FOUNDATIONAL FRAMEWORK OF Laboratory Medicine as a Postgraduate Discipline

A Made-in-India Discipline at AIIMS, Delhi, since 1988 Now, Nationally & Globally Relevant

Department of Laboratory Medicine: The Department of First contact for Clinicians and Patients MD in Laboratory Medicine: The Laboratory Physician of First contact for Clinicians and Patients

Prof. A. K. Mukhopadhyay, MD Head, Dept. of Laboratory Medicine, AIIMS, New Delhi April, 2018

CREATION OF THE DEPARTMENT OF LABORATORY MEDICINE, 1ST DEC. 1988

ALL INDIA INSTITUTE OF MEDICAL SCIENCES

No.F.1-13/83-Estt.I

VIAL DESIGNATION OFFICE ORDER

Ansari Nagar, New Delhi-29 Dated the:01-12-1988 Balance and Institution of the State and American Street

Subject :- Establishment of the Department of Laboratory Medicine at the A.I.I.M.S.

With the approval of the Academic Committee/Governing Body, the present Centralised Clinical Laboratory Services will constitute an independent Department of Laboratory Medicine with immediate effect.

With the creation of the Department of Laboratory Medicine, the following faculty and non faculty posts are converted/re-designated as under:sectore male of the brook

Sr.No. Name of existing No. Post Post		No.of Post	Re-designation of the <u>Bost</u>
1.	Prof. of Cl.Pathology	One	Prof. of Laboratory Medicine
2.	Lecturer in Pathology	0ne	Lecturer in Labora- tory Medicine
3.	Haematologist	One	Lecturer in Labora- tory Medicine (Haematology)
4.	Pathologist-cum- Bactrologist	One	Lecturer in Labora- tory Medicine (Microbiology)
5.	Senior Biochemist	two	Lecturer in Labora- tory Medicine (Biochemistry)

The technical, administrative and other staff sanct-ioned for the existing contralised Clinical Laboratory Services will form part of the newly created department of Laboratory Medicine.

Dr. R.A.Bhujwala, Assoc. Prof. of Microbiology will continue to act as Officer-in-Charge of the Department of Laboratory Medicine till further orders.

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vereinigen is in marsona and in an dama fait dit. 1. Dr. R.A. Bhujwala, Associate Prof. of Microbiology and Officer-in-Charge, Hospital Laboratory Services. 2. The Medical Superintendent

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in their meeting held on 26.9.88.

Authority:- Item No. A.C. f of Academic Committee meeting

held on_20,9.88 as approved by Governing Body

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3. All Centres/Departments/Units/Sections.

4. The P.S. to Director/Dean/D.D.A.

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AIIMS'S SOLUTION OVER Two Competing Worldviews

I. Pathology & Laboratory Medicine

II.Biochemistry & Laboratory Medicine

<u>Gap</u> Expertise in Automation & Quality Assurance



AIIMS's Solution

Established Central Lab: Laboratory of First Contact for Clinicians and Patients. Made it an Independent Discipline. Brought Faculty from Pathology, Biochemistry & Microbiology to start with. Started Residency Program for three years leading to MD degree in Lab Med. & created Laboratory Physician of First Contact. This initiated Structural (Three Tier organization of all Laboratories) & Academic Reforms

(creating super specialty course) in different Laboratory related Disciplines.

Laboratory Medicine The Objectives in the Vision

Patient Centric Discipline:

The Central Lab: One window solution, Minimum TAT, Reliable Report

 Integration of about 80% of common Investigations: *Contextual Nesting* of investigations for *Relevance of Outcome* in Patient care

Core Skill development:

Laboratory Management Skill, Skills for basic Laboratory Technology Procedures and methods, Investigation and Operational Skill, Integrated Reporting Skill and Research Skill

• Research-hub

• State-of-Art Laboratory Ambience: Space, Experts, Equipments



The Discipline of Laboratory Medicine is Unique in many senses

- This is the Laboratory of First Contact for Clinicians and Patients: Central Laboratory is the 1st Tier in the hierarchy of different laboratory disciplines in a medical Institution. (2nd Tier: Path./Micro./Biochem. 3rd Tier: Common Research Facility Lab)
- Integration of Laboratory Investigations: (Contextual nesting to make it clinically relevant). Specialty for Test Selection, Test Operation & Test Interpretation
- Unique Combination of skill in Automation and Microscopy in the same expertise
- It has its **Core skill** in Total Quality Management, Accreditation and Quality Assurance
- Creates skilled <u>Laboratory Physician of First Contact who is globally relevant</u>, Laboratory Scientist of global relevance and Laboratory Technologist

