GET Journal of Biosecurity and One Health

GET Global Emerging Pathogens Treatment Consortium

GET JOURNAL OF BIOSECURITY & ONE HEALTH

PUBLISHED BY:

Global Emerging Pathogens Treatment Consortium

JOURNAL WEBSITE

www.getjournal.org

Identification of the Requirements and Expectations of Interested Parties in a Biobank in Sub-Saharan Africa

Diané KM[1,2*], Money M[1,2] Bouagnon JJR[1,2], Cissé S[1,2], Aka KAE[1,2], Kintossou KA[1,2], Coulibaly L[1,2], N'Guessan F[1,2], Setchi LO[3], and Dosso M[4]

[1]Biological Resource Center of IPCI

[2]Regional Biobank of ECOWAS countries

[3]Quality, Health and Safety Department of IPCI

[4]Direction of Institut Pasteur of Côte d'Ivoire

*Corresponding Author: Diané Kouao Maxime: 22 bp 1271 Abidjan 22

ORCID: https://orcid.org/0000-0003-0953-7704

ABSTRACT

Biobanks are important infrastructures facilitating biomedical research. It is recognized that improving the health of individuals and populations increasingly requires the use of large-scale collections of human biological samples and associated data. In this regard, biobanks are a valuable resource to facilitate effective research. The objective of this study was to identify the current and future needs and requirements of our stakeholders, so that measures to satisfy them could be put in place. An exploratory, quantitative and qualitative study was carried out by means of an anonymous survey, on the expectations and requirements of the stakeholders of biobank. This descriptive cross-sectional study which took place over 3 weeks in 2021. Fifty (50) participants working in Abidjan and in the interior of the country agreed to answer the anonymous survey. Among them, 32 (64.0%) were men. The professions of research biologists represented 19 (38.0%) physician-pharmacist practitioners 11 (22.0%). The overall expectations of stakeholders in relation to operational processes were: compliance with regulations, standards and best practices 42 (84.0%); feedback on uses 40(80.0%); staff safety 40(80.0%); information on the possible use of biological resources 38(76.0%). The administrative authorities who took part in the survey unanimously identified practically all the expectations relating to biobank management processes as important. The following essential expectations were identified: acquiring the necessary skills, internal communication concerning quality and operations, performance/efficiency of support activities, satisfaction of interested parties, 100% staff safety. For the development of biobanks for research purposes, political decision-makers, regulators and researchers should take into account the opinions of all social sectors, in particular the general public.

Keywords: Stakeholders; Biobank; Sub-Saharan Africa; Knowledge; Needs and Expectations

Corresponding Author's Email: dianekouao@yahoo.fr

INTRODUCTION

Biobanks are organized collections of human biological material with associated information stored for research purposes [1]. They are essential sources for basic epidemiological research, because information they contain allows researchers to discover genetic associations in complex diseases and to develop new therapies and prevention strategies [2,3]. Biobanks are important infrastructures that facilitate biomedical research. It is recognized that improvement in the health of individuals and populations increasingly requires the use of large-scale collections of human biological samples and associated data. In this regard, biobanks are valuable resource to facilitate effective research [4,5].

The increasing number of biobanks around the world reflects their importance in enhancing the reproducibility and significance of biomedical research results. Reproducibility is possible because human biological material are collected and stored according to strict and standardized methodologies [4]. However, in biobanks, there are several stakeholders and the use of biological material does not always involve the delivery of individual results, mainly because of the importance of the information of the participants for posterity [6].

In the literature, stakeholders are worried about data confidentiality, genetic discrimination, data and sample quality, the regulation of scientific research, and donor remuneration or other requirements linked to the donated material [7,8].

The IPCI biobank is an infrastructure at the interface of various players involved in the life of biological resources and/or collections, it must go beyond taking into account the satisfaction of the "end customer" or researcher who uses biological resources and pay attention to all interested parties defined as any person (legal or natural) having an interest in the operation of the Biological Resource Center (BRC) (3.6 of standard NF S 96-900)

It is therefore essential for a BRC to:

- Define all the interested parties who will be the focus of its quality management system,
- Understand their present and future needs,
- Identify the expectations to which the BRC can respond,
- Implement its organization and activities to meet these expectations,
- Monitor stakeholder satisfaction,
- Continuously improve its quality management system.

