

7th Club

Sunday 10th August 2025



Club Founder
Dr. Mahmoud Bahgat



International Pharmacists Club

Biostatistics

& Research Methodology as a Career

الإحصاء الحيوي وأساليب البحث العلمي

10pm EGY 10pm KSA 11pm UAE



By Dr. Dina Hafez

Pharmacist Consultant Biostatistics
& Bioinformatics Alex. University



Dr. Dina Mohamed Hanaa Hafez

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Phone: +201007486253, +201200554675

Location: Alexandria, Egypt

Profile Summary

Accomplished Biostatistics Consultant with a PhD in Biomedical Informatics and Medical Statistics, focusing on Health Economics and Quality Improvement. Extensive expertise in clinical research, statistical analysis, epidemiology, and healthcare quality management. Proven leadership in academic and healthcare settings, with a strong track record of research publications, mentorship, and innovative healthcare initiatives. Dedicated to enhancing public health standards through evidence-based practices, research, and continuous professional development.

Education

PhD in Biomedical Informatics and Medical Statistics, Medical Research Institute, Alexandria University (Jan 2020 - Aug 2024)

- GPA: 3.45
- Specialization: Health Economics and Quality Improvement.

Master's degree MA in public health (Epidemiology), Alexandria University (2013 - 2019)

- Grade: Excellent

Diploma in Top Management, Alexandria Pharmacists Syndicate (2015 - Present)

Diploma in Training of Trainers (TOT), Alexandria University (2013 - 2014)

- Grade: Excellent

Bachelor of Pharmacy (BPharm) in Pharmaceutical Sciences, Alexandria University (1995 - 2000)

- Grade: Very Good



Professional Experience Associate Professor of Biostatistics (Prospective Role)

- Designing and delivering undergraduate and postgraduate courses in Biostatistics and Public Health.
- Supervising student research projects and guiding them in statistical analysis methodologies.
- Publishing research articles in peer-reviewed journals in the fields of Biostatistics, Public Health, and Epidemiology.
- Collaborating on research projects related to Health Economics and Quality Improvement

Experience:

Alexandria University Pharmacist Internship Program - Preceptor (Academic year 2024-2025) till now.

- Mentored pharmacy interns, providing training on Quality, clinical pharmacy, and biostatistics concepts.

Postoperative Pain Management Improvement Project Founder (Sep 2019 - Present)

- Designed and implemented quality improvement strategies in postoperative pain management.

Pharmacovigilance Team Leader (Jun 2015 - Present)

- Developed protocols and led initiatives in medication safety and regulatory compliance.

HIV/AIDS Prevention & Control Team Coordinator (May 2011 - Present)

- Coordinated awareness and prevention programs.

Technical Skills

- Data Analysis & Biostatistics
- Statistical Software (SPSS, Advanced Excel, R, Minitab, JASP)
- Research Methodology & Systematic Reviews
- Quality Improvement (Six Sigma, Lean Six Sigma, PDSA)
- Health Economics

Soft Skills

- Leadership & Mentoring
- Strategic Planning & Decision-Making
- Presentation & Public Speaking
- Collaboration & Teamwork



- Analytical Thinking & Problem Solving
- Software: SPSS, Minitab, R, JASP, Jamovi, Revman, EndNote

Publications

- Postoperative pain management quality improvement project using Six-Sigma methodology in Alexandria University Students Hospital, Egypt *International Journal of Lean Six Sigma*

2025-06-17 | journal-article

- DOI: [10.1108/ijlss-05-2024-0106](https://doi.org/10.1108/ijlss-05-2024-0106)

- Gastrocolic Fistula Due to Staple Line Leak Following Metabolic Bariatric Surgery: A Systematic Review. *Obesity Surgery*

2025-06 | journal-article

- DOI: [10.1007/s11695-025-07844-2](https://doi.org/10.1007/s11695-025-07844-2)

- Efficacy and safety of the novel clindamycin phosphate 1.2%, benzoyl peroxide 3.1%, and adapalene 0.15% triple combination in treating acne: systematic review and meta-analysis. *Archives of Dermatological Research*

2024-12-10 | journal-article

- DOI: <https://doi.org/10.1007/s00403-024-03641-6>

- Knowledge, Attitude, Practice, and Barriers among Physicians in the Middle East and North Africa Region Toward Influenza Vaccination for the High-risk Group of Patients: A Cross-sectional Study *Tropical Diseases, Travel Medicine and Vaccines*

2024-12-10 | journal-article

- COVID-19 Vaccine Booster Dose Acceptance: Systematic Review and Meta-Analysis *Tropical Medicine and Infectious Disease*

2022-10 | journal-article

- DOI: [10.3390/tropicalmed7100298](https://doi.org/10.3390/tropicalmed7100298)

- Systematic Review and Meta-analysis on COVID-19 Vaccine Hesitancy

2021-05-18 |

- DOI: [10.1101/2021.05.15.21257261](https://doi.org/10.1101/2021.05.15.21257261)

Publications under Review:

- Knowledge and Attitudes Toward Prenatal Non-Invasive Screening Tests for Down Syndrome: A Systematic Review and Meta-Analysis



- The Effects of Sodium Supplementation on Growth, Electrolyte Balance, and Neurodevelopmental Outcomes in Preterm Infants: A Systematic Review and Meta-Analysis
- Reviewer, Obesity Surgery Journal (Springer Nature) (Since May 2025)

Reviewed original manuscripts in the field of bariatric surgery, obesity interventions, and related clinical research.

Certifications & Training

1. Quality in Healthcare & Statistical Tools Course – Alexandria University (2022, 36 hours)
2. Health Economic Beginner and Intermediate Levels Courses (PhD Curriculum) - Alexandria University (2021)

Inspector Roles:

1. Training sessions on High Alert Medication and safe administration protocols (2024).
2. Research Designs, Sample size calculations (2024)
3. Reliability and validation of different survey tools (2024)
4. Basic and Intermediate Statistics. (2025)
5. Clinical audit and healthcare quality workshops at the Global Research Center (GRC).
6. Workshops on KPIs in infection control measures.

Attended Courses

1. Quality Standards in Teaching – Faculty and Leadership Development Center, Alexandria University. (September 2024)
2. Research Ethics and Plagiarism – Faculty and Leadership Development Center, Alexandria University. (September 2024)
3. Communication and Presentation Skills – Faculty and Leadership Development Center, Alexandria University. (October 2024)
4. Competitive Research Projects Proposals – Faculty and Leadership Development Center, Alexandria University. (October 2024)
5. Exams and Student Evaluation Systems – Faculty and Leadership Development Center, Alexandria University. (October 2024)

Conferences



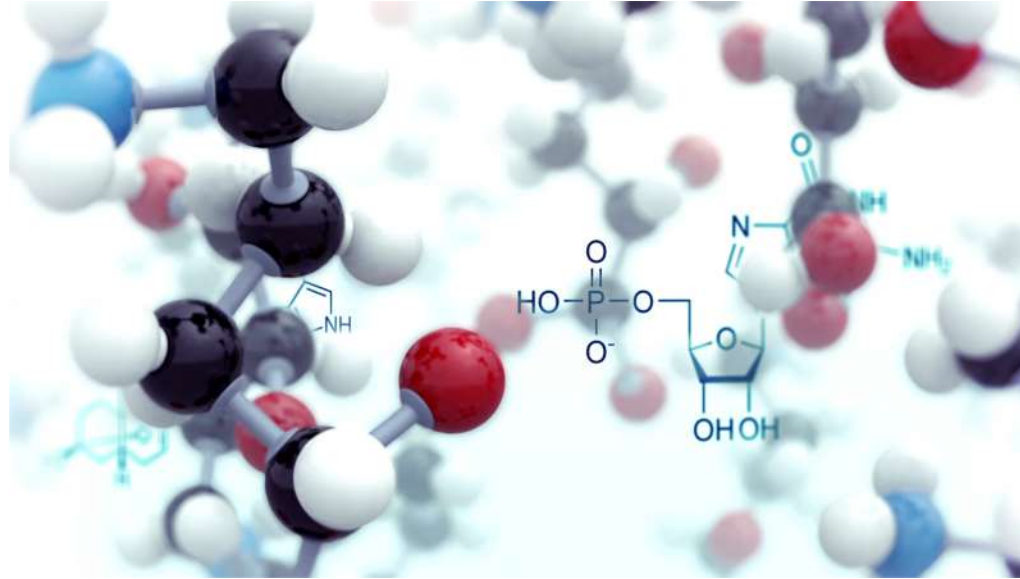
Definition of Statistics



Statistics is the science concerned with the collection, organization, analysis, interpretation, and presentation of data. It provides methods for transforming raw data into meaningful information to support decision-making, scientific research, and policy development.