12 Core Skills of Laboratory Medicine Post graduates

- Skill of Implementing One window Solution for the Patients
- Skill of Minimizing TAT for all investigations
- Operational Skill and Integrated reporting of Fluids and Excretions, Chemical analysis of blood and body fluids, hematology and investigation of Infectious disease
- Skill of Maintaining confidentiality of report, and taking Responsibility of disclosing Error
- Skill of **Referral of patient's further investigation to a specialist** *laboratory physician*, when required
- Skill of relevant Dialogue with clinicians and remaining in constant touch with Patient's condition (Internal Medicine)
- Skill of Total Quality Management of First-line Hematological, Biochemical, Microbiological and Clinical Pathological Investigations and Point-of-Care Testing
- Skill of Managing Track-based Single Lab
- Skill of getting the Laboratory Accredited and getting approval of other Regulations
- Skill of Ensuring Laboratory Safety
- Skill of handling Legal aspect of Laboratory Medicine
- Skill of Laboratory Auditing, procurement of equipment and reagents, identification of real essentiality of investigation in patient's management, cost-effectiveness of investigation, participation in Hospital's "Death Conferences"

Educational contributions for Medical disciplines

- The Discipline of Laboratory Medicine brings a patient centric curriculum creating Laboratory physician-of-First-Contact for both Clinician and Patients, that contributes to better patient care
- Supporting clinicians in their Test Selection and Test interpretation
- The department of Laboratory Medicine could be the nodal point in training of medical undergraduates – right from their foundation course, early clinical exposure, electives, in addition to the core UG competency based curriculum
- Postgraduates of various clinical departments will get a chance to be exposed to the department of Laboratory Medicine for understanding the pre-analytical, analytical and post-analytical sources of errors in test-reporting and the need for appropriate quality control measures at their end.
- The discipline could be a support source for the basic laboratory departments in teaching and training some components of their curriculum related to laboratory investigations.
- Help in expansion of paramedical resources associating with the courses like DMLT, B.SC MLT, M.Sc MLT etc.

Possible Research contribution by the Discipline

• To support First-line clinical research

Intramural projects, which include lab investigations

Extramural Projects, which require lab investigations, asks for a Good support Laboratory

Even required for basic laboratory investigations in a Randomized Control Study

The discipline is a research- and publication-hub, because of sheer gamut of clinical materials & availability of different types of equipment

- To enable research oriented to the field of Laboratory Medicine; On methodology, on reagents, even on equipment devices
- Laboratory Medicine is the First Tier of the Three-Tier Laboratory Systems of any Medical Institute and therefore could anchor a variety of research projects

Is it overlap with Existing Discipline or Integration?

No discipline in Medicine is an Island or, a Stand-alone discipline!

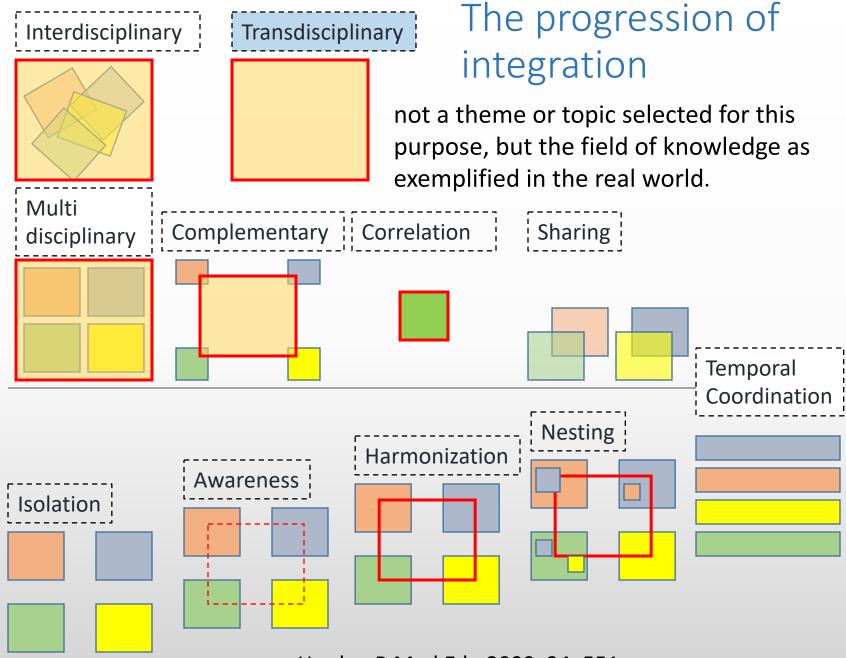
Twelve Core Skills as mentioned are of its own. There is no overlap with any other discipline

