# Early Recognition and Response to Increases in Surgical Site Infections – the Early 2RIS Trial: A Multicenter Stepped Wedge Cluster Randomized Controlled Trial

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Duke Center for Antimicrobial Stewardship and Infection Prevention

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    *Early Recognition and Response to Increases in Surgical Site Infections using Optimized Statistical Process Control Charts*

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  - Advisory Board – Arthur Baker

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# Background: Surgical Site Infections

- Surgical site infections (SSIs) are common and costly healthcare-associated infections.
  - 160,000-300,000 SSIs occur each year in the US.
  - SSIs are associated with significant morbidity and mortality.
  - Annual hospital costs of SSI range from $3 billion to $10 billion in the US.
- No standard algorithm for SSI surveillance or outbreak detection exists.
- Traditional surveillance techniques may detect important SSI rate increases late or fail to detect rate increases altogether.

Anderson DJ, et al. *Infect Control Hosp Epidemiol*. 2014 June; 35(6): 605–627.
Baker AW, et al. *BMJ Qual Saf*. 2018 August; 27(8): 600–610.

# Background: Statistical Process Control (SPC)

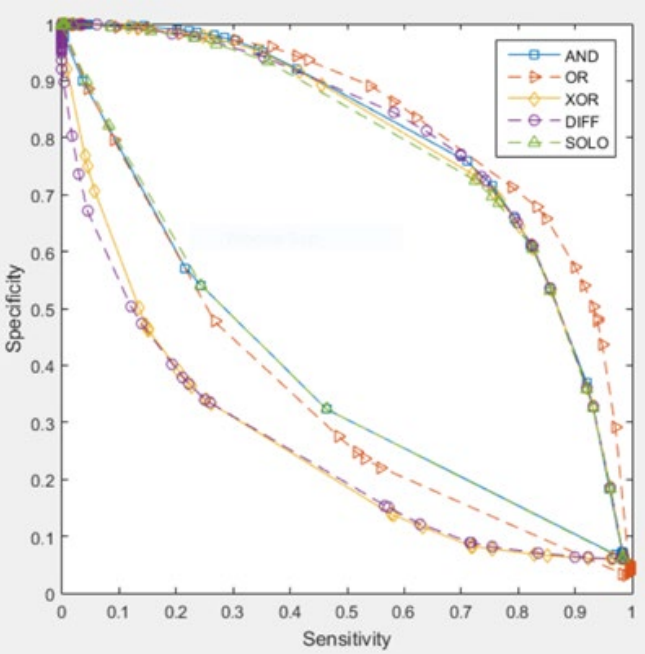
- Branch of statistics that uses time series analysis and graphical presentation of data
- Detects when a process is "out of control" versus when changes in a process or rate are due to natural statistical variation
- Increasingly used to monitor and improve healthcare processes but not commonly used for SSI surveillance



Benneyan JC, et al. *Int J Qual Health Care*. 1998;10:69–73.

# Optimized SPC Methods for Identification of SSI Rate Increases

- Goal: identify charts with high sensitivity and acceptable specificity
- Retrospective review of 12 years of SSI data
  - >1.2 million surgical procedures
  - 3,600 chart variations
  - 32 million chart combinations



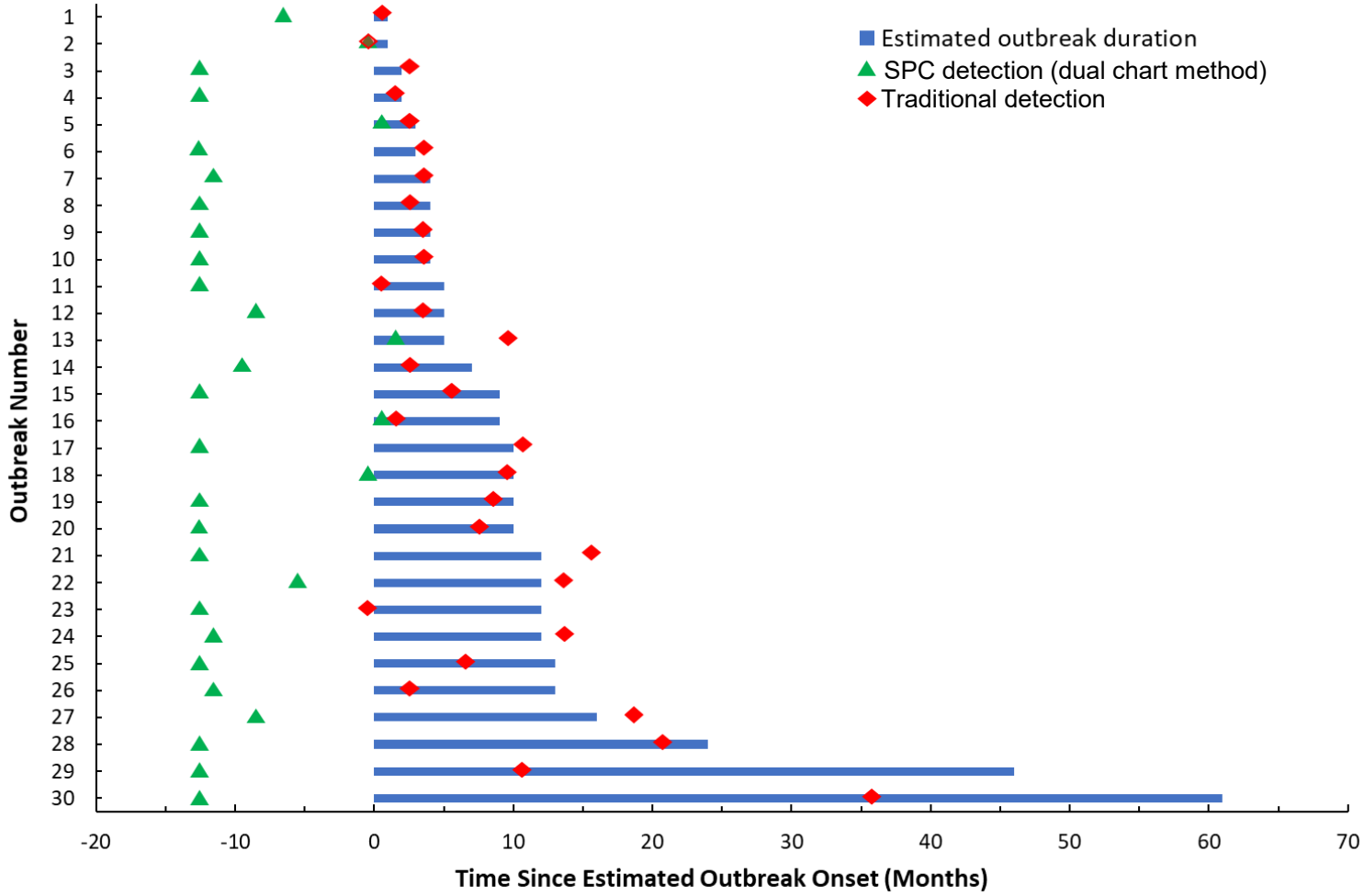

| Chart | Network baseline | Baseline size | Baseline lag | MA span | Control limits | Chart type |
|---|---|---|---|---|---|---|
| **A** | Yes | 18 | 6 | 12 | 1σ | MA |
| **B** | No | 3 | 3 | 6 | 1σ | MA |

MA = moving average

| Sens | Spec | PPV | NPV |
|---|---|---|---|
| **0.90** | 0.67 | 0.56 | 0.94 |

Ilies et al., *BMJ Qual Safety*, 2019

# Optimized SPC Detection of 30 Past SSI Outbreaks at Community Hospitals




- Optimized SPC methods detected all 30 outbreaks
- SPC detected 29 outbreaks prior to traditional surveillance detection

Baker et al., *BMJ Qual Safety*, 2020.

