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REDUCING BONE REJECTION BY UMMC BONE BANK THROUGH IMPROVED WORK PROCEDURES

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INTRODUCTION

UMMC Bone Bank has been supplying frozen sterile bone allografts for orthopaedic transplants since 2009. Bones donated by arthroplasty and trauma patients were femoral heads and knee slices. Annual rejection during the verification phase of the bone banking (2013-2016) was initially 36.8% in 2013 and reached the highest of 50.0% in 2015. Out of 205 rejected bones during that phase, 75 were due to non-technical or human handling factors. By having quality system in place, the bank introduced interventions in 2017-2018 (remedial phase) with the aim to reduce the annual rejection of the donated bones from the orthopaedic patients in UMMC, thus ameliorate bones for clinical transplantation. Therefore, more recipients will benefit from the bone allografts produced by the bank.
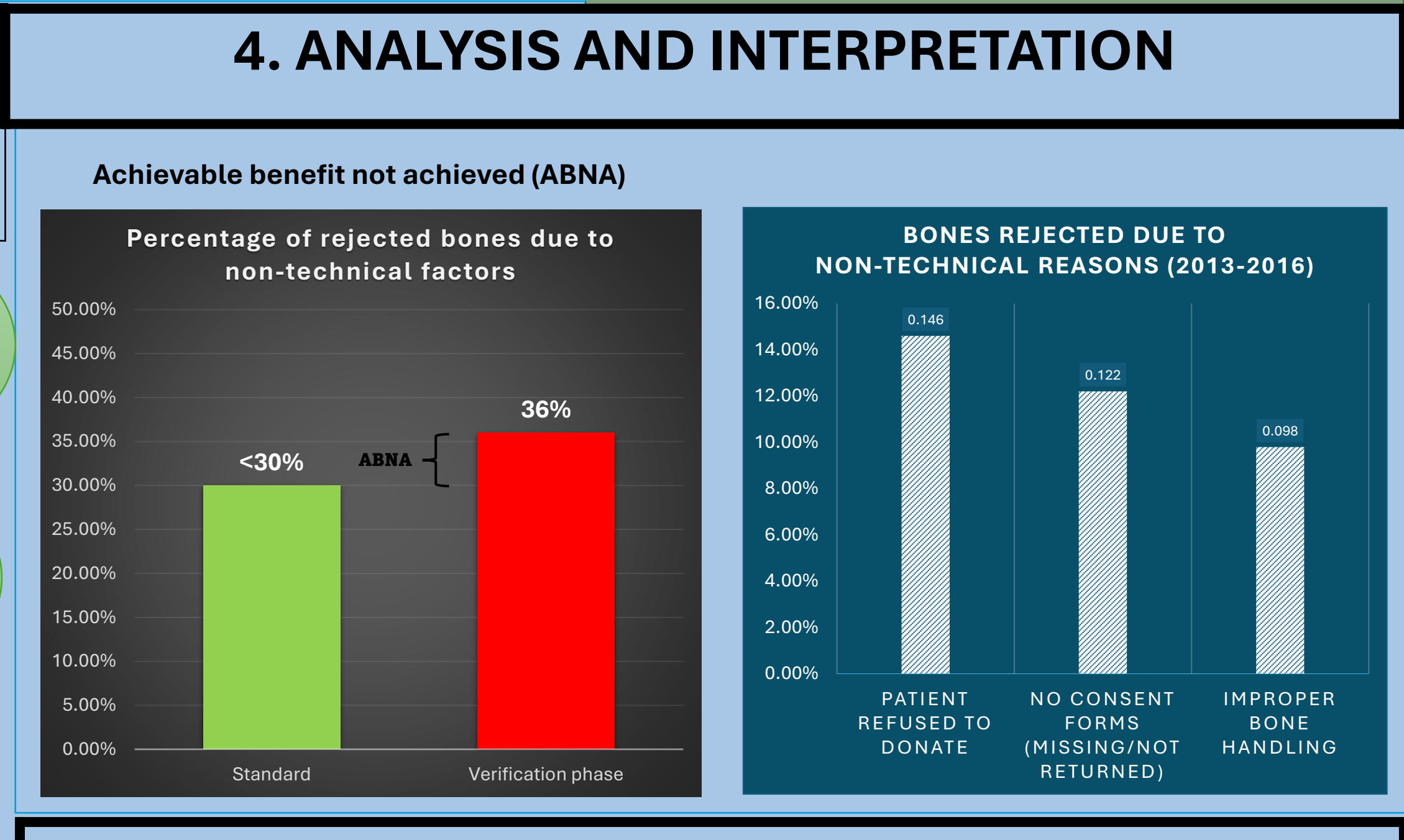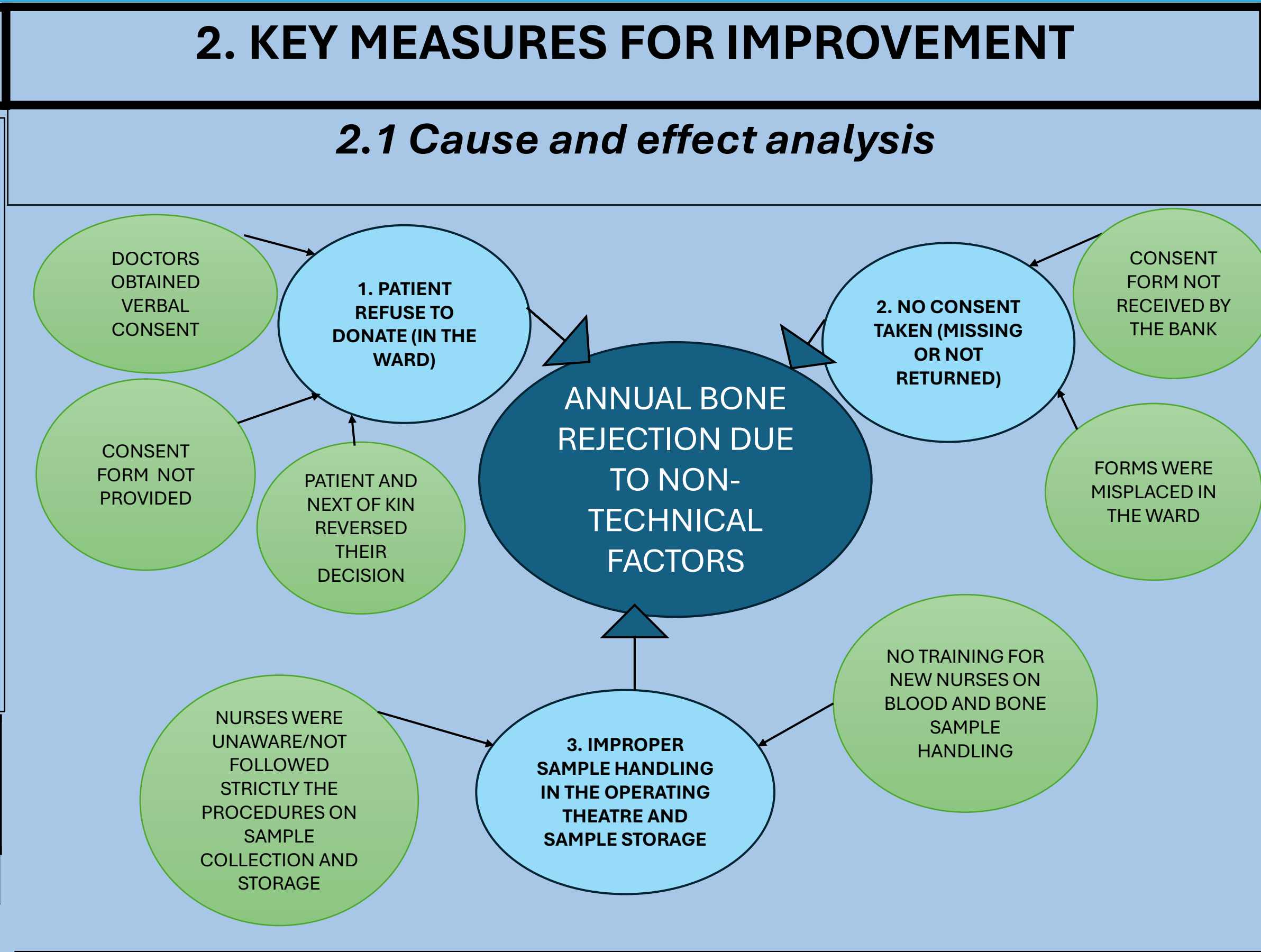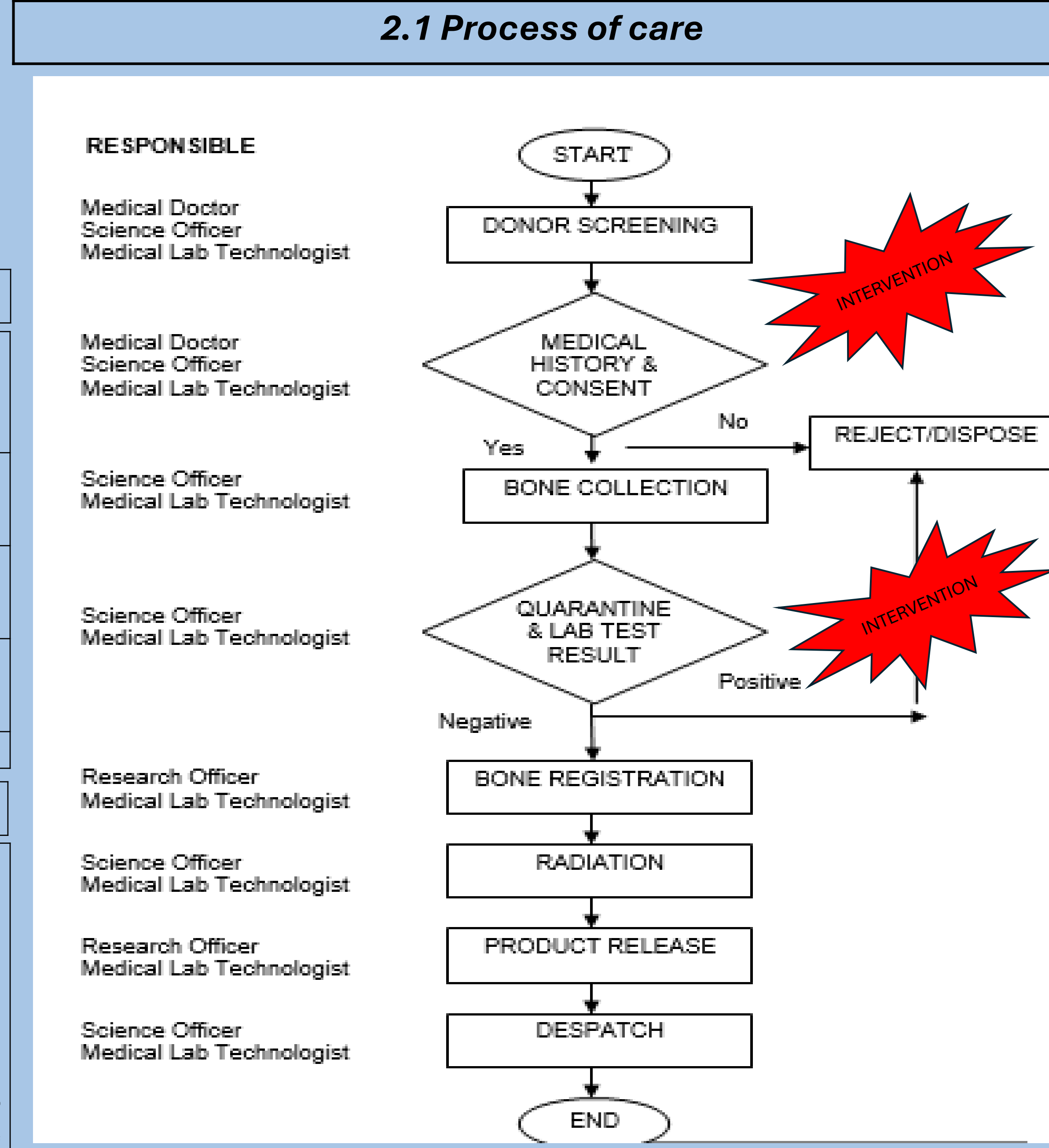
1. SELECTION OF OPPURTUNITY FOR IMPROVEMENT

