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Monitoring, Surveillance, and Feedback

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- After listening to, viewing, and studying the lecture materials in this course, you will be able to do the following:
 - Describe the evolution of immunization monitoring, surveillance, and feedback systems
 - Understand the use of rapid assessments, lot quality assurance, and cluster surveys to generate monitoring and surveillance data



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Section A

Immunization Informatics

Three Elements of Immunization Information Systems

1. Epidemiological surveillance

- Identifies program impacts on target diseases

2. Monitoring

- Shows how well program processes are working

3. Feedback

- Keeps managers, providers, and stakeholders informed about the program's implementation and achievements

- According to the World Health Organization, surveillance is "... Ongoing systematic collection, analysis and interpretation of outcome-specific data for use in planning, implementation and evaluation of public health practice"

Source: WHO, 2001

Purposes of Surveillance Systems

- Measure disease burdens
- Informed decision making
- Identify best control strategies
- Reveal high-risk subpopulations
- Demonstrate impacts, facilitate collective action

▼ Notes Available

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Source: WHO, 1993

- Routine reporting
 - Useful for monitoring trends
 - Includes cases, adverse events
 - Main weaknesses
 - ▶ Under-registration
 - ▶ Inaccurate population denominators
- Sentinel sites
 - Ideally to supplement routine surveillance
 - Referral facilities, high-risk areas

- Community-based reporting
 - Underserved areas, eradication
 - Markets, house-to-house visits
 - Publicity, rewards
- Active surveillance
 - All facilities report weekly zero or more cases
- Links with other sources of data
 - Assessments, surveys, outbreak investigations

Monitoring Some Program Indicators WHO Monitors

- Plan of action
- National EPI budget line item
- Injection safety plan
- Type of injection equipment
- Year of last EPI assessment
- Feedback of data to sub-national levels
- Hepatitis B in routine schedule

▼ Notes Available

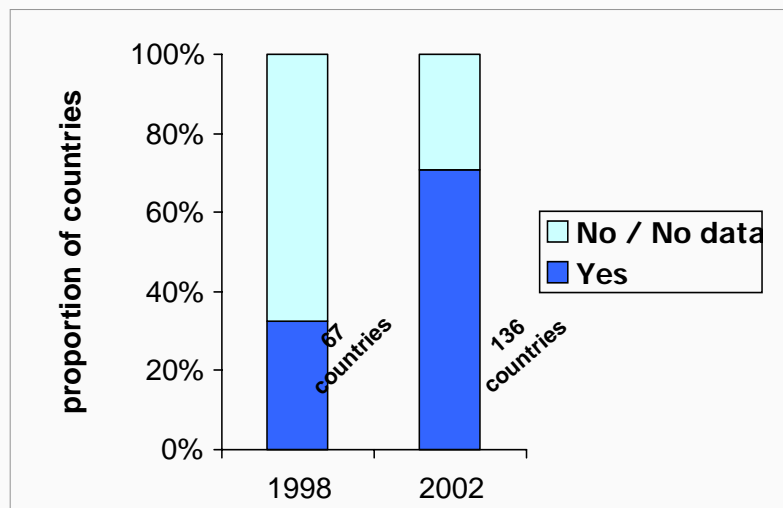
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Source: WHO 2002.

<http://www.nt.who.int/vaccines/globalsummary/Immunization/CountryProfileResult.cfm>)

Written Feedback on Immunization to District Level

- Written feedback on immunization to district level at least every quarter, 1998–2002



▼ Notes Available

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Source: WHO/UNICEF joint reporting form, 1998, 2002 data from 192 WHO member states

- Some vaccine provider indicators the U.S. National Immunization Program routinely monitors:
 - Completeness of immunization records
 - Missed opportunities
 - Parent education
 - Injection, other office practices
 - Vaccine handling, storage
 - Office hours

U.S. Vaccine-Preventable Disease Surveillance

- By law, health care providers and laboratories must report cases of 60 currently notifiable diseases— including poliomyelitis, measles, pertussis, tetanus, diphtheria, tuberculosis, hepatitis B, haemophilous influenzae—to local or state health departments
- Local departments initiate control measures, report case(s) to the state level
- State, territorial health departments receive, analyze, and report the data to the CDC using the National Electronic Telecommunications System for Surveillance (NETSS)
- CDC tabulates, validates, and disseminates the data; it also provides technical support to state, territorial health departments

