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Direct Observation as an Assessment Tool for Evaluation of Technical Competence of Intern Medical Technologists: A Realistic Approach

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ABSTRACT

Background: Medical laboratories play a vital role in patient care and needs a competent skilled workforce to deliver this essential service. The current process of medical technologist training is a summative assessment consisting of two written 3 hour papers that correlates theoretical knowledge acquired at a tertiary level with the practical internship. There is no requirement for the assessment of technical competence by the Health Professional Council of South Africa (HPCSA).

Methods: A quantitative design was used for assessing the technical competence of the candidates who were eligible to write the National Board Examination by using an adapted South African National Accreditation System (SANAS) witnessing tool across ten Clinical Pathology test procedures by direct observation.

Results: Some candidates that were directly observed in each of the Clinical Pathology test procedures were deemed not yet competent in compliance and adherence to Standard Operating Procedures (SOP's), acceptability of results, internal quality control procedures and the acceptability of the outcome and availability of signed training and competency records on the direct observation checklist.

Conclusion: From this study it can be concluded that assessment of technical competency for Intern Medical Technologists in Clinical Pathology could augment current assessment systems of Intern Medical Technologists for conferment of professional designation and a policy review is recommended.

Keywords: assessment, direct observation, medical education, internship

INTRODUCTION

Medical laboratories play a crucial role in patient care and require a competent skilled workforce, which consists of technical and non-technical staff members to deliver this essential service. The technical staff categories are made up of Pathologists, Medical Technologists, Medical Technicians, and Medical Laboratory Assistants. Medical Technologists are the backbone of the laboratory service because they are mainly responsible for all acts performed during the analysis of all samples and support medical practitioners in the diagnosis and treatment of patients (Africa, 2008). The minimum entry requirement for the National Diploma in Biomedical Technology is a National Senior Certificate (NSC) or Senior Certificate (SC). Scholars are required to comply with individual minimum admissions criteria as well as selection criteria before they are accepted into the programme for Biomedical Technology offered at various Higher Education Institutions

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(HEIs) across South Africa (SA) (Kruger, Eagleton, & Maule, 2016). This full-time, three-year diploma programme is unique to South Africa(Du Pré, 2009). It comprises of two and half years of study at a higher education institution followed by six months of experiential training in the workplace referred to as work integrated learning (WIL). The Society of Medical Laboratory Technologists of South Africa (SMLTSA) National Board examinations are then written after one year of internship has been completed in a registered training laboratory within a chosen discipline. This qualification leads to registration with the Health Professions Council of South Africa (HPCSA) as a fully qualified Medical Technologist. (Kruger & Eagleton, 2017).

The high failure rates of Intern Medical Technologists (MTINs) in the National Board examinations have been an ongoing concern over the last decade (Kruger et al., 2016). Academic staff from Higher Education Institutions (HEIs) and all laboratories involved in the training of learners are required to comply within certain criteria. Learners also have selection criteria, before they are accepted into the programme for Biomedical Technology.

The summative assessment consists of two written 3 hour papers correlating theoretical knowledge that was acquired at the training institution with the practical internship. Once an intern technologist passes this National Board Examination and satisfies all other rules, such as completing a structured practical training in an approved laboratory for a period of at least 12 months as prescribed by the Professional Board for Medical Technology, registration as a fully qualified Medical Technologist with the HPCSA for independent practice follows as the professional body confers the professional designation.

Currently there is no stipulated requirement for the assessment of technical competence of Intern Medical Technologists (candidates) by the HPCSA. The lack of assessment of technical competence makes this important aspect of training of learners to be an optional activity for some clinical training institutions (Carr, 2004). Furthermore, considering paradigm the shift from structure and process based to competency–based education and measurements of outcomes, a single theory assessment method is not optimal for medical professionals (Baartman, Bastiaens, Kirschner, & van der Vleuten, 2007; Baartman, Prins, Kirschner, & van der Vleuten, 2011).

Deliberations with other laboratory managers have revealed fears regarding the current situation where candidates who are technically competent have failed the written Board Examination and, also those candidates who have passed the Board Examination in Clinical Pathology are not yet technically competent in some laboratory processes. This is a serious challenge as these candidates are hired on the evidence that they are “qualified” and have an HPCSA registration for independent practice. To date no study has been conducted regarding the poor pass rates of Intern Medical Technologist in National Board examination in South Africa. This study was undertaken to assess technical competence of candidates by direct observation in a Clinical Pathology discipline prior to them writing the National Board Examination.