The biobank of IPCI is committed to a quality approach. He must guarantee the rights of all interested parties and take into account their needs and expectations (chapter 5.2 "Needs and expectations of interested parties" of standard NF S 96-900; chapter 4.2 "Listening to 34. Customers" of standard ISO 9001).

The knowledge needs or requirements of stakeholders around biobanks are critical elements for its success because of the need to meet these expectations to improve services.

After a decade of deployment of this important infrastructure (biological resource center) involved in biomedical research, a shift in focus on the sustainability of biobanks has been observed in recent years. In this regard, an increase in the still relatively low utilization rates of biobanks was formulated as a goal. A higher rate of use can only be achieved if the perspectives of potential users of biobanks, especially researchers not yet collaborating with biobanks – are adequately taken into account [5].

However, the biobank of IPCI has no evidence of the identification of the needs and expectations of its interested parties. To better understand their views, a survey was conducted at the IPCI's biobank. In this context, this study therefore aims mainly to identify the present and future needs and requirements of stakeholders in connection with the activities of the biobank of IPCI in order to put in place all the measures to bring them satisfaction.

METHODOLOGY

A-Materials

Study Framework

This study took place within the framework of the IPCI and the services of the interested parties. The IPCI has two sites: Cocody, near the University Hospital of Cocody, and Adiopodoumé, on the road to Dabou. The IPCI has 11 departments, 43 laboratories and units, National Reference Centers, all coordinated by the HSQE service (Health, Safety, Quality and Environment). All departments follow a quality approach according to the Director's objective, as set out in the institute's quality policy. The main activities of the IPCI are grouped into various fields: primarily microbiology (parasitology-mycology, bacteriology and virology, production of inputs for analyses, conservation of biological resources, molecular biology and cell biology of infections) and secondarily biochemistry and haematology analyses.

Center for Biological Resources (CeReB) or biobank of IPCI

At the express request of WHO to ensure the containment of wild Poliovirus strains in 2004, the idea of a better-structured organization of collections was born.

The Biological Resource Center (CeReB) of the IPCI was created by Ministerial Decree 64. No. 105 of February 11, 2010 of the Ministry of Higher Education and Scientific Research.

The CeReB IPCI is made up of three units:

- Sample Management Unit (SMU)
- Microorganism Management Unit (MMU)
- Document Management, Information and Communication Systems Unit(DMICSU)

Study Population

Our study population consisted of all the staff of the IPCI, the staff of the structures of the interested parties.

Interested parties were diverse. They could be natural or legal persons. These were, among others, patients/donors of Biological resources (BR) ; Biological resources depositors (doctors, clinicians and hospital staff, initiators of collections), BR researchers/users, IPCI's biobank staff, support services, companies and organizations involved in Biological resources centers (BRCs), administrative authorities, networks: laboratories, BRC networks.

Concept Definitions

Interested parties, or stakeholders are people or companies likely to be impacted by an IPCI biobank activity or decision. Each interested party has expectations towards the IPCI biobank.

Biological resource user: Individual or legal entity authorized to use biological resources for research purposes. The user of biological resources may be a research partner, a biobank, a clinical investigation center or one of their staff.

Biological Resource Center (BRC) or biobank: Structure that acquires, preserves, validates, studies and makes available collections of biological resources, maintains databases accessible to users, and may provide access to data processing services and tools (bioinformatics). BRCs may be set up for therapeutic or research purposes.

The collection and preservation of human, animal and plant biological samples has been a long-standing practice, but was only recently formalized in the 90s. The term "biobank" only appeared in scientific literature in 1996, and the name "Biological Resource Centre" was adopted in 1999 at the OECD's Tokyo '99 Workshop on Scientific and Technological Infrastructure - Support for BRCs. France approved the name and acronym "CRB" in 2001 [9].

Support departments/functions (of a company): refer to all management activities that do not constitute the company's core business. Their mission is to ensure the smooth running of the company and support the operational teams on a day-to-day basis.

Data Collection, Observation and Survey Tools

The survey was carried out by distributing questionnaires to interested parties. Data was collected using this unique data collection form. This form detailed the items required to compile the indicators defined for this study. The questionnaire has 4 parts:

- Socio-demographic characteristics,
- Identification of interested parties,
- Requirements and expectations related to operational processes,
- Requirements and expectations related to management processes.

B-Method

Study Design and Duration

An exploratory, quantitative study was carried out by means of an anonymous survey, on the expectations and requirements of the organic resource center's stakeholders. This descriptive cross-sectional study took place over 3 weeks in the month of May 2021.

