

Pfizer Independent Grants for Learning & Change
Grant ID 23087301

The Cognitive Decision-Making Process of Vaccine Hesitant Parents:

Uncovering Personal Stories, Reasoning Biases, and Flawed Causal Knowledge to Develop and Test a Knowledge-Tailored Vaccine Educational Toolkit

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The goal of this project is to increase completion rates of pediatric immunization series by developing and testing an innovative, knowledge-tailored educational toolkit informed by an exploration of vaccine-hesitant parents' cognitive decision-making (e.g., their personal vaccine stories, reasoning biases, and the ensuing flawed causal knowledge). The primary audience for this study is the vaccine-hesitant parents who request nonmedical vaccine waivers for their children ages 6 and under and attend a mandatory vaccine education class at Michigan's Genesee County Health Department. The research will be conducted by an inter-disciplinary research team that includes researchers and practitioners from pediatrics, immunization and marketing fields. The research team will elicit parents' deep-rooted and complex vaccine stories with a story/situation-based script and record key story elements, parents' flawed causal knowledge about the safety and need of vaccines, and underlying reasoning biases. The research team will develop an innovative, knowledge-tailored vaccine educational toolkit that corrects parents' flawed causal knowledge by addressing their reasoning biases within their very own vaccine stories. The effectiveness of this toolkit will be tested against the State of Michigan's current, untailed vaccine educational program. This will be achieved by comparing the change in parental attitudes towards vaccines and the change in vaccination rates for the two groups of parents – the baseline group (parents who will have received the State of Michigan untailed vaccine education program), and the intervention group (parents who will have received the knowledge-tailored educational toolkit).

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RESPONSE TO REVIEWER COMMENTS (Section C)

We are very happy to learn that the review panel found our **research program to be well developed, innovative, and to address the Request for Proposal**. The members of this interdisciplinary research team take great interest in the topic of pediatric immunization, both professionally and personally, as parents of young children living in communities with dwindling pediatric immunization rates. We have thought deeply about the cognitive causes of delayed vaccination and refusal to vaccinate infants and children and believe we have identified innovative ways to address them. We have worked hard to present these ideas in a systematic and scientifically rigorous manner in both the initial letter of intent and the current proposal. Thank you for your recognition of our work!

We understand that some panelists felt the **budget** requested may be excessive. We appreciate this input and now provide extensive details on the complexity and depth of work needed to complete this innovative research program. A few of tasks are listed below; a comprehensive list can be found in the *Project Design and Methods* and the *Detailed Workplan and Deliverables Schedule* sections.

Little more than 70% of the requested funds are allocated toward direct labor costs for the principal investigators and the GCHD participating staff. These funds will support *extensive qualitative, non-automated research* of the cognitive decision-making processes of an estimated *880 vaccine-hesitant parents* and will inform the proposed vaccine educational toolkit. The following tasks are proposed:

- Investigation of reasons for not following recommended pediatric immunization schedules and of complex vaccine stories provided by 880 parents.
- Qualitatively and reiteratively coding the list of reasons provided by 880 parents when asked about not following recommended pediatric immunization schedules.
- Qualitatively and reiteratively coding the complex vaccine stories provided by 880 parents in response to the situation/story-based script (i.e., document key story elements such as the people, their actions, behaviors, feelings, location and events).
- Qualitatively and reiteratively coding the flawed causal knowledge 880 parents possess about the safety and need of vaccines.
- Identifying and classifying 880 parents' reasoning biases that underlie their flawed vaccine causal knowledge.
- Providing a vaccination message tailored to parents' vaccine stories and reasoning biases for 440 parents (the intervention group).

This reiterative and arduous work will be supported by *extensive and thorough reviews of the psychology, marketing, medical, and political science literatures* which will identify a comprehensive list of reasoning biases and current effective messages to counteract them. These counteracting messages, embedded in parents' vaccine stories, will represent the core of the proposed vaccine educational toolkit.

OVERALL GOAL & OBJECTIVES (Section D1)

The goal of this project is to increase completion rates of pediatric immunization series by developing and testing an *innovative, knowledge-tailored educational toolkit* informed by an exploration of *vaccine-hesitant parents' cognitive decision-making* (e.g., their personal vaccine stories, reasoning biases, and the ensuing flawed causal knowledge). Parent causal beliefs about vaccine safety and need represent significant barriers to immunization series completion and have been identified as the source of recent vaccine-preventable disease outbreaks in the U.S.¹⁻⁶ The need to research the underlying cognitive processes that give rise to these erroneous beliefs is heightened by increasing coverage of vivid and sensational stories produced by the anti-vaccination movement and by recent attacks on vaccine programs by politicians in the popular media.⁷

We will pursue this goal within the realm of a well-timed collaborative effort between the University of Michigan (UM) and the Genesee County (Michigan) Health Department (GCHD). Our goal of increasing pediatric immunization rates is fully aligned with UM's goal to excel in medical education, patient care and research, and GCHD's mission to prevent diseases and promote health among its residents. As of January 1, 2015, the GCHD became the Genesee County's *sole provider of mandatory non-medical vaccine waivers* for children enrolled in public or private daycare centers, preschools or primary schools showing incomplete immunization records. As part of releasing vaccine waivers, the GCHD staff requires that vaccine-hesitant parents visit the health department and attend a short one-on-one education class on vaccine risks and benefits provided by the county's nurses.

The **first objective** is to uncover the underlying *cognitive decision-making processes* that give rise to flawed causal knowledge about vaccines. In order to achieve this objective, we will capture parents' complex *vaccine stories*, which involve friends, family and acquaintances, as well as children who may have experienced adverse outcomes coinciding with the timing of vaccine schedules. Within these vaccine stories, we will document parents' *reasoning biases* (e.g., disregard of non-visible causes of adverse outcomes or causal discounting bias), which have led to parents acquiring flawed causal knowledge about the need for and safety of vaccines.

The **second objective** is to develop an *innovative, knowledge-tailored vaccine educational toolkit* aimed at correcting parents' flawed causal knowledge by addressing the reasoning biases within their very *own vaccine stories* (e.g., by exposing non-visible causes of adverse outcomes).

The **third objective** is to *test the effectiveness* of the knowledge-tailored vaccine educational toolkit against the State of Michigan's current, untailored vaccine educational program. The effectiveness of the proposed toolkit will be assessed within the entire GCHD system and measured as change in both parental attitudes toward vaccines and as completion rates of pediatric immunization series.