METHODS

The Context of the Study

The context of this study is a graduate Clinical Pathology discipline aimed at assessing technical competence of candidates, eligible to write the Board Examination, by direct observation. Currently the assessment being implemented to confer professional designation to Intern Medical Technologists is an external summative written Board Examination. This study sought to present another perspective of practical, technical competence and if attached to other methods of assessment may provide a more integrated assessment of competence for conferring a professional designation into Medical Technology.

The quantitative design was chosen as it was felt it would be appropriate for assessing the technical competence of the candidates within a Clinical Pathology discipline by direct observation that were eligible to write the National Board Examination. A validated structured Likert type questionnaire was used to collect data from the candidates using direct observation. The questionnaire was validated by piloting with 4 newly qualified technologists who had completed their internship.

Study Design and Participants

An observational study, using a structured questionnaire was conducted in nine National Health Laboratory Services (NHLS) laboratories in KwaZulu-Natal. The laboratories were near a semi-urban area. The population comprised Intern Medical Technologists who were eligible to write the forthcoming National

Table 1. Summary of rating categories of competency on the witnessing tool

1. Lacks experience - little or no competency
2. Some experience requires further practice and/or assistance
3. Competent to perform independently
4. Competent to perform independently and train junior staff/students
5. Competent to perform independently and able to assess competency of other Medical Technologists

Board Examination and was therefore convenience sampling. Ethical clearance to conduct the study was obtained from the Durban University of Technology Ethics Committee with clearance certificate number REC138/15.

Inclusion Criteria

- All candidates who are eligible to write the National Board Examination in Clinical Pathology at the nine training laboratories were eligible for inclusion.
- Candidates who had rotated through all three sections (viz. Haematology, Chemical Pathology and Microbiology) of a Clinical Pathology were included in the study.
- Candidates who were medical technicians with prior learning bridging to a Medical Technologist qualification and who were eligible to write the National Board Examination in Clinical Pathology laboratory were included.

Exclusion Criteria

- Candidates who had written the National Board Examination on more than one occasion.
- Those who had participated in the pilot study.

Sample Size

Twenty-eight intern technologists participated in the study (n=28) in which direct observations were conducted by the principal investigator across ten Clinical Pathology procedures. The sample size is justified as it was used in a similar study by Desjardins and Fleming, where laboratories were requested to review their competency assessment records. In this study a randomly selected sample of twenty eight Intern Medical Technologists were recruited. A checklist (modified validated SANAS F15) for direct observation was used to collect the data. The data were collected over a period of two and a half months. The interns were directly observed on different days per Clinical Pathology discipline in their respective laboratory. There were some interns who were not available on the appointment date and the principal investigator set up alternate appointments. All participants gave written informed consent. A letter was issued to each participant to notify the participants about the type of study they would participate in, the possible risks involved, as well as their rights.

Questionnaire

The direct observation tool was adapted from the SANAS F15 Witnessing tool of activity was used to assess technical competencies of the candidates. The witnessing tool had closed-ended statements that were directly observed by the researcher and the technical competencies were assessed using criteria that were graded on Likert scale 1-5, ranging from “Little or no competency” to “Competent to perform independently and able to assess competency of other Medical Technologists” as in **Table 1**.

Direct observation of candidates and the recording of observed scores was undertaken by the principal investigator. The witnessing tool was adapted to answer the objectives of this study and it was validated by way of a pilot study. There was full participation by all intern technologists in ten procedures. The ten Clinical Pathology test procedures that interns were assessed on, for technical competency, were within the three sections of a Clinical Pathology laboratory, i.e., Microbiology, Haematology and Chemical Pathology. These are tabulated in **Table 2**.