Selection criteria

Given the limited resources (human and financial) at our disposal, we propose to sample by reasoned choice (empirical sample). During this study, we interviewed patients, IPCI researchers and practitioners from regional hospitals.

Inclusion criteria: The survey sample included people who were among the potential stakeholders at the time the study sample was selected.

Non-inclusion criteria: People who were not interested will not be included in the survey. Any IPCI worker who refused to participate in the study or who is administrative staff will be excluded from our sample.

Sampling and sample size

Empirically, we expected differential participation rates between interested parties within the IPCI and parties outside the IPCI. Study sample sizes were defined accordingly. We targeted an approximate number of at least 30 respondents, which would provide sufficient statistical power to answer the main study question.

Investigations
Respondents were sent a paper questionnaire with an information letter asking them to complete the questionnaire and hand it in to the secretariat of the management or biological resource center. The single data collection form was used as a tool for collecting the data required to conduct the study. The interviewer distributed the forms to selected respondents. Respondents completed the data collection form and returned it to the biological resource center.

C- Data Processing
Data Extraction
For the purposes of our study, all data were entered using EpiData software, then imported into Excel.

Statistical Analysis
Characteristics Description
Socio-demographic characteristics and party needs are described in terms of numbers and percentages for the qualitative variables. The distribution of quantitative variables was described by the mean with standard deviation and extremes.

The data collected after the survey were entered using EpiData 3.1 software, French version. Descriptive and comparative analyses were performed using Epiinfo 7 version 7.1.3.0.

D-Ethical Issues
In accordance with the rules of good survey practice, we have protected the information provided by respondents, by assigning an anonymity number to each survey form. Respondents' participation was voluntary and obtained by consent.

No invasive procedures were considered as part of the data collection in this study, and no money was paid to any respondent as part of the data collection. Data collection in this study did not involve any risk to participants, as the investigator did not oblige the participant to be a donor of biological resources.

RESULTS
Socio-Demographic Characteristics
During our study period, 50 participants working in Abidjan and in the interior of the country agreed to take part in the anonymous survey. Of these, 32 (64.0%) were men. Research biologists accounted for 19 (38.0%) and medical-pharmacists for 11 (22.0%). (Table1).

Table 1: Distribution of socio-demographic characteristics of the 50 participants who responded to the questionnaire on the needs and expectations of biobank stakeholders

	Number	Percentage
Sex		
Male	32	64.0
feminine	18	36.0
Occupation		
Biologist-Researcher	19	38.0
Trader/trader	2	4.0
Biobank Consultant	1	2.0
Student	8	16.0
Engineer / Supply manager	2	4.0
Doctor/pharmacist	11	22.0
Administrative manager/secretary	2	4.0
Retirement	1	2.0
Biological Technician	4	8.0
Total	50	100.0

GET Journal of Biosecurity and One Health (2023), 2(2), 9-18.
DOI: 10.36108/GJOBOH/3202.20.0220

Table 2 shows that 32 (86.5%) of the participants said they were users of biological resources, compared with 26 (70.3%) who said they were depositors of biological resources.

Global Identification of Stakeholder Expectations

Table 3 shows that the top 5 overall expectations of stakeholders in relation to operational processes were: Compliance with regulations, standards and best practices 42 (84.0%); feedback on uses 40(80.0%); personnel security 40(80.0%); information on the possible use of biological resources 38(76.0%) and respect for patients' opinions regarding the use of biological resources 38(76.0%).

In terms of participants' overall expectations in relation to management processes, the top 5 expectations were Protection of the individual 37 (74.0%); Protection against risks to personnel 37 (74.0%); Compliance with regulations in scientific research 36 (72.0%); Compliance with human rights and ethics 36 (72.0%); Compliance with quality policy 35 (70.0%) (Table 4).

Expectation and Requirements by Interested Parties

Table 5 shows that all the administrative authorities who took part in this survey unanimously (100%) perceived almost all the expectations in relation to the biobank's management processes.

For their part, 100% of BR users indicated that their needs were: Access to Biological Resources and Quality of BR and associated data (Table 6).

In expressing their expectations, depositors emphasized their rights. These included: The right to use RB collections, with the possibility of co-authorship of publications using RBs, compliance with regulations and ethics, and communication with the IPCI biobank (Table 7).

