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EDITORIAL

Editorial code of conduct

Rob Siebers
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ORIGINAL ARTICLE

Change management in healthcare: managing paradigmatic change in the Australian National Cervical Screening Programme

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ABSTRACT

The healthcare sector is subject to continuous pressure to improve its processes, methods and technologies. Improvement is enabled by global research activity driving changes in the delivery of healthcare services, and in some cases resulting in widespread disruption to employment in sectors of the healthcare workforce. We examined and reviewed organisational change as it relates to the healthcare sector. Adopting action research methodology we report a study of the effect on a skilled workforce in Australia of the change from morphological manual testing for cervical cancer to automated molecular testing. We adopt, and report the efficacy of the ADKAR model of change management.

Keywords: change management; action research; cervical screening.

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INTRODUCTION

Disruptive technologies can result in rapid changes to skilled workforces. In the health sector, new technology combined with research that demonstrates the efficacy of that technology has the potential to make existing skillsets of workforce sectors obsolete. This inevitably leads to redundancy, re-training and stressful employment situations. The management of human resources during these periods of revolutionary change is a significant issue for healthcare professionals.

In April 2014 the Medical Services Advisory Committee (MSAC) released recommendations to change the National Cervical Screening Programme (NCSP) in Australia. These recommendations were based on an extensive evidence-based assessment report, MSAC application no. 1276, which detailed information relating to screening tests and pathways, including a review of the safety, effectiveness and cost-effectiveness of new medical technologies and procedures (Australian Government Department of Health, 2014).

A driver of change to the cervical screening approach to was to improve the incidence and mortality rates of cervical cancer. There is strong evidence that replacing the morphologically assessed conventional Pap test with the molecular assessed human papillomavirus (HPV) test is more effective and accurate in detection of disease, especially in women over the age of 30 years (1). In addition, the impact of the National Human Papillomavirus Vaccination Programme (NHPVP) has seen a drop in high grade abnormalities in the 20-25 year age group (2) and there is also evidence of herd immunity in vaccinated and unvaccinated women (3).

The Renewed NCSP (referred to as the Renewal), effective from December 2017, will change from the Pap test to the HPV test, forcing pathology laboratories and cytology departments to re-evaluate staffing and workflow. It is estimated that six out of seven scientists involved in screening Pap tests will no longer be required as the test changes from being microscopically viewed to an automated test processed on an analyser (A. Farnsworth, personal communication, May 30, 2015).

The 2014 announcement regarding the Renewal signalled the onset of job insecurity, workload pressures due to loss of staff, the inability of management to replace skilled individuals, and a general lack of motivation; all these exacerbated by expectations from referrers regarding turnaround time. The challenge for management was how to maintain the same high quality service, retain, motivate and engage staff, plan for the transition phase of the Renewal, and implement the changes all at the same time.

We recognised that despite high numbers of predicted redundancies, individuals should have the ability to control their destinies. The organisation and its managers were responsible for creating awareness of choices and enabling staff to make them. Meanwhile, the critical nature of health services demanded that the day-to-day operation of the workforce continued to perform at a high standard.

The objectives of our study were:

1. Identify management initiatives and strategies that might assist staff and management with the transition whilst maintaining staff engagement and high quality standards.
2. Identify interventions that would allow individuals to successfully manage the transition.
3. Examine the efficacy of action research as a strategy and methodology for change management in a healthcare context, and
4. Assess the appropriateness of the ADKAR model as a vehicle for change management in combination with action research.

To achieve these objectives we investigated:

- The effect the new cervical screening programme paradigm has had on cytology staff.
- Staff members' understanding of the impact of the Renewal during and after the transition period.
- Individual awareness in understanding the impact of the Renewal on their future career, and
- Individual willingness to start a new career in light of the Renewal.

History
The Medical Services Advisory Committee (MSAC) advised the Minister for Health and Ageing on "evidence relating to safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures, and under what circumstances public funding should be supported" (4). In late 2011 the review process for the Renewal began with a planned completion date set for mid-2014. On April 4 2014, MSAC provided recommendations (endorsed 19-9-2014) for the Federal Government that the HPV test should replace the current Pap smear (4).

On May 10 2015 the Ministry of Health announced the Australian Government's new approach to cancer screening with the introduction of the Renewal from 1 May 2017 (later revised to 1 December 2017).

The workforce
A 65% workload reduction was anticipated from the change from two-yearly Pap test to a five-yearly HPV test with a reflex liquid-based cytology (LBC) triage. The current 2.4 million per annum conventional Pap tests will become zero. Cervical cytology will be processed as a triage to a HrHPV detected test only and therefore, the transition to LBC will be the only cervical cytology processed and only if the HPV test is positive.

Therefore, the transition will result in 340,000 LBC tests and an estimated 1.3 million HPV tests annually. These changes will alter the existing and future workforce in a cytology laboratory with an estimated 75-80% staff redundancy across Australia (T. Bessell, personal communication, April 28, 2014). Similar drastic changes have been reported elsewhere (5).

Cytology - practitioners and current practice
Cytology scientists require up to two years specialised training to establish competence and consistent performance in detecting abnormal Pap smears. Accuracy indicators, measured by sensitivity, specificity, positive predictive value, and negative predictive value are reported to the Royal College of Pathology Australasia (5). For accreditation purposes performance indicators are reported to the National Australian Testing Authority (6).

The ADKAR model
Prosci's ADKAR model is designed to understand change management from an individual's perspective, based on five elements:
- Awareness
- Desire
- Knowledge
- Ability
- Reinforcement.

By understanding how these five elements affect individuals, successful changes are more likely to occur for the individual and the rest of the team when undergoing change. The model, in conjunction with a business model, should assist management in the successful transition of changes in the following areas:

- Planning change management activities.
- Diagnosing gaps.
- Developing corrective actions.
- Supporting managers and supervisors (7).

The five ADKAR elements can be compared to four stages of project change (preparing, designing, implementing, and sustaining). Factors influencing success (Table 1) have been proposed as the "natural order" of how a person experiences change (8). Desire cannot come before awareness because it is awareness of the need to change that stimulates our desire or triggers our resistance to that change. Knowledge cannot come before desire because we do not seek how to do something that we do not want to do. Ability cannot come before knowledge because we cannot implement what we do not know. Reinforcement cannot come before ability because we can only recognise and appreciate what has been achieved.

Several authors have published their experiences using the ADKAR change management model (9-10). An example of its usage includes the ADKAR model deployed to support a company in overcoming resistance to change by assisting management to "develop a plan to induce willingness to accept change" (9).

Table 1. Factors influencing each element of the ADKAR model (adapted from Hiatt, 2006, p. 45).

A	**Awareness** of the need to change	A person's view of the current state. How a person perceives problems. Credibility of the sender of awareness messages. Circulation of misinformation or rumours. Contestability of the reasons for changes.
D	**Desire** to support and participate in the change	The nature of the change (what the change is and how it will impact each person). The organisational or environmental context for the change (his or her perception of the organisation or environment that is subject to change). Each individual's personal situation. What motivates a person (those intrinsic motivators that are unique to an individual).
K	**Knowledge** of how to change	The current knowledge base of an individual. The capability of this person to gain additional knowledge. Resources available for education and training. Access to or existence of the required knowledge.
A	**Ability** to implement required skills and behaviour	Psychological blocks. Physical abilities. Intellectual capability. The time available to develop the needed skills. The availability of resources to support the development of new abilities.
R	**Reinforcement** to sustain the change	The degree to which the reinforcement is meaningful and specific to the person impacted by the change. The association of the reinforcement with actual demonstrated progress or accomplishment. The absence of negative consequences. An accountability system that creates an ongoing mechanism to reinforce the change.

METHODS

To achieve our purpose of assisting management in understanding the needs of cytology employees and to support the process of change implementation, we adopted an exploratory approach, focussing on the impact of the Renewal on professionals in the cytology laboratory. Laboratory management specifically sought:

- Better understanding of the problem facing the workforce.
- Knowledge of potential change management strategies that could be adopted during the transition period.

The research methodology was two-stage:

- Interviews with all staff members in the cytology department.
- A questionnaire was developed and offered to participants employed in four different cytology laboratories, in four states of Australia, to complete on a voluntary and confidential basis.

The initial approach was participatory action research with non-probability convenience sampling techniques. This method was used to assess each individual's awareness and understanding about the proposed changes to the national approach to cervical screening. The research method was then broadened to a survey sampling the original and three further laboratories.

Participatory action research technique was selected as the most relevant approach because it was deemed most appropriate for the hands-on small-scale research project where the issues and problems were real and new to the workplace (11). Seven reported criteria led us to select this method (12). Action research is:

- Educative.
- Deals with individuals as members of social groups.
- Problem-focused, context-specific and future-orientated.
- Involves a change intervention.
- Aims at improvement and involvement.
- Involves a cyclic process in which research, action and evaluation are interlinked.
- Founded on a research relationship in which those involved are participants in the change process.

Each of these criteria fulfilled the research project's aims and objectives. Both the individual and researcher gained knowledge from the interviewing process into possible future outcomes for each employee and all were treated as individuals from within the group. We questioned what impact the Renewal would have on the workforce and how the department would progress towards the inevitable down-sizing through individual choices such as redeployment, retraining and redundancy whilst retaining enough staff to maintain critical services prior to the Renewal.

Management adopted a strategic intervention, changing operational procedures with the involvement of staff members, adjusting and improving operations during the transition period. Staff members who wished to redeploy into other areas within the organisation during the transition period were supported. Other staff upskilled into different areas of medical laboratory science whilst still working in the cytology department. This approach assisted in staff retention despite individuals retraining for redeployment. Action, evaluation and re-evaluation were linked; all staff members were managed on an individual basis according to the requirements of the department as well as the individual.

Prosci's ADKAR change management strategy is focussed on the people side of change, providing guidance to managers. ADKAR is designed specifically to understand change management from an individual's perspective through its five elements (8). It also adapts well with the action research approach through planning, initiating, implementing and reflecting on the change process in real time. Prosci argued that by understanding how these five elements affect individuals, successful changes are more likely to occur for the individual and the rest of the team when undergoing change.

The interviews

Following the announcement of the proposed Renewal in April 2014, staff members were interviewed separately over a period of one month from May to June 2014. Assuming that few individuals fully understood the full impact of the Renewal, the researcher engaged with staff on a one-to-one basis. Individuals were given opportunity to ask questions and 'be heard'.

The semi-structured interview questions were brief; designed to provoke informal discussion to establish how informed staff members were about the Renewal and to understand their expectations. Forty-five scientists, laboratory assistants, and office staff were interviewed face-to-face by the researcher by way of appointment. The interviews generally lasted between 30 and 45 minutes and notes were recorded by the researcher using a template for each participant. The closed questions were as follows:

1. On the scale of 1-10, with 10 being strongest desire, what is your desire to stay in the cytology profession?
2. Would you consider upskilling in another department within our organisation? If so, which one?
3. Would you consider redeployment to another organisation within the company?
4. Would you consider retraining in another occupation at university or online?
5. Would you like assistance with career advice?
6. Would you like assistance with CV writing and interviewing skills?
7. Would you like any financial advice?
8. Are you likely to leave before the restructure of the department?
9. Would you consider voluntary redundancy?
10. Do you have any comments?

A year later, between May and August 2015, all staff members were re-interviewed with the same set of questions by the researcher. Some turnover had occurred due partly to resignations. Only the data from those individuals who took part in both sets of interviews (n=38) was compared to identify significant changes over that year from their original replies.

Data analysis

Two statistical methods were adopted for interview analysis:

- A parametric paired-samples t-test was used to compare the responses of the 2014 and 2015 interviews (SPSS version 22 statistics programme.)
- Pearson's product-moment correlation coefficient (r) was used to measure the strength and direction of the linear relationships between the variables (13). We accepted 0.3 to be weak and 0.7 a reasonably strong correlation (11).

The questionnaire

A questionnaire was developed to explore further how individuals felt about the future changes. A survey was considered less confronting than interviews, especially for individuals with whom the researcher had no prior relationship. It was voluntary, anonymous and confidential; potentially offering management improvements in the approach to handling the transition.

The sample
Staff members from the original laboratory plus personnel from three further cytology departments from three further Australian States were invited to participate. All four laboratories, located in Brisbane, Sydney, Melbourne and Perth, were owned by the same healthcare group. Note that this sample group relates to the questionnaire. The interviews were conducted with 45 staff members from the original laboratory. They included scientists, laboratory assistants, and office staff. With appropriate management permissions, participating staff members were provided with instructions to complete the survey within one week. A postal box was made available to deposit completed surveys.

The instrument
The research instrument was designed to be as simple as possible using the five ADKAR variables (Table 1). Each variable had four items designed to measure the concept mapped from factors that influence each element as described by Hiatt (8). The survey consisted of 20 questions, grouped as follows:

- Items 1 to 4 – measured awareness to change.
- Items 5 to 8 – measured desire to change.
- Items 9 to 12 – measured knowledge of the change.
- Items 13 to 16 – measured ability to perform during and after the change.
- Items 17 to 20 – measured reinforcement of change.

Participants' answers were rated according to a 5-point Likert scale where 1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, and 5=strongly agree. It included some demographic and work-related questions, such as length of service in the field and time with the organisation, qualifications, and age bracket. Statements were phrased with the positive and negative to control acquiescent response bias. Only a limited number of negatively phrased statements were used to minimise potential reader confusion. Reverse-keyed items 6, 7, 12, 15, 17, 18, and 20 were calculated whereby 5=strongly disagree to 1=strongly agree.

Factors described as influencing successful change management (7) informed the development of four items per element intended to provide understanding of the respondent's attitude to change (Table 2).

Table 2. ADKAR model: factors influencing the items designed for the questionnaire (adapted from Hiatt, 2006, p.45).

ELEMENT	FACTORS	ITEMS
REINFORCEMENT	The degree to which the reinforcement is meaningful and specific to the person impacted by the change. The association of the reinforcement with actual demonstrated progress or accomplishment. The absence of negative consequences. An accountability system that creates an ongoing mechanism to reinforce the change.	I do not feel supported by my organisation I am uncertain about my future career. I am willing to upskill and retrain in another occupation within the organisation if necessary . I have been forced to look at other job prospects elsewhere due to the Renewal.
AWARE	A person's view of the current state. How a person perceives problems. Credibility of the sender of awareness messages. Circulation of misinformation or rumours. Contestability of the reasons for changes.	I understand the issues that are being addressed by the Renewal. I agree with the Government's reasons to change. I have been well informed by my organisation about the necessary changes relating to the Renewal to date. I have been well informed by the external authorities about the changes involved in the Renewal to date.
DESIRE	The nature of the change (what the change is and how it will impact each person). The organisational or environmental context for the change (his or her perception of the organisation or environment that is subject to change). Each individual's personal situation. What motivates a person (those intrinsic motivators that are unique to an individual).	I am happy to be part of the Renewal. I expect reduced job satisfaction when the Renewal is implemented. I am certain the Renewal will impact on my job security . I support any changes necessary to do my job due to the Renewal .
KNOWLEDGE	The current knowledge base of an individual. The capability of this person to gain additional knowledge. Resources available for education and training. Access to or existence of the required knowledge.	I regard my current skills sufficient to continue to do my job after the Renewal. I am willing to undergo further training within cytology when the Renewal commences. I would like access to educational support and resources outside the scope of cytology prior to the Renewal. I have little knowledge about HPV as a primary screening test.
ABILITY	Psychological blocks. Physical abilities. Intellectual capability. The time available to develop the needed skills. The availability of resources to support the development of new abilities.	I will be able to perform better in my job after the Renewal. I have the ability to cope at work and do my job prior to the Renewal. My job has been more stressful since the announcement of the Renewal. I would like regular feedback about my performance against desired outcomes leading up to the Renewal.

To test the variance between the group mean scores One-way ANOVA analysis was performed (IBM SPSS version 22). The five AKDAR elements were treated as dependent variables and the groups (different laboratories) as independent variables (13). Correlation analysis was also performed.

Limitations

The sampling strategy used for the interview process (in the department in which the 1st author was a manager) was non-probability sampling as it included every staff member in the department. Personnel were requested to participate, although they had the natural right to refuse.

Using a non-random sampling technique with a small sample size arguably jeopardises the level of accuracy of the data and therefore the validity of the results. However, using the pragmatic approach the aim was to get accuracy that was "good enough for the purposes of research with the resources available for research" (11). This source specifies a heuristic of n=30 as the lowest safe sample size.

RESULTS

Results from Laboratory 4 were returned late and excluded from the result and two returned surveys from both Lab 1 and Lab 2 were incomplete and also excluded. The overall response rate was 52% from a total of 54 respondents out of 106 surveys distributed. Table 3 shows the response rates from the four laboratories, while Tables 4-6 show the reliability statistics for the interviews, inter-item correlations for the interviews, and the Cronbach's coefficient for the questionnaire respectively.

Table 3. Questionnaire response rates from four laboratories.

Lab	Sent	Returned	Discarded	Total	Percentage
Lab 1	44	21	2	19	43.18
Lab 2	46	27	2	25	54.34
Lab 3	16	10	0	10	62.5
Lab 4	25	0		0	0
Total	131	58	4	**54**	
Revised total	106	58	4	**54**	**52**

Table 4. Cronbach's alpha coefficient for the interviews.

