

## **Letter to Editor**

### **In-house diagnosis test research in Thailand**

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Dear Editor,

In medicine, diagnosis and treatment are two important activities. To reach the final diagnosis, a diagnostic test is usually required. Several diagnostic tests are presently in use. The development of a new diagnostic test is an important biomedical research activity. A significant proportion of such research is conducted by the big medical diagnostic companies. Some research is undertaken by local research groups. In-house diagnostic tests are locally developed tests for local use. In a good and conducive research environment, high quality local in-house diagnostic tests may be successfully developed. However, there are many problems in standardization and quality control. We summarize our findings on previously conducted research in the area of diagnostic test development in Thailand and discuss relevant issues arising from our findings.

A retrospective review of in-house diagnosis test research in Thailand was conducted. Relevant articles were searched for using an international database, PubMed, and a local database, ThaiIndexMedicus. The search key words include “diagnosis”, “in-house” and “Thailand”. Papers were excluded if there was no complete data. The details on study design and quality control process in each selected reports were analysed. Descriptive statistical analysis was used where appropriate.

In this study, 11 papers met the criteria<sup>1-11</sup>. Two reports are collaborative studies between Thai and foreign researchers. Focusing on the study design, all except one report are comparative studies with reported diagnostic properties (sensitivity, specificity and predictive values). However, only two reports contained complete data on statistical acceptance of the number of subjects, the control of confounding factors and the repeatability of the tests.

As Thailand is a developing country, the limited number of such papers is not unexpected. There are only a few reports on in-house diagnosis tests and there are even fewer good quality publications. Reports in local journals often lack scientific rigour. There are only 2 reports that contain statistical data on the number of subjects, the control of confounding factors and the repeatability of the tests. These two papers of acceptable quality arose from collaborations between Thais and foreigners.

This analysis reflects the weakness in research on in-house diagnosis test in Thailand. This may be due to the lack of knowledge on how to perform a good scientific study in the field of laboratory medicine. A similar situation may also exist in developing countries with similar socioeconomic background.

The following factors need to be addressed in all studies of diagnostic test development.<sup>12</sup>

1. Basic requirement of basic biomedical research
  - Statistical acceptability
  - Control of conditions and confounding factors
2. Basic requirement of clinical study
  - Ethical approval
  - Diagnostic properties verification
  - Accuracy and precision
  - Repeatability and stability
  - Cost-effectiveness

A recent publication has pointed out that there are often weaknesses in research methodology, in particular the statistical aspects, in Thai research reports.<sup>13</sup>

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