In Table 8, we can see that patients' requirements concerned the confidentiality of personal and medical information related to patients/donors (100%), respect for patients' opinions regarding the use of BR (100%) and freedom to withdraw consent (100%).

For biobank staff, the five (5) most important expectations are identified as: acquiring the necessary skills, internal communication concerning quality and operations, performance/efficiency of support activities, satisfaction of interested parties, 100% staff safety. (Table 9).

Table 10 shows that the most important expectation of the Support Services remains the precise knowledge of the RB biobank's needs (100%).

Table 2: Distribution of participants by interested parties in the survey on the needs and expectations of biobank stakeholders

Interested parties	Numbers	Percentage
Administrative authorities (MSHP, MESRS, IPCI° direction)	7	25.0
Researchers / users of Biological Resources (BR)	32	86.5
Depositors of Biological Resources (doctors, clinicians, hospital staff, initiator of collections)	26	70.3
Patients/donors of Biological Resources	7	20.0
CeReB IPCI staff	15	50.0
Support services	14	40.0

GET Journal of Biosecurity and One Health (2023), 2(2), 9-18.
DOI: 10.36108/GJOBOH/3202.20.0220

Table 3: Overall participant requirements and expectations related to business processes in the survey on the needs and expectations of biobank stakeholders

	Number	Percentage
Compliance with regulations, standards and best practices	42	84.0
Feedback on uses	40	80.0
Staff Safety	40	80.0
Information on the possible use of BRs	38	76.0
Respect for patients' opinions on the use of BRs	38	76.0
Comply with regulations and ethics	38	76.0
Safe storage of BRs	38	76.0
Stakeholder satisfaction	37	74.0
Make RBs available	36	72.0
Quality of BRs and associated data	36	72.0
Acquire the necessary skills	35	70.0
Mastering the quality of BR	35	70.0
Publish research results obtained through BRs	35	70.0
Freedom to withdraw consent	34	68.0
Possibility of being co-authors of publications using BRs	33	66.0
Access to Biological Resources	32	64.0
Information on the service rendered	32	64.0
Citation in publications using BRs	31	62.0
Be able to communicate with the biological resource center BRC	31	62.0
Confidentiality of personal and medical information relating to patients/donors	30	60.0
Obtain a BR that meets the criteria defined by the research project (quality, quantity, nature, etc.)	30	60.0
Internal communication regarding quality and operations	29	58.0
Precise knowledge of the needs of the BRC	29	58.0
Have bioclinical data associated with BR	28	56.0
Right to use BR collections	28	56.0
Performance/efficiency of support activities	27	54.0
Manage the logistics for the establishment, processing and conservation of BRs	25	50.0
Keep all BRs	24	48.0
Be involved in the operation of the BRC Santé	23	46.0
Specific requirements defined in the project request	23	46.0

GET Journal of Biosecurity and One Health (2023), 2(2), 9-18.
DOI: 10.36108/GJOBOH/3202.20.0220

Table 4: Overall requirements and expectations of participants in relation to management processes in the survey on the needs and expectations of biobank stakeholders.

	Number	Percentage
Protection of the person	37	74.0
Risk protection for personnel	37	74.0
Compliance with regulations in scientific research	36	72.0
Respect for human rights and ethics	36	72.0
Compliance with the quality policy	35	70.0
Regulatory compliance of biological collections	34	68.0
Compliance with regulations, standards and best practices	33	66.0
Good use of funds	32	64.0
Obtain and maintain certification	32	64.0
Transparency regarding research activities	32	64.0
Knowledge of the specific activity concerning the management of collections	31	62.00
Management of collections for scientific research	29	58.00
Appropriate use of allocated resources	29	58.00
Compliance with the overall strategy defined for the organization	25	50.00
Obligation for the BRC to be above all an infrastructure dedicated to the organization's research teams	22	44.00

Table 5: Requirements and expectations related to the management processes of administrative authorities (MSHP, MESRS, DIRECTION IPCI°) in the survey on the needs and expectations of biobank stakeholders (n=7)

	Number	Percentage
Regulatory compliance of biological collections	7	100.0
Knowledge of the specific activity concerning the management of collections	6	85.7
Obligation for the BRC to be above all an infrastructure dedicated to the organization's research teams	7	100.0
Obtain and maintain certification	7	100.0
Management of collections for scientific research	7	100.0
Protection of the person	7	100.0
Risk protection for personnel	7	100.0
Compliance with regulations in scientific research	6	85.7
Compliance with the overall strategy defined for the organization	7	100.0
Respect for human rights and ethics	7	100.0
Compliance with regulations, standards and best practices	7	100.0
Compliance with the quality policy	7	100.0
Transparency regarding research activities	6	85.7
Appropriate use of allocated resources / Proper use of funds	7	100.0

