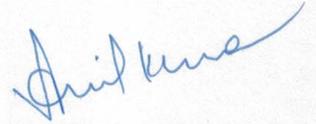


Z.28015/03/2021-MH.II
Government of India
Dte.GHS, Ministry of Health and Family Welfare (MoHFW)
National Council of Secretariat

Nirman Bhawan, New Delhi.
Dated: 08th June, 2021

MINUTES OF MEETING

The minutes of the meeting of the Sub-committee for drafting of Minimum Standards of Collection Centre, point of care testing etc held through hybrid mode, under the Chairpersonship of Dr Promila Gupta, Principal Consultant on 15.04.2021, at Nirman Bhawan, New Delhi are enclosed herewith for information and necessary action.



Dr. Anil Kumar
Addl.DDG

Tel: 011-23061329

Email id dr.anilkumar@nic.in

To

All Participants as per the list at Annexure 1 of the minutes

Copy for information to:

1. PPS to PC(PG), Dte.GHS
2. PPS to JS (PS), MoHFW
3. PA to Addl.DDG(AK), Dte.GHS
4. National Council Secretariat, Dte.GHS

Minutes of the meeting held under the Chairpersonship of Dr.Promila Gupta, Principal Consultant on 15.04.2021 at 2:30 pm Resource Centre, Room No.445-A Wing, Fourth Floor, Nirman Bhavan, New Delhi

A meeting of the Sub-committee for drafting of Minimum Standards of Collection Centre, point of care testing etc. was held under the Chairpersonship of Dr Promila Gupta, Principal Consultant on 15.04.2021 from 2:30 pm to 4:30 pm in the Resource Centre, Room No. 445-A Wing, Fourth Floor, Nirman Bhawan, New Delhi. The meeting was organized through hybrid mode i.e. both physical and online participation.

List of participants is at annexure 1.

After welcome and introduction, Dr Promila Gupta informed the members that the purpose of meeting is to discuss and formulate the Minimum Standards of Collection Centre, point of care testing and any other lab related issues. She emphasised on importance of drafting these minimum standards so that uniformity and accuracy can be ensured in getting Laboratory reports, resulting in better medical care to the patients and overall improvement in the health care services provided.

Soft copies of following documents were shared with participants in advance:

1. Meeting notice with agenda
2. Draft of Minimum Standards of Collection Centre,
3. Draft of Minimum Standards of Point of care testing

A power point presentation was made by Dr.Niharika Singh, Consultant (CE), regarding various agenda points followed by discussions with the participants

The Minimum Standards of Collection Centre

The draft of Minimum Standards of Collection Centre was discussed with participants in a point wise manner and inputs/suggestions were included in the draft. A few points which needed further research/study/confirmation, Dr Promila Gupta asked the subject matter experts to give their valuable and well informed inputs by Email as soon as possible to further improve the draft.

Based on these inputs, the updated draft of minimum standard of collection centres is at annexure 2.

Court case regarding the issue of illegal online health service aggregators

The court case regarding the illegal online health service aggregators operating in Delhi was discussed to bring to everyone's notice the unregulated online health aggregators all over the country leading to faulty/wrong reports and thus wrong diagnosis thus misleading the general public. Dr Promila Gupta said that it's a prevailing problem and these aggregators are not regulated and most of them don't even mention the name of the labs where the samples were

being sent for analysis thus there was no reliability and accountability. They operate through apps etc and are hard to regulate. She then invited the subcommittee member to give their inputs regarding the same. After extensive discussion on the matter it was suggested that we need to make the public aware of such illegal online health aggregators and there is a need for some IT laws/ Digital laws/rules to regulate them. Further it was suggested that it should be mandatory that they have a registration number and they should provide proper information regarding the lab where the samples were being sent for testing.

Dr.Ritu Singh has provided her inputs after the meeting in which she suggested that under “Patient information and Education” a collection centre should also display list of affiliated Labs to which it sends samples with their details regarding NABL accreditation /Lab incharge/addresses etc. She has also provided the list of minimum equipment for Biochemistry lab collection centre with number. The Labs with which the collection centre is empanelled will provide this list as well as Sample collection guidelines to the collection centre.

Further she said that the Online Aggregators who collect from homes and give sample directly to lab should be registered with District Administrations and should provide the list of Labs to which they are affiliated. The labs who are allowing these online aggregators to collect samples for them will be responsible to educate the aggregators about sample collection and transport guidelines.

Dr.Parul Goyal has provided her inputs after the meeting in which she suggested that a collection centre may have tie ups with multiple labs and they can have MOUs signed with more than one lab as this is a business and profit making venture for them.

Centrifuges have calibration certificates and have to get the calibrations done at least once a year. For Legal/ Statutory Requirements she suggested that “wherever applicable” phrase can be added to all the clauses eg GST if applicable, NOC for fire safety if applicable.

Regarding VAT Registration she informed that these days it is GST and that too is applicable only to clinical research.

