

## SPECIAL ARTICLE

# The journey of Malaysian external quality assurance program for general diagnostic histopathology

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### Abstract

International Academy of Pathology, Malaysian Division has initiated and run the external quality assurance program for general diagnostic histopathology since the year 2017. This article introduces the educational philosophy of this external quality assurance program and the technicalities in running such a national program. Challenges in ensuring the successful running of this program to gain wide acceptance by histopathology laboratories in Malaysia as well as experience in overcoming these challenges are detailed. This article charts the future direction of this external quality assurance program.

**Keywords:** External quality assurance program; Diagnostic Histopathology; ISO 15189

### INTRODUCTION

Under the auspices of the International Academy of Pathology, Malaysian Division, the external quality assurance (EQA) program for general diagnostic histopathology was initiated and formally run in the year 2017. This article aims to explain the background of establishing such a program, the guiding principles in program management, and the running cycles of the program. Experience and challenges in running such a program for the past 3 years are discussed.

#### **The needs for an external quality assurance (EQA) program for evaluation of quality performance**

The majority of the histopathology laboratories in Malaysia are accredited or in the process of gaining accreditation under the Laboratory Accreditation Scheme of Malaysia, Standards Malaysia for the field of medical testing, fulfilling the requirements of the standard MS ISO 15189:2012. As a part of the requirements, the accredited laboratory is required to participate in interlaboratory comparisons such as the EQA program<sup>1</sup>. Popular EQA programs in the field of histopathology available for international

subscription are listed in Table 1. Prior to this Malaysian EQA program, laboratories in Malaysia have been subscribing to EQA programs run by the Royal College of Pathologists of Australasia (RCPA). Although the RCPA quality assurance programs for the field of diagnostic histopathology are well run and of high standard with accreditation based on ISO/IEC 17043, the major concern for Malaysian laboratories, especially the government laboratories, is the increasingly high subscription fees to these RCPA programs. In addition, the quality assurance items (cases) do not necessarily reflect the case-mix normally encountered in Malaysia. Thus, it is desirable to have a locally run EQA program. International Academy of Pathology, Malaysia Division, an independent professional body took heed and conducted a trial run in the year 2015 and formally launched the EQA program for general diagnostic histopathology by invitation in the year 2017. International Academy of Pathology, Malaysia Division was formally established in the year 2013 and is affiliated to the International Academy of Pathology. With its role to promote and advance the knowledge and practice of anatomic pathology through educational exchanges within the country and

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**Table 1. Popular EQA programs in the field of histopathology available for international subscription**

External quality assurance program	Provider	URL
RCPAQAP General Diagnostic	The Royal College of Pathologists of Australasia (RCPA) Quality Assurance Programs Pty Ltd	<a href="https://rcpaqap.com.au/">https://rcpaqap.com.au/</a>
Performance Improvement Program in Surgical Pathology	College of American Pathologists	<a href="https://www.cap.org/laboratory-improvement/">https://www.cap.org/laboratory-improvement/</a>
CheckPath	American Society for Clinical Pathology	<a href="https://www.ascp.org/content/learning/quality-improvement-education">https://www.ascp.org/content/learning/quality-improvement-education</a>

worldwide, this association does not have vested commercial interests to conduct this EQA program.

### Guiding principles in program management

At the outset, this EQA program is posited as the platform in favour of educational purpose rather than emphasizing the performance evaluation of individual laboratories. Nevertheless, this external quality assurance program does provide a unique evaluation mechanism for the performance of individual laboratories. A centralised performance evaluation of each laboratory is not provided but each laboratory takes the responsibility for self-evaluation. This program maintains confidentiality and has a mechanism in place when a breach of confidentiality is requested by regulatory authorities. Subscription is based on an individual laboratory basis and not on an individual pathologist.

### Structure of the program

This EQA program is coordinated by a coordinator and assisted by a part-time secretary and the treasure for handling matters regarding subscription. There are two permanent committees established under this program: one committee acts as the primary source of quality assurance items by providing appropriate cases (primary source committee) and the other committee acts as the panel to vet and select suitable cases for circulation (evaluation panel committee).