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.607	.607	9

Table 5. Inter-item correlations for the interviews.

	Mean	Min.	Max.	Range	Max./Min.	Variance	N of Items
Inter-Item Correlations	.147	-.296	.621	.917	-2.096	.050	9

Table 6. Cronbach's alpha coefficient for the questionnaire

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.683	.687	20

The interviews

Paired-samples statistics was used to establish if there were any changes to the opinions of the individuals when asked the same question during the interviews in 2014 and in 2015 (Table 7),

Table 7. Paired-samples t-test for the interviews.

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	desire to work in cytology 2014	.82	38	.457	.074
	desire to work in cytology 2015	.82	38	.457	.074
Pair 2	upskill in another dept 2014	.74	38	.503	.082
	upskill in another dept 2015	.74	38	.503	.082
Pair 3	move to another role within the company 2014	.47	38	.647	.105
	move to another role within the company 2015	.37	38	.633	.103
Pair 4	retrain higher education 2014	.34	38	.534	.087
	retrain higher education 2015	.29	38	.515	.084
Pair 5	career advice 2014	.58	38	.500	.081
	career advice 2015	.63	38	.489	.079
Pair 6	skills in CV interview 2014	.66	38	.481	.078
	skills in CV interview 2015	.74	38	.446	.072
Pair 7	financial advice 2014	.16	38	.370	.060
	financial advice 2015	.13	38	.343	.056
Pair 8	intention to leave before restructure 2014	.24	38	.634	.103
	intention to leave before restructure 2015	.32	38	.702	.114
Pair 9	intention to take voluntary redundancy 2014	.39	38	.718	.116
	intention to take voluntary redundancy 2015	.37	38	.675	.109

There was little difference between the mean scores, however, there was a slight decrease in the 2015 values for 'move to another role in the company', 'retrain higher education', 'financial advice', and 'intention to take voluntary redundancy', which indicated that some individuals changed their minds from the previous year. Similarly, the mean value increased slightly in 2015 for 'career advice', 'skills in CV writing and interviewing', and 'intention to leave before the restructure'. However, the paired-samples t-test results showed no statistical significance.

The interview data analysis, measuring 9 items produced a (sub - optimal) Cronbach's alpha coefficient of 0.6. Similarly, the mean inter-item correlation of .147 is below the optimal 0.2 (Tables 4 & 5). We regard these findings as having a common sense, face validity. We acknowledge the limitations of the small sample size potentially impacting reproducibility. The Pearson product-moment correlation coefficient was calculated for the group of variables from the interviews held in 2014 and 2015. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. There significant positive correlations are evident (Table 8).

Table 8. Pearson product-moment correlations between measures of 2014 and 2015 interview items.

	Scale	1	2	3	4	5	6	7	8
1	Desire to work in cyto 2014		.87**	0.304		-0.178		.489**	
2	Desire to work in cyto 2015	.87**			0.148		-0.112		.372*
3	Move to another role in the company 2014					0.3		.476**	
4	Move to another role in the company 2015						.658**		0.312
5	Retrain higher education 2014							0.243	
6	Retrain higher education 2015								0.302
7	Upskill in another dept 2014								
8	Upskill in another dept 2015								

**Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

The relationship between retraining to a higher education in 2015 and moving to another role within the company in 2015 showed there was a strong, positive correlation between the two variables, $r = .66$, $n=38$, $p < .01$. The equivalent correlation result for 2014 was not statistically significant.

The desire to work in cytology 2014 and upskill in another department showed a medium, positive correlation between the two variables, $r = .49$, $n=38$, $p < .01$. The correlation between the same two variables dropped in 2015 however there was a small, positive correlation $r=.37$, $n=38$, $p < .05$.

In 2014 there was a medium, positive correlation between the two variables 'move to another role in the company' and 'upskill in another department', $r=.47$, $n=38$, $p < .01$ however there was no statistically significant correlation for the same variables in 2015. Evidence for a desire to upskill in, and move to another department that was evident in 2014 was not evident in 2015.

Comments
In addition to the semi-structured questions, individuals were invited to comment. Most staff wanted to stay until the "restructure of the department". However, many wanted to know if they were likely to have a position or be made redundant, as soon as practically possible. In 2014 only three staff members had decided to take voluntary redundancy, and only seven were unsure. In 2015 the numbers changed to six employees being certain and four who were unsure whether to take voluntary redundancy. Some of the comments made by staff during the interviews in 2014 were as follows:

"I am concerned the job will become less of a daily challenge with the change in screening"…..
"Taking on new career through a university would be either too expense" or "too hard" or "too time consuming"…..
"I don't expect to get a job as I don't do all the tasks"……

In the 2015 round there were no new comments to add and most personnel had decided that if there was no position for them in the department then redeployment was the most favoured option.

Questionnaire results
The one-way ANOVA means plot results demonstrated a statistically significant difference among the means scores of dependent variable Desire for the participants from three (of four) laboratories where the Sig. value was .029 ($p \leq .05$). Multiple comparisons were unable to be calculated which would have provided the statistical significance of the differences between each laboratory. It was assumed the sample size affected these results.

The Spearman's rho correlation coefficient analysis revealed positive relationships between Desire and three other variables – Awareness, Ability and Reinforcement. There was also a weak, positive relationship between Reinforcement and Knowledge and a positive relationship between Reinforcement and Ability.

The Cronbach's alpha coefficient calculated for internal consistency was .68 (ideally 0.7 or above) (Table 6). Deleting the item 'non-cyto educational support' would achieve 0.7, however, we considered it preferable to leave the data unchanged.

Response rate
Due to the sensitivity of the subject matter a low response rate was anticipated. Some personnel were strongly impacted, even traumatised by the Renewal so were expected to question the value in filling out a questionnaire (personal communication, 2015). The actual response rate of 52% was better than anticipated. The response rate for the questionnaire for Lab 1 was below 50% (Table 5). Laboratory 4 responded, but the response was too late for inclusion in the analysis due to the time constraints of the academic research project.

DISCUSSION

The Renewal projected up to 75% redundancies in most cytology laboratories across Australia (A. Farnsworth, personal communication, May 30, 2015). Therefore it was imperative to minimise as many forced redundancies in the researcher's department as possible; a challenging task given that the privately-owned cytology department processing over 200,000 Pap tests per annum had a workforce of around 48 full-time equivalents.

One of the aims of the research was to encourage and inform individuals of their options with timeframes so they might take personal initiatives to pre-empt the inevitable redundancy and re-deployment. Participatory action research allowed for open communication and ongoing support for individuals who chose to move to another career either within the company or elsewhere. Eight staff members, from the laboratory in which interviews were conducted, left between the 2014 and 2015 interviews; three were transferred to other departments within the organisation, two secured cytology jobs elsewhere - one interstate and the other overseas; two moved to a different role outside the organisation and one was made redundant through mutual agreement. According to the interview notes of each of these staff members, seven out of the eight individuals were already planning to leave the department if the right opportunity arose.

At the time of the first round of interviews in 2014 management were unsure of the details and mechanisms of the inevitable future downsizing. At one stage it was thought there would need to be a complete restructuring of the department; staff members needing to apply for the available positions. However, action research allowed for reflection and re-evaluation of any tentative plans through the collection and review of information from staff members. In the event, the research confirmed previously reported support for action research at this scale, proving appropriate in a workplace where problems arose in real-time from external influences (11,14).

In 2014 those individuals who rated their desire to stay in the cytology profession below 7 (1-10 scale) were individuals who had decided to take voluntary redundancy (n=5) or were investigating alternative training options (n=2). The latter two increased to six individuals in 2015 which suggests that in the interim the individuals were able to evaluate the impact of proposed changes on their current role and/or identify alternative opportunities.

These responses related to dealing with change. The job will change; the individual would need to determine if the new, different job would interest them. Some staff were concerned that retraining in a completely different career would be expensive, challenging and difficult; however, in 2015 the data suggested there had been some changes in opinion to further study. Most staff members were willing to upskill into another department in the organisation (options being haematology, microbiology, immunology, genetics, marketing and phlebotomy). The interview correlations could be interpreted to mean that some individuals were planning ahead with respect to further study; upskilling to suit redeployment in another department within the company.

The change in attitude from 2014 to 2015, a reduction in desire to upskill and move to another department may have been due to staff members making choices in 2014 without thinking about how that option might impact on them in the long term. The correlation between desire to stay in the cytology profession and upskilling in another department was statistically significant in both years. Possible reasons for these apparently conflicting results include: one, that employees desire to stay in the medical laboratory science field; and two, employees desire to stay with the company either for a range of reasons such as job security, continuation of service, ease of transfer, or even loyalty.

Finally, the strong, positive correlation between retraining at an institution for a higher education and moving to another role within the company (but not medical laboratory science) shown in the 2015 correlation results but not the 2014 correlations is interesting. This indicates that some personnel have recognised that studying towards a new career was a possible option after all.

In 2015, no negative comments were recorded during the interviews, suggesting staff members had moved through at least some of the seven stages in reaching acceptance to change (15,16). A contributory factor to minimising resistance to change was ongoing communication from internal and external sources; reported elsewhere as a positive influence (17-20). Middle managers are reported to have a significant role in implementing and directing change management strategies (21-23).

The low response rate for Laboratory 1 might have been be due to a perception that anonymity, despite being ‘promised’ in the accompanying letter, could be compromised by their familiarity with the researcher. The same individuals may have felt that their contribution to the interview rounds was enough and so declined to respond to the survey. In addition, some staff members were absent during the limited period offered for submission of completed questionnaires.

The response rates from the other two laboratories were higher; however, the researcher had little control about how the external participants were instructed to complete the survey by their managers. The researcher did, however, emphasise to the participating managers that employees were not to be pressurised or feel anyway obliged to participate.

The laboratory executive team assumed that the researcher (middle management) would lead the change management process, delegating the selection of approach to the researcher. The application of successful change management strategies is, however, reported to require a sound knowledge of theoretical concepts (24,25). The Renewal presented new challenges to the researcher and required careful and considered planning. Whilst the process of change implementation was not unfamiliar to the researcher, most previous changes made were small in comparison. A competent middle manager willing to take on a challenging task involving change is more likely (than a more senior manager) to be successful as they are in direct contact with the individuals affected by the changes (25). Our experience suggests that while the level of trust given to the researcher may have been risky, the overall approach of a middle manager engaging in action research is sound.

The ADKAR model is a framework for understanding change at the individual level (8). The model is designed to assist management in the successful transition of changes in the planning of change management activities; diagnosing gaps; developing corrective actions; and supporting managers and supervisors (7).

The results from the questionnaire provided information for developing support strategies for individuals through the transition period. Desire was one of the elements from the ADKAR model that had a positive relationship to Awareness, Ability and Reinforcement. The significant means test result for Desire suggests that individuals may be struggling to want to accept the changes of the Renewal; understandable as the outcome of the Renewal will affect everyone - some will need to change their careers. Many individuals have had a long working history in their current roles and many have also been with the same employer for years. Therefore the desire to change effectively means accepting a new role with new work colleagues and possibly with a new organisation.

Some specific change management tactics that have been reported to influence and create Desire include:

- Effectively sponsor the change with employee.
- Equip managers to be change leaders.
- Assess risks and anticipate resistance.
- Engage employees in the change process.
- Align incentive programmes.

We developed strategies for management to assist individuals in creating the desire to accept change. Each element of the ADKAR model has associated factors and tactics designed to build awareness, develop knowledge, foster ability and reinforce change.

Participation in our survey was voluntary, anonymous and confidential (response rate from the researcher’s laboratory - 43%). An alternative strategy might be to use the ADKAR model following discussions with those individuals who require more assistance. The information gathered from surveys using the ADKAR framework would arguably be of greater benefit to the individual and the change-agent if the questionnaire was completed by all staff members who could subsequently be identified; however, this would comprise the confidentiality of the survey and pose potential ethical risks.

The combined research approach of participatory action research and ADKAR modelling proved complementary. Both methods focussed on the individual to facilitate change. Through open and ongoing communication, support, encouragement, and advice many staff members have acted independently and taken up opportunities to change their future job prospects. Our research has arguably achieved a reduction in redundancy and redeployment, benefitting all staff members, those remaining and those leaving, while providing financial benefit for the organisation.

An extensive body of knowledge exists on the subjects of change management strategies and models and on action research. To date, the ADKAR model has only attracted limited research (9-10). The framework is relatively recent, limiting researcher awareness and uptake; however, recent and continuing research shows promise of greater uptake of the method and growing understanding of its application (26-28).

CONCLUSIONS

Changes may be forced on areas within the health sector due to ongoing research and the imperative to respond rapidly to new knowledge, technology or medical techniques. Those changes can impact the lives and well-being of skilled individuals, who in other sectors might reasonably expect to complete a career without being forced to re-train. Organisations have a responsibility to manage change so as to mitigate the negative impacts of change on individuals.

Participatory action research is an effective methodological strategy to undertake in the workplace to manage such change. In the present case it provided better understanding of individuals' perspectives on change, and demonstrated potential to achieve beneficial outcomes for the workforce. In this study, participatory action research was found to empower all involved, enabling the operational aspects of the organisation to continue almost uninterrupted in maintaining its continued quality service to its customers.

The results demonstrated both the strength and limitations of participatory action research: the people whose lives were impacted by change were supported; the negative effects of change were mitigated; but while changes in individuals' perceptions and attitudes could be demonstrated, the wider benefit to a group not be rigorously demonstrated in comparison to a control group, as might be expected in a traditional scientific study.

The ADKAR model proved effective and appropriate as vehicle for change management in combination with the action research methodology. Change management models provide added information especially when the change process is complex and difficult to implement. As a guide they can effectively direct the change-agent to sources of resistance and offer strategies to overcome complex issues.

These results in which Desire, Ability and Reinforcement had a positive correlation with each other, and variables Awareness and Desire; and Reinforcement and Knowledge were positively correlated can be interpreted to mean:

- The more the individual was aware of change, the stronger was the desire of the individual to change.
- The stronger the desire the individual had to change, the more capable the individual will be to change and reinforce the changes.

Information, and therefore knowledge, reinforces change. The relationships revealed in this research support the ADKAR model descriptions in which the five elements are linked and promote successful change management (8).

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The listed persons below reviewed submitted articles to the Journal between August 2016 and July 2017, some more than once. All submitted articles undergo peer review in order that the Journal maintains its high standard. Additionally, thoughtful comments and suggestions made by reviewers help authors in ensuring that their articles, if accepted, are put in front of the reader in the best possible light. The Editor thanks the reviewers for their valuable time and effort, and Dr. Nevil Pierse, the Journal's Statistical Editor, for statistical review of submitted articles.

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NOTICE OF THE NZIMLS ANNUAL GENERAL MEETING 2017

Notice is hereby given of the 73rd Annual General Meeting of the New Zealand Institute of Medical Laboratory Science (Inc) to be held at the Rutherford Hotel, Nelson on ***Thursday 24th August 2017*** *commencing at 7.00am sharp for a 7.30am start (a breakfast meeting). Register for the meeting via the ASM Registration page on the NZIMLS website.*

ORIGINAL ARTICLE

Identification of ISO 22870:2016 conformance requirements for medical laboratory internal auditing

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ABSTRACT

Objectives: The main aim of this study was to quantify the conformance requirements in ISO 22870:2016 that are connected to internal auditing. The contributing objectives include the identification of conformance requirements in ISO 22870:2016 for quantification purposes as well as determination of relative effort required for each subclause to be considered by internal auditors in a process-based quality management system framework.
Methods: The conformance requirements were identified and located in Clauses 4 and 5 of ISO 22870:2016 by conducting a comprehensive content analysis. The identified conformance requirements were then allocated to the process-based quality management system framework, which consists of four major stages for distribution analysis: 'strategic management', 'process control, design and planning', 'analytical processes' and 'process evaluation and improvement'.
Results: A total of 1,604 conformance requirements were identified in Clauses 4 and 5 of ISO 22870:2016. Clauses 4 and 5 contained 668/1,604 (41.6%) conformance requirements and 936/1,604 (58.4%) conformance requirements respectively. The overall percentage ranged from 4/1,604 (0.2%) conformance requirements in Subclause 4.8 to 333/1,604 (20.8%) conformance requirements in Subclause 5.3. Extensive cross-referencing of ISO 22870:2016 to ISO 15189:2012 was also identified; a total of 1,308/1,604 (81.5%) conformance requirements were from ISO 15189:2012. The distribution of conformance requirements was then arranged according to the four major stages, and it was found that 404/1,604 (25%) conformance requirements were associated with 'strategic management', 669/1,604 (42%) conformance requirements with 'process control, design and planning', 281/1,604 (18%) conformance requirements with 'analytical processes' and 250/1,604 (16%) conformance requirements with 'process evaluation and improvement'. Among the identified conformance requirements, there were four areas of concern to which internal auditors need to pay extra attention in order to optimise the internal audit process. Areas include the authorisation and training processes of operators, electrical safety of medical equipment, compliance of relevant regulations, and the specificity of the internal audit.
Conclusions: The present study contributes to existing knowledge of ISO 22870 application by providing insights into how ISO 22870:2016 requires the medical laboratory to fulfil relevant management system and technical competence requirements. This enables the medical laboratory to develop a sound internal audit process appropriate to the organisation. An effective and efficient internal audit process is highly likely to provide additional assurance to patients through active management of risks of the medical laboratory.
Keywords: continuous quality management; point-of-care testing; quality control; quality improvement; total quality management.

