



QUALITY ASSURANCE AND QUALITY CONTROL IN COHORT STUDY

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OUTLIE OF THE PRESENTATION

Introduction

Definition of the quality assurance and quality control (QAQC)

Processes of developing of protocol for QAQC

The components of the QAQC

Discussion and conclusion

INTRODUCTION

QAQC has always been considered as a fundamental principle in any study but in conducting cohort studies, this component is particular importance. The reasons for this are:

- Large scale of the study
- Collecting large amount of data in various methods such as (interview, measurment and biomarkers testing).
- Duration of the study is considerable (using now equipment)
- clear expectations of requirements

- communication among all study staff within different centers

OBJECTIVE

The objective of this presentation is to discuss minimizing potential sources of error in (cohort) studies based on QAQC Protocol.

QUALITY ASSURANCE

quality assurance consists of those activities undertaken *prior to data collection* to ensure that the data are of the highest possible quality at the time they are collected.

QUALITY CONTROL?

quality control consists of those activities that take place *during and after data collection* to identify and correct any errors or discrepancies in the data that have been collected

Quality assurance activities	Quality control activities
<i>Development of protocol and recruitment</i>	
Protocol development and design	Checking for participant eligibility
<i>Questionnaires and data collection instruments</i>	
Design	Data cleanup
Pilot testing	Local and central evaluation
Coding and editing procedures	Problems with self-report data
Trouble shooting	
Missing values	
Updating	
<i>Interviewer and technician protocol</i>	
Development/pilot testing	For each interviewer and technician:
Training of interviewers	Observe application of protocol
Training of technicians	Monitor certification maintenance
Certification procedures	Completeness of data
Recertification procedures	Retraining when needed
	Regular feedback on quality control
	Training of new personnel
<i>Data entry packages</i>	
Development/pilot testing	Updating systems
Training of personnel	Double entry
<i>Study wide</i>	
Development of local quality assurance/ quality control	Monthly quality control reports
	Reliability/reproducibility studies
	Site visits
<i>Use and maintenance of study equipment</i>	
Develop and pilot equipment use	Routine maintenance of equipment
Training of personnel	Trouble shooting
Maintenance and schedules	Quality of equipment data

ORGANIZATION OF QAQC

QAQC should be implemented in two lines:

Field component

And paraclinice component

PROCESS OF DEVELOPING PROTOCOL IN THE PERSIAN COHORT

The protocol was divided into different sections and each section was assigned to the experts in the field.

Also protocol of the study were reviewed by PIs at the university level and involved team in the field. To collect their recommendations in appropriate manner we used special check list.

The protocol of the study were used in the pre pilot and pilot study.

based on receiving feedbacks protocol were modified.

The aim of pilot phase of study is the feasibility study of using resources / equipment / manpower / time, applicability of the study and data analysis to determine limitations in the study.

QUESTIONNAIRES AND DATA COLLECTION METHODS

To assure the quality of data following methods and tools were used :

The variable and information of each cohort study can be categorized in 3 types based on collected method: **self report (physical activity)** , **measurement (BMI)** and **biomarkers (Blood glucose)**

reviewing and selection the appropriate scientific methods to achieve the final goals of the cohort study.

Design data collection methods based on available literature and also we take advantage of the expertise and tools used in previous studies (GCS) and Pars (Pars).

THE PROCESS OF DESIGNING QUESTIONNAIRES (1)

Literature review on national and international studies

Since some studied questionnaires used in previous cohort studies, so they can confirm the validity and reliability of the questionnaires. some other parts of the questionnaires have already been used in cohort studies abroad was used. At first texts were translated into Farsi and then in the Scientific Committee were reviewed in several sessions. Some sections of of the questionnaires were translated from English to Farsi, hence this part were **back translation**.

Review the draft of questionnaires by scientific committee that consists of experts from various fields and Pls.

Correction and customizing of questionnaires were made based on feedback

THE PROCESS OF DESIGNING QUESTIONNAIRES

(2)

Different parts of the questionnaire in four centers (pilot phase) were assessed and some parts were revised.

These limitations of the questionnaires were identified based on a feedback from people in the field and by meetings with scientific teams.

TRAINING AND CERTIFICATION OF STUDY PERSONNEL

interviewers and technicians should be trained in different areas, general information, nutrition, health and laboratories.

They have been qualified based on central committee criteria.

Twice number of study personnel should trained and $\frac{1}{2}$ were selected and hired.

In Persian Cohort, interviewers and technicians in two main phases were assessed The first phase by the executive team at the University of the second phase by a central team.

Study personnel were trained in two stage (Locally and centrally).

Training of new personnel and retrain of current personnel in a continues way.

COMPUTER PROGRAM FOR DATA ENTRY

Online or offline software?

Training of personnel of study

Paperless data collection (Tablet).

