**WIse CHoices in the ICU (WICH-ICU): Protocol and Statistical Analysis Plan for a Stepped-Wedge Cluster Randomized Trial of Choosing Wisely Interventions in Swedish Intensive Care Units**

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Word Count

**Abstract**

**Background:** Healthcare overuse, including unnecessary diagnostic testing and procedures, contributes to patient harm, increased healthcare costs, and resource waste. The Choosing Wisely initiative aims to reduce low-value care through evidence-based recommendations. However, limited evidence exists regarding the safety and effectiveness of implementing Choosing Wisely recommendations in intensive care settings.

**Methods:** The WICH-ICU is a registry-based stepped-wedge cluster randomized controlled trial designed to evaluate the implementation of specific Choosing Wisely interventions in Swedish intensive care units (ICUs). The study will include adult patients treated in participating Swedish ICUs. The intervention consists of three evidence based Choosing Wisely recommendations: (1) reduced frequency of arterial blood gas sampling, (2) reduced routine venous laboratory testing, and (3) reduced routine chest radiography. The primary outcome is ICU length of stay. Secondary outcomes include duration of mechanical ventilation (invasive and non-invasive), continuous renal replacement therapy duration, and 30-day mortality. Data will be collected through the Swedish Intensive Care Registry (SIR) and local monitoring. The stepped-wedge design allows each participating ICU to serve as its own control, with randomized timing of intervention implementation.

**Discussion:** This study will provide crucial evidence on the safety and effectiveness of implementing Choosing Wisely recommendations in intensive care settings. The stepped-wedge cluster randomized design minimizes contamination while allowing all participating sites to eventually receive the intervention. The results will inform evidence-based de-implementation strategies in critical care.

**Trial Registration:** NCT07013175

**Keywords:** Choosing Wisely, intensive care, cluster randomized trial, stepped-wedge, healthcare overuse, de-implementation

## Background

Healthcare systems worldwide face mounting pressure to optimize resource utilization while maintaining high-quality patient care. Healthcare overuse—defined as the provision of medical services when the potential for harm exceeds the potential for benefit—represents a significant challenge in modern medicine 1. This phenomenon is particularly pronounced in intensive care units (ICUs), where the critical nature of patient conditions often drives defensive medicine practices and the routine ordering of diagnostic tests and procedures 2 3.

The Choosing Wisely initiative, launched in 2012 by the American Board of Internal Medicine Foundation, represents a physician-led effort to advance conversations between clinicians and patients about avoiding unnecessary medical tests, treatments, and procedures 4 5. The initiative has since expanded globally, with professional societies developing evidence-based recommendations to reduce low-value care 6. However, despite widespread adoption of Choosing Wisely recommendations, implementation in clinical practice remains challenging, particularly in high-acuity settings such as intensive care units 7.

### Rationale for Choosing Wisely in Intensive Care

Intensive care units are characterized by high resource utilization, complex patient populations, and frequent diagnostic testing 8 9. Several factors contribute to potential overuse in ICU settings:

1. **Defensive medicine practices**: The critical nature of ICU patients often leads to overcautious approaches, including frequent laboratory testing and imaging studies 10 .
2. **Routine ordering patterns**: Many ICU protocols include standing orders for daily laboratory tests and imaging studies, regardless of clinical indications 11 .
3. **Shift-based care**: The 24-hour nature of ICU care, with multiple handoffs between providers, may contribute to redundant testing 12.
4. **Technological availability**: The immediate availability of diagnostic technologies in ICU settings may lower the threshold for ordering tests 13.

### Evidence for Choosing Wisely Interventions in Critical Care

Several Choosing Wisely recommendations specifically target intensive care practices:

**Arterial Blood Gas Sampling**: Routine arterial blood gas (ABG) sampling in stable ICU patients may not improve clinical outcomes while increasing patient discomfort, healthcare costs, and risk of complications 14 . Evidence suggests that stable patients on mechanical ventilation may not require hourly ABG sampling, with extended intervals being safe and cost-effective 15.