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INTRODUCTION

Quality management plays a pivotal role in direct support of medical laboratory capacity to produce technically competent results. Recently, developments in the field of point-of-care testing (POCT) have made it imperative that medical laboratory professionals adapt to rapid changes in diagnostic practices (1,2). POCT has been defined by the International Organization for Standardization (ISO) as 'testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient' (3). Medical laboratory professionals, especially the medical laboratory scientists who have in-depth management and technical knowledge, bear the brunt of the implementation of POCT by strengthening quality management practices and implementing suitable control measures to comply with all relevant guidelines and recommendations.

Reputable international non-governmental organisations, such as the ISO and the International Electrotechnical Commission, continue to provide universally recognised requirements in the form of standards in accordance with the editorial rules of ISO/IEC DIR 2:2016 entitled 'Principles and rules for the structure and drafting of ISO and IEC documents' (4) to support the optimisation of such quality management systems. For the medical laboratory, the implementation of ISO 15189:2012 entitled 'Medical laboratories — Requirements for quality and competence' (5), which is based on the momentum set by ISO 9001:2008 (6), ISO 9001:2008/Cor.1:2009 (7), ISO/IEC 17025:2005 (8) and ISO/IEC 17025:2005/Cor.1:2006 (9), continue to provide specific requirements for competence and quality for medical laboratory quality management operations. Together with further local, regional and national regulations, there are many implementation requirements to consider during the sustainment of POCT operations.

POCT technology is rapidly changing and increasingly innovative, especially with the latest advances in microfluidics and nanotechnology (10-13), which allow size reduction with enhanced connectivity (14). To maintain the operational currency of the POCT environment, the ISO has updated ISO 22870:2006 entitled 'Point-of-care testing (POCT) — Requirements for quality and competence' (15) to ISO 22870:2016 entitled 'Point-of-care testing (POCT) — Requirements for quality and competence' (3) to reflect contemporary concepts and opinions relating to POCT quality management. The popularity of using POCT, particularly in medical device format, to support the main medical laboratory has led to an increased interest in the implementation by various international organisations, such as the International Council for Standardization in Haematology (16), the International Federation of Biomedical Laboratory Science (17), the International Federation of Clinical Chemistry and Laboratory Medicine (18) and the World Health Organization (19).

To date there has been limited research in the internal auditing aspects of ISO 22870:2016, especially in the area of requirements management. No previous study has focused on the quantitative analysis of conformance requirements in Clauses 4 (management requirements) and 5 (technical requirements) of ISO 22870:2016 (3,pp.1-10). The main idea of this paper is to clarify the requirements management aspect of ISO 22870:2016 by quantifying the conformance requirements which are associated with internal auditing purposes. In order to determine how many conformance requirements there are for the medical laboratory to consider, the investigation comprised two main steps. First, the conformance requirements were identified by analysing the relevant contents of ISO 22870:2006 (15) and ISO 22870:2016 (3) for quantification purposes by content analysis. The data was managed by a computer-aided qualitative data analysis software (CAQDAS) package, as previously described (20). Second, a distribution analysis of conformance requirements was performed for the four major stages of the process-based quality management system framework modelled in ISO 9001:2005 entitled 'Quality management systems — Requirements' (21,pp.vii-ix) and ISO 15189:2012 (22), so as to facilitate the logistic process of allocating the necessary administrative resources for internal auditing. Finally, this paper identifies four points that merit further consideration by internal auditors in order to address and clarify potential issues relevant to planning and preparation. Overall, this paper provides useful starting points for medical laboratories intending to design a comprehensive checklist for internal audit (IA) purposes with greater effectiveness and efficiency while satisfying the conformance requirements of Subclause 4.14 (internal audits) of ISO 22870:2016 (3,p.6).

The findings should make an important contribution to medical laboratories that plan to implement an IA process. Subclause 4.14 of ISO 22870:2016 (3,p.6) specifies that the medical laboratory must conduct IAs at planned intervals to determine whether all activities in the quality management system conform to the requirements established by the medical laboratory. It is important to note that the information is particularly useful if the medical laboratory plans to prepare checklists for recording audit evidence, as suggested by Subclause 6.3.4 (preparing work documents) of ISO 19011:2011 (23,p.18). The IA audit is a continuous process in the medical laboratory, and it may operate under the pressure of both commercial and compliance considerations. Comprehensive and up-to-date checklists to support the IA process can provide the medical laboratory with additional assurance that the processes are operating as per expected specifications. Due to practical constraints, this study cannot provide a comprehensive review of the compliance obligations that the medical laboratory needs to consider. The medical laboratory must determine further compliance requirements associated with relevant local, regional, national and international regulations.

MATERIALS AND METHODS

Content analysis of Clauses 4 and 5 of ISO 22870

The content analysis was performed using ISO 22870:2006 (15) and ISO 22870:2016 (3) published by the ISO (24). Textual analysis was used to identify the occurrences of the specific term 'shall' and conceptual analysis was used to check the frequency of conformance requirements, as previously described (20). The specific areas of interest were Clauses 4 and 5 of ISO 22870:2006 (15,pp.1-10) and Clauses 4 and 5 of ISO 22870:2016 (3,pp.1-10). ISO 22870:2006 (15) refers to relevant subclauses of ISO 15189:2003 (25), and ISO 22870:2016 (3) refers to relevant subclauses of ISO 15189:2012 (5). However, the ISO published a corrected version of ISO 15189:2012 in 2014 (5). The corrected version contains various editorial corrections in the presentation format only, the results of content analysis performed on the original version of ISO 15189:2012 remains valid and applicable information related to conformance requirements was used from previous analysis (20).

Computer-aided qualitative data analysis

A CAQDAS package, NVivo™ 10 for Window® (version 10.0.638.0) (QSR International, Doncaster, Victoria, Australia) (NVivo™), was used for the quantitation of conformance requirements during the content analysis (26,27), as previously described (20).

RESULTS

Identification and location of ISO 22870 conformance requirements in Clauses 4 and 5 of ISO 22870

Content analysis was used to identify and locate the conformance requirements in Clauses 4 and 5 of ISO 22870:2006 (15,pp.1-10) and Clauses 4 and 5 of ISO 22870:2016 (3,pp.1-10). The main characteristic of ISO 22870 is the number of cross-references to ISO 15189. The extent of cross-referencing for ISO 22870:2006 and ISO 22870:2016 can be calculated by extracting the relevant ISO 15189 inclusion information from the respective ISO 22870 (Table 1). The results show that ISO 22870:2006 and ISO 22870:2016 cross-reference to ISO 15189:2003 (n = 39) and ISO 15189:2012 (n = 42) respectively (Table 1).

The next section of the content analysis was conducted on ISO 22870. The first session of content analysis was performed on ISO 22870:2006. Conformance requirements were distributed between Clauses 4 and 5 of ISO 22870:2006 (15,pp.1-10) (Table 2). A total of 1,153 conformance requirements were identified, with Clause 4 containing 552/1,153 (47.9%) conformance requirements and Clause 5 containing 601/1,153 (52.1%) conformance requirements. The conformance requirements were concentrated in Subclause 4.2 containing 152/1,153 (13.2%) conformance requirements. In order to determine the changes that have occurred in the latest publication of the standard, the second set of content analysis was conducted on ISO 22870:2016, conformance requirements were distributed between Clauses 4 and 5 of ISO 22870:2016 (3,pp.1-10) (Table 2).

A total of 1,604 conformance requirements were identified, with Clause 4 containing 668/1,604 (41.6%) conformance requirements and Clause 5 containing 936/1,604 (58.4%) conformance requirements. To illustrate the extent of cross-referencing of ISO 22870:2016 to ISO 15189:2012, the quantity of conformance requirements was expressed in stacked bars (Figure 1).

Table 1. Cross-referencing between subclauses of ISO 22870 and applicable subclauses of ISO 15189. The first column represents ISO 22870:2006 and ISO 22870:2016. Subclauses of ISO 22870:2006 (n = 33) cross-reference to subclauses of ISO 15189:2003 (n = 39) represented in the second column whereas subclauses of ISO 22870:2016 (n = 29) cross-reference to subclauses of ISO 15189:2016 (n = 42) represented in the third column.

ISO 22870 (n = 33)	**ISO 15189:2003** (n = 39)	**ISO 15189:2012** (n = 42)
4.1.1	**4.1.1**	**4.1.1.2** *Legal entity* **4.1.1.3** *Ethical conduct*
4.1.2	**4.1.2**	**4.1.2.2** *Needs of users*
4.1.3	**4.1.3**	**4.1.1.1** *General*
4.2.1	**4.2** *Quality management system*	**4.1.2.3** *Quality policy* **4.1.2.4** *Quality objectives and planning* **4.1.2.6** *Communication*
4.2.4	**4.2.3**	**4.1.2.3** *Quality policy* **4.1.2.4** *Quality objectives and planning*
4.2.5	**4.2.4**	**4.2.2** *Documentation requirements*
4.3 *Document control*	**4.3** *Document control* **4.3.1** **4.3.2** **4.3.3**	**4.3** *Document control*
4.4 *Service agreements*	**4.4** *Review of contracts*	**4.4** *Service agreements*
4.6 *External services and supplies*	**4.6** *External services and supplies*	**4.6** *External services and supplies*
4.7 *Advisory services*	**4.7** *Advisory services*	**4.7** *Advisory services*
4.8 *Resolution of Complaints*	**4.8** *Resolution of complaints*	**4.8** *Resolution of complaints*
4.9.1	**4.9** *Identification and control of nonconformities*	**4.9** *Identification and control of nonconformities*
4.10.1	**4.10** *Corrective action*	**4.10** *Corrective action*
4.11.1	**4.11** *Preventive action*	**4.11** *Preventive action*
4.12.1	**4.12** *Continual improvement*	**4.12** *Continual improvement* **4.14.6** *Risk management* **4.14.7** *Quality indicators*
4.13.1	**4.13** *Quality and technical records*	**4.13** *Control of records*
4.14 *Internal audits*	**4.14** *Internal audits*	**4.14.1** *General* **4.14.5** *Internal audit*
4.15.1	**4.15** *Management review*	**4.15** *Management review*
5.1 *Personnel*	**5.1** *Personnel*	**4.1.1.4** *Laboratory director* **5.1** *Personnel*
5.1.2	**5.1.3**	
5.1.3	**5.1.4**	**4.1.2.5** *Responsibility, authority and interrelationships*
5.1.4	**5.1.7**	**5.1.2** *Personnel qualifications* **5.1.6** *Competence assessment* **5.1.8** *Continuing education and professional development*
5.1.5*	**5.1.4** **5.1.9** **5.1.11** **5.1.12**	
5.2.1	**5.2** *Accommodation and environmental conditions*	**5.2** *Accommodation and environmental conditions*
5.3.1	**5.3** *Laboratory equipment*	**5.3** *Laboratory equipment, reagents, and consumables* **5.9.2** *Automated selection and reporting of results* **5.10** *Laboratory information management*
5.4.1	**5.4** *Pre-examination procedures*	**5.4.1** *General* **5.4.4.2** *Instructions for pre-collection activities*
5.5.1	**5.5** *Examination procedures*	**5.5** *Examination processes*
5.6.1	**5.6** *Assuring quality of examination procedures*	**5.6** *Ensuring quality of examination results*
5.6.4†	**5.6.4**	
5.6.7‡	**5.6.6**	
5.6.8§	**5.6.7**	
5.7.1	**5.7** *Post-examination procedures*	**5.7** *Post-examination processes*
5.8.1	**5.8** *Reporting of results*	**5.8** *Reporting of results* **5.9** *Release of results*

* Subclause 5.1.5 of ISO 22870:2006 cross-references to Subclauses 5.1.4, 5.1.9, 5.1.11 and 5.1.12 of ISO 15189:2003 only.
† Subclause 5.6.4 of ISO 22870:2006 cross-references to Subclause 5.6.4 of ISO 15189:2003 only.
‡ Subclause 5.6.7 of ISO 22870:2006 cross-references to Subclause 5.6.6 of ISO 15189:2003 only.
§ Subclause 5.6.8 of ISO 22870:2006 cross-references to Subclause 5.6.7 of ISO 15189:2003 only.

Table 2. The frequency of conformance requirements in ISO 22870. Clauses 4 and 5 of ISO 22870:2006 contain 1,153 conformance requirements represented in the second column whereas Clauses 4 and 5 of ISO 22870:2016 contain 1,604 conformance requirements represented in the third column.

	Frequency	
ISO 22870 subclause number (n = 23)	**ISO 22870:2006 (total n = 1,153)**	**ISO 22870:2016 (total n = 1,604)**
Subclause 4.1 *Organization and management*	41/1,153 (3.6%)	52/1,604 (3.2%)
Subclause 4.2 *Quality management system*	152/1,153 (13.2%)	148/1,604 (9.2%)
Subclause 4.3 *Document control*	36/1,153 (3.1%)	31/1,604 (1.9%)
Subclause 4.4 *Review of contracts*	29/1,153 (2.5%)	35/1,604 (2.2%)
Subclause 4.5 *Examination by referral laboratories*	0/1,153 (0.0%)	0/1,604 (0.0%)
Subclause 4.6 *External services and supplies*	46/1,153 (4.0%)	26/1,604 (1.6%)
Subclause 4.7 *Advisory services*	5/1,153 (0.4%)	11/1,604 (0.7%)
Subclause 4.8 *Resolution of complaints*	5/1,153 (0.4%)	4/1,604 (0.2%)
Subclause 4.9 *Identification and control of nonconformities*	56/1,153 (4.9%)	43/1,604 (2.7%)
Subclause 4.10 *Corrective action*	21/1,153 (1.8%)	21/1,604 (1.3%)
Subclause 4.11 *Preventive action*	20/1,153 (1.7%)	19/1,604 (1.2%)
Subclause 4.12 *Continual improvement*	20/1,153 (1.7%)	60/1,604 (3.7%)
Subclause 4.13 *Quality and technical records*	35/1,153 (3.0%)	72/1,604 (4.5%)
Subclause 4.14 *Internal audits*	25/1,153 (2.2%)	80/1,604 (5.0%)
Subclause 4.15 *Management review*	61/1,153 (5.3%)	66/1,604 (4.1%)
Subclause 5.1 *Personnel*	117/1,153 (10.1%)	214/1,604 (13.3%)
Subclause 5.2 *Accommodation and environmental conditions*	59/1,153 (5.1%)	96/1,604 (6.0%)
Subclause 5.3 *Equipment*	121/1,153 (10.5%)	333/1,604 (20.8%)
Subclause 5.4 *Pre-examination procedures*	88/1,153 (7.6%)	17/1,604 (1.1%)
Subclause 5.5 *Examination procedures*	49/1,153 (4.2%)	73/1,604 (4.6%)
Subclause 5.6 *Assuring the quality of examination procedures*	70/1,153 (6.1%)	79/1,604 (4.9%)
Subclause 5.7 *Post-examination procedure*	14/1,153 (1.2%)	29/1,604 (1.8%)
Subclause 5.8 *Reporting of results*	83/1,153 (7.2%)	95/1,604 (5.9%)
Total	**1,153/1,153 (100%)**	**1,604/1,604 (100%)**

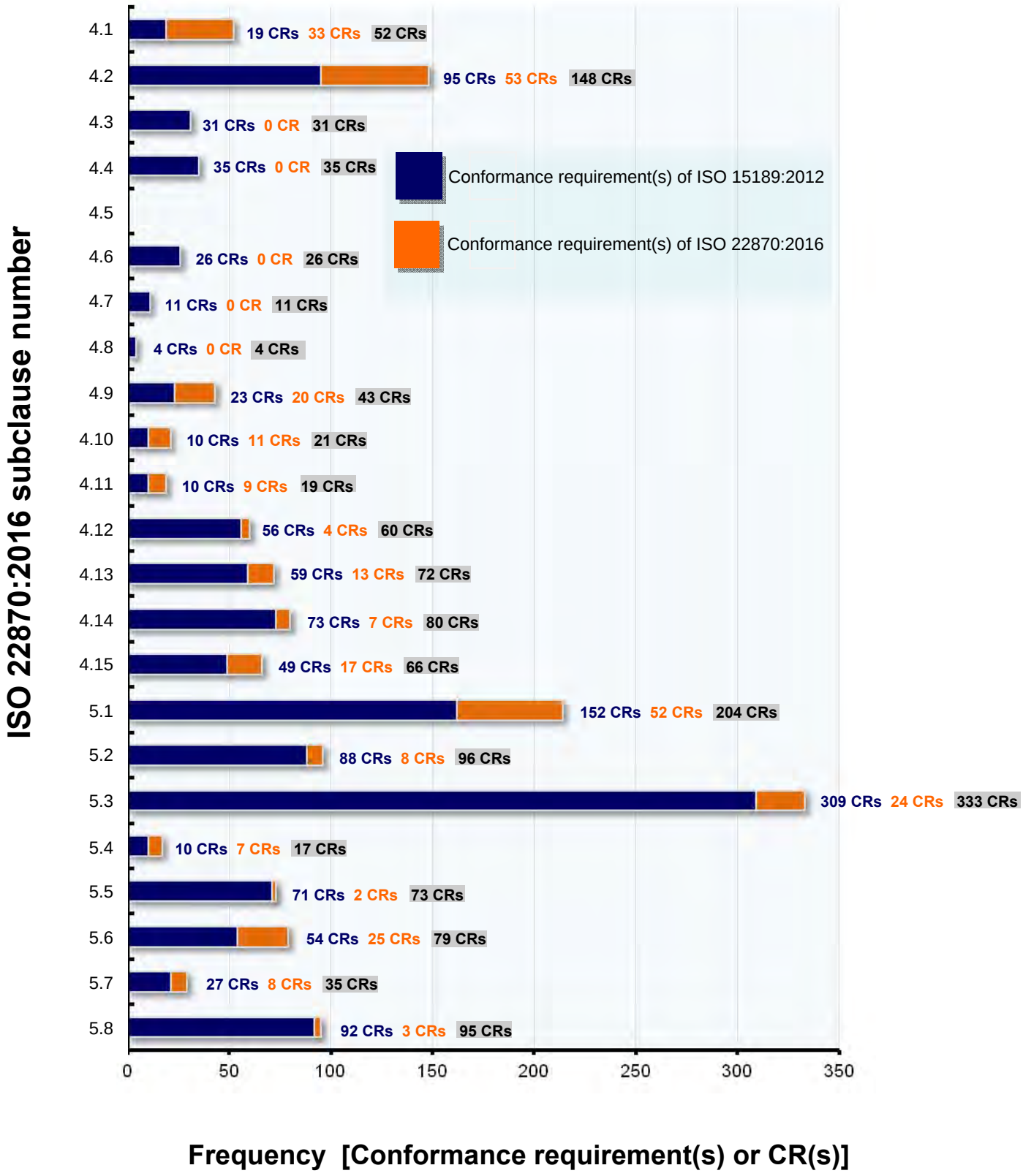

Figure 1. The frequency of conformance requirements in ISO 22870:2016. The quantitation of conformance requirements is expressed in stacked bars. Blue indicates the quantity of conformance requirements in ISO 15189:2012 while orange indicates the quantity of conformance requirements in ISO 22870:2016. Bold black type highlighted in grey indicates the total number of conformance requirements.

