DESIGN, IMPLEMENTATION AND EVALUATION OF
A STRUCTURED MEDICAL RECORD IN UROLOGY

A thesis submitted to the University of London for the
Degree of Doctor of Medicine

By

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Abstract

Traditional narrative medical records (TNR) have become multidisciplinary tools, however, the quality of documentation in them remains poor and their lack of structure inhibits the retrieval of information. Previous attempts to restructure the TNR have achieved limited success because they have entailed duplication of the information in the existing TNR.

The aims of this thesis were to; agree a minimum dataset, design a structured medical record (SMR) around the dataset, compare the completeness of documentation of key clinical information when using the SMR versus TNR, determine the time taken to use a SMR versus TNR, implement the SMR in routine clinical practice in a variety of settings (i.e. ward, outpatients, theatre) and assess its acceptability.

A SMR designed around a dataset agreed by consensus was successfully implemented in routine practice throughout one specialty (urology). The SMR resulted in improved completeness of documentation without adding extra time to the consultation and was acceptable to the majority of users.

Agreeing a structure for medical records is not only pertinent to the paper records but is a necessity before they can be converted electronically. This locally agreed dataset and structure could form the template for re-structuring of the medical record irrespective of specialty or medium used.
<table>
<thead>
<tr>
<th>Contents</th>
<th>Page number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>2</td>
</tr>
<tr>
<td>List of Chapters</td>
<td>3 - 10</td>
</tr>
<tr>
<td>List of Tables</td>
<td>11 - 12</td>
</tr>
<tr>
<td>List of Figures</td>
<td>13 - 14</td>
</tr>
<tr>
<td>Abbreviations</td>
<td>15 - 16</td>
</tr>
<tr>
<td>Statement of originality</td>
<td>17</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>18</td>
</tr>
</tbody>
</table>

| Chapter I                                          | 19 - 70     |

| 1.1 History of the medical record                  | 21 - 26     |
| 1.2 Current medical record                         | 26 - 36     |
| 1.2.1 Structure                                    |             |
| 1.2.2 Content                                      |             |
| 1.2.3 Guidelines                                   |             |
| 1.3 Limitations of the medical record              | 37 - 47     |
1.3.1 Documentation

1.3.2 Legibility

1.3.3 Availability

1.4 Consequences of limitations of the medical record 47 - 56

1.4.1 Communication

1.4.2 Clinical governance

1.4.3 Research

1.4.4 Medico-legal

1.4.5 Management

1.5 Attempts to change the medical record 56 - 69

1.5.1 Problem orientated medical records

1.5.2 Integrated care pathways

1.5.3 Proformas

1.5 Summary of introduction and historical review 69-70
Chapter II  Aims and objectives  71 - 73

Chapter III  The design and piloting of a structured medical record in urology  74-103

3.1  Methods  75 - 80

3.1.1  Study population and setting
3.1.2  Design of the structured medical record
3.1.3  Outcomes measured

3.2  Results  81-103

3.2.1  General design decisions
3.2.2  Out-patient form designs
3.2.3  Inpatient form designs
3.2.4  Pilot phase evaluation

3.3  Summary of results  103
Chapter IV  Randomised controlled trial using the structured versus the traditional medical record for new outpatient consultations

4.1  Methods  105 - 9

4.1.1  Study design
4.1.2  Study population and setting
4.1.3  Interventions
4.1.4  Outcomes measured
4.1.5  Sample size and statistical analysis

4.2  Results  109-17

4.2.1  Study population characteristics
4.2.2  Evaluation of the completeness of documentation
4.2.3  Comparison of time taken to document information
4.2.4  Learning and transfer effects

4.3  Summary of results  117
Chapter V  Observational study of the use of an inpatient structured medical record  118-30

5.1  Methods  119-23

5.1.1  Study design
5.1.2  Study population
5.1.3  Study setting
5.1.4  Intervention
5.1.5  Outcomes measured
5.1.6  Statistical analysis

5.2  Results  125-9

5.2.1  Study population characteristics
5.2.2  Evaluation of compliance
5.2.3  Evaluation of the completeness of documentation

5.3  Summary of results  130
Chapter VI  Development and use of a questionnaire to assess users perceptions of the structured record  

6.1  Methods  

6.1.1  Choice of questionnaire  
6.1.2  Questionnaire development  
6.1.3  Questionnaire pilot  
6.1.4  Questionnaire administration  

6.2  Results  

6.2.1  Study population and setting  
6.2.2  Users views about the use of structured forms  
6.2.3  Previous exposure to the intervention  
6.2.4  Clinician preference  
6.2.5  Consultation time  
6.2.6  Uniform presentation of information  
6.2.7  Clinician patient interaction  
6.2.8  Limit recording of information  
6.2.9  Improved communication  
6.2.10  Training  
6.2.11  Effort required will not be worth the gains
6.2.12 Successful use of the forms
6.2.13 Further comments made

6.3 Summary of results 144

Chapter VII Discussion 145-58

7.1 Overview of results 146

7.2 Limitations of thesis 146-53

7.2.1 Design and implementation of SMR
7.2.2 Randomised controlled study of out-patient SMR
7.2.3 Observational study and evaluation of inpatient SMR
7.2.4 Evaluation of acceptability of SMR

7.3 Implications of the findings of this thesis 153-55
<table>
<thead>
<tr>
<th>Section</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.4 Further research</td>
<td>155-8</td>
</tr>
<tr>
<td>Appendices</td>
<td>159-207</td>
</tr>
<tr>
<td>Bibliography</td>
<td>208-20</td>
</tr>
<tr>
<td>Presentations and publications arising from thesis</td>
<td>221-4</td>
</tr>
</tbody>
</table>
List of tables

Chapter I

1.2.1 Structure of medical records  28
1.2.3 Sections of Royal College of Surgeons Guidelines  36
1.3 Limitations of the medical record  39
1.4 Functions of the medical record  48
1.4.1 Users of the medical record  50

Chapter III

3.2.1.a Hierarchy of new out-patient forms  83
3.2.1.b Comparison of advantages and disadvantages of different response coding  87
3.2.4 Form names and edging colours  100

Chapter IV

4.1.4 Fifteen items of clinical information  107
4.2.1 Study population characteristics 110

4.2.2a Comparison of completeness of documentation 112

in the SMR versus TNR

4.2.2b Comparison of completeness of documentation 114

in the SMR and letter versus the TNR and letter

4.2.2c Comparison of completeness of documentation 115

in the SMR letter versus the TNR letter

Chapter V

5.1.5 Evaluation of inpatient medical records 124

5.2.3 Evaluation of completeness of documentation 129

in the SMR versus TNR during February

Chapter VI

6.1.2 Features of questionnaire design 135

6.2.1 Summary of questionnaire responses 138
<table>
<thead>
<tr>
<th>List of Figures</th>
<th>Page number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chapter I</strong></td>
<td></td>
</tr>
<tr>
<td>1.1 Paragraphs from two case studies of Hunter</td>
<td>23</td>
</tr>
<tr>
<td>1.2.1 Traditional medical record</td>
<td>27</td>
</tr>
<tr>
<td><strong>Chapter III</strong></td>
<td></td>
</tr>
<tr>
<td>3.1.2.a Example of part of a form showing different</td>
<td>78</td>
</tr>
<tr>
<td>response coding</td>
<td></td>
</tr>
<tr>
<td>3.1.2.b Example of part of a form showing a single</td>
<td>80</td>
</tr>
<tr>
<td>response question</td>
<td></td>
</tr>
<tr>
<td>3.2.1 Inter-relationship of forms</td>
<td>85</td>
</tr>
<tr>
<td><strong>Chapter V</strong></td>
<td></td>
</tr>
<tr>
<td>5.2.1.a Use of structured medical record and</td>
<td>126</td>
</tr>
<tr>
<td>traditional narrative record by month of study</td>
<td></td>
</tr>
<tr>
<td>5.2.1.b Use of structured medical record and traditional narrative record by clinician</td>
<td>127</td>
</tr>
</tbody>
</table>
Chapter VI

6.2.1 Grade of clinician 139
Abbreviations

A+E  Accident and Emergency
ACP  Association of Coloproctology
ASA  American Society of Anaesthesiology
BAUS British Association of Urological Surgeons
CNP  Clinical nurse practitioner
CNS  Central nervous system
CNST Clinical negligence scheme for trusts
COAD Chronic obstructive airways disease
CP   Clinical pathways
CT   Computerised tomography
CVA  Cerebrovascular accident
CVS  Cardiovascular system
DGH  District general hospital
Dr   Doctor
EHR  Electronic health record
EPR  Electronic patient record
FT   Freetext
GA   General anaesthetic
GI   Gastro-intestinal
GMC  General Medical Council
GP   General practitioner
ICP  Integrated care pathways
IHD  Ischaemic heart disease
IIEF International index of erectile dysfunction
IPSS International prostate symptom score
IT   Information technology
LA   Local anaesthetic
Lab  Laboratory
LUTS Lower urinary tract symptoms
MCQ  Multiple choice questions
MDU Medical Defence Union
MR   Medical records
NHS  National health service
OCR  Optical character recognition
O&G  Obstetrics and gynaecology
PAS  Patient administration system
POMR Problem orientated medical records
PRHO Pre-registration house officer
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCS</td>
<td>Royal College of Surgeons of England</td>
</tr>
<tr>
<td>RS</td>
<td>Respiratory system</td>
</tr>
<tr>
<td>SHO</td>
<td>Senior house officer</td>
</tr>
<tr>
<td>SMR</td>
<td>Structured medical record</td>
</tr>
<tr>
<td>SN</td>
<td>Specialist nurse</td>
</tr>
<tr>
<td>SOAP</td>
<td>Subjective, Objective, Assessment, Plan</td>
</tr>
<tr>
<td>SF</td>
<td>Structured forms</td>
</tr>
<tr>
<td>SpR</td>
<td>Specialist registrar</td>
</tr>
<tr>
<td>TB</td>
<td>Tickbox</td>
</tr>
<tr>
<td>TCC</td>
<td>Transitional cell carcinoma</td>
</tr>
<tr>
<td>TEDS</td>
<td>Thrombo-embolic stockings</td>
</tr>
<tr>
<td>TH</td>
<td>Teaching hospital</td>
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<tr>
<td>TNR</td>
<td>Traditional narrative record</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>XR</td>
<td>X-ray</td>
</tr>
</tbody>
</table>
Statement of originality

The studies described and presented in this thesis are the original work of the author.

No part of this work has been submitted to any other University for consideration for a higher degree.

All the clinical studies in this thesis were performed in accordance with protocols approved by the local ethics committees and research and development departments.
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Last but never least my parents deserve special thanks for their patience and constant encouragement.
Chapter I

Introduction and historical review
Medical records (MR) are the basis on which clinical decisions are taken and yet there is often concern about the quality of the information documented [Patel 1993]. They are frequently incomplete, illegible, inaccurate or worst of all occasionally unavailable [Gibby 1998]. The volume of information stored in the MR is increasing as a result of chronic disease, longevity and the development of more investigations [Wyatt 1998]. Consequently, maintenance of the MR and retrieval of data is becoming more difficult. Clearly electronic medical records offer a solution to some (not all) of these problems, but they are still under development and not available in most hospitals [NHS Executive 1998].

Clinical governance, increasing public awareness and media vigilance mean that clinicians are under closer scrutiny than ever before, with the MR being used as a evidence of the quality of care a patient has received [NHS Executive 1998]. This thesis evaluates the feasibility of developing and implementing a structured medical record in one specialty (urology) with the aims of improving the completeness of documentation, retrieval of information and enabling a transition towards electronic medical records.

Section 1.1 of the introductory chapter traces the development of the medical record, section 1.2 describes the current medical record, section 1.3 summarises the limitations of the current medical record, section 1.4 discusses the consequences of these limitations and section 1.5 presents the previous attempts to improve the medical record.
Although there is evidence from stone carvings and hieroglyphics on pyramid walls that medical records have existed for many years, their purpose and structure has changed considerably. In Britain particularly, changes in the infrastructure of medical practice have been paralleled by changes to the medical record [Benjamin B 1977].

1.1 – History of the medical record

Medical records have been reported from as early as 4000BC. When a leader died the Sumarians carved his name, diagnosis, treatment and his doctor’s name onto a stone tablet [Marsh 1998]. This tablet was then buried with the leader and the sacrificed doctor. Around 3200BC the Egyptians documented the diseases, medication and manner of death on the walls of their Pharaohs tombs. These are both examples of the MR as a historical document rather than as a contemporary source of information in the management of a patient’s disease.

The first detailed case reports are attributed to Hippocrates in 460BC. He practised medicine as a science by making careful observation of patients, which were promptly and meticulously, recorded [Kurtz 1943]. Although detailed and precise, these notes were used for personal study and teaching rather than in the direct care of patients.

The practice of systematic case note recording was introduced into England by Theodore de Mayerne (1593-1654) an expatriate French
physician. He was a supporter of Sydenham’s proposal that physicians should spend less time studying and more time observing their patients at the bedside. Mayerne took a careful history from his patients, performed a thorough examination and undertook basic investigations as required [Copeman 1965]. Other physicians quickly followed suit, but, the activity of recording clinical observations remained limited to private notes, kept by physicians primarily for their own interest rather than to improve patient care.

Provided that a family doctor could attend to their patients satisfactorily there was felt to be no need for them to keep MRs routinely. Records of the patient’s disease and treatments were instead kept for general academic and scientific purposes rather than as an information source for other clinicians that may become involved in their care at a future date. They were not intended for use to inform clinical management or to improve the treatment of the individual patient.

In the eighteenth century, teaching hospitals were established. As the practice of teaching clinical medicine developed so did the practice of keeping detailed MRs [Payne 1958]. John Hunter, a famous surgeon of the time kept many details notes of interesting cases (Figure 1.1). Similarly, Heberden a physician kept commentaries which were a distillation of his systematic notes that were both published and presented monthly. These notes were, however, still for the purpose of teaching
Figure 1.1– Paragraphs from two case studies by Hunter

(Reproduced by permission from the Royal College of Surgeons Archives)
students and for the sharing of interesting cases with other physicians. They were not used to directly improve the quality of patient care.

With increased hospitalisation of patients and specialisation of clinicians it became usual practice to keep MRs on all patients, the management of which became the responsibility of the hospital. During the 1800s-1900s hospitals experimented with how to keep and store these MRs [Kurtz 1943]. Some were simply stored in bundles but more commonly they were bound chronologically or alphabetically by patient name in huge heavy volumes, one volume for each member of the medical staff per year. As the need to understand and retrieve information from the MRs became clear, index cards were introduced on which the name of the patient, diagnosis and treatment were recorded. Some hospitals tried to bind MRs according to diagnosis but this was unreliable, as there was no agreement of diagnostic terms. Although the MR was being preserved and stored it was still difficult to retrieve information i.e. how many cases of a specific disease had been seen in the last month or to follow the progress of an individual patient. In most hospitals out-patient and inpatient records were kept separately with each specialty keeping its own out-patient records. It was, therefore, possible for one patient to have a multiplicity of MRs all filed separately. Retrieval of previous records was a difficult and complicated process, unless the patient could give precise details of the year(s) of treatment and the name(s) of the consultant(s) involved.
In 1913 the American College of Surgeons was established for the purposes of introducing standards of surgical work. Each candidate for fellowship of the college was required to provide details of patients he had operated on. It soon became clear that most hospitals were unable to provide this information. Shortly after this in 1916 the Presbyterian Hospital, New York introduced the unit medical record system which was the

"practical expression of a fundamental medical concept that the individual – not some part of him or some episode in his history but the whole individual – is the unit of medical practice and study"

The patient and not the disease episode was taken as the unit for MR compilation and, therefore, only one MR folder was required per patient [Kurtz 1943]. In this folder all documents relating to past and present care were placed. This system had the advantage of making complete medical histories available to all practitioners involved in the care of the patient. It also improved the retrieval of information and MRs and was, therefore, backed by the American College of Surgeons.

In Britain the organisation of the MRs remained haphazard until after the Second World War (1939-1945). During this the clinicians realised the value of keeping and having access to MRs especially for the study and follow up of new techniques and treatments. They began to make demands for assistance in the maintenance and organisation of MR. However, it
was not until the establishment of the National Health Service (NHS) and the Association of Medical Records Officers in 1948 that the unit system was widely adopted in Britain [NHS Bill, Ministry of Health 1949, Royle 1948]. This Association continued to and still does have an active role in setting standards for the organisation of medical records and training of its members [Benjamin 1977].

1.2 Current medical record

1.2.1 Structure

Medical records are usually paper-based documents that contain all the information pertaining to an individual patient’s care within one institution. They consist of fragile cardboard folders containing a variety of documents including typed letters, hand written clinical notes, referral letters, prescription charts, observation charts and laboratory reports (Figure 1.2.1) [Hutchinson 1987]. These documents are usually grouped into sections, the content of which differs between institutions [Nygren 1998]. There is also considerable variation in the order in which documents are filed within these sections (Table 1.2.1).
Figure 1.2.1 – Traditional medical record
<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correspondence</td>
<td>Typed letters - discharge summaries / GP</td>
</tr>
<tr>
<td></td>
<td>(filed chronologically with most recent first)</td>
</tr>
<tr>
<td>Out-patient*</td>
<td>Clinical hand-written entries for clinic visits</td>
</tr>
<tr>
<td></td>
<td>(filed chronologically with earliest entry first</td>
</tr>
<tr>
<td></td>
<td>occasionally subdivided by specialty i.e. oncology)</td>
</tr>
<tr>
<td>In-patient*</td>
<td>Clinical hand-written entries for ward patients</td>
</tr>
<tr>
<td></td>
<td>(filed chronologically with earliest entry first)</td>
</tr>
<tr>
<td>Results</td>
<td>Investigation results filed</td>
</tr>
<tr>
<td></td>
<td>(often subdivided by lab i.e. biochemistry, haematology)</td>
</tr>
<tr>
<td>Other</td>
<td>All other documentation i.e. observation charts, drug charts, nursing notes, consent sheet</td>
</tr>
</tbody>
</table>

* These may be together under a section called Clinical Notes
1.2.2 Content

There are different methods of entering and displaying clinical information in the medical records; handwriting, typing, diagrams, tables, graphs and images. Each of these methods has particular advantages and disadvantages.

Hand-written

This is the most commonly used method of recording clinical information. It has remained the preferred method of documentation because it is efficient, flexible, familiar and simple. Any clinical situation can be described using the minimum number of words and taking very little space. Often only the relevant positive and negative features of a consultation are recorded. The limitations of hand written “prose” records, however, are illegibility, interpretation of “missing” information and lack of structure [Winslow 1997].

Typed text

There are two main methods of entering typed text in the medical record. The first is dictation of a letter or discharge summary, which is often a duplication of the hand written entry [Frain 1996]. The letter is dictated by the clinician, transcribed by a secretary then two copies are made one for the general practitioner (GP) and the other to file in the medical record.
[Adams 1993]. Dictation is also used in some specialties, notably orthopaedics for documentation of ward rounds, which are then transcribed by a secretary and pasted into the record. However, this is a resource that is not available to many clinicians.

The other method of typed entry of information into the medical record is the use of computer generated letters. Clinical information is entered (usually by the clinician) onto a computer template. The fields are then used to generate a standard letter, which is sent to the GP and filed in the notes.

Typed text ensures that clinical notes are legible whilst maintaining flexibility in the content of information recorded [Dawdy 1997]. However, they still have the same lack of structure as the hand written record unless the information is entered in a structured manner as with some of the computer generated letters [Paterson 1999].

_Diagrams / pictures_

Diagrams can be an efficient way of describing a complex problem. They are particularly useful for explaining the spatial relationship or position of something i.e. a lump. [Wyatt 1998]). As an aide-memoire for a clinician looking back at his or her own notes they may be very useful but for others the usefulness may depend on the skill of the artist. Also a badly drawn diagram can be misleading especially if it is not anatomically precise.
Tables/graphs

These are not suitable for the display of hand-written clinical information but are easily generated from data that is held electronically i.e. laboratory results. The main advantage of table and graphs is that they can highlight trends and act as a summary of results [Powsner 1994]. Tables can be formatted to distinguish normal and abnormal results by the use of different size fonts, colours or position [Powsner 1998; Wright 1998]. However, caution should be taken in the formatting of graphs as several authors have found that, when using the same data, small differences in appearance of the graph i.e. scale had a significant and sometimes adverse influence on clinicians decision making [Cartmill 1992; Wyatt 1999]. In particular Elting et al studied the effect of decisions to continue hypothetical clinical trials by showing clinicians 4 different displays of the same data (table, pie chart, bar graph and icon). The clinicians, however, were told that these were 4 separate trials. The least preferred method of display using icons actually produced the most accurate decisions [Elting 1999]

Images

Images are increasingly being used in routine practice. Initially photographs were pasted directly into the notes. It was, therefore, possible for clinicians to keep a visual account within the medical record of a
disease process e.g. healing ulcer or a procedure e.g. reconstructive surgery [Tapia 1999]. The image then acted both as a historical document and a source of discussion with the patient to help explain their disease or reassure them about their progress.

Traditional film cameras are now being superseded by digital cameras, which have become affordable and easy to use. The advantage of digital cameras is that with little technical expertise they can be used to produce good quality images which can be both stored in a database and printed off for pasting into the notes [DeLange 1999; Price 1997]. With the image stored on a database the information is available for research and audit without retrieving the MR.

1.2.3 Guidelines

Many guidelines for the storage, retrieval, structure and general content of the MR both international and national have been published and updated over the years [World Health Organisation 1980; Department of Health 1989; Audit Commission 1995; Audit Commission 2000; Royal College of Surgeons of England 1994; 2000; Royal College of Surgeons of England 2002; General Medical Council 1999, NHS Executive 1999]. The WHO guidelines embrace all aspects of the MR including: content, structure, confidentiality, numbering, filing, coding, audit, function and transport. Despite these, MRs have developed in a relatively “ad hoc” manner. The “Tunbridge report” in 1965 called for a common structure for the medical
record but differences between institutions still exist. [Standing Advisory Committee 1965].

In 1995 the Audit Commission published results of a study of hospital MRs called “Setting the Records Straight” [Audit Commission 1995]. The key areas examined were;

- Quality of individual MRs
- Arrangements for ensuring that MRs were available when and where needed
- Management arrangements for MRs departments
- Opportunities from alternative approaches and new technologies

After the study the following recommendations for good practice for the maintenance of MRs were suggested incorporating recommendations from the Tunbridge report, Department of Health HC(89) 20 document and the Institute of Health Record Information and Management (IHRIM).

