

# Successful Establishment of an Antimicrobial Stewardship Program (ASP) for Outpatient Parenteral Antimicrobial Therapy (OPAT)

Ramesh V. Nathan, MD<sup>1</sup>, John S. Adams, MD<sup>2</sup>, Robin H. Dretler, MD<sup>3</sup>; Quyen Luu, MD<sup>4</sup>; Brian S. Metzger, MD<sup>5</sup>;

Claudia P. Schroeder PharmD<sup>6</sup>, PhD; Kimberly Couch, PharmD<sup>6</sup>; Lucinda J. Van Anglen, PharmD<sup>6</sup>

<sup>1</sup>Mazur, Statner, Dutta, Nathan, PC, Thousand Oaks, CA; <sup>2</sup>Knoxville Infectious Disease Consultants, PC, Knoxville, TN; <sup>3</sup>Infectious Disease Specialists of Atlanta, PC, Decatur, GA;

<sup>4</sup>Central Georgia Infectious Diseases, Macon, GA; <sup>5</sup>Austin Infectious Disease Consultants, Austin, TX; <sup>6</sup>Healix Infusion Therapy, Inc. Sugar Land, TX



## Abstract

**Background:** IDSA guidelines for implementing an ASP were published in 2016 with required standards by The Joint Commission for hospitals beginning January, 2017. To date, no guidelines have been established in the US for ASP specific to OPAT. Using current guidelines, along with those proposed for the UK, we developed an ASP program unique to OPAT provided in US physician office infusion centers.

**Methods:** We identified 5 core elements of the ASP pertinent to OPAT: antimicrobial use based on pathogen susceptibility, duration of OPAT, lack of *C. difficile* infection, and no emergency department (ED) visit or hospitalization related to OPAT. Other measurable elements included initial patient (pt) education, standard order forms, labs obtained as ordered, adherence to drug stability standards and completion of OPAT as ordered. An assessment tool was developed to measure ASP compliance. Assessments were performed on 250 randomly assigned culture positive pts from each of 5 POICs receiving OPAT in 2016.

**Results:** A total of 250 pts were evaluated for each of the ASP elements. Mean scores were 70.5 for core elements and 24.4 for other elements resulting in 94.9 of 100 possible. Early IV to PO conversion was documented in 8 pts resulting in a reduction of 117 days of OPAT.

Core Elements	Scoring Grid (possible points per patient)	No. of Pts with goal met (n=250)	Overall Score (average points per patient)
Appropriate antimicrobial selection	15	244 (97.6%)	14.6
Duration of OPAT does not exceed guideline	15	201 (80.4%)	12.1
No <i>C. difficile</i> infection during OPAT	15	247 (98.8%)	14.8
No therapy-related ED visit	15	244 (97.6%)	14.6
No therapy-related hospital visit	15	239 (95.6%)	14.3
<b>Score for Core Elements</b>	<b>75.0</b>		<b>70.5</b>
Other Elements	Scoring Grid (possible points per patient)	No. of Pts with goal met (n=250)	Overall Score (average points per patient)
Initial patient education performed	5	249 (99.6%)	5.0
Standard order form used	5	248 (99.2%)	5.0
Labs performed as ordered	5	235 (94.0%)	4.7
Adherence to drug stability	5	245 (98.0%)	4.9
OPAT completed as ordered	5	234 (93.6%)	4.8
<b>Score for Other Elements</b>	<b>25.0</b>		<b>24.4</b>
<b>Total Score</b>	<b>100.0</b>		<b>94.9</b>

**Conclusion:** Antimicrobial stewardship is essential in all settings of care, particularly in OPAT with extended durations of therapy. We report the first US OPAT ASP with assessment of compliance. High rates of adherence were achieved in all elements. Implementation of an ASP should be considered in all OPAT settings.

## Background and Methods

Antimicrobial stewardship encompasses strategies and interventions aimed at improving appropriate use of antimicrobials in all healthcare settings with the goals to improve patient outcomes and safety, reduce antimicrobial resistance, preserve antimicrobial treatment options and limit costs associated with inappropriate therapy.<sup>1,2</sup> The President's Council of Advisors on Science and Technology recommended that ASPs should be in place for inpatient and long-term care facilities by the end of 2017. Required compliance with standards for stewardship in hospitals and nursing care centers was implemented by The Joint Commission, effective January, 2017.<sup>3</sup>