NOTE. Subclause 4.5 does not apply to ISO 15189:2016.

It was determined that a total of 1,308/1,604 (81.5%) conformance requirements were from ISO 15189:2012, and the remaining 296/1,604 (18.5%) conformance requirements were from ISO 22870:2016. A comparison of the two results reveals that there is a clear trend of increasing conformance requirements; an increase of 451 conformance requirements in ISO 22870:2016 was observed. The overall percentage was ranged from 4/1,604 (0.2%) conformance requirements in Subclause 4.8 (resolution of complaints) of ISO 22870:2016 (3,p.4) and 333/1,604 (20.8%) conformance requirements in Subclause 5.3 (equipment) of ISO 22870:2016 (3,p.8). The percentages are summarised in a doughnut chart (Figure 2). The single most striking observation to emerge from the relative percentages is in Subclause 5.3 of ISO 22870:2016 (3,p.8) relating to equipment. The percentage suggests that there is a strong emphasis on the handling of equipment. The overall percentage presentation over Clauses 4 and 5 of ISO 22870:2016 (3,pp.1-10) has highlighted the proportion of effort required for internal auditing in each subclause.

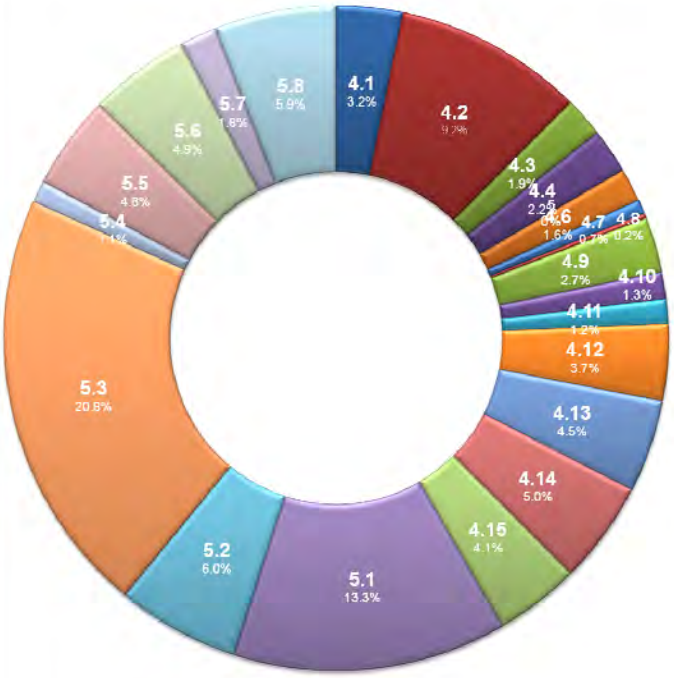

Figure 2. Percentage of conformance requirements distribution over Clauses 4 and 5 of ISO 22870:2016.

The frequency of conformance requirements in the ISO 22870:2016 process-based quality management system framework

Content analysis identified and located the conformance requirements in the four-stage process-based quality management system framework (Figure 3). Each subclause of ISO 22870:2016 is allocated to a specific stage according to their activities. The four stages include 'strategic management', 'process control, design and planning', 'analytical process' and 'process evaluation and improvement'.

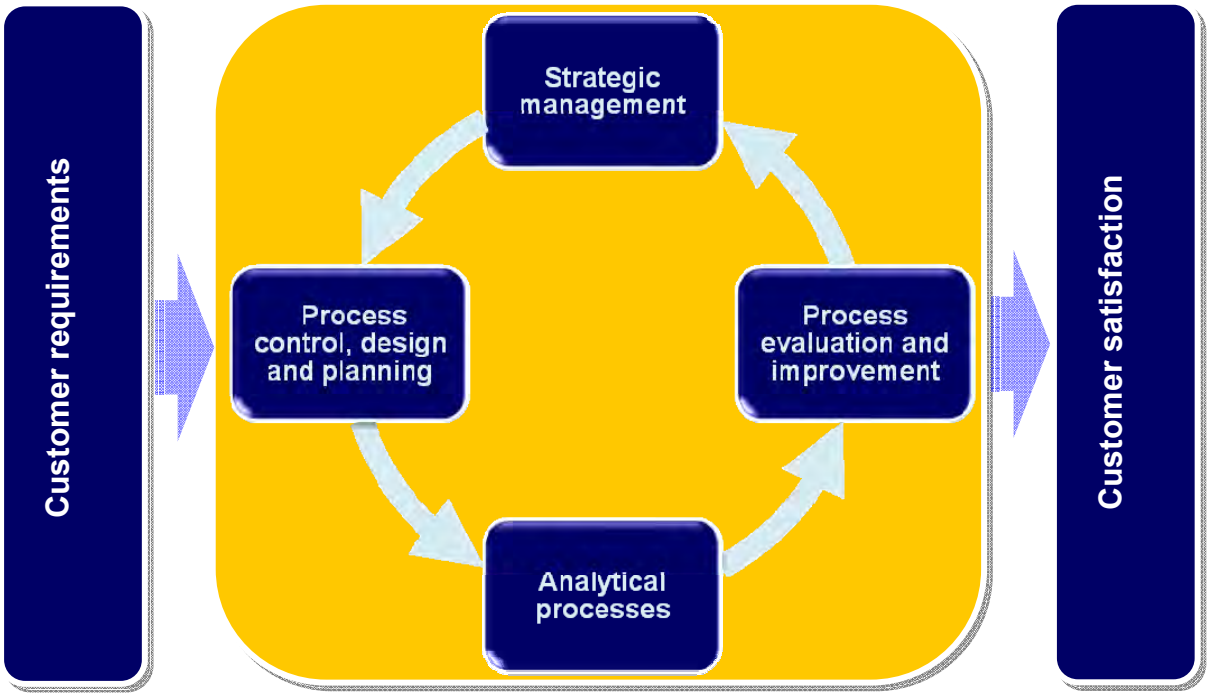

Figure 3. Overview of the ISO 22870:2016 process-based quality management system framework. The framework consists of four major stages: 'strategic management'; 'process control, design and planning'; 'process evaluation and improvement'; and 'analytical processes'. Each stage contains specific subclauses of ISO 22870:2016.

The distribution of conformance requirements is further arranged according to the stages (Figure 4). The 'strategic management' stage contained a total of 404/1,604 (25%) conformance requirements. The 'process control, design and planning' stage contained a total of 669/1,604 (42%) conformance requirements. The 'analytical processes' stage contained a total of 281/1,604 (18%) conformance requirements. The 'process evaluation and improvement' stage contained a total of 250/1,604 (16%) conformance requirements. In summary, these results demonstrate that the 'process control, design and planning' stage is the most technically demanding area for the purpose of internal auditing.

Strategic management	**Subclause 4.1**	*Organization and management*	52/1,604 (3.2%)
	Subclause 4.2	*Quality management system*	148/1,604 (9.2%)
	Subclause 4.3	*Document control*	31/1,604 (1.9%)
	Subclause 4.4	*Service agreements*	35/1,604 (2.2%)
	Subclause 4.13	*Quality and technical records*	72/1,604 (4.5%)
	Subclause 4.15	*Management review*	66/1,604 (4.1%)
		Subtotal	404/1,604 (25%)
Process control, design and planning	**Subclause 4.6**	*External services and supplies*	26/1,604 (1.6%)
	Subclause 5.1	*Personnel*	214/1,604 (13.3%)
	Subclause 5.2	*Accommodation and environmental conditions*	96/1,604 (6.0%)
	Subclause 5.3	*Equipment*	333/1,604 (20.8%)
		Subtotal	669/1,604 (42%)
Analytical processes	**Subclause 4.7**	*Advisory services*	11/1,604 (0.7%)
	Subclause 5.4	*Pre-examination procedures*	17/1,604 (1.1%)
	Subclause 5.5	*Examination procedures*	73/1,604 (4.6%)
	Subclause 5.6.1		54/1,604 (3.4%)
	Subclause 5.6.2		2/1,604 (0.1%)
	Subclause 5.7	*Post-examination processes*	29/1,604 (1.8%)
	Subclause 5.8	*Reporting of results*	95/1,604 (5.9%)
		Subtotal	281/1,604 (18%)
Process evaluation and improvement	**Subclause 4.8**	*Resolution of complaints*	4/1,604 (0.2%)
	Subclause 4.9	*Identification and control of nonconformities*	43/1,604 (2.7%)
	Subclause 4.10	*Corrective action*	21/1,604 (1.3%)
	Subclause 4.11	*Preventive action*	19/1,604 (1.2%)
	Subclause 4.12	*Continual improvement*	60/1,604 (3.7%)
	Subclause 4.14	*Internal audits*	80/1,604 (5.0%)
	Subclause 5.6.3		1/1,604 (0.1%)
	Subclause 5.6.4		1/1,604 (0.1%)
	Subclause 5.6.5		7/1,604 (0.4%)
	Subclause 5.6.6		14/1,604 (0.9%)
		Subtotal	250/1,604 (16%)
		Total	**1,604/1,604 (100%)**

Figure 4. Distribution of conformance requirements among the four major stages of ISO 22870:2016 processes.

DISCUSSION

The present content analysis study aims to quantitatively determine how many conformance requirements there are for the medical laboratory to consider for the implementation of ISO 22870:2016 internal auditing. The content analysis demonstrates that there are 1,604 conformance requirements contained in Clauses 4 and 5 of ISO 22870:2016 (3,pp.1-10). More specifically, this study, which builds on a previous content analysis study on ISO 15189:2012 (20), provides information that can aid the establishment of an IA programme as specified in Subclause 4.14 of ISO 22870:2016 (3,p.6). This is relatively important for fulfilment of conformance requirements in Subclause 4.1.3 of ISO 22870:2016 (3,p.2) on the declaration of conformity. The quantitative analysis of conformance requirements in ISO 22870:2016 has the potential to enhance the feasibility of application and internal auditability of the quality management system.

Key contributions of the study

A number of useful contributions to a growing body of literature in medical laboratory quality management, especially in the field of internal auditing follow from the identification of 1,604 conformance requirements in Clauses 4 and 5 of ISO 22870:2016 (3,pp.1-10). The findings of this study suggest that internal auditing can be performed with a relative precision if requirements are defined and quantified. This is highly practical in combination with using checklists. Checklists are recommended work documents for internal auditing. Subclause 6.3.4 of ISO 19011:2011 (23,p.18) recommends that 'audit team members should collect and review the information relevant to their audit assignments and prepare work documents'. One major advantage of such checklists with the quantified requirement information is that their use is highly likely to enhance the effectiveness to recording of audit findings. The audit findings are essential as objective evidence for both conformities and nonconformities as well as fulfilment of Subclause 4.14 of ISO 22870:2016 (3,p.6) which specifies that the medical laboratory must 'conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination conform to the requirements of this International Standard and to requirements established by the laboratory, and are implemented, effective, and maintained'. Hence, the identified conformance requirements can provide direct support to the applicability of the IAs.

Another potential contribution of the findings is the reduction of susceptibility of personal bias in conformance requirements interpretation and decision-making during the IA process. The internal auditors are supposed to collect objective evidence by using desirable personal behaviours, such as decisiveness, open-mindedness, perceptiveness, self-reliance and tenacity (23), as well as skills such as 'evaluating and judging' (28), which together with the internal auditors' own professional knowledge, form the auditor's competence. However, it seems possible that there are times when internal auditors need to use their own intuitive judgments, such as when ambiguous information is encountered or when subclauses may be open to conflicting interpretation because they have not been defined precisely. Judgment can be defined as 'an informed and educated opinion' (29) and can mediate between facts and opinions and is supposed to be incorporation of skills and thoughtful consideration (30). It is especially important when skilled judgment is used to derive the final audit outcome. The identified conformance requirements can provide further direct support by enabling the internal auditors to take into consideration potential ambiguous interpretations and thus facilitating the exercise of better judgment before and during the IA.

In terms of the distribution of conformance requirements in ISO 22870, both ISO 22870:2006 and ISO 22870:2016 exhibited cross-referencing to ISO 15189:2003 and ISO 15189:2012 respectively. The results indicate that subclauses of ISO 22870:2016 (n = 33) cross-reference to subclauses of ISO 15189:2003 (n = 39) whereas subclauses of ISO 22870:2016 (n = 29) cross-reference to subclauses of ISO 15189:2012 (n = 42) (Figure 1 and Table 1). The major difference in the cross-referencing is the overall increase of conformance requirements in ISO 22870:2016 (n = 1,604) from ISO 22870:2006 (n = 1,153). The significant increase is due to the increased conformance requirements in Subclauses 4.12 (continual improvement), 4.13 (quality and technical records), 4.14, 5.1 (personnel), 5.2 (accommodation and environmental conditions) and 5.3 of ISO 22870:2016 (Table 2). Major contributors to the increase are Subclause 5.1 (personnel) of ISO 22870:2016 (3,pp.6-7) which contains 214/1,604 (13.3%) conformance requirements and Subclause 5.3 of ISO 22870:2016 (3,p.8) which contains 333/1,604 (20.8%) conformance requirements.

These two subclauses represent the most demanding areas for internal auditing purposes. An explanation for this majority distribution is because Subclause 5.3 of ISO 22870:2016 (3,p.8) cross-references to Subclause 5.3 (laboratory equipment, reagents, and consumables) of ISO 15189:2012 (5,pp.23-26), Subclause 5.9.2 (automated selection and reporting of results) of ISO 15189:2012 (5,pp.37-38) and Subclause 5.10 (laboratory information management) of ISO 15189:2012 (5,pp.38-39) as well as its own Subclause 5.3.2 of ISO 22870:2016 (3,p.8). It seems possible that the increased complexity in the management of medical laboratory items and information demand more attention than previous version. These two subclauses continue to represent the biggest effort for both internal auditing and implementation purposes based on the relative percentages.

Implications for internal auditors

In terms of the distribution of conformance requirements of ISO 22870:2016 in the four-stage process-based quality management system framework, the results indicate that the 'process control, design and planning' stage contains 669/1,604 (42%) conformance requirements and is thus the most demanding area for internal auditing purposes. An obvious explanation for this is because this stage has incorporated Subclauses 5.1 of ISO 22870:2016 (3,pp.6-7) and Subclause 5.3 of ISO 22870:2016 (3,p.8). This stage is of prime importance for sustaining the overall process. The implications for internal auditors that emerge from these findings fall into two main areas and concern further reasonable steps to ensure the adequacy of conformance by the medical laboratory. The first area involves numerous considerations relating to manageability of training; the second involves electrical safety considerations. These considerations are discussed in detail below.

Manageability of training

The main advantage of having a high-performance workforce to achieve the intended results is to build its capability by effective training (31). The ultimate aim is to maintain the production and service requirements of the work process by empowered personnel that have the necessary knowledge and skills to perform within prescribed limits. Subclauses 5.1 of ISO 22870:2016 (3,pp.6-7) and Subclause 5.3 of ISO 22870:2016 (3,p.8) specify the conformance requirements which require training to fulfil. Subclause 5.1 of ISO 22870:2016 (3,p.6) specifies that the medical laboratory is responsible for providing appropriate training to all personnel. Training has been defined by the ISO as 'process to provide and develop knowledge, skills and behaviours to meet requirements' (32,p.1). However, the medical laboratory has no general rules governing how detailed the training should be in order to ensure the provision of effective delivery. The medical laboratory needs to ensure that the training specifications are reasonably practicable for both employees and providers to achieve and that all competence-related conformance requirements are addressed (33). Overall, general guidance in implementation and improvement of training can be sought from ISO 10015:1999 entitled 'Quality management — Guidelines for training' (32).