CURRENT ASSESSMENT OF NEED IN TARGET AREA (Section D2)

Michigan and Genesee County have an underimmunized pediatric population compared to national statistics. Queries of Michigan's comprehensive immunization registry of all administered and refused vaccines show that during the 2013-2014 school year, Michigan had the 4th highest immunization waiver rate in the country for kindergartners,⁹ averaging 4.9% for public schools, 10.2% for private schools, and 5.3% overall.

Genesee County is representative of Michigan's low rates of pediatric immunization series completion. In June 2015, the average waiver rate in Genesee County for kindergarten students was as high as the State's 2014 rate (5.3%),⁹ with some schools having as many as 33% of their students inadequately vaccinated and requiring waivers.¹⁰ Compared to the State averages, Genesee County also recorded lower rates of vaccine series completion on all seven recommended series for infants 19 to 35 months, failing all Healthy People 2020 goals.⁹ The county's health department (GCHD) estimates that it will receive approximately 900 vaccine waiver requests during the remainder of the 2015 year.

Hesitant parents' doubts and concerns regarding vaccine safety and need are a major cause of incomplete pediatric immunization series. Many experts have argued that one of the leading causes of incomplete pediatric immunization series and waiver requests is an increase in the proportion of parents with doubts and concerns about the safety and need of pediatric vaccines.¹⁻⁶ A recent national poll revealed that, in 2009, as many as half of the parents polled were concerned about adverse effects of pediatric vaccines, and one in four believed some vaccines caused autism.¹¹

There is an acute need to research the cognitive decision-making processes and knowledge of vaccine-hesitant parents and use this research to produce tailored vaccine communication strategies. Many experts argue that vaccine communication strategies can effectively increase completion rates of pediatric immunization series only if (1) they include "messages tailored to the audience needs"¹ and (2) they call on public health groups to fund interdisciplinary "research carried out by scientists in the areas of psychology, sociology, anthropology and their related subspecialties" aimed at understanding vaccine psychology and cognitive decision-making.⁴

Only a few studies have followed this call; these studies have either surveyed the reasons invoked by vaccine-hesitant parents¹¹ or only theorized about hesitant parents' different styles of cognitive decision-making processes^{4, 13} (e.g., denialist, fear-based, heuristic, bandwagoning). However, to the best of our knowledge, **no work has directly elicited and documented the parent decision-making processes associated with incomplete pediatric vaccination series.** As a result, current vaccine communication studies do not provide messages tailored to the decision-making of the audience; instead, they provide dry, abstract probabilistic information about vaccine risks and benefits.^{1, 4} Recent reviews of published studies have found these studies to be ineffective.^{14, 15}

Our interdisciplinary study answers experts' calls in the field and argues that implementation of a vaccine educational toolkit based on recipients' cognitive decision-making will significantly increase vaccination series completion rates within the pediatric population. **Our proposed research aims to uncover and classify vaccine-hesitant parents' personal stories and reasoning biases, and our educational toolkit will aim to correct flawed causal knowledge within parents' very own personal stories, by exposing non-visible causes of adverse outcomes and other reasoning biases.**

TARGET AUDIENCE (Section D3)

The **immediate primary audiences** for this study are (1) the vaccine-hesitant parents who reside in Genesee County and are requesting nonmedical vaccine waivers for their children ages 6 and under, and (2) the GCHD healthcare providers who provide waiver education classes to these parents. The GCHD oversees 46 Vaccines for Children (VFC) sites. To reach a wider audience, GCHD will disseminate study findings to parents and physicians at each of these VFC sites. Beyond this, it will be possible to scale the proposed program to Michigan's 84 health departments and affiliated pediatric clinics.

The immediate target audience, vaccine-hesitant parents requesting non-medical waivers for their children (ages 6 and under) at the GCHD, represents an ideal population available at an opportune time (the point at which they are requesting waivers). The insights gained from this particular group can be expected to effectively inform vaccine educational tool kits aimed at *all* vaccine-hesitant parents for several reasons. *First*, the vaccine-related knowledge and cognitive decision-making of parents requesting vaccine waivers at the GCHD likely reflect those of other U.S. parents who either do not fully vaccinate their children or who complete immunization series but still express doubts in discussions about vaccine safety and need. *Second*, parents who remain unpersuaded by their family doctors and pediatricians, and go on to request vaccine waivers at the GCHD are likely to be most invested in their decisions and most vocal against vaccines in their online or offline discussions with family, friends, and acquaintances. *Third*, the new rule by the State of Michigan requiring mandatory waivers at county health departments ensures concentrated access to the entire population of vaccine-hesitant parents requesting waivers for their children in Genesee County. This type of access supports optimal quantity and quality in the collected data.

Recruitment and Commitment of Study Participants. We plan to approach all parents requesting non-medical vaccine waivers for their children ages 6 and under at GCHD and offer each the opportunity to anonymously participate in our study in return for a \$10 gift card. Participation in the study involves approval to digitally record the mandatory vaccine education session which may include questions that capture parents' complex vaccine stories and tailored vaccine educational responses. In addition, each participant will be committed to completing a brief electronic survey prior to and following the vaccine education session.

PROJECT DESIGN AND METHODS (Section D4)

Table 1 lists the timeline and deliverables of the proposed project and presents the following overall strategy:

- *Objective 1.* We will first uncover the underlying cognitive decision-making processes of vaccine-hesitant parents that give rise to their flawed causal knowledge about vaccines. We will achieve this objective by eliciting parents' deep-rooted and complex vaccine stories with a story/situation-based script and by qualitatively coding (1) key story elements such as the people present, their actions, behaviors, feelings, location and events, (2) the flawed causal knowledge parents possess about the safety and need of vaccines, and (3) parents' reasoning biases which underlie their vaccine causal knowledge.
- *Objective 2.* We will develop an innovative, knowledge-tailored vaccine educational toolkit that corrects parents' flawed causal knowledge by addressing their reasoning biases within their very own vaccine stories. We will pursue this objective by (1) crafting an effective debiasing message in response to each of the reasoning biases identified and by (2) tailoring the debiasing messages to the message recipients to incorporate key elements of recipients' vaccine stories.
- *Objective 3.* We will then test the effectiveness of the knowledge-tailored vaccine educational toolkit against State of Michigan's current, untailored vaccine educational program and disseminate the results of the study and the insights acquired.

