ORIGINAL ARTICLE

The design and implementation of a novel standardised training and assessment tool at LabPlus, Auckland Hospital, New Zealand for anti-nuclear antibody pattern reading using indirect immunofluorescence methodology in a non-automated digital microscopy setting

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ABSTRACT

Background: To reach a level of mastery in reading anti-nuclear antibody (ANA) pattern patterns using indirect immunofluorescence (IFF) methodology is a complex and difficult process. In New Zealand, for new BMLSc graduates, this process becomes far more difficult as both the Universities offering the degree course do not invest strongly in the procedure during the first three years. Furthermore, the fourth year clinical placements, can, at best, only provide a brief introduction due to time restrictions. It therefore falls to the employing diagnostic laboratories to both train and validate individual practitioner competency. As a consequence of the low levels of theoretical and practical experiences of new graduates, we recognised that the historical methods of training and assessment were inappropriate for both the organisation and the new graduates.

Aims: To design, implement and assess the value of a novel integrated training and assessment tool for ANA testing using IIF methodology.

Methods: Five new recent BMLSc graduates employed at LabPLUS, Auckland were the test subjects of the novel training and assessment system. Individual performance data was collected, analysed and fed back to participants in real time both verbally and in graphical format. All participants, after completing the programme, were invited to respond to a questionnaire where each question (10 in total) had a choice of five selectable options. Responses were collated and results presented.

Results: All five participants reached the set KPI values within one month of starting their assessment phases. All participants demonstrated an initial rapid reading agreement which then settled into a phase of gradual incremental improvement. Feedback from the survey was positive overall, with highlights for participants being (1) the "real-time" graphical presentation of their progress (2) identifying with the process being supportive and improving their analytical skill sets and (3) the system was superior to other programmes they had been involved with.

Conclusions: The conceptualisation and implementation of a novel ANA IIF training and competency assessment system at LabPLUS, was an operational success. The system effectively allowed the objective assessment and development of participants in what is essentially a subjective test setting. The features of the system gave it high flexibility and allows adaptation to other tests or areas either within or external to the diagnostic pathology laboratory.

Key words: Anti-nuclear antibody, indirect immunofluorescence, training, competency, participant feedback.

N Z J Med Lab Sci 2021; 75: 42-50

INTRODUCTION

Anti-nuclear antibody (ANA) testing visualising nuclear and cytoplasmic patterns from fixed human epithelial (HEp-2) cell lines using indirect immunofluorescence (IIF) methodology has been in use since the early 1970's and is widely regarded as the first choice diagnostic assay in the setting of a suspected systemic autoimmune-based rheumatic disease (SARD) (1).

Multiple technical factors impact on the output of the ANA test, principally (a) serum screening dilution (b) fixation and type of HEp-2 cell line (c) conjugate isotype and working strength and (d) IIF illumination source (2). It is due to these factors and, that the output of the assay relies upon the training, expertise and experience levels of the medical scientists (MLS's) / medical laboratory technicians (MLT's) tasked with the analyses. For every patient specimen under test the following assessments are made:

1. Determination of the presence of any artefacts or features that would compromise the subsequent visual assessment.
2. Discrimination of reactive versus non-reactive.
3. Assuming reactive, establishment of the location of reactivity (cytoplasmic versus nuclear or both).
4. Identification of the correct pattern(s). In our laboratory setting of 4 reportable cytoplasmic patterns and 8 nuclear, mathematically this equates to 12! or 479,001,600 possible combinations. Typically, for our ANA positive patients, on average we observe 1.5 any combination of cytoplasmic and / or nuclear patterns per patient, thus the formula becomes 12!/(12-1.5)! = 40 possible combinations per patient.
5. Determination of the strength of the observed reactivities.
6. Ensuring there are no abnormalities (e.g. suspected contamination) in the titration sequence that would preclude result reporting.

