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RIVISTA DELLA SOCIETÀ ITALIANA DI ANTROPOLOGIA MEDICA
FONDATA DA TULLIO SEPPILLI

Fondazione Alessandro e Tullio Seppilli (già Fondazione Angelo Celli per una cultura della salute) - Perugia

In copertina: Buddha della medicina, Buddha di guarigione. *Pittura su cotone tibetana / Pittura sacra di Thangka* per la meditazione e la buona fortuna in salute, 1700 circa (The Art Institute of Chicago).

Il logo della Società italiana di antropologia medica, qui riprodotto, costituisce la elaborazione grafica di un ideogramma cinese molto antico che ha via via assunto il significato di "longevità", risultato di una vita consapevolmente condotta lungo una ininterrotta via di armonia e di equilibrio.

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AM
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Indice
Contents

n. 58, dicembre 2024
n. 58, December 2024

AM
Rivista della Società italiana di antropologia medica / 58, dicembre 2024, p. 9

Editoriale di AM 58

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Questo numero 58 è miscellaneo.

Pubblichiamo sette ricerche: Ylenia Baldanza sulle comunità trans online, Amalia Campagna sulla psichiatria forense, Federico Divino che prova ad applicare la nozione demartiniana di "presenza" al buddismo, Elena Fusar Poli sul Covid-19 a Oaxaca in Messico, Rosanna Gullà che studia la sclerosi multipla, Ilaria E. Lesmo sulla sicurezza dei vaccini pediatrici in Italia, Federica Manfredi che osserva il dolore e i suoi significati simbolici nel caso delle sospensioni del corpo attraverso ganci metallici inseriti nella pelle.

Seguono le recensioni di testi.

Nel complesso abbiamo una nuova testimonianza della vitalità dell'antropologia medica, che effettivamente è tra le specializzazioni dell'antropologia italiana maggiormente sperimentali.

Buona lettura!

AM
Rivista della Società italiana di antropologia medica / 58, dicembre 2024, pp. 181-211

Ecologies of Practices within the Italian Vaccine Pharmacovigilance
Antinomies in Vaccine Knowledge

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Riassunto

Ecologie delle pratiche nella vaccinovigilanza italiana. Antinomie nel sapere vaccinale

La vaccinovigilanza è stata concepita come una pratica in grado di monitorare la sicurezza dei vaccini, tuttavia si tratta di un processo socio-culturale complesso, che richiede di essere indagato. In questo articolo, esploro alcune ecologie delle pratiche che operano all'interno della farmacovigilanza relativa ai vaccini pediatrici in Italia. Baso la mia analisi su una ricerca etnografica condotta tra il 2017 e il 2021. Evidenzio, in particolare, due processi: un "lavoro del negativo" che opera mantenendo stabile l'equilibrio rischi-benefici nelle rappresentazioni pubbliche relative ai vaccini; il modo in cui tale "lavoro della conoscenza" può paradossalmente generare frizioni, sfiducia e finanche mondi alternativi.

Parole chiave: Italia, ecologie delle evidenze, epistemologia biomedica, farmacovigilanza, vaccini pediatrici

On a hot summer day in August 2020, I was waiting for Lucia[1] in front of the bar in a small village in Piedmont (a region of North Western Italy). A common friend had told me that her adolescent son had presumably experienced a very serious vaccine adverse reaction when he was a baby. Therefore, I asked if she would accept to be interviewed for my anthropological research regarding children vaccination practices[2] in Italy: the research that I had been carrying out for three years.

Lucia and I found ourselves at the table of the bar where I explained to her that my research was focusing on the production of knowledge re-

garding vaccines, which were usually depicted as safe in public discourses and documents. However, many people I had met until then challenged such a perspective. Lucia told me about Marco, her fourteen-year-old son. She recalled the first two months of her child's life, when she and her husband automatically accepted the hexavalent vaccination (which is a combination of six individual vaccines conjugated into one single product) scheduled in Italy in that period. The vaccine was against tetanus, diphtheria, poliomyelitis, hepatitis b, pertussis and haemophilus type B; a booster vaccination was required after two months. After the booster, the atopic dermatitis that affected Marco since his birth and made his skin dry, itchy and inflamed, became quite unmanageable. Shortly after, Marco stopped growing and eating, lost weight, and became totally hypotonic. After many examinations, he had to be hospitalized for a month, he was diagnosed with serious allergies, and had to have an intervention in order to be nourished through an intravenous line. All the same, nothing changed. «So pale, he couldn't sit, didn't react, didn't laugh anymore… It was a catastrophe», Lucia told me. After some time, she and her husband had a meeting with the full hospital team that was following Marco, and was composed of different pediatricians and an allergist. The specialists told them that, after having excluded all the eventual and possible causes, they hypothesized a vaccine reaction. Lucia's voice broke: «They did tell us! […] They did. I… well… it was as if someone opened a cold shower on my head. Because, I mean, I then said: "Well, what's happening?"». Lucia passionately narrated the hospital discharge, the further examinations, and the useless therapies. She also explained that the medical team never gave them any certification about a possible vaccine adverse event, nor it made an adverse event report within the Italian pharmacovigilance system, despite what it had verbally hypothesized during the meeting. After some time, Marco started following another therapeutic path with a private homeopath and no more vaccines were given to him. He slowly recovered, but he should have to carefully take care of his allergies for all his life.

In 2017, when a new vaccine Law (Law 119/2017) was approved in Italy and ten vaccines became mandatory for the pediatric population, Marco was called to complete his vaccination schedule. Hoping for an exemption, Lucia and her husband went to see the main pediatrician who had followed their son when he was a baby. «She stared at us as if we… And she said: "Of course I don't remember any of this! And even if I did, there wasn't… there isn't any certainty, any link. However, if you want to vaccinate your

son, I'll do it in a safe place, here at the hospital, where there's an emergency room"». Lucia's words exuded a sad sense of betrayal.

In this article I focus on the reported, and the unreported, Adverse Events Following Immunization (AEFI)s, and on some ecologies of practices related to this step of the pharmacovigilance process. In doing so, I analyze how such practices operated on the field, and how uncertainty, distrust, and even vaccine hesitancy can be actively, and paradoxically, produced within the Italian pharmacovigilance itself. I maintain that sometimes they did not precede the choice to vaccinate a child or not; rather, they were specifically produced along the pharmacovigilance process, which took place within the current neoliberal pharmocracy – or «the global regime of hegemony of the multinational pharmaceutical industry» (Rajan 2017: 6). Here, public, private, parastatal, and multilateral institutions intertwined in healthcare governance. Experiences within the pharmacovigilance process contribute to informing the ways people accept, mobilize, or challenge them.

Vaccine Pharmacovigilance

The European Medicines Agency (Ema) – the supranational agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in EU – defined pharmacovigilance as «the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem» (Ema, https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance-overview).

In the case of vaccines, and especially of pediatric vaccines, pharmacovigilance acquires a very strong relevance. Vaccinations are usually represented as one of the most effective interventions in public health, and their usage relies on the balance between risks and benefits (Cioms/Who 2012; Ema 2013; Italian Ministry of Health 2017*a*; Who 2013; Who 2018). Indeed, according to the medical literature as well as the current data in vaccine pharmacovigilance, the risk of an adverse event is impressively small, even though it is publicly acknowledged that vaccines, as any other pharmaceutical product, can cause some, yet rare, adverse reactions. However, unlike other pharmaceuticals, they are multi-component products of biological origin with a potentially less stable safety profile, and they are usually administered to extensive and healthy populations, sometimes compulsorily.

