Management Review of SNSC performance based on internal audit Audit cycle-II - July to December 2011 Dated 10.3.2012

Attendance: By list (Sheet enclosed). The representations were from the SN main lab for hematology and clinical pathology, routine biochemistry, sp. biochemistry, Microbiology and serology, Histopathology, cytogenetics and the support services, CSFU, HRD, Commercial, Housekeeping, Biomedical, Electrical and all Internal auditors.

The stipulated agenda points presented by the Quality Manager, Dr. N. Angayarkanni.

1. Follow up of previous management review
2. Status of Corrective and Preventive Actions taken (CAPA)
3. Report from Managerial and supervisory personnel of each of the lab on QC/Measures
4. Out come of recent internal audits, NC's.
5. Assessments of external bodies.
6. Outcome of Quality Control: External/Internal/Daily of each lab: EQAS, ILQC.
7. Volume and type of work undertaken.
8. Feedback including complaints and other relevant factors for Internal and external
9. Quality Indicators for monitoring the laboratories contribution to patient care
10. Non-conformities.
11. Monitoring Turn around time.
12. Continual improvements.
13. Evaluation of suppliers.
14. Points for Discussion for action

The details on each of the points are self explanatory on the slides enclosed.

Audit Team Members and Audited labs:

- Quality System : Ms. Mohanambal
- Front Office / Reporting: - Ms. R.Punitham
- Collection/Pre analytical area: Dr. B. Mahalakshmi.
- Clinical pathology and Hematology: Dr. K. Coral
- Clinical and Special Biochemistry: Ms. R. Selvi
- Clinical Microbiology and Serology: Ms. Soumya
- Histopathology and cyto pathology: Dr. Doreen Gracias
- Human Resource Department : Dr. N. Angayarkanni
- Commercial and stores: Ms. Mohanasundari
- Central Sterilization facility : R. Selvi.

KEY POINTS

1. **Recertification** : We have received the NABL certificate for third consecutive year with validity period of 4.8.2011 to 3.8.2012.

Number of tests accredited as in the Scope :

1. Clinical Hematology 20 and clinical pathology : 22
2. Clinical and special Biochemistry. 27
3. Clinical Microbiology and Serology22
4. Clinical Histopathology 15
5. Cytopathology : 8

New tests added /removed from the scope

a: Cl Microbiology and serology : removed Immuno fluorescence stain for HSV)
b. Main lab. : removed cloting time and Mantox

2. **New signing Authority**

1. Dr. Coral Miriam Magdalene name included in the Clinical Biochemistry will be followed up during surveillance.
2. Ms. Mohana sundari name requested for the Clinical Microbiology and serology needs follow up with NABL. (Pending with NABL).

3. **New post created**
   1. The technical staff number is adequate.
   2. Six new senior technicians appointed in all labs.
   3. Two lab assistant posts converted in to technician post.

4. **Promotions :** No promotions.
5. **Reporting system**
   1. Copy report issued by the respective consultant secretary.
   2. Lab reports can be viewed at all locations by the consultant and nursing dept, physician by HMS and EMR.
   3. Monthly stats for measure of TAT on "collection to report generation" can now be done in HMS-data will be given by IT on request
   4. Specimen transport entry registration made online.
   5. Training classes conducted in each lab has been entered in HMS and Heads of the lab shall ensure the same.
   6. Feedback analysis for the patient is done by HMS by the Main laboratory. IT shall give details on request by the Lab
   7. Outsourced sample reporting is uploaded through HMS and viewed by all he consultants through EMR.

8. Needle prick procedure and the spillage procedure are revised and implemented in SOP and available in intranet for easy access. Implemented date: 10.12.11

6. Version numbers of documents revised in 2011 (July to December)

1. Quarterly summary for reporting to QM : SNSC/QREP/2011/isu-1.3
2. Histopathology Form and Reporting form-F/SNSC/OP/HREP/Rev.1.

