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Medicalisation and Pharmaceuticalisation: A Conceptual Analysis

Tom Douglass and Michael Calnan

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Abstract:

Medicalisation has been one of the major conceptual and empirical interests in medical sociology since the late 1960s. A widely accepted definition is that medicalisation is the process whereby social problems come to be defined and treated as medical conditions. During its long history, the concept of medicalisation has passed through several phases of thought, and its influence on the concepts and ideas of medicine and health reflects broader changes in society. This chapter covers three main phases of thought and the associated changes in society, setting out how these have led scholars to question the limits of the explanatory power of medicalisation and the need for alternative concepts, notably pharmaceuticalisation. It begins by exploring the initial accounts of medicalisation encompassing the late 1960s-early 1980s and the focus on how deviant behaviours came to be socially defined as a medical issue. It then moves to explore more contemporary arguments, beginning in the mid-1980s. As well as discussing the medicalisation of risk and lifestyle, this section reflects on whether medicalisation is superseded by newer concepts, or whether they are complementary to medicalisation. The following section uses a case study of cardiovascular disease (CVD) and the prescription of statins to illustrate the different strands of the conceptual analysis of medicalisation and pharmaceuticalisation. The final section examines how medicalisation and pharmaceuticalisation can provide one lens to analyse and process the COVID-19 pandemic.

Key Words:

Medicalisation, pharmaceuticalisation, deviance, risk, pharmaceuticals, statins, COVID-

19

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Michael Calnan is a Professor of Medical Sociology who is involved with teaching and research in the Sociology of Health and Health policy. His research has involved a mixture of theoretical, policy and empirical analysis which has used both quantitative and qualitative methods. His recent funded research has included projects which have focused on trust in different health systems, dignity in health care for people in later life and the social influences on decision-making by the National Institute for Health and Care Excellence (NICE) in relation to technological appraisals. He has published extensively in journals and books about a range of health-related topics. His most recent book, which was published in the Spring 2020, is entitled: *Health Policy, Power and Politics: Sociological Insights* (Emerald).

Introduction

Medicalisation has been one of the major conceptual and empirical interests in medical sociology since the late 1960s (Pitts 1968). A widely accepted definition for medicalisation is the process whereby social problems come to be defined and treated as medical conditions (Conrad 2007). During its long history, the concept of medicalisation has shifted over time with varying levels of significance given to different actors (Busfield 2017, Conrad 1975, 2005, Williams 2003). In the early scholarship, the medical profession was a central actor in the process of medicalisation, but over time other actors such as the pharmaceutical industry have gained greater significance in the definition and treatment of disease, even to the extent that the explanatory power of medicalisation as a concept has been questioned, with associated arguments made for replacing it with a new concept.

This chapter unpacks the history of medicalisation and divides its conceptual development into three phases. The first two phases have broadly been established by other scholars (Lupton 1997, Williams 2003), but this chapter argues that there is now a third phase of scholarship. This section begins by exploring the initial accounts of medicalisation, from the late 1960s to early 1980s with a focus on how deviant behaviours came to be socially defined as a medical issue (Conrad and Schneider 1980). It then moves to explore more contemporary arguments beginning in the mid-1980s concerned with how the process of medicalisation has shifted increasingly to individual lifestyle choices and the risk of disease, and then turns to explore the very latest thought on medicalisation in the 2000s and 2010s. The focus here is on the continuing explanatory power of the concept and whether contemporary concepts should replace or can complement medicalisation. The section introduces the concept of pharmaceuticalisation and its development, defined by Williams et al. (Williams, Martin, and

Gabe 2011b, 711) as a process concerned with the “transformation of human conditions, capacities or capabilities into opportunities for pharmaceutical intervention”. It then illustrates the different strands of the conceptual analysis of medicalisation and pharmaceuticalisation through a case study of cardiovascular disease (CVD) and the prescription of statins.

The chapter concludes by considering how medicalisation and pharmaceuticalisation can provide one lens to analyse COVID-19 (particularly in terms of the risk and vaccination) as well as areas that that might be the focus of analysis in the future (such as new digital technologies and use of pharmaceuticals in animals).

