

VACCINE HESITANCY IN PARENTS/GUARDIANS OF SCHOOL-AGE CHILDREN: A QUALITATIVE REVIEW AND
CASE-STUDY ANALYSIS IN MICHIGAN

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ABSTRACT

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Background: Non-medical vaccination exemption rates for kindergartners increased from 4.9% to 5.4% across the state of Michigan and increased from 7.3% to 11.6% in Grand Traverse County (MI) over the 3-year period covering the 2011/12, 2012/13, and 2013/14 school years.

Objectives: This thesis seeks to interpret the results of the 2015 Michigan Department of Health and Human Services (MDHHS) administrative rule change modifying complexity of non-medical exemption filing procedures across Michigan and the 2015 special effort by local school and health officials to reduce the proportion of students with non-medical exemptions and incomplete vaccination records in Traverse City Area Public Schools (TCAPS).

Study Design: This thesis utilizes a combination review/cross-sectional design to interpret the results of the MDHHS rule change and special effort by local officials in Traverse City.

Results: 31.5% decrease in non-medical exemption rates across 73 counties, plus city of Detroit, and 66.27% reduction in total number of students with non-medical exemptions or incomplete vaccination records in TCAPS appear to (a) be consistent with previously observed inverse associations between complexity of non-medical exemption filing procedures and non-medical exemption rates and (b) further validate Peretti-Watel et al.'s theoretical approach to vaccine hesitancy.

Conclusion: Increasing complexity of non-medical vaccination filing procedures at state level and requiring school-entry immunization requirement compliance at local level may motivate passively and actively hesitant parents/guardians to fully vaccinate their school-age child/children in Michigan.

Dedicated to Keri, Kenny, Mr. Biggs, Bowie, and Molly

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INTRODUCTION

Against a backdrop in the state of Michigan where non-medical vaccination exemption (waiver) rates for kindergartners exceeded median corresponding national rates over the 2011/12, 2012/13, and 2013/14 school years (table 1) – which placed Michigan among the top five states with the highest non-medical exemption rates for kindergartners during the same 3-school year period (table 3) – the Michigan Department of Health and Human Services (MDHHS) initiated a new administrative rule change on January 1, 2015 that required parents/guardians seeking non-medical vaccination waivers for their school-age children entering kindergarten, 7th grade, or a new school district across the state to first attend a special educational session conducted at a local health department focused on the risks of vaccine preventable diseases (VPDs) and the risks/benefits of vaccination. This requirement to obtain a health department-certified non-medical waiver replaced the former school-based non-medical waiver filing system, under which parents/guardians submitted a signed, easy-to-complete form available on the internet to the local school attended by their child/children.

Table 1: Comparison of Michigan and U.S. Non-Medical Vaccination Waiver Rates in 3 Years Prior to MDHHS Waiver Filing Procedural Rule Change

	2011-2012 school year	2012-2013 school year	2013-2014 school year
Non-medical exemption percentage for kindergartners in Michigan	4.9%*	5.3% **	5.4%***
Median state non-medical exemption percentage for kindergartners in United States	1.2%*	1.5%**	1.7%***

*Vaccination Coverage Among Children in Kindergarten—United States, 2011-2012 School Year [1]

** Vaccination Coverage Among Children in Kindergarten—United States, 2012-2013 School Year [2]

*** Vaccination Coverage Among Children in Kindergarten—United States, 2013-2014 School Year [3]

Similarly, against a backdrop in Grand Traverse County (MI) where non-medical exemption rates for kindergartners exceeded median county rates in Michigan over the 2011/12, 2012/13, and 2013/14 school years (table 2) – and where pertussis and measles outbreaks occurred in late 2014 (MLIVE) [4] –

school officials in Traverse City Area Public Schools not only followed the MDHHS non-medical exemption filing procedural change for parent/guardians of kindergartners, 7th graders, and new school district entrants, but also issued recall letters in May 2015 requiring parents/guardians of school-age children **in all other grades** attending school under a previously valid non-medical vaccination waiver or incomplete vaccination records to either: 1. obtain a newly health department-certified non-medical vaccination waiver by first attending a special education session conducted at the local county health department focused on risks of VPDs and the risks/benefits of vaccination prior to commencement of the 2015/2016 school year, or 2. demonstrate compliance with school-entry immunizations requirements through complete vaccination prior to commencement of the 2015/2016 school year.

Table 2: Comparison of Grand Traverse County and Michigan Non-Medical Vaccination Waiver Rates in 3 Years Prior to MDHHS Waiver Filing Procedural Rule Change**

	2011-2012 school year	2012-2013 school year	2013-2014 school year
Non-medical exemption percentage for kindergartners in Grand Traverse County	7.3%	8.8%	11.6%
Median non-medical exemption percentage for kindergartners in Michigan counties	4.3%	4.8%	3.8%

**Data provided by Cristi Bramer, Vaccine Preventable Disease Epidemiologist, MDHHS [5]

In Chapter 1: Qualitative Review, Part A, in order to establish a broader context for understanding the 2015 efforts by officials in Traverse City, MI to decrease non-medical exemption rates and increase compliance with school-entry immunization requirements and by MDHHS to decrease non-medical exemption rates across Michigan, this thesis:

- Reviews major trends in non-medical exemption epidemiology, including: 1. national increase and acceleration of non-medical exemption rates from 1991-2011 as observed by Omer and colleagues; 2. questionable impact of the introduction of philosophical exemptions in states with religious only exemptions on increasing/accelerating non-medical exemption rates; 3.

tendency of parents/guardians filing for exemptions on behalf of their school-age children to concentrate/cluster in the same geographic location; and 4. uneven distribution/concentration of students whose parents/guardians file non-medical exemption at state (2011-2014) and county levels (2010-2014).

- Reviews linkages and positive associations between non-medical exemptions and vaccine-preventable diseases (VPDs); associations between “easy” non-medical exemption filing procedures and increasing non-medical exemption rates; associations between “easy” non-medical exemption filing procedures and increasing VPD risk; and recommendations for tightening non-medical exemption filing procedures.
- Reviews two globally-orientated reviews of intervention studies (that is, interventions designed to counter vaccine hesitancy/refusal), which identify no effective interventions germane to U.S. context (i.e., as a high income nation with relatively complete vaccination coverage).
- Reviews two U.S.-oriented reviews of intervention studies, including Sadaf et al. review assessing association between complexity of exemption filing procedures and non-medical exemption rates, which identify no convincingly effective interventions to counter vaccine hesitancy/refusal (although Sadaf et al. recommend tightening exemption filing procedures despite data-quality concerns over available evidence).

In Chapter 2: Qualitative Review, Part B, in order to continue contextualizing the 2015 efforts by officials in Traverse City, MI and by MDHHS across the state of Michigan, this thesis:

- Reviews Peretti-Watel et al.’s groundbreaking critique of vaccine hesitancy (VH) as a problematic concept when not approached as a decision-making process and builds upon Peretti-Watel et al.’s critique by introducing an explicit set of guidelines that researchers can utilize to realize the full potential of invoking VH as a decision-making process.

- Demonstrates value of new guidelines through 1. critique of limitations in previously formulated categories of parental/guardian VH and 2. assessment of existing practical and theoretical models, including a theoretical framework offered by Peretti-Watel et al., highly suitable for fully approaching VH as a decision-making process.

In Chapter 3: Quantitative Case-Study Analysis, in order to analyze/interpret the results of the 2015 efforts by officials in Traverse City, MI to decrease non-medical exemption rates/increase compliance with school-entry immunization requirements and by MDHHS to decrease non-medical exemption rates across Michigan, this thesis:

- Demonstrates practical applicability of Peretti-Watel et al.'s theoretical framework, based on approaching VH as a decision-making process (i.e., linking the decision-making determinants of trust in health authorities and self-efficacy in health management with vaccinating/non-vaccinating behaviors), by utilizing it to interpret results of the natural experiment in school-entry immunization requirement compliance that occurred in Traverse City, MI in summer/Fall 2015: that parents/guardians of students with non-medical exemptions or incomplete vaccination records who responded to the recall letter by electing to fully vaccinate their child/children transitioned from the decision-making orientation of "passive hesitancy" to "passive conformism;" parents/guardians who responded to the recall letter by first attending the special education program and subsequently electing to fully vaccinate their child/children transitioned from a decision-making orientation of "rationalized hesitancy" to "enlightened conformism;" and parents/guardians who responded to the recall letter by first attending the special education program and subsequently electing to file a non-medical exemption for their child/children maintained a decision-making orientation of "rationalized hesitancy."
- Demonstrates the practical applicability of Peretti-Watel et al.'s theoretical framework by utilizing it to interpret the results of a survey – offered by the Grand Traverse County Health

Department to 1. the parents/guardians of students with incomplete vaccination records or non-medical exemptions obtained under the previously simplified school-based filing system who responded to the TCAPS' recall letter by electing to attend the special education program and 2. parents/guardians from TCAPS and other districts who sought to meet the requirement for obtaining a new health-department certified non-medical exemptions by first attending the special education program – that was ostensibly designed to evaluate the perceived value of information presented at the program on: (a) VPD risk to other children in immediate family, (b) risk of non-vaccination to larger community, and (c) school exclusion risk in outbreak situations in relation to intention-to-vaccinate; that is, through frequency, regression, and conditional probability analyses, parents/guardians appeared to disregard the value of health department-presented information on VPD risk to children in the immediate family and non-vaccination risk to the wider community more readily (information remained less resistant to the healthism decision-making orientation of parents/guardians seeking information from other competing sources of authority) than health department-presented information on school exclusion risk (information remained more resistant to the healthism decision-making orientation of parents/guardians as the health department persisted as the undisputed authority on school outbreak exclusion policy).

- Demonstrates consistency of results between the natural experiment in Traverse City, MI and multiple studies reporting an observed inverse association between complexity of non-medical exemption filing procedures and non-medical exemption rates through comparison of the 1. relatively large proportion of parents/guardians of students with non-medical exemptions or incomplete vaccination records who elected to fully vaccinate their child/children when facing the prospect of following a more complex procedure (i.e., attending a special education program at the local health department) to comply with school-entry immunization

requirements and 2. relatively small proportion of parents/guardians of students with non-medical exemptions or incomplete vaccination records who elected to follow the more complex procedure of obtaining a newly certified, health department-approved non-medical exemption required by the MDHHS rule change.

- Demonstrates consistency of results between regression analysis of correlated data and Paired T-test analysis finding a significant reduction in non-medical exemption rates for the 73 counties (plus city of Detroit) modifying non-medical exemption filing procedures as a result of the 2015 MDHHS administrative rule change and multiple studies reporting an observed inverse association between complexity of non-medical filing procedures and non-medical exemption rates.
- Details implications of Traverse City, MI natural experiment results on results of MDHHS effort to modify non-medical exemption filing procedures across the state of Michigan that: 1. parents/guardians identified in the Traverse City, MI case as “passively hesitant” or “actively hesitant” due to their election to fully vaccinate their child/children following receipt of the recall letter or attendance at the special education session likely correspond to a similar population of parents/guardians across the state of Michigan who also can be characterized as “passively hesitant” or “actively hesitant” due to their election to fully vaccinate their child/children following the MDHHS effort to modify non-medical exemption filing procedures and 2. parents/guardians of children attending school with incomplete vaccination records identified as “active refusers” in the Traverse City, MI case likely correspond to similar population of parents/guardians of children with incomplete vaccination records across the state who also can be characterized as “active refusers”
- Details implications of results of MDHHS effort to modify non-medical filing procedures across state of Michigan on results of Traverse City, MI natural experiment: that reduction in

substantial number of parents/guardians filing non-medical exemptions for their child/children across the state of Michigan following implementation of the MDHHS non-medical exemption filing procedural change is consistent with notion that a substantial number of parents/guardians in Traverse City, MI who originally filed non-medical exemptions for their child/children under the simplified, school-based system opted to fully vaccinate their child/children when faced with requirement to attend a special education session at the local health department.

CHAPTER 1: QUALITATIVE REVIEW, PART A

The following chapter details: 1. nature and scope of the non-medical exemption problem in the United States and Michigan, 2. vital connections between non-medical exemption rates, ease of non-medical exemption filing procedures, and VPD risk, and 3. recommendations to modify non-medical exemption filing procedures despite absence of robust evidence to utilize this or other interventions to counter vaccine hesitancy and refusal.