7. The QC reports of all the laboratories are satisfactory and CAPA filed as applicable.

8. The Quality Indicators:

The measures of Pre analytical/Analytical/ post analytical issues – is satisfactory and CAPA is filed wherever there is a fall. Corrective action taken.

a. Specimens receiving/TAT/ satisfactory and met the objectives in all the labs.

b. Machine downtime is within objective. No delayed reporting in all the labs.

9. New machineries were installed.

a. Clinical Haematology & Clinical Pathology : 1. Coagulometer installed 11.8.2011.
2. Vesmatic -20 installed on 20.07.2011

b. Clinical Microbiology & Serology : Laminar flow hood installed on 12.11.2011

10. Continual Improvement.

a. Interfacing of the Clinical Hematology, Clinical Biochemistry, Clinical Pathology results with HMS and specimen entry made on line since 11.7.2011
Manual entry in the ledger and data entry in the computer system was reduced and automatic up date with the systems for reporting

b. Five senior technician posts have been created by converting the Technician and lab assistant post based on Qualification and other eligibility.

c. With the help of IT, report and copy generation through HMS by authorized personals completely implemented. Copy report given to the patients through DPS-consultant secretaries identified /lab enquiry. Copy reports are also issued in the lab enquiry on patient request, without sending the patient to each lab. Hard copy reports stopped for MRD.

d. New joiners who completed technical training, evaluation- after 6 months probation.
-Clinical Main lab.
1. Ms. Brinda, 2.Ms. Priya, 3. Ms.M.Sumathy,
4. Mr. Purusothaman, 5. Ms. Rajalakshmi

e. Plasma glucose sample cup has been used for estimation. The tubes are adjusted without using the cups and the cost is reduced to Rs-2/- per cup.

f. Separate record for cytology and histopathology correlation of specimens received.

g. Uploading histopathology and cytology reports online in case of SN patients from11th October 2011
h. For Quality of reporting FANA dilution of serum has been increased to 1:40, 1:80, 1:160 dilutions.
i. Registered for ANAEQAS programme conducted by Institute of Quality Assurance, Euroninum Germany, for detection of ANA by Immuno fluorescence method and ELISA method.
j. Department time was changed to 8.00am to 6.00pm- Clinical microbiology and Serology
k. Qualitative of HIV, HBsAg, HCV, ANA screening, ANA SLE profile were performed- Clinical microbiology and Serology
l. Single channel pipette changed to multi channel pipettes for faster work at Clinical microbiology and Serology
m. Scope for needle prick injury revised and updated in QSM.
n. Co-ordinated activity for NABH by providing monthly, quarterly indicators .

Non NABL

- Bicarbonate / Lactate/ pyruvate : introduced kit method in place of manual. (Non NABL)
- Out source test Uric acid implemented in special biochemistry lab. (Non-NABL)
- Zinc /Copper and other element analysis is offered for diagnostics (Non-NABL)

11. Feedback analysis

a. Analysis of internal customer feedback: revealed that the statistics with regards to the no of forms issued/collected was maintained. The measure was 86.6 % at main lab for the internal customer (consultant, physician, nursing and surgery fixing centers).
b. External Customers: Around 10 to 15% of Questioner collected form the out patients every month and consolidated the suggestions for analysis. Complaints were acted upon and 17 points were addressed in the MR meeting.
c. Microbiology and Histopathology also done the feedback analysis and its satisfactory levels are checked and suggestions were addressed.

12. Vendor Evaluations

1. The approved vendor list prepared by the commercial after evaluation was presented the same will be circulated to all labs. No vendor is removed from the list.

Other information

- The non-technical and the technical training schedule in all the labs were satisfactory. The evaluation component done and documented. For the Main lab technical staff. All the other labs have been advised to do the same in the forth coming year
- Tamil Nadu Pollution control Board certificate for disposal of waste has been received and the validity is till March 2012. Waste disposal is done by G.J multiclave it will continue. For renewal of the certificate initiation done.

