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AN INVESTIGATION INTO AN INFORMATION ARCHITECTURE AND A RELATED PRODUCT CODE FOR MEDICINAL PRODUCTS

by

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ABSTRACT

There are many ways of coding and classifying medicinal products, each for its own purposes. This work seeks to investigate and establish the entities of an information architecture for medicinal products. The entities are used to establish a unique product code based on what are perceived to be the most important elements of a medicinal product. The resultant code should be of a suitably flexible construction to allow any of its constituents to be classified in any combination and, importantly,to allow access to the information architecture. This is particularly important as the use of a code and the constituents of the information architecture differ according to the needs of the user. The concept of using product modelling to determine information architecture is supported by writers in many disciplines.

The study was carried out by determining all the activities in several hospital pharmacies by analysing job descriptions and interviewing pharmacists. From this, Business Activity Models and data flow diagrams were constructed and entity types identified. Study of the entities showed that the entity type MEDICINAL PRODUCT was present in 85% of the total entity types.

The entity type MEDICINAL PRODUCT was modelled on the basis of the legal requirements for Data Sheet information, since it was reasoned that this was the minimum amount of information required to define an information architecture for a MEDICINAL PRODUCT. Additions to the theoretical legal model were also identified which were necessary in order to apply practically the model.

The MEDICINAL PRODUCT was then modelled on the basis of practical experience and experiment. By comparing these models with the theoretical model, the comprehensiveness of these practical models was determined to provide a comprehensive information architecture for a MEDICINAL PRODUCT and a product coding system.

The usefulness of the information architecture to provide a basis for classification was also investigated by developing a tablet and capsule identification system based on one model. The findings showed that it was possible to identify tablets and capsules except when their attributes of colour, size and markings were identical. It was concluded that the model was suitable for classification purposes but was limited in practice by the product attributes.

Importantly, the minimum amount of code to identify uniquely medicinal products was determined. However, certain product groups, eg Insulins and dextrans, did not conform to the unique code and had to be allocated local codes. The code also provides a method of dosage calculation, and together with the validated model for ingredients, provides a method of calculating total dose of similar ingredients. The code was compared and contrasted with existing coding systems in order to validate its advantages and disadvantages.

The modular structure of the code gives opportunities for expansion and user choice modules.

TO MY WIFE

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ABBREVIATIONS

ATC	Anatomical, Therapeutic, Chemical Drug Classification System
BP	British Pharmacopoeia
BNF	British National Formulary
BAM	Business Activity Model
CASE	Computer-aided Software Engineering
CBS	Common Basic Specification
CD	Controlled Drug
CI/SfB	Construction Index/Samarbetskommittén för Byggnadsfrågor
COSSH	Control of Substances Hazardous to Health
CSM	Committee on Safety of Medicines
DS	Data Store
EDI	Electronic Data Interchange
EP	European Pharmacopoeia
EAN	European Article Number
EC	European Community
GP	General Practitioner
GPP	General Practitioner Prescribing System Database
GSL	General Sale List
ICD	International Classification of diseases
ICD-CM	International Classification of diseases - clinical modification
ICPC	International Classification of Primary Care
INR	International Normalised Ratio
LDFD	Logical Data Flow Diagram
NSV	National Supplies Vocabulary
NHS	National Health Service

OPCS	Office of Population Censuses and Surveys
PACT	Prescribing Analysis and Cost Data
PAS	Patient Administration System
PCA	Prescription Cost Analysis
PPA	Prescription Pricing Authority
PIP	Pharmaceutical Interface Products Code
PL	Product Licence
P	Pharmacy medicine
POM	Prescription Only Medicine
QC	Quality Control
SESAME	Standardisation in Europe on Semantical Aspects of Medicine
SI	Système International d'Unités
SSADM	Structured Systems Analysis and Design Method
UPC	Universal Product Code
USP	United States Pharmacopoeia
WCC	Standing Committee of the National Council for Public Health (Netherlands)

1. INTRODUCTION

Traditionally, information about products, including medicinal products, is in a textual form, e.g. data sheets and catalogues. For basic data collection or use, a code may not be necessary and information may be stored in files, which has been the traditional method for many years. However, files get soiled, additional information needs to be added, files are lost and need replacing with fresh files (Briz-Kishore and Avadhanulu, 1983). Information from files, if it is to be put into a database, requires structuring. In fact any information, whether in files or on databases, requires structure if it is to be used for comparative or statistical purposes etc. Structuring often involves classifying the information into different categories. Whilst there is no specific requirement for coding, what is required is a defined label for a category or class. This can be bulky and so is likely to be coded for economy of space or time when writing the label. This has been referred to as a compressed data set by Wright, Lockley and Wiltshire (1992).

Where products are coded, this is usually according to the needs of the products' manufacturers or users. The codes used are often developed in-house or by an organisation to service its own needs (Hurley and McNeil, 1989). For compatibility between codes, look-up tables are required to ensure their usefulness when information is transmitted between different organisations. Some effort has been made with EAN codes to allow transmission of product information (Thomas, 1991). However, this is only of use to subscribers to the organisation and the information transmitted is dependent upon the amount of information the organisation wishes to transmit.

When information is transmitted by electronic means, like hardcopy, it needs to be accurate and understandable (Thomas, 1991) at all points in the transmission train, e.g. manufacturer, wholesaler or retailer, all of whom need some specific information and some specialised information for their own use. This implies that essential specific information is necessary to identify products. When this information is coded the nature of the information should not be altered.

Many of the problems associated with products in general also exist in the world of medicine and pharmacy and product information has to be conveyed accurately and succinctly.

It is, therefore, at this point useful to discuss methods of classification and coding, together with their advantages and disadvantages.

1.1 Classification and Coding

Classification is the grouping together of items on the basis of common criteria. It is often possible for items to be classified in different ways since the classifying criteria may be different. For example, a book may be classified by The Dewey System. This is an hierarchical system based on the subject-matter of the book. Another method of classifying books might be by size or colour, a concept that is valid for personally identified books. In other words, classification depends upon the perspective of the user.

The allocation of books to classes using the Dewey System is, like other classification systems, open to interpretation. A consequence can be that a book may fall into more than one of the available

classes. Classifications do not, therefore, necessarily provide unique categorisation of products, since there is a possibility of multiple entries. Indeed, the number of available classes may increase, decrease or change in the future, dependent upon knowledge, practice and the needs of users.

Classification systems are often abbreviated by allocating codes to each category. This could be a simple system in which the subjects are initially separated into nine categories coded 1 - 9. Each category could then be further divided into nine subgroups 1.1 to 1.9 etc. This could then be broken down further to as many levels as required. 1.1.1.1 to 9.9.9.9 would be a four level hierarchy. If we want to identify a product uniquely, we need as many levels and categories as required to get to an unambiguous item. Whilst classification systems can produce a code for an item and can be useful in categorising products, the system is often used in reverse, i.e. the code is used to identify a product. It must be borne in mind that a code is not per se a classification system, neither does a classification system need to be coded.