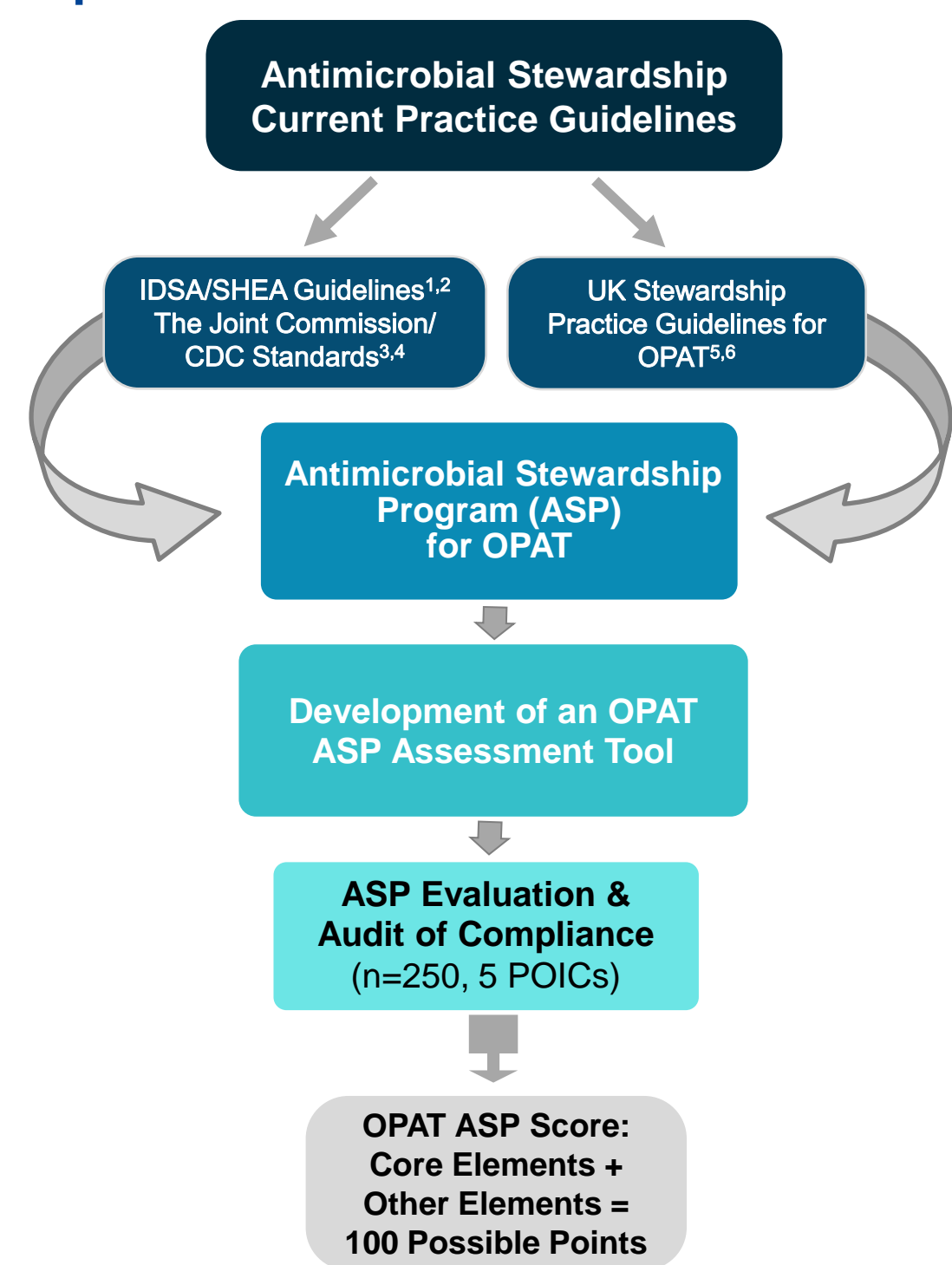
To date, no US guidelines exist for antimicrobial stewardship specific to OPAT. We believe that antimicrobial stewardship should be exercised in the OPAT setting, possibly even more so than in a hospital setting, due to extended length of therapy often required. Healix manages Infectious Disease (ID) physician office infusion centers and pharmacies under similar standards of practice. ID physicians and ID pharmacists reviewed the current literature for ASP from the Infectious Diseases Society of America (IDSA) Guidelines<sup>1,2</sup>, The Joint Commission (TJC)<sup>3</sup> and CDC Standards<sup>4</sup> as well as OPAT stewardship guidelines from the United Kingdom (UK).<sup>5,6</sup> Several elements of an effective ASP were identified as important for an OPAT ASP. Of those, we selected IDSA guidelines incorporating all strong recommendations.<sup>1</sup> Added to these were appropriate and measurable elements from The Joint Commission<sup>3</sup>, CDC<sup>4</sup> and those developed for OPAT in the UK.<sup>5,6</sup>