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# Early 2RIS Trial: Methods

- Prospective, multicenter cluster randomized controlled trial using stepped wedge design
- 29 community hospitals in Duke Infection Control Outreach Network (DICON)
  - 13 procedures divided into 6 types of clusters
  - 105 total clusters (cluster = unit of randomization)
- "Active" study period: March 2017 through Feb 2020 (36 months)
  - 12 month baseline occurred immediately prior to active study
- Overall objective: To measure the effectiveness of surveillance using optimized SPC methods and feedback on rates of SSI compared to traditional surveillance methods and feedback

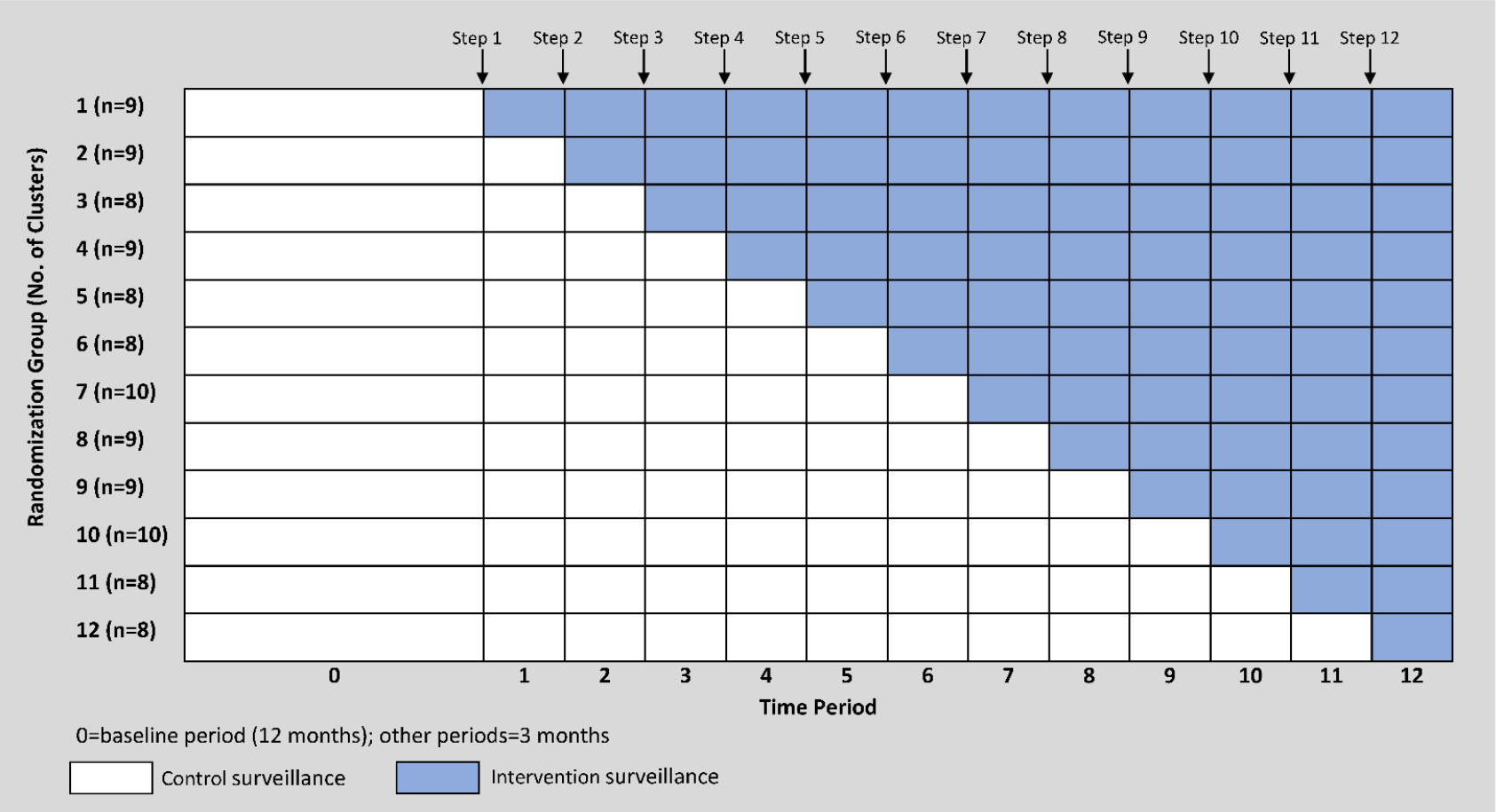
| Surgical procedures included in each cluster | |
|---|---|
| **Cluster** | **Procedure** |
| Cardiac | Coronary artery bypass graft<br>Cardiac valve replacement |
| GI | Colon<br>Herniorrhaphy |
| Joint | Knee arthroplasty<br>Hip arthroplasty |
| OB-GYN | Cesarean section<br>Hysterectomy<br>Vaginal hysterectomy |
| Spine | Spinal fusion<br>Laminectomy |
| Vascular | Carotid endarterectomy<br>Peripheral venous bypass |

NCT03075813; Anderson et al., *Trials*, 2020

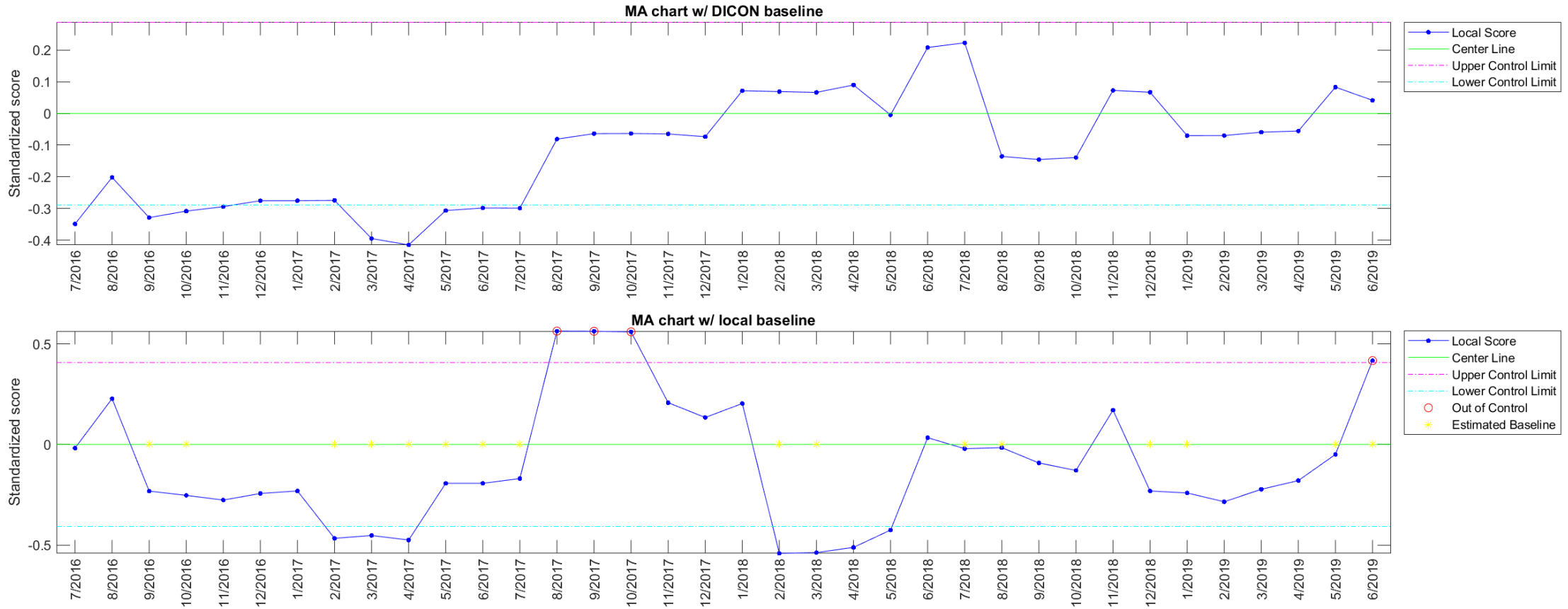
# SSI Surveillance

- Control arm – Traditional surveillance
  - SSI data review by local infection prevention team and DICON infection preventionist
  - Standardized reports comparing SSI rates to benchmark rates every 6 months
- Intervention arm – Traditional surveillance + addition of SPC surveillance
  - Traditional surveillance as done in control arm
  - Weekly application of optimized SPC charts
- SSI rate increases identified by either traditional or SPC surveillance were investigated by the same standardized SSI investigation algorithm.