All these characteristics require a particularly reliable pharmacovigilance in order to constantly detect AEFIs, or «any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of a vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease» (Cioms/Who 2012: 40-41). European Medicines Agency (Ema) have drawn up specific guidelines regarding AEFIs' detection in the EU (Ema 2013): single reported cases should provide data about the specific vaccine, vaccinated people, and vaccine administration in order to later allow the causality assessment through a standardized algorithm shared by Who. The complexity of these procedures, discourses, agencies, and expertise plays an important role in structuring a WetNet, or «a conceptual space that names an infrastructure by which fluid exchanges – some purposeful and others accidental, some known and others unknown or unknowable, and all living in the hyphen of nature-culture – take place and are justified, explained, or ignored» (Jain 2020: 506). Along this network, vaccinations are strongly related to bodily, social and political dimensions. They «are special in linking the most global with the most local and personal» (Leach, Fairhead 2007: 2): personal data and experiences navigate through complex networks of supranational, national, and local healthcare interconnected governances.

Vaccines Pharmacovigilance in Italy

In Italy, AEFIs are detected and assessed by the Italian Medicines Agency (Aifa) through a specific electronic system, the National Pharmacovigilance Network, which is connected to the European and the global vaccine surveillance databases (EudraVigilance and VigiBase). Aifa should publish a report on vaccine post-marketing surveillance every year. The detection system is mainly "passive": doctors or even patients/parents should voluntarily insert adverse events either directly on the Internet or by using a reporting form to send by email or by fax to the responsible for pharmacovigilance. The name of the vaccine, expiry date, batch number, data and way of administration, as well as the names of the vaccinating physicians, are required for each received dose. These data have not always noted on the vaccination certificate, but they are filed in the Record of Vaccination at the Local Health Authority (Asl). Therefore, if a single person wishes to report an adverse event, s/he will often have to request this Record to the Asl. This explains why laypeople seldom report AEFIs by themselves even

when they are aware of this possibility. More often, they ask their doctors to file the report. However, as Lucia and other people on the field told me, this does not always happen.

The last report about the surveillance of non-Covid-19 vaccines in Italy, which refers to data inserted in 2021, states that about 20,5 million doses of non-Covid-19 vaccines were administered throughout the year, and 18.088 reports concerning AEFI were detected, including both passive and active pharmacovigilance (15.978 cases occurred in 2021, 786 in other years, 1.296 have no reference date; 28 are double reports). Hence, there were 78 reports in 100.000 doses. Among the whole of reports, 94,5% refer to children under 11 (Aifa 2022). It is undoubtedly difficult to quantify how many AEFIs that parents reported to their doctors were not recorded on the database. However, the percentage difference between 2020 and 2021 is noteworthy, and it would be interesting to consider the role of passive and active pharmacovigilance systems in such difference. As a matter of fact, Aifa states there is an increase in reports of about ten times in 2021 with respect to the previous year, and expressly related it to active pharmacovigilance programs that were promoted by some regions (Puglia, Campania and Veneto) in 2021 (Aifa 2022).

My goal in the present article is to unpack some practices in vaccine pharmacovigilance through an ethnographic gaze. In order to do this, I address the "ecologies of practices" occurring in the pediatric vaccine pharmacovigilance, which I explored during my ethnography in Piedmont, Italy.

Theoretical Background

In this article I resort to ecologies of practices to explore the AEFIs report in pharmacovigilance. As Stengers wrote (Stengers 2005), the ecology of practices is a tool through which thinking knowledge – in this case pharmacovigilance – by considering the practices that construct it within a specific historical environment. The interactions between the human and non-human beings inhabiting it, which are in a relationship of reciprocal construction, have to be analyzed. By adopting this perspective, I also chose to embrace a pragmatic ethos and to think «in minor key» (Stengers 2005: 186): I wish to avoid any central positioning defined by strong oppositions between Truth and illusions, and I rather involve myself within the landscape, in order to create new possible assemblages, conjunctions and consistencies «where there is currently only confrontation» (Stengers

2010: VII). In the vaccine field, such confrontations are prominent: debates about vaccines often produce fracture and separations. In Italy, the public contentions have been continuously represented as opposition between the so-called "pro-vax" and "no-vax" groups, and the Covid pandemic further amplifies such discourses. Such an opposition must be analyzed as a historical product, through which specific groups are pitted against each other, and their discourses are legitimized or not. Some authors suggested to consider vaccine anxiety (LEACH, FAIRHEAD 2007), dissent (RAFFAETÀ 2012) and hesitancy and refusal (LELLO 2020) as tools able to question socio-cultural processes. Hence, I resort to the experiences of the people I met on the field in order to unpack the "work of knowledge" (RAJAN 2017), and its role in producing social contrasts and oppositions.

Many social scientists explored the controversies regarding vaccinations, and they specifically focused on the 'gulf' that separates the experiences, knowledge and practices of some parents from those of experts and institutional actors. Some authors analyzed the parents' perspectives of vaccinations, often in order to improve trust and confidence (SOBO 2015, 2016*a*, 2016*b*; CASIDAY, COX 2006). Some of them specifically explored the socio-cultural perspectives that pre-exist the vaccination practice: Sobo observed how vaccine refusal was built in Waldorf schools and how it contributed to actively shape social relationships and groups (SOBO 2015, 2016*a*); while Kasstan pointed out how moral and religious perspectives could intertwine with vaccine decision-making, and could produce specific discourses and rhetorical devices, which questioned the relation among minorities, State, public health, and bodily governance (KASSTAN 2021a, 2021*b*). Some researchers specifically analyzed the reasons that contributed to distrust and hesitation toward vaccination in different contexts. Sobo especially underlined the social dimensions relating to vaccine decision-making: in communities that promoted perspectives that were alternative to the conventional ones about individuals and their health, parents were keener to delay or avoid vaccination because such choices further strengthened their belonging to the group (SOBO 2015, 2016*a*). Even Santullo pointed out that a "community of thought", which attached specific value to nature, health, disorders and healing, could influence the vaccination choices of parents (SANTULLO 2021). Moreover, she highlighted that a widespread distrust in public institutions, especially during the Covid emergency, oriented the decision of avoiding or refusing vaccination. Such a distrust was mainly produced by the exclusion of citizenship from the debates concerning healthcare, the irresponsibility of the

State in healthcare management, and the infodemic that characterized that period (Santullo 2023).

Other scholars had already stated the role of the population's distrust toward public institutions and healthcare policies in producing resistance and/or hesitation to vaccinations. Research carried out in Cameroon about the anti-tetanus campaign in the nineties highlighted how miscommunication around the vaccination practices proliferated in a context of harsh economic and political crisis. The memories of colonial medicine and the difficult current relationships between the State and the local communities nourished distrust in the public health policy, and inflamed rumors about vaccination as a coercive tool aiming to control the growth of a part of the population (Feldman-Savelsberg 2000). Blume went further in exploring such dynamics in various countries in the world through a historical gaze. He stated that the loss of trust in vaccines and vaccination specifically related to the way of producing vaccines and managing vaccination policies. He added that vaccines and vaccinations had a relevant symbolic power in expressing commentaries about policy and historical memories. They often became a site of resistance against inadequate primary healthcare, the supranational organizations that drove the healthcare programmes, and the global market economies governing them (Blume 2017).

