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# Vaccine Hesitancy in the post-COVID-19 era: An interdisciplinary approach for a Trust-and-Risk paradigm with governmental and intergovernmental implications

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## **ABSTRACT**

Vaccine hesitancy was described as a major global health challenge by the World Health Organization before the outset of the COVID-19 pandemic (Ten Health Issues WHO Will Tackle This Year, 2019).

During the COVID-19 pandemic, the introduction of several new vaccines (notably Pfizer, Moderna, J&J) and with them new vaccine technologies (mRNA) under emergency use authorization (EUA), combined with the political context of these vaccines' accelerated development, triggered a heightened level of vaccine hesitancy and refusal in the United States and around the world (FDA, 2021).

This paper study undertakes to investigate the foundations and recent evolution of this phenomenon of vaccine hesitancy (and refusal) using a broad, inductive, and interdisciplinary approach with a focus on the role of risk perception and trust in risk/benefit assessment.

(1) In particular, this study considers the issue of risk perception based on both objective and subjective criteria, using the well-known phenomenon of 'fear of flying' as a point of reference as well as successful interventions developed to address this common problem (Slovic, 2013).

(2) This study then considers existing vaccine hesitancy interventions against the framework of risk perception and trusted sources (Jarrett et al., 2015).

(3) An additional contribution to knowledge takes the form of a possible model able to offer a credible risk/benefit calculator which could be used as part of such an intervention.

Overall, this research makes a significant contribution to the study of vaccine hesitancy by identifying the complexity of the underlying issues, the inadequacy of current

responses, as well as a need for a comprehensive interdisciplinary approach to improve both local and global public health policies.

## 1. Introduction

In 2019, the World Health Organization designated “vaccine hesitancy” as one of the top 10 threats to global health. It aptly and succinctly defined it as “the reluctance or refusal to vaccinate despite the availability of vaccines” and noted that “threatens to reverse progress made in tackling vaccine-preventable diseases” ‘Ten Health Issues WHO Will Tackle This Year’, 2019, <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019..>

In this short document/web page, the WHO wisely and correctly avoided oversimplification and stated that “the reasons why people choose not to vaccinate are complex” and further identified “complacency, inconvenience in accessing vaccines, and lack of confidence” as “key reasons.”

“Confidence” and “trust” being almost synonymous, the WHO elaborates on what must be considered a key concept in this matter: “Health workers, especially those in communities, remain the **most trusted** advisor and influencer of vaccination decisions, and they must be supported to provide **trusted, credible information** on vaccines (emphasis added).”

Overall, this WHO only mentions three vaccines/pathologies: (1) measles; (2) HPV; and (3) polio. However, these are quite different situations, inasmuch as measles is a highly contagious disease with little general public awareness of its high case fatality rate; HPV is a sexually transmitted disease associated with cervical cancer and a still-controversial vaccine; polio is eradicated in most industrialized countries and difficult to fully eradicate in certain regions where both the wild-strain and vaccine-strain remain problematic. As the trusted *Nature* magazine announced in 2020, “Africa declared free from wild polio — but vaccine-derived strains remain” Giorgia Guglielmi, ‘Africa Declared Free from Wild Polio — but Vaccine-Derived Strains Remain’, *Nature*, 28 August 2020, <https://doi.org/10.1038/d41586-020-02501-3>.

If vaccine hesitancy was listed as a major WHO concern in 2019, it is almost common knowledge that vaccine hesitancy was a major issue during the COVID-19 pandemic. A December 2021 article by Melissa Suran, PhD, MSJ published on the official site of the American Medical Association (JAMA) was entitled “Why Parents Still Hesitate to Vaccinate Their Children Against COVID-19.” The author noted that “Although a vaccine

that's 90.7% effective in preventing the illness was authorized for younger kids in late October, these figures apparently aren't convincing enough to persuade many parents to vaccinate their children" Melissa Suran, 'Why Parents Still Hesitate to Vaccinate Their Children Against COVID-19', *JAMA* 327, no. 1 (4 January 2022): 23–25, <https://doi.org/10.1001/jama.2021.21625>.. However well-intentioned and at the time data-based this statement may have been, a few months later (02/2022), Pfizer-BioNTech and the CDC reported on much less encouraging results:

To many parents' dismay, a new report from the US Centers for Disease Control and Prevention found that the Covid-19 vaccine is less effective against the Omicron variant for children ages 5 to 11 than for older children and adults. Two doses of the Pfizer/BioNTech vaccine reduced the risk of Omicron infection by 31% among children 5 to 11 years old... Vaccinated children ages 5 to 11 were about 46% less likely to need medical treatment for Covid-19 from an urgent care clinic or emergency department, compared with unvaccinated children, a previous CDC study found Alexander Tin, 'Pfizer's COVID Vaccine Less Effective against Omicron in Younger Children, New Study Suggests', 2022, <https://www.cbsnews.com/news/covid-vaccine-less-effective-against-omicron-infections-younger-children/>.

Because Dr Suran made an error in emphasizing "preventing the illness" as opposed to 'preventing severe illness or death' (which the vaccine did accomplish with higher success), the risk is very real that parents will not only be 'dismayed' but hesitant, all the more that the Pfizer preauthorization clinical trials only involve 3,109 children (age 5-11), a remarkably small cohort.

This introduction, based on the widely publicized WHO statement, allows us to set forth several important points and directions for this research:

- Vaccine hesitancy has been widely identified as a concern and threat by the WHO and other public health stakeholders
- Vaccine hesitancy is a complex phenomenon, for which this study will seek to apply a broad interdisciplinary analytical and theoretical framework
- "Confidence/trust" is considered a key concept associated with vaccine hesitancy among parents and patients
- "Trusted sources" therefore identified as another and related key concept in understanding and addressing vaccine hesitancy
- "Risk" is a critical concept in public health policy as well as personal health behavior, used 6 times in the WHO document of reference but not in the section dealing with vaccine hesitancy

i) The US context for trust and distrust

Even though this research aims to consider the phenomenon of vaccine hesitancy in a globally relevant framework, some aspects are uniquely associated with the United States, including the quantitative clergy-trust dimension of this study.

In fact, it seems useful to mention that the 2019 WHO document was published at a time when the United States had withdrawn from the organization under the Presidency of Donald Trump who served between 2016 and 2020. This was a time when polarization and distrust became obvious features of American society, right in time for the inception of the COVID-19 pandemic (December 2019).

The phenomenon of trust and distrust in the Trump era was thus explained by the US Center for American Progress:

Put simply, if voters like Trump and what he is doing, they trust in the government more and see more positive impacts and benefits. If voters dislike Trump and what he is doing, they distrust government more and see many more negative impacts and fewer benefits from government 'Trust in Government in the Trump Era', Center for American Progress (blog), accessed 21 March 2022, <https://www.americanprogress.org/article/trust-government-trump-era/>.

The COVID-19 pandemic, understandably, resulted in a pressing public demand, if not outcry, for a safe and effective vaccine against the infection. In May 2020, the Trump administration launched Operation Warp Speed, "a public-private partnership initiated by the United States government to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics." The resulting vaccines, strongly endorsed by the controversial US President, were associated with significant distrust from political opponents, including current US Vice-President Kamala Harris. A mainstream news site summarized her position as a candidate with this title: "Harris says she wouldn't trust Trump on any vaccine released before election" Evan Semones, 'Harris Says She Wouldn't Trust Trump on Any Vaccine Released before Election', POLITICO, accessed 21 March 2022, <https://www.politico.com/news/2020/09/05/kamala-harris-trump-coronavirus-vaccine-409320..> However, the whole US government was involved in this critical vaccine, including the FDA, CDC and NIAID. Would the much-awaited COVID-19 vaccines be associated with "trust in science" or 'distrust in institutions?'

For most Americans doing through the trauma of the COVID-19 pandemic, trust became the often unspoken cornerstone issue: trust the Trump administration including federal agencies?; trust a senior and visible public health official such as Anthony Fauci?; trust corporate entities such as Pfizer or Moderna?; trust news sources or academic journals?; trust one's one doctor or other trusted sources.

Not only individuals but also medical doctors and public health administration were put in the difficult position to make important decisions based on a complex if not impossible risk/benefit assessment. Taking account this unique situation and the aftermath thereof, this research aims to consider the issue of vaccine hesitancy in the post-COVID-19 era.

## 2. Towards an interdisciplinary approach to vaccine hesitancy

One would be hard-pressed to find a better introduction than the following statement by Elizabeth Golembiewski, currently Postdoctoral Researcher at Mayo Clinic:

Public health issues are rarely solved or fully understood from a single disciplinary perspective. Addressing the complex social, behavioral, and biological phenomena that influence health requires the application of perspectives from seemingly disparate disciplines (Golembiewski et al., 2018).

The interconnectedness of public health and other disciplines (economics, ethics, international law) has been illustrated throughout the course of the COVID-19 pandemic: economic considerations, diplomatic interferences, legal disputes, mental health implications of lockdowns and even unintended public health consequences such as delayed immunizations, screenings and treatments.

As our literature review and inductive analysis has revealed, this research affirms the need to a comprehensive interdisciplinary approach to better understand the phenomenon of vaccine hesitancy, especially in the post COVID-19 era.

### 2.1. Theoretical Frameworks

In this section, we consider a number of theoretical frameworks that will in many instances coincide with our interdisciplinary research.

Health Belief Model

The Health Belief Model (HBM) is central to understand the phenomenon of vaccine hesitancy, as is implied in the very definition of the approach:

[a] theoretical model that can be used to guide health promotion and disease prevention programs. It is used to explain and predict individual changes in health behaviors... The model defines the key factors that influence health behaviors as an individual's perceived threat to sickness or disease (perceived susceptibility), belief of consequence (perceived severity), potential positive benefits of action (perceived benefits), perceived barriers to action, exposure to factors that prompt action (cues to action), and confidence in ability to succeed (self-efficacy) (The Health Belief Model – Rural Health Promotion and Disease Prevention Toolkit, n.d.).

The obvious application to immunization policies as been explored by many researchers, including Jones and colleagues in *The Health Belief Model as an Explanatory Framework in Communication Research: Exploring Parallel, Serial, and Moderated Mediation* (Jones et al., 2015). In this case, HBM was considered in the case of the H1N1 vaccination campaign. Others, such as Nexoe, Kragstrup, and Sogaard (1999) found that the HBM components of perceived severity, perceived barriers, and perceived benefits were mutually significant predictors of influenza vaccination acceptance. The Jones study confirms the need for a comprehensive interdisciplinary approach as the relationship between information exposure and behavior/decision was recognized to be complex and hierarchical:

The HBM is one of the most widely utilized and heavily studied theories in public health. Decades of research have helped to refine the model, yet variable ordering remains a relatively understudied topic. The present study explored three plausible models—parallel, serial, and moderate mediation—and identified a complex underlying hierarchy with a moderator (self-efficacy), one mediator (barriers), and a causal chain (barriers → benefits). The results suggest a potential hierarchy for targeting HBM constructs and provide a platform for future model testing in this area (ibid).

We conclude by affirming the foundation relevant of HBM in this study as we posit as almost self-evident that the decision to vaccinate (or not) is related to an individual's analysis – rational or not; well-informed or not – of the relationship between benefits and threats.

### Biosocial analysis

Vaccine hesitancy is not a new phenomenon since it can be traced to the very beginning of the vaccine era, with a full spectrum of positions ranging from absolute

vaccine refusal and its flipside on the public policy side, namely mandatory vaccination enforced by the State. It is well documented that entire towns refused to pursue the smallpox eradication campaign (using the smallpox vaccine developed by Edward Jenner), and controversy remains regarding the safety and efficacy of the initial small box vaccine considering the primitive technological and medical context (Schwartz, 2012). The polio vaccine, which was welcome with immense relief by the US population as a whole, was not a complete success story. Vaccine advocate Dr Paul Offit expresses surprise that the vaccine hesitancy or vaccine refusal movement did not gain significant traction at the time, in view of the admitted medical errors which resulted in a large number of vaccine-caused cases of paralysis (Offit, 2010). Offit goes on to document the rise of the anti-vaccination movement to the DTP shot (Shot in the Dark documentary by Barbara Fisher and Harris Coulter) and the creation of what became the influential (and vaccine adverse) National Vaccine Information Center in the United States.

