

UNIVERSITY OF COPENHAGEN
FACULTY OF SOCIAL SCIENCES



A Matter of Course

An Ethnographic Assemblage of
the Routinization of Statins in Denmark

PhD Dissertation / January 2018 / Sofie Rosenlund Lau

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Preface and Acknowledgements

After having lived in the rural jungle of Sierra Leone for almost a year, serving as the medical coordinator of a small NGO-run hospital and collecting data on patient-centred communication for my Master's thesis in social pharmacy, I realised that I could not return to the biomedical world of pharmaceutical sciences. While most of my university colleagues and close friends aspired to jobs in the pharmaceutical industry, I felt an urgent need to know more about the rarely mentioned end-users of pharmaceutical products: the mysterious patients. For more than five years I had struggled in the basement laboratories of Nørre Campus, University of Copenhagen, to master the skills of redox titration, chromatography and protein synthesis, all necessary elements of the art of making pharmaceutical products. I had learned about the processes of pharmaceutical regulation and quality assurance, the keys to ensuring that products are safe and have the intended effects when released into the 'real world'. I had briefly touched upon the fields of pharmacoepidemiology and clinical pharmacy, which are concerned with the research into the effects and harms of medicines in order to ensure optimal and rational use of pharmaceuticals in the interplay between society and medical practice. Finally, I had landed in the field of social pharmacy, which in a broad sense encompasses the perceptions and uses of medicines in society: that is, as political objects in healthcare policies, as sales commodities in pharmacies, and as treatment devices between doctors and patients. The social pharmacy environment in Denmark occasionally touches upon everyday life and user experiences; however, most research concerns healthcare professionals and the interspace between healthcare systems and homes, mainly in the global north. Thus my time in Sierra Leone helped me understand how health and medicine reconfigure in the interplay with other cultures and opened my eyes to the inequalities and social capacities of medicines. The experience abroad sparked a desire to know more about the social lives of medicines, and I was therefore thrilled to be offered a year as research assistant at the Section for Social Pharmacy at the University of Copenhagen. As I became familiar with social science research on pharmaceuticals in the Global South, an interest in the role of pharmaceuticals in my own lifeworld emerged: Why are medicines so popular that they define most aspects of healthcare today? What are the driving forces behind the extensive use of pharmaceuticals in the Global North? And how does the role of medicines impact other aspects of social life?

My application for the position as a PhD fellow in the interdisciplinary research project LIFESTAT (short for Living with Statins) became an opportunity to engage with the interspace between biomedicine and social science, while exploring matters of health and medicine use in the Global North. The project's access to the Department of Anthropology provided me with an opportunity to pursue my interest in understanding medicine use as a social phenomenon, which resulted in an amazing journey into unforeseen aspects of fieldwork, theory-driven analysis and ethnography production, all elements that were new and exciting to learn and become proficient in.

This journey would not have been possible without the contributions of numerous people along the way. First of all, I thank the many informants who shared their knowledge and experiences of cholesterol-lowering and preventive medicine, and who gave me access to their lives and thoughts. I want to extend a special thanks to my

supervisor Bjarke Oxlund, who made the journey possible in the first place, and who trusted my ability to succeed despite various bumps on the way. I truly appreciate getting to know anthropology through you and I am incredibly grateful for your invaluable support and thoughtful readings and discussions of my work and dissertation. Thanks to John Sahl Andersen, associate professor at the Department of General Medicine, who initially gave me access to the field of statin users and who has continued to inspire me with suggestions and inputs from the field of general practice. I was fortunate to spend four months at the Department of the History of Medicine at Johns Hopkins University in Baltimore as a Fulbright Fellow in 2016, and I owe a deep debt of gratitude to Professor of Medicine and the History of Medicine Jeremy Greene, my supervisor during the stay, for his encouragement, support, and tremendous insights in the field of preventive medicine. Thanks also to the PhD fellows at the Department of the History of Medicine and the Department of the History of Science and Technology for adding a new dimension to my research portfolio, and special thanks to Delphine Olivier for sharing the time as strangers in Baltimore and for some fun and delightful American experiences.