Initial Accounts of Medicalisation

Situating Medicalisation

Before exploring the work of the first scholars of medicalisation, it is first necessary to discuss two key aspects. First, the foundations of the sociological study of deviance and, second, the emancipatory culture of the 1960s and 1970s, which led to critical analysis of powerful actors and institutions, including the medical profession (Gabe, Kelleher, and Williams 2006).

To understand the genesis of the concept of medicalisation it is important to appreciate the foundations of the sociological study of deviance – which lie as far back as the work of Emile Durkheim (1895/1933). The ability to define and control deviance was a central issue in the initial work on medicalisation. It is important to note that Durkheim did not write in the language of medicalisation, and suggested that as societies mature from simple to complex that deviance management transitions from repressive to restitutive, which results not only in a change in how deviance is controlled but also how it is thought of and defined (Conrad and Schneider 1980). Later, Parsons (1951), in his functionalist account of the sick role, highlighted how the separation of intentional deviance (criminal) and unintentional deviance (sickness) were

necessary with regard to appropriate disciplinary or treatment mechanisms. Criminals are punished, with an end goal of reshaping behaviour in line with convention, whilst sick people are treated with an end goal of removing the illness barriers to convention (Conrad and Schneider 1980). For those that are ill, the existence of a sick role legitimises the 'deviant' behaviour of being sick, suggested Parsons. For society, this sick role helps to manage the potentially damaging and disruptive nature of sickness. The sick role has four parts, comprised of two accepted exemptions and two obligations. The sick individual (1) is exempt from normal responsibilities for the period of illness, and (2) is not held to be personally responsible for their illness. The two obligations, namely that the individual (1) must understand that illness is an undesirable state and (2) that they are obligated to co-operate with relevant medical professionals to aid in their recovering to normal functioning.

Whilst alluding to a social control dynamic at play, Parsons focused on how the sick role allowed society to function by restoring individuals to normal social roles. These first scholars of medicalisation saw the need to go further in the study of deviance and socially critique medicine's ability to define deviant behaviours as medical. Durkheim's and Parsons' theoretical work suggests that medicine has functioned as an agent of social control particularly through restoring individuals to normal social functioning. Later scholars, building on the insights about deviance proposed by Durkheim and Parsons, saw the necessity of critiquing medicine's sphere of social control which was going beyond what was considered legitimately a medical problem to increasingly encompass social problems (Conrad and Schneider 1980). In this regard, scholars of medicalisation, beginning in the 1960s and 1970s, sought to problematise medical social control and show that disease could also be socially constructed (Williams 2003, 9-28). This was

particularly because, as Conrad and Schneider (1980, 8) state, “the greatest social control power comes from having the authority to define certain behaviours, persons, and things.”

It is important to understand that the concept of medicalisation developed out of the radical and emancipatory culture of the late 1960s and early 1970s, which, for a short time turned the world, including medicine, upside down (Gabe, Kelleher, and Williams 2006). Indeed, Gerhardt (1989) suggested that (medical) sociologists, inspired and provoked by student revolution and demonstrations of the late 1960s, began to see injustice and inequality as a cornerstone of academic enquiry and applied this to a critique of medicine. In the same period radical critiques of psychiatry were also emerging that challenged conventional thinking. The anti-psychiatry movement was significant, where it was argued forcefully and critically that a dominant psychiatric lens was increasingly classifying normal behaviours and feelings as illness (Laing 1960, 1961, Szasz 1960, see also, Crossley 1998)

The Birth of Medicalisation and the Social Construction of Disease

Social constructionism has been a central tenet in the scholarly development of medicalisation. It has been argued that disease is constructed and defined socially and reflects the influence of powerful social forces, not least the professional authority and cultural significance of medicine (Freidson 1970, Pitts 1968, Zola 1972). The first phase of thought about medicalisation, which has been described as the ‘orthodox’ position (Lupton 1995, Williams 2003), argued that medicine actually served to reinforce the moral order of society (Conrad and Schneider 1980) despite attempts to portray itself as objective and neutral. In this way, initial medicalisation scholarship was concerned with ‘deviant’ behaviours such as alcoholism, childhood delinquency, child abuse, and hyperactivity, and for a period of time, homosexuality, and the shift in spheres of control of such phenomena from the other institutions of social control