Table 2. Clinical Pathology section and test procedures

Clinical Pathology Section	Test Procedure
Microbiology	Tuberculosis (TB) microscopy
	Stool – microscopy, culture and antimicrobial sensitivities
	Urine – microscopy, culture and antimicrobial sensitivities
	Pus swab – microscopy, culture and antimicrobial sensitivities
	Rapid plasma regain (RPR)
Chemical pathology	Chemical Pathology Analyser
Haematology	Full Blood count (FBC) analyser
	Erythrocyte sedimentation rate (ESR)
	Coagulation analyser
	Slide differential count (DIFF)

Table 3. Questionnaires used for witnessing of procedures from Intern Medical Technologists

Section	Questionnaires
A	Comply and adhere to Standard Operating Procedure Question 1 to 10
B	Acceptability of results, as witnessed(where applicable) Question 11 to 16
C	Internal Quality Control procedures witnessed and acceptability of the outcome Question 17 to 24
D	Proficiency testing (PT)/ External Quality Assurance (EQA) programme for this method/test and acceptability of performance(where applicable) Question 25 to 26
E	Reference standards, reference materials and/or controls used (where applicable) Question 27 to 29
F	Equipment used (where applicable) - Calibrations, Maintenance up to date etc. Question 30 to 35
G	Training and competency records of the staff member witnessed for this method Question 36 to 37
H	Accommodation and environmental conditions (where applicable) Question 38

The rationale for selecting ten tests was that they are the most common tests with high test request volumes within a Clinical Pathology HPCSA registered training laboratory. Samples for interns were mainly sourced and utilized from previously analysed patient specimens to allow for comparisons for the analytical part of the test procedure. It must be noted that the procedure for full blood counts was unable to be directly observed for five interns due to replacement of a full blood count analyser in the Haematology section of one laboratory as the interns were not trained on the new full blood count analyser when the competency assessment was conducted.

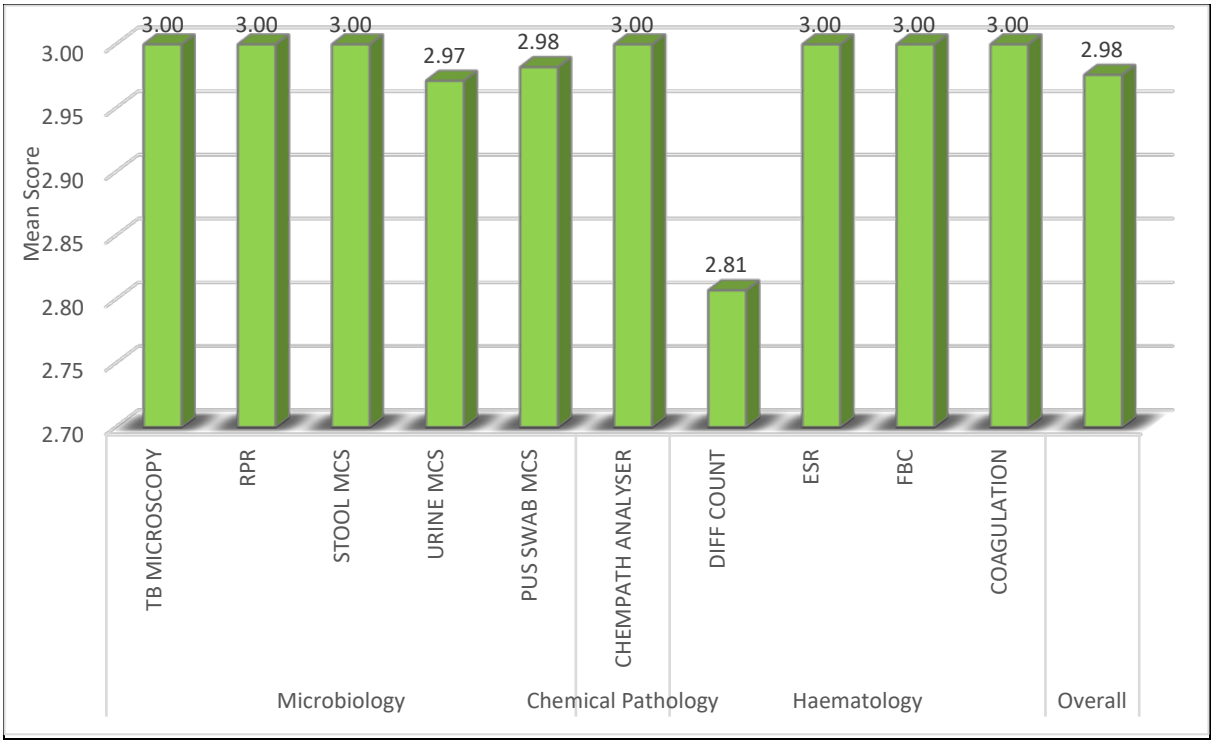
The primary research instrument consisted of 38 items, and the data gathered was ordinal in nature. The questionnaire was divided into 8 sections which measured various themes as shown in **Table 3**.

