



The impact of compliance with FDA Food Code

control measures in preventing foodborne norovirus illness from retail food establishments



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The impact of compliance with FDA Food Code control measures in preventing foodborne norovirus illness from retail food establishments.



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Human Foods Program

Today's Outline

- Background on Norovirus as a source of foodborne illness in the retail food industry.
- The importance of hands as a source of norovirus foodborne illness.
- How the Food Code provisions control norovirus.
- Why we did a risk assessment on NoV from infected food employees in food establishments, and what can it tell us?
- Overview of the risk assessment and major results.
- Summary of the major risk assessment results.

- Leading cause of foodborne illness globally
- Characterized by a sudden onset of vomiting, diarrhea, and abdominal cramps with a duration of 1-3 days

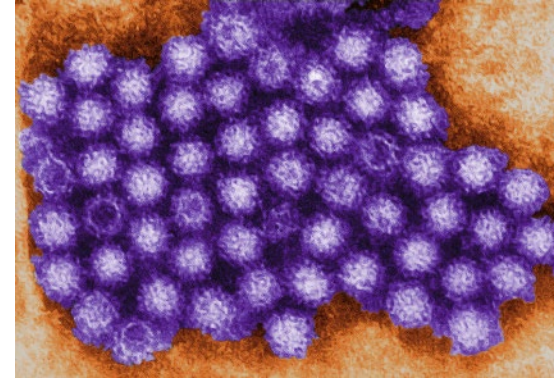


Photo Credit: Charles D. Humphrey, Centers for Disease Control and Prevention

- Large amounts of virus shed during symptoms
 - 10^{12} Genome Equivalent Copies (GEC) NoV / g of feces
 - 8×10^5 GEC NoV/ ml of vomit
 - **Viral shedding duration in adults lasts 20-30 days**

- Infectious dose low or very low (?)

50% human infectious dose = 18 NoV particles

(Teunis *et al.*, 2008)

Food employees play a significant role in norovirus foodborne outbreaks

- Restaurants are the most common setting (64%) of food preparation reported in outbreaks in the U.S. (Hall *et al.*, 2014).

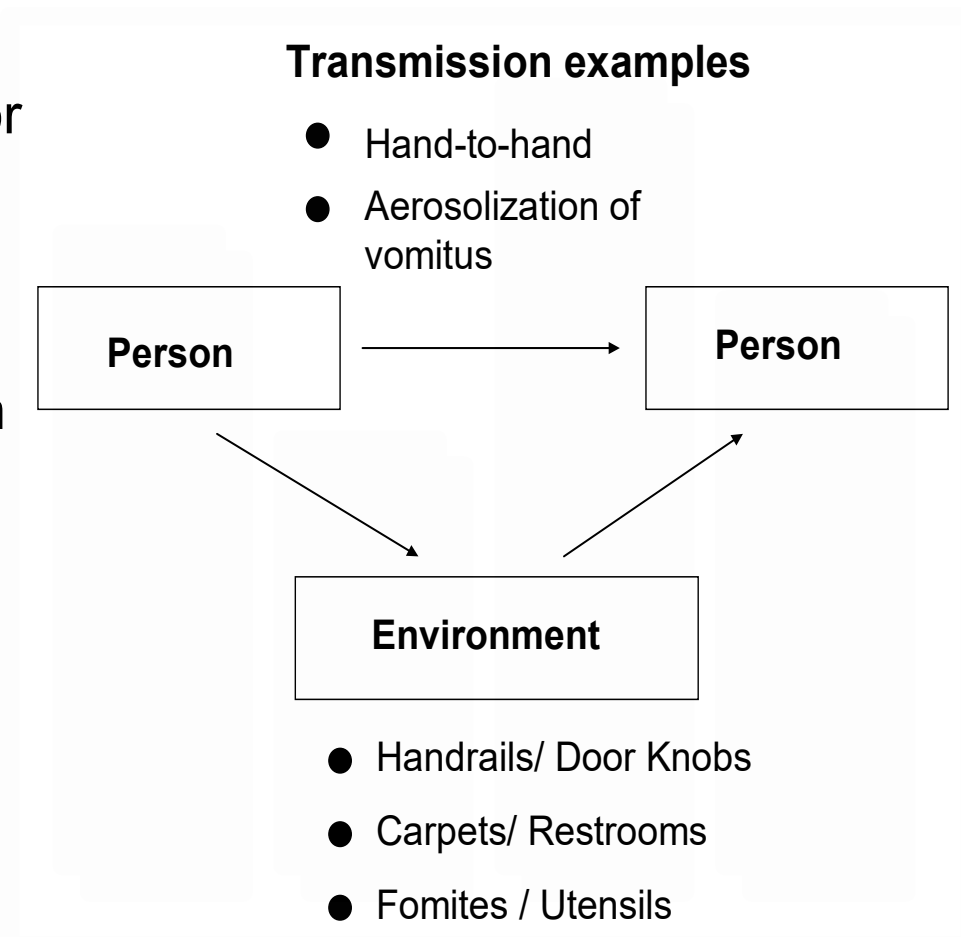


- Most foodborne outbreaks linked to food establishments are traced to food employee contamination of Ready-To-Eat (RTE) food (FAO/WHO 2008, Patel *et al.*, 2009, Hall *et al.*, 2013a, Hall *et al.*, 2013b)



Environment to Person & Person-to-Person Norovirus Transmission

- Contaminated fomites are the most likely factor responsible for sustaining a succession of outbreaks
- Hands play a significant role in NV transmission**, either through direct fecal-oral contact, or through the contamination of ready-to-eat food items



Hand Contamination

Hands: The major mode of transmission and have the highest degree of NoV contamination, in a comparison of potential NoV contamination levels for environmental surfaces (Mokhtari & Jaykus, 2009)

Do You Trust Your Toilet Paper?

- Hutchinson (1956): compared the permeability of 5 types of toilet paper to *Shigella sonnei* from 3 types of feces to fingers
 - *All types of TP failed to protect the fingers with fluid or semi-solid stools*
 - *4 out of 5 TP failed to protect the fingers with solid stools*



Hand Transmission

Hand contamination study using bacteriophage MX174 (Rheinbaben *et al.* 2000):

- 8×10^8 pfu of phage on 1 door handle of an apartment shared by 4 students: Resulted in spread throughout room---all surfaces tested & phage on all hands even after handwashing within 6 hrs.
 - Telephone in living room
 - Drawer handles in kitchen and bathroom
 - Water faucet in kitchen and bathroom
 - Light switch in kitchen
 - Refrigerator handle in kitchen
 - Bar of Soap
 - Teapot Handle

Transfer from Contaminated Fingers

- Liu, P. et al (2009) w/ Feces: Found NoV RNA on fingers for up to **2 hours**
- Barker (2004) found that NV can transfer from contaminated fingers, sequentially to 7 different environmental surfaces
- Secondary Transfer of NV (from contaminated surfaces to clean fingers, to other surfaces)
 - can transfer sequentially to 4 different surfaces
- Detergent cleaning, followed by rinsing was not effective in cleaning contaminated surfaces, unless followed with a disinfectant.

