Immunization Information System – Trends in Immunization Practices System (IIS-TIPS)

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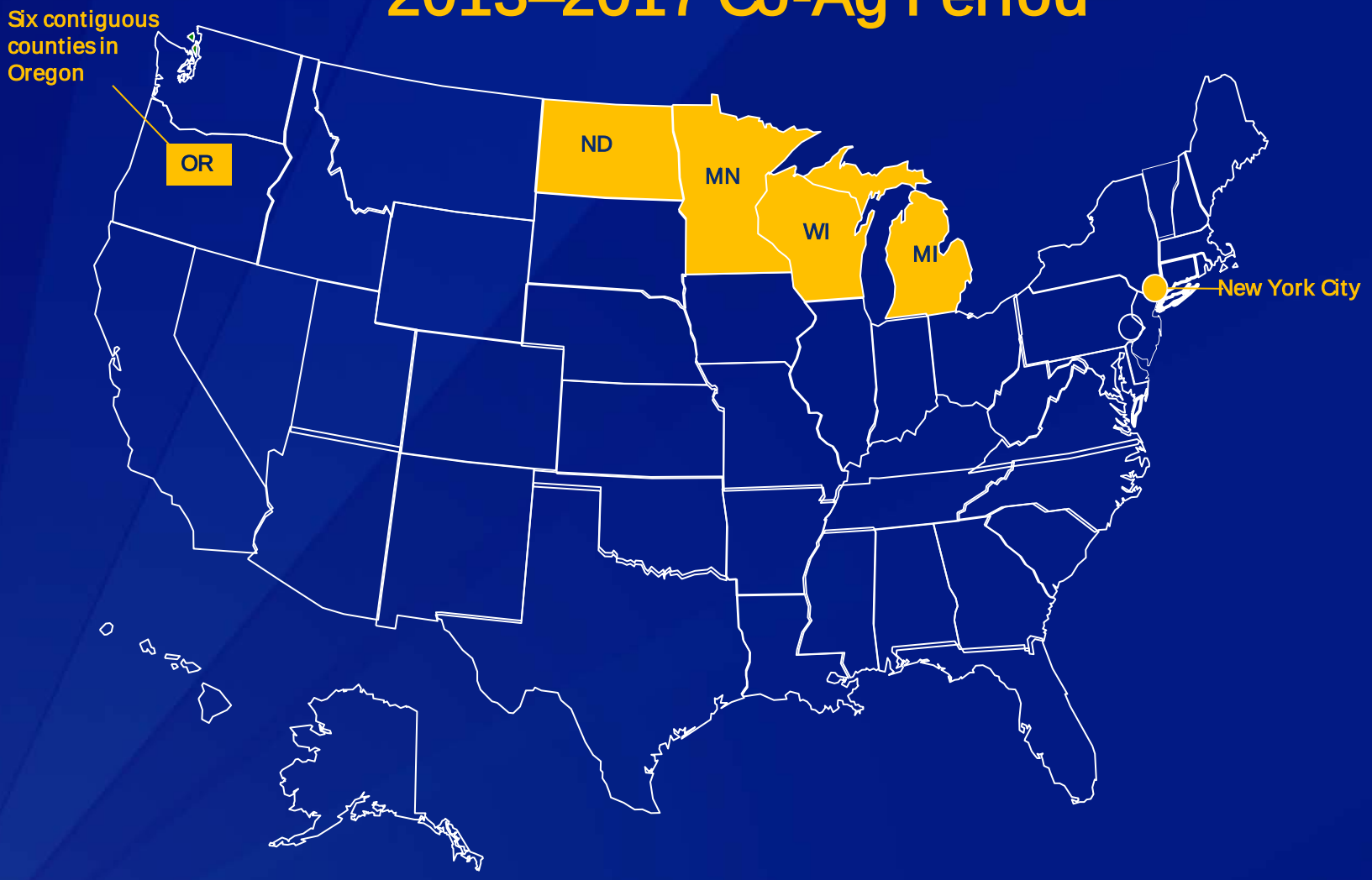
Immunization Information System (IIS) Sentinel Sites

- Program evaluation and vaccine use assessments
- Eligibility requirements
  - >85% child participation
  - >85% provider participation
  - >70% of administered doses reported to the IIS within 30 days
  - Can be entire IIS jurisdiction or a geographic subset
- Activities
  - Participate in CDC-based vaccine use / coverage evaluations
  - Present and publish findings from their own IIS evaluations

Six IIS Sentinel Sites
2013–2017 Co-Ag Period



Sentinel Site data offer unique analytic value

- **Advantages of IIS data**
  - Timely
  - Flexible
  - High data quality (participation and timeliness are high)
- **Requests for IIS data for vaccine use evaluations**
  - CDC leadership & subject matter experts
  - Advisory Committee on Immunization practices (ACIP)

Data submission, pre-TIPS

- **Quarterly Reports**
  - Standard format
  - Aggregate results
  - Submitted quarterly via web-interface

- **Ad hoc queries**
  - Data submitted in aggregate
  - Limited opportunities for follow-up questions and methodology changes
  - Potential for inconsistent methodology
  - Limited resources at Sentinel Sites

So…

- Need to conduct more vaccine use evaluations
- Need to ensure high quality data in IIS

But, we're limited to meet either of those needs

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But, we're limited to meet either of those needs

So…

Immunization Information System – Trends in Immunization Practices (IIS-TIPS) was born!!!

