Detecting the unknown in a sea of knowns: Health surveillance, knowledge infrastructures, and the quest for classification egress

Citation for the original published paper (version of record):
Lee, F. (2022). Detecting the unknown in a sea of knowns: Health surveillance, knowledge infrastructures, and
the quest for classification egress. Science in Context, 35(2): 153-172.
http://dx.doi.org/10.1017/S0269889723000133

(article starts on next page)

Science in Context (2023), 1–20
doi:10.1017/S0269889723000133

CAMBRIDGE UNIVERSITY PRESS

RESEARCH ARTICLE

Detecting the unknown in a sea of knowns: Health surveillance, knowledge infrastructures, and the quest for classification egress

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Abstract

The sociological study of knowledge infrastructures and classification has traditionally focused on the politics and practices of classifying things or people. However, actors' work to escape dominant infrastructures and pre-established classification systems has received little attention. In response to this, this article argues that it is crucial to analyze, not only the practices and politics of classification, but also actors' *work to escape dominant classification systems*. The article has two aims: First, to make a theoretical contribution to the study of classification by proposing to pay analytical attention to practices of escaping classification, what the article dubs *classification egress*. This concept directs our attention not only to the practices and politics of classifying things, but also to how actors work to escape or *resist classification systems* in practice. Second, the article aims to increase our understanding of the history of quantified and statistical health surveillance. In this, the article investigates how actors in health surveillance assembled a knowledge infrastructure for surveilling, quantifying, and detecting unknown patterns of congenital malformations in the wake of the thalidomide disaster in the early 1960s. The empirical account centers on the actors' work to detect congenital malformations and escape the dominant nosological classification of diseases, the International Classification of Diseases (ICD), by replacing it with a procedural standard for reporting of symptoms. Thus, the article investigates how actors deal with the tension between the-already-known-and-classified and the unknown-unclassified-phenomenon in health surveillance practice.

Introduction

How do we know if a new pandemic, a new syndrome, or a new pharmaceutical disaster is lurking around the corner? More generally expressed: how can we find evidence of an unknown health threat when we do not know what we are looking for? In short, how can we surveil and detect the unknown? These questions, which are constantly being posed by actors in health surveillance, are the theoretical and empirical interests of this article.

These questions also point to a difficulty in health surveillance more broadly. The roster of potentially catastrophic cases is not limited to those that have already been identified as known threats—a list that includes such infamous calamities as Covid-19, Thalidomide, SARS, Ebola, Yellow Fever, Dengue, Chikungunya. Importantly, it also includes those things that are *outside* the gallery of usual suspects—the unknown threats that lurk beyond the surveillance systems we use to detect the already known and classified.[1]

[1]For more discussions about the challenges of global disease surveillance, see for instance Keck 2020; Shapin 2020; Kelly et al. 2020; Sanches and Brown 2018; Lakoff 2017; Caduff 2015; MacPhail 2014; Mackenzie 2014; Fearnley 2008.

Surveilling the world for unknown disease threats is seen as one of the most difficult and momentous problems in health surveillance. Detecting patterns of known symptoms, syndromes, or pathogens—any familiar health threat—is a challenging proposition. However, an additional difficulty of health surveillance lies in detecting unknown health threats, which might give rise to previously *unknown* patterns of symptoms—and therefore might not be recognized as a new syndrome at all. To compound the issue, new and unknown health threats might give rise to the same pattern of symptoms as a known disease: For example, in 2019 what at first glance might have looked like a pneumonia epidemic local to China or a new SARS variant, both known disease threats, soon became reclassified as the deadly Covid-19 pandemic.

One of my informants from the European Center for Disease Control and Prevention compared the challenge of the unknown health threat in syndromic surveillance to drinking from a firehose whilst trying to taste the water. There are so many signals that *could* potentially be a threat. But which signals out of this multitude really *are* that unknown threat lurking around the corner?[2]

The overarching aim of this article is to explore how actors in syndromic surveillance—the surveillance of signs and symptoms of disease—work to surveil and detect unknown health threats in a sea of known diagnoses and threats. The focus is on a particular set of actors and their struggle to navigate between the surveillance of a sea of standardized and known diagnoses and the detection of the unknown and unclassified health threat. These actors are struggling with a constant tension between the detection and classification of *something new* (an impending unknown threat) and the clinical diagnosis and classification of *something previously known*. In short, the actors struggle with how to sense the unknown, in a world of medical standardization that pushes clinical diagnoses toward the already known and standardized (cf. Timmermans and Berg 1997; Weisz et al. 2007; Kveim Lie and Greene 2020).[3]

The article approaches this conundrum from a historical perspective, from the point of view of the surveillance of congenital malformations in the 1960s. In the case that we follow below, the actors are searching for unknown patterns of symptoms, unknown syndromes, of congenital malformations—in the hope of preventing a new thalidomide disaster. The surveillance of malformations is a particularly interesting site in which to explore these questions, as actors constantly struggle between standardized and pre-established medical diagnoses and the drive to detect the unknown, unruly, and hitherto unclassified health threat (cf. Latimer 2013; Sturdy 2007).

The empirical case addressed here is the historical practice of surveilling congenital malformations in the nascent Swedish Register for Congenital Malformations in the early 1960s. The early days of the Swedish Register for Congenital Malformations, before practices had been fully been established, provide a compelling example for analyzing the tension between the known and the unknown in syndromic surveillance. As the register worked to set itself up as a center of classification, it was constantly struggling with standardized and unruly medical diagnoses, the dangerous and unknown anomaly lurking in the shadows, and quantified health surveillance.[4] The actors' constant question was: how do you detect syndromes, patterns of congenital malformation, which are still unknown and unstandardized?

[2]Quote from my fieldnotes from the European Centre for Disease Control and Prevention. The surveillance of signs of health challenges is today called syndromic surveillance, and has become an important part of the arsenal of health surveillance in the modern world (Henning 2004; Fearnley 2008; Cakici and Sanches 2014; Hulth, Rydevik, and Linde 2009; Roberts and Elbe 2017). The historical development from nosology to a focus on syndromes seems to point to an increasing focus on multiple causations of disease, such as genetic risk factors in combination with other factors (cf. Bynum 2013, 354).

[3]This is not to say that medical diagnoses are simple to classify, or that the clinical work is constantly certain about their diagnoses. Medical diagnosis is challenging, and often contradictory signs from different specialists need to be handled in practice (cf. Latimer 2013; Berg and Bowker 1997; Mol 2002). This tension between routine diagnosis and detection of new phenomena also seems similar to what Sturdy (2007) has observed in the relationship between clinical work and basic science.

