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# The Impact of National Systems of Innovation on Therapeutic Cloning: A Comparison between the UK and China in the Clinical Area of Diabetes

# November 2008

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# **Content Page**

	<b>3</b>	Page
	Abstract	4
Chapter One	Introduction and Context	_
	Introduction and Aims	6
	The Business Problem:  Health	8
	Diabetes	10
	Research Innovation	16
	Intellectual Property	20
	Stem Cell Research	22
	Ethics	33
	Summary	35
Chapter Two	Literature and Conceptual Development	
	Innovation	39
	Innovation Theory	48
	Innovation Structure	56
	National Systems of Innovation Innovation in the UK and China	57 65
	Politics of Innovation	70
	Summary	82
Chapter Three	Methodology	
	Introduction	84
	Justification: Policy Rationale	84
	Theoretical approach to Research	87
	Research Design	89 93
	Data Capture Statistical Analysis of Data	95 96
	Limits of the Research	97
	Part One:	
	Questionnaire	99
	Summary of Responses	106
	Part Two: Economic Analysis	109
	Introduction	109
	Preliminary Analysis	111
	Innovation and Diabetes	115
	Innovation in China Innovation in the UK	117
	Comparing the UK and China	117
	Economics of Innovation	123
	Summary	125
	•	

Part Three: Research Interviews

### DBA Final November 2008

	Introduction Investment Strategies Legislation Regulation Diabetes Societal Acceptance Summary	125 127 130 131 133 134 136
Chapter Four	Discussion Introduction Research Design Qualitative Analysis strengths & weaknesses Strengths and Weaknesses of NSI Economic Analysis 1990-2002 Strengths and Weaknesses of NSI Part Two Summary Conclusion	141 143 146 147 149 156 161 166 169
Chapter Five	Summary and Conclusions Review Policy Implications Future Work Strengths and Weakness of Work Reflection on Learning Contribution to Knowledge and Learning Conclusion	174 173 180 182 183 184 185 186
Bibliography		187
Appendices	<ul> <li>A: Questionnaire</li> <li>B: Pilot Questionnaire Analysis</li> <li>C: Questionnaire Analysis</li> <li>D: Graphs</li> <li>E: Correlation</li> <li>G: Normality Analysis</li> <li>H: Normality Plots</li> <li>I: Multiple Regression Analysis</li> <li>J: Stem Cell Companies</li> <li>K: List of People Interviewed</li> </ul>	201 205 210 237 239 244 245 248 251 267

### **Abstract**

Since the discovery of genetic inheritance by Mendel (1890) and the identified role of DNA in cell division (Crick/Watson 1950), scientists have worked to advance stem cell technologies to treat and cure human disease. The broad techniques of therapeutic cloning are gene therapy, stem cells growth and pharmacogenetics together constitute a complex and demanding science. Each involves the alternating and growth of new cells including the use of human embryos undifferentiated cells and a potential to grow into any organ and tissue type.

This work explores the national context in which stem cell science is advancing in a case study between the UK and China using National Systems of Innovation (NSI) as a theoretical structure. NSI is defined by the literature, which includes economic performance, political and legislative structure, research investment, and societal values (Freeman 1997; Fagerberg 2004). Using ethnographic and statistical analysis, it compares the effect each National System of Innovation is having on the advance of therapeutic cloning. Diabetes is chosen as the clinical model because of its global prevalence, affecting over 200m people (BHF 2004) and accounting for 9% of mortality (WHO 2002). and the prediction that it will become the world's most major non-communicable cause of death by 2025 (Atlas 2004).

During this study, China experienced unprecedented economic growth underpinned by strong research investment, which is now three times the size of that in the UK (Wilsden 2006). It has a permissive social culture for stem cell research (Mann 2003), having adapted much of the European legislation (Salter 2007) with much of its research led by doctors, enabling a quicker advance of stem cell therapies to the clinic (Prescott). The

### **DBA Final November 2008**

UK is, in comparison, a global leader in stem cell science, having a prestigious record of achievements including the final mapping of the human genome (Goodfellow 2001), the cloning of Dolly the Sheep (PHGU 2002), and being first to legislate for such embryo research (HFA 1990). The UK's economic performance is also strong during this study, but well behind that of China, and neither does it enjoy the relaxed ethical stance of the Chinese structure. This is evidenced in its research investment, which has fallen as a proportion of GDP from 2.24 in 1990 to 1.78 in 2005 (National Statistics 2007), whereas China has increased from 0.7 to 1.31 (Wilsdon 2006).

There is evidence in the literature of the importance of innovation to economic growth (OECDa 2004) and the relationship of this to GDP performance. This research explores the impact the National System of Innovation is having on the advance of stem cell research in the UK and China, using diabetes as a clinical model.

# DBA Chapter One Introduction and Context

### Introduction and Aims

The research question is 'how will therapeutic cloning be influenced by the respective National Systems of Innovation (NSI) in China and the United Kingdom, using diabetes as a model?' The hypothesis is that NSI in China and the UK will determine the pace of translating stem cells into a clinical service – the null hypothesis being that the innovation systems of the UK and China will not adversely impact the advance of stem cell technologies. These technologies cover a range of processes, of which therapeutic cloning is one, involving the use of adult or embryo cells. The approach is a case study using the construction and comparison of the two National Innovation Systems to establish how stem cell research is progressing. The National System is constructed from the literature and taken to cover the economic, political, social, and research systems as they relate to stem cell science. National Systems of Innovation is the theoretical base used as a framework to explore the relative strengths and weaknesses within the UK and China. The clinical area of diabetic stem cell research is used as a model for comparison. Although other clinical areas are more advanced (most notably cancer), diabetes is chosen because of its major contribution to human morbidity and mortality and the prediction that it will become the world's most significant noncommunicable disease (WHO 2002).

The comparison between the UK and China is taken from a UK perspective and chosen for a number of reasons. China is claimed to have a vast history of innovation, including claims of cloning a fish 37 years before 'Dolly the Sheep' and synthesising human insulin before its discovery in the late 1980's in Canada (Poo 2004). In addition,

the UK and China had a similar GDP by 2002, enabling easy economic comparison with China in research investment and spending on education and international trade. China has also adopted UK/European legislation and regulation for stem cell research (Salter 2007) and published literature to advance their strategic objectives (Wilsden 2006). These create a permissive climate for stem cell research and a new partnership with the West that has become more apparent during the time of this research. Through the collection of evidence from within the UK, this study takes a UK perspective of China and offers an opinion from that vantage point.

The United States might be considered a more natural comparison for the UK due to its evidential lead in the biotechnological market (Brown 2003 Zimmern/Cook 2000 PH Genetics 2001) and its historic policy influence in the UK. Its consumer-driven health market is also said to mean it is more likely to experience the impact of advances in genetic science ahead of the UK (Zimmern/Cook 2000). It is, however, like several Western economies, struggling with the ethical dilemmas of stem cell science. This struggle is due, in part, to the country's deeply religious orientation and the fundamental challenge to the creation of human life that therapeutic cloning elicits. Such concern has distinguished the research status of embryonic therapeutic cloning in the US from all others, resulting in the prohibition by federal law of the use of public research funds. Indeed, it has been interesting to observe over the period of this research the number of strategic alliances US scientists have formed with those working in China, as well as the UK's intention to extend these alliances (BBC 2008b).

China experiences no such dilemma. Indeed, its ethical culture proactively promotes the scientific advance of stem cell technologies in permitting both human embryo and

primate research (Mann 2003 Yank 2004). In this way, China and the UK share similar motives to advance therapeutic cloning, very similar legislative and regulatory structures, and a similarly permissive scientific environment, albeit with social differences.

These will be explored in more detail in this research, but first it is helpful to understand the business problem that stem cell technology seeks to address. This problem includes issues such as population health status, diabetes research innovation, research structure, and ethics. The business problem has a number of themes arising from these, including the medical and economic costs of treating people with diabetes and the untold costs of human suffering.

### The Business Problem: Health

The underlying business problem is faced by every global government as they seek to maximise health spend with the health status of their population. Health spend is a major consumer of GDP for all Countries, with the UK spending 7.7% in 2003 compared to 5.8% in China. Public expenditure was 82.2% of total spend in the UK for the same year and 33.7% in China. In the United States, where health care is almost entirely privately funded and market-driven, it has achieved some of the highest survival rates for common diseases, arguably related to access to new drugs and technologies up to five years ahead of other countries, including the UK (Dyer 2003). They spent a greater proportion of GDP on health (13.3%) than the UK in 2003. In contrast, the UK has a predominately public-based system, which is revered across the world (Williams 1997). It operates an artificial market using containment strategies to ration and control access to services and new technologies (WHO 1998 Raftery 2001). The result of these systems is that the UK lags behind most of its international competitors in the

introduction of new health technologies (Wray 2004) and has correspondingly higher morbidity rates associated with common diseases such as heart disease, cancers and diabetes (Wanless 2002; WHO 2002).

China, in contrast, moved away from public-funded health care in the late 1980's in favour of a market-managed system with serious inequality and health consequences (Watts 2004). Whilst morbidity data is not available, its non-communicable disease profile is similar to the UK in areas such as diabetes, heart disease and some cancers. It is at variance, however, in terms of a number of communicable diseases such as Tuberculosis and HIV/Aids. In addition, it has high levels of suicides, liver and stomach cancers, respiratory disease and accidents (Jin et al 1995; Beach 2001; Riley 2004). Access to and use of health technologies is also considerably different in China, being partly due to China's economic motivations being orientated towards export rather than domestic use. The main conclusion to draw here is that the prioritisation of treatment in China is not comparable with that of the UK (Fuller 1985 WHO 2002). These issues will be explored more closely in Chapter Two..

These differences are evidenced in average life span, which is 76 for men and 82 for woman in the UK compared to 70 and 73 in China. These figures mask morbidity, which is said to be 17 years on average in the UK (Acheson Report 1997) and undefined in China. The economic consequence of premature morbidity for diabetes is estimated to be up to five times more than its direct treatment costs (WHO 2002). Although China's treatment costs are about 20% of the UK's due to limited access to treatment, the health costs associated with treating diabetes in China in 2003 was £840,500,000 (4,100,000 people were treated at an average cost of £205 per person) compared to

**DBA Final November 2008** 

£2,720,695,692 in the UK. These are, however, only estimates as no accurate data exists.

The distinction in funding stream is important as it is said to influence access to care, health status, and how new health technologies are introduced. This, in turn, has a fundamental impact on how new technologies are developed and their entry managed within the health market of each country. Stem cell research is a new technology defined largely in the research field, but affording untold potential to revolutionise treatment and health outcomes. This is of major interest to all governments because of its associated economic and social opportunity, although it will potentially bring into question the way new services become available to a population.

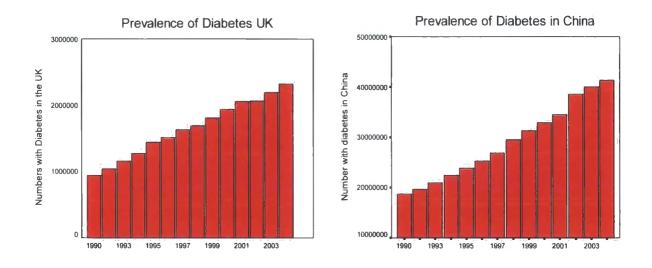
The business problem facing both the Chinese and UK health markets is therefore twofold. The first issue is how to afford the treatment costs and economic loss associated with the forecast prevalence of diabetes (Atlas 2004). The second issue is how to compete in the international arena of genetic science to lead in making the research discoveries that afford the potential to revolutionise the treatment solution for diabetes and enable the associated economic and scientific status. To understand these implications it is necessary to explore the history of diabetes, its treatment and its relationship to therapeutic cloning.

### The Business Problem: Diabetes

Diabetes is a metabolic disorder of multiple actiology characterised by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, action or both (Alberti et al 1998). It currently affects an

estimated 200 million people, or 4.6% of the total world population, making it the most common non-communicative disease in the world (Marks 1996; Gatsby 2002; BHF 2004). It affects all parts of the body and causes other conditions (most notably heart, renal and limb failures), with up to 80% of diabetics dying from heart disease or strokes (Fuller 1985). In virtually every developed society, diabetes is ranked amongst the leading causes of blindness, renal failure and lower limb amputation, and it is allied with huge socio-economic costs resulting from premature morbidity and mortality (Diabetes Atlas 2004). An estimated 339,035 people below the age of 65 died in the UK in 2000 from diabetes, accounting for 757,096 years of life lost (Barcela et al 2003). It accounts currently for 9% of total mortality and is projected to be one of the world's leading causes of death by 2025 (WHO 2002).

The disease is defined in two categories: type 1 being the early onset of the disease, usually occurring in children and young adults. Type 1 diabetes involves the complete failure of the pancreas to secrete insulin, and individuals with this type require insulin replacement therapy to survive. People with this form of the disease in the UK will, on average, die twenty years early (DoH 2001). In China these figures are higher, with many people dying within five years of diagnosis as treatment is limited to diet and homeopathic remedies (Reed 2000).



Type 2 (or late onset) diabetes is more common, accounting for 90% of diabetes cases, and involves deterioration in pancreatic function. It is treated by dietary change with oral medication for some. People with this type of the disease in the UK lose an average of ten years of life (Wanless 2003). In the UK diabetes accounts for 10% of all hospital expenditure, equating to 1.1 million bed days (Diabetes UK 2006). The data does not make a distinction between types 1 and 2, although costs and complications are more likely to be associated with type 1. The prevalence of diabetes has increased rapidly since the early 1990's, and it has more than doubled between 1960 and 1980 (Gadsby 2002). The UK has experienced a 60% increase up to 1996, accounting at this time for just fewer than 2% in 1995 (Marks 1996) with current levels reported to be 3.9% of the total population (Diabetes UK 2003).

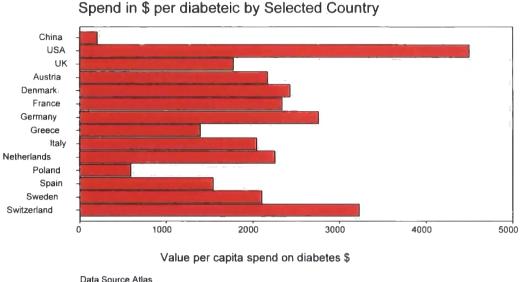
China has also experienced major increases in diabetes, with 2.5% of their population affected by 1985, illustrating a three-fold increase over ten years (Pan et al 1997). Other heavily affected countries include India, the United States, Indonesia, Japan, Pakistan, Russia, Brazil, Italy and Bangladesh. In the United States in 1989, 10.4 million people were diabetic with demographic prediction estimating this to increase to 29 million (Boyle

et al 2001). The number of people affected worldwide is projected to double by 2010 to over 221 million (Gadsby 2002). This is variable across the world and across regions, with projections of an increase of 111% in Asia, 93% in Africa, 82% in Latin America, 51% in and 35% in North America. (Gadsby 2002). The World Health Organisation estimated that 333 million people across the world will be living with diabetes by 2025. These rates of increase related largely to type 2 diabetes. Stem cell research, notably therapeutic cloning, has developed with a focus on insulin dependence where the greatest complications are seen. However a review in the British Medical Journal in 2001 of adult, animal, embryo and therapeutic cloning concluded that therapeutic cloning would be of significance to both type 1 and 2 diabetes (Serup et al 2001).

In the UK diabetes affects 2.4% of the population but consumes 8.4% of the total health resource (Marks 1996) with predictions taking this to 15% of the total heath resource by 2011 (Bagust et al 2002). This consists of £5m each day (DoH 2005) spent on ambulatory care, 37% on hospital admissions, 36% on oral agent therapy, 4% on insulin, and 20% on other drugs (Gadsby 2002). Each year 600 diabetic patients require renal replacement therapy (costing in excess of £70m), 1.5% have serious retinopathy problems, 3.3% have ulceration of their feet, 1% have limb amputation (costing £15m), and up to 3.2% are diagnosed with ischemic heart disease. Of all people who die from heart disease, 55% will be diabetic (BHF 2004).

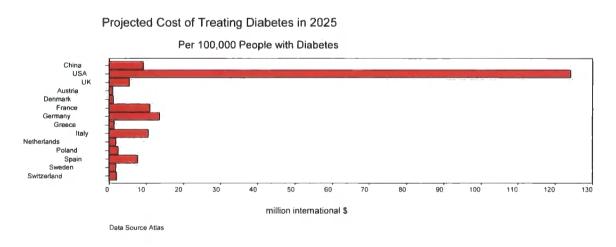
Internationally, costs vary from 2.5% to 15% of total health budgets depending on the types of intervention and the health budget available (WHO 2002). In India the cost accounts for 25% of a family's income whilst the corresponding figure in the US is between 10% and 16% of its entire hospital budget (WHO 2002). Comparative

spending varies enormously across the world, depending on many economic features of a country and the availability of treatment.



Data Source Atlas

Western therapies are becoming available in China with the Pharmaceutical Industry (for example, Nova Nordisk Biotechnological Company commenced the production of insulin in 2003). The international costs of treating people with diabetes if prevalence rates grow at the predicted level will be up to \$396bn (13% of international health expenditure) by 2025 (Atlas 2004).



Diabetes is an incurable disease with a relatively short treatment history. Prior to the discovery of insulin in 1921, people with type 1 (juvenile) diabetes died. Eli Lilly was first to purify insulin as a commercial product in 1923, but it wasn't until 1956 that products

for type 2 diabetes came on the market. Chinese scientists made this discovery earlier than Eli Lilly, but their discovery was neither recognised nor commercialised (Mann 2003).

By the 1960's the first human pancreas transplants were undertaken and, despite problems associated with anti-rejection drugs, the world's first successful human pancreas transplant was undertaken in 1966. Even today such transplants are restricted to seriously ill patients and still have significant associated morbidity (Robertson et al 2000). In 1977 the first Islet Cell Transplant was undertaken, involving the injection of cells into the liver that then create their own blood supply and stimulate the production of insulin. By the 1980's, the first human insulin using recombinant DNA technology was created, the world's first insulin pump was developed, and glucose monitoring equipment was introduced. In 1987 the first genetic marker relating to type 1 diabetes was discovered, and by 2000 mice had been successfully bred with gut cells that could produce insulin (DTT 2001). British Surgeon James Shapiro carried out the first Islet Cell

Transplantation in January 2001, and by the end of 2003 there had been over 10,300 pancreas transplants across the world, 35 of these in London. Results show a 64% cure at 7 days and 47% at one year. If more than 30,000 islets are transplanted, the success rate rises to 71% (Diabetes UK 2003). However, cells from two human pancreases are currently required, which makes therapeutic cloning the only hope most people living with diabetes have for a cure. Stem cell research is being undertaken in both type 1 and 2 diabetes, and some suggest that its use to treat type 2 has shown evidence that cells can be re-programmed to secrete insulin (Smikodub 2006; Medical

News 2006; Serup 2001). Some scientists also believe that stem cell science will offer the greatest impact to those with type 2 diabetes, who make up approximately 85% of all diabetics (WHO 2002).

Research to improve management of the disease continues alongside the development of implantable pumps with miniature computers, implantable glucose sensors, infrared light testing glucose, nasal transdermal, oral insulin and insulin analogues. In April 2004, Chromosome 17 was mapped, identifying the fourth gene of the estimated twenty associated with diabetes (Guo et al 2004; Smyth et al 2005) and the Life Sciences Department at Newcastle University obtained the first UK license to clone human embryos for stem cell research (Pincock 2004). By August, work to identify a neonatal test for diabetes found a gene variant that intensifies immune response causing type 1 diabetes SMUO4, which controls the production of cytokines. By the following summer, a scientist in Japan had successfully transplanted islet cells from a mother to her daughter, thereby curing her diabetes (Manning 05 Science Daily, 2005). The type of diabetes involved in this case was caused by an illness rather than the usual autoimmune attack, making a wider application of its technique less likely. Research carried out between American and Brazilian scientists published at the end of 2007 claimed to have cured diabetes using stem cells, but their trial focused on 15 people who had been diagnosed within the six weeks of the trial (Voltarelli 2007). Therapeutic cloning remains the only long-term hope of a general cure for diabetes – both types 1 and 2.

Following its rejection in 2003, the National Institute of Clinical Excellence approved pancreatic transplants in a small number of UK centres after initial results showed 52%

of people who had undergone transplants were insulin free after 4 years, with a reduction of hypoglycaemic episodes from 87% to 5% (NICE 2008).

### The Business Problem: Research Innovation

The importance of innovation to economic performance was recognised after the Second World War, although at this time it was interpreted simply as Research and Development (OECD 2004). Growth theory in the 1980's extended the definition to include those processes associated to R&D, which is now widely accepted in economic analysis (HM Treasury 2000). More recent thinking extends this concept to include the whole innovation system (OECDa 2005), including a range of factors from the conception of an idea through to the marketing of its related product and sales. These may be influenced by research investment, intellectual property structures, operational environment, workforce (OECD 2004dOECD 2005a) and knowledge flows between the public and private sectors McKeekin et al (2002). There is, however, no universal definition of the components of innovation but a shared agreement that its constitutional factors make the most important contributions to economic growth (OECDd 2004) (OECD 2005a).

Analysis by the European Commission evidences that whilst R&D investment remains central to economic performance, there has been an accumulative decline in Research and Development investment across Europe since 2002. The UK announced in 2002 its intention to reach 2.5% of GDP by 2010, which appears unlikely to be achieved. The significance of this is that Europe may lose its opportunity to become a leader in the global knowledge-based market economy (Potocnik 2005) and be a less attractive place to carry out research (EC 2005). China, in contrast, has seen a four-fold increase in real

spending, making it the second highest research investor in the world (Wilsdon 2006). There are a number of reasons for these concerns, which are broader than just research investment. China is claimed to have used gene therapy to cure solid cancerous tumours in humans (Pearson Jia and Kandachi 2004) and to have begun human trials using therapeutic cloning to cure leukaemia (Hepeng 2005). This has a real and serious consequence for the interface with science, which is still reported to be the greatest source of economic growth (EU 2005 OECDa 2004).

The biotechnological sector is argued to be the most important research area in leading innovation and economic growth (European Commission 2001 OECDa 2004). As such it is identified as a priority area of development for all governments (CEC 2002), with many economists seeking to design a model to capture the components incorporated in biotechnology innovation. One approach is the Instituted Economic Process and Complex Causality (Harvey 1999), building on Polyanyi's (1957) idea of instituted economic processes of supply, demand, competition, markets, exchanges and price being historically and socially driven. This model assumes market processes are framed by institutional structure, resulting in an institutional bias in the character, timing and adoption of innovation (Metcalf et al 2000). The basis of the argument as applied to biotechnological innovation is that competition within the research fields, as well as the organisational arrangements in which it operates, plays a part in economic growth. This has an interesting relationship to innovation theory in supporting the proposition that national dimensions can be stronger than the operational components, and it goes right to the heart of this research thesis, which seeks to explore these elements.

The United States has first-mover advantage in the biotechnology industry, securing high returns on its capital ventures and thereby attracting new industry (EC 2001). Evidence of this competitive advantage is seen in its co-location between companies, geographic specialisation and strong relationships with its universities and academic institutions. Europe, in contrast, is a late entrant with its markets largely defined by the US (ICC 2003). Its advantage is said to be specialist legislation, offset by limited access to venture capital, intellectual property and industrial development (OECD 2001). Other areas of weakness include an absence of integration between teaching and research institutions and an inflexibility of labour, which decreases knowledge flows (OECD 2001). In Europe 50% of existing biotech companies are located in the UK or Germany, and the highest integration between technology and application is between the UK and France (OECD 2000).

In the biotechnological sector, genetic science is distinguished by the magnitude of its potential to revolutionise the treatment and management of human disease (Dept of Energy Human Genome Programme 2003; Spink el at 2004). It offers the potential for personalised medication to create new therapies, to cure disease and, in time, to regrow or repair damaged organs. Genetic science also offers untold potential to expand the 479 known molecular targets against which all drugs in the world act (Zimmern 2001) and to understand the interaction with the 40% that are ineffective on an individual basis (Melzer 2003).

The pharmaceutical industry is an important component in biotechnology, providing major sources of investment and a pivotal role in influencing how genetic discoveries are translated into health care (Melzer et al 2003). The industry is responsible for

developing the majority of new drugs and tests and has strong economic drivers to produce personalised medicines in the form of pharmacogenetics (McCarthy 2001). In the UK the pharmaceutical sector produced exports of £11.9bn and imports of £8.3bn in 2003 (Customs and Exercise) making it one of the highest exporters within Europe and an important source of revenue for the UK.

In 2003 the average spend per head in the UK was £168 compared to £462 in the US (Office for National Statistics). Access to new medicines in the UK is tightly controlled by the National Institute of Clinical Excellence (NICE), leading to only 16% of new products entering the UK market compared to 50% in the US. In 2003 Medicines accounted for 11.8% (£8bn) of the total NHS spend, £277m of this being on diabetics (ABPI 2004). Drug development research in the area of diabetes almost tripled between 1995 and 2003 from 93 projects to 272, over 50 of which were stage 11 trials (Pharmaprojects 2003). Pfizer and Aventis have stage 111 projects; Lilly has projects at stage 11. Such innovations are potentially greater than anything seen previously and represent a major shift from historically incremental adaptations. Exceptions are said to be penicillin, anaesthetics and anti-psychotic medication (NEMJ 2000). Investment in research trials is influenced by the estimated return, which is itself influenced by the regulatory framework of intellectual property.

### The Business Problem: Intellectual Property

Intellectual Property Regulation (IPR) has an increasingly important role in the area of biotechnologies (OECDe 2004). The nature of patent rights allows owners to exclude others from making, using, selling, or importing the patented invention (Nottenburg 2003). The biotechnology industry relies heavily on such protection to secure the returns

needed to offset vast research costs and associated production costs. Patents underpin the licensing deals between the biotechnology and pharmaceutical companies and permit monopoly control over new tests and treatments - even those not yet discovered.

Patent registration is also vital in attracting venture capital, providing a proxy for knowledge flows and a potential measure of the impact of an invention (Brown 2003 OECD1 2005). Citation data is a vital proxy for technological and economic value, and an indication of knowledge flow between institutions (EC 2001). They also underpin the licensing deals across the biotech markets, offering unprecedented monopoly control over new tests and treatments. This has a profound affect on how money and power are distributed both in and between countries (Baird 1998 ICC 2003). The nature of IPR allows patent holders to exclude others from making, selling, or importing the invention (Nottenburg 2003), thereby creating monopoly providers and price control mechanisms (Giannakas 2002). The numbers of filed applications has increased by over 40% between 1992 and 2002 in Europe, Japan and America (OECDe 2004).

Despite this increase, over 85% of those relating to human genetics are owned in the US (Baird 1998).

Patents are awarded by nations where interpretation of the legislation can differ, with lax enforcement suggested by some to be a deliberate strategy of governments to increase their international competitiveness (Giannakas 2002). Certainly China, prior to joining the World Heath Organisation in 2002 was so accused. Consistency between international patent laws is important in providing certainty to research and industrial investment. The most notable example is, perhaps, Pfizer's attempt to uphold its patent for Viagra in China. Patents are awarded for only 7.5 years in China, against the

European standard of 20 years, thereby undermining the perceived advantage to an investor.

The European system of intellectual property evolved from consumer protection regulation and aims to separate the distinction between discovery and invention.

European law states: 'The Human Body, at the various stages of its formation and development is not patentable making a distinction between discovery and invention' (Is this actually a direct quote?) (Burham 1997). American law requires similar compliance, but the definition is open to interpretation, often by the courts. Intellectual property rights create monopoly providers and price control mechanisms that enable premiums to be charged in the market. Infringement increases the competitiveness of domestic producers who use new technology and place compliant foreign producers at a cost disadvantage.

In Europe the European Commission oversees the legal system of biotechnological invention across 25 Countries, providing a framework for consistency. Implementation in law is, however, an individual decision, but to date 21 of its member states have translated its recommendations to statute. The Commission recently reviewed the two most contentious issues surrounding the scope of IPR -- genetic sequences of human DNA, and the patentability of human pluripotent embryonic cells and cell lines taken from them (EC 2005). At this time no prescriptive direction has been given despite calls for consistency from the industry (Jenson 2005). Consistency in Europe is said to be imperative if it is to compete as a serious world player, but this requires countries with very different religions and cultures to align their ethical concerns about scientific advance and global inequalities. On a more basic level, it requires consensus about

what each country accepts as patentable and coherent regulation of their respective research sectors.

John Sulston (2002), Nobel Prize winner for the mapping of the human genome, believes this consistency should mean only actual products are eligible to be patented, leaving gene discovery available to all scientists (DNA 2003). The reality is somewhat different because most research is privately sourced (Phillips Dierker 2001), as evidenced in the agricultural sector where venture capitalists (Who are 'they'? Scientists?) wanted to secure a return on their investment (Graff 2003), a position supported by the European Commission (2001), who argues that reward is essential to stimulate investment. The charity, Cancer UK, established an important precedent in successfully reversing the patent registration by the US company Myraid for their predisposition breast cancer test BRCA 2 test in the UK in 2004 (PHGU 2004).

Whilst the area of patents in genetic science remains largely unresolved, it is relevant to this research as it may provide a deeper understanding its impact on current research investment in the UK and China.

### The Business Problem: Stem Cell Research

The science of genetics originates from the meticulous pea-breeding experiments of physicist Gregor Mendal in 1865. He discovered the constituent facts of biological inheritance, proving for the first time that characteristics are inherited in pairs of recessive and dominant alleles, one from each parent (Edelson 1999). Genetic science involves the study of biological information, its contribution to making an organism, and how this information is transmitted from one generation to another (Steward et al 2002).

Inheritance is enabled via the DNA, located mainly in the nucleus of the cell, being read by the cell and converted to RNA before transmission to those parts of the cell responsible for the creation of protein. A small amount is found outside the nucleus in the mitochondria, passed down the female line, and relates to the cell's metabolic function.

DNA is a linear molecule with a long backbone of sugar molecules joined by phosphate groups. A nucleotide base, which may be one of four types, joins the sugar molecules: A (adenine), G (Guanine), C (Cytosine) and T (Thymine), forming together to make the double helices along the sugar backbone as discovered by Frankin, Francis and Crick in 1950 (Fuller 2003). Information is coded in base pairs along 23 corresponding chromosomes, with one gene programming for one protein. Each gene contains regulatory instruction on when and where in the body the protein is to be created (Ridley 1999). Cells divide to duplicate their DNA by unwinding their helices and copying the sequence of bases to form two that split to create new duplicate cells.

Mendal's work was never published but ran concurrent to that of Charles Darwin who, unaware, presented his own hypothesis of inheritance, arguing it to be based on an underlying principle of survival of the fittest (Darwin/Griffiths 1998). In the century that followed, the knowledge emanating from these original discoveries translated into biotechnology, genetics and information research. The discovery of DNA in 1950 by Rosaline Franklin, James Watson and Francis Crick, led to the first stem cell processes in the 1960's. Technological advance has since enabled specific genes to be identified and mapped to human disease, for proteins to be isolated and for function and micro

array analysis to be used in sequence variations and structure. The resulting techniques fall into three broad areas of science: stem cells, gene therapy and pharmacogenetics.

Stem Cell research produced its first results in 1968, with the successful bone marrow transplants of adult stem cells in immunodeficient patients. Berg cloned the first gene in 1973 (Denoon 2004) and DNA was linked to specific genes five years later. By 1986, 20 genes known to suppress tumours had been cloned with stem cell transplants used to treat leukaemia and lymphoma in 1993. By 1997 the gene for telomerase enzyme had been cloned and shown to cure cancer in mice (Ricchetti and Buc 1997). In 1998 US scientists became the first to grow embryonic stem cells from human embryos (Shamblott 1998 Thompson 1998), leading to a number of advances in cell development. This culminated in 2005 with South Korean Scientists announcing the world's first stem cell match for an individual treatment (BBC 2005) and British Scientists announcing the creation of its first cloned human embryo (Lawless 2005). These advances were set back in 2005 when the South Korean claims were found to be fraudulent. While Professor Hwang faces a lengthy prison sentence, stem cell programmes around the world reel in the wake of shock and public concern (Faiola 2006 Williams 2006).

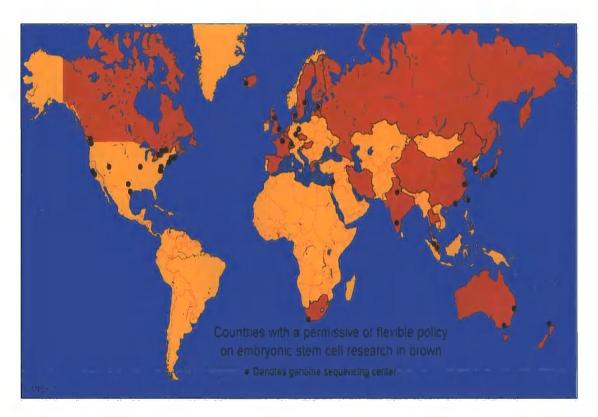
Gene therapy, in comparison, involves the specific targeting of stem cells to repair or replace non-functional genes. The discovery in 1970 that retroviruses can make DNA copies from RNA made gene therapy feasible. A molecular vector)usually a virus modified to carry human DNA) carries replacement genes to the repair site. When successful, it results in the re-growth of new tissue, but the mechanics of this process remain unclear. The application of this knowledge affords major technological advances

in its ability to manipulate DNA using enzymes isolated from bacteria and electrophoresis to cut it in specific places, enabling the copying or cloning and the insertion of DNA sequences into the cells of a host organism. The complication is convincing the host that this forms part of its own natural replication process, with this achieved by joining to a vector or piece of DNA with all the necessary coding. This technique is currently being researched in the areas of Parkinson's, Diabetes, Heart Disease and Cancer (Hardy 2001, Yechoor & Chan 2005, Spink & Geddes 2004 and Gottesman 2003).

The third area, Pharmocogenetics, is the stem cell science of personalised medicine. It offers the potential to engineer medication and intervention to gene type, affording individual and economic potential for that 20-40% of people for whom current medicines are ineffective (Ridley 1999). The technique involves identification of an individual's susceptibility to medicines from their genetic profile and creating a drug tailored to the molecular response. This pre-disposition testing is available for many monogenetic diseases, with 900 such tests available worldwide, 300 of which are in the UK NHS system (Watson 2003). One such example is Herceptin treatment for breast cancer where one out of four women are shown to have gene susceptibility (Dargie 2000).

Each area of stem cell research offers opportunities for human health since the 1902 discovery by Garrod that disease, or mutation in DNA sequences, can be inherited. At least 5.5% of the population will develop a genetic disease by the age of 25, rising to 60% during their lifetime (DoH 2003). This variation is accounted for by the polygenetic nature of inheritance and differing susceptibility to environmental influence (Zimmern 2001 BER 2004). Genetic science fits within the broader umbrella of biotechnology,

which, as illustrated in the map below, is dominated by the US. This is open to challenge (DoTI 2004 MRC 2006) with Singapore, South Korea and China all developing biotechnology industries with some of the best-equipped stem cell institutions in the world (DoTI 2004).



Examples in the Far East include Singapore, which has world-class research facilities and invests 2.2% of its GDP in research (DTI 2004). They have an integrated strategy between academic and commercial research and many business incentives, with stem cell research being made an explicit national priority. To date, Singapore has undertaken very little work on human embryos, and there is no evidence of outcome in the clinic setting (DTI 2004). South Korea has also established world-class laboratory facilities supported by a comprehensive government funding programme. They have produced some impressive results, being first to clone half-humanised pigs using somatic cell transfer for therapeutic cloning. Without the constraints of Western ethics, they have also been successful in cloning human embryos (DoTI 2004). They have,

however, suffered a set-back following fraudulent claims by Hwang Woo-suk (Faiola 2006).

China also recognises the importance of stem cell science to economic growth as evidenced in its increase in research investment from 0.7% of GDP in 1997 to 1.31% in 2003. It is on target to meet its 2010 goal of 2.2% GDP spent on research (EC 2005), having invested heavily in the related technology with a published strategic aim of becoming a dominant partner on the world stage (Hsiao 2004). It also has the largest number of university students in the world (Wu 1991), has a low cost science base, and has the second highest spend in the area of Research and Development (DoTI 2004 Wilsdon 2006). It enjoys substantial and long-term government support but its overriding success is in translating its science to clinical outcomes. Despite its historically low research investment, China is reported to have a prestigious history in innovation, having invented paper, printing, the magnetic compass and gunpowder (Temple 1972). They used iron and created tools 1000 years before the rest of the world, and some claim they cloned a fish some 37 years before the UK cloned 'Dolly the Sheep'. They are also said to have been first to synthesise human insulin (Poo 2004).

The historic problem in China is similar to that in the UK in failing to translate discovery to commercial product, but for very different reasons. China's history of conflict and closed economy created a lack of academic recognition, preventing the translation of their discoveries to commercial advantage. This was redressed by economic reforms in the early 1980's, which introduced an open market economy, international trade, and led to substantial GDP growth (Wang 1999). Internationalisation has been encouraged by a number of financial incentives, leading to an increasing trend of overseas investors

locating their research in China (OECD1 2005). It is an explicit strategic intention of China to become a world leader in biotechnology (Jing 2003 Mann 2003) and to be a front-runner in international science by 2010 (Cong et al 2006). Therapeutic cloning is an explicit goal, with China hoping to maximise its strategic advantage in this field from its relaxed ethical stance (Yank 2004), access to both primate and human research (Chien 2004), and correspondingly lower research costs.

China's historic global isolation brings an additional advantage for the Chinese people, since having bred largely within their own populations affords opportunities in researching genetic risk and biomarkers (Chien 2004 Yank 2004). Culture is at the heart of the most significant opportunity, with the Chinese having few moral objections to the use of embryos for research and therapeutic cloning (Yank 2004). Human life is considered broadly to begin at birth, not conception, with personhood achieved only concurrently to the ability to participate in society. To this way of thinking, the foetus is not recognised as human (Mann 2003).

Research into therapeutic cloning is a priority for the Chinese Ministry of Science (Dennis 2002 Depeng 2004), who has begun work in a number of disease areas including diabetes. The goal is economically based around international trade, since associated treatment costs are likely to be prohibitive for most Chinese people. It is claimed China has already achieved a number of successes in stem cell science (Ning 2005), including the world's first available gene therapy cure in 2004 for solid cancer tumours (Pearson, Jia & Kandachi 2004) and the treatment of Leukaemia in clinical trials in 2005, with explicit plans to extend this to diabetes (Hepeng 2005). For this goal to be attained China has a number of its own challenges to overcome. These include the

communication of their science, access to international specialisms (Yank 2004), investment in basic science (Hepeng 2002), and improvement to the quality of its published research (Wu 2004). In addition, it has a number of internal social and economic issues to address, most notably the failing of its health structure within its economic reform.

The UK, in contrast, has the most sophisticated legislative framework for stem cells but has not advanced to human research trials. Its research regulation requires an explicit operational understanding before such techniques can be considered. Although the UK is considered a late entrant to the field of biotechnologies, it is said to lead in both scientific advance and permissive legislation (DoH 2003). It has world-leading centres of excellence, including Neuroscience at Oxford, Cancer at Dundee, and Genomics at the Sanger Centre in Cambridge. It is responsible for the cloning of Dolly the sheep (the first animal of its kind) in 1997, and is said to have the best regulatory framework in the world (PHGU 2002). Offering extensive tax incentives, the UK has a cost-effective research environment and has been working in the field of genetics longer than any other country (Best 2005). It led the final mapping of the human genome (Goodfellow 2001), the computer technologies to read gene codes, and the development of haplotype mapping. It is said to be unique in Europe in having a high degree of organisational diversity across both government and non-profit research, leading to a disproportionately high share of main research breakthroughs (Brown 2003). It is responsible for 4.5% of the world's spend on science despite having only 1% of the population, produces 8% of the world science papers, accounts for 50% of all drugs under development (Guardian 2002), receives 9% of citations, and claims around 10% of internationally recognised science prizes (Dasgupta 1996).

The UK was the first country to legislate for human fertilisation techniques in establishing the Human Fertilisation and Embryology Act in 1991, creating the Human Fertilisation Embryology Authority in August 1991. It is said to have the most permissive legislation for embryonic stem cell research and to be responsible for setting up the world's first bio-bank to co-ordinate access to and use of genetic material across commerce and academia. In Europe there is said to be little comparative development, influenced in part by the September 02 announcement by the European Council of a one-year moratorium on embryonic stem cell research. This was superseded by guidelines allowing research on embryos created via IVF before June 2002 (Watson 2003).

Successively, the UK was the first country to licence therapeutic cloning at Newcastle University in August 2004 (Pincock 2004) and to create therapeutic cell clones (BBC 2005).

The main challenge facing the UK is the translation of its science to services. Of particular interest are the ethical and societal concerns (Knight 2004), comparatively low levels of research investment, and the length and cost of clinical trials (Dyres 2003). Research investment has fallen from 2.4% to 1.9% of GDP over the last twenty years, with the government contributing only 0.6% (EC 2005). This has reduced further to 1.76 in 2005 (National Statistics 2007). Indeed, government investment consistently underperformed in G7 countries between 1980 and 1999 (OECD 2001). This contrasts with the US, where research expenditure between 1997 and 2002 has increased by five times that of Europe (EC 2005). In 1980, eight out of ten new discoveries were in Europe, where now eight out of ten occur in the US. Innovation (as measured by patent registration, new product innovation or manufacturing turnover) is also low in the UK

when compared to Europe. This is in-spite of its permissive legislative framework and strong productive science base, which are said to attract foreign research and development. This weakness is suggested to arise from poor historic collaboration between commerce and universities (Dasgupta 1996).

The UK aims to redress these problems with a number of policy changes designed to improve them by stimulating partnerships across academia, health management and the private sector (DoH 2002; DTI 2002; DoH 2003). These include a statutory framework for the National Health Service to form Venture Companies (DoH 2002) in addition to a number of structural changes, such as the creation of Knowledge Parks linking commerce and universities. It set up the world's first bio-bank and has introduced new tax incentives to encourage research industries to locate their work in the UK (Graff 2003). But even with these advances, the Department of Trade and Industry (2004) has warned further policy initiatives will be required if the UK is to strengthen its research base.

The overriding challenge for both the UK and China remains therefore the translation of discovery into actual innovations in service. With a science market estimated to be worth 2,000bn Euros by 2010 (the pharmaceutical representing more than 25%) (Melzer 2003), there are significant economic incentives to produce results (McCarthy 2001 Feldman 2003). It is the pace at which both countries advance that is of interest in this research, with particular focus on understanding how their respective innovation structures influence this. A significant area to be overcome in advancing this is the management of the ethical issues as stem cell science ignites an ethical legacy of prejudice (Pinnick 2002), including concern about its potential to create weapons of

mass destruction (OECDc 2004). These concerns form a cultural climate for therapeutic cloning and dictate both the acceptance and timeframe of its associated research. In the UK, the Department of Health publicly promotes the opportunities of genetic science (DoH 2003), although the absence of any realistic service or timeline suggests the ethical concerns are still to be managed. China, in contrast, is comparatively free from these concerns – indeed, Chinese scientists are reported to have been creating therapeutic human clones since 1999 and attracting American and German scientists where such procedures are not currently permitted (Yank 2004). This absence of ethical objections is suggested to make China one of the leading nations in genetic innovation over the next decade (Dennis 2002l; Mann 2003; Jing 2003; Yank 2004).

### The Business Problem: Ethics of Stem Cell Research

Research in the UK shows public understanding and opinion of genetic technologies and their service implication to be poor. A survey carried out in Bio News found that around 75% of people asked about the cloning of embryos for medical research purposes were not aware this type of work was permitted (June 2003). A separate study undertaken by the Nuffield Council concerning the ethics of pharmacogentics obtained only 84 responses to 3000 questionnaires (Nuffield Council 2003). Aerni (2001) suggests this lack of understanding in the population is almost a pre-requisite to communication. Indeed, as Ridley (1999) points out, such inaction can be very significant in producing change exampled by IVF, which was never sanctioned by the public until Louise Brown was born. Ridley suggests therapeutic cloning may well happen, not because the majority approves of it but because only the minority act.

Whether people express a view or not, there are many implications arising from genetic science and its commercialisation. These include the communication and use of people's biological data, ownership of actual tissue, existing and future knowledge about an individual's and their family's health, and insusceptibility to treatments (particularly for some ethnic groups). Many argue that the public will expect certainty in all these areas before the potential advantages of genetic technologies are accepted (Vahakangas 2001). Others suggest scientific expertise and benefits must be weighed against public perception (Aerni 2001), whist others simply say the economic argument is so great that governments will act regardless of ethical concern (Vahakangas 2001). Yet the reality of the consumer voice in biotechnology has already been evidenced, as its scientific knowledge began to enter the agricultural industry in the 1990's.

The first genetically modified products entered the human food chain in 1994 (Phillips 2003), creating differential uncertainty across global markets. Despite huge economic potential, the uncertainty about the science in Europe, exacerbated by food scandals, led to distrust in the regulatory institutions (Aerni 2001). The significance of this was a new generation of trade restriction (Eugenio 2003) resulting in major changes in the pattern of World trade (Phillips 2003). The transferable lesson for health genetics is that 'regardless of science, if consumers decide not to accept a technology, the markets will adjust to different scenarios, to prohibition, market segmentation and product differentiation' (Eugenio 2003).

In addition to ethical concern, there maybe psychological reasons behind the resistance people have to genetic services. Human nature is said to be resistant to change in terms of lifestyle and value systems, particularly if these present a challenge to nature and life itself. Cognitive research demonstrates that risks are socially constructed, influenced by

media coverage, depend on trust in public and private institutions, are socially conveyed and individually accumulated. This makes the relationship between knowledge construction, its use and communication complex for governments to manage, with much opportunity for mistrust.

This mistrust, Aerni suggests, is directed at government, not science (2001). Psychology in the Western world regards trust as a prerequisite for social orientation. It is claimed that modern society trades off increasing complexity by transferring trust to the institution that takes responsibility for managing the complexity. The response to public concern therefore tends to be further regulation rather explanation, as evidenced in the agricultural industry (Eugenio 2003). Public perception and attitudes can thereby affect the economic and regulatory conditions under which an industry operates, can impact supply channels, the economics of production or product demand, and industrial technique. These concerns relate in part to 'subtle eugenic effect' of genetic commercialism, both in terms of its financial motive and the way drugs and therapies are controlled and prioritised (Caulfield 1998). Genetic predispositions will, for example, be different between ethnic groups, compounding ethnic division and inequalities. Perhaps of some comfort is the landmark agreement to cut costs of patented drugs and products to poor countries, offering some indication of how these difficult issues might in the future be managed (Fleck 2003).

Understanding public perception and opinions about therapeutic cloning is vital to the research question, as they represent some of the most significant differences in the National Innovation System between the UK and China.

# **Summary**

The business problem that underpins this research is two-fold.

The first is the economic and social challenge for both the UK and China in managing the major increase in the prevalence of both type 1 and type 2 diabetes and its associated morbidity and mortality. The drive to manage this change derives from its complexity, the cost of its treatment, and its predicted growth rates. The UK spends 7.7% of its GDP on health (2002) while the corresponding figure for China is 5.8%.