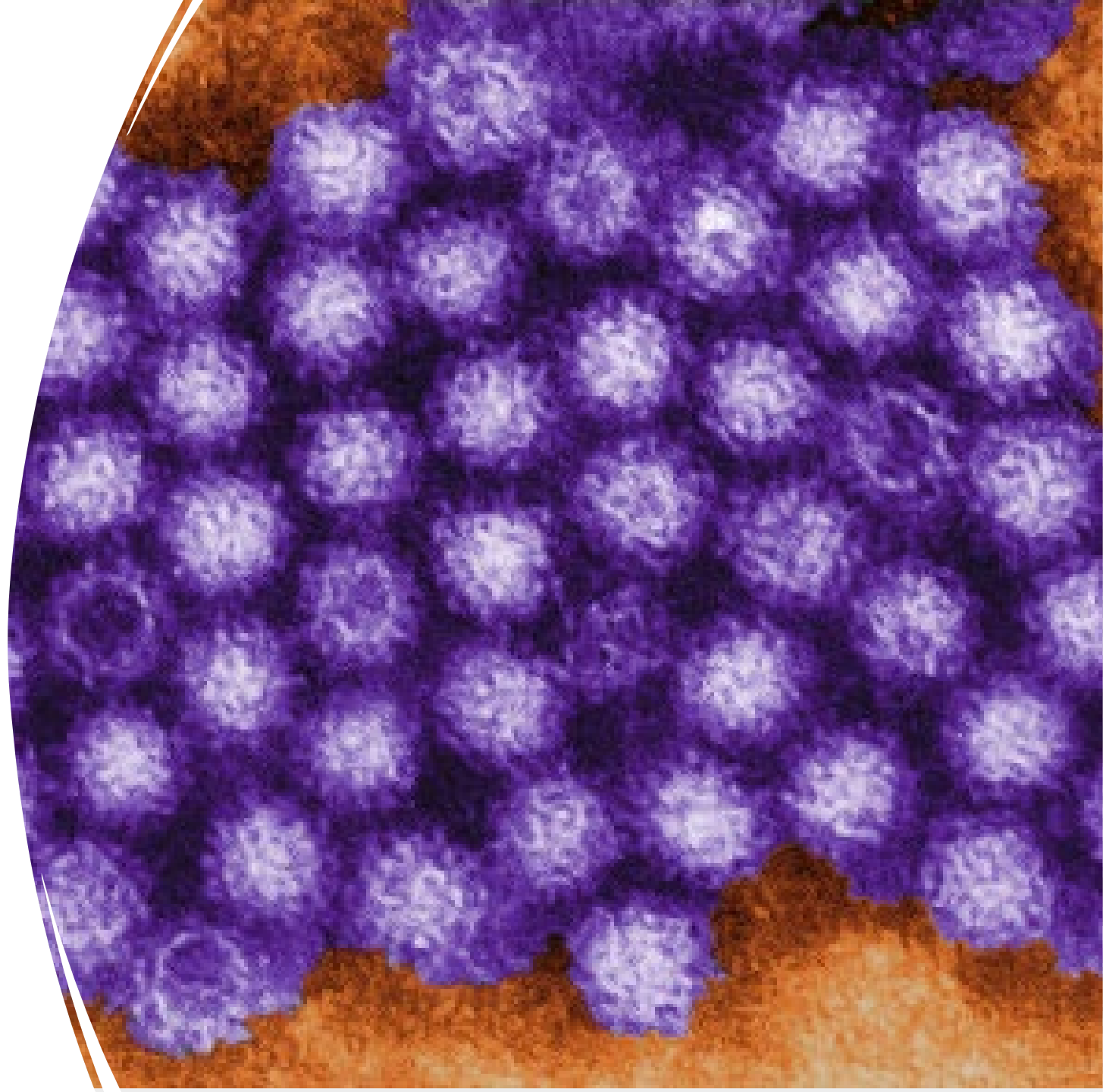
Potential Control Measures

FOLLOW THE FECES

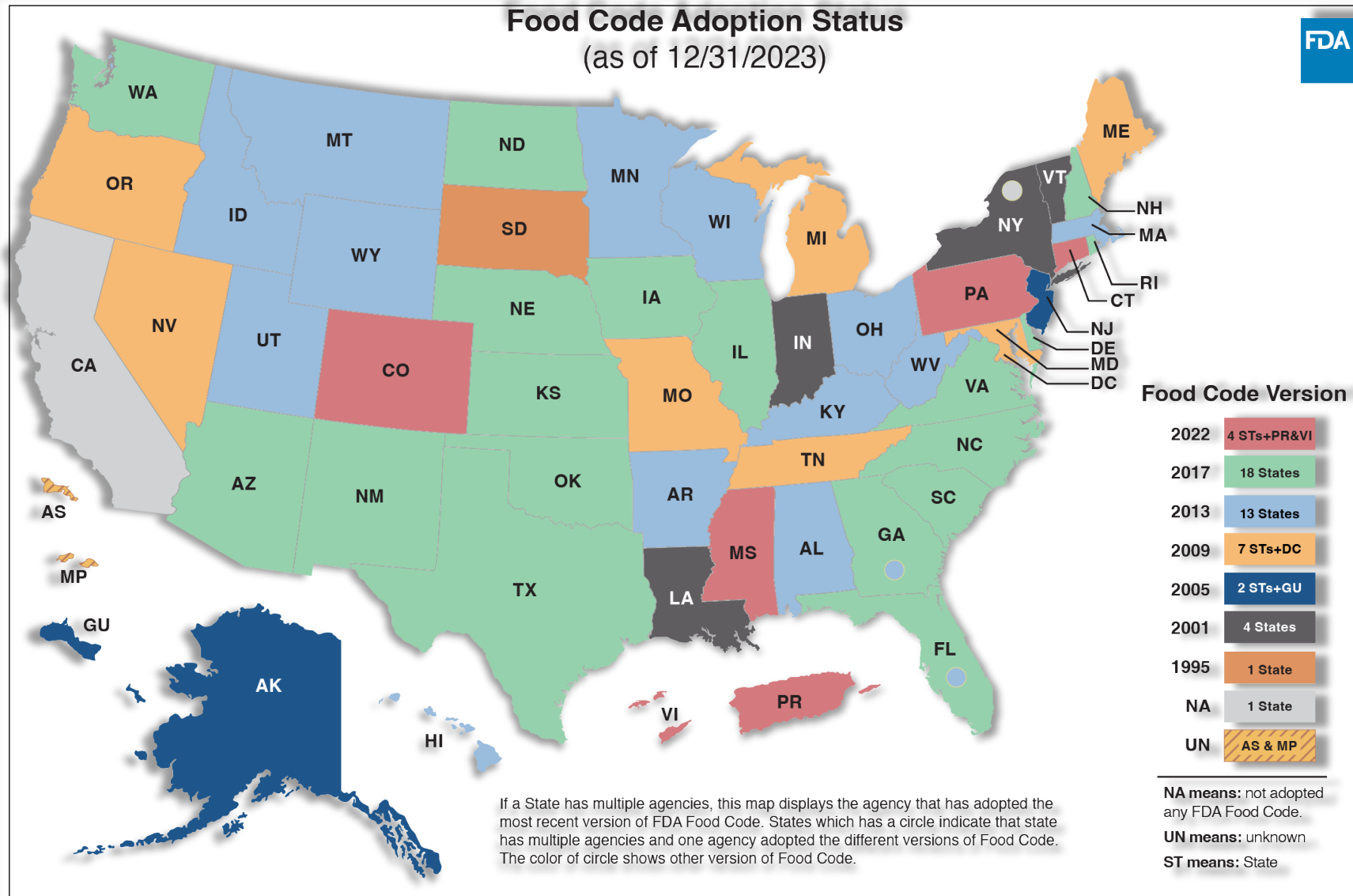
- Interruption of transmission from:
 - Humans: Remove Symptomatic Food Workers
 - Environment: Focus on Cleaning & Disinfection of Surfaces with human fecal contamination (Restrooms are Key Fecal Reservoirs)
 - Food: Prevent Human Contamination

How Does the Food Code Currently Control Norovirus?

- **Uses a Mixture of 4 Different Mitigation Strategies:**
- **Exclusion of Ill, Symptomatic food employees**
- **Handwashing**
- **No Bare Hand Contact with Ready-to-Eat Food**
- **Cleaning and Sanitizing Food-Contact Surfaces**



Food Code Adoption Status in 2023



35 States have adopted one of the three most recent versions (2022, 2017, and 2013 version), representing **63.36%** of the U.S. population. This is an increase of one State from the 2022 reporting period.

22 States have adopted one of the two most recent versions (2022, and 2017 version), representing **47.37%** of the U.S. population. This is an increase of four States from the 2022 reporting period.

4 States have adopted the most recent version (2022 version), representing **7.65%** of the U.S. population. This is an increase of two States from the 2022 reporting period.

2 Territories have adopted the most recent version (2022 version).

Why a Risk Assessment on NoV Transmission in Food Establishments?

- No single preventive measure can eliminate the risk of foodborne norovirus from a symptomatic food employee
- Need for better understanding of how effective Food Code intervention strategies are when used individually or in combination to reduce or prevent the incidence of norovirus foodborne illness.
- Need for consideration of actual practices and level of compliance to determine current intervention impact and any need for policy modification.

- Does not provide “the answer”
- Provides an analysis of contributing factors and options for use in regulatory decisions and for reducing the risk to public health
- Tells us where the probability of contamination is highest in the food system being evaluated, and which methods are most effective in preventing or reducing food contamination & subsequent foodborne illness.