The primary source committee comprises pathologists from various laboratories that

voluntarily provide the cases. The evaluation panel committee comprises four senior pathologists and the coordinator of this program. On average, each senior pathologist has 26 years of practising experience after obtaining a postgraduate qualification. The coordinator has 7 years. They have subspecialty training or interests in gastrointestinal pathology, renal pathology, dermatopathology, cytopathology and gynaecologic pathology apart from general surgical pathology. Two of them are from academic pathology departments whereas the other three are from servicing pathology departments.

### Design of the program and the running cycles

The coordinator of this program is responsible for the planning of this EQA program. This program runs for two cycles each year, in May and October respectively, and each cycle takes two months. The program has these processes:

- (a) A call for the contribution of quality assurance items is made in the prior year to the primary source committee to solicit appropriate cases. Simple criteria are set: (1) General diagnostic cases that usually can be diagnosed with H&E staining alone. (2) These cases have some salient features that have educational purposes.
- (b) The evaluation panel committee will sit once a year to evaluate the solicited cases for circulation for the two cycles. This evaluation panel committee is composed of four senior pathologists and the coordinator, who examine each case under a multiheaded microscope for a consensus targeted diagnosis (the assigned value). The accuracy

of this consensus targeted diagnosis (the assigned value) is substantiated firstly by confirmation of the primary diagnosis submitted by the contributing pathologist and secondly by consensus agreement of all pathologists in the evaluation panel committee. In other words, each case has at least been interpreted by six pathologists to reach the consensus targeted diagnosis (the assigned value). The levels of difficulty for each case are determined and a mixture of cases of different levels of difficulty from different organ systems are selected.

- (c) Slide digitization and EQA materials distribution is subcontracted to a private company after an open call to bid for the tasks. The private company solely involves slide digitization and EQA materials distribution in the form of DVDs and online access to the cases. The company does not have any authority to access the responses of individual laboratories.
- (d) Each cycle opens for a month for evaluation by the individual laboratories after receiving EQA materials. Each cycle contains 10 cases. Responses are submitted via online form to the EQA program. Only the coordinator of the program has access to the responses.
- (e) The final report for each cycle is issued after a month from the closing date of submission of responses. This final report contains information for the individual laboratory to self-evaluate against the peers (vide infra).

### **Unique evaluation mechanism for laboratory performance**

The final report of each cycle releases the targeted diagnosis (the assigned value) for each case. This assigned value is based on the consensus diagnosis of the evaluation panel committee. In addition, a tabulated list of diagnoses submitted by participating laboratories for each case is appended and followed by discussion and possible differential diagnoses on the case. This also acts as a mechanism for post-circulation assessment of the targeted diagnosis (the assigned value) of each case, i.e. the majority of the submitted diagnoses by the participating laboratories shall ideally similar to the targeted diagnosis (the assigned value). A guide on the acceptability of the variation of the responses is given by the evaluation panel committee. Thus, it is the responsibility of the participating laboratory to self-evaluate the performance of each cycle for the number of

responses concordant to the targeted diagnoses or acceptable diagnoses. By this mechanism, the participating laboratory is pro-active in self-evaluation and has a greater awareness of the diagnostic competency as compared to the peer laboratories. Corrective actions and monitoring of the performance of the laboratories are out of the scope of this EQA program; nevertheless, the individual laboratory would have to comply with the accreditation standard MS ISO 15189:2012 during the audits by Standards Malaysia for participation in the EQA program. Samples of past final reports are available at <https://www.iapmd.net/>.

### **Experience and challenges**

#### **(i) Participants**

FIG.1 shows the number of participating laboratories for each cycle since 2017. For the first cycle of the year 2017, the participation was by invitation free of a subscription fee. A total of 27 laboratories responded out of 35 invitations. From the second cycle of 2017 onwards, a subscription fee was imposed. The number of subscribed laboratories was around 21 for each cycle composed exclusively of government hospitals. It seems that this local EQA is not as attractive as compared to RCPA EQA for private laboratories because the cost of subscription might not be a consideration for private laboratories. Awareness of the existence of this national EQA program is not widespread among the private laboratories as well.