# Schematic for Stepped Wedge Design



# Blinded Review of SPC Signals – Example

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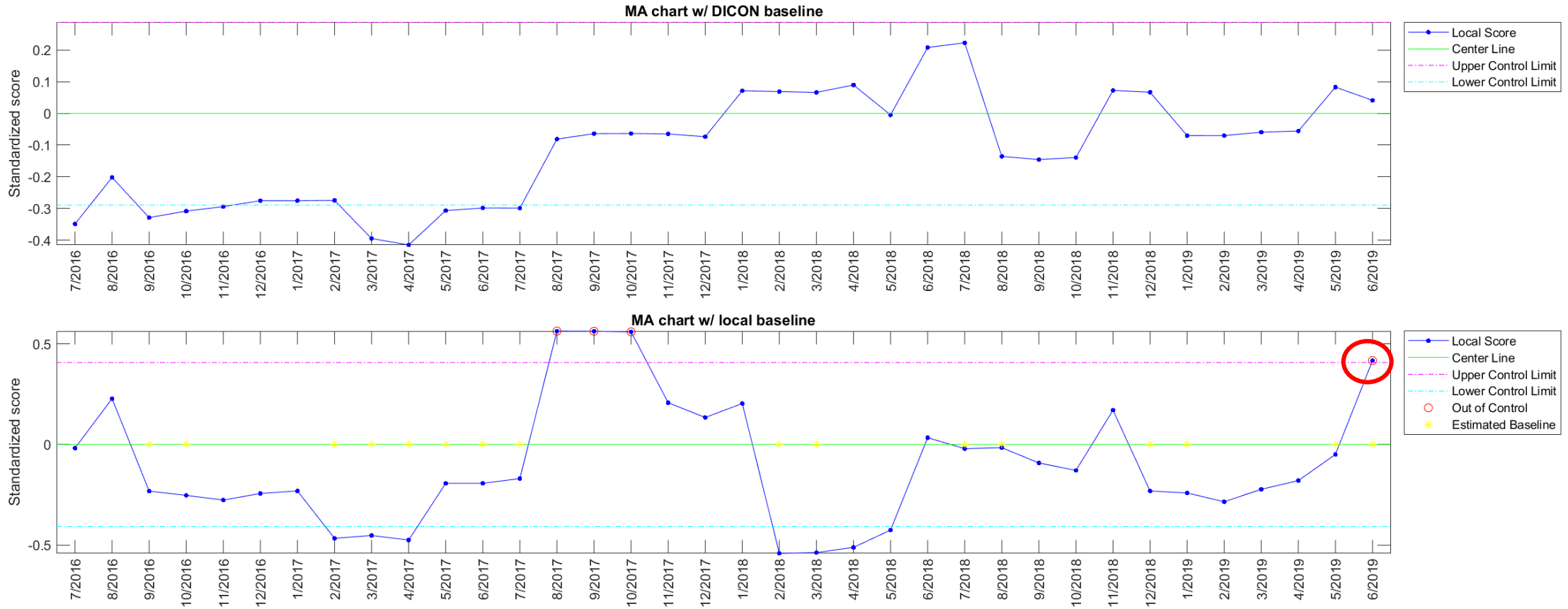


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# Standardized Algorithm for Evaluation of SSI Signals (Identified by Traditional or SPC Surveillance)

1. Review initial signal data to decide if further investigation is indicated
2. Discuss with DICON and local hospital infection preventionists
3. Data collection and detailed line listing to evaluate adherence to best practices for SSI prevention
   --10 best practices included in 4 sets of SSI prevention consensus guidelines
4. Feedback to surgical personnel, including specific recommendations

Anderson DJ et al., *ICHE* 2014.
WHO; "Global Guidelines for the Prevention of SSI." 2018.
Ban, KA et al., *J Am Coll Surg* 2017.
Berrios-Torres SI et al., *JAMA Surg* 2017.

# Outcomes Compared between Intervention and Control SSI Surveillance Arms

**Primary Outcome**

Overall SSI prevalence rate

**Secondary Outcomes**

SSI prevalence rates stratified by type of SSI

Number and timing of SSI signals

Number of SSI signals leading to formal SSI investigations

Preventability of SSIs based on adherence to best practices

# Statistical Methods

- Randomized at cluster level
  - Only one cluster per hospital allowed to change from control to intervention per step

- Model: Generalized estimating equations (GEE) with Poisson distribution
  - Baseline (12 months) and 12 steps (36 total months) = 4 years
  - SSI rate modeled at cluster level with effects for time (step) and intervention
    - Included hospital and cluster-level risk-adjustment variables (median wound class, median ASA score, operation time score as a proportion)
  - Exchangeable correlation structure used (based on QIC criterion)

# Statistical Methods – Power Calculation

- Power calculation using simulation study
  - 3 years of data from 101 clusters in 29 hospitals
    - 1,622 SSIs following 154,554 procedures
  - log (SSI rate) was generated for each cluster from a multivariate normal distribution with the following assumptions
    - (1) cluster-specific SSI rate for traditional surveillance phases calculated from the pilot data (average rate including procedures from all clusters was 1.33%)
    - (2) residual variance for log (SSI rate) of 0.76
    - (3) within-cluster correlation of 0.36
    - (4) between cluster correlation of 0.39 in the same time step and 0.2 in different steps
    - (5) 12 3-month steps and average of 127 procedures per cluster
- 90% power to detect 25% decrease in SSI rate

Anderson et al., *Trials*, 2020

# RESULTS

# Description of surgical procedures

| Surgical Procedure Descriptive Data | | | |
|---|---|---|---|
| **Characteristic** | **Control** | **Intervention** | **Total study period** |
| Total procedures | 148,365 | 89,339 | 237,704 |
| Surgical patients (unique) | 129,997 | 74,236 | 204,233 |
| Age | | | |
| Median (IQR) | 59.0 (42.0, 70.0) | 59.0 (44.0, 70.0) | 59.0 (42.0, 70.0) |
| Sex, n/N(%) | | | |
| Female | 81,139 (62.4%) | 42,388 (57.1%) | 123,527 (60.5%) |
| Procedures by type, n (%) | | | |
| CABG | 3372 (2.3%) | 1902 (2.1%) | 5274 (2.2%) |
| CARD | 1517/ (1.0%) | 1036 (1.2%) | 2553 (1.1%) |
| CEA | 1209 (0.8%) | 760 (0.9%) | 1969 (0.8%) |
| COLO | 7723 (5.2%) | 8046 (9.0%) | 15,769 (6.6%) |
| CSEC | 22,046 (14.9%) | 10,827 (12.1%) | 32,873 (13.8%) |
| FUSN | 16,078 (10.8%) | 9540 (10.7%) | 25,618 (10.8%) |
| HER | 21,141 (14.2%) | 20,699 (23.2%) | 41,840 (17.6%) |
| HPRO | 19,127 (12.9%) | 8995 (10.1%) | 28,122 (11.8%) |
| HYST | 8953 (6.0%) | 4836 (5.4%) | 13,789 (5.8%) |
| KPRO | 27,790 (18.7%) | 12,571 (14.1%) | 40,361 (17.0%) |
| LAM | 15,526 (10.5%) | 8520 (9.5%) | 24,046 (10.1%) |
| PVBY | 677 (0.5%) | 535 (0.6%) | 1212 (0.5%) |
| VHYS | 3206 (2.2%) | 1072 (1.2%) | 4278 (1.8%) |

# Age and sex

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# Procedure types and frequency

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# SSI Types and Overall SSI Rate

| Type of SSI | Control | Intervention | Total study period |
|---|---|---|---|
| Superficial-incisional | 432/1171 (36.9%) | 309/781 (39.6%) | 741/1952 (38.0%) |
| Deep-incisional | 351/1171 (30.0%) | 175/781 (22.4%) | 526/1952 (26.9%) |
| Organ/space | 388/1171 (33.1%) | 297/781 (38.0%) | 685/1952 (35.1%) |

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**Overall SSI Rate:**

1,952 SSIs / 237,704 total surgeries = 0.82 SSIs per 100 procedures

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# Primary Outcome – SSI rates

| Outcome | SSIs, Intervention | Procedures, Intervention | Crude SSI PR, Intervention | SSIs, Control | Procedures, Control | Crude SSI PR, Control | PRR (95% CI) | *P* Value |
|---|---|---|---|---|---|---|---|---|
| All SSIs | 781 | 89,339 | 0.87 | 1,171 | 148,365 | 0.79 | 1.10 (0.94–1.30) | .25 |
| Complex SSIs | 472 | 89,339 | 0.53 | 739 | 148,365 | 0.50 | 1.09 (0.89–1.34) | .40 |
| Superficial SSIs | 309 | 89,339 | 0.35 | 432 | 148,365 | 0.29 | 1.26 (1.00–1.58) | .07 |

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[a]Complex SSIs include deep incisional and organ-space SSIs.