Training and testing of the program.

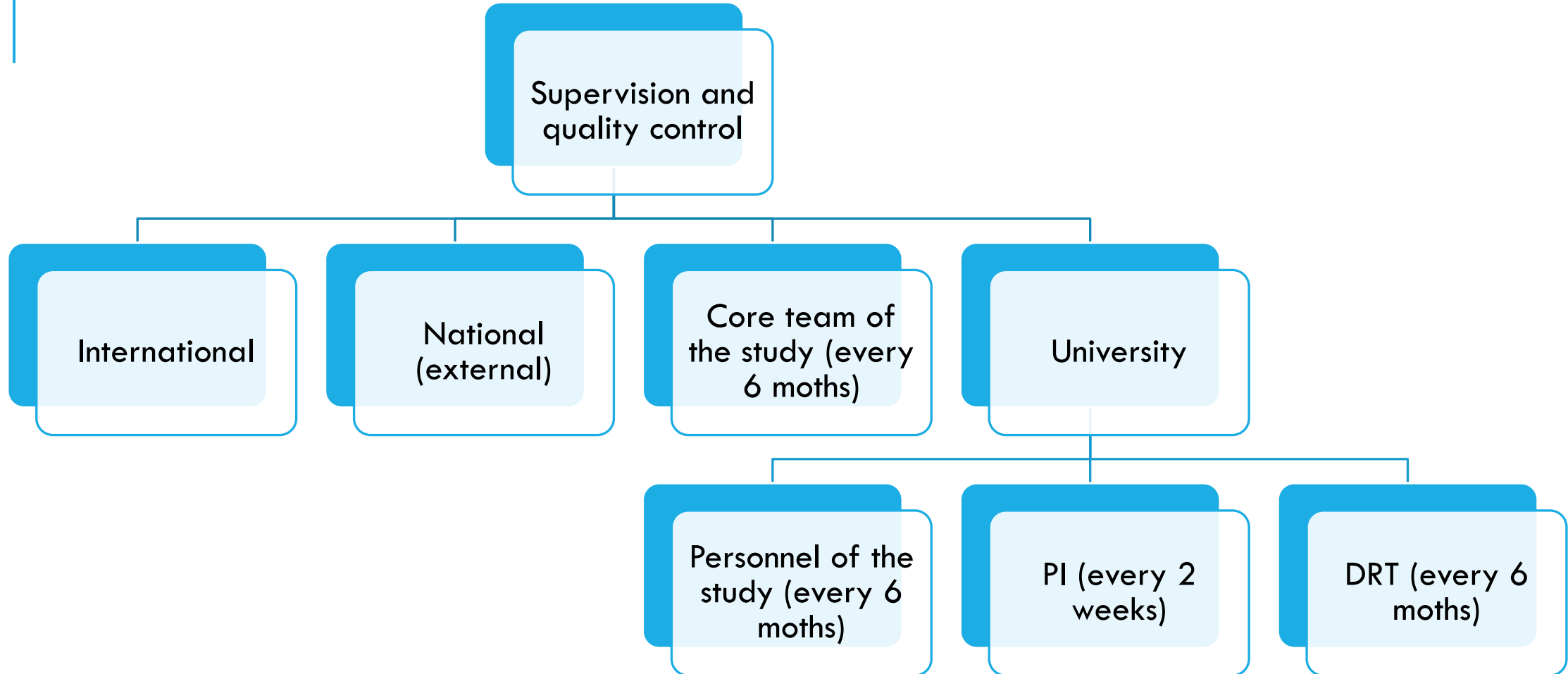
data accuracy and data consistency

QUALITY CONTROL COHORT STUDY

The protocol performance in the field
reviewing the study cases based on inclusion and exclusion criteria of the study

In each province there is a defined population for the study. So if people outside the target range comes cohort criteria is not met.

STRUCTURE OF SUPERVISION AND CONTROL IN THE PERSIAN COHORT



QUALITY CONTROL QUESTIONNAIRES AND DATA COLLECTION METHODS

Checking the practicality and functionality of protocol in the field

Check and clean the collected data (quality control of data at regional and central level)

first step data will be checked by quality control team at university level and sending the report to core team of the study monthly.

The second step assurance and quality control of data analysis done by the core team. The feedback will be sent to university.

Notably, in the Persian study coding is done in two stages, the first in admission of case and the second in a laboratory (regardless of the coding in the admission section). The result is a two-stage coding are compared and if discrepancies are reported.

CONCLUSION

Quality assurance and quality control is essential in cohort study.

This need various activity over time so, a unit with standard protocol is required.

Since QAQC needs communication between centers, communication in appropriate method is necessary.

Monitoring and quality control of various stages and components of the study should be consider as a key issue.



THANK YOU FOR YOUR ATTENTION