**Laboratory Testing**: Daily routine laboratory testing in stable ICU patients has been questioned, with studies suggesting that selective testing based on clinical indication may be equally safe while reducing costs and iatrogenic anemia 16 17. The Society of Critical Care Medicine has specifically recommended against daily laboratory testing in stable ICU patients 18 .

**Chest Radiography**: Daily routine chest X-rays in ICU patients, particularly those on mechanical ventilation, have limited diagnostic yield and may not improve clinical outcomes 19 20. Multiple professional societies recommend against routine daily chest radiography in favor of clinically indicated imaging 18 21 .

### Knowledge Gaps and Study Rationale

Despite theoretical benefits and professional society recommendations, several knowledge gaps exist regarding Choosing Wisely implementation in intensive care:

1. **Safety concerns**: Limited high-quality evidence exists regarding the safety of reducing diagnostic testing frequency in ICU patients [23].
2. **Implementation strategies**: Effective methods for implementing Choosing Wisely recommendations in ICU settings remain poorly understood [24].
3. **Patient outcomes**: The impact of Choosing Wisely interventions on patient-centered outcomes in critical care requires further investigation [25].
4. **Healthcare utilization**: The broader effects of Choosing Wisely implementation on ICU resource utilization and efficiency need evaluation [26].

### Swedish Healthcare Context

Sweden's healthcare system, characterized by universal coverage and integrated delivery systems, provides an ideal setting for evaluating the systematic implementation of Choosing Wisely interventions. The Swedish Intensive Care Registry (SIR), established in 2001, captures comprehensive data on all ICU admissions nationwide, enabling robust outcome assessment 22. The registry's high coverage rate (>95% of Swedish ICU beds) and standardized data collection procedures facilitate large-scale implementation research 23 24.

Swedish ICU practice patterns align with international standards, with similar approaches to diagnostic testing and monitoring. However, regional variations exist in practice, providing natural variation for studying implementation effects 25 26.

**Objectives**

**Primary Objective**

To evaluate the safety and effectiveness of implementing specific Choosing Wisely (CW) recommendations in Swedish intensive care units through a stepped-wedge cluster randomized trial design. We want to assess the impact of CW recommendation on 30-day mortality after ICU admission.

**Secondary Objectives**

1. To assess the impact of Choosing Wisely interventions on ICU length of stay
2. To evaluate effects on invasive mechanical ventilation duration
3. To evaluate effects on non-invasive mechanical ventilation duration
4. To evaluate effects on continuous renal replacement therapy duration
5. To analyze changes in diagnostic testing patterns and healthcare resource utilization
6. To identify factors associated with successful implementation
7. To develop evidence-based guidelines for Choosing Wisely implementation in intensive care settings

**Hypotheses**

We hypothesize that the implementation of targeted Choosing Wisely interventions in Swedish ICUs will:

1. Reduce diagnostic testing frequency without compromising patient safety
2. Maintain equivalent clinical outcomes while improving resource efficiency
3. Be feasible to implement across diverse ICU settings
4. Result in cost savings without negatively impacting quality indicators

**Methods**

**Study Design**

WICH-ICU is a registry-based stepped-wedge cluster randomized controlled trial. The stepped-wedge design was selected for several reasons:

1. **Ethical considerations**: All participating sites eventually receive the intervention, addressing ethical concerns about withholding potentially beneficial interventions
2. **Pragmatic implementation**: The design allows for staged implementation, facilitating training and resource allocation
3. **Statistical efficiency**: Each cluster serves as its own control, increasing statistical power
4. **Contamination minimization**: The temporal separation reduces risk of contamination between intervention and control periods

**Setting and Participants**

**Participating Sites**

The study will be conducted in Swedish intensive care units participating in the Swedish Intensive Care Registry (SIR). Eligible ICUs must:

* Be registered with SIR with >95% data completeness
* Treat adult patients (≥18 years)
* Provide general intensive care services
* Have committed local leadership support
* Designate a clinical monitor for data collection

**Patient Population**

All adult patients (≥18 years) admitted to participating ICUs during the study period will be included in outcome analyses. No individual patient consent is required due to the registry-based design and quality improvement nature of the interventions.