(religion and law) to medicine – or from ‘badness to sickness’ (Conrad and Schneider 1980). This reflected, for example, greater secularisation in society, changing social norms and values about what is considered a crime, and the growing social status afforded to the medical profession. Deviant behaviours were becoming increasingly controlled and treated by medicine with the aim of minimising disruption to society. With these shifts sociologists further developed the concept of medicalisation. Early work was primarily concerned with conceptualising and analysing how problems come to be defined within the sphere of medical control and treatment. They explored whether these behaviours were legitimate medical problems requiring medical treatment or they were really social problems requiring social solutions (Conrad 1975, Spector and Kitsuse 1977).

Early Medicalisation Thinkers

Zola (1972) and Illich (1975) most famously espouse what we now can think of as the critical and problematising tendencies of the initial medicalisation thesis. Zola suggested that an objective, scientific, supposedly morally neutral medicine was becoming the repository of truth, replacing or incorporating religion and law as the source of judgment. Zola (1972) suggested that the process whereby medicine was displacing other institutions of social control was often a low-key and potentially insidious process. In essence, the attachment of the labels ‘healthy’ and ‘ill’ was argued to be becoming increasingly relevant to ever further elements of human life. Zola saw medicalisation, not as a reflection of a type of medical imperialism but rather as our bureaucratic and technological social system having led to a reliance on experts. Illich (1975) also wrote critically about the extension of medicine’s sphere of control. He wrote of the threats of the medical establishment to health. Again, writing with a systemic focus, he saw industrial

society as expropriating personal responsibility for health and as removing autonomy from the individual.

While some scholars located doctors as seeking out and discovering illness (Freidson 1970), helping to drive medicalisation through their professional activity, Conrad and Schneider (Conrad and Schneider 1980, see also Conrad 1992) influentially conceptualised medicalisation as (potentially) occurring across three distinct levels that may or may not involve professionals. These levels were the conceptual (use of medical vocabulary), the institutional (organisational adoption of a medical approach often with non-medical personnel conducting the routine work), and the interactional (resulting from the doctor-patient relationship where physicians are necessarily involved). This shows importantly that the medicalisation critique was not necessarily a critique of the medical profession directly, who are not always involved, or their expansionist tendencies, despite what some have claimed (e.g., Strong 1979).

The period also witnessed an emergent Marxist and feminist scholarship that engaged with the ideas around medicalisation. Taussig (1980) and particularly Navarro (1975, 1980) took issue with much of the framing of the social constructionist medicalisation critique, suggesting that it had neglected to sufficiently engage with the role that medicine played in reproducing capitalist power relations in society. Feminists (Ehrenreich and English 1973, Martin 1987, Oakley 1986) argued that medicine is a patriarchal institution that has used illness and disease definitions to subjugate and reinforce existing inequality between men and women – by emphasising female ‘weakness’ and ‘illness susceptibility’, as well as seizing control of areas such as pregnancy/childbirth.

The Medicalisation of Lifestyle and Risk

In the late 20th century the concept of medicalisation was expanding to include natural life processes. The medicalisation of matters beyond those traditionally considered deviance and the problematising of the risk of disease arose as a result of health surveillance (Armstrong 1995, 395), where “the dissolution of the distinct clinical categories of healthy and illness... [establish] everyone within its network of visibility.” In other words, with an increasing focus on lifestyle as impacting health and preventative medicine, even the idea of ‘health’ was inherently problematised – with bodies both healthy and ill simultaneously (Hughes 1994).

Foucauldian Influence

The work of Michel Foucault went further than the initial scholars of medicalisation in terms of asserting the socially constructed nature of disease and, in a sense, challenged biological realities.

