

MIND THE GAP: Comparing risk-based versus system audits on their effectiveness in identifying PIC/S nonconformities

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BACKGROUND & IMPORTANCE

With the introduction of PIC/S PE010-4, Belgian hospital compounding units must implement internal audits to identify issues. This increases compliance with legislation but also the quality and safety of compounds if given sufficient attention to these results. The implementation and evaluation of corrective and preventive actions (CAPAs) will lead to **continuous improvement** of the compounding unit. To optimize audit resources, we researched risk-based approaches.

We encountered the following problems:

- Limited resources in a hospital setting
- Incomparable setting with audit research in literature

HYPOTHESIS

Risk-based internal auditing (RBIA) is more effective than compliance-based system auditing (SA) for the identification of PIC/S nonconformities in the hospital compounding unit.

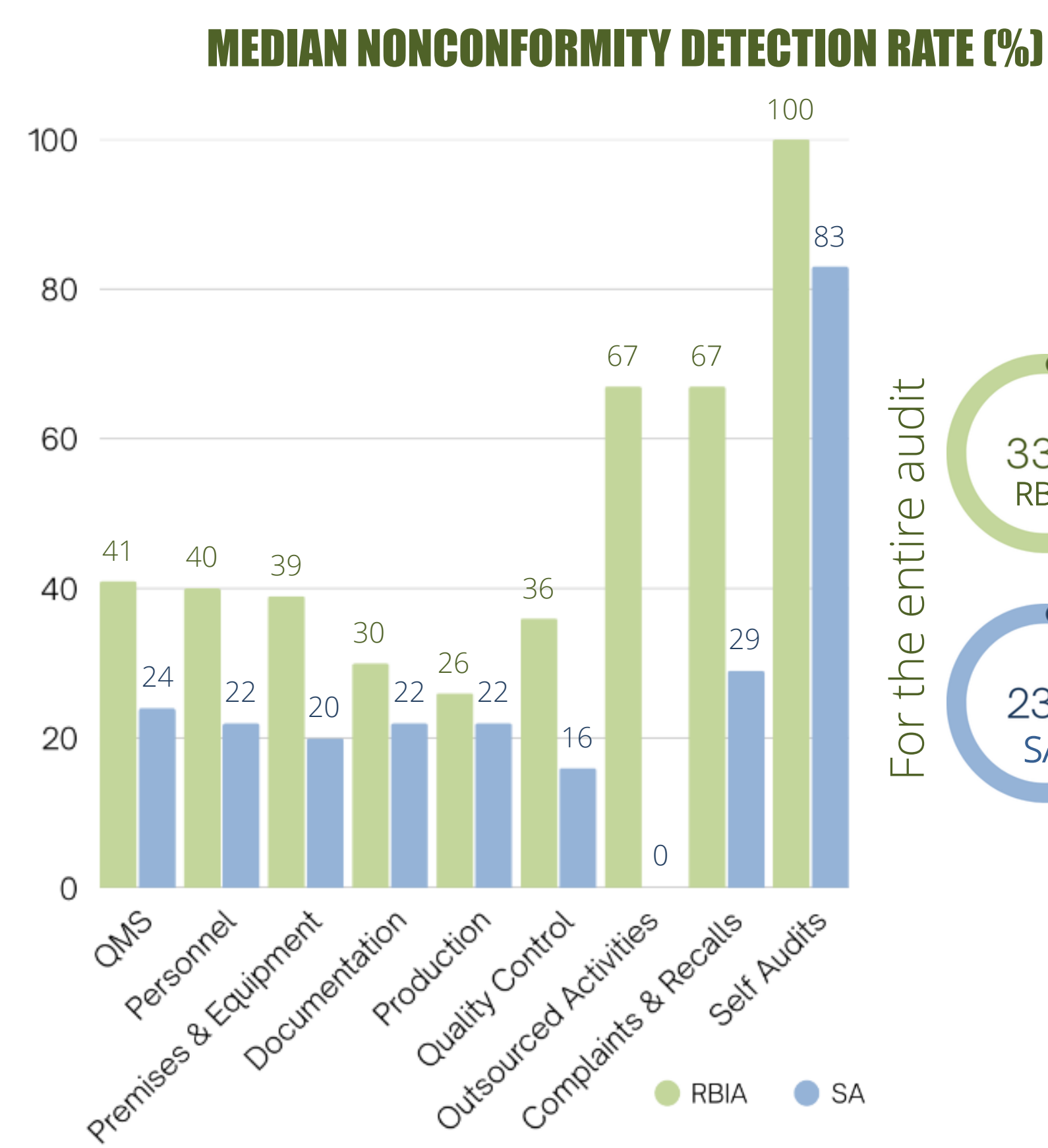
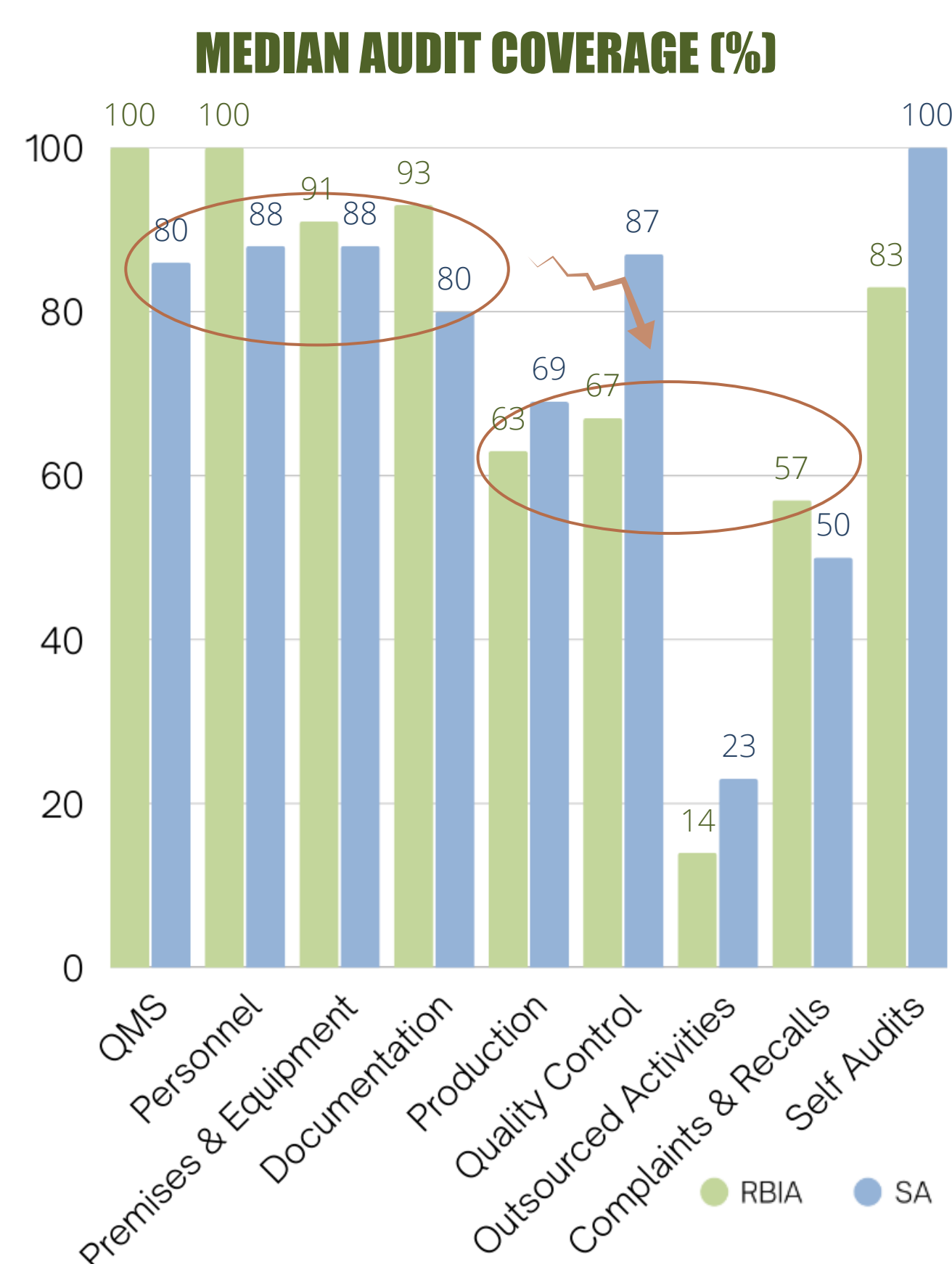
We measured:

- Audit coverage
- Overall nonconformity detection rate
- Severe nonconformity detection rate

METHODS



RESULTS



NONCONFORMITY DETECTION

Paired Wilcoxon signed-rank test:

RBIA found significantly more nonconformities per standard:

- All nonconformities (unclassified) ($p < .001$)
- Critical nonconformities ($p = .049$)
- Major nonconformities ($p = .005$)

Focus on high-risk areas

- Practical PIC/S chapters
 - Personnel ($p = .044$) - critical
 - Production ($p = .020$) - critical
 - Premises & equipment ($p = .007$) - major

Focus on compounding process

ADDITIONAL FINDINGS

- Low interrater reliability for nonconformity detection (Krippendorff's alpha)
 - $\alpha = .246$ for RBIA, $\alpha = .030$ for SA
 - Low criterion validity for nonconformities (median matching benchmark results (%))
 - 31% (20-49%) for RBIA, 21% (9-48%) for SA
- Human behaviour (personal & cultural factors, decision-making styles & personality traits) influences audit results.

CONCLUSION & RELEVANCE

- ✓ Risk-based auditing >> compliance-based auditing
 - Risk-based approach for audit of compounding processes
 - Multiple, shorter audits to avoid ego depletion
- ✓ Algorithm-driven process selection
 - Objective way to perform risk analysis
 - Further adaption to hospital setting is necessary
- ✓ First study on this subject in the hospital compounding unit setting
- ✓ Low interrater reliability → influence of human behaviour on decisions
 - Auditor training → ↓ influence on audit results

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