



# Meningococcal Carriage Evaluation in Response to a Serogroup B Meningococcal Disease Outbreak and Mass Vaccination Campaign at a University — Oregon, 2015–2016

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2016 Oregon Flu Summit and More

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# Overview

- Background
  - Meningococcal disease
  - *Neisseria meningitidis*
  - Meningococcal transmission and carriage
  - Meningococcal vaccines
  - Vaccine impact on meningococcal carriage and herd protection
- Meningococcal carriage evaluation
  - Context
  - Methods
  - Findings
- Summary

**Background**

# Meningococcal Disease

- Presentations:
  - Meningitis
  - Bloodstream infection
- Symptoms:
  - Fever, headache, stiff neck, confusion, rash
- 10-15% of patients die even with appropriate treatment
- 11-19% of survivors have long-term health issues



Necrosis due to meningococcal infection  
in a young adult

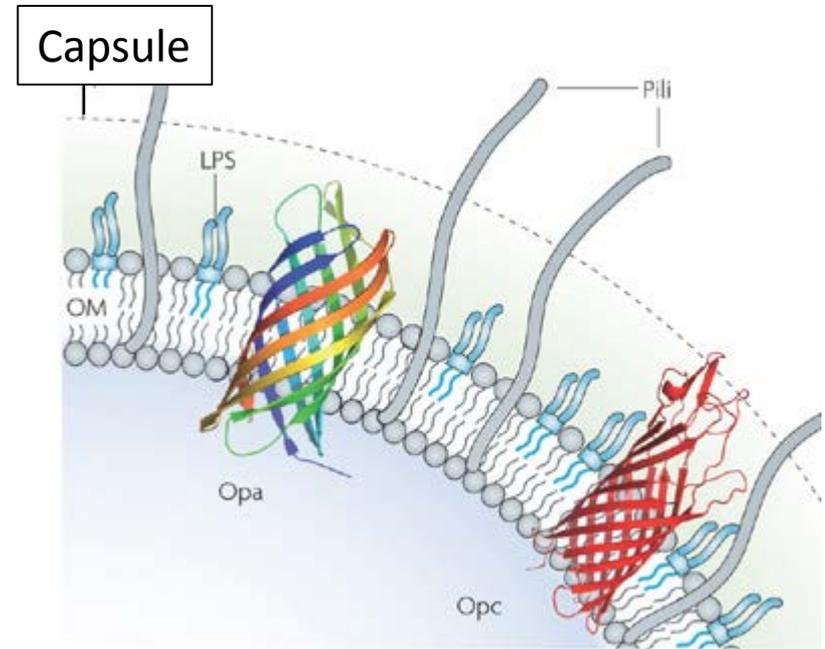
# *Neisseria meningitidis* (meningococcus)



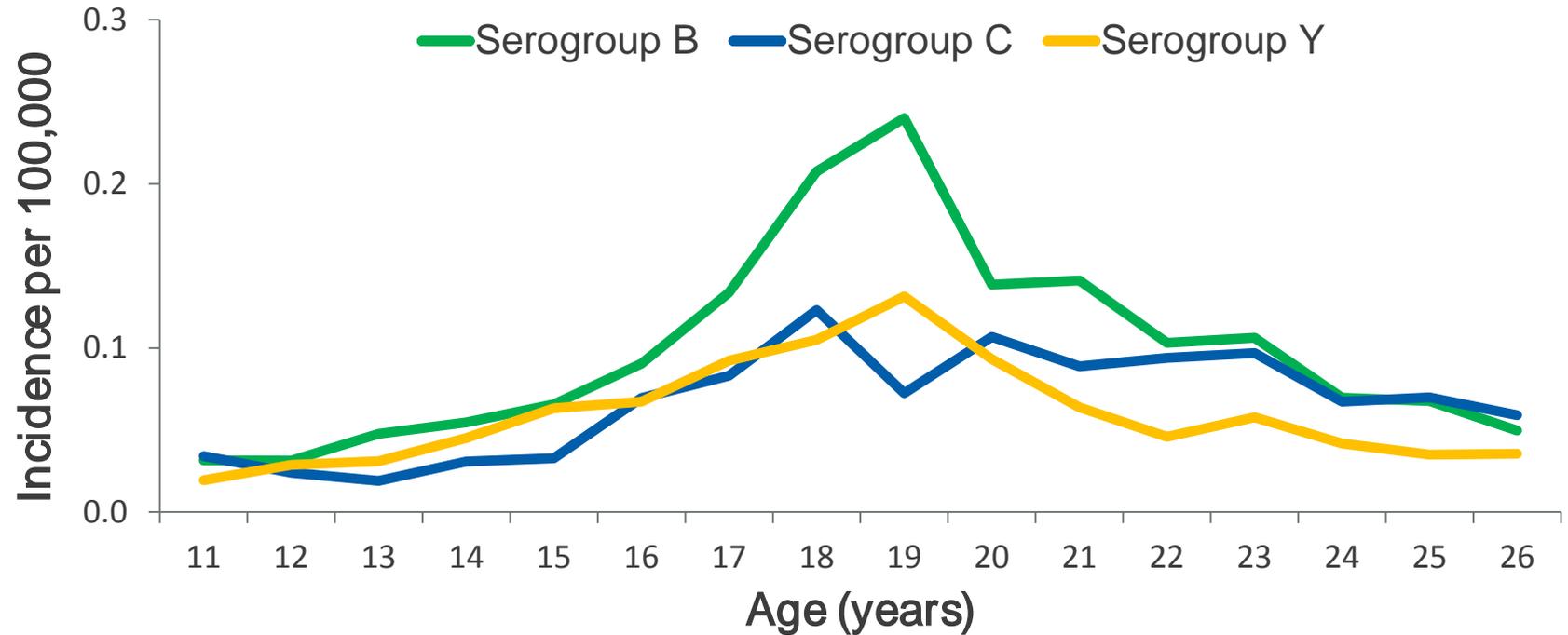
- Gram-negative diplococcus
- Genus includes *Neisseria gonorrhoeae* and commensal organisms
- Humans are the only reservoir

# Meningococcal Serogroups

- Polysaccharide capsule
  - Classified into serogroups based on capsule
- 12 serogroups
  - A, B, C, W, X, and Y primary causes of disease



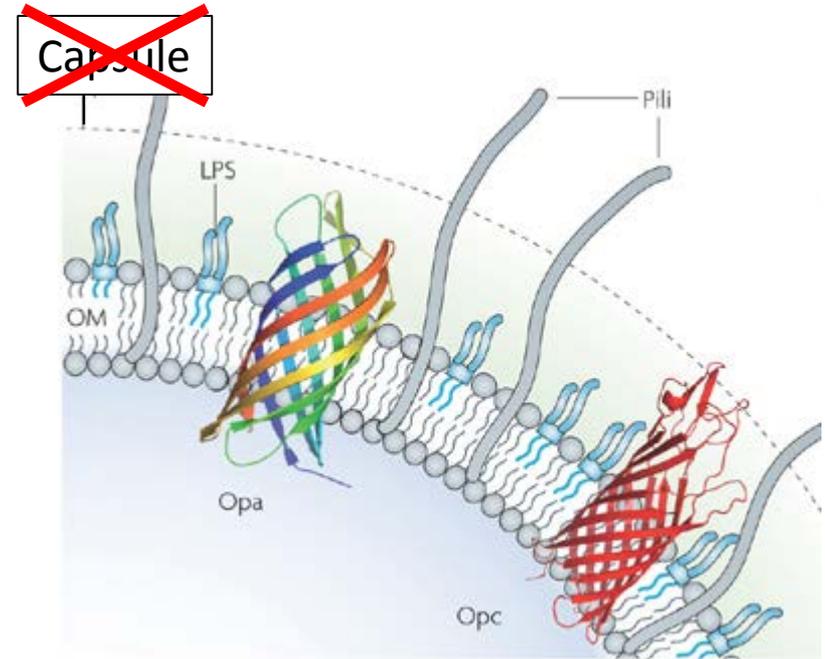
# Meningococcal Disease Incidence in Adolescents and Young Adults by Serogroup, 2005–2014



Source: National Notifiable Diseases Surveillance System (NNDSS) data with additional serogroup data from Active Bacterial Core surveillance (ABCs) and state health departments. Unknown serogroup (21%) and other serogroups (7%) excluded

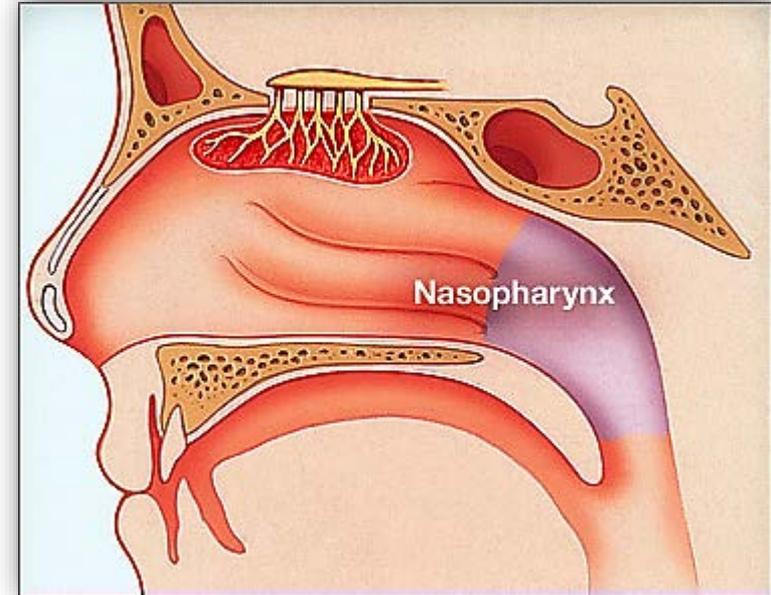
# Nongroupable *N. meningitidis*

- No capsule expression:  
“Nongroupable”
- Two reasons an isolate can be classified as nongroupable:
  - May lack capsule gene: incapable of expressing polysaccharide capsule
    - Rarely cause invasive disease
  - May have capsule gene but not currently expressing
- Asymptomatic carriage is common



