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AN EXPERIENCE WITH THE ACCREDITATION OF PRIVATE LABORATORIES

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INTRODUCTION:

THERE ARE a number of private laboratories in various towns in Malaysia which perform biomedical tests. There has been no restriction on their establishment and no official effort to place them under surveillance to ensure the quality of their work. This situation was rectified to a small and limited extent when the Ministry of Health introduced its "Code of Practice for the exportation of Cooked Frozen Prawns" in 1974. Under this code, batches of cooked frozen prawns would be cleared for export only if they were covered by a satisfactory bacteriological report from an accredited laboratory. Initially only Government laboratories were recognised but in view of the big work load anticipated it was decided to allow private laboratories to perform this work provided that they had passed through a stringent accreditation procedure applied by a special committee on Accreditation of private laboratories for the examination of cooked frozen prawns. This committee comprised of representatives from the Ministry of Health, The Institute for Medical Research, The Chemistry Department and MARDI, with the senior author as chairman of the committee. While the work of this committee was restricted to overseering the laboratories with respect solely to the examination of cooked frozen prawns, the experiences gathered and lessons learnt could be of value in gauging the overall standards of private laboratories in this country and the possible role that government agencies could play in ensuring their quality. This paper sums up those experiences.

ACCREDITATION PROCESS:

Laboratories desiring accreditation are requested to apply formally to the Ministry of Health. On receipt of such applications the Accreditation Committee arranges for a suitable period during which members could make an on-site visit and carry out the protocol for accreditation which is described in detail elsewhere (Jegathesan, 1977). The applicant laboratory should satisfy the following conditions:-

Physical Facilities:

There should be reasonably adequate laboratory space which should be well lit and well ventilated (or air-conditioned) and should be partitioned off or be separate from other testing or administrative areas of the laboratory. There should be sufficient supply of electricity, gas, water, washing facilities and bench space. The tops of the latter must be covered by a material that is non-porous and should be easily disinfected. There should be adequate storage space for glassware, chemicals and reagents and perishable material must be stored at refrigerator temperature. Adequate precaution must be taken at all times to prevent the spread of pathogenic organisms from specimens to laboratory personnel. All material used for work should be adequately sterilised before washing or discarding and contaminated glassware should be placed in a chemical disinfectant immediately after use and prior to cleaning and sterilisation. Contaminated material must be properly disposed of.

Equipment:

The laboratory should have the following equipment maintained in good working order. Autoclave, freezer, hot air oven, refrigerator, incubator, glassware, water bath, weighing balance,

homogeniser, colony counter, microscope and pH meter.

Personnel:

Testing staff should be adequately qualified. A minimal academic qualification would be a Diploma or Bachelor of Science degree in Microbiology, Food Technology or a related subject from a reputable institution and the candidate should have had adequate practical experience in food microbiology. The candidate should be found to have satisfactory working knowledge on all aspects related to food microbiology and bacterial enteropathogens and should be able to recognise and solve any unusual problem which may arise. Preferably there should be at least one technical helper whose experience and knowledge should be commensurate with the work on which he is engaged.

Methodology:

The Committee does not insist that any particular method be followed provided that the method employed by the laboratory is an acceptable and recognised one. The method employed should bear reference to published works and be thorough in every step of the analysis. The method should be typed out neatly and made readily available to working staff at the bench and should cover every step of the procedure including the preparation of media. A copy should be submitted to the committee with the application for accreditation. The laboratory should have at least minimal reference texts applicable to the tests performed.

Materials:

The laboratory should have available all media, chemicals and reagents necessary to follow the method. The laboratory should show evidence of sources of ready supply for these materials which should be bought from a reliable source and should be made up according to the manufacturer's instructions.

Quality Control:

The laboratory should employ some basic quality control measures such as the keeping of stock cultures to test the efficacy of media in supporting growth or in showing differential reactions; to test reactivity of biochemical tests; and staining reactions.

Test Sample:

The laboratory should satisfactorily perform a bacteriological analysis on a sample provided by the committee who will watch the entire procedure. Such samples may be doctored to contain certain enteropathogens so as to test the laboratory's capability in isolating and identifying them. This test normally takes about three days after which the laboratory is required to submit a formal report (typifying their usual report format) to the chairman of the committee.