Objective 1: To uncover the underlying **cognitive decision-making processes of vaccine-hesitant parents** that give rise to their flawed causal knowledge about vaccines.

1.1. Recruit participants. We will attempt to recruit all parents residing in Genesee County, Michigan, who are requesting a non-medical waiver at the GCHD for their children (6 years and younger) between January and August 2016. We will approach parents as they check in at the GCHD, immediately before they attend their mandatory one-on-one vaccine education class, and request their anonymous participation in the study in exchange for either a \$10 Amazon e-gift card or a \$10 Starbucks card. Parents' informed consent will be obtained prior to the vaccine education class. In this portion of the study (January to August 2016), participants will receive the standard vaccine educational messages developed by the State of Michigan.

The GCHD estimates they received a total of 1,100 parent-initiated waiver requests for children ages 6 and under during 2015, and they anticipate receiving a similar number during 2016. Roughly half of these waiver requests (or approximately 550) are likely to occur from January through August, given that the new school year starts in September. We expect to recruit roughly 80% of parents (or approximately 440) to participate in our study during this period.

1.2. Uncover the cognitive decision-making processes of vaccine-hesitant parents. We will investigate participating parents' decision-making processes concerning pediatric immunizations using (1) the current approach for learning about vaccine-hesitant parents and (2) a technique informed by the latest research in psychology and marketing.

The current approach entails *soliciting parents' reasons for not following recommended pediatric immunization schedules*. This approach usually uncovers statements that parents have associated with vaccines and rehearsed over time. Such associative statements (e.g., "I have read about problems with this vaccine") are void of the contexts in which they originated and, thus, not particularly useful in understanding parents' underlying cognitive processes.¹⁷⁻²⁰

The latest research in psychology and marketing provides guidance on how to uncover vaccine-hesitant parents' cognitive processes. It suggests that knowledge of vaccines be elicited following a story/situation-based script.²⁰ Recent theoretical and empirical studies provide evidence that concept knowledge (such as knowledge of vaccines) is not stored associatively, as a set of abstract and context-free statements. Instead, concept knowledge is stored as a series of situations or stories where the context or background information is a critical part.¹⁷⁻²⁰ For example, accompanying the statement "I have read about problems with this vaccine" may be information about another mother's recollection of her child's sudden onset of high fever while on vacation, which occurred immediately after her son's scheduled immunizations. The background information may also include the mother's panic and rush to the nearest emergency room, her feeling of helplessness and guilt as the symptoms later proved to be associated with autism. After quickly browsing the Internet, she concluded that the MMR vaccine her child had received at his one-year checkup was the cause of the onset of autism. Research suggests that it is the background or context that accompanies the rehearsed, associative statements that guide behavior and form the core of our conceptual understanding. (The importance of background information is illustrated in the footnote below.¹)

¹ To illustrate the importance of background information to the conceptual meaning, we use an everyday concept (i.e., *chair*) in a short exercise. We ask that you close your eyes and visualize a *chair*. Please take your time and be thorough in your visualization. What do you see? What is happening? Please bring your attention to every little detail... Some people visualize a chair set in a classroom; they may have started by focusing on the chair and noticed its seat, its pneumatic leg, and its padded back enclosed in strong material. The chair may have appeared sturdy, well-built, and comfortable. As they spent more time visualizing the chair, the focus of their lenses likely widened and captured the background, or the region of space immediately surrounding the chair: they perceived the chair set in a classroom, next to other similar chairs and desks, ready to be occupied by cheerful, chatty students who slowly filled the room for their next lecture. Their knowledge of the chair is embedded in a classroom background with information about classroom size and technological devices, the students occupying it, their age, attire, mood, and upcoming activities. In this example, the conceptual understanding of a classroom chair is informed by knowledge of chair's physical representation (e.g., the fact that it has a pneumatic leg, a seat and back, is well-built and comfortable), but also by the background in which the chair is situated (e.g., the classroom, which communicates information about the use of the chair).

This situation is just one of the many situations we store in our memory for the concept of *chair*. Other situations may relate to dining room chairs set in an eating room, armchairs placed in the front of a TV, or task chairs found in offices. Each situation includes information about the physical representation of the concept (e.g., product components and properties), and is situated in its surrounding context, or background (e.g., with information of events, entities, and people).

In light of these recent findings, we will follow a *story/situation-based script and solicit parents' deep-rooted and complex vaccine stories*. The script will ask parents to *visualize* a story or situation they find representative of vaccines and describe its physical setting or location, people present, their actions, behaviors, feelings, and any events that may unfold. The script includes pointed questions such as “what do you see?” and “what is happening?” We will ensure through adequate pretesting that the script is tailored to the vaccine context.

In addition, we will gather demographic, psychographic and attitudinal information. Upon checking in at the GCHD, but prior to attending the vaccine education class, participants will be electronically surveyed to gather data on demographic characteristics (e.g., age, zip code, gender, income) and psychographic characteristics (e.g., habits, sources of health information, values). Using a Likert-type scale, participants will be asked to rate their attitudes toward vaccines, pediatricians, other health providers, and the federal government.²¹ Prior to checking out, participants will be electronically surveyed to evaluate changes in these attitudes.

1.3. Document the vaccine decisions of participating parents. Up to six months following the vaccine education class, we will search the Michigan Care Improvement Registry (MCIR) to determine whether participating parents vaccinated their children, and we will record parents' vaccination decisions.

1.4. Document and classify the cognitive decision-making processes of vaccine-hesitant parents. We will professionally transcribe all one-on-one educational classes provided by the GCHD. We will then qualitatively code the list of reasons participants provide when asked about not following recommended pediatric immunization schedules for their children. We will proceed to code the complex vaccine stories provided in response to the situation/story-based script (i.e., document key story elements such as the people present, their actions, behaviors, feelings, location and events), and we will also code the flawed causal knowledge parents possess about the safety of and need for vaccines.

Through extensive qualitative coding, we will then identify and classify parents' reasoning biases underlying their vaccine causal knowledge. For example, the parent may have disregarded the non-visible causes of the child's illness (i.e., *causal discounting bias*) and attributed it to the recent MMR immunization (*temporal covariation to causation bias*). To thoroughly identify and classify parents' reasoning biases, we will first conduct an extensive review of the psychology and marketing literatures and document biases such as causal discounting (the tendency to prefer a single cause to multiple causes when explaining events), and confirmation bias (the tendency to search for, interpret, focus on and remember information in a way that confirms one's preconceptions), among others. Lastly, we will statistically analyze the qualitative and quantitative data collected under Objective 1.