General Trend I: National Increase and Acceleration in Prevalence of Non-Medical Exemptions, 1991-2011

Non-medical exemption rates in the United States began to increase starting (at least) as early as 1991. In states allowing personal belief exemptions (synonymous with philosophical exemptions in the following study only) to school-entry immunization requirements, Omer, Pan, et al. in a 2006 national study (focused on exemption rates for kindergartners and 1st graders) reported a significant average annual increase of 6% for philosophical exemptions from 1991-2004 (Incidence Rate Ratio or IRR: 1.06; 95 CI: 1.01-1.12, for yearly change), but found no significant average annual change in exemptions over the same period in states allowing only religious exemptions (IRR: 0.95; 95 CI: 0.90-1.01, for yearly change). [6] In a 2012 national follow-up study, in states allowing philosophical exemptions, Omer, Richards, et al. reported a significant average annual increase of 10% for philosophical exemptions from 2006-2011 (IRR: 1.10; 95 CI: 1.05-1.14, for yearly change) and found a significant average annual increase of 20% for religious exemptions over the same study period in states allowing only religious exemptions (IRR: 1.20; 95 CI: 1.11-1.30, for yearly change). [7] In comparing results of the 2006 and 2012 studies, Omer, Richards, et al. concluded that the utilization rate of non-medical exemptions, including religious and philosophical exemptions, not only increased over the 20-year period from 1991-2011, but also accelerated. [7] To provide necessary context to evaluate the magnitude of the problem associated with increasing and accelerating non-medical exemption rates at the conclusion of the 20-

year study period, the CDC reported – for the 2011-2012 school year – a median 1.2% non-medical exemption rate for the 49 states providing data. [1]

General Trend II: Impact of Allowing Philosophical Exemptions on Non-Medical Exemption Rates

Studies have consistently reported higher mean non-medical exemption rates in states allowing philosophical exemptions compared to states allowing religious exemptions only (e.g., Omer, Richards, et al.) [7], but a straightforward interpretation of this trend has been complicated by at least two factors: 1. evidence that a subgroup of states with religious only exemption policies actually permit philosophical exemptions as a matter of practice and 2. potential complicating influence of exemption application/procurement complexity on exemption rates. For example, in a 2001-published study based on direct surveys of state immunization program managers, Rota et al. identified 7 states with religious only exemption policies that allowed for the filing of exemptions by parents/guardians acting out of secular motivations and questioned the validity of the distinction between religious and philosophical exemptions in these states where a broad definition or flexible interpretation of religious exemption allowed for the accommodation of philosophical exemptions. [8] Reclassifying a subgroup of religious only exemption states as states allowing philosophical exemptions (by actual practice) could potentially alter the magnitude of the contrast between mean exemption rates in states allowing different types of exemptions. In addition, Blank et al. (2013) reported a mean non-medical exemption rate for kindergartners during the 2011-2012 school year of 2.8% in states allowing philosophical exemptions, compared to 1.5% in states allowing religious exemptions only; but after stratifying non-medical exemption rates by level of exemption application/procurement complexity (as “easy,” “medium,” and “difficult”), the investigators reported a lower mean exemption rate (1%) in states allowing philosophical exemptions with “difficult” exemption filing procedures, compared to mean exemption rate (1.2%) in states allowing religious only exemptions with “difficult” exemption filing procedures [9], suggesting that the complexity of exemption application/procurement complicates the relationship between

exemption type and non-medical exemption rates (a relationship potentially further complicated by misclassification of states by exemption type). Eliminating philosophical exemption does not, therefore, appear to be a viable option for decreasing non-medical exemption rates.

General Trend III: Non-Medical Exemptions Cluster Geographically

In a retrospective cohort study including 50,233 young children enrolled in a Northern California-based health-care plan/system (Kaiser Permanente of Northern California) who turned age 36 months between 2010 and 2012 and whose residential addresses spanned 13 counties in Northern California, Lieu et al. 1. utilized a software package known as SatScan and a “spatial scan statistic” [10, p.282] to scan for statistically significant clusters of young preschool-aged children whose parents/guardians refused vaccination on their behalf and 2. subsequently mapped 5 geographically-delineated clusters of young preschool-aged children in Northern California with statistically significant higher rates of vaccine refusal compared to children residing outside the clusters. [10] In a 2010-published investigation of a 2008 measles outbreak in San Diego County (California), Sugarman et al. identified 4 contiguously situated school districts with significantly higher rates of personal belief exemptions in 2007 for kindergartners, compared to other school districts located within the county. [11] In state-level analyses, Atwell et al. (2013) and Omer, Enger, et al. (2008) utilized Kulldorff’s scan statistics, respectively, to identify 39 statistically significant clusters of kindergartners attending school with personal belief exemptions in California from 2005 to 2010 and 23 statistically significant clusters of kindergartners attending school with a non-medical exemption in Michigan between 1993 and 2004. [12][13] As noted by Omer, Salmon, et al. (2009), although several factors, including local population characteristics (e.g., education levels), beliefs of local medical and non-medical thought leaders, and local media representations, have been considered as possible contributors to the clustering of parents/guardians who obtain non-medical exemptions on behalf of their school-age children, a

complete understanding of the factors contributing to the geographic clustering of these parents/guardians has remained elusive. [14]

General Trend IV: Heterogeneous Distribution of Non-medical Exemption Prevalence at State Level (2011-2014) and County Level (2010-2014)

While the general trend from 1991-2011 indicated an increasing and accelerating utilization of non-medical exemptions among parents/guardians of young school-age children, and while the national median non-medical exemption rate remained relatively low for the 2011-2012 school year, the prevalence of non-medical exemptions followed an unequal distribution across the states from 2011-2014, due to the tendency of parents/guardians seeking non-medical exemptions for their child/children to cluster in similar geographies. In the period encompassing the 2011-2012, 2012-2013, and 2013-2014 school years, the proportion of kindergartners attending school with non-medical exemptions ranged from as low as 0.0% in states not allowing non-medical exemptions (i.e., Mississippi and West Virginia) to as high as 7% in states (i.e., Oregon) allowing non-medical exemptions (table 3).

Table 3: State Variation in Proportion of Kindergartners with Non-Medical Exemptions by 5 States with Highest and Lowest Proportions, 2011-2014 (for All Reporting States)

School Year	5 States with Highest Proportion of Non-medical exemptions	5 States with Lowest Proportion of Non-medical exemptions
2011-2012*	Oregon (5.8%), Alaska (5.7%), Vermont (5.4%), Idaho (5.1%), & Michigan (4.9%)	Mississippi (0.0%), West Virginia (0.0%), Delaware (0.4%), Kentucky (0.4%), & tie: Alabama (0.5%), New York (0.5%), and Tennessee (0.5%)
2012-2013**	Oregon (6.4%), Vermont (5.7%), Idaho (5.5%), Michigan (5.3%), & Illinois (4.8%)	Mississippi (0.0%), West Virginia (0.0%), New Mexico (0.2%), Virginia (0.4%) & tie: Delaware (0.5%), Kentucky (0.5%), and Louisiana (0.5%)
2013-2014***	Oregon (7.0%), Idaho (6.1%), Vermont (6.1%), Michigan (5.4%), & Maine (5.2%)	Mississippi (0.0%), West Virginia (0.0%), Virginia (0.4%) & tie: Alabama (0.6%), Kentucky (0.6%), and New York (0.6%)

*Vaccination Coverage Among Children in Kindergarten—United States, 2011-2012 School Year [1]

** Vaccination Coverage Among Children in Kindergarten—United States, 2012-2013 School Year [2]

Table 3 (cont'd)

*** Vaccination Coverage Among Children in Kindergarten—United States, 2013-2014 School Year [3]

The prevalence of non-medical exemptions exhibited even greater variability at the country level from 2010-2014. In selected states, the proportion of kindergartners attending school with non-medical exemptions ranged from as low as 0.0% in counties to as high as 20.9% (table 4).

Table 4: County Variation in Non-Medical Exemption Rates for Kindergartners by County with Lowest and Highest Rates in Selected States, 2010-2014

State	Exemption Type	Included Years	Included Grades	Lowest County Exemption Rate (county listed when available)	Highest County Exemption Rate (county name listed when available)
California*	Personal Belief	2012	K	0.0% (Sierra County)	20.9% (Nevada County)
Washington**	Non-medical	2012-2013	K	0.0%	11.4%
Oregon***	Non-medical	2013-2014	K	0.0% (Wheeler County)	16.4% (Grant County)
North Dakota****	Personal Belief	2010-2011	K-12	0.0%	18.2%

*[15], **[16], ***[17], ****[18]

(Table design adapted from Ernst and Jacobs)

In Michigan's 83 counties (plus Detroit), for the 2013-2014 school year, 3 counties exhibited kindergarten exemption rates (possibly including medical exemption) which ranged between 15.1% and 20+%, while 45 counties exhibited kindergarten exemption rates which ranged between 0.0% and 5.0%. [19]

Vaccine Refusal/Exemption and Measles Risk

Findings from analytical epidemiological studies have demonstrated a positive association between vaccine refusal/exemptions and measles. In a 1999-published national retrospective cohort study, with relative risk calculation based on: 1. number of observed measles cases in the vaccinated and exemptor populations of school-age children, aged 5-19 years, reported by the states to the CDC's Measles Surveillance System from 1985-1992 and 2. estimated size of the vaccinated and exemptor student

populations (with estimated exemptor population size derived by multiplying the actual or estimated proportions of exemptions available in state surveys from 1990-1994 by U.S. Census population figures and estimated vaccinated population size derived by assuming 98% national measles immunization coverage from 1985-1992 and multiplying coverage rate by U.S. census figures), Salmon, Haber, et al. reported a 35-fold (95 CI: 34-37) increased average risk for students with exemptions contracting measles, compared to vaccinated students. [20] Feiken et al. reported a similarly high 22-fold (95 CI: 15.9-31.1) increased average risk for students, aged 3-18 years, with non-medical exemptions contracting measles, compared to vaccinated students, in Colorado from 1987-1998 – in a retrospective cohort study, with relative risk calculation based on: 1. number of observed measles cases in the vaccinated and exemptor student populations in Colorado (derived by mandatory state-level surveillance) and 2. estimated size of vaccinated and exemptor student populations in Colorado (derived from multiplying the annual proportion of vaccinated students and exemptors available in the state summary report by the annual student population). [21]

Vaccine Refusal/Exemption and Pertussis Risk

In addition, Feiken et al. reported a nearly 6-fold (RR: 5.9; 95 CI: 4.2-8.2) increased average risk for students, aged 3-18 years, with non-medical exemptions contracting pertussis, compared to vaccinated students in Colorado from 1996-1998 in same retrospective cohort study referenced above (Note: pertussis and measles study dates differed due to the lack of exemption data available for pertussis prior to 1996). [21] In a 2008-published study identifying 23 significant exemption clusters and 6 significant pertussis clusters in Michigan between 1993 and 2004, Omer, Enger, et al. reported 1. in an unadjusted analysis that the odds of a census tract lying within both an exemption cluster and a pertussis cluster were approximately 3 times greater (OR: 3.02; 95 CI: 2.51-3.61) than the odds of a census tract lying outside an exemption cluster and within a pertussis cluster and 2. in an analysis adjusted for several census tract-level demographic variables (e.g., population density) that the odds of a census tract

overlapping with both exemption and pertussis clusters were 2.73 times greater (OR: 2.73; 95 CI: 2.25-3:31) than the odds of a census tract lying outside an exemption cluster and within a pertussis cluster. [13]

Vaccine Refusal/Exemption and Risk of Other Vaccine Preventable Diseases

In a 2010-published matched case-control study assessing the association between parent/guardian vaccine refusal for non-medical, personal-beliefs and varicella (chickenpox) diagnosis in a population of young children, aged 12 months to 8 years, enrolled continuously for a minimum of 6 months in a managed health-care plan (Kaiser Permanente Colorado) in Colorado from 1998-2008, Glanz et al. reported approximately 9-fold greater odds (OR: 8.6; 95 CI:2.2-33.3) of contracting varicella in children whose parents refused vaccination for non-medical, personal-beliefs, compared to children whose parents accepted vaccination. [22] Similarly, Glanz et al., in a separate 2010-published nested case-control study assessing the association between parent/guardian refusal of “seven-valent pneumococcal conjugate disease (PCV)” [23, p. 990] for non-medical, personal beliefs and risk of hospitalization due to pneumococcal-related disease in a population of young children, aged 2 months to 5 years, born after December 31, 1999 and enrolled continuously for a minimum of 6 months in the Kaiser Permanente Colorado managed health-care plan in Colorado from October 2004 through September 2009, reported 6.5 greater odds (OR: 6.5; 95 CI: 1.7-24.5) of hospitalization due to pneumococcal-related disease in children whose parents refused PCV7 for non-medical, personal beliefs, compared to children whose parents accepted PCV7. [23]

States with Easy Administrative Exemption Application/Procurement Procedures and Exemption Rates

In addition to the observed significant association between higher non-medical exemption rates and higher risk of VPDs, a significant association between less complex administrative exemption application/procurement procedures and higher non-medical exemption rates has been observed in

multiple studies. In a 2001-published national study, based on survey data collected from immunization program managers in 48 states (in 1998) regarding exemption application/procurement procedures and state-level exemption rates (from 1994-1996), assessing the association between 3 categories of exemption application/procurement complexity (ranging from 1-3, depending on whether parents/guardians were required to visit the local health department, compose justification statements/letters, obtain a seal/signature from a notary, or procure additional letters/signatures from religious/secular officials) and 3 categories of exemption frequency (low: less than 0.5%; medium: 0.5% - 1.0%; and high: greater than 1.0%), Rota et al. reported a significant inverse association between the level of effort required by parents/guardians at the state-level to obtain exemptions and the proportion of students at the state-level attending school exempt from immunization requirements ($p=.0167$, CHI-SQUARE Test). [8] In addition, in a 2013-published national survey, based on interviews/discussions conducted with immunization program managers in 48 states and reviews of exemption application/procurement procedures on state health department websites and state-level non-medical exemption rates for the 2011-2012 school year compiled/reported by the CDC, assessing the association between 3 categories of exemption application/procurement complexity (that is, “easy,” “medium,” and “difficult” adapted from Rota’s et al.’s criteria) and the proportion of kindergartners attending school with non-medical exemptions, Blank et al. reported a mean non-medical exemption rate of 2.9% in states exhibiting “easy” level of exemption application/procurement complexity; 1.5% in states with “medium” level complexity; and 1.1% in states with “difficult” level of complexity. [9] Furthermore, in a national study, based on survey data collected from immunization program managers regarding the complexity of exemption application/procurement procedures in the 48 states permitting non-medical exemptions and exemption rates compiled/reported by the CDC, assessing the association from 1991-2004 between administrative complexity of exemption application/procurement procedures (characterized as “easy,” “medium,” or “difficult,” depending on whether parents/guardians were

required to (a) submit pre-existing form or letter, (b) obtain pre-existing form or letter at school or health department, (c) obtain a notary's seal and signature on form, and/or (d) expend effort adding additional language to a letter) and the average annual change in non-medical exemption rates, Omer, Pan, et al. reported a significant average annual increase of 5% in non-medical exemption rates in states exhibiting "easy" exemption administrative procedures (IRR:1.05; 95 CI: 1.01-1.09, for yearly change), but reported no significant annual changes in states exhibiting "medium" complex procedures (IRR: 0.99; 95 CI: 0.96-1.03, for yearly change) or in states exhibiting "difficult" procedures (IRR: 0.96; 95 CI: 0.86-1.07, for yearly change). [6] In a follow-up study, covering the period 2005-2011, Omer, Richards, et al. reported 1). highest non-medical exemption rates in the final year of the study, 2011, in states with "easy" exemption administrative procedures, 2). acceleration in the (significant) average annual increase of non-medical exemption rates from 2005-2011 in states with "easy" exemption filing procedures, and 3). significant average annual increases for the first time in non-medical exemption rates in states with "medium" and "difficult" administrative exemption procedures (table 5). [7]