U.S. Vaccine Coverage Monitoring

- U.S. vaccine coverage is not reported but estimated by the rolling cross-sectional National Immunization Survey
- An increasing number of states and metropolitan areas are consolidating data from providers into immunization registries

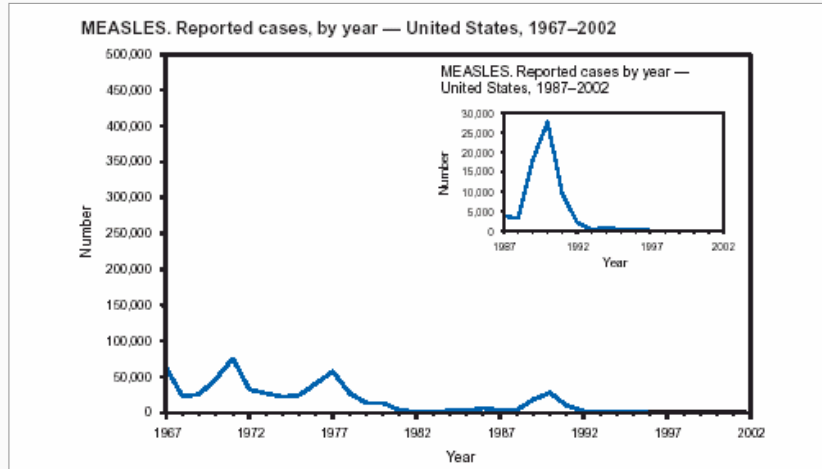
- Vaccine-preventable disease incidence, vaccine coverage levels, and other programmatic indicators are fed back to the public
 - Weekly: in the *Morbidity and Mortality Weekly Report* (MMWR)
 - Annually: in the *MMWR Summary of Notifiable Diseases, United States*
- Here are some recent examples:

TABLE 2. (Continued) Reported cases of notifiable diseases, by geographic division and area — United States, 2002

Area	Lyme disease	Malaria	Measles		Meningococcal disease	Mumps	Pertussis	Plague
			Indigenous	Imported*				
UNITED STATES	23,763	1,430	26	18	1,814	270	9,771	2
NEW ENGLAND	7,807	85	-	-	95	8	925	-
Maine	219	6	-	-	7	-	21	-
N.H.	261	8	-	-	14	5	78	-
Vt.	37	4	-	-	4	-	172	-
Mass.	1,807	33	-	-	48	2	602	-
R.I.	852	12	-	-	6	-	22	-
Conn.	4,631	22	-	-	16	1	30	-
MID. ATLANTIC	11,873	375	4	5	222	34	694	-
Upstate N.Y.	5,476	52	-	1	60	5	442	-
N.Y. City	59	230	3	3	37	4	24	-
N.J.	2,349	43	-	1	29	3	34	-
Pa.	3,989	50	1	-	96	22	194	-

From the CDC. <http://www.cdc.gov/mmwr/>

- Reported cases (thousands) by year, United States, 1967–2002



Source: CDC

Source: CDC. Summary of notifiable diseases. 1998.

Estimated Vaccination Coverage

TABLE 1. Estimated vaccination coverage among children aged 19–35 months, by selected vaccines and dosages — National Immunization Survey, United States, 1999–2003

Vaccine	1999*	2000†	2001‡	2002¶	2003**
	% (95% CI)††	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
DTP/DT/DTaP§					
≥3 doses	95.9 (±0.4)	94.1 (±0.5)	94.3 (±0.5)	94.9 (±0.6)	96.0 (±0.5)
≥4 doses	83.8 (±0.8)	81.7 (±0.8)	82.1 (±0.8)	81.6 (±0.9)	84.8 (±0.8)
Poliovirus ≥3 doses	89.6 (±0.6)	89.5 (±0.6)	89.4 (±0.7)	90.2 (±0.7)	91.6 (±0.7)
Hib¶¶	93.5 (±0.5)	93.4 (±0.5)	93.0 (±0.6)	93.1 (±0.6)	93.9 (±0.6)
MMR*** ≥1 dose	91.5 (±0.6)	90.5 (±0.6)	91.4 (±0.6)	91.6 (±0.7)	93.0 (±0.6)
Hepatitis B ≥3 doses	88.1 (±0.7)	90.3 (±0.6)	88.9 (±0.7)	89.9 (±0.7)	92.4 (±0.6)
Varicella ≥1 dose	57.5 (±1.0)	67.8 (±0.9)	76.3 (±0.8)	80.6 (±0.9)	84.8 (±0.8)
pcv†††					
≥3 doses	—	—	—	40.9 (±1.1)	68.1 (±1.0)
≥4 doses	—	—	—	—	36.7 (±1.1)
Combined series					
4:3:1§§§	79.9 (±0.8)	77.6 (±0.9)	78.6 (±0.9)	78.5 (±1.0)	82.2 (±0.9)
4:3:1:3¶¶¶	78.4 (±0.9)	76.2 (±0.9)	77.2 (±0.9)	77.5 (±1.0)	81.3 (±0.9)
4:3:1:3:3****	73.2 (±0.9)	72.9 (±0.9)	73.7 (±0.9)	74.8 (±1.0)	79.4 (±0.9)
4:3:1:3:3:1††††	—	54.1 (±1.0)	61.3 (±1.0)	65.5 (±1.1)	72.5 (±1.0)