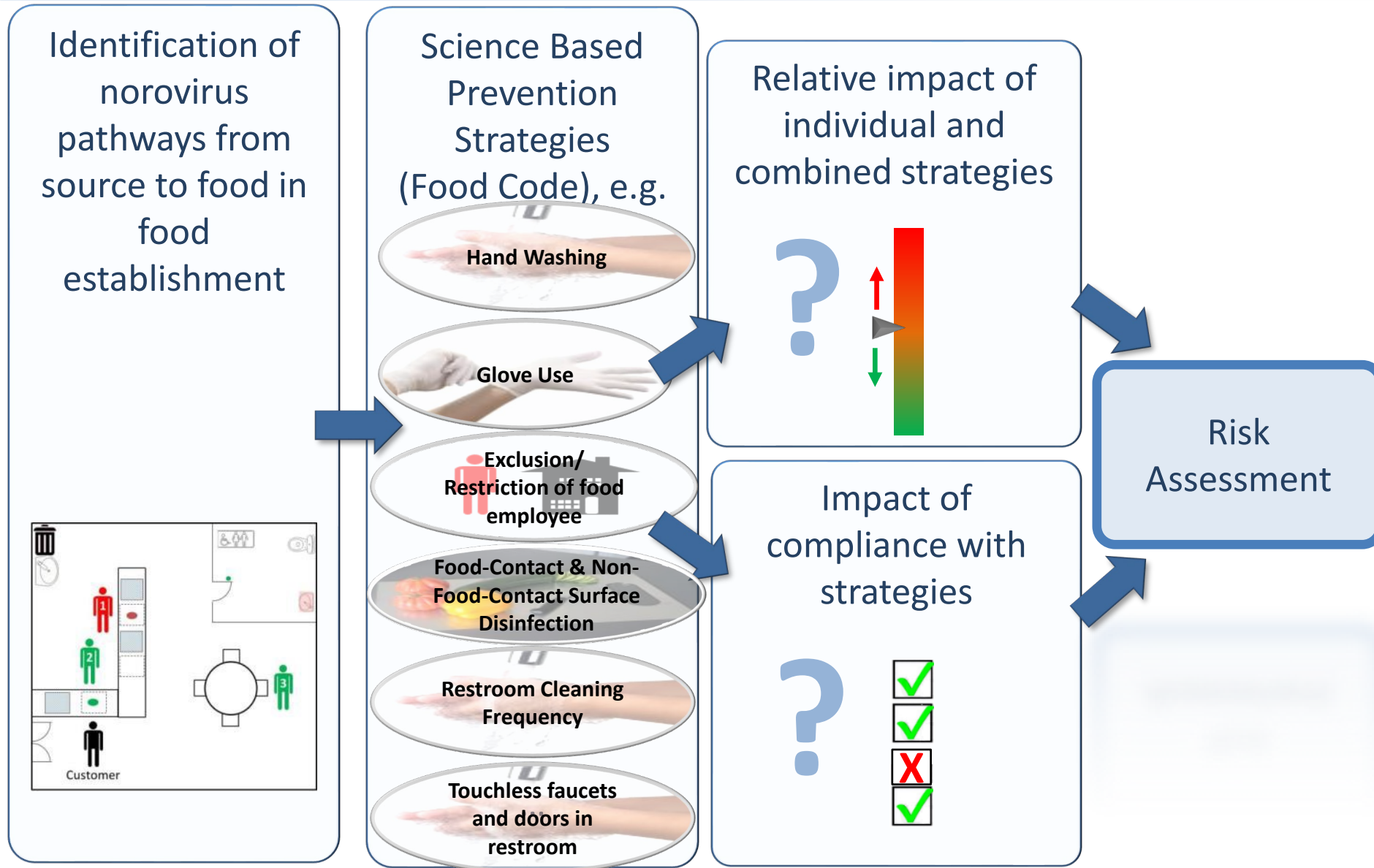
GOAL

Identify strategies to significantly reduce NoV transmission and illness from contaminated food in retail establishments

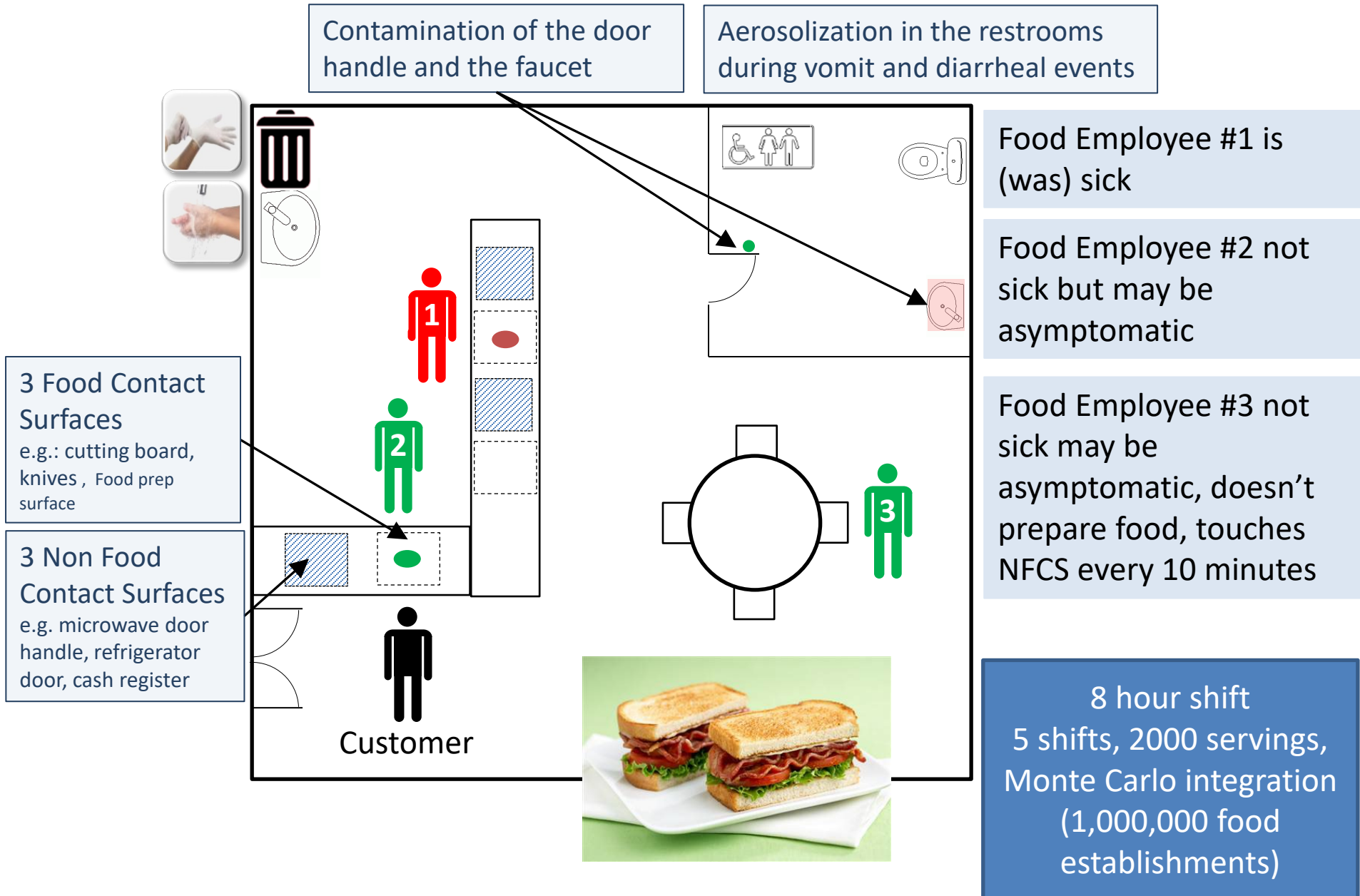
OUR STUDY

- Quantified impact of key mitigations (individual and combined) in the FDA Food Code
- Examined the impact of compliance (human behavior) with these mitigations on the risk of illness
- Identified ways to enhance the impact of key strategies