This was then developed into an official ASP program with criteria suitable and important for OPAT. Numerous elements had been incorporated into daily practice and several were added. An "OPAT ASP Assessment Tool" was created to audit and track ASP compliance. Those factors deemed most important for an ASP program were placed into a section of "Core Elements", with a stronger weighting in the assessment. Additional elements that were identified as useful were added to "Other Elements" with less weighting to the assessment. This was designed to be used as both a development and evaluation tool, with a scoring grid as part of the tool. With conversion from intravenous (IV) to oral (PO) therapy considered an important element of an ASP program, this was added as an additional factor to analyze, with the addition of bonus points to encourage use. Therapeutic drug monitoring (TDM) was also captured for those pts receiving vancomycin or aminoglycosides. Several other parameters are important for OPAT, but were not included since they were already implemented in the managed infusion centers overall. This is summarized in Table 1.

The OPAT ASP was then assessed in 5 ID private practices with Healix-managed pharmacies and infusion centers. The multidisciplinary team consisted of an ID physician, ID trained clinical pharmacists and highly trained infusion nurses. From each site, 50 culture-positive pts, who received OPAT for any diagnosis in 2016 were randomly selected. Each record was then audited and scored using the OPAT ASP Assessment Tool. Compliance with each element was assessed with descriptive statistics.

## OPAT ASP Development

### Development Process



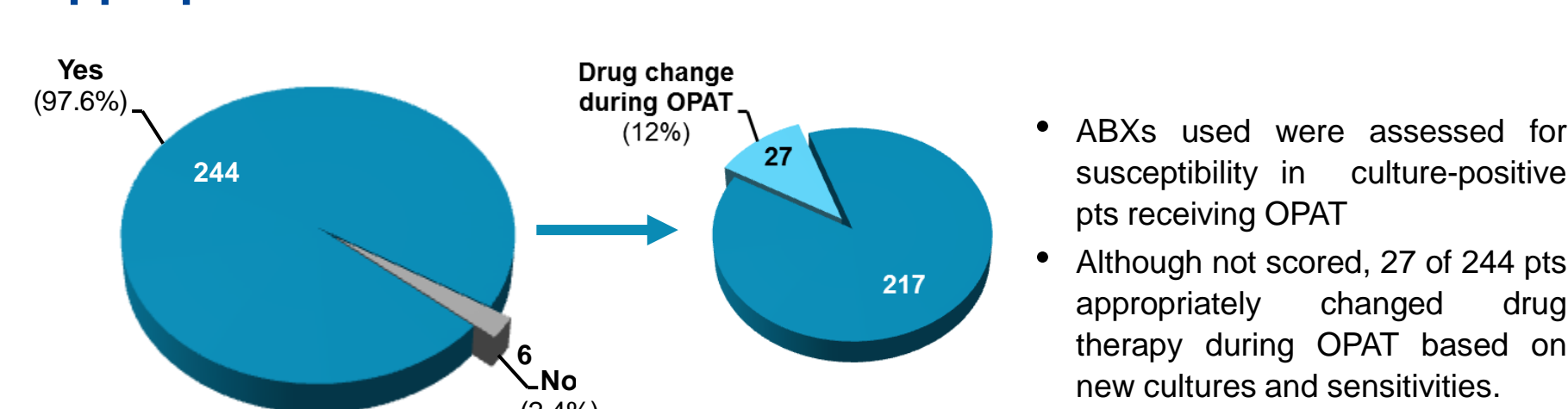
### Selection of Elements for OPAT

ASP Element	Source	Included in OPAT ASP	Added to Assessment Tool	Description
Leadership by Physician and Pharmacist	IDSA, TJC, CDC, UK	Y	N	in place
Multidisciplinary team Drug expertise	IDSA, TJC, CDC, UK	Y	N	in place
Prospective audit Preauthorization	IDSA, TJC, CDC	P	P	assessed retrospectively, preauthorization frequently performed but not assessed in place for staff and pts, assessed for pts
Education Guidelines	IDSA, TJC, CDC, UK	Y	Y	assessed with standard order forms, application of appropriate stability guidelines
Clinical pathways OPAT plan	IDSA, UK	P	P	assessed actual incidence of CDI
Reduce risk of CDI	IDSA, TJC, CDC, UK	P	P	assessed appropriate ABX regimen for culture-pos. pts
Appropriateness of ABX regimen Patient selection	IDSA, TJC, CDC, UK	P	P	partially in place, formulary phone app with drug and device option, payor coverage assessed TDM for vancomycin and aminoglycosides, assessed laboratory testing performed as ordered
Computer surveillance Decision support Formulary	IDSA	P	N	assessed as IV days saved
PK monitoring program Routine laboratory testing OPAT monitoring	IDSA, UK	Y	Y	assessed duration of therapy with published guidelines
IV to oral conversion	IDSA, TJC, CDC	P	Y	created Assessment Tool, measured and scored
Syndrome specific with shortest effective duration	IDSA, TJC, CDC	Y	Y	completion of OPAT, ED visits, and hospitalizations
Action Tracking Reporting	TJC, CDC	Y	Y	
Outcome measures	TJC, CDC, UK	Y	Y	