* Born during February 1996–June 1998.

† Born during February 1997–June 1999.

‡ Born during February 1998–June 2000.

§ Born during February 1999–June 2001.

¶ Born during February 2000–June 2002.

†† Confidence interval.

§§ Diphtheria and tetanus toxoids and pertussis vaccine, diphtheria and tetanus toxoids, and diphtheria and tetanus toxoids and acellular pertussis vaccine.

¶¶ *Haemophilus influenzae* type b.

*** Measles, mumps, and rubella vaccine.

††† Pneumococcal conjugate vaccine.

§§§ Comprises ≥4 doses of DTP/DT/DTaP, ≥3 doses of poliovirus vaccine, and ≥1 dose of measles-containing vaccine.

¶¶¶ 4:3:1 plus ≥3 doses of Hib vaccine.

**** 4:3:1:3 plus ≥3 doses of hepatitis B vaccine.

†††† 4:3:1:3:3 plus ≥1 dose of varicella vaccine.

Source: CDC

- WHO is the definitive source of data on vaccine coverage and vaccine-preventable diseases in the developing world
- Ministries of health report most of the data
- These routine data are often supplemented by rapid assessments, surveys, and audits
- Results are fed back in several publications

2004, 79, 369-376

No. 41

Weekly epidemiological record Relevé épidémiologique hebdomadaire

8 OCTOBER 2004, 79th YEAR / 8 OCTOBRE 2004, 79^e ANNÉE
No. 41, 2004, 79, 369-376
<http://www.who.int/wer>



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Recommended composition of influenza virus vaccines for use in the 2005 influenza season

This recommendation relates to the composition of vaccines for the forthcoming winter in the southern hemisphere (May–October 2005). A recommendation will be made in February 2005 which relates to vaccines that will be used for the winter in the northern hemisphere (November 2005–April 2006). Epidemiological considerations will influence which recommendation (September 2004 or February 2005) is more appropriate for countries in equatorial regions.

Composition recommandée des vaccins antigrippaux pour la saison 2005

La présente recommandation s'applique à la composition des vaccins pour le prochain hiver dans l'hémisphère austral (mai–octobre 2005). Une recommandation relative aux vaccins à utiliser pendant l'hiver dans l'hémisphère boréal (novembre 2005–avril 2006) sera formulée en février 2005. La recommandation la mieux adaptée (de septembre 2004 ou de février 2005) aux pays des régions équatoriales s'appuiera sur les données épidémiologiques.

Source: The WHO. <http://www.who.int/wer/2004/7942/en/>

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From the WHO, <http://www.who.int/wer/2004/7942/en/>



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Section B

Tools for Improving Surveillance: Rapid
Assessments,
Lot Quality Assurance (LQA), and Cluster Survey

- Several types
 - Comprehensive EPI program review
 - Immunization data quality audits
 - Injection safety audits
- Performed by international teams
- 1–2 weeks duration
- Qualitative and quantitative methods
- Immediate feedback

- Purpose: to check quality of reported data
- Lots can be health facilities, geographic areas, administrative records, etc.
- Combines stratified random sampling and one-sided hypothesis testing
- Lot results can be combined to estimate coverage

- Declare number of lots using census or other data as sampling frame
- Fix “acceptable” upper threshold for performance (e.g., 80% fully immunized) and a lower threshold (say, 50%)
 - Based on local information
 - Any lots below the upper threshold are rejected
- Define “power” (i.e., probability of a Type I error)
- Fix acceptable level of random error (e.g., 5%)
- Calculate total sample size: n units
- Calculate number of units needed per lot
- Set critical value (maximum no. defective units/lot) using standard tables