[4]Center of classification is a word-play on the term "center of calculation" in Bruno Latour's work (cf. Latour 1986; 1987).

https://doi.org/10.1017/S0269889723000133 Published online by Cambridge University Press

Classification egress: Standardized classification and the unknown health threat

To analyze the tension between the already classified and the unknown, the article introduces the theoretical concept of "classification egress" to describe the practices that actors use to break out of a pre-established grid of classifications in an attempt to detect the unknown. An important theoretical point is therefore that classification work is not always about classifying, but is sometimes also about escaping classification, or trying to fit things into a different grid of classes.[5]

Theoretically, the article situates itself in the intersection between the social study of infrastructures and the sociology of science. It seeks to contribute to the lively and extensive discussion about infrastructures and classification (Bowker and Star 1999), which has found renewed interest today, as new types of information infrastructures seem to be invading every corner of our world.[6] This renewed interest in infrastructures and classification has been expressed as a concern for knowledge infrastructures (Bowker 2020; Edwards et al. 2013), sensing infrastructures (Lee 2021b; Klimburg-Witjes, Poechhacker, and Bowker 2021), or thinking infrastructures (Bowker et al. 2019), as well as a concern for categorization, classification, and quantification (Mennicken and Espeland 2019; Fourcade and Healy 2017; Fourcade 2016).

The work of negotiating the discovery and classification of phenomena is also a classic topic in the sociology of science. Much research in this vein has been done, for instance, on deciding if experiments and observations have identified gravity waves (Collins 1975) or pulsars (Woolgar 1976), making diagrams from observations of lizards or genes (Lynch 1985, 1988), classifying birds in bird watching (Law and Lynch 1988), deciding what experiments show in genetics (Amann and Knorr Cetina 1988), producing rainforest diagrams from soil samples (Latour 1995), diagnosing patients (Mol 2002), or determining how large crowd sizes are (Martin and Lynch 2009). Thus, translating an observation, an experiment, or a syndrome into a phenomenon or object, and then stabilizing it as a fact that can travel outside the laboratory walls demands much practical work (cf. Latour and Woolgar 1986; Latour 1987).

Importantly for this article, the actors' work to detect and classify the unknown in the surveillance of congenital malformations is related to a classic problem in laboratory studies: the experimenter's regress (Collins 1985). This concept highlights how the experimental testing of previously unproven theories leads to problems in assessing whether or not the experiments are successful. The basic challenge here is that if a theory has not already been proven, there is no way to use the theory to validate the success or the experiment, nor is there a way to use the experiment to validate the theory. Collins argued that "where the detection of a novel phenomenon is in question, it is not clear what should count as a 'successful outcome'" (Collins 1985, 34). Experiment and theory are supposed to validate each other, which is not possible when a new and untheorized phenomenon is discovered.

Disease surveillance faces a related but inverse problem: symptoms and patterns of symptoms (syndromes) are often overdetermined by pre-established theories, diagnoses, and classifications—the grid of nosology seems inescapable. For many syndromes there might exist several ready-made diagnoses or classifications that fit. In addition, observations of syndromes are often made by clinical practitioners that work within highly pre-classified practices of medical diagnosis, which posit nosological, *terminological standards* of ready-made categories that are used to classify

[5]The tension between the discovery of a new phenomenon and standardized knowledge systems is evident in the sociological study of standardization. For instance, delving into "Other" categories in systems of classification can signal uncertainties about how to classify and standardize a particular thing (Bowker and Star 1999). In certain cases, unknown phenomena might even be made invisible by being relegated to the status of "not fitting"—and consequently not be counted as a phenomenon at all (cf. Bowker 2000). The point is that the unruly things that do not fit are an avenue through which sociology can understand the complexities of processes of classification and categorization.

[6]Keywords for the sociological and anthropological interest in this development include Big Data, Algorithms, and AI (See for instance, Lee and Björklund Larsen 2019; Gillespie 2014; Gitelman 2013; Boellstorff and Maurer 2015; Ziewitz 2017; Seaver 2018).

https://doi.org/10.1017/S0269889723000133 Published online by Cambridge University Press

patterns of syndromes: for instance in the International Classification of Diseases (the ICD).[7] But the entities that disease surveillance is trying to detect, at least the ones the actors are most afraid of, are the *unknown* threats—not classified, not theorized, and hitherto undetected. Thus, the actors' work to discover, classify, and construct an unknown health threat, often stands in tension with the already known and classified grid of nosology (cf. Sturdy 2007).

The concept "classification egress" thus aims to describe actors' work to escape a classification system. In this case, it refers to the actors' work to create a new classification infrastructure geared toward the detection of unknowns through symptom detection, rather than using the already-known categories from the ICD.

The enactment of the unknown health threat and infrastructural inversion

Methodologically, the article approaches the detection of unknown disease anomalies through what has come to be called post actor-network theory sensibilities (cf. Law 1999). This perspective emphasizes the assembled, fractional, and multiple nature of objects and phenomena, as well as how non-human actors shape how the objects and phenomena are put together (Mol 2002; Law 1999; 2002; Callon and Law 1995; Latour 1987; Callon 1984). The consequence of this perspective is that new health threats—such as pandemics or teratogenic disasters—are seen as being assembled, or enacted, in practice (Lee 2021a; 2021b).[8]

In other words, through various methods of data collection and statistical work the unknown health threat *comes into being*—it is assembled or enacted—but as one particular version of many possible versions of this phenomenon (Mol 2002). Thus, a disease outbreak can be enacted as having very different shapes depending on which methods of surveillance are used. For instance, an investigation using genetic technologies might enact one version of a disease outbreak, while traditional epidemiological methods might enact another version (cf. Lee 2021b). Consequently, the infrastructures of disease surveillance shape how disease outbreaks—or in this case teratogenic disasters—are assembled.

This article approaches classification egress through a move that Bowker and Star have called infrastructural inversion, which highlights infrastructures as a sociological problem (Bowker and Star 1999). Through this move, the article highlights the challenges of assembling an infrastructure for syndromic surveillance in practice (Bowker and Star 1999; cf. Lee 2021b),[9] and reveals how actors set up a materialized infrastructure for quantifying and surveilling unknown threats (cf. Lee 2021a). The article is thus concerned with how actors work to design and implement a nascent infrastructure for syndromic surveillance. Below, we follow the actors in the Swedish Register for Congenital Malformations, exploring how they designed this new infrastructure for surveilling, quantifying, classifying, and analyzing congenital malformations.

Source material

The article makes use of several kinds of materials for the analysis. These include the published version of a government inquest evaluating if statistical surveillance of malformations was feasible,

[7]Of course, it is well-known that, classification, including the classification of disease at the bedside, is a complex and difficult matter. Bodies and diseases do not neatly fit into the ICD's categories and slots (cf. Latimer 2013; Casper and Clarke 1998; Timmermans and Berg 1997; 2003; Timmermans and Almeling 2009; Epstein 2009; Timmermans and Epstein 2010).

[8]One might say that the actor-network theory perspective has affinities with the onto-epistemological perspective developed by Barad (2003). In this view, it is impossible to disentangle epistemological and ontological questions, but only to study various and localized *cuts* that have come to perform the phenomenon in particular ways.