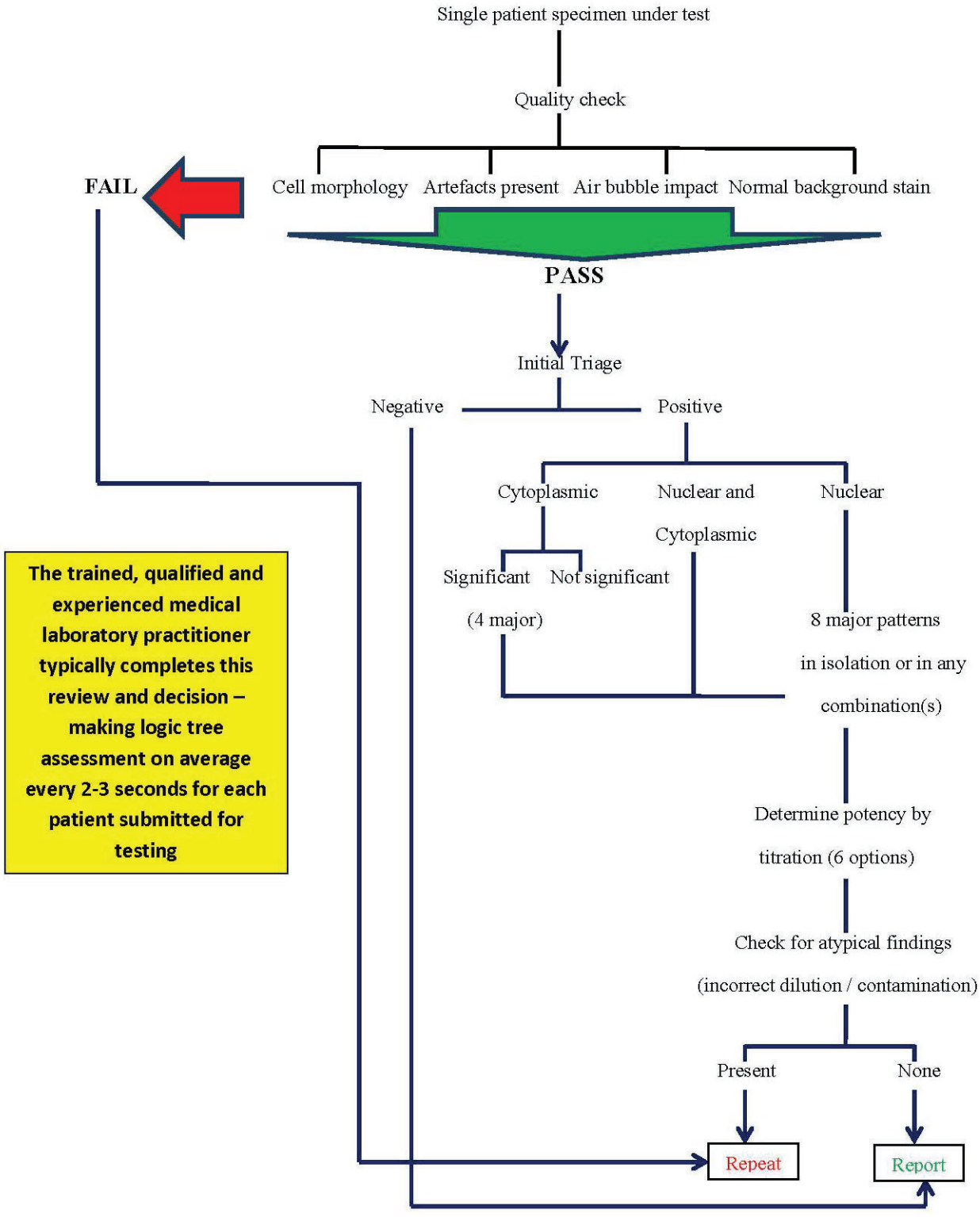

Figure 1. Logic assessment tree for reading the ANA IIF test.

To add to the challenge and complexity facing MLS's / MLT's some patterns may be masked and will only be revealed on a dilution sequence while for some cytoplasmic based antibodies (typically Ribo-P and Jo-1) there may be a complete absence of nuclear staining.

It follows, that harmonisation of ANA reporting across diagnostic laboratories continues to be a challenge. In 2015, in an attempt to address the lack of standardised reporting, the International Consensus on ANA patterns (ICAP) produced a set of standardised (AC1 – AC28) reporting codes based upon whether reactivity seen was nuclear or cytoplasmic based with or without mitotic reactivity. A further level of discrimination was applied by indicating some of the reportable patterns would only be recognised by expert-level readers (3-5). Despite the technical and interpretative challenges associated with the ANA IIF test as described, a recent review by the American College of Rheumatology indicated that the method should remain the gold standard despite other technologies being available (6).

There are numerous external quality assurance (EQA) proficiency programmes for ANA testing which, while useful and, participation being mandatory for continued laboratory accreditation (New Zealand-IANZ), are limited in terms of

assessing competence of individual practitioners across the wide potential spectrum of reportable ANA patterns. In New Zealand, a recent niche EQA ANA programme has been developed and implented to allow multiple reader inputs (7).

Over the past five years, a number of commercial ANA slide manufacturers have developed closed systems for automated reading of IIF ANA patterns. Typically, systems have algorithm–based triaging capacity (positive or negative) and then either software-driven pattern identification or user-selectable pattern identification. The latest versions of such systems usually have an on-board digital image library to assist with pattern identification. These systems are effective tools to not only assist in standardised ANA reporting but also to aid laboratories in staff training. In 2014 Bizzaro *et al* identified that, although systems available at that time could triage positive versus negative equivalent to manual reading, there was generally poor (52-79%) recognition across the six systems where mixed patterns were present (8). Such automated systems are expensive and are outside the purchasing ability of many laboratories performing ANA testing by IIF.