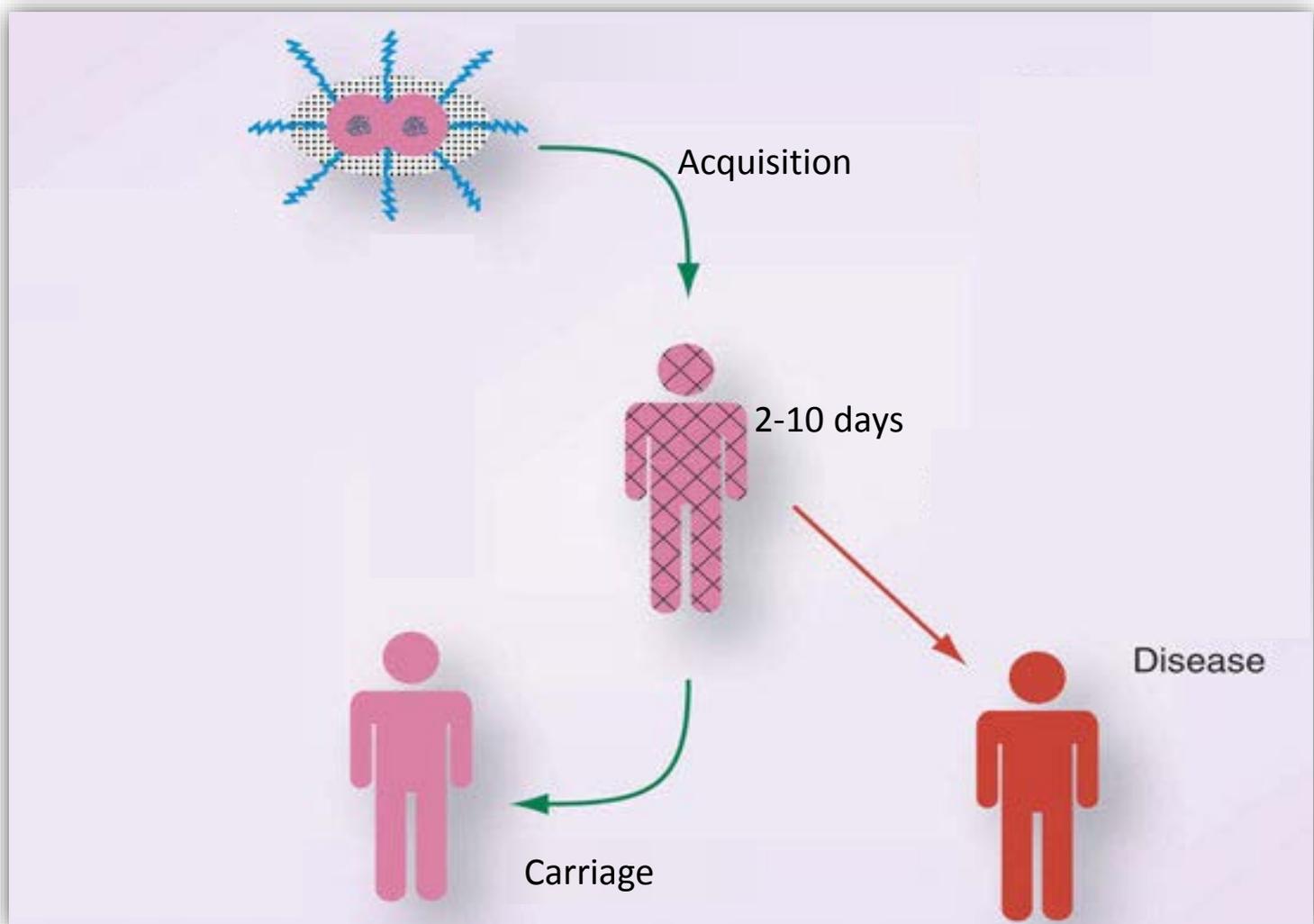
# Meningococcal Carriage

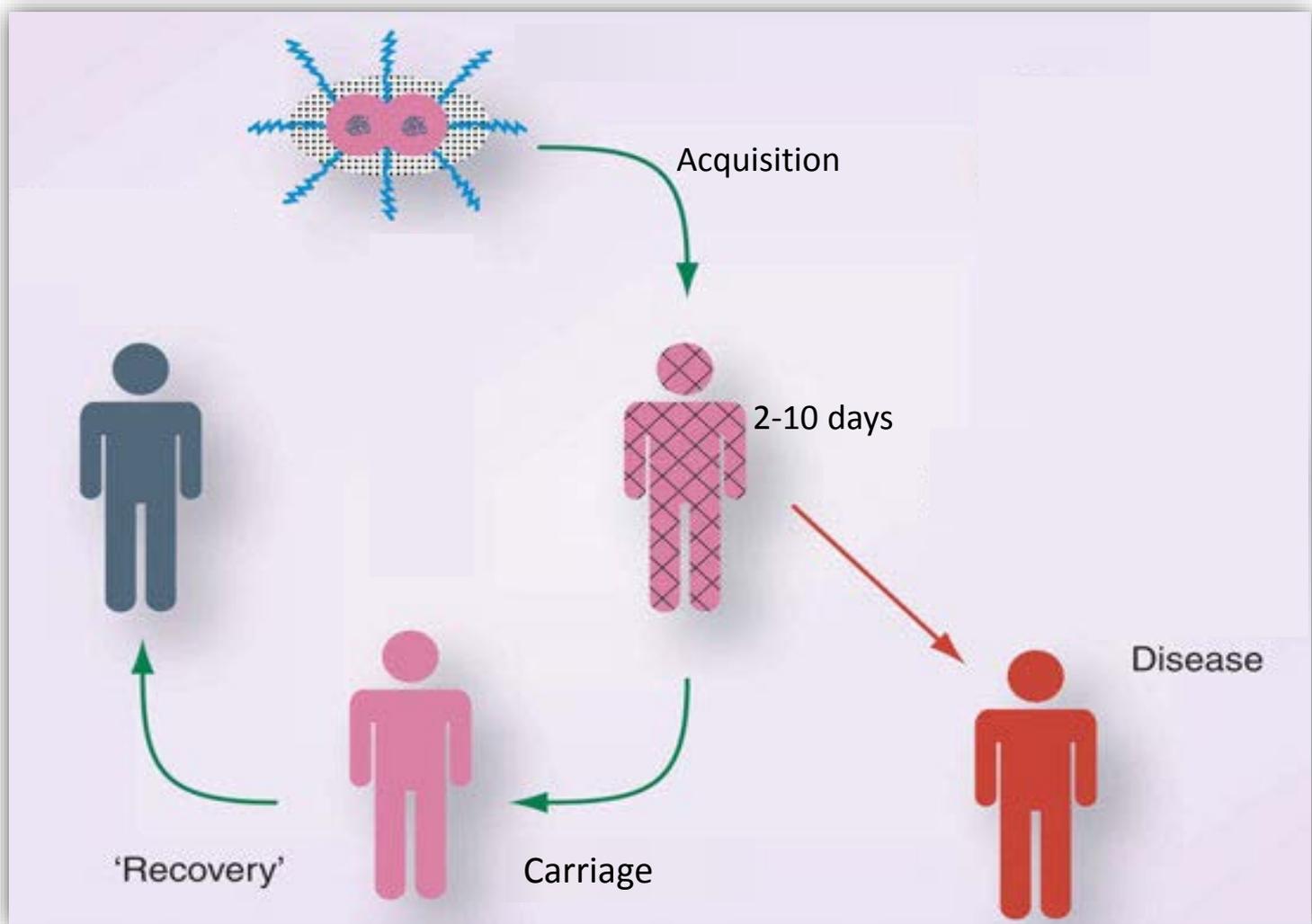
- Asymptomatic nasopharyngeal carriage
- More than 100x as common as meningococcal disease
- Carriage prevalence varies from <1 to >20% of population
  - Adolescents and young adults have highest carriage
- Lasts weeks to months<sup>1,2</sup>



# Meningococcal Carriage vs Meningococcal Disease

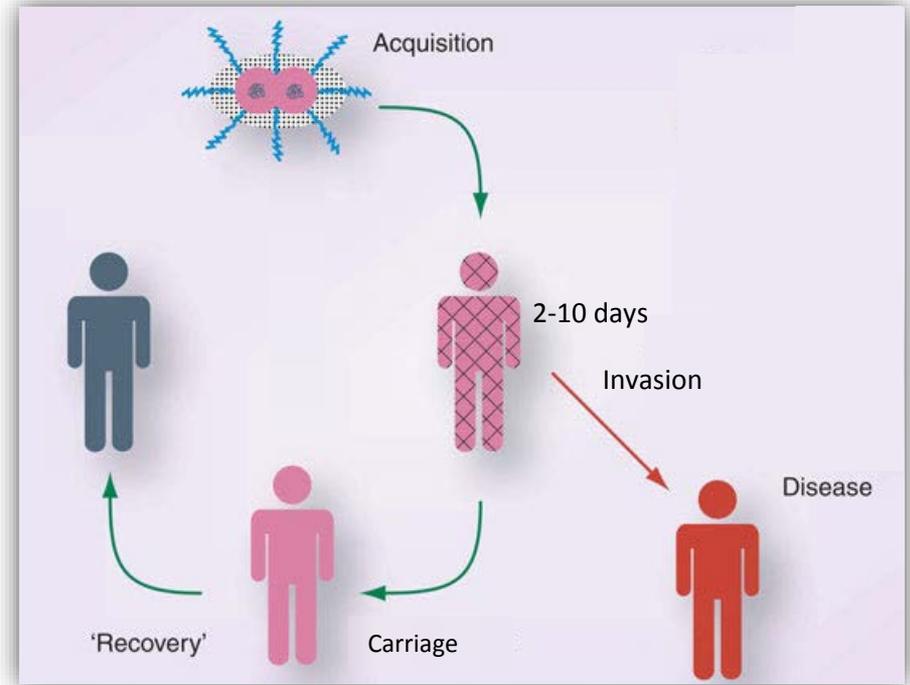
- Carriage not considered to increase disease risk
  - Carriage and disease are distinct outcomes of acquisition

