormously to have DM course in their own subject as super-specialties.

One More option for the Students

Mono-disciplinary Courses

Multi-disciplinary Course

New Opening for Teachers in Mono-disciplines

Pathologists who do not find Histopathology interesting

Biochemistry MD, who is far more inclined to Clinical Biochemistry

Microbiology MD, who likes to be a holistic laboratorian

May join and contribute as the Faculty of Laboratory Medicine

Medicine/
Pediatrics and its
super specialty

Surgery
Its super
specialty

Gynae & Obs.
Its
superspecialty

ENT

Ophthalmology

Laboratory Physician

Consultant of Consultants
Doctor of Doctors

Medical Detective

Add 'quality' by practice of
evidence-based Medicine

Science of Medicine

Mono-disciplinary MDs
Poly disciplinary MDs
(Holistic report interpretation)

Specifics of Laboratory Medicine

1. One window solution for patients.
2. Central Lab concept in several Medical Colleges and Hospitals.
One-Lab concept for multidisciplinary lab investigations
One-Equipment Concept: Several Equipments (Flow cytometer, Thermo cycler, Chemiluminescence analyzer) have dissolved the boundary between Pathology, Microbiology and Biochemistry
3. All-rounder Laboratory Physician is required to supervise, guide and instruct all-rounder Laboratory Technicians
4. In summary, Manpower economy, Space economy, Time economy, Equipment economy, Knowledge economy and Budget economy, all in real time, are in favor of the discipline of Laboratory Medicine.

Case Study I

A patient is brought to casualty with high fever and hemorrhage (DIC). It requires PS examination for leukemia, coagulation study, hematocrit, blood culture, Dengue antibody/Ag testing, PS examination for MP.

Do you want Consultant, one each from Pathology, Microbiology Hematology or, A Laboratory Physician, who can deliver the confirmed report within an hour?

Case Study II

A patient has been brought to emergency with passage of red colored urine

Is it hematuria or hemoglobinuria? Is it hemoglobin or myoglobin? What is PS picture?

Do you want Consultant, one each from Pathology, Biochemistry, Microbiology and Hematology or, A Laboratory Physician, who can deliver the confirmed report within an hour?

Case Study III

A patient of Hepatitis reports for lab investigations. He requires (i) Serum enzymes (ii) Prothrombin Time and (iii) Viral markers.

Where will the clinician send the patient? Send it to Pathology – they will ask for liver biopsy. Main Microbiology department is UNLIKELY to be concerned with viral markers of Hepatitis. Hematology Dept. will say it is not a primary hematological disorder!

Do you want Consultant, one each from Pathology, Biochemistry, Microbiology Hematology or, A Laboratory Physician, who can deliver the confirmed report within a few hours?

Case Study IV

A patient presented in ENT or dental OPD with gingival swelling. Routine blood sent to **Lab Medicine** shows Monocytic leukemia. Hematology Dept. of AIIMS usually does not entertain such blood examination since it is a requisition of *a routine* hemogram from a *routine* OPD. About 800-1000 such routine hemograms from all departments are sent to Dept. of Lab Medicine.

A patient reports to **GI OPD** with hepatosplenomegaly. **Routine** blood smear sent, shows picture of CML. Special Hematology Dept. does not accept routine blood smear! Following diagnosis of CML in the Dept. of Laboratory Medicine, the patient goes to Hematology Dept. for follow up!

Case Study V

CSF has been sent to Emergency Lab. Technician calls on the doctor to report, “Sir, under microscope there are some round structures which look like lymphocytes but their size is larger than that of lymphocyte”. Senior resident rushes in, and finds that these are fungi, called *cryptococcus*. He makes an *India ink preparation* and confirms the diagnosis.



By this time, sugar and protein of CSF has already been done by biochemistry Laboratory.