- Went live: April 2013

What is IIS-TIPS?

- **IIS-TIPS is an analytic system that collects:**
  - De-identified → No names, addresses, etc
  - Record-level → Child # 1234's IIS record
  - IIS data → Demographic & vaccination
  - From IIS grantees → Sentinel sites & non- sentinel sites
  - Routinely → 4 times / year (sentinel sites)

- **For the purpose of:**
  - Evaluating vaccine use (e.g. uptake of new vaccines, adherence to ACIP recommendations, etc.)
  - Assessing IIS data quality

IIS-TIPS is NOT…

- **Not a centralized IIS**
  - No names/addresses, etc.
  - No forecasting
  - No reminder/recall
  - No direct reporting from providers to IISSB
- **Not a survey**
  - No sampling
  - No weighting (*yet*)

Sites send two delimited flat files

- **Demographic file**
  - Contains demographic info on each child in the birth cohort
  - PII: no names or addresses; contains DOB and race/ethnicity
  - No geographic identifiers within Sentinel Site
- **Vaccination file**
  - Contains vaccination info for each child in the demographic file

Demographic variables – Submitted by IIS

- Grantee
- Region (e.g. sentinel site, whole state, etc.)
- Unique patient ID
- Date of birth
- Date the demographic record was established in the IIS
- Race (multiple)
- Ethnicity
- Sex
- Registry status (e.g. Active, MOGE, etc.)
- Non-vaccination related immunity to varicella
- Person-level eligibility (e.g. VFC eligibility)

Demographic variables – Created by TIPS

- CDCID
- Date of birth flag
- Dem est date flag
- Age flag
- Race flag
- Ethnicity flag
- Sex flag
- Status flag
- Vax immunity flag
- Person-level eligibility flag
- Delete demographic record
- Doses at 2 years >35
- >7 DTaP by 7 yrs
- >10 vax on same day
- # valid doses received by vaccine group (e.g. Hib)
- # valid and invalid doses received by vaccine group (e.g. Hib)

Vaccination variables – Submitted by IIS

- Vaccination date
- Date vax entered into IIS
- CVX
- CPT
- MVX
- Trade name
- Lot #s (up to three)
- Route of admin (e.g. intramuscular)
- Admin site (e.g. left deltoid)
- Admin or historical
- Completion status
- Refusal reason
- IIS-derived validity
- ID of reporting provider site
- Provider site characteristic (e.g. public/private)
- Vaccine-level eligibility (e.g. VFC eligibility)

Vaccination variables – Created by TIPS

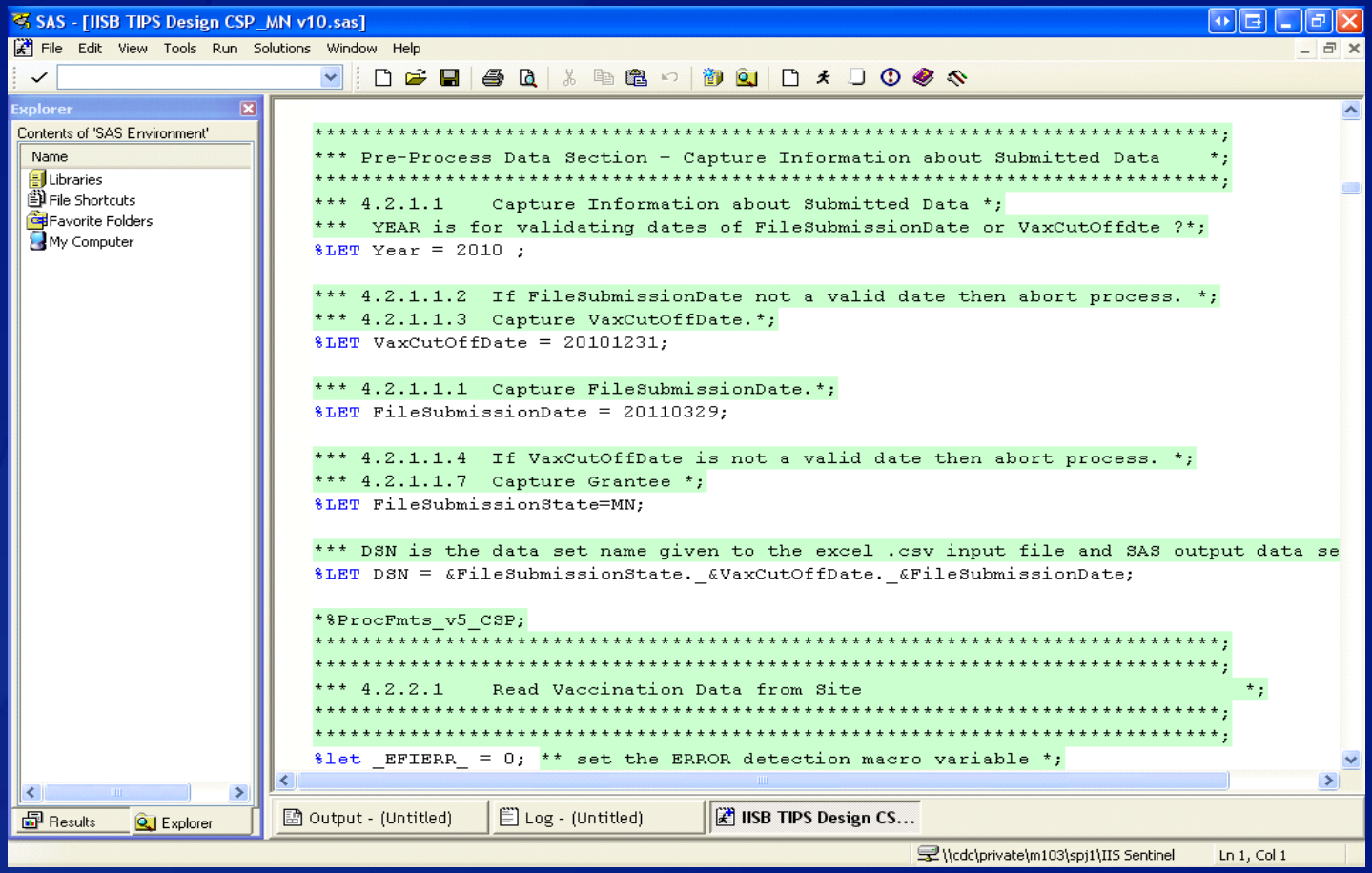
- Unique vaccination ID
- Combo vax ID
- Vaccine group (e.g. Hib)
- IISSB-derived validity
- Improbable dose
- Sequential # of valid doses (e.g. 3rd valid DTaP)
- Sequential # of valid & invalid doses (e.g. 5th Hib)
- Vax date flag
- Vax ent date flag
- CVX / CPT flags
- MVX flag
- Trade name flag
- Lot #s
- Route of admin flag
- Admin site flag
- Admin or historical flag
- Completion status flag
- Refusal reason flag
- IISSB-derived validity flag
- Provider site characteristic flag
- Vaccine-level eligibility (e.g. VFC eligibility) flag
- Delete vaccination record

