

Updating Professional Society Guidelines for Bacterial Infections

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Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development
in the United States
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Disclosures

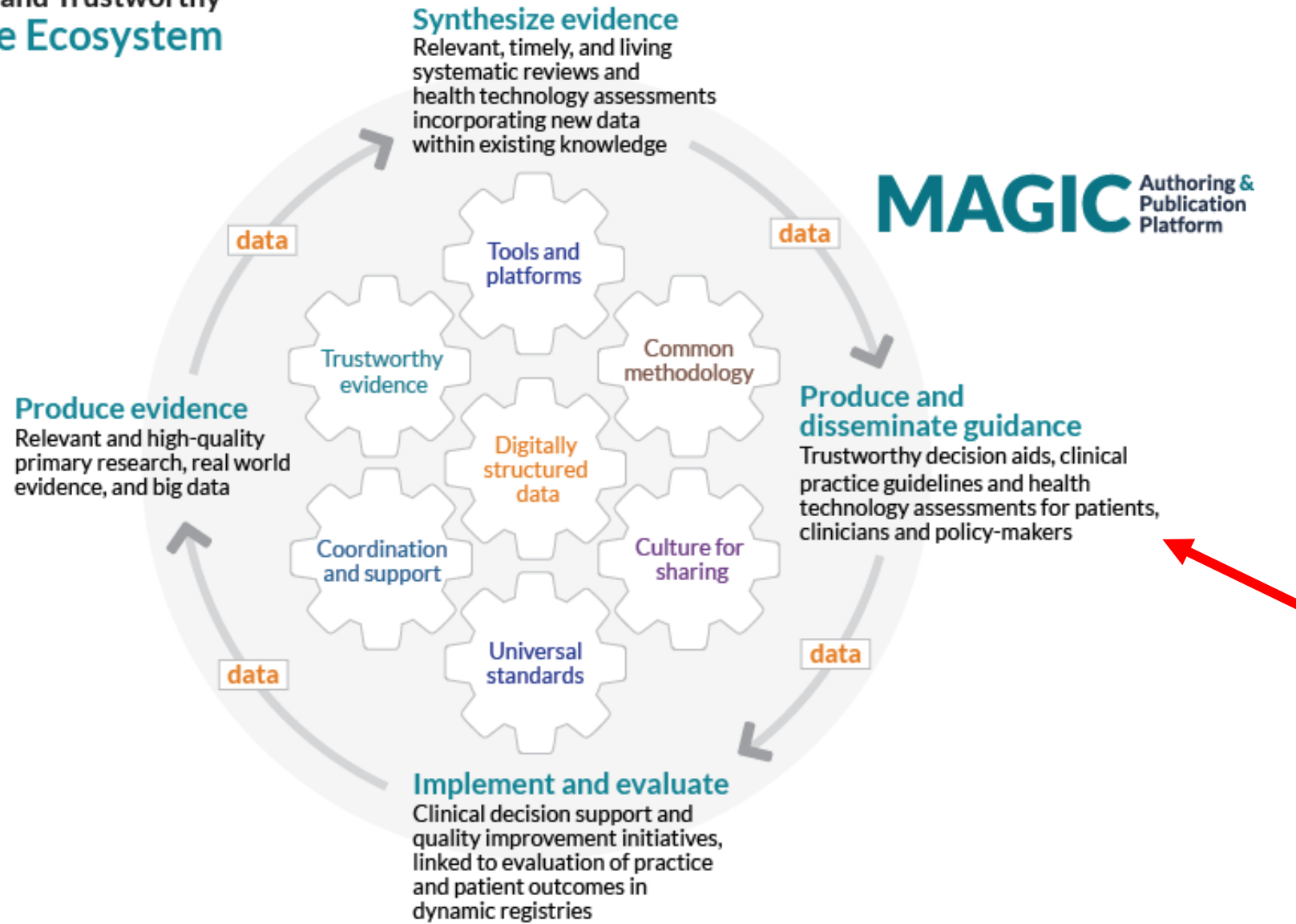
Bristol Myers Squibb (research grant, microbiome & cancer immunotherapy)

Janssen (research grant, microbiome & colorectal cancer)

Past President, IDSA

UpToDate (reviewer, author)

The Digital and Trustworthy Evidence Ecosystem



Source: <http://magicproject.org/research-and-tools/the-evidence-ecosystem/>

What is the purpose and promise of clinical guidelines?

