Metabolic syndrome: The construction of a 'new' medical condition and its ethical consequences

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Abstract

The work presented here is a sociological and bioethical analysis of the medical condition known as syndrome X/metabolic syndrome. The term is a recent name given to a group of cardiac/diabetic risk factors that include high cholesterol, insulin resistance, obesity, high blood pressure and high fat levels in the blood (Garber, 2004). Interest in the topic was reawakened by Reaven (1988) who first coined the term 'syndrome X' to describe a cluster of risk factors that he believed was linked to insulin resistance. In recent years the number of 'new' diseases that have been detected and identified by medicine has increased rapidly, with examples such as clinical obesity and infertility. Commentators have speculated as to why this may be happening, and one suggestion is that our lives are becoming ever more medicalised (Moynihan and Smith, 2002).

The thesis consists of three main strands. The first strand is a sociological analysis of the metabolic syndrome concept and how it came to be constructed as a medical condition, with particular emphasis on whether the syndrome represents an example of the medicalisation of obesity. The second strand looks at the relationship between sociology and bioethics, and whether research from the former can help inform the ethical debate in the latter. In this regard, I hope to show in this thesis that it is possible to conduct social and bioethical analyses side by side, and that these can be complementary and provide a richer understanding of a topic. The third strand is a discussion of the main ethical issues surrounding this 'new' diagnosis, with particular emphasis on the issue of blame and responsibility in relation to this condition.

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Contents

Chapter 1
Introduction

In this thesis I will be adopting a multidisciplinary approach, using analytical methods from the social sciences and bioethics, to explore the emergence of the medical concept known as syndrome X/metabolic syndrome. I have chosen to follow the concept from December 1988, when it was first described, until the publication of a definitional 'harmonisation' document in October 2009. The latter date was chosen as the cut off point for my analysis because it was a significant moment of closure in the debate about the way in which the concept of syndrome X/metabolic syndrome should be understood and used. During my analysis, I will be using a constructionist approach to explore the different ways the concept has been constructed and who has been involved, with a particular emphasis on the issue of medicalisation. I will also be exploring some of the key ethical issues that are raised by the creation, diagnosis and treatment of this 'new' condition.

Background

At its most basic level, the term 'metabolic syndrome' describes a group of cardiac/diabetic risk factors that include high cholesterol, insulin resistance, obesity, high blood pressure and high fat levels in the blood (Garber, 2004). Although Kylin identified an early form of the concept at the beginning of the 20th Century, there was little interest in the topic until Reaven revisited the issue in 1988 and coined the term 'syndrome X' to describe a cluster of risk factors for heart disease that he believed was linked to insulin resistance (Kylin, 1923; Reaven, 1988).

This condition is one of a number of 'new' diseases that have been created by medicine over the past 30 years, with other examples including hypertension (high blood pressure) and infertility (Hofmann, 2001). In modern medicine, one group of conditions that has apparently seen a significant rise in number has been the so-called 'risk conditions', which concentrate on the identification of risk factors for future diseases (Skolbekken, 1995). This is a category that the metabolic syndrome certainly fits into.

This apparent growth in the number of 'risk conditions' has had an impact on many areas of medicine, including primary care, with Hetlevik writing that 'There are already many "risk conditions" to be considered in general practice, such as hypertension, diabetes type 2, osteoporosis, and abnormal pap-smears from the uterine cervix' (Hetlevik, 2004:137). Hofmann (2001) suggests that the increasing number of 'risk conditions' can in part be explained by technological developments. These have made it easier for scientists and physicians to measure various aspects of the body, which has led to the creation of a number of 'new' conditions. Developments in medical biochemistry and physics, for example, have made it easier for doctors to monitor patients' blood chemistry and bone density, which has led to that 'new' diagnoses emerging in the form of conditions such as hypercholesterolaemia (high cholesterol), hypertension (high blood pressure), and osteoporosis (low bone density).

This apparent increase in the number of 'new' conditions has led some commentators to suggest that our lives are becoming ever more medicalised (Moynihan and Smith, 2002). The issue of medicalisation and so-called 'non-diseases' was discussed in a special edition of the *British Medical Journal* (*BMJ*) published in 2002, which suggests that it is taken seriously by the medical profession. Over the course of a number of articles, medical professionals questioned whether issues such as old age, baldness, pregnancy and obesity should really be seen as medical problems (Smith, 2002).

Medicalisation itself is described as 'a process by which non medical problems become defined and treated as medical problems, usually in terms of illnesses or disorders' and 'is a sociocultural process that may or may not involve the medical profession' (Conrad, 1992:209 and 211). However, a number of commentators from the UK and US now argue that medicalisation is increasingly being driven by the pharmaceutical industry. Moynihan et al (2002) highlighted the examples of social phobia and osteoporosis to illustrate how companies often hyped the impact and prevalence of these conditions in order to increase their drug sales. They suggest that 'some forms of "medicalisation" may now be better described as "disease mongering" – extending the boundaries of treatable illness to expand markets for new products' (2002:886). They showed, for example, how osteoporosis was often portrayed as a medical certainty in promotional material produced by pharmaceutical companies, and yet a significant number of medical experts still regarded it as a poorly understood and ill-defined concept. Conrad

and Leiter (2004) also believe that the process of medicalisation is changing, and using developments in North America as an example they argue that the process is being increasingly influenced by 'corporations', 'insurers', and 'consumers'. (2004:158-176).

Therefore, earlier versions of the medicalisation theory (Conrad, 1975) that put the medical profession at the heart of the process are now being challenged by newer versions of the concept that recognise the importance of other groups, such as the commercial sector (Clarke et al, 2003; Conrad, 2005). In fact, the syndrome X construct has even been used in one of the publications that has attempted to update the theory as an example of the type of 'new' condition that has emerged in recent times (Clarke et al, 2003). In the paper, Clarke et al argue that their 'biomedicalisation' theory represents the next stage in the medicalisation continuum, and that this has resulted in the emergence of 'new individual and collective identities' that have been 'produced through technoscience', and then as examples gave '"high risk" statuses, DNA profiles, Syndrome X sufferers' (2003:162).

However, trying to assess the precise role of the medical profession or commercial sector in the construction of a particular condition is not easy, and requires the analysis of a number of sources.

Using the metabolic syndrome concept as an example again, an article on the condition in the journal *Pharmaceutical Executive* suggests that there has been input from both the commercial sector and medical profession during its construction (Breitstein, 2004). The author even highlighted the role of construction herself when she noted that: 'Unlike a new pathogen bursting from the jungle like Ebola or mutating from something familiar like each year's "new" strain of influenza, Metabolic Syndrome must be both socially and scientifically constructed. Well-known medical facts have been reorganized into a new understanding.' (2004:2).

Bretstein (2004) also hinted at the potential role of the commercial sector when she commented that 'Already, some critics complain that the syndrome is simply the [*pharmaceutical*] industry's effort to medicalise obesity' (2004:8). While later on in the article, John Buse from the American Diabetes Association (ADA) was quoted as saying that: 'It [*obesity*] is being medicalised – but not just by the pharma companies

[…].The ADA is also doing so by giving it a name [*metabolic syndrome*] and calling it a risk marker.' Therefore, for this expert the concept of the metabolic syndrome is an example of the medicalisation of obesity by both the commercial sector ('pharma companies') and medical profession ('ADA'). The description of the concept as an example of the medicalisation of obesity is understandable, when many of the constructs refer to obesity (and in particular a large waist circumference) as being a key component of the condition. In my thesis I will be exploring these perspectives, and by the end of my research I hope to answer which of these three hypotheses is correct, and therefore determine whether the metabolic syndrome is a product of industry, medicine, or a combination of both.

A brief history of the metabolic syndrome: 1988–2009

Before I start to explore the different ways in which the metabolic syndrome has been constructed as a medical condition, it is helpful to outline the 'official' chronology of the concept, as viewed by the professionals involved. This enables us to gain an early insight into how the different interested parties viewed the emergence of this condition. The following history is based on information taken from a number of scientific/medical review articles on the metabolic syndrome (Alexander, 2003; Garber, 2004; Eckel et al, 2005; Reaven, 2005a; Grundy, 2006a).

All the review articles on the metabolic syndrome concept acknowledge that the field has a long history, and that work from the early 20th Century helped lay the foundations for 'syndrome X', and in particular the concept of a 'cluster of cardiac risk factors'. This has included highlighting the work of the Swedish researcher Kylin, who described a group of metabolic risk factors in 1923, as well as the British diabetes expert Himsworth, who developed the concept of 'insulin resistance' and its potential role in diabetes in 1936. The work of the French scientist Vague (1947) who put forward the notion of 'android obesity' (fat around the middle) in humans and its potential risk to health, is also mentioned as influencing the concept of the metabolic syndrome; along with Yalow and Berson's publication from 1959, where they suggest that obesity is a key factor in insulin resistance. Other work regularly mentioned includes research by the Italian team Avogaro et al (1967), who described a 'clustering of cardiovascular risk factors'; and separate publications by the German researchers Haller (1977) and

Singer (1977), who both independently first used the term ‘metabolic syndrome’ to describe a similar ‘clustering of cardiovascular risk factors’; along with Kahn’s (1978) work on ‘insulin resistance’.

Reviews of the metabolic syndrome concept, however, universally agree that it was not until Gerald Reaven gave his Banting memorial lecture at the ADA’s annual scientific conference in 1988, when he first described ‘syndrome X’, that interest in the notion of ‘insulin resistance’ and its related ‘risk factor cluster’ really took off. This led to his ‘classic’ publication in the journal *Diabetes* that was also published in 1988. The review articles state that from 1988 to 1998, interest in ‘syndrome X’ (also referred to as Reaven’s syndrome and insulin resistance syndrome) grew as the issue began to be discussed more often and the number of papers on the topic increased (Alexander, 2003; Kahn et al, 2005). However, at this stage in the condition’s development, interest in the syndrome was largely restricted to the diabetes field.

The creation of the World Health Organization (WHO) definition of the ‘metabolic syndrome’ is usually highlighted as being the next significant development in the field. The backdrop to this was that in 1998 the WHO organised a consultation meeting on the ‘Definition, diagnosis and classification of Diabetes Mellitus and its complications’ (WHO, 1999). The primary aim of the consultation was to come to a consensus regarding the update and reclassification of the diagnosis of diabetes. This ultimately led to the replacement of the terms insulin dependent diabetes mellitus (IDDM) and non-insulin dependent diabetes (NIDDM), with type I and type II diabetes, respectively.

However, in addition to the reclassification of diabetes itself, the group also looked at the associated complications surrounding diabetes, which included risk factor clusters such as syndrome X. They suggested that the syndrome was significant, but was not widely known, partly because there was no ‘internationally agreed definition’. They therefore decided to use the term ‘metabolic syndrome’ to describe the cluster, and put together a working definition for the condition. This was an important development because the cluster had now become an institutionalised concept. This reclassification process was led by two diabetes specialists, Professor George Alberti from the UK and Professor Paul Zimmet from Australia, whom the WHO had picked because of their world-renowned reputations in the field.

Reviews of the field often highlight the emergence of another closely-related set of diagnostic criteria as developed by the European Group for the study of Insulin Resistance (EGIR) in 1999 (Balkau and Charles, 1999). This was a modification of the basic WHO definition and was aimed at individuals who did not have diabetes. It was intended to be easier to use in the clinical setting. Eckel et al (2005), for example, stated that 'These definitions agree on the essential components – glucose intolerance, obesity, hypertension, and dyslipidaemia' (2005:1415). While the EGIR (Balkau and Charles, 1999) definition is regularly mentioned in review papers, it has never enjoyed the same level of recognition as the WHO set of criteria.

The awarding of an International Classification of Disease (ICD-9) code for the metabolic syndrome in 2001 is cited as another key milestone in the development of the concept in many review articles. This followed a request from the American Association of Clinical Enchronologists (AACE) for a code in 2000, for a construct they termed 'dymetabolic syndrome X'; the code eventually given to it was 277.7. Many in the medical profession saw this as significant, because the concept had now gained a level of institutional legitimacy that meant it was recognised by the insurance industry as a 'billable condition'.

The next significant development in the field occurred in 2001, with the launch of the Adult Treatment Panel III (ATP III) diagnostic definition for metabolic syndrome. The US National Heart Blood and Lung Institute (NHBLI) in conjunction with the American Heart Association (AHA) published and launched the National Cholesterol Education Program's (NCEP) ATP III report in May 2001 (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001). This was a government-backed initiative with the primary aim of giving guidance to medical professionals and the lay public on the 'detection, evaluation, and treatment of high blood cholesterol in adults' (Grundy, 2001). This followed the publication of similar ATP I and ATP II reports, which were published in 1988 and 1993, respectively, and also gave guidance on this issue.

However, within the ATP III guidelines there was an acknowledgement that if all other strategies had been employed in the management of high cholesterol in a given patient,

physicians should then turn their attention to 'the Metabolic Syndrome as a secondary target for therapy' (Grundy et al, 2001:2492). This led to the creation of a new set of diagnostic criteria for the metabolic syndrome, the NCEP ATP III guidelines(Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001), which introduced 'abdominal obesity' as a risk factor. In order for an individual to be diagnosed as having metabolic syndrome using this definition, they had to have three or more risk factors from a list of five, which included central obesity, high blood pressure, high cholesterol, high triglycerides (blood fats), and evidence of abnormal glucose regulation (Grundy et al, 2001). This meant that insulin resistance was no longer an absolute requirement for a diagnosis of metabolic syndrome, as it had been for the WHO (1999) definition. These guidelines quickly became seen by physicians working in the field in the US as the standard definition for diagnosing the metabolic syndrome, and they also started to be used in a number of other countries (Garber, 2004; Grundy et al, 2005). The ICD-code for the condition was unaffected by these changes, and could be applied to this new definition.

In 2002, partly as a result of the emergence of the WHO (1998) and ATP-III (2001) definitions, the American College of Endocrinology (ACE) created their own construct, which they termed 'insulin resistance syndrome (IRS)' (Einhorn et al, 2003). This was backed by Gerald Reaven and put insulin resistance centre stage again. Although the experts behind this concept produced a list of components of the IRS, they stated that their concept was not intended as a diagnostic tool, but 'to provide guidance to clinicians and the many others involved in and affected by the Insulin Resistance Syndrome' (Einhorn et al, 2003: 237). Here the physicians were left to use their own clinical judgement in deciding whether an individual had the condition or not, which changed the way the concept would be used in terms of medical practice, with more localised decision making but also the potential for greater inconsistencies in relation to medical disposals.

In regard to diagnostic developments, the review articles suggested that the next significant change occurred when the International Diabetes Federation (IDF) created their own definition, which they claimed was a more simplified version of the ATP-III construct. Here central obesity (by measurement of waist circumference) was made a prerequisite for a positive diagnosis, along with any further two risk factors from a list

of four, which included high blood pressure, high cholesterol, high triglycerides (blood fats) and evidence of abnormal glucose regulation or a diagnosis of type 2 diabetes (IDF, 2005a, b, Alberti et al, 2006). The definition was officially launched in April 2005 at an International conference on '"Prediabetes" and the Metabolic Syndrome' that was held in Berlin, Germany. The key players behind this definition were again George Alberti and Paul Zimmet, who were instrumental in the creation of the original WHO definition for metabolic syndrome. Therefore a number of experts saw this new definition as having replaced the earlier WHO criteria (Grundy, 2006a: 1094).

Following the launch of the IDF definition for metabolic syndrome in April 2005, a number of experts argued that this was a step too far, and started to raise their concerns regarding the wider concept (Kahn et al, 2005; Gale, 2008). In September 2005, for example, the ADA and European Association for the Study of Diabetes (EASD) released a joint statement where they called into question the very existence of the metabolic syndrome and also raised concerns about the main diagnostic definitions (from the WHO, ATP-III and the IDF). However, the medical media portrayed this as being a fight between US diabetologists and cardiologists, and their respective professional bodies (Mitka, 2005). The concerns raised by these two diabetes organisations were similar to criticisms that Gerald Reaven had raised in earlier work discussing the concept of the metabolic syndrome (Kim and Reaven, 2004; Reaven 2005a, b).

In 2006, as a consequence of this perceived disagreement, the ADA and AHA were compelled to release a joint statement in which they highlighted their commitment to tackling diabetes and cardiovascular disease. They categorically denied that the two organisations were at war over the metabolic syndrome (Eckel et al, 2006).

In October 2009, a joint interim statement entitled 'Harmonizing the Metabolic Syndrome' was released on behalf of a range of international organisations, which included the IDF, National Heart, Lung, and Blood Institute (NHLBI), AHA, World Heart Federation, International Atherosclerosis Society, and International Association for the Study of Obesity. This followed a meeting they had held where the primary aim was 'an attempt to unify (the diagnostic) criteria' for metabolic syndrome (Alberti et al, 2009: 1640). The groups claimed that the confusion and controversy surrounding

the different diagnostic criteria for the metabolic syndrome was beginning to affect how the concept was viewed by the medical profession and beyond, and believed that a conference and statement to clarify the situation was needed. During the meeting the groups laid out some basic principles concerning the creation of a 'single agreed-upon set of diagnostic criteria', but no definitive conclusions were reached (2009:1643). They did, however, agree to continue to work towards this goal.

The outline above is a summary of how the review articles have portrayed the development of the metabolic syndrome concept, and gives the reader an idea of how the key players and claims-makers have both constructed and viewed the field. And in my data chapters I will be exploring these various constructions in more detail.

Terminology used in the metabolic syndrome field

During my analysis of the concept of the metabolic syndrome I have had to become an expert on the different scientific/medical terms used in the diabetes field. This is because the claims-makers behind the different constructs have made extensive use of such terminology. I am not expecting the reader to be an expert, but a basic understanding of diabetes is essential, particularly when reading my analysis of the different constructs. This is therefore a logical point, being at the start of the thesis, at which to introduce some of the key terms because this should make it much easier for the reader when they come to look at the later chapters.

The first term is diabetes. The WHO definition states that: 'The term diabetes mellitus describes a metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both. The effects of diabetes mellitus include long–term damage, dysfunction and failure of various organs.' (WHO, 1999: 2). The term hyperglycaemia (high blood glucose) is key here and individuals with a fasting glucose level of 126 mg/dL or above would be identified as having the condition (WHO, 1999: 5). There are two forms of diabetes: type I and type II; the first is an autoimmune condition that requires treatment with insulin, and the second more common type is a disorder of insulin that can be treated with lifestyle changes (WHO, 1999: 17-18). Medical professionals have also started to use the term

pre-diabetes. This is described as ‘a condition in which glucose (blood sugar) is above normal but not high enough for a diagnosis of diabetes’ and is also referred to as ‘impaired glucose tolerance (IGT) or impaired fasting glucose (IFG)’ (DiabetesHealthOnline, 2005). It is believed to dramatically increase the risk for progression to clinical diabetes (Edelstein et al, 1997)’ (Norris et al 2005:2). Interestingly, the first International Conference on Metabolic Syndrome, which was held in Berlin in April 2005, was entitled the ‘1st International Congress on ‘“Pre-diabetes” and the Metabolic Syndrome’, which suggests that some experts clearly believe that these two concepts are closely related.

This then brings us on to probably the most important term in relation to the concept of the metabolic syndrome, and that is insulin resistance. The hormone insulin plays a key role in the regulation of glucose in the human body. Individuals with insulin resistance do not respond to normal levels of insulin, and usually also have accompanying hyperinsulinaemia (high levels of insulin) because their bodies try and compensate for this by producing more insulin. Insulin resistance is therefore seen as an indicator of impaired glucose regulation (Gale, 2008). However, individuals with type II diabetes, who do not produce enough insulin, can still have insulin resistance, which means that the condition is also another marker for the metabolic syndrome (Reaven, 2001). Unfortunately, trying to measure insulin resistance within the body is notoriously difficult and often produces highly variable results (Gale, 2008). This is why the measurement of blood glucose levels is still regarded as one of the most useful diagnostic tests in this field.

It is important to remember that not every individual with insulin resistance necessarily has type II diabetes. In recent years, the medical profession has started to take a greater interest in insulin resistance, as more research (including work by Reaven) has been published that appears to show that this state is linked to a number of medical conditions, including cardiovascular disease and hypertension (Einhorn et al, 2003). This therefore neatly ends the ‘science lesson’ by bringing us back to conditions such as syndrome X and the IRS, which are believed to have insulin resistance as their primary underlying cause. These are of course just two examples of a number of constructs that surround the concept of the metabolic syndrome, and therefore form part of my analysis.

A word about nomenclature

In this thesis, I will mainly be using the terms 'metabolic syndrome concept', 'condition', 'metabolic syndrome construct', and 'metabolic syndrome' to describe the subject of interest. When referring to the numerous different permutations of the metabolic syndrome as a whole, I will use the first two terms. I chose to use the term 'condition' rather than 'medical condition' or 'disease', because this word is fairly neutral, and could equally mean a non-medical 'state of being' rather than a specific 'medical state'. When referring to a specific construct of the metabolic syndrome, such as the ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001) definition, I will either refer to it directly, or use the third term 'metabolic syndrome construct'. When using the last term, 'metabolic syndrome', I will only be referring to the WHO (1999), EGIR (1999), ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001, 2004), IDF (2005b), and 'JIS' (2009) constructs. When using other terms such as 'syndrome', 'concept', or 'construct', the context in which they appear should help the reader to understand what I am referring to.

The structure of the thesis

Chapter 2: Literature review

In this chapter, I will be exploring three main areas. In the first section, I will conduct a review of the sociological literature on the construction of medical knowledge, with particular emphasis on the issue of diagnosis. In the review I will identify some of the key themes and issues highlighted in the literature and discuss how these relate to the metabolic syndrome concept. This will also include looking at publications that have been critical of this approach. In the second section, I will be concentrating on the literature related to medicalisation, and discussing how this theory has developed, again with an emphasis on how this relates to the metabolic syndrome. As above, this will include looking at literature that has been critical of this approach. In the third and final section, I will be exploring the literature on the debate over the relationship between the social sciences and bioethics, and in particular whether research from one field can

complement work in another, and how this influenced my decision to use a multidisciplinary approach in this thesis.

Chapter 3: Methods

In this chapter, I will outline the key methodological approaches I used during the thesis. I will also explain how I conducted the research, with sections on my analysis of the medical and scientific literature on the metabolic syndrome and the interview data I collected. Therefore there will be a strong emphasis on what I actually did during my research. Towards the end of the chapter, I will also discuss my decision to use a multidisciplinary approach, where I used methods from both the social sciences and bioethics.

Chapters 4–6 (empirical data): Construction of the metabolic syndrome

In the first three chapters, I present my empirical data on the construction of the metabolic syndrome concept from 1988 to 2009. In Chapter 4, I will be concentrating on the constructs that emerged during the early period (1988–2000). These originated from the diabetes medical community and emphasised the key role played by 'insulin resistance' in the aetiology of the condition. In Chapter 5, I will be exploring the middle period between 2001 and 2005, which was characterised by claims-makers from a range of backgrounds and constructs that tended to concentrate on the role played by 'obesity'. And in Chapter 6, I will be discussing the period from late 2005 until 2009, which was characterised by the construction of the metabolic syndrome as a controversial concept. For each period, I will be analysing how the key constructs were conceptualised, identify the main players and claims-makers, and how these affected the way in which the metabolic syndrome field developed.

Chapter 7: Bioethical analysis

In this chapter, I will be exploring the ethical issues raised by the creation of the metabolic syndrome concept and its various constructs. The approach I will be using here is based on the ethical theory of principlism from bioethics, which uses the four principles of autonomy, beneficence, non-maleficence and justice with which to examine an issue. I will also be using the medicalisation theory from the social sciences as a means to highlight further ethical issues surrounding the concept.

Chapter 8: Summary

In the final chapter, I will attempt to summarise the key findings from my sociological and bioethical research into the metabolic syndrome. Here, I will discuss where this leaves the concept, particularly in relation to criticism that it is an example of the medicalisation of obesity. I will also briefly explore the potential for future research work in this area and what direction this may take.

Chapter 2
Literature review

Introduction

In this chapter, I will be exploring the three main areas of literature that have shaped my approach to studying the metabolic syndrome. The first area encompasses the literature on the sociology of medical knowledge, with particular emphasis on the construction of diagnosis. The second body of literature I will be reviewing concerns the closely-related sociological topic of medicalisation, and how this relates to the metabolic syndrome. In the third section, I will be discussing the literature on the relationship between the fields of sociology and bioethics, and how the approach I used here fits in with the approaches outlined.

In relation to how these three areas relate to my thesis, the metabolic syndrome concept is described as a controversial medical condition, and I am interested in how the knowledge surrounding the concept has been determined and how this has then been applied in the clinical setting. Therefore the first area of literature I will be exploring relates to the sociology of knowledge, and in particular how knowledge is made and the processes involved. This will aid understanding of the construction of the metabolic syndrome concept. The concept has also been described as an example of the medicalisation of obesity (Breitstein, 2004). Therefore the second area of literature I will be exploring relates to medicalisation and the different interpretations of the concept, which will help me determine whether the metabolic syndrome is an example of this process.

In the thesis, I was also interested in exploring the potential consequences of the creation of the metabolic syndrome from a bioethical perspective. However, I was aware that the fields of sociology and bioethics, although often interested in exploring the same topics, have a strained relationship. The final area of literature I will be exploring therefore looks at the debate between the two disciplines, and in particular at the issues surrounding joint research. It will explain how this helped to inform my

decision regarding the research approach I used here, which led to me presenting the social and bioethical research in separate chapters.

I. Sociology of medical knowledge

Health, disease and diagnosis

The medical profession sees the classification and diagnosis of disease as a 'central tenet of medicine' (Murphy, 1976). Health and disease are important concepts in medicine and society, and attempts to define them have often been controversial. One widely-used definition of health, which was created by the WHO, states that 'Health is a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity' (WHO, 1946). Defining disease has been an equally difficult philosophical and practical challenge. In 1975, however, the philosopher Boorse developed one definition that is now widely used in Western medicine. He adopted a naturalist/normativist approach and defined disease as 'A deviation from normal species-typical functioning' (Boorse, 1975). The concept's popularity is partly due to its compatibility with the biomedical model of disease, which sees the human body in mechanistic terms. The definition has not been without its critics; with the main criticisms being that it is not value-free as claimed and is over-reliant on biological knowledge (Reznek, 1987; Cooper, 2002).

The consequences of defining something as a disease or an individual as having a medical condition can be significant, with both positive and negative outcomes. For example, Rosenberg (2003) noted that 'Though disease categories are in one dimension abstract they have […] real-world consequences for particular men and women in terms of clinical treatment, of quality of life, perhaps even of life chances' (2003:14). In a similar vein, Jutel (2006) highlighted how 'A state which might otherwise have been seen as simply bothersome or irritating takes on a new significance when it becomes a diagnosis' and that 'Having a disease leads diagnostic, curative, and preventative strategies to fall into place, conveying both legitimacy to, and structure for the patient's complaint' (2006:2268-2269). This idea, that a state is somehow given 'legitimacy' when it is defined as a condition or disease, is also at the heart of the debate over the

metabolic syndrome concept. For example, an article on the condition quoted a representative from Takeda (a drug company) as stating that: 'The fact that metabolic syndrome has been identified as an *actual disease state* is a huge step in the right direction' (Breitstein, 2004:3).

Bowker and Star (1999) argue that medical classifications are not the objective that many people assume them to be; rather they are the result of a complex mix of historical, social and political factors, which have all contributed to the complex system that is currently in use. They looked at the ICD and showed how this grew out of a much earlier historical system of recording the incidence of disease (Bowker and Star, 1999). Hedgecoe in reference to Bowker and Star's work noted that '"Disease Classification" is one of the more socially constructed aspects of medical science' but that 'accepting this does not require an abandonment of the material aspects of disease'. (2002:11).

In medicine, diagnosis is important because it affects all aspects of the work practices of the profession, giving medical experts the authority to decide whether people are ill, what treatments should be given, and even whether lifestyle intervention is necessary (Murphy, 1976). As a result, diagnosis has also become an important area of study for medical sociologists interested in understanding how medicine and the medical profession operate, with many different aspects of the topic having been investigated, from the social function of diagnosis through to the consequences of disease labelling (Blaxter, 1978; Mishler, 1984; Bartley, 1990). Brown for example, highlighted how 'Diagnosis is central to the work of all medical professionals' (1995:39). The issue of diagnosis has also been at the centre of much of the discourse surrounding the metabolic syndrome, with many of the constructs (such as those from the WHO in 1999 and ATP-III in 2001) being based on different interpretations of the concept as a 'diagnostic definition'.

A positivist biomedical view of diagnosis is that the expert knowledge of the medical professional enables them to make an informed decision about the cause and treatment of a condition (White, 2002). This viewpoint makes a number of assumptions about the world and the way in which health and disease are understood. This includes the idea that disease exists and has a biological reality, the so-called 'material aspects of disease'

as outlined above by Hedgecoe (2002:11). It also assumes that diseases can be objectively discovered and catalogued, and that the medical profession will be able to offer treatment, or even a cure (White, 2002). Most physicians take a pragmatic view, and while sticking to a material explanation of disease acknowledge that social, cultural and historical factors also play a part in determining which 'conditions' become seen as medical diagnoses (Moynihan and Smith, 2002). Other commentators take a more constructionist view, and see diagnosis as being mainly determined by social factors. For example, Armstrong argued that 'The recognition of a new disease or syndrome is sometimes the result of serendipity, but more often the result of determined investigation and scientific entrepreneurship' (1998:2025); while the medical historian, Rosenberg, noted that 'social influences largely explain which symptom clusters have made it as diseases' (2001:808).

Creation of 'new' medical knowledge

An article on the metabolic syndrome published in the journal *Pharmaceutical Executive* in 2004 described the creation of the concept as follows:

Unlike a new pathogen bursting from the jungle like Ebola or mutating from something familiar like each year's 'new' strain of influenza, Metabolic Syndrome must be both socially and scientifically constructed. Well-known medical facts have been reorganized into a new understanding.

(Breitstein 2004:2)

Although this statement acknowledged that the metabolic syndrome concept had to be 'socially' as well as 'scientifically constructed' before being recognised as a 'new' medical condition, this gave little insight into the complexities involved in this process. One of the key themes that researchers identified in relation to the construction of medical knowledge was the role that 'dispute and controversy' play in the process. Rosenberg for example, noted that 'Conflict and negotiation at the boundaries of particular ills' is commonplace and important in the creation of disease concepts' and that 'Such conflict is a logical consequence of the very power and persuasiveness of specific disease categories' (2003:500-501). This is because, as Rosenberg highlighted, disease labels have a legitimising effect and are therefore often contested. For example, the creation of a 'new' medical condition brings with it significant consequences for

patients and medical professionals, with individuals being recognised as ill and medical experts being given the authority to treat the problem. Depending on how patients view their condition, this can be seen as beneficial or potentially harmful. For example, individuals with chronic fatigue syndrome (myalgic encephalomyelitis) sought a medical label for their condition in order to legitimise their symptoms, while individuals classed as having a mental health problem such as 'social phobia' may not see themselves in this way and view a 'disease' label as unhelpful (Ware, 1992; Scott, 2006). Consequently, as Gregory and Atkinson noted 'There are many clinical entities that are controversial, and that are subject to dispute' (2007:602).

One type of medical condition that researchers consistently identify as being problematic is the syndrome (Rosenberg, 2001). This is because as Eckel noted in an interview on the metabolic syndrome that 'when something is called a syndrome, it means the definition is not perfect' (Mitka, 2005:2010). In the medical field, the uncertain nature of the knowledge claims around many syndromes means that they are often controversial and contested, with exponents and critics arguing over their legitimacy. In her study of foetal alcohol syndrome, for example, Armstrong argued that 'syndromes are often contested diagnoses – and as such are ripe for social construction analysis' (1998:2025). This is because scientific/medical controversies often make it easier to identify the underlying social factors, such as rivalry between different claims-makers, which play an important part in the creation of knowledge. However, as Gregory and Atkinson noted 'Medical controversies, like controversial knowledge in the natural sciences, are perfectly normal features of the intellectual fields in which they take place' (2007:602). The metabolic syndrome concept is described as being contested and controversial (Kahn et al, 2005), and therefore makes it an ideal candidate as a case study.

Social construction of knowledge

The approach highlighted above that offers social factors as the primary explanation for the construction of a diagnosis has its methodological roots in the wider theory of 'social constructionism'. This theory was one of a number to emerge during the 1960s and 70s, when sociologists began to explore the processes involved in the creation of scientific knowledge, a field that became known as the 'sociology of scientific knowledge' (SSK) and, later, science and technology studies (STS). In its broadest

sense, social constructionism views reality as something that is socially and culturally constructed, and which analytically concentrates on the actors and interests that are involved with the phenomenon (Giddens, 2004).

The concept has its roots in Berger and Luckman's (1966) influential work *The Social Construction of Reality*, although the work of Wittgenstein (1953), Winch (1958) and Kuhn (1962) has probably been the most influential in the development of STS. For example, the philosopher Kuhn in his book *Structure of Scientific Revolutions* questioned the assumption that science progressed through a series of stepwise discoveries. Instead, he suggested that there were periods of what he called 'normal science' that continued within a particular 'paradigm', which he described as a particular set of assumptions about the world that meant that only scientific ideas that fitted with this view were taken seriously. However, he suggested that paradigms are not permanent and that eventually they are swept away. These periods, which he referred to as 'revolutions', resulted in the creation of a new set of ideas, in a process that he described as a 'paradigm shift'. He also claimed that separate paradigms were 'incommensurable', which meant that it was difficult for researchers used to working within one paradigm to translate their work to another, meaning that progress in science is by no means certain. He then noted that after things had settled down, a period of 'normal science' would resume within the confines of this new paradigm. Social constructionism encompasses a broad range of approaches, with examples including Foucault's (1969, 1973) sociology of knowledge, the 'strong programme' from the sociology of scientific knowledge (SSK) (Barnes, 1974; Bloor, 1976), the Empirical Programme of Relativism (EPOR) (Collins, 1981), the Social Construction of Technology (SCOT) (Pinch and Bijker, 1987; Bijker, 1995), and 'Actor Network Theory' (ANT) (Latour, 1987).

The constructionist approach I decided to use for my study was the 'strong programme' in the SSK. This was first developed by Barnes (1974) and Bloor (1976), and is also referred to as the 'Edinburgh School' of SSK in recognition of where the concept was created. This is social constructivist in approach and is also referred to as 'social interest theory'. It focuses on how beliefs come to be seen as true or false, and how this is achieved. This approach also highlights how knowledge claims are often influenced by social factors, such as the 'interests' of the researchers themselves, which can be at the

macro level – such as the class of the workers – or at the micro level – such as the specific professional interests of those involved. Bartley describes the latter as 'technical interests', which she defined as 'the interest a group has in perpetuating the demand for its own special type of skill' and 'the interest of occupational subgroups in creating a continuing market for their specific techniques and forms of expertise of which they can claim 'ownership''(1990:378 and 380). The issue of 'interests' is therefore a key aspect of the 'strong programme' approach.

Researchers interested in the construction of medical knowledge argue that professional/technical interests have also played a key role in shaping this knowledge. For example, Brown in his paper on 'the social construction of diagnosis and illness' highlighted how 'professional factors' and 'organizational and institutional factors' played an important part in the process of 'the social discovery of disease' (1995:43-45). He claimed that this could also occur within the same discipline, with fights to control the creation of new diagnoses in psychiatry between experts who took a more biological view of mental illness *versus* those that adopted a more psychoanalytic approach, which he described as 'an intraprofessional variant of moral entrepreneurship' (1995:44). In a later paper, Gregory and Atkinson highlighted how 'Medical knowledge reflects socially distributed interests, including the interests of employers and insurers, and the interests of medical practitioners themselves' and that 'The organised practices of medical specialists themselves are a key source in framing knowledge and reflecting sectional interests' (2007:604). In my analysis of the construction of the knowledge-claims surrounding the metabolic syndrome concept, I will therefore be paying particular attention to the issue of 'interests'. This is because the medical profession and the pharmaceutical industry have both been identified as being key players in the process, and I am keen to gain a better understanding of the professional/technical interests of those involved.

The analytical approach of the 'strong programme' is based around four key tenets, which are causality, impartiality, symmetry and reflexivity. Causality refers to understanding how beliefs come to be seen as true or false. Reflexivity means that researchers must recognise that their knowledge claims are also subject to the same influences as those under their scrutiny, and that their discipline and work can be critiqued in this way. The next two tenets, symmetry and impartiality, are seen as being

particularly important. Bartley (1990) wrote one of the best descriptions of the latter, where she defined them as follows: 'Symmetry: the sociologist of science should address as research topics all knowledge claims, whether these are presently regarded as true or false. These should then be analysed in terms of the interests which give rise to them' and in reference to 'Impartiality: all types of knowledge claim and all sides of any debate must be investigated sociologically. There is no appeal to 'the contents of the real world' as sufficient condition for the acceptance of knowledge claims as 'true' (1990:377).

Another approach closely associated with the 'strong programme' is Collins's EPOR (Collins, 1981). This also views scientific knowledge as socially constructed, and its analytic approach is based around three stages. In discussing the EPOR's methodology, Collins noted that 'Interpretative flexibility (of experimental data) was the main message of the 'first stage' of the relativist empirical programme' (Collins, 1981: 4, 6–7). This relates to the idea that scientific data are often open to different but equally valid interpretation. In relation to 'the second stage of the programme' this refers to 'the mechanisms which limit interpretative flexibility and thus allows controversies to come to an end' (1981:4). The third stage is concerned with how this all relates 'to the wider social and political structure' (1981:4). This approach is also described as methodologically relativist, meaning that researchers treat all knowledge claims with equal analytical scepticism. This methodology is particularly useful in the analysis of scientific controversies, therefore I intend to use the approach, and in particular the concept of 'interpretive flexibility', in my analysis of the controversy surrounding the metabolic syndrome concept.

The 'strong programme' of SSK and its related approaches has been used by sociologists of science to explore the creation of scientific knowledge in a number of different fields. The insights gained have also helped to create a much more diverse study of history, philosophy and sociology of science, in addition to the related topics of technology and the public understanding of science (Shapin, 1975; Mackenzie, 1978; Latour and Woolgar, 1979; Knorr-Cetina, 1981; Barnes and Bloor, 1982; Pickering, 1984; Shapin and Schaffer, 1985). Mackenzie (1978) investigated how the development of statistical tools and related knowledge during the late 19th and early 20th Century was strongly influenced by the social class of the scientists involved. Similarly, Pickering

(1984) explored how social factors, such as the technical interests of the scientists involved in the formulation of the idea of quarks in physics, played an important role in how this theory was able to gain prominence.

Critique of social constructionism

Social constructionism, and the 'strong programme' of SSK in particular, has not been without its critics, with criticism coming from a number of quarters (Bury, 1986; Latour, 1987; Hacking, 1999). For example, Hacking in his book *The Social Construction of What?* published in 1999, set out to discover what researchers actually meant when they referred to something as socially constructed. In the work, he argued that this approach often carries with it a number of implicit assumptions about the object under analysis, and that researchers that use this method often use 'social constructionism' as shorthand for 'we do not believe that the object exists in reality, that it is a bad thing, and that we do not need it, or the object is not "real"' (Hacking, 1999: 15). Hacking was particularly critical of studies that appeared to query the material reality of an object or topic, but was more sympathetic to approaches that questioned the way the object had been described or portrayed. Therefore he is happy with constructivist analyses that implicitly state that they are questioning the 'idea' of something, rather than the object itself (1999:25). In addition, Best highlighted how critics of constructionist approaches that view social problems as claims making describe the approach as 'merely debunking'. (1995:340-341).

Summarising the specific criticism of the 'strong programme', Sismondo noted that 'From the perspective of many of its critics, the strong programme rejects truth, rationality, and the reality of the material world' and that 'For other critics, the programme retains too much commitment to truth and the material world' (2004:49). He also noted that 'the strong programme has been criticised for being too committed to the reality and hardness of the social world' (2004:49). Here the criticism seems to be coming from all sides, with differing views in relation to its stance on materiality. I do not share many of the concerns highlighted above, because the accusation that such approaches 'reject truth, rationality and reality' is not borne out by the studies that have used this methodology. In addition, the critics assume that researchers that have used the approach and found it helpful as an analytical tool are all wedded to the 'doctrine' of social constructionism, which again is not borne out in the subsequent publications.

I also think that these approaches have got the balance right, in relation to their view on 'truth and the material world', questioning many of the assumptions but at the same time still accepting the concept of a material reality. I also agree with Hacking (1999) that studies which question the 'idea' of something can be helpful. Again, when looking at the studies that have been carried out, most researchers make it clear that they are questioning the way things are constructed and understood, rather than the reality of the object itself. I am also not against the concept of relativism, because analytically it makes sense to explore a topic from different perspectives, however unorthodox, if you want to fully understand what is going on around an issue.

Social construction of medical knowledge

One of the first areas to be studied by sociologists interested in the creation of scientific knowledge was medicine (Bloor, 1976; Wright and Treacher, 1982; Nicolson and McLaughlin, 1988). Here researchers showed that, just like other types of scientific knowledge, medical classifications are also socially constructed, and that medical professionals usually drive the process. Many of the studies showed that like other forms of knowledge, the claims around medicine were often incomplete and contested, and that in order to become an accepted medical 'fact' additional social work was often needed. If the claims-makers were successful, then the claims would become legitimate medical knowledge, and for example become an accepted medical condition. In the case of the metabolic syndrome, because the 'condition' is seen as controversial this suggests that more work is still required before it becomes recognised as a legitimate medical concept.

One of the first publications to look at medical knowledge from a constructionist perspective was Bloor's (1976) paper on 'Variation in the social construction of medical disposals', which is now seen as a classic by those in the field (Berg, 1992; Gregory and Atkinson, 2007). The term 'medical disposals' was also used by Berg in his 1992 paper, and refers to 'medical problem solving' whereby physicians find solutions to medical problems through 'processes' such as diagnosis and treatment (Berg 1992:154). In his study, Bloor looked at adeno-tonsillectomy (children having their tonsils taken out) and showed how 'Assessment of children for adeno-tonsillectomy is, for ENT [*ear, nose and throat*] specialists, a routine event' (1976:47). He found that there was considerable variation, however, between specialists in the way

they decided whether a child needed surgery. A situation that he suggested was because 'specialists differ considerably from one another in the nature of their routines and therefore in their assessments of patients' (1976:53). He argued that this was because 'The very nature of medical knowledge provides for the possibility of these differences, since the theoretical construction of a disease entity is essentially arbitrary and value-laden and since any disease entity is in effect a general name which can refer to a wide variety of different particular conditions' (1976:43).

This research illustrates how medical knowledge is socially constructed, and can be interpreted in numerous different ways and influenced by 'social factors' such as the medical training of the professionals involved in its creation. It also shows that because the evidence for particular concepts in medicine is often uncertain, additional factors are needed before an issue becomes accepted medical knowledge. Bloor concluded that 'Variation in medical assessments is a natural concomitant of the structure of medical knowledge' (Bloor, 1976: 59). This variation is still limited by the socially and culturally determined notion of medical convention, and the concept of 'good practice', which the physicians will have had instilled into them during their training.

At the time, this represented a new way of looking at medical knowledge, however, other researchers soon followed. For example, a study by Yoxen (1982) showed how renewed interest in genetic science meant that more conditions were being constructed as 'genetic diseases'. Medical sociologists themselves have been far less involved in this work than one might expect, an issue that Bartley suggested was because 'medical sociology has traditionally been concerned with the ways in which medical knowledge is applied' and therefore 'less work has been done on the construction of knowledge in the laboratories of the basic medical sciences' (Bartley, 1990: 371). In the paper, Bartley therefore argued that medical sociologists should adopt social constructionist approaches such as the 'strong programme' to study medical knowledge. She also suggested that this 'new way of looking' at medical knowledge challenged previous Mertonian ideas about the objective nature of medicine, and while there were advantages and disadvantages, this approach had been successfully used by other branches of sociology and she saw no reason why medical sociologists should not take advantage of the 'great opportunities' that this method offered (1990: 387 and 371).

This was a view also echoed by Brown in his 1995 paper on 'The social construction of diagnosis and illness', where he called for the creation of 'a sociology of diagnosis'.

One study that used the 'strong programme' approach to investigate medical knowledge is Nicolson and McLaughlin's (1988) study of the debate surrounding the causation of Multiple Sclerosis (MS). In explaining the methodology, they noted that 'our account of the dispute between the vascular and the auto-immune theory is a thoroughly relativist one' and that 'our explanation of both sides of the dispute is, at least in principle, perfectly symmetrical' (1988:252). In the work, Nicolson and McLaughlin investigated the controversy surrounding two rival claims concerning the aetiology of MS. One claim stated that the condition was an 'auto-immune disease' and had the backing of the mainstream medical profession and was seen as orthodox, whereas the other claim suggested that the condition was a 'vascular disorder' and was seen as more controversial, and only had the backing of a small number of neurology experts. Their analysis showed that social factors, such as the 'skills, interests and backgrounds of the medical personnel involved' in the rival claims were critical in determining the way MS was constructed, with for example specialists in immunology unsurprisingly seeking an immunological explanation for the condition (1988:234). Discussing their findings, Nicolson and McLaughlin concluded that because the incumbent 'auto-immune theory' had the backing of the powerful medical discipline of immunology, supporters of this approach had access to a wider range of social resources and were able to successfully discredit the rival claim. In arguing that the proponents of this theory had to rely on the power of their discipline for the concept to be accepted, suggests that the empirical data behind the theory was under-determined, and that the interests of the players involved then came into play.

In the discussion, Nicholson and McClaughlin highlighted how their 'account of the debate has accorded an important role to prestige, power, authority, and interpersonal and intergroup rivalry. But to acknowledge the presence of these features is merely to recognise that social life in medical and scientific communities shares many of the characteristics of social life elsewhere' (1988:254). They reached this conclusion because the controversy highlighted how both theories were supported by data that were uncertain, and the proponents involved in the 'debate' each claimed that their theories were more scientifically valid, which meant that the only way the controversy would

be resolved was through other social factors coming into play, such as the 'power' and 'authority' of the groups making the claims. In their study they also showed how a number of different expert groups had been involved in the debate over the aetiology of MS, publishing various accounts of their findings. This led Nicholson and McClaughlin to conclude that the 'rivalry' between these groups had been a key factor in keeping the 'debate' going. The controversy only came to a conclusion when social factors, such as the interests and power of the rival groups, began to have an impact.

Although Nicholson and McClaughlin investigated a medical condition that is quite different to the metabolic syndrome concept, both have had concerns raised in relation to their diagnosis and underlying aetiology. Similarly, the medical knowledge surrounding metabolic syndrome is also seen as controversial, and just like MS there are a number of different expert groups involved in the debate over the concept. Therefore the 'strong programme' approach that the researchers used so successfully here to analyse the debate over the causes of MS appears to be an appropriate choice for studying the controversy around the metabolic syndrome concept.

The next area of literature that I will be reviewing relates to the theory of medicalisation, which according to Nettleton 'is perhaps related only indirectly to social constructionism, in that it does not question the basis of medical knowledge as such, but challenges its application' (Nettleton, 2006: 25). Therefore in the next section, I will be looking at how the medicalisation concept is understood, and how it has been used to study the way in which medical knowledge is applied.

II. Medicalisation literature

Medicalisation: Definition and background

In its basic form, 'medicalisation' is the process by which problems that were not originally seen as medical become re-conceptualised in these terms, and can therefore be seen as a form of medical expansion. Conrad, a key exponent of the concept, has described medicalisation as 'a process by which non medical problems become defined and treated as medical problems, usually in terms of illnesses or disorders' (Conrad, 1992: 209). Numerous 'conditions' have been identified as being examples of

medicalisation. These include issues such as drinking too much alcohol, which was originally viewed as a social problem but has increasingly been redefined as a disease, 'alcoholism', which is described as an addiction and comes under the control of the medical profession. Medicalisation theory is also constructivist in approach because it views 'medical' problems as being shaped by social factors, such as disciplinary rivalry. For example, in the field of mental health there is a strong rivalry between physicians and psychologists that has resulted in different explanatory and treatment models emerging for particular conditions. The first group of experts often see problems in biochemical terms, with treatments usually being drug-based; whereas the latter group often see the same issues in cognitive/behavioural terms, and favour 'talking therapies'.

The medicalisation concept was influenced by the work of Zola (1972) and Illich (1976), who were the first to use the term. In both cases the authors were highly critical of medicine and the medical profession. Zola, for example, highlighted how medicine had begun to infringe on people's everyday life, and was concerned that the profession was becoming a tool for 'social control'. Illich was even more strident in his criticism, questioning the entire enterprise of medicine and arguing that in many cases allopathic medicine was actually doing more harm than good in relation to health. Consequently, the term became synonymous with a highly critical approach to medicine, and while academics acknowledge the importance of their work, many have sought to distance themselves from their extreme stance. Hedgecoe, for example, described their approach as the 'Extreme Medicalisation Theory' and criticised Illich's work for being 'driven by polemic rather than empirical data' (Hedgecoe, 1998: 238).

Medicalisation: Early interpretations

In the 1970s medical sociologists began to take an interest in medicalisation and started to use the term themselves. In 1975, Conrad used the concept as an analytical tool to study the medical condition known as hyperkinesis (a term for what today would be described as ADHD or attention deficit hyperactivity disorder and related conditions). In the work he used the theory and example of hyperactivity in children to demonstrate how deviant and unsocial behaviour was increasingly being viewed as a medical problem rather than as a personal moral failing. He outlined the potential consequences of this, which he described in terms of positive and negative outcomes. In the first category he included the potential for 'less condemnation of the deviants (they have an

illness, it is not their fault) and perhaps less social stigma' (Conrad, 1975: 66). In the second category he highlighted four potential negative outcomes, which were 'the problem of expert control', 'medical social control', 'the individualisation of social problems', and 'the depoliticization of deviant behaviour' (Conrad 1975:66-67). The first outcome relates to when conditions or situations are seen as being the preserve of particular expert groups. Therefore when a condition becomes 'medical' it is often seen as being best dealt with by medical professionals. Although expert control can be positive, there can also be downsides, for example alternative viewpoints that may be of benefit to patients may be dismissed because they do not fit with the 'expert' view. In addition, experts can end up wielding too much power over an issue, which again can lead to other less prominent voices being heard. The next outcome relates to the idea that in societies throughout history there have been attempts to control the behaviour of individuals and populations, with social institutions such as the church and the law being used in this task. Since the beginning of the 20th Century, this role has been increasingly taken over by medicine. The third outcome relates to the idea that when conditions become medicalised, the attention automatically tends to go towards the individual because they invariably become the focus as the site of the 'disease' and the treatment. The 'problem' is then increasingly seen as an issue for the individual, even if the factors that caused it are social, such as social inequality, unemployment and poverty. The final outcome relates to the way that by medicalising a particular behaviour, any political factors that may be influencing it may then be ignored. Taking obesity as an example, by constructing it as a medical problem the onus is put back on the individual, while political factors that can influence this such as the promotion of a consumer society are denigrated.

Conrad and Schneider (1980) further developed the concept and published their findings in a book entitled *Deviance and Medicalisation: from Badness to Sickness*, which is now regarded as a key text in the field. In the work, they used the approach to study another group of conditions, which they described as 'madness', opium use and the over-consumption of alcohol; and showed how they had been medicalised and reconstructed as problems of mental illness, heroin addiction and alcoholism, respectively. They again highlighted how these conditions, which had originally been seen as 'moral failings', were now being described as 'diseases', and individuals were being held less accountable.

The early construction of the 'metabolic syndrome' as a medical condition that increases the risk of heart disease/diabetes appears to fit this process because although obesity is acknowledged as playing a role, the issue of insulin resistance is given primacy, which makes the issue appear 'more' medical with the individual identified as experiencing a biochemical rather than moral failing. Even the later constructs of the 'metabolic syndrome' that give prominence to the role of obesity describe this in terms of 'abdominal obesity', which is viewed as a consequence of biological (genetic) as well as environmental (lifestyle) factors. Therefore this concept, which is regarded as an example of the medicalisation of 'obesity', may lead to more individuals being seen as 'sick' rather than 'bad'; the latter opinion being a widely held view in relation to individuals identified as 'eating too much' and/or being 'fat', with a history of moral opprobrium stretching back to the ancient concept of 'gluttony', through to more modern interpretations, such as the notion of the 'beer belly'. However, this absolution of blame is tempered by the fact that the metabolic syndrome concept focuses on the role of individual 'lifestyle' and how this impacts on the condition, with the main treatment option 'therapeutic lifestyle change' also putting the onus back on the individual. It would therefore be more accurate to describe the metabolic syndrome as an example of a partial medicalisation.

Returning to Conrad and Schneider's work, they again looked at the potential impact of medicalisation and expanded on the five consequences that Conrad had described in his 1975 paper, with the addition of two further ones. The first issue was that 'Medical language hides the value judgements made in defining even a medicalized deviance,' where they argued that even though conditions were defined as medical, and individuals were less likely to be blamed, the fact that the particular behaviour had been chosen for medical scrutiny suggests that underneath the 'medical language' moral judgements were still being made about which behaviours were deemed suitable and which were in need of control. This also makes it harder for those wanting to challenge the assumptions about particular behaviour, because when the issues are wrapped up in medical terms they are often seen as more objective. The second issue was that medicalisation leads to the 'exclusion of evil from the discourse of deviance and normalcy' and refers to how behaviour or conditions that would have previously been

described in religious terms as 'evil', for example individuals with a propensity for physical violence, may now be viewed as having an underlying medical condition.

When Conrad revisited the concept in a paper published in 1992 entitled 'Medicalisation and social control', he again highlighted how 'The key to medicalisation is the definitional issue' (1992:211). Elaborating on this, he stated that 'Medicalisation consists of defining a problem in medical terms, using medical language to describe a problem, adopting a medical framework to understand a problem, or using a medical intervention to "treat" it' (1992:211). In highlighting the importance of the 'definitional' side of the issue, Conrad was therefore encouraging researchers to go back and concentrate on the key components of the process in order to gain a better understanding of medicalisation as a whole.

These early interpretations of the process of medicalisation, from Conrad's 1975 work through to the studies published during the 1980s and early 1990s, focused on its role in holding individuals less to blame for their behaviour or condition. They also all consistently put the medical profession at the centre of the process. In relation to the metabolic syndrome concept, however, the latter issue is contested, with some commentators arguing that the process is being driven by the pharmaceutical industry (Gardner, 2006) while others see it as being professionally driven (Buse quoted in Breitstein, 2004). This was an issue that Conrad noted in his 1992 publication, when he acknowledged that medicalisation was 'a sociocultural process that *may or may not* involve the medical profession' (1992:211). The issue of which groups have been driving this process is not only a key point of discussion in the literature on the medicalisation concept, but is also of particular concern to me in relation to the construction of the metabolic syndrome concept. This is because knowing who the main constructors have been has implications for the way in which the concept is constructed, and how medical professionals and patients may view the condition. In this regard, later interpretations of the medicalisation process claim that it is no longer being driven by the medical profession but by other groups, such as the commercial pharmaceutical industry.

