Analysing clinical practice guidelines. A method of documentary analysis

Jane V. Appleton BA(Hons) MSc RGN RHV PGCEA
Senior Lecturer in Nursing, School of Health and Human Sciences, University of Hertfordshire, Hatfield, England

and Sarah Cowley BA PhD PGDE RGN DipN RHV FWT HVT
Senior Lecturer, Department of Nursing Studies, King's College London, London, England

APPLETON J.V. & COWLEY S. (1997) *Journal of Advanced Nursing* **25**, 1008–1017

Analysing clinical practice guidelines. A method of documentary analysis
This paper will describe a method of documentary analysis used in a study examining the validity of clinical guidelines issued to health visitors to assist them in identifying families requiring increased health visitor support. This forms the preliminary work for a wider study examining how health visitors decide to increase support to vulnerable families. Although a number of published research texts discuss the value of records and documents as important data sources for health service researchers, there is relatively little information available about the processes of documentary analysis. This paper offers one method for analysing clinical practice guidelines, it describes the development of a critique and analysis tool and explores the strengths and weaknesses of this particular analysis instrument.

INTRODUCTION

Recent health policy initiatives indicate that there is considerable interest in the development and use of clinical practice guidelines in the United Kingdom. These guidelines are widely in use in the USA, where Tingle (1995) has suggested that there are now over 20 000 clinical practice guidelines/standards currently available. Confusion over terminology sometimes arises in the fact that the terms 'protocol', 'clinical practice guideline' and 'healthcare/nursing standards' are often used interchangeably in nursing and health visiting practice. Protocols and standards differ from clinical guidelines in that they are formal written procedures which address the management of patient/client care in specific situations. Protocols and standards are meant to be adhered to by practitioners in all circumstances.

Clinical guidelines however are 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances' (Field & Lohr 1992 p. ??). Eddy (1990) has provided a useful distinction between standards and guidelines stating that standards describe appropriate health care and should be followed in all circumstances, whereas clinical guidelines while providing guidance to the practitioner, do allow flexibility and acknowledge professional discretion (Grimshaw and Russell 1993). It is important to clarify that the purpose of a clinical practice guideline is to aid decision making processes and it should certainly not be viewed as a replacement for professional judgement (Sullivan & Mann 1994, Carruthers 1995).

Correspondence: J.V. Appleton, School of Health and Human Sciences, University of Hertfordshire, Hillside House, Hatfield Campus, College Lane, Hatfield, Hertfordshire AL10 9AB, UK.

Optimism

In the current British NHS there appears to be an increasing optimism surrounding the use of clinical guidelines in improving standards of patient and client care (University of Leeds 1994, Deighan & Hitch 1995). Among the medical profession the current focus on 'evidence based medicine' is highlighting the need to develop clinical practice guidelines based on evidence from randomised controlled research designs (Sackett & Rosenberg 1995; Russell & Grimshaw 1995). Within nursing and health visiting much emphasis has traditionally been placed on the development of practice standards, yet over the last two years there has been considerable interest surrounding clinical prac-

tice guidelines. Clinical guidelines are being introduced into many areas of practice, for example, pressure sore prevention and management, the management of leg ulcers and post-natal depression risk scoring. The Royal College of Nursing (1995) however has recognised that few research studies have been undertaken to evaluate the effectiveness of clinical practice guidelines in nursing, midwifery and health visiting practice.

The evaluation of clinical practice documents is therefore a pertinent issue, particularly in view of current research and policy initiatives which stress the potential of clinical guidelines for promoting clinical effectiveness and quality of client care. Researchers have also outlined the possibility that clinical practice guidelines could reduce variations in clinical practices, as well as promoting cost-effective care (Carruthers 1995; Klazinga 1995; Russell & Grimshaw 1995). However, erring on the side of caution Carruthers has stated that

> whilst guidelines should promote cost-effective practice, it must nevertheless be recognised that they may actually increase resource use where optimal practice is actually more expensive than current practice.
>
> (Carruthers 1995 p. 112)

Grimshaw & Russell (1993) have highlighted the need for rigour in guideline development, stressing the importance of clinical practice guidelines being valid and supported by sound research based evidence. Anecdotal evidence would suggest that a problem with many clinical guidelines being used in nursing and health visiting practice is the fact that many are formed without sufficient empirical data.

Health visiting

In health visiting practice the use of clinical guidelines has been encouraged by a policy emphasis on specifying needs for which families are to be targeted (Audit Commission, 1994) and the imperative to find suitable criteria to use in service contracts set by purchasers. Many Community Trusts (provider units) are considering the inclusion of clinical guidelines in contract specifications in an attempt to market health visiting services and make health visitors' work practices explicit to purchasers. Two recent NHS Executive documents have recommended that clinical practice guidelines be used to inform contract specifications (NHSME 1993, NHSME 1994). However in a more recent paper focussing on evidence based health care, Hutchinson *et al.* (1995) note that

> Currently there are two key problems with the majority of clinical guidelines. These are
> a) many clinical guidelines do not show an explicit link between the evidence on which they are based and the recommendations contained in the guidelines.
> b) there are relatively few examples… where guidelines have been shown to have a demonstrable and sustained positive effect on health care.
>
> (Hutchinson *et al.* 1995 p. 50)

It seemed highly relevant therefore to complete a study to evaluate the clinical practice guidelines issued to health visitors in England to assist them in identifying families deemed to require increased health visiting support.

