PANDORA

Pan-African Network For Rapid Research, Response and Preparedness for Infectious Diseases Epidemics

INFRASTRUCTURES AND UTILITIES

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Laboratory quality control in low and middle income countries

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INFRASTRUCTURES AND UTILITIES

- As part of global health security initiatives, cooperative threat reduction efforts and international development programmes, sophisticated laboratories have been provided to mitigate biological threats and bolster a country's capacity for detection, diagnosis and storage of high-consequence pathogens.
- There can sometimes be limited local technical capacity and capability, which can result in a high reliance on imported expertise, skills, equipment and other resources. Sustainability can therefore be hard to achieve.
- Four topic sections are essential functional aspects to considere prior to embarking on establishing or repurposing a laboratory: finance, human resources, operations, and infrastructures and utilities.

INFRASTRUCTURES AND UTILITIES

- Suitable infrastructures and adequate access to utilities are fundamental requirements for laboratory sustainability.

- Consideration should be given to:
  - ✓ the most suitable location for the laboratory,
  - ✓ security measures need to be in place, and
  - ✓ risks in terms of power supply, access to water, transport links and buildings, and environmental conditions

- Consideration of measures to be taken to mitigate such risks.

Biosafety Levels

Biosafety Levels (BSLs)

- Biosafety: Containment principles, techniques and practices implemented to avoid unintentional exposure to pathogens or toxins or their accidental release.

- Biosecurity : Protection, control and accountability for valuable biological materials in laboratories, in order to restrict access and avoid loss, theft, misuse, diversion or deliberate release

BSLs

- ✓ Biological materials:
  - Samples (blood, urine, tissue, secretions etc.) in common use in laboratories and research units are a source of risk sometimes identified but often unrecognized and difficult to assess
  - Microorganisms including those which are genetically modified, cell cultures and human endoblasts capable of causing infection, allergy or intoxication
- ✓ Biological risk: Probability of being exposed to a biological hazard
  - Directly: agent triggering the disease
  - Indirectly: toxin

BSLs

- ✓ Biological agents are divided into 4 hazard groups:
  - By the pathogenicity of biological agents
  - By the risk of illness of the exposed person
  - By the risk of spread in the community
  - By the existence of a prophylaxis or an effective treatment

BSLs

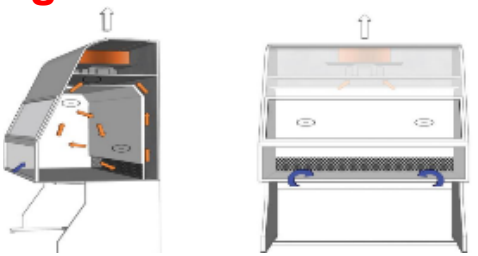
Classification of biological agents

Groups	Characteristics	Examples
1	Does not cause disease in humans.	Lactobacillus, Adenovirus, *E. coli*…
2	Could cause illness in humans and be a danger to workers ; Their spread in the community is unlikely ; There is usually effective prophylaxis or treatment.	*Staphylococcus aureus*, influenza virus, measles virus, Hepatitis virus A, B, C, E, *Plasmodium*…
3	Could cause serious illness in humans and pose a serious danger to workers ; Spread to the community is possible, but there is usually effective prophylaxis or treatment	**SARS-CoV-2**, Yellow fever virus, Dengue virus, HIV, Rift valley fever virus, West Nile virus…
4	Cause serious illness in humans and pose a serious danger to workers ; The risk of their spread to the community is high ; There is usually no prophylaxis or effective treatment.	Lassa virus, Ebola virus, Crime Congo virus …

BSLs

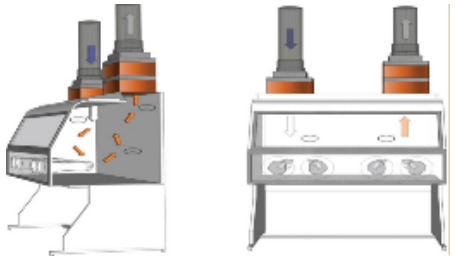
Facilities: Types of laboratory – Biosecurity level and corresponding Microbiological Safety Cabinets

Containment level	Local	Specific equipment	Good practices
BSL1	Room ventilated and insulated by a door and closed windows. Easily washable benches, walls and floors.	Autoclave in the building	Protective clothing. Clean and tidy mats. GLP
BSL2	**BSL1 +** Regulated access for authorized personnel , making of premises, hermetic closure for fumigation (optional), sinks with non-manual controls. Autoclave	Microbiological safety cabinet (MSC) Secure centrifuges.	PPE : Blouse, gloves, glasses, use of needle box, use of disposable materials, inactivation of contaminated material (alcohol 70 etc.) and waste
BSL3	**BSL2 +** airlock, filtration of incoming and outgoing air, intercom (optional), negative pressure with alarm system, generator, shower (optional)	MSC II, double entry autoclave	Same layouts as in **BSL2** **+** wearing overboots and overcoats
BSL4	**BSL3 +** Emergency ventilation system, intercom compulsory, double airlock, shower compulsory	MSC III	Same layouts as in **BSL3** **+** use a protective suit



