Antibiotic Stewardship for the Newborn Population: Ample Opportunities for Improvement

October 29, 2020
ILPQC Annual Conference

Dmitry Dukhovny, MD MPH
Associate Professor of Pediatrics, Oregon Health & Science University
Co-leader, Northwest Neonatal Improvement Priority Alliance

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Disclosures

- Dr. Dukhovny served as faculty and consultant for Vermont Oxford Network
- Most antibiotics are not FDA approved for neonates

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Objectives

- To define what antibiotic stewardship means in the NICU
- To assess your NICU/hospital current practices with respect to antibiotic stewardship
- To identify and apply key resources available to build/enhance antibiotic stewardship programs

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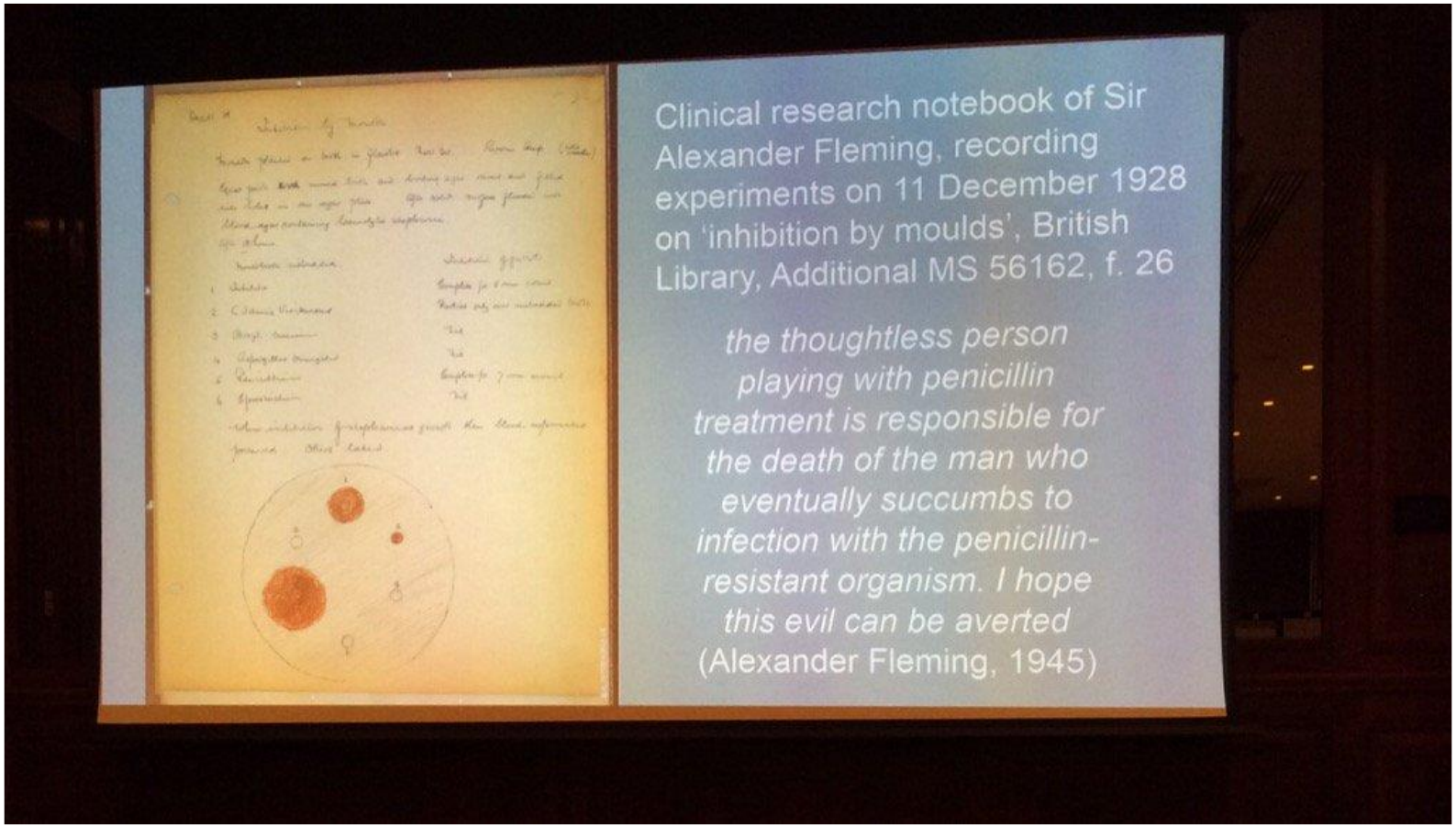

Alexander Flemming's note book from 1945 – twitter – Univ of Warwick

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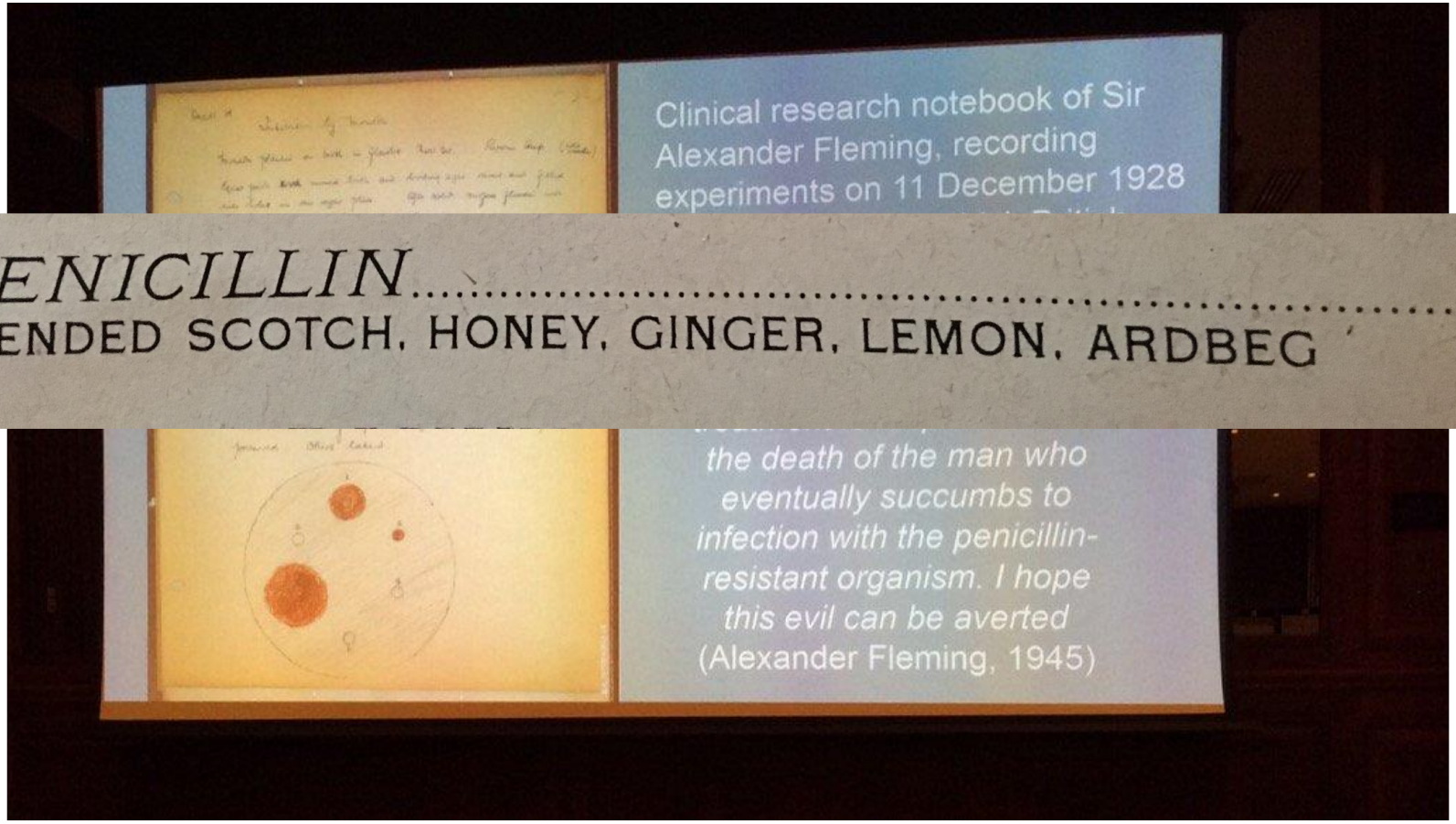

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Variation in antibiotic use in NICU

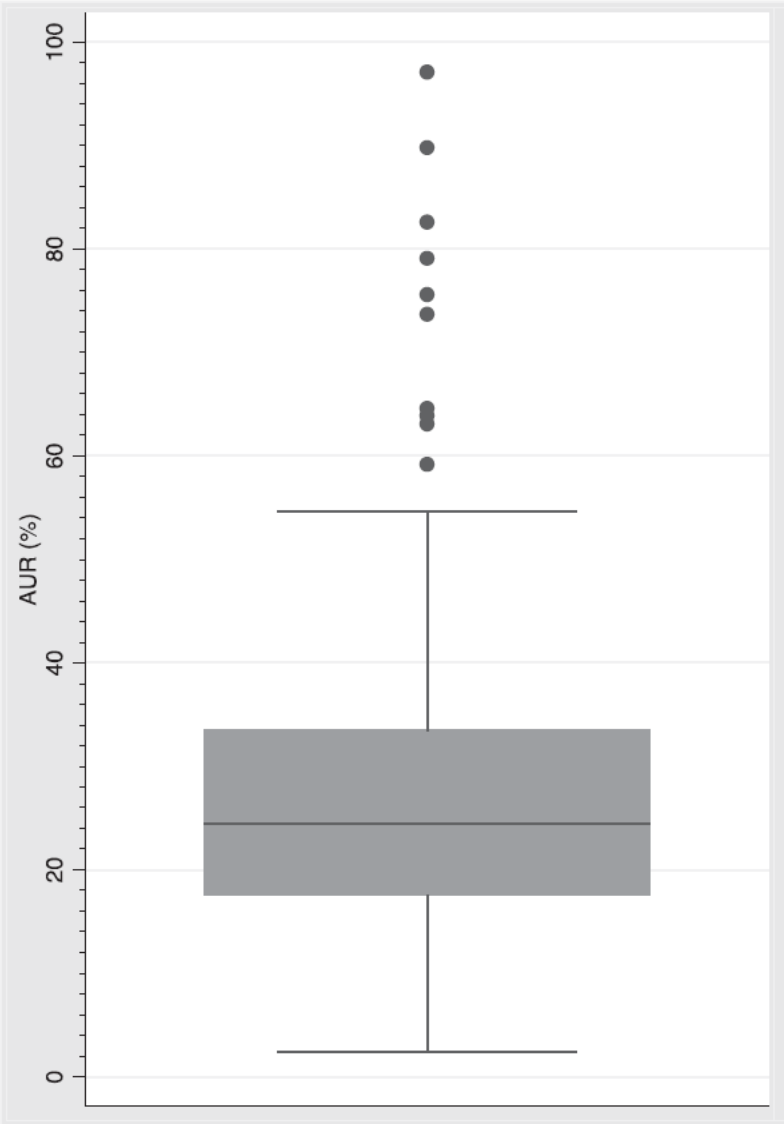

Figure 1 from Schulman et al. *Pediatrics* 2015.

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Antibiotic Stewardship

- "coordinated interventions designed to improve and measure the appropriate use of [antibiotic] agents by promoting the selection of the optimal [antibiotic] drug regimen, including dosing, duration of therapy, and route of administration" (PIDS, SHEA, IDSA)

- Many components to an Antibiotic Stewardship Program (ASP):
  - Right antibiotic
  - Right dose
  - Right duration
  - Right patient

- Some (many) patients are getting unnecessary exposure to antibiotics in the NICU
  - But…"Babies are sick and vulnerable to infection"

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Antibiotic Exposure in Well Appearing Newborns

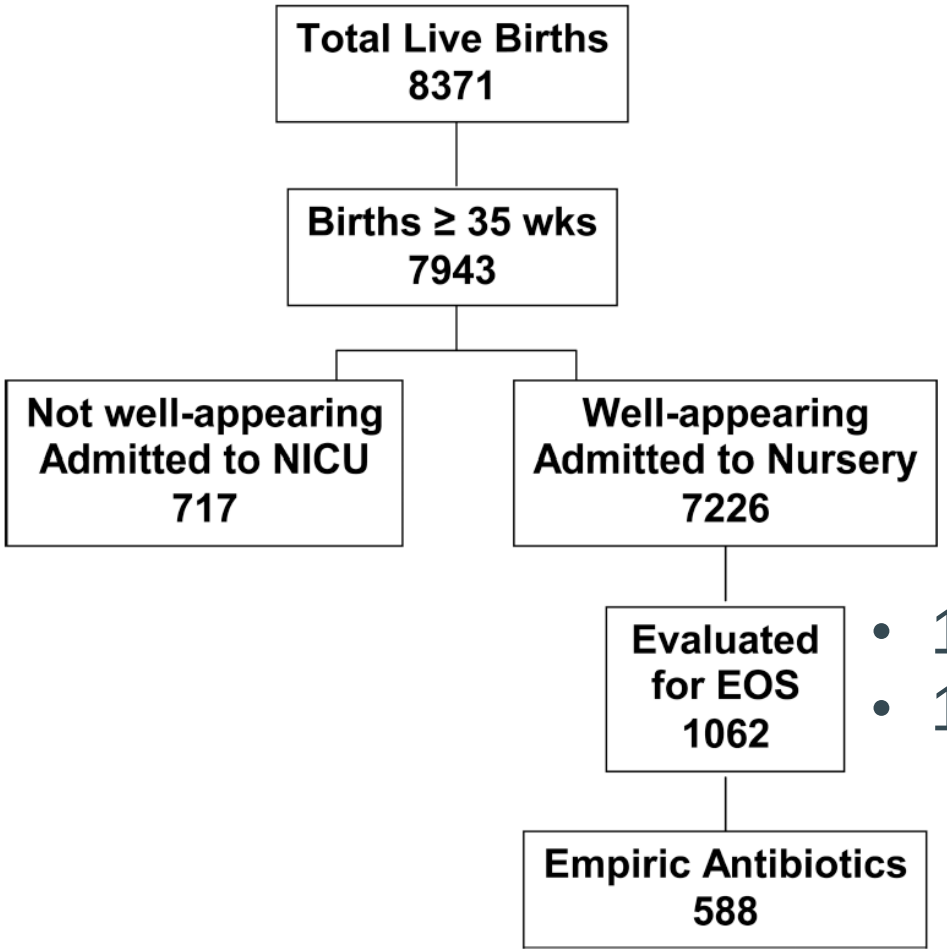

Figure 2. Study Population

- 14.7% of well appearing infants
- 12.7% of total live births

Figure 2 from Mukhopadhyay et al. *J. Perionatology* 2013

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Introduction of Early Onset Sepsis Risk Calculator (Kaiser) – Blood Cultures