Biostatistics (Medical Statistics)



Medical Statistics

Application of statistics to health sciences, medicine, and biology.

Example: Designing clinical trials, analyzing patient survival data



Biostatistics and Decision- Making

Evidence-Based Decisions

- Biostatistics provides numerical evidence to guide medical and pharmaceutical decisions.
- Example: Choosing the most effective drug based on clinical trial outcomes.

Quality Improvement & Risk Assessment

- Quantifying the likelihood of health outcomes (e.g., adverse effects, disease occurrence).
- Example: Calculating relative risk of complications after treatment.

Resource Allocation

- Using statistical models to optimize distribution of healthcare resources.
- Example: Determining the number of hospital beds needed during an epidemic.



Biostatistics and Decision- Making

Supporting health policy decisions with data-driven insights.

Example: Setting vaccination schedules based on epidemiological data.

Treatment Optimization

- Personalizing treatments using statistical predictions from patient data.
- Example: Selecting chemotherapy regimens based on survival analysis.

Uncertainty Management

- Using confidence intervals and probability to make decisions under uncertainty.



Data

Quantitative

1. Numerical Data - Two Types
2. Discrete - (Counting)
3. Continuous - (Measurement)

Qualitative

1. Descriptive data based on observations
2. Involves 5 senses
3. See, feel, taste, hear, smell

Quick & Simple!



Types of Statistics

- **Descriptive Statistics**

- **Definition:** Methods used to summarize and describe the main features of a dataset.
- **Purpose:** To provide a clear overview of data without making inferences about a larger population.
- **Examples:**
 - Measures of central tendency: Mean, Median, Mode
 - Measures of dispersion: Range, Variance, Standard deviation
 - Graphical presentations: Histograms, Pie charts, Box plots



Types of Statistics

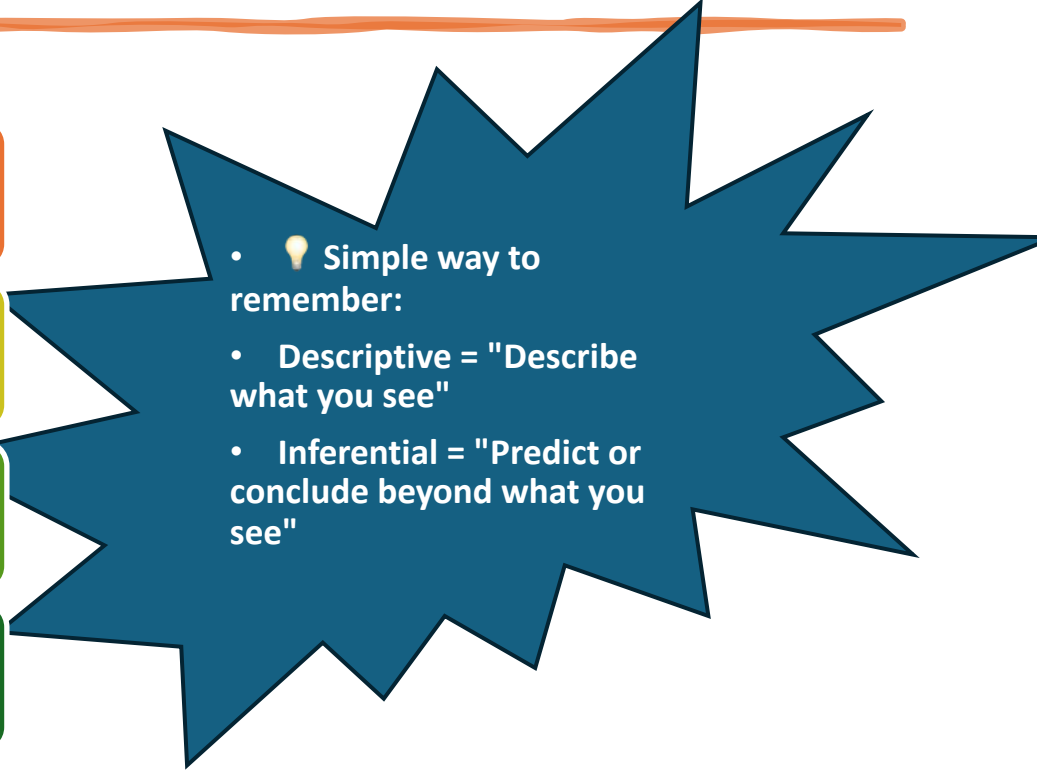
Inferential Statistics

Definition: Methods used to generalize, predictions, or decisions about a population based on data from a sample.

Purpose: To draw conclusions beyond the immediate data at hand.

Examples:

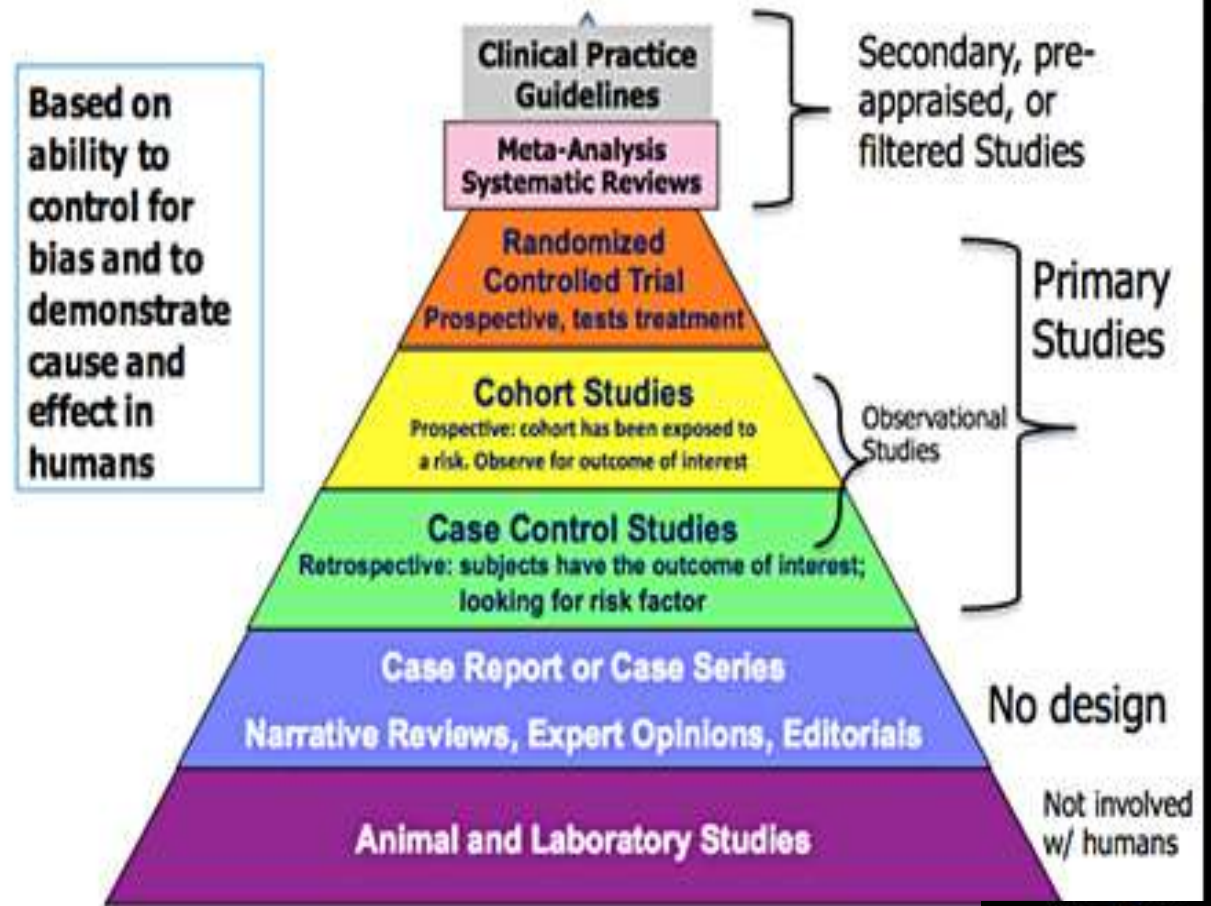
- Hypothesis testing (t-test, ANOVA, Chi-square test)
- Confidence intervals
- Regression analysis
- Correlation analysis