MSC I

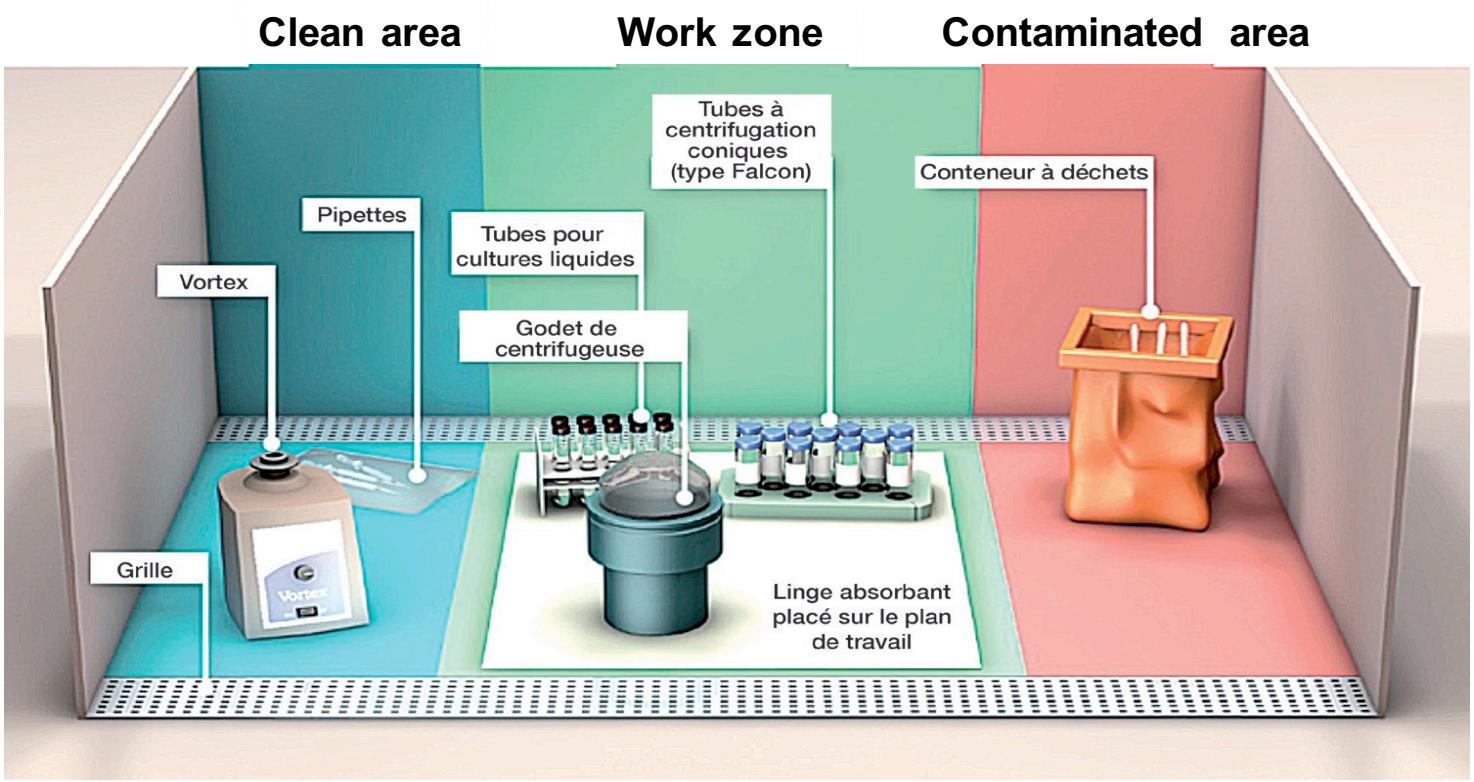
MSC II



MSC III

BSLs

Workspace organization under MSC



Laboratory biosafety manual

Third edition

World Health Organization
Geneva
2004

BSLs

Facilities:

- Appropriate size, structure and location
- Space to avoid contamination of samples with separation of activities, limited access
- Storage areas: controlled temperature, defined limits, alarm, backup
- Good maintenance

Waste disposal pathways

Waste disposal pathways

- **minimise** waste and do not accumulate large amounts in the laboratory. Regular disposal from the laboratories must be part of the laboratory WHS program.
- **segregate** waste - have a separate residue container if you are generating a large amount of any particular type of waste. Ensure the waste container is compatible with the waste you are collecting.
- **label** the waste residue container with the appropriate waste label.
- **store** waste in a suitable area prior to collection. For example, chemicals and solvents should be stored in ventilated areas and residue container lids must be secure. Ensure container is not leaking and no spillage on the exterior of the container. Primary container should be placed in a suitable bund.
- **handle** waste only if you are aware of the hazards associated with the waste and appropriate risk controls are used.
- **dispose** waste as per relevant UOW guidelines.
- **record** all disposal on Waste Tracking Log to ensure evidence of correct waste management.

Waste disposal pathways

Waste

Risk-free (non-infectious waste)

