

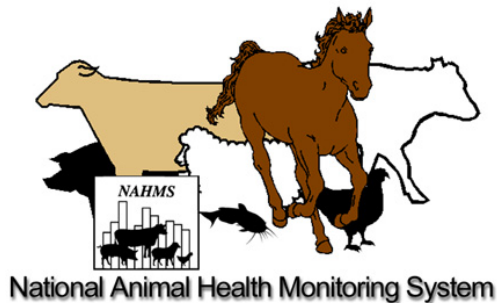
Current Status of the National Johne's Disease Demonstration Herd Project

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National Johne's Disease Demonstration Herd Project (NJDDHP)

- Primary Objective
 - Evaluate long-term effectiveness and feasibility of management-related control measures for Johne's disease on dairy and beef operations
- Primary Hypothesis
 - Control of Johne's disease can be achieved through implementation of on-farm management practices to reduce transmission of infection to susceptible cattle

NJDDHP Objectives (cont'd)

- Secondary Objectives
 - Provide materials for education and training
 - Evaluate management, testing, and monitoring strategies
 - Create opportunities for additional research

NJDDHP Outcomes to be Measured

- Incidence of clinical disease
- Prevalence of infection
- Culling as a result of testing
- Risk and management changes

NJDDHP Herd Enrollment Criteria

- Herds must have had a history of Johne's disease and be documented as infected by organism detection methods
- Willing to keep good records
- Plan to be in business at least next 5 years
- Must have time/labor/facility/cash resources necessary to implement a control plan

NJDDHP Data Collected Annually

- Risk assessments
- Animal information (lactation number, milk production, source, removal information, etc.)
- Test results