An example of a submitted demographic file (redacted)

```
Grantee,Region,PatientID,DOB,DemEstDate,Race1,Ethnicity,Sex,Status,VaricellaImmune
NDA,SS13,[redacted]U,A,
NDA,SS13,[redacted]106-3,2186-5,F,A,
NDA,SS13,[redacted]2106-3,2186-5,M,A,
NDA,SS13,[redacted],,M,A,
NDA,SS13,[redacted],,U,A,
NDA,SS13,[redacted],,F,A,1
NDA,SS13,[redacted]2106-3,2186-5,F,A,
NDA,SS13,[redacted],,F,A,
NDA,SS13,[redacted],,F,A,
NDA,SS13,[redacted]2106-3,2186-5,F,A,
NDA,SS13,[redacted],,F,A,1
NDA,SS13,[redacted],,F,A,
NDA,SS13,[redacted]1002-5,2186-5,F,A,1
NDA,SS13,[redacted],,M,A,
NDA,SS13,[redacted],,M,A,
NDA,SS13,[redacted]2106-3,2186-5,F,A,1
NDA,SS13,[redacted],,M,A,
NDA,SS13,[redacted],,M,A,
NDA,SS13,[redacted],,U,A,
NDA,SS13,[redacted]2106-3,2186-5,M,A,1
NDA,SS13,[redacted]2106-3,2186-5,F,A,1
NDA,SS13,[redacted],,U,A,
NDA,SS13,[redacted],,F,A,1
```

What does TIPS look like?