THE STUDY

In November 1994 a postal questionnaire was sent to all the chief nurses of NHS Trusts in England employing health visitors. (The term Chief Nurse is used to describe the senior nursing member of the Community Trust, that person is sometimes referred to as the 'Director of Nursing' or 'Trust Nurse'). The sample number involved was initially 195; 16 chief nurses contacted the researcher stating that they did not employ health visitors, thus the total sample was reduced to 179. A covering letter accompanied the questionnaire explaining the nature of the research study and inviting participation in the project. A stamped self-addressed envelope was included to enhance the response rate.

Purpose of questionnaire

The major purpose of the questionnaire was to gain information about and examine clinical guidelines currently in use for identifying and prioritising families requiring extra health visiting support. Copies of guidelines in use locally were also requested from each Chief Nurse and the covering letter encouraged inclusion of these documents/policies. This was an essential step to find out what sort of guidelines, if any were in existence and to establish whether current policy guidelines were valid and helpful. It was intended that this part of the study would provide a national picture of the existence of guidelines in England for the identification of vulnerable children/families requiring increased health visitor support. It was also anticipated that useful information may be obtained which could help inform future policy guidelines and provide indicators of need to Community NHS Trusts and GP fundholding purchasers.

A log of returned questionnaires was maintained throughout this stage of data collection. Follow-up letters were sent to non-respondents and a total response rate of 87% was obtained.

Development of the research tool

As there was no suitable questionnaire schedule available for use, the researchers designed a questionnaire for use in data collection. The questionnaire designed for this part

of the study was a short two sided document, printed on A4 white paper, simply laid out to enhance visual appeal. As Oppenheim notes 'it is best to aim at a relatively 'conservative' but pleasant appearance' (Oppenheim 1992 p. 105). The questionnaire was planned so that straight forward 'tick response' closed questions could be answered first, before moving onto the more thought provoking open statements later. Each questionnaire was office coded so that non-respondents could be identified and targeted. The coding also enabled respondents willing to participate further in the second stage of the study to be identified.

Analysis

The questionnaire produced three sets of data each requiring a different method of analysis.

Questionnaire — Quantitative Data A code book was produced for the quantitative questionnaire data obtained from the six closed questions/statements on the questionnaire. All questionnaires were coded by hand. These data were then entered onto the statistical package Minitab (1991) and analysed descriptively.

Questionnaire — Qualitative Data The two open-ended questions on the questionnaire were analysed using a simple process of qualitative content analysis. The data were subjected to the three stage analysis method described by Miles & Huberman (1994) — data reduction, data display and conclusion drawing.

Documentary Evidence/Data Of the 98 (63·2%) Trusts stating that they had official guidelines to assist health visitors in identifying and prioritising vulnerable families requiring increased health visitor support, sixty-seven (68·37%) areas enclosed a copy of the guidelines. What was particularly interesting was the fact that eight Community Trusts sent copies of two different types of guidelines which they distribute to staff and one area sent three. This obviously raises questions about the purpose and nature of the guidelines. Altogether therefore seventy-seven separate guidelines were sent to the researcher from sixty-seven Community NHS Trusts. This paper will focus on the method undertaken to analyse these documents.

DOCUMENTARY ANALYSIS — A RESEARCH METHOD

For the purposes of this study the documents and guidelines for identifying and prioritising vulnerable families have been critiqued as if they were research instruments in their own right. The aim was to examine the incidence and nature of clinical practice guidelines currently in existence in NHS Trusts in England for identifying/prioritising families requiring extra health visiting support. Anecdotal evidence has suggested that the content of such guidelines varies markedly between different NHS Trusts (Appleton 1993) and that many risk indices are fairly subjective.

Official records, protocols and clinical guidelines can provide the researcher with a wealth of easily accessible and readily available research data. Treece & Treece note 'records are a valuable and lucrative source of nursing research data.' (Treece & Treece 1982 p. 262) Clearly health visiting data are available in a variety of forms from official statistics to policy documents. In this study the authors were specifically interested in those official Trust records and protocols issued to health visitors to assist them in identifying and assessing vulnerable families.

Using this type of material in a research study means that the documents are recorded as secondary data sources in the fact that they contain material

> not specifically gathered for the research question at hand
>
> (Stewart 1984 p. 11)

This differs from primary research data where the researcher is responsible for the entire research process from the design of the project, to collecting, analysing and discussing the research data (Stewart 1984).