Table 5: Non-Medical Exemption Rates, 2011, and Average Yearly Non-Medical Exemption Rate Increase, 2005-2011, by Complexity of State Exemption Filing Procedure

Relative Ease of State-Level Exemption Application/Procurement Procedures	2011 Non-medical Exemption Rate	Average Annual Increase in Non-medical Exemption Rates from 2005-2011
Easy	3.3%	13% (IRR: 1.13; 95 CI: 1.05-1.21, for yearly change)
Medium	2.0%	18% (IRR: 1.18; 95 CI: 1.10-1.26, for yearly change)
Difficult	1.3%	8% (IRR: 1.08; 95 CI: 1.02-1.14, for yearly change)

Source of data for table: Omer, Richards, et al. [7]

In the only national study (2015-published) assessing the association between the individual components of state laws governing administrative exemption application/procurement procedures (derived from "State Vaccination Requirements and Exemption Law Database" [p. 1.388] and

kindergarten exemption rates for any given state), Bradford and Mandich in a random effects regression analysis covering the period from 2002 to 2012 reported:

1. Significant reduction in proportion of exempt kindergarteners associated with policies that (a) mandated criminal or civil penalties for non-compliance with school-entry immunization requirements (p-value <0.01) or (b) permitted parents to selectively opt out of one or more vaccines (p-value <0.05);
2. Nearly significant reduction in proportion of exempt kindergartners associated with policies that (a) prohibited non-physicians from signing exemption form (p-value <0.1) or (b) required health department approval of non-medical exemptions (p-value <0.1);
3. Non-significant reduction in proportion of exempt kindergartners associated with policies that (a) allowed for provisional enrollment of unvaccinated, non-exempt students, (b) required notary's seal and signature on forms, (c) required health department approval of medical exemptions, (d) required additional documentation for religious exemptions, (e) allowed non-physicians to sign exemption forms, or (f) required annual review of exemption applications;
4. Significant increase in the proportion of exempt kindergartners associated with policies that allowed for (a) utilization of a pre-existing, standardized exemption application from (p-value <0.01) and (b) philosophical exemptions (p-value <0.01). [24]

In a more geographically limited 2005-published study, based on survey data collected from school officials in 2001-2002 most closely involved with parents/guardians seeking to fulfill school immunization requirements in two states allowing philosophical exemptions, Colorado and Washington, and in two states, Massachusetts and Colorado, allowing religious exemptions only, assessing the association between administrative exemption application/procurement complexity (based on a 0-4 point construct, with 1 point assigned for the each of the following requirements: 1. annual exemption review, 2. parental letter for religious exemptions, 3. signature from religious or school official or from

physician, and 4. review of risks associated with non-vaccination) and exemption status of enrolled students, Salmon, Omer, et al. departed from the typical classification of exemption administrative application/procurement complexity in studies utilizing summative classification schemes by including an annual renewal requirement for exemptions, but nonetheless reported a significant inverse association between the level of effort required by parents/guardians at the school level to obtain an exemption and the positive exception status of children attending school in the two states not allowing philosophical exemptions (OR: 0.74; 95 CI: 0.59-0.94), but found no significant association between administrative complexity of exemption application/procurement and exemption status of children attending school in the two states allowing philosophical exemptions (OR: 0.90; 95 CI: 0.68-1.18), possibly due to a lack of study power (according to authors) [25, p.440]. [25]

Special Case of Arkansas: Potential Impact of Complex Administrative Exemption

Application/Procurement Requirements on Exemptions Rates

The inclusion of annual renewal, notarization, health department approval, vaccine education, and selective vaccine exemption requirements in criteria to classify administrative exemption application/procurement complexity that have been significantly and non-significantly associated with reductions in non-medical exemption rates may explain – at least in part – the relatively low exemption rate, 0.5%, for kindergartners that existed in Arkansas during the 2009-2010 school year [26], despite accelerating annual increases that occurred in the state following implementation of ACT 999 in 2003, which expanded the category of non-medical exemption beyond the religious only exemption previously offered to include a philosophical exemption option, but also required parents/guardians to: 1. seek exemption approval at the health department only, 2. obtain notary's seal and signature on exemption forms, 3. renew exemptions annually, and 4. review vaccine education materials. [27] In a 2007-published study that examined exemption rates in Arkansas in the 2 school years (2001-2002, 2002-2003) preceding and in the 2 school years (2003-2004, 2004-2005) following implementation of ACT 999

in 2003, Thompson et al. reported that exemption rates for kindergartners increased approximately 4-fold (from 0.049 to 0.187%) between 2002-2003 and 2003-2004 and increased approximately 6-fold (from 0.049 to .302%) between 2002-2003 and 2004-2005 [28], and in a 2012-published follow up study that examined the impact of ACT 999 over the 2003-2010 period, Safi et al. reported that exemption rates for kindergartners increased over 16-fold (from 0.05 to .821%) between the 2002-2003 and the 2009-2010 school years [29]; yet Thompson et al. acknowledged that the overall exemption rate for students in all grades remained “well under 1.0%” [28, p.199], and Safi et al. noted that the CDC compiled/reported exemption rate for kindergartners in Arkansas of 0.45% for the 2009-2010 school year mirrored similar rates in other states bordering Arkansas that offered religious and philosophical exemptions (Louisiana: 0.45%; Oklahoma: 0.89%; and Tennessee: 0.45%). [29] In addition, Safi et al. observed that non-medical exemption rates of less than 1% for kindergartners in southern states, including Arkansas, remained well below the rates in other states outside the region (Washington: 5.7%) during the same period and subsequently concluded that the 2003 legislative change in Arkansas permitting philosophical exemptions “...does not, therefore, appear to have increased or retarded the increase in exemptions compared to other states in the region” [29, p.604] without considering the possible effect of complex administrative exemption application/procurement procedures on inhibiting the overall magnitude of the rise in exemption rates in Arkansas and in neighboring states.

States with Easy Administrative Exemption Application/Procurement Procedures and Risk of Vaccine Preventable Diseases

Less complex administrative exemption application/procurement procedures have been associated with increased incidence of VPDs. Omer, Pan, et al., in a 2006-published national cross-sectional study referenced above, which assessed the association between administrative complexity of exemption application/procurement procedures characterized as “easy,” “medium,” or “difficult” and pertussis risk (with the pertussis incidence numerator, number of observed pertussis case-patients, aged 18 and

younger, derived from the “CDC’s Nationally Notifiable Infectious Disease Surveillance System” [6, p. 1,759] and the pertussis incidence denominator, estimated population size, aged 18 and younger, derived from the “U.S. Census Bureau’s Population Estimates Program” [6, p. 1,759] in the 48 states offering non-medical exemptions from 1986-2004, reported that compared to states exhibiting “difficult” exemption application/procurement procedures, states exhibiting “easy” and “medium” exemption procedures were significantly associated with higher average annual pertussis risk, ranging from 27% higher pertussis risk (IRR: 1.27; 95CI: 1.06-1.51, for yearly change) in states with “medium” procedures to 90% higher pertussis risk (IRR: 1.90; 95 CI: 1.06-2.28) in states with easy procedures. [6]

Similarly, in a 2015-published national cross-sectional study assessing the association between effectiveness of state-level exemption policies (with states grouped into quartiles, characterized as “most,” “moderately,” “less,” and “least” effective, based on the number of policies significantly associated with reduced exemption rates for kindergartners) and pertussis incidence (derived from CDC) from 2002-2012 and in 2012, Bradford and Mandich reported in a random effects regression analysis that compared to states with “least” effective exemption application/procurement policies, states with “most” effective exemption policies exhibited 702 significantly fewer pertussis cases per 100,000 (p-value < 0.01) in 2012, while states exhibiting “moderately” and “less” effective exemption policies also exhibited significantly fewer pertussis cases. [24]

Recommendations to Increase Administrative Complexity of Exemption Application/Procurement Process

Omer et al. have advocated fulfilling the need for “effective administrative controls” over the non-medical exemption application/procurement process as a means to ensure sincerity of belief among parent/guardians seeking to opt their children out of school-entry immunization requirements against the broader context of balancing parent/guardian autonomy with the collective benefit of full vaccination. [6, p.1763] In addition, Rota et al. have suggested that increasing the procedural complexity

associated with claiming exemptions beyond the simplest level can test the sincerity of vaccination beliefs held by parents/guardians and protect against parents/guardians seeking exemptions out of convenience or based on the misplaced belief that VPDs no longer pose a public health threat. [8] In enumerating several challenges to reduce the volume of filed exemptions on an annual basis, Salmon et al. have called for the utilization of “more detailed administrative procedures” requiring parents/guardians to expend greater degrees of effort when seeking exemptions. [25, p.440] And finally, while explicitly rejecting the idea of testing the sincerity of vaccine-related beliefs held by parent/guardians through more complex administrative procedures (to increase vaccination rates), Blank et al. nonetheless have concluded that 1. the process of opting out of immunization requirements via exemption should not prove easier than the process of fulfilling the requirements through vaccination, 2. incorporating vaccine education into exemption administrative application/procurement procedures is desirable/justifiable, and 3. the use of discretionary authority available in state health departments to “add modest exemption restrictions” is potentially an efficient approach to altering exemption policy. [9, p.1288]

Review of Other Potential Interventions in Global Context

In a 2015-published systematic review assessing the impact of interventions on vaccine hesitancy (that is, the association between interventions and vaccine utilization or “knowledge, attitudes, or beliefs” [p.4182] toward vaccination), Jarrett et al. conducted an examination of the peer-reviewed literature from January 2007 – October 2013 published in the six languages officially utilized by the United Nations (“Arabic, Chinese, English, French, Russian, and Spanish”) and grey literature published in English up to October 2013 that:

1. Included studies (for peer-reviewed literature) with: (a) research conducted on vaccine hesitancy, (b) information related to vaccines/vaccination programs, (c) key words in abstracts

- and titles associated with interventions, and (d) evaluation of vaccination uptake as primary outcome or changes in vaccination knowledge, attitudes, or beliefs as secondary outcome;
2. Included studies (for grey literature) with key words related to vaccines/vaccination programs, interventions, vaccine knowledge/attitudes/beliefs;
 3. Excluded studies (for peer-reviewed and grey literature) with research relating to (a) non-human or currently unavailable vaccines and (b) vaccines still underdevelopment (unless research directly addressed issues related to vaccine hesitancy);
 4. Identified for final inclusion in review: (a) 115 studies in the peer-reviewed literature and 9 studies in the grey literature evaluating the outcome of vaccination uptake; (b) 37 studies in the peer-reviewed literature and 3 grey literature studies evaluating the outcome of vaccination knowledge/attitudes/beliefs; and (c) 14 studies in the peer-reviewed literature and 3 studies in the grey literature evaluating both the outcomes of vaccination uptake and vaccination knowledge/attitudes/beliefs;
 5. Grouped and characterized studies (aimed at various populations) that reported a diverse set of interventions associated with (a) greater than 25% increase or less than 10% increase in vaccination uptake or (b) greater than 20% improvement in knowledge/attitudes/beliefs toward vaccination;
 6. Subjected a subset of 13 studies, categorized by 3 intervention themes: (a) “dialogue-based,” (b) “incentive-based (non-financial)”, and (c) “reminder/recall-based” [30, p.1481], to PICO (“Population, Intervention, Comparator, Outcome”) [30, p.4181] evaluation questions (to investigate the modifying effects of population characteristics) and GRADE (“Grading of Recommendations, Assessment, Development, and Evaluation” [30, p.1481] evaluation (to assess the quality of evidence generated by the PICO evaluation questions. [30])

Jarrett et al. identified six studies with interventions associated with a greater than 25% increase in vaccine uptake or a greater than 20% improvement in vaccination knowledge/attitudes/beliefs, but these studies either targeted special populations (e.g., drug users or pregnant women), assessed interventions not germane to vaccine hesitancy refusal in the U.S. (e.g., out of cold-chain vaccine access in rural China), or measured uptake for vaccines typically not included under U.S. school-entry immunization requirements (i.e., HPV vaccine). [30] For the subset of studies subjected to PICO and GRADE evaluation, Jarrett et al. found some significant effects for dialogue-based, non-financial incentive-based, and reminder/recall system-based interventions, but many of the studies targeted populations in low income countries and settings with under-vaccinated populations, and the quality of evidence ranged from very low to moderate. [30]

In a 2015-published companion to the Jarrett et al. study, Dube' et al. conducted a review of review studies published between January 1, 2008 and November 30, 2014 in English that:

1. Included reviews and meta-analyses with interventions (a) designed to impact vaccine hesitancy or refusal or (b) aimed at parents and health-care workers;
2. Excluded non-reviews (that is, "original studies, guidelines, letters, or editorials" [31, p.4192] and reviews of interventions related to increasing uptake of the influenza vaccine).

