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Reconstructing Vision: Undone Science and Anti-VEGF treatment of Wet Age-related Macular Degeneration

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Abstract

Treatment of wet AMD with the anti-VEGF drug Lucentis can be vital to maintaining central vision and therefore quality of life. This drug treatment is heavily subsidised by the Australian Government. In 2009 over \$150 million was spent by the Australian Government's Pharmaceutical Benefits Scheme on this particular AMD treatment drug. Yet, while a cheaper drug exists which costs less than one tenth of this price to treat wet AMD, the Australian Government's own policies and the apparent lack of scientific testing of the cheaper anti-VEGF drug (Avastin) means that it will be some time before cheaper drugs are available through the Australian health system. There is little incentive for the pharmaceutical and biotechnology companies to conduct costly research into cheaper drug options and health systems across the developed world have faced various barriers to conducting their own clinical trials on cheaper drugs. This dilemma is an example of what is known as the problem of undone science (Hess 2006), where here the lack of research on Avastin as a treatment of wet AMD has held back the reform of drug treatments for wet AMD. This brief working paper seeks to investigate how the undone science of medical retinal drug treatments came to influence the options available to treat someone experiencing wet AMD, and more broadly, how the problem of undone science can shape the financial and treatment burden of Age-related Macular Degeneration on the Australian community.

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Abstract

Treatment of wet AMD with the anti-VEGF drug *Lucentis* can be vital to maintaining central vision and therefore quality of life. This drug treatment is heavily subsidised by the Australian Government. In 2009 over \$150 million was spent by the Australian Government's Pharmaceutical Benefits Scheme on this particular AMD treatment drug. Yet, while a cheaper drug exists which costs less than one tenth of this price to treat wet AMD, the Australian Government's own policies and the apparent lack of scientific testing of the cheaper anti-VEGF drug (*Avastin*) means that it will be some time before cheaper drugs are available through the Australian health system.

There is little incentive for the pharmaceutical and biotechnology companies to conduct costly research into cheaper drug options and health systems across the developed world have faced various barriers to conducting their own clinical trials on cheaper drugs. This dilemma is an example of what is known as the *problem of undone science* (Hess 2006), where here the lack of research on *Avastin* as a treatment of wet AMD has held back the reform of drug treatments for wet AMD.

This brief working paper seeks to investigate how the undone science of medical retinal drug treatments came to influence the options available to treat someone experiencing wet AMD, and more broadly, how the problem of undone science can shape the financial and treatment burden of Age-related Macular Degeneration on the Australian community.

The role of social theory in the reshaping of primary care

Health professionals take pride in the ongoing search for best practice. Often evidence based studies are performed that demand the practitioner rethink their approach to an area of

expertise. Most times these studies come from an area of scientifically recognised research, but social theory can also influence the way a health practitioner can think. For example, an awareness of the societal and historical aspects of the technoscientific practices that optometry inhabits, and the way social theory can help explain and interpret the changes that are taking place is becoming more important as social change occurs more rapidly and in ever more complex ways.

Each clinical encounter is an opportunity to apply and adapt best practice both within the clinic and in the society at large. This is because in primary care optometry we meet the individual statistics that make up the construct of epidemiological thinking mediated by health statistics and models. This encounter has multiple truths. A clinical encounter is mediated by communication occurring in an essentially social space which is an area where the tools provided by social theory can find immediate application. Social reconstruction is a process offered by recent social theorist that in some ways invites a re-thinking of the way technoscientific practices are justified. It is a process that involves critical analysis of recent historical cases used in such diverse areas of greening of industries, non-weapon based defence and alternative medicine. Reconstruction of a social practice, especially a technoscientific social practice which can be so prone to technocratic absolutism, is an idea that can be important to achieving significant reform. If we continue to make the same underlying comfortable assumptions and do not challenge the status quo with new ideas then there is little hope for the evolution of social practices to fit the requirements of the society that creates and sustains them.

In the context of this study a partisan approach was used which hoped to see reform of the case study area of Anti- VEGF treatment and treatment research. Treatment of wet AMD was approached a quality of life issue where effective treatment is highly valued. *Lucentis* treatment of wet AMD is heavily subsidized in Australia and yet treatment with another Anti-VEGF drug *Avastin*, has faced unique challenges. David Hess' concept of undone science was applied to this comparative case study of Anti-VEGF wet AMD treatments. The application of the concept of undone science came as a result of analysis of Anti-VEGF treatment options from 2005 up to 2010. At certain stages during this period the main problem with *Avastin* use was the lack of comprehensive clinical trials research, hence the problem of undone science for those who may have wished to justify its use as a treatment for wet AMD.

This case study of Anti-VEGF treatment research gave an opportunity to apply David Hess' concept of undone science. Hess' work in this field examines how certain societal aspects of conducting research can create a process of uneven development.