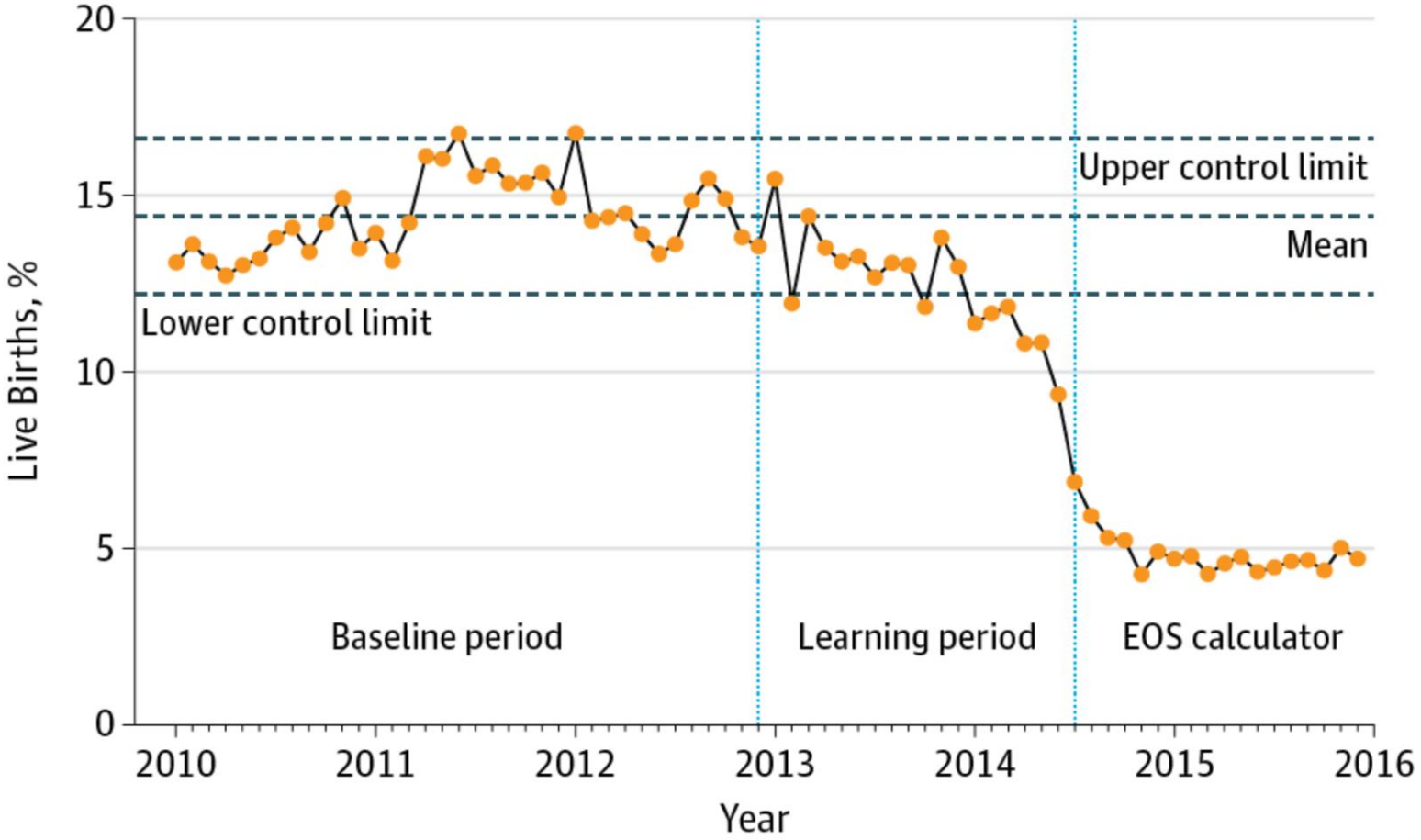

Figure 1 from Kuzniewicz et al. *JAMA Pediatrics*. 2017

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Introduction of Early Onset Sepsis Risk Calculator (Kaiser) – Antibiotics

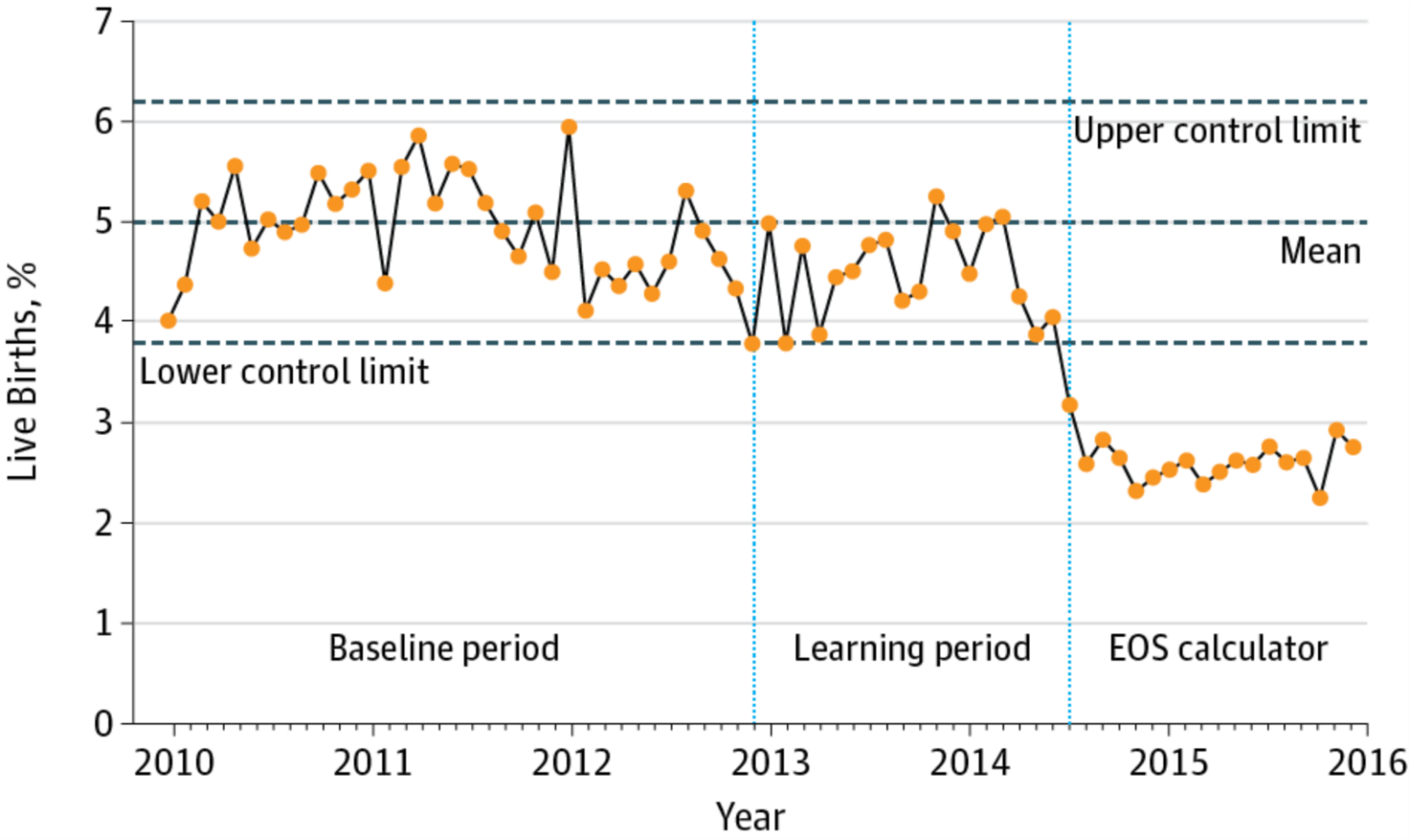

Figure 2 from Kuzniewicz et al. *JAMA Pediatrics*. 2017

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We Are Over-treating preemies: 22-28 weeks, NRN Study

Early Onset Sepsis Incidence: 0.5% 2.5%

TABLE 5 Antibiotic Use in Low-Risk and Comparison Infants Surviving >12 Hours

N (Column %) or as Shown	Low Risk of EOS, *N* = 5640	Comparison Group, *N* = 8422	*P*[a]
Antibiotics for ≥5 d starting within 72 h	1940 (34.4)	4106 (48.8)	<.001
Antibiotics in the absence of EOS	1911/5611 (34.1)	3897/8213 (47.4)	<.001
Antibiotics in the absence of positive EOS culture (cases and contaminants)[b]	1890/5590 (33.8)	3862/8177 (47.2)	<.001
Antibiotics in the absence of a positive blood or CSF culture result, NEC, or SIP ≤7 d[c]	1771/5334 (33.2)	3649/7752 (47.1)	<.001
No. infants given prolonged early antibiotics per EOS case	66	19	<.001

Table 5 from Puopolo et al. *Pediatrics*. 2017

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Variation Persists

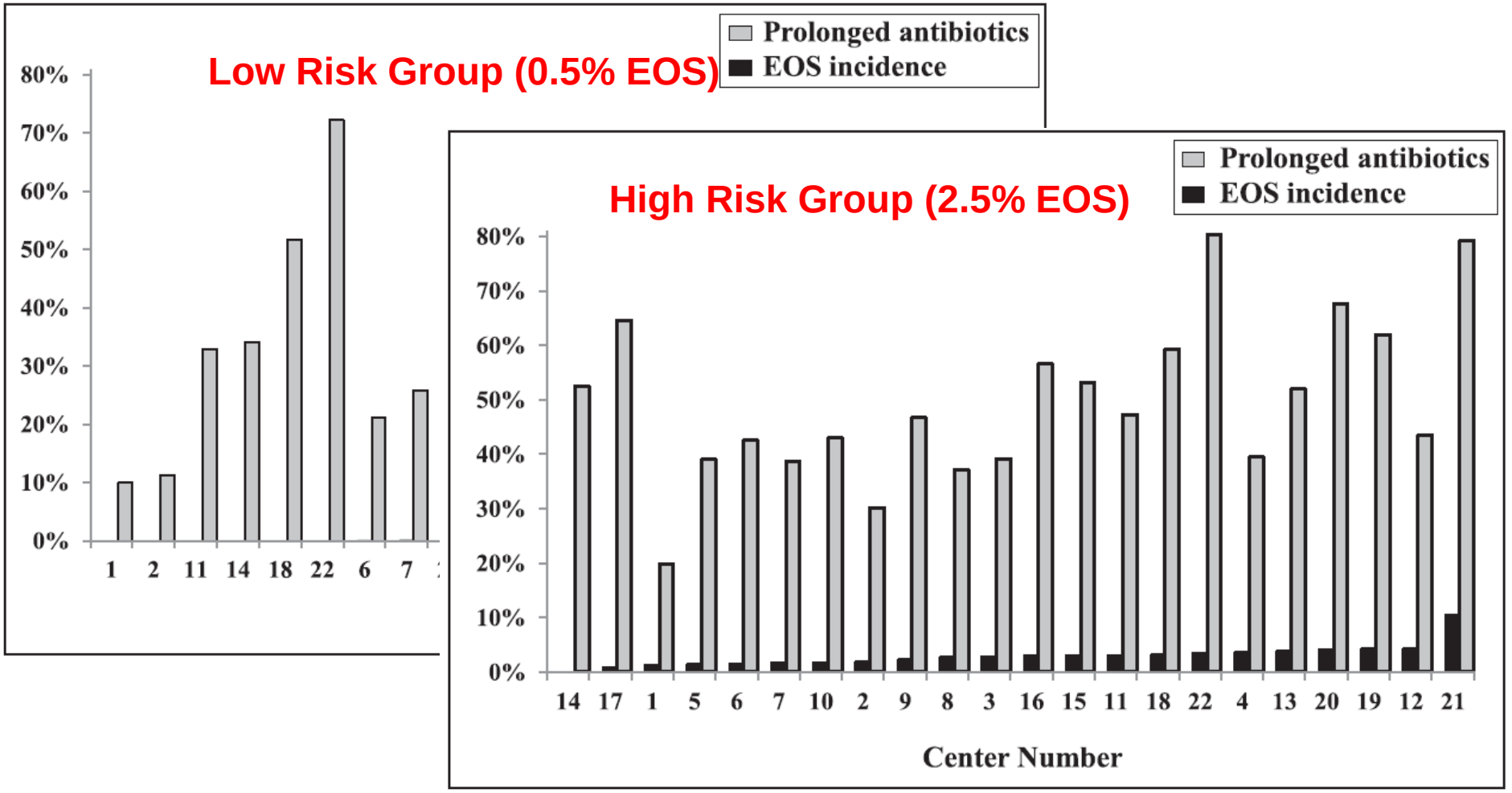

Figure 1 from Puopolo et al. *Pediatrics*. 2017

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What are the downsides to Antibiotics?

- Increasing resistant organisms - can be helped by modified use of antibiotics Marston et al. *JAMA* 2016
- NICU Problems:
  - NEC from prolonged empiric antibiotics Cotten et al. *Pediatrics* 2009

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Antibiotics and NEC in ELBWs

TABLE 5 Multivariate Logistic Regression Analysis of Antibiotic Duration and NEC or Death

Outcome	Duration of Initial Empirical Antibiotic Treatment (Odds per Day)		Prolonged Initial Empirical Antibiotic Treatment	
	OR (95% CI)	*P*	OR (95% CI)	*P*
NEC or death (total, $N = 3883$; with outcome, $n = 884$)	1.04 (1.02–1.06)	<.01	1.30 (1.10–1.54)	<.01
NEC (total, $N = 3899$; with outcome, $n = 427$)	1.07 (1.04–1.10)	<.001	1.21 (0.98–1.51)	.08
Death (total, $N = 3882$; with outcome, $n = 631$)	1.16 (1.08–1.24)	<.001	1.46 (1.19–1.78)	<.001

ORs were adjusted for study center, gestational age, small-for-gestational age status, gender, black race, 5-minute Apgar score of <5, rupture of membranes for >24 hours, outborn, prenatal steroid treatment, intrapartum antibiotic treatment, maternal hypertension, maternal hemorrhage, and multiple birth. The total numbers of infants shown represent the numbers of infants with nonmissing outcome and covariate data who were included in each model.

Table 5 from Cotten et al. *Pediatrics* 2009

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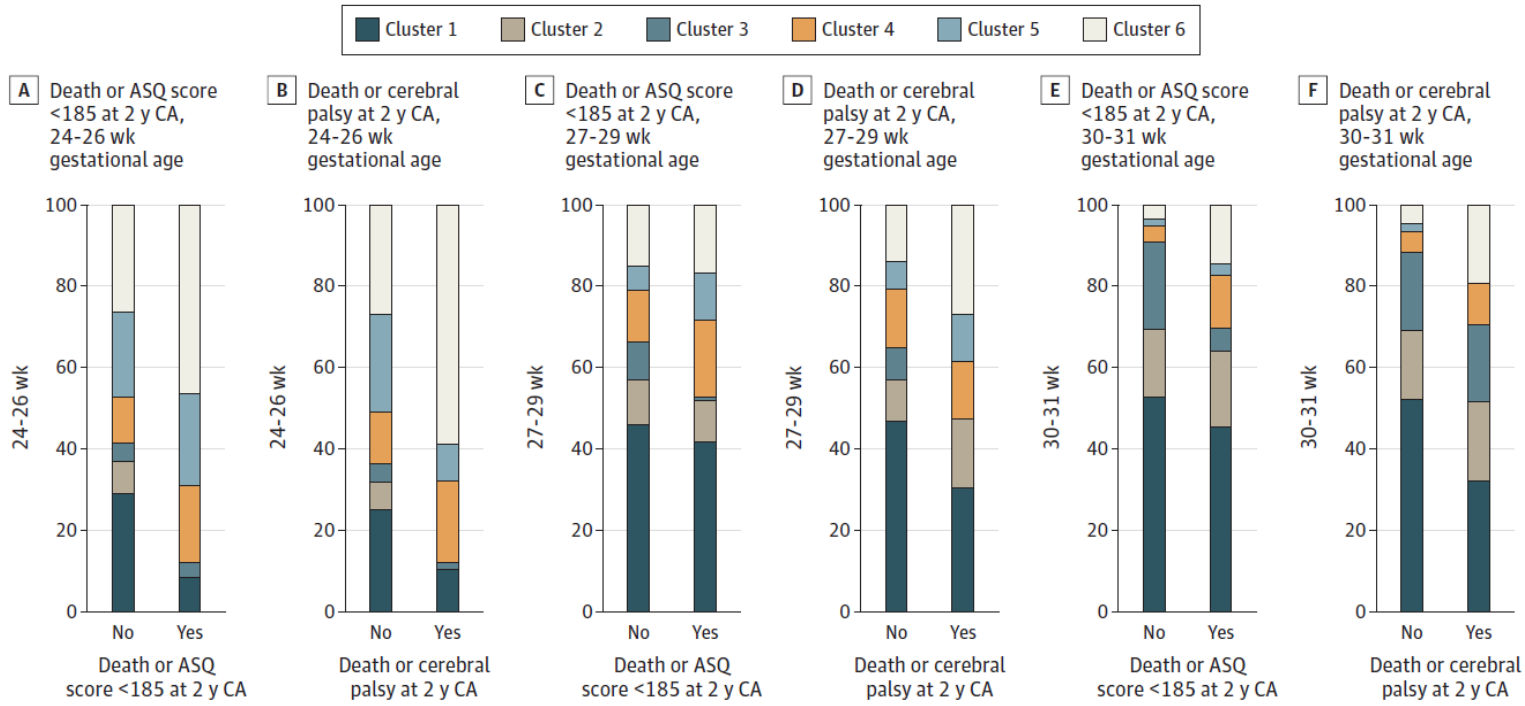
Microbiome and Neurodevelopment

Figure 3. Repartition of Microbiota Clusters According to Gestational Age and 2-Year Outcome



CONCLUSIONS AND RELEVANCE Gut microbiota of very preterm newborns at week 4 is associated with NICU practices and 2-year outcomes. Microbiota could be a noninvasive biomarker of immaturity.