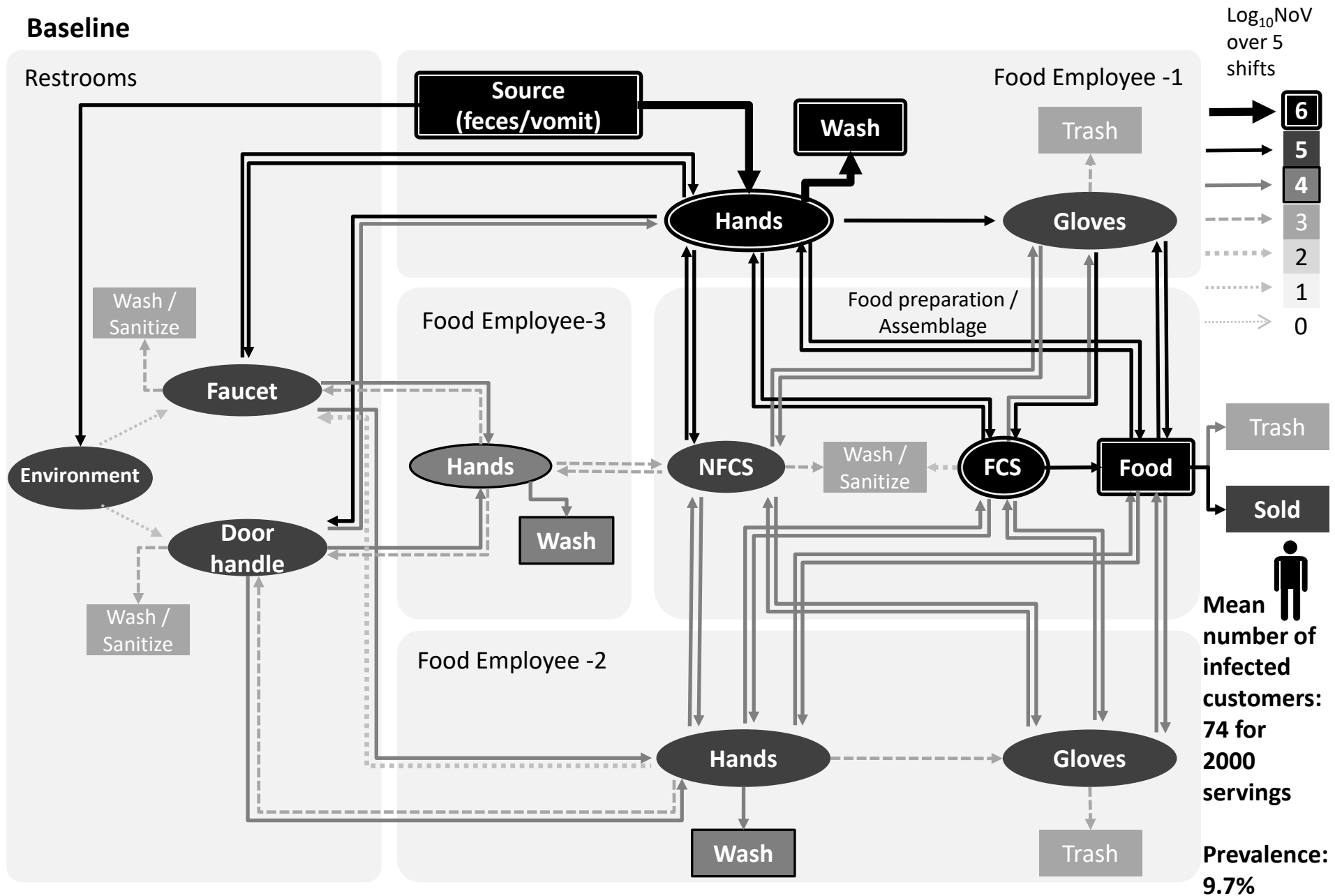
Discrete Event Model



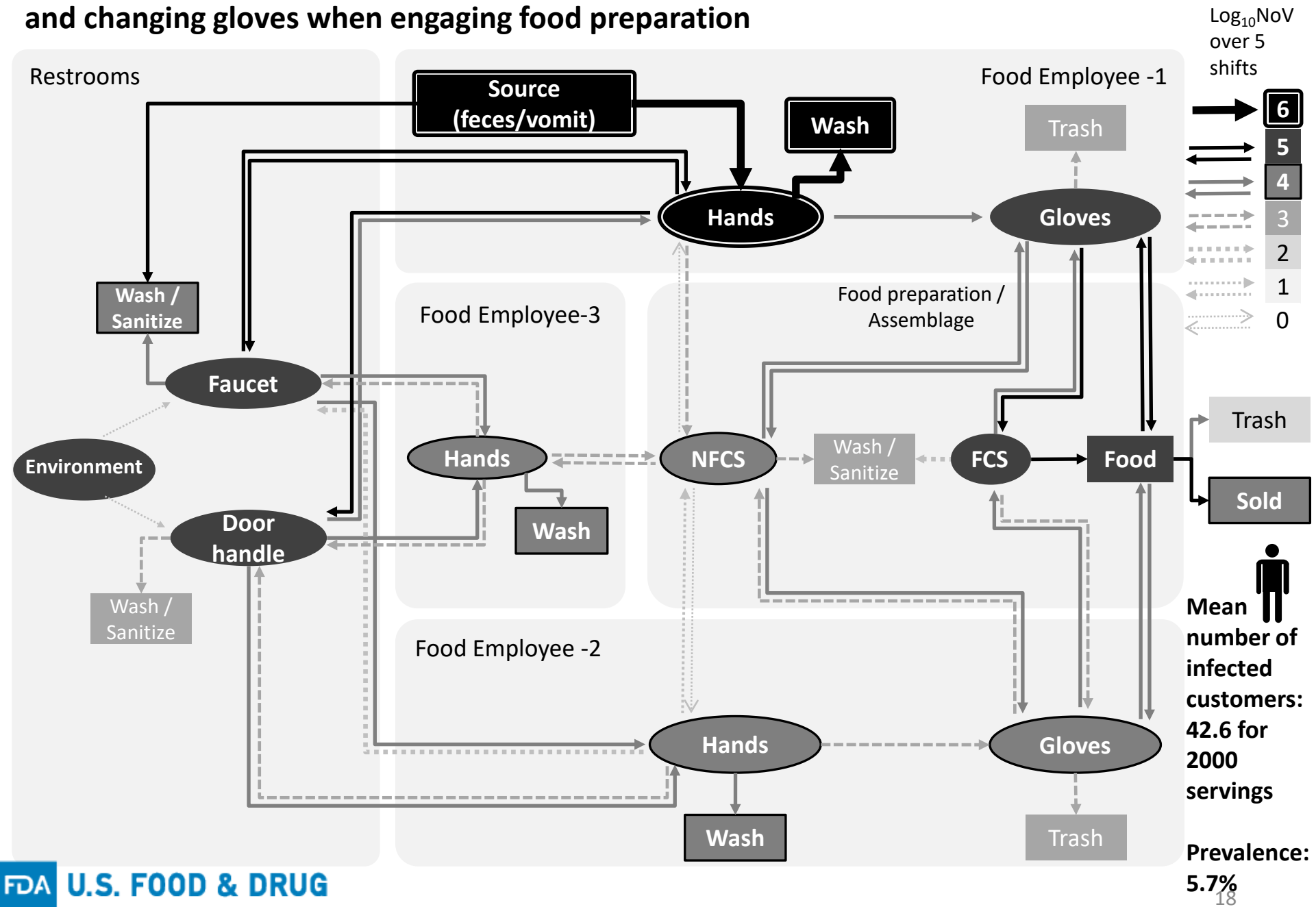
Setting



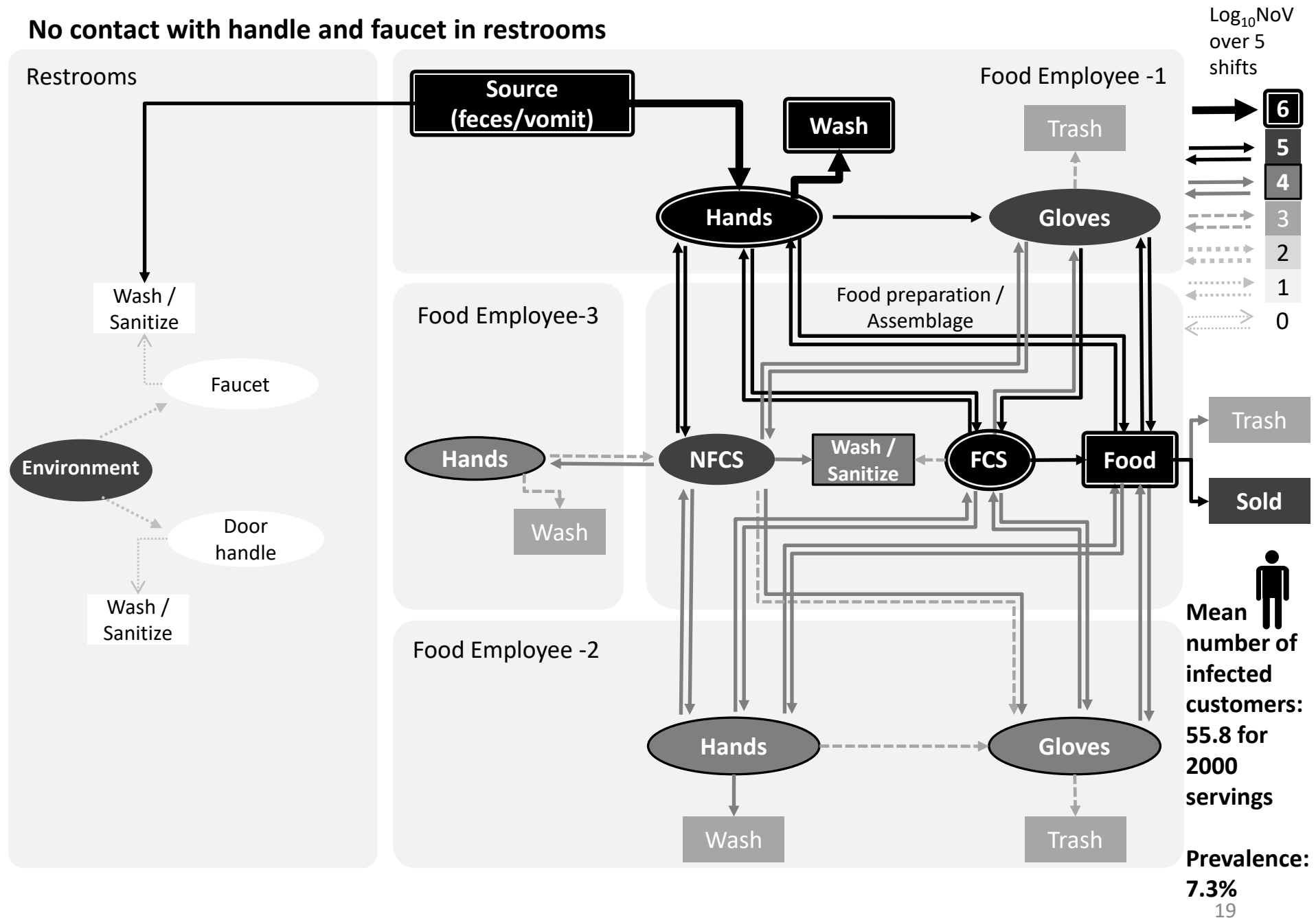
Baseline



Full compliance of handwashing in restrooms and in food preparation area, wearing and changing gloves when engaging food preparation



No contact with handle and faucet in restrooms



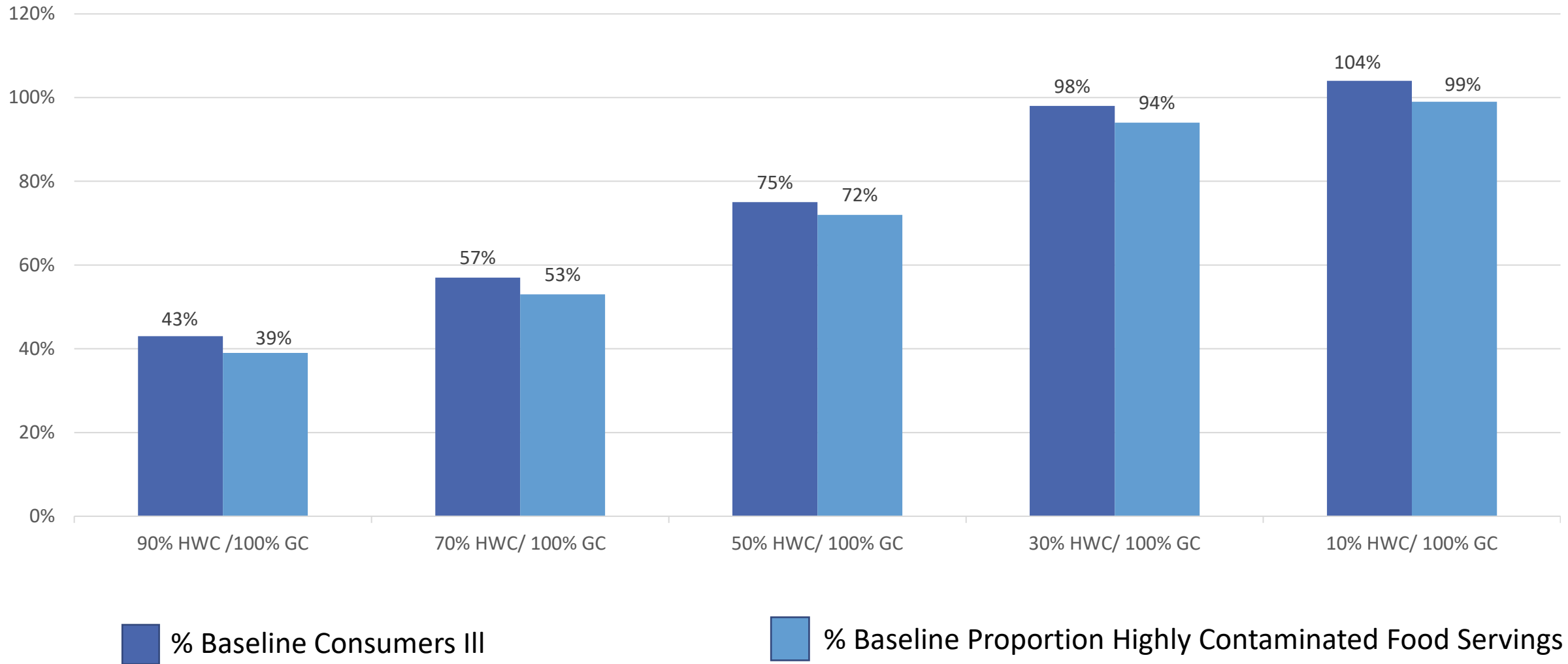


Model Results: Handwashing Impact

- Hand hygiene had one of the highest impacts on consumer illnesses