For such cases the Hospital requires in One person, a clinical pathologist, a microbiologist and a biochemist, which is available only in the discipline of Laboratory Medicine

Elaboration on Knowledge Economy

Laboratory Physicians have three roles

1. Test Selection
2. Test Operation
3. Test interpretation

How can one interpret the Laboratory Reports unless one knows all sub-disciplines of Laboratory Medicine?

Diagnosis of a Disease has two Complementary Facets before the Final Call

1. Clinical Diagnosis
2. Laboratory Diagnosis

Laboratory Diagnosis can be made by an all-rounder Laboratory Physician

WHAT SHALL I ASK...? FREQUENTLY ASKED CLINICAL QUESTIONS

- × What test should be used to...
- × Should this test be used to...
- × Which one of these alternative index tests should be used to...
 - + screen for,
 - + diagnose,
 - + differential diagnose,
 - + stage,
 - + monitor,
 - + prognose,
 - + assess the risk of
 - + this target condition?



Laboratory-Clinician Interaction:

Meet the Clinician: The residents and Faculty of Lab Med meet the Clinical counterparts

Residents of Lab Medicine participating in rounds of clinicians

Clinician-Laboratory Interaction:

Clinical Residents posted in Laboratory Medicine

Laboratory-oriented Thesis work

To Emerge Laboratory Medicine as Ground Discipline

Three Steps:

- 1. Developing a Central Laboratory with 24-hour service**
- 2. Establishing a Department with its own Faculty**
- 3. Developing a postgraduate course, Residency program leading to M.D. degree**

Laboratory Medicine as a Generic name

Laboratory Medicine as an Umbrella Discipline which overarches all disciplines related to laboratory investigations including Anatomic Pathology, Microbiology and Clinical Biochemistry.

III. SERVICE TO SCIENCE

RESEARCH

- Most of the Research Publications in Medicine requires laboratory Investigations. Laboratory produces Evidence.
- Many Papers are published without authorship from laboratory, even without acknowledgement to laboratory physician. Many journals ask for authorship from laboratory.

The Current Status

1. State Medical Colleges

2. Institutions like, AIIMS, PGI, JIPMER

3. Public health Foundations

3. NGOs

Research: Present Scenario

No sensitization on the subjects like,

Clinical Epidemiology

Research Methodology

Funding Agency

Most of the funds go to Apex Institutes

Every important faculty in the Apex Institute has

Research Project with intramural and extramural funds

Research laboratory

Research equipments

Research scholars

Technical staff

Outcome:

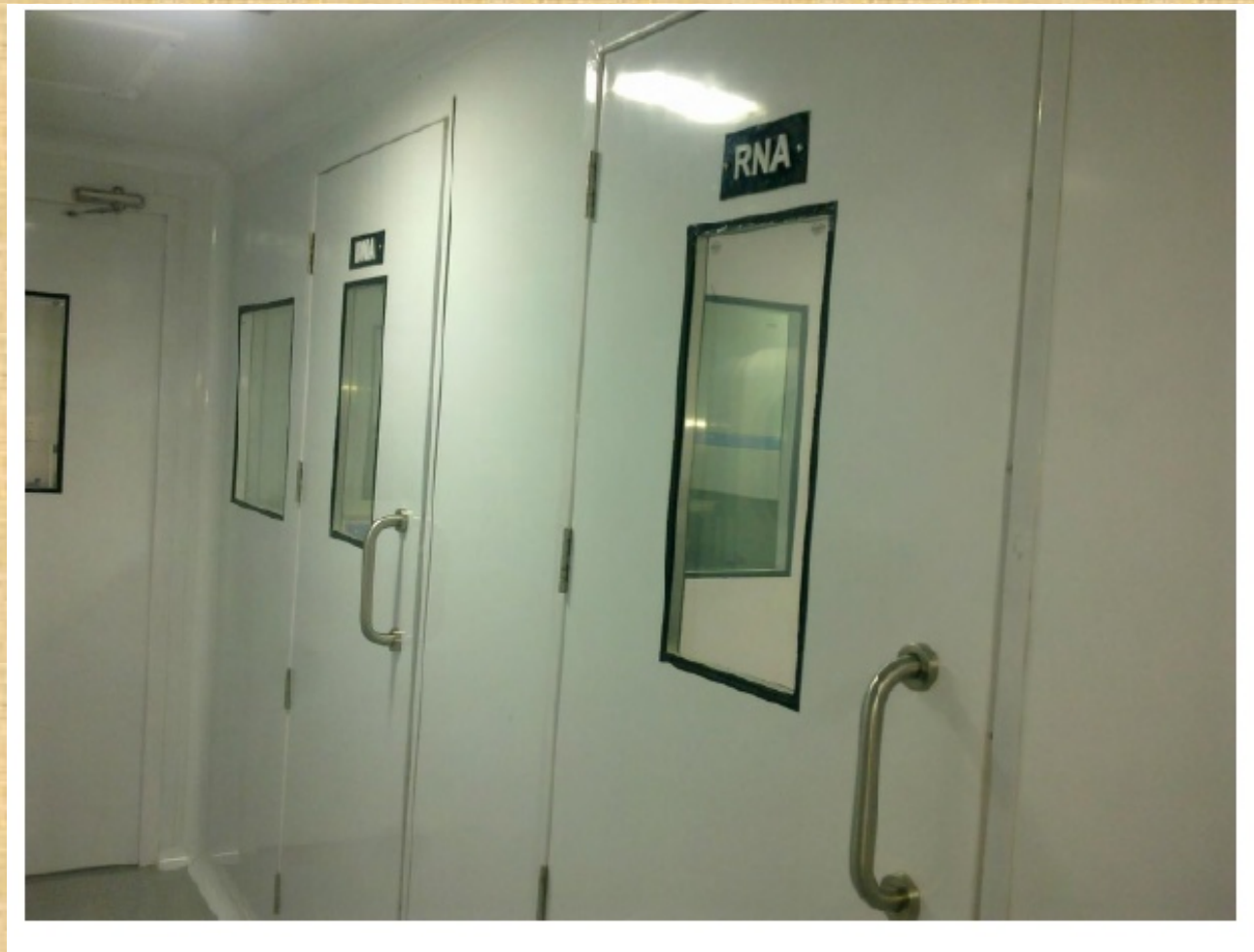
- * It has become a Private enterprise
- * Duplication of Equipments in the same Institute, same Department
- * Waste of Tax-payer's Money
- * Heterogeneous standards
- * Discontinuity of Research following cessation of the Projects

What is the Solution?

- Common Research Facility Laboratory
(Tier III of laboratory discipline)
- Scientist cadre (with PhD degree in Laboratory Disciplines)
- Research Faculty (with PhD degree in Laboratory Disciplines)