Figure 3 from Roze et al JAMA OPEN Network 3 (9); 2020

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What's the downside to Antibiotics?

- Increasing resistant organisms - can be helped by modified use of antibiotics Marston et al. *JAMA* 2016
- NICU Problems:
  - NEC from prolonged empiric antibiotics Cotten et al. *Pediatrics* 2009
  - Change individual AND NICU flora (resistance)
  - Long term effects?
  - COSTS!!!

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EXHIBIT 3

Characteristics of bacterial infections in the study sample with and without antibiotic resistance

		Infections without antibiotic resistance ($n = 12,766,374$), mean	Infections with antibiotic resistance ($n = 1,232,541$), mean	p value[a]
Expenditures				
Office based		[illegible]	[illegible]	[illegible]
Emergency department		132	250	0.001
Prescription drugs		96	305	0.017
Outpatient		77	114	0.288
Home health		68	181	0.068
2011	14,563,893	1,201,543		
2012	11,786,935	1,229,999		
2013	12,881,578	1,225,623		
2014	14,290,029	1,568,221		
Yearly average, 2002–14	13,998,915	1,232,541		

$2.2 Billion Dollars (2014) attribute to infections with antibiotic resistance

Thorpe et al. *Health Affairs* 2018

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NATIONAL ACTION PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA

2020-2025

October 2020

From the Federal Task Force on
Combating Antibiotic-Resistant Bacteria

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What's the downside to Antibiotics?

- Increasing resistant organisms - can be helped by modified use of antibiotics Marston et al. *JAMA* 2016
- NICU Problems:
  - NEC from prolonged empiric antibiotics Cotten et al. *Pediatrics* 2009
  - Change individual AND NICU flora (resistance)
  - Long term effects?
  - COSTS!!!
- Asthma risk with exposure in the 1st year of life Mara et al. *Pediatrics* 2009
- Mitigate benefits of breastfeeding Korpela et al *JAMA Peds* 2016
- 90% of adult patients with cancer receive antibiotics in last week of life Juthani-Mehta et al *JAMA* (viewpoint) 2016

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Reducing Unnecessary Antibiotic Exposure Works!

- Vancomycin reduction strategy in the NICU Chiu et al *PIDJ* 2011
- Inpatient pediatrics ASP programs Smith et al. *JPIDS* 2015
  - Reduce antibiotic utilization
  - Decrease costs
  - Reduce prescribing errors
- ASP implementation using different components Nguyen-Ha et al *Pediatrics* 2016
  - Education
  - Restriction on prescribing antibiotics
  - Audits
  - Clinical practice guidelines
- No increased safety concerns noted

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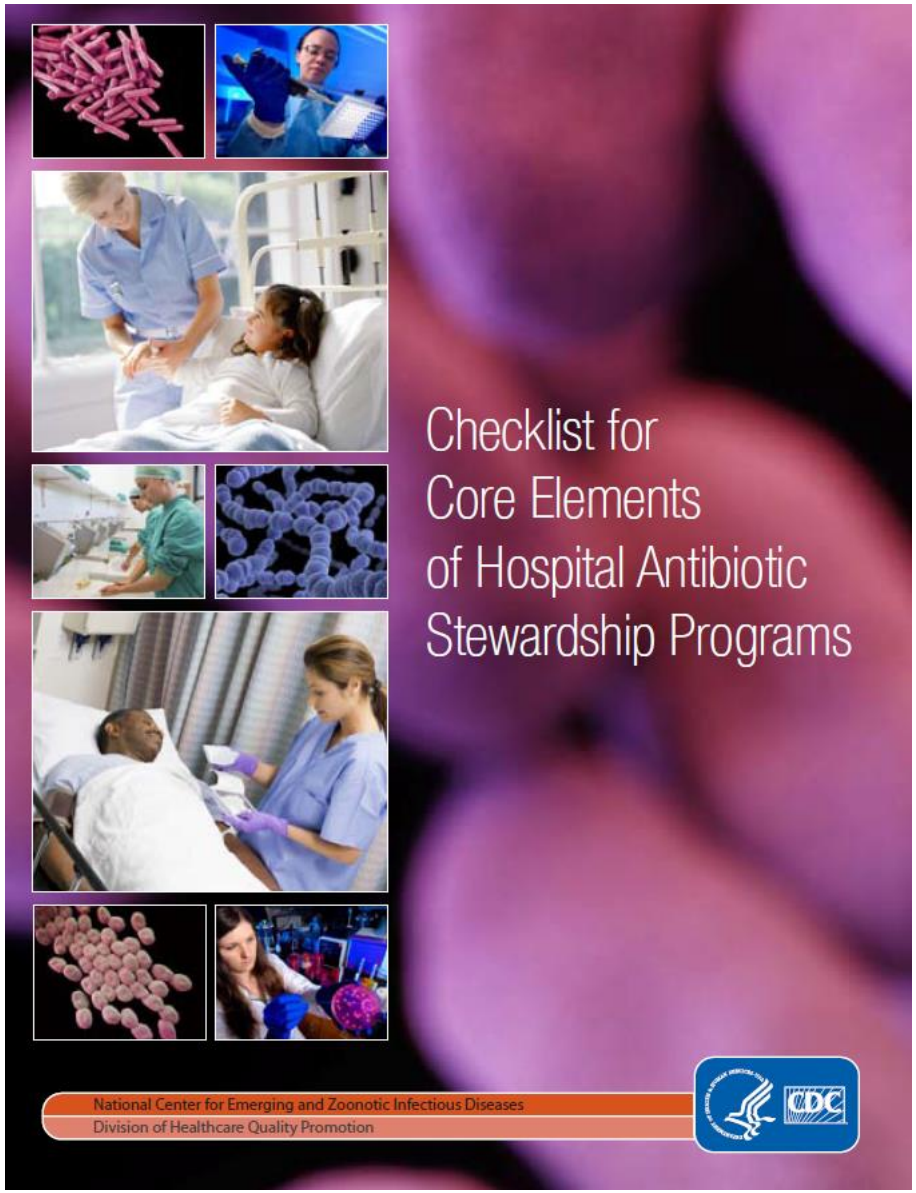
CDC Core Elements for ASP



- Leadership support
- Accountability
- Drug expertise (i.e. pharmacy/physician leaders)
- Policies to support optimal antibiotic use (i.e. clinical consensus)
- Tracking
- Reporting/Sharing
- Education

- Family Engagement
- Equity

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VON Initiative: *Choosing* Antibiotics *Wisely*

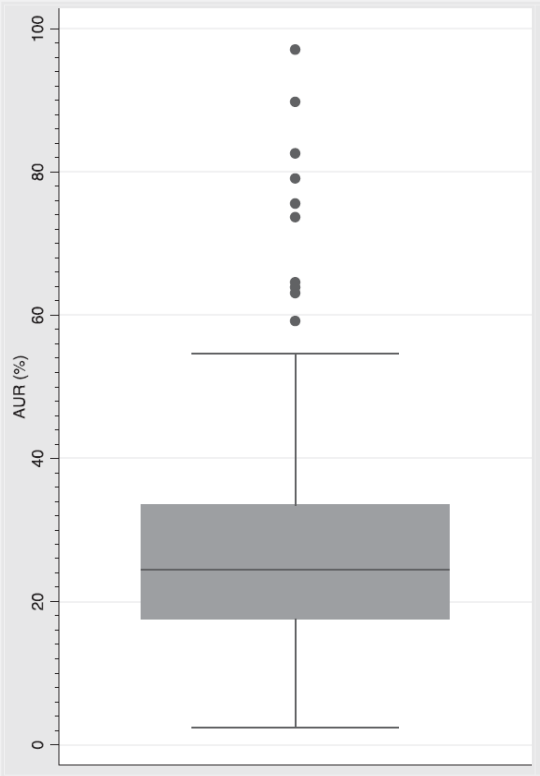

Figure 1 from Schulman et al. *Pediatrics* 2015

Choosing Wisely®

An initiative of the ABIM Foundation

- Avoid routine continuation of antibiotic therapy beyond 48 hours for initially asymptomatic infants without evidence of bacterial infection.

- Avoid routine screening term-equivalent or discharge brain MRIs in preterm infants.
- Avoid routine daily chest radiographs without an indication for intubated infants.
- Avoid routine use of pneumograms for pre-discharge assessment of ongoing and/or prolonged apnea of prematurity.
- Avoid routine use of anti-reflux medications for treatment of symptomatic gastroesophageal reflux disease (GERD) or for treatment of apnea and desaturation in preterm infants.

Ho et al. *Pediatrics* 2015

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Brazil
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Chile
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Finland
Germany
Ireland
Israel
Italy
Kuwait
Malaysia
Mexico
Namibia
Netherlands
Northern Ireland
Portugal
Qatar
Romania
Saudi Arabia
Scotland
Singapore
Slovenia
South Africa
Spain
Switzerland
Taiwan
Turkey
United Arab Emirates
Wales

Over 1300 members

Slide modified and shared with permission from VON

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iNICQ Choosing Antibiotics Wisely 2016, 2017, 2018

- Webinars (6-9/year)
  - Topic content
  - QI content
  - Coaching
- Antibiotic Stewardship Toolkit
  - Potentially better practices
- Day audits of policies/stewardship/practice (2/year)
- On the ground team work
- Network of learning
  - Web based
  - Discussion list-serve

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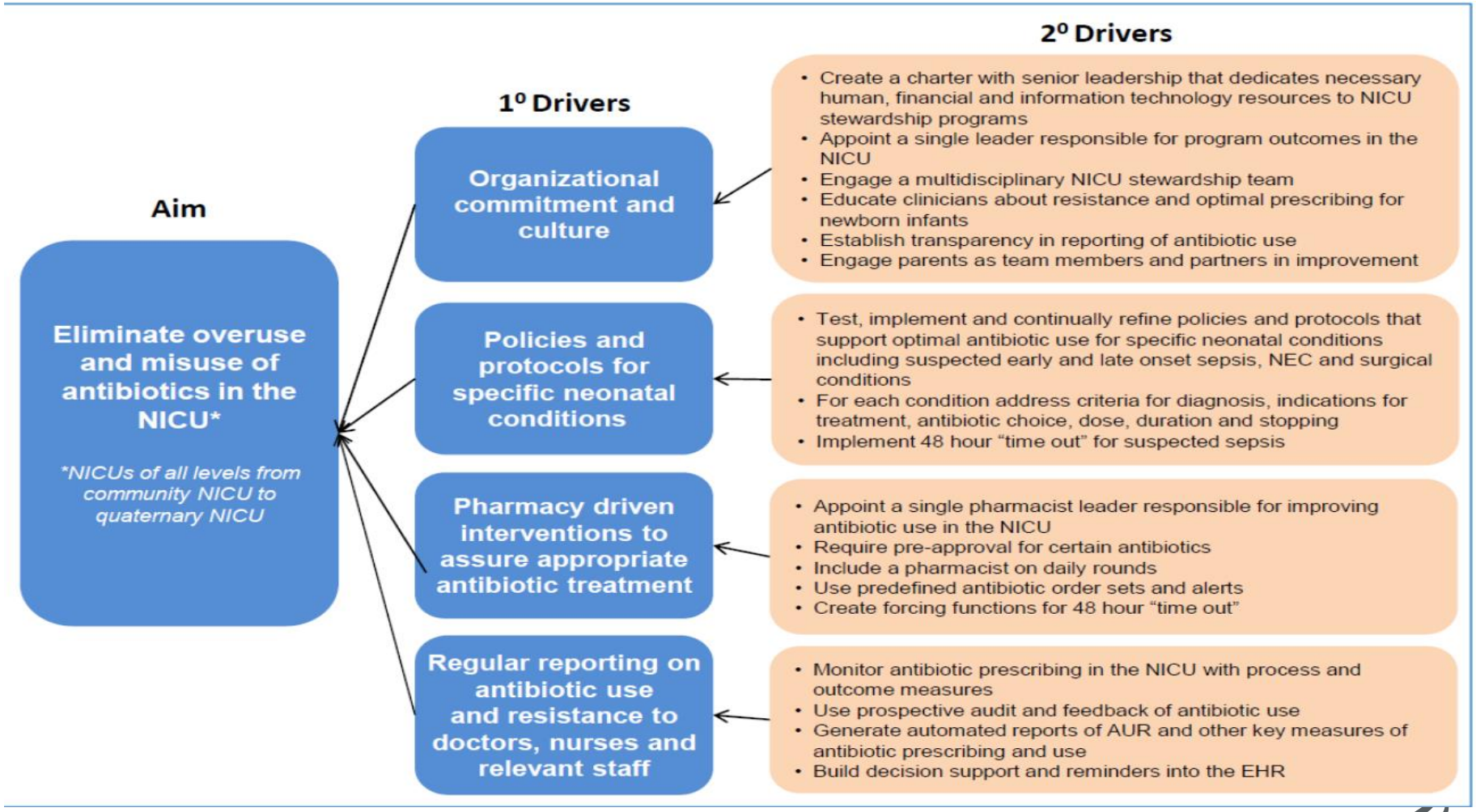
Goals of being part of iNICQ

- Different for every center
- Follow the Institute for Health Care Improvement (IHI) Model for Improvement to do on the ground, multi-disciplinary work
- Participating centers have a range of expertise doing QI work

VON iNICQ Key Driver Diagram



Starting Point

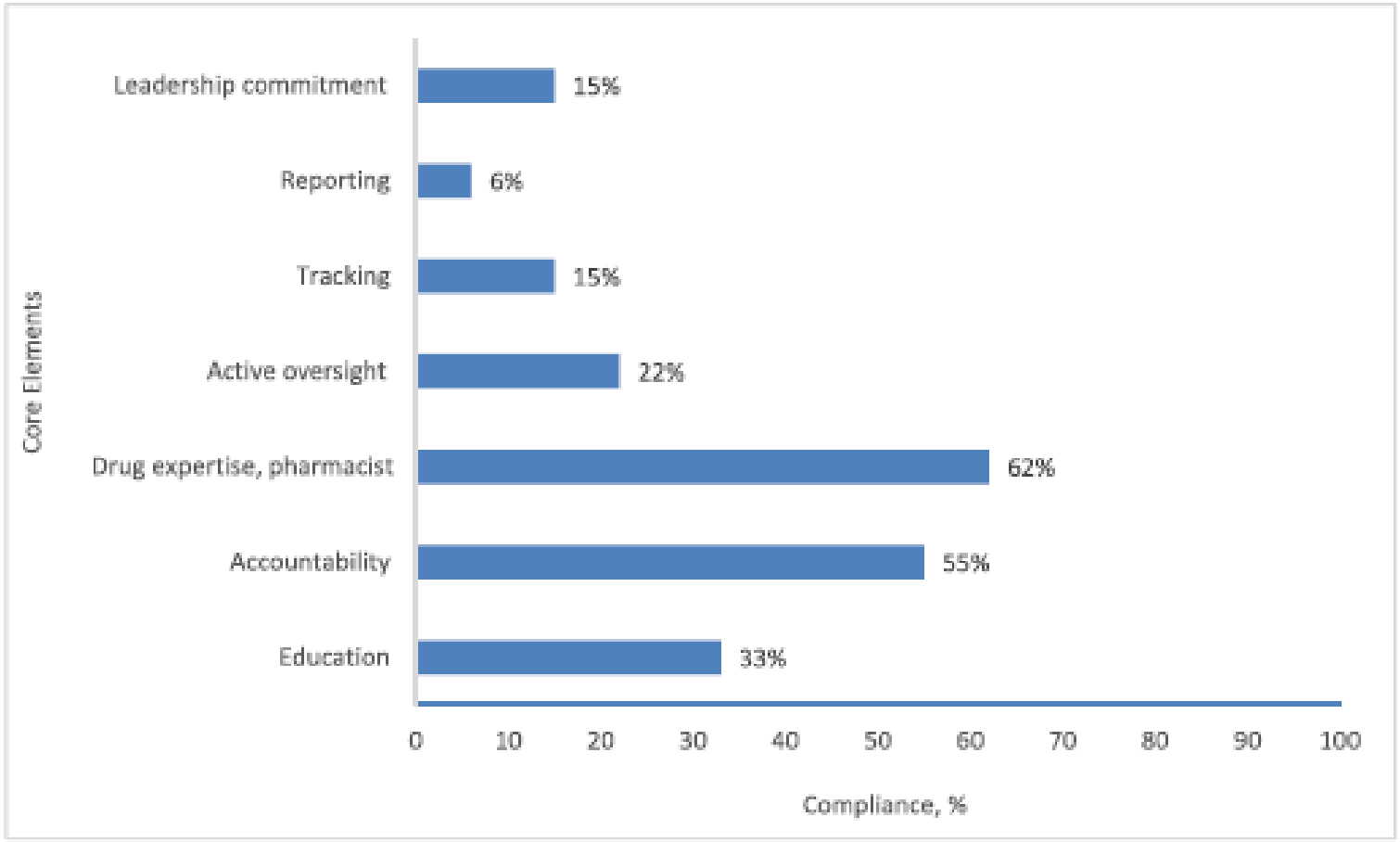


FIGURE 1
Percent compliance with the CDC's Core Elements of Hospital ASPs among 143 NICUs.