[9]In the sense of Star and Ruhleder (1996) the register formed an infrastructure in that it became deeply *embedded* in the Swedish healthcare system, connecting the register for congenital malformations with *several conventions of practice*. It also created and implemented a new locally curated *classification* of malformation syndromes and implemented *standardized* reporting of malformations nationally (cf. also Hess 2018 on paper machines).

https://doi.org/10.1017/S0269889723000133 Published online by Cambridge University Press

a large archival collection of medical records from births that were used in the governmental inquest,[10] the two versions of the ICD that were in use in Sweden, as well as a local standard for malformations produced in the Register for Congenital Malformations. It also draws upon different texts written by one of the main actors in establishing the register, Bengt Källén, as well as an interview with Källén about the historical practices of surveilling congenital malformations.[11] Taken together, these materials give a glimpse of the practices and challenges involved in surveilling congenital malformations in the 1960s and allows an analysis of how actors worked to manage the tension between the known and classified and the unknown and unclassified.

The article proceeds in four sections. First, it situates the birth of the Swedish Register for Congenital Malformations in relation to the thalidomide disaster, the quantification of research, and the push toward registering the population. Second, it examines the state of medical classification of malformations in Sweden during the period: the multiple versions of the ICD standard that were used in Sweden, the standardized reporting forms, the differing levels of commitment from local actors, the difficulty of standardizing the practices of medical diagnosis, and the challenges this posed for the statistical surveillance of birth defects. Third, the article examines the infrastructural practices that the actors around the Register for Congenital Malformations created in order to organize statistical surveillance of malformations. It delves into the practices that were instituted in order to handle the challenge that seeing through the nosological grid of the known diagnosis—the ICD—posed, and how the register attempted to break free of these challenges to detect the unknown. Last, the article discusses these practices from the point of view of the challenge of quantifying, detecting, and classifying unknown health threats in a sea of already known and classified syndromes of malformations.

Thalidomide, registries, and the quantification and standardization of medicine

The birth of the Swedish Register of Congenital Malformations can be dated to the eighteenth of December in 1964, when the Swedish Medical Board, the governmental agency that oversaw the Swedish healthcare system, made the reporting of congenital malformations mandatory and permanent. This decision had been preceded by a government inquest and a temporary trial period of birth defect registration in all of Sweden. Both of these aimed to determine the feasibility of the statistical surveillance of malformations, and the decision to make the register permanent made it obligatory for most maternity wards in Sweden to report congenital malformations. This marked the birth of a register that has survived until today.[12]

The decision to found the register can be said to be a direct consequence of the thalidomide disaster, where thousands of infants across the globe were born with a distinctive set of malformations due to the prescriptions of thalidomide to pregnant mothers (Lenz 1988; Vargesson 2015; Lennerhed 2015; cf. Fairchild, Bayer, and Colgrove 2019, 155–56; Daemmrich 2004, 60–69). The shock of the thalidomide disaster led to many countries establishing registers of congenital malformations in the 1960s, among them Finland (1963), England and Wales (1964), and the USA and Norway (1967) (Edmonds et al. 1981; Bjerkedal 2000; Misra 2005; Fairchild, Bayer, and Colgrove 2019; Institutet för hälsa och välfärd 2020). Nevertheless, it is worth noting that registries and registry-based research in general were a sign of the times in the Nordic

[10]The archive from the investigation comprises thirty-six boxes of material. Sixteen boxes are made up of copies of medical records from births of children with congenital malformations. The medical records are drawn from hospitals all over the country, ranging from small rural hospitals to large central university hospitals. The boxes contain records of the childbirth itself, as well as descriptions of the infants with congenital malformations and their treatment.

[11]The interview was done by the author.

[12]Medicinalstyrelsen, "Kungliga Medicinalstyrelsens cirkulär angående rapportering av nyfödda med missbildning 18 dec 1964," *Samlingar av författningar och cirkulär m.m. angående* medicinalväsendet, 1965, no 96. [The medical board, "The Royal Medical Board's circular regarding the reporting of newborns with malformations 18 dec 1964," Collections of statutes and circulars etc. regarding the medical system, 1965, no 96.]

https://doi.org/10.1017/S0269889723000133 Published online by Cambridge University Press

countries (Bauer 2014). Several other Swedish registries were established during this period: the death register was centralized to the Swedish Statistics Central Bureau in 1951 (Johansson 2010), *Tvillingregistret*, the Swedish Twin Register, was set up in the end of the 1950s (Lichtenstein et al. 2002; 2006), and the Swedish patient register was inaugurated in 1964 (Lichtenstein et al. 2002; Socialstyrelsen 2019).

Also, during this period, the quantification and standardization of medical research was gaining ground internationally. Clinical practice guidelines were proliferating in the US (Weisz et al. 2007) and statistics were gaining a foothold in clinical and pharmaceutical research (Marks 2000). In addition, many regulatory changes were being made in the surveillance, clinical testing, and reporting of pharmaceutical compounds (Olszynko-Gryn et al. 2018). For instance, it was during this time that the famous three phase double blind RCT was born (cf. Hobæk and Lie 2019; Marks 2000; Daemmrich 2004, 48–80). In sum, the Register for Congenital Malformations can be said to be situated in a broader shift towards what has been called "surveillance medicine," where quantified population-based studies delineated the normal, as well as defined abnormalities and risk factors in individuals (Armstrong 1995; Rose 1979).

The founding of the Swedish register was consequently part of an international movement to prevent another pharmaceutically induced catastrophe, as well as a movement toward quantification and health surveillance of the population. The goal of creating the Swedish Register for Congenital Malformations was to give early warning of a new unknown syndrome of malformations. In particular, as I will show below, it was to prevent another thalidomide disaster.

Bengt Källén, the Tornblad Institute, and the government inquiry

The birth of the Swedish Register for Congenital Malformations was closely entwined with the work of its the founder and longtime head, professor of embryology Bengt Källén. Källén was also the director of the Tornblad Institute in Lund, which was founded by professor of anatomy Ivar Broman as an institute of comparative embryology in 1934.[13] Källén finished his PhD in comparative embryology at the Tornblad Institute in the early 1950s. The Register for Congenital Malformations was housed at the Institute, and was consequently tightly linked to older work on comparative embryology (Källén 2014).[14]

Prior to the establishment of the Register for Congenital Malformations, information on congenital malformations in Sweden was collected and reported on a yearly basis (Källén and Winberg 1966). However, following the thalidomide disaster, this was argued to be unsatisfactory as an early warning system. In 1962 it was suggested in *Läkartidningen*, the official journal of the Swedish medical association, that "a continuous, central registration and analysis of certain malformations" was a promising avenue for surveilling, discovering and understanding congenital malformations (Bergström et al. 1962).

During 1962, the Swedish Medical Board began surveilling malformations and drug consumption on a trial basis, and simultaneously instigated a government inquiry into the teratogenic effect of drugs. The inquiry was christened the Inquiry into the Relationship Between Pharmaceuticals and Congenital Malformations. Pediatrician Jan Winberg, who had co-authored the 1962 article in *Läkartidningen*, was tasked with running the inquiry. The inquiry's findings

[13]Broman was also involved internationally in the standardization of anatomical nomenclature (Buklijas 2017, 9).