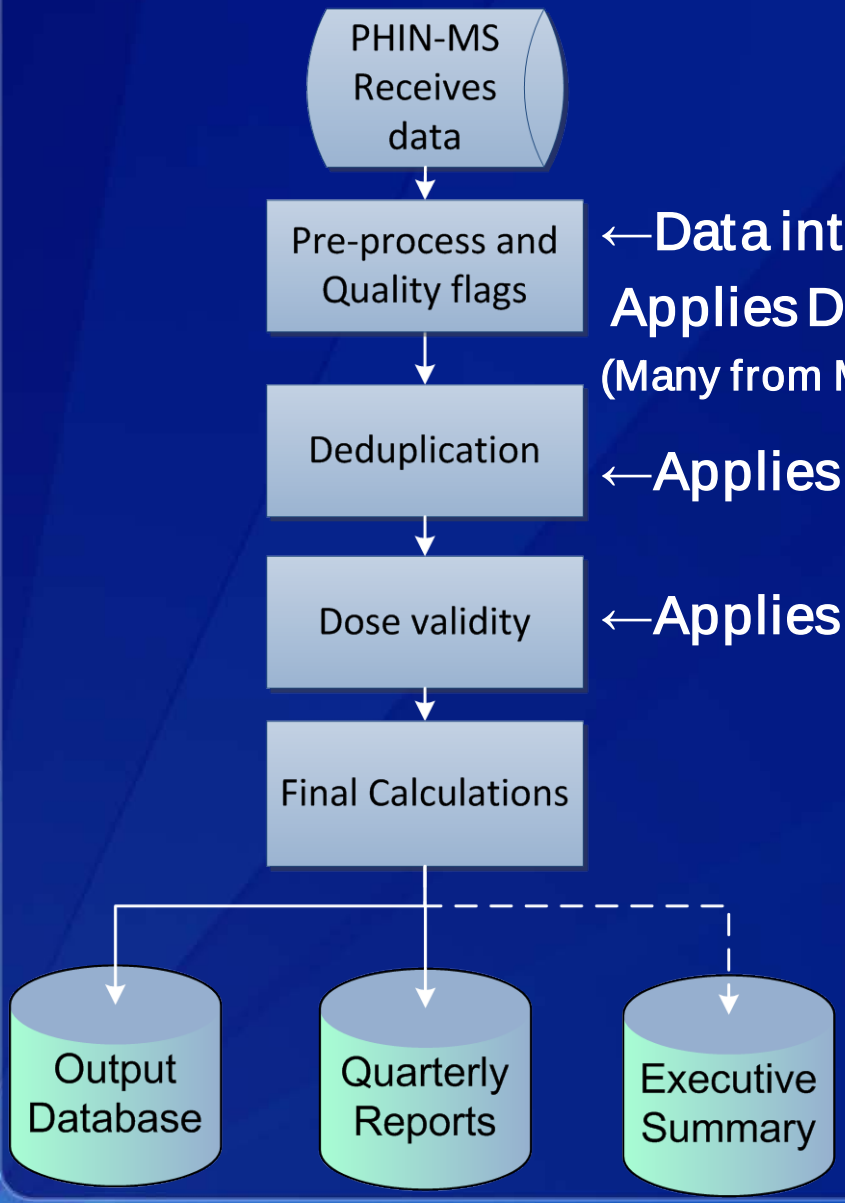
- SAS-based
- No web interface



How does TIPS work?

- Submitters electronically submit files to CDC
- Input IIS data
- Process IIS data
- Outputs
  - Summary report generated
  - Analytic data file creation

How does TIPS process data ?

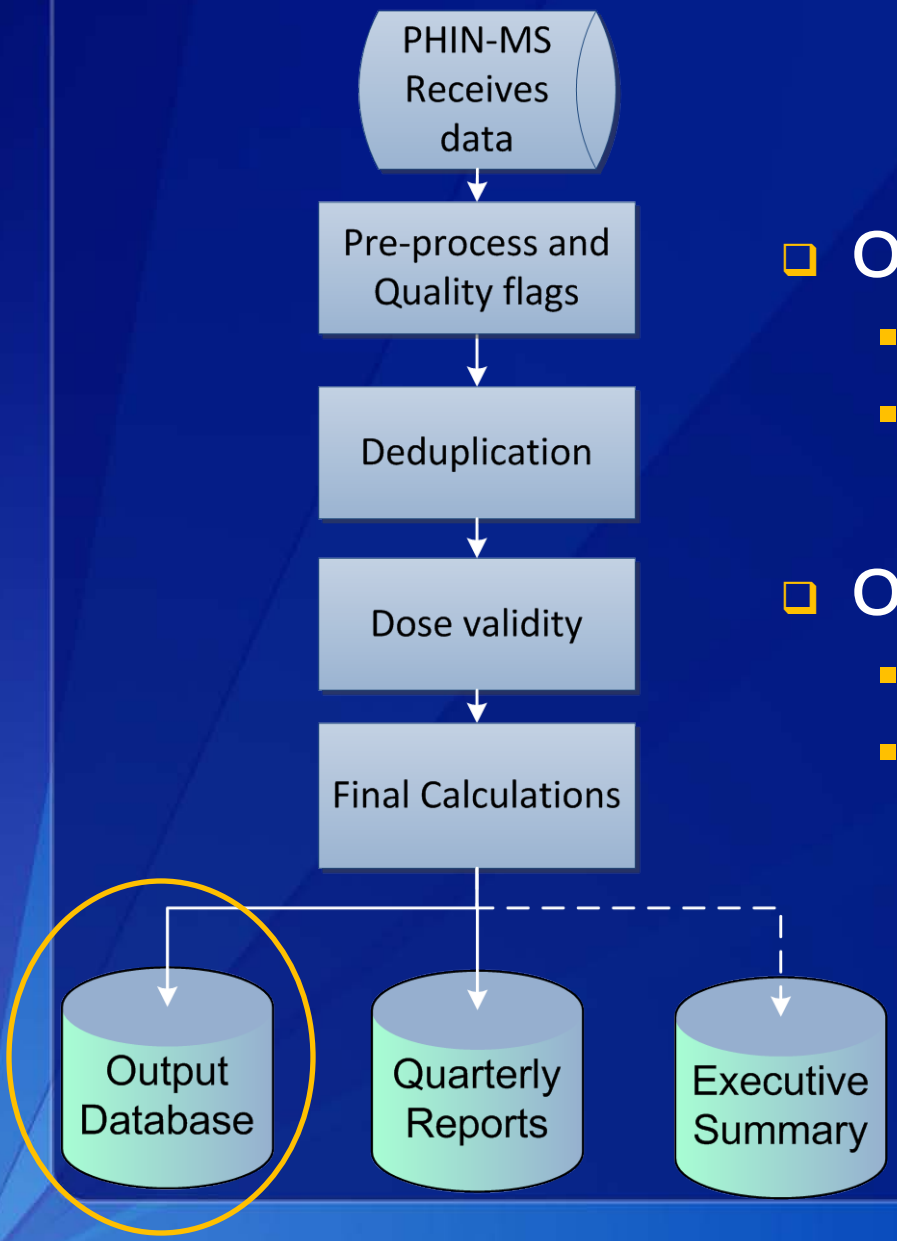


←Data integrity checks;
Applies Data Quality Business Rules
(Many from MIROW, some novel)