Of the 15 reviews included in the mega-review, Dube' et al. noted that 1. only two reviews directly addressed vaccine hesitancy and 2. these two reviews examined original studies almost exclusively conducted in the U.S. and reported no convincing evidence of the effectiveness of interventions on vaccine hesitancy. [31] In addition, Dube' et al. observed that school-entry immunization mandates were viewed in several reviews as an effective strategy to increase vaccine uptake in high income countries, including the U.S., but expressed 1. concern that mandates fail to tackle the underlying causes of vaccine hesitancy and 2. reservations about the potential transferability of mandates to other settings, particularly to low-income countries, and the potential counter-productive civil liberty

consequences (i.e., increased distrust) of mandating vaccination. [31] More globally, Dube' et al. concluded that reminder/recall systems aimed at parents and health-care providers were effective interventions to increase vaccination, but cautioned that this evidence remained limited in individuals exhibiting vaccine hesitancy. [31]

Review of Other Potential Interventions in U.S. Context

In a review of interventions (2014), published in English between 2003 and 2013, aimed at parents and providers to foster routine childhood immunizations and HPV childhood immunizations, Sarah E. Williams: 1. included studies that (a) focused on vaccine-hesitant parents who intentionally elected to delay/forgo vaccination despite possessing sufficient knowledge, access, and resources to obtain vaccination(s) for their children and (b) focused on transforming attitudes toward vaccination and reporting tangible outcome measures, including changes in vaccination attitudes, intention to vaccinate, and vaccination uptake and 2. excluded studies based on qualitative research, as well as editorials and commentaries. [32] In the seven identified studies pertaining to routine childhood vaccinations that assessed associations between diverse interventions and changes in attitudes toward vaccination and vaccination behavior, Williams identified only two studies directly aimed at vaccine-hesitant parents, with the remaining 5 studies not specifically identifying vaccine-hesitant parents prior to administration of the intervention. [32] In the studies not specifically aimed at vaccine-hesitant parents, Williams identified a host of interventions, including multi-component approaches (consisting of information transmission, group discussions, and coaching), communication strategies utilizing loss- and gain-framed messaging, and decision aids, plus vaccination manuals, leaflets, and brochures, significantly associated with improvements in vaccine attitudes, increases in intention-to-vaccinate, and increases in vaccination uptake. [32] However, in studies specifically aimed at VH parents, while noting the potential promise of presumptive communication strategies (utilized by providers), Williams identified no interventions

convincingly demonstrated to counter VH in parents/guardians responsible for the vaccinating status of their school-age child/children. [32]

In response to an observed paucity of studies reviewing the effects of interventions on parent/guardian vaccine refusal/hesitancy, Sadaf et al. (2013) performed a systematic review of English language studies published between July 1, 1990 and July 1, 2012 that:

1. Included only intervention studies with tangible assessment of vaccination or exemption behavior, intention-to-vaccinate, or attitudes toward vaccination;
2. Excluded non-intervention studies and other scholarly articles (e.g. “historical articles”) without tangible outcome assessments;
3. Grouped all identified studies into 3 broad categories by types of intervention, including (a) state school-entry immunization laws, (b) implementation procedures of state immunization laws at state- or school-level, and (c) educational initiatives aimed at parents/guardians (e.g., brochures);
4. Summarized the direction and consistency of effects across the 3 intervention categories on measures of parent/guardian vaccine refusal/hesitancy
5. Judged quality of intervention evidence based on pre-determined and generally-accepted criteria within each reviewed study and across studies grouped into the 3 broad intervention categories [33].

In terms of comparing direction of effect and effect consistency across the three categories of interventions, the effect of parent/guardian-aimed educational initiatives on intention-to-vaccinate and attitudes toward vaccination exhibited the greatest variation in results, which, when coupled with limited confidence in evidence quality, led Sadaf et al. to conclude that the value of this intervention category remains un-demonstrated. [33] Studies assessing the impact of state school-entry immunization laws consistently reported significant associations between laws introducing personal

belief of philosophical exemptions and rising exemption rates, but Sadaf et al. expressed limited confidence in the overall effect estimate of state laws on exemption rates based on concerns about evidence quality. [33] In addition, studies assessing variation in procedural implementation of state immunization laws consistently reported significantly reduced exemption rates associated with 1. early parent/guardian notification of school-entry requirements, 2. presence of a nurse or clinic at school, 3. “exclusion of non-compliant students” [33, p.4297], and 4. increasing complexity of administrative exemption application/procurement procedures, but Sadaf et al. expressed limited confidence in the effect estimate of increased exemption filing complexity on exemption rates due to data-quality concerns. [33] However, despite finding no convincing evidence for the impact of interventions on parent/guardian vaccination refusal – and apparently based on the direction and consistency of the effect of exemption application/procurement complexity on parent/guardian vaccine hesitancy/refusal – Sadaf et al. encouraged public health officials in states with “easy” administrative exemption requirements to make necessary adjustments:

Another important observation that has emerged from our review is the evidence of increasing procedural complexity for obtaining exemptions to curtail the rise in non-medical exemption rates. In some states filing for exemptions may be easier than completing immunization records for school entry and may encourage some parents to seek exemptions. States and schools alike should review their exemption policies to prevent unjustifiable exemptions from being allowed. [33, p.4301]

In the absence of convincing evidence demonstrating the beneficial impact of alternative interventions on parent/guardian vaccine refusal/hesitancy, states with high overall exemption rates or with pockets of high rates at the county level appear to possess few options beyond the ability to adjust the procedural complexity of the exemption application/procurement process.

CHAPTER 2: QUALITATIVE REVIEW, PART B

In addition to 1. tracing the emergence of VH and 2. detailing Peretti-Watel et al.'s critique of VH as a frequently misapplied concept and call to approach VH as a decision-making process, this chapter introduces a new set of guidelines for scholars to consider when invoking VH in their research. By applying these new guidelines to a subset of previously conceptualized VH categories in the scientific literature, this chapter further demonstrates the disadvantages of not approaching VH as a decision-making process; and by applying these new guidelines to existing practical and theoretical models of VH that explicitly link decision-making determinants with actual (or theoretical) vaccinating behaviors, this chapter further demonstrates the advantages of completely approaching VH as a decision-making process.

Parent/Guardian Vaccine Hesitancy as Driver of Increased Non-Medical Exemption Use: The Value of Conceptualizing Parental Vaccine Hesitancy as a Decision-Making Process

Increased use of non-medical exemptions by parents appears closely related to rising levels of vaccine anxiety in parents who, according to Kestenbaum et al., have shifted their focus from the concerns typically associated with VPDs (as the prevalence of VPDs in children has dropped since the 1960s) to concerns related to the safety of vaccines themselves. [34] Original efforts to understand parental fears about vaccine safety were originally grounded in a model, according to Smith et al., that sought to elucidate the decision-making process of parents anxious about the safety of the polio vaccination in the 1950s (following an earlier botched introduction of the vaccine that in some cases actually caused poliomyelitis in vaccine recipients). [35] Although recent introduction of the term “vaccine hesitancy” or VH has seemingly increased conceptual clarity by de-dichotomizing vaccine refusal/acceptance through establishment of a vaccine hesitancy spectrum (allowing for more precise grouping and comparison), Peretti-Watel et al. in 2015 have 1. questioned the utility of VH as a concept based on its definitional ambiguities (and even contradictions); 2. raised the fundamental question as a result: is VH “a

belief/attitude, a behavior, or a decision-making process?” (36, p.3); and 3. proposed their own specific theoretical model approaching VH as a decision-making process linking together parental motivations toward vaccinations (and contextual factors influencing these motivations) and vaccinating behaviors. [36] In other words, it may be helpful to know that many parents fall somewhere in between vaccine acceptance and refusal, but by focusing solely on the behavior of this group of VH parents, according to Peretti-Watel et al., all parents within this group are inadvertently homogenized by placement in a “catch-all” category; as a result, important within-group differences in the beliefs and attitudes driving VH can be lost. [36] For example, Peretti-Watel et al. note that 1. parents who are simply uninformed about (or indifferent to) vaccination and 2. parents who actively seek information about vaccines and consciously elect to selectively delay or refuse vaccination are aggregated in the same category determined by their vaccine hesitant behavior although the beliefs and attitudes driving their VH are significantly different – differences that would presumably preclude utilization of a uniform or “one-size-fits-all” intervention. [36] Peretti-Watel et al. have also noted that conceptualizing VH as a spectrum of behavior can obscure the existence of VH in parents/guardians who still elect to fully vaccinate their child/children. [36]

Absence of General Guidelines for Approaching VH as Decision-Making Process

While offering an insightful critique of VH as a problematic construct and proposing their own specific model that approaches VH as a decision-making process to overcome this deficiency, Peretti-Watel et al. have not sought to create a general set of guidelines for approaching VH as a decision-making process. As a point of departure, the current author seeks to build on the work of Peretti-Watel et al. by 1. proposing an enhanced definitional framework for approaching VH as a decision-making process that researchers can safely employ to avoid the definitional pitfalls related to VH and 2. applying this enhanced definitional framework to previous VH-focused scholarship to demonstrate its value in elucidating the potential disadvantages of not (or incompletely) approaching VH as a decision-making

process and the potential relative advantages of completely approaching VH as a decision-making process .

Proposing an Enhanced Definitional Framework for Approaching VH as a Decision-Making Process

The current author proposes that VH is best approached as an individual decision-making process when strictly meeting the following set of conditions:

- As a process, VH must include two interconnected, but non-overlapping components: (1) parent/guardian decision-making determinants and (2) specific vaccinating behaviors. In addition, decision-making determinants must appear common in each and every conceptualized category of VH-differentiated parents, sufficient for comparative evaluation across the entire range of specific vaccinating behaviors;
- Decision-making determinants, including individual attitudes, beliefs, cognitive styles and predispositions, plus psycho-social influences and environmental conditions/factors, must be adequately specified to enable assessment of informative associations with specific vaccinating behaviors;
- Specific vaccinating behaviors must be tangible and verifiable across the entire range of plausible parent/guardian action, including acceptance, delay, delay and selective refusal, and refusal.

Applying Enhanced Decision-Making Framework to Further Explore Limitations of VH as a Concept

As noted above, introduction of the term “vaccine hesitancy” was initially embraced because it seemed to offer conceptual clarity by placing parents anxious about vaccines on a spectrum, ranging from vaccine-accepting parents to vaccine-refusing parents at the polls, with a heterogeneous group of VH parents, including parents who delay vaccination or selectively refuse vaccinations, occupying the intermediate position. For example, Kestenbaum et al. cite three studies that seemingly illustrate the advantages of sorting parents by degrees of VH into better delineated categories for more precise

comparison based on a wide range of influences, including “relevant social, cultural, political, and personal factors that impact vaccine decision-making.” (34, p.e72) Although Kestenbaum et al. appear to approach VH as a decision-making process by linking together varying levels of parental indecision, influences impacting parental indecision, and vaccine uptake, the researchers do not explicitly call for approaching VH as a decision-making process and do not provide a set of conditions that must be met for this type of approach to be considered valid:

Individuals who are vaccine hesitant are a heterogeneous group who hold varying degrees of indecision about specific vaccines or vaccination in general. Along this spectrum of indecision, there is a range of vaccine uptake, depending on additional influences that move an individual toward or away from ultimately accepting a particular vaccine. (34, p.e72)

However, closer examination of each study cited by Kestenbaum et al. reveals important limitations to approaches that incompletely conceptualize VH as a decision-making process: 1. when parental attitudes and beliefs regarding vaccination are adequately specified to qualify as decision-making determinants – but sporadically identified and not isolated in each and every category of defined parental VH – researchers compromise their ability to identify common decision-making determinants that can be evaluated across the entire range of actual parental vaccinating behavior, 2. when adequately specified decision-making determinants are isolated in each and every category of defined parental VH – but not explicitly linked to the entire range of actual parental vaccinating behavior – researchers compromise their ability to evaluate the effect of isolated parental decision-making determinants across the entire range of actual parental vaccinating behavior, and 3. when parental attitudes and beliefs regarding vaccination – irrespective of their qualification as vaccine decision-making determinants – are aggregated with parental vaccinating behavior by researchers seeking to create distinctive categories of VH parents, researchers compromise their ability to establish an explicit connection between vaccine decision-making determinants and specific parental vaccinating behavior.