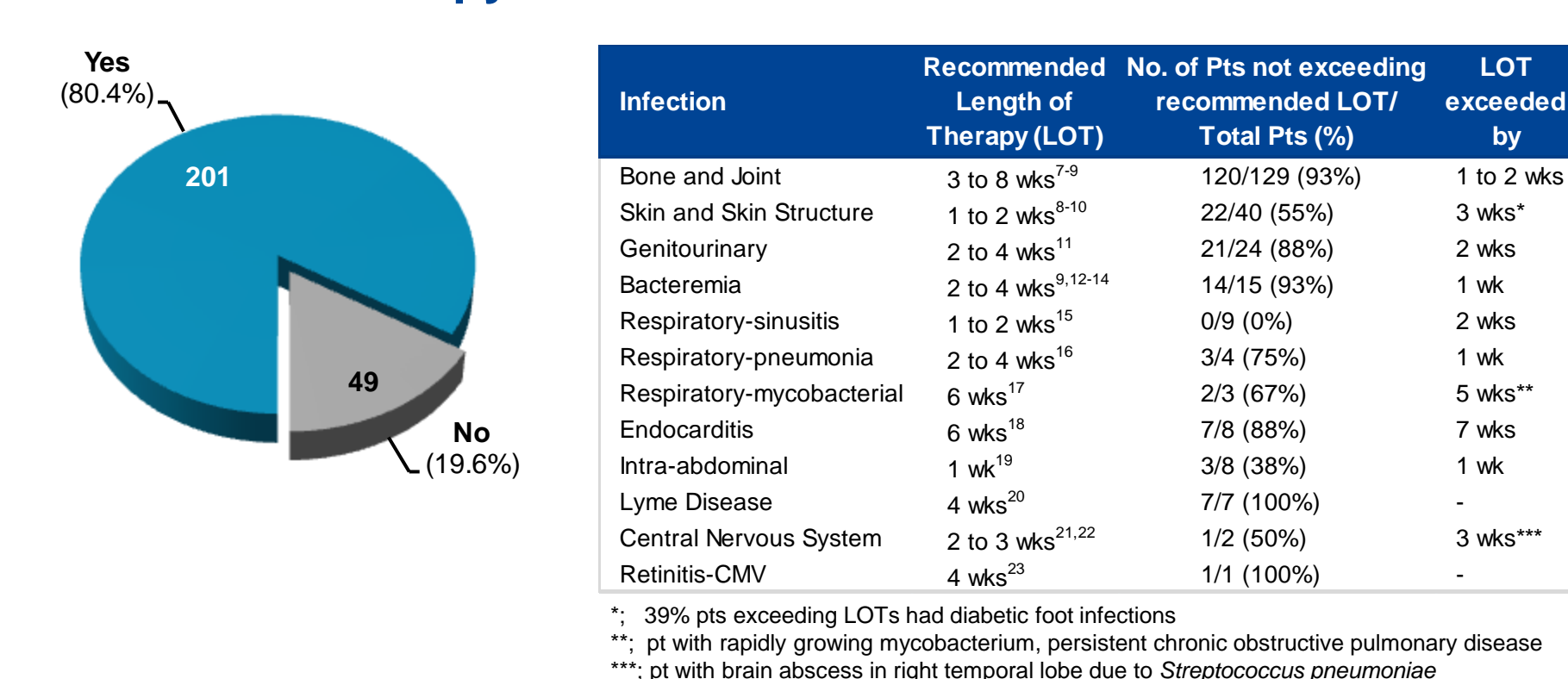
Abbreviations: ABX: antibiotic, CDI: *C. difficile* infection, IV: intravenous, N: No, CDC: Center for Disease Control, UK: United Kingdom guidelines, P: Partially, PK: pharmacokinetic, TDM: Therapeutic drug monitoring, TJC: The Joint Commission, Y: Yes.