Guba & Lincoln (1981) distinguish between documents and records. They define a record as

> any written statement prepared by an individual or an agency for the purpose of attesting to an event or providing an accounting
>
> (Guba and Lincoln 1981 p. 228)

Examples of records include:- birth registration documents, health visiting notes and audit reports. A document is defined as

> any written material other than a record that was not prepared specifically in response to some request from the investigator
>
> (Guba and Lincoln 1981 p. 228)

and includes letters, HMSO publications and policy statements. Silverman (1993) has provided a classification of documents as i) files, ii) statistical records, iii) records of official proceedings and iv) images. Guidelines to assess families requiring increased health visitor support fall into the category iii) official proceedings and appear to be an important part of legitimating the practice activities of health visitors.

Table 1 explores the advantages and disadvantages of using records, documents and clinical guidelines in a research study. The main advantages for the use of existing records/documents/clinical guidelines in a research study is that the data are readily available, take little time to collect and provide a relatively inexpensive form of data (Bailey 1982, Treece & Treece 1982, Webb *et al.* 1984, Lincoln & Guba 1985, Polit & Hungler 1991). This seems a particularly important consideration in the current health service climate of efficiency and cost effectiveness, where little time may be allocated for research purposes.

Table 1 Some advantages and disadvantages of using documentary evidence in a research study

Advantages	Disadvantages
1) Data readily available.	1) Limited by the availability of data.
2) Inexpensive and economical form of data.	2) Inaccuracies in original material.
3) Save time.	3) Bias — 'selective deposit'.
4) 'Non-reactivity' — records unbiased by data collection process.	4) Bias — 'selective survival' — missing/ incomplete data.
5) Researcher does not have to be present during data collection.	5) Total document or part of document?
6) Useful for hypothesis/problem formulation	6) Data studied out of context.
	7) Preparation before analysis.

Non-reactivity

A further strength of the use of documentary evidence is its 'non-reactivity' (Webb *et al.* 1984 p. 114), the fact that records tend to be unbiased as the documents are collated usually for other purposes. As Bailey notes 'the data collection method itself generally does not change the data being collected.' (Bailey 1982 p. 303) The researcher is not in a position to bias subjects and the authors of documents are unlikely to assume their future use in research studies. Another advantage is the fact that the researcher can obtain data without being 'present' in the field, this was demonstrated in the present study where documents were requested from NHS Trust's via the use of a questionnaire. This has the advantage that a researcher is able to gain data by fairly unobtrusive methods (Treece & Treece 1982, Guba & Lincoln 1981).

Webb *et al.* (1984) and Stewart (1984) also raise the important issue for researchers of using documentary data in hypothesis and problem formulations. This certainly appeared an important issue in the present study, where a preliminary national view on the existence of guidelines to assist health visitors in identifying vulnerable families was sought, in an attempt to clarify concepts and to explore the intended relationship between official guidelines/protocols and the issue of professional judgement and vulnerability.

The literature reveals the disadvantages and weaknesses of documentary data (Bailey 1982, Treece & Treece 1982, Stewart 1984, Webb *et al.* 1984, While 1987, Hakim 1993). Documentary analysis is limited by the availability of material, missing or incomplete data, inaccuracies in material and inherent biases. Webb *et al.* identify the major sources of bias in documentary evidence when they describe the two problems of 'selective deposit' and 'selective survival' (Webb *et al.* 1984 p. 114). Selective deposit refers to the representativeness of the sample. The researchers tried to address this sampling issue, by requesting copies of guidelines from all areas under study. A number of strategies were also employed to chase up missing documents, for example respondents who ticked the box on the questionnaire stating they would include a copy of their local guidelines and then did not were contacted by letter. This follow-up proved effective in that most promptly sent a copy of their local guidelines.

One area wrote and stated that the health visitor manager would be responding shortly, this did not occur but the researchers did not pursue this avenue further as placing NHS Trusts under pressure would be both unprofessional and unethical (RCN, 1977). 'Selective survival' (Webb 1984 p. 114) refers to missing or incomplete data, 'relevant data may be censored for confidentiality reasons' (Hakim 1993 p. 136) or because their content may be perceived as reflecting badly on the institution/organisation (Webb *et al.* 1984).

Further difficulties

Three further difficulties can arise with the analysis of documentary research data and were experienced in this study. Firstly the difficulties inherent in being sure that the documents sent by organisations reflected the total document and not just 'part' of an official document. Secondly, in analysing documents taken out of context the researcher needs to be aware that information within documents may lack the clarification from associated teaching sessions. Finally, probably one of the major difficulties with this research instrument is that documentary data, because it is presented in word form, usually requires a lot of preparatory work before analysis can take place. This is particularly the case when documents lack a standard format. As Hakim succinctly states

> perhaps the most common mistake is to think of data from records as ready to use research data whereas they usually require more preparation, care and effort than an equivalent analysis of a research data set
>
> (Hakim 1993 p. 1141)

This preparatory work will be described in detail in the analysis section.