- The patient should be clearly identified and the MRs should set out diagnosis, history, treatment, results and care plans
- MRs should be kept neat and tidy with legible entries signed and dated, preferably in black ink
- They should be kept up to date and filed in chronological order with the most recent on top
- MRs should have a clear structure which is agreed with users and should be organised into sections
• There should be a policy determining which documents should remain in the MRs after discharge (culling)

• There should be one set of MRs for each patient

These recommendations were mainly concerned with maintaining the MR so that it was available as a source of clinical information. They have been further refined in a supplementary document published in 2000 [Audit Commission 2000]. In addition to these national guidelines, however, many Trusts have developed local guidelines that reflect their legal requirement to maintain the MR [Gould 1994]. Annually Trusts have to pay large indemnities to cover themselves against litigation. The indemnity scheme used by all but one trust in England (similar policies also exist in Wales and Scotland) is the Clinical Negligence Scheme for Trusts (CNST) [NHS Litigation Authority 1999]. The policy is comprised of 14 standards, each of which addresses a different area of risk management. Compliance with each of these areas is used to determine the members’ contribution to the scheme. Standard 8 is concerned with MRs and is subdivided into 16 areas for assessment (Appendix 1.2.3.a). It states that

"A comprehensive system for the completion, use, storage and retrieval of medical records is in place. Record keeping standards are monitored through the clinical audit process."

At an individual rather than Trust level, there are guidelines for clinicians as to how information should be documented in the MR. In the General
Medical Council (GMC) publication "Good Medical Practice" no detailed guidance on the layout or content of a clinical entry was given it merely stated that clinicians should:

"keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed" [General Medical Council 1999].

Of all the specialty colleges, only the Royal College of Surgeons of England (RCS) appears to have published its own guidelines for clinicians [Royal College of Surgeons of England 1994]. As well as looking at relevant papers to establish what guidelines had been used, each of the specialty colleges were telephoned. Their libraries and publications offices were asked if any guidelines for their members existed. The Royal College of Surgeons of England was the only college to have any guidelines, which were first published in 1989, revised in 1994 (Appendix 1.2.3.b) and are currently under revision [Royal College of Surgeons of England 2002] (Appendix 1.2.3.c). The guidelines are divided into 9 sections (Table 1.2.3). Particular emphasis is placed on patients undergoing surgery, with specific recommendations for consent, operation notes, anaesthetic records and discharge documentation.
Table 1.2.3 – Sections of Royal College of Surgeons guidelines

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<tbody>
<tr>
<td>1</td>
<td>The hospital record</td>
</tr>
<tr>
<td>2</td>
<td>The clinical record</td>
</tr>
<tr>
<td>3</td>
<td>The nursing record and care plan</td>
</tr>
<tr>
<td>4</td>
<td>Patients undergoing surgery</td>
</tr>
<tr>
<td>5</td>
<td>Patients in intensive therapy units</td>
</tr>
<tr>
<td>6</td>
<td>Details on discharge</td>
</tr>
<tr>
<td>7</td>
<td>Post-mortem report</td>
</tr>
<tr>
<td>8</td>
<td>The management of hospital records</td>
</tr>
<tr>
<td>9</td>
<td>Secretarial support</td>
</tr>
</tbody>
</table>
1.3 Limitations of the medical record

The MR may not fulfil the demands made on it for a number of reasons (Table 1.3).

1.3.1 Documentation

The guidelines for documentation in MRs produced by the RCS and the GMC are very general as they are intended to be applicable to all patients [Royal College of Surgeons of England 1994; General Medical Council 1999]. Studies have been conducted to establish the standard of documentation using these and locally agreed guidelines. Inpatient, outpatient and accident and emergency medical records have all been studied, with regard to the standard of documentation in particular areas such as medical clerking, operation note, consent/counselling and discharge summaries.

Inpatient medical records

In 1983 the Swansea Physicians’ Audit group evaluated the quality of medical records in 2 hospitals [Swansea Physicians' Audit Group. 1983]. Consensus was reached on the standard of documentation required then random samples were drawn from inpatient admissions over 1 year for 3 common medical diagnoses and each consultant. A trained data abstractor conducted a retrospective review of 285 MRs auditing 3 main areas;
accuracy of filing, completion of forms and the medical clerking on admission. Correct filing of certain documents in the MR varied between the 2 hospitals but was particularly poor for discharge summaries (62% filed) and radiology reports (24%) when compared with other documents for example, laboratory reports (76%) and admission sheets (91%). The completion of the “front sheet” detailing patient demographics, discharge summary form and drug chart was examined. Completeness of the “front sheet” was good with the exception of the GP details, a discharge summary form was completed for 85% of admissions with the diagnosis and treatment being stated in 96% and 53% respectively. However, in 8% of drug charts a drug dose was omitted, the route and frequency were missing in 7% and no signature was present on 2% of the charts. In general the recording of most features of the history in the medical clerking was reasonable (80%) with the exception of allergies (53%). For each of the diagnoses the documentation of specific physical signs was noted. The recording of these varied considerably from 99% for heart sounds to 7% for carotid bruits. In conclusion the authors recommended regular audit with consultant involvement and the introduction of guidelines as a means of improving the quality of the MR. Although the audit was performed in only 2 hospitals with clinicians from one specialty and a limited number of diagnoses it highlighted the variation in the quantity and quality information within the MR.
Table 1.3 – Limitations of the medical record

<table>
<thead>
<tr>
<th>Limitation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor documentation</td>
<td>Essential clinical information missing</td>
</tr>
<tr>
<td>Illegibility</td>
<td>Illegible handwriting</td>
</tr>
<tr>
<td></td>
<td>Abbreviations</td>
</tr>
<tr>
<td>Incomplete</td>
<td>Clinical notes lost out of the record</td>
</tr>
<tr>
<td></td>
<td>Clinical information not filed in the record</td>
</tr>
<tr>
<td>Missing</td>
<td>Medical record unavailable at point of care</td>
</tr>
<tr>
<td>Difficulty retrieving data</td>
<td>Structure of record makes retrospective analysis</td>
</tr>
<tr>
<td></td>
<td>difficult</td>
</tr>
<tr>
<td></td>
<td>Record too bulky due to long history of patient</td>
</tr>
</tbody>
</table>
Following publication of the RCS guidelines in 1990, Patel et al performed a retrospective audit of 200 MRs in both a teaching (TH) and district general hospital (DGH) [Patel 1993]. Using a questionnaire based on the RCS guidelines each MR was scored according to whether certain criteria were documented. The poorest areas of documentation were name and hospital number on each history sheet (13% TH and 34% DGH) and advice to patients and relatives (0% and 0%). The authors noted that the standard of doctors’ documentation was far inferior to that of the nurses and speculated that lack of emphasis during medical training on the importance of adequate documentation and a lack of structured format were responsible. This was a retrospective study with no information as to the numbers of clinicians sampled or description of the surgical units in which it was conducted. However, it provides valuable information on compliance with the RCS guidelines.

A similar process was described by Crawford et al for auditing record keeping within their surgical department [Crawford 2001]. They reported a score, which deducted “points” if certain aspects of the medical record were incomplete e.g. patient name, date of clinical entry, and responsible consultant’s name. This “CRABEL” score was used routinely for audit of the medical record and the results presented at their monthly audit meeting.
In addition to the studies discussed looking at documentation in all aspects of the MR, there have been others that have focused on one aspect of the MR, in particular the operation, consent and discharge summary.

The two specialties in which operation notes are usually found are obstetrics and gynaecology (O&G) and surgery. In O&G, a retrospective analysis of the operation notes of 101 caesarean patients was performed by Roach et al [Roach 1998]. The authors found that 16.3% of the patients were inadequately identified in the operation note and that details of important operative findings were also missing in up to 63% of patients.

A similar review was conducted in general surgery where 264 operation notes from two DGHs were reviewed retrospectively for completeness of documentation [Baigrie 1994]. The results showed that trainees produced more complete, legible operation notes than the consultants (92% trainees 31% consultants) and recorded postoperative instructions more often (59% and 24%). The serial number of prosthesis used was frequently omitted in both hospitals (24 and 33%) regardless of whether a description of its placement had been documented.

Communication with GPs, patients and their relatives is an essential aspect of hospital medicine. Evidence of this communication should be documented in the MR as it forms part of the patient’s care. Several studies, however, have shown that the standard and completeness of documentation regarding information given to patients/relatives during the
consent/counselling process is often poor [Melltorp 1996; Schachter 1998; Harris 1999].

Liesenfeld et al found that the management of diabetic patients was being potentially compromised by the failure to record important complications and investigations in the discharge summaries [Liesenfeld 1996]. Such omissions can potentially compromise the communication with GPs.

Out-patient

The general content of out-patient MRs was assessed by Twigg et al [Twigg 1993]. Ten consecutive sets of MRs were selected for each of the 11 surgical consultants. The presence or absence of specific contents i.e. out-patient letter, X-ray report was noted. Three main reasons for missing information were suggested by the investigators. As 51% of the MRs were unbound, it was postulated that this might account for the absence of the operation note in 11% and the anaesthetic chart in 9% of records. With regard to post-operative notes (37% missing) and discharge summaries (26% missing) it was unclear whether these had been lost or never completed. In the case of histopathology reports (40% missing) the authors concluded that it was probable that the clerical staff had never filed these.

This study had several limitations. Firstly, selection of the MRs was open to bias as they were not selected randomly and some of the consultants had less than 10 MRs. Secondly, the consultants scored their own MRs introducing another potential source of bias. Despite these limitations the
study showed the frequency with which information regarded by clinicians as important is not present in the MR.

Other studies on out-patient documentation have studied the accuracy and completeness of documentation of particular aspects of the MR. Monson et al compared the out-patient MRs of 355 patients with their pharmacy files with regard to the names, dosage and directions of drugs prescribed [Monson 1978]. Inaccuracies of drug dosage or directions were present in 62% of records and inaccuracies of the drug name in 21%. Peters et al found that although diabetic patients were regularly attending a specialised clinic, fasting blood glucose was not documented in 65% of patients and documentation of a foot examination was absent in 94% [Peters 1996]. It was impossible to determine whether these patients had these preventive measures but were not recorded or whether they had ever been performed.

**Accident and emergency**

Accident and emergency (A&E) medical records are often stored in the A&E department separate from the main hospital MR department. Because of this and also the potential legal repercussions of many A&E consultations several studies have been performed, which specifically examine the documentation in A&E MRs {Schoenfeld 1991, Parra 1997, Ryan 1998, Christopher 1995}. 
Ryan et al highlighted the variations in documentation of important aspects of the history, examination and observations of epileptic patients seen in A&E departments in one health region [Ryan 1998]. Of particular concern was the widespread failure to advise patients not to drive after a seizure in 99.1% of cases. These findings stimulated agreement of treatment protocols and the use of a proforma for use in these patients.

Similarly, Williams et al found that the existing level of documentation during severe trauma was poor with 40% of records documenting all four vital signs being audited [Williams 1997]. Based on these findings trauma documentation charts were introduced. Following this it was found that the level of documentation improved significantly especially for patients referred onto tertiary centres.

The studies discussed have mainly been retrospective audits of the standard of documentation in various parts of the MR. Although they have examined different aspects of the MR, the findings have been similar, that the level of documentation within the MR shows wide variation. The workload that a clinician is practising under has been cited by some as the cause of poor documentation [Dawdy 1997]. However, others have stressed that this is not the reason and that the problem lies with the lack of emphasis by clinicians on the importance of complete and accurate documentation [Patel 1993, Jolobe 1993]. It is clear that the current standard of documentation in the MR is not adequate and that improvement is required.
1.3.2 Legibility

Much of the MR is hand-written, therefore, the usefulness of the information recorded is dependent on the quality of the handwriting of the person documenting it. Information can be regarded as absent if the clinical entry is illegible and cannot be deciphered. A study by Lyons et al concluded that doctors have worse handwriting than other professions [Lyons 1998]. Handwriting was assessed by asking participants to write individual numbers and letters in boxes, which were then “read” by optical character recognition software. The findings of this study were limited because the authors were assessing individual characters and numbers rather than a sample of normal handwriting, the study was not conducted in a routine clinical setting and a computer was used to assess legibility. Although the computer provided an objective measure of legibility, the authors did not make it clear as to the generalisability of this to the human perception of legibility.

In contrast to this study Berwick et al found that doctors’ handwriting was no worse than that of the other health professionals tested [Berwick 1996]. They asked participants to write a sentence in a set period of time. As with the previous study, this study was not performed in the routine clinical environment and the relevance of its findings are, therefore, difficult to interpret.
Baigrie et al reviewed operation notes of 264 patients in 2 DGHs for legibility. They found that the legibility of emergency notes were better than elective (100% - 52%) and that trainees’ writing was more legible than that of the consultants (92% - 31%) [Baigrie 1994]. The assessment of legibility was made subjectively and only amongst surgeons, therefore, this study cannot answer whether clinicians in general have poor handwriting.

1.3.3. Availability

Despite the limitations of the MR that have been discussed it is still a valuable aid for clinical decision making. However, clinicians frequently experience the frustration of not having the MR available when seeing a patient [Duncan 1988]. This occurs most commonly with emergency “out of hours” admissions, when the MR department locked, and out-patient clinics when the receptionist has been unable to locate the MR [Dunnill 1992; Clements 1992]. The incidence of missing records depends on the institution but is a universal problem [Krarup 1991]. Gulliford et al attempted to retrieve the records of 609 patients with bladder cancer treated in South Thames [Gulliford 1991]. They found that the retrieval rate was lower for deceased patients than patients who were still alive. Retrieval of the deceased patients’ MRs varied with district of residence (0-91%) but not region of residence, year of death or teaching status of hospital. For surviving patients the response rate varied with district of residence (38%-100%), teaching status of hospital (63% TH – 89% DGH)
and region of residence (81%-92%). The authors concluded that the
commonest reason for not obtaining MRs was because they had not been
stored in a systematic manner. They highlighted the importance of
ensuring that MRs were stored such that they could be easily accessed for
both clinical practice and audit.

1.4 Consequences of limitations of the medical record

The current MR acts as a historical account of the care that an individual
patient has received in a single institution. The information it contains is
used to aid communication, inform clinical governance, for clinical
research and to provide evidence for medico-legal claims (Table 1.4). If
any of this information is incomplete for the reasons described in section
1.3 this has adverse consequences for each of these functions.

1.4.1 Communication

The essential function of the MR is as a communication tool. In the past
when records were held by an individual clinician they predominantly
acted as an aide memoire to remind him of previous encounters with the
patient and treatments given [Copeman 1965]. This is still the case in
much of the private sector where the legislation associated with the NHS,
is obviously not applicable (BUPA personal communication).
Table 1.4 – Functions of the medical record

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>Between clinicians, nurses and paramedical specialties</td>
</tr>
<tr>
<td>Clinical governance</td>
<td>Evidence of the quality of care patient has received</td>
</tr>
<tr>
<td>Audit</td>
<td>Audit of treatments given or diagnoses made</td>
</tr>
<tr>
<td>Research</td>
<td>Identification of patient groups or the incidence of particular drug use or treatment</td>
</tr>
<tr>
<td>Legal</td>
<td>Used as a legal record of patient care used in court as evidence</td>
</tr>
<tr>
<td>Administrative</td>
<td>Financial planning and resource management</td>
</tr>
</tbody>
</table>
Within the NHS MRs have developed into multi-disciplinary tools with many users (Table 1.4.1). When seeing a patient for the first time clinicians will “scan” through the MR to gain an idea of what has happened to the patient [Nygren 1998]. This enables them to direct their questions within the context of the patient’s past medical history and to make future management decisions based on previous events. If information is incomplete or clinicians are unable to find it, this has a number of potential consequences.

- Unable to make a decision about the patient or perform a procedure

- Re-ordering of investigations [Hutchinson 1987]

- Increased consultation time searching for information [Wyatt 1998; Duncan 1988]

- Dangerous drug interactions if allergies are not clearly documented [Cantrill 1997]

Although these consequences are recognised by clinicians, few reports quantify them. Rather they can be implied from the available literature that has found that MRs are often incomplete, illegible and missing (section 1.3). Or they can be assumed from indirect evidence as discussed.
<table>
<thead>
<tr>
<th>Users of the medical record</th>
<th>Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinicians</td>
<td>Aide-memoire</td>
</tr>
<tr>
<td></td>
<td>Continuing care</td>
</tr>
<tr>
<td></td>
<td>Liase with other specialties</td>
</tr>
<tr>
<td>Nurses</td>
<td>Follow medical treatment of patients</td>
</tr>
<tr>
<td>Paramedical staff</td>
<td>Gain information about patient</td>
</tr>
<tr>
<td>(occupational therapy, dietician, physiotherapy, social worker)</td>
<td>Communicate their intervention</td>
</tr>
<tr>
<td>Researchers</td>
<td>Retrospective analysis of treatments</td>
</tr>
<tr>
<td>Administrators</td>
<td>Case mix information</td>
</tr>
<tr>
<td></td>
<td>Business planning</td>
</tr>
<tr>
<td>Lawyers</td>
<td>Evidence of patient care</td>
</tr>
</tbody>
</table>
The MR also contains copies of letters dictated in clinic and discharge summaries and, therefore, acts as a historical record of the communication with the patient's GP [Macaulay 1996]. In cases were the MR is illegible these typed letters act as a valuable source of information [Medical Defence Union 1998]. They may also contain information that has not been documented in the hand-written part of the MR (Chapter IV).

The MR is a means of communication with nursing and para-medical staff (physiotherapy, occupational therapy, dieticians and social workers). Although these users often keep separate records they may refer to the clinical hand-written entry for information about a patient that they are looking after or have been asked to see. On surgical wards in particular the MR may be the only method of communicating important clinical information if a clinician is in theatre all day [Baigrie 1994].

1.4.2 Clinical governance

Clinical governance is the means by which trusts are explicitly accountable for their quality of care [NHS Executive 1998]. It incorporates many facets of quality assurance one of which is audit [Royal College of Surgeons 1995]. The MR acts as evidence of the quality of care a patient has received. It can, therefore, be used for retrospective audit of certain aspects of care e.g. specific operation, tracing patients following an adverse incident (misreporting of cervical smear results, 3M capital hip failure,
hepatitis B positive doctor) and outcome or treatment of a particular
disease [Foubister 1989; Gompertz 1994].

The MR can become the subject of audit [Heath 1990]. Many departments
regularly examine a random sample of their MRs to ensure that guidelines
for documentation, filing and maintenance are being adhered to [Opila
1997; Grebe 1995]. Although, as Grebe et al found, whilst it is possible to
demonstrate an improvement in documentation with regular audit and
feedback it is often difficult to show that this leads to any increase in the
numbers of abnormal results detected or acted on [Grebe 1995]. To prove
that good documentation makes a difference to clinical care would require
a large sample of MRs, instead a case-control study may be more useful.
The standard of documentation in the MR of the medico-legal cases could
be compared with controls to establish whether it has any affect on patient
care.

1.4.3 Research

Although the primary function of the MR is not as a research tool, retrieval
of information from it is crucial for many research projects [Clements
1992]. Suitable cases may be identified or the frequency of particular
diagnoses noted, allowing researchers to identify potential study subjects
or establish whether a centre has enough cases for the study to be
conducted there. It can also be used as the source of information for case
control studies [Black 1996].
Lack of structure in the MR can hamper retrieval of information making it time consuming and inefficient [Nygren 1998]. Also if information is documented but not given a context e.g. a treatment is documented but without an explanation of why it was chosen, this can render the information useless for research purposes [Wyatt 1994]. As highlighted previously (section 1.3.3) it is often difficult to obtain the MR, therefore, the population of available MRs may not always represent the true population [Williams 1990]. This potential selection bias along with the lack of structure and context in routinely recorded clinical information has limited the use of retrospective studies of MRs to answer research questions [Anderson 1994]. Instead research projects have required large investments in prospective data collection using mechanisms separate from those routinely available in the hospitals (MRs, theatre database, patient administration system). In a recent discussion in the Lancet, Black suggested the development of high quality clinical databases as a way of reducing the cost of prospective data collection [Black 1999].

1.4.4 Medico-legal

In Britain the incidence of medico-legal cases is increasing rapidly. The MR is now regarded as a medico-legal document [McCaman 1979]. Regardless of the case or specialty involved the MR is scrutinised by lawyers of both sides [Wiemerslage 1983]. It is often found to be incomplete and inaccurate in the information it contains (section
1.3.1) [Gibbs 1989]. Poorly kept MRs are one of the main reasons for a case being lost or settled out of court [Weintraub 1999] [Knowles 1995]. This is particularly true for the highly litigious specialty of O&G. The need for detailed and accurate MRs in O&G has been emphasised and recommendations for their completion and regular audit suggested as a means of risk management [Medical Defence Union 1991]. Similar articles have been published in other specialties.

An American study analysed ophthalmic malpractice lawsuits which had led to large monetary awards in order to identify factors that may be important in risk prevention [Kraushar 1996]. The operations and diagnoses most frequently associated with claims were described. In addition the detrimental effect on defence of claims from incomplete (8%) or altered MR (8%) was reported.

In a review of 1000 emergency department cases of emergency detention of psychiatric patients Reeves et al found that in 4.2% of the cases documentation of either the mental state examination or reason for detention was inadequate [Reeves 1998]. This has clear implications for civil liberties and medico-legal claims in the future.

In the past some authors have felt that there should not be any specific requirements from a clinicians MRs other than that he can show a reasonable standard of care [Powers 1994]. However, more recently the legal requirements for MR documentation have been discussed in special
legally themed issues of journals (usually surgical) [Gorney 1999; Bramley 2000]. Often these editions contain advice from a lawyer or medico-legal expert regarding the pitfalls and legal aspects of medical documentation.

In a special legal edition of *Clinics of Plastic Surgery* 1999 Gorney et al state that a doctors’ hand-written entry that includes the entry’s date and time can make the difference between a totally defensible case and one that is lost. They then go on to advise against changing the MR in the event of an adverse incident and describe the forensic methods that can be used to detect this. The complexity and sophistication of these tests indicate the importance with which the MR is regarded in American law.

In a special medico-legal issue of the *British Journal of Urology International* 2000 Bramley discusses all legal aspects of MRs in the UK including documentation, confidentiality and access [Bramley 2000]. He recommends the use of black ink and that all alterations are signed, timed and dated. The need for legible handwriting is emphasised and because of the difficulty in interpretation of abbreviations, their use is strongly discouraged. [Lyons 1998].