However, in order to identify an item uniquely, it should be, at any one time, that one product is assigned only one code; a situation that is not always possible with classification systems if the data item has multiple entries.

According to Murray (1985), an identification code is an abbreviation used to identify a particular piece of data, e.g. a product, patient etc. Murray also states that an identification code should have the following characteristics:

"1. It should be **unique** (i.e. the code should identify only one data item). The same code should not represent two or more data items.

2. It should be **expandable** (i.e. it should be possible to easily add new identification codes as new data items are added).

3. It should be **compact** (i.e. it should represent a set of data items in a minimum number of characters).

4. It should be **precise** (i.e. the rules for the creation of an identification code for a new data item should result in only one possible code).

5. It should be of **fixed size** (i.e. each identification code for a set of data items should contain the same number of characters).

6. It should be **meaningful** (i.e. the code should convey to a user at least some information on the data item represented)."

Therefore, a code is a "label" attached to a data item that should not change. It may also be independent of language and so, if appropriate definitions are made, then language differences are sorted out. Longevity is an important attribute of a code. The label can be alphabetic, numeric or a combination.

1.2 Types of code

There are several types of code, e.g. serial, linear, hierarchical and block codes, each of which may be unstructured, semi-structured or structured. Some codes may be hybrids, i.e. a mixture of serial and hierarchical. All the codes, however, have properties according to their nature, which are discussed below.

1.2.1 Structured, unstructured and semi-structured codes

A structured code is one in which the various elements of the code are defined by and adhere to predetermined rules. This obviously applies to hierarchical and modular codes. In contrast, serial codes may be

totally unstructured and may be allocated to data items in a random manner. Semi-structured codes are a mixture of the two.

1.2.2 Linear codes

Linear codes are non-hierarchical in nature consisting of strings of alphanumeric characters, all of which have equal significance and are independent of each other. Some of these coding systems are said to be unstructured, eg. European Article Number (EAN) (according to Thomas, 1991), but in effect they are semi-structured. The EAN and Universal Product Code (UPC) codes consist of strings of digits. In the EAN code, the first two digits denote the country of origin, then five digits denote the manufacturer or user. The next five digits are allocated by the code purchaser to a product and can be used in any way the purchaser wishes. These codes are, therefore, modular in nature. It could be argued that these codes are structured, although the contents of the owner-specific part may vary. This type of code requires that a code owner must communicate the commercial portion of the code (non-structured part, according to Mader (1987) and Thomas (1991)) to his customers. Since the method of structuring the commercial portion is not standard throughout industry, the use of look-up tables is therefore unavoidable. These codes are a mixture of defined modules and uncontrolled modules and can be described as semi-structured.

1.2.2.1 Serial codes

In serial codes, products are assigned a code in sequential order: product 1 = 1, product 2 = 2 etc.

These may be citation codes that can be used inside or outside the system to point always to the same item.

The advantage of codes of this type are that they are unique, short and precise. The disadvantages are that data items cannot be maintained in any order, other than that in which the code was originally set up, and the code is not very meaningful. Insertions mean recoding of at least part of the code and deletions leave gaps in the code (Murray, 1985). An example of this type of code is the Prescription Pricing Authority's pricing code, which has defined gaps left for additional products. Williams (1990), in the Journal of the Society of Archivists, says that gaps in numbering systems frustrate security checks and stocktaking and may disguise the existence of missing or misplaced items.

1.2.2.2 Modular codes

Modular codes are linear codes that have been divided into segments (modules): every module fits into a set of rules. Each module identifies a characteristic and is independent of other modules. The modules can be grouped together in any combination to provide a unique identification code or to address specific characteristics required by particular users of a product, e.g. a manufacturer may require to know a product's weight or volume and a prescriber its form or strength. Entry to the code can be via any module and the modules used, are dependent on the required purpose. Such a code has the advantage that, since the modules are independent and since there is no hierarchy, a program needs only to pass through the defined field or fields once to identify records (Green 1990). It is therefore quicker than a hierarchy and no extraneous information is involved. Modules can also be added as they are defined (Murray, 1985).

1.2.3 Hierarchical Codes

These are in effect coded classification systems that are constructed

in an hierarchical manner, giving increased levels of detail as they decompose. The structure of such a coding system is illustrated in Figure 1.1. This figure shows an imaginary hierarchical scheme composed of four levels, in which level four needs to be accessed to provide unique information. In this code, entry must be made at a high level to ensure that a descent can be made through the lower levels to the required information level, e.g. A to B to C etc. If a level of information is missing then the levels below the missing information cannot be accessed. At the point, F, only "generalised" information can be accessed. In theory, the code could be entered at any point or level but the preceding hierarchical information must be known in order to do this. Otherwise there are potentially several branches that could have the same identifier at that particular level. Entry at level 3 with an identifier of ..1 could be at F or C since their level 3 values are identical. Therefore to identify the relevant branch of the hierarchy, the codes for the preceding levels need to be known, i.e. 1.1 or 1.2. It is, therefore, necessary to use the whole code, that is 1.1.1 or 1.2.1 as a unique handle to enter the database at the right point. Thus, in effect, the code is driven by classification, which means additional information is involved, even if not overtly used. In practice, a coding system like this would not be entered from a low level but only from the top and the whole code would need to be used.

The additional information leads to a multiplicity of codes for a product with multiple categories.

This type of code has the potential for the categorisation of large numbers of items with only a few levels of decomposition. But it can

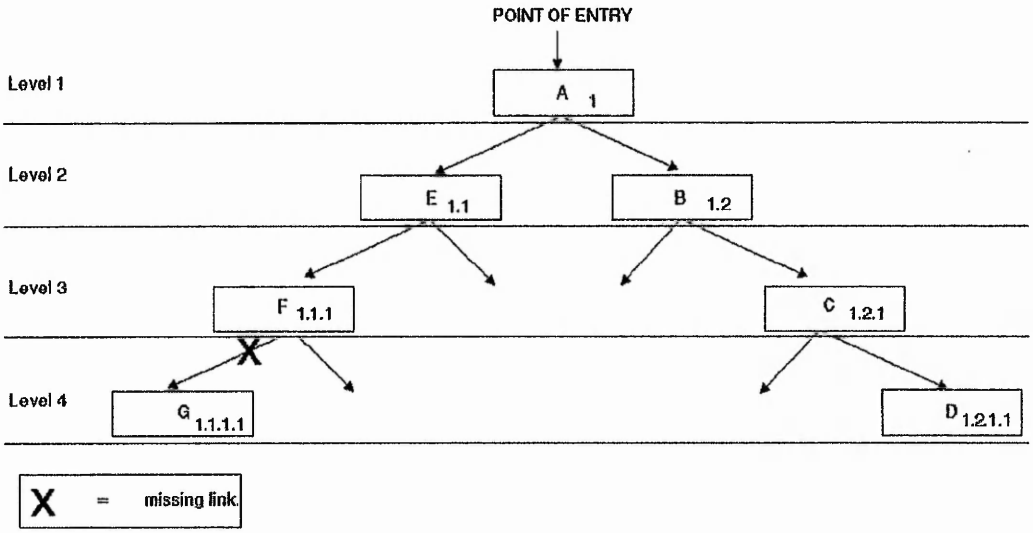


Figure 1.1 Example of hierarchical code structure.

have the drawback that only limited information about each item may be conveyed if insufficient levels are used. In many instances, the final level can only refer to a group of closely related but not unique items.