My purpose here is to contribute to this topic by showing how, in some cases, distrust and dissent originate from specific practices within the WetNet itself. In my fieldwork, I actually stated that the appearance of different discourses about vaccines, as well as different "languages of risk" (Casiday 2007), was strongly connected to the parents' experience within the infrastructure related to AEFIs' detection. Hobson-West (2003) had specifically focused on the relationship between risk and uncertainty: she highlighted that "risk" assumes it will be possible to make something uncertain calculable, while "uncertainty" would allow us to better accept the «unknowable unknowns» – or those unknowns that «would clearly be difficult to factor in, no matter how much risk assessment is carried out» (Hobson-West 2003: 279). Since «unknowable unknowns» are always intrinsic to biomedicine, she suggested using the concepts of «uncertainty» instead of «risk» when considering the possible adverse events to vaccination. Kaufman recalled this topic and observed how doubts could be socio-culturally produced (Kaufman 2010): since the risk can never be fully calculated, a «precautionary rationale» drove the choices of many parents whose factual knowledge was grounded on direct experiences, empirical observation and individual reason.

I wondered whether such «factual knowledge» could result from the hegemonic knowledge itself, and whether some untoward occurrences had to be conceived as «unknown knowns» (Geissler 2013: 13), rather than as «unknowable unknowns». The concept of «unknown knowns» assumes that the boundaries between knowledge and unknowledge become sometimes fuzzy, and that some «public secrets» make certain kinds of knowledge possible: the known and unknown could be deeply interrelated, and sometimes even interdependent (Geissler 2013: 15). Taussig had explored such a relationship when he specifically developed the Foucauldian concept of «labor of negative»: he highlighted that knowing what has not to be known is an important tool in analyzing the social practices of knowledge production and the power/knowledge relationship (Taussig 1999: 7). The complex movements through which some experiences could, or could not, become evidence and produce knowledge have been further examined by Briggs (2016). He showed how individual experiences may exist, or not, within the institutional knowledge through specific «ecologies of evidence», which are «broader assemblages of interlocking ways of producing specific types of evidence and rendering them mobile, demoting other forms to the status of ignorance, superstition, or pathology, and simply rendering others unthinkable» (Briggs 2016: 151). In the work of knowledge, some experiences, narratives, people, and data are mobilized in order to produce evidence, but at the same time, they can be limited, hindered or impeded in some other ways (Briggs 2016).

In my ethnography I collected many narratives about experiences of AEFIs on the WetNet, which have been immobilized outside the infrastructures that could produce biomedical knowledge. Here, I highlight how, and why this sometimes happens in pediatric vaccine pharmacovigilance in Italy. In doing so, I place this work of knowledge within a historically situated ecology of practices, where specific constraints act in materializing ideas, discourse, subjects and worlds (Stengers 2010).

Material and Method

My ethnographic research in vaccination practices began in 2017, when bitter controversies about the obligation to immunize children with ten vaccines exploded in Italy, because of the discussion of a new law regarding pediatric vaccinations: the Law 119/2017 (Italian Ministry of Health 2017*b*). Ten vaccines (against tetanus, diphtheria, poliomyelitis, hepatitis b

pertussis, haemophilus type B, measles, mumps, rubella, and chickenpox) would then become mandatory for the pediatric population. Through the new law, the public health care institutions had two main goals: they aimed to guarantee a good vaccination coverage in the population and, at the same time, they wanted to reassure trust. However, some professionals publicly highlighted issues concerning the new vaccine schedule and/or regulation. Because of their remarks, some of them have been warned, suspended or even expelled by professional orders. Public opinions navigated this landscape, which I aimed to explore. As both a medical anthropologist interested in biomedicine, and as a mother of two young girls, I was really interested in the topic. It seemed to me that some epistemological uncertainties were too hastily solved in public debates. The opposite concepts of "pro-vax" and "no-vax" have been sharply produced as two dichotomic and almost self-explanatory discrete categories, which strongly divide knowledge and unknowns. Grey areas seemed to be scotomized. In my fieldwork, I wished to explore such epistemological uncertainties starting from those specific areas. Placing myself in an uncertain space, induced me to look for new points of contact among different perspectives: I aimed to explore the possibilities of a new consistency among them, which could arise "through the middle" and "with the surroundings" – as Stengers notes when she suggests to think "in minor key" (Stengers 2005).

I mainly carried out my fieldwork in Piedmont, Italy. There, I conducted participant observations in both critical and mainstream sites of discourse, including parents' support group meetings, public demonstrations, public health meetings, and scientific conferences. Even though I was not able to explain my specific role as a researcher during public debates and conferences, in private events I always introduced myself as an anthropologist, and I openly explained the goals of my ethnographic fieldwork, since that the topic was very sensitive (as it is still now after the pandemic emergency). At the same time, in order to protect the privacy of the people I met and to ensure them a safe place where they could express their perspectives, I always used pseudonyms (even when some of them told me that I could use their real names).

The main part of participant observations was carried out in two different periods: 2017/2018 and 2020/2021. As a matter of fact, between these two periods, the vaccine controversies temporarily slowed down, and arose again in 2020 when the Covid-19 vaccinations were released.

Starting from 2019 I tried to organize some semi-structured interviews with different subjects. I sent an information paper regarding the aims, the methods and the context of the research to the possible participants (by email or by whatsapp). I aimed to involve subjects with heterogeneous roles and positionings: parents with children of different ages, physicians with different specializations and positions, biologists, and pharmacologists. However, the involvement of these subjects was not an easy task, as Santullo (2021; 2023) also noticed. Most people whom I contacted declined my proposal. Many of the parents that had thoroughly told me about their experiences in informal conversations, refused to meet me for more formal interviews. Even among physicians it was not easier. I contacted some doctors who were experts in different fields: pediatrics, immunology, hygiene and preventive medicine, general medicine, forensic medicine, and homeopathy. They were working in national health care systems, in private medical practices, or in both. Some of them were retired; some participated in foundations or organizations promoting public health, contrasting conflict of interests in healthcare, or acting for occupational health. From what they have told me, none of them participated in organizations that specifically focused on vaccine promotion or critics, even though this topic could be dealt with within their organizations. However, when I asked to interview them, many of them never replied to my requests. One physician declined my proposal, curtly answering that he was not a vaccine specialist. Another practitioner preferred to send me pages and pages of scientific documents he collected during the years, but then he requested to delete his name from any correspondence. It took a long time to find available subjects and arrange the meetings. In the end, I was able to formally interview nine parents and nine professionals with different specializations, roles, ages, and opinions regarding the Italian vaccine schedule and the Italian law. Among the physicians, some of them had had disciplinary notices or informal warnings because of their position regarding vaccinations, some had been suspended for a period, and one was expelled from the Professional Order. The informed consent was requested from all the participants and all the interviews were transcribed verbatim.

During the interviews, I even tried to arrange future meetings with the doctors I met; however, just one of them agreed to meet with me again (we had three meetings of about two and a half hours each at her and her mother's place). The other professionals declined my proposal in different ways: some of them invited me to contact other colleagues; two doctors suggested me to participate in public meetings where they were involved

and to look for further documentation on the Internet; two simply refused (both of them specifically told me that because of the Covid-emergency they were very busy).