### 1.4.5 Management

Although they rarely consult the MR directly, managers are interested in the information it contains in terms of waiting list planning, bed allocation
and staffing levels [Goldacre 1983]. The information used for these tasks is usually taken from hospital administrative systems, the accuracy of which relies on that of the MR [Kenny 1999, Jarman 1999, Mant 1997, Ballaro 2000]. The quality of the information in the MR is, therefore, of value to the managerial staff even though they may not retrieve it from the MR directly.

High quality information about patients is the foundation for decisions at all levels in a health care system [Wyatt 1995]. The Audit Commission report "For your Information" revealed a wide variation in investment in information management between acute hospitals [Audit Commission 1995]. It identified that chief executives, boards and senior managers often fail to appreciate the potential benefits of good information or the costs and negative impact of poor information. In the report recommendations were made for hospital boards in the planning, investment and evaluation of both current and future systems of information management.

1.5 Attempts to change the medical record

There have been attempts to structure the MR. These have recognised the need for structure to improve both the documentation and retrieval of information. They have not, however, become the standard method of recording clinical information because they have not managed to be flexible enough to encompass all disease states.
1.5.1 Problem orientated medical records (POMR)

The problem orientated record (POMR) was first proposed by Weed in 1968 [Weed 1968]. It differed from traditional methods by considering the patient in a more holistic manner. The POMR comprised a problem list, which was revised frequently during a patient's stay with titled progress notes. The acronym SOAP (Subjective, Objective, Assessment, and Plan of treatment) was introduced as the format to use in a POMR. The proposed advantages of this method when compared with traditional documentation were the ease with which another clinician reading the notes could grasp the essential features of a case and the improved retrieval of information for research, audit and teaching. Weed recognised that computers would become a means of organising and sorting information for clinicians in the future, but that the crucial step of structuring the MR was necessary before this could be achieved [Weed 1968].

After publication of this article POMRs became popular and were widely adopted, however, there were few objective studies comparing them with traditional narrative records (TNR) until 1974 when Fletcher compared the speed and accuracy of each type of record [Fletcher 1974]. Four complex case histories from recent admissions were documented in both POMR and TNR formats. The validity of the formats was confirmed by three independent reviewers and the complexity of the cases found to be higher than average when compared with random samples of other ward patients'
records. 10 multiple-choice questions (MCQ) were prepared to test the factual content of each of the histories.

2 groups of clinicians were selected from 2 hospitals, one where clinicians had been using and liked the POMR (18 clinicians) and the other where POMRs had been used but the clinicians had not expressed a preference (18 clinicians). Outcomes measured were time in seconds to read the record and answer the MCQs, number of correct answers and identification of errors in medical care. In the group that had used POMRs and preferred them there was no difference in any of the outcomes whereas in the other group the POMR took significantly longer (8%) to read than the TNR. Interestingly although the "enthusiasts" felt that they could abstract quicker from the POMR than the TNR the opposite was true for 13 of the 18 clinicians. Also only 1/3 of the medical errors was detected by all 36 clinicians.

The authors felt that the false environment of the study may have contributed to the lack of difference found for most of the outcomes. They also recognised that there may be other advantages to using a POMR that were not tested in this study. It is difficult to draw any firm conclusions regarding the outcomes measured in this study as the sample size may not have been large enough to detect any differences between the two methods.
After Weed’s paper was published there was a particularly high uptake of POMRs in rehabilitation centres in the United States. Of the 238 institutes questioned in 1977, 155 had some experience of using them despite the lack of evidence that they were more beneficial than traditional records [Reinstein 1977]. In the UK the effect of using a POMR on clinical management was evaluated across 28 firms in 3 London teaching hospitals [Fernow 1978]. The findings suggested that POMR might have improved the thoroughness of patient management. When medical students in the UK were asked for their opinion regarding POMR and TNR the majority preferred the former, however, they were still encouraged and taught how to use the TNR [Burroughs 1978].

Although POMRs were introduced over 30 years ago and are still used their benefits have not been proven in any high quality studies [Wyatt 1994]. The original SOAP structure of the POMR has been re-evaluated in recent years with the introduction of computerised medical records [Salmon 1996]. A new structure called the problem focused medical record using the headings of Orientation. History, Exam, Assessment and Plan (OHEAP) has been suggested as a way of bringing the POMR up to date [Meyers 1998].
1.5.2 Integrated care pathways

Integrated care pathways (ICP) or clinical pathways (CP) were introduced into the UK in the late 1980s as part of a general move in the National Health Service (NHS) towards cost effectiveness, efficiency, quality and evidence based practice [Middleton 1998]. They are multi-disciplinary documents that detail the expected care and progress of a patient with a particular condition or undergoing a specific procedure [Campbell 1998]. They are used both to support standardised care of patients and for documentation instead of the MR. Although ICPs are standardised documents they frequently reflect the nuances of care in an individual institution i.e. availability of certain diagnostic tests, therefore, most of them are not easily transferable to another unit. Thus despite the development of ICPs for many conditions and procedures, existing ones are often used merely as a template for adaptation to the local circumstance. ICPs now form part of the government agenda for improving the quality of care within the NHS with their development set as a target for Trusts [NHS Executive 1998]. This has resulted in many trusts setting up a “care pathways” team [Ellis 1997].

The aims of ICPs are:

- Facilitate the use of national guidelines in clinical practice
- Provision of high quality information for audit
- Improve multi-disciplinary communication and care
- Reach or exceed existing standards of care
• Decrease unwanted practice variation

• Improve clinician-patient interaction and patient satisfaction

• Identify research and development questions

The ICP is used for documentation by all those involved in the patient’s care, kept at the end of the bed during the patient’s admission, then filed as part of the patient’s MR after discharge. Pathways are designed to require the minimum amount of freetext hand-written documentation, instead checklists are used with tick boxes to record that an event or intervention has taken place. However, there is also space to note any variation from the expected path and the reasons for this. These variations are analysed regularly and used to refine the pathway and / or clinical practice [Kitchiner 1996]. This method of structured precoded documentation results in uniform, legible records from which information can be easily extracted i.e. for audit or research.

There are ICPs for over 45 conditions or procedures in the UK, many of which are in surgical specialties because of the more predictable care [Barker1999;Rossiter 1995;Kelly 2000;Pestian 1998]. There have been many reports in the literature from groups describing their experience of developing and implementing an ICP. Most of these, however, have been uncontrolled before and after studies. Those that have claimed to randomise patients have mainly done so in an “ad hoc” fashion. Reported benefits have been uptake of national guidelines, reduced costs of patient care, improved patient outcomes, increased patient satisfaction, improved
communication between doctors and nurses, increased participation of patients in their own care and reduction in time spent by staff carrying out paperwork [Kitchiner 1998].

The only formal randomised controlled trial comparing the ICP with the traditional medical record was performed by Dowsey et al [Dowsey 1999]. 163 patients undergoing hip and knee arthroplasty over a 1 year period were randomly allocated to either a control (71) or ICP (92) group. Outcomes used were length of stay, time sitting out of bed and ambulation, complications, readmission and delayed discharge. They found that length of stay was significantly shorter for the pathway than the control group with no increase in complication or readmission rates. This was the first scientific evidence for the benefit of using an ICP.

Another study was performed by the same group using ICPs for fractured neck of femur [Choong 2000]. 111 patients were allocated using their hospital number, odd to control (56), even to ICP (55) group. A power calculation was performed to determine the number of patients needed to show a reduction in length of stay of a third at a significance level of 0.05. Outcomes measured were duration of stay, inpatient complications and post discharge complications or re-admissions. Length of stay was significantly reduced in the ICP group from 8 to 6.6 days, however, they found no difference between the groups for the other outcomes. Although the authors were unable to comment on the cost effectiveness of using the
ICP as the study was not designed to measure this a reduction in cost can be assumed from the reduced length of stay.

These two studies were the most rigorous in their assessment of ICPs, however, interesting benefits have been found in other papers. Use of ICPs for elective surgical and acute medical admissions was found to result in fewer investigations being ordered [Board 2000]. This was a limited study, however, as the authors did not perform a cost analysis and made no comment as to the outcome of these patients.

In contrast Markey et al tried to ascertain the effect of ICPs on cost for patients undergoing thyroidectomy and parathyroidectomies, by comparing costs over 2 financial years [Markey 2000]. The length of stay and hospital costs were compared with patients undergoing the same procedures the previous year. A reduction of 37.5% in length of stay and 15% for hospital costs was shown for the parathyroidectomy cases and a reduction of 14% in length of stay and 0.2% for hospital costs in the thyroidectomy group using the ICPs. However, these differences were not statistically significant. This may have been due to the relatively small numbers of patients involved, 41 in the ICP group and 55 in the control. A 10% reduction in cost was also reported by Kelly et al in a case-control study of using a paediatric ICP [Kelly].

There is growing enthusiasm for ICPs at present, much of which has been stimulated by their anticipated benefits. Whilst these have been reported in
descriptive studies there is a paucity of rigorous evidence to support them. It is possible that the mere exercise of developing a pathway in facilitating multi-disciplinary teamwork is beneficial in itself. However, further work is required to demonstrate that using a pathway confers the benefits claimed by enthusiasts and that its use does not adversely affect patient care i.e. that it is “safe” to use.

1.5.3 Proformas

Proformas are structured forms used to record clinical information. They have been used in a variety of clinical settings; as data collection tools for audit or research, templates for patient consultations and laboratory reports.

Thorpe et al used proformas to abstract data retrospectively from medical records, operation lists and theatre books on the documentation of information given to all patients undergoing transurethral resection of prostate, regarding the potential adverse effect of the operation on sexual function [Thorpe 1994]. Magee et al used proformas for the prospective collection of data during an audit of theatre delays for general surgery emergencies [Magee 1995]. The benefits of using proformas for prospective audit compared with retrospective review of MRs has also been demonstrated in the increased rate of complications reporting [Eardley 1993; Ryan 1997].
Proformas were designed for paediatric health maintenance encounters in one American hospital [Shiffman 1999]. For a short period of time both the proformas and the traditional narrative record (TNR) were in use, then the proformas alone were used. The difference in documentation between the two was evaluated for a small number of patients (32). Overall more data elements were documented in the proforma alone group than the TNR group. This study is an example of the benefits of using proformas to replace the TNR albeit in a limited setting.

One particular aspect of the patient consultation was evaluated by McCahy et al [McCahy 1997]. They wanted to determine the accuracy of information regarding documentation of certain occupations (e.g. aniline dye, rubber industry) known to be risk factors for patients with transitional cell carcinoma (TCC) of the bladder. 108 patients with known TCC were re-interviewed and the consultation recorded on a proforma. The proforma was then compared with the TNR. Occupations that may have been significant in the aetiology of the TCC were omitted in 71% of TNRs and no occupational history was recorded in 12%. The authors concluded that this information may have been useful for financial redress and future research and recommended, therefore, that a proforma be used in the future. It is unclear from this study what effect recall bias may have had when re-interviewing the same patients.

Documentation using proformas versus TNRs were compared by Marill et al in an American A&E department [Marill 1999]. Over sixteen days 1,228
patients were randomised using their hospital number. Outcomes measured were total time that the clinicians spent with the patient, clinicians professional billing (based on procedure coding) and clinicians satisfaction. The difference in time was not significant between the two groups. Gross billing was higher in the proforma group due to more accurate coding. All the clinicians preferred the proforma system. The authors concede that this study only compared the proforma with the hand-written part of the TNR and that many clinicians were also starting to combine this with dictation and voice recognition.

Complaint specific proformas were used in a separate study of an A&E department [Wrenn 1993]. These were developed following prospective audit of the content of documentation for 4 common A&E complaints; laceration, pharyngitis, asthma, closed-head injury. The proformas were substituted for the TNR and their use was followed observationally. The proforma significantly improved the completeness of documentation for some but not all items when compared with the TNR. As discussed in the paper, this was an observational study in which clinicians chose their preferred method of documentation. Not all of the differences seen can, therefore, be attributed to the proforma alone as they may not have been used for the more complex cases and may have been used by clinicians who were already more meticulous in record keeping. This study highlights the value of proformas to ensure complete documentation for specific diseases.
The use of a proforma as a prompt has been evaluated for pre-clerking in an admission clinic. The accuracy of documentation in such a clinic was compared for a specialist nurse using a proforma versus a pre-registration house officer (PRHO) using a TNR [Whiteley 1997]. 100 consecutive patients undergoing surgery on varicose veins, hernia, gallbladder or colon were recruited. Patients were seen by the specialist nurse first then the PRHO. After the operation the documentation of each were compared and the accuracy of the history, examination and investigations determined. The specialist nurse performed as well as the PRHO for all but the following aspects of the clerking: drug dosage, frequency, allergies, social, alcohol and smoking history. Omission of drug dosage, frequency and allergies may be explained by their absence from the proforma. Whitely et al have, therefore, shown the potential for using a proforma for pre-clerking in the admission clinic but also the danger of missing important features of the clerking if these items are not included in the proforma. It would be interesting to conduct a similar study but compare the standard of documentation with both the PRHO and the specialist nurse using the proforma.

The use of proformas to improve reporting in specialties such as pathology and radiology has also been described [Elahi 1996]. Cross et al studied the effect of four interventions on the inclusion of data items for reporting of colorectal cancer [Cross 1998]. They noted that when a proforma was used 100% of the required data items were recorded. Rigby et al compared pathology reports on 98 patients who underwent surgery for colorectal
cancer in a 15 month period both before and after introduction of a proforma [Rigby 1999]. In addition to the usual free text report, reporting pathologists also completed a proforma report. The completeness of 12 items deemed essential by the Association of Coloproctology (ACP) was then assessed for both the free text (54 patients) and proforma (44 patients) reports. 85% of free text reports had one or more items missing compared with 15% of the proforma reports. This is a relatively small study in one disease process at one hospital and does not comment on how many pathologists were involved but it did show that the comprehensiveness of pathological reporting (in particular resection margin and apical node status) was improved by the introduction of the proforma.

A novel method of proforma use is via the internet [Pal 1999]. A rheumatology proforma was placed on the hospital website and GPs were invited to complete it and e-mail it back to the authors. A consultant reviewed the GP version. The majority of diagnoses, investigations requested and treatments suggested were the same for the GPs and consultant. Thus supporting the concept of an internet based consultation and advisory service in rheumatology and perhaps in the future other specialties.

The benefits of using proformas to record structured clinical data are recognised but their use has been limited to specific diseases or procedures and has often been recommended in addition to the TNR. The extra time to
write in both the TNR and the proforma has, therefore, hampered their widespread use. They could be used in more general settings as a replacement for the TNR but this has yet to be evaluated.

1.6 Summary of introduction and historical review

This review describes the historical change in the function of the medical record over hundreds of years. It has changed from being notes made as an aide memoire for the individual clinician to the systematic documentation of clinical details for use in teaching and academic meetings. With the development of teaching hospitals came the unit system (i.e. one set of medical records per patient) to simplify documentation and improve the sharing of information between clinicians.

Current medial records have a variety of means of recording information; handwriting, typed text, diagrams, pictures, tables, graphs and images. There have been many guidelines published to improve and standardise the structure, content and maintenance of the medical record. Despite these, limitations of the MR have been identified which have led to adverse consequences for; communication, clinical governance, research, legal and management.

Previous attempts at improving the medical record (POMR, ICP, proforma) have been limited by their failure to scientifically demonstrate
the benefits claimed, requirement for increased effort and more time to complete. It has been demonstrated that there is still plenty of scope for improvement in the current medical record. In particular there is a need for a simple structured medical record that can be completed prospectively.
Chapter II

Aims and objectives
Medical records (MR) have become multidisciplinary tools. They aid communication, inform clinical governance, provide evidence for medico-legal claims and form the basis of clinical research. However, the quality of documentation in them remains poor and their lack of structure inhibits the retrieval of information.

Previous attempts to structure the medical record (POMR, ICP and proforma) have achieved limited success. All have required agreement about how to structure the MR and the information that should be documented. Various benefits have been attributed to the use of these specialised records; increased completeness and accuracy of documentation, reduced ordering of investigations, improved use of guidelines and uptake of evidence based medicine, decreased cost of patient care and easier retrieval of information for audit and research. Few of these benefits have been proved by scientifically conducted trials, instead evidence is based on reports of experience from enthusiasts.

The use of structured forms (proformas) has been shown to both improve the quality of documentation and facilitate retrospective analysis but they have usually been used in addition to the MR. This practice has restricted their use to the documentation of detailed information on a specific disease or set of symptoms or collection of data in the context of audit or research. Duplication of data in this manner is labour intensive and expensive, consuming most of the budget for a research or audit project.
If the traditional narrative medical record (TNR) were to be replaced by structured forms, the benefits described above might be realised and duplication avoided. Any substitution of the TNR should be formally evaluated. This thesis describes the evaluation of the development and implementation of structured forms to achieve a structured medical record (SMR) throughout one specialty (urology). This specialty was chosen for the study because of the clinical background of the investigator.

Aim of thesis

To design, implement and evaluate a structured medical record in urology.

Objectives of thesis

- Agree a minimum dataset in urology.
- Design a SMR around the dataset.
- Compare the completeness of documentation of key clinical information when using SMR versus TNR.
- Determine the time taken to use SMR versus TNR.
- Implement the SMR in routine clinical practice in a variety of settings (i.e. ward, outpatients, theatre).
- Assess acceptability of the SMR.
Chapter III

The design and piloting of a structured medical record in urology
3.1 Methods

3.1.1 Study population and setting

The structured medical record (SMR) was designed and piloted with clinicians in a large urology department in a teaching hospital (Institute of Urology, University College Hospital).

3.1.2 Designing the structured medical record (SMR)

Structured forms replaced the hand-written part of the medical record. These forms were intended for use instead of writing in the traditional narrative record (TNR), thereby achieving a structured medical record (SMR). In the context of this thesis the SMR, therefore, refers to forms substituted for the blank page on which clinicians have traditionally documented information rather than the overall structure of the medical record. TNR refers to the existing unstructured, prose style of clinical entry in the medical record.

Prior to creating the forms, design decisions had to be made in three main areas:

- Hierarchy i.e. structure of the record to accommodate different health care settings, diseases, organs and symptoms.
• *Content* i.e. a minimum dataset of clinical information to be recorded.

• *Response coding* i.e. methods of documenting specific items of information.

**Hierarchy**

The hierarchy issue was most critical in the out-patient setting because inpatient settings (ward and theatre) were more predictable with respect to the information to be recorded. Out-patient traditional narrative records (TNR) were sampled to establish what type of information was already being recorded. Analysis of these records revealed that the information recorded in out-patients records e.g. investigations requested is often conditional on information recorded earlier e.g. presenting symptoms and clinical signs, creating a hierarchy of information. As the consultation progresses, the number of conditional “branches” can result in a very large number of possible permutations. With traditional narrative records the “blank page” is flexible enough to accommodate any patient consultation regardless of the presenting health problem. Ideally a structured record needs to have the same flexibility but in a pre-coded fashion.

A single structured form that could cover any health problem would be too cumbersome for routine clinical practice. To incorporate all the possible options for any given patient attending an outpatient consultation the form would have to include many data items and, therefore, be very complicated, lengthy and unwieldy. To overcome this issue a hierarchy of
forms was required, such that a relevant form could be chosen at key points in the management of a patient's condition thus "tailoring" the information to be recorded for a particular patient whilst minimising the complexity and length of the form.

Content

A focus group discussed the anticipated content of the forms. Draft forms were designed on the basis of the deliberations of the focus group and then interviews with consultant urologists were scheduled to discuss refinements. The forms were revised to accommodate comments and suggestions and then piloted. A second focus group discussed users' experiences with the forms, which led to further revisions and a second phase of piloting.

Response coding

There were three main ways in which information could be documented (Figure 3.1.2.a):

- pre-coded responses (tickboxes)
- uncoded responses (freetext boxes)
- numeric responses (number objects)
Figure 3.1.2.a - Example of part of a form showing the different response coding

**Tickboxes**

<table>
<thead>
<tr>
<th>Presenting complaint</th>
<th>other +/- details of presenting complaint</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUTS</td>
<td>$\checkmark$</td>
</tr>
<tr>
<td>Haematuria</td>
<td></td>
</tr>
<tr>
<td>Loin pain</td>
<td></td>
</tr>
<tr>
<td>Dysuria</td>
<td></td>
</tr>
<tr>
<td>Incontinence</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

$\text{Use blank scannable page if more space required for history}$

<table>
<thead>
<tr>
<th>IPSS (0 - 35)</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Life (0 - 6)</td>
<td>2</td>
</tr>
</tbody>
</table>

*Number objects*
Numeric information was relatively straightforward as it commonly existed in this format already and could be merely transcribed into the record e.g. blood biochemistry. It was considered important to record raw numeric data wherever possible rather than categorising the data, as this would allow flexibility when analysing it in the future. The crucial choices, therefore, were between pre-coded (tickbox) and uncoded (freetext) responses. Where a precoded response was used, consideration as to whether more than one code i.e. single or multiple responses could be chosen by the clinician was necessary. Some of the pre-coded responses were multiple response whereas others allowed only a single response (Figure 3.1.2.b).

3.1.3 Outcomes measured

Simple qualitative evaluation was conducted during piloting of the forms when the following were observed:

- Ease of selecting the correct form
- Ease of completing the forms
- Effect of using forms on the consultation
Figure 3.1.2.b - Example of part of a form showing a single response question

ASA grade

1  2  3  4  5

1= healthy  2= mild systemic disease  3= severe systemic disease (not incapacitating)  
4= incapacitating systemic disease (constant threat to life)  5= moribund
3.2 Results

Out-patient forms (7 forms) were designed first. A lot of the design issues encountered were equally important in the development of the inpatient forms (3 forms). Consequently the latter were designed more efficiently. A consultant from each of the urology specialties (see below) was involved in the initial design and refinement of the relevant out-patient form. This phase took from 1 month to 3 months depending on the complexity of the form. All staff were given the opportunity to comment on and change the inpatient and out-patient forms either via the focus group discussions or during piloting. Nine consultants, 9 registrars, 5 senior house officers and 6 clinical nurse practitioners in urology used the forms.

Focus group

A focus group was established to consider the dataset to be recorded, design of the forms and to feedback users views [Kitzinger 1995]. There were 2 focus groups each consisting of 4 members, one for development of the out-patient forms (group 1) and the other for the inpatient forms (group 2). Group 1 consisted of a consultant, registrar, senior house officer and clinical nurse practitioner. Group 2 consisted of a senior house officer and 3 clinical nurse practitioners. Both groups met regularly to discuss the experiences of piloting the forms and to feedback any issues to the research fellow.
The other method of communication with users was a weekly departmental meeting. This was attended by all members of the department; consultants, registrars, senior house officers, clinical nurse practitioners, ward sisters, ward nurses, specialist nurses and departmental manager. Presentations of the forms were made during these meetings and comments solicited.

