

CHAPTER I

INTRODUCTION

Background and problems

From the observation of Professor Somwang Danchaivijitr, he said that the infections in hospital can result from the residual disease that is present on the "tools" and accumulate in hospital waste and on medical equipment used in the operating room. Infection cases can occur occasionally, as the sources are difficult to control. Several years of his experience contributed to his view that infections from surgery are likely to occur and mostly cannot be traced. Hospitals all around the world face this problem also. [1] Reports of infection incidents showed an increasing trend in all hospitals. Blood contamination on medical devices is an important source of infectious agents such as microbes (*Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Streptococcus spp.*), drug resistant agents such as Extended-spectrum Beta-lactams (ESBL) Methicillin-resistant *S. aureus*, and Vancomycin resistant Enterococcus etc., as well as Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). Some viruses can survive in blood outside the body for 7 days, for example HBV. If there is any blood contamination on medical devices, the user might be at risk of infectious diseases[1, 2, 3] Many medical devices are likely to contact with blood, such as glucose meters, cholesterol meters, triglyceride meters, dentistry equipments, laboratory equipments and ambulance equipments. Glucose meters are the most widely used meter on the point of care testing (POCT), and are commonly used in the hospitals and public health centers or primary care units (PCU) in Thailand. In the POCT, trained and untrained person can use this device due to the ease of operation this device use the minimal blood so it is popular use in the site of patient care. Hematology analyzers is one of the equipment that highly risk to contaminate with blood. In case of the cleaning method is not suitable, it might be a source of infection for this reason, the medical organization must be frequency check the contamination of blood on medical devices.

The Kastle-Meyer or reduced phenolphthalein test is a forensic presumptive blood test commonly used around the world. The test principle is based on the

chemical indicator phenolphthalein, and relies on the peroxides-like activity of hemoglobin in blood to catalyze the oxidation of phenolphthalein (the colorless reduced form of phenolphthalein). [4, 5, 6] In this blood test, a positive result is indicated by a bright pink color. The reduced phenolphthalein reagent can be prepared in the laboratory and kept in alkali and cool condition to prevent reaction with oxygen from the air. However, the risks of manual preparation of the reagent still occur, whether from laboratory utilities due to the time consuming for the reflux process, instability of the reduced phenolphthalein, or difficulty in preparation and insufficient quality control of materials. For this reason, small laboratories in Thailand commonly purchase the commercial reduced phenolphthalein kit used for blood detection. The commercial test kit is more expensive when compared to the manually-prepared reagent (costs per kit are ranged from \$50 to \$250 USD). [5, 7]

The goal of this study was to develop an effective reduced phenolphthalein reagent for blood detection and for commercial purposes.

Objectives

1. To develop sensitivity, precision, specificity, and stability of the reduced phenolphthalein reagent by modifying the original Kastle-Meyer method.
2. To compare sensitivity, precision, specificity, and stability between the new modified methods obtained from objective 1 and the commercial test kits.
3. To survey the user's satisfaction of the new test.
4. To apply the new test kits for blood contamination on glucose meters and hematology analyzers in hospitals and primary care units (PCU) of Uttaradit and Pichit Provinces, Thailand.

Scope of the study

This study aimed to develop an efficient reduced phenolphthalein test by optimization of chemical compositions such as types of reducing agents and chemical ratios of original reduced phenolphthalein reagent. The study was divided into six modification methods. Sensitivity, precision, specificity, and stability of each formulary was performed and compared to a commercial test kit. Then the new modified test kit was formed, designed, packaged, and sent to users at hospitals and

PCUs to evaluate the satisfaction of the product. Using the new modified reduced phenolphthalein test kit, blood contamination on glucose meters and hematology analyzers was surveyed in 20 community hospitals and 100 primary care units of Uttaradit and Pichit Province, Thailand, during July to September 2009. One hundred and fifty questionnaires (Appendix A) were sent to glucose meter users, 50 questionnaires were sent to community hospitals and 100 questionnaires were sent to primary care units. In addition, 20 questionnaires (Appendix B) were sent to users of hematology analyzers at 50 community hospitals. These entities were questioned about personal information, type of agency, model of tools, frequency of use, frequency of cleaning, method of cleaning, cleaning detergent used, and whether gloves wearing.

Basic Assumption

1. This study focused only on the detection of occult blood contamination on glucose meters and hematology analyzers. It did not correlate to infectious agents. Therefore, positive blood detection might or might not have infectious agents.

2. Oxidizing substances might be give false positive results to the reduced phenolphthalein testing beside hemoglobin.

Definitions and specifications

1. Original reduced phenolphthalein was prepared using the principles of Kastle Meyer.

2. Modified methods are methods that vary the ratio of some reagents from the Kastle-Meyer method.

3. The modified method is equal or better than the original method

4. The commercial test kit is a reduced phenolphthalein test kit (WARD'S Natural Science) [7] purchased from Saengvith Science Co.,Ltd.

5. A glucose meter is the device that is used to detect blood glucose concentration from the fingertip.

6. A hematology analyzer is the equipment used in hematology laboratory to measure complete blood count and blood indices.

Hypothesis

1. Optimization using the modified reduced phenolphthalein method can enhance sensitivity, precision, specificity and stability more than the original method
2. The new reduced phenolphthalein test kit is more efficient or equal to the commercial test kit
3. The new reduced phenolphthalein test kit can be easily used for detection blood contamination on glucose meters and hematology analyzers.