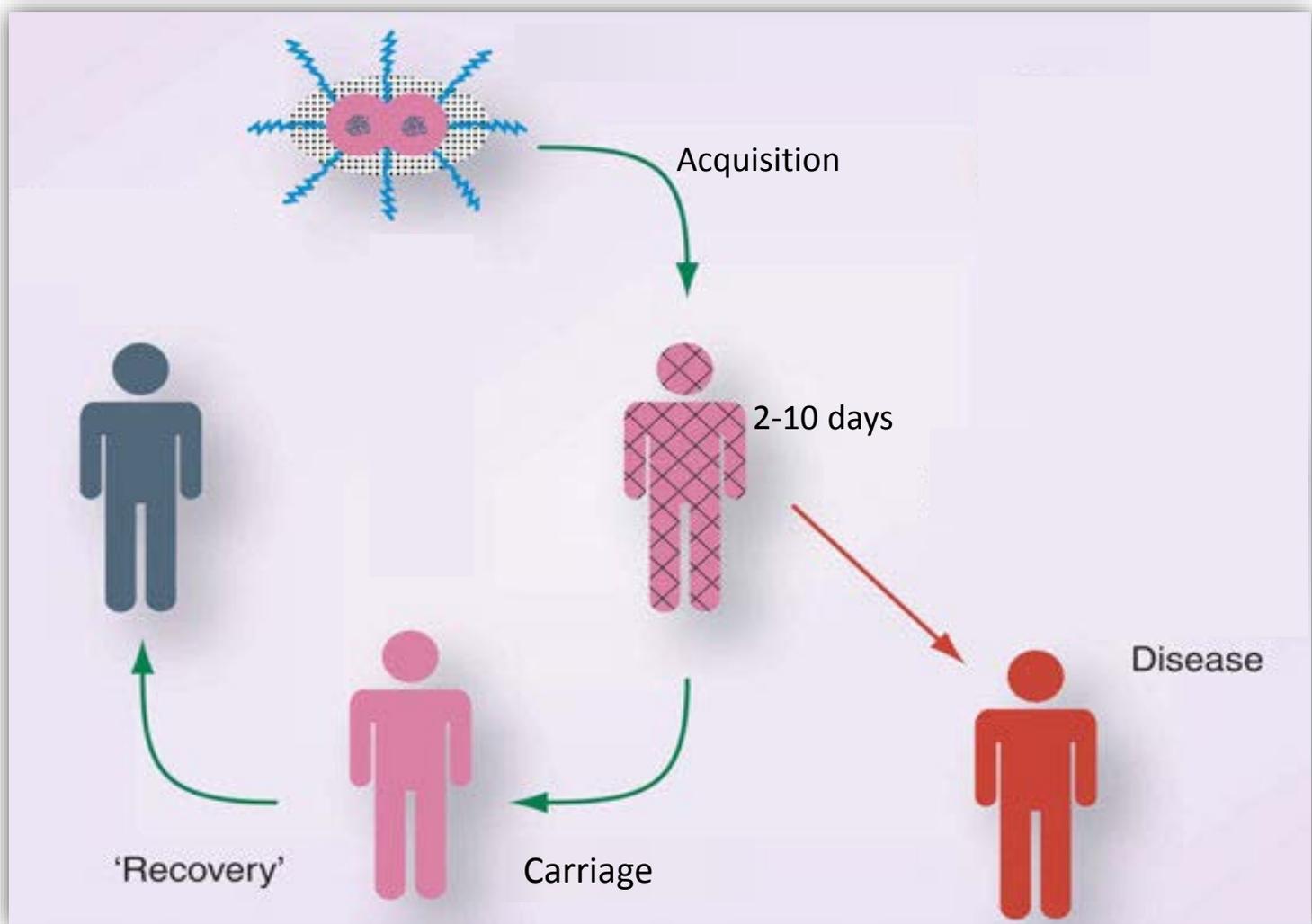


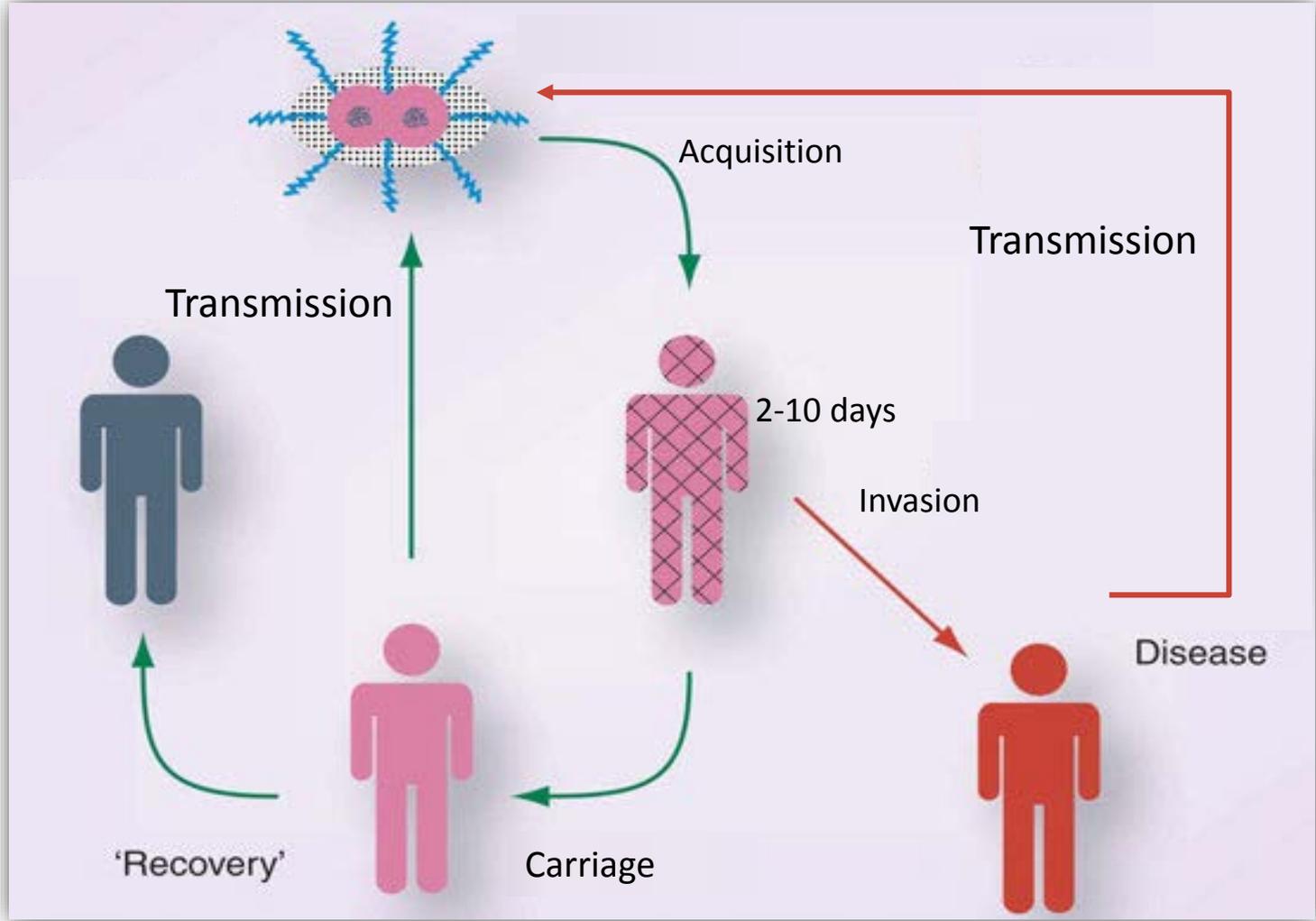


# Meningococcal Carriage vs Meningococcal Disease

- Carriage not considered to increase disease risk
  - Carriage and disease are distinct outcomes of acquisition
  - No treatment recommended for carriage
  - Might provide protection against invasive disease
- Likelihood of establishing carriage vs. invasive disease varies by strain
  - Nongroupable frequently carried







# Meningococcal Transmission

- Transmission through close contact
  - Respiratory or oral secretions
- Risk factors for carriage among adolescents and young adults
  - Social mixing<sup>1,2</sup>
  - Age<sup>3,4</sup>
  - Smoking<sup>3</sup>

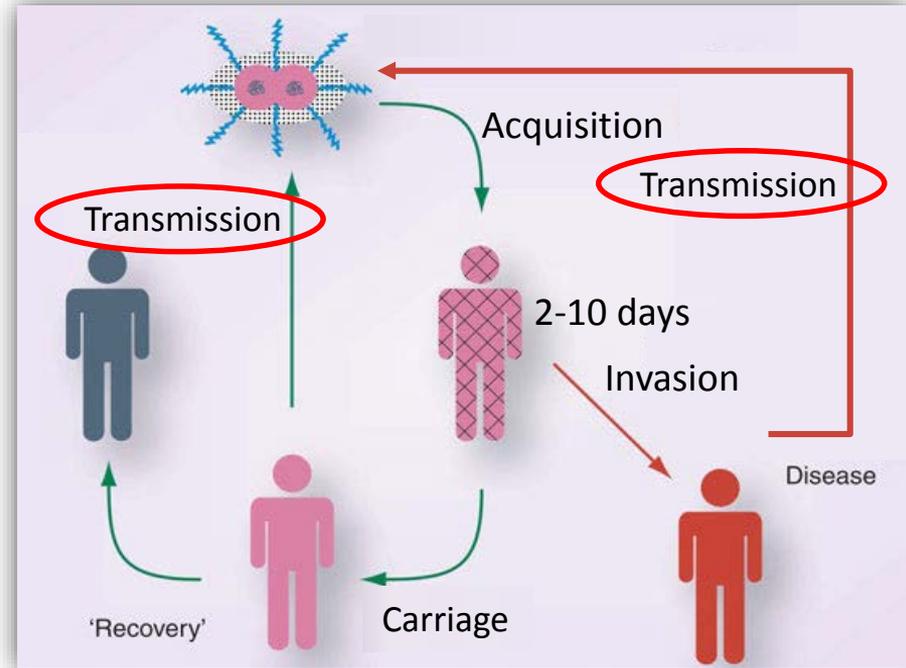


Sources: 1. Mandel et al. JID 2013. (US) 2. MacLennan et al. EID 2006 (UK) 3. Harrison et al. JID 2014. (US) 4. Jeppesen et al. J Infect 2015. (UK)