4.6% of the entire world population is already diabetic -- 3.9%, in the UK (Diabetes UK 2006) and 2.5% in China. The Chinese figure may be an underestimation but already represents a three-fold increase since 1990 (Pan et al 1997). The cost of treating diabetes is projected to consume 13% of the entire world spend on health by 2025 (Atlas 2004).

The business problem is in funding a cure to ameliorate the significant human and economic burden of a disease that consumes 15% of all health costs (and five times the value in social costs) (BHF 2004), plus the untold cost of human suffering. These include both type 1 and 2 diabetes, and research evidence shows embryonic stem cell research is being undertaken to find a cure (Smikodub 2006/Serup 2001).

The second area of the business problem arises from the unprecedented opportunity presented by stem cell research to cure diabetes and other human disabilities and disease. Therapeutic cloning is still at an early stage of development, although its research techniques have progressed to the use of human embryos, raising ethical and cultural concern that is very different in the UK and China. This is also important with respect to economic performance, as the literature shows clearly the link between them. In the UK there has seen a decline in research investment, reducing from 2.4% of GDP to only 1.9% (Dasgupta 1994). As a proportion of GDP, this has reduced further to 1.76% in 2005 (National Statistics 2007). Although the UK is said to be receptive to new ideas and accessing global knowledge, it is slow to translate these to commercial

**DBA Final November 2008** 

success (Dasgupta 1994). This is it problem the UK shares with China but for very different reasons.

This research will focus on these differences between the two National Innovation Systems. The aim is to compare the strengths and weaknesses in China and the UK and consider how these, in turn, influence the development of stem cell research in the area of diabetes. The innovation system is taken to cover the political, legal, societal and economic factors and will be explored in detail in Chapter Two. This will cover the literature on innovation theory and offer further insight into the organisation and practice within the UK and China. The softer aspects of innovation, such as structure and culture will be explored in addition to the respective backgrounds in stem cell science, including China's claims to having cloned a fish (Mann 2003) and finding cures for cancers (Thomas 2006).

Chapter Three will set out the methodological approach, covering the research design, data capture and analysis. After setting out the theoretical approach, it will explore three forms of analysis. The first form will be statistical analysis of economic data for both countries, showing the respective positions on research investment. The second and third approaches will be ethnographic, involving the collection of data from a survey with the general population and interviews with stem cell researchers in the UK and China. The public survey is UK-biased, as research in China was outside the scope of this study, with its validity justified within the methodology. In a detailed account, it describes the process of using data to compare progress in stem cell science between the UK and China from three distinct forms that enable a complete comparison of the innovation

factors. At the time of design it was a new approach, but a similar study has since been initiated at Anglia University (Salter 2006).

Chapter Four discusses the approach to exploring the National Systems of Innovation for the UK and China and interprets the findings from the data. Drawing together the comparison from the three distinct approaches, it interprets the results and sets out a direction for measure and interpretation. Chapter Five concludes the review of how therapeutic cloning is being influenced by the National System of Innovation in the UK and China and sets out the policy implications of these. With two distinct cultures and histories, this work will review those aspects of the innovation system that are complimenting advances in stem cell technologies and identify policy considerations that arise from these.

The Thesis will explore the business implications surrounding stem cell research and the impact its National Systems has on its advance. This study will take its place in the innovations literature in the field of clinical innovation, representing a new approach in the use of National Systems of Innovation. Its focus is on the development phase of innovation, which is the central part of the cycle covering invention, the generation of ideas, risk assessment and design. The invention phase is where stem cell science currently exists (aside from a small number of treatments using adult stem cells, such as bone marrow transplants). This focus on the invention phase of stem cell science is justified by its position in discovery within the innovation cycle. It will build on the work of Freeman (1997) in making a comparison between the systems of two Countries and the work of Edquist (1997) in understanding the importance of economic performance.

# DBA – Chapter Two Literature and Conceptual Development

# Innovation

Many researchers have sought to define innovation but there is no single definitive approach. According to Shackle (1979). Innovation is the 'imagined deemed possible', a by-product of invention, or an amalgamation of process from invention to practice (Tidd et al 2001). Klien and Rosebury (1986) suggested it is simply a characterisation of the problem to be solved. Schumpeter (1934) classified innovation by comparing it to an existing technology, suggesting that it could be defined in categories including product, methods, supply, markets and business organisation. He developed a Marx-Schumpeter model, which argues that long run economic performance relies more on technological competition under capitalism than the influence of the firm or the traditional supply and demand model (Tidd 2001). In making these propositions, he sought to define innovation and identify its key characteristics. These he identified as the tendency for innovations to cluster in certain industries and time periods highlighting the importance of co-dependencies in success (Tidd et al 2001). He also identified uncertainty to be inherent in innovation (for example, a need to move guickly before someone else does), and he interestingly outlined the resistance to change from all levels of society (Tidd 2001).

Schumpeter's work was significant in establishing both the importance of innovation to economic performance and in identifying some key features to its success. He classified innovation into five categories or stages, including new products, method, supply sources, market exploitation and business organisation. Many of these remain true today, offering valuable insights for this research topic in areas such as competition,

securing innovative solutions, and the role of culture and societal values in shaping permissible legislation. Schumpeter's model of innovation, although important in establishing the role of innovation in economic performance, was found in practice to be too simplistic, often leading to a difference between actual and projected growth, the gap becoming known as 'Slowo (is this meant to be Slowo or Slow?) Residual'. However, his approach formed an important foundation for others including Nelson and Winters (1982), who built on his work by introducing behaviour of and within organisations into the innovation process. They argued that firms are guided by routine that becomes practice, in turn being influenced by outcomes in a feedback system that leads to improvement. This they termed innovation or technological change, which they suggested was more significant than radical innovation in delivering improvements to economic performance.

Following the Second World War, the political climate favoured an emphasis of innovation in economic performance but focused only on an unsophisticated model of research and development investment (Freeman 1997). Growth theory followed as evidence of the impact innovation has on economic success increased throughout the 1960's (Freeman 1997). Over time the components of innovation were deconstructed. Hollander used one example (1965) in identifying the impact workforce was having on economic performance, most notably in its diffusion. Nelson and Winters' (1982) work introduced organisational behaviour and interactions into the innovation process, broadening further the factors said to be incorporated (Freeman 1997; Tidd 2001). By the 1980's, new growth theory had been introduced, describing innovation as a process and systems of networks rather than the more traditional labour and capital. One of the most notable features of this broader identification was the recognition of the

contribution of knowledge to productivity and efficiency (Plummer 2004). New Growth

Theory opened up the debate on the constitution of innovation and introduced
recognition of some of the less tangible contributions, such as knowledge accumulation.

From the literature it is clear that the innovation system refers to an entire process including creativity and research of new ideas, studies to evaluate cost effectiveness and risk, design and development, marketing, and the introduction of new products (Branscomb 2002). The innovation cycle starts with the identification of an opportunity before clarifying objectives, researching the background, assessing feasibility and risk, designing and developing, creating the policy environment, and completing the ultimate stage of design and implementation. This cycle, simplistically described, covers creation, development and diffusion. This view is based on evidence accumulated from Europe, America and Japan which showed productivity to be influenced by more than traditional assumptions of research and development. In particular, the impact on performance by people involved in the implementation of change had started to become apparent, most notably amongst engineers, technicians and shop floor workers (Hollander 1965). At the same time, the relationships between firms began to show an influence on productivity and the diffusion of innovation (Freeman 1997). It is apparent, as these studies show; the focus of these was predominately industrial, with little or no focus on the service sector.

This exclusion of the service sector is partly due to the varying nature between service and manufacturing industry. Service products tend to be intangible, interactive, consumed in the course of supply, and historically difficult to protect via patents. Their contribution to economic performance is complex, as they are in themselves said to be

agents of innovation transfer (Faberberg 04). However, advances in service-led industry and the introduction of Information Technology has increased the importance of focus on this less tangible but vital area of innovation. Growth in the service sector has resulted in its dominant position in current industrial economics with its understanding suggested to be fundamental to innovation (Fagerberg 04). There have been some innovation studies focused on the service sector but these are said to have taken a production line approach in exploration (Levitt 1972). Indeed, many service industries have emulated the lessons of manufacturing in the adoption and development of innovation in looking for examples of quality and efficiency. Metcalf et al (2000) explored this in their supply chain analysis of the ophthalmic industry. In their work they illustrate the importance of interdependencies between the service and manufacturing industry in delivering new treatments.

The influence of competition from rival firms is seen as the second main driver of change, influenced by the ability to exploit and access knowledge beyond current boundaries. Equally, implementation of innovation in the service sector needs to be systematic and standardised, as exampled by McDonald's and call centres whose operating processes are identical in separate units. The focus in this context is the interactions of product characteristics, customer proximity, relationships and networks (Metcalf 2000). These approaches produce economic efficiencies but are suggested to generate low quality (Faberberg 04). Implementation aside, understanding the details of the service sector is now said to be vital in identifying those aspects of importance in mutual interdependencies and success (Lundvall 1988; Van Hippel 1992). The final point of context is that innovations in the service sector are positive only where there are market options for adoption. In some government services innovation leads to

increased cost, as exampled in health where 'innovations in a health market often expand treatments creating an explosion of expenditure' (Weisbrod 1991). The overall value of innovation to economic performance is now widely accepted (OECD 2004) with the competitive focus, which Schumpeter argued to be important and evident at a national level. The issues of collaboration, competition and market strategies are core components of the regulatory environment, as are societal values and the status of the current science within the innovation process. Innovation is said to be the very basis of economic growth in stimulating competition, GDP growth, and technological change (Feldman 2004). The study of its contribution to economic performance began in the 1950's with the work of Robert Slow, who was awarded the Nobel Peace Prize. He demonstrated that 87% of economic growth in the US between 1909 and 1949 was due to technological change.

Innovation is said to be subtly different from technology, which is the embodiment of knowledge into its physical form (Feldman 2004). Innovation encompasses incremental improvement to something that already exists and is said to extract economic growth from advances in knowledge (Feldman 2004). Innovation is critical to long-term growth, although most is incremental. Sustained economic growth relies on radical technological innovations that disrupt markets and create new industries (Branscomb Auerswald 2002). In this regard innovation is seen to be far more about prospecting, mining, refining and adding value than it is about pure invention. Innovation is argued by some to be more important than invention (Branscomb Auerswald 2002), which is about discovery and the creation of something novel. The terms innovation and invention are often used interchangeably so it is helpful to understand the UK Parliament's definition of invention, which is said to be those things that can be patented whilst innovation is the

description for those that cannot (Feldman 2004). Schumpeter suggests that innovation could be described according to how radical it is compared to an existing process. In doing so, he defines innovation in terms of determinants and factors of influence (Ludvall 1992; Nelson 1993). Tidd et al (2001) developed this concept in suggesting that the design space within the boundary (including relationships and interdependencies) need to be explored.

In his work, Edquist (1997) defines innovation as any new creations of economic significance. These, he suggests, may be brand new or, more likely, a combination of existing elements and may include the process by which innovation is shaped. These changes occur over time, and are said to be complex in being influenced by many factors. A position supported by Ludvall (1992) and Niosi et al (1993) is one that defines innovation as the outcome of on-going processes of learning and searching which results in new products, markets, institutions, organisational change and techniques.

Dosi (1988) adds an important dimension, which is that of historic context. In keeping with Schumpeter, he argues the importance of historical information and formal knowledge being incorporated and codified in problem solving. A position supported by Metcalf (2000) suggests that history is essential to understanding abortive pathways and past boundary changes. Historic contingency is suggested by others to be important in providing a context to past influences (Dosi 1988; Metcalf 2000; Fagerberg 2004).

In their work, Oresnigo (1998) and Dosi move away from defining innovation by focusing on its characteristics instead, describing these as sector-specific knowledge, an ability to search and find knowledge, and their applications to a specific search goal. Freeman (1997) broadens these dimensions to include a social context, especially in the field of

technological policy, although there is little written to evidence such an approach. Tidd et al (2001) go on to describe innovation as a collection of all the processes that lead to the first attempt to put an invention into practice. History shows these can be separated by considerable time lags, either whilst an invention finds a place in the market or has been shown to be safe. This suggests innovation needs a context in real time.

Leonardo da Vinci drew sophisticated drawings explaining the twisting mechanics of the human heart, yet his discoveries are only in the 21<sup>st</sup> Century finding a place in cardiac surgery (Wells 2005). He designed a flying machine in the mid 16<sup>th</sup> Century, some 400 years before an engine was invented to make it fly, illustrating again the importance of context. This context is evidenced again in the present by claims that China cloned a fish some 37 years ahead of the rest of the world.

With no single way to define innovation, it becomes necessary to understand the options for its capture and use in this research study. Carr (1986) suggests defining innovation by the use of a framework to capture and explain the multi causal and relative importance of various determinants to help establish a hierarchy of causes. Tidd et al (2001) suggested the use of a linear model to provide insight and interpretation to the activities involved in innovation. They classify this linear approach as research science, development, production, and marketing. Mina et al (2004) argue instead for a problem sequence to be used in constructing the innovation process. They suggest that since the goal of innovation is to solve a problem, one way to define the process is to explore the design space of path dependencies within a boundary set by the perception of the problem. Edquist (1997) simply divides innovation into two process categories: technological and organisational. A division is evidenced in the 20<sup>th</sup> Century economic

success of the United States, where change related largely to organisational innovations and, more laterally, to growth in new industries and mass production (Tidd 2001).

Defining the core properties of this series is one suggested approach to articulating the process of innovation. This, according to Fagerberg, should include the investment and knowledge created, the relationships, connections and networks, process interactions and modifications through experiment and learning (2004). Mina et al (2004) go on to describe the innovation processes as systematic and interdependent on knowledge generation, which is greater than its components, requiring therefore an understanding of its connections and boundaries. They argue it is the ecologies that are important in innovation systems and the focus on regulation of the system misses the principles that underpin and connect innovation and its diffusion. The system of innovation is seen from the literature to be described in a number of complimentary and, at times, different ways. What is clear is that it is said to comprise a range of factors from the conception of an idea through to the marketing of its related product and its impact on sales or services. It also consists of those elements that influence its creation, including legislation, regulation, workforce and society (Freeman 1997; Fagerberg 2004). One of the challenges for Innovations Theory is to help understand which factors influence success and in what ways.

Nelson and Roseberg (1993) and Nelson (1992) studied the process used to put innovation into practice, arguing that diffusion was one of the most important areas. Diffusion includes recognition of the impact on existing technologies and the systems in which they operate. This is said to bring change to an existing system, which evolves over time while the internal dynamics become part of the innovation sequence itself

(Mina et al 2004). Similarly to constructing a pattern to fit an outcome, the literature covers many complimentary and independent designs. Freeman (1997) suggests an approach using institutional networks to span the relationships between the private and public sector. Included in this he supports the examination of culture, political institutions, economics, social structures, interdependencies, wars, labour change, capital, and transfer of technologies. Edquist (1997) suggests that political aspects and policy are the most important of these.

In designing an Innovation model, Edquist (1997) advises that innovation and learning need to be at its center. He suggests taking a holistic and interdisciplinary perspective, focusing on the interdependencies and non-linear relationships, and being historic and identifying differences and connections between systems. Sterlacchini goes on to suggest cost as a further dimension of innovation, including those associated with manufacturing set-up product design and organisational change. Mina et al (2004) states another way to define the process of innovation is to explore the design space of the path dependencies within a defined boundary that is set by the perception of the problem. Fagerberg (2004) suggests the use of a framework designed to encapsulate the components and relationships to be defined. Building on the work of Edquist (1997), she suggests the framework could include the impact of the research, identify links between universities and public research organizations, consider the strength created in the system, identify the proposed market, consider legislation and regulation, and define the boundaries.

Each of the many ways to define innovation and its characteristics offers an approach and structure to design a study, most notably in highlighting the areas for inclusion in a

framework at a national level. Such consensus, as there is in the literature, demonstrates that innovation is a process far broader than traditional research and development, with its contribution greater than its historic value on a balance sheet (Sterlacchini et al 1999). Innovation is shown to involve both process and systems and to facilitate a framework with many design options from which to explore therapeutic cloning between the UK and China.

# **Innovations Theory**

Innovations theory places an understanding of the innovative process at the centre of its analysis (Fagerberg 2004), making it ideal for a case study on therapeutic cloning systems between the UK and China. It is also said to be a useful structure against which to describe economic progress, historic trends and contextual change (McKelvery 1996) - which fits well with the challenge of exploring the national context of stem cell science. There are a number of theories that can be used to explore the structures of therapeutic cloning between the UK and China. Evolutionary theory is an example of one, which is concerned with understanding the process and relationship between innovation theory and natural evolution. Many writers note the similarities between biological mutation to the evolution of ideas, hypothesises, and selection mechanisms. The assertion being that the process of technological innovation can be likened to that of biological development. The contrast is the trial and error of the discovery process in open-ended systems, which can be blind and involve a certain amount of path dependency (Gregersen 97). The comparator in technological innovation is the process whereby agents act to transform new knowledge, invention, or scientific techniques into economic value. This is seen through production or changes to the organisation, for example.

Darwin (1859) might, to some degree, be happy with an argument that aligns the innovative process to that of nature, believing humans to be very much part of nature, without privilege or God. His belief in the importance of relationships and mutual influences, such as those between organisms and the environment, fits well with an innovative systems approach. So too does his principle of competition over time and the suggestion of an apparent order to the selection process. Darwin's use of historic events to support his theoretical argument and his belief in interpretation of evolutionary progression within an environmental context fit well together.

Innovation Theory, too, emphasises historical contingencies, patterns of change, and contextual interpretation. Correlating to human innovation, agents act to transform new knowledge, invention or scientific technique into economic value (McKelvery 1996), with the theoretical approach aiming to provide structure. The analogy of particular interest here is the process by which new variety or variation is introduced. Invention, as in evolutionary processes, introduces change by introducing new variety. McKelvery (1996) argues that the development and diffusion of information, done in a way simililar to that by which nature selects between alternatives, produces a strong analogy to the innovative process. The challenge is to understand what is happening at each stage of the comparable process and the influences made at each point of selection. This comparison applies equally to genetic science as do insight into the chemical codes that instruct the choice and behaviour of cells.

This is an inductive comparison, no doubt, but one cautioned by Stephen Gould (2002), who argues the basic topologies of biology and culture to be different and the comparison to be misleading. In biology the chemical pathways are absolute and not

experimental. Science is seeking to understand how messages are deferred rather than options in the signalling pathways. Human innovation, by comparison, operates with some degree of free will, without pre-determined pathways and, often, without a clear outcome. Gould suggests the timeframes are distinct. Complex biology requires sex selection to determine the dominant, recessive or mutated influence to be evidenced, whilst human innovation is said to be culturally influenced, directly learnt, and quick to share. McKelvery (1996) suggests, however, that the comparison is still a useful one, in accepting that learning, however it occurs, is an important feature of both innovation and evolution.

McMeekin et al (2002) support this analogy, pointing particularly to the role of learning in the innovation system. They argue that innovation is created and adjusted through the process of knowledge acquisition, and its system adjusts from these interactions. The systems themselves diversify, reinforcing the importance of the relational interdependencies. This is comparable to biology, where cells take their instructions from adjacencies, specialising and developing, yet are dependent on the interrelationships such as the hormones from the entire body. The work of Metcalf et al (2000) on developing an ocular lens (in the clinical field of optometry) serves to illustrate these points in identifying the importance of interdependencies in successful innovation.

Understanding the creation of innovation is one aspect of the whole system from within which it is created and diffused. Diffusion is the process by which innovations are introduced, organised and sustained through channels, over time amongst members of a social system (Rogers 1976). Nelson and Roseberg (1993) and Nelson (1992) studied the process used to put innovation into practice, arguing diffusion to be one of the most

important areas. Diffusion includes recognition of the impact upon existing technologies and the systems within which they operate. This is said to bring change to an existing system, which evolves over time while the internal dynamics become part of the innovation sequence itself (Mina et al 2004).

The concept of diffusion originates from the 1903 French Sociologist Gabriel Tarde, who first plotted the 'S'-shaped diffusion curve. The rate of adoption, or slope of the curve, is the important feature, illustrating the rate of diffusion. In the 1940's a hybrid-corn study by Bryce and Neal Gross (1943) identified five segments amongst farmers adopting the hybrid corn seed. They labelled these Innovators, Early Adopters, Early Majority, Late Majority, and Laggards. The ability to diffuse innovation is said to be complex and multifaceted (Metcalf et al 2000), being correlated to many things including the economic influence between the performances of countries. Rogers categorised diffusion into four dimensions: an idea as perceived, means to communicate, an adoption rate over time, and interrelated social systems engaged in the problem/issue. Roger's work built on the premise that groups could be defined by characteristics he saw as evident in successful innovation. These included risk-taking, access to control of finance, understanding of complex knowledge, and ability to cope with uncertainty (1962).

Extending the work of Bryce and Gross, Rogers described in detail the characteristics of each group. Early Adopters, he believed, tend to be an integral part of their local system, have some aspect of leadership, were successful, respected, and often acted as a role model. Characteristics of Early Majority he defined as being interactive within peer group, seldom in leadership positions, and prone to deliberation before adopting

new ideas. The Late Majority, he argued, was influenced by peer pressure, from a background of economic necessity, and tends to be sceptical and cautious.

Research by Johnson and Vandan Ban (1959) found that discontinuance was twice as high in the Late Adopters group and this had nothing to do with a superior innovation, suggesting pressure to conform was only temporary. Rogers defined Laggards as being isolated without opinion, having limited control or resource and distrusting of change and innovation. He went on to describe how innovation is adopted within five stages, the first being *Awareness*. He believed individuals would first become aware of an innovation without having the complete information. The second stage he defined as *interest*. For some of those who become aware of the innovation there will be an interest in the new idea and a drive to discover more information about it. Next, he argued that the individual would *evaluate* the information available, mentally applying the innovation to future situations. His forth and fifth stages involve *trial* and then *adoption* of the innovation, including marketing strategies to be formed.

His model is simplistic and appears to change from an individual focus to an organisational one by the time it reaches *adoption*. Various researches have pointed out that the diffusion of the innovation process can happen over several decades, although his model appears to suggest a shorter time. There is, however, universal agreement that the adoption process or the rate of diffusion can be chartered on an S-shaped curve regardless of the timeframe (Doggson and Bessant 1996). Rogers' work went on to define the process an individual goes through in deciding whether or not to accept an innovation. He summarised these as being from first knowledge of innovation to forming an attitude towards innovation, a decision to adopt or reject it, implementation of a new

idea, to confirmation of decision. Doggson and Bessant (1996) added the need for an individual to perceive an opportunity or a need at the beginning of the process. They also believe an ability to search, compare, select, acquire and implement information are integral to this process.

Rogers identified and described a number of personal characteristics that would influence the decision-making process of an individual. These included experience of previous innovation, recognition of a problem or need for change, being comfortable with change, and for the innovation to fit in with their social norms (Rogers 1976). Rogers' work goes on to identify three types of knowledge necessary in the first stage of innovation. He summarised these as awareness, how-to knowledge, and knowledge of the underlying principles of the innovation. He went on to conclude that 'early knowers' have more formal education, a higher socio-economic status, more exposure to mass media and interpersonal channels, are change agents, and are more socially integrated. The importance of personal characteristics in the diffusion process is challenged in the work of Amendola and Gafford (1988). They compared the process of innovation with that of diffusion and examined the extent and speed at which a superior innovation or technique was implemented, concluding that economic process played a stronger role in the entry of a new technology than the absorption of if by the population. They suggested that Rogers; (1962) work on diffusion should include a definition of the degree of risk involved, identifying financial controls, defining areas of uncertainty, and understanding the complexity of the knowledge created.

Sanson-Fisher (2004) used the work of Rogers (1983) to develop ideas about those characteristics necessary for successful diffusion of innovation in a clinical context.

They define the characteristics they found to be influential as research evidence, role models, relationship to existing procedures, and whether it is open to further modification. Similar work by Tamblyn et al (2003) includes further variability, gender, medical speciality training, time from graduation, location, practice workload, and patient demographics. Diffusion Theory is seen to offer a plausible explanation as to why some clinical activities are adopted rapidly whist others are not (Sanson-Fisher 2004). The distinction of this work in transferring Rogers' Diffusion of Innovation model to clinical practice is the recognition that the outcome is more than economic.

Rogers' 'Trialability' and 'Observability' are found to be particularly important features influencing the take-up of new clinical innovation since visibility is critical in influencing clinical change. Denis et al (2002) suggest that this feature in clinical practice is reported to be highly influential, as peers perceive professional disadvantage at being left behind. Compatibility to existing clinical practice, values and experience are also important, as evidence shows diffusion in clinical practice can be rapid where innovation leads to an improvement of an existing procedure, as exampled by mammography screening and testing for prostate cancer (Goodman 2002; McDougall et al 2000). Sanson-Fisher (2004) developed Rogers' decision-making process for the diffusion of innovation and suggests five clinically oriented steps. This, they suggest, begins when researchers first acquire knowledge about a possible clinical change. An individual or group are then persuaded of the advantage of the change, leading to other clinicians learning about it. Innovation, it is said, is then adopted into routine clinical life, followed by reinforcement discussions with peers. This growth of knowledge involves the exploration of the systematic interactions of dispersed groups, channels, and incentives in a process distributed across time, space and epistemic domains. Correlating to the

nature of the medical problem and the search for a solution (Mina et al 2004), it involves the exploration of systematic interactions of dispersed groups, communication channels, and response to incentive structures.

Many clinical innovators work at an international level, influenced by other aspects of relational power as identified by Sanson-Fisher et al (2004). They highlight the impact between professional groups that hold varying perceptions about the efficacy of new innovations, which can influence diffusion. The nature of communication chosen is also said to influence clinical innovation, with direct personal contact argued to be the most effective (Bero et al 1998). This model fits the historic approach to clinical innovations in the NHS (BMA 1995), but not the regulatory and policy context at each stage of adoption, particularly when noting the role of the National Institute of Clinical Excellence, who, since 1999, have had a powerful influence upon determination or otherwise of innovation into the NHS. Nor does it reflect the international context of medical innovation, as described my Mina et al (2004) in their work on the introduction of cardiac stent technology. It could, however, reflect less substantial innovations such as changes in surgical techniques learnt by one surgeon and picked up by others. The characteristics of clinical innovation fall into both categories. This is equally true historically for China, with current diffusion of health technology technically available in its market system, but, in practice, severely restricted by poverty.

Diffusion is a central tenet of innovation theory, which is aimed at identifying the factors influencing its uptake. Although outside the remit of this study (as stem cell services are yet to be created), it allows an insight into the relationships and priorities in the research

field. Over time, understanding diffusion of the services from therapeutic cloning will be vital to understanding patient choice, expectations, and patterns of service delivery.

#### **Innovation Structures**

Understanding how innovation evolves and its systems occur requires a structure from which to explore. Regional Systems of Innovation is one such approach, in that it proves a geographic context. Cooke et al (1997) was first to introduce the concept of a Regional System of Innovation, which was further developed by Braczyk et al (1998), Cooke (2001), Asheim et al (2002) and Fagerberg (2004). It takes the same economic and algometric principles as a National System (Arcangelis 1993) when identifying factors at a geographic level. The Regional approach is said to have two types of constituents. Firstly, it has a shared component or commodity that links them and, secondly, a geographic relationship (Fagerberg 2004). Their systems are linked networks of activity with strong complementarities between components (Tidd 2001) within defined boundaries (Fagerberg 2004).

Mina et al (2004) support this deconstruction of innovation theory to a regional level, suggesting that national boundaries fail to capture sufficiently the purpose and function of innovation. They support an approach that breaks down the evaluation to a system perspective, thereby enabling the examination of individual industries within their own boundaries. The regional or sectorial approach was first used by Malerba (1997) to examine the use of technology amongst a group of firms in a similar industry.

Regional Systems illustrates the key features that structure an innovations research. A Regional approach does not fit the design of this study as stem cell research is

organised at a National level. National Systems of Innovation lends itself more naturally to this design.

# **National Systems of Innovation**

National Systems of Innovation is one approach within the innovations literature, with an emphasis on understanding performance at a national level. In particular, this approach places emphasis on the political and policy boundaries (Edquist 1997) and enables an exploration of their national difference and application. Freeman (1997) defines these political structures as culture, political institutions, economics, social structure, interdependencies, capital infrastructure, and technology transfer. Understanding National Systems of Innovation is suggested by Edquist to be critical to predicting long-term economic growth, as it is said to afford a powerful explanation of performance. National Systems of Innovation (NSI) is a relatively new theory based on the work of Freeman (1997), with its origins said to be in the work of Friedrich List (1841) and Joseph Schumpeter (1883-1953). Each made links between economic performance and the role of technologies in its advancement (Landes 1969; Plummer 2004). Schumpeter (1883-1953) extended this work by arguing technological competition was the driving force behind economic development, thereby placing innovation at the centre of growth (Tidd 2001).

Joseph Schumpeter (1883-1953) was an economist, said to have ideas before his time, whose work focused on the relationship of learning and the application of new technologies to economic performance. He was critical of classical economists for what he saw as their scant attention to science and technology when considering issues of

national growth. He rejected the classical economist view that economic performance focused on capital and labour as the two most important factors of production (Plummer 2004). Schumpeter wrote instead of the interdependences between foreign technology and the role of diffusion and imitation in performance (Landes 1969). His insights led to Germany delivering one of the best technological educations and training systems in the world, leading to their economic advance over Britain in the mid 19<sup>th</sup> Century.

The National Systems of Innovation takes many of its features from previous economic and social analysis including network, power relationships, and organisational behaviour (Coombs et al 2001). Christopher Freeman (1997) was first to use NSI in his work, assessing the contribution of public policy to Japanese national performance. Freeman defined National Systems of Innovation as a collection of institutional networks spanning the public and private sector whose activities interact, initiate, import, modify, and diffuse new technology. The unit of analysis in explaining National Systems is national boundaries, the important features according to Edquist (1997) being the political and policy aspects. National System of Innovation is used to explain the performance of a country in terms of its special features and national boundaries. It is designed to provide a qualitative framework to conceptualise policy implementation and take explicit account of the systems and interactions.

The ontology for NSI is that innovation is crucial for long-term economic growth, that successful industries tend to develop in geographic clusters and that it is a powerful explanatory factor behind differences in performance (Edquist 1997). The first major book was written by Bengt-Ake Lundval (1992), who focused on an empirical case study which looked at National Research and Development systems in Denmark. Richard

#### **DBA Final November 2008**

Nelson edited this work comparing the National Systems of twelve countries. His aim was to develop a more theoretical alternative to neo-classical economic tradition by placing interactive learning and user-produced interactions at the centre of the analysis. They sought to define innovation in terms of its determinants and factors at influence in the innovation process. Edquist (1997) gives a more general definition of National Systems of Innovation, describing it as an 'all important economic, social and political organisational and other factors that influence the development, diffusion and use of innovation'. (Is this a direct quote? If so, it may be worth checking to see if you've taken down the punctuation exactly as written.) Although there is no formal theoretical framework to describe National Systems of Innovation (Edquist 1997a; Holbrook and Wolfe 2000; Fagerberg 2004), there is broad agreement to a number of principles within it. Edquist summarised these as:

- · having innovation and learning at its centre
- a holistic and interdisciplinary approach
- focusing on Interdependence and non-linear assumptions
- providing an historical perspective
- looking at the differences between systems and non-optimality
- assuming technologies and innovations are measurable

# with Fagerberg (2004) adding

- Research and Development
- New markets
- · Articulation of quality requirements

## **DBA Final November 2008**

- Organisational consequence
- Changing institutions, e.g. new regulations and laws
- Financial innovation
- Technology transfer
- Boundary distinction of what is inside and outside

The main strengths of NSI are said to be in placing innovation at the centre of evaluation and learning at the heart of change (Fagerberg 2004), thereby distinguishing it from other approaches where the role of technology in economic performance is said to be exogenous. This approach is said to be holistic and interdisciplinary, attempting to encompass a wide array of determinants in organisational, social, economic and political activity. It takes an historic and evolutionary perspective to enable comparison between real systems over time and space (Fagerberg 2004), emphasising the interdependence and non-linear activity of an organisation. These include internal and external relationships with their environment, their feedback mechanisms, and their relationships. Its main weakness is that, as a concept, it is diffuse; the framework and boundaries are not prescribed and its use to formulate conjecture for empirical testing is said to be limited (Edquist 1997). It is not a formal theory providing specific propositions regarding casual relations among variables and there are issues of interpretation in its language. The terms 'organisational' and 'institutional' have, for example, been used to mean different things. For example, Ludvall (1992) used the term 'organisation' to mean rules of the game, whilst Nelson (1993) used it to distinguish between different types of organisations.

Edquist and Johnson (1997) describe organisations as formal structures consciously crafted for an explicit purpose, they regard whilst institutions as common habits, norms,

routines, established practices, rules, or laws that regulate the relations and interactions between individuals. This makes the explanation and classification of components in the research design vital. More recently its use has extended to the service industry (Fagerberg 2004). It has also been applied to research in a number of clinical areas including optometry, cardiology, and cancer (Metcalf 2000; McDougal 2000; Goodman 2002; Mina 2004). It has been used in agricultural research to consider the impact of generic engineering and linked as a model to that of evolutionary theory. At the centre of each approach are a definition of the innovation that is being studied and a clarification of its boundary.

The most striking feature of National Systems of Innovation is said to be the absence of any form of empirical framework (Edquist 1997). The unit of analysis is the National Boundary, with Edquist (1997) suggesting the associated political structures to be of fundamental importance. For this study, this means understanding the permissive status of government legislation, their investment strategies, and how these apply to the research question. There are a number of flexibilities and suggested approaches in the literature that provide options for defining NSI as they relate to the research question. Freeman suggests that the overall aim is to identify those activities which increase knowledge and those institutional rules that promote successful innovation.

Mina et al (2004) support this in agreeing that the identification and definition of the core properties influencing innovation are critical to understanding growth and performance. He suggests the use of case studies as a means to develop NSI theory building on the earlier suggestion by Carr (1986). Fagerberg (2004) suggests that, in addition, there needs to be more focus on the non-tangible aspects of knowledge and agrees that a

framework and case study is the most useful approach. Ludvall (2003) suggests, however, that if the use of NSI is to be of assistance to policy makers its focus needs to be more realistic, particularly in defining the relationship between theoretical analyses and its related environment.

The concept of national boundaries as a definition of innovation, although widely accepted, is also open to challenge. Such challenge is based largely around concern about the number of trans-national corporate successes that sit across and supersede national boundaries, with the examples of Coco-Cola and McDonald's cited. This is supported by Ohmae (1990), who suggests that the significance of national boundaries has been overwritten by the interdependencies of economies at a national level (Freeman 97). This suggests the definition of what is national to be unclear or to be reliant upon external factors other than the National Policies of a country. For genetic science within the biotechnology sector, it certainly transcends national boundaries in terms of co-dependencies in knowledge; specialist techniques, and discovery. Where national boundaries are distinct, however, and therefore relevant to this research topic is in the realms of legislation, policy, and the societal context of a country. These do, in fact, define what is acceptable in scientific research within a national boundary. One example of this is the patent law of a country, which can only bind itself, (as evidenced by Myraid's patent for the BRCA2 test in the US, which was successfully overturned in the UK) (PHGU 2004).

Mina et al (2004) also question the usefulness of national boundaries as a basis for assessing innovation, arguing that this approach fails to provide sufficient focus on purpose or function. They favour the deconstruction of innovation theory to break down

the evaluation into a system and network, thereby enabling industries to be examined within their own boundaries. The issue of relevance and use appears, however, to depend on the topic of research, as many of the concerns are based on industrial-related studies (Fagerberg 2004). It may be the future aligns with Ohmae's argument as the International Standards Organisation (ISO) and European Commission seek to agree upon international standards for genetic science, but as yet this is some way off.

National Systems of Innovation theory has been applied in a number of clinical areas including optometry, cardiology, and cancer (Metcalf 2000; McDougal 2000; Goodman 2002; Mina 2004). Although there is nothing to-date on stem cell research for diabetes, its application to a new clinical area fits easily with its flexible design and its recent transition to service areas. Many writers suggest future application of National Systems of Innovation Theory with Storper and Harrison (1991) asserting that despite the body of literature there needs to be a better understanding of how it can be applied as a structured model. They go on to suggest that the power dynamics need to be identified, with a view to indicating which are of most influence. Storper and Harrison also recommend a focus on those indicators that are shown to deliver change, overcome risk, and drive market performance.

Freeman (1997) suggests the need for more research into the impact of NSI and the determinants that influence its development and diffusion. In particular, he suggests, those activities that increase knowledge and the identification of organisations that are key to its development or diffusion. Tidd et al (2001) argue that our understanding of the way knowledge and innovation operate at an organisational level is fragmented and needs further research to conceptualise why and how innovation occurs. They suggest

that one potential avenue for future research is to apply evolutionary and characteristicsbased approaches to service innovation. As with the previous suggestions, identification of key drivers is at the heart of the challenge.

National Innovation Studies has, according to Fagerberg (2004), focused on traditional technological processes and the production of goods rather than organisational or service innovations. Fagerberg argues that this creates a strong reason to give more attention to non-technical and intangible aspects within the model. She supports Tidd et al (2001) in suggesting the application of evolutionary and characteristics-based approaches to service innovation. She also supports a focus on the impact of innovation within the marketplace with particular emphasis on the skills and capabilities required for effective implementation. This relates, in part, to earlier suggestions by McKelvery (1996), who described the challenge of NSI to be an understanding of what is happening at each stage of the innovation process, and how and what is being influenced at each point of selection. This, he suggests, will help identify the development process and its corresponding diffusion of information.

The NSI literature includes a range of suggestions and arguments relating to its construction and use. In addition, it covers strengths, weaknesses, and opportunities for its development, including its links into related theory. Its recent application in the service sector - with several examples in clinical innovation - makes it an ideal choice for this research topic. The flexibility of its construct and its use in case study models is also relevant. The challenge will be constructing the research design in the absence of a defined structure for a national system of innovation in therapeutic cloning. Its structure and approach are, however, underpinned by a number of related innovation

theories set out in the literature, which are important to understand when constructing a model. Before moving to consider how this model and methodology is constructed, it is helpful to understand the background to the national innovation structures in China and the UK.

## Innovation in China and the UK

China is reported to have a long and prestigious history in innovation, having invented paper, printing, the magnetic compass, and gunpowder (Temple 1972). They used iron and created tools 1000 years before the rest of the world and are claimed to have cloned a fish some 37 years before the UK cloned 'Dolly the Sheep' (Mann 2002). They are said to have been the first to synthesise human insulin, but this was not validated nor marketed (Poo 2004). China's complex history of wars and conflict is given as a reason for losing their innovative lead in the 18<sup>th</sup> Century. Other reasons include their historic isolation from the rest of the world and the absence of market mechanisms.

Having had a prestigious history, China wants desperately to reclaim it and to achieve a Nobel Prize (Mann 2003; Qiming 2005). With the biotechnological industry recognised as the most powerful source of innovation (Geroski 1993; OECD 2000; DTI 2002; HM Treasury 2002), China has focused its strategy on gaining international collaboration within this field. From these objectives, China derived its strategic goal to be the front-runners in international science by 2010, a leader by 2020, and ranked amongst the world greats by 2049 (Wilsdon and Keeley 2006). Within this aim they identify stem cell technologies as a priority. Their goal is to attain prestigious and economic prowess, as success in the biotechnological field would make China a world leader (Jing 2003; Mann 2003). Early success is evident in internationalisation of their science and of overseas

investors choosing to locate biotechnological research in China (OECD1 2005).

Incentives include a relaxed ethical stance (Yank 2004), access to both primate and human research (Chien 2004), and lower research costs.

Culture is said to sit at the heart of their opportunities, with the Chinese having few moral objections to the use of embryos for research and therapeutic cloning (Yank 2004). In China human life is considered to begin at birth, not conception, with personhood achieved only when the person is able to participate in society. To this way of thinking, the foetus is not considered human (Mann 2003). Whilst the Chinese government is regarded as having the most liberal stem cell research in the world, it does not permit cloning for the purpose of human reproduction (Yank 2004). Despite their ethical stance, China has a number of issues to overcome. These include the communication of their science, access to international specialism (Yank 2004), investment in basic research (Hepeng 2002), and improvement in the quality of its published research (Wu 2004). China has, in addition, a number of social and demographic features to reconcile if it is to achieve its goal of a xiaokang society.

Being of similar size to America, China is home to 20% of the world's population (Riley 2004), has a wealth of natural resource, and a health profile similar to that of a developed country (WHO 2004). Prevalence of diabetes affects about 2.5% of its population (Pan et al 1997), with cancers, respiratory disease, water-born infection. HIV/AIDS, and accidents all considered other major causes of death (Jin et al 1995; Beach 2001b; Riley 2004). In addition, SARS, a deadly respiratory disease, emerged in southern China with major political consequences (WHO 2004). 70% of the population live in rural villages (WHO 2004) and the entire population is subject to national birth

planning policies. This has led to an unnatural skewing in official birth statistics of the ration of male: female births (Watts 2005).

The main environmental problems are water, coal, and land erosion. China is the world's largest producer and consumer of bituminous coal, most of it burned without emission treatment. It also suffers from a shortage of usable water, with water in only six out of 27 cities being drinkable (Smil 1996). The absence, for many, of a decent water supply leads to liver and stomach cancers skin disease, congenital deformities, and water-born infections such as dysentery (Riley 2004). The associated morbidity and mortality is greater in rural areas (Beach 2001a). Many of these have worsened since China's move to a market economy in the 1980's, leading to a predominately private health system (Riley 2004), leaving 90% of the rural community without medical support (Beach 2001) and 85% without health insurance (WHO 2004).

A typical family earning \$60 per year would pay 30% of their annual salary for one visit to a medical facility with hospitals demanding \$181-\$362 before admission. The absence of public facilities resulted in an increase in private facilities and a fall in government expenditure on health from 36% to 15% by 1999 (WHO 2004). To date, the government spends 12.8% of its budget on health, or \$261 per person with 66.3% of health expenditure privately funded. This amounted to 5.8% GDP in 2001 (Lopez 2002), indicating that the investment in China's health care system has now fallen well behind China's economic growth (Watts 2005).

Britain also has a prestigious and current history, being a world leader in genetic science and discovery (DoH 2003). It is a small island, densely population with limited natural

resources. The ethnic balance is largely white with 8% made up from minority races (mainly of Asian, African or Chinese decent). Its climate is mild and often wet, with overcast skies prevalent for 300 days of the year. As a consequence, it is lush and green with rolling plains in the south and east and rough hills and mountains to the west and north. Economically, it is highly developed, leading to high standards of living and an eminence in both art and science. It exhibits affluent trends in lifestyle, including fatty diets, smoking, and low levels of exercise. Infectious disease has declined since the early 20<sup>th</sup> Century, with current morbidity associated with non-communicative disease and comparatively poor health outcomes (Wanless 2003). There are significant inequalities in both mortality and morbidity across gender, socio-economic and geographic location (Wanless 2003). At least 5% of the UK population is currently known to have single gene disorders, with 60% developing a genetically related disease during their lifetime (DoH 2003). 3.9% of the population is currently known to be diabetic (Diabetes UK 2003 Atlas 2004)

Economically, the UK has a mixed history, having led the world in overseas trade during the 19<sup>th</sup> Century. It was the first to revolutionise its industrial production in the 18<sup>th</sup> Century and the world's first society dominated by the middle class (Weisser 2005). Thereafter it faced persistent problems with its balance of trade, having to import one tenth of its food and many of its raw materials and manufactured goods. Industrial inefficiencies and high cost of nationalised industries in the first half of the 20<sup>th</sup> Century led to more problems, culminating with an unemployment rate of 11% in the 1980's. Since the mid 1970's, the UK has benefited from an economic upswing, growing at a rate of 2.5% by 1997, one of the highest in Europe (Weisser 2005). This prosperity has

enabled centres of excellence, including neuroscience at Oxford, Cancer at Dundee, and Genomics at the Sanger Centre, Cambridge.

The UK is responsible for the cloning of Dolly the Sheep, the first such animal in the world. It has the best regulatory framework (PHGU 2002) and a raft of financial and tax incentives. It led the final mapping of the human genome (Goodfellow 2001), the computer technologies to read gene codes, and it developed haplotype mapping and accounts for half of all drugs currently under development. It is regarded as a cost-effective place to conduct stem cell research and has been working in the field of genetics longer than any other country (Best 2005). As a direct consequence, it has the most comprehensive legislative structure, having established the Human Fertilisation and Embryology Act and created the Human Fertilisation Embryology Authority in 1991. It was the first country to licence therapeutic cloning at Newcastle University in August 2004 (Pincock 2004) and has succeeded in creating therapeutic cell clones (BBC 2005).

Access to new technologies and services has been strictly controlled by the National Institute of Clinical Excellence (Raftery 2001) since 1999. Linked to the Horizon Scanning Unit at Birmingham University and the National Co-ordinating Centre for Health Technologies in Europe, they review all pharmaceuticals, devices, diagnostics, surgical procedures and therapies. The outcome of most reviews is to restrict a new technology to a treatment of last option (Raftery 2001), with an allegedly economic motive (Claxton et al 2002). As a result, most new technologies take between five and twenty years to become available (May 1993; Dargie 2000; Raferty 2001; Wanless 2002; Dyers 2003). Genetic technologies in the UK will be controlled by this mechanism unless they are marketed privately. They are likely to cost more to research and

develop than previous technologies and the ownership of their associated property rights are already predominately in the US private sector (Graff 2003). Already there is early evidence of genetic tests becoming available over the Internet (for example, sex testing in early pregnancy) (PHGU 2005). In addition to their structural innovations, both the UK and China are influenced by political and legal structures that influence their stem cell research.

#### **Politics of Innovation**

China has a Communist Government whose reforms of the last twenty years are aimed specifically at improving its economic and social well-being. Prominent in the government's strategy is the 'Five Co-ordinations': to coordinate urban and rural development, interregional development, socio-economic development (WHO 2004). (This isn't a list of five – are there others?) International trade and development in the areas of communication and biotechnologies underpin these policies. The government launched Science and Technology Parks in 2000, created a number of technology transfer entities to develop and diffuse common technologies (OECDb 2004), and opened a new tissue-re-engineering centre in Shanghai. Research funding is made available through a number of routes, including the Chinese National High Tech R&D Programme, National Natural Science Foundation, Ministry of Science and Technology, and Chinese Academy of Science (Hsiao 2004). A related initiative is to educate the entire population in the scientific agenda (Hepemg 2002), although public debate and open communications are in reality rarely seen (Poo 2004).

Due to China's isolation from the scientific world for the last two centuries (Chien 2004; Poo 2004), its research structure was severely devastated (Wu 2004), resulting in an urgent drive for Chinese Scientists to become familiar with new discoveries (Chien

2004). By 2000 the number of biologists, government funded laboratories, and total number of publications had recovered to match those of the US, but the number of high-impact papers was only 4% in comparison (Wu 2004). Research investment is skewed towards developmental research, resulting in only 5% of its research budget being spent on basic research compared to 16-22% in more advanced countries (OECD 2002). This undermines international recognition and transferability and is probably the biggest issue to be addressed.

China has doubled its GDP spend on research between 1996 and 2002, increasing it from 0.6 to 1.2( although this is still significantly below that of the US) (OECDc 2004). It rose again to 1.3 in 2005 making it the second largest spend, taking over from Japan (Wilsdon 2006).

No. of the last of	\$bn R&D % GDP		Gov R&D		
China	12.5	1.1	0.28		
US	281	2.8	0.76		
Japan	96	3	0.64		
South Korea	20	2.7	0.64		

An interesting feature of the Chinese research system is the length of time research trials takes for new drugs in clinical trials. This is five years, compared to 15 in the US (Yank 2004) and 20 in the UK. With the average cost of \$900m to produce one new drug in the US, this has proved historically prohibitive for research in China, resulting in over 97% of drug production in China being generic (Hepeng 2005). Large drug companies are motivated to set up in China due to its cost effectiveness and China's expertise in chemical research (Chien 2004). Dr Zhao Chunhua runs China's first stem cell research programme in Beijing with both government and public support, making his work and access to embryos much easier than in America. Cells taken from second-

trimester terminated foetuses are used to treat diseases in ways that are not acceptable in the US and other parts of the world due both to the ethical concern and the absence of substantial clinical trials (DTI 2004 BBC 2005).

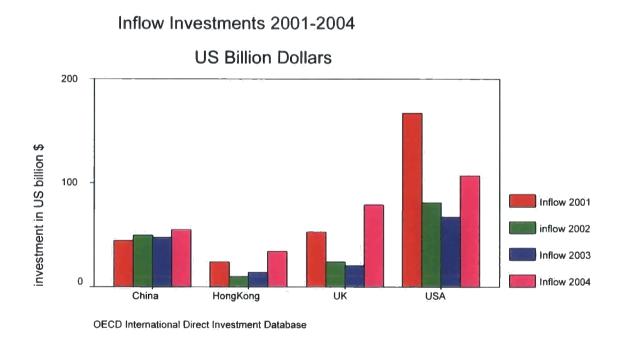
There are already reported to be a number of commercial stem cell services available in China, including gene therapy for cancer and cord blood therapies for spine and neurological injuries and disease. In addition, stem cell research is being undertaken between a number of universities and commercial organisations (DTI 2004). The Ministry of Science and Technology is supportive of research into therapeutic cloning for a number of disease areas including diabetes (Hepeng 2004). Centres using embryonic cells to research diabetes are supported across China (Dennis 2002). By October 2004 the following institutions were working on stem cell research in the area of diabetes:

- University of Beijing
- Chinese National Human
- Genome Centre Shanghai
- Shanghai Huashan Institute
- Xiangya Reproduction and Genetics Hospital China
- Sun Yat-sen University

Economic performance in China advanced from reform in the 1980's from a centrally planned economy to that of an open market (Keidel 2001). This resulted in annual growth rates of 8-9% and a quadrupling in GDP. They became the second largest economy in the world, creating the fourth-largest import volume, resulting in a reduction in poverty rates from 31.6% at the beginning of 1980 to 3.5% in 2001 (WHO

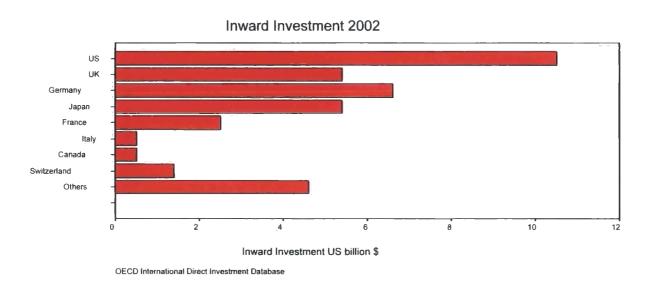
2004). From 2000 to 2001 they achieved moderate economic performance, their budget deficits and national debt were manageable and foreign trade, debt, investment and reserves were excellent (Keidel 2001).

By 2001 industry and construction accounted for 52.9% of the economy, 32.3% service and 14.8% agriculture (WHO 2004). The success of the Chinese economy is based on policy reforms aligning its internal programme with international priorities (OECDb 2004). These strategies replace traditional Greenfield projects with an internal market founded on mergers and acquisitions and a low production cost-base, making it attractive to foreign investment (Christiansen et al 2005; OECDa 2005). By 2004 China had achieved inward foreign investment of \$54.9bn and developed exceptional synergies with the US (Hsiao 2004; OECDa 2005), all having a significant impact on their research environment.



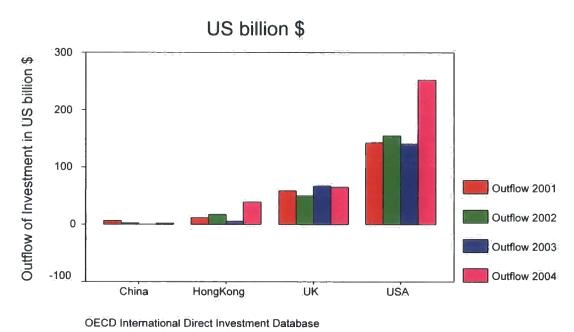
Despite real term growth in GDP of 8% in 2002, state-owned enterprise made losses of 36% (Wetzel 2003), leading to government policy to sell most state-owned enterprise

with the exception of national security (Wetzel 2003). To make its systems more flexible, the government has replaced its mandatory planning structures with one of direction and guidance, moving away from approving projects to a more functional one of evaluation. It has also streamlined its mechanisms for venture capital investment, procurement and tendering in favour of more open market processes (OECDb 2004). However, the Communist Party maintains its authority to approve all economic policies and managerial appointments in all financial institutions and major industrial enterprises (Wetzel 2003).



China has a comprehensive industrial base but lags behind in high technologies and modern management practice. The government sought to address this in 2000 by making explicit its intention to increase market shares in the technology industry (Christiansen et al 2005). Its goal was to improve exports and acquire overseas acquisitions aimed at stimulating the modernisation of its internal industry, exampled by the acquisition of IBM by Lenovo.

# Investment Outflow 2001-2004



Foreign R&D investment has increased in line with the government strategy to become competitive in the field of international R&D, to develop world-class research centres, and to improve the scientific literacy of its people (OECDb 2004). Investment from the US alone has risen from \$7m in 1994 to \$500m in 2000 (OECDc 2004) with such reforms in its science technology and innovation being central to their policy. This policy incorporates a number of strategies to build capacity, optimise structures and rationalise existing systems. This is exampled by preferential taxation structure providing 50% returns for any business attaining 10% in real growth.

Other incentives include tax holidays on technology transfers, technological constructions, services and training, communications, import of foreign advanced technologies, and pre-tax salaries (OECDb 2004). In addition, the Chinese government has introduced changes in legislation, more resources for scientific research, standard evaluation processes for science and technology, and flexibility in their workforce

structures. Human resource is regarded as the primary source of innovation, with 16 million students registered in higher education in 2002. China has 100 priority universities, 30 with international reputations (Qiming 2005). Its universities admitted 30.25 million students in 2002, including 202,600 postgraduate research students (OEDCb 2004). Recognising that many Chinese graduates are educated abroad, their government has policies to encourage this. It supports them to work in international Knowledge Parks, thereby expanding channels of communications and bringing the expertise back to China.

Economic performance in China, in terms of inward and outward investment as well as in levels of established research, all show strong improvement. There are, however, alternative ways to measure economic improvement in research, one being the nationality and number of registered patents (OECD1 2005). These are directly linked to the legislative structure for research.

The Chinese legal system is a complex amalgamation of custom and statute, based largely around criminal law, which has had a rudimentary Civil Code since July 1<sup>st</sup>, 1987. Historically, the Chinese had insufficient systems or experience of Intellectual Property as they related to research institutes (OECDb 2004). The process of patent registration is governed by the Regulations of the Management of National Science and Technology Programs and Projects of Intellectual Properties. The State may, under special circumstances, retain its right to freely use and exploit a discovery. Until recently there was a loophole in their patent law that permitted Chinese companies to copy drugs with foreign patents. An intellectual property system that is respected and trusted is an

essential aspect to research innovation, so China has had to respond quickly to make improvements.

Firstly, China introduced a systematic approach to guidance and demonstrations aimed at stimulating the internal accumulation of property rights and to accelerate the conversion of its findings to actual products (OECDb 2004). Secondly, they joined the World Health Organisation, which improved their international standing, particularly in the area of enforcement (Hsiao 2004). The Patent system in China shows relatively low numbers of registrations, but higher numbers for design and utility. This may in part be explained by the relatively short time it takes to market a product, and the fact that patents used only to be awarded for seven and half years (Qiming 2005). Despite recent improvements, patent enforcement in China remains a difficult issue, with many Western companies withholding details of their products in their patent registration for fear of fraud. Pfizer, for example, had their patent for Viagra suspended due to allegations that incomplete details of the product had been filed. As a result, 90% of Viagra sold in China is either counterfeit or fake (Mooney 2004).

The UK government, in contrast, is democratic and based on historically constituted laws. Its legislature is made up of a House of Lords, the House of Commons and the Monarch. The prime minister is Chief Executive, and member of commons consists largely of Ministers, some of whom head public departments (such as the health department). The government has established six Knowledge Parks linked to prestigious universities to lead the interface on partnerships, knowledge creation, and other legal, social and ethical issues associated with stem cell research (Milburn 2002). Public accountability for genetics is delivered by a number of formal structures within the

Department of Health and private partnerships with the Wellcome Trust, the Medical Research Council and Commercial Industry. One example is the world's first Bio-Bank, its management overseen by the National Institute for Biological Standards and Control, which opened in April 2003 to hold and make available stem cell lines for research (MRC 2003).

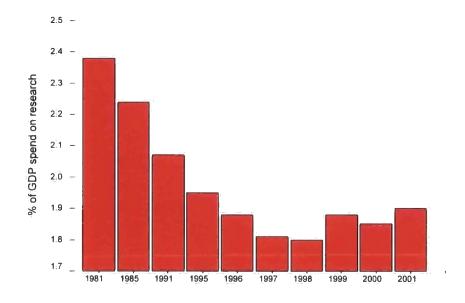
The UK Government has made a number of policy statements in support of stem cell technologies: Investing in Innovation (DTI 2002), the NHS as an Innovative Organisation (DoH 2002) and Our Inheritance: Our Future (DoH 2003). Further, the UK is regarded as a cost effective place to conduct research having a longer cumulative history in the field of genetics than any other country (Best 2005). Its approach to building infrastructure, protocols and capacity means it is consistent with European standards and well placed for the introduction of global standards that are expected in due course (Best 2005). The UK research sector in genetic stem cell technologies is defined by its legislation, regulation, partnerships funding and organisational structures. A new centre devoted to stem cell research was opened at Cambridge University in July 2004 and research at Newcastle University is reported to be producing results. Having taken eggs from eleven women, it has produced therapeutic cloned cells that were a perfect match, thereby eliminating the problems of rejection (BBC 2005).

It is this difference in regulation governing product licensing that varies between countries and explains why Gene Therapy is reported to be available in China, many years before it will be in America and parts of Western Europe (Luck 2004). The UK systems require a stem cell process free from animal products, an understanding of how the technologies work in the human body (Dyers 2003), and a clinical trials process that

takes up to twenty years and a policy assessment by the National Institute of Clinical Excellence (NICE) before any procedure will become available in the UK. To date, NICE has reviewed a small number of genetic technologies offering some insight into how these might be managed in the future. The first, an orthopaedic repair adult stem cell repair 9Chrondracyte Transplantation), was rejected on the basis that there is an adequate alternative in the form of a prosthetic knee replacement (Rafety 2001). The second was the use of herceptin for breast cancer, which was approved subject to the use of a genetic test first to prove susceptibility. The third is islet cell transplantation to cure diabetes where guidance reports the benefits in 2003 to be insufficient to approve (NICE 2003). This has subsequently been approved (NICE 2007).

Innovation Policy for stem cell research in the UK is underpinned by research investment strategies which have in the UK been seen to decline as a proportion of GDP from 2.8 to 1.9% of GDP (OECD 2002).

# Spend on Research in the UK as a % of GDP 1985 to 2001



source OECD

In 1980 eight in ten new discoveries were made in Europe, and now eight out of ten are made in the USA. This historic under-investment in UK research has led to privately-driven investment and ownership of new technologies. An absence of government strategy and investment in public research has also resulted in the majority of genetic research being privately resourced and owned within the US (Caulfield 1998; Graff et al 2003). There is much speculation that these economic factors will drive the private sector to market and supply new genetic technologies (as is already evidenced in the field of genetic predisposition testing) (HGC 2003). The Human Genetic Commission is in favour of appropriate legislation to prevent this (HGC 2003b), but others suggest this would be anticompetitive. The government has yet to decide (DoH 2003).

In July 2004 the UK government indicated its commitment to new genetic technologies, pledging an extra £50m. This covers upgrades to genetic laboratories, support for research trials, research into personalised medicine, and support for a new research centre at Birmingham University (Mednews 2004). In addition, it announced an increase to the science budget from 3.9bn in 2004 to 5bn by 2008 and a target increase in GDP to 3% by 2014 (Brown 2004). Its permissive legislation supported the first European licence for embryo research and therapeutic cloning (MedNews 2004). This was enabled by its comprehensive legislation for genetic research set out in the Human Fertilisation and Embryology Act (1990), which established the license and monitoring of fertility treatments and the creation of embryos for therapeutic cloning. The act also makes legal the creation of human embryos for the purpose of research and to carry out somatic cell nuclear replacement, thereby cloning the donor nucleus. Human Cloning has been explicitly banned under the Human Reproductive Cloning Act of 2001. The

HFEA merged with the Regulatory Authority for Fertilisation and Tissue in 2004 and relaxed the rules on pre-implementation screening for saviour siblings (PHGU 2004).

The Patent Act (1997), in addition to the European Convention and European Directives on legal protection of biotechnological inventions (98/44/EU), set out conditions for registering patents related to genetic discovery. These state that the human body and its elements are not patentable, but those elements that can be isolated from the body may be. It is a complex area of law with many biotechnology companies already staking claims to parts of the human body through patents on human genes, cells, and other tissues for commercial use (Juma 2003). In 1998 the associated human rights were clarified. Article 2 set out the rights to life, Article 3 the freedom for degrading treatment, Article 8 the right to privacy, and Article 14 freedom from discrimination in the enjoyment of these rights (HRA 1998). This developing protection is evidenced by the withdrawal of patent protection for the US giant Myraid in February 2004 (PHGUb 2004)

Genetic products will be within the scope of the Medicines Act (1971), which gives the Committee of Safety of Medicines responsibility for ensuring drug safety. The Medicines Control Agency is responsibility for licensing pharmaceutical products and Medical Devices Agency for medical devices including diagnostic tests. Genetic services and products can also be approved under European Directives on Medical Devices. A product licence is then needed to market from either the European Medication Evaluation Agency (EMEA 1995) (this is an obligatory route for biotech products and treatments related to AIDS, Cancer, neuro-degenerative disease and diabetes) or the Medicines and Healthcare Products Regulatory Agency (MHRA), in which phase one

studies require authorisation for medical products manufactured to good standard. A product must have an identified sponsor to be considered for a clinical trial.

#### Summary

Innovation theory provides a context to study stem cell research between the UK and China, as there are demonstrable comparisons between biological and human systems. From the literature it is shown that NSI affords flexibility in constructing a structure and the opportunities for exploring influence within this. As a relatively new theory, the literature covers a number of approaches, with National Systems of Innovation being chosen for this study because it enables a comparison between two independent nations, it suits a case study approach, and it has a focus on the political and economic systems within which innovation is constructed. This enables national dimensions of the regulatory and research environments for stem cell technologies to be compared whilst also supporting a construct for a framework around which to fit the softer aspects of cultural and societal value. From the literature, the innovation systems in the UK have made a number of significant steps in advancing stem cell research, including permissive legislation, enabling policy, and increased investment. The UK was the first country to approve, under license, the use of human embryos for research and has made a number of policy and investment changes to improve the climate of such work. There are 20 universities involved in stem cell research, three of which are working directly on diabetic issues, in addition to a number of pharmaceutical companies. The underpinned business priority is to reduce morbidity and mortality for diseases such as diabetes.

China also knows the opportunities of stem call science and knows big change leads to big fortune. They want tomorrow's biotech tycoons to speak mandarin (Mann 2003) and are counting on the West's cultural difficulties to build their lead (Mann 2003). Their innovation system is underpinned by a relaxed ethical stance, with many suggesting such advantage will ensure they become a world leader in biotechnologies (Mann 2003; Hsiao 2004). China's innovation structure has a number of obstacles to this, including the reliability of their patent system, reliance of their clinical trials, and the recognition of their scientists (OECDb 2004).

The essence of this research study is to understand which aspects of the National System of Innovation in the UK and China are of advantage to the advance of stem cell science and how these compare with each other. The next chapter will set out the methodological approach used to explore the research question.

# DBA Chapter Three Methodology

#### Introduction

The research question is: how will therapeutic cloning be influenced by the respective National Systems of Innovation in China and the UK using diabetes as a model? The Hypothesis is that the National Innovation Systems in China and the UK will determine the pace of scientific advance and the translation of therapeutic cloning into a clinical service. The null hypothesis is that the innovation systems of China and the UK will not adversely impact the advance of therapeutic cloning.

The questions to be answered are:

- What are the strengths and weaknesses of the National Innovations Systems in the UK and China as they relate to therapeutic cloning?
- How does the National Systems of Innovations in the UK and China influence the translation of stem cell science into the clinical treatment?
- Because of its National System of Innovation, which country will be first to develop a stem cell cure for diabetes?

# **Justification: Policy and Rationale**

Economic performance is widely accepted to be more complex than historic analysis, which focused on labour and capital (HM Treasury 2000). The economist Friedrich List (1841) is said to have been first to make the link between the impacts of technologies on

economic performance. He was critical of classical economists and wrote widely about the influence of science in national growth (Landes 1969 Plummer 2004). Joseph Schumpeter (1883-1953) held similar views, arguing that the Marxist position of capitalism ignored the influence of technological competition, which he believed drives economic advancement (Tidd 2001). Schumpeter went on to define these components as innovation, which he termed as a new combination of existing resources, pointing to case studies as the methodology for studying these (Tidd et al 2001). Robert Slow advanced the study of innovation, demonstrating that 87% of GDP growth in the US is attributed to technological change. Innovation, he showed, was the embodiment of knowledge into a physical form of technology (Feldman 2004), with sustainable economic growth shown to rely on this (Branscomb Auerswald 2002).

Stem Cell science is one area of biotechnology said to make the largest contribution to economic growth and therefore impact on innovation (European Commission 2001; OECDa 2004). This sector includes genetically modified food, advances in new knowledge-based industries, and a contribution to world health. Genetic science is one aspect, and it is the part on which this research is focused. This is distinguished from all other technologies by its potential to revolutionise the treatment and management of human disease (Spink el at 2004). It offers the potential for personalised medication to create new therapies to cure disease and, in time, to re-grow or repair organs (BBC 2007). It is a competitive and controversial area of science, made more so by the recent use of human embryos in its research techniques. In the UK this became legal in 2004, raising fresh debate to concerns of eugenics, abuse of knowledge, and societal division. China began this work in 1999 with no such concern (Yank 2004). The difference in the Western world is based around concerns of biological warfare, the destruction of human

life and the unknown consequence for future generations caused by manipulated mutations of cell structures. There is no way of knowing how a mutated cell will behave in future generations, and therefore no absolute guarantee of safety.

In the UK, many of these concerns are speculative since the majority of therapeutic cloning is limited to animal models. There are currently two research teams working on human embryos under licence at the Newcastle Life Sciences and Kings College London. Whilst in China, the use of human embryos, primates and aborted foetuses are widely used in stem cell research, which advanced to human trials commencing in February 2005. Cancer is expected to be the first clinical area to benefit from stem cell research; indeed China is reported to have announced success in the world's first cure for solid tumours in 2004 using gene therapy (Pearson Jia Kandachi 2004). Diabetes, in comparison, is a complex disease, positioned as a research priority due to its international prevalence and unprecedented growth rates evidenced over the last decade. Prevalence has doubled in the last eight years, and is predicted to affect 333m people by 2025. It already consumes between 2 and 15% of a country's total health budget depending on the interventions available, with associated economic loss put at five times the financial one (WHO 2002).

The justification for this research is therefore part economic and part social. Genetic science affords untold economic and social advantage from the research underway for a stem cell cure for many common diseases, including cancer, heart disease and diabetes (Thomas 2006).

# **Theoretical Approach to Research**

The business problem is how the National Innovation Systems of the UK and China will influence the goal of securing a stem cure for diabetes. This research has an objectivist approach, an ontology position of realism and a positivist epistemology, requiring a structured theoretical approach (Burrell & Morgan 1997). These assume the world to be tangible, and that it may be interpreted and explained. Assumptions about the environment are deterministic, believing the environment itself to be involved in the creation of what is perceived. The research is functionalist, objective, and seeks to explain. It assumes the world is managed, definable, that nature works to ordered principles, and that it can be understood and manipulated. Indeed, the very essence of genetic science supports these principles as it seeks to interpret and influence the order of nature by controlling the mutation in cell division to selected advantage.

This is a social research study and, as such, it comprises qualitative research methods, which is an umbrella term covering a range of techniques that seek to describe, code, translate, and provide an interpretation of meaning (Cassell 1999). Its epistemological and theoretical stance is interpretive and deductive, with meaning being ascribed from the data collected, emergent themes, and idiographic description. Methodologies include questionnaires, interviews, focus groups, and interpreting text. It can be distinguished from empirical methods in using language as its main communication and measure, which gives rise to a number of criticisms. Miller (1997) suggests its measures are often elusive, with Hawkins (2001) adding a lack of precision and definition, researcher bias (Frost 1992 Silverman 2002), and data production, which is less objective (McCarl 1990).

Silverman identifies its separation from theory, its limited measures, and a lack of transference. The main advantages of qualitative research methodologies are in enabling a social context and its use of methods, which are inclusive and study people in a natural setting. With the aim of research, whether qualitative or quantitative, being analytical integrity, McCarl (1990) argues it is the outcomes that are important. The concerns can be mitigated somewhat by a number of strategies. In using interviews, Silverman (1993) cautions the interpretation of what is actually being said because language is historic, figurative, specialised, interpretive, culturally transmitted and encoded (Coffee 1997). Questionnaires, which May (2001) argues are imprecise, can, it is suggested, be strengthened by pre-testing and triangulation of data (Miller 1997). Silverman (2002) suggests the researcher, being aware of his position in the design of the study, can address the issue of bias. The importance of consistency and loss of data in the questions can be assisted too by pre-testing (Lowe 1993; Silverman 2002). Researchers can also be trained to be aware of personal bias, can use an open systematic approach and use different methods of data collection (Miller 1997).

The theoretical basis in this work is the National Systems of Innovation (NSI) theory, chosen for two unique characteristics. The first is its relationship to historic understanding, where the events of the past are reviewed in order to understand the opportunities of the future. The second is an inherent assertion in its ontology that linear methods of prediction are insufficient and there needs instead to be an understanding of the related components (Freeman 1997; Fagerberg 2004). This second feature of National Systems of Innovation requires a definition of a boundary and identification of the important features within it. National Systems of Innovation is a relatively new theory based on the work of Freeman (1987) with its origins said to be

from new-growth theory. Its most notable feature is described by Edquist (1997) when he summarised its approach as being more like a series of related assumptions than an empirical framework within which to place research. This lack of formal structure offers an opportunity to shape its design and relates directly to the research question. Indeed the flexibility of its design is argued by many to encourage new and different innovation approaches, thereby affording new areas and opportunities for its use (Storper and Harrison 1999; Ludvall 2003; Fagerberg 2004). The challenge of this approach, for this research, is that all the components (including the research topic), access to data, and the theoretical design make new contributions to knowledge.

# Research Design

There are a number of views in the literature directing the structure of an innovations study (in this case, looking at China from a UK perspective). In part, these depend on the area of innovation being considered and the level of its development or implementation. This work looks at the innovations structure at a national level for the UK and China, from a UK perspective, in stem cell technologies (specifically, therapeutic cloning), and takes a number of propositions in its design from the existing research material. A case study approach is to be used, as suggested by Schumpter (1934), underpinned by a framework to capture and explain the key relationships in the study as recommended by Carr (1984), Edquist (1997), Freeman (1997), Fagerberg (2004), and Mina et al (2004). There is no single approach to define a framework to explore innovation, so the literature suggests using the problem to define the boundaries. The literature also suggests that not all the components of the problem need to be included, but the boundaries and relationships within it must be defined (Fagerberg 2004). The validity of this approach is taken from the economic design of national innovation policy,

which requires these descriptions to be more than geographically delineated and to explain the relationship nationally constructed and the power so attached (Fagerberg 2004). The strength of this is said to be in capturing patterns of specialisation and innovativeness, its weakness being its broad generalisation.

In this work the framework is designed to capture the core factors of innovation as they related to the research area of therapeutic cloning. The framework also describes the boundaries of this work and the relationships within it. In this study the core aspects of the related innovation are:

- Political Context
- Government Legislation and Regulation
- Research Investment
- Intellectual Property Regulation
- Public opinion, culture, ethics
- Demography/morbidity and mortality history and trends
- Current Treatments or Diabetes
- Economic Performance
- Research Underway/evidence
- Current knowledge/evidence to date

In defining the framework, the boundaries are set by the respective regulation and legislation for therapeutic cloning at a National level. These cover the range of permissible stem cell research within the UK and China and an examination of progress as this relates to diabetes. The financial structure will be defined by research

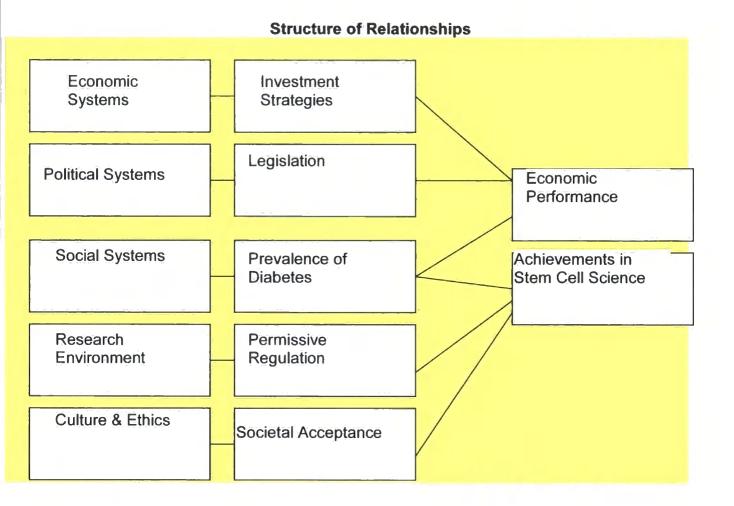
investment and the relationship with economic performance and demography, whilst the societal boundary will be set by public position and culture. Research evidence, historic economic performance, morbidity and mortality trends, workforce and culture for therapeutic cloning will be explored within the boundary of permissible legislation. This is set out in the table below, which also indicates the research methods proposed to collect the supporting data.

	Data Table 1990-2002	Public Questionnaire	Researchers Interviews
Economic Performance		Questionnaire	
GDP	X		
Trade in Goods and Services	X		
Inflation	X		
Balance of Payments	X		
Spend on Education	X		
Spend on Health	X		
Spend on Research	X.		
Political Influence			
Legislation		X	
Regulation		X	X
Investment Strategies	X	X	X
Patents	A	X	X
Social			
Population Size	X		
Prevalence and trends in diabetes	X		
Treatment Regimes		X	
Workforce	X		
Research			
Spend on Research	X	X	
Research Underway	The state of the s	A	X
Evidence to-date		X	X
Computer Ownership (proxy for technology)	X		X
Culture			1
Current Knowledge		X	
Investment in research		X	
Opinions on therapeutic cloning		X	
Ethical Stance		X	X

The structure of this table incorporates advice from Edquist (1997) to place innovation at the centre, as it is holistic, interdisciplinary, and enables the interdependencies and non-linear relationships in the data to be explored. Edquist recommends an historical perspective, which is reflected in the economic analysis from 1990 to 2002. This approach reflects that recommended by Fagerberg (2004), who suggests the inclusion of R&D, the impact of innovation on legislation and regulation, and the relationship

between economic and social performance. Hollander (1965) and Fagerberg (2004) also recommend the inclusion of workforce, the impact of knowledge (Plummer 2004), and a context that is real-time (Tidd 2001). The overall unit of analysis are the national boundaries of the UK and China (Edquist). Tidd (2001) recommends that the process that puts innovation into practice is included in the study. As therapeutic cloning has not yet advanced to service transfer, this is taken to cover the ethical context, clinical trials regulation, and legislation of the actual research. Validation of this research construct can be taken from work led by Professor Salter in his policy study using Innovations Systems between the UK and China (EESCN 2007), although he started three years after this study began. The structure he has used for his research is similar, providing further validity to this approach.

The relationship of the research design is set out diagrammatically below. This shows the independent variables and the main factors of innovation at a national level. These are the economic and social systems that set the context in each country for stem cell research and are moderated by the influences of a number of performance areas including the economy, investment strategies, and societal boundaries of acceptance. The outputs in the final column are the influence on economic performance and its achievements in stem cell science.



# **Data Capture**

Data against this framework will be collected from three sources. The first is economic and demographic data for the UK and China collected between 1990 and 2002. This includes population data, economic performance (including GDP spends on education), health research, and morbidity trends in the area of diabetes. These data sources will be used to provide trend and correlation analysis. Sources of trend data for China is not easily available, but this study will aim to build this profile, as the national economic context is an essential component of the framework of innovation for therapeutic cloning. This part of the work will be looking to explore the relative strengths and weaknesses over time of the economic structures that underpin research

investment and structure at a national level. This will include:

- Research spend and trends
- · Patents registration and trends
- Education spend and trends
- Cost of health care and trends
- Clinical staff and trends
- Economic performance in terms of trade, balance of payments, and inflation
- Historic and predicted levels of diabetes
- Morbidity trends for diabetes
- Population growth

(A summary of the data table is set out in appendix D)

The second area of data capture is to survey the general population to gain data on those areas of the research question where there is no existing data source. The focus for this view is within the UK population, as access to people in China was unfortunately unsuccessful. This approach covers many of the softer interpretations of the public's current knowledge of genetics and their opinions on what they believe to be acceptable and unacceptable in stem cell research. The population groups will be distinguished by ethnic origins, gender, age, employment status, and whether they or a family member are diabetic. The questions cover the areas of government investment in research, views about access to new stem cell technologies and questions to gain an ethical context to their opinion. The questionnaire will be piloted first on a sample of thirty to check the validity of the questions. The full study aims to get two hundred returned questionnaires. A copy of the questionnaires is attached as Appendix A with a summary of the areas it covers set out below:

**Classification Questions** Context : Questions (10) **Boundary Questions (4)** Gender Views & Knowledge on: Gov spending on Research Religious beliefs Cloning and stem cell research Stem Cell Research Diabetic status Age Chinese Research Occupation **Human Cloning** Licensing Cure for Cancer Potential Impact Questions (3) **Knowledge Created Questions (2)** Relationship to Existing Services (1) Impact of genetics Views on investment and embryo research Replacing existing therapies Affording new technologies Risks (3) Incentive Questions (5) **Ethical Questions (4)** Timeline Motivation in UK Views on embryo research Access on the NHS Use of Internet Pace of change and ethical stance of population Becoming available abroad first Views on genetic tests Going abroad for treatment Concerns about treatment abroad **Acceptance Questions (2)** Legislative Questions (4) Views of potential outcomes Discoveries and access to technologies Who will lead discovery

The target population for the questionnaire is the general population, including sixth form college students, university students, a stakeholder group for diabetes, magistrates, gym members, office workers, clinicians, the unemployed or retired, and senior managers. The groups selected aim to cover a spectrum of the population between the ages of 16 and 70 within definable population groups. Magistrates are, for example, considered to be a fair cross-representation of the adult population. The stakeholder reference group for diabetes is representative on the disease area. Gym members are generally considered to be the fittest society members, and each of the other groups offer an alternative view for three employment areas.

The third component of this work involves researching all the current biotech companies involved with stem cell research in the UK and China, identifying those specifically involved in diabetic research. A similar approach will be taken in researching the institutional arrangements in China. The aim is to access views of researchers in the political, research, and ethical environment in which they work. A detailed search across

published literature, research institutions, universities, and commerce will be undertaken to build a directory of these, including contacts and emails. Contact will be made electronically with the aim of collecting idiographic responses in the following areas:

- The advantages and disadvantages of their current research environment
- · Views of their legislative framework, including patents
- Will China lead in producing a cure for diabetes?
- Is the ethical stance of the East a substantial advantage?
- Will people go abroad for treatment if it is not available in the UK?

#### Statistical Analysis of Data

The data collected from these three approaches will be both qualitative and quantitative. The questionnaire will be translated into numerical values depending on the answers and analysed to show themes and their relationships to variables such as age, gender and prior genetic condition. A Likart scale of 5 will be used and the questions closed. The pilot sample will be reused in the final questionnaire to provide a reliability test and compare validity. T-tests will be used to explore differences between genders. The questions will be closed.

The hypothesis to be tested in the statistical data is:

 The UK is stronger in the core economic components of its National System of Innovation covering GDP, trade, inflation, spend on research, health and education, and balance of payment.

- The National System of Innovation does not influence the advance of stem cell science
- UK will be first to produce a stem cell cure for diabetes

The data will be checked initially for distribution and normality. Cronbach's co-efficient alpha will be used to test consistency in the measurements between items. Pearson Correlation will be used to measure the relationship between the variables and measure the strength of relationship as one variable increases. Multiple regression will be used to test the size and strength of the mean in comparing the data for the UK and China against each other with an Independent T-test and Levene's test used to measure equity of variance.

The third area of this analysis gathers opinion from research and policy leaders in the field of stem cell science about the national boundaries, their research work, views on legislation including patents, and ultimately their views on the respective opportunities between the UK and China in therapeutic cloning.

#### **Limits of Research**

There are many limits and risks associated with this research. This area of research is new and there is no obvious existing research study with which to compare this.

Collecting economic data over time to assess its innovation structure is not straightforward, as data of the range required is not readily available for China. Data since 2002 is, however, easier to find since China joined the World Health Organisation. In China there is very little certification of death, therefore statistics for the prevalence

and mortality from diabetes are not available (Yang et al 2005). The difficulties of economic data are also evident in the policy work of Professor Salter (East of England 2007). There are a number of research papers that have estimated prevalence rates, and these will be used to estimate numbers (Li et al 2005). Economic data for China on a trend basis is not routinely available, but through the search of databases and research papers, the figures will be collected and pieced together. The economic data will be translated into US\$ to enable comparison.

The second challenge will be succeeding in getting the questionnaire completed, as previous research of this nature has shown a reluctance of people to provide this information (Nuffield Council 2003). Access to the Chinese population has been unsuccessful despite two attempts. Contacting Chinese researchers that are not based in the UK has also been made more difficult by Korean fraud and the reluctance now of many Eastern scientists to discuss their work. Other limits include the focus area of innovation being therapeutic cloning, which is in the research stage itself. This work is further limited in its focus on diabetes. Stem Cell research is underway in a number of other clinical areas including heart disease, Parkinson's, Osteoporosis and cancer. Although success is predicted in some of these areas before diabetes, it has been selected, as explained earlier, as its prevalence rates make it a greater threat to human health now than heart disease (BHFS 2004).

The research design is constructed using existing research in NSI theory. Using a case study model, the data is to be collected from three sources to form a picture of the national factors of innovation between the UK and China in the area of therapeutic cloning research. These data sources are new, but together they provide the detail at a

national level of the major factors influencing therapeutic cloning research. The justification of the core areas has been taken from the theory, and it covers the political and economic structures, social, cultural and existing research (Edquist 1997; Freeman 1997; Fagerberg 2004).

This research is planed (planned?) in three parts. Together they explore the influence of the National Innovations Systems in the UK and China on therapeutic cloning. The hypothesis is that National Innovation Systems in China and the UK will determine the pace of scientific advance and the translation of therapeutic cloning into a clinical service in the area of diabetes. The null hypothesis is that the innovation systems of China and the UK will not have an impact on the outcome of therapeutic cloning in the clinical area of diabetes.

#### Part One: Public Questionnaire

The questionnaire was piloted on a sample of 70 people, with 34 providing a return. The pilot covered 11 males and 23 females within an age range of 14 to 77. The mean age was 33. It was constructed to take ten minutes to complete, and to capture opinion and knowledge at a particular moment in time. The pilot was used to test the validity of the questions, identify outliers in the analysis, and gain an estimate of the likely level of response, as advised in the qualitative literature (Miller 1997 May 2001 Silverman 2002). The sample was constructed from students and their families at Essex University. In returning the questionnaire, some people indicated their discomfort with the content, which fits with the experience of other social researchers in genetics (Nuffield Trust 2002).

The results were tested in a number of ways to check both the validity of the questions and the ability of the data collected to answer the research question. Reliability analysis showed all minimum and maximum values to be within an expected range for the 39 questions and six categorical questions around gender, occupation, age, health and nationality. Preliminary analysis was used to describe the characteristics of the data, as well as to check variables for violation, frequency, descriptive and explore. Descriptive analysis was used to review the range, mean and standard deviation and explore were used to assess normality. All the questions in the pilot scored above 0.05, confirming normality in their Kolmogorov-Sminov score. The Cronbach's alpha coefficient score was 0.8595; confirming reliability of the scale for the questions and that none of them violated the reliability test, confirming good internal consistency and validity (Pavot, Diener, Colvin and Sandvik 1991).

Correlation was used to test the value and contributed to the overall score of each question, with all found to have a value over 0.3, confirming consistency of the questions within the scale. Finally, histograms were used, as recommended by Gravelter and Wallnow (2000), to explore the distribution of the responses. These are set out in Appendix B. From these it can be seen that the pilot cohort believed strongly that Dolly was the first cloned creature, that human cloning was illegal, and uncertainty about whether or not the UK led the world in stem cell science. They did believe the UK government spent enough on research, had a strong legislative framework, and that ethical concern will slow progress.

Although the pilot is too small to draw any substantive conclusions, it did show consensus that stem cell therapies will be available in the UK within ten years for

diabetes and that such therapies would be available abroad first. There was agreement that embryo research would lead to cures for human disease that genetic discoveries should be available on the Internet, that finding a cure for diabetes is worth the financial investment, but that ethical concerns in the UK will slow progress. There was no consensus on whether there should be more human embryo centres in the UK or if genetic discoveries and tests should be available on the Internet. Neither was there agreement on whether the creation of embryos for research in order to find a cure for diabetes was worthwhile or essential. The pilot cohort had the widest variation in answering whether they would go abroad for stem cell treatment not available in the UK.

#### Questionnaire

The final questionnaire was revised following the pilot to include categorical data on occupation, origin, religious beliefs, and genetic diseases other than diabetes. A number of questions were also rephrased. The target population for the final questionnaire includes sixth form college students, university students, a stakeholder group for diabetes, magistrates, gym members, office workers, clinicians, unemployed, retired professionals, and non-professionals. This aims to cover a spectrum of the population aged 16 to 70 within definable population groups. An application was made to the NHS North Essex Ethics Committee to allow the inclusion of NHS staff and clinicians in this study, but this was rejected on the basis that this study was not considered suitably focused on the NHS.

From a distribution of 400, 157 questionnaires were returned. The age ranged from 17 to 78 with a mean of 41.66. Every age between 16 and 70 was represented. Of these, eleven people are diabetic and nine indicated they had another genetic illness. Forty-

nine said they have a family member who is diabetic, and thirty-four that a family member had another genetic illness. The population who responded were evenly split in terms of religious beliefs, with 73 indicating they had such beliefs. In terms of occupation, there are 22 students, 10 clinicians, 48 other professionals, 34 non-professionals, and 43 others. The majority of responses are from people of British nationality (144), with two Americans, four Europeans and seven others.

Without taking these categorisations into account, the basic data for the entire population shows:

- · Half of the people believe Dolly was the first animal cloned
- More than half are not sure if the UK leads the world in stem cell research or whether China was first to clone a fish
- Almost 80% know human cloning is illegal in the UK but almost 60% were not sure if it was legal in China, with 50% believing therapeutic cloning to be illegal in the UK. Almost 70% knew human embryo research is legal in the UK, suggesting an issue of terminology
- Nearly 70% were not sure if the UK had the world's first licence for therapeutic cloning, although 49.4% said the UK is highly motivated in new innovations
- Over 60% did not believe that China has produced a gene therapy cure for solid cancer tumours and 73% do not believe China will lead a cure for diabetes
- 75.8% agree that genetic advances will cure existing diseases, but only 48.7 that
  it will find a cure for diabetes, with 65.4% saying the cure for diabetes will be
  found in the UK and 14.8% saying China. 32.7% believe such advances will not
  be available on the NHS

- 60.2% do not think the UK government spends enough on research, 48.7%
   believing it spends less than other countries, although 34.4% think the amount spent has increased in recent years. 57.1% say the UK needs to spend more on stem cell research
- 53.2% say the UK has a strong legislative framework for stem cells but that more centres should be licensed
- 69.9% say genetic discoveries should be accessible over the internet but only
   29.1% said they would use the internet in this way
- 43.6% agree that the creation of human embryos for research is worthwhile to cure diabetes, increasing to 63.2% who believe such advances will be available abroad first
- 47.4% had no opinion on whether such potential cures would reduce the availability of existing therapies
- 58.3% had no view on whether such advances would happen in the next ten years, with 29.5% believing a cure for diabetes would be found within this time
- 70.05% of people said they would go abroad for treatment that was not available
  in the UK, although 35.3% said they would have some concerns about this
  approach
- 56.5% agree human embryo research is essential to finding cures for existing diseases, but only 28.2% believe these are the views of the UK population
- 87.5% believe the ethical concerns in the UK will slow progress
- 52.3% support the use of patents as essential to this area of science

# **Summary of Responses**

Questions		True	False	Not Sure	<u> </u>
Dolly the sheep was the first animal cloned		49	31.8	19.1	<del></del>
The UK lead the world in stem cell research		17.8	28.7	53.5	
China cloned a fish 30 years before Dolly	-	21	19.7	59.2	
Human cloning is illegal in the UK		79.6	10.2	0.6	
	_				<del>_</del>
Human Cloning is legal in China		19.1	22.3	58.6	
The UK has the world's first licence for therapeutic cloning		15.9	15.3	68.2	
China has produced a gene therapy cure for cancer		9.6	28	62.4	
China will lead the world in producing a cure for diabetes		13.5	12.8	73.1	
Therapeutic cloning is legal in the UK		28.2	22.4	48.7	
Human embryo research is legal in the UK under licence		67.9	9	18.6	
	Strong				Ctrongly
			No		Strongly
	Agree	Agree	•		Disagree
The UK government spends enough on research	3.2	12.8	23.7	44.2	16
UK spend on research has increased in recent years	3.8	30.6	41	21.8	2.6
UK government spends as much as other countries	3.2	12.8	35.3	44.2	4.5
UK government needs to spend more on stem cell	12.2	44.9	33.3	9.6	0
UK has a strong legislative framework for stem cell	8.3	44.9	32.7	13.5	0.6
More centres (should?)be allowed to carry out human embryo	9.6	44.9	20.5	21.8	3.2
Genetic discoveries should be available on the internet	19.9	50	10.3	15.4	4.5
Human embryo research will cure existing disease	15.4	60.3	21.2	3.2	0
Human embryo research will cure diabetes	5.8	42.9	46.8	4.5	0
A potential cure for diabetes will?not be affordable on the NHS	6.4	32.7	39.1	19.2	2.6
Curing diabetes is worth creating embryos	12.8	43.6	21.2	17.9	4.5
A stem cell cure would replace existing diabetic therapies	7.1	31.4	47.4	12.8	1.3
A stem cell cure for diabetes will be available in 10 years	1.3	28.2	58.3	11.5	0.5
Stem cell therapy for diabetes will not be available on NHS	3.8	37.2	32.1	25.6	1.3
Stem cell therapies will be available abroad before UK	11	63.2	23.9	1.9	0
The UK is highly motivated to find new innovations	5.8	49.4	22.4	20.5	1.0
I use the internet to find out about health abroad	5.2	23.9	20.6	38.1	12.3

**DBA Final November 2008** 

I would buy genetic tests using the internet		19.9	14.1	41	22.4
I would go abroad for treatments not available in the UK	15.4	55.1	14.1	14.1	1.3
No concerns accessing stem cells treatment abroad	7.1	28.2	18.6	37.8	8.3
Human embryo research essential to cure disease	10.3	46.2	24.4	16.7	2.6
UK population supports human embryo research	1.9	26.3	32.7	35.3	3.8
Ethical concerns will slow progress in the UK	9.6	67.9	12.2	9.6	0.6
Patent registration is essential to support discovery	11	41.3	33.5	12.9	1.3
Human embryo research will find a cure for diabetes	4.5	44.2	45.5	5.8	0
The UK will be first to cure diabetes	6.4	59	32.7	1.9	0
China will be the first country to cure diabetes	2.6	12.2	75	10.3	0

The answers for people that are diabetic show that most did not know if therapeutic cloning is legal in the UK, and that most agree that there should be more centres undertaking embryo research and that genetic discoveries need to be available on the internet. They didn't think the UK government spends enough on research or that it spends as much as other countries and they had no opinion about whether such spend has increased. They did believe more money needs to be spent on stem cell research and that such research is essential. They are not sure if therapeutic cloning will cure diabetes or if a cure will be found within the next ten years, and, if so, whether such a cure would be available on the NHS. They believe ethical concerns in the UK will slow progress, although they agree that there is strong motivation to find new innovations. If, however, a cure were found, they believe it would be available abroad first but that they would not be willing to travel to access this. Indeed they would have concerns about therapeutic cloning abroad. They would not use the Internet to find out about this or any genetic tests that may become available. They agree patents are necessary in this area of science and have no view on whether China will lead in a cure for diabetes.

#### **Analysis of Variance between Categories**

One-way Anova was used to establish if any of the answers between the various categories showed a statistically significant variance (with regards to age, status, gender, occupation and health).

#### **Diabetes**

Homogeneity of variance is above 0.05 and therefore does not violate the required assumptions for this test. For the people with diabetes, variance of mean scores was found in the following questions:

- When a stem cell cure is available for diabetes it will not be available on the NHS (0.012)
- The first country to cure diabetes will be China (0.04)
- Embryo stem cell research will find a cure for diabetes
- Finding a cure for diabetes is worth the creation of human embryos for research

The test of variance was then applied to those with a family member with diabetes. This found variance of mean in the following questions:

- The amount the UK government spends on research has increased in recent years (0.036)
- Human embryo research in time will produce a cure for diabetes (0.025)
- A stem cell cure would replace existing therapy for diabetes (0.025)
- Embryo stem cell research will find a cure for diabetes (0.002)

These results show that people with diabetes are far more optimistic about the leadership of China in finding a cure for diabetes through therapeutic cloning than the rest of the population group, who strongly believe it will be the UK. Both people with diabetes and those who have a family member living with the disease believe more

strongly than the rest that human embryo stem cell research will produce a cure for diabetes. Those with diabetes also believe more strongly that the creation of embryos for such research is worthwhile. They do not believe the potential cure will be available in the UK.

Variance of mean was then carried out on the results for people with other genetic illnesses. The only difference statistically shown in this category was that they believed more strongly than the main cohort that the UK spends as much on research as other countries (0.019). Interestingly, when this was carried out on those with a family member with a genetic illness other than diabetes, they believe more strongly (like those with diabetes) that China will be first to find a stem cell cure for diabetes. Variance of mean test was applied to those with a religious belief where two questions were found to be outliers to the main population. These were that human embryo research is legal in the UK, suggesting that people with religious beliefs know less about what is legal in terms of embryo research. The second area related to the use of patents to protect discoveries, suggesting this group is less supportive of the patenting of such material.

Variance was then tested by occupation. In this group there were:

- Student=22
- Clinical=10
- Other professional=48
- Non-professional=34
- Other= 43

The variation in occupation was knowing whether human embryo cloning is illegal in the UK (0.032) and whether stem cell therapies will be available in the clinical area of

diabetes within ten years (0.036). In terms of nationality, the only question which had a variance was whether stem cell therapies would be available abroad before becoming available in the UK (0.013).

Half of people responding said the UK has a strong legislative framework for therapeutic cloning but more centres should be licensed to undertake this research. Nearly two thirds do not think the UK government spends enough on research and needs to spend more on stem cell research. Half believe other countries spend more, with only one third saying the UK had increased spend in recent years. Just over half of people believed the patenting of discoveries in this area were necessary. In terms of current knowledge about genetics, half believed Dolly was the first animal cloned, but over half were not sure whether China had cloned a fish. Most did not think China had cured solid cancer tumours or that it would find a cure for diabetes. Most people, however, knew human cloning was illegal in the UK but were not sure if it was permitted in China. Occupation was shown to make a statistical variation in knowledge about stem cell legislation.

Just over half of the respondents believe human embryo research in the UK is essential to finding cures for existing diseases, but less than a third believe this to be the universal view of the UK population. Two-thirds say genetic tests should be available over the Internet, but less than one third said they would access genetic tests via the Internet. Over 70% of people said they would go abroad for stem cell treatments that were not available in the UK, although half of these said they would have some concern in doing this. Only one third of people believe there will be a cure for diabetes in the next ten years, with almost 90% of people saying the ethical concerns in the UK will slow progress. Only 43% of people in the UK believe the creation of human embryos for

research is worthwhile. However, people with diabetes or those with family members with other genetic illnesses do believe China will lead the world in advancing a cure.

Relating these findings to the factors of innovations, they show the political structure covering legislation and regulation in the UK to be strong, although China's systems are considered by the UK population to be less so. There is support for the patent system in this area, but people with religious beliefs are less supportive. Investment strategies for stem cell research are thought to be weak compared to those of other countries with more resources for stem cell work, and these strategies are said to be needed in the UK. Only half of those surveyed support the use of human embryos in therapeutic cloning research. Only 15% believe China will lead the world in curing diabetes, although people with diabetes or with a family member with other genetic illnesses are shown statistically to believe that China will be successful.

Part Two: Economic Analysis

#### Introduction

This second part of the analysis involves a comparison of the economic performance of the National Innovation System between the UK and China. This work is measured against data collected for the UK and China on economic performance, workforce trends, health spend, prevalence of diabetes, and computer ownership, constructed in a time series from 1990 to 2002. These factors form the economic influence to the development of therapeutic cloning at a national level. The data is also transposed into a categorical form between the UK and China to enable additional comparison. The aim of this section is to explore the first part of the research question and provide an understanding of the relative strengths of the economic aspect of the National Innovation

Systems in the UK and China.

The data is constructed using SPSS for 1990 to 2002 from a search of a range of literature and database sites across the UK and China. Two areas where trend data could not be found were the cost of treating diabetes in both countries and patent registrations in China for some dates. Data on diabetes has only recently been attributed in this way in the UK and, in China, where treatment is limited for many, it has not been collected. The second area was for patent registrations between 1990 and 1995 in China. The statistical tests take account of missing data and treatment costs were excluded from the analysis. All the financial data were transposed to US dollars (the values are included in the table) to enable comparison between the UK and China.

#### Included in Spreadsheet

- Year
- Population
- Number with diabetes
- Percent of Population with diabetes
- Cost of diabetes (only 2002 data)
- · GDP growth as a percent
- Total NHS Spend
- GDP spend on health
- Health spend per head of population
- GDP per head of population
- Total value of GDP in US\$
- · Percent of heath spend that is private and from government
- Total health spend in US\$
- Spend on research as % of GDP
- Total value of research spend in US\$
- Number of doctors
- Number of nurses
- Number of researchers
- Number of patent registrations

- Balance of payments in US\$
- Change in trade position year on year
- Total value of trade
- Inflation
- Spend on education as % of GDP and total value in US\$
- Ownership of computers per 1000 population
- Import and export values as % of GDP

## **Preliminary Analysis**

The data were analysed to check the symmetry of its distribution (skewness), peakedness (kurtosis), and to check normality in its distribution. The trend data ranged between seven samples in the case of Chinese patents to twenty samples in relation to population and trend. These numbers are small, and therefore kurtosis is expected to be flat. High kurtosis can result in an underestimate of variance (Tabachnick and Fidel 1996). For all the indicators, the Kolmogovor-Smirov levels are over 0.005, indicating normal distribution. Explore was then used to review the probability plots for the data. The data is plotted against a line of normal distribution, which is for all the data except the number of doctors and nurses in the UK. The reasons for this appears to be two long periods of very slow growth followed by a period of significant increase, most notably in nurses. The preliminary analysis is set out in Appendices G and H.

Reliability Analysis (ALPHA) was used to check the reliability of the scale to ensure the same underlying construct is being measured. The Cronbach's alpha coefficient score - when taking the data for the UK and China for populations, total spends on research and education, numbers with diabetes and total spend on health - is 0.8353. As this is over 0.7, the internal consistency is confirmed. The alpha value when reviewing the UK data for total population, numbers with diabetes, GDP, NHS spend, total spend on health, percentage of health spend by government, numbers of doctors and nurses, patent

registration, balance of payment, total trade, inflation, import, exports, spend on education, and total spend on research is 0.7636, again confirming consistency in the data. For China, corresponding measures show the alpha score for total population, the numbers with diabetes, health spend, total spend on research and education, total GDP, exports and imports, doctors nurses, inflation, and balance of payments to be 0.7256. These tests collectively confirm the dataset to be normal and reliable.

Graphs were used to investigate the size and trend shapes for the economic factors on innovation in the UK and China as set out in Appendix D. This show:

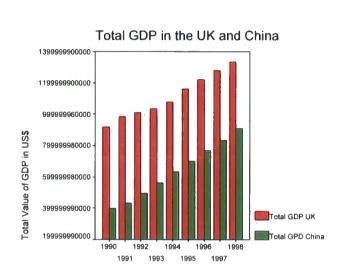
- China has a declining population compared to growth in the UK.
- Diabetes has increased rapidly in both countries but more notably in China
- Health spend has increased in both countries most significantly since 1996 in China
- Private health spend has increased four-fold in China and remained consistent in the UK
- Total value of GDP is now equal in both countries
- Total spend on research has increased five-fold in China to about one-third that of the UK
- Spend on research as a % of GDP has risen to 1.5% in China and 1.9% in the UK
- GDP growth has been around 8% in China and between -2 to 4% in the UK
- Doctor numbers. have increased in China while the number of nurses has decreased
- Doctor numbers have been constant in the UK with a substantial increase in nurses

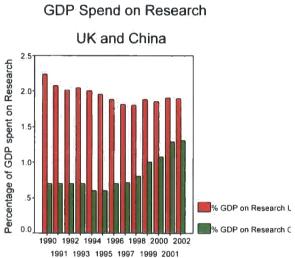
- BofP has improved substantially in China and remains negative in the UK
- Inflation in both countries has been volatile, with China reaching 24% in the mid
   90's and reducing this down to 2%. The UK has gone from 9% in 1990 to 3.5% in
   2004
- GDP spend on education has increased in China and both are now around 5%
- Total value of GDP has risen rapidly but most significantly in China
- Ownership of Computers has risen ten-fold in China to be half that of the UK

For China, these indicate a strong economic context for stem cell research, having low inflation, strong GDP growth of 8% annually, a positive balance of payment, an increase in education to 5% of GDP, and research investment, which has doubled against GDP in the last 12 years. These translate to growth in available research funds and a prosperous environment to enable stem cell research. The economic framework for the UK shows spend on education is equal to that in China, as is the total value of GDP. Total research spends as a proportion of GDP has fallen from 2.24% in 1990 to 1.98 in 2003. Balance of payments is negative and GDP growth varied between 2% and 4%. Computer ownership, taken as a proxy for technology, is still twice that for China despite their ten-fold increase.

The population of China is seen to be slowing by the shape of the curve in the graph. The prevalence of diabetes has doubled in both countries, with over 40 million people now affected in China. Spend on health has increased in China following a massive fall in the early 1990's culminating in a drop to only 2.7% of GDP in 1996. The increase in the following years is due to private investment, resulting in only 41% of spend now provided by the government. UK health spend, in contrast, has seen a massive increase in government contribution from 6% of GDP in 1990 to 7.7% in 2003, with a

projection of 9.2% to be achieved by 2010. Total spend on research in China has increased four-fold in terms of actual spend and doubled as a percent of GDP. The UK still spends more on research than China, but the proportion of GDP is increasing rapidly (though this remains 0.5%, below that of the UK). GDP performance over the time period has seen the most marked and consistent change in China where growth has averaged 8% compared to 2.5% in the UK.

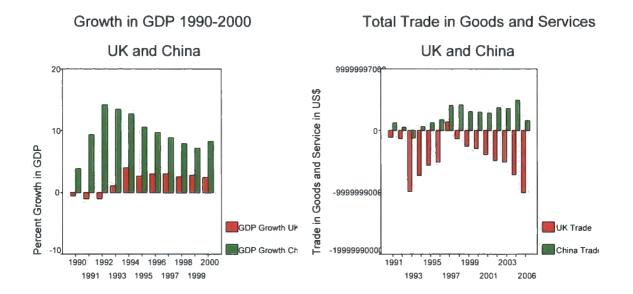




In relation to workforce, the number of doctors has grown by 35.7% in the UK compared to 18.3% in China, and 5.9% for nurses compared to 29.25% in the UK. Chinese balance of payments and trade in goods and services have increased rapidly since the mid 1990's.

The UK has seen major increases in both these indicators, but overall performance in each is negatively balanced. Inflation is shown to have been most volatile in China, reducing from 24.10% in 1994 to 0.4% in 2001. The UK, whilst more stable, had 4.9% inflation in 2002. China has matched the UK on proportion of GDP spent on education, with the actual amount in US\$ showing a four-fold increase over the period. The UK, however, spends 40% more on education in actual expenditure. Ownership of

computers is shown to have increased ten times over in China to just over half of that per 1000 people in the UK.



#### **Innovation and Prevalence of Diabetes**

As set out in Chapter One, the numbers of people who are diabetic has more than doubled in both the UK and China over the last ten years, making it important to understand its relationship to innovation in this study. Although the treatment regimes are different leading to a differential cost base, the rapid increase in both the UK and China presents both social and economic challenge. This part of the analysis is aimed at establishing any statistical relationships between those factors of innovation being studied and the prevalence of the disease. This relates to the third part of the research question involving who is likely to lead in producing a stem cell cure for diabetes. It might provide an indication of the internal motive of a country to tackle this disease.

The relationship between GDP per person and the numbers of people with diabetes was investigated using Pearson-moment correlation coefficient. Preliminary analysis was performed to ensure no violation of the assumptions of normality, linearity, and

homoscedasticity. For China this shows a strong positive correlation between the two variables (r=.96, n=15), with the numbers of people with diabetes increasing in line with wealth, as measured through GPD per person. The UK position is almost identical at (r.=97, n=15). The relationship between spends on research and the prevalence of diabetes was investigated using Pearson-moment correlation coefficient. Preliminary analysis was performed to ensure no violation of the assumptions of normality, linearity, and homoscedasticity. For China and the UK this shows a very strong positive correlation between the two variables (r=.95, n=15 for China and r=.95 for the UK), again suggesting the number of people with diabetes increasing in line with increased investment in research.

The co-efficient was used to test whether the strength in relationship is real or a function error. The co-efficient of determination, which measures the variation between variables, was 90% for China and 88% for the UK, confirming the relationship. The relationship between spends on education and prevalence of diabetes produced less clear results between the two countries. For China the Pearson moment correlation coefficient was r=.96, n=15, suggesting increases were also related to rises in education. This is also supported by the co-efficient of determination results, which are 96% for China and 81% for the UK. These results confirm there is a statistical relationship between increased national wealth and investment in research and diabetes, but it does not exclude the possibility of influences outside the calculation.

# Innovation and the prevalence of diabetes in China - Regression

The impact of the factors of innovation in China on the prevalence of diabetes is shown to be ownership of computers, followed by education, then inflation. None were shown in this test to make a statistically significant contribution.

Innovation Factors	Correlation	Collinearity	Standardised	Significance	
		Tolerance	co-efficient	of contribution	
Total spend education	0.985	0.001	-1.182	no value	
Total spend research	0.959	0.003	-0.137	no value	
Total GDP	0.994	0.001	no value	no value	
Computer/1000 pop	0.977	0.001	2.048	no value	
Inflation	-0.894	0.052	-0.449	no value	
Patent Registrations	0.924	0.012	-0.114	no value	

When the test is carried out for just GDP this is shown to make a statistically significant contribution to the prevalence of diabetes in China.

When all the economic factors of innovation are used in the T-test calculation, education, GDP performance, medical workforce and ownership of computers are all found to have a relationship to prevalence in diabetes. Nursing workforce and inflation are shown to make a statistically significant contribution to the prevalence of diabetes in China.

**UK** - Multiple regression analysis was used to compare the factors of innovation and supports the earlier findings using correlation, again showing for the UK the GDP performance gives the greatest indication of prevalence in diabetes followed by ownership of computers, inflation, then education. None of the contributions are statistically significant.

Innovation and Prevalence of Diabetes in the UK

Innovation Factors	Correlation	Collinearity	Standardised	Significance
		Tolerance	co-efficient	of contribution
Total spend education	0.902	0.049	0.181	0.747
Total spend research	0.954	0.038	0.062	0.9227
Total GDP	0.976	0.004	0.885	0.641
Computer/1000 pop	0.947	0.004	-0.393	0.850
Inflation	-0.880	0.050	-0.304	0.596
Patent Registrations	-0.427	0.272	0.009	0.969

When this test is repeated for only GDP contribution, it is shown to make a statistically significant contribution to the prevalence of diabetes in the UK. When the multiple regression calculation is repeated using all the economic factors of innovation, total spend on research, followed by total trade and balance of payments, are shown to make the greatest contribution to predicting prevalence in diabetes for the UK. None of the variables are shown to make a statistically significant contribution.

Summary - Correlation provides an indication that there is a relationship between two variables but cannot indicate that one variable causes the other. This analysis shows for both the UK and China the prevalence of diabetes is closely related to those innovation factors that indicate prosperity and growth. When using correlation it is GDP for the UK that offers the best indication of prevalence in diabetes, but for China it is the number of doctors. This might be explained by China's doctor-led health structure (WHO 2002). This point is illustrated using multivariate analysis of variance MANOVA, where a strong positive correlation is found in the relationship between the prevalence of diabetes and ownership of computers. Having examined the statistical relationship between innovation and prevalence of diabetes, a paired sample T-tests were used to

compare the findings between the UK and China. In terms of prevalence levels for diabetes between 1990 and 2002, the probability value was shown to be less than 0.05, confirming that there is a statistically significant difference between the two countries. The mean score is higher for China with the eta squared, indicating this difference to be large. This result confirms that prevalence in diabetes is not equal in the two countries. The statistical calculations are set out in Appendix I.

If prevalence of the disease continues to develop in line with projected wealth as predicted by the World Health Organisation and Atlas (2002), the drive to find ways to manage or even cure diabetes becomes an urgent economic and social challenge.

This represents a major policy area for both Governments.

## Comparing Innovations between the UK and China

This section aims to extend the comparison to cover each of the innovation factors between the two countries. The research question being explored relates to the relative strengths and weaknesses of the respective economic national systems of the UK and China. The hypothesis is that the economic factors of innovation are stronger in the UK. The statistical calculations for this section are set out in Appendix I and cover:

- GDP
- Trade in Goods and Services
- Inflation
- Balance of Payments
- Spend on Education
- Spend on Health
- Spend on Research
- Workforce

- Patents
- Education
- Technology (proxy computers)

**Total Spend on Research -** T-test analysis shows statistically significant differences between the UK and China on research expenditure. This might reflect the historically low levels of investment in China or that the UK has reduced it's spend in real terms since the 1990's while China has increased rapidly.

Total Spend on Research and Balance of Payment - A paired sample t-test was conducted to evaluate the difference in total spend on research and the balance of payments for the UK and China. This showed a statistically significant difference between research and balance of payment in the UK (probability of 0.0), but in China the two are statistically related (probability 0.05). This suggests there is a strong link in China between research investments and their improved trade performance.

**Total Spend on Education and Balance of Payments -** A paired sample T-test was also conducted to evaluate the difference in total spend on education and the balance of payments for the UK and China. This showed a statistically significant difference between education and balance of payment in both the UK and China.

Economic Factors of innovation and GDP performance – When testing to find which of the economic factors makes the greatest contribution to GDP performance in the UK, the standardised co-efficient is used from the T-test to indicate the size of contribution each of the variables makes towards GDP performance. Workforce and total spend on research are seen to make the largest contribution, but all the measures of significant

contribution are over 0.5, suggesting that none make a statistically unique contribution. Total spend on research in China is shown to make the largest contribution to GDP performance. The number of doctors, total spends on workforce, and the proportion of the population owning computers also contribute. Spend on research (0.029), the number of doctors (0.000), and computer ownership (0.002) all make a statistically unique contribution.

Health spend and total Trade in Goods and Services - Health spend in the UK does not make a statistically significant contribution to total trade in goods and services in the UK. This means the impact of increased health spend is not shown to translate to overall performance in Trade for the UK. In China the percent of GDP spent on health care and the percent of that spend contributed by the government is shown to make a statistically significant impact on their trade in goods and services. This is likely to reflect the social structure, wherein 70% of their population lives in rural areas and many cannot afford to pay for health care. With a substantial decrease over the last decade in the government's contribution to health care, this result suggests that unless this is reviewed the impact may be evidenced in their performance on trade.

Impact on GDP and Balance of Trade by investing in research - Investment in research in the UK is shown to have a statistically significant impact on total GDP, but not on trade in goods and services. Investing in research in China has a statistically significant impact on total GDP but not in trade of goods and services.

Impact on GDP and Balance of Trade of investing in education- In the UK, investment in education makes a statistically significant contribution to total GPD but not

on trade in goods and service. Investing in education in China also makes a statistically significant contribution to performance in GDP but not in trade in goods and services.

# T-Tests - Economic Comparison

T-Test analysis was used to explore the relative strengths and contribution of the economic factors of innovation in the UK and China. The analysis shows there is a statistical difference between the UK and China in terms of total research investment over the period from 1990 to 2002. When the test was repeated to include balance of payment there was a significant difference for the UK but not for China. This suggests China's recent improvement in its trade balance is closely related to its increase in spend on research. When the impact of total spends on education and balance of payments was tested, both countries showed significant differences. Investment in health care was not found to make a statistical contribution to total performance in goods and services in the UK.

In China, both healths spend and the proportion contributed by its government was found to make a statistical contribution to total trade in goods and services. For both the UK and China, spend on education and spend on research were found to make a statistical contribution to overall GDP performance, but not to trade in goods and services. The data file was then transposed into a categorical one for the UK and China to enable comparison of the data on continuous variables between the economic factors of innovation.

## Comparing the Economic factors of Innovation Using ANOVA

In the table below, the results for the factors of innovation are compared using an independent sample T-test, Levene's tests for equity of variance. This is used to test the research hypothesis that the UK is stronger in the core economic components of its National Innovation System.

Factor of Innovation	Equal Variance	Equality of Mean	Significant difference
in Mean			
Nos with diabetes	Ñ.	0	Y
Total health spend	Υ	0.038	Υ
Nos of nurses	Y	0	Υ
Total population	Ň	0	Υ
Nos of Doctors	Ň	0	Ý
Patent Registrations	Ň	0	Υ
Total Balance of Trade	Ÿ.	0	Y.
Inflation	Ň	0.574	N
Total GDP	N	0.104	Ň
Total Education	N	0.007	Υ
Total Research	N	0.	Ŷ
Total Computer	Y	0.012	Υ

Using Levene's test for equity of variance, the mean score is below 0.05 in all variables except inflation and total GDP. For all other variables, equal variation of the mean scores cannot be assumed. The variables were retested using one-way ANOVA. The factors of innovation for the UK and China that were shown to have ANOVA values of below 0.05 are indicating in the table below that there is a significant difference in the mean scores for all variables except inflation and total GDP (Tabachnick and Fidell 1996).

Factors of Innovation	Homogeneity of var.	Anova	Levene's	Between subject
			effect	
Total spend on health UK and China	.060	.032	.022	.026
Number of doctors in the UK and China	.000	.000	.001	,0
Number of nurses in UK	.344	.000	.270	.Ó.
Trade balance total in \$ UK	.721	.000	.531	0
Balance of Payments UK and China	.106	.000	.019	0
Inflation UK and China	.002	.574	.002	.835
Total GDP in US\$ in UK and China	.033	.104	.213	0
Total spend on education in the UK in US\$ and China	.019	.007	.020	0
Total spent on research in the UK in US\$ and China	.015	.000	.082	.0
Total no computers in the UK and China	.176	.012	.161	.022

Levene's test tests the null hypothesis that the error of variance of the dependent variable is equal across the factors of innovation. The Wilk's Lambda test gives a significant value of 0, indicating that there is a statistical significance between China and the UK in the factors of innovation. Because there is a statistical difference a Bonferroni, adjustment was made to the alpha value to help prevent finding a significant result when there is not one. This sets a higher alpha value - the number of dependent variables (10) and becomes 0.005.

The between-size effect shows that for seven of the factors of innovation that there is statistically significant difference in the scores. A one-way between groups multivariate analysis of variance was preformed to investigate these differences. The independent variable is the country. Preliminary assumption testing was conducted to check normality, linearity, univariate and multivariate outliers, homogeneity of variance-covariance matrices, and multicollinearity with no serious violations noted. On inspection, using the estimated marginal mean, it is clear that the gap is large.

The table below summaries the size of the variation between the mean values of the factors of innovation between the UK and China.

Estimated Marginal Mean		
	Size	
Difference		
Total number of doctors China	2X greater in cn	
Total number of nurses China	0.38 greater cn	
Trade Balance in China	4.6Xs greater cn	
Balance of Payments China	5Xs greater cn	
Total GDP UK	1.48 greater uk	
Total Education UK	2.11 greater uk	
Total Research UK	3.79 greater uk	

## **Part Two Summary**

This part of the analysis involves testing the hypothesis that the UK has stronger economic factors of innovation than China. The factors of innovation are those identified as having an influence over the advance of therapeutic cloning. The T-test analysis shows that the mean scores for most of the variables are different, with the exception of inflation and total GDP. One-way ANOVA is used to assess the differences in the variables and, importantly to this work, the variation in mean scores. This shows that for the period between 1990 and 2002 the UK had a GDP of 1.48 times that of China, education spend of 2.11 times greater, and a spend on research of 3.79 times greater. China, however, had a trade balance of 4.6 times and a balance of payments of 5 times that of the UK.

This shows that historically the UK is stronger in the economic factors of innovation as they relate to therapeutic cloning, most notably in the area of research investment.

When, however, the rate of change during the time period is considered. China is seen

to have increased it's spend on research four-fold and is fast approaching an equal position to the UK.

#### Part Three - Research Interviews

#### Introduction

The third part of this analysis involved examining the opinions of researchers and policy makers working in the field of stem cell science. It provides context to the overall research question in capturing the views of those working within their National Systems of Innovation in stem cell research. A data table was constructed after a wide search of the Internet, policy documents, and stem cell research centers, particularly in the area of diabetes across the UK and China. These cover all those organisations receiving government research funds as well as the private sector. This information is set out in Appendix J. Each organisation was contacted - twice by email and, where willing, by telephone. The overall response rate was low in terms of numbers but was successful in receiving contact from some of the most eminent stem cell researchers in the UK and China. These people and the questions asked are set out in Appendix K.

Conventional qualitative research would involve the recording and transcribing of interviews to ensure accuracy and limit personal bias (Silverman 2002). In this approach some interviews were conducted over the phone, some in person and some via email. To ensure the same high standards of validity the notes of each transcript were returned to the interviewee for validation and correction. In this way it was possible to ensure an accurate transcription as recommended by Cassell (1999) and limit personal bias by triangulation, as recommended by Miller (1997).

An acknowledge goes to Professor Cathy Prescott from Avlar Bio Ventures Limited in Cambridge who facilitated many of these contacts.

Each person was asked the same questions taken from the areas identified in the research design. These were:

- views on the advantages and disadvantages of the research environment for stem cells in the UK and China
- views on the current patent system for stem cell research
- views on whether achievements in translating stem cell technologies into clinical therapies will occur first in China
- views on any associated risk if such therapies were to be available in China

Quotes were used from all the interviewees in the reporting of opinion against each of the relevant research questions. The issue of personal bias discussed by the likes of Silverman (2002), Cassell (1999), Hawkins (2001), May (2001), and Miller (1997) were reduced as direct quotes were used that had been validated following translation by the interviewee.

# **Investment Strategies**

Considering first investment in stem cell research, Young (Business Relations Manager at the Department of Trade and Industry) says, "UK Government investment in stem cell research is okay". He goes on to explain that the funds available to the Medical Research Council and others are underpinned by strong technology programs, run by the Department of Trade and Industry. This is a view supported by many, including

Professor Clarke from the Oxford Center for Diabetes, Endocrinology and Metabolism.

She explains that although research investment is short, "many researchers share support" to maximise its use. Professor Minger from Kings College London suggests, "it is the longer term commitment that is needed and early indications of this will be forthcoming". Holland, Chief Executive of Cord Blood London cautions, however, that the "cost of stem cell research is high in the UK compared to other parts of the world".

These views are not universal with Professor Przyborski, Director and Chief Scientific Officer at Re: innervate Limited, saying "the position is terrible". However, he reports that planned changes in the UK government funding strategy for stem cell science towards larger projects may help. He suggests funding needs to be focused towards projects with tangible commercial outcomes. Surani from the Cambridge and Wellcome Institute of Cancer and Developmental Biology agrees that funding is a constraint, a view supported by Professor Minger who reports "very few disadvantages in the UK except perhaps funding". Professor Bobrow, Nuffield Council on Bioethics, Head of Medical Genetics at Cambridge and former Deputy Chair of the Wellcome Trust says, "the UK spends less on research than its major competitors", but suggests that whether more money is needed "is in doubt". This view is supported by Dr Archer, who says "money is not the limiting factor in this case as stem cell science does not require enormous capital investment or complex computers or machines for analysis". Professor Rimoldi from Imperial College London goes on to suggest that "funds are wasted on managers".

Moving on to broader aspects of the investment strategies, Professor Murdoch from the Newcastle Life Sciences highlights the UK's regulatory structure as a strength, saying, "it explains clearly what can and can not be done", reporting this to be "a big issue for a

number of other countries". Stacey, Chief Executive of the UK BioBank, confirms the UK regulatory system"is generally facilitative of stem cell research whilst retaining careful controls, i.e. allowing therapeutic cloning and use of embryos for research coupled with stringent regulation". Professor Minger from Kings College London agrees the UK is "very supportive unlike the current situation in the United States". This is a position supported by Professor Bobrow, who says, "the UK has a very supportive research environment".

Holland, Chief Executive of Cord Blood London (a private organisation dealing in adult stem cells) adds the dimension of strong academic links in the UK with independent research that is prestigious and has easy communication channels. Professor Prescott from Avlar Bio Ventures Limited agrees, saying "UK centers of excellence are very positive in enabling a critical mass for stem cell research". She explains stem cells research is technically demanding and "the proximity of expertise is therefore essential". She reports the centre at Newcastle as one of the most important and currently the only place in the UK working on laboratory-based translation therapeutic cloning. The UK is, she reports "very strong on biological innovation but reticent to move forward into the clinic". Dr Archer, Chair of the East England Stem Cell Network, reports the UK in "punching well above its weight in all areas of research methods" and has "university departments of international standing". She says the UK has a "good culture for communicating results" and "an honest and transparent regulatory and trials system". Mountford, Chief Executive of Stem Cell Sciences, adds further context to the UK investment strategies in reporting them to be multi-national, which enables his business to manage issues specific to different countries within their UK work.

The corresponding strategies in China are said to be permissive legislation, access to primates and humans for research, access to human embryos and aborted fetuses, access to long-term research funds, state-of-the-art laboratory facilities, and a permissive cultural environment. UK research investment for stem cells is said to contrast to China, where its government has made major investments and provided some of the best-equipped laboratories in the world. Their funding streams are reported to be long-term, affording commitment and security to its research. The corresponding disadvantages in China are said to be a lack of investment in basic research and a predominate focus on developmental research. They also reportedly lack credibility in their absence of published research. Dr Archer suggests, "historically Chinese scientists were not considered to be so creative in thinking", but "China is now motivated to produce results because stem cell therapies can be cheap".

# Legislation

Patents are one aspect of the legislation that influences investment strategies.

Young, from the UK Department of Trade and Industry confirms, "they have not had any patent issues raised". Minger reports, "the patent system seems okay but broad patents impede field work". Some, however, feel the current system is inadequate for the complexities of stem cells. Stacey suggests that "the suspension in the 1600's by the King of England (in that case, due to corruption) needs to happen again and the process restarted from scratch". His believes we may again be approaching a situation where the patent system requires reform. Professor Wang from Newcastle Life Sciences confirms "all universities and stem cell centers have their own dedicated patent office with scientific support. The problem she suggests is "knowing what could or could not be patented and how far to take this". Murdoch reports a push "to achieve patent

registrations" although "historically we have not been good at exploiting these". Holland points out that the process of IVF resisted patenting.

Professor Prescott agrees the patent system for stem cells is "horribly complicated with many tiers, fragmented, and dominated by the US". One way forward, she suggests, is to expend licensing, but this requires new legislation. In the US, patents of specific stem cells are permitted, which is argued by many to be wrong. Walker - Business

Development Director at St John's Innovation Center – agrees, describing the patent system as "a minefield and far from adequate in its current status". Mountford, Chief Executive of Stem Cell Sciences, reports "researchers in the UK seem satisfied to allow patents on how to produce or use stem cells but not on the base material – it is too broad in application and patents slow development". Przybroski is involved in patenting the technology that enables stem cell science rather than the cell technology itself and agrees that only the technology that enables the process should be patentable.

Patents are a bigger problem in China where, despite joining the World Health Organisation in 2002, enforcement and infringement are major problems. Although China has strengthened its legal framework for intellectual property, amending its 1984 legislation in 1992 and 2000, 70% of the world's counterfeit is produced there. This is a worry for the Chinese government, which desperately wants to encourage international investment. Companies are now being taken to court on a daily basis for infringement, although detection remains a problem. Dr Bennett, who leads a task group on public perception, suggests it is not just patients that it concerns, but that "all aspects relating to the management of stem cell research have become a priority for the Chinese government", a situation made worse by the Korean fraud.

Researcher opinions on the Chinese regulatory system appear to depend somewhat on whether researchers have visited or worked there. Both Prescott and Minger, having visited China, report the Chinese approach as" robust and open". Their scientists reportedly work within clear legal guidance in terms of what is and is not accepted.

## Regulation

The regulatory system in the UK is said by Young to be "sorted and stable" in relation to embryonic stem cells, including therapeutic cloning. Researchers know where and how to apply to the Human Fertilization Embryo Authority for a license, which he says is in contrast to the United States, where there is still no control on investment in this area. The quality of science and scientists is regarded as high with many centers of excellence, most notably at Newcastle, Cambridge, and Edinburgh. Young goes on to explain that from the Department of Trade perspective there are no obvious bad things about the UK regulations. This position is supported by Dr Minger, who confirms the UK has "the best regulation for stem cell research in the world". He goes on to explain that "the details are the tightest and are not dependent on the source of money as they are in the United States". He explains that "the UK has a pragmatic approach that requires everybody, whether a private company or academics, to operate within the same rules". He ascribes this rigor to the 2001 Select Committee consultation. This, he says, has led to "a considered legislative structure that sets out the UK landscape for stem cell and therapeutic cloning research".

Surani, from the Cambridge and Wellcome, agrees the UK has "a good and stimulating working environment with clear guidelines and possibilities for recruiting high quality

students and post-doctoral students". Holland agrees, "the UK has made the most significant inroads into reviewing and implementing the appropriate regulatory environment". Walker adds, "there is a good critical mass of researchers across a wide range of stem cell projects in the UK". There are also close links between researchers and clinicians willing to pull developments into the clinic". Przyborski agrees that the UK "has the best clear-cut regulation in the world and researchers know exactly where they stand". Murdoch from Newcastle Life Sciences highlights one tension within the regulatory system, drawing an analogy linked to the justice system. She likens the tension between prison officers and inmates, saying they are 'always assuming you are doing something wrong or bad. It is the process of regulation that is the problem at the moment".

Despite speaking well of the UK, some UK researchers appear to envy the permissibility of the Chinese regulation for innovation, pointing out that the strict clinical trial regulation across much of Europe means that the pioneering experiments on percutaneous angioplasty that produced the advance in heart surgery would no longer be possible here (Rimoldi). This is an obvious concern for the future advance of stem cell science, with Rimoldi suggesting this complicated area of concern belongs more in social than medical science.

#### **Diabetes**

Stem cell research in diabetes is led in the UK at Newcastle Life Sciences, whose work is currently focused on adult stem cell transfer rather than embryonic. Clarke explains that the work on diabetes at Oxford is focused on a number of independent groups working on the biological and biophysical aspects of diabetes, but that they are not

currently involved in stem cells. The contrast is explained by Professor Zhang from Xuan Wu Hospital Cell Therapy Centre in China, who is leading work into a cure for diabetes. Although reluctant to speak, he does explain that his team is already able to expand progenitor cells within human or monkey pancreatic islets and make large numbers of artificial islets in test tubes. He acknowledges this has been done in other places but that the advantage they have is using diabetic monkeys in their studies. His team aims to establish the optimal number of differentiated islet cells necessary to cure diabetes in monkeys. Although huge sensitivities exist in this work, he is confident of success.

Prevalence and associated economic and health costs for diabetes are serious problems in both China and the UK. The issue is whether people will be willing to travel to places like China in the future in search of a cure. With many stories of people already traveling abroad for stem cell treatments, Dr Bennett hypothesizes, "if you have diabetes, hear of a treatment in China, have the money and are a risk-taker, an individual may choose to get treatment", but he cautions "this can not be generalised to the majority". Young suggests, "most people are suspicious of this", with Murdoch adding, "people who might choose to go abroad will not necessarily understand". Walker describes the health risk of deciding to go abroad "to be far less of an issue than managing patient expectations". "If patients travel to less regulated markets for

treatment and are disappointed, this will have a negative impact on the entire field", she cautions. "The Chinese environment is not well understood, as there is very little published research".

## **Societal Acceptance**

China reportedly has excellent animal research facilities, resulting in cheaper research than invitro models. The associated risk Bennett, suggests, is that "their findings may not work in humans". Others claim the ethical controls are too loose in China and worry that not all doctors guarantee safety. Professor Wang agrees that Chinese doctors "tend to be a bit more adventurous, especially on patients with end stage conditions", although Professor Prescott who has visited China on several occasions confirms "all its studies on patients are ethically approved, far more so than appreciated. Their work is very carefully controlled with many of their researchers having trained in the US". Indeed, she reports that "the Chinese are aware that there is great suspicion following the false claims from Korea". Dr Wang acknowledges that the ethical controls are clear and proper in China, suggesting it is compliance that is the issue. Professor Minger points out that the ethical stance in China means "if somebody is sick and there is a possibility a new intervention may help it is almost criminal to withhold it". From his experience he agrees that China is responsible and "there are no concerns about the ethics of their stem cell research". Indeed many, including Professor Rimoldi, suggest that the comparison of ethical constraints in the UK is "unhelpful to the research".

Because of (or in spite of) the ethical context in the UK, Young reports the biggest challenge is "its lack of ability to commercialise stem cell research or to even take steps towards this". He predicts a very long wait before the outcomes of this work are seen in the UK market. Professor Wang provides context in having just come back from visiting several stem cell laboratories in Shanghai. She suggests, "the UK advantage is in terms of mechanisms", but explains that China has the advantage in terms of application. She confirms China is already using stem cell therapies in clinical settings and is very keen

to develop collaboration with the West. She explains, "doctors in China are undertaking procedures on patients that clearly work, but they lack the basic understanding about how or why".

The reason for this difference is largely around UK regulation and the clinical trial process, which require an understanding of the mechanisms before human research trials. Professor Minger confirms the "UK is cautious and is not yet transplanting". Professor Wang suggests that may in fact be a better approach for patients. Professor Prescott describes the contrast between the UK and China, explaining the reason progress is being made rapidly in China is that "most of the research is carried out by clinicians". This gives, she explains, significant advantage in "understanding how to translate the findings in the laboratory into in a clinical setting". Many say it will be decades before stem cell therapies become available in the UK, especially in brain disease.

Whether China is placed to advance a lead on the world, therapeutic cloning is an area that attracts many views. Surani suggest such an achievement depends on the quality of their basic research, which is improving as they are recruiting people from overseas (especially Singapore). Young says "I wonder, China has different regulations and ethics but also lots of biotech expertise, but I am not sure how successful China is in turning this into treatments. The Korean scandal has affected the standing of science in the East badly". Professor Murdoch agrees, reporting that "the Korean fraud has put a big stop to progress in East Asia. Until this the Far East was expected to lead".

Professor Clarke suggests, "the experience from Asia has engendered distrust and it will

be a while before the scientific world recovers". She suggests patient demand in the US is more likely to drive success.

Professor Wang is clear from her work in both the UK and China that "therapies will be available in China before the West". Mountford takes an opposing view, saying simply "no, China will not lead. The time limiting challenge is scientific, not ethical". Professor Minger sees both points of view, saying "yes and no. India is already working in embryonic stem cells without any regulation. China has more restrictions and is moving quickly to the clinic". Professor Rimoldi points out that even if China did find a cure for diabetes and patients choose to flock to China in search of a miracle therapy, the evidence-based approach to medicine would remain a requirement for the West. Holland takes a more extreme view in saying 'there is no real future for embryonic stem cell therapy in any country. The technical, medical, legal and ethical and religious objections are too great. "I doubt China would take the lead, and if they did their techniques many not be acceptable".

Professor Precott says "absolutely yes. China is clinically driven, has lots of money and has an ethical context and will produce therapies well ahead of the West". Others, including Walker and Professor Przyborski, support this position, but they suggest their lead will be more to chance and lack an understanding of how or why. One example is that bone marrow stem cells are currently transplanted into the heart, resulting in an increase in the output of the heart, but nobody yet understands how or why this happens. Professor Przyborski suggests the really important question is does it matter from a patient point of view? Whilst academics are hesitant to take a leap into the clinic, the Chinese doctors and stem cell scientists are already treating people with notable

success. The risks, he suggests, is "if it all goes wrong" like the gene therapy treatment of leukemia in France where blood bone marrow led to cancer.

Internationally there are many countries undertaking "unregulated tissue procurement all over the world" (Professor Minger), with concern highlighted in Barbados, the Ukraine, and India. He reports China and the Far East as "a small part of what is happening". Explaining the advance in China, he says, "none of this will be permitted to operate in the UK", as evidenced to date by the cord blood companies. Professor Clarke agrees that legislation in the West requires that evidence be produced locally before any clinical acceptance can be made. Whilst she cautions that "less ethical institutions could adopt stem cell treatments", she suggests these are unlikely to present a large-scale risk. The absence of any international regulatory body to police this work is said to be a risk within the current research and Professor Minger hopes the World Health Organisation will take on this role.

## Summary

This research is structured to explore the National Systems of Innovation in the UK and China as they apply to stem cell research. The specific areas to be answered are what the strengths and weaknesses of the respective systems are, how they influence the translation of stem cell science to treatment, and which of the two countries are most likely to lead in curing diabetes. Diabetes is taken as a clinical example against which to make this assessment. A definition of the composition of the National System of Innovation is taken from the literature and includes economic, legislation, research investment, and softer aspects of culture and public opinion (Edquist 1997; Freeman 1997). From this, it was clear that a range of data structures were necessary to explore

the research question in detail. This was designed in three parts to explore all the economic components of the National System in an historic trend that enabled comparison over time between the two countries. The economic table was constructed to bring together a range of data sets that had not previously been gathered or compared from 1990 to 2002. The details of data collected and structure of the table and analysis are set out earlier in this chapter. A summary of the data set is attached in Appendix D.

This analysis shows that between 1990 and 2002, the UK historically had stronger economic factors of innovation, although by 2002 China became its equal, as a proportion of GDP was spent on education. China in addition has far stronger underlying factors of innovation, evidenced by the country's positive balance of payments and the size of their trade in goods and services. Spend on research also increased rapidly and, as a proportion of GDP, had increase by 2005 in China to 1.35 and reduced it in the UK to 1.76 (National Statistics 2007). The softer aspects of culture and opinion could not be assessed from economic statistics and required the formulation of a public questionnaire. This was designed to capture opinion from a UK perspective from a representative sample, which broadly showed that people think the government needs to spend more on stem cell research, and that human embryo research is more widely supported than appreciated, with a strong correlation between religious belief and concern. During the time of this study the understanding of what is happening in China may have changed, but this work found very little knowledge of the Chinese achievement in this field.

China is applying its scientific knowledge in a clinical setting, enabled because its clinicians lead much of its research. It is said to be tightening up its patent and enforcement systems, although detection is still said to be an issue. It has large animal facilities, including access to primate research, which makes its research costs lower. Indeed work to cure diabetes in monkeys is undertaken with reports due imminently on the optimum numbers of islet cells to produce a cure. The ethical stance of its country is reported to be more adventurous, often trying new procedures on people at the end stage of their disease. The opinion on whether China will use its advantages to lead the world in therapeutic cloning is mixed. Certainly those scientists who have visited China and seen first-hand its investment, state-of-the-art laboratories and practices believe it will. China is reportedly curing solid cancer tumors, treating leukemia with stem cells, and has publicly announced its intention to cure diabetes (Pearson et al 2004; Hepeng 2005). However, such claims are challenged by some due to the absence of published research evidence.

The UK has a strong international reputation in stem cell science, having led in establishing legislation to enable human therapeutic cloning. In doing so, it is said to have provided the clarity that is necessary for discussion and understanding and to have strong government support. The funding structure for stem cell research in the UK is not reported favorably by all, with some claiming the short-term nature of the current system is limiting and lacks a focus on projects with planned tangible outcomes. However the UK is reportedly changing some of this and turning its strategy towards support for larger projects and longer-term strategies. The UK is also reportedly reticent to move into the clinic, due to the complexity of the science, clinical trials regulation, and

societal concerns. This area of science is said to be expensive, its patent system horrifically complicated, and predictions are for a long wait before any services result from its stem cell science.

Views are mixed on which country will lead in curing diabetes. Some researchers, with first-hand experience in China, are clear that it will lead. Some argue this to be speculative and call for concrete evidence. What are available are the changes in economic performance in China, which are shown to be underpinned by increasing and long-term investment in research and education. History is often a useful predictor of the future. The UK has a strong research background and is a global leader in science and innovation, but there is clear and continued evidence of a decline, as a proportion of GDP in research investment (National Statistics 2007).

# DBA Chapter Four Discussion

#### Introduction

This is an interesting time to be writing about stem cell research in both the UK and China, not least as the news carries daily yet another story of its potential to cure disease. Last week it was heart disease, this week it's muscular dystrophy, and tomorrow maybe diabetes. Even UK dramas are getting in on the act with story lines showing a motor neuron sufferer travelling abroad for stem cell treatment (Holby City 2006). The reality is whatever the science may deliver; it will be a long time before these are available in the UK (BBC 2005).

In China, advances in genetic science are also reported in explicit advertising of stem cell treatments that offer cures for a whole range of disease. Indeed UK national news carried the story of gene therapy treatment for cancer in China (BBC 25/5/07). China's move to the clinic has happened quickly, having cloned their first human embryo in 1999 (Yank 2004) one year after the world's first was achieved in the United States (Shamblott and Thompson 1998). It was 2005 before the UK matched this achievement in cloning its first human embryo (Lawless 2005). This and its permissive legal and social culture have enabled China to move quickly in transplanting stem cells in humans (Ning 2005). China claims to have delivered the world's first gene therapy cure for cancer (Pearson Jia and Kandachi 2004), started the first human trials for leukaemia, and published explicit plans to extend this to diabetes (Hepeng 2005). In addition, China is reported to have successfully cloned hybrid embryos in 2003, an achievement the UK

is yet to match (Chen 2003). This research found evidence of the Chinese successfully curing diabetes in primates some two years ago.

China is reported to be using adult stem cells to cure brain disease, and has cloned goats, pigs, cattle, mice, rats, and established a network of cord blood (Times 2005). Their research spend is now the world's second highest (Lombardi 2006), representing a four-fold increase over the last ten years. China's approach is underpinned by an explicit strategy to become an international leader in technology (Mann 2003; Wilson 2006). Their motive is to gain prestige and economic growth, as genetic science affords the potential to become the most significant contributor in the biotechnological industry (itself identified as the most important aspect of economic growth) (EC 2001 OECDa 2004).

This study used NSI as a framework for exploring the factors of innovation influencing progress of stem cell technologies in the UK and China. The definition of NSI was taken from the literature, the most significant being Freeman (1997), Edquist (1997), and Fagerberg (2004), who in summary suggest a definition that includes political context, government legislation/regulation, research investment, society/culture, economic performance and current evidence. These offered a framework against which a comparison of stem cell innovation between the UK and China is afforded. Both the UK and China have published policy intention for stem cell science in China in its 15-year scientific strategy (Cong 2006) and DoH 2003 in the UK.

The focus is on therapeutic cloning which is one area of stem cell research whose technique involves the transplantation of cells from human embryos, human cord blood,

or adult stem cells to repair damaged or diseased cells. Embryo cells are said to have an advantage in being undifferentiated and potentially able to grow into any cell type (Moore 2004), although how this happens is beyond current knowledge. That advantage has more recently been disputed as Western scientists seek to find procedures that do not involve the destruction of the human embryo (BBC 2006). Indeed such is the concern in America that the use of government funds is still prohibited by law except for embryos created for use in IVF treatment prior to August 2001 (Bush 2001).

The UK has managed to temper such an approach by introducing clear legislative and regulatory processes that control the approval and management of the science (Leather 2005). The Human Fertilisation and Embryology Authority has taken this one step further in issuing the first licence in the UK to Newcastle Life Sciences to invite non-beneficiary egg donors following its public consultation in October (HFEA 2006). This enables women to become egg donors outside of the current IVF process, a policy publicly criticised by Dr Minger (Dreaper 2006). China, in contrast, is largely free from such ethical concern, having different beliefs about when human life begins (Yank 2004).

The science of therapeutic cloning, in whatever culture, is aimed at finding cures for human disability and disease (Spink et al 2004). The basis is that stem cells can be transplanted into diseased or damaged tissue where they can either be reprogrammed before transplantation or take instruction from their host cells. This research discovered that how this science translates to therapies depends as much on the innovation system in which it develops as the skill of its research team. This includes its government's

legislative and research strategies, its economic system; it's ethical and social structure, and the complexity of the disease to be treated.

### **Research Design**

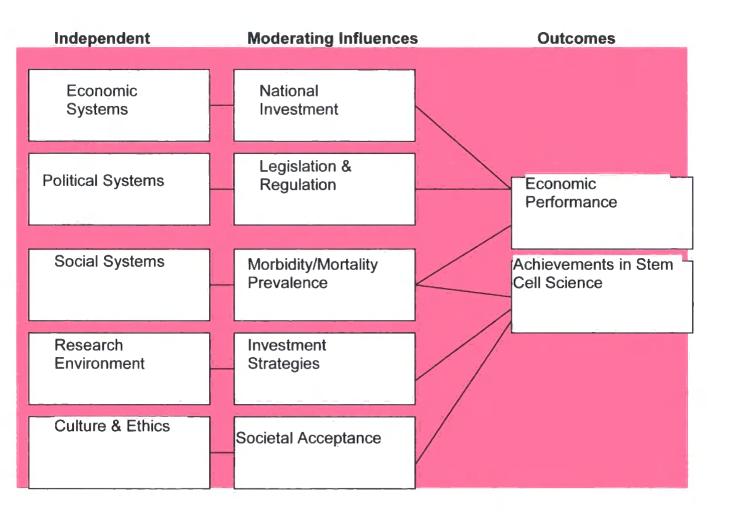
This is a case study researching how therapeutic cloning will be influenced by the National Systems of Innovation in China and the UK, using diabetes as a model.

National Systems of Innovation is defined in the literature by Edquist (1997), Freeman (1997), Fagerberg (2004), and others. This includes a political context, legislation, research investment, intellectual property, public opinion, ethics, demographic trends, economic performance, and current research. The definition and boundaries of National Innovation in this field are validated by a study that began after this work, led by Professor Salter at Anglia University. In this, he too uses the Innovations literature to frame his study of stem cell technologies between the UK and China and uses very similar categorisation to this study.

National Systems of Innovation Theory is concerned with the political and economic factors at a national level. It does not have an empirical framework (Edquist 1997), so the use of a framework designed to fit the research challenge is one suggested approach (Freeman 1997; Fagerberg 2004). Its application in the service sector has been historically limited (Fagerberg 2004), although there is recent evidence of its use in a number of clinical studies. Perhaps the most relevant aspect for this study is that suggested by Storper and Harrison in 1992, and Freeman in 1997, who recommended using NSI in studies that focus on factors that influence delivery of innovation or change. Freeman also recommends its use to identify those activities that increase knowledge about those aspects that make innovation successful. These fit this case study, which

makes comparisons between the national innovation systems as they relate to the the repetition of the the related to the repetition of the related to the re

The approach to the research is shown diagrammatically below. The independent variables in the NSI for stem cell science are those forming its structure such as legislation, political structure, and societal values. The influences that moderate these are their translation to operational values such as available resource, actual legislation/regulation, and what society is prepared to accept. The outcomes are those that the science is able to advance within the respective structure for the UK and China.



The study is designed in three parts. The first covers economic data on populations,

demography, patent registrations, and investment strategies constructed in a quantitative data-table covering the period from 1990 to 2002. This approach is supported by the literature in enabling interdependencies and non-linear relationships in the NSI to be explored (Edquist 1997). A public questionnaire is used to collect the less tangible areas of information covering individual opinions, culture, current knowledge, and ethics. The sample for the questionnaire is taken from a range of community groups that represent the UK population as explained in the research design. This sample represents the population in covering nine key groups. These include students, unemployed people, people working in professional and non-professional roles, stakeholders with diabetes, gym members, retired people, and magistrates who are selected as a representative sample of the population. The validity of this approach is seen in the results, which show a representative mix of age, gender, religious belief, employment status, experience of diabetes, and ethnic origin in the results. Although two routes were tried to use the questionnaire in China, these unfortunately failed. This was redressed in the third data collection method where access to Chinese researchers was successful.

Telephone, email and interviews are used in the research sector across the UK and China to explore the political and regulatory environment, culture, and stem cell research underway. These contacts were initiated from a database that was built covering all the stem cell research being funded at that time in the UK and China (Appendix J). Together these three approaches incorporate the recommendations of Fagerberg (2004) to include the relationship between R&D, legislation, and economic performance and the impact of knowledge created (Plummer 2004). Tidd (2001) recommended the study be in real time, which is evident in both the questionnaire and interviews. Workforce

productivity was something that researchers and the competitive focus Schumpeter (1934) suggested to be important in these studies, as they are reflected in the investment and regulatory strategies, the societal values, and the status of the current science in each country.

The overall research question is how will therapeutic cloning be influenced by the respective National Systems of Innovation in China and the UK using diabetes as a model? The hypothesis being NSI will not adversely impact the advance of stem cell science. This breaks down into three specific questions to be answered:

- 1. What are the strengths and weaknesses of the National Innovation Systems in the UK and China as they relate to therapeutic cloning?
- How do the National Systems of Innovations in the UK and China influence the translation of stem cell science into the clinical treatment? The hypothesis is that NSI of each country has an influence on the advance of stem cell technologies
- Because of their National System of Innovation, which country will be first to develop a stem cell cure for diabetes? The hypothesis is that one of the countries will have a more permissive NSI.
- 1. Strengths and Weaknesses: National Systems of Innovation in the UK and China

There is no published study using NSI to explore therapeutic cloning, yet the content of the literature supports its application to new areas in being flexible and outcome focused. The structure of the framework that underpins this research is formed from the

literature and populated by three methods of data collection. This approach is supported by current research being undertaken by Professor Salter (EESCN 2007).

The research structure is underpinned by a review of the UK and China in Chapter Two.

For China this illustrates a highly innovative history, with comparatively little commercial advantage, set within a major demography challenge. Home to 20% of the world's population, it suffers from many natural hazards including earthquakes, drought, tsunamis, land subsidence, and air and water pollution. These are somewhat offset by huge natural wealth, including coal, iron ore, natural gas, and the world's greatest supply of hydropower (Riley 2004). Its health profile is similar to that of a developed country, but there are considerable variations and massive poverty in the rural populations (Watts 2005). Led by a Communist government, it has since the early 1980's achieved rapid economic reform (Keidel 2001), enabling many advances including a four-fold increase to its GDP spend on research (OECD 2004c). Within this, China is shown to struggle with credible and accountable regulatory systems for stem cell research (DTI 2004; BBC 2005; Williams 2006). The government leads investment in stem cell infrastructure within a population with little, if any, ethical concern as the foetus is not considered human (Yank 2004).

Reputation for the UK is contrastingly high, having led the world in genetic science and discovery (DoH 2003). Like China it has an impressive innovative history, having led the world in innovation until the mid 19<sup>th</sup> Century (Weisser 2005). With a democratic political structure, it has used its position to provide a cost-effective and comprehensive structure for stem cell research (Best 2005). Economically it is highly developed, with strong public health structure leading to high standards of living. Strong economic growth since

the late 1990's has led to strategies to increase research funding, although this reduced significantly from 2.4% of GDP in 1981 to 1.9% in 1997 (OECD 2002). Policies to increase this to 2.5% by 2010 are in place (DTI 2002). Access to new technologies for health is controlled by a government agency (National Institute for Clinical Excellence), which results in controlling access to new technologies by up to twenty years (May 1993; Dargie 2000; Raferty 2001; Wanless 2002; Dyers 2003). As a developed country, it operates within a mixed religious base where the relationship of the human foetus to God is, for many, intrinsically linked.

# **Economic Analysis 1990-2002**

The first approach covers the economic data at a national level and includes economic performance, research Investment, education, health spends, workforce trends, demographics of diabetes, patent registrations and computer ownership. Its structure is taken from the innovations literature and used to provide a quantitative framework to the research.

Analysis shows for the research period 1990 to 2002 that China has a declining population compared to that of the UK. Diabetes has increased rapidly over the previous 12 years, most notably in China. Health spend has increased in both countries, most significantly in China since 1996 with private contributions increasing four-fold in China whilst remaining static in the UK. The value of GDP is equal between the two countries whilst spend on research has increased five-fold in China and the percentage of GDP spend has fallen in the UK. Growth in GDP remains constant at around 8% in China and between -2 to 4% in the UK. The number of doctors has increased in China whilst the number of nurses has decreased, with doctors remaining static in the UK as

the numbers of nurses increasing. Balance of payments has improved substantially in China whilst remaining negative throughout the period in the UK. Inflation in both countries has been volatile, with China reaching 24% in the mid 90's and reducing down to 2% by 2002. The UK has reduced from 9% in 1990 to 3.5% in 2002. GDP spend on education has increased in China to match that of the UK at 5%. Total value of GDP has risen rapidly in both countries but most notably in China. Ownership of computers has risen ten-fold in China to become half the level per head of population in the UK.

This analysis shows China had a lower level in many of the economic factors of innovation, such as research investment and education, but by 2002 had equalled the value of total GDP and its spend on education with the UK. Whilst research spend is still much lower at 1.3% compared to 1.98% of GDP for the UK, China is on target to equal UK investment by 2010. Whilst China has doubled is spend on research in the last six years, the UK spend as a percent of GDP has declined. China has also seen an annual GDP growth of at least 8% compared to 3% in the UK, has a positive balance of payments, compared to the negative value for the UK, and its trade balance is outperforming the UK by 4.6 times. Inflation appears to be in control in both economies but is lower in China at 1.6 compared to 4.5 in the UK (2002).

These show that many of the economic indicators in the Chinese National System of Innovation are now comparable to the UK, with overall performance, as indicated by total GDP, outrunning that of the UK by some 5% annually. For China these afford a strong economic context for stem cell research, having low inflation, strong GDP growth of 8% annually, a positive balance of payment, 5% GDP for education, and a four-fold increase in research investment. There is evidence that the increase in research spend

**DBA Final November 2008** 

has led to investment in state-of-the-art stem cell labs (DTI 2004).

The corresponding position for the UK shows GDP spend on education and total GDP are equal to China. Total research spend as a proportion of GDP has fallen 2.24% in 1990 to 1.98 in 2003; balance of payment is negative and GDP growth has varied between 2% and 4%. Computer ownership is still twice that for China despite their tenfold increase. These factors together suggest a strong, stable economic environment, but one, when compared to China, that shows comparatively little growth.

Statistical analysis of the national economic factors of innovation was used to establish which variables were contributing statistically to economic strength of GDP. In the UK the results shows that spend on research and education make a statistically significant contribution to GDP performance. When repeated for China, total spend on research is shown to make the largest statistically significant contribution to GDP. The number of doctors, total spends on workforce, and the proportion of the population owning computers also contributes toward GDP performance in both countries. Spend on research, the number of doctors, and computer ownership all make a statistically unique contribution. These findings are supported by the literature, which reports the importance of research investment to economic performance (OECD 2004) and the workforce on GDP performance (Schumpeter 1934). China's strong economic growth is shown in the analysis to underpin its research investment.

Computer ownership, when taken as a proxy for technology, is shown to have a strong impact of GDP performance in both countries. When testing the impact of spend on health on trade in goods and services in the UK, health spend is not shown to have a

statistically significant impact. Repeated for China, the percent spend of GDP on health care and the percent of health care contributed by the government are shown to have a statistically significant impact on trade in goods and services. This suggests the health system is having a far greater influence on economic productivity in China than the UK. Research investment in both countries is shown to have a statistically significant impact on the country's GDP, supporting the literature in substantiating the importance of research investment in economic performance. Investment in education in both countries is shown to make a statistically significant impact on both GDP performance and balance of payment.

The use of correlation to assess a linear relationship between variables is useful in establishing a relationship but neither proves a direct link between two variables nor causality (Carter 1984). Its use in establishing statistical significance in the above summary is in providing a strong indication of patterns between the variables (Easterby-Smith 2002). The factors of innovation were then tested for relative strength between the UK and China, using an independent sample T-test. There was no significant difference in the scores for inflation and total GDP. Total health spend, number of nurses, total population, number of doctors, patent registrations, total balance of trade, total education, research, and total computers are all significantly different as indicated by the Wilk's Lambda test. Levene's test and a one-way between groups' multivariate analyses were used to find the equality of variation across the factors of innovation and to establish the relative strengths in each. Collectively, these tests show the UK had stronger factors of innovation from 1990 to 2002 in most areas, including spends on education, research, health, and overall GDP performance. These statistical tests

#### **DBA Final November 2008**

focused on historic trend data which, in order to be predictive of future performance, would require the economic factors to remain constant.

Summarised in the table below is can be seen that China has a trade balance over 4.5 times stronger than the UK, to employ more health staff and have a balance of payments 5 times greater than the UK. Extrapolation of these results suggests the UK has a stronger national economic infrastructure to enable the advance of therapeutic cloning. This is taken to include current research investment, workforce-to-population ratios, and GDP performance. However, based on the rate of change within the data, this suggests that the Chinese economy is on the verge of surpassing UK performance in areas of research investment spend on education and total GDP.

Estimated Marginal Mean	
	Size
Difference	
Total number of doctors China	2X greater in cn
Total number of nurses China	0.38 greater cn
Trade Balance in China	4.6Xs greater cn
Balance of Payments China	5Xs greater cn
Total GDP UK	1.48 greater uk
Total Education UK	2.11 greater uk
Total Research UK	3.79 greater uk

The respective strengths of the NSI for each country are further explored using qualitative methods.

### Qualitative Analysis of Strengths in NSI for UK and China

Public questionnaire and email/telephone interviews with researchers were used to explore the relative strengths and weaknesses in the NSI. This approach provides a qualitative measure of NSI taken from a UK viewpoint. The areas covered by this

approach link the structure set out in the literature and research design in Chapters Two and Three, covering political influence, including legislation, regulation, investment strategies, patents, and culture - including current knowledge and views on therapeutic cloning and research investment.

Of those people responding to the questionnaire, 52.2% believe the UK has a strong legislative framework for therapeutic cloning, 79.6% believe that human cloning is illegal in the UK, but 19.1% think it is legal in China. 28.2% believe therapeutic cloning is legal in the UK, although 67.9% believe it is legal under license. In terms of investment for stem cell research, almost two-thirds (60.2%) do not believe the UK spends enough on research, with one in three saying spend has actually decreased in recent years. Only half (48.7%) believe the amount the UK invests is similar to other countries, with 57.1% saying the UK needs to spend more on stem cell research. Just over half (55.2%) acknowledge the UK as being highly motivated to find new innovations, but only 15.9% believe the UK had the first license to undertake therapeutic cloning when in fact it did. Half (49%) believe Dolly the Sheep was the first animal cloned, with 59.2% not believing China cloned a fish 37 years before dolly.

Only 9.6% believe China has a gene therapy cure for cancer when both are claimed to have been achieved. The majority (74.2%) believes stem cell treatments will be available abroad before the UK, although 65.4% believe the UK will lead in using therapeutic cloning to cure diabetes. Only 28.2% believe the UK population supports the creation of human embryos for research, although over half say they themselves do. These results suggest the population in the UK has some knowledge of what is legal in the UK but very little about China. They appear to have little faith or trust in China from

the answers given, one in five believing China to be undertaking human cloning. Very few people appear to consider China to be capable of any advance in therapeutic cloning, including a cure for diabetes. People are individually twice as likely to support the creation of human embryos for research as they consider the UK population to be.

The third approach to NSI involved email/telephone and personal interviews with senior policy leaders and scientists leading stem cell research. This approach was successful in obtaining comment for both the UK and China.

Amongst the researchers the UK is regarded as having strong, clear legislation for therapeutic cloning, with some skepticism about the corresponding legislation and enforcement of breaches in China. Some researchers regard the Chinese approach as unethical whilst others, who work there or have visited, report a very responsible approach to therapeutic cloning. Human cloning is illegal in both countries and therapeutic cloning is operated under license in both, with the difference said to be enforcement (East of England Network 2007). In the UK, enforcement is said to be so tight as to suggest a lack of trust, which in turn causes tension. The reality is unregulated tissue procurement is happening across the world with Chinese research reported to be well and legally organised from those with first-hand experience (Minger).

Overall, these results suggest the UK population believe more money should be spent on stem cell research if it wants to compete successfully with other countries. And whilst they regard the UK as a great innovator, they do not see it as an implementer of invention in stem cell therapies. Most people do not consider China to be capable of comparable results in this field of science. These views are at odds with the scientists

and policy representatives, most of who say the UK is well resourced for stem cell research but has a poor history of turning science to commercial advantage. They say that China enjoys more and longer-term funding and has state-of-the-art laboratories, which are mostly government funded. Although the UK is said to be planning on moving towards longer-term funding for stem cell projects, any potential results from the investment are a long way from entering the UK market. They say the UK is clearly reported as having the advantage in terms of mechanisms, but that China has the advantage in terms of application. China is reportedly using stem cell therapies in a clinical setting with most of the research led by doctors, which has brought rapid progress in this field. They are reported to be undertaking procedures on patients that are shown to work, but they do not have a detailed understanding of how or why.

## Part One Summary - Strengths and Weakness of NSI

National Systems of Innovation is defined in this study by the economic; political and social systems that underpin the legislative and research structures for stem cell science. Their strengths and weaknesses within the NSI for the UK and China have been explored in this section and are summarized for each country.

China's economic profile has changed rapidly during the time frame of this study. It has delivered a five-fold increase in its research investment with its GDP spend rising from 0.7% to 1.3% between 1990 and 2002 and, since December 2006, has the second highest spend in the world (Lombardi 2006). Research spend has been shown in the analysis of this research to make a statistically significant contribution to GPD performance, which is steady at 8/10% in China. The second area found to be of significance to economic performance in China is education, which has increased from

**DBA Final November 2008** 

2.3% of GDP in 1990 to match that of the UK at 5% by 2002. Expenditure on workforce and computer ownership in its population is also found to make a statistical contribution to GDP performance and to have increased rapidly. The importance of research investment in China is seen in its trade balance, which is positive in contrast to the UK and has an inflation rate below 1%. Strategically China's economic performance has been seen to translate to state-of-the-art-research facilities and long-term investment commitments for its researchers.

Its economic advance has enabled new research facilities and its investment strategies have attracted international researchers to locate their work in China. US investment in China has increased from \$7 in 1994 to 500m in 2000 (OECDc 2004), thereby increasing its market share in the biotechnology industry (Christiansen et al 2005). Its research investment is, however, skewed towards discovery rather than understanding, spending 5% of its total resource on basis science this compares to 16-22% of total spends in the UK (OECD 2002; Hepeng 2002). It has set up science and technology parks and knowledge transfer entities (OECDb 2004), supported by public funding for stem cell research from higher technology R&D programmes, National Natural Science Foundation, Ministry of Science and Technology, and Chinese Academy of Science (Hsiao 2004). Collectively these findings support a strong economic context for China in advancing stem cell research.

The social context is an interesting one. China is reported to have cloned a fish 37 years before Dolly the Sheep (Poo 2004), to have synthesised insulin before the Americans, and to have cured solid cancer tumors (Pearson et al 2004). China is currently working to cure diabetes in primates (Hepeng 2005) and has expanded

### **DBA Final November 2008**

progenitor cells within human or primate pancreatic cells, aiming to find the optimal number of cells necessary to cure the disease. It has published its intentions to become a leader in biotechnology (Jing 2003; Mann 2003; Quiming 2005), and it plans to maximise its advantages in having a relaxed ethics stance (Yank 2004) and access to primate and human research (Chien 2004). Its population has no ethical objection to the use of human embryos in this type of research (Dennis 2002), since the foetus is not considered human (Yank 2004). Neither does it face public opposition to the use of cells taken from terminated second-trimester foetuses (DTI 2004 BBC 2005).

The main strength of China's NSI identified in this research is its application of its stem cell science in the clinic (Salter 2007). It is already using stem cell techniques on humans with reported success. Its stem cell science is clinically led by qualified doctors, bringing significant advantage in knowing how to translate the findings in the laboratory into a clinical setting. Its patient studies are reportedly ethically approved in a societal context that suggests it is almost criminal to withhold a treatment that may help. Their research is reported by those who have been to China as both ethically and carefully controlled with an awareness and sensitivity to the views in Europe. In addition, China has excellent animal model research facilities and access to human subjects who, due to the historic isolation of China, afford homogeneous gene traits and a cheap research base (Mann 2004). With clinical trials only taking five years compared to 15 in the US and 20 in the UK (Yank 2004), a potential cure may be available to those able and willing to travel.

There are a number of weaknesses in China, one being the communication of its research (including published research findings), which reduces its credibility within the

international scientific community (Wu 2002). It is also said to suffer from structural vulnerabilities in reliance on imported technologies and to lag behind R&D intensity (Wilsdon 206). Compliance with legislation and regulation is said to have blighted their systems with plagiarism and research misconduct (Wilsdon 2006; Salter 2007). Although it has strong government support in terms of long-term funding and-state-of-the-art laboratories (DTI 2004), it is criticised for spending only 5% on basic research compared to 22% in the UK (OECD 2002 Hepeng 2002).

The UK has worked longer in the field of genetics (Best 2005), and its legislative and regulatory framework is regarded in the UK to be the best for therapeutic cloning (PHGU 2002). It was first to licence therapeutic cloning (Pincock 2004), and is said to have cost-effective research facilities (Best 2005) and accounts for 9% of global research (OECD 2000). Its scientists agree they are working within the best regulation in the world, with clearly structured research processes to apply for a licence for embryo stem cell research. The quality of science and its scientists are said to be high, with many centres of excellence. This enables a strong and stimulating work environment with clear guidelines and the ability to attract high quality recruits. The UK's academic links are reportedly strong, with easy communication, a prestigious reputation, and plans to increase its science budget from 3.9bn to 5bn by 2008. Researchers report the UK to have strong academic links, affords independent research, prestige, critical mass, and easy communication.

The NSI for the UK is shown to have a strong economic base against which to place stem cell research. Its main economic weaknesses are its investment in research as a proportion of GDP having fallen during 1990 and 2002 from 2.2 to 1.9% (OECD 2002).

The UK has explicit aims to reach 3% by 2014 (Brown 2004), although to date it's reported to be behind target. The analysis shows research investment to make a statistically significant contribution to GDP growth in the UK, which is suggested by the literature to affect economic performance (OECD 2004). Investment in education was the second area found to impact GDP growth with the analysis shows an increase in spends as a percent of GDP by 1995 to 5.5%, but a fall back to the 1990 level of 5% by 2002.

The UK is reputed for its strong government support for therapeutic cloning, having led the world in passing legislation to clarify the context for this work, and was first to issue a license to legalise it. It has been successful in cloning cells (BBC 2005), and this research found strong support amongst its scientists. The strength in regulation and policy is underpinned by increases in funding that aim to stimulation both innovation and its translation to commercial and therefore economic advantage (DoH 2002; DTI 2000; DTI 2002). From the public survey, these views are not always supported with many saying more investment is needed to compete with other countries. Interestingly, over half of the survey supports the use of human embryos and over 75% believe the UK will lead in finding a cure for diabetes, suggesting enormous confidence in its scientists.

Amongst the researchers, there is a view that more money and longer-term commitment to research programmes are this field is needed. Some even claims that the UK is being short-sighted in failing to provide sufficient infrastructure for stem cell research in comparison to other countries calling specifically for longer-term financial commitment.

Weaknesses include realisation of new technologies, as these are said to take 15-20 years longer in the UK (Dargie 2000; Raferty 2001; Wanless 2002; Dyers 2003; May 2003), with the House of Commons concluding in 2005 that many new technologies are simply not being implemented. It is this difference in clinical trials and market regulation that explains why gene therapy is available in China for cancer and not the UK (Luck 2004). Indeed the UK's approach to research funding and tight regulation is said by some to threaten the UK's global leadership position as well, and it has been suggested that China may make the steps more quickly (Mathur 2005). Culture and ethics are also highlighted as areas of concern in the UK (Knight 2004); its research trials take longer (Dyer 2003) and it has a poor history of turning its science to commercial advantage (DTI 2001).

In conclusion, the UK has led the world in developing stem cell science and has strong legislation, regulation and government support. Its economic climate is stable, growing at around 2.5% annually, and research funding for stem cell science is reported to be 'improving'. It is highly regarded internationally and has been a major player in the most significant genetic advances, such as decoding the human genome (Goodfellow 2001) and creating Dolly the Sheep (PHGU 2002). Its weaknesses are found to be its ability to commercialise its research; reduce GDP spend on research, the short-term nature of such investment, and the ethical values which hold stem cell science within the laboratory. Where China appears to have strength is in its economic growth that averages 10% (Wilsdon 2006) and its ethical context, which enables primate and human research (Chien 2004 Yank 2004). With much of this led by its clinicians, stem cell therapies have already advanced to the clinic.

# Part 2 - How do the National Systems of Innovations in the UK and China influence the translation of stem cell science into clinical treatment?

The NSI of a country sets the boundary within which its stem cell science is organised and may advance. This covers its government policy, its translation to research strategies and funds, and the cultural values of its society. Each will influence what is permissive, its pace, and the organisation of science and its ultimate advance to cures for human disease. There are notable differences, as discussed in question one, between the UK and China in each of these.

This part of the research is concerned with understanding which aspects of the National Systems of Innovation enable the creation of the science of therapeutic cloning and its diffusion. Although some of this is speculative, as therapeutic cloning for diabetes is not currently available in either county, there are indications of the issues to be understood or redressed from the introduction of related medical science. These include legislation and regulation, investment strategies, alternative access, and public opinion, which include acceptance and societal ethics.

Both the UK and China have strong political support for therapeutic cloning; suggesting the legislative pathway for stem cell therapies is permissive. This is evidenced in China by strategic intentions and long-term research investment (Wilsdon 2006) and in the UK by leading the world in major advances that stimulate public and private innovations. This is validated by the questionnaire where over 50% believe the UK has a strong legislative and regulatory environment for stem cell research and the scientists interviewed reported the situation as 'sorted and stable'. From the questionnaire results it is shown the UK public has little knowledge about the legislation in China, with only

**DBA Final November 2008** 

21% sure that human cloning was not legal there, too. The reality is much of the legislative structures for stem cell science are adapted from European structures (Salter 2007), so a degree of consistency with UK standards is to be expected.

Patent legislation is a proxy for stem cell technologies ownership and their translation within the innovation system (Brown 2003; OECD 2005). This offers a view on how money and power are distributed between countries (Baird 1998; ICC 2003). Human genes have been distinguished in many Western countries, including the UK, from being patented by the separation of discovery from invention (Burham 1997). It is a complex area of law, surrounded by concerns about the control of human life and scientific advance and an absence of prescriptive direction (Jenson 2005). UK patents provide protection for 20 years whilst the Chinese had been 7.5 years (Qiming 2005), although they have recently aligned this to European standards (Salter 2007). All research centers in the UK are encouraged under the 2002 science and technology regulation to exploit their 'findings' using patent registrations, but many report its application to stem cell research as being 'horribly complicated'. Some argue the patent system is impeding developments and point out that patenting the IVF process was resisted. UK researchers say 'the system is a minefield and far from adequate', some suggesting that an alternative system needs to be designed that is license-based. Of those questioned in the survey, 52.4% believe patent registration in this area of science is necessary while 14.2% do not.

In China, lax enforcement of its patent legislation (Giannakas 2003; Wilsdon 2006) is having an influence on how stem cell technologies are operating. This is evidenced by the effect on those organisations willing to set up research institutions in China and the

accuracy of the corresponding patent details so registered. The most public example is that of Pfizer, and its dispute surrounding Viagra when they refused to register the entire details of their product in their patent licence (Mooney 2004). China is working hard to improve the regulation of their patent market under the control of its national science and technology programmes. Its current enforcement, although improved since joining the World Health Organisation in 2002 (Hsiao 2004), reduces the effectiveness and attraction of its stem cell science.

The regulatory system is seen to be permissive in both systems, with strong government support, although enforcement undermines the Chinese credibility.

Societal values and culture are the next major aspects of the NSI that influence how stem cell research is translated to clinical treatments. This is where the greatest difference is found between the UK and China and the area suggested by many to separate the potential between the two countries (Mann 2004). The ethical climate of the UK is very different. From the questionnaire, just under half of the UK population support human embryo research in the UK, believing it to be essential to find cures for existing disease, but less than a third believe this to be the universal view of the UK population. That is an interesting position, as essentially people are saying they are supportive of this type of research but they believe it is other people who are not.

60.3% believe stem cell technologies will cure existing disease, 42.9% say human embryo research will lead to a cure for diabetes, and 43.6% agree the creation of human embryos is worthwhile to cure diabetes. The majority think a cure will be available abroad before it happens in the UK. UK scientists say that people will not travel abroad for such treatments and the risks of managing peoples' expectations will be harder than

any health risk. Many of its scientists believe the ethical focus is misplaced and does not help the position of UK stem cell research, urging social scientists to take on this focus. Others claim there is no future for stem cell therapies in any country because the medical, legal, ethical and religious objections are all too great to overcome. Put simply, the UK is said to have the advantage in terms of legislation and operational practice, while the Chinese are putting their research into practice.

The public survey found that almost 90% of people believe that ethical concerns will slow the advance of stem cell science in the UK. The survey found 43% supported the creation of human embryos for research, a proportion that rose when separated by those with diabetes or other genetic illness. The ethical context is wider than personal opinion in the West, as it underpins religious belief and values and challenges, some believe, the very structure of human civilisation. In the West the science of genetics (of which stem cell techniques are a major part) afford the potential use of these technologies to promote ethnic prejudice (Pinnick 2002) as weapons of mass destruction (OECDc 2004) and playing God in selecting to destroy human life (Epstein 2002). There is an analogy here to the creation of human embryos for IVF where many fertilised eggs are destroyed, but this technique was never given public sanction (Ridley 1999). Once the first 'test tube baby', Louise Brown, was born this procedure was largely accepted. This study found a clear division between those holding religious beliefs and those who do not in the issue of embryonic stem cell research.

In China there is no such concern. The Chinese see only prestige and economic advantage in advancing stem cell science in the clinic. Indeed they are counting on this aspect of their national innovation system above all others to give them a lead (Mann

2003; Hsiao 2004). The ethics in China are that if somebody is sick and there is a possibility a new intervention may help, it is almost criminal to withhold it. China is said to be approaching this responsibly and it should not raise any concern, although ethical controls are considered by many to be looser in China, with doctors said by some to be unable to guarantee safety in their work. The social aspect of the NSI is shown to be restricted in the UK and permissive in China, affording a distinct advantage.

# Part Two Summary – How do the NSI of the UK and China influence the advance of stem cell science?

Ultimately the NSI for each country influences how stem cell advances by determining the boundaries of acceptability. In China the permissive nature of its societal culture and values alongside government funding has enabled it to translate its science into human treatments. Dr Xia Wang from Newcastle Life Sciences believes this application of its research in a clinical setting is China's most notable advantage. Chinese scientists are said to be a bit more adventurous, especially if the patient has end-stage disease. Its research systems are found to be as advanced as the UK and to benefit from clear long-term funding strategies. It political and legislative systems are also permissive and advanced, with strong long-term research funding. These aspects translate to enable the application of stem cell science in a clinical setting, within a strong regulatory structure. The NSI for China is found to be permissive and operational.

The UK NSI is highly organised, having led in determining the structures for managing the control and ethics of stem cell research in the Western world. Its political system is also supportive, but it is more cautious. This is evidenced by the current debate on chimera research, which was almost banned in the UK, but subsequently approved

under licence. Research investment is still short-term and within a failing GDP target that looks unlikely to reach 3% by 2014 (OECD 2004f; National Statistics 2007). Its stem cell research remains largely laboratory-based, although there are examples of stem cell trials. Its NSI is broadly facilitative but limited by long-term funding, cultural ethics, and clinical regulation.

# Part 3 - Due to the NSI, which Country will first develop a stem cell cure for Diabetes?

In the UK Stem Cell research is led by the Newcastle Life Sciences and Kings College London where their work is still currently focused on the use of adult stem cells in the process of therapeutic cloning. Work in China has already advanced to curing diabetes in primates at Xuan Wu Hospital Stem Cell Therapy Centre. One of the main reasons for this difference is cultural ethics, as evidenced by almost 90% of people in the UK questionnaire who say the ethical stance of the UK will slow progress in stem cell research in the UK. China has excellent animal facilities, making research cheaper. They tend, therefore, to be more adventurous, although some scientists claim this approach makes their controls too loose and gives too much power to doctors who cannot always guarantee safety. Those who have witnessed this work in China say these claims are not true and that China has clear and proper ethical control. However whatever the advances in China, they would not be permitted in the UK due to controls and clinical trial regulations. Indeed many in the UK now say past advances such as percutaneous angioplasty are no longer possible because of tight clinical trial regulation.

The challenge of this work is to explore whether the UK will advance therapeutic cloning into a clinical setting for diabetes ahead of China. Of those responding to the UK questionnaire, 6.6% are diabetic. Their views can be distinguished from all other

categories in the analysis in believing consistently that China would be the first country to cure diabetes. They also agreed that embryo stem cell research was essential to advance this. 29% of the study had a family member with diabetes, and they too supported human embryo research more than the average. There are many scientists who also believe China will advance clinical services more quickly than the UK, although it is suggested that China may lack an understanding about how these work. The requirement of clinical trials at a European level will control the translation of these in the Western World (Neergaard 2006).

The Chinese appear to have a number of advantages that are driving their research into clinical practice. Access to primate research, strong long-term government funding, and a cultural acceptance that appears to make therapeutic cloning more easily translated into clinical therapies. In China, stem cell therapies have advanced to the clinic with many therapies advertised on the internet, encouraged by reported success in curing diseases such as motor neurone disease (Goldkorn 2005). Evidence in this work appears to suggest the Chinese have an environment fuelled by strong government funding, economic growth, public compliance, and clinically-led science. Opinions gathered from senior science and policy-makers do vary, but all those with connections to China believe it will be first in using therapeutic cloning. In this study the majority of the UK public did not. Because of this difference of opinion, it is helpful to use innovation theory to answer the question of which country will lead.

Nelson and Roseberg (1993) and Nelson (1992) studied the process used to get innovation into practice, suggesting the need to understand the system in which they are to be introduced. Understanding the internal dynamics of the innovation sequence is

said by Mina et al (2004) to happen over time and involves an understanding between investment, knowledge creation, and process interactions (Fagerberg 2004). In applying this approach to the question of which country will achieve a cure first, it is helpful to order the respective strengths of the National Systems of Innovation along a simple innovation sequence.

	UK	China
Economic Infrastructure (2002)		
Current GDP Performance	equal	equal but growing at + 8%
Trade in Goods and Services	-1.6%	24%
Inflation	3% stable	2% stable
Balance of Payments	Negative	Positive
Investment in Education (GDP)	4.9%	5.23%
Investment in Health (GDP)	7.7%	5.8%
Spend on Research (GDP)	1.89%	1.31%
Legislation/Regulation	permissive	permissive
Research Investment	short term	long term
Research Workforce	academic	clinical researchers/doctors
Culture	ethical concerns	ethics an advantage
Existing Research Evidence	laboratory only	cured diabetes in monkeys
		Work/evaluate islet cell required
		Some treatments in clinic

This design sequence captures the values for the NSI of China and the UK. It illustrates clearly that China has a stronger overall economic context for research investment, equals the UK with permissive legislation, and has been able to advance to the clinic due primarily to the absence of ethical concern. The UK leads in legislation and research investment but has lower measures of economic performance and growth. Using these measures, the innovation sequence is weighted in China's favour.

## Conclusions

Three approaches have been used to explore the research question of understanding how the National System of Innovation for the UK and China is influencing their work in stem cell science. The definition and structure of the design is taken from the innovations literature and extended to this clinical research. The economic aspects of national innovation are structured in an historic time series from 1990 to 2002 and show the UK statistically to have stronger economic factors of innovation. GDP investment in education and research were found for both the UK and China to make a statistical contribution to economic growth.

In China, this increased during the research period of 1990 to 2002 from 2.3% to 5% and from 5.5% to 5% in the UK. UK spends for the same period on research fell from 2.2% to 1.9% whilst it rose from 0.7% to 1.3% in China. There is further evidential improvement in China during the time of this study, most notably in the area of research investment, which rose to 1.3% in 2005, becoming the second largest research spend globally (Wilsden 2006; BBC 2006a). The UK-based research interviews expose further the differences in the two NSI, most notably the relaxed ethical stance in China and the strong regulatory leadership in the UK. The various strengths and weaknesses between the two systems are compared in an innovation sequence in the final section of analysis, where diabetes is used as a model to make the comparison. This result suggests when all the factors of innovation are taken together that China has a stronger NSI for stem cell research.

The strengths in the NSI for China are shown to be the size and long-term nature of its research investment, it's historic and projected economic growth, its state-of-the-art infrastructure, doctors leading its stem cell research, adoption of European legislation,

**DBA Final November 2008** 

its relaxed and permissive ethical stance, and how these have enabled it to translate the science to clinical practice. The weaknesses that undermine these are its lax enforcement of Intellectual Property Law, the absence of creditable publications and suspicion of its operational culture (due to Korean fraud). The corresponding position for the UK shows it strengths to be its high global reputation, historic leadership in science, and strong government support. Its weaknesses are found to be its short-term investment strategy, decline in research investment as a proportion of GDP, societal concerns, and the requirement of its clinical trails, which prevent the advance of much of its science to the clinic.

These can be summarised using the same framework from Chapter Three used to structure the research question.

Strengths and weakness of National System of Innovation			
Factors of Innovations	UK	China	
Economic Systems	Improving	Significant strength	
(National Investment Strategies)			
Political Systems	Permissive	Permissive	
(Legislation and Regulation)	Global leader	Adopt European	
	IPR system regarded	Weak IPR system	
	Reputable and trusted	Western Distrust	
Social Systems	Access to health care	Limited access to health	
(Disease and Morbidity 2002)	2.2m	40m	
Research Environment	Laboratory based	Treatments in clinic	
(Investment Strategies)	short-term	long-term	
	Global leader in science	Little published research	
		Low investment in basic	
		Cloned hybrid 2003	
Culture and Ethics	Moral and Religious	Societal acceptance	
(Societal Acceptance)	objections	Primate and human research	

The importance of this study and its findings are in offering an insight to the policy position and opportunity for an area of science considered by many to be potentially the most important scientific advance to man. Its importance is more than social, in affording cures for diseases such as cancer and heart disease (Hepeng 2005) with economic advancement is shown to correlate to research and development (OECD 2004a). The NSI of a country is found in this research to impact the advance of stem cell science in a number of ways. When taking the NSI to be its economic, legal, and social features, it can be shown that some aspects are more permissive and enabling for

stem cell research. These include societal positions on the use of human embryos, the application of cures that cannot yet be explained, the nature and stability of research investment and the underlying economic position of a country. As the business problem is defined in two parts, so too is the importance of the contribution of this study.

On an economic level, investment in research and its focus on marketable outcomes are shown to be vital if a country is to improve its performance (and all the life quality issues that are associated with this). China is found in both to have stronger underlying economic performance and growth and to have a stable, long-term commitment to its research funding for stem cell science. The second aspect is in providing an understanding of the societal context, which is evidenced by the values and ethics of a government and its population. The UK, like many Western cultures, struggles to advance its genetic science exampled by its hybrid research (BBC 2008) whilst China has no such concern (Poo 2004). This research found about half of the UK sample did in fact support embryo research, a finding substantiated by a subsequent study on-line. The two difficulties it faces that need to be understood further are the communication of complex issues and the relationship with those people holding religious beliefs.

# DBA Chapter Five Summary and Conclusion

#### Review

This research set out to explore the advance of stem cell science in the UK and China from a UK perspective using National Systems of Innovation as a theoretical structure and diabetes as the clinical model. Although stem cell research applies largely to Type 1 diabetes, work reported in the BMJ shows its advance will have significant application to both types of the disease (Serup et al 2001). This case study between the UK and China has been undertaken from a UK perspective, with Chinese information taken from the creation of a new economic data set from 1990 to 2002 and interviews with scientists who work in both countries.

Therapeutic cloning has, since the US cloned human embryo cells in 1998, offered major opportunity to cure human disease and disability (Shamblott and Thompson 1998). In this type of research the cells are undifferentiated affording the potential to grow into any cell or tissue type. The technique of using human embryos for research offends many, including religious and pro-life groups covering swathes of Western populations. This leaves governments with the challenge of regulating this new science, of managing public opinion, and advancing its potential. This research found strong and consistent objection to the use of human embryos amongst those holding religious belief.

The US did this by prohibiting the use of public research funds on embryos, except those created for use in IVF prior to 2002. The European Union issued a one-year moratorium before issuing new guidance that permits the use of government funds for

human embryo research, although this is objected to in Germany, Austria, Lithuania, Malta, Poland, Slovakia, and Luxemburg (BBC 2006). The UK adopted European guidelines into its legislation and permits embryos to be used and created for the purpose of research under licence by the Human Embryo Fertilisation Authority up to 14 days from fertilisation. It succeeded in cloning for therapeutic purposes its first human embryo in 2005 (Lawless 2005). China has also introduced permissive legislation for human embryo research and has, since 1999, been successful in cloning human embryos (Yank 2004), implementing European regulation to support this. It has reportedly translated this to clinical practice, since its first gene therapy cure for cancer in 2004 (Pearson) to many advertised conditions including Epilepsy, Muscular Dystrophy, Cerebral Palsy, and Motor Neurone Disease at Medra (www.medra.com).

This research is structured around the Systems of Innovation, as they relate to stem cell therapies at a National level for each country. The definition of NSI as it relates to therapeutic cloning was framed from the literature and covers the political context, including economics and legislation, intellectual property, public culture, demography, knowledge, and the relationship to diabetes, the disease area being studied. These were taken from the works of several, including Edquist (1997), Freeman (1997), and Fagerberg (2004).

The first area examined was the relative strengths and weaknesses of these for the UK and China as they relate to therapeutic cloning. This established that the UK has a stronger economic background, but China is growing at a far greater rate, with total GDP growth in China being more than twice that of the UK. Perhaps of most significance in the economic indicators is spend on research, which has doubled as a percent of GDP

between 1990 and 2002, while the UK spend reduced from 2.2 to 1.76 (National Statistics). Indeed, China had by the end of 2006 the second highest international spend on research (Lombardi 2006). Despite policy to reform research investment in the UK, on current projections China will equal GDP performance with the UK by 2010. China also has inflation rates at less than half that of the UK and a positive balance of payment while the UK is negative, suggesting a stronger underlying economy.

The relationship between research investment and GDP performance was found in this work to be statistically significant, suggesting potential economic weaknesses in the UK position. The respective strengths were explored using a public questionnaire and email/telephone interviews with researchers. These found that the majority of the UK public are suspicious of China and believe very little of its achievements or possibilities. This varied when people living with diabetes were separated from the samples, as they were found to have a more positive perception of Chinese science. Amongst the scientists themselves the views were mixed. Those who have visited or worked in China appeared to hold their science with respect and admiration.

The UK was well-regarded too, especially in system areas such as legislation and organisation of the science, although funding is said by some to limit their work. Ethical concerns are said to restrict UK science, as evidenced by the debate on Chimera cloning and changes in the legislation to permit women to donate embryos outside of clinical treatments (HEFA 2006). Chimera cloning involves using a rabbit or cow embryo and was expected to be banned in January 2007. While a decision was awaited, a public survey was carried out on AOL on 14<sup>th</sup> January 2007 asking 'do you support the use of embryos for research?' 66% replied yes, which is a very similar result to this study. UK approval was finally granted (BBC 2008). The interesting point is public

**DBA Final November 2008** 

support appears, from both studies, to be stronger than the government appears to recognise.

The Chinese Government, in contrast, is said to have substantial and long-term financial support leading to some of the best quality laboratories in the world. But overall it appears to be the relaxed ethical stance of China that has enabled major advances in therapeutic cloning and has offered the advantage. China is found to have moved into the clinical setting to treat patients (Ning 2005), is reported to have cured cancer using gene therapy (Pearson et al 2004), and is reported to have advanced to treating leukaemia with plans to progress shortly to working on diabetes (Hepeng 2005).

This work considered whether any of the factors of innovation, as identified, were able to predict the trend in diabetic prevalence, which is a major economic and social threat to human health (WHO 2002). This found that growth in GDP and trade in goods and service gave the strongest indication, suggesting China might be facing significant and rapid increase in the disease if alignment to its economic success continues. The next area to be examined was how the respective National Systems of Innovation might influence the translation of therapeutic cloning in the treatment of diabetes. This found the UK legislative system to take at least 20 years compared to 5 in China for clinical trials and research (Yank 2004). China's lack of investment in basic research is thought to restrict its credibility in its stem cell and scientific advance.

Those aspects of the NSI found to influence the translation of the science to treatment includes investment in the research, legislation of the clinical trials, and societal values.

The questionnaire results found most of the population did not consider China capable

of curing diabetes (85%), a view supported by some of the researchers. However, those who have visited or worked in China were confident it not only could, but that it would. The issue here appears to be that even if China does cure diabetes; European legislation of clinical trials would require the results to be replicated before they could be considered. This study found that most people with (or having family members with) diabetes would be willing to travel to China to find a cure, believing such therapy would not ever be available on the NHS.

The respective strengths and weaknesses of therapeutic cloning between the UK and China were also compared. The advantage the UK was found to have is a prestigious reputation, first class scientists and institutions, strong government support, and a strong history of invention (PHGU 2002; Best 2005). Already it accounts for 9% of global research whilst having only 1% of the world's population (OECD 2000). It has worked in the field of genetics longer than anywhere else (Best 2005) and is reported to have the best regulation of stem cell science in the orld. Its disadvantages were found to be short-term research funding strategies, a decline in research investment as a proportion of GDP (Dasgupta), the length of its clinical trials (Dyers 2003), and a poor history of turning innovation to commercial advantage (DTI 2001). Indeed, some will go as far as to suggest the UK is in serious danger of losing any perceived advantage it may have because of its tight funding and regulation regime (Mathur 2005).

The advantages of the Chinese in therapeutic cloning are said to be its evident success in application of the science in the clinic (Hepeng 2005), its relaxed ethics (Yank 2004), the length of its clinical trials (Yank 2004), and their advanced infrastructure (OECDb 2004). They also have access to human and primate research (Chien 2004) (making

their cost base cheaper), strong and long-term Government funding (Hsiao 2004), and a strong advancing economic base. Their weaknesses are said to be in their basic science, which has been greatly affected by their isolated history and the absence of focus on the communication of their research in the published literature (Wu 2002).

The final question for this research was which country is likely to cure diabetes first. The national factors of innovation were summarised and compared. This found GDP performance to be equal but growing at a far greater rate in China and for trade in goods and services to be far stronger. Inflation is slightly lower in China but stable in both, balance of payments is negative for the UK but positive for China, and investment in education is equal. Research as a proportion of GDP is higher in the UK, but both countries have permissive legislation. China's research investment is long-term while the UK's is short-term. China has an advantage in its ethical stance and is already treating patients while the UK research is still laboratory based.

These findings should be taken in context with China's economic growth of over 10% of GDP for the last five years 10.5% in 2006 – which suggests it is, has a far stronger investment potential to support its stem cell research. Aside from some very serious social issues to manage within its economic success (Zheng and Chen 2006), it has played a major part in Asia taking over from Europe as the second largest spender on research as 32% of the world total (Wagdy 2006). By the end of 2006, China will have taken over Japan to become the second highest spender on research, spending \$136bn in 2006 (a 77% increase between 1995 and 2004) compared to \$330bn in the United States. They now employ 926,000 researchers compared to 1.3bn in the US (Lombardi C 2006). It is against this backdrop of investment and personnel that China's strength to succeed appears greater.

#### **Policy Implications**

During the six years of this research thesis, there have been many views on the position of China's role in stem cell treatments, some based on experience, others from the absence of evidence available. Indeed, current news now regularly reports on variable treatments. What is clear from this is that there are a number of policy implications from this work that will shape the NSI in both China and the UK, as the science advances.

#### These are:

- The length of time taken for clinical trials in the UK is suggested to threaten its position in leading innovation
- Stem cell research in the UK needs to advance into human clinical trials more quickly
- Tight regulation in the UK is important for public safety but maybe slowing the pace of innovation
- Research funding for stem cell science needs a longer term financial strategy.
   In this study half of those responding believed the UK needed to spend
   more on stem cell research
- The UK needs to align its research funding with clear commercial strategies

- There needs to be more meaningful and simple communication with the public about stem cell science, the use of human embryos, and clinical trials. There may be more public support for embryonic stem cell research than reported.
- 75% of people said they would access a stem cell cure abroad if it were not available in the UK. Current structures are restricting innovations for many years in the UK without any real debate with the public. New health innovations need to be available more quickly in the UK, which will require opening up market opportunities for the independent sector and changes in legislation. This is an issue that goes wider than stem cell science, involving the containment of innovation in the UK NHS system.
- For China, its spend on health care and the percentage contributed by its
  government were shown statistically to impact its performance in trade in goods
  and service, suggesting its health system is having a far greater influence on
  economic productivity than the UK. Finding long-term solutions to its health
  structures is suggested to be essential to its sustained economic performance.
- China already knows detection of fraud and enforcement of its legislation and regulation of its stem cell science go to the heart of its credibility
- China needs to publish more data on its current work, using standards for clinical trials that are recognised by the Western world

**DBA Final November 2008** 

#### **Future Work**

There are many ways this work might be taken forward. An obvious one is repeating the public questionnaire and research interviews in China to obtain some comparison, but my suspicion is that their relaxed approach to the ethics of embryo research would prevail and strengthen the Chinese position. Another area of significant interest from this study would be to explore further whether people really are willing to travel to China for treatment and cure and how real the concerns of safety are. Most people, whether of the public or researchers in this field, do not think this is likely, but it would be interesting to understand the basis on which people might make such a choice against going. Probably the biggest question arising from this work is whether the highly regulated environment of the UK is an advantage or disadvantage in therapeutic cloning. Clearly the complexity and ethical concerns demand such accountability, but with thesis comes restrictions such as clinical trial regulation and the assessment body, NICE.

There appears to be a strong possibility that therapeutic cloning will cure disease long before science is able to explain why; indeed, this is already happening in China (Medal). I wonder how long people in the UK might wait before the function of all genes is understood with their relationship to human characteristics, including systematic mutation, or for the calculation of activity in proteins produced by specific cells or tissue, and how these proteins combine to perform specific functions. Indeed some of the research scientists interviewed in this study also questioned whether an explanation was really necessary. History shows many innovations have advanced outside formal clinical trials and without explicit public debate. The birth of Louise Brown was the event that made IVF a reality but was not a technique agreed publicly (Ridley 1999), with both stents in heart surgery and bone marrow transplants surviving disastrous early results to

become mainstream procedures. From this research China suffers from neither the social nor regulatory restriction making it well placed for the next major step-change in the management of human health.

#### Strengths and Weaknesses of the Research

There are a number of strengths in this research, most notably in its construction. It was a difficult area to place a study, as there was nothing in the historic literature to afford a structure. This was achieved in a tripartite approach in the research design, taking the key components from the literature. This has extended the use of NSI to a new clinical area and offered an empirical framework in its design. The research provides an insight to the views of the UK public in the area of stem cell research and establishes links between the views held and the personal characteristics of an individual. For example, the relationship between people and their families living with an incurable disease and those with religious belief is established. This research also includes comment from some of the most eminent policy and scientific researchers in the field of stem cells. The structure and design would be easy to follow if another study was taken to replicate or extend the results. It also provides a database of economic information for the UK and China that did not previously exist. It would be easy to extend the statistical analysis and show change since 2002.

Its weaknesses include not extending the public questionnaire to the Chinese population and limiting the data to 2002. Although the study was not designed to include the Chinese public, two attempts were made to distribute the questionnaire in China, neither proving successful. Although this is redressed somewhat in the policy and research interviews, it would have added a useful dimension to the results. Limiting the economic

data to 2002 occurred because it was simply the most recent date at the time of analysis. This has been strengthened by including reference to the more recent statistics, where available, in the discussion (National Statistics 2007).

#### Reflections on Learning

It has been a fascinating six years studying both the advance in stem cell science and the position of China in the global market. Perhaps earlier in these studies it was more difficult to justify the research interest to business, but this is not apparent in areas far wider than this research. It is an Interesting and stimulating research topic as it touches on the concept of life, its creation, and manipulation, and at a level no other species on earth could come close to. The ethical aspects of eugenics, equity and human suffering are all incorporated, as are the philosophical aspects of right and wrong, good and evil. In addition, building an economic comparison for the UK and China in a way that had not previously been achieved highlighted some fascinating trends, such as the strength of China's economic foundation and this pace of its advance.

It was a difficult study that suffered from many blind alleys and time on work that never found its way into the thesis. Developing a theoretical framework over the first two years was complicated, involving many structures and drafts that were too vague. Using NSI was not a simple transfer, requiring absolute clarity about how it was used in other clinical studies and the justification of extending this to stem cell science. Building a database on economic factors of innovation for the UK and China was difficult, as many of the indicators were not routinely available and I had to search many databases and publications to build, in some cases, year-by-year numbers. Having built this great economic data and a list of all stem cell research in the UK and China involved in

diabetes, I couldn't get many of the science and policy leaders to speak to me.

Professor Cathy Prescott from Avlar Bio Ventures Limited changed this and enabled many contacts, including Professors Murdoch and Minger.

#### Contribution to Knowledge and Learning

There are a number of ways this work contributes to knowledge and learning:

- It provides an economic comparison between the UK and China that had not previously been achieved
- It provides a framework and an empirical structure for the use of National
   Systems of Innovation in stem cell science
- It proves the relationship between religious belief and the absence of support for embryo stem cell research
- It proves that half of the sample population supports therapeutic cloning
- It proves further evidence of the position and role of China in stem cell science in identifying and validating the strengths of its national system
- It provides further validation of the importance of research to economic performance and highlights the decline, as a portion of GDP performance, in the UK
- It provides evidence of the contributions GDP spend on research and education are making to economic performance
- It provides evidence of the translation of stem cell procedures in clinical practice
   that is already happening in China yet restricted by European legislation in the UK
- It identifies the strengths and weakness of the NSI for the UK and China as they
   relate to stem cell science

**DBA Final November 2008** 

#### Conclusion

This work set out to explore the relationship between the National Systems of Innovation in the UK and China and the advance of stem cell research. It found strengths and weakness in both systems and describes how these are influencing their science, offering an opinion on which country is likely to advance a cure for diabetes. The UK clearly has a global reputation with much attributed success in the field of stem cell research (DoH 2003; PHGU 2002; Best 2005).

In this work, China is found to have a stronger economic future, greater and faster research investment, and perhaps most significantly, an ethical and political advantage.

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# Appendix A

Gail Newmarch

# Questionnaire Stem Cell Technologies and Health Questionnaire – Stem Cell Technologies and Health

Personal Details	What is your Nationality?
Gender  Male  Female   Please indicate your age:	British
	Yes No
What is your occupation?	Do you have any religious   beliefs?
Student	Do you have diabetes?
Clinical  Other Professional  Non-Professional  Other	Do you have a family member with diabetes?
	Do you have any other genetic illnesses?
_	Do any members of your family have genetic illnesses?
Please indicate your views about the following s	tatements by ticking the corresponding box
Dolly the sheep was the first cloned creature in the world?	The UK lead the world in stem cell research
<ul><li>□ True</li><li>□ False</li><li>□ Not Sure</li></ul>	<ul><li>□ True</li><li>□ False</li><li>□ Not Sure</li></ul>
China cloned a fish 30 years before Dolly was born	Human cloning is illegal in the UK
<ul><li>□ True</li><li>□ False</li><li>□ Not Sure</li></ul>	<ul><li>□ True</li><li>□ False</li><li>□ Not Sure</li></ul>
Human cloning is legal in China	The UK has the world's first licence for therapeutic cloning

203

Gail Newmarch

<ul><li>□ True</li><li>□ False</li><li>□ Not Sure</li><li>China has produced a gene therapy cure for Cancer</li></ul>	☐ True ☐ False ☐ Not Sure  China will lead the world in producing a cure for diabetes	
<ul><li>□ True</li><li>□ False</li><li>□ Not Sure</li></ul>	<ul><li>□ True</li><li>□ False</li><li>□ Not Sure</li></ul>	
Therapeutic cloning is legal in the UK  True False Not Sure	Human embryo research is legal in the UK under license  □ True □ False □ Not Sure	
Please indicate how strongly you agree or disagree with the following statements		
The UK Government spends enough money on research	The amount of money the UK Government spends on research has increased in recent years	
<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>	<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>	
The UK Government spends as much on research as other countries	The UK Government needs to spend more on stem cell research if it wants to compete with other countries	
<ul><li>☐ Strongly Agree</li><li>☐ Agree</li><li>☐ No Opinion</li><li>☐ Disagree</li><li>☐ Strongly Disagree</li></ul>	<ul><li>☐ Strongly Agree</li><li>☐ Agree</li><li>☐ No Opinion</li><li>☐ Disagree</li><li>☐ Strongly Disagree</li></ul>	
The UK has a strong legislative framework to manage and control stem cell research	More centres should be allowed to carry out human embryo research in the UK	
<ul><li>☐ Strongly Agree</li><li>☐ Agree</li></ul>	<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li></ul>	

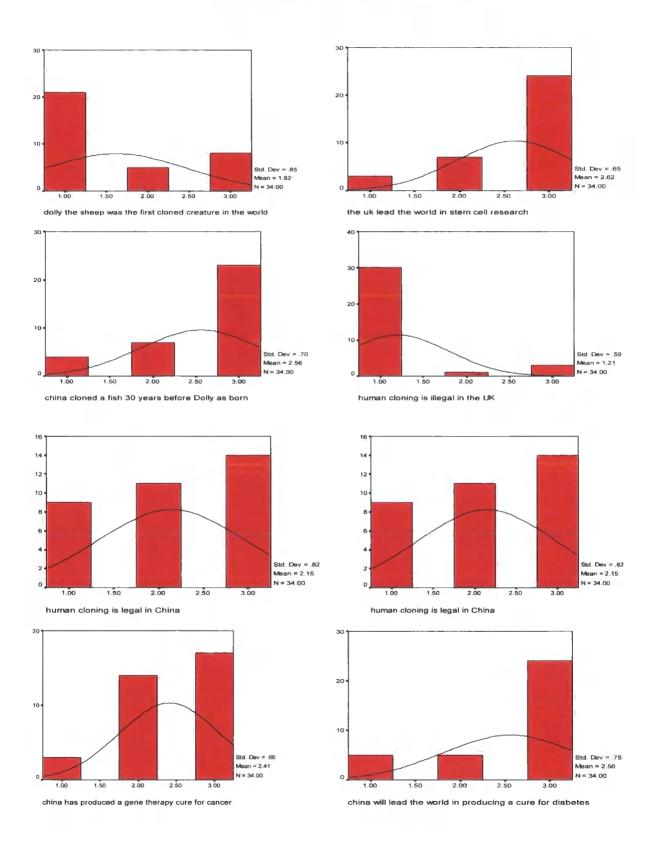
204

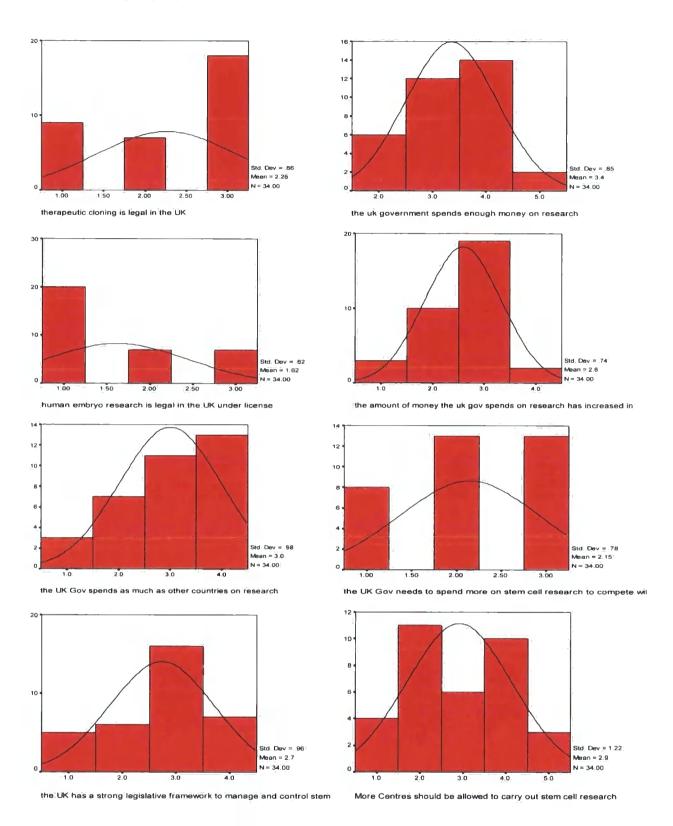
<ul><li>□ No Opinion</li><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>	<ul><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>
New genetic discoveries should be available to the public from the internet	Human Embryo research will produce cures for existing diseases
<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>	<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>
Human embryo research will in time cure diabetes	Any potential cure for diabetes will not be affordable under the UK NHS
<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>	<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>
Finding a cure for diabetes is worth the creation of embryos for research	A stem cell cure would replace existing therapies for diabetes
<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>	<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>
Stem Cell Therapies will be available in the clinical area of diabetes within the next 10 years	When stem cell therapy for Diabetes is found it will be available in the NHS
☐ Strongly Agree ☐ Agree ☐ No Opinion ☐ Disagree ☐ Strongly Disagree	<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li><li>□ Disagree</li><li>□ Strongly Disagree</li></ul>
Stem Cell Therapy for diabetes will be available abroad before is it in the UK	The UK is highly motivated towards finding new innovations
<ul><li>☐ Strongly Agree</li><li>☐ Agree</li><li>☐ No Opinion</li></ul>	<ul><li>□ Strongly Agree</li><li>□ Agree</li><li>□ No Opinion</li></ul>

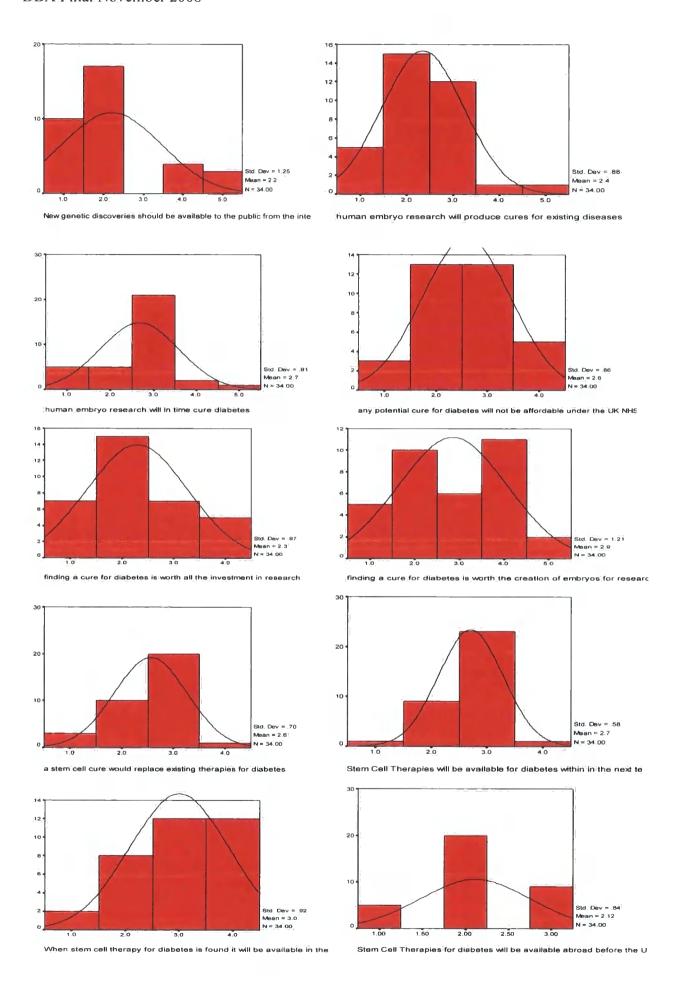
□ Disagree	□ Disagree
□ Strongly Disagree	☐ Strongly Disagree
I use the internet to find out about health	I would buy genetic tests using the interne
services abroad	- 0
☐ Strongly Agree	☐ Strongly Agree
□ Agree	□ Agree
□ No Opinion	□ No Opinion
□ Disagree	□ Disagree
□ Strongly Disagree	☐ Strongly Disagree
I would go abroad for treatment that is not	I would not have any concerns about
available in the UK	accessing stem cell treatments abroad
☐ Strongly Agree	☐ Strongly Agree
□ Agree	□ Agree
□ No Opinion	☐ No Opinion
□ Disagree	□ Disagree
□ Strongly Disagree	☐ Strongly Disagree
Human embryo research is essential to	The UK population supports human
find cures for existing diseases	embryo research
□ Strongly Agree	☐ Strongly Agree
□ Agree	□ Agree
□ No Opinion	□ No Opinion
□ Disagree	□ Disagree
☐ Strongly Disagree	☐ Strongly Disagree
Ethical concerns about creating embryos	Patent Registration for genetic discoveries
for research in the UK will slow down	is essential to support investment in
discoveries	discovery
□ Strongly Agree	
□ Agree	☐ Strongly Agree
□ No Opinion	□ Agree
□ Disagree	□ No Opinion
□ Strongly Disagree	□ Disagree
	□ Strongly Disagree
Embryo stem cell research will find a cure for diabetes	The UK will be first country to find a cure for diabetes
☐ Strongly Agree	☐ Strongly Agree
□ Agree	□ Agree
☐ No Opinion	□ No Opinion
□ Disagree	□ Disagree
□ Strongly Disagree	□ Strongly Disagree
The first country to find a stem cell cure	PLEASE RETURN BY EMAIL TO
for Diabetes will be China	
☐ Strongly Agree	Gail.newmarch@dur.ac.uk
□ Agree	Or post to Four Elms Brook Road
☐ No Opinion	Tolleshunt Knights
☐ Disagree	Maldon
□ Strongly Disagree	CM98EX

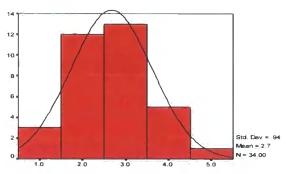
## Appendix B

# Pilot Questionnaire - Histograms

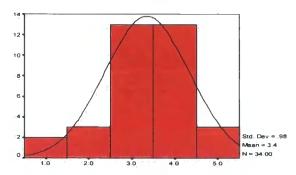




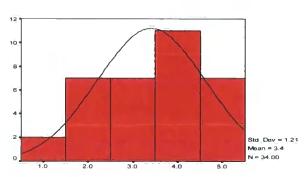




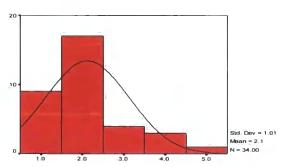
The UK is highly motivated towards finding new innovations



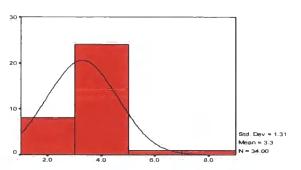
Luse the internet to find out about health services abroad



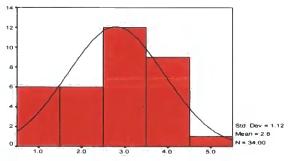
I would buy genetic tests using the internet



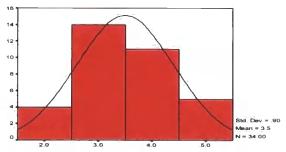
I would go abroad for treatment that is not available in the UK



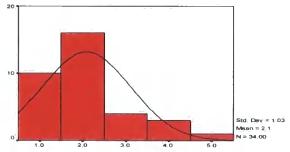
I would not have any concerns about accessing stem cell treatment ab



Human Embyro research is essential to find cures for existing disease

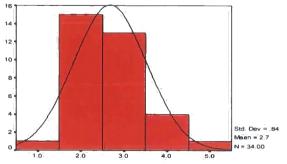


The UK population supports human embryo research

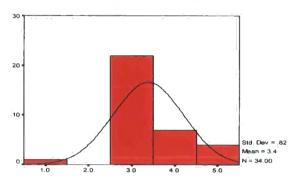


Ethical concerns about creating embryos for research in the UK will slo

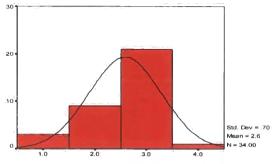
### DBA Final November 2008



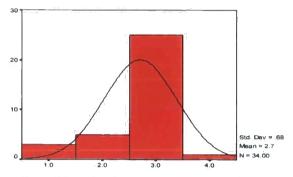
Patent registration for genetic discoveries is essential to support inve



The UK will be the first Country to find a cure for diabetes

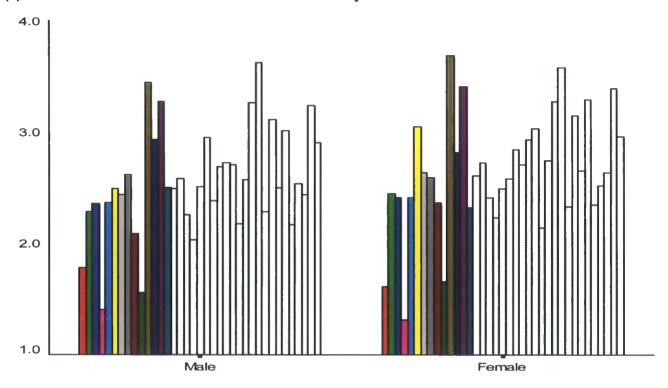


Embryo stem cell research will find a cure for diabetes

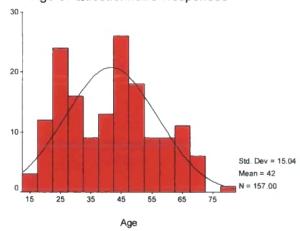


China will be the first Country to find a cure for diabetes

Appendix C: Data from Questionnaire Analysis

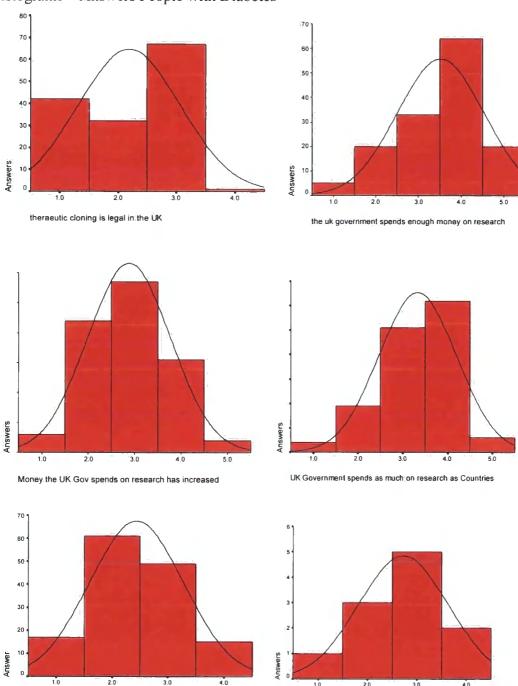




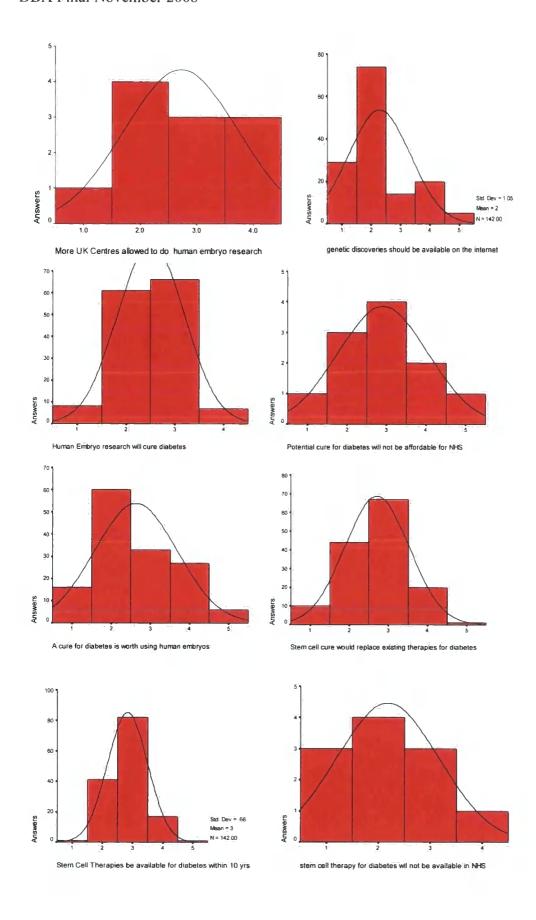


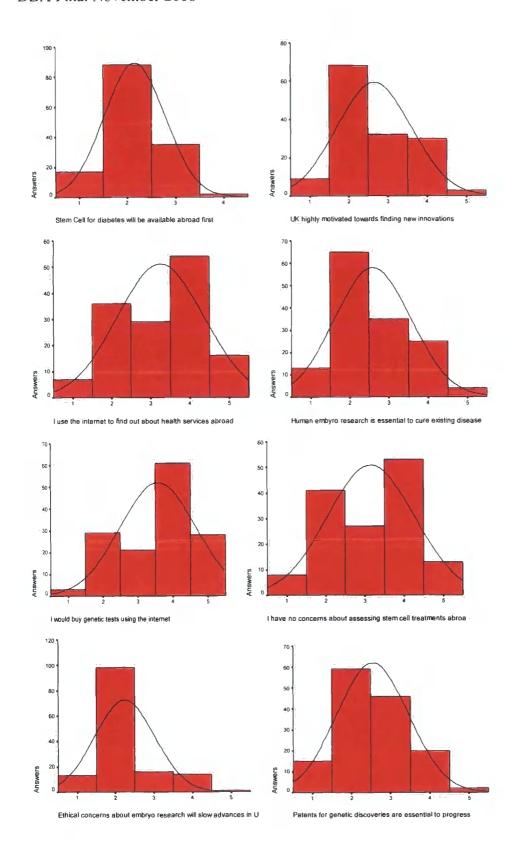
## Histograms – Answers People with Diabetes

UK Government needs to spend more on stem cell research

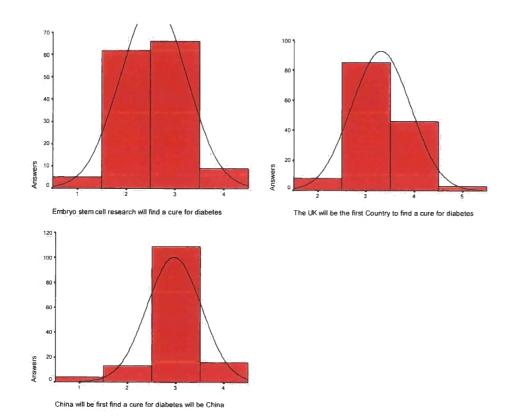


UK has strong legislative framework for stem cell research





## DBA Final November 2008



Tests of Normality

			olmogorov-Smirnov		0, ,, ,,	Shapiro-Wilk	
dolly the sheep was the	gender 1	Statistic .273	df 84	Sig. .000	Statistic .784	df 84	Sig000
first cloned creature in the	2				,		
world the uk lead te world in		.342	69 84	.000	.732	69 84	.000
stem cell research	2					-	
		.350	69	.000	.724	69	.000
china cloned a fish 30 years before dolly the	1	.364	84	.000	.700	84	.000
human cloning is illegal		.404	69 84	.000	.686	69 84	.000
in the UK	2	488	69	.000	.486	69	.000
Human cloning is legal in	1	.355	84	.000	.713	84	.000
China	2	.368_	69	.000	.700	69	.000
the UK has the world's first license for	1 2	.402 .490	84 69	.000 .000	.656 .204	84 69	.000.
china has produced a	1	.430	84	.000	.727	84	.000
gene therapy cure for	2	.431	69	.000	.614	69	.000
china will lead the world	1	.470	84	.000	.532	84	.000
in producing cures for theraeutic cloning is legal	2 1	.411	69 84	.000	.677	69 84	.000
in the UK	2	.263	69	.000	.773 .729	69	.000
human embryo research	1	.432	84	.000	.621	84	.000
is legal in the UK under	2	.391	69	.000	.686	69	.000
the uk government spends enough money	1	.247	84	.000	.893	84	.000
The amount of money the		.288	69 84	.000	.865 .892	69 84	.000
UK Gov spends on	2	.210	69	.000	.883	69	.000
The UK Government	1	.232	84	.000	.876	84	.000
spends as much on	2	.291	69	.000	.839	69	.000
The UK Government needs to spend more on	1 2	.238	84	.000	.875	84	.000
The UK has a strong	1	.276	69 84	.000	.843 .862	69	.000
legislative framework to	2	.267	69	.000	.866	69	.000
More Centres should be	1	.307	84	.000	.851	84	000
allowed to carry out	2	.244	69	.000	.877	69	.000
New genetic discoveries should be available to the	1 2	.305	84	.000	.834	84	.000
Human Embryo research		.350	69 84	.000	811 780	69	.000
will produce cures for	2	.346	69	.000	.803	69	.000
Human Embryo research	1	.303	84	.000	.804	84	.000
will in time cure diabetes	2	.267	69	.000	.828	69	.000
Any potential cure for diabetes will not be	1 2	.234	84	.000	.901	84	.000
Finding a cure for		.289	69 84	.000	.839	69 84	.000
diabetes is worth the	2	.266	69	.000	.865	69	.000
A stem cell cure would	1	.290	84	.000	.861	84	.000
replace existing therapies	2	.216	69	.000	.883	69	.000
Stem Cell Therapies will be available in the clinical	1 2	.307 .310	84 69	.000 .000	.798 .821	84 69	.000
When stem cell therapy	1	.228	84	.000	.891	84	.000
for diabetes is found it will	2	.239	69	.000	.785	69	.000
Stem Cell Therapy for diabetes will be available	1	.339	84	.000	.784	84	.000
The UK is highly	1	.357	69	.000	.778	69	.000
motivated towards finding	2	.280 .314	84 69	.000 .000	.868 .816	84 69	.000 .000
I use the internet to find	1	.234	84	.000	.896	84	.000
out about health services	2	.252	69	.000	.883	69	.000
I would buy genetic tests using the internet	1	.268	84	.000	.855	84	.000
I would go abroad for	1	.285	69 84	.000	.868	69 84	.000.
treatment that is not	2	.305	69	.000	. <del>048</del> .781	69	.000.
I would not have any	1	.277	84	.000	.863	84	.000
concerns about	2	.196	69	.000	.894	69	.000
Human embyro research is essential to find cures	1	.263	84	.000	.883	84	.000
The UK population	1	.293	69 84	.000	.848	69 84	.000
supports human embryo	2	.275	69	.000	.855	69	.000
Ethical concerns about	1	.414	84	.000	.688	84	.000
creating embryos for	2	.368	69	.000	.783	69	.000
Patent registration for genetic discoveries is	1 2	.209 .294	84 69	.000 .000	.900 .837	84 69	.000
Embryo stem cell	1	.294	84	.000	.797	84	.000
research will find a cure	2	.261	69	.000	.828	69	.000
The UK will be the first	1	.358	84	.000	.761	84	.000
Country to find a cure for	2	.307	69	.000	.800	69	.000
The first Country to find a	1	.414	84	.000	.669	84	.000

a. Lilliefors Significance Correction

# **Descriptive Statistics**

Descriptive oralistics	No.	Min.	Maxi mu	Mean		Ske wne		Kurtosi	
			m Stati	Statistic	atio n Stati	SS Stati Std	Error	Statisti Std	Error
nationality	157	1	stic		stic	stic 3.73		c 12.888	.385
do you have religious beliefs do you have diabetes		1	4 2	1.55 1.93		6 .438 -	.194 .194	.658 9.692	.385 .385
do you have a family member with diabetes	157	1	2	1.60	.465	3.40 1	104	4 247	205
,						.819	. 194	-1.347	.385
do you have any other genetic illness	157	1	2	1.94	.233	3.84 5	.194	12.952	.385
do any family members have genetic illnesses	157	1	2	1.78	.413	1.39 0	.194	070	.385
age	157	17	78	41.66	15.0 <b>4</b> 0	_	.194	925	.385
occupation	156	1	5	3.43		.480	.194	765	.386
dolly the sheep was the first cloned creature in the world	157	1	3	1.70			.194	-1.097	.385
the uk lead te world in stem cell research	157	1	3	2.36	.768	- .711	.194	953	.385
china cloned a fish 30 years before dolly the sheep	157	1	3	2.38	.813	.809	.194	-1.004	.385
human cloning is illegal in the UK	157	1	11	1.36	1.00		.194	55.291	.385
Human cloning is legal in China	157	1	3	2.39	_	.830	.194	897	.385
the UK has the world's first license for therapeutic cloning	157	1	33	2.72	2.54 7		.194	130.14 2	.385
china has produced a gene therapy cure for cancer	157	1	3	2.53		1.09	.194		.385
china will lead the world in producing cures for diabetes	156	1	4	2.61	.724	1.42 3	.194	.609	.386
therapeutic cloning is legal in the UK	156	1	4	2.22	.867	.379	.194	-1.454	.386
human embryo research is legal in the UK under license		1	5	1.60	.962	1.31 3	.194	.519	.386
the uk government spends enough money on research		1	5	3.57		.575	.194	159	.386
The amount of money the UK Gov spends on research has increased in recent years	156	1	5	2.88	.880	.113	.194	395	.386
The UK Government spends as much on research as other Countries	156	1	5	3.34	.876	.606	.194	.142	.386
The UK Government needs to spend more on stem cell research to compete with others	156	1	4	2.40	.825	.173	.194	462	.386
The UK has a strong legislative framework to manage and control stem cell research	156	1	5	2.53	.853	.309	.194	347	.386
More Centers should be allowed to carry out human embryo research in the UK	156	1	5	2.64	1.02 8	.407	.194	708	.386
New genetic discoveries should be available to the public from the internet	156	1	5	2.35	_	.812	.194	154	.386
Human Embryo research will produce cures for existing disease	156	1	4	2.12	.694	.419	.194	.404	.386
Human Embryo research will in time cure diabetes	156	1	4	2.50	.677	.126	.194	190	.386
Any potential cure for diabetes will not be affordable under the UK NHS	156	1	5	2.79	.916		.194	367	.386
Finding a cure for diabetes is worth the creation of embryos for research	156	1	5	2.58	1.06 6	.493	.194	521	.386
A stem cell cure would replace existing therapies for diabetes	156	1	5	2.70		.002	.194	.009	.386
Stem Cell Therapies will be available in the clinical area of diabetes within 10 years	156	1	5	2.82	.667		.194	.308	.386

When stem cell therapy for diabetes is found it will be available in the NHS	156	1	5	2.83 .900 .	.121 .1	94	876	.386
Stem Cell Therapy for diabetes will be available abroad before the UK	155	1	4	2.17 .633 .	.1 318	95	.449	.387
The UK is highly motivated towards finding new innovations	156	1	5	2.63 .937 .	.507 .1	94	604	.386
I use the internet to find out about health services abroad	155	1	5	3.28 1.11 5 .	1 .269	95	882	.387
I would buy genetic tests using the internet	156	1	5	3.61 1.11 6 .	.1 503	94	776	.386
I would go abroad for treatment that is not available in the UK		1	5	2.31 .941 .	.759 .1	94	.034	.386
I would not have any concerns about assessing stem cell treatments abroad	156	1	5	3.12 1.12 6 .	1. – .1 188.	94	-1.020	.386
Human embryo research is essential to find cures for existing disease		1	5	2.55 .972 .	.493 .1	94	366	.386
The UK population supports human embryo research	156	1	5		.104	94	814	.386
Ethical concerns about creating embryos for research in the UK will slow down discoveries	156	1	5	2.24 .780 1	9		1.388	.386
Patent registration for genetic discoveries is essential to support investment in discovery		1	5	2.52 .900 .		195	283	.387
Embryo stem cell research will find a cure for diabetes		1	4	2.53 .676 .		194	196	.386
The UK will be the first country to find a cure for diabetes	156	2	5	3.30 .616 .	.211 .1	194	.039	.386
The first country to find a cure for diabetes will be China Valid N (list wise)		1	4	2.93 .569	1 .862	94	2.730	.386

Tests of Normality

			olmogorov-Smirnov			Shapiro-Wilk	
dolly the sheep was the	gender 1	Statistic	df	Sig.	Statistic	df	Sig.
first cloned creature in the	,	.273	84	.000	.784	84	.000
world	2	.342	69	.000	.732	69	.000
the uk lead te world in stem cell research	1 2	.321	84	.000	.745	84	.000
	2	.350	69	.000	.724	69	.000
china cloned a fish 30	1	.364	84	.000	.700	84	.000
years before dolly the	2	.377	69	.000	.686	69	.000
human cloning is illegal in the UK	1 2	.404 .488	84 69	.000 .000	.345 .486	84 69	.000
Human cloning is legal in	<del></del>	.355	84	.000	.713	84	.000
China	2	.368	69	.000	.700	69	.000
the UK has the world's first license for	1	.402	84	.000	.656	84	.000
china has produced a	1	.490	69 84	.000	.727		.000
gene therapy cure for	2	.431	69	.000	.614	69	.000
china will lead the world	1	.470	84	.000	.532	84	.000
in producing cures for	2	.411	69	.000	.677	69	.000
theraeutic cloning is legal in the UK	1 2	.263 .361	84 69	.000 .000	.773 .729	84 69	.000
human embryo research	1	.432	84	.000	.621	84	.000
is legal in the UK under	2	.391	69	.000	.686	69	.000
the uk government	1	.247	84	.000	.893	84	.000
spends enough money The amount of money the	1	.288	69 84	.000	.865 .892	69 84	.000
UK Gov spends on	2	.207	84 69	.000	.892 .883	69	.000
The UK Government	1	.232	84	.000	.876	84	.000
spends as much on	. 2	.291	69	.000	.839	69	.000
The UK Government needs to spend more on	1 2	.238 .276	84	.000 .000	.875 .843	84 69	.000
The UK has a strong	1	.266	69 84	.000	.862	84	.000
legislative framework to	2	.267	69	.000	.866	69	.000
More Centres should be	1	.307	84	.000	.851	84	.000
allowed to carry out  New genetic discoveries	<u>2</u>	.305	69	.000	.877	69 84	.000
should be available to the	2	.350	84 69	.000	.834 .811	69	.000
Human Embryo research	1	.308	84	.000	.780	84	.000
will produce cures for	2	.346	69	.000	.803	69	.000
Human Embryo research will in time cure diabetes	1 2	.303 .267	84 69	.000. 000.	.804 .828	84 69	.000. 000.
Any potential cure for	1	.234	84	.000	.901	84	.000
diabetes will not be	2	.289	69	.000	.839	69	.000
Finding a cure for diabetes is worth the	1	.277	84	.000	.864	84	.000
A stem cell cure would	2	.266	69 84	.000	.865	69 84	000.
replace existing therapies	2	.216	69	.000	.883	69	.000
Stem Cell Therapies will	1	.307	84	.000	.798	84	.000
be available in the clinical	2	.310	69	.000	.821	69	.000
When stem cell therapy for diabetes is found it will	1 2	.228	84 69	.000 .000	.891 .785	84 69	000. 000.
Stern Cell Therapy for	1	.339	84	.000	.784	84	.000
diabetes will be available	2	.357	69	.000	.778	69	.000
The UK is highly motivated towards finding	1	.280	84	.000	.866	84	.000
I use the internet to find	1	.314	69 84	.000	.816 .896	69 84	.000.
out about health services	2	.252	69	.000	.883	69	.000
I would buy genetic tests	1	.268	84	.000	.855	84	.000
using the internet	2	.285	69	.000	.868	69	.000
I would go abroad for treatment that is not	1 2	.306 .371	84 69	.000 .000	.848 .781	84 69	.000.
I would not have any	1	.277	84	.000	.883	84	.000
concerns about	2	.198	69	.000	.894	69	.00
Human embyro research	1	.263	84	.000	.883	84	.000
is essential to find cures The UK population	<u>2</u> 1	.188	69 84	.000	.848	69 84	.000.
supports human embryo	2	.188	84 69	.000	.855	69	.000
Ethical concerns about	1	.414	84	.000	.688	84	.000
creating embryos for	2	.368	69	.000	.783	69	.000
Patent registration for genetic discoveries is	1 2	.209	84	.000	.900	84	.000
Embryo stem cell	1	.294	69 84	.000	.797	69 84	.000.
research will find a cure	2	.261	69	.000	.828	69	.000
The UK will be the first	1	.358	84	.000	.761	84	.000
Country to find a cure for	2	.307	69	.000	.800	69	.000.
The first Country to find a cure for diabetes will be	1 2	.414 .384	84 69	.000 .000	.669 .713	84 69	000. 000.

a. Lilliefors Significance Correction

### Reliability Analysis - Alpha

R	E I	I	Α	B ]	L	I	Т	Y	Α	N	Α	L	Y	S	Ι	S	-	S	С	Α	L	, Е	:	(A	L	P	Н	A)	1
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		Mean	Std Dev	Cases
1.	DOLLY	1.7059	.7685	153.0
2.	UKLEAD	2.3595	.7662	153.0
3.	CHINAFIS	2.3791	.8192	153.0
4.	CLONING	1.3660	1.0115	153.0
5.	CLONINCN	2.3856	.7957	153.0
6.	LICENUK	2.7386	2.5746	153.0
7.	CANCER	2.5294	. 6694	153.0
8.	CNDIABET	2.6078	.7276	153.0
9.	CLONINUK	2.2092	.8710	153.0
10.	LICENUK2	1.6013	.9620	153.0
11.	RESEARCH	3.5490	1.0062	153.0
12.	INCREASE	2.8758	.8835	153.0
13.	SAME£	3.3333	.8811	153.0
14.	COMPETE	2.4183	.8241	153.0
15.	STRONGLE	2.5425	.8506	153.0
16.	CENTRES	2.6471	1.0226	153.0
17.	INTERNET	2.3268	1.0872	153.0
18.	CURE	2.1242	.6913	153.0
19.	DIABETES	2.5033	. 6798	153.0
20.	NHS	2.7843	.9244	153.0
21.	WORTH	2.5882	1.0546	153.0
22.	REPLACE	2.6993	.8358	153.0
23.	YEARS10	2.8170	.6731	153.0
24.	NHS2	2.8497	. 9015	153.0
25.	ABROAD	2.1634	. 6331	153.0
26.	INNOVATI	2.6471	.9422	153.0
27.	USEINTER	3.2680	1.1122	153.0
28.	BUYINTER	3.6013	1.1082	153.0
29.	ABROAD2	2.3072	.9339	153.0
30.	NOCONVER	3.1242	1.1199	153.0
31.	ESSENTIA	2.5686	.9717	153.0
32.	SUPPORTS	3.1373	.9181	153.0
33.	ETHICALC	2.2484	.7804	153.0
34.	PATENT	2.5294	.8963	153.0
35.	CUREDIAB	2.5294	. 6792	153.0
36.	LEADUK	3.3072	. 6207	153.0
37.	LEADCN	2.9281	.5747	153.0

Statistics for Mean Variance Std Dev Variables SCALE 96.3007 105.4222 10.2675 37

RELIABILITY ANALYSIS - SCALE (ALPHA)

Item-total Statistics

	Scale	Scale	Corrected	
	Mean	Variance	Item-	Alpha
	if Item	if Item	Total	if Item
	Deleted	Deleted	Correlation	Deleted
DOLLY	94.5948	104.5847	.0157	. 6988
UKLEAD	93.9412	101.6478	.2063	. 6892
CHINAFIS	93.9216	101.1649	.2176	.6885
CLONING	94.9346	106.0483	0792	.7075
CLONINCN	93.9150	100.9598	. 2395	. 6874
LICENUK	93.5621	92.6162	.1247	.7232
CANCER	93.7712	101.4407	.2620	.6871
CNDIABET	93.6928	100.5563	.2972	.6850
CLONINUK	94.0915	103.5047	.0654	.6970
LICENUK2	94.6993	104.9222	0216	.7031
RESEARCH	92.7516	106.2669	0895	.7081
INCREASE	93.4248	106.2460	0881	.7058
SAME£	92.9673	103.7423	.0503	.6980
COMPETE	93.8824	98.0255	.4117	. 6777
STRONGLE	93.7582	101.9872	.1578	. 6917
CENTRES	93.6536	94.5832	.4924	.6689
INTERNET	93.9739	98.5256	.2648	. 6847
CURE	94.1765	97.4884	.5462	. 6736

### **DBA Final November 2008**

DIABETES NHS	93.7974 93.5163	98.8205 100.6724	.4542 .2100	.6782 .6887
WORTH	93.7124	97.3904	. 3324	.6799
REPLACE	93.6013	97.2018	. 4564	.6749
YEARS10	93.4837	101.8961	.2261	.6887
NHS2	93.4510	102.8676	.0952	.6955
ABROAD	94.1373	101.2113	. 2991	.6859
ITAVONNI	93.6536	104.7542	0114	.7022
USEINTER	93.0327	97.4660	.3060	.6815
BUYINTER	92.6993	96.3564	. 3602	.6774
ABROAD2	93.9935	99.8223	. 2533	.6860
NOCONVER	93.1765	95.6331	. 3897	.6751
ESSENTIA	93.7320	94.3948	.5340	.6670
SUPPORTS	93.1634	99.0587	. 3021	.6830
ETHICALC	94.0523	103.9709	.0529	.6970
PATENT	93.7712	100.3223	.2393	.6870
CUREDIAB	93.7712	97.9276	.5232	.6750
LEADUK	92.9935	105.7829	0584	.7005
LEADCN	93.3725	104.0379	.0899	. 6945

RELIABILITY ANALYSIS - SCALE (ALPHA)

Reliability Coefficients

N of Cases = 153.0

N of Items = 37

Alpha = .6951

### dolly the sheep was the first cloned creature in the world

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	77	49.0	49.0	49.0
	2	50	31.8	31.8	80.9
	3	30	19.1	19.1	100.0
<u> </u>	Total	157	100.0	100.0	

#### the uk lead te world in stem cell research

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	28	17.8	17.8	17.8
	2	45	28.7	28.7	46.5
1	3	84	53.5	53.5	100.0
	Total	157	100.0	100.0	

### china cloned a fish 30 years before dolly the sheep

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	33	21.0	21.0	21.0
	2	31	19.7	19.7	40.8
	3	93	59.2	59.2	100.0
	Total	157	100.0	100.0	

### human cloning is illegal in the UK

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	125	79.6	79.6	79.6
	2	16	10.2	10.2	89.8
1	3	15	9.6	9.6	99.4
	11	1	.6	.6	100.0
	Total	157	100.0	100.0	

### Human cloning is legal in China

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	30	19.1	19.1	19.1
	2	35	22.3	22.3	41.4
	3	92	58.6	58.6	100.0
	Total	157	100.0	100.0	

### the UK has the world's first license for therapeutic cloning

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	25	15.9	15.9	15.9
	2	24	15.3	15.3	31.2
	3	107	68.2	68.2	99.4
	33	1	.6	.6	100.0
	Total	157	100.0	100.0	

### china has produced a gene therapy cure for cancer

					Cumulative
		Frequency	Percent	Valid Percent	Percent
Valid	1	15	9.6	9.6	9.6
	2	44	28.0	28.0	37.6
	3	98	62.4	62.4	100.0
	Total	157	100.0	100.0	

### china will lead the world in producing cures for diabetes

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	21	13.4	13.5	13.5
	2	20	12.7	12.8	26.3
	3	114	72.6	73.1	99.4
	4	1	.6	.6	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

### theraeutic cloning is legal in the UK

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	44	28.0	28.2	28.2
	2	35	22.3	22.4	50.6
	3	76	48.4	48.7	99.4
	4	1	.6	.6	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

### human embryo research is legal in the UK under licence

	_	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	106	67.5	67.9	67.9
	2	14	8.9	9.0	76.9
	3	29	18.5	18.6	95.5
	4	6	3.8	3.8	99.4
	5	1	.6	.6	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

### the uk government spends enough money on research

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	5	3.2	3.2	3.2
	2	20	12.7	12.8	16.0
	3	37	23.6	23.7	39.7
	4	69	43.9	44.2	84.0
	5	25	15.9	16.0	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		•

# The amount of money the UK Gov spends on research has increased in recent years

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	6	3.8	3.8	3.8
	2	48	30.6	30.8	34.6
	3	64	40.8	41.0	75.6
	4	34	21.7	21.8	97.4
	5	4	2.5	2.6	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

The UK Government spends as much on research as other Countries

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	5	3.2	3.2	3.2
	2	20	12.7	12.8	16.0
	3	55	35.0	35.3	51.3
	4	69	43.9	44.2	95.5
	5	7	4.5	4.5	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

The UK Government needs to spend more on stem cell research to compete with others

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	19	12.1	12.2	12.2
	2	70	44.6	44.9	57.1
	3	52	33.1	33.3	90.4
	4	15	9.6	9.6	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

The UK has a strong legislative framework to manage and control stem cell research

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	13	8.3	8.3	8.3
	2	70	44.6	44.9	53.2
	3	51	32.5	32.7	85.9
	4	21	13.4	13.5	99.4
	5	1	.6	.6	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

More Centres should be allowed to carry out human embryo reserach in the UK

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	15	9.6	9.6	9.6
	2	70	44.6	44.9	54.5
	3	32	20.4	20.5	75.0
	4	34	21.7	21.8	96.8
Ì	5	5	3.2	3.2	100.0
İ	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

### New genetic discoveries should be available to the public fromt the internet

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	31	19.7	19.9	19.9
	2	78	49.7	50.0	69.9
	3	16	10.2	10.3	80.1
	4	24	15.3	15.4	95.5
	5	7	4.5	4.5	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total	_	157	100.0		

### Human Embryo research will produce cures for existing disease

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	24	15.3	15.4	15.4
	2	94	59.9	60.3	75.6
	3	33	21.0	21.2	96.8
	4	5	3.2	3.2	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

### Human Embryo research will in time cure diabetes

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	9	5.7	5.8	5.8
	2	67	42.7	42.9	48.7
	3	73	46.5	46.8	95.5
	4	7	4.5	4.5	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

### Any potential cure for diabetes will not be affordable under the UK NHS

_		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	10	6.4	6.4	6.4
	2	51	32.5	32.7	39.1
	3	61	38.9	39.1	78.2
	4	30	19.1	19.2	97.4
	5	4	2.5	2.6	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		_

Finding a cure for diabetes is worth the creation of embryos for research

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	20	12.7	12.8	12.8
	2	68	43.3	43.6	56.4
	3	33	21.0	21.2	77.6
ļ	4	28	17.8	17.9	95.5
]	5	7	4.5	4.5	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0	_	

### A stem cell cure would replace existing therapies for diabetes

200		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	11	7.0	7.1	7.1
Į.	2	49	31.2	31.4	38.5
	3	74	47.1	47.4	85.9
	4	20	12.7	12.8	98.7
	5	2	1.3	1.3	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0	_	

# Stem Cell Therapies will be available in the clinical area of diabetes within 10 years

	-	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	2	1.3	1.3	1.3
	2	44	28.0	28.2	29.5
	3	91	58.0	58.3	87.8
	4	18	11.5	11.5	99.4
	5	1	.6	.6	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

### When stem cell therapy for diabetes is found it will be available in the NHS

	_	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	6	3.8	3.8	3.8
	2	58	36.9	37.2	41.0
ļ	3	50	31.8	32.1	73.1
	4	40	25.5	25.6	98.7
	5	2	1.3	1.3	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

Stem Cell Therapy for diabetes will be available abroad before the UK

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	17	10.8	11.0	11.0
	2	98	62.4	63.2	74.2
	3	37	23.6	23.9	98.1
	4	3	1.9	1.9	100.0
	Total	155	98.7	100.0	
Missing	System	2	1.3		
Total		157	100.0		

### The UK is highly motivated towards finding new innovations

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	9	5.7	5.8	5.8
	2	77	49.0	49.4	55.1
	3	35	22.3	22.4	77.6
	4	32	20.4	20.5	98.1
	5	3	1.9	1.9	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

#### I use the internet to find out about health services abroad

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	8	5.1	5.2	5.2
	2	37	23.6	23.9	29.0
	3	32	20.4	20.6	49.7
	4	59	37.6	38.1	87.7
ł	5	19	12.1	12.3	100.0
	Total	155	98.7	100.0	
Missing	System	2	1.3		
Total		157	100.0		

### I would buy genetic tests using the internet

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	4	2.5	2.6	2.6
	2	31	19.7	19.9	22.4
İ	3	22	14.0	14.1	36.5
	4	64	40.8	41.0	77.6
	5	35	22.3	22.4	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0	_	

I would go abroad for treatment that is not available in the UK

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	24	15.3	15.4	15.4
	2	86	54.8	55.1	70.5
1	3	22	14.0	14.1	84.6
	4	22	14.0	14.1	98.7
	5	2	1.3	1.3	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

# I would not have any concerns about assessing stem cell treatments abroad

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	11	7.0	7.1	7.1
	2	44	28.0	28.2	35.3
ļ	3	29	18.5	18.6	53.8
	4	59	37.6	37.8	91.7
	5	13	8.3	8.3	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

### Human embyro research is essential to find cures for existing disease

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	16	10.2	10.3	10.3
	2	72	45.9	46.2	56.4
	3	38	24.2	24.4	80.8
	4	26	16.6	16.7	97.4
	5	4	2.5	2.6	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0	_	

### The UK population supports human embryo research

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	3	1.9	1.9	1.9
	2	41	26.1	26.3	28.2
	3	51	32.5	32.7	60.9
	4	55	35.0	35.3	96.2
	5	6	3.8	3.8	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

# Ethical concerns about creating embryos for research in the UK will slow down discoveries

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	15	9.6	9.6	9.6
	2	106	67.5	67.9	77.6
1	3	19	12.1	12.2	89.7
	4	15	9.6	9.6	99.4
	5	1	.6	.6	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

# Patent registration for genetic discoveries is essential to support investment in discovery

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	17	10.8	11.0	11.0
	2	64	40.8	41.3	52.3
	3	52	33.1	33.5	85.8
	4	20	12.7	12.9	98.7
	5	2	1.3	1.3	100.0
	Total	155	98.7	100.0	
Missing	System	2	1.3		
Total		157	100.0		

### Embryo stem cell research will find a cure for diabetes

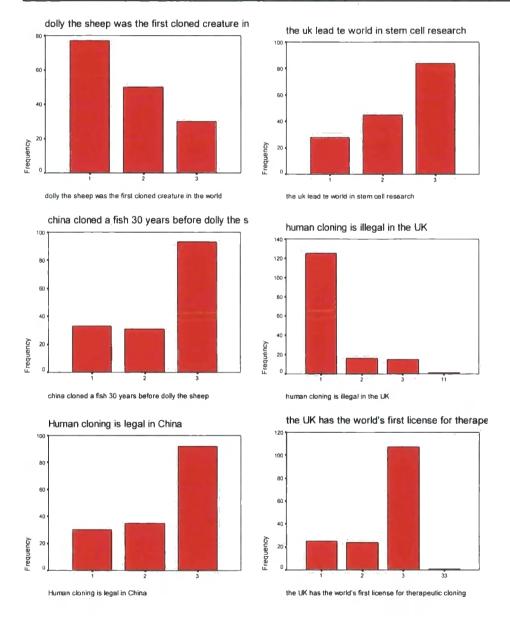
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	7	4.5	4.5	4.5
	2	69	43.9	44.2	48.7
	3	71	45.2	45.5	94.2
	4	9	5.7	5.8	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

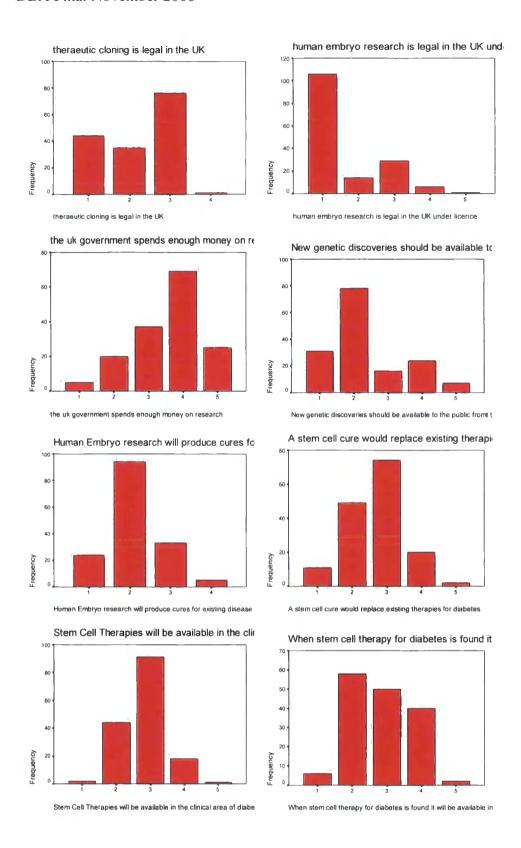
### The UK will be the first Country to find a cure for diabetes

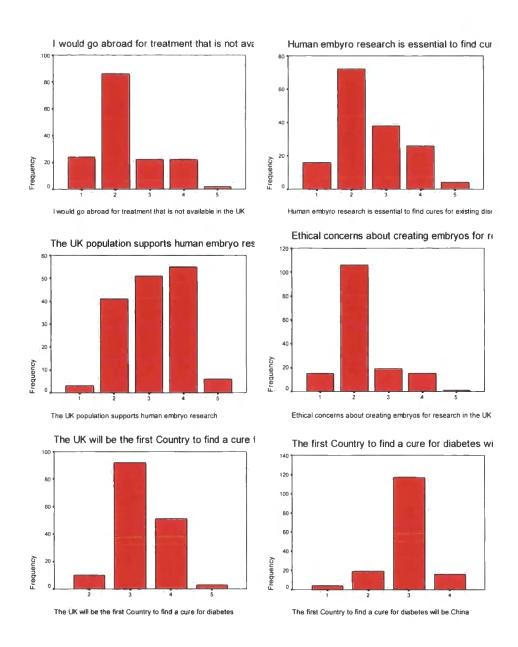
		Frequency	Percent_	Valid Percent	Cumulative Percent
Valid	2	10	6.4	6.4	6.4
	3	92	58.6	59.0	65.4
	4	51	32.5	32.7	98.1
Ì	5	3	1.9	1.9	100.0
	Total	156	99.4	100.0	
Missing	System	1	.6		
Total		157	100.0		

The first Country to find a cure for diabetes will be China

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	4	2.5	2.6	2.6
	2	19	12.1	12.2	14.7
	3	117	74.5	75.0	89.7
	4	16	10.2	10.3	100.0
	Total	156	99.4	100.0	
Missing	System	. 1	.6		
Total		157	100.0		_







Correlations								
		nationality	do you have religious beliefs	do you have diabetes	do you have a family member with diabetes	any other		age
nationality	Pearson Correlation	1	011	152	.060	.068	.057	051
	Sig. (2-tailed)		.891	.058	.452	.397	.479	.527
	Ń	157	157	157	157	157	157	157
do you have religious beliefs	Correlation	011	1	.001	.099	004	.047	207
	Sig. (2-tailed)	.891		.988	.219	.964	.559	.009
	Ń	157	157	157	157	157	157	157
do you have diabetes		152	.001	1	.246	.147	.159	-,171
	Sig. (2-tailed)	.058	.988		.002	.066	.047	.032
	N	157	157	157	157	157	157	157
do you have a family member with	Correlation	.060	.099	.246	1	.189	.380	042
diabetes								
4,420,00	Sig. (2-tailed)	.452	.219	.002		.018	.000	.601
	N	157	157	157	157	157	157	157
do you have	Pearson	.068	004	.147	.189	1	.403	031
any other genetic illness	Correlation	.000	.001		. 100	·	.400	.001
	Sig. (2-tailed)	.397	.964	.066	.018		.000	.698
	Ň	157	157	157	157	157	157	157
do any family members	Correlation	.057	.047	.159	.380	.403	1	.133
have genetic illnesses								
	Sig. (2-tailed)	.479	.559	.047	.000	.000		.096
	N	157	157	157	157	157	157	157
age	Pearson Correlation	051	207	171	042	031	.133	1
	Sig. (2-tailed)	.527	.009	.032	.601	.698	.096	
	Ň	157	157	157	157	157	157	157

<sup>\*\*</sup> Correlation is significant at the 0.01 level (2-tailed).

\* Correlation is significant at the 0.05 level (2-tailed).

<sup>(.1-.29</sup> small .30-.49 medium .50 -1 large)

# Appendix D

# **Summary of Data**

Year	Pop UK	Pop Cn	Diabetes	Diabetes	GDP	GDP	Total GDP China	Total GDP Rese	
			UK	Cn	UK	Cn		UK	GDP Cn
1990	57285000	1.14E+09	933746.0	18637000	1.8	8.00	240775920000	3.44E+11 2.24	.70
1991	57472000	1.15E+09	1034496	19563600	-1.4	8.80	263763360000	3.64E+11 2.07	.70
1992	57593000	1.17E+09	1151860	20970000	.3	8.80	320608000000	3.68E+11 2.01	.70
1993	57700000	1.18E+09	1269400	22389600	3.7	8.80	418332000000	1.03E+12 2.04	.70
1994	57825000	1.19E+09	1445625	23836000	2.9	8.80	564865528000	1.10E+12 2.00	.60
1995	57958000	1.20E+09	1506908	25302900	2.8	8.80	706601556000	1.16E+12 1.95	.60
1996	58076000	1.22E+09	1626128	26787200	2.8	9.60	820260592000	1.22E+12 1.88	.70
1997	58204000	1.23E+09	1687916	29522400	3.3	8.80	899572130000	1.30E+12 1.81	.71
1998	58349000	1.25E+09	1808819	31346975	3.1	7.80	955593724690	1.36E+12 1.80	.80
1999	58536000	1.26E+09	1931688	32883864	2.9	7.10	998429996880	1.40E+12 1.88	1.00
2000	58655000	1.28E+09	2052925	34430805	3.9	8.00	1.09095E+12	.49E+12 1.85	1.07
2001	589000	1.28E+09	2057615	38549160	2.3	7.30	1.17196E+12	.57E+12 1.90	1.29
2002	59234000	1.29E+09	2191658	40060370	1.8	8.30	1.64303E+12	.66E+12 1.89	1.31
2003	59422000	1.29E+09	2317458	41352640	2.2	9.10	1.69377E+12	.78E+12 1.76	1.31
2004		1.31E+09			2		1.64933E+12	.14E+12 1.72	1.50
2006					2.6		8.15800E+12	1.87E+12 1.76	•

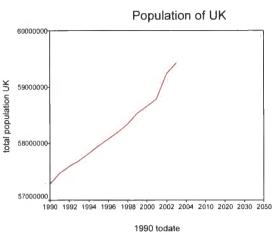
Year	Patents UK	Patents Cn	Balance of Payment UK	Balance of Payment Cr	Trade UK	Total Trade UK	Trade Cn	Trade GDP Cn	Total Trade Cn
1990	3265		-3.9E+10 .		-4.0	-2.5E+10	14	42.27	
1991	3307		-1.9E+10	1.30E+10	-1.8	-1.1E+10	15	40.74	1.20E+10
1992	3331		-2.3E+10	6.00E+09	-2.1	-1.3E+10	16	41.06	5.00E+09
1993	3019		-1.8E+10	-1.2E+10	-1.9	-9.8E+10	15	37.05	-1.2E+10
1994	3517		-1.0E+10	8.00E+09	-1.0	-7.3E+10	21	39.45	7.00E+09
1995	3648	45064	-1.4E+10	2.00E+09	-1.3	-5.6E+10	20	43.53	1.20E+10
1996	2737	43780	-1.1E+10	7.00E+09	-1.0	-5.1E+10	20	45.54	1.80E+10
1997	2792	50992	-3.0E+10	3.00E+10	2	1.40E+10	21	47.56	4.00E+10
1998	3168	67889	-6.7E+10	2.90E+10	5	-1.3E+10	19	46.89	4.20E+10
1999	2883	100156	-3.9E+10	2.10E+10	-2.7	-2.5E+10	21	44.82	3.10E+10
2000	2962	105345	-3.7E+10	2.10E+10	-2.6	-2.9E+10	25		2.90E+10
2001	2788	114251	-3.2E+10	1.70E+10	-2.2	-3.9E+10	24		2.80E+10
2002	3310		-2.5E+10	3.50E+10	-1.6	-4.8E+10	28		3.70E+10
2003			-2.8E+10	4.60E+10	-1.5	-5.1E+10 .		-	3.60E+10
2004			-4.3E+10	6.90E+10	-2.0	-7.2E+10 .			4.90E+10
2006			-3.8E+10	1.29E+11	-2.3	-1.0E+11 .			1.68E+10

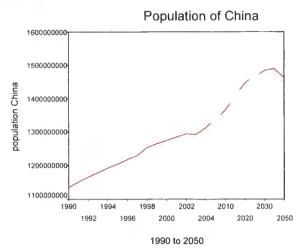
Year	% growth GDP Cn	% growth GDP UK	Inflation UK	Inflation Cn	Education GDP UK	Education GDP Cn	Computers/ 1000 pop	Computers 1000 pop UK	Imports as proportion GDP UK	Imports as Proportion GDP Cn
1990	3.80	50	9.50	3.70	4.90	2.30	.43	144.79	27.00	14.00
1991	9.30	-1.00	10.10	3.40	4.98	3.38	.68	164.95		
1992	14.20	-1.00	9.10	6.40	5.12	3.25	.92	169.51		
1993	13.50	1.00	7.50	14.70	5.15	3.07	1.17	201.32		
1994	12.70	4.00	8.20	24.10	5.11	3.19	1.65	215.96		
1995	10.50	2.60	8.20	17.10	5.50	3.27	2.27	238.92	29.00	
1996	9.70	3.00	7.80	8.30	4.90	3.38	3.61	268.41		
1997	8.80	3.00	7.10	2.80	4.70	3.46	5.99	302.51	29.00	
1998	7.80	2.50	5.50	80	4.50	3.83	8.91	377.81		
1999	7.10	2.70	5.10	-1.40	4.50	4.16	12.23 .		30.10	
2000	8.20	2.40	5.30	.40	4.40	4.36	15.90 .		28.10	23.20
2001		1.80	4.90	.70	4.60	4.86			29.00	
2002		2.00	4.90	20	4.90	5.29				
2003		2.20	4.50	1.60	5.10				30.10	31.80
2004 2006		2.30 2.10	4.90	3.30	5.30		•		28.10	39.20

### **DBA Final November 2008**

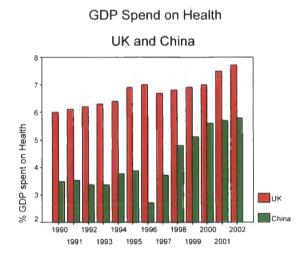
Year	Total Imports China	Exports GDP UK	Exports GDP Cn	Total value Exports Cn	Total value GDP US\$ UK	Total Value GDP US\$ Cn	Tot Education UK US\$	Tot Education Cn US\$	T Research UK US\$	TResearch China US\$
1990 1991	5.33E+10 6.38E+10	24	18	6.21E+10 7.18E+10	9.19E+11 9.87E+11	3.96E+11 4.33E+11	4.50E+10 4.91E+10	5.54E+09 8.92E+09	2.06E+10 2.04E+10	2.77E+09 3.03E+09
	8.06E+10	•	•	8.49E+10	1.01E+12	4.95E+11	5.17E+10	1.04E+10	2.04E+10 2.03E+10	3.46E+09
1993			•	9.17E+10	1.03E+12	5.61E+11	5.32E+10	1.28E+10	2.11E+10	3.93E+09
	1.16E+11		•	1.21E+11	1.08E+12		5.50E+10	1.80E+10	2.15E+10	3.80E+09
1995	1.32E+11	29		1.49E+11	1.16E+12	7.00E+11	6.38E+10	2.31E+10	2.26E+10	4.20E+09
1996	1.39E+11			1.51E+11	1.22E+12	7.67E+11	5.97E+10	2.77E+10	2.29E+10	5.37E+09
1997	1.42E+11	28		1.83E+11	1.28E+12	8.35E+11	6.01E+10	3.11E+10	2.31E+10	5.93E+09
1998	1.40E+11			1.84E+11	1.33E+12	9.09E+11	6.01E+10	3.66E+10	2.40E+10	7.27E+09
1999	1.66E+11		26	1.95E+11		9.72E+11		4.15E+10		9.72E+09
2000	2.25E+11	28	26	2.49E+11		1.05E+12	•	4.76E+10	•	1.12E+10
2001	2.44E+11	27		2.66E+11		1.17E+12		5.70E+10	•	1.51E+10
2002				1.64E+12	•	8.69E+10	•	5.15E+10		
2003	•	25	34			1.67E+12		•	•	
2004	•		40					•		
2006										

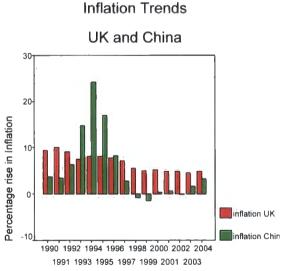
## **Graphs**



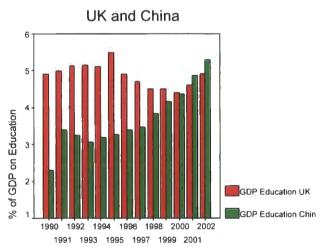


Prevalence of Diabetes **UK and China** 500000000 40000000 Total number with Diabetes 30000000 200000000 10000000 1997 1999 2001 2003





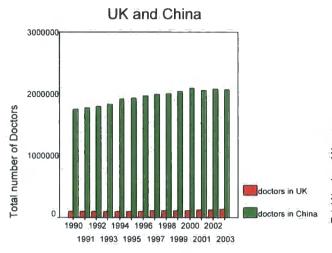
1993 1995

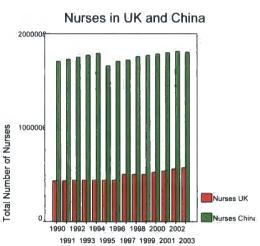


**GDP Spend on Education** 

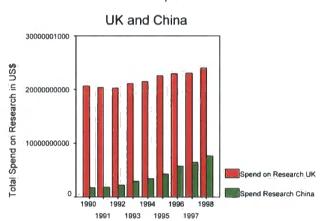
### **DBA Master Final November 2008**

### **Total Number of Doctors**

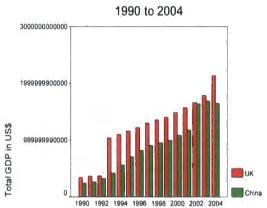




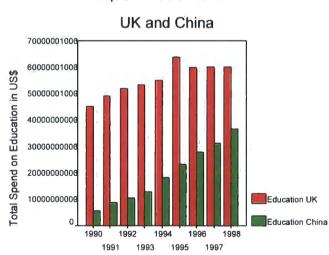
### Research Spend

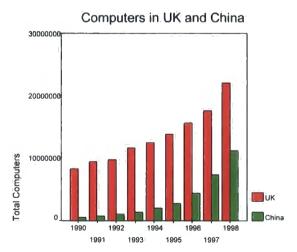


# Total GDP in UK and China

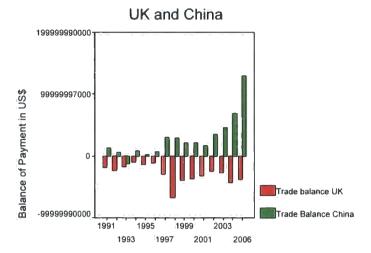


### Spend on Education



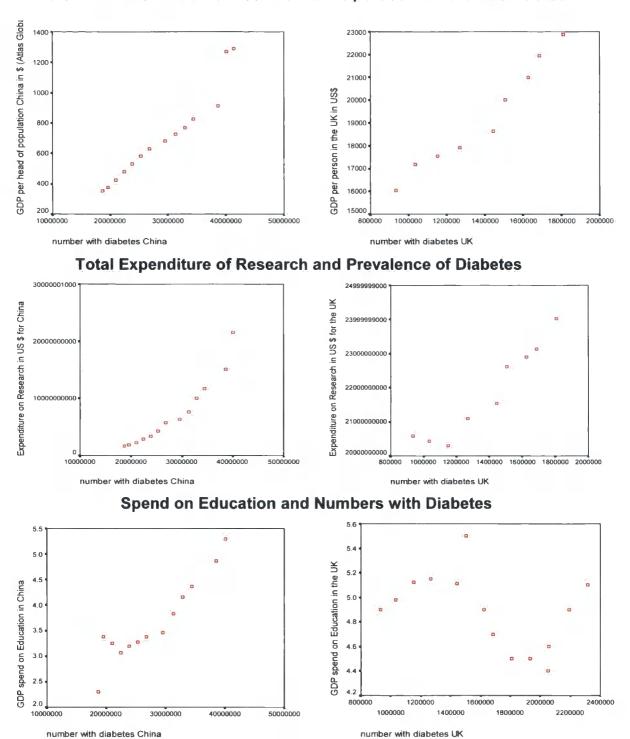


# Balance of Payment 1990-2005

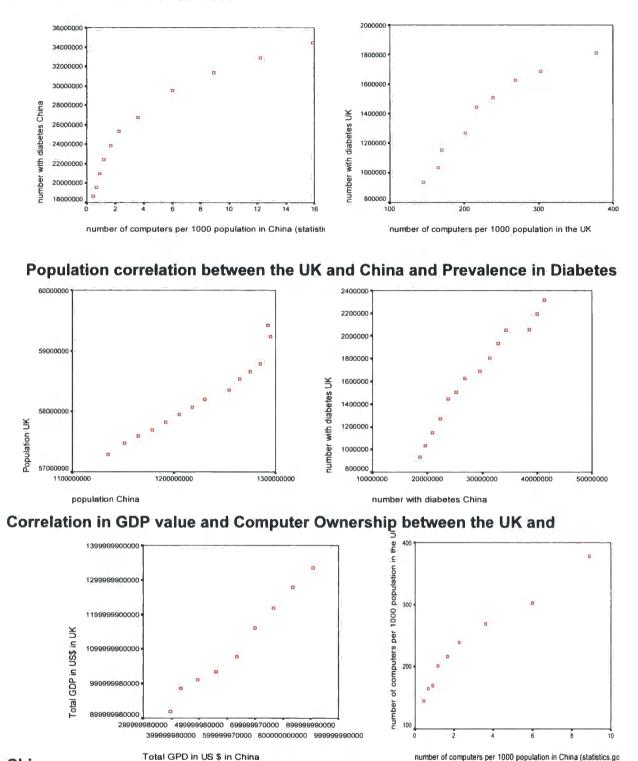


### Correlation

### Diabetes and GDP Performance/Head of Population for the UK and China



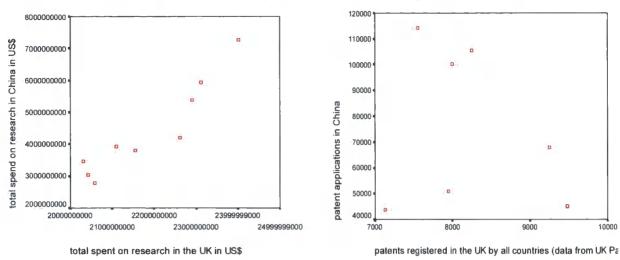
Ownership of Computers and Prevalence of Diabetes in China and the UK



As the following graphs indicate investment in research in the UK and China is shown to loosely correlate and there is no relationship in patent registration between the two Countries.

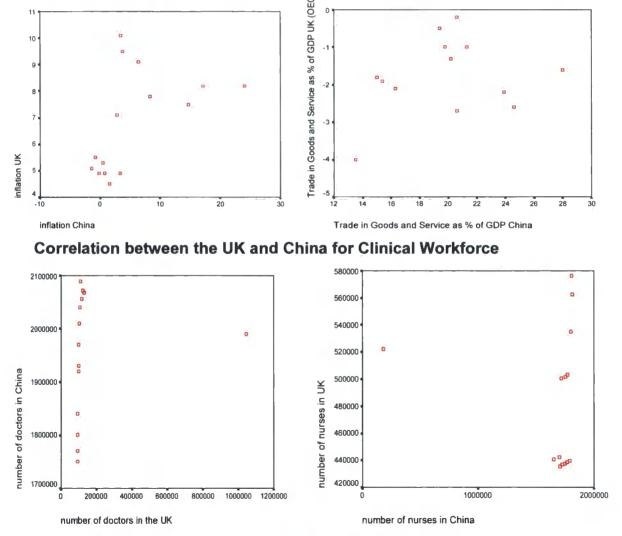
China

### Correlation of GDP Research Spend and Patent Registrations: UK and China

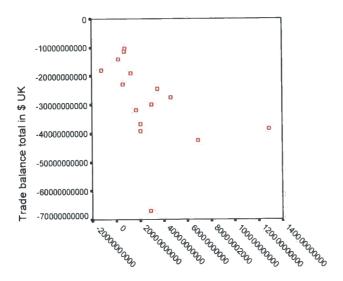


Analysis found there to be no relationship in the data when comparing the performance of Trade in Goods and Services as a percent of GDP between the UK and China of between their total values for Balance of Payments. There is also no relationship between inflation performance, or numbers of clinical staff.

### Correlation between the UK and China for Inflation and Trade as % of GDP



Correlation for Trade Balance between the UK and China



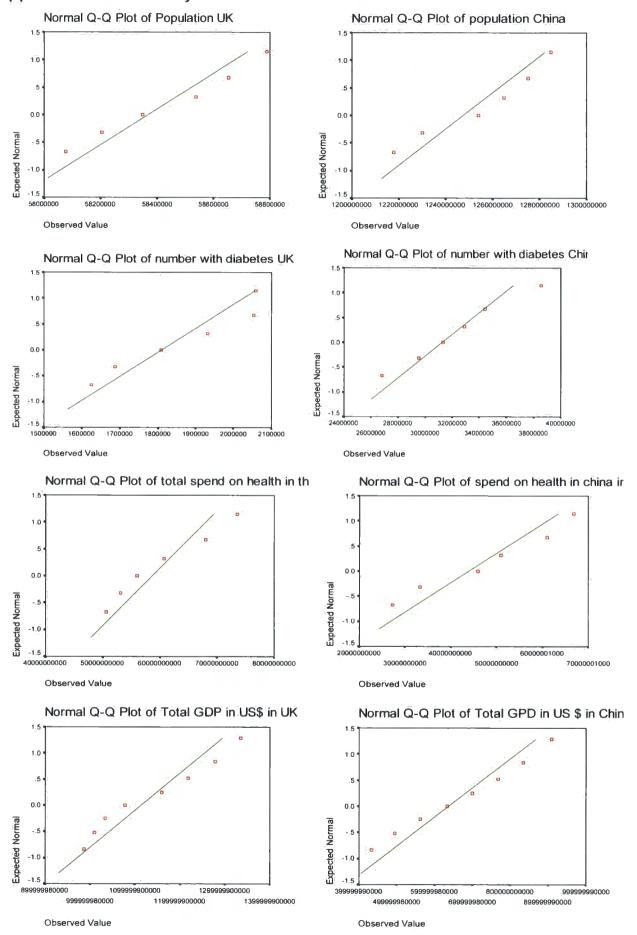
Trade Balance total in \$ China

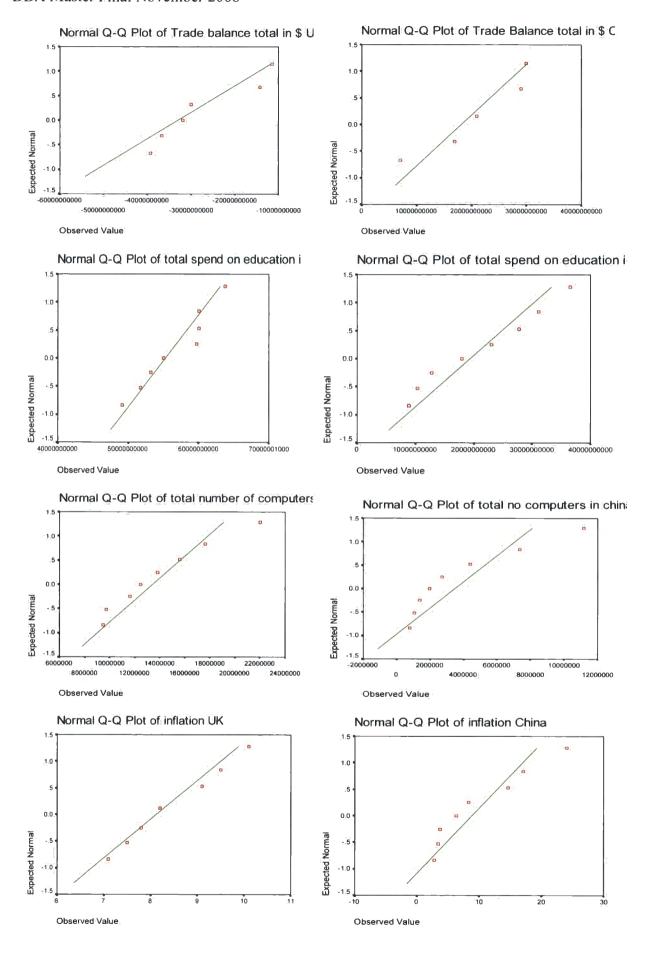
### **APPENDIX G**

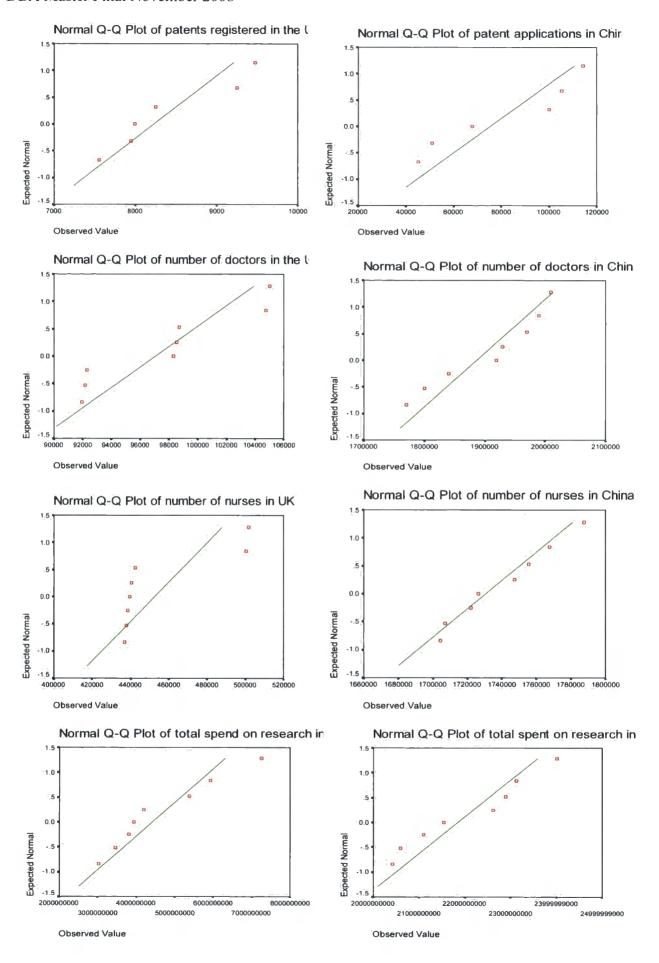
### **Normality Tests Data Table**

	N	Ske	wness	Kurt	osis	Kolmogovor- Smirov
		Statistic	Std. Error	Statistic	Std. Error	<u> </u>
Population UK	14	.448	.597	616	1.154	0.089
Population China	20	683	512	585	.992	0.165
Number with diabetes UK	14	- 136	.597	-1.128	1.154	0.109
Number with diabetes China	15	.372	.580	997	1.121	0.117
Percentage of pop with diabetes UK	15	.270	.580	274	1.121	0.077
Percentage of pop with diabetes China	15	1.139	.580	1.638	1.121	0.115
Cost for diabetes UK \$ per person	2	1.100	.000	1.000		0.170
Costs for diabetes China \$	2	·	· ·	·	·	
% real growth in GDP per year in UK	16	-1.833	.564	3.868	1.091	0.204
% growth in GDP per year in China	1 14	504	.597	301	1.154	0.272
NHS budget by year	15	416	.580	-1.000	1.121	0.108
Percent of GDP on health UK	15	1.440	.580	2.891	1.121	0.161
Percent of GDP on health China	13	.446	.616	-1.312	1.191	0.101
GDP on health per head UK \$	13	.540	.616	166	1.191	0.225
GDP per person in UK in US \$	10	1.777	.687			1
Total spend on health in the UK in £	14	436		3.840	1.334	0.158
			.597	943	1.154	0.820
GDP per head of pop China in \$	15	3.623	.580	13.591	1.121	0.111
GDP billion in US\$ for China	16	3.569	.564	13.565	1.091	0.152
% of GDP private health Cn	10	.456	.687	-1.321	1.334	0.185
% of GDP Gov Health China	10	-2.067	.687	3.636	1.334	0.421
Total value of GDP in the UK is US\$	16	526	.564	245	1.091	0.237
Exchange rate yuan per dollar	14	-1.171	.597	528	1.154	
Exchange rate pound against the US \$	16	.779	.564	164	1.091	
Spend on health in China in \$	13	1.039	.616	.500	1.191	0.242
Gov health in UK as % of total spend	14	-1.620	.597	4.884	1.154	0.315
Gov health China as % of total spend	10	992	.687	-0.66	1.334	0.210
Private health spend UK/person in \$	14	1.477	.597	4.396	1.154	0.319
Private health spend v china/person in \$	10	.982	.687	-0.81	1.334	0.210
Health spend per head pop Chine \$	14	.383	.597	-1.240	1.154	0.146
R&D as % of GDP in UK	14	1.199	.597	1.627	1.154	0.141
Expenditure Research \$ UK	9	.325	.717	-1.465	1.400	0.159
R&D as % of GDP China	14	1.042	.597	274	1.154	0.344
Expenditure Research \$ for China	13	1.343	.616	1.463	1.191	0.174
International rate of the dollar	13	051	.616	-1.657	1.191	0.178
Number of doctors in the UK	14	3.726	.597	13.914	1.154	0.500
Number of doctors in China	15	-0.459	.580	-1.126	1.121	0.134
Number of nurses in UK	1 14	0.566	.597	-1.163	1.154	0.312
Number of nurses in China	15	-3.781	.580	14.490	1.121	0.451
Number of researchers in the UK	10	3.162	.687	10.000	1.334	0.492
Number of researchers in China	13	3.553	.616	12.725	1.191	0.468
Patients registered UK by all countries	13	-1.462	,616	-1.172	1.191	0.207
Patients in the UK by UK resident	13	0.195	.616	-1.057	1.191	0.207
Patent applications in China	17	0.193	.794	-2.354	1.587	1
						0.241
Trade balance total in \$ UK	16	943 2.040	.564	1.616	1.091	0.213
Trade balance total in \$ China	15	2.049	.580	5.185	1.121	0.258
Trade in Goods/Service % of GDP UK	16	-0.474	.564	1.119	1.091	0.140
Trade in Goods/Services total \$ UK	16	-0.271	.564	-0.357	1.091	0.185
Trade in Goods/Service % GDP China	13	0.264	.616	-0.205	1.191	0.274
% of GDP on Trade in China	10	-0.231	.687	-0.806	1.334	0.146
Trade in Goods/Services Total \$ China	15	-0.443	.580	-0.298	1.121	0.172
% growth year on year in GDP China	11	-0.142	.661	0.017	1.279	0.164
% growth year on year in GDP UK	16	-1.026	.564	0.268	1.091	0.304
inflation UK	15	0.291	.580	-1.470	1.121	0.149
inflation China	15	1.481	.580	1.513	1.121	0.166
GDP spend on Education in the UK	15	-0.024	.580	-0.693	1.121	0.153
GDP spend on Education in China	13	0.589	.616	0.274	1.191	0.329
Computers/1000 population in China	11	1.219	0.661	0.362	1.279	0.254
Computers/1000 population in the UK	9	0.887	.717	0.352	1.400	0.218
Imports as a proportion of GDP UK	8	-0.345	.752	-0.194	1.481	0.385
Import as a proportion of GDP China	4	-0.196	1.014	-1.256	2.619	0.260
Import value is US & China	12	0.602	.637	0.022	1.232	0.260
Exports as a percentage of GDP UK	6	-0.664	.845	-1.155	1.741	0.260
Exports as a percentage of GDP China	5	0.190	.913	-0.700	2.000	0.260
Export value in US China	12	0.339	.637	-0.892	1.232	0.260
Total GDP in US \$ in UK	9	0.339	.637 .717	-1.208	1.400	
						0.156
Total GPD in US \$ in China	14	0.938	.597	0.217	1.154	0.118
Total on education in the UK in US \$	9	-0.330	.717	-0.816	1.400	0.208
Total on education in China in US \$	13	1.192	.616	1.544	1.191	0.170
Total on research in the UK in US \$	9	0.325	.717	-1.465	1.400	0.159
Total on research in China in US \$	13	1.606	.616	2.235	1.191	0.225

### Appendix H Normality Plots Data Table







### Appendix I

### T-Test: Trends in diabetes between the UK and China

t-value -14.113 degree of freedom (df) 13 probability value 0.000

mean 1644017/293E+07

standard deviation 440330.2398/7677655.7739

eta squared 212.18

#### Expenditure of research between the UK and China

T 61.725
Probability 0.000
Df 8

An independent-samples t-test was conducted to compare the factors of innovation between the UK and China. There was no significant difference in the scores for Inflation (UK= 6.9786 SD=1.91881 Cn=5.7714 SD=7.70499) and Total GDP (UK=110000000000 SD=1420000000000 China=8.70000000000 SD=403500000000).

Total Spend on Research and Balance of Payment in the UK

Paired Sample T-test	UK	China
t-value degree of freedom (df) probability value mean standard deviation eta squared***	-7.683 8 0.000* -2.6E+10/2.2E+10** 1.800E+10/1357896606 0.88	2.207 11 0.050 1.5E+10 7.0E+09 1.346E+10/5661250512 0.302

Total Spend on Education and Balance of Payments in

	UK	China
Paired Sample T-test		
t-value	-12.841	3.797
degree of freedom (df)	8	11
probability value	0.000	0.003
mean	-2.4E+10/5.5E+10	1.5E+10/3.7917
standard deviation	1.800E+10/6095702054	1.3462+10/0.72261
eta squared	0.9374	0.5672

### Total GDP, Education and Total Research on the prevalence of diabetes in China

Innovation Factors	Correlation	Collinearity Tolerance	Standardised co-efficient	Significance of contribution
Total GDP	0.963	0.002	0.309	0.875
Total Education	0.922	0.022	-0.387	0.531
Total Research	0.960	0.001	1.031	0.670

Impact do the factors of innovation have on GDP performance in the UK

Innovation Factors	Correlation Collinearity Tolerance		Standardised co-efficient	Significance of contribution	
Total Nurses	0.816	0.044	0.783	0.160	
Total Doctors	0.447	0.137	-0.352	0.200	
Total Patents	-0.432	0.442	-0.131	0.288	
Balance of Trade	-0.368	0.078	0.296	0.302	
Total Trade Goods & Service	0.233	0.440	0.111	0.332	
Total spend Education	0.868	0.079	0.263	0.328	
Total spend Research	0.969	0.055	0.323	0.326	

Impact do the factors of innovation have on GDP performance in China

Innovation Factors	Correlation	Collinearity* Tolerance	Standardised co-efficient**	Significance of contribution
Total Research	0.984	0.082	0.869	0.029
Total Education	0.980	0.008	0.470	0.171
Total Goods/Service	0.391	0.008		
Balance of Payment	0.421	0.072	-0.301	0.261
Patents	0.952	0.423	0.067	0.361
Total Nurses	-0.293	0.502	0.081	0.138
Total Doctors	0.989	0.222	0.746	0.000
Total with Computers	0.921	0.158	0.318	0.002

Factors of innovation has an impact on the prevalence of diabetes in the UK

Innovation Factor	Correlation	standardised Co-efficient	Significance of Contribution
Total Research	0.954	0.584	0.378
Total Education	0.902	0.093	-0.151
Computers/1000 pop	0.947	239	0.512
Inflation	-0.880	283	-0.505
Total trade good/services	0.054	0.356	0.181
Balance of Payments	-0.248	0.387	0.513
Total Patents	-0.337	021	0.124

Factors of innovation has an impact on the prevalence of diabetes in China

Innovation Factor	Correlation	standardised Co-efficient	Significance of Contribution
Total Education	0.994	2.044	-
Total GDP	0.997	1.670	0.647
Computers/1000pop	0.942	964	0.80
Inflation	-0.548	0.160	0.020
Total Goods/Services	0.790	0.137	-0.217
Trade Balance	0.678	0.004	0.229
Total Doctors	0.974	-1.975	-0.529
Total Nurses	-0.520	0.166	0.010
Total Research	0.943	0.067	

Health spend impact on total trade in goods and services in the UK

Innovation Factors	Correlation	Collinearity Tolerance	Standardised co-efficient	Significance of contribution
Spend in the NHS	-0.004	0.03	12.069	0.11
Health spend per person	-0.45	0.03	-12.093	0.11

Health spend impact on total trade in goods and services in China

Innovation Factors	Correlation	Collinearity Tolerance	Standardised co-efficient	Significance* of contribution
% GDP on health	0.564	0.058	2.170	0.018
GDP /head on health	0.781	0.080	-0.999	0.120
% health spend by Gov	-0.253	0.087	-1.744	0.019

The impact on GDP and Balance of Trade by investing in research in the UK

Innovation Factors	Correlation	Collinearity Tolerance	Standardised co-efficient	Significance* of contribution
Total GDP Total Trade Good/Service Rsquare= 0.928	0.969 0.146	10.136 -0.869	0.989 -0.085	0 0.418

### The impact on GDP and Balance of Trade by investing in research in China

Innovation Factors	Correlation	Collinearity Tolerance	Standardised co-efficient	Significance* of contribution
Total GDP Total Trade Goods/Service	0.968 0.860	0.146 0.146	1.192 -0.242	0 0.235
Rsquare=0.973				

The impact on GDP and Balance of Trade of investing in Education in the UK

The impact on our and Balance of Trade of Involuting in Education in the off				
Innovation Factors	Correlation	Collinearity Tolerance	Standardised co-efficient	Significance* of contribution
Total GDP	0.868	0.946	0.932	0.002
Total Trade Goods/service Rsquare 0.825	-0.057	0.946	-0.274	0.170

The impact on GDP and Balance of Trade by investing in Education in China

The impact on ODI and Bulance of Trade by investing in Education in Online				
Innovation Factors	Correlation	Collinearity Tolerance	Standardised co-efficient	Significance* of contribution
Total GDP Total Trade G/S RSQUARE= 0.995	0.998 0.917	1.035 -0.040	0.146 0.146	0 0.455

# Appendix J

# **Stem Cell Research**

Institution	Research	Contact Details
	Area	
Steering Committee UK Stem Cell Bank	World's first Biobank	Professor Tom Baldwin – Bio ethicist Head of Department York University Prof Sir David Carter Vice Chairman and Principal Edinburgh Prof Martin Evans Director of School of Biosciences Cardiff University Prog Douglas Higgs Director Molecular Haematology Oxford Dr Jennie Flatman Pharmaceutical assessor medicines and health care products regulatory agency
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Birmingham	diabetes related	Prof Logan (402k)
	gene slicing	Prof Turner (243k)
Cambridge	derivation of cells  Multiple Sclerosis	A Surani (220k) JW Fawcett (247k) B Gottgens (277k) JB Gurdon (456k) Prof Ffrench-Constant (194k) Dr Chandran (311k)
	l	
	Damage C Nervous S Olfactory mucosa	Prof Fawcett (233k)
Cambridge Stem Cell		
Cambridge Stem Cell Institute Cardiff		Prof Fawcett (233k) Dr Franklin (304k) Prof Anne Cooke  Prof Dunnett (317k)  AR Clarke (206k) Dr Allen (272k)
Institute	Olfactory mucosa  imaging neural stem cells intestinal epithelial cells brain protocols for storage  epithelia into skin and stem cells	Prof Fawcett (233k) Dr Franklin (304k) Prof Anne Cooke  Prof Dunnett (317k)  AR Clarke (206k)
Institute Cardiff	Olfactory mucosa  imaging neural stem cells intestinal epithelial cells brain protocols for storage	Prof Fawcett (233k) Dr Franklin (304k) Prof Anne Cooke  Prof Dunnett (317k)  AR Clarke (206k) Dr Allen (272k) Prof Dunnett (280k)

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	Huntington's	Dr Darren G Monskton
	Cancer	Dr Peggy Shelbourne
	Epithelial stem cells in repair	Dr Joanna B Wilson
	<u> </u>	Dr Barnett (322k)
Keele	Activation of stem cells	AJ EL Haj (335k)
Kings College London	Second UK Licence for embryo	Dr Susan Pickering
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	Neural differentiation	BP Williams (354k Dr S Minger (365k
	Derivation of human Embryonic Stem Cells	Di 3 Miliger (303k
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Genetics and Genomics	Fate after transplantation	Prof Maggie Dallman
	Heart	C Toumazou (672k)
		Prof Fisk (182k)
		Dr Rimoldi (265k
Liverpool	Enhancing propagation of ES cell	Dr Edgar (315k)
Manchester	Characterization of development	AD Whetton (472k)
manonous.	Cartilage and joint repair	Prof Hardingham (190k)
	Surface markers in SC	Dr Chopra (184k)
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Institute of Human Genetics	Change in endothelial cells	Dr Helen Arthur and Dr John Burns
	Leukaemia	Dr Colin Miles
		Dr David Basset
	Generating new beta cells from	Dr D Elliott Dr S Lindsay
	human pancreatic stem cells and generation of glucose responsive	Dr Sarah Newbury
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Oxford		alison.woollard@bioch.ox.ac.uk - cell determination  Prof Graham (192k) – reprogramming nuclei adult cells
Oxford		alison.woollard@bioch.ox.ac.uk - cell determination Prof Graham (192k) - reprogramming nuclei
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Oxford Churchill Hospital Within Oxford Centre for	transplant of insulin producing islet	alison.woollard@bioch.ox.ac.uk - cell determination  Prof Graham (192k) - reprogramming nuclei adult cells  Prof Waldmann (313k) - reprogramming immune sys  Dr Paul Johnson  Director of Islet Transplantation Programme
Oxford Churchill Hospital Within Oxford Centre for Diabetes and Endocrinology	transplant of insulin producing islet cells into a patient's liver. Believe	alison.woollard@bioch.ox.ac.uk - cell determination  Prof Graham (192k) – reprogramming nuclei adult cells  Prof Waldmann (313k) – reprogramming immune sys  Dr Paul Johnson
Oxford Churchill Hospital Within Oxford Centre for	transplant of insulin producing islet cells into a patient's liver. Believe within 5 to 10 years they will have	alison.woollard@bioch.ox.ac.uk - cell determination  Prof Graham (192k) – reprogramming nuclei adult cells  Prof Waldmann (313k) – reprogramming immune sys  Dr Paul Johnson  Director of Islet Transplantation Programme  Paul.Johnson@medsci.ox.ac.uk
Oxford Churchill Hospital Within Oxford Centre for Diabetes and Endocrinology	transplant of insulin producing islet cells into a patient's liver. Believe within 5 to 10 years they will have a simple procedure for curing	alison.woollard@bioch.ox.ac.uk - cell determination Prof Graham (192k) - reprogramming nuclei adult cells Prof Waldmann (313k) - reprogramming immune sys Dr Paul Johnson Director of Islet Transplantation Programme Paul.Johnson@medsci.ox.ac.uk Funded by diabetic research and wellness
Oxford Churchill Hospital Within Oxford Centre for Diabetes and Endocrinology	transplant of insulin producing islet cells into a patient's liver. Believe within 5 to 10 years they will have a simple procedure for curing diabetes. Cells in research are	alison.woollard@bioch.ox.ac.uk - cell determination Prof Graham (192k) – reprogramming nuclei adult cells Prof Waldmann (313k) – reprogramming immune sys Dr Paul Johnson Director of Islet Transplantation Programme Paul.Johnson@medsci.ox.ac.uk Funded by diabetic research and wellness foundation. Executive Director Sarah Bone
Oxford Churchill Hospital Within Oxford Centre for Diabetes and Endocrinology	transplant of insulin producing islet cells into a patient's liver. Believe within 5 to 10 years they will have a simple procedure for curing	alison.woollard@bioch.ox.ac.uk - cell determination Prof Graham (192k) - reprogramming nuclei adult cells Prof Waldmann (313k) - reprogramming immune sys Dr Paul Johnson Director of Islet Transplantation Programme Paul.Johnson@medsci.ox.ac.uk Funded by diabetic research and wellness
Oxford Churchill Hospital Within Oxford Centre for Diabetes and Endocrinology and Metabolism	transplant of insulin producing islet cells into a patient's liver. Believe within 5 to 10 years they will have a simple procedure for curing diabetes. Cells in research are donated from another person's	alison.woollard@bioch.ox.ac.uk - cell determination Prof Graham (192k) – reprogramming nuclei adult cells Prof Waldmann (313k) – reprogramming immune sys  Dr Paul Johnson Director of Islet Transplantation Programme Paul.Johnson@medsci.ox.ac.uk  Funded by diabetic research and wellness foundation. Executive Director Sarah Bone subs@drwf.org.uk www@ocdem.ox.ac.uk
Oxford Churchill Hospital Within Oxford Centre for Diabetes and Endocrinology	transplant of insulin producing islet cells into a patient's liver. Believe within 5 to 10 years they will have a simple procedure for curing diabetes. Cells in research are donated from another person's	alison.woollard@bioch.ox.ac.uk - cell determination Prof Graham (192k) – reprogramming nuclei adult cells Prof Waldmann (313k) – reprogramming immune sys  Dr Paul Johnson Director of Islet Transplantation Programme Paul.Johnson@medsci.ox.ac.uk  Funded by diabetic research and wellness foundation. Executive Director Sarah Bone subs@drwf.org.uk www@ccdem.ox.ac.uk  DA Lee (214k) – differentiation
Oxford Churchill Hospital Within Oxford Centre for Diabetes and Endocrinology and Metabolism	transplant of insulin producing islet cells into a patient's liver. Believe within 5 to 10 years they will have a simple procedure for curing diabetes. Cells in research are donated from another person's	alison.woollard@bioch.ox.ac.uk - cell determination Prof Graham (192k) – reprogramming nuclei adult cells Prof Waldmann (313k) – reprogramming immune sys  Dr Paul Johnson Director of Islet Transplantation Programme Paul.Johnson@medsci.ox.ac.uk  Funded by diabetic research and wellness foundation. Executive Director Sarah Bone subs@drwf.org.uk www@ocdem.ox.ac.uk  DA Lee (214k) – differentiation IC Mackenzie (209k) – tissue engineering
Oxford Churchill Hospital Within Oxford Centre for Diabetes and Endocrinology and Metabolism	transplant of insulin producing islet cells into a patient's liver. Believe within 5 to 10 years they will have a simple procedure for curing diabetes. Cells in research are donated from another person's	alison.woollard@bioch.ox.ac.uk - cell determination Prof Graham (192k) – reprogramming nuclei adult cells Prof Waldmann (313k) – reprogramming immune sys  Dr Paul Johnson Director of Islet Transplantation Programme Paul.Johnson@medsci.ox.ac.uk  Funded by diabetic research and wellness foundation. Executive Director Sarah Bone subs@drwf.org.uk www@ccdem.ox.ac.uk  DA Lee (214k) – differentiation

		www.roslin-biocentre.com
·		Dr McWhir (313K) – bone repair
Sheffield		P Andrews (376k) - mechanism differentiation
		Prof Crossman (318k) vascular repair Prof Placzek (176k) – differentiation of hypothalmic
		cell
		B Caterson (197k) differentiation
		P Andrews (208k) – notch signalling
		Prof Andrews (291k) – changes of HES in culture
		P Andrews (955k) – ES resource centre
Southampton	<del></del>	Dr Coffey (276k) – retinal  RO Oreffo (89k) – activation of stem cells
Southampton		Dr Gray (236k) – cell proliferation
		RO Oreffo (307k)
UCL	Retinal	Dr Limb (325k)
Peninsular Medical School	Development and treatment of	Professor Andrew Hattersley
	diabetes molecular genetics in	a.t.hattersley@ex.ac.uk
	diabetes	Commercial Stem Cell
		Companies
Acatrom	Alanca annia anna infantia.	Aastrom Biosciences, Inc.
Aastrom Biosciences, Inc.	tissue repair, cancer, infectious disease	Domino's Farms, Lobby L, 24 Frank Lloyd Wright
biosciences, inc.	disease	Drive
		Ann Arbor, MI 48105 USA
		Telephone: (734) 930-5555
		Fax: (734) 665-0485
		mail@aastrom.com
		http://www.aastrom.com/
ViaCell, Inc	Cord blood	ViaCell, Inc.
		245 First St
		Cambridge, MA 02142
		Telephone: 1-866-842-2355
		http://www.viacellinc.com Email - info@viacellinc.com
Stem Cell Therapy	SCTI is the world's largest	Stem Cell Therapy International Corp.
International Corp.	manufacturer of precursor stem	2203 North Lois Ave. 9th Floor
memaneral corp.	cell xeno-transplants, which have	Tampa, FL 33607 USA
	been used to treat a wide range of	Telephone: 813.600.4088
	conditions including: complications	Fax: 813.830.6112
	of diabetes, aging disease,	E-mail: info@scticorp.com
	neurological disorders, genetic	http://www.scticorp.com/
	diseases and immune deficiency disorders	
Advanced Cell Technology	leading biotech company in the	One Innovation Drive, Biotech Three
Inc.	field of regenerative medicine	Worcester, Mass. 48105 USA
	nois of regenerative medicine	Telephone: (508) 756-1212
		Fax: (508) 756-4468
		info@advancedcell.com
		http://www.advancedcell.com/
AnorMED, Inc.	cancer and HIV	AnorMED, Inc.
		#200 - 20353 64th Avenue
		Langley, British Columbia, V2Y 1N5 Canada
		Telephone: 604.530.1057
		Fax: 604.530.0976 E-mail: info@anormed.com
		http://www.anormed.com/
AVI BioPharma	drugs to treat life threatening	AVI BioPharma
AVI DIUF IIdillid	disease cancer restenosis poly	One SW Columbia Suite 1105
	cystic kidney disease drug	Portland, Oregon, 97258 USA
	metabolism	Telephone: 503-227-0554
		E-mail: avi@avibio.com
		http://www.avibio.com/
BioE, Inc.	diagnostic therapeutic products	BioE Technical Support Department
	predictive test for alzheimers	4280 Centerville Road
		St. Paul, MN 55127
		United States Telephone: 800-350-6466
		Fax: 651-426-5740
		Email: tech@bioe.com
		http://www.bioe.com/
Bio-Matrix Scientific Group,	tissue engineering and gene	Bio-Matrix Scientific Group, Inc.
nc.	therapy	1010 University Avenue #40
	''	San Diego, CA 92103 USA
	1	Telephone: 619.702.1404
		l — `a.a.a.a.a.
		Fax: 619.330.2328 E-mail: info@bio-matrix.org

		http://www.bmxgonline.com//
BrainStorm Cell	Parkinson and multiple S	15 Gonen St.
Therapeutics, Inc.		P.O.Box: 7779, Petach Tikva ISRAEL, 49170
		Telephone: +1-212-946-2823 E-mail: <u>ybeck@brainstorm-cell.com</u>
CHEMICON International.	diagnostic kits	Corporate Headquarters
Inc.	diagnostic kits	28820 Single Oak Drive
		Temecula, CA 92590
		United States
		Telephone: 800-437-7500
		Fax: 800-437-7502
		E-mail: custserv@chemicon.com
•	<del> </del>	http://www.chemicon.com/
Cord Blood America Corp.	cord blood	Legal Counsel
Cold Blood / Wholica Colp.		Winderweedle, Haines, Ward & Woodman, P.A.
		Attn: Gary Lipson
		390 North Orange Avenue
		Suite 1500
		Orlando, FL 32801
		Telephone: 407-246-6577 Matthew L. Schissler
		Chairman & CEO
		E-mail: mls@cordpartners.com
		http://www.cordblood-america.com/
Cord Blood Registry (CBR)	cord blood	Cord Blood Registry
		1200 Bayhill Drive, Suite 301
		San Bruno, California 94066
		United States Telephone: 1-888-932-6568
		International callers: (650) 635-1420
		Monday to Friday (6am - 9pm PST)
		Saturday (7am - 4pm PST)
		Fax: 1-800-844-2202
		General questions@cordblood.com
Coming Inco	<del>                                     </del>	Corporate Website - http://www.cordblood.com/
Curis, Inc.	drug development kidney disease	61 Moulton Street
	and cancers	Cambridge, MA 02138 USA Telephone: (617) 503-6500
	1	Fax: (617) 503-6501
		Contact page on web site
		http://www.curis.com/
Cryo-Cell International, Inc.	cord blood	Cryo-Cell International, Inc.
		700 Brooker Creek Blvd., Suite 1800
		Oldsmar, FL 34677 USA
		Telephone: (813) 749-2100
		Fax: (813) 855-4745 Contact page on website
		http://www.cryo-cell.com/
Cytori Therapeutics	spinal injury and gastro disorders	6740 Top Gun Street
Cyton merapedios	Spirial rightly and gastro disorders	San Diego, CA 92121
		United States
		Telephone: 858-458-0900
		Fax: 858-458-0994
		products@cytoritx.com
		Corporate Website - http://www.cytoritx.com/
Favrille, Inc. Corp.	immunotherapies non-hodgkin's	10421 Pacific Center Court
	lymphoma	San Diego, CA 92121
	1	United States Telephone: 858-526-8000
		Fax: 858-597-7040
		hr@favrille.com
		Corporate Website - http://www.favrille.com/
Genentech, Inc.	founder in biotech among world	1 DNA Way
	leaders	South San Francisco, CA 94080-4990 USA
	Barbara Lippe most senior	Telephone: (650) 225-1000
	medical director	Fax: (650) 225-6000
Genzume Comoration	one of the world's loading history	http://www.gene.com/gene/index.jsp
Genzyme Corporation	one of the world's leading biotech working in 30 countries	500 Kendall Street
	working in 30 Countries	Cambridge, MA 02142 USA Telephone: 617 252 7500
		Fax: 617 252 7600
		Contact page on website Corporate Website - http://www.genzyme.com/
Geron Corporation	cancer, spinal cord, diabetes,	Contact page on website

		Telephone: 650-473-7700 Fax: 650-473-7750 info@geron.com http://www.geron.com/
LifeCell Corporation	orthopaedics and burns	One Millennium Way Branchburg, New Jersey 08876-3876 USA Telephone: 1-908-947-1100 Fax: 1-908-947-1089 contact page on website - http://www.lifecell.com/
Mesoblast Limited Contact Inc	orthopaedic	Level 39 - 55 Collins Street Melbourne, 3000 AUSTRALIA Telephone: +61 3 9639 6036 Fax: 617 252 7600 http://www.mesoblast.com/ Email: info@mesoblast.com
MultiCell Technologies, Inc.	Liver	Multicell Research & Development Headquarters 701 George Washington Highway Lincoln, RI 02865 USA Telephone: 401-333-0610 info@multicelltech.com MultiCell Technologies, Inc. Corporate Headquarters 701 George Washington Highway Lincoln, RI 02865 USA Telephone: 401-333-0610 Fax: 401-333-0659 info@multicelltech.com http://www.multicelltech.com/
Osiris Therapeutics, Inc.	immune heart attach and arthritis	Osiris Therapeutics, Inc. 2001 Aliceanna Street Baltimore, MA 21231-3043 USA Telephone: (410) 522-5005 Fax: (410) 522-6999 osiris@osinstx.com http://www.osiristx.com
PharmaFrontiers Corporation	autologous therapies for MS diabetes congestive heart failure (clinical test and vaccine)	2408 Timberloch Place Suite B7 The Woodlands, TX 77380 USA Telephone: 281-272-9331 Fax: 281-272-1088 ir@pharmafrontierscorp.com http://www.pharmafrontiers.net/
PhereSys Therapeutics Corp.	remove disease causing substances from blood chief medical advisor richard.sweetmd@pheresys.com	Corporate Headquarters 1107 Investment Boulevard Suite 240 El Dorado Hills, CA 95762 United States Telephone: 916-939-9550 Fax: 916-939-9553 http://www.pheresys.com/
Pluristem Life Systems, Inc.	expansion of stem cells T cells and other blood cells	Pluristem Life Systems, Inc. MATAM Advanced Technology Park Building No. 20, Haifa 31905, Israel Telephone: 972-4-850-1080 Fax: 972-4-850-1085 E-mail: info@pluristem.com http://www.pluristem.com/
Serological Corporation	provide products	Serological Corporation 5655 Spalding Drive Norcross, GA 30092 USA Telephone: (678) 728-2000 E-mail: info@serologicals.com http://www.serologicals.com/
Stem Cells, Inc.	Parkinson's Alzheimers spinal cord MS liver and juvenile diabetes  UK Australian and Japan embryo stem cells	3155 Porter Drive Palo Alto, California 94304-1213 USA Telephone: 650.475.3100 Fax: 650.475.3101 http://www.stemcellsinc.com/ Stem Cell Sciences UK Ltd. Corporation Roger Land Building King's Building University of Edinburgh West Mains Road Edinburgh EH9 3JQ

Research Register	Beijing China	ENGUINE TOUTH ATTEMPT TOUTH ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT TO THE ATTEMPT
Bioethics and Society	http://www.cams.ac.cn/#	zxqclx@hotmail.com xmzhai@hotmail.com
WHO	Representative in China	wrchn@chn.wpro.who.int
Health Ministry  National People's Congress	Ministry of health in china  Government	Xi xhi men and wai nan lu www.moh.gov.cn/ Hu Jintao President Wen Jiabao Prime Minister
China	Ministry of health in ahir-	Wishings advisions to
China	regenerative medicine.	Telephone: 626-961-0562 Fax: 626-961-8179 E-mail: info@usbiodefense.com Corporate Website - http://www.usbiodefense.com/
U.S. BioDefense, Inc.	Advanced Cell Technology, Inc. is the leading biotechnology company in the emerging field of	http://www.usbiodefense.com/ U.S. BioDefense, Inc. 13674 E. Valley Blvd. City of Industry, CA 91746 USA
U.S. BioDefense, Inc.	explore licensing	U.S. BioDefense, Inc. 13674 E. Valley Blvd. City of Industry, CA 91746 USA Telephone: 626-961-0562 Fax: 626-961-8179 E-mail: info@usbiodefense.co
		Ireland Telephone: +353-(0)1-409-7757 Fax: +353-(0)1-409-8179 U.S. Headquarters 500 7th Ave., 10th floor /B New York, NY 10018 USA Tel: +1-212-201-0920 Fax: +1-212-201-0921 Thromb-X N.V. Building O&N Level 9 Herestraat 49 3000 Leuven Belgium E-Mail: ESinfo@thromb-x.com/ http://www.thrombogenics.com/
ThromboGenics Ltd.	Cardiovascular Disease and evaluating and exploring licensing	Corporate Headquarters 14 Bridgecourt Office Park Walkinstown Avenue Dublin 12 Ireland
		2711 Citrus Road Rancho Cordova, CA 95742 USA Telephone: (916) 858-5100 Fax: (916) 858-5199 web@themogenesis.com Corporate Website - http://www.thermogenesis.com/
Stacie ThermoGenesis Corp.	Cord blood	400 Rolyn Place Arcadia, CA 91007 United States Toll Free: (866) 783-6298 Local Ph: (626) 821-9860 E-mail contact@stemcyteinc.com http://stemcyte.com/ ThermoGenesis Corp.
Stem Cell Therapeutics, Corp.	Huntington's	Suite 1000, 1520 4th St SW Calgary, AB, T2R 1H5, Canada Telephone: 403.245.5495 Fax: 403.245.5411 E-mail: info@stemcellthera.com http://www.stemcellthera.com/
		UNITED KINGDOM Telephone: +44 (0)131 662 9829 Facsimile: +44 (0)131 662 9779 http://www.stemcellsciencesltd.com

Health and Science Centre – clinical research organisation (Shanghai Institutes for Biological Science Shanghai Second Medical University and Chinese Academy of Sciences)		225 South Chongqing Road Shanghai 200025 China hsc@sibs.ac.cn Chief Specialist Huizhen Sheng
Research Centre Peking	Stem Cell (differentiation of human embryonic germ cells)	Chief Specialist Lingsong Li
Chinese National Human Genome Centre at Shanghai	4th Floor, Bldg. 1, No.351, Guo Shou Jing Road,Zhang-jiang Hi- Tech Park, Pudong, Shanghai, 201203,P.R.China	Director Chen Zhu web@chgc.sh.cn http://www.chgc.sh.cn Honorary Director: Jia-Zhen TAN (Member, Chinese Academy of Sciences) Director: Zhu CHEN (Member, Chinese Academy of Sciences) Executive Director: Guo-Ping zhao Standing Deputy Director: Wei HUANG Deputy Director: Long YU Director Assistant: Ze-Guang HAN, Gang FU, Shuang-Xi REN, Shen-Yue Wang
State Council		Minister for foreign affairs Li Zhaoxing Minister for science and technology Xu Guanhua Minister for health Gao Qiang www.moh.gov.cn Intellectual property office Director Wang Jingchuan Research office Director Wei Liqun Development Research Centre Director Wang Mengkui
Peking University - Beijing China - Department of Cell Biology and Genetics College of Life Sciences.	Working on experiments to induce embryonic stem cells to become pancreatic beta cells.	Contact <u>hongkui_deng@pku.edu.cn</u> and Mingziao Ding <u>dingmx01@pku.edu.cn</u>
China European International Business School Shanghai – Health Care Management		www.ceibs.edu
Chinese Academy of Engineering		Hou Yunde Vice Chairman (says only a small gap between Developed World and China in biomedicine. Value \$2.41bn year) Hou Yunde academic attracted to China since joining WHO, investors in bio-tech attracted to China due to preferential policies, improved investment environment and possibility of huge profits <a href="https://www.xinhaunet.com">www.xinhaunet.com</a>
Beijing Chinese Academy of Medical Science	In February 05 scientists approval for Chinas first clinical trial using human stem cells to treat Leukaemia. Most projects are funded solely by the government. In future develop other areas including diabetes.	Zhao Chunh leading the team www.bimu.edu.cn
Chinese Academy of Medical Science		Zheng Bin researcher
China National Centre for Biotechnology Development		Li Quing Chief of the Biotech Policy at (affiliated with Ministry of Science and Technology) Director Prof Wang Yu wangyu@cncbd.org.cn Hui Hong huihong@cncbd.org.cn
SinoCells Biotechnology Co Ltd (Beijing Based)		- Dong Ziping Chief Executive
Beijing Military Medical College		Pei Xuetao Division Stem Cell Research  1284 million people can be helped annually with stem cell therapies
Stem Cell Research Centre (Peking) (differentiation of human embyronic germ cells)	introduced genetic material into a stem cell to produce a glandular structure that secretes chemicals useful to treat diabetes and parkinson's	Chief Specialist Huizhen Sheng – hsc Chief Specialist Lingsong Li
China Medical University Shenyang		- Prof Xinshan Jia Head of Department of Molecular Pathology
University of Medical Sciences	(stem cell research) -	Shunong Li Sun Yat-Sen
Peking University Stem Cell Research Centre		Hongmei Peng

China Medical University		Xining Pang
Shenyoung -		Alling Fang
Stem Cell Centre Beike		biotech company funded by Beijing University and China State National Fund – since August 2001 treating patients with stem cell injections. ALS (89 Brain Trauma (32) Cerebral Infarction (36) Cerebreal Hemorrhage (20) Cerebral Palsy (20) Diabetic Foot (152) They use cord blood injected into the spine. Day-care no surgery.
Chinese Association of Traditional Chinese Medicine	Research into diabetes	Wu Yi Ling Director
Sun Yat-sen University		
Research presented at Global Conference on Stem Cells Sept 04 in Boston.	Researchers from China reported reversing diabetes in Mice by injecting fetal liver cells from other mice. Korea reported generating insulin producing cells from human embryos	
AMMS Stem Cell and Regenerative Medicine Centre affiliated to Beijing Institute of Transfusion Medicine.		Research application of stem cell biology an regenerative medicine including tissue regeneration of blood, heart, liver pancreas and nerve. Also run cord blood therapy for leukaemia and haematopoiesis and limb revascularisation (Professor Pei)
Dr Huang Dr Wise Young (Rutgers University).		Chaoyang Hospital Beijing 500 treatments for spinal cord injury 150 ALS. Costs \$20,000 stay one month
Beijing Tiantan Puhua Hospital		stem cell work focuses on Brain Trauma Spinal Cord Injury ALS and clinical trials for Parkinson's (Dr Han Xiaodi Sherwood Yang)
Huashan Hospital Shanghai		Prof Zhu research autologous application of adult neural stem cells in traumatic brain injury
Institute of Haematology and National Centre for Stem Cell Engineering and Technology 28 Nanjing Road Tianjin 300020	Union Stem Cell and Gene Engineering company exploiting their research in cord blood therapies	treatment of blood disease in Tianjin - Prof Zhong Chao Han (head of centre)
Beijing Institute of Transfusion Medicine AMMS Stem Cell and Regeneration Medicine (Cancer)		Dr Pei Xuetao
Wu Hospital Medical University Shanghai		Dr Shen Huizhen Xuan– Head of Shanghai Laboratory of Developmental Biology
Stem Cell Centre Beijing Medical University 38 Xue Yuan Road Beijing 100083 China		Prof Li Dr Ziping Dong – neural and pancreatic Prof Lingsong Li <u>lingsongli@bjmu.edu.cn</u>
Hong Kong University	spinal cord and paralysis neuronal degeneration	Dr Wu Wutian -
SinoCells Biotechnologies Co Ltd 116 Zhongguaneun North Street Haidian District 100871		Dr Ziping Dong is CE (hES for clinical application by 2010) www.sinocells.com
Beike currently at National Natural Science Foundation of China		Dr Yang Bo - Parkinson's Brain Injury Stroke
StemGene Union Stem Cell and Gene Engineering Co Ltd 11 Hongkan Road Tianjin 300073	company focusing on research and commercialisation of stem cell technology. Established Tianjin Cord Blood Bank where people store their cord blood	Union Stem Cell and Gene Engineering unionstemcell@yahoo.com
Xuan Wu Hospital Cell Therapy Centre	and neural cells for neurodegenerative disorders. Expects to be first to clinic With diabetic work	Prof Zhang working on pancreatic progenitor cells as a possible therapy for diabetes Hospital Prof Yu Zhang <u>vaz@bisap.org</u> (working on pancreatic) emailed 5/3/06
Institute of Zoology Chinese Academy of Medicine	Main research biological consequence of animal cloning in the use of technologies	Prof Zhou successfully cloned a rat Pro Qi Zhou <u>qzhou@ioz.ac.cn</u>
Chinese National Human Genome Centre at Shanghai		Director Chen Zhu

Sleeboom M (2002 Nov) Stem Cell Research in China: An Intertwinement of International Finances, Ambition and Bioethics IIAS Newsletter 29 Shanghai Institutes for Biological Science	China also transplanted embryo cells into human brain cloned pulsating heart cells and cured paralysis in mice  Hepeng Jia (2005) China Supports Therapeutic Cloning China Business Weekly 31 <sup>st</sup> March China voted against the United Nations non-binding statement condemning all forms of human cloning.  Health and Science Centre — clinical research organisation	Yan Shi, Lingling Hou, Fochou Tang, Wie Jiang, Peigang Wang, Mingxiao Ding Hongkui Deng (2005) Inducing Embryonic Stem Cells to Differentiate into Pancreatic B Cells by a Noval Three-Step Approach with Activin A and All-Trans Retinoic Acid Stem Cells 23;656-662  m.sleeboom.let.leidenuniv.nl researching genomics in Asia  (Shanghai Second Medical University and Chinese Academy of Sciences) 225 South Chongqing Road Shanghai 200025 China
Da Du Life esiamose Asia		hsc@sibs.ac.cn
Dr Du Life sciences Asia Pacific		
jiansheng.du@pera.com		
Centre for Excellence in		ProfRobert Zhao Chunhua
Tissue Engineering		chunhuaz@public.tpt.tj.cn
		Clinical pharmacogenetics
		geoff.johnston@pfizer.com Stephen.minger@kcl.ac.uk
		Stem cell sciences
		peter.mountford@stemcellsciences.com
		Neuroscience research part
		Ignacio_munoz_sanjuan@merek.com Chief science officer cellcentric ltd
		cathy.prescott@Avlar.com
		Director of Centre for Cellular Behaviour
		j.price@iop.kcl.ac.uk
		Innovation and Enterprise c.quest@gmul.ac.uk
		Public law g.richardson@gmul.ac.uk
		World wide business development
Academy of Military Medical		Malcolm.7.skingle@gsk.com www.amms.ac.cn prof Xuetao pei
Sciences		www.aimins.ac.on prof Auctao per
Chinese Academy of Medical	-	Zhao Chunhua www.stemnews.com/archives/stem-
Science		<u>cellanddiabetes.html</u>
biographic and a		Prof Lui Depei http://cmbi.bjmu.edu.cn
biomedicine in china		nttp://cmbi.bjmd.edd.cn
		www.chinaethics.com
	:	www.stemcells.alphamedpress.org
SinoCells Biotechnologies China		hr@sinocells.com
National Science Foundation		Prof Zhu Zuoyan
Beike Biotech Company		
Institute of Genetics CAS China		Prof Yang Huanming
Chinese Engineering Sciences Beijing		Prof Hou Yunde
China World Best Beijing	†	Prof Wang Guihai
Chinese National Human		www.chgc.ch.cn
Genetic Centre		www.chgc.org.cn Yang Huanming Director
Tianjin Science and Technology Commission 287 Hepping Road 300041		
Genon Bioengineering Co Ltd (Dr Guoxiang Cheng) 88 Laiun Road Zhangjang Rudong Shanghai		www.cngenon.com
Xinhua New China Hospital 1665 Kong Jiang Road Shangahi		
Huashan Hosptial Fudan		www.huashan.org.cn
University 12 Wulumuqi		prof Wen Yu-Mei

200040		
Peking Union Medical College in co-operation with Tsinghua University	(leading Chinese university in combining stem cell technology with tissue engineering) Has five research units an Islet Unit, heart, liver, adult stem cells, biomaterials	
Xinhua Hospital part of Shanghai second medical university.		Prof Hui Sheng (she) Cell differentiation Xinhau Hosptial pro hui zhen sheng hzsheng@sh163a.sta.net.cn
Ru-Jin Hospital Shanghai Institute of Haematology	houses key labs for human genome research medical genomics and ministry of public health	
Jianxi Medical College 161 Ba Yi Street Nanchang 330006		
China Medical University92 Bei Er Road Heping District Shenyang 110001		
Nanjing University School of Medicine 22 Handou Road Nanjing 210093		
Shanghai Medical University 138 Medical College Road Shanghai 200032		
San Yat Sen University of Medical Sciences 74 Zhong Shan Road 1 Guangzhou 510089		
Tianjin Medical University 22 Qi Xiang Tai Road Tianjin 300070		
West China University of Medical Sciences 17 Section 3 South Ren Min Road Chengdu 610044		
Xian Medical University West Xiao Zhai Road Xian 710061 Peking University Stem Cell		
Research Centre  Martial Medicine Academy of Science Transfusion		
Department Peking University People's Hospital Cell Therapy Centre		
Beijing Xuanwu Hospital Beijing Society of Biotechnology		
Beijing Biotechnology and New Medicine Industry Promotion Centre		
Beijing Society of Biotechnology Stem Cell Commission Beijing Sinocells		chenl@mail.newlifebp.org.cn www.stemcell.com.cn
Biotechnologies Co Ltd		
Rest of the World		Stem Cell Research into Diabetes
Stamford University United Stated	Researching brain cells into producing insulin. Tested on animals not humans	Dr Seung Kim Ass Prof Dept Developmental Biology
Stamford University	Coax immature cells to develop into islet cells	
Hospital in San Nicolas, North of Buenos Aires.	Cured diabetes by taking stem cells from ileum bone manipulating in lab and injecting into the pancreas using a catheter through the femoral artery (3/01/05)	Fernandez Vina leads team
Massachusetts General Hospital	(Jan 05) discovered spleen might be source of stem cells to produce islet cells from	

Harvard University	developed method to provide individual sequence of their genome. Current cost 2.2m but project this would be £562 when available.	George Church glmlcl@receptor.med.harvard.edu  (ref Journal of Science)
Harvard University	to find a cure for diabetes working in partnership with Seoul National University Prof Kwang Woo-Kuk (two of Dr Meltons children have diabetes)	Dr Douglas Melton dmelton@biohp.hav.ord.edu prof natural science Harvard
University of California San Francisco Diabetic Centre		Michael German mgerman@biochem.ucsf.edu
University of Minnesota	Reversed diabetes in monkeys by transplants of islet from pigs. Plan to commence human trials in 2009	Associate professor of surgery and lead investigator Bernhard Hering
Washington University School of Medicine	Cured diabetes in rats with pig embryonic tissue without need for anti-injection therapy	
Toronto University	Work published in journal of nature biotechnology (generating new beta cells to produce insulin in mice)	Lead Researcher Dr Simon Smukler
Viacell Incorporated (NASDAQ:VIAC) Genzyme Corp	Working on cure for juvenile diabetes	
AmCyte Inc Los Angeles Leads in encapsulated islet cell and pancreatic adult stem cells. Presented Bio 2005 conference	(Largest biotech Company in the World lead in transplants for type 1 diabetes 15/3/05 first transplant without immune suppression	www.amcyte.com
Vitro diagnostic Inc	Filed for new patent in US for procedure to generate beta cells	
France	showed adult human stem cells are able to be differentiated into insulin expressing cells	Moriscot Christine, Fraipont de Florence, Richard Marie-Jeanne, Merchand Melanie, Savatier Pierre, Bosco Domenico, Favrot M, Benhamou Pierre-Yves (2005) Human Bone Marrow Mesenchymal Stem Cells can Express Insulin and Key Transcription Factors of the Endocrine Pancreas Developmental Pathway upon Genetic and/or Micro environmental Manipulation in Vitro Stem Cells 23:594-603
Japan (Kyoto)	islet cells used to cure daughter	
WHO Emailed 5/3/06	Work on diabetes in China	Dr P Puska <u>puskap@who.int</u> Dr G Roglic <u>roglicg@who.int</u> Mr D Porter <u>porterd@who.int</u> <u>www.who.int</u> <u>www.unaids.org</u> <u>www.sustainable-development.gov.uk</u>
	Researching in the clinical area of diabetes in the UK and China	Pharmaceutical
Astra Zeneca	provides cardiac drugs     not diabetes. Nothing on     diabetes in their published     research programme	
Abbots	involved mainly in monitoring and management of diabetes. Products include freestyle, freestyle flash and CoZmonitor, all blood glucose monitoring. Co Pilot and precision link both health management system, precision Xtra advance diabetes management system, insulin syringes (precision sure dose) and a range of nutritional products.	www.abbott.com
Sanofi-synthelabo	no research in diabetes. Produces insulin (lantus). amaryl oral for type 2 diabetic's	www.sanofi-avantis.us www.sanofi-aventis.com
Sanofi Aventis  Eli-Lilly	world's third largest company.  Lilly is a leader in diabetes	- Headquarters in Shanghai. www.lilly.com
LII-LIII <b>y</b>	research, dating back to our role	www.lillychina.com

Bayer	in developing the world's first commercially available insulin product, lletin®, in 1923. They pursue a number of diabetes-related targets. We're also working to develop a therapy to treat some of the complications of diabetes.  1990 Glucobay (china's best selling medication) 1997 Glucometer 2003 Ascensia monitoring Shanghai Polymer Research Development CentreChina. Produces blood glucose monitoring include ketone testing	Sidney Taruel CE Alan Breier Medical Director Bryce Carmine Global Brand Development Team Steven Paul Senior Vice President for Science and Technology Steven R Plump Global Market Thomas Verhoeven Product Research and Development  www.bayer.com info@china@bayer-ag.de  Novartis Institutes for Biomedical research Cambridge MA Novartis institute for medical
		science London www.novartis.com Board: Dr HC Daniel Vasella Chair and CE Prof Helmut Sihler Vice Chair and Lead Director Bruno Heynen Corporate Secretary
Takeda	- Existing products – ACTOS insulin sensitiser type 2 BASEN – decrease postprandial hyperglycaemia in diabetes. Compound promotes energy consumption. In phase 1 clinical trial in US world marketing rights excluding China blopress TCV-116 Diabetic Nephropathy Japan Phase 11 Ao-128 Voglibase impaired glucose intolerance Japan Phase 111 Tsakuba research centre Osaka research centre Global Research and Development Centre US Europe Research and Development Centre Research at home with Keio University in genome relating to hypertension and diabetic organopathy joint research on human genome with celera partnership with oxford diabetic centre drug related research on diabetes and obesity Harvard Medical School developed new anti diabetic agent AJ-9677 in partnership with Dainippon.	Www.takeda.co.jp Kiyoshi Kitazawa General Manager Pharmaceutical Development Makoto Yamaoka General Manager Marketing Division Yasuhiko Yamanaka Corporate Strategy and Planning Kazuaki Ikeya Strategic Product Planning Naohisa Takeda Department of Europe and Asia
Wyeth	no products relating to diabetes but involved in genetic research.	Located in UK and China www.wyeth.com cambridge-material@wyeth.com
Glaxosmithkline	anti-diabetic One of worlds largest research programmes Has genomic and new drug discovery technologies First company to fund pharmaceutical R&D in China 1999 launch Heptodin in china world first treatment hepatitis B Avandia type 2 diabetes first class 1 drug in China for diabetes DREAM trial 2000 to use avandai and or ramipril to prevent type 2 diabetes Canada SB 418790 beta3 adrenergic receptor type 2 diabetes Phase 1 (Seretide/Advair) GW427353 beta3 adrebergic receptor type 2 Phase 1 (Ventolin) G1262570 PPAR gamma agonist type 2 Phase 3 (Seroxat/Paxit) Involved in pharmacogenetics Metabolic Research Triangle Park	USA www.gsk.com Dr Jean-Pierre Garnier CE Dr Tadataka Yamada Research and Development Glaxosmithkline (Tianjin) Company Limited – aiming to enter the Chinese market  Has Chinese base in Tianjin
	products 1955 for	(Manufacturing) <u>www.servier.com</u>

	hypertension and diabetes. Servier Laboratories Limited British subsidiary Buckinghamshire. 16% of Its product market is diabetes, cardiovascular 72%.	Servier (Tianjin) Pharmaceutical Company Limited producing Diamicron – for metabolic and vascular conditions in type 2
Novo Nordisk French Company	clinical trial in number of areas of diabetes. Current provider of NovaMix 30, Nova Rapid, Levemir, Actapid, Insulatard, Mixtard, GlucaGen HypoKit, Flex Pens, Nova Pen, Nova Pen Siver, Innolet, Novalet, innova Induce Needles, novafine novafine auto (Type 2) NovaNorm, Nova Let, also 80 year history of pioneering diabetic research and drug development. Industries broadest range of diabetic products. Research pipeline: insulin analogues, several anti-diabetic drugs, pathophysiology and new delivery systems for injection or inhalation. Also stem cell biology, diabetic immunity and many aspects of type 2 including beta cell stress, insulin secretion, glucose production by the liver insulin resistance.	Also based in China www.novonordisk.co.uk www.novonordisk.com.cn Lars Rebien Sorensen CE and President Mads Krogsgaard Thomsen Chief Science Office Nova Nordisk – first biotech company to manufacture insulin in china www.novanordisk.con.cn
Pfizer - Largest Pharmaceutical Company in the UK.	Produce Glucotrol XL type 2 diabetes.	Operates in China <u>www.pfizer.com</u> Corporate HQ New York, Research and Development UK Sandwich Michael S Brown – Chair in biomedical science William H Gray – public policy
Merck	vast research pipeline in diabetes. Has diabetic research in pre-trial and phase 1 trials and phase 111. Looking at lipid disorders in diabetics. In china (AIDS).	- enquiries@merckpharma.co.uk Richard T Clark CE William N Kelley Pro Medicine Biochemistry and Biophysics Rochella B Lazarus World Marketing and Communications Samuel O Prof Medicine and Health care Policy
Roche located Zhangjiang Hi Tech Park Pudong New District Shanghai	world's largest manufacturer of cancer drugs and diagnostic tests. Blood monitoring systems for diabetes. Opened global R and D centre in Shanghai Nov 2004	General Manager or Roche China Andrew Tschirky,  www.roche.com Giagnostics.com Pudong, Shanghai – although key bands such as saridon, rocephin and referon are all late comers into the market compared with competitors shanghai Roche has gained a considerable market share year after year
Tianjin Newscan Coast Bio- Pharmaceutical Company Itd Tianjin Teda Biomedical	produced diabetic Hba1ctests	food products for diabetics
Engineering Company Limited		

#### Appendix K

**Questions Asked:** 

Your views on the advantages and disadvantages of your research environment

Do you consider the current patent system to be adequate for stem cell research?

Do you think the ethical stance of China will make it likely that they achieve success first in translating stem cell technologies into clinical therapies?

If such therapies were to become available in China before the US or UK, do you consider there would be any risks associated with this?

#### **Interview List**

Dr David Bennett - Task Group on Public Perspective on Biotechnology

Azim Surani - Cambridge and Wellcome Institute of Cancer and Developmental Biology

Ian Young – Business Relations Manager Department of Trade and Industry

Glyn Stacey Chief Executive Bio Bank UK

Prof X.N.Wang Newcastle Life Sciences

Prof Alison Murdoch Newcastle Life Sciences

Prof Anne Clarke Oxford Centre for Diabetes Endocrinology and Metabolism

Prof Stephen Minger Kings College London

Prof Ornell Rimoldi Imperial College London

Peter Holland Chief Executive Cord Blood London

Prof A Zhang Xuan Wu Hospital Cell Therapy Centre

**Prof Cathy Prescott Avlar Bio Ventures Limited** 

Peter Mountford Chief Executive Stem Cell Sciences

Jeanette Walker Business Development Director ERBI St John's Innovation Centre

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Dr Mary Archer - Chairman East of England Stem Cell Network

Prof Martin Bobrow - Nuffield Council Bioethics/Head of Medical Genetics Cambridge

University Former Deputy Chair Wellcome Trust

