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Abstract

During a pandemic, such as current H1N1 'swine flu', decisions are made with a sense of urgency. Yet, current policies emphasise the need to ground policies on evidence. This paper studies the tension that remains in decision-making processes when evidence is weak or 'silent' due to the sudden or unpredictable course of an event. The main focus is on the so-called 'known unknowns', factors of which we have only limited or weak evidence in the pandemic risk assessment processes. These processes cover, for example, monitoring the course of the pandemic, estimating the most affected age groups, and assessing population-level pharmaceutical interventions. This paper conceptualises the 'unknown' within these processes as silence of evidence. As the case of pandemic risk assessment shows, a new, emerging situation has not yet accumulated a robust body of evidence for decision making. These uncertainties are conceptualised as silent evidence. In a similar way, historical and archaeological studies acknowledge that there is evidence that is not yet discovered, interpreted or found. This paper develops a new way to look at unknown factors that affect risk assessment under a pandemic by focusing on the tension that remains in decision-making processes under pressure.

Introduction

A pandemic carries fearful connotations of its severity and potential loss of lives. These images are easily nurtured by media.[1] Past pandemics are reminders of risk and uncertainty that are alleviated by careful preparedness planning. Pre-pandemic planning is grounded on predictive actions, such as modelling[2] and surveillance that aim at anticipating the course of pandemic and help building scenarios to test various mitigation strategies for decision-making processes. The nature of pre-pandemic planning is, in a way, emulating the potential situation. However, the planning process itself is free from the sense of urgency. This changes when a pandemic occurs such as the current H1N1 'swine flu' outbreak when different kinds of uncertainties arise. This paper explores the limits of evidence: what is known and what remains unknown during a pandemic. These limits create conditions within which urgent and broad-ranging decisions will be made. Policy about antiviral distribution or prioritising the access to vaccines has potential consequences that cannot be fully examined at the moment the decision is due.

When a pandemic occurs and affects people across the globe, its rapid development increases the need to know, predict, anticipate and guess. What will happen to us? How does this affect me? At times, uncertainties may be hard to tolerate. Let me reflect on two personal experiences that capture the difficulty of accepting the uncertainties during a pandemic. When the number of cases of pandemic influenza H1N1 arose rapidly in mid July 2009 in the UK, media reached out to researchers who would shed some light on the case. A journalist from BBC4 News Hour called me. He was keen to know about the potential risks of the pandemic: How is the distribution of *Tamiflu*[3] organised? Who are actually at risk? What kinds of effects are anticipated from the spread of the pandemic? One of his broad-ranging questions was: 'What will happen globally?'. Discussion with him showed that uncertainties, which were inevitably a part of the course of the pandemic were not welcomed. 'We don't know for sure, but the models assume that', was not an acceptable answer. This example led me to think about the limits of knowing – and of *unknowing*. How could we effectively communicate[4] these dimensions of knowledge to various interest groups, such as decision-makers, public, researchers, who may assume that we *should* know for sure, and may acquire robust, reliable evidence?

Another example reminds us of the scope of unknowing, in the case of a pandemic. In August, my sister flew from Helsinki to London. Before the flight, she was concerned about the risk of catching the flu, since swine flu in the UK had a rather severe media image in Finland. On the plane, she sat next to a couple who were seriously ill, coughing and sneezing for the best part of the flight. Five days later in London, she

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[1] A good example of a rather strong expression is 'Armageddon virus' that appeared in the news in the early days of the current pandemic (BBC News, 29 April 2009).

[2] Use of model-based evidence is emphasised in 'Pandemic flu - A national framework for responding to an influenza pandemic' (Department of Health, November 2007). I have discussed the predictive capacity of models when they are used in encountering public health risks (Mansnerus 2009).

[3] *Tamiflu* is the market name for *oseltamivir*, an antiviral medicine manufactured by Roche.

[4] This was also emphasised in Professor Spiegelhalter's talk on communicating risks and uncertainties at Judge Business School, 22 October 2009.

reported being unwell with headache, joint and muscle pains, cough and high temperature. I became a 'flu buddy'[5] for her. After a self-assessment of her symptoms on an online form, I had a designated code from the NHS Direct website, and picked up a pack of *Tamiflu* from a pharmacy. But did she actually have the H1N1 viral infection? We don't know for sure, since she was not clinically tested or diagnosed. The microbial cause of her influenza remains uncertain. These experiences highlight two aspects of the uncertainties of a pandemic: those affecting the population and those related to the viral behaviour.