STEPS OF DATA ANALYSIS

Each questionnaire was identified by a new randomly allocated code number during the analysis stages to ensure

confidentiality. Any guidelines accompanying the questionnaires were similarly office coded, so that any documents separated during the process of analysis could be traced back to their original source. To further enhance confidentiality, any Community Trust logos/headings were deleted from the documents received by the researcher prior to analysis.

The seventy-seven documents varied markedly and ranged from one page in length to eighteen pages. This resulted in a great deal of deliberation taking place over how the documents were actually going to be analysed. A major problem facing the authors was the fact that although a number of texts discuss the use of documents and records as a data source, limited information exists about the actual process of qualitative documentary analysis. As there was no suitable tool available to analyse the documents a critique and analysis instrument had to be developed. Data analysis took the following five steps.

Step I — Familiarisation with the data

Familiarisation with the data involved reading through the seventy-seven documents to gain a general picture of the material sent to the researchers. Reading through and digesting the documents was a lengthy process as the documents were quite broad in nature and provided a very rich and detailed data source.

Step II — Simple sort

A simple process of data reduction took place as documents were sorted into piles according to the nature of each document. Similar documents were thus collated together, for example, (i) Documents which consisted of a health visiting 'Standard' statement. (ii) Documents which were composed of a list of risk factors/vulnerability indices (iii) Documents which were vulnerability/screening tools (iv) Documents which focused mainly on health visitors' professional judgements. This was an essential preliminary step in data reduction and enabled the researchers to gain a feel for the breadth and variety of the documents accessed.

Step III — Development of the criteria for critique

As no suitable research tool was available a critique and analysis instrument was developed for use in the study. Each document has been critiqued as if it were a 'research instrument'. The critique tool has been developed to determine the nature of each document and to see if the document can stand up to simple tests of reliability and validity. A number of researchers have highlighted the difficulties associated with content analysis of documents and particularly the coding difficulties encountered when the analyst is faced with a plethora of documents which lack any standard format (Guba & Lincoln 1981, Bailey 1982, Treece & Treece 1982, Hakim 1987). Grimshaw & Russell (1993) have suggested an approach to assessing the validity of clinical practice guidelines where sound empirical research exists. This approach recommends that clinical guidelines should preferably be developed using evidence from randomised controlled trials (Russell & Grimshaw 1995). However, this approach did not seem particularly helpful when the researchers were faced with large numbers of practice guidelines and protocols which appeared to be constructed with little empirical evidence.

REFLECTION

Before constructing a critique and analysis tool it is important for the researcher to carefully consider the purpose of this stage of the study. This helps to direct analysis towards the initial objectives of the study. The reasons for undertaking this particular documentary analysis are described as follows

1) To evaluate existing documents to describe their nature and content.
2) To consider what underlying assumptions the documents make about the nature of 'vulnerability' and families requiring increased health visitor support.
3) To analyse the indices/concepts/risk factors represented in the documents, to examine how far these indices/concepts/risk factors are supported by research evidence.
4) To consider how well supported by research are the approaches that health visitors have taken to identify vulnerable families.
5) To consider whether the clinical guidelines are intended as an aid to or replacement for professional judgement.

Although content analysis of documents usually takes either a structured quantitative method or a more unstructured non quantitative approach (Bailey 1982), the critique tool designed for use in this study utilised a combination of quantitative and qualitative approaches. The tool developed was informed by a number of texts but has been adapted primarily from the work of Lucas (1974), Guba & Lincoln (1981), Bailey (1982) and Treece & Treece (1982). Guba & Lincoln (1981) have proposed a method of 'Case-Survey Aggregation Analysis' initially developed by Lucas (1974) which is used to bring

> diverse case studies together under a common conceptual framework so that findings will be cumulative… to identify what it is we already 'know', what it is we do not know and what it is we suspect
>
> (Lucas 1974 p. 1)

The Case-Survey Aggregation Analysis consists of six factors, the first characteristic of this method involves developing a 'checklist', which Guba & Lincoln describe as

> a set of tightly defined question and answers intended to ascertain information about certain outcomes of interest and the alternative determinants of those outcomes.
>
> (Guba & Lincoln 1981 p. 248)

The document analysis and critique tool which the researcher developed for use in this study was based on a 'checklist' of 38 questions/statements developed to be applied to each of the seventy-eight documents. These questions were split into five separate sections within the critique tool.

CRITIQUE AND ANALYSIS TOOL

The five parts of the critique and analysis tool are described as follows

The aim of Part A was to record/obtain a broad overview of the nature of each document/research instrument. Each document was logged according to its office code number. Treece & Treece state that in order to establish accurate, credible and authentic data three criteria must be applied to all documents

> **(i)** authorship — who conceived the material
> **(ii)** body — the form on which the data are found
> **(iii)** function — the purpose or reason for them.
>
> (Treece & Treece 1982 p. 268)

Part A of the critique tool focuses mainly on authorship and body. Questions were raised about whether any instructions accompany the guidelines/document as this could influence reliability. One question focused on how and where assessment data is recorded by health visitors using the research instrument.