It is often repeated that vaccine hesitancy, both historically and in people's minds, is primarily linked to a Lancet article by Andrew Wakefield linking the MMR vaccine with autism. Almost all articles whose aim it is to address and refute vaccine hesitancy make reference to his now-discredited article, which may well be a mistake for many reasons.

Today, vaccine hesitancy exists for both legitimate and irrational reasons, and this research put forward the proposal that this phenomenon may be usefully compared to another psychological/behavioral phenomenon known as "the fear of flying."

Many airplane travelers experience some degree of fear of flying, to an extent because airplanes can and have crashed (DePillis, 2014). At the same time, airline accidents are exceedingly rare, to the point that driving from one's residence to the airport is, in most cases, statistically riskier than the flight itself.

The biosocial model (which seeks to link behavior to genetic or biological predisposition) may seem 'extreme' in the vaccine hesitancy (or fear of flying). These are generally not considered as phobias or psychological pathologies, except in rare and extreme cases. However, Mobbs and colleagues have convincingly argued for the relevance of a biosocial approach in their paper entitled The ecology of human fear: survival optimization and the nervous system (Mobbs et al., 2015). Relevant concepts mentioned in the study, such as "safety seeking" and "threat value" can become activated in particular social circumstances, which is exactly what the biosocial model seeks to explore. For human beings dealing at a deep level with issues of safety and threat (also relevant to the Health Belief Model), vaccine hesitancy exists in the same

way that 'airplane hesitancy' exists: because vaccines do present a very small but real degree of risk which, due to a certain biosocial and psychological context, can evolve into a high level of anguish and outright refusal. Most vaccine-hesitant parents realize that the risk of serious vaccine injury is very small compared to the overall societal necessity of preventing the return of possibly deadly childhood diseases such as measles. In the case of fear of flying, there are very specific statistics comparing fatalities caused by airplanes compared to fatalities caused by automobiles. This has led to the development of successful fear of flying interventions documented in peer-reviewed journals (Campos et al., 2016). These interventions are surprisingly relevant and applicable to the design of similar interventions aimed at addressing vaccine hesitancy.

### Other analytical frameworks

Psychological and social analysis is very useful when applied to vaccine hesitancy, in particular to under the genesis and ongoing development of this phenomenon.

### Social construction of reality

For instance, Social construction of reality is a social theory introduced by Peter Berger and Thomas Luckmann in their book, *The Social Construction of Reality: A Treatise in the Sociology of Knowledge* (1967). This approach stresses the importance of one's perception of reality (understood as knowledge rather than opinion) as being shaped by human interactions. These interactions often take place online and tend to reinforce a certain perception of reality based on the echo chamber phenomenon. It is recognized that vaccine hesitancy has become a more significant phenomenon due to the effect of technology on the social construction of reality. This social theory illustrates the challenge of addressing the issue of the social environment and ultimately informs any possible intervention as needed to balance and reshape the social network influencing the Social Construction of Reality.

### Unintended consequences of purposive action

An extremely important biosocial concept when studying vaccine hesitancy is known as Unintended consequences of purposive action. It is named after an essay by Robert Merton published in 1936 (Merton, 1936). This social theory emphasizes the "unintended outcomes may be positive or negative, but they are often overlooked by the official outcome, resulting in poor understanding of their consequences." Vaccine hesitancy is related to this social theory because many parents that the possible

unintended consequences of immunization policies is what they perceive to be an unacceptable (or unknown) risk to their children. A possible intervention would have to address the Unintended consequences of purposive action, which is the real and perceived risk of serious vaccine adverse event. It is only by being convinced that the risk/benefit analysis is undoubtedly in favor of immunization (at least specific immunizations) that vaccine hesitancy will be addressed (Oto, n.d.).

### Weber's "vision of modernity"

Weber's "vision of modernity" concept is also applicable to the study of vaccine hesitancy because this phenomenon is clearly associated with a high level of distrust in institutions (CDC, FDA, Congress). Max Weber's prediction was that "power in the 20th century would shift from families and communities to institutions and their associated bureaucracies" (Byrkjeflot, 2018). There is a counter-reaction to the bureaucratization of health care, including immunization practices, which is associated with vaccine hesitancy. Some parents believe that the medical system forms a local moral world which has its own rules and interests, at odds with their family's welfare. Conversely, pediatricians feel that parents who refuse to vaccinate their children operate in a local moral world of their own, which presents a public health risk to the community at large (Kleinman, 2007). In theory, parents are the decision-makers when it comes to vaccine uptake, but public health policy must take into account the welfare of the population as a whole, which may or may not always coincide with individualized decisions. For instance, public health officials may have a perfectly rational reason to maintain polio immunization to prevent the return of a disease which has had no cases in the United States for several decades (Polio | U.S. Polio Elimination | CDC, 2019). However, for individual parents thinking along purely risk and benefits lines for their own household, the polio vaccine has a much different risk/benefits profile (compared to Hib for example) since the benefit is perceived as being zero and the medical risk as being unknown. For a public health researcher considering a vaccine hesitancy intervention, Weber's theory is important because it shows the necessity to address loss of confidence in institutions, notably the CDC and FDA. This can be done in a number of ways, not by ignoring real past or present issues but mostly by document the CDC's reactivity and transparency on vaccine safety concerns.

### Biopower

Biopower is a concept introduced by French philosopher Michel Foucault. According to the Oxford Reference Dictionary of Critical Theory, it describes "a form of political power that revolves around populations (humans as a species or as productive capacity)

rather than individuals (humans as subjects or citizens) (Biopower, n.d.). This is extremely relevant to public health in general and to resistance to a real or perceived abuse of power by government authorities, including in the form of vaccine hesitancy or refusal. The Dictionary entry notes:

[another] form of thinking about power began to be formulated by the nameless bureaucrats and policy-makers who actually run governments, which had no other concern than the power of the state... Foucault termed this new kind of political rationality biopower because it concerned itself with every aspect of life, right down to its most minute parts, though only in the abstract. It was interested in the health of the people in statistical terms, not existential terms—it cared about how people live and die, but not who lives and dies. For the first time in history, Foucault argues, biological existence was reflected in political existence (idem).

For a significant percentage of the population, the reaction of public health authorities in a number of countries or states has represented a new form of biopower. Although a fully review of relevant articles (with searches on biopower, Foucault, COVID-19, some listed in the bibliography) is beyond the scope of this dissertation, the main takeaway is that Foucault's biopower theory is highly relevant to understand psychological and sociological reactions to COVID-19 public health policies, including EUA and mandates, in the post COVID-19 era.

### Social Suffering

Skepticism in the pharmaceutical industry (which may be associated with the growing distrust for large corporations such as Monsanto) is part of the perception that the poor and uninformed are the victims of immunization policies fueled by greed and desire for power rather than genuine concern for human welfare. Social suffering – a social theory named after a 1997 book by Kleinman, Lock and Das – serves to illustrate the challenge of modern-day, social-justice and environmentally conscious Americans to understand and navigate such a complex world. Parents are struggling to figure out how to make the best possible decision and many resent the impression of biopower expressed in the recent radicalization of the situation which led California in particular to enact extremely strict vaccination laws in which the state has ultimate authority to grant or deny medical exemptions (State of California, n.d.).

## 2.2. Relationship with VH interventions

For the many reasons listed above, vaccine hesitancy has become a serious challenge, one that has sometimes been addressed by strict legal mandates (e.g., Mississippi,

California, France) but rarely by carefully designed public health interventions. This does not mean that vaccine hesitancy interventions do not already exist, on the contrary, and these form the basis of this capstone project (ECDPC, n.d.).

When trying to understand and address the issue of vaccine hesitancy, several assumptions can and should be challenged, notably:

- That distrust in the CDC and FDA cannot be repaired (Kowitt et al., 2017)
- Vaccine hesitancy is primarily linked to the fear of autism, or associated with the Andrew Wakefield (now retracted) Lancet paper
- That vaccines are bound always to be managed as for-profit products, as opposed to carefully managed and produced public goods
- That in an era of genomics and individualized medicine, it is impossible to create a personalized vaccine schedule for very hesitant parents
- That an all or nothing dialectical clash between “I will advocate for vaccines until my last breath” (Winter 2016) and a radical ‘antivax’ stance is unavoidable
- That exact risk/benefit computations cannot be obtained due to issues with accurate reporting of vaccine injuries
- That the risk/benefit profile of all vaccines is the same and that parents are willing to discuss their vaccine hesitancy without reference to specific vaccines and schedule factors
- That vaccine mandates cannot in fact increase public trust (regardless of bioethical and biosocial concerns associated with medical coercion) (La confiance dans les vaccins revient, estime Buzyn, 2019).

A major benefit of engaging in a comprehensive and interdisciplinary analysis of vaccine hesitancy would be to design more effective ways to assess and develop vaccine hesitancy interventions.

### 3. Interdisciplinary research

According to Harvey Graff, (a professor of English and history at Ohio State University and the author of a new book, *Undisciplining Knowledge: Interdisciplinarity in the 20th Century*):

In my view, interdisciplinarity is among the most misunderstood and misused term[s] in contemporary academic discourse... Well-grounded, knowledgeable interdisciplinarity is among the most important critical paths to new approaches and path-breaking research, teaching and program development. It remains rare. I strongly suspect that 'mild' or 'slight' interdisciplinarity refers much more to cross- or multidisciplinary — or even to faux interdisciplinarity — rather than developed interdisciplinarity (Graff 2015).

The article containing this citation notes the importance and growth of interdisciplinary research in dissertation work, but also the actually narrow scope of most research:

Further, some of those aren't even leaving the disciplines that house their programs but consider it interdisciplinary when they work with another subfield within their own discipline. The overall trend, the report found, is for people to stay close to home when going interdisciplinary (Jaschik, 2015).

In this research, it is clear that the scope of inquiry needs to take place both within subdisciplines of public health (epidemiology, biostatistics, clinical trials, health communications, global health) but also across the very different disciplines identified in the phase of inductive research.

### 3.1. Philosophy and Epistemology

Epistemology is widely defined as “the theory of knowledge, especially with regard to its methods, validity, and scope. Epistemology is the investigation of what distinguishes justified belief from opinion” (Oxford Languages). This is precisely at the heart of the phenomenon of vaccine hesitancy, namely the inability of individuals to reach a decision in vaccine acceptance based on “justified belief” rather than anyone’s mere “opinion” (although informed opinion must be considered a major input of justified belief). In turn, epistemology and the related discipline of critical thinking requires precise definition to avoid the fallacy of equivocation. In particular, two concepts must be defined for individuals (and communities) to articulate scientific data into discourse: safe and effective (and the two are often combined in a single expression). Here, it is important to distinguish between the legal/official use of “safe and effective” by the FDA and how these words may be perceived by individuals. For the FDA, “safe and effective... means that the benefits of the drug must be greater than the known risks” (Research, 2021). By

contrast, in more common parlance, “safe” generally conveys a much higher level of “safety” as in: “protected from or not exposed to danger or risk; not likely to be harmed” (Oxford) or “free from harm or risk” (Merriam-Webster).

Safety can actually be expressed in both relative (the FDA approach in the context of treatment) or absolute terms, as in the case of road safety, air travel safety and the risks associated skydiving or base-jumping.

As a case in point in view of our discussion of ‘fear of flying,’ precise statistics can be offered as to the safety of flying a commercial airline, but these statistics have a geographical component and they can be expressed in various ways (fatality per hour of flight or per km travelled). Hence, The Economist notes that “air travel is safer by distance travelled, but trains are as safe as planes; and cars four times more hazardous for deaths per time travelled, and cars and trains are respectively three times and six times safer than planes by number of journeys taken” (“Difference Engine,” 2013). The importance of this point is that flying can (and should be) considered as extremely safe, even though some people experience great anxiety at the thought (or action) of being in a commercial aircraft. An acceptable estimate of the risk of dying in a commercial flight per person per flight can be rounded up to between 1/1,000,000 and 1/5,000,000. This risk is not null, but it can serve as a baseline for “extremely safe.”