3.2.1 General design decisions

Hierarchy (out-patient forms only)

During the sampling of traditional narrative out-patient records it was noted that information documented for a new patient was similar regardless of the diagnosis but that information recorded at follow-up visits varied considerably. From this observation, it was decided to adopt a generic new patient form to record the new out-patient consultation and use specific forms at follow up.

Following focus group discussions, four main options for the recording of information at follow up consultations emerged, the relative advantages and disadvantages of which are shown in Table 3.2.1.a. Initially organ specific forms were chosen, as they were believed to represent the simplest structure. After piloting it became obvious that although an easy anatomical distinction existed there were too many common conditions that involved more than one organ to make this a practical option.
<table>
<thead>
<tr>
<th></th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease specific</td>
<td>Patient usually has only one disease</td>
<td>Patient with more than one disease would need two forms for one consultation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disease unknown when patient first presents, therefore, unable to use a form</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Many diseases, could not have a form for each, so would have to be grouped</td>
</tr>
<tr>
<td>Organ Specific</td>
<td>Limited number of organs in urology</td>
<td>Organ unknown with new patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td>More than one organ involved i.e. transitional cell carcinoma (TCC) of the</td>
</tr>
<tr>
<td></td>
<td></td>
<td>bladder, kidney and ureters</td>
</tr>
<tr>
<td>Symptom specific</td>
<td>Synchronise with GP letter description</td>
<td>Symptoms not exclusive to one disease i.e. haematuria could be due to bladder</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TCC, renal cell carcinoma, urinary tract infection or haemorrhage from prostate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No obvious way to pool symptoms</td>
</tr>
<tr>
<td>Subspecialty specific</td>
<td>Familiar subdivision as Consultants are often</td>
<td>Idiosyncratic division based on symptoms and disease</td>
</tr>
<tr>
<td></td>
<td>subspecialists,</td>
<td></td>
</tr>
</tbody>
</table>
Symptom specific forms were considered next but as they were not exclusive to one disease and a method of grouping them could not be agreed this option was not even piloted. Disease specific forms had the advantage that most people have only one disease but there was no consensus as to how they should be grouped, as it would not be possible to have a form per disease. To overcome this problem, subspecialty specific forms were chosen as being essentially disease based but taking advantage of an existing structure familiar to clinicians. The interactions of the forms in the hierarchy used are shown in Figure 3.2.1. The new out-patient form was used only for the first consultation, thereafter one of the subspecialty follow up forms was used i.e. lower urinary tract symptoms (LUTS). Each subsequent consultation may then be documented on the same follow up form or the nature of the suspected pathology may change and a different form be used i.e. Oncology.

Content

The content of the forms was based on the clinical experience of the consultants interviewed and the focus group participants. A consensus was reached on the level of detail required. After the content of the form had been agreed the layout was debated. Although it was important to keep the forms as short as possible it was necessary to use more than 2 sides for some of them to accommodate the amount of “freetext” required and also to space out the responses to make it easier for the clinicians completing the forms.
Figure 3.2.1 - Inter-relationship of forms used

New out-patient form

Follow up forms

General (LUTS)  Oncology  Erectile dysfunction  Female urology  Stone

New in-patient form

Operation note

Continuation sheet
Response coding

The advantages and disadvantages of the three main options for documenting information are summarised in Table 3.2.1.b. The extent to which each response type was used varied according to the form. Difficult compromises sometimes had to be reached between clinicians who required extensive coding and those who wanted to retain the freedom to record prose style observations. Forms initially contained a lot of coding but during piloting it was noted that many of the coded response options were not used and the balance between coded responses and freetext shifted to freetext in later versions.

3.2.2 Out-patient form designs

New out-patients

This was the first form developed and most of the relevant design issues were encountered during its development. Lessons learnt were applied to the design of subsequent forms, which were, therefore, finalised more quickly. Using the new patient consultations sampled from the TNR a dataset of information required for the new urology patient was agreed between one consultant and the research fellow. Initially it was considered important to keep forms short, 2 sides if possible. To achieve this the free text spaces were small and most of the information was coded.
Table 3.2.1.b – Comparison of advantages and disadvantages of different response coding

<table>
<thead>
<tr>
<th></th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-coded</strong></td>
<td>Standardises the information to be recorded</td>
<td>Cumbersome as covering all eventualities</td>
</tr>
<tr>
<td></td>
<td>Stops idiosyncratic styles of recording</td>
<td>Inefficient use of space to record on event</td>
</tr>
<tr>
<td></td>
<td>Legible</td>
<td>Have to agree on terms beforehand</td>
</tr>
<tr>
<td></td>
<td>Allows quick recording of information</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quick retrieval of information</td>
<td></td>
</tr>
<tr>
<td><strong>Numeric</strong></td>
<td>Economical use of space</td>
<td>Only suitable for certain data</td>
</tr>
<tr>
<td></td>
<td>Allows use of hand-written entry</td>
<td>May be illegible</td>
</tr>
<tr>
<td></td>
<td>Quick location of information</td>
<td></td>
</tr>
<tr>
<td><strong>Freetext</strong></td>
<td>Flexible, versatile style of documentation</td>
<td>May be illegible</td>
</tr>
<tr>
<td></td>
<td>Efficient use of space</td>
<td>Slow retrieval of information</td>
</tr>
<tr>
<td></td>
<td>Allows for the unusual or complex patient</td>
<td>Unstandardised recording of information</td>
</tr>
<tr>
<td></td>
<td>Familiar style</td>
<td></td>
</tr>
</tbody>
</table>
Information was grouped under headings used in the TNR and which, therefore, were familiar to clinicians; presenting complaint, previous surgery, past medical history, family history, drug history, allergies, social history, examination, investigations, diagnosis, treatment and outcome [Bourne 1931]

The first draft of the form incorporated detailed coding of previous urological operations and examination findings (Appendix 3.2.2.a). All of the data items were very close together. This draft was piloted in one clinic with the research fellow sitting in on consultations to observe at first hand any comments or problems experienced by users. Following this pilot it was obvious that there were a few problems; there was not enough room for free text comments, tickboxes were too close together so that ticks often went through adjacent boxes and coding of examination was felt to be too detailed and inflexible.

In response to these observations and comments by users, a second draft of the form was produced. The detailed coding of surgical history was removed creating more space on the form whilst keeping it the same length (2 sides). The extra space was used to increase the size of the freetext boxes. In addition tickboxes were staggered to avoid completion errors. The most common presenting complaints were pre-coded using tickboxes but the option to enter freetext as well was preserved.
Further refinement was required after piloting and, therefore, a third draft of the form was designed. This version was longer (3 sides) allowing more room for freetext and more space between tickboxes. Data items were grouped under the section headings described earlier e.g. drug history, and enclosed inside a box (Appendix 3.2.2.b). Grouping similar information was aimed at helping users to identify relevant sections quickly either during completion of the form or when retrieving information. Minor changes to the spacing of text were made and the form piloted. Some clinicians (particularly the junior trainees) felt that there was not enough freetext space, but most found it to be adequate.

Further modifications were made on the basis of users’ suggestions before production of a fourth draft (Appendix 3.2.2.c). In this draft the boxes grouping the sections were removed. Doctor’s ID was changed to initials as clinicians were finding it difficult to remember their ID consistently. Consultant’s name was changed to their clinic code, as this was shorter and unique to the clinic. The IPSS (International prostate symptom score), a patient completed symptom questionnaire was included. Whilst observing users it was noted that they tended to ask patients how many cigarettes they smoked before how long they had been a smoker. The boxes to record this information were presented in the opposite order, which was both a minor source of irritation and confusion for users. The order of the boxes was, therefore, changed to reflect the usual pattern of the consultation and improve accuracy of completion. The ASA (American Society of Anaesthesiology) score was introduced as a measure of
outpatient case-mix in order to allow case-mix to be considered in any statistical analysis of the data. The selection of pre-coded drugs was reduced to include the most frequently taken and most relevant e.g. anticoagulants. The option to record “none” under past medical history, previous operations, family history, drug history and investigations was included using a tickbox. This was to distinguish between the relevant question being asked but having nothing relevant to record (none ticked) and the question never having been asked (blank section). A freetext box to record patient information was also included along with a wider variety of consultation outcomes; follow up after investigation, open appointment, admit and book operation – local anaesthetic (LA) or general anaesthetic (GA).

After piloting of the fourth draft the final version of the form was produced (Appendix 3.2.2.d). This was printed in a more professional style using a coloured band down the right hand side of the page, with writing down the side as well. It was double sided and incorporated the departmental logo at the top of the page. Shading around the section boxes was piloted but not used because clinicians found it a distraction rather than an aid to completion. The typeface was changed and the boxes grouping sections were re instituted after demand from users.

The time was removed, as it was agreed that patients were unlikely to have more than one urology new patient consultation in one day and, therefore, the date alone would suffice. During piloting it had been noted that
clinicians either did not know or could not remember the consultants clinic
code. This was changed to consultant’s initials instead for brevity and ease
of remembering. The space for the patient label was moved to the top right
rather than left-hand side of the first side as this made it easier to spot the
patient’s details when searching through the records. Urinalysis was
performed on all new patients attending a urology clinic. A section to
record this was, therefore, incorporated. The symptom score could not be
completed by some patients and was not applicable to others; tickboxes to
reflect this were added.

Under past medical history clinicians had been merely grouping the type
of problem into a category; cardiac, endocrine, neurological, respiratory,
trauma and vascular. The specific disease was then recorded in the freetext
box. From all the diseases recorded during the pilots the most frequent
were chosen and used as pre-coded items in the past medical history;
hypertension, IHD (ischaemic heart disease), diabetes, COAD (chronic
obstructive airways disease), asthma and CVA (cerebrovascular accident).

Categorising alcohol consumption into mild, moderate and severe was
abandoned in favour of simply recording the number of units consumed.
This was considered to be less judgmental and easier for the clinicians to
complete. Using the same process as employed for the past medical history
the most frequent diagnoses were calculated and added as pre-coded
tickboxes. When piloted this form met with satisfaction from users and no
further changes were suggested.
Follow up out-patients

Many of the design solutions used to refine the new out-patient form were used during design of the follow out-patient forms. After deciding to use a specialty specific hierarchy a consultant from each specialty was approached for their view on what the dataset for that form should include. Forms were developed in parallel, with the time taken to complete them being between 1 and 3 months depending on the amount of piloting required, consultant availability and form complexity.

All forms followed the same template with regard to the header; patient label, date, consultant initials and Dr / CP initials; outcome; information given and signature. They were all double sided (although they have been reproduced as single sided for display in this thesis) with the departmental logo and a different coloured band down the right hand side for instant recognition and ease of retrieval when filed in the medical record. Data items were grouped under section headings and enclosed inside a box.

Once the follow up forms had reached the final draft stage they were sent to all users and comments invited both in writing and also in the weekly departmental meeting. Few changes were suggested and, therefore, the final draft versions of the forms were implemented.
Lower urinary tract symptoms

A draft was prepared incorporating the data items suggested by the relevant consultant and taking account of the design issues encountered with the new patient form. After piloting, changes to the dataset were made to incorporate patients with strictures. A pre-coded ‘striction’ tickbox was included in the section on presenting complaint and stricture specific investigations were added (Appendix 3.2.2.e). This next draft was the final version of the form used in routine practice.

Oncology

The dataset for this form was taken from the British Association of Urological Surgeons (BAUS) Section of Oncology national registry of new urological tumours (Appendix 3.2.2.f). The BAUS dataset was used to avoid clinicians duplicating data and because it had already undergone a consensus process at national level. The main difficulty encountered with this form was making it flexible enough to incorporate the diversity of follow up, for example, the newly diagnosed oncology patient as well as the patient with a 10-year history of prostate cancer. Errors made in the first draft were omission of a place to record tumour marker results and examination. The content of subsequent forms did not change much but it took five drafts to get the order and expression (in terms of amount of coding used) of data items correct such that the form could be easily understood and completed (Appendix 3.2.2.g).
Female urology

One of the consultants already had a form that was used for female patients in addition to the medical record for personal audit. This form had very little coding so although the general structure was used to design the female urology form, extensive coding was added. In contrast to the other follow up forms part of the examination section was pre-coded, otherwise the same template was followed (Appendix 3.2.2.h). Because of the pre-existing form there was little pilot work and refinement required compared with the previous forms described.

Erectile dysfunction

During discussions with the relevant consultant it became clear that a first consultation and follow up erectile dysfunction form was necessary. The first visit form was used for the first follow up visit only, with subsequent consultations being documented on the follow up erectile dysfunction form. The dataset was agreed and the first draft of the forms designed accordingly. The follow up erectile dysfunction form was only one side in length and contained many of the same data items as the first visit erectile dysfunction form to try and preserve consistency (Appendices 3.2.2.i and j). After piloting the forms were changed to include a patient symptom score (International index of erectile function), the dose of treatment given and the NHS categories for treatment of erectile dysfunction. The forms were piloted with these changes and no further revisions were required.
Stone

The dataset having been agreed, the first draft was designed using the
same template as before and was then piloted. The only part of the form
that caused problems was the description of number and size of stones.
This section was adequate if the patient had only one stone but was
impossible to complete if they had more than one stone. The solution to
this was to have a freetext box to enter the size of the stone next to the
tickbox for its site. After making these changes the final form was
produced (Appendix 3.2.2.k).

Paediatrics

At first the adult forms described above were used for paediatric patients
but it soon became obvious that they were not suitable. Instead specific
paediatric new out-patient and follow up forms were devised. These have
only just started to be used and are still in pilot stages. The main
differences between these forms and their adult counterparts were the
inclusion of height, weight, ethnicity and congenital problems (Appendix
3.2.2.1 and m).
3.2.3 Inpatient form designs

Admission

This form was designed after extensive consultation with all the trainees who were responsible for clerking and admitting patients. The first draft was produced while the new out-patient forms were still being refined and, therefore, contains some of the same mistakes in design (Appendix 3.2.3.a). Nevertheless it acted as a stimulus for further group discussions as to how it could be improved. This particular form went through many small changes, mainly due to the difficulty after the first session of getting all of the users together. This meant that feedback occurred on an ad hoc basis through a combination of small groups and interviews with individuals. Consequently, there were probably more drafts than was desirable.

In the course of several drafts, substantial changes to the layout, coding and size of freetext boxes were made. The history of presenting complaint was enlarged so that it took up about half of the first side of the form. A coded section for urological symptoms was included with yes / no responses to show that the appropriate enquiries had been made. Many of the single tickboxes were changed to yes / no responses to allow clinicians to record a negative answer to each question. This modification overcame the problem of interpreting an empty tick-box, which previously had meant that on reading the SMR it was unclear, for example, whether the
patient was asked and did not have any history of diabetes or was never asked. The systems review section was split into four separate sections; GI (gastro-intestinal), RS (respiratory system), CNS (central nervous system) and CVS (cardiovascular system).

A place to record the temperature had been omitted from the first draft because during the discussions everyone had focused on elective admissions. Since the form was intended to cover emergencies as well a numeric box to record the temperature was included in subsequent drafts. Examination was simplified from four separate sections into one. A pre-op plan and results freetext box was added and the diagnosis box moved from the last side of the form to the first. After a long iterative pilot phase the form was ready for use (Appendix 3.2.3.b).

*Continuation*

In a similar manner to the admission form this underwent many pilot phases only the main stages of which will be described. When designing the first draft there was a desire for extensive coding to provide a rich data source of inpatient recovery patterns (Appendix 3.2.3.c). In particular detailed information regarding complications was requested. During the first stages of piloting it was clear that the form was impossibly complicated and not user friendly.
Suggestions made by users were incorporated into the next draft (Appendix 3.2.3.d). The complex admission days tickboxes were simplified into one box. Milestones were removed as users felt that they took too long to complete and were unlikely to be worth the effort when examined retrospectively. A section for the investigations requested was deemed helpful by users and was, therefore, included.

Despite these changes the form was still too complicated and long. Users were concerned about the length of time to complete the form on busy ward rounds and also by the amount of paper used. Often patients were seen twice a day so that one page (2 sides) of paper was needed every day. The amount of paper used especially for longer stay patients who had very little clinical recovery to be documented per day was felt to add an unacceptable bulk to the medical record. Eventually users chose to revert to an almost blank sheet (Appendix 3.2.3.e).

*Operation note*

The Royal College of Surgeons of England guidelines for operation notes were used to guide the content of the first draft, which was then sent to the whole department for comment (Appendix 3.2.3.f) [Royal College of Surgeons of England 1994]. Boxes for procedure codes were included with the intention of getting surgeons to code operations at source, the aim being to improve coding accuracy [Ballaro 2000, Mant 1997]. This idea was not pursued with further drafts as the training required to change current practice was outside the scope of this thesis. More detail was
requested regarding material left in the patient i.e. drains, stents and packs. Also an explicit space in which to draw diagrams or make extra notes was created on the second side of the form. The final result was then implemented (Appendix 3.2.3.g).

3.2.4 Pilot phase evaluation

*Ease of selecting the correct out-patient form*

Design features were included to ensure that the forms were easy to choose, did not take up too much space and were readily available at the point of care. Different coloured bands were used to distinguish the forms. The bands were placed along the right hand side of the forms so that when the clinician was searching through a set of records they would be easy to find (Table 3.2.4). The name of the form was written in two places; at the top and within the coloured band on the side of the form. A document rack was designed in landscape format to hold the forms so that they were stored separately, the coloured edges of the paper and name of the form could be seen and they were instantly available to the clinicians on their desk without taking up too much room.

Coloured bands and writing along the right hand side of the page were also used for the inpatient forms so that they could be easily located when searching through a set of records.
Table 3.2.4 – Form names and edging colours

<table>
<thead>
<tr>
<th>FORM</th>
<th>COLOUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>OUT-PATIENT</td>
<td></td>
</tr>
<tr>
<td>New patient</td>
<td>Turquoise</td>
</tr>
<tr>
<td>Oncology</td>
<td>Lime green</td>
</tr>
<tr>
<td>Lower urinary tract symptoms</td>
<td>Pink</td>
</tr>
<tr>
<td>Female urology</td>
<td>Green</td>
</tr>
<tr>
<td>Stone</td>
<td>Orange</td>
</tr>
<tr>
<td>Andrology</td>
<td>Brown</td>
</tr>
<tr>
<td>Paediatrics</td>
<td>Yellow</td>
</tr>
<tr>
<td>Transplant</td>
<td>None*</td>
</tr>
</tbody>
</table>

| IN-PATIENT                  |              |
| Admissions sheet            | Purple       |
| Continuation sheet          | Orange       |
| Operation note              | Blue         |

* No form as existing database
During the piloting of the specialty specific out-patient forms, a researcher was present during consultations. It was noted that clinicians were able to select the correct form accurately (98%), confirming that this hierarchy was practical.

*Ease of completing the forms*

Training time to complete the forms was short (15 minutes) but some of the clinicians required a second session to remind them not to write in the traditional notes as well. Clinicians demonstrated a learning curve with respect to the correct completion of the forms because, although the layout of key elements was based on a sample of traditional records, the pattern was different to some clinicians' normal style.

*Impact of scanning on the form design*

Although the forms were primarily being used to structure the handwritten medical record, they were also intended as an intermediate step towards rendering the medical record electronic (electronic patient record). To achieve this they were designed using optical mark technologies which allowed the form to be scanned and each of the boxes to be "read" [Reeves 1999, Schiffman 1999]. This second functionality of the forms thus further complicated their design as completion of the form that might be understood by the human eye had to be clear to the scanner. Several
completion problems that were resolved during the piloting of the forms are described.

When the forms were first implemented some users had put crosses in boxes to indicate negative responses and ticks in the boxes to indicate positive responses. When these forms were optically read after completion the computer was unable to distinguish between a tick and a cross and, therefore, handled both as a positive response. Once this completion error had been detected it was fed back to clinicians who changed their practice accordingly. If the response was positive they put a mark in the tickbox and if it was negative they left it blank. It then became clear, however, that it was sometimes necessary to document a negative response to a question i.e. past medical history of diabetes. This situation was resolved by having a yes/no response to certain data items.

A similar problem was encountered when a response was deemed not applicable to a patient, as some clinicians would strike through the entire section. Although the purpose of this is clear to the human eye, the computer would consider any part of the line that went through a box to be a positive response. This type of completion error was easily corrected by further training of the clinicians.
Effect of using the forms on the consultation

Using the forms did not appear to interfere with the doctor patient interaction. When questioned by the researcher after their consultation, patients were unaware that the clinician was using a different record and did not feel that it had detracted from the consultation.

3.3 Summary of results

A structured medical record (SMR) was successfully achieved using structured forms. These forms were designed using input from clinicians and extensive piloting. They were divided dichotomously into out-patient and inpatient. The out-patient forms were then further divided into a generic new out-patient form and specialty specific follow up forms. The new out-patient form was the first designed and the method of its development and design then used as a template for the creation of the subsequent out-patient and inpatient forms. Each of the follow up out-patient forms were designed with input from a consultant of the relevant specialty and the focus group. The main areas of difficulty encountered; freetext space and agreement of the amount of pre-coded and freetext information were resolved during piloting and a compromise reached.

Following extensive piloting both the out-patient and inpatient forms were successfully implemented in routine clinical practice amongst clinicians of all grades throughout one specialty (urology).
Chapter IV

Randomised controlled trial using the structured versus the traditional medical record for new outpatient consultations
4.1 Methods

4.1.1 Study design

A randomised-controlled trial was designed to compare the use of structured medical record (SMR) versus the traditional narrative record (TNR). Consultations with new patients were randomly assigned to be documented using the SMR or TNR. The randomisation schedule, in blocks of unequal length and stratified by hospital, was prepared by an investigator who was not involved in the allocation process. The research fellow then performed the allocation using consecutively numbered sealed, opaque envelopes. Randomisation was performed as patients booked into the clinic without reference to any details about the patients other than the name. Allocation was delayed until patients arrived to avoid any loss of randomised patients as a consequence of some patients failing to attend the clinic.