GENOMIC LABORATORY

DNA & RNA ROOM



AMPLIFICATION & DETECTION ROOM



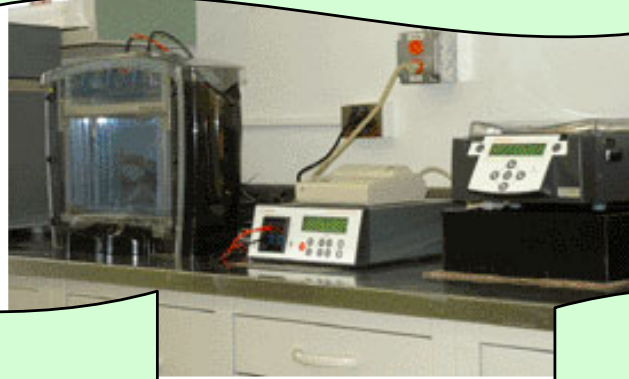
NGS (3rd Gen) DNA Sequencer Lab



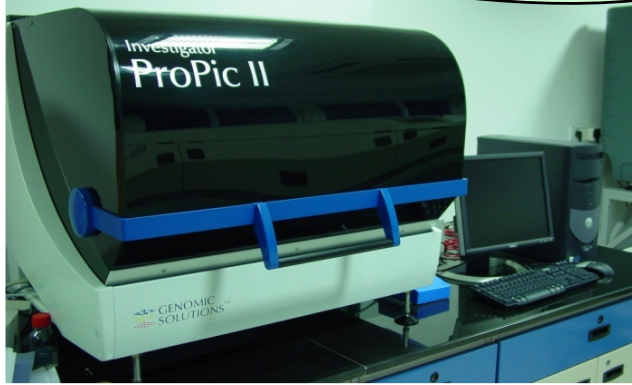
TRANSCRIPTOME & CYTOGENETIC LAB



2D Gel Electrophoresis



Spot Picker

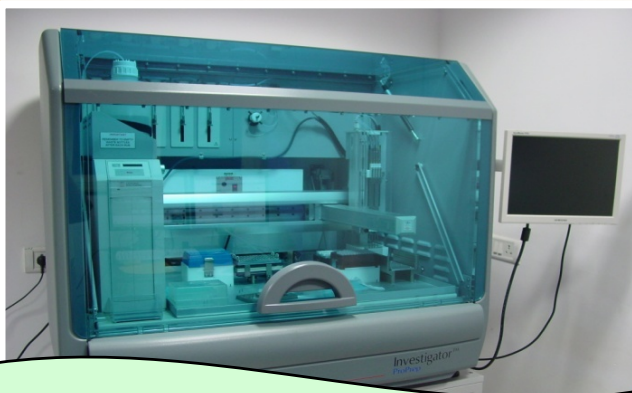


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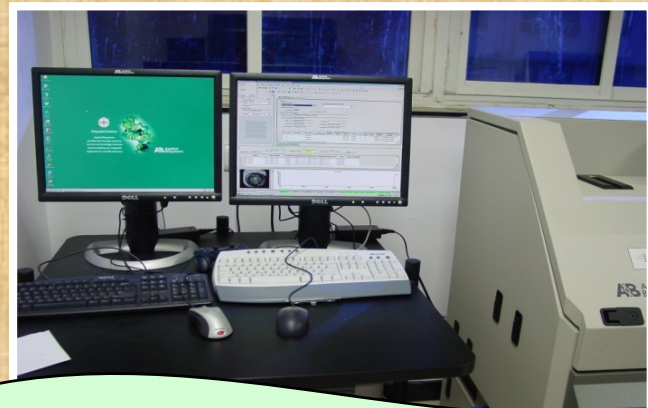


PROTEOMICS LAB

Protein Digester



In Silico Analysis



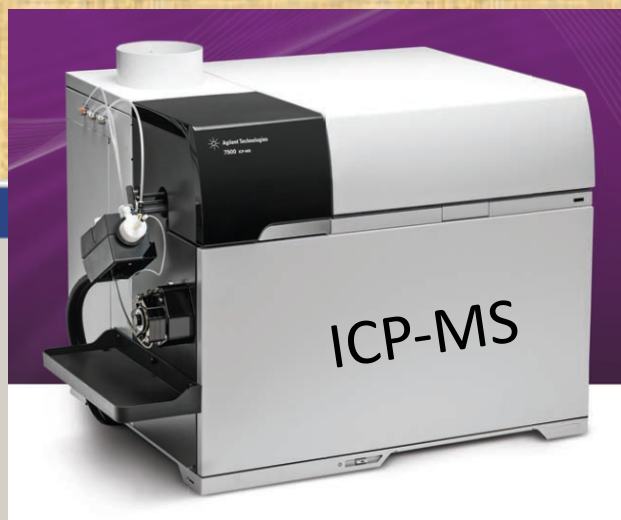
Confocal Microscopy



BD INFLUX CELL SORTER



METALLOMICS LAB (ICP-MS)