## ASP Core Elements

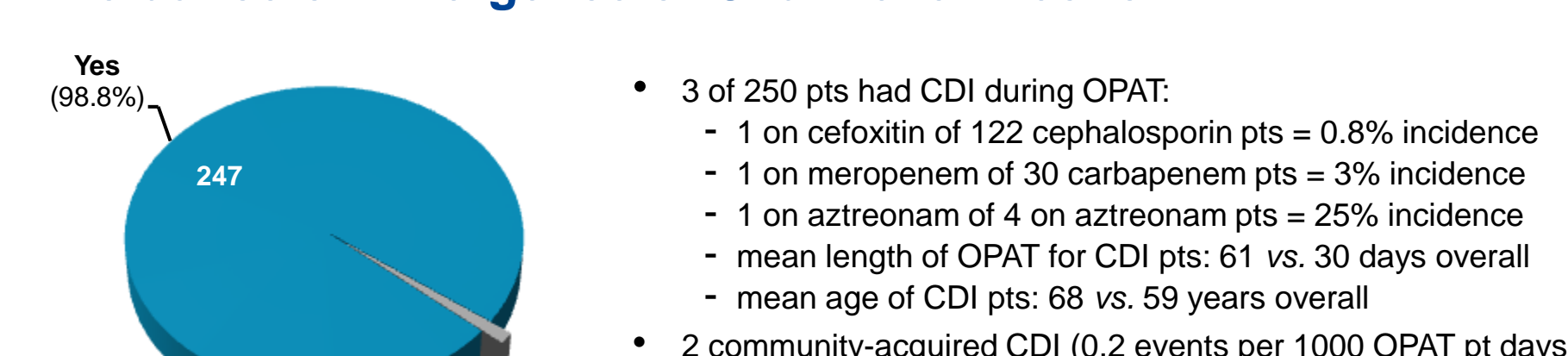
### Appropriate Antimicrobial Selection



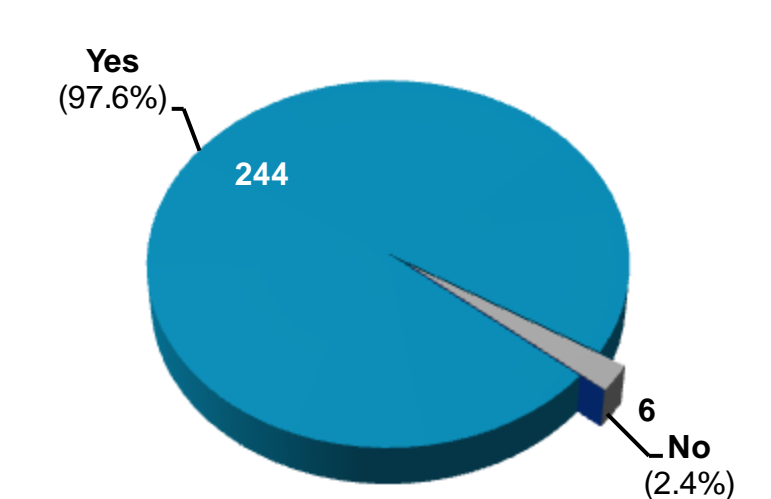
### Duration of Therapy within Guidelines



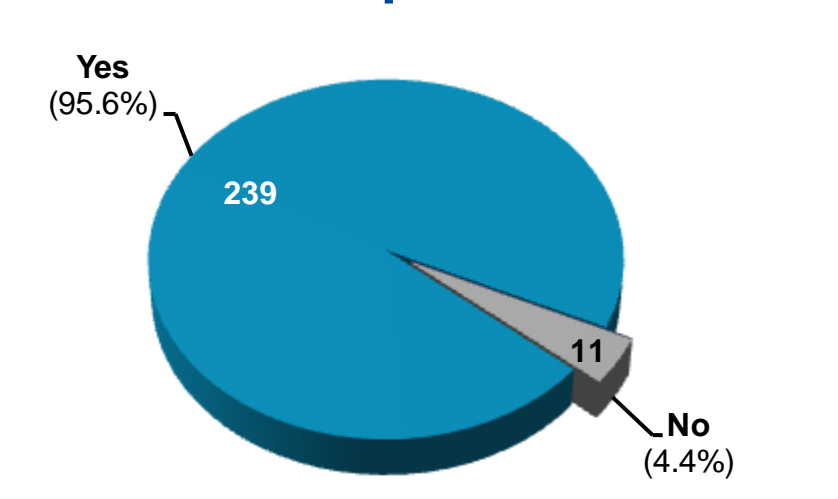
### Avoidance of Emergence of *C. difficile* Infection



