Making alpha-gal count

HOW TO ADVANCE MANDATORY REPORTING OF ALPHA-GAL SYNDROME IN ***YOUR*** STATE

ALPHA-GAL ALLIANCE
AGA | ACTION FUND

- Intro to mandatory reporting
- How to advance mandatory reporting in your state

- How to ask your state representatives to introduce a bill to make AGS a mandatory reportable disease

- How to testify in support of a bill

What is mandatory reporting?

Every state has a list of diseases which doctors and laboratories are ***required*** to report to the state health department

VIRGINIA REPORTABLE DISEASE LIST

Reporting of the following diseases is required by state law (Sections 32.1-36 and 32.1-37 of the Code of Virginia and 12 VAC 5-90-80 of the Board of Health Regulations for Disease Reporting and Control). Report all conditions when suspected or confirmed to your local health department (LHD). Reports may be submitted by Confidential Morbidity Report Portal (Epi-1 form), computer-generated printout, CDC or VDH surveillance form, or upon agreement with VDH, by means of secure electronic submission.

REPORT IMMEDIATELY

- Anthrax *(Bacillus anthracis)*
- Botulism *(Clostridium botulinum)*
- Brucellosis *(Brucella* spp.)
- Cholera *(Vibrio cholerae* O1/O139)
- Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)
- Diphtheria *(Corynebacterium diphtheriae)*
- Disease caused by an agent that may have been used as a weapon
- *Haemophilus influenzae* infection, invasive
- Hepatitis A
- Influenza-associated deaths if younger than 18 years of age
- Influenza A, novel virus
- Measles (Rubeola)
- Meningococcal disease *(Neisseria meningitidis)*
- Orthopoxviruses (e.g., Monkeypox virus, Variola virus/Smallpox, Vaccinia disease or adverse event)
- Outbreaks, all (including foodborne, healthcare-associated, occupational, toxic substance-related, waterborne, and any other outbreak)
- Pertussis (Whooping cough) *(Bordetella pertussis)*

REPORT WITHIN 3 DAYS

- Alpha-gal Syndrome (AGS)
- Amebiasis *(Entamoeba histolytica)*
- Arboviral infections (e.g., CHIK, dengue, EEE, LAC, SLE, WNV, Zika)
- Babesiosis *(Babesia* spp.)
- Campylobacteriosis *(Campylobacter* spp.)
- *Candida auris*, infection or colonization [c]
- Carbapenemase-producing organism, infection or colonization
- Chancroid *(Haemophilus ducreyi)*
- Chickenpox (Varicella virus)
- *Chlamydia trachomatis* infection
- Coronavirus disease 2019 (COVID-19 or SARS-CoV-2)
- Cryptosporidiosis *(Cryptosporidium* spp.)
- Cyclosporiasis *(Cyclospora* spp.)
- Ehrlichiosis/Anaplasmosis *(Ehrlichia* spp., *Anaplasma phagocytophilum)*
- Giardiasis *(Giardia* spp.)
- Gonorrhea *(Neisseria gonorrhoeae)*
- Granuloma inguinale *(Calymmatobacterium granulomatis)*
- Hantavirus pulmonary syndrome

What diseases are on these lists?

- Diseases of public health concern
- Each state has a different list
  - Every state must include all ***nationally notifiable diseases***
  - Each state also has additional diseases on its list, called ***mandatory reportable diseases***

Nationally notifiable diseases vs mandatory reportable diseases

Nationally notifiable diseases

- National list
- Every state must report them
- Examples:
  - **Some infectious diseases**, like Measles, Polio, Rubella, Anthrax, Botulism, Lyme disease, Malaria, Tuberculosis, Plague
  - **Food & waterborne illnesses:** Shigellosis, Salmonellosis
  - **Emerging threats:** Zika virus, Monkeypox

Mandatory reportable diseases

- State lists
- Vary from state to state
- Examples:
  - Tularemia (KS)
  - Rocky Mountain Spotted Fever (NC)
  - St Louis encephalitis (AZ)
  - Alpha-gal syndrome (11 states)

For example, let's look at Virginia…

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30 of the Board of Health Regulations for Disease Reporting
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IMMEDIATELY

- [flask] [box]
- [flask] [box]
- ., SARS-CoV, MERS-CoV) [flask] [box]
- *ntheriae)* [flask] [box]
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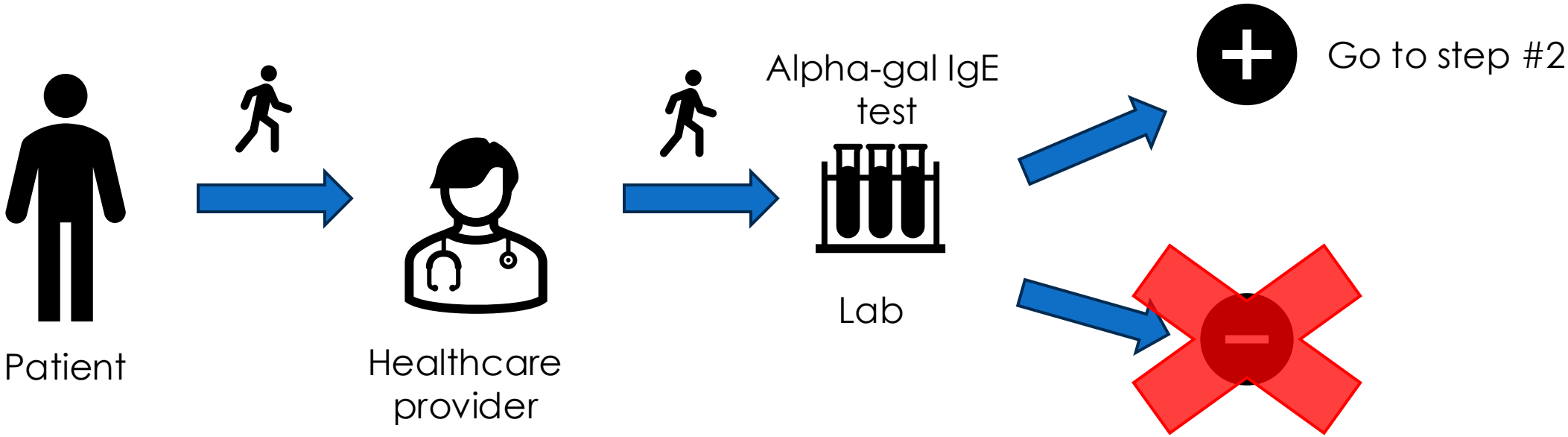
- Chancroid *(Haemophilus ducreyi)* [flask]
- Chickenpox (Varicella virus) [flask]
- *Chlamydia trachomatis* infection [flask]
- Coronavirus disease 2019 (COVID-19 or S