GET Journal of Biosecurity and One Health (2023), 2(2), 9-18.
DOI: 10.36108/GJOBOH/3202.20.0220

Table 6: Requirements and expectations related to the operational processes of users of Biological Resources in the survey on the needs and expectations of biobank stakeholders (n=32)

	Number	**Percentage**
Access to Biological Resources	32	100.0
Have bioclinical data associated with BR	32	100.0
Specific requirements defined in the project request	32	100.0
Obtain a BR that meets the criteria defined by the research project (quality, quantity, nature, etc.)	32	100.0
Publish research results obtained through BRs	24	75.0
Quality of BRs and associated data	32	100.0
Comply with regulations and ethics	30	93.8

Table 7: Requirements and expectations related to the operational processes of the Depositors of Biological Resources (doctors, clinicians, hospital staff, initiator of collections) in the survey on the needs and expectations of biobank stakeholders (n=26).

	Number	**Percentage**
Right to use BR collections	26	100.0
Feedback on the uses of BRs	23	88.5
Keep all BRs	23	88.5
Manage the logistics for the establishment, processing and conservation of BRs	25	96.2
Comply with regulations and ethics	26	100.0
Safe storage of BRs	24	92.3
Make BRs available	25	96.2
Possibility of being co-authors of publications using BRs	26	100.0
Be able to communicate with the BRC	26	100.0
Mastering the quality of BR	26	100.0

DISCUSSION

This is the pilot phase of the survey of potential biobank stakeholders to identify stakeholder needs and expectations as part of the process towards ISO 20387 certification. However, some of the results should be taken into account in future strategic decisions by the biobanking community [5].

Firstly, we were able to show that only a small percentage of participating researchers obtained biosamples from a centralized university biobank (around 12%). This result should be alarming, as it calls into question the sustainability of biobanks. It is therefore important to develop strategies to increase collaboration between researchers and biobanks.[5].

Participants were asked to indicate which stakeholder group they belonged to in their institution. They were given the opportunity to select more than one group. The same was true for expectations and requirements (therefore the figures do not add up to 100%)

The results of this study revealed the complexity of the biobanking business and the lack of knowledge that exists among the country's various social sectors on the subject. Biobanks are not ends in themselves, but instruments to support excellent biomedical research. Their existence facilitates access to and exchange of biological material and is one of the most strategically valuable tools for both basic and clinical research.

The development of a quality management system is essential for good laboratory organization and continuous improvement. [9,10] Clinical laboratory quality systems require

vigilance of all processes involved in the production of results, including extra-analytical processes, in order to detect errors and take corrective action. [11]. Internal quality control (planning to achieve a predetermined quality), external quality assessment (evaluation of laboratory performance for legal or educational purposes) and, more recently, external quality assurance (evaluation of extra-analytical performance) of the analytical process are well-known and widely used procedures in laboratory medicine. [12,13].

STUDY LIMITATIONS

Due to the limited sample size of our survey, the representativeness of our results cannot be clearly stated. The survey was carried out in only two types of establishments.

We do not know whether researchers from other institutions have had similar experiences. In addition, industrial researchers were not represented in the sample. In particular, questions concerning the expectations and needs of stakeholders.

For reasons of transparency, the local biobank had to send the questionnaire by e-mail to some researchers from other institutions to no avail. As a result, those who had no previous involvement with biobanks may have been discouraged from taking part in the survey, as they might have assumed that they could contribute nothing.

CONCLUSION

Based on these findings, it is suggested that when developing biobanks for research purposes, policymakers, regulators, and researchers should take into account opinions of all social sectors, especially general public, as they are the ones on whom the potential success of biobanks is based. Biobanks can learn a great deal from the survey results. In particular, external communication and awareness-raising need to be improved. In addition, biobanks may need to reassess whether their particular collection strategies are adapted to the needs of local researchers.