- 
- 💡 Simple way to remember:
 - Descriptive = "Describe what you see"
 - Inferential = "Predict or conclude beyond what you see"



Evidence Based Medicine

Hierarchy of Research Designs & Levels of Scientific Evidence



Real life Example



Postoperative pain management quality improvement project using Six-sigma Methodology in Alexandria University Students Hospital, Egypt

Dina M. Hafez¹, Adel Zaki², Mohamed Abd Allatif³, and Iman El Sayed²

¹Pharmacy Department, Alexandria University Student Hospital, Alexandria University

²Department of Biomedical Informatics and Medical Statistics, Medical Research Institute, Alexandria University, Alexandria, Egypt

³Department of General Surgery, Alexandria University Student Hospital, Alexandria University



Abstract

* Purpose: This study intends to assess the effect of the implementation of the Six Sigma approach to improve the quality of post-operative pain management in patients at Alexandria University Student Hospital.

Results

Cause-and-effect diagram (Ishikawa diagram)



Conclusion

The effect of the implementation of the Six Sigma approach to improve the quality of post-operative pain management in patients at Alexandria University Student Hospital.

Interventional study involving patients exposed and planned for any surgical Hospital. We used Six Sigma's define, measure, analyze, improve, and control (DMAIC) improvement process. Data gathered from the Six Sigma project's implementation and control. The areas selected for improvement were the overall mean (SD) of the worst pain and post-intervention 2.7 (1.8) phases in the DFMO between pre-and post-intervention. That decrease was followed by an increase from 1.375 to 3 sigma level.

Introduction

* Acute postoperative pain (APP) affects about 70% of postsurgical patients, with many experiencing moderate to severe pain. Poorly managed APP can lead to chronic postoperative pain (POP), longer recovery, increased opioid use, and higher costs. Effective postoperative pain management (POPM) requires addressing psychological and social factors, multidisciplinary approaches, staff education, and patient involvement.

* National and international bodies like the Joint Commission and Egypt's GAHAR emphasize pain assessment, management protocols, and staff training to ensure quality care. Programs for healthcare professionals, particularly nurses, enhance knowledge and techniques, improving patient outcomes.

* Six Sigma methodology, with its DMAIC phases, minimizes variability, reduces errors, and optimizes processes like POPM. Tools like FMEA and SPC improve operational efficiency and patient satisfaction, promoting a culture of continuous improvement for sustainable, high-quality care.



Aim of the Research

* The purpose of this study was to employ the Six Sigma methodology to implement a post-operative pain management quality improvement project at Alexandria University Students Hospital.

Methodology

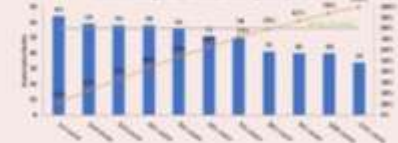
* The methodology for the project utilized the Six Sigma DMAIC framework – Define, Measure, Analyze, Improve, and Control. The project began with defining the scope and objectives, identifying gaps in current POPM practices. Data on postoperative pain outcomes and processes were collected and measured using pain assessment tools and hospital records. Root cause analysis and statistical methods were employed to analyze inefficiencies and variations in pain management. Interventions, including staff training, protocol standardization, and enhanced pain assessment tools, were implemented to improve outcomes. Continuous monitoring and control measures ensured the sustainability of improvements, focusing on

Results

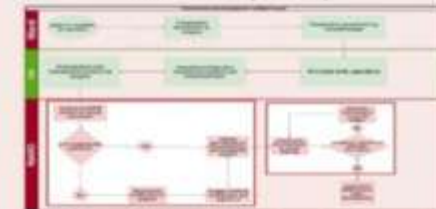
Cause-and-effect diagram (Ishikawa diagram)



Factors affecting postoperative pain management process



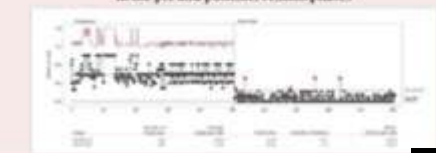
Modified POPM process map



Xbar-R chart for the patients' worst pain through pre and post-intervention phases



U-chart of the number of defects per POPM protocol in the pre and postintervention phases



Conclusion

Quality Improvement Project



International



Pharmacists Cfu6

Sharpen your skills

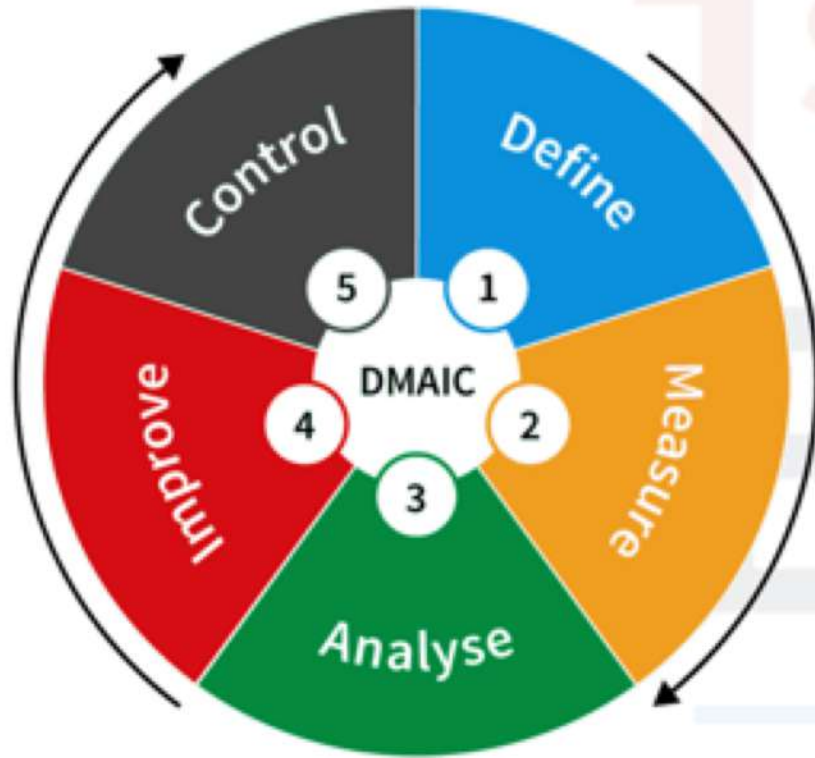
"How does improving pain management contribute to enhancing the overall quality of healthcare?"



- Enhances Patient Comfort
- Supports Patient-Centered Care
- Improves Health Outcomes
- Reduces Hospital Stays
- Prevents Medical Complications
- Enhances Patient Satisfaction
- Promotes Safer and More Effective Care



Six-sigma Approach



- Six Sigma is a **data-driven** methodology used to improve processes by:
 - Identifying and eliminating **defects**
 - Reducing **variability**
 - Enhancing **efficiency**
- The goal is to achieve a **defect rate of less than 3.4 defects per million opportunities (DPMO)**.
- Developed by **Motorola** in the 1980s.