- High levels of Handwashing compliance with glove-use results in the lowest reduction of NoV consumer illness and contaminated food observed from a single mitigation strategy in the model

High Handwashing Compliance with Glove-Use can decrease NoV Illness by 43%

Change from Baseline in Ill Consumers and Prevalence of Contaminated Food Servings



Impact of a Restricted Food Employee

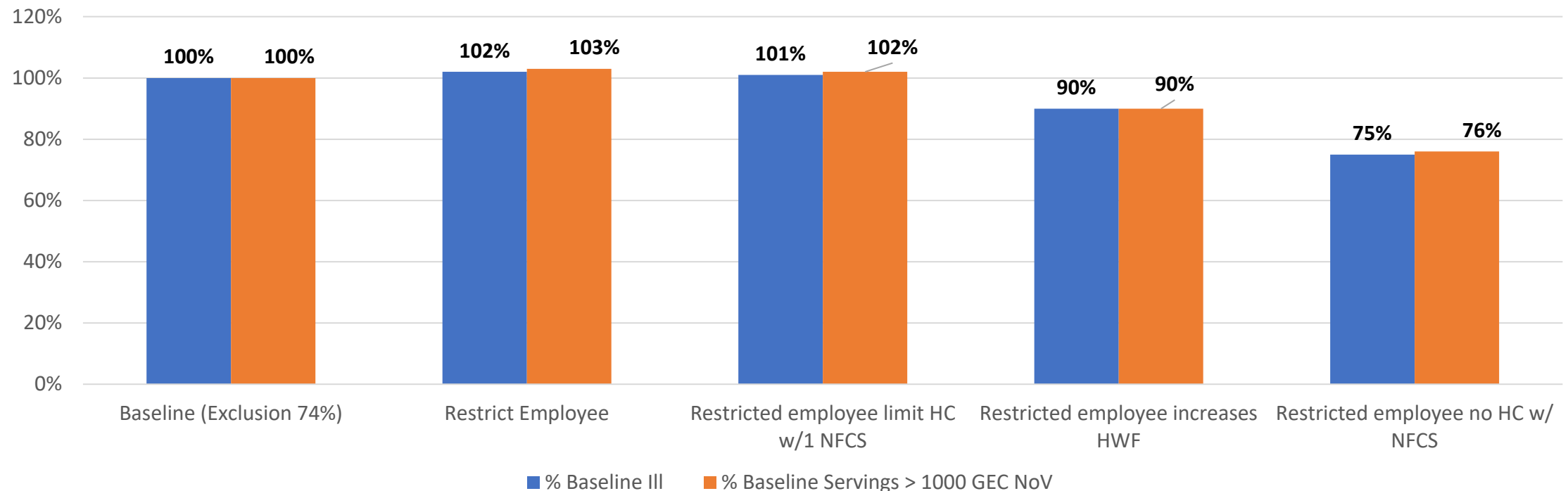
“It’s all about the hands”