In Conrad's 1992 paper, he also sought to differentiate 'medicalisation' from the related concept of 'healthicization (surveillance medicine)'. The latter term was used by

Armstrong (1995) to describe the way medicine in the latter quarter of the 20th Century had changed towards a situation where there was greater emphasis on risk factors, screening programmes and medical surveillance of the general population. The concept has its origins in Foucault's 1973 work *The Birth of the Clinic*, where he discussed the notion of the 'clinical gaze' and self-surveillance. Conrad himself described 'healthicization' as 'when social or behavioural activities are deemed medical risks for well-established biomedical conditions' (1992:223). The metabolic syndrome concept, with its focus on 'lifestyle' and 'risk factors', therefore appears to be just the type of condition that Armstrong was referring to when he described the concept of 'healthicisation'. In the coming chapters I will show how the metabolic syndrome concept is still an example of medicalisation.

In outlining the key differences between the two concepts, Conrad claimed that 'with medicalisation, medical definitions and treatments are offered for previous social problems or natural events; with healthicization, behavioural and social definitions are advanced for previously biomedically defined events (eg heart disease)' and that 'one [medicalisation] turns the moral into the medical, the other [healthicisation] turns health into the moral' (Conrad, 1987)' (1992: 223). This shows that for Conrad the definition of medicalisation is very specific. Other workers view the concept in broader terms and do not make this distinction (Clarke et al, 2003). The concept of healthicisation is therefore another example of the expansion of the medical profession into new domains. The differences between the two concepts here also highlights how conditions and the way they are defined can have significant consequences for patients, which in this case relates to the issue of blame, a topic I will be exploring further in Chapter 7.

Medicalisation: Later interpretations

A different interpretation of the mediclisation theory was put forward by Clarke et al (2003), who argued that the older conceptualisations of medicalisation were no longer valid and that a new concept was needed. This led them to develop their theory of 'biomedicalisation'. This is a process that they described as following on from medicalisation ('the expansion of medical jurisdiction, authority, and practices into new realms'), but being more complex and wide ranging, and more importantly driven by 'technoscientific innovations' (2003:161). Other researchers also claim that technology has been driving the creation of 'new' medical conditions (Hofmann, 2001; Rosenberg,

2003). Rosenberg, for example, used the term ‘technocreep’ to describe the way technology in the form of diagnosis and treatment has become an important influence on disease concepts (2003:502), while Hofmann argued that technology has played a key role in the creation of new diseases in modern medicine because it ‘constitutes the signs, markers and endpoints that define disease entities’ that he called the ‘technological gaze’ (2001:14).

Returning to Clarke et al’s publication, they argued that American medicine and society has been increasingly transformed by ‘technoscientific innovations’ within biomedicine, and therefore the standard medicalisation concept in which medicine moves into areas that were once outside its boundaries, no longer reflects the changes that have taken place. They suggested that this ‘transformation’ occurred around 1985, and that the phenomenon was ‘co-constituted through five central (and overlapping) processes’ (2003:166), one of which was ‘major political economic shifts’ that had led to the increasing ‘corporatization and commodification’ of health in the United States (2003:161 and 167). In relation to the metabolic syndrome, this fits with the claims of some commentators that the creation of the concept was being driven by the commercial pharmaceutical industry (see Breitstein, 2004).

Another two of the processes that Clarke et al highlighted were ‘a new focus on health and risk and surveillance biomedicines’ and ‘the transformation of bodies and the production of new individual and collective identities’ (2003:166 and 180). Again these are relevant to the metabolic syndrome. The first because the condition is based on the identification of a group of cardio-metabolic risk factors, and as such is indicative of a renewed interest in risk and surveillance medicine. The second, because Clarke and colleagues even used the syndrome as an example of the latter process, when they referred to ‘“high risk” statuses, DNA profiles, Syndrome X sufferers’ (2003:162). In their discussion of the theory, they also noted that ‘In biomedicalisation, the focus shifts to behavioural and lifestyle modifications (eg exercise, smoking, eating habits, etc)’ (2003:182), which again fits the metabolic syndrome concept and its emphasis on ‘therapeutic lifestyle change’ as a first line of treatment. Therefore, at first glance this new concept seemed to be a good approach for me to use in my analysis of the condition.

Some commentators, however, are not entirely convinced by Clarke et al's biomedicalisation theory, and have highlighted a number of potential issues with the concept. One significant critic has been Conrad himself. In a paper published in 2005 he acknowledged that 'the authors are certainly correct in many of their contentions' (Conrad 2005:12 notes). He also agreed that 'the shift to biomedicalisation' is an example of 'moving from medical control over external nature to controlling and transforming inner nature' (2005:12 notes). However, Conrad argued that the concept 'loses focus on the definitional issues, which have always been a key to medicalisation studies' and that 'Clarke et al (2003) lose sight of the process of medicalisation itself' (Conrad 2005:5 and 12).

Therefore for Conrad the issue of 'definition' is a key part of 'the process of medicalisation'. For example, one way in which actors claim ownership over social problems is to define them, therefore when medical professionals describe something as a disease, such as alcoholism, they are claiming the issue as their own. Conrad believes that understanding this process is a key part of medicalisation, and that by making their biomedicalisation concept so wide-ranging Clarke et al are not concentrating enough on this important aspect of the process. This shows that medicalisation as a concept has, like the process itself, expanded into so many new areas that the value of these later interpretations as analytical tools for studying particular issues has been diminished. Consequently, while I see advantages in using the approach in my sociological analysis of the metabolic syndrome, I agree with Conrad's assessment that the biomedicalisation concept is too wide ranging, and I will therefore be adopting an approach that is more in line with the earlier interpretations of medicalisation, as exemplified by Conrad and Schneider (1980).

In later publications, Conrad also began to suggest that the process of medicalisation was changing. For example, in a paper published in conjunction with Leiter he argued that in countries such as the United States 'corporations and insurers are becoming more significant determinants in the medicalisation process' (Conrad and Leiter, 2004: 158). In particular, they suggested that the issue of direct-to-consumer advertising of drugs in the US was leading to greater medicalisation.

Conrad developed this hypothesis further, in a paper published in 2005 entitled 'The shifting engines of medicalisation'. In the publication, he argued that 'Doctors are still gatekeepers for medical treatment, but their role has become more subordinate in the expansion or contraction of medicalisation' and that 'the engines of medicalisation have proliferated and are now driven more by commercial and market interests than by professional claims-makers' (2005:10). In highlighting this, Conrad also suggested that 'new pharmaceutical and potential treatments are increasingly drivers for new medical categories' (2005:3), This was in contrast to earlier periods of medicalisation, which he argued had been 'driven' by 'the medical profession, interprofessional or organizational contests, and social movements and interest groups' (2005:10). This therefore represented a significant departure from his earlier work, which had always placed the medical profession at the centre of the process.

In explaining his new interpretation of the process, Conrad claimed that in countries such as the United States 'the engines behind increasing medicalisation are shifting' and that 'biotechnology, consumers, and managed care organisations' are now the most important players (2005:10). In particular, he highlighted the role that pharmaceutical companies have played in promoting conditions such as social anxiety disorder (or 'social phobia') and ADHD. In reference to the issue of obesity, Conrad argued that in the past medical insurance companies 'would not pay for gastric bypass operations' but that 'this is no longer the case' (2005:10). He also noted that 'The recent Medicare policy shift declaring obesity as a disease could further expand the number of medical claims for the procedure' (2005:10). This therefore bolstered his claim that 'managed care organisations' (medical insurance companies) in the US were now one of the main drivers behind medicalisation. In his concluding remarks, Conrad therefore suggested that the best way to analyse this process was by 'supplementing our social constructionist studies with political economic perspectives', but reminded readers that 'Medicalisation still doesn't occur without social actors doing something to make an entity medical' (2005:12).

Contemporary research appears to support elements of Conrad's 'new' theory. In her study of 'shyness', Scott showed how this had become medicalised as 'social phobia' and was an example of 'the medicalisation of social deviance' (2006:148). She also argued that 'In contemporary Western society, therefore, shyness is emerging as a

"new" social problem' (2006:138). In her conclusion, Scott suggested that there were 'at least three main sites in which the medicalisation of shyness is taking place' and listed them as 'in pharmacological remedies and genetic theories, in the therapeutic regimes of shyness clinics, counselling and CBT, and in the disciplinary practices advocated by self-help books and internet resources' (Scott, 2006: 149). The first and last sites match Conrad's hypothesis that 'new pharmaceutical and potential treatments are increasingly drivers for new medical categories' as well as 'commercial and market interests' (2005: 3 and 10). However, with the second site, 'in the therapeutic regimes of shyness clinics, counselling and CBT', Scott clearly still sees a role for medical professionals (albeit 'allied') (2006:149).

In another example, Moynihan, Heath and Henry (2002) claimed that osteoporosis was being promoted as an important disease by a number of pharmaceutical companies, and suggested that this was an example of 'disease mongering' (medicalisation). In the paper, they highlighted how 'like high blood pressure or raised cholesterol levels, the medicalisation of reduced bone mass – which occurs as people age – is an example of a risk factor being conceptualised as a disease' (2002:888-889). These types of 'conditions' often remain symptom-less, and just like metabolic syndrome are regarded as 'risk conditions' that predispose individuals to future disease. For example, high blood pressure and cholesterol are associated with heart disease, and 'reduced bone mass' is linked to osteoporosis. Therefore in many ways these 'conditions' are not true diseases in the medical sense, because they are pre-diseases rather than fully developed conditions. Moynihan et al's argument is that by promoting these conditions, and presumably suggesting early intervention with drug treatments, the pharmaceutical industry is essentially medicalising 'risk factors' and turning them into 'diseases' in their own right. Therefore Moynihan in another paper, this time with Smith, claimed that our lives are becoming ever more medicalised (Moynihan and Smith, 2002).

Conrad's 2005 version of medicalisation is therefore very different from how he originally described the concept in 1975, and was clearly influenced by the economic and social changes that had occurred over the same period. He accepts that 'Doctors are still gatekeepers for medical treatment' but argues that 'their role has become more subordinate in the expansion or contraction of medicalisation', while maintaining that 'the definitional centre of medicalisation remains constant' (Conrad, 2005: 10). Conrad

therefore placed a new emphasis on 'the shifting engines of medicalisation'. However, although this new approach has much to offer, in concentrating on the US where 'commercial and market interests' are prevalent, Conrad is open to the same criticism that he has levelled at others, namely that he has also lost 'sight of the process of medicalisation', particularly given his claim that medical professionals now have a diminished role (Conrad 2005:10 and 12).

Critique of medicalisation theory

Although medicalisation theory has proved a popular approach by which to explore a huge range of conditions, and a significant number of papers have been published on the topic, critics have raised concerns about the concept (Fox, 1977; Bury, 1986; Williams and Calnan, 1996). These have ranged from questions about its applicability as an analytic tool through to how pervasive the process actually is, and whether there is sufficient empirical evidence to support the many claims surrounding the concept. One of the key questions, for example, has been how widespread is the process of medicalisation and what impact has it had on society? Of course, proponents of the concept regard it as being a widespread problem and having a real impact on society, while critics are more sceptical.

One early critic was Fox, who expressed scepticism about the extent of medicalisation. In a paper published in 1977, for example, she showed that the process can also work in the opposite direction. She highlighted how in the United States homosexuality, which had once been defined as a psychiatric condition, had undergone a process of de-medicalisation and was now no longer seen in this way. Another critic was Bury, who again highlighted the rival processes at play in society, when he stated that 'Tendencies towards the medicalisation and rationalisation of society, are, indeed, serious issues, but resistances and limits to this process should be recognised' (1986:165). He also argued that the impact of medicalisation on society was often over-hyped, when he noted that 'In its preoccupation with medicine's supposed role in social surveillance and control it frequently exaggerates the processes at work' (Bury 1986:166).

Bury's first point is backed by research from Williams and Calnan (1996), who explored the 'limits of medicalisation' in contemporary societies and showed that 'far from being simply passive and dependent, a "critical distance" is beginning to emerge

between modern medicine and the lay populace' (1996:1609). As a result, the lay public is now far more likely to question medical authority, and therefore less likely to be influenced by medicalisation. In another article, Moynihan and Smith (2002) argued that 'the Internet, this most contemporary of technologies – combined with the move to patient partnership – is shifting power from doctors back to people' and that 'People may increasingly take charge, more consciously weighing the costs and benefits of the 'medicalisation' of their lives' (2002:859).

Metabolic syndrome and the medicalisation of obesity

The medicalisation of obesity is regarded as a growing problem (Gard and Wright, 2005). The issue of 'fatness' is seen as having been medicalised through the use of terms such as 'overweight' and 'obesity', and the creation of medical specialisms (such as obesity specialists, dieticians, bariatric surgeons), the creation of 'weight loss treatments', and development of 'anti-obesity' drugs (Jutel, 2006; Monaghan, 2007). For example, a report by the WHO stated that 'Obesity has reached epidemic proportions globally, with more than one billion adults overweight – at least three hundred million of them clinically obese – and is a major contributor to the global burden of chronic disease and disability' (WHO, 2003:1-2). A study by Jutel, for example, showed how the term 'overweight' was now being increasingly used as a medical category in its own right, with the author suggesting that this was further proof of the ever-expanding role of medicine in issues to do with weight. The concept of 'overweight' was therefore itself the subject of medicalisation (2006:2268-2269). Similarly, Monaghan suggested that the concept of the 'Body Mass Index' (BMI) was also being used to problematise men's weight, and was critical of the way medicine was defining overweight and obese people by using a measure that many believe is flawed (2007:585). The author further argued that such 'medicalised measures' could lead to the emergence of 'potentially corrosive obesity epidemic psychology' (2007:584).

Throughout the thesis, I have highlighted how metabolic syndrome itself is also regarded as an example of the medicalisation of obesity (Breitstein, 2004). For example, a speaker at the National Obesity Forum's (NOF) annual conference held in London in October 2004 gave a talk that was entitled 'Obesity in the 21st Century – Metabolic Syndrome' (NOF, 2004). Similarly, in an article on metabolic syndrome, John Buse from the ADA was quoted as saying that 'Although there are some overweight people

who don't have the syndrome, obesity is, in essence, the problem' (Breitstein, 2004:8). I also showed that some commentators believe that this is being driven by the pharmaceutical industry; while others believe that the medical profession have been the main movers (Breitstein, 2004; Gardner, 2006).

My analysis of the metabolic syndrome from the perspective of the medicalisation of obesity therefore fits into a growing literature on the topic, with many studies now having been published that have explored the issue from a number of different angles (Chang and Christakis, 2002; Jutel, 2006; Boero, 2007; Monaghan, 2007). For example, Chang and Christakis studied progressive volumes of a US medical textbook – *Cecil Textbook of Medicine* – which had been published between 1927 and 2000, and analysed how obesity had been described in the different editions. Using content analysis they found that obese individuals had been 'progressively held less responsible for their condition in successive editions of the text' and while 'initially cast as societal parasites, they [had been] later transformed into societal victims' (2002:151). In the discussion, the authors therefore concluded that 'The subjection of a behaviour or condition to a medical conceptualisation has been associated with both an increased and a decreased attribution of individual responsibility. In our case – example of the construction of obesity in a fixed source over time, we find elements of both tendencies' (2002:165). Boero (2007) came to a similar conclusion, when she used discourse analysis to investigate the construction of the 'obesity epidemic' in the print media in America, and showed how it had 'come to be defined as a social problem (Spector and Kitsuse, 1977; Sobal and Maurer, 1999) at the same time as it is framed as a problem of individuals' (2007:42). The issue of blame is something I will be exploring later in my analysis of ethical concerns in relation to the metabolic syndrome, in Chapter 7. This therefore brings me on to the third area of literature that I will be reviewing, which relates to the on-going debate between sociology and bioethics. Here I will discuss how the literature helped inform my decision to use a multi-disciplinary approach.

III. The debate between sociology and bioethics

Introduction

In this section, I intend to give an overview of the debate that has taken place between the social sciences and bioethics in relation to the possibility of the two disciplines being able to conduct joint research, and how this influenced my decision to adopt a multidisciplinary approach in my thesis. Before I move on to discuss some of the main themes that emerged during the debate, I will first discuss how the two disciplines differ. The US bioethicist, Daniel Callahan, described bioethics' 'main task' as being 'the determination, so far as that is possible, of what is right and wrong, good and bad, about the scientific developments and technological deployments of biomedicine' (Callahan, 1999). Bioethics is also both a profession and academic discipline. In regard to the latter, bioethics is described as a sub-discipline of philosophy, and a branch of moral philosophy. It is also sometimes referred to as being an example of 'applied ethics' (Hoffmaster, 1992). For example, Zussman (2000) noted that 'philosophical medical ethics is fairly explicitly a branch of applied philosophy' (2000:7).

In contrast social science, according to Emmerich 'does not search for abstract ethical 'fact' in empirical data. Social science seeks to uncover what people think, say and do' (2008:205). Therefore there is a significant contrast between the theoretical and methodological outlook between the two disciplines, with sociology tending to focus on the empirical aspects of everyday life, while bioethics has traditionally dealt with more abstract issues, such as rights and wrongs (Callahan, 1999; Hedgecoe, 2004).

The disciplines of sociology and bioethics have had a difficult relationship over the years, however since the Millennium academics from both sides have attempted to bridge the disciplinary divide and work more closely together (Nelson, 2000; Haimes, 2002, De Vries, 2003, Hedgecoe, 2004; Lopez, 2004; Levitt and Hayry, 2005). For example, in highlighting the potential crossover interests of the two disciplines, Haimes and Williams noted that 'ethics and sociology share a common interest in the ways in which individuals and institutions are both shaped by and shape a range of moral imperatives' (2007:469).

Relationship between the two disciplines

DeVries (2003) suggested that 'The 'sociology in/sociology of' distinction is a useful starting point for thinking about the relation between bioethics and sociology' (2003:283). The 'sociology in' part refers to work conducted by sociologists (although not exclusively) that is then used by bioethics to help explore the particular topic of interest, whereas the 'sociology of' part refers to work also usually carried by sociologists that treats the discipline and/or approaches of bioethics as the subject and studies how it operates. This latter work is therefore of more interest to sociology (DeVries, 2003). The 'sociology in' approach is regarded as a positive relationship, whereas the 'sociology of' approach is regarded as more antagonistic, because here sociology is essentially critiquing the discipline of bioethics. However, even the 'sociology in' approach has not been without its problems, with sociologists perceiving their role as sometimes subordinate to bioethics.

Social science critique/empirical bioethics

Over the past 20 years, the relationship between the two disciplines has become more strained, due in part to increasing criticism of bioethics and its various approaches from the social sciences. Much of the critique has centred on the belief that bioethics is too 'theory-driven' and that the discipline would really benefit from input from the social sciences, in particular empirical data. For example, Tausig et al suggested that 'some scholars argue that bioethics suffers from a low level of rigor because bioethics discourse requires expertise in both ethics/philosophy and biomedical science' (2006:847). Hedgecoe (2001a) in his paper on 'Ethical boundary work' suggested that within the social science critique of bioethics there is a 'spectrum' of views, with Hoffmaster (1992) at the extremely critical end and Callahan (1999) at the more friendly end; with a number of academics somewhere in the middle, who in Hedgecoe's words are 'authors who feel that it is time to reconsider the relationship between traditional philosophical ethics and social science approaches, such as sociology and ethnography' (2001a:307). In promoting the potential role of social scientists and their research, DeVries and Conrad for example noted that 'Sociologists can show bioethicists how social structures, cultural settings, and social interaction influence their work' (1998:233).

The rise of empirical bioethics

The above critique of bioethics resulted in an increasing number of studies where researchers have applied and successfully used social empirical methods to explore bioethical questions (Hoffmaster, 1992; Zussman 2000; Borry et al, 2005). The apparent rise in the use of this method within bioethics has led to some commentators to refer to these developments as the 'empirical turn in bioethics' (Ashcroft, 2003; Borry et al, 2005).

In his paper, 'Ethical boundary work', Hedgecoe discussed the problem of the disciplinary tensions between sociology and bioethics, and in highlighting what social research could offer he suggested that 'philosophers need to accept that the social sciences can play a vital role in assessing the ethical and societal impact of science. This means bioethics has to find a way of incorporating empirical evidence into its considerations, instead of regarding it as threat' (2001a:307–8). In further outlining the advantages of this approach, Borry et al noted that 'It can rule out certain moral choices by pointing out the occurrence of certain unexpected consequences or effects' (2004:41). Similarly, Zussman argued that 'A good deal of medical ethics is based on consequentialist claims that social scientists are well equipped to assess. If an ethical claim is based on the assertion that a practice or arrangement is ethically questionable because it results in a particular outcome, then that claim is empirically testable' (2000:9).

Another approach that has started to gain support is the concept of 'critical bioethics'. This was first described by the social scientist Hedgecoe in a paper published in *Bioethics* that was entitled 'Critical bioethics: Beyond the social science critique of applied ethics'. Here he proposed the introduction of a 'moderate version of the social science critique', and borrowed the term 'critical bioethics' (from Parker 1995) to describe the approach (2004:121). Hedgecoe also stated that this was complementary to Haimes' (2002) earlier work. In discussing the concept, Hedgecoe stated that 'critical bioethics requires bioethicists to root their enquiries in empirical research, to challenge theories using evidence, to be reflexive and to be sceptical about the claims of other bioethicists, scientists and clinicians' (2004:120). He also argued that 'critical ethics must be more than purely descriptive if it is to judge the decisions and choices it documents' (2004:134). Concluding, Hedgecoe suggested that 'bioethicists seem quite

capable of carrying out empirical social science research, without losing their sense of disciplinary identity, while accepting that the way things are can tell us something about the way things ought to be' (2004b:143).

Many bioethicists remain unconvinced and hostile to the critique raised by social science (Turner, 2009). For example Callahan, although receptive to this approach, argued that 'While much of the social-science critique of bioethics has focused on its abstract concepts, its stance of detached objectivity, and its search for universal principles, that is not the whole story' (1999:278). Here he was questioning the social science focus on specific issues in bioethics, which he clearly thought was too narrow a critique. Callahan also questioned the 'empirical turn', when he stated that 'I am uneasy with the contention that the social sciences, and particularly ethnography, offer a better way forward' (1999:285).

Further criticism of the approach came from Robinson and Garratt, who argued that 'You can't prove moral beliefs by using logic, which means you can't prove moral propositions just by piling up facts' (1989:99).

Barriers to joint research: The 'is–ought' problem

One of the many reasons put forward as to why the two disciplines cannot and should not work together is the so-called 'is–ought gap' that the philosopher Hume (1740) identified in his work *An Abstract of a Treatise of Human Nature*. In discussing the problem, Emmerich for example stated that the 'Is–ought distinction firmly displaces moral and ethical "fact" from the empirical (and, possibly, the rational) world' (2008:205). In addition, Robinson and Garratt highlighted how Hume argued 'that we can't use logic or reason to "prove" the truth of moral beliefs' (1999:89). Yet bioethicists and social scientists who that believe it is possible and advantageous to use methods and empirical data from sociology to explore ethical issues are therefore often criticised by opponents of this approach, who refer to the 'is–ought' problem.

Robinson and Garratt highlighted how 'some modern philosophers are now less sure that Hume is right' and that 'there is a growing suspicion that the "is–ought gap" may be more of a doctrine than a fundamental truth about ethics' (1989:92). Therefore many

researchers, including myself, believe that it is possible to conduct sociological and bioethical work side by side, and that this criticism has more to do with disciplinary rivalry than a fundamental problem with the approach.

The issue of the potential disciplinary barriers and the 'is–ought' problem was also raised by Hoffmaster, who noted that 'To train philosophers to be good ethnographers could make them bad philosophers; to train ethnographers to be good philosophers could, in turn, make them bad ethnographers' (1992:1429). However, he claimed that 'The latter worry assumes the legitimacy of the disciplinary boundaries, as well as the exaggerated demarcation between facts and values that helps to sustain those boundaries, that is being challenged here' (1992:1429)..

Concerns regarding the 'sociology in' role

Many social researchers have expressed concern about sociology only being given a minor role in bioethical discussions, for example Nelson (2000) claimed that 'Social science is often seen as able to provide 'just the facts', while philosophy attends to moral values and conceptual clarity and builds formally solid arguments' (2000:12). In outlining how he saw the relationship, Nelson stated that 'The common picture of the relationship between bioethics and the social sciences assigns responsibility for accurately gathering the pertinent facts to epidemiologists, sociologists, anthropologists, and their kin, and for assessing those facts to bioethicists wielding explicitly normative techniques' (2000:13), again highlighting the widely-held view that sociologists often end up playing a subordinate role, when conducting joint research with bioethics. Zussman raised similar concerns, when he noted that 'The notion that the task for social scientists interested in medical ethics is to test consequentialist claims leaves the sociology of medical ethics in an uncomfortable position. It makes the social scientist a junior partner to the philosopher, someone who responds to ideas generated elsewhere but who generates few if any ideas on his or her own' (2000:10). Similarly, Levitt noted that 'Whilst normative ethicists do see the need for empirical input from science and medicine, they tend to want 'facts' rather than insights' (2004:81).

A number of social scientists have challenged this viewpoint. For example, Haimes (2002) in her paper on 'What can the social sciences contribute to the study of ethics?'

argued that 'By virtue of their theoretical as well as their empirical interests, the social sciences have more to contribute than just "the facts"' (2002:91). Outlining her perspective on the issue, Haimes noted that 'besides providing many of the methodological tools used by others, the social scientist has the broad range of theoretical and epistemiological resources that assist him/her to make further sense of those situated practices' (2002:107). She also highlighted the unique set of skills that sociologists could bring to studying an issue, when she further noted that 'It is these attempts to connect the empirical data with theoretical explanations that make the social science enterprise distinctive and which take it beyond the handmaiden, "scooping up" role'. (2002:107).

Implications for my research approach

The debate between the social sciences and bioethics in regard to conducting research together has exposed a number of serious issues concerning the adoption of such an approach. It has also highlighted the numerous theoretical and methodological differences between the two disciplines. As a result, many researchers have concluded that joint research and/or the use of approaches from each other's disciplinary field is simply impossible. For example, Callahan argued that 'Ethics must, in the end, be ethics, not social science' (1999:285). In addition, Lopez also suggested that 'Perhaps it is best to accept that bioethics and sociology each do their own thing' (2004:892). However, there does seem to be a genuine desire on the part of the two groups involved to work together and somehow accommodate 'empirical research' into bioethical discussions.

Having reviewed this literature, while there is clearly scope for collaboration between the two fields and joint research offers much potential, the methodological and disciplinary barriers make this task highly problematic. For this reason, after consideration I decided that while I still wanted to use analytical approaches from both disciplines, that trying to combine them in a quasi-socio-/bioethical approach would lead me away from the main focus of my project, which was the metabolic syndrome concept and the social and ethical issues that it raised. As a result, I decided to adopt a multidisciplinary approach, keeping the two disciplines distinct. This enabled me to explore my topic of interest from the two perspectives. I would then be able to present my data 'side-by-side' in the thesis, in much the same way that a larger project with

researchers from different backgrounds would do, when presenting their joint findings in a report. This way you enjoy the benefits of looking at an issue from two perspectives, without having to engage with the associated methodological and disciplinary baggage, which would come with more integrated/interdisciplinary approaches.

Chapter summary

The literature outlined in this chapter helped me to formulate my research questions in relation to the metabolic syndrome concept. Regarding my sociological analysis, the work here showed that social construction played a key role in the creation of 'new' medical knowledge, and that factors such as interests and the rivalry between different groups were important in this process, therefore showing that these were areas that I should explore in relation to the metabolic syndrome concept. My discussion here also highlighted the applicability of using approaches such as the 'strong programme' from SSK to study controversies, such as the one surrounding the metabolic syndrome.

The literature on the medicalisation concept also gave me direction in regard to analysing the claims that metabolic syndrome was an example of the medicalisation of obesity, particularly in relation to the different claims regarding who the main players behind the process have been, with the medical profession and pharmaceutical industry both implicated. For example, the work here showed that early interpretations of the medicalisation process put the medical profession at the centre and as the main driving force, while more recent interpretations claim that the process is now being driven by the commercial sector. In my examination of the metabolic syndrome concept, I will therefore be paying particular attention to this issue, and where the condition fits in relation to these two competing theories.

The literature here also highlighted how researchers had investigated the potential implications of medicalisation, and had shown that it had both positive and negative consequences. This therefore helped inform my bioethical analysis because it highlighted areas of potential interest in relation to my study of the potential ethical consequences associated with the creation of the metabolic syndrome concept.

In addition, the literature on the debate between sociology and bioethics highlighted the numerous differences between the two disciplines, and the difficulties and problems encountered when joint research had been attempted. This therefore helped to inform my decision in relation to using a multi-disciplinary approach when analysing the metabolic syndrome concept from the perspective of sociology and bioethics.

Chapter 3
Methods

Introduction

This thesis explores the metabolic syndrome from a social and bioethical perspective, paying particular attention to the way ethical issues raised by the concept have been discussed. I therefore make use of theoretical and methodological approaches from two disciplines: sociology and bioethics. More specifically, I have used constructivist approaches drawn from sociology to complement the 'four principles' approach of bioethics.

This chapter describes the theoretical and methodological approaches I used during the collection of the data. The chapter is divided into five sections. In the first, I discuss the theory underpinning my sociological analysis. In section two, I outline the theory and methods used in my bioethical analysis. In section three, I discuss the specific approach — thematic analysis — that I used to analyse the data. In section four, I detail my approach data collection and analysis, with specific reference to documentary analysis and interview methods. The chapter concludes with a short section on methodological reflections.

1. Sociological analysis

This section sets out the philosophical underpinnings of the approach adopted, the methods used to collect the data and techniques used to analyse these data.

Philosophical foundations: science and technology studies

There is a wide range of research that can be gathered under the label of science and technology studies (STS). For example, in addition to the strong programme proposed by David Bloor (1976), there are several other influential approaches that also claim to explore the ways in which scientific knowledge is socially constructed. These include: the empirical program of relativism (Collins, 1981), laboratory studies (Knorr-Cetina, 1981; Latour and Woolgar, 1986 [1979]; Collins, 1985, 1991), ethnomethodological studies (Garfinkel et al, 1981), discourse analysis (Gilbert and Mulkay, 1984), reflexivity and new literary forms (Ashmore, 1989) and (Latour and Woolgar, 1986

[1979]; Latour 1987, 2005). If the emphasis is extended to include the development of technologies as well as science, then you can also add the social construction of technology (SCOT) (Pinch and Bijker, 1987; Bijker, 1995) and large technical systems (Hughes, 1987) to the list.

A different classification of the field can be produced by focusing on the problem addressed, rather than the epistemological project the authors claim to be following. In a review of the STS field, Hess (2001) distinguishes between two generations of ethnographic research in STS. According to Hess, the first generation of STS was concerned with describing the processes by which scientific knowledge-claims acquired their credibility. This category contained many of the canonical works of STS including, but not limited to, Bloor (1976), Shapin (1975), Mackenzie (1978), and Latour and Woolgar (1986[1979]). In contrast, the second generation of STS research was characterised by more explicitly political research that takes the core ideas of symmetry and applies them in a more directly engaged form of scholarship. Feminist STS (Clarke, 1998; Martin, 1991b; Haraway, 1991) is the paradigm case, but post-colonial studies (Harding, 1993; Abraham, 2000) and post-positivist studies (Fischer, 2003) also use STS insights in a similarly proactive way.

In developing my own study, my approach has been more closely influenced by the studies within the first generation of STS works. Specifically, I have drawn on the constructionist approaches developed in the canonical STS literature to study the creation of the metabolic syndrome concept as a context and culturally-dependent negotiation about the interpretation of empirical data (Bloor, 1976, 1991; Collins, 1985, 1991; Shapin, 1994, Barnes et al, 1996). In drawing on this interpretivist tradition, I am primarily interested in the way that actors make sense of data and how meaning is constructed through the interplay of ideas and actions (Winch, 1958). This requires a symmetrical approach (Bloor, 1976, 1991) and what Collins has characterised as 'methodological relativism' (see Labinger and Collins, 2010, chapters 12, 15 and 26) in which all empirical claims made by participants in the debate are analysed in the same way (Mackenzie, 1978; Collins, 1981; Nicolson and McLaughlin, 1988; Martin, 1991a). Rather than attempting to replicate biomedical research into the relationship between particular definitions of metabolic syndrome and other health problems, such as high blood pressure, type 2 diabetes and heart disease, the focus here is on the ways

in which different ideas of the metabolic syndrome gain and lose legitimacy within the medical and scientific communities (Nicolson and McLaughlin, 1988; Collins, 1991; Richards, 1991).

In developing this interpretive approach, I was particularly influenced by approaches that related to the strong programme (Bloor, 1976, 1991) and the empirical programme of relativism (Collins, 1981). In this way, my study is not connected to the STS literature through its adoption of a particular method of data collection and analysis, such as ethnography or discourse analysis, as both approaches are compatible with a wide range of qualitative methods, such as Shapin and Schaffer (1985) (historical approach), Lynch (1985) (ethnomethodological), Atkinson (1995) (ethnographic), and Collins (2004) (participant comprehension). Instead, the link to STS comes via the question I sought to answer — i.e. how is the idea of metabolic syndrome created and contested over time — and the recognition that the under-determination of evidence (Duhem, 1962; Quine, 1961; Collins, 1985, 1991) means that when seeking to explain how scientific controversies emerge and are eventually closed down, social factors need to be considered alongside empirical data collected by participants.

This interpretive approach has been used in a number of historical and contemporaneous studies that have used methods as diverse as case studies (Nicolson and McLaughlin, 1988), anthropological strangeness (Latour and Woolgar, 1986 [1979]), ethnography (Cetina, 1999), and documentary analysis and interviews (Hislop and Arber, 2003; Jutel, 2006). The reason I decided to use this approach, and what links the methodologically diverse range of studies that use it, is the role of 'interests' in the construction of scientific knowledge and the adherence to the four 'tenets' of causality, reflexivity, symmetry and impartiality (Bloor, 1976, 1991).

The last two tenets of symmetry and impartiality are seen as being key components of the approach (Bartley, 1990; Hacking, 1999:202) and are also the link to the empirical programme of relativism (Collins, 1981). Focussing on symmetry and impartiality directs researchers to explore 'knowledge claims' from all perspectives, irrespective of them being seen as correct or not, to study the interests of those involved, and to put forward social explanations for both successful and failed claims (Bloor, 1976, 1991; Barnes et al, 1996).

Studies (such as MacKenzie, 1978) using this approach have shown how the 'interests' of scientists can influence their knowledge claims, and that this can be at the macro level (e.g. social class position, such as Shapin (1975) and Mackenzie (1978)), or at the micro level (specific professional interests) of those involved (Pickering, 1984; Nicholson and Mclaughlin, 1988). Bartley referred to these types of studies as being either 'social interest' or 'technical interest' studies (1990:377). The classic studies in this tradition include McKenzie's (1978) socio-historical analysis of the development of statistical tools during the late 19th and early 20th centuries in which he argued that the creation of this knowledge had been strongly influenced by the social class of the scientists involved, or Pickering's (1984) study of the formulation of the idea of 'quarks' in physics in which he showed how the technical interests of the scientists involved had played an important role in the theory gaining prominence. More recent studies that again show how social and technical interests combine to challenge and, in some cases, change scientific consensus include Jasanoff (2005), Hilgartner (2000), and Bijker, Bal and Hendricks (2009). All influenced my work through their interest in the background of the scientists and wider social context, rather than through the specific method of data collection or analysis.

There are also many studies that apply the same approach to medical settings. These include Nicholson and McLaughlin's (1988) work on the construction of competing theories for the underlying cause of multiple sclerosis (MS), which used a 'strong programme' methodology and showed the suitability of this approach for the analysis of medical knowledge. Here they applied the principles of symmetry and impartiality to explore the controversy surrounding the aetiology of MS, exploring the conventional 'immunological theory' and controversial 'vascular theory', treating both theories equally and offering sociological explanations for the success and/or failure of the respective knowledge claims. Similar results have also been reported by a number of other symmetrical studies of medical research, including Epstein (1996), Featherstone et al (2005), and Latimer et al (2006).

Although, as the idea of a second generation of STS suggests, there are some who now regard a narrow focus on the construction of scientific knowledge as somewhat outdated (Woolgar, 1981; Callon, 1986; Latour, 1987), the value of the approach

remains important. Even those who explicitly advocate the need for more engaged forms of STS (e.g. Collins and Evans, 2002, 2007; Harding, 1986; Haraway, 1991; Keller, 1992) still insist on the value of the more traditional STS approach.

2. Bioethical Analysis

Principlism: introduction

The bioethical aspects of the study draw on an approach known as 'principlism', which is an ethical theory developed by Beauchamp and Childress and published in *Principles of Biomedical Ethics* (2001[1979]). The method is based on the four key ethical principles of respect for autonomy ('freedom of choice'), beneficence ('do good'), non-maleficence ('do no harm') and equity (fairness/ justice). The approach has a strong affinity with the ideals laid down in the 'Hippocratic oath' taken by medical professionals (Shickle and Chadwick, 1994: 14; Calman and Downie, 2002:387).

The individual and their autonomy are central in this ethical framework and the approach has enjoyed support in countries that place individual rights at the centre of their social, cultural and political systems. This includes the United States, where the approach chimes with one of American society's fundamental principles, namely the rights of the individual and personal freedom (Callahan, 1999; Evans, 2000; Kuhse and Singer, 2001). This bioethical approach is also popular with medical professionals, because it is seen as complementary to Western medicine's notion of patient-centred care, informed consent and choice (Bosk, 1999; Evans 2000).

The principlist approach to bioethics does have limitations, however, and has come in for significant criticism (Hoffmaster, 1992; Holm, 1995; Bosk, 1999; Hedgecoe, 2004). The core of these criticisms is the claim that 'principle-based approaches reduce ethics and bioethics to the analysis and resolution of moral quandaries and dilemmas' (Childress, 2001:69). This, in turn, leads to the argument that principlism is of little practical value, with critics such as Hoffmaster arguing that 'the principles standardly regarded as constituting the core of theoretical medical ethics – principles of autonomy, beneficence, non-maleficence and justice for example (Beauchamp and Childress 1983) – are too general and vague to apply determinately to concrete situations' (1992:1422).

This distance between the principles and their application is also highlighted by Hedgecoe, who writes that ‘While it is perfectly possible for social science research to support the principlist approach (for example), it is also quite likely that in some, if not many cases, the evidence will not fit into this particular way of structuring the social world’ (2004:137). In addition, Gillon (an advocate of principlism) also noted how the approach had received 'sometimes incredibly powerful hostility’ (2003:307).

In regard to my study, even at this early stage it was apparent that the Metabolic Syndrome encompassed a number of different concepts and that the issue was complex. I therefore wanted to use a bioethical method that was well proven and had already been used to study a wide range of topics. Principlism meets this requirement as even its critics acknowledge that ‘Although the “applied ethics” model (as represented by principlism) may not represent all opinion in bioethics, it is the mainstream approach, both in academia, the clinic, and in media representations of bioethics’ (Hedgecoe 2004:123). For this reason I chose the ‘four principles’ approach as the starting point for my bioethical analysis.

The principlist approach to bioethics is based on applying ethical principles to practical situations in order to reach ethically acceptable outcomes. In outlining the approach, Evans notes that ‘the principles [principlism] were created to enhance calculability or, in more common language, to simplify bioethical decision-making’ (2000:32). This is not to say that these rules are applied automatically, however. As Beauchamp and Childress stated when setting out the fundamental principles of the approach ‘rule-orientated theories allow for discretionary judgments when rules [*principles*] are conceived, as we propose, as prima facie binding rather than as absolute or as rules of thumb’ (1989:62). This means that the approach is capable of developing highly nuanced ethical arguments as the ethical analysis considers how best to apply the rules in any given context. As Gillon argues ‘Although the approach is basically simple […] it is also indefinitely complexifiable – certainly complexifiable enough to incorporate the many insights offered by alternative approaches, with most of which it is compatible’ (2003:311).

Principlism: using the approach

In my analysis, I used the 'four principles' approach to explore the ethical arguments put forward by the protagonists in the medical / scientific debate surrounding the Metabolic Syndrome concept. This included categorising and analysing the arguments that were made and using the principles to identify other relevant ethical issues that were not discussed in the medical / scientific literature. The exploration of these concerns was also consequentialist in approach, with outcomes described in terms of being 'good' / positive or 'bad' / negative.

As I will be using each of the four principles analytically, it is important to define what I mean by these terms. Beginning with the principle of autonomy, although this has been defined in a number of ways many of these definitions describe autonomy 'as an individual's self-determination' or a variation of this theme (Andorno, 2004:436). This is the definition that I will be using during my analysis. Following Nilstun et al (2008) I treat the principles of beneficence ('do good') and non-maleficence ('do no harm') as a single concept. This leads to the following definition:

The principle of beneficence (including non-maleficence) affirms the obligation on health care professionals to minimize harm and maximise benefits. Harm can only be justified if unavoidable and if it occurs during attempts to achieve greater good (mostly but perhaps not exclusively) to the individual concerned

(Nilstun et al 2008:4)

In defining the fourth principle of equity (fairness/justice), I follow Calman and Downie (2002), who stated that 'Equity is about fairness and justice. It has an ethical dimension in that judgements need to be made in relation to society as a whole. It is concerned, therefore, with avoiding unfairness in opportunity and choice [and] implies that everyone should have an opportunity to attain his or her full potential for health' (2002:387 and 388). Wikler (1987) also explored the issue of fairness in his paper 'Who should be blamed for being sick?' in which he questioned many of the assumptions around 'personal responsibility for health'; this also influenced my approach.

Public Health Ethics and Medicalisation

Although Calman and Downie (2002) used 'ethical principles' to explore public health in their chapter in the *Oxford Textbook of Public Health* (Detels et al, 2002), the 'four principles' approach is typically seen as less applicable in relation to public health ethics. This is because the public health puts a greater emphasis on ethics at the population level rather than at the individual level (Bayer and Fairchild, 2004). As a result, I additionally made use of the concept of medicalisation and its consequences to identify further ethical concerns in relation to the Metabolic Syndrome and its related versions. The idea for this approach primarily came from Verweij's 1999 paper in which he highlighted how 'preventive medicine is sometimes criticised as it contributes to medicalisation of normal life' and later that 'Although 'medicalization' is used as a *description* of certain social processes, the term has a strong pejorative connotation' (1999:89 and 92).

In the work, Verweij described how he had changed his position on the issue, rejecting his initial attempts to separate the 'normative' from the 'descriptive' elements of the term and instead concluding that 'this simplification of the concept is(*was*) not appropriate, because in moral debates about preventive medicine people do use the term 'medicalisation' to express moral intuitions which criticise this increasing importance of health, illness and medicine in daily life' (Verweij, 1999:93).

He then went on to explore these 'moral intuitions' in more depth, identifying six potential negative effects / moral problems of medicalisation in relation to preventive medicine, which he divided into two groups: those that had an 'effect on peoples well-being' and those that had an 'effect on people's freedom and moral beliefs'. The former is sub-divided into two issues, the 'iatrogenic risks of prevention' and 'the accumulation of uncertainty' (1999:94-96). In regard to the latter, Verweij highlighted four further issues: 'responsibility for health and victim blaming'; 'the loss of autonomy and independence'; 'the importance of the value of health in the lives of persons'; and 'the obligation to participate in prevention' (1999:98-107). Many of these issues are the same as those already identified by Zola (1972), Illich (1977), Wikler (1987), Conrad (1992) and others, and Verweij acknowledged that his discussion builds on this earlier work. Verweij's (1999) paper has also been influential in its own right and is cited by

a number of researchers including Dondorp and De Wert (2009), Radoilska (2009), Brennan et al (2010), De Wert, Dondorp and Knoppers (2012).

In relation to my study of the ethical concerns surrounding the Metabolic Syndrome concept, I made particular use of the first four of these six issues. This involved exploring each individual issue in relation to the Metabolic Syndrome and its related concepts, and seeing how these could potentially impact on individuals identified with the 'condition' and what if any ethical concerns they raised. Here I used the data collected from my documentary and interview analysis, to see whether any of these issues (such as the 'iatrogenic risk of prevention') were a potential problem in relation to the Metabolic Syndrome and its related concepts. For a more detailed explanation of my constructionist analysis, please refer to later sections in the chapter.

Drawing on a different approach, but still focusing on medicalisation, De Vries (2007) explored 'the ethical intricacies of professional engagement with obesity, and particularly childhood obesity' (2007:56). Discussing the potential consequences of this scientific construction of the 'obese child' as an object of medical intervention, De Vries concluded that 'The medicalisation of the condition confronts the overweight and obese child and his or her parents with a set of fixed expectations, not the least of which is the social expectation of "getting better"' (2007:65). Taken together, these studies illustrate the value of medicalisation as a conceptual tool for exploring the ethical issues raised by public health medicine

3. Thematic analysis: a qualitative methodology

Introduction

The specific approach used for my data collection and analysis of the materials related to metabolic syndrome was 'thematic analysis' (Aronson, 1994; Miles and Huberman, 1994; Silverman, 1997; Boyatzis, 1998; Attride-Stirling, 2001; Tuckett, 2005; Braun and Clarke, 2006; Saldana, 2009; Guest et al, 2012). The approach is described as 'a method for identifying, analysing, and reporting patterns (themes) within data' that 'involves the searching *across* a data set — be that a number of interviews or focus

groups, or a range of texts — to find repeated patterns of meaning' (Braun and Clarke, 2006:79 and 86). Although this method is often associated with 'grounded theory' (Glaser, 2002), this is not a requirement and researchers using it can decide for themselves what theoretical position to take (Braun and Clarke, 2006:81). In fact, thematic analysis is regarded as 'a flexible approach that can be used across a range of epistemologies and research questions' and this is often highlighted as one of the main reasons why researchers should use the method (Braun and Clarke, 2006:97).

Although thematic analysis offers many advantages and is popular, many researchers are still reluctant to use the method (Braun and Clarke, 2006). It has been suggested that this is because the approach 'is poorly demarcated and claimed, yet widely used' and therefore 'currently has no particular kudos as an analytic method' (2006:97). Braun and Clarke also suggest that it is perceived as a method 'simply carried out by someone without the knowledge or skills to perform a supposedly more sophisticated — certainly more kudos-bearing — 'branded' form of analysis like grounded theory, interpretative phenomenological analysis or discourse analysis' (2006:97). However, they claim that 'Through its theoretical freedom, thematic analysis provides a flexible and useful research tool, which can potentially provide a rich and detailed, yet complex account of data' (2006:78).

Themes

In describing this approach in more detail, Guest et al (2012) noted that 'Thematic analyses move beyond counting explicit words or phrases and focus on identifying and describing both implicit and explicit ideas within the data, that is, themes' (2012:10). Therefore the identification of 'themes' is seen as a key part of this analytical approach (Ryan and Bernard, 2003; Tuckett, 2005). In describing what a 'theme' is, researchers such as Braun and Clarke suggest that 'A theme captures something important about the data in relation to the research question, and represents some level of *patterned* response or meaning within the data set' but that 'the 'keyness' of a theme is not necessarily dependent on quantifiable measures' (2006:82). They also described how 'A thematic analysis at the latent level goes beyond the semantic content of the data, and starts to identify or examine the underlying ideas, assumptions, and conceptualizations — and ideologies — that are theorized as shaping or informing the semantic content of the data' (2006:84). This is the approach I used in relation to my

study of the metabolic syndrome, where I treated the 'themes' identified as part of the wider claims-making process around the concept.

Coding

Following on from the identification of potential themes, Guest et al highlighted how 'Codes are then typically developed to represent the identified themes and applied or linked to raw data as summary markers for later analysis' (2012:10). Therefore 'coding' is an integral part of this qualitative analysis (Coffey and Atkinson, 1996; Boyatzis, 1998; Payne and Payne, 2004; Hruschka et al, 2004; Saldana, 2009). However, Payne and Payne noted that 'Interpretation also involves returning to the original texts and summaries to test explanations' and that 'Thus "coding", "data analysis" and "interpretation" merge into one another' (2004:41). The blurring of the boundary between data and their analysis was also recognised by Braun and Clarke, who noted that 'Analysis involves a constant moving back and forward between the entire data set, the coded extracts of data that you are analysing, and the analysis of the data that you are producing' (2006:86). There are numerous ways of carrying out 'coding', from manual through to computer-based approaches (Coffey and Atkinson, 1996; Boyatzis, 1998; Fielding and Lee, 1991). In regard to my study, I used manual coding that involved identifying and creating codes by annotating hard copies of documents, an approach that I will be explaining in greater detail later in the chapter.

Inductive thematic analysis

The specific approach I used for my thematic analysis was an exploratory (content-driven) approach, which is also referred to as an 'inductive thematic analysis', as outlined by Braun and Clarke (2006) and Guest et al (2012). This is where 'the themes identified are strongly linked to the data themselves (Patton, 1990)' (Braun and Clarke, 2006:83). This method was also appropriate for my analysis of the metabolic syndrome because I was specifically interested in the question of how, why and who had constructed the concept. I also adopted an iterative approach to my thematic analysis, meaning that when new issues or developments emerged, I was able to react to these and adjust my data collection and analysis accordingly (Miles and Huberman, 1994; Cox and McKellin, 1999; Hruschka et al, 2004).

In 2006, Braun and Clarke published a set of guidelines for using thematic analysis, in which they produce a more formalised definition of the approach based on six phases. This work influenced the way I carried out my thematic analysis of the metabolic syndrome concept, and I be discussing the approach and its affect on the study later in this chapter.

Inductive thematic analysis: study examples

There are numerous analytical methods available to explore texts/documents, which include approaches such as content analysis, discourse analysis, and thematic analysis (Coffey and Atkinson, 1996; Silverman, 1999; Denzin and Lincoln, 2011). These approaches have been used to study data sets of widely varying sizes, from Jutel's (2006) study into the emergence of overweight as a disease entity in medical publications between 1964 and 2003, in which she used content analysis to analyse well over 1,600 documents; and Boero's study of the American 'obesity epidemic' in the media in which she used discourse analysis to explore '751 articles on obesity that appeared in *The New York Times* between 1990 and 2001' (2007:43); through to Chang and Christakis's (2002) work on the medical modelling of obesity, which also used content analysis to look at five editions of a US medical textbook that were published between 1927 and 2000. All of these studies took a constructionist perspective to their topic of interest.

As highlighted above, many researchers with an interest in the creation of scientific/medical knowledge have used discourse analysis as a means of analysing documents and texts. Some workers favour studying a small number of texts in great detail, for example Hedgecoe's (2003) study of the construction of cystic fibrosis was based on the analysis of two review articles, and used a methodological approach pioneered by Myers (1990). In contrast, Kerr who had also studied the construction of cystic fibrosis opted to analyse 80 professional accounts (2000:852), However, as Hedgecoe later noted 'That we both reach largely the same position regarding the expansion of CF classification supports both of our individual approaches as well as the social constructionism underpinning our work' (2003:53). Thus the range of approaches taken, even when researchers are using the same type of analysis, can vary greatly, but this does not alter their validity. Braun and Clarke in discussing the decision to use a specific analytical approach argued that 'What is important is choosing a

method that is appropriate to your research question, rather than falling victim to 'methodolatry', where you are committed to method rather than topic/content or research questions (Holloway and Todres 2003)' (2006:97).

I also chose to use this approach to explore the medical construction of the metabolic syndrome because its flexibility means it is well suited to the constructivist approach required by an STS-inspired analysis. The flexibility of the approach is also demonstrated by its ability to handle data sets of widely varying size. For example, Cox and McKellin's (1999) study of predictive testing and the construction of risk for Huntington's disease used a thematic approach to analyse in-depth interviews with 21 families (62 individuals in total). Although this produced a significant amount of data, the researchers were able to carry out an analysis and to later claim that 'This process yielded new insight into familial constructions of hereditary risk, patterns of communication, experiences of predictive testing and interpretations of clinical information' (1999:628). This research therefore shows that thematic analysis is a suitable approach for my study, which although smaller in size will also be exploring the construction of risk using a comparatively large qualitative data set.

Similarly, Scott's (2005) research on shyness in which she explored 'accounts of managing the shy identity in everyday life' also used thematic analysis and was based on data collected from 40 self-defined shy people. Here she used 'a combination of unstructured, in-depth interviews and an e-mail based distribution list', which enabled her to produce 'a wealth of rich, qualitative data in the form of personal narratives about living with shyness' (2005:93). However, Scott did not use Braun and Clarke's (2006) approach to thematic analysis, but instead coded by hand and then used the qualitative software package ATLAS/ti, which enabled her to identify a number of different themes in relation to 'living with shyness'. Although Scott used a different theoretical approach here, which was symbolic interactionist, this presented no additional problems and again highlighted the flexibility of using a themes-based analytical method.

In contrast to the above studies, Hislop and Arber's (2003) work 'Understanding women's sleep management' was largely based on data collected from 10 focus groups (82 participants), although they did also carry out five interviews with GPs. This collection method (focus groups) again generated a significant amount of data;

however, the researchers were still able to identify three broad themes, which were based around ideas of 'personalisation', 'medicalisation' and 'healthicisation' (2003:820, 825 and 832). This study was also of interest to me because the researchers had additionally used the concepts of medicalisation and healthicisation ('surveillance medicine'), and I was considering using a similar approach in my analysis of the metabolic syndrome and its relationship to obesity.

Although there are various ways of carrying out thematic analysis, as highlighted above, the approach advocated by Braun and Clarke (2006) has been used in a number of studies in recent years. For example, Marcu et al (2011) used the approach in their paper 'Making sense of unfamiliar risks in the countryside: the case of Lyme disease'. This work was based on data collected from 66 semi-structured interviews that 'were conducted with 82 visitors in Richmond Park, New Forest, and Exmoor National Park in the UK' (2011:843). Taking a constructionist perspective, the researchers were able to identify a number of themes that enabled them to gain a better understanding of the lay interpretation of the risk associated with Lyme disease. This showed the suitability of Braun and Clarke's approach for my analysis, because this study also explored a contested 'condition' from a constructivist perspective, and was based on a data set of a similar size to the one I was intending to use in my work.

Fielden et al (2011) also used Braun and Clarke's approach in their work on children's understandings of obesity; however this study was much smaller than the one above and was based on the analysis of data from four focus groups (12 participants). Following the six stages suggested by Braun and Clarke in their guidelines, the researchers were able to identify four main themes that they defined 'as 'knowledge through education', 'role models', 'fat is bad', and 'mixed messages' (2011:7174). Although this study took an uncritical view of the biomedical perspective on obesity and was therefore theoretically quite different to my study, it again highlighted the adaptability of thematic analysis as a method.

The previous five studies all used data collected from interviews, focus groups or e-mail discussion, but as noted earlier the approach can equally 'be used to analyse free-flowing text from secondary data sources, such as in document analysis' (Guest et al, 2012:4). For example, Carroll et al (2011) used the method to study manufacturers'

submissions to the NICE Single Technology Assessment (STA) process. Here they were particularly interested in 'the textual descriptions of the strengths and weakness of manufacturer submissions' (2011:136), the research itself being based on 'a documentary analysis of the first 30 ERG (*Evidence Review Group*) reports produced for the STA process' (2011:137). Following the analysis, the researchers claimed that 'various themes emerged from the data' (2011:136). This work was again of interest, because it showed that it was possible to analyse a documentary data set of this size using thematic analysis, therefore proving that it was feasible to study the metabolic syndrome concept using a similar methodology and number of documents as this.