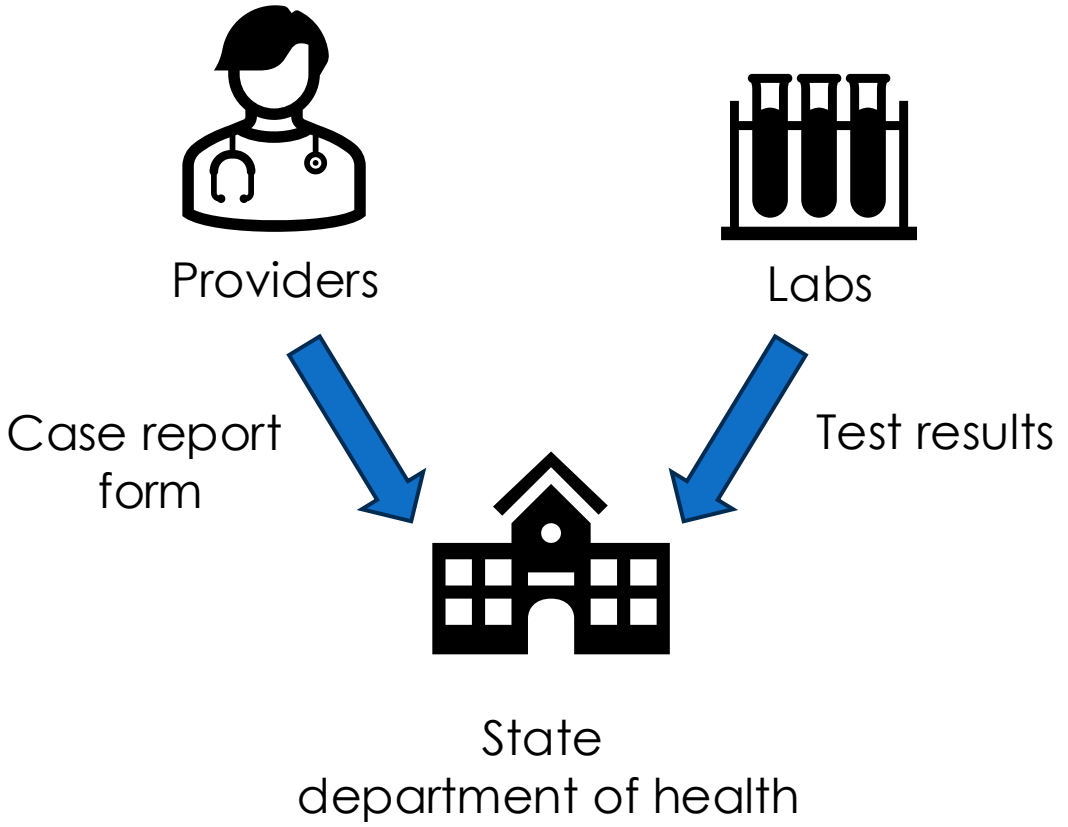
How does mandatory reporting work?

Step #1:
Patient is tested

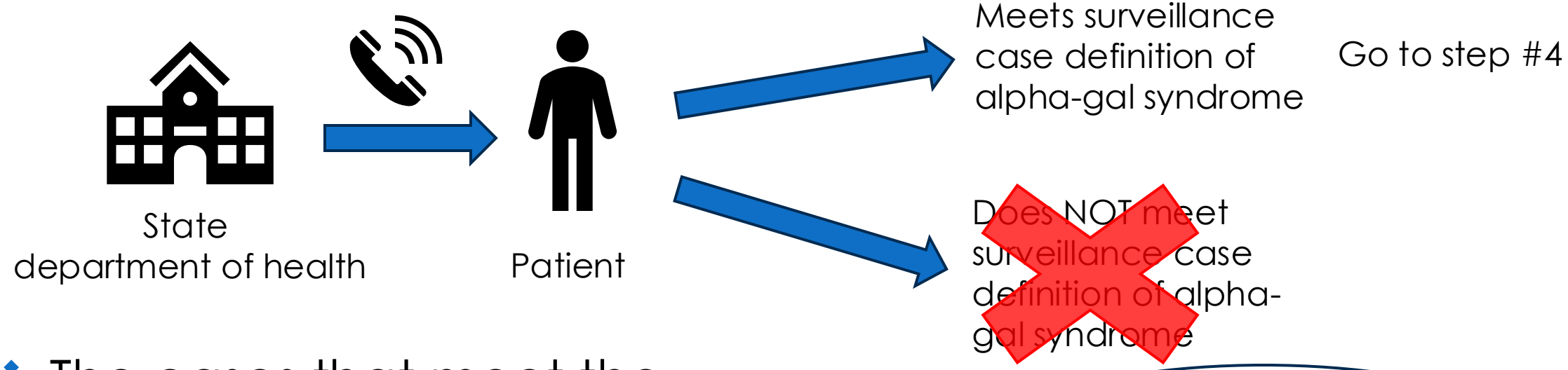


Step #2:
Providers & labs report positive cases

- These cases are considered **"suspected cases."**



Step #3:
State health department follow-up



- The cases that meet the case definition are considered **"confirmed cases."**

This is the time-consuming and expensive part!

Step #3:
State health department follow-up

Step #3: health department follow-up

Go to step #4

Important for communicable diseases like TB

Step #3:
State health department follow-up

Step #3: health department follow-up

surveillance

Go to step #4

For alpha-gal syndrome, may not be viable in high prevalence areas, due to the large number of cases

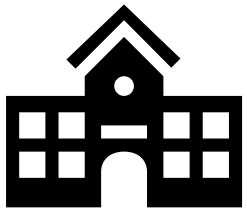
Mandatory reporting: the process

ALL REPORTS ARE CONFIDENTIAL

Patient

Does NOT meet surveillance case definition of alpha-gal syndrome

Step #4
Health department reports data to the CDC



State department of health

Patient's identifying information *removed*

Deidentified information

Case definition & reporting form

Surveillance case definition of alpha-gal syndrome

Alpha-gal syndrome case report form

Alpha-gal Syndrome Case Report Form

Use for Alpha-gal syndrome (AGS) case reporting. Visit https://ndc.services.cdc.gov/ for complete case definition.