Another Variant of the LQA Method

- 1st stage
 - Sampling frame: list all potential lots
 - Randomly select, say, 10–30 clusters
 - Sketch map, segment each cluster
- 2nd stage
 - Randomly select one segment/cluster
 - Interview all respondents in segment (usually 10–40 households, depending on thresholds, power, critical value)

- Bobo Dioulasso, Burkina Faso
 - 11 lots defined by census data
 - 11 children/lot
 - Critical value: 4
 - Power: .10
 - For full immunization, ages 12–23 months, 4/11 lots rejected

Source: WHO Weekly Epidemiological Record, 1995,70,261–268)

Standard WHO 30—Cluster Survey

- Purpose: to estimate population coverage level
- $n = 210$ children ages 12–23m, in 30 clusters (k)
 - Assumes coverage = 50%, power = .10
 - n, k can be expanded to measure other, less common variables
- First sampling stage: randomly draw k clusters from a list of all possible clusters

Standard WHO 30—Cluster Survey

- Second sampling stage (each cluster):
 - Randomly choose a starting point household
 - Randomly choose a cardinal direction from the starting point (“spin a bottle”)
 - Systematically sample the next six eligible households in that direction
- Interview using standard questionnaire

Standard WHO 30—Cluster Survey

- Alexandra Township, South Africa
 - Compared 1990 to 1988 survey
 - Expanded to 45 clusters, 10 units each
 - Acceptable random error: 5%
 - Measured age-appropriate vaccinations, full immunization, K-A-P
 - Results: 12% age-appropriate, 58% fully immunized at 12 months (a 10% increase)

Source: Coetzee, Ferrinho and Reinach 1993)



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Section C

Trends in Immunization
Monitoring and Surveillance

Some Global Trends in Monitoring and Surveillance

- Analysis of data at district levels
- Immunization data quality audits (DQAs)
- Surveillance system performance audits
- Inclusion of private sector data
- Active, case-based surveillance
- Injection safety
- Adverse events, rumors
- New diseases (e.g., rubella, H. Influenzae B)

- As data management capabilities improve and countries increasingly set disease-reduction targets, the distinction between monitoring and surveillance is blurring
- Example: current WHO/UNICEF core recommendations for EPI surveillance (WHO 2004)

WHO/UNICEF Core Surveillance Indicators

- Written feedback on EPI performance, surveillance to peripheral levels at least quarterly
 - At least DPT3 by district
 - At least measles, neonatal tetanus, acute flaccid paralysis cases
- Annual retrospective hospital record reviews
 - Neonatal tetanus
 - Measles
 - Polio/AFP

WHO/UNICEF Core Surveillance Indicators

- Zero reporting surveillance ongoing for:
 - Neonatal tetanus
 - Measles
 - Polio/AFP
- Active surveillance ongoing for:
 - Neonatal tetanus
 - Measles
 - Polio/AFP

- Technological advances are leading to online data management systems
- Example: WHO vaccine-preventable diseases monitoring system
 - <http://www.who.int/vaccines-surveillance/StatsAndGraphs.htm>

Selected WHO/UNICEF Core EPI Performance Indicators

	AFRO		AMRO		EMRO		EURO		SEARO		WPRO	
	2001	2002	2001	2002	2001	2002	2001	2002	2001	2002	2001	2002
states	46	46	35	35	22	22	51	51	10	11	27	27
states reporting	46	45	35	33	20	20	43	47	10	11	26	26
all districts with >80% DPT3	3	2	8	7	9	8	21	22	1	2	7	7
2+ interagency meets	30	32	15	14	6	8	23	18	9	6	13	11
adverse events monitored	19	17	17	15	13	11	32	42	6	9	15	14
Hepatitis B vaccine in use	5	7	29	30	8	10	28	29	0	0	7	8



- In the United States, NETSS, HIV/AIDS, Vaccine Adverse Events, and other national surveillance systems are being integrated into the National Electronic Disease Surveillance System (NEDSS)
- NEDSS will:
 - Standardize case definitions, reporting forms
 - Allow states to transmit real-time data via the Internet
- Currently, WHO member countries are striving to meet three main disease reduction targets
 1. Reduce measles by 90%
 2. Eliminate neonatal tetanus
 3. Eradicate poliomyelitis

Newest Surveillance Quality Indicators

- To accomplish these targets, WHO has redefined “essential epidemiological capabilities” to include:
 - **Timeliness/completeness** of reporting
 - Proportion of reported cases/outbreaks that are **investigated**
 - Proportion of investigated cases/outbreaks that are followed with a **response**