- Strategies to improve the collections and the number of investigations :- **Brochure is prepared** for SNSC clinical laboratory but has not been approved by GM due to fresh plans on diagnostics.

- IT related issues completed. :Lab reports can viewed at all locations by the consultant and nursing dept, physician by HMS and EMR.

Reminders:

- Reviews: of contracts / records / SOP/ Calibration plan / status documentation of the obsolete record shredded
- Inputs for vendor evaluation / material specification sheet to be monitored.
- Interaction with clinical consultants to be documented and sent to QM for record.
- Protocols to be followed on inclusion of new tests and included in the collection manual.
- Safety measures to be reviewed and training implemented/ evaluated
- CAPA: Effectiveness of preventive actions to be evaluated
- Quality Check of stored specimen is documented.
- Quality Plan for the year 2012 to be framed and all HOD to send their plan to QM.
- The next internal audit is due in June 2012.

Thank You

Forwarded by:

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Date: 14.03.2012.

Management Review of SNSC performance based on internal audit
Audit cycle-I - January to June 2012
Dated 29.08.2012

Minutes of the MR meeting : Prepared and presented by the QM, Dr. N.Angayarkanni discussed in the laboratory service meeting attended by the Heads of all the laboratories as headed by the MR – NABL and the Director of the laboratory Dr.SB Vasanthi

Attendance: By list (Sheet enclosed). MR, QM, Heads of the laboratories, Technical Manage, Dy.Tech Managers, Secretary -NABL

The stipulated agenda points discussed .

1. **Follow up of previous management review**
2. **Status of Corrective and Preventive Actions taken (CAPA)**
3. **Report from Managerial and supervisory personnel of each of the lab on QC/Measures**
4. **Out come of recent internal audits, NC's.**
5. **Assessments of external bodies.**
6. **Outcome of Quality Control: External/Internal/Daily of each lab: EQAS, ILQC.**
7. **Volume and type of work undertaken.**
8. **Feedback including complaints and other relevant factors for Internal and external**
9. **Quality Indicators for monitoring the laboratories contribution to patient care**
10. **Non-conformities.**
11. **Monitoring Turn around time.**
12. **Continual improvements.**
13. **Evaluation of suppliers.**
14. **Points for Discussion for action**

Details on the agenda points :

1. Previous Management Review Meeting Minutes was reviewed

- **Audit Team Members and Audited labs : Current Internal Auditors Under the scope of NABL**
  - Quality System : Dr. B. Mahalakshmi & Ms.Gayathri
  - Front Office / Reporting: Ms. Mohanasundari & Ms.Jayanthi
  - Collection/Pre analytical area: Ms. Mohanasundari & Ms.Jayanthi
  - Clinical pathology and Hematology: Ms. Mohanasundari & Ms.Jayanthi
  - Clinical and Special Biochemistry: Ms. Saumya
  - Clinical Microbiology and Serology: Dr. Doreen Gracias & Ms.Kamatchi
  - Histopathology and Cytopathology: Ms. R.Punitham
  - Human Resource Department : Ms. R. Selvi
  - Commercial and stores: Dr. K. Coral
  - Central Sterilization facility : Dr. N. Angayarkanni & Ms.Jayanthi

Non NABL :

- *JKCN Lab : Ms.Vanitha*
- *Navasuja Lab : Ms.Vanitha*
- *Cytogenetics : Ms. Mohanambal*

2. Status of Corrective and Preventive Actions taken (CAPA) The QC reports of all the laboratories verified every quarter . The following are the details of CAPA filed

a. EQAS Clinical Haematology & Clinical Pathology lab : Unsatisfactory –1 CAPA filed
b. EQAS Clinical Biochemistry : Unsatisfactory – 1 CAPA filed
c. EQAS Microbiology & Serology : Unsatisfactory – 1 CAPA filed
d. ILQC Special Biochemistry : Unsatisfactory – 1 CAPA filed

3. Report from Managerial and supervisory personnel of each of the lab on QC/Measures

a. Copy report issued by the respective consultant secretary.