Objective 2: To develop an **innovative, knowledge-tailored vaccine educational toolkit** that corrects parents’ flawed causal knowledge by addressing their reasoning biases within their very own vaccine stories.

2.1. Craft an effective debiasing message in response to each of the reasoning biases underlying parents’ flawed causal knowledge about the safety and need of vaccines. Our first step in developing an innovative, knowledge-tailored vaccine educational toolkit is to undertake an extensive review of empirical studies in the fields of psychology, marketing, and medical and political science²²⁻²⁶ to identify effective strategies to counteract parents’ reasoning biases. Reasoning biases have been studied in numerous contexts and a comprehensive interdisciplinary review will allow us to identify the most effective strategies currently in place. We will then adjust these strategies to the medical and vaccine contexts.

We anticipate that effective debiasing messages will include pertinent bias information. For example, to address the *causal discounting bias*²⁷ of ignoring other possible causes of an autism diagnosis, debiasing messages may point to research on genetic makeup and other parent-related characteristics as other causes of autism. In response to the *temporal covariation to causation bias*,²⁸ debiasing messages may inquire about and suggest possible autism symptoms occurring prior to the MMR immunization.

2.2. Tailor the debiasing messages to the message recipients by incorporating key elements of recipients’ vaccine stories. Current attempts to change vaccine-hesitant parents’ beliefs about vaccines entail the provision of abstract and dry probabilistic information. A parent questioning the safety of the MMR vaccine and its possible link to autism may receive formal, context-void statements such as “Well-designed and conducted studies that I can share with you show that MMR vaccine is not a cause of autism,” and “Scientists in the United States and other countries have carefully studied the MMR shot. None has found a link between autism and the MMR shot.”²⁹ While these statements are accurate and should result in revision of parents’ causal knowledge about vaccines, numerous studies across many disciplines have shown that they are ineffective at best, given people’s inability to process and store context-free, abstract information. In addition, these messages do not address the recipients’ vaccine stories, which gave rise to their flawed causal inferences.³⁰⁻³¹

Recent attempts to sway parents’ opinions include tragic stories of unvaccinated children who become the victims of vaccine-preventable diseases and later die. These stories are meant to be memorable and persuade parents to vaccinate their children by instilling fear. For example, one Michigan Department of Health and Human Services’ flier relates the story of a three-month old baby who contracted pertussis from her unvaccinated three-year-old brother and later died. Such stories do not address parents’ own vaccine stories—which gave rise to their flawed causal inferences; instead, they create new stories or situations in parents’ minds. Parents can easily dismiss these new stories as not relevant or not applicable. For example, parents may reason that they live in a community where most people are vaccinated against pertussis and therefore, it is unlikely their children will contract the disease. Following such fear stories,

parents may continue to reject vaccination programs for their children given that their vaccine stories (and ensuing flawed causal knowledge) remain unaddressed.³¹

We believe that debiasing messages can be effective in changing parents' original flawed causal inferences only if they address parents' own vaccine stories. This can be achieved by incorporating key elements of recipients' vaccine stories such as people, events, location and time, and people's actions and feelings. For example, when a parent ignores other non-visible causes of a child's autism diagnosis (i.e., *causal discounting bias*) and infers that a temporally preceding MMR immunization was the cause of the autism onset (*temporal covariation to causation bias*), debiasing messages can set the evidence provided within the parents' vaccine stories. In this example, the person delivering the message should engage the parent in a discussion about whether the child's autism diagnosis could have been caused by several other factors such as the mother's genetic makeup or other parent-related characteristics (e.g., mother and father age) in order to address the causal discounting bias. This person may also inquire about possible autism symptoms prior to the MMR vaccination to counter the temporal covariation to causation bias.

Having a discussion about other potential causes and the temporal timeline of symptoms and diagnosis *within the parents' own vaccine stories* ensures that parents are able to quickly comprehend, process, and store the debiasing messages they receive (i.e., their processing fluency is high). In addition, these tailored debiasing messages should augment parents' very own vaccine stories and their existing causal structures (e.g., from one cause model to two potential cause models) and reduce anti-vaccination beliefs.

2.3. Pretest and test the debiasing messages to ensure highest possible effectiveness. We will fine tune the tailored debiasing messages through a series of pretests and tests within the vaccine education classes at the Genesee County Health Department. We will monitor the effectiveness of the tailored debiasing messages with change in parental attitude towards vaccines following the vaccine education class.

2.4. Develop parent-oriented educational materials for each of the reasoning biases identified. Once our tailored debiasing messages are finalized, we will produce printed handouts for parents to take home after the vaccination education class. These materials will include representative vaccine stories with associated reasoning biases followed by debiasing messages. We will identify clusters of vaccine stories and match them with reasoning biases to produce the representative vaccine stories and reasoning biases. These materials will serve to continue to guide parents in recognizing the biases they employ when processing vaccine information and aid them in making accurate causal assertions about vaccines.

Objective 3: To test the effectiveness of the knowledge-tailored vaccine educational toolkit against the State of Michigan’s current, untailored vaccine educational program.

3.1. Train the GCHD nurses on the use of the knowledge-tailored vaccine educational toolkit.

We will develop a protocol to facilitate rapid tailoring of debiasing messages. This protocol will include quick ways GCHD nurses can (1) identify a parent’s reasoning biases and key elements of his or her vaccine story, (2) retrieve corresponding debiasing messages, and (3) tailor these messages to recipient’s knowledge by introducing key elements of that parent’s vaccine story.

During the last week of August 2016, we will train the GCHD nurses on the value and use of this educational tool.

3.2. Implement the knowledge-tailored vaccine educational toolkit at the GCHD for all vaccine education classes.

The recruitment and surveying of participants would follow the same procedure outlined under Objective 1 (item 1.1. above). We expect to recruit roughly 80% of parents (i.e., approximately 440) to participate in our study during this period. Upon checking in at the GCHD, but prior to attending the vaccine education class, participants will be electronically surveyed to gather data on demographic characteristics (e.g., age, zip code, gender, income) and psychographic characteristics (e.g., habits, sources of health information, values). Using a Likert-type scale, participants will be asked to rate their attitudes toward vaccines, pediatricians, other health providers, and the federal government. Prior to checking out, participants will be electronically surveyed to evaluate changes in these attitudes. Similarly to the procedure followed for Objective 1, we will solicit participating parents’ reasons for not following recommended pediatric immunization schedules (current approach for learning about vaccine-hesitant parents) and also their deep-rooted and complex vaccine stories with a story/situation-based script.