1.3 Overview of Coding of Medicinal Products

To facilitate information flow in the health services, a great deal of data has been classified and coded. Medicinal products have been subjected to this process. The use of computers and other automated systems have encouraged this process. The codes are often developed in-house or by an organisation to service its own needs (Hurley and McNeil, 1989). Uncontrolled development of computer systems has led to the development of many incompatible coding systems, resulting in inefficient information flow.

The following extract from a private paper by Maddock (1992) to the Royal Pharmaceutical Society illustrates this point:

> "It has always been the Department of Health's policy that as independent contractors to the NHS, pharmacists, medical practitioners, dentists and opticians are free to choose and obtain the computer systems that best suit their own individual needs.
>
> The consequences of such a policy are that there are many diverse systems in use throughout the Family Health Service sector.
>
> There are currently about 110 different systems in use by medical practitioners and 160 options available for dental practitioners. Within community pharmacy there are less than 20 systems currently in use. This great variety of choice has made it evident that there is a need to identify the essential common elements of the activity of primary care practitioners, if progress is to be achieved in ensuring compatibility of systems.
>
> The Department of Health is committed to research and to improve information systems in primary and community care as a result of recently implemented NHS reforms. Our aim is to develop a seamless flow of information between all sectors of primary and secondary care, another is to ensure

> the availability and maintenance of good quality information to promote the cost effective use of pharmaceutical care. Speed and accuracy in the transfer of information will be of paramount importance."

As well as the systems in use in the primary services, there are some 20 systems in use within the hospital sector and most wholesalers and manufacturers have their own systems. Many of these systems have their own information systems, which are not compatible with each other. There is, therefore, a need for the essential common elements of the activities of all users to be identified (Sibley, 1985; Thompson and Smith, 1986; Vanguard, 1988; Kneale, 1989; NETHRA, 1989; SESAME, 1989a, 1990a, 1990b; Green, 1990; NHS IMC, 1990a, 1990b, 1990c, 1991; Pharmaceutical Journal, 1990a, 1990b, 1993; Worling, 1990; Veth and Gehlen, 1991; Davies and Read, 1993).

Love (1989) stated that the NHS Procurement Directorate had issued a mission statement on the use of Electronic Data Interchange (EDI) between Health Authorities and their trading partners. EDI should link computer to computer without human intervention to assess or to consider the content en route.

He also says,

> "The concept of messages structured in a way understandable to trading partners first grew in response to the demands of the business community for accurate, cost effective and timely exchange of information."

This implies that the data should be structured. Love (1989) defines structured data as a precise, recognised and accepted method of assembling data.

One of the tasks in providing common data within the health service is to determine a coding structure of medicinal products in order to

provide a solid basis for standard messages known to all parties.

To date, little attempt has been made to develop a coding system for medicinal products that meets the requirement for structured information. This is borne out by the following statements. According to Sprince (1990),

> "The lack of standards makes the interchangeability of patient medication record information very difficult. The nature of commercial product development is such that manufacturers are reluctant to co-operate with each other in order to develop standard information bases. This is borne out by the fact that, while the PIP code is almost universally used for re-ordering one manufacturer still uses a six digit code ....."

and Kneale (1989) said,

> "To achieve a single uniform E.C. marketing authorization, clear but flexible data requirements would have to be applied consistently."

This is further confirmed by Markwell (1993) of the FHS Computer Unit who said,

> "A European standard must be written using terms that translate in an unambiguous manner."

In Australia, a similar situation exists:

> "..... currently no standardization exists in the drug codes that are used to record prescribing in Australia." (Hurley and McNeil, 1989).

At this point, it is pertinent to consider existing coding systems and to determine whether any exist or can be modified to meet the foregoing requirements.

1.3.1. European Article Number Code (EAN)

The EAN code is a general purpose product code, which has been used for medicinal products. It is a semi-structured code consisting of thirteen digits. Digits 1 and 2 identify the country of origin,

digits 3 to 7 identify the company and the following 5 digits are assumed by the company to identify their products. The final digit is a check digit. The design of the system is such that no two codes can be identical. The owner of the code, therefore, has to notify users of his codes and their contents. Whilst this system was designed to speed transmission of data by electronic data interchange (Thomas, 1991), it does not provide any structure for the open transmission of information and communication between non-trading partners, which is necessary in the health environment. The code was designed to facilitate the use of barcode readers, although it can be used with optical characters as these are inherent within the total design of the code. An example of an EAN code is shown in Table 1.1 for paracetamol tablets manufactured by Sterwin Medicines.

EAN Code 5000282581346		
Category	Code	Meaning
Country of origin	50	UK
Manufacturer	00282	Sterwin Medicines
Product	58134	paracetamol Tabs
Check digit	6	

Table 1.1 The Structure of the EAN code for paracetamol tablets manufactured by Sterwin Medicines.

1.3.2 Manchester System (1965 - 1984)

In common with early coding systems for medicinal products, the Manchester System consisted of a series of numbers allocated serially and allocated arbitrarily to each medicinal product. For example,

000180 = Water for Injections BP 10ml,

001396 = Ampicillin Capsules 250mg.

There was no way of obtaining any information from this code, other than the identification of the medicinal product, which required a look-up table. This code was, therefore, particularly user-unfriendly and of no interest to prescribers or pharmacists, except as part of a stock control system. It was abandoned in 1984 since it resulted in excessive input errors by staff.

1.3.3 Drug Master Index (DMI)

Personal Communication with Mrs Donnelly of the Prescription Pricing Authority showed that the Drug Master Index was a manually allocated code, which originated in the mid 1950s. Products were numbered serially from 0000 as prescriptions were received by the Authority. The system was abandoned in 1991 when the Prescribing Analysis and Cost (PACT) code was introduced. At that time, there were approximately 7500 items on the index. It was also known as the Central Drug Index (CDI).