1.1 Reason for selection (Non-technical factors)

PROBLEMS	S	M	A	R	T	Σ (TOTAL)
No consent taken (missing or not returned)	14	13	11	11	13	62
Refusal to donate	6	5	9	13	15	48
Improper sample handling	10	12	11	12	10	55
Positive bacteriology detected	6	6	6	5	6	29
Positive virology detected	5	5	5	4	4	23
Medical history	4	5	4	4	4	21

Rating scale: 1= low 2= medium 3= high   Group members: 5

1.2 Problem analysis

S (Seriousness)	Failure in obtaining patient consent and improper handling of donated bones causing the most wastage which may lead to incapability of the bone bank in producing enough bone grafts for needy patients.
M (Measurable)	Percentage of rejected bones can be calculated through number of donors with no consents and donated bones with no laboratory results.
A (Attainable)	Continuous education to medical practitioners, nurses and paramedics on consent and bone handling protocols.
R (Remedial)	Identify interventions for improvement: Implement new approach in getting consent and introduce donor kit for proper handling of collected bones.
T (Timeliness)	This study was conducted for 10 years (2013 - 2023).

1.3 Literature review

1. Mohd *et.al* (2015) stated that 40 bones (22.3%) at UMMC Bone Bank were rejected due to donors refused to donate bones, failed to obtain consent, and improper bone sample handling from 2004 to 2013.
2. Stepanovic *et.al* (2021) stated that 42 donors (15.72%) refused to perform serological re-test.
3. Pampeu *et.al* (2014) mentioned 3 factors that influenced bone tissue donation were refusal of family members to donate, lack of understanding of which bones would be removed (92.9%) and how the body would be reconstructed after bone removal (96.5%).
4. Nather and David (2007) reported rejection rate of femoral head NUH Tissue Bank reduced from 42.5% (1989-1994) to 20% (1995-2003) after interventions.

1.4 Problem statement

❖ Bone rejections due to human factors were no consent, refusal to donate and improper sample handling.
❖ Failure to provide consent forms by doctors after verbally agreed led to patients' refusal to donate.
❖ Many consent forms not received by the bank.
❖ Improper sample handling in the operating theatre after bone collection that led to unnecessary wastage of bone.
❖ High bone rejection leads to less bone grafts could be supplied by the bone bank for transplantation.
❖ Less patients will benefit from bone allografts supplied by the local bone bank.

1.5 General objective

To reduce the annual rejection of bone donated by living donors by implementing improved consent approach and introducing donor kit.
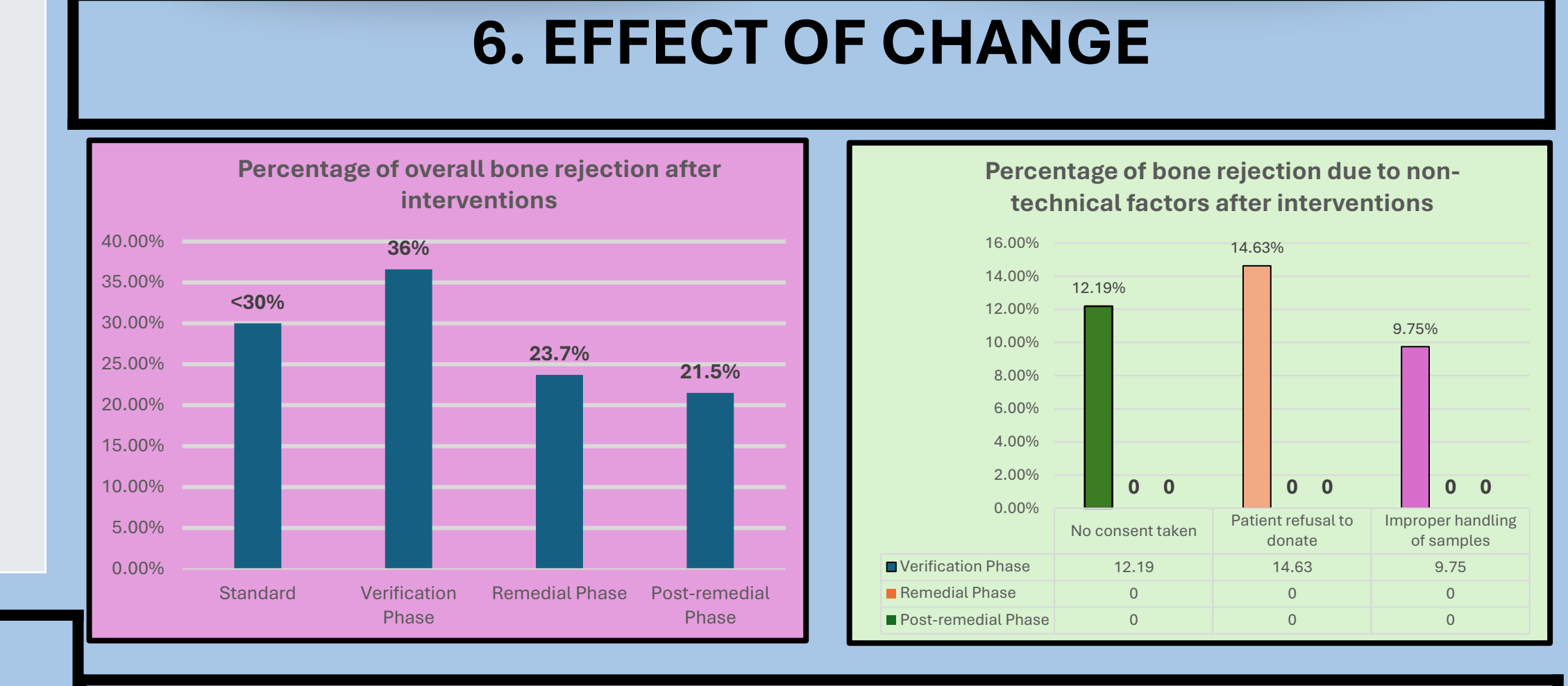
1.6 Specific objective