←Applies MIROW Deduplication Business Rules

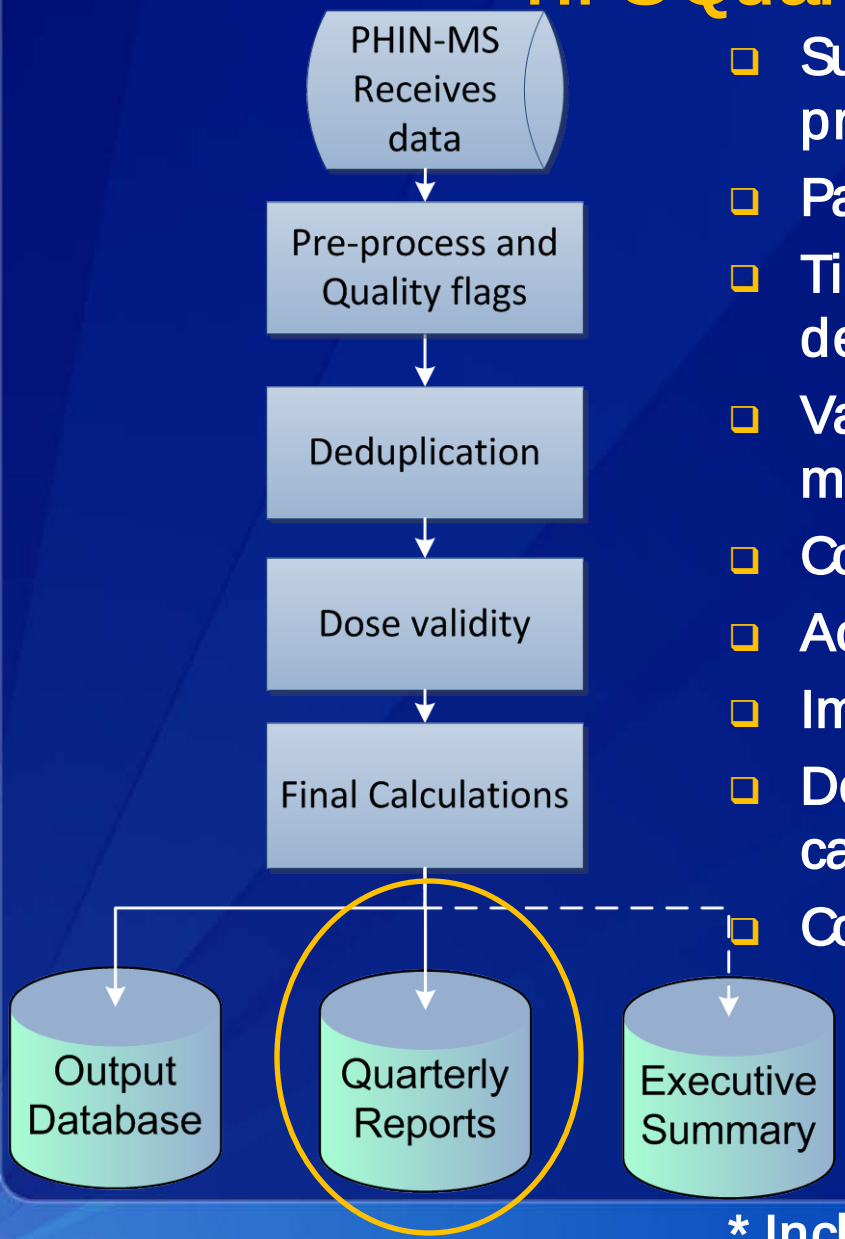
←Applies CDSi/ACIP Validity Logic

How does TIPS process data ?



- **Outputted SAS files**
  - Processed Demographic records
  - Processed Vaccination records
- **Outputted CSV files**
  - Improbable dose records
  - Facilitates identifying/resolving problematic doses

TIPS Quarterly Reports



- Summary of processed and not processed records
- Participation in IIS by age*
- Timeliness (vaccination reporting and demographic record establishment)*
- Vaccination coverage (comparison with most NIS and NIS-teen metrics)*
- Core data element completeness*
- Accuracy
- Improbably vaccination counts*
- Dose validity by antigen and validity category
- Comments from CDC/IISSB staff