Regular trash can

At risk of infection

Solid

Yellow trash can

Pungent or sharp

Chemical

HDPE containers

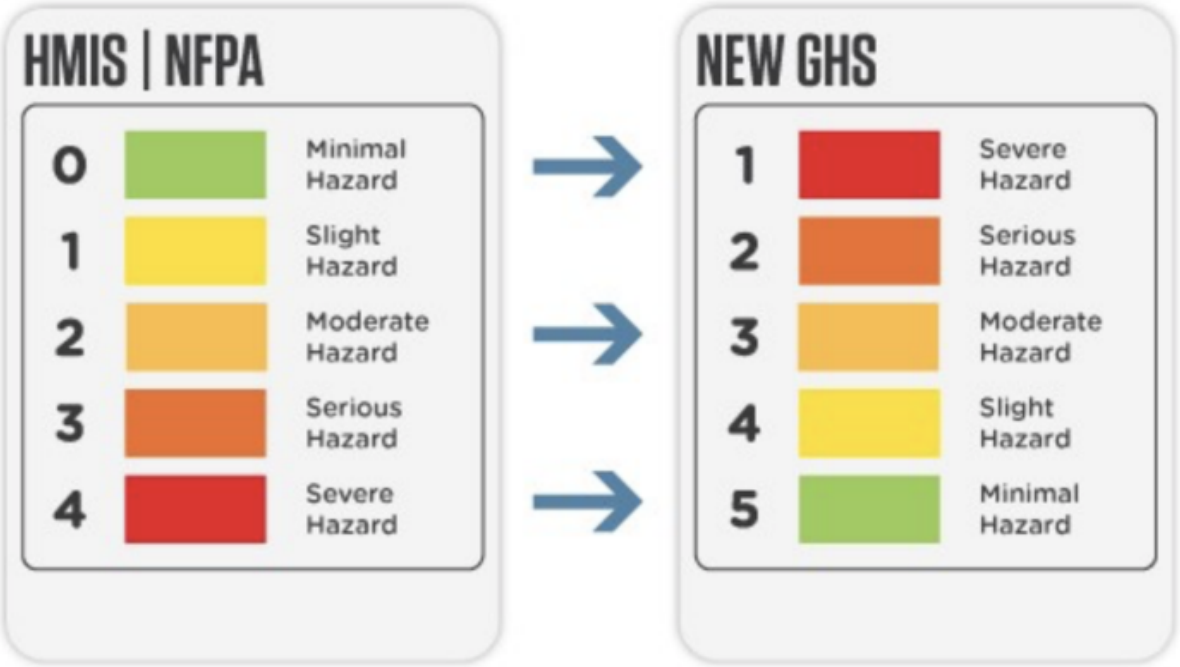
Other liquids

Decontamination/ neutralization before elimination

Incineration

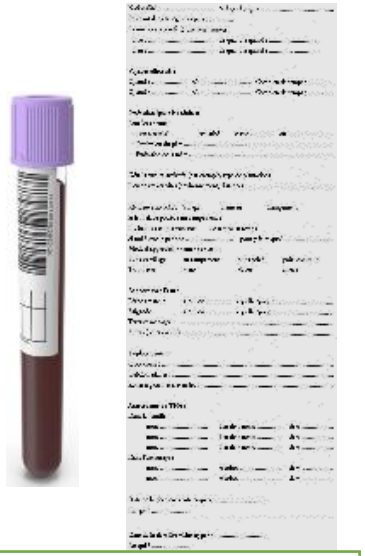
Waste disposal pathways

Case of chemical waste with limited volumes



Computerised Laboratory Management Information systems (LIMS)

Why is it so important?



Pre-analytical phase

Analytical phase

Post-analytical phase

Computerised Laboratory Management Information systems (LIMS)

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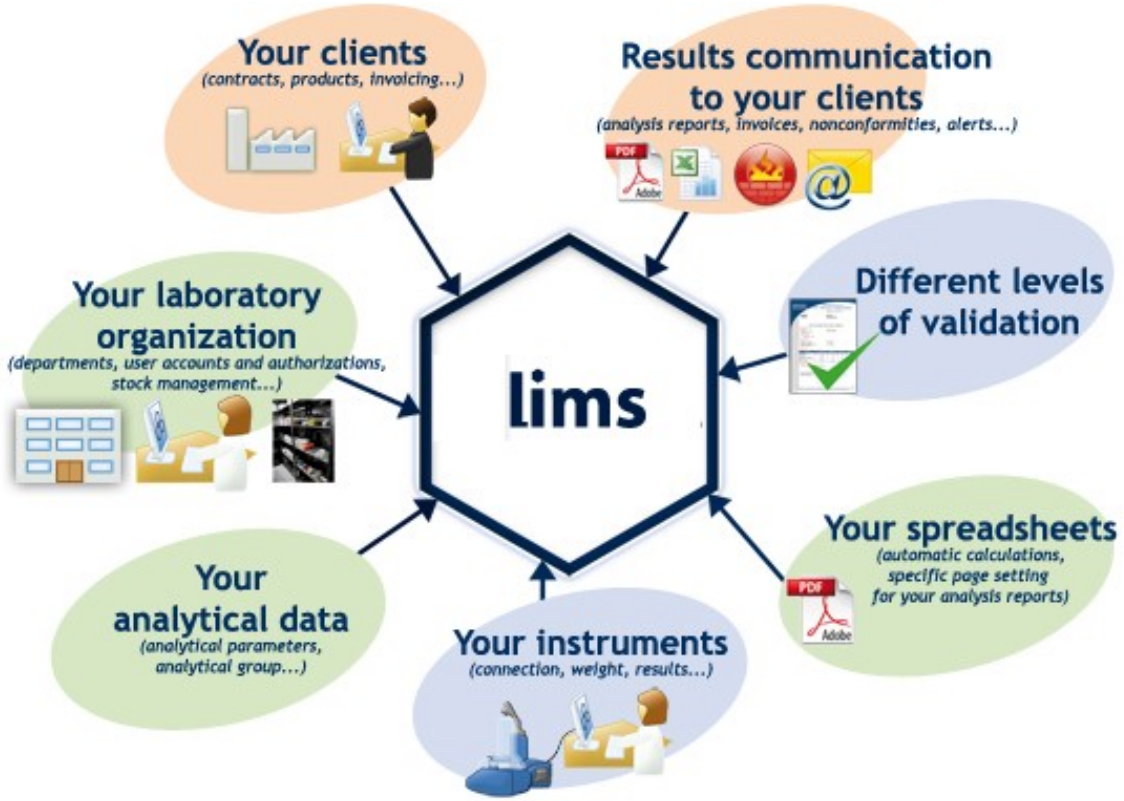
Why is it so important?

Computerised Laboratory Management Information systems (LIMS)

What is it?



Computerised Laboratory Management Information systems (LIMS)

How is it advantageous?