Each of the preceding limitations undermined the ability of the researchers referenced below by Kestenbaum et al. to approach VH as a decision-making process:

1. Keane et al. (as briefly described by Kestenbaum et al.) sort parents into 4 categories based on increasing degrees of VH: “(1) convinced of the benefits of vaccination, (2) emotionally invested in their children and cautious about vaccination, (3) more skeptical of vaccine, and (4) distrustful of vaccines and vaccination policies.” [4, p.e72]

Although the sorting method of Keane et al. (as described by Kestenbaum et al.) disaggregates groups of parents based of their degree of VH, the identified attitudes of *confidence* in category 1 parents, *caution* in category 2 parents, *skepticism* in category 3 parents, and *distrust* in category 4 parents appear not to qualify as decision-making determinants (that is, appear insufficiently informative to identify the common source of the 4 attitudes plausibly shaping specific vaccinating behaviors); but Keane et al., in actuality, define a wide range of factors, including concerns over vaccine safety, with adequate specificity to qualify as decision-making determinants. [37] However, the mere utilization of decision-making determinants is not sufficient to qualify an approach to VH as a decision-making process because decision-making determinants must also be isolated in each and every parental category of VH and directly linked to the entire range of tangible and verifiable parental vaccinating behaviors, including acceptance, delay, delay and selective refusal, and refusal. For example, when defining the factors that best predicted membership in each parental category (based on beta-coefficients), Keane et al. identify several factors – including “thinking style” and “emotional investment with child” – common to some but not all parental categories; but this sporadic identification precludes comparisons across the entire range of parental VH-differentiated categories. [37] When Keane et al. identify only one factor – vaccine concern – common to each and every parental category, in contrast, the researchers enable comparisons of this decision-making determinant across the entire range of parental VH-differentiated categories; but since this

approach focuses primarily on defining group membership, the researchers cannot evaluate the effect of this specific factor across the entire range of specific vaccinating behaviors (because they did not collect data related to vaccination delay and selective refusal). [37] That is, although Keane et al. subsequently link the VH-differentiated parental categories to disease-specific parental vaccinating behavior through “parent-reported child vaccination rates for specific disease, by parent group” (37, p.2491), this analysis ultimately lacks the capacity to connect specific decision-making determinants and specific parental vaccinating behaviors. In fact, the analysis actually determines that no significant difference exists in measles vaccination rates between the “Vaccine Believer,” “Cautious,” “Relaxed,” and “Unconvinced” parent categories, yet cannot evaluate (or determine as a result) whether a significant difference exists in vaccine concern expression between parents who elected to fully accept, delay, delay and selectively refuse, or refuse all vaccinations. [37]

2. Streefland et al. (as briefly described by Kestenbaum et al.) group parents from low income-countries into 3 categories of vaccine non-acceptance based on varying degrees of VH: “(1) [those who] are willing to go to immunization centers, but are logistically unable to do so; (2) [those who] refuse to go based on inadequate services, and (3) [those who] question the need for vaccination.” [34, p.e72]

In respect to parents grouped in category (1) and (2), as described by Kestenbaum et al., Streefland et al. appear to establish an explicit connection between vaccine decision-making determinants and vaccinating behaviors: in this case, the decision-making determinant can be defined as an environmental condition – challenges in transportation and service quality infrastructure – and the vaccinating behavior can be defined as non-acceptance (as these parents would have likely accepted vaccines in the event of improved infrastructure). [34] In contrast, Streefland et al. (as described by Kestenbaum et al.) appear not to establish the same type of explicit connection in category (3) parents between vaccine decision-making determinants and vaccinating behavior because the act of

simply questioning the need for vaccination cannot be considered the underlying cause of this group's vaccine refusing behavior (that is, some other factor must have contributed to parental questioning of vaccination necessity in the first place) [34]; but in actuality, Streefland et al. provide adequate specificity in at least one example linking parental concerns about vaccine safety and refusal in the Netherlands. [38] Nevertheless, even in the event of satisfying this requirement of specificity, the approach of Streefland et al. to VH cannot be considered a decision-making process because it appears not to strictly delineate parental decision-making determinants and vaccinating behaviors:

If we want to understand vaccination behaviour, the concepts "active demand" and "passive acceptance" are not sensitive enough as instruments for assessing actual vaccination behaviour. Instead, we propose the basic concepts of "acceptance", "social demand", and "non-acceptance", which has individual and collective forms: "refusal" and "resistance." (38, p.1709)

By expanding the parental vaccinating behavior continuum to include "social demand," Streefland et al. confuse the psycho-social influence of social demand (or group pressure) with an actual vaccinating behavior. This can be best visualized when considering that Streefland et al. utilize level of social demand to distinguish active acceptance ("active demand") from passive acceptance, but fail to recognize that this same psycho-social influence could also be applied to distinguish active refusal (when parents receive social support for non-vaccination) from passive refusal (when parents remain indifferent toward non-vaccination). Since the presence of social demand or group pressure can potentially influence the entire range of parental vaccinating behavior from acceptance to refusal, social demand cannot be appropriately placed on the parental vaccinating behavior continuum; it is more appropriately conceptualized as a decision-making determinant explicitly distinguished from parental vaccinating behavior.

3. Leaske et al., as briefly described by Kestenbaum et al., divide parents into 5 categories based on increasing degree of VH: “(1) unquestioning acceptors, (2) cautious acceptors, (3) parents who are hesitant, (4) late or selective acceptors, and (5) those who refuse all vaccines.” [34, p.e72]

Despite Kestenbaum et al.’s observation that Leaske et al. sort parents into categories of VH according to parental attitudes, Leaske et al. actually divide parents into categories of VH according to parental positions based on a combination of parental attitudes and behaviors in some cases; based exclusively on attitudes in other cases; and based exclusively on behaviors in still other cases. [39] That is, category 1 blends attitude (“unquestioning”) and behavior (“acceptors”), and category 2 blends attitude (“cautious”) and behavior (“acceptors”); while category 3 focuses exclusively on attitude (“hesitant”); and while category (4) focuses exclusively on behavior (“acceptors”), as timing of the behavior or the differential selection of vaccine types cannot be properly considered attitudes, and category (5) focuses exclusively on behavior (refusal). The utilization of positions that in some instances depend on attitudes and in other instances depend only on attitudes or behaviors to categorize levels of parental VH appears to compromise the ability of Leaske et al. to consistently approach VH as a decision-making process because attitudes (or other influences qualifying as decision-making determinants) cannot be sufficiently differentiated, isolated, and evaluated across the entire continuum of actual vaccinating behavior. More specifically, Leaske et al. examine attitudes, beliefs, and cognitive styles, such as trust/distrust in health authorities, self-efficacy, and analytical cognitive-styles, with adequate specificity to qualify as decision-making determinants and then link these determinants to actual vaccinating (or non-vaccinating) behaviors within categories of VH on a sporadic basis, but fail to examine the impact of each of these determinants within each and every category, thereby undermining effective comparisons across the entire range of tangible and verifiable vaccinating behaviors. For example, Leaske et al. identify trust as a possible decision-making determinant in each and every parental position expect “cautious acceptor,” in which they

attribute the parental decision to vaccinate in spite of minor concerns about vaccine safety to a “hope and pray mentality,” but perhaps this mentality represents the decision-making determinant of trust in the health system outweighing the potentially competing determinant of vaccine concern (a reasonable hypothesis given that these parents elect to vaccinate). [39] However, such a determination is impossible to make without the capacity to evaluate the impact of trust in the health system across each and every category of VH and the entire continuum of actual vaccinating behavior.

Applying Enhanced Definitional Framework to Demonstrate Value of Models Approaching VH as Decision-Making Process

As noted above, when VH is not approached (or incompletely approached) as a parental decision-making process, effective comparisons between parent/guardian groups displaying differentiated levels of VH can be compromised. In contrast, models that focus on effectively approaching VH as a decision-making process: 1. identify and/or examine parental attitudes/beliefs/influences or cognitive styles shaping vaccination decisions with adequate specificity to qualify as decision-making making determinants, 2. identify and isolate decision-making determinants in each and every parental category of VH so differences in their effects can be compared across the entire range of actual and verifiable parental vaccinating behaviors, and 3. actually or theoretically maintain strict delineations between parental vaccine decision-making determinants and actual verifiable parental vaccinating behaviors necessary to enable effective comparisons of VH-differentiated parent groups. The following types of models actually (or theoretically) approach VH as a decision-making process:

Health Beliefs Model

In a 2011-published study, based on data collected from the 2009 National Immunization Survey, from data related to a subsample of children aged 19-35 months, Smith et al., in part, analyze correlations between 1. parental beliefs and influences regarding vaccination categorized into four “psycho-social”

domains, including parental beliefs related to risk of VPDS, necessity of vaccination, efficacy of vaccines, and safety of vaccines (note: this category also included other factors potentially influencing parental vaccinating behavior, such as quality of relationship with and trust in health-care providers/medical professionals) and 2. four categories of parental vaccinating behavior, including acceptance (“neither delay nor refusal”), “only delay”, “only refusal” and “delay and refusal.” [35] While reporting important findings: “Compared with parents who neither delayed nor refused vaccines, parents who delayed and refused vaccines were significantly less likely to believe that vaccines are necessary to protect the health of children (70.1% vs. 92.2%), that their child might get a disease if they aren’t vaccinated (71.0% vs. 90.0%), and that vaccines are safe (50.4% vs. 84.9%)” [35, p. 135]; Smith et al. approach VH as a decision-making process because the researchers identify parental beliefs, concerns, or influences with adequate specificity to qualify as decision-making determinants that establish logical/informative connections between parental vaccination belief and behavior without raising questions about the underlying origin/source of belief driving parental vaccinating behavior. That is, VH parents in the study who “only delayed” vaccination were less likely to agree with the statement “vaccines are safe” compared to parents who neither delayed nor refused vaccination for their children. In this example, no uncertainty exists relative to the underlying belief driving parent vaccinating behavior: heightened concerns about vaccine safety drive the behavior of VH parents delaying vaccinations compared to parents less concerned about the safety of vaccines. In addition, Smith et al. effectively identify and isolate decision-making determinants across the entire range of tangible and verifiable parental vaccinating behavior, enabling the researchers to effectively compare differences in the intensity of decision-making determinants as parents moved from acceptance to refusal. In fact, when the researchers themselves invoke the concept of VH, they utilize it to illustrate that the intensity of beliefs questioning VPD susceptibility and vaccines tended to increase as parents moved from acceptance to delay and refusal: “Our analysis suggests that there is a gradient within the psychosocial domains of the

Health Belief Model that signifies that increased parental hesitancy is associated with parents' decision to delay or refuse vaccinations for their child, and that this decision is associated with lower vaccination coverage." [35, p.143] And finally, Smith et al. maintain strict definitional boundaries between parental disease/vaccination beliefs and parental vaccinating behavior by unambiguously defining parental vaccinating behavior through tangible confirmable actions (acceptance, delay, refusal, and delay and refusal). [35]

Bounded Rationality-Based Models

Mathematical models based on bounded rationality also approach understanding VH as a decision-making process by examining the interaction of multiple parameters typically rooted in the health belief model (e.g. parental concerns about disease and vaccinations) and the effects of these highly specified interactions on vaccine uptake on the population level. In a 2015 study, Oraby and Bauch evaluate the predictive power of "disease behavior" models on vaccine uptake by exploring the limitations of previous models based on the "rational actor" theory and by introducing a new model, based on the concept of bounded rationality combined with prospect theory, capable of transcending these limitations. [40] Previous models predicted that efficacious childhood vaccinations cannot reach high levels of coverage across the population due to the "free-rider" problem (that is, the likelihood of parents ceasing vaccination after realizing the protective advantages of herd immunity), but this prediction repeatedly has been proven false by efficacious childhood vaccinations that have consistently reached high levels of coverage (e.g., average school coverage for the MMR vaccine in the United States reached 94.7% in 2013-2014). [40][3] In contrast, the new model has successfully predicted high uptake of efficacious childhood vaccinations because it includes additional parameter estimates, such as the effect of injunctive social norms (or group pressure), which expand commonly held definitions of "good parenting" in the public consciousness to include childhood vaccination in spite of the protection offered by existing herd immunity. [40] This type of mathematical modeling approaches VH as a

decision-making process because the researchers identify highly specified parental beliefs/influence regarding vaccination and explicitly linked these decision-making determinants to (in this case) a proxy for tangible and confirmable parental vaccinating behavior (that is, total vaccination coverage on the population level).

Cognitive Style- and Cognitive State-Based Models

In a 2011 editorial appearing in *Vaccine*, Poland and Poland call for a fundamental reconsideration of parental vaccination education that approaches parental VH as a decision-making process. [41] More specifically, the authors advocate for a new approach expanding beyond the current undifferentiated model that operates under the assumption that all parents share the same cognitive style when making vaccination-related decisions, and subsequently calibrates parental vaccination education exclusively to this style, to a new differentiated model that, in contrast, operates under the assumption that parents rely on individual cognitive styles when making vaccination-related decisions, and subsequently calibrates parental vaccination education to a wider range of cognitive styles (exhibited by a diverse group of parents making vaccination-related decisions). [41] In addition to expanding the types of cognitive styles addressed by parental vaccination education campaigns beyond the “analytical” style to include “denialist,” “innumerate,” “fear-based,” “heuristic,” and “bandwagoning” styles, the authors call for a corresponding expansion of approaches to parental vaccination education specifically fitted to each newly included parental cognitive style. [41] For example, under this new differentiated model, parents exhibiting VH and displaying an “innumerate” cognitive style (that is, a cognitive style characterized by difficulty in understanding/contextualizing numbers and probabilities) would be best served, according to the authors, by an educational approach that “provide[s] nonmathematical information, analogies, or comparators using a more holistic “right brain” or emotive approach.” [41, p.6147] This type of cognitive style-based model approaches VH as a decision-making process because the researchers identify a highly specified grouping of cognitive-styles qualifying as decision-making

determinants that can be potentially correlated to the entire range of confirmable parental vaccinating behaviors (if such a study were ever undertaken), enabling effective evaluation of difference in the intensity of cognitive-style expression across the entire spectrum of parental vaccinating behavior.