CDC#

Patient Name: _____ Date submitted *(mm/dd/yyyy)*: _____

Address: _____ Healthcare provider's name: _____

City: _____ Local Patient ID. *(if reported)*: _____ Local ID _____ Site _____ State

1. State of residence (postal abbrev.): _____

2. County of residence: _____

3. Sex: ◯ Male ◯ Female ◯ Unknown

4. Patient age (years) at time of case investigation: _____

5. Race (check all that apply):
☐ White ☐ Black or African American ☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander ☐ Other race ☐ Unknown ☐ Refused

6. Hispanic or Latino ethnicity: ◯ Yes ◯ No ◯ Unknown

CLINICAL CHARACTERISTICS AND OUTCOMES OF AGS

Enter as much information that is known, with the year (YYYY) at a minimum. For an unknown day or month, that value may be entered as '99'. If no date available, leave blank.

7a. Date of most recent AGS reaction that prompted this report *(mm/dd/yyyy)*: _____

7b. Has the patient had prior AGS reactions? ◯ Yes ◯ No ◯ Unknown

7c. Date of first AGS reaction *(mm/dd/yyyy)*: _____

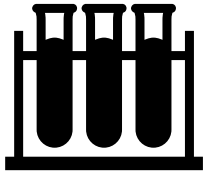
7d. Date of first AGS diagnosis by a healthcare provider *(mm/dd/yyyy)*: _____

8. Has the patient ever experienced any of the following signs or symptoms of AGS during a reaction? *(Check all that apply)*
☐ Abdominal pain ☐ Nausea ☐ Diarrhea ☐ Vomiting ☐ Heartburn/indigestion ☐ Hives ☐ Itching ☐ Swelling of lips, tongue, throat, face, eyelids, or other associated structures ☐ Shortness of breath ☐ Cough ☐ Wheezing ☐ Acute episode of hypotension ☐ Other (specify):

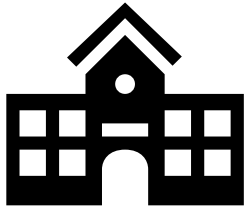
9. Has the patient ever experienced signs or symptoms of an AGS reaction within 2–10 hours after consumption of any of the following? *(Check all that apply)*
☐ Beef ☐ Pork ☐ Lamb/mutton ☐ Goat ☐ Game meat (such as venison, boar, bison, elk, rabbit) ☐ Milk or milk products (such as cow's milk, cheese, yogurt, butter, ice-cream) ☐ Gelatin/glycerin-containing food products (such as gelatin dessert, pudding, gummy candy, marshmallows) ☐ Gel-cap medications ☐ 'Red meat', not specified ☐ Other food product or additive (specify):

10. Has the patient ever experienced signs or symptoms of an AGS reaction within two hours after receiving any of the following pharmaceutical or medical products intramuscularly, intravenously, or subcutaneously?
☐ Vaccines (specify):
☐ Monoclonal antibodies (specify):
☐ Anti-venom ☐ Heparin ☐ Other (specify):

Variations on reporting #1: Electronic laboratory reporting (ELR) ONLY



Labs



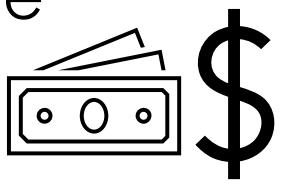
State department of health

Deidentified information

Pros & cons of electronic laboratory reporting (ELR) ONLY

PROS

- Less labor intensive
- Much cheaper
- Less push back



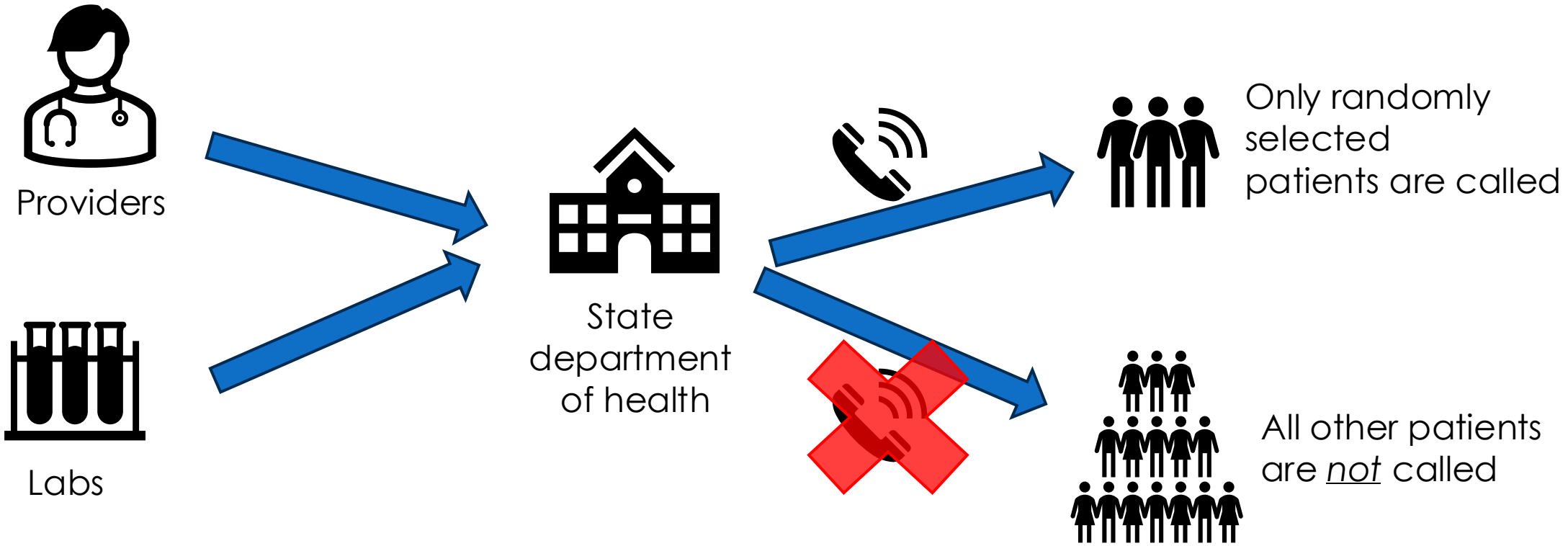
CONS

- Suspected cases ONLY (not confirmed)
- Less data for public health interventions

EXAMPLES

- NYC (AGS cases)
- Lyme disease (high prevalence states)

Variations on reporting #2: Follow up w/ randomly selected patients ONLY



Pros & cons of follow up with randomly selected patients ONLY

PROS

- Less labor intensive
- Much cheaper
- Data on confirmed cases
- More data for public health interventions

CONS

- Less data than following up with every patients

EXAMPLE

- Virginia
- Virginia DOH representative will be briefing us on how this works

Making the Case

Why Should Alpha-gal Syndrome Be a Reportable Disease?