Sharing with, <u>up to 20%</u>, the core concept-based subjects, in fact, is the strength of this discipline

There is no overlap of Skill at the level of "P" (Performance) The purpose is *Contextual Nesting* of the Investigations to get the *Relevant outcome*

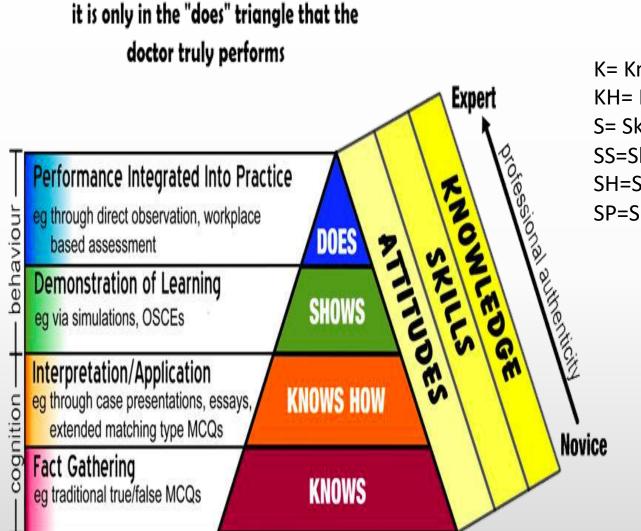
It is the discipline with Patient-centric integration of investigations

- To reduce TAT, for one-window solution to Patients, and Quality Reporting
- To correlate the Outcomes of Investigations in Patient Care
- To complement the Outcomes of Investigations in Patient Care



Harden R Med Edu 2000. 34; 551

MILLER'S PRISM OF CLINICAL COMPETENCE (aka Miller's Pyramid)



K= Knowledge KH= Knowledge, How S= Skill SS=Skill show SH=Skill How, Under supervision SP=Skill, Perform independently

Based on work by Miller GE, The Assessment of Clinical Skills/Competence/Performance; Acad. Med. 1990; 65(9); 63-67 Adapted by Drs. R. Mehay & R. Burns, UK (Jan 2009)

How much of "Pathology" is in Lab Med?

Only 20% of Pathology could be integrated with Lab Med. e.g., General Pathology (KH), Fluid Pathology Invest. (SP), General histopath. slides (SS), Cytology (SP) etc.

Core 80% of Pathology remains with Pathology Department e.g., General & Systemic Pathology (KH), Anatomic Pathology (SP), including EM, IHC, Molecular diagnostics on Tissue (SP) etc. Pathology Dept. is responsible for Concept-building for MBBS students

Responsibility for Consultation with, or Referral to Dept. of Pathology, as and when felt necessary, remains with the Faculty/SR of Lab Medicine

How much of Microbiology is in Lab Med?

Only 20% of Microbiology could be integrated with Lab Med e.g., General Microbiology (KH), Common Staining and microscopy (SP), Automated Serology (SP), ELISA, Rapid Diagnostic tests (SP) etc.

Core 80% of Microbiology remains with Microbiology Department e.g., General & Systemic Microbiology (KH), Species identification of Microbes for Bact., Parasite, Fungus, Virus ("SP"), Special serological tests (SP), Epidemiological Study (SP), Hospital Infection Control (SP) etc. Microbiology Dept. is responsible for Concept-building for MBBS students

Responsibility for Consultation with, or Referral to Dept. of Microbiology, as and when felt necessary, remains with the Faculty/SR of Lab Medicine

How much of Biochemistry is in Lab Med?