Unlike the procedure for Objective 1, during the one-on-one vaccine education classes, nurses will communicate a tailored debiasing message to parents and end the education class by providing corresponding printed educational materials. At check-out, parents will complete an electronic survey to identify changes in their attitudes toward vaccines, pediatricians and other health providers, and the federal government.

Six months after the vaccine educational class, we will search the Michigan Care Improvement Registry (MCIR) to determine whether participating parents vaccinated their children following the vaccine education class. Following this search, all parent data will be de-identified and the resulting dataset will be submitted for analysis.

3.3. Document and classify the cognitive decision-making processes of vaccine-hesitant parents.

We will follow the same procedure outlined for Objective 1 (item 1.4) and professionally transcribe all conversations between participating parents and GCHD nurses. We will then code all qualitative items. These items include: reasons participants provide when asked about not following recommended pediatric immunization schedules for their children;

parents’ complex vaccine stories³³ provided in response to the situation/story-based script; and parents’ reasoning biases underlying their vaccine causal knowledge.

3.4. Statistically test the effectiveness of the knowledge-tailored vaccine educational toolkit against State of Michigan’s current, untailed vaccine education program. We will compare and statistically analyze the change in parental attitudes towards vaccines and rates of vaccination for parents who will have received the State of Michigan untailed vaccine education program (recruited for Objective 1, in months 1-8, Jan-Aug 2016) to those of parents who will have received the knowledge-tailored educational toolkit (recruited for Objective 3, in months 9-12, Sep-Dec 2016). The figure below depicts the timeline of the study design.

Figure 1. Study Design

Months 1-8 (Jan-Aug 2016)	Last week of Month 8 (Aug 2016)	Months 9-12 (Sep-Dec 2016)
Baseline (MI’s untailed education program)	Training	Intervention (Proposed knowledge-tailored vaccine educational toolkit)

3.5. Disseminate the results of the study and the insights acquired. Results of the study will be made available to Michigan’s 84 departments of health and human services and the 46 Vaccine for Children (VFC) sites the GCHD oversees. We will also disseminate the results of the study to the medical community through publication in top medical and vaccine journals.

3.6. Submit final report. We will submit the final report to Pfizer upon completion of the research program.

EVALUATION DESIGN (Section D5)

Addressing practice gaps. This project aims to **address the low pediatric immunization rates** by (1) gaining a better understanding of the **cognitive decision-making processes of vaccine-hesitant parents** and (2) instructing healthcare providers in the use **an effective knowledge-tailored educational toolkit** in their conversations with vaccine-hesitant parents.

We plan to explore the **(1) cognitive decision-making processes of vaccine-hesitant parents** by uncovering their complex and deep-rooted vaccine stories and qualitatively and quantitatively analyzing them. We will recruit approximately 880 parents residing in Genesee County and requesting non-medical vaccine waivers for their children (age 6 and under) during the entire year of 2016 (under *Objective 1 and Objective 3*). We will exclude from our analyses parents requesting a vaccine waiver on religious grounds. We will elicit parents’ complex vaccine stories using a story/situation based script and qualitatively record the following *data or variables* using electronic devices:

- parents' demographic characteristics (e.g., age, zip code, gender, income) and psychographic characteristics (e.g., habits, sources of health information, values);
- key elements of parents' vaccine stories such as physical setting or location, people present, their actions, behaviors, feelings, and any events that may unfold;
- parents' flawed causal knowledge about the safety and need of vaccines;
- parents' reasoning biases contributing to the flawed causal knowledge about vaccines;
- parental attitudes towards vaccines, pediatricians and other health providers, and the federal government; and
- parental change in attitude towards vaccines and vaccine authorities.

Descriptive *analyses* will be performed for parents' demographic and psychographic characteristics, and for parental original attitude and attitude change towards vaccines and vaccine authorities. Using NVivo qualitative data analysis software, we will identify themes within parents' complex vaccine stories, as well as their flawed causal knowledge and reasoning biases. Bivariate analyses and multivariate logistic regressions will be used to identify demographic and psychographic characteristics associated with certain vaccination themes, reasoning biases and parental attitudes towards vaccines and vaccine authorities. We also anticipate that our analysis will result in a list of four to five different vaccine stories and their representative reasoning biases common to the majority of vaccine-hesitant parents.

We will test the effectiveness of the proposed **(2) knowledge-tailored educational toolkit** by comparing the parental change in attitude towards vaccines and vaccine authorities and the realized immunization rates for the baseline and intervention groups in a field experiment design. Our *baseline* group will consist of roughly 440 parents recruited at the GCHD between January and August 2016 and participating in Michigan's untailored vaccine education class. Our *intervention* group will consist of roughly 440 parents recruited at the GCHD between September and December 2016 and participating in an education class delivering a knowledge-tailored debiasing message as well as offering corresponding printed educational materials.

The two groups will be exposed to the same procedures at the GCHD from checking in to checking out, with the exception of the message the nurses provide in response to their anti-vaccination or delayed vaccination reasons (e.g., untailored vs. containing debiasing messages and tailored to their vaccine stories). Both groups will answer questions on demographic and psychographic characteristics and attitude toward vaccines and vaccine authorities at checking in and prior to attending the education class; both groups will interact with the same five nurses employed by the GCHD during the education class; both groups will provide reasons for not following recommended pediatric immunization schedules as well as describe their deep-rooted and complex vaccine stories during the education class; and both groups will answer questions regarding changes in their attitudes towards vaccines and vaccine authorities following the educational class.

To assess the effect of the knowledge-tailored educational toolkit (i.e., intervention), we will collect the following *data* or *variables*:

- parental change in attitude towards vaccines and vaccine authorities (e.g., pediatricians, other health providers, the federal government) as answered electronically by vaccine-hesitant parents following the educational class
- immunization rates of children (6 years and under) up to 6 months following the education class as recorded in the comprehensive and mandatory Michigan Care Improvement Registry.