Origin of the virus and its geographical spread, its infectivity and the potential immunity response in a population, and the effectiveness of pharmaceutical interventions can be regarded as unknown factors. These unknown factors are present when a distance between the event itself (e.g. a pandemic) and the action required (e.g. vaccination or an antiviral treatment) seems to diminish. The changing situation, development of the course of the pandemic, its spread and transmission, weaken the capacity to 'act at a distance', to govern the situation by reporting activities or with the development and use of technological devices (cf. Miller and Rose 2008). Yet, this distance is continuously recreated and maintained by the production of evidence. This could be seen as an attempt to overcome unknown factors that are present in the risk assessment of a pandemic. However, these factors need to be accommodated in the decision-making processes that consider the efficacy of mitigation strategies[6] for a pandemic or assess interventions to contain[7] the outbreak. Public health policy-makers aim at grounding their decisions on reliable evidence in order to plan and execute effective interventions.

This paper explores the tension that is present when decisions are made during a pandemic, but the evidence needed to support them remains 'silent' by which I mean evidence that contains unknown factors.[8] Silence of evidence, as an intrinsically controversial notion, shows that actions taken to retrieve factual evidence may either increase the transparency or nurture opacity of the evidence production processes. By definition, this notion carries a tension within itself.[9] What actually remains unknown? How is this 'lack of knowledge' conceptualised? In what sense could unknowing be seen as *silence of evidence* in the decision-making processes? Whose evidence remains silent, whose evidence speak for themselves? What then are the implications of 'silent evidence' for pandemic influenza risk assessment? A recent report identifies a set of unknown factors that remain unclear during the process in which the decisions about public health interventions are made at the local, national and international levels. Urgency and unpredictability, which are present in the course

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[5] NHS information on pandemic flu advises us to name 'flu buddies' who would collect antivirals from a pharmacy.
[6] Cf. Ferguson et al. (2006) model-based study on mitigation strategies for a pandemic outbreak.
[7] In the United Kingdom, containment policy, which meant that the spread of the pandemic was contained at the site of the outbreak by closing schools and treating those who had been in contact with the infected with antivirals, was changed in July. Due to the rapid spread of the pandemic, only mitigation strategies, such as antiviral distribution, were reasonable. (Department of Health, 30 September 2009)
[8] The concept is an adaptation of Trouillot's (1995) idea of how silences are left within historical narratives, which was elaborated by Wylie (2008)
[9] I'm grateful to the anonymous referee for pointing out this aspect.

of a pandemic, require that decision-making accommodates unknown factors, perhaps by standardising them over time. The aim is to show that despite various attempts to standardise factual knowledge, there remains a tension that manifests itself at a level of uncertainty. This tension – between the known and unknown factors – is potentially alleviated through accumulation of sufficient evidence, which is a process when risk assessment draws upon multiple sources of knowledge to produce well-informed, sound decisions.

The main aim of this paper is to develop a conceptual framework for exploring situations where actions are taken under urgency and evidence remains limited or scarce; therefore the case remains as a mere example. The second section of this paper elaborates the notion of silence of evidence. The third section analyses how health policy documents acknowledge and discuss risk factors in the current H1N1 influenza pandemic. The main interest is to look at the documentation in terms of how uncertainties and unknown factors are presented. The main sources for these documents are the European Centre for Disease Control (ECDC 2009a, 2009b, 2009c, 2009d) and the Department of Health (2007, 2009) in the UK.[10] The final section discusses how silent evidence influences decision-making processes.

Silence of evidence

Standardisation of knowledge which is addressed through the development of evidence-based medicine (EBM) and expands towards the ever growing importance of evidence-based policies, dominates decision-making processes. However, evidence as a mode of standardising knowledge makes decision-making prone to contestations. As Naomi Oreskes' forthcoming study shows delays in accepting the evidence for climate change as an anthropogenetic process were based on prolonged disagreements of what counts as good, reliable evidence. Various interest groups within the oil industry, who benefited from the delays in sanctioning CO_2 emissions, maintained these disagreements. One source for disagreements was the mode of producing evidence. Simulations of the various scenarios of global warming were contested, as Oreskes argues. She shows that different interest groups 'manipulated' the competing views by weakening each other's evidence. The scientific evidence, produced by computer simulations was labelled weak and unreliable. This convinced the broader audience of the uncertainty of evidence. At the same time, weakening the evidence was a selective choice. The lobby groups in oil industry, maintained and manipulated the construct of denial of anthropogenetic origin of climate change, for example, through publicity campaigns in radio. It seems that processes and practices that standardise evidence are ways to work towards overcoming unknown factors. Standardisation of evidence is closely linked with the mode of producing evidence. In this section, I will briefly explore the nature of evidence to elaborate the idea of the silence of evidence.