- Elimination of Human Error
- Real Time Tracking & Time Saving
- Consumption based Inventory Alert
- Quality control management
- Easier data searching and access to patient information
- Easier reports generation and tracking
- Financial management
- Integration with sites outside the laboratory

Computerised Laboratory Management Information systems (LIMS)

What are the disadvantages?

- Training
- Time to adapt to a new system
- Cost
- Physical restrictions
- Need for backup system

Computerised Laboratory Management Information systems (LIMS)

How to implement it?

- There are a number of options available to those interested in developing a LIMS:
  - Fully developed laboratory systems, which usually include computers, software and training.
  - In-house computer network with locally developed systems based on commercially available database software.

Computerised Laboratory Management Information systems (LIMS)

TERANGA : Digital platform of Institut Pasteur de Dakar

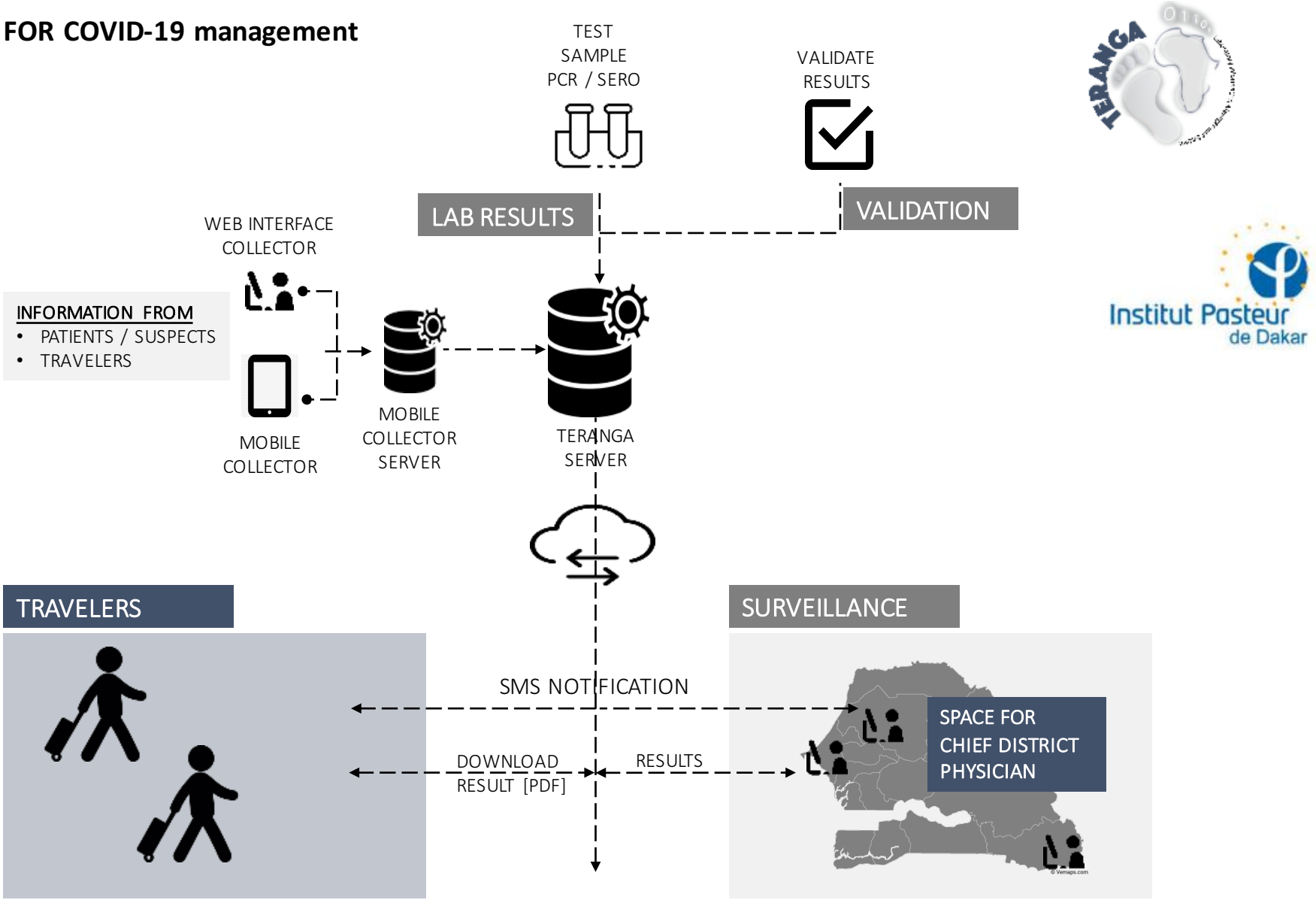
Some components :