Descriptive *analyses* will be performed for parents' attitude change towards vaccines and vaccine authorities and for realized immunization rates. Univariate analysis (ANOVA) will be used to establish whether the difference in parental change towards vaccines and vaccine authorities and realized immunization rates between the two groups is statistically significant. In addition, we will statistically compare the baseline and intervention groups after adjusting for select demographic, psychographic characteristics, and healthcare provider seen.

Expected change. We expect the use of the tailored educational toolkit (i.e., intervention) to result in a 30% to 40% reduction in parents' negative attitudes towards vaccines and vaccine authorities; this is because the toolkit provides debiasing messages tailored to parents' own reasoning biases and vaccine stories. We anticipate that the increase in realized vaccination rates may be smaller (under 10%) because such change requires the logistical effort of scheduling an appointment for the child at a pediatrics or family practitioner's office, which may not occur during the 6-month timeframe considered. Future queries of the Michigan Care Improvement Registry (MCIR) will be employed to shed further light on this expected change.

Dissemination. Our findings will be presented at several scientific meetings such as the Pediatric Academic Societies, Annual Conference of Vaccine Research, and will be submitted for publication in peer-reviewed, high-impact journals in the fields of pediatrics, vaccines, and transformative consumer research. Our results will be disseminated to Michigan's 84 health departments and the 46 Vaccine for Children sites the GCHD oversees. We will also develop a protocol to aid in rapid application of the knowledge-tailored educational toolkit to increase vaccine coverage at vaccine-hesitant parents' first point of contact (e.g., pediatrician and family doctor offices).

Innovation. This project is novel given its interdisciplinary approach to correcting vaccine-hesitant parents' flawed causal knowledge about the safety and need of vaccines. Research in psychology, marketing, and the medical fields provide a fresh perspective to the very important social issue of low pediatric immunization rates. The cross-pollination of these fields has resulted in a novel approach to uncovering vaccine-hesitant parents' cognitive decision-making processes and delivering a powerful and convincing message built on parents' own vaccine stories and reasoning biases. This project also takes advantage of a timely requirement in the State of Michigan that mandates parents of unvaccinated children to visit their county health department and obtain a non-medical vaccine waiver following an educational vaccine class. This requirement along with our collaboration with the GCHD has resulted in timely and concentrated access to the study's population.

The proposed intervention, while requiring more input and planning from a healthcare provider, is based on extensive theoretical and empirical research; it has the potential to be an effective strategy in changing parents' flawed causal knowledge about vaccines and help increase pediatric immunization rates. Our extensive qualitative analysis, which includes classification of vaccine stories and reasoning biases, will facilitate quick and easy replication of the proposed protocol across many clinic settings. Thus, if this intervention proves to be successful in increasing pediatric immunization series, its proposed protocol can be expanded to other venues such as pediatric and family practitioners offices, hospitals, and other health departments across the U.S.

DETAILED WORKPLAN AND DELIVERABLES SCHEDULE (Section D6)

The researchers on this project will schedule weekly meetings to review and plan upcoming items, and study's design, implementation, and evaluation. The project team will address and solve potential issues and make any modifications necessary. Please refer to Table 1 for a list and timeline of deliverables.

Months 1-8 (January-August 2016). During this period, we will focus on uncovering the underlying cognitive decision-making processes of vaccine-hesitant parents (*Objective 1*). We will recruit participants from among all parents attending the Michigan-provided, untailed educational classes at the GCHD, record and qualitatively code their reasons for not vaccinating their children, their complex vaccine stories and reasoning biases, as well as their demographic and psychographic characteristics.

We estimate recording and manually coding approximately 440 conversations between parents and the GCHD nurses providing the education class; coding will be performed by two of the team members to ensure intercoder reliability. The amount of work will be extensive and time consuming as, for each conversation, we will identify and classify (1) all reasons participants provide when asked about not following recommended pediatric immunization schedules for their children, (2) key elements of complex vaccine stories, such as the people present, their actions, behaviors, feelings, location and events, (3) parents' flawed causal knowledge parents about the safety and need of vaccines, and (4) parents' reasoning biases underlying their vaccine causal knowledge. In addition, the project's PI will undertake an extensive review of the psychology and marketing literatures and provide a comprehensive list of reasoning biases.

In addition, we will record parents' change in attitudes towards vaccines and vaccine authorities and realized immunization rates as a result of the State of Michigan's vaccine education class. This will represent the baseline data against which we will compare the effectiveness of our intervention.

At the end of this period we will also statistically analyze the qualitative and quantitative data collected and submit a scientific meeting abstract and manuscript describing the cognitive decision-making processes (e.g., complex vaccine stories and reasoning biases) of vaccine-hesitant parents,

At the end of this period, during **months 5-8 (May-August 2016)**, we will build on the insights acquired from Objective 1 and begin working on crafting effective debiasing messages that would address each of the reasoning biases identified (*Objective 2*). The project's PI will again undertake an extensive review of empirical studies in the fields of psychology, marketing, medical and political science to identify effective messages to counteract reasoning biases. Following this, each debiasing message will be tailored to the message recipient and include key elements of recipients' vaccine stories and parent-oriented educational materials will be developed for each reasoning bias identified. The results of this labor-intensive work will be disseminated in a scientific meeting abstract and manuscript.

During the last week of August (**month 8**), we will train GCHD personnel on the use of the knowledge-tailored vaccine educational toolkit following a newly developed protocol.

Months 9-12 (September-December 2016). During this period, we will implement our intervention, which will consist of embedding a knowledge-tailored vaccine educational toolkit in the vaccine educational class (*Objective 3*). Just as for Objective 1, we estimate a time intensive and labor-intensive effort to record and manually code approximately 440 conversations between parents and the GCHD nurses providing the education class by two of the team members (to ensure intercoder reliability). We will follow the same coding procedures for the same data/variables as in Objective 1. We will also record parents' attitudes towards vaccines and vaccine authorities and realized immunization rates; these will represent the intervention data to be compared against the baseline data of Objective 1. This coding effort will begin starting **month 9 (September 2016)** and end in **month 14** of the project (**February 2017**).

Results of statistical analyses of the qualitative and quantitative data at this stage and its comparison to the baseline data of Objective 1 will be submitted as a scientific meeting abstract and result in a manuscript describing the protocol of the intervention and its effects on pediatric vaccination beliefs and rates. Results will also be disseminated to Michigan's 84 health departments and the 46 Vaccine for Children sites the GCHD oversees. This will be accomplished **between months 15 and 18 (March-June 2017)**.