Over a 5 month period during 2017/2018 at LabPLUS, the serology unit (which performs ANA testing by IIF) lost 50% of its staffing level, the majority of those that left having posessed high experience and expertise in reading ANA patterns. It was realised that new staff recruitments would almost certainly have to be well supported in becoming proficient in performing the IIF test and reading ANA patterns. The reason for this, is that across the New Zealand Universities that offer the Bachelor of Medical Laboratory Science (BMLSc) degree, gaining practical expertise in ANA IIF methodology is either very limited or not included in their curricula. Rather, the only exposure students receive during their degree course is when they are on their fourth year clinical placements at diagnostic laboratories. Because the placement time is restricted to 16 weeks in total and, there are multiple assays that the student is required to demonstrate technical proficiency in, only a very limited exposure to ANA IIF testing is the usual outcome.

It was against this setting that the decision was made that the historical paper record system of training and recording ANA proficiency (sign-off being competent or not with a sub-classification into technical performance and pattern recognition) was deemed unsuitable for the needs of both the organisation and our new staff members. The challenge then became to design and implement a new sytem of training and assessment. This article details the training and assessment system that was developed and provides evidence of its effectiveness in producing staff that have high technical profiencies in the science and art of reading ANA patterns by IIF methodology.

METHODS

System design considerations

While acknowledging that newly qualified individual practitioners may bring with them (a) theoretic knowledge, (b) some IIF expertise (with or without ANA application) and (c) reading preconceptions through use of alternate cell lines and ANA frequencies in different test populations our design criteria required:

1. A standardised numeracy–based assessment tool that examined every component of ANA reading for both screening and screen reactive sera undergoing titration.
2. ANA pattern reading training delivery to be restricted to those practitioners with a minimum of 10 years experience and expertise.
3. A standardised KPI target based on compliance (% agreement) with senior staff reading. There were two senior staffs involved in the training assessment. They had a <1% inter-practitioner non-agreement in reading ANA patterns.
4. Availability and use of catalogued digital microscope images obtained by testing patient sera under our conditions. The digital microscopy image facility acted as an enabler during the active assessment process where features of individual patient images and pattern classification discussions could occur without image deterioration due to quenching.
5. Detailed collation of competency assessment data in real time with graphical output demonstrating practitioner development.
6. Specific one on one feedback and discussion during the training/assessment process using the data collected (point 4).
7. A system that was viewed as supportive and had a high empahsis on skill development.

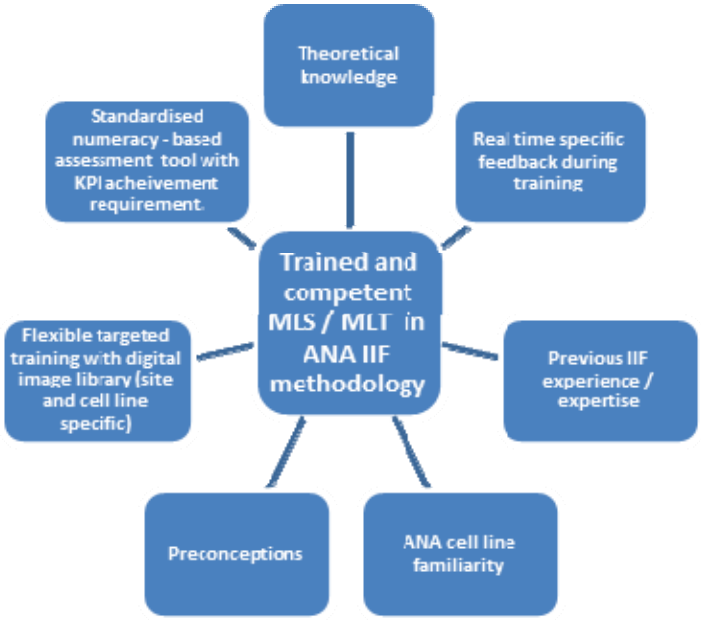

Figure 2. Inputs affecting the training of MLS and MLT practitioners in reading ANA patterns by IIF methodology.