For Compliance under Air (Prevention & Control of Pollution) Act 1981 she said that Labs are not polluting industries so ideally this is not applicable. In any case only compliance (in terms of yes/no) is required and not certificates

Under “Booklet of SOPs of all procedures available” she suggested that the terminology of 'Booklet' is not appropriate and standard. We can just write “SOPs of all procedures should be available”

The draft of point of care testing could not be discussed as the meeting exceeded the time assigned so it was decided to take it up for discussion in the next meeting of the sub-committee.

The meeting ended with a vote of thanks to the Chair and participants.

Annexure 1

LIST OF PARTICIPANTS

S.No	Name	Designation	Address	Email ID
MoHFW/DGHS				
1.	Dr.Promila Gupta	Principal Consultant	Dt. GHS	Gupta.promila@nic.in
National Council Secretariat (specific staff)				
2	Dr.Niharika Singh	Consultant CE	Room No-647, NirmanBhawan, New Delhi	ncs.consultantce@gmail.com
3	ShriAtul Gupta	Consultant (IT)	Room No-647, NirmanBhawan, New Delhi 9910875140	atul.gupta11@nic.in
4	Mrs.Anuradha	Statistical Assistant	Room No-647, NirmanBhawan, New Delhi 9654638860	anusharma.ani@gmail.com
Representatives of Associations/ Subject Experts				
5.	Dr.RajniGand	Professor and Head Department of Microbiology.SJH		Rgand2@hotmail.com Rgand5@hotmail.com
6.	Mr. Aanjaney Shahi	Senior Consultant (NHSRC)		Nhsrc.india@gmail.com
7.	Dr Atul M Kocchar	CEO NABH	Representative QCI	ceo@nabh.co
8.	Dr.Punam Bajaj	Director NABH		punam@nabh.co
9.	Dr SumitSundriyal	Representative NABL		ceo@nabl.qcin.org
10.	Dr RituKulshrestha	Representative NABL		
11	Dr.NishantVerma	Micro. (AIIMS)		drnishant2K@yahoo.co.in
12	Dr.ShyamPrakash	Associate Professor Bio. Chem/. Lab. Med. (AIIMS)		prakashaiims@gmail.com
13	Dr.SudipDatta	Associate Professor Bio. Chem/. Lab. Med. (AIIMS)		dr.sudipdatta@gmail.com
14	Dr Ganesh Kumar Viswanathan	Assistant Professor		ganesh@aiims.edu

		Dept. of Hematology (A.I.I.M.S)		
15	Dr.MeetuAgrawal,	Department of Pathology, Safdarjung Hospital & VMCC		meetu.dr.meetuagrwal@gmail.com
16	Dr.AmitaYadav	Department of Biochemistry, Safdarjung Hospital & VMCC		dramita.md@gmail.com
17	Dr.RavinderKaur	HOD Microbiology. (LHMC)		drkaur@hotmail.com
18	Dr Ritu Singh	Director Professor & HOD Deptt. of Biochemistry LHMC		drritusingh19@gmail.com
19	Dr.GarimaBaweja	Department of Pathology, ABVIMS &Dr.RML Hospital		garima228@yahoo.com
20	Dr. Mala Chhabra	Department of Microbiology, ABVIMS &Dr.RML Hospital		malachhabra@yahoo.co.in
21	Dr.ParulGoyal	Professor, Dept of Biochemistry, ABVIMS &Dr.RML Hospital		drparulgoyal@yahoo.com

Minimum Standards for Collection Center

Template for Minimum Standards for Collection Center	
The Compliance to the minimum standards for collection centre will be the responsibility of parent laboratory.	
Definition	Collection Centre for Pathology/Microbiology/Biochemistry Laboratories
Scope of Services	<p>Patient preparation</p> <p>Collection and labeling, preliminary preparation (if applicable), storage and transport of human sample/specimens e.g. Blood, sputum, stool, swabs, urine etc.</p> <p>Maintaining the integrity of the test sample at all the stages of collection, labeling handling, storage and transportation till it is received in the testing medical diagnostic laboratory.</p> <p>Receiving of samples/specimen collected at home/hospitals/health centre/clinics/field (provided the sample integrity is maintained). It is desirable that such samples should be directly deposited in the Medical diagnostic laboratories.</p>
Infrastructure	1. Location: Easily accessible and as per State
	2. Signage
	2a. Informative Signage – A signage within or outside the facility should be made available containing the following information
	a) Name of the collection center (if applicable)