Skydiving, by comparison, is obviously a “less safe” proposition, with annual US fatalities between 13 and 21, the risk can be estimated at 1 fatality in every 167,000 events (jumps). Down the safety spectrum, “Base jumping has a risk of death of 1 in every 2,300 jumps, whereas with hang gliding the risk is 1 in 116,000 flights” (Risk of Dying and Sporting Activities, n.d.).

If “safe” is relatively easy to articulate using this comparative model, “effective” also requires some clarification. The case of the COVID-19 vaccine has illustrated the need to associate effective with a particular metric, for instance “80% protection/risk-reduction against death (or can be expressed as severe form including death) for a given duration.” In the case of the MMR vaccine, the data can be easily presented and explained, as in:

One dose of MMR vaccine is 93% effective against measles, 78% effective against mumps, and 97% effective against rubella. Two doses of MMR vaccine are 97% effective against measles and 88% effective against mumps (Measles, Mumps, and Rubella (MMR) Vaccination | CDC, 2021).

In addition, “they are considered to have life-long immunity once they have received the recommended number of MMR vaccine doses or have other evidence of immunity” (Ask the Experts: Measles, Mumps, and Rubella (MMR) Vaccines, n.d.).

Moreover, it should be noted that according international rules, “to be approved, vaccines are required to have a high efficacy rate of 50% or above” (Vaccine Efficacy, Effectiveness and Protection, n.d.).

A major contribution of this discipline is to provide concerned patients (or parents) which a data-based and easy to understand definitions of “safe” and “effective.”

## 3.2. Psychology

Psychology is defined as the scientific study of the human mind and its functions, especially those affecting behavior in a given context, and the mental and emotional factors governing a situation or activity (Oxford). We have already mentioned the complex psychological factors associated with vaccine hesitancy and other forms of hesitancy, including in the case of risk perception. A still recent article by Murphy and colleagues entitled Psychological characteristics associated with COVID-19 vaccine hesitancy and resistance in Ireland and the United Kingdom illustrates the importance of psychological analysis in the study of vaccine hesitancy (Murphy et al., 2021). An important finding of this study was that, with regard to vaccine hesitant individuals:

For example, recognising their preference for social dominance and authoritarianism, and their distrust of conventional authority figures, vaccine hesitant or resistant persons may be more receptive to authoritative messages regarding COVID-19 vaccine safety and efficacy if they are delivered by individuals within non-traditional positions of authority and expertise. Engagement of religious leaders, for example, has been documented as an important approach to improve vaccine acceptance. Key to the preparation of a COVID-19 vaccine is, therefore, the early and frequent engagement of religious and community-leaders, and for health authorities to work collaboratively with multiple societal stakeholders to avoid the feeling that they are only acting on behalf of government authorities (Murphy et al., 2021).

It is therefore from the perspective of psychological analysis that the importance of religious leaders is emphasized, a point directly relevant to this research. This is directly related to the critical issue of trust and distrust, as the same article notes in its abstract:

In both populations, those resistant to a COVID-19 vaccine were less likely to obtain information about the pandemic from traditional and authoritative sources and had similar levels of mistrust in these sources compared to vaccine accepting respondents (Murphy et al., 2021).

These two concepts will be further explored in this research. In the end, however, the date of this important article (2021) reveals the perils of what was then the understandable expectation that the COVID-19 vaccines would perform compared to other vaccines. The authors' hope that to discover "how to persuade a sufficient proportion of their populations to accept the vaccine to effectively suppress the virus," but in the end, COVID-19 vaccines were only truly effective against severe forms of the disease, not complete suppression of infections and virus circulations. This excessive optimism in pro-vaccine communications will be discussed under the umbrella of ethics and bioethics.

### 3.3. Sociology / Mass formation

Sociology and psychology are closely related disciplines as are considered social sciences. Psychology is focused on understanding the individual, while sociology — like its name suggests — focuses on social groups, communities, and cultures (Similarities and Differences Between Sociology and Psychology, 2021).

#### Polarization and Echo Chambers

Polarization, for instance, can be seen as a sociological phenomenon which is not limited to politics but also to other issues. In 2008, Schmidt and colleagues analyzed the echo chamber effect in an article entitled Polarization of the vaccination debate on Facebook. The article noted that:

[the] consumption of content about vaccines is dominated by the echo chamber effect and that polarization increased over the years. Well-segregated communities emerge from the users' consumption habits i.e., the majority of users consume information in favor or against vaccines, not both (Schmidt et al., 2018).

This was associated with what is known as the 'echo chamber effect' defined as "environments in which the opinion, political leaning, or belief of users about a topic gets reinforced due to repeated interactions with peers or sources having similar tendencies and attitudes" (Cinelli et al., 2021). The author then notes that "selective exposure and confirmation bias (i.e., the tendency to seek information adhering to preexisting opinions) may explain the emergence of echo chambers on social media." As a result,

one's perception of 'what is true' is heavily influenced by sociological factors, especially when the science is complex or 'in the making' and even 'subject to change.' This is a reference to Dr Leana Wen's (a frequent and qualified medical commentator on CNN) statement in February 2022 that "the science as changed." In this context of confusion and distrust, the phenomenon of sociological tribalism fostered by social media.

Especially in the United States, political polarization has 'spilled over' into other societal areas, including vaccine policy. In this context, we see vaccine hesitant parents or patients labeled as "anti-vax" and vaccine proponents accused of collusion with corrupt corporate forces. This phenomenon of polarization veering to radicalization and extremism is something found on the pro-vaccination camp, for instance on the home of the ProtectUS organization:

But in recent years, a small but growing group of science deniers and conspiracy theorists have organized a dangerous anti-vaccine movement. The anti-vaxxers defy vaccination requirements, attack vaccination sites, and spread misinformation (ProtectUS, n.d.)

Sadly, this 'broad-strokes' rhetoric, found on both sides, only serves to support a polarization which makes the much-needed dialogue difficult to engage in.

#### Fourth Turning Generational Theory

An interesting theory in sociology is that societies go through historical cycles that seem to repeat with similar patterns. In 1997, Neil Howe and William Strauss authored *The Fourth Turning* which argue that history moves in 80-year cycles (each cycle corresponding to the length of one long human life). The end of the cycle is the 20-year period that is described as the "winter" stage of the cycle and which Howe and Strauss called the fourth turning and which they predicted for 2020. A major aspect of this generation would be that "political and economic trust will implode" (Hoffower, 2021). This is congruent with previously cited research in our Psychology section. This was well understood by Maya Goldenberg in her 2021 book *Vaccine Hesitancy: Public Trust, Expertise, and the War on Science* considered in our literature review.

#### Mass formation

A final consideration for this review of the contribution of sociology to this research on vaccine hesitancy is the phenomenon of mass formation which stands at the

intersection of psychology and sociology. “Mass formation theory” was defined in a 2021 article – before it became controversial – as:

Mass formation also known as mob or crowd psychology — is the study of how individual behavior is influenced by large group of people. This branch of social psychology has been studied by Sigmund Freud, Floyd Allport, Gustave Le Bon, and many others (CAPM, 2022).

Two of the stages associated with crowd psychology are (1) contagion when individuals ideas and emotions greatly influenced by the dynamics of their surrounding masses; and (2) suggestion, when groups have developed a shared unconscious which affect their decisions and feelings. During the course of the COVID-19, Dr. Mattias Desmet, professor of clinical psychology at Ghent University, suggested that the population’s reaction to the COVID-19 pandemic had features of Mass Formation Psychosis. The application of this theory to COVID-19 societal changes (e.g. lockdowns) soon became controversial, but studies did confirm “crowd” or “group” patterns in COVID-19 pandemic perception. For instance, Soyoung Kwon noted that:

Democrats were more likely to experience COVID-induced mental distress than Republicans, and higher risk perception and expected infection severity were associated with mental distress. Furthermore, risk perception and expected infection severity of COVID-19 (Kwon, 2022).

A similar study by de Bruin and colleagues confirmed and elaborated:

According to theories of decisions about health behavior, people who perceive greater risks are more willing to implement protective behaviors and more likely to prefer government policies designed to mitigate risk (Bruine de Bruin et al., 2020).

This was amply confirmed by a Pew study which concluded:

Democrats remain much more likely than Republicans to view the coronavirus as a major threat to their personal health, regardless of whether they live in counties that have experienced high, medium or low impacts from the outbreak. In fact, Democrats living in low-impact counties are 14 percentage points more likely than Republicans living in high-impact counties to say the coronavirus is a major threat to their own personal health (46% vs. 32%) (Tyson, n.d.).

This leads us back to the Health Belief Model and the issue of trusted sources, as well as an inquiry into the role of politics and governance in the problem under consideration.

### 3.4. Actuarial science

Actuarial science is a term more typically used in the insurance industry. It refers to describe the discipline or science of risk assessment. Actuarial scientists using data and mathematics to estimate the probability of unexpected and adverse events, such as death or illness, occurring in a given population. As a result, individuals practicing skydiving must pay a premium to obtain life insurance, which is also true of private pilots. Underwriters are not interested in risk perception, only in a risk assessment that closely matches the situation at hand. As we have seen, a risk of death or extremely serious adverse event estimated at 1 per 5,000,000 (commercial aviation) or even 1 per 1,000,000 events is considered extremely safe. In view of the benefits, individuals have no reason to hesitate, although admittedly there is no such thing as zero risk, including in commercial aviation.

A risk range of 1/100,000 to 1/200,000 (similar to skydiving) may be reasonably described as “safe” or indeed “reasonably safe.” However, even actuaries would qualify that this level of risk (the risk being multiplied by the number of jumps).

When dealing with infectious diseases and therefore vaccines, the ability to provide realistic risk data is important, but not always easy. In the case of the measles, the risk of contracting the disease is extremely low, thanks to high immunization rates. The last case of measles fatality was in 2015, in the case of a woman with a suppressed immune system (Szabo, n.d.). In other words, the risk of dying from the measles for a US person is virtually nil, as long as everyone else continues to be immunized to maintain this remarkable herd immunity. However, in an environment where a large segment of the population would refuse the vaccine, outbreaks would undoubtedly reoccur with a case fatality rate as high as 1/1,000 or more realistically 1/5,000 with medical care. Moreover, in the context of an outbreak and in view of the extreme contagiousness of the virus, the risk of contracting the disease would also be significant (as high as 1/100), resulting in a personal risk of about 1/100,000, which brings us to ‘skydiving territory.’

In general, the risk of serious adverse events associated with each vaccine (and each associated disease) is well documented through long-term and international epidemiological studies. The contribution of actuarial science to the issue of vaccine hesitancy is clearly essential: the risk/benefit calculation needs to be squarely in factor

of vaccine acceptance in a context of trusted sources, which should be the central object of related interventions.

### 3.5. Politics and governance

Our interdisciplinary study of sociology has led this research to consider the importance of politics and governance in issues related to vaccine hesitancy, especially in the COVID-19 era. Politics and governance are broad topics and disciplines, dealing with the administration of society in the specific context (United States) of a democratic society. In the United States, the major institutions are (1) The Executive Branch headed by the President, which includes all executive agencies including the CDC and FDA, (2) the Legislative Branch which is Congress (Senate and House), (3) the Judicial Branch at the top of which is the Supreme Court. During the COVID-19 pandemic and the development of the societal response and COVID-19 vaccines and therapeutics, the polarization of US politics became a serious issue. Public health decisions and debates were clearly influenced by partisan politics while Trump administration officials including 'non-partisan' administrators such as Anthony Fauci become divisive figures.

One aspect of good governance, related to ethics, is the disclosure and management of conflicts of interest. However, the obvious persistence of such conflicts of interest in vaccine-related areas continues to affect public trust in vaccines. A case in point is the fact that the FDA receives a significant portion of its budget from the pharmaceutical industry. As one sympathetic fact-checking article confirmed:

About 45% of the FDA's budget, or \$2.7 billion, comes from industry user fees, according to a fact sheet released by the FDA in November 2020. The other 55%, or \$3.2 billion, comes from federal funding. For regulatory activities involving human drugs (which account for a third of the agency's total budget), 65%, or about \$656 million, is funded by industry user fees. For biologics, which includes vaccines and represents 7% of the FDA's total budget, industry fees pay about 40%, or around \$337 million. While there is a concern industry-based funding – which increased nearly 42% between the fiscal years 2017 and 2021 – may pose a conflict of interest, the FDA has said its drug approval decisions are independent of where the funding comes from (Fauzia, n.d.).