Part B of the critique and analysis tool focused on the concept of 'vulnerability' and increased support being offered to vulnerable families by health visitors. The five questions in this section concentrated on the stated 'function' (Treece & Treece 1982 p. 268) of the guidelines. Question 12 asked about what underlying assumptions are made about 'vulnerability' and families seen to be requiring increased health visitor support. In view of previous research findings (Appleton 1993) it appeared important to determine whether or not the guidelines recognise vulnerability as a complex, ambiguous and transient concept. Exploring whether family vulnerability and hence increased health visitor support is linked with child protection was also addressed. This was because an earlier review of the literature (Appleton 1994) indicated that the majority of studies in which health visitors have been involved in making assessments of vulnerable families have tended to focus on the use of screening procedures for families 'at risk' of child abuse.

The third section of the critique tool considered professional judgement and decision making skills. The questions in this section were planned to elicit information about professional decisions and the relationship between official guidelines and professional judgements. This appears highly pertinent in view of the fact that a recent review of the literature revealed that the majority of research studies in which health visitors have been involved in making assessments of vulnerable families include the use of checklists/screening tools and not an evaluation of the health visitors' own assessment processes. Secondly, an earlier study indicated that despite the presence of official guidelines for identifying vulnerable families, health visitors in the three areas studied were in fact using their own professional judgements in the assessment of vulnerable families (Appleton 1995).

The fourth section of the critique and analysis tool, Part D, concentrated on the research base of the guidelines. Five questions focused specifically on the reliability of the documents. Reliability is 'the extent to which a measure gives consistent results' (Nolan & Behi 1995 p. 472). Three aspects of reliability are usually explored when studying the reliability of a measuring instrument, these are internal consistency, stability and equivalence and all were considered in the documentary analysis. Internal consistency 'the extent to which all the instruments subparts or items are measuring the same attribute' (Polit & Hungler 1991 p. 386) was considered first in the critique tool. To estimate internal consistency the researcher had to consider whether all the indices on the instrument were in fact measuring the same construct/concept. Thus it was important to consider how clearly detailed and defined were the indices within the documents and to consider how they had been sampled.

Stability of a measure

The stability of a measure 'refers to the extent to which the same results are obtained on repeated administrations of the instrument. Estimation of reliability here focuses on the instruments susceptibility to extraneous factors from one administration to the next' (Polit & Hungler 1991 p. 368). The researcher felt it was inappropriate to consider the 'stability' of the documents sent as no test/retest measurement facility existed. However, it is likely that fluctuations in measurement will occur over a period of time because of the nature of what is being measured i.e. the need for families to receive increased health visitor support. For this reason alone instruments are likely to have low reliability.

The third aspect of reliability which needs to be considered in relation to the documents is 'equivalence'. 'Equivalence' is the extent to which different health visi-

tors using the same instrument applied to the same individual/family at the same time, or when two parallel instruments are applied to the same individual/family at the same time, obtain consistent results (Reardon Castles 1987, Polit & Hungler 1991). This is commonly known as inter-rater reliability

> whereby two (or more) researchers score an event independently using agreed scoring criteria. Correlation coefficients between the scores are [then] determined
>
> (Gibbon 1995 p. 50)

In terms of the equivalence of the health visitor documents, the researcher considered whether the following issues had been addressed:- training for users of the instrument, competency and ability of the health visitors, inconsistencies between health visitors using the instrument, health visitor bias and standardised measurement scale/structured assessment format to reduce the risk of bias. However, it is important to recognise that just because a document did not actually mention training for users of the instrument, this does not mean that it does not happen in practice in the NHS Trusts. This illustrates one of the disadvantages highlighted earlier of 'incomplete data' which can be problematic when analysing documents. As Bailey notes

> many documents provide an incomplete account to the researcher who has had no prior experience with or knowledge of the events or behaviour discussed
>
> (Bailey 1982 p. 305)

Validity

Evidence of validity was also considered in Part D of the critique tool. Validity is defined as 'the degree to which an instrument measures what it is intended to measure' (Polit & Hungler 1991 p. 657). The validity of a measure is usually considered in terms of (i) face validity, (ii) content validity, (iii) criterion-related validity which is differentiated as (a) concurrent validity and (b) predictive validity and (iv) construct validity (Bowling 1991, Polit & Hungler 1991, LoBiondo-Wood & Haber 1994, Nolan & Behi 1995b).