### Avoidance of OPAT-Related ED Visit

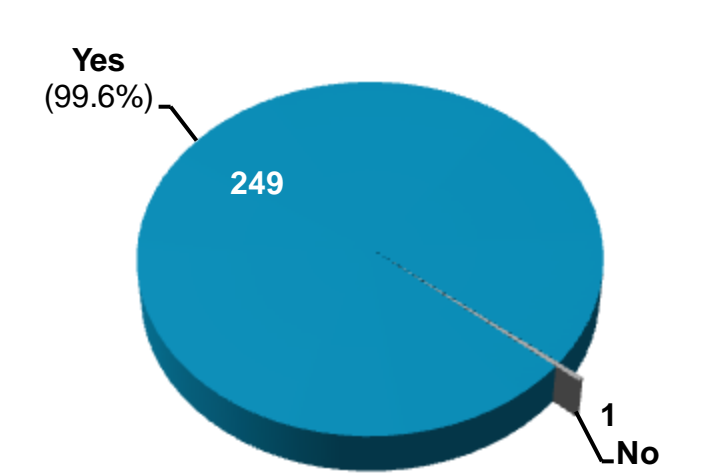


### Avoidance of OPAT-Related Hospitalization

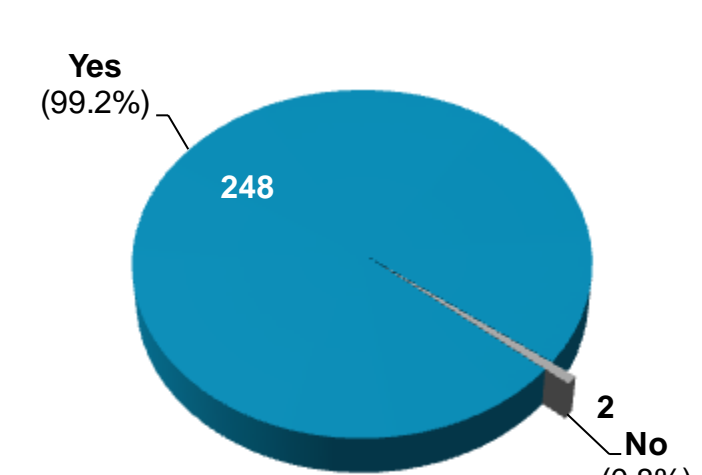


## ASP Other Elements

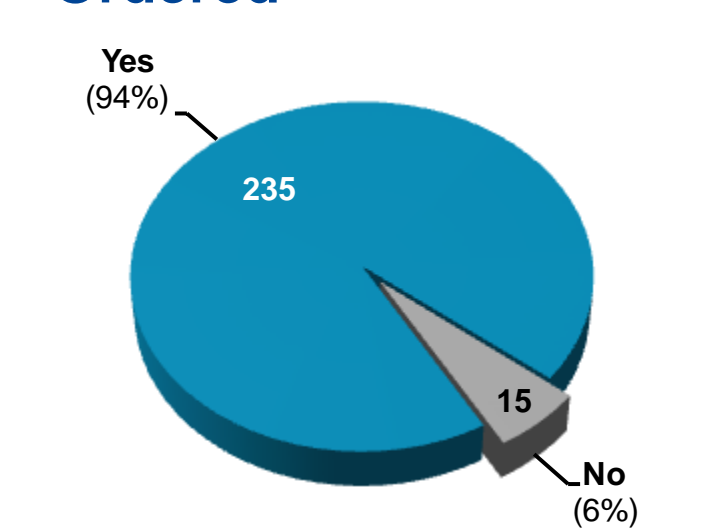
### Patient Education



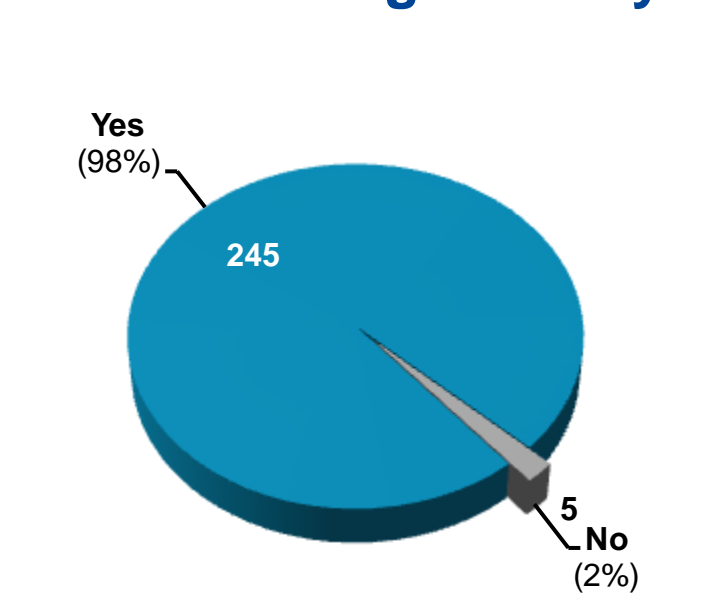
### Standard Order Form



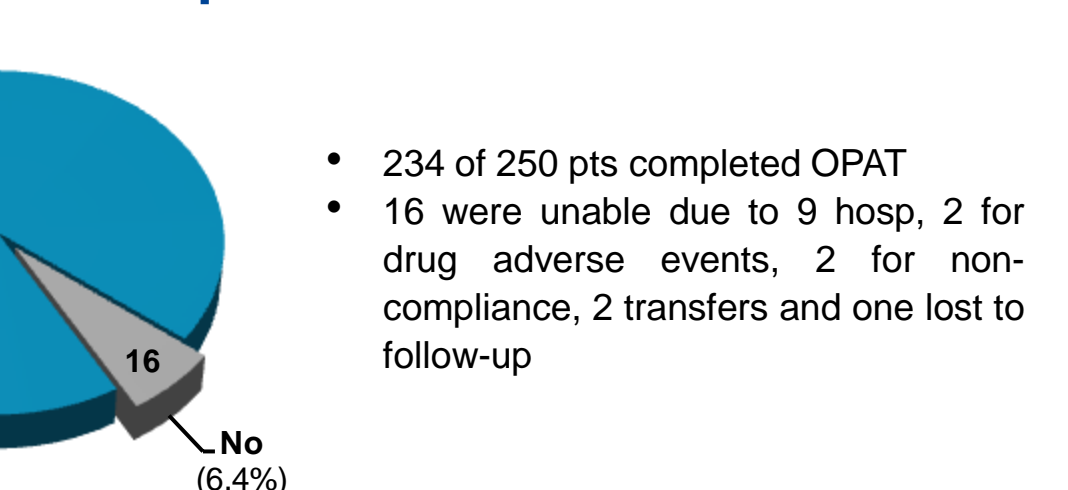
### Labs Obtained as Ordered



### Correct Drug Stability



### Completion of OPAT

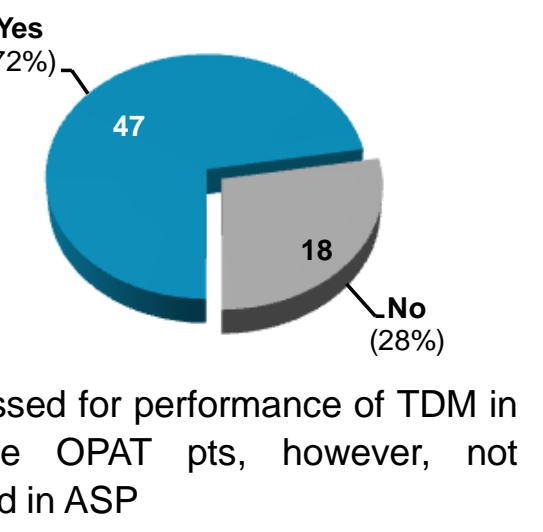


### Supplemental Data

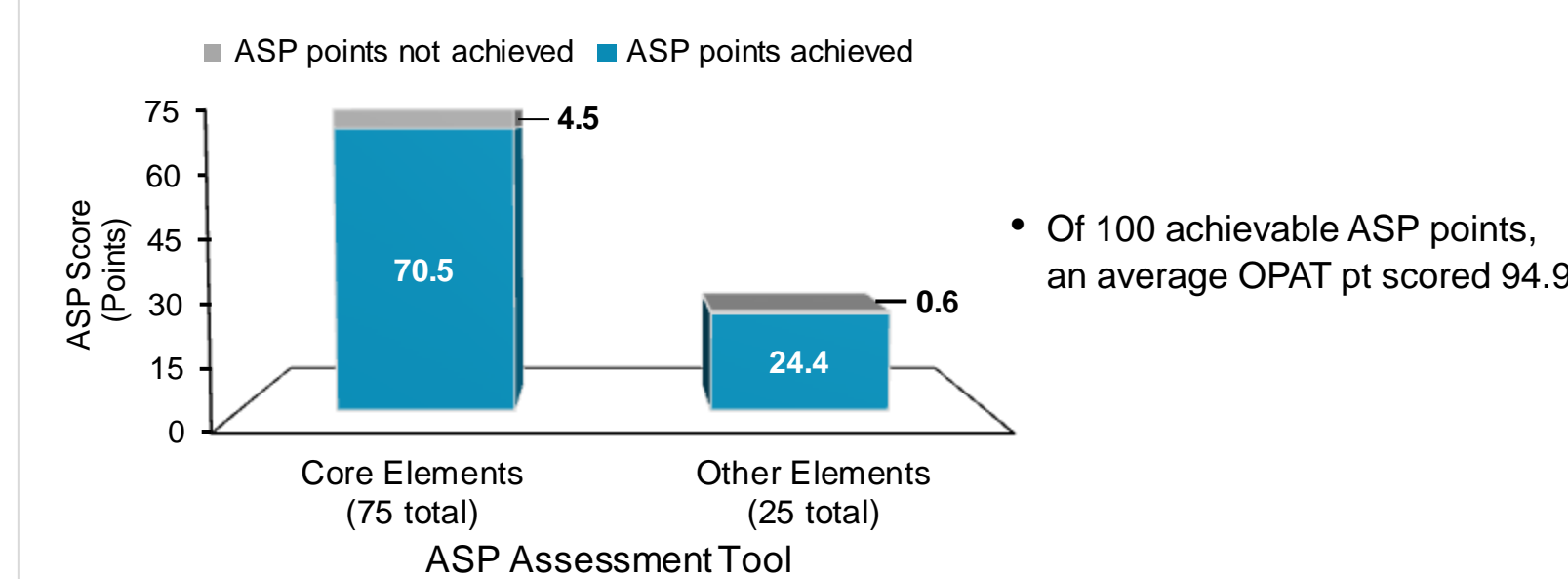
#### IV to PO Conversion

- Assessed days saved by conversion from IV to PO therapy vs. treatment guidelines
- 8 of 250 pts (3.2%) had early IV to PO conversion, saving a total of 117 IV treatment days

#### TDM Performed



## Overall OPAT ASP Score



## Discussion & Conclusion

- This study highlights the development of the first US ASP unique to OPAT
- In our OPAT setting, all pts are treated by ID physicians through their office infusion center and pharmacy under standardized systems with consistently trained staff. Key parameters important for successful implementation and management of an ASP were carefully evaluated by ID physicians and pharmacists for appropriate inclusion into an OPAT ASP (Table 1).