# Secondary Outcome: Complex and Superficial SSI Rates

| Outcome | SSIs, Intervention | Procedures, Intervention | Crude SSI PR, Intervention | SSIs, Control | Procedures, Control | Crude SSI PR, Control | PRR (95% CI) | *P* Value |
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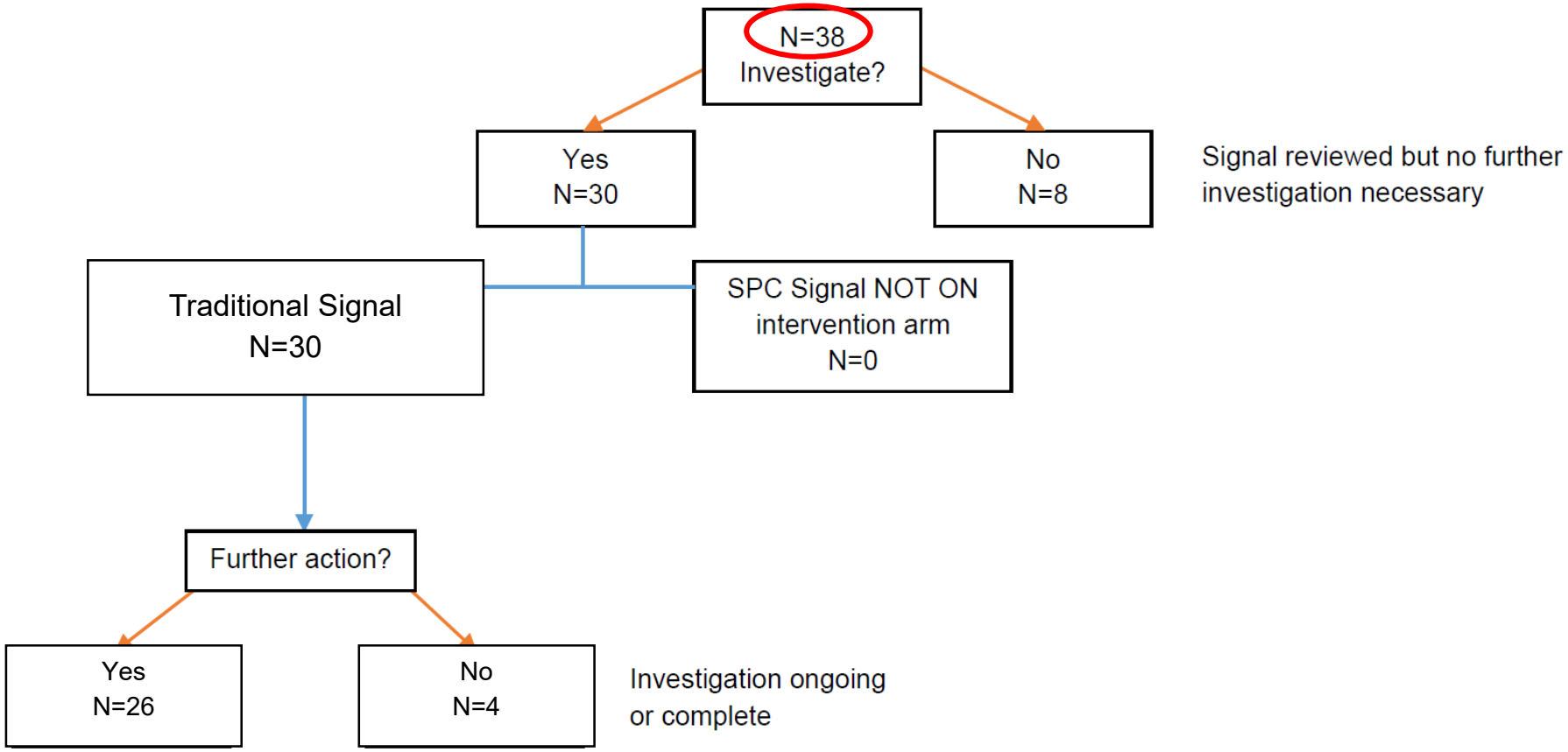
# SSI rates stratified by type of cluster

| Cluster | Crude SSI rate per 100 procedures, Control | Crude SSI rate per 100 procedures, Intervention |
|---|---|---|
| Cardiac | 0.63 | 0.58 |
| GI | 1.04 | 1.11 |
| Joint | 0.85 | 0.72 |
| OBGYN | 0.61 | 0.87 |
| Spine | 0.62 | 0.65 |
| Vascular | 1.86 | 2.16 |
| Overall | 0.79 | 0.87 |

# Secondary Outcomes: Quality Measures

- Performance in detection of important SSI rate increases
- Detection of SSI rate increases associated with deficiencies in SSI prevention best practices

# Traditional Surveillance Signal Detection: 38 Signals Adjudicated



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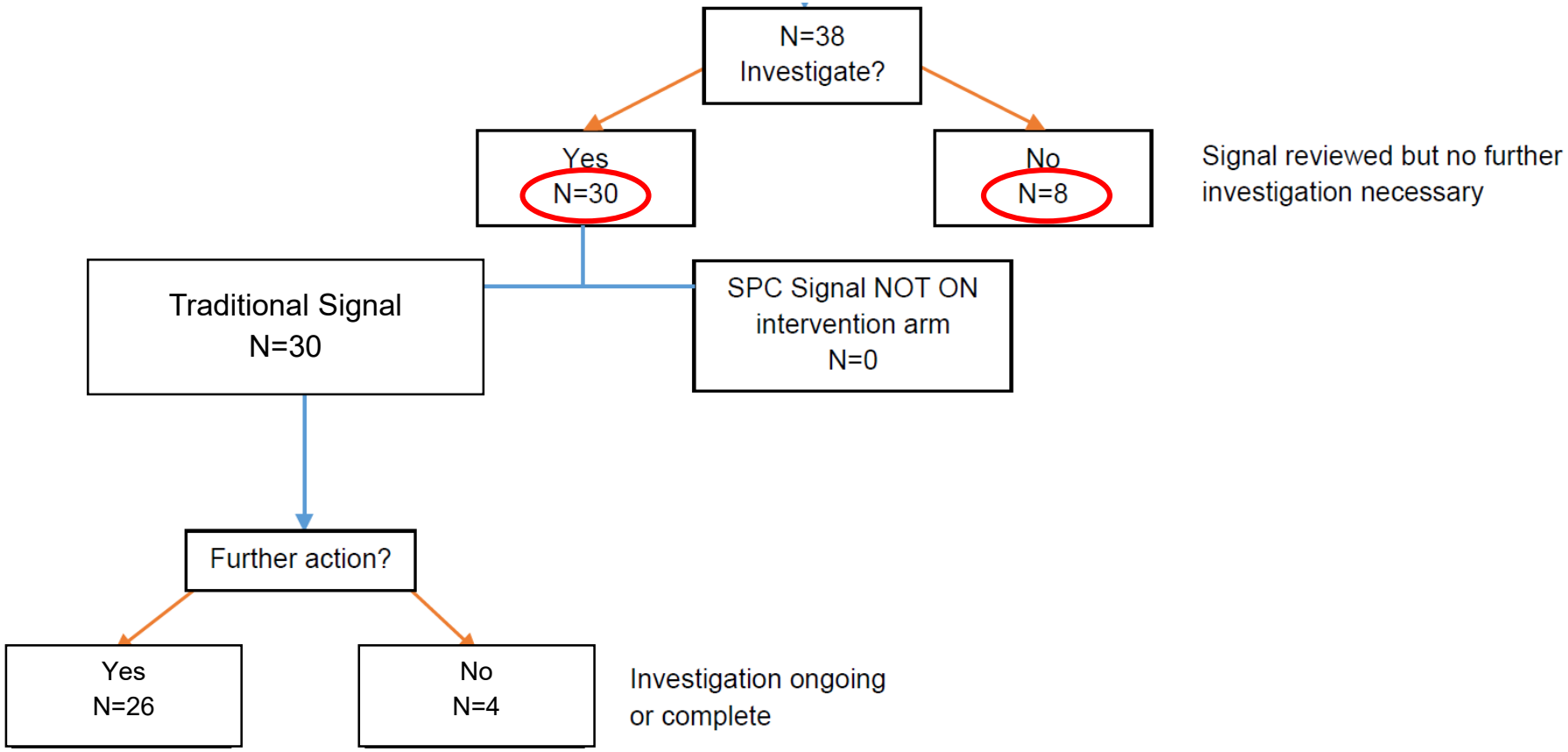