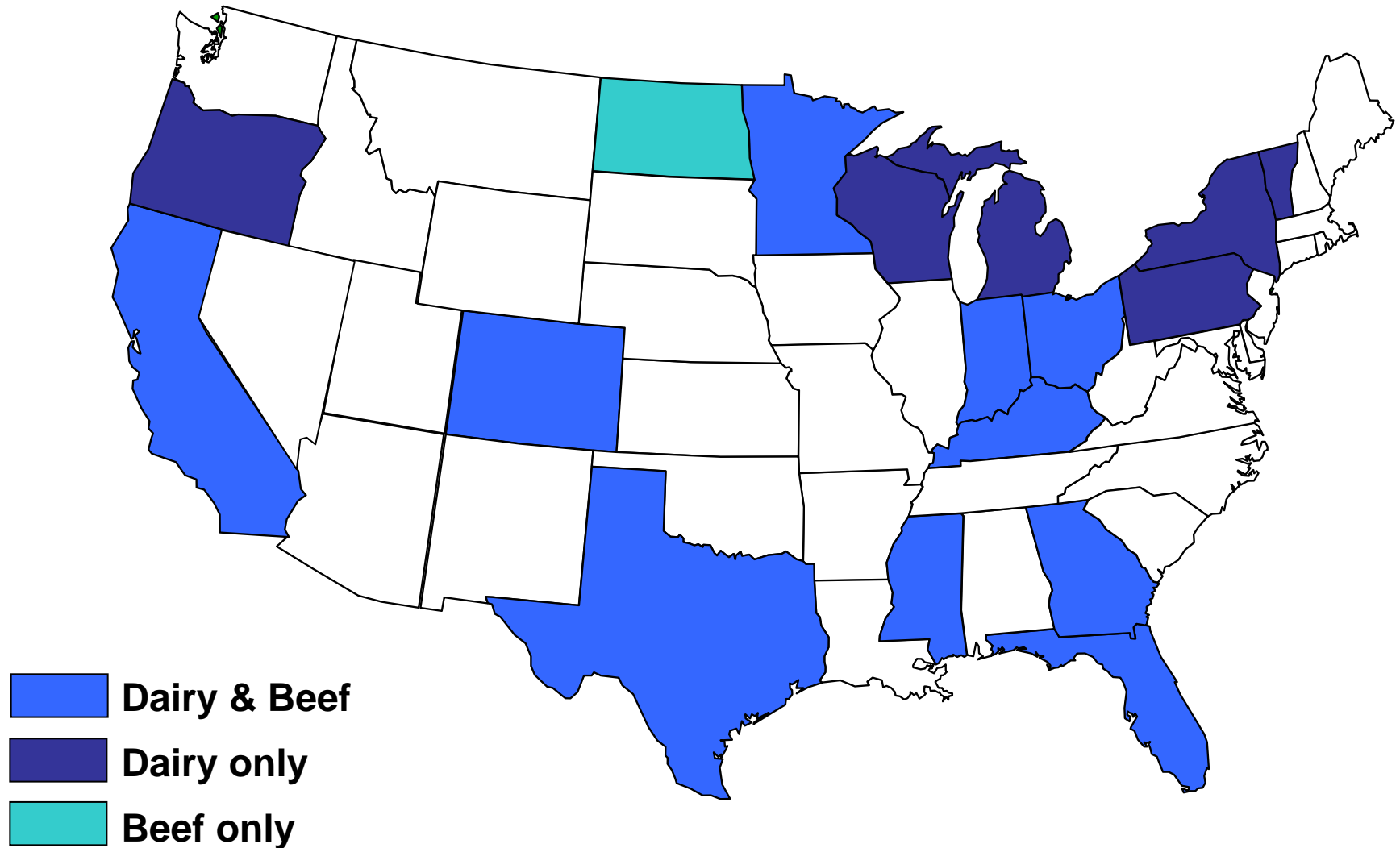
NJDDHP Herd Testing

- Flexible testing strategy
 - Preferably whole herd fecal culture and ELISA annually
 - Statistical subset if very large herd or limited resources
 - Whole-herd ELISA with fecal culture confirmation of positives
 - Tests determined by investigators
 - (e.g., Biocor vs. Idexx)