Table 1. Timeline and Deliverables of Proposed Project

Activities	Measures	Deliverables	Project Months
<p>Objective 1: To uncover the underlying cognitive decision-making processes of vaccine-hesitant parents that give rise to their flawed causal knowledge about vaccines.</p>			
<p>1.1. Recruitment of participants.</p> <ul style="list-style-type: none"> ✓ Approach all parents requesting a non-medical vaccine waiver for their child(ren) ages 6 and under and attending the mandatory one-on-one vaccine education class at the Genesee County Health Department. ✓ Obtain parents’ informed consent to anonymously participate in the study in exchange for either a \$10 Amazon e-gift card or a \$10 Starbucks card. 	<ul style="list-style-type: none"> ✓ 80% participation rate, or 440 one-on-one education classes 	<ul style="list-style-type: none"> ✓ Submitted IRB (Obj. 1, already approved) 	<p>1-8 (Jan-Aug 2016)</p>
<p>1.2. Uncovering the cognitive decision-making processes of vaccine-hesitant parents.</p> <p><i>Upon checking in at the GCHD but prior to attending the vaccine education class:</i></p> <ul style="list-style-type: none"> ✓ Electronically survey participating parents on their demographic characteristics (e.g., age, zip code, gender, income, etc.) and psychographic characteristics (e.g., habits, sources of health information, values). ✓ Survey participating parents on their attitudes towards vaccines, pediatricians and other health providers, and the federal government. <p><i>During the untailored one-on-one vaccine education class (baseline):</i></p> <ul style="list-style-type: none"> ✓ Solicit parents’ reasons for not following recommended pediatric immunization schedules (current approach for learning about vaccine-hesitant parents and also current practice at the GCHD), and ✓ Pretest, finalize, and solicit parents’ complex vaccine stories with a story/situation-based script (informed by research in psychology & marketing) <ul style="list-style-type: none"> • The script asks parents to <i>visualize</i> a story or situation they find representative of vaccines and describe its physical setting or location, people present, their actions, behaviors, feelings, and any events that may unfold. The script includes pointed questions such as “what do you see?” and “what is happening?” 	<ul style="list-style-type: none"> ✓ Parents’ demographic and psychographic characteristics ✓ Lists of associative /rehearsed reasons for not vaccinating ✓ Complex, deep-rooted vaccine stories ✓ Parental attitude towards vaccine and vaccine authorities ✓ Parental change in attitude towards vaccine and vaccine authorities following MI’s untailored education program (baseline) 	<ul style="list-style-type: none"> ✓ Submitted Abstract (Obj. 1) ✓ Submitted Manuscript (Obj. 1) 	

Activities	Measures	Deliverables	Project Months
<p><i>At checking out:</i></p> <ul style="list-style-type: none"> ✓ Electronically survey participating parents on changes in their attitudes towards vaccines, pediatricians and other health providers, and the federal government. 			
<p>1.3. Documenting the vaccine decisions of participating parents</p> <ul style="list-style-type: none"> ✓ Survey the Michigan Care Improvement Registry up to a month following the vaccine education class to determine whether participating parents vaccinated their children following the vaccine education class ✓ Record parents' vaccination decisions. 	<ul style="list-style-type: none"> ✓ Immunization rates following MI's <i>untailored education program (baseline)</i> 	<ul style="list-style-type: none"> ✓ Submitted IRB (Obj. 1, already approved) 	
<p>1.4. Documenting and classifying the cognitive decision-making processes of vaccine-hesitant parents.</p> <ul style="list-style-type: none"> ✓ Professionally transcribe all one-on-one education classes provided by the GCHD. ✓ Qualitatively code the list of reasons participants provide when asked about not following recommended pediatric immunization schedules for their children. ✓ Qualitatively code the complex vaccine stories provided in response to the situation/story-based script (i.e., document key story elements such as the people present, their actions, behaviors, feelings, location and events). ✓ Qualitatively code the flawed causal knowledge parents possess about the safety and need of vaccines. ✓ Identify and classify parents' reasoning biases underlying their vaccine causal knowledge <ul style="list-style-type: none"> • Undertake an extensive review of the psychology and marketing literatures and provide a comprehensive list of reasoning biases ✓ Statistically analyze the qualitative and quantitative data collected. 	<ul style="list-style-type: none"> ✓ Transcription of all vaccine education classes ✓ Qualitatively coding of associative /rehearsed reasons for not vaccinating ✓ Qualitative coding of complex, deep-rooted vaccine stories ✓ Qualitative coding of flawed causal knowledge about the safety and need of vaccines ✓ Classification of reasoning biases 	<ul style="list-style-type: none"> ✓ Submitted Abstract (Obj. 1) ✓ Submitted Manuscript (Obj. 1) 	<p>1-8 (Jan-Aug 2016)</p>

Activities	Measures	Deliverables	Project Months
Objective 2: To develop an innovative, knowledge-tailored vaccine educational toolkit that corrects parents' flawed causal knowledge by addressing their reasoning biases within their very own vaccine stories.			
2.1. Craft an effective debiasing message in response to each of the reasoning biases underlying parents' flawed causal knowledge about the safety and need of vaccines <ul style="list-style-type: none"> ✓ Undertake an extensive review of empirical studies in the fields of psychology, marketing, medical and political science to identify effective messages to counteract reasoning biases ✓ Adjust the above identified strategies to the vaccine context 	<ul style="list-style-type: none"> ✓ Review of current debiasing strategies ✓ Adjusting of debiasing messages to vaccine context 	<ul style="list-style-type: none"> ✓ Submitted IRB (Obj. 2, already approved) 	5-8 (May-Aug 2016)
2.2. Tailor debiasing messages to the message recipients by incorporating key elements of recipients' vaccine stories <ul style="list-style-type: none"> ✓ Embed key elements of parents' own vaccine stories within the debiasing message to alter parents' causal knowledge of vaccines within <i>its</i> very own originating context. 	<ul style="list-style-type: none"> ✓ Identify strategies for tailoring debiasing messages to message recipients 	<ul style="list-style-type: none"> ✓ Submitted Abstract (Obj. 2) 	
2.3. Pretest and test the debiasing messages to ensure highest possible effectiveness <ul style="list-style-type: none"> ✓ Fine tune the tailored debiasing messages through a series of pretests and tests at the GCHD 	<ul style="list-style-type: none"> ✓ Pretest and test tailored debiasing messages 	<ul style="list-style-type: none"> ✓ Submitted Manuscript (Obj. 2) 	
2.4. Develop parent-oriented educational materials for each of the reasoning biases identified <ul style="list-style-type: none"> ✓ These materials would help continue to guide parents in recognizing the bias they employ when processing vaccine information and aid in making accurate causal assertions about vaccines after the educational class 	<ul style="list-style-type: none"> ✓ Educational materials to accompany each reasoning bias 		