Image from: <http://www.barsandnightclubs.com.au/perth/leederville/hipe-club/photos/2/>

# Herd Protection

- Transmission from both patients and asymptomatic carriers must be reduced
- Cases
  - Chemoprophylaxis for close contacts → prevents secondary cases
- Carriers
  - Not readily identifiable
  - Need a method to reduce carriage at the population level

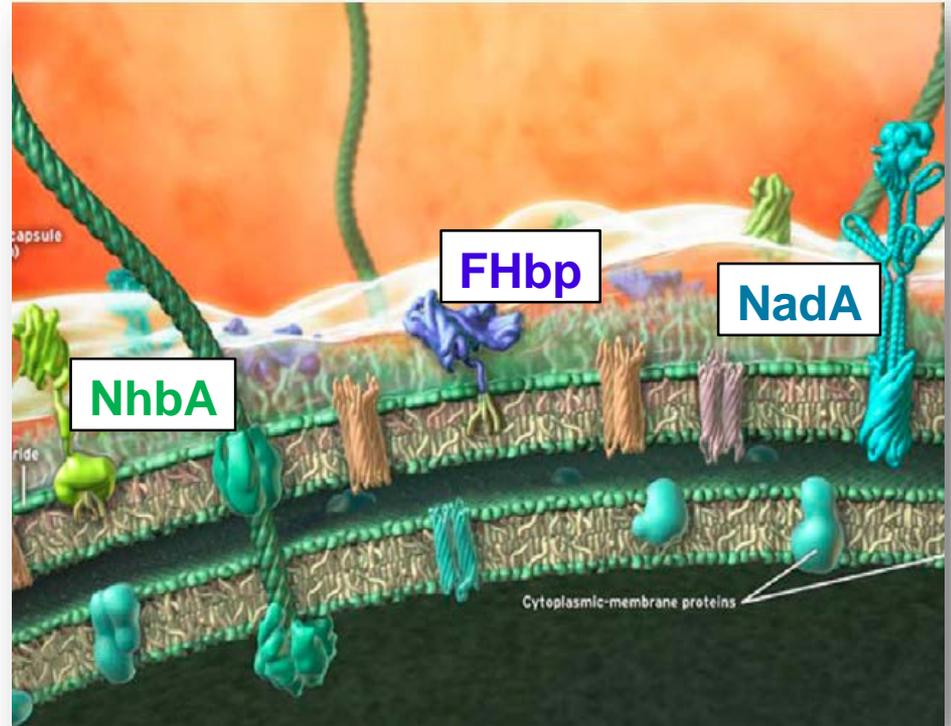


# Meningococcal Vaccines

- Traditionally based on capsular polysaccharide specific to each serogroup
- US: conjugate meningococcal vaccine for serogroups A, C, W, and Y (MenACWY)
  - Routinely recommended for adolescents and young adults:
    - First dose at age 11-12
    - Second dose at age 16
- Serogroup B vaccines
  - Serogroup B polysaccharide capsule is poorly immunogenic
    - Similar to human antigens

# Serogroup B Meningococcal (MenB) Vaccines

- Based on outer membrane proteins
- Proteins have multiple alleles and variable expression
  - MenB vaccines not protective against all serogroup B strains
  - Could protect against other serogroups



# Serogroup B Meningococcal (MenB) Vaccines



- 2 vaccines recently licensed in U.S. for persons aged 10-25 years
  - Trumenba® (Pfizer) – Oct 2014
    - 2 alleles of one outer membrane protein
    - 2 or 3 doses
  - Bexsero® (GlaxoSmithKline) – Jan 2015
    - 4-component
    - 2 doses

# MenB Vaccine Recommendations

- Recommended for use in persons at increased risk for serogroup B meningococcal disease<sup>1</sup>
  - Includes outbreak settings
- Category B recommendation: MenB vaccine series may be administered to people aged 16-23 years<sup>2</sup>

# Princeton to make meningitis B vaccine available

By Elizabeth Landau, CNN

Updated 3:36 PM ET, Wed November 27, 2013

## Providence College students to receive final vaccination against meningitis

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NEWS

## Rutgers-New Brunswick students urged to get meningitis shot

## Meningitis: UCSB Health Gave It a Shot

May 15, 2014 at 5:00 am by Julia Govan

## Santa Clara University students urged to get meningitis vaccine

By Kimberly Veklerov Updated 4:24 pm, Wednesday, February 3, 2016

# University of Oregon meningitis vaccination will be largest in US since approval of new drug

# MenB Vaccines and Herd Protection

- Low disease incidence → Difficult to directly assess vaccine effectiveness
- MenB vaccines licensed based on immunogenicity and safety data
  - Suggests vaccines help protect against serogroup B meningococcal disease
- **Can MenB vaccines also reduce meningococcal carriage?**
  - Required to provide herd protection

# Vaccine Impact on Meningococcal Carriage

- Some meningococcal conjugate vaccines have been shown to reduce carriage:
  - MenC vaccines reduced serogroup C carriage in UK by 66%<sup>1</sup>
  - MenA vaccine dramatically reduced serogroup A carriage in Burkina Faso<sup>2</sup>
- Limited data on MenACWY conjugate vaccines used in the US
  - One study found 36% reduction in serogroup C/W/Y carriage<sup>3</sup>

# MenB Vaccine Impact on Meningococcal Carriage

- MenB vaccines contain outer membrane proteins
  - Can potentially reduce carriage of all meningococcal serogroups and nongroupable bacteria
- Limited data on MenB vaccine impact on carriage
  - Bexsero<sup>®</sup>: one study found 18% (95% CI: 3-31%) reduction in carriage of any meningococcal bacteria<sup>1</sup>
    - No impact on serogroup B
  - Trumenba<sup>®</sup>: no data

# Background Summary

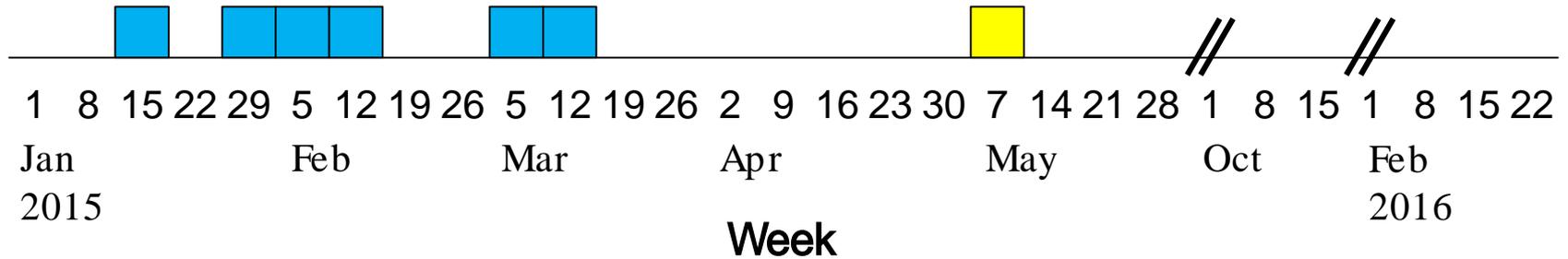
- What do we know?
  - Asymptomatic meningococcal carriage is an important source of transmission
  - 2 licensed MenB vaccines recommended to help protect individuals from serogroup B meningococcal disease during outbreaks
- What don't we know?
  - Impact of MenB vaccine on meningococcal carriage and herd protection

# **Serogroup B Meningococcal Disease Outbreak**

Oregon, 2015–2016

# University of Oregon Serogroup B Meningococcal Disease Outbreak

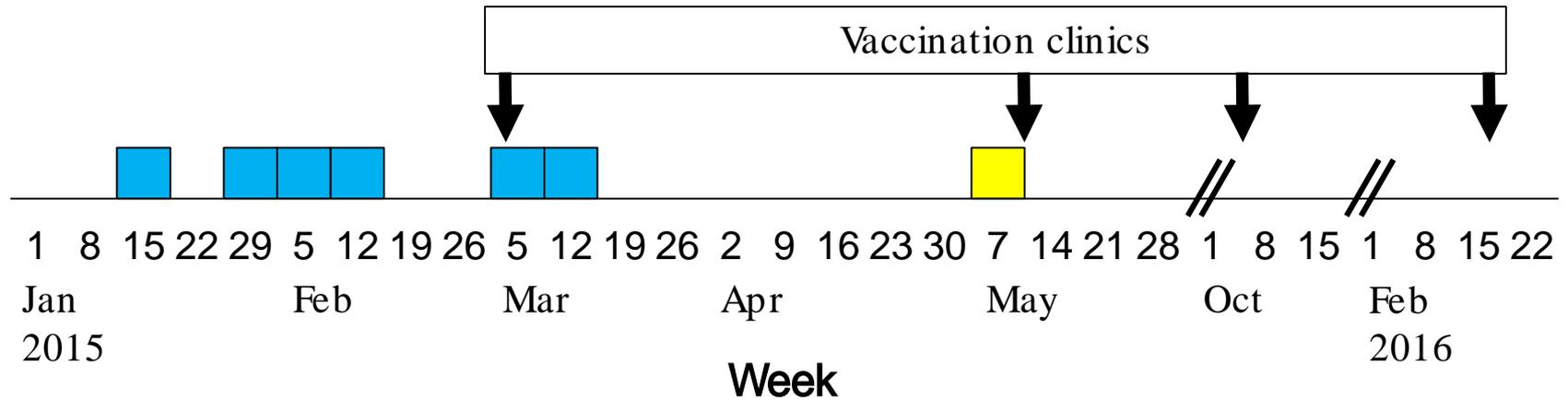
- 7 serogroup B cases in January–May, 2015
  - 1 death
  - All caused by sequence type (ST) 32
- Bexsero<sup>®</sup> provided to a limited number of students beginning in February 2015