4.1.2 Study population and setting

All new patients attending consultations at 1 urology clinic at a Teaching hospital (TH) and 2 clinics at a District General hospital (DGH) from May 1999 to January 2000 were eligible for the trial. Patients were seen by all grades of clinician. Men and women of all ages with general urological problems were seen in the clinics. The consent of patients whose
consultations were included in the study was not sought because the study did not require any change in the provision of care. Approval for the trial was obtained from the ethics committees at both hospitals.

4.1.3 Interventions

Consultations were recorded on history sheets in the traditional manner for patients allocated to the TNR group (control) or structured forms for those allocated to the SMR group (intervention). The forms were designed and developed by the research fellow over the preceding six months by a process of consultation and consensus with urologists of all grades and extensive piloting. (Chapter III)

4.1.4 Outcomes measured

The primary outcome measure in this study was the completeness of 15 items of key clinical information recorded in each type of record (Table 4.1.4). These items were agreed by the clinicians prior to the study. They encompassed both clinical and administrative aspects of documentation. Completeness was assessed simply by whether a key item was present or absent. If there was any evidence of a key item having been documented, e.g. documentation of an examination this item was scored as being present regardless of whether the examination itself was complete.
Table 4.1.4 – Fifteen items of clinical information

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date</td>
</tr>
<tr>
<td>2</td>
<td>Consultant responsible</td>
</tr>
<tr>
<td>3</td>
<td>Patient name</td>
</tr>
<tr>
<td>4</td>
<td>Hospital number</td>
</tr>
<tr>
<td>5</td>
<td>Doctors name</td>
</tr>
<tr>
<td>6</td>
<td>Signature</td>
</tr>
<tr>
<td>7</td>
<td>Presenting complaint</td>
</tr>
<tr>
<td>8</td>
<td>Past medical history</td>
</tr>
<tr>
<td>9</td>
<td>Drug history</td>
</tr>
<tr>
<td>10</td>
<td>Allergies</td>
</tr>
<tr>
<td>11</td>
<td>Social history</td>
</tr>
<tr>
<td>12</td>
<td>Examination</td>
</tr>
<tr>
<td>13</td>
<td>Investigation</td>
</tr>
<tr>
<td>14</td>
<td>Diagnosis</td>
</tr>
<tr>
<td>15</td>
<td>Outcome</td>
</tr>
</tbody>
</table>
A secondary outcome measure was the duration of both the control and intervention group consultations. This outcome was assessed because of concern that using the SMR might lengthen the consultation. The duration of consultations was timed without the knowledge of clinicians. As clinics at the two hospitals were organised differently, the method of timing differed. At the TH, patients were timed going into and out of the consulting room, thus the length of the whole consultation was measured. At the DGH, where clinicians wrote up the consultation after seeing the patient, clinicians were timed from the start to finish of writing their notes.

4.1.5 Sample size and statistical analysis

When designing the study, a 10% improvement in the completeness of documentation was considered worthwhile. It was anticipated that the completeness of documentation with TNRs would vary for the 15 key items and that the difference would also be likely to be less for items already documented well. It was calculated that a total of 400 patients would be required to detect a 10% difference with 80% power at a 5% (two-tailed) significance level when the existing rate of documentation using TNRs was 80%. All calculations and statistical tests were performed using STATA v.7 (Stata Corporation, Texas).

Presence of a key item scored 1 and absence 0. The scores were summed across patients for each item and the percentage calculated. Differences in completeness and 95% confidence intervals (CI) were calculated to
compare documentation using the TNR versus the SMR. Differences in
the average duration of consultations using TNR and SMR were compared
separately for the two clinics using t-tests. Interactions of time period
(first and second half of the study) and intervention were investigated by
multiple regression to investigate possible learning and transfer effects.

4.2 Results

4.2.1 Study population characteristics

Eleven clinicians of varying grades were involved in the study (2
consultants, 5 registrars, 3 senior house officers and 1 clinical nurse
practitioner). Four hundred new patients were randomised, 198 to a SMR
consultation and the other 202 to a TNR consultation. An additional 23
patients attended during the study period when the research fellow was not
present in the clinic. The characteristics of patients in both groups were
similar with regard to age, sex and presenting complaint (Table 4.2.1).
Completeness of clinical information was determined for all the
randomised patients immediately after the clinic.
Table 4.2.1 - Study population characteristics

<table>
<thead>
<tr>
<th></th>
<th>TNR</th>
<th>SMR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Allocation</strong></td>
<td>202</td>
<td>198</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>50.8</td>
<td>52.8</td>
</tr>
<tr>
<td>Std deviation</td>
<td>20.8</td>
<td>20.3</td>
</tr>
<tr>
<td>Std error</td>
<td>1.46</td>
<td>1.44</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>174</td>
<td>168</td>
</tr>
<tr>
<td>Female</td>
<td>28</td>
<td>30</td>
</tr>
<tr>
<td><em>Chi squared p</em>=0.956</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower urinary tract symptoms</td>
<td>68</td>
<td>67</td>
</tr>
<tr>
<td>External genitalia problem</td>
<td>59</td>
<td>53</td>
</tr>
<tr>
<td>Haematuria</td>
<td>21</td>
<td>25</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>23</td>
<td>18</td>
</tr>
<tr>
<td>Pain</td>
<td>18</td>
<td>16</td>
</tr>
<tr>
<td>Cancer</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td><em>Chi squared p</em>=0.714</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.2.2 Evaluation of the completeness of documentation

*Comparison of the completeness of documentation in the TNR versus SMR*

Documentation of the date, doctors name, past medical history, drug history, allergies, social history, diagnosis, outcome and signature were all significantly improved (p<0.0001) by the use of the structured medical (Table 4.2.2.a). Documentation of the patient's name, hospital number, examination findings and investigations requested was also improved, but to a lesser extent (p<0.05). There was no statistically significant difference in completeness for date, consultant responsible and presenting complaint.

*Comparison of the completeness of documentation in the TNR and letter versus the SMR and letter*

During pilot work for the study it became apparent that information is sometimes documented in the letter to the GP but not written in the TNR. It might be argued that, when using TNRs, clinicians are simply being efficient in recording information only once in the medical record. Completeness was, therefore, compared on the basis of the TNR and letter combined versus the SMR and letter combined for a subset of nine items.
Table 4.2.2.a - Comparison of the completeness of documentation in the SMR versus TNR

<table>
<thead>
<tr>
<th></th>
<th>TNR</th>
<th>SMR</th>
<th>Difference 95%</th>
<th>&quot;p&quot; value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>72.8%</td>
<td>89.9%</td>
<td>17.1%</td>
<td>(p&lt;0.0001)</td>
</tr>
<tr>
<td>Consultant responsible</td>
<td>91.6%</td>
<td>90.0%</td>
<td>-0.7%</td>
<td>(p=0.8112)</td>
</tr>
<tr>
<td>Patient name</td>
<td>95.5%</td>
<td>99.5%</td>
<td>4.0%</td>
<td>(p=0.0114)</td>
</tr>
<tr>
<td>Hospital number</td>
<td>88.1%</td>
<td>93.9%</td>
<td>5.8%</td>
<td>(p=0.042)</td>
</tr>
<tr>
<td>Doctors name</td>
<td>24.3%</td>
<td>90.4%</td>
<td>66.1%</td>
<td>(p&lt;0.0001)</td>
</tr>
<tr>
<td>Signature</td>
<td>74.3%</td>
<td>97.4%</td>
<td>23.2%</td>
<td>(p&lt;0.0001)</td>
</tr>
<tr>
<td>Presenting complaint</td>
<td>96.5%</td>
<td>98.5%</td>
<td>2.0%</td>
<td>(p=0.2116)</td>
</tr>
<tr>
<td>Past medical history</td>
<td>69.8%</td>
<td>97.0%</td>
<td>27.1%</td>
<td>(p&lt;0.0001)</td>
</tr>
<tr>
<td>Drug history</td>
<td>53.0%</td>
<td>87.9%</td>
<td>34.9%</td>
<td>(p&lt;0.0001)</td>
</tr>
<tr>
<td>Allergies</td>
<td>32.1%</td>
<td>86.9%</td>
<td>54.7%</td>
<td>(p&lt;0.0001)</td>
</tr>
<tr>
<td>Social history</td>
<td>22.8%</td>
<td>89.4%</td>
<td>66.6%</td>
<td>(p&lt;0.0001)</td>
</tr>
<tr>
<td>Examination</td>
<td>76.2%</td>
<td>85.9%</td>
<td>9.6%</td>
<td>(p=0.0142)</td>
</tr>
<tr>
<td>Investigation</td>
<td>83.1%</td>
<td>91.9%</td>
<td>8.8%</td>
<td>(p=0.0081)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>23.8%</td>
<td>86.4%</td>
<td>62.6%</td>
<td>(p&lt;0.0001)</td>
</tr>
<tr>
<td>Outcome</td>
<td>44.1%</td>
<td>93.9%</td>
<td>49.9%</td>
<td>(p&lt;0.0001)</td>
</tr>
</tbody>
</table>
The significant differences (p<0.0001) in documentation that had been found when comparing just the clinical entry were still found to exist for past medical history, drug history, allergies, social history, examination and diagnosis (Table 4.2.2.b). Investigations and outcome were also documented more frequently in either the SMR or letter (p<0.05) but there was no significant difference in documentation of the presenting complaint.

Comparison of the completeness of documentation in the letter in SMR and TNR groups

Given that there was still a benefit to using the SMR when the letter was taken into account, it was interesting to see whether the method of documentation had any impact on the letter itself. Letters from each group were compared using the same nine items as before. Significant differences (p<0.0001) were found to exist between the completeness of documentation within the letter for the past medical history, drug history and social history (Table 4.2.2.c). The investigations and diagnosis were more complete for the SMR at p<0.05 but there was no statistically significant difference for documentation of the presenting complaint.
Table 4.2.2.b - Comparison of the completeness of documentation in the SMR and letter versus the TNR and letter

<table>
<thead>
<tr>
<th></th>
<th>TNR</th>
<th>SMR</th>
<th>Difference 95%</th>
<th>&quot;p&quot; value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presenting complaint</td>
<td>100.0%</td>
<td>99.5%</td>
<td>-0.5%</td>
<td>p=0.3119</td>
</tr>
<tr>
<td>Past medical history</td>
<td>73.3%</td>
<td>99.0%</td>
<td>25.7%</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Drug history</td>
<td>55.0%</td>
<td>91.9%</td>
<td>37.0%</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Allergies</td>
<td>32.1%</td>
<td>86.9%</td>
<td>54.7%</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Social history</td>
<td>25.7%</td>
<td>90.4%</td>
<td>64.7%</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Examination</td>
<td>81.7%</td>
<td>98.5%</td>
<td>16.8%</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Investigation</td>
<td>90.6%</td>
<td>97.0%</td>
<td>6.4%</td>
<td>p=0.0084</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>60.9%</td>
<td>96.5%</td>
<td>35.6%</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Outcome</td>
<td>92.1%</td>
<td>98.5%</td>
<td>6.4%</td>
<td>p=0.0026</td>
</tr>
</tbody>
</table>
Table 4.2.2.c - Comparison of the completeness of documentation in the SMR letter versus the TNR letter

<table>
<thead>
<tr>
<th></th>
<th>TNR</th>
<th>SMR</th>
<th>Difference 95%</th>
<th>&quot;p&quot; value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presenting complaint</td>
<td>99.0%</td>
<td>99.5%</td>
<td>0.5%</td>
<td>p=0.5740</td>
</tr>
<tr>
<td>Past medical history</td>
<td>31.1%</td>
<td>63.1%</td>
<td>31.9%</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Drug history</td>
<td>15.3%</td>
<td>33.8%</td>
<td>18.5%</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Allergies</td>
<td>4.5%</td>
<td>11.6%</td>
<td>7.2%</td>
<td>p=0.0083</td>
</tr>
<tr>
<td>Social history</td>
<td>11.4%</td>
<td>36.9%</td>
<td>25.5%</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Examination</td>
<td>77.7%</td>
<td>94.4%</td>
<td>16.7%</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Investigation</td>
<td>88.1%</td>
<td>97.0%</td>
<td>8.9%</td>
<td>p=0.0008</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>57.4%</td>
<td>76.3%</td>
<td>18.8%</td>
<td>p=0.0001</td>
</tr>
<tr>
<td>Outcome</td>
<td>90.6%</td>
<td>94.9%</td>
<td>4.4%</td>
<td>p=0.0931</td>
</tr>
</tbody>
</table>
4.2.3 Comparison of time taken to document information

Duration of consultation was measured for 99 (48 TNR, 51 SMR) patient consultations at the DGH and 55 (29 TNR, 26 SMR) consultations at the TH. At the TH hospital, the mean duration of consultation was 17.9 and 16.7 minutes for the TNR and SMR groups respectively. The mean difference in duration (1.20 minutes, 95% confidence interval −2.8 to +5.2, p=0.55), with the TNR taking longer than the SMR, was not significantly different from zero. There was also no significant difference in the mean duration of documentation using TNR and SMR at the DGH, with average durations of 3.9 and 4.2 minutes for TNR and SMR groups respectively (mean difference = -0.3 minutes, 95% confidence interval -1 +0.4, p=0.45).

4.2.4 Learning and transfer effects

Completeness of the TNR and SMR was compared separately for the first three months and the second three months of the study to investigate possible learning (increase in completeness over time with SMR but not TNRs) and transfer effects (increase in completeness over time with TNRs but not SMRs). Interactions (p<0.05) were observed for only 4 of the 15 items (Appendix 4.2.4). Completeness of the date of consultation and the consultant responsible improved over time with SMRs but not TNRs. Completeness of the doctor’s name also improved over time with SMRs.
and decreased with TNRs. Completeness of the examination findings also decreased over time with SMRs and increased with TNRs.

4.3 Summary of results

Documentation of new patient consultations, both for the letter to a patient’s GP and the clinical entry, was better when using the SMRs than TNRs for the majority, but not all parts of the consultation. In particular the date, doctor’s name, past medical history, drug history, allergies, social history, diagnosis, outcome and signature were all documented more frequently when using the SMR. The past medical history, drug history, social history and examination were included in the SMR letter more frequently than the TNR letter. The improvement in completeness when using the SMR was found not to adversely affect the time to document the consultation.
Chapter V

Observational study of the use of an inpatient structured medical record
5.1 Methods

5.1.1 Study design

There are three main elements to the documentation of inpatient information; the initial consultation during the patients admission (whether emergency or planned), the patient's daily progress and details of any operation performed. A form for each of these was designed, developed and extensively piloted over the preceding months (Chapter III, section 3.2.3.). The aim of this study, however, was to compare only the medical documentation of a patient's admission using the structured medical record (SMR) versus the traditional narrative record (TNR).

An observational study was chosen to achieve this for two main reasons. Firstly, a team of junior clinicians (clinical nurse practitioners, senior house officers and registrars) working for one or more consultant looks after each patient. Randomisation at clinician level would, therefore, not be possible. Patient level randomisation requires clinicians to use both TNR and SMR for different patients, which would be open to the bias of contamination. Secondly, patients may be admitted into hospital at a variety of places and times of day or night. This caused concern that an allocation bias may occur within a randomised trial due for example, to patients admitted at 4am via accident and emergency being less likely to be entered into the study. If the tendency is for clinicians to revert to the
TNR at “unsociable” hours then this would be observable within an observational study. If, however, these patients were not recruited into a randomised study then it would not be possible to observe this behaviour systematically. For these reasons it was felt that an observational study would be the most suitable means of evaluating the use of the SMR in routine clinical practice.

5.1.2 Study population

Urology patients admitted to one teaching hospital (TH) for four months from 1st January – 30th April 2000 were eligible for the study with the exception of day surgery, paediatric and renal transplant patients, who were excluded from the study. Day surgery patients were excluded, because they were not admitted onto the main urology wards and there was a pre-existing multidisciplinary day surgery document on which their admission details were recorded. Paediatric patients were excluded from this study because the paediatric consultants felt that the admission forms were not suitable for this group and wished to design paediatric specific forms (Chapter III, section 3.2.2). Although urologists operated on the renal transplant patients they were not admitted onto the renal wards by the urology clinicians but rather the renal clinicians and, therefore, were excluded from the study. Only the medical documentation of a patient’s admission was evaluated, with the nursing records for example remaining separate.
Men and women of all ages with general and specialist urological problems e.g. prostatic enlargement, stress incontinence, prostate cancer and renal stones were included in the study. The consent of patients was not sought because the study did not require any change in the provision of care. Approval for the study was obtained from the hospital ethics committee.

5.1.3 Study setting

There were two main initial points of contact between the junior clinicians and the urology patients. These were (a) planned (elective) or emergency admission onto one of the three main urology wards for investigation or operation or (b) pre-admission clinic where patients' details and investigations were organised prior to their admission into hospital usually for an elective operation.

5.1.4 Intervention

The SMR admission forms and TNR sheets were available on the relevant wards and in the pre-clerking clinics. These areas were regularly inspected on alternate days by the research fellow to ensure that adequate numbers of the forms remained. Staff were given a contact number and encouraged to contact the research fellow directly if in the meantime stocks ran low.
Clinicians were encouraged to document admission consultations on the forms but were able to use either the SMR or TNR. On discharge of patients all the medical records were sent from the wards to the administrative offices for coding and the discharge summary to be typed. At this stage the medical records were reviewed by the research fellow.

5.1.5 Outcomes measured

Two outcomes were measured; compliance of clinicians in using the SMR and the completeness of the SMR versus the TNR.

Originally it was intended that all the medical records used during the study would be compared with those from an equivalent time period before the forms were implemented. This design would have compared a similar amount of data for each clinician before and after implementation of the forms and would, therefore, have controlled for individual differences in the documentation of admission information. However, as some of the clinicians admitting patients between the two time periods had left or joined the department this made the comparison unfeasible. Instead, the second month of implementation was chosen as the point at which to compare the two methods of documentation as both the SMRs and TNRs were still being used during this month. It was felt that clinicians had been using the SMR for long enough to overcome any learning curve effect.
The number of patients admitted for whom each type of record was used was counted when the notes were reviewed on discharge. SMRs and TNRs were also reviewed and scored according to the completeness of documentation. Completeness of 20 items of clinical information was assessed simply by whether an item was present or absent. These items were of two types; 10 were general areas considered by the clinicians as important features to be documented for any admission consultation, 7 were more specific items relating to patients undergoing an operation e.g. history of diabetes and 3 were included as reminders on the SMR e.g. consent (Table 5.1.5).

5.1.6 Statistical analysis

The proportions of patients for whom each of the 20 items of clinical information were documented were compared between TNR and SMR groups. "Risk" differences (i.e. differences between groups in the proportion of patients for whom an item was documented) and 95% confidence intervals (CI) were calculated. The probability (2 sided) of the Null hypothesis (i.e. no difference between groups) was estimated by Fishers exact tests. All calculations and statistical tests were performed using STATA v.7 (Stata Coporation, Texas). In view of the similarity of patients for whom TNR and SMR were used, no multivariable analyses were carried out.
Table 5.1.5 - Evaluation of inpatient medical records

<table>
<thead>
<tr>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant’s name</td>
</tr>
<tr>
<td>Clinician’s name</td>
</tr>
<tr>
<td>Diagnosis / elective procedure</td>
</tr>
<tr>
<td>Examination</td>
</tr>
<tr>
<td>Investigations requested</td>
</tr>
<tr>
<td>Results of investigations</td>
</tr>
<tr>
<td>Treatment / plan</td>
</tr>
<tr>
<td>Signature</td>
</tr>
<tr>
<td>Contact number</td>
</tr>
<tr>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>COAD</td>
</tr>
<tr>
<td>Asthma</td>
</tr>
<tr>
<td>Smoker</td>
</tr>
<tr>
<td>Allergies</td>
</tr>
<tr>
<td>Blood pressure on admission</td>
</tr>
<tr>
<td>Consent</td>
</tr>
<tr>
<td>TEDS</td>
</tr>
<tr>
<td>Drug chart</td>
</tr>
</tbody>
</table>
5.2 Results

5.2.1 Study population characteristics

492 new patients admitted under urology over the four month period were eligible for the study. The medical records of 443 (90%) patients were reviewed on discharge (Figure 5.2.1a). The missing records for 49 (10%) patients were due to medical records being sent elsewhere before the research fellow could review them. Seven clinicians took part in the study; 2 senior house officers (clinicians 1+2) and 5 clinical nurse practitioners (clinicians 3-7) (Figure 5.2.1b).

5.2.2 Evaluation of compliance

Of the 443 medical records reviewed, 362 contained admission consultations documented in the SMR (Figure 5.2.1a). There was a noticeable increase in the use of the SMR over the course of the study. However, even at the initial implementation, uptake of the SMR was quick with 80% of admissions being documented on the SMR in the first month (Figure 5.2.1a). Most of the admission consultations were documented by the clinical nurse practitioners (clinicians 3-7) (Figure 5.2.1b).
Figure 5.2.1.a - Use of structured medical record and traditional narrative record by month of the study

Data table

<table>
<thead>
<tr>
<th></th>
<th>Medical records</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
</tr>
<tr>
<td>January</td>
<td>115</td>
</tr>
<tr>
<td>February</td>
<td>133</td>
</tr>
<tr>
<td>March</td>
<td>130</td>
</tr>
<tr>
<td>April</td>
<td>114</td>
</tr>
<tr>
<td></td>
<td>492</td>
</tr>
</tbody>
</table>
Figure 5.2.1.b - Use of structured medical record and traditional narrative record by clinician
5.2.3 Evaluation of the completeness of documentation

During February all of the medical records reviewed by the research fellow were scored as to whether the 20 items of clinical information described earlier were present (Table 5.2.3). 28 TNR records versus 92 SMR s were evaluated. The existing level of documentation in the TNR was already high (>70%) for 18 of the 20 items assessed. The exceptions were history of COAD (chronic obstructive airways disease) (35.7%) and the presence of TEDS (thrombo-embolic stockings) (35.7%). When the SMR was used, however, the medical record was consistently more complete.