Lupton (1997) provides a useful overview of the influence of Foucauldian thought on medicalisation. Above all else the scholarship of Foucault influenced a realignment in conceptual understandings of power, which was in itself important for understandings of medicalisation. Whereas the institution of medicine had previously been lambasted and castigated by some for wielding a repressive power (Illich 1975), Foucault (1973, 1979) suggested that power is a complex phenomenon that is not reducible to only one entity or set of actors. Rather it emerges and is propagated by a variety of social actors and institutions, and may be productive and positive, rather than solely repressive. Medicine is part of a wider system of disciplinary techniques in an expanding apparatus of control oriented towards moral regulation rather than more overt forms of violence or coercion – what Foucault terms a panoptic system of surveillance. Power cannot be reduced to dualisms of state versus people, or a powerful medical profession versus patients/lay knowledges (Lupton 1995). Power does not simply constrain or

dominate patients/citizens it works to shape/produce/make-up individuals who have a regulated autonomy/freedom. As such, as Lupton (1995, 99) observes, Foucauldian scholars see medicine as a disciplinary power. This scholarship suggests that medicine provides systems of knowledge/practice whereby we not only understand the body but that also shapes the way in which we experience it. Power relations “work in and through the human body” (Lupton 1995, 5). In this sense, Foucauldian scholarship suggests that there is no biophysical or authentic body that exists beyond medical discourse – or in other words that the body is constructed through discourse and the clinical gaze of health professionals and other actors/entities (Lupton 1997). Williams (Williams 2001, 147) states, the emergence of this more thorough critique seemed to strip away, or at least critically question, “former acknowledgment or acceptance of an underlying ‘natural’ or ‘biophysical’ reality...” which had always existed in the initial analysis of medicalisation.

Lifestyle, Risk of Disease and Surveillance

In the final stages of the twentieth century power/control became entrenched at the level of the individual, widening the medical realm into everyday aspects and spaces. Strategies for the individual to affect their own bodies in the name of health, or technologies of the self, became increasingly important (Rose 1996, 1999). As such, this “fundamental remapping of the space of illness” and “the problematisation of the normal” (Armstrong 1995, 395) occurring in the latter stages of the second half of the twentieth century, resulted in the distinction between health and illness taking on a new form in terms of a focus on prevention and the relationship between lifestyle and *risk* of disease. In other words, new truths and realities occurring at the site of and through the body have been opened up, and thus how we experience health and (potential) illness. In particular there was a growing focus on lifestyle choice as determining disease. This

shift might be termed healthism (Crawford 1980, 2006) or lifestylism (Hansen and Easthope 2007) and central to this focus is a strong moral component/imperative to take responsibility for one's own health, or responsabilisation (Crawford 2006, Rose 1999). As Hansen and Easthope (2007, 56) state, "[u]nlike the traditional medical model of disease where understandings are limited to physical aberrations from 'normal', the focus on risk, future disease, individual behaviours mean that under a lifestyle approach almost every aspect of living is seen as health related." It is in this broader context of the medicalisation of lifestyle choice and risk that, for example, medical interest in cholesterol and the risk and prevention of future cardiovascular disease (despite lack of disease) emerges (Green 2007, and see case study below). This way of thinking about disease causation emerged out of the broader influences of epidemiological multivariate analysis of chronic disease determinants, public health and government promotional activities, as well as increasing focus on risk in society.

In the Foucauldian manner discussed above, Nettleton and Bunton (1995, 47) suggested that that the methods and techniques of lifestyle-oriented health promotion have fostered "an all-encompassing network of surveillance and observation." Armstrong (1995) similarly discussed the rise of 'surveillance medicine' alongside and to an extent as displacing hospital medicine as the hegemonic model of medicine. Surveillance medicine means an expansion of the clinical gaze into an "extracorporeal space – often represented by the notion of lifestyle – to identify the precursors of future illness" (Armstrong 1995, 401). In adopting a lifestyle approach there is a growing penetration of the medical gaze into the everyday lifestyle choices of citizens (Lupton 1997). As discussed above, this surveillance, due to the complex assemblages of power, also occurs at the level of self-surveillance, as well as at the state/institutional level, as a result of the development of what might be thought of as the health promoting self (Nettleton and Bunton

1995). In other words, the medicalisation of everyday lifestyle occurs as citizens became the target of technologies of monitoring, risk assessment and population-level treatment interventions, which in turn make citizens aware in these terms of their own potential contributions to their own health 'project' (Nettleton and Bunton 1995).

