1. Introduction

1.1. The purpose of this book

The aim of this book is to present a full cost-benefit analysis of In-Vitro-Fertilisation (herein referred to as IVF). The research undertaken that led to this book, was designed and implemented to offer guidance on policy making for public funding of this form of intervention. In essence the research sought to shed some light on the economic rationality to use government resources to provide IVF, a relatively sophisticated and expensive procedure that increases the chances of infertile couples of having a baby. This book is about the allocation of resources in public health care systems and aims to illustrate how cost-benefit analysis could assist in making decisions about rationing.

The concepts of rationing and priority setting applied to healthcare are now receiving greater attention in many industrialised countries. In Italy, the Netherlands, New Zealand, Norway, Sweden, United Kingdom and the United States of America various initiatives have openly recognised that diverse forms of rationing take place in healthcare systems and that potentially, there are merits in taking some steps towards more explicit, systematic and democratic rationing.

Although it is increasingly recognised that implicit rationing is becoming less sustainable, so far only a few concrete initiatives have made rationing more explicit. Very often the policy debate tends to remain on the ground of principles and general criteria. However, economic evidence is required for reimbursement or coverage of pharmaceuticals in many countries (Taylor et al., 2004). The National Institute of Health and Clinical Excellence (NICE) in England and Wales and the Scottish Medicines Consortium (SMC) in Scotland regularly produce guidance based on economic evidence (Cairns, 2006). In Australia, Canada, Italy, the Netherlands and Sweden, economic evidence is often required by regulatory bodies, but the process according to which economic data is

analysed and assessed, appears to be less established than in the United Kingdom. Over the last ten years there have been significant moves towards making government decisions about funding medicines and, to a lesser extent, other technologies and interventions based on evidence of effectiveness and cost-effectiveness.

Despite the advances in explicit and systematic approaches to rationing and a wider use of economic evaluation studies to guide policy making, there are only a few explicit exclusions from public coverage in Europe. Despite clear evidence that resources made available by governments are not sufficient to meet demand, rationing decisions are often left at organisational level and at the point of service delivery (Klein et al., 1996).

Nevertheless, there are some services that represent exceptions, as they tend to be a preferred target for explicit exclusion from public coverage - IVF is one of these exceptions. In 1994, almost a quarter of the Health Authorities in Britain refused to purchase IVF services (Evans, 1995). President Clinton's ill-fated Health Security Act, in the USA, specifically excluded IVF services from the minimum package of services to be covered by insurance plans. In the Netherlands, the Dunning Committee (a committee set up to define the legal responsibilities of insurance schemes), argued that IVF should not be considered necessary, since childlessness does not interfere with the normal functioning of Dutch society.

Despite IVF having been targeted by explicit rationing in several situations, little is known about what IVF is worth to patients and to society. In particular, very few studies have been carried out to measure the value generated by the money spent on IVF treatment. This book reports on research that aimed to investigate the value generated by resources used on this intervention, which increases the probability of couples with fertility problems to have a child.

1.2. Why Cost-benefit Analysis?

As argued by New and Le Grand (1996) moving towards more explicit, systematic and democratic forms of rationing is fraught with danger. In the areas where there is explicit rationing, decisions are to be made on the basis of facts rather than hypotheses. There is a clear need to identify rational approaches. One way to offer guidance to decision makers on a specific rationing decision is to perform an economic evaluation. In this type of evaluation, healthcare decisions are assessed by comparing costs of alternatives with their consequences or outcomes (Drummond et al., 1997). Traditionally, economic evaluations in the healthcare field have been carried out as either cost-effectiveness analysis or cost-utility analysis (ACU). In cost-effectiveness analysis (ACE) the cost per unit of health effects (i.e. life-years) gained by the adoption of the programme is

estimated. In cost-utility analysis health effects are measured in terms of utility, in order to capture and combine in a single measure the different health benefits according to individuals' judgement. Both cost-effectiveness and cost-utility analysis are inappropriate in the context of IVF. While it is theoretically possible to estimate the cost per new life or even the cost per Quality Adjusted Life Year (QALY) attributable to this intervention, it is likely that these approaches will miss the real benefit of IVF: the increase in welfare of giving an infertile couple a chance to have a baby.

Cost-effectiveness analysis may provide important economic insights about IVF and other Assisted Reproduction Technologies (ARTs). The incremental cost-effectiveness ratios, where effectiveness is measured in terms of live births or pregnancies, may be used to make a preliminary assessment about the "value" of the intervention and can be used to compare different ARTs or different categories of patients undergoing ARTs. Indeed, later in this book a cost-effectiveness analysis of IVF is presented and used to make sense of the data obtained in the contingent valuation (CV) survey. However, the cost per live birth of using IVF or other ARTs cannot be compared to the cost per life saved or per year of life gained. Simply, new babies and saved lives are not commensurable as they refer to two completely different categories of benefits. Inspite of the fact that both categories are related to life, there is no reason to assume that the contribution to the wellbeing of a new life is similar to that of a saved life. Therefore, cost-effectiveness data provides weak evidence, if any, to make decision about public coverage of IVF in general.