#### **(ii) Subscription process**

Subscription for the program by the Ministry of Health hospitals was impeded due to purchasing regulation set by the Ministry of Finance, Malaysia. This hindrance was resolved by registration of this EQA program with the Ministry of Finance, Malaysia as well as training the secretary to handle the online purchasing platform “e-perolehan”. The public universities and private laboratories however subscribed directly to the program.

#### **(iii) Soliciting EQA materials**

For each year, members of the primary source committee contributed around 60 cases to the program coordinator. Only one-third of the cases, i.e. 20 cases were chosen by the evaluation panel committee deemed suitable for circulation. Thus, there is a need to solicit more cases to ensure

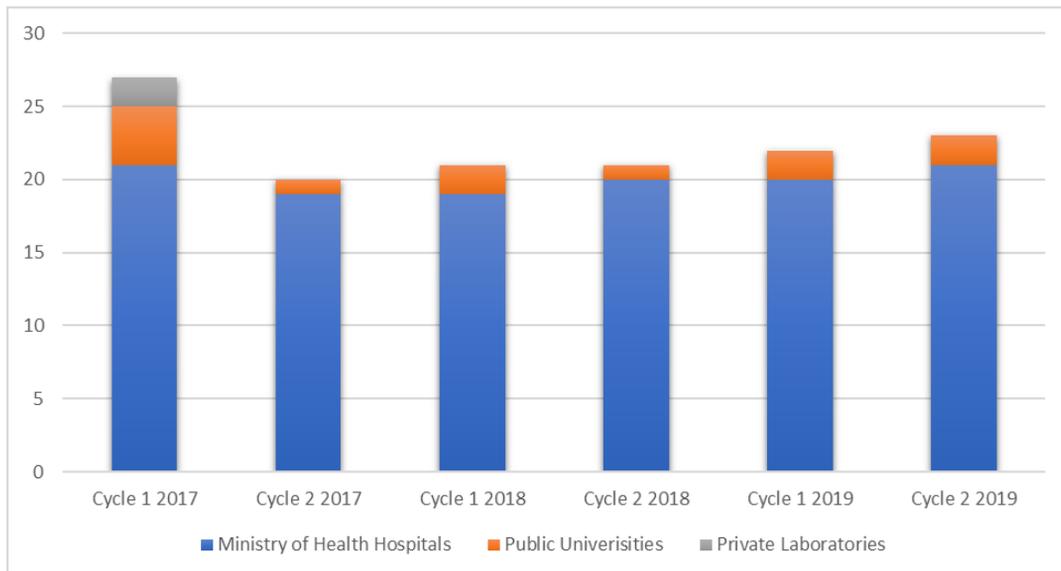


FIG 1. Number of participating laboratories in each cycle from 2017 to 2019

a better mix of levels of diagnostic difficulties from different organ systems.

#### (iv) EQA materials

Ideally, duplicated glass slides are to be circulated, which is reflective of the actual diagnostic work process of the participating laboratories. However, to ensure homogeneity of the EQA materials and better logistics, digitized virtual slides were made as EQA materials. Visual inspection of the quality of the scanned images was performed before circulation. Online access to scanned images was provided as an option; however, this was not well received by participating laboratories due to the slow transmission of data over the internet in most hospitals to view the images in real-time.

A total of 60 cases have been circulated for the past 3 years. FIG. 2 shows the distribution of the cases according to organ systems. The cases are distributed across different organ systems with the majority of the cases belong to gastrointestinal, gynaecologic, head and neck, and breast and endocrine pathology. Strikingly, no respiratory case is circulated to date. Twenty-three (38%) cases carry non-neoplastic diagnosis whereas 37 (62%) cases carry the neoplastic diagnosis.

#### (v) Feedback from participating laboratories

Continuous feedback from the participating laboratories was obtained from each cycle. There

is overwhelming approval for the EQA (98.5%, 132 out 134 responses) that expressed interests in continuously joining this EQA. Occasional feedback on the quality of the scanned slides was received, which was attributed to the quality of the original glass slides.