During this examination the committee will look for:

(i) Sound bacteriological technique
(ii) Sterile procedures
(iii) Proper use and maintenance of equipment
(iv) Proper performance of the tests
(v) Suitable reporting and interpretation of results

ACCREDITATION:

If the laboratory satisfies all the requirements of the committee it will be awarded accreditation with the following conditions:

Accreditation is specifically only for the examination of cooked frozen prawns. Any notorisation used by the laboratory should state this quite clearly: "The laboratory is accredited by the Ministry of Health, Malaysia for the bacteriological examination of cooked frozen prawns." The accreditation does not cover other tests done by the laboratory.

The laboratory must notify the committee if there is any change in physical facilities, personnel, equipment and methodology and must obtain its approval of the committee. Depending on the change the committee reserves the right to withhold this approval until another site visit is made.

The committee reserves the right to make spot checks on the laboratory from time to time and whenever deemed necessary.

Accreditation is granted at the discretion of the committee and it may be withdrawn at any time should it be warranted.

RESULTS:

Four laboratories applied for accreditation during the period 1974–1976. All failed to satisfy the standards at the first examination. One did not reapply. One passed after a second examination while the remaining two did so after a third examination.

Of 4 new laboratories which applied in 1977, 3 passed at the first examination mainly because they were fully aware by now of the standards required of them. The other did not reapply.

Some of the shortcomings of the laboratories are tabled below. Figures in parenthesis indicate

the number of laboratories where a particular shortcoming was apparent until rectified.

A. *Physical facilities*
1. No separate room for microbiological work (2)
2. No sink or washing facilities in microbiology room (1)

B. *Equipment*
1. Insufficient glassware (2)
2. No autoclave/hot air oven (1)
3. Inadequate freezer space (2)
4. Inadequate supplies of media and reagents (2)

C. *Personnel*
1. No appropriately qualified microbiologist (4)
2. Insufficient knowledge leading to inability to detect pathogens (2)
3. Although there is a qualified microbiologist there was a lack of experience and working knowledge (1)
4. Inadequate preparation for the accreditation exercise (1)

D. *Methodology*
1. Not strictly following the methodology which was submitted by the laboratory itself (1)
2. Not performing coliform counts (1)
3. Homogenisation of sample is incomplete (2)
4. Colony counting plates not well dried (1)
5. Insufficient media added to plates (2)
6. Poor bacteriological technique (1)
7. No quality control of media (4)
8. Media not prepared and kept available in advance (1)
9. Improper diluent used (2)
10. Sample size too small (2)
11. Too few dilutions for colony counts (3)
12. Increments between dilutions is too wide (1)
13. Inability to perform biochemical tests and dependance on morphology alone for identification of pathogens (3)
14. No enrichment media used for isolation of pathogens (3)
15. Not enough duplicates for colony counts (3)

E. *Reporting*
1. Usage of the term "Health Certificate" instead of "Laboratory report" on reports issued by the laboratory (3)
2. Including in the report work that is not actually carried out (1)
3. Inclusion of a statement concerning "fitness for human consumption" when the limited tests carried out do not really justify such a blanket statement (4)
4. Insufficient sample identification on the report (2)

F. *Administrative*
1. Returning remaining portion of samples after testing to the requesting factory (3)

DISCUSSION:

Of 8 laboratories that applied for accreditation 6 eventually satisfied the standards expected. Two did not reapply after their initial unsuccessful attempt.

Of the 6 successful laboratories the 3 which had been in operation for some time before the implementation of the "Code of Practice", all failed in spite of the fact that they had been performing food bacteriology for quite a while. However until that time they were free to do what they liked and this first attempt at an accredition showed clearly that the standard of work that they performed was not satisfactory enough to warrant accreditation. This makes one wonder what the standard of unassessed laboratories are. It must be emphasised that the current accreditation exercise assessed the laboratory with regard to its microbiological expertise in general and the examination of cooked frozen prawns in particular. No attempt was made to look into other aspects of the laboratories' work which covered quite a wide range.

New laboratories which only applied recently had the benefit of knowing the requirements for accreditation and setting up their work on a proper footing from the very start. This is always much easier to do than to try to rectify well entrenched old practices among staff who are generally resistant to change. It was not surprising therefore to find that these new laboratories all satisfied the requirements without much difficulty.