Masses

H																	He				
Li	Be															B	C	N	O	F	Ne
Na	Mg															Al	Si	P	S	Cl	Ar
K	Ca	Sc	Ti	V	Cr	Mn	Fe	Co	Ni	Cu	Zn	Ga	Ge	As	Se	Br	Kr				
Rb	Sr	Y	Zr	Nb	Mo	Tc	Ru	Rh	Pd	Ag	Cd	In	Sn	Sb	Te	I	Xe				
Cs	Ba	L	Hf	Ta	W	Re	Os	Ir	Pt	Au	Hg	Tl	Pb	Bi	Po	At	Rn				
Fr	Ra	A																			
		L	La	Ce	Pr	Nd	Pm	Sm	Eu	Gd	Tb	Dy	Ho	Er	Tm	Yb	Lu				
		A	Ac	Th	Pa	U	Np	Pu	Am	Cm	Bk	Cf	Es	Fm	Md	No	Lr				

Periodic Table
 Mass Scale

Clear All Mass Table OK Cancel Help

Taking Care of I, II & III

Concrete & Complete Proposition

Redefined Three-Tier Discipline of Laboratory Sciences

Laboratory

Tier I	Tier II	Tier III
Central Laboratory	Respective Dept. Laboratories	Common Central Research Facility Laboratory
1. TOT: 2-8 hours	12 hours-72 hours	Usually a week
2. Timing: Round the clock	Routine hours (9.00 AM to 5.00 PM)	Always accessible
3. Run by: Laboratory Physician; MD ('Multiple' in One)	Respective MDs	Scientists (Cadre as per ICMR guidelines)
2. Cl. Pathology, Cl. Hematology, Cl. Biochemistry, Cl. Microbiology, & Rapid Molecular investigations including Immunology	Departments of Pathology, Departments of Microbiology, Departments of Biochemistry, Dept. of Transfusion Medicine	Molecular labs Mass spectrometry Cell imaging etc.

Redefined

Three Tier Discipline of Laboratory Sciences

Academics

Tier I	Tier II	Tier III
Central Lab	Respective Dept. Lab	Common Central Research Facility
<ol style="list-style-type: none">1. Sensitization of MBBS students2. MD course in Laboratory Medicine3. Medical Laboratory Technology Course4. Quality Management course5. DM course Molecular Medicine Immunology6. Ph.D. program	<ol style="list-style-type: none">1. MBBS teaching2. MD in respective subject3. DM program in Metabolic diseases Nanomedicine Infectious diseases Virology, Parasitology, Hematology, Anatomic Pathology Neuropathology etc.4. Ph.D. program	<p>Ph.D. Program</p> <p>Helping MD and DM students in their Thesis</p>