Process - overview

For every practitioner, the following process was followed:

1. A two week one on one theoretical overview linking the technical aspects of the procedure with the visible outputs and the clinical significance of the patterns seen. The retained comprehensive digital image library was used for this purpose. Strong emphasis was made at this time that the final image quality and therefore the ANA pattern discrimination ability being directly linked to the 'hands-on' technical element of applying coverslips to slides with mounting media. Poor practitioner technique for this final pre-evaluation technical step may result in a combination of either (a) changes in refractive indicies diminishing fluorescence and distorting cell morphology and/or (b) physical damage to fixed cells giving rise to artefact's that may be mis-interpreted as true ANA patterns.
2. A one to three week period (dependent upon the individual practitioner) prior to the formal assessment process where practitioners could view slides to establish and fine tune their observation skills until such time they believe they could (a) confidently discriminate positives from negatives and (b) identify the commonest ANA patterns of Homogeneous, Speckled, Centromere, Nucleolar, Nuclear Membrane, Nuclear Dots, Cell-Cyclic and Hyper-expressed SSA (Hep-2000 cell line in use).

3. The formal period of assessment. The MLS/MLT would independently perform the first ANA slide reading, the senior MLS performing the second. Within 48 hours the assessment data was collated and there was a conversation between the assessee and the assessor based upon the data. The conversation/feedback loop was mandatory before the second reading / asssessment event.
4. The cycle of assessment/feedback continued until the required KPI's (≥ 85% reading concordance with senior MLS's and a minimum of 350 patients had been reviewed) had been met.
5. Issuing of a personalised certificate stating their competence achievement and graphical representation of their personal journey of development.

Process – system scoring

The assessment scoring is a standardised numeracy system whereby [1] point is allocated for agreement and [0] point for non-agreement with the senior MLS reader. There are different elements for review dependent upon whether the patient serum is undergoing a first-round screen or a full titration after an initial reactive screen.

Points for screening and titration reading are then added together and a batch compliance percentage is calculated. Subsequent batch readings follow the same process allowing the calculation of both individual batch and cumulative percentage complaince. The required KPI point is referenced against the cumulative percentage compliance.

Screening scoring

There are two elements for comparison and point accumulation, namely (a) agreement of positive versus negative for each patient and (b) for those scored positive by the senior MLS, pattern identification.

In the mock ANA read sheet example (Figure 3), 11/16 possible points were scored for positive/negative compliance and 4/8 points for pattern identification, totalling 15/24 possible points.

Titration scoring

There are three elements for comparison and point accumulation, namely (a) agreement of positive versus negative for each patient (b) for those scored positive by the senior MLS, pattern identification and (c) for those scored positive by the senior MLS, a point is awarded if the MLS/MLT end point dilution read is within a single dilution step of that determined by the senior MLS.

In the mock ANA read sheet example (Figure 3), 6/6 possible points were scored for positive/negative compliance, 3/5 points for pattern identification, and 4/5 points for end-point titre determination totalling 13/16 possible points.

Process – post-IIF read feedback/discussion

As aluded to earlier in this paper, the feedback/discussion phase occurs after the reading phase and before any subsequent readings. It allows a real time analysis of the strengths and weaknesses of the MLS/MLT trainee in a non-judgemental, unemotional supportive setting underpinned by an in-depth standardised objective data set.

In the mock ANA read sheet example (Figure 3), identified strengths would have been generally good pattern identification with excellent determination of end point in a dilution sequence. Areas to focus on would be (a) to have an awareness that masked patterns may be revealed on dilution (b) to understand that where there is SSA hyper-expression, the end point titre is established on the non-hyper-expressing cells and (c) as there was evidence of slight over reading and assignment of low titre speckled reactivity for a proportion of patient sera undergoing screening, a minor re-calibration in this area would be indicated.

Participant feedback

Five qualified MLS staffs (designated in this paper MLS 1 through MLS 5) were employed in serology over the period April 2017 to March 2018 to replace staff resignations that had occurred over the same time frame. All five went through the ANA IIF training and assessment programme over the period October 2017 to November 2020. There were differences across the five MLS candidates in terms of their knowledge base and laboratory experiences prior to their LabPLUS employment as detailed in Table 1.

All five MLS staffs achieved the desired KPI requirement. After course completion, each staff member was offered the opportunity to provide feedback on elements of the training and assessment scheme in terms of a questionnaire (Table 2).

Each question had a single selectable response, where responses (a) and (b) were designated below average, response (c) was average and responses (d) and (e) were above average. Using the assumption that there was equivalence between each response numbers were assigned a numeric value 1-5 in the order of response (a) – (e).

Furthermore, the ten questions made up four separate categorial groups for analysis:

Participant engagement:	Question 1
Specific elements:	Questions 2, 3, 7
Participant training confidence:	Questions 4, 5
System review:	Questions 6, 8, 9, 10

RESULTS

Participant training/competency assessments

All participants attained the KPI requirements of (a) a minimum of 85% agreement with those obtained by senior staffs and (b) a minimum of 350 patient specimens assessed (Table 3, Figure 4).

