

Vaccine Safety Datalink and Immunization Information Systems



AIRA
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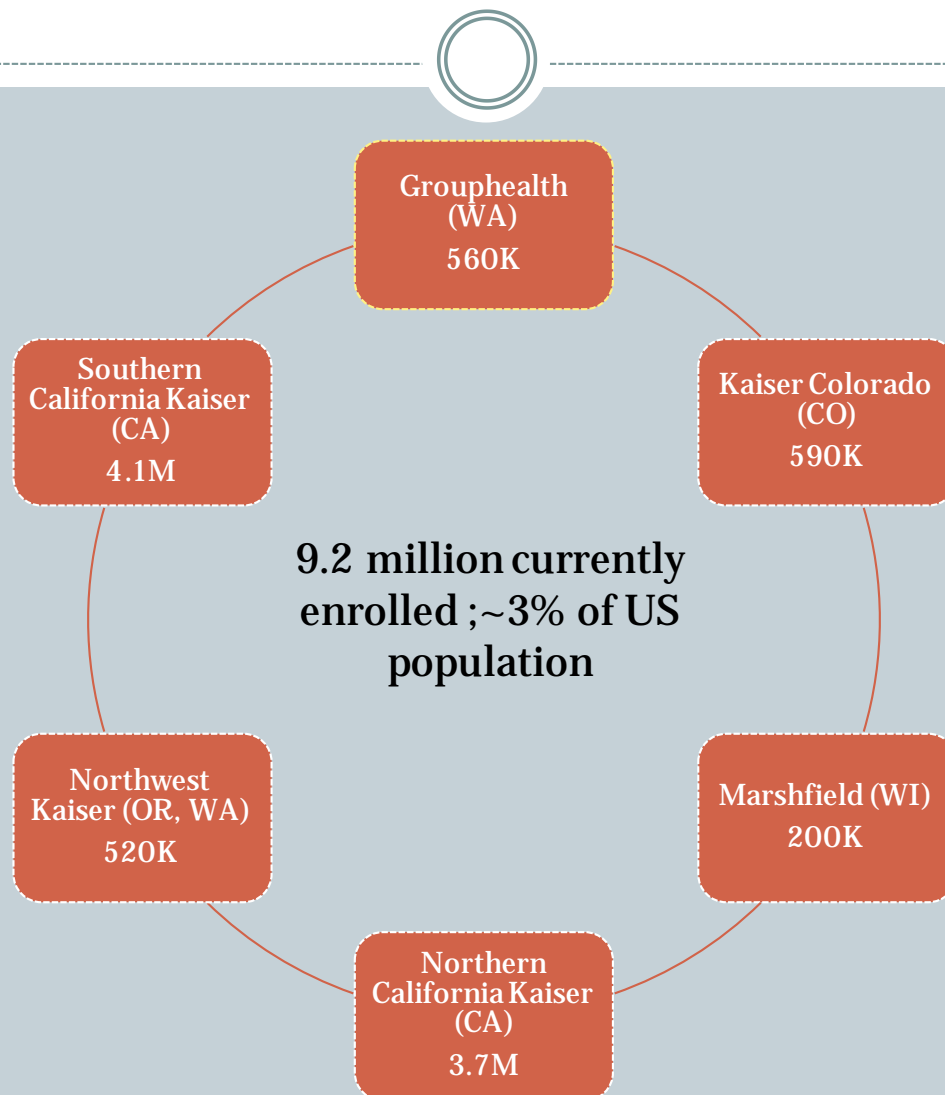
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What is the Vaccine Safety Datalink (VSD)?



- Established in 1990
- A collaborative project between CDC and 8 U.S. health systems (6 data-contributing)
- Allows for planned vaccine post-licensure safety studies, as well as:
 - Rapid safety assessment for routine and emergency vaccination campaigns
 - Monitoring changes in immunization patterns following schedule changes, or the introduction of new vaccines
 - Informs national immunization policy (e.g. MMRV)

VSD: data-contributing sites



Do VSD sites include IIS data?



Site	IIS	Bidirectional Exchange?	Include IIS data in VSD vaccine file?
Grouphealth	CHILD Profile	Yes	Yes
Kaiser CO	CIIS	Yes	Selectively
Marshfield	WIR	Yes	Yes
Kaiser NW	ALERT CHILD Profile	Yes	ALERT-Yes CHILD Profile-No
Kaiser Northern CA	CAIR SJRR	Send only	No (unless provider incorporates manually)
Kaiser Southern CA	CAIR SJRR San Diego Registry	Send only	No (unless provider incorporates manually)