■ Case in U of O student     
 ■ Case in close contact of a student

# University of Oregon Serogroup B Meningococcal Disease Outbreak

- Mass vaccination clinics with Trumenba®
  - Also available during freshman orientation and at local pharmacies
- As of March 2016, estimated 52% of targeted students received 1-3 doses of a MenB vaccine



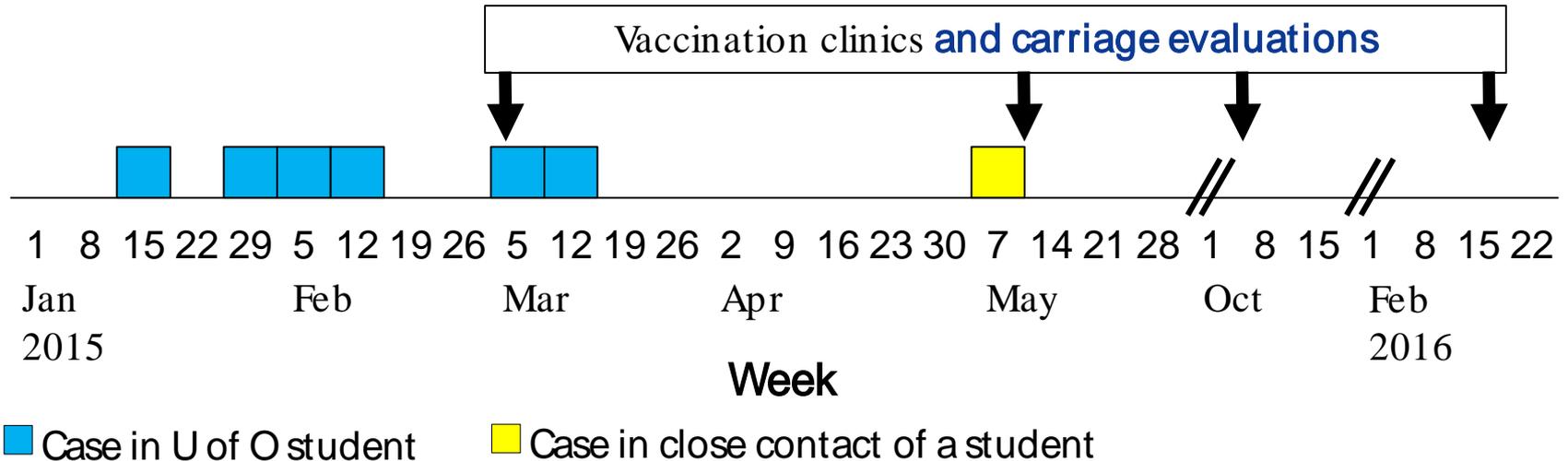
■ Case in U of O student     
 ■ Case in close contact of a student

# Meningococcal Carriage Evaluation

- Mass vaccination would help protect individual students
- Unknown whether campaign would reduce transmission
- Proposed carriage evaluation to understand:
  - Specific impact of the vaccination campaign at the university
  - Impact of MenB vaccines on carriage in general

# Meningococcal Carriage Evaluation

- Assess meningococcal carriage at the time of each mass vaccination clinic
- Objectives:
  - Assess the effect of vaccination on overall and serogroup B carriage
  - Determine baseline carriage of *N. meningitidis* and the outbreak strain



# Carriage Evaluation Methods

# A Monumental Undertaking

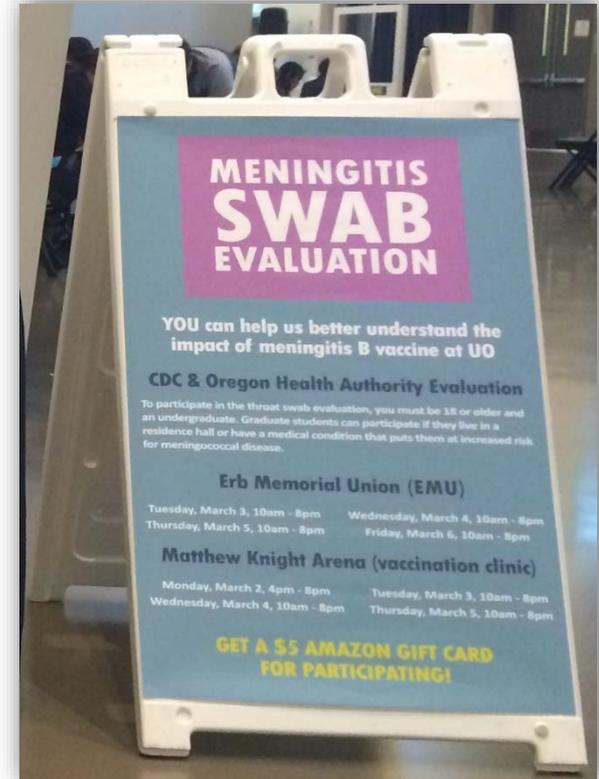
- Limited time to prepare
  - Drafted protocol and mobilized first round resources in 1 week
- Sent teams of ~15 epidemiology and laboratory staff to the field for each carriage evaluation round
- Enormous support from state and Lane County health departments and the university

# Eligibility and Recruitment

- All students eligible to receive MenB vaccine at mass vaccination clinic were eligible for carriage evaluation
  - Undergraduate students
  - Graduate students living in undergraduate dormitories or with specific medical conditions
- Students eligible regardless of whether they had received MenB vaccine
- Could participate in multiple rounds but only once per round
- Recruited at:
  - Mass vaccination clinics
  - High-traffic sites on campus

# Meningococcal Carriage Evaluation Methods

- Recruit, consent, enroll participants
- Questionnaire
  - Demographics
  - Risk factors for meningococcal carriage and disease



# CDC Meningococcal Carriage Evaluation Methods



# CDC Meningococcal Carriage Evaluation Methods

- Oropharyngeal swab of tonsils and posterior oropharynx
- Plated on Modified Thayer-Martin media



# Laboratory Methods

- On site
  - Bacterial culture
  - Gram stain
  - Biochemical testing
- At CDC
  - Real-time PCR
    - Species and serogroup
  - Additional testing:
    - Slide agglutination
    - Additional molecular testing
    - Whole genome sequencing



# Vaccination Record Abstraction

- Asked students to report MenB and MenACWY vaccination status
- Verified meningococcal vaccination history through:
  - Student medical records at university student health
  - Vaccination clinic attendance records
  - Oregon immunization registry (ALERT)



# Statistical Analysis

- Descriptive statistics of participant characteristics
- Proportion with overall meningococcal and serogroup B carriage
  - Examine changes over time
  - Estimate prevalence ratios (PRs)
    - Poisson regression with generalized estimating equation methods for repeated measures
- Within-individual changes in carriage over time

# Carriage Evaluation Findings

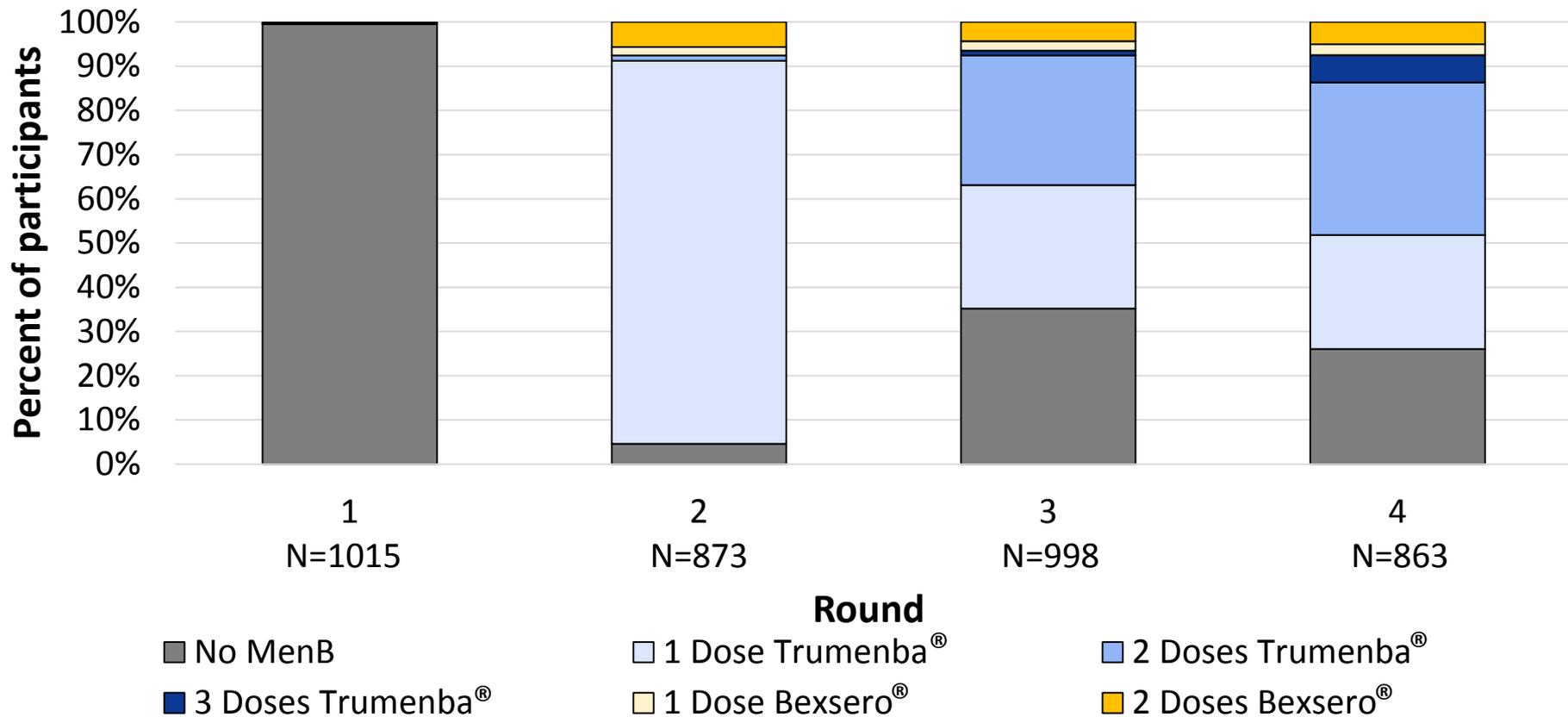
# Carriage Evaluation Participation

Carriage Evaluation Round	Date	Carriage Evaluation Participants, N
1	March 2015	1173
2	May 2015	1069
3	October 2015	1045
4	February 2016	938
<b>Total</b>		<b>4,225</b>