- To compare the annual bone rejection during verification phase (2013-2016), remedial phase (2017 - 2018) and post-remedial phase (2019-2023).
- To collect annual data on bone rejections due to non-technical factors during these periods.
- To formulate improvement strategies to reduce the bone rejections.
- To implement the remedial actions under the improvement strategies.
- To evaluate the effectiveness of the strategies in minimizing the rejection.

1.7 Indicators

- Percentage of rejected bones due to refusal to donate, absence of consent and improper handling.
- Annual rejection after interventions: < 30%

1.8 Terms and definitions

TERMS	DEFINITION
Bone allograft	Bones procured from human and transplanted to another human.
Donor consent	Donor's permission in written manner for donating bone samples and knowing the benefits and risks
Donor kit	A kit that consists all the necessary item for sample collection during bone procurement

2. KEY MEASURES FOR IMPROVEMENT

2.1 Cause and effect analysis

ANNUAL BONE REJECTION DUE TO NON-TECHNICAL FACTORS

- 1. PATIENT REFUSE TO DONATE (IN THE WARD)
  - DOCTORS OBTAINED VERBAL CONSENT
  - CONSENT FORM NOT PROVIDED
  - PATIENT AND NEXT OF KIN REVERSED THEIR DECISION
- 2. NO CONSENT TAKEN (MISSING OR NOT RETURNED)
  - CONSENT FORM NOT RECEIVED BY THE BANK
  - FORMS WERE MISPLACED IN THE WARD
- 3. IMPROPER SAMPLE HANDLING IN THE OPERATING THEATRE AND SAMPLE STORAGE
  - NO TRAINING FOR NEW NURSES ON BLOOD AND BONE SAMPLE HANDLING
  - NURSES WERE UNAWARE/NOT FOLLOWED STRICTLY THE PROCEDURES ON SAMPLE COLLECTION AND STORAGE

2.1 Process of care

RESPONSIBLE	
Medical Doctor / Science Officer / Medical Lab Technologist	START → DONOR SCREENING
Medical Doctor / Science Officer / Medical Lab Technologist	MEDICAL HISTORY & CONSENT — No → REJECT/DISPOSE (INTERVENTION)
Science Officer / Medical Lab Technologist	Yes → BONE COLLECTION
Science Officer / Medical Lab Technologist	QUARANTINE & LAB TEST RESULT — Positive → REJECT/DISPOSE (INTERVENTION)
Research Officer / Medical Lab Technologist	Negative → BONE REGISTRATION
Science Officer / Medical Lab Technologist	RADIATION
Research Officer / Medical Lab Technologist	PRODUCT RELEASE
Science Officer / Medical Lab Technologist	DESPATCH → END