Data Analysis

Descriptive statistics were used to analyse and describe the sample features. For comparisons, inferential statistics were used which included the use of correlations and chi square test values; which are interpreted using p-values. The data were analysed using the statistical software Statistical Package for Social Sciences (SPSS version 24.0) (Coakes & Steed, 2009).

RESULTS

All candidates who participated in the current study were due to write the National Board Examination in March of 2016 and had completed training in all ten Clinical Pathology test procedures. Data were collected one or two months before the writing of the 2016 National Board Examination and analysed.



3=competent and <3 not yet competent

Figure 1. Mean competency score of candidates for section A- compliance and adherence to SOP's across clinical pathology tests

Compliance and Adherence to Standard Operating Procedure (SOP)

However, during data analysis, scores of 3, 4 and 5 were consolidated as competence, while levels of non-competence were scores of 1 and 2. Descriptive statistics of compliance and adherence to standard operating procedures for intern technologists across ten most common Clinical Pathology tests are as presented in **Table 3** and **Figure 1**.

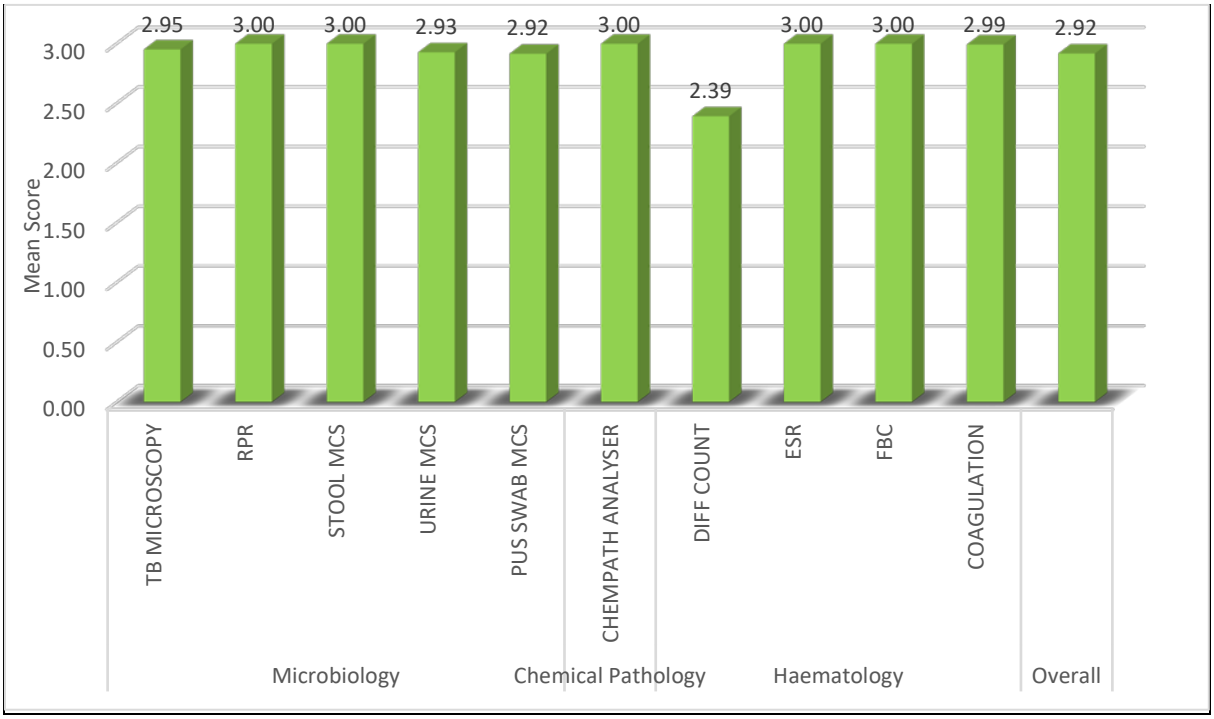
A vast majority, 23 candidates (where n=28, 82%) were competent in the ten Clinical Pathology test procedures assessed except for urine (Microscopic analysis, Culture and antimicrobial Sensitivity) MCS, pus swab MCS and differential count test procedures. However, four candidates for urine MCS, 2 candidates for pus swab MCS and 23 candidates for differential counts were not yet competent to perform the test and follow the procedure correctly according to the SOP. Similarly, 25 candidates were not yet competent to complete all the required documentation for differential counts (**Figure 1**), a mean score of less than 3 indicated that some candidates were not yet competent in the urine MCS, pus swab MCS and differential count as they had some experience, however, required further practice and assistance.