There are additional training implications that require further consideration by the medical laboratories. First, Subclause 5.3.1 of ISO 22870:2016 (3,p.8) specifies that POCT medical devices must be operated only by 'trained and authorized personnel'. It does not exclusively state that the medical laboratory professionals are the only candidates for operating POCT medical devices. The lack of clarity in Subclause 5.1 of ISO 22870:2016 (3,p.6) can generate a range of interpretations on eligibility criteria for operating POCT medical devices. While there are no general rules governing how to become a 'trained personnel' in operating POCT medical devices, the medical laboratory should consider non-medical laboratory

professionals, such as nurses (34) and pharmacists (35) operating POCT medical devices within its area of responsibility by establishing a policy on specific positions on who could operate POCT medical devices. If the medical laboratory decides to establish a formal certification process involving third -party, then it is important that the content of the training programme is documented as specified in Subclause 5.1.4(c) of ISO 22870:2016 (3,p.7). This particular may not be achievable due to proprietary information limitations on documentation (36). The POCT medical device must also be operated by 'authorized personnel'. The idea of authorisation is to administer operators' privileges to access certain process information (37). The authorisation process should be a formal system of assessment. The process should consider whether personnel exhibit the necessary competencies and personal attributes to perform assigned tasks. This enables effective selection without having potential bias (38) and is in line with general obligations to procedural fairness (39).

Second, the medical laboratory should consider that implications of Subclause 5.1.4(b) of ISO 22870:2016 (3,p.7) which specifies that only personnel who have completed the training and demonstrated competence must carry out POCT. Assessments in competence, knowledge and skills are specified distinctly in Subclause 5.1.4 of ISO 22870:2016 (3,p.7), therefore separate assessments need to be implemented in order to meet the related conformance requirements (40). These are different assessments because the ISO has defined competence as 'ability to apply knowledge and skills to achieve intended results' (41), knowledge as 'facts, information, truths, principles or understanding acquired through experience or education' (42) and skill as 'ability to perform a task or activity with a specific intended outcome acquired through education, training, experience or other means' (42). These are distinctly different items; however it is feasible to incorporate them into a combined format, as long as there is sufficient documented information available for records purposes.

Third, a further additional consideration in competency assessment is specified in Subclause 5.1.4 of ISO 22870:2016 (3,p.7). While the personnel making professional judgments must have the applicable practical and theoretical background and experience, there are no specific obligatory or regulatory requirements for the medical laboratory to conduct competency assessments of personnel who express professional judgments. In order to promote the provision of efficient and qualified POCT activities by all relevant personnel, the medical laboratory may wish to establish internal guidelines regarding the use of credentialing as an acceptable record of training (43). Overall, this recommendation offers an additional safeguard to the medical laboratory that provides personnel to operate POCT medical devices and give professional opinions within their scopes of practice.

Fourth, a final additional consideration for training is incorporating software and team training into the training program. Subclause 5.1.1 of ISO 22870:2016 (3,p.6) specifies that required training must be provided to personnel performing POCT, but it does not specify what the subjects should be. These two considerations are highly likely to improve POCT productivity in terms of enhancing human and technical communication. Two suggestions for training are offered here. The first suggestion is to incorporate further training in the operating of relevant software. While Subclause 5.1 of ISO 22870:2016 (3,pp.6-7) specifies that the medical laboratory must provide training in the applicable medical laboratory information system, it does not specify clearly how detailed the training should be (44). The overreliance of outsourcing of information technology support and ever-increasing complexity of connectivity between systems have created a knowledge gap for most medical laboratory professionals (45).

The recent emergence of various types of 'middleware' has added further considerations for implementation. Middleware is defined by the ISO as 'enabling technology of enterprise application integration describing a piece of software that connects two or more software applications so that they can exchange data' (46). The middleware is likely associated with the connectivity between the POCT medical devices to the central medical laboratory information system. The data transfer technology requires the POCT personnel to operate a system with either cabled or wireless connectivity or manual transfer protocol. These processes are likely associated with an 'admission, discharge, and transfer system' within a health care information network (47). In addition, the International Council for Standardization in Haematology demands one more step to ensure connectivity efficiency (16) and interoperability optimisation (48): conformance to ISO/IEEE 11073-20101:2004 entitled 'Health informatics — Point-of-care medical device communication — Part 20101: application profiles — Base standard' (49).

Despite the complexity, it is recommended that the medical laboratory include additional training in connectivity management in order to ensure efficient transfer of clinical data. It is important to note that there are unique challenges in designing software training for personnel, particularly because of technical acronyms and jargon used by the information technology industry (50). A special evaluation consideration needs to be noted here because the POCT medical device personnel have strong influence in this specific area of information technology implementation. An evaluation of the workflow in health information technology implementation should be established as required in Subclause 4.14 of ISO 22870:2016 (3,p.6). The second suggestion is to include team training in order for the POCT medical device operator to work more efficient with other health professional personnel as well as patients (51). The POCT medical device operator should possess competent communication skills (52), including listening (53). An implication of this is to enhance the POCT medical device operators' ability to communicate with other health professional personnel and patients accurately and professionally. Effective inter-communication has direct influence on reputation management (54-56) and patient safety (57). Overall, the medical laboratory must design and develop learning solutions that aim to improve organisational performance.

Electrical safety

The second main area into which implications of this study fall is electrical safety considerations of POCT medical devices. These considerations concern both the POCT medical device operators and patients. Subclause 5.3.1 of ISO 22870:2016 (3,p.8) specifies that equipment must be maintained in a safe working condition at all times. The medical laboratory does not have specific obligatory or regulatory requirements governing how to identify and implement a suitable maintenance to retain equipment in a serviceable or task worthy condition. The prevention action can range from visual inspection, testing, servicing and preservation. However, the medical laboratory must take reasonable steps to ensure there is adequate protection against the effects of undesirable events.

One major concern is electrical safety because injury or death by electrocution may occur in certain contact conditions (58). The practical answer for the POCT medical devices to remain electrically safe is to run an effective maintenance programme (59). The programme must conform to relevant requirements that address the preventability of both electrical and mechanical risks (60,61). The recommended requirements are detailed in IEC 60601-1:2005 (62), IEC 60950-1:2005 (63), IEC 62353:2014 (64) and their related amendments and corrigenda (65-70) (Table 3).

Table 3. Selected International Electrotechnical Commission guidance documents (n = 9) associated with Subclause 5.3.1 of ISO 22870:2016.

Guidance
IEC 60601-1:2005. *Medical electrical equipment – Part 1: general requirements for basic safety and essential performance* (62)
IEC 60601-1:2005/COR1:2006. *Corrigendum 1 – Medical electrical equipment – Part 1: general rquirements for basic safety and essential performance* (65)
IEC 60601-1:2005/COR2:2007. *Corrigendum 2 – Medical electrical equipment – Part 1: general rquirements for basic safety and essential performance* (66)
IEC 60601-1:2005/AMD1:2012. *Amendment 1 – Medical electrical equipment – Part 1: general requirements for basic safety and essential performance* (67)
IEC 60601-1:2005/AMD1:2013/COR1:2014. *Corrigendum 1 – Amendment 1 – Medical electrical equipment – Part 1: general requirements for basic safety and essential performance* (68)
IEC 60950-1:2005. *Information technology equipment – Safety – Part 1: general requirements* (63)
IEC 60950-1:2005/AMD1:2009. *Amendment 1 – Information technology equipment – Safety – Part 1: general requirements* (69)
IEC 60950-1:2005/AMD2:2013. *Amendment 2 – Information technology equipment – Safety – Part 1: general requirements* (70)
IEC 62353:2014. *Medical electrical equipment — Recurrent test and test after repair of medical electrical equipment* (64)

When non-medical electrical equipment, such as a computer, is used within the patient environment, then it is subject to the safety requirements of medical electrical equipment (71). An additional consideration is the 'functional safety' aspects. These mostly concern POCT medical devices that connected to a 'programmable electronic system' (72). When a programmable electronic system is used to maintain a safe status, then further general requirements should be met as specified in IEC 61508-1:2010 entitled 'Functional safety of electrical/electronic/ programmable electronic safety-related systems – Part 1: general requirements' (73). The safety management of medical technology requires special considerations for the medical laboratory (74,75), this is to enhance operational effectiveness and efficiency.

Overall, the distribution and locations of conformance requirements in the four major stages were identified and quantified. These findings enable the design of comprehensive IA checklist based on the process-based quality management system framework. In addition, the findings contribute to an enhanced situational awareness of quality-related requirements in the implementation of ISO 22870:2016. There are further generic implementation considerations for which each organisation may need to invest extra resources in the implementation and these can be verified by IAs.

Table 4. Relevant areas of interest for the application of local, regional and national regulations in ISO 22870:2016.

ISO 22870:2016 subclause number	Relevant contents
Subclause 4.1.1**	*… an entity that can be held legally responsible for its activities*. (5,p.6)
Subclause 4.1.1**	*… according to relevant legal requirements*; (5,p.6)
Subclause 4.2.3	*The documentation may be in any form or type of medium that can be maintained and retrieved up to the specified retention times, which is dependent upon local, regional and national requirements*. (3,p.3)
Subclause 4.2.5**	*… applicable regulations, standards and other normative documents*. (5,p.10)
Subclause 4.13.1**	*… retrievable for as long as medically relevant or as required by regulation*. (5,p.15)
Subclause 5.1.4**	*… in accordance with national, regional and local regulations and professional guidelines*. (5,p.19)
Subclause 5.2.1**	*… local regulations may apply*. (5,p.22)
Subclause 5.2.2	*The premises, in which POCT is undertaken and the equipment are used, shall conform to applicable national legislation or to regional or local requirements*. (3,p.8)
Subclause 5.3.1**	*… with national or international requirements regarding data protection.* (5,p.39)
Subclause 5.5.1**	*… in international consensus standards or guidelines, or national or regional regulations*. (5,p.30)
Subclause 5.7.1**	*Safe disposal of samples shall be carried out in accordance with local regulations or recommendations for waste management*. (5,p.35)
Subclause 5.7.1	*The organization shall handle and dispose safely of all samples, reagents and kits according to local, regional or national regulations*. (3,p.9)

** Subclauses 4.1.1, 4.2.5, 4.13.1, 5.1.4, 5.2.1, 5.3.1, 5.5.1 and 5.7.1 of ISO 22870:2016 cross-reference to the applicable subclauses in ISO 15189:2012.

Further implications

In addition to the implications related to Subclauses 5.1 of ISO 22870:2016 (3,pp.6-7) and Subclause 5.3 of ISO 22870:2016 (3,p.8), there are two more areas where the internal auditors should have prior knowledge of the processes involved before developing IA checklists. The first area is where the fulfilment of compliance obligations is required by the medical laboratory. Clause 1 (scope) of ISO 22870:2016 (3,p.1) states that relevant local, regional and national regulations need to be taken into consideration during the implementation. The medical laboratory must ensure the business practices comply with relevant compliance obligations by completely fulfilling relevant compliance requirements. Compliance requirement is simply defined by the ISO as a 'requirement that an organization has to comply with' (76). ISO 22870:2016 contains many relevant areas of interest for compliance considerations, while nine of these cross-reference to applicable ISO 15189:2012 subclauses (Table 4). Some of the issues emerging from this finding relate specifically to Subclause 4.13.1 of ISO 22870:2016 (3,p.5) which requires the ability to retrieve reported results as required by regulation. Retrieval can be defined as 'the process of finding items that have been stored' (77).

Two important implications emerge from these conformance requirements. First, the medical laboratory needs to determine the minimum retention period required for reports as required in Subclause 4.2.3 of ISO 22870:2016 (3,p.3). The recommendation needs to be aligned with relevant legal requirements, statutory limitation periods or best practice. Often there are no legislative or regulatory provisions prescribing the retention periods, but permanent retention is recommended. The medical laboratory can seek general guidance in documentation retention from the ISO (78,79). In addition to legal justifications, the medical laboratory needs to align the mechanisms of documentation retention with its documented contingency plan. The contingency plan needs to be able to maintain the medical laboratory information system serviceability when routine access to vital records are disrupted in the unlikely event of an information system failure, as described in Subclause 5.3.1 of ISO 22870:2016 (3,p.8). The medical laboratory must take reasonable steps to protect vital records from disruption, loss and from unauthorised access, disclosure and modification. The medical laboratory can seek further guidance in continuity management from the ISO (78,79). Second, a retrieval system must be effective in locating the items from archival records when required. This could be an administrative challenge when the health records are not readily available for access. Failure to comply or delayed compliance with its obligations has the potential for liability determination in the case of count orders. Relevant compliance requirements must be carefully identified, so that the medical laboratory can fulfil them with due care and diligence in order to promote alignment with both industry regulations and government legislation.

The second area where internal auditors should have prior knowledge of the processes involved before developing IA checklists concerns the implementation of evaluation process specified in Subclause 4.14 of ISO 22870:2016 (3,p.6). It is important for the medical laboratory to distinguish the differences between IA and evaluation. The ISO has defined evaluation as a 'systematic process that compares the result of measurement to recognised criteria to determine the discrepancies between intended and actual performance' (80) and IA as a 'systematic, independent and documented process for obtaining evidence and evaluating it objectively in order to determine the extent to which requirements are fulfilled' (81). These two distinctly separate processes can generate valuable information for management review input as required in Subclause 4.15.1 of ISO 22870:2016 (3,p.6). The medical laboratory needs to ensure that the evaluation process is economical and feasible to use in the timeframe and operations of the organisation.

CONCLUSIONS

The present study was designed to quantitatively analyse conformance requirements contained in ISO 22870:2016 for internal auditing requirements management. In order to show the distribution of conformance requirements in a process-based approach, the conformance requirements were classified into the four-stage process-based quality management system framework; ranging from 250/1,604 (16%) to 669/1,604 (42%) conformance requirements. It also derived from this study that four areas have implications for the efficacy of the IA process. These areas include: aspects in manageability of training relating to authorisation process, competency assessment, potential use of credentialing and special consideration in software training; serviceability of equipment in electrical safety relating to both operators and patients; fulfilment of relevant compliance obligations, especially in the accountability of documentation retention; and, positive assurance of conformity to the quality management system by suitable application of IA and evaluation processes.

The evidence from this study suggests that it is possible to determine the requirements quantitatively for the development of internal audit work documents, such as checklists. While there are different approaches to determine the specific areas for internal auditing, it is important to note that the number of conformance requirements expressed in relative percentages for each subclause can reflect the resources required for internal auditors to consider during the audit activities preparation stage. In addition, this study provides a clear and detailed picture of the extent to which ISO 22870:2016 requires the medical laboratory to fulfil the management system and technical competence requirements, and this in turn enables internal auditors to develop effective and efficient IA process appropriate to the medical laboratory. The process is highly likely to support the implementation of ISO 22870:2016, especially if new technologies are introduced to the areas of operations (82) as well as supporting the team-approach in the promotion of patient safety (83,84). Further research effort will be able to establish the relationship between the provision of value assurance using ISO 22870:2016 and patient safety. Taken together, at the strategic level, the IA process has the ability to review the critical vulnerability of medical laboratory operations by providing insights into the complexity and rigours of the activities in the quality management system. Overall, a competently conducted IA process can ultimately lead to the enhancement of patient confidence in the medical laboratory services by improving patient safety and the reducing potential risk relating to pre-analytical, analytical and post-analytical phases.

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NZIMLS ASM 2017 – NELSON – PLENARY SESSIONS: Wednesday 23 August	
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1100 – 1230	**Plenary Session**
	Kindness in Business *Dr Robin Youngson, Physician and Anaesthetic Specialist & Hearts in Healthcare Founder, Auckland* **Babies First Laboratory Test: Continual Improvement in Bloodspot Newborn Screening in New Zealand** *Mark de Hora, Specialist Chemical Pathology, LabPlus, Auckland City Hospital*

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ORIGINAL ARTICLE

The effect of anti-sulphonamide antibodies on blood cell counts of patients with malaria in Benin City, Nigeria

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ABSTRACT

Objectives: Drug-induced hematologic disorders have been reported to affect red blood cells, white blood cells and platelets. This study determined the effect of sulphonamide antibodies on the cellular components of blood among patients undergoing treatment for *Plasmodium falciparum* malaria in an environment where antibiotic use is not regulated.

Methods: Standard hematologic techniques were used to measure hemoglobin concentration, platelet count, total white blood cell and differential counts from 500 patients with malaria. The presence of sulphonamide antibodies was detected using drug-absorption and immune complex methods.

Results: The presence of sulphonamide antibodies was associated with aneamia (OR = 4.67, 95% CI = 2.81-7.76; P< 0.0001) and thrombocytopenia (OR = 19.03, 95% CI = 11.33-31.94; P<0.0001). The presence of sulphonamide antibodies was also associated with significant increases in the neutrophil count (P = 0.0449) and decreased lymphocyte count (P=0.0189). However, it did not significantly affect the total white blood cell count (P = 0.1999).