The average starting (threshold) agreement level was relatively high (80%). We believe this was principally due to (a) the structure of the ANA programme where there was a "lead-in" time before the formal assessment process commenced and (b) all participants had a minimum 2 month period of viewing non-ANA autoimmune IIF 's (neuronal antibodies, skin antibodies, adrenal antibodies and ANCA IIF) before commencing the ANA programme (Table 3).

Due to the high starting points for all candidates, identified improvements were relatively small being in the order of approximately 5-10% (Table 3). All candidates demonstrated a sharp initial reading agreement improvement which then settled into small gradual incremental improvements consistent with increases in volumes read and time invested (Figure 4). All candidates met the KPI requirements within a month of starting the training/assessment process (Table 3).

By way of comparison, the program was also applied to a medical registrar training for their theory and practical examinations. The registrar had no laboratory experience. In their case, the KPI was reduced to 70%. Their threshold point was 55% agreement and it took 3 months to attain the 70% KPI threshold, reading 750 patient tests during the process. The improvement in their case was three times higher than that seen in the MLS group.

Screen (S) / Titre (T)	MLS / MLT	Senior MLS
	1+ S	0
S2	0	0
S3	0	0
S4	1-2+ H/S	1+ H/S
S5	1-2+H/S	1+ S
S6	±	0
T1 – 80	3+ H	>3+H
T1-160	2-3+ H	3+ H
T1-320	2+ H	2-3+ H/S
T1-640	1+ H	1-2+ H/S
T1-1280	±	±
S7	>3+C	>3+C
S8	1+S	±
T2-80	±	0
T2-160	0	0
T2-320	0	0
T2-640	0	0
T2-1280	0	0
T3-80	1-2+ S	1+S
T3-160	1+S	±
T3-320	±	0
T3-640	0	0
T3-1280	0	0
T4 – 80	2-3+ H/N	3+ H/N
T4-160	2+ H/N	2-3+ H/N
T4-320	2+ H/N	2+ H/N/S
T4-640	1+ H/N	1-2+ H/N/S
T4-1280	±	±
T5 – 80	3+ S/SSA	1-2+S /SSA
T5-160	3+ S/SSA	1+S/SSA
T5-320	3+ S/SSA	0/SSA
T5-640	3+ S/SSA	0/SSA
T5-1280	2+ S/SSA	0/SSA
T6 – 80	2+ H/S	1-2+H/S
T6-160	1+ H/S	1+ H/S
T6-320	±	0
T6-640	0	0
T6-1280	0	0
S9	1+S	0
S10	0	0
S11	3+H	>3+H
S12	2-3+N	3+H/N
S13	1-2+ S /ND	2+S
S14	0	1+S
S15	1+S	±
S16	2+ NM	3+NM

Screen assessment (N=16)
11/16 Positive / Negative points
4 / 8 Pattern recognition points
15 / 24 possible points

Titre assessment (N=6)
6/6 Positive / Negative points
3 / 5 Pattern recognition points
4 / 5 End point titre agreement points
13 / 16 possible points

Screen and Titre assessment combined
N = 22 patients
15/24 + 13/16 = 28 /40 possible points per batch
Overall agreement: 70%

Figure 3. Mock ANA reading record sheet with assigned accumulated points based upon concordance of reading between the trainee practitioner and their trainer.

Participant feedback

Overall, feedback was positive. For the 10 questions, across the five participants a total of 50 points could be scored. The average was 40.4/50 (81%) with a participant range of 66% to 94% and a 95%CI range of 71.5% to 90.0% (Table 4[a]). All candidates had very high levels of engagement at the start of the process (Table 4 [a] and [b]).

The specific elements of (1) the availability of digital images as a training tool and (2) 'one on one' feedback sessions were well received [questions 2 and 3, Table 4 [a]). However, the specific feature of the programme that had almost complete approval (80% scored this feature as empowering) was the ability for participants to visually see and track their development over time [Question 7, Table 4 [a]).

Questions 4 and 5 were linked. They queried participant confidence levels regarding achieving the set KPI at the start of and mid-way through the training and assessment process. A single candidate (20%) felt confident at the start of the process. At the half-way point all remaining candidates had improved their confidence levels (Table 4 [a]). An associated question [9] asked participants to assess the difficulty level of the programme with hindsight. None gave a rating lower than 'Fair' and most felt it was challenging but achievable (Table 4 [a]).