b. NABH requirement : The copy reports are given by the floor coordinator

c. On line verification done by the technician and supervisors in all laboratories implemented completely.

d. Lab reports can viewed at all locations by the consultant and nursing dept, physician by HMS and EMR.

e. Monthly statistics for measure of Turn around time (TAT) on "collection to report generation" can now be done in HMS and data will be given by IT on request

f. Specimen transport entry made online.

g. Training classes conducted in each lab has been entered in HMS and Heads of the lab shall ensure the same.

h. Feedback analysis for the patient is done by HMS by the Clinical Haematology & Clinical Pathology lab. IT shall give details on request by the Lab

i. Outsourced sample reporting is uploaded through HMS and viewed by all the consultants through EMR.

4. The First internal audit January to June'12 has been conducted by the trained and Approved internal auditors and details are given the Technical manager / internal auditors and Dy Tech managers of each lab as supervised.

5. Assessments of external bodies: updated in all the laboratories :

a. Tamil Nadu Pollution control Board certificate for disposal of waste has been received and the validity is till October 2012. Waste disposal is done by G.J multiclave it will continue. For renewal of the agreement done on May 2012.

b. Assessment of the referral labs updated by all the departments.

6. Outcome of Quality Control: External/Internal/Daily of each lab: EQAS, ILQC.

- **The QC reports of all the laboratories (Refer Point No.2)**

7. <u>Number of tests accredited as in the Scope :</u>

- **Revised Scope : We have received the NABL certificate with revised scope on 18.05.2012 with validity period of 4.8. 2011 to 3.8.2013.**
  - **a. <u>Clinical Hematology</u> : 19 <u>and clinical pathology :</u> 20**
  - **b. <u>Clinical and special Biochemistry</u> : 26**
  - **c. <u>Clinical Microbiology and Serology</u> : 26**
  - **d. <u>Clinical Histopathology</u> : 14**
  - **e. <u>Cytopathology</u> : 8**

Total: 113 Tests

- **New tests added /removed from the scope**
  - **a. Cl Microbiology and Serology :** Removed Immuno fluorescence stain for HSV
  - **b. Clinical and Special Biochemistry :** Amino acid profile CV% changed as in revised scope Dated : 18.05.2012

- **New signing Authority**
  - a. Dr. Coral Miriam Magdalene name requested for the Clinical Biochemistry needs follow up with NABL. (Pending with NABL).
  - **b.** Ms. Gayathri name requested for the Clinical Microbiology and serology **needs** follow up with NABL. (Pending with NABL).

- **New post created**
  - **a.** The technical staff number is adequate.
  - b. 7 New senior lab technicians are appointed and trained for Clinical Haematology & Clinical Pathology lab.
  - c. One secretary appointed for assistance on the NABL work

- **Promotions/resignations :**
  - c. Three lab technicians promoted as Senior lab technicians-(Microbiology & Haematology)
  - d. One lab technician promoted as Junior Executive (Microbiology)
  - e. One secretary promoted as Junior Executive (NABL)
  - f. One Junior executive promoted as Executive (Histopathology)
  - g. Ms. Sagaya Shylaja completed technical training evaluation after 6 months of probation.
  - h. 4 technicians, Three Secretaries resigned before probation period in Clinical Haematology & Clinical Pathology lab.
  - i. One Junior Scientist, One Senior Lab Technician and Two Secretaries resigned before probation period in Microbiology lab

8. Feedback analysis

a. Internal customer feedback: The observed measure was 86 % (Jan – Jun 2012) for the expected 80% in the Clinical Haematology & Clinical Pathology lab).

b. External Customers: 20 types of feedbacks (after grouping) were analyzed and 2 was proceeded with action and settled.

c. Microbiology and Histopathology : has done their feedback analysis and its satisfactory levels are checked. In Histopathology suggestions were addressed and settled.