**Patient Exclusion Criteria**

* Age <18 years

**Interventions**

The WICH-ICU intervention consists of three evidence-based Choosing Wisely recommendations:

**1. Arterial Blood Gas Sampling Protocol**

**Current Practice**: Routine hourly arterial blood gas sampling in many ICUs

**Intervention**: Structured protocol for arterial blood gas frequency:

* **Hourly sampling**: Unstable patients where results directly change treatment
* **Every 2 hours**: Unstable patients where results may not immediately change management
* **Every 4 hours**: Stable patients where results may change management
* **Less than every 4 hours**: Stable patients where results unlikely to change management

**2. Venous Laboratory Testing Protocol**

**Current Practice**: Daily routine laboratory panels regardless of clinical status

**Intervention**: Risk-stratified laboratory testing approach:

* **Daily testing**: Essential parameters (albumin, blood count, CRP, creatinine)
* **Every other day/twice weekly**: Intermediate priority tests (liver enzymes, coagulation studies, electrolytes, procalcitonin)
* **Avoid routine testing**: Low-yield tests without specific clinical indication

**3. Chest Radiography Protocol**

**Current Practice**: Routine chest X-rays after insertion of central venous lines, after insertion of naso-gastric tubes, after initiation of invasive ventilation and for many mechanically ventilated patients

**Intervention**: Clinically indicated chest radiography only:

* Chest X-rays performed *only when diagnostic information would directly affect clinical management*
  + Examples of appropriate indications: suspected pneumothorax, line placement confirmation in “difficult” cases, acute respiratory deterioration

**Implementation Strategy**

**Pre-Implementation Phase (5 days)**

* Baseline monitoring of current testing practices
* Staff education and training sessions
* Distribution of protocol materials and decision support tools

**Implementation Phase**

* Phased rollout according to randomization schedule
* Local champion identification and training
* Regular feedback on adherence and outcomes
* Continuous quality improvement processes

**Post-Implementation Monitoring**

* Ongoing assessment of protocol adherence
* Safety monitoring and adverse event tracking
* Periodic reinforcement and education sessions

**Outcomes**

**Primary Outcome**

30-day mortality

**Secondary Outcomes**

* ICU length of stay
* Duration of invasive mechanical ventilation (hours)
* Duration of non-invasive ventilation (hours)
* Duration of continuous renal replacement therapy (hours)
* ICU readmission within 30 days

**Process Outcomes**:

* Number of arterial blood gas samples per patient-day
* Number of venous laboratory tests per patient-day
* Number of chest X-rays per patient-day
* Adherence to intervention protocols

**Outcome Measurement**

**Registry Data Collection**: Primary and secondary outcomes will be collected through SIR, which captures standardized data elements for all Swedish ICU admissions including:

* Demographics and comorbidities
* Severity of illness scores (SAPS 3)
* Interventions and procedures
* Outcomes and discharge status

**Local Monitoring**: Participating sites will collect process outcomes through designated clinical monitors during specified monitoring periods:

* Baseline period (5 days pre-implementation)
* 1-month post-implementation (5 days)
* 3-months post-implementation (5 days)

**Sample Size and Power Calculations**

**Study Population Size**

This pragmatic study will evaluate a clinical paradigm shift (Choosing Wisely) across Swedish intensive care units. With approximately 10,000 patients, the study will capture 25% of Sweden's annual intensive care population. If implementation of Choosing Wisely interventions among small, medium, and large intensive care units does not negatively affect outcomes, the intervention can be classified as patient-safe.

**Non-Inferiority Power Analysis**

We conducted a non-inferiority-based power calculation for our primary outcome of mortality, using a standard non-inferiority margin of 4%. The analysis is based on data from the Swedish Intensive Care Registry, though the intra-cluster correlation (ICC) depends on the specific ICUs participating in the study. While we know which regions are participating, the exact ICUs from each region are not yet determined, creating some uncertainty in this analysis. Moreover, we expect more regions and ICUs to sign up for the study, again explaining lack of ICC data.