Braun and Clarke's approach has also been successfully used to study much larger data sets. For example, De Brun et al (2013) used inductive thematic analysis to explore the Irish media representation of obesity. The work itself was based on a study of '346 print news articles' (2013:19). Using a constructionist perspective, they were able to identify 'three main sub-themes under the broad theme of gender roles and responsibility for obesity' (2013:19). This research showed that the ability to carry out a successful thematic analysis is not effected by the size of the data set. In another example, Attard and Coulson (2012) used Braun and Clarke's approach to study patient communication in Parkinson's disease online support group discussion forums. Here they collected data from 'four Parkinson's disease discussion forums' in which '1,013 messages were selected and downloaded for analysis' (2012:504 and 502). Following the analysis Attard and Coulson identified six major themes. Describing them in detail they stated that 'The first three themes highlighted the positive aspects of the peer to peer communication in the Parkinson's disease forums and the second three illustrated the negative aspects' (2012:501–502). This again shows the flexibility of thematic analysis and its ability to cope with large data sets.

4. Data collection and analysis

Introduction

The primary source materials for my documentary analysis were medical/scientific publications, with particular emphasis on literature related to the diagnostic definitions and review articles. This included an analysis of Reaven's 1988 paper on IR and human disease, which re-ignited interest in the issue and led to the creation of syndrome X and

the formation of this 'new' field of research. In addition to my documentary/textual analysis, I also collected interview data. This involved conducting interviews with two of the main academic players in the field, Gerald Reaven and Robert Eckel, individuals who were recognised as being 'key' claims-makers by their academic peers. I transcribed these interviews and then used this material to aid my analysis of the construction of the metabolic syndrome. I will be discussing the methods/analysis used in regard to the interviews in more detail in a later section.

Documentary analysis

Documentary sources

Texts and documents are an important source of data for social researchers, particularly those using an interpretive approach (Silverman, 1993; May, 2001; Platt, 2003; Prior, 2003). For example, Hammersley and Atkinson in their publication on 'ethnography' explicitly remind readers that 'In recommending attention to written sources and accounts, in appropriate social settings, we are aware of their historical place in the intellectual tradition of interpretative social science' (2003:158).

In discussing the types of documentary sources/materials available, Hammersley and Atkinson also noted that 'they may be ranged along a dimension ranging from the "informal" to the "formal" or "'official"' (2003:159). However, there are a number of different ways to approach the 'classification of documents' (May, 2001:181). For example, Payne and Payne suggested that 'documents fall into three main categories: personal, private and public, depending on *who* wrote them' (2004:61). May also highlighted how researchers often define them in terms of 'primary, secondary and tertiary documents', as well as 'public and private documents' (2001:180). In outlining the differences between them, he stated that 'primary sources refer to those materials which are written or collected by those who actually witnessed the events which they describe'; 'secondary sources' are 'written after an event which the author had not personally witnessed'; and that 'tertiary sources enable us to locate other references' (2001:180). The literature that I analysed in my study therefore consisted of what would be described as 'formal' documents, authored by 'private' and 'public' professionals

and/or organisations. Most of these documents would also be classed as primary sources. I will be discussing this material in more depth later in the chapter.

Classic examples of STS work that have made use of documentary/textual resources include Gilbert and Mulkay's study of scientists' discourse, in which they used 'transcripts of interviews, letters, and other informal material, as well as access to the formal research literature' (1984:1). Here they carried out discourse analysis and identified two types of repertoire, with scientists using different ones depending on the context. They showed, for example, that in research papers and when presenting, scientists tended to use an empiricist repertoire (quite formalised and foregrounds empirical and scientific explanations); whereas in more informal settings such as chatting to colleagues over a coffee, scientists were more likely to use a contingent repertoire (which tended to explain things in terms of social factors). They also highlighted how scientists often switched back and forth between the different repertoires, and that this was dependent on the particular situation they were in, which often led to the creation of complex discourse.

Other examples include Latour and Woolgar's (1986) work on the construction of scientific fact, where they conducted a lab study of a Nobel prize winning biochemistry research group and showed the key role that texts played in the production of knowledge, which they described as 'inscriptions'. Collins and Pinch (1979) also highlighted the role of publications and texts in the development of scientific knowledge, although unlike Mulkay and Gilbert they drew attention to the different contexts of talk and publication in what they called the contingent and constitutive forums. The key point of their analysis was that, although both forums contributed to the production of scientific consensus, the social rules that governed them were very different.

In using a constructionist approach for my study of metabolic syndrome I am taking texts as performative, in the sense that they seek to bring about a particular state of belief or reality (Ayer, 1956; Winch, 1958; Wittgenstein, 1953, 1991; Potter and Wetherall, 1987). Physicians and/or scientists ('claims-makers') use academic texts, oral presentations and other means to make claims about the nature of the material world. Academic documents or texts are, therefore, seen as important 'tools of

persuasion' (Gilbert, 1977:115) where 'claims-making' refers to the process in which the best possible arguments are put forward in support of a particular viewpoint (Best, 1987). For example, Conrad highlighted how 'Medical claims-making usually takes the form of writing in professional journals (*scientific papers*), official professional reports, activities in speciality organisations, and developing special clinics or services' (1992:219).

As a result, in planning my study into the construction of metabolic syndrome I decided to put formal academic publications (such as research papers, review articles, scientific statements, conference proceedings, and professional reports) at the centre of my analysis and use them as my primary source material. In doing this I, of course, recognise that other forms of discourse and publication are important. Nevertheless, given that my interest is in tracking changes in the professional consensus around metabolic syndrome, starting with the published literature is an appropriate way to proceed.

Retrieval and storage of the documentary material

I made extensive use of Cardiff University's online journal access, which enabled me to find and save electronically the majority of the publications I needed. The literature was saved in the form of Word documents and PDF files. I was also able to gain access to and use University College London (UCL) Medical School's library facilities at the Royal Free Hospital. This proved to be invaluable, because ironically the publication I found hardest to get hold of was Reaven's pivotal 1988 paper on syndrome X. This was due in part to its age and popularity, so accessing an electronic copy of this paper proved difficult. Fortunately, I discovered that UCL had the original journal in its archive store, and for a small fee I was able to request a photocopy of the original article. I was given another document (Despres et al, 2001) while attending a conference on obesity in London in October 2005, and was sent additional material by one of my interviewees (Gerald Reaven). The documentary material itself came from a wide range of sources, which included academic journals, professional groups, international organisations, governmental organisations, and pharmaceutical companies.

Timetable of the documentary collection and analysis

The documentary collection and analysis was carried out in three stages:

- **Stage one:** a preliminary, scoping study, carried out in autumn 2004, where potential issues and actors were identified.
- **Stage two**: the main data collection and thematic analysis, which lasted for all of 2005, in which documents and individuals identified during the scoping study were analysed in detail.
- **Stage three**: a final, contemporaneous stage in which developments that took place as the thesis was being written up between 2006 and 2009 were monitored and incorporated.

Although the documentary collection was carried out over three stages, in each case, I followed the same procedure as described below.

The selection of relevant documents

Documentary analysis has the advantage that material and data are often easy to collect, especially with the development of the Internet, and can include current and historical material (Silverman, 1993; May, 2001; Payne and Payne, 2004). However, there are drawbacks to this approach, as with other qualitative methods, particularly in relation to the validity, reliability and generalisability of the data (Platt, 1981; Forster, 1994; Scott, 1990; Calvert, 1991; Silverman, 1993). I tried to minimise these by collecting material from recognised journals and over a wide topic area. In addition, I chose to study formal medical/scientific publications because I was particularly interested in the claims that represented and influenced medical practice surrounding the metabolic syndrome, and for this I needed documents that had been certified through publication.

In discussing documentary analysis in their publications on social research, May (2001) and Payne and Payne (2004) both highlighted Scott's (1990) work where he argued that researchers should always assess documents in terms of 'authenticity, credibility, representativeness and meaning' (2001:188-9, 2004:63). This was an issue that I kept in mind when deciding which documents to include in my study, and as a result I subjected every publication to an interrogation in which I asked a series of 10 questions. These questions were used to make initial decisions about whether or not a particular publication should be retained for more detailed analysis. These judgements were then revised and updated as my understanding of the field increased.

The questions were:

1. When was the paper published?
2. What type of paper was it? (Experimental, review or other type)
3. What journal was it published in? What country was it published in?
4. Was this a general or specialist publication?
5. Who were the authors (claims-makers)?
6. What was their disciplinary background?
7. Had they published work on the topic before?
8. What was the status of the publication/author within debates about metabolic syndrome?
9. Were the authors affiliated to a particular professional organisation?
10. Was the paper published on behalf of one of these groups?

These questions served two purposes: first, they enabled me to be more confident in the reliability/validity of the publications chosen (Scott, 1990; Silverman, 1993; Payne and Payne, 2004); and second they also provided information that was useful for the more detailed analysis that followed. Where the answers could not be taken directly from the bibliographic information or the article itself, some judgement was required. In most cases relatively little additional knowledge was required and judgements were relatively straightforward.

The most difficult question to answer on first reading was question 8. This requires an in-depth knowledge of the area, so decisions about influence and status were informed by the knowledge gained through being immersed in the literature. Relevant features here included the frequency with which articles and authors were cited, but also the ways in which these citations were phrased (e.g. as a 'seminal' contribution etc). Other criteria for identifying status and/or influence were noting whether the authors had been asked to write a review/commentary in a respected journal, formally honoured in some way, and/or given a 'keynote' speech at a relevant international conference. For example, at the First International Congress on Prediabetes and the Metabolic Syndrome in Berlin (April 2005), Professor Sir George Alberti (documents 5, 18, 29, 30) was honoured with a presentation entitled 'Celebrating Professor Sir George Alberti's First 40 Years in Diabetes Research' in which his 'outstanding contributions to diabetes research, care and prevention' were outlined (Prediabetes Congress, 2005).

He was also asked to take part in an organised debate at the formal dinner, while Professor Paul Zimmet (documents 5, 18, 19, 29, 30) was asked to be chairperson at the conference's opening ceremony (Prediabetes Congress document, 2005). These are all positions that require individuals to be highly regarded by their peers in that particular academic medical field.

At the Second International Congress on Prediabetes and the Metabolic Syndrome, which was held two years later in Barcelona, the following authors were all asked to give presentations at the main plenary sessions, with Alberti, Zimmet, and Eckel (documents 5, 18, 19, 22, 27, 29, 30) all presenting at the opening session, while Grundy (documents 8, 12, 13, 16, 17, 19, 22, 26, 30) and Haffner (document 4) gave separate plenary talks (Prediabetes Congress, 2007). Similarly at the Third Annual World Congress on IRS in San Francisco in 2005, Reaven (documents 1, 11, 14, 15, 16) was chair of two of the main sessions, presented and also took part in a panel discussion; while Einhorn (documents 11 and 23) gave a presentation (main session) at the event (IRS Congress, 2005). Reaven has also been widely honoured for his work, and this has included the ADA Banting Award for Distinguished Scientific Achievement (1988), the Novartis Award for Longstanding Achievement in Diabetes (2000), and the Sixth Linus Pauling Functional Medicine Award (2001), along with numerous other honoraria (Reaven Biography, 2005d).

Citations (referencing the publication) are another indicator of an individual's and/or paper's status within the debates surrounding the metabolic syndrome field. It is not possible to tell whether an individual and/or paper is well regarded from high citation rates alone; however, this does usually indicate that the individual/material has at least had an impact on the area. A classic example would therefore be Reaven's 1988 paper on syndrome X, which as well as being regarded as 'seminal' (Kahn et al, 2005) in the field has, according to statistical data from Medline (an online database of academic medical publications managed by the US National Institutes of Health), been cited by 748 other publications (PubMed Central, accessed 29 January 2014). Although these data are limited to the publications filed at PubMed Central, it is still a good indicator of the paper's significance to the field. In 2005, Reaven was also credited with having 'published over 500 peer-revised research articles in scientific journals' during his

career (Reaven biography, Stanford University, 2005). A figure that now stands at 753 publications based on statistical data from Medline (PubMed Central, accessed 29 January 2014). This is another indicator of Reaven's status with the academic community.

Of the 30 documents that I analysed in stages two and three, nearly half (14 documents) were the launch publication for a new definition, were outlining changes/reaffirmations/updates to an existing one, or represented an organisational response on the issue (documents 1, 2, 5, 6, 7, 8, 9, 11, 12, 15, 21, 22, 23, 27, and 30). Therefore these documents are not minor publications, and as such have been extensively cited. For example, Ford et al's (2002) paper (document 10) was cited in 622 other publications; Alberti et al's (2009) paper (JIS definition) (document 30) was cited in 472; and Eckel et al's (2005) review paper on the metabolic syndrome published in the *Lancet* (document 16) was cited in 427 publications (PubMed Central, accessed 29 January 2014). Although not as well cited as the publications above, still significant were Kahn et al's (2005) review paper (*Diabetes Care* version) (document 22) that was cited in 170 other publications, and Einhorn et al's (2003) IRS position statement (document 11) that was cited in a further 56 publications.

In addition, over two-thirds of the publications (23 documents) studied were written by/or linked to just 10 key individuals:

- Alberti (documents 5, 18, 29 and 30)
- Despres (document 9)
- Eckel (documents 19, 22, 27 and 30)
- Einhorn (documents 11 and 23)
- Ford (documents 10 and 20)
- Grundy (documents 8, 12, 13, 17, 19, 22, 26 and 30)
- Haffner (document 4)
- Kahn (documents 21 and 27)
- Reaven (documents 1, 11, 14, 15, and 16)
- Zimmet (documents 5, 18, 19, 29 and 30).

According to statistical data from Medline, these individuals are credited with having published a significant number of peer-reviewed papers, with for example Alberti credited with 813 publications and his long-term writing partner Zimmet with 603 publications (PubMed Central, 29 January 2014). These include the WHO (1999) definition (document 5) and IDF (2005a) consensus definition (document 18), which were cited in 720 and 462 other publications, respectively. Grundy is credited with 624 publications, including the ATP-III (2001) guidelines (document 8) that were cited by 2,177 other publications. Of the others, Despres is credited with 630 publications, Haffner with 527, Eckel with 271, Ford with 333, and Einhorn with 40 publications (PubMed Central, accessed 29 January 2014). Although these data do not definitively prove that these academics are important in the field, taken in conjunction with other evidence (such as being asked to write 'review articles') this does indicate that these individuals hold more senior positions, and therefore their work is more likely to be seen as significant. In addition, many of these individuals/publications were backed by professional organisations (such as the ADA and AHA), which added to their credibility. Taken together, these indicators demonstrate that the documents selected were important scientific papers published in prestigious journals by researchers who were well-regarded by their peers.

It is important to remember, however, that citation rates can be affected by numerous factors. For example, the citation figures for the WHO and ATP-III definitions (documents 5 and 8), must be treated with caution (they appear to be very high), because these particular definitions were embedded in publications whose primary aims were 'diabetes reclassification' and 'cholesterol education', respectively, and as such will have been cited in other publications in relation to issues not directly related to the metabolic syndrome concept. In addition, Kahn et al's (2005) publication (document 21) has a relatively low citation rate of 170 (for the *Diabetes Care* version) because the ADA/EASD Statement was jointly published across two journals, *Diabetes Care* and *Diabetologia*, which effectively reduced the potential impact of each document. Another key factor affecting the citation rate relates to the impact of the journal, with papers in more prestigious publications (such as *JAMA* and the *Lancet*) tending to be cited more often.

However, as with any qualitative (or quantitative) study there are always potential concerns in regard to the validity and reliability of the data (Silverman 1993, Payne and Payne 2004). According to Wetherell et al 'validity, refers to the truth or accuracy of the generalisations being made by the researcher' and 'reliability, is a criterion applied to measurement and means that the tools or instruments being used can be relied upon to measure consistently' (2001:318). In regard to the latter, Payne and Payne noted that 'Research instruments are the ideas, concepts and techniques of data collection and analysis that researchers use to make sense of the social world' (2004:234).

In my qualitative study, the data collected was based on documentary and interview material, therefore the main concerns over validity and reliability centred on the quality/credibility of the documents and interviewees chosen, and in regard to my methodology (constructionist / thematic analysis), its ability to produce data of suitable rigor. Documentary evidence / data is problematic because 'to varying degrees, documents are unrepresentative, incomplete, inaccessible and unreliable' (Payne and Payne 2004:230). As stated earlier, I was interested in how the medical and scientific understanding of the Metabolic Syndrome changed over time and the peer review literature is a good source in this context as all publications have been assessed and certified. In addition, several of the documents/studies were explicitly designed to synthesise the then current research into a single statement. Whilst such documents clearly omit much in order to achieve their purpose, this purpose was a good match for my own research questions.

I did not rely solely on these documents, however, but also conducted interviews with professionals and attended conferences in order to understand how the field as a whole was developing. This experience provided additional data, which helped put the documents in context. However, interview data can also be uncertain due to issues such as 'interviewer bias' (Payne and Payne 2004:131), as well as problems with recording / transcribing the material. I tried to reduce this by being reflexive in regard to my interview approach and by cross-referencing between interview and documentary data.

There are a number of other ways the concerns over validty and reliability can be reduced or controlled. Barbour highlights the use of approaches 'such as purposive sampling, grounded theory, multiple coding, triangulation, and respondent validation'

as a means of 'improving rigour in qualitative research' (2001:1115). The last two approaches, in particular, are widely used (FitzPatick and Boulton 1994:112). Describing triangulation, Wetherell et al stated that 'this refers to the use of more than one (although not necessarily three) methods or forms of data to investigate the same phenomenon or problem' (2001:322). However, triangulation can take a number of different forms (Denzin 1970, Silverman 1993, Payne and Payne 2004), with 'methodological triangulation' as developed by Denzin in the 1970s (Denzin 1970, Payne and Payne 2004) being one of the most widely used approaches in qualitative research. Hammersley and Atkinson describe this approach as 'approaching data with multiple perspectives and hypotheses in mind' (2003:214).

The other widely used approach 'respondent validation', which is described as 'Taking one's findings back to the subjects being studied. Where these people verify one's findings, it is argued, one can be more confident of their validity' (Silverman 1993:156). Other commentators noting that this 'represents one kind of triagulation: the checking of inferences drawn from one set of data sources by collecting data from others' (Hammersley and Atkinson 2003:230). However, regardless of the particular approach 'the more extensive the triangulation, the more confident we (*you*) can be about the findings' (Payne and Payne 2004:230).

In relation to my study, I was able to keep the potential concerns over validity and reliability to a minimum by making use of both 'triangulation' and 'respondent validation'. Triangulation was accomplished by using different methods, which enabled me to analyse the topic from a number of different angles (offering a degree of 'triangulation'), and also helped me to check the reliability of the data (Denzin 1970, Bryman 1988, Silverman 1993, Payne and Payne 2004). This 'triangulation' also extended to my use of other forms of data collection (Denzin 1970, Silverman 1993, Payne and Payne 2004), which included for example interviews with key players (Reaven and Ecke) in addition to my documentary analysis. These interviews also provided an element of respondent validation as I was able to test my understanding of the field against that of two of the leading research scientists working in the field.

Stage one: scoping/preliminary study (Autumn 2004)

This made use of review articles. The rationale for this approach draws on Arribas-Arribas-Ayllon et al's 2009 study of the construction of 'psychiatric genetics', itself influenced by the work of Myers (1991), Sinding (1996), and Hedgecoe (2001b). Arribas-Ayllon and colleagues argue that:

Review articles are important not only because they provide information but because they engage in multiple activities such as popularisation (Hilgartner 1990), fact construction (Myers 1992), and narrative reconstruction (Hedgecoe 2001b)

(Arribas-Ayllon et al, 2009:3).

Although I do not use the same 'rhetorical/discursive approach' to analyse the review articles, I agree with Arribas-Ayllon et al that review articles are a good place to start when trying to understand the construction of a field.

When conducting my preliminary study in Autumn 2004, I started by collecting literature from medical databases and the websites of leading medical journals and research charities. For example, I began by searching Medline and a number of other medical websites (*BMJ*, *Lancet*, Reuters Health (US and UK), Health Centres Online (US), BHF, Heart UK, Diabetes UK, NHS Online). I initially searched for scientific/medical publications using only the term 'metabolic syndrome', because the medical professional who had first suggested the 'condition' to me as a possible topic of interest had used this term. As I began to learn more about the issue, however, it became apparent that the terms 'syndrome X' and 'insulin resistance' were widely used in relation to the concept, and I therefore decided to expand my search to include these additional terms.

In my initial search, I used filters where I could, to look for 'review' type articles, and limited the period of publication from 1988 to 2004. The first date was chosen because even at this early stage I was aware that Gerald Reaven was seen as the 'founding father' (Breitstein, 2004; Sternberg, 2005b) of the field and his original paper on the topic had not been published until 1988. The second date was chosen because this was when the search was initially carried out and I wanted recent (as of 2004) publications to be

included. In trying to identify specific 'review articles', I discovered that they were often defined differently in every journal. This is an issue that Arribas-Ayllon et al (2009) also encountered in their study, when they noted that 'The peculiarity of this genre of scientific writing (*review articles*) is highlighted by the variety of ways in which journals accommodated these articles into their existing categories, being described as 'reviews', 'updates', or 'editorials' (2009:3).

Search results and sampling strategy for the preliminary study

My initial search identified over 120 potential publications for analysis. I therefore decided to narrow the search down to include only review papers that had been published in academic journals over the previous two years (2003–2004), because this would identify current (as of 2004) orthodox academic thinking on the topic. The number found dropped to a more manageable 20 potential publications.

As this was only a preliminary study, I decided to pick four examples, three from American academic journals and one from a British journal. This ratio was chosen because by this point I knew that the concept had emerged in North America through the publication of Reaven's paper, and that many later developments such as the ATP-III definition (Expert Panel on the Detection, Evaluation and Treatment of High Blood Cholesterol in Adults, 2001) and IRS concept (Einhorn et al, 2003) had also been US-based, but that other equally important developments such as the creation of the WHO definition (Alberti and Zimmet, 1998) had originated from outside the US. I therefore included a non-US publication to reflect this wider perspective, and chose a UK text because another one of the key players behind the metabolic syndrome concept was Sir George Alberti (a British diabetes specialist), and the publication would also give me an insight into the UK medical perspective on the issue (Imperial College website, 2005). Three of the papers came from general medical journals and one was from a specialist diabetes journal. This ratio was chosen because the main purpose here was to gain an understanding of the general medical perspective on the issue, but I was also aware that the concept had emerged from the diabetes field (Reaven, 1988) and therefore wanted the documents chosen to reflect this specialism.

During the initial trawl of the literature, my search also identified a review article that was published in a US pharmaceutical industry journal called *Pharmaceutical Executive*; this caught my eye because at this early stage in the analysis I was interested

in understanding how involved the pharmaceutical industry was in the construction of this concept. This proved to be a useful source document, particularly in relation to the identification of some of the key academic players, both individuals and organisations, involved in the field. Although this was not strictly an academic review, I decided to include this additional paper because the article was part of the wider medical/scientific discourse surrounding the concept and offered an up to date (as of 2004) insight into the pharmaceutical industry perspective on the topic. The sampling method I used here was therefore purposive sampling, which Payne and Payne describe as the type that 'picks its sub-set for a particular, non-statistical purpose' (2004:210). I examined a total of five publications as part of my preliminary study and the details of the documents that were chosen are outlined in Table 1.

Table 1. Documents studied during the stage one, preliminary study of the metabolic syndrome literature (in date order).

Review number	Author and date	Journal	Type and subject of paper	Journal field
i.	Alexander (2003)	*Diabetes Care* (ADA)	Review, metabolic syndrome	Diabetes specialism
ii.	Meigs (2003)	*BMJ*	Editorial, metabolic syndrome	General medicine
iii.	Deen (2004)	*American Family Physician (AAFP)*	Review, metabolic syndrome	General medicine
iv.	Garber (2004)	*Medical Clinics of North America*	Review, metabolic syndrome	General medicine
v.	Breitstein (2004)	*Pharmaceutical Executive*	Review, metabolic syndrome	Pharmaceutical Industry

Outcomes of the preliminary study

As noted above, the main aim of this short study was to lay the foundations for more substantial analysis to be carried out in stage two. Through careful and iterative reading of these papers, I first gained an overall understanding of the issues and then began to identify the key players, organisations and potential themes. Braun and Clarke highlighted how 'Immersion usually involves repeated reading of the data, and reading the data in an *active* way — searching for meanings, patterns and so on' (2006:87). This was similar to the method outlined by Arribas-Ayllon et al, who described their initial approach as 'a process of systematic reading and note-taking (*that*) identified common themes and rhetorical devices' (2009:3).

What emerged from this preliminary analysis was a provisional map of the metabolic syndrome debate, highlighting the key players, publications, themes and events. As stage one was only intended as a scoping study, this was all that was required at this point. However, this initial study was still important because although it was not part of the main thematic analysis, it represented the start of the analytical process through its identification of a number of potential 'key players' and 'themes' in regard to the metabolic syndrome concept, as well as pointing to further publications of interest. The outcome of this study was the identification of eight areas of interest, which could potentially be followed up later in the main thematic analysis. These included the following:

1. Gerald Reaven and his 'syndrome X' concept from 1988 were identified as playing a key role in kick-starting renewed interest in the topic of 'insulin resistance' (IR).
2. The metabolic syndrome concept was universally described as representing a significant medical/social problem because of its causative links to heart disease and diabetes.
3. The articles highlighted that there were a number of different names and definitions for the concept, and that this had become an issue for the field.
4. That a number of 'metabolic syndrome' definitions were in use during 2003–4. These included: 'syndrome X' (1988), the 'deadly quartet' (1989), WHO definition (1999), EGIR definition (2002), ICD-9 code (2000),

'hypertriglyceridemic waist' (2001), the NCEP ATP-III definition (2001), and ACE insulin resistance syndrome (IRS) (2003).

5. That certain individuals and organisations had played and/or were continuing to play, important roles in the field. These included Gerald Reaven, Norman Kaplan, George Alberti and Paul Zimmet, Richard Kahn, Jean-Pierre Despres, and Scott Grundy; and organisations such as the WHO, EGIR, NCEP, NHLBI, AHA, ADA and ACE.
6. That 'IR' and 'obesity' were seen as key factors in the underlying aetiology (cause) of the condition, but that there was uncertainty over their precise roles.
7. That there were a number of contested issues surrounding the 'metabolic syndrome', particularly around the definition and aetiology, and some experts saw the concept as 'controversial'.
8. That researchers had identified 'lifestyle modification' as the primary approach to the treatment and/or prevention of the metabolic syndrome, though drug treatments were also available as a fall-back option.

Stage two: analysis of key definitional literature (2005)

Based on this preliminary analysis, the main data collection proceeded in two ways. The first was a 'backward-looking' analysis in which the studies and papers that were repeatedly cited in review articles were identified and retrieved. These papers began with Reaven's 1988 paper on 'syndrome X', which is widely recognised as playing a pivotal role in the emergence of the concept. By understanding this paper and how it constructed syndrome X, this should provide a better understanding of the wider metabolic syndrome literature and how this publication has helped to shape many of the different constructs.

Following on from this, the data collection was then expanded to include other publications focusing on the definition and, to a lesser extent, aetiology of metabolic syndrome. These were significant because, it is in these documents, that the features distinguishing the different constructions around the concept are articulated and defended. As with Reaven's paper, these documents were fairly easy to identify because the review articles consistently highlighted the same definitions.

Having begun my study of the metabolic syndrome in late 2004, by the time I commenced stage two of the analysis in mid 2005 I had spent a considerable amount of time 'immersed' in the field. This included attending scientific meetings (the All-Party Parliamentary Group n obesity meeting May 2005 and National Obesity Forum conference October 2005), speaking with 'metabolic syndrome' specialists (Reaven, Eckel, and a number of UK obesity specialists), as well as becoming familiar with the wide range of scientific literature on the topic such as Reaven (1988), WHO (1999), Expert Panel on the Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (2001), and Eckel et al (2005). This meant that I was able to make informed judgements on what constituted the 'key definitional literature', and when unsure I relied on cross-referencing and talking to experts to aid my decision-making. This led me to identify and analyse a group of 17 publications, which are listed in Table 2.

Table 2.

Initial group of documents studied during stage two of the thematic analysis, which formed the main data set and included key definitional publications (in data order).

Document number	*Author and date*	*Journal*	*Type and subject of paper*	*Journal field*
1.	Reaven (1988)	*Diabetes* (American Diabetes Association, ADA)	Banting lecture, Syndrome X 'definition'	Diabetes specialism
2.	Kaplan (1989)	*Archives of Internal Medicine*	Original investigations, 'deadly quartet' definition	General medicine
3.	DeFronzo and Ferrannini (1991)	*Diabetes Care* (ADA)	General paper, 'Syndrome of insulin resistance'	Diabetes specialism

4.	Haffner et al (1992)	*Diabetes* (ADA)	Prospective analysis paper, 'Insulin-resistance syndrome (Syndrome X)'	Diabetes specialism
5.	Alberti and Zimmet (1998)	WHO publication	Report of a WHO consultation, Metabolic syndrome definition	Diabetes specialism
6.	Balkau and Charles (1999)	*Diabetic Medicine* (Diabetes UK)	European Group for the study of Insulin Resistance comment piece, 'Insulin resistance syndrome' definition	Diabetes specialism
7.	Dickey (2000)	National Centre for Health Statistics (NCHS) communication	ICD-9 code for 'dysmetabolic syndrome X'	US NCHS document
8.	Expert Panel on the Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (2001)	*JAMA*	Special communication, National Cholesterol Education Program Adult Treatment Panel III, Metabolic syndrome definition	General medicine

9.	Despres et al (2001)	*BMJ*	Clinical review, 'Hyper-waist' definition	General Medicine
10.	Ford et al (2002)	*JAMA*	Brief report US epidemiological data	General medicine
11.	Einhorn et al (2003)	*Endocrine Practice* (American College of Endocrinology)	American College of Endocrinology, Position statement, Insulin resistance syndrome 'definition'	Endocrinology specialism
12.	Grundy et al (2004a)	*Circulation* (American Heart Association, AHA)	National Heart, Lung, and Blood Institute (NHLBI)/AHA conference proceedings, Metabolic syndrome definition	Heart specialism
13.	Grundy et al (2004b)	*Circulation* (AHA)	AHA/NHLBI/ADA conference proceedings, Clinical management of metabolic syndrome	Heart specialism
14.	Kim and Reaven (2004)	*Diabetes and Vascular Disease Research*	Review, Critique of metabolic syndrome	Specialism
15.	Reaven (2005a)	*Clinical Chemistry*	Review, Critique of metabolic syndrome	Specialism

16.	Reaven (2005b)	*Clinical Chemistry*	Counterpoint, Critique of metabolic syndrome	Specialism
17.	Grundy (2005)	*Clinical Chemistry*	Point, In defence of metabolic syndrome	Specialism

Taken together, these 17 publications covered a range of genres (conference proceedings, scientific statements, reviews, research papers, official reports, and comment pieces). This variety has some advantages in this context, as I was interested in how the 'diagnostic definition' was being constructed and therefore wanted to engage with publications from across the expert literature. Many other researchers have used such an approach. For example, Hedgecoe in reference to Kerr's (2000) paper on cystic fibrosis highlighted how 'Kerr provides(*ed*) a widespread analysis of 80 papers from different genres (letters, research reports, conference papers)' and described her work as being 'an extensive review' (2003:53). Although Kerr used a different analytical methodology in her study, thematic analysis is equally capable of dealing with such a range of material. Guest et al, for example, highlighted how thematic analysis is useful for 'analysing, and making sense of, a set of field notes or transcripts from focus groups or in-depth interviews' but that it can equally 'be used to analyse free-flowing text from secondary data sources, such as in document analysis' (2012:4).

Returning to why these particular publications were analysed, document 1 (Reaven, 1988) was chosen because it was the catalyst for the emergence of the whole 'syndrome X'/metabolic syndrome field. Document 2 (Kaplan, 1989) was chosen because it referred to the closely-related but alternative (non-aligned) definition of the 'deadly quartet'; whereas documents 3, 4 and 6 all related to versions of the 'insulin resistance syndrome'. Document 5 (Alberti and Zimmet, 1999) was included as it outlined the first working definition for metabolic syndrome and was backed by the WHO. Document 7 was analysed because it related to the creation of the ICD-code for 'dysmetabolic syndrome'. Document 8 (Expert Panel on the Detection, Evaluation and Treatment of High Blood Cholesterol in Adults, 2001) was also important and included because it outlined the widely-used NCEP ATP-III definition of metabolic syndrome.

Document 9 (Despres et al, 2001) related to another one of the closely-linked definitions of the 'hypertriglycidemic waist'.

Although document 10 (Ford et al, 2002) did not focus on definition — instead it highlighted the prevalence of the condition in the US — the paper was so widely referenced in the literature that I included it because it represented an integral part of the construction of the metabolic syndrome by the medical profession. Document 11 (Einhorn et al, 2003) related to the creation of another definition for IR syndrome, this time professionally aligned to ACE. Documents 12 and 13 were identified and analysed because they related to two conferences organised by the NHLBI/AHA in the US, which specifically discussed the NCEP ATP-III definition of the metabolic syndrome and its management.

The next three publications, documents 14 (Kim and Reaven, 2004), 15 (Reaven, 2005a) and 16 (Reaven, 2005b), were all originally sent to me as draft manuscripts by Reaven, following my interview with him in September 2005. I did not want to use this 'unpublished material' in my analysis, however, because I was only interested in documents that could influence medical practice around the metabolic syndrome concept, and for this they needed to be certified through publication. I therefore only analysed the peer-reviewed published versions of these manuscripts, which appeared in the journals *Diabetes and Vascular Disease Research* (Kim and Reaven, 2004) and *Clinical Chemistry* (Reaven, 2005a, 2005b). The unpublished material was still useful documents because it shed further light on Reaven's views on the development of the metabolic syndrome field, and I therefore decided to include these among the literature I looked at during stage two of my analysis. Document 17 (Grundy, 2005) was included in this initial analysis because it was written by another one of the key players in the field, and represented a direct response to Reaven's earlier critical review of the metabolic syndrome (Reaven, 2005a).

Documents relating to 'developments' that occurred in 2005

In 2005, while I was collecting the key definitional literature for my analysis, the construction of the metabolic syndrome concept continued apace with the announcement of a number of further 'developments' in the field. These included:

- The launch of a new definition of the metabolic syndrome by the IDF in April (document 18)
- The publication of a review article by Eckel et al on metabolic syndrome in the *Lancet* in April (document 19)
- The publication of a paper by Ford that looked at the use of the ICD-code in July (document 20)
- The release of a joint statement from the ADA/EASD critiquing the metabolic syndrome definition in August (document 21)
- An update to the NCEP ATP-III definition in October (document 22)
- The release of an ACE position statement 'reaffirming' its commitment to the IRS in October (document 23)
- The publication of an article on 'Rimonabant' in the *New Scientist* in December 2005 (document 24).

The fact that these 'developments' had occurred while I was in the middle of my research into the construction of the metabolic syndrome concept was fortuitous, because this enabled me to analyse these new constructions as they happened. I therefore collected and analysed an additional seven documents. The documents analysed during this later period of stage two are outlined in Table 3.

Table 3. Additional documents studied during stage two of analysis of the metabolic syndrome literature.

Document number	*Author and date*	*Journal*	*Type and subject of paper*	*Journal field*
18.	Alberti et al (2006)	*Diabetic Medicine*	Special report, International Diabetes Federation consensus statement, Metabolic syndrome definition	Diabetes specialism
19.	Eckel et al (2005)	*Lancet*	Seminar,	General medicine

			Metabolic syndrome (review)	
20.	Ford (2005)	*Diabetes Care* (American Diabetes Association, ADA)	Brief report, Metabolic syndrome ICD-code use in US	Diabetes specialism
21.	Kahn et al (2005)	*Diabetes Care* (ADA) and *Diabetologia* (European Association for the Study of Diabetes)	Reviews/commentaries/ADA statements: ADA statement, Critique of metabolic syndrome	Diabetes specialism
22.	Grundy et al (2005)	*Circulation* (American Heart Association, AHA)	AHA/National Heart, Lung, and Blood Institute Scientific statement, ATP-III definition (update)	Heart specialism
23.	Einhorn et al (2005)	*Endocrine Practice* (American College of Endocrinology)	American College of Endocrinology position statement, Reaffirmation of inslin resistance syndrome concept	Endocrinology specialism
24.	Martindale (2005)	*New Scientist*	Magazine article, The drug Rimonabant	Popular science

This combined set of 24 publications, which were analysed in stage two, therefore formed the core of my qualitative data set.

Stage three: additional documentary material (2006–2009)

Originally I had planned to limit my data collection to documents published during the period 1988–2004, but this was extended until the end of 2005 due to the extra 'developments' outlined above. Although this material had enabled me to gain a valuable insight into the construction of the metabolic syndrome concept and who had been the key players, I decided to watch out for any further definitional changes. As a result, I extended my collection to include documents published in 2006 and beyond, and although things certainly quietened down post-2005, two further changes occurred (one in 2006 and another in 2009) that I wanted to include in my analysis. This therefore led me to identify a further group of six documents for analysis, and I stopped monitoring the literature towards the end of 2009. I decided to stop at this particular point due to the publication of the 'harmonisation' statement (Alberti et al, 2009) on metabolic syndrome that was published in October 2009, which was an attempt by a number of the key players to bring the debate surrounding the concept to a close. This represented a break in the proceedings and was a logical point with which to stop following the literature.

These additional six documents were chosen for the following reasons. This was a press release to coincide with the launch of Rimonabant, a drug claimed to treat metabolic syndrome, by the pharmaceutical company Sanofi-Aventis in June 2006 (document 25). The Grundy (2006) publication (document 26) was chosen because apart from being an in depth overview of the topic, it offered an insight into the direction that the field was taking, as viewed by one of the key players behind the concept. The Eckel et al (2006) and Alberti et al (2009) publications (documents 27 and 30) were chosen because they were both published as joint-statements, and were backed by a number of the key players (individuals and groups), and was their response to the 2005 controversy. The Gale (2008) and Alberti and Zimmet (2008) articles (documents 28 and 29) came from the same publication, the *BMJ*, and were chosen because they were an example of the continuing debate over the concept. They also gave a non-US perspective on the issue. Although the construction of the metabolic syndrome concept has mainly been a US-based process, many of the developments in the field have occurred outside the US (such as the creation of the WHO (1999) and IDF (2005) definitions), therefore any documents that shed light on this wider perspective are especially valuable.

Again one of the documents, Alberti and Zimmet (2008) (document 29), was written by two of the leading players, and so gave an insight into the way the field was developing. This therefore effectively became stage three of my data collection and analysis, and included documents published in 2006–2009. The documents that I collected are listed in Table 4.

Table 4. Documents collected during stage three, which included additional material published during the period 2006–2009.

Document number	Author and date	Journal	Type and subject of paper	Journal field
25.	Sanofi-Aventis (2006)	Non applicable	Press release (June 2006) The drug Rimonabant	Pharmaceutical industry
26.	Grundy (2006a)	*JACC*	State-of-the-art paper, Metabolic syndrome (review)	Heart specialism
27.	Eckel et al (2006)	*Circulation* (American Heart Association AHA) and *Diabetes Care* (American Diabetes Association)	American Diabetes Association/AHA, Scientific statement, 'Truce' document	Heart specialism/ diabetes specialism
28.	Gale (2008)	*BMJ*	Head to head, Critique of metabolic syndrome	General medicine
29.	Alberti and	*BMJ*	Head to head,	General medicine

	Zimmet (2008)		In defence of metabolic syndrome	
30.	Alberti at al (2009)	*Circulation* (AHA)	Joint scientific statement (International Diabetes Federation, National Heart, Lung, and Blood Institute, AHA, World Heart Federation, International Atherosclerosis Society and International Association for the Study of Obesity), 'Harmonisation' document, Metabolic syndrome definition	Heart specialism

This key definitional literature was therefore analysed in two stages, with the first 24 documents analysed during stage two and the final six documents analysed during stage three. Although these data sets were analysed separately, I used the same thematic analysis approach for each analysis, and combined the findings in my final write up. A detailed summary of my thematic analysis is outlined in the next section.

With the inclusion of the six additional documents, I therefore studied a combined total of 30 publications (documents 1–30) during my qualitative analysis of the metabolic syndrome concept. This was because the five review articles (documents I–V) I looked at were part of my preliminary study, where my main aim was to familiarise myself with the topic and identify further publications of interest. This data set of 30 documents therefore consisted of 17 academic (medical/scientific) papers, two conference proceedings, eight statements from professional organisations, one report from an

international organisation, one pharmaceutical industry press release, and one popular science magazine article.

Specific qualitative approach: applied thematic analysis

My approach to the thematic analysis was influenced by the guidelines outlined by Braun and Clarke that were based on six phases (2006:87). Using this approach I was able to identify some of the main themes in the definitional literature on the metabolic syndrome. This involved studying the documents both individually and collectively in order to build up a picture of the field, then developing codes for the data, before going on to identify potential key themes. The six phases and how I used them in relation to my study are highlighted below.

Phase 1: familiarising yourself with your data

According to Braun and Clarke, the first phase in your analysis requires immersion in the data, which they suggested 'usually involves repeated reading of the data, and reading the data in an *active* way — searching for meanings, patterns and so on' (2006:87). I had effectively already begun to do this in my earlier 'preliminary study' of the review articles in stage one, but would now be applying the same approach to my main data set of 'key definitional publications' in stages two and three. I did not return to the five documents I reviewed in stage one, because these were only intended to inform rather than be a part of my later analysis (stages two and three).

Braun and Clarke further noted that it was helpful 'to read through the entire data set at least once before you begin your coding, as ideas and identification of possible patterns will be shaped as you read through' (2006:87). Therefore, the approach I used here was to subject every publication to an interrogation based on a series of six questions, and then compare the findings to see whether any patterns emerged in the literature as a whole. The six questions I used are:

1. What was the paper about? (Brief summary)
2. What were the main claims? Were 'rival' claims discussed?
3. How was it relevant to the metabolic syndrome concept?
4. How was the concept described (constructed)? (Detailed description)

5. Were any ethical concerns or issues specifically highlighted?[1]
6. Was there anything else unique to the paper?

I kept my research question of how the metabolic syndrome definition was constructed in mind when studying these documents, while also looking at how the various constructions used ethical arguments and/or raised particular ethical concerns. Therefore not only was I able to identify 'possible patterns' in relation to the construction, but also in the sections where different ethical arguments were being put forward (Braun and Clarke 2006:87). An example of this analysis is given in Box 1.

Box 1. Document 21: Kahn et al, 2005

Taking Kahn et al's (2005) paper (document 21) as an example, when I subjected this to the series of questions outlined above, this gave me the following information:

1. A review of the medical/scientific literature on metabolic syndrome.
2. The metabolic syndrome is a problematic concept. The WHO 1999, ATP-III 2001, and IDF 2005 definitions were highlighted.
3. This was an important critique of the concept by two professional organisations.
4. The concept was described as ill thought through and controversial.
5. There were ethical concerns over 'whether medical science is doing any good' by 'labeling millions of people with a presumed disease that does not stand on firm ground'.
6. The medical and lay press were quick to report the paper's findings.

This approach helped me to build up a detailed picture of each publication and directly influenced my later coding and identification of potential 'themes' in the literature as a whole.

[1] Note that question 5 is the only one that asks about ethical issues directly. However, although questions 1–4 and 6 were primarily aimed at discovering more about the construction of the metabolic syndrome concept, the ethical arguments put forward in support of and against the concept were also picked up in the answers to these questions.

Phase 2: generating initial codes

Having completed phase 1, 'an initial list of ideas about what is in the data and what is interesting about them' (Braun and Clarke, 2006:88) needed to be produced. These 'initial codes' then form the basis for later analysis. Braun and Clarke noted that 'Codes identify a feature of the data (semantic content or latent) that appears interesting to the analyst' (2006:88). They also suggested that 'There are a number of ways of actually coding extracts' and that 'If coding manually, you can code your data by writing notes on the texts you are analysing, by using highlighters or coloured pens to indicate potential patterns' (2006:89). In my analysis of the 'key definitional literature' on the metabolic syndrome, I also used manual coding, and made notes and highlighted text of interest in each document. This enabled me to identify and create a number of different codes, which included the following:

1. 'Metabolic syndrome' is a serious public health problem (E)
2. 'Metabolic syndrome' is a serious individual health problem (E)
3. The 'condition' is linked to heart disease
4. The 'condition' is linked to diabetes
5. There is much uncertainty around the concept (E)
6. 'Insulin resistance' has a key role to play
7. 'Obesity' plays a key role
8. An individual's 'lifestyle' (diet and exercise) is an important factor (E)
9. Genetic factors have a role to play
10. There are a number of 'risk factors'/diagnostic criteria
11. The 'condition' is simple to diagnose
12. The 'metabolic syndrome' is rarely diagnosed by medical professionals (E)
13. There are a number of diagnostic definitions
14. The 'condition' is best defined as 'metabolic syndrome'
15. The 'condition' is best defined as 'insulin resistance syndrome (IRS)'
16. The 'WHO definition' is best
17. The 'ATP-III definition' is best
18. The 'IDF definition' is superior
19. Waist circumference/'abdominal obesity' is a key measurement
20. 'Lifestyle treatments' are available (E)

21. Drug treatments are available
22. Social and cultural factors also affect the prevalence of the ‘condition’ (E)
23. The ‘condition’ is controversial in medicine (E)
24. Proponents widely accept that the ‘condition’ is controversial (*stage three*)
25. The ‘condition’ is an example of medicalisation (‘experts’/‘Big Pharma’) (E)
26. Diagnosing and treating the ‘condition’ is a ‘private good’ (E)
27. Diagnosing and treating the ‘condition’ is a ‘public good’ (E)
28. Diagnosing the ‘condition’ has no medical value and may be harmful (E)
29. Development of a standard definition is within reach (*stage three*)
30. The ‘condition’ offers many opportunities for ‘Big Pharma’ (E)

The majority of these codes were identified during stage two of my analysis, however, some were created during stage three, and these have been marked accordingly (see codes 24 and 29). In addition, I used the terms ‘metabolic syndrome’ and ‘condition’ here to mean all the potential constructs, unless specifying a particular definition such as in code 15. The letter ‘E’ was used to denote any code that referred to a potential ethical issue. The development and use of the codes can be illustrated an extract from Grundy et al (2004a), see Box 2:

Box 2. Example of coding: Document 12: Grundy et al, 2004a, p. 434

Abdominal obesity *especially correlates with metabolic risk factors. Excess adipose tissue releases several products that apparently exacerbate these risk factors. They include nonesterified fatty acids (NEFA), cytokines, PAI-1, and adiponectin. A high plasma NEFA level overloads muscle and lipid, which enhances insulin resistance. High CRP levels accompanying obesity may signify cytokine excess and a proinflammatory state. An elevated PAI-1 contributes to a prothrombotic state, whereas low adiponectin levels that accompany obesity correlate with worsening of metabolic risk factors. The* ***strong connection between obesity (especially abdominal obesity)*** *and risk factors led* ***ATP III*** *to define the* ***metabolic syndrome*** *essentially as a clustering of metabolic complications of obesity.*

Code 7. 'Obesity' plays a key role
Code 14. The 'condition' is best defined as 'metabolic syndrome'
Code 17. The 'ATP-III definition' is best
Code 19. Waist circumference/'abdominal obesity' is a key measurement

In relation to the usefulness of codes, Braun and Clarke highlighted how 'Some initial codes may go on to form main themes, whereas others may form sub-themes, and others still may be discarded' (2006:90). This was also the case for my study, where I created a number of codes, many of which did not lead to the creation of new themes.

Coding issues: the 'lumper-splitter problem'

Guest et al noted that 'A commonly encountered phenomenon in coding (or any group categorising task) is the "lumper-splitter problem" (Weller and Romney 1988)' and highlighted how 'individuals vary in the level of abstraction at which they process data' (2012:73). They described how some 'researchers generate a codebook with more than 500 codes (many with values) for a data set of moderate size' and claimed that 'These types of coders are splitters; every detail of text is coded' (2012:73–4). In contrast, they suggested that 'a lumper may only derive 6 to 10 high-level codes from, say, 50 in-depth interviews' but that 'Most people are somewhere in the middle' (2012:74). With my identification of 30 codes based on a data set of 30 documents, I am therefore more of a 'lumper', but would probably describe my approach as being 'somewhere in the middle'. In addition, my thematic analysis was not based on line-by-line coding as

favoured by some researchers, but instead used a more expansive approach to identify potential codes.

Phase three: searching for themes

Braun and Clarke stated that 'Phase three begins when all data have been initially coded and collated' (2006:89). In describing the next part of the analysis in more detail, they noted that 'This phase, which re-focuses the analysis at the broader level of themes, rather than codes, involves sorting the different codes into potential themes, and collating all the relevant coded data extracts within the identified themes' and that therefore 'Essentially, you are starting to analyse your codes and consider how different codes may combine to form an overarching theme' (2006:89).

Regarding the identification of themes, Braun and Clarke noted that 'Researcher judgement is necessary to determine what a theme is' and argued 'that you need to retain some flexibility, and rigid rules really do not work' (2006:82). Having studied the definitional literature for a number of months, this certainly aided my identification of potential themes in the data. In addition, when developing the themes I tried to be as flexible as possible in my approach.

Following my initial coding I started to look at potential themes. For example, I observed that many of the codes related to the wider issue of aetiology (underlying cause) and these tended to fall into two camps, which were based around 'IR and 'obesity'. I also found that a number of the other codes were grouped around the idea that the knowledge-claims surrounding the concept were uncertain and contested. Ultimately, this led me to identify eight candidate themes, which are outlined in Table 5, along with a number of sub-themes.

Table 5. Potential 'candidate themes' and their related codes

Potential theme	Description	Related codes
1.	Insulin resistance is key	6, 9, 15 and 16
2.	Obesity is a key factor	7, 8, 17, 18, 19 and 22

3.	The concept is contested	5, 12, 13, 24, 26 and 28
4.	Waist circumference/'abdominal obesity' is important	7 and 19
5.	The diagnosis is a 'private good'	31
6.	The diagnosis is a 'public good'	32
7.	The diagnosis may cause harm	33
8.	Uncertainty over the knowledge claims	5, 10, 12, 13, 23 and 24

After finishing this part of the analysis, Braun and Clarke concluded that 'You end this phase with a collection of candidate themes, and sub-themes, and all extracts of data that have been coded in relation to them' (2006:90). I was able to achieve this; the candidate themes and sub-themes I identified were based around aetiological, epistemiological and moral concerns.

Phase four: reviewing themes

Braun and Clarke noted that 'This phase involves two levels of reviewing and refining your themes' in which 'level one involves reviewing at the level of the coded data extracts' and 'level two involves a similar process, but in relation to the entire data set' (2006:91). In regard to my own study, I also undertook a period of 'refinement', which involved a careful reassessment of the themes and data.

Here Braun and Clarke also highlighted how 'it will become evident that some candidate themes are not really themes (eg if there are not enough data to support them, or the data are too diverse), while others might collapse into each other (eg two apparently separate themes might form one theme)' and that 'Other themes might need to be broken down into separate themes' (2006:91). This was also the case for my study where the eight 'potential themes' eventually became five, with theme 4 being assimilated into theme 2, while theme 8 was amalgamated with theme 3, and themes 5 and 6 became one simplified theme. This is all outlined in the next section.

Braun and Clarke concluded that 'At the end of this phase, you should have a fairly good idea of what your different themes are, how they fit together, and the overall story they tell about the data' (2006:92).

Phase five: defining and naming themes

In the next part of the analysis, Braun and Clarke noted that 'you then define and further refine the themes that you will present for your analysis, and analyse the data within them' (2006:92). In relation to my study, continuing the work begun in phase four this led to the creation of five themes, which came to form the backbone of the analysis. These are outlined in Table 6.

Table 6. The final five themes

Theme	Name/definition
1.	Insulin resistance is key
2.	Obesity is a key factor
3.	The concept is contested
4.	The diagnosis represents a 'good'
5.	The concept may cause harm

These five themes identified in the data set then went on to play a key role in both my analysis of the construction of the metabolic syndrome and later discussion of the ethical issues raised by the creation of the concept.

Phase six: producing the report

Braun and Clarke noted that 'Phase six begins when you have a set of fully worked-out themes, and involves the final analysis and write-up of the report' and that 'your analytic narrative needs to go *beyond* description of the data, and make an *argument* in relation to your research question' (2006:93). In relation to my study, the 'themes' identified here therefore represented the beginning rather than the end of my analysis of the metabolic syndrome because they were then used as key components in my main constructionist and bioethical exploration of the concept.

Thematic analysis: implications for my main study

Through my thematic analysis of the 'key definitional literature' (30 documents) on the metabolic syndrome, I was able to investigate how the knowledge claims surrounding the condition had evolved and create a detailed chronology of the construction of the

concept; as well as identify any specific ethical issues raised by the medical/scientific experts involved in the field.

This led me to identify three groups of constructs that emerged between 1988 and 2009. The first two groups were based on how the different claims-makers portrayed the underlying cause (aetiology) of the 'condition'. The first group of constructs was based around IR as the main underlying factor, while the second group was based on obesity being the key issue. The third group of constructs were based around the idea that the concept was 'controversial'.

Analysis also showed that the construction of the metabolic syndrome concept from 1988 to 2009 could be divided into three distinct periods, with the first period being from 1988 to 2000, the second from 2001 to mid 2005, and the third from late 2005 to 2009. The first period included claims-makers from the diabetes medical community, and the constructs were predominantly centred on IR (theme 1) while the second period included claims-makers from a range of medical disciplines that included diabetologists and cardiologists, as well as other groups, and where the constructs were centred on obesity (theme 2). The third period again included claims-makers from a number of medical disciplines, and the constructs centred on the idea that the concept was controversial (theme 3). In regard to my exploration of the ethical issues raised by the concept, the thematic analysis also identified two themes that were widely discussed in the literature. The first (theme 4) referred to the 'condition' as a threat to health and that the diagnosis represented a 'good' (private and public), and usually came from proponents of the concept; whereas the second (theme 5) referred to the 'condition' as ill thought through and with the potential to 'do harm' (individuals and wider population), and usually came from critics of the concept.

The thematic analysis therefore enabled me to identify some of the key themes in the literature, and I was then able to use this information in my main constructionist/bioethical analysis of the metabolic syndrome. In the following three chapters, I will be discussing the results of this analysis in more detail.

Interview methods

Primary interview data

In addition to the qualitative data collected from the documentary sources, further evidence was also gathered by interviewing two of the key players involved in the construction of the metabolic syndrome concept. Following an initial trawl of the general academic literature related to the metabolic syndrome concept, and subsequent immersion in the material, it became apparent that a number of names kept appearing, or were identified as being key individuals involved in the construction of the concept. The top of these was Gerald Reaven, followed in no particular order by George Alberti, Paul Zimmet, Scott Grundy, Robert Eckel, Jean-Pierre Despres, and Richard Khan. As these individuals were scattered across the world — USA, UK, Australia, Canada — for practical reasons and a limited PhD travel budget, I decided that telephone interviews would be the best option. I also decided to try to limit the length of the interview to between 30 and 45 minutes, because I knew they would be very busy individuals who would probably not be able to give much longer. If they were willing to talk longer on the topic, I was of course happy to extend the interview time. I was aware that this would still give me a considerable amount of material, and mindful of the fact that the conversations would also need to be transcribed afterwards.