I wish to thank the Department of Anthropology at the University of Copenhagen for providing me a base from which to conduct my research, as well as all the inspiring people who work there. I extend a special thanks to anthropologist Birgitte Bruun, for continuously reading and discussing my work and for teaching me the hidden language and logics of medical anthropology. I truly appreciate the invaluable support you have given me during most of the project period, and for the informal sharing of the ups and downs of interdisciplinary research. I also want to thank the CEHA (Center for Healthy Aging)/LIFESTAT group, which in addition to Birgitte Bruun included Susan Reynolds Whyte, Bjarke Oxlund, Nete Schwennesen, Henrik Hvenegaard, Mikka Nielsen, Line Hillersdal, Loa Kristine Teglgaard Christensen, Nanna Hauge Kristensen, Simon Meggers Matthiesen, and Anja Steinmejer. Thank you all for reading and commenting on some of my initial article drafts and guiding my overall analytical thoughts and theoretical understandings. Special thanks also to all members of the PhD group for making the time at the department pleasant and for sharing academic insights when needed. Thanks to John Brodersen, Klaus Hoyer and Janine Traulsen for important conversations about my work. I also owe special thanks to the Social Pharmacy Research Group at the University of Copenhagen for continuously supporting my academic travel and for inviting me to events, including the annual Nordic PhD Meeting. Special thanks go to Karin Svensberg for her friendship and mutual sharing of life as a PhD student and as a new parent. And I of course owe particular gratitude to the LIFESTAT research group, without whom the project would never have been possible in the first place. Thank you to Margit Kriegbaum and Kasper Bering Liisberg for creating a space for the practice of interdisciplinarity, and to the people, researchers and informants, who contributed to the production of the statin dialogue tool. And thank you to Nicolai Paulsen and Aileen Itani for helping me with the proofreading of the articles and thesis. Many thanks also go to Katrine Fjelding-Larsen and Anja Steinmejer for helping me manage hundreds of kilos of the thirty years of editions of the Danish Medical Journal, as well as pivotal bits and bobs along the way.

Also, I owe a special thanks to the assessment committee, who helped me point out important limitations of the first version of the thesis, and provided me with the feedback needed to strengthen my theoretical framework and analytical argument.

Last, but not least, I am so grateful to Søren, the love of my life, for his tremendous help and support, for always being there for me and for giving me time and space to pursue my academic endeavours. Thank you for being an offbeat pharmacist like myself and for sharing a common desire to leave a mark on the social aspects of medicine use. I am truly looking forward to continuing the journey of life with you, our Elliot and expected baby brother.

I

Introduction:

The Matters of Statins

Staging Statins

Bodil (aged 61) found out about her elevated cholesterol during a standard health assessment at her general practice seven or eight years ago. It has been monitored frequently over the past years without any intervention, but the last time she went to the doctor, her total cholesterol number was 7.6 mmol/l and her general practitioner (GP) decided to prescribe cholesterol-lowering medicine; statins. She had taken statins for some months when I interviewed her in her home in September 2013. When I asked her, how she felt about the medicines, she said: “Honestly, I don’t give it much thought. It has become part of my everyday routine, one of those things you just do, like brushing your teeth. One of those ordinary practices. So I feel kind of relaxed about it. As long as it makes my number drop, I think it’s for the better”.

This dissertation revolves around the use of statins as something ordinary and mundane; a practice that over the past 20 years has become embedded into the everyday routines of a large amount of people to

such a degree that no one gives it much of a thought anymore. As long as it keeps the blood cholesterol down, there is no need for concern. In many ways, statin use has become routinized; in health politics, in the clinic and in everyday life. In this thesis, I argue that it has become a matter of course.

But it has not always been like that. As shown in Table 1, since the late 1990s, the use of preventive pharmaceuticals has increased tremendously in Denmark, and the picture is the same for many other high-income countries (Aronowitz 2015a; Dumit 2012; Greene 2007b; Kaufman 2015). While in fact being a rather new technology, today, pharmacological management of ‘at risk’ states constitutes one of the primary areas of focus in preventive medicine, a medical field concerned with the management of the absence of disease (Clarke 1974). This thesis focuses explicitly on the case of high cholesterol, a risk factor for cardiovascular disease (CVD), as a way to explore the widespread use of pharmaceuticals to lower risk. The market for the use of statins is gigantic. Pfizer’s statin Atorvastatin (Lipitor), for instance, has generated annual revenues of more than \$10 billion each year since 2004, making it the best selling drug in history (Petursson 2012, 25). In a population of approximately 5.7 million people, 625,752 Danish citizens redeemed a prescription for a cholesterol-lowering drug in 2016 (Sundhedsdatastyrelsen 2017). This is almost 11% of the total population or 21% of all citizens above the age of 40.