Why people with AGS should care about reporting of AGS cases

- AGS is likely the most common vector-borne disease in the U.S.
- Cases have increased exponentially from 2009.
- AGS is not prioritized by federal or state governments.
- AGS is grossly underfunded compared to other VBD.
- It is critical to document the true number of cases in order to build support for priorities like:
  - Labeling laws
  - Provider education
  - Funding of AGS research

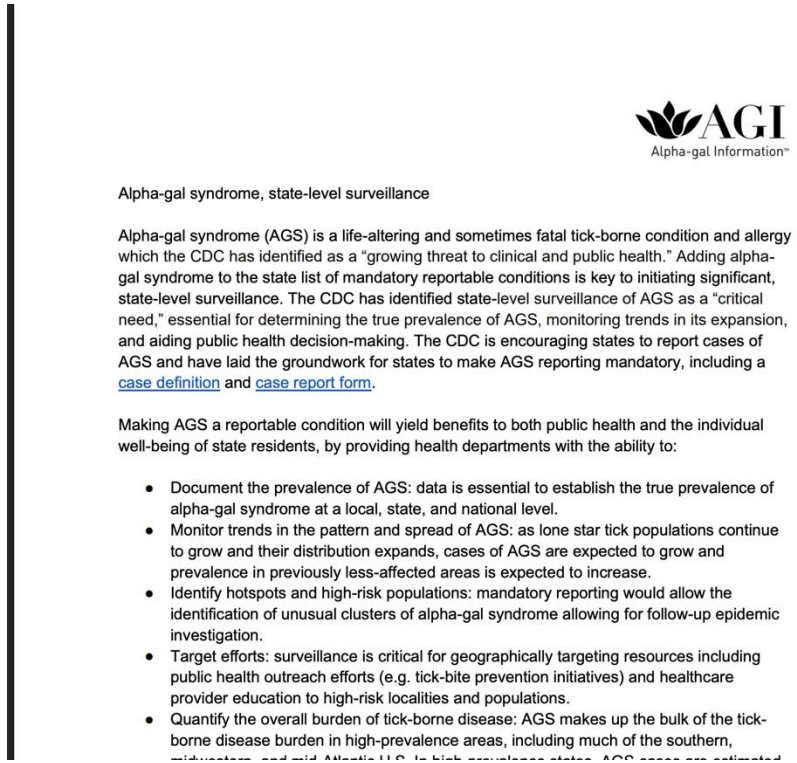
Why health departments & elected officials should care about reporting of AGS cases

- Alpha-gal syndrome (AGS) is a life-altering and sometimes fatal tick-borne disease and allergy.
- The CDC has identified AGS as a "growing threat to clinical and public health."
- The CDC has identified state-level surveillance of AGS as a "critical need," essential for:
  - Determining the true prevalence of AGS
  - Monitoring trends in its expansion, and
  - Aiding public health decision-making.
- The CDC is encouraging states to report cases of AGS and have laid the groundwork for states to make AGS reporting mandatory, including a case definition and case report form.

More info

Key benefits of state-level surveillance

- Why is alpha-gal syndrome surveillance needed?
- This document explains this



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Alpha-gal Information™

Alpha-gal syndrome, state-level surveillance

Alpha-gal syndrome (AGS) is a life-altering and sometimes fatal tick-borne condition and allergy which the CDC has identified as a "growing threat to clinical and public health." Adding alpha-gal syndrome to the state list of mandatory reportable conditions is key to initiating significant, state-level surveillance. The CDC has identified state-level surveillance of AGS as a "critical need," essential for determining the true prevalence of AGS, monitoring trends in its expansion, and aiding public health decision-making. The CDC is encouraging states to report cases of AGS and have laid the groundwork for states to make AGS reporting mandatory, including a case definition and case report form.

Making AGS a reportable condition will yield benefits to both public health and the individual well-being of state residents, by providing health departments with the ability to:

- Document the prevalence of AGS: data is essential to establish the true prevalence of alpha-gal syndrome at a local, state, and national level.
- Monitor trends in the pattern and spread of AGS: as lone star tick populations continue to grow and their distribution expands, cases of AGS are expected to grow and prevalence in previously less-affected areas is expected to increase.
- Identify hotspots and high-risk populations: mandatory reporting would allow the identification of unusual clusters of alpha-gal syndrome allowing for follow-up epidemic investigation.
- Target efforts: surveillance is critical for geographically targeting resources including public health outreach efforts (e.g. tick-bite prevention initiatives) and healthcare provider education to high-risk localities and populations.
- Quantify the overall burden of tick-borne disease: AGS makes up the bulk of the tick-borne disease burden in high-prevalence areas, including much of the southern,

Advancing mandatory reporting of alpha-gal syndrome in your state

Step by step!

Step #1:
Find out if alpha-gal syndrome already reportable in YOUR state

States with ***mandatory*** reporting

- Arkansas
- Delaware
- Iowa
- Kentucky
- Nebraska
- North Dakota
- Oregon (by end of 2025)
- South Carolina (2026)
- Tennessee
- Virginia
- West Virginia

States with ***voluntary*** reporting

- Minnesota
- New Jersey
- Rhode Island
- Wisconsin

Often the first step towards mandatory reporting

If AGS is already reportable in your state, there is other state-level legislation you can work on!

STAY TUNED FOR MORE INFORMATION ON THIS IN THE FUTURE!

Step #2
Identify your **STATE** representative(s) & **STATE** senator

Use the Ballotpedia Who Represents Me? website to help you identify your state senator and representative (or representatives).