Recruitment and sampling

One of the main problems I encountered was not being able to gain access to some of the 'key claims-makers/players' involved in the construction of the metabolic syndrome concept. These individuals had been identified earlier in my analysis following a period of immersion in the data, which enabled me to make informed decisions about who the 'key players' were. Again the sampling method I used here was 'purposive sampling', which Payne and Payne describe as the type that 'picks its sub-set for a particular, non-statistical purpose' and used the example of 'deliberately select(*ing*) key informants because they are *not* typical: they know more about the community or organisation than other people' (2004:210). The key players in the construction of the metabolic syndrome concept are therefore the equivalent of 'key informants', and included individuals such as George Alberti and Scott Grundy.

I initially contacted all the main players I had identified by e-mail, to request a telephone interview. This led to immediate positive responses from Gerald Reaven and Robert Eckel, but I was less successful with the other key players. Paul Zimmet, for example, initially said he would be prepared to answer questions sent to him by e-mail. When I wanted to do this he said that he was too busy, but that I should contact him again at a later date. By the later point, however, I had amassed a significant amount of data and therefore decided not to follow this up. George Alberti, the only UK-based key player, never got back to me regarding my request for an interview. Stephens (2007) highlighted the problems of negotiating access in his paper 'Collecting data from elites and ultra elites'. In the work, he outlined 'differing techniques for negotiating access' (2007:212), but suggested that 'telephone interviewing with elite and ultra-elite respondents is both a productive and valid research option' (2007:203).

A further problem I encountered related to the inaudibility of parts of my recordings, which is evident in some of the gaps in the transcripts. As I became more adept at the technique and replaced my tape-based recorder with a digital one, the recordings improved. Although this occurred infrequently, it was still frustrating to know I had lost potentially useful data. From a research ethics perspective, I also asked each interviewee whether it was ok for me to quote them directly, and fortunately they all verbally agreed that I could quote them as I wanted. I offered to send them a transcript of their interviews afterwards, but they all declined my offer.

Research ethics

During my period of study I adhered to the Economic and Social Research Council (ESRC) code of conduct, which is available from their website (ESRC, 2004). The ESRC provided funding for my research. I also referred to Cardiff University's School of Social Sciences own guidelines for research (Cardiff University School of Sciences, 2006).

Interviews conducted

I was only able to interview two of the key players, Gerald Reaven the widely acknowledged 'founding father' (Breitstein 2004, Sternberg 2005b) of the field, and Robert Eckel a past president of the American Heart Association (AHA). The interviews were semi-structured in approach and lasted approximately one hour. As

stated above, because these two key players were based in the United States the interviews were telephone based. The first interview (with Reaven) took place in September 2005, which was towards the end of stage two of my documentary analysis, while the second interview (with Eckel) took place in July 2006, which was at the beginning of the final phase (stage three). By the time I was ready to interview these two key players, many of the coding categories (from my documentary analysis) were already well developed and on the way to becoming fixed. This detailed and in-depth understanding of the concept really helped in developing my approach to the interviews, because I knew many of the key points in the debate, and therefore knew when and which issues to explore in more detail.

In addition to these key individuals, I also conducted semi-structured interviews with a local general practitioner (GP), hospital dietician, two obesity specialists, an epidemiologist, whole food expert, commercial expert, and even a 'celebrity chef'. However, I decided that because I had already collected a substantial amount of data during my documentary analysis of the metabolic syndrome concept, and with the key individuals highlighted above and the constraints of my PhD thesis, that I would not use the data here. Despite this, the extra interviews still gave me a valuable insight into the wider understanding of the concept and I certainly hope to make use of the data in the future.

Interview questions

The main aim of my research was to analyse the construction of the metabolic syndrome concept. I therefore wanted to explore numerous aspects of the concept with my interviewees. I decided to use a semi-structured qualitative interview approach, where I had a general list of basic questions to ask, but allowed interviewees to go down other paths if the conversation went that way (Fielding, 1988; Silverman, 1999; May, 2001; Wetherell et al, 2001; Bryman, 2008). I tried to make the questions specific enough that the answers were useful to me, but also open-ended enough to give my interviewees the opportunity to expand on an issue if they wished to do so. As May noted, 'These types of interviews are said to allow people to answer more on their own terms than the standardised interview permits, but still provide a greater structure for comparability over that of the focused interview' (2001:123).

I deliberately used the term ‘condition’ because this is fairly neutral. I avoided using ‘syndrome X’, ‘IRS’, ‘metabolic syndrome’ or any other specific term because I was aware that a number of the experts were sensitive about this. I knew that if I used an ‘incorrect’ term in their eyes during the interview this may make things difficult for me, particularly as I wanted the participants to talk freely about the concept. When I initially contacted Gerald Reaven, for example, I mentioned that I wanted to talk to him about ‘metabolic syndrome’ and he categorically stated that he would only talk to me about ‘syndrome X’ and/or the ‘IRS’, which showed that for him the use of particular terms was very important. The first question was deliberately expansive and open-ended because I wanted to get off to a good start with the interviewee, and thought that ‘generalised’ questioning at the beginning would be the best approach.

I only had eight general questions to ask the interviewees (see Box 3) because I wanted to keep the interview as close to a normal conservation as possible. Although difficult, I thought that too many questions might overload the individual and also cause the flow of the interview to be disrupted (May, 2001).

Box 3. Basic interview questions

1. Can you tell me about the condition in general?
2. Can you tell me about diagnosing the condition?
3. Can you tell me about what, if any, treatments are available?
4. What do you think are the main underlying causes?
5. Can you do anything about preventing the condition?
6. Do you think the condition is a public health issue?
7. How do you think the condition will impact on society?
8. Who should take most responsibility for this condition?

If it became apparent that they wanted to talk about one question more than the others, I was happy to probe them on particular issues. I also had a series of follow up questions ready to ask them if required (see Box 4).

Box 4. Follow up questions

1. Can you tell me about the condition in general?
    - What term are you most comfortable with?
    - How would you describe the condition?
    - When did you first hear about the condition?
    - How do you see the condition developing?

2. Can you tell me about diagnosing the condition?
    - Which definition do you prefer?
    - Do you find the diagnosis helpful?
    - When is diagnosis most appropriate?
    - Do you mention the diagnosis to your patients?

3. Can you tell me about what, if any, treatments are available?
    - Which treatments do you favour?
    - Are there any new treatments available?
    - Which professionals should be involved in treatment?
    - Do you think the condition can be cured?

4. What do you think are the main underlying causes?
    - Is the aetiology well understood?
    - Does 'lifestyle' have a role to play?
    - Does genetics have a role to play?
    - Do you favour one explanation more than others?

5. Can you do anything about preventing the condition?
    - Is 'lifestyle' important?
    - What can medical professionals do?
    - Does society have a role to play?
    - What can individuals do?

6. Do you think the condition is a public health issue?

- If so, why?
- If not, why?
- How prevalent is the condition?
- How do you tackle it at the population level?

7. How do you think the condition will impact on society?
    - In terms of health?
    - In terms of health care?
    - In terms of financial costs?
    - Can you think of any other affects?

8. Who should take most responsibility for this condition?
    - What is role of the individual?
    - What is the role of society?
    - What is role of medical professionals?
    - Do other groups have a role to play?

Interview transcription and analysis

I transcribed the interviews verbatim, which means that some of the text sounds strange in places, but I wanted to leave them largely unaltered in order to maintain the integrity of the data (Gilbert, 1993; Silverman, 1999). This produced two documents of considerable length. These were then individually analysed by taking the 'themes' that had been identified during my analysis of the documentary material, and seeing how these compared to what was being said during the interviews. The analysis was therefore also thematic in its approach, but this time was restricted to the data collected from the eight interview questions (plus follow-up questions) highlighted above. I designed these questions to be complementary to the series of six questions asked during my documentary analysis (see 'Phase 1: familiarising yourself with your data').

This enabled me to identify a number of key issues and themes from the data from the interview transcripts (May, 2001 (chapter six), Wetherell et al 2001 (chapter one), Guest et al 2012), as I had done before. I also looked out for comments that either

confirmed or disagreed with statements that the individuals had made in previous publications. This enabled me to triangulate the data with my documentary analysis and see whether there were any differences between what the interviewees wrote and how they perceived the metabolic syndrome (Denzin, 1970; Silverman, 1993; Payne and Payne, 2004; Bryman, 2008).

Primary interview data: summary

The interview data proved particularly illuminating because it gave a much greater insight into the documentary evidence, particularly in relation to what these key players were hoping to achieve, and what they thought about rival constructions and the wider literature on the topic. Below is a brief description of how the interviews with Reaven and Eckel went, based on field notes that I made at the time.

Gerald Reaven

I conducted a telephone interview with Gerald Reaven on 30 September 2005 that lasted for 53 minutes. During my discussion with him, he came across as a very personable individual, who was not afraid to air his views. He seemed to treat my interview as an 'informal chat' and I was able to cover a wide range of topics relating to the syndrome X/metabolic syndrome/IRS concepts. Reaven also explored other related issues, which I gave him the opportunity to do, and was out spoken in places.

Robert Eckel

I conducted a telephone interview with Robert Eckel on 21 July 2006 that lasted for 56 minutes. At the time he had recently retired from his post as president of AHA, and at the start of the interview he described himself as an 'AHA past president' and 'co-author of an AHA/NHLBI report (Fall 2005) that redefined the syndrome'. The latter was in reference to his involvement as co-chair of the 11-member AHA committee that was responsible for the ATP-III update definition (Sternberg, 2005b:2). My interview therefore related to his time as AHA president, and particularly his role in shaping one of the key definitional constructs. During my discussion with him, he also came across as a very personable individual, but was more measured and cautious than Reaven when discussing his views in relation to the metabolic syndrome concept. He seemed to treat my interview as a professional encounter, rather than an informal discussion, which was disappointing because Reaven's candid approach was more illuminating. I was still

able to explore a number of different issues in relation to the metabolic syndrome with him, however, and gained another useful insight into the field.

Secondary interview data

As well as the primary interview data, I was also able to collect additional secondary interview data from two further key players, namely Scott Grundy and Paul Zimmet (see Box 5). This material consisted of four additional documents, which included two media interviews (newspaper and medical press), press conference comments, and radio programme transcript (Grundy, 2001; Mitka, 2004, Maley, 2005; Swan, 2005).

Box 5. Secondary interview data

Scott Grundy

- Press conference remarks: release of the third report of the National Cholesterol Education Program expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (ATP-III), 15 May 2001.
- Interviewed for Mitka article entitled 'Metabolic syndrome recasts old cardiac, diabetes risk factors as a 'new' entity', published in the *Journal of the American Medical Association*, 5 May 2004.

Paul Zimmet

- Interviewed for Maley article entitled 'Our fat future, death by beer gut', published in the *Sydney Morning Herald*, 16 April 2005.
- Radio interview given to The Health Report with Norman Swan, Australian Broadcasting Company (ABC) on 'Diabetes/metabolic syndrome', 6 June 2005.

I then analysed these documents using the same approach as the one used during my analysis of the interview transcripts. This time I concentrated on the text/quotes that were attributed to the key players in question. Again, I was able to identify a number of 'key themes' during my analysis of this material.

As before, these secondary interview data were useful in enabling me to gain a greater insight into how some of the other key players (Grundy and Zimmet) involved in the construction of the metabolic syndrome viewed the concept. I also looked out for comments that either confirmed or disagreed with statements that the individuals had

previously made, which enabled me to see whether there were any differences between what they wrote and how they perceived the metabolic syndrome. Such data come with their own set of problems (Payne and Payne, 2004), however. I treated this material with more caution than my own primary interview data because of its 'secondary' nature and the risk that the participants had been misquoted or their comments taken out of context (May, 2001; Payne and Payne, 2004).

Interview data as triangulation

By this time the interviews were conducted the documents had been studied in some detail and a fairly stable set of coding categories developed. The interviews enabled me to test the validity of these categories in two ways. First, by conducting the interviews I was able to test my understanding of the field and its controversies in conversation with two leading experts. The fact that the interactions were generally successful, and went on for longer than anticipated suggests that my understanding was sufficient to hold an interesting conversation, which Collins and Evans (2002) suggest can be used as a marker of interactional expertise. Second, I was able to analyse the interview transcripts, both primary and secondary, as data in their own right. This provided an opportunity to check the utility of the coding categories developed from the documents (Denzin, 1970; Silverman, 1993; Payne and Payne, 2004; Bryman, 2008). This analysis provided another form of triangulation as it allowed me to examine the extent to which the same themes emerged in both documentary and interview data. This was indeed the case, with no new categories or themes emerging from the interview data, suggesting that the coding categories successfully capture the key elements of the controversy.

5. Methodological reflections

Reflexivity

While carrying out my documentary analysis on the medical and scientific literature surrounding the metabolic syndrome and additional interview data, I was aware that my research itself and this thesis are open to the same critique as the academic work I analysed, namely that my work is also an example of claims-making, a construction of metabolic syndrome as a subject suitable for sociological and bioethical analysis, and that the aim here is to persuade people of my ideas (Miles and Huberman, 1994; Denzin and Lincoln, 1998; Payne and Payne, 2004). Potentially this presents researchers with

a problem, but by being aware of the issue in relation to my own work I was at least able to try and minimise this by using methodological triangulation (Denzin, 1970; Payne and Payne, 2004:230). The information gained from the primary interviews (with the two key players) acted as a cross-check to help verify the validity and reliability of my data (Silverman, 1993; Payne and Payne, 2004). Reflexively I also acknowledge that my own work is a product of construction (Miles and Huberman, 1994; Denzin and Lincoln, 1998; Payne and Payne, 2004).

Multidisciplinary research: some reflections

Before moving on to the next chapter, the first of three outlining my sociological analysis of the metabolic syndrome, I want to briefly discuss the issue of 'multidisciplinary work'. At the very beginning of this project I decided that I did not want to limit my research to a single disciplinary perspective, because after reading some of the key medico-scientific literature on the metabolic syndrome it became apparent that the 'condition' raised a number of social and ethical questions that would not be adequately dealt with using a single disciplinary approach. I therefore chose to analyse the concept from both sociological and bioethical perspectives. The metabolic syndrome seemed to lend itself to such an approach because of its own status as a 'condition' that crossed a number of medical disciplinary boundaries. As a result, I ended up using theoretical and methodological approaches from both sociology and bioethics. Unfortunately, these disciplines have a long history of being at odds with each other, although in recent years academics from both sides have attempted to bridge the disciplinary divide and work more closely together (Nelson, 2000; Haimes, 2002; de Vries, 2003; Hedgecoe, 2004; Lopez, 2004; Levitt and Hayry, 2005). For example, a number of researchers advocate the adoption of sociological theory and methods in bioethics (Hoffmaster, 1992; Zussman, 2000; Borry et al, 2005). This was an area of literature that I explored in Chapter 2.

Conducting multidisciplinary work presents the researcher with a number of additional problems, especially in relation to the contrast in theoretical and methodological outlook between disciplines. This is particularly true for sociology and bioethics, with the former tending to focus on the empirical aspects of everyday life, while the latter has traditionally dealt with more abstract issues, such as rights and wrongs (Callahan, 1999; Hedgecoe, 2004). Reflexively, my own academic background is one of

disciplinary boundary-crossing, having originally studied biological sciences and then spent a number of years in medical research, before moving towards medical sociology and bioethics. This may account for my greater willingness, or foolhardiness — depending on your perspective — to attempt such an approach.

Using a multidisciplinary approach requires discipline, flexibility and commitment from the researcher, but the rewards can be significant, particularly in terms of gaining a greater insight into your topic by exploring the issue from more than one perspective (Evans and Marvin, 2006). Carrying out such work is often difficult, particularly when each discipline has its own set of approaches, as it requires the researcher to have an understanding of both, and makes it much harder to maintain high academic standards. This is concern highlighted by Tausig et al in their work on the bioethical problems of infectious disease, when they noted that:

Some scholars argue that bioethics suffers from a low level of rigor because bioethics discourse requires expertise in both ethics/philosophy and biomedical science. This difficulty is compounded in the context of infectious disease where rigorous discourse also requires an in-depth understanding of social science (Selgelid 2005)

(Tausig et al, 2006:847).

I was fortunate to be based within a multidisciplinary organisation, namely Cesagen (Centre for the Economic and Social Aspects of Genomics) that was funded by the ESRC and was in collaboration with Lancaster and Cardiff Universities. Cesagen had researchers from a range of disciplines, including medicine, natural sciences, social sciences and bioethics, which was useful because it was a small centre and I was able to discuss my work with individuals from a number of different academic backgrounds and tap into their knowledge.

Introduction to Chapters 4, 5 and 6 (data chapters)

Metabolic syndrome: what's in a name?

Best noted that one of the first and easiest ways to define something is 'to give it a name' (1987: 104). A number of different names have been used to describe the metabolic syndrome concept over the years. To make the situation even more complex, whenever claims-makers have come up with a new construction they have invariably also given it another new name. As an illustration of how important particular terms can be for those with an interest in the field, when I contacted Gerald Reaven in 2005 concerning a possible interview and asked to speak to him about metabolic syndrome, he replied that he would only talk to me about syndrome X or insulin resistance syndrome (IRS).

The list below highlights some of the main names that have been used during the 20-year period covered in this study to describe the metabolic syndrome concept, but is by no means exhaustive:

Table 7. The names used to describe the metabolic syndrome concept (Waine 2004)*

- **Insulin resistance syndrome**
- **Syndrome X**
- **Reavens syndrome**
- **Metabolic syndrome**
- Metabolic syndrome X
- Plurimetabolic syndrome
- Multiple metabolic syndrome
- **Dysmetabolic syndrome**
- Cardiovascular metabolic syndrome
- Cardiometabolic syndrome
- 'H' phenomenon
- **The deadly quartet**
- Chronic cardiovascular risk syndrome

*The names in bold are more commonly used

The names highlighted in bold are the constructs that are most commonly used and hence are the ones I will be looking at in detail during my analysis. The fact that there is still no universally recognised name, many years after the concept was first described, shows that it is contested and that the controversy is still on-going. However, the majority of the terms at least agree on one aspect, which is that the concept is an example of a syndrome. One definition of the term syndrome, put forward by Alberti et al is that it is 'a recognizable complex of symptoms and physical or biochemical findings for which a direct cause is not understood' and 'With a syndrome, the components coexist more frequently than would be expected by chance alone', and that 'When causal mechanisms are identified, the syndrome becomes a disease' (2006:473). In medicine, 'syndromes' therefore tend to be seen as more flexible and less well defined than 'diseases'. Murphy in his discussion of the philosophical underpinnings of medicine for example noted that 'A syndrome is a more precarious entity in which the elusive facts are propping each other up by their association' (1976:112). This issue is important in relation to this study, because metabolic syndrome is specifically defined as a 'syndrome' and not a 'disease', and is therefore also regarded as a more uncertain and contested object by medicine.

Metabolic syndrome: 1988–2009

In this thesis, I will explore how the debate surrounding the metabolic syndrome developed, from the concept's early origins in 1988 with Reaven, through to the highly-publicised disagreements of 2005, and on to 2009 with the publication of a 'harmonisation' statement.

During my analysis of the key literature surrounding the metabolic syndrome concept, I was able to identify a number of different constructs that emerged as the academic debate and controversy unfolded. These I believe can be broadly divided into three main conceptualisations. The first two are based on how the different claims-makers view the underlying aetiology (cause) of the syndrome, with the first group of constructs being based around 'insulin resistance' and the second group based around 'obesity' as the main underlying factor. In contrast, the third group of constructs are based around the idea that the syndrome is 'controversial'.

It is possible to identify three distinct periods during the construction of the metabolic syndrome concept. The first, which runs from 1988 to 2000, was dominated by claims-makers from the diabetes medical community, and the constructs were predominantly centred on insulin resistance. The second period, from 2001 to mid-2005, included claims-makers from a range of medical disciplines that included diabetologists and cardiologists, as well as other groups and where the constructs were predominantly centred on obesity. The third period, from late 2005 to 2009, also included claims-makers from a number of medical disciplines, but now the debate largely centred on the idea that the concept was 'controversial'. The main features of each of these three constructs is summarised below and then analysed in more detail in the chapters that follow.

Group 1: insulin resistance constructs

These constructs conceptualised the syndrome as an identifiable condition that was linked to 'insulin resistance' and increased the risk of developing coronary heart disease (CHD) and/or type 2 diabetes. The constructs in this group included: syndrome X (Reaven, 1988), IRS (as envisaged by Defronzo and Ferrannini, 1991; Haffner et al, 1992; American College of Endocrinology [ACE], 2003), the metabolic syndrome (as envisaged by the WHO, 1999; EGIR, 1999), and dysmetabolic syndrome X (as put forward by the American Association of Clinical Endocrinologists [AACE] 2002 and backed by the ICD/WHO). The claims-makers responsible for these constructs all come from the diabetes medical community.

Group 2: obesity constructs

These constructs conceptualised the metabolic syndrome as an identifiable condition linked to 'obesity' that increased the risk of developing CHD and/or type 2 diabetes. The constructs in this group included: 'The Deadly Quartet' (Kaplan, 1989), 'Hypertriglyceridemic waist' (Despres et al, 2001), the metabolic syndrome (as envisaged by the NCEP ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001), the metabolic syndrome (as envisaged by the IDF Consensus definition (IDF, 2005a), the metabolic syndrome (as envisaged by the NCEP ATP-III 2005 update). In contrast to Group 1, the claims-makers responsible

for these constructs are not restricted to the diabetes community but come from a range of medical disciplinary backgrounds.

Group 3: controversy constructs

These constructs largely appeared from 2005 onwards and conceptualised the metabolic syndrome (as interpreted by the WHO (1999), ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001) and IDF (2005a,b)) as being 'controversial', not a 'real' syndrome and of limited use clinically. The constructs in this group included the metabolic syndrome as perceived by:

- the ADA/EASD (Kahn et al, 2005)
- Kim and Reaven (2004), and Reaven (2005a, b)
- ADA/AHA (Eckel et al, 2006)
- AHA harmonisation statement (Alberti et al, 2009).

Again the claims-makers behind these constructs predominantly come from the endocrinology/diabetes field.

Claims-makers' interests/disciplinary rivalry

Social factors, such as the disciplinary/technical and organisational interests of those constructing new medical concepts, invariably has an influence on how knowledge is constructed. In addition, rivalries between different disciplinary interest groups can also have an impact on the process of construction. For example, Conrad highlighted how 'inter-professional or organisational contests' have previously been seen as one of the 'prime movers toward medicalisation' (2003:3). The metabolic syndrome concept has been no exception, with individuals from different disciplinary/technical backgrounds and rival medical professional organisations all having an impact on the various constructs.

The analysis that follows focuses on how these rivalries have developed, and what if any impact these have had on the way the metabolic syndrome concept has been constructed. Even as early as my preliminary analysis, it became clear that a number of the key documents in relation to the metabolic syndrome had been published in direct response to the publication of definitions and/or updates by 'rival' organisations. The creation of the NCEP ATP-III definition of the metabolic syndrome in 2001 for

example, was seen as a result of the publication of the WHO definition in 1999 (Eckel et al, 2005; Grundy, 2006b). The publication of the ACE definition for IRS in 2002, was seen as a response to the emergence of the ATP-III definition (Alberti et al, 2006). The development of the IDF consensus definition in 2005 (itself thought to be an update of the WHO 1999 definition, see (Grundy, 2006)) was also viewed as a response to the ATP-III definition (Eckel et al, 2005). Following the publication of the IDF definition in April 2005, the AHA and NCEP released a significant update of their own ATP-III definition in August 2005, which they stated was 'intended to provide up to date guidance for professionals on the diagnosis and management of the Metabolic Syndrome in adults' (Grundy et al, 2005:2735).

In the case of metabolic syndrome, the two disciplines that are central to the debate are endocrinology and cardiology. Indeed, a superficial analysis might even suggest that the whole process can be described as a straightforward 'difference of opinion' or even 'turf war' between the two. The reality was more complicated than this, particularly as obesity constructs become important. In particular, while it is certainly true that the claims-makers behind the constructs in Group 1, which give priority to the role of insulin resistance all come from the endocrinology/diabetes world, those in Group 2, which give priority to the role of obesity, are far more heterogeneous with individuals and groups coming from a range of backgrounds, including endocrinology/diabetology, cardiology, the field of lipid research, obesity specialisms, and general internal medicine. In the final phases of the controversy, as the status of the metabolic syndrome becomes less certain, the number and range of claims-makers is reduced and endocrinology, once again, makes up the vast majority of participants.

While the constructs in Groups 1 and 3 that privilege insulin resistance and controversy, respectively, were almost certainly a reflection of the disciplinary background of those involved; the situation is more complex for the constructs in Group 2 that privilege obesity, with evidence of diabetes specialists apparently 'going against type' and giving priority to 'obesity explanations' in the case of the IDF (2005) consensus definition construct.

In relation to professional rivalries, my preliminary analysis of general articles on the metabolic syndrome identified a number of professional organisations with an interest

in the concept; therefore the potential for significant rivalries to develop was certainly there. The AHA and ACE, for example, both created potential 'rival' versions of the metabolic syndrome concept (ATP-III 2001 and IRS 2002, respectively) within a year of each other and published them, therefore opening them up for scrutiny by the wider medical community.

Chapter 4

The early years (period 1: the diabetes years, 1988–2000)

The first period was characterised by the introduction of syndrome X, which was conceptualised as an identifiable condition that was linked to insulin resistance and increased the risk of developing CHD and/or type 2 diabetes. The constructs in this group were all variations on this basic concept, and the claims-makers responsible for them came from the diabetes medical community.

Construct 1.1. Syndrome X (Reaven, 1988)

Since its publication, Reaven's 1988 paper has come to be seen as highly significant by the diabetes community. A review article written jointly by the ADA and EASD, for example, described Reaven's work as a 'landmark publication' and 'seminal paper' (Kahn et al, 2005). Another review by Alexander (2003) described the paper as a 'landmark article'. This paper therefore represents an obvious starting point for any exploration of the construction of the metabolic syndrome concept.

When Professor Gerald Reaven was given the honour of presenting the Banting memorial lecture at the ADA's annual scientific conference in 1988, he was already a highly distinguished member of the diabetes medical community in the United States and beyond. A clinician by training, since the 1960s he has also conducted scientific research, with a particular interest in insulin and its role in the human body (Reaven, 2005d). Reaven's lecture and subsequent paper entitled the 'Role of Insulin Resistance in Human Disease' was published in 1988 in the journal of the ADA, *Diabetes*, and is widely seen by professionals within the diabetic field and metabolic syndrome sub-discipline as being the catalyst for renewed interest in this area by the wider biomedicine.

It is not uncommon in scientific research for some papers to become seen as key publications, and this can often occur many years after their publication, when for example an article is published reviewing the research work in a particular field. Gilbert noted, for example, that 'certain papers, through their repeated use as authoritative grounds for further work, begin to achieve an exceptional status, and may come to be

regarded as 'exemplars' […] of valuable work in the field' and that there are 'a few 'exemplary' papers receiving very high rates of citation' (1977:117 and 118). Reaven's (1988) paper would certainly fit this category with publications related to the field universally referencing his work and regarding it as highly significant.

Reaven's publication is an example of a typical experimental paper, although at 13 pages (including two pages of references) it is quite long, and is data-rich with the inclusion of 16 different graphs. It is also a considerable time before he first mentions the Syndrome X concept, not discussing the idea until 11 pages into the document, where it is introduced to the reader with very little fanfare.

As mentioned above, the early phase (1988–2000) of the construction of the Metabolic Syndrome concept was characterised by the emergence of constructs from the diabetes community, all of which gave insulin resistance a key role. Reaven's 'Syndrome X' paper was the catalyst for this activity; therefore it is useful to see how he first referred to the issue in the publication. He introduced the concept with the following statement:

Based on available data, it is possible to suggest that there is a series of related variables – syndrome X – that tends to occur in the same individual and may be of enormous importance in the genesis of CAD

(Reaven, 1988: 1605)

Here the claim is initially made in a relatively tentative way, using terms such as 'it is possible' and 'may be' when putting his ideas forward, but this is fairly typical for this genre of writing (academic/scientific). On the same page, Reaven then highlights the key variables that he believes constitute the syndrome. He summarised these in table form, which I have reproduced in Table 8.

Table 8. Syndrome X (Reaven 1988)*

- **Resistance to insulin-stimulated glucose uptake**
- **Glucose intolerance**
- **Hyperinsulinaemia**

• Increased very-low-density lipoprotein triglyceride • Decreased high-density lipoprotein cholesterol • Hypertension
*Variables in bold relate to insulin resistance

This is the point where the construction of syndrome X really gets going, with Reaven starting to define the concept in terms of being a 'problem of insulin resistance'. By doing so he is then able to claim that the condition is best dealt with within the domain of diabetes research and treatment, and that his technical skills, experience and professional background make him an ideal candidate to explore the issue. The three variables highlighted in bold all relate to insulin resistance directly or indirectly, which means that Reaven has linked half of all the variables that he outlined to this problem.

He is even clearer in the main text on 'insulin resistance' and its role in the syndrome, when he states that:

The common feature of the proposed syndrome is insulin resistance, and all other changes are likely to be secondary to this basic abnormality

(Reaven 1988:1605)

In the abstract, Reaven highlights the importance of insulin resistance in human disease, when he links it to what he describes as 'three major related diseases', when he states that:

… the possibility is raised that resistance to insulin-stimulated glucose uptake and hyperinsulinemia are involved in the etiology and clinical course of three major related diseases – NIDDM (non-insulin-dependent diabetes mellitus), hypertension, and CAD (coronary artery disease)*

*The terms NIDDM (and insulin-dependent diabetes mellitus or IDDM) are no longer used in the diabetic field to describe the different forms of this condition, having been replaced by the terms type 2 and type 1 diabetes, respectively (WHO, 1999)

(Reaven 1988:1595, Abstract)

By suggesting that insulin resistance may be the underlying cause behind three other important medical conditions, namely NIDDM, hypertension and coronary artery disease (CAD) — and therefore by association syndrome X — Reaven is constructing his concept as representing an even more significant social/medical problem. In addition, by highlighting the latter two conditions of high blood pressure and heart disease, he effectively invites other interest groups from medicine, the obvious ones being cardiologists (medical professionals who specialise in conditions related to the heart and arterial system), to include syndrome X within their conceptual and diagnostic repertoire.

Returning to the main body of text, having highlighted the importance of insulin resistance in the syndrome, Reaven goes on to speculate as to why insulin resistance may differ between individuals, when he suggests that:

Although it is likely that a significant portion of the variance in insulin resistance observed from person to person is genetically determined (Bogardus et al 1985), insulin action can also be modulated by environmental influence

(Reaven 1988:1605)

In highlighting the importance of environmental influence on insulin resistance, he is then able in the next section to discuss the potential role that obesity and a sedentary lifestyle may play in driving the syndrome. Here he writes that:

Consequently, the more obese and sedentary an individual, the greater the degree of insulin resistance, regardless of genetic influences. Not surprisingly, obesity and decreased physical activity have also been shown to be correlated with hyperinsulinemia, glucose intolerance, increased plasma triglyceride concentration, decreased HDL-chol concentration, and high blood pressure.

(Reaven 1988:1605)

By discussing the role that obesity and decreased physical activity may play in insulin resistance and therefore the syndrome, Reaven is positioning syndrome X as an

important public health issue. In addition, by linking obesity and decreased physical activity to insulin resistance and the other components (such as high blood pressure) of the syndrome X concept, he is also medicalising a specific type of behaviour and lifestyle. Yet while Reaven readily acknowledges the role played by obesity in relation to insulin resistance here, he does not include this factor among his list of variables for syndrome X, an omission that is regularly highlighted by rival claims-makers in order to critique and undermine this concept. This difference in emphasis between claims-makers such as Reaven, who concentrate more on insulin resistance, and those who highlight obesity in relation to the underlying aetiology (cause), as I will show later, has become one of the main sources of tension between the different interest groups. In addition, this has also become the main focus of division between the different constructs, an issue that I will be exploring shortly. In the next section Reaven offers possible preventative and treatment strategies to tackle the condition, when he states:

In light of these considerations, it seems obvious that variations in life-style, in particular avoiding obesity and remaining physically active, provide an approach to minimize the risk factors for CAD associated with resistance to insulin-stimulated glucose uptake

(Reaven 1988:1605)

By highlighting potential treatment options, Reaven therefore moves the construct away from just being of probable interest to researchers and epidemiologists, towards something that may be of use in the clinical setting. In doing so, he is medicalising obesity and physical activity still further, by suggesting that as well as being the main causative factors ('obesity and decreased physical activity'), they also represent the most 'obvious' preventative/treatment strategy ('avoiding obesity and remaining physically active').

On two occasions in the paper Reaven refers to the earlier work of Himsworth, one of the acknowledged academic giants of the diabetes field. This was primarily done to put his work in context, but by aligning his work with such a figure, the aim was to also give it added authority and legitimacy. The first occasion when Reaven mentions Himsworth's work is at the start of paper, when he states that:

The fact that a large number of patients with diabetes are 'insulin insensitive' was first demonstrated by Himsworth ~50yr ago

(Reaven 1988:1595)

The second occasion is in the conclusion, where Reaven attempts to compare his situation to when Himsworth first suggested that a defect in insulin action could lead to human disease in 1936, when he stated that:

These conclusions suggest that resistance to insulin-stimulated glucose uptake is involved in the etiology of NIDDM, hypertension, and CAD. Although this concept may seem outlandish at first blush, the notion is consistent with available experimental data.

Approximately 50 yr have elapsed since Himsworth (1936) first suggested that human disease could be secondary to a defect in insulin action. It now seems clear that he was correct, and the point of view he introduced has become well established

(Reaven 1988:1606)

In the first paragraph, Reaven tries to pre-empt possible criticism by acknowledging that his hypothesis may currently seem 'outlandish', but that there is empirical evidence to support his claims. In the second paragraph he reminds readers that Himsworth's earlier pronouncements now represent the orthodoxy, in a rather unsubtle way suggesting that his own work on insulin resistance and syndrome X will in time come to be seen in the same light. In his final remarks in the conclusion, Reaven deliberately plays down the potential importance of his work, again typical of this genre of writing. In the last sentence, for example, he portrays his work as simply pointing the way for others to explore the issue, when he states:

What remains to be seen is the magnitude of the role that resistance to insulin-stimulated glucose uptake plays in the etiology of human disease. I can only hope that this presentation has outlined the possibilities for future efforts to answer this question

(Reaven 1988:1606)

Reaven 1988: themes and key ideas

Reaven's 1988 paper is seen as a key factor in reawakening interest in the topic of insulin resistance and disease. Analysing the paper you realise that the amount of space dedicated to discussing the syndrome X concept is comparatively small, but as a template for future documents and discourse in relation to the wider metabolic syndrome concept it has been important in introducing the central ideas and themes that have shaped the wider narrative, and which are widely repeated in later documents. These have included:

- The basic idea that the concept is a 'risk factor cluster'
- That it can lead to heart disease and/or type 2 diabetes
- The syndrome and related disease are a significant social/medical problem
- That the underlying cause is probably insulin resistance
- That environmental factors, such as obesity, have an important role to play
- The condition is both preventable and treatable
- That some aspects of the knowledge surrounding the concept are controversial

In the interview I conducted with Reaven in September 2005, he only briefly discussed his early concept of syndrome X. This still gives a useful insight into how he viewed the construct, when he stated that:

Yeah, because Syndrome X to me […] was simply to say insulin-resistant people are more at risk for heart disease

(Reaven transcript 2005: 13)

While earlier in the interview he also stated that:

Syndrome X, just to point out, the heart disease was as much a threat as type 2 diabetes, if not more so

(Reaven transcript 2005:9)

This additional information again confirms that, for Reaven, the syndrome X concept was all about highlighting the issue of insulin resistance and its role in heart disease.

Reaven specifically chose not to label his construct as a disease, and in a later publication noted 'that insulin resistance is not a disease, but a description of a physiological state that greatly increases the chances of an individual developing several closely related abnormalities and associated syndromes' (Reaven 2005a:935). However, in his 1988 paper Reaven still described insulin resistance as being 'pathogenic' and having a 'role in human disease'. Syndrome X is still an example of medicalisation because Reaven has taken what are essentially only probable indicators of future disease and has re-conceptualised them as a 'clustering of risk factors for coronary artery disease' (1988:1595).

Not everyone agrees with Reaven. Jarrett, for example, in a paper critiquing the concept from 1992 argued that 'Although hyperinsulinaemia is not part of the syndrome, it is generally assumed that the supposedly malign effects of insulin resistance are mediated by raised concentrations of insulin' and that 'a supposed hypertensive effect of insulin in man is an inference from acute, circumstantial experiments and has not been directly demonstrated' (1992:469 and 471).

Construct 1.2. Syndrome of insulin resistance/IRS, 1990s

Defronzo and Ferrannini (1991)

In 1991, two more diabetes specialists, DeFronzo (a US expert) and Ferrannini (an Italian expert) published a paper in *Diabetes Care* (another journal of the ADA) where they discussed insulin resistance and its related complications. In the title of the publication, they described insulin resistance as 'a multifaceted syndrome'. In the abstract, they noted that:

In summary, insulin resistance appears to be a syndrome that is associated with a clustering of metabolic disorders, including non-insulin dependent diabetes mellitus (NIDDM/type 2 diabetes), obesity, hypertension, lipid abnormalities, and atherosclerotic cardiovascular disease (ASCVD)

(DeFronzo and Ferrannini 1991:173)

To back up their claims, the authors stated that they had reviewed a 'considerable

amount of published data' on insulin resistance (1991:174). This included research work by Reaven, such as the 1988 publication. In the article, they also referred to the problem as being a 'syndrome of insulin resistance' (1991:174). The claims-makers therefore put the issue of insulin resistance at the heart of their construct.

Haffner et al (1992)

A year later, another paper was published that was described as a 'prospective analysis of the insulin-resistance syndrome (Syndrome X)' (Haffner et al, 1992). This was another US diabetes expert-led publication that included Steven Haffner (who was actively involved in the metabolic syndrome field) and Michael Stern (a longstanding colleague of Gerald Reaven), which was released through the ADA academic journal *Diabetes*. The research was based on data collected from the San Antonio Heart Study. In the work, the authors acknowledged Reaven's concept of 'syndrome X', however, they argued that:

Because insulin resistance is thought to be the underlying defect of this syndrome, we prefer the term insulin-resistance syndrome (IRS) to highlight the presumed pathogenetic sequence

(Haffner et al, 1992: 715)

The apparent renaming of the concept as IRS enables the claims-makers to do two things here: first to differentiate their construct from Reaven's earlier concept; and second to again highlight the importance they attach to insulin resistance. Reaven sees his concept as a syndrome of insulin resistance; therefore this highlights the similarities between the two concepts. In the discussion section of the paper, the authors summarised their findings as follows:

In summary, we have shown that increased insulin concentrations predict a cluster of metabolic disorders including dyslipidemia (__), hypertension (__), and NIDDM. Because the relationships reported herein are prospective, the inferences with respect to causality are stronger than with previous cross-sectional data. Furthermore, these associations cannot be explained solely on the basis of obesity or body fat distribution.

(Haffner et al, 1992: 722)

Here the authors claim that their prospective study gives the findings greater importance in relation to causality, and they also question the role of obesity. In describing their work in this way, they are suggesting that their research is some how better than other studies, and therefore that their views on the role of increased insulin resistance should also be accepted.

Construct 1.3. Metabolic syndrome (WHO, 1999)

The first organisation to create a diagnostic definition for the metabolic syndrome was the WHO in 1998. This was while undertaking a much larger consultation into the 'Definition, diagnosis and classification of diabetes mellitus and its complications', and led to the publication of an official report in 1999. The section of the report where the metabolic syndrome was first outlined was in 'Part 1: Diagnosis and classification of diabetes mellitus', which was 49 pages in length. Only three pages of this document were given over to the discussion of the metabolic syndrome and its definition. This suggests that the concept was still seen as a relatively minor part of the much larger project of the classification of diabetes.

In constructing their concept, the creators of the WHO definition began by suggesting that there was a clinical need for the definition, when they stated that:

A major classification, diagnostic and therapeutic challenge is the person with hypertension, central (upper body) obesity, and dyslipidaemia, with or without hyperglycaemia. This group of people is at high risk of macrovascular disease

(Alberti and Zimmet, 1999: 31)

By suggesting that there was an unmet 'need' for the concept, this enabled the claims-makers to justify the development of their definition, and to claim that their construct now met this need. However, the WHO experts did acknowledge that other workers, including Reaven, had also identified the 'cluster', when they noted that:

This clustering has been labelled variously…

In 1988 Reaven focused attention on this cluster, naming it Syndrome X

(Alberti and Zimmet, 1999: 31)

One of the ways the WHO claims-makers sought to differentiate their construct from the earlier concepts was by renaming the condition metabolic syndrome, which they justified by suggesting that:

Central obesity was not included in the original description so the term Metabolic Syndrome is now favoured

(Alberti and Zimmet, 1999: 31)

although they also still conceptualised the metabolic syndrome as a problem of insulin resistance when they stated that:

Evidence is accumulating that insulin resistance may be the common aetiological factor for the individual components of the Metabolic Syndrome

(Alberti and Zimmet, 1999: 31)

The experts then outlined how useful the concept could be as a clinical tool, when they suggested that:

… vigorous early management of the syndrome may have a significant impact on the prevention of both diabetes and cardiovascular disease

(Alberti and Zimmet, 1999: 32)

The WHO experts again link these two major diseases to the syndrome, just as earlier claims-makers had done, in order to highlight the potential importance of the condition. In the section following this, which was entitled ‘Definition’, the authors also outlined how:

There is no internationally agreed definition for the Metabolic Syndrome

(Alberti and Zimmet, 1999: 32)

Here the authors are again trying to convince the reader that there is a 'need' for an internationally agreed definition. A solution to which the WHO is presumably best suited to solving, with their new concept. In the next paragraph, they outlined the main components of this definition, when they stated that:

The following is a working definition to be improved upon in due course: glucose intolerance, IGT or diabetes mellitus and/or insulin resistance together with two or more of the other components listed below:

- *Impaired glucose regulation or diabetes*
- *Insulin resistance*
- *Raised arterial pressure ≥ 140/90 mmHg*
- *Raised plasma triglycerides (≥1.7mmol/dl, 150mg/dl) and / or low HDL-cholesterol (<0.9mmol/l, 35mg/dl men; < 1.0mmol/l, 39mg/dl women)*
- *Central obesity (males: waist to hip ratio >0.90; females: waist to hip ratio >0.85) and/or BMI >30 kg/m2*
- *Microalbuminuria (urinary albumin excretion rate ≥20μg/min or albumin: creatinine ratio ≥30mg/g)*

(Alberti and Zimmet, 1999: 32)

The decision to make impaired glucose regulation or diabetes/insulin resistance a requirement, along with 'two or more of the other components' shows that the claims-makers behind this construct again put insulin resistance on centre stage. In the final section, entitled 'Future needs', the WHO experts argued that:

'A clear description of the essential components of the syndrome is needed together with data to support the relative importance of each component'

'Internationally agreed criteria for central obesity, insulin resistance and hyperinsulinaemia would be of major assistance'

(Alberti and Zimmet, 1999: 33)

These statements act as signposts of how the claims-makers think the definition should develop, and reinforce the notion that the WHO is in a good position to do this, as well

as seeming to encourage other interest groups to get involved. Although a panel of experts were involved in the WHO's (1998) consultation on diabetes, the key authors of the document (including the section on metabolic syndrome) were acknowledged as George Alberti (UK diabetologist) and Paul Zimmet (Australian diabetologist). They were also intimately involved in the creation of the later IDF 2005 consensus definition; therefore these two academics should be regarded as key players in the construction of the concept and field as a whole.

Construct 1.4. Insulin resistance syndrome (Balkau and Charles, 1999)

An alternative construction of the metabolic syndrome concept emerged in 1999 when another organisation, the European Group for the study of Insulin Resistance (EGIR), put forward their set of diagnostic criteria (Balkau and Charles, 1999). This group consisted of European physicians and scientists with an academic interest in 'insulin resistance', who largely came from the diabetes research community.

In their comment article, although the EGIR were complementary about the WHO's concept and acknowledged that 'a definition was sorely needed for the syndrome', they raised some concerns (Balkau and Charles, 1999). This enabled them to undermine the 'rival' claim and promote their concept as a possible alternative. In the publication, they also sought to differentiate their construct from this and other concepts that had gone before. They did this in two main ways. First they returned to using the term IRS, rather than using the newer WHO term the metabolic syndrome, which they justified by claiming that:

... because the syndrome includes non-metabolic features, a more appropriate name would be the 'insulin resistance syndrome

(Balkau and Charles, 1999: 442)

By highlighting the issue of 'non-metabolic features' they were able to claim that the name change was made purely on scientific grounds. Second, they differentiated their concept from the WHO's by claiming that their definition was aimed at identifying a different group of people, when they stated that 'The definition we propose is for non-diabetic individuals only' (1999:442). The two definitions are, however, viewed as

being very similar by many of the medical and scientific professionals involved in the field. In their review article on metabolic syndrome, Eckel et al for example, stated that 'These definitions agree on the essential components – glucose intolerance, obesity, hypertension, and dyslipidaemia' (2005:1415).

Although the EGIR definition is regularly mentioned in review papers, it has never enjoyed the same level of recognition as the WHO set of criteria. This has been due to a number of factors, the main one being that the EGIR is a small, specialised European organisation that could never match the institutional power of the UN-backed and internationally-recognised WHO. In addition to this, because the WHO construct came first, the EGIR definition was never really able to step out of its shadow.

Construct 1.5. Dysmetabolic syndrome X (Dickey, 2000)

In May 2000, the AACE created another construct, which it called 'dysmetabolic syndrome X' (Dickey 2000). This was the name it used when putting forward a formal request to the ICD-9-CM Coordination and Maintenance Committee for the assignment of an ICD code for the syndrome X concept (Dickey, 2000). The name is quite interesting because it appears to be a composite of the terms metabolic syndrome and syndrome X, with a 'dys' added at the front that suggests the experts who asked for the new code did not want to alienate any of the interest groups by using a term that was associated with one particular concept. In the committee meeting agenda document, the 'condition' was described as:

Among endocrinologists, the term Syndrome X has been widely understood to pertain to a cluster of metabolic disorders that are related to a state of insulin resistance without elevated blood sugar levels, in turn, often related to obesity. Syndrome X is a major risk factor for coronary artery disease and hypertension.

(Dickey, 2000: 2)

Later in the document it was further stated that:

The American Association of Clinical Endocrinologists (AACE) has requested a unique code for Dysmetabolic Syndrome X.

(Dickey 2000:2)

The professional organisation AACE therefore sought to take Reaven's basic syndrome X construct and reconceptualise it as a formalised diagnosis of disease that was identifiable by an ICD-code. The ICD is an organisation of the UN and in particular the WHO. Attempts to classify causes of death and the compilation of lists of diseases has an extremely long history dating back to the 1700s, with international efforts beginning in the late 1800s. The ICD emerged after the amalgamation of the international list of causes of death and international lists of diseases. The ICD came under the control of the WHO in the late 1940s, and the organisation has been involved in regularly updating the classification ever since, with major updates announced in 1955, 1965, 1975 and beyond (WHO, 2004).

The classification is regarded as an important tool by the international medical community, and viewed as the 'gold standard' for the identification and classification of diseases. The ICD gives a unique code to every medical entity it regards as legitimate. Medicine across the world has become highly bureaucratic and the classification of disease and use of such codes has been an integral part of this process. This has been particularly true in the United States, which has a healthcare system that is insurance-based, where these codes have taken on even greater significance because insurance companies will often only pay out on treatment for conditions that are officially recognised and have the 'correct' code. Therefore these codes carry significant clout among the medical community and beyond.

In October 2001, the Centres for Disease Control and Prevention in the United States (the CDC) approved the use of a WHO ICD-9 Code for 'Dysmetabolic Syndrome X' (277.7) (AACE, 2001). In an AACE document outlining the decision, it was stated that:

The CDC does not require that a given number of components of Dysmetabolic Syndrome X be present when using ICD-9-CM diagnosis code 277.7. The code may be used if in the professional opinion of the physician Dysmetabolic Syndrome X is present.

(AACE, 2001)

The creation of the ICD-code for 'Dysmetabolic Syndrome X' was therefore a

collaborative effort, with experts from AACE, the WHO and the CDC all having an input. Although this led to the creation of a specific diagnostic code, 277.7, the actual process of diagnosing this 'new disease' was less precise, with the decision still being based on 'the professional opinion of the physician' (AACE, 2001). In the same document, the AACE Coding Committee tried to make the process easier for the physician by clearly defining the syndrome and providing a list of criteria (see Table 9.)

Table 9. Diagnostic criteria and operational definition developed by the AACE (2001)

Dysmetabolic syndrome denotes a constellation of metabolic abnormalities in serum or plasma insulin/glucose level ratios, lipids (triglycerides, LDL cholesterol subtypes and/or HDL cholesterol), uric acid levels, coagulation factor imbalances and vascular physiology

Major criteria:

- Insulin resistance (denoted by hyperinsulineamia relative to glucose levels) or
- Acanthosis Nigricans
- Central obesity (waist cvircumference > 102cm for men and > 88cm for women)
- Dyslipidemia (HDL cholesterol < 45mg/dl for women, HDL cholesterol < 35mg/dl for men, or triglycerides > 150mg/dl)
- Hypertension
- Impaired fasting glucose or Type 2 diabetes
- Hyperuricaemia

Minor features:

- Hypercoagulability
- Polycystic ovary syndrome
- Vascular endothelial dysfunction
- Microalbuminuria
- Coronary heart disease

The creation of what AACE described as an 'operational definition' and 'diagnostic

criteria' for dysmetabolic syndrome was a further move away from Reaven's earlier basic concept towards a more institutionalised definitional and diagnostic construct. This concept was certainly very different to what Reaven had in mind for his original hypothesis, which he outlined as being 'a series of related variables – Syndrome X – that tends to occur in the same individual and may be of enormous importance in the genesis of CAD (coronary artery disease)' (Reaven, 1988: 1605). There was no discussion in that publication of it being used as a definition or diagnosis.

Later publications looking back on the creation of a specific ICD-code for 'Dysmetabolic Syndrome X' saw this as an important development. For example, Kahn et al in a later statement on the subject noted that 'The fact that a version of the Metabolic Syndrome has its own ICD-9 code (277.7) also suggests that it is well thought out' (Kahn et al, 2005: 2290). In contrast, in an article in the journal *Pharmaceutical Executive*, another expert Yehuda Handelsman was quoted as saying that 'Nothing helped Metabolic Syndrome more than the establishment of the ICD-9 code' (Breitstein, 2004: 4). In the same article, it was also stated that 'In a world in which a condition isn't really a disease until it becomes part of a physicians' paperwork, Metabolic Syndrome had crossed an important threshold' (2004:3). It has also been suggested that the creation of the ICD-9 code for the metabolic syndrome concept was a catalyst for the pharmaceutical industry to then become genuinely interested in the condition (Breitstein, 2004).

The dysmetabolic syndrome X construct, however, was still very much a product of the American endocrinology community, with the main proponents being the AACE. A later publication described the organisation as 'a professional medical organisation with more than 5,200 members in the United States and 84 other countries. Founded in 1991' that 'is dedicated to the optimal care of patients with endocrine problems' (ACE/AACE, 2005). This background is also reflected in the way that insulin resistance remains at the very centre of the concept.

Construct 1.6. Insulin resistance syndrome (ACE, 2003)

Although strictly falling outside the main period for Group 1 constructs of 1988–2000, I have decided to include this later construct, which the ACE experts termed IRS,

because it is still very much a part of the insulin resistance continuum. The AACE and its scientific arm the ACE again developed the concept. This was the same US professional medical organisation that had pushed for the awarding of an ICD-code for dysmetabolic syndrome X in 2000.

A later publication stated that the construct had been created following the convening of a consensus conference on IRS in Washington, DC several years earlier where it was formally defined (ACE/AACE, 2005). This ultimately led to the AACE issuing a position statement in 2003 in support of this 'new' formal definition for IRS (Einhorn et al, 2003). This was a path that had already been trodden by the WHO 1999 and APT-III 2001 definitions, which emerged after a consultation and an expert panel, respectively, and which had both led to the publication of official reports.

Although the definition was seen as being created under the auspices of an AACE/ACE initiative, one of the main drivers behind the process was none other than Gerald Reaven, who was able to secure the backing of this professional organisation (Bloomgarden, 2003). In fact, he is second author (along with Einhorn and Cobin) of the ACE position statement that was published in 2003. Reaven's involvement here seems to be at odds with his opinion on the suitability of insulin resistance as a diagnosable entity (Reaven, 2005a). However, the experts (Reaven included) behind the IRS concept do not see it as a diagnostic definition, but as something distinct from the other definitional constructs (such as the WHO, ATP-III and IDF). It is therefore not a coincidence that the concept matches Reaven's views on the issue.

In the position statement, the authors claimed that 'diagnosing' the concept was not possible because 'the experimental evidence available does not exist that can be translated into simple criteria for diagnosing the IRS' and that 'The IRS is not a specific disease, any more than insulin resistance is' (Einhorn et al, 2003: 244). The authors claimed that the main aim was 'to work toward this consensus and so to provide guidance to clinicians and the many others involved in and affected by IRS' (2003:240). They further noted that 'An approach to identifying those individuals who do not have diabetes, but who do have IRS, is not simple and is the primary goal of this report' and

that ‘A secondary goal is to outline briefly the therapeutic approaches to prevent, or attenuate, the pathophysiological consequences of the IRS’ (2003:241).

