The Research on Establishment of "Clinical Practice Guide of Blood Specimen Collection, Preservation and Delivery for Clinical Nurse": Protocol Description

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Abstract

INTRODUCTION AND OBJECTIVE:

The correctness of the blood test is closely related to the sample. According to the recent reported data, 80 percentage unsatisfactory results of the clinical test are due to the poor quality of sample, especially the blood sample. Clinical practice guide (CPG) is directly to instruct the clinical nursing practice. And the recommendations in the clinical practice guide are based on the best available study evidences. There is lack of CPG about blood sample specimen collection, preservation and delivery (BSCPD) in China. Additionally, related published clinical studies are accumulated in a great deal. Therefore, establishing a CPG is necessarily and practicable. The detailed objectives are: 1) to describe and analyze the research status of BSCPD in China; 2) to describe and analyze the practice status of BSCPD in China; 3) to systematic appraise the available evidences of BSCPD; 4) to establish the clinical practice guide of BSCPD; 5) to judge the clinical practice guide of BSCPD.

METHODS:

Objective 1): Bibliometric analysis is applied, the database include China National Knowledge Infrastructure Database (CNKI) and Sino-med and the research period is from the year of 2003 to 2013; Objective 2): Questionnaire survey for all the registered clinical nurses in a grade three hospital; objective 3): Systematic review according to Cochrane collaboration handbook 5.1.0 is applied which includes assessment of risk of bias, data extraction, data analysis; Objective 4) and 5): Using the appraising guidelines research and evaluation (AGREE) to evaluate of the draft of CPG of BSCPD.

RESULTS:

Bibliometric analysis started in 2013, and search strategies have been established. Questionnaire survey setting and depth interviewees have been identified and communicated.

CONCLUSIONS:

The CPG of BSCPD will serve as an important resource in instructing and modifying clinical nursing practice. Given this CPG of BSCPD will be a draft version, the applicability and suitability of it will need a further evaluated in the real clinical nursing world.

Keywords: Blood specimen; Clinical Practice Guide; Evidence based Nursing

I. INTRODUCTION

A. Numerous problems involved in the Collection, preservation and delivery of blood specimens causing dire consequences

The accuracy of the clinical test results is directly related to specimens. Existing data reveal that 80% of the unsatisfactory clinical test results could be attributed to unqualified specimens [1]. The worst problems are to be found in the blood specimens, accounting for 96.31% (2565/2663) of all the unqualified blood, urine and stool specimens [2]. Analysis shows that reasons leading to unqualified blood specimens vary, they are respectively: clots in the anticoagulation specimens, incorrect ratio of blood to anticoagulant, specimen hemolysis, specimen type error, contaminated specimens, specimen container breakage, severe blood fat, specimen barcode error, delayed submission of specimens and no specimens. Unqualified blood specimens could, in one way or another, is ultimately attributed to the failure to exert rigid quality control over collection, preservation and delivery of blood specimens [3-5].

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Unqualified blood specimens could bring about dire consequences. For the sake of accurate diagnosis, perfection of therapeutic schedule and better monitoring of the change of patients' condition, medical staffs tend to collect blood specimens of the patients and conduct routine tests, such as biochemical tests, microbial culture, blood grouping and cross-match test, etc. The unqualified blood specimens mentioned above not only affect the accuracy of the test results but hamper proper diagnosis and treatment even leading to misdiagnosis and missed diagnosis, and thus causing terrible consequences. Before the stage of testing, nurse clinician is the only person handling the blood specimens [6-8]. As a result, nurse clinicians play a very important role in each of the stage of collection, preservation and delivery of the blood specimens.

B. *It is imperative to establish "A Clinical Practice Guideline for Collection, Preservation and Delivery of Blood Specimens" that conforms to situation in China*

Evidence-based nursing is a notion and working procedure under the influence of evidence-based practice, it is also a process where nurses consciously and prudently integrate scientific research conclusion, clinical experiences and patient's wishes and then acquire evidences guiding clinical care. Bearing the influence of the notion of evidence-based practice, Clinical Practice Guideline (CPG) directly guides clinical nursing practice [9]. Based on a stringent evaluation and integration of evidential matter, CPG converts numerous and jumbled research results to recommendation, helping to save time and promote the application of the best evidence [10]. The successful application of CPG is conducive to scientific decision-making on the part of nurses; to reducing the variability of clinical practice; to safeguarding the safety of the patients, and thus improving the cost-effectiveness of the health services.

Currently in China, the establishment of disease diagnosis and treatment guidelines is widely under way, and the establishment of these guidelines all bears the guidance of evidence-based medicine, serving to standardize scientific clinical treatment. In the domain of nursing, some foreign countries already boast the evidence-based practice guideline standardizing the collection, preservation and delivery of blood specimens. While here in China, we haven't yet heard any report on the evidence-based practive guidelines for the collection, preservation and delivery of blood specimens. Because of the humanistic attribute of nursing, foreign guidelines need to be domesticated before being applied to China's clinical situations. In addition, foreign guidelines didn't refer to any of China's published literature; therefore it is not advised to directly apply foreign guidelines to China's clinical situations.