Example: Polio Surveillance

- Routine active surveillance identifies high-risk geographic areas
- Sentinel surveillance, case-finding increase system sensitivity
- All suspected polio cases are investigated and followed up
- Monitoring and feedback keep all actors informed

Example: Polio Surveillance

- WHO supports polio surveillance by:
 - Standardizing definitions, procedures
 - Monitoring and disseminating national surveillance performance measures
 - Controlling quality of reference laboratories
 - Providing training, technical assistance to countries as needed

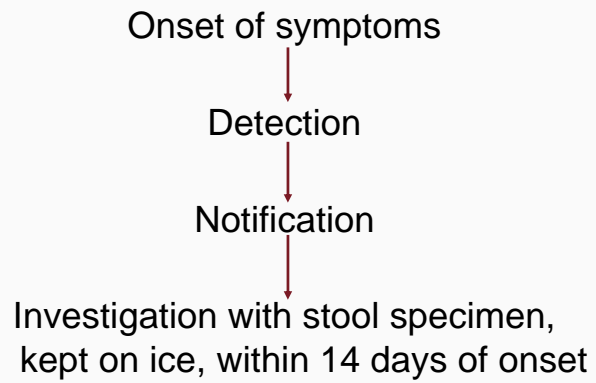
Example: Polio Surveillance

- Standard WHO-recommended definition of a **suspected case** (that should be notified)
 - “Any child under fifteen years of age with acute, flaccid paralysis (AFP) or any person with paralytic illness at any age when polio is suspected”

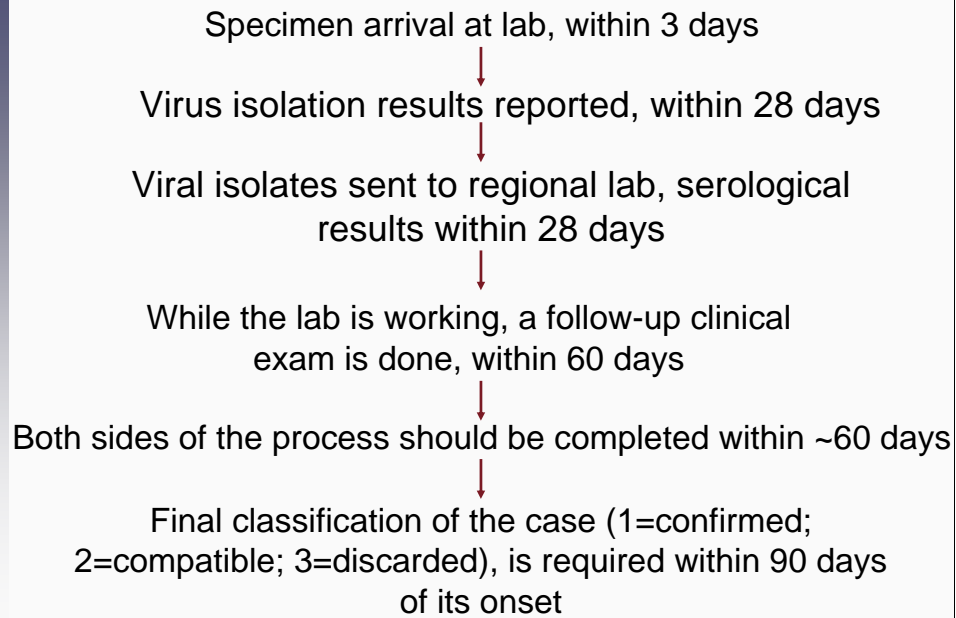
Example: Polio Surveillance

- AFP is a useful proxy for polio because:
 - AFP is visible and dramatic
 - AFP doesn't require bloodwork or other invasive techniques to detect
 - It can be recognized by health workers who are not sophisticated clinicians
 - It has a known background rate of around 1/100,000 population/year

Tracking AFP: The Steps



Tracking AFP: The Steps



Continued 44

Summary of Polio Surveillance Performance Indicators

- % of all expected monthly reports that were received (> 90%)
- Annualized non-polio AFP rate per 100,000 children under 15 years of age (> 1/100,000)
- % of AFP cases investigated within 48 hours (> 80%)
- % of AFP cases with two adequate stool specimens collected 24–48 hours apart and < 14 days of onset (> 80%)

**Number of Reported Cases of Acute Flaccid Paralysis (AFP),
Number of Confirmed Poliovirus Cases, and Key Surveillance Indicators,
by Year—Angola, 1998–2002***

Year	No. AFP Cases	No. Confirmed Poliovirus Cases (Laboratory Confirmed)	Polio-Compatible Cases	Non-Polio AFP Rate †	% of Persons with AFP with Adequate Stool Specimen §
1998	16	7 (3)	–	0.1	56%
1999	1,176	1,103 (53)	–	1.2	7%
2000	213	115 (55)	–	1.6	55%
2001	149	1 (1)	10	2.0	66%
2002	100	0	0	3.4	89%

* As of June 30, 2002.