**Power Calculation Parameters:**

* **Primary endpoint**: 30-day mortality
* **Design**: Non-inferiority trial
* **Power**: 80%
* **Alpha level**: 0.025 (one-sided 97.5% CI)
* **Non-inferiority margin**: 4%
* **ICC**: 0.0019 (based on SIR mortality data)

**Mortality Assumptions:**

* **Intervention group (pE)**: 0.27 (27% mortality)
* **Control group (pC)**: 0.23 (23% mortality, based on average 30-day mortality in proposed participating ICUs)
* **Allocation ratio**: 1:1 between exposed (intervention/CW) and unexposed (controls)

**Cluster Parameters:**

* **Average cluster size (m)**: 676 patients (based on admission numbers in proposed participating ICUs)

**Sample Size Results:** The required sample size is a minimum of 8 clusters of size 676 in the intervention group and 8 clusters of size 676 in the control group.

* **Total required sample size**: 10,816 patients
* **Total clusters required**: 16 ICUs

**Randomization and Allocation**

**Cluster Definition**

Individual ICUs represent clusters for randomization purposes.

**Randomization Scheme**

A computer-generated randomization sequence will determine the order of intervention implementation across participating ICUs using a stepped-wedge design with [X] time periods and [Y] clusters per step.

**Allocation Concealment**

The randomization sequence will be generated by an independent statistician and concealed from investigators until cluster allocation is revealed according to the predetermined timeline.

**Statistical Analysis Plan**

**General Principles**

* Analysis will follow intention-to-treat principles at the cluster level
* Mixed-effects models will account for clustering and temporal trends
* Multiple imputation will address missing data when >10% missing for key covariates
* Sensitivity analyses will explore robustness of findings
* Statistical significance will be set at α = 0.05 for superiority analyses and α = 0.025 (one-sided) for non-inferiority analyses

**Primary Analysis - Mortality (Non-Inferiority)**

The primary analysis will assess non-inferiority of 30-day mortality between intervention and control periods using:

**Statistical Model:**

* Generalized linear mixed-effects model with logistic regression
* Random effects for cluster (ICU) to account for clustering
* Fixed effects for time period, intervention status, and patient-level covariates
* Non-inferiority margin: 4% absolute difference in mortality rates

**Covariates for Adjustment:**

* Age (continuous)
* Sex
* SAPS3 score (continuous)
* Admission type (emergency vs. elective)
* Admission diagnosis category
* Comorbidity burden
* Surgical status

**Secondary Analyses**

**ICU Length of Stay:**

* Linear mixed-effects model accounting for clustering
* Log-transformation if distribution is highly skewed
* Adjustment for same covariates as primary analysis

**Mechanical Ventilation Duration, and CRRT Duration:**

* Time-to-event analysis using Cox proportional hazards model with shared frailty
* Competing risks analysis accounting for death
* Adjustment for baseline severity and other confounders

**Process Measures:**

* Descriptive statistics for testing frequencies before and after intervention
* Interrupted time series analysis to assess immediate and sustained changes
* Comparison of testing rates between intervention and control periods

**Handling of Clustering and Temporal Effects**

**Stepped-Wedge Design Considerations:**

* Explicit modeling of time trends using calendar time variables
* Random effects for clusters to account for unmeasured cluster-level confounders
* Autoregressive correlation structure to account for temporal correlation within clusters
* Sensitivity analyses using different correlation structures

**Intra-Cluster Correlation:**

* ICC estimated at 0.0019 for mortality based on SIR data
* Sensitivity analyses will explore different ICC values
* Design effect calculations to assess clustering impact

**Missing Data Strategy**

* Complete case analysis as primary approach given high data completeness in SIR (>95%)
* Multiple imputation using chained equations if missing data >10% for key variables
* Missing data patterns will be assessed and reported
* Sensitivity analyses comparing complete case and imputed results