C. *Compared to the mature clinical practice guidelines and their application in foreign countries, China has few such guidelines based on evidence-based practice*

There still lack a universal recommendation even though all the hospitals are collecting, preserving and delivering blood specimens in accordance with certain standards. Moreover, published literature in China concerning the collection, preservation and delivery is sufficient enough to form a resource basis for the establishment of such guidelines. All in all, it is not just imperative but feasible to establish "Clinical Practice Guideline for The Collection, Preservation and Delivery of Blood Specimens" that conforms to situation in China.

Taking advantage of the evidence-based resources in the Center for Evidence-based Nursing of Beijing University of Chinese Medicine and integrating the expertise of the elites in the domain of clinical nursing management and evidence-based nursing in 3 Class-A hospitals in Beijing, this study draws on the experience of the foreign guidelines for collection, preservation and delivery of blood specimens to establish China's "Clinical Practice Guideline for The Collection, Preservation and Delivery of Blood Specimens" under the guidance of the methods of evidence-based practice while giving due consideration to China's clinical situation. An expert panel would then be organized to review the guideline using AGREE evaluating system so as to improve its clinical feasibility. Hopefully, such a guideline would help to reduce the rate of unqualified blood specimens and to eliminate all sorts of potential negative impact caused by unqualified blood specimens on the patients.

II. OBJECTIVES

Using JBI evidence-based health care model as the conceptual framework, this study starts by evaluating and integrating evidences concerning the collection, preservation and delivery of blood specimens. This study then moves on to establish "Clinical Practice Guideline for The Collection, Preservation and Delivery of Blood Specimens" (draft). Finally an expert panel will review and amend the guideline draft to establish a formal guideline. Specifically, objectives include:

- *To describe and analyze the research status of the collection, preservation and delivery of blood specimens in China.*

- *To describe and analyze the status quo of the practice of the collection, preservation and delivery of blood specimens in China.*
- *To systematically evaluate and integrate all the valid evidences concerning the collection, preservation and delivery of blood specimens.*
- *To establish "Clinical Practice Guideline for the Collection, Preservation and Delivery of Blood Specimens".*
- *To establish "The Best Practice Information Booklet for the collection, preservation and delivery of blood specimens".*
- *To review and evaluate the "Clinical Practice Guideline for the Collection, Preservation and Delivery of Blood Specimens".*

By getting to understand the research status of the collection, preservation and delivery of blood specimens and analyzing the key problems involved in this process in China, this study intends to establish the following two workable document: "Clinical Practice Guideline for The Collection, Preservation and Delivery of Blood Specimens" and "The Best Practice Information Booklet for the Collection, Preservation And Delivery of Blood Specimens " in hope of improving all the aspects of the collection, preservation and delivery of blood specimens in clinical nursing practice.

III. METHODS

Methods vary when it comes to different research objectives, specifically:

1. Research methods for the research status of the collection, preservation and delivery of blood specimens in China:

1.1 Bibliometrics and content analysis

1.1.1 Data source

Databases retrieved include China National Knowledge Infrastructure and Chinese Biomedical Literature Database (CBMdisc). The retrieval time will be from 2003 to 2013. Key words: "collection of blood specimens", "preservation of blood specimens", "delivery of blood specimens" and "management of blood specimens", etc.

1.1.2 The method of literature review and analysis

The index system of literature review: indexes reflecting the basic information of the literature and indexes reflecting nursing research content of blood specimens' collection.

1.1.3 Statistical analysis method

Quantitative analysis is going to be analyzed by SPSS13.0; mainly descriptive analysis.

2. Research method of the status quo of the practice of the collection, preservation and delivery of blood specimens in China

2.1 Registered nurses in one of the Class A hospitals in Beijing would be required to fill out the questionnaires.

- Inclusion criteria: Nurses doing daily nursing work.
- Exclusion criteria: Excluding nurses in administrative departments (nursing department, priority ward, supply room, operating room).

2.2 Research tool

The method of questionnaire survey is adopted: The questionnaire falls into 3 parts: Part 1: general information; Part 2: How are they concerned about the collection, preservation and delivery of blood specimens and how would they comment on the current process of collection, preservation and delivery of blood specimens; Part 3: Open-ended questions are designed to investigate into the major problems involved in the collection, preservation and delivery of blood specimens.

2.3 Method of data collection

Envelopes containing questionnaires with double sides' adhesive tapes would be distributed to the head nurse of each department. The envelopes would be then distributed to individual nurses. The nurses are required to complete the questionnaires within 3 days upon receipt and return the sealed envelopes back to the head nurses, and finally back to the researchers.