Only 20% of Biochemistry could be integrated with Lab Med

General Biochemistry (KH), Automated Serum Chemistry, Electrolytes & ABG (SP), Analysis in chemiluminescence analyser, Urine Chemistry (SP), Colorimetry, Spectrophotometry & Nephelometry (SP), HPLC (SP) etc.

Core 80% of Biochemistry remains with the Department of Biochemistry e.g., General and Systemic Biochemistry (KH), TLC & Gas Chromatography (SP), Mass spectrophotometry (SP), Molecular Analysis (SP), Receptor study (SP), Chanellopathy study (SP), Cell signaling (SP) etc.

Biochemistry Dept. is responsible for Concept-building for MBBS students

Responsibility for Consultation with, or Referral to Dept. of Biochemistry as and when felt necessary, remains with the Faculty/SR of Lab Medicine

How much of Hematology is in Lab Med?

Only 20% of Hematology could be integrated with Lab Med

General Hematology (KH), Automation (SP), Hemogram, ESR & Retic Count, common staining (SP), Examination of blood peripheral smear & Diagnosis of Hemoparasite (SP), Buffy coat, Screening of Bleeding Disorders and DIC Studies (SP), Diagnosis of Leukemia, Anemia (SP) & Screening of nutritional anemia etc.

Core 80% of Hematology remains with Hematology super-specialty e.g., General & Systemic Hematology (KH), Coagulation factor assay & Platelet functions (SP), Leukemia genetics (SP), special investigations of anemia & leucocyte functions (SP), Therapeutics (SP), Follow up (SP), etc.

Responsibility for Consultation with, or Referral to Dept. of Special Hematology, as and when felt necessary, remains with the Faculty/SR of Lab Medicine

How much of Transfusion Medicine (TM) is nested in Lab Med.?

Only 20% of could be integrated with Lab Med in Teaching-Learning methods

General TM (KH), Donor Screening & Collection (SP), Blood grouping & Cross matching (SP), Comb's Test (SP), Infection Screening (SS), Component Preparation & Preservation (SS) etc.

Core 80% of TM, remains with Transfusion Medicine specialty. e.g., General & Systematic TM (KH), Quality Management of Blood Banking (SP), Donor Screening & Collection (SP), Blood grouping & Cross matching (SP), Comb's Test (SP), Antibody screening (SP), Infection Screening (SP), Component Preparation, Preservation & Therapy (SP), Apheresis (SP), Automation in TM (SP), Investigations of Transfusion Reactions (SP) etc.

Given the Responsibility for running the Blood Bank service in suburban/rural areas, Lab Med MD is capable of doing this. Consultation with, or Referral to nearby Dept. of Transfusion Medicine,

How much of Immunology is nested in Lab Med?

Only 20% of could be integrated with Lab Med.

e.g., General Immunology (KH), RF (SP), Autoantibodies (SP), Ab & Complement estimation (SP) etc.

Other 80% of Immunology is distributed in Pathology, Microbiology, Biochemistry, Hematology etc.

Responsibility for Consultation with, or Referral to respective Depts. as and when felt necessary, remains with the Faculty/SR of Lab Medicine