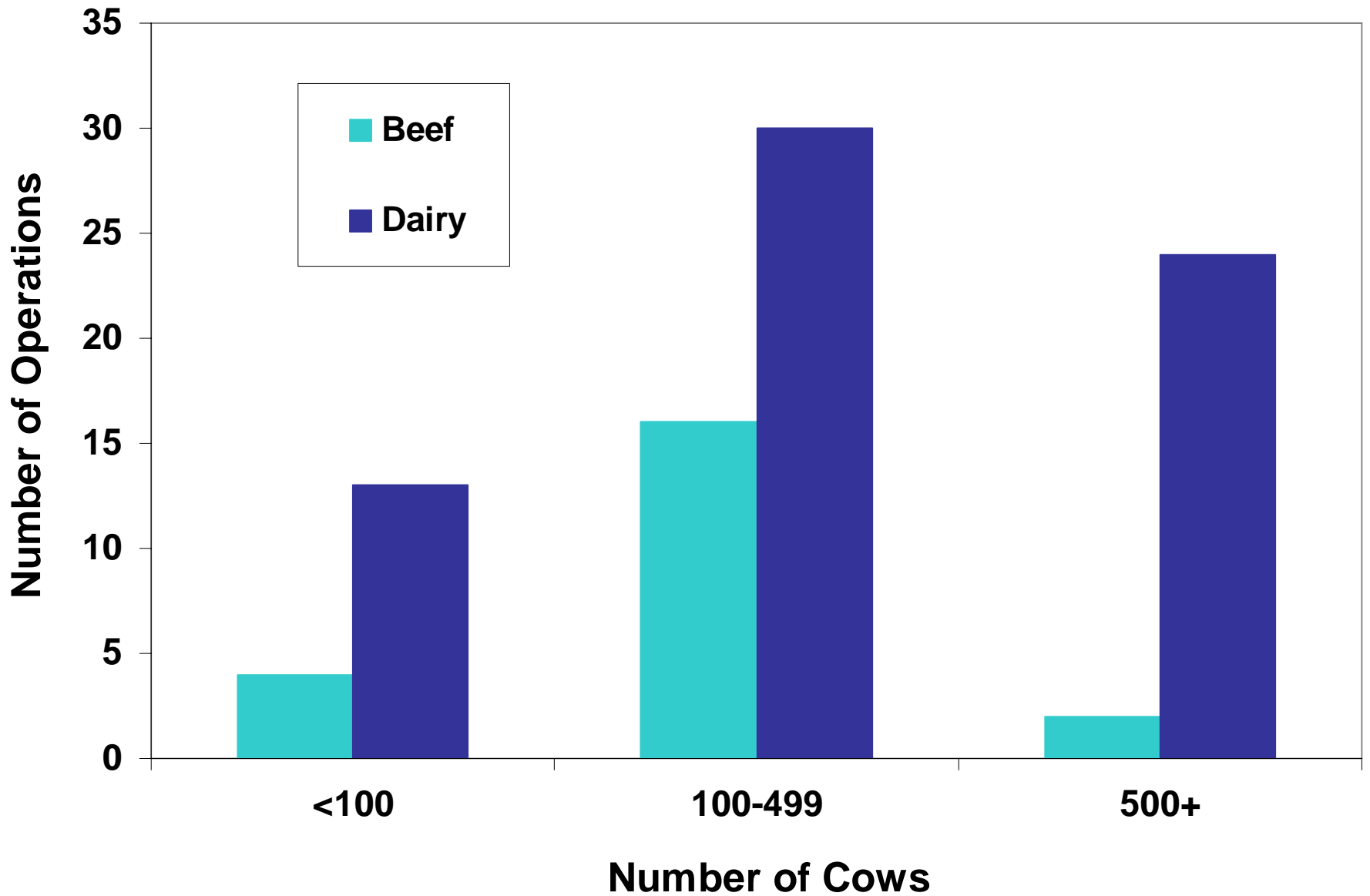
NJDDHP Status

- National project started in late 2003
- Status (10/1/07):
 - Fourth year of study
 - 17 States have enrolled herds
 - 66 dairy herds from 16 states
 - 22 beef herds from 10 states

States Participating in NJDDHP in 2007



Herds Enrolled in NJDDHP 2007



Running Totals for States, herds, and cattle tested by study year

Study year	Number of states	Number of beef herds	Number of dairy herds	Number of Cattle Tested
1999	1	1	0	221
2000	1	2	5	1,757
2001	3	3	8	2,910
2002	5	5	20	6,932
2003	11	7	37	16,781
2004	16	15	62	32,303
2005	17	22	66	33,146
2006	17	22	66	33,322
2007	17	22	66	incomplete

Beef herds by testing strategy

Testing Strategy	Number of Herds
Whole herd elisa with fecal culture follow-up	7
Whole herd fecal and elisa	15

Dairy herds by testing strategy

Testing Strategy	Number of Herds
Whole herd fecal and elisa	41
Whole herd fecal and elisa some years/whole herd elisa with subset fecal other years	9
Whole herd elisa with fecal culture follow-up	6
Whole herd or subset of herd elisa with fecal subset (herds over 500 cows)	6
Whole herd fecal-no elisa	4

Environmental Sampling

Study Year	Number of Beef Herds	Number of Samples-Beef	Number of Dairy Herds	Number of Samples-Dairy
2003	0	0	6	98
2004	6	96	25	313
2005	10	185	40	549
2006	13	226	31	867
Total	14	507	43	2,489

Test Types-Serum

Test Type	Number of Herds	Number of States	Number of Years Used	Tests*
BIOCOR	28	10	7	25,197
IDEXX	58	11	9	85,641
KELA	6	2	4	10,587
Univ. of FL	2	1	3	1,759

*One serum sample per cow counted for each study year

Test Types-Feces

Test Type	Number of Herds	Number of States	Number of Years Used	Tests
TREK ESP	41	12	8	41,873
BACTEC	19	5	6	15,845
MGIT	7	2	3	4,050
HEY	49	10	9	28,663
LIQUID CULTURE	2	2	3	349
CULTURE	31	10	5	5,651
PCR	14	3	4	4,164