[14]It would, of course, be interesting from a historical standpoint to investigate the disciplinary tensions between the traditional study of fetuses and case histories in teratology and the development of quantified epidemiological work in the surveillance of malformations (cf. Al-Gailani 2009; Hopwood, Schaffer, and Secord 2010). Källén described himself as being part of an older guard of teratologists, focusing on cases and case histories, and lamented the dominance of a new breed of epidemiologists who focused predominantly on quantification. This tension seems similar to what Fujimura and Chou (1994) describe in their work on the AIDS/HIV controversy in the 1980s. In our interview, Källén even described the state of malformation surveillance as having finally been conquered by the quantifiers. However, this interesting historical tension is beyond the scope of this article.

https://doi.org/10.1017/S0269889723000133 Published online by Cambridge University Press

were published during 1964 in *Läkartidningen*. Those findings criticized the state of malformation-reporting in Sweden, noting that it was imprecisely classified, and that "meaningless" malformations were being overreported (Winberg 1964b; 1964c; 1964a).

However, in 1964—before the inquiry came to an end—the Medical Board decided, on a pilot basis, to test the feasibility of monthly registration of congenital malformations (Källén 2014). The task of running the pilot study was given to Bengt Källén and Jan Winberg. In January 1965 this form of reporting was made permanent, and the Register for Congenital Malformations was born (Källén and Winberg 1966).

Multiple standards and an ever-growing list of malformations

The Register for Congenital Malformations was established in a period when standardization and quantification were growing increasingly prevalent in healthcare and medical research, often based on the premise that "the standardization of categories and records" was necessary "in order to make data comparable" (Weisz et al. 2007, 706). The basis of medical classification in Swedish medicine was the well-known ICD standard, the International Statistical Classification of Diseases, Injuries and Causes of Death. In Sweden there were two versions of the ICD in use during this period. Both Swedish editions were derived from the Seventh ICD, which was ratified in 1955. One version was printed in 1957 and one in 1965. The 1957 version classifies congenital malformations in section XIV, and the list of fifty-nine malformations fits on two pages, starting with monsters (*Monstra*) and ending with unspecific and unclassified malformations (*Maleformationes congenitae aliae s. Non definitae, alibi non classificatae*). The 1965 version subdivides the main categories further. For instance, as seen in figure 1, the general term *Monstra* is subdivided into four subcategories: *Acrania, Monstrum* (duplex type), *Monstrum* (of undeveloped body shape—usually of the type where the head transitions directly to the trunk), and *Monstrum aliud et* UNS (where UNS stands for unspecified). Thus, in the later edition, more and more categories are defined to bring the malformed infant into the medical classification system.

As the difference between the two editions of the ICD shows, the development of the standardization of congenital malformations trends toward more specificity and detailed classification over time, reflecting the ongoing effort to bring the abnormal under standardized control for classification and medical statistics (cf. Kveim Lie and Greene 2020). However, each category and sub-category ends in the open-ended Other category—"*aliae* et UNS"—which, of course, points to the Sisyphean character of standardizing bodies, diseases, and malformations. For example, the Other category of the congenital malformations in the newer version of the Swedish ICD is numbered 759,00, and includes thirty-seven "Other" malformations that are not classified elsewhere (cf. Bowker and Star 1999). The ever-expanding catalog of malformations in these versions of the ICD points to how the theoretical problem of the standardization of abnormalities becomes a practical problem, giving rise to an ever-expanding catalog of classifications. For each new syndrome a new category needs to be made. As Bowker and Star (1999) have observed, the work of classification is truly never done.

Global standards, local practices, and uncertain classification

The challenge of classifying the world is, of course, immense—in medicine and elsewhere.[15] Medical practitioners have to make difficult judgments at the bedside and fit the ailments of patients into the standardized format of the medical record and the ICD. As we will see, the

[15]Classification has of course been of continuing interest in Science and Technology Studies and cognate fields (see for instance Law and Lynch 1988; Lynch 1988; Goodwin 1994; Latour 1995; Zerubavel 1996; Clarke and Casper 1996; Timmermans and Berg 1997; Epstein 2009; Latimer 2013; Fourcade and Healy 2017).

https://doi.org/10.1017/S0269889723000133 Published online by Cambridge University Press

XIV. Maleformationes congenitae

Medfödda missbildningar

Här beskrivna tillstånd bör betraktas som medfödda, om de diagnosticerats vid nedan angivna ålder och antydan saknas, att de förvärvats efter födelsen.

Under 1 år: Aneurysma aortae, stenosis aortae, atrophia cerebralis, cysta cerebralis, hypoplasia organorum, morbus valvulae cordis.

Under 4 veckor: Endocarditis, hjärtsjukdom UNS, hydrocephalus UNS, myocarditis.

* **Monstra**
750,00 Acrania
750,10 Monstrum (av typ duplex)
750,20 Monstrum (av outvecklad kroppsform — vanligen av typen huvudet går direkt över i bålen)
750,99 Monstrum aliud et UNS

* **Spina bifida. Meningocele**
751,00 Encephalocele
751,01 Myelomeningocele, meningocele (ej hudtäckt)
751,02 Myelomeningocele, meningocele (hudtäckt)
751,10 Cysta dermoides sacralis
751,11 Cysta dermoides cervicalis
751,19 Cysta dermoides alia s. UNS
751,99 Maleformationes spinales aliae et UNS

* **Hydrocephalus congenitus.** Medfött vattenhuvud
752,00 Hydrocephalus internus
752,01 Hydrocephalus externus
752,99 Hydrocephalus alius et UNS

× **Aliae maleformationes systematis nervosi et organorum sensus**
Andra missbildningar av nervsystemet och sinnesorganen
753,00 Cataracta congenita
753,10 Anophtalmus
753,11 Microphtalmus
753,12 Coloboma uveae
753,13 Buphtalmus
753,14 Cyclopia
753,15 Retinitis pigmentosa
753,16 Glaucoma infantile
753,19 Maleformationes oculorum aliae
753,20 Aplasia auris externae
753,21 Dysplasia auris externae
753,22 Appendix (fibroma) praeauricularis(-e)
753,29 Maleformationes auris aliae
753,30 Epiloia (tuberös scleros)
753,31 Microcephalia
753,99 Maleformationes systematis nervosi et organorum sensus aliae (ej klassificerbara under 753,00—753,31) s. UNS