1.3.4 National Supplies Vocabulary (NSV)

The National Supplies Vocabulary was developed as a total coding system for the National Health Service. The code consists of three letters then three numbers. The product types, consisting of all products used within the Health Service, are arranged serially in alphabetical order; medicinal products are allocated section D. Section D includes all medicinal products with a product licence and raw materials that are the subject of a British Pharmacopoeia monograph. However, foods and alcoholic beverages, used as medicinal products, are included in Sections H and A, respectively, whilst dressings, other than medicated dressings, are in Section E. This, therefore, means that products used as drugs can be prefixed with D, H, E or A. The group D is further

sub-divided into DA-DT, medicines; DW, radiopharmaceutials; DY, medicated dressings and medical gases. The codes in group D are further sub-divided to encompass groups of similar drugs, e.g. DGA = Haemodialysis solutions; DHK = inhalation devices; WHL and PHM = insulin preparations.

There are no sub-divisions in groups H or E to distinguish products that may be used as drugs from others included in the group. The numbers within the code groups are distributed arbitrarily, e.g. DFT740 equates to Fulcin tablet 125mg. There are also different numbers allocated to proprietary products and generic products, e.g. DFT740 equates to Fulcin tablet 125mg and DFT760 equates to Grisovin tablet 125mg, respectively.

It will be seen that within this code there is no method of identifying the presentation of the product except by reference to a textual description, e.g. tablet or capsule. Although not part of the code, there is a textual link to proprietary names, product licence, Drug Master Index and British National Formulary (BNF) Coding. Legal category, modified action and route of administration cannot be identified except by text. There is also cross-referencing with EAN codes (Watling, 1990).

This method of coding, whilst it goes some way to providing a coding system, is insufficient and not sufficiently structured for use as a complete coding system without textual support; its main use is product identification. It has the characteristics of serial codes.

Its only link with clinical activity is via its textual link with BNF

coding.

1.3.5 Manufacturers' and Wholesalers' Codes

Manufacturers and wholesalers use many codes, e.g. Prosper and Pharmaceutical Interface Products Code (PIP) and some developed in-house. They are used mainly for ordering purposes. They are serial codes consisting of alphanumeric characters, sometimes separated by a hyphen. Many systems used in community pharmacies are based on these codes, such as that supplied by John Richardson Computers Ltd, a major supplier. An example of a widely used code is explained below.

1.3.5.1 The Pharmaceutical Interface Products Code (PIP Code)

The PIP code was developed in the early 1980s as a common computer code for pharmacy, to allow inter-computer data transmission. It consists of a six-figure code allocated randomly to products. It is just a key to a database containing information on price, VAT etc. It is cross-referenced to the EAN code and other wholesaler codes.

As these codes are unique to the users, there is no facility for the interchange of information between systems. As a result, several codes have to be quoted on correspondence or in catalogues to ensure the accurate identification of medicinal products, e.g. Loestrin tablets, Table 1.2.

Loestrin Tablets, 20 pack 3 x 21	
Type of Code	Code Number
Parke Davis Code	64786
EAN Code	5010123647865
PIP Code	261-958
Prosper Code	204-263

Table 1.2 - The many codes, at present, in use for a single product, in this case, packs of Loestrin tablets.

1.3.6 Standard Drug System for the United States

The United States Pharmacopoeia (USP) Convention is proposing to set up a letter and number coding system for prescription and over-the-counter drugs. The USP proposes that each drug or unique combination of drugs be assigned a three-character alphanumeric code using the ten numbers and twenty-three letters from the alphabet. There would be around 36,000 combinations to choose from. The strength of the product would not be included as part of the code (Pharmaceutical Journal, 1990a). It is, in effect, a serial code with minimal structure.

It appears, therefore, that look-up tables would be necessary to use this unique code, and its components would not be of use in providing secondary information.

1.3.7 Read Codes

The Read Clinical Classification, named after James Read the author of the system, is a five level hierarchy, used to code for clinical conditions and not medicinal products, Table 1.3

Level	Example of terms	Read code
1	Circulatory system disease	G
2	Ischaemic heart disease	G3
3	Acute myocardial infarction	G30
4	Acute anterior myocardial infarction	G301
5	Acute anteroseptal myocardial infarction	G3011

Table 1.3 - Example of Read Clinical Code System

Each preferred term in the Read Codes has an unambiguous five character alphanumeric code that gives a unique identifier to the medical term it represents. The characters used, are A-Z upper and lower case, excluding I, i, O and o, and the numeric characters 0 to 9.

These codes are mapped to and compatible with all the widely used standard statistical, national and international classifications, e.g. International Classification of Diseases (ICD-9, 1977), International Classification of Diseases 9th Revision (ICD-9-CM, 1980), Classification of Surgical Operations and Procedures (OPCS-4, 1987), International Classification of Primary Care (ICPC, 1987).

The Read Code Drug Dictionary follows a structure similar to the Read Clinical Classification, i.e. a five level hierarchy. Although at present only four levels are used, they define ultimately a drug in terms of name, strength and form. Using ulcer-healing drugs as an example, the code is structured as in Table 1.4

Level	Example of terms	Read code
1	Gastro intestinal system	.a
2	Ulcer healing drugs	.a6
3	CIMETIDINE	.a61
4	TAGAMET 200mg tabs	.a611
4	TAGAMET 400mg tabs	.a612
4	TAGAMET 800mg tabs	.a613
4	TAGAMET 200mg/5ml	.a614
4	TAGAMET 200mg/2ml inj	.a615

Table 1.4 - The structure of the Read Code Drug Dictionary

The name, form and strength of the product are in textual form, in a field that is in one of three issued formats of 30, 60, or 198 characters but it does not distinguish between these components. Each product is mapped to a BNF code.

A. Davies of the NHS Management Executive Centre for Coding and Classification (personal communication) showed that in order to accommodate modified forms of products, look-up tables had to be produced or the modification accommodated within the name part of the textual field. Because some products have several therapeutic uses, modification to the product descriptions had to be carried out, e.g. clonidine was represented as "clonidine" for antimigraine treatment and "clonidine (HYP)" for treatment of hypertension. It is, therefore, a code useful only for the provision of prescribing information.

The code does not yet identify uniquely proprietary and generic brands. With only ten numbers and 48 letters giving a total of fifty eight characters available for coding, there is also a possibility of insufficient low level codes to accommodate products. To overcome the

problem the code could be extended to more significant figures but this would lengthen the code. SESAME (1989b) confirms this view.

Davies and Read (1993) state that the

> "... drug section is currently being rewritten to take advantage of the 5 character structure and will enable proprietary and generic brands to be uniquely identified."

Personal Communication with Davies confirmed these will be in a textual form, which will require look-up tables.

1.3.8 The Anatomical Therapeutic Chemical (ATC) Drug Classification System

The ATC system has been developed and is the common classification system for all medicines in the Nordic countries and according to Le Roux and Russell (1990):

> "... is an attempt at developing an international (universal) system of classification for all pharmaceutical preparations."