Beyond Medicalisation?

Medicalisation as a concept has since its inception been subject to critique. For example, the extent to which it is 'rampantly' occurring (Fox 1977); of medical sociologists who are no less imperialist than the institution of medicine itself (Strong 1979); through to issues surrounding the regard, reliance, understandings and expectations that lay individuals place on medical technologies (Williams and Calnan 1996), and the particular dismissiveness of constructionist modes of thought surrounding biological realities and the positives and promises of bodies of knowledge such as medicine (Bury 1986, Williams 2001).

Throughout 2000s the relevance of the explanatory effectiveness of medicalisation has been subjected to increasing scrutiny.

Abandon Medicalisation?

Medicalisation has significant intellectual baggage attached to it not least due to the initial efforts to frame and explain illness. Rose (2007a, see also Rose 2007b, 2019) argues that medicalisation implies medical authority has extended beyond what is legitimate, and that to de-medicalise society is desirable. He suggests that arguing in this manner is of little help to social scientists, calling for a deeper examination starting with an abandonment of the term. He goes on to suggest that medical meaning is entangled with every part of our life and influences how we experience the world.

The Continuing Value of Medicalisation: Reconfiguration

Meanwhile, one of the most eminent and influential scholars of medicalisation, Conrad (2005, 2007), argues for a reconfiguration and development in understanding of the drivers of medicalisation without abandoning the term. Drivers, Conrad argues, include the pharmaceutical industry alongside other biotechnology industries (marketing solutions to new health problems), consumerism (where consumers help shape the scope and demand for medical treatments) and managed care. He argues that these changing drivers of medicalisation have served to reduce the influence of medical professionals, but that the broader underpinnings of the medicalisation thesis remain valid and important. Broadly he argues that changes in medicine and society do not invalidate the premise of medicalisation, rather that there must be an appreciation of the shifting drivers of medicalisation. Davis (2006) offers another argument, suggesting there is a need to reposition the medical profession as a central player in the process of medicalisation rather than disconnect from it.

The initial scholarship of medicalisation emphasized it as a problematic framing, however, this has changed over time. The need for medicalisation to be conceptualised neutrally is exemplified in the areas of contested illnesses which are diffuse conditions which fall between labels of physical and mental health such as chronic fatigue syndrome, repetitive strain injury and fibromyalgia. The patient's experience is problematised so they are required to look for 'hard' medical evidence and diagnosis which validates their condition as a clinical disease (Wainwright et al. 2006). In this way, patients themselves fight for appropriate diagnostic recognition – or, in other words, to become medicalised appropriately or at all. As Annandale (Annandale 2014, 214) states “diagnosis is an arena for struggle where professionals and lay people fight over the roles and functions of illness: diagnostic processes underpin discussions of medicalisation.” This quotation highlights how patients have agency and good reasons for both

accepting medical labels as well as resisting them (Wainwright and Calnan 2002, Williams and Calnan 1996) and thus the need for medicalisation to be considered a neutral process.

The Need for a New Concept?

Nevertheless, others have argued for a more radical (re)framing of medicalisation (whilst still utilising similar terminology) in line with developments in bioscience and technological development. Clarke et al. (2003) have framed such notions as biomedicalisation.

Biomedicalisation has been defined as the “increasingly complex multisited, multidirectional processes of medicalisation that are both being extended and reconstituted through the emergent social forms and practices of a highly and increasingly technoscientific biomedicine” (Clarke et al. 2003, 162). They argue that the ‘bio’ in biomedicalisation reflects the developments and transitions made possible by various biological and medical sciences and technologies, ranging from genomics to transplant medicine.