Ho et al. *Pediatrics* 142 (6) Dec 2018

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iNICQ Collaborative Progress

TABLE 2 CDC Core Elements of ASPs Among Participating NICUs Across the 4 Audits

	February 2016 (*N* = 143)	November 2016 (*N* = 137)	February 2017 (*N* = 146)	November 2017 (*N* = 141)	*P*
	%	%	%	%	
Leadership commitment	15.4	51.1	60.3	68.8	<.0001
Accountability	54.5	89.1	89.7	95.0	<.0001
Drug expertise	61.5	85.4	83.6	85.1	<.0001
Time out	21.7	56.9	61.6	72.3	<.0001
Tracking	14.7	68.6	63.7	78.0	<.0001
NHSN reporting	6.3	13.1	14.4	17.7	.0046
Ongoing education	32.9	73.0	75.3	87.2	<.0001
All of the above	0	5.8	5.5	9.9	.0005

The table shows the percent of NICUs that participated in 1 or more of the VON Day Audits that met each of the core CDC elements of antibiotic stewardship. *N* refers to the number of individual NICUs that participated in each audit.

Dukhovny et al. *Pediatrics* 144 (6) Dec 2019

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VON Day Audit

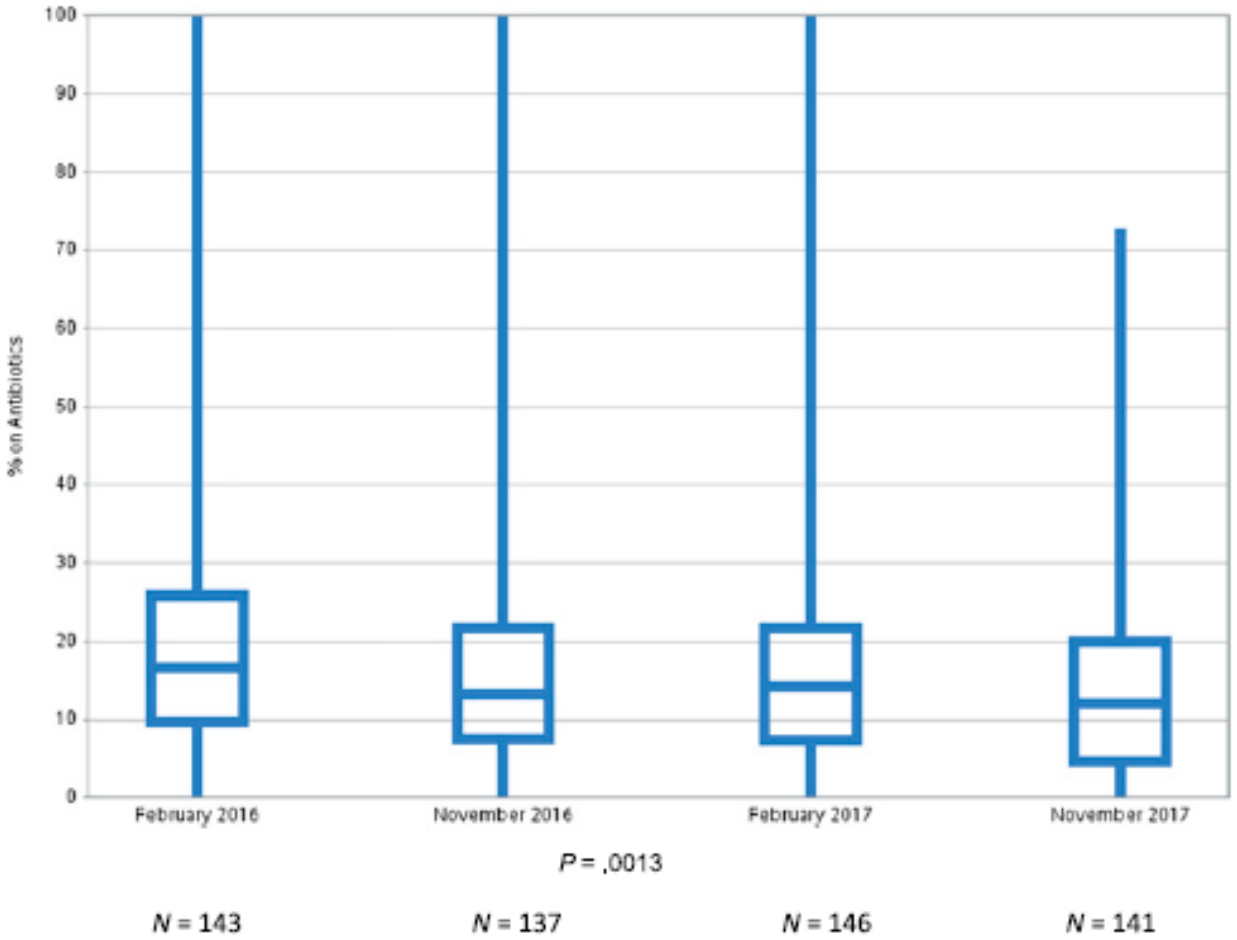

FIGURE 1

NICU AUR among participating NICUs across the 4 audits. The box and whiskers plot represents the median (solid line), interquartile range (box) and lowest to highest values for each of the four audits. The p-value represents the Cochrane-Armitage test for trend.

Dukhovny et al. *Pediatrics* 144 (6) Dec 2019

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PBP: Policies and Protocols for specific Neonatal Conditions

TABLE 3 Percent of NICUs With Policies, Protocols, or Guidelines To Standardize the Diagnosis and Antibiotic Treatment of Common Neonatal Conditions

	February 2016 (*N* = 143)	November 2017 (*N* = 141)
	%	%
Maternal risk factors,	53.1	71.6
Suspected or proven		
Early-onset sepsis or meningitis	44.8	73.8
Late-onset sepsis or meningitis	32.9	50.4
Ventilator-associated pneumonia	13.3	27.7
Central venous line infection	30.8	48.9
Urinary tract infection	14.0	34.0
Necrotizing enterocolitis	31.5	44.7
Surgical site infection	9.8	19.1
Prophylaxis for urinary tract infection	19.6	30.5
Prophylaxis for surgery	25.2	27.7
Prophylaxis for fungal sepsis	35.0	40.4
MRSA colonization	43.4	51.1

The table shows the percent of NICUs that participated in 1 or more of the VON Day Audits that had a policy, protocol, and/or guideline for 1 of the listed common neonatal conditions. *N* refers to the number of NICUs that participated in the respected audit.

Dukhovny et al. *Pediatrics* 144 (6) Dec 2019

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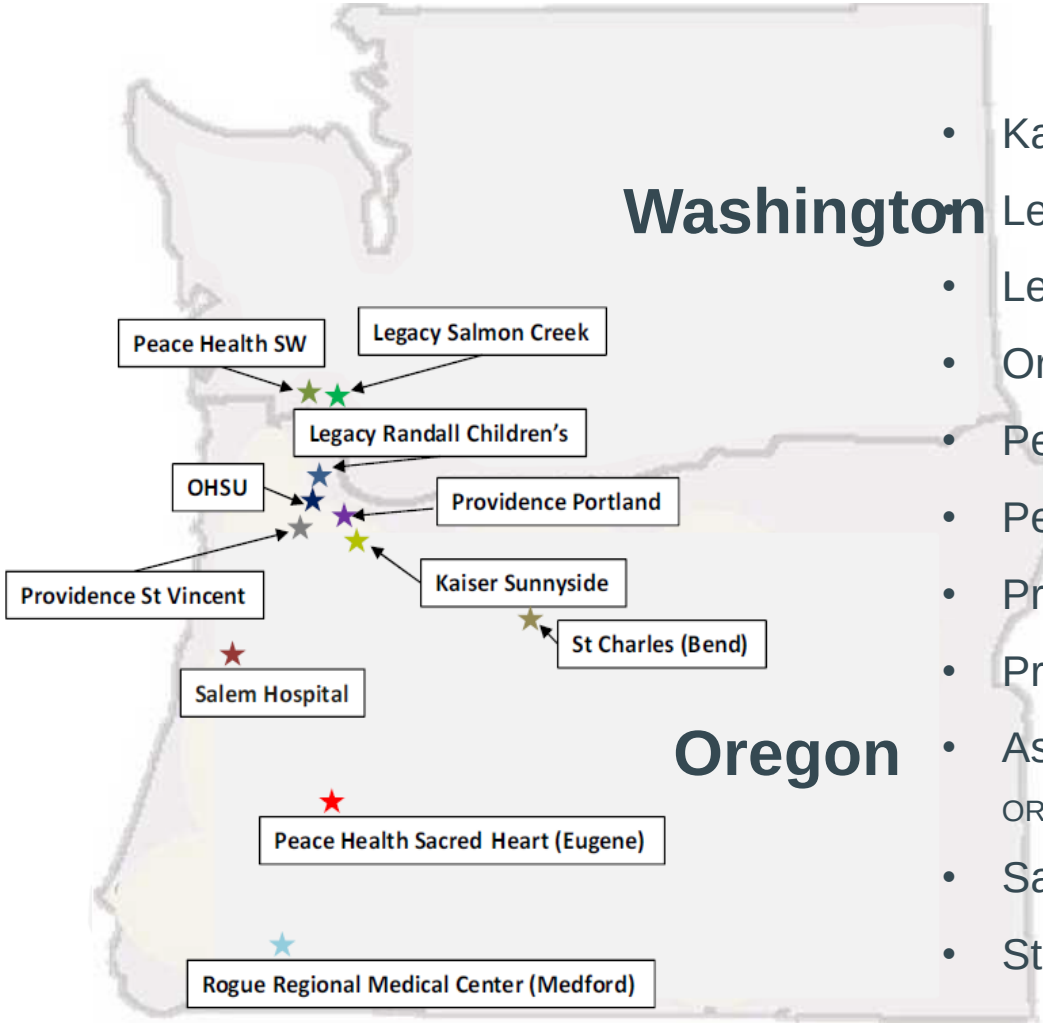
Northwest Improvement Priority: Antibiotic Stewardship (NW IPAs)



- Kaiser Sunnyside Portland, OR
- Legacy Randall Children's Hospital Portland, OR
- Legacy Salmon Creek Salmon Creek, WA
- Oregon Health & Science University Portland, OR
- Peace Health Southwest Vancouver, WA
- Peace Health Sacred Heart Eugene, OR
- Providence Portland Portland, OR
- Providence St. Vincent Portland, OR
- Asante Rogue Regional Medical Center Medford, OR
- Salem Hospital Salem, OR
- St. Charles Bend, OR

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NWIPA

Northwest Neonatal
Improvement Priority Alliance

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Who are the NW IPAs?

- ALL 11 NICUs in Oregon and Southwest Washington
  - the remaining hospitals/birthing centers in the region provide care to well newborns, as well as triage and stabilize newborns with issues
- ~50,000 live births/year regionally
- All hospitals are members of VON

NWIPA
Northwest Neonatal Improvement Priority Alliance

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Overall Aims

- Build an ongoing regional collaboration among the 11 NICUs in the region in order to help reduce morbidity and mortality in our patient population

- Develop a partnership with the Oregon Health Authority (OHA), March of Dimes, Oregon Perinatal Collaborative (OPC) and other local/regional organizations to help optimize neonatal care and outcomes

NWIPA
Northwest Neonatal Improvement Priority Alliance

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Antibiotic Stewardship SMART AIM

- Decrease the number of antibiotic doses per newborn per NICU per month by 10% (from baseline) by December 2016

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Northwest Neonatal Improvement Priority Alliance

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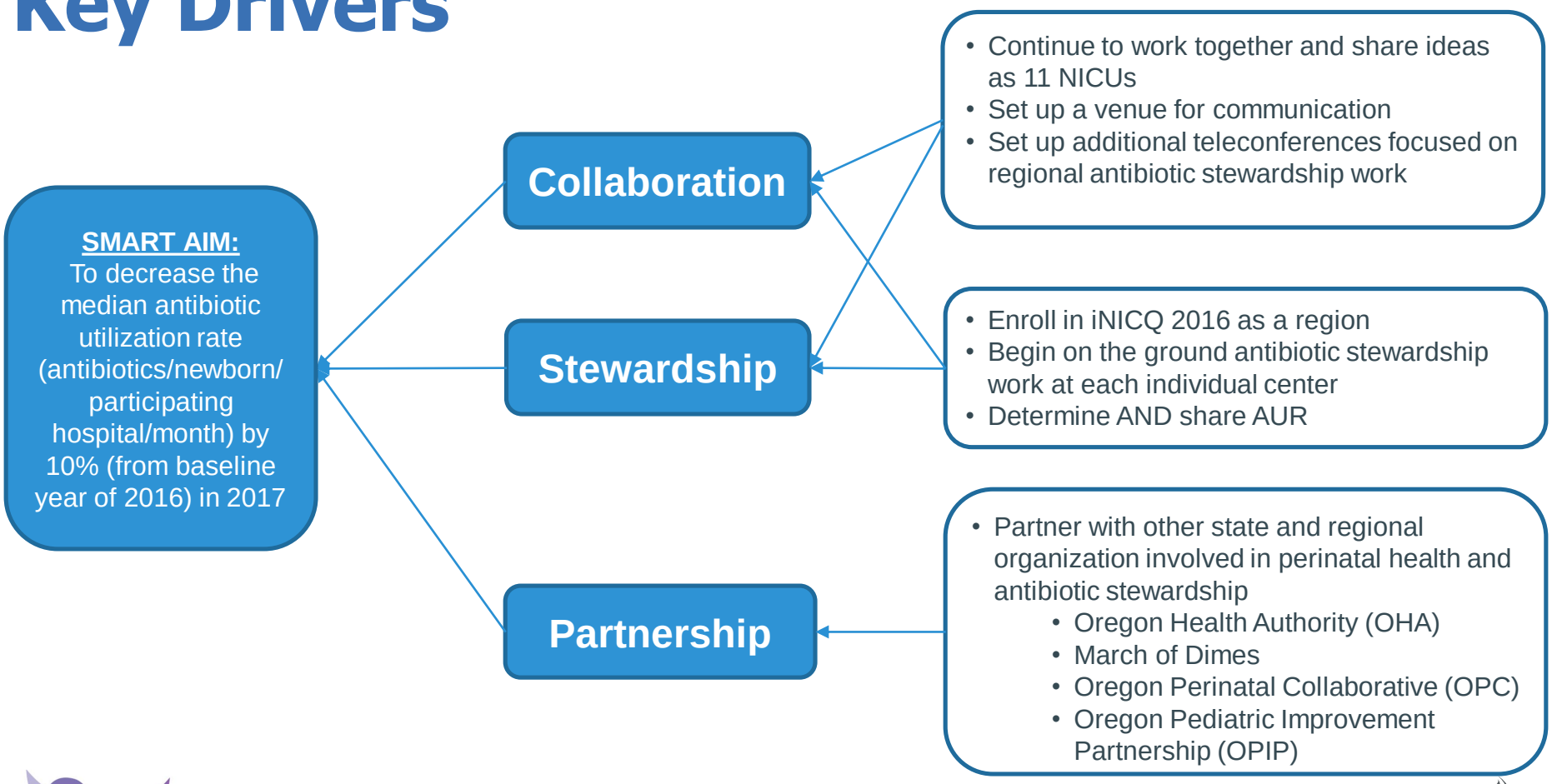
Key Drivers