Another related phenomenon of current US governance affecting trust and credibility is the phenomenon of 'revolving doors' between regulatory agencies and the for-profit industry. A paper by Meghani and Kuzma (2010) examining this situation concluded that:

We have argued that the current situation and lack of control over the revolving door between industry and regulatory agencies occasions at least three ethical and policy problems that have to do with public trust and fair representation. They indicate a public failure of the regulatory review process... We hold that this system-wide change in the current approaches to regulation of new technologies is needed to control for industry bias (Meghani & Kuzma, 2011).

This concern was also manifest in the case of the approval of the Moderna COVID-19 vaccine for which the US government held patent rights. Worse, a credible article by Ambati and colleagues published in *Frontiers in Virology* presented compelling evidence that a unique feature of the SARS-COV-2 virus (spike protein) was the object of a 2016 Moderna patent, concluding prudently that “highly unusual. Potential explanations for this correlation should be further investigated” (Ambati et al., 2022).

In view of the above, it seems impossible to avoid the conclusion that vaccine hesitancy cannot be separated – or addressed – apart from the less-than-perfect system of governance and regulation that applies to vaccine manufacturing. Parents and patients are often hesitant to accept recommended vaccines because they perceive, rightly in part, that the system of governance that produces this recommendation does not that their best interest at heart and that it is contaminated by corporate conflicts of interest. Public health messaging will in all likelihood be insufficient to overcome informed hesitancy as long as much-needed structural reforms are delayed.

### 3.6. Geopolitics

Even a discipline seemingly distant and unrelated to public and vaccine hesitancy such as geopolitics should be considered in a truly interdisciplinary study of vaccine-related issues. In the case of COVID-19, observers noticed that the vaccine policy response was influenced by geopolitical rather than purely scientific considerations. For instance, China deployed its Sinopharm then Sinovax/ CoronaVac vaccines which were not used in the United States and European Union. Yes, trusted (and controversial) French researcher Didier Raoult came forward in support of the Chinese option CoronaVac as “the most effective [and] reasonable” (Lanen, 2021). However, neither the Chinese nor the Russian vaccines were authorized and used in most Western countries. However, both China and Russia delivered their vaccines internationally in what has been called “vaccine diplomacy” (Zhang & Jamali, 2022).

The United Kingdom preferred to promote the use of its own, ‘home developed’ (Oxford) vaccine known as The Oxford/AstraZeneca (ChAdOx1-S [recombinant] vaccine).

However, in March 2021, the AstraZeneca vaccine against COVID-19 was suspended in three Nordic countries and, soon after, in other European countries (Norway, Iceland, Austria, Estonia, Lithuania, Luxembourg, Italy, and Latvia). The overall conclusion was that the safety profile of AstraZeneca vaccine seemed to be favorable than that of the Pfizer alternative, at least for specific age and gender categories. Also, it should be noted that AstraZeneca vaccine was never approved (EUA) by the US FDA. This does not mean that various countries adopted a 'preferred national product' against scientific evidence, but it does show the role of geopolitics and reluctance to suspend a national product in the face of safety concerns. Eventually, even the UK announced that "Under-30s in the UK are to be offered an alternative Covid vaccine to the AstraZeneca jab due to the evidence linking it to rare blood clots" (Triggle, 2021).

The issue comparative international practice is relevant in the case of surveillance and risk assessment, as side effects may be more prevalent in certain countries or populations on account of genetic or geographic factors (e.g., vitamin D deficiency). With regards to the risk of Vaccine-induced immune thrombotic thrombocytopenia (VITT):

The highest incidence was reported from Norway, in which five cases were reported from among approximately 130,000 individuals vaccinated with ChAdOx1 nCoV-19, suggesting an incidence of 1 in 26,000 [4]. A January 2022 report from the VAERS surveillance system to the CDC and FDA identified 54 cases of thrombosis with thrombocytopenia (in some cases, anti-PF4 antibodies were not tested) from among over 14 million recipients of Ad26.COV2.S, for an incidence of 3.8 per million (approximately 1 in 263,000) (Warkentin, 2022).

This shows that vaccine-related policies have a national and international dimension with geopolitical aspects. Risk perception as well as real-risk factors are also linked with population factors, which may influence decision-making processed at the national level. Whether the decisions of certain national authorities to prefer, suspend or change the recommendation parameters of certain vaccines during the COVID-19 crisis to whether these decisions will be perceived positively by the population as a sign of appropriate and fast response or rather as a factor of distrust would be a relevant area of future research but also sound public health messaging.

### 3.7. Ethics and bioethics

Ethics and bioethics and related and perhaps too often ignored disciplines related to public health. A 2017 article by Doudenkova and colleagues attempted to analyze the

place of ethics and bioethics in public health programs, only to conclude that “there is still significant room for improvement” (Doudenkova et al., 2017). Yet, ethics (defined as the “moral principles that govern [...] behavior or the conducting of an activity”) is central to the issue of vaccine hesitancy. The real problem of conflicts of interest in medicine has led to improvements (requirement to disclose such conflicts) but not to a satisfactory resolution. A 2020 article by Roussel and Raoult entitled “Influence of conflicts of interest on public positions in the COVID-19 era, the case of Gilead Sciences” argued on a quantitative basis between pharmaceutical funding and medical recommendations. Even when it comes to the generally praiseworthy and scientifically sound desire to increase vaccine uptake, ethical considerations should remain foremost.

A 2017 paper by Fahlquist (of the Centre for Research Ethics and Bioethics, Uppsala University, Sweden.) entitled “Vaccine hesitancy and trust. Ethical aspects of risk communication” served as reminder that well-intentioned health communications campaign should be forgo ethical principles. The article offered a review of the highly problematic H1N1 vaccination campaign in Sweden, reminding the reader that:

During the Swedish H1N1 vaccination policy in 2009, the message was that the vaccine is safe. However, a group of adolescents developed narcolepsy as a side effect of the vaccine. Taking this into account, it becomes clear that the government should communicate risks and benefits responsibly and take responsibility for individuals affected negatively by populational health interventions (Nihlén Fahlquist, 2018).

The conclusion and recommendation of this important article are worth quoting in full:

To communicate respectfully entails not treating vaccine sceptics as ill-informed or less educated, but instead taking the concerns of the vaccine hesitant, who potentially could change their minds, as a starting-point of a respectful discussion. There will inevitably be individuals who suffer from side effects of justifiable population-based health promotion activities. However, the public should be able to trust the message and count on the government to take responsibility for individuals affected by side effects. This is important for normative reasons but is additionally likely to contribute to restored and maintained trust (idem).

This is an important consideration in the quest to advance one’s position; that effective means of communication may be not always be ethical, or that overzealous optimism in vaccine safety and efficacy may in some cases backfire. A case in point is the temptation to use anecdote (used here as a scientific term) or rather “emotionally

stirring stories” to move the pendulum in one direction or another. A 2021 article by Barry and colleagues concluded that “Sharing positive emotions and stories may be more effective than sharing data when attempting to reduce vaccine hesitancy in SNF staff” (Berry et al., 2021). For better or worse, positive as well as negative stories do exist on both sides of this divide, but public health practitioners should keep in mind that “anecdotes” do not have any epidemiological and therefore scientific value.

Last but not least, bioethics is relevant to the issue of vaccine hesitancy in view of the use of cells derived from aborted fetuses. For instance, the National Catholic Bioethics Center (NCBC) issued the following statement:

The Church has consistently pointed out the ethical problems with vaccines produced and/or tested using abortion-derived cell lines. The Church has judged it permissible for people to either accept (under protest) or reject the use of such vaccines. In other words, there is no universal moral obligation to accept or refuse them, and it should be a voluntary decision of the individual (NCBC Statement on COVID-19 Vaccine Mandates, n.d.).

On the Orthodox side, the semi-official body known as the Orthodox Theological Society in America offered a strong endorsement of all COVID-19 vaccines, stating that “the vaccines present the best ethical option to promote health and life, despite their connection with the use of aborted fetal cells” (Orthodox Theological Society in America, 2021). The role of this document among Orthodox Christians will be discussed in our quantitative section.

Another aspect of personal ethic is the issue of making decisions that are either entirely self-centered “what is best for me and my family” or that are willing to take into account the common good, even if this path make present a reasonably lower risk/benefit ratio. As we have seen in our discussion of the contribution of the discipline of actuarial science, the risk to have severe consequences or death from measles (in the USA) is virtually non-existent. In this context of herd immunity, it is almost certain that the risk of side effects from the measles vaccine is higher than the risk from the disease, which make it reasonable for an individual decision-maker to decline the vaccine. In other words, a parent declining the measles vaccine (we will also discuss the MMR aspect) may well fully agree with the CDC statement that “Most people who get MMR vaccine do not have any serious problems with it. Getting MMR vaccine is much safer than getting measles, mumps or rubella” but would still decline the vaccine because the risk of contracting the measles is made incredibly low on account of herd immunity. However, this cannot be the perspective of public health policy makers who are well

aware that this 'protective shield' against measles outbreak is made possible by maintaining a very high immunization rate. The interplay between taking advantage of a situation made possible by everyone else's willingness to take part in a 'public health social contract' has ethical, if not moral and religious implications. Health and public health actors engaging the issue of vaccine hesitancy should be able to understand the dilemma presented by this situation. Game theory (the study of mathematical models of strategic interactions among rational agents) would also be a relevant discipline to consider, but this would not be practically helpful in terms of vaccine hesitancy interventions. As we shall discuss in our paradigm model, what would be helpful would be to (1) articulate why the public health perspective may not always line up with personal self-interest in the context of 'other people maintaining herd immunity;' (2) provide credible figures on risk factors and the ethical willingness to slightly increase one's risk profile (within a certain factor and under certain generally-accepted limits) to help support the common public health ecosystem.

### 3.8. viii) Theology and religion

Religion remains a very important dimension of human life, including (and perhaps especially) in the United States among developed countries. The proportion of religiously unaffiliated Americans, after years of increase, seems stable at around 25% ("The 2020 Census of American Religion," n.d.). This means that most Americans (75%) do express religious affiliation, and about 50% of Americans said they belonged to a church, synagogue or mosque (Gallup, 2021a). Clearly, one's perception of risk may be influenced by one's religious beliefs. For instance, acceptance of a 'fatalistic' or 'predestination-driven' doctrines may lead a person to express the view "it will happen if God wills or if it is meant to be, or it is my time." Others may believe that God will protect if they go to religious services during a pandemic, or that God will heal them if they become sick and if they have faith. According to the Health Behavior Model, religious beliefs may affect risk perception and affect decision making. Conversely, religious may lead others to embrace vaccines as means to protect the community and vulnerable individuals. Pope Francis, the leader of the world's 1 billion Catholics, "urged people to vaccinated against Covid-19" (Vatican News, 2021).

Surprisingly, a PubMed search on "vaccine hesitancy religion" reveals the dearth of research in this critical area. The leading result, a 2021 article by Williams and colleagues entitled Associations between religion, religiosity, and parental vaccine hesitancy, failed to find "an association parental vaccine hesitancy, religiosity, or adherence to a major faith tradition," but this study concerned a relatively small sample

of “sample of mostly poor, Latino, Christian mothers” (Williams et al., 2021). However, a 2021 study by Corcoran and colleagues found that “Christian nationalism is one of the strongest predictors of COVID-19 vaccine hesitancy and is negatively associated with having received or planning to receive a COVID-19 vaccine” (Corcoran et al., 2021). However, this study functioned on the basis of a very narrow definition of “Christian nationalism” associated with a positive reply to the question: “To what extent do you agree or disagree that the federal government should declare the United States a Christian nation?” It seems difficult, therefore, to find significant in either of these studies. This research suggests that more subtle theological criteria need to be investigated in the study of risk perception and vaccine hesitancy. In particular, our quantitative survey will explore risk perception among Orthodox Christians with regards to theological situation, confirm the relevance of theology and religion to the issue of vaccine hesitancy.

### 3.9. ix) The importance of public health subdisciplines

The disciplines discussed above are not closely related to public health, but a number of public health subdisciplines should also be considered when research vaccine hesitancy. Several have been discussed indirectly, such as the connection between ethics and public health communications. Likewise, governance is closely related to the issue of clinical trials standards and oversight.