Pharmaceuticalisation

The explanatory power of both medicalisation and biomedicalisation has been critiqued by those specifically concerned with the expanding usage of pharmaceuticals and the power, influence and wealth of the pharmaceutical industry in contemporary societies. The concept of pharmaceuticalisation has been developed to grapple with a lack of specificity and focus on pharmaceuticals in other concepts (Abraham 2009, 2010, Williams, Gabe, and Davis 2009, Williams, Martin, and Gabe 2011b). Pharmaceuticalisation is a sociological process that is defined by Williams et al. (2011b, 711) as the “transformation of human conditions, capacities or capabilities into opportunities for pharmaceutical intervention”. Williams et al. (2012) argue that pharmaceuticalisation is a more specific term than the ‘catchall’ term of biomedicalisation, whilst they also claim that the extent of the processes of biomedicalisation have been

overestimated by Clarke et al (2003), particularly when considering, for example, that the promises attached to genomic development and personalised medicine have as yet not come to fruition.

Pharmaceuticalisation is a term that was actually first used in anthropology (see chapter 9, by Mark Nichter “Pharmaceuticals, the commodification of health, and the health care-medicine use transition” in Nichter and Nichter 1989, also Bell and Figert 2012, Gabe et al. 2015), although the term has only really entered widespread academic and particularly sociological usage since the late 2000s and early 2010s (Abraham 2009, 2010, Fox and Ward 2008, Williams, Gabe, and Davis 2009). The sociological study of pharmaceuticals was somewhat limited prior to the twenty-first century. Some scholarship considered pharmaceuticals (e.g. attention deficit hyperactivity disorder drugs) under the auspices of medicalisation (Conrad 1975, Conrad and Schneider 1980), or, for example, as a ‘social problem’ (Conrad 1975, Conrad and Schneider 1980) but generally not with pharmaceuticals as the primary sociological focus themselves (Gabe et al. 2015). Perhaps the most significant body of medical sociological work on pharmaceuticals prior to the concept of pharmaceuticalisation has been within the sociology of prescribing (Gabe 1990, Gabe and Lipshitz-Phillips 1984, Parish 1974). This body of work focused on the social factors shaping prescribing and did empirically engage with pharmaceuticals as analytic entities in and of themselves – though without the sophisticated conceptual apparatus offered by pharmaceuticalisation.

The Conceptual Frameworks of Pharmaceuticalisation

Two main conceptualisations and frameworks for analysis have been proposed in the literature. It is important to note that neither framework proposes the displacement of medicalisation – rather that both can occur at the same time (and drive one another) but that the

concept of pharmaceuticalisation possesses greater analytical specificity and is sensitive to examples of expanding availability or use of pharmaceuticals without any medicalisation (e.g. lack of a new diagnostic category).

Abraham (2010) sets up his concept and framework for analysis as concerned with assessing the ‘real’ impacts of pharmaceuticals – arguing that the necessity of expanding pharmaceuticalisation can and should be judged against whether or not it meets healthcare need, has efficacy, and is safe for patients. Pharmaceuticalisation according to Abraham is “the process by which social, behavioural or bodily conditions are treated or deemed to be in need of treatment, with medical drugs by doctors or patients” (Abraham 2010, 604). Abraham is referring not to the sociological concept of biomedicalisation discussed by Clarke et al. (Clarke et al. 2003) but the ideological underpinning of contemporary biomedical drug development (in similar terms to what Busfield (2010) terms the ‘progressive model’). He argues that in biomedical science, drug development is seen as the process of meeting objectively defined and established health problems, but in actuality, this is an inherently problematic assumption.

Williams et al. (2011a, b) set out a more theoretically fluid conceptualisation and framework for analysis that is not tied to a realist philosophical position – thus possessing greater conceptual dexterity. These authors reject a grand synthesis in favour of an adaptable, eclectic, multilevel and multidimensional conceptual understanding so as to stimulate research with a variety of (interconnected) concerns. Williams and colleagues conceptualise pharmaceuticalisation as a “dynamic and complex heterogeneous socio-technical process that is part of what we might call a pharmaceutical regime” (Williams, Martin, and Gabe 2011b, 711).