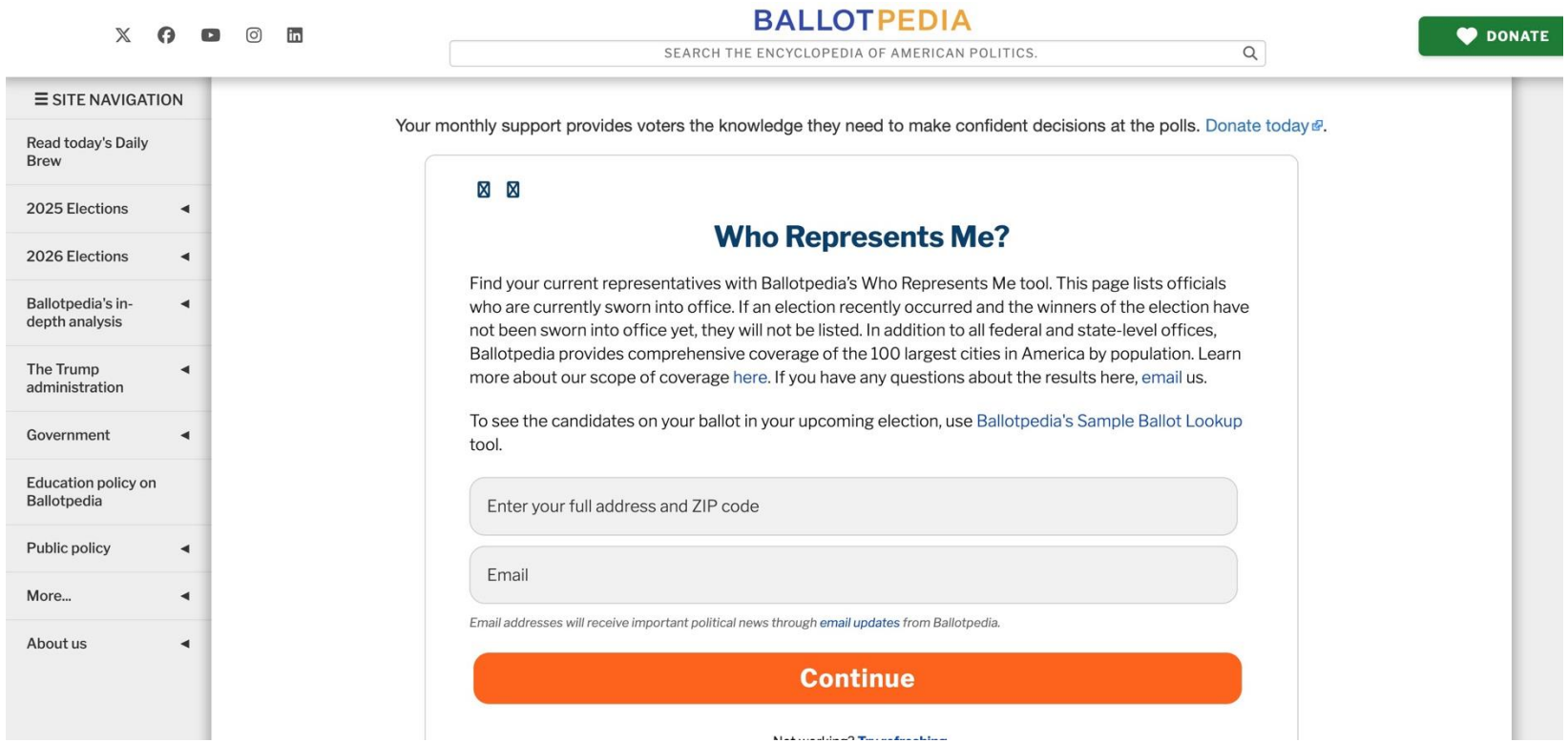
Note: make sure you identify the lawmakers who represent you in the **STATE** legislature, NOT Congress!

Step #3

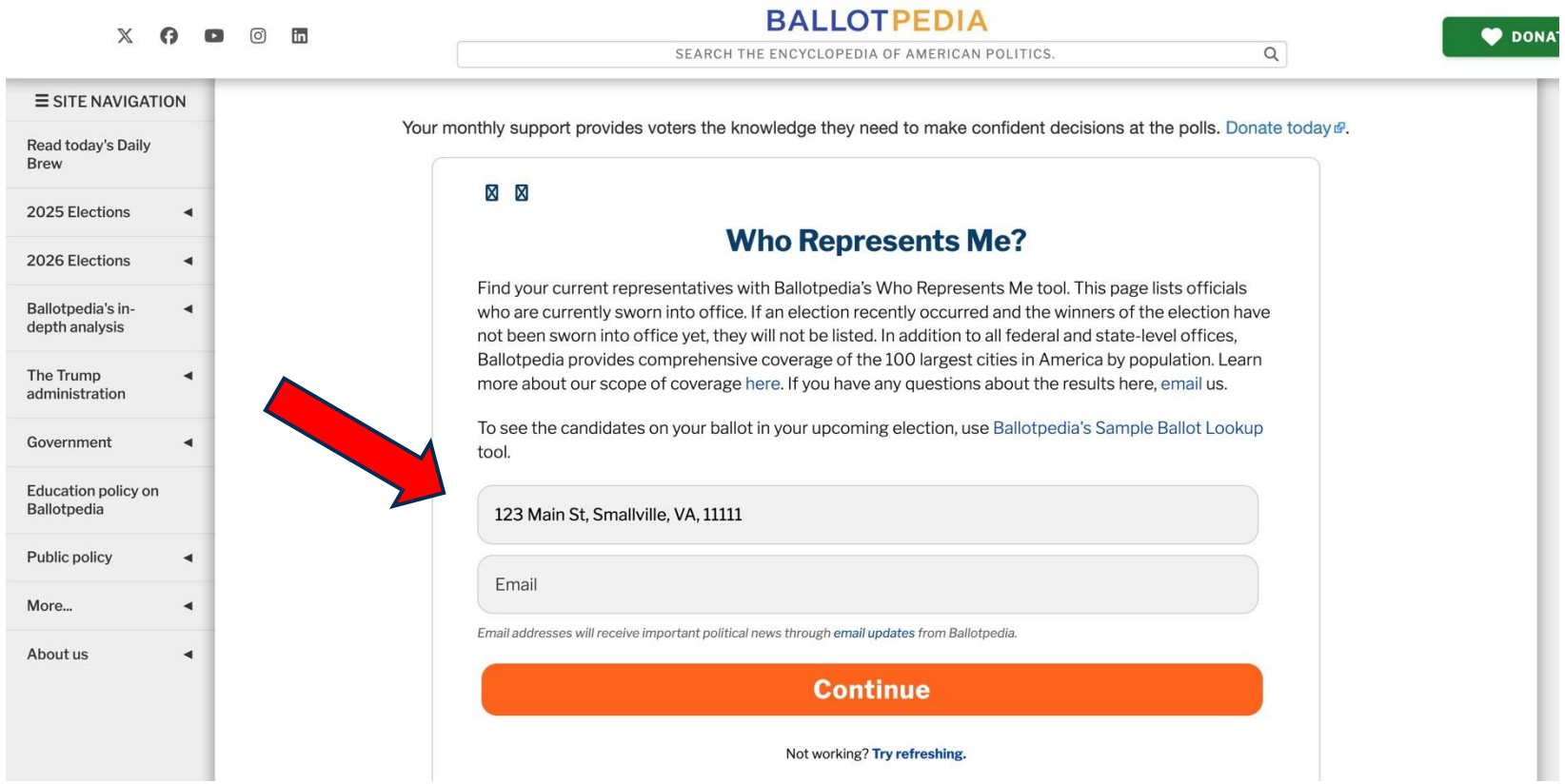
Identify the committees that your **STATE** representative & **STATE** senator are on

- To find the committees, click on the links on the Ballotpedia results.
- This is important because if your representative or senator is on a key committee (like the health committee) that is very helpful.