Aim of the study

- *Implement post-operative pain management quality improvement project using the Six Sigma approach at Alexandria University Students Hospital.*
- **Quasi-experimental pre-post study design**
- **300 pts pre-intervention**
- **300 pts post-intervention**



dreamstime.com



Study Setting

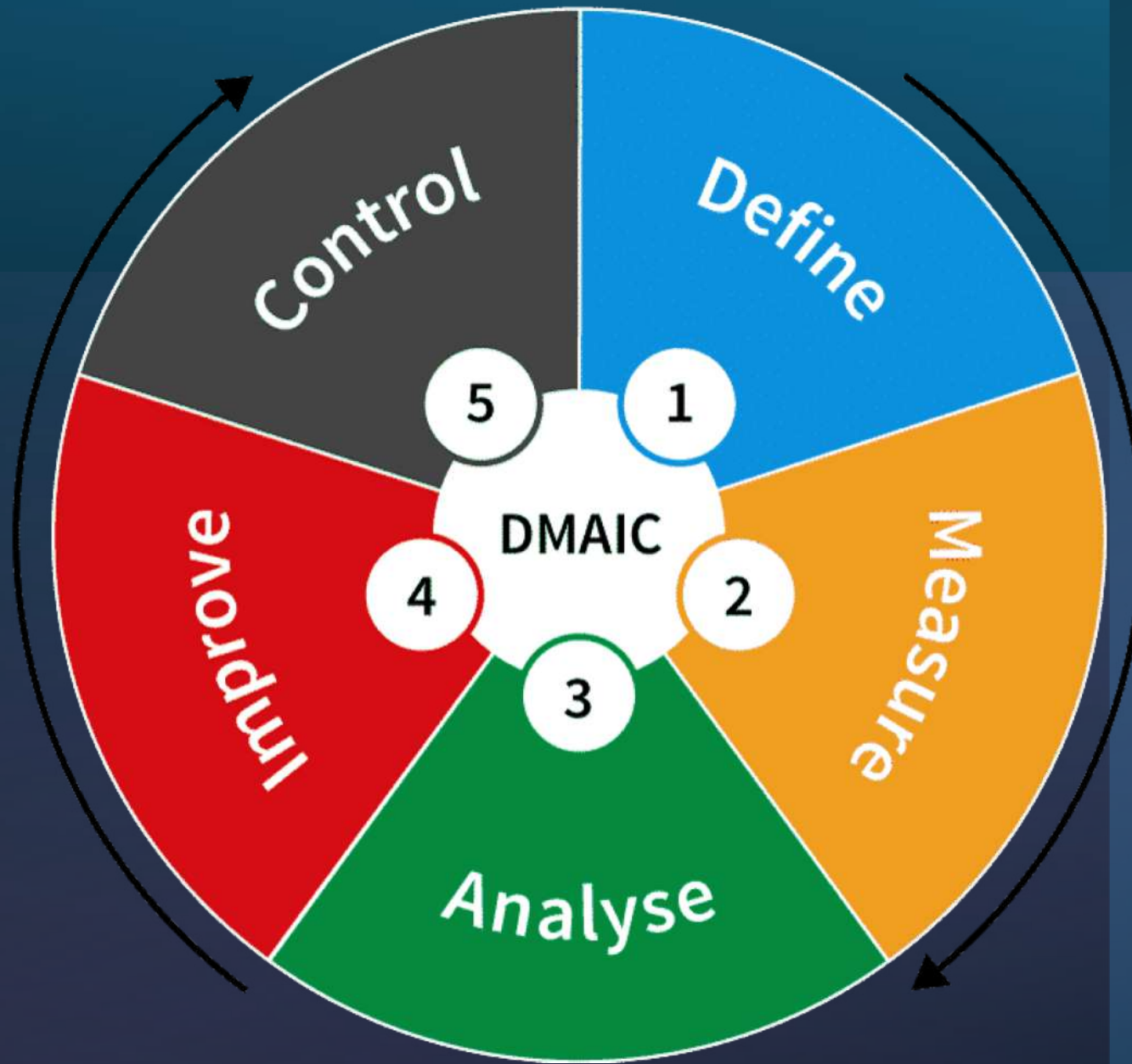


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مستشفى طلبة جامعة الإسكندرية



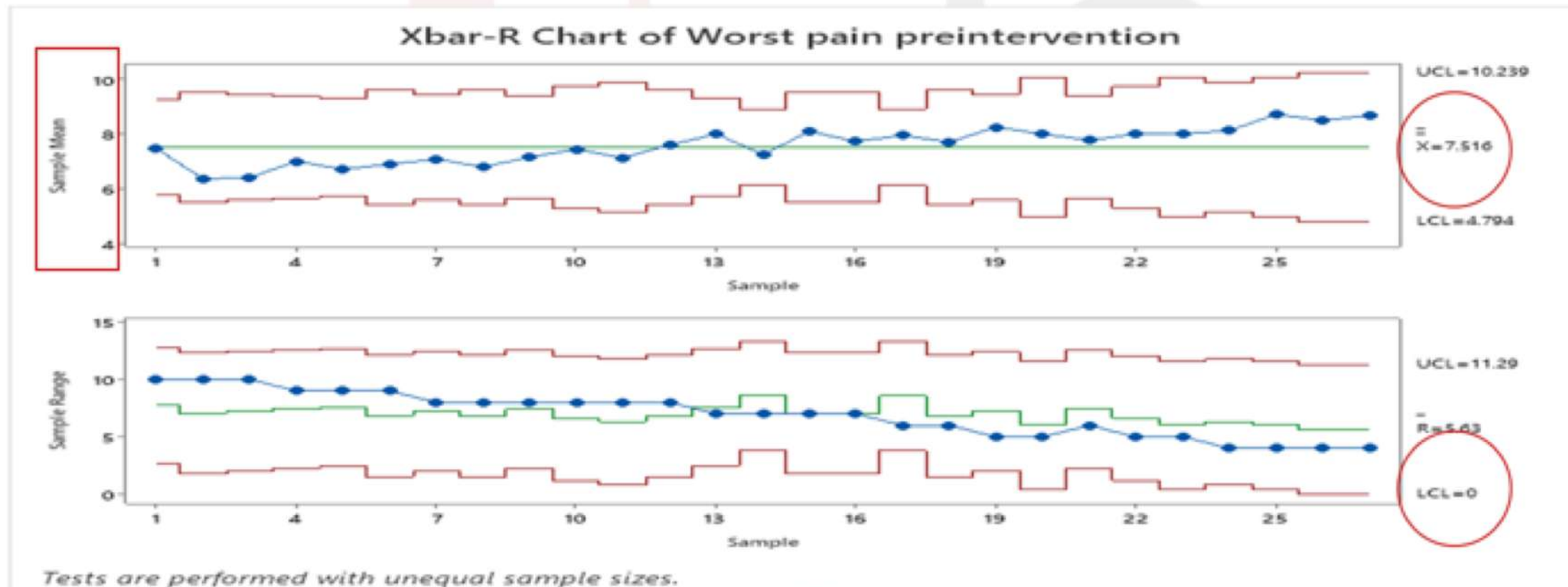


General Project Information		
Project Name		Date Prepared
Post-operative pain management; a quality improvement project using Six-sigma methodology at Alexandria University Student Hospital, Alexandria Egypt		May 2022
Team Members		
- Hospital manager - General Surgery consultant - Orthopedic consultant	- Anesthesiology consultant - Quality specialist	- Clinical Pharmacist - Nursing Specialist
Problem Statement		
Alexandria University Students Hospitals performed more than 300 operations in the last six months. More than half of patients suffered from severe postoperative pain (>7 on NRS 0-10) which is furthermore than the accepted pain level (2-4 on NRS 0-10) according to the American Society of Pain POP practice guidelines. Therefore, the current POPM process results in a low-quality level of healthcare service.		
Project Goals and Objectives (Deliverables)		
- Decrease the level of the postoperative pain level to the accepted level - Raising the sigma level of the POPM process - Decreasing the number of defects in the POPM process	- Raising Communication skills between patients and the nursing staff - Raising knowledge and attitudes of the nursing staff towards POPM	
Benefits		
- Patients will suffer less from POP - Patient satisfaction level will increase - Nursing staff will gain important knowledge and improve their attitudes toward POP - Hospital will fulfill the GAHAR requirements regarding patient safety		
Metrics		
- Postoperative pain score (NRS 0-10) - Strategic and Clinical Quality Indicators in POPM (SCQIPP) - Number of defects in the POPM process - Nurses' knowledge and attitude regarding POPM Level		

	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-	Jun-23	Jul-23	2023
2022														
<i>Define phase</i>														
<i>Measure phase</i>														
<i>Analyze phase</i>							1st July - 31st Dec.							
<i>Improve phase</i>							1st Jan - 31st Jan							
<i>Control phase</i>									1st Feb.- 22nd April					
											23rd April - 31st July			