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[10] The empirical case presented in this paper is best seen as a preliminary study for a more comprehensive analysis of pandemic preparedness planning in the UK and Finland (2009- 2011).

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Our public health programs will not be effective if absolute proof is required before we act; the best available evidence must be sufficient (Michaels 2008: 91).

What kind of evidence is, then, sufficient for decision-making? The starting point is to look at the incompleteness of evidence that allows one to characterise evidence as silent. After all, evidence could easily be seen to incorporate a heterogeneous set of 'facts', by standardising them through a set of practices and procedures. This standardisation of knowledge is required for reliable decision-making processes. In a similar way, Mary Morgan (2008) argues in her case study of Nigerian economic planning in the 1960s, decisions in the planning processes relied on 'mutable mobiles', which are facts that are not fixed but provide sufficient validity to be acted upon.

Interestingly, current ways of analysing evidence seem to occupy a critical position. On the one hand, those favouring evidence-based approaches conceptualise the hierarchies of evidence, which arise from the mode of evidence (e.g. Pettigrew and Roberts 2003). On the other hand, critical accounts suggest that evidence-driven knowledge production might have its pitfalls, such as 'ghost writing', overvaluation of quantifiable knowledge, diminishing or ignoring the role of actors involved in the process (Lambert 2006; Sismondo 2007). Daston (1992) argues that evidence itself should not be disconnected from intentionality. This means that evidence is, at least to some extent, related to the practices that produce, apply and evaluate it. In a similar way, Timmermans and Berg (2003) explore how standardisation of both medical knowledge and nursing practices preceded the approach now known as EMB. In their analysis of medical practitioners, active engagement with standards, procedures and facilitating tools turned out to be important. It would appear that Timmermans & Berg (2003) and Daston (1992) underline a similar aspect: standardisation of knowledge happens through intentional practices. This observation points towards the importance of addressing experiential, practical knowledge as a part of evidence (cf. Hastrup 2004).

Generally speaking, the ideal of a solid, robust body of knowledge that is gained by synthesising available sources of knowledge is questionable. Medical anthropologists (e.g. Hastrup 2004; Lambert 2006) argue that the 'ideal evidence' is exclusive to the heterogeneity of knowledge production by favouring, for example, randomised control trials as a main source of knowledge. Sismondo (2007) shows that this emphasis can lead to distorted practices, such as 'ghost writing' or excess production of evidence in favour of marketing or product launch. These practices are also critically reviewed by Michaels (2008), who emphasises that decisions are grounded on sufficient evidence. Is this a 'battle' between different experts, such as field researchers and normative statisticians and their modes of rational decision-making, as Boumans (2008) suggests? It appears that by excluding some modes of knowledge production, evidence is, perhaps, wilfully or intentionally silenced. By exposing the manipulative practices as described by Sismondo (2007) and Michaels (2008) described, the more obvious effect is silencing the evidence. I suggest broadening the

perspective. Silenced evidence leaves someone uninformed or ignorant of the subject matter. If it is done wilfully, we may talk about strategic ignorance, as McGoey (2007: 217) argues. In her analysis of the safety of antidepressants, she shows that 'ignorance allows those in authority to deny knowledge of the truths which they are increasingly expected to share'. This resembles ignorance as a maintained, manipulated, strategic or active construct, that Proctor and Schiebinger (2008) suggest. In order to develop a broader perspective, it is useful to look beyond the manipulative and intentional side of silenced evidence. What are the sources of silence in evidence? Who remains silent in the production and utilisation of evidence?

Who remains silent?

> ECDC assesses the overall evidence as weak at present as it comes mostly from early observations of the pandemic and reported cases (ECDC, 2009b)

A risk assessment report on the current pandemic H1N1, from July 2009 states that the available evidence is 'weak'. What is weakness of evidence in this case? The report explores what is known and not known about the various risk factors of the pandemic. In short, 'weak evidence' is evidence not yet known, not yet available, or not yet tested. Instead of subscribing to evaluative term, I suggest that weakness of evidence, in this sense, could be regarded as silence. As silent, the evidence is not yet 'comprehensible to all', or may not have a voice yet. One could consider that evidence in this mode is evidence for *use*, for assisting a decision-making process, but it may not be of a phenomenon or for theoretical claims, since these modes of evidence further accumulation of factual knowledge (Mansnerus forthcoming).