Go to the Ballotpedia Who Represents Me? website



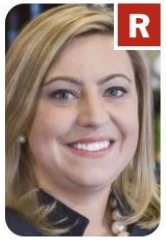
Enter your address



Scroll down to your state representatives

Virginia State Senate District 17

Virginia State Senate District 17



R **Emily Jordan**

Virginia House of Delegates District 83

Virginia House of Delegates District 83

R **H. Otto Wachsmann Jr.**

Virginia House of Delegates District 83

Virginia House of Delegates District 83

R H. Otto Wachsmann Jr.

Click on each of your representatives' names to see what committees they are on

Committee assignments

Note: This membership information was last updated in September 2023. Ballotpedia completes biannual updates of committee membership. If you would like to send us an update, email us at: editor@ballotpedia.org.

2023-2024

Wachsmann was assigned to the following committees:

- Counties, Cities and Towns Committee
- Health and Human Services Committee
- House Privileges and Elections Committee

Step #4: Fill in the Alpha-gal Alliance Action Fund Google form

- ***<u>This is necessary if you want support and materials from Alpha-gal Alliance Action Fund.</u>***
  - We will offer support as our time and resources allow.
  - We will prioritize states to assist based on:
    - State population
    - Prevalence of alpha-gal syndrome
    - Other factors that favor a positive outcome

Mandatory reporting constituent form

This form is for gathering information about people interested in working to alpha-gal syndrome made a mandatory reportable condition in their state. U.S. residents ONLY.

* Indicates required question

Email *

Your email

What is your first name? *

Your answer

- Only I will have access to the information you share.
- I will *not* share ANY of your information with ANYONE without your permission.
- I will not contact you unnecessarily.

If you aren't comfortable sharing this information that is fine, but ***without it, I cannot work with you or support your effort.***

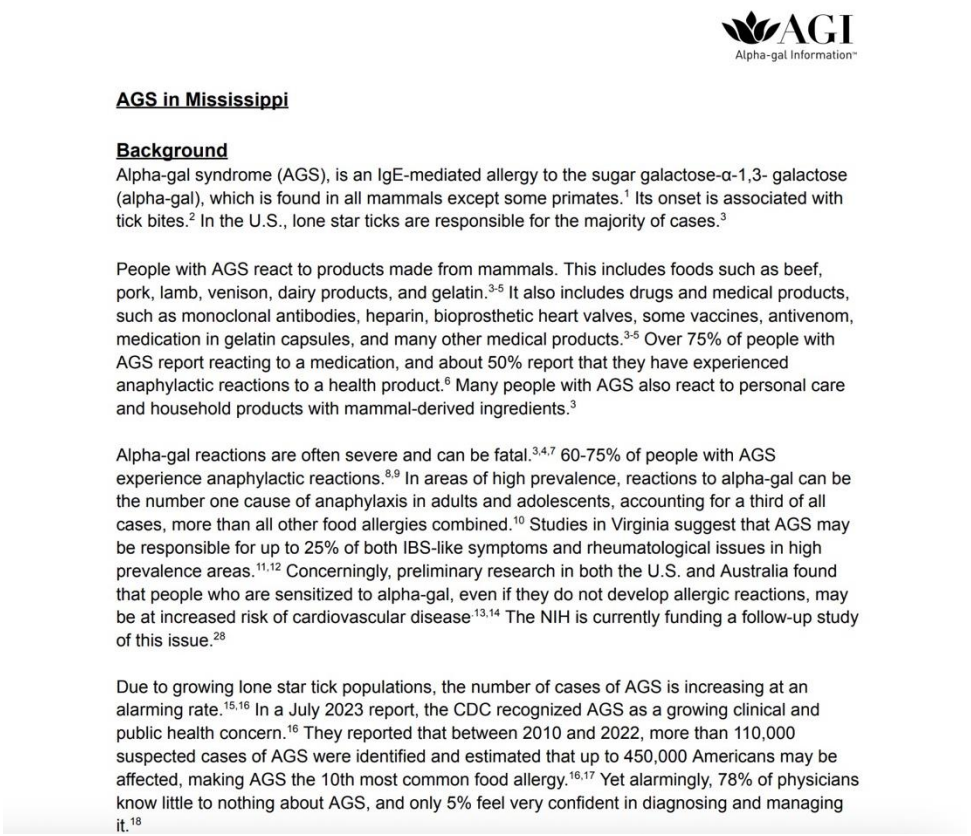
Step #5:
Review resources on the Alpha-gal Alliance Action Fund website

1. Go to the Alpha-gal Alliance Action Fund ***state-level initiatives*** page.
2. Carefully review all the materials on this page.

Examples of AAAF materials you can use to advocate for mandatory reporting

State-level background information

- Strengthens your request by providing AGS information specific to your state
- If there isn't one for your state, ask if I can write one



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AGS in Mississippi

Background

Alpha-gal syndrome (AGS), is an IgE-mediated allergy to the sugar galactose-α-1,3- galactose (alpha-gal), which is found in all mammals except some primates.[1] Its onset is associated with tick bites.[2] In the U.S., lone star ticks are responsible for the majority of cases.[3]

People with AGS react to products made from mammals. This includes foods such as beef, pork, lamb, venison, dairy products, and gelatin.[3-5] It also includes drugs and medical products, such as monoclonal antibodies, heparin, bioprosthetic heart valves, some vaccines, antivenom, medication in gelatin capsules, and many other medical products.[3-5] Over 75% of people with AGS report reacting to a medication, and about 50% report that they have experienced anaphylactic reactions to a health product.[6] Many people with AGS also react to personal care and household products with mammal-derived ingredients.[3]

