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Futuristic view for quality and cost effective histopathology service in Sri Lanka

The word Pathology has been derived from 2 Greek words – Pathos (suffering) and logy (study). Therefore, Pathology is a study of suffering. It is defined as the scientific study of diseases. Histopathology (HP) is microscopic examination of biological tissues to observe the appearance of diseased cells and tissues in very fine detail. Furthermore, this is a separate entity in laboratory service with other specialties in pathology. Histopathologists issue reports after examining tissue microscopically.

Immunohistochemistry and Molecular biology

Histopathologists not only establish tissue diagnosis (whether a lesion cancerous or not) but they provide a report with data, which are crucial in clinical management and provide important prognostic information such as extent of disease, the grade in case of malignancy, and adequacy of the excision.

Histopathology report guides the treatment of patient using latest immunohistochemistry (IHC) and Molecular biology. For example, in breast carcinoma, use of IHC to detect estrogen and progesterone receptors and Her-2 neu antigen is essential to determine adjuvant therapy. As a result pathology report without these IHC information carry less value. All these technologies should take place in medical laboratories under the supervision and involvement of Histopathologists and molecular biologists.

Furthermore, when we further analyse tissue by applying molecular biology, the genetic nature of the tumour can be identified giving a molecular diagnosis for tumours. According to variable molecular expression occurring along the lines of differentiation of

breast carcinoma, there will be a molecular sub-classification. Molecular sub classification has divided breast carcinoma into 5 different subtypes currently (Luminal A and B, Her - 2,Basal like, Triple negative non-basal).

Presence or absence of immunohistochemical and molecular markers has a great impact on cancer treatment, especially targeted treatment, thus moving away from the practice of blanket toxic therapy. Hence, testing for immunohistochemical and molecular markers are not merely an academic activity and provision of such data is the responsibility of the Histopathologist.

Immunotherapy is the latest addition to cancer treatment. Here, the patient's own immune system is modified to attack the cancer. In immunotherapy patient's own immune cells are harvested, engineered outside the body to identify tumour cells using the identified genetics of the tumour, then cultured and perfused back to the patient. Therefore, identifying the genetic nature of tumor is a prerequisite for Immunotherapy. Hence, histopathology laboratories form a crucial component in quality health care in a country as they provide essential data for i) patient care and treatment, ii) for prevention and control of diseases and iii) to develop public health policies.

Therefore, laboratory reports must be accurate, reliable, and must be delivered timely in order to be useful in a clinical or public health setting. Histopathology reports should have 100% accuracy level because even 1% error rate can have compounding effects on the final assessment. If not, i) patients are less likely to get best possible care such as unnecessary treatment,



treatment complications, and delay in correct diagnosis, ii) preventative laboratory test done for major communicable and noncommunicable diseases will not be reliable and iii) valuable financial, human and other resources will be wasted.

Quality assurance

Quality assurance ensures accurate, reliable and timely laboratory reporting. Currently, in Sri Lanka, there is no systematized quality assurance system for histopathology in both public and private health care systems.

In the development of quality assurance system for laboratory services, five critical stages are involved:

- i. Discussion pertaining quality assurance plan
- ii. Formation of committees to develop strategic plan
- iii. Formation of strategic plan
- iv. Implementation of strategic plan.
- v. Evaluation.

Recently Ministry of Health (MoH) made a move to develop quality assurance system for laboratories in collaboration with professional colleges. As a result, National Laboratory Quality Assurance committee was formed at MoH in collaboration with professional colleges. Implementation and subsequent steps are to come in future.

To have a functional quality assurance system, a strong supporting organizational structure and management with commitment are needed. Recent studies published in the USA, show that diagnostic errors in histopathology lay mainly at analytical level: 89% at a analytical level i.e. technical and reporting level, 8% at pre-analytical level, and 2% at post-analytical level. Accordingly, quality assurance steps are mainly focused at analytical level in histopathology. A few recommended Quality assurance steps in histopathology are listed below.

1. Arrangement of daily intradepartmental slide discussions which enable pathologists

to get other pathologists' opinion - peer reviewing.

2. Arrangement of Multidisciplinary meetings (prospective as well as retrospective) with the involvement of clinicians, surgeons, radiologists, oncologists etc.
3. Arrangement of periodic review meeting among laboratories which would facilitate sharing of professional experiences and build up research culture in the field of pathology.
4. Conduct of audits.
5. Participation of Internal QA and External QA programmes.
6. Obtaining International Accreditation e.g. ISO 15189/ CAP./ Australia.

Resource management

If we look at the current organizational structure in Sri Lanka, as in 2016, there are 78 histopathologists for the entire country and of these, 58 work for the MoH and the rest is attached to universities. Figure 4 illustrates the distribution of pathologists, under MoH, in different Districts of Sri Lanka. Pathologists at MoH share over 90% of the routine clinical workload according to the database at the College of Pathologists.

There are 50 histopathology laboratories with basic facilities, and 4 national Immunohistochemistry (NIHC) laboratories in Sri Lanka. Currently, there is no reference laboratory for histopathology.