× **Maleformationes organorum circulationis.** Cirkulationsorganens missbildningar
754,00 Tetralogia Fallot
754,01 Trilogia Fallot
754,02 Pentalogia Fallot
754,10 Ductus arteriosus persistens (Botalli)
754,20 Defectus septi ventriculorum
754,30 Defectus septi atriorum
754,40 Myocardiopathia familiaris
754,41 Fibroelastosis cordis
754,50 Cor biloculare
754,51 Cor triloculare
754,52 Dextrocardia
754,53 Ectopia cordis
754,54 Atresia valvulae pulmonalis
754,55 Atresia valvulae aortae
754,56 Atresia valvulae mitralis s. tricuspidalis
754,57 Stenosis valvulae aortae
754,58 Stenosis valvulae pulmonalis
754,59 Stenosis valvulae mitralis s. tricuspidalis
754,60 Coarctatio aortae (adult typ)
754,61 Coarctatio aortae (juvenil typ)
754,62 Coarctatio arteriae renalis
754,63 Coarctatio arteriae pulmonalis
754,69 Coarctatio arteriae alterius
754,70 Aneurysma arteriovenosum congenitum
754,71 Morbus Ebstein
754,72 Korrigerad transposition
754,73 Transposition
754,74 Truncus arteriosus
754,75 Maleformatio arteriae coronariae congenita
754,78 Maleformationes organorum circulationis aliae
754,79 Maleformationes organorum circulationis UNS

60

Figure 1. From the Swedish version of the ICD, which was adapted to computerized indexing and printed in 1965.

practitioners were also committed to the endeavor of standardized medical coding, but in varying degrees. After all, in the medical profession, the main focus of attention is most often the patient—not the production of standardized medical statistics.[16]

The archive from the government inquest into the feasibility of conducting statistical surveillance of congenital malformations offers us a glimpse of the practices for diagnosing and classifying congenital malformations that were employed in Sweden during this period. The medical birth records in the archive were collected as part of the government inquest, but from their unstandardized and varied appearance, with differing pre-printed forms, different standards of work, different charts, and different traditions of documentation, we can deduce that they were part of the varying routine medical practices of different hospitals. It was in relation to the differing local practices of, and differing commitments to, classification that the register had to

[16]On actors' various commitments and trajectories to standardization, see Timmermans and Berg (1997). Case in point, there might be multiple commitments to both clinical practice and research for medical doctors (cf. Sturdy 2007).

https://doi.org/10.1017/S0269889723000133 Published online by Cambridge University Press

work. It was these unruly medical professionals who were the first part of the infrastructure that would serve as a bulwark against an impending new and unknown thalidomide disaster.

In the archive stemming from the inquest, the medical records are often jotted on pre-printed and standardized forms. However, the forms were for the most part used in only one hospital and printed at a local print shop. In some cases they were printed by ESSELTE, a Swedish national conglomerate of printers. The scope of the records varies widely: some are short handwritten notes documenting a birth and a malformation, others are carefully constructed case histories spanning twenty or more pages, including documentation of temperature, weight, RH factor, and feeding schedule, as well as statements from specialists of different kinds.

Stamps were also in use: some records are stamped with "*Partus Normalis* 660a" or a scribbled note documenting "Y20,0"—both of which were codes for a normal birth, stemming from the two versions of the ICD in use in Sweden at the time. The use of stamps to classify the medical records testifies to the routine and repetitive nature of ICD coding in some Swedish hospitals. Standardization work with the ICD varied widely, but standardized coding was common enough that stamps were used to streamline the classification of normal childbirth.

The medical records in the archive reflect the varying local commitments to the use of the standardized medical classification of the ICD (cf. Timmermans and Berg 1997; Clarke and Casper 1996; Casper and Clarke 1998). Records vary in their use of the ICD codes, testifying to an ongoing struggle to standardize diagnoses in Sweden. They also reflect the shifting state of medical classification at the time. Different records used codes from the different Swedish versions of the ICD, and some records use codes from both versions. For instance, "752" can be found next to "Y38,7," though both are ICD codes for *Hydrocephalus* from the two different versions of the Swedish ICD that were in use at the time. Both Latin and Swedish were used to classify the malformations.

In addition to the challenge of classifying and coding, the challenge of diagnosing is evident in the records. Question marks, jotted annotations, and markers of uncertainty are common. The difficulty of fitting any phenomenon into a predetermined nosological category is evident (cf. Law and Lynch 1988; Star 1990; Berg and Bowker 1997; Latimer 2013). Doctors constantly displayed uncertainty by using language such as "possibly," "relatively," "suspicion," and "uncertain" in the records. Classifying the malformed infant body in a system of ICD diagnoses was fraught with difficulty (cf. Latimer 2013).

The point is that there are many practicalities and difficulties of classification with which the Register for Congenital Malformations had to contend. Malformations were diagnosed in local practices, with varying degrees of commitment to the standardized coding, and utilizing different versions of the Swedish ICD (cf. Timmermans and Berg 1997; Casper and Clarke 1998).

The records also reveal the difficulty of making a certain diagnosis—a certain classification—in hospital practice (cf. Berg and Bowker 1997; Latimer 2013). In the social study of standards, the tension between the standardized and the unruly practices of medicine has been given much attention (Timmermans and Berg 2003; Epstein 2009; Timmermans and Almeling 2009). Importantly, each standard needs constant manual work and tinkering to function in the practices in which it is used—to make the unruly biologies of disease fit into a standardized classification. Global or universal standards need negotiations between different actors to function locally (Timmermans and Berg 1997; Casper and Clarke 1998; Clarke and Casper 1996).

In the medical records collected for the government inquest, we can observe the constant practical work of producing medical statistics. These are the infrastructural practices in relation to which the Register for Congenital Malformation had to function: a constant stream of local practices being translated into standardized records, diagnoses, and classifications. To be able to produce a statistical surveillance of the unknown threat, the Register for Congenital Malformations needed to coerce these multiplicities into a statistical and quantified grid of classifications (cf. Berg and Bowker 1997; Hess 2018).

Furthermore, in the surveillance of syndromes, every pattern—every mundane diagnosis, malformation, and uncertainty—is potentially a sign of something new and unknown. A new syndrome might be visible in very mundane ways, and well-known clinical symptoms might well point to new and unknown syndromes. For example, as we are acutely aware in these post-pandemic times, everyday symptoms of the cold or influenza could well point to a new and unknown health threat such as Covid-19.

The same thing is true for malformations: seemingly mundane patterns of malformations can very well point to a new teratogenic disaster. This is one of the reasons why new and unknown syndromes are a particularly wicked challenge in disease surveillance. Consequently, these mundane and everyday clinical diagnostic practices and uncertainties are an integral part of attempting to detect the impending new and unknown health threat, and the well-known and mundane might be a marker for the new and unknown.

Woes of classification: Judgment, training, and the drawing of boundaries

In the context of the existing classification practices in the Swedish hospital system, organizing the Register for Congenital Malformations was a challenge. How do you discover the unknown in a sea of uncertain classification? One challenge, for instance, was that the very definition of a phenomenon is often uncertain and malleable (cf. Woolgar 1976; Amann and Knorr Cetina 1988; Law and Lynch 1988). What is a malformation? Where do we draw the line between an anatomical variation and a malformation? Different studies define malformations in different manners, and different types of malformations are included in each study. As Källén, the founder and longtime director of the Register for Congenital Malformations described the challenge:

> The definition of malformation is fluid. The boundary against anatomical variations is often uncertain. Some materials have included anatomical variations that are excluded in other materials. This often pertains to comparatively insignificant defects with relatively high frequency, which can completely skew the statistics. A clear definition of what has been registered as a malformation in a specific study is required, if the frequency numbers are to have any value. (Källén 1967, 31)

Källén's problem was that different definitions of what constitutes a malformation could have considerable effects on the statistics. In other words, the local practices of diagnosing and classifying the malformation could lead to different statistical results.