Handwashing frequency is so important that “Restricting” a food employee to a job requiring less frequent handwashing, can increase NoV transmission

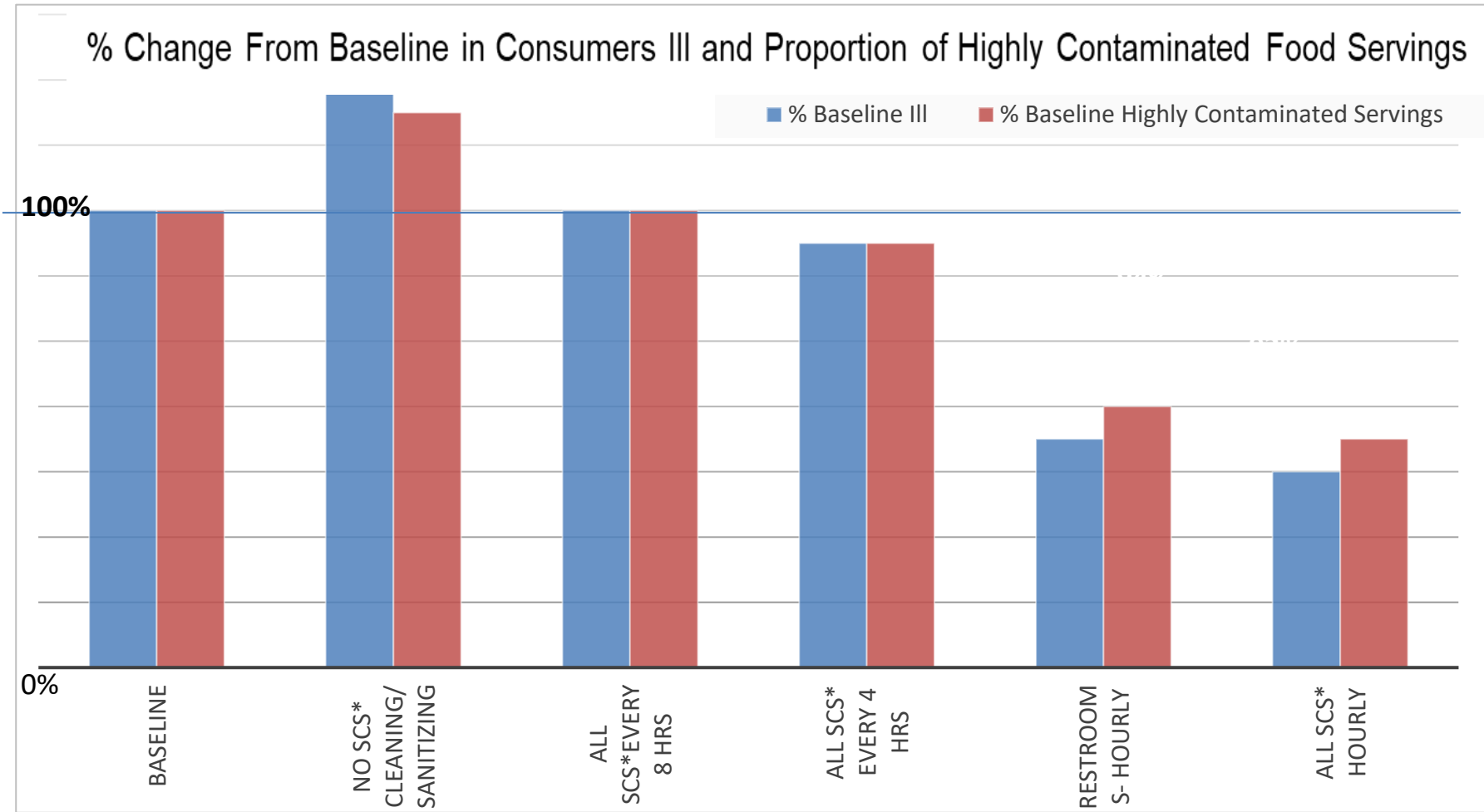


Restriction of Ill Food Employees Without Increased Handwashing Has Little Impact in NoV Illness Levels

% Change from Baseline in Ill Consumers & Prevalence of Highly Contaminated Food Servings



Frequency of Cleaning/Sanitizing Surfaces –Ranging from No Surface Cleaning/Sanitizing to Surface Cleaning/Sanitizing on an Hourly basis had Minimal Impact



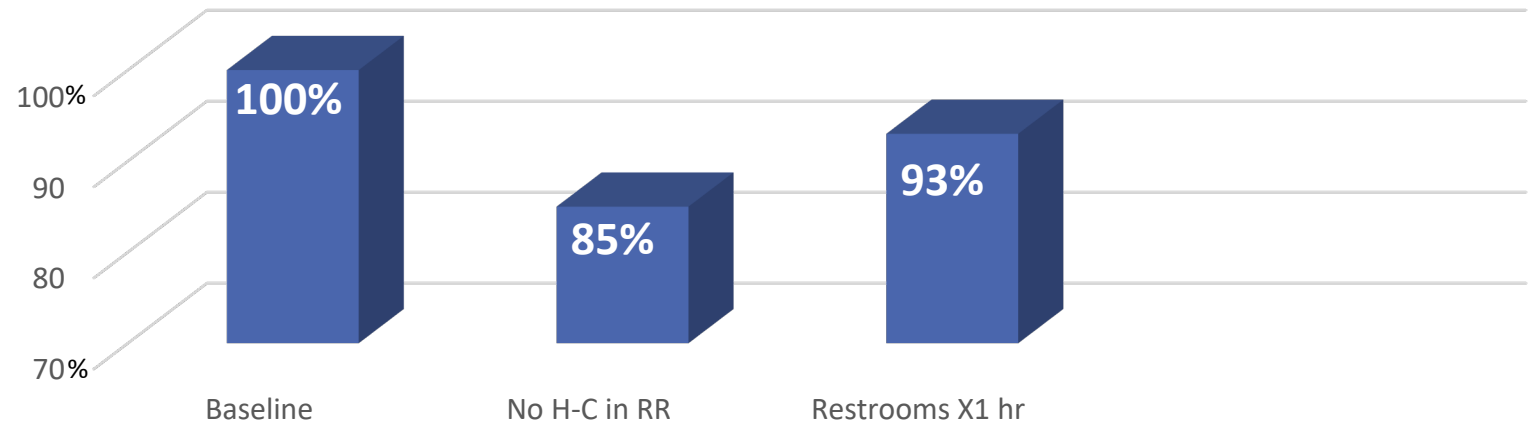
Baseline = Food Code Cleaning/Sanitizing Frequency; *SCS= Surface Cleaning/Sanitizing
FCS= Food Contact Surfaces *NFCS= Non-Food Contact Surfaces



What is the impact of contacts between hands and faucet in the restrooms and cleaning frequency in the restrooms?