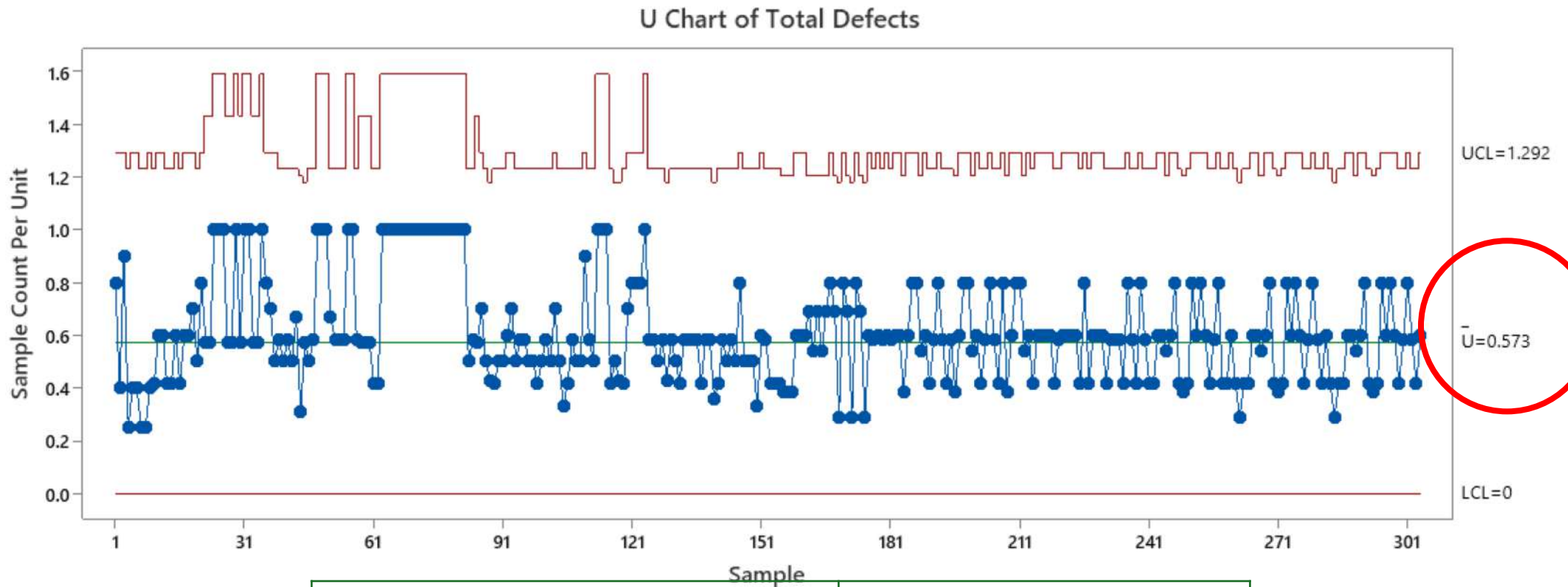
KPI.5: Postoperative Pain Intensity (outcome measure)



Xbar-R chart of the worst pain reported in the postoperative period



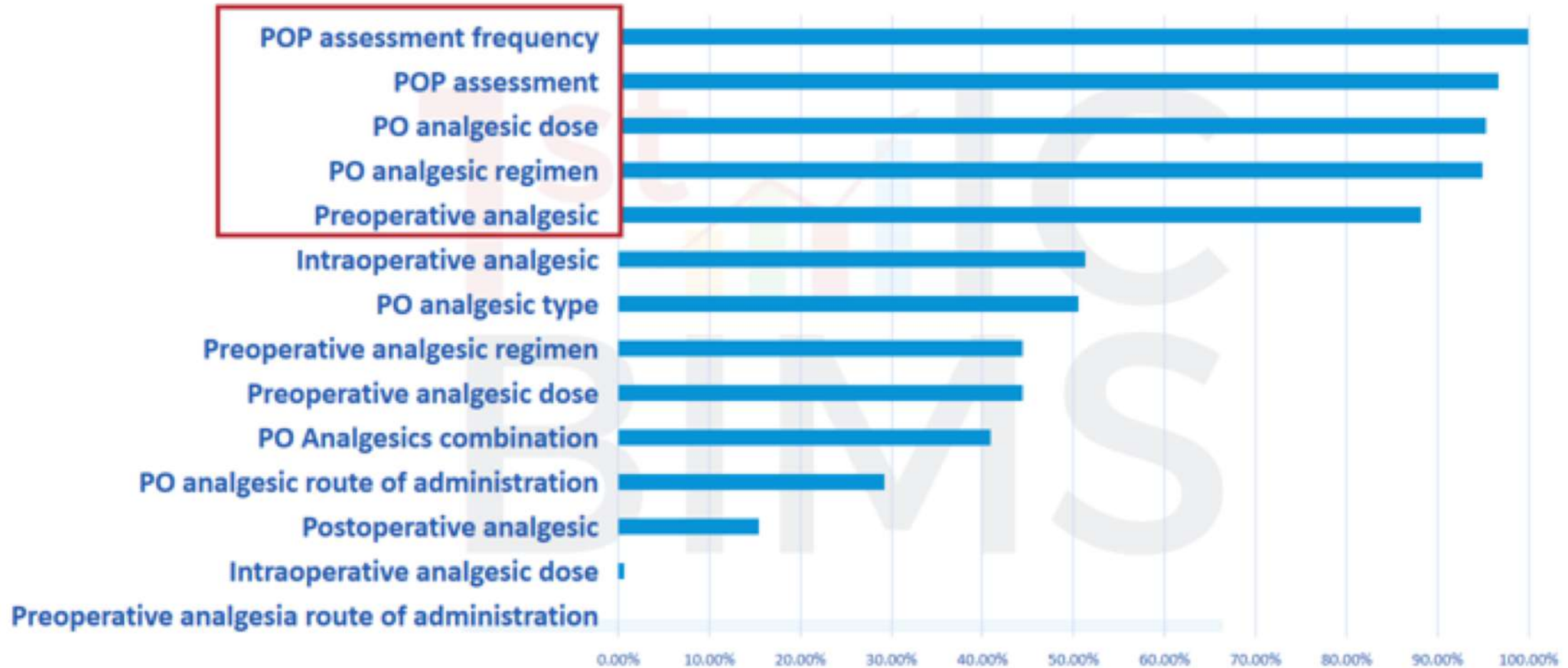
KPI.4: Number of defects in POPM

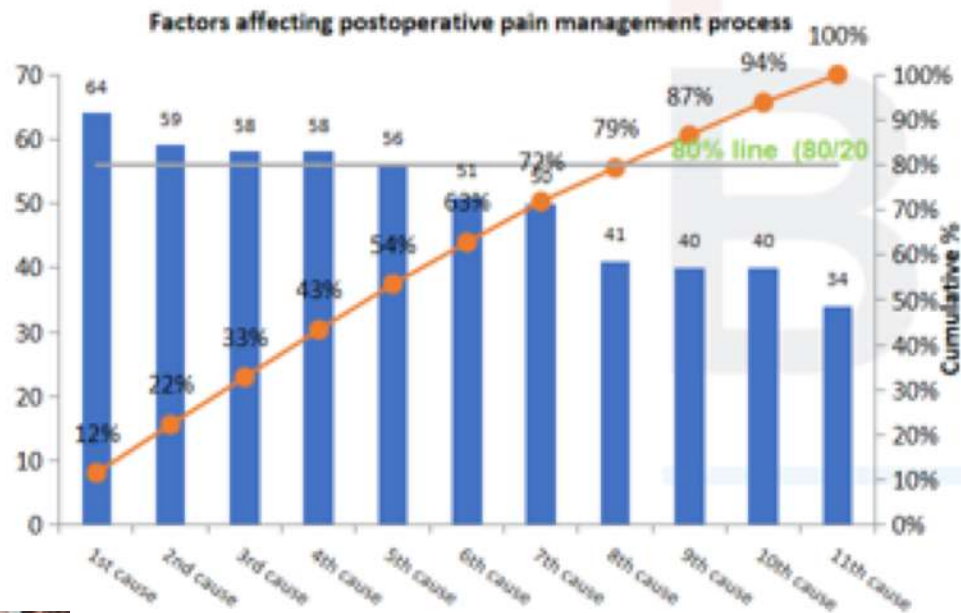
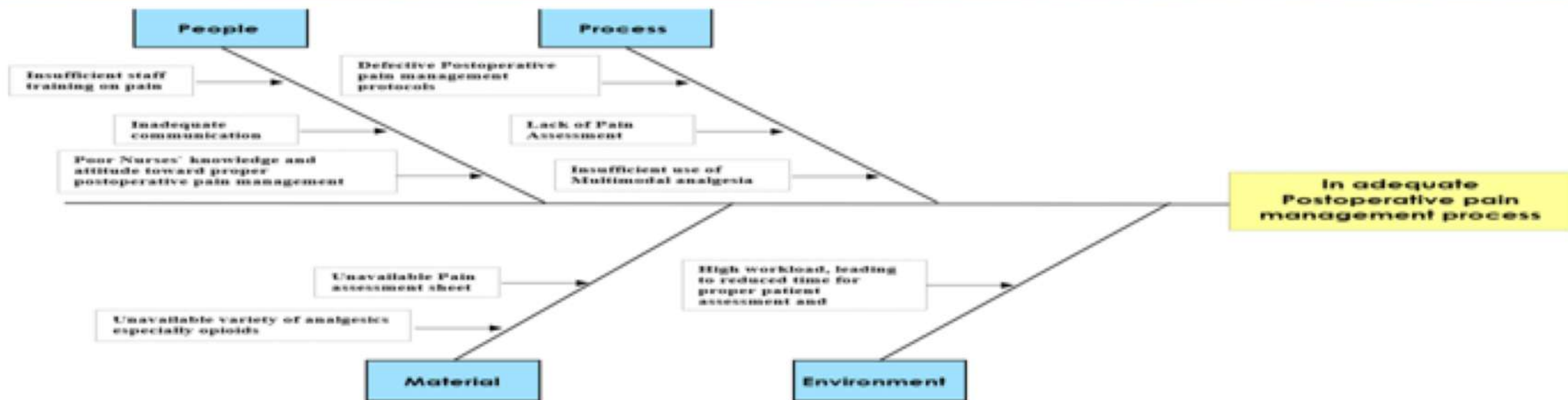