Källén also highlighted the role of the healthcare professionals, and how the role of different "investigators," their training or specialization, infrastructures of diagnosis, and standardized reporting could lead to an underreporting of malformations:

> The diagnosis of a malformation can vary in exactness between different investigators. . . . In standardized reporting there is a larger risk that malformations are omitted. Experience shows that even easily observed malformations, for example, cleft lip, and grave defects of extremities, are underreported. The precision of the diagnosis will also be dependent on if autopsy is performed, if different exams (e.g. x-ray) have been performed, and whether the exam is performed by a pediatrician or pathologist or by non-specialist physicians, midwives etc. (Källén 1967, 31)

Källén was acutely aware of how hospital practices, infrastructures, and the different commitments and training of the involved actors shaped the statistics of malformations. Here the challenges of producing statistics from the diagnosis of malformations was clearly highlighted. Individual investigators, professional training, practices of diagnosis, technical infrastructures,

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and the formalization of diagnosis were all brought to the fore by Källén. He also pointed out the problem of standardized reporting as a culprit in the underreporting of common malformations. Standardized diagnoses were seen as a problem for malformation statistics.

Becoming a Copernicus of malformations and the discipline of stiff paper

While serving as head of the Register, Källén devised several methods for detecting emerging threats through the surveillance of new patterns of congenital malformations. He worked tirelessly towards the detection of unknown and constantly impending disasters. In an interview, reflecting on the early years of the register, he talked about the challenge of using the standardized ICD classification to discover new syndromes of congenital malformation. Källén argued that the classification matrix of the ICD was unfit to capture the unknown and unclassified malformations that the register sought to detect.[17]

To break free from the terminological standard of the ICD classification, the Register for Congenital Malformations replaced the ICD with a procedural standard, implemented via specialized reporting cards that were distributed to all maternity wards in Sweden (cf. Timmermans and Berg 2003, 24–27). The reporting cards showed a schematic image of an infant, in which the physician was supposed to indicate graphically where on the infant body the malformation was located. There was also a space for the physician to explain, in text, the nature of the malformation through a verbal account. The reporting card did not include any premade categories or checkboxes. Instead it relied on the free visual and verbal description of the malformations, thus eschewing the pre-established categories of the ICD and replacing them with visual marking and verbal accounting (see figure 2).

According to Källén, the reporting cards were printed on thick and stiff paper to make it easier for doctors to jot down their observations at the bedside, but also to make it difficult for medical secretaries to get the cards into their typewriters. Källén wanted the information straight from the bedside, not from a delegated-to medical secretary in another room (cf. Berg and Bowker 1997, 522–23).[18]

After the Register for Congenital Malformations was formed, a constant stream of report cards were sent to the National Board of Health and Welfare. Källén harvested these report cards regularly, classified them, and entered them into a statistical analysis. Using this system, Källén sought to avoid the pre-established nosological matrix of the ICD as well as the diagnostic inclinations of the reporting physician. The reporting card purposefully did not ask for a classification or an ICD code, or any other pre-established categories or checkboxes, relying on the diagram and description of the malformation. The intention was to create a system that described symptoms, without relying on the already classified and known interpretations of those symptoms. The impending unknown threat could, after all, be found outside the grid of standardized categories of known diseases.

Though they circumvented the use of preexisting categories, Källén's statistical methods also demanded categorization; but instead of disease categories, the categories that the register employed were based on symptoms. Thus, in addition to the reporting cards, Källén devised his own local coding scheme, which was only used in the register, where Källén himself classified the reported malformations. This locally developed coding scheme was meant to avoid the ICD entirely. The advantage, he maintained, was that it allowed a complete flexibility in adding categories: for each new symptom that was reported, Källén could easily add a new category to his local grid of classification (see figure 3).[19]

[17]Interview with Källén, October 2018.
[18]Interview with Källén, October 2018.
[19]Interview with Källén, October 2018.

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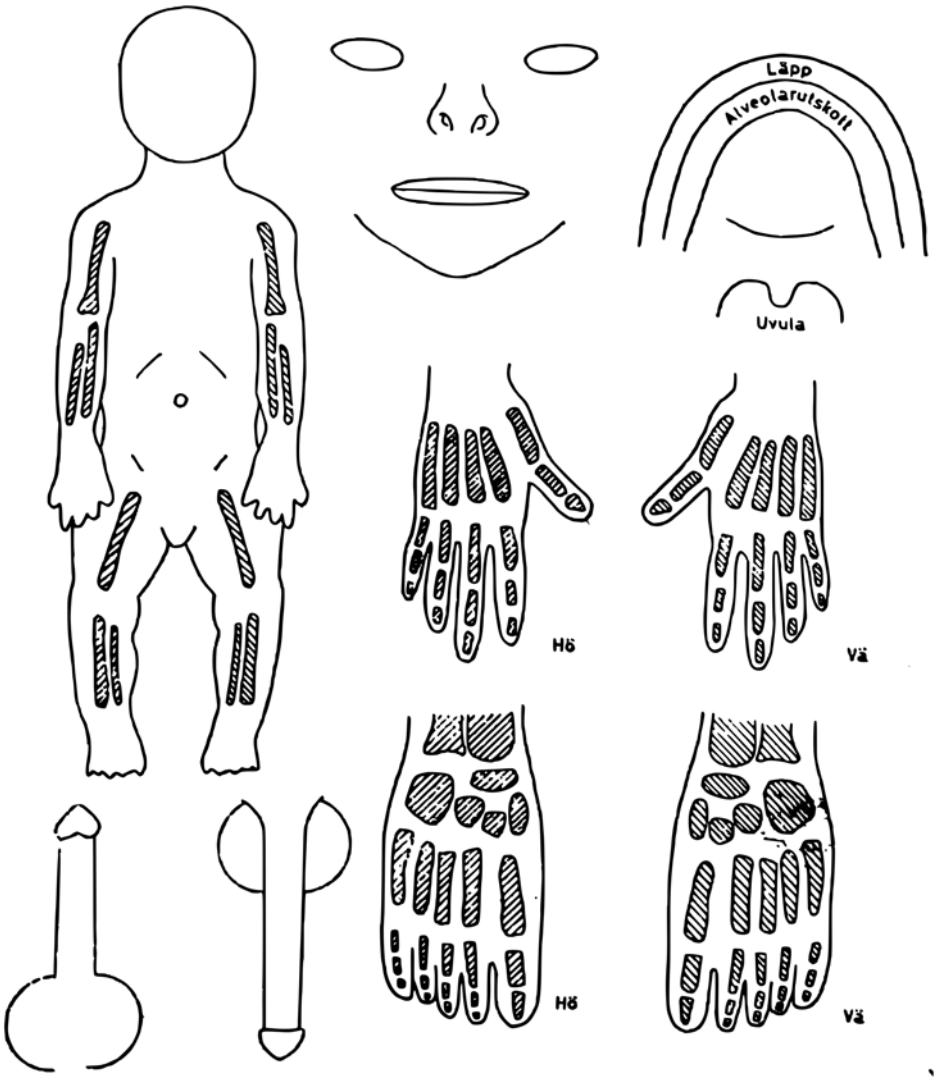

Figure 2. The report card designed by Källén. Originally published in Källén and Winberg 1966, 1943.