- a LIMS – Laboratory Information Management System

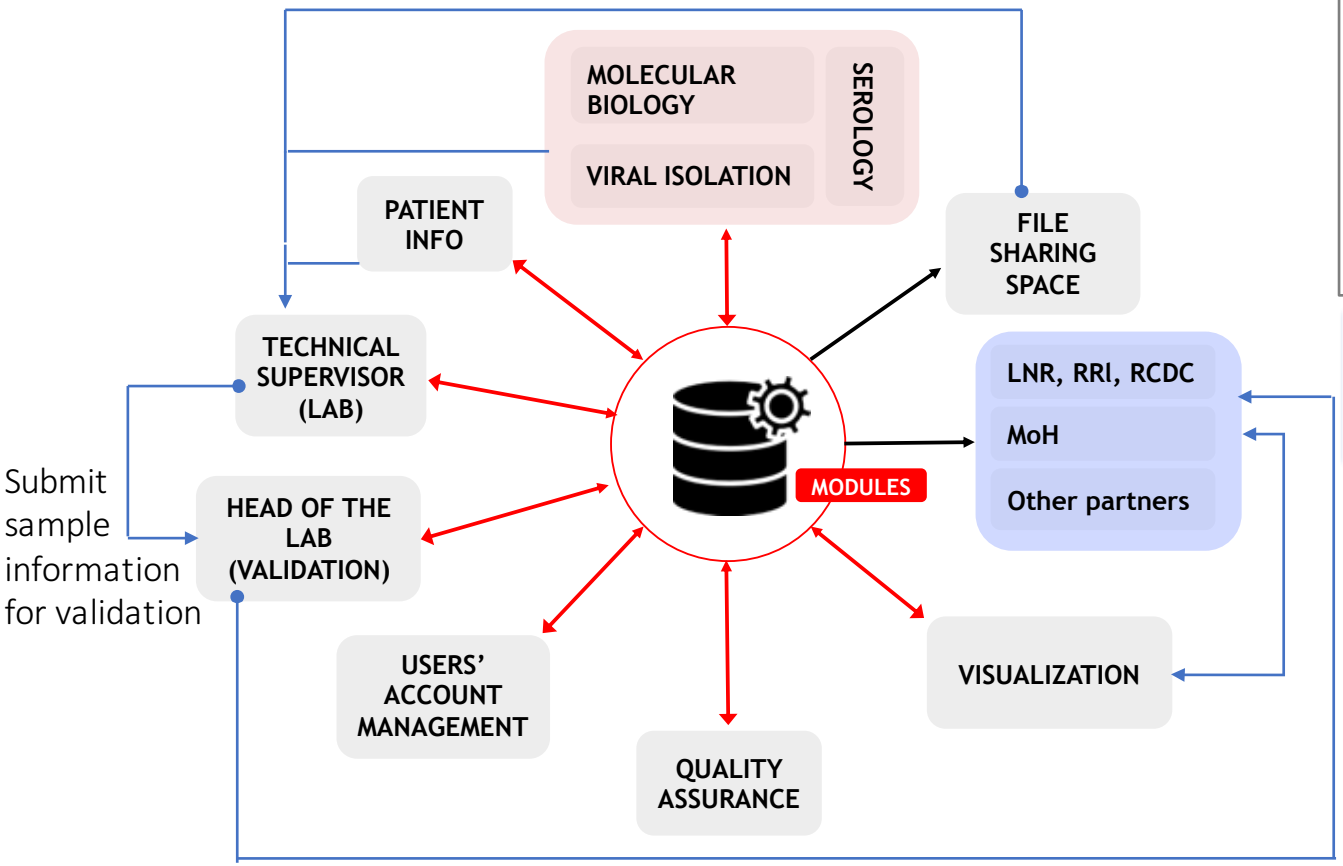
- modules for
  - epidemics
  - specific research projects

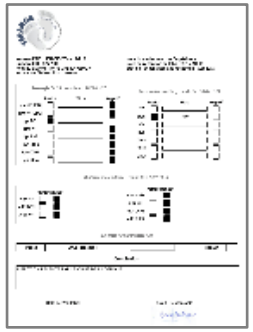
- **T**eranga **M**obile **C**ollector (**TMC**)
  - a platform allow from creation and administration on mobile device

PIPELINE FOR COVID-19 management



Functional Architecture



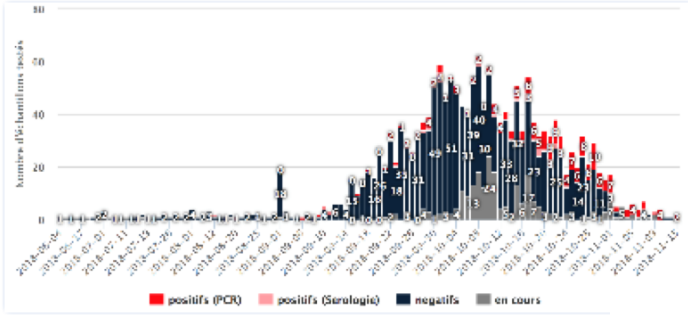


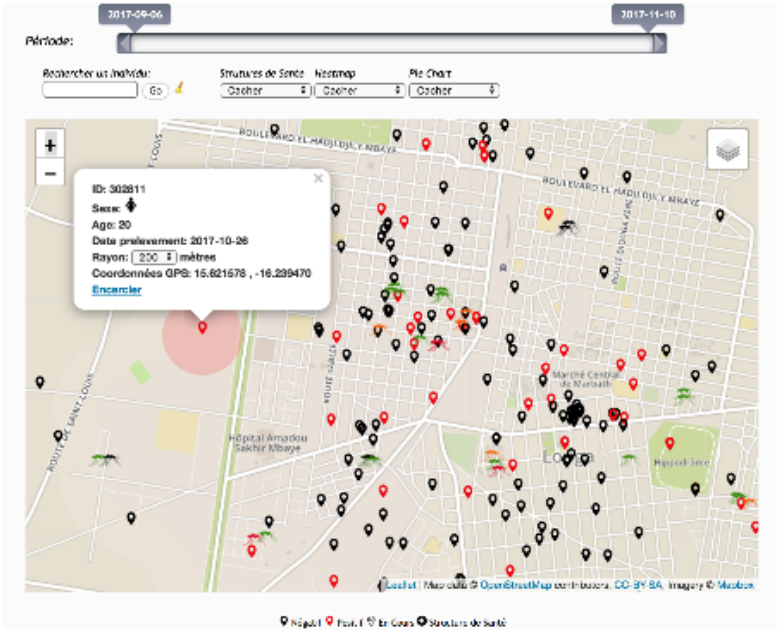
Once sample information are validated, entitled partner is notified