Face validity is the weakest form of validity and is usually regarded as a highly subjective measure (Treece & Treece 1982, Reardon Castles 1987). Within this critique tool face validity was addressed by simply looking at each document and considering whether all the items included dealt with vulnerability and appeared to measure families requiring increased support from health visitors. Content validity is

> the extent to which the instrument samples the factors or situation under study. The content of the instrument must be closely related to that which is to be measured
>
> (Treece & Treece 1982 p. 127)

To estimate content validity the researcher considered whether the content of the documents had been judged to be appropriate for the purposes of the document (Treece & Treece 1982, Gibbon 1995). The content of a document might be judged to be appropriate if a literature review has been undertaken which informs and supports its content (Grimshaw & Russell 1993). Pilot work may have been completed to assess the representativeness of the document's content, or possibly a group of experts may have been consulted about the items within a document, particularly the risk indices presented within an official guideline (Treece & Treece 1982, Burns & Grove 1993).

In analysing the documents it was not feasible to address criterion-related validity

> This is the validity estimated by comparing the test outcome with one or more external variables, or criteria, known or assumed to measure the attribute under consideration
>
> (Herbert 1990 p. 52)

This aspect could not be assessed because both concurrent and predictive validity involve the measure being correlated with some external criterion [standard/instrument] which has in itself already been judged to be valid (Powers & Knapp 1990). The researchers are unaware of any clinical guideline issued to health visitors to assist them in the identification of families requiring increased support in existence, which has been proven to be truly valid and reliable.

Construct validity

Construct validity refers 'to the validity of the theory behind the [measure]' (Herbert 1990 p. 53) and is considered to be the most important aspect of validity. Construct validity in relation to the documents would be concerned with the extent to which the results of applying the documents reflect the underlying theoretical concepts, the vulnerability indices. This would be

> the extent to which the theoretical concepts have been successfully operationalised
>
> (Herbert 1990 p. 17)

and

> the process of translating research concepts into measurable phenomena
>
> (Polit & Hungler 1991 p. 650)

In terms of the vulnerability indices the researcher considered whether they are accepted measures. Whether or not the indices are robust and valid concepts and what research evidence supports this. Questions were raised regarding how the concepts are detailed and defined, this is important to ensure that the same meaning is shared by health visitors in order to reduce the risk of bias. Concepts were considered in terms of their degree of operationalism,

were each of the concepts/indices measuring what they were designed to measure? Could the health visitor read in meanings never intended by the individual/organisation who produced the measurement instrument? The final section of the critique tool listed and coded all risk factors/indices mentioned in each document.

Step IV — Establishing a data base

Having developed the checklist of 38 questions/statements to be applied in the critique of each document (Guba & Lincoln 1981), a computer data base was established using Microsoft Excel. Use of the computer data base also enabled the researchers to consider units of analysis, which was an important consideration to avoid being overloaded with data during the analysis stages. Units of analysis for Questions 1–37 were the 'sentence/s'. Answers to questions were limited in length due to predetermined cell size on the computer — each cell was a maximum of four lines in length. Units of analysis for Question 38 onwards were the risk factors/listed indices described in the documents. These generally consisted of a single word or short phrase.

Critiquing each document and registering information on the data base was a time consuming and laborious process and took between 1·5 and 3 hours per document. However, consolidating the documentary data on Microsoft Excel enabled pertinent issues to be explored more easily and allowed the researcher to print off all the answers to the 77 documents for each individual question posed. When dealing with documents of different formats and lengths it allowed the comparison of documents for similarities and differences an easier task to complete. Finally, a short précis of each document was made on a separate computer file to aid ease of reference when determining overall content of a document.

Step V — Final analysis

The qualitative documentary data were analysed question by question separately for words, descriptions and recurrent categories. Diagrams were then constructed to illustrate in visual form how the categories linked together. The data were continually compared with the associated questionnaire data. As Bailey (1982) has recommended taxonomies were developed to illustrate the range of points within the documents and their theoretical basis. In the final report qualitative data are thus presented and illustrated by excerpts from the guidelines/documents.

The listed risk factors/indices (Question 38 onwards) were analysed using a simple quantitative enumeration approach — a

> simple binary coding to indicate whether or not the category appears in the document
>
> (Bailey 1982 p. 319)

This was useful to illustrate the range of risk factors utilised in the documents, to explore their popularity, the frequency with which they are cited and most importantly to examine the research evidence supporting their use in the documents.

DISCUSSION

The analysis of the postal questionnaire data and clinical practice guidelines resulted in the formation of six major themes. The six themes are 1. The nature of existing guidelines 2. Contract specifications 3. The research basis of the guidelines 4. The assumed link between vulnerability and child protection 5. Professional judgement 6. The maze of risk indices. The study findings showed that ninety-eight (63·2%) Community NHS trusts in England issue clinical practice guidelines to health visitors to aid in the identification families needing increased health visitor support.

Many of the guidelines sent to the researchers were presented as formal protocols and quite significantly there was a lack of uniformity amongst them. A substantial number of guidelines contained risk indices which are not supported by sound research based evidence. On classification, the most common category of documents was 'checklists, scoring systems & screening tools' which made up 35 (45·45%) guidelines. These documents appear to be heavily influenced by the scoring approaches of non-health visitors used in screening for risk assessment in child abuse. Many of the guidelines gave equal weighting to risk indices and contained subjective criteria. The research based evidence supporting the use of guidelines is limited with only 19 (19·39%) community trusts stating that their guidelines were based on published research.