In the initial year of the accreditation exercise none of the laboratories which applied had qualified microbiologists. The laboratories were essentially profit motivated and were reluctant to pay the relatively high salaries required by qualified personnel and considered that they could very well do with some school leavers who could be taught some simple basic techniques. What they failed to realise was that to carry out microbiological analyses one has to have sound theoretical and practical knowledge that can come only through years of systematic study. When this point was made clear to the laboratories concerned they sought qualified personnel and subsequently were able to produce a satisfactory quality of work. New laboratories, realising the unlikelihood of their gaining accreditation without qualified personnel, employed microbiologists from the very start and had little difficulty in successfully obtaining accreditation.

It is an accepted practice in many developed countries that there must be some form of surveillance over private laboratories. The legislation and mechanisms of these vary.

In Australia, for instance this function is served by the National Association of Testing Authorities (NATA) which is their organisation for the accreditation of testing laboratories. It registers laboratories which meets its standards of performance. NATA registered laboratories are authorised to issue NATA endorsed reports. NATA endorsed reports provide you with an assurance that the tests have been performed with care and competency. Every aspect of laboratory operation and management is kept under close surveillance by NATA. All registered laboratories are regularly visited by specialist assessors. Laboratories are registered for performance of specific groups of tests within a field of testing. NATA is an organisation made up of representatives from the laboratories themselves (NATA, 1966) and therefore represents a desire from within to ensure standards and maintain the good reputation of the laboratories.

In the United States, the College of American Pathologists started a voluntary programme of inspection and accreditation in the 1960's for pathology laboratories with the aim of promoting laboratory improvement. The programme is peer review in its ultimate sense and should be thought of as an educational experience for the laboratory concerned (Townsend, 1974). The accreditation is based on an inspection of the applicant laboratory to see if it complies with the "Standards for Accreditation of Medical Laboratories of the College" (Commission on Laboratory Inspection 1974). In carrying out the exercise the Inspector closely follows the "Inspector's Manual" (Carlson, 1975) and makes the necessary observations and recommendations. While this inspection and accreditation programme had been going on for some time the Federal Government of the United States passed the Clinical Laboratories Improvement Act of 1967 for licencing of clinical laboratories engaged in interstate commerce (Horn, 1974). A modification was written into the law which provided that any laboratory accredited by the Joint Commission on Accreditation of Hospitals, by the American Osteopathic Association or by the College of American Pathologist's Commission on Inspection and Accreditation would be exempt from the requirements of federal licensure. The Centre for Disease Control in Atlanta was given the responsibility to develop standards. This eventually led to the proliferation of state laboratory licensing laws. With each passing year congress and various state legislatures are enacting more and more laws which demand that laboratories meet certain standards. There are many agencies, both governmental and non-governmental that are setting standards and inspecting this or that activity within the laboratory.

The need to introduce some similar system in this country is quite apparent. The results shown from the experience with the accreditation of private laboratories for the examination of cooked frozen prawns indicate the surprisingly large number of shortcomings even in laboratories that had been functioning for some time and issuing reports on analysis. Inadequately qualified staff, poor technique, insufficient equipment, lack of quality control and bad reporting are the important ones. If any reliance is to be placed on reports issued by these laboratories, there must be assurance that there is a continuous monitoring of their quality by an independant unbiased authority. The successful implementation of the accreditation programme for cooked frozen prawn examination illustrates that high standards can be generated. It appears logical that similar programmes can be instituted to cover other aspects of these laboratories' testing facility. The question arises as to who would be given this task. It does not appear feasible at this stage to rely on a peer review system as carried out in Australia and the United States. Professional associations do not have the sufficient authority, manpower or financial resources to carry out such a task. The duty therefore appears to fall on the shoulders of government agencies such as the Ministry of Health or the Institute for Medical Research. The *modus operandi* of the Special Ministry of Health Committee on Accreditation of Laboratories for the examination of cooked frozen prawns can serve as a suitable model for a national system to cover all laboratories performing work in the medical area. A step by step programme can be implemented to gradually cover the different aspects of laboratory testing. The mechanics of carrying this out can be a subject of debate and discussion but the philosophy must be accepted to ensure that standards are established and maintained.

But it must be done, not by coercion but by friendly persuasion and an awakening of an awareness in the private laboratories themselves that inspection and accreditation is advantageous to them and will in the long run prove beneficial in enhancing their reputation.

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