It is an hierarchical system, dividing drugs into several levels, as illustrated in Table 1.5.

Level	Example of term	ATC Code
1	Central Nervous System	N
2	Psycholeptics	NO5
3	Tranquillisers	NO5B
4	Benzodiazepine Derivatives	NO5BA
5	Diazepam	NO5BA01

Table 1.5 - The ATC drug classification system

Level one is in anatomical groups. These are further subdivided into levels two and three, which are therapeutic main group and subgroups. The fourth and fifth levels are the chemical/therapeutic subgroup and the single chemical, substance, respectively. The lower levels are only text fields and have no facility for "splitting" information for subsequent use. This textual field does not contain information on strength or form of the product.

The problem of identifying preparations/chemical substances with different therapeutic uses, whilst satisfactory for prescribing, causes the product, as with the Read code, to be duplicated with two or more therapeutic groups. For example, chloroquine may be classified as M01 (anti-inflammatory and anti-rheumatic products) or P01B (antimalarials).

A drug that is available in two or more strengths, each with different therapeutic uses, may be classified in two or more groups, e.g. clonidine, which is classified as C02 (hypotensive) and N02C (antimigraine). The situation becomes more complicated where a product contains two or more active ingredients. The main therapeutic use of the product usually decides the classification.

Combined preparations with the same primary ingredient are usually classified at the same 5th level. Thus, acetylsalicylic acid with caffeine and acetylsalicylic acid with codeine are both classified as N02BA51. This is confirmed in the SESAME (1989b) report. This is unlike the Read Code Drug Dictionary, which classifies them as distinct products. Le Roux and Russell (1990) state that the ATC code is suitable for identifying medicinal products. However, it only

identifies products on a therapeutic basis. Even then, there is doubt about which product constitutes the active ingredient in combined products. In fact, they all may be active. The system demands that the main therapeutic use would decide the classification. Clearly, as it stands, it cannot provide unique identification of a product only to a group of similar products. It could be argued that, depending on the condition being treated, the main therapeutic use embodied in the code may not be the one for which it is being used (Freeman, 1978).

1.3.9 British National Formulary

The BNF code is intended to be a rapid reference pocket-book that is supplemented by information from more specialised publications. It tends to concentrate on the more common conditions and their treatment. This leaves very specialised treatments, not frequently encountered, to be supplemented by specialist information and knowledge, e.g. chemotherapy and immunosuppression. These, therefore, are not included in its coding system.

The information contained within each group of drugs is relatively comprehensive, with indications, cautions, side-effects, doses and proprietary product information presented in a textual form. It gives only sketchy details of a drug's presentation and appearance.

It is arranged in fifteen groups, twelve of which are for the treatment of various body systems, e.g. gastro-intestinal system, and three according to the pharmacological activities of the drugs, including infections, immunological products and vaccines. It, therefore, classifies medicinal products in two different ways. Each group is further organised and coded as shown in Table 1.6.

BNF layout	Format	Cumulative Digits
BNF chapter	2 numeric	00
BNF section	2 numeric	0000
BNF paragraph	2 numeric	000000
BNF sub paragraph	1 numeric	0000000

Table 1.6 - The structure of the British National Formulary Code

This is illustrated by the coding of paracetamol 500mg tablets, Table 1.7.

BNF	Code	Code	Code	Example of Terms
BNF chapter 4	04			drugs acting on the Central Nervous System
BNF section 7		07		analgesics
BNF paragraph 1			01	non-opioid analgesics (includes paracetamol, aspirin etc.)
Total Code for non-opioid analgesic group	04	07	01	

Table 1.7 Coding of paracetamol by the British National Formulary method

Within each group there is a group of drugs and the classification, therefore, although it is at a comparatively low level, is only to therapeutic group and not to individual products. This is illustrated in Table 1.7.

One of the problems with this type of classification is that drugs may appear in more than one classification, e.g. bromocriptine is in Sections 4.9 (Drugs used in Parkinsonism and related disorders) and 6.7 (other endocrine drugs). The classification of the product is therefore not unique, because it is not product-orientated but condition-orientated.

1.3.10 The Prescription Pricing Authority Coding Systems

The Prescription Pricing Authority uses two separate codes, one for pricing, Prescription Cost Analysis (PCA), and the other for producing information for determining Prescribing Analysis and Cost (PACT).

Alexander (1993) and Ball (1993) report that the Prescription Pricing Authority is also looking towards paperless prescribing and towards nurse prescribing. To this end, since there is no other suitable coding system available, the PPA is about to design two further coding systems for these purposes.

1.3.10.1 The Pricing Code

The pricing code is an eight digit code plus one check digit. The drugs are numbered serially from the drug name. There is no meaning to the various portions of the code. Table 1.8 shows the structure of the code excluding allocation of the check digit. The part related to the drug name consists of five numerical digits allocated arbitrarily. Presentation is associated with the next two digits and pack is allocated to one more digit. All digits are allocated to the product with no relational structure to other drug codes. Table 1.8 shows how an imaginary drug, XXXXX, is serially numbered 08371. XXXXX has a presentation of syrup 100mg/5ml coded 01 and pack size 200ml coded 1, in their respective fields. In the imaginary drug, ZZZZZ, which is serially numbered 14149, presentation code 01 is equivalent to ZZZZZ ointment. Digit 1 in the pack size field equals 100g, 200ml or 100 tablets in XXXXX or 50g in ZZZZZ. In other words, there is no inherent meaning to the value of individual code components.

	DIGITS			
	12345	6	7	8
	DRUG	PRESENTATION		PACK
DRUG NAME XXXXX	08371	0	0	0
PRESENTATION SYRUP 100mg/5ml	08371	0	1	0
PACKS 200ml	08371	0	1	1
PRESENTATION TABLETS 200MG	08371	0	3	0
PACKS 100	08371	0	3	1
500	08371	0	3	2
DRUG NAME ZZZZZ	14149	0	0	0
PRESENTATION OINTMENT	14149	0	1	0
PACKS 50g	14149	0	1	1
100g	14149	0	1	2

Table 1.8 - Prescription Pricing Authority Pricing Codes (excluding check digit)

Because gaps are not left between presentations, as each new medicinal product is released, it will be allocated the next available code, which means that the drug presentations are not necessarily in alphabetical order.

It will be seen, therefore, that using this system of coding that:

a. there is no grouping of records to make data inputting easier;

b. there are no meaningful parts to the code (as suggested by Murray, 1985) to make data inputting easier;

c. the presentation part of the records has to be duplicated to ensure that different pack sizes can be accommodated within presentation;

d. since the records are all textual there can be no convenient, automated manipulation of the information.