This documentary analysis has thus revealed evidence that formal, but generally subjective and invalidated clinical practice guidelines are widely in existence throughout the country to identify families requiring additional health visiting support. A further worrying feature is the fact that many respondents from areas not currently using clinical guidelines were also planning to introduce guidelines in the near future to assist in contracting processes. This stage of the study has thus provided some important empirical data upon which to base the main part of the research study.

CONCLUSIONS

Documentary evidence can provide the researcher with a wealth of rich and detailed data which is unbiased by the data collection process. This paper has described the processes which the researchers undertook when developing a method for data analysis of clinical guidelines used in health visiting practice. The weaknesses of this type of critique tool must be acknowledged. Data are studied out

of context, this could result in missing, incomplete or inaccurate data being used. Questions may also be raised about selective deposit and the representativeness of the sample. The whole process of preparing the data for analysis using the critique and analysis instrument is a very time consuming activity and researchers would need to consider this factor quite carefully in their research timetables.

Probably one of the major areas of criticism is the fact that the whole critique process is open to subjective interpretation by the researcher. Despite these criticisms, this approach to documentary analysis is particularly useful when the researcher is faced with the task of analysing a variety of documents which have no common format and which appear to be being developed without sufficient empirical evidence. This type of measurement tool facilitates a detailed critique of each clinical guideline document including consideration of aspects of validity and reliability. It appeared the most feasible approach to collating and comparing this type of data and use of a computer database enabled easy storage and access to the data.

In view of the recent concerns raised by the RCN (1995) and Hutchinson *et al.* (1995) surrounding clinical guidelines it is essential that practitioners and nurse researchers start to consider the validity and relevance of clinical practice guidelines to nursing and health visiting practice. In many areas of nursing and health visiting clinical practice guidelines are already in use, for example in the areas of pressure sore prevention and management, pain assessment and post-natal depression risk scoring. With the emphasis on clinical guidelines informing contracts the impetus to develop them is likely to increase. The current interest in clinical guidelines, largely espoused by the medical profession, focuses very much on the application of clinical guidelines to scientifically quantifiable procedures. Before nursing too climbs onto the bandwagon of wholesale adoption of clinical practice guidelines, a certain amount of caution needs to be applied and practitioners must address a number of salient points.

Practitioners need to consider whether the use of clinical guidelines could constrain professional practice and examine the legal and ethical issues surrounding their use. For those areas contemplating the introduction of clinical practice guidelines, practitioners and managers need to consider their appropriateness. Where clinical practice guidelines are already in existence practitioners should be determining whether or not the guidelines are valid and based on sound research findings. In terms of the guidelines issued to health visitors to assist them in identifying vulnerable families, this documentary analysis method has exposed the lack of validity and reliability of these types of guidelines upon which so much emphasis is placed by managers and purchasers.

This raises the important question of whether it is ever appropriate to attempt to replace professional judgement as suggested by the shift towards greater use of clinical guidelines in contract specifications. It seems only sensible that these issues are addressed and the authors suggest that this critique and analysis tool could be used by managers and practitioners to evaluate and improve their own clinical practice guidelines.

Acknowledgements

Many thanks to all the Senior Nurses from Community NHS Trusts who participated in this study.

References

Appleton J.V. (1995) Health visitor assessment of vulnerability. *Health Visitor* **68**(6), 228–231.

Appleton J.V. (1994) The role of the health visitor in identifying and working with vulnerable families in relation to child protection: a review of the literature. *Journal of Advanced Nursing* **20**, 167–175.

Audit commission (1994) *Seen but not heard* HMSO, London.

Bailey K.D. (1982) *Methods of Social Research* (2nd Ed.) Free Press, New York.

Bowling A. (1991) *Measuring Health: A Review of Quality of Life Measures* Open University Press, Milton Keynes.

Burns N. & Grove S.K. (1993) *The Practice of Nursing Research. Conduct, Critique and Utilization* W.B. Saunders Company, Philadelphia.

Carruthers I. (1995) Clinical Guidelines: A Health Commission perspective. In *Clinical Effectiveness from Guidelines to Cost-Effective Practice* (Deighan M. & Hitch S. Eds) Earlybrave Publications Ltd./Health Services Management Unit, Brentwood. pp. 111–118.

Deighan M. & Hitch S. (1995) *Clinical Effectiveness from Guidelines to Cost-Effective Practice* Earlybrave Publications Ltd./Health Services Management Unit, Brentwood.

Eddy D.M. (1990) Practice policies — what are they? *Journal of the American Medical Association* **263**, 877–880.

Field M.J. & Lohr K.N. (1992) *Guidelines for Clinical Practice. From Development to Use* National Academy Press, Washington DC.