NWIPA
Northwest Neonatal Improvement Priority Alliance

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Practically Speaking…

- Every NICU in the NW IPAs were tasked with:
  - Joining the VON Collaborative
  - Putting together a local multi-disciplinary antibiotic stewardship team
  - Developing a SMART Aim
  - Starting PDSA cycles to decrease their unnecessary antibiotic utilization
  - Participate in NW IPAs activities
  - Determine/share their Antibiotic Utilization Rate (AUR)* with NW IPAs

- NW IPA Leadership:
  - Organization and structure for collaborative QI
  - Coaching to the teams

NWIPA
Northwest Neonatal Improvement Priority Alliance

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*CDC definition of antibiotic days per 1,000 patient days

Results

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Northwest Neonatal Improvement Priority Alliance

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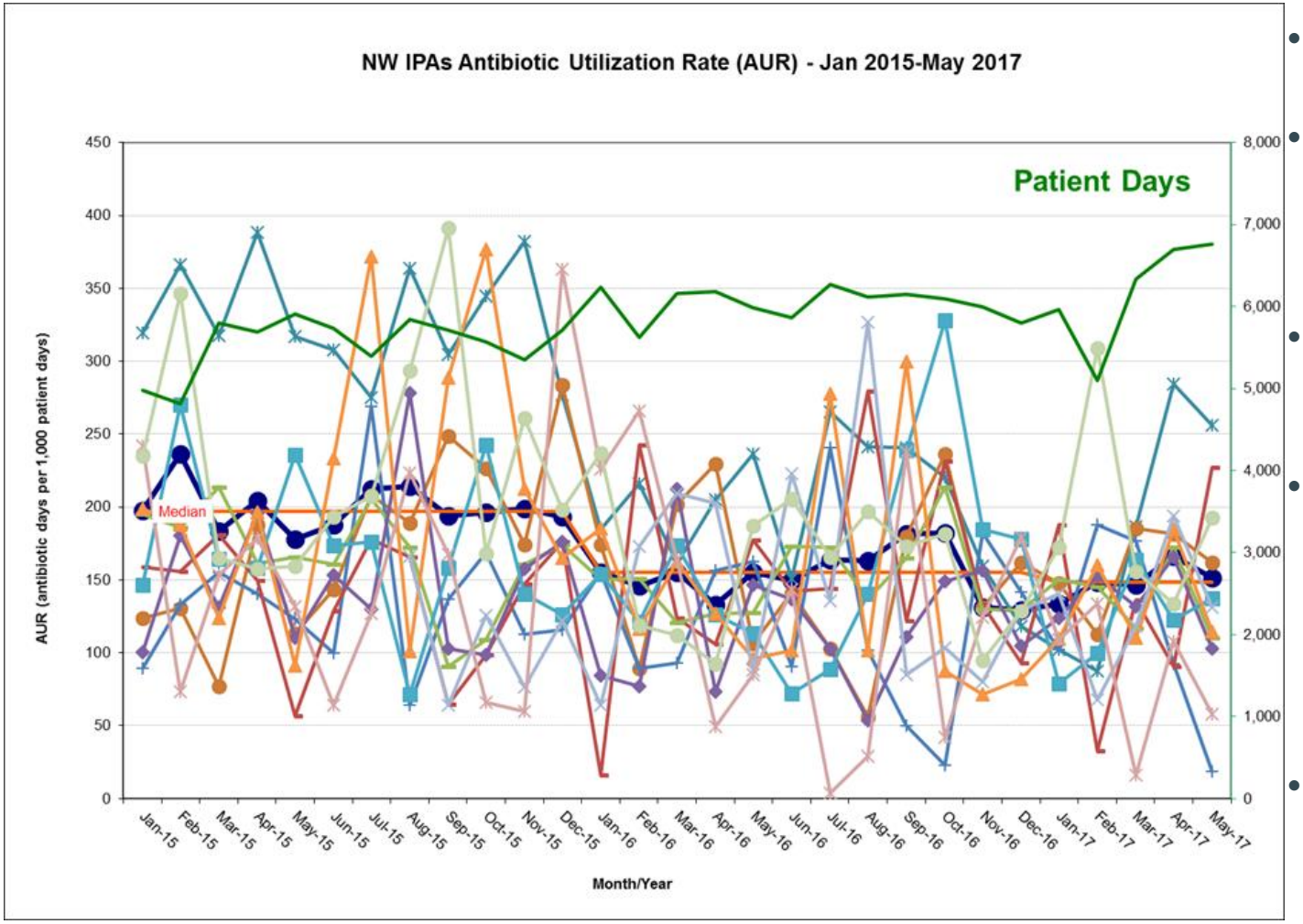
Individual AURs for NW IPA Centers: Jan 2015 – May 2017



- Y-axis (left) – AUR
- Y-axis (right) – total patient days for NW IPAs
- X-axis – month/year
- Thick dark blue line- combined AUR of participating centers in NW IPAs
- Individual lines – NW IPAs individual centers monthly AUR

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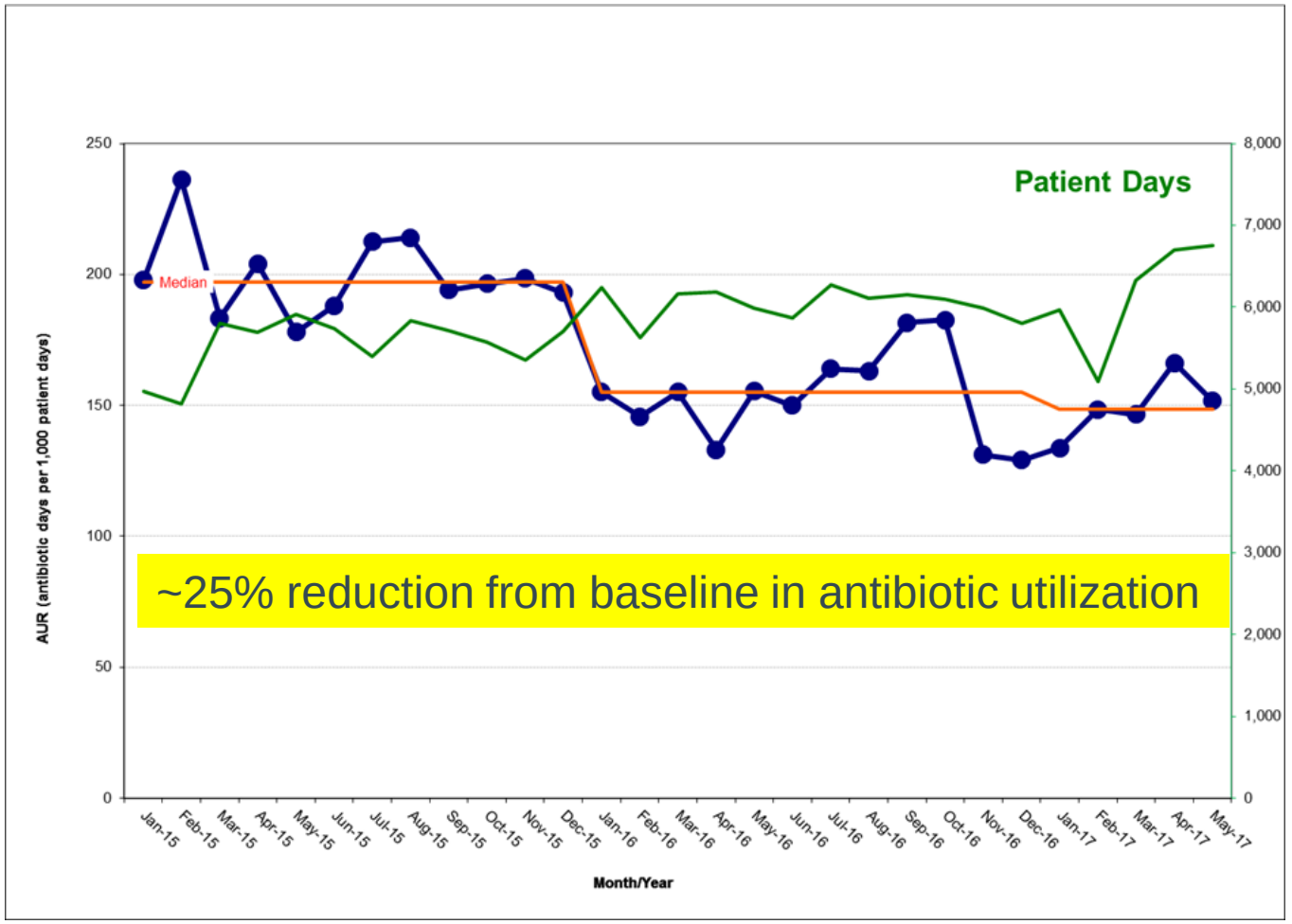
Combined AUR for NW IPAs: Jan 2015 – May 2017



- Y-axis (left) – AUR
- Y-axis (right) – total patient days for NW IPAs
- X-axis – month/year
- Thick dark blue line – combined AUR for NW IPAs

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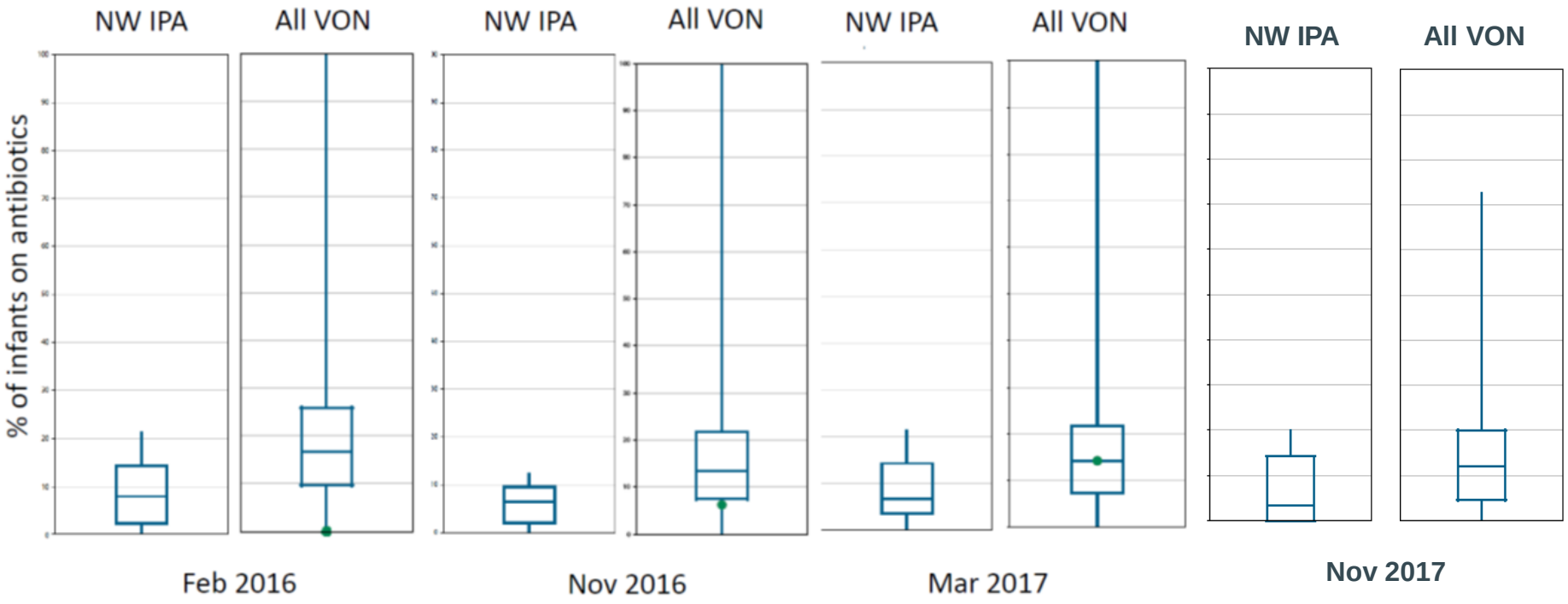
VON Day Audit



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Sample Report Sent to Each Center

(along with excel template) :

NW IPAs AUR Report

Oregon Health & Science University

January 2015-December 2016

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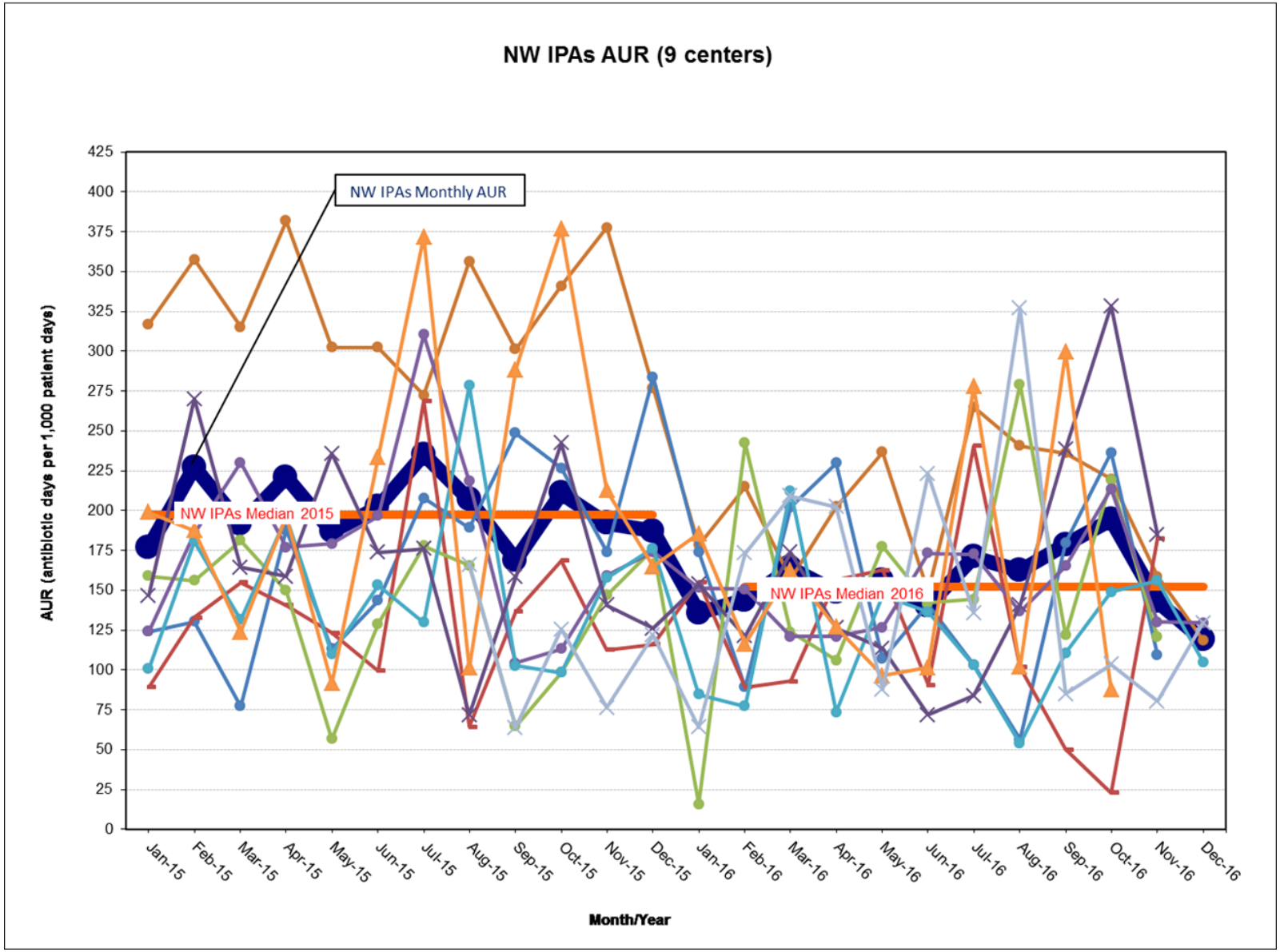