1.3.10.2 Prescribing Analysis and Cost (PACT)

In order to provide information on prescribing, a new drug coding system was designed in 1988 by the PPA. This system, which now forms the basis of the GP prescribing (GPP) system data base, is founded on the BNF coding system. However, because the BNF identifies products only to therapeutic group and not to individual product, the code has been modified by the Prescription Pricing Authority in order to produce data specifically for PACT purposes. The reason for this is shown by the following example. The BNF code 020802 relates to the oral forms: Warfarin Sodium, Nicoumalone and Phenindione. It is not possible to identify either the proprietary preparations of these products or their strengths. 020802 for Warfarin Sodium includes Marevan 1mg, 2mg, 3mg, 5mg and 10mg tablets and Warfarin WBP 1mg, 3mg and 5mg tablets. In order to provide information for PACT, it is necessary to identify individual products in order to determine prescribing habits of general practitioners. For example, whether they prescribe generic or proprietary forms of a product and, if the latter, the actual product that is prescribed.

Since the BNF drug code does not in many cases identify individual products but rather groups of similar products, it has been modified by the addition of extra fields to meet the Prescription Pricing Authority's needs. Green (1990), however, counsels against the practice of inserting additional fields.

The modifications used by the Prescription Pricing Authority to identify individual products are shown in Table 1.9. The first seven characters are allocated according to the categories allocated in the BNF.

BNF layout		Cumulative Characters
BNF chapter	2 numeric	00
BNF section	2 numeric	0000
BNF paragraph	2 numeric	000000
BNF subparagraph	1 numeric	0000000

Modification by PPA		
additional digits appended after 0000000		
Drug/chemical substance	1 alpha	A
Preparation	2 alpha	AAA
Equivalence Indicator	1 alpha	AAAA
Total code size	0000000AAAA	11 characters

Table 1.9 - Modification of British National Formulary Code by the Prescription Pricing Authority

The modifications are as follows:

1. Drug/chemical substance - the eighth character. This is coded serially as A to Z in alphabetical order of the names listed in the relevant BNF group. Compound preparations are coded as 0.

2. Preparation - the ninth and tenth characters. The ninth character represents the type of product, A = generic, B to Z represents relevant proprietary products arranged in alphabetical

order. The tenth character, coded as A to Z, represents the strength/formulation of the product that is coded at the ninth character.

3. Equivalence indication - eleventh character. This is designed to link proprietary preparations to their generic equivalents and is coded A to Z. The code value is the same as that of the eleventh character of the generic preparation with the same strength. If there is no generic equivalent then the eleventh character is coded as 0.

As an example, the above system produces the following modified BNF code for oral anticoagulants, as shown in Table 1.10

BNF Code	PACT Modification	Significance
02.		Cardiovascular System
02.08		Anticoagulants and Protamine
02.08.020		Oral Anticoagulants
02.08.020	.W	Warfarin Sodium
02.08.020	.W.AA.A	Warfarin Sodium Tab 1 mg
	.AB.B	Warfarin Sodium Tab 3mg
	.AC.C	Warfarin Sodium Tab 4mg
	.AD.D	Warfarin Sodium Tab 5mg
	.AE.E	Warfarin Sodium Tab 10mg
	.BA.A	Marevan Tab 1mg
	.BB.B	Marevan Tab 3mg
	.BC.D	Marevan Tab 5mg
	.BD.E	Marevan Tab 10mg
	.BE.O	Marevan Tab 2mg
	.CA.A	Warfarin WB Tab 1mg
	.CB.B	Warfarin WB Tab 3mg
	.CC.D	Warfarin WB Tab 5mg

Table 1.10 **The modified drug code as adopted by the Prescription Pricing Authority, as shown for examples of oral anticoagulants.**
(Full stops are included only to help understanding and are not delineators included in the code.)

Note: The proprietaries Marevan Tab 1mg and Warfarin WB Tab 1mg link to the generic equivalent Warfarin Sodium Tab 1mg; similarly for the 3, 5 and 10mg preparations. The proprietary Marevan Tab 2mg does not have a generic equivalent.

The use of the code in practice has shown that there are several anomalies.

1. For certain Drug/Chemical Substances, the preparations are split into two or more groups and recorded under different chemical substance codes, pending extension of the code to provide further sub-divisions in this category. For example,

Spironolactone Capsules, Powder and Tablets are recorded under the BNF Chemical Substance Code 02.02.030.S, but the elixir, liquid, syrup, solution, suspension and mixture are recorded under BNF Chemical Substance Code 02.02.030.T.

2. Compound preparations are coded as single Drug/Chemical Substances and not as compounds where:

- the generic title is an official title, i.e. BP, BPC, or BAN; or

- the preparation is listed in the BNF under a Drug/Chemical Substance heading, e.g. Magnesium Trisilicate Mixture.

3. Compound preparations, which are one of a family of preparations where the main active constituent and therapeutic purpose are the same as the single drug preparation, are coded as different preparations of that single drug. For example, Altacite Plus is coded as a preparation of Hydrotalcite.

Where a product appears in more than one BNF section, e.g. promethazine, it is allocated to the BNF chapter associated with the greatest use of the product. If there is any doubt, it is allocated to a chapter by a pharmacist employed in the PPA for classification. Products, which are not included in the BNF, are coded by the pharmacist on the basis of data sheets, professional knowledge, journal articles etc. to a BNF chapter that he feels accommodates them (personal communication: Mrs Donnelly of the Prescription Pricing Authority).

The problems in allocating things to the correct section are,

therefore, those highlighted in the ATC code review. Thus, a code that begins life in a rational manner becomes adapted and finally becomes, what Green (1990) refers to as an ad hoc code.

1.3.11 WCC Classification of Medicines

This method of classification has been developed for drugs registered in the Netherlands. It identifies products by their characteristics. The structure of the classification system is textual and based on eight characteristics of medicines that, it is considered, describe and distinguish medicines. These are shown in Table 1.11.

1. Substance
2. Strength
3. Pharmaceutical Dosage Form
4. Route of administration
5. Trade name
6. Information regarding original and legal registration
7. Packaging
8. Batch number

Table 1.11 - The characteristics of the WCC Classification of Medicines

This classification system has led to the development of the next stage in the classification of characteristics 1-4 and 7. Substance classification is developed to the locus of action, pharmacotherapeutic group (Nationale Raad voor de Volksgezondheid, 1989a) and Dosage Forms, classified according to Route of Administration (Nationale Raad voor de Volksgezondheid, 1989b) and Standard Routes of Administration (Nationale Raad voor de Volksgezondheid, 1988).

Strength classification has been built up using the International

System of Units for health professions.

Criticisms of this system of classification are that it is textual and does not support a unique coding system and that all levels of development are not consistent. Also, a thesaurus has to be used to obtain information on terms used and preferred terms. This could be considered to be a further classification in its own right, since it identifies product characteristics.