	<p>b) Name of the person in-charge of Collection center with qualification and registration number if applicable.</p> <p>c) Name of the associated parent laboratory (ies).</p> <p>d) Accreditation with any agency/organization (if applicable)</p>
	<p>e) Entry / patient waiting area</p>
	<p>f) Reception and registration area</p>
	<p>g) Specimen/sample collection area</p>
	<p>h) Specimen/sample receiving and sorting area (if patient is bringing the sample from home etc)</p>
	<p>i) Timings of the facility and collection of report.</p>
	<p>j) Internet facility (Website/email) or Telephone and mobile number for appointment.</p>
	<p>2b. Safety Signage's (wherever applicable)</p> <ul style="list-style-type: none"> • Safety hazard and caution signs • Biomedical waste segregated in colored bins and bags as per Biomedical Waste Management Rules, 2016 including radioactive materials, toxic chemicals, microbial agents, infected biological material.
	<ul style="list-style-type: none"> • Appropriate fire safety provisions like Fire exit ,available water, minimum one fire extinguisher etc as per applicable State/ local laws
	<ul style="list-style-type: none"> • Emergency shower and eye flushing facilities; drainage to a

	separate holding area (desirable)
	3.Space Requirement - sample collection area must be secure with restricted access to dedicated staff only
	<p>a) Reception, Registration (computerized desirable), billing and report handover and patient waiting area, Public Utilities, Safe drinking water etc.</p> <p>b) Disabled friendly entry(desirable)</p>
	c) Sample collection area including patient toilets (this area may also be located remotely in Ambulatory Care areas); the collection area shall have a workbench, comfortable chair with arm rest for patient seating and hand washing facilities (wash basin)
	d) adequate diffuse and spot lighting(desirable)
	e) Separate toilet for male and female. (desirable)
	f) Staff room -Male and female different where 24 hours services are being provided(desirable if applicable)
	g) Washing area (for laboratory use)
	h) Area for Preservation of the specimens and slides
	i) Electrical facilities with 24hrs

	back up. (if applicable)
	j) Ambient temperature control for specialized equipment ex. Refrigerators, autoclave for sterilization etc.(If applicable)
	k) FNAC room with bed and chair etc for sample collection(if applicable)
	l) Couch or Couch like bed for management of Vasovagal Syncope or hypoglycemic attacks.
	m) Counseling room/ separate area for HIV counseling etc
	4. Furniture & Fixtures – as per the scope of services
	5. Communication system –Telephone / mobile number/ email/ website for appointment etc
	6. Wash basins- (number as per scope of services)
	7. Patient Information and Education- A directory of services provided including list of type of investigation sample type and rate/charges i.e., Special and routine tests
Human Resource	Lab technician with qualification as per minimum standards of laboratories (minimum 1)
	Support staff like Lab assistant /Lab attendant/ Phlebotomist, and housekeeping staff etc (as per scope of services)
	Periodic health checkup and vaccination for hepatitis B and tetanus for staff with records to be maintained.
Equipment / Instruments / Drugs	List of minimum Equipment with

	number.(as per scope)
	List of minimum inventory needed for Sample/Specimen Collection.(as per scope)
	List of reagents and Consumables required.(as per scope)
Legal/ Statutory Requirements	Legal / statutory requirements such as registration with State Pollution Control board with registration number and date of expiry (if applicable). Site, Space, Location and building and fire safety requirements to be as per State/local bye law
	Bio-medical waste(BMW) collaboration certificate with any agency/local authority etc(if applicable)
	NOC for Fire Safety (if applicable)
	Collection Center agreement /MOU with medical diagnostic laboratories.
	Compliance under Water (Prevention & Control of Pollution) Act 1974(if applicable)
	Compliance under Air (Prevention & Control of Pollution) Act 1981(if applicable)
	Hg free environment (no mercury instruments) (if applicable)
Record Maintenance (with appropriate access control)	Daily logs for refrigerator, centrifuge, room temperature and humidity etc.
	Reports of patients date wise and specialty wise for ex Histopathology, Cytology, Hematology and Laboratory Medicine etc. including electronic records to be maintained.(if applicable)
	Medico legal records if applicable
	Annual Maintenance records for

	equipment/instruments.
	Record of technicians/Phlebotomist etc working in collection center indicating their details of qualification training and others. Degree/ diploma certificate of lab technicians working in collection
	Instruments' and equipment calibration records/certificates as applicable
	Availability of reference SOPs in hard or soft copy (desirable)
Standards on Basic Processes (SOPs)	Compliance to infection Control practices
	Compliance to BMW management as per latest Bio Medical Waste Management Rules. BMW disposal collaboration certificate with any agency/local authority etc.(if applicable)
	Document of specific instructions for proper collection and handling of primary samples e.g. order of draw of samples including duration of preservation of record
	Proper labeling- it desirable to have barcoding of samples to maintain sample identification and avoid mixing up Packaging of sample/specimen and proper transportation including compliance to temperature maintaince requirement and transit time as per SOPs of samples/ specimen
	Safety considerations-Fire safety, First aid measures to be taken and use of disposable needles, syringes, vacutainer etc.
	Management of Vasovagal Syncope : as per SOP (Couch or Couch like bed is required)

	Spillage : Management of blood / mercury spills etc. as per SOP
	Occupational Safety: Needle stick injury and the action taken as per SOP and report to be maintained.
	Patient Information and Education including the list of affiliated Labs to which it sends samples with their details regarding NABL accreditation /Lab in charge/addresses etc
	Process of calibration of equipment and instruments. (desirable)
	Grievance Registration and Disposal mechanism