Conclusion: Information provided in this study will be useful in the management of malaria patients undergoing treatment with sulphonamide-containing drugs.

Keywords: Sulphonamide; antibodies; white blood cells; platelets; aneamia, malaria; treatment; Nigeria.

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INTRODUCTION

Plasmodium falciparum malaria infection is still one of the main causes of under-five child morbidity and mortality in sub-Saharan Africa (1). A number of antimalarial agents are available for the treatment of malaria parasite infection. The use of antimicrobial agent in Nigeria is unregulated and over the counter sales of antimicrobial agents is common (2–4). It has been reported that sulfadoxine-pyrimethamine is the preferred first drug of choice for the treatment of malaria in Nigeria (5). Hematological disorders have long been a potential risk of modern pharmacotherapy (6). Adverse drug reactions are a major risk of pharmacotherapy, although serious adverse events are less common (7). These reactions are not related to the known pharmacology of the drug, do not show any simple dose-response reaction and resolve only when treatment is discontinued (8). Drug-induced hematologic disorders as one of the unpredictable adverse drug reactions vary in incidence based on geographical location and the associated drug (6). Sulphonamides have been reported to have some side effect, such as hypersensitivity and cytopenia (9, 10). The cytopenia caused by sulphonamide may be due to presence of antibodies to sulphonamide, among other mechanisms (7,10,11).

In our environment, where malaria is endemic, unregulated use of all antimicrobial agents is common and sulphonamide-containing anti-malarials are the preferred drug to treat malaria infection, it is possible that the effect of sulphonamide antibodies on hematological disorders (which varies with geographical location) may be different in our setting. We have previously reported on the prevalence and risk factors for sulfadoxine antibody among malaria treated patients in Benin City, Nigeria (12). In this study we report the effect of sulphonamide antibodies on anaemia, thrombocytopenia, and total and differential white blood cell counts from that study.

MATERIALS AND METHODS

Study population

This study was carried out in the Central Hospital, Benin City, Nigeria, among out–patients with signs and symptoms of malaria infection. A total of 500 patients consisting of 223 males and 277 females with ages ranging from 5 to 65 years were recruited for this study, as previously described (12). All patients used in this study had consumed sulphonamide–containing drugs at least once within a month prior to specimen collection, and those confirmed not to have *P. falciparum* malaria by laboratory diagnosis (microscopic examination of thick and thin blood films) were excluded from this study. Informed consent was obtained from each patient or their parents/guardian in case of children prior to specimen collection. This study was approved by the Ethical Committee of the Central Hospital, Benin City, Nigeria.

Collection and processing of specimens

From each patient, 10ml of blood was collected by venepuncture and dispensed in 5ml amounts into plain and ethylene diamine tetra-acetic acid (EDTA) containers. The samples in plain containers were allowed to clot and sera obtained were used to detect antibody to the sulphonamide sulfadoxine. The blood samples in EDTA containers were used to determine hemoglobin concentration, platelets count, total white blood cell, and differential counts using a Sysmex K21N hematology analyser (Sysmex, Kobe, Japan). Anaemia was defined as hemoglobin concentrations less then 120g/L for females and less than 130g/L for males in adults and children (13,14). Thrombocytopenia was defined as a platelet count less than 150,000 x 10^9cells/L (15).

Detection of sulphonamide antibody

Sulphonamide antibodies were detected using two methods - drug-absorption and immune complex methods (16). Briefly, 0.5 grams of sulfadoxine (Xian Lyphar Biotech Co. Ltd, Shaanxi, China) was dissolved into 10ml of sterile normal saline and this was used for the detection of sulfadoxine antibodies using the two methods described below.

Drug-absorption method

Equal volumes of 10% group O washed red blood cells and sulfadoxine solutions were placed in test tubes and incubated at 37^0C for 30 minutes. The tubes were then washed four times with normal saline to remove excess drug. Equal volumes of patient serum and drug-red cell suspension was placed inside a test tube and incubated for 30minutes at 37^0C. After incubation, the test tube was centrifuged briefly and was observed for the presence of agglutination or hemolysis. If negative, the mixture was washed four times with normal saline and antihuman globulin (AHG) was added. (This was performed to detect either erythrocyte directed IgG in plasma or IgG or complement coating on the surface of circulating erythrocytes. Neither of these molecules can cause direct agglutination of erythrocytes, so, to detect their presence, monoclonal antihuman globulin (AHG) with specificity for IgG or various complement proteins was added to a suspension of erythrocytes. The AHG reagent is sufficiently large to cause agglutination of erythrocytes that are coated with IgG or complement. It was washed to remove excess protein which can neutralize the AHG reagent). The tubes were then centrifuged briefly and observed for agglutination or hemolysis. Control was carried out as above but consisted of patient serum and group O red cells without drug, and drug-red cell suspension without patient serum. Both controls were negative (no agglutination or hemolysis was observed).

Immune complex method

Equal volumes of sulfadoxine solution, patient serum, and 5% washed group O red blood cells were placed inside a test tube and incubated at 37^0C for 1 hour. After incubation, the tubes were centrifuged briefly and observed for agglutination or hemolysis. If negative, the mixture was washed four times with normal saline and AHG added. This was followed by brief centrifugation and observed for agglutination or hemolysis. Control was carried out as above but consisted of patient serum, red blood cells and normal saline without sulfadoxine solution; and red blood cells, sulfadoxine solution and normal saline, without patient serum. Both controls were negative (no agglutination or hemolysis).

Statistical analysis

The data obtained were analysed with the statistical software INSTAT® (Graph Pad Software Inc., La Jolla, CA, U.S.A). Parametric data were analyzed with the student t-test while non –parametric data were analyzed with the Chi square test and odd ratio analysis. Statistical significance was set at $P<0.05$.

RESULTS

The presence of sulphonamide antibody was associated with anaemia (OR = 4.67, 95% C1 = 2.801-7.76; $P<0.0001$). Similarly, individuals with sulphonamide antibody had approximately an 11 to 32-fold risk of developing thrombocytopenia (OR = 19.03, 95% CI = 11.33-31.94; $P< 0.0001$) (Table 1).

The presence of sulphonamide antibody did not significantly affect the total white blood cell count ($P = 0.1999$). However, the presence of sulphonamide antibody was associated with a significant increase in the neutrophil count ($P = 0.0449$) and a significant decrease in the lymphocyte count ($P = 0.0189$) (Table 2).

Table 1. Effect of sulphonamide antibodies on the prevalence of aneamia and thrombocytopenia.

Characteristics	No tested	No. positive (%)	OR	95%CI	P value
Anaemia					
Yes	268	88(32.8)	4.67	2.81-7.76	<0.0001
No	232	22(9.5)			
Platelet count (x10^9cells/L)					
<150	117	76(95.0)	19.03	11.33-31.94	<0.0001
≥150	383	34(8.1)			

Table 2. Effect of sulphonamide antibodies on white blood cells.

Parameters	Presence of sulphonamide antibodies (n=110)	Absence of sulphonamide antibodies (n=390)	P value
Total white blood cell count (x10^9 cells/L)	7.83 ± 6.84	7.22 ±3.42	0.1199
Neutrophils (%)	56.0±15.48	52.87±14.11	0.0449
Lymphocytes (%)	34.99±13.98	38.42±13.35	0.0189

Results mean ± SD

DISCUSSION

Drug-induced hematological disorders can span almost the entire spectrum of hematology affecting red cells, white cell, platelets, and the coagulation system (17). The prevalence of drug-induced hematological disorders varies with geographical location (6). Sulfadoxine is the preferred drug of choice in the treatment of malaria in Nigeria (5), where antibiotic usage is unregulated (2–4). The effect of sulphonamide antibodies on the cellular component of blood has not, to our knowledge, been evaluated in our environment. Hence, this study was conducted.

We have previously reported that the prevalence of sulphonamide antibodies observed in this study group was 22% by both methods – drug-absorption and immune complex methods (12). This indicates that sensitized cells (cells coated with sulfonamide antibody) can be destroyed both intravascularly and extravascularly.

Anaemia was significantly associated with sulfonamide antibodies (OR = 4.67, 95% CI = 2.81-7.76; p<0.0001). Sulphonamide antibodies have been shown to increase oxidative stress of the red blood cell membrane resulting in extravascular and intravascular destruction of red cells (18,19). Patients with sulphonamide antibodies are on average 19 times more likely to have a platelet count of <150,000/µL as recorded in this study. Indeed, it was observed that the presence of sulphonamide antibodies was significantly associated with thrombocytopenia. This agrees with the finding of Curtis *et al.* (20). Drug-induced immune thrombocytopenia results from antibodies to the drug binding to platelet glycoprotein only in the presence of the drug and thereby resulting in destruction of platelets (21,22). This may explain the association of thrombocytopenia with sulphonamide antibodies in this study.

Although the presence of sulphonamide antibodies did not affect the total white blood cell count (p = 0.1999), it was associated with a higher neutrophil count (p =0.0449) and a lower lymphocyte count (p=0.0189). The finding of a higher neutrophil count in this study is not in agreement with previous reports where lower counts were observed (6,23). Geographical location may partly explain this discrepancy (23). Sulphonamides were not reported among drugs that cause severe neutropenia (23). Rao (6) lists sulphonamide among drugs that cause neutropenia (agranulocytosis) from observational studies, but were not listed among those that cause neutropenia (agranulocytosis) in case report studies. Neutrophils are known to phagocytose red cells infected with malarial parasites (24). Autologous IgG and complement C3 fragments are markers of phagocytes removal (24). IgG and complement C3 coated red blood cells are partially ingested by macrophages of the spleen, which result in their destruction. Neutrophils may therefore be needed to phagocytize sulphonamide antibodies-coated red blood cells leading to their ultimate extravascular destruction. This may lead to increased production of neutrophils and may explain why the neutrophil count was significantly higher in patients with sulphonamide antibodies in our study. It is important to note that the neutrophil count was determined by a hematology auto-analyser (Sysmex K21N) which does not supply information on a neutrophil shift to the left or right, and other reactive changes which would have been useful in the import of the high neutrophil count. Lymphocytes are responsible for antibody production and may be used up in the process of sulphonamide antibody production. This may explain the lower lymphocyte count observed in this study.

In conclusion, the presence of sulphonamide antibodies resulted in anaemia and thrombocytopenia. Although sulphonamide antibodies did not affect the total white blood cell count, instead it resulted in higher neutrophil counts and lower lymphocyte counts. The finding of this study may be useful in the management of patients with malaria undergoing treatment with sulphonamide-containing drugs. Futures studies to determine the effect of dosage and change of drug on blood cell counts is needed to have a better understanding of the drug action on patients' care.

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A sneak peak at the invited speakers for the NZIMLS Annual Scientific Meeting, August 22 - 25 2017

Dr Bryan Betty MD, FRCP, FRCPath, FFPath
Deputy Medical Director Primary Care, PHARMAC,General Practitioner at the Porirua Union and Community Health Service, in East Porirua.

Roslyn Bonar
Senior Scientist in charge of the haemostasis component of the Royal College of Pathologists of Australasia Quality Assurance Programs located at St Leonards Sydney.

Dr Emmanuel J Favaloro
Principal Hospital Scientist, and in charge of the Haemostasis laboratories at the Institute of Clinical Pathology and Medical Research (ICPMR), located at Westmead Hospital, and part of NSW Health Pathology.

Mark de Hora
Section Leader in Specialist Chemical Pathology at LabPlus. Fellow of the Faculty of Science in the Royal College of Pathologists.

Jacqui Gardner
Over the last 5 years, Jacqui has been involved in the development of Ministry of Health driven melanoma tumor standards focusing on the pathology and has developed a keen interest in the molecular aspects of melanoma, especially the high risk primary cases and of course, the metastatic ones.

Dr Brent Gilpin
Science Leader in the Environmental Science team at the Institute of Environmental Science & Research (ESR) in Christchurch.

Jo Hughson LLB (Hons), BA
Jo is a Wellington barrister with many years' experience in professional regulation and complaints and disciplinary processes.

Lynn Palmer
Section Head of Morphology at Middlemore Hospital

Dr Sandy Slow
BSc (Hons 1st Class; Biochemistry) and PhD (Molecular Genetics) Lincoln University-conferred 2001
Research Fellow, Department of Pathology, University of Otago, Christchurch

Dr Graeme Taylor
Histopathologist from Nelson working in Nelson, Christchurch and Wellington. His primary interest is in lymphomas and he also has a longstanding interest in the pathology of infectious diseases.

Marianne Wilkinson
Recognised as one of the most experienced employment relations practitioners in New Zealand.

Dr Robin Youngson
Anaesthetic Specialist in New Zealand, internationally renowned for his work on compassion in healthcare.
Founder of Hearts in Healthcare, and founding member of the national Quality Improvement Committee in New Zealand.
"Healthcare's focus on physical and bio-medicine is unbalanced. We need to pay much more attention to emotional, psychological and spiritual wellbeing and the huge importance of healing relationships." Dr Robin Youngson; Time to Care.

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ASA 2017 Adelaide

The Australian Society of Antimicrobials Annual Scientific Meeting was held in Adelaide, Australia, from 23 to 25 February 2017. This meeting is attended by a varied group including microbiology clinicians, Infectious Diseases specialists, laboratory scientists, managers, and antimicrobial stewardship specialists. It attracts delegates from around the world and the calibre of presentations and speakers is excellent. The focus is on antimicrobial resistance – mechanisms, detection, trends, new rapid methods, prevention and stewardship. The meeting runs from 7am to late, for 3 days. It is very full-on and really challenging to take it all in! However the annual ASA meeting is without doubt one of the most informative and directly relevant meetings for microbiology. It is not possible to condense all of the sessions into one review, but here are some of the highlights for me.

This year the concept of **One Health** was a major focus. Professor Stefan Schwarz, Institute of Microbiology and Epizootics, Berlin, presented one of the plenary sessions titled "*One Health Aspects of Antimicrobial Resistance in Gram Negative Bacteria and Enterococci*." Professor Schwarz explained the One Health Triad, which consists of People, Environment and Animals; recognising that human health is interconnected to the health of animals and the environment. Interdisciplinary collaborations and communications are necessary to solve health care, especially the most critical area of continuing antimicrobial resistance. The main drivers are the integration between humans and animals (companion, farm and wild); increasing population size, increasing meat consumption, leading to a greater use of resources and corresponding waterway pollution; expanding human population into new habitats, where people are potentially exposed to new viruses and organisms as the human population encroaches on wildlife areas; climate changes bringing tropical diseases to new geographical areas – it is estimated that up to 75% of emerging or re-emerging diseases are either zoonotic or vector-borne e.g. Dengue virus, West Nile virus, Chikungunya virus, Zika virus. Furthermore global trade and travel can potentially turn local outbreaks into pandemics. For further reading on One Health, visit www.onehealthinitiative.com.

Carbapenemase-producing organisms (CPO) are still top 'bad boys' of the WHO-listed antimicrobial resistant threats. The mortality rate from serious infections caused by CPO is the same as for Ebola! It is predicted that by 2050, at least 10 million people will die annually from antibiotic resistant infections. Professor Timothy Walsh (Cardiff University, Wales) gave an excellent Howard Florey oration, "*UN Agenda on Antimicrobial Resistance: Dream or Scream?*" In 2009, Prof Walsh and his team where the first to discover the New Delhi Metallo-β-Lactamase (NDM) in India, and he is a leading researcher in this field. He discussed his involvement with the BARNARDS project, funded by the Gates foundation, which aims to investigate the problem of antibiotic resistant infections, and to determine possible solutions, in neonates in low income countries such as Nigeria, Pakistan, Bangladesh and Ethiopia. Tim spoke about the difficulties in setting up a laboratory in places that often don't have adequate sanitation systems, trying to get supplies through corrupt officials and working in countries with civil unrest. Other confounding problems include the easy availability of antibiotics across-the-counter, huge amounts of antibiotics included in farm animal supplements, especially in poultry and pig farming, and a lack of infection control programmes. Antibiotic resistant organisms, including MRSA, ESBLs and CPO have been found in a variety of companion and farm animals around the world. In some countries contaminated animal manure is then sprayed onto crops!

The emerging issue of **colistin resistance**, due to the mobile plasmid-mediated lipid-A transferase gene *mcr*-1, was discussed by a number of presenters. Professor Stefan Schwarz explained that colistin has been around since the 1950s, but went out of favour in 1980s due to nephrotoxicity and neurotoxicity. Colistin is currently used for cystic fibrosis patients and gut decontamination but there has been a recent resurgence of use as part of treatment regimens for infections caused by carbapenem resistant organisms. It is used in huge quantities in poultry and pig farming. Chromosomal resistance to colistin has been known for years and some Enterobacteriaceae are intrinsically resistant e.g. Proteus, Serratia. This type of resistance is not a big threat as spread would have to be via a clonal outbreak. However of more concern is the *mcr*-1 gene, which was found in *E.coli* in 2015 (incidentally by Professor Timothy Walsh!). This mobile resistant element is mostly carried on a self-conjugating plasmid without other resistance markers (it can form its own circular mobile element and move between plasmid and chromosome), but has also been found in larger plasmids, carrying a variety of resistance markers. Of course these attributes make for excellent opportunities for co-selection and persistence! *mcr*-1 has been found globally and more commonly in animal strains (with such large colistin consumption, it's no wonder).