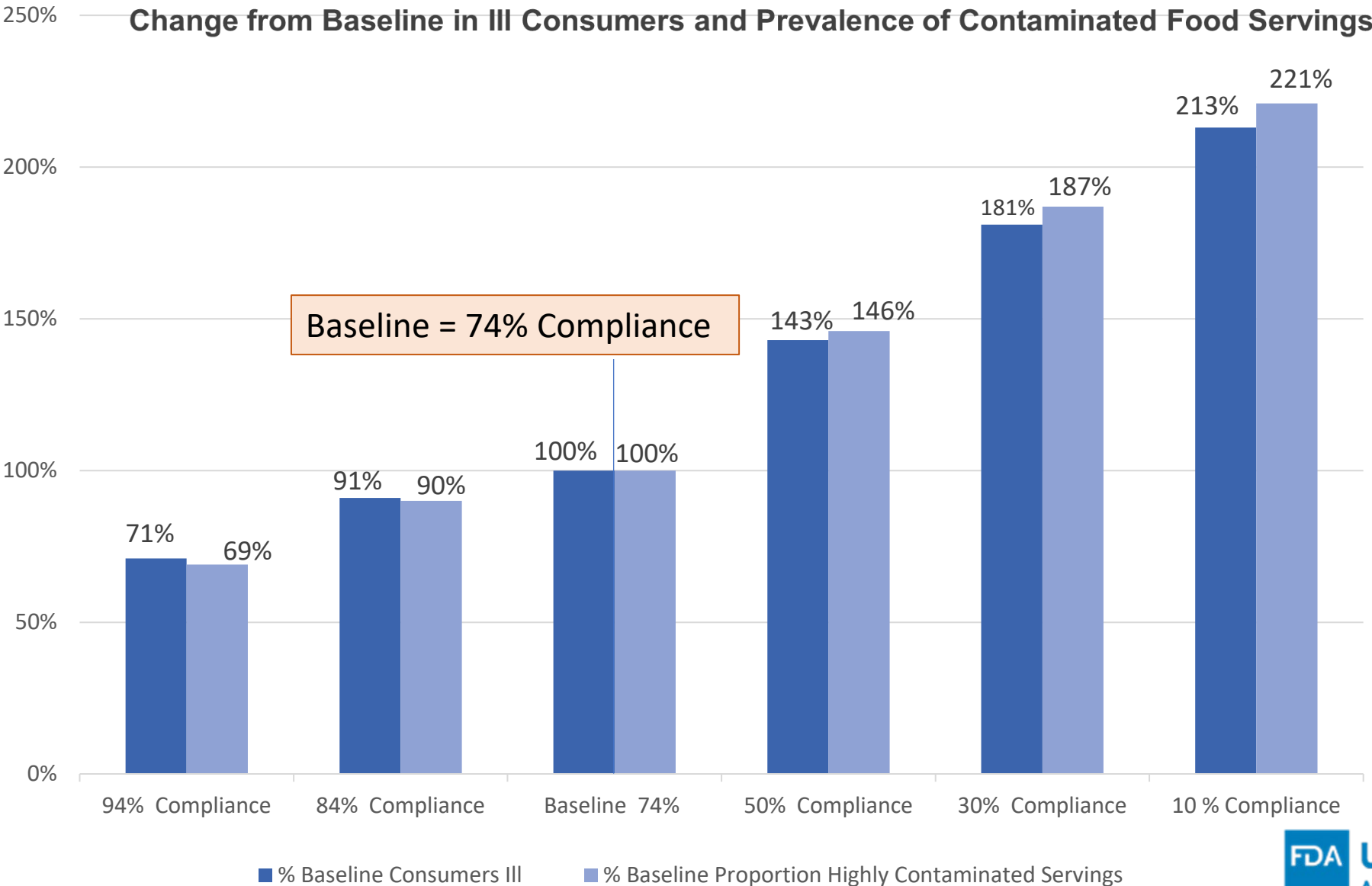
%Baseline Number of ill customers

Removing hand contacts between hands, faucet and door in the restrooms appears to be effective



Scenario	Baseline	No H-C in RR	Restrooms C/S-1hr
Scenario description Current = (FCS X 4hrs, NFCS X 8hrs, & Restrooms X 8 hrs)	Current practices	Touchless faucet and door in the restrooms	Restrooms are washed and disinfected every hour

Poor Compliance w/Exclusion of Ill Food Employee Can Result in an Increase in NoV Illness Over 200%

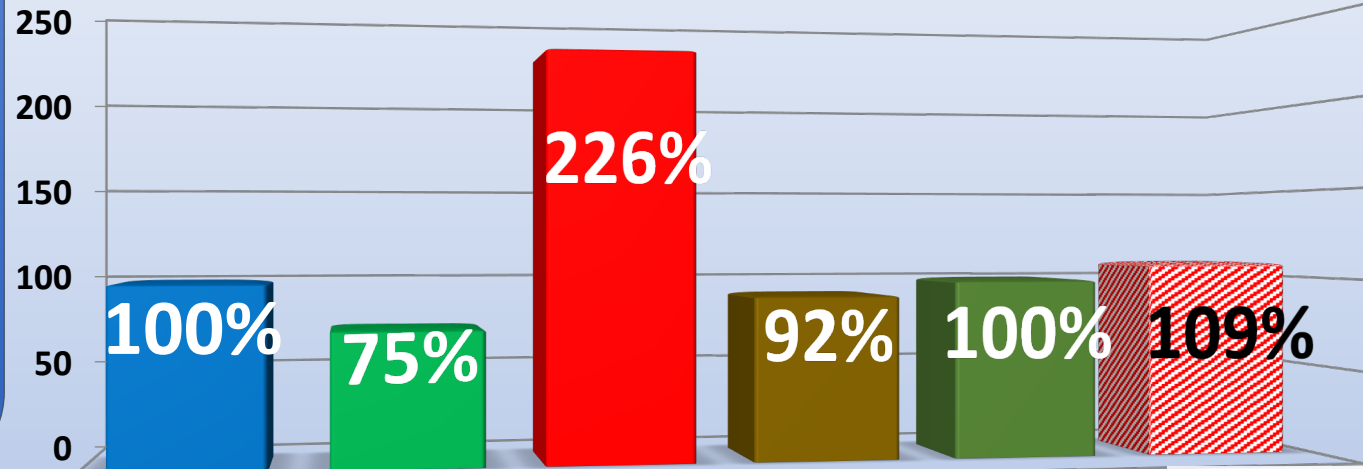




What if the extension of the exclusion time period to 48h leads to a decrease with the compliance?

The public health benefit from extending the exclusion period after symptom resolution may be eliminated or may result in an increase in the burden of illness if compliance decreases