By arranging the symbolic and material practices of malformation surveillance in this manner, Källén aimed to work around the many challenges that faced the detection infrastructure. By using his own reporting cards to foster description rather than classification, and by developing his own code list, which was unfettered by the pre-established nosological grid of the ICD, the sensitivity to unknown threats would be retained. Also, by centralizing the coding of malformations to the Register, Källén solved the difficulty with different professionals' knowledge, interests, and commitments to the classification endeavor.[20] In a sense he set himself up as a center of classification of malformations—a veritable Copernicus of malformations.[21]

[20]Interview with Källén, October 2018.

[21]This is of course a wordplay on Latour's (1987) work on Copernicus and centers of calculation. That is, Källén set up symbolic and material resources (the report cards and the local classification scheme) that centralized the power to classify and detect malformations with Källén and the register for congenital malformations.

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1XXXX missbildning i CNS	*CNS malformation*
11XXX slutningsmissbildning CNS	neural tube defect
11100 anencefali (akrani)	anencephaly
11210 myelomeningocele anterior	anterior MMC
11220 myelomeningocele posterior	spina bifida aperta
11300 encephalocele	encephalocele
11400 spina bifida utan myelomeningocele	spina bifida without MMC
11500 dermal sinus motsvarande spina bifida	dermal sinus at spina bifida
11600 defectus capilliti eller ländrygg	defectus capilliti or lumbar
12000 mikrocefali	microcephaly
13000 hydrocefali	hydrocephaly
14100 hydranencefali	hydranencephaly
14200 porencephali, hjärncystor	porencephaly, cerebral cysts
15000 holoprosencephali, arrhinencefali	holoprosencephaly
16XXX övriga CNS-missbildningar	other CNS malformations
16100 Möbius syndrom	Moebius syndrome
16110 centronukleär myopati	centronuclear myopathy
16210 cerebellär hypoplasi	cerebellar hypoplasia
16220 övrig cerebellär missbildning	other cerebellar malformation
16310 pakygyri i cerebrala cortex	pakygyria of cerebral cortex
16320 mikropolygyri i cerebrala cortex	micropolygyria, cerebral cortex
16330 övrig missbildning i cerebrala cortex	other cerebral cortex malform.
16400 agenesi av corpus callosum	agenesis of corpus callosum
16401 AV fistel corpus callosum	AV fistula in corpus callosum
16402 dysgenesi av corpus callosum	dysgenesis of corpus callosum
1650x facialispares	facial paresis
16600 diastematomyeli	diastematomyelia
16700 makrocefali	macrocephaly
16800 cebocefali (=15000)	cebocephaly (=15000)
16900 diverse hjärnmissbildningar	other brain malformations
16901 Dandy Walker cysta	Dandy Walker cyst
16902 aplasi av occipitalloben	occipital lobe aplasia
16990 oklar ryggmärgsmissbildning	unclear spinal cord malform.
16991 del av ryggmärg saknas	part of spinal cord missing
2XXXX missbildningar i sinnesorgan	*sensory organ malformations*
21XXX ögonmissbildningar	*eye malformations*
21100 cyklopi	cyclopia
21101 pseudocyklopi (tättsittande ögon)	pseudocyclopia
2121x anoftalmi	anophthalmia
2122x mikroftalmi	microphthalmia
2123x kryptoftalmi	cryptophthalmia
213XX slutningsdefekter av ögonen	eye closure defect
21311 iriscolobom	coloboma of iris
21312 retinacolobom	coloboma of retina
21313 linscolobom (=2151X)	coloboma of lens (=2151X)
21314 komplicerat colobom	complicated coloboma
21315 excentrisk pupill	excentric pupilla
21316 colobom av palpebrae	coloboma of eye lid
2132x mikroftalmi med cysta	microphthalmia with cyst
2140x aniridi	aniridia
2151x coloboma lentis	coloboma lentis
2152x afaki	aphakia
2153x linsektopi	lens ectopia

Figure 3. A page from Källén's list of malformations. Shared in a personal communication by Bengt Källén.

Just as in the case of death statistics, the standardization work in the register was geared toward making clinical observations into *commensurable* data-points for compilation and statistical processing (cf. Espeland and Stevens 1998; Weisz et al. 2007, 697). However, rather than using a global standard for comparison of malformations, Källén created a locally workable grid of classification (Clarke and Casper 1996; Timmermans and Berg 1997; Casper and Clarke 1998). This was built on the pooling of the symbolic and material infrastructures of classification

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(classification schemes, reporting cards, databases) in a center of calculation—one might call it a *center of classification* (cf. Latour 1987).

Thus, rather than relying on the ready-made and standardized nosological grid of malformations that the ICD provided, Källén developed a local system of classification that was based on his own list of symptoms (see fig. 3). The pre-established nosological categories of the ICD were replaced by symptom-based categories that were under Källén's control. Källén's method was thus based on creating malformation statistics based on collecting incidences of particular malformations—rather than using the ready-made disease categories that the ICD wielded.

Källéns argument was that the collection of statistical patterns based on symptom-reporting would be more useful than the pre-established ICD categories for detecting the impending unknown health threat. In essence, Källén attempted to circumvent the ICD's standardized nosology and replace it with syndromic surveillance—the detection of new patterns of symptoms. Thus, he attempted to escape, *egress*, from the pre-established nosological global standard of the ICD and replace it with locally workable system of classification that he controlled.

Coda: Classification egress becomes classification regress

Did the register detect a new thalidomide disaster? A new unknown health threat? Over the years, the register was involved in numerous investigations, studying the effects of things like food additives, pesticides, pharmaceuticals, x-rays, smoking, and radiation from computer screens. Sometimes an alarm about malformations was sounded internationally, and a follow up study was done in Sweden. A recurring worry for the register was the pesticide *Hormoslyr,* since it was composed of the same chemicals as Agent Orange, which had been banned in Sweden in 1977. In the mid-1970s, the register detected an increase of incidence in malformation in the *Värmland* region, which—according to the media—was suspected to be tied to *Hormoslyr*. However, the cause of the malformations was never seen as conclusively established.

In the mid-1980s, Källén was severely criticized in the media for never being able to find the causes of malformations. For instance, a professor of toxicology at the Karolinska Institute argued that the register was a failure, as it had not been able to find any causes for increased incidence of malformations (Åkerman 1983). In 1985, in conjunction with a much-publicized investigation into the risks of computer screens causing malformations, the national Swedish evening paper *Aftonbladet* published a series of articles and opinion pieces that chastised Källén for never finding any causal links for malformations (Anér 1985a, 1985b; Sivers 1985a, 1985b, 1985c; Anon 1985). The fear of the unknown threat was alive and well, but the usefulness of Källén's work was questioned.