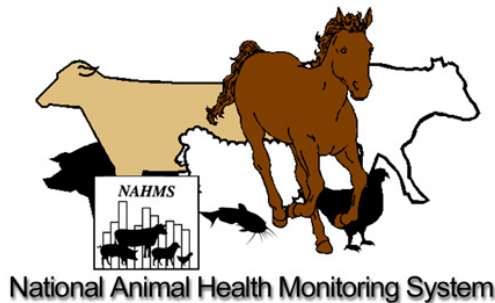
*One fecal sample per cow counted for each study year

Database changes

- New database will be online soon—will offer report for risk assessments
- New database will be refined to prevent uploading of duplicate records
- May be changes to standardize naming of fecal test types and environmental samples

Prevalence and Incidence of Johne's Disease in Herds Participating in the National Johne's Disease Demonstration Herd Project (NJDDHP)

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Prevalence of Johne's Disease

- Purpose
 - Examine changes in prevalence in participating herds after the first three years of NJDDHP participation
- Notes on prevalence
 - Hard to separate effects of culling from those of management changes
 - Does give an indication of how many cattle may be shedding in the farm environment

Methods

- Limited to herds with at least 3 years of testing
- First 3 years of participation are included
- Limited to samples collected prior to January 1, 2007
- First test date within a study year for a given cow used when more than one test performed
- Cattle age computed as difference between birthdate and date of sample collection

Methods (cont'd)

- Outcomes not adjusted for test performance (Se, Sp)
- Three separate models with the following outcomes
 - ELISA-positive
 - Fecal-culture positive at any level
 - Fecal-culture positive at moderate or high shedding levels (level 3 or 4)

Analysis Methods

- Logistic regression using generalized estimating equations approach (GEE)
 - Proc Genmod in SAS Version 9.1
 - Adjusted for effects of herd
 - Adjusted for effects of cattle age at the time of sampling

Results—Risk Assessment Scores

- Dairy Herds
 - Year 1 ave. = 67
 - Year 3 ave. = 56

- Beef Herds
 - Year 1 ave. = 66
 - Year 3 ave. = 53

Test Results

Year in Project	Beef-ELISA (14 herds)		Dairy-ELISA (54 herds)		Dairy-Culture (45 herds)		Dairy-Culture (mod. to high shedding) (45 herds)	
	# cattle	% pos.	# cattle	% pos.	# cattle	% pos.	# cattle	% pos.
1	2,154	6.8%	16,131	7.8%	9,886	9.4%	9,886	2.6%
2	2,602	5.8%	18,456	6.3%	14,169	8.9%	14,169	2.8%
3	3,294	2.6%	22,017	6.1%	16,356	7.6%	16,356	2.0%
Total	8,050	4.7%	56,604	6.7%	40,411	8.5%	40,411	2.4%

Results from logistic regression

Year in Project	Beef-ELISA (14 herds)		Dairy-ELISA (54 herds)		Dairy-Culture (45 herds)		Dairy-Culture (mod. to high shedding) (45 herds)	
	% pos.	95% CI	% pos.	95% CI	% pos.	95% CI	% pos.	95% CI
1	6.6%	(3.9,11.1)	3.0%	(1.9,4.7)	2.7%	(1.2,5.6)	0.7%	(0.2,2.2)
2	5.7%	(2.3,13.5)	2.4%	(1.2,4.6)	2.5%	(0.9,7.2)	0.8%	(0.2,3.0)
3	2.5%	(0.9,6.4)	2.3%	(1.2,4.3)	2.1%	(1.2,5.6)	0.5%	(0.1,2.1)

Highlighted values are significantly different from Year 1 results

Incidence of Johne's Disease

- Purpose
 - Examine incidence of Johne's positive cattle in cattle born after beginning participation in the NJDDHP compared to those born before participation started

Incidence of Johne's Disease

- Incidence relates to number of new cases of disease within a specific period, whereas prevalence relates to cases of disease at a point in time (includes both new and existing disease)
- Why incidence?
 - Offers better look at effects of management on disease occurrence (not confused with effects of culling)