Epidemiology and biostatistics should obviously be considered as core disciplines in the matter at hand. In the case of the Pfizer COVID-19 vaccine clinical trials for the 5-11 age group, it is the small size which was acceptable in terms of standard computation but problematic in view of the impossibility to detect rare adverse events such as myocarditis. Right or wrong, this resulted in a major US state (Florida) breaking from the federal CDC recommendation and suspending its recommendation “for healthy children.” Specifically, on March 7, 2022, the “state’s surgeon general Dr. Joseph Lapado cited studies that showed few COVID fatalities among healthy children and elevated risk among young boys receiving the vaccine of side effects such as myocarditis” (Whitcomb, 2022).

While it is near-impossible to expect the general public to understand the fine points of epidemiology and statistics, the above illustrates the state of confusion of patients and parents during the COVID-19 pandemic and the risk of increased confusion and hesitancy in the post-COVID-19 era.

### 3.10. Section conclusions

This section illustrates the contribution and explanatory of interdisciplinary research applied to the phenomenon of vaccine hesitancy. During the literature and preliminary research phase, it had been noted that a search in PubMed on “vaccine hesitancy interdisciplinary” did not result in any significant results. This research intends not only to highlight this gap in knowledge but also to provide information and recommendations based on such an interdisciplinary induction.

## 4. Towards a paradigm of trust and risk

### 4.1. Introduction

Our literature review and interdisciplinary research leads us to set forth the combined importance of trust/distrust and risk perception in vaccine hesitancy. The WHO is well aware that “Vaccine hesitancy is complex and context specific, varying across time, place and for different vaccines. This phenomenon is influenced by factors such as complacency, convenience and confidence” Noni E. MacDonald and SAGE, ‘Vaccine Hesitancy: Definition, Scope and Determinants’, *Vaccine* 33, no. 34 (14 August 2015): 4161–64, <https://doi.org/10.1016/j.vaccine.2015.04.036>.. Here “complacency” is obviously associated with risk perception, convenience is hardly a consideration in the US context, and confidence is synonymous with trust. A relevant systematic review by Cella and colleagues (*Resources for assessing parents’ vaccine hesitancy: a systematic review of the literature*) clarifies:

In the [WHO EURO] “3 Cs” model, confidence is defined as trust in the effectiveness and safety of vaccines, and in the system that delivers them. This includes the reliability and competence of health services and health professionals and the motivations of policy-makers who decide on the needed vaccines P Cella et al., ‘Resources for Assessing Parents’ Vaccine Hesitancy: A Systematic Review of the Literature’, *Journal of Preventive Medicine and Hygiene* 61, no. 3 (6 October 2020): E340–73, <https://doi.org/10.15167/2421-4248/jpmh2020.61.3.1448>..

This definition and scope of “trust” are useful as we propose to suggest how trust “in the system” has been affected and why root causes of distrust are difficult to address. The second part of this paradigm analysis is to document how in like manner risk and risk/benefit assessment is proving to be daunting task for concerned parents, and what

recommendations might be made to address the second dimension of the proposed paradigm.

## 4.2. The paradigm of trust and distrust

Our foray in the discipline of sociology and the Fourth Turning theory encountered the proposition that American society in particular suffers from “a pervasive distrust of institutions and leaders, an edgy popular culture, and the splitting of national consensus into competing “values” camps” Lifecourse Associates, ‘The Four Turnings’, accessed 23 March 2022, <https://www.lifecourse.com/about/method/the-four-turnings.html>.. In this section, we consider this phenomenon of loss of trust and appropriate ways to both acknowledge and correct this societal problem.

## 4.3. Trust in Institutions

Among the US institutions or “system” involved in vaccine development, approval, delivery and monitoring are public entities such as the FDA and CDC but also private actors such as GlaxoSmithKline, Merck, Sanofi and Pfizer. These for-profit and publicly traded companies derive considerable revenue from the sale of vaccines considered as pharmaceutical products, in many cases with state mandate and exemption of legal liability.

Figure 1: Top 10 pharmaceutical companies

Apart from their vaccine activities, these companies, for lack of better term, sell other pharmaceutical products, and in doing so have not always acted as trustworthy actors in public health but rather as profit-seeking corporations. In 2012 for example, the US Department of Justice announced that “U.S. Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection with Unlawful Promotion of Vioxx” and that it was fined “\$322 Million For Illegal Marketing” DOJ, ‘U.S. Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection with Unlawful Promotion of Vioxx’, 2012, <https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-sentenced-connection-unlawful-promotion-vioxx>.. A few years before, in 2009, the same US Department of Justice had announced the “Largest Health Care Fraud Settlement in Its History: Pfizer to Pay \$2.3 Billion for Fraudulent Marketing” DOJ, ‘Justice Department Announces Largest Health Care Fraud Settlement in Its History’, 2009, <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history>.. In both cases, the business practices of these leading vaccine manufacturers were described as “criminal” and “fraudulent.” This still-recent corporate

background explains in part the low level of trust experienced in the United States by the pharmaceutical industry. According to one report:

Pharma's score of 38 puts it firmly in distrusted territory, while scores in the 50s in previous years had pegged it as neutral. Overall trust in healthcare in the U.S. fell by nine points, down to 53% of consumers, which made it the least trusted of the 15 industry sectors that Edelman studies. The global score for pharma—as opposed to U.S.-only—remained neutral with a score of 55 Beth Snyder Bulik, 'Trust Pharma? Not so Much, Annual Survey Shows, with Biggest Loss Ever', Fierce Pharma, 13 June 2018, <https://www.fiercepharma.com/marketing/pharma-trust-plummets-u-s-consumers-annual-edelman-survey-biggest-dive-to-date..>

The article also mentions “the opioid epidemic” which resulted not only in national public health disaster and the condemnation of the pharmaceutical company involved (Purdue) but also in the consulting firm (McKinsey) which had helped Purdue increase the sales of the deadly substance. According to the BBC:

McKinsey has agreed to pay \$573m (£419m) to resolve claims it faced across the US related to its role fueling America's opioid epidemic. The consulting firm was under investigation for its work with Purdue Pharma, which aimed to boost sales of the addictive Oxycontin painkiller 'McKinsey Agrees \$573m Opioid Settlement in US – BBC News', accessed 23 March 2022, <https://www.bbc.com/news/business-55939224..>

This same firm was actively involved in designing French COVID-19 response policies, to the point of being allowed to write reports on official Ministry of Health letterhead Le Point, 'Vaccination anti-Covid : le cabinet McKinsey conseille le gouvernement', Le Point, 6 January 2021, [https://www.lepoint.fr/sante/vaccination-anti-covid-le-cabinet-mckinsey-conseille-le-gouvernement-06-01-2021-2408491\\_40.php..](https://www.lepoint.fr/sante/vaccination-anti-covid-le-cabinet-mckinsey-conseille-le-gouvernement-06-01-2021-2408491_40.php..)

In view of the above, it is understandably hard to blame the American public for its distrust in the pharmaceutical industry, especially when a leading actor such as Pfizer is frank enough to announce in its Mission Statement that “Our mission is to become the world's most valued company.” For companies such as McKinsey and Pfizer, what the public would consider as “patients” are fundamentally “consumers,” as explained in a McKinsey report from September 2021 entitled *Who's left? Engaging the remaining hesitant consumers on COVID-19 vaccine adoption*. The public health situation of the COVID-19 pandemic is articulated with an almost complete business-like mindset, using terms such as “consumers” “demand,” “marketing to consumers,” and “vaccine brand” McKinsey, 'Who's Left? Engaging the Remaining Hesitant Consumers on COVID-19

Vaccine Adoption', 2021, <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/whos-left-engaging-the-remaining-hesitant-consumers-on-covid-19-vaccine-adoption..> This article was well aware that “trust” was a key factor, and that the trusted source here would not be the manufacturer or even the system but rather family doctors and pediatricians:

For example, those concerned about safety or side effects value information from trusted sources that speak directly to specific concerns (for example, fertility)... Across the ‘Cautious’ and ‘Unlikely’ groups, an opportunity exists to address potential barriers, including communication from trusted advisers... Providers can lean on their existing relationships and trust with patients to engage in a meaningful fact-based dialogue in order to address concerns or unanswered questions, thereby increasing conviction... However, it is important for physicians to leverage this trust to provide recommendations that can influence the ‘Cautious’ and ‘Unlikely.’ Currently, many healthcare providers are not doing so... Healthcare provider sites that already offer the vaccine may consider various approaches to building trust with new and existing patients McKinsey..

Clearly, these companies have financial interest in overcoming vaccine hesitancy, but this should not be the case of government oversight or medical professionals. We suggest here that authors addressing vaccine hesitancy should openly recognize what may be a legitimate crisis of confidence in the top level of the vaccine ecosystem, namely the rather small group of vaccine manufacturers. It may seem unrealistic to recommend here the transformation of publicly traded companies in other forms of ownership and control, such as the Canadian model of Crown corporations. Still, this political reflection should be part of the broader discussion of vaccine hesitancy as a complex and partly justified societal phenomenon. Once this issue is acknowledged, interventions and communications addressing vaccine hesitancy should emphasize the determination and success – albeit delayed – of government authorities, notably the US Department of Justice in serving the public interest. The DOJ statement is worth citing on account of its ability to reassure a concerned public:

The United States will not tolerate unlawful conduct by pharmaceutical companies,” said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department’s Civil Division. “As the court’s sentence makes clear, those who put profits before patient safety by promoting their products for unapproved uses will be prosecuted and held accountable (DOJ 2012).

In order to maintain public trust in the advice offered by trusted medical professionals (with reference to the McKinsey article), it is also important to regulate financial incentive targeted to medical professional as representing a major conflict of interest and a violation of ethical principles in medicine. This is not to be taken for granted as a 1999 article by Fairbrother and colleagues entitled *The impact of physician bonuses, enhanced fees, and feedback on childhood immunization coverage rates* indicated that such financial incentives were in use and even encouraged.

#### 4.4. Trust in Mass Media and News Services

A Gallup survey conducted in September 2021 painted a bleak picture of Americans' trust in media outlets and news sources. The report indicated that:

Americans' trust in the media to report the news fully, accurately and fairly has edged down four percentage points since last year to 36%, making this year's reading the second lowest in Gallup's trend. In all, 7% of U.S. adults say they have "a great deal" and 29% "a fair amount" of trust and confidence in newspapers, television and radio news reporting Gallup, 'Americans' Trust in Media Dips to Second Lowest on Record', Gallup.com, 7 October 2021, <https://news.gallup.com/poll/355526/americans-trust-media-dips-second-lowest-record.aspx>.

The report also confirms the phenomenon of polarization evoked in our interdisciplinary discussion:

Partisans' trust in the media continues to be sharply polarized. Currently, 68% of Democrats, 11% of Republicans and 31% of independents say they trust the media a great deal or fair amount. The 57-point gap in Republicans' and Democrats' confidence is within the 54- to 63-point range for the two groups since 2017... Just as Americans' trust in the three branches of government is faltering, so too is their confidence in the fourth estate — the media. Confidence in the media among Republicans over the past five years is at unprecedented lows (idem).