Dr Andrew Ginn, Westmead Hospital, Sydney, discussed the results of their study, looking at the colistin MIC of 4555 Enterobacteriaceae (excluding those intrinsically resistant species), from 2007 to 2016. They found 96 (2.1%) strains resistant to colistin. PCR and sequencing confirmed that two *E.coli* isolates harboured *mcr*-1. Both strains were found in patients with UTI, but were isolated two years apart, with no geographical connection, and neither patient had recent travel history. The strains were distinct sequence types and plasmids, but the plasmids were identical to those that have been found in Asia. It is possible that the strains were transmitted by migratory birds.

Another area covered by several presenters was the **human microbiota or microbiome** (microbiota usually refers to the community of organisms/viruses/parasites present, whereas the microbiome refers to the collective microbial genetic pool).

Microbiome studies have grown exponentially in the last few years as next generation sequencing systems have become faster and cheaper. The Human Microbiome Project, which was completed in 2003, cost nearly 3 billion dollars; compared to current costs of <$1000. Microbiome research is helping to better understand the development and spread of resistance, especially the interplay between the environment, humans and agriculture (back to the One Health theme again). The first Plenary Session was presented by Dr Geraint Rogers, Flinders University, Adelaide, a molecular microbiologist and microbial ecologist. His talk was titled "*Antimicrobial Resistance and the Human Microbiome*". Dr Rogers discussed how new studies have shown that early antibiotic use in children can have life-long consequences for immune response (e.g. weakened response to vaccines), development of diabetes, obesity risk, and future mental health issues (reference= Nat Immunol. 2014 Apr;15(4):307-10. doi: 10.1038/ni.2847). In adults, antibiotic use can also affect lipid and glucose metabolism, immune regulation, CNS function, nutrition, and prevention of infection. Antibiotic pressure leads to selection, mutation and adaptation of the microbiota. This is often systemic. The antibiotics with the greatest 'antibiotic risk index' includes cephalosporins, carbapenems, quinolones and clindamycin. The Royal Adelaide Hospital has a research programme, developing faecal microbiota transplants for people who have had many courses of antibiotics as well as recurrent *Clostridium difficile* infections.

Professor Anton Peleg, Director of Infectious Diseases, Alfred Hospital and Monash University, Melbourne, continued the microbiome topic with a symposium session titled "*The gut as a resistance reservoir*". Anton described how humans are composed of 10x as many bacterial cells as human cells; with the highest density in the gut. These gut bacteria play a critical role in human health, including nutrition, immunity, and protection against pathogenic organisms. Associations or commonalities between gut health and human health have been found with a variety of diseases including inflammatory bowel disease, type 2 diabetes, obesity, colorectal cancer, liver cirrhosis and rheumatoid arthritis. The gut is under constant flux from the environment and other selective pressures, creating a huge 'resistome pool'. Anton also reiterated that the impact of antibiotics early on in life appears to lead to less bacterial diversity and less stability of flora. At the time of antibiotic use e.g for β-lactams, there is a big increase in the number of organisms in the gut expressing plasmid mediated resistance, and these can remain in the gut for months afterwards. Metagenomics are now being used to characterise the antimicrobial resistance reservoir of the gut – PCR can be used to target specific genes, or functional metagenomics can be used to find specific plasmids and express in a host strain, or next generation sequencing can be used to align to known resistance genes.

Moving away from the gut, but still with the microbiome topic, Dr Alkis Psaltis, Department of Otolaryngology, Queen Elizabeth Hospital, Adelaide, spoke about the microbiome of the upper airways. Chronic rhino sinusitis affects 10-20% of the population, across all age groups, with symptoms including pain, discharge, poor smell, and nasal blockage. It is a debilitating condition that results in poor life functionality for many people. The cause is largely unknown but could be due to bacteria (with biofilm formation in the nasal/sinus epithelium), fungal, allergic reactions or polyps. A dysbiosis of the normal sinus flora can lead to chronic rhino sinusitis. Dr Psaltis is investigating ways to reverse this dysbiosis including snot transplants!

There were many more interesting and informative presentations during this three day meeting. If you are interested in all things antimicrobial, the next ASA meeting will be held in Sydney, February 2018 (www.asainc.net.au). I totally recommend attending!

Julie Creighton
Canterbury Health Laboratories, Christchurch

Quick Quiz

Question 1

A 49 year old woman receiving hormone replacement therapy (HRT), was found to have a thyroid nodule with no lymphadenopathy and was clinically euthyroid. A technicium scan identified a 'cold' nodule and ultrasound identified the nodule as cystic. Besides routine biochemistry the T_4 was 185noml.l^{-1} and the TSH was 0.40mU.l^{-1}. Why was the T_4 elevated?

Question 2

A 59 year old man woke during the night with severe pain in his left toe. He was shivering and feverish. The severity of the pain prevented any weight bearing from the bed-clothes. What would be the main diagnostic biochemical test for this patient?

Question 3

A 40 year woman, who had been a vegan for many years, presented with a history of lethargy, breathlessness and dizziness. On examination she had brittle hair and finger-nails. In addition she indicated that she had heart palpitations and was not yet post-menopausal, had heavy periods. The blood results returned to the GP were: serum iron 3mmol.l^{-1}; transferrin saturation 8% and ferritin <5mg.l^{-1}. What was the diagnosis and what other investigation should the GP have done first?

Question 4

A male one-year old child presenting with failure to thrive was diagnosed with cystic fibrosis and had three older siblings (two brothers and a sister). How would the one-year old be routinely diagnosed and how should his siblings be tested?

Answers on page: 67

NZIMLS
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All applications will be considered by a panel consisting of the President and Vice-President of the NZIMLS and the Editor of the New Zealand Journal of Medical Laboratory Science (who are ineligible to apply for the scholarships). The applications will be judged on your professional and academic abilities together with your participation in the profession. The panel's decision is final and no correspondence will be entered into.

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- A budget comprising airfares, conference registration and accommodation costs
- The abstract of your intended oral or poster presentation and whether it has been accepted for presentation (proof required)
- Your intentions to publish your results
- State briefly your history of participation in the profession over the last 5 years
- State the reasons why you wish to attend your nominated scientific meeting

Successful applicants will be required to provide a full written report on return which will be published in the Journal. If not intended to publish elsewhere, successful applicants will be required to submit their study results for consideration by the *New Zealand Journal of Medical Laboratory Science*.

Previous recipients
2014. Maxine Reid, Aotea Pathology
2013. Julie Creighton, Canterbury Health Laboratories
2012. Holly Perry, Auckland University of Technology
2011. Bernard Chambers, Middlemore Hospital
2010. Sandy Woods, Canterbury Health Laboratories

NZIMLS ASM 2017 – NELSON – PLENARY SESSIONS: Thursday 24 August	
0700 – 0830	**NZIMLS Annual General Meeting & Breakfast**
0900 – 1030	**Plenary Session**
LIGHTING THE WAY 2017 Nelson NZIMLS Annual Scientific Meeting 22—25 August, Rutherford Hotel, Nelson	**The World's Largest Waterborne Campylobacteriosis Outbreak: Havelock North August 2016** *Dr Brent Gilpin, Molecular Biologist, Environmental Science Group, Christchurch* **Alternative Medicine and the Role of the Laboratory in Testing** *Dr Cindy de Villiers, General Practitioner, Health Function Integrative Medicine, Nelson*
1030 – 1100	Morning Tea
1100 – 1230	**Plenary Session**
	Targeted Treatment *Dr Bryan Betty, PHARMAC, Wellington* **Melanomonia** *Dr Jacqui Gardner, Melanoma Specialist, Anatomical Pathologist, Canterbury Health Laboratories*

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Fellowship regulations and the application process are available on the NZIMLS web site at www.nzimls.org.nz

CURRENT FELLOWS

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Dates announced for the NZIMLS Annual Scientific Meeting, 2018

Mark it in your diary!

Christchurch, 21—24 August

Email: fran@nzimls.org.nz

Science Digest

Hope for restoring hearing: Ushers syndrome Type 1 is an inherited disorder that causes childhood deafness, progressive blindness and balance disorders. Researchers in the USA using a mouse model for the disease have injected a synthetic virus carrying the normal gene (harmonin) into the inner ears of newborn mice. The gene incorporated into the sound sensitive cells and also restored balance raising the possibility of the technologies use in humans.

A new approach to heart pacemakers: Scientists in Canada have developed a human pluripotent stem cell line, which they believe will replace the current electronic pacemaker. Currently when the sinoatrial node cardiomyocytes that control the heart rate fail, the electronic pacemaker is the only solution to maintain normal cardiac function, which has a life of approximately seven years before replacement. It is anticipated that the novel stem cell line will overcome these problems by establishing a biological pacemaker.

Myelodysplastic syndrome (MDS) may have a new predictive test: MDS are a group of disorders closely related to clonal haematopoetic disorders characterized by peripheral blood cytopaenias resulting from dysfunctional haematopoiesis at the bone marrow stem cell level. Results from the analysis of mutations from 1500 patients with poor prior clinical outcome have identified a key mutation in the TP53 gene consistent with early relapse and poor survival rates. These results are considered to be useful in predicting patient outcome prior to bone marrow transplants.

Circulating tumour DNA (ctDNA): a new test for cancer detection: As tumour cells die they release fragments of DNA in to the circulation known as ctDNA. Patient's blood will often contain fragments of released ctDNA. Using PCR, next generation sequencing and whole genome sequencing, a trial is under way in the UK using lung and breast cancer to develop proof of concept. It is anticipated that ctDNA analysis could replace many solid tumour biopsies, identify tumour mutations and monitor treatment.

Chemical attractant helps malaria: People infected by malaria become more attractive to the vectors of this parasitic disease. This facilitates the spread of malaria. Recent research has identified that the host's cells respond to a parasitic derived isoprenoid (4-hydroxy-3-methyl-but-2-enyl pyrophosphate, HMBPP). HMBPP interacts indirectly by increasing the release of red cell carbon dioxide, aldehydes and monoterpenes, which act together to attract vector feeding. The parasites effectively manipulate its mammalian host making it more attractive to the insect vectors.

Disposable sweat-based blood glucose device: Diabetes has become one of the most prevalent diseases. To ensure blood glucose stability patients are required to monitor blood glucose concentrations. Although Point of Care monitoring has reduced the complications of diabetes significantly the control of blood glucose still represents a clinical problem. Research from South Korea has invented a wearable/disposable system, which monitors sweat glucose and responds with insulin when required. The device uses miniaturized sensors for monitoring blood glucose and delivers insulin via sensitized nanoparticles thereby providing a 'closed-loop' monitoring system.

What clogs blood vessels in sickle disease?: It is well established that the substitution of glutamate to valine in the b-globin protein results in the polymerization of haemoglobin producing the sickle-cell shaped red blood cells. Although the pathogenesis is understood, the mechanisms for capillary clogging were not. Recent research has identified that the initial blockage by sickled red cells activates endothelial cells followed by platelet activation leading to aggregation and vaso-occlusion amplification. The protein P-selectin has been identified as a causative agent in the adhesion process and the blocking of P-selectin release reduces the frequency of vaso-occlusion in sickle cell disease.

Potential new player in rheumatoid arthritis: Autoantibody production is an important factor in seropositive rheumatoid arthritis (RA). Typically, T-cell populations promote B-cell response in the synovium but the mechanism for the overall cellular response is unclear. Recent research has identified a novel subset of T-cells that are responsible for driving autoantibody production in the synovium by B-cells. The subset of T-cells has been 'dubbed' 'T peripheral helper cells' and this population increases in patients with seropositive RA. The mechanism of action is reported to be infiltration of inflamed tissues and drive B-cell responses and antibody production. In patients with seropositive RA the peripheral helper cells accounted for up to 25% of all $CD^{+}4$ T-cells, but were not increased in seronegative RA, psoriatic arthritis or juvenile idiopathic arthritis.

Does *Mycobacterium tuberculosis* beat the system?: *Mycobacterium tuberculosis* (TB) causes approximately 300 infections per year in New Zealand. The WHO estimates that in 2015 there were approximately 10.5 million new cases of TB worldwide with approximately 500,000 being drug resistant and approximately 2.5 million people died of TB in 2015. An improved understanding of the biology of infection could enhance treatment of TB especially re-infection and drug resistance. A joint research programme between UK and Norwegian groups has identified that *M. tuberculosis* can shield itself using macrophages, thereby increasing the potential for pathogenesis. Using human macrophages they identified that following infection the bacteria can disarm the host macrophages by inducing plasma membrane damage. The bacteria can then replicate within the macrophage nutrient rich environment thereby avoiding the extracellular environment until macrophage cell death. The release of the bacteria then causes a re-infection. Additionally the ability to exploit the necrotic macrophages as hosts may contribute to microbial resistance.

Does an enzyme provide the dust mite asthma link?: For some time there has been a linkage with dust mites and asthma. Research from the USA may have identified a potential link between insect dust and the activity of an enzyme, acidic mammalian chitinase (AMCase) an enzyme located in lung epithelial cells. Chitin is a polysaccharide that is located in invertebrate skeletons and fungal cell walls. Using mice 'knocked out' (enzyme deficient) for the enzyme AMCase, and exposed them to insect dust, as the mice aged they developed significant breathing problems and started to die. Their lungs absorbed less oxygen than normal controls and showed signs of inflammation and fibrosis. Their airways contained more chitin than the controls. When AMCase was restored in the deficient mice by inhalation the lung inflammation and fibrosis declined. Preliminary data indicates that people with interstitial lung disease (ILD) had twice as much chitin in their airways as non-disease people, however the ILD people did have AMCase activity but no enzyme variants have been investigated to date.

Mike Legge

THE Pacific WAY

Haematology 2017

A haematology course was provided by the PPTC in April 2017 at its centre in Wellington, and the following two students attended:

- Adi Litia Dabulim from Fiji
- Angeline Dick from Nauru

Students and staff – Haematology 2017

Biochemistry 2017

A biochemistry course was provided by the PPTC in June 2017 at its centre in Wellington, and the following three students attended:

- Komal Maharaj from Fiji
- Sylvester Ruethin from Federated States of Micronesia
- Terry Kalorib from Vila Central Hospital, Vanuatu

Students and staff – Biochemistry 2017

Pacific Paramedical Training Centre training courses 2017

- Laboratory Quality Management Systems 7 August - 1 September
- Microbiology 18 September - 13 October
- Blood Transfusion Science 30 October - 24 November

For further information contact:
Navin Karan, Programme Manager
PO Box 7013
Wellington, New Zealand
Telephone: +64 4 389 6294,
Email: pptc@pptc.org.nz; navink@pptc.org.nz
Website: www.pptc.org.nz

Thank you to the New Zealand Red Cross

The PPTC and its Board of Governance wish to thank the New Zealand Red Cross for its continued support in providing an annual scholarship for one nominated Pacific Island student to attend our Blood Transfusion course scheduled for November of each year. To date, the New Zealand Red Cross has sponsored 51 students to attend courses in Wellington.

The numbers of scholarships awarded to Pacific students are extremely limited in terms of availability which fails to align with the increasing demand for the acquisition of fundamental knowledge and diagnostic skills. The New Zealand Red Cross Health Sciences Scholarship, provided by New Zealand Red Cross, is a learning opportunity which carries enormous value to both the student and the Blood Transfusion Laboratory from where the student has originated, and aims to provide a comprehensive theoretical component and a series of practical workshops to equip students with sufficient knowledge to be able to work confidently in their home laboratories and be able to provide quality diagnostic test results to clinicians using the medical laboratory services for patient management and better health outcomes.

The length of this course is four weeks in duration and contains units of study covering the theoretical and practical aspects of the following topics: routine blood grouping, blood group antigens, crossmatch techniques, antibody detection, transfusion reactions, haemolytic disease of the newborn, screening blood for infectious agents, blood donor selection, organisation of a blood bank and the appropriate use of blood components in transfusion medicine.

The progress of each student is monitored throughout the training programme, and towards the conclusion of this training, students are required to sit both a theoretical and practical examination to demonstrate their understanding of the materials delivered during the duration of this course.

The PPTC expresses its gratitude to New Zealand Red Cross for its continued support and looks forward to an interactive and productive relationship in the future.

Thank you to our New Zealand Donors

On behalf of the Vaiola Hospital Laboratory, Nuku'alofa, Tonga, the PPTC would also like to sincerely thank Remeny Weber, (Anatomical Pathology Whangarei Hospital,) Robyn Rawstorn, (Histology laboratory Medlab South, Timaru Hospital) and Steven McCullough, (New Zealand Veterinary Pathology, Hamilton) for the generous donation of Histology equipment no longer required by their own laboratories. The Vaiola Hospital Histology Laboratory suffered an immense loss through fire which destroyed not only the laboratory but also the essential equipment within.

Remeny, Robyn and Steven together as a team were able to supply a tissue processor, a paraffin bath and a microtome which they no longer had use for, assisting Vaiola Hospital to re - establish its Histology Service. Thermofisher Scientific NZ also generously helped to complete equipment requirements by assisting the PPTC in providing a new tissue embedder heavily reduced in cost as its contribution towards such a worthy cause.