Relevance & Rationale



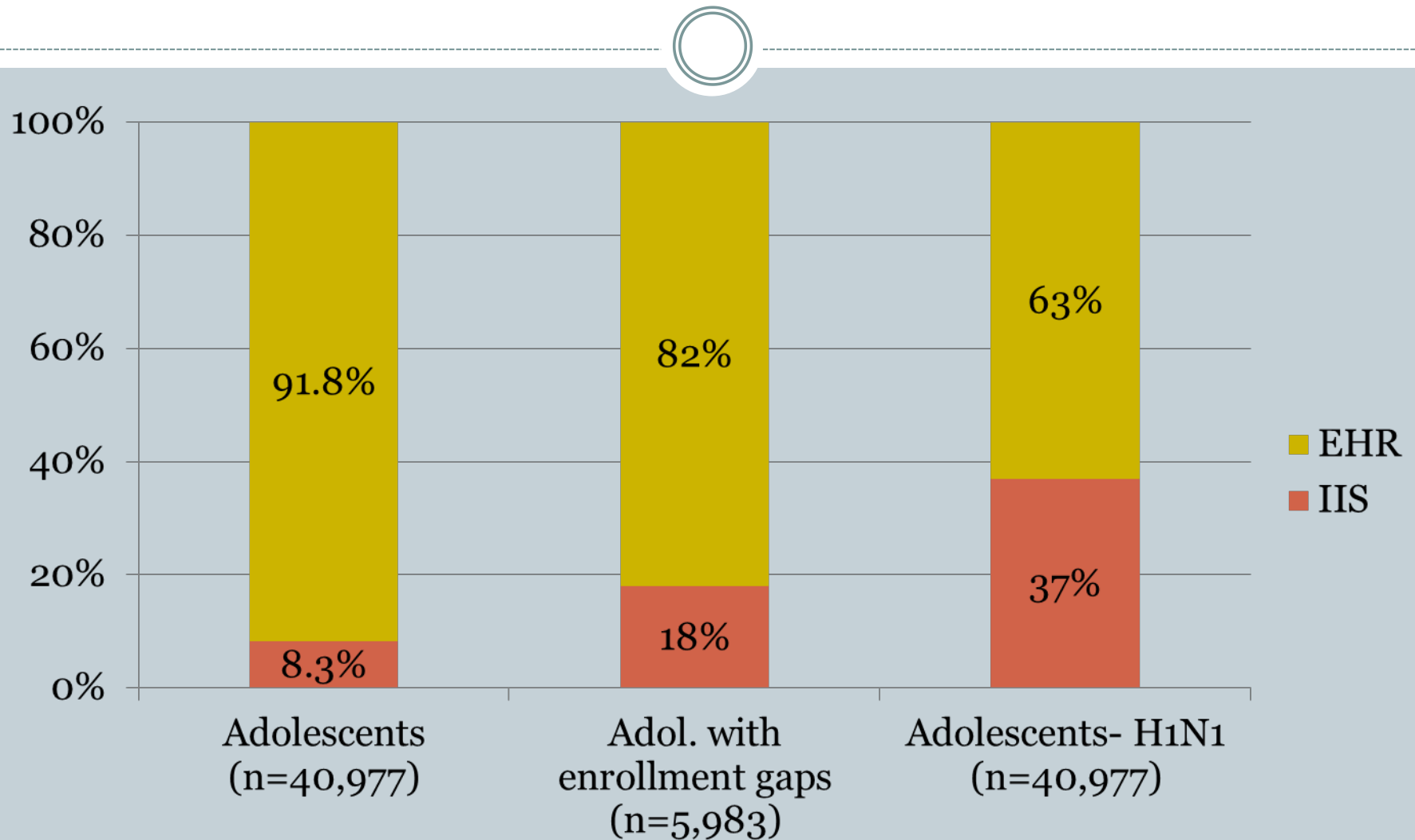
- High data quality standards needed for valid assessments of vaccine safety, vaccine uptake, and vaccine coverage
- VSD data completeness has not been systematically evaluated for adolescents or adults, and only for children in 1999
- Previous evaluation of IIS data integration in **2009** suggested there were barriers to advancing data exchange in the VSD, but there could be value in doing so

Project Goal



- Provide an updated description of the current state of data exchange between each of the 6 VSD data-contributing sites and their jurisdictional IIS; evaluate contributions of IIS data to VSD vaccine files
 - What do IIS data ADD to the health care system data?
 - Age
 - Enrollment duration
 - Vaccine type (e.g. H1N1, MenB)

EHR & IIS Data: NWK adolescents



NWK Case Study: HPV



Using data from a current HPV study

- Population: 2,172 females age 20-29
- Enrollment criteria: Enrolled in health plan from 2014-2015

# of HPV doses	# study members, (pre-IIS)	# study members (post-IIS)	% change
0	1,170 (53.9)	1,058 (48.7)	-9.6
1	193 (8.9)	182 (8.4)	-5.7
2	113 (5.2)	139 (6.4)	23.0
3	696 (32.0)	793 (36.5)	13.9

5.2% misclassified as unvaccinated, 4.5% misclassified as incomplete

Impact of 5% misclassification



- Vaccine safety studies
 - Certain study designs (e.g., case series) where the population is limited to vaccinated individuals
 - ↓
 - Inadvertent exclusion of 5% eligible population (some of whom may have AE outcome)
 - ↓
 - Fewer cases limits ability to detect rare adverse events
 - ↓
 - If AE present, results in bias toward null

Impact of 5% misclassification



- **Vaccine coverage/uptake studies**
 - Studies focused on assessing coverage rates to inform practitioners, public health decision makers, and the public
 - ↓
 - Under-estimates vaccine coverage and vaccine-series completion rates
 - ↓
 - Over-estimates unvaccinated population (whom are often focused upon for targeted intervention)
 - ↓
 - Vaccinated may appear as unvaccinated, especially biased for those with more “fragmented care”

Impact of 5% misclassification



- Vaccine effectiveness studies
 - Studies of effectiveness rely on accurate assignment of exposure status
 - ↓
 - Under-estimates of vaccinated/completely vaccinated
 - +
 - Over-estimates of unvaccinated
 - ↓
 - Leads to bias toward null, particularly when VE is high

Summary



- Inclusion of IIS data can increase VSD capture of vaccine data, reduce misclassification bias, and potentially improve accuracy of VSD studies
- IIS data completeness is not of concern, for this project
- Potential to develop best practices for an informed approach to inclusion of IIS data within the VSD

Next Steps



- **Prioritize age group(s) and vaccines**
- **Adapt data quality checks to IIS data inclusion process**
- **Develop data deduplication business rules (MIROW)**
 - Same vaccines, different date
 - Specified vs. unspecified vaccine type
 - Combination vaccine listed as separate antigens
- **Produce summary report of IIS data contribution for select sites**

Study Team



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Questions?



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Incorporating IIS Data at NWK