It is not the intention of pharmaceuticalisation scholars to argue for the abandonment of the concept of medicalisation. The links between medicalisation and pharmaceuticalisation are

“complex and contingent” (Williams, Martin, and Gabe 2011b, 711). Both can occur at the same time through, for example, expansion in pharmaceutical deployment reflecting widening diagnostic criterion (Abraham 2010). Nevertheless, a conceptual assumption apparent in pharmaceuticalisation scholarship to date is that pharmaceuticalisation has greater explanatory scope in matters pertaining to drugs (where they are central to the case or disease area under study) than medicalisation or biomedicalisation (Coveney, Gabe, and Williams 2011, 387, Williams et al. 2017).

Case Study: The (Widening) Primary Prevention of Cardiovascular Disease

In July 2014, the National Institute for Health and Care Excellence (NICE), a regulatory body concerned primarily with cost-effectiveness and standardisation, issued an update to its guidance on the assessment and reduction of cardiovascular disease and lipid modification. The most publicly and professionally visible aspect of this guideline was the recommendation to lower the primary prevention risk threshold from $\geq 20\%$ risk of developing cardiovascular disease (CVD) over ten years to a $\geq 10\%$ risk over ten years. This was an extremely significant development not least because it vastly expanded the numbers of people eligible to be offered CVD risk assessment and potentially advice on prophylactic measures against CVD, including, saliently, the offer of a pharmaceutical solution. It has been estimated that lowering the risk threshold makes 4.5 million additional people in England eligible for the class of drugs called statins (National Clinical Guideline Centre 2014, National Institute for Health Care Excellence 2021). This is in addition to the millions of individuals already taking a statin at higher thresholds of risk and in the secondary prevention of CVD (to prevent further cardiovascular events). Analysis has suggested that more than 30% of all adults aged 30-84 under this guidance would be deemed at significant enough risk of CVD to be eligible for a statin, with 95% of males

and the majority of females aged over 60, and all men and women aged 75-84 being eligible for the drugs (Ueda et al. 2017).

Statins reduce LDL cholesterol (or bad cholesterol), a key risk factor for CVD. A complex picture of risk factors is additionally taken into account within risk calculation by tools such as QRISK2 (a cardiovascular disease prediction algorithm). CVD is strongly associated with age, mostly occurring in people older than 50. QRISK2 risk calculation also takes into account sex, family history, ethnicity, modifiable lifestyle risk factors such as smoking, blood pressure, and geographical factors such as whether an individual lives in the north or south of England (National Clinical Guideline Centre 2014, 5). These risk factors are in part bound up together. For example, modifiable lifestyle risk factors contribute to cholesterol levels in most cases of high cholesterol (or hypercholesterolemia) and broadly statins can be thought of as ‘risk reducers’ that are prescribed as a result of overall risk calculation and strategy.

What drove this changing threshold? First, the widening generic availability of drugs within the statins class at the time of NICE’s guideline development process, including the expiry of the patent for atorvastatin, previously marketed by Pfizer as *Lipitor* (in its patented lifetime, the world’s most profitable drug). This drug became generic in the UK after its patent expired in 2012. This seems to have influenced NICE’s decision to begin in 2012 what was by their standards a relatively early full update of CVD prevention/lipid modification guidance. There were also reanalysis of data that changed understandings of acceptable levels of risk and the associated benefits of statins at lower levels of risk. Rather than the ground-breaking addition of randomised controlled trial (RCT) evidence, this was primarily secondary meta-analyses. Alongside the significantly lower cost of generic statins, this kind of analysis, which suggested benefit at lower levels of risk than codified in clinical practice guidelines, created an appetite for

widened availability and should, as such, also be considered one of the core driving forces behind NICE's decision to update their guidance.

Greene (2007) suggests a centrality of pharmaceuticals to fostering the legitimacy of treating risk and gradually widening the numbers of people to treat. Saukko et al. (Saukko et al. 2012, 562) summarise: "Rather than the risk factor being identified first and treatment second, cholesterol gained traction as a risk factor only after the development of targeted drugs. This co-development of a risk factor and drugs has continued in the last decade, as the category of high cholesterol [and thus risk of CVD] has expanded to encompass increasingly lower levels of cholesterol [and thus lower levels of risk of CVD]." There is, overall, a clear interconnectedness between medicalisation and pharmaceuticalisation apparent in this case, with both changing understandings of unacceptable levels of risk of disease and the further availability of drugs shaping and driving one another.