Michael Glick links the concept of unfalsifiability to VH by describing the appeal of unfalsifiable beliefs (beliefs that cannot be tested nor subjected to verification or falsification, such as the belief in god, or beliefs immune to verification or falsification even in the presence of adequate testing methods) when scientific rationales for serious human problems remain unavailable (e.g., belief in the link between vaccinations and autism in the absence of other scientific explanations of autism's etiology). [42] The cognitive state of unfalsifiability is similar to the denialist cognitive style listed above, as the denialist "disbelieves accepted scientific fact, despite overwhelming evidence," [41, p.6147] and people holding beliefs with unfalsifiable elements seek to maintain the integrity of their belief even in the presence of evidence that could prove the contrary. [41] Justin P. Friesen et al. investigated the psychological value of utilizing unfalsifiable beliefs both in an offensive function to affirm the value of closely held worldviews on the personal level and in a defensive function to protect such worldviews when challenged by contradictory evidence:

We propose to explore two benefits of unfalsifiability, an "offensive" function that allows people to hold their beliefs more strongly and a "defensive" function that allows people to reconstruct their beliefs behind unfalsifiable justifications and become more resistant to contrary facts. Across four studies, in the context of both religious and political beliefs, we offer the first empirical tests that show that people can derive psychological benefits from worldviews that contain unfalsifiability and can actively shield their beliefs with unfalsifiability in response to threat. [43, p.516]

In addition, Friesen et al. found that strength of belief predicted preference for and reliance on the concept of unfalsifiability: "We also show that individual differences in the strength of religious and political ideology predict the strength to which people prefer and turn to unfalsifiability." [43, p.516]

Although Friesen and collaborators examine the significance of unfalsifiability in the context of religious

and political beliefs, the cognitive state (or predisposition) of unfalsifiability nevertheless qualifies as a decision-making determinant in the context of VH because it displays adequate levels of specificity that could theoretically shape tangible and confirmable parental vaccinating behaviors across the entire range of plausible action: vaccine acceptance, delay, delay and selective refusal, and refusal. As such, researchers could potentially search for significant differences in the intensity of unfalsifiability (belief) expression across the entire continuum of parental vaccinating behavior.

Peretti-Watel et al. Model

Peretti-Watel et al. approach VH as a decision-making process by: 1. identifying a set of interconnected, but non-overlapping decision-making determinants and specific vaccinating behaviors, 2. identifying and defining the decision making determinants of trust (in “health authorities”) and risk culture/healthism (or self-empowerment/-efficacy in health-related matters) with adequate specificity to feasibly shape specific vaccinating behavior, and 3. defining specific vaccinating behaviors linked to varying levels of trust and risk culture/healthism. To do so, Peretti-Watel et al.:

- Create a 4-quadrant, 2-dimensional diagram by placing trust on a vertical axis (or y-axis), which ranges from high trust in health authorities at the top end of the continuum to low trust at the low end of the continuum, and by placing risk culture/healthism on the a horizontal axis (or x-axis), which ranges from low risk culture (or low self-empowerment/-efficacy) at the extreme left end of the continuum to high healthism (or high self-empowerment/-efficacy) at the extreme right end of the continuum;
- Situate individuals who display varying levels of trust in health authorities and varying levels of risk culture/healthism (or self-empowerment/-efficacy in making their own health decisions or decisions for their children) in the appropriate quadrant;
- Correlate quadrant placement with specific (probable) vaccinating outcomes. [36]

For example, under this theoretical framework, individuals exhibiting low risk culture and high trust would be placed in the upper left quadrant, signifying passive acceptance of the need for vaccination from health authorities; and in contrast, individuals exhibiting high healthism and low trust would be placed in the lower right quadrant, signifying active refusal of the need for vaccination from health authorities. [36] This model presented by Perreti-Watel and collaborators meets the strict conditions necessary for approaching VH as a decision-making process because it identifies and isolates the parental decision-making determinants of trust and risk culture/healthism with the specificity required to potentially shape specific parental vaccinating behaviors across the entire spectrum of plausible action; and in doing so, it theoretically enables the making of effective comparisons (that is, the determination of significant differences or not) between the intensity of trust and health expression at and across each and every node on the parental vaccinating behavior continuum.

CHAPTER 3: QUANTITATIVE CASE-STUDY ANALYSIS

This chapter 1. applies the theoretical framework of Peretti-Watel et al., 2. draws upon the scientific literature with findings suggesting an inverse association between complexity of non-medical exemption filing procedures and non-medical exemption rates, and 3. utilizes comparisons of basic proportions, logistic regression analysis, regression analysis for correlated data, and Paired T-test analysis to interpret the results of the natural experiment in school-entry immunization requirement compliance in Traverse City, MI and the results of the MDHHS effort to modify non-medical exemption filing procedures across the state of Michigan.

Results of Natural Experiment in School-Entry Immunization Compliance in Traverse City, MI

The practical import of the theoretical framework introduced by Peretti-Watel et al. is demonstrated by utilizing it to interpret the results of a natural experiment that occurred in Traverse City, MI in 2015, when the administration of Traverse City Area Public Schools (TCAPS) issued recall letters requiring parents/guardians of students in all grades attending school with previously valid non-medical exemptions or incomplete vaccination records to either: 1. fully comply with school-entry immunization requirements through vaccination or 2. meet the new (2015) MDHHS procedural requirement for obtaining a health department-certified exemption by attending a special education program at a local health department focused on the risks of VPDs and the risk/benefits of childhood vaccinations. In May 2015, recall letters were sent to the parents/guardians of 765 students in total, of which 572 attended school with incomplete vaccination records and 193 attended school with waivers originally obtained by parents/guardians downloading, completing, and signing a simple pre-existing form available on the internet and then submitting it to the local school attended by their child/children (figure 1). Of the original 765 students with waivers or incomplete vaccination records in aggregated form, it is not possible to discern the underlying motives driving parent/guardian decision-making and to place these caregivers accurately in the decision-making matrix suggested by Peretti-Watel et al. (figure 2) without

conducting a closer examination of caregiver response to the recall letter. That is, the large proportion of caregivers, “Passive Hesitants” (59.61%, N=456) (figure 1), electing to fully vaccinate their child/children following receipt of recall letter fits into the lower left quadrant labeled as “passive hesitancy” by Peretti-Watel et al. (figure 2) – corresponding to the motives of “passiveness, inaction, and dependence” [36, p.6], as typified by the statements (according to Peretti-Watel et al.): “‘I didn’t think about it,’ ‘I didn’t manage to do it.,’” [36, p.6] – because parents/guardians in this passively hesitant group, when required to take action affirming skepticism or antipathy toward vaccination by attending a special education program at their local health department, instead sought out vaccination, likely shifting their position in the Peretti-Watel et al. matrix from the lower left quadrant of “passive hesitancy” to the upper left quadrant of “passive conformism” (figure 3). In contrast, the proportion of caregivers, “Active Hesitants and Refusers” (40.39%, N=309) (figure 1), electing to attend the special health department education session following receipt of recall letter fits into the lower right quadrant labeled as “rationalized hesitancy” by Peretti-Watel et al. (figure 2) – corresponding to “reflection” and deliberation, as typified by the statements (according to Peretti-Watel et al.): “‘after some deliberation I have decided not to do it,’ ‘I realized that the disease is not serious, that it is not spreading.’” [36, p.6] – because parents/guardians in this actively hesitant and refusing group, when required to take action affirming skepticism or antipathy toward vaccination, elected to attend a special education session at their local health department required for obtaining a non-medical vaccination waiver. Interestingly, following completion of the special education session, a smaller proportion of “active hesitants” (6.66%, N=51) (figure 1) distinguished itself from a larger proportion of “active refusers” (33.72%, N=258) (figure 1) – possibly due to differential levels of trust in health authorities – by electing to fully vaccinate their child/children in accordance with school-entry vaccination requirements (figure 1) and thereby likely shifting their position into the upper right quadrant of the Peretti-Watel et al. matrix labeled “enlightened conformism” (figure 3), while members of the larger “active refusers” group maintained

their position in the lower right quadrant of the Peretti-Watel et al. matrix labeled “rationalized hesitancy” (figure 3) by electing to obtain health department-certified waivers (figure 1).

Figure 1: Results of Traverse City, MI Natural Experiment in School-Entry Immunization Requirement Compliance

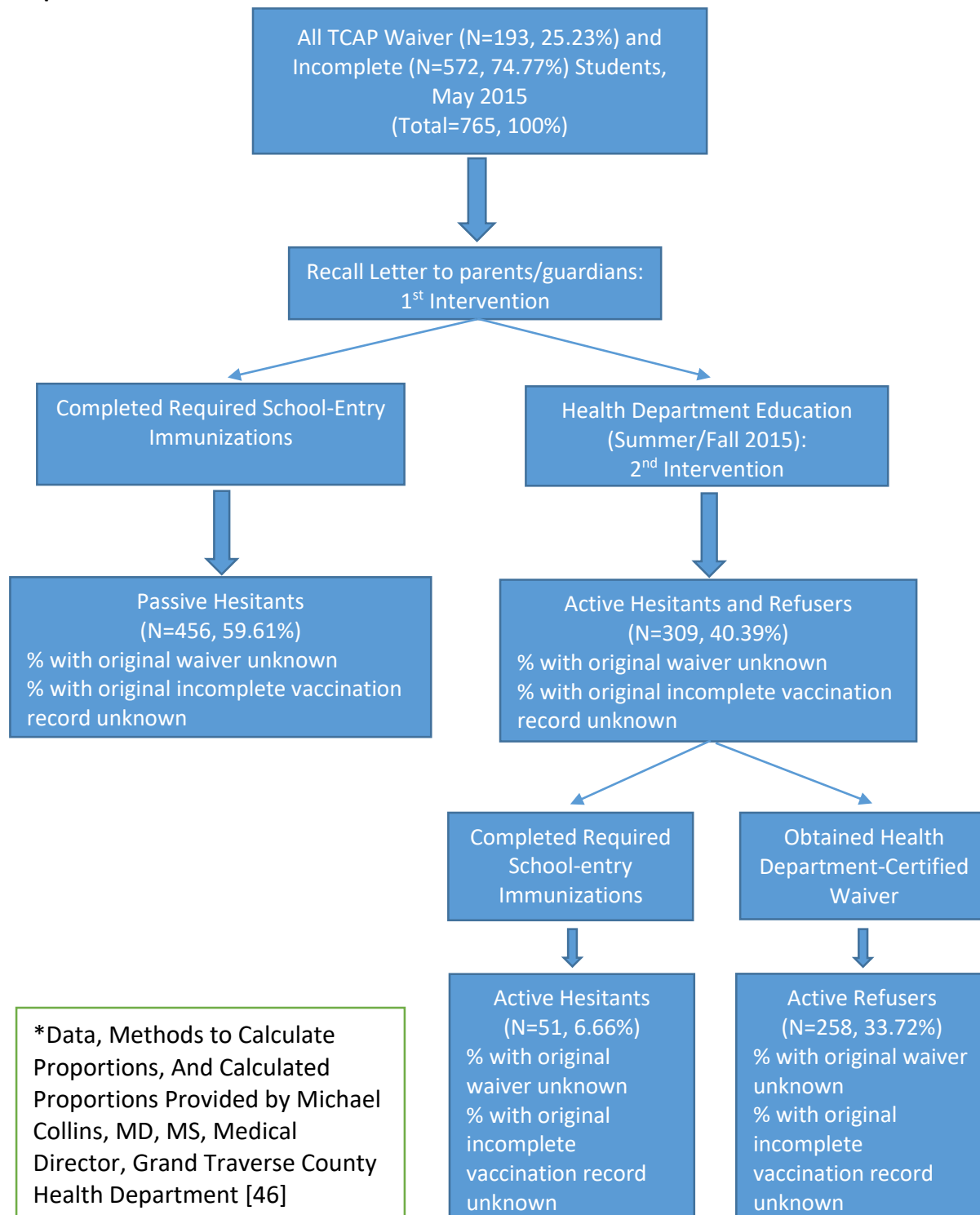
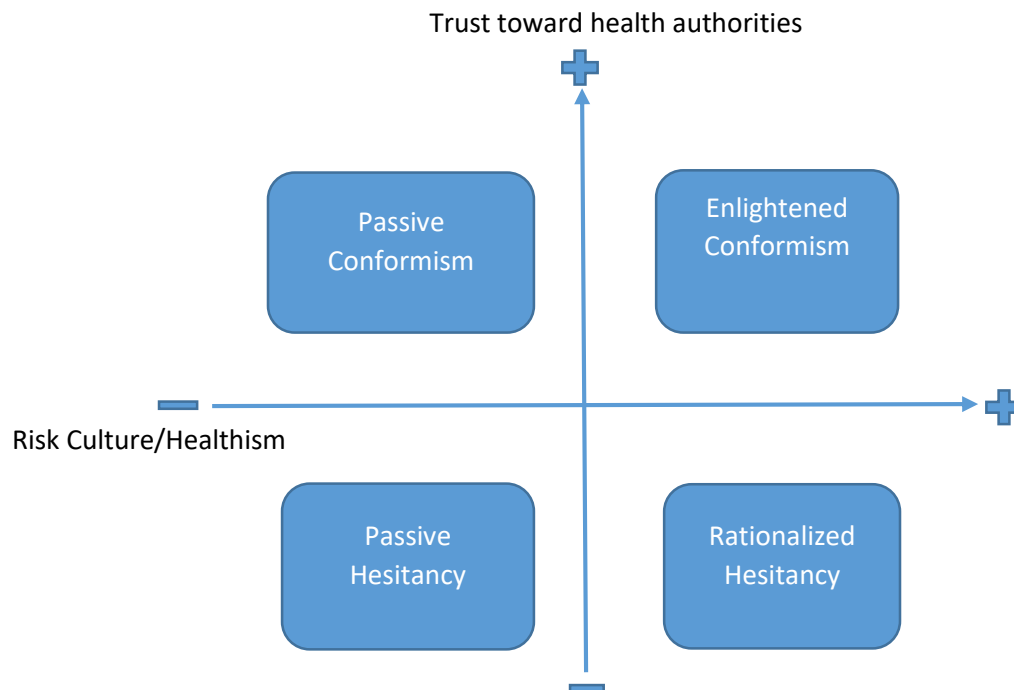
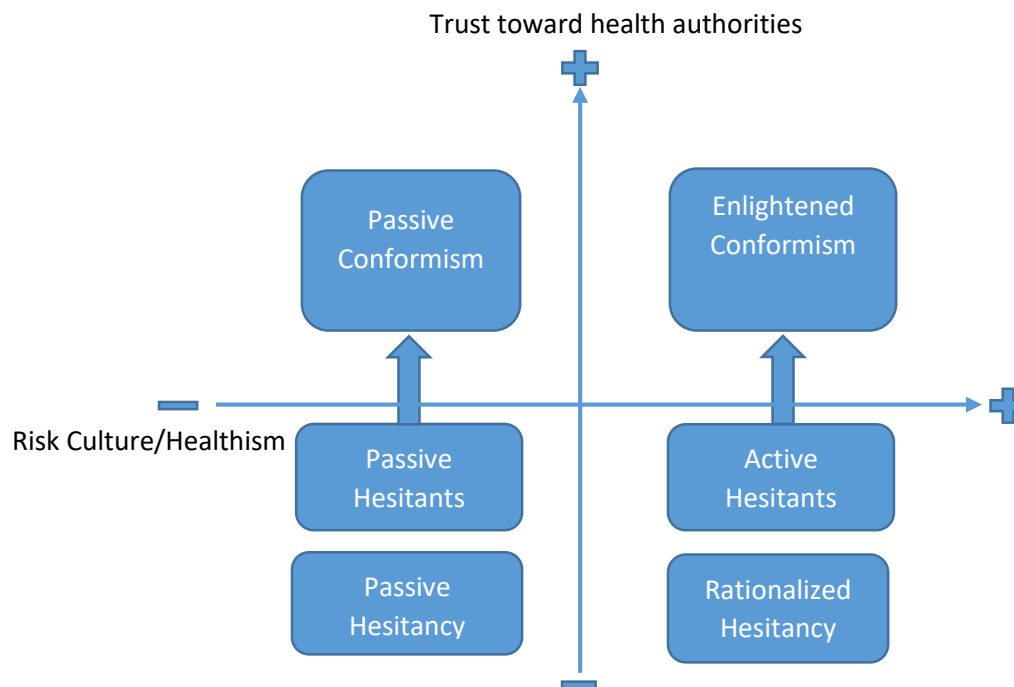