DPMO	580773.4
Sigma Level	1.375-1.25



% Defects

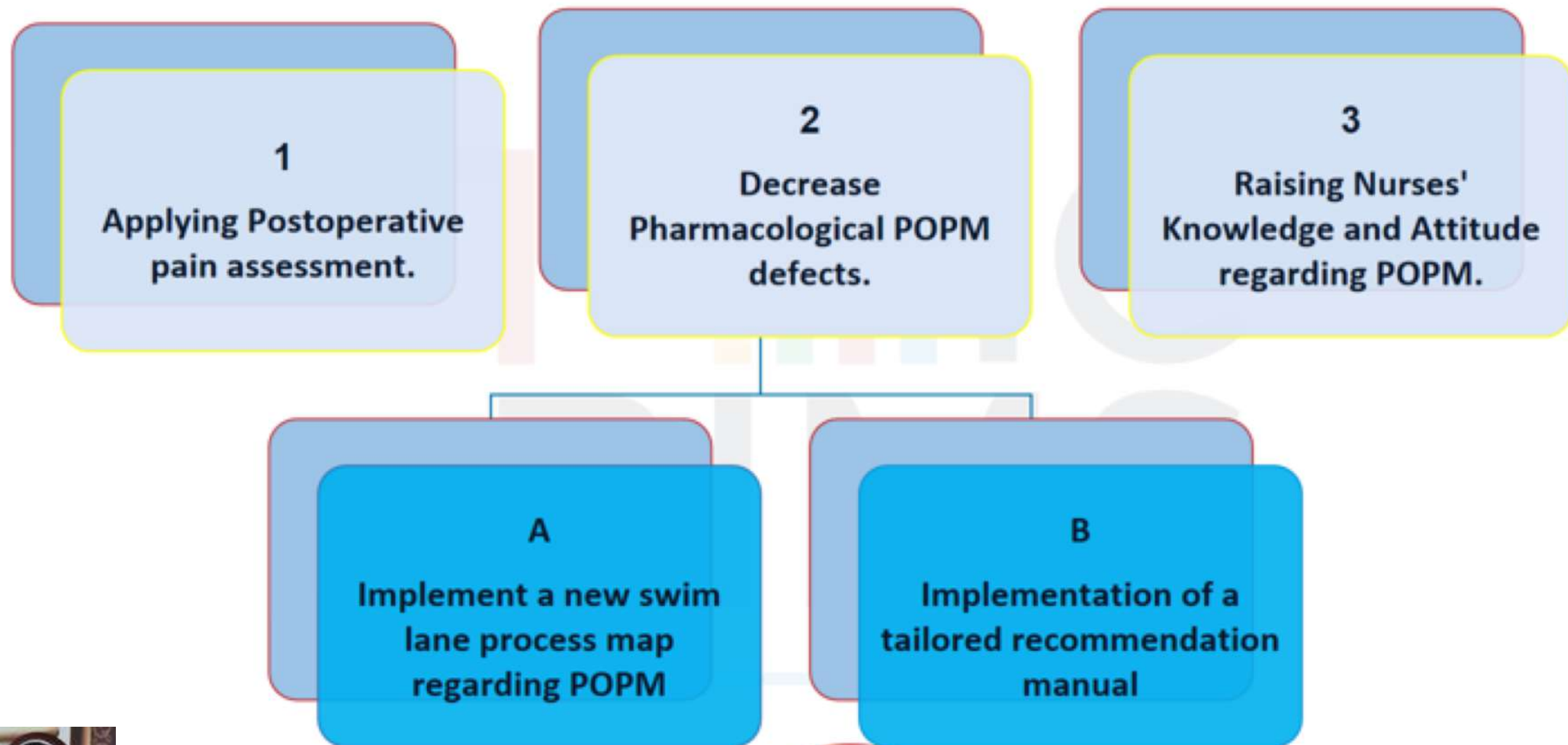


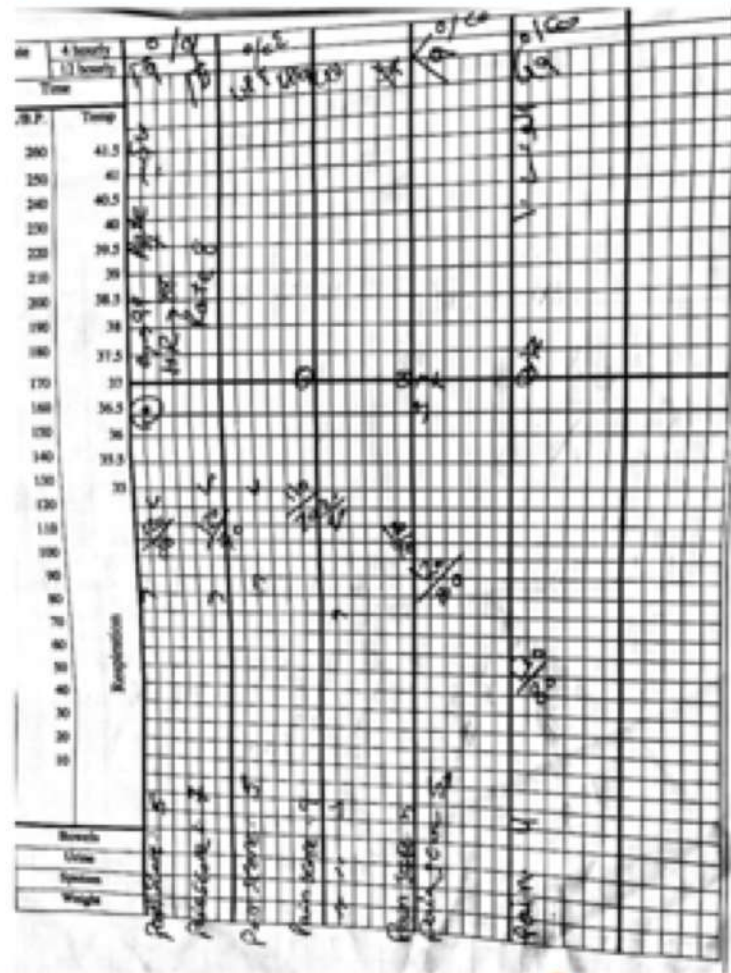


Factors

- 1-Absence of Postoperative pain assessment (Pain assessment sheet in patient file NRS)
- 2-Pharmacological POPM defects
- 3-Nurses Knowledge and Attitude regarding POPM
- 4-Low communication between staff and patients
- 5-Absence of activated Acute pain service team by pain management specialist
- 6-Patients poor knowledge about their rights toward pain relief
- 7-Absence of tailored POPM plan for each patient
- 8-Unacceptable level of Action toward Postoperative pain
- 9-Non-pharmacological POPM defects
- 10-Unacceptable Environmental conditions
- 11-Low Trust between staff and patients