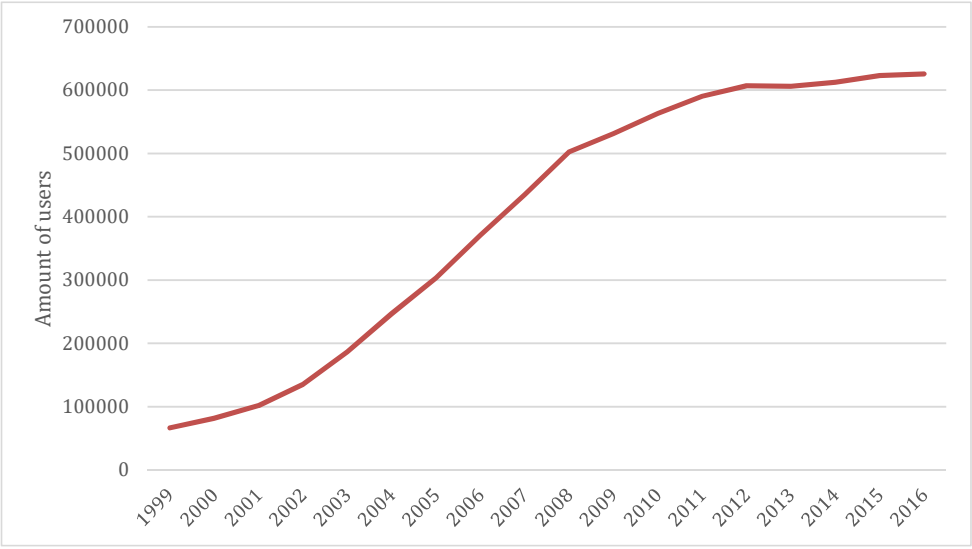


Table 1: Rise in the amount of statin users in Denmark 1999-2016. Data derives from (Sundhedsdatastyrelsen 2017)

At the same time, the efficacy and safety of statins are highly contested and the evidence behind the massive uptake of this treatment logic is a subject of intense scholarly debates (Garrety 1997; Steinberg 2007; Greene 2007b). This dispute ranges from disagreement about the aetiology of CVD and the relevance of blood cholesterol as a risk factor for the development of CVD – also known as ‘the cholesterol controversy’ (Ravnskov 2014; Malhotra 2013; Garrety 1997; Marks 1997) - to the safety and efficacy of pharmacological intervention (Abramson and Wright 2007b; Godlee 2014; Greene 2007b; Petursson 2012). Yet, in medical practice, pharmaceutical treatment of high cholesterol has become standard of care and the use of statins is in general perceived as a cornerstone for the management of CVD (Stroes et al. 2015). In contemporary clinical practice guidelines – the political instrument to standardize and regulate clinical practice – statins hold a pivotal position as one of the main interventions to control CVD, both from the perspective of the treatment of individuals as well as in relation to controlling the health and life-expectancy of populations (Collins et al. 2016; Horton 2016). To healthcare politicians, professionals and users alike, the prescription of statins thus stands out as a self-evident response to the situation of being at risk of CVD. As the medicines are effective in lowering blood cholesterol and not known to cause any serious side effects, most see no reason why they should not be widely applied in order to control potential future illness. Some have even suggested that statins should be added to the drinking water in order to secure an even distribution of this ‘wonder drug’ (Roberts 2004). Hence, statin use constitutes an established logic and is rarely a cause of wonder or concern. As such, the use of statins can be framed as a matter of course in the sense that the treatment in general matters very little to politicians, to prescribers or to those who take them.

At the same time, there is nothing ordinary about the mass treatment of healthy individuals with pharmaceuticals. While the prevalence and severity of side effects to statins is rare in clinical trials, a wide range of register studies and observational studies have documented much higher rates of adverse reactions associated with the use of the medicines (Thompson et al. 2016; Stroes et al. 2015). In particular negative effects on the muscles, impaired body movement and pain, are frequently reported (Stroes et al. 2015). Also, there seems to be causality between statin use and the development of diabetes (Thompson et al. 2016), and statin use has been linked to other adverse reactions including cognitive impairment, sexual disorders, as well as liver and renal failure, depression and sleep disturbances (Thompson et al. 2016; Sundhedsstyrelsen 2012). At the same time, the effects of statins on mortality and morbidity, especially among heart healthy individuals, is modest to say the least. While there is clear evidence that statins lower the risk of reoccurring cardiovascular events in patients with manifested CVD, little evidence point to the benefits of treating heart healthy individuals (Taylor et al. 2011). Also, effects on mortality are ambiguous. For instance, a Danish meta-analysis of randomized controlled trials with statins found

that death was postponed between -5 and 19 days in primary prevention trials and between -10 and 27 days in secondary prevention trials (Kristensen, Christensen, and Hallas 2015). Still, many claim that the benefits of statins outweigh the risk (Collins et al. 2016; Minder, Blumenthal, and Blaha 2013) and some even argue that statins are underused (Madsen, Varbo, and Nordestgaard 2017).