As a result, access to a trusted source lacks consensus, not only on political views but more critically on fact-based information, raw data, and scientific positions. Moreover, trusting one's information source (CNN, MSNBC for Democrats and Fox News for Republicans) does not mean that the trusted source is in fact reliable. In other words, Republicans typically view news originating from 'the other side' as 'fake news' or 'misinformation' whereas Democrats hold the same perception of 'right-wing media.' Not unexpectedly, there is a measure of reality on both sides, and what was once viewed as

misinformation may well end up being recognized as valid news, including in the case of COVID-19 vaccine related information. For instance, a USA Today fact-check on the origins of the SARS-COV-2 virus had to be revised twice (with a change of rating) as new information became available. For instance, an article entitled *Fact check: Did the coronavirus originate in a Chinese laboratory?* (03/21/2020 using web archives) concluded:

Our ruling: False | The claim is that the coronavirus began in a Chinese laboratory. We rate this claim FALSE, based on our research. Overwhelming scientific evidence suggests the coronavirus originated in nature, and there is no evidence to suggest otherwise ‘Fact Check: Did Coronavirus Originate in a Chinese Laboratory?’, accessed 23 March 2022, [http://web.archive.org/web/20200322225604/https://www.usatoday.com/story/news/fact-check/2020/03/21/fact-check-did-coronavirus-originate-chinese-laboratory/2881150001/..](http://web.archive.org/web/20200322225604/https://www.usatoday.com/story/news/fact-check/2020/03/21/fact-check-did-coronavirus-originate-chinese-laboratory/2881150001/)

However, what was described as a “conspiracy theory” eventually gained traction, leading the newspaper to edit the article twice, with a much less trenchant conclusion. The very real challenge of having to publish a true or false (or information/misinformation) label on a piece of information must be acknowledged. If it is importance to reject the very concept of “alternative facts,” it is critical to properly deal with the issue of human fallibility and lack of objectivity. Vaccine hesitancy researchers do recognize the importance of this issue, but one wonders is the proposed solution to this very real problem is ethical and workable. Both the SPARS (2017) and EVENT-201 documents emphasize the problem of trust in media and misinformation:

At the same time, great potential exists for the public to encounter misleading or dangerous information about pharmaceuticals... Misinformation is proving especially challenging in connection with vaccines where social media users encounter disproportionate negative reporting and images, are more swayed by personal narratives about vaccination’s adverse effects than the science E Brunson, ‘The SPARS Pandemic 2025-2028: A Futuristic Scenario’, Johns Hopkins Center for Health Security, 2020, <https://www.centerforhealthsecurity.org/our-work/publications/the-spars-pandemic-2025-2028-a-futuristic-scenario-to-facilitate-medical-countermeasure-communication..>

The EVENT-201 recommendations were even more specific, and, to an extent, extreme:

Governments will need to partner with traditional and social media companies to research and develop nimble approaches to countering misinformation. This will require developing the ability to flood media with fast, accurate, and consistent information. Public health authorities should work with private employers and trusted community leaders such as faith leaders, to promulgate factual information to employees and citizens. Trusted, influential private-sector employers should create the capacity to readily and reliably augment public messaging, manage rumors and misinformation, and amplify credible information to support emergency public communications. National public health agencies should work in close collaboration with WHO to create the capability to rapidly develop and release consistent health messages. For their part, media companies should commit to ensuring that authoritative messages are prioritized and that false messages are suppressed including through the use of technology.

JHCHS, 'Public-Private Cooperation for Pandemic Preparedness and Response', Johns Hopkins Center for Health Security, 2019,  
<https://www.centerforhealthsecurity.org/event201/recommendations.html>..

This approach led to the creation of the so-called Trusted News Initiative (TNI) by the British Broadcasting Corporation (BBC) in cooperation with major news, technology and social media companies. During the COVID-19 crisis, the result of this global cooperation was the suppression of information considered disinformation (at the time) and the promotion of information originating from trusted sources such as the World Health Organization. The fundamental objective, according to both the SPARS and EVENT-201 documents was to foster trust in vaccines.

It is questionable, however, if these measures, especially in the US context, have any chance of restoring trust in official or preferred news sources. Generally, vaccine-hesitant parents and patients do not immediately trust official recommendations issued by "the system." Information-control policies and platforms such as the TNI may only have a short-term effect as the fundamental concept of relinquishing credibility through debate rather than through suppression may not be viable or desirable in the long-term.

#### 4.5. Trust in academic authorities

Not only researchers and institutions but indirectly the general public have relied on academic institutions and journals as sources and repositories of authoritative research. Among academic journals, *The Lancet* was widely regarded as a leading authority, owing in part to its rigorous peer-reviewed process. A rare warning call against excessive trust in publisher research was published in 2005 by John Ioannidis, Stanford Professor of Medicine, Epidemiology and Population Health under the striking title *Why*

*Most Published Research Findings Are False.* He writes: “A major problem is that it is impossible to know with 100% certainty what the truth is in any research question. In this regard, the pure “gold” standard is unattainable” John P. A. Ioannidis, ‘Why Most Published Research Findings Are False’, *PLoS Medicine* 2, no. 8 (30 August 2005): e124, <https://doi.org/10.1371/journal.pmed.0020124>.. As it is, the Lancet was affected by a vaccine-related problem when it published, then retracted (12 years later), an article by Wakefield and colleagues with an obscure title (*Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children*) and equally vague conclusion that:

We have identified a chronic enterocolitis in children that may be related to neuropsychiatric dysfunction. In most cases, onset of symptoms was after measles, mumps, and rubella immunization. Further investigations are needed to examine this syndrome and its possible relation to this vaccine A. J. Wakefield et al., ‘Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children’, *Lancet* (London, England) 351, no. 9103 (28 February 1998): 637–41, [https://doi.org/10.1016/s0140-6736\(97\)11096-0](https://doi.org/10.1016/s0140-6736(97)11096-0)..

Even though the conclusion was non-committal, publicity surrounding this case-study led a significant percentage of the British public to forego MMR immunization. This exposed the Lancet to a crisis of credibility and academic integrity, leading the journal to eventually retract the controversial article (mostly due to undisclosed conflict of interest on the part of Wakefield). The Lancet editorial obviously realized the influence of the journal on public discourse and policy and should have been led to exercise heightened scrutiny on sensitive issues. However, at an early stage of the COVID-19 pandemic when potential therapeutics were being evaluated (May 2020), the Lancet published a now-infamous article entitled *Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis*. The article, based on the mysterious Surgisphere database, essentially concluded that “hydroxychloroquine or chloroquine (with or without a macrolide) was associated with no evidence of benefit, but instead was associated with an increase in the risk of [heart conditions]” Mandeep R. Mehra et al., ‘RETRACTED: Hydroxychloroquine or Chloroquine with or without a Macrolide for Treatment of COVID-19: A Multinational Registry Analysis’, *The Lancet* 0, no. 0 (22 May 2020), [https://doi.org/10.1016/S0140-6736\(20\)31180-6](https://doi.org/10.1016/S0140-6736(20)31180-6).. The influence of the Lancet was noted by the Canadian Broadcasting Corporation (CBC):

Although it wasn’t a rigorous experiment that could give definitive answers, the Lancet study had wide influence because of its size. The World Health Organization said it

would temporarily stop a study of hydroxychloroquine and France stopped allowing its use in hospitals Thomson Reuters / CBC, “‘Serious’ Questions Raised about Hydroxychloroquine Study, Medical Journal Says | CBC News’, CBC, 2020, <https://www.cbc.ca/news/health/hydroxychloroquine-lancet-1.5595575..>

The above article mentions France where a leading scientist, Prof. Didier Raoult, had become a vocal proponent of hydroxychloroquine. He was among the very first to notice the impossibility of the Lancet article being based on actual hospital data. Raoult’s own studies on hydroxychloroquine soon become controversial, as did other clinical trials such as the major Recovery trials led by Oxford University. For some reason, the HCQ dosage adopted for these trials was extremely high. An article published with the imprimatur of the BMJ entitled Covid-19: The inside story of the RECOVERY trial presented a serious critique of these trials, noting:

The high doses of hydroxychloroquine used in RECOVERY—800 mg at 0 and 6 hours followed by 400 mg at 12 hours and then every 12 hours for up to nine additional days—have raised concern among experts. David Jayne, professor of clinical autoimmunity at Cambridge University, said that current recommended doses for rheumatologic disease are typically 300-400 mg/day and that the maximum dose for malaria has been 800 mg in the first 24 hours. “The reasons behind the dose selection in the RECOVERY trial are unclear,” he says. “Hydroxychloroquine overdose is associated with cardiovascular, neurological, and other toxicities, occurring with doses over 1500 mg, and higher doses are associated with fatality.” He is concerned that hydroxychloroquine toxicity may have contributed to the adverse outcomes and that conclusions based on these results may be unreliable Jacqui Wise and Rebecca Coombes, ‘Covid-19: The inside Story of the RECOVERY Trial’, *BMJ* 370 (8 July 2020): m2670, <https://doi.org/10.1136/bmj.m2670..>

Similar issues of scientific credibility affected another possible (and in this case authorized and recommended) treatment for COVID-19, Remdesivir. This product obtained FDA approval in 2020 and was also purchased in large amounts by the European Commission. Further, Remdesivir was widely used in the United States as part of the COVID-19 standard of care, including in the case of Luke Letlow, a 41-year old congressman elect from Louisiana who eventually died from COVID, or perhaps from Remdesivir-induced kidney failure Alexandre O. Gérard et al., ‘Remdesivir and Acute Renal Failure: A Potential Safety Signal From Disproportionality Analysis of the WHO Safety Database’, *Clinical Pharmacology and Therapeutics* 109, no. 4 (April 2021): 1021–24, <https://doi.org/10.1002/cpt.2145>. Jaclyn Diaz, ‘Louisiana Congressman-Elect Dies From COVID-19’, *NPR*, 30 December 2020, sec. Obituaries,

<https://www.npr.org/2020/12/30/951332740/louisiana-congressman-elect-dies-after-battling-covid-19..>[1]

However, and thankfully, Remdesivir also came under scrutiny, in particular in a July 2021 article by Hoek and colleagues entitled *Rethinking remdesivir for COVID-19: A Bayesian reanalysis of trial findings*. The authors noted:

Following testing in clinical trials, the use of remdesivir for treatment of COVID-19 has been authorized for use in parts of the world, including the USA and Europe. Early authorizations were largely based on results from two clinical trials... We recommend that regulatory bodies take all available evidence into account for endorsement decisions Joyce M. Hoek et al., 'Rethinking Remdesivir for COVID-19: A Bayesian Reanalysis of Trial Findings', PLOS ONE 16, no. 7 (23 July 2021): e0255093, <https://doi.org/10.1371/journal.pone.0255093..>

A less cautious and earlier review of this debacle was published on Science.org in October 2020. As the subtitle summarized, "The Food and Drug Administration held no advisory meeting on antiviral, and the European Union signed contract without knowing of failed trial" John Cohen, 'The 'very, Very Bad Look' of Remdesivir, the First FDA-Approved COVID-19 Drug', 2020, <https://www.science.org/content/article/very-very-bad-look-remdesivir-first-fda-approved-covid-19-drug>.

Returning to the case of Didier Raoult in France, it is remarkable to notice that in spite of his controversial views and problematic clinical trials, the outspoken, charismatic and highly-publisher Frenchman remained highly trusted, as indicated by this obviously unreliable still telling online survey (translated):

Figure 2: A trusted but controversial figure

The failure of the various institutions to uphold the highest standards of science and ethics has caused significant harm to public trust in these actors of the public health and vaccine ecosystem. These failures should be acknowledged, and long-term solutions discussed and implemented, but the public should also take some comfort in the realization that factual and scientific truth does seem to triumph in the end. Trust is not easily obtained by command, mandate or suppression, but rather by a consistent and transparent behavior.

#### 4.6. Trust in religious institutions vs religious figures

It is remarkable that the recommendations resulting from the controversial EVENT-201 had anticipated the role faith leaders:

Public health authorities should work with private employers and trusted community leaders such as faith leaders, to promulgate factual information to employees and citizens JHCHS, 'Public-Private Cooperation for Pandemic Preparedness and Response'..

As it is, the level of trust Americans hold for religious leaders has been difficult to ascertain, especially in the aftermath of the Roman Catholic sexual abuse scandals. Still, a number of surveys have confirmed the high level of trust congregants have for their own pastor or leader. A 2019 Pew Research study thus announced that "Most congregants trust clergy to give advice about religious issues, fewer trust clergy on personal matters" Pew Research, 'Most Congregants Trust Clergy to Give Religious Advice', *Pew Research Center's Religion & Public Life Project* (blog), 2019, <https://www.pewforum.org/2019/11/15/most-congregants-trust-clergy-to-give-advice-about-religious-issues-fewer-trust-clergy-on-personal-matters/>.. During the COVID-19 pandemic, the same organization conducted a survey (09/2020) which conclude that "Most Americans Who Go to Religious Services Say They Would Trust Their Clergy's Advice on COVID-19 Vaccines." As a result, religious leaders such as Franklin Graham were asked – and agreed – to encourage COVID-19 vaccine acceptance E McFarlan Miller, 'Franklin Graham Urges Evangelicals to Get Vaccinated before It's "Too Late"', *Religion News Service* (blog), 17 May 2021, <https://religionnews.com/2021/05/17/franklin-graham-urges-evangelicals-to-get-vaccinated-before-its-too-late/>.. It should be noted that a close relative of Rev. Graham, also an Evangelical pastor (and probably unvaccinated), later ended up in critical condition after a COVID-19 infection WTVD, 'Billy Graham's Grandson, an Evangelical Pastor, in "critical Condition" with COVID-19', ABC11 Raleigh-Durham, 26 July 2021, <https://abc11.com/jonathan-graham-lotz-covid-anne/10910566/>.. The United Methodist Health Ministry Fund went as far as to produce an information booklet entitled *Faith in Vaccines*.<sup>[2]</sup>

The role of faith leaders is therefore increasingly being recognized, precisely because they are perceived as having no conflict of interest or financial motives but rather a person's well-being. This conclusion led to the design of a quantitative survey examining the role of particular category of faith leaders, namely Orthodox Christian clergy.