1.4 Summary of Classifications and Codes

It can be seen, from the details of the coding systems discussed, that coding systems for medicinal products have been developed for specific purposes. They are, in general, without useful structure. For example, with EAN and UPC codes it is not possible to translate the code completely, unless the code owner devolves the information contained in the user-specific section.

Several of the coding systems discussed are hierarchies, e.g. Read, ATC and BNF. These are the most used systems available in Britain and Europe and have been developed for a specific purpose, i.e. prescribing. It is, in general, only possible to enter these systems at their highest levels.

All the codes that are based on the BNF have the inherent fault that the BNF uses two different classification systems as its basis.

The final classification of a product determines the product code. But a product may be included in several classifications, allowing multiple entries and thus, codes.

The Read Code Drug Dictionary has multiple entries.

The Prescription Pricing Authority uses two separate codes, the PCA for pricing and the other for producing information for PACT data. The PACT data codes began as rational codes, based on the BNF codes, but rationality has been sacrificed to accommodate anomalies.

In the Read, BNF, ATC and PACT codes the final detail is in textual form and does not allow easy manipulation of data.

Most of the remaining systems, Prescription Pricing Authority's Pricing Code, NSV, Manufacturers' codes etc., are serial in nature, having the characteristics already discussed. The code links only to the individual product and final detail is textual in form.

In order to translate from one code to another, look-up tables are required.

The only system that identifies product characteristics is the WCC Classification of Medicines but this does not support a coding system. The authors, however, are gradually defining lower levels, e.g. locus of action (Nationale Raad voor de Volksgezondheid, 1989a) and dosage forms classified according to route of administration (Nationale Raad voor de Volksgezondheid, 1988).

The introduction has, therefore, determined that no coding system for identification of medicinal products exists that meets the requirements of being unique, expandable, compact, precise, fixed size, meaningful and non-hierarchical: attributes considered essential and described by

Murray (1985) and Green (1990).

This strengthens the argument for a common structured coding system that will accommodate all facets of the information-providing system.

For universal application, therefore, the development of a product code, based on readily available, structured principles and rational criteria, having the facility to add other information as necessary, would be a method of overcoming the shortcomings of existing systems.

1.5 Product Modelling

How can the information for a code be ascertained? It could be either by asking potential users their requirements, based on experience, or by modelling the information environment through techniques that have been used successfully in other areas; such as those described by Corrigall, Lee, Young and Bell (1992). The latter method has the advantage that, because of the completeness of the analysis, the model should be more comprehensive than one based on experience alone. Modelling techniques are often called product modelling or data modelling, depending on the environment in which the technique is being applied. The information obtained by modelling can provide an information architecture from which structured coding systems can be developed.

Literature searches showed little has been published about data modelling of medicinal products except NETHRA (1989), SESAME (1990c), NHS IMC (1991) and Thompson (1991). However, in other disciplines, notably engineering and building, there are many published papers on data modelling, the principles of which can be applied to

pharmaceutical practice. The principal reasons for using data modelling in the building industry, according to Sanvido (1990) of the Department of Architectural Engineering, Pennsylvania State University, are that,

> "Computer-integrated construction involves the application of computers to better manage information and knowledge in their various forms with the goal of totally integrating the managing, planning, design, construction and operation of facilities. In order to utilize the computer, the users need a clear definition and architecture to organise, classify and manage the recorded information."

This is analogous to pharmacy in that in order to classify and manage information, a total definition of pharmacy and the architecture of its components is necessary when determining its characteristics and attributes. This global view of product modelling is shared by Wierda (1991). Wierda (1991) from the Department of Mechanical Engineering Design, Delf University has defined product modelling thus:

> "What is needed is a product description that is complete, that contains semantical information, that reflects the need of different engineering domains, that reflects the different level of detail required for different tasks, and clarifies the whole process of creation of the product."

Wix (1989) also shares this view:

> "A product model may be regarded as a representation of the real thing in a manner which allows its behaviour to be observed without having to build it - the computer equivalent of the plastic, scale model of an aeroplane."

This definition brings out the essential difference between a logical data model, i.e. one that takes no regard of the environment surrounding the data, as opposed to a physical model, which takes account of the environment, e.g. database structure, working practices etc.

The nature of the product models may be from very general to very specialised. The higher levels (general) have readily available data,

some of which may be available to other members of the design team. But a significant amount of information, which is environment specific, will depend on expert knowledge being added to it in order to provide specialised lower level product models.

Modelling may involve several strategies. The resulting product model at each stage may be of use to different people.

Wright, Lockley and Wiltshire (1992) state:

> "For a given domain, increasing specialisation results in a product model, which when compared to the original data set
>
> - is suited to a particular set of applications
> - has a compressed data set [i.e. can be coded or labelled]
> - incorporates implicit environment knowledge
> - contains more assumptions."
> [B H THOMPSON'S COMMENTS]

This infers, therefore, that in a product model of pharmacy, the information determined, together with its relationships, will form an information architecture. If the information is defined, the 'bricks' of this architecture can be assembled or used in any combination, and used on a 'global' basis. The information architecture can form the basis for classification, coding and information itself.

This leads, therefore, to the objectives of the project, which will be to determine an information architecture from which a coding system can be developed.

1.6 Aims and Objectives of the Study

The earlier parts of the introduction have shown the need for the development of a coding system that produces a unique code for each

medicinal product. Such a coding system is unlikely to be based on a hierarchy. But the coding system will still need to have a rational structure in order to support rules governing the generation of product codes. The overall aims of this study are to determine an information architecture for hospital pharmacy and from this to determine the components that can be used to develop and test the validity of a product code.

A question that needs to be answered is what is the extent of the occurrence of medicinal products in the operational functions of a hospital pharmacy. The answer to this question will indicate whether a coding system for medicinal products will have a trivial or substantial role to play in hospital pharmacy. The hypothesis that medicinal products are a major entity in the operation of a hospital pharmacy will be tested.

Pharmacy is governed by legislation. However, in pharmacy practice, specific-domain knowledge and information is needed that is not explicitly covered by legislation. Thus, it is imperative that comprehensive product models incorporate both statutory and practical information. The hypothesis that data models can be produced to represent both practical and statutory information relating to medicinal products will be tested.

The next stage is to determine if a structured product code can be derived from elements of the data models. If so, what is the minimum number of characteristics needed for product identification, how can these be coded and what length of code will be generated? This leads

to the hypothesis that data models can be used to structure a coding system that allows the generation of unique product codes.

The utility of modelling in terms of product identification from physical characteristics will be investigated by testing the hypothesis that medicinal products can be uniquely from the information held by the parts of data models that relate to their physical characteristics.