3. The systematic review strategies for BSCPD

3.1 Search methods for identification of studies

The retrieval of trials will be performed in the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library Issue 6 2013); MEDLINE (1966–June 2013); Chinese National Knowledge Infrastructure (CNKI, 1979–June 2013); Chinese Scientific and Technological Periodical Database (VIP, 1989–June 2013). Searches were

conducted to identify all relevant studies regardless of language or publication status. The search strategy will be constructed according to different problems which based on the previous research part.

3.2 Data collection and analysis

Study selection. Papers will be initially screened and excluded based on title and abstract by two independent researchers. Full text was obtained for the remaining papers and these were assessed independently by both researchers against an inclusion and exclusion checklist. Disagreements were resolved through discussion: if this failed a third researcher was consulted.

Data extraction. All data extraction and calculations will be performed independently by two researchers using a standardized data extraction form. They will be not blinded to study authors, institutions, or journals of publication. Both sets of data will be then compared for discrepancies and there will be resolved through discussion. Data on study characteristics including study design details, participants' characteristics and baseline demographics, interventions, and outcomes will be extracted. For dichotomous outcomes, the number of responders and the total number of participants for each study arm will be extracted. For continuous outcomes, the Mean change and Standard Deviation (SD) for the Mean in each group of the trial will be extracted along with the total number.

Assessment of risk of bias in included studies. Articles will be assessed by two reviewers independently. To assess the methodological validity of the studies included in this review the following aspects were evaluated: sequence generation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting, and other potential threats to validity. According to the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0,[11] which included the assessments of Each domain was judged to be of low risk, high risk or uncertain risk ('yes' for a low risk of bias, 'no' for a high risk of bias, 'unclear' otherwise). Based on these criteria, each study could be divided into three grades as follows: low risk of bias (low risk of bias for all key domains); unclear risk of bias (unclear risk of bias for one or more key domains); and high risk of bias (high risk of bias for one or more key domains). Disagreements will be resolved by consultation with a third reviewer.

Data synthesis. In this study, statistical analyses will be conducted using software provided by the Cochrane Collaboration (RevMan 5.1.2).[12] All *P*-values will be two-sided and $P<0.05$ will be considered statistically significant. We are going to do the meta-analysis by pooling similar studies. Dichotomous data are presented as rate ratio (RR), while continuous data are expressed as weighted mean difference (WMD), all with 95% confidence interval (CI). The presence of statistical heterogeneity will be explored by I^2 test with significant set at $P<0.1$. For I^2 less than 50%, a fixed-effect model will be used; for $I^2 \geq 50\%$, a random-effects model will be applied.

4. The establishment of "Clinical Practice Guideline for The Collection, Preservation and Delivery of Blood Specimens" (draft) and "The Best Practice Information Booklet for the collection, preservation and delivery of blood specimens"

4.1 To organize development team of the guideline

The development team would be composed of evidence-based practice methodology experts, clinical quality management experts and nursing management experts. All the team member need to have received evidence-based nursing practive training.

4.2 The establishment of the draft of the guideline

4.2.1 Data source

Based on the study of the first two stages (systematic evaluation and analysis result of the status quo), the guideline would be established rigidly under the guidance of evidence-based methodology by referring to such guidelines in foreign countries.

5. Composition of the guideline

The guideline is composed of: introduction, research background, clinical background, systematic evaluation, nurse clinician's management strategies of the collection, preservation and delivery of blood specimens and their suggestions for the use of guidelines.

6. Review of the BSCPD

An expert panel consisting of clinical nurse specialist, clinical care managers and experts in the Center for Evidence-based Nursing would be formed to individually review the guideline. A discussion meeting would be called upon to review the guideline for the second time if necessary to determine the final draft of the guideline.

IV. RESULTS

Bibliometric analysis started in 2013, and search strategies have been established. Questionnaire survey setting and depth interviewees have been identified and communicated.

V. ANTICIPATED OUTCOMES

1. The identification of the problems through analyzing the research status of the collection, preservation and delivery of blood specimens in China;
2. The identification of the problems in the management strategies and the preventive measures against specimens collection errors through analyzing the practive status quo of the collection, preservation and delivery of blood specimens in China.
3. Identification of the valid evidences through systematically collecting and evaluating the literature concerning the management strategies and preventive measures against errors in the collection, preservation and delivery of blood specimens;
4. Reduction of the rate of errors involved in the collection, preservation and delivery of blood specimens through establishing Clinical Practice Guideline and The Best Practice Information Booklet for the collection, preservation and delivery of blood specimens.

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AUTHOR CONTRIBUTIONS

Conceived and designed the protocol: Fen Zhou, Hong Guo, Yufang Hao, and Ling Tang; Wrote the paper: Fen Zhou and Hong Guo.

CONFLICTS OF INTEREST

None declared.

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