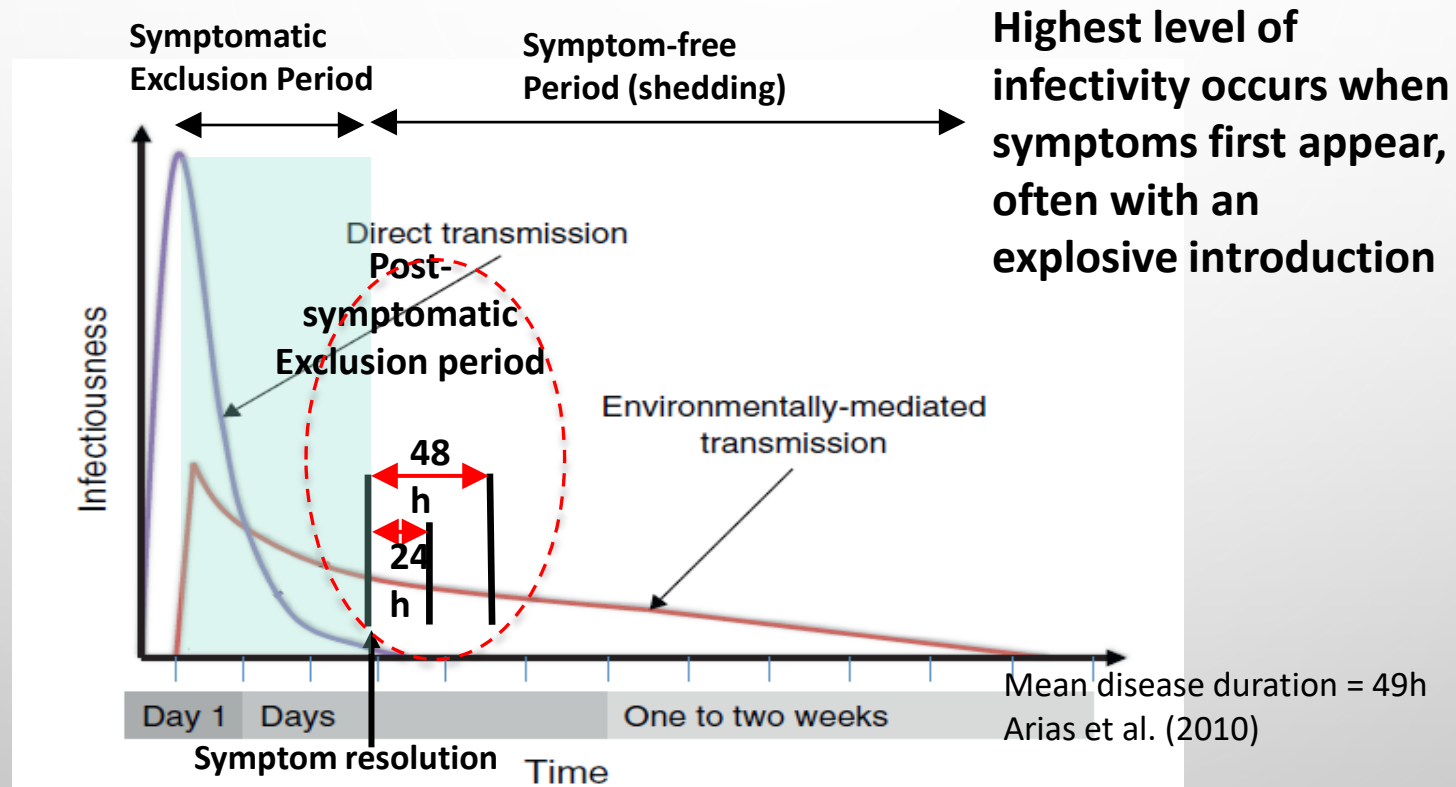
%Baseline Number of infected customers



Scenario #	Baseline	#2	#3	#4	#5	#6
Compliance with exclusion	74%	100%	0%	74%	64%	54%
Duration of the post-symptomatic exclusion period	24h	24h	-	48h	48h	48h
Simplified description of the scenario	Current compliance Sumner et al. (2011)	Full Compliance	Employee always works while ill	Exclusion extension	Exclusion extension	Exclusion extension

WHAT IS THE IMPACT OF EXCLUSION PERIOD AFTER SYMPTOM RESOLUTION? WHAT IS THE IMPACT OF EXTENDING IT TO 48 HOURS?

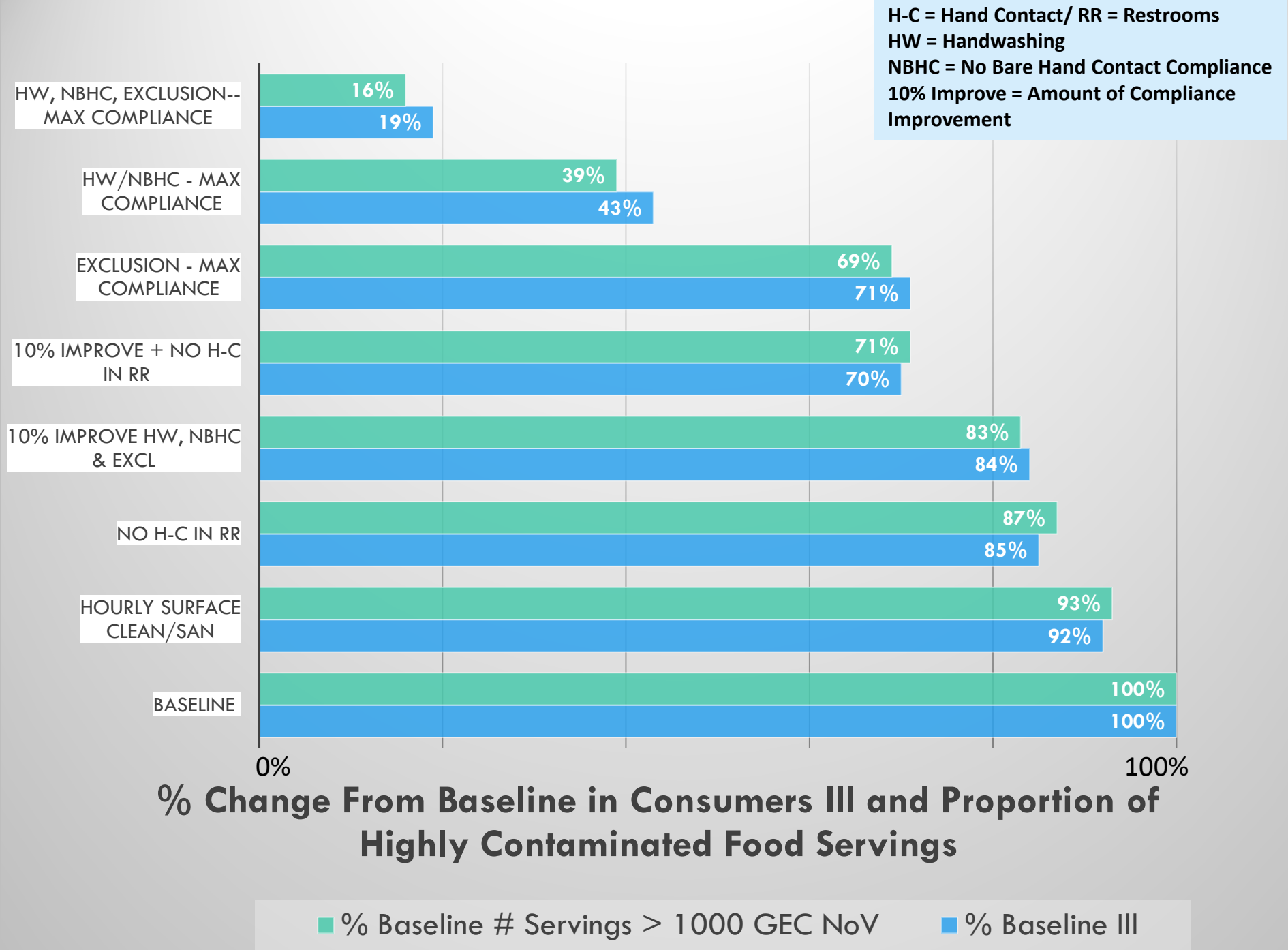
“INDIRECT AND DIRECT TRANSMISSION POTENTIAL OF NOV OVER TIME”



Adapted from Lopman, B., et al. (2012).

Impact of Employee Compliance w/ Exclusion

- *Prevention strategies based on human behavior need to look at compliance to determine effectiveness*
- *The current reality for food employees in the restaurant industry puts the economic burden of exclusion on the employee through loss of pay, and increasing this burden may result in more employees hiding their illness.*
- *Results show that the risk of increasing the number ill consumers by extending the exclusion period from 24 to 48hrs is higher than any benefit, due to potential loss in the level of compliance with “Exclusion”*



SUMMARY OF RISK ASSESSMENT RESULTS

1

Excluding symptomatic food employees at the peak of their infectiousness* is the priority to reduce the burden to public health associated with norovirus transmission in food establishments

*see Lopman et al 2012, Zelner et al. 2013, Teunis 2013

2

Handwashing, No Bare Hand Contact and Exclusion of ill food employees are the most effective preventive strategies in reducing the transmission of NoV from ill food employees in retail food establishments.

SUMMARY OF RESULTS CONTINUED:

3

Eliminating hand-contact in the restroom is an effective additional preventive strategy to the transmission of NoV & is more effective than washing and sanitizing the restroom every hour

4

Restrooms serve as the source of environmental norovirus contamination in food establishments, and need more focus on cleaning/disinfection to have an impact on reducing viral surface contamination in food establishments

5

Results support the current recommendations of the FDA Food Code--Better compliance with current Food Code interventions would reduce Nov transmission

References

For more information, see full report:

***Quantitative Risk Assessment of Norovirus Transmission in Food...**

- Available free from

Risk Analysis 2017 Mar 1. doi: 10.1111/risa.12758.

- <https://onlinelibrary.wiley.com/doi/pdfdirect/10.1111/risa.12758>

And:

***Evaluation of the Impact of Compliance with Mitigation Strategies...**

- Available free from:

J Food Protection 2022 Aug 1;85(8):1177-1191. doi: 10.4315/JFP-21-423

- <https://pubmed.ncbi.nlm.nih.gov/35358310/>

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Questions??



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