* Includes comparisons with other sites

IIS–TIPS Summary Report

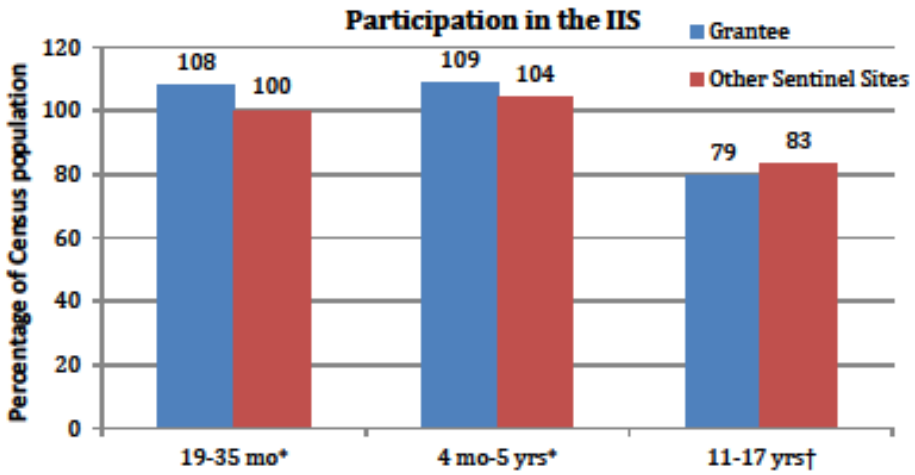
Grantee:
Region: Sentinel site
End of reporting period: 3/31/2013
File submitted: 5/1/2013
Report generated: 5/22/2013

Summary

Number of Demographic Records Submitted	n
Number of Vaccination Records Submitted	n
Demographic Records Deleted due to Errors*	n (0.00%)
Vaccination Records Deleted due to Errors†	n (0.01%)
Not-Processed or NVP Vaccination Records:	n (1.8%)
Vaccination Records Deleted due to Deduplication	n (0.22%)

* Demographic records were deleted if they contain a missing patient ID, missing or invalid date of birth, missing or invalid grantee, or missing region.
† Vaccination records are deleted if they contain a missing patient ID, missing or invalid vaccination date, missing or invalid CVX and CPT codes, if there is no associated demographic record, or the associated demographic record has been flagged for deletion based on the criteria above.

Participation

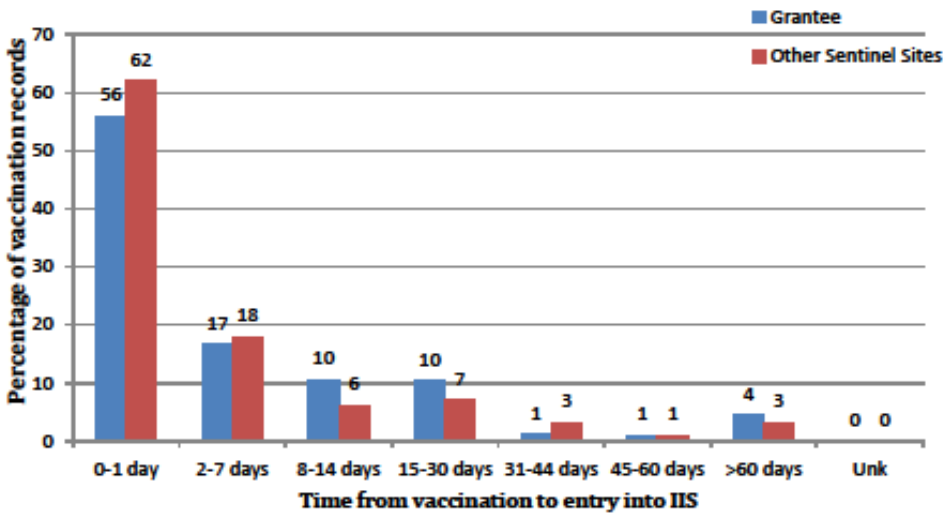


* ≥2 vaccination records in the IIS, excluding H1N1 vaccine and travel vaccines
† ≥2 vaccination records in the IIS that were administered from age 11-17 years, excluding H1N1 vaccine and travel vaccines

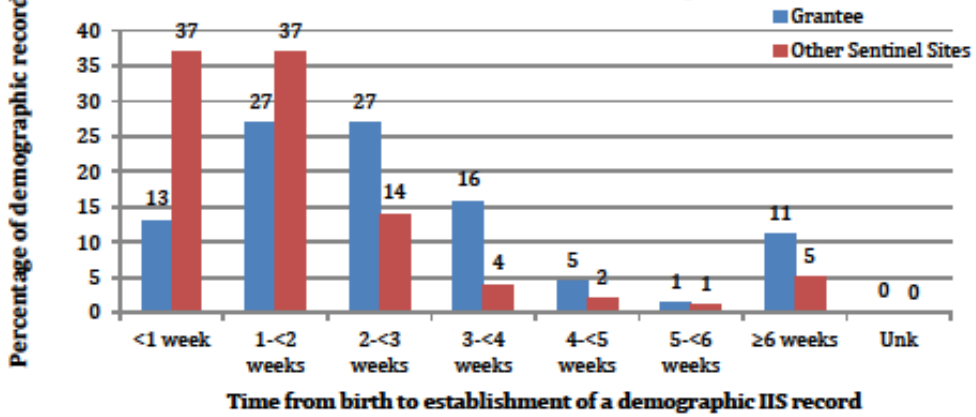
IIS-TIPS Summary Report, Quarter 1, 2013

Timeliness

Percentage of vaccinations administered during 2012 quarter 4 to children <19 years of age (on March 31, 2013) that were submitted to the IIS within a specified period of time



Percentage of children born during quarter 4 2012 with a demographic record established in the IIS within a specifc time



IIS-TIPS Summary Report, Quarter 1, 2013

Vaccination Coverage

19-35 months.