However, the use of phrases such as ‘guidance to clinicians’, ‘identifying those individuals’ and ‘therapeutic approaches to prevent’, is exactly the type of language you would expect to see when discussing diagnoses, which makes it difficult for the reader not to view the IRS construct in these terms. This was further compounded by the ACE experts producing a table of components of the IRS on the very next page, which they highlighted as:

Components of the IRS

1. *Some degree of glucose intolerance*
2. *Abnormal uric acid metabolism*
3. *Dyslipidemia*
4. *Haemodynamic changes*
5. *Prothrombotic factors*
6. *Markers of inflammation*
7. *Endothelial dysfunction*

(Einhorn et al, 2003:242)

This list contains similar elements to the criteria laid out by the WHO in 1999 and ATP-III in 2001, such as glucose intolerance, dyslipidaemia and haemodynamic changes (blood pressure), although obesity was not included and there were a number of additional biochemical markers. Again this makes it hard not to see the IRS construct in diagnostic terms, even though these factors were not described as such in the text. On the following page, however, the ACE experts did include another table that was entitled ‘Factors that increase the likelihood of the IRS’, where both BMI (>25) and sedentary lifestyle were highlighted, along with other factors such as age and family history (Einhorn et al, 2003). Later in the document, the ACE experts included a third table:

Identifying abnormalities of the IRS

Triglycerides (>150 mg/dL)
HDL cholesterol (Men 40 mg/dL, Women 50 mg/dL)
Blood pressure (.130/85 mg/dL)
Glucose (Fasting, 110-125 mg/dL, 120 min post-glucose challenge, 140-200 mg/dL)

(Einhorn et al, 2003:245)

This looks even more like a potential list of diagnostic criteria, and yet the ACE experts maintain that their IRS construct is not intended for this purpose. In the conclusion to the statement, the ACE experts stated that 'This document has attempted to provide a means of understanding the IRS and a practical clinical approach to identifying and managing individuals at risk' (2003:249). The description of the document as offering 'a practical clinical approach to identifying and managing individuals at risk' again makes the construct seem more like a diagnostic tool. However, by deliberately defining their IRS concept as not being suitable for diagnosis, the claims-makers were then able to clearly differentiate their construct from the many others in the field (such as the WHO, ATP-III, and IDF), and therefore help make it standout from the crowd. This aspect of the IRS concept was picked by rival claims-makers, with for example Alberti et al noting that 'The AACE statement deliberately does not provide a specific definition of the syndrome and allows the diagnosis to rely on clinical judgement' (2006:471).

IRS: Insulin resistance is the key, not obesity

Although the claims-makers (experts from ACE) behind the IRS concept created a construct that was in some aspects very different from its rivals, such as not wanting to be seen as a diagnostic definition, in other respects it has many similarities. The most important of these probably being its continued focus on insulin resistance and the role this plays in the aetiology of the 'condition'. As mentioned earlier, this focus is not surprising given that the claims-makers behind this concept come from a professional medical organisation, ACE, whose members have a strong interest in endocrinology and often diabetes in particular. In the introduction of the position statement, for example, the ACE experts make it very clear that:

We (they) will use the term Insulin Resistance Syndrome to describe the consequences of insulin resistance and compensatory hyperinsulinemia, thereby focusing on the underlying pathophysiology that unites the cluster of related abnormalities

(Einhorn et al, 2003: 240)

In this regard, they were also critical of the alternative terms, such as metabolic syndrome and dysmetabolic syndrome X, when they stated that:

Use of alternative labels such as 'the metabolic syndrome' or the 'dysmetabolic syndrome' relies on an unclear definition of 'metabolic', and these terms are likely to become even less appropriate as the abnormalities associated with insulin resistance and compensatory hyperinsulinaemia continue to expand.

(Einhorn et al, 2003: 240–241)

They then claimed that:

In contrast, the IRS offers a clear statement of the presumed pathogenesis of the syndrome, is based on evidence that insulin resistance and compensatory hyperinsulinemia significantly increase the likelihood of an individual developing a cluster of related abnormalities …

(Einhorn et al, 2003: 241)

Here the claims-makers (ACE experts) are again highlighting the importance of insulin resistance to the reader, while at the same time undermining rival definitions and promoting their own IRS concept. This confirms that the construct sits squarely within the insulin resistance camp; the ACE experts make it clear that they see obesity as playing a lesser role. In a section entitled 'Obesity and the IRS', they stated that 'The relationship between obesity and the IRS outlined in this document differs in two respects from many other published considerations of this topic' (Einhorn et al, 2003: 244). First, they viewed 'abdominal obesity, as one of the features of the syndrome, rather than as a lifestyle factor that, because of its adverse effect on insulin-mediated glucose disposal, increases the risk of the IRS' (2003:244). They also highlighted how 'not all insulin resistant individuals are overweight/obese, nor are all overweight/obese

individuals insulin resistant' and that 'For clarity of the physiological construct of the IRS, it is important that obesity be viewed as contributing to the insulin resistance/hyperinsulinemia, rather than being a consequence of the abdominal insulin metabolism' (2003:244). This interpretation of the relationship between obesity and insulin resistance is critical, because the creation of the later diagnostic definitions and disagreement that followed is largely based on this difference in understanding. Experts who are critical of the later metabolic syndrome constructs, such as the ATP-III definition, argue for example that they place too much emphasis on obesity as a marker for, rather than cause of, the condition — a view that proponents of the concept strongly refute. This is also an issue that Gerald Reaven would return to in later publications on the topic, when writing independently as a single author with no organisational allegiances (Reaven 2005a, b). Returning to the ACE statement, second the experts believed that 'BMI (Body Mass Index), rather than abdominal circumference, be used to identify individuals at increased risk to have the IRS' (Einhorn et al, 2003: 244).

The institutional goals of the AACE/ACE, such as the promotion of the technical skills of the members of this medical discipline, were therefore advanced by the creation of the IRS because this concept requires an in-depth understanding of endocrinology, and particularly the issue of insulin resistance. However, although the AACE/ACE is seen as being the primary mover behind this concept, Reaven's individual contribution should not be overlooked. For example, as chair of the International Committee for Insulin Resistance he was instrumental in organising the 1st Annual World Congress on IRS, which was held in November 2003. The pre-conference advertising material stated that the event was open to individuals from all disciplinary backgrounds and would also appeal to those interested in the syndrome X/metabolic syndrome concepts (IRS Congress flyer, 2003). This suggested that the organisers wanted the conference to appeal to a wide audience, and engage with professionals who differed in their views of the concept, including those who sat in the rival camps of syndrome X and the metabolic syndrome.

Reaven's plans to develop the syndrome X concept while critiquing other constructs were therefore complimentary to the objectives of the AACE/ACE, and made collaboration between these two parties an easy proposition. As early as 1994, Reaven wrote in the *Journal of Internal Medicine,* for example, that 'the time seems appropriate

to update the original version of syndrome X' (Reaven, 1994: 13). He also noted while discussing the role of obesity that 'some of the terms used to describe syndrome x, ie 'the deadly quartet' or 'GHO syndrome' [glucose intolerance, hypertension, and obesity] are misleading in that they imply obesity is an essential attribute of the system complex being described' (Reaven, 1994: 17).

During his 2005 interview, Reaven discussed his decision to move away from the syndrome X concept and embrace the IRS, when he stated that:

I think I have to explain why. Because the insulin resistance syndrome is a much broader physiological construct. Trying to point out that people who are insulin resistant are at increased risk of developing a whole series of abnormalities and clinical syndrome […] is a very different concept from the metabolic syndrome….

and later that:

So the insulin resistance syndrome is an expansion of the relationship between insulin resistance and a whole series of clinical conditions….

(Reaven transcript 2005: 2)

He clearly wants the IRS construct to be seen as a further development of his previous syndrome X concept, and later in the interview he notes that:

And all that's happened since […] that notion [syndrome X] *was introduced, at least in my mind, is that the number of abnormalities and the clinical syndromes that are related to insulin resistance […] have grown exponentially*

(Reaven transcript 2005:9)

The IRS concept is therefore part 'institutional construct', having been created under the auspices of an AACE/ACE backed by the consensus conference in 2002, and part Gerald Reaven, who was clearly more than just a 'guiding hand' during the construction of this concept.

Chapter summary

In this first period of construction from 1988 to 2000, the metabolic syndrome concept was conceptualised as an identifiable condition that was linked to insulin resistance and increased the risk of developing CHD and/or type 2 diabetes. This set the foundations for the field as a whole and introduced many of the key themes. The period was dominated by claims-makers from endocrinology and the diabetes medical field, with the constructs all coming from this community. Without a doubt the key player here was Gerald Reaven, who first described syndrome X in 1988; however, other important interest groups included the WHO, EGIR, and AACE/ACE. The constructs here were also influenced by and reflected the disciplinary/technical and organisational interests of those involved in their creation. The data also pointed to the development of rivalries between professional organisations, such as the WHO and AACE/ACE.

These constructs are an example of the medical profession taking a group of risk factors, and particularly insulin resistance, and moulding them into something that could be identified and treated, and therefore for all intents and purposes a diagnosable medical 'condition'. Therefore the constructs here can also be seen as an example of 'the medicalisation of risk factors', a phrase used by Gotzsche in his critical commentary piece on the issue published in the *BMJ* in 2002. At this early stage in the metabolic syndrome concept's development, the claims-makers behind the process all originate from the medical profession, and there is no evidence that the pharmaceutical industry has had any input in the process. In the next chapter, I will move on to look at the second period of construction, the middle years from 2001 to mid-2005, which was characterised by the expansion of the metabolic syndrome concept and proliferation of constructs based around the idea that obesity was the key underlying factor. In contrast to the period outlined in this chapter, the claims-makers responsible for these constructs came from a range of medical disciplinary backgrounds.

Chapter 5

Period 2: the obesity years, 2001 to mid-2005

Introduction

This second period of construction, from 2001 to mid 2005, was characterised by the creation of another set of constructs, which were this time based around the idea that the metabolic syndrome was an identifiable condition linked to obesity that increased the risk of developing CHD and/or type 2 diabetes. In contrast to the first period, the claims-makers responsible for these constructs came from a range of medical disciplinary backgrounds.

Before moving on to discuss these particular metabolic syndrome constructs, it is important to note that they owe their origins to earlier conceptualisations of specific types of obesity being linked to disease risk. Therefore these constructs can be seen as representing more of a continuum of these ideas, than as something completely new. Many of the review articles on metabolic syndrome, for example, highlight the work of the French researcher Vague in the 1940s and 1950s. He put forward the idea that in human, the sexes tend to store their fat differently, with females storing most of their fat around the bottom and thigh region ('gynoid'), while males tend to store their fat around the tummy/middle region ('android'). Vague (1947) argued that if people put on weight, it was 'android obesity' that was much more dangerous to health because it increased the risk of developing heart disease and type 2 diabetes (see Despres et al, 2001; Waine, 2004).

Although the creation of the obesity-orientated constructions of the metabolic syndrome predominantly occurred during the period 2001 to mid-2005, one closely-related concept that is often referred to in the same breath as these is 'the deadly quartet', which was created much earlier by Kaplan in 1989. Therefore although not strictly constructed during this period, I have included the concept here because it is seen by many experts in the field as part of the same metabolic syndrome continuum (see Breitstein, 2004; Waine 2004; Alberti et al, 2006).

Construct 2.1. The deadly quartet (Kaplan, 1989)

Kaplan's 'deadly quartet' paper was published in the journal *Archives of Internal Medicine* in 1989, only a year after Reaven's field-changing syndrome X paper. Kaplan suggested that 'Obesity, hypertension, hypertriglyceridemia, and glucose intolerance are common and they often coexist' and that 'The four conditions coexist more commonly than by chance' (Kaplan, 1989: 1515). He further noted that 'The common coexistence of these four conditions suggests a shared pathogenesis for at least some of those who suffer from two or more of these conditions' (1989:1515). This was a very similar concept to syndrome X, and although Kaplan did refer to some of Reaven's work in the paper, this related to a publication from 1987. Kaplan also referred to his concept as 'the deadly quartet'.

Kaplan therefore clearly wanted his construct to be the focus of attention and for readers not to be distracted by the other concept. He wanted his idea to be seen as a totally different entity. In this regard, Kaplan's construct was based around the idea that obesity is the key factor, whereas Reaven concentrated on the issue of insulin resistance. In the paper, Kaplan for example highlighted the specific issue of upper-body fat, when he noted that:

The following have all been shown to be more prevalent with increasing upper-body fat distribution: diabetes; hypertriglyceridemia and low high-density lipoprotein cholesterol; hypertension; and coronary disease.

(Kaplan, 1989: 1516)

and further that:

Waist-to hip ratios have similarly been found to be more tightly correlated to the risk for coronary disease than have measures of weight and height.

(Kaplan, 1989: 1516)

an issue that he had earlier reminded the reader, had been identified by French researchers many years before, when he stated that:

However, the importance of the distribution of body fat was really first clearly stated by Vague, in 1947 in French, and in 1956 in English

(Kaplan, 1989: 1515)

In justifying his approach, Kaplan suggested that the medical profession had largely ignored the role of obesity in CHD, when he stated that:

The contribution of obesity to cardiovascular risk has not been adequately appreciated because of a failure to recognise the involvement of upper-body predominance of body weight with hypertension, diabetes, and hypertriglyceridemia even in the absence of significant overall obesity.

(Kaplan, 1989: 1514)

and further noted that:

Nonetheless, many view moderate degrees of obesity as more of a social or cosmetic problem than a medical one, inadvertently leading to a serious oversight in the recognition of its importance as a major contributor to the other risk factors that so often accompany it.

(Kaplan, 1989: 1514)

Therefore, by centring his construct on obesity Kaplan was able to claim that his concept was helping to fill in the knowledge here, following medicine's 'failure to recognise' the issue, due to an apparent 'oversight'. By highlighting the issue of upper-body fat in particular, he was also able to differentiate his concept from rivals, such as Reaven's syndrome X. He did, however, acknowledge that insulin resistance had a role to play, when he noted that:

Obesity is usually accompanied by an increase in pancreatic insulin secretion and hyperinsulinaemia. This is thought to reflect peripheral insulin resistance with a secondary increase in insulin secretion to maintain euglycaemia

(Kaplan, 1989: 1516)

Thus in constructing his deadly quartet concept in this way, Kaplan was further medicalising the natural process of fat distribution in males (upper-body fat) by linking this to a range of medical conditions such as high blood pressure, diabetes and heart disease, which had started with Vague's work in the 1940s–50s. This was an issue that would be developed further in the later (post 2001) constructs of the metabolic syndrome concept.

Construct 2.2. Hypertriglyceridaemic waist (Despres et al, 2001)

Although this is not a specific metabolic syndrome construct, it is another example of a concept that is often highlighted (in review articles) as being closely related to the topic; therefore I have included it here (see Alexander, 2003). Lemieux et al (2000) initially outlined the 'hypertriglyceridaemic waist' in a paper in *Circulation*, a journal of the AHA. However, Despres et al (2001) took the concept to a wider audience with the publication of an article on the 'treatment of obesity' in the *BMJ*, and it is this publication I will be discussing here.

Despres et al began their paper by highlighting how 'It is generally accepted that obesity is a health hazard because of its association with numerous metabolic complications such as dyslipidaemia, type 2 diabetes, and cardiovascular diseases' (Despres et al, 2001: 716). They then claimed that '…there is currently overwhelming evidence that abdominal obesity is a major clinical and public health issue' (2001:716). Again, this is an example of medical claims-makers focusing on the potential health consequences of a 'condition', in this case obesity, in order to justify their decision to conceptualise it as a medical problem in need of identification and treatment.

The authors then went on describe their concept, which they referred to as the hypertriglyceridaemic waist, and defined as 'a new clinical phenotype defining a high risk form of overweight/obesity' (Despres et al, 2001: 718). In the paper, they argued that by using 'simple screening variables, such as waist circumference and fasting triglyceride concentrations' that it was possible 'to discriminate a large proportion of carriers from non-carriers of the features of the atherogenic metabolic triad,' (2001:718) where they identified the latter as being:

A triad of 'new' atherogenic metabolic markers – fasting hyperinsulinaemia, increased apolipoprotein B concentration, and an increased proportion of small, dense, low density lipoprotein particles (abnormalities found together in viscerally obese men, even in the absence of type 2 diabetes) – was found to be associated with a 20-fold

increase in the risk of developing coronary heart disease in initially asymptomatic middle aged men followed over a period of five years.

(Despres et al, 2001:718)

And further that:

Therefore, this atherogenic metabolic triad of risk markers observed in viscerally obese patients with insulin resistance is associated with a marked increase in the risk of coronary heart disease.

(Despres et al, 2001:718)

In other words, their construct was useful because it was able to identify viscerally obese individuals at particular risk of heart disease. Although this concept shares many similarities to the various syndrome X/metabolic syndrome constructs, the claims-makers here are again keen to portray it as separate entity.

The authors do acknowledge the work of Vague (1947) in the paper, but conspicuously make no mention of the more recent syndrome X, deadly quartet, or metabolic syndrome constructs. Numerous papers had been published on metabolic syndrome and the importance of abdominal obesity before 2001, therefore the absence of these 'rival' constructs in the paper suggests that they were deliberately left out in order to give their concept pre-eminence.

The pharmaceutical company Sanofi-Aventis later used this particular publication (along with a number of others) in the marketing of their anti-obesity drug rimonabant (Acomplia), as evidence to justify the development of their product. In a pamphlet from 2005 entitled 'Measuring waist circumference can accurately predict your patients' risk of cardiovascular disease,' for example, this paper was one of the first to be referenced. The text stated that 'Abdominal obesity, and the associated increase in visceral fat, is associated with a number of risk factors for cardiovascular (CV) disease' (Sanofi-Aventis pamphlet, 2005). The same paper was also referenced in the 'press pack' for the launch of rimonabant (Acomplia) in Europe in June 2006 (Sanofi-Aventis, 2006). In an earlier press release, the company stated that 'Abdominal obesity is recognised as a significant risk factor in the development of cardiovascular disease,' and argued that their drug was 'thought to represent a new approach for the comprehensive

management of cardiovascular risk factors' (Sanofi-Aventis press release 2005). This showed that the company was keen to promote the drug as more than just tackling obesity, but also as a potential treatment for heart disease, therefore potentially expanding the market for the product. The hypertriglyceridaemic waist could again be seen as an example of the medicalisation of a 'socially undesireable' corporeal-state, in this case visceral obesity (a fat stomach); a condition that may have previously simply been described (often disparagingly) in lay terms as having a 'spare tire', 'pot belly', or 'paunch'.

Construct 2.3. Metabolic syndrome (ATP-III)

In 2001, an expert panel of the NCEP published their third report on the detection, evaluation, and treatment of high blood cholesterol in adults (the ATP-III; Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001). This was a US Government-backed initiative from the NHLBI, one of the institutes that form part of the US National Institutes of Health. It was stated that the report's primary aim was to update 'the existing recommendations for clinical management of high blood cholesterol' (Grundy et al 2001:2486) and further that 'While ATP III maintains attention to intensive treatment of patients with CHD, its major new feature is a focus on primary prevention in persons with multiple risk factors' (Grundy et al 2001:2486). This issue was highlighted again in a later version of the report, published in 2002, when the experts stated that 'It [ATP-III] focuses on the role of the clinical approach to prevention of coronary heart disease' (Grundy et al 2002:I-1). The NCEP ATP-III (2001/2002) report with its concentration on the issues of cholesterol and heart disease, and the publication by the NHLBI, are very much products of the US cardiology community. The emphasis on cholesterol is also a reflection of the NCEP's institutional goals.

The metabolic syndrome (a concept previously only linked to the diabetes medical community) is also referred to in the report, when the authors highlighted that 'Many persons have a constellation of major risk factors, life-habit risk factors, and emerging risk factors that constitute a condition called the Metabolic Syndrome' (Grundy et al 2001:2488). They then further noted that the 'ATP III recognises the Metabolic Syndrome as a secondary target of risk-reduction therapy, after the primary target – LDL cholesterol' (2001:2488). Grundy (one of the key players behind the process)

confirmed this secondary aim during a press conference to highlight the ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001) guidelines, when he stated that:

After the goals for LDL cholesterol have been achieved, physicians should turn their attention to the Metabolic Syndrome, if it is present. First line therapy is weight reduction and increased physical activity. This will help to control insulin resistance and will reduce all metabolic risk factors

Press conference remarks (Grundy, 2001: 4)

This showed that not only were US cardiologists now taking a direct interest in the metabolic syndrome, but that they were also becoming involved in its construction. The primary focus of the ATP-III guidelines was the reduction of cholesterol, with metabolic syndrome seen as a secondary target. The concept had therefore been constructed as an 'add on' issue that was to be dealt with later. This was significant because by constructing the concept in this way, it was likely that the issue would be given a lower priority by cardiologists.

The fact that the AHA/NHLBI had identified the concept as a 'target' for the ATP-III, however, showed that the issue was being taken seriously by the cardiology community. They also reconstructed the concept for their own purposes, which was confirmed when the expert panel produced their own set of diagnostic criteria. This resulted in the creation of the ATP-III definition of the metabolic syndrome, the details of which are outlined in Table 10.

Table 10. Clinical identification of the metabolic syndrome (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001) / (Grundy et al 2001)

Risk factor	**Defining level**
Abdominal obesity (waist circumference):	
Men	>102 cm (>40 inches)
Women	>88 cm (>35 inches)

Triglycerides	≥ 150 mg/dL
High-density lipoprotein cholesterol: Men Women	 < 40 mg/dL < 50 mg/dL
Blood pressure	≥130 /≥/85 mmHg
Fasting glucose	≥ 110 mg/dL

This table showing the risk factors required for the clinical identification of the metabolic syndrome was published within the ATP-III guidelines, where it was stated that 'For the purposes of ATP-III, the diagnosis of the Metabolic Syndrome is made when three or more of the risk determinants shown in Table 8 [see Table 10 above] are present' (Grundy et al 2001: 2492). This was an important change from the previous WHO definition because a diagnosis of metabolic syndrome could be made if an individual had three (in any combination) out of these five risk factors, and of particular importance was the fact that insulin resistance was no longer an absolute requirement and that obesity could be measured by waist circumference. These changes made the ATP-III definition a very different concept to the early metabolic syndrome constructs and is an issue that I will be returning to shortly.

The report also noted that 'These determinants include a combination of categorical and borderline risk factors that can be readily measured in clinical practice' (Grundy et al 2001: 2492). This last comment showed that not only was the metabolic syndrome now being accepted as a 'real' condition that could be diagnosed in the clinic by cardiologists, but it also showed that the claims-makers were trying to position it as being ideal for general use, rather than just research, in order that their concept would appeal to a much broader medical audience. This claim that was again made in a review article by Eckel, Grundy and Zimmet in the *Lancet* in 2005, where the authors suggested that:

In retrospect it is apparent that the WHO definition was better suited as a research tool whereas the NCEP ATP III definition was more useful for clinical practice. Clinicians prefer simple tools with which to assess patients and improve their management, and it is generally agreed that the NCEP ATP III definition is simpler in practice

(Eckel et al, 2005: 1415)

As well as reinforcing the idea that 'the NCEP ATP III definition was more useful for clinical practice', this text can also be seen as another example of rival claims-makers taking the opportunity to undermine the earlier WHO (1999) definition. It also showed that the medical professionals here were continuing with the process of medicalisation by expanding the domain of the concept to include the clinic as well as research setting.

As mentioned above, one of the key differences between this construct and the earlier WHO (1999) diagnostic criteria was that insulin resistance was no longer an absolute requirement for a diagnosis to be made. This represented a significant departure from Reaven's syndrome X concept and the WHO definition, which both required evidence of insulin resistance. The ATP-III definition only included a list of five key risk factors. In terms of the sociology of knowledge, this represented a significant change, because although the concept was still referred to as the metabolic syndrome, the entity was now different ontologically, due to these changes in diagnostic criteria. These changes also highlight the different disciplinary priorities at play here, with the diabetes specialists behind syndrome X and WHO definitions making insulin resistance a requirement *versus* the cardiologists behind the ATP-III definition giving it less prominence, making it only one of five key risk factors. This again showed that construction of the metabolic syndrome concept has been influenced by the different disciplinary backgrounds of those involved. The nature of the condition had also been altered by these changes. For example, by not making insulin resistance a key component, as in previous definitions, this meant that other factors such as obesity came to the fore and were recognised as having an important role to play. This also meant that in treatment terms there was a greater emphasis placed on tackling obesity, rather than insulin resistance, which although often linked to obesity could also occur independently from it.

Another key difference is that while the WHO experts used central obesity measured by 'waist to hip ratio and/or BMI' in their concept (Alberti and Zimmet, 1999: 33), while the new ATP-III construct referred to abdominal obesity that could be measured by 'waist circumference' (Grundy et al 2001). This was a similar approach to the one advocated by the EGIR in their IRS construct, where they noted that 'the waist circumference is to be preferred' (Balkau and Charles, 1999: 443). Many medical

experts argued that the previous measurements had the potential to miss individuals with the condition, but that waist circumference was a better method for picking up people with lateral obesity, the 'spare tyre' type of obesity strongly associated with the metabolic syndrome. They also claimed that waist circumference was easier to measure in the clinical setting. By changing the way these measurements were taken, the claims-makers were again creating new realities surrounding the metabolic syndrome concept. For example, the ATP-III definition was seen as more clinician-friendly and able to identify more people with the condition; the focus on waist circumference put renewed emphasis on the role of obesity. It is therefore not surprising that the metabolic syndrome concept, and this construct in particular, is often referred to as an example of the medicalisation of obesity.

In the ATP-III report, the expert panel stated that:

Factors characteristic of the Metabolic Syndrome are abdominal obesity, atherogenic dyslipidaemia (elevated triglyceride, small LDL particles, low HDL cholesterol), raised blood pressure, insulin resistance (with or without glucose intolerance), and prothrombotic and proinflammatory states

(Grundy et al 2001: 2488)

Later comments attributed to Grundy (the lead author of the report) in a news article published in the US medical journal *JAMA* showed that he saw the concept as less complex, when he was quoted as saying that 'the emergence of the term [metabolic syndrome] primarily came about to remind physicians not to dismiss patients with vague suggestions to exercise more and weigh less' (Mitka, 2004:2062). He was further quoted that 'Inclusion of Metabolic Syndrome into the document [ATP-III report] was done primarily to highlight physician responsibility' (Mitka, 2004:2062).

These statements by one of the key players behind the ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001) definition, suggest that the concept had largely been constructed as an 'aide memoir' for medical professionals about the health risks associated with obesity. This is very different to the way the medical/scientific literature has described the development of the definition, where it is usually portrayed as identifying a specific syndrome and that

its creation had been based on hard scientific evidence (see Alexander, 2003; Deen, 2004; Garber, 2004).

Grundy was also quoted as claiming that 'With obesity receiving an unprecedented emphasis […] the idea of Metabolic Syndrome has struck a chord among doctors' (Mitka, 2004:2063). This again highlighted how the claims-makers behind the ATP-III definition in reconstructing the metabolic syndrome as a concept that could be easily adapted to the clinical setting, had changed the focus of the condition away from insulin resistance towards obesity. In doing this, they were making it potentially more 'useful' as a definition for physicians in the clinic, but in the process they had also changed the nature of the concept itself.

The author of the *JAMA* article, Mitka, also highlighted to readers how the experts behind the ATP-III definition had 'dedicated only a 3-page chapter to the Metabolic Syndrome out of the 279-page report' (2004:2062). This again suggested that while they were interested in the topic, the inclusion of the metabolic syndrome was more of an addition to the main part of the report, which was dedicated to cholesterol and its role in heart disease. This has been used by opponents of the construct as a way to undermine its credibility in the eyes of the medical profession. For example, Kim and Reaven argued that because 'the primary purpose of the ATP-III document was not to define the Metabolic Syndrome but to update clinical guidelines for cholesterol testing and management' that the concept had therefore been influenced by the 'institutional goals' of the groups who had created it (2004:69).

However, the ATP-III (2001) construct received a significant boost in the US in 2002, with the publication of another paper, this time by Ford et al (2002), which looked at the prevalence of the metabolic syndrome among US adults. This was published in the prestigious US medical journal, *JAMA* and presented findings from the US Centres for Disease Control (CDC) and Prevention, and was based on data collected by the Third National Health and Nutrition Examination Survey (NHANES III). The authors claimed that up to 47 million Americans could be suffering from the metabolic syndrome based on the ATP-III definition. This highlighted how the 'condition' was now being used to medicalise a significant percentage of the US population, and was

evidence of the further expansion of the concept into new areas, such as the public health arena. For example, the authors stated that:

Using ATP-III's new definition, we estimate that approximately 22 percent of US adults (24 percent after age adjustment) have the Metabolic Syndrome

(Ford et al, 2002: 358)

However, the researchers acknowledged that the figure of 47 million was only an estimate when they stated that

Application of the age-specific prevalence rates to US census counts from 2000 suggests that 47 million US residents have the Metabolic Syndrome

(Ford et al, 2002:358)

With the creation of so many potential patients based on the ATP-III definition that views obesity as being a key component, this medicalisation also raises questions about the role of the individual and society in the aetiology of the condition. For example, if so many individuals are potentially affected, is this purely down to individual lifestyle choice, or the result of the society in which they live?

Since publication, these research data and the figure 47 million have become widely quoted (see Eckel et al, 2005), to the extent that the statistic has now become synonymous with the metabolic syndrome, particularly in the US. As a result the statistic has become an important component in the construction of the metabolic Syndrome concept. Experts in the field took the data very seriously, as evidenced by the number of times the statistic has been quoted in publications, because the findings came from the powerful US Government health body, the CDC, and were centred on data collected in North America. These were both factors that would have positively influenced many of the authors who quoted the research, many of whom were based in the United States. The CDC is also a well-respected organisation outside the US, and medical experts in many Western countries with growing obesity rates would have also seen these data as significant. In the paper, Ford et al were also highly complementary about the ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001) report and related construct, when they stated that

it ‘draws attention to the importance of the metabolic syndrome and provides a working definition of this syndrome for the first time’ (Ford et al, 2001: 356). This is a claim that the creators of the earlier WHO definition of the metabolic syndrome would no doubt dispute.

In 2003, the main claims-makers behind the ATP-III construct, the NHBLI, organised two scientific conferences on the subject. One was dedicated to the issue of the definition of the metabolic syndrome, while the other focused on the clinical management of metabolic syndrome (Grundy et al, 2004a, b). The former was a joint conference held with the AHA, a professional medical organisation consisting of members largely from the discipline of cardiology; while the latter was a joint conference held with the NHBLI/AHA and ADA, the latter a professional medical organisation consisting of members with a specialist interest in diabetes. The AHA published reports of both conferences in their academic journal *Circulation*, which outlined the main findings.

Conference report: definition of metabolic syndrome (Grundy et al, 2004a)

The fact that the claims-makers behind the ATP-III definition organised this conference suggests that even though they claimed that the medical profession had accepted the concept, there must have been some uncertainty remaining over the diagnosis. This also suggests that the medical community may have resisted the changes to the definition, particularly in relation to the decreased role of insulin resistance. Medical professionals may also have been concerned that this ‘new’ definition was identifying too many individuals as being ‘ill’, particularly as obesity is seen as a key underlying factor, and that such a change could have significant public health implications in the US. There is some evidence of the uncertainty over the definition of the metabolic syndrome (WHO and ATP-III) in the medical/scientific literature of the period. For example, an editorial was published in the *BMJ* in July 2003 by Meigs, in which the author asked if the metabolic syndrome diagnosis was ‘a guidepost or detour to preventing type 2 diabetes and cardiovascular disease’ (Meigs, 2003: 61). In another editorial in the journal *Diabetes Care* from 2003, Alexander, a proponent of the metabolic syndrome, acknowledged that ‘there are [were] at least four available definitions [as of 2003]’.

The conference, which was held in 2003, can therefore be seen as an early attempt to create a consensus around the 'definition', with over 20 participants from a range of disciplinary backgrounds, many of which had been key players in the construction of the various concepts up to that date. For example, they included Scott Grundy (the ATP-III lead author), Robert Eckel (the AHA president), Daniel Einhorn (ACE/IRS concept developer, 2003) and Steven Haffner (who had written on IRS in 1992). The conference was therefore US-centric, with the majority of the participants coming from the American medical/scientific community; this reflected the fact that most of the key players involved in the controversy were based in the US. Gerald Reaven's name was also among the list of attendees, which was not surprising since he had created the syndrome X concept in 1988 and was also involved in the development of the IRS concept in 2002–3. By this point, however, he was a strong critic of the metabolic syndrome as interpreted by the WHO and ATP-III definitions.

The lead author of the report was again Scott Grundy, who had been a key player in the creation of the ATP-III 2001 construct, and was instrumental in getting the two scientific conferences off the ground. The report of the meeting stated that 'The scientific evidence related to definition was reviewed and considered from several perspectives' (Grundy et al, 2004a: 433). The authors then listed them:

1. *Major clinical outcomes,*
2. *Metabolic components,*
3. *Pathogenesis,*
4. *Clinical criteria for diagnosis,*
5. *Risk for clinical outcomes, and*
6. *Therapeutic outcomes*

(Grundy et al, 2004a: 433)

Although the conference included diabetes specialists and cardiologists, because the meeting had been jointly organised by the NHLBI and AHA it was still very much a cardiology show and openly favoured the ATP-III 2001 construct. This was also reflected in the report of the conference proceedings that was published in *Circulation*, which concentrated on the issues of heart disease and the role of obesity in the metabolic syndrome, while appearing to question the importance of insulin resistance (Grundy et

al, 2004a). The latter three issues appeared to fit more closely with the cardiac medical community's interpretation of the metabolic syndrome concept. As an example, at the beginning of the report the authors claimed that:

The National Cholesterol Education Program's Adult Treatment Panel III report (ATP-III) identified the Metabolic Syndrome as a multiplex risk factor for cardiovascular disease (CVD) that is deserving of more clinical attention. The cardiovascular community has responded with heightened awareness and interest.

(Grundy et al, 2004a: 433)

Then in the next section on the clinical outcomes of metabolic syndrome, the authors again promoted the ATP-III construct and its role in cardiovascular disease when they noted that 'ATP-III viewed CVD as the primary clinical outcome of Metabolic Syndrome' (Grundy et al, 2004a: 433). For these experts, therefore, a diagnosis of metabolic syndrome put an individual well on the road to developing heart disease. In the section on 'Components of metabolic syndrome' they again concentrated on the ATP-III construct and its links to cardiovascular disease when they highlighted that:

ATP-III identified 6 components of the Metabolic Syndrome that relate to CVD:

- *Abdominal obesity*
- *Atherogenic dyslipidemia*
- *Raised blood pressure*
- *Insulin resistance ± glucose intolerance*
- *Proinflammatory state*
- *Prothrombotic state*

(Grundy et al, 2004a: 433)

The authors also promoted the role of obesity in the text, when they highlighted how 'ATP-III considered the "obesity epidemic" as mainly responsible for the rising prevalence of Metabolic Syndrome' (2004a:434). This again highlights how obesity was being medicalised through the ATP-III definition, where the experts concluded that

obesity was the predominant cause of metabolic syndrome that in turn leads to heart disease. They later noted that:

The strong connection between obesity (especially abdominal obesity) and risk factors led ATP-III to define the Metabolic Syndrome essentially as a clustering of metabolic complications of obesity

(Grundy et al, 2004a: 434)

while towards the end of the report, they claimed that their view of obesity was widely accepted, when they stated that:

Most conference participants held that obesity contributes significantly to development of the Metabolic Syndrome in the general population

(Grundy et al, 2004a: 437)

With the ATP-III definition, however, an individual can still be diagnosed as having metabolic syndrome even if they do not meet the criteria for abdominal obesity. Reaven makes a similar point in relation to individuals with syndrome X/insulin resistance, who although more likely to be obese can still have the problem and not be classed as obese (Reaven, 1994).

At the same time, the authors appeared to be trying to undermine the role of insulin resistance in the text when they stated that:

Reaven and subsequently others postulated that insulin resistance underlies Syndrome X (hence the commonly used term insulin resistance syndrome). Other researchers use the term Metabolic Syndrome for this clustering of metabolic risk factors. ATP-III used this alternative term. It avoids the implication that insulin resistance is the primary or only cause of associated risk factors

(Grundy et al, 2004a: 433)

while in a later section, they highlighted how the

… mechanisms underlying the link to CVD risk factors are uncertain, hence the ATP-III's classification of insulin resistance as an emerging risk factor

(Grundy et al, 2004a: 434).

However, the authors did accept that 'most people with this syndrome have insulin resistance, which confers increased risk for type 2 diabetes' and acknowledged that 'Many investigators place a greater priority on insulin resistance than on obesity in pathogenesis' (Grundy et al, 2004a:433 and 434). Although Grundy et al accepted that many experts still viewed insulin resistance as important, they did not suggest returning to a definition based around this factor, and therefore reaffirmed their commitment to the obesity hypothesis.

In the report's 'Conclusions', the authors again showed where their priorities lay when they noted that:

Conference participants agreed that CVD is the primary clinical outcome of Metabolic Syndrome. Additionally, risk for type 2 diabetes is higher, and diabetes is a major risk factor for CVD

(Grundy et al, 2004a: 438).

They also showed their continued commitment to the ATP-III construct, when they stated that 'ATP-III criteria provide a practical tool to identify patients at increased risk for CVD' (2004a:438). This conference can therefore be seen as an example of the claims-makers behind the ATP-III concept and US cardiology community seeking to strengthen their control of the metabolic syndrome concept. In doing so, they were also medicalising a particular obese body-shape, 'abdominal obesity', due to its association with metabolic syndrome and its related problems, such as diabetes and heart disease. This again highlighted the importance of social factors, such as disciplinary background, in shaping the construction of the metabolic syndrome concept.

Conference report: Clinical management (Grundy et al, 2004b)

The conference held in 2003 looked at the clinical management of metabolic syndrome. Again there were over 20 participants from a range of disciplinary backgrounds, many of which had been key players in the construction of the concept. As with the conference

on the definition of the metabolic syndrome, the majority of the participants came from the American medical scientific community. They included Scott Grundy (ATP-III lead author), Robert Eckel (AHA president), Steven Haffner (who advocated the IRS in 1992) and Richard Kahn (ADA president). The report of the meeting stated that the conference would the following issues:

- Pathogenesis and presentation of the metabolic syndrome
- Management of underlying risk factors
- Management of metabolic risk factors
- Unresolved issues and research challenges

(Grundy et al, 2004b: 551)

The main difference with this conference, apart from its emphasis on clinical management, was that as well as the AHA and NHLBI, the ADA was involved in its organisation. However, this greater input from the US diabetes medical community was not reflected in the report on the conference, with the latter condition and closely-related issues (such as insulin resistance) receiving the same limited level of attention in the text as in the previous report on the definition conference. In the conclusion of the latter document the authors referred to cardiovascular disease as the 'primary clinical outcome of metabolic syndrome' (Grundy et al, 2004a:433-438), whereas in the conclusion of the report on the clinical management conference, where the ADA was directly involved, the authors stated that 'The Metabolic Syndrome consists of a constellation of factors that raise the risk for CVD and type 2 diabetes' (Grundy et al, 2004b: 555). This suggests that by giving equal billing to cardiovascular disease and diabetes in the latter document, the authors were at least taking some account of the potential sensibilities of the US diabetes medical community. However, the authors continued to emphasize the role of obesity in the report when they noted that 'Although genetic susceptibility is essential, the Metabolic Syndrome is relatively uncommon in the absence of obesity and physical inactivity' (Grundy et al, 2004b: 555). Their construction of the metabolic syndrome was therefore still strongly based around the notion that the underlying risk factor for the condition was obesity.

The effect of the conference reports

These two conferences and their related reports, which were organised by the NHLBI in conjunction with the AHA and ADA, were therefore important in helping to establish the ATP-III (2001/2004) definition of the metabolic syndrome. In the conclusion of the definition conference report, the experts all agreed that the metabolic syndrome played a key role in cardiovascular disease and that therapeutic lifestyle change was the best treatment option. Although the conclusion of the clinical management conference report also referred to type 2 diabetes and insulin resistance, the experts essentially came to the same conclusions in relation to cardiovascular and therapeutic lifestyle change. Therefore neither report resulted in any significant changes being made to the metabolic syndrome construct as envisaged by the ATP-III definition.

The fact that both conference reports were published in the AHA's journal, *Circulation*, meant that the ATP-III construct received wide exposure among cardiologists in the United States. This, combined with the concept's concentration on cardiovascular disease risk, made the ATP-III definition an attractive proposition for this discipline, and therefore made the establishment of the construct within this part of the medical community more likely.

For proponents of the ATP-III definition of the metabolic syndrome, the construct is therefore all about obesity and heart disease. However, as I have already shown, the concept often means different things to different people. This is an issue that Gerald Reaven also highlighted during an interview with me, when he noted that:

Physicians know about it in the most bizarre way because if you ask a physician to define the metabolic syndrome you would get as many definitions. I don't mean different criteria. Some people still really use metabolic syndrome in more the sense that I'm talking about, the insulin resistance syndrome; other people are really talking about heart, a risk of heart disease

(Reaven transcript, 2005: 5)

The latter comment about heart disease is in reference to constructs such as the ATP-III definition. Although Reaven is critical of such interpretations, texts from the period

suggest that the medical profession as a whole was largely supportive of this construct. For example, a review article published in *The Medical Clinics of North America* in July 2004, claimed that 'Conceptualisation of the Metabolic Syndrome as a unique, high risk cardiovascular state, as defined by the NCEP, is gaining acceptance as the basis for diagnosing the Metabolic Syndrome' (Garber, 2004: 837). Another review article published in *American Family Physician* in June 2004 suggested that it was 'time for action' in relation to the metabolic syndrome, and described how although 'Initially defined by an expert panel of the WHO in 1998, the NCEP-ATP III has created an operational definition of Metabolic Syndrome' (Deen 2004: 2875). Both publications are aimed at general physicians in the US, which suggests that even at the grassroots level of medicine the concept was gaining acceptance. Although Reaven is regarded as a highly distinguished academic, his comments on the metabolic syndrome at this point in time, 2003–4, marked him out as something of a 'maverick'.

Construct 2.4. Metabolic syndrome (IDF consensus)

In 2005, the IDF constructed yet another definition for the metabolic syndrome, which they called the 'IDF consensus definition'. The concept was officially launched at the 1st International Congress on 'Pre-diabetes' and the Metabolic Syndrome, which was held in Berlin (13–16 April 2005). In a later publication on the topic, however, the key players behind the concept described how the definition had emerged after the IDF convened a workshop held on 12–14 May 2004 in London, UK (Alberti et al, 2006). In the document, they stated that the main aim had been:

To establish a unified working diagnostic tool for the Metabolic Syndrome that is convenient to use in clinical practice and that can be used world wide so that data from different countries can be compared

(Alberti et al, 2006: 469)

Here the IDF claims-makers were again concentrating on this 'new' definition's potential usefulness within the clinic, much as the proponents of the ATP-III definition had done when promoting their construct. The IDF also argued that 'a unified working diagnostic tool for the Metabolic Syndrome' was still needed. Yet this is exactly what

the experts behind the ATP-III definition claimed they were doing when they created the definition in 2001, and then held a conference in 2003 to refine the definition.

The WHO had also used the same argument to justify the development of its definition in 1999, when it noted that 'There is no internationally agreed definition for the Metabolic Syndrome' (WHO, 1999: 32). Four years later, however — even after the publication of the ATP-III definition — Ford and Giles were still claiming that a single definition was needed, when they noted that 'a unified definition of the Metabolic Syndrome is desirable for clinical, epidemiological and surveillance purposes' (Ford and Giles, 2003: 581). Therefore neither the WHO or ATP-III constructs had brought closure to the debate over a diagnostic definition for the metabolic syndrome.

An IDF statement supporting the 'new' definition that was published in *Diabetic Medicine*, a journal of Diabetes UK, noted that the expert workshop had been held:

…to examine how the currently available definitions of the MetS [metabolic syndrome] could be improved and developed with the aim of reaching a consensus for the introduction of a new, unifying and working world-wide definition

(Alberti et al, 2006: 473)

The statement also highlighted how 'The IDF considers the obesity epidemic to be one of the main drivers of the high prevalence of the MetS' and that 'According to the new definition, for a person to be defined as having the MetS, they must have central obesity plus any two of four additional factors' (Alberti et al, 2006: 474 and 475). This represented another significant change in the knowledge claims surrounding the metabolic syndrome, because obesity (central obesity) was now a requirement for the diagnosis of the condition, therefore changing the nature of the concept. The basic concept — that obesity leads to metabolic syndrome, which in turn can lead to heart disease and other conditions, and therefore sees obesity as a medical issue — remained unchanged.

The IDF experts further noted that:

The presence of the MetS in patients with type 2 diabetes conveys particularly high risk

for CVD [cardiovascular disease]

(Alberti et al, 2006: 478)

In these three short statements the IDF experts were able to layout their main claims in relation to the concept, highlighting the importance of obesity, and in particular abdominal obesity, outlining their new definition, as well as linking the concept to diabetes and cardiovascular disease. Again, the authors behind the IDF statement used a familiar tactic to justify the creation of their 'new' definition, by criticising potential rivals while at the same time promoting their concept. In criticising rival concepts that put insulin resistance at the centre of their definition for example, Alberti et al argued that 'The mechanisms underlying the link between insulin resistance and CVD still need(ed) further investigation' (2006:471). At the same time, they promoted their 'new' definition as being easier to use in the clinical setting, referring to the concept as being a 'working diagnostic tool' and 'convenient to use' (Alberti et al, 2006:469).

As with the other constructs, the IDF experts were keen to promote the uniqueness of their concept in order to help it stand out. They achieved this through their 'new' definition's emphasis on central obesity, which they suggested could be easily identified in the clinical setting by the measurement of waist circumference. In their supporting statement, for example, they noted that 'The new IDF definition differs from the ATP-III definition in that it requires evidence of central obesity for the diagnosis of MetS' and that 'The rationale for this requirement is that central obesity is more strongly correlated with the other MetS features than is any other parameter and is highly correlated with insulin resistance' (Alberti et al, 2006: 475). Using this new definition, a diagnosis of metabolic syndrome could be made if an individual has a particular waist circumference along with any two of four factors, which included high trigliceride (fatty acid) levels, low HDL ('good') cholesterol, high blood pressure and high blood glucose levels/insulin resistance.

Therefore from a clinical perspective this 'new' construct does not represent a significant change to the concept, apart from making obesity a requirement for the diagnosis of metabolic syndrome. However, in terms of the medicalisation of obesity, the IDF definition represents a further progression because central obesity is now identified as being a requirement for the diagnosis of metabolic syndrome. This type of

body-shape ('pot-belly' in colloquial terms) is therefore now synonymous with poor health and illness, when in combination with other lifestyle factors such as high blood pressure and cholesterol. The moral opprobrium associated with gluttony in the past has now simply been replaced by a medicalised version, where individuals with central obesity are targeted to make changes to their lifestyle in order to prevent ill health.

The full list of diagnostic criteria for the IDF definition is outlined in Table 11.

Table 11. IDF metabolic syndrome world-wide definition (Alberti et al 2006:475)

Central obesity: Waist circumference (ethnicity specific) plus any two of the following:	
Raised triglycerides	≥1.7mmol/L (150mg/dL) or specific treatment for this lipid abnormality
Reduced HDL-cholesterol	<1.03mmol /L (40 mg/dL) in males <1.29mmol/L (50 mg/dL) in females or specific treatment for this lipid abnormality
Raised blood pressure	Systolic: ≥130mmHg or Diastolic: ≥8.5mmHg or treatment of previously diagnosed hypertension
Raised fasting plasma glucose	Fasting plasma glucose ≥5.6mmol/L (100mg/dL) or Previously diagnosed type 2 diabetes if >5.6mmol / L or 100 mg/dL Oral glucose tolerance test is strongly recommended but is not necessary to define presence of the syndrome

In their supporting statement, the IDF experts again described their concept as being easy to use, and constructed the new definition as being particularly suitable for use in the clinical setting. This is a common theme used by many of the claims-makers to justify the development of their constructs and why medical professionals should use them. In the case of the IDF definition, this centred on the apparent ease with which

physicians could make a preliminary diagnosis of metabolic syndrome, based on the measurement of an individual's waist circumference, which could then be confirmed by simple laboratory tests. This made it even easier for the 'pot-belly' body-shape to become medicalised — any general physician with a tape measure in a clinic could now make a diagnosis.

The IDF experts hoped the concept would become the new 'gold standard' for diagnosing the metabolic syndrome, because in the conclusion they stated that:

The participants at the IDF workshop hope that this new MetS definition emphasizing the importance of central obesity, with modifications according to ethnic group, will be adopted world-wide and prove convenient and useful in clinical practice and epidemiological studies

(Alberti et al, 2006: 478)

The key medical/scientific players behind this 'new' definition were once again professors George Alberti and Paul Zimmet, diabetes specialists from Britain and Australia, who had both been instrumental in the creation of the original metabolic syndrome definition during a WHO-led reclassification of diabetes in 1999. Since then, the US-backed ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001) definition had become the definition of choice for the metabolic syndrome, and one can speculate that Alberti and Zimmet were probably keen to reclaim the concept as their own.

As with the earlier WHO (1999) definition, this 'new' IDF construct appeared to be going 'against type'. It was a product of the diabetes medical community, with the institutional backing of the IDF, while concentrating on the issue of central obesity rather than insulin resistance. The latter was the favoured causative factor in many of the constructs of metabolic syndrome developed by experts with a disciplinary background in endocrinology or diabetes; the other explanation of obesity tended to be preferred by experts with a background in cardiology. This showed that disciplinary alliances were now beginning to form around the metabolic syndrome, taking the basic idea of the concept and developing into a clinical tool that could then be used to identify, monitor and treat individuals with this alleged condition. During the launch of their

'new' definition of metabolic syndrome at the Berlin conference in April 2005, Alberti and Zimmet organised a press conference and press release in order to maximise publicity. The latter document again promoted the concept as a 'clinically accessible definition of the Metabolic Syndrome' (IDF, 2005a).

In addition to this, Zimmet (IDF) was a joint author of a review article on metabolic syndrome that was published in *The Lancet*, a highly-respected UK medical journal, on 16 April which neatly coincided with the Berlin conference (Eckel et al, 2005). This review was written in conjunction with two US cardiologists, Scott Grundy (NHLBI) and Robert Eckel (AHA). The former individual had been a key player in the construction of the ATP-III 2001 definition, while the latter was president of the AHA at the time. The timing and contents of the publication were important, because as well as being part of the promotional effort for the 'new' IDF concept, the paper also showed that some rival claims-makers, such as the NHBLI/AHA and IDF, were beginning to work together. In promoting the 'new' concept, the authors highlighted how one definition was needed when they noted that:

Since several definitions of the syndrome are in use, it is difficult to compare prevalence and impact between countries [… and that as a result] a group of experts was convened by the IDF to attempt to establish a unified definition for the Metabolic Syndrome

(Eckel et al, 2005: 1416).

They then speculated that:

Ultimately, the combined efforts of the IDF and NHLBI-American Heart Association will result in a new definition(s) of the Metabolic Syndrome that will be suitable for use in clinical practice worldwide

(Eckel et al, 2005: 1416)

This shows that professional interests continue to drive the development of new definitions for the metabolic syndrome, because by creating a standardised definition comparative research is then possible, which further expands the domain within which the medical experts can work.

This air of cooperation between diabetology and cardiology was also reflected in the way the article highlighted how 'The Metabolic Syndrome is associated with an increased risk of both diabetes and cardiovascular disease' and later that 'The presence of the Metabolic Syndrome carries risk for cardiovascular disease and type 2 diabetes' (Eckel et al, 2005: 1417 and 1422). Here the two outcomes were treated as being equally important, whereas in many documents cardiovascular disease is given priority. This suggests that the authors had put their disciplinary priorities to one side in order to portray a united front. This is also evidence of further medicalisation of the concept, because this 'new' definition is creating work for both cardiologists and diabetologists.

The 'new' IDF consensus definition is in many ways much closer to the hypertriglyceridaemic waist concept as outlined by Lemieux et al (2000) and Despres et al (2001) than the ATP-III 2001 definition for the metabolic syndrome as put forward by the NHLBI/AHA (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults) (Grundy et al, 2001). This is because the IDF definition and hypertriglyceridaemic waist concept both have waist circumference as a key component; whereas in the ATP-III construct it is one of five key factors. In their review article, Eckel, Grundy and Zimmet (2005) also acknowledged this work, when they noted that 'Lemieux and colleagues have suggested the importance of abdominal obesity and the so-called hypertriglyceridaemic waist phenotype as a central component (of "increased risk of cardiovascular disease (CVD)")' (2005:1415).

In the review, the authors also took the opportunity to undermine rival concepts such as ACE's IRS, when they stated that:

Obesity is not a component of their definition. Given the mounting evidence that central obesity is a major factor for type 2 diabetes and cardiovascular disease, this omission is rather surprising

(Eckel et al, 2005: 1416)

while later in the paper, the experts further noted that:

Despite the substantial amount of evidence in support of the notion that the Metabolic Syndrome is an insulin resistance syndrome, quantification of insulin action in vivo is not always strongly related to the presence of the syndrome

(Eckel et al, 2005:1422)

This shows that the key players behind the metabolic syndrome — both ATP-III and IDF definitions — were now actively engaged in defending their concept and undermining rival definitions. They want the focus of the metabolic syndrome to remain on obesity, and for the construct to stay the same, and not become a different entity based around insulin resistance. Another example of this in the review article is the way in which the authors continued to promote the role of obesity, when they stated that:

Although the first description of the Metabolic Syndrome was in the early 20th century, the worldwide obesity epidemic has been the most important driving force in the much more recent recognition of the syndrome

(Eckel et al, 2005:1418)

but they did acknowledge that:

Although some strong positions have been taken, the cause of the syndrome is still not settled' and later that 'controversies have raged about its cause.

(Eckel et al, 2005:1415)

IDF definition: summary

The IDF definition remains the first and only one of the 'obesity' constructs to make 'central obesity' an absolute requirement. Commenting on this, Grundy et al in their ATP-III 'update' statement, suggested that the main reason the IDF did this was because 'Abdominal obesity is highly correlated with and easier to measure than other indicators of insulin resistance' and that 'The IDF therefore concluded that abdominal obesity incorporates both concepts of obesity and insulin resistance as being the 2 major underlying risk factors of the Metabolic Syndrome' (Grundy et al, 2005: 2736). Many experts in the metabolic syndrome field therefore regard the IDF (2005) definition as a logical progression (and simplification) of the concept, moving from when the WHO first included central (upper body) obesity in their definition, through to the ATP-III

definition that made abdominal obesity one of five key components, and on to the IDF definition that made central (abdominal) obesity a key requirement. In giving central obesity such a key role, the IDF construct can also be seen as the ultimate example of where metabolic syndrome has been used to medicalise obesity.

Construct 2.5. Metabolic syndrome (ATP-III update 2005)

In Autumn 2005, the NHLBI and AHA again teamed up to produce another scientific statement on the mtabolic syndrome, which was this time entitled 'Diagnosis and management of the Metabolic Syndrome' (Grundy et al, 2005). This was published on 18 October in *Circulation* and was intended as an update to the ATP-III (2001) definition. Looking at the timing of the publication — the NHLBI and AHA approved it in July and August 2005 respectively — the document appears to be a response to the emergence of the 'new' IDF consensus definition in April 2005 (see Alberti et al, 2006).

In the introduction, the experts claimed that the statement was 'intended to provide up to date guidance for professionals on the diagnosis and management of the Metabolic Syndrome in adults' (Grundy et al, 2005: 1). However, in the main text the experts then went on to state that:

In the absence of compelling scientific reasons for change, the AHA and NHLBI affirm the overall utility and validity of the ATP-III criteria and propose that they continue to be used with minor modifications and clarifications (Table 1).