Redefined

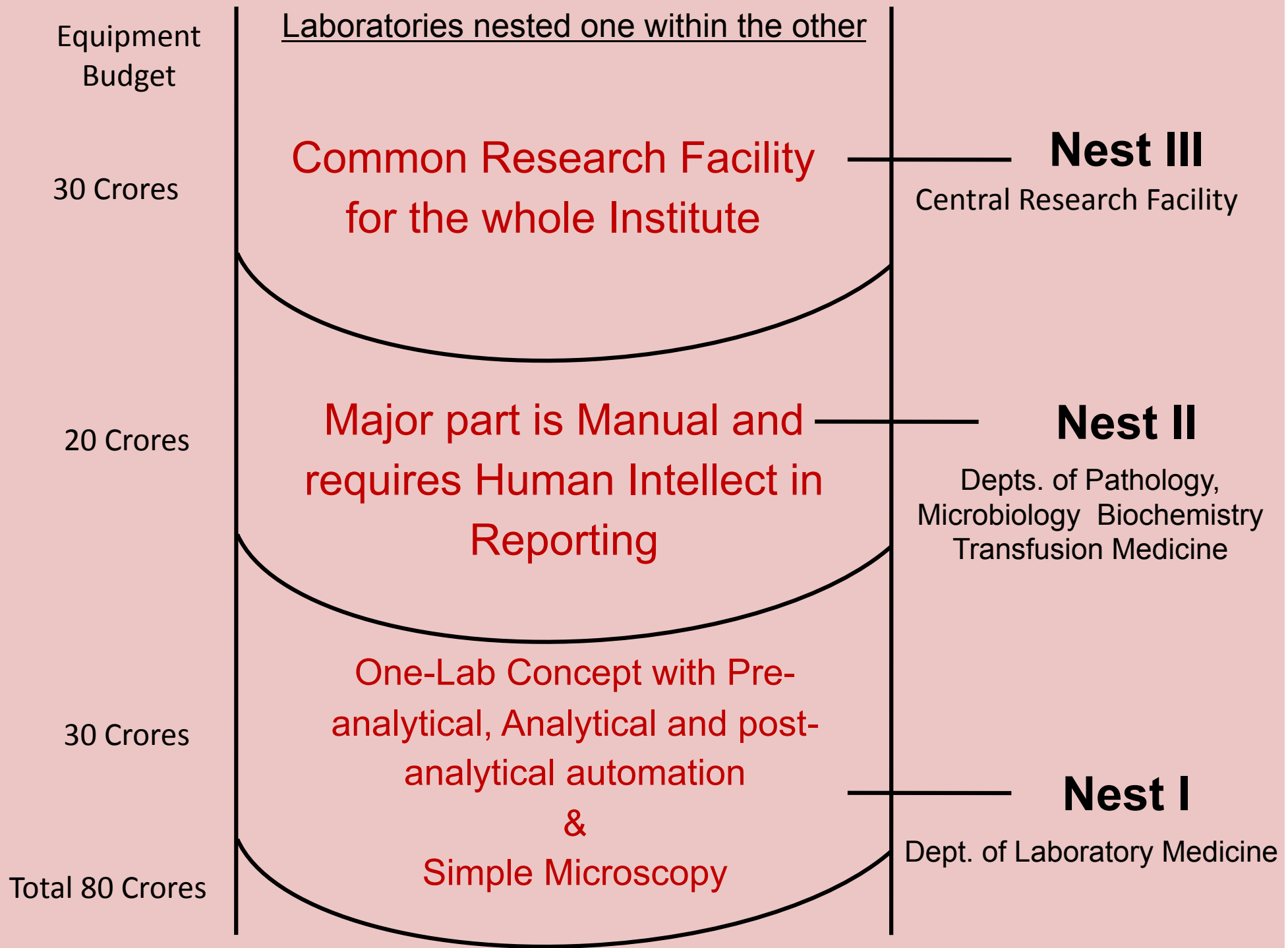
Three Tier Discipline of Laboratory Sciences

Costing

Tier I	Tier II	Tier III
Central Lab	Respective Dept. Lab	Common Central Research Facility
A. Establishment cost (2016) Rs. 30 crores	Rs.5 cores x 4 = Rs.20 crores	Rs. 30 crores
B. Running cost (with 1000 samples/day) 4-5 crores/year	0.5 crores/year x 4	Variable

Space

Tier I	Tier II	Tier III
Central Lab	Respective Dept. Lab	Common Central Research Facility
20,000 sq. ft.	10,000 sq. ft. each x4	10,000 sq. ft.



Branching of Laboratory Medicine

Retrogressive Thinking:

Divisions of Clinical Biochemistry, Cl. Pathology, Hematology, Microbiology etc.
No future of such Division. The Dept. with such name already exist.

Progressive Thinking:

Pediatric Lab Medicine

Geriatric Lab Medicine

Antenatal Lab Medicine

Psycho-Neuro Lab Medicine

Sports Lab Medicine

Occupational Lab Medicine, etc.

Policy Revision Proposal

To open up post graduation in Laboratory Medicine in all Medical Council recognized Postgraduate Medical Colleges and Institutes.