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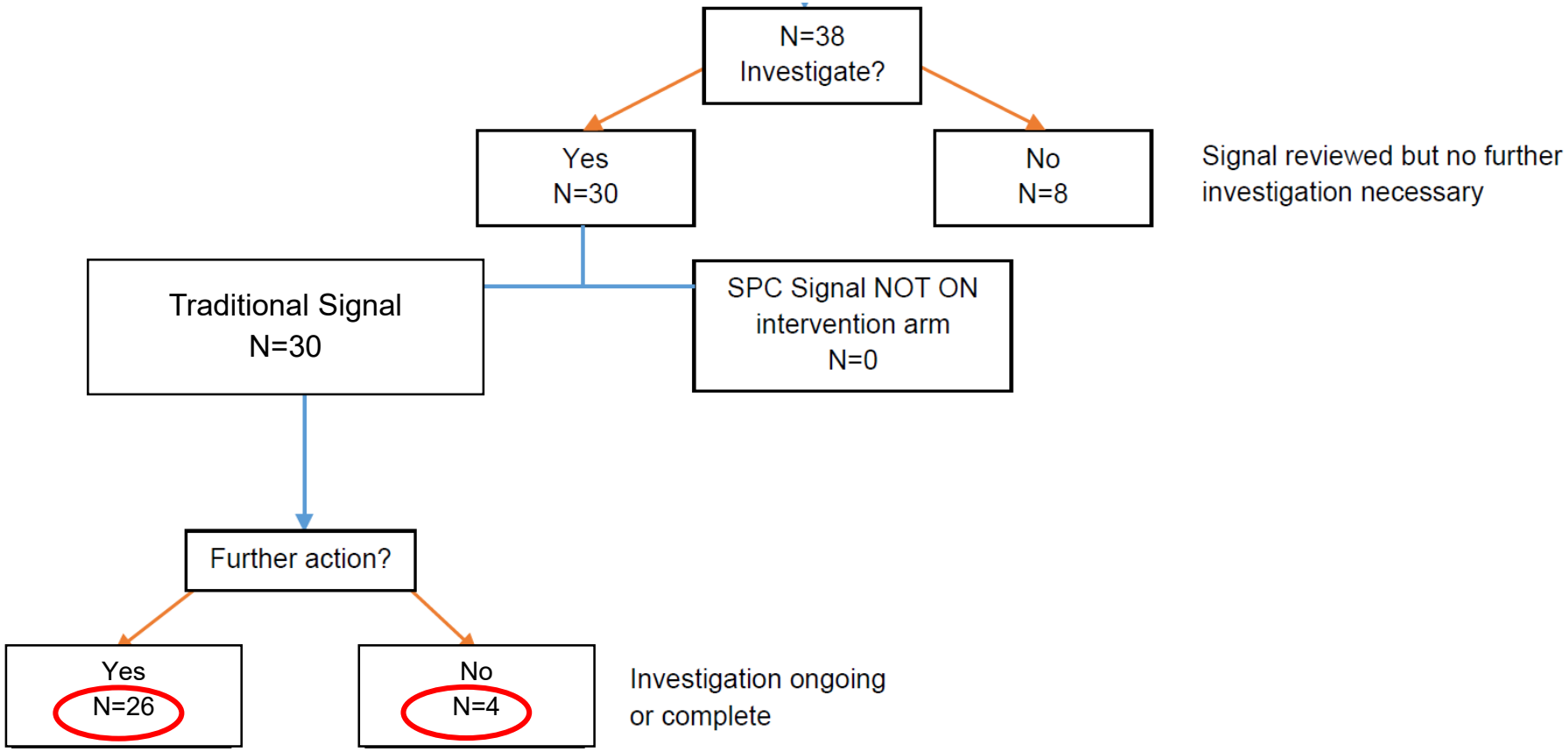

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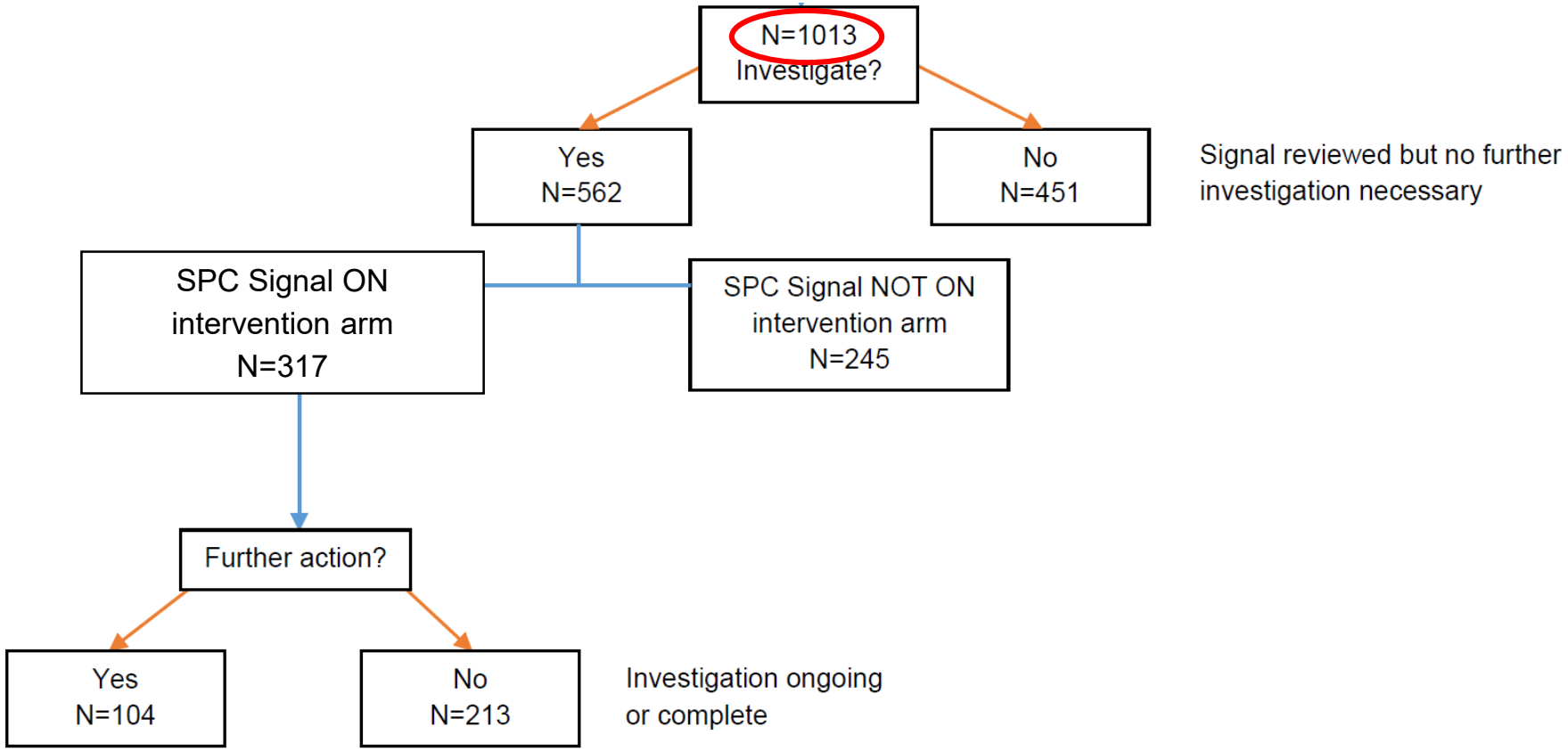

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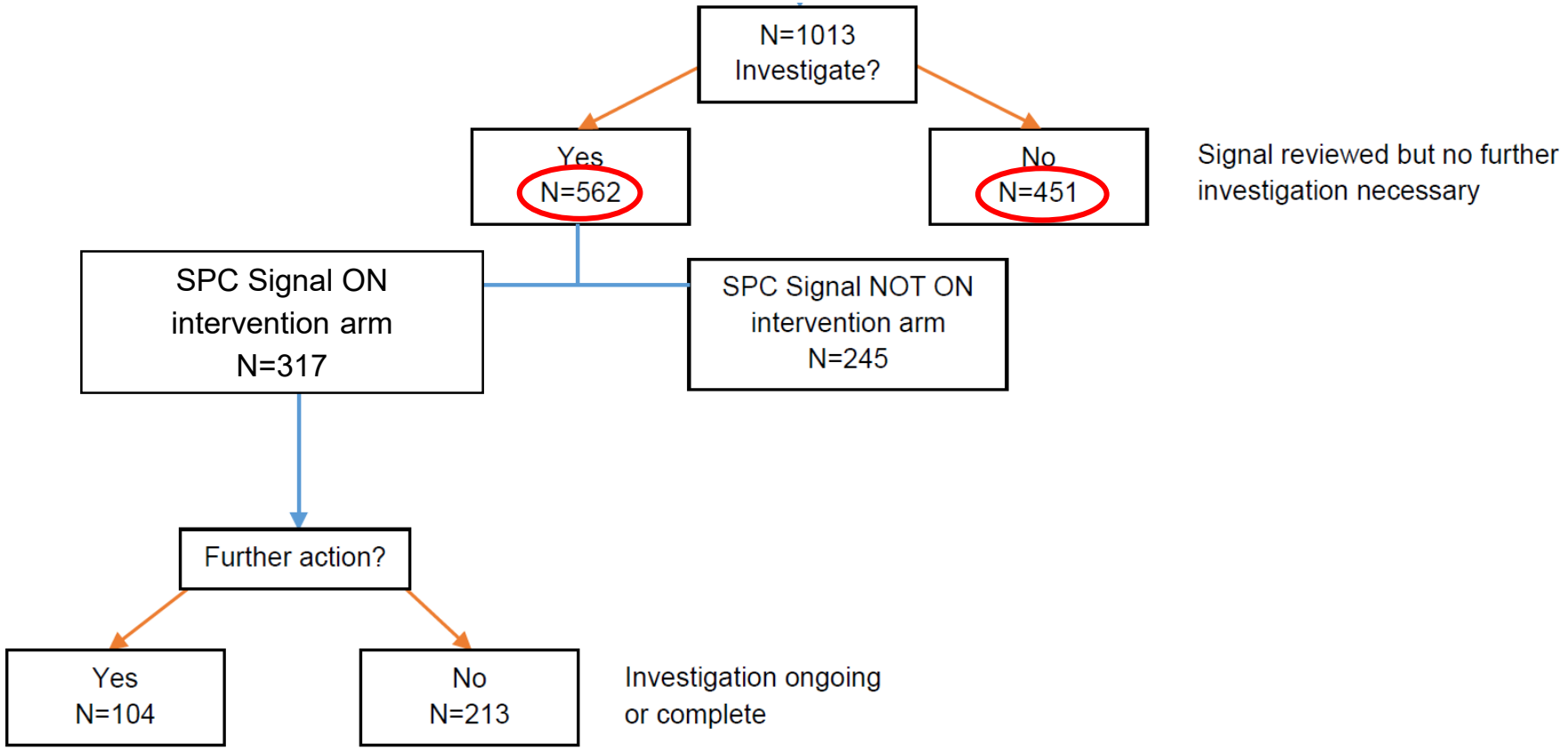