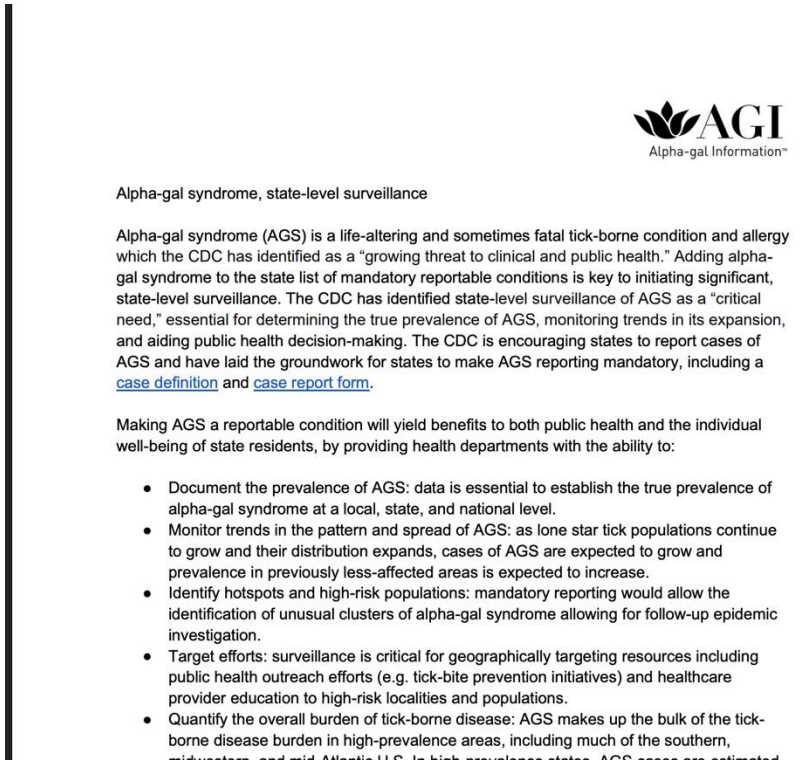
Alpha-gal reactions are often severe and can be fatal.[3,4,7] 60-75% of people with AGS experience anaphylactic reactions.[8,9] In areas of high prevalence, reactions to alpha-gal can be the number one cause of anaphylaxis in adults and adolescents, accounting for a third of all cases, more than all other food allergies combined.[10] Studies in Virginia suggest that AGS may be responsible for up to 25% of both IBS-like symptoms and rheumatological issues in high prevalence areas.[11,12] Concerningly, preliminary research in both the U.S. and Australia found that people who are sensitized to alpha-gal, even if they do not develop allergic reactions, may be at increased risk of cardiovascular disease[13,14] The NIH is currently funding a follow-up study of this issue.[28]

Due to growing lone star tick populations, the number of cases of AGS is increasing at an alarming rate.[15,16] In a July 2023 report, the CDC recognized AGS as a growing clinical and public health concern.[16] They reported that between 2010 and 2022, more than 110,000 suspected cases of AGS were identified and estimated that up to 450,000 Americans may be affected, making AGS the 10th most common food allergy.[16,17] Yet alarmingly, 78% of physicians know little to nothing about AGS, and only 5% feel very confident in diagnosing and managing it.[18]

AAAF Materials

Key benefits of state-level surveillance

- Why is alpha-gal syndrome surveillance needed?
- This document explains this



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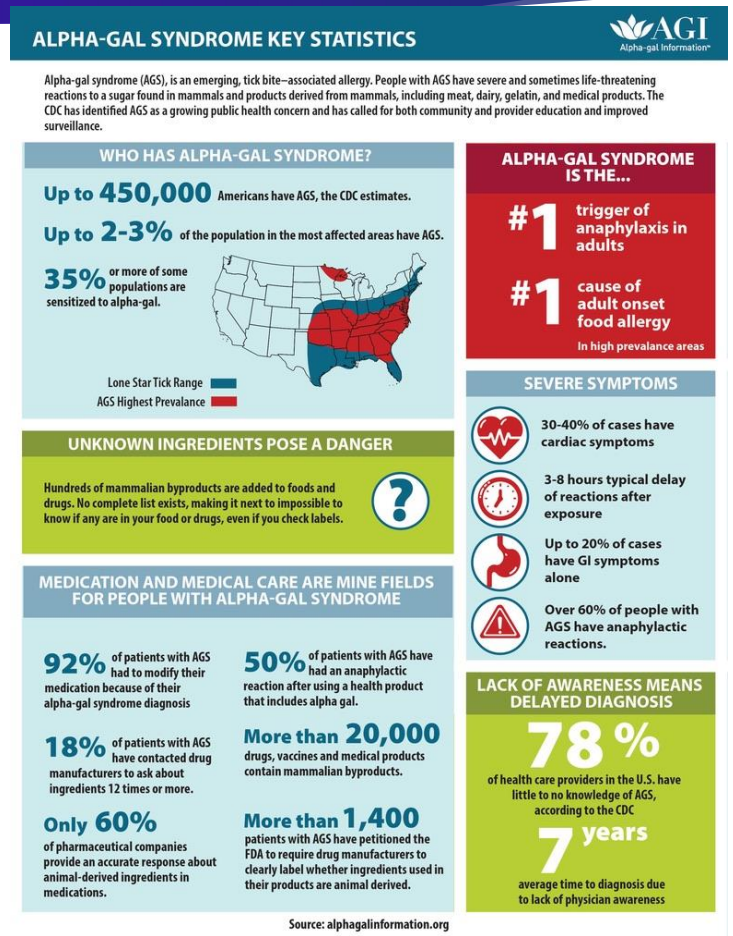
AAAF Materials

Key statistics on alpha-gal syndrome

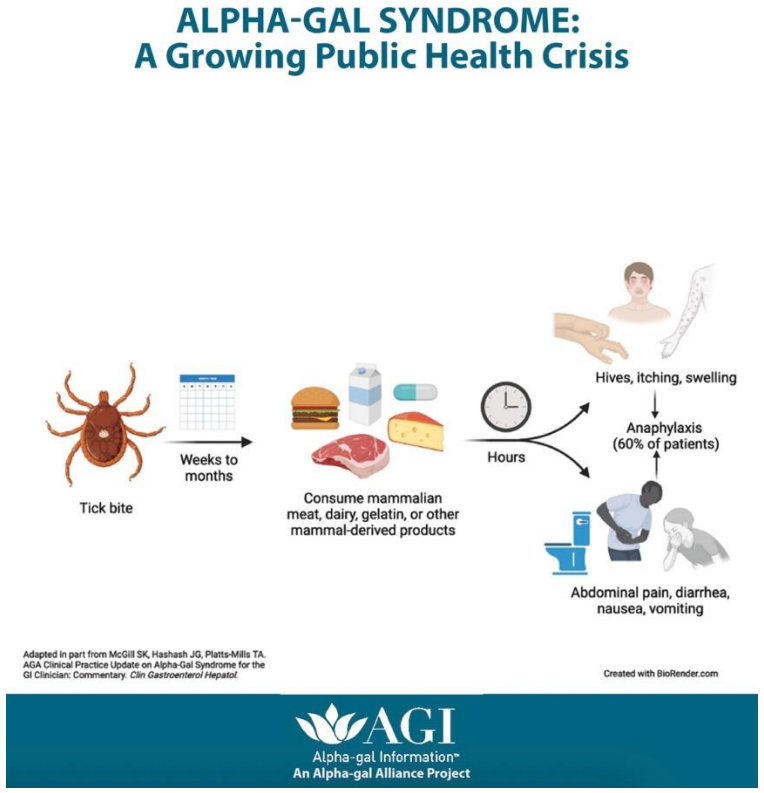
- Highlights AGS as a public health threat