Purpose

To provide evidence-based—'trustworthy'—recommendations to support patient care.
To develop a framework for determining acceptable clinical care.

Action

Systematically synthesize typically complex data into a format readily used by physicians and other health care providers to inform patient care decisions.

'Promise'/'Hope'

To support more uniform care for patients, yielding better patient outcomes.
Diminish health disparities.

Physicians/health care providers must be able to judge the quality of the evidence & whether the recommendations apply to their patient or populations in care.

Has the publication of methicillin-resistant *Staphylococcus aureus* (MRSA) treatment guidelines increased the survival associated with MRSA bacteraemia?

Richard Brindle* on behalf of Wessex Microbiologists†

Multisite retrospective comparison of 28 day all-cause mortality in 1675 patients with MRSA bacteremia before & after UK National MRSA Treatment Guidelines.

Table 1. Characteristics of the three patient groups

Group	Years during which data were collected	No. of patients	Mean age (SD)	Deaths within 28 days	28 day survival (95% confidence interval)
A	<2000–2003	535	70.1 (17.8)	191	64.3% (60.1%–68.4%)
B	2004–2005	589	69.3 (18.6)	219	62.8% (58.8%–66.7%)
C	2006–2008	551	69.9 (19.3)	205	62.8% (58.6%–66.8%)