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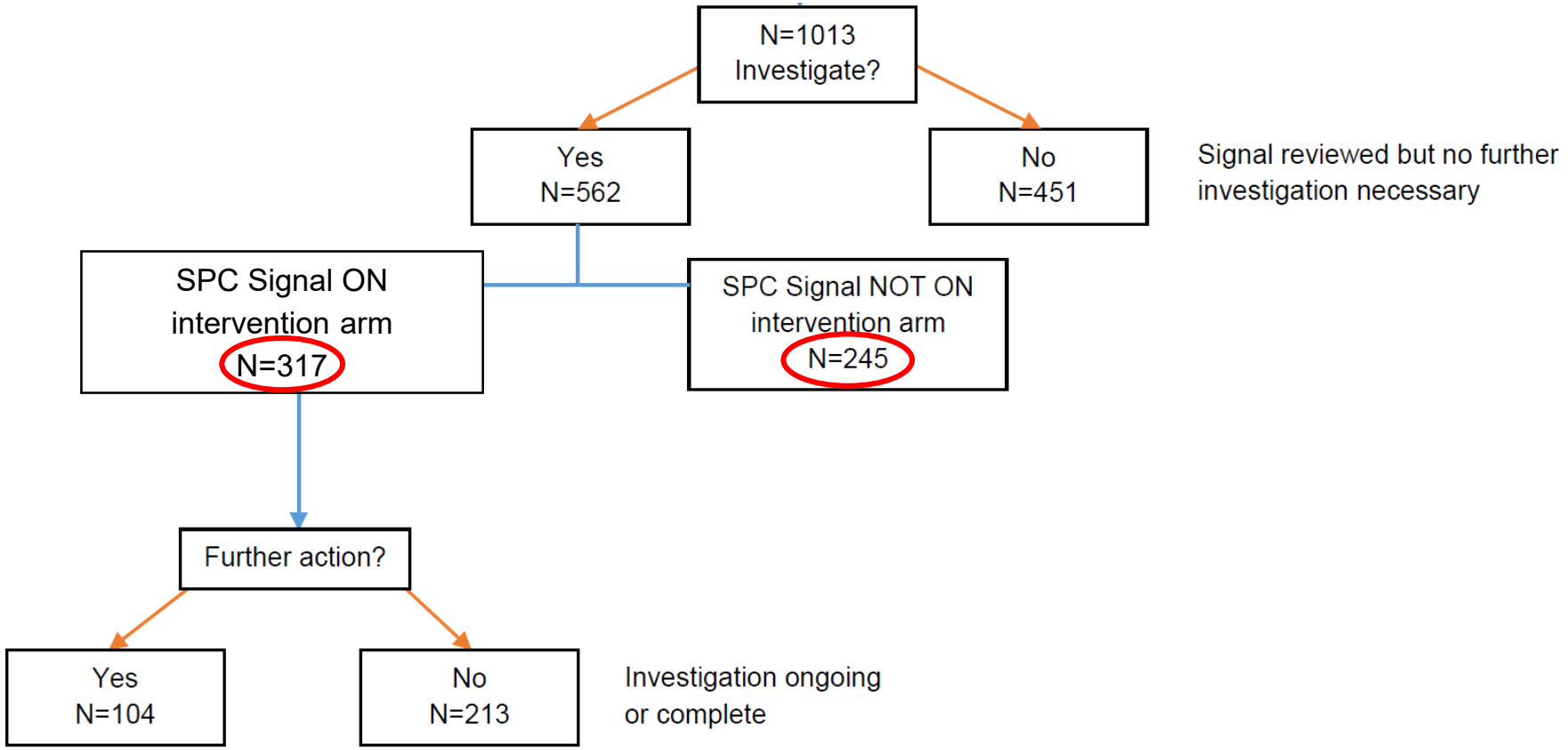

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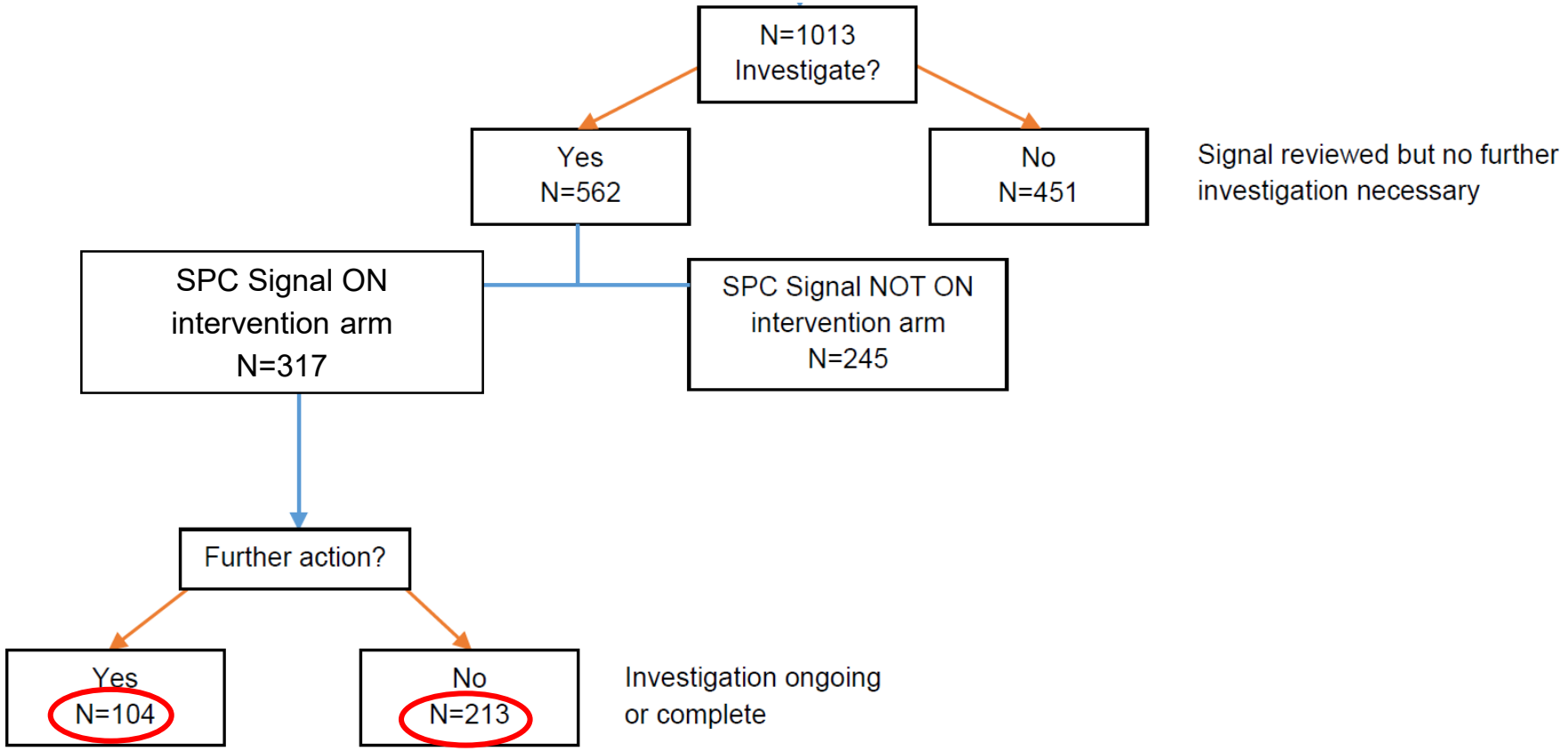