Overseas travel

From the commencement of 2017 to the present:

Feb 6th – 10th TONGA
TB surveillance. Consultant - Russell Cole

Feb 13th – 17th KIRIBATI
TB surveillance. Consultant- Navin Karan

Feb 13th – 17th SAMOA
Accreditation training and service development.
Consultant - Filipo Faiga

Feb 20th – 24th NAURU
TB Surveillance. Consultant - Russell Cole

Feb 27th – 3rd March NIUE
TB surveillance. Consultant - Navin Karan

March 13th – 17th SAMOA
TB Surveillance. Consultant - Russell Cole

March 13th – 17th SOLOMONS
Strategic planning. Consultant - Navin Karan
Procurement training. Consultant - Filipo Faiga

March 27th – 31st VANUATU
TB surveillance. Consultant -Navin Karan
Accreditation training: Pathologist strengthening.
Consultant - John Elliot

March 27th – 31st TUVALU
TB surveillance. Consultant – Russell Cole

April 3rd – 7th SOLOMON ISLANDS
HOD biochemistry training. Consultant - Filipo Faiga

April 3rd – 7th SAMOA
HOD histology training. Consultant - Fuianina Washburn

May 8th – 12th TONGA
Service development. Consultant - Filipo Faiga

May 8th – 12th COOKS
TB surveillance. Consultant - Navin Karan

May 22nd – 26th SOLOMON ISLANDS
Accreditation training. Consultant - Navin Karan

May 29th –June 2nd SAMOA
Accreditation training. Consultant - Filipo Faiga.

June 19th – 30th FEDERATED STATES OF MICRONESIA
(Yap and Pohnpei)
Microbiology and laboratory quality management.
Consultants - Russell Cole and Navin Karan

Quick Quiz Answers

Question 1
HRT stimulates the synthesis of thyroxine binding globulin, therefore to maintain physiologically active T_4 the total serum T_4 needs to be increased.

Question 2
Urate, with joint aspiration to identify urate crystals and culture to exclude septic arthritis.

Question 3
Iron deficiency anaemia. A blood film would have shown a hypochromic microcytic anaemia.

Question 4
The child diagnosed with cystic fibrosis would normaly be tested by the sweat test as elevated sweat chloride is diagnostic for cystic fibrosis. As the other siblings did not show any clinical symptoms the only option of testing would be to test for mutations in the CFTR gene. The sweat test is not diagnostic for identifying carriers of cystic fibrosis.

ASM 2017 SOCIAL FUNCTIONS

Icebreaker / Opening of the Exhibition

The welcome function will give you the opportunity to catch up with friends and colleagues whilst enjoying drinks and nibbles. It is also a special time for our exhibitors to host this function around their exhibits.

Date:	Tuesday 22 August 2017
Time:	6:30pm to 8:30pm

Poster Session

Date:	Wednesday 23 August 2017
Time:	5:00pm to 6:00pm
Authors:	Poster authors will be available to speak about their work.

ASM Dinner

Date:	Thursday 24 August 2017	***Entertainment:***	Kramit
Time:	7:00pm to midnight	***Theme:***	Nautical

Journal Questionnaire

Below are ten questions based on articles from the August 2017 issue. Read the articles carefully as most questions require more than one answer.

Answers are to be submitted through the NZIMLS web site. Make sure you supply your correct email address and membership number. It is recommended that you write your answers in a word document and then cut and paste your answers on the web site.

The site has been developed for use with Microsoft's Internet Explorer web browser. If you are having problems submitting your questionnaire and you are using the Firefox web browser, try re-submitting using Microsoft's Internet Explorer.

You are reminded that to claim valid CPD points for successfully completing the journal questionnaire you must submit an individual entry. It must not be part of a consultative or group process. **In addition, members who have successfully completed the journal questionnaire cannot then claim additional CPD points for reading the articles from which the questions were derived.**

The site will remain open until Friday 13th October, 2017. You must get a minimum of eight questions right to obtain five CPD points.

The Editor sets the questions but the CPD Co-ordinator, Jillian Broadbent, marks the answers. Please direct any queries to her at cpd@nzimls.org.nz.

AUGUST 2017 JOURNAL QUESTIONNAIRE

1. Name the elements of the ADKAR model.
2. The ADKAR model in conjunction with a business model should assist management in what?
3. What factors influence the knowledge element of the ADKAR model?
4. In the change management of healthcare study what did participatory action research allow for?
5. Name four reported criteria of participatory action research.
6. Increased oxidative stress of the red cell membrane due to sulphonamide antibodies results in what?
7. What are known markers of phagocytes removal?
8. In the anti-sulphonamide antibodies article what may have explained the study's finding of lower lymphocyte counts?
9. What may explain why the neutrophil count was significantly higher in patients with sulphonamide antibodies?
10. What were the significant haematological findings of the presence of sulphonamide antibodies?

APRIL 2017 JOURNAL QUESTIONNAIRE ANSWERS

1. What is point 9 of the NZIMLS Code of Ethics.
   All members are bound by the Privacy Act and shall respect the confidential and personal nature of patient records and shall not disclose information to anyone without patient's consent except where the best interests of the patient requires or the law demands.
2. What should CPD participants do when their submitted answers to the journal questionnaire are returned to them, and why?
   Compare them against the model answers which are published in the next edition of the Journal. This should be seen as an important part of the learning or professional development process.
3. What is thought to be the mechanisms of sickle cell disease associated priapism?
   Dysfunctional nitric oxide synthase and Rho-associated protein kinase (ROCK) signaling, and increased oxidative stress associated with NADPH oxidase mediated signaling.
4. What are the typical cavernous blood gas values in ischaemic priapism?
   pO_2: <30 mm Hg; pCO_2: > 60 mm Hg; pH: <7.25.
5. Define priapism, and where is the tem derived from.
   A persistent erection of the penis that continues more than four hours beyond, or is unrelated to, sexual stimulation. Derived from Priapus, the Greek God of fertility.
6. What is antithrombin, and how does it act?
   A single-chain serpin glycoprotein that acts as a key regulator of clotting through its inhibitory effect on thrombin and factor Xa.
7. What are antithrombin deficient patients at increased risk of?
   Venous thromboembolism, pulmonary embolism, and fetal loss.
8. Inherited antithrombin deficiency Type IIb alters what and results in what?
   The heparin-binding ability of AT, resulting in less than normal augmentation of AT activity in the presence of heparin and normal AT activity in the absence of heparin.
9. Name the antithrombin heparin binding site methods that have been used.
   Progressive AT assays (functional assays performed in the absence of heparin), molecular genetic testing, and two dimensional gel electrophoresis.
10. Recent research has shown that vascular disease and hypertension are driven by what, and what was this associated with.
    Overactive thrombin-driven factor X1 feedback loop by platelets. This was associated with a coagulation-inflammation circuit promoting vascular dysfunction and hypertension.

North Island Seminar 2017

The NZIMLS North Island Seminar was held at the Corpthorne Hotel & Resort, Bay of Islands – Paihia on Saturday 6 May. The annual event was attended by 102 participants from all over New Zealand. One member even travelled all the way from Invercargill to get away from the South Island snow and cold. She wouldn't have found anything better than the beautiful Bay of Islands.

There were fifteen speakers for the day. Dr Nigel Cane from Bay of Islands Hospital started the session. He spoke on "A refuge for drunkards and scoundrels – why we work in a rural hospital?" The day was enjoyed well by all the participants with very informative presentations. Professor Rob Siebers gave an interesting talk on "Author template, an aid for first-time authors" followed by Shirley Gates presenting a case study in haematology.

Phillip Shepherd's presentation won one of the two NZIMLS Best Presentation Awards. Phillip spoke on "Targeted Oncogene Mutation Detection in Non-Small Cell Lung Cancer by Multiplexed Array Mass Spectrometry Genotyping: results of a clinical validation study-what does that even mean?" This study is part of Phillip Shepherd's Master's Thesis. We hope to read more on Phillip Shepherd's study in the NZIMLS Journal in future. The best presentation was won by Jason Copedo from Labtests Auckland. Jason spoke on "Molecular Growth in Microbiology". Both the winners got cash prizes from NZIMLS.

Geoff Herd spoke on Point of Care Testing – Back to the Future. He discussed about the history of POCT and the current and future advances in Point of Care Testing. This topic followed well into Melanie Adriaansen and Stephanie Williams joint presentation on "Implementing POCT strategies into rural Auckland".

Dr David Hammer talked about the 10 steps we can take at home to prevent the end of the world as we know it. He talked about the high incidence of antibiotic resistance, statistics and how each individual can help. Dr Richard Charlewood spoke on two topics. Firstly, he spoke on "Transfusion-related mortality and alternatives to transfusion" and later in the session he spoke on "Fresh blood (and should we be using it?)".

Neil Wood from Kaitaia Hospital Laboratory spoke on "Microbes, make-up and Foot Soldiers". He talked on some very interesting fungal, bacterial and parasitic skin infections. Khundker Hossain spoke about mitochondrial donation and whether it should be allowed in New Zealand. Dr David Wei spoke on Molecular Haematology followed by Dr Betsie Lombard, who spoke on "Lymphocytes in peripheral blood – the good, the bad and the ugly." The final speaker, Mijoo Kim spoke on "Design the future you want".

The presentations concluded with a drink and nibble session around 1730 hours. Special thanks to Abbott Diagnostics, Beckman Coulter, Bio-Rad, LabPlus and Roche for sponsoring the seminar; and also to the following Northland Wineries: Longview Estate, Byrne Wines, Cottle-Hill Winery, Kainui Road Winery, Marsden Estate, Ake Ake Winery, and Taraire Block Winery for sponsoring bottles of wine for all our speakers.

Sailesh Singh
NIS Convener 2017

NZIMLS ASM 2017 – NELSON – PLENARY SESSIONS: Friday 25 August	
0900 – 1030	**Plenary**
	'The mysterious death of a man from Nelson – can the lab crack the case?' *Graeme Taylor, Anatomical Pathologist, SCL Nelson* **Haematologist Talk** *Speaker to be confirmed*
1100	**Final Plenary and closing lunch**
	Topic TBA *Dr Richard Everts, Specialist Physician, Medical Microbiologist, Infectious Diseases Specialist, Richmond Health Care and Nelson Hospital* **Choosing Wisely** *Dr Derek Sherwood, Ophthalmologist, & Dr Juliet Elvey, Medlab South, Nelson* **Turning Barriers into Stepping Stones – MLS a personal view** *Ross Hewett, immediate past NZIMLS President* **Official Closing** *NZIMLS President*

Rutherford Hotel August 22 - 25

LIGHTING THE WAY

2017 Nelson

NZIMLS Annual Scientific Meeting

NZIMLS
THE NEW ZEALAND INSTITUTE OF MEDICAL LABORATORY SCIENCE (INC)

Pre-Analytical Special Interest Group Meeting

- *Phlebotomy*
- *Donor Services*
- *Specimen Services*

Waipuna Hotel and Conference Centre, Auckland
Saturday, 7 October 2017

For your opportunity to present, contact
Jane Kendall
janek@medlabcentral.co.nz

Registration, start and finish times will be available on the NZIMLS website:
www.nzimls.org.nz

MOLECULAR DIAGNOSTICS SIG SEMINAR 2017

FRIDAY
13 OCTOBER

COMMODORE HOTEL
MEMORIAL AVENUE, CHRISTCHURCH

Molecular Diagnostics is the field of the future, hear what's happening now within the disciplines of Molecular Genetics, Molecular Virology and Microbiology, Molecular Haematology and Cytogenetics!

Closing date for Abstracts: Friday 8 September

Contact: kevin.barratt@cdhb.health.nz

Register online at www.nzimls.org.nz

HAEMATOLOGY SIG

October 14, 2017
Christchurch

NZIMLS
THE NEW ZEALAND INSTITUTE OF MEDICAL LABORATORY SCIENCE (INC)

Come join us in Christchurch for a day filled with everything Haematology based.

PRESENTATIONS INVITED

It is never too soon to register interest!

WHERE:

Sudima Hotel at Christchurch Airport (5 minutes walk from the domestic terminal).

For further information, or to register a presentation, please contact Rob Allan at robert.allan@sclabs.co.nz

Registration available online only at www.nzimls.org.nz

SEMINAR

MORTUARY SPECIAL INTEREST GROUP

WHEN

SATURDAY
28 OCTOBER 2017

WHERE

CHRISTCHURCH HOSPITAL

MORTUARY

WE WILL BE SEEING YOU SOON

ACTION-PACKED DAY

OFF-SITE VISITS

SUNDAY BREAKFAST MEETING FOR MORTUARY TECHS
(BUT NOT TOO EARLY...)

ACCOMMODATION CLOSE TO HOSPITAL

EMAIL FOR MORE DETAILS

LOU.MCGUINNESS@CDHB.HEALTH.NZ

Registration opening soon!
www.nzimls.org.nz

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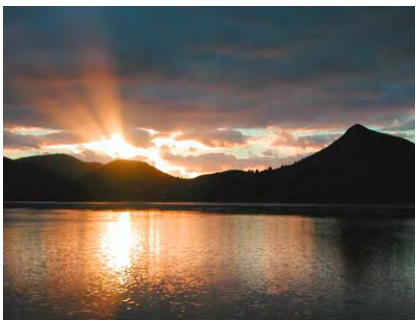
AP IN THE BEAUTIFUL SOUTHERN ALPS
The Anatomical Pathology
Special Interest Group Meeting
Copthorne Hotel, Queenstown
28 October 2017
Register Online at
www.nzimls.org.nz
Email: remeny.weber@northlanddhb.org.nz



Immunology Special Interest Group

Hutton Theatre
Otago Museum, Dunedin

Saturday 11th November 2017

Call for papers, auto-immune and infectious disease, 10-20 minutes, to Helen van der Loo helen.vanderloo@sclabs.co.nz

Evening meal – We will organise for all those interested to go out for a casual meal.

Registration information and further details to follow at www.nzimls.org.nz

2017 NZIMLS CALENDAR
Dates may be subject to change

DATE	COUNCIL	CONTACT
21-22 August	Council Meeting, Nelson	fran@nzimls.org.nz
December	Council Meeting	fran@nzimls.org.nz
DATE	**SEMINARS**	**CONTACT**
7 October	PreAnalytical SIG Seminar, Auckland	janek@medlabcentral.co.nz
13 October	Molecular Diagnostics SIG Seminar, Commodore Hotel, Christchurch	kevin.barratt@cdhb.health.nz
14 October	Haematology SIG Seminar, Sudima Hotel, Christchurch	robert.allan@sclabs.co.nz
28 October	Anatomical Pathology SIG Seminar, Copthorne Hotel, Queenstown	remeny.weber@northlanddhb.org.nz
11 November	Immunology SIG Seminar, Dunedin	emcgrath@adhb.govt.nz
28 November	Mortuary SIG Seminar, Christchurch Hospital, Christchurch	lou.mcguinness@cdhb.health.nz
DATE	**CONFERENCE**	**CONTACT**
22-25 August	Annual Scientific Meeting, Rutherford Hotel, Nelson	tony.barnett@medlabsouth.co.nz fran@nzimls.org.nz
DATE	**MEMBERSHIP INFORMATION**	**CONTACT**
28 January	Membership and CPD enrolment due for renewal by 28 February 2018	sharon@nzimls.org.nz
31 January	CPD points for 2017 to be entered before 31 January 2018	cpd@nzimls.org.nz
15 February	Material for the April issue of the Journal must be with the Editor	rob.siebers@otago.ac.nz
15 June	Material for the August Journal must be with the Editor	rob.siebers@otago.ac.nz
23 June	Nomination forms for election of Officers and Remits to be with the Membership (60 days prior to AGM)	fran@nzimls.org.nz
13 July	Nominations close for election of officers (40 days prior to AGM)	fran@nzimls.org.nz
2 August	Ballot papers to be with the membership (21 days prior to AGM)	fran@nzimls.org.nz
10 August	Annual Reports and Balance Sheet to be with the Membership (14 days prior to AGM)	sharon@nzimls.org.nz
17 August	Ballot papers and proxies to be with the Executive Officer (7 days prior to AGM)	fran@nzimls.org.nz
15 September	Material for the November Journal must be with the Editor	rob.siebers@otago.ac.nz
Date	NZIMLS Examinations	Contact
04 November 2017	QMLT Examinations	fran@nzimls.org.nz

cobas u 701 microscopy analyzer

Automation of Gold-Standard

The cobas u 701 urine analyzer with a sample-throughput of 116 per hour is a reagent-free system and uses disposable cuvettes. Urine samples are pipetted carry-over free into cuvettes, designed to work like a slide, and centrifuged to create a mono layer sediment. High-resolution images are taken and evaluated automatically thus operator variabilities are removed. This all leads to excellent accurate results.

Full automation and standardization of microscopy
All working processes and steps of the gold-standard in sediment analysis – the urine microscopy – are fully automated and standardized – even improving the gold-standard by removing variability and subjective judgment

Excellent counting performance
The **cobas u** 701 urine analyzer counts 11 different particle types in the microscopy photograph by evaluating against a database of images, the latest version with millions of real photographs, producing accurate counting results

Storage of real images
Sediment images are reported automatically to the LIS and to experts to validate the results without the need to take an additional sample. Images are documented and retained for later reference and training of operators, all improving workflow efficiency

Roche

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