Medicalisation and Pharmaceuticalisation in the COVID-19 Pandemic

How can the concepts of medicalisation and pharmaceuticalisation be used to understand and provide a framing of the responses to the COVID-19 pandemic? At the time of writing, the world is struggling to contain the COVID-19 pandemic with several vaccines offering "a way out". Medicalisation is certainly occurring in terms of everyone being labelled as 'at risk' of developing and transmitting the virus (Armstrong 1995). Risk of disease has been used to justify increased surveillance of and constraints on the liberty of citizens in many countries around the world.

Vaccines are viewed as the quickest and most effective (in terms of the economy and public health) way to allow a degree of normalcy to return to everyday life. National vaccination programmes need to cover a substantial proportion of the population to control the pandemic.

The development of a vaccine in 2020 has highlighted the explanatory power of a pharmaceuticalisation. (Vaccination is described in some research as a form of pharmaceuticalisation (Manca 2018, Mulinari and Vihelmsson 2020). The Williams et al. (2011b) pharmaceuticalisation framework, with its focus on the pharmaceutical regime, offers sociologists to analyse all of the moving parts of the COVID-19 pandemic. This is not to say that pharmaceuticalisation via vaccination does not respond necessarily to the real health threats of COVID-19, but rather that there are social forces and interests shaping vaccine development, regulation and who and how quickly people can be vaccinated.

Governments and the pharmaceutical industry, motivated by their own aims, are working together in the research and development of a vaccine. As Calnan and Douglass (2020) note, initially some disquiet existed in the scientific community that as a result of the haste required to save lives and protect economies, efficacy and safety might not be given sufficient attention. It was feared, for example, that there would be an emphasis on vaccines that reduce severity of illness rather than protect against infection and provide only short-lived immunity, which might be beneficial for industry profit, and/or political interests (including, for example, election campaigns), but not for global public health (Godlee 2020). Indeed, it normally takes many years to develop a vaccine – although, reflecting the significant impacts on public health and economic interests, vaccine developers have been able to attract unprecedented levels of research funding from governments. The first vaccines have been shown to safe and effective and have achieved regulatory. However, there are still questions about lasting immunity, about the evidence for the use of ‘mix and match’ approaches to vaccination (by the UK government) to the use of different brands for first and second doses (Mahase 2021) and about how inequalities between countries as

well as within countries might shape affordability and access to vaccines globally (Calnan and Douglass 2020, Douglass and Calnan 2020).

Traditional print media and web-based media have covered the work of vaccine development and the scientific debate about it, providing widely divergent narratives that seem simultaneously to proffer hope and despair. Also, while people trust that there will be an end to the health and economic threats posed by the pandemic, there are a significant community of people who are hesitant or who hold anti-vaccination views (often due to concern about safety, the unnaturalness of vaccination or because of a lack of trust in governments or commercial actors). Trust in professionals and governments is one highly important factor in public take-up of vaccines (Calnan and Douglass 2020). Whether these complex dynamics, interests and beliefs cohere sufficiently to result in widespread vaccination remains at this point in time unclear.

Conclusion

This chapter clearly shows that medicalisation is a resilient concept and has been one of the major theoretical and empirical interests in medical sociology since the late 1960s. It has been the focus of considerable debate and the definition of medicalisation has shifted over time with changing conceptual significance given to different actors and drivers. The latest thought and debate about medicalisation has focused on the continuing explanatory power of the concept and whether it is necessary for the concept to be abandoned altogether or refined and narrowed in scope or replaced by more sophisticated conceptual apparatus such as biomedicalisation or pharmaceuticalisation. As this chapter shows, the diagnostic setting of CVD and the prescription of statins provides an insightful example of the interconnectedness between medicalisation and pharmaceuticalisation and the utility and importance, as such, of both concepts.

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