In Hess'(2006) chapter *Antiangiogenesis Research and the Dynamics of Scientific Fields* he identifies certain factors as important to the study of Undone Science: Denaturalization of the material world, Universalization of values, Expansion of scale and Differentiation of institutions.

When describing denaturalization of the material world Hess identifies that science and technology can tend to become more distanced from living entities over time.

Denaturalization is important to the historical context of the emergence of Anti-VEGF drugs as a treatment of unwanted blood vessel growth. The discussion of denaturalization is an idea that is also leads to an understanding of the importance of identifying patentable substances, as opposed to substances that may be effective but are deemed to natural to be patented and therefore more difficult to converted into a successful drug treatment. In the case of *Lucentis* where this drug was produced specifically for the treatment of retinal blood vessels the question of patent was uncomplicated and the ease of predicting an economic return meant that research was able to be funded. On the other-hand *Avastin* was already available as treatment of bowel cancer when it began to be used to treat retinal blood vessel growth. This meant that any research that was conducted on *Avastin* as a wet AMD treatment would need to be performed without the expectation of the same economic returns as *Lucentis*. Also as successful *Avastin* research would hurt the profitability of *Lucentis* it is not surprising that the company conducting *Lucentis* research would not support the funding of *Avastin* research. By denaturalizing the material world and creating patentable substances we can see in this case how the priority can quickly become conducting research in the most economically productive areas of a scientific field.

Hess also describes the universalization of values, a tendency for fields of science to develop formal methodologies of dispute resolution such as the use of Randomised Controlled Trials (RCTs) in the area of clinical medicine. RCTs are recognized as the gold standard for evaluating treatment but also impose large costs and scale requirements on the required research. This makes the imperative to use the most economically viable substance more important when looking to make a profit on investment in drug treatment options. Phase I, II and III drug trials can cost many millions of dollars and are seen as important to ensure that new drug treatments are safe and effective. These experiments are conducted in a way that attempts to minimise certain forms of bias. But the social factors at play in undone science are rarely taken into account when addressing the case for and against using particular drug treatments. For example it may be the case that comprehensive research has not been conducted on *Avastin* as a treatment for wet AMD, the clinician that wished to justify using this drug may point to the way that due to the social circumstances of this area of undone science the potential bias of the observer is not the only bias to take into account when evaluating the relevant research. The societal factors at play also need to be addressed in the way they shape the research available to the clinician.

Expansion of scale is also identified by Hess as shaping the contours of research, where the cost and scale of laboratory sciences has expanded faster than the ability of public institutions to fund research. As the cost and scale has out paced the public purse this has led to the involvement of many more institutions and organizations to bring new science to the public. Many of these organizations are only involved in order to realize a financial return on their investment. Thus the way these organizations go about their business can further shape the contours of scientific progress. This can be demonstrated in the case of the privately funded *Lucentis* and the public funding of *Avastin* wet AMD treatment research. The expansion of

scale means that it is not always possible to conduct research in areas that are for the common good.

So in scientific fields there can be lots of organizations, both public and private and large amounts of money at stake. Hess shows the importance of the differentiation of these institutions in shaping science. Hess points out that conflicts regarding roles and organizational goals increasingly arise within and between various fields of action of science.

In the case study of *Lucentis* and *Avastin* this differentiation of institutions has been identified as a challenge and an opportunity for bringing about organizational and political change that can help institutions evolve to the changing needs of the community. For example, the way public institutions such as hospitals and professional organisations can bring about reform of a scientific field by cooperating in ways that address the lack of research in an area where there is little hope of a financial return but huge cost savings for the community. *Avastin* may not be as profitable a treatment of wet AMD as *Lucentis* but this does not mean that the potential benefits of this treatment are not a good reason for institutions to cooperate in order to fund and conduct the relevant research.

Overall an awareness of societal and historical aspects of technoscientific practices has been shown in recent literature to be important in the progress of science and the modernization of society. Hess' study of undone science when applied to this case of Anti-VEGF treatment of wet AMD, is a robust example of how societal factors can be the key consideration for people in their everyday encounter with clinical best practice. An understanding of the implications of denaturalization of the material in the current era of patent for profit is important for those seeking reform. Also finding ways to break down way the problems of institutional differentiation, expansion of scale and universalization of values is becoming essential when trying to find ways to resolve disputes. Thus an ongoing examination of the way that progress in biosciences can be interpreted in terms of social theory such as that of Hess' undone science is also important for community at large.

Hess, D. J. (2006). Antiangiogenesis Research and the Dynamics of Scientific Fields. The New Political Sociology of Science: Institutions, Networks and Power. S. Frickel and K. Moore. Madison, Wisconsin, The University of Wisconsin Press.