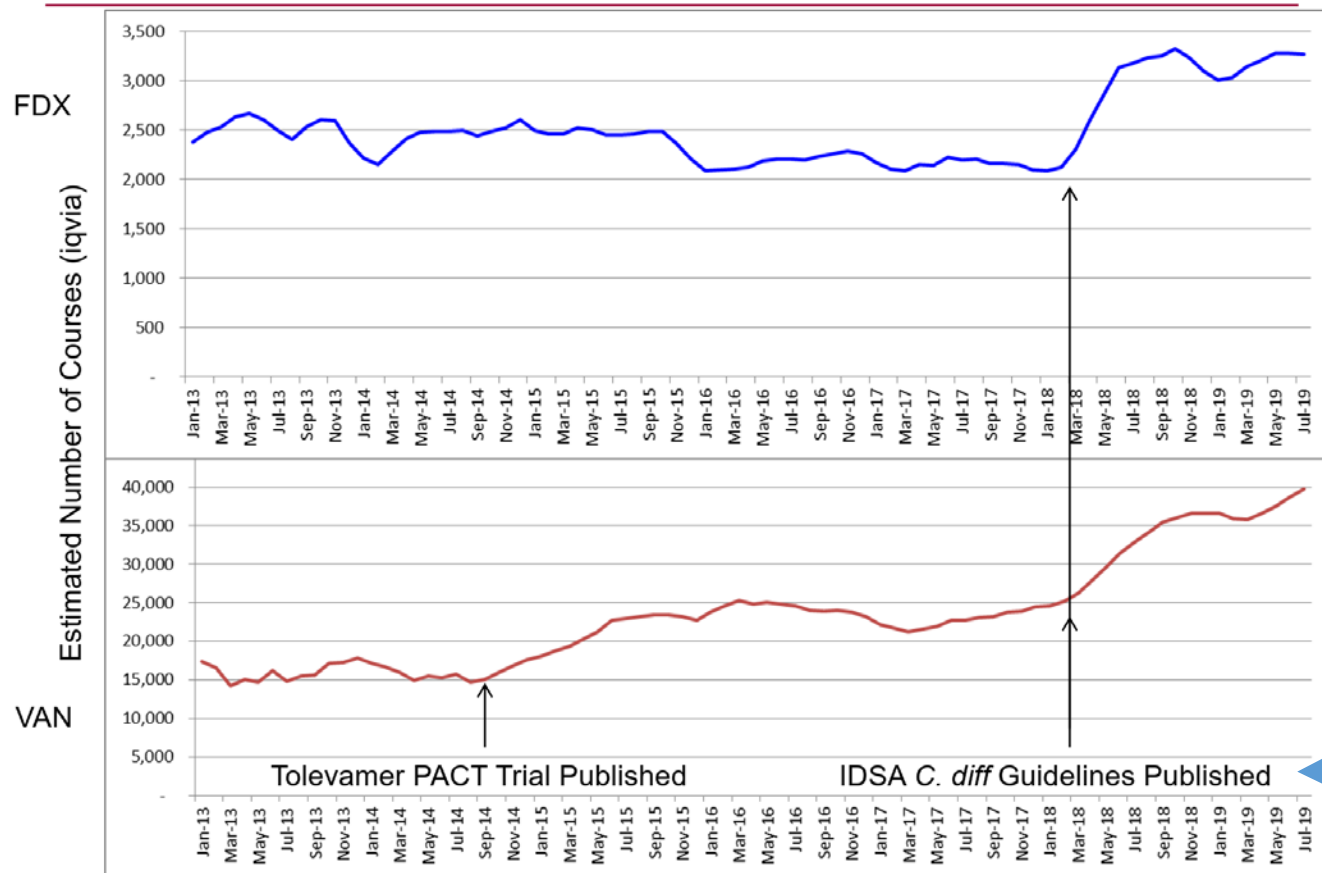
← Guideline published

Data only adjusted for age
Failed to adjust for: time to diagnosis
time to appropriate therapy
patient co-morbidities
hospital or practice setting

This paper & others have questioned clinical acceptance of guidelines, impact of guidelines on care & veracity of guideline processes. Guideline approaches highly variable.

Impact of IDSA/SHEA *C. difficile* Guidelines on Fidaxomicin and Vancomycin Therapeutic Use

Are physicians aware of the drugs and do they know when to use them?



March 2018



*PACT Phase 3 data initially presented 2007 ICAAC and 2008 ECCMID; IDSA Guidelines 2010

Slide by Alan Carr, Ph.D.
 Managing Director
 Equity Research
 Needham & Company
Presented ASM/ESCMID 2019
 Shared by Helen Boucher, M.D.

Clinical Practice Guidelines We Can Trust



IOM Standards for Trustworthy Guidelines

Establishing transparency

Management of COI

Systematic review

Establishing evidence foundations for
& rating strength of recommendations

Articulation of recommendations

External review

Updating

In stages, IDSA has sought to implement IOM standards in its guideline process.

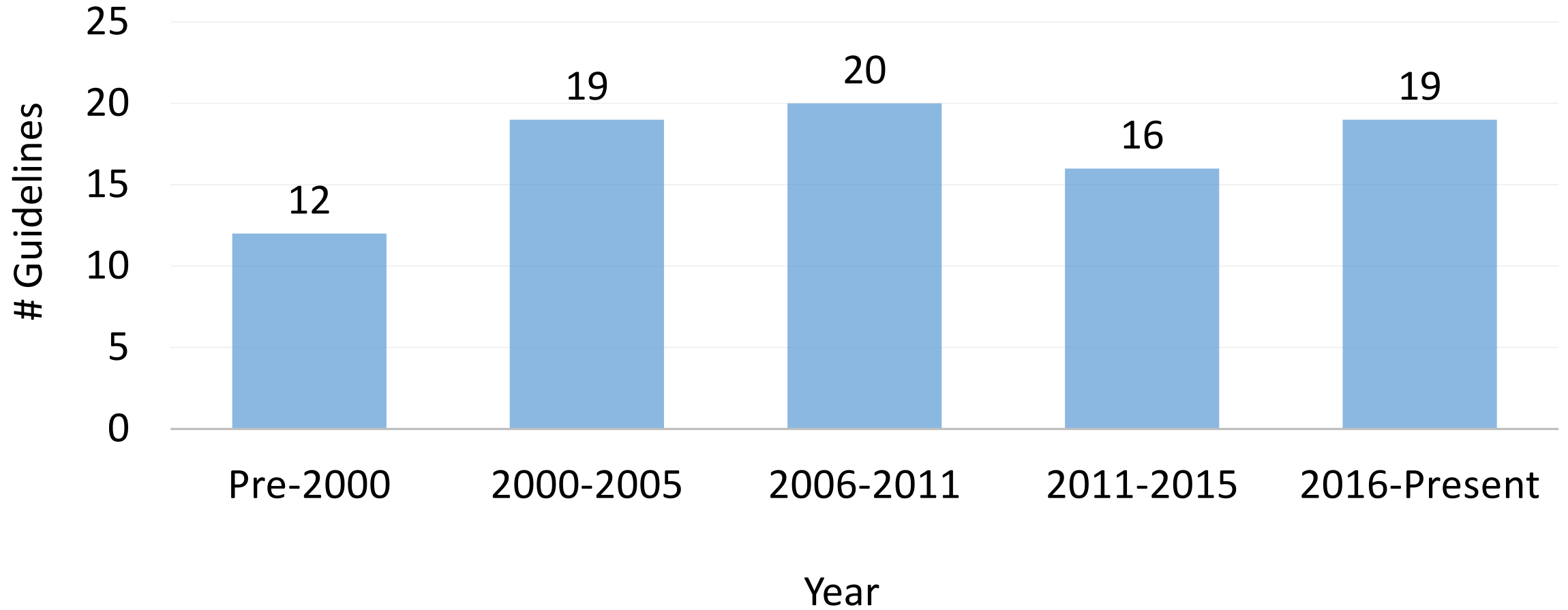
IDSA Guidelines are:

Highest-rated IDSA member product

Critical to member satisfaction

In parallel, member and guideline panel member dissatisfaction with long timelines for development and updates of IDSA guidelines.

ID Guidelines Published in CID to Date



What constitutes the guideline process?

Meeting IOM standards

Grading of Recommendation Assessment, Development & Evaluation (GRADE)

Pre-development:

Compose panel, methodologist, COI, agreements

Development:

Define scope of topic

Frame clinical questions*

Select patient-important outcomes

Systematic literature search

Literature screen, risk of bias assessment

Evidence synthesis and grading

Development & grading of recommendations**

Writing manuscript

Post-development:

Review process and approval

Guideline dissemination & implementation

Overall timeline: 1.5-2 years

Issues:

Time of member volunteers

Paucity of methodologists

& librarians

Poorly understood process

*Common clinical questions that typically apply to a large proportion of patients; termed PICO questions (Patient, Intervention, Comparator, Outcome)

** Recommendations—designed to answer a focused, sensible clinical question

IDSA-Led Guidelines





	Guideline Name	Estimated Publication
→	Babesiosis	Winter 2020
→	Bone & Joint Infections Osteomyelitis - Joint w/PIDS	Winter 2020
→	Bone & Joint Infections Septic Arthritis - Joint w/PIDS	Spring 2020
→	Lyme Disease - Joint w/AAN & ACR	Spring 2020
→	IV Catheter Infections	Fall 2019
→	C-diff Rapid Update	Spring 2020
→	Intra-abdominal Infections	Spring 2020
→	Staphylococcus aureus Bacteremia - Joint w/ESCMID	Spring 2020
→	Community-Acquired Pneumonia (CAP) in Children	Summer 2020
→	Cystitis UTI	Winter 2021
	Cryptococcal Disease	TBD

→ Designates IDSA guideline involving anti-bacterial therapy

Jointly-Developed Guidelines (not IDSA led)

	Name	Lead Organization	Estimated Publication
→	Vancomycin, Dosing and Monitoring of - Joint w/ASHP, SIDP & PIDS	ASHP	Fall 2019
→	Community-Acquired (CAP) - Joint w/ATS	ATS	Fall 2019
→	NTM Statement - Joint w/ATS, ERS & ESCMID	ATS	Fall 2019
→	MDR-TB - Joint w/ATS, ERS & CDC	ATS	Fall 2019
→	Critically Ill Patients - Joint w/SCCM	SCCM	Winter 2021
→	Antimicrobial prophylaxis in surgery update - Joint w/ASHP, SIS, SHEA	ASHP	Winter 2021

IDSA-Endorsed Guidelines

Name	Lead Organization	Estimated Publication
Diagnosis of Periprosthetic Joint Infections w/AAOS	AAOS	TBD
Initiation of Abx in LTC w/SHEA	SHEA	Fall 2019
Appropriateness Criteria Suspected Spine Infection	ACR	Fall 2020
 Sepsis in Emergency Medicine w/ACEP	ACEP	Spring 2020
Appropriateness Criteria Osteomyelitis, Septic Arthritis-Child	ACR	Spring 2021
 Infection Prevention and Control in LTC w/SHEA	SHEA	Fall 2021
White Paper on Healthcare Workers Infected with Hepatitis/HIV w/SHEA	SHEA	Winter 2021
Sterilization and High-Level Disinfection Expert Guidance w/SHEA	SHEA	Winter 2021
 Sepsis in Adults w/SCCM	SCCM	Winter 2021
 Pediatric Sepsis Definition w/SCCM	SCCM	Winter 2021

What are other options for conveying science-derived, actionable bedside advice to clinicians?

'Guidance'

Marquis examples:



HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C



DHHS/NIH HIV Guidelines

- Clinical consensus statements
- Practice guidance
- Provisional clinical opinions

Most applicable when evidence base is insufficient for a clinical practice guideline, but significant practice variations and quality improvement opportunities exist.