2.2 Model of good care

No.	Process	Criteria	Standard	Verification phase	Remedial phase	Post-remedial phase
1	Obtaining patient consent by medical officers/nurses in the ward	1. Consult patient regarding bone donation	100%	10%	80%	100%
		2. Obtain signed consent by patient and next of kin	100%	10%	90%	100%
		3. Place the signed consent form in the patient's medical folder	100%	10%	100%	100%
2	Blood and bone sample collections in the operating theatre (OT)	1. OT staff nurse check the signed consent form before bone procurement	100%	0%	90%	100%
		2. Retrieve donor kit	100%	0%	80%	100%
		3. Collect patient's blood sample	100%	50%	100%	100%
		4. Perform bone swab	100%	50%	100%	100%
		5. Pack the blood and bone samples	100%	50%	100%	100%
		6. Store the blood and bone samples in the fridge (blood in 4°C and bone in -20°C) located in specimen room	100%	50%	100%	100%

3. PROCESS OF GATHERING INFORMATION

3.1 Methodology

METHODOLOGY	
STUDY DESIGN	Retrospective
STUDY SETTING	Orthopaedic wards and operation theatre
STUDY PERIOD	**Verification Phase** 1 January 2013 - 31 December 2016 **Remedial Phase** 1 January 2017 – 31 December 2018 **Post-Remedial Phase** 1 January 2019 – 31 December 2023
STUDY POPULATION	Arthroplasty and trauma patients who underwent hip and/or knee replacement surgeries
SAMPLING TECHNIQUE	Universal sampling
INCLUSION CRITERIA	Based on UMMC Bone Bank's inclusion criteria
EXCLUSION CRITERIA	Based on UMMC Bone Bank's exclusion criteria
SAMPLING TOOLS	Observational, performance and quality control (QC) checklist

This poster was prepared for presentation at the 12th National QA Convention, 8-10 October 2024, Negeri Sembilan

4. ANALYSIS AND INTERPRETATION

Achievable benefit not achieved (ABNA)

Percentage of rejected bones due to non-technical factors
- Standard: <30%
- Verification phase: 36%
- (ABNA)

BONES REJECTED DUE TO NON-TECHNICAL REASONS (2013-2016)
- PATIENT REFUSED TO DONATE: 0.146
- NO CONSENT FORMS (MISSING/NOT RETURNED): 0.122
- IMPROPER BONE HANDLING: 0.098

5. STRATEGIES FOR CHANGE

5.1 Remedial phase – 1st part (Handling patient refusal issues)

1. Old consent form
2. Revised consent form – addition of screening criteria and endorsed by UMMC Medical Record and Quality units
3. Introduction of bone bank brochure for donors and medical officers
4. CME for medical officers

5.2 Remedial phase – 2nd part (Handling improved consent form and bone samples)

1. Donor kit consists of necessary item for bone sample collection
2. CNE for OT and ward nurses
3. Organ and Tissue Donation Awareness Campaign for public

6. EFFECT OF CHANGE

Percentage of overall bone rejection after interventions
- Standard: <30%
- Verification Phase: 36%
- Remedial Phase: 23.7%
- Post-remedial Phase: 21.5%

Percentage of bone rejection due to non-technical factors after interventions

	No consent taken	Patient refusal to donate	Improper handling of samples
Verification Phase	12.19	14.63	9.75
Remedial Phase	0	0	0
Post-remedial Phase	0	0	0

7. CONCLUSION

❑ The percentage of annual bone rejection significantly dropped to 29.1% in 2017, 21.5% during 2019-2023, reached the lowest at 14.8% in 2021 (p<0.05). No bone was rejected due to consent or handling issues.
❑ By minimizing bone rejections, more bone grafts are available for transplantation.

8. THE NEXT STEP

This achievement underscores the efficacy of our targeted strategies in optimizing procedures for donated bones in UMMC Bone Bank. Continuous trainings for doctors and nurses will be conducted annually to ensure no bone rejection due to non-technical or human handling factors. Future efforts will focus on maintaining these gains and identifying further opportunities for improvement.

ACKNOWLEDGEMENT