9. Quality Indicators for monitoring the laboratories contribution to patient care

a. Specimens receiving - Satisfactory and met the objectives in all the labs**.**

b. Turn around time – Biochemistry – Below the objective - 1 CAPA filed
Histopathology– Below the objective - 1 CAPA filed

c. Machine downtime – Histopathology – Unsatisfactory – 1 CAPA filed
Microbiology - Unsatisfactory – 1 CAPA filed

10. The entire NC raised in the internal audits is closed (Except CSFU)

11. The measures of Pre analytical/Analytical/ post analytical issues (Refer Point No.9)

12. Continual Improvement.

a. Interfacing of the Clinical Hematology, Clinical Biochemistry, Clinical Pathology
b. Online verification by the technician started from 06.07.12
c. Plasma Homocystenine- introduced commercial quality control materials for method validation
d. ACE test was shifted from semi auto mated method to spectra max e2 for better accuracy and precision from February 2012
e. Quantitative estimation of CRP and RA factor in human serum, by Nephlometry methodology, using Agappe kit.
f. Introduction of 17 hrs of processing schedule for eyeballs.
g. Introduction of staining procedure for PAS stain
h. Ms. Mohana Sundari name was included as Authorised Signatory for Microbiology from 2nd July 2012.

i. New machineries

Histopathology : Purchase order sent for new Trinocular Microscope
Clinical Pathology : Machine Merck- Uriscan proII with external Barcode Reader Installed in Clinical pathology on 12.05.12.
Clinical Haematology: Microwave oven for electrophoresis installed on 29.06.12

j. Version numbers of documents revised in 2012 (January to June)

a. Referral Lab Evaluation Form : REF/SNSC/10/Version 1.3
b. Histopathology Feed back Form : F/SNSC/OP/CFF – Rev.1

k. Training programme: elaborate SOP is now given in the QSM/QSP

Regular attendance by all technicians for soft skill training programme / evaluation / feedback and documentation of the same is now initiated. The newly created training department shall have all the details apart from the respective laboratories.

l. Promotions & New posts created & New signing Authority (Refer Point No.7)

Non NABL : *JKCN and NSN labs are now included in the internal audits during the internal audit of the NABL*

- *Uric acid kit changed with spin react company. (Non-NABL)*
- *Software : All the department staff attended a webminar with an online demo of the software from Progeny, UK. Progressively trial version of the software is being installed in the department.(Cytogenetics)*
- *Techniques : To improve the G banding method and lessen the time period for report generation. Standardization of the method is under progress (Cytogenetics)*
- *Training Plan : A theory class on FISH (Fluorescent in-situ hybridization) was conducted by Ms.Srilekha on 12.04.12 (Cytogenetics)*
- *Equipment : 2-D Bar coding system - The equipment is budgeted and has been approved by VRF. (Cytogenetics)*

13. Vendor Evaluations

- **The approved vendor list prepared by the commercial after evaluation was presented the same will be circulated to all labs. No vendor is removed from the list.**

14. Other information:

- **DESKTOP AUDIT** : Desk top audit was conducted by NABL (June 2011 to May 2012) data was sent to NABL office. The result is awaited.

- **Reminders:**
  - **Reviews: of contracts / records / SOP/ Calibration plan / status documentation of the obsolete record shredded**
  - **Inputs for vendor evaluation / material specification sheet to be monitored.**

- **Interaction with clinical consultants to be documented and sent to QM for record.**
- **Protocols to be followed on inclusion of new tests and included in the collection manual.**
- **New books to be purchased to update the SOPs in all the laboratories.**
- **Safety measures to be reviewed and training implemented/ evaluated .**
- **Quality Plan for the year 2012 to be completed by the respective HODs.**
- **Documentation and Evaluation of training has to be effectively implemented through all the laboratories in co-ordination with the training department .**
- **It is strongly advised that all the CAPA are filed on the same day and the action completed at the earliest.**
- **The next internal audit is due in December 2012.**

Thank You

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Date: 29.08.2012.