- Several important elements of an ASP were already in place including:
  - leadership with an educated multi-disciplinary team
  - standardized policies, orders and laboratory testing
  - common EHR and pharmacy database
  - access to a computerized formulary and roster application
- Other important measurable elements were added to create an OPAT ASP Assessment tool
- Overall assessment of the ASP indicated high adherence to all measurable parameters for a mean score of 94.9 including 250 OPAT patients.
- Opportunities for improvement include:
  - identification of appropriate empiric use of OPAT (no cultures available)
  - shorter durations of OPAT with increased IV to PO conversions
  - improved therapeutic drug monitoring
  - prospective auditing
  - expansion to other OPAT centers
- The practice of antimicrobial stewardship is crucial to providing high quality, low risk appropriate ABX therapy to OPAT pts. This has been described in the UK, but not in the US. We present the successful development, implementation and assessment of an OPAT ASP in the US.

## References

- Barlam TF, et al. *Clin Infect Dis* 2016; 62(10):1197-1202
- Delitt TH, et al. *Clin Infect Dis* 2007; 44:159-77
- Joint Commission Perspectives® Jul 2016; 36(7):1-8
- CDC 2014. Core elements of hospital antibiotic stewardship programs; available at: <http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>
- Chapman AL, et al. *J Antimicrob Chemother* 2012; 67(5):1053-62
- Gilchrist M and Seaton RA. *J Antimicrob Chemother* 2015; 70:965-70
- Osmon DR et al. *Clin Infect Dis* 2013; 56(1):e1-25
- Lipsky BA, et al. *Clin Infect Dis* 2012; 54(12):132-173
- Liu C, et al. *Clin Infect Dis* 2011; 52(3):e18-e55
- Stevens DL, et al. *Clin Infect Dis* 2014; 59(2):a10-52
- American Urological Association. <https://www.auanet.org/guidelines/urinary-tract-infection>
- Hof H, et al. *Clin Microbiol Rev* 1997; 10(2):345-57
- Mermel LA, et al. *Clin Infect Dis* 2009; 49:1-45
- Pappas PG, et al. *Clin Infect Dis* 2004; 38:161-89
- Rosenfield RM, et al. *Otolaryngol Head Neck Surg* 2015; 152(2S):S1-S39
- Mandell LA, et al. *Clin Infect Dis* 2007; 44:S27-72 (PNA)
- Griffith DE, et al. *Am J Respir Crit Care Med* 2007; 175:367-416
- Baddour LM, et al. *Circulation* 2015; 132:1435-86
- Solomkin JS, et al. *Clin Infect Dis* 2010; 50:133-64
- Wormser GP, et al. *Clin Infect Dis* 2006; 43:1089-134
- Tunkel AR, et al. *Clin Infect Dis* 2004; 39:1267-84
- Solomon T, et al. *J Inf* 2012; 64:347-73
- Carmichael A, et al. *Eye* 2012; 26:237-40
- United US Pharmacopoeial Convention, Inc. *USP 37*. Chapter <797> Rockville, MD; 2014:410-453
- Bing CD, et al. 2013; ASHP, 5th edition