ABBREVIATIONS

CeReB IPCI - IPCI's Biobank Name

CRB – Centre Resource Biological

IPCI – Institut Pasteur de Cote d'Ivoire

MESRS – Ministry of Higher Education and Scientific Research

MSHP – Ministry of Health and Public Hygiene

OECD – Organization for Economic Cooperation and Development

ACKNOWLEDGMENTS

Our sincere thanks go to the management of the Institut Pasteur de Côte d'Ivoire, to the staff of the biobank and to all those who agreed to take part in this survey.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTIONS

DKM and DM designed, performed the methodology and DKM, MM data analysis. The manuscript was written and edited by DKM and MM, BJJR, CS, AKAE and KKA, CL, NF, KLO collected the data. All authors contributed to the article and approved the submitted version.

Table 8: Requirements and expectations related to the operational processes of the patients/donors of Biological Resources in the survey on the needs and expectations of biobank stakeholders (n=7)

	Number	Percentage
Confidentiality of personal and medical information relating to patients/donors	7	100.0
Information on the possible use of BRs	5	71.4
Respect for patients' opinions on the use of BRs	7	100.0
Freedom to withdraw consent	7	100.0
Feedback	4	57.1

Table 9: Requirements and expectations related to the operational processes of IPCI's biobank in the survey on the needs and expectations of biobank stakeholders' staff (n=15)

	Number	Percentage
Acquire the necessary skills	15	100.0
Citation in publications using BRs	13	86.8
Internal communication regarding quality and operations	15	100.0
Be involved in the operation of the BRC Santé	10	66.7
Performance/efficiency of support activities	15	100.0
Compliance with regulations, standards and best practices	14	93.3
Feedback on the uses of BRs	14	93.3
Stakeholder satisfaction	15	100.0
Staff Safety	15	100.0

Table 10: Requirements and expectations related to the operational processes of support services in the survey on the needs and expectations of biobank stakeholders (n=14)

	Number	Percentage
Precise knowledge of the needs of the BRC	14	100.0
Information on the service rendered	12	85.7

REFERENCES

[1] Kauffmann F, Cambon-Thomsen A. Tracing biological collections: between books and clinical trials. JAMA. 21 mai 2008;299(19):2316-8.
[2] Hewitt RE. Biobanking: the foundation of personalized medicine. Curr Opin Oncol. janv 2011;23(1):112-9.
[3] Khoury MJ, Millikan R, Little J, Gwinn M. The emergence of epidemiology in the genomics age. Int J Epidemiol. oct 2004;33(5):936-44.
[4] Serrano NC, Guio-Mahecha E, Becerra-Bayona S, Luna-González ML, Quintero-Lesmes DC. The perception of different social agents in Colombia regarding biobanks for research purposes. Biomedica. 1 déc 2018;38(4):569-76.
[5] Klingler C, von Jagwitz-Biegnitz M, Baber R, Becker KF, Dahl E, Eibner C, et al. Stakeholder engagement to ensure the sustainability of biobanks: a survey of potential users of biobank services. Eur J Hum Genet. 24 mai 2021;
[6] Cambon-Thomsen A, Rial-Sebbag E, Knoppers BM. Trends in ethical and legal frameworks for the use of human biobanks. European Respiratory Journal. 1 août 2007;30(2):373-82.
[7] Barr M. 'I'm not Really Read up on Genetics': Biobanks and the Social Context of Informed Consent. BioSocieties. 1 juin 2006;1(2):251-62.
[8] Jack AL, Womack C. Why surgical patients do not donate tissue for commercial research: review of records. BMJ. 31 juill 2003;327(7409):262.
[9] Nevalainen D, Berte L, Kraft C, Leigh E, Picaso L, Morgan T. Evaluating laboratory performance on quality indicators with the six sigma scale. Archives of pathology & laboratory medicine. 2000;124(4):516-9.
[10] Ricós C, García-Victoria M, de la Fuente B. Quality indicators and specifications for the extra-analytical phases in clinical laboratory management. Clin Chem Lab Med. 2004;42(6):578-82.
[11] Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. Clinical chemistry. 1997;43(8):1348-51.
[12] Westgard JO, Barry PL, Hunt MR, Groth T. A multi-rule Shewhart chart for quality control in clinical chemistry. Clin Chem. 1981;27(3):493-501.
[13] Petersen PH, Fraser CG, Jørgensen L, Brandslund I, Stahl M, Gowans EM, et al. Combination of Analytical Quality Specifications Based on Biological Within- and Between-Subject Variation. Ann Clin Biochem. Nov 2002;39(6):543-50.