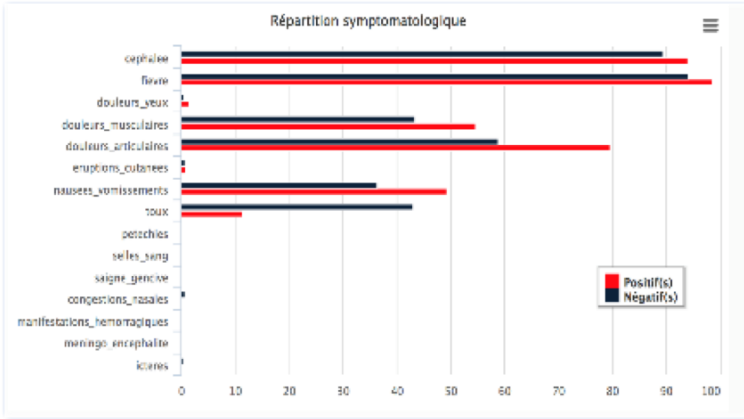
Dashboard for Outbreak Management

This modular based platform have been used as an outbreak data management tool during the **2 previous dengue epidemic that occurred in Senegal**.

Enabling MoH to follow-up the epidemic curve, spatiotemporal spread of cases and vectors on a map, etc.







Calibrating equipment yourself – guidelines

Calibrating equipment yourself – guidelines

- *Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.* (International Vocabulary of Metrology (VIM) of the BIPM (Bureau International des Poids et Mesures or International Bureau of Weights and Measures))

- Calibration is the act of comparing a device under test (DUT) of an unknown value with a reference standard of a known value.

Calibrating equipment yourself – guidelines

- International System of Units (SI) consists of seven base units which are the second, meter, kilogram, ampere, kelvin, mole and candela.

Defining constant	Symbol	Numerical value	SI Unit
hyperfine transition frequency of Cs	Δv_{Cs}	9 192 631 770	Hz
speed of light in vacuum	c	299 792 458	$m\ s^{-1}$
Planck constant	h	$6.626\ 070\ 15 \times 10^{-34}$	J s
elementary charge	e	$1.602\ 176\ 634 \times 10^{-19}$	C
Boltzmann constant	k	$1.380\ 649 \times 10^{-23}$	$J\ K^{-1}$
Avogadro constant	N_A	$6.022\ 140\ 76 \times 10^{23}$	mol^{-1}
luminous efficacy	K_{cd}	683	$lm\ W^{-1}$

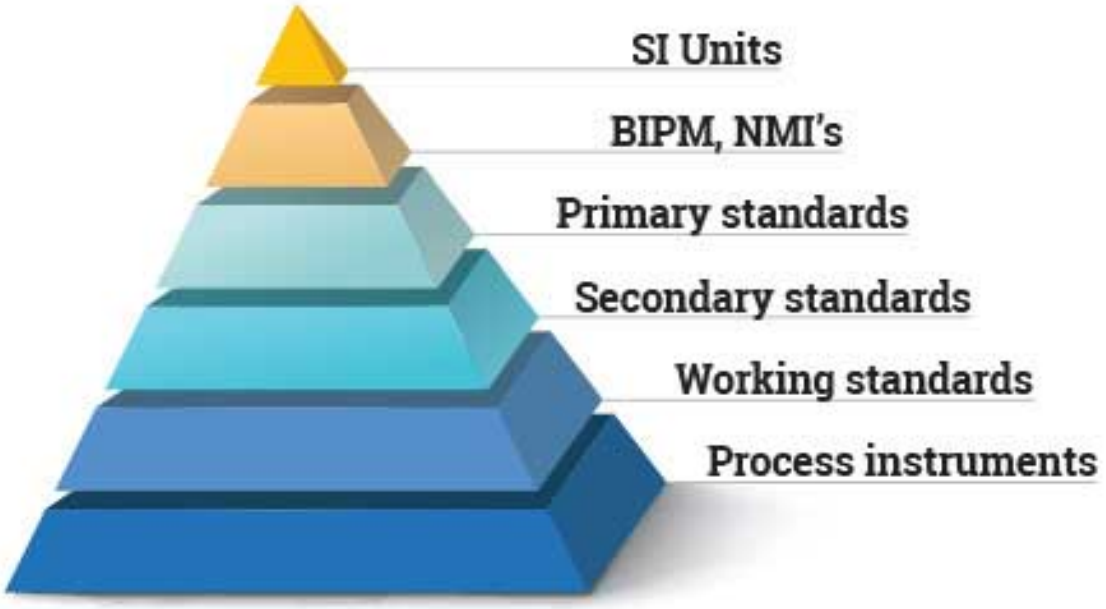
Calibrating equipment yourself – guidelines

- BIPM is the coordinator of the worldwide measurement system and is tasked with ensuring worldwide unification of measurements.

- Calibration interoperability

Calibrating equipment yourself – guidelines

The Calibration Traceability Pyramid



Calibrating equipment yourself – guidelines

- **Calibration Accreditation** gives an instrument owner confidence that the calibration has been done correctly.
- ISO/IEC 17025 is the international metrology quality standard to which calibration laboratories are accredited.
- Accreditation services are provided by independent organizations that have been certified to do this type of work:
  - ✓For example, in the United States, the National Voluntary Laboratory Accreditation Program (NVLAP), A2LA, and LAB
  - ✓In England, the United Kingdom Accreditation Service (UKAS)

Calibrating equipment yourself – guidelines

- Instrument Calibration can be called for:
  - ✓with a new instrument
  - ✓when a specified time period is elapsed
  - ✓when a specified usage (operating hours) has elapsed
  - ✓when an instrument has had a shock or vibration which potentially may have put it out of calibration
  - ✓sudden changes in weather
  - ✓whenever observations appear questionable

Calibrating equipment yourself – guidelines

How is a Calibration performed?