† Number of persons with AFP per 100,000 population aged < 15 years; minimum expected rate is one case of non-polio AFP per 100,000 per year.

§ Two stool specimens collected at an interval of ≥ 24 hours within 14 days of paralysis onset and shipped properly to the laboratory.

Source: WHO (Reprinted in MMWR, Vol 51, No 34;762 08/30/2002)

AFP and Polio Reporting

AFP and polio reporting, year-to-date (Data received at WHO Geneva as of 20 February 2002)

Region	2000 (As of 17 February 2001)				2001 (As of 20 February 2002)			
	Non-Polio AFP Rate	Adequate Stool Specimens	Polio Confirmed Cases	Wild Polio Virus Cases	Non-Polio AFP Rate	Adequate Stool Specimens	Polio Confirmed Cases	Wild Polio Virus Cases
African	1.30	53%	1,537	137	3.01	71%	110	62
The Americas	1.08	65%	12	0	1.25	89%	* 10	0
Eastern Mediterranean	1.42	67%	441	248	1.89	83%	139	139
European	1.14	83%	0	0	1.23	81%	** 3	** 2
South-East Asia	1.73	81%	593	271	1.75	83%	267	267
Western Pacific	1.53	87%	0	0	1.39	88%	* 3	0
Global Total	1.55	75%	2,583	656	1.59	81%	535	470

* Vaccine-derived poliovirus

** Importations

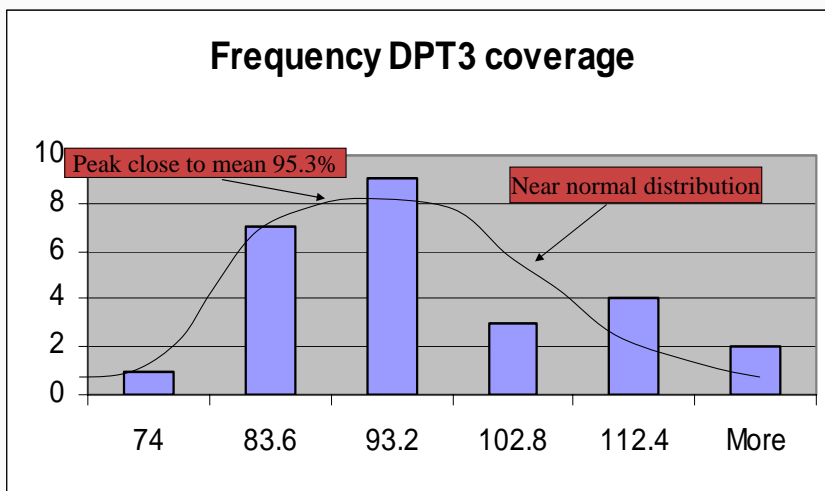
Example: Analyzing District-Level Data in Malawi

- By 2001, Malawi was able to routinely generate EPI performance indicators from each of its 26 health districts
- Here we analyze just three indicators
 - DPT3 coverage rates
 - DPT dropout rates
 - DPT wastage rates
- Here are two problems we can analyze
 - How coverage, dropout and wastage co-vary
 - Which districts are outliers

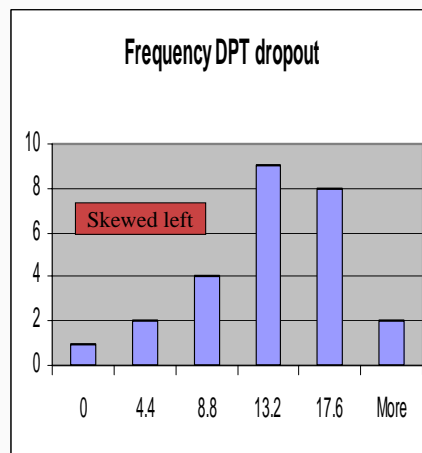
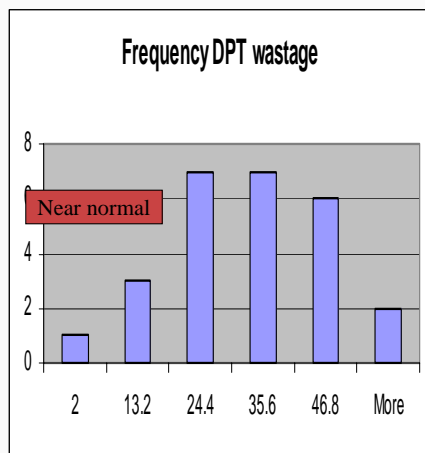
Administrative EPI Data