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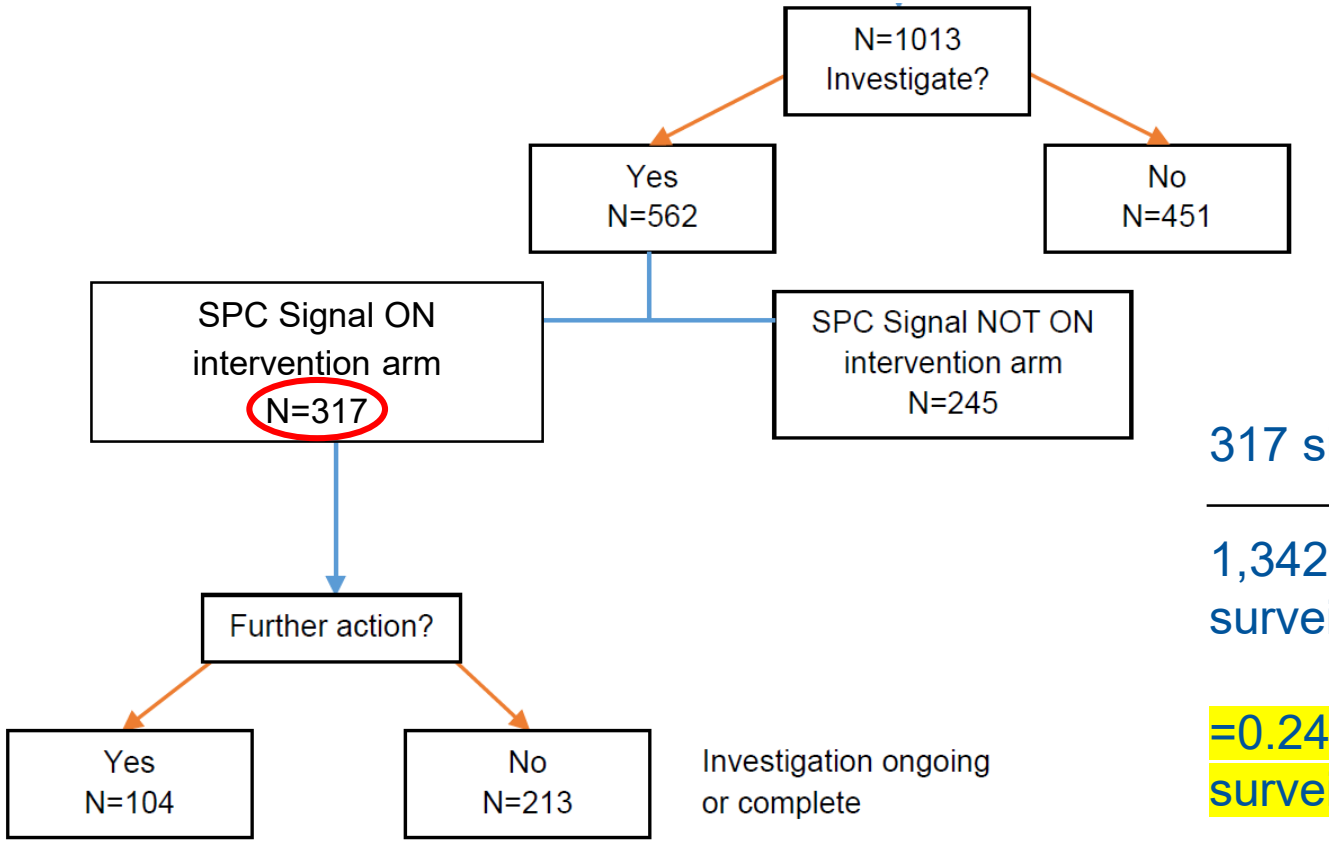


317 signals requiring further action

1,342 procedure-months of surveillance on intervention arm

=0.24 signals per month of surveillance, per procedure type

# SSI signals that progressed to formal investigation

- Traditional surveillance (clusters randomized to control or intervention):
  - 26 signals progressed to formal SSI investigations
- SPC surveillance (only clusters randomized to intervention)
  - 104 signals progressed to formal SSI investigations
- →In total, 130 formal investigations were performed.

# SSIs analyzed via investigation line lists

| Procedure Type | Unique SSIs Analyzed, n (%) (N=643) |
|---|---|
| Colon surgery | 217 (33.7) |
| Hip prosthesis | 78 (12.1) |
| Knee prosthesis | 78 (12.1) |
| Cesarean section | 70 (10.9) |
| Hysterectomy | 65 (10.1) |
| Spinal fusion | 52 (8.1) |
| Herniorrhaphy | 33 (5.1) |
| Laminectomy | 21 (3.3) |
| Coronary artery bypass graft | 15 (2.3) |
| Peripheral vascular bypass surgery | 11 (1.7) |
| Vaginal hysterectomy | 3 (0.5) |

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| Vaginal hysterectomy | 3 (0.5) |

# Compliance with best practices for SSI prevention (Analysis for SSIs reviewed via line lists)

| Best Practice for SSI Prevention | Compliance with Best Practice, n/N (%) |
|---|---|
| Choice of prophylactic antibiotic(s) | 578/643 (90%) |
| Timing of prophylactic antibiotic(s) | 534/643 (83%) |
| Weight-based dose of prophylactic antibiotic(s) | 557/643 (87%) |
| Re-dosing of prophylactic antibiotic(s)[a] | 44/77 (57%) |
| Skin antisepsis with appropriate agent | 528/643 (82%) |
| Maintenance of perioperative normothermia | 467/643 (73%) |
| Operative and postoperative supplemental oxygen[b] | 89/503 (18%) |
| Postoperative glucose monitoring and control | 264/643 (41%) |
| Use of SSI prevention checklist | 195/643 (30%) |
| Prophylactic oral antibiotics and mechanical bowel preparation[c] | 28/217 (13%) |

[a]Analyzed for surgeries requiring re-dosing based on surgery duration and antibiotic chosen.

[b]Analyzed for surgeries requiring general anesthesia and mechanical intubation.

[c]Analyzed for colon surgeries.

# Antibiotic prophylaxis best practices

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| Operative and postoperative supplemental oxygen[b] | 89/503 (18%) |
| Postoperative glucose monitoring and control | 264/643 (41%) |
| Use of SSI prevention checklist | 195/643 (30%) |
| Prophylactic oral antibiotics and mechanical bowel preparation[c] | 28/217 (13%) |

[a]Analyzed for surgeries requiring re-dosing based on surgery duration and antibiotic chosen.

[b]Analyzed for surgeries requiring general anesthesia and mechanical intubation.

[c]Analyzed for colon surgeries.

# Skin antisepsis – appropriate agent required

| Best Practice for SSI Prevention | Compliance with Best Practice, n/N (%) |
|---|---|
| Choice of prophylactic antibiotic(s) | 578/643 (90%) |
| Timing of prophylactic antibiotic(s) | 534/643 (83%) |
| Weight-based dose of prophylactic antibiotic(s) | 557/643 (87%) |
| Re-dosing of prophylactic antibiotic(s)[a] | 44/77 (57%) |
| Skin antisepsis with appropriate agent | 528/643 (82%) |
| Maintenance of perioperative normothermia | 467/643 (73%) |
| Operative and postoperative supplemental oxygen[b] | 89/503 (18%) |
| Postoperative glucose monitoring and control | 264/643 (41%) |
| Use of SSI prevention checklist | 195/643 (30%) |
| Prophylactic oral antibiotics and mechanical bowel preparation[c] | 28/217 (13%) |

[a]Analyzed for surgeries requiring re-dosing based on surgery duration and antibiotic chosen.

[b]Analyzed for surgeries requiring general anesthesia and mechanical intubation.

[c]Analyzed for colon surgeries.