Wylie (2008) suggests that silence of evidence as presented in historical studies, refers to the idea that there are past events, past narrative or ancient objects that have yet to tell their story, that they have only left traces for us to reconstruct their histories. Wylie builds her analysis on Trouillot's idea of silences in history. According to Wylie (2008: 187), Trouillot argues that in historical studies, the narrative itself is produced at innumerable sites. She claims that: 'What we know, as much as we do know, tracks power as it operates in social contexts both past and present'. By opening the discussion to archaeological context, she argues that the contextual factors that shape ignorance are socio-political, economic, and cultural. Her observations show that ignorance is a function of poverty of empirical data. Perhaps the relevant evidence has not survived. She also brings about the question of ignorance[11] as irreducible, if complexity of the phenomenon is an intrinsic and characteristic feature.

Let us focus more on Truillot's approach. His starting point is to understand how a

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[11] Her approach broadens Proctor and Schiebinger's (2008) classification of variations of ignorance. According to the authors, ignorance is not only a manipulative state. It could be a native, original state, a resource that invites us to gain more knowledge. It may also be a passive construct or a lost realm, which may have political significance, or ignorance is a form of resistance.

historical narrative is constructed: what has happened and what is told to have happened. This distinction allows him to look at the different ways in which silence is left in the historical narrative. Trouillot's examples are drawn from the Haitian Revolution in Western historiography. He underlines that there are various forms of silencing that took place in the narratives. Silence was due to the poverty of sources, hence silences buried a story he was able to tell on the basis of his archival work. There were also events of general silencing, which is due to uneven power in the production of sources, archives, and narratives. In that case, Trouillot made the silences speak for themselves by juxtaposing the available narratives of the event itself. Furthermore he talks about the abundance of sources and materials. In this case, silences appear in the interstices of the conflicts between previous interpreters. According to Trouillot (1995: 26):

> Silences enter the process of historical production at four crucial moments: the moment of fact creation (the making of sources), the moment of fact assembly (the making of archives), the moment of fact retrieval (the making of narratives) and the moment of retrospective significance (the making of history in the final instance). These moments are conceptual tools, second-level abstractions of processes that feed on each other. As such, they are not meant to provide a realistic description of the making of any individual narrative. Rather, they help us understand why not all silences are equal and why they cannot be addressed – or redressed – in the same manner. To put it differently, any historical narrative is a particular bundle of silences, the result of a unique process, and the operation required to deconstruct these silences will vary accordingly.

As Trouillot points out, in historical studies, silences arise in generation of textual traces, compilation of these traces as an archive, the retrieval of traces as facts to be built into historical narratives, and the construction of narratives that have retrospective significance. I will apply these four stages into my exploration of the silence of evidence in the pandemic. Firstly, there is the moment of generation: traces of evidence are needed. These traces are compiled, not into a historic archive, but collected by the centres that monitor the development and spread of a pandemic. These two phases take place continuously. However, it is the moment when evidence is needed for decision making, when something emerges that the traces are retrieved as facts and built into narratives. Later on, narratives are constructed so that they carry some retrospective significance, such as perhaps the capacity to predict the course of the pandemic. However, each of these phases is subject to the epistemological and ontological factors in their manifestations of silence. The poverty of empirical data, the fact that 'traces of evidence' are scarce when the behaviour of the phenomenon itself is complex, leaves space for silence.

We can see that wilful silencing of evidence emerges from the uneven power relations in the production of sources. But silence may originate as a poverty of sources, which limits the narrative a historian is able to tell. Or it may be a result of conflicts between previous interpreters. These dimensions of silent evidence broaden

the idea of intentional or wilful silencing. At a particular moment in time, silence of evidence may be a combination of these dimensions. As he says: 'I walked in silence between the old walls, trying to guess the stories they could never dare to tell' (Trouillot 1995: 31). In the following, I will elaborate on the notion of silence of evidence in case of the H1N1 influenza pandemic.