Administrative EPI data from 26 districts, Malawi 2001			
District	DPTdropout	DPTwastage	DPT3coverage
1 Chitipa	10	15	80
2 Karonga	5	19	100
3 Mzimba	10	31	82
4 Nkhata Bay	0	38	91
5 Rumphu	13	18	103
6 Dedza	14	18	92
7 Dowa	15	19	90
8 Kasungu	16	47	74
9 Lilongwe	4	6	84
10 Mchinji	22	29	82
11 Nkhota kota	14	28	82
12 Ntcheu	6	37	97
13 Ntchisi	13	41	75
14 Salima	15	58	76
15 Balaka	10	27	93
16 Blantyre	9	2	87
17 Chikwawa	14	25	85
18 Chiradzulu	12	42	87
19 Machinga	5	38	122
20 Mangochi	14	24	85
21 Mulanje	19	29	76
22 Mwanza	15	38	108
23 Nsanje	13	31	98
24 Phalombe	9	20	119
25 Thyolo	8	6	109
26 Zomba	1	8	105
Total	11.0	26.7	91.6

- Analytic strategy
 - Plot each indicator, check their distributions
 - Check their correlations
 - Plot them together



District-Level Data in Malawi



Check Correlations

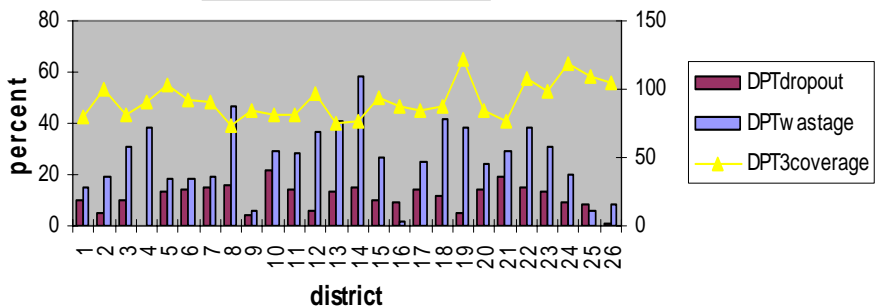
<i>Corrdations</i>			
	<i>Dropout</i>	<i>Wastage</i>	<i>Coverage</i>
Dropout	1	0.31 **	-0.46
Wastage		1	-0.26 **
Coverage			1

**t-test significant at $p < 0.001$

- As expected, the higher the coverage level, the lower the dropout and wastage rates
- Also, the higher the dropout rate, the higher the wastage rate
- A t-test shows these relationships are significant
- We conclude the data are valid
- How do the indicators look together?

Administrative EPI data, 26 districts, Malawi 2001

correlations (all sig at $p < .001$):
 wastage*coverage=-.26,
 dropout*coverage=-.46,
 wastage*dropout=.31



- Positive outliers
 - Districts 19, 24
 - ▶ High DPT3 coverage, very low dropout rates
 - District 24 has it all
 - ▶ High coverage, low wastage, low dropout
- Negative outliers
 - Districts 8, 13, 14 have very high wastage rates



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Section D

Case Study: Hispaniola Polio Outbreak, 2000–
2001

- Routine AFP surveillance system reports a suspected polio case in October, 2000, in Monseñor Nouel Province, Dominican Republic
 - Onset of symptoms: July 18, 2000
 - Age: 9 months
 - Vaccinations: none
- By mid-December, four additional confirmed cases are linked to index case

- Another AFP case is reported from Anse a l'Ombre, near Port-de-Paix, Haiti
 - Onset of symptoms: August 30, 2000
 - Age: 2 years
 - Vaccinations: none
- By mid-December, house-to-house search finds 13 more suspected cases in Haiti