The syllabus, course material, examination schedule as followed in AIIMS are available in the AIIMS–Lab Medicine website

<http://www.aiims.edu/aiims/departments/Labmedicine/Labcourses.htm>.

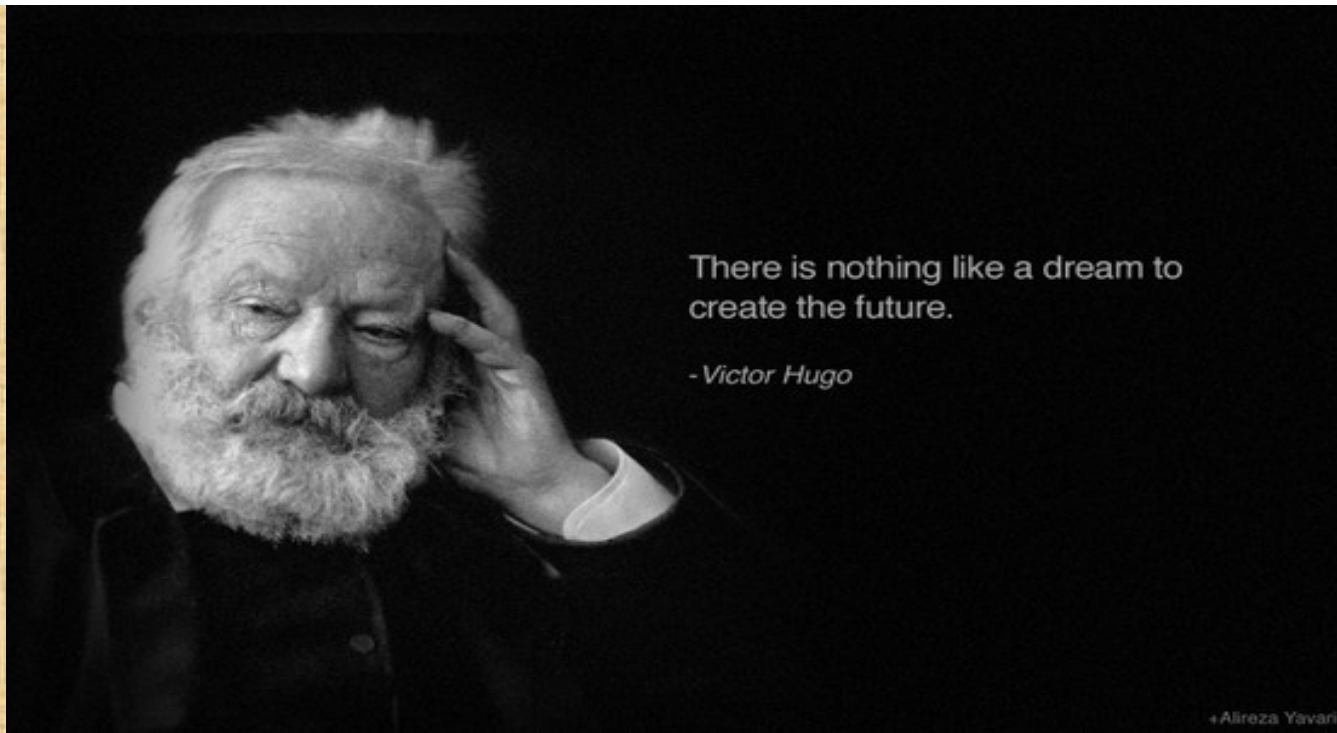
Simultaneously preparation for Various DM Courses

**Alignment with other State and
Central Legislation**

This vision requires to be 'through' with Medical Council and Ministry of Health & Family Welfare, Govt. of Bangladesh and then can be aligned with other state and Medical legislation.