# Participant Characteristics

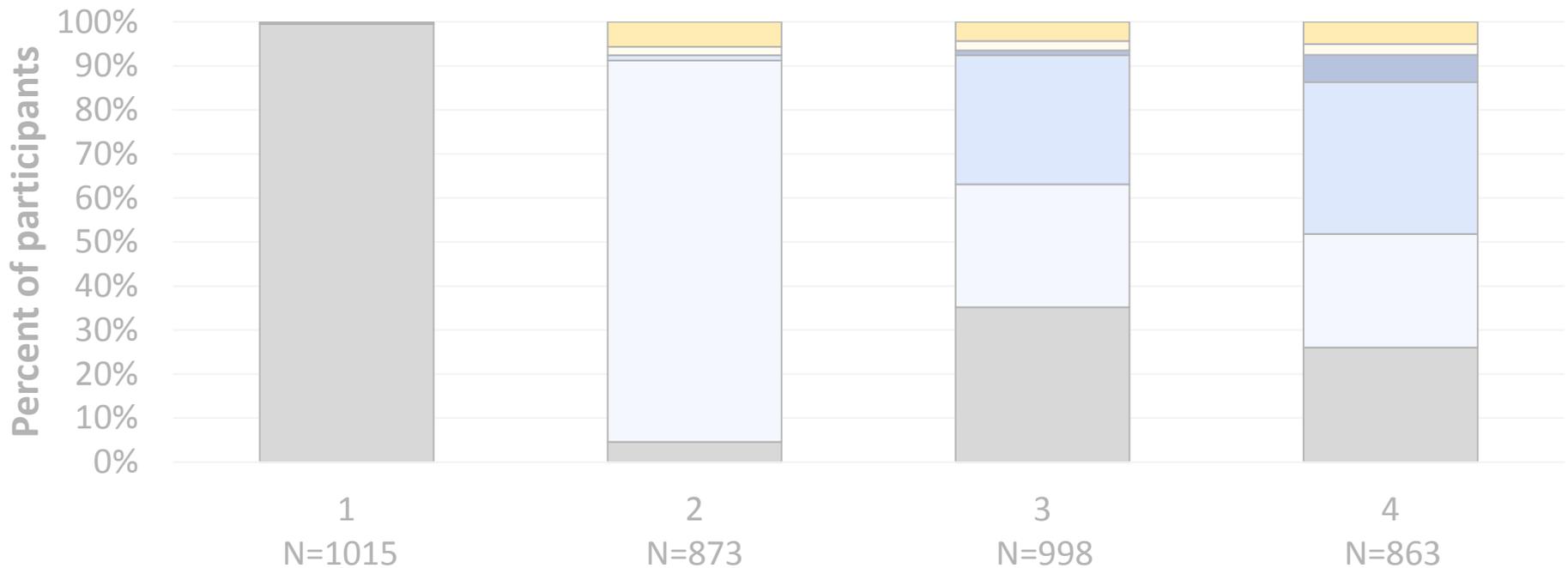
- 41% male
- All four undergraduate class years
- Median age: 20 years (range 18-58)
- 82% had received MenACWY vaccine
  - Likely an underestimate