- These are the first polio cases in the Americas region since 1991
- Laboratory results
 - Same Sabin Type I vaccine-associated virus isolated from Dominican, Haitian stool samples
- Recommended actions
 - Immediate mass vaccination to interrupt transmission; continued aggressive case-finding

Immunization Day Near Thiotte, Haiti, March 2001



- By mid-March, 2001, there are 17 confirmed polio cases: 14 in Dominican Republic, 3 in Haiti
 - 14 isolates from cases, 3 from contacts
 - Only one was completely vaccinated
 - Median age: 3 years
 - Most in low-OPV coverage districts

By Mid-March 2001

Indicator	Dominican Republic	Haiti
Stool samples collected: AFP cases	84	17
Stool samples collected: contacts	205	34
Polio cases confirmed	14	3

- In the **Dominican Republic**, two national immunization days (NIDs) plus house-to-house vaccinations stop the outbreak
- In **Haiti**, transmission continues, despite two NIDs
 - LQAs show coverage < 40% (next slide)
 - Here is an excerpt of one LQA series in Region Sud-Est, following the 2nd NID

**OPV vaccinations, children 6-23m,
before and after mass campaign, Jacmel
Region, Haiti, March 2001**

lot	1	2	3	4	5	6	7	8	9
before									
yes	27	29	17	22	14	14	7	24	26
no	11	6	4	3	5	12	9	24	12
total	38	35	21	25	19	26	16	24	38
reject	yes	no	no	no	yes	yes	yes	no	yes
after									
yes	35	34	19	23	16	16	8	24	33
no	3	1	2	2	3	10	8	24	5
total	38	35	21	25	19	26	16	24	38
reject	no	no	no	no	yes	yes	yes	no	no

- The Haitian strategy is switched to “rolling campaigns” + school + house-to-house vaccination in areas where uptake lags

By Mid-June 2001

Indicator	Dominican Republic	Haiti
AFP cases	95	29
AFP stool samples collected	94	27
Polio cases confirmed	14	6

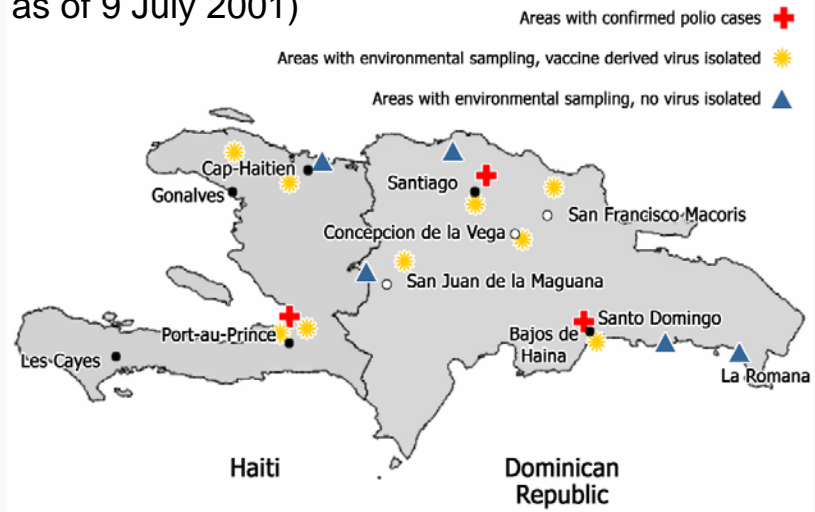
- During May–July, 2.1 million children under 10 are vaccinated throughout Haiti
 - Systematic LQAs show ~90% coverage for OPV1
- Surveillance continues to improve following health worker case search retraining
 - WHO/PAHO announces a US\$100 reward for anyone identifying a new polio case



- Last confirmed polio case has onset on 12 July, 2001
- Sabin-1 derived polioviruses are found in sewage samples near recent cases in Dominican Republic and Haiti—more evidence the outbreak was entirely vaccine-derived

Isolation of Vaccine-Derived Poliovirus

- Isolation of vaccine-derived poliovirus in AFP cases and environmental sampling (data of cases as of 9 July 2001)



- National immunization campaign ends in November, 2001
- Routine surveillance system reinstated, sentinel sites added, active case search continues in 100 facilities
- Cost of containing the outbreak: \$4.82m (U.S.\$)

- Surveillance, monitoring, and feedback are essential elements of any immunization program
- Together, they:
 - Document program achievements and problems
 - Reveal and disseminate epidemiological data and trends
 - Allow managers to focus resources where they are most needed
 - Keep actors informed and motivated