(Grundy et al, 2005: 1)

Here the claims-makers behind the ATP-III definition were using this 'update' statement to show their continued support and to argue that although there was controversy surrounding the concept, that their particular construct did not require any significant changes and was still valid. This also highlighted how the creation of the 'new' IDF definition in April and the ADA/EASD critique that had been published that August had clearly had an impact on the field. The experts behind the ATP-III definition saw these developments as a potential threat to their construct, and then responded by producing this 'update' statement (Grundy et al, 2005; Kahn et al, 2005; Alberti et al,

2006). Ths update of the ATP-III definition was more about the claims-makers from the AHA/NHBLI trying to consolidate their position, rather than taking the concept in a new direction. In the document, they outlined their proposed changes for the ATP-III definitional 'update'. Most of these changes centred on the levels at which the diagnostic markers (such as triglycerides, cholesterol, blood pressure, and glucose levels) would elicit a diagnosis. In addition to this, the experts suggested changes in the way waist circumference was used in the diagnosis, when they stated that:

These modifications and clarifications include allowing for adjustment of waist circumference to lower thresholds when individuals or ethnic groups are prone to insulin resistance

(Grundy et al, 2005: 1–2)

This latter 'modification' was an attempt to address the concerns raised in a number of quarters about waist circumference and ethnicity in relation to the metabolic syndrome diagnosis (Kahn et al, 2005; Reaven 2005a). The authors of the statement therefore created an updated definition, which they summarised in table form (see Table 12.)

Table 12. Diagnostic criteria for metabolic syndrome (Grundy et al, 2005)

Measure (any 3 of the 5 criteria constitute a diagnosis of metabolic syndrome)	Categorical cut points
Elevated waist circumference*: Men Women	 ≥ 102cm ≥ 88cm
Elevated triglycerides	≥ 150 mg/dL (1.7 mmol/L) or drug treatment for elevated triglycerides
Reduced HDL-cholesterol: Men Women	 <40 mg/dL (0.9mmol/L) <50mg/dL (1.1mmol/L) Or drug treatment for reduced HDL-cholesterol

Elevated blood pressure	≥ 130mmHg systolic blood pressure or ≥ 85mmHg diastolic blood pressure or Drug treatment for hypertension
Elevated fasting glucose	≥100mg/dL or drug treatment for elevated glucose
*Some US adults of non-Asian origin (e.g., white, black, Hispanic) with marginally increased waist circumference (e.g., 94–102 cm (37–39 inches) in men and 80–88 cm (31–35 inches) in women) may have strong genetic contribution to insulin resistance and should benefit from changes in lifestyle habits, similar to men with categorical increases in waist circumference. Lower waist cut point (e.g., ≥90cm (35 inches) in men and ≥80cm (31 inches) in women) appears to be appropriate for Asian Americans.	

In the publication, the authors claimed that these changes meant that the two 'rival' definitions (ATP-III and IDF) now shared many similarities. They stated, for example, that:

Recently, the International Diabetes Federation (IDF) has proposed a set of clinical criteria that are similar to those of the updated ATP-III criteria

(Grundy et al, 2005: 2)

However, they were also keen to point out the differences, when they noted that:

The major difference is that the IDF proposed that waist circumference thresholds be adjusted for different ethnic groups

(Grundy et al, 2005: 2).

In fact, the AHA/NHLBI experts discussed the IDF concept at some length in the statement. They noted, for example, that 'Abdominal obesity is highly correlated with and easier to measure than other indicators of insulin resistance' and how:

The IDF therefore concluded that abdominal obesity incorporates both concepts of obesity and insulin resistance as being the 2 major underlying risk factors of the

Metabolic Syndrome; thus, they made increased waist circumference a required element for diagnosing the Metabolic Syndrome

(Grundy et al, 2005: 2)

In reference to their own concept, however, they pointed out that:

In the updated ATP-III classification, increased waist circumference is <u>not</u> deemed a necessity if 3 other risk factor criteria are present

(Grundy et al, 2005:2)

Here the claims-makers behind the ATP-III definition re-affirmed their commitment to this particular construct, by choosing not to make obesity an absolute requirement. Therefore this 'update' of the definition did not lead to any significant changes in the nature of the construct, as may have been expected, after the IDF made obesity a requirement in their concept.

The AHA/NHLBI experts were again keen to point out the similarities between the two 'rival' definitions when they stated that 'Despite these minor differences in criteria for diagnosis, in the US populations, updated ATP-III and IDF criteria identify essentially the same individuals as having the Metabolic Syndrome' and that 'Moreover, recommendations for the clinical management of the Metabolic Syndrome are virtually identical in updated ATP-III and IDF reports' (Grundy et al, 2005: 2). These comments may seem conciliatory, but the claims-makers behind the 'updated' ATP-III definition are essentially arguing that the differences between the two constructs are now so small that the IDF definition does not bring anything new to the concept. The ATP-III experts ignore the fact that the IDF definition had medicalised obesity still further by making it a requirement for the diagnosis of metabolic syndrome, something that the AHA/NHLBI had not done with their construct. Therefore in terms of the medicalisation of obesity, the ATP-III 'update' represents a halt in the proceedings, when compared to the IDF definition.

The comments also suggest that the experts behind the AHA/NHLBI 'update' statement (which included Grundy and Eckel) were optimistic that the two groups would find enough common ground and be able to work together, rather than being rivals. The update to the ATP-III definition certainly suggested that the two constructs were

coming closer together. The conciliatory tone here followed a similar approach to that taken by Eckel, Grundy and Zimmet in their review article from April, where they suggested that 'the combined efforts of the IDF and NHLBI-American Heart Association will result in a new definition(s) of the Metabolic Syndrome' (Eckel et al, 2005: 1416).

In the conclusions section of the AHA/NHLBI ATP-III update statement, the experts claimed that:

The writing group found the ATP-III criteria for clinical diagnosis of the Metabolic Syndrome to be robust and clinically useful tool. This scientific statement recommends that the ATP-III criteria be maintained with minor modifications.

(Grundy et al, 2005:4–5)

Here the experts reaffirmed their commitment to the ATP-III construct and again promoted the concept as being a 'clinically useful' diagnostic definition. They then went on to state that:

It is recognised that the Metabolic Syndrome is a complex disorder, with no single factor as cause. Nevertheless, its prevalence rises with increasing obesity, particularly abdominal obesity.

(Grundy et al, 2005: 5)

This showed that the AHA/NHLBI experts still believed in the key role of obesity in the metabolic syndrome, and therefore that the basic premise of the ATP-III definition had not been altered by their decision to 'update' the concept.

Chapter summary

This second period of construction, the middle years from 2001 to mid-2005, was characterised by the expansion of the metabolic syndrome concept and proliferation of constructs based around the idea that obesity was the key underlying factor. However,

the idea that the condition increased the risk of developing CHD and/or type 2 diabetes still remained a key feature of the concept.

The key interest groups involved in the creation of what was now widely known as the metabolic syndrome were the AHA/NHLBI and the IDF. Kaplan (1989) and Despres et al (2001) respectively introduced the 'deadly quartet' and 'hypertriglyceridaemic waist', which were viewed as being closely related concepts. One of the key players here was Scott Grundy, a cardiologist who was the academic figurehead behind the US-based NCEP ATP-III (2001 and 2005) definitions of the metabolic syndrome, although the diabetologists Alberti and Zimmet returned to the fray with the development of the IDF consensus definition in 2005, where they were lead authors. Again, these constructs were influenced by social factors, such as the technical interests of those involved in their creation. Although the claims-makers responsible for these constructs came from a range of medical disciplinary backgrounds, the field of cardiology was particularly well represented.

The key feature of this period was the increasing focus on obesity, and how it became an ever more critical part in the diagnosis of the metabolic syndrome, going from being one of five key factors in the ATP-III definition to being the most important factor in the IDF definition. During this stage in the concepts development there was still no evidence that the pharmaceutical industry had any significant input in the process. Although the WHO (1999) definition was the first to include central obesity as a diagnostic component, the constructs created during this second period focused even more heavily on the measurement of waist circumference and its links to the metabolic syndrome. The definitions, for example, used medical terms such as abdominal obesity (ATP-III), lateral obesity (IDF), the hypertriglyceridaemic waist (Despres et al, 2001) to describe what the *Sydney Morning Herald* called 'the beer gut' in reference to the condition (Maley, 2005). This led some commentators to suggest that the metabolic syndrome concept was an example of 'the medicalisation of obesity' (Breitstein, 2004). The evidence here does suggest that the medical experts and professional organisations behind these constructs were indeed taking a specific body shape (large stomach region) and trying to develop it into a diagnosable medical 'condition'.

While the WHO was the main group behind the original metabolic syndrome concept, this second period was marked by the involvement of a number of other professional organisations that included the AHA/NHLBI (2001 and 2005) and IDF (2005). This meant that there was a strong possibility that rivalries would develop between these competing organisations, which appeared to have become a reality with the apparent mirroring of publications of ‘new’ or ‘updated’ definitions (Grundy et al 2001; Alberti and Zimmet, 2005; Grundy et al, 2005). However, from 2005 onwards publications by the AHA/NHBLI and IDF, showed that they were increasingly willing to work together to develop a definition of the metabolic syndrome.

Chapter 6

The later years (period 3: 'the controversy years', mid-2005–2009)

Introduction

This third period of construction from mid-2005 to 2009 was characterised by the portrayal of the metabolic syndrome concept as being uncertain, confusing and controversial. The constructs in this group included:

- The metabolic syndrome (WHO, 1999; Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001) as perceived by Kim and Reaven (2004) and Reaven (2005a, b), who saw the entire concept as flawed
- The metabolic syndrome (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; IDF, 2005a,b) as perceived by the ADA/EASD (Kahn et al, 2005), who again viewed the concept as deeply flawed and of limited value.
- The metabolic syndrome (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; ATP-III 'update' Grundy et al, 2005; IDF 2005a,b) as viewed by the ADA/AHA (Eckel et al, 2006), who acknowledged the controversy but sought to defuse the debate over the concept.
- The metabolic syndrome (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; ATP-III 'update' Grundy et al, 2005; IDF, 2005a,b) as viewed by Alberti et al (2009), who acknowledged the controversy surrounding the issue but still saw value in the concept.

The construction of the concept as controversial was particularly centred on the unravelling of the later consensus definition as put forward by the IDF in 2005. It was predominantly critics of this approach that portrayed the concept in this way, and these claims-makers mainly came from the endocrinology/diabetes field (Kahn et al, 2005). An example of this construction can be seen in the conclusion of the ADA/EASD statement on the metabolic syndrome, which was based on a review of the medical/scientific literature surrounding the concept, where the experts argued that:

There is much fundamental, clinically important, and critically missing information about the Metabolic Syndrome to warrant a more serious examination of whether medical science is doing any good by drawing attention to and labelling millions of people with a presumed disease that does not stand on firm ground.

(Kahn et al, 2005: 2304)

However, in later publications even proponents of the metabolic syndrome concept, began to acknowledge that this particular construct (IDF, 2005b) was controversial, although the authors often tried to downplay the significance of the controversy (for example Grundy, 2006a).

Although the widespread portrayal of the metabolic syndrome concept as controversial did not occur until mid-2005, a number of commentators had expressed misgivings much earlier. An early example of this can be found in Reaven's 1994 'update' to his syndrome X concept, where he stated that:

Because all the clinical features of Syndrome X can develop independently of obesity, sedentary activity etc, some of the terms used to describe Syndrome X, ie 'the deadly quartet' or the 'GHO syndrome' (glucose intolerance, hypertension, and obesity) are misleading in that they imply that obesity is an essential attribute of the system complex being described

(Reaven, 1994: 17).

Another example is Meigs' review article on the metabolic syndrome published in 2000, in which he suggested that there is:

little consensus about whether insulin resistance really is the unifying underlying abnormality, or about which metabolic variables constitute essential features, such that a case of the syndrome can be defined; even the name of the syndrome is the subject of uncertainty

(Meigs, 2000: 908)

Meigs also published a further editorial article on the subject in 2003, where he asked whether the concept 'May be a guidepost or detour to preventing type 2 diabetes and cardiovascular disease' (Meigs, 2003: 61). In the article, he argued that:

Substantial uncertainties remain about the clinical definition of the syndrome and whether risk factor clusters collectively indicate a discrete, unifying disorder

(Meigs, 2003: 61)

He also noted that the 'Inclusion of insulin resistance or diabetes itself as diagnostic components is also controversial' (Meigs, 2003: 61). The fact that the various limitations of the metabolic syndrome concept were being openly discussed in prestigious journals such as the *BMJ* suggests that the questions about how best to understand it were being seen as serious and of concern to the medical profession as a whole.

In addition to debates in the professional literature, the same players also published a number of non-academic/lay articles highlighting the controversial nature of the metabolic syndrome concept. These appeared in 2004 and early 2005. For example, an article in the industry journal *Pharmaceutical Executive* published in January 2004 suggested that:

Already, some critics complain that the syndrome is simply the industry's effort to medicalise obesity

(Breitstein 2004: 8)

The article also claimed that, following the creation of the ICD-code for dysmetabolic syndrome X in 2001

Pharma then opened its floodgates and began to publicly fund market development initiatives to make physicians more aware of the role of insulin resistance in diabetes and heart disease

(Breitstein 2004:4)

The implication was that the condition was controversial and another example of the

pharmaceutical industry 'disease mongering'. This implied that the condition was not real (Moynihan et al, 2002).

In a similar vein, another article in the US business magazine *Forbes* published in February 2004 noted that 'There is still debate about whether Syndrome X is a disease in its own right or a fancy label for symptoms common to a Western lifestyle' (Egan, 2004: 10). An article in *The Washington Post* that was published a year later claimed that:

Many aspects of the syndrome remain unclear and controversial. There are several competing definitions, and experts disagree about how dangerous it is and how intensively it should be treated

(Stein, 2005: 2)

Although these critical voices represented only a fraction of the lay and academic publications on the metabolic syndrome, their portrayal of the concept as controversial laid the groundwork for the later expansion of this viewpoint.

Construct 3.1. Metabolic syndrome (as perceived by Kim and Reaven 2004; Reaven 2005a,c)

Gerald Reaven has been one of the most vociferous critics of the metabolic syndrome concept as exemplified by the WHO, ATP-III and IDF definitions. In this section, I will be examining his criticism by looking at a series of three papers he published during the period from late 2004 to late 2005 (Kim and Reaven, 2004; Reaven 2005a,b). Although the first paper strictly falls outside my designated 'controversy period' of mid-2005 to 2009, I have included it here because this was one of three papers that Reaven sent me following my interview with him in September 2005 that as a set neatly summarise his opinions on the subject at the time.

Reaven's criticism of the metabolic syndrome may initially come as something of a surprise, since he is often described as the founding father of the field (Sternberg 2005b). In fact, he finds this claim particularly annoying, as shown by his initial hostility towards my interview request, when I used the term 'metabolic syndrome'

rather than ‘syndrome X’. He reiterated this position during my interview with him in September 2005, when he stated that:

What I don’t like is when they [people] *tell me I’m the father of the metabolic syndrome. That really pisses me off*

(Reaven transcript, 2005: 11)

This is because Reaven regards his syndrome X concept as being very different to these later manifestations of the concept. In my interview with him, Reaven did not comment directly on the controversy surrounding the concept, but instead continued his attack on the metabolic syndrome. As an example, he stated that:

I think that the problem with the metabolic syndrome concept is that it just focuses again on any two or three or four — pick your number [of risk factors] — *rather than trying to educate the physician in terms of the notion that people who are more insulin resistant are more likely too have hypertension, liver disease, potential hypertension, cardiovascular diseases, etc.*

(Reaven transcript, 2005: 8)

Here he is again making a not so subtle attack on the ATP III definition with his comment about ‘two or three or four — pick your number’, which is in reference to the concept requiring the identification of any three of five risk factors before a diagnosis of the metabolic syndrome can be made.

Kim and Reaven (2004): one-step forward, two steps back

The first paper in the set of three was written jointly with Sun Kim and published *Diabetes and Vascular Disease Research* in October 2004. It was entitled ‘The Metabolic Syndrome: One-step forward, two steps back’. Even though Reaven is not the lead author, the paper strongly reflects his views and is still very much in his style. For example, the publication was quick to attribute ‘social factors’ (different institutional goals) as the main reason behind the differences between the WHO and ATP-III definitions, with the authors stating that:

Although using the same term, the two groups have different goals for creating this diagnosis and different criteria to identify individuals, which relate to their different institutional goals

(Kim and Reaven, 2004: 68)

Here the paper is referring to the fact that the WHO definition came out of an initiative from the diabetes field, whereas the ATP-III definition emerged from a programme to reduce heart disease that was coordinated by the NHLBI, a US governmental organisation with close links to the field of cardiology. This is an example of Kim and Reaven trying to undermine the rival definitions (WHO and ATP III) to their syndrome X/IRS concept by suggesting that they were influenced by 'institutional goals' and were therefore somehow less scientific.

In a later section, Kim and Reaven used this to portray the WHO and ATP-III definitions as problematic by highlighting how these emerged from processes where they were not the main focus, when they stated that 'the primary purpose of the [WHO] report was to update the classification and diagnosis of diabetes mellitus' and that 'the primary purpose of the ATP-III document was not to define the Metabolic Syndrome but to update clinical guidelines for cholesterol testing and management' (Kim and Reaven, 2004: 69). The authors again highlighted the contingent nature of the condition when they stated that 'the two groups proposed different sets of criteria to diagnose what they believed constituted "the metabolic syndrome", a discrepancy that stems from their differing organisational goals and understanding of the syndrome' (Kim and Reaven, 2004: 70).

Kim and Reaven also questioned the suitability of abdominal obesity as a diagnostic factor when they further noted that 'neither group discusses how these measurements should be taken, the procedure is not inconsequential' (Kim and Reaven, 2004: 71). In drawing the paper to a close, they also questioned whether the concept could actually do harm, when they stated that:

Not only is it possible to question the relevance of making a diagnosis of the Metabolic Syndrome, but the decision that a patient does not have the Metabolic Syndrome has the potential to impede treatment aimed at decreasing CVD risk

(Kim and Reaven, 2004: 74)

Here the authors are again trying to undermine the metabolic syndrome by questioning the empirical evidence behind the concept, an approach that is often used in the formal confines of an academic paper.

This paper therefore represented a wide-ranging attack on the metabolic syndrome concept, with the authors querying both the scientific evidence and motivation of the researchers, while portraying the condition as uncertain and controversial. The other two papers in the set of three were both published in 2005 in *Clinical Chemistry* and were respectively entitled 'The metabolic syndrome: rest in peace' and 'Just being alive is not good enough' (Reaven, 2005a,b).

Reaven (2005a): metabolic syndrome: rest in peace (review)

In this single-author paper, Reaven begins by highlighting how the publication of US epidemiological data in 2002 had a significant effect on the field, when he stated that:

Since the original report by Ford et al in 2002 describing the prevalence of the Metabolic Syndrome in the United States, multiple papers have been published addressing the same issue

(Reaven, 2005a: 931)

In the paper, Ford et al suggested that 47 million Americans may have the condition, based on an extrapolation of the data from a smaller study (the Third National Health and Nutrition Examination Survey) on the incidence of the condition (ATP III) in combination with US consensus data. Since the publication of this research, the figure of 47 million has been widely cited in documents related to the metabolic syndrome, and has become synonymous with the concept. Reaven sees this as acting as a catalyst for many future publications, but critiques their potential use when he states that:

Although the burst of creative activity has led to an enormous amount of published data, it is not clear that it has led to the delivery of any new information of significant utility to the practicing clinician

(Reaven, 2005a: 931).

Here he again attempts to undermine the scientific credibility of the concept by suggesting that all these publications are just repeating earlier findings and have not produced 'any new information' to help 'the practicing clinician'. His claims also illustrate the interpretive flexibility of these published data, because he is able to portray it very differently to the way proponents have used the material, to reinforce the view that the metabolic syndrome is an important medical/scientific problem (Collins and Pinch, 1979).

In the paper, Reaven further noted that 'Perhaps the most crucial issue is that the diagnostic criteria for the Metabolic Syndrome did not result from a prospective study and do not represent the outcome of an evidence-based process, but are a reflection of the best estimates of a panel of "experts"' (Reaven, 2005a: 932). Here he questions both the apparent lack of scientific evidence to support the diagnostic criteria, and the professional expertise of those involved by the judicious use of quotation marks on the word 'experts'. This is another example of Reaven attempting to portray the ATP-III definition as being unscientific, in contrast to his own allegedly more scientific syndrome X/IRS concept. Reaven then concluded the paper, with a series of highly critical comments:

In conclusion, it appears that making the diagnosis of the Metabolic Syndrome does not bring with it much in the way of pathophysiological understanding or clinical utility, and deciding that individuals do not have it because they fail to satisfy three of five arbitrarily chosen criteria may withhold relevant therapeutic intervention.

Does the ATP-III concept of the Metabolic Syndrome have any redeeming virtues? That is a question that only the reader can answer.

(Reaven 2005a: 936)

This leaves the reader in little doubt about how Reaven views the metabolic syndrome, and represents further evidence of his attempts to undermine the concept by constructing the knowledge claims surrounding the condition as being uncertain and of limited use.

Grundy responded to Reaven's critique, with the publication of the paper 'The metabolic syndrome still lives' in the same journal, in which he vigorously defended the concept (Grundy, 2005). In the paper, Grundy accuses Reaven of restricting his attack to the ATP-III definition, when he states that:

Of interest is the fact that Dr Reaven's sharp blade cuts only into the ATP-III definition of the Metabolic Syndrome. Other definitions escape his knife, especially those of the WHO, the EGIR, and the AACE. The definitions put forward by these organisations are similar to those of ATP-III, but apparently Dr Reaven believes that the ATP-III is the most flawed of the group.

(Grundy, 2005: 1352)

This was an apparent attempt to undermine Reaven's comments by suggesting that his critique was motivated by factors, presumably social, beyond his basic querying of the scientific knowledge behind the concept. The 'other definitions' that Grundy listed all came from the diabetes field, the inference here being that Reaven (a diabetes specialist) is therefore biased and unfairly targeting the cardiac disciplines ATP III concept. Again this is another example of Grundy trying to undermine Reaven's viewpoint, this time by suggesting that he was being influenced by his disciplinary background and hence social interests. Reaven's apparent decision to target the prominent ATP-III definition is also further evidence of his attempts to undermine the metabolic syndrome as a whole, because by singling out this particular definition as 'unscientific' he could then argue that the various other constructs associated with the concept were also flawed. As Reaven appears to have limited his attack to the ATP-III construct, however, this may also indicate that his critique is in fact quite weak and not particularly relevant.

Reaven (2005c): Just being alive is not good enough (reply to Grundy)

Reaven responded to Grundy's paper with the publication of his third paper in the set of three, which was entitled 'Just being alive is not good enough' and again published in *Clinical Chemistry*. In the article, he again systematically attacked the metabolic syndrome concept. For example, at the beginning of the document he stated that:

Although Dr Scott Grundy assures us that the Adult Treatment Panel III (ATP-III) version of the metabolic syndrome is still alive, the real question is whether its continued existence provides us with any useful information.

(Reaven, 2005c: 1354)

Reaven also took the opportunity to reply to Grundy's veiled accusation of 'bias' and defend his reputation, and attempt to reclaim his position in the academic community, by reminding readers that his critique was applicable to all the metabolic syndrome constructs, when he wrote that:

Before addressing the substance of Dr Grundy's comments, I must defend myself against his charge that I have limited my critical comments to the ATP-III version of the metabolic syndrome. I am not xenophobic, and in a recent editorial addressed what I perceived to be the drawbacks of both the ATP and WHO versions of the metabolic syndrome.

(Reaven 2005c: 1354–5)

Although he was not accused of being 'xenophobic' in Grundy's paper, Reaven interpreted his comments as such, and vigorously defended himself against these accusations. In concluding the paper, Reaven was less critical of the metabolic syndrome as a 'theoretical construct', but continued his attack on the ATP-III definition, when he stated that:

If the number of citations were the only measure, the introduction of the Metabolic Syndrome has certainly been a success. However, it is important to separate the theoretical construct of a 'Metabolic Syndrome' from the effort by the ATP-III to create a new diagnostic category.

(Reaven, 2005c: 1356)

In this short paragraph Reaven is trying to do a number of things. He is again querying the significance of the large number of publications that cite metabolic syndrome. In this case, he attempts to draw a distinction between the 'theoretical construct' and 'ATP-III diagnostic category' of the metabolic syndrome. Reaven views the first

construct as having some scientific value, but is highly dismissive of the second concept. Most commentators do not make this distinction, however, this again highlights the interpretive flexibility of the knowledge claims surrounding the metabolic syndrome concept.

Reaven: media interviews and additional critique

Reaven did not just restrict his criticism to academic texts. He also gave a number of interviews during this period where he was equally scathing about the metabolic syndrome concept. This showed that he wanted his concerns to be heard by as wide an audience as possible and was not afraid to engage with the lay media. Again this is another example of the claims-makers using both lay and professional arenas during the construction of the metabolic syndrome concept. In an article on the condition in *The Washington Post* published in February 2005, for example, he was quoted as saying that 'Conceptually, it's a step backwards […] and I think it has the real potential to bring about damage clinically' (Stein, 2005: 1). His 'rest in peace' article published in 2005 also continued to attract attention, with a letter by Meisinger et al entitled 'Metabolic syndrome: older than usually assumed, but still too young to die' appearing in *Clinical Chemistry* in April 2006. Reaven responded to the letter with a reply entitled 'The metabolic syndrome: what's in a name?' that was also published in 2006. Here he again concentrated his attack on the diagnostic category side, however this time he did not limit his attack to a single definition but questioned all three. Reaven was characteristically forthright in his reply, when he stated that:

However, I do think it important not to confuse the contributions made by many investigators to promote understanding of these relationships with the efforts of the WHO, ATP-III, and the IDF to introduce a diagnostic category of dubious pedagogic and clinical utility, referred to as the Metabolic Syndrome.

The former efforts advance knowledge; I do not think that the various definitions of the diagnostic category of the metabolic syndrome fulfil that criterion.

(Reaven, 2006: 899)

At the same time, proponents of the concept began to increasingly acknowledge the uncertainty surrounding the concept in their own work. For example, Eckel et al in a

review article published in *The Lancet* in April 2005 — which coincided with the launch of the new IDF definition — noted that 'Although some strong positions have been taken, the cause of the syndrome is not settled' (Eckle et al, 2005: 1415). This was a pattern that would continue in later publications, as the concept become seen as ever more controversial.

Construct 3.2. ADA/EASD statement

In August 2005, a joint-statement was released by the ADA and EASD that was entitled 'The metabolic syndrome: time for a critical appraisal' in which the organisations queried the existence of the metabolic syndrome concept and its clinical usefulness. The publication, which the experts claimed was the result of 'an extensive review of the literature in relation to the syndrome's definition, underlying pathogenesis, and association with CVD and to the goals and impact of treatment' was simultaneously published in the organisation's respective academic journals, *Diabetologia* and *Diabetes Care* (Kahn et al, 2005:2289). In the statement, the experts from these two organisations began by highlighting the work carried out by Reaven in 1988, which they described as 'landmark' and 'seminal'. They also acknowledged that because 'a version of the Metabolic Syndrome has its own ICD-9 code (277.7)' that this 'also suggests that it is well thought out' (Kahn et al, 2005: 2289).

In the remainder of the paper, however, they systematically constructed the metabolic syndrome as a flawed concept. They argued for example that 'the Metabolic Syndrome is not nearly as well defined and characterised as often assumed, and that the notion that it is a useful marker of CVD risk above and beyond the risk associated with its individual components is uncertain' (Kahn et al, 2005:2290). They also discussed some of the uncertainties around insulin resistance, and noted how 'insulin resistance or hyperinsulinaemia may not be present in subjects with the syndrome' and that 'the extent to which elevated risk of CVD is due to insulin resistance itself, versus some other related factor is still unclear' (2005:2299). The experts also highlighted apparent gaps in the knowledge, when they stated that 'the fact that the multitude of reports relating insulin resistance to any risk factor or CVD are all association studies. It may well be that there is a more basic defect that can result in insulin resistance and / or other CVD risk factors' (Kahn et al, 2005:2300).

In the statement's conclusion, the authors argued that the metabolic syndrome concept had now 'Taken on meaning and import greater than is justified by our current knowledge' (Kahn et al, 2005: 2304). They also turned their attention to the contentious issue of whether the metabolic syndrome was really a 'syndrome', which they defined as 'an 'aggregate of symptoms associated with any morbid process, and constituting together the picture of the disease' (2005:2304). In the last paragraph of the statement, the experts gave a highly critical appraisal of the concept, when they stated that:

In almost every way – from the term itself to the underlying pathophysiology, to the variables included or excluded, to the value of making the diagnosis, and finally to its treatment – the Metabolic Syndrome requires much more study before its designation as a 'syndrome' is truly warranted and before its clinical utility is adequately defined. We hope this reappraisal gives pause to the growing use of the term, as well as stimulates urgently needed research.

(Kahn et al, 2005: 2304)

The experts then followed this with a series of 'recommendations to clinicians' that were based on the review, one of which being that:

Providers should avoid labelling patients with the term 'Metabolic Syndrome', as this might create the impression that the Metabolic Syndrome denotes a greater risk than its components.

(Kahn et al, 2005: 2304)

This joint-statement by the ADA/EASD constructed the metabolic syndrome as a deeply flawed concept that required a thorough reassessment. This therefore represented a significant challenge to the construct, because the knowledge claims surrounding it were now being openly questioned by two important professional organisations. The publication of the statement also pitted a number of powerful organisations against each other, with the NHLBI/AHA and IDF who supported the metabolic syndrome concept on one side, and the ADA/EASD who were critical on the other.

This was therefore not a straightforward 'battle' between the rival disciplines of cardiology and diabetology, because the IDF was effectively 'siding' with the cardiologists. In addition, up until the publication of the joint statement, the ADA had been actively involved with the metabolic syndrome concept, as shown by its co-sponsoring of a conference on the clinical management of metabolic syndrome with the AHA/NHLBI in 2004 (Grundy et al, 2004b). The IDF is also strongly associated with Alberti and Zimmet, who had been key players in the original WHO definition of the metabolic syndrome, which had emerged during a reclassification of diabetes (WHO, 1998). It would therefore be wrong to see the metabolic syndrome as a purely cardiac construct because the diabetes medical community have also played a key part in its construction, as shown in Chapter 4 where I highlighted their key role in the creation of the original WHO construct and in helping to establish its ICD-code, although a number of commentators have suggested that the metabolic syndrome concept has been more readily accepted by cardiologists (Alexander, 2003; Grundy, 2006a).

The dispute was not based on national differences, because the disagreement was between one US and one European group on one side (ADA/EASD) *versus* two US and one Australian-based group on the other (NHLBI/AHA and IDF). Therefore although the creation of the various constructs based on the underlying aetiology (insulin resistance *versus* obesity) is more closely associated with a split between diabetology and cardiology, with the latter community tending to back the obesity hypothesis, the wider definitional dispute has been more complicated. Here there was a disagreement between apparent rival professional medical organisations, but it was not simply based on disciplinary factors.

ADA/EASD critique: Reaven's response

Although other academics such as Meigs had raised concerns about the metabolic syndrome prior to the release of the ADA/EASD statement, Reaven was seen as being the most important critic of the concept (Grundy, 2005). This was due in part to his academic seniority and status as the alleged 'founding father' of the field (Eckel et al, 2006). However, his criticism did not stop the AHA/NHLBI from continuing to develop their ATP-III definition, or prevent the IDF from creating its own version, suggesting that his attacks only had a limited affect. Proponents of the concept also attempted to blunt the effectiveness of his criticism. One way they tried to achieve this was by

portraying him as a lone voice, which was made easier because they could argue, rightly or wrongly, that his comments were the result of bitterness about the direction in which the field had taken. This is another example of Reaven's opponents trying to portray his position as going against prevailing scientific opinion.

During my interview with him in September 2005, Reaven specifically referred to the ADA/EASD critique, when he stated that:

I'm sure you've seen the recent ADA and European diabetes statements.

That's gonna create an enormous stir because they're saying, pretty much what I'm telling you — what I'm saying right now — this is a silly notion and that one should focus on the risk factors not the diagnosis factors.

(Reaven transcript, 2005: 14)

Reaven therefore saw this as vindication of his views on the topic. The fact that two important medical professional organisations now appeared to be raising the same concerns also suggests that some experts had taken his critique seriously. This therefore made it much harder for proponents of the concept to claim that Reaven was a 'lone voice' and that his views were unrepresentative of the current medical/scientific opinion on the topic. The publication of the ADA/EASD statement can also be seen as a success for Reaven because his earlier social constructive work and network building appears to have paid off.

Media response to the critique: constructing the controversy

The ADA/EASD publication received significant media coverage, with articles appearing in both the lay media and medical press. Here the debate surrounding the concept was constructed as a significant controversy, in which the conditions reality was being questioned and that it represented a 'battle' between rival medical organisations. For example, an article published in *USA Today* in August 2005, had the headline 'Metabolic syndrome doesn't exist, diabetes groups claim' (Sternberg, 2005a). The report also included interview quotes from Richard Kahn, the lead author and senior figure in the ADA, in which he stated that:

We don't believe there's a syndrome. We don't believe that the whole is greater than the sum of the parts. We don't believe that the formula is grounded in scientific evidence.

(Kahn quoted in Sternberg, 2005a: 1)

His approach here of questioning the 'scientific evidence', is a commonly used tactic in scientific disputes when one rival group wants to undermine the knowledge claims of another group.

The *Houston Chronicle/Bloomberg News* also reported on the developments in an article that was published in August 2005, entitled 'Groups question existence of 'Metabolic Syndrome'' (Ryerson-Cruz, 2005). Here the author highlighted how 'US and European diabetes groups questioned whether "Metabolic Syndrome", a cluster of conditions that raises risks of heart disease and diabetes, is actually a syndrome at all' (Ryerson-Cruz, 2005: 1). This also included a quote from Richard Kahn (described as 'the American Diabetes Association's chief scientific officer') who was quoted as saying that '("a diagnosis of the syndrome") misleads the patient into believing he or she has a unique disease' (Ryerson-Cruz, 2005: 1).

The medical press also picked up on the story, where they also constructed the situation as representing a dispute between rival organisations. For example, an article appeared in the journal *Nature Reviews Drug Discovery* in October 2005 that was entitled 'Groups question existence of metabolic syndrome', in which the author commented that:

Two of the biggest diabetes organisations have stirred up a hornet's nest by arguing that there is not enough scientific evidence to justify diagnosing patients with Metabolic Syndrome.

(Frantz, 2005: 796)

Here both the lay and medical press constructed the controversy as predominantly being a dispute between 'rival' medical professional organisations. The articles also attempted to portray the situation as being 'non-scientific' and due to social factors such

as organisational/disciplinary rivalries. However, this is not unusual because when a controversy emerges into the public domain it is invariably portrayed in these terms. Often the technical aspects of the dispute are also dropped and there is little discussion of the interpretive flexibility of the data.

The *Nature Reviews* article also included quotes from Grundy, who mounted a strong defence of the concept, when he stated that:

To say that the major mechanisms are unknown is not strictly true, as obesity is a major driving force behind the prevalence of this clustering, and diet and exercise is known to reduce risk

(reported in Frantz, 2005: 796)

Grundy accepted that there were some areas that were not fully understood, but rejected the idea that this meant the concept should not be used as a way to identify individuals potentially at risk, when he further stated that:

Finding out how these risk factors play out in the body, I agree that's for future research – but does that mean we shouldn't deal with an obese patient that has those risk factors?

(Grundy quoted in Frantz, 2005:796)

This showed that Grundy, just like Reaven, was ready to use any platform including the media to defend his approach to and views on the metabolic syndrome concept.

The story was also reported in the widely-read US medical journal *JAMA* and was published under the heading 'Does the Metabolic Syndrome really exist? Diabetes and heart disease groups spar over issue' (Mitka, 2005). Here the author was even more explicit in his construction of the disagreement as a battle when he stated that:

The battle over the issue has been joined. On one side are the ADA and the EASD; on the other, the AHA and the NHLBI.

The ADA and the EASD fired the first shot in late August with publication of a joint statement, based on a literature review, that concluded that the Metabolic Syndrome has been imprecisely defined (Kahn et al 2005).

(Mitka, 2005: 2010)

The author, Mitka, was the same individual who had reported on earlier developments in the metabolic syndrome concept the year before for the same journal, under the heading 'Metabolic syndrome recasts old cardiac, diabetes risk factors as a 'new' entity' (Mitka 2004). This was largely based on an interview given to him by Scott Grundy, a key player behind the ATP-III definition. Here too the author appeared sceptical about the concept, asking questions such as 'But is the syndrome really new?' Mitka's later article in which he described the disagreement as a 'battle' may therefore simply reflect his own negative viewpoint about the concept, particularly as both appeared in a section of *JAMA* that was entitled 'Medical news and perspectives', the latter implying that these were as much opinion pieces as news articles.

Construct 3.3. ADA/AHA joint statement 2006

As commentators had predicted, the release of the ADA/EASD statement did cause an 'enormous stir' within the metabolic syndrome field, and this led to a number of consequences that I will be discussing in more detail shortly (Frantz, 2005; Reaven interview, 2005). However, a number of the proponents behind the metabolic syndrome, while acknowledging the 'controversy' surrounding the concept, attempted to play down its significance. For example, one direct consequence came a few months later, when the ADA and AHA released a joint statement in the journal *Circulation* that was entitled 'Preventing cardiovascular disease and diabetes: A call to action from the ADA and AHA' (Eckel et al, 2006). The two groups made their intentions very clear at the start of the document, when they stated that:

The intent of this article is to clarify and reinforce the notion that our organisations remain unified and committed to reducing the burden of diabetes and CVD. The importance of identifying and treating a core set of risk factors (pre-diabetes, hypertension, dyslipidemia, and obesity) cannot be overstated, and our commitment is evidenced by other previous joint publications.

(Eckel et al, 2006: 2943)

Here the two main groups who had been portrayed as being at loggerheads over the metabolic syndrome concept — the ADA and AHA — were attempting to downplay the significance of the dispute by highlighting what they agreed on, tackling diabetes and cardiovascular disease, rather than discussing their differences. They also attempted to diffuse the definitional disagreements surrounding the concept by describing a 'core set of risk factors' that they were in agreement about. However, it is telling that in their two-page statement they only once referred directly to the metabolic syndrome, and this only consisted of two brief paragraphs, which suggests that the concept was still a sensitive issue for these two organisations.

The authors of the statement also felt it necessary to refer directly to the media coverage surrounding the issue, and again attempted to downplay the dispute, when they stated that:

Unfortunately, some of the medical press have positioned the scientific issues related to the Metabolic Syndrome as a battle between the ADA and the AHA, implicitly suggesting that CVD risk factor identification and treatment is now questionable.

We are concerned that the presumed dispute will lead to a reduction in the favourable trend of many aspects of CVD risk factor reduction.

(Eckel et al, 2006: 2943)

This showed that the two organisations were clearly concerned about the impact this was having on the metabolic syndrome concept and related field, and were trying to reconstruct the 'controversy' as just being a minor disagreement over 'scientific issues' rather than anything more significant (Eckel et al 2006). Their willingness to defend the concept so publicly also suggests that the area was important for both organisations, and they may also have been concerned about the potential damage this was having on their respective reputations. The experts here may also have been attempting to recast the debate as not being a battle between professional organisations, as portrayed by the media, but as an example of the scientific method, where disagreements are a normal part of the process, and therefore portraying the situation in a way that was more

favourable to science. The lay media continued to cover the story, and following on from their earlier portrayal of the disagreement as a battle between the different organisations, one report in *MedPage Today* described the publication of the document as representing a 'truce' between the groups (Peck, 2006).

In his position as lead author of this 'truce' document and key member of the AHA, Eckel downplayed the significance of the 'controversy'. However, during my interview with him in July 2006 he was more open and referred to the issue on a number of occasions. At the start of the interview for example, he stated that 'I think some of the controversy is justified, yes' (Eckel transcript, 2006: 1). However, he did not agree with commentators who had tried to portray the situation as a battle between US cardiologists and endocrinologists, but accepted that they saw the concept differently when he noted that 'I'm not sure if it breaks down to cardiology versus endocrinology' and 'So I do think these terms can engender different responses, perhaps among endocrinologists and cardiologists' (Eckel transcript, 2006: 2).

During the interview Eckel did attempt to downplay some aspects of the 'controversy', when he stated that 'I do sense that, part of the problem is the argument over terminology' (Eckel transcript, 2006: 4). He also argued that 'we are talking about clustering of risk factors that to a large extent can be adequately explained…' and 'why don't we move on from there… and try to understand ways to modify risk and also get people healthier' (Eckel transcript, 2006: 10). He then stated:

Let's talk about clustering… let's talk about, you know, terms that the metabolic syndrome can be an acceptable term, so we don't need to die calling it cardio-metabolic risk […] move on to a better understanding

(Eckel transcript, 2006: 10)

The latter comments can also be seen as an example of Eckel attempting to claim the moral/epistemic high ground by suggesting that researchers should be concentrating on the more important issue of trying to reduce the burden on patients through correct diagnosis and suitable treatments, rather than on the disagreements 'over terminology' (Eckel transcript, 2006: 4).

Construct 3.4. Additional 'controversy' publications (2005–6)

A number of other publications from key proponents of the metabolic syndrome had also started to acknowledge the uncertainty over the concept, but again attempted to downplay its significance and even use this to their advantage. For example, Zimmet, Alberti and Shaw in a paper on the IDF definition published in the *Medical Journal of Australia* in 2005, described how the creation of 'numerous definitions' of the metabolic syndrome had caused much 'confusion' around the concept (2005:175). They also noted that 'Much recent discussion about the Metabolic Syndrome has appropriately raised questions about its definition, its clinical role, and even its existence' (Zimmet et al, 2005: 175). They then claimed that 'Because of the confusion, the IDF embarked on the process of developing consensus on a new global definition' (Zimmet et al, 2005: 175). Here they therefore used the 'controversy' to their advantage, by arguing that the 'new' IDF definition was created as a way to overcome these difficulties. Another paper by Alberti et al on the IDF definition published in 2006 also referred to the uncertainty, when they noted that 'The existence of multiple definitions for the MetS has inevitably led to confusion and to the publication of many studies and research papers comparing the merits of each definition' (Alberti et al, 2006: 472). And this was again used as a way to justify the construction of the IDF definition.

Another key proponent, Grundy, also referred to the controversy surrounding the metabolic syndrome in a review paper published in 2006. Here he again downplayed the significance of the uncertainty, and claimed that diabetologists were largely to blame for the controversy. For example, he claimed that 'The cardiovascular community generally has embraced the concept of risk-factor clustering as a *syndrome*, even though it originated in the diabetes field' but that 'Conversely, the name *Metabolic Syndrome* poses problems for some investigators in diabetes' (Grundy, 2006a: 1095). And in the conclusions section, he further argued that:

The Metabolic Syndrome should serve to bring cardiovascular and diabetes fields together in a joint effort to reduce both ASCVD and diabetes. At present this joint action is being hampered by the issue of how to integrate the Metabolic Syndrome into

concepts of insulin resistance, prediabetes, and type 2 diabetes, all of which are important to the diabetes field.

(Grundy, 2006a:1097–8)

Although Grundy was ready to acknowledge the uncertainty and confusion around the concept, he laid the blame on 'the diabetes field' and therefore attempted to deflect any criticism away from cardiologists by constructing the controversy as a product of the diabetes discipline.

In the next section, I will be discussing the controversy as seen through the eyes of the authors behind the AHA 'harmonisation' statement published in 2009. I nearly included this document in the previous chapter, as another example of the construction of the metabolic syndrome as an obesity construct, although in the end decided not to because it fell well outside the cut-off date for period two ('the obesity years') of mid-2005. Therefore this shows how documents do not necessarily create one construct, but are often used to make various claims and have the potential to make multiple constructs. This means that although I divided the constructs into three main groups for my analysis — 'insulin resistance', 'obesity' and 'controversy' — some of the documents cross these boundaries and may therefore be useful to more than one group of claims makers. This is another example of the interpretive flexibility of the knowledge surrounding the metabolic syndrome, and again highlights the barriers faced by those experts wanting to close the debate over the concept.

Construct 3.5. AHA 'harmonisation' statement 2009

In October 2009, a joint interim statement (JIS) on the metabolic syndrome was published in *Circulation* entitled 'Harmonising the metabolic syndrome' (Alberti et al, 2009). The statement was released by the following organisations: the IDF Task Force on Epidemiology and Prevention, NHLBI, AHA, World Heart Federation, International Atherosclerosis Society, and the International Association for the Study of Obesity. The publication was the result of a meeting held between the different professional organisations, with the aim of trying to reach a final agreement on 'a single agreed-upon set of diagnostic criteria' for the metabolic syndrome (2009:1643). This was in response to the controversy that had built up around the condition, particularly since

2005, with the organisations that supported the concept wanting the issues over the definition to be resolved. In the document, the authors acknowledged that it was controversial, when they stated that:

Although there is general agreement in the medical community that obesity and its medical complications, including the Metabolic Syndrome, deserve greater attention, there has been considerable disagreement over the terminology and diagnostic criteria related to the Metabolic Syndrome.

(Alberti et al, 2009: 1641)

Although they claimed that:

Despite this disagreement, there appears to be a consensus in the medical field that the term Metabolic Syndrome is acceptable for the condition of the presence of multiple metabolic risk factors for CVD and diabetes.

(Alberti et al, 2009: 1641)

However, they also acknowledged that:

On the other hand, several clinical definitions of the metabolic syndrome have been proposed. This has led to some confusion on the part of clinicians regarding how to identify patients with the syndrome. Some controversy also exists about whether the Metabolic Syndrome is a true syndrome or a mixture of unrelated phenotypes.

(Alberti et al, 2009: 1641)

Here the 'controversy' was again used as a way to justify the involvement of this group of organisations in yet another attempt to construct 'a single agreed-upon set of diagnostic criteria' for the metabolic syndrome (2009:1643). However the participants (who included Alberti, Eckel, Grundy and Zimmet) were only partially successful because they were unable to reach an overall agreement concerning the concept. Instead they reached a compromise position that was based on the creation of a set of 'common criteria for the clinical diagnosis of the Metabolic Syndrome' (Alberti et al, 2009: 1643). This statement therefore effectively led to the creation of yet another definition of the concept; although because this was described as a 'joint interim statement' the new 'common criteria' must be regarded as temporary (2009:1640 and 1643). In later

publications this 'new' construct is referred to as the 'JIS (Joint Interim Societies) definition' (Athyros et al 2010:713), the details of which are outlined in Table 13.

Table 13. Criteria for clinical diagnosis of the metabolic syndrome (Alberti et al, 2009)

Measure	**Categorical Cut Points**
Elevated waist circumference*	Population- and country-specific definitions
Elevated triglycerides (drug treatment for elevated triglycerides is an alternate indicator)	≥150 mg/dL (1.7 mmol/L)
Reduced HDL-cholesterol (drug treatment for reduced HDL-C is an alternate indicator)	<40 mg/dL (1.0mmol/L) in males <50 mg/dL (1.3mmol/L) in females
Elevated blood pressure (antihypertensive drug treatment in a patient with a history of hypertension is an alternate indicator)	Systolic ≥130mmHg and/or Diastolic ≥85mmHg
Elevated fasting glucose (drug treatment of elevated glucose is an alternate indicator)	≥100mg/dL
*It is recommended that the IDF cut points be used for non-Europeans and either the IDF or AHA/NHLBI cut points used for people of European origin until more data are available.	

Although there were six professional groups represented at the meeting, only three of these, the AHA, NHLBI and IDF, had previously been involved in the construction of definitions for the metabolic syndrome: the AHA/NHLBI with the ATP-III (2001 and 2005) definition, and the IDF (2005) with it's consensus definition. It is therefore likely that these groups also took the lead in the 2009 definitional negotiations, particularly when the same three organisations appeared to be moving towards working together to create a 'new' definition in 2005 (see Eckel et al, 2005; Grundy et al, 2005).

In not being able to reach an overall agreement, the experts acknowledged that the main sticking point was the issue of waist circumference, when they noted that:

A single set of cut points would be used for all components except waist circumference, for which further work is required' but that 'In the interim, national or regional cut points for waist circumference can be used

(Alberti et al, 2009:1640)

However, the authors claimed that these issues would be resolved, when they stated that:

It is expected that new groups will be formed to assess the evidence with regard to waist circumference threshold and associated risk in the near future

(Alberti et al, 2009:1643)

In relation to this, they highlighted how the WHO and NHLBI were 'reconsidering the definition of Metabolic Syndrome'.

In relation to the medicalisation of obesity, it appears that the approach used by the AHA/NHBLI won through, when the experts stated that:

It was agreed there should NOT be an obligatory component, but that waist measurement would continue to be a useful preliminary tool.

Three abnormal findings out of five would qualify a person for the Metabolic Syndrome.

(Alberti et al, 2009: 1640)

The first statement was in reference to the IDF consensus definition, which had made central obesity an absolute requirement, a development that was seen as controversial in some quarters (Kahn et al, 2005). The experts therefore decided to abandon this requirement. Just as the ATP-III 'update' had done, this new JIS definition rejected the direction taken by the IDF in making obesity a key component of their definition. In terms of the medicalisation of obesity, this was another indication that the process had come to a halt with regard to the metabolic syndrome, with the experts behind the JIS 2009 definition not wanting to follow the IDF's lead. The second statement also shows how similar the new JIS definition was to the ATP-III guidelines, again a reflection of its shared heritage.

The meeting and joint statement that followed illustrated that a number of the 'rival' claims-makers (AHA/NHLBI and IDF) were now working together in an apparent

attempt to create one definition and try and bring an end to the controversy surrounding the concept. However, as all previous attempts had failed it was unlikely that the confusion and uncertainty around the concept would have gone away, even if they had succeeded.

Construct 3.6. Metabolic syndrome as a 'Big Pharma' construct

The critics who see the metabolic syndrome as a pharmaceutical industry construct have also portrayed the concept as being controversial. This criticism has largely been restricted to comments in the non-academic literature, such as business journals and the lay press. For example, as previously mentioned, an article in *Pharmaceutical Executive* published in January 2004 claimed that 'Already, some critics complain that the syndrome is simply the industry's effort to medicalize obesity' (Breitstein, 2004: 8). In the same article, Nikolaos Karachalias, a representative from Datamonitor was quoted as saying that 'Pharma companies understand the potential market, so they are trying to bring some light to it and push their products towards it' (Breitstein, 2004: 8). Here the critics of the metabolic syndrome are invoking social interests, in this case the commercial interests of the pharmaceutical industry, as a way to discredit the legitimacy of the concept.

The medical/scientific literature on the metabolic syndrome concept is also consistent in its acknowledgement that if 'lifestyle intervention' fails, then drug treatments should be considered. For example, in the report of the NHLBI/AHA conference on the metabolic syndrome definition in 2003, the experts noted that 'In patients in whom lifestyle changes fail to reverse metabolic risk factors, consideration should be given to treating specific abnormalities in these risk factors with drugs' (Grundy et al, 2004a: 437).

In another example, a report on the metabolic syndrome was published in the business journal *Forbes* in June 2004, entitled 'Inventing a new heart disease' (Herper, 2004). In the article, the author suggested that 'It's a drugmaker's dream: a newly defined syndrome that ups the risks of heart attacks, strokes and maybe even cancer' (2004:1). Herper also highlighted the 'controversy' surrounding the concept, when he noted that 'doctors have argued over exactly what to call the disorder, and exactly how to define

it, even as drug firms have raced to come up with treatments' (2004:1). The portrayal of the concept as a 'Big Pharma' construct in non-academic journals is not surprising, given the level of hype surrounding the potential drug market. For example, in April 2005 Scrip (a 'market prediction' company) published a report on obesity and metabolic syndrome in which it claimed that 'There is an enormous market potential for anti-obesity treatment' (Warne, 2005).

In another article published in *USA Today* in September 2005, the author commented on the 'controversy' surrounding the concept, where he noted that:

The trouble is, a roster of equally eminent experts — including the Stanford doctor [Reaven] who identified Metabolic Syndrome, dubbing it 'Syndrome X' — say Metabolic Syndrome isn't an ailment that lends itself to diagnosis or treatment. They say that AHA and NHLBI have marched beyond the borders of scientific fact

(Sternberg, 2005b: 1)

This is another example of rival claims-makers, in this case expert critics of the metabolic syndrome, attempting to de-legitimise the ATP-III construct by suggesting that it is unscientific. The reporter, Sternberg, then asked 'The debate has left many doctors grappling with a bigger question: When does a diagnosis genuinely describe an illness and when does it simply give pharmaceutical companies a bigger market?' (2005b:1). Later in the article, he also claimed that 'The drug firm Sanofi-Aventis has already begun positioning its experimental drug Rimonabant as a treatment for all the risk factors underlying Metabolic Syndrome' (Sternberg, 2005b: 2). Here the author of the article is again invoking social interests — commercial interests of the drug firms — as a way to undermine the validity of the knowledge claims surrounding the concept.

The issue of 'disease mongering' (medicalisation) by the pharmaceutical industry has been highlighted by a number of commentators. For example Moynihan et al discussed the issue in a publication in the *BMJ* in 2002, where in reference to the medical condition of osteoporosis they argued that:

Drug companies have sponsored meetings where the disease was being defined, funded studies of therapies, and developed extensive financial ties with leading researchers

(Moynihan et al, 2002: 889)

Although such accusations have been widely discussed in relation to the metabolic syndrome, and some companies have sponsored events related to the condition, there is no empirical evidence to support the idea that Big Pharma has had anything other than a minor role in the construction of the concept. Instead, my research has shown that medical professional organisations such as the AHA have been the main players behind the creation of the various constructs.

Consequences of the controversy over the metabolic syndrome

The controversy surrounding the metabolic syndrome and its construction as an uncertain concept has directly affected those involved in the field, leading to a number of different consequences. One of the potential consequences was highlighted by Ford in a paper entitled 'Rarer than a blue moon' that was published in the journal *Diabetes Care* in July 2005. In the study, he analysed the number of times the ICD-9 code for metabolic syndrome (277.7) had been used in two large US datasets on diagnosis, and found that in 2002 out of over 350,000 diagnoses, the code had only been used 18 times; which suggested that physicians were reluctant to make this a main diagnosis and were either using alternatives or tackling the individual symptoms, such as high blood pressure. One possible explanation for this was the continued uncertainty surrounding the concept. For example, Ford suggested that 'Some health care professionals may not think that the Metabolic Syndrome is a meaningful concept' (2005:1809). He also suggested that another potential explanation was the issue of funding when he noted that '…if third-party players [medical insurance companies] are not providing reimbursement for the Metabolic Syndrome, the use of this ICD-9-CM code may be discouraged' (Ford, 2005: 1809). Although the research was based on data from 2002, and therefore the concept had not yet been affected by the '2005 controversy', this does suggest that the earlier uncertainties over the condition were at least partly to blame for its poor standing among medical experts. Ford therefore argued that this 'raise(ed) serious questions about how successful the translation of recommendations about the Metabolic Syndrome has proceeded from guidelines to clinical practice' (Ford, 2005: 1808).