In this contribution, I mainly focus on the experience of six doctors I interviewed, because they dwelled especially on their personal experiences with parents who maintained that their children had had adverse reactions after vaccination. Among the remaining three professionals, one was a retired health director with whom we mainly discussed historical, political and socio-cultural subjects related to the immunization practices in Italy. The second one was a biologist who had been working in the vaccine sector for some time. We mostly focus on the vaccine manufacturing processes, and on the safety procedures set up by the supervisory authorities and the company in which he worked. The last practitioner answered my questions succinctly and he seldom referred to his personal experience. However, his answers mostly confirmed what emerged in the interviews I report here.

Even though the low number of interviews could be a limit of the research, and it imposes further research on the topic in order to understand if these results could be generalized and to what extent, the resistance to participate was an interesting data to consider. As a matter of fact, the gap between the informal narratives I collected during the fieldwork and the difficulty to arrange formal interviews, points out the obstacles in translating some subjective experiences into more formal data – one of the specific topics I focus on and that I will further discuss later.

The Context: Pediatric Vaccination in Italy

Since July 2017, when the Law 119/2017 was approved, ten vaccines are mandatory in Italy for the pediatric population until the age of sixteen (tetanus, diphtheria, poliomyelitis, hepatitis b pertussis, haemophilus type B, measles, mumps, rubella, and chickenpox); other five vaccines are recommended for children (pneumococcus, meningococcal group B, meningococcal group C, rotavirus, and papillomavirus). They have been scheduled on a calendar – the *Calendar for Life [Calendario per la Vita*] – and created by the Ministry of Health in 2017 along with the *National Vaccine Prevention Plan (PNPV)* (Italian Ministry of Health 2017*a*).

Even though mandatory vaccines are mainly free for citizens, vaccines' research and manufacturing are outsourced to the private sector. In this way

the public-private partnership – the «quintessential neoliberal» idiom (Rajan 2017: 69) – became the political and economic tool through which a pediatric WetNet was made in Italy. As even Raffaetà noticed in her study about pediatric vaccinations in Italy, «they are a public intervention, so they should be part of the "logic of care", but they are silently promoted by the "logic of market"» (Raffaetà 2012: 9). So, one «fundamental antinomy» (Rajan 2017: 23) of the State appears here, since it is caught between the interest of its citizens on the one hand, and of local, national, and global capital on the other hand: the private and public sector intertwined their interests and skills in many ways along the complex local/global networks (Matteucci, Missoni 2022; Rajan 2017).

In the vaccine field, Italy was chosen among forty Countries to lead world vaccination strategies for the following five years, during a meeting of the Global Health Security Agenda (Ghsa) Steering Committee in September 2014. The Committee is composed of the ministries of different countries, international organizations and non-governmental stakeholders. About two years after the Ghsa summit, the Italian Minister of Health licensed the *National Vaccine Prevention Plan (Pnpv)*, which defined the new vaccination schedule in Italy. The Plan, which was based on the European Vaccine Action Plan 2015-2020 (Evap) and on the Global Vaccine Action Plan 2011-2020 (Gvap), specifically considered the role of vaccinations in the European and national economy and politics: it focused on the «estimated saving» enabled by the new vaccine schedule, or upon the increased productivity ensured by a healthy population. Moreover, the Italian Pnpv expressed particular concerns about the decreasing vaccination coverage for measles and rubella, which undermined «the international credibility of our Country» (Italian Ministry of Health 2017*a*: 25). As Blume outlined «Parents *have* to be convinced because otherwise coverage will be low and the country will look bad in international comparisons» (Blume 2017: 220). So, the new lawmaking seemed also to drive a specific «harmonization process» (Rajan 2017: 5-6), by relating the Italian vaccination programs to the European, and the global expectations: however, as Rajan highlighted, the positive and benevolent meaning of the "harmonization" concept, could also imply other processes, sometimes related to a hegemonic order that involves complex national, supranational, and multinational relationships.

In Italy, the approval of Law 119 occurred shortly after the Pnpv. The Government introduced it as an «urgent measure»,

> in order to ensure the protection of public health and the maintenance of adequate epidemiological safety conditions in terms of prophylaxis and vaccination coverage, as well as to guarantee the achievement of the priority objectives of the 2017/2019 National Vaccine Prevention Plan […] and compliance with the obligations assumed at European and international level (Italian Ministry of Health 2017*b*).

Since that moment children without the ten mandatory vaccinations could not access preschool and their parents would be fined. Despite the obligation, the Law aimed to promote a «voluntary and aware participation to vaccination» and to spread «the culture of vaccinations» among the population and healthcare professionals (Italian Ministry of Health 2017*b*). The idea of «a culture of vaccination» was already mentioned in the Pnpv, since one of its objectives was to promote «a culture of vaccination consistent with the guiding principles of the Plan in the general population and in healthcare professionals» (Italian Ministry of Health 2017*a*: 12). However, what this "culture" was is not clear, and it should be considered. Indeed, in public discourses vaccines are radically disconnected from the historical, socio-cultural, economic, and political practices where they are rooted. The concept of "vaccine" is often used as a general category unifying very different objects and histories. Information regarding specific commercial products against different diseases are rarely addressed, as well as the logics about switching to different products in the national schedule, or the trade agreement between the State and the pharmaceutical companies remains often unsaid.

In the absence of this information, the reference to "the culture of vaccination" in public speech is often perceived as opaque despite the stated purpose by the Ministry of Health to «develop increased awareness about the vaccine potentiality in the citizen, and contrast the spreading of falsehoods and dangerous prejudices» (Italian Ministry of Health 2017*a*: 18). Because of that gap, the "culture of vaccination" might sometimes resemble the "scientific culture", which Stengers wrote about: vague and always missing, it acts as a powerful ghost, which operates as a «religious engine of war, pointing out the path to salvation, condemning sin and idolatry» (Stengers 2010: 25).

Missing AEFIs: Parents' Narratives

In June 2017, I started to participate in the meetings of the Asti provincial committee for free choice and in meetings of the regional committee. Parents, healthcare professionals, teachers, and representatives of free choice organizations attended such meetings. In these occasions, people seldom described their personal experiences with adverse events publicly, even though these narratives quietly circulated in chats and personal conversations. On the contrary, difficulties in reporting AEFIs were often openly addressed during the meetings. In one occasion, for instance, the representative of a free choice organization explained how he had personally witnessed an interruption in the AEFIs' detection process and registration in the National Database. As a matter of fact, after specific investigations he carried out through his organization, he discovered that some of the AEFIs he had personally reported never reached the National Database. «Many reports were missing», he said «they were blocked in their pathways».

One day, during a meeting break, I was chatting with Cinzia – a young woman with whom I attended the meetings and who I had started to get to know well. Quietly speaking, she unexpectedly mentioned her personal experience with a vaccine adverse reaction. She told me about her seven-year-old daughter, Marika. When Marika was four months old, she stopped growing. Especially the measure of the circumference of her head concerned her family pediatrician. After some tests, the doctor suggested that Cinzia went to the hospital, where Marika was finally hospitalized for further medical tests and observations. The doctors suspected a case of secondary microcephaly. However, no specific causes were found. One day, a hospital doctor asked Cinzia to speak privately, and led her to a dark, tiny room. According to Cinzia's narration, the doctor whispered a few words: «We don't know what happened to your daughter», she said «but I'm going to tell you something that you didn't hear from me. I'm not saying this to you. I think it was a vaccine reaction. I won't repeat it again. However, I suggest you don't vaccinate Marika anymore». Marika was dismissed from the hospital some days later and, after some time, she started growing again. Cinzia did not vaccinate Marika anymore.