- There are a couple of approaches to calibrate a DUT:

  A) conduct testing to verify that the instrument meets the in-house lab performance specifications;

  B) conduct testing to verify that the instrument meets the manufacturer's stated specifications.

Calibrating equipment yourself – guidelines

- Instrument performance specifications can be captured in three main categories:
  - accuracy/precision
  - technical
  - Environmental

- Using instrument performance specifications plus established in-house, national, and/or international standards for data collection, quality control, and product output, protocols can be developed to allow for testing an instrument to verify that it meets performance expectations.

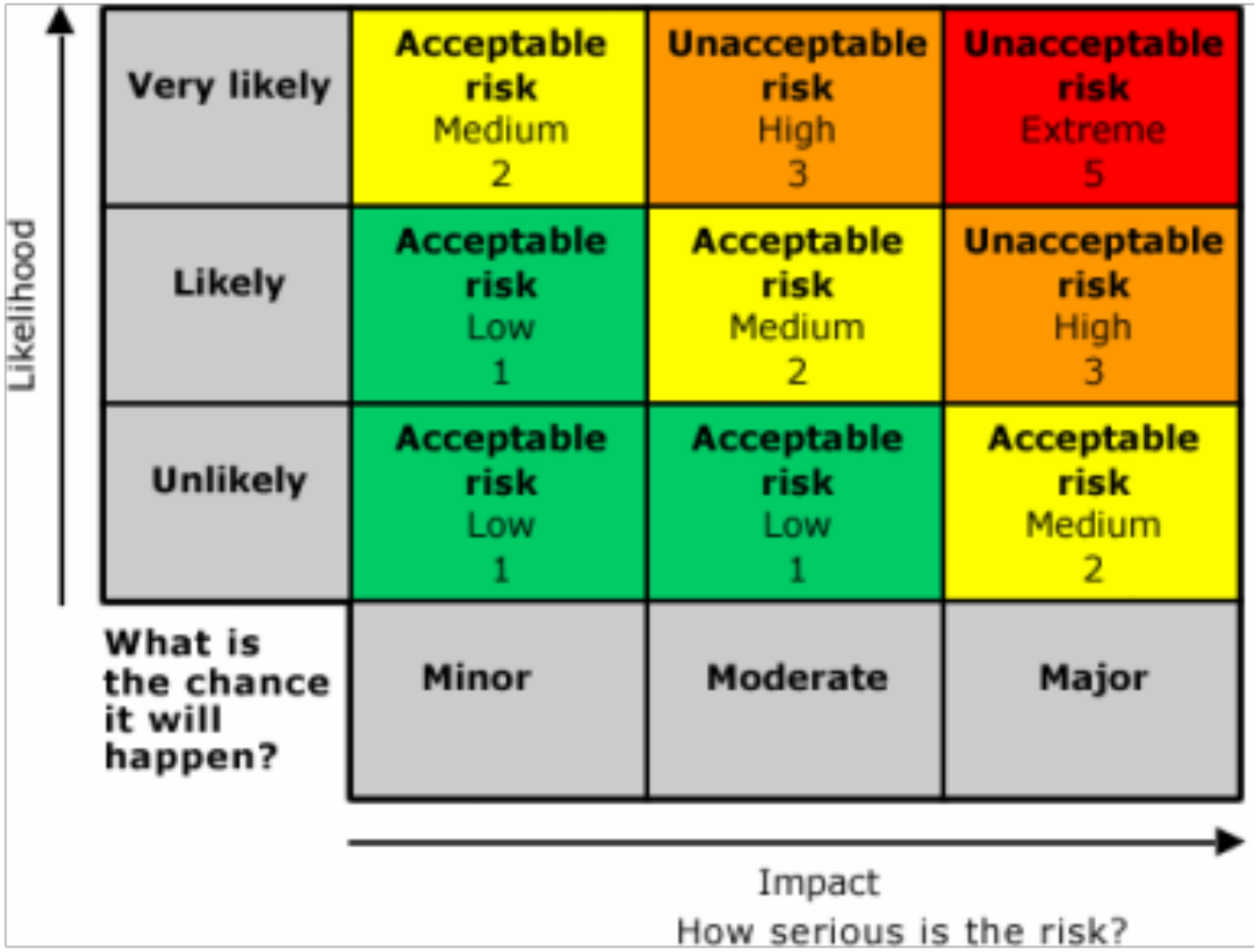
Calibrating equipment yourself – guidelines

Why calibration is important?

- Calibration eliminates waste in production, such as recalls required by producing things outside of design tolerances.
- Calibration helps identify and repair or replace manufacturing system components before they fail, avoiding costly downtime in a factory.
- Calibration prevents both the hard and soft costs of distributing faulty products to consumers.
- With calibration, costs go down while safety and quality go up.