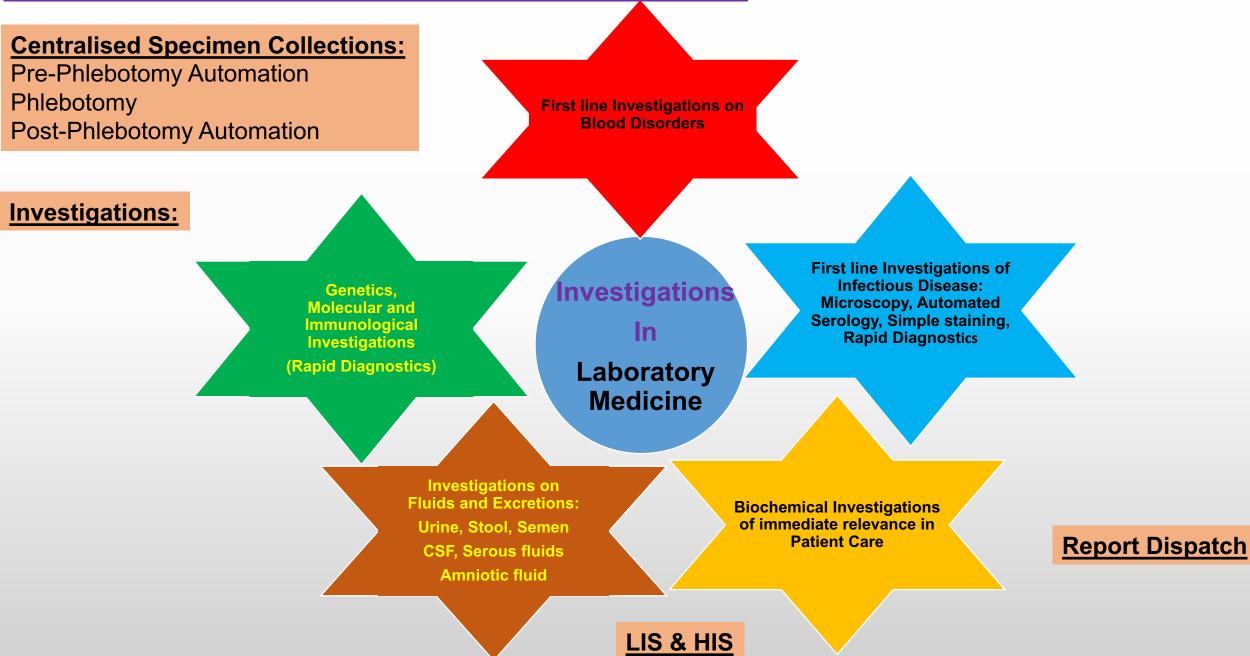
How this new PG discipline will help the specialty of Pathology/Hematology, Biochemistry and Microbiology?

- As soon as any Medical College/University/Institution opens this Dept. of Laboratory Medicine, one postgraduate each from the above streams will be recruited as Faculty, thus opening up new job opportunity for them in addition to opportunity for their own department
- A new option for Pathologists, Hematologist, Microbiologists, and Biochemist who prefer to be more holistic in investigative approach rather than remaining confined to their own postgraduate expertise. They might join newly opened department of Laboratory Medicine
- The second tier of Laboratory discipline departments could start super-specialty DM course in specified area

SERVICES RENDERED BY DISCIPLINE OF LABORATORY MEDICINE

- Services to Patients
- Services to Students
- Services to Science

Elaboration on Service to Patients



Responsibility of Laboratory Medicine Dept. in Patient Care Environment

Test Selection

Test Operation

Test Interpretation

TEST SELECTION

Q. How does Test Selection by a Laboratory Physician differ from Test Selection by a Clinician?

Contextual Nesting of the Investigations to get the *Relevant* outcome is better done by a Laboratory physician than a Clinician

Practical Knowledge on Sensitivity & Specificity, Positive & Negative Predictive value of relevant investigations is prerogative of Laboratory Physician

Irrelevant investigations increase the workload, compromise with quality, and add to financial burden Results in "Audit Para" in Laboratory Audit

Laboratory round of Clinical Residents is recommended

TEST OPERATION

Q. How does Test Operation done by a Technician, in absence, and in presence of a Laboratory Physician differ?

Technician cannot do Contextual Nesting of the Investigations. Nor, he fully understands the Relevance of outcome

TEST INTERPRETATION

Q. How does Test Interpretation by a Clinician and a Laboratory Physician differ?

- Contextual Nesting of the Investigations & the Relevance of their outcome is the Expertise of Laboratory Physician
- The Knowledge on Sensitivity & Specificity, False Positivity & False Negativity, Positive & Negative Predictive value of any relevant investigation are prerogative of Laboratory Physician

Clinical ward round by Laboratory Medicine Residents is *recommended*

 Non-funded Departmental Research from the sea of Investigations and clinical materials

Intramurally / Extramurally Funded Research

Self-directed Research

Special Thrust: Equipment Innovation, Reagent modification & Production, Technology Patenting

Elaboration on Service to Students

Creations of Human Experts:

- Three-year Residency Program leading to MD degree in Laboratory Medicine (creation of <u>Laboratory Physician of First Contact who is</u> <u>globally relevant</u>)
- PhD Program in Laboratory Medicine (creation of <u>Laboratory Scientist</u>, <u>globally relevant</u>)
- MLT course (BSc, MSc) (creation of <u>Laboratory Technologist</u>)

National Need of the Course

- To facilitate the implementation of present honourable PM's National Health Mission free diagnostic service
- To run a clinical laboratory
 - in Zonal/ District/Sub-divisional hospitals in various states
 - in hospitals of remote areas of the armed forces, paramilitary forces and other central government organisations like ESI and Railways.
 - in private hospitals and diagnostic centres
 - as central facility even in medical colleges(government and private) not having the Dept. of Laboratory Medicine.
- To create Expert Resources by the department of laboratory medicine in major hospitals attached to a Medical college
- To facilitate availability of an authorised signatory as per Clinical Establishment Act.
- The attempt will result in economical gain in terms of budget, manpower experts (human resources and knowledge), material resources, space and time.

Employment opportunities for postgraduates with MD degree in Laboratory Medicine

The Ministry of Health, Govt. of India is to <u>include this MD degree in Laboratory</u> <u>Medicine in their Rules and Regulation for recruitment of Laboratory Physician</u>

• In Govt. Health Care Sector:

In all hospitals **not attached** to any Medical College but having a central lab. Hospitals may be situated in metro, other city, urban, semiurban, district and even sub-divisional hospitals

In Armed Forces: Where it is not possible to post three specialists in remote areas.

• In Private Health Care Sector:

Private sector hospitals across the country have started preferring to appoint a MD in Laboratory Medicine expert than to appoint three/four specialists.

Future scopes for Postgraduates in Laboratory Medicine?

- Service: As mentioned above in the job opportunity. In addition, they can serve in medical college hospitals too.
- Academic: They may join as Faculty in Dept. of Laboratory Medicine Super-specialization:
 - They could pursue super specialty DM degree in laboratory-related DM courses already existing. <u>Medical Council of the Nation has to make necessary changes for inclusion of this eligibility criteria</u>.
 - Laboratory Medicine discipline might open up its own DM Course as super specialty
- **Research:** In suitable Institution they may join research with or without pursuing for PhD degree

Academic Scopes for Postgraduates in Laboratory Medicine, elaborated

- They could **join as Faculty** of Laboratory Medicine, once the discipline opens up in several Medical Institutions in the country (subject to MCI approval).
 - It is envisaged that in the Department of Laboratory Medicine, there will be one faculty MD in Pathology, one faculty MD in Microbiology and one faculty MD in Biochemistry. With gaining eligibility, three faculty with MD in Laboratory Medicine degree will join. The proportion will remain like this. With 12 Faculty strength in the department, there will be two from pathology stream, two from biochemistry stream and two from microbiology stream and six from laboratory medicine stream.
- They could **pursue science** by entering into PhD Program in Laboratory Medicine. The discipline is a research- and publication-hub, because of sheer gamut of clinical materials & availability of different types of equipments
- They, as versatile Laboratory Physician, could join super specialty DM Courses related to Laboratory Discipline (subject to MCI/NMC listing, and approval, not required for certain autonomous medical Institutions) and open up super specialty DM course in its own discipline

Gains from Establishing the Discipline and its Growth with a Postgraduate Course

- Man-Power Economy (Salary of one Laboratory Physician vs. Salary of 4 Experts)
- Equipment Economy (Budget & Expenditure of the Institute)
- Space Economy (Laboratory Ambience for service, education and Research)
- Time Economy (TAT of investigations)
- Knowledge Economy (Correlation, Complementation, Integration of investigations)
- Skill Economy (Skill for Microscopy, Automation, Quality Assurance in one person)
- Communication Economy (LIS, HIS, Soft skill to communicate with clinicians & patients)

LONG TERM CONSEQUENCES

- Expert Human Resource as Laboratory Physician for Health Sector of the Nation
- Structural Reform of All Laboratory Disciplines (Three-Tier Systems)
- Academic Reform of Laboratory-related Degrees (MD and super specialty DM degrees)



Sorry, we have not achieved everything what everyone has been looking for! Let us take a deep breath, And begin the next chapter. Everything is going to be okay!