TAKE-HOME MESSAGE

Don't refight the last war



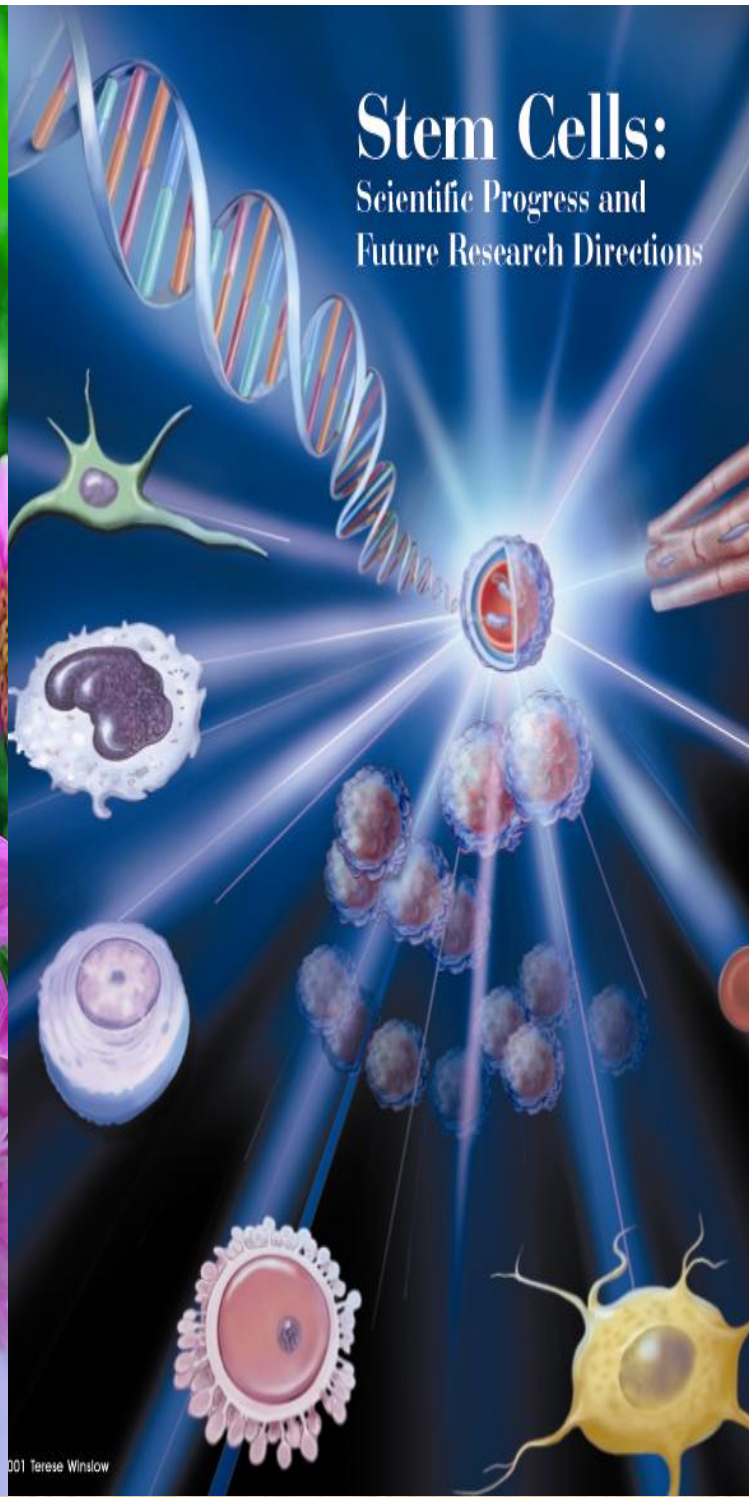
“Nothing is more Powerful
than an Idea
whose
Time has come!”

ACKNOWLEDGEMENT:

- The Faculty,
- Residents,
- PhD Students,
- Staff of the Dept. Of Laboratory Medicine,
AIIMS, New Delhi



**Thank
you**



Stem Cells:

Scientific Progress and
Future Research Directions