Known unknowns during a pandemic H1N1[12] influenza

Monitoring and surveillance activities on new and emerging infectious diseases[13] expected that *avian influenza* virus (H5N1) would have caused a potential pandemic. While the focus was on Southeast Asia, current pandemic[14] emerged in Mexico in April 2009. Some studies traced back (on the basis of previous pandemics and viral mutations caused by them) that most likely, a new, emerging pandemic would occur in Asia (Pyhälä 2006a, 2006b). This was explained by the close connection between human and poultry populations (poultry farming, and selling the meat at open street markets are typical). Prior to influenza cases caused by H5N1, the monitoring activities followed keenly the SARS epidemic in 2002.

By late April 2009, human cases of a novel influenza type A virus were confirmed. These cases were identified in the United States and in Mexico. The virus, according to epidemiological evidence, had been circulating in Mexico since February 2009 and may have already emerged earlier. It was also confirmed that the new human strain was identical to a strain[15] of virus that had been circulating in pigs in North America. The strain spread rapidly and WHO reacted to the public health emergency by raising the Pandemic Alert Level from 4 to 5 (sustained community outbreaks in a limited number of countries) at the end of April. On the 11 June 2009, WHO declared a pandemic and raised the Alert Level to phase 6, which means wide geographical spread, but does not indicate the severity of the infection. According to the ECDC situation report (14 September 2009), there are, currently, 50,892 confirmed cases[16] and 137 deaths within the EU/EFTA countries. In the United Kingdom, there are 13,322 cases and 76 deaths among those cases.

Currently, the main concern is when the second wave of the pandemic is likely to appear, how severe it is and how to protect the risk groups[17] in population. This

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[12] The case description in this section overlaps with Mansnerus (2009), which studies the predictive capacities of models in pandemic preparedness planning.

[13] WHO maintains a Global Outbreak and Alert Network (GOARN).

[14] This summary is based on Flusurvey.org.uk site (situation on 27 July 2009), which is an internet-based monitoring system for Influenzae Surveillance, in collaboration with Health Protection Agency, London School of Hygiene and Tropical Medicine, EU FP7 and Epiwork.

[15] Flusurvey reports that the current strain has a complicated history: 'some of its genes moved to birds to pigs in 1918, other genes from birds to pigs at the end of the 20th century, some got into pigs in the 1960s having first passed through humans'.

[16] The confirmation policies depend on national laboratory testing policies.

[17] For public health professionals, risk groups are those who suffer from chronic conditions, are pregnant or immunocompromised. ECDC (2009d) lists following population groups as risk groups: 'chronic respiratory diseases, chronic cardiovascular diseases, chronic metabolic diseases, chronic renal and hepatitic diseases, persons with deficient immunity, chronic neural or neuromuscular conditions, any other condition that impairs a person's

uncertainty is summarised as following by ECDC (August, 2009): 'Pandemic viruses are unpredictable, and can change their characteristics as they evolve and perhaps reassert with other influenza viruses ....'

Along with the uncertainty in predicting the origin of the pandemic, there are other 'known unknowns' taken into account in a recent risk assessment report from ECDC (2009a, 2009d). I will categorise these factors into three groups:

> (1) Known unknowns related to or caused by the microbiological factors,
> (2) Lack of *precise* parameters for modelling and forecasting purposes, and
> (3) Effectiveness and safety of pharmaceutical interventions.

What do these factors mean? Or what kind of risks they embody? Ortwin Renn (2008: 20) states 'risks are mental constructions. They are not real phenomena but originate in the human mind'. When we look at these three groups of unknown factors, or risks it seems to me that the risks they represent are not purely 'mental constructions'. The microbiological factor, the virus itself exists and it is unknown how it behaves in terms of infectiousness and mutability. When assessing the effectiveness of pharmaceutical interventions, i.e. antivirals and vaccinations, these properties of the microbiological agent are taken into account. What remains unknown is the interaction between the virus and the population. Policies around antiviral distribution, or optimising the dose for a pandemic vaccine aim at maximising the protection and minimising the risk from the viral infection on a population. In this context, the risk groups[18] are carefully monitored and extensive measures are taken to support their health and recovery. These three groups of known unknowns are worth looking at more closely as they would appear to embody different dimensions or variations of the silence of evidence. These three sets of unknowns reflect the silence about the microbiological factors. Only after the identification of the viral strain, can evidence of its severity be assessed. The unknown parameter values and estimates are fully uncovered after some of the microbiological unknowns are detected. The nature of the microbiological factors, again affects the effectiveness of pharmaceutical interventions. However, it is worth considering how the quality of risk changes throughout these three groups. Microbiological factors present the constant risk of emerging infections, whereas effectiveness of pharmaceutical interventions contains more variation from the governance of risks by human efforts. In other words, when assessing the risk of the pandemic through these factors, we can identify the silences within them. Silence as a part of the unknown nature of the microbiological phenomena seems not to be intentional, whereas unknown factors of safety and efficacy of pharmaceutical interventions urge us to ask – unknown to whom? – as discussed in McGoey (2007).