Collectively, the four system review questions together (6, 8-10), across all participants scored 91 of a possible 100 points. (Table 4 [b]). Specifically, the majority of participants endorsed the use of a numeric-based system for objective assessment in what is essentially a subjective technical setting (Table 4 [a]). Equally high gradings were given for the core system principles (Question 8) and, in comparisons with other assessment schemes participants had been involved with (Question 10) (Table 4 [b]).

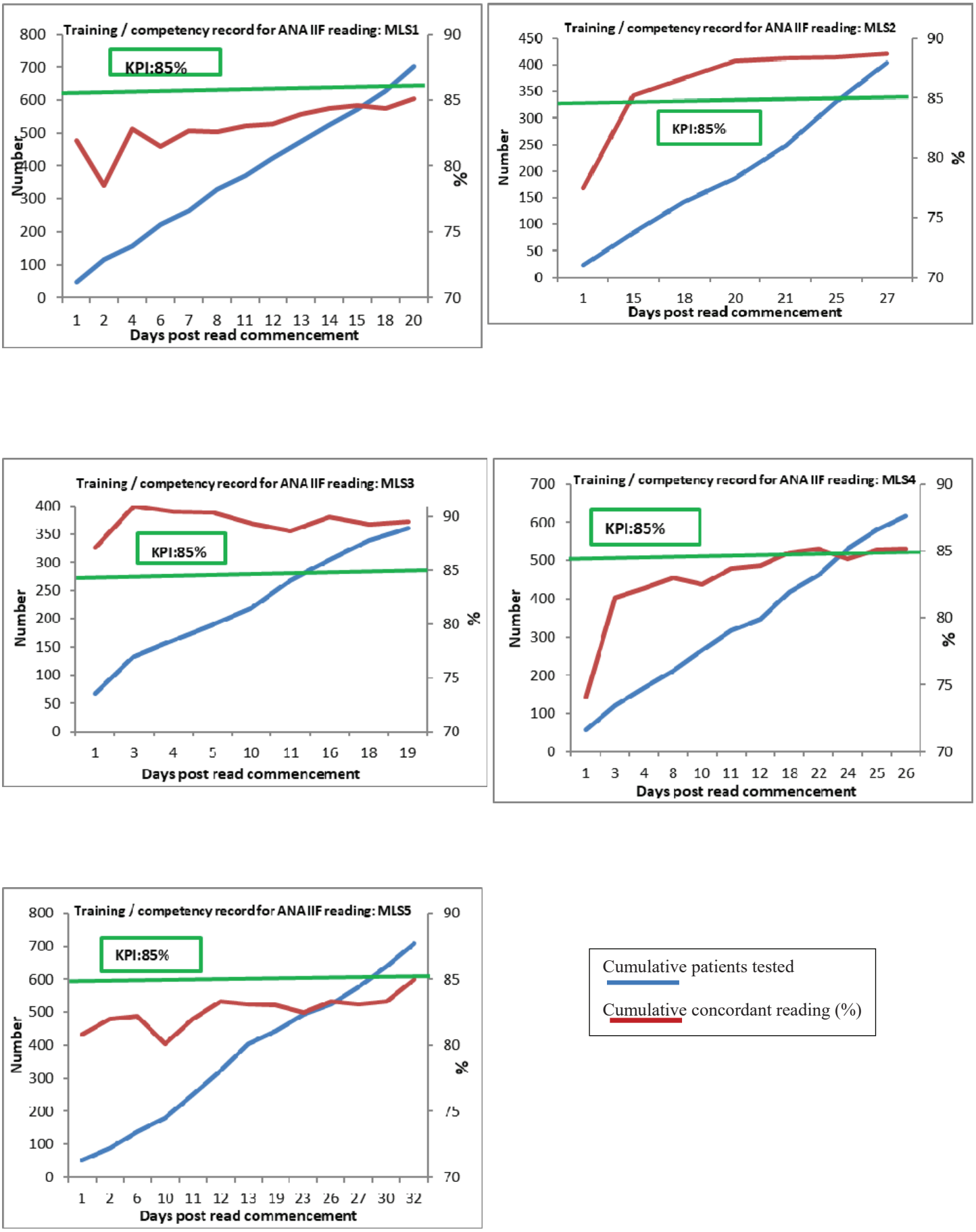

Figure 4. ANA IIF competency assessment journeys of five qualified MLS staffs over the period October 2017 – November 2020 at LabPLUS, Auckland Hospital presented in graphical form.

Table 1. Backgrounds of 5 recently qualified MLS practitioners who participated in the novel ANA IIF Training and Assessment programme at LabPLUS.