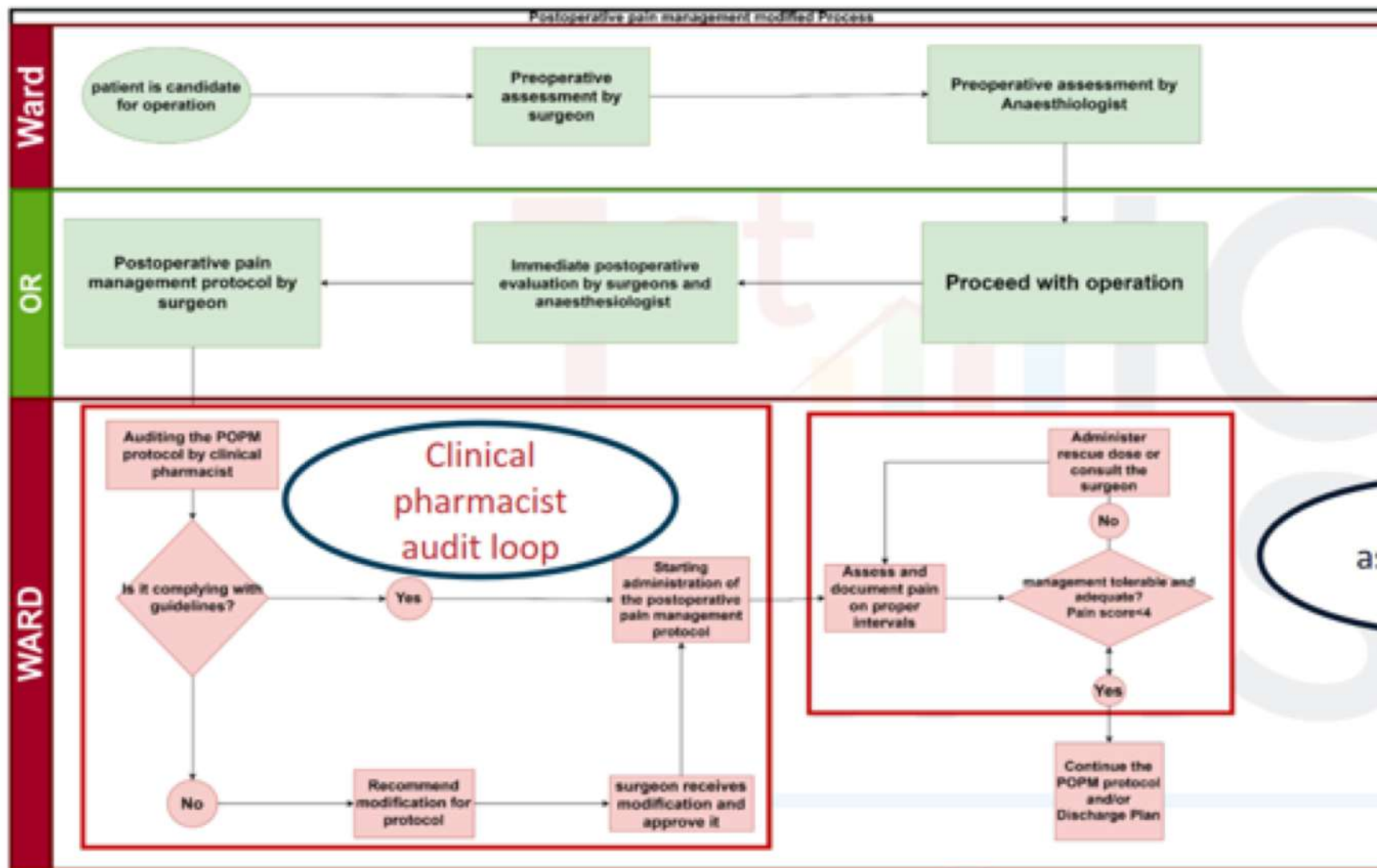






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Applying
Postoperative
Pain Assessment:



Implement a new swim lane process map regarding POPM

Clinical pharmacist audit loop

Pain assessment loop



Pain management suggested protocol IN ADULTS ACCORDING TO THE EXTENT OF SURGICAL TRAUMA

Slight Surgeries

- **SURGICAL PROCEDURES ASSOCIATED WITH SLIGHT TISSUE DAMAGE**
- Procedures of small extent
- Post-operative pain intensity < 4 points according to NRS or VAS

Pain Management

- Pre-operative (Pre-emptive analgesia):
 - Paracetamol (IV/PO) 1-2 g/6hrs
 - + NSAID (Ketolac 1 amp/8hrs Or Voltaren 1 amp/8hrs)
- Postoperative Pain regimen:
 - Day-0:
 - Paracetamol (IV/PO) 1-2 g/6hrs
 - + NSAID (Ketolac 1 amp/8hrs Or Voltaren 1 amp/8hrs)
 - Day-1: Paracetamol & NSAID oral
- Take home regimen: Paracetamol & NSAID oral

1

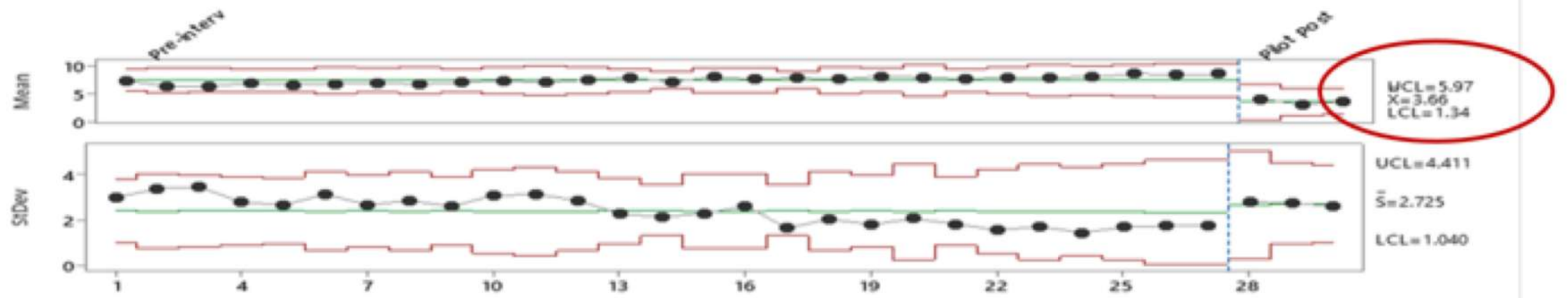
Implementation of a tailored
recommendation manual



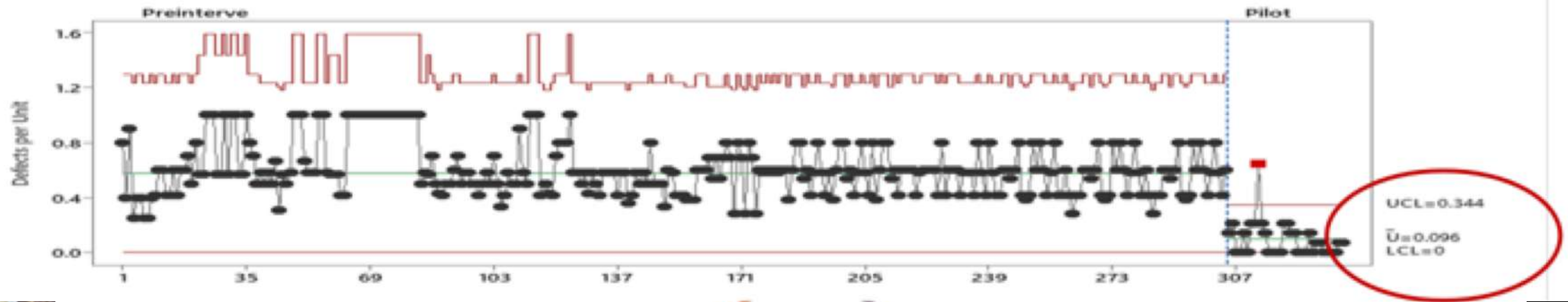
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Raising Nurses' Knowledge and
Attitude regarding POPM.