#### 4.7. The paradigm of risk and risk perception

In the context of vaccine hesitancy and decision making, the public needs to be able to trust information associated with vaccines, which is hard to separate from the entirety of the vaccine ecosystem and the issues of trust discussed above. In particular, patients need and desire access to reliable data on the risks and benefits associated with each particular vaccine.

### Vaccine(s) risk perception

Here, it seems important to make a comment on the temptation by vaccine confidence advocates to treat all vaccines as equal. The very expression “vaccine hesitancy” is itself non-specific, even though studies have shown that acceptance is high for a number of vaccines (DTAP, HIB, MMR) but low in case of others (HPV, COVID-19). It seems important, as a recommendation, that each vaccine be discussed and explained on its own merits, both from a personal and societal risk/benefit perspective.

In the United States, access is not an issue; trust is often the missing or problematic link in that reliable data is deemed difficult to obtain. However, such documents are not easy to find. For instance, a Google search on “hib vaccine risk benefits” did not produce any meaningful results in terms of easy to read and documented presentation. The CDC result,<sup>[3]</sup> disappointingly, did not include what may have been important information, such as:

The number of cases and deaths of invasive H. influenzae infections in the United States increased from 3,400 in 1997 to 6,840 in 2018. Approximately 11.8% of cases died ‘Pinkbook: Haemophilus Influenzae (Hib) | CDC’, 17 August 2021, <https://www.cdc.gov/vaccines/pubs/pinkbook/hib.html>..

Between 3% to 6% of Hib cases in children are fatal. People ≥65 years of age with invasive H. influenzae disease (Hib, non-b, and nontypeable) have higher case-fatality ratios than children. Up to 20% of patients who survive Hib meningitis have permanent hearing loss or other long-term neurological sequelae CDC, ‘For Clinicians: Haemophilus Influenzae | CDC’, 9 March 2022, <https://www.cdc.gov/hi-disease/clinicians.html>..

Hib disease was once a leading cause of bacterial meningitis among U.S. children younger than 5 years old. Every year about 20,000 young children got serious Hib disease and about 1,000 died CDC, ‘Hib Vaccination: What Everyone Should Know | CDC’, 3 June 2021, <https://www.cdc.gov/vaccines/vpd/hib/public/index.html>..

This number of 20,000 refers to the pre-vaccine era, but we may use it to modelize the risk/benefit ratio in a context of generalized HIB vaccine refusal.

With about 20,000,000 children under 5 in the US, the annual risk factor was 20,000/20,000,000/ or 1/1,000 which is significant. Over the course of 5 years, the risk to acquire and develop a serious case of HIB was far from negligible. The HIB vaccine demonstrates a high level of effectiveness (announced at 93%-95%) and therefore of risk reduction. What then is the risk of receiving the HIB vaccine in its recommended series? Data is available from two main sources: the VAERS database (a useful system plagued by both under and overreporting) and the vaccine inserts which provide serious adverse event statistics. For HIBERIX, for instance, the rate of serious adverse event was about 1/1,000. However, death is not listed as a potential outcome 'Package-Insert—HIBERIX.Pdf', accessed 23 March 2022, <https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Package-Insert—HIBERIX.pdf>.. In the case of ActHIB, the insert documented SAEs in instances when multiple vaccines were administered, for instance:

In Study P3T06, within 30 days following any of Doses 1-3 of DAPTACEL + IPOL + ActHIB vaccines, 50 of 1,455 (3.4%) participants experienced a serious adverse event (SAE). One SAE of seizure with apnea occurring on the day of vaccination with the first dose of the three vaccines was determined by the investigators as possibly related. Within 30 days following Dose 4, four of 418 (1.0%) participants who received DAPTACEL + ActHIB vaccines experienced a serious adverse event 'Side Effects of ActHIB (Haemophilus b Conjugate Vaccine), Warnings, Uses', RxList, accessed 23 March 2022, <https://www.rxlist.com/acthib-side-effects-drug-center.htm>..

These serious side effects did not result in the death of any patient and seem to be mostly associated with multiple concurrent immunizations. The same challenge exists with VAERS data. A search of fatalities associated with HIB vaccine (ages 0-5; years 2015-2020) produced 235 entries. In virtually every case, suspected vaccine-associated deaths made reference to multiple vaccines. In fact, this research was unable to locate a single case of vaccine-associated death linked solely to the HIB vaccine.

The above serves to illustrate how difficult it is for parents to obtain a clear picture of vaccine-specific risks and benefits in the two configurations of pre-vaccine risks and current (with herd protection but no concern for societal responsibility) risks. This one example where the experience of an experienced pediatrician should be considered. Even the now controversial Dr Robert Sears notes, with regards to the HIB vaccine:

Summary of HIB Vaccine Reactions. In my experience, common HIB vaccine reactions are mild and well tolerated. Severe reactions are virtually unheard of Robert Sears, *The Vaccine Book: Making the Right Decision for Your Child*, Revised edition (Little, Brown Spark, 2011), 12..

This researcher would further agree that Dr Sear's advice on the choice of a HIB vaccine is sound and may also play an important psychological role in giving parents a sense of choice and informed decision-making:

The safest choice is to make sure your child is receiving one of the aluminum-free brands. If you don't have that option, then at least make sure your child is getting no more than one aluminum-containing vaccine at a time (idem, p13).

The case of the HPV vaccine

The same inquiry could be made of other vaccines, notably the HPV which as of 2020 failed to present a clear risk/benefit ratio. A credible systematic study by Jørgensen and colleagues concluded:

At 4 years follow-up, the HPV vaccines decreased HPV-related cancer precursors and treatment procedures but increased serious nervous system disorders (exploratory analysis) and general harms. As the included trials were primarily designed to assess benefits and were not adequately designed to assess harms, the extent to which the HPV vaccines' benefits outweigh their harms is unclear. Limited access to clinical study reports and trial data with case report forms prevented a thorough assessment Lars Jørgensen, Peter C. Gøtzsche, and Tom Jefferson, 'Benefits and Harms of the Human Papillomavirus (HPV) Vaccines: Systematic Review with Meta-Analyses of Trial Data from Clinical Study Reports', *Systematic Reviews* 9, no. 1 (28 February 2020): 43, <https://doi.org/10.1186/s13643-019-0983-y..>

This situation is problematic and may explain why educated parents – those who consult these types of articles – may find themselves unable to reach vaccine acceptance when two unknowns need to be considered.

We suggest that more research and publishing is indispensable to provide patients will credible, clear and actionable intelligence and each individual vaccine. It is also important to communicate ethically and frankly when the risk/benefits of a vaccine (typically a new vaccine) are unknown. In this regard, the CDC is to be commended for providing a detailed document entitled *Benefits-Risks of Pfizer-BioNTech COVID-19*

*Vaccine for Ages 5 to 11 Years* which included assumptions and 6 scenarios Hong Yang, 'Benefits-Risks of Pfizer-BioNTech COVID-19 Vaccine for Ages 5 to 11 Years', 2021, 23.. However, this document and other resources indicate a lack of clarity as to represents an acceptable risk per injection and for the vaccine schedule as whole.

The concept of acceptable risk

This study previously illustrates the challenge to agree on what would constitute "acceptable risk" within the general population. As a matter of fact, this assessment was done by the WHO with regards to water safety, with the generally accepted conclusion that:

- 1 in 10,000 as the 'maximum tolerable risk' for members of the public from any single non-nuclear plant.
- 1 in 100,000 as the 'maximum tolerable risk' for members of the public from any new nuclear power station.
- 1 in 1,000,000 as the level of 'acceptable risk' at which no further improvements in safety need to be made Lorna Fewtrell and Jamie Bartram, eds., *Water Quality: Guidelines, Standards, and Health: Assessment of Risk and Risk Management for Water-Related Infectious Disease*, World Health Organization Water Series (Geneva: World Health Organization, 2001)..

This is, perhaps, surprisingly congruent with risk perception (and actuarial assessment) of certain human activities, with:

- 1 in 100,000 as an approximation of sky diving, a slightly risky activity with a 'maximum tolerable risk'
- 1 in 1,000,000 as an approximation of international air travel, or the level of 'acceptable risk' at which no further improvements in safety need to be made.

However, this sense of 'tolerable risk' does not quite align, at this time, with what is deemed rare and therefore tolerate in the realm of vaccine side-effects. For instance, the French authority on COVID-19 vaccine safety offers the following classification (translated from the French):

Adverse drug reactions (ADRs) are organized by MedDRA System Organ Class (SOC). The frequency of occurrence of side effects is defined as follows:

- very common ( $\geq 1/10$ );
- common ( $\geq 1/100$  to  $< 1/10$ );
- uncommon ( $\geq 1/1,000$  to  $< 1/100$ );

- rare ( $\geq 1/10,000$  to  $< 1/1,000$ );
- very rare ( $< 1/10,000$ )

Groupe d'études en préventologie (GEP), 'Mon Carnet de Vaccination Électronique, Pour Être Mieux Vacciné, sans Défaut Ni Excès', Mon carnet de vaccination électronique, pour être mieux vacciné, sans défaut ni excès, accessed 28 March 2022, <http://www.mesvaccins.net/web/vaccines/650-vaxzevria-covid-19-vaccine-astrazeneca>.

This scale does not reflect general-public public perception what would constitute a rare and therefore tolerable risk by factor of 10, if not 100. We suggest that this disconnect should be a matter of concerned and revised communication.

Are risk perception and trust correlated?

Perhaps the most intriguing aspect of this qualitative and inductive section is the consideration that risk perception and trust are not independent but rather correlated factors. According to an important paper by Katherine Kortenkamp of the University of Wisconsin:

There is evidence that the public's perceptions of risk are related to whether they view these sources of risk information and policy as credible and trustworthy Katherine Kortenkamp and Colleen Moore, 'Psychology of Risk Perception', 2011, <https://doi.org/10.1002/9780470400531.eorms0689..>

This an international and complex phenomenon, as indicated in the paper entitled *Trust and Risk Perception in Western Europe: A Cross-National Study* by Mattias Viklund:

Trust was a significant predictor of perceived risk within countries, but the strength of the relationship varied from weak (Spain and France) to moderate (United Kingdom and Sweden). General trust was also a significant source of variation in perceived risk among countries, but much of the variation in perceived risk remained unexplained. Correlations between trust and risk perception also varied depending on the type of risk (i.e., nuclear risks were more influenced by trust) and trust measure (i.e., general trust explained perceived risk better than specific trust). It is concluded that trust may be an element in models explaining risk perception, but it is not as powerful as often argued in the risk perception literature Mattias J. Viklund, 'Trust and Risk Perception in Western Europe: A Cross-National Study', *Risk Analysis* 23, no. 4 (2003): 727–38, <https://doi.org/10.1111/1539-6924.00351..>

This phenomenon was also described in the context of the COVID-19 pandemic:

Trust was a significant predictor of perceived risk within countries, but the strength of the relationship varied from weak (Spain and France) to moderate (United Kingdom and Sweden). General trust was also a significant source of variation in perceived risk among countries, but much of the variation in perceived risk remained unexplained. Correlations between trust and risk perception also varied depending on the type of risk (i.e., nuclear risks were more influenced by trust) and trust measure (i.e., general trust explained perceived risk better than specific trust). It is concluded that trust may be an element in models explaining risk perception, but it is not as powerful as often argued in the risk perception literature Michael Siegrist, Larissa Luchsinger, and Angela Bearth, 'The Impact of Trust and Risk Perception on the Acceptance of Measures to Reduce COVID-19 Cases', *Risk Analysis* 41, no. 5 (2021): 787–800, <https://doi.org/10.1111/risa.13675>..