Another consequence of the controversy surrounding the concept was that the professional organisations behind two of the metabolic syndrome constructs, the ATP-III definition and IRS, released statements highlighting their continued support for the concepts. Again the fact that the organisations made the decision to release these statements just after the publication of the ADA/EASD critique suggests that they were concerned that it may undermine their concepts. The AHA/NHLBI published a scientific statement and update to the ATP-III definition in the September/October 2005 edition of *Circulation*, which was also partly in response to the announcement of the IDF definition in April 2005 (Grundy et al, 2005). In the statement, the experts argued that:

In the absence of compelling scientific reasons for change, the AHA and NHLBI affirm the overall utility and validity of the ATP III criteria and propose that they continue to be used with minor modifications and clarifications

(Grundy et al, 2005: 2735)

Even here they acknowledged some of the uncertainties around the concept when they noted that:

At present, it is not clear whether the Metabolic Syndrome has a single cause and it appears that it can be precipitated by multiple underlying risk factors

(Grundy et al, 2005: 2735).

The claims-makers behind the ATP-III construct continued to promote their concept here by suggesting that it should continue to be used by medical professionals, because they claimed that there was an 'absence of compelling scientific reasons for change' (Grundy et al, 2005), therefore dismissing the claims made by the IDF in relation to their 'new' definition, and the critique of the metabolic syndrome concept published by the ADA/EASD, as being less 'scientific' than their own work. This also shows the interpretive flexibility of the data surrounding the concept; with the ATP-III experts arguing that their construct still has 'utility and validity' following 'minor modifications and clarifications' (Grundy et al, 2005). By doing this, the AHA and NHLBI experts are also keeping the debate going, and resisting any attempt to resolve the controversy.

The publication of this document was also reported in the media, with an article appearing in *USA Today* in September 2005, which was entitled 'Metabolic Syndrome guidelines expand' (Sternberg, 2005b). In the article, it was reported that John Spertus (AHA/NHLBI committee member) a proponent of the concept, had acknowledged 'that doctors risk labelling patients with a syndrome that may not reveal anything more about a patient's susceptibility to heart disease than each individual risk factor' (2005b:2). It was also reported that James Cleeman (NHLBI), who was described as 'an ardent advocate of the approach', admitted 'that there's no evidence showing that reducing Metabolic Syndrome can prevent heart disease or extend life' (2005b:2). This again showed that even strong supporters of the approach were now openly discussing the uncertainties surrounding the condition.

In October 2005, the ACE/AACE also announced they had put together 'a rapid response team to assess these statements [ADA/EASD statement and ATP-III 2005 'update'] and review their position' in relation to the IRS concept (AACE website, 2005). This led to them publishing another position statement, where they reaffirmed their commitment to the original IRS concept created in 2002–3 (ACE, AACE, 2005). On the AACE website, the experts claimed that they had done this 'Because of concern that these statements [ADA/EASD] would create uncertainty and controversy among physicians and further confuse the general public' (AACE website, 2005). The website also included quotes from Daniel Einhorn (a key member of ACE/AACE), who claimed that 'The research, diagnosis and treatment of IRS is rapidly evolving and we expect changes in definitions and understanding as new evidence is presented' and that 'With regard to this evolution, ACE and AACE hope that healthy debate will not be misconstrued as fractious controversy and that further research in this field will clarify the remaining areas of uncertainty' (AACE website, 2005). The experts behind this concept were again clearly concerned that the critique by the ADA/EASD may damage their own construct, even though they had tried to distance the IRS from the other metabolic syndrome concepts by giving it a different name and saying that it was not intended for use as a diagnostic definition. Einhorn, one of the key claims-makers, also tried to down play the 'controversy' by claiming that it was a natural part of the 'evolution' of the concept (AACE website, 2005).

This again highlights the interpretative flexibility of the data, with one of the experts responsible for the IRS concept highlighting how the knowledge surrounding the construct was still 'rapidly evolving' and that alterations to the definition were likely. Einhorn also attempted to restore scientific credibility of the field by suggesting that the disagreements were part of the 'healthy debate' around the issue and not a 'fractious controversy' (AACE website, 2005). In addition, he sought to close the debate by claiming that further research would help to 'clarify the remaining areas of uncertainty' (AACE website, 2005). The above statements are another example of scientific claims-making, with Einhorn claiming that new evidence and further research would help resolve many of these issues, again the inference being that the AACE's work was more scientifically grounded than its rivals. The continued development of the IRS concept also shows the key role that professional organisations such as the AACE have played in the medicalisation of the metabolic syndrome concept, again illustrating the importance of social/technical interests in helping to push this process along.

Another potential affect of the controversy, and particularly the release of the ADA/EASD statement in 2005, was the impact on drug development for the metabolic syndrome concept. For example, it was reported by *Reuters* that:

…the statement is seen as hampering prospects for Sanofi-Aventis's new drug Acomplia, which is positioned as a way to treat 'Metabolic Syndrome' […] a potential multibillion-dollar-a-year seller for the French company

(MSNBC News Services, *Reuters***,** 2005: 3)

This issue was also highlighted in an article in the *Houston Chronicle/Bloomberg News* that was published in August 2005, which reported that

The statements, made in a joint paper published on Web sites for both groups, may affect how US and European regulators view Sanofi-Aventis' experimental anti-obesity drug Acomplia

(Ryerson-Cruz, 2005: 1)

Reaven also highlighted how uncertainty over the concept was hampering drug development in his interview with me in September 2005, when he stated that

I think it would be very interesting but I think there's a vicious circle, a sense that the compan[ies] *don't want to do a big trial because they're not sure if the FDA will give it unless they can really show something substantial* [and then] *the FDA will give them approval for a clinical cluster*

(Reaven interview transcript, 2005: 7)

He claims that the pharmaceutical companies are reluctant to conduct big trials of potential treatments for the metabolic syndrome because of its uncertain status as 'a clinical cluster', for which the US Food and Drug Administration would be unlikely to give approval to treat. Again Reaven attempts to undermine the legitimacy of the concept by focusing on the uncertainty, which again highlights the interpretative flexibility of the knowledge surrounding the concept.

The fall-out from the 'controversy' surrounding the concept also shows little sign of petering out. For example, in March 2008 the *BMJ* published two papers in the 'head to head' section of the journal, which is where academics with opposing views on a topic are invited to write two short comment pieces, which are then published side by side. The theme chosen was 'Should we dump the metabolic syndrome?' In the first paper, Gale (a UK diabetes specialist) argued this was justified, while in the second paper Alberti and Zimmet (key exponents of the concept) argued that the concept was still a useful diagnosis (Alberti and Zimmet, 2008; Gale, 2008). Gale, commenting on the ADA/EASD critique of the IDF definition, claimed that 'this is not a turf war: the confrontation reflects perplexity within the diabetes community' (Gale, 2008: 640). He further argued that 'In sum, the Metabolic Syndrome is a handy label that lacks a useful definition' and that 'A flourishing academic industry has been funded on a diagnostic artefact with little prognostic or therapeutic value' (2008:640).

In their opposing article, Alberti and Zimmet tried to downplay the controversy by claiming that 'There was little argument about the existence of the clustering but confusion about its diagnosis' (Alberti and Zimmet, 2008: 641). They also acknowledged that 'Recently the ADA and the EASD questioned both the existence and usefulness of the Metabolic Syndrome' (2008:641). They also claimed that 'The syndrome is not creating a new disease but identifies a risk state, like pre-diabetes

(which was created by the ADA) or dyslipidaemia' (2008:641). The *BMJ* is a well-respected journal that has a wide readership, and the fact that the metabolic syndrome was the theme for the 'head to head' section, with experts so publicly disagreeing, suggests that the controversy surrounding the concept was still very much alive in the academic medical community and beyond.

Chapter summary

In the previous two chapters, I showed how the construction of the metabolic syndrome concept could be divided into two periods. The first period represented the early years of the concept from 1988 to 2000 and was characterised by constructs based on the theory that insulin resistance was the main causative factor, with the claims-makers responsible for these all coming from the diabetes medical community (Chapter 4). The second period represented the middle years of the concept from 2001 to mid-2005 and was characterised by constructs based on the theory that obesity was the main causative factor, however, the claims-makers responsible for these constructs were not restricted to the diabetes community but came from a range of medical disciplinary backgrounds (see Chapter 4). In both cases medicalisation was the main driving force behind the construction of the various metabolic syndrome concepts, with professional medical organisations being the key players in this process. In this chapter, I showed how during this third period of construction, from mid-2005 to 2009, the metabolic syndrome concept was increasingly portrayed as being uncertain and controversial. Although critics of the concept have been the main drivers behind this process, I have highlighted how in later publications proponents were also acknowledging its uncertain status, and were then often using this to their advantage by claiming that new constructs could resolve the problems.

I also showed how an apparent consensus had built up around the concept during the period before mid-2005, where although different constructs had been created there had been some social agreement concerning how the 'condition' should be defined (for example as a 'risk condition' linked to diabetes and heart disease) and which uncertainties should be taken seriously. I was also able to show how this was based on social factors, and that when the knowledge-claims were challenged by individuals and groups (such as the ADA/EASD) not directly involved in the creation of the various

metabolic syndrome constructs (WHO, ATP-III and IDF), the claims-makers behind these concepts were forced into justifying their positions. The result of this was that the views of critics such as Gerald Reaven, who had to an extent been marginalized, were given greater prominence. As a consequence, a significant controversy developed around the metabolic syndrome within the medical/scientific community that led to a gradual weakening of the legitimacy of the concept. These findings could equally be applied to scientific knowledge in general, with a number of sociologists arguing that social networks are required to maintain the various knowledge claims.

In addition, I showed how critics of the metabolic syndrome had portrayed the concept as being controversial due to its supposed links to the pharmaceutical industry. I then concluded with a discussion of the potential consequences of the 'controversy' in terms of how the construction of the concept was effected, how medical professionals and the media then viewed the issue, and how this may have impacted on medical practice and drug development.

Chapter 7

Metabolic syndrome: main ethical concerns

Introduction

In the previous three chapters, I presented the findings of my sociological analysis of the key academic literature on the metabolic syndrome concept. I showed that there had been significant disagreement in relation to the definitional and aetiological claims around the concept (Kahn et al, 2005; Mitka, 2005), that social factors such as the technical interests of the claims-makers themselves were largely responsible for these differences, and that this had resulted in the construction of a number of different versions of the concept — such as syndrome X (Reaven, 1988), the 'deadly quartet' (Kaplan, 1989), WHO definition (Alberti and Zimmet, 1999), ATP-III guidelines (Grundy et al, 2001; Grundy, 2005), hypertriglyceridaemic waist (Despres et al, 2001), IRS (Einhorn et al, 2003; ACE/AACE, 2005), IDF definition (Alberti et al, 2006), and Joint Interim Statement (JIS) definition (Alberti et al, 2009). My analysis showed that these could be divided into three main camps, with the first group including those constructs that saw insulin resistance (IR) as being the key underlying cause, while the second group included those constructs that viewed 'obesity' as being the key issue. In addition, a third group of constructs was based around the idea that the syndrome was 'controversial'. The first two groups consist exclusively of particular definitions of the concept, whereas the last group includes constructs that deal more generally with the idea that the concept is controversial, apart from the JIS (2009) definition (construct 3.5). These groups are summarised in 1.

An alternative way to view these constructs is in terms of their 'inclusive' and 'exclusive' nature. The 'IR' group of constructs (Reaven, 1988; Alberti and Zimmet, 1999; Einhorn et al, 2003) that includes syndrome X, for example, all require evidence of IR, which means that they tend to be more exclusive and identify fewer patients than the 'obesity' group of constructs (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Despres et al, 2001; Grundy, 2005; Alberti et al, 2006, 2009). The latter include the ATP-III version of the metabolic syndrome,

and concentrate more on the role of obesity and do not make IR an absolute requirement. This means that they tend to be more inclusive and result in the identification of a greater number of patients. For example, Ford et al (2002: 358) noted that 'Using ATP-III's new definition, we estimate that approximately 22 percent of US adults (24 percent after age adjustment) have the metabolic syndrome'.

Among the constructs (obesity and IR versions), however, there is a continuum that goes from the least inclusive, such as the WHO definition (Alberti and Zimmet, 1998), to the most inclusive that is probably the IDF definition (Alberti et al, 2006). As a further example, the hypertriglyceridaemic waist (construct 2.2) is towards the IDF end of the scale, as it was designed as a simple way to screen individuals at risk of CHD (Lemieux et al, 2000:179; Despres et al, 2001). These differences also have the potential to raise different ethical concerns, an issue that I will be exploring shortly. Later in my bioethical discussion of the metabolic syndrome, I will be referring to the more 'inclusive' and/or 'exclusive' versions of the concept.

Table 14. Metabolic syndrome: three main groups of constructs

Insulin resistance constructs (Group 1)	**Obesity constructs (Group 2)**	**Controversy constructs (Group 3)**
Syndrome X (construct 1.1)	'Deadly quartet' (construct 2.1)	Metabolic syndrome (as viewed by Reaven) (construct 3.1)
Insulin resistance syndrome (construct 1.2)	Hypertriglyceridaemic waist (construct 2.2)	Metabolic syndrome (as viewed by ADA/EASD) (construct 3.2)
Insulin resistance syndrome (ACE, 2003) (construct 1.6)	Metabolic syndrome (ATP-III version) (construct 2.3)	Metabolic syndrome (as viewed by ADA/AHA) (construct 3.3)
Metabolic syndrome (WHO and EGIR versions) (constructs 1.3 and 1.4)	Metabolic syndrome (IDF version) (construct 2.4)	Metabolic syndrome (JIS version) (construct 3.5)

Dysmetabolic syndrome X (construct 1.5)	Metabolic syndrome (ATP-III update version) (construct 2.5)	

These sociological findings also influenced my bioethical analysis of the topic, because I could no longer treat the 'metabolic syndrome' as a single entity, having established that there were numerous different interpretations. This led me to explore the ethical issues in this chapter, in terms of how they related to the various concepts and what, if any, differences there were between the groups. This again highlights the advantages of conducting such analyses side-by-side; I was able to produce a much richer analysis of the ethical issues. The creation of these different versions of the metabolic syndrome also made the concept appear uncertain and controversial to some members of the medical profession and beyond (Mitka, 2005). This raises further ethical concerns in relation to the efficacy of the concept, which I will be discussing shortly.

In this section, I will be following the same symmetrical approach adopted in the sociological analysis, and will not be trying to settle the medical debate over how best to characterise the metabolic syndrome. Instead, I will be focusing on the ethical issues raised by each construct and the potential consequences if these were to be widely adopted in the clinical and/or public health setting. Therefore in this chapter, while I accept that such a cluster does exist and that it has the capacity to affect individuals, I am more interested in how the various interpretations of the concept have the potential to raise different ethical issues. This matches the medical/scientific literature, where although there has been significant disagreement over the diagnostic value of the numerous definitions of the metabolic syndrome (Reaven, 1988; Alberti and Zimmet, 1998, Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Grundy, 2005; Despres et al, 2001; Einhorn et al, 2003; Alberti et al 2006, 2009) and their use in medicine, all the publications — even those written by strong critics such as Reaven (2005a) and Kahn et al (2005) — accept that no 'risk factor clustering' for heart disease exists.

Bioethical methodology

Here I used a bioethical approach, the theory of principlism ('four principles'), as an analytical tool through which to explore these issues (Beauchamp and Childress, 2001[1979]). For a more in-depth discussion of the methodology I used please see Chapter 3 (Methods). I also made use of the theory of medicalisation, as a further tool with which to explore the ethical issues associated with the various interpretations of the Metabolic Syndrome (such as Reaven, 1988; Alberti and Zimmet, 1998; Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Grundy et al, 2005; Despres et al, 2001; Einhorn et al, 2003; Alberti et al 2006, 2009). Again, for a more in-depth discussion of this please see Chapter 3 (Methods).

The issues highlighted by principlism and medicalisation also resonate with many of the ethical concerns raised about both the inclusive and exclusive versions of the metabolic syndrome and their role in prevention. In addition, the concept is often seen as an example of the medicalisation of obesity, and matches the type of condition Verweij was talking about. During my bioethical analysis of the various interpretations of the metabolic syndrome, I made particular use of the first four issues outlined by Verweij when using medicalisation alongside principlism as an analytical tool with which to explore the concept.

Chapter structure

This chapter is divided into key sections based on the ethical issues raised by the creation of the metabolic syndrome and its related concepts. These were discussed in terms of the four principles approach (Beauchamp and Childress, 2001[1979]) and concerns raised in relation to medicalisation (Verweij, 1999), with many of the issues overlapping. There are four separate sections on the issues of beneficence, non-maleficence, respect for autonomy, and equity in relation to the concept, with the closely-related medicalisation issues nested within these. Section five explores additional ethical concerns in regard to the issue of 'values' and their role in shaping the various versions of the metabolic syndrome concept (such as Reaven 1988; Kaplan, 1989; Alberti and Zimmet, 1998; Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Grundy et al, 2005; Despres et al, 2001;

Einhorn et al, 2003; Alberti et al, 2006, 2009). The bioethical analysis here was influenced by the data collected during my sociological study, and a further period of general reading of the same medical/scientific literature on the topic, in order to identify any additional ethical concerns.

The main ethical issues raised

The metabolic syndrome and its various permutations are universally described as an example of preventative medicine. In reference to the NCEP/AHA construct, for example, Grundy et al stated that 'While ATP III maintains attention to intensive treatment of patients with CHD (*coronary heart disease*), its major new feature is a focus on primary prevention in persons with multiple risk factors' (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001: 2486). In a later version of the report, published in 2002, the experts noted that 'It (*ATP-III*) focuses on the role of the clinical approach to prevention of coronary heart disease (CHD)' (Grundy et al, 2002: I-1).

It is also widely accepted that the concept was primarily created as a way to identify individuals at risk of developing heart disease and/or diabetes, and then offering them 'treatment' in order to prevent these conditions. In fact, each of the various constructions of the metabolic syndrome concept emphasise its importance as a 'risk condition' for future diseases, such as heart disease and type 2 diabetes. Grundy et al, in reference to the 'ATP-III construct' for example, stated that 'The Metabolic Syndrome consists of a constellation of factors that raise the risk for CVD and type 2 diabetes' (2004b: 555). Consequently, the main ethical concerns raised in relation to the metabolic syndrome and its various concepts relate to their capacity to 'do good' and/or potential 'harm' in the context of health. In bioethical terms, these broadly equate to the principles of beneficence ('doing good') and non-maleficence ('doing no harm').

Additional concerns can also be raised in relation to the principle of fairness ('justice/equity') and in particular to what extent individuals and/or society can be held responsible ('blamed') for the 'condition'. The universal treatment strategies of behavioural change/lifestyle treatments also have the potential to raise further concerns

over the principle of the 'respect for autonomy ('freedom of choice')' (Beauchamp and Childress, 2001[1979]).

I will also show that while many of the ethical concerns highlighted above apply equally to the different interpretations of the concept, some constructs are likely to raise more significant concerns in relation to certain principles than others. For example, the group of constructs that view IR as the key component in the 'condition' identify fewer patients than the more 'inclusive' definitions. This means that they have the potential to raise greater concerns in relation to 'harm' by failing to identify individuals that would otherwise benefit from treatment. In contrast, by not concentrating on 'obesity' they may do less harm in terms of 'blaming the victim', and/or by not medicalising otherwise healthy people.

Section 1: beneficence

Identifying the 'metabolic syndrome' is a good thing

The ethical arguments used to justify the diagnosis and treatment of the metabolic syndrome are remarkably consistent across all the different constructs, including the 'less inclusive' (Reaven, 1988; Alberti and Zimmet, 1999; Einhorn et al, 2003) and 'more inclusive' (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Grundy et al 2001; Grundy et al, 2005; Alberti et al 2006, 2009) versions. They all assume that medical intervention will 'do good' by preventing 'harm' through stopping or delaying the development of conditions such as diabetes and heart disease.

Diagnosis: a 'good' through improvements to health

Proponents of the various concepts, for example, argue that recognising the metabolic syndrome represents both a private and public good in terms of improved health (individual and population). They suggest this can be achieved through a greater understanding of how lifestyle and obesity can lead to conditions such as diabetes and heart disease, which offers the potential to develop treatment and preventative strategies. In addition, they claim that this would also lead to a reduction in both

individual suffering and the wider economic, social and healthcare consequences associated with these conditions.

Description of the diagnosis of the metabolic syndrome concept as a 'public good' is often discussed in the context of public health, where the benefits are felt at the population level. In contrast, the identification of the concept as a 'private good' is usually discussed in the context of the clinical setting, where an individual patient may be helped.

In the earlier medical/scientific literature on the concept, where the 'less inclusive' IR versions of the concept — such as syndrome X (Reaven, 1988), IRS (Haffner et al, 1992), and WHO/EGIR definitions (Alberti and Zimmet, 1999; Balkau and Charles, 1999) — were first introduced, there was a greater focus on the potential benefit to individuals of identifying the condition. For example, when Reaven introduced the term 'syndrome X' in his Banting Memorial lecture, his focus was very much on the individual, describing it as follows:

Based on available data, it is possible to suggest that there is a series of related variables — Syndrome X — that tends to occur in the same individual and may be of enormous importance in the genesis of CAD (*heart disease*)

(Reaven, 1988: 1605).

Later in the same paper, he also noted that 'Although it is likely that a significant portion of the variance observed from person to person is genetically determined, insulin action can also be modulated by environmental influence' and that 'Consequently, the more obese and sedentary an individual, the greater the degree of IR, regardless of genetic influences' (Reaven, 1988: 1605), where here the emphasis is very much on the 'person' and the 'individual' again. In another example, when the experts behind the WHO (1999) definition first introduced the metabolic syndrome in their report, they described how 'A major classification, diagnostic and therapeutic challenge is the person with hypertension, central (upper body) obesity, and dyslipidaemia, with or without hyperglycaemia' and later that 'Thus, vigorous early management of the syndrome may have a significant impact on the prevention of both diabetes and

cardiovascular disease' (Alberti and Zimmet, 1999: 31–2). Here again the focus is very much on the potential benefit to individuals of identifying the condition.

In the later publications in which the 'more inclusive' obesity-centred definitions (such as those relating to the hypertriglyceridaemic waist (Despres et al, 2001), ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; ; Grundy et al, 2005) and IDF (Alberti et al, 2006)) were outlined, although the experts did discuss the 'private' benefits to the individual, there was now more emphasis on the 'public' benefits of identification.

Consequently, it was noticeable that the 'public health' aspects of the concept were more widely referred to in the later literature, particularly in publications where the 'more inclusive' obesity-centred definitions were being discussed (such as Grundy et al, 2005; Alberti et al, 2006, 2009). One explanation for this is that many healthcare professionals view 'obesity' as predominantly a 'public health issue' (Nuffield Council on Bioethics, 2007: 79). In describing their concepts in this way, this also enabled the claims-makers to tap into another set of resources, namely public health medicine. For example, Zimmet et al in an editorial on the 'IDF definition' published in the *Medical Journal of Australia* stated that 'The Metabolic Syndrome — the clustering of abdominal obesity, dyslipidemia, hyperglycaemia and hypertension — is a major public health challenge worldwide' (Zimmet et al, 2005: 175). In addition, Robert Eckel (a key backer of the original ATP-III definition) in his interview with me in July 2006 also described the concept as being a significant problem, when he stated that 'A large percentage of people around the world have (the) syndrome' (Eckel transcript, 2006:1). Similarly, Alberti and Zimmet in an opinion piece in the *BMJ* claimed that the IDF definition 'provides a simple public health strategy to define those at higher risk (*of cardiovascular disease*)' (2008: 641), again seeing this version of the metabolic syndrome as an important 'public health' concern, as well as 'individual care' issue.

In defining their constructs as primarily a 'public health' issue, the claims-makers were also changing the way the metabolic syndrome concept would be seen, because the public health paradigm is different to that of clinical medicine (Food Ethics Council, 2005: 11). This is because the former tends to be viewed as being aimed at the

population rather than at the individual level, and is seen as raising different ethical issues (Nuffield Council on Bioethics, 2007: 3).

This represented a significant change in the nature of the metabolic syndrome because the earlier versions of the concept (such as syndrome X and the WHO definition) were primarily constructed as a clinical tool, whereas the later versions were being redefined as important 'conditions' in the field of public health (Despres et al, 2001; Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Grundy et al, 2005; Alberti et al, 2006, 2009). This meant that these constructs would then be subject to a different set of priorities, with for example greater emphasis on prevention at the population level.

Consequently, this made the later versions of the metabolic syndrome concept (such as the ATP-III, IDF and JIS definitions) more complex from an ethical perspective because the focus was now also on the wider population. Bioethics tends to concentrate on the individual, whereas public health ethics is concerned with issues at the population level (Wikler and Brock, 2007). Conflicts can arise, with personal autonomy, a key issue in bioethics; whereas in public health ethics the rights of the individual may be secondary to the greater good. In addition, Roberts and Reich noted that 'Public-health regularly encounters serious ethical dilemmas, such as rationing scarce resources, influencing individuals to change their behaviour, and limiting freedom to diminish disease transmission' (2002: 1055). I will also be discussing these issues in more detail shortly.

Diagnosis: a 'good' through increased awareness

Another ethical justification put forward by proponents of the various versions of the metabolic syndrome (or creating them) was that they would help increase awareness of the general concept among medical professionals, research scientists and health policy makers. The idea being that this increased awareness would translate into greater interest being taken in the issue, leading to potential improvements in patient care, more experts becoming involved, more research being carried out, and the securing of additional funding for the area. The concept represented a 'public good' in terms of raising the profile of the issue of IR/obesity and its role in diabetes and heart disease, which had allegedly been neglected by the medical profession. By potentially making

it easier for researchers to access materials to study the area, the chances of new treatments being developed would be increased.

These arguments in particular were used in the defence of the later versions of the concept, such as the ATP-III (Grundy et al, 2001) and IDF (Alberti and Zimmet, 2006) definitions, which had received some of the heaviest criticism (Kahn et al, 2005; Reaven, 2005a). For example, Grundy in a reply to Reaven's critique of the ATP-III version of the metabolic syndrome argued that 'It can be said that the ATP-III definition increased the concept of the metabolic syndrome to a level of clinical urgency that requires greater investment of resources into research on the pathogenesis of the syndrome' (Grundy, 2005: 1353). The implication being that a greater understanding of the 'condition' could lead to improvements in treatment that would represent a public good.

In a later publication, Grundy further claimed that 'One advantage of identifying this particular cluster of risk factors is that it should bring together the fields of cardiovascular disease and diabetes for a concerted and unified effort to reduce risk for both conditions simultaneously' (2006a: 1093). A similar point was also made by Alberti and Zimmet in an opinion piece, when they noted that 'Focus on the syndrome has brought diabetologists and cardiologists together, ensuring better appreciation of risk of diabetes among cardiologists and cardiovascular disease among diabetologists' (2008: 641). The argument here was that by bringing these two medical disciplines 'together', the metabolic syndrome (as interpreted by the IDF and updated ATP-III definitions) represented a public good, because the concept has the potential to significantly improve the healthcare for diabetes and heart disease.

Diagnosis: a 'good' by reducing the economic burden of disease

A further ethical argument used by numerous claims-makers to justify identifying the metabolic syndrome and its various versions has been to highlight the potentially significant financial consequences of the condition. The argument here was that tackling it represented a public good in terms of reducing the financial burden on the wider population. For example, Ford et al in reference to the ATP-III definition argued that 'The high prevalence of the condition may also have serious implications for US health care costs' and that 'the high prevalence of this syndrome underscores the urgent

need to develop comprehensive efforts directed at controlling the obesity epidemic and improving physical activity levels in the United States' (2002: 359). The public good here being that identifying the condition will encourage action to be taken, thus preventing 'health care costs' from rising.

Taskinen, a Finnish expert on the condition, used a similar argument in an interview published on the Metabolic Syndrome Institute website, when he highlighted how 'These harmful consequences (type 2 diabetes and CVD) of the Metabolic Syndrome represent a substantial economic burden at population level worldwide' (Taskinen, 2005). Here again he was referring to the later 'more inclusive' obesity-centred versions of the metabolic syndrome concept, such as the ATP-III definition. Similarly, an IDF statement from 2006 outlining their concept argued that 'Diabetes and the metabolic syndrome' were 'driving the CVD (*cardiovascular disease*) epidemic' and that 'The cardiovascular complications of diabetes […] account for much of the social and financial burden of the disease' (IDF, 2006: 5 and 6). Again the claim here being that the 'development' of these further versions of the metabolic syndrome was a public good, in terms of improvements in the prevention of CVD, which in turn should also reduce 'the social and financial burden' of these conditions on society.

Section 2: non-maleficence

Identifying 'metabolic syndrome' could cause harm: introduction

Critics of the concept have predominantly focused on its potential 'to do harm'. In bioethical terms, this violates another of the 'four principles', namely non-maleficence. The issues raised here have predominantly focused on the uncertainty over the knowledge-claims surrounding the concept, and the potential to do harm as a consequence of this.

Metabolic syndrome: an uncertain and controversial concept

Meigs (2003) in an editorial published in the *BMJ* claimed that 'The current focus on the metabolic syndrome [*all versions pre-2003*] will possibly prove to be a distracting detour on the route to encouraging more widespread application of evidence-based practices to prevent diabetes and cardiovascular disease' (2003:61). Two years later,

the ADA/EASD published a joint statement based on a review of the literature surrounding the metabolic syndrome as exemplified by the WHO (Alberti and Zimmet, 1998), ATP-III (Grundy et al, 2001) and IDF definitions (Alberti et al, 2006), where they also criticised the concept (Kahn et al, 2005). Making a similar point to the one above, the authors argued that '…the metabolic syndrome is not nearly as well defined and characterised as often assumed, and that the notion that it is a useful marker of CVD risk above and beyond the risk associated with its individual components is uncertain' (Kahn et al, 2005: 2290). Later in the same document, the experts also suggested that

Providers [clinicians] *should avoid labelling patients with the term 'metabolic syndrome', as this might create the impression that the metabolic syndrome denotes a greater risk than its components, or that it is more serious than other CVD risk factors, or that the underlying pathophysiology is clear*

(Khan et al, 2005: 2304).

Criticising both the earlier 'less inclusive' versions of the metabolic syndrome, such as the WHO definition, and the later 'more inclusive' versions (such as the ATP-III and IDF definitions), the experts here raise ethical concerns over the potential impact of the continued use of these uncertain knowledge claims. For example, individuals could be harmed through medical professionals offering unnecessary treatments and/or becoming fatalistic about their health and the ability to change it, when in fact the evidence to support these 'risk predictions' is limited.

An article in *The Washington Post* on the metabolic syndrome published in 2005 also highlighted many of these issues, with the author noting that:

Some [professionals] *argue that the syndrome arbitrarily lumps together risk factors that doctors already recognize and treat. Combining them into a 'syndrome' could prompt doctors to put patients on drugs too quickly or, paradoxically, delay treating patients who need therapy….* (Stein, 2005: 1)

Here the discussion was centred on the later 'more inclusive' versions of the metabolic syndrome concept, and in particular the ATP-III definition (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Grundy et al,

2005), where the risk to individuals of early and potentially unnecessary treatments was highlighted, along with the opposite concerns over individuals not being treated. The latter can happen because although more people overall are identified as having metabolic syndrome when the 'obesity-centred' definitions are used due to their 'more inclusive' diagnostic criteria, some individuals remain undiagnosed, because as Stein later noted 'Doctors following the guidelines could miss patients who should be treated just because they have only two instead of the three risk factors required under the definition, or because their test results fall just outside thresholds in the guidelines' (Stein, 2005: 4).

In relation to the metabolic syndrome, and in particular its later 'more inclusive'/public health-orientated versions (such as the ATP-III and IDF definitions), medical professionals face an ethical dilemma because they see identifying the condition as 'doing good' by preventing diabetes and/or heart disease in some individuals, but there is the possibility that in borderline cases (those who reach the criteria but are unlikely to develop these conditions) they may end up 'doing harm' by applying potentially unnecessary and/or harmful treatments. Although the risks associated with using drugs to treat the 'condition' were discussed in the medical/scientific literature (see Breitstein, 2004), there was little discussion of the possibility of harm caused by the main treatment strategy, therapeutic lifestyle change, such as the potential loss of autonomy.

A further problem with so-called 'risk conditions' (Skolbekken, 1995; Hofmann, 2001) such as the metabolic syndrome concept is that the estimates of risk are often based on population data, and yet these are then taken and applied to individuals (Davison et al, 1991; Rose, 2001[1985]; Clarke et al, 2003). This issue was highlighted by Clarke and colleagues in their discussion of the 'biomedicalisation' concept. They noted that:

Of particular salience in the biomedicalisation era is the elaboration of standardized risk-assessment tools (eg to assess risk of breast cancer, heart disease, diabetes, hypertension, etc) that take epidemiological risk statistics, ostensibly meaningful only at the population level, and transform them into risk factors that are deemed meaningful at the individual level (Gifford 1986; Rockhill et al 2001).

(Clarke et al, 2003: 172).

This is ethically problematic, because people are then being encouraged to make changes to their lifestyle in the belief that this may help them individually, whereas in reality experts have no idea whether it will benefit them directly. This also has the potential to harm individuals by giving them a false sense of security that by following a particular lifestyle they will no longer be at risk from these conditions, when the situation is a great deal more complex, with genetic as well as environmental factors playing a role. Since all the metabolic syndrome constructs make extensive use of 'risk factors', the same ethical concerns highlighted above can also be raised in relation to this concept.

Later versions of the metabolic syndrome: problems with over-diagnosis

Critics of the metabolic syndrome, particularly the later 'more inclusive' versions (such as the ATP-III and IDF definitions), argue that the evidence supporting their use as diagnostic tools is simply not there. Using these definitions, physicians risk doing harm to their patients' health through the application of this uncertain knowledge. For example, if the diagnostic criteria used are too wide, there is the potential for over-diagnosis, with the possibility of causing harm through the creation of greater numbers of the 'worried well', as well as the widespread introduction of unnecessary lifestyle and drug treatment/prevention strategies, both of which have the potential to harm individuals, either psychologically or physically. The risk of apparently healthy individuals being labelled as potentially ill has also been used as moral justification (doing no harm) for not making use of these definitions.

Reaven — a longstanding critic of the later 'diagnostic' interpretations of his syndrome X concept — for example, in reference to the ATP-III definition (Grundy et al 2001) argued that '…it is not clear that it has led to the delivery of any new information of significant utility to the practicing clinician' and that '…if taken at face value there is a real possibility that use of the ATP-III criteria could do more harm than good' (Reaven, 2005a: 931). In addition, the experts behind the ADA/EASD critique of the metabolic syndrome stated that

It should be remembered that the current definitions of the syndrome [WHO, ATP-III And IDF definitions] *capture many people with frank disease (eg, diabetes, hypertension, clinical CVD), as well as those who have milder conditions or 'normal'*

values that, while qualifying them for the diagnosis of the syndrome are not high enough to warrant specific therapy.

(Kahn et al, 2005: 2302)

Concluding the paper, they also argued that:

There is much fundamental, clinically important, and critically missing information about the metabolic syndrome to warrant a more serious examination of whether medical science is doing any good *by drawing attention to and labelling millions of people with a presumed disease that does not stand on firm ground*.

(Kahn et al, 2005: 2304)

Here the authors refer directly to the notion of 'doing (any) good' in regard to identifying the metabolic syndrome concept, a group of definitions that they see as uncertain and potentially harmful, describing the condition as 'a presumed disease'. The harm here is through the increased anxiety of those individuals identified as part of this medical surveillance, with the issue made more problematic due to the uncertainty over whether these concepts count as 'real' conditions or not (Frantz, 2005; Kahn et al, 2005; Mitka, 2005). The latter raise concerns about fairness due to the risks associated with individuals being given unnecessary treatments for a condition (or conditions) that may not even exist. Richard Kahn, the lead author of the above statement and head of the ADA, was also quoted in the *Houston Chronicle* as saying that 'A diagnosis of the syndrome "misleads the patient into believing he or she has a unique disease"' (Ryerson-Cruz, 2005: 1). In addition, if individuals are labelled as having the 'condition', this could also potentially lead to increased health insurance premiums or them not being given full access to all available services.

Too great a focus on the diagnostic criteria?

Another concern regarding the metabolic syndrome, and in particular the more 'diagnostically-orientated' versions of the concept (such as the WHO, ATP-III and IDF definitions), is that by concentrating so heavily on the diagnostic aspects — and particularly on whether an individual has the condition or not — the medical profession may have neglected other areas, such as the underlying causes and treatment strategies.

This may impact on patient care and lead to 'harm' through lack of understanding of the 'condition' and delaying development of effective treatments. This issue is raised by Kim and Reaven, who argued that 'The greatest potential drawback is to focus on whether a patient has the Metabolic Syndrome, rather than addressing the abnormalities associated with insulin resistance and compensatory hyperinsulinaemia' (2004:74).

This is seen as less of an ethical issue for syndrome X (Reaven 1988) and the IRS concept (Einhorn et al 2003), however, with Reaven describing how the latter 'was simply to say insulin resistant people are more at risk for heart disease' (transcript, 2005: 13), and the ACE experts claiming that with their construct they were 'focusing on the underlying pathophysiology that unites the cluster of related abnormalities' and that 'the experimental evidence available does not exist that can be translated into simple criteria for diagnosing the IRS' (Einhorn et al, 2003: 240 and 244). Here the researchers behind these two concepts were more interested in the probable causes than diagnosing the 'condition' itself.

Problems with under-diagnosis

Making the diagnostic criteria too stringent, as in the case of the earlier 'less inclusive' definitions that required evidence of IR (such as syndrome X and the WHO definition), creates the possibility of under-diagnosis, with individuals that may have benefited from treatment/prevention not being identified. This is a dilemma with no simple solution, however, that professionals often have to face when they do not have access to a reliable diagnostic tool for a particular 'condition' and have to make a moral judgement about weighing up the risks associated with potential 'false positives' and 'false negatives'.

Again the issue of under-diagnosis has ethical implications in terms of harm, with the potential that missed individuals may go on to develop medical conditions that could have been prevented. The arbitrary nature of the various definitions of the metabolic syndrome mean that individuals with many of the risk factors associated with the condition remain undiagnosed because they do not meet the diagnostic criteria. As Kim and Reaven highlighted in their paper criticising the WHO and ATP-III (original) versions of the concept:

Not only is it possible to question the relevance of making a diagnosis of the metabolic syndrome, but the decision that a patient does not have the metabolic syndrome has the potential to impede treatment aimed at decreasing CVD risk.

(Kim and Reaven, 2004: 74).

In a solo publication, Reaven in reference to the same two definitions also noted that 'I clearly am not impressed with this notion [*the diagnostic category of the metabolic syndrome*] and question the utility of either form of the metabolic syndrome, ATP-III or WHO' and 'I am also quite concerned as to the risks that might result from failure to initiate appropriate efforts to reduce CVD risk in individuals not meeting the diagnostic criteria' (Reaven, 2005b: 1357). Reaven argues that, by concentrating on meeting a list of specific risk factors, these two versions of the concept (WHO and ATP-III) raise ethical concerns over potential harm to patients due to under-diagnosis, in contrast presumably to his favoured IRS concept (Einhorn et al, 2003) that does not rely on a rigid set of guidelines.

Potential 'harm' due to greater uncertainty over health

The potential of preventative medicine to cause harm to individuals through the creation of uncertainty over their health was another one of the ethical concerns raised by Verweij, who described the issue as 'the accumulation of uncertainty' (1999:96). In his publication, he argued that 'Inevitably, preventive medicine and health promotion stimulate healthy people to think, wonder and worry about the possibility that they may become ill' and that this can have a negative affect on individuals because 'a certain degree of confidence and feelings of security are important considerations for well-being' (Verweij, 1999: 96 and 97).

The metabolic syndrome concept raises similar concerns, particularly the later 'more inclusive' versions (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Despres et al, 2001; Grundy et al, 2005; Alberti et al 2006, 2009) that have the potential to identify significant numbers of people (Ford et al, 2002), many of whom would be classed as having only a slightly increased risk of developing diabetes/heart disease. For example, Rury Holman (a diabetes specialist

from Oxford and exponent of the concept) raised the issue in an interview on the Metabolic Syndrome Institute website, in which he stated that: 'Labelling, largely asymptomatic, people as having the metabolic syndrome inevitably will have a downside in increasing anxiety and raising uncertainty about their future well being' (Holman, 2005). He claimed, however, that this 'uncertainty' could be reduced through 'comprehensive information about the condition and highlighting the possibilities to minimise the consequences' (Holman, 2005). Both statements were speculation on his part, but there is some evidence to suggest that the identification of 'risk conditions' can lead to increased anxiety among those affected (Misselbrook and Armstrong, 2001). In discussing the issue, Marteau and Kinmonth (2002), for example, argued that 'identification of diabetes, hypertension, or hyperlipidaemia creates demands for clinical monitoring and adherence to drug treatment, potentially resulting in a life lived in fear of a heart attack or stroke' (2002: 78–80).

Potential 'harm' as a result of treatment

Verweij in his discussion of 'medicalisation as a moral problem for preventive medicine' also identified the 'iatrogenic risks of prevention' as being of ethical concern, which he defined as 'the risk that a person's health is harmed rather than protected by preventive interventions' (Verweij, 1999:94–95). An issue that he argued was best viewed through the concept of 'non-maleficence' (1999:95-96).

In reference to the metabolic syndrome concept, ethical concerns can be raised in regard to the apparent lack of evidence for the various treatment/preventative strategies, for example the evidence supporting the effectiveness of the therapeutic lifestyle change and drug-based treatments, particularly where the problem of IR is limited. Deen, in a review article published in 2004, noted that 'Currently, no randomised controlled trials *specifically* examining the treatment of metabolic syndrome have been published' (2004: 2877). Orchard et al, however, published a study that was based on secondary analysis of data collected from the Diabetes Prevention Program in the US, in which they claimed that 'lifestyle intervention and metformin each reduced the development of the metabolic syndrome [*as defined by the ATP-III definition*] among the 45 percent of participants who did not have it at baseline' and that 'The impact of lifestyle intervention was much more marked than that of metformin' (Orchard et al 2005:611–9, Editors' Notes). They also noted that because the data only covered a short period of

time, the long-term effectiveness of both types of treatment was still unknown. In an article in *USA Today* from September 2005, it was reported that James Cleeman (NHLBI), who was described as 'an ardent advocate of the approach', also admitted 'that there's no evidence showing that reducing metabolic syndrome can prevent heart disease or extend life' (Sternberg, 2005b: 2).

Specific concerns in regard to the implementation of therapeutic lifestyle change

Further concerns raised in the literature relate to the applicability of therapeutic lifestyle change treatment in the clinical setting and beyond. For example, in a report on the proceedings of the NHLBI/AHA conference on metabolic syndrome (ATP-III definition) in 2003, the authors noted that 'Some participants questioned whether such changes [*therapeutic lifestyle change*] could successfully be implemented in clinical practice' (Grundy et al, 2004a: 437). They further argued that 'the potential for benefit certainly exits; implementation is the challenge' (2004a: 437). Deen also discussed the issue of lifestyle intervention in a review article on the metabolic syndrome concept published in 2004, where he highlighted that 'many patients find weight loss difficult to achieve' (Deen, 2004: 2875 and 2877). In addition, Grundy in a later review claimed that 'lifestyle intervention unfortunately is often neglected in routine practice' (Grundy, 2006a: 1096). The lack of evidence for the efficacy of preventative treatments such as therapeutic lifestyle change and additional concerns over their use and practically raises a number of ethical issues. For example, questions can be raised over the fairness of offering such treatment/preventative strategies to patients when there is such uncertainty over their chance of success. There is also the potential that these 'treatments' may cause harm to the patients, in relation to increased fears and anxieties over their failure to make the necessary changes.

Another potential problem in relation to the use of treatments such as therapeutic lifestyle change is that in countries such as the United States, which have insurance-based healthcare schemes, such approaches may not be funded. This may discourage medical professionals from advocating therapeutic lifestyle change-based treatment/preventative approaches, and instead steer them towards the drug-based treatment/preventative options. Ford et al in their paper on the prevalence of the metabolic syndrome (ATP-III definition) in the US, for example noted that 'The cornerstones of treatment are the management of weight and ensuring appropriate levels

of physical activity' but that the 'lack of reimbursement [*for medical professionals*] for weight management and physical activity interventions constitutes a major barrier' (Ford et al, 2002: 358 and 359). Therefore in the US, because insurance companies do not reimburse physicians for their work encouraging patients to adopt 'therapeutic lifestyle change approaches, they may be less likely to support such measures and instead favour drug treatment/preventative strategies. This raises further ethical concerns in relation to the potential to cause harm because the risk of 'side effects' from drug-based treatment/preventative strategies is likely to be greater than with therapeutic lifestyle change-type approaches.

In another paper on preventive cardiology by lifestyle intervention, published in 2006, Eckel claimed that 'Reimbursement remains an issue, especially for the services of dieticians and exercise therapists, and for preventive services in general' and that 'We [*cardiologists*] need to continue to advocate for change in this area' (2006: 2661). This raises further ethical concerns in relation to fairness, if the reason for not funding the preferred treatment/preventative strategy/therapeutic lifestyle change for the later more 'prevention-orientated' versions of the metabolic syndrome (such as Grundy et al 2005 and Alberti et al 2006) is because of the type of healthcare system in place in the US that gives priority to drug and/or surgical interventions, particularly if the costs (well-being and financial) to individuals and society were found to be lower with the therapeutic lifestyle approach.

Conrad also claimed that lack of funding had originally been a barrier for the medicalisation of obesity in the US, when he noted that 'In the 1980s I would frequently say to my students that one of the limits on medicalisation of obesity is that Blue Cross/Blue Shield [*then a dominant insurance/managed care company*] would not pay for gastric bypass operations' (Conrad, 2005: 10). However, he then noted that 'This is no longer the case' and that 'The recent Medicare policy shift declaring obesity as a disease could further expand the number of medical claims for the procedure' (2005: 10). Earlier in the paper, Conrad also claimed that 'Today physicians prescribe the Atkins or South Beach diet and exercise' (2005: 7), although it is not clear from his paper whether US medical insurers are directly funding this or medical professionals are just telling their patients to go on a diet and take more exercise. What this does show, however, is that while funding is certainly a barrier, it is not a complete one, and

that ‘lifestyle’ treatments can still be offered as an option — although probably without the funded support of physicians and allied professionals, such as dieticians and physiotherapists. This may also be more rational from the patient perspective, because by avoiding being labelled as having the metabolic syndrome and offered relatively minor interventions such as therapeutic lifestyle change, they may feel that treatment/prevention is now more on their own terms, with further benefits in relation to reduced healthcare premiums and other social costs.

Treatment/prevention: summary of the ethical concerns

The above issues raise a number of potential ethical concerns, particularly in relation to fairness. For example, if there is little evidence to support the use of therapeutic lifestyle change and drug-based preventative/treatment options, and there are significant barriers to the implementation of such approaches, is it fair to identify individuals with the metabolic syndrome or one of its versions (such as Reaven, 1988; Kaplan, 1989; Alberti and Zimmet, 1998; Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001;Despres et al, 2001; Einhorn et al, 2003; Grundy, 2005; Alberti et al 2006, 2009) and offer ‘treatments’ that may be difficult to implement, are not funded, and are ineffective in the long run.

Further concerns: Respect for autonomy and justice

The ethical discussion in the medical/scientific literature on the metabolic syndrome and its various concepts has predominantly focused on issues relating to ‘doing good’ and ‘the potential to do harm’. There are other ethical issues that the concept raises, however, and these relate to the principles of ‘respect for autonomy’ and ‘justice (fairness)’ (Beauchamp and Childress, 2001). These issues also map to two of the concerns highlighted by Verweij in his publication on ‘medicalisation as a moral problem for preventive medicine’, which were ‘the loss of autonomy and independence’ and ‘responsibility for health and victim blaming’ (1999: 98–107).

Section 3: respect for autonomy

Metabolic syndrome and therapeutic lifestyle change

Another key ethical concern that arose in regard to all versions of the metabolic syndrome concept (all versions) relates to the potential loss of autonomy following diagnosis and the instigation of therapeutic lifestyle change treatment, which closely matches one of the issues highlighted by Verweij.

The discussion surrounding the preventative treatment options for the metabolic syndrome in the medical/scientific literature indicates that there is agreement across all the different versions of the concept that the first line of treatment should be therapeutic lifestyle change. The literature on the main diagnostic constructs of the metabolic syndrome concept — syndrome X (Reaven, 1988), IRS (Einhorn et al, 2003), WHO (Alberti and Zimmet, 1998) and ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001) definitions, the IDF 'consensus' definition (Alberti et al, 2006), and JIS definition (Alberti et al, 2009) — has universally backed 'lifestyle change' as the main preventative treatment strategy.

To illustrate this concordance, here are some of the ways in which therapeutic lifestyle change and its related approaches have been introduced in the literature surrounding the metabolic syndrome concept. Reaven in his paper on syndrome ' was the first to outline these measures, when he stated that 'It seems obvious that variations in life-style, in particular avoiding obesity and remaining physically active, provide an approach to minimize the risk factors for CAD associated with resistance to insulin-stimulated glucose uptake' (1988: 1605). The ACE experts behind the IRS concept that included Reaven also back the approach: 'We are supportive of current concepts in medically supervised therapeutic lifestyle change' (Einhorn et al, 2003: 250). In addition, Paul Zimmet in a press release coinciding with the launch of the 'new' IDF consensus definition in April 2005 was quoted as saying that 'While no single treatment for the metabolic syndrome as a whole yet exists, we know that lifestyle changes, for example changes in diet and an increase in exercise, form the underlying strategy of treatment' (IDF 2005a: 2).

Getting people to change their behaviour (in terms of diet and exercise) individually or collectively is a distinctly moral issue. This is because it raises a number of ethical concerns, such as the potential loss of autonomy, issues of paternalism, as well as fairness concerns in relation to blame. Consequently, the identification of the various versions of metabolic syndrome and their suggested treatment with therapeutic lifestyle change raises particular ethical concerns in regard to autonomy and justice. This is no different to many other medical conditions, where 'patients' are required to give up some degree of autonomy in order to enable medical professionals to treat them.

Although the bioethical principle of autonomy has been defined in a number of ways, many of the definitions describe it 'as an individual's self-determination' or a variation of this theme (Andorno, 2004: 436). In relation to how this plays out in modern Western societies, Grill and Hansson noted that 'At the core of liberal political thought is the individual's right to direct her (or his) own life' (2005: 650). In regard to conditions such as the metabolic syndrome, autonomy is often discussed alongside the concept of paternalism. In the context of medicine, this is where physicians may end up having to 'do things against their [*patient's*] immediate wishes or without consulting them, indeed perhaps with a measure of deception, to do what is in their best interests' (Gillon, 1986: 67). This is seen as being the opposite of autonomy. As a result, those who regard 'respect for autonomy' as being the most important principle often view paternalism in negative terms. Paternalism does not have to be seen in this way, however; for example if a paternalistic treatment can be shown to be preventing disease, other principles such as beneficence and non-maleficence can come into play, and thus make the approach ethically justifiable.

Despite this, the application of treatments for medical condition, whether they are drug-based, surgical or behavioural, all raise potential concerns over loss of autonomy. This is no different for the metabolic syndrome concept, where the main treatment/preventative strategy is therapeutic lifestyle change, which although appearing more benign than other 'medical' approaches still involves persuading individuals to change their diet and exercise more, with the primary aim of getting them to lose weight and reduce the other 'risk factors' associated with the 'condition', such as high blood pressure and cholesterol. The medical professionals use the incentive that if patients achieve this, they will no longer be classed as having metabolic syndrome or

one of its related constructs and will have significantly reduced their risk of developing diabetes and/or heart disease. Achieving this involves interfering in an individual's life by getting them to change their lifestyle (such as diet and exercise), however, which could be seen as an infringement of their private life as well as affecting their right to an autonomous life, raising ethical concerns over the potential loss of autonomy. These issues were not raised in the medical/scientific literature on the metabolic syndrome concept, suggesting that there was a consensus among the medical professionals involved that prevention/treatment approaches such as therapeutic lifestyle change raised few ethical concerns. This applied across all the various constructs, both the 'less and more inclusive' versions, showing that the differences between them did not seem to matter in regard to this particular issue. This also highlights the shared values that exist across medical disciplines.

Of course, it could be argued that individuals are free to ignore such advice, meaning that in principle their personal autonomy would be unaffected. Even in this scenario, however, the fact that this information has been imparted means that any future decisions they make regarding 'lifestyle' choices will be influenced by this knowledge, and will have therefore led to some loss of personal independence in regard to independent thought. This is because approaches such as therapeutic lifestyle change are trying to get individuals to change their preferences and behaviour. For example, Allmark in his publication on the UK White paper on health entitled 'Choosing Health' (Department of Health, 2004), suggested that critics argue that '*Choosing Health* and similar initiatives are attempting to change the culture of the poor, to make them behave as the middle class do' (Allmark, 2006: 5).

If the preventative treatments were effective and did indeed lead to a reduction in the risk of diabetes and/or heart disease, then this 'minor' infringement into their private life would be ethically justifiable, as the benefits to their health would outweigh the risks associated with the loss of personal autonomy. There do, however, remain significant uncertainties surrounding the metabolic syndrome and its various versions, particularly in relation to the effectiveness of preventative treatments such as therapeutic lifestyle change, which means that the benefits to the individual may be far less than the medical professionals suggest. This would then mean that the ethical justification put forward for the identification and treatment of the 'condition' on the

grounds that it was preventing harm would no longer be valid. In addition, some ethicists regard autonomy as being such a key concept that any interference in an individual's 'lifestyle' would be seen as ethically unjustifiable because it represented an infringement of this principle, irrespective of whether it was being done in an attempt to improve their health or not (Allmark, 2006).

Another issue that makes the situation around the metabolic syndrome more complex is the fact that the concept can be seen as a 'clinical' and/or 'public health' problem, depending on the type of construct used. These two approaches, 'clinical' and 'public health', are quite different from both the medical and ethical perspectives. For example, the authors of the 2009 'harmonisation' statement in which the JIS definition of the metabolic syndrome was first introduced, noted that 'In the *public health arena*, more attention must be given to modification of lifestyles of the general public of all nations to reduce obesity and to increase physical activity' and that 'At a *clinical level*, individual patients with the metabolic syndrome need to be identified so that their multiple risk factors, including lifestyle factors, can be reduced' (Alberti et al, 2009: 1641). Although both approaches involve 'persuading' people to alter their lifestyle, the scales are different. The public health approach aims at getting the population to make collective changes, whereas the clinical approach aims at getting individuals to make personal changes.

As mentioned earlier, the experts behind the 'more inclusive' versions of the concept (such as the ATP-III, IDF and JIS definitions) put greater emphasis on portraying the condition as a public health issue. This changed the nature of the concept from a predominantly clinical problem to a public health issue, which makes the ethics more complex. This is particularly relevant in relation to the issue of autonomy, with bio-ethicists such as Dawson and Verweij highlighting how 'Personal autonomy, cherished in modern individual health care, might not be given priority in *public health care*, where other values, such as the protection of the health of individuals and groups, the prevention of harm to others, and the promotion of health equity, are central' (2007: 2). They further noted that 'In an age in which medicine and health care have learned to see patient autonomy and the well being of each individual as core values, public health programmes that limit freedom, impose treatment, and aim to adjust unhealthy behaviour might seem overly paternalist or potentially coercive' (2007: 5).