In general, recommendations based on expert consensus utilize a less formal process (non-GRADE)

Potential hazards: accuracy, completeness, COI, transparency

The Challenge: Upholding methodological rigor while meeting a reduced development timeframe

Potential Solution: Rapid Guidelines*

Rationale:

Response to emergencies, rapid increases in cases of a condition or disease severity, or new evidence regarding treatment

Examples:

- Interim Guidelines (CDC)
- Short Clinical Guidelines (UK National Institute for Health and Care Excellence)
- Rapid Advice (WHO)

Limitation:

It requires a high concentration of skilled resources to be rigorous and rapid.

* Kowalski et al. 2018. Development of Rapid Guidelines: 1. Systematic Survey of Current Practices and Methods. Health Res Policy Syst. 16:61. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6044042/>

STRATEGIC PLANNING FOR IDSA: 2018-2019

Stakeholder interviews

Member survey

Task Force for Strategic Planning

IDSA leadership staff

IDSA Board of Directors

Vigorous Debate

A Strategic Model: R-G-T



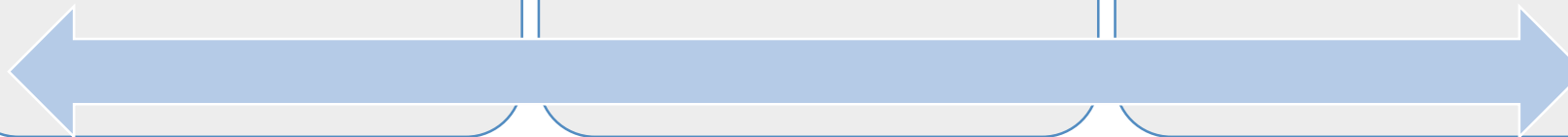
Run: Continual process and quality improvements focused adding value to existing programs and functions.



Grow: Targeted, meaningful investments to extend, adapt, reposition, reimagine, or innovate within priority areas.



Transform: Long-term, high-impact efforts to bring about profound, lasting change within the association, profession, or society at large.



2019 IDSA STRATEGIC PLAN: TRANSFORMING THE SOCIETY AND THE PROFESSION

Clinical Infectious Diseases

IDSA FEATURES



Charting the Path Forward: Development, Goals and Initiatives of the 2019 Infectious Diseases of America Strategic Plan

Cynthia L. Sears,^{1,a} Thomas M. File,^{2,a} Barbara D. Alexander,^{3,a} Daniel P. McQuillen,^{4,5,a} Ann T. MacIntyre,^{6,a} Upton D. Allen,^{7,a} Jonathan A. Colasanti,^{8,a} Javeed Siddiqui,^{9,a} Kelly R. Reveles,^{10,a}, and Chris Busky^{11,a}; for the Infectious Diseases Society of America (IDSA) Board of Directors^b



Clinical
Infectious
Diseases



Optimize Guidelines

Communicate **ID Value**, Advance
Professional Fulfillment and Ensure
Appropriate Compensation

Grow the **ID Workforce**

Invest in and Lead Efforts to **Decrease
AMR**

Gap


Trustworthy, real-time, focused guideline/guidance on treatment of antimicrobial resistant infections.

Moment of Opportunity

Completion of the 2019 Strategic Plan means
IDSA intends to invest significant staff
and financial resources beginning in 2020.

Expanding IDSA's Guideline Program to Meet the Needs of the Clinical ID Community

Development

- Guideline Methodology – continuous quality improvement
 - Prioritization & Harmonization
 - Expand the Portfolio of Guidance Products
 - Interim recommendations supplementing standard clinical guidelines
- 

Dissemination & Implementation

- Format
- Connect guidelines and measures
- Technology- EHR integration to allow for data capture and clinical decision support

Proposal:

Antimicrobial Treatment Alert & Clinical Commentary from IDSA

- Rapid dissemination of emerging trial and drug data on antimicrobials
- New drug/innovation placed in context by clinical experts – clinical expert recommendations
- Comparison charts of new versus current treatments for bacteria involved
- ‘In progress’ antibiotics?
- Delineation of questions in need of further research

Provide your suggestions and input for action.

Questions for consideration:

What should be the format and components of real-time AMR treatment advice?

What is/are the clinical audiences?

What are the requirements & standards for data inclusion & changes in treatment advice provided?

How should dissemination of this information be approached?

What are the concerns about such a process & approach?