Acceptability of Results, as Witnessed

Most candidates were competent in Clinical Pathology test procedures assessed except for TB microscopy, urine MCS, pus swab MCS, differential count and coagulation test procedures (**Table 4**). Nonetheless, 4 candidates for TB microscopy, 3 candidates for urine MCS, 4 candidates for pus swab MCS and 25 candidates for differential counts were not yet competent (**Figure 2**) to correctly and accurately record all findings. Also, 4 candidates for TB microscopy,1 candidate for urine MCS, 2 candidates for pus swab MCS and 24 candidates for differential counts were not yet competent to follow established procedures for results reporting and entering correctly on laboratory information system (LIS).

Table 4. Different sections in questionnaires used for witnessing of procedures from Intern Medical Technologists

Section A	Comply and adhere to Standard Operating Procedure Question 1 to 10
Section B	Acceptability of results, as witnessed(where applicable) Question 11 to 16
Section C	Internal Quality Control procedures witnessed and acceptability of the outcome Question 17 to 24
Section D	Proficiency testing (PT)/ External Quality Assurance (EQA) programme for this method/test and acceptability of performance(where applicable) Question 25 to 26
Section E	Reference standards, reference materials and/or controls used (where applicable) Question 27 to 29
Section F	Equipment used (where applicable) - Calibrations, Maintenance up to date etc. Question 30 to 35
Section G	Training and competency records of the staff member witnessed for this method Question 36 to 37
Section H	Accommodation and environmental conditions (where applicable) Question 38



3=competent and <3 not yet competent

Figure 2. Acceptability of results as witnessed across clinical pathology tests

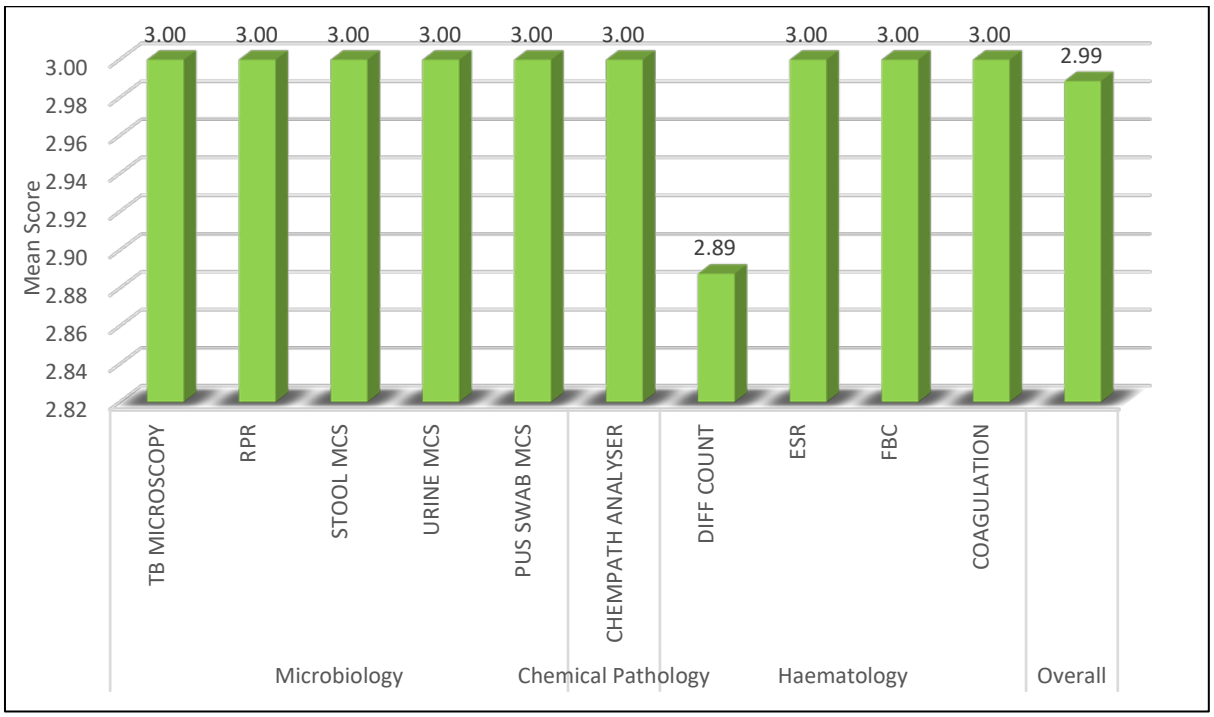
Internal Quality Control Procedures Witnessed and Acceptability of the Outcome