Documentation of a history of COAD, consent, TEDS, drug chart and clinicians signature were all significantly improved (p<0.0001) by the use of the structured medical record (Table 5.2.3). Documentation of the consultant responsible, clinician, clinicians contact number and history of asthma were also improved to a lesser extent (p<0.05). There was no statistically significant difference in completeness for date, diagnosis, examination, investigations requested, investigations results, treatment, history of myocardial infarction (MI), diabetes mellitus (DM), smoking, blood pressure and drug allergies. Of note the only items that were documented with 100% accuracy in both the SMR and TNR were examination and drug allergies.
Table 5.2.3 - Evaluation of completeness of documentation in SMR versus TNR during February

<table>
<thead>
<tr>
<th>Missing values</th>
<th>TNR (28)</th>
<th>SMR (92)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Consultant’s name</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Clinician’s name</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Diagnosis / elective procedure</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Examination</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Investigations requested</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Results of investigations</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Treatment / plan</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>Signature</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Contact number</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Illnesses</th>
<th>TNR</th>
<th>SMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial infarction</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Diabetes</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>COAD</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>Asthma</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Smoker</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Allergies</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Blood pressure on admission</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Condition</th>
<th>TNR</th>
<th>SMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>TEDS</td>
<td>18</td>
<td>4</td>
</tr>
<tr>
<td>Drug chart</td>
<td>8</td>
<td>2</td>
</tr>
</tbody>
</table>
5.3 Summary of results

Uptake of the SMR was generally good with >75% of admissions during the course of the study were documented using the SMR. Documentation of admissions was better when using the SMR than the TNR for the majority of the items analysed. In particular history of COAD, consent TEDS, drug chart and clinicians signature were all documented more frequently when using the SMR. There was already an excellent pre-existing level of documentation in the TNR.
Chapter VI

Development and use of a questionnaire to assess
users perceptions of the structured medical record
6.1 Methods

6.1.1 Choice of questionnaire

A Medline search from 1966 to 2000 was conducted using the words instrument, documentation, medical records, questionnaires and measure. Further literature was sought by reviewing references from selected articles, using the Internet and asking experts in questionnaire use. During this search no suitable questionnaire was found for the measurement of clinician’s attitudes towards using a structured form in routine clinical practice. Existing questionnaires were focused either on attitudes of clinicians towards computerised medical records or were designed for an individual study and were, therefore, too specific [Schiffman 1999, Moore 1991, Farrell 1988, Teach 1981].

A questionnaire was, therefore, designed specifically to address the attitudes of clinicians towards using a structured medical record (SMR) to replace the traditional narrative record (TNR) (Appendix 6.1.1). To minimise potential bias from the research fellow being known to most of the clinicians, the questionnaire was designed for self-completion, rather than for administration by the research fellow [Britten 1995].
6.1.2 Questionnaire development

Content

A focus group discussed the potential areas that may be important when assessing a change in practice regarding documentation in the medical record i.e. the use of a structured medical record [Kitzinger 1995]. The focus group consisted of 2 urology clinical nurse practitioners, 1 urology senior house officer and 1 urology registrar. Opinions were also sought via semi-structured interviews with 4 general surgery senior house officers and 4 general surgery registrars. Seven main areas were highlighted by the group as important considerations when assessing a change in practice.

It was felt that clinicians that had previously used a similar type of structured medical record might have a different view to the “naïve” users. Therefore, experience of previous use of a structured form was asked and a description of the type of record used solicited (Q4). A particular concern for the group was the potential impact that using the structured form might have on the length of the consultations as it was felt that clinicians would take longer to document their findings on the form when compared with the traditional “prose” style medical record (Q6a). An anticipated benefit of the structured form was the documentation of information in a uniform style that should facilitate the retrospective searching and retrieval of information (Q6b and e). An area of special caution amongst the group was the interference of using the form with the clinician’s interaction with
the patient because the clinician would be distracted by trying to complete
the form and, therefore, neglecting things such as eye contact and listening
to the patient (Q6c). Some of the group felt that whilst using the structured
form would make the documentation more uniform it might also be
restrictive in the amount and manner of information documented (Q6d).
Although it was acknowledged that there would be a "learning curve" to
using the forms the group disagreed on how long this would take and
whether specific training would be required (Q6f). As described in Chapter
III the structured forms had two main uses; firstly, as a means of
structuring the paper medical record and secondly, they could be scanned
to render the information documented electronic, producing a database. It
was felt by some that users may feel that completing the forms was an
extra burden that was not outweighed even by the benefit if having
electronic information (Q6g).

The investigators were keen to know what measures could be taken to
maximise the use of the structured forms and, therefore, asked the focus
group for the three most important factors in use of the forms (Q7).

_Design_

With these areas in mind, individual questions were developed using
accepted principles of questionnaire design regarding question wording
and sequencing (Table 6.1.2) [Black 1998, Oppenheim 1992].
Table 6.1.2 – Features of questionnaire design

**Question wording**

<table>
<thead>
<tr>
<th>Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple language without abbreviations or jargon</td>
</tr>
<tr>
<td>Short questions (&lt; 20 words)</td>
</tr>
<tr>
<td>Avoid more than one idea per question</td>
</tr>
<tr>
<td>Avoid ambiguous words or ideas</td>
</tr>
<tr>
<td>Avoid double negatives</td>
</tr>
<tr>
<td>Avoid leading questions</td>
</tr>
<tr>
<td>Avoid loaded questions</td>
</tr>
</tbody>
</table>

**Question sequencing**

<table>
<thead>
<tr>
<th>Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>General questions before specific questions</td>
</tr>
<tr>
<td>Mixture of positively and negatively worded questions</td>
</tr>
<tr>
<td>Start with open ended questions</td>
</tr>
</tbody>
</table>
Closed response methods were used for the majority of questions with either dichotomous answers or a Likert scale (5 points). Free text open-ended responses were used to capture the previous experience of users and any comments they had about the structured forms that were not covered by the questionnaire. Tickboxes were used to aid completion of the questionnaire and subsequent data analysis. An explanation of the purpose of the questionnaire was attached to the front of it and the preservation of anonymity explained (Appendix 6.1.1).

6.1.3 Questionnaire pilot

A draft questionnaire was developed and piloted with a group of 10 clinicians not involved in the study. These were 6 general surgery senior house officers and 4 general surgery registrars. After piloting, adjustments were made to improve the clarity of the questions and minimise ambiguity.

6.1.4 Questionnaire administration

The SMR was implemented in 2 urology departments (Chapter III). After one month the questionnaire was sent to all clinicians using the SMR to measure their views. Non-responders were sent a further questionnaire with a stamped addressed envelope enclosed. If there was still no answer no further action was taken.
6.2 Results

6.2.1 Study population and setting

The questionnaire was sent to 17 clinicians in the 2 urology departments using the SMR, replies were received from 15 clinicians. A summary of all the questionnaire responses is shown in Table 6.2.1. Clinicians used both inpatient and out-patient forms in the first department (teaching hospital - TH) and the out-patient forms only in the second department (district general hospital - DGH). The distribution of users by grade was established for both the departments (Graph 6.2.1).

6.2.2 Users views about the use of structured forms

Q3. In general what are your views about the use of “structured forms” to record routine clinical information?

The majority of clinicians (12) either approved (A) or strongly approved (SA) of the use of structured forms to record routine clinical information with only 2 clinicians staying neutral (N) and one disapproving (D). None of the clinicians strongly disapproved (SD) of the use of the forms.
Table 6.2.1 – Summary of questionnaire responses

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>In general what are your views about the use of “structured forms” to record routine clinical information</td>
<td>5</td>
<td>7</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Completing the form will add to consultation time</td>
<td></td>
<td>7</td>
<td>3</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>The “structured form” will present information in a uniform manner</td>
<td>1</td>
<td>11</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Completing the form will not affect the interaction between clinician and patient</td>
<td>3</td>
<td>7</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Using a “structured form” will not prevent the clinician form recording a wide variety of information</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>“Structured forms” will improve the communication of information within the notes to all users</td>
<td>3</td>
<td>7</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Extensive training will be required to become familiar with the “structured forms”</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>The effort required to fill in the forms will not be worth the benefit of having data in a database</td>
<td>1</td>
<td>1</td>
<td>8</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SF</th>
<th>TN</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>3</td>
</tr>
</tbody>
</table>
Graph 6.2.1  Grade of clinician

- Consultant
- Registrar
- SHO
- CNP

TH  DGH

0  1  2  3  4  5  6  7  8
6.2.3 Previous exposure to the intervention

Q4. Have you used a similar style of form to record clinical information before?

Only 4 clinicians had experience of using a structured form to document clinical information. Those that had used them before reported that they had been completed in addition to writing in the medical record. They had generally found the forms helpful but commented that the amount of time taken to complete both types of medical record and the lack of feedback of the information had limited their use in routine clinical practice. The comments made were transcribed and are included in the Appendix (Appendix 6.2.3).

6.2.4 Clinician preference

Q5. If you were given the choice, would you use a “structured form” or traditional notes?

When asked to decide which type of medical record they would prefer, all but 3 clinicians chose the structured forms.
6.2.5 Assessment of perceived impact of structured forms

Q6a. *Completing the form will add to consultation time*

Seven clinicians agreed (A) that the forms would increase the consultation time. Three clinicians remained neutral (N) whilst 4 strongly disagreed (SD) whilst one third (1/3) disagreed (D) or strongly disagreed (SD).

Q6b. *The "structured form" will present information in a uniform manner*

The majority (12) of the clinicians agreed (A) or strongly agreed (SA) with this statement.

Q6c. *Completing the form will not affect the interaction between clinician and patient*

Although the potential impact of using the form was of particular concern to the research fellow and focus group, most of the clinicians (10) agreed (A) or strongly agreed (SA) that it would not have an effect on the clinician-patient interaction.
Q6d. Using a “structured form” will not prevent the clinician from recording a wide variety of information

Six of the clinicians disagreed (D) with this and felt that the use of the forms would prevent the recording of a wide variety of clinical information whilst 8 agreed (A) or strongly agreed (SA) that the forms would not do this.

Q6e. “Structured forms” will improve the communication of information within the notes to all users

There was strong agreement (SA) with this from 3 of the clinicians with a further 7 agreeing (A) and 3 remaining neutral (N). Only 2 disagreed (D) with the statement.

Q6f. Extensive training will be required to become familiar with the “structured forms”

The majority of the clinicians felt that training in how to complete the forms would not be required. Only 4 agreed (A) or strongly agreed (SA) that extensive training would be necessary, although the type of training that they felt would be required was not solicited.
Q6g. The effort required to fill in the forms will not be worth the benefit of having data in a database

13 of the clinicians either agreed (A) or strongly agreed (SA) with this, therefore, the benefits of having data in a database were felt to be worth the effort.

6.2.6 The most crucial factor determining the successful use of the forms

Of the three choices identified by the focus group, the design of the form was considered the most important by 10 clinicians, with 4 feeling it was important for users to see a benefit and only one favouring the length of form. No other suggestions were made in the “other comments” section.

6.2.7 Any further comments made regarding the use of the structured forms

This opportunity for users to comment was widely used with nearly half of the users making additional comments. Most of them were regarding specific parts of forms in use but others were more general comments. All the comments have been transcribed (Appendix 6.2.7).
6.3 Summary of results

In general clinicians were favourable in their attitudes towards using the structured forms, with the majority of them preferring them to the traditional record (Section 6.2.4). The main concerns raised (albeit by a minority) were regarding additional time for consultations, limiting freedom of documentation and adversely affecting the interaction with patients. The main advantages reported by users were the improved communication, uniform recording of information and the increased availability of data.
Chapter VII

Discussion
7.1 Overview of results

During the course of this thesis it has been shown that it is possible for a group of clinicians to agree on a dataset of information that should be documented in the medical record (Chapter III). It has also been demonstrated that a structured medical record (SMR) can be designed around this dataset and successfully implemented in routine practice. Using this SMR improved the completeness of documentation for outpatient consultations when compared with the traditional narrative record (TNR) for both the written clinical entry and dictated letter with no adverse effect on the duration of the consultation (Chapter IV). For documentation of inpatient consultations users rapidly adopted the SMR (Chapter V). The SMR was widely accepted with the majority of users preferring it to the TNR (Chapter VI).

7.2 Limitations of thesis

7.2.1 Design and implementation of structured medical record

The use of paper forms as the medium for producing a structured medical record (SMR) has the advantage of being familiar to clinicians. They can be filed in the usual manner in the MR and, therefore, “read” by all other users. However, using paper also limits the extent to which the MR can be restructured. A balance has to be reached between imposing structure whilst keeping the forms “user friendly”. To achieve this there was
inevitably compromise between the number of data items desired versus the number of forms and pages designed.

Only the documentation by clinicians within the MR was addressed as it is generally considered the most complicated and least structured part of the MR. Most MRs, however, contain information from other health care professionals e.g. nursing staff, physiotherapist in addition to extra information e.g. results and drug charts. The same method of structuring could also be used to integrate this information.

Ideally more than one centre should have been used for the piloting of the forms as widening consultation about the design of the forms may have revealed hierarchical and design options that were not tested. However, there was neither the manpower nor resources to do this. Also, the process for agreeing the minimum dataset should preferably involve a group chosen to represent the diversity of urology practice at a national level rather than the small local group used in this thesis.

There was extensive involvement of users during all phases of development and piloting of the forms. It is, therefore, possible that the success in implementation was due to the “ownership” of the forms by users. This is unlikely, however, as the same forms were successfully implemented at a different site where users had not been involved in the development process. Following presentation of the work other centres have taken up the forms and adapted them to their own local practice.
Although this work has been performed within urology, throughout the design and development process effort was made to ensure that the methodology could be applied to any other specialty.

7.2.2 Randomised controlled study of out-patient structured medical record

A randomised controlled trial design was chosen to evaluate the use of an out-patient SMR. With concealment of allocation, this study design should have prevented any confounding. However, clearly clinicians could not be blinded to the allocation of consultations (to either SMR or TNR) and this may have introduced bias. The possibility that the clinicians who preferred the SMR documented their consultations better when using the SMR and vice versa for those preferring the TNR cannot be excluded. Although as the SMR and TNR were also medico-legal documents it is unlikely that clinicians would have deliberately altered the completeness of their documentation. If, however, this had occurred any potential bias is likely to have err in favour of the TNR as most clinicians were sceptical about SMRs at the outset. Therefore, if this bias exists it should act to minimise the differences detected between the SMR and TNR.

Because of local factors in the organisation of out-patient clinics, patients rather than clinicians were randomised to a consultation using a SMR or TNR. Requiring participating clinicians to use both TNRs and SMRs might have caused contamination. To evaluate this, consultations using the
TNR versus the SMR in the first three months and second three months were compared for completeness to elicit possible learning and transfer effects (Section 4.2.4). There appeared to be no general improvement in completeness with either SMRs or TNRs over time. Documentation with SMRs improved for three items and one item for the TNR during the course of the study, but the improvement for one item on the SMR was associated with a change in practice by clerical staff. As the level of completeness did not change significantly during the study it can also be concluded, therefore, that clinicians' experience with the forms prior to the evaluation (Chapter III) was sufficient for them to learn how to use the forms effectively.

Completeness of documentation for participating clinicians using TNRs prior to the study was not measured so the possibility that these clinicians were documenting consultations better than usual in the TNR during the whole study cannot be ruled out. However, any such bias would have led to an underestimate of the effect of the SMR on completeness.

The comparison of the duration of consultations using SMRs and TNRs was hampered by the different ways in which clinicians wrote in medical records in the two hospitals. In the TH, the large variation in the duration of consultations meant that an important difference in consultation time, e.g. 1 minute, could not have been excluded even with a much larger sample size. However, the very small difference in the duration of documentation of consultations at the DGH (where the variation in
duration was much less) suggests that any effect on the total length of consultation is unlikely.

72.3 Observational study and evaluation of inpatient structured medical record

An observational study was chosen to achieve this for two main reasons. Firstly, a team of junior clinicians (clinical nurse practitioners, senior house officers and registrars) working for one or more consultant looks after each patient. Randomisation at clinician level would, therefore, not be possible. Patient level randomisation requires clinicians to use both TNR and SMR for different patients, which would be open to the bias of contamination. Secondly, patients may be admitted into hospital at a variety of places and times of day or night. This caused concern that an allocation bias may occur within a randomised trial due for example, to patients admitted at 4am via accident and emergency being less likely to be entered into the study. If the tendency is for clinicians to revert to the TNR at “unsociable” hours then this would be observable within an observational study. If, however, these patients were not recruited into a randomised study then it would not be possible to observe this behaviour systematically. For these reasons it was felt that an observational study would be the most suitable means of evaluating the use of the SMR in routine clinical practice.
Only a small number of clinicians participated in this study, some of whom had been involved in the development of the SMR. It is, therefore, difficult to establish whether the rapid adoption of the forms observed will be generalisable as there may have been an element of "ownership", although this was not observed with the out-patient SMR.

Minimal improvement in completeness of documentation in the SMR versus the TNR was demonstrated. This could be due to two factors; the existing high standard of documentation in the TNR and the rapid uptake of the SMR only allowing comparison of small numbers of consultations.

Initially an equivalent number of TNRs from prior to the study were to be compared with the SMRs. Pre and post intervention analysis may have shown whether clinicians with a pre-existing high standard of documentation adopted the forms more rapidly than those with a poorer standard. However, as explained in Chapter V, there were considerable changes to staff just before the study started which would have confounded a direct comparison. Instead only a sample of records were compared; these were chosen from the second month of the study when clinicians were still using both types of record but were not in the learning phase. Consequently the sample was small and unequal i.e. 28 TNRs and 92 SMRs, and the power of this comparison may not have been enough to detect an important difference for some of the items compared.
As described it was not possible to review some of the records and, therefore, it cannot be determined which type of record was used for these patients. It is unclear without being able to obtain the records whether these patients were unusual. The fact that their records could not be obtained suggest that the patients did not follow the usual process and, therefore, that they may differ from the patients whose records were reviewed. Most of the records were missing because they were required for a clinic implying that these patients were also under the care of other specialties. The complexity of these patients may be reflected in the standard of documentation in their records, in which case an important group of medical records may have been missed during this study.

Exclusion of certain groups of patients such as day surgery, paediatric and renal transplant patients may have introduced some bias. The reasons for exclusion are explained in Chapter V and they are not insuperable. To have a truly comprehensive SMR in urology, documentation for these groups should also be addressed and a way of incorporating them into the SMR explored.

7.2.4 Evaluation of acceptability of structured medical record

The questionnaire was developed using established principles of questionnaire design and with the involvement of experts. However, as it was developed specifically for this thesis it was not an established validated instrument. To produce a validated instrument it would have
been necessary to more rigorously test the phrasing of the questions. To do this would have required more subjects, psychometric evaluation and a longer time period than available for this thesis. Further validation could also be carried out by correlation of user’s responses to the questionnaire with their subsequent uptake and quality of documentation in the SMR (i.e. is what they say the same as what they do). It was not possible to do this as the questionnaires were completed anonymously.

There are disadvantages to using a self-completion questionnaire; the inability to probe or prompt respondents, errors in completion and lack of control over the response process (e.g. order in which questions are answered). This method of administration was chosen over structured interviews, however, because many of the clinicians knew the research fellow and this could have caused bias at an interview. To reduce this potential bias the questionnaire was posted to users and they were encouraged to return it anonymously. Although the research fellow would know the grade of the respondent there was no other identifying information on the questionnaire.

7.3 Implications of the findings of this thesis

This thesis has demonstrated that it is possible to replace the traditional narrative record (TNR) with a structured medical record (SMR). Use of the SMR has improved the completeness of documentation in the handwritten out-patient clinical entry and dictated letter without increasing the
consultation time. It was widely adopted for inpatient consultations and preferred by the majority to the traditional record. These findings illustrate that it is possible for clinicians to prospectively record high quality data on all areas of clinical practice (both inpatient and out-patient) as part of their routine practice. This is a novel concept, which differs significantly from previous initiatives, which have required the completion of lengthy datasets in addition to the medical record for a specific procedure or diagnosis (Section 1.5.3, Chapter I). Once high quality prospective data is available it is of use both at a local and national level.

Locally for example, detailed complete information regarding an individual department's inpatient and out-patients activity can be used to support claims for a larger pharmacy budget, more operating time, specialist clinics, specialist nurses, new equipment and extra staff [Newton 1999]. In addition the data can provide support for audit projects and identify potential research subjects or centres. High quality data is also necessary to facilitate good clinical governance practice. Having complete and legible information is essential in the defence of medico-legal claims and illustrates another benefit of using the SMR.

Outcome measures can be easily incorporated into the SMR as shown in this thesis e.g. ASA score, IPSS and IIEF. These can be used at a local level to audit individual surgeons or patient outcomes, or nationally with other factors such as length of stay and complications for comparative audit of surgeons and units.
National minimum datasets e.g BAUS oncology rely on regular submissions of data from participating units. Despite this being a relatively small dataset, collection of the data is difficult with most consultants performing this retrospectively. This inevitably leads to incomplete data with upto 20% of cases received having missing information [BAUS Section of Oncology 1999]. By using a SMR the dataset items are incorporated into the routine method of documentation, thereby facilitating accurate data collection.

The uniformity of the SMR means that information for research can be more easily retrieved retrospectively. Improved completeness also ensures that the necessary data is more likely to have been documented. The cost of research projects may also be reduced if the SMR is used as a system of prospective data collection is already in place and, has been observed by Black and others this is usually the most expensive part of setting up a clinical trial [Black 1999, Fleisher 1999].

7.4 Further research

It has been proven in this thesis that using the SMR improves the completeness of documentation for new out-patient and inpatient consultations. However, no evaluation was performed for the out-patient follow up consultations. Data was collected on the patients involved in the
randomised-controlled trial when they returned for follow up appointments but in the time period of research the numbers who returned were too small to allow meaningful comparison. All that can be established regarding the follow up patient consultations at present is that the SMR was successfully implemented. To know whether the effect on completeness seen when using the new out-patient forms applies with the follow up forms it would be necessary to perform another evaluation study.

To establish generalisability of using a SMR such as described in this thesis, agreement of a dataset and design and implementation of a SMR in other specialties would be necessary. Within urology the SMR should be implemented at other sites to ensure that it has not been developed in a “bespoke” fashion and is generalisable to other units.

Although the improved completeness in documentation achieved when using the SMR has been presumed to improve the retrieval of information both for clinical needs and retrospective studies, this has not been specifically addressed in this thesis. To establish this, the ease of abstraction and the quality of the information retrieved from the SMR when compared with the TNR should be evaluated.

Imposing structure on the medical record is not only important for the paper medical record but is a necessity before electronic patient records can be developed [Wyatt 1994]. Although it would be possible to merely
enter information in the same way that it is currently hand-written this would solve none of the limitations of the medical record (Section 1.3, Chapter I). It would be more accurate and efficient to structure the information entered. Structuring the paper medical record as has been achieved in this thesis is a way of preparing for the transition to electronic patient records (EPR). Once a dataset of items has been agreed they can be translated into fields on a computer screen laptop or mobile device. The SMR used in this thesis was designed using “scannable” forms. These were chosen because they offered an inexpensive, flexible and familiar method of rendering a paper record, electronic. Clearly direct entry of information via typing, voice-recognition, touch screens or bar codes will be a more accurate, efficient and versatile method to use in the future but regardless of how data is ultimately entered into an EPR agreement of a structure for it is essential.