**Sensitivity Analyses**

1. **Per-protocol analysis**: Including only patients treated according to protocol
2. **Different ICC assumptions**: Varying ICC from 0.001 to 0.005
3. **Time trend specifications**: Alternative modeling of temporal trends
4. **Outlier ICUs**: Excluding ICUs with extreme characteristics
5. **Intervention intensity**: Analysis stratified by level of protocol adherence
6. **Baseline period**: Varying length of baseline observation period

**Subgroup Analyses**

Pre-specified subgroup analyses will examine intervention effects across:

* ICU size (small <500, medium 500-1000, large >1000 annual admissions)
* Patient severity (SAPS3 quartiles)
* Admission diagnosis categories
* Age groups (<65, 65-79, ≥80 years)
* Length of ICU stay (<3 days, ≥3 days)

**Safety Monitoring**

Interim safety analyses will be conducted:

* Monthly monitoring of mortality rates by intervention status
* Predefined stopping rules for safety concerns

**Software and Analysis Plan**

All analyses will be conducted using R statistical software (version ≥4.0). Specific packages:

* **lme4**: Mixed-effects modeling
* **survival**: Survival analysis
* **mice**: Multiple imputation
* **ggplot2**: Data visualization
* **tidyverse**: Data manipulation

**Reporting Standards**

Results will be reported according to:

* CONSORT extension for cluster randomized trials
* CONSORT extension for stepped-wedge cluster randomized trials
* STROBE guidelines for observational studies
* Complete statistical analysis code will be made available

**Data Management and Quality Assurance**

**Data Collection and Management**

**Data Sources**

**Primary Data Source - Swedish Intensive Care Registry (SIR):** All patient outcome data will be extracted from SIR, which includes:

**Demographic Data:**

* Unit name
* Sex, age
* Admission time, arrival time, discharge time
* Care episode ID (for SIR internal use only)
* Route of admission, reason for admission
* Emergency admission status, surgical status
* Discharge reason, care outcome, time of death
* Parent clinic

**Severity of Illness Assessment:**

* **SAPS3 (Simplified Acute Physiology Score)** including all component parameters, total score, and estimated mortality risk

**Treatment and Interventions:**

* All treatment strategy parameters
* All care intensity measurement parameters
* All registered interventions with start and end times
* Mechanical ventilation (invasive and non-invasive) duration
* Renal replacement therapy duration and type
* Complication codes
* Care limitations and withdrawal decisions

**Outcomes:**

* 30-day mortality
* ICU length of stay
* Hospital length of stay
* Mortality data with precise timing
* ICD diagnosis codes

**Process Measures - Local Monitoring:** Clinical monitors will study the utilization/frequency of arterial blood gases, venous laboratory testing, and chest radiography during both control and intervention phases. Since this data is not registered in SIR, an electronic Case Report Form (eCRF) will be created to capture:

* Number of arterial blood gas samples per patient-day
* Number of venous laboratory tests per patient-day
* Number of chest X-rays per patient-day
* Timing and clinical indications for testing
* Protocol adherence measures

**Data Quality and Validation**

* SIR maintains >95% coverage of Swedish ICU beds with rigorous data validation procedures
* Local monitors will receive standardized training on data collection protocols
* Random audits will be conducted to ensure data quality and protocol adherence
* Data completeness will be monitored continuously throughout the study period

**Data Security**

* All data will be handled according to Swedish data protection regulations
* Personal identifiers will be removed for analysis datasets
* Secure data transfer protocols will be implemented

**Ethical Considerations**

**Regulatory Approval**

The study has received approval from the Swedish Ethical Review Authority (reference number: [to be added]).

**Patient Consent**

Individual patient consent is not required due to:

* Registry-based design using existing data collection systems
* Quality improvement nature of interventions
* Minimal risk profile of interventions
* Impracticality of individual consent in ICU settings

**Risk-Benefit Assessment**

The interventions represent evidence-based recommendations from professional societies with established safety profiles. Potential benefits include reduced patient discomfort, healthcare costs, and iatrogenic complications, while risks are minimized through careful monitoring and safety protocols.

