

The Role of Vaccines in Combating Antimicrobial Resistance: *An Industry Perspective*

NVAC Meeting, February 10, 2015

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AMR Vaccine Development by Industry

- Industry is actively pursuing vaccines as part of the solution to AMR.
- Vaccine companies assess AMR-related targets based on same criteria used for all vaccines and pharmaceuticals:
 - Scientific feasibility, cost/time to develop, medical need, treatment availability, market size, revenue, fit with existing portfolio/platform
- Resistance does affect whether there is an unmet medical need, which is an important consideration for companies.
- Vaccines are generally not developed specifically against the resistant strains of a pathogen, but rather against all strains.
- AMR vaccines are often designed to protect against pathogens for limited populations (e.g. healthcare-associated infections).

Current Industry AMR Vaccine Pipeline

Target	Clinical-Stage Pipeline				FDA Licensed
	Ph 1	Ph 2	Ph 3	Total	
2013 CDC AMR Threat List & FDA Qualifying Pathogens List for GAIN Act:					
<i>Candida</i>		1		1	
<i>Clostridium difficile</i>		1	1	2	
<i>Escherichia coli</i>	1			1	
<i>Group B Streptococcus</i>		1		1	
<i>Pseudomonas aeruginosa</i>		1		1	
<i>Salmonella typhi</i>					2
<i>Staphylococcus aureus</i>	2	1		3	
<i>Streptococcus pneumoniae</i>	1	3	1	5	3
<i>Mycobacterium tuberculosis</i>	1	4		5	2
FDA Qualifying Pathogens List for GAIN Act:					
<i>Neisseria meningitidis</i>		1		1	5
<i>Vibrio cholerae</i>			1	1	
				21	12



Vaccines against Healthcare-associated Infections

- 79% of deaths reported in 2013 CDC AMR Report are due to HAIs

Challenges	Opportunities
Limited populations vs. routine vaccines	Prevention of infections <ul style="list-style-type: none">- reduce morbidity & mortality- reduce hospitalizations- reduce antibiotic use
Defining at-risk patients to vaccinate	
Target populations with high co-morbidities	
Vaccines require immunocompetence	Durable protection <ul style="list-style-type: none">- reduce recurrent infections/readmission
Rapid protection may be required	

AMR Vaccines - Challenges & Opportunities

	Challenges	Opportunities
R&D Funding	<ul style="list-style-type: none"> • High & increasing cost of vaccine R&D • Investment in ID low vs. cancer/orphan • AMR vaccines are for limited populations • Need NIH/DoD funding for early pipeline 	<ul style="list-style-type: none"> • Perceived threat of AMR increasing • White House CARB Initiative • New potential funding for AMR vaccines
Regulatory	<ul style="list-style-type: none"> • Vaccines not included in GAIN Act 	<ul style="list-style-type: none"> • Expand GAIN incentives to vaccines • Increase FDA use of ID biomarkers • Improved diagnostics for clinical trials
ACIP	<ul style="list-style-type: none"> • ACIP recommendations more uncertain • ACIP recommendation does not equate to Medicare coverage as it does for private plans per ACA 	<ul style="list-style-type: none"> • Increase ACIP transparency/consistency • Ensure ACIP safety/efficacy bar not higher than FDA • ACIP consider AMR in health economics • Medicare coverage follows ACIP
Reimbursement	<ul style="list-style-type: none"> • Cost-sharing for vaccines in Medicare Part D • Risk being bundled into hospital payments 	<ul style="list-style-type: none"> • Eliminate cost-sharing for new vaccines • Pass DISARM Act to unbundle payments
Delivery	<ul style="list-style-type: none"> • Low adult immunization rates • Low proportion of providers are immunizers 	<ul style="list-style-type: none"> • Increase adult rates & immunizers • Address vaccine hesitancy

Potential Roles for NVAC

- Champion a broad approach to the problem of AMR and emphasize the important role of vaccines.
 - Request the inclusion of vaccine experts and developers on the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (CARB), which will be convened by HHS under Exec Order.
- Call for increased surveillance and more research on the impact of vaccination rates on the threat of AMR.
- Make vaccines part of the stewardship discussion – if providers are being stewards of antibiotics, they should also be immunizers.
- Continue efforts to drive overall immunization rates in the U.S.



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