Liliana described a situation in some ways similar. Even in this case she spoke to me about the experience of her second son, Lorenzo, just after almost four years of acquaintance: we participated in some public events together, and we shared discussions and material about vaccines. In 2021, when Lorenzo was eight years old and he had been diagnosed with an im-

munological rare disease, Liliana confided in me. She recalled the first months of her baby, when he had to be hospitalized for almost a month for severe and repeated seizures whose causes neither pediatricians nor neurologists understood. One of the neurologists told her in a private meeting that she thought the seizures were a reaction to vaccinations. However, since she was not able to prove such a hypothesis, she would have not sustained it in front of her colleagues. In any case, she suggested not vaccinating Lorenzo anymore. More than a month later, Lorenzo was dismissed and the seizure finally stopped. Liliana, a very composed woman, was softly weeping while she was telling me her experience.

I collected similar narratives also during my interviews.

Simone has a son with a pervasive developmental disorder, and a doctor suggested that it might have been triggered by vaccine adjuvants. However, no AEFI has been detected. Simone told me that «the GP should report the event» and that «at that time, I actually didn't know about the pharmacovigilance».

Also Giulio, whose son has a neurologic disorder for which the family pediatrician exempted him from further vaccinations, explained to me that, after some time, he would have wanted to report the event. However, he (mis) understood that he should have reported the AEFI within 48 hours, and exclusively through the pediatrician, who in the meantime had changed and refused to proceed.

Antonella, instead, told me about her son Alessandro, who had a very high fever and severe seizures after the vaccination. At that time Antonella did not even know about the reporting system: «No. No, no, no, no, no, no. Nobody… Nobody ever told me anything».

Other stories were similar: parents did not know, had not been informed, or asked their doctors who refused to report the AEFIs; moreover, some of them were too worried and busy when their children got ill to spend time on "bureaucracy".

Involving parents in formal interviews about this topic remained difficult nevertheless. In my opinion, that was not just because of the emotional distress relating to such memories. Beside the relevancy of this distress, the strong perception that some things must not be mentioned in public and/or formal situations was somehow pervasive. In a way, doctors themselves contributed to giving such a perception when they spoke on the sidelines and assured that those words should not have been repeated. It remained

a kind of unspoken knowledge, which required a lot of confidence to be shared, and could barely enter the more formal knowledge infrastructure (neither biomedical infrastructures, nor formal research projects). Secret and suspicion reinforced each other, as I noticed on several occasions on the field: fears and concerns of being controlled by authorities and multinational corporations spread during the meetings, for example rumors circulated about two participants who were suspected of being informants from pharmaceutical companies.

As I explained above, I faced even more difficulties in getting and keeping in contact with doctors with the aim of discussing the topic. However, as in the parents' case, also the doctors I interviewed shared with me discourses and logics that I had been collecting on the field.

Ecologies of Evidence in Clinical Practice

«Stop, don't go there»

The first doctor I met for a formal interview was Dr. Porcellana, a retired pediatrician who had been a vaccinator for a period of time. We met in a city park on a late summer morning. We walked along the river and had a long conversation on a bar's terrace. Speaking of vaccine pharmacovigilance, he told me he had seen different kinds of side effects and adverse events after the vaccination practice. Even though both side effects and adverse events should be reported, he explained that this usually did not happen. Speaking softly, but in a steady voice, he described two dynamics that finally contribute, more or less indirectly, to such a labor of negative. The first one could probably appear to be really trivial, but, as Taussig considers, «something may be obvious, but needs stating in order to be obvious» (Taussig 1999). It concerns the amount of time required by the reporting system. Reporting AEFIs was not a fast procedure. Sometimes, data was lacking, sometimes the online platform did not work properly. His considerations recalled what other physicians had already described to me as a complex and boring procedure; among the professionals I met, only one doctor told me that «the procedure for detecting adverse reaction is very easy: you just have to open the website http://www.vigifarmaco.it/ and follow the procedure».

Especially in personal communications the detection appears as a convoluted and quite slow dispositive. A general practitioner who was also an alternative medicine practitioner, told me about the problem she had with

the pharmacovigilance platform. She seemed discouraged and a little bit angry: «You can hardly connect to it – then you have to wait a long time for each passage. Sometimes everything stops and you are automatically logged out. You have to restart from the beginning». During our conversation, she compared the platform with the one used for booking the anti-Covid vaccination: the latter was set up in a short time, worked properly, and was able to manage the vaccination campaigns for a huge population. «How do you explain this?», she asked. «They have knowledge, when they want to use it». She supposed that the informatic platforms for AEFIs' detection were themselves an intentional deterrent to reporting.

Dr. Porcellana did not express the same concern; however, he considered that the poor investment in a more effective platform, or in rewarding doctors who detect AEFIs outlined a disinterest in promoting such practice. Even for these reasons, doctors who wanted to report an adverse event had to dedicate specific working time to it, but nobody would compensate them for the extra effort. Reporting adverse events represented extra work after already long and intense working days, as other authors have stated in different contexts (Bäckström *et al.* 2000; Sevene *et al.* 2012; Osimani, Ilardo 2022). Actually, the fact that growing bureaucracy and time squeezing in healthcare systems produce potentially dangerous corner-cutting is not new, even in healthcare studies (Bowers, Becker 1992; Catchpole *et al.* 2009; Jones *et al.* 2016; Rimmer 2018). Jain referred to the bureaucratic overload as well when analyzing the debate about cancer screening, where the work of both doctors and patients appeared to be strongly influenced by a swollen bureaucracy (Jain 2013). According to Dr. Porcellana, workload pressures related to specific healthcare policies and economies operated in cutting corners even in vaccine pharmacovigilance and they shaped data and knowledge.

The second point that Dr. Porcellana stated is related to another kind of labor. According to him, producing too many reports meant trouble, since a doctor would be classified as "no vax" and would become a "suspect". «It's better to go unnoticed», Dr. Porcellana said. It is maybe noteworthy that also a private physician and homeopath in his sixties, Dr. Turini, made similar considerations. I met him in the garden of his country house among hills and fields. He had significant experience in treating patients with vaccine adverse effects:

> It's always a chilling experience – he said – because you listened to the stories of these young parents who told you how, a week after the vaccine, their wonderfully merry, lively and happy child started to become listless, they

> wouldn't look at you anymore… wouldn't react anymore… It's heart-wrenching, humanly speaking.

During our meeting, he spoke about the strategic attitude that a doctor should have about vaccinations in the present political and economic context. He considered that «It's a time in which you really have to lay low. With a helmet and laying low. And trying to survive». During our conversation, Dr. Turini mentioned an open letter that more than a hundred physicians had addressed to the President of the Higher Institute of Health in 2015. The signatories had noticed behavioral and physical changes in some children after vaccinations and demanded for better investigating the situation through scientific studies. «The answer was the inquisition of the signatories by the Italian Orders» Dr. Turini told me. The doctors had to justify their writing, since the deontological code required them not to frighten the population with information without scientific evidence. Dr. Porcellana as well had described some legal provisions that specifically discouraged doctors who did not follow mainstream discourses, like the law about medical responsibility (Law 8 March 2017 n. 24). Such a law, that was approved in 2017 as well, regulates the safety of care, the professional liability, and the management of health risk. Dr. Porcellana especially referred to the amendments it introduced to the article of the penal code concerning the culpable liability for death or personal injury in the medical field: the article 6 of the Law states that healthcare professionals are not punishable in case of malpractice, if they acted in accordance with recommended guidelines published under the law (however, it is up to them to provide evidence about that).