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immunity or prejudices their respiratory function, including severe or morbid obesity, pregnant women, children (especially those under two years)'.

Unknown microbiological factors and their effect on population

When the pandemic occurs, the antigenic type and phenotype are unknown until the virus is isolated and analysed. It remains unknown, how well the virus will respond to available antivirals[19] and how this response changes when the epidemic matures. 'Known unknowns' related to the microbiological characteristics of the virus also indicate the potential risk of complicating conditions. The main concern is that some individuals who contract the virus develop potentially life-threatening conditions (such as viral pneumonia) as a result of the infection. What also remains as an unknown factor is whether the pandemic strain will dominate over the seasonal type A influenza.

One characteristic of a pandemic is that it is more likely to affect children and young adults. The most recent observations confirm that so far, the highest number of cases is in the group of 10-29 year olds and 89.6% of the cases are among those under 40 (Gianella et. al., 2009).

Severity of the pandemic is measured as estimates of the case-fatality rates, clinical attack rates and hospitalisation rates. Interestingly, the pandemic risk assessment report (ECDC 2009b: 7-8) describes these rates as difficult to estimate in the following way:

> [On case fatality rate] This is difficult to estimate with great accuracy at this stage and it should anyway be remembered that it is a measure that is sensitive to social factors.
>
> [On clinical attack rate] In previous pandemics it was unusual to observe population clinical attack rates of less than 20%, while for seasonal influenza, rates are usually between 5% and 10%. However, this pandemic may be unusual since it seems that older people may be missing from those infected.
>
> [On hospitalisation rate] As this is a difficult figure to derive for Europe. A rate observed from reported cases for the United States (11%) is correct, but should not be used for planning, as it will be an overestimate ... .

What lies behind the difficulties for measuring the estimates of these rates? Garske et. al. (2009: 339) explain the potential bias of these estimates. By definition, 'the case fatality ratio is the ratio of the total number of deaths from a disease divided by the total number of cases'. According to Garske et. al., this simple method of estimation works perfectly in a 'fully ascertained (and complete) epidemic. Often, this is not the case. They argue that in most infectious diseases, there is "underascertainment" of cases. This means that "people who have only a mild infection or remain asymptomatic are not likely to search for health care and are not likely to be tested. In other words, more severe cases are more likely to be diagnosed, which is a source of

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[19] Antivirals that are authorised for use in the European Union are *Tamiflu* (oseltamivir) and *Relenza* (zanamivir).

bias for the estimate" (p.339). Another source of bias arises from the delay between disease onset and final outcome in severe cases. This effect is called *censoring* and it means that case fatality ratio will be too low and will change (i.e. it is likely to grow) during the epidemic. In a similar way, Lipsitch et. al. (2009: 113) mention two sources of uncertainty that 'critically affect severity estimates': overestimation of the proportion of the cases, (i.e. the 'underascertainment' mentioned by Garske et. al.), and the downward bias, because these estimates are calculated as simple ratios, (i.e. the bias caused by *censoring*). Common to these biases is the lack of observations and data, which leads to profound situation at the beginning of a pandemic, but changes when the epidemic matures. However, variations in surveillance practices and different policies for the distribution of antivirals may prevent the collection of data of confirmed clinical cases. For example, the current policy in the United Kingdom of distributing antivirals on the basis of self-assessment is likely to lead to a lack of confirmed clinical cases and maintain the bias in the estimates, and may also have an effect on the viral mutations.