AUR of 9 out of the 11 centers in the NW IPAs from January 2015-December 2016
Notes: (a) 1 center only started data collection in August 2015; (b) only 4 centers have data through December 2016
The thick dark blue line represents the overall AUR for all the centers reporting (NW IPAs Monthly AUR)

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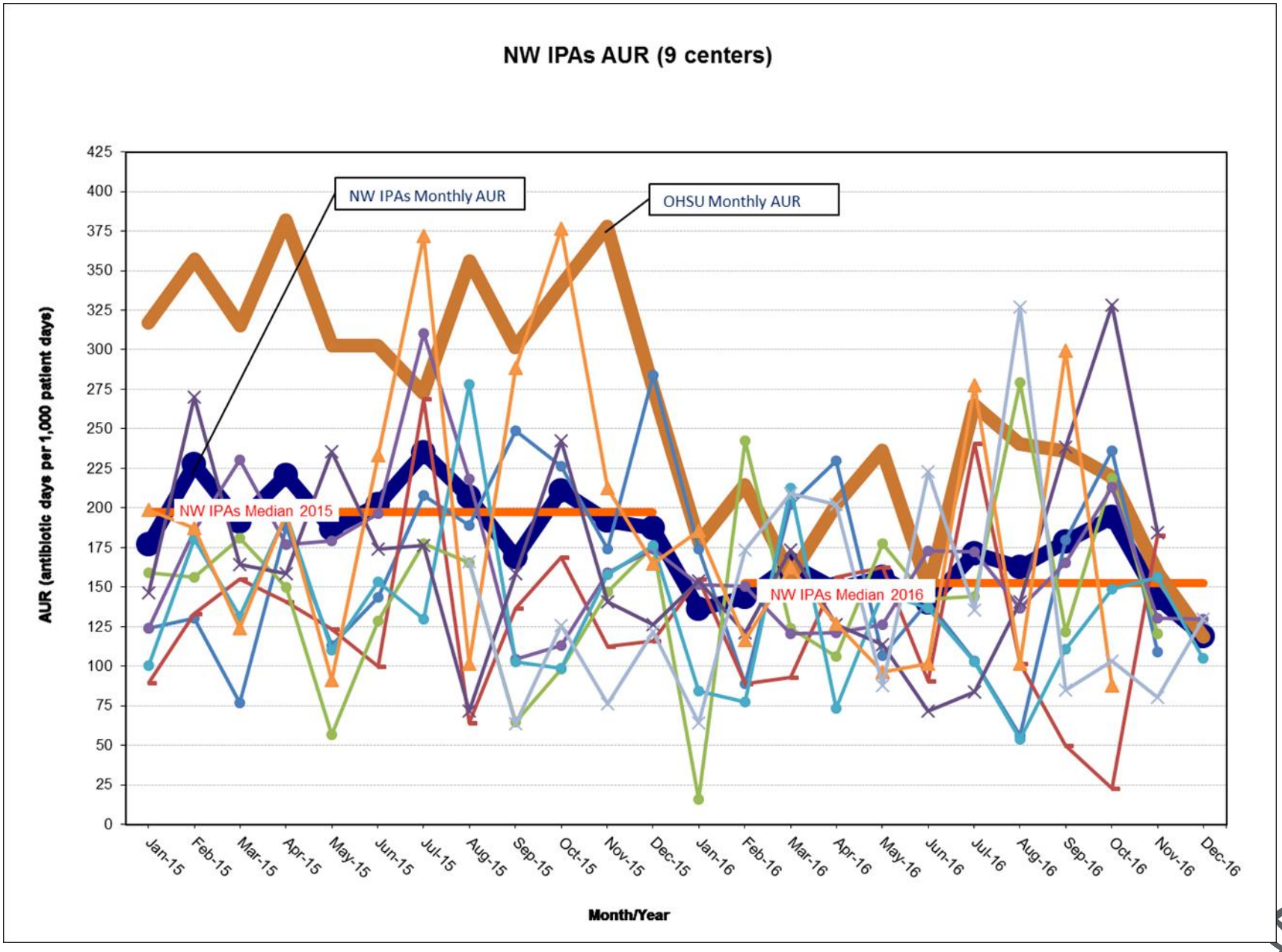

The thick dark blue line represents the overall AUR for all the centers reporting.
The other dark thick line represents the AUR for your center (OHSU)

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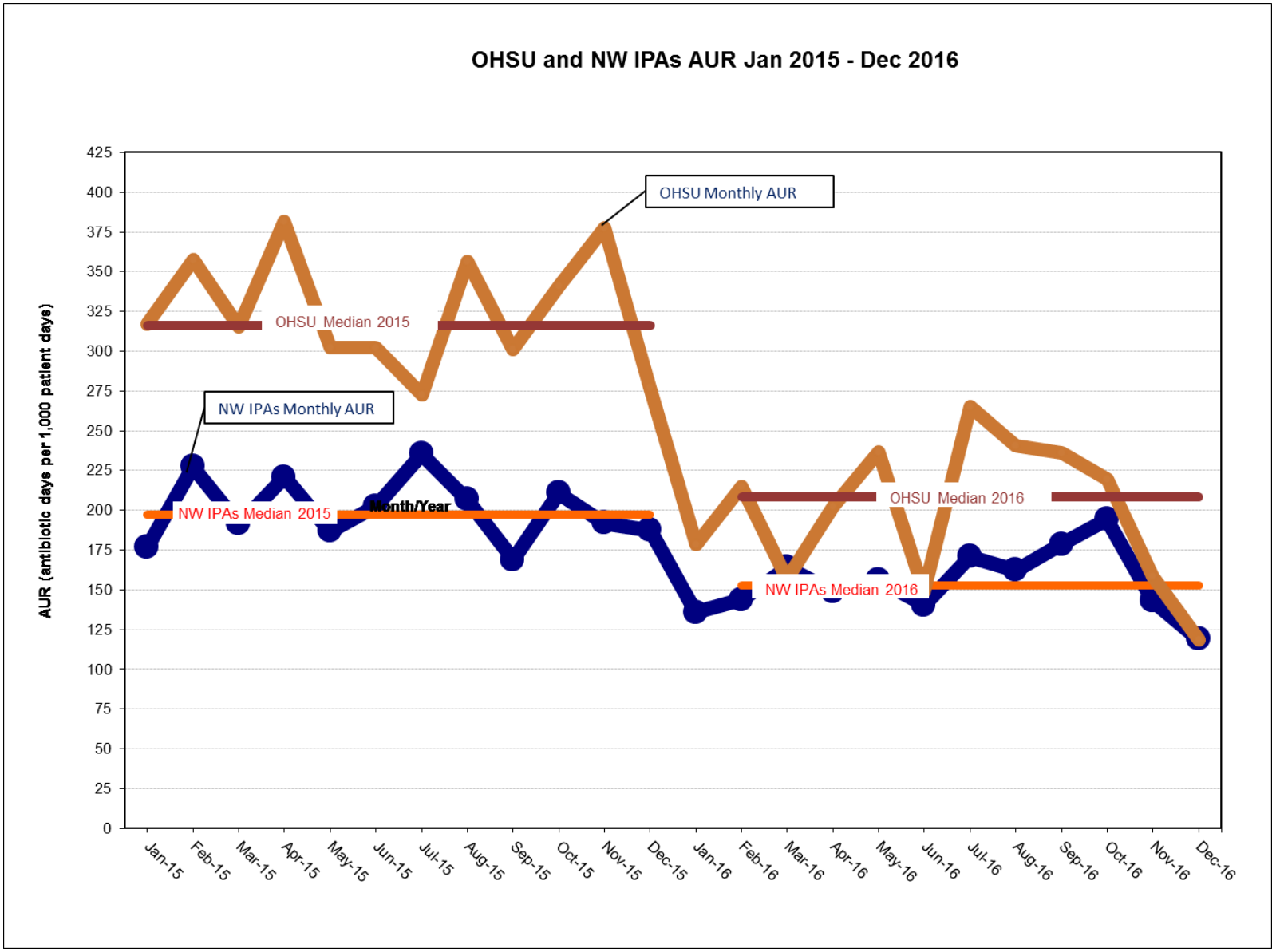

Please note that this is not a risk adjusted graph. If your center median is above the NW IPAs, then you are utilizing more antibiotics then the other 9 centers represented. If it is below the NW IPAs, than you are averaging less.

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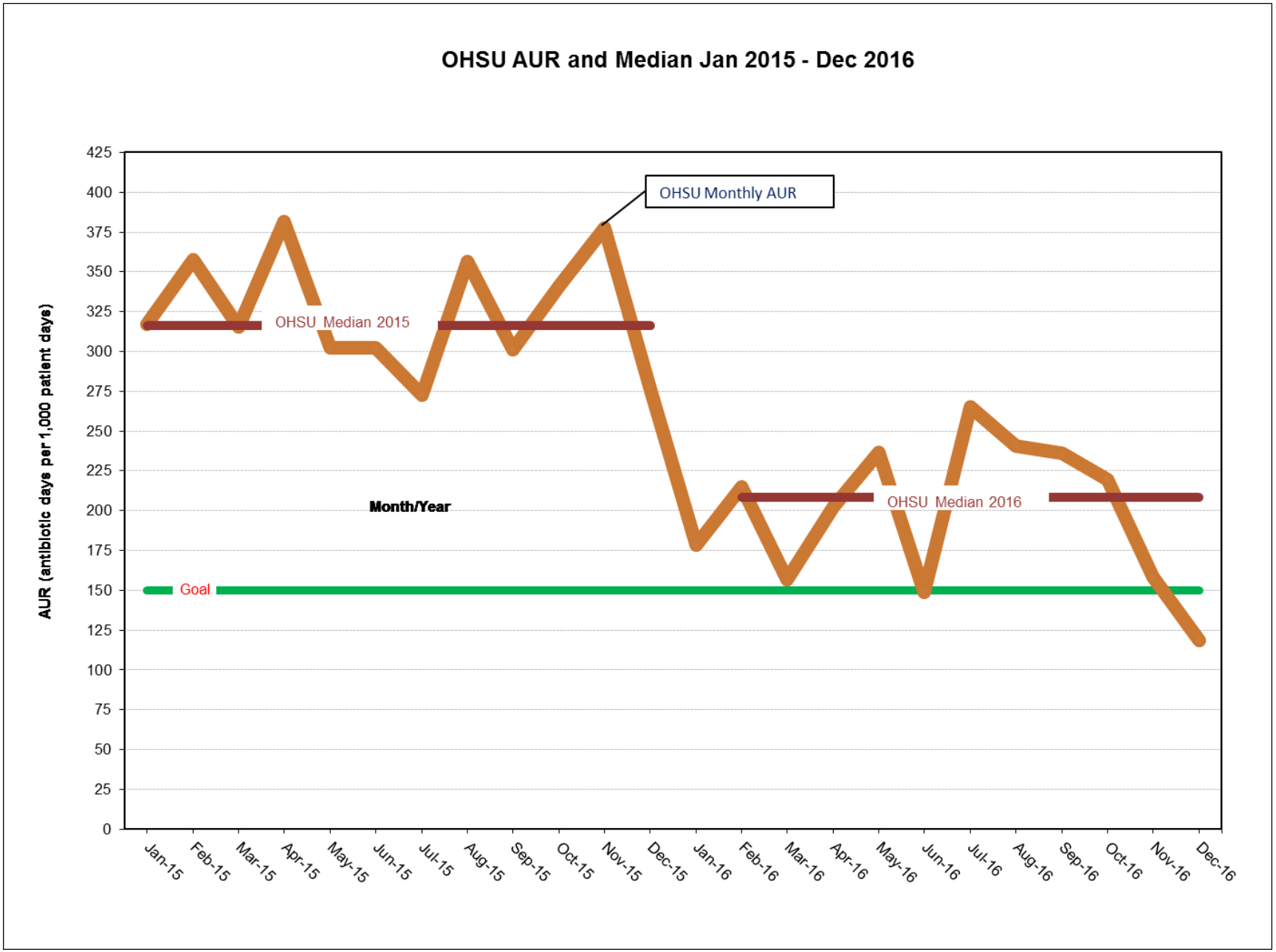

Each center should set it's own goal line (that should be realistic and attainable– 150 was set arbitrarily for purposes of demonstration)

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Summary

- NW IPAs have successfully engaged all 11 NICUs in the region in collaboration and participation around antibiotic stewardship
- All 11 centers have been able to determine their AUR*
  - Labor intensive (getting better)
  - Not risk adjusted
- 2017 iNICQ participation for NW IPA centers was supported in part by the Healthcare Associated Infections Program of the Oregon Public Health Division with funding from the CDC Epidemiology and Laboratory Capacity Grant
- First collaborative QI project in region that includes all NICU participation

*CDC definition of antibiotic days per 1,000 patient days

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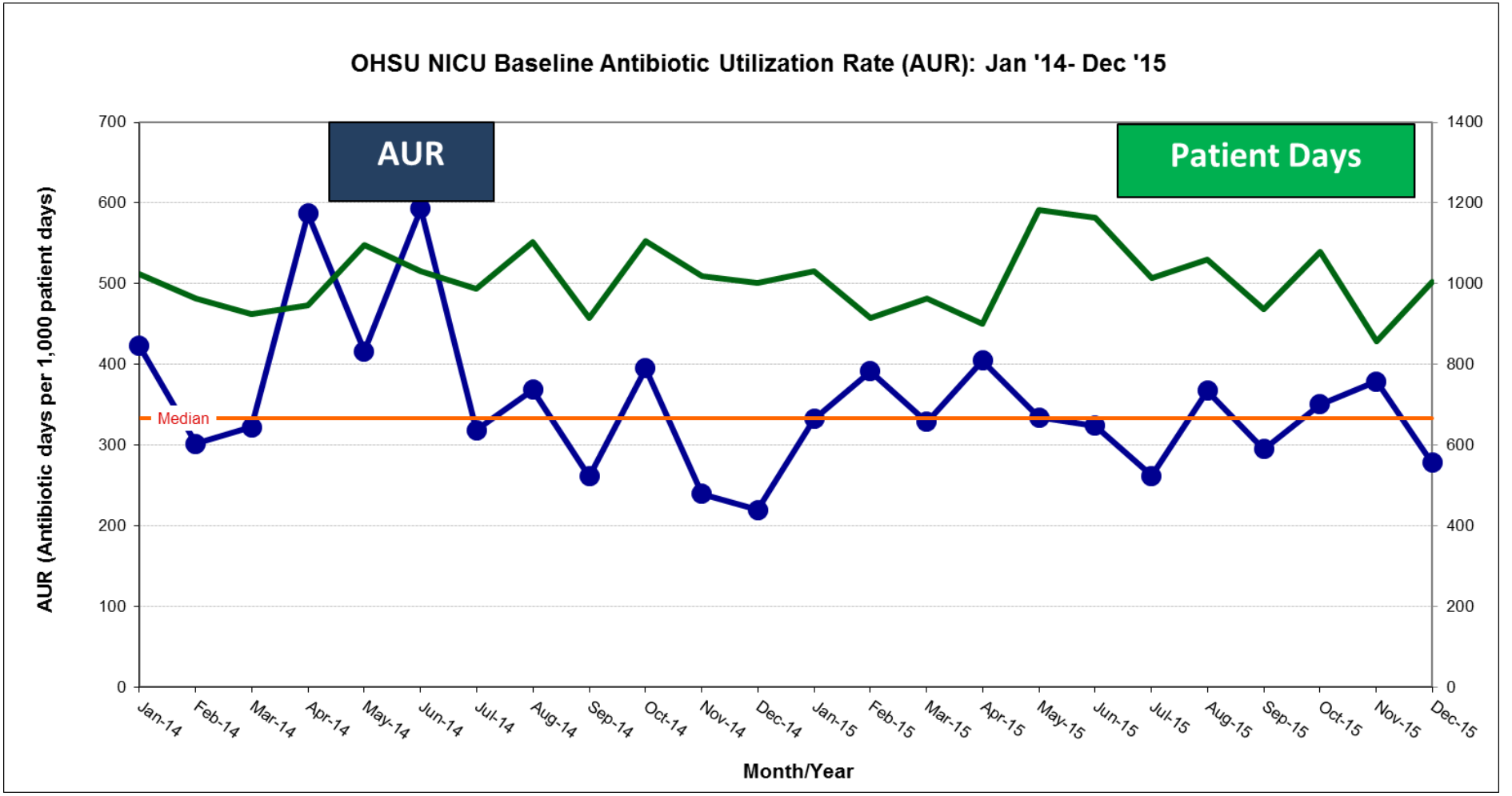
Our Local Improvement Story: OHSU