Even though new Laws appeared in that period and Dr. Porcellana deeply dwelled on them, I did not believe that these normative devices were just external structures imposed on passive, frightened or fearful professionals. Practitioners did not simply avoid the AEFIs' reporting because of a coercive power directly acting on them. As the biologist who had worked in a pharmaceutical company told me, it was not possible that all people working on vaccines were so unscrupulous «as some conspiracy theorists suggested». Nor, on the other side, doctors denouncing such a situation could just be obsessed by some persecutory and imaginative ideas. Therefore, I needed to understand how the practitioners internalized some sociocultural norms, devices and conceptions, eventually producing lacking reports. Put otherwise, I aimed to grasp how the hegemonic order could operate in this field, by developing and naturalizing specific sensibilities, values and practices.

Dr. Gobbi, another retired physician whom I met during a public debate, gave me some interesting suggestions. I formally interviewed him in an online meeting, during which a bitter disappointment toward the public health policies and its current relationships with multinational companies and supranational policies informed his whole statements. He told me that vaccination is «a subject on which we must not have doubts», even if there was no scientific evidence about the safety and the effectiveness of the new Italian vaccination schedule as a whole. Nor could it be effectively assessed by pharmacovigilance, since most AEFIs were not reported. He addressed the problem ascribing the missing reports to a «sense of guilt».

> It's a self-absolving act: I know that the whole healthcare system tells me that vaccines can't do that kind of damage, so I absolve myself! Because I can't have caused it! Because the vaccine has nothing to do with that! It's self-absolving. But this is the normal position of the vast majority of physicians! According to me, physicians are complicit with the current medical system. But ideologically, before than economically […]. Before anything, there's the fact that the whole system states that it cannot be the vaccine. Stop, don't go there.

Dr. Gobbi describes an interrupted path, an unbridgeable gulf, generated by a sense of guilt. In his opinion, the whole system allowed it, since it was based on the assumptions that the vaccination practices were safe. Individual, social and cultural dynamics immobilized other experiences («stop, don't go there») because of some a priori considerations that structured biomedical knowledge and, in doing so, repeatedly reconfirmed the assumption itself.

Antinomies in the Ecology of Evidence

I formally interviewed three pediatricians who defined themselves as "pro vax", "pro vaccines" and "pro Calendar for Life" during our meetings. Even though I did not mean to use such expressions, the doctors spontaneously resorted to them: I supposed they aimed to take a specific position within our discussions, as well as in the wider Italian debates that were shaping public discourses. They were three women, between thirty and forty-five years of age, working as family pediatricians within the Italian national healthcare system. I met two of them – Dr. Falasi and Dr. Torelli – in two online meetings (one with each of them), while I saw Dr. Mirandi at her studio. Obviously, they were not statistically representative, nor could they be gathered in a specific category of "pro vax physicians/pediatricians".

They actually had very different ideas about care and medicine, biomedicine, and pediatrics. Dr. Falasi, for instance, maintained that many healing approaches could be useful in healthcare, and in her practice she usually mixed «traditional medicine» (that in her discourse was biomedicine) and homeopathy. Instead, Dr. Mirandi radically refused the possibility of any other kind of effective medicine, apart from the «scientific» one.

These doctors acted in different ways regarding vaccination practices as well: Dr. Falasi always saw her young patients some days before their vaccinations, and then she was also present at the vaccination center during the injection. Dr. Torelli did not schedule to see a patient before the vaccination, but she gave full availability to parents who felt safer with a previous check. Dr. Mirandi said that she never evaluated a patient before the vaccination, since this procedure had been excluded by any guidelines and «the real contraindications are few».

Despite the great differences among their approaches, these doctors shared a common point: none of them had ever had to report an adverse reaction. Dr. Falasi was the only one who left room for some doubts. During our meeting we could share our personal positions about vaccines: we expressed personal doubts and understandings about them. Dr. Falasi told me: «Objectively, it has never happened to me [to detect an adverse event]. However… at times there have been temporal occurrences, but not serious situations». She considered that «the real problem» was the coincidence between the period of vaccination and the period during which some auto-immune neuro-muscular pathologies appeared independently from vaccines, «but you can't wait to vaccinate children». When I asked her how she could exclude any causal relationship, she explained that there were specific studies, maybe a Swedish one. Dr. Torelli, with whom I had long exchanges during another online interview, pointed out similar considerations.

> No, no. Reports, never. Never. Only a couple of times parents with children with a retarded psychomotor development said that they had noticed something after the vaccination. But unfortunately, this is a thing we often see… you notice it when the child is about six-month-old […] So… it's difficult to find an effective cause. To be honest, about side effects… […] I've seen febrile seizures at most, but in subjects who already had it, and in any case… well, they are benign manifestations that may happen.

In a way, Dr. Torelli shared the same point with Dr. Falasi: they had seen just «benign» or «not serious situations», not worthy to be reported. On the other hand, however, they automatically excluded severe neuro-muscular or psychomotor disorders from detection, since they considered them

as «independent from vaccines». It seemed that no «sufficient suspects» (Cioms/Who 2012) for a possible link arose, because scientific studies had already demonstrated such unrelatedness. However, both the doctors did consider the possibility of a multifactorial causation of such disorders, whose aetiologies have not been fully understood yet. In fact, in her interview, Dr. Torelli explained that such a lack of knowledge was the real problem, since it made the parents frustrated and led them looking «for all the things that could be a cause».

The most radical in assuring me that she had never had to report any adverse reaction was Dr. Mirandi. I met her in front of her medical studio in the suburbs of the city, where she was smoking a cigarette. Then, we entered the studio and had a very quick conversation. She gave short and curl replies to my questions and sometimes she just answered «no comment» or ironically asked if the recorder was on (she knew it was), suggesting that she would have been more critical toward the parents refusing the vaccination if it had not been on. Thanks to this interview, however, I could understand more clearly what kind of practices acted in immobilizing some experiences within a specific ecology of evidence, diverging them to other discourses. When I asked her if she had ever had to report an adverse event, she answered:

> No, because it depends on which kind of adverse events they are. There are some expected adverse events, and they can't even be considered as such: fever, cutaneous reaction… They aren't adverse events. Real adverse events, such as an anaphylactic reaction… it's never happened to me.
>
> Me: Ok, and have you met parents who came and claimed they had encountered adverse events?
>
> Dr. Mirandi: Yes! Abundantly.
>
> Me: Ok. And how did you manage this?
>
> Dr. Mirandi: You explain that that's not an adverse reaction, that it's expected. It's a side effect, but not a real adverse event worthy of being reported, since it's already known.

Dr. Mirandi depicted a system of exclusion producing the "real adverse events" and distinguishing them from what "was not worthy" to medical knowledge. Indeed, what was pivotal in her opinion was reassuring parents about vaccines' safety, since promoting vaccination was «an ethical task of ours [physicians]». However, in doing so, she did not consider the antinomy emerging here: the already known limited what should have surveilled this very knowledge. In this way, it paradoxically reduced some parents' trust in the vaccine surveillance system and in biomedicine.