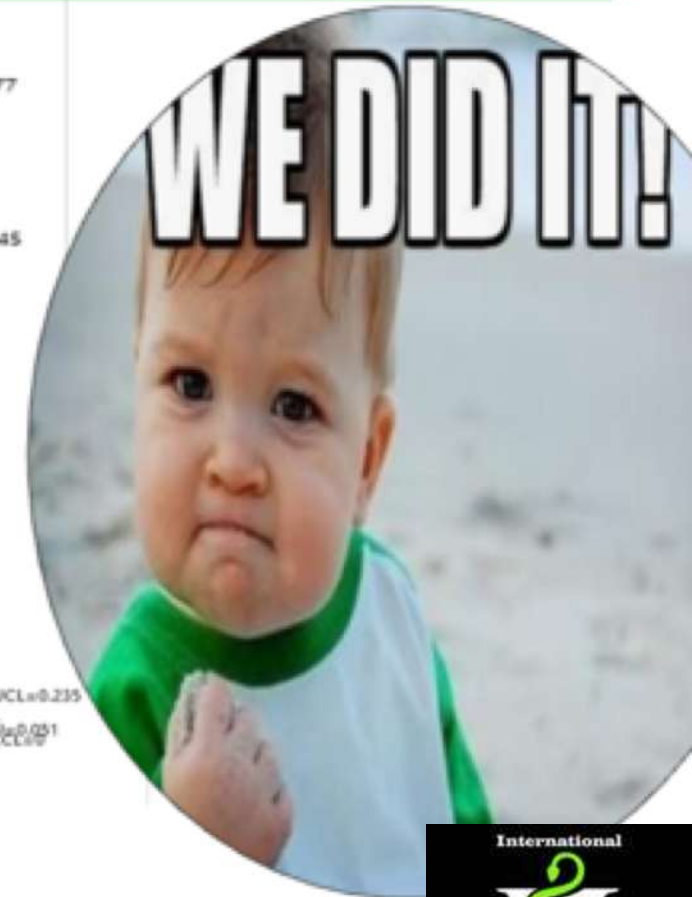
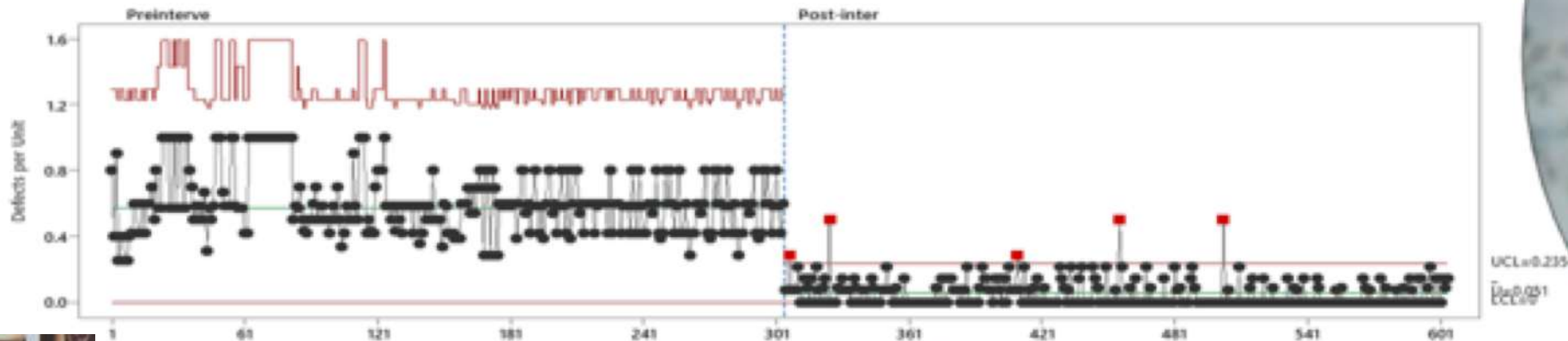
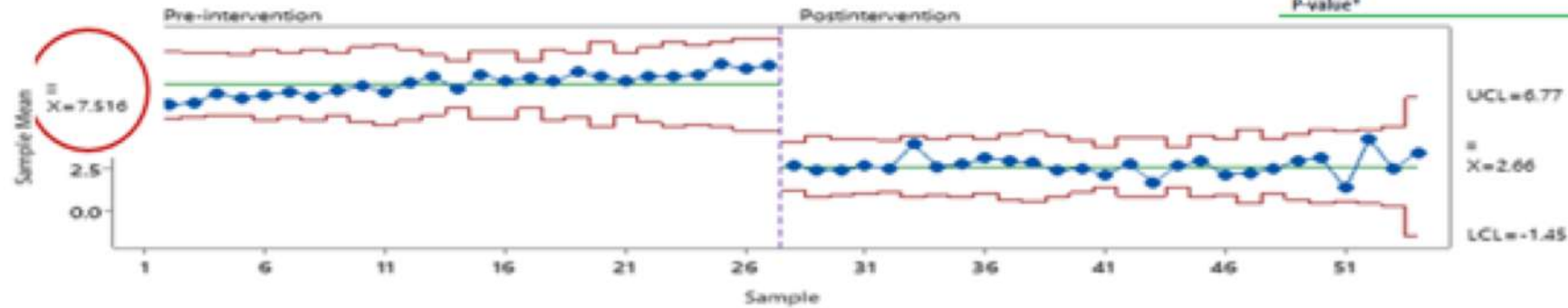


Pilot study



•Monitoring & control of the process by Statistical control process

	Pre - interventi on	%	Post - interventio n	%
Total number of defects in the POPM process	1607	59.1	300	7.8
DPMO	580773.4		78678.2	
Sigma level	1.375-1.25		2.9-3	
P-value*	<0.001			



Pathway of Pharmacists to Enter the Field of Biostatistics



1. Strengthen Academic Background

1. Take courses in statistics, mathematics, and research methodology during or after pharmacy school.
2. Pursue postgraduate diplomas, master's, or PhD in biostatistics, epidemiology, or public health.

2. Learn Statistical Software

1. Gain hands-on skills in tools like **SPSS**, **R**, **SAS**, or **STATA**.
2. Practice analyzing real-world health datasets.

3. Engage in Research Projects

1. Participate in hospital, academic, or industry-based research studies.
2. Contribute to study design, data collection, and statistical analysis.

4. Attend Workshops & Conferences

1. Join professional events related to **biostatistics**, **clinical trials**, or **epidemiology**.
2. Network with statisticians, data scientists, and clinical researchers.

5. Specialize in a Subfield

1. Choose a niche like **clinical trials**, **pharmacovigilance**, **HEOR**, or **genomics**.
2. Build expertise and portfolio in that area.

6. Collaborate with Interdisciplinary Teams

1. Work with physicians, epidemiologists, and data scientists to broaden applied knowledge.

7. Stay Updated

1. Follow latest statistical methods, guidelines, and software updates in medical research.





Work Settings for Biostatisticians



***Pharmaceutical Industry**

Drug development and clinical trials.
Pharmacovigilance and post-marketing surveillance.
Health economics & outcomes research (HEOR) teams.

***Grant-Funded Research:** Collaborating on projects funded by pharmaceutical companies to evaluate new therapies or conduct post-marketing studies.

***Hospitals & Healthcare Systems**

Clinical research departments.
Quality improvement and patient safety units.
Epidemiology and infection control programs.

***Public Health Agencies**

Ministries of Health, CDC, WHO.
Surveillance of diseases and outbreak modeling.
Health policy and program evaluation.

***Academic & Research Institutions**

Universities and medical schools.
Teaching biostatistics and supervising research projects.
Collaborating on multidisciplinary health studies.

***Contract Research Organizations (CROs)**

Designing and analyzing multi-center trials for pharmaceutical companies.

***Regulatory Authorities**

Drug approval agencies (FDA, EMA, local equivalents).
Reviewing statistical data for new drug applications.

***Non-Governmental Organizations (NGOs)**

Global health research and program evaluation.

***Private Consulting**

Providing statistical expertise to multiple healthcare and pharma clients.

***Freelance Work**

Offering biostatistical analysis and research support as an independent contractor.

Freelancer Platforms:

Upwork
Freelancer.com
Fiverr
PeoplePerHour
Toptal
Kolabtree (*specialized in scientific & medical experts*)



**Without data, you're
just another person
with an opinion.**

W. Edwards Deming

Q&A