#### (vi) Financial substantiality of the program

The cost to run this program was mainly honorarium paid to the coordinator and part-time secretary for a total of RM2,000 per year. Slide digitization, EQA materials distribution and online access were provided free of charge by the company after successful bidding. With the subscription fee of RM1000 plus RM20 of processing fee per laboratory, this local EQA program is able to be self-sustained.

#### (vii) Accreditation of the program based on ISO/IEC 17043

Although this EQA has been running for the past three years, this EQA program is yet ready to be accredited based on ISO/IEC 17043:2010 conformity assessment - general requirements for proficiency testing<sup>2</sup>. Documentation of the process, dedicated personnel to manage this program, and physical infrastructure to support the processes are major challenges to conform to this standard.

#### (viii) Future direction

The specific technical requirements of

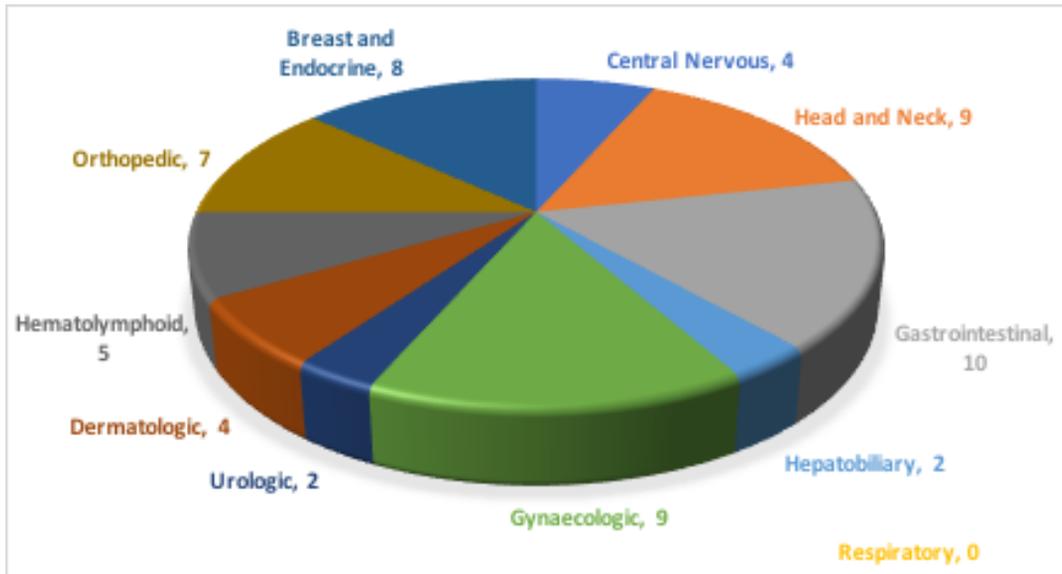


FIG 2. Distribution of 60 circulated cases according to organ systems

accreditation standard MS ISO 15189:2012 include the subscription to EQA of technical module covering the test methodology in histopathology laboratories.<sup>1</sup> Thus, in future, this local EQA program will be expanded to fulfil the needs in this aspect as well as subspecialty modules such as the dermatopathology module, which is scheduled to be launched in the mid of the year 2020. Nevertheless, the challenges of setting up more modules depend much on local pathologists' lead in championing the cause.

## CONCLUSIONS

International Academy of Pathology, Malaysian Division as the EQA program provider for general diagnostic histopathology has successfully run the program for the past 3 years with simple guiding principles, diligently adherence to the planning and minimal workforce. There are challenges to sustaining this program, but the program receives unconditional support from the member pathologists who contributed and vetted the cases voluntarily. The trust in this professional body forms the basis of this program that aims to improve diagnostic competency with educational intent.

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*Conflict of interest: E.S.C and N.H.O. run the external quality assurance (EQA) program for general diagnostic histopathology under the auspices of the International Academy of Pathology, Malaysian Division.*

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