As a matter of fact, a specific way through which evidence was produced in pharmacovigilance arose: just some experiences were mobilized within the online database, while others were demoted out of it, on the narrative, and anecdotal side. In doing so, the doctors described a particular ecology of evidence, where demotion operated in a double way. On the one hand, the severe events that the medical literature had already considered as independent from vaccination were excluded by the detection, regardless of the temporal correlation. On the other hand, the minor and «already known side effects» were considered as not worthy to be reported. This seemed to confirm what Dr. Porcellana stated when he said:

> Adverse events are considered as a part of the vaccine event. It's normal that a vaccinated child has a little fever, could be irritable… it's part of the kit. Vaccination benefits are surely many more than the risk of an adverse event […]. And, therefore, a vaccination, even though it is a drug, is useful with respect to the risk of adverse events.

In this way, the risk/benefit balance evaluation anticipated and produced the practices that, according to the international agencies, should constantly re-evaluate this balance itself. In fact, a priori statements excluded the possibility that some experiences «resisted to the evidence» (Stengers 2010) and eventually changed the first statements. A circular antinomy arose: AEFIs reporting, that is supposed to constantly re-evaluate the risk/benefit balance of vaccines, was determined by the pre-existing statements about the risk/benefit itself. So, the exclusion of some experiences from the online databases contributed to publicly reconfirm an "harmonic view" in vaccine benefit through a labor of negative. However, at the same time, it also challenged the "harmonic" perspective itself in some people's perceptions. Indeed, when some experiences were diverted toward the narrative, anecdotal, and uncertain side, criticism and distrust grew.

Ecologies of Practices in Pharmacovigilance

Reciprocal capture

Lucia, Cinzia, Liliana, and other parents as well told me that practitioners themselves had hypothesized a possible relationship between her child's ailments and the vaccination. Therefore, some doubts arising on the field suggested suspicions of relatedness, which could have interrupted the closed circularity in the ecology of evidence I described. However, it did not happen: as we saw, even in these cases AEFIs were not detected.

Something else remained to be understood – something containing and decreasing the power of these suspicions, pushing them outside knowledge about vaccination.

The doctors I met helped me again in better understanding this point. When I asked them what they thought about the doctors that had been expelled by the Professional Order, Dr. Falasi and Dr. Torelli specifically explained that the experience of a single doctor was «very limited». Dr. Falasi highlighted how «reliable scientific studies» required «significant numbers». Dr. Torelli went even further when she stated that the clinical experiences of a doctor could not oppose the scientific literature. In her opinion, what a doctor sees in her/his clinic might actually provide some important and good considerations, but a single experience counts just as «small numbers». She repeatedly came back to the concepts of «big numbers» and «scientific thought». In her opinion, a single doctor might «think something», but s/he could not decide through «her/his own reasoning». She highlighted that critical thinking should have limits beyond which the only thing to do is trust, since «there are things we can understand, and things we can't». She added that «it's important for the medical role to put up a united front. At this moment the risk of the immunization coverage decreasing is too high, so you can have a personal opinion, but before promoting the no-vax maybe… you need to have a structure behind it that is strong enough». This «structure» arose during her interview and it depicted the hierarchy of the evidence described by Evidence Based Medicine. Here, meta-analyses and Randomized Controlled Trials (RCTs) are located at the top, while expert opinions are at the bottom. Moreover, the ethical duty to «not promote the no-vax» influenced the epistemic order. By reshaping their own doubts in an epidemiological language, doctors feared that such doubts could become «[…] types of information and modes of communication that enable suspicion and recognition» (Kaufman 2010: 15). So, they would rather prefer that their doubts remained «unknowable unknowns» – even though they could be rather conceived as «unknown knowns» – in the hope of improving trust in vaccination and in Ebm, even by enforcing the intellectual authorities on which they both relied.

Dr. Torelli seemed to have fully internalized this hegemonic hierarchy: in her discourses she repeatedly stated that a single doctor's experience had to be recognized as a kind of unknowledge – or at least insufficient knowledge – in front of the scientific production. Therefore, the physician's doubts had to be put aside if they conflicted with the top levels of evidence: the only way of questioning an already known assumption was by means

of other scientific studies. Understanding how to immobilize what was unknown, and having a «united front» by distinguishing between knowledge and unknowledge were fundamental skills for practitioners.

Obviously, as Geissler (2013) pointed out, the borders between knowledge and unknowledge were always fuzzy and not really impermeable. Clinical experiences could move and become part of a scientific study. However, neither Dr. Torelli nor Dr. Falasi were naïve about this. Especially Dr. Torelli admitted how difficult it was for «someone small» to launch a study about «big numbers», especially because these should not receive funding from pharmaceutical companies. Both doctors shared some worries about the role of such companies in biomedical knowledge. However, in this case as well, they explained how to discern between the economical influences of «big pharma» and the vaccine administration practices. Even though pharmaceutical companies do have an influence on scientific studies, and «there isn't a totally independent study» (Dr. Torelli), this situation did not justify the risk to miss a vaccination. Dr. Falasi specifically told me that discourses about the interests of pharmaceutical companies sometimes bothered her:

> Well, all that stuff has nothing to do with everyday reality: big pharma, etcetera… […] You hear so many things, but they actually remain as background noise. You leave them out of the clinic, because what you care about is your patients and your way of being a pediatrician.

In this way, she effectively described some «systems of exclusion» (Foucault 1981) implying the rejection of some discourses from a specific field of knowledge. She strongly related these practices of separation to the «way of being a pediatrician». In fact, the discourses about what had to be left «out of the clinic», could more generally relate to professionals left outside from the biomedical field. Dr. Mirandi expressly agreed on the expulsion of doctors that expressed doubts about vaccines. She firmly maintained that these doctors really worried her.

> Thank goodness! Where'd they go otherwise? Vaccination is the foundation of modern medicine. It's provided a benefit in the fight against some diseases you no longer hear about: people don't perceive the seriousness because vaccines did work! And if a doctor doesn't believe in vaccines – especially a pediatrician in pediatric vaccinations – maybe he chose the wrong job.

In her opinion, trust in vaccination was a precondition for being a pediatrician. Even though the expressions of Dr. Torelli and Dr. Falasi were maybe less extreme, they had similar opinions. Dr. Torelli suggested a very enlightening metaphor: she observed that also different architects had to maintain a certain pillar in a house, otherwise without it the house would fall

down on you: «Well, those who disagree should do a study and explain how that house can stand without that pillar […] There are some cornerstones that… I think, are untouchable. They are untouchable because the risk is too much. And then there's a common cause».

This image strongly joined biomedicine and immunization practices. Since biomedicine has its basis in vaccines, questioning them would question biomedicine, the intellectual authorities working in it, and more specifically the physician's role itself. A single doctor cannot express doubts about vaccinations since her/his own identity is strongly intertwined with them: as Dr. Mirandi sustained, a doubt regarding vaccines would expel a physician out of biomedicine, instead of bringing her/his doubt into it. That sounded somehow paradoxical, since physicians were the ones who could eventually notice specific untoward occurrences (maybe within a new vaccination schedule, or because of the specific interrelationships between certain drugs, environments and individuals, such as Dr. Porcellana and Dr. Gobbi suggested). «Sufficient suspicions» from doctors would make pharmacovigilance – so important in immunization practices (Cioms/Who 2012; Ema 2013) – effective. Also in the public opinion, doctors are considered to be entitled to assess vaccinations. Nonetheless, they lose their role precisely when questioning them.