Cost-utility of healthcare intervention is becoming increasingly popular. In this type of study, health consequences of interventions are evaluated according to indexes (Quality Adjusted Life Years to mention the most widespread) that should represent a summary of patients' preferences for different health states. In theory, the QALY construct could be used to measure the intensity of preference of a person (or a couple) for having a child in the case of infertility. For example, standard gamble exercises could be designed to ask respondents to trade between their years of life and the probability of having a child using IVF treatment. However, asking a person to trade their personal years of life with the probability of a newborn from IVF is logically distant from the QALY concept and the way it can be elicited.

An alternative approach to assess IVF from an economic perspective is to carry out a cost-benefit analysis (CBA). The main difference between CBA and the other techniques mentioned above is that the former seeks to place monetary values on both the inputs (costs) and outcomes (benefits) of the programme being evaluated, while the latter provides monetary measures of only the costs.

CBA is more appropriate than ACE and ACU because it allows for the capture of the full value that IVF treatment holds for people. In the other two techniques, the value of programmes is strictly related to the contribution to the health improvements that the beneficiaries enjoy. Even in ACU, which makes use of the utility concept, the basic idea is to measure health-related quality of life rather than quality of life in general. Infertility is a medical condition; IVF is a medical intervention, being childless can be a very distressful condition - childlessness can sometimes lead to psychological disorders. Nevertheless, the gain that people derive from IVF is not mainly related to the health of the parents. It derives from fulfilling the desire to become a parent and its impact is on the overall wellbeing of the person/couple.

Cost-benefit analysis is more appropriate that ACE and ACU because it is more flexible and can thus go beyond the narrow health implications of procreating babies through IVF. It can measure the value of obtaining a child when one is infertile as well as also capture the benefits of undergoing the entire process, which can be associated with avoiding regret feelings (Ryan, 1999). In addition, CBA appears better grounded in welfare economics theory and provides clearer decision rules than ACE and ACU.

There are three steps in conducting a CBA for this specific medical intervention:

a) to perform a cost-analysis to estimate the cost per cycle of treatment;
b) to review effectiveness evidence to calculate the cost per unit of success, that is the cost per delivered baby; and
c) to compare the cost per delivered baby with the monetary value placed by society to have a baby from IVF.

The research that led to this book covered all three of these steps and attempted to provide innovative advancement in terms of methodology on both costing and benefit measuring systems.

In order to measure the benefits of the treatment, one option is to refer to the human capital concept. According to this concept, the benefits of a health care intervention can be measured in terms of the future flow of income that is freed by the intervention (Robinson, 1993). The human capital approach has several limitations (Robinson, 1993; Johannesson 1996a). From a pragmatic point of view it has the disturbing consequence of assigning very small values to poor people and to individuals who are not in the labour force. From a theoretical point of view, the approach is not consistent with welfare economics because it is not rooted in the proper concept of willingness to pay (WTP), as measured by Kaldor and Hicks. Finally, at an intuitive level, the fallacy of the human capital approach derives from the fact that better health is measured in terms of enhanced productivity only, thus neglecting that individuals value good health

per se. As a consequence, the human capital approach is no longer popular among economists and standard cost-benefit analysis is now generally carried out using the WTP approach. In this approach, monetary values are placed by observing or eliciting how much money individuals are prepared to pay for a particular good.

WTP can be measured using two main approaches: revealed preferences or expressed preferences. The revealed preference approach is based on the observation of actual behaviour, while the expressed preference approach is based on the direct elicitation of WTP from individuals through the use of carefully designed and administered sample surveys. This approach is usually named the contingent valuation (CV) method.

In the research that led to this book the CV method was used to perform a full cost-benefit analysis of a government programme providing IVF to infertile couples. The CBA aims to provide solid evidence to policy makers. In particular, it aims to use economic analysis to inform decisions relating to government coverage of a major medical intervention that has been specifically targeted by explicit rationing decisions. More specifically, two main research questions were addressed by the empirical study that led to this book:

1. Can a contingent valuation survey conducted via the internet be a feasible method to measure benefits of a health care programme in general, and of a programme providing IVF in particular?

2. Given the experimental nature of the methodology, is the expressed WTP of Italians for a public programme providing IVF to infertile couples greater than the costs of implementing the programme? In other words, would the benefits of such programme exceed its costs?

These research questions were strongly connected to four broader issues that are discussed in the subsequent chapters in this book. The first issue dealt with is IVF. Through the survey undertaken during the reaserch, evidence was gathered to broaden knowledge about attitudes towards this particular service. IVF, despite absorbing relatively small amounts of resources, well represents the new medical technologies that raise exceptional ethical problems and in which treatments aim at improving human functioning and general wellbeing rather than curing diseases.

The second issue is the relationship between economics and health policy. By investigating the feasibility of a specific economic tool thte expectation was to better understand how economic “rationality” can establish a fruitful dialogue with the multitude of perspectives that influence decision making processes within the health care sector. The IVF case was analysed in the broader context

of the problem of the scarcity of resources in the healthcare system. The specific focus of the empirical part of the study that led to this book is on the feasibility of using economic analysis to offer guidance to rationing decisions.

Previous contingent valuation studies have mainly investigated the perspective of IVF users. Given that the research refered to in this book measured the willingness-to-pay (WTP) of a sample of the general population it enabled an investigation into the role of caring externalities. Therefore, the third aspect discussed in this book concerns the distinction between egoism and altruism in the context of reproductive medicine.

Finally, this book investigates a thorny issue in contingent valuation studies: the format to elicit WTP. Since our sample was asked three WTP questions we could compare the "Referendum" to the "Payment Card" formats and investigate how they differ.

1.3. Structure of the book

A full understanding of a cost-benefit analysis of IVF requires some understanding about infertility, its treatment and a variety of issues that makes this medical intervention rather special. Chapter 2 deals with these issues thus presenting the background of the rest of this book. It also mentions some policy issues raised by the use of this intervention and its government funding.

In a full cost-benefit analysis both estimates of costs and benefits are important. Therefore attention has been paid to both of these issues in this book. Chapter 3 provides a review of literature on contingent valuation and specifically focuses on previous contingent valuation studies on ARTs. The review of the vast literature review on CV in healthcare provided important elements to the design of the survey.

To provide a solid background to the costing part of the study a rather different approach was used. Literature on cost accounting was looked at, which is generally considered a sub-discipline of management, from which it was learned how to conduct a cost study for the purpose of a cost-benefit analysis aimed at providing guidance about public coverage of an intervention (Chapter 4). Briefly, the conclusion was reached that cost-benefit analyses should be based on solid cost studies, rather than on the use of tariffs and prices, and that the full costing methodology has must be used.

Chapter 5 presents the methods used in the cost-benefit analysis and details the source of the data. The measurement of benefits is based on a large survey conducted via internet that was specifically designed for the purpose of this research. The survey collected information about the knowledge, attitude and

willingness to pay for IVF of a sample of the Italian population. The sample is not probabilistic but it was built to make a representative picture of adult Italians with respect to age, gender, education and residence. To our knowledge, this is the first attempt to investigate WTP for a medical intervention through a CV survey administered via internet to a large national sample. The last part of Chapter 4 presents the methods used to estimate the cost of IVF. It explains how the calculations for the cost of an IVF cycle according to a full costing procedure were arrived at and how they were used in the context of the CBA. The cost analysis presented in this book is based on data collected in two Assisted Reproduction Centres located in northern Italy, one run by the Italian National Health Service and the other private.

Presentation of results is split into two chapters. Chapter 6 reports the results of the survey to provide a picture of the information about infertility and IVF, attitude towards this technology and WTP. The purpose of this chapter is to provide a snapshot of what the people in the sample think about these issues and to assess possible correlations. In this chapter, there is a presentation of results from several regression analyses that try to explain how demographic and socio-economic variables influence knowledge, attitude and willingness to pay for IVF. In addition to improve our understanding of what people think about IVF, this chapter provides some important insights about the validity of the survey and the contingent valuation method.

Chapter 7 focuses on the economic results of the study *strictu sensu*. It presents the estimates of mean WTP for personal use of IVF in case of infertility on the basis of the data of the Payment Card questions. It also presents WTP for a national programme providing IVF to infertile couple with public funding on the basis of the answers to a referendum format question and to a second Payment Card battery of questions. Results are then compared, discussed and used to investigate their validity. The chapter then reports results of the cost analysis and briefly reports results of a cost-effectiveness analysis. Finally, estimates of benefits and costs are assembled to perform the cost-benefit analysis of a programme providing IVF to infertile couples in Italy. On the basis of reasonable assumptions, results show that such a programme would generate net benefit and thus should be endorsed by the government.

This book concludes with a discussion of several methodological issues encountered and raised by the study (chapter 8). Overall, the study is encouraging as it shows that collecting information for cost-benefit analysis in population surveys is feasible and valid. The spectacular advancements of Information and Communication Technologies create more opportunities to use public opinion to make collective choices, including public opinion data that can be used in the framework of rigorous economic analysis.

Overall, this book reports on research that provides evidence in favour of the public funding of IVF. This funding is consistent with recent trends in many affluent countries where IVF to infertile couples has become part of the benefits of statutory coverage. Nevertheless, it is important to underline that the results of this study are mainly driven by a minority of respondents that have high willingness-to-pay for the programme. This study confirms that measurement of benefits in cost-benefit analysis may favour the point of view of those who are more affluent and thus have higher willingness to pay.