Methods

- Limited to herds that began project in 2003 or before
- Limited to samples collected prior to January 1, 2007
- Whole-herd sampling except for herds with over 500 cows
- Purchased cattle excluded

Methods

- Test results for cattle between 24 and 45 months of age included
- Censored at occurrence of first positive test, at 45 months of age, or at last recorded test of 2006 (follow-up ends at time of censoring)
- Follow-up time computed as number of months difference between birthdate and collection date
- Cattle assumed negative until first positive test
- Failure = first positive test

Methods

- Cox Proportional Hazards
 - Proc TPHREG, SAS Version 9.1
 - Adjustment for effects of herd
- Outcomes
 - ELISA-positive
 - Fecal-culture positive at any level
 - Fecal-culture positive at moderate or high shedding levels (level 3 or 4)

Incidence of Johne's Disease

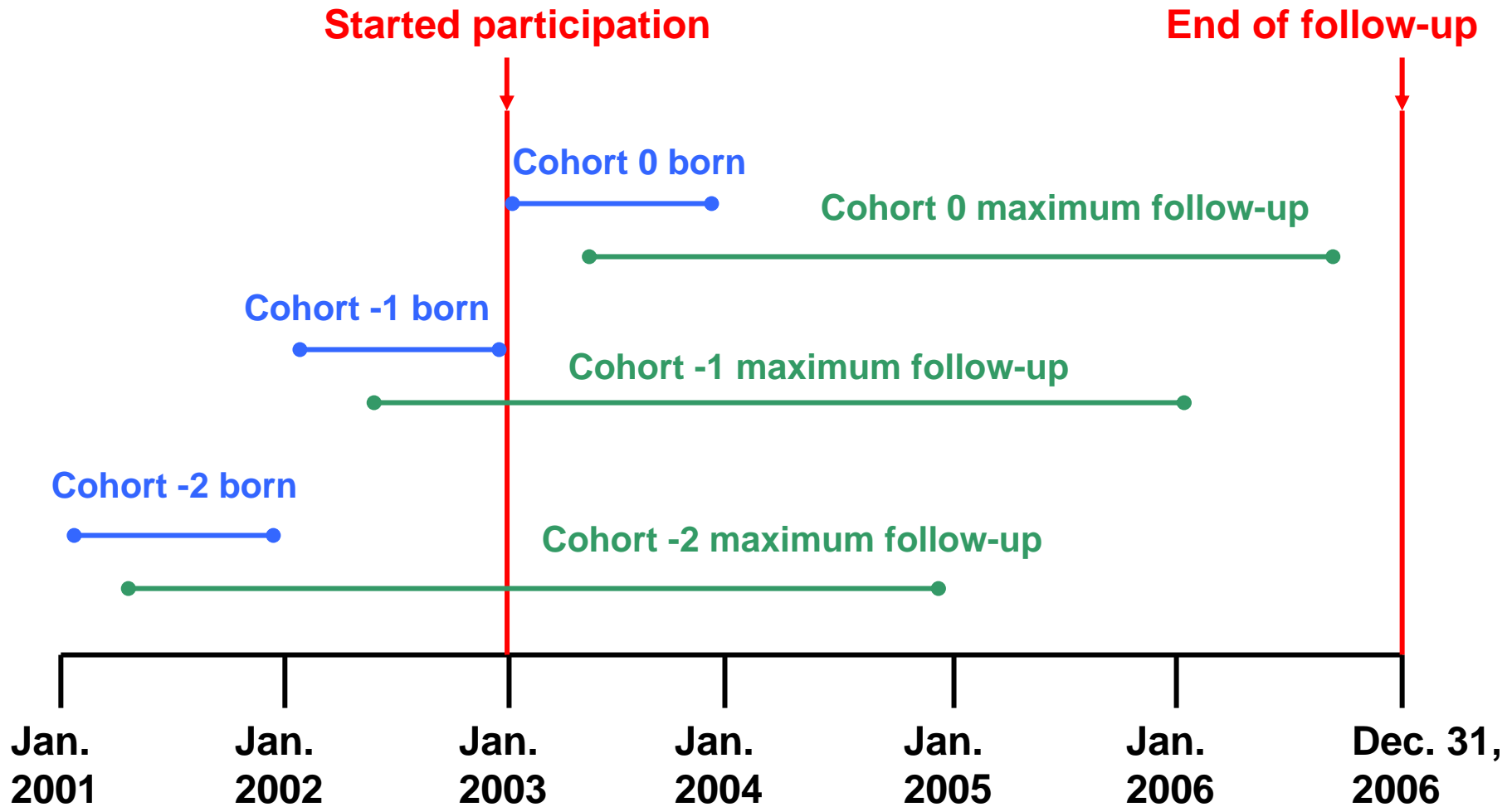
- What is a Hazard Ratio?
 - Measure of risk
 - Can be thought of as the number of events per interval of time
 - E.g., If hazard for contracting a cold is 0.15 with time measured in months, you would expect to contract a cold 0.15 times in a given month
 - Lower hazard ratio = lower risk