In our interview, Källén lamented that his work had been unable to find any causes of malformations. Furthermore, he related that the register had repeatedly been threatened with being shut down, but was saved on the premise that it might prevent another thalidomide disaster. The specter of the unknown health threat to unborn children was enough to ensure that the registration of malformations would continue.

The Swedish Register for Congenital Malformations was made permanent in 1964. The register is still active today, in 2023, and is run under the auspices of the National Board of Health and Welfare. In 1980 the register was merged with the Swedish Medical Birth Registry, and in 1999 the register changed Källén's reporting forms to adhere to the Swedish version of the ICD-10. With this change, Källén's work to escape the world of the standardized and pre-established nosological grid of the ICD was ended.

Discussion: Classification egress and the centralizing of classification judgment

Bowker and Star (1999) have argued that we need to study the unruly "Other" category in order to understand the power of classification and standardization. However, for the actors around the

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Register for Congenital Malformations, the Other category was not a scrap heap of the unfitting and unwieldy, but the point of departure and one of their main interests. Thus, one of the great challenges for the surveillance of congenital malformations was—as it is for disease surveillance more broadly—to detect, classify, and act upon the emerging unknown and unclassified.

In response to the tension between diagnosing the known syndrome and discovering the unknown and untheorized threat, the Swedish Register for Congenital Malformations sought to avoid pre-established and standardized nosological classifications. The pre-existing medical diagnoses and categorizations were seen as a problem rather than a solution, and the use of pre-existing categories was understood as a hindrance to the identification of new threats to the population's health. The clinical gaze of the reporting physicians needed to be forced to *not* classify using the ready-made nosological categories of the ICD. The thrust of the register's work was to undo pre-established and standardized classification through a procedural standard that emphasized reporting through description, in the form of a pre-printed graphic of an infant, where malformations were to be indicated visually and described in text. The global *terminological standard* of diagnosis in the ICD was replaced by a *procedural standard* of visual indication and description (cf. Timmermans and Berg 2003).

To this end, the register utilized a local and open-ended classification system that was geared towards the constant addition of categories—an ever-expanding and locally curated list of malformations. Källén developed this local, open-ended classification of malformations to work around the tension between the *pre-established nosological classifications in the ICD* and the *new emerging and unknown threat*. Consequently, the register existed in a constant tension between the drive for global standardization and classification of diseases, and the need for local and open-ended, yet commensurable, investigations of new syndromes (cf. Espeland and Stevens 1998).

In the register for congenital malformations, discovery based on description without standardization and statistics of symptoms was seen as a sought-after state. The standardized nosological grid of classification, the ICD, which meant that bodily malformations were sorted in a pre-established and standardized matrix, was a challenge to avoid, rather than a resource to draw upon. The surveillance aimed to perceive new syndromes without classification. But rather than getting stuck in an experimenter's regress (cf. Collins 1985), where theory and experiment could not validate each other, the surveillance of malformations aimed to exit the overdetermining grid of standardized ICD classifications: *classification egress*; an attempt to perceive without the standardized and pre-established nosological categories of the ICD.

In statistical disease surveillance, the properties of any new disease are unknown—as it is impossible to know what to be on the lookout for. What are the symptoms of a new thalidomide disaster? What is a warning signal that a new pandemic flu has emerged? How do we know if a new hemorrhagic fever is taking down its first cases? What unknown disaster or disease might even now be imminent, obscured in mounds of patient records—in the unruly diagnostic practices of different physicians, hospitals, or professions? By exiting the world of standardized and pre-established diagnoses, the Register for Congenital Malformations attempted to quantify, classify and perceive the unknown threat. In the words of one of my informants at the European Centre for Disease Control and Prevention: to drink from a firehose—and taste the water.

Conclusion: Classification egress, or to know the unknown in a world of knowns

This article set out to explore the tension between discovering unknown health threats in a sea of known and already classified diseases. This challenge is of increasing importance today, as disease surveillance detects and reacts to regular disease threats in an increasingly globalized world. The actors constantly ask: How do you know if a new pandemic, a syndrome, or a new pharmaceutical disaster is lurking around the corner? The theoretical argument has been that, to understand how classification works in practice, the sociology of classification also needs to pay attention not only

https://doi.org/10.1017/S0269889723000133 Published online by Cambridge University Press

the crucial practices and politics of classifying things and people, but also to actors' work of escaping and resisting pre-established classification systems (cf. Martin and Lynch 2009; Bowker and Star 1999). Consequently, to highlight how actors attempt to escape the confines of pre-established classification infrastructures, the article introduces the concept of *classification egress*. This concept highlights how actors translate, escape, or resist different modes of classifying the world and the infrastructural practices that are used to break out of pre-established classification grids (cf. Lee 2021b).

Empirically, the article focused on the actors' efforts to escape ready-made classification systems in order to discover new and previously unclassified health threats. Specifically, the article traced how a set of actors working to surveil congenital malformations in the 1960s attempted to construct an infrastructure for escaping the standardized nosological matrix of the ICD in order to discover new patterns of congenital malformations in the wake of the thalidomide disaster. By examining these practices, we gained insight into a challenge that still faces health surveillance today, but is also a more general difficulty in statistical analysis: if we build systems for detecting new and unknown phenomena using historically pre-established classifications, data, or training sets, it becomes truly troublesome to detect the unknown that does not fit into our classification systems.

The increasing use of AI, Big Data, and algorithms—digitalized and quantified methods—to discover new phenomena underscores the importance of the politics and practices of categorization and classification. However, the use of pre-existing categories, or the invention of new and open-ended new classification schema, inevitably shapes our quantified and statistical perception of the world. If we are to better understand this classification work, we also need to pay attention to those moments where the dominant classification systems are resisted, translated, or challenged.

Acknowledgements. Thanks for comments and readings go to Steve Woolgar and the Values group at Linköping University, to Tora Holmberg and the Cultural Matters Group, and to Solveig Jülich and the Medicine at the Borders of Life—both the latter groups at Uppsala University. Thanks also go to Tatjana Buklijas, Mikaela Sundberg, Jesse Olszynko-Gryn, Hedvig Gröndal and Jenny Lee for close readings and comments. Lastly thanks go to my anonymous reviewers, *Science in Context* editor Moritz Epple, and managing editor Thom Rofe, for their productive and helpful comments along the way. This research was partly funded by the Swedish Research Council (Dnr 2014–1749), and partly by the Wallenberg Foundations in the Wallenberg Autonomous Systems Program - Humanities and Society (WASP-HS).

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Cite this article: Lee, Francis. 2023. "Detecting the unknown in a sea of knowns: Health surveillance, knowledge infrastructures, and the quest for classification egress," *Science in Context*. doi:10.1017/S0269889723000133