A vast majority, 23 candidates (n=28, 82%) were competent (**Table 5**) in most of the Clinical Pathology test procedures assessed except for differential count. However, 25 candidates assessed for differential counts were not yet competent to perform the following activities : use appropriate quality control procedures, demonstrate knowledge of frequency of running controls during a 24 hour period or per batch and verify and sign off QC results, take corrective action if required or describe corrective action for out of range control results, take or verbally describe the appropriate corrective action in the event of failed control values and take corrective action or describe corrective action for inaccurate control results and how to troubleshoot. A mean score of 3 indicated that the candidates were competent to perform independently with respect to acceptability of results as witnessed by the assessor for some of the test procedures or methods. Similarly, a

Table 5. Competency count summary for candidates across ten Clinical Pathology test procedures for compliance and adherence to SOP's

Section A	Competency	Clinical Pathology Test Procedures									
		TB MICROSCOPY	RPR	STOOL MCS	URINE MCS	PUS SWAB MCS	CHEM PATH ANALYSER	DIFF COUNT	ESR	FBC	COAGULATION
		Count	Count	Count	Count	Count	Count	Count	Count	Count	Count
Carefully read the information provided on the request form and verify sample numbers vs request forms	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Demonstrate knowledge of the criteria for rejecting samples	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Handle samples correctly	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Perform the test and follow procedure correctly according to the SOP	Not yet competent	0	0	0	4	2	0	23	0	0	0
	Competent	28	28	28	24	26	28	5	28	23	28
Demonstrate knowledge of basic principle	Not yet competent	0	0	0	4	3	0	25	0	0	0
	Competent	28	28	28	24	25	28	3	28	23	28
Verbally demonstrate knowledge of the criteria for rejection of unsuitable samples	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Demonstrate knowledge of troubleshooting procedures	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Complete all the required documentation if applicable	Not yet competent	0	0	0	0	0	0	3	0	0	0
	Competent	28	28	28	28	28	28	25	28	23	28
Perform correct housekeeping and dispose of materials correctly and follow all other safety procedures	Not yet competent	0	0	0	0	0	0	0	0	0	0
	Competent	28	28	28	28	28	28	28	28	23	28
Limitations of test procedure understood	Not yet competent	0	0	0	0	0	0	3	0	0	0
	Competent	28	28	28	28	28	28	25	28	23	28

mean score of less than 3 (**Figure 3**) indicated that some candidates were not yet competent in differential counts and they required re-training and practice.



3=competent and <3 not yet competent

Figure 3. Internal quality control procedures witnessed and acceptability of outcome

Training and Competency Records of the Staff Member Witnessed

A vast majority, 20 candidates (n=28, 71%) were unable to deliver training and competency records except eight candidates who were able to provide both training and competency records signed by both the candidate and trainer or assessor in Full Blood Count (FBC) , coagulation and Erythro Sedimentation Rate (ESR) methods.

DISCUSSION

Although the sample number is low, some were found to be not yet competent in three manual test procedures under direct observation i.e. urine and pus MCS and TB microscopy. All interns that were found to be not competent, are re-trained and re-assessed under direct supervision until they are competent in the testing procedures and thereafter allowed to perform testing on patient's samples independently.

When non-compliances with the SOP increases it must be established whether the SOP is clear, or is there a lack of understanding or an oversight from the candidate in some steps, or were they trained by more experienced staff incorrectly. Essentially, omitted steps of the SOP could have a negative impact on the patient's results (Howanitz, Valenstein, & Fine, 2000). Particularly each laboratory has different SOP to be followed and this could be possibly due to different instruments or methods used. Our findings are in agreement with a recent study reported by Woods et al (Woods, Longmire, Galloway, & Smellie, 2000) where it was observed that if the SOP is altered, then appropriate training must be documented to ensure that all members of staff are kept up to date in that procedure.

When SOPs are not been adhered to, the results will not be accurate, acceptable or correct. Also procedures for the reporting of results will not be able to be followed. Candidates were unable to demonstrate knowledge of interpreting results and understanding of the clinical significance of abnormal results.