In sum, the dispute over the use of statins makes an interesting case for the analysis of how contested facts are transformed from experimental to standard of care (Koenig 1988; Wahlberg 2016). Who are the actors involved in this process of routinization? What other factors or entities contribute to the process? And not least, what does the routinization entail in relation to how risk of CVD is perceived and managed in clinical practice and everyday life? Based on a historical review of the implementation of statin treatment in Denmark, 12 months of ethnographic fieldwork and a cross-sectional survey, this thesis explores these questions by revealing how the field of CVD prevention was established in Denmark from 1960s up until today, and, from an ethnographic perspective, how the logic of high cholesterol management unfolds in contemporary encounters between and among healthcare professionals and people identified as being at risk.

Carving out a Space for the Study of Statins in Denmark

In many ways, the routinization of statins resembles the shift from cure to prevention in contemporary public health and medicine (Armstrong 1995; Lupton 1995; Rosenberg 2009; Aronowitz 2015a). Embedded in the logic of prevention is the emergence of risk as a fundamental concept and category of knowledge, which has transformed how illness is understood and experienced and hence how ‘ill bodies’ are identified and treated (Lupton 1995; Shim, Russ, and Kaufman 2006; Mol 2008). According to Nikolas Rose, the practices of preventive medicine have modified the very life form that is the contemporary human being, which has by many means made us the kind of living creatures that we are at the beginning of the 21st century (Rose 2001; 2007b). Through transformations in the notion of risk and the explanatory power of statistics (Hacking 1990; Porter 1995), new risk-identities have been shaped that require new forms of medical attention and makes us live in a world of enclosing fear (Rosenberg 2009; Douglas and Wildavsky 1982). The field of prevention thus transcends into many other aspects of healthcare than CVD, e.g. prenatal care (Schwennesen 2011), reproductive medicine (Wahlberg forthcoming), HIV and Aids (Biehl 2009; Persson et al. 2016) and cancer (Löwy 2010; Koch and Nordahl Svendsen 2005) just to mention a few. Yet, cardiology and CVD prevention stands out as pivotal for the very foundation of preventive medicine through the construction of ‘risk factors’ and the emergence of

epidemiology (Aronowitz 2011; Marks 1997; Greene 2007b). Hence, prevention of CVD is essential to the establishment of the ‘risk reduction paradigm’, defined as the new approach to the management of risk through the practices of preventive medicine. Therefore, this paradigm holds a central place throughout the thesis as the logic that dominates contemporary uses of pharmaceutical prevention and self-management of risk (Lupton 1995 and 2013; Boholm 2015).

Medical technologies, including pharmaceuticals, have had a tremendous influence on the shaping of preventive medicine and the risk reduction paradigm. For instance, medical doctor and professor of the history of medicine, Jeremy Greene, has looked into how the development of a ‘pharmacopeia of risk reduction’ has created a new model of disease based on numerical derivations rather than symptoms (Greene 2007b). By tracing the careers of three preventive pharmaceuticals (an antihypertensive, an antidiabetic and a statin), Greene has shown how the development and implementation of these pharmaceuticals in US healthcare intertwine with the definition and practice of preventive medicine. Hence, the pharmaceutical industry played (and still plays) a pivotal role in shaping, not only the market for medicines, but also the core logics on which the diagnosis and treatment of risk are based (ibid).

Furthermore, professor of anthropology, Joseph Dumit, has highlighted the impact of media and direct-to-consumer advertisement in the definition of a new mode of health; ‘surplus health’, which connotes the need to constantly lower risks through the extensive uses of pharmaceuticals, but with very little benefit for the individual user (Dumit 2012). The sub-title of his book; “how pharmaceutical companies define our health”, gives away the main argument, namely that ‘surplus health’ is a co-production of the pharmaceutical industry’s ability to pursue profit-making ideas of mass-treatment with new definitions of health. In turn, people are transformed into ‘pharmaceutical selves’ in the sense that they take on this need for treatment despite any (or very little) proven effects on their health. Thus via marketing of pharmaceuticals, people first become aware of risk, then they become capable of performing self-diagnosing, and finally they are provided with the tools to convince the doctor to prescribe treatment (ibid 55-85). In essence, this new ‘mode of biomedical living’ is incorporated so strongly into everyday life through notions of normalization that it becomes almost impossible to discontinue treatment (ibid 182). Dumit bases his argument on eight years of research into pharmaceutical companies’ marketing strategies, clinical trial data and interviews with healthcare professionals and patients. However, the book provides only very short glimpses into the everyday life of statin users. Furthermore, the accounts offered by both Greene and Dumit are specific to the context of the United States, which stands out for instance by being one of the few nations worldwide that allows direct-to-consumer drug advertisement of prescription products. Finally, the healthcare sector in the US is hugely impacted by the health insurance