Assessing predictions and population-level interventions

Most common population-level interventions when preventing transmission of a pandemic or mitigating its effects are mass vaccinations and antiviral treatments. ECDC report (2009b) mentions two known unknowns related to these interventions: 'the effectiveness of interventions and counter-measures including pharmaceuticals' and 'the safety of pharmaceutical interventions'. What does this mean in terms of evidence? Firstly, the effectiveness of these interventions is dependent on the microbiological characteristics of the virus that causes the pandemic. Its responsiveness to antivirals may vary and is subject to change during the course of a pandemic. Secondly, the vaccine development against the pandemic strain can only begin when the strain is identified. In order to prepare for the vaccine development, there are two types of vaccines developed as a 'rehearsal' – the so called 'mock-up' vaccines and pre-pandemic vaccines. Mock-up vaccines are vaccines that contain 'a strain of the influenza virus that has been specifically chosen, because the population has never been exposed to it' (European Medicines Agency [EMEA] October 2009). The idea of a mock-up vaccine is to allow a company to develop and test a vaccine with a 'look-alike' strain that can easily be changed once the pandemic strain is identified. This procedure shortens the time for producing the vaccine. Pre-pandemic vaccine contains a strain of virus that is assumed to cause the pandemic. It is a vaccine that is prepared on a basis of a 'best guess'. For the current situation, pre-pandemic vaccines contain the strain of the A/H5N1 (avian flu), which was thought to cause the next pandemic (EMEA 2009).

Currently, the EMEA has approved two pandemic vaccines: *Pandemrix*, produced by GlaxoSmithKline (GSK) and *Celvapan* by Baxter. The GSK's *Pandemrix* is a split virion[20] vaccine, whereas the Baxter vaccine contains a whole, inactivated virion.

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[20] A virion is a complete infective form of a virus outside a host cell.

These vaccines are brought to market and were given in a mass vaccination campaign in the United Kingdom to the risk groups. The vaccination will be given in two doses with a three-week interval. A similar policy has been adopted in Finland. The Department of Health (2009) recommends the following prioritisation of the groups to be vaccinated:

(1) Individuals aged 6 months and up to 65 years in the current seasonal flu vaccine clinical at-risk groups
(2) All pregnant women, subject to licensing conditions on trimesters
(3) Household contacts of immunocompromised individuals
(4) People aged 65 and over in the current seasonal flu vaccine clinical at-risk groups.

The same document discusses all the aspects related to the vaccine. One concern related to the 'swine flu' vaccine is the risk of Guillain-Barre Syndrome (GBS), which is a rare, but serious neurological condition. There are two reasons to discuss these concerns. Firstly, an increased risk of GBS was associated with the 1976 swine influenza vaccines used in the United States. Secondly, the syndrome is documented to follow after an influenza type illness. However, the documentation from the Department of Health underlines that there is no evidence to suggest that either of the licensed vaccines will carry an excess risk of GBS (Department of Health 2009).

But vaccinations easily raise other concerns when they are offered for the population. Leach and Fairhead (2007) name various factors that are present in what they call 'vaccine anxiety'. These anxieties are grounded in experiential knowledge. They are not necessarily rational nor can they be addressed only rationally. In Leach and Fairchild's account, 'anxieties' arise in relation to the body, to various social processes and practices that influence thinking about the vaccination, and to wider political concerns. It seems to me that these dimensions are at least partially represented in the concerns related to the vaccine safety of the pandemic vaccine. For example a document from the Department of Health explores the safety aspects of the vaccines; it raises the question whether there is evidence that pandemic vaccine with H1N1v component increases the risk of GBS syndrome. This concern is bothers those, who remember something from the 'past'. However, the recent incident in which a teenager collapsed and died after being given a HPV[21] vaccination at school[22] may refresh the memory of 'bad side effects' of vaccinations. The notorious case in this regard is of course the MMR vaccination and the false claims that the vaccine causes autism or other adverse conditions. Looking at the vaccinations from this perspective reminds us how unknowing may maintain risk. The evidence, however thoroughly produced may fail in being in properly communicated to the participants. In this case the evidence remains silent. Individuals assess their individual risk, often without a wider, communal or altruistic perspective. This perspective may not even be available directly.

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[21] HPV stands for human papillomavirus.
[22] BBC News online, 'Schoolgirl dies after cancer jab', 29 September 2009.

One way to give voice to this silent evidence is through modelling and forecasting activities. As we learned, these activities embody one set of known unknowns, since modelling and forecasting purposes rely on available data to estimate parameter values. For example, there are difficulties in estimating the precise parameters needed for modelling and forecasting. These parameters estimate, for example, the numerical value of transmissibility, as a basic reproductive rate. Why is this? Again, we can see that links between the known unknowns as the microbiological factors remain undetected at the time these models are built for estimation purposes. The case of estimating precise parameter[23] values can be linked to the broader discussion on model calibration and its problems. In this context, however, it is worth noticing that modelling exercises begin at the moment when evidence is 'silent'; when only available estimates are derived from past data. Yet, these estimates are used in scenarios to look at the various mitigation strategies, of which pharmaceutical interventions form a significant group.