Figure 2: “VH along two axes: commitment to risk culture/healthism (horizontal axis) and distrust/trust toward health authorities”* (prior to exemption procedural change in Traverse City)



*Source: Peretti-Watel et al. [36]

Figure 3: “VH along two axes: commitment to risk culture/healthism (horizontal axis) and distrust/trust toward health authorities”* (following exemption procedural change in Traverse City)



*Source: Peretti-Watel et al. [36], plus author interpretation

The practical import of the Peretti-Watel et al.'s theoretical framework is also affirmed by utilizing it to interpret the results of the survey administered by local health department officials in Grand Traverse County on a voluntary and anonymous basis to the parents/guardians of 309 students with incomplete vaccination records or non-medical waivers who elected to complete the special education session following receipt of the recall letter (figure 1) and to an unknown number of parents/guardians both inside and outside TCAPS who elected to meet the requirement for obtaining a new health department-certified non-medical waiver by first attending the special education program. While the survey was ostensibly designed to assess potential associations between the perceived informational value – beyond what was already known by parents/guardians – of the three major educational components of the session (measured on a 3-pt scale: a=3=[learned] “a great deal;” b=2=[learned] “a little;” and c=1=[learned] “hardly anything”), including 1. VPD risk to own child/children, 2. non-vaccination risk to wider community, and 3. school exclusion risk in outbreak situations, and intention-to-vaccinate (measured on 10-pt scale: 1=“won’t vaccinate;” 10=“will vaccinate;”), the survey results represent not so much an assessment of the quality of the special education program as a representation of the pre-disposition of the survey respondents toward a high degree of healthism on the X-axis in the Peretti-Watel et al. matrix (figure 2, quadrants 1 and 2). Such expression of healthism (i.e., self-empowerment/-advocacy in VPD/vaccination knowledge attainment) is reflected in the high frequency of [learned] “hardly anything” or [learned] “a little” responses to the first question focused on assessing the perceived informational value of VPD risk in the family (cumulative percent of both responses: 90.71%), to the second question focused on assessing the perceived informational value of non-vaccination risk in the community (cumulative percent of both responses: 95.68%), and to the third question focused on assessing the perceived informational value of school exclusion risk (cumulative percent of both responses: 86.33%) (tables 6-8).

Table 6: Perceived Value of Health Department-Presented Information on VPD Risk to Other Children in Immediate Family

VPIs	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	70	50.00	70	50.00
2	57	40.71	127	90.71
3	13	9.29	140	100.00
Frequency Missing = 4				

Table 7: Perceived Value of Health Department-Presented Information on Non-Vaccination Risk to Wider Community

Community	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	84	60.43	84	60.43
2	49	35.25	133	95.68
3	6	4.32	139	100.00
Frequency Missing = 5				

Table 8: Perceived Value of Health Department-Presented Information on School Exclusion Risk

Exclusion	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	56	40.29	56	40.29
2	64	46.04	120	86.33
3	19	13.67	139	100.00
Frequency Missing = 5				

[The output for tables 6, 7, and 8 was generated using SAS software, Version 9.4. Copyright © 2016. SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA]

Information presented on school exclusion risk by the local health department appears to be more informative (highest frequency, N=19, of [learned] “a great deal”) to the respondents than information related to VPD risk in the family and non-vaccination risk in the community in tables 6-8; and the school exclusion variable is the only response variable significantly associated ($p < 0.0061$) with greater odds of intention-not-to-vaccinate (the outcome variable), when dichotomized into 1=“won’t vaccinate” versus 2-10=“will vaccinate” (due to the high frequency of “1” responses: 63/144, with 6 missing values), in a

main effects model including all three response variables (school exclusion risk, plus VPD risk and non-vaccination risk) dichotomized into [learned] “hardly anything” versus [learned] “a great deal” and “a little” (table 10, appendix). In other words, learning “hardly anything,” compared to learning “a little” or “a great deal,” about VPD and non-vaccination risk has no significant effect on intention-not-to-vaccinate, while learning “hardly anything,” compared to learning “a little” or “a great deal,” about school exclusion risk has a significant effect on intention-not-to-vaccinate. The absence of a stronger contrast between the learning hardly anything and “learning more” responses to questions evaluating the perceived value of health department-presented information on VPD/non-vaccination risk – and the presence of a stronger contrast between the learning hardly anything and “learning more” responses to the question evaluating the perceived value of health department-presented information on school exclusion risk – may indicate that respondents disregarded health department-presented information on VPD/non-vaccination risk in favor of other information mitigating against vaccination previously obtained through their own self-directed research/advocacy efforts (i.e., healthism expression) more readily than they disregarded health department-presented information on school exclusion risk. The existence of this stronger contrast in response levels to the question evaluating the perceived value of health department-presented information on school-exclusion risk can be further demonstrated through a comparison of the conditional probabilities between parents/guardians who marked “1” on the intention-to-vaccinate scale (indicating intention-not-to-vaccinate): parents/guardians who marked [learned] “hardly anything” exhibited more than a 2-fold higher probability of intention-not-to-vaccinate compared to parents/guardians who marked [learned] “a little” or “a great deal” (66.07% versus 30.00%) (table 11, appendix). The comparative receptiveness to the health department message regarding school exclusion risk may relate to: 1. absence of competing sources of authority on school exclusion risk existing outside the health department (as health departments typically establish school exclusion policies in outbreak situations) or 2. higher levels of trust afforded to the health department

on school exclusion risk compared to VPD risk in families and non-vaccination risk in the wider community (although trust levels were not assessed as part of the survey instrument). Importantly, this survey interpretation only applies to a special population of actively hesitant (including actively refusing) parents/guardians either responding to the recall letter or seeking new health department-certified non-medical exemptions for their child/children; and within this special population, additional selection bias may be present due to the greater propensity of actively refusing parents/guardians to complete the voluntary survey in the first place. Despite these limitations, the survey results open a valuable window into the relative receptiveness of actively refusing parents/guardians to health-department information regarding school exclusion risk.

The results of the 2015 Traverse City, MI natural experiment in school-entry immunization requirement compliance are consistent with the findings of Rota et al., Blank et al., Omer, Pan, et al., Omer, Richards et al., and Salmon et al. that reported an observed inverse association between general complexity of non-medical exemption filing procedures and non-medical exemption rates. [8][9][6][7][25]

Interpretation of the results is complicated by 1. the total population of interest (N=765) (figure 1) including a mixture of students with non-medical waivers (N=193, 25.23%) (figure 1) and incomplete vaccination records (N=572, 74.77%) (figure 1) and 2. absence of the following information:

- Exact number/percentage of parents/guardians of students with incomplete vaccination records (N=572, 74.77%) (figure 1) or waivers (N=193, 25.23%) (figure 1) following receipt of recall letters from the school system who ultimately elected to 1. fully vaccinate their child/children or 2. attend the required special education session at the local health department (figure 1);
- Exact number/percentage of parents/guardians of students with incomplete vaccination records (N=572, 74.77%) (figure 1) or waivers (N=193, 25.23%) (figure 1) following attendance at the special education session who ultimately elected to 1. fully vaccinate their child/children or 2. obtain a certified, health department-approved non-medical waiver (figure 1);

- Exact number/percentage of parents/guardians of students attending school with waivers originally obtained under the simplified school-based procedure (N=193, 25.23%) (figure 1) following receipt of recall letters who ultimately elected to fully immunize their child/children (figure 1).

This missing information prohibits a direct comparison of non-medical exemption rates between “passive hesitant” and “active hesitant and refusers” following first intervention (receipt of recall letter) (figure 1) and between “active hesitant” and “active refusers” following second intervention (completion of health-department-based special education program) (figure 1). Without the capacity to directly compare non-medical exemption rates in these subgroups of interest, it is theoretically possible, albeit unlikely, that parents/guardians of the same 193 students who originally procured non-medical waivers for their child/children under the simplified, school-based filing system elected to file for a certified, health-department-approved replacement waiver following receipt of the recall letter and completion of the health department-based special education program. In this theoretical scenario, parents/guardians of these 193 students would need to be joined by parents/guardians of 65 students who originally attended school with incomplete vaccination records to reach the 258 students with parents/guardians falling into the “active refuser” category (figure 1). However, after temporarily setting aside this remote theoretical possibility, the following is clearly evident: that while a minority of parents/guardians of students with waivers or incomplete vaccination records (258/765 or 33.72%) (figure 1) ultimately elected to obtain a certified, health department-approved non-medical waiver after receipt of recall letter and attendance at the special education session, a strong majority of parents/guardians of students with waivers or incomplete vaccination records (456/765 or 59.61%) elected to fully vaccinate their child/children following receipt of recall letter and replacement of a relatively simple non-medical exemption filing procedure (i.e., completing and returning a pre-existing form available on the internet to a local school) with a more complex procedure requiring

parents/guardians to obtain a certified, health department-approved non-medical waiver through completion of a special education program focused on VPD risk and vaccination risks/benefits.

In addition, the results of the 2015 Traverse City, MI experiment in school-entry immunization requirement compliance are not only consistent with the findings that 1. Traverse City is known to exist within a previously identified non-medical exemption cluster [13] and 2. non-medical exemption rates in Grand Traverse County (the county in which Traverse City is located) have exceeded the corresponding median rate for all counties for several years leading up to the 2015 exemption filing procedure rule change (table 2), but are also consistent with the findings that select local population characteristics of Traverse City from 2010-2014 were similar to population characteristics that have been previously associated with vaccine delay/refusal and exemptions. For example, in Traverse City over the 2010-2014 period, approximately 40% of the adult population, aged 25 and older, held a bachelor's degree or higher (compared to the state mean of 26.4%) (Table 9) and 96.4% of the population, aged 5 and older residing at home, spoke English (compared to the state average of 90.1%) (Table 9); and in a 2009 national study (cross-sectional) of parents of children aged 24-36 months, Smith et al. reported 1. statistically significant ($p < .05$) higher proportion of households including a mother preferring to speak English who delayed and refused vaccination (98.2%), compared to households including a mother preferring to speak English who neither delayed nor refused vaccination (84.5%), and 2. statistically significant ($p < .05$) higher proportion of households including a mother with a college degree who delayed and refused vaccination (44.9%), compared to households including a mother with a college degree who neither delayed nor refused vaccination (32.1%) [35], and in a case-control study conducted in 4 states over the 2002-2003 period, Salmon, Moulton, et al. reported a statistically significant ($p < .02$) higher proportion of parents of exempt children exhibiting levels of education beyond "some college" (the median level of education in the study) (57.6%), compared to parents of vaccinated children exhibiting educational levels beyond some college (47.2%). [45]

Table 9: Select Population Characteristics of Traverse City, MI and State of Michigan*

Geographic Unit	Estimated population (2015)	Proportion of persons in home, aged 5 or older, speaking language other than English (2010/14)	Proportion of adults, aged 25 or older, with high school diploma or higher (2010/14)	Proportion of adults, aged 25 or older, with Bachelor's degree or higher (2010/14)	Median household income (2010/14)
Traverse City, MI	15,218	3.6% 	95.0%	40.6% 	\$47,836
Michigan	9,922,576	9.1% 	89.3%	26.4% 	\$49,087

*Data Source: <http://www.census.gov/quickfacts/table/PST045215/26,2680340,26055> [44]