Activities	Measures	Deliverables	Project Months
Objective 3: To test the effectiveness of the knowledge-tailored vaccine educational toolkit against State of Michigan’s current, untailed vaccine educational program.			
<p>3.1. Train the GCHD nurses on the use of the knowledge-tailored vaccine educational toolkit</p> <ul style="list-style-type: none"> ✓ Develop a protocol to allow for a rapid customization or tailoring of the debiasing message. This protocol would include quick ways to identify parents’ reasoning biases, key elements of their vaccine stories; it would also help identify a corresponding debiasing message and tailor it to the recipients’ knowledge by introducing key elements of parents’ vaccine stories. ✓ Train the GCHD nurses on the value and use of this educational tool (during the last week of the month). 	<ul style="list-style-type: none"> ✓ Protocol to tailor debiasing messages to message recipients ✓ Training on the value and use of the educational tool 	<ul style="list-style-type: none"> ✓ Submitted IRB (Obj. 3, already approved) 	<p style="text-align: center;">8 (last week of Aug 2016)</p>
<p>3.2. Implement the knowledge-tailored vaccine educational toolkit at the GCHD for all vaccine education classes</p> <p><i>Recruit participants</i> (same as 1.1. above)</p> <p><i>Upon checking in</i> at the GCHD but prior to attending the vaccine education class:</p> <ul style="list-style-type: none"> ✓ Electronically survey participating parents on their demographic characteristics (e.g., age, zip code, gender, income, etc.) and psychographic characteristics (e.g., habits, sources of health information, values) ✓ Survey participating parents on their attitudes towards vaccines, pediatricians and other health providers, and the federal government <p><i>During the knowledge-tailored one-on-one vaccine education class (intervention):</i></p> <ul style="list-style-type: none"> ✓ Solicit parents’ reasons for not following recommended pediatric immunization schedules (current approach for learning about vaccine-hesitant parents and also current practice at the GCHD), and ✓ Solicit parents’ deep-rooted and complex vaccine stories with a story/situation-based script ✓ Respond with a tailored debiasing message and provide parents with corresponding printed educational materials 	<ul style="list-style-type: none"> ✓ 80% participation rate, or 440 one-on-one education classes ✓ Parents’ demographic and psychographic characteristics ✓ Lists of associative /rehearsed reasons for not vaccinating ✓ Complex, deep-rooted vaccine stories ✓ Parental attitude towards vaccine and vaccine authorities 	<ul style="list-style-type: none"> ✓ Completed Intervention 	<p style="text-align: center;">9-12 (Sep-Dec 2016)</p>

Activities	Measures	Deliverables	Project Months
<p><i>At checking out:</i></p> <ul style="list-style-type: none"> ✓ Electronically survey participating parents on changes in their attitudes towards vaccines, pediatricians and other health providers, and the federal government <p><i>A month after the vaccine educational class:</i></p> <ul style="list-style-type: none"> ✓ Survey the Michigan Care Improvement Registry to determine whether participating parents vaccinated their children following the vaccine education class 	<ul style="list-style-type: none"> ✓ Parental change in attitude and Immunization rates following the <i>tailored education program (intervention)</i> 		
<p>3.3. Documenting and classifying the cognitive decision-making processes of vaccine-hesitant parents.</p> <ul style="list-style-type: none"> ✓ Professionally transcribe the conversations between participating parents and GCHD nurses. ✓ Qualitatively code the list of reasons participants provide when asked about not following recommended pediatric immunization schedules for their children. ✓ Qualitatively code the complex vaccine stories provided in response to the situation/story-based script (i.e., document key story elements such as the people present, their actions, behaviors, feelings, location and events). ✓ Qualitatively code the flawed causal knowledge parents possess about the safety and need of vaccines. ✓ Identify and classify parents’ reasoning biases underlying their vaccine causal knowledge 	<ul style="list-style-type: none"> ✓ Transcription of all vaccine education classes ✓ Qualitatively coding of associative /rehearsed reasons for not vaccinating ✓ Qualitative coding of complex, deep-rooted vaccine stories ✓ Qualitative coding of flawed causal knowledge about the safety and need of vaccines ✓ Classification of reasoning biases 		<p style="text-align: center;">9-14 (Sep 2016-Feb 2017)</p>

Activities	Measures	Deliverables	Project Months
<p>3.4. Statistically test the effectiveness of the knowledge-tailored vaccine educational toolkit against State of Michigan’s current, untailed vaccine educational program</p> <ul style="list-style-type: none"> ✓ Compare and statistically analyze the change in parental attitude towards vaccines and rates of vaccination for parents who will have received the State of Michigan untailed vaccine education program (recruited for objective 1, in months 1-8, Jan-Aug 2016) to those of parents who will have received the knowledge-tailored educational toolkit (recruited for objective 3, in months 9-12, Sep-Dec 2016). 	<ul style="list-style-type: none"> ✓ Statistical analyses 	<ul style="list-style-type: none"> ✓ Submitted Abstract (Obj. 3) ✓ Submitted Manuscript (Obj. 3) 	<p style="text-align: center;">15-16 (Mar-Apr 2017)</p>
<p>3.5. Disseminate the results of the study and the insights acquired</p> <ul style="list-style-type: none"> ✓ Results of the study will be made available to Michigan’s 84 health departments and the 46 Vaccine for Children sites the GCHD oversees ✓ Results of the study will also be made available to the medical community through publication in top medical and vaccine journals. 	<ul style="list-style-type: none"> ✓ Objectives achieved ✓ Assessing intervention impact ✓ Developing dissemination strategies 		<p style="text-align: center;">17-18 (May-Jun 2017)</p>
<p>3.6. Submit final report</p>		<ul style="list-style-type: none"> ✓ Final Report 	<p style="text-align: center;">18 (Jun 2017)</p>

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