Birth cohort description

Cohort	Cohort definition
-2	Born 13-24 months prior to beginning participation*
-1	Born 1-12 months prior to beginning participation*
0	Born 0-12 months after beginning participation*

* Beginning of project is defined as Jan. 1 or July 1 of year when testing first recorded in database

Cohort Illustration



Number of events by cohort

Cohort	Beef-ELISA (7 herds)		Dairy-ELISA (35 herds)		Dairy-Culture (24 herds)		Dairy-Culture (mod. to high shedding) (24 herds)	
	# in cohort	# pos.	# in cohort	# pos.	# in cohort	# pos.	# in cohort	# pos.
-2	380	9	4,217	188	2,614	196	2,612	61
-1	354	6	4,632	165	3,107	143	3,109	44
0	335	14	3,772	118	2,108	65	2,108	20
Total	1,069	29	12,621	471	7,829	404	7,829	125

Results from the Cox Models

Cohort	Culture (pos. vs neg.)		Culture (mod. to high shedding)	
	HR	p	HR	p
-2	1	-	1	-
-1	0.64	0.03	0.68	0.07
0	0.53	0.02	0.54	0.04

Summary

- Results suggest that prevalence has decreased in participating herds since start of project
- Results suggest that management changes have been effective in reducing incidence of Johne's disease in younger cattle
- Further work is needed to identify factors that have the greatest effect on incidence
- 2-3 more years of following these herds would provide much better evidence of effects of NJDDHP participation because additional cohorts could be included (i.e., born 1-2 years after project began) and could also include those herds that began project in 2004 and 2005

Principal Investigators

- John Adaska – CA
- Frank Garry – CO
- D. Owen Rae – FL
- C. Dix Harrell – FL
- Mel Pence – GA
- Ching Ching Wu – IN
- Jenks Britt – KY
- John Kaneene – MI
- Scott Wells – MN
- James Watson – MS
- Thomas Moss – ND
- Joy Bennett – NY
- Bill Shulaw – OH
- Don Hansen – OR
- David Wolfgang – PA
- Ellen Jordan – TX
- Todd Johnson – VT
- Elizabeth Patton – WI
- Michael Collins - WI

Data analysis plan

- Overview of NJDDHP and of herds at program outset
 - Under internal review prior to submission to JAVMA
- Change in prevalence of *M. paratuberculosis* infection after 3 years
 - In preparation
- Economic cost of Johne's Disease and Johne's Disease Control Programs
 - Initial draft near completion

Data analysis plan (cont'd)

- Changes in incidence of clinical disease in culled cattle and incidence of infection in young adults
- Association between changes in management and prevalence of infection after 3 years
- Associations between environmental and cattle test results
- Effects of vaccination

Future Direction

- How long should demo herd project continue?
 - Dairy herds
 - Beef herds
- Do we need to maintain the number of herds/states currently enrolled?
- Are there specific Voluntary Control Program questions/issues that could be addressed via the demo herds?