In this way, a broader antinomy emerged in the ecology of practices regarding vaccine pharmacovigilance. My interlocutors described a «reciprocal capture», which created value through a dual process of construction (Stengers 2010: 20). Stengers observed how, in the process of reciprocal capture, two identities mutually shaped themselves by embodying value from each other. In this case, the value of vaccinations contemporaneously was produced by doctors and produced the doctors' value. So, the professional identity of those entitled to assess vaccines depended on the values they gave to vaccines themselves. Casting doubt over them on the grounds of their experiences would cast doubt over their professional identity as well. An internal, legitimizing logic was thus emerging within the practice of AEFIs' detection, but it contributed to sacrificing part of its external legitimacy, and to build alternative worlds. It operated someway like the internal logic in the vaccine-critical movements that Kirkland analyzed, when she observed that such movements constituted an alternative world of internal legitimacy, which however was not able to analyze its own logics and politics: those logics and politics diverted such a world from the possible cooperation with external actors (as for instance vaccine policy makers, Kirkland 2012).

Conclusions: Circularities, In-Stability and Alternative Worlds

Stengers considered that the scientists' passions, dreams, worries and anxieties are embedded in historical contingencies, and they move modern sciences. She gave a very different picture from the rationalistic representation of a «cold» science, and described how science is rather rooted in performed practices, which make a specific knowledge exist. Even the challenge between sciences and opinions – or, we could say, between knowledge and unknowledge – is reciprocally built, since «the opinion against which a science is invented is not opinion in general. It is an opinion created with reference to the invention itself, to the possibility of a new "measurement", of the creation of a new way, always local and relative, of differentiating science from fiction» (Stengers 2010: 11).

In my ethnography different experiences and perspectives about vaccination – sometimes similar, sometimes opposing – emerged as strongly interrelated. I especially explored why some experiences did not enter the institutional knowledge apparatuses. A dual movement made this disavowal possible. Firstly, a closed circularity in the ecology of evidence that immobilized some experiences of suffering when scientific studies had already admitted or excluded a causal relationship between such sufferings and vaccinations. In this way, already existing evaluations about vaccines shaped the practices that should have constantly re-evaluated them. The second circular movement concerned an ecology of practices relating biomedicine and vaccination and, consequently, physicians and vaccines. Since some professionals had deeply internalized the hegemonic order concerning vaccinations and EBM, they immobilized some experiences, preventing such experiences to be conceived through a language of risk, which potentially increased distrust (as Kaufman noticed). In doing so, such experiences counted just as «unknowable unknowns» in biomedical knowledge, but they should be instead conceived as «unknown knowns» (Geissler 2013: 13), which were actively produced and, at the same time, contributed to produce biomedical knowledge. An implicit «labor of the negative» arises: it would continuously assure the «immunization social order» - which is «the set of institutions, laws, pharmaceutical technologies, and social practices that work together to produce high levels of vaccine coverage to prevent a wide range of diseases» (Kirkland 2016) by maintaining the vaccine benefit/risk balance stable. As Stengers stated, our tradition cannot tolerate the instability inherent to the *pharmakon*: «We require a fixed point, a foundation, a guarantee. We require a stable distinction between the beneficial medicament

and the harmful drug, between rational pedagogy and suggestive influence, between reason and opinion» (Stengers 2010: 29). My ethnography showed that vaccine surveillance could produce such a fixed point, rather than a constant re-evaluation of risks and benefits. In a way, this also complies with the public documents stating that pharmacovigilance must provide reassurance, confidence, and a specific «culture of vaccination». At the same time, however, this fixed point was also a point of friction where the fracture between languages, discourses, and worlds originates. Here, paradoxically, distrust in vaccination, healthcare institutions, and biomedical epistemology sprang. Through my work, I aimed to reshape the scenario by re-connecting different views that were not so far as they seemed to be (Lello 2020). By gathering the bitter tears of Lucia, the critical claims of Dr. Porcellana, the heartfelt worries of Dr. Torelli, and the other narratives I collected, I hope to harmonize them within a common world.

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Notes

(1) All the names and surnames I used in the present article are pseudonyms.

(2) With "vaccination practices", I refer to the actions and the discourses relating to vaccines, which different subjects shape in a specific socio-cultural context. So, this expression encompasses the full continuum of vaccine production, administration, record-keeping, knowledge production, acceptance, hesitation, and refusal.

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Abstract

Ecologies of Practices within the Italian Vaccine Pharmacovigilance. Antinomies in Vaccine Knowledge

Vaccine pharmacovigilance has been conceived as a system able to constantly monitor vaccines' safety. However, it is a complex socio-cultural practice, which needs to be unpacked. In this article I explore some ecologies of practices operating within the pediatric vaccine pharmacovigilance in Italy. I base my analysis on the ethnographic research I carried out from 2017 to 2021. I show two main processes: firstly, a "labor of the negative" operating in vaccine pharmacovigilance, which maintains the vaccine benefit/risk balance stable within public representations; secondly, the way through which this "work of knowledge" paradoxically generates frictions, distrust and even alternative worlds.

Keywords: Italy, biomedical epistemology, ecologies of evidence, pediatric vaccines, pharmacovigilance

Resumen

Ecologías de las prácticas en la farmacovigilancia italiana de vacunas. Antinomias en el conocimiento sobre las vacunas

La farmacovigilancia ha sido concebida como un sistema capaz de supervisar con constancia la seguridad de las vacunas. Sin embargo, es una práctica sociocultural compleja, que debe ser investigada cuidadosamente. En este artículo, exploro algunas ecologías de las prácticas que operan en la farmacovigilancia relativa a las vacunas

pediátricas en Italia. Baso mi análisis en una investigación etnográfica realizada por mí misma entre 2017 y 2020. Destacan especialmente dos procesos: un "trabajo del negativo" que opera manteniendo estable la relación riesgo-beneficio los riesgos-beneficios en las representaciones públicas; y la manera en que este "trabajo de conocimiento" paradójicamente puede generar fricciones, desconfianza, y mundos alternativos.

Palabras clave: Italia, ecologías de las prácticas, epistemología biomédica, farmacovigilancia, vacunas pediátricas

Résumé

Écologies des pratiques dans la vaccinovigilance italienne. Antinomies sur le savoir relative aux vaccins

La pharmacovigilance a été conçue comme un système capable de surveiller constamment la sécurité des vaccins. Toutefois, il s'agit d'une pratique socioculturelle complexe qui exige d'être examinée en détail. Dans cet article, j'explore certaines écologies des pratiques qui opèrent dans la pharmacovigilance relative aux vaccins pédiatriques en Italie. Je base mon analyse sur une recherche ethnographique que j'ai conduit entre 2017 et 2021. Je souligne, en particulier, deux processus: un "travail du négatif" qui agit en maintenant stable le rapport bénéfice-risque dans les représentations publiques; la façon dont ce "travail de la connaissance" peut, paradoxalement, générer frictions, méfiance et aussi mondes alternatifs.

Mots-Clés: Italie, écologies des preuves, épistémologie biomédical, pharmacovigilance, vaccins pédiatriques