	MLS 1	MLS 2	MLS 3	MLS 4	MLS 5
Qualification	BMLSc	BMLSc	BMLSc	BSc MLT (India) Grad dip. Sci. (NZ)	BMLSc
Time from graduation to LabPLUS employment	4 months	4 months	12 months	36 months	3 months
NZ University	Otago	Otago	AUT	AUT	AUT
Degree placements	Immunology / Haematology	Immunology / Microbiology	Haematology / Transfusion Science	Chemical Pathology	Immunology / Chemical Pathology
ANA IIF at University practicals	None	None	None	None	None
ANA IIF Theory at University	Brief	Brief	Brief	Brief	Brief
ANA IIF while on placement	80 Hours 15% placement time	128 Hours 25% placement time	N/A	N/A	32 Hours without formal training 6% placement time
Specific ANA IIF cell line experience	IC Hep-2000 (Placement)	IC Hep-2000 (Placement)	N/A	Biorad Hep-2 (2 years routine)	Biorad Hep-2 (Placement)
Microscopy expertise with cell morphology identification	Yes Haematology during placement	Yes Two years in University practicals	Yes As part of Haematology training	Yes In India (Haematology)	No

Table 2. MLS participant ANA IIF training and competency process feedback questionnaire.

1. Please select your engagement level during the training / assessment process (a) Very Low (b) Low (c) Average (d) High (e) Very High
2. What was your opinion of the retained digital image library as a training tool? (a) No value (b) Minimal value (c) Sometimes useful (d) Very helpful (e) Superb resource
3. What was your opinion of the value of the feedback / discussion sessions during the assessment process? (a) No value (b) Minimal value (c) Sometimes useful (d) Helpful (e) Very helpful
4. Define your confidence level in achieving the 85% KPI read agreement level before the formal assessment period started (a) Very concerned (b) Mildly concerned (c) Ambivalent (d) Confident (e) Very confident
5. Define your confidence level in achieving the 85% KPI read agreement level mid-way through the formal assessment period. (a) Very concerned (b) Mildly concerned (c) Ambivalent (d) Confident (e) Very confident
6. How do you rate the standardised numerical – based system as an assessment tool? (a) Unhelpful (b) Poor (c) Adequate (d) Good (e) Excellent
7. Please identify how you felt about being able to visually see and track your development over time? (a) Pointless (b) Little value (c) Ambivalent (d) Helpful (e) Empowering
8. What is your opinion of the statement ***"I viewed the process of training and assessment as supportive and skill-based driven"*** (a) Totally disagree (b) Disagree (c) Somewhat agree (d) Endorse (e) Fully endorse
9. Overall, with hindsight, what is your opinion reagrding the difficulty level for the training and assessment system (a) Near impossible (b) Easy (c) Fair (d) Acheivable with persistence (e) Challenging but acheivable
10. Compared to other training / competency assesments you have been involved in for subjective material, how did this system rate? (a) Much worse (b) Poorer (c) Same (d) Better (e) Significantly better

Table 3. Summary table of MLS participant's performance from their individual ANA IIF training and competency assessments.

	Threshold (start) read agreement (%)	Completion read agreement (%)	Improvement (%)	Days to meet KPI (≥85% read agreement) over 350 specimens assessed	Total patients tested	Time reading non-ANA autoimmune IIF before ANA training and assessment (months)
MLS 1	81.9	85.1	3.9	20	703	2
MLS 2	77.5	88.7	14.5	27	404	2
MLS 3	87.1	89.5	2.4	19	361	13
MLS 4	74.1	85.2	15	26	617	3
MLS 5	80.8	85.0	5.2	32	709	11
Mean	**80.3**	**86.7**	**8.2**	**25**	**559**	**N/A**
SD	4.9	2.2	6.1	5	166	N/A
95% CI	**76.0-84.6**	**84.8-88.6**	**2.8-13.5**	**21-29**	**413-705**	**N/A**

Table 4. MLS participant questionnaire responses with [a] individual gradings and [b] categorial groupings.

4 (a)

	Questions	MLS1		MLS2		MLS3		MLS4		MLS5			
Category: A = Answer S = Score		A	S	A	S	A	S	A	S	A	S	Total/ 25	Frequency (%)
Engagement	1	D	4	E	5	D	4	D	4	E	5	23	92%
Specific elements	2	C	3	E	5	D	4	E	5	A	1	18	72%
Specific elements	3	D	4	E	5	C	3	E	5	B	2	19	76%
Training confidence	4	B	2	A	1	B	2	D	4	C	3	12	48%
Training confidence	5	C	3	B	2	D	4	D	4	D	4	17	68%
System review	6	D	4	E	5	E	5	E	5	C	3	22	88%
Specific elements	7	E	5	E	5	E	5	E	5	C	3	23	92%
System review	8	E	5	E	5	D	4	E	5	D	4	23	92%
System review	9	D	4	E	5	E	5	E	5	C	3	22	88%
System review	10	E	5	E	5	D	4	E	5	E	5	24	96%
Total / 50			39		43		40		47		33		
Frequency (%)			78%		86%		80%		94%		66%		