In parallel to the work of this thesis, software for an electronic patient record was developed and tested. Design and development of the EPR was a multi-disciplinary project. The key players involved were; clinicians, nurses, secretaries, epidemiologists, information technology department, trust clinical governance department, trust managers and a commercial software company. The ideal EPR was designed to incorporate scanning of paper (both the structured forms and referral letters), dictation, direct keyboard entry, hand held devices, touch screen and infra-red transfer. It was also capable of integrating with existing hospital information systems e.g. patient administration system (PAS). A variety of outputs could be
generated; activity reports, discharge summary, clinic letter, audit report
and downloads to registries or datasets e.g. BAUS oncology. The system
had multi-level use for secretaries, clinicians, coders and adminstrators.
Security measures such as password protection and audit trails were put in
place to prevent tampering with the data. Testing of the software involved
tracking of data to ensure that it was not corrupted in anyway during
transfer from various parts of the programme.

Clinicians must become involved in such projects if EPRs are to be
achieved [Wyatt 1994, Severs 1999]. The technical capability to develop
an EPR is already available but agreement of how to structure information
and definition of essential data items is a pre-requisite to establishing a
robust, EPR that fulfils clinicians expectations.
Appendices
Appendix 1.2.3.a
Risk Management Standard Number 8

Standard:

A comprehensive system for the completion, use, storage and retrieval of medical records is in place. Record-keeping standards are monitored through the clinical audit process.

Rationale:

Complete and timely records allow a clear picture of events to be obtained which is imperative for managing complaints and litigation.

Areas for assessment:

(The assessor may wish to visit the records store(s) so that he/she can gauge whether or not the criteria laid out below have been met).

8.1.1 There is a unified medical record which all specialties use. [1]

(Policy/procedure document on record keeping)

(List of specialties)

8.1.2 Records are bound and stored so that loss of documents and traces are minimised for inpatients and outpatients. [1]

8.1.3 The medical record contains clear instruction regarding filing of documents. [1]

8.1.4 Operation notes and other key procedures are readily identifiable. [1]

8.1.5 CTG and other machine produced recordings are securely stored and mounted. [1]
8.1.6 There is a computer system, or other, for identifying and retrieving X-rays.

8.1.7 The storage arrangements allow retrieval on a 24 hour / 7 day arrangement.

8.1.8 There is clear evidence of clinical audit of record-keeping standards for all professional groups in high risk specialities, within the 12 months prior to the assessment.

(Audit proformas, reports and action plans).
(The audit should address clinical note keeping and quality of documentation - cf "Setting the Record Straight" - Audit Commission, and King's Fund Organisational Audit standards for medical records)
(High risk in this context means obstetrics, all surgical specialities including podiatry and dental surgery, anaesthetics and A&E including minor injury units)

8.1.9 There is a mechanism for identifying records which must not be destroyed.

8.2.1 A&E records are contained within the main record for patients who are subsequently admitted.

8.2.2 Nursing, medical and other records (e.g. Care Plans) are filed together when the patient is discharged.

8.2.3 There is a system for measuring efficiency in the recovery of records for inpatients and outpatients.

8.2.4 The medical record contains a designated place for the recording of hyper-sensitivity reactions.

8.2.5 There is a system for ensuring that the GP is sent a copy of the A&E record.

8.2.6 There is clear evidence of clinical audit of record-keeping standards in 50% of the specialities, within the 12 months prior to assessment.

(See also 8.1.8 above)
8.3.1 An author of an entry in a medical record is clearly and easily identifiable. [3]

8.3.2 There is clear evidence of clinical audit of record-keeping standards in all specialties, within the 12 months prior to assessment. [3]

(See also 8.1.8 above)

8.3.3 There is a computer based Patient Administration System. [3]
THE ROYAL COLLEGE OF SURGEONS OF ENGLAND

GUIDELINES FOR CLINICIANS ON MEDICAL RECORDS AND NOTES

The ‘Guidelines to Clinical Audit in Surgical Practice’ issued in March 1989 by The Royal College of Surgeons of England comprised an outline of the underlying principles of clinical audit and the basic components of a surgical audit programme.

These ‘Guidelines for Clinicians on Medical Records and Notes’ have been prepared to assist clinicians with the medical records which are fundamental for clinical care and the audit of surgical services.

The College’s Hospital Recognition Committee, as part of its quinquennial inspection of accredited hospitals, will scrutinise hospital records to ensure that optimum standards of surgical care are being provided. Where surgical notes are produced by computer a paper copy should always be made and filed in the hospital record.

Those recommendations of particular relevance to clinicians are set out in bold type in this document.

The RCS emphasises to Units and Hospitals the importance of maintaining and securely storing Medical Records. Accessible medical records are essential to clinical care, follow up and audit.

Clinicians are reminded that an accurate record should be made of the regular clinical review and surgical audit. The maintenance of this record is the responsibility of the Royal College of Surgeons’ Tutor. The records should include the names of all consultants and trainees attending each meeting, the topics discussed and the decisions reached.

Trainees are also reminded that log books are now required for higher examinations. Accurate clinical records are essential for the preparation of log books.

Guidelines produced 1990 and revised and reissued 1994

163
1. **THE HOSPITAL RECORD**

A hospital record must be maintained for every patient. Each record should contain the following identification data:

(i) A unique medical record number or reference on every page.
(ii) Name in full on every page.
(iii) Address and postcode.
(iv) Telephone number.
(v) Date of birth.
(vi) Sex.
(vii) Person to notify in an emergency (next of kin).
(viii) Occupation and Marital Status.
(ix) The patient’s Registered General Practitioner.

2. **THE CLINICAL RECORD**

A. The notes should contain the following details:

(i) An initial patient history with details of previous illnesses, the social and environmental context of the illness when appropriate and details of medication.

(ii) Details of the initial physical examination, including the patient’s height and weight.

(iii) A working diagnosis and medical care plan should be written down, signed and dated by the appropriate doctor.

B. These notes should be supplemented and updated regularly to include details and reports of all investigation, treatments and verbal advice given to the patient and his or her relatives.

C. An entry must be made on discharge recording the clinician responsible for the decision to discharge, the status and destination of the patient, and arrangements for follow up. A copy of the preliminary discharge letter (section 6A) should be filed in the notes.

3. **THE NURSING RECORD AND CARE PLAN**

The nursing record is an important part of the hospital record and should be filed in a clearly designated part of the clinical record.

4. **PATIENTS UNDERGOING SURGERY**

A. For patients undergoing surgery, records should include details of the following:

(i) Signed evidence that informed consent has been obtained by a doctor or an appropriately trained Nurse Practitioner.

(ii) Signed evidence that the correct procedure was followed when obtaining consent for children under the age of 16 years.

(iii) The medical care plan should include the site and side of any operative procedure. Sites and sides must be written out in full and not abbreviated.

B. A record of the operation should be made immediately following surgery and should include:

(i) The name of the operating surgeon(s) and the name of the consultant responsible.

(ii) The diagnosis made and the procedure performed.
(iii) Description of the findings.
(iv) Details of tissue removed, altered or added.
(v) Details of serial numbers of prosthetics used.
(vi) Details of sutures used.
(vii) An accurate description of any difficulties or complications encountered and how these were overcome.
(viii) Immediate post-operative instructions.
(ix) The surgeon's signature.

C. The record should also contain information relating to anaesthesia including:
   (i) The name of the anaesthetist and, where relevant, the name of the consultant anaesthetist responsible.
   (ii) Pre-operative assessment by the anaesthetist.
   (iii) Drugs and doses given during anaesthesia and route of administration.
   (iv) Monitoring data.
   (v) Intravenous fluid therapy, if given.
   (vi) Post-anaesthetic instructions.
   (vii) Name and signature of anaesthetist.

D. The anaesthetic record should be filed with the clinical record NOT separately in another place.

5. PATIENTS IN INTENSIVE THERAPY UNITS

A. The record should include:
   (i) A clear statement why the patient was admitted to the ITU.
   (ii) An accurate record of monitoring of the physiological state while the patient was in ITU.
   (iii) Contemporaneous details of all therapeutic manoeuvres performed.

B. When the patient is moved from the ITU, a description of the patient's clinical status must be written down and the reason for transfer adequately described in the notes.

6. DETAILS ON DISCHARGE

A. On discharge all patients should take with them a brief summary note containing the name of the consultant in charge, operation(s), diagnosis, current ongoing medication and arrangements for wound management.

B. For each patient there should be a discharge summary/letter which is completed within 14 days of the patient’s discharge. This should include a precis of the clinical notes, the full diagnosis and the name of the consultant(s) in charge. This should be sent to the general practitioner, hospital or institution to which the patient is discharged.
C. The front sheet must be completed at the time of discharge or as soon as the relevant information is available. It should contain details of all diagnoses and procedures and significant complications. Read coding using the terms developed by the Clinical Terms Project is recommended as the recognised standard because it is intelligible to clinicians and allows easy mapping to the current revision of the International Classification of Disease (ICD 9) and OPCS 4 coding for operative procedures. Consultants in charge are responsible for entering a diagnosis and ensuring that the coding process is correct.

D. When a patient dies similar documentation should be completed and sent to the patient's general practitioner.

E. Details of the Death Certificate entry should be written into the patient's notes.

7. POST-MORTEM REPORT

A. When a post-mortem is performed a provisional anatomical diagnosis should be noted in the medical record within 72 hours and the medical record should be completed within one month following the death. A copy of the post-mortem report must be filed in the medical record.

B. A review of the clinical diagnosis and the findings of the post-mortem examinations are an important part of the clinical process and should be contained in the notes.

8. THE MANAGEMENT OF HOSPITAL RECORDS

A. The methods by which hospital records are managed and maintained should be discussed and developed locally. The hospital should maintain a good diagnostic index. It should be possible to locate records quickly and resources must be made available to ensure that the records service is adequately staffed and equipped to do this. Hospital records must be maintained in a tidy condition and proper maintenance ensured; adequate arrangements should be made by hospitals for support staffing.

Policies should be established locally with regard to the following:

(i) Safeguarding information in the records against loss, damage, or use by unauthorised persons. Where computerised records are maintained specific measures should be taken to ensure confidentiality in accordance with the Data Protection Act 1984, Department of Health Guidance and the professional code of ethics.


(iii) Retention, destruction and microfilming of medical records (in accordance with British Standards Guidelines and Health Circular (89) 20 and Guidelines for the appropriate storage of active and inactive records).

(iv) Storage of records stored separately from the main record, eg accident and emergency records.

9. SECRETARIAL SUPPORT

It is essential that consultant staff are supported by appropriately trained secretarial staff in sufficient numbers to allow the clinician to follow these guidelines.
Appendix 1.2.3.c

Guidance on medical records for surgical patients

Royal College of Surgeons of England

Prepared by Kay Thomas and Mark Emberton on behalf of the Professional Standards Board, Clinical Effectiveness Unit.

Guidelines produced 1990 and revised and re-issued 1994 and 2001
About this document

This update to previous editions of Clinical Guidelines on Medical Records for Surgical Patients was produced in order to incorporate important changes in the way that current medical records are used in everyday clinical practice. The update was not produced using formal methodologies for guideline production. Instead it is the product of wide consultation and an inevitable distillation of views from a number of interested parties.

Whilst the limitations of this document need to be acknowledged by the user we believe that it is considerably superior to the existing versions that were woefully out of date. The sheer size and complexity of undertaking a formal approach to the production of Clinical Practice Guidelines on the medical record of surgical patients at a time when the rate of change in that record is likely to exceed our ability to generate practice policies was why a process of consultation was adopted instead of the more formal methods.

Introduction

Hospital medical records have changed little in appearance since the introduction of the National Health Service. The way that they are used has. The hospital medical record has a number of functions:

1. Definitive chronological account of events
2. Summary of the clinical status of the patient at a point in time
3. Means of communication between healthcare professionals
4. Basis for coding
5. Source of information for the following activities; clinical audit, governance, research and medico-legal disputes

The value of the medical record for all these functions relies on accurate and contemporaneous documentation of the clinical information within it.

These guidelines have been prepared in order to help clinicians achieve and maintain a medical record that will enable the modern requirements of that record to be met.
General structure and management of medical records

- A unique medical record should be created and maintained for every patient attending the hospital. This should contain inputs for all the specialties involved in the patients’ care (the only exceptions to this are Accident and Emergency and Genitourinary Medicine).

- Medical records should be stored in a manner that facilitates easy retrieval 24 hours a day.

- Each record should contain a front sheet documenting the following identification data:

  (i) A unique patient number (i.e. the NHS or hospital registration number)
  (ii) Name in full
  (iii) Address and postcode
  (iv) Telephone number
  (v) Date of birth
  (vi) Sex
  (vii) Person to notify in an emergency (next of kin) & contact telephone number
  (viii) The patient’s Registered General Practitioner
  (ix) Allergies
• Information within the record should be filed chronologically in clearly defined sections e.g.
  – Correspondence
  – Clinical notes (in and out patient filed together or separately)
  – Results of investigations
  – Miscellaneous (Nursing plan, integrated care pathway and drug charts)

Inpatient documentation

Clinical entry

• Each page should be marked with the patient’s name and hospital number
• Either handwritten or typed notes but must be clearly legible
• The following details should be recorded:
  – Specialty and Consultant responsible for that particular episode of care
  – Initial patient history with details of previous illnesses, the social and environmental context of the illness when appropriate and details of medication.
  – Details of the initial physical examination.
– A working diagnosis and medical care plan, signed and dated by the appropriate clinician with a contact number, grade and the surname printed in full.

• The entry should be supplemented and updated regularly (at least every three days) to include details and reports of all investigations, treatments and verbal advice given to the patient and his or her relatives.

• When a patient dies details of the Death Certificate entry should be written into the patient’s notes (i.e. date, time, provisional diagnosis).

*Patients undergoing surgery*

• Medical records should include details of the following:

– Signed evidence that informed consent has been obtained by an appropriately trained doctor or Nurse Practitioner. Whilst the signing of a consent form provides a record that this has been done it should also be recognised that gaining consent is a continuous process started at the time that a decision to operate is made at consultation. Details of the specific complications and outcomes discussed with the patient (and their relatives) and any information leaflets provided should be in the record. Ideally the person performing the procedure should obtain
consent from the patient. Specific guidance about the issues surrounding consent of patients can be obtained from the General Medical Council, Department of Health, British Medical Council and the Royal College of Surgeons.

- Sites and sides of any operative procedure must be written out in full and not abbreviated. If operating on a limb or one of a pair of organs, the relevant side and site of the patient should be marked pre-operatively when they are awake and alert.

- Operations should not be undertaken without the medical record (and imaging if appropriate) being present in the operating theatre before the patient is anaesthetised. If an operation is performed without the medical record present this must be stated and the reason for proceeding be documented.

- A record of the operation should be written or dictated immediately following surgery and include:
  - Date of operation (and time for every operation)
  - The name of the operating surgeon(s) and consultant responsible and the names and grade of all participating surgeons.
  - The reason for the operation (presumptive diagnosis)
  - Procedure performed.
  - Description of the findings.
  - Details of tissue removed, altered or added.
- Details of serial numbers of any prosthesis used.
- Details of sutures used and wound closure.
- Description of any difficulties or complications encountered and how these were overcome.
- Immediate post-operative instructions.
- The surgeon's signature, surname printed legibly and contact number.

- The record should also contain information relating to anaesthesia including:
  - The name of the anaesthetist and, where relevant, the name of the consultant anaesthetist responsible.
  - Pre-operative assessment by the anaesthetist
  - Drugs and doses given during anaesthesia and route of administration.
  - Intra-operative monitoring data and intravenous fluid therapy given.
  - Post-anaesthetic instructions.
  - Signature of anaesthetist, surname printed and contact number.

Discharge information

- On discharge all patients should take with them a brief summary note containing the name of the consultant in charge, operation(s), diagnosis, current ongoing medication and arrangements for wound management. Contact details in the event of a problem (e.g. telephone number of ward or clinic) should be given.
• For each patient there should be a discharge summary/letter which is completed within 14 days of the patient's discharge. This should include a précis of the clinical and operation notes, the full diagnosis and the name of the consultant(s) in charge. This should be sent to the general practitioner, hospital or institution to which the patient is discharged.

• The consultant in charge of the episode of care is responsible for ensuring that codes assigned to the discharge diagnosis and operative procedure(s) are accurate.

**Out-patient documentation**

• New out-patient consultations should include the following;
  - Specialty and Consultant responsible for that particular episode of care
  - Date of consultation
  - Initial patient history with details of previous illnesses, the social and environmental context of the illness when appropriate and details of medication.
  - Details of the initial physical examination (including the patient’s height, weight blood pressure and urinalysis where appropriate).
  - A working diagnosis and medical care plan
  - Record of the discussion re options for treatment or complications of a procedure planned
  - Signature with the doctor’s surname printed in full and contact number
• After all out-patient consultations a letter should be dictated to the referring clinician and or the General Practitioner.

• Follow up consultations whether by telephone or in person should be documented in the medical record, not in a separate place.

• Action taken when a patient does not attend an out-patient consultation should be documented in the medical record (e.g. further appointment sent or patient discharged).

Summary

These are predominantly intended as guidelines for medical records in NHS hospitals, however, they apply equally to the records of private patients. If clinicians wish to hold any information on patients in addition to or as well as that contained within the medical record (i.e. logbooks or research database) they are required by law to register under the Data Protection Act 1998 (http://www.dataprotection.gov.uk).

These guidelines outline the documentation required in the medical record. This will become more detailed as we move towards electronic medical records. If these records are to be compatible across trusts the structure and information contained within them will have to be standardised at a national level.
Related references


6. Royal College of Surgeons. Good Surgical Practice. 2000


Appendix 3.2.2.a  First draft of new out-patient form
<table>
<thead>
<tr>
<th>Presenting complaint</th>
</tr>
</thead>
</table>

### Past Medical History
- Cardiac
- Endocrine
- Neurological
- Respiratory
- Trauma
- Vascular
- Extra information

### Drug History
- Alpha-blocker
- Antibiotics
- Antihypertensives
- Aspirin
- Cardiac drugs
- Finasteride
- Hormones
- Hypoglycaemics
- Insulin
- Oxybutynin
- Tolterodine
- Warfarin
- Other

### Family History

### Social History
- Lives alone
- With others
- Occupational risk
- Job

### Alcohol
- Units/week
  - None
  - M<21 F<12
  - M 21-40 F 12-25
  - M>40 F>25

### Smoking
- Yes
- Never
- Given up
- How long: ___ yrs
- How many: ___/day

### Previous Surgery
- Cystoscopy
- Hysteroscopy
- Procto-biopsy
- BNI
- TURP
- TURBT
- Circumcision
- Hernia
- Vasectomy
- Testicular
- Prostatectomy
- Cystectomy
- Nephrectomy
- Urethroplasty
- U. Diversion
- Orthotopic surgery
- Other

### Survey: 6

Automatic Data Capture by Formic Ltd
**UROLOGY OUTPATIENTS**

**New Patient**

<table>
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<tr>
<th>D</th>
<th>D</th>
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**Investigations**

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<th>urodynamics</th>
<th>video-urodynamics</th>
<th>CT</th>
<th>abdo pelvis chest</th>
<th>bone scan</th>
<th>MRI</th>
<th>abdo pelvis chest</th>
<th>other</th>
<th>US</th>
<th>bladder renal testicles prostate prost+Bx</th>
</tr>
</thead>
</table>

**Scrotum + testicles**

- normal
- epididymal cyst
- hernia
- hydrocele
- malignant
- orchitis
- varicocele

**PR**

- normal
- yes
- no

**Prostate**

- benign
- inflamed
- malignant

**tumour stage**

- mild
- mod
- large

**Diagnosis**

**Treatment**

**Outcome**

- discharge
- follow up [Wks]
- refer
- other

---

Survey: 6

Automatic Data Capture by Formic Ltd
Appendix 3.2.2.b Third draft of new out-patient form
UROLOGY OUTPATIENTS

New Patient

D D M M Y Y Y Y

ID number

NG HISTORY

a-blocker
biotics
hypertensive
irin
diabetic drugs
deridines
oglycaemic
ulcin
butynin
teridine
farin

Allergies

penicillin
latex
none
other

SOCIAL HISTORY

Occupation

lives alone
with others
social services

Alcohol units/week

M<21 F<12
M 21-40 F 12-25
M>40 F>25
none

Smoking

yes never given up

how long yrs number /day

XAMINATION
<table>
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<td>Urine cytology</td>
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<td></td>
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<tr>
<td>Flow rate</td>
<td>prostate + Bx</td>
<td></td>
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<tr>
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<tr>
<td>Follow up in wks</td>
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</tr>
<tr>
<td>Refer</td>
<td></td>
</tr>
<tr>
<td>Other</td>
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</tr>
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</table>

Please leave the form on the front of the notes and send the notes to the secretary.
UROLOGY OUTPATIENTS

New Patient

Presenting complaint

LUTS
Haematuria
Loin pain
Dysuria
Incontinence
Pain
Other

IPSS (0 - 35)

Quality of Life (0 - 6)

PAST MEDICAL HISTORY

cardiac
endocrine
neurological
respiratory
trauma
vascular

Previous operations

Family history

none

none

Survey : 601

Page : 1

Designed by Kay Thomas
Appendix 3.2.2.d  Final draft of new out-patient form
DRUG HISTORY

NONE □

antibiotics □
antihypertensive □
aspirin □
cardiac drugs □
insulin □
warfarin □

OTHER □

ALLERGIES

NONE □

specify □

SOCIAL HISTORY

Occupation □
lives alone □
with others □
social services □

Alcohol NONE □

Smoking □

yes □
ever □
given up □

units/wk □

number/day □

how long yrs □

EXAMINATION

ASA grade

1 □
2 □
3 □
4 □
5 □

1 = healthy
2 = mild systemic disease
3 = severe systemic disease (not incapacitating)
4 = incapacitating systemic disease (constant threat to life)
5 = moribund
### INVESTIGATIONS