Here the authors view public health programmes in a particular way. Such programmes are rarely this strict, however, and often allow individuals the freedom to ignore doctors' advice, and are completely compatible with the 'cores values' of 'patient autonomy and well-being of each individual'. In relation to the metabolic syndrome, there are still no large screening programmes specifically for any of the various versions of the concept, even though proponents claim that that 'the syndrome [*IDF 2005 definition*] provides a simple public health strategy to define those at higher risk [*of CVD*]' (Alberti and Zimmet, 2008: 641).

Respect for autonomy: summary

The above issues raise a number of potential concerns in relation to autonomy. These are largely centred on the main treatment strategy of therapeutic lifestyle change and its impact on an individual's private life in terms of potential loss of autonomy. If the approach was of benefit, then any loss of autonomy could be ethically justifiable; however, the evidence supporting the use of therapeutic lifestyle change approach in the treatment/prevention of the metabolic syndrome remains uncertain. Both the 'less inclusive' (Reaven, 1988; Haffner et al, 1992; Alberti and Zimmet, 1998; Einhorn et al, 2003) and 'more inclusive' (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Despres et al, 2001; Grundy et al, 2005; Alberti et al, 2006, 2009) versions of the metabolic syndrome have emphasised the use of therapeutic lifestyle change treatments, and in terms of the 'loss of autonomy' there was little difference between the different concepts, although the latter group with their focus on public health, may be assumed to have a stronger interest in preventative treatments such as therapeutic lifestyle change.

The fact that therapeutic lifestyle change treatments require an individual's consent and cooperation, and individuals are free to ignore the advice, means that any concerns over 'loss of autonomy' are likely to be minor, based on the idea that such approaches represent an intrusion into an individuals private life potentially affecting their personal autonomy. The lack of discussion in the medical/scientific literature of ethical concerns in regard to the use of therapeutic lifestyle change treatments, including the issue of 'autonomy', suggests that medical professionals do not see this approach as being a

significant problem. Yet the potential for such approaches to raise ethical concerns in regard to 'loss of autonomy' remains a possibility.

Section 4: justice (fairness)

Fairness and the issue of responsibility for the metabolic syndrome

Another potential ethical concern in regard to the metabolic syndrome concept relates to the issue of justice (fairness) and who should be held responsible or blamed for the 'condition'. This matches the issue of 'responsibility for health and victim blaming' highlighted by Verweij (1999), and is also linked to one of the main 'negative consequences' of medicalisation, which is 'the individualisation of social problems' (Conrad, 1975). Again, these issues are likely to be of greater concern to the later 'more inclusive' versions of the concept (such as the ATP-III and IDF definitions) due to their focus on 'obesity', which is commonly seen as a blameworthy condition (Gard and Wright, 2005).

Although there has been significant disagreement over many aspects of the concept, all the main medical/scientific publications accept that there is 'risk factor clustering' for heart disease and that it is linked in some way to 'lifestyle' (see for example Reaven, 1988; Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Kahn et al, 2005). Over the past 25 years, 'lifestyle' and its role in disease has become an important concept in medicine, particularly with developments in information technology that have enabled ever-larger data sets to be analysed, which have led to more predictions about the risks associated with various conditions (Skolbekken, 1995; Getz et al, 2003). For example, the Nuffield Council on Bioethics in their 2007 report on public health ethics highlighted how 'Many of the issues discussed in the context of public health arise from what some commentators call "lifestyle diseases", such as obesity- and smoking-related conditions' (2007: 4).

For many researchers, however, the notion of 'lifestyle' and its role in disease is highly problematic. For example Boddington, in her paper on the ethics of heart disease, noted that the 'Language of "lifestyle" should not be allowed to obscure the inescapable fact that much of what passes for individual lifestyle is shaped, if not dictated, by social

factors' (2009: 125). The 'social factors' referred to included issues such as 'food availability, transport options [*and*] income' that Boddington argued 'help to mould the choices of individuals' (2009: 125). If individuals are being held more accountable for conditions that are related to lifestyle, and this is something that is not entirely in their control, then this raises ethical concerns in relation to fairness.

In many Western countries there has been a move towards encouraging people to take more responsibility for their lives, and this has included areas such as their health. For example, the Food Ethics Council published a report in 2005 where they highlighted how UK public health initiatives were encouraging individuals to take more 'personal responsibility' for their 'dietary health'. This approach is unproblematic in regard to fairness, as long as people are in a position to be able to influence their lifestyle and to make changes if necessary. If this is not the case, however, then ethical concerns can be raised.

In regard to the related concepts of metabolic syndrome, abdominal obesity and IR, there is strong empirical evidence that 'social factors' such as social inequality, social position and stress levels in society — which are often beyond the control of the individual — have a significant effect on the aetiology and incidence of these conditions (Brunner et al, 2002; Lawlor et al, 2002). The research showed that these factors influence an individual's lifestyle and the choices they make.

A team of health epidemiologists based at University College London (UCL) in the UK, for example, have been researching the issue for over 15 years (Brunner, 1997; Brunner et al, 1997, 2002; Chandola et al, 2006). Much of this work is based on data collected from the Whitehall II Study, which is described on the UCL website as 'A prospective cohort study of cardiovascular disease (CVD) among 10,308 civil servants. Several waves of data collection between 1985 and the present provide a wealth of biomedical, behavioural and psychosocial information on participants' (UCL website, 2004). The researchers have highlighted, for example, the role of 'social inequality in coronary risk' and how it is closely linked to 'central obesity and the metabolic syndrome' (Brunner et al, 1997). In later work, they also claimed to have found evidence that individuals who had positions that were described as being of 'middle

management' level or lower had a higher incidence of metabolic syndrome (as defined by Brunner et al 1997/8) and its related complications of diabetes and heart disease, compared to individuals who held more senior positions (Brunner et al, 2002). The Medical Research Council (MRC) who jointly funded the study with the British Heart Foundation publicised the findings in their annual review (2002–3) of research, where they claimed that the work 'showed that men with the syndrome (as defined by Brunner et al 1997/1998) produced more stress hormones, had higher than normal heart rates and were more obese than controls' and that 'It provides the best evidence to date that chronic stress can be part of a chain of events that may lead to heart disease' (MRC Annual Review, 2002–3:27). Further research by Chandola et al on data from the Whitehall II study (1985–99), also suggested that stress plays an important part in conditions such as the metabolic syndrome (as defined by Brunner et al 1997/8), diabetes and heart disease (Chandola et al, 2006). The media in the UK reported on the research, with The Times newspaper publishing an article under the heading 'Workplace stress link to higher heart risk' (Lister, 2006).

A review of data from other studies (that did not use the Whitehall II study), also suggests that 'Abdominal obesity and disease are linked to social position' (Brunner et al, 1998). The authors of the review conclude that:

As follow up continues we will be able to determine the extent to which abdominal obesity and the metabolic syndrome can identify people who later develop diabetes and coronary disease, and we should be able to account for differences in disease incidence according to social position

(Brunner et al, 1998: 308).

Here they used the terms IRS and metabolic syndrome interchangeably, and when referring to the latter meant their own version of the concept in which

subjects were considered to have the metabolic syndrome if three or more measures were in the top fifth for their sex: post-load glucose concentration, systolic blood pressure, fasting triglyceride concentrations, high density lipoprotein cholesterol concentration (bottom fifth), and waist: hip ratio.

(Brunner et al, 1998: 308)

This was very similar to, but not exactly the same as, the later ATP-III definition developed by the AHA/NHLBI (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001). Despite this, during my analysis of the medical/scientific literature on the metabolic syndrome across the wide range of concepts I found that this work was hardly discussed, and instead the publications tended to concentrate on the individual in terms of diagnosis, lifestyle and prevention/treatment. This again raises fairness concerns, because by largely ignoring this evidence and concentrating on the individual and their lifestyle, the medical professionals are treating these individuals as being outside of society, and unfairly burdening them with responsibility for their lifestyle, when other scientific evidence suggests that 'social factors' — such as social standing, that may be very difficult to change — have a key role to play in the condition.

Many of these publications were aimed at addressing issues in the clinical setting, where of course primary care physicians are in a limited position to tackle these wider issues of society, such as social inequality and stress — apart from offering individuals that are affected with the condition therapeutic lifestyle change-type treatments. From an ethical perspective, these experts are doing as much as they can given their circumstances. As mentioned earlier, however, the later versions of the metabolic syndrome concept — such as the ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Grundy et al, 2005) and IDF (Alberti et al, 2006) definitions — are increasingly discussed in terms of being a 'public health' problem, which if those involved in developing these constructs are serious about tackling, requires input from a number of other groups, such as government officials (to introduce policies that help to reduce social inequality), private employers (to help reduce stress levels), agricultural sector (to make 'healthier food' more affordable), and the education sector (to make people more aware of these issues). Currently, because particular specialists in the medical community (those with a direct interest) have defined the various versions of the concept as being medical 'conditions', their profession is seen as having the legitimacy to tackle the issue, even when other groups such as nutritionists and exercise experts may be just as well-qualified to deal with it. This is despite the fact that other sections of the medical profession, who are

highly critical of the metabolic syndrome — as interpreted by the WHO (Alberti and Zimmet, 1998), AHA/NHLBI (Grundy et al, 2001) and the IDF (Alberti et al, 2006) among others, including many diabetes specialists (as well as the ADA) — have highlighted the uncertainty and confusion surrounding the issue. This highlights how the controversy surrounding the metabolic syndrome concept is predominantly a disagreement between different clinical disciplines (diabetes and heart disease specialists), and this has largely dictated the way in which the debate has developed. Significantly, the controversy over the concept only really seemed to take off when it began to encroach on the public health area.

Even here, although critical of the concept as portrayed by the various organisations, the experts behind the numerous critiques never questioned the idea that as medical professionals they may not be the ones best placed to tackle the problems associated with obesity/IR, such as diabetes and heart disease. As a result, even though medical professionals may have shied away from using these concepts, they still view the issue as being predominantly a medical problem that requires a medical solution, in the form of treatments such as therapeutic lifestyle change. The onus is then back on the individual to make the necessary changes in order to 'improve' their health, which means that the ethical concerns over fairness remain.

In addition, if those further down the social strata are at the most risk of developing abdominal obesity, IR, metabolic syndrome, and related conditions such as diabetes and heart disease as Brunner and colleagues suggest (Brunner et al 2002, Chandola et al 2006), then societies with the highest levels of inequality surely have a moral duty to try and prevent or at least alleviate the consequences of this. Many countries in the world now take the association between heart disease and inequality very seriously, and in countries such as Finland the authorities have been introducing measures to try and reduce this (Tuomilehto et al 2001). These have included measures to try and prevent type 2 diabetes, as well as screening individuals at 'high risk for CVD' and then offering 'lifestyle intervention' (Ketola et al, 2001; Tuomilehto et al, 2001). In fact, Finland is one of the few countries where these measures have been attempted on a large scale and which has actually seen a reduction in the incidence of heart disease, since they were introduced (Ketola et al, 2001). This suggests that other countries with high rates of CVD should also be introducing these types of approaches, in order to prevent harm.

From a justice (fairness) perspective, however, this would only be ethically justifiable if it could be done by not putting an unfair burden on the individual. Yet when societies do react, because 'conditions' such as the metabolic syndrome (particularly the later 'obesity-centred' versions) are usually seen in preventative medical terms, the onus is often on the individual to change rather than the society. Further ethical concerns can also be raised in relation to whether this ought to be done at all, given that doubts remain about whether there is a 'condition' that needs treating (Kahn et al, 2005), as highlighted earlier.

Fairness and the issue of medicalisation

According to researchers such as Conrad, medicalisation is a process that can lead to 'the individualisation of social problems' in which 'we tend to look for causes and solutions to complex social problems in the individual rather than in the social system' and that 'we then seek to change the "victim" rather than the society' (Conrad, 1975: 67). Although individualisation does not necessarily mean that an individual will be blamed for having their condition, the fact that the focus is on them rather than, say, society makes this more likely.

Taking alcoholism as an example, if an individual becomes medically defined as an 'alcoholic' the condition is regarded as an addiction, which is seen as a fault in their biological/psychological makeup, and the focus is on the individual to overcome this 'fault' through changing his or her behaviour. As a result, there is much less emphasis on the role of society in this process, such as the widespread availability of alcohol, stress and pressures of modern life, and the breakdown of social support networks. This is not unlike the situation around the metabolic syndrome concept, where following diagnosis there is a strong focus on the individual's 'lifestyle' and their need to change. In this case, the 'victim' is therefore 'the diagnosed' who is then offered suitable treatment in the form of therapeutic lifestyle change. This applies to both the insulin resistance- and obesity-centred versions of the metabolic syndrome concept, which all advocate the need for individualised treatment strategies such as therapeutic lifestyle change. Yet even with work such as Pickett et al's (2005) study highlighting the links between 'obesity and income inequality', the role of society in 'conditions' such as the

metabolic syndrome often still gets lost because experts see the issue as a medical rather than social problem and end up concentrating on the individual.

This is doing the opposite of one of the other outcomes of medicalisation highlighted by Conrad: the potential for 'less condemnation of the deviants (they have an illness, it is not their fault) and perhaps less social stigma' (Conrad, 1975: 66). Chang and Christakis (2002) in their study on how obesity had been portrayed in one US medical textbook during the 20th Century, for example, showed how individuals had been held progressively less responsible for their condition as obesity became more medicalised over this time period. They also acknowledged, however — as highlighted above — that 'The subjection of a behaviour or condition to a medical conceptualisation has been associated with both an increased and a decreased attribution of individual responsibility' (Chang and Christakis, 2002: 165). This issue is not just of academic interest, because the extent to which an individual is blamed for having a particular condition can have very real consequences in terms of how they are dealt with by medical professionals and/or wider society (Wikler, 1987). Paradoxically, medicalisation has the potential to lead to both the apportioning of blame and its alleviation, and that this is largely dependent on circumstances.

In the case of the metabolic syndrome, a condition that has been described as an example of the 'medicalisation of obesity' (Breitstein, 2004: 8), the concept focuses on the individual and his or her 'lifestyle', with the main treatments also based around changing this. From this perspective, it is hard for medical professionals not to see blame as being anything other than an individualised issue. In addition, the 'more inclusive' versions of the concept (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Despres et al, 2001; Grundy et al, 2005; Alberti et al, 2006, 2009) are likely to make the individual appear more blameworthy, due to their emphasis on 'obesity' and its role in the condition.

For Conrad, conditions such as the metabolic syndrome (and in particular its later 'more inclusive' versions with their greater emphasis on prevention and the role of obesity) are not an example of medicalisation, but rather 'healthicization' (surveillance medicine), which he described as 'when social or behavioural activities are deemed medical risks for well-established biomedical conditions' (Conrad, 1992: 223). In

outlining the differences, he argued that 'With medicalisation, medical definitions and treatments are offered for previous social problems or natural events' but that 'with healthicization, behavioural and social definitions are advanced for previously biomedically defined events (eg heart disease)' (1992: 223) and that 'One [*medicalisation*] turns the moral into the medical, the other [*healthicisation*] turns health into the moral' (Conrad, 1992: 223).

Other researchers such as Clarke et al do not make this distinction. In discussing the closely-related concept of 'biomedicalisation', they suggested that one of the key features of this was 'a new focus on health and risk and surveillance biomedicines' (Clarke et al, 2003: 161 and 166). They saw 'healthicization' as being part of biomedicalisation rather than as a separate process. In explaining the issue further, they noted that 'The extension of medical jurisdiction over health itself (in addition to illness, disease, and injury) and the commodification of health are fundamental to biomedicalization' and that 'health itself and the proper management of chronic illnesses are becoming individual moral responsibilities to be fulfilled through improved access to knowledge, self-surveillance, prevention, risk assessment, the treatment of risk, and the consumption of appropriate self-help / biomedical goods and services' (Clarke et al, 2003: 162). In the context of biomedicalisation, they argued that both 'health' and 'chronic illness' are increasingly being seen as the moral responsibility of the individual.

Clarke and colleagues also identified a paradox in the biomedicalisation theory that was similar to the one found in relation to medicalisation, which was that:

Health is thus paradoxically both more biomedicalized through such processes as surveillance, screening and routine measurements of health indicators done in the home, and seemingly less medicalized as the key site of responsibility shifts from the professional physician/provider to include collaboration with or reliance upon the individual patient/user/consumer.

(Clarke et al, 2003: 173)

If this is correct, the later 'more inclusive' versions of the metabolic syndrome concept should more accurately be described as an example of the (bio)medicalisation of obesity

and/or lifestyle, where the responsibility for the condition rests more with the individual. In constructing these versions of the concept, the medical professionals are not only medicalising obesity, but they are also influencing the apportioning of blame by constructing the concept as a (bio)medical condition, where the onus is on the individual to take responsibility for his or her health and any related ailments, a situation that raises ethical concerns in relation to justice (fairness) if, as has been shown, an individuals 'lifestyle' is not entirely in his or her control. From this perspective, the later 'more inclusive' definitions or the metabolic syndrome are likely to be more ethically problematic (than the earlier 'IR-concepts' such as syndrome X, WHO, and IRS) in terms of apportioning blame due to their greater emphasis on obesity: a 'condition' that has in the past been, and in many instances continues to be, seen as a problem that is predominantly the fault of the individual, by both the medical profession and society at large (Chang and Christakis, 2002; Boero, 2007).

Fairness concerns over intervention and duty to participate

In portraying the identification and treatment/prevention of the metabolic syndrome and its related concepts as being both a private and public good, the experts were also using this as a way of ethically justifying their intervention in individuals' lives. In a statement outlining the IDF consensus worldwide definition of the metabolic syndrome published in 2006, the authors neatly summarised many of the justifications given in a single paragraph, when they stated that:

With the metabolic syndrome driving the twin global epidemics of type 2 diabetes and CVD there is an overwhelming moral, medical and economic imperative to identify those individuals with metabolic syndrome early, so that lifestyle interventions and treatment may prevent the development of diabetes and/or cardiovascular disease.

(IDF, 2006: 8)

Here the IDF experts claim that 'there is an overwhelming moral, medical and economic imperative' in making use of the metabolic syndrome (IDF version) diagnosis. This approach echoes what de Vries described in her paper on the 'obesity epidemic' when she noted that 'the medicalisation of a condition that is socially undesirable, such as obesity, has historically proven to be a very successful strategy for the legitimisation of intervention' (de Vries, 2007: 56).

The ADA and AHA also used the moral argument of trying to 'prevent harm' in a joint statement on the issue of heart disease and diabetes, where they justified the identification of the metabolic syndrome (as interpreted by the WHO, ATP-III and IDF definitions) by arguing that 'The growing prevalence of this condition threatens to undermine all of our recent gains to prevent and control chronic disease' (Eckel et al, 2006: 2944). Here the medical professionals used the spectre of potential set backs in medicine's perceived progress 'to prevent and control chronic disease' as justification for their intervention in individuals' lives, in trying to tackle the metabolic syndrome concept.

This raises a number of ethical concerns, many of which relate to fairness. For example, by focusing so heavily on the perceived benefits of 'lifestyle interventions' (IDF, 2006), the experts behind the various concepts could be seen as promoting the idea that individuals have a duty to accept such treatments. However, this is potentially problematic if the risks (such as increased anxiety) to the individual are uncertain, along with the benefits (such as improvements in health) of treatment, yet they are required to make significant changes to their lives.

A similar concern was also highlighted by Verweij in his publication on 'medicalisation as a moral problem for preventive medicine', where he discussed 'the obligation to participate in prevention' and suggested that it could 'be justified as well in cases of persons in specific roles in which they have a crucial responsibility to care for the well-being of other persons or animals' where he highlighted 'roles such as parent, employer, farmer, and — in some cases — employee' (Verweij, 1999: 108).

In relation to the metabolic syndrome, the later 'more inclusive' versions of the concept — the hypertriglyceridaemic waist (Despres et al, 2001), and the ATP-III (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001) and IDF (Alberti et al, 2006) definitions — are also more likely to raise concerns over the promotion of this idea (that individuals have a moral duty to accept such treatments), than the earlier 'IR-based concepts' due to their greater emphasis on obesity and its prevention through therapeutic lifestyle change. This is because portraying the 'condition' as obesity-centred and largely preventable (through changes in lifestyle)

puts the onus back on the individual who, due to their culpability, may feel that it is his or her duty to make changes to his or her lifestyle. In contrast, the issue of blame is more ambiguous in relation to the earlier concepts — such as syndrome X (Reaven, 1988) and the WHO (Alberti and Zimmet, 1999) definition — because they focused more on the role of IR, which is regarded as being effected by both genetic and environmental factors (behavioural/lifestyle). As conceptually the situation is different, individuals cannot be entirely blamed for having the 'condition' here, because while their behaviour may be modifiable, the genetic component is fixed and beyond their control.

Fairness and the issue of who benefits from the metabolic syndrome

Another ethical concern that is related to justice (fairness) is the issue of who has benefited from the various metabolic syndrome concepts created? From an ethical perspective, this raises fairness concerns in regard to those groups who have been affected by the condition, but who have benefited least from the creation of the concept. During my analysis of the medical/scientific literature, I identified three groups who potentially benefited most from the construction of the various metabolic syndrome concepts. These were physicians/scientists, patients, and the pharmaceutical industry ('Big Pharma'). If the creation of a particular concept appears to favour one group over the other two, however, then this potentially raises fairness issues. Although these concerns were highlighted in the medical/scientific literature, they were only briefly mentioned in a small number of publications, with the majority of the discussion taking place in the professional and lay media. With the data currently available it has not been possible to draw any significant conclusions about which group has benefited most from the creation of the concept. Instead, in this section I will be exploring the different ways in which the groups have benefited, and the ethical concerns that these have raised.

A concept primarily created for and by Big Pharma?

Was the metabolic syndrome and its related concepts primarily created for the benefit of the pharmaceutical industry? One of the strongest critiques of the concept is 'that the syndrome is simply the industry's effort to medicalize obesity' (Breitstein, 2004: 8). This concern was also raised in an article in *USA Today* on the update of the ATP-III definition in 2005 and related controversy, in which the

reporter claimed that 'The debate has left many doctors grappling with a bigger question: When does a diagnosis genuinely describe an illness and when does it simply give pharmaceutical companies a bigger market?' (Sternberg, 2005b: 4). This appeared to be confirmed when Decision Resources, a market prediction company, published a report in 2004 that claimed that the 'Metabolic syndrome drug market (was) to increase to nearly $13 billion by 2013' (Decision Resources Inc, 2004).

Grundy, a key proponent of the ATP-III concept, was dismissive of this idea in a review article from 2006, where he wrote that 'It is curious that one criticism levelled against the Metabolic Syndrome concept [*as described by the ATP-III definition*] is that the pharmaceutical industry has tried to take advantage of it to promote or develop new drugs' (Grundy, 2006a: 1097). He also argued that 'New drug development need not detract from the priority given to lifestyle modification' (2006a: 1097). Here Grundy sees the involvement of Big Pharma as evidence of them following rather than leading the charge to develop different versions of the metabolic syndrome concept. This is the same conclusion I came to following my sociological analysis of the construction of the metabolic syndrome, where it was clear that physicians/scientists (such as Grundy) with the backing of particular medical professional organisations (such as the AHA and NHLBI) were the main players in the medicalisation process (that had led to the development of 'new' versions), rather than the pharmaceutical industry. In addition, the fact that all the main versions of the concept (Reaven, 1988; Kaplan, 1989; Alberti and Zimmet, 1998; Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Despres et al, 2001; Einhorn et al, 2003; Grundy et al, 2005; Alberti et al, 2006, 2009) backed therapeutic lifestyle change as the primary treatment may be another indicator of the medical profession's influence over the process rather than Big Pharma.

Commentators have also highlighted other barriers to the development of drugs for the metabolic syndrome and its various versions. For example, Rouhi in an article on the metabolic syndrome concept in *Chemical and Engineering News* from 2004 claimed that 'Because of its complexity, this set of disorders teems with opportunities for drug development, but regulatory criteria for therapeutic outcomes are still lacking' (Rouhi, 2004: 83). Grundy also highlighted this issue in a later review article on the concept, where he noted that 'regulatory agencies are unlikely to allow registration for new

targets in the cardiovascular field without clinical end-point trials' (2006a: 1097). In addition, Jeremy Quirk (a cardiovascular analyst for Decision Resources) was quoted in a *Pharmaceutical Executive* article as saying that 'Physicians are saying "Show me the evidence". Because without it, why would physicians prescribe massively expensive drugs to a patient who appears healthy, when they can just tell them to exercise three times a week?' (Breitstein, 2004: 8). Again the fact that the 'IR-centred' and 'obesity-centred' versions of the metabolic syndrome concept all favour the use of therapeutic lifestyle change over drug-based approaches as the primary treatment suggests that these concerns may be justified.

Not everyone shares this view, however. Critics of the metabolic syndrome concept (as defined by the WHO, ATP-III and the IDF), such as Reaven, believe that the pharmaceutical industry has been indirectly driving the construction of the various versions, and is the most likely to benefit. During my interview with him in September 2005, for example, he suggested that 'I'm sure a lot of the emphasis on trying to get a definition has been in order to make drug companies happy so they can say their drug works for this entity' (Reaven transcript, 2005: 7). This criticism has been widely used as a way to undermine the concept. Despite this, my sociological analysis suggests the opposite, with the evidence showing that the medical profession has been the primary mover behind the concept while the pharmaceutical industry has sat on the sidelines. If the metabolic syndrome and its various versions were primarily created for the benefit of Big Pharma, this would certainly raise ethical concerns over the fairness of labelling individuals as having a 'genuine' medical condition when this may not be true. There is currently little evidence to support this hypothesis.

A concept primarily created for physicians/scientists?

Was the metabolic syndrome and its related concepts primarily created for the benefit of physicians/scientists? This is certainly the conclusion drawn from comments attributed to Grundy (the key player behind the ATP-III definition) that appeared in the US medical journal *JAMA*, where he was quoted that 'the emergence of the term [*metabolic syndrome as envisaged by the ATP-II]* primarily came about to remind physicians not to dismiss patients with vague suggestions to exercise more and weigh less' (Mitka, 2004: 2062). In relation to the ATP-III (2001) definition, Grundy was further quoted as saying that the 'inclusion of metabolic syndrome into the document

was done primarily to highlight physician responsibility' (Mitka, 2004: 2062). Other commentators suggest that it was the creation of the ICD-code and concept for 'dysmetabolic syndrome X' in 2001 that was the catalyst for getting physicians and the pharmaceutical industry interested in the topic. For example, Yehuda Handelsman (co-chair of the International Committee for Insulin Resistance) was quoted in *Pharmaceutical Executive* as saying 'Nothing helped metabolic syndrome more than the establishment of the ICD-9 code' (Breitstein, 2004: 4). In the same article, the author also concluded that 'In a world in which a condition isn't really a disease until it becomes part of physicians' paperwork, metabolic syndrome had crossed an important threshold' (2004:3). This suggests that in medicalising the condition, through the creation of the ICD-code and later attempts to institutionalise it through the ATP-III (Grundy et al, 2001) and IDF (Alberti et al, 2006) definitions, the medical experts were attempting to expand their professional disciplinary domain to include this issue. This benefited them because their skills would be in greater demand, with the potential for more clinical and research work, and the possibility of further personal and financial gain. However, it is less clear how this would help 'patients' and potentially raises fairness concerns, if labelling individuals as having the 'condition' does not offer them any real benefit. Although diagnosing an individual with the metabolic syndrome does at least give him or her access to treatment/preventative approaches that he or she had previously not had access to, but whether this is an advantage depends on how effective such approaches really are.

Another closely-related issue is that in insurance-based healthcare schemes such as the one in the United States, the codes are also important for funding. Referring to the metabolic syndrome concept, for example, Lehrman noted that 'Many physicians may not realise that a couple of ICD-9 codes now relate to the syndrome so they can bill for treatment' (2004: 3). Critics such as Reaven have also highlighted the issue when questioning the motivation behind the concept. For example, in an article in *Forbes* from 2004 Revan was quoted as saying that 'The metabolic syndrome thing [*WHO and ATP-III versions*] is very appealing to a lot of physicians, because if you have a diagnostic category you can begin billing for it' (Herper, 2004: 1).

If the metabolic syndrome and its related concepts were primarily created for the benefit of physicians and scientists, this would again lead to questions about whether the

condition was ‘genuine’, and raise ethical concerns that individuals were being labelled as having a medical condition more as an aid to medical professionals than the patients themselves. This is a difficult issue because the same concerns could be raised for any condition that medicine has defined as a ‘disease’, and without being able to identify (diagnose) the problem the medical profession is able to offer only limited help. In the case of the metabolic syndrome, the issue is whether the creation of the different concepts has been an aid or hindrance to the delivery of effective help for individuals with, or at risk of developing, the various problems that are associated with the condition. This is a debate that shows no signs of ending in the medical/scientific literature on the concept (Meigs, 2003; Alberti and Zimmet, 2008; Gale, 2008). My analysis of the metabolic syndrome, however, showed that the uncertainty and confusion around the various versions of the concept has had an impact on the way in which the condition is seen by medical professionals, and this has the potential to impact on patient care. From a patient perspective, the various versions of the metabolic syndrome do raise ethical concerns, particularly in relation to what benefits they bring and whether they have the potential ‘to do good’.

A concept primarily created for the benefit of the ‘at risk’?

Was the metabolic syndrome concept primarily created for the benefit of individuals ‘at risk’ of developing diabetes and/or heart disease? This is certainly the view that the professional claims-makers behind all the documents proclaiming the benefits of identifying the concept would like readers to believe (see Alberti and Zimmet, 2008).

Exponents of the metabolic syndrome (as defined by the ATP-III and IDF) such as Grundy, for example, claim that ‘One advantage of identifying this particular cluster of risk factors is that it should bring together the fields of cardiovascular disease and diabetes for a concerted and unified effort to reduce risk for both conditions simultaneously’ (Grundy, 2006a: 1093). In other words, making it easier for the medical professionals to work together to tackle the condition, therefore improving patient care. Others such as Alberti and Zimmet in defending the approach stated that ‘We believe the syndrome has clinical value’ and in reference to the IDF’s 2005 definition argued that ‘in the “real world” of primary care, this definition helps identify people at high risk without the need for sophisticated technology’ (2008: 641).

One of the main ethical arguments put forward in support of the metabolic syndrome by medical professionals who back the concept is that irrespective of the uncertainties and disagreements over the particular diagnostic definitions, patients still benefit by renewed interest in the area. This is particularly the case if this leads to more resources being brought to bear on the issue — in terms of medical professionals, research funding and drug development — and results in improved health. Consequently, the creation of the metabolic syndrome and its various versions would still be ethically justifiable in patient terms, even if they were created for the primary benefit of another group, because patients benefit indirectly. The ends would therefore justify the means. However, this does not alter the fact that both the 'less inclusive' and 'more inclusive' versions of the concept raise many other ethical concerns, particularly in relation to the issue of autonomy and therapeutic lifestyle change, and the potential to do harm (due to some diagnostic criteria being too strict and potentially missing individuals 'at risk'), while others are too inclusive (meaning that potentially 'healthy' individuals were given unnecessary treatments).

Section 5: value-judgements and prejudice

In addition to the ethical concerns over responsibility and 'victim-blaming' in relation to the metabolic syndrome and its related concepts, another problem that was not widely discussed in the medical/scientific literature, but which I identified during my analysis of the data, relates to the issue of value-judgements and the prejudice that often surround so-called 'lifestyle conditions', such as obesity and the metabolic syndrome. For example, Gard and Wright in their book on obesity argued that 'the obesity epidemic can be seen as a complex pot-pourri of science, morality and ideological assumptions about people and their lives' (2005: 3). They further noted that 'The simplification and misreading of the evidence about human body size reinforces our cultural prejudices about the sinfulness of being fat' (2005:106). In another example, Shickle conducted a study that analysed NHS public surveys and found that there was 'a willingness to discriminate against those patients who were *partially responsible* for their illness due to choice of 'unhealthy' lifestyle (eg smoking cigarettes, drinking excess alcohol)' (Shickle, 1997: 277). In addition, Bowman and Spicer highlighted how it was often hard for physicians to remain objective and morally neutral, particularly in

relation ‘to what extent patients actions contribute to their condition’ and that it was often difficult not to ‘blame patients for their actions’ (2007: 41–47).

In regard to the medical/scientific literature on the metabolic syndrome and its related concepts, there is certainly evidence that some of the language used is value-laden, with frequent references to individuals needing to rectify their ‘bad’ behaviour. For example, Ford et al in their 2002 paper on the incidence of metabolic syndrome (as defined by the ATP-III) in the US suggested that ‘the root causes of the metabolic syndrome for the overwhelming majority of patients are *improper* nutrition and *inadequate* physical activity’ (Ford et al, 2002: 359). In another example, the authors of a joint ADA/AHA statement that discussed the advantage of identifying ‘cardiometabolic risk factors’ (where all the main versions of the metabolic syndrome concept were referred to) that was published in 2006, stated that ‘It must be remembered that obesity is far more than an *unattractive* appearance but can be prevented’ (Eckel et al, 2006: 2944).

It is widely recognised that individuals defined as being ‘overweight’ and/or ‘obese’ experience more prejudice and stigma in society than those defined as being of ‘normal’ weight (Laslett and Warren, 1975; Schur, 1987; Chang and Christakis, 2002; Gard and Wright, 2005; Jutel, 2006; Monaghan, 2007). The fact that the numerous metabolic syndrome constructs are inextricably linked to obesity, either directly through the later ‘obesity-centred’ versions (such as the hypertriglyceridaemic waist, ATP-III and IDF definitions), or indirectly through the early ‘IR concepts’ that still recognised obesity as an issue (such as syndrome X, the IRS (DeFronzo and Ferrannini, 1991; Haffner et al, 1992) and WHO (Alberti and Zimmet, 1998) definitions), means that individuals defined as having the condition are also potentially open to similar levels of criticism. If individuals have experienced prejudice in relation to their weight, however, this is likely to have occurred prior to and not because of the diagnosis (of the metabolic syndrome) due to the visible nature of the condition. Yet during one of my interviews with a UK obesity specialist in 2005, he stated that they had renamed the obesity clinic a metabolic syndrome clinic, because the latter condition was less stigmatising for his patients (Hartland interview transcript, 2005). The situation is complex, and with the data available it is difficult to assess whether the metabolic syndrome and its related concepts add to or reduce the levels of stigma surrounding obesity. A further example of this apparent moralising, however, can be seen in an article published in the popular

science magazine *New Scientist* on 'Rimonabant', a drug created by the French pharmaceutical company Sanofi-Aventis that is designed to tackle the metabolic syndrome (as defined by Despres et al, 2001). This drug was described as being a 'vice buster' and 'a pill that helps see off your flab and kick your *bad* habits' (Martindale, 2005: cover and 46) and Sanofi-Aventis press release (2006). The term 'vice' is described as being 'an evil or wicked action, habit, etc' (*Collins English Dictionary*, 1985: 943). In another example, an article on the metabolic syndrome (using IDF definition) published in the *Sydney Morning Herald* in April 2005 entitled 'Our fat future: death by beer gut' again implies a level of personal blame and is moralistic (Maley, 2005). It is also surely no coincidence that the ancient concept of the 'seven deadly sins', which includes the vices of 'sloth' and 'gluttony', matches perfectly with modern physicians mantra 'to exercise more and weigh less' (Schwartz, 2000:125 and 149; Mitka, 2004:2062).

Even though the number of texts that used this type of language was small, this still shows that there are individuals within the medical/scientific community and the lay media who regard the metabolic syndrome concept as being a 'vicious' condition. The documents highlighted here referred to the hypertriglyceridaemic waist, ATP-III and IDF versions, and the metabolic syndrome concept in general (Ford et al, 2002; Maley, 2005; Martindale, 2005; Eckel et al, 2006). It is possible, however, that the later 'more inclusive' versions of the concept (such as the ATP-III and IDF definitions) are viewed as more 'vice-like' because of their greater focus on obesity, which has historically been seen as a moral failing. This has the potential to cause 'harm' because if the professionals view the metabolic syndrome in these terms, they are also more likely to view 'diagnosed' individuals in a negative way, which could lead to poorer treatment and lack of compassion. Further ethical concerns are raised here in relation to fairness, if individuals are being labelled as having the 'condition' and then blamed, particularly when it is possible for one individual to have IR without being overweight, while another can be overweight and not have IR. This example highlights the uncertainty surrounding the aetiology of the concept. There is also the question of to what extent an individual should be held responsible for his or her weight when 'social factors' that are often beyond his or her control (such as social inequality) play such an important role.

Chapter summary

In this chapter I showed how the metabolic syndrome and its various versions have raised a number of ethical concerns. Some of these have been discussed in the medical/scientific literature surrounding the condition, while others were either not mentioned at all or were only briefly discussed. I also highlighted how a number of the concerns were raised in documents outside the professional domain, such as in newspaper articles in the lay media. Methodologically, I used the 'four principles approach' (Beauchamp and Childress 2001) from bioethics as an analytical tool through which to explore the wide range of issues here, in addition to making use of the medicalisation concept from sociology, and particularly its consequences, as a means of highlighting a number of further ethical concerns, in a similar way to the approach used by Verweij in his 1999 publication.

I explored the ethical issues raised by the creation of the metabolic syndrome and its related concepts, which were discussed in terms of the four key principles of respect for autonomy ('freedom of choice'), beneficence ('do good'), non-maleficence ('do no harm'), and equity (fairness/justice) (Beauchamp and Childress and 2001[1979]). I showed how the ethical discussion predominantly centred on the principles of 'doing good' and 'doing no harm' in the medical/scientific literature on the concept. Here the positives of the concepts were discussed in both private and public terms, and were related to the potential to improve health, increase awareness, and reduce the disease burden; while the possible harm related to the risks associated with over- and under-diagnosis, and the uncertainty around the treatment options, were analysed. The concerns around over-diagnosis, particularly in relation to the later 'more inclusive' definitions of the concept, (such as Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Grundy et al, 2005, Despres et al 2001, Alberti et al 2006, 2009), centre on the potential for causing unnecessary harm to individuals by labelling them with a 'condition' that they may not even have, the increased anxiety they may experience due to concerns about their health, and the potential harm caused by unnecessary treatments. In contrast, the potential harms related to under-diagnosis, particularly in relation to the earlier 'less inclusive' definitions (such as Reaven 1988, Haffner et al 1992, Alberti and Zimmet 1999, Balkau and Charles 1999), concerned the possibility that individuals that may have benefited

from treatment could miss out because they did not meet the particular diagnostic criteria being used to identify the condition.

In addition, ethical concerns over the potential loss of autonomy, and the issue of fairness in relation to responsibility and blame for the condition, were explored, as were further concerns over who has benefited most from the creation of the various concepts. (such as Reaven 1988, Kaplan 1989, Alberti and Zimmet 1998, Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001; Grundy et al, 2005; Despres et al 2001, Einhorn et al 2003, Alberti et al 2006 and 2009). The first concern related to whether being diagnosed with the condition and then being offered therapeutic lifestyle change treatments represented a loss of autonomy, which I have shown is potentially possible. The second concern related to the issue of responsibility and blame, where I have provided evidence that through medicalisation individuals are unfairly blamed for having the condition, particularly when the evidence for 'social factors' (such as stress and inequality) is equally important (Brunner et al 2002, Chandola et al 2006). The third concern related to the issue of for who benefitted from the various metabolic syndrome concepts constructed, where I suggest that if one group appears to benefit more than the others, then this raises fairness concerns regarding the other two.

In the final section, I explored additional ethical concerns in regard to the issue of 'values' and their role in shaping the various concepts. Here I showed how 'victim-blaming' is sometimes accompanied by value-judgements and prejudice towards those diagnosed with the condition.

Chapter 8

Summary

Introduction

In the thesis I used a multidisciplinary approach, drawing on analytical methods from the social sciences and bioethics to explore the emergence of the medical concept known as syndrome X/metabolic syndrome. I have divided the key findings from my analysis of the metabolic syndrome into three main areas:

- In the first section I will be discussing the conclusions that can be draw from my sociological analysis of the concept with particular emphasis on the issue of medicalization
- In the second section I will concentrate on the ethical analysis and the conclusions that can be drawn from this, in relation to the potential impact of the creation of the metabolic syndrome concept
- In the third section I will discuss the multidisciplinary approach that I used, and whether this has any implications for future studies wanting to engage with the academic fields of sociology and bioethics.

I finish the chapter with a discussion on the potential for future research on the metabolic syndrome concept.

Sociological analysis: key findings

The findings of my sociological analysis of the key academic debates on the metabolic syndrome showed that there had been significant disagreement in relation to the definitional and aetiological claims around the concept and that social factors, such as the technical and professional interests of the individual claims-makers and organisations behind them, were largely responsible for these differences. This, in turn, led to the creation of a number of different constructs of the metabolic syndrome.

In relation to the issue of medicalisation, my analysis of the emergence of the different constructs showed that the process had originally centred on insulin resistance but that in later versions of the concept obesity had been given more of a central role. Metabolic

syndrome therefore can be seen as another example of continuing efforts to medicalise obesity. This has had implications for the diagnosis of the condition, with later definitions concentrating more on obesity, particularly central obesity, as being a key diagnostic feature. This process has also influenced the treatment strategies, with significant emphasis on therapeutic lifestyle change, which involves persuading individuals to change their lifestyle in terms of diet, weight loss and increased exercise; another example of medical expansion into lifestyle and private life. The later construction of the metabolic syndrome concept as 'controversial', however, showed that there was significant resistance to the obesity hypothesis, which suggests that the medicalisation process had only been partially successful here.

The most important finding from my research relates to the issue of who the main drivers were behind this medicalisation. In the introduction to my thesis I highlighted how some critics claimed that the metabolic syndrome concept was simply an example of the medicalisation of obesity by the pharmaceutical industry (Breitstein, 2004; Gardner, 2006). Other commentators, in contrast, argued that the construction of the metabolic syndrome had also been driven by medical professional organisations (Buse quoted in Breitstein, 2004).

The first hypothesis that metabolic syndrome is a creation of Big Pharma also appears to confirm what theorists such as Conrad and others have been arguing for a number of years, which is that 'the engines of medicalisation have proliferated and are now more driven by commercial and market interests than by professional claims-makers' and that 'the availability and promotion of new pharmaceutical and potential genetic treatments are increasing drivers for new medical categories' (Conrad, 2005: 10-11). This sentiment was echoed by Clarke et al when discussing their related biomedicalisation theory, in which they argued that 'technoscientific innovations', such as drug development, were one of the main drivers behind the process (Clarke et al, 2003: 161). The authors also highlighted that one of the consequences of this was the creation of 'new individual and collective identities', where they used syndrome X sufferers as an example.

The empirical evidence from my study contradicts this more recent interpretation of the medicalisation hypothesis. Instead, it suggests that the construction of the metabolic

syndrome concept was driven by traditional concerns and interests, namely 'the medical profession, interprofessional or organisational contests' (Conrad, 2005: 10). The process began with the creation of the original metabolic syndrome definition by the WHO in 1998/9, which was then later constructed into the ATP-III definition by the NHLBI/AHA in 2001. In addition, other closely related concepts were created by the EGIR in 1999 and in 2002. Yet another definition was constructed by the IDF in 2005.

These definitions resulted in a complex mix of rivalries and alliances being formed at both the professional/disciplinary and organisational level, with cardiologists (such as Robert Eckel and Scott Grundy) and diabetes specialists (such as Gerald Reaven, Richard Kahn, George Alberti and Paul Zimmet), as well as their respective expert groups such as the ACE, ADA, AHA, NHLBI and IDF, all being involved. This further contributed to the construction of a number of different versions of the metabolic syndrome, which resulted in a controversy developing over the knowledge claims surrounding the concept.

Returning to the issue of medicalisation, I am not claiming that the pharmaceutical industry has had no influence on the construction of the metabolic syndrome concept, because that would be incorrect. For example, some of the events where the definition was discussed were supported by grants from pharmaceutical companies, and one company did launch a drug in 2006 that it claimed could treat the metabolic syndrome (IDF, 2006; Sanofi-Aventis, 2006). However, when compared to the work put in by medical organisations such as the AHA and IDF, the pharmaceutical industry has only played a minor role, with the process leading to the creation of numerous constructs all shaped for the benefit of the different professional groups involved. The controversy surrounding the 'obesity' constructs and incomplete medicalisation of obesity hindered the construction of the metabolic syndrome into a public health problem, and also meant that obesity had not been medicalised in the way that the pharmaceutical industry had envisaged.

The 'commercialisation hypothesis' put forward by Clarke et al (2003) and Conrad (2005) regarding the direction of medicalisation is therefore not supported by the case study of the metabolic syndrome. This raises concerns over the claims made by these researchers in relation to how medicalisation appears to be evolving. This is especially

true for Clarke et al's biomedicalisation hypothesis, where they actually referred to syndrome X sufferers as an example of the type of condition being created by this new process (Clarke et al, 2003: 162). If their theory does not even hold true for a 'condition' created within the highly-commercialised US healthcare sector, this does not bode well for its applicability elsewhere. I do, however, agree with Conrad's assessment of the biomedicalisation concept, which is that it is now too wide ranging and has lost its analytical focus (Conrad, 2005).

I am less critical of Conrad's 2005 approach, because he does at least acknowledge that 'Doctors are still gatekeepers for medical treatment' and that 'the definitional centre of medicalisation remains constant' ('professional claims-makers') (Conrad, 2005: 10). His argument that medicalisation is 'now more driven by commercial and market interests', however, is a step too far. In regard to the metabolic syndrome, the medical profession, through disciplinary rivalries, has been the main driver behind the medicalisation of this concept, while the pharmaceutical industry has remained largely on the sidelines. Researchers looking to explore other newly-created conditions should not, therefore, start from the assumption that all medicalisation is driven by the pharmaceutical industry but treat each case individually.

My work here shows the potential value of returning to a more limited and restricted definition of medicalisation that is more in line with Conrad's earlier interpretations of the concept (Conrad, 1975, 1992; Conrad and Schneider, 1980).

Another way of interpreting my analysis of the construction of the Metabolic Syndrome is to see it as supporting earlier STS research that drew on the ideas of 'boundary work' (Gieryn 1983 and 1995). This approach was developed by Gieryn, where he argued that science conducts 'boundary work' to distance itself from non-science and noted that 'Thus, 'science' is no single thing: its boundaries are drawn and redrawn in flexible, historically changing and sometimes ambiguous ways' (1983:781). This also highlights the type of work that groups or disciplines put in to maintain control over an area.

In regard to the Metabolic Syndrome, medical professionals from different disciplinary backgrounds have been trying to legitimise particular claims as medical knowledge,

while de-legitimising claims from rival disciplines, which would be defined as disciplinary boundary work. Diagnostic classification can also be understood as a form of 'boundary work' (Gieryn 1983), since the aim is to 'maintain the boundaries' between social groups, in order for them to keep control of their area of interest, which in the case of medicine is health and disease. The documents and interviews analysed in my study contain numerous examples of experts trying to discredit rival claims and / or promote their own hypotheses, many of which can be viewed as 'boundary work' (Gieryn 1983). For example, Reaven in his paper entitled 'Metabolic Syndrome: Rest in peace', argued that 'Perhaps the most crucial issue is that the diagnostic criteria for the Metabolic Syndrome (*ATP-III definition*) did not result from a prospective study and do not represent the outcome of an evidence-based process, but are a reflection of the best estimates of a panel of 'experts'' (2005a:932). Here the 'boundary work' involves an attempt to undermine the credibility of the concept by claiming that there is a lack of scientific evidence for the diagnostic criteria, as well as the expertise of those involved by the judicious use of quotation marks on the word 'experts'.

Rival claims-makers have also been involved in 'boundary work', with for example Grundy et al claiming that 'In the absence of compelling scientific reasons for change, the AHA and NHLBI affirm the overall utility and validity of the ATP III criteria and propose that they continue to be used with minor modifications and clarifications' (Grundy et al 2005:2735). Here proponents of the ATP-III concept are engaging in 'boundary work' by claiming that this should 'continue to be used' because there was an 'absence of compelling scientific reasons for change' (Grundy et al 2005). Consequently, there is significant scope for exploring the construction of the Metabolic Syndrome concept in the future, using 'boundary work' as the main analytical approach.

Ethical analysis: key findings

In my ethical analysis of the metabolic syndrome, I was able to show that the construction of the concept raised a number of ethical issues, including those related to the potential to do harm as well as good, along with further concerns in relation to the issue of respect for autonomy and justice. Here I showed that the 'goods' were

discussed in both private and public terms, and related to the potential to improve health, increase awareness, and reduce the disease burden; while the 'harms' related to the risks associated with 'over- and under-diagnosis', and the uncertainty around the treatment options. The concerns around 'over-diagnosis' related to the potential for causing harm by labelling individuals with a 'condition' that they may not have, as well as the anxiety associated with increased concerns over their health, and potential harm caused by unnecessary treatments. The potential harms of 'under-diagnosis' related to the possibility that individuals could miss out on treatment because they did not meet the diagnostic criteria.

I also showed that while some of these ethical issues were identified in the medical/scientific literature on the topic, others remained unmentioned but were raised in documents outside the professional domain, such as in newspaper articles in the lay media. Therefore one of the key findings from my work was that while physicians and scientists were often good at identifying certain ethical concerns, such as the potential to do good and/or harm, they remained blind to other issues of ethical importance, such as the loss of autonomy, and justice concerns in relation to responsibility for the condition. This again confirms the value of disciplines such as sociology and bioethics in being able to highlight issues that may not have been obvious to or purposively ignored by those closely involved with a topic. Although my sociological analysis of the metabolic syndrome identified a number of concerns regarding the construction of the concept, my ethical analysis added to this by giving me a further insight into the topic, and enabled me to identify a number of additional concerns, particularly in relation to the issues of autonomy and justice.

As my ethical discussion was influenced by what I had learnt during my sociological analysis of the construction of the concept, this also shows the advantages of using more than one approach to gain a different perspective on a topic. My earlier research, for example, highlighted the uncertainty and contestation over the knowledge claims surrounding the concept, which raised ethical concerns in regard to the potential harm and fairness of labelling individuals with an uncertain medical diagnosis. This situation was made more ethically problematic by holding individuals responsible for their 'condition', and then expecting them to make substantial changes to their lifestyle based on scientific evidence that was highly contested.

My analysis highlighted how the interests of professional medical organisations were often the main priority in the creation of the various diagnostic definitions, as demonstrated by the continual references to the need for the development of simple criteria for use in the clinical setting in the medical/scientific literature. This issue raises ethical concerns in relation to fairness, and who has benefited from the construction of the various definitions.

In the analysis I showed how the concept of medicalisation and its potential consequences was a useful tool in exploring ethical concerns surrounding the concept, particularly regarding the issue of individualisation. This was an approach that Verweij (1999) used to great effect in his publication on the ethical concerns surrounding 'preventive medicine'. My analysis in particular highlighted how medicalisation could be used as both a means to apportion blame and absolve individuals of responsibility for having a condition, and that this was largely dependent on the context, which again raises ethical concerns in regard to fairness. For example, the early constructs of the metabolic syndrome concept concentrated on the role of insulin resistance, which the experts suggested could be influenced by a number of factors, such as genetics, biochemistry and lifestyle. Therefore although the role of diet and exercise was highlighted, it was only one of a number of potential risk factors that were discussed in relation to the concept. The later medical constructs concentrated more on obesity and lifestyle in relation to the aetiology of the condition, therefore making it much easier to blame the individual.

Another key finding from my ethical analysis was that there was a substantial amount of scientific data from epidemiologists on the relationship between metabolic syndrome and social inequality that appeared to have been largely ignored by the wider medical and scientific literature. This raised ethical concerns in regard to the fairness of downgrading social factors, such as social structure, as the causal explanation for the 'condition' by medical/scientific experts in the field, who tended to focus on the role of 'lifestyle', with the inevitable result that blame was centred on the individual rather than society.

Multidisciplinary approach: implications for sociology and bioethics

Talk of greater cooperation between the disciplines of sociology and bioethics has been discussed for a number of years, particularly with regard to using social research within bioethics and the adoption of more interdisciplinary and integrated approaches (Hoffmaster, 1992; Zussman, 2000; Haimes, 2002; Hedgecoe, 2004; Borry et al, 2005). Although this may seem straightforward on paper, in reality it has proved much harder to develop truly integrated approaches, with a number of significant obstacles being identified. When this has been achieved it often gives researchers the opportunity to explore an issue in much greater depth than would be possible if the research had been carried out from a single perspective. Achieving this, however, requires a high level of expertise in both disciplines. In view of the potential pitfalls and complexity of such a methodology, I therefore decided to use a multidisciplinary approach for my thesis (Evans and Martin, 2006). This is where a topic is studied from separate disciplinary perspectives and the conclusions drawn relate to each particular field; no attempt is made at integrating the approaches. This is more commonly seen in the context of much larger projects, where teams of investigators from different fields are brought together to study a particular area of interest where their disciplinary perspectives can then be brought to bear on the issue. This approach has the advantage that a topic can be explored from numerous angles without having to worry about trying to integrate the various methodologies. There is nothing to stop such an approach being used on a smaller scale, with one researcher using two separate disciplinary approaches to explore an issue and then putting the research findings next to each other in a single thesis. This was the approach that I used in my study of the metabolic syndrome concept, where I placed the social and bioethical analyses side by side within the same thesis. Again, this had the advantage that I was able to explore the concept from two different disciplinary perspectives and gain a deeper understanding of the topic without getting distracted by the complexities of interdisciplinary research.

Although my sociological analysis influenced my ethical discussion by providing background information on the metabolic syndrome, as well as helping me to identify the different ethical arguments used in support of and against the concept, the main focus of the research was in understanding how the condition was being constructed, a social rather than bioethical question. The distinction between the two areas can,

however, become blurred. For example when I was exploring the issue of medicalisation, which is seen as a sociological concept, the research highlighted both social and ethical concerns. My social research data therefore helped to inform rather than dictate the direction of my ethical analysis, with the theoretical and methodological boundaries between the two disciplines remaining intact. In this sense, my approach is more akin to Levitt's view of the role of social empirical research in bioethics, which she saw as one of 'complementarity rather than integration' (Levitt, 2004: 81).

Future work

Although the modern concept of the metabolic syndrome has now been around for 25 years, the field is still evolving and the knowledge claims surrounding this 'new' condition remain highly contested. One potential area for future research will therefore be to see how the concept evolves and whether the controversy surrounding it continues, is finally resolved, or just slowly peters out.

Another key area for future research relates to the issue of medicalisation, and whether the medical profession remains the driving force in the construction of the metabolic syndrome concept. If this is the case, the metabolic syndrome concept will continue to support the earlier interpretations of the medicalisation hypothesis that placed medicine at the centre of the process. Or it may be the case that the pharmaceutical industry starts to take a more active role, and the metabolic syndrome begins to resemble the type of 'condition' described in later versions of the medicalisation hypothesis (Clarke et al, 2003; Conrad, 2005), which see the commercial sector and its interests as being the main driving force behind the process.

A final area for future research relates to how patients and the lay public view the metabolic syndrome concept. Currently their voices are entirely lost among the medical/scientific discourse on the topic. Gaining a better understanding of their perspective would help complete the picture of the construction of the concept, and fill in some of the gaps with regard to the wider controversy surrounding the condition.

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