Vaccine Doses (valid & invalid)	Your Site*	Other Sentinel Sites*	NIS****
3+ DTaP			
4+DTaP			
3+ Polio			
UTD Hib**			
3+ HepB			
1+ HepB			
Day 0			NA*****
Day 1			NA*****
Day 2			NA*****
3+ Pneumococcal			
4+ Pneumococcal			
1+ MMR			
1+ Varicella***			
2+ Hep A			
4313314 series			

* Denominators: census population

** 4+ Hib-containing vaccines or 2 Hib-Merck followed by 1 Hib of any type.

*** Administered at age ≥12 months.

**** Based on National Immunization Survey, 2011. Point estimate ± 95% confidence interval.

***** NIS data were not available at the time that the report was generated.

IIS-TIPS Summary Report, Quarter 1, 2013

13-17 years.

Vaccine Doses (valid & invalid)	Your Site*	Other Sentinel Sites*	NIS-Teen**
1+ Tdap/Td			
History of Varicella Disease			
1+ Varicella with no history of varicella disease			
2+ Varicella with no history of varicella disease			
1+ Varicella or history of varicella disease			NA***
2+ MMR			
3+ Polio			NA***
1+ HPV			
Females			
Males			NA***
2+ HPV			
Females			NA***
Males			NA***
3+ HPV			
Females			
Males			NA***
1+ MCV or Meningococcal NOS			
1:1 series (≥1 Tdap/Td and ≥1 MCV or mening NOS)			
Females			NA***
Males			NA***
1:1:3 (≥1 Tdap, ≥1 MCV or mening NOS, and ≥ 3 HPV)			
Females			NA***
Males			NA***

* Denominators: census population
** Based on National Immunization Survey-Teen, 2011. Point estimate ± 95% confidence interval.
*** NIS-Teen data were not available at the time that the report was generated.

IIS-TIPS Summary Report, Quarter 1, 2013

Core Data Element Completeness I: vaccinations administered in the most recent quarter

Data Element	Percentage of records complete in Your Site	Percentage records complete in other Sentinel Sites
Sex*		100%
Race*		91%
Ethnicity*		62%
Vaccine manufacturer†		37%
Vaccine lot number†		72%

* Includes children born in the most recent quarter
† Includes vaccinations administered in the most recent quarter

Core Data Element Completeness II: all vaccinations administered

Data Element	Percentage of records complete in Your Site	Percentage records complete in other Sentinel Sites
Sex*		100%
Race*		50%
Ethnicity*		37%
Vaccine manufacturer		16%
Vaccine lot number		28%

* Includes all children 0-18 years
† Includes all vaccinations administered

IIS-TIPS Summary Report, Quarter 1, 2013

Accuracy

Demographic Data

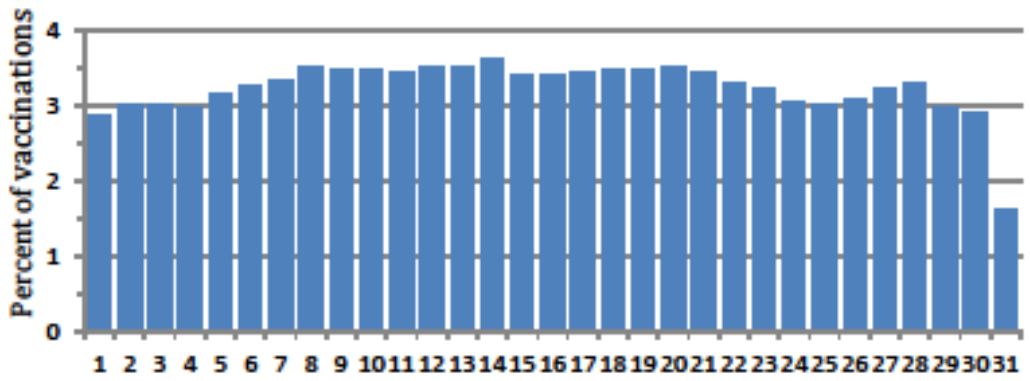
Invalid sex code	0.00%
Invalid race code	0.00%
Invalid ethnicity code	0.00%
Invalid registry status code (e.g. MOGE)	0.00%
Invalid eligibility code (e.g. VFC eligibility)	0.00%
Invalid demographic establishment date	0.16%

Vaccination Data

Invalid MVX or MVX inconsistent with CVX	Not available *
Invalid trade name code or trade name inconsistent with CVX	Not available *
Invalid route or route inconsistent with CVX	Not available *
Invalid administrative site or site inconsistent with route	Not available *
Invalid eligibility code (e.g. VFC eligibility)	0.00%
Invalid provider characteristic	0.00%
Invalid vaccine entry date	0.00%
Invalid record type (i.e. administered or historical)	0.00%
Invalid vaccine completion code	0.00%
Invalid vaccine refusal code	0.00%

* Not calculated for Q1 2013 due to analytic code development.