<table>
<thead>
<tr>
<th>None</th>
<th>Flexible Cystoscopy</th>
<th>CT</th>
<th>Abdo</th>
<th>Pelvis</th>
<th>Chest</th>
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<tr>
<td>MSU</td>
<td>US USCD</td>
<td>Renal</td>
<td>Testicles</td>
<td>TRUS</td>
<td>TRUS + Bx</td>
</tr>
<tr>
<td>Urine cytology</td>
<td>Flow rate</td>
<td>Bone Scan</td>
<td>Abdo</td>
<td>Pelvis</td>
<td>Chest</td>
</tr>
<tr>
<td>FBC</td>
<td>Electrolytes</td>
<td>MRI</td>
<td>Abdo</td>
<td>Pelvis</td>
<td>Chest</td>
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<tr>
<td>PSA</td>
<td>KUB</td>
<td>Loopogram</td>
<td>Urodynamicsm</td>
<td>Video-Urodynamicsm</td>
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<tr>
<td>Other Investigations</td>
<td>IVU</td>
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### DIAGNOSIS

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<th>UTI</th>
<th>Interstitial Cystitis</th>
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<th>Haematuria</th>
<th>Erectile Dysfunction</th>
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<tbody>
<tr>
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<td>Other</td>
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</table>

### TREATMENT


### OUTCOME

- Discharge [ ]
- Follow up in [ ] wks
- [ ] mths after investigation
- Open appt [ ]
- Refer [ ]
- Admit [ ]
- Book operation [ ] LA [ ] GA [ ]

### INFORMATION GIVEN TO THE PATIENT


### SIGNATURE and name printed


Appendix 3.2.2.e  LUTS follow up form
UROLOGY OUTPATIENTS  LUTS Follow-up

Office Use Only

Put patient label in box below

Date

Consultant

Initials

Dr / CP

Initials

DIAGNOSIS

LUTS

UTI

haematuria

prostatitis

stricture

catheter change

urethral

supra-pubic

post-operative

TURP

BNI

TURBT

other - specify

CURRENT PROBLEMS

IPSS

(0-35)

Quality of life

(0-6)

not appropriate

unable to complete

EXAMINATION

Survey: 10033

Page: 1

### INVESTIGATIONS

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<thead>
<tr>
<th>Option</th>
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<tr>
<td>flow rate</td>
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<td>KUB</td>
<td></td>
</tr>
<tr>
<td>IVU</td>
<td></td>
</tr>
<tr>
<td>FBC</td>
<td></td>
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<tr>
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<td>asc urethrogram</td>
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<td>penile doppler</td>
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### TREATMENT

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<td>- supra-pubic</td>
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<td>CISC</td>
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<tr>
<td>LA</td>
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<td>GA</td>
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### OUTCOME

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<td>Follow up mths</td>
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<td>After investigation</td>
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<td>Open appt</td>
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<tr>
<td>Refer</td>
<td></td>
</tr>
<tr>
<td>Admit</td>
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<tr>
<td>book operation LA</td>
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<tr>
<td>book operation GA</td>
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### INFORMATION GIVEN TO THE PATIENT


### SIGNATURE AND NAME PRINTED


Appendix 3.2.2.f  

BAUS Oncology form
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<th>Question</th>
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<td>Consultant Number &amp;/or Centre Number</td>
</tr>
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<td>Q2</td>
<td>Patient Hospital Number</td>
</tr>
<tr>
<td>Q3</td>
<td>Patient NHS Number</td>
</tr>
<tr>
<td>Q4</td>
<td>Postcode</td>
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<td>Q5</td>
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<td>Female</td>
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<tr>
<td>Q6</td>
<td>Date of Birth</td>
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<td>D D M M Y Y Y Y</td>
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<td>Organ</td>
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<td>Testis</td>
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<td>Penis</td>
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<td>Is there histological confirmation of diagnosis?</td>
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<td>Yes</td>
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<tr>
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<td>No</td>
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<td>If NO histology, is diagnosis based on information from:</td>
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<tr>
<td></td>
<td>Cytology</td>
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This form current until 31.12.1999

P. T. O.
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<tr>
<td>S category: S0</td>
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<td>S1</td>
<td>S2</td>
<td>S3</td>
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<th>Choose one option only</th>
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<td>Curative</td>
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<td>Surveillance only</td>
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<th>Choose more than one option if required</th>
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<td>Radical Ablative Surgery</td>
<td>Organ Conserving Surgery</td>
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Appendix 3.2.2.g  Oncology follow up form
**UROLOGY OUTPATIENTS**

**Oncology Follow-up**

**Office Use Only**

**Date**

**Consultant Initials**

**Dr / CP Initials**

**Put patient label in box below**

**NEW DIAGNOSIS**

*Only fill in the details below for new diagnoses*

- **Organ**
  - kidney
  - pelvis/ureter
  - bladder
  - prostate
  - testis
  - penis
  - other

- **Histology**
  - adenocarcinoma
  - TCC
  - SCC
  - mixed TCC/SCC
  - seminoma
  - teratoma
  - mixed teratoma/semimoma
  - NONE
  - other

  If no histology what is the basis for diagnosis

**CURRENT PROBLEMS**

- appetite good
- weight change
- loss of energy
- independent
- mobile
- LUTS
- potent
- normal libido
- incontinence - urinary
- faecal
- other

**TUMOUR MARKERS**

- last PSA
- taken on
- last beta HCG
- taken on
- last AFP
- taken on

**S category for testis cancer**

- See BAUS guidelines for staging groups

**EXAMINATION**

Survey: 10015

Has the stage or grade of the tumour changed since the patient was last seen
if yes or this is a new diagnosis fill in the details below

<table>
<thead>
<tr>
<th>STAGING</th>
<th>histological</th>
</tr>
</thead>
<tbody>
<tr>
<td>clinical</td>
<td>T [ ] a [ ] b [ ] c [ ] N [ ] M [ ]</td>
</tr>
<tr>
<td>path</td>
<td>T [ ] a [ ] b [ ] c [ ] N [ ] M [ ]</td>
</tr>
</tbody>
</table>

TREATMENT

<table>
<thead>
<tr>
<th>Medical</th>
<th>Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td>alpha-blockers</td>
<td>cystoscopy</td>
</tr>
<tr>
<td>flutamide</td>
<td>TURBT</td>
</tr>
<tr>
<td>cyproterone acetate</td>
<td>channel TURP</td>
</tr>
<tr>
<td>zoladex</td>
<td>orchidectomy</td>
</tr>
<tr>
<td>stilboestrol</td>
<td>radical nephrectomy</td>
</tr>
<tr>
<td>warfarin</td>
<td>radical prostatectomy</td>
</tr>
<tr>
<td>hydrocortisone</td>
<td>radical cystectomy</td>
</tr>
<tr>
<td>other</td>
<td>palliative cystectomy</td>
</tr>
</tbody>
</table>

Chemotherapy

* intra-vesical |
  - mitomycin [ ]
  - BCG-treatment [ ]
  - BCG-maintenance [ ]

* systemic [ ]

* immunotherapy [ ]

other

Radiotherapy

* external beam [ ]
* strontium [ ]
* brachytherapy [ ]
<table>
<thead>
<tr>
<th>INVESTIGATIONS</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NONE</td>
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<td></td>
<td>CT</td>
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<td></td>
<td>abdo</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>pelvis</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>chest</td>
<td></td>
</tr>
<tr>
<td>MSU</td>
<td></td>
<td></td>
<td>KUB</td>
<td></td>
</tr>
<tr>
<td>urine cytology</td>
<td></td>
<td></td>
<td>IVU</td>
<td></td>
</tr>
<tr>
<td>FBC</td>
<td></td>
<td></td>
<td>US</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>renal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>bladder</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>testicles</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>prostate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>prostate+Bx</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MRI</td>
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<td></td>
<td>abdo</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>pelvis</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>chest</td>
<td></td>
</tr>
<tr>
<td>Other Investigations</td>
<td></td>
<td></td>
<td>bone scan</td>
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</table>

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>INFORMATION GIVEN TO THE PATIENT</th>
<th>SIGNATURE and name printed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow up in</td>
<td>wks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>mths</td>
<td></td>
</tr>
<tr>
<td></td>
<td>after investigation</td>
<td></td>
</tr>
<tr>
<td>Open appt</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Book operation</td>
<td>LA</td>
<td>GA</td>
</tr>
</tbody>
</table>
Appendix 3.2.2.h  Female urology follow up form
UROLOGY OUTPATIENTS  Female Urology

Office Use Only  

Date  

Consultant Initials  Dr / CP Initials  

Put patient label in box below  

DIAGNOSIS  

Incontinence  
- Stress  
- Urge  
- Mixed  

Dysuria  

Detrusor instability  

Detrusor failure  

Other - specify  

Interstitial cystitis  

Chronic bladder pain  

Vesico vaginal fistula  

Cystocele  

Rectocele  

Enterocoele  

Clam ileocystoplasty  

CURRENT PROBLEMS  

EXAMINATION  

Abdominal  

Grade  

PV 1 2 3  

Cystocele  

Enterocoele  

Rectocele  

Genuine stress incontinence  

Hypermobility  

Atrophy  

Survey: 10090  

Page: 1  

INVESTIGATIONS

NONE □

MSU □ KUB □ urodynamics □
electrolytes □ US bladder □ video-urodynamics □
FBC □ renal □
Other □

TREATMENT

Pelvic floor exercises □ Catheter change □ - urethral □
Intermittent self catheterisation (CISC) □ suprapubic □
Antibiotics □ trimethoprim □
ciprofloxacin □ Cystoscopy □ LA □ GA □
nitrofurantoin □ Oxybutynin □
Other □

OUTCOME

Discharge □
Follow up □ wks
□ mths

After investigation □
Open apt □
Refer □
Admit from clinic □
Book operation □ LA □
GA □

INFORMATION GIVEN TO THE PATIENT

SIGNATURE AND NAME PRINTED
Appendix 3.2.2.i  Erectile dysfunction new patient form
**HISTORY OF ERECTILE DYSFUNCTION**

Use blank scannable page if more space required for history

**SEXUAL HISTORY**

- Duration of ED: [ ] / mths [ ] onset - sudden [ ] gradual [ ]
- Libido: [ ] normal [ ] reduced [ ]
- Orgasm: [ ] yes [ ] no
- Married: [ ] yes [ ] no
- Partner: [ ] yes [ ] no

**Quality of Erections**
- Normal: [ ] mod: [ ] poor: [ ] none: [ ]
- During sex: [ ]
- Self stimulation: [ ]
- Early morning: [ ]

**IIEF Score Today**

- Q1 [ ] Q2 [ ] Q3 [ ] Q4 [ ]
- Q5 [ ] Q6 [ ] Q7 [ ] Q8 [ ]
- Q9 [ ] Q10 [ ] Q11 [ ] Q12 [ ]
- Q13 [ ] Q14 [ ] Q15 [ ]

Total score: [ ] / 75

**Previous ED Treatments**

- Viagra: - 50mg [ ] - 100mg [ ]
- MUSE: - 250mcg [ ] - 500mcg [ ] - 1000mcg [ ]
- ICI: - 5mcg [ ] - 10mcg [ ] - 20mcg [ ] - 40mcg [ ]
- Vacuum [ ]
- Prosthesis [ ]
- Testosterone [ ]
- Counselling [ ]

**Other Risk Factors Identified**

- Cardiac [ ]
- Hypertension [ ]
- Diabetes [ ]
- Smoking [ ]
- Post Surgical [ ]
- Radiotherapy [ ]
- Neurological [ ]
Appendix 3.2.2.j

Erectile dysfunction follow up form
**UROLOGY OUTPATIENTS**

**Erectile Dysfunction Follow up**

**Office Use Only**

**Date**

**Consultant Initials**

**Dr / CP Initials**

**Was the treatment successful?**

- **yes**
- **no**

**Any side effects**

- **yes**
- **no**

**Comments**

**Results of investigations**

**IIEF score today**

<table>
<thead>
<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Q5</th>
<th>Q6</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Q7</th>
<th>Q8</th>
<th>Q9</th>
<th>Q10</th>
<th>Q11</th>
<th>Q12</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total score =**

- **/ 75**

**TREATMENT**

- **NONE**

**OUTCOME**

- **discharge**

- **follow up in**
  - **wks**
  - **mths**

- **after investigation**

- **open appointment**

- **refer to**

**SIGNATURE, name + bleep / tel number**

**NHS category for treatment**

- **diabetes**
- **poliomyelitis**
- **radical pelvic surgery**
- **emotional distress**

- **MS**
- **prostate cancer**
- **RF dialysis/transplant**
- **neurological disorder**

- **Parkinson’s**
- **prostatectomy**
- **severe pelvic injury**
- **spinal cord injury**

- **counselling**
- **spina bifida**
**UROLOGY OUTPATIENTS**

**Stone**

Office Use Only

Date

Consultant Initials

Dr / CP Initials

Tertiary Referral

### DIAGNOSIS

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal colic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal calculus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ureteric calculus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staghorn</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Post treatment -

- JJ Stent
- ESWL
- PCNL
- Ureteroscopy

### Number of Stone(s)

<table>
<thead>
<tr>
<th>Side</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Site of Stone(s)

- **Kidney** - Upper pole
- **Lower pole**
- **Calyx**
- **Pelvis**

- **Ureter** - Upper
- **Middle**
- **Lower**
- **Other**

### Size of Stone(s)

<table>
<thead>
<tr>
<th>Size</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-10 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10-15 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 15 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staghorn</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Drug History

### Past Medical History

### Investigations
- MSU
- U+E
- Stone Screen
- KUB
- IVU
- US
- Renogram

### Treatment
- Watch / Conservative
- Medical treatment
- Dietary modification
- Increase fluid intake
- Ureteroscopy - rigid
- Ureteroscopy - flexi
- ESWL
- Stent
- PCNL
- Nephrectomy
- Open nephrolithotomy
- Other

### Outcome
- Discharge
- Follow up in [ ] wks [ ] mths
- After Investigation
- KUB on arrival
- Open appointment
- Refer
- Admit

### Signature and Print Name
Appendix 3.2.2.1 Paediatric new patient form
### INVESTIGATIONS

<table>
<thead>
<tr>
<th>BLOOD/URINE</th>
<th>RADIOLGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSU</td>
<td>AXR</td>
</tr>
<tr>
<td>FBC</td>
<td>MAG3</td>
</tr>
<tr>
<td>U+E</td>
<td>IVU</td>
</tr>
<tr>
<td></td>
<td>Isotope cystography</td>
</tr>
<tr>
<td>Chloride</td>
<td>US</td>
</tr>
<tr>
<td>B12</td>
<td>CT</td>
</tr>
<tr>
<td>GFR</td>
<td>MCUG</td>
</tr>
<tr>
<td></td>
<td>MRI</td>
</tr>
<tr>
<td></td>
<td>DMSA</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
</tbody>
</table>

- Urodynamics
- Videourodynamics

### DIAGNOSIS

- Renal
- Ureteric
- Bladder
- Urethra
- Foreskin
- Genitalia
- Other

### TREATMENT

### OUTCOME

- Discharge
- Follow up in [□] wks
- [□] mths after investigation
- Open appt
- Refer
- Admit
- Book operation [□] LA [□] GA

### INFORMATION GIVEN TO THE PATIENT

### SIGNATURE and name printed
Appendix 3.2.2.m

Paediatric follow up form
Follow Up in Clinic

Office Use Only

Date

Consultant Initials
Dr / CP Initials

Put patient label in box below

URINALYSIS

blood

trace

++

+++  Height

Weight

Referral letter (scanned in)

Review of Investigations
Post Op Follow Up
Long Term Review
Other

DIAGNOSIS

Renal

Urethra

Ureteric

Foreskin

Bladder

Genitalia

CLINICAL PROGRESS

EXAMINATION

COSMETIC OUTCOME

Photo Taken
Pre-Op
At Operation
Post-Op
Today
Appendix 3.2.3.a  Draft inpatient admission form
UROLOGY IN - PATIENTS

Admission details

[patient label in box below]

[patient hospital number]

[Date] / [ ] / [ ]

[consultant code]

[Dr initials] [Time seen] [ ] : [ ]

[admission] [ ] A+E [ ] GP [ ] elective [ ] other

[ ] clinic admission [ ] hospital transfer

Presenting complaint

[ ] retention
[ ] haematuria
[ ] pain
[ ] elective procedure
[ ] investigation
[ ] other

Further details of presenting complaint

If more room required use a blank scannnable page

Past Medical History

[ ] IHD [ ] diabetes [ ] hypertension [ ] COAD [ ] CVA [ ] asthma

[ ] bleeding diathesis

[ ] any additional details below e.g. previous surgery
UROLOGY IN - PATIENTS

Admission details

Examination
- Anoide
- Anaemia
- Cyanosis
- Clubbing
- Lymphadenopathy

CVS
- Pulse: __________ bpm
- Blood pressure: __________ / __________ mmHg
- IVP: __________ cm H₂O
- HS: normal
- Murmur
- Edema: leg
- Sacrum
- Specify murmur: ___

Respiratory
- Respiratory rate: __________

Abdominal

CNS / musculo-skeletal
### Urological Symptoms

<table>
<thead>
<tr>
<th>Frequency</th>
<th>hesitancy</th>
<th>Yes</th>
<th>No</th>
<th>supra pubic pain</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. times OR hourly</td>
<td>straining</td>
<td></td>
<td></td>
<td>coneen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>day</td>
<td>incomplete emptying</td>
<td></td>
<td></td>
<td>incontinence - stress</td>
<td></td>
<td></td>
</tr>
<tr>
<td>night</td>
<td>haematuria</td>
<td></td>
<td></td>
<td>- urge</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>urgency</td>
<td></td>
<td></td>
<td>- mixed</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>dysuria</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
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<td></td>
<td>erectile dysfunction</td>
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<td></td>
<td>incontinence pads</td>
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### Past Medical History

<table>
<thead>
<tr>
<th>MI</th>
<th>asthma</th>
<th>Yes</th>
<th>No</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>diabetes</td>
<td>CVA</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>hypertension</td>
<td>epilepsy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COAD</td>
<td>jaundice</td>
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</table>

### Other - Specify

### Drug History

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<tr>
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<th>warfarin</th>
<th>aspirin</th>
<th>Allergies</th>
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<tr>
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<td>penicillin</td>
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<tr>
<td></td>
<td></td>
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<td>latex</td>
</tr>
</tbody>
</table>

### Social History

- Smoker: yes [ ] no [ ]
- Alcohol intake:

### Family History

- NONE [ ]
Appendix 3.2.3.c  Draft inpatient continuation form
Appendix 3.2.3.d  Intermediate inpatient continuation form
Appendix 3.2.3.e  Final inpatient continuation form
Appendix 3.2.3.f  Draft operation note
Appendix 3.2.3.g  Final operation note
Appendix 4.2.4

Date

![Graph showing % completeness by date (Early vs. Late) for TNR and SMR.

Consultant

![Graph showing % completeness by consultant (Early vs. Late) for TNR and SMR.]
Appendix 6.1.1 – Clinical questionnaire
CLINICAL QUESTIONNAIRE - 1

We are interested in your views about the use of "structured forms" (as described below) to record clinical information routinely. We would be grateful if you could complete this short questionnaire. All the information you provide will be kept confidential.

Background

The intention is to start recording clinical information obtained during a consultation or patient clerking on "structured forms" instead of on the traditional history sheets. By "structured forms" we mean, forms that use a mixture of small "tickboxes" and larger "free text" boxes to capture clinical information.

Example of part of form

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>renal colic</th>
<th>interstitial cystitis</th>
<th>ED</th>
<th>incontinence</th>
<th>other</th>
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</thead>
<tbody>
<tr>
<td>LUTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UTI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>haematuria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Once completed the "structured form" is scanned and then filed in the notes as a permanent record. When the "structured form" is scanned, if a box has been completed the information is stored in a database. This can then be analysed to produce a variety of reports e.g. a surgeon’s case-mix or the number of diagnoses of a particular disorder in the last month.
Personal details

Q1  Date

Q2  Position held  Consultant  Registrar  SHO  CP

Questions

Q3  In general what are your views about the use of "structured forms" to record routine clinical information?
   strongly approve  approve  neutral  disapprove  strongly disapprove

Q4  Have you used a similar style of form to record clinical information before?
   yes  no

If NO got to Q5

If YES, please describe the form, the circumstances in which it was used and what your views about using it were

Q5  If you were given the choice, would you use a "structured form" or traditional notes?
   structured form  traditional notes
Q6  The following are issues that have been voiced about the use of "structured forms" to record clinical information routinely. Please indicate your views.

a) Completing the form will add to consultation time
   strongly agree □  agree □  neutral □  disagree □  strongly disagree □

b) The "structured form" will present information in a uniform manner
   strongly agree □  agree □  neutral □  disagree □  strongly disagree □

c) Completing the form will not affect the interaction between clinician and patient
   strongly agree □  agree □  neutral □  disagree □  strongly disagree □

d) using a "structured form" will not prevent the clinician from recording a wide variety of information
   strongly agree □  agree □  neutral □  disagree □  strongly disagree □

e) "Structured forms" will improve the communication of information within the notes to all users
   strongly agree □  agree □  neutral □  disagree □  strongly disagree □

f) Extensive training will be required to become familiar with the "structured forms"
   strongly agree □  agree □  neutral □  disagree □  strongly disagree □

g) The effort required to fill in the forms will not be worth the benefit of having data in a database
   strongly agree □  agree □  neutral □  disagree □  strongly disagree □

Q7 Which of the following is the most crucial factor in determining the successful use of the form?
   length of the form □  design of the form □  users seeing the benefit of the data collected □
   none of the above - please specify other

Q8  Do you have any further comments to make regarding the use of "structured forms"?

Yes □  No □

If YES write the comments on the back of the introductory sheet.

Thank-you for your assistance in completing this questionnaire
Appendix 6.2.3 – Comments made by users about previous use of structured forms

“Routine admission (emergency and elective) proforma for all specialties including space for all aspects of history taking. The only tickboxes being systems review. Space for investigations done and results”

“Structured forms used to assess the prostate patients in Brighton. Very useful as assessment was uniform and allows uniform data collection”

“In Addenbrookes hospital, in house computer form for data collection (Audit) only, mirrored notes! Needed to be typed into computer by dedicated personnel”
Appendix 6.2.7 – Further comments regarding the use of structured forms

“Need much more space for history of presenting complaint.”

“Structured format good as long as don’t have to do traditional history sheet as well”

“Forms are generally a good idea, however, due to the complications of some patients the space available is not always sufficient”

“Initially forms were much more time consuming than traditional notes, but once you get used to the format it was easier and stopped me missing things out”

“Abbreviations can be confusing”

“Very important to only have one history sheet and not two”

“The structured form does not allow the important facts to be highlighted – all parts of the form are given equal weight”
Bibliography


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