Contingency plans

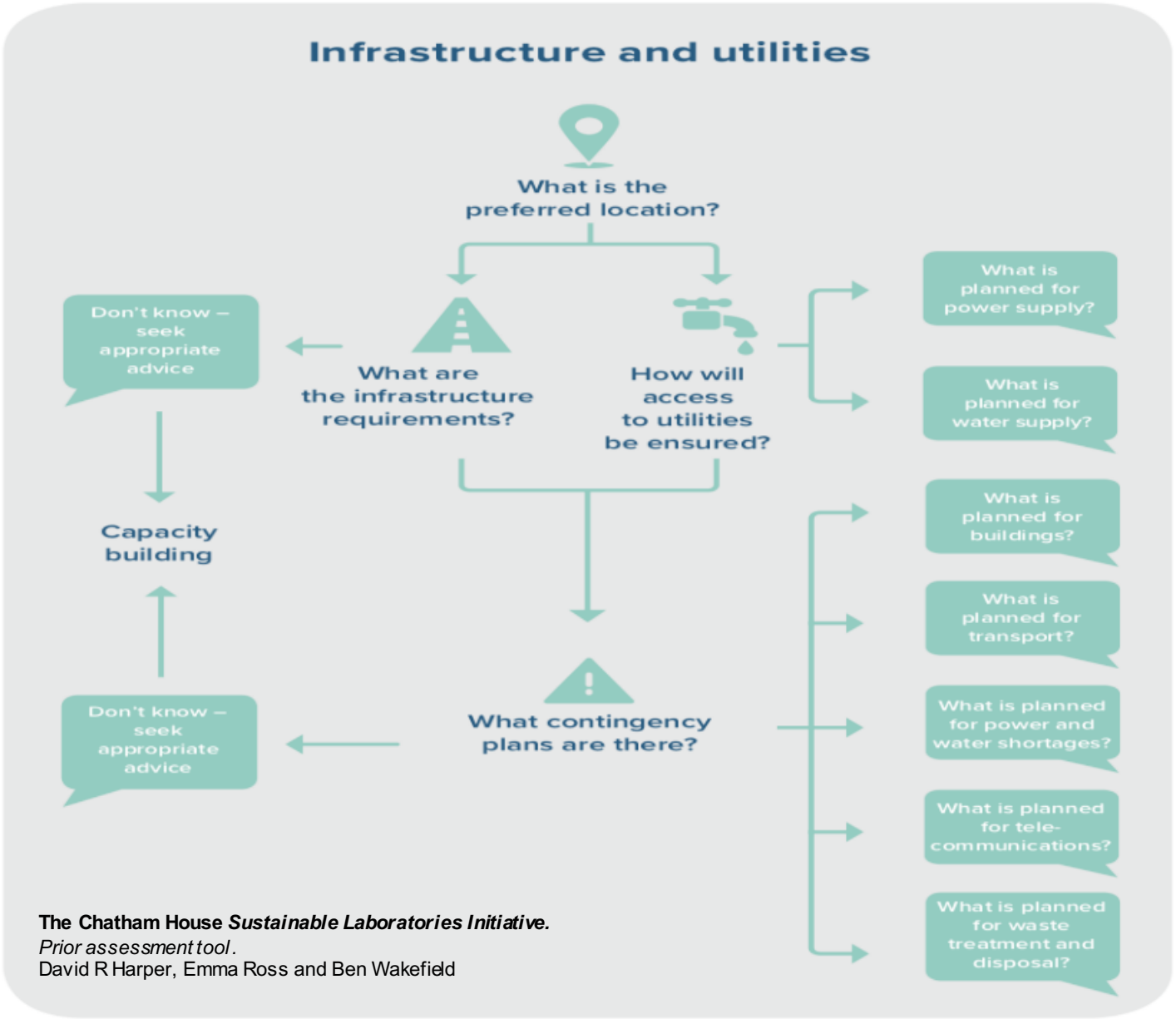
Contingency plans



Contingency plans

Contingency plans

- Space Planning
- Safety Equipment
- Backup Equipment (Redundant)
- Business continuity plan
- Involving staff
- Will management buy-in?



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ALERRT
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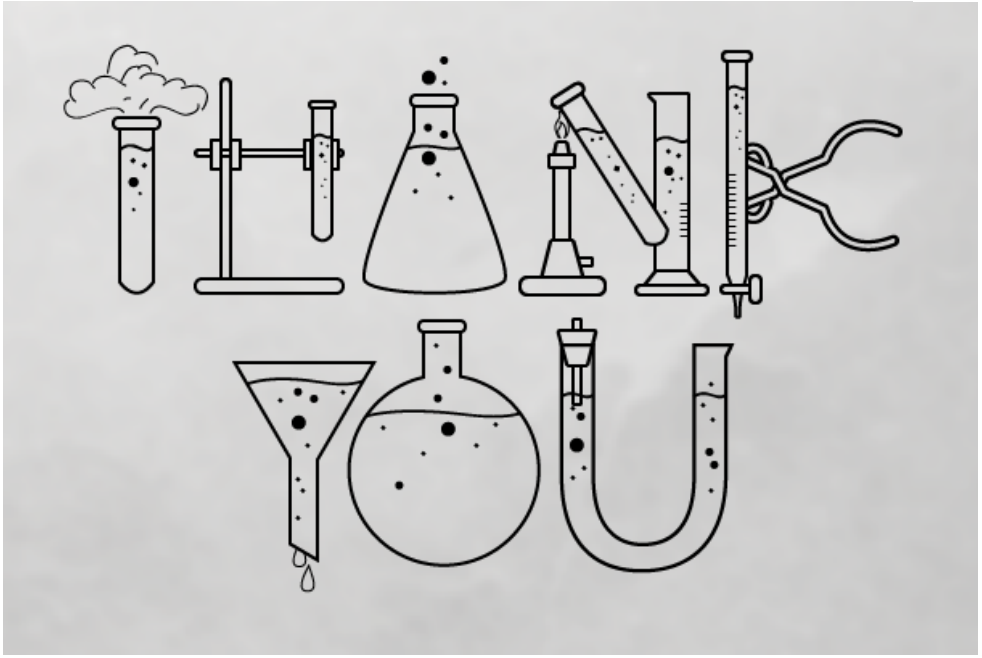

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