# Received $\geq 1$ Dose MenB\*



\*At least 14 days previously

# Received $\geq 1$ Dose MenB\*



■ No MenB

**N = 64**

■ 3 Doses Trumenba®

Round

■ 1 Dose Trumenba®

■ 1 Dose Bexsero®

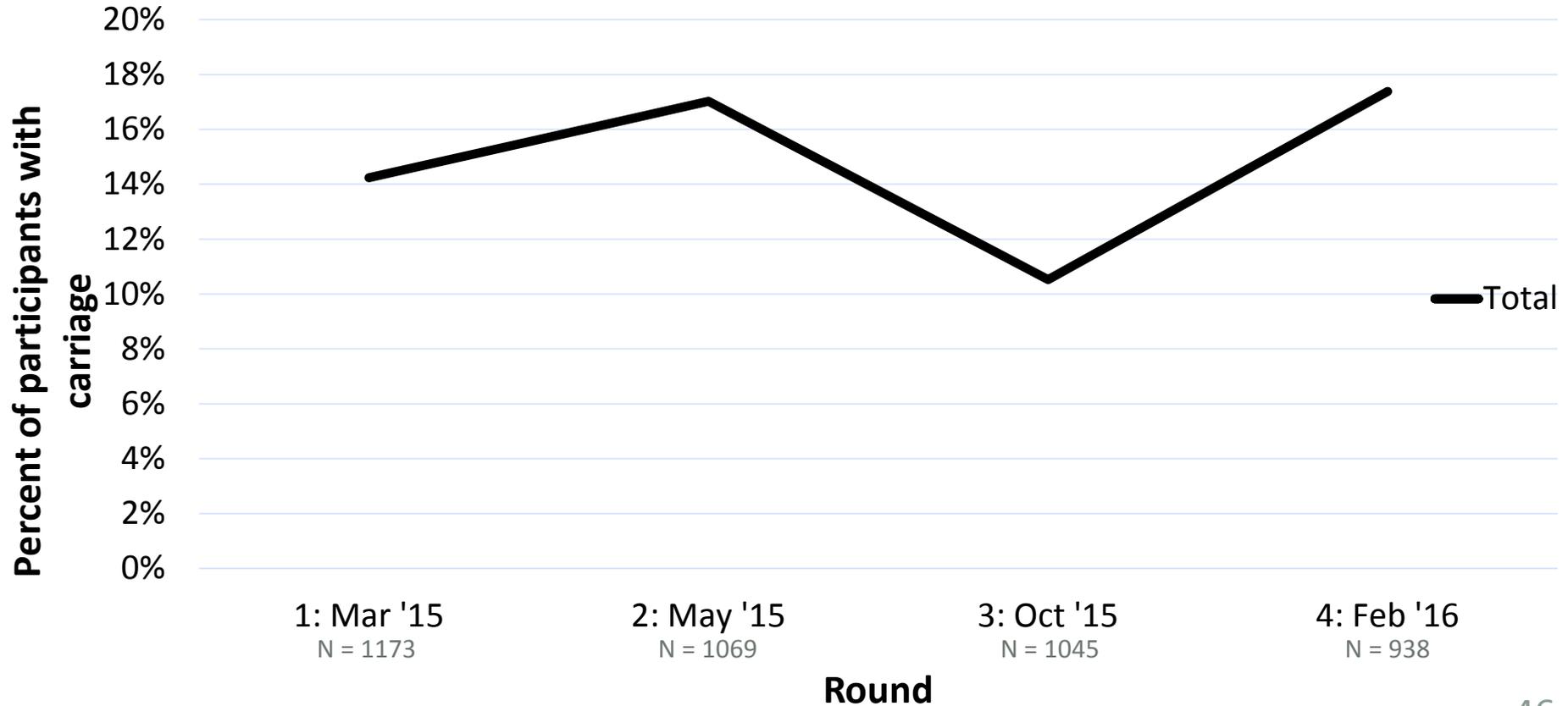
■ 2 Doses Trumenba

**N = 135**

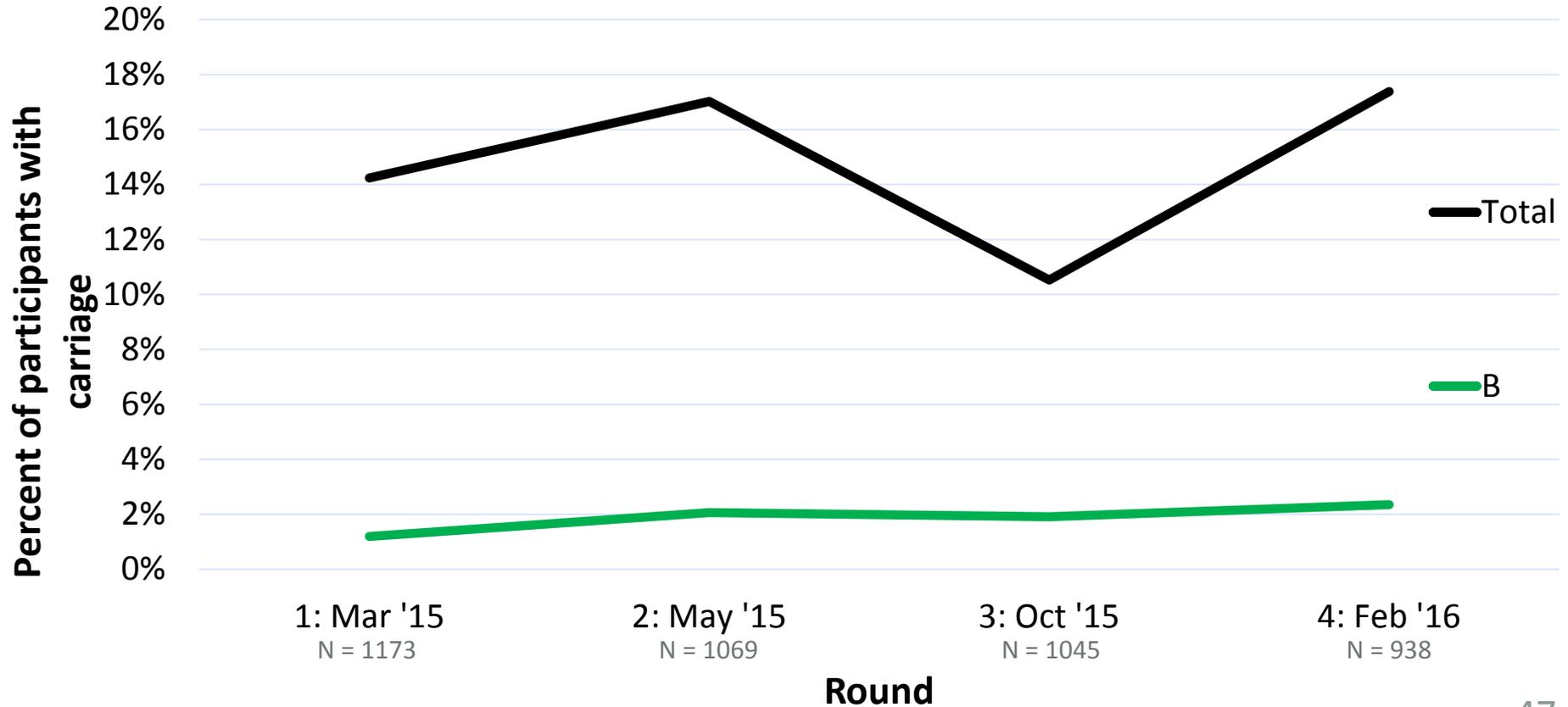
■ 2 Doses Bexsero®

\*At least 14 days previously

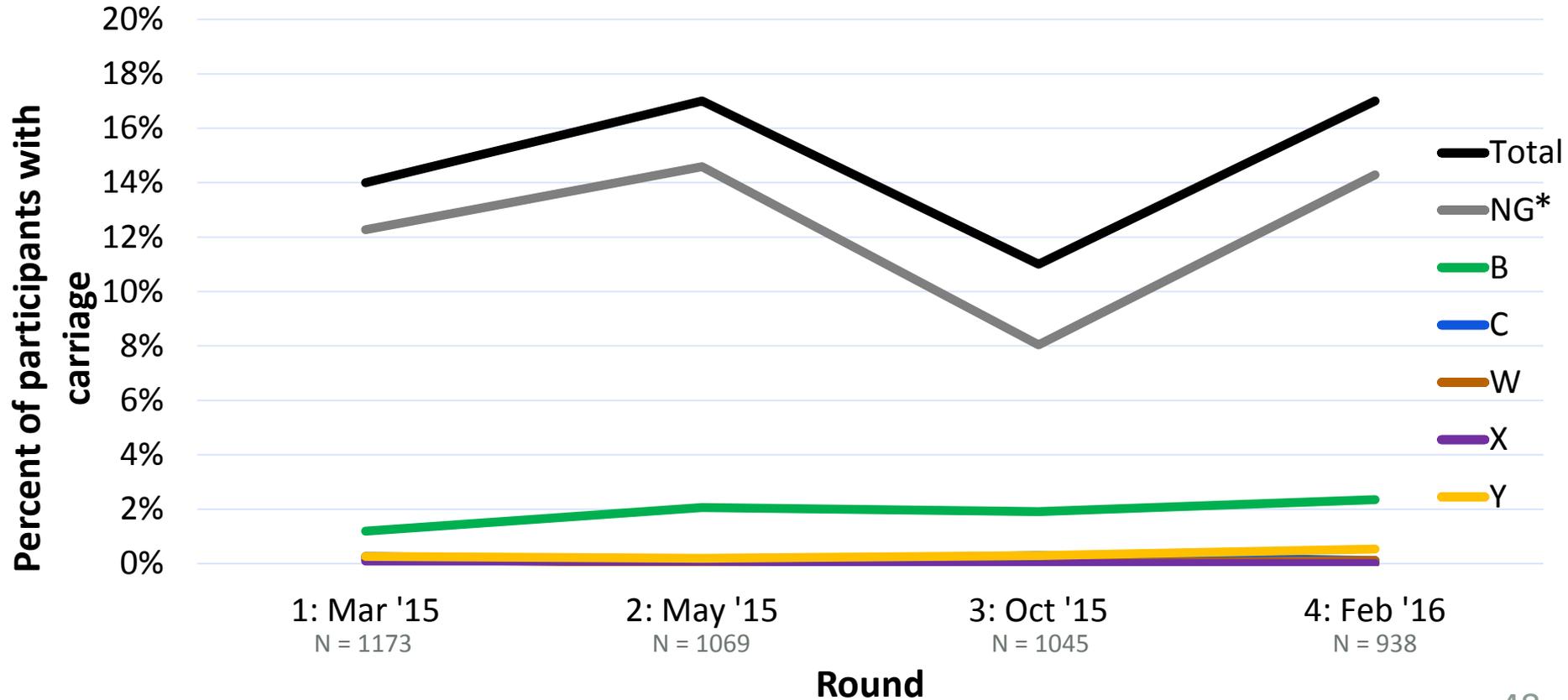
# Overall Meningococcal Carriage



# Overall Meningococcal and Serogroup B Carriage



# Serogroup Results by PCR



\*Includes 8 isolates not tested by PCR because they were serogroup E by SASG

# Associations with meningococcal carriage

Characteristic	Multivariable Prevalence Ratio <sup>1</sup> (95% CI)	p-value
Round		
1	Reference	
2	1.0 (0.7-1.5)	0.9
3	0.8 (0.6-1.1)	0.1
4	1.2 (0.9-1.7)	0.3

<sup>1</sup> Prevalence ratios account for repeat participants using GEE methods

# Associations with meningococcal carriage

Characteristic	Multivariable Prevalence Ratio <sup>1</sup> (95% CI)	p-value
Male	<b>1.2 (1.0-1.5)</b>	<b>0.03</b>
Year in school		
Freshman	Reference	
Sophomore	0.8 (0.6-1.1)	0.2
Junior	0.7 (0.5-1.1)	0.2
Senior	0.8 (0.5-1.4)	0.5

<sup>1</sup> Prevalence ratios account for repeat participants using GEE methods

# Associations with meningococcal carriage

Characteristic	Multivariable Prevalence Ratio <sup>1</sup> (95% CI)	p-value
Age		
18	Reference	
19	1.2 (0.9-1.6)	0.3
20	<b>1.6 (1.1-2.3)</b>	<b>0.02</b>
21	1.1 (0.7-1.8)	0.8
22	0.8 (0.5-1.5)	0.6
23-29	0.8 (0.4-1.5)	0.5
30+	1.8 (0.7-5.2)	0.4

<sup>1</sup>Prevalence ratios account for repeat participants using GEE methods

# Associations with meningococcal carriage

Characteristic	Multivariable Prevalence Ratio <sup>1</sup> (95% CI)	p-value
Live off-campus	1.3 (0.7-2.2)	0.4
Type of residence		
Residence hall	Reference	
Apartment/house	0.9 (0.5-1.8)	0.8
Sorority/fraternity	1.3 (0.7-2.4)	0.4

<sup>1</sup> Prevalence ratios account for repeat participants using GEE methods

# Associations with meningococcal carriage

Characteristic	Multivariable Prevalence Ratio <sup>1</sup> (95% CI)	p-value
Roommates		
0	Reference	
1	1.0 (0.7-1.4)	1.0
2	1.0 (0.7-1.5)	1.0
3+	1.2 (0.8-1.7)	0.3
Live with family	0.6 (0.3-1.4)	0.2

<sup>1</sup>Prevalence ratios account for repeat participants using GEE methods

# Associations with meningococcal carriage

Characteristic	Multivariable Prevalence Ratio <sup>1</sup> (95% CI)	p-value
Recent upper respiratory symptoms <sup>2</sup>	1.1 (0.9-1.3)	0.2
Smoking <sup>3</sup>	<b>1.4 (1.2-1.7)</b>	<b>0.0008</b>
Second-hand smoke <sup>3</sup>		
Some days	1.1 (0.9-1.3)	0.4
Every day	1.2 (0.8-1.7)	0.4
Recent antibiotic use <sup>3</sup>	<b>0.4 (0.3-0.7)</b>	<b>&lt;0.0001</b>

<sup>1</sup>Prevalence ratios account for repeat participants using GEE methods; <sup>2</sup>In the past 2 weeks; <sup>3</sup>In the past 30 days

# Associations with meningococcal carriage

Characteristic	Multivariable Prevalence Ratio <sup>1</sup> (95% CI)	p-value
Attend bars, clubs, parties		
<1/week or never	Reference	
1/week	2.0 (1.6-2.5)	<0.0001
2-3/week	2.8 (2.2-3.6)	<0.0001
≥4/week	2.7 (1.6-4.4)	0.01
Received MenACWY vaccine <sup>2</sup>	--	--

<sup>1</sup> Prevalence ratios account for repeat participants using GEE methods

<sup>2</sup> Not included in multivariable model as this variable was nonsignificant in bivariate analysis

# Associations with meningococcal carriage

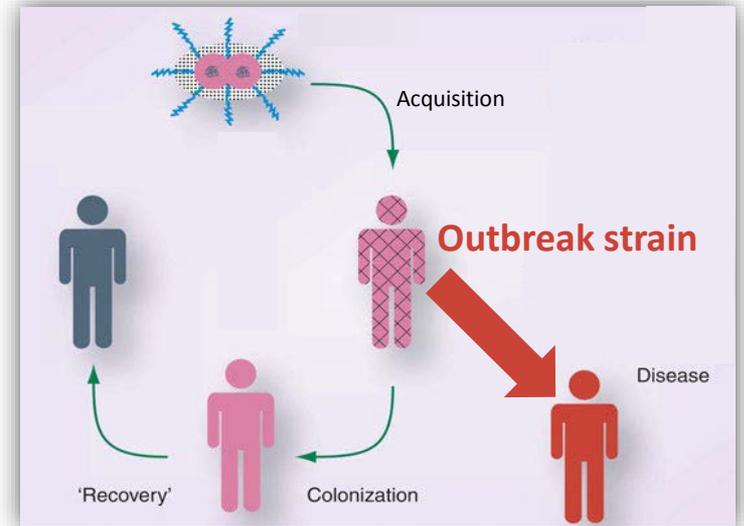
Characteristic	Multivariable Prevalence Ratio <sup>1</sup> (95% CI)	p-value
Received MenB vaccine doses <sup>2</sup>		
1 dose Trumenba®	1.0 (0.8-1.4)	0.8
2 doses Trumenba®	1.2 (0.9-1.6)	0.2
3 doses Trumenba®	1.3 (0.7-2.2)	0.4
1 dose Bexsero®	0.9 (0.4-1.9)	0.7
2 doses Bexsero®	1.5 (1.0-2.3)	0.08