OHSU NICU Baseline Data



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SMART Aim

- To decrease Antibiotic Utilization Rate (AUR) (defined as antibiotic days/1,000 patients days per CDC) from 333 antibiotic days/1,000 patient days to 283 antibiotic days/1,000 patient days (15%) by December 31, 2016

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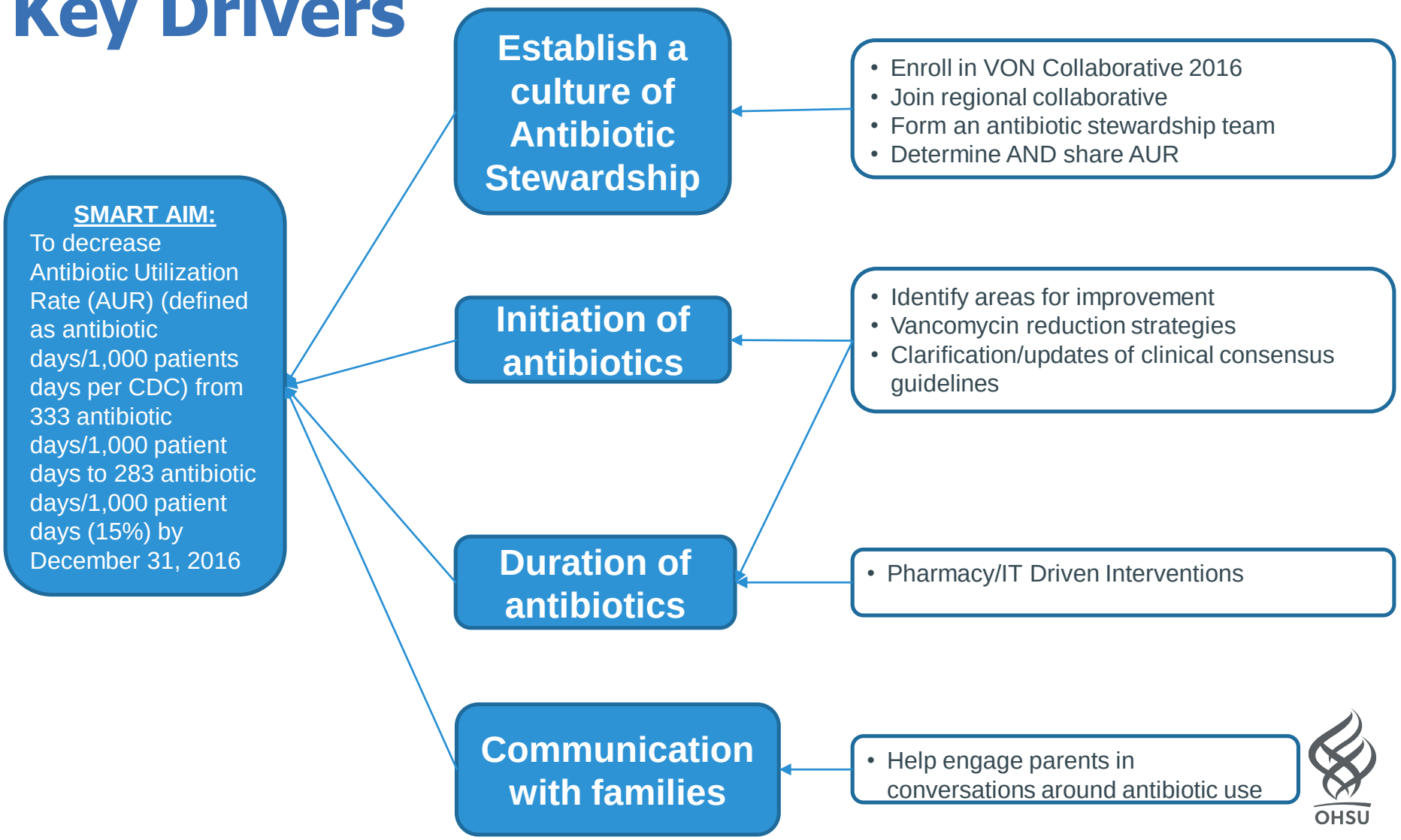
Key Drivers


SMART AIM:
To decrease Antibiotic Utilization Rate (AUR) (defined as antibiotic days/1,000 patients days per CDC) from 333 antibiotic days/1,000 patient days to 283 antibiotic days/1,000 patient days (15%) by December 31, 2016
Establish a culture of Antibiotic Stewardship
Initiation of antibiotics
Duration of antibiotics
Communication with families
• Enroll in VON Collaborative 2016
• Join regional collaborative
• Form an antibiotic stewardship team
• Determine AND share AUR
• Identify areas for improvement
• Vancomycin reduction strategies
• Clarification/updates of clinical consensus guidelines
• Pharmacy/IT Driven Interventions
• Help engage parents in conversations around antibiotic use
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Interventions

Interventions	Time	Description
Pre-NICU ASP	July 2015	Introduction of Kaiser Sepsis Calculator
1	December 2015	NICU ASP Team Formed
2	March 2016	Clinical Consensus Guidelines Changes: -48 to 36 hour rule out -Vancomycin reduction
3	January 2017	Monthly OHSU ASP Meetings
4	February/March 2017	“Hard Stops” for rule out sepsis for early and late onset sepsis
5 – DCH Wide	October 2017	Pediatric ASP Team Rounds M-F
6	November 2017	Parent Information Cards

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Results

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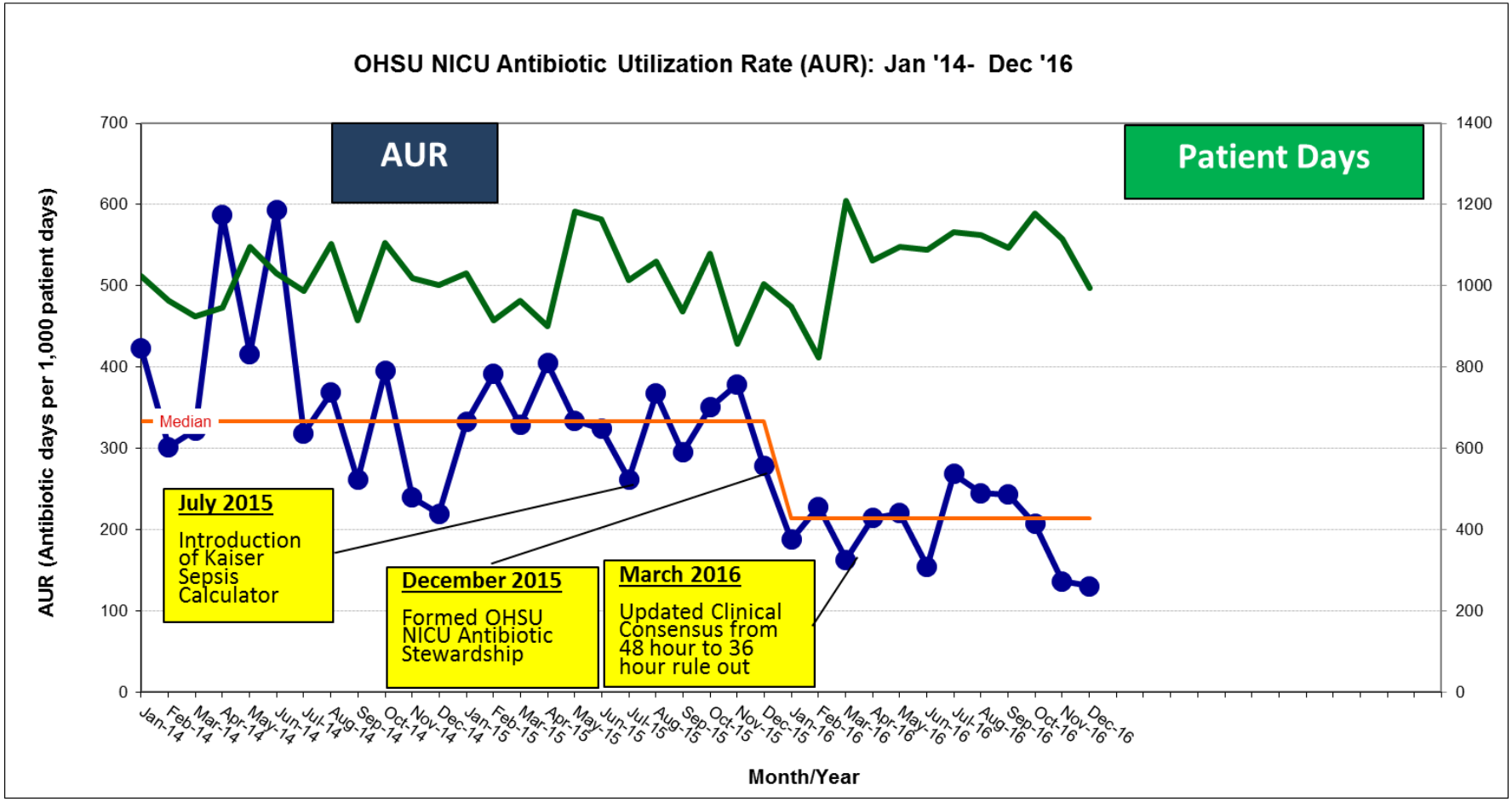
OHSU NICU AUR – Year 1



- In 1 year, our median AUR decreased from baseline of 333 to 214 antibiotic days per patient days (35.7% reduction)

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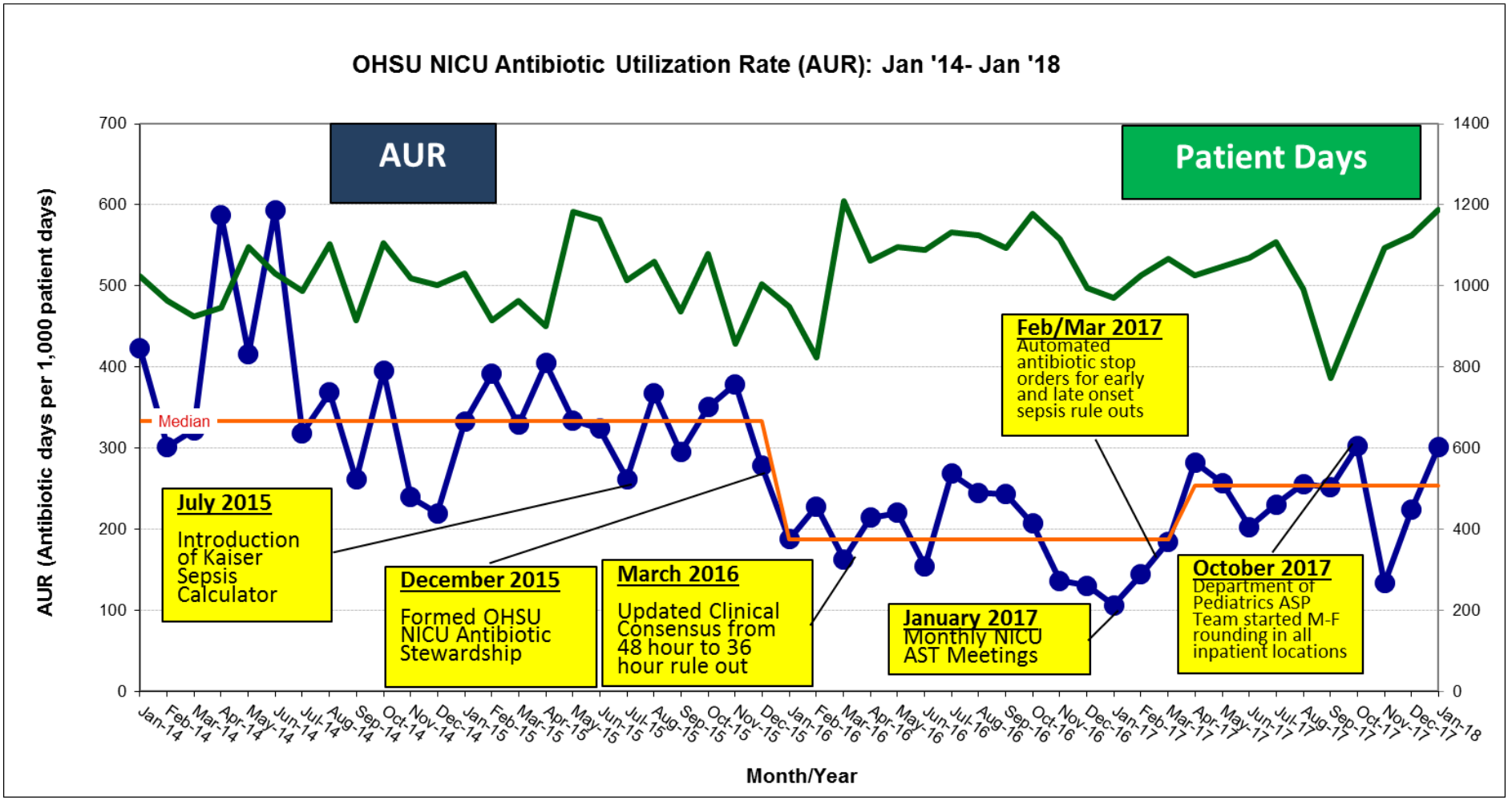
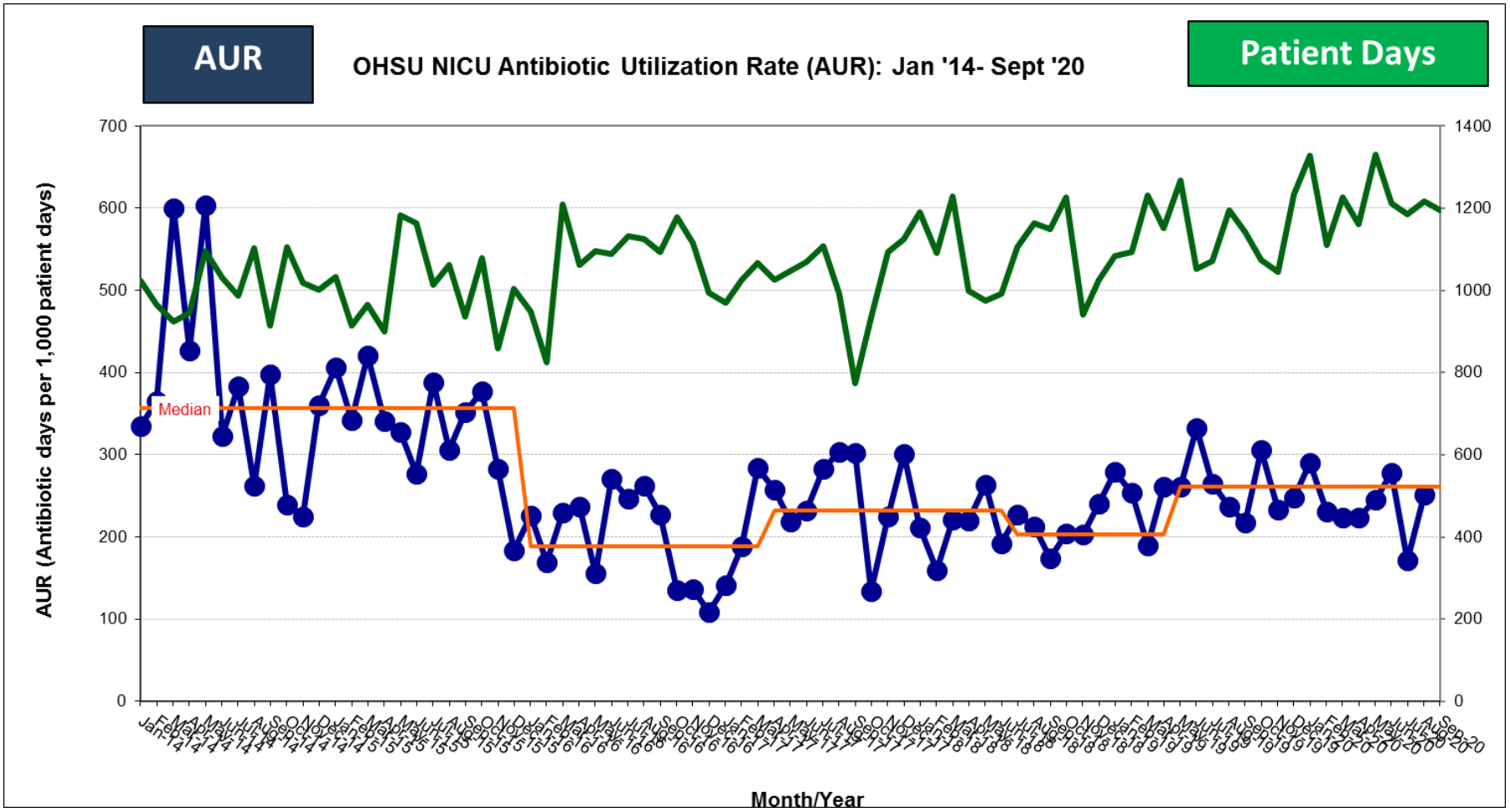
OHSU NICU AUR – Year 2