The hypotheses lead to the objectives of the study which are to:

(a) investigate all the activities of a hospital pharmaceutical service and their relationships with other disciplines within the service as well as their relationships with bodies outside the service, e.g. commercial suppliers, Department of Health and Royal Pharmaceutical Society, in order to draw up Business Activity Models, Data Flow Diagrams and Logical Data Flow Diagrams,

(b) determine the basic entities that constitute the service,

(c) identify whether the entity type MEDICINAL PRODUCT is a major entity type in the activities of hospital pharmacy and other activities associated with pharmacy, e.g. wholesaling and prescribing, to model the entity type on a theoretical basis based on legal principles and

(d) develop and validate a model based on practical experience and out of this develop a product code.

1.7 Summary of Hypotheses

1. Medicinal products are a major entity in the operation of a hospital pharmacy.

2. Data models can be produced to represent both practical and statutory information relating to medicinal products.

3. Data models can be used to structure a coding system that allows the generation of unique product codes.

4. Medicinal products can be uniquely identified from the information held by the parts of data models that relate to their physical characteristics.

2. DEFINITION OF ENTITIES ASSOCIATED WITH PHARMACY

2.1 INTRODUCTION

This part of the project was carried out as part of a project for North East Thames Health Authority and the Information Management Centre, NETHRA (1989). The project was designed to develop a pharmacy computer specification for North East Thames Authority and to match that specification to the Common Basic Specification evolved by the Information Management Centre. The author took part in the project as a member of the quality assurance team and as one of the senior pharmacists whose job description and tasks were assessed. Throughout the project, my help was used to construct initial models. These were then modified by the information received from interviews and workshops. Although the objective of the North East Thames project was to develop a computer specification, the objective of the author, as well as assisting in this attainment, was to attain the secondary objectives for this research of:

(a) investigating all the activities of a hospital pharmaceutical service and their relationships with other disciplines within the service, as well as the relationships with bodies outside the service (e.g. commercial suppliers, Department of Health and Royal Pharmaceutical Society) in order to draw up Business Activity Models, including Data Flow Diagrams and Logical Flow Diagrams and

(b) determining the basic entities which constitute the service.

This part of the project shows a method of determining the entities required to produce a coding and classification system.

2.2 METHODOLOGY

The initial prototype models were drawn up by a team, consisting of a pharmacist, systems analyst, and data modeller with advice from other pharmacists: the core group. At each stage of the process, workshops were held with pharmacists experienced in the area under consideration. The initial models were examined and modified in the light of the discussions.

In order to ensure the completeness of the information, the job descriptions of six senior hospital pharmacists were analysed by the members of the core group and any further information added to the models. The six senior pharmacists were also interviewed by members of the core group since it was reasoned there may be differences between job descriptions and tasks carried out. This information was fed into the modelling process. Since, with one exception - South Lincolnshire Health Authority, the participants were all from the North East Thames Region, it was reasoned that there may be some regional variations. Therefore, pharmacists from other regions were interviewed and their job descriptions studied. Job descriptions were studied and interviews carried out for other professions that interface with pharmacy, e.g. finance and supplies. The information gained was fed into the modelling process. Pharmacists from the Royal Pharmaceutical Society and the Department of Health were also interviewed.

As each stage of the modelling was completed, the models were quality

As each stage of the modelling was completed, the models were quality assured by a group of ten hospital pharmacists, a data modeller and representatives from the finance and supplies functions. At this stage, the validity and structure of the models were assessed. There were sixteen sessions in all, involving thirty-five hospital pharmacists from approximately seven regions and many hospitals, to ensure the information was accurate, up-to-date and as comprehensive as possible. The sequence of model building and testing is illustrated in Figure 2.1.

In order to facilitate the understanding of the modelling processes used in this project, guidance is given in Appendix 5.

2.3 THE PROJECT

2.3.1 Data Flow Diagrams (DFDs)

These were constructed on the experience of six large hospital pharmacy departments. The DFDs were used to 'scope' the project and to determine the perceived paper movements and their relationships around the pharmacy departments.

2.3.2 Business Activity Models (BAMs)

These were constructed on the experience of six large hospital pharmacy departments from the top level PLAN, ENABLE (Resource), DELIVER and REVIEW. The BAMs are presented as a vertical slice, though not to the lowest levels and were to provide the basis for model testing.

2.3.3 Logical Data Flow Diagrams (LDFDs)

These were overlaid on the original BAMs using the latter as activities

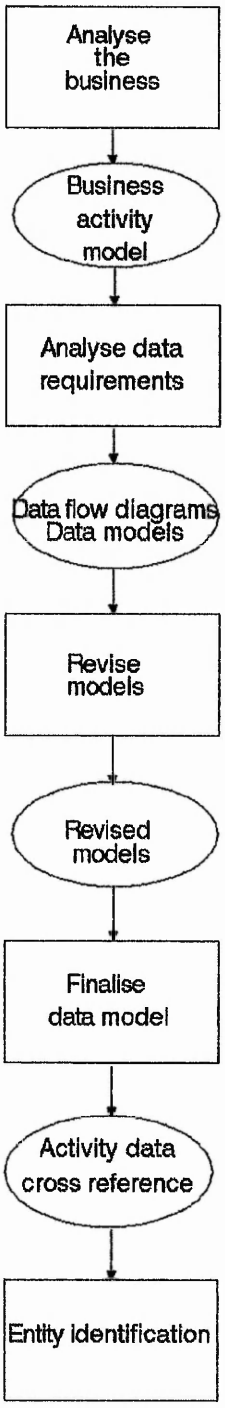


Fig. 2.1

The modelling process leading to the identification of entities.

for their construction.

2.4 TESTING AND MODIFICATION OF MODELS

At this first stage, Data Stores' input and output began to be generated, although only at a very high level.

The next stages were to:

(1) test and modify the DFDs, BAMs and LDFDs, on the basis of information received from interviews, job descriptions, and workshops and to quality assure the modified models;

(2) draw up final BAMs and LDFDs after rescoping the project in the light of its size and logical activities and define Activity Descriptions;

(3) determine the contents of Data Stores;

(4) determine the entities that comprise a hospital pharmaceutical service and select those that are found in many activities and may form the basis of a classification and coding system for further investigation.

The final stage was to begin structuring draft product models with a view to providing a method of testing and evaluation.

Although the North East Thames Project was constructed to provide a final data model for computer application, for the purpose of this project, the activity-data cross-reference section with its associated

definition of entities, was to provide the basis for this particular study, i.e. determining whether MEDICINAL PRODUCT was a key entity in many entity types and, if so, to model it in the next part of the project in order to produce a coding system capable of unique identification.

2.5 RESULTS AND ANALYSIS

Figure 2.2 illustrates the various levels of activity analysis undertaken.

For the purpose of this part of the project it is intended to illustrate the method used by taking a "vertical slice" through one series of activities illustrated