**Timeline**

* **Month 1-3**: Site recruitment and ethics approval
* **Month 4-6**: Baseline monitoring and staff training
* **Month 7-18**: Stepped-wedge intervention implementation
* **Month 19-21**: Final data collection and cleaning
* **Month 22-24**: Statistical analysis and manuscript preparation

**Discussion**

**Expected Contributions**

The WICH-ICU trial will address several important knowledge gaps in critical care and implementation science:

1. **Safety Evidence**: Provide high-quality evidence regarding the safety of implementing Choosing Wisely recommendations in ICU settings
2. **Implementation Strategies**: Develop and test pragmatic approaches for systematic implementation of evidence-based de-implementation interventions
3. **Patient Outcomes**: Examine effects on patient-centered outcomes beyond process measures
4. **Healthcare Economics**: Evaluate economic implications of Choosing Wisely implementation
5. **Environmental action**:Fewer unnecessary tests means less consumables and decreased environmental impact27
6. **Generalizability**: Assess feasibility across diverse ICU settings within a national healthcare system

**Strengths**

**Design Strengths**

* **Stepped-wedge design**: Maximizes statistical power while ensuring all sites receive intervention
* **Registry-based approach**: Leverages existing high-quality data infrastructure
* **Cluster randomization**: Minimizes contamination and reflects real-world implementation
* **Multi-site design**: Enhances generalizability across diverse settings

**Implementation Strengths**

* **Professional society endorsement**: Interventions based on established professional recommendations
* **Pragmatic approach**: Interventions designed for routine clinical implementation
* **Local champion model**: Leverages existing clinical leadership for sustainability
* **Continuous monitoring**: Enables real-time safety assessment and protocol refinement

**Limitations**

**Design Limitations**

* **Secular trends**: Temporal changes may confound intervention effects
* **Unmeasured confounding**: Registry data may not capture all relevant variables
* **Implementation variation**: Differences in local implementation may affect outcomes
* **Contamination risk**: Knowledge of intervention may influence control period practices

**Generalizability Limitations**

* **Healthcare system context**: Results may not generalize to other healthcare systems
* **Cultural factors**: Swedish healthcare culture may influence implementation success
* **ICU characteristics**: Participating ICUs may not represent all intensive care settings

**Future Directions**

Results from WICH-ICU will inform several areas of future research and implementation:

1. **Scale-up strategies**: Methods for implementing successful interventions at national scale
2. **Adaptation frameworks**: Approaches for adapting interventions to different healthcare contexts
3. **Long-term sustainability**: Strategies for maintaining intervention effects over time
4. **Economic evaluation**: Comprehensive cost-effectiveness analyses
5. **Patient perspectives**: Understanding patient and family experiences with reduced testing

**Implications for Policy and Practice**

WICH-ICU has potential implications for multiple stakeholders:

**For Clinicians**

* Evidence-based guidance for implementing Choosing Wisely recommendations
* Tools and protocols for safe reduction of diagnostic testing
* Quality improvement frameworks for ICU practice optimization

**For Healthcare Systems**

* Models for systematic implementation of de-implementation interventions
* Economic evidence for resource allocation decisions
* Quality metrics for monitoring low-value care reduction

**For Policymakers**

* Evidence base for national quality improvement initiatives
* Framework for evaluating similar interventions in other clinical areas
* Data to support healthcare efficiency initiatives

**Conclusion**

The WICH-ICU trial represents a comprehensive evaluation of Choosing Wisely implementation in intensive care settings. By combining rigorous experimental design with pragmatic implementation strategies, the study will provide crucial evidence for safe and effective reduction of healthcare overuse in critical care. Results will inform evidence-based approaches to improving the value of intensive care while maintaining high-quality patient outcomes.

The stepped-wedge cluster randomized design, leveraging Sweden's exceptional registry infrastructure, positions this study to make significant contributions to both critical care medicine and implementation science. Success of this trial may serve as a model for similar initiatives globally, advancing the goal of reducing low-value care while optimizing patient outcomes and healthcare efficiency.

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