Discussion

This paper studies unknown factors within a pandemic risk assessment process and conceptualises the process through a notion of a silence of evidence. The notion shows that silences may remain intentional or unintentional depending on the source of silence. This means that the unknown microbiological factors represent a risk that is not only a mental construct, whereas the risks related to the safety of pharmaceutical interventions indicate the role of agents in the assessment process. This triggers the question of who remains silent. The paper elaborates the notion of silence of evidence from Trouillot's approach to historical narratives. This is seen useful, since it opens the steps in risk assessment and introduces transparency of the processes into it. Renn (2008: 24) defines the purpose of risk assessment as 'the generation of knowledge linking specific risk agents with uncertain but possible consequences'. By exploring this process of 'generating knowledge' and acknowledging the silences embedded in it, we will have a more accurate idea of the limits of evidence that is to be used within the assessment processes.

Silence of evidence, as shown here, is present in three ways in the unknown factors related to the pandemic. Firstly, 'poverty of sources', the fact that 'we know that we don't know', as it is commonly phrased, limits the available evidence. This dimension of silence may not necessarily imply intentional silencing of evidence, but simply acknowledges the lack of microbiological certainty especially in the early days of a pandemic. Intentional silencing of evidence is more likely to happen when there is uneven power in the production of evidence such as whether manipulative practices of 'ghost writing' in the evidence production are used to secure fast access to markets within pharmaceutical industry, or that conflicts of interest direct the interpretation of the available evidence. In either case, silence of evidence need not to be seen as something undesirable. As historical studies suggest, accumulation of interpretations

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[23] The predictive use of models in public health risks assessment is studied in Mansnerus (2009).

broaden the perspective. Or in Trouillot's terms: 'Facts are not created equal: the production of traces is always creation of silences' (1995: 29). How do these silences manifest themselves in the decision-making processes, in which they are considered as unknown factors?

This paper describes three groups of known unknowns, the factors that cannot be fully supported by evidence in the case of a pandemic. These groups are unknowns related to the microbiological characteristics of the pandemic, parameter-estimation in modelling exercises and the effectiveness and safety of pharmaceutical interventions. Each of these known unknowns can be identified as silent evidence. In other words, these are not seen as manipulative or strategic ignorance, maintained wilfully. Considering the lack of robust, certain knowledge as silent evidence, highlights a new aspect of unknowing. As Wylie (2008: 199-200) summarises:

> Ignorance is atlantic, to be sure, but focusing on how it is produced and maintained holds the potential for systematic, empirically and theoretically well-informed calibration of what we know. The greatest challenge lies in resisting the pressure to assume that when comprehensive, definitive knowledge lays out of reach the result is undifferentiated ignorance.

In other words, this paper contributes to the discussion of risk assessment by showing a middle ground, where the lack of definitive knowledge is yet a fruitful or necessary position to operate on. This is a central characteristic of the evolvement of risk assessment.

During a pandemic, such as the current H1N1, decisions are made with a sense of urgency. This may, indeed, result in a difficulty faced in decision-making processes. As Lipsitich et. al. (2009: 112) claims: 'a combination of urgency, uncertainty, and the costs of interventions makes the effort to control infectious diseases especially difficult'. This uncertainty raises the question of how to provide evidence for these processes. One way of approaching these questions is to take into account the environment in which the decisions are made, as Boumans (2008) suggests. His account supports the idea that the ways, in which evidence is obtained, should be assessed as rational throughout the process of decision making. However, it may not be straightforward to gain evidence on an emerging situation. Lipsitch et. al. (2009: 112) argue that: 'in practice, decisions have had to be made before definitive information was available on the severity, transmissibility or natural history of the new A/H1N1 virus'. It seems to me that unpredictability of viruses, in terms of their capacity to mutations, uncertainties related to known unknowns diminishes once human interventions in a form of increased control, predictive power of computational tools, surveillance, and monitoring practices are introduced to the pandemic planning. This implies that risk assessment is an unfolding process in which unknown factors mature once more evidence is gained. Conceptualising this development as silence of evidence acknowledges that there remains a degree of uncertainty within the process.

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