The sharing of workload among those 50 laboratories are, 31/50 handle 1500 - 4500 specimens per year, 11/50 handle over 4500 specimens and 8/50 handle less than 1500 specimens per year. According to these data, there is a maldistribution of workload among laboratories as well as among pathologists.

Currently, there are 58 histopathologists serving over 20 million population, and 107 hospitals with over 1000 consultants. It should be noted that nearly half of the

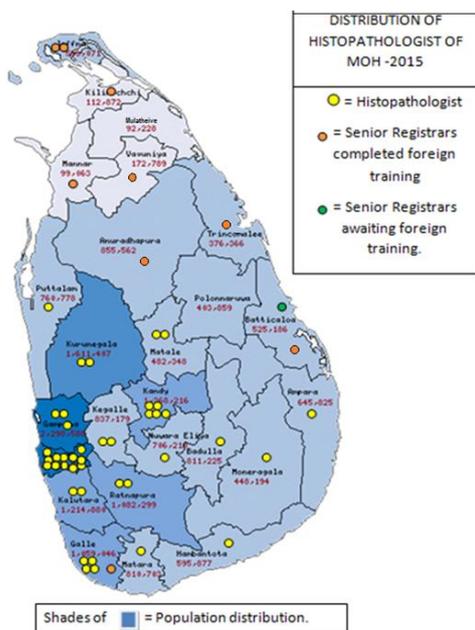


Figure 1 Distribution of histopathologists (HP) and senior registrars (SR) in Ministry of Health with shades of blue indicating the distribution density.

pathologists are concentrated in and around the Western Province (Figure 4). The shortage as well as maldistribution of histopathologists jeopardize the quality of histopathology service delivered to the country, and is detrimental to the development of the specialty.

Most of the Histopathologists are unable to utilize the skill and knowledge they have gathered in their training because of the very limited availability of IHC most histopathologists and non-availability of clinical molecular diagnostic services. In order to face the challenge of developing a quality histopathology service with this setup, the College of Pathologists suggests MoH to consolidate the Histopathology service.

The suggested model consists of one Reference Laboratory for the country and establishment of a well-equipped, histopathology laboratories at provincial level.

A provincial well-equipped laboratory with 4-5 pathologists serving surrounding hospitals or labs in the province, which are

Table 1 The rate of production of histopathologist in Sri Lanka.

	Number entered for Histopathology Training	Number sat for MD Histopathology	Number Pass	Pass rate	Number Returned After Overseas training
2015	3	8	7	87%	2
2014	10	7	4	57%	2
2013	Nil	10	7	70%	2
2012	4	10	6	60%	2
2011	11	11	7	64%	5
2010	8	5	5	100%	9
2009	12	6	6	100%	7
2008	8	13	12	92%	7
2007	6	9	7	78%	3
2006	11	16	12	75%	5

interconnected by a virtual communication system and an efficient courier service. Establishment of aforementioned laboratories should be done according to standard guidelines and should have facilities for histochemical stains, IHC, immunofluorescence and frozen section facilities in addition to basic facilities. A fully fledged cytopathology department should also be included. In addition, molecular diagnostic and electron microscopy facilities should be established in the reference laboratory.

Furthermore, ever increasing knowledge in histopathology has led to the unavoidable development of sub-specialization within the field. Therefore, provisions for the pathologists to develop their interests in sub-specialty should be made. Sub-specialization always leads to improvement in quality.

In summary, following are the advantages of establishing a consolidated system in Sri Lanka.

1. Overcome the adverse effects of shortage and maldistribution of pathologists.
2. Reduce brain drain of trained histopathologists.
3. Implementation of Quality management system can be done without much hassle.

4. Cost effectiveness. Currently it costs more than Rs. 15 million to establish a histopathology laboratory irrespective of the workload, excluding the cost of human resources such as pathologists, laboratory technicians and other staff. With consolidation, there will be maximum utilization of this capital investment.

The concept of consolidated system is well practiced in all developed countries over the years with a very good outcome, i.e., e.g., UK, Australia, USA, Singapore. Moreover, it is a recommended model to deliver a standard laboratory service in limited resource setting (human, physical and finance). Furthermore, in the UK, current economic reforms address further consolidation of pathology service as a cost cutting mechanism. In the USA, it has been the identified medical negligence as the 3rd commonest cause of death. To overcome laboratory errors they have suggested hierarchical pattern of reporting, and development of subspecialties, double-checking of slides before signing out of reports, and involvement of more than one pathologist in certain cases. This can be made available in a consolidated system where many pathologists working together in a well equipped laboratory having subspecialized pathologists.

Conclusion: There is a pressing need to improve the quality in the clinical histopathology service in Sri Lanka. Based on many recent studies and proven models in other countries, it has been identified that a consolidated histopathology service with subspecialization of histopathologists working together in a centralized working environment will provide the necessary remedies to accomplish a world standard quality assurance system for Sri Lankan histopathology service.

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