Vaccine Administration by Day of the Month



IIS-TIPS Summary Report, Quarter 1, 2013

Improbable Vaccinations

Improbable Dose Condition	Your Site	Other Sentinel Sites
Children with Rotavirus vaccine administered after age 8 months		0.44%
Children with DTaP administered at or after age 7 years		1.65%
Children with HepA (adult formulation) administered by age 19 years		1.65%
Children with HepB (adult formulation) administered by age 19 years		1.41%
Children with Tdap/Td administered by 7 years		0.62%
Children with Vaccine administration date within 30 days of birth for any vaccine except HepB		1.73%
Male children with HPV vaccine administered before 2009		0.03%
Children with Hib PRP-D (CVX code 46) administered after 2000		0.30%
Children with DTP containing vaccines administered after 1997		8.14%
Children with OPV administered after 2000		1.58%
Children with Whole cell influenza virus vaccine administered after 2002		0.57%
Children with RotaShield administered after 1999		0.61%
Children with Meningococcal C conjugate vaccine administered		0.00%
Children with Infanrix-hexa vaccine administered		0.00%
Children with >35 vaccinations by age 2 years		0.00%
Children with >50 vaccinations by age 5 years		0.00%
Children with >7 DTaP by age 7 years		0.10%
Children with >10 vaccinations on the same day		0.00%
Children with HibTITER (CVX code 47) administered after 2007		2.75%
Children with PPV administered by 2 years		0.93%
Children with >70 total vaccinations		0.00%

Dose Validity – Percentage of invalid doses by reason*

	DTaP	HepA	HepB	Hib	HPV	Flu	MMR	Mening	PCV	PPV	Polio	Rota	Tdap	Td	Var	All Vaccine Groups
All Reasons**	0.42%	0.11%	0.25%	0.37%	0.01%	0.05%	0.09%	0.05%	1.71%	0.06%	0.22%	0.03%	0.16%	0.04%	0.07%	3.62%
Minimum Age Violation	0.09%	0.02%	0.12%	0.24%	0.00%	0.03%	0.04%	0.05%	0.02%	0.06%	0.19%	0.00%	0.00%	0.00%	0.02%	0.89%
Minimum Interval Violation	0.07%	0.06%	0.05%	0.01%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.04%	0.00%	0.00%	0.00%	0.00%	0.24%
Live Vaccine Violation	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.03%
Partial Dose	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Product Rule Violation	0.12%	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	0.00%	1.68%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%	1.82%
Maximum Age Violation	0.15%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.07%	0.02%	0.00%	0.27%
Maximum Interval Violation	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Unvalidated*** Dose	0.06%	0.04%	0.09%	0.11%	0.01%	0.02%	0.04%	0.00%	0.02%	0.00%	0.02%	0.01%	0.09%	0.01%	0.02%	0.53%

*Denominators for dose validity percentages are all vaccination records assigned to any vaccine group. TIPS has partially integrated dose validity logic defined by the Clinical Decision Support Initiative (CDSI) and will be implementing additional improvement to increase CDSi-compliance.

**This is not the sum of the percentages of all listed reasons because there is overlap among different reasons for a given dose. For example, one dose could violate both minimum age and minimum interval and is counted for both reasons but is only counted once for "All Reasons".

*** An unvalidated dose is a dose administered after the recommended number of valid doses has already been received. For example, a 3rd hepatitis A vaccine administered to a child who has already received 2 valid hepatitis A doses.

Benefits of IIS-TIPS

- **Replaces quarterly reports and ad hoc queries**
  - Improve timeliness of evaluations
  - Increase number of evaluations
  - Increase complexity of evaluations
  - Flexibility to develop and revise evaluation parameters
  - More consistent data processing across sites
- **Sentinel Site will have more time to conduct their own evaluations**
- **Support IIS with limited resources for vaccine use and data quality assessments**

What does IISSB do with IIS-TIPS data?

- **Data quality assessments**
  - Grantee-specific guidance
  - IIS community-wide guidance
- **Programmatic investigations**
  - Guide immediate public health action (e.g. response to a vaccine shortage, inform ACIP discussions, etc.)
- **Scientific investigations**
  - Publication and presentation to scientific audiences (e.g. MMWRs, peer-review journal articles, conference presentations, etc.)

Quarter 1 Summary

- **Received 9.5 million demographic records**
  - Range: 203,000 to 2.9 million records per site
- **Received 156 million vaccination records**
  - Range: 3.9 million to 56.6 million records per site

Challenges

- File transmission
- Data submission might increase
  - Additional age groups
  - Additional sites
  - More frequent transmission
- Data not nationally representative

Future Directions

- Provide support for non-sentinel sites
  - Data quality assessment
  - Analytic support
- National generalizability → maximize utility for rapid monitoring of national-level coverage

Summary

- IIS-TIPS is an analytic tool at IISSB for:
  - Vaccine use evaluations
  - Data quality evaluations
- Has replaced existing sentinel site quarterly reports and ad hoc queries
- Improved number, quality, complexity, and flexibility of current vaccine use evaluations
- Support data quality evaluations beyond sentinel sites

Acknowledgments

- Current TIPS Personnel
  - Sandra Edgemon
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  - Richard Byrd
  - Max Harrigan
  - Sang Kang
  - Michelle Lin
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  - Gary Weeks
  - Barenda Whitaker
  - Max Worlund
- Supporting Organizations
  - Sentinel Sites
  - Evaluations Team
  - CDSi and ACIP
  - Disease SMEs
  - PHIN-MS

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