- In 2 year, our median AUR increased (May 2017) from baseline of 188 to 253 antibiotic days per patient days (34.6% increase)
- Remains 24% below the baseline data pre-intervention

OHSU NICU AUR – Year 5



Keys to Our Success

- We have successfully reduced unnecessary antibiotic utilization
- Keys to our success:
  - Easy topic for staff to buy into (subtracting rather than adding care)
  - Pharmacy Engagement
  - IT Support
  - Infectious Disease/Control (Adult ASP Team)
  - Just getting started
  - Collaboration - first collaborative QI project in region that includes all NICU participation

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Opportunities for Improvement

- Understanding variation in AUR
  - Antibiotics by indications
  - Mapping to infections/NEC
  - Getting to the provider level/feedback
- Improving the timing of antibiotic administration on initiation
- Family engagement
- Measuring impact on disparity
- Standardization of guidelines
  - Low hanging fruit (early and late onset sepsis)
  - Culture negative sepsis, VAP, etc
- Balancing Measures

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Balancing Measures

SUPPLEMENTAL TABLE 2 Balancing Measures

Year	Nosocomial Infection Rate[a]	Total Deaths	Deaths Attributed to Infection[b]	Infection-Related Mortality[c]
2013	1.19	21	4	0.19
2014	1.23	17	4	0.24
2015	0.77	23	3	0.13
2016	0.62	31	5	0.16
2017	1.06	25	4	0.16
2018	0.56	24	4	0.17

[a] Defined as the number of cases after 72 h of life where bacteria was isolated from blood or cerebrospinal fluid per 1000 patient-days.

[b] Defined as having a diagnosis of sepsis, pneumonia, or meningitis that contributed to death.

[c] Deaths attributed to infection divided by total deaths.

Meyers et al. *Pediatrics* 146 (5) Nov 2020

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Balancing Measures

- Impact on family
- Disparity gap
- Process measures
  - Delay in initiation of antibiotics
  - Antibiotics stopped too early
- Outcomes
  - Mortality, Sepsis, NEC
  - Long term outcomes (beyond scope?)

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Newborn ASP Strategies

- Implementation of Early Onset Sepsis Calculator
  - Engagement of the Mother-Baby Units
- Shortening the time of rule out from 48 to 36 hours (some to 24 hours)
- IT interventions – hard stops
- Engaging the families in conversation
- Education of staff
- Multidisciplinary
  - Pharmacy
  - Microbiology lab
  - ID

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What Can You Do?

- NICU/Newborn Level
  - What are your antibiotic prescribing practices?
  - How does your microbiology lab work?
  - Do you track them?
- Hospital Level
  - Is there an antibiotic stewardship program?
    - Adult vs. Pediatric
    - Data (NHSN AU/AR Modules)
- System/State
  - What are other centers doing?
  - Does your state department of public health have funding and support?

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Antibiotic Stewardship

- “coordinated interventions designed to improve and measure the appropriate use of [antibiotic] agents by promoting the selection of the optimal [antibiotic] drug regimen, including dosing, duration of therapy, and route of administration” (PIDS, SHEA, IDSA)

- Many components to an Antibiotic Stewardship Program (ASP):
  - Right antibiotic
  - Right dose
  - Right duration
  - Right patient

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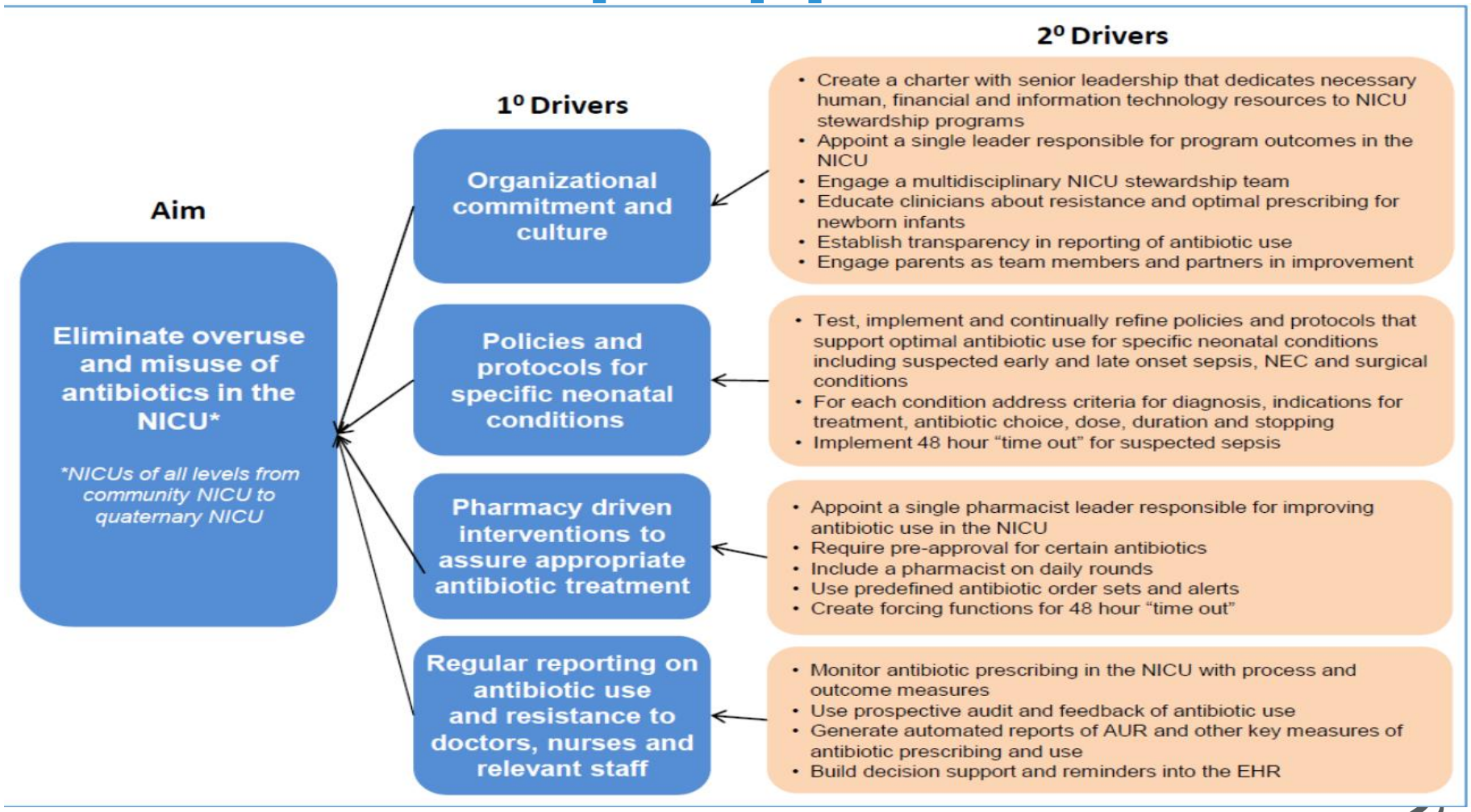
Stewardship Opportunities



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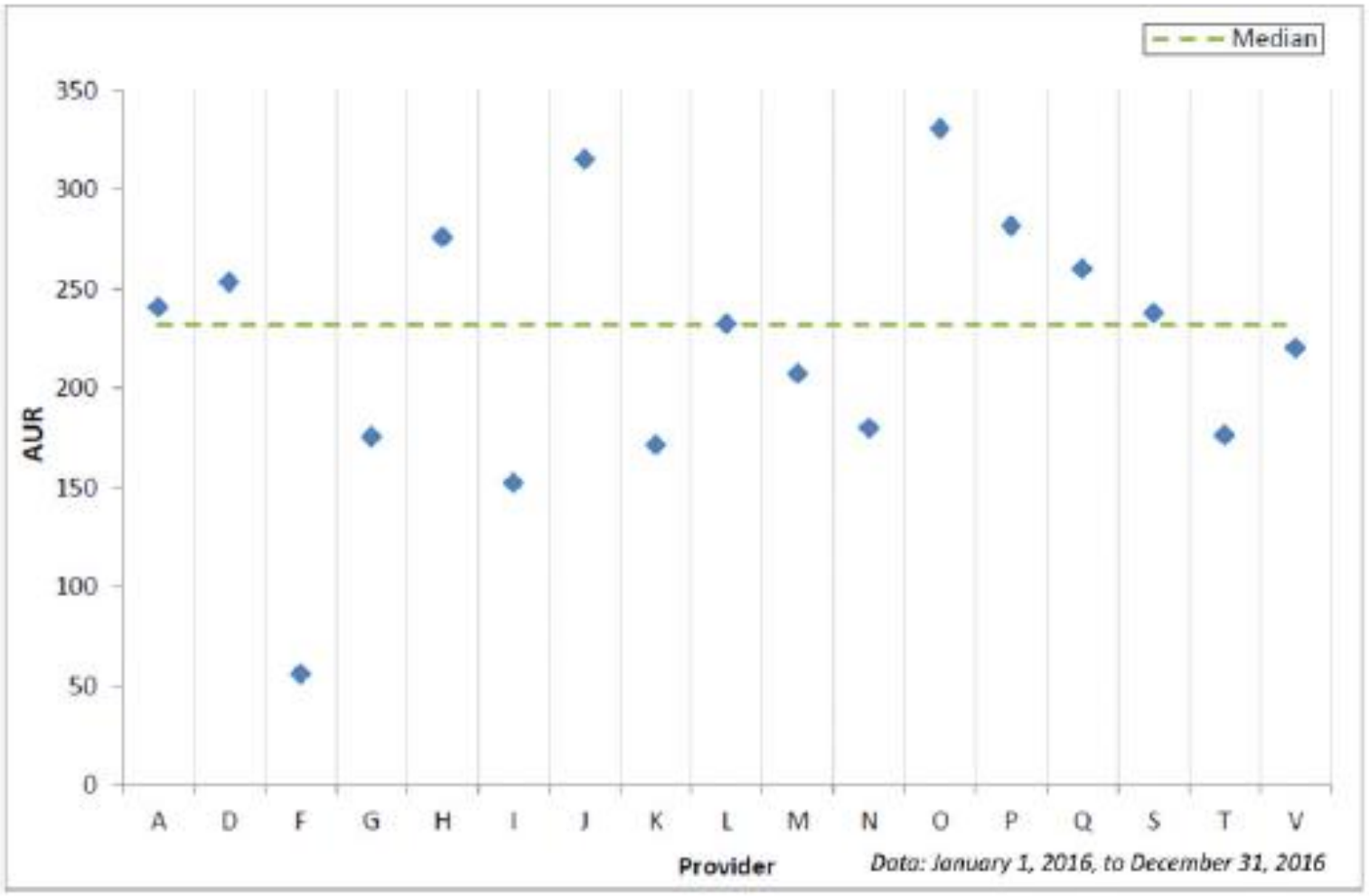

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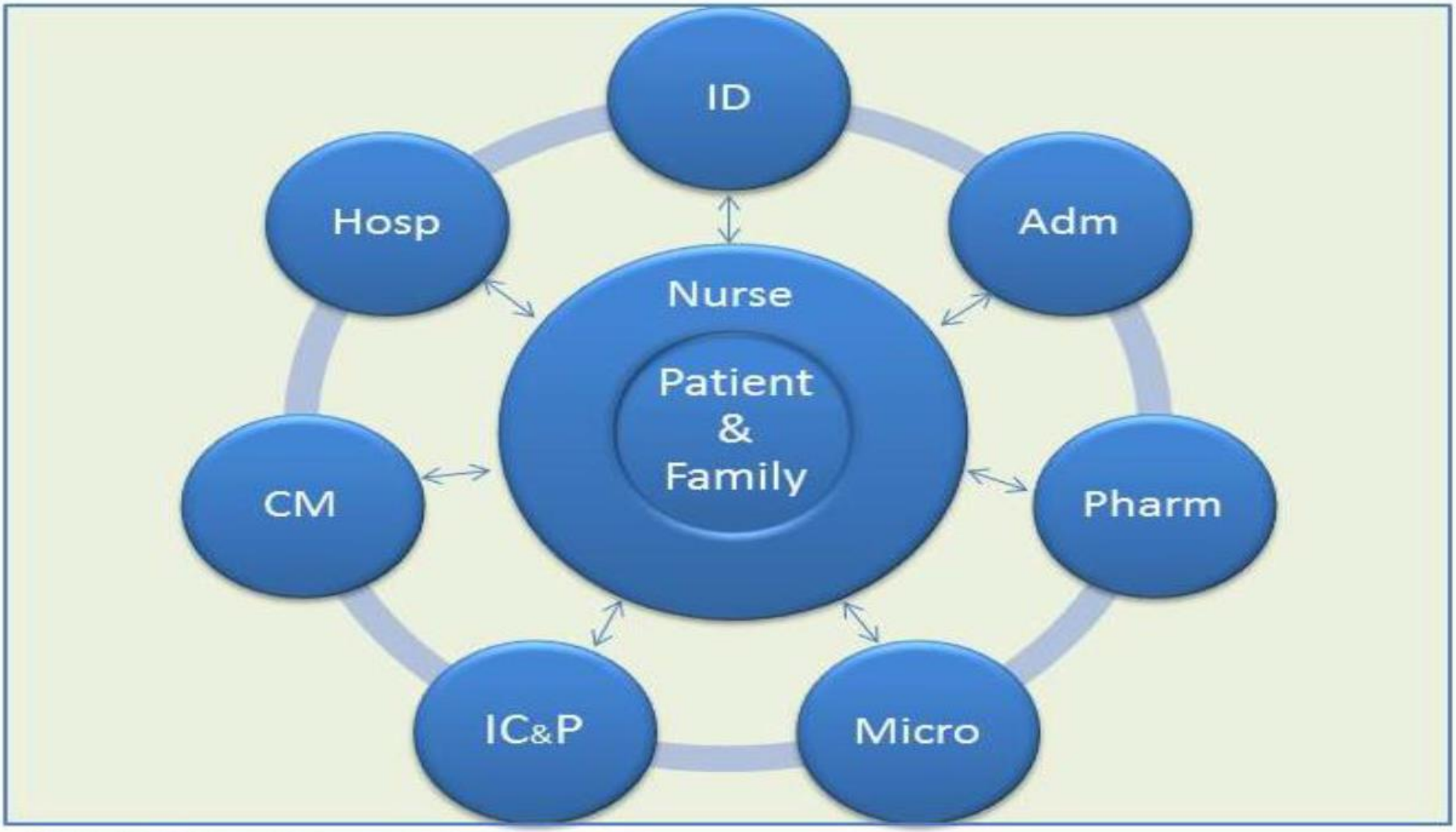

Figure 1 from American Nurses Association White Paper & CDC “Redefining the Antibiotic Stewardship Team” 2017
www.nursingworld.org

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Thank You!

Questions/Comments

dukhovny@ohsu.edu