The authors emphasized, rightly in our view, that:

Building the basis for social trust already begins before a pandemic. Ill-prepared government agencies may not be in a good position to be trusted by the public. Perceived risks are important for people's acceptance of government measures and their adoption of the recommended behavior changes regarding physical distancing from others or increased hygienic behavior. However, if people do not perceive any risks for themselves or if they perceive the measures as riskier than COVID-19, they may be unwilling to follow public recommendations. In such a situation, governments might be tempted to heighten public risk perceptions by emphasizing single events (e.g., one young person died of COVID-19). However, in our view, this is a risky strategy because communication whose only aim is to increase people's risk perceptions may undermine social trust at the end. Such persuasion strategies may result in less support of government measures due to a lack of social trust, instead of the intended opposite outcome (*idem*).

It may be suggested that individuals have to rely on trusted sources to ascertain the level of risk associated with a particular event (contracting COVID-19 vs. receiving a vaccine). The problem here is that even if a risk is accurately portrayed (as in "this condition has a survival rate that exceeds 99.9%"), this may not accurately convey the actual risk of such information: a 99.9% survival rate actually conveys a case fatality risk of 1/1,000 which would be considered very high under rational and comparative risk assessment.

The relationship between risk perception and trust, complex as it is, confirm the necessity to address what should be considered as the two pillars of effective vaccine hesitancy interventions.

### Section conclusion

This research suggests that vaccine hesitant individuals, not unlike any other individuals faced with decisions involving certain risks and benefits, seek to reach a place of inner conviction that the decision is based on rational discussion of these risks and benefits at the personal and societal level. This place of inner conviction requires access to trusted sources, both information and personal, as well as scale of risk tolerance that is congruent with general experience and perception.

In many countries, it seems well-documented that this difficult in accessing (real or perceived) “trusted sources” together with transparent risk/benefit information is associated with vaccine hesitancy. This research, after the quantitative section, will offer recommendations on addressing these foundational issues.

## 5. OVERALL CONCLUSIONS AND RECOMMENDATIONS

### 5.1. Introductory considerations

Our interdisciplinary research, supported by the quantitative research in the target group, confirm the importance of trust in the complex issue of vaccine hesitancy and conversely the phenomenon of distrust in major societal institutions. If a majority of the population or even a significant portion thereof perceive, rightly or wrongly, that major public-health institutions are not trustworthy and do only have their own interests in mind, the context for widespread vaccine hesitancy is set. In a ‘normal’ or perhaps ‘ideal’ environment of trust in public health institutions including one’s own doctor, patients would trust that the information received from these participants in the “vaccine ecosystem” is accurate, scientifically sound and trustworthy, but for complex reasons, this is no longer the case for significant portions of the population. To consider one case outside the United States, France – the country of Pasteur – has reached such a critical level of distrust, as noted in a still-recent CS Monitor article entitled *For the French, distrust of vaccines predates COVID-19*:

Anti-vaccine sentiment in France is at one of the highest rates in the world. A 2018 Gallup-Wellcome Trust survey of more than 140 countries showed that France had the lowest level of trust in vaccines, with a third disagreeing that they were safe. The pandemic has only served to highlight the phenomenon. A 15-country survey conducted by Ipsos and the World Economic Forum at the end of December showed that France had the lowest rate of intent to receive the COVID-19 vaccine of those polled, at 40%, compared with China's 80%. Between 2% and 10% of French people are considered die-hard anti-vaccination while experts put those who are "vaccine hesitant" between 25% and 70% Colette Davidson, 'For the French, Distrust of Vaccines Predates COVID-19', Christian Science Monitor, 20 January 2021, <https://www.csmonitor.com/World/Europe/2021/0120/For-the-French-distrust-of-vaccines-predates-COVID-19..>

In the case of the COVID-19 crisis, the French government found it impossible to address such a great trust deficit and resorted to coercive measures including a vaccine mandate. The same phenomenon and set of policies were observed in several US states and at the Federal level. To echo our interdisciplinary discussion of geopolitics, France was a country where geopolitical considerations affected vaccine policy and hesitancy, as the initially endorsed AstraZeneca vaccine was eventually suspended (02/2021) then reinstated but only for patients over 55 Marie Sasin, 'Vaccin contre le Covid-19. Où est passé AstraZeneca ?', Ouest-France.fr, 28 January 2022, <https://www.ouest-france.fr/sante/vaccin/vaccin-contre-le-covid-19-ou-est-passe-astrazeneca-0515363a-7526-11ec-9c0f-7017d87d73ec..> Likewise, the Moderna vaccine was eventually reserved to individuals over 30, while the Janssen vaccine was essentially abandoned. For one kind of individual, this is proof that health authorities are reactive to adverse-effects signals and willing to adjust their recommendations and authorization, where for others, this is proof of the 'risky' nature of trusting government recommendations at face value, especially in times of crisis or when large financial (or geopolitical) interests are involved. As one article concluded with regards to vaccine hesitance in the post COVID-19 context (in France):

France remains a very vaccine-hesitant country, and this hesitancy does not seem to have decreased much as a result of either the COVID-19 health pass or mandatory infant vaccines, which were extended in 2017. One of the rationales for extending mandatory infant vaccination was that such a strong gesture would signal to the public the complete faith of authorities in these vaccines<sup>13</sup>. Although this policy did not elicit a public backlash, trust in vaccines does not seem to have significantly improved and France is still a very vaccine-hesitant country, as demonstrated in earlier stages of the

pandemic Jeremy K. Ward et al., 'The French Health Pass Holds Lessons for Mandatory COVID-19 Vaccination', *Nature Medicine* 28, no. 2 (February 2022): 232–35, <https://doi.org/10.1038/s41591-021-01661-7>.

The authors further warned:

Vaccinating people who are hesitant or reluctant has potentially negative consequences, which can reinforce mistrust of institutions and of the healthcare system. A feeling of coercion while being vaccinated can cause a nocebo effect, in which negative outcomes occur because of a belief that the vaccine will harm them (idem).

## 5.2. Policy Recommendations

This research therefore recommends some of the following actions on the part of governmental authorities:

Limit the use of mandates or coercive measures to exceptional situations, ideally with personalized medicine elements (for comorbidities) and consultations with one's doctor.

- Engage in a long-term effort to remove 'barriers to trust' in the health and public health ecosystems, notably by:
- Regulate, reduce and possibly eliminate 'revolving door' relationships between regulators (FDA, CDC) and manufacturers.
- Exploring other models of corporate ownership and mission statements, for instance on the model of Canadian crown corporations
- Regulate, reduce and ultimately eliminate conflicts of interest within the broad vaccine ecosystem such as joint patent holdings with for-profit companies and financial incentives associated with vaccine uptake
- Improve the reliability of the adverse reporting system (VAERS) by making the system truly mandatory and reliable.
- Avoid the mistake of presenting or treating all vaccines as identical both in terms of public perception and public health importance and treating with each vaccine as a unique medical decision to building incremental trust in vaccine safety.
- Avoid the expression "anti-vaxx[er]" (except in specific cases of individuals who refuse all vaccines under any circumstance and advocate this stance) to mitigate the phenomenon of polarization and maintain constructive dialogue.
- Consider implementing a 'personalized medicine' rather than 'one size fits all' approach to immunizations, for instance in the case of HepB and HPV.

- Recommend against multiple immunizations being administered on the same day.
- Adopting a definition of 'rare/safe' and 'tolerable risk' with odds that match generally accepted perceptions of safe vs risky activities (e.g. 1/1,000,000 for very safe vs 1/100,000 for risky but acceptably so, with reference to commercial air travel and skydiving).[4]
- Consider how 'fear of flying' seminars and interventions may be relevant to similar interventions dealing with vaccine hesitancy.
- Document for each vaccine both the personal and communal risk/benefit consideration, a critical aspect of regain trust according to a report by Heidi Larson:
- Those who have the most to gain by a successful Covid-19 vaccine introduction – and the most to lose if that effort fails – have committed to engage their respective communities in a sustained dialogue about vaccines' merits and risks Katherine Bliss, Heidi Larson, and J. Stephen Morrison, 'Vaccine Confidence & National Security in the Covid-19 Crisis', 2020, <https://www.csis.org/features/vaccine-confidence-national-security-covid-19-crisis..>
- Consider require vaccine vs placebo rather than vaccine vs other vaccine or non-insert substance clinical trials, most urgently in the case of the HPV vaccine. As one recent study noted on this sensitive but important topic:

At 4 years follow-up, the HPV vaccines decreased HPV-related precursors to cervical cancer and treatment procedures but increased serious nervous system disorders (exploratory analysis) and general harms. As the included trials were primarily designed to assess benefits and not adequately designed to assess harms, the extent to which the benefits outweigh the harms is unclear... A large industry-independent multicentre trial of two doses of Gardasil 9 vs. saline placebo would likely be informative in identifying a more accurate benefit-harm balance, but we recognise that such a trial will be considered unethical in most settings Jørgensen, Gøtzsche, and Jefferson, 'Benefits and Harms of the Human Papillomavirus (HPV) Vaccines'..

- Consider using the data and information from other countries, notably those with a record of great caution (e.g., Japan) if national data sources are not trusted or deemed incomplete (US perception of VAERST).

In summary, every effort should be made to create a real (not manufactured) environment of trust and informed decision making (which is indeed required by US Federal law) in the aftermath of the COVID-19 crisis.

### 5.3. In fine

The SPARS report and EVENT-201 recommendation documents correctly noted the issue of “trust/distrust” as a critical element in pandemic management. However, null or limited mention was made of the fact that clergy remain, in the United States, among the most trusted figures.

During the COVID-19 pandemic which took place in a context of widespread lack of trust in mainstream institutions, the trusted voice of religious become more widely appreciated and at times leveraged.

This study confirms that the issue of ‘whom to trust’ was and remains a central aspect of the COVID-19 pandemic and more generally of the state of American society Raymond John D. Vergara, Philip Joseph D. Sarmiento, and James Darwin N. Lagman, ‘Building Public Trust: A Response to COVID-19 Vaccine Hesitancy Predicament’, *Journal of Public Health (Oxford, England)* 43, no. 2 (7 June 2021): e291–92, <https://doi.org/10.1093/pubmed/fdaa282>.

The effect of politicization, widely acknowledged by sociologists Thomas May, ‘Anti-Vaxxers, Politicization of Science, and the Need for Trust in Pandemic Response’, *Journal of Health Communication* 25, no. 10 (2 October 2020): 761–63, <https://doi.org/10.1080/10810730.2020.1864519>., was clearly recognized by this particular category of clergy and with it the diversity of opinions of trusted sources, even in a seemingly homogeneous group.

This study also supports the value of interdisciplinary analysis on the causes of institutional distrust, determination of risk perception, and the lasting effect of ‘politicization’ of reality, including on grave medical and scientific issues.

Finally, as the issue of ‘finding trusted sources’ is likely to remain a major concern in the post-COVID-19 pandemic era, civil authorities would do well to acknowledge the long-term efforts that will be required to recover, obtain and maintain a high level of public trust while seeking adequate means of positive engagement with vaccine-hesitant patients as well as religious leaders.

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[1] Interestingly and hopefully as a coincidence, this information could not be located using a Google search on "Luke Letlow remdesivir." A non-filtered search engine (DuckDuckGo) had to be used to retrieve this result.

[2] Still available at: <https://healthfund.org/a/wp-content/uploads/Faith-In-Vaccines-COVID-19-Toolkit.pdf>

[3] CDC URL at <https://www.cdc.gov/vaccines/parents/diseases/hib.html>

[4] One example would be "What Skydiving Taught Me About Fear" (Youtube: <https://www.youtube.com/watch?v=bFIB05LGtMs>) by actor Will Smith, but also Tom Cruise Forces James Corden to Skydive (<https://www.youtube.com/watch?v=G1wsCworWk>) which totalled 52 million views as of 2022.

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