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Motivation, support and cooperation by health care professional towards achieving accreditation at a small sized HIV laboratory in government hospital

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INTRODUCTION

Accreditation is understood as a procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks as given in the terms and definition in ISO 15189:2012. 1,2 In India, NABL is an autonomous body whose objective is to provide third party assessment of quality and technical competence.3,4

FACILITIES AVAILABLE IN 2007

Centre for HIV Testing (CHT), LHMC (Lady Hardinge Medical College) is recognised as State Reference Laboratory (SRL) by NACO. It receives samples for EQAS from linked ICTCs, PPTCTs and blood banks. It was a one-room laboratory, understaffed; only few files were maintained, few equipments were available and calibration of micropipettes was done in the laboratory by technicians (in-house procedure). The first round of independent external SRL assessment was done by NACO to determine the level of adherence to the 12 Quality system essentials (QSEs) as per CLSI & ISO 15189:2007.5,6 The laboratory scored a total of 130 out of a maximum of 244 (53%) achieving a 2-star status.

STEPS TOWARDS ACCREDITATION

The accreditation of CHT laboratory was started by focusing primarily in following areas.^{7,8}

Human resource

Two trained laboratory technicians and a technical officer were appointed by DSACS-NACO with welldefined roles and responsibilities in the laboratory. A quality manager trained in 'Laboratory quality

management according to ISO15189:2007 and Internal Audit' was appointed in 2011.The core responsibility of the quality manager was to address all the issues of laboratory and monitor adherence to ISO 15189 standards.

Documentation

Standard operating procedures (SOPs), Quality supporting procedures (QSPs), equipment laboratory maintenance files, budget records, correspondence files, personal files, immunization records of staff, outdated records and internal audit and management review records were maintained as per ISO 15189:2007.

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Conflict of Interest-none

Funding—none

Equipment

The in-house calibration of micropipettes was one of the non-conformities in the NABL pre-assessment. So calibration of all equipments was outsourced to NABL accredited calibrating laboratory (maintaining

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the traceability). It was ensured that regular scheduled cleaning, disinfection and temperature charting was done for each refrigerator, incubator and deep freezer using digital thermometers provided for each refrigerator. All possible measures were taken to control various factors affecting the quality of test results.

Infrastructure

A common room of HIV laboratory was compartmentalized into four separate strictly isolated areas each defined for separate functioning i.e. one room each for counseling, testing, primary sample collection and record section in 2009. Biohazard symbol was pasted and restricted entry was enforced in the laboratory. In 2011, the interiors of the laboratory underwent changes when various cupboards, tables, almirahs, working chairs were placed. Arrangements were made for client's comfort in waiting area wherein benches and ceiling fans were provided.

Financial assistance

NACO in collaboration with CDC has extended support to HIV testing laboratories. This includes allocation of funds to DSACS and linked SRLs, provision of kits, consumables and stationery items, appointment of trained staff as well as constant assessments and supervisory visits by experts.

The issues which were found to be pending encompassing all QSEs were addressed within defined time interval (i.e. 3 months) by the laboratory. SRL-LHMC scored 90% in the second round of independent external SRL assessment achieving a 5-star status and CDC appreciated the laboratory's progress. Laboratory applied for NABL accreditation and NABL pre-assessment was held followed by final assessment. CHT LHMC was issued an accreditation certificate (M-0492) by NABL on 23.01.2013.

IDENTIFICATION OF PROBLEMS IN BEHAVIOR AND ATTITUDE OF STAFF

One of the biggest challenges faced by laboratory was motivation of staff towards accreditation. The word 'ACCREDITATION' was itself felt

'UNACHIEVABLE'. The general questions asked were 'What will I get?' or 'Why do we need to work hard for quality?' or 'Is Quality an important issue?' or 'We are doing good work. Why should we do extra effort?' or 'How will accreditation happen without money and infrastructure', etc.

ROLE OF LEADERSHIP IN MOTIVATION OF STAFF

It was emphasized that accreditation is a team effort leading to good quality of results from the laboratory to the clients. 9,10 Frequent interactions with laboratory staff, periodic training, prompt redressal of staff's issues, maintenance of discipline, division of labor, and involvement of staff in quality improvement made a lot of difference in their attitude. These efforts were made constantly and staff's motivation was seen to rise. Competency assessments and quality related assessments were conducted and the passing percentage was defined which gave them a boost to score more. Their ideas and suggestions were always welcome. Staff's knowledge and awareness on the need to use the equipment that are well-maintained, strictly follow standard operating procedures (SOPs) as stated, documentation and participation in all QA programmes to include quality control (QC) and external quality assessment (EQA) was emphasized.

IMPLEMENTATION

The implementation of QMS and laboratory accreditation is a big challenge in developing countries like India. The accreditation of CHT LHMC is attributed to the visionaries at HIV testing laboratory at Lady Hardinge Medical College, a wonderful coordination effort between nodal officer at CHT and NACO-DSACS and constant inspiring effort by laboratory staff.

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