AAAF Materials

Alpha-gal syndrome a growing public health crisis

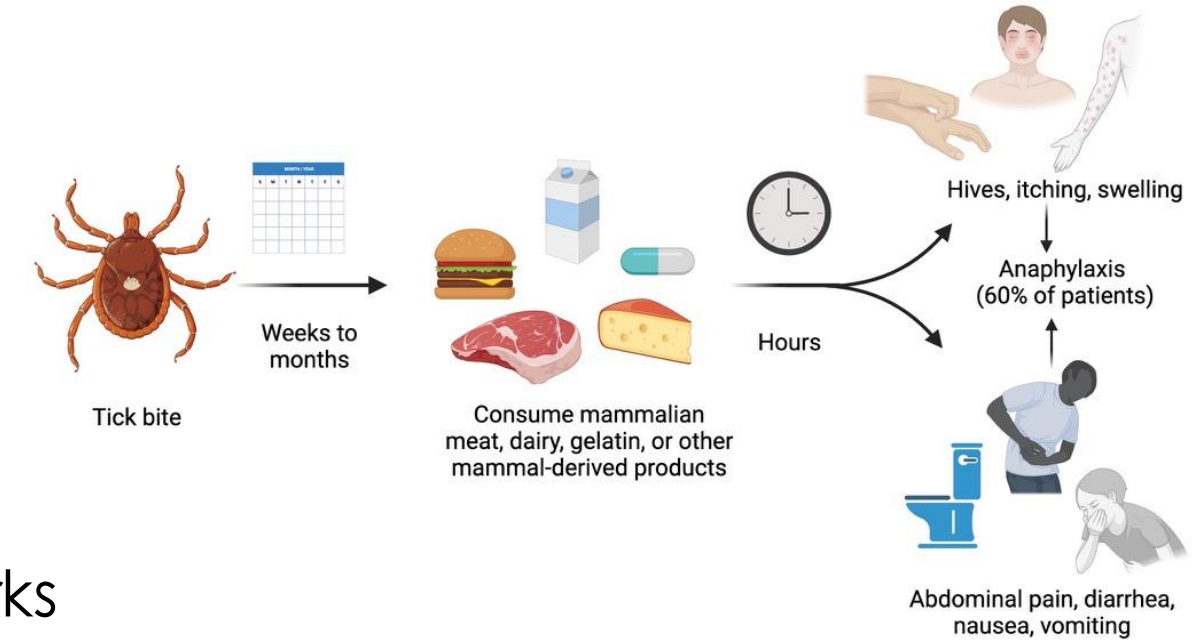
- Eight pages
- You can print & staple, or ask me to send, or print



AAAF materials

Alpha-gal syndrome infographic

- Explains how AGS works



Adapted in part from McGill SK, Hashash JG, Platts-Mills TA. AGA Clinical Practice Update on Alpha-Gal Syndrome for the GI Clinician: Commentary. *Clin Gastroenterol Hepatol.*

AGI
Alpha-gal Information™
https://alphagalinformation.org/

Created with BioRender.com

Step #6: Join the Alpha-gal: Mandatory Reporting Facebook group

- Where you can:
  - Connect with others in your state
  - Organize efforts

Step #7:
Contact Sharon to discuss next steps

- ***Together we will:***
  - Figure out who else in your state you can work with.
  - Develop a strategy
  - Figure out what materials you need and make sure you have them
  - Discuss how best to approach your representatives and/or the board of health

Step #8:
Connect your representatives

- How and when you connect with your representatives or board of health is critical
  - You can start with an email or a call—**Marilyn**
  - Follow-up is important
  - In most cases, it is critical to request a face-to-face meeting with your representative
  - If the representative is not available, ask to meet with their staff.
  - Prepare for this meeting and bring materials.

So, you have a bill… now what?

Working to pass a bill

Working together to pass a bill: What's your role?

Representatives' role

- Take the lead
- Introduce the bill
- Take the lead on finding cosponsors and support
- Communicate their needs to constituents

Constituents' role (YOU)

- Respond to the needs of your representative
- Offer & distribute materials to support representatives' efforts
- Drum up constituent support, find others to contact their own representatives & ask them to cosponsor the bill
- Organize testimony
- Testify in support of the bill--**Debbie**

How Alpha-gal Alliance Action Fund can help

Support representatives

- Provide advice based on lessons learned in other states
- Connect them to representatives in other states
- Connect them to health departments implementing mandatory reporting
- Provide information and materials
- Provide written testimony
- Garner support of other nonprofits
- Troubleshoot

Support constituents

- Provide advice based on lessons learned
- Help with strategy & organization
- Use our software to email representatives
- Provide materials
- Prep for testimony
- Troubleshoot

Welcome, Marilyn Paquet!
See Marilyn's letter below

State Delegate Howard Otto Wachsmann, Jr.,

On July 27, 2023, the CDC released an updated report about the potenti drome, caused by a tick bite. Originally estimated at 5,000 cases in 2013, the llergy.

At this time, New Jersey is the only state that reports cases of Alp

I strongly urge you to add Alpha-gal Syndrome to the list of tick- Council of State and Territorial Epidemiologists (CSTE) new AGS su across jurisdictions to monitor cases and to aid in a better understan

As an add-on, I was diagnosed in 2017, with AGS. We, as a hotspot state, MUST medical professionals will be informed, which will help people who suffer with this syndrome! Please help us.

Thank you so much for your consideration. Urls are provided below.

Best regards,

Marilyn Paquet
Smallville, VA

Note that the text of this email is dated. We will create a new template soon.

Welcome, Debbie Nichols!

Questions?

More information: https://alphagalaction.org/
Email: sharon@alphagalaction.org