Results of MDHHS Efforts to Reduce Non-Medical Exemption Rates Across Michigan

Similar to the results of the “natural experiment” in school-entry immunization requirement compliance that occurred in Traverse City, MI over the summer/fall 2015, the results of the MDHHS effort to implement a new administrative rule across the state of Michigan that required parents/guardians seeking non-medical waivers for public and private school students entering kindergarten, 7th grade, or a new school district prior to commencement of the 2015-2016 school year (or for students transferring school districts in spring 2015) to expend additional time/effort obtaining a health department-certified waiver through completion of a special education program focused on VPD risk and risks/benefits of vaccination, compared to the cohort of parents/guardians seeking non-medical exemptions for students entering kindergarten, 7th grade, or a new school district under the simplified, school-based system in the previous year, are consistent with the observations of Rota et al., Blank et al., Omer, Pan et al., Omer, Richards et al., and Salmon et al. reporting an inverse association between general complexity of non-medical exemption filing procedures and increased non-medical exemption rates [8][9][6][7][25] and the observations of Bradford and Mandich reporting a nonsignificant association (at $p < 0.10$ level) between the specific requirement for health departments to approve exemptions and decreasing exemption rates. [24] Prior to the MDHHS non-medical waiver filing rule change, ten Michigan counties, including Allegan, Branch, Cass, Hillsdale, Huron, Kalamazoo, Muskegon, Ottawa, St. Joseph, and Van Buren, had required parents/guardians seeking non-medical exemptions for their child/children to

complete an additional educational requirement, but 73 Michigan counties, plus the city of Detroit, still operated under the former school-based non-medical exemption filing system. Across 73 examined counties, plus the city of Detroit, the mean non-medical exemption rate decreased from 4.69% in the pre-intervention period to 3.21% in the post-intervention period, resulting in a 31.5% reduction. In utilizing two distinct methods to analyze the difference in non-medical exemption rates in these 73 counties and Detroit between the period immediately preceding (i.e., the 2014/15 school year) and the period immediately following (i.e., the 2015/16 school year) implementation of the MDHHS non-medical waiver filing procedure change for statistical significance, the primary method of pre-/post-regression analysis – selected due to the highly correlated nature of the pre-post data (exchangeable working correlation = 0.8) – yielded a result of significantly lesser odds (OR: 0.61; 95CI: 0.55, 0.67) of children attending school with a non-medical exemption in the post-intervention period, compared to the pre-intervention period (table 12, appendix), in a model assessing the effect of pre-intervention and post-intervention time variables on the binary outcome of event/non-event (that is, non-medical exemption OR medical exemption, incomplete vaccination record, provisional vaccination status, or completed vaccination status) (table 13, appendix); and the secondary method of paired T-test analysis yielded a significant result ($p < .0001$) (table 14 and figure 4, appendix), allowing for rejection of the null hypothesis that the mean difference between pre-intervention mean non-medical exemption rates (4.69%) and post-intervention mean non-medical exemption rates (3.21%) equals 0. However, caution must be exercised when interpreting the above regression and paired T-test results because randomization and control groups could not be utilized in this observational setting; and, as a result, it is possible that the observed effect of the MDHHS rule change might have resulted alternatively from the influence of other non-measured variables operating in the examined Michigan counties. [Cristi Bramer, Vaccine Preventable Disease Epidemiologist, MDHHS, provided raw data and suggested Paired T-test method of analysis. Author responsible for any errors in data transformation, analysis, and interpretation].

Results of State and Traverse City, MI Efforts Examined Together

The results of the effort by MDHHS to modify non-medical exemption filing procedures have implications for the results of the Traverse City, MI natural experiment in school-entry immunization compliance and vice versa. That is, the reduction observed in non-medical exemption rates between the two cohorts of parents/guardians filing non-medical exemptions for their child/children pre-/post-intervention in the 73 Michigan counties, plus city of Detroit, implies that some parents/guardians pre-disposed toward filing non-medical exemptions modify their behavior when faced with more complex filing procedures; and when applied to the Traverse City natural experiment, this vaccination modifying behavior observed at the state level suggests that at least a small proportion of parents/guardians originally filing non-medical exemptions under the simplified, school-based system (N=193) (figure 1) in Traverse City elected to fully vaccinate their child/children when faced with the new requirement to visit the health department, which, in turn, suggests that the total number of active refusers (N=258) (figure 1) is not equal to a simple sum of the 193 students originally attending school with non-medical waivers plus 65 students originally attending school with incomplete vaccination records. In other words, the total number of “passive hesitant” (N=456) (figure 1) likely includes an undiscernible number of students originally attending school with non-medical exemptions. The results of the natural experiment in Traverse City have even more profound implications for the results of the MDHHS rule change across the state of Michigan. That is, the natural experiment in Traverse City demonstrates that:

1. significant state-level reductions in non-medical exemption rates observed through county level (plus city of Detroit) pre-/post-intervention analysis are likely attributable to minimizing the number of passively and actively hesitant parents/guardians seeking non-medical exemptions for their child/children by making non-medical exemption filing procedures more complex and by providing a special education program;
2. an unknown proportion of parents/guardians responsible for their child/children attending school with incomplete vaccination records likely fall into the category of active

refusers and would file non-medical exemptions for their child/children if required to comply with school-entry immunization requirements.

CONCLUSION

In addition to reviewing the scope and nature of the non-medical exemption problem in the United States and Michigan; key linkages between non-medical exemption rates, non-medical exemption filing procedures, and risk of VPDs; and recommendations to increase the complexity of non-medical exemption filing procedures despite a lack of convincing evidence supporting utilization of any intervention to counter vaccine-exempting/refusing behavior in parents/guardians responsible for the exemption/vaccination status of their school-age child/children, this thesis generates knowledge by:

1. Building on the previous scholarship of Peretti-Watel et al. to introduce a set of guidelines for researchers to consider when invoking the concept of VH;
2. Employing Peretti-Watel et al.'s theoretical framework to interpret the results of the natural experiment in Traverse city, MI and related health-department survey results;
3. Applying the results of the Traverse city, MI natural experiment to interpret the results of the MDHHS effort to modify non-medical exemption filing procedures and vice versa;
4. Demonstrating consistency of results between (a) findings in the scientific literature pointing toward an inverse association between complexity of non-medical exemption filing procedures and non-medical exemption rates and (b) results of the Traverse city, MI natural experiment and the MDHHS effort to modify non-medical exemption filing procedures.

However, additional research is necessary to address a limitation of this study – the potential complicating role of measles and pertussis presence in the Traverse City area prior to commencement of the natural experiment there – by seeking to replicate results of the Traverse City natural experiment in an area of Michigan with high proportions of students attending school with incomplete vaccination records and still attending school with non-medical exemptions obtained under the previously simplified, school-based system (following implementation of the MDHHS rule change), but free of a recent VPD outbreak. Such an experiment would control for the potential confounding or modifying

effect of an intensified perception of VPD risk on parent/guardian response to the recall letter issued by TCAPS officials. In addition, while exploring the decision-making process of passively hesitant, actively hesitant, and actively refusing parents/guardians responsible for the vaccination/exemption status of their child/children, this thesis examines the effect of an intervention (i.e., modification of non-medical exemption filing procedures) appearing correlated with improved outcomes (i.e., reduction of non-medical exemption rates) only in passively hesitant and actively hesitant parent/guardian groups, but not in the actively refusing parent/guardian group. As a result, additional research is needed focusing on the actively refusing parents/guardians who elected to file non-medical exemptions for their child/children following completion of a special educational program at a local health department, with the aim of focus-group discussions to 1. assess the effects of the current educational approach on the healthism/distrust tendencies of this actively refusing parent/guardian group and 2. identify new interventions and possible entry points to falsify previously unfalsifiable beliefs about the trustworthiness of health professionals/vaccine-delivery system and to harness the power of healthism tendencies (to create more collaborative and mutually trust-enhancing relationships with health authorities) in this actively refusing parent/guardian group.

APPENDIX

Table 10: Parameter Estimates for VPD Risk, Non-Vaccination Risk, and School Exclusion Risk

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square	Pr > ChiSq
Intercept	1	-1.1558	0.3211	-1.7852	-0.5264	12.95	0.0003
dummy_VPIs	1	-0.2132	0.5685	-1.3275	0.9010	0.14	0.7076
dummy_Community	1	0.8490	0.5634	-0.2552	1.9532	2.27	0.1318
dummy_Exclusion	1	1.2335	0.4495	0.3526	2.1144	7.53	0.0061
Scale	0	1.0000	0.0000	1.0000	1.0000		

Table 11: Comparison (in Red) of Conditional Probabilities: Parents/Guardians Who [learned] “hardly anything” Versus [learned] “a little” or “a great deal” about School Exclusion Risk on Intention-Not-To-Vaccinate

Frequency Percent Row Pct Col Pct	Table of dummy_vac by dummy_Exclusion			
	dummy_vac	dummy_Exclusion		
		0	1	Total
	0	56 41.18 74.67 70.00	19 13.97 25.33 33.93	75 55.15
	1	24 17.65 39.34 30.00	37 27.21 60.66 66.07	61 44.85
	Total	80 58.82	56 41.18	136 100.00
Frequency Missing = 8				

Table 12: Results of Pre/Post MDHHS Rule Change Regression Analysis

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > Z
Intercept		-2.9942	0.0977	-3.1858	-2.8027	-30.63	<.0001
Time	post	-0.4891	0.0562	-0.5993	-0.3789	-8.70	<.0001
Time	pre	0.0000	0.0000	0.0000	0.0000	.	.

Table 13: Outcome and Parameter Specifications for Pre/Post MDHHS Rule Change Regression Analysis

Response Profile		
Ordered Value	Binary Outcome	Total Frequency
1	Event	29130
2	Nonevent	721118

Parameter Information		
Parameter	Effect	Time
Prm1	Intercept	
Prm2	Time	post
Prm3	Time	pre

Table 14: Results of Pre/Post MDHHS Rule Change Paired T-Test Analysis

Difference: rtonmedbefore - rtonmedafter

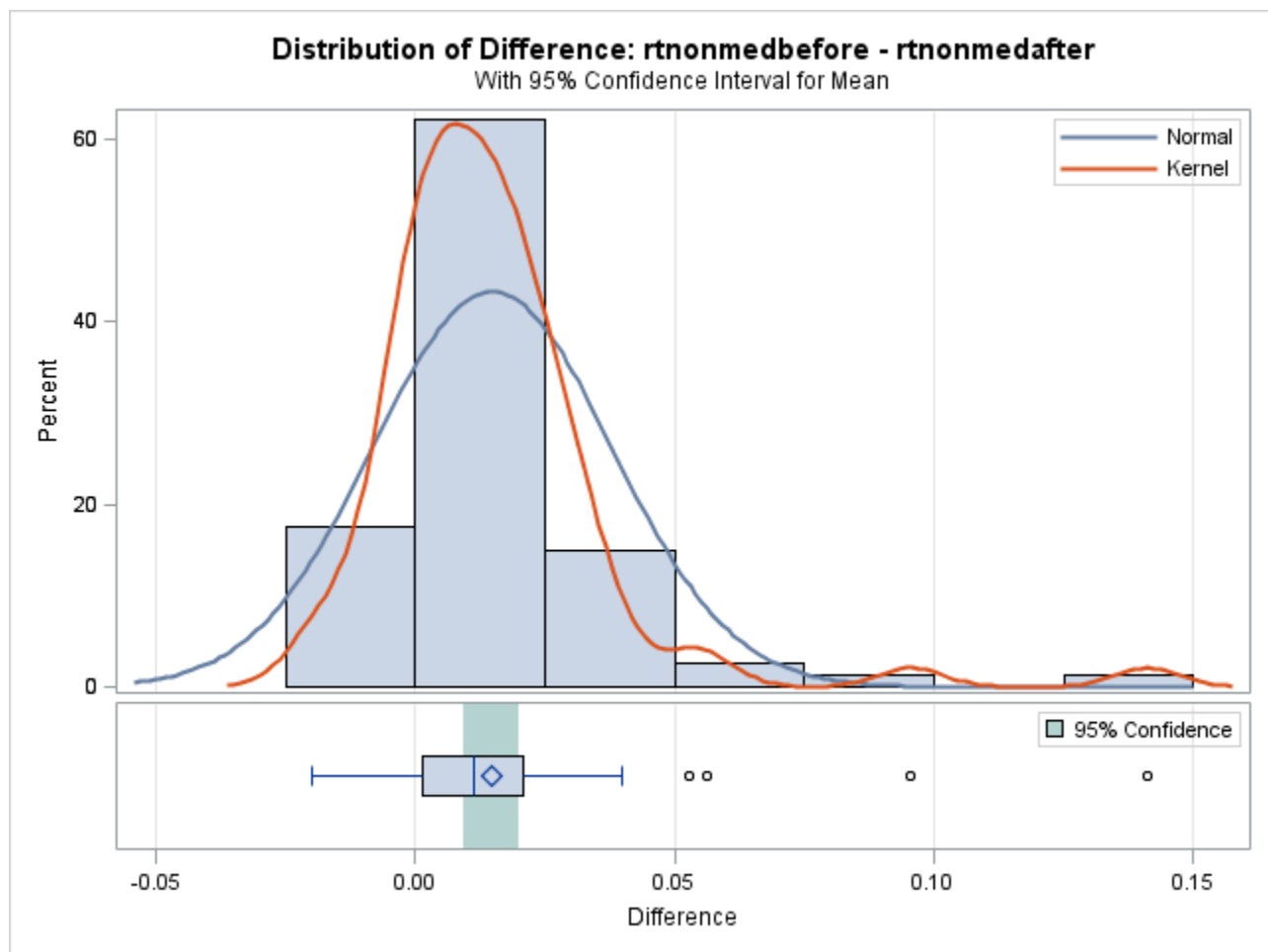
N	Mean	Std Dev	Std Err	Minimum	Maximum
74	0.0149	0.0230	0.00268	-0.0199	0.1412

Mean	95% CL Mean	Std Dev	95% CL Std Dev
0.0149	0.00952 0.0202	0.0230	0.0198 0.0275

DF	t Value	Pr > t
73	5.55	<.0001

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Figure 4: Results of Pre/Post MDHHS Rule Change Paired T-Test Analysis



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