Gibbon B. (1995) Validity and reliability of assessment tools. *Nurse Researcher* **2**(2), 48–55.

Grimshaw J. & Russell I. (1993) Achieving health gain through clinical guidelines. I: Developing scientifically valid guidelines. *Quality in Health Care* **2**, 243–248.

Guba E.G. & Lincoln Y.S. (1981) *Effective Evaluation* Jossey-Bass Publishers, San Francisco.

Hakim C. (1993) Research Analysis of Administrative Records. In *Social Research, Philosophy, Politics and Practice* (Hammersley M. Ed.). Sage Publications Ltd, London.

Herbert M. (1990) *Planning a research project. A guide for practitioners and trainees in the helping professions* Cassell, London.

Hutchinson A., McIntosh A., Roberts A. & Sutton P. (1995) Evidence based health care: The challenge for general practice. In *Clinical Effectiveness from Guidelines to Cost-Effective Practice* (Deighan M. & Hitch S. Eds) Earlybrave Publications Ltd./Health Services Management Unit, Brentwood. pp. 49–57.

Klazinga N. (1995) Clinical guidelines bridging evidence based medicine and health services reform: A European perspective. In *Clinical Effectiveness from Guidelines to Cost-Effective Practice* (Deighan M. & Hitch S. Eds) Earlybrave Publications Ltd./Health Services Management Unit, Brentwood. pp. 11–14.

Lincoln Y.S. & Guba E.G. (1985) *Naturalistic Inquiry* Sage Publications, California.

Lobiondo-Wood G. & Haber J. (1994) *Nursing research: methods, critical appraisal and utilisation* Mosby, St. Louis, Missouri.

Lucas W. (1974) *The Case-Survey Method: Aggregating Case Experience* Rand Corporation, California.

Miles M.B. & Huberman A.M. (1994) *Qualitative Data Analysis. An Expanded Sourcebook* Sage Publications, California.

Minitab (1991) Minitab statistical software. Cle.com, Minitab Inc., Birmingham

NHSME (1993) *Improving clinical effectiveness* Department of Health, (EL 115) Leeds.

NHSME (1994) *Improving the effectiveness of the NHS* Department of Health (EL 74), Leeds.

Nolan M. & Behi R. (1995a) Reliability: consistency and accuracy in measurement. *British Journal of Nursing* **4**(5), 472–475.

Nolan M. & Behi R. (1995b) Validity: a concept at the heart of research. *British Journal of Nursing* **4**(9), 530–533.

Oppenheim A.N. (1992) *Questionnaire Design, Interviewing and Attitude Measurement* Pinter Publishers, London.

Polit D.F. & Hungler B.P. (1991) *Nursing Research. Principles and Methods* J.B. Lippincott Company, Philadelphia.

Powers B.A. & Knapp T.R. (1990) *A Dictionary of Nursing Theory and Research* Sage Publications, California.

Royal College of Nursing (1977) *Ethics Related to Research in Nursing* RCN, London.

Royal College of Nursing (1995) *Research Society Newsletter. Clinical Guidelines* September. RCN, London, pp. 16–18.

Reardon Castles M. (1987) *Primer of Nursing Research* W.B. Saunders Company, Philadelphia.

Russell I. & Grimshaw J. (1995) Health technology assessment: Basis of valid guidelines and test of effective implementation? In *Clinical Effectiveness from Guidelines to Cost-Effective* (Deighan M. & Hitch S. Eds) Earlybrave Publications Ltd./Health Services Management Unit, Brentwood, pp. 71–82.

Sackett D. & Rosenberg W. (1995) In *Clinical Effectiveness from Guidelines to Cost-Effective* (Deighan M. & Hitch S. Eds) Earlybrave Publications Ltd./Health Services Management Unit, Brentwood, pp. 15–21.

Silverman D. (1993) *Interpreting Qualitative Data. Methods for Analysing Talk, Text and Interaction* Sage Publications, London.

Stewart D.W. (1984) *Secondary Research. Information Sources and Methods* Sage Publications, Newbury Park, California.

Sullivan J.M. & Mann R.J. (1994) Clinical Practice Guidelines: Implications for use. *Dermatology Nursing* **6**(6), 413–418.

Treece E.W. & Treece J.W. (1982) *Elements of Research in Nursing* The C.V. Mosby Company, St. Louis.

Tingle J. (1995) Clinical protocols and the law. *Nursing Times* **91**(29), 27–28.

University of Leeds (1994) *Effective Health Care. Implementing Clinical Practice Guidelines: can guidelines be used to improve clinical practice?* Bulletin from the Institute for Health, December No 8.

Webb E.J., Campbell D.T., Schwarz R.D. & Sechrest L. (1984) The Use of Archival Sources in Social Research. In *Sociological Research Methods — An Introduction* (Bulmer M. Ed.) MacMillan, London.

While A.E. (1987) Records as a data source: the case for health visitor records. *Journal of Advanced Nursing* **12**, 757–763.