# Maintenance of normothermia (≥35.5°C)

| Best Practice for SSI Prevention | Compliance with Best Practice, n/N (%) |
|---|---|
| Choice of prophylactic antibiotic(s) | 578/643 (90%) |
| Timing of prophylactic antibiotic(s) | 534/643 (83%) |
| Weight-based dose of prophylactic antibiotic(s) | 557/643 (87%) |
| Re-dosing of prophylactic antibiotic(s)[a] | 44/77 (57%) |
| Skin antisepsis with appropriate agent | 528/643 (82%) |
| Maintenance of perioperative normothermia | 467/643 (73%) |
| Operative and postoperative supplemental oxygen[b] | 89/503 (18%) |
| Postoperative glucose monitoring and control | 264/643 (41%) |
| Use of SSI prevention checklist | 195/643 (30%) |
| Prophylactic oral antibiotics and mechanical bowel preparation[c] | 28/217 (13%) |

[a]Analyzed for surgeries requiring re-dosing based on surgery duration and antibiotic chosen.

[b]Analyzed for surgeries requiring general anesthesia and mechanical intubation.

[c]Analyzed for colon surgeries.

# Supplemental O2: FiO2 ≥80% in OR and for 2-6 hours in PACU

| Best Practice for SSI Prevention | Compliance with Best Practice, n/N (%) |
|---|---|
| Choice of prophylactic antibiotic(s) | 578/643 (90%) |
| Timing of prophylactic antibiotic(s) | 534/643 (83%) |
| Weight-based dose of prophylactic antibiotic(s) | 557/643 (87%) |
| Re-dosing of prophylactic antibiotic(s)[a] | 44/77 (57%) |
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| Postoperative glucose monitoring and control | 264/643 (41%) |
| Use of SSI prevention checklist | 195/643 (30%) |
| Prophylactic oral antibiotics and mechanical bowel preparation[c] | 28/217 (13%) |

[a]Analyzed for surgeries requiring re-dosing based on surgery duration and antibiotic chosen.

[b]Analyzed for surgeries requiring general anesthesia and mechanical intubation.

[c]Analyzed for colon surgeries.

# Glucose control in first 24 hours after surgery:
## at least 1 glucose value was checked, and all values were ≤180 mg/dl

| Best Practice for SSI Prevention | Compliance with Best Practice, n/N (%) |
|---|---|
| Choice of prophylactic antibiotic(s) | 578/643 (90%) |
| Timing of prophylactic antibiotic(s) | 534/643 (83%) |
| Weight-based dose of prophylactic antibiotic(s) | 557/643 (87%) |
| Re-dosing of prophylactic antibiotic(s)[a] | 44/77 (57%) |
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| Use of SSI prevention checklist | 195/643 (30%) |
| Prophylactic oral antibiotics and mechanical bowel preparation[c] | 28/217 (13%) |

[a]Analyzed for surgeries requiring re-dosing based on surgery duration and antibiotic chosen.

[b]Analyzed for surgeries requiring general anesthesia and mechanical intubation.

[c]Analyzed for colon surgeries.

# SSI prevention checklist

| Best Practice for SSI Prevention | Compliance with Best Practice, n/N (%) |
|---|---|
| Choice of prophylactic antibiotic(s) | 578/643 (90%) |
| Timing of prophylactic antibiotic(s) | 534/643 (83%) |
| Weight-based dose of prophylactic antibiotic(s) | 557/643 (87%) |
| Re-dosing of prophylactic antibiotic(s)[a] | 44/77 (57%) |
| Skin antisepsis with appropriate agent | 528/643 (82%) |
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| Postoperative glucose monitoring and control | 264/643 (41%) |
| Use of SSI prevention checklist | 195/643 (30%) |
| Prophylactic oral antibiotics and mechanical bowel preparation[c] | 28/217 (13%) |

[a]Analyzed for surgeries requiring re-dosing based on surgery duration and antibiotic chosen.

[b]Analyzed for surgeries requiring general anesthesia and mechanical intubation.

[c]Analyzed for colon surgeries.

# Colon surgery: oral antibiotics and mechanical bowel prep

| Best Practice for SSI Prevention | Compliance with Best Practice, n/N (%) |
|---|---|
| Choice of prophylactic antibiotic(s) | 578/643 (90%) |
| Timing of prophylactic antibiotic(s) | 534/643 (83%) |
| Weight-based dose of prophylactic antibiotic(s) | 557/643 (87%) |
| Re-dosing of prophylactic antibiotic(s)[a] | 44/77 (57%) |
| Skin antisepsis with appropriate agent | 528/643 (82%) |
| Maintenance of perioperative normothermia | 467/643 (73%) |
| Operative and postoperative supplemental oxygen[b] | 89/503 (18%) |
| Postoperative glucose monitoring and control | 264/643 (41%) |
| Use of SSI prevention checklist | 195/643 (30%) |
| Prophylactic oral antibiotics and mechanical bowel preparation[c] | 28/217 (13%) |

[a]Analyzed for surgeries requiring re-dosing based on surgery duration and antibiotic chosen.

[b]Analyzed for surgeries requiring general anesthesia and mechanical intubation.

[c]Analyzed for colon surgeries.

# Compliance with best practices for SSI prevention

| Best Practice for SSI Prevention | Compliance with Best Practice, n/N (%) |
|---|---|
| Choice of prophylactic antibiotic(s) | 578/643 (90%) |
| Timing of prophylactic antibiotic(s) | 534/643 (83%) |
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| Skin antisepsis with appropriate agent | 528/643 (82%) |
| Maintenance of perioperative normothermia | 467/643 (73%) |
| Operative and postoperative supplemental oxygen[b] | 89/503 (18%) |
| Postoperative glucose monitoring and control | 264/643 (41%) |
| Use of SSI prevention checklist | 195/643 (30%) |
| Prophylactic oral antibiotics and mechanical bowel preparation[c] | 28/217 (13%) |

- **Surgeries resulting in SSI with at least 1 best practice deficiency: 638/643 (99%)**

# Compliance with best practices for SSI prevention

| Best Practice for SSI Prevention | Compliance with Best Practice, n/N (%) |
|---|---|
| Choice of prophylactic antibiotic(s) | 578/643 (90%) |
| Timing of prophylactic antibiotic(s) | 534/643 (83%) |
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| Postoperative glucose monitoring and control | 264/643 (41%) |
| Use of SSI prevention checklist | 195/643 (30%) |
| Prophylactic oral antibiotics and mechanical bowel preparation[c] | 28/217 (13%) |

- **Surgeries resulting in SSI with at least 1 best practice deficiency: 638/643 (99%)**
- **Surgeries resulting in SSI with at least 2 best practice deficiencies: 578/643 (90%)**

# Compliance with best practices for SSI prevention: Stratified by study arm

| Best Practice for SSI Prevention | Compliance with Best Practices Intervention Arm | Compliance with Best Practices Control Arm |
|---|---|---|
| Choice of prophylactic antibiotic(s) | 449/507 (89%) | 129/136 (95%) |
| Timing of prophylactic antibiotic(s) | 423/507 (83%) | 111/136 (82%) |
| Weight-based dose of prophylactic antibiotic(s) | 449/507 (89%) | 108/136 (79%) |
| Re-dosing of prophylactic antibiotic(s) | 38/65 (58%) | 6/12 (50%) |
| Skin antisepsis with appropriate agent | 408/507 (80%) | 120/136 (88%) |
| Maintenance of perioperative normothermia | 383/507 (76%) | 84/136 (62%) |
| Operative and postoperative supplemental oxygen | 77/420 (18%) | 12/83 (14%) |
| Postoperative glucose monitoring and control | 222/507 (44%) | 42/136 (31%) |
| Use of SSI prevention checklist | 151/507 (30%) | 44/136 (32%) |
| Prophylactic oral antibiotics and mechanical bowel preparation | 28/217 (13%) | --- --- |
| **Procedures with at least 1 best practice deficiency** | **504/507 (99%)** | 134/136 **(99%)** |
| **Procedures with 2 or more best practice deficiencies** | **458/507 (90%)** | 120/136 **(88%)** |

# Hospital Responses to Recommendations for SSI Prevention

- 97 SSI investigations led to formal written recommendations for SSI prevention
  - All recommendations followed in 21/97 (22%) of investigations
  - Some recommendations followed in 73/97 (75%) investigations

# Conclusions

- SPC surveillance detected many more important SSI rate increases than traditional surveillance.
- SSI investigations almost always revealed multiple deficiencies in SSI prevention best practices.

# Conclusions

- SPC surveillance detected many more important SSI rate increases than traditional surveillance.
- SSI investigations almost always revealed multiple deficiencies in SSI prevention best practices.
- SPC surveillance and feedback did not decrease SSI rates.
  - Disconnect between SSI cluster identification and key surgery personnel buy-in
  - Recommended interventions almost never followed with 100% compliance
- We need better strategies to improve the impact of SSI investigations and adherence to SSI prevention best practices.