Chapter 2: Methodology

This chapter examines the established methodological traditions of research in the two fields of health technology assessment and information design. It also suggests how research can be performed in an area that might be expected to draw on both of these traditions. The aim is to show how the research studies detailed in this thesis fit within a broader context of research and methodological discussion.
2.1 Methodological discussion

2.1.1 Health technology assessment

Returning to the history of HTA provided in Chapter 1.2, we can see that its origins can be traced back to the ideas that form the basis of evidence-based medicine (Banta 2003). While EBM uses scientific evidence to inform medical practice, HTA provides empirical evidence to inform policy decisions about the adoption of new health technologies by health systems (Szczepura & Kankaanpää 1996) (see Figure 2.1 – 1). This empirical evidence comes in many forms, mainly quantitative but also qualitative. Most HTA that informs decision-making is secondary research, in that it brings together the results of different primary research studies, to provide a more manageable account of the effectiveness, costs, and cost-effectiveness of a health intervention (Eddy 2009). However, a discussion of HTA methodologies should perhaps include the methods used in both the secondary research of HTA and those used in the primary research on which it draws.

As discussed in Chapter 1.2, the primary research used as the basis for HTA work can include formally conducted trials (giving efficacy in ideal situations), effectiveness studies, data from patient registers, expert opinion, cost data from manufacturers, and other sources. The ‘gold standard’ for gauging the efficacy of an intervention is the randomised controlled trial (RCT) (Banta 2003). However, in some cases, studies of this type are not available (or possible). For example, where a large and immediate benefit becomes obvious in a randomised trial, it would be considered unethical to continue to withhold the more efficacious treatment from one group. Thus, the primary research on which HTA draws employs many different study designs, as different methods are appropriate for analysing the effects of different interventions.

Trials that measure the efficacy of an intervention generally report numerical data on one or more ‘outcome measures’, using standard scales. These measures are usually previously developed to be able to measure participants’ functional abilities, pain levels, quality of life, etc. Advanced statistical
techniques are commonly used to show the relative efficacy of different treatments, often in comparison to a placebo in the case of drug trials.

However, by the time that an HTA is performed to inform a policy decision, new health technologies are likely to have been the subject of more than one trial already. Therefore, most health technology assessment work is secondary research, using the published reports of a number of trials to show an overview of the efficacy and/or effectiveness of an intervention (Egger, Smith, & Altman 2001).

The principal method used for summarising and synthesising a number of studies is the ‘systematic review’. In this method, papers reporting on trials are obtained from database searching. Particular data is then extracted from each of these, often by more than one reviewer to prevent biases. The review team then use standard methods for quality assessment of the included trials, often favouring rigorously conducted, large, double-blinded randomised controlled trials (where these are available). Statistical methods are sometimes used for meta-analysis of these extracted numerical results, showing a pooled estimate of the efficacy of an intervention (Egger, Smith, & Phillips 1997).

Even in the (rare) situations where a large pool of good quality evidence on efficacy is available, the effects of adopting a health intervention in a particular health system often take place over a longer time than even the longest of the trials available. For this reason, mathematical modelling is often used to extend the results of these trials, and look at the medium and long-term impacts of interventions. These techniques simulate what might happen to a group of patients over a long period of time. While there is always a degree of uncertainty in such simulations, the mathematical models can help to show how certain or uncertain the currently available evidence is.

The efficacy of an intervention in trials does not always equate to its effectiveness in the less controlled environment of clinical practice in a specific health system. For this reason, comparing the results of meta-analysis with patient data from registers or eliciting clinical experience and beliefs is often necessary. These data can also be incorporated into simulation models to suggest how interventions might be expected to perform in the long term.

As well the effectiveness of interventions, the costs of adopting it are frequently of interest to policy-makers. Some more developed health technology assessments relate the effectiveness of a treatment to its costs (which can be both financial and social costs) (Eddy 2009). This means that health resources
can be channelled to the interventions that have the highest cost-effectiveness. In the HTA performed to inform the NICE appraisal process in the UK, this is generally presented in terms of the effectiveness gains of an intervention, versus its additional financial costs.