# Associations with serogroup B carriage (PCR)

- Bivariate analysis:
  - Round, age, having 3+ roommates, smoking, social mixing associated with B carriage
- Multivariate analysis:
  - Only smoking and social mixing associated with increased B carriage
- No association between Trumenba<sup>®</sup> or Bexsero<sup>®</sup> receipt and B carriage in bivariate or multivariable model

# Outbreak Strain

- Carriage of the outbreak strain was not detected at any time point
- HOWEVER, we know it was still in circulation during round 1 – additional outbreak cases through May 2015
- Suggests strain circulating but with low prevalence
- Low carriage of outbreak strain has been seen in other meningococcal disease outbreaks<sup>1</sup>
  - Acquisition of pathogenic strain more likely to lead to disease
  - Shorter duration of carriage<sup>2</sup>



1. Weiss et al. (2009) 2. Marks et al. (1979)

Image modified from: Trotter and Maiden 2009, Expert Rev Vaccines 8(7):851-61

# Within-individual changes in carriage over time (N=328)

Rounds

1

2

3

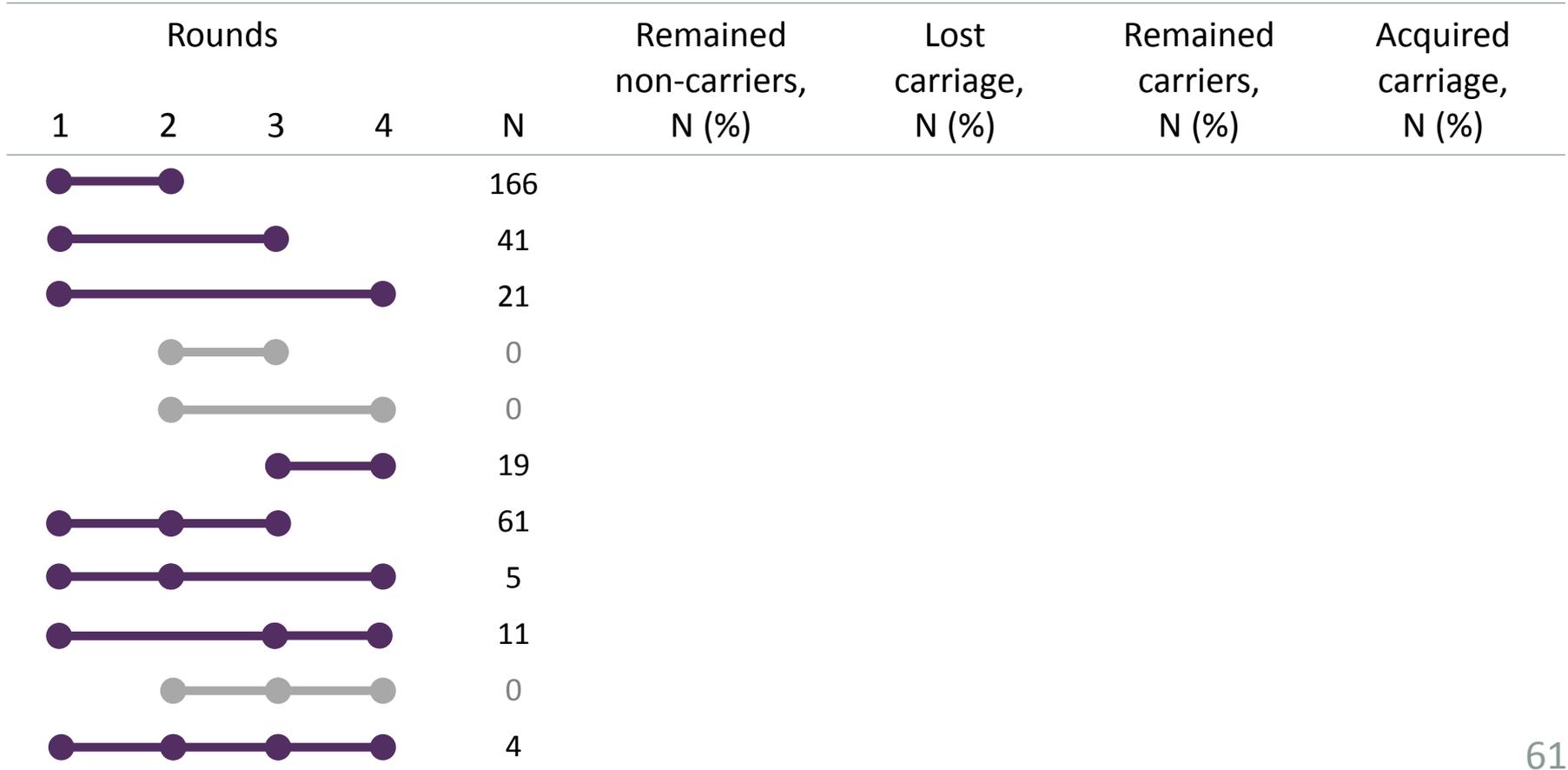
4

N





# Within-individual changes in carriage over time (N=328)



# Within-individual changes in carriage over time (N=328)

Rounds					N	Remained non-carriers, N (%)	Lost carriage, N (%)	Remained carriers, N (%)	Acquired carriage, N (%)
1	2	3	4						
					166	133 (80)	3 (1.8)	16 (9.6)	14 (8.4)
					41	32 (78)	3 (7.3)	1 (2.4)	5 (1.2)
					21	16 (76)	1 (4.8)	2 (9.5)	2 (9.5)
					0	--	--	--	--
					0	--	--	--	--
					19	19 (100)	0 (0)	0 (0)	0 (0)
					61	57 (93)	0 (0)	2 (3.3)	2 (3.3)
					5	4 (80)	0	0	1 (20)
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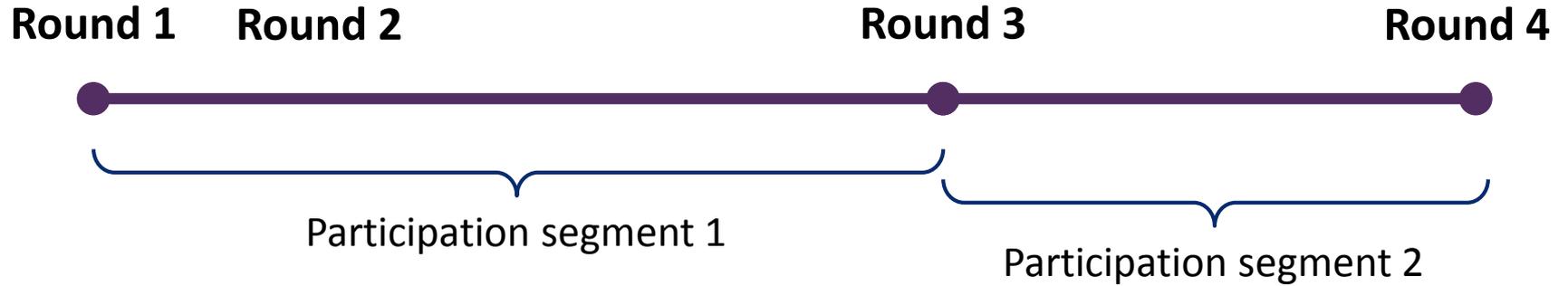
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				0	--	--	--	--
				4	4 (100)	0 (0)	0 (0)	0 (0)

# Carriage loss and acquisition by MenB vaccination status



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MenB Vaccine Doses <sup>1</sup>	N	Remained	Lost	Remained	Acquired
		non-carriers, N (%)	carriage, N (%)	carriers, N (%)	carriage, N (%)
0	18	18 (100)	0 (0)	0 (0)	0 (0)
1 dose Trumenba <sup>®</sup>	234	197 (84)	4 (1.7)	17 (7.3)	16 (6.8)
2 doses Trumenba <sup>®</sup>	113	96 (85)	3 (2.7)	7 (6.2)	7 (6.2)
3 doses Trumenba <sup>®</sup>	20	17 (85)	0 (0)	2 (10)	1 (5.0)
1 dose Bexsero <sup>®</sup>	2	2 (100)	0 (0)	0 (0)	0 (0)
2 doses Bexsero <sup>®</sup>	9	6 (67)	0 (0)	2 (22)	0 (0)

<sup>1</sup> Refers to vaccine doses received ≥2 weeks prior to date of second specimen collection

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# Summary

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- In each round: 11-17% meningococcal carriage, 1-2% serogroup B carriage
  - Carriage prevalence similar in two other recent carriage evaluations at US universities (CDC unpublished data)
  - Higher than other recent U.S. estimates of 1-8% among general population<sup>1,2</sup>
- Despite high carriage prevalence, no carriers of outbreak strain identified
- Male gender, age, smoking, social mixing associated with higher carriage
- Antibiotic use associated with lower carriage
- No association between Trumenba<sup>®</sup> or Bexsero<sup>®</sup> vaccination and carriage

# Challenges

- Observational methods
  - Potential for unidentified confounding
- Methods have high specificity but unknown sensitivity
  - Bacterial density
  - Variation in oropharyngeal swabbing techniques
  - Difficulty in obtaining swab
- Limited longitudinal data
- Evaluation crossed 2 academic school years and summer vacation

# Discussion

- **Trumenba<sup>®</sup> and Bexsero<sup>®</sup> do not have a rapid, large impact on meningococcal carriage**
- If MenB vaccines do not provide herd protection, reinforces need for:
  - High vaccination coverage during outbreaks
  - Chemoprophylaxis of close contacts
- Results will inform MenB vaccine guidelines
- Need more data on MenB vaccine effectiveness and duration of protection

# Oregon Meningococcal Carriage Evaluation Team

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