Differential count was the only test procedure that candidates could not demonstrate internal quality control procedures. This could be as a result of no training in that test procedure or that the students did not grasp the training provided.

All laboratories are expected as part of the accreditation requirements to participate in Proficiency Testing (PT) programs for all tests performed (ISO, 2012). The laboratory proficiency testing or external quality control

(EQC) is performed by qualified staff registered with the HPCSA independent practice and the records are filed within the laboratory. The candidates were able to provide these proficiency testing records for the relevant tests and explain the corrective action processes that would be followed in the event of a failed EQC.

As part of the accreditation requirements, all laboratories have checklists and mechanisms to ensure that the lot numbers of reagents and quality control measures are checked and that stability is maintained correctly. Candidates were able to produce these checklists with the relevant lot numbers and the reagents were appropriately stored at the correct temperatures. Some candidates produced checklists with their signatures on them as they performed certain checks.

In professional training the student must be allowed to develop and practice skills in a setting similar to the work environment, and training must be documented as this could be required by regulatory bodies or other Education Institutions. Another reason for a training documentation is that it serves as a foundation that is used to assess competency and mastery of knowledge and skills.

The candidates were incompetent to provide training and competency documents, except for 8 candidates who were able to provide training and competency records for three test procedures. These 8 candidates were placed all at one Haematology laboratory. Upon further investigation, it was revealed that the trainer was vigilant about training documentation. This is very concerning as it is considered that if an action is not documented then it is not performed. Furthermore, there was no documented record of the objectives and activities that the training was conducted against, which leaves room for much debate on whether the candidate was trained or not. Formalised training coupled with competency assessment with documented records is an accreditation requirement which all laboratories must comply with.

Recently, Woods et al (Woods et al., 2000) reported that each of the competency forms is part of the training portfolio for that member of staff and interpretation with respect to retention of competency records on regulatory, accrediting agency and organisational requirements. Attaining and maintaining staff competence require constant care and this prerequisites both time and money (Štajdohar-Pađen, 2008). Though utilisation of both financial and human resources used optimally, it should not be regarded as an expense, but an investment. The rationale is that if a laboratory invests time and money in training of staff, it is critical that it has systems in place to check whether the training was effective.

Records of competence must reflect the date on which competence was confirmed to ensure traceability in the event of an investigation regarding nonconformity. Assessors when examining compliance of competence in a laboratory against the relevant accreditation standard, look for evidence of competence defined in writing also, that corresponds to retention of competency records based on regulatory, accrediting agency and organizational requirements.

Though some medical errors can be due to either inadequate training or the provided training is not effective, the problem augments as training is not documented and is considered as incomplete. Strategic and organized training in competence assessment processes are vital to verify and document that employees can demonstrate the requisite knowledge, skills and attitudes to perform their duties (Adcock, Favaloro, & Lippi, 2016).

CONCLUSION

This research highlights that written testing and direct observations can be combined for an integrated evaluation of Intern Medical Technologists in the Clinical Pathology discipline. Also, the study adds value to the current knowledge as it provides a mechanism for feedback and remediation for those not yet competent as well as provides a system to monitor compliance of training and competency records. Furthermore, the study could supplement current assessment systems of Intern Medical Technologists for conferment of professional designation and a policy review.

Further research needs to be done similarly in virology to understand standardised development and implementation of Portfolio of Evidence (PoE) aimed at workplace based learning in Biomedical Science that comprises all training and competency records remains warranted and the implementation thereof. Further research will be required to create a model of integrated assessment for evaluating competence of practitioners who require professional designation in Medical Technology. Competency based education has a learner centred approach and research into learner preferences of assessment methods for conferment of professional designation is required.

LIMITATIONS

The major limitation of the study due to high logistical demand, restricted the number of sites that could be included.

RECOMMENDATION

Based on the conclusions of the study, the following recommendations are made with special reference to assessment of technical competence and licensure exams for professional designation:

1. Regulation of training and competency records for Intern Medical Technologists combined with the National Board Examination as an integrated assessment for the conferment of professional designation for independent practice by the HPCSA.
2. Additional focus and commitment in the training and competency assessment of Intern Medical Technologists in the manual test procedures especially for differential counts of peripheral blood smears should be made mandatory.

Disclosure statement

The authors declare no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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