4 (b)

Group	Questions	MLS1	MLS2	MLS3	MLS4	MLS5	Total scored	Total possible	Frequency (%)
Engagement	1	4	5	4	4	5	22	25	88
Specific Elements	2,3,7	12	15	12	15	6	60	75	80
Training Confidence	4,5	5	3	6	8	7	29	50	58
System Review	6,8,9,10	18	20	18	20	15	91	100	91

DISCUSSION

To achieve competency in consistently reading the ANA IIF assay is a challenge. Specifically, at our laboratory, acting in the capacity of a tertiary referral site for both New Zealand and neighbouring Pacific Islands we see a high frequency of ANA positive sera (approximately 30-40%). Associated high complexity with observed patterns is not an uncommon occurrence. In New Zealand, this challenge is exacerbated by the fact that the tertiary Universities offering an Immunology placement as part of the BMLSc degree resource this core autoimmune test (both theoretic background and practical exposure) at very low levels. Effectively, new BMLSc graduates come into the workforce without expertise in this technique. It thus falls to the diagnostic laboratory to both train and assess the competencies of newly recruited graduates.

In our laboratory we were faced with having to employ a number of newly qualified graduates, all of whom had limited experience with the ANA IIF method. We viewed this somewhat unique situation as an opportunity to comprehensively review our historical systems of training and assessment. With the transition from an experienced workforce to largely inexperienced one, historical embedded systems of annual assessment were deemed inappropriate.

We chose to maximise the resources we had to hand namely (a) highly experienced senior staffs and (b) a retained digital library of images. These assets were then augmented by designing a numeracy–based scoring system which targeted every aspect of reading the ANA IIF and was customised for either screen or titre reads. To bring the system together we focussed on supporting our new graduates by (a) delivering specific one on one feedback after each reading session and then (b) enabling them to visualise their own progression in real time via graphical output. The process as outlined in this paper has proved to be successful as evidenced by the performance graphs of all participants whereby their technical acheivements matched their questionnaire responses.

The challenges we face in New Zealand are seen elsewhere in the world. A survey in 2019 by the American Association of Medical Laboratory Immunologists (AAMLI) identified 65% of their respondents (almost exclusively USA laboratories) had “on the job” training with 10% stating they received “no training” (9). In the same survey, responders identified competency assessment as compliant performance in EQA programmes (9). The authors of the AAMLI paper concluded that improved training could be mediated through “hands-on” and “wet-bench” workshops. Improvements in EQA proficiency programmes would help in optimising the detection and measurement of HEp-2 based ANA IIF results and reports (9).

We believe that this is a unique publication in that it clearly outlines the processes to implement in both training and assessment phases. Additionally, it is our contention that for new inexperienced staffs the two phases should be viewed as integrated compatible elements of a whole as opposed to segregated un-associated elements. We further believe that compliant performance in existing EQA programmes for ANA speaks more to the systems employed within diagnostic units as opposed to being a measure of the competence of individual practitioners.

A possible weakness in this study was the low number of participants. However, when we consider the similarity of the training and assessment outcomes of the participants, matched with the uniformity of their questionnaire responses, from what can be considered a highly diverse group of newly qualified graduates, the small pool number is unlikely to have biased our conclusions.

The system we have developed and implemented has high flexibility. Dependent upon the desired setting, while maintaining the scoring component without modification, achievable levels can be set by simple manipulation of the desired KPI’s. The system can be easily adapted for both initial and re-assessments.

We chose a high KPI setting of 85% reading concordance because we wanted to develop future leaders (i.e. was part of a clear mid to long-term succession plan). It will be a relatively small step up from where practitioners currently sit to the required 95% agreement to be considered the second senior IIF reader as opposed to the first reader in our facility.

In conclusion, while “system fine-tuning” will invariably occur over subsequent years the underlying principles and core operational specifics will, in our opinion need little modification. Not only has this integrated system of training and assessment proven to be successful for the ANA IIF procedure, adaptation into other clinical areas (not restricted to the diagnostic pathology laboratory) where a subjective assesment is required should be easily attainable.

ACKNOWLEDGEMENTS

The authors would like to acknowledge and thank all five recently qualified BMLSc graduates for buying into the novel processes of training and assessment that had been designed for the ANA IIF test and, by their individual and combined performances validated the proof of concept. The authors would further like to thank all participants for completing the review questionnaire and giving permission for their personal training and assessment records to be used in this publication. Additional thanks to Yulia Hwang and Theresa Dieckermann for manuscript proof-reading and formatting suggestions.

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