In health care, the metric commonly used to represent effectiveness indicates how much longer a person will live, at a given quality of life. Quality of life is represented by a ‘utility’ value, generally between 1 (a practically unattainable state of perfect health) and 0 (dead). The effectiveness of a treatment is presented with a metric called the ‘quality-adjusted life year’ (QALY). This is nominally the amount of time that a treatment extends a person’s life at perfect health. For example if a health intervention was expected to give a gain of one QALY, this could be extending someone’s life for two years at a utility of 0.5, or for ten years at a lower utility of 0.1. In the UK, NICE is generally thought to support health service expenditure of between £20,000 and £30,000 for one QALY (Devlin & Parkin, 2004).

The methods used in HTA to show the costs, effectiveness and cost-effectiveness of interventions are based on specialist statistical, mathematical and economic techniques. These can produce significant quantities of numerical data, which can be difficult to interpret and apply to practical decision-making tasks.

### 2.1.2 Information design

Similarly, information design is a collaborative and multidisciplinary field (Easterby and Zwaga 1984). It draws on principles of graphic design, statistical analysis, typography, computer software design and applied psychology, amongst others.

In many other design disciplines, such as graphic design, practitioners work within a consumerist model of success and failure. The success of the product, advertisement or corporate identity is ultimately judged on its effect on the financial success or failure of the associated product or brand. The financial results, in a sense, justify the design. There is often a degree of risk in this model, which can be accepted in a way in which it wouldn’t be in health technology assessment, where people’s health is at stake.

Books produced by graphic designers such as Alan Fletcher (Fletcher 2002) make extensive use of anecdotal evidence. This can be a powerful and engaging
tool when speaking to a designer. If the designer has noticed something about the world, and this strikes a chord with the reader also, it is quite likely that it affects others as well. A common way of approaching design is to make such an observation, and then test it by designing. This is known as practice-based research (Gray & Malins 2004).

While not solely interested in information design, the Design Council gives an overview of design process, gained from interviewing designers from eleven design companies (Design Council 2007). They found that designers often start by considering the scope of the problem that they seek to address. This enables a design specification document to be produced, forming an agreement between designer and client. Testing is an essential part of this design process, in which a designer produces series of prototypes to be tested, refined, and tested again (iterative design). This generic design process model is shown in Figure 2.1 – 2.

The Design Council's designer/client model may not be applicable in HTA, where the designer of information graphics requires a specialist knowledge of health research. However, it does suggest a general model that may be adapted to use in HTA.

Information design, however, has a rather different function than an advertisement or corporate identity – design products that fall within the model used by the Design Council. While there may be an element of attracting attention in an information graphic, its primary function is to explain data or information. There may be different attitudes to the value of aesthetics, possibly dependent on the context of use. Research in information design
tends to focus more on the communication and explanation of data (providing information) (Sless 2008) than on the design's reception and marketability.

Research in information design tends to be with small samples of users, and a focus on qualitative data on how people gain understanding from an information presentation. This can provide feedback to a designer on how to refine their designs, but doesn't necessarily show how effective the design is in relation to alternative presentations. Much information design research takes the form of observational studies, using one-on-one interviews with potential users. These are often referred to as ‘usability studies’ (Dumas & Redish 1999), particularly by researchers with a computing background.

Using the terminology of education theory, ‘formative evaluation’ (Biggs & Tang 2007), in which research is performed to refine and adapt designs, tends to dominate in information design. In health technology assessment, ‘summative evaluation’ is perhaps more common, in which research demonstrates effectiveness or ineffectiveness of an existing product.

Some studies of information displays tend to make sweeping generalisations based on their findings. For example, So & Smith, working in studies of decision-making in finance, suggest that “graphics are useful when complexity is low” and that “females prefer colour” (So & Smith 2002). However, such findings do not apply to different graphical presentations used in different situations. For example, Remus (working in a management context) tells us that “tabular aids outperform the graphical aids in environments with low complexity” and “In intermediate complexity environments, the graphical aids outperform the tabular aids” (Remus 1987). It has been suggested that it is challenging to link the practical outputs of information design with any kind of theoretical basis, even in applied psychology (Waller 1979). This has meant that studies of information displays have lacked a theoretical basis for findings, inhibiting generalisation (Wright, 1978). It is therefore likely that individual information graphics will be shown to be more or less applicable in different situations, having advantages as well as disadvantages in comparison to numerical and textual presentation.

One study of different algorithms for creating ‘tag clouds’,* (Seifert et al. 2008) concluded that different information presentations are likely to be suitable for use in different situations – specifically where aesthetic considerations were likely to be more or less important. Research must be performed within the context of HTA to assess what is appropriate, given the requirements this unique area of applied policy research.
Using an example of government information leaflets, David Sless describes three stages of information design at which research can (and should) take place (Sless 2008). Firstly, he recommends a process of ‘benchmarking’ to find the performance of the currently used information presentation method. Secondly, he suggests (in agreement with the Design Council model) that iterative testing should take place during the design process, with prototype designs. Thirdly, he suggests that designs should be evaluated at regular intervals once they have been deployed (Stages 2, 5 and 7 in Figure 2.1 – 3). This suggestion is in response to an observation that research in information design is often conducted without measuring the effectiveness of the original information presentation which is to be replaced. In health technology assessment, this might be seen as akin to performing research with no comparator.

![Figure 2.1 – 2](image)

David Sless - design process model for information design.

In fact, there seem to be at least some in the information design community that are averse to research that compares two designs, sometimes referred to as ‘a/b testing’. In a recent discussion thread on the ‘Info-design café’ email list (InfoDesign Cafe 2010), participants stated that:

“All personally, as a designer, I have never ever seen ANY empirical research results that didn’t either:

1. Merely state the obvious.

2. Indicate preference for a design direction that any half decent designer could have directed you to in five minutes.

3. Create results that are essentially useless or at worst completely misleading.”

—Participant known only as ‘Randall’

And also that:
“The results [of A/B testing] tend to be pieces that are remarkably ugly but effective.”

—Caroline Jarrett

This is not a universally accepted view, as there were also comments in favour of this kind of empirical research in this discussion. Similar debates are common at conferences with an information design theme. There does seem to be a fear in at least parts of this community of the research methods being used as a substitute for creative designs, which may stem from the fairly obvious fact that designers themselves are not often also trained researchers.

The empirical research that is conducted on information design outputs tends to be spread out through many subject-specific journals, depending on the nature of the information being presented. Some research with general methodological interest to information design is published in the Information Design Journal (Information Design Journal 2010). However, unlike HTA, empirical research in information design has much less of a standard form of reporting. There are no standard ‘outcome measures’ which can give a numerical scale of the effectiveness of an information graphic, like those that are commonly used to measure the effectiveness of health interventions. Thus it is difficult to find an objective measure with which to compare different graphical techniques. This may perhaps be due to the fact that individual designs can vary so much in terms of style, purpose and information presented.

Research in information design remains focussed on improving individual designs, rather than showing their benefits in relation to other techniques. This kind of empirical evaluation of the functions and abilities is needed for them to be accepted in scientific fields such as HTA.

2.1.3 Existing studies of information displays in health research

Empirical, controlled studies of the effectiveness of information graphics are widely distributed through the research literature, and spread across many fields of application (such as health, management, business, finance, design, and engineering, amongst others.) A systematic literature review in this area is therefore challenging. Table 2.1 – 1 shows details of some empirical studies of information graphics. These have been sourced from bibliographic searches as well as a request for information made through the PHD-DESIGN email list on
JISCmail (PHD-DESIGN on JISCmail, 2009). They address visual information presentations in management (3 papers), health (2 papers) and finance (1 paper). These papers cover quite a wide period of time, which potentially causes difficulties with outdated technologies being used to create and distribute information graphics. However, since many static, black and white, printed graphics are currently used in printed health technology assessment reports, the research methods used to test them are still likely to be relevant.

The two studies based in a health context (Elting, 1999; Feldman-Stewart, Brundage & Zotov, 2007) focus on clinician and patient decisions respectively, rather than a health policy-making audience, although the methods used could be applied to decision-makers in HTA. However, the displays tested in all of these studies would seem primitive to an information designer. For example, in the Feldman-Stewart et al. Graphics (shown in Figure 2.1 – 4) the horizontal
positioning of the numbers on the scale for the ‘horizontal bars’ display are potentially confusing (it is difficult to quickly see which mark corresponds to 60). In the ‘random ovals’ display, the scales are essentially meaningless and almost certainly confusing.

For the Elting et al. display (see Figure 2.1 – 5), the green and red colour scheme tested would be impossible to use for around 5% of the male population with red/green colour blindness. Also, the pie chart seems to be mislabeled, as the ‘investigational treatment’ is shown as having higher response rates in all other displays. The labelling for good and poor prognosis in the pie chart is also rather ambiguous, and could apply to a single segment of the display, although it is intended to encompass two segments.

While the displays themselves are unsophisticated, the research methods used in these papers may be adapted to evaluate information design outcomes. As shown in Table 2.1 – 1, there are three commonly used measurements in these empirical studies:

Response time: how long it takes for a participant to make a decision, or take some other action, based on information presented in different formats.

Accuracy: how close a participant’s response is to an already established ‘best answer’ (or correct answer).
Preference: each participant chooses between multiple information presentations (such as numerical vs. graphical format, or between different graphical presentations).

These variables can then be analysed with a range of different statistical techniques, including ANOVA (analysis of variance), t-tests, and regression analysis, among others.

One study (Benbasat & Dexter, 1985) also recorded qualitative data, in the form of participants’ comments, about the different information presentations given. Although these comments were referred to in the discussion section, no formal qualitative analysis was included in the paper.

2.1.4 Researching information graphics in HTA

The foundations of HTA lie partly in the development of evidence-based medicine (Banta 2003), using scientific evidence to inform policy decisions. Given the degree of highly technical and specialist knowledge required to perform HTA research, it is likely that there are few people with specialist training in visual communication working in the field. Due to the evidence-based roots of HTA, the use of empirical testing might effectively be used to
show which new graphical techniques might have benefits in the field. This would provide a way of showing where it is and is not appropriate to use information graphics. This would provide a way of showing the advantages and disadvantages of visual information presentation through the language of empirical research, which should be widely understood in HTA.

However, as described in the previous section, what testing there is in the field of information design tends to be with small samples, and qualitative in nature. This kind of research is less familiar in HTA, in which the standard evidence base is large, quantitative trials. Qualitative data is rarely incorporated in HTA work, as it is difficult to synthesise (Leys 2003). Methods for scientific evaluation of information graphics are underdeveloped, and not widely perceived as necessary (Daru 1989).

There are fundamental differences between research in information design and HTA. Compromises must be reached in order to address these through the methods adopted by the research in this thesis. The research clearly needs to be regarded as methodologically acceptable in HTA for the graphics to be used at all. Results must be sound, so as to reach defensible, rational conclusions. The research also must stand in the field of information design so that the designs can be discussed, and improved by those with a background in visual communication. This is the only way of ensuring continuing innovation in the graphical presentation of HTA data.

The distrust of quantitative data in much information design outside web design must be allayed by including at least some qualitative research in all studies. This should address the need of the information design community to understand the audience and context for a display. Conversely, it would be sensible to include at least some quantitative measures in all studies to provide a solid foundation that those working in HTA, and therefore used to seeing numerical measures, can quickly and easily interpret. This naturally points toward the use of a triangulation strategy (Gray & Malins 2004), where quantitative and qualitative results are used together to explore the use of information graphics in HTA. For example, measuring task completion time can show where a presentation method reduces search time, and what the people performing the task are saying and doing can suggest why this is, and how to change the design in response.

Information design is often a creative and individual process. It allows particular quantities and kinds of data to be presented, taking into account the use to which the design will be put. A designer might argue that an entirely
different presentation technique would be more appropriate for the same data if the hierarchy of importance of different dimensions within that data was changed (say, for a different audience or purpose). A different design might be more effective for presenting a set of variables when a large number of samples is collected than with a small number (Thomas & Cook 2005). A different design might even fit better within one person's cognitive model of the world than another's, meaning that one person would make better use of it than another.

HTA work, likewise, tends to be very specific. Different health conditions require very different health interventions. The quality and quantity of evidence varies greatly. The process of collecting and assimilating all the necessary information requires a good deal of intellect and diverse knowledge and skills. However, it has to be a systematic process to reduce bias (Egger, Smith, & Altman 2001). Methods must be explicitly stated, and searches performed according to specified rules.

This produces a potential conflict in that, if data is collected in a systematic manner, and information design is creative and individual, could the presentation process itself introduce bias? Tufte tells us that visual presentation can be used to deceive, but only as much as verbal, or numerical presentation of information if that is the intention of the author (Tufte 2001). However, empirical evidence of the effects of graphical presentation may serve to address this possible conflict.

The process of randomising participants is something that is often regarded as a ‘gold standard’ in HTA (dependent on the question being asked). However, it is rarely seen outside web design in the field of information design. A rigorous scientific experimental design like this could easily be imported into information design studies. However, unlike a health intervention, which might take months or years to show a result, the ‘delivery’ of an information graphic takes seconds or minutes. This means that a participant in an information graphic evaluation can be shown multiple information presentations and given the opportunity to discuss their preferences and the relative strengths and weaknesses of the two. For this reason, the studies in this thesis use a randomised, crossover design where possible, so that each participant receives both presentations, but in a random order.

There are some complementary aspects of HTA and information design, however. It is possible to think of both information graphics and HTA reports as the presentation and documentation of data. Both fields are familiar with
research on the documentation (outputs) of the work in the field.

Also, the disciplines’ common goals of providing clear information to those that need it align well. Therefore, a focus on the needs of users will be a starting point for the research in the thesis. The information graphics produced should address the information needs of the expert users of HTA through the provision of information in a graphical form. The research will focus on the successful communication of HTA research data.
This thesis adopts a design process similar to that defined by the design council (Design Council 2007), in terms of identifying user needs, surveying the currently used materials, agreeing specifications, developing information graphics, and then testing these. However, it also attempts to incorporate testing at multiple stages, as suggested by David Sless (Sless, 2008). Also, the process of development and use of information graphics in the scientific field of HTA requires many parts of these processes to be adapted and formalised. In this new HTA information graphics design process model, scientific methods are used for needs evaluation and surveying currently used techniques. Prototype techniques are subjected to rigorous task-based evaluation. However, it is hoped that a creative and experimental approach to design practice is retained. The thesis demonstrates something that is, in essence, a design process model, but one that is supported and augmented by some scientific research methods, as appropriate to the area of application in health technology assessment (see Figure 2.2 – 1).
Figure 2.2 – 1
Design process for information graphics in HTA
This process model begins with establishing potential information needs. This phase involves careful study of existing information presentation methods, observation of working patterns and information flow, and consultation with key stakeholders. It shares much with the Design Council’s initial ‘discover’ phase. It requires creative thought, and a consideration of a broad number of sources – so much so that it is somewhat hard to define the boundaries of the activity. An idea for improving information presentation may come from a formally-conducted needs research study, based on documentation or interviewing stakeholders, but it may equally come from a remark from a colleague or a conference delegate, perhaps noting that they find difficulty in presenting or interpreting a particular kind of data. It is likely that a realisation that an information presentation need exists may emerge from a consideration of multiple of these sources. This information needs assessment also corresponds somewhat with David Sless’ information design process model, which begins with a phase which he calls ‘scoping’. However, the new HTA model at this stage includes scientific study, while it also acknowledges the part that can be played by less formal discussions. Two examples of formal research studies that could be conducted at this stage are provided in Chapter 3.

After this point, the HTA information design process model diverges from Sless’. He moves next to ‘benchmarking’, or evaluating the performance of an existing display that is to be improved. However, in research studies for medical interventions, testing in isolation without randomised comparison to a new intervention would not be considered good practice. For this reason, testing of existing presentations is carried out later, when there is a new prototype to be tested in comparison. The HTA model moves instead to a stage more akin to the Design Council’s second ‘define’ phase – when identified information needs are brought together to form a more formal specification of a particular problem area. The goal in this specification phase is to produce documents that detail the scope of the proposed design work and the information need(s) to be addressed. It may be appropriate to show a range of techniques that others have used in the past when attempting to present similar information, or techniques used outside HTA that could be used. Hand-drawn or rough computer-built design sketches and ideas could also be included to give an idea of what would be possible, although these will probably not use real data, beyond perhaps finding the range of values that will probably be displayed. This stage should, where possible, be a collaborative experience, drawing together HTA producers, potential users and information design professionals. Ten examples of this stage are shown in Chapter 4.2.

Once a broad agreement has been reached, the next phase is the production
of a prototype (or multiple prototypes). Again, this is an inherently creative task, and involves using real data to create ‘one-off’ designs. Depending on the volume of data to be presented, this may involve a variable amount of computer processing. In many cases, a single design can be produced by hand, even if this will take many days of data entry into a design and layout program such as Adobe Illustrator. The idea is to produce an accurate, usable display, that could be used at the appropriate part of the HTA process. For this thesis, most of the displays developed during this stage were static, multi-page documents created in Illustrator or InDesign, that could be used in HTA reports. However, if interactive, screen-based presentations are being developed, these need to be fully functional at this stage. The design of these prototypes can be usefully refined during this phase by showing designs at various stages of development to colleagues in an informal way, which will feel natural for many design professionals. It may even be useful to present techniques at meetings and conferences to gather informal suggestions and refinements. This phase is very similar to David Sless’ ‘prototyping’ stage, and the Design Council’s ‘develop’ stage. However, this informal testing that is a key part of prototype development may also incorporate some of what David Sless refers to as the ‘testing’ and ‘refining’ loop. This is included in the Design Council’s ‘develop’ phase as iterative design loops, in which a design is tested and refined many times. Five examples of the ‘prototype development’ phase are shown in Chapter 4.3.

In the new HTA process model, a distinction is made between the informal testing of the prototype phase, which will be quite natural to most information designers, and the next phase of the process model: comparative or individual studies. The idea is to test the new prototype technique in a formal way, with some kind of experimental evaluation. The main aim of this is to extend the prototype testing, in refining the designs. However, it is also an opportunity to give both designer and potential users of the technique some idea of how the display is performing. If the display is replacing an existing technique (such as a numerical table in a report) it may be appropriate to perform a comparative evaluation. This phase incorporates both of David Sless’ ‘benchmarking’ phase and his ‘refining’ phase, in a way which will be methodologically acceptable to the HTA audience: using randomised experiments with potential users. A third potential benefit of such studies, alongside refining the displays, and showing whether improvements are being made in comparison to existing practice, is that such studies can potentially be published. This may lead to increased awareness of the display technique in a scientific field such as HTA, making later stages of deploying and monitoring easier. Some techniques developed for this thesis, however, presented data that was not commonly included in reports,
and as such no comparator was available. In this situation, an evaluation study can still be performed at this stage, but the focus shifts more to showing that the displays are understood as intended by their audience, and to discover how to refine the display. Studies of both kinds have the potential to uncover other information needs or adaptations that are significant enough to be thought of as new prototypes, so the model includes possible feedback loops at this stage. An example of a comparative study is shown in Chapter 5, and an individual study is shown in Chapter 6.

After testing, the model includes a phase called ‘deploy’. This corresponds to Sless’ ‘implementing’ and the Design Council’s ‘deliver’ phases. At this stage, decisions have to be made about how a technique should best be produced in a scale useful to the HTA process. It may be that the technique can reasonably be produced by HTA researchers using standard statistical analysis software. Alternatively, specialist display software may have to be constructed. In some cases, it may only be appropriate for the displays to be produced by professionally trained information design specialists, using graphic design software alongside systems that can automate some of the process, such as the Processing language. This thesis shows one example of a display being deployed in Chapter 7, using the individual design approach. It is hoped that software can be developed in future for producing such displays. However, this would require time and skills not available for this PhD research project, so this is not included here.

The last phase is the ‘monitor’ phase suggested by David Sless. This involves testing the new display in a context of real use. This is important because an experimental test can never replicate the real conditions of use. A report may be read on a busy train rather than a quiet office. Lighting conditions might not be ideal, or the report could be printed on a poor quality printer, or low resolution display such as a notebook or tablet computer. Such factors are challenging to capture in a research study, but this could take the form of testing decision-makers use of information graphics after an appraisal, or interviewing them on usefulness and/or difficulties encountered while using displays. Also, such studies might capture how displays are used after they have become more common, reducing the learning overheads of unfamiliar displays. It is hoped that such studies might shed new light on information needs, prototypes, or existing deployed designs, so feedback loops are included in the model at this point also. However, as such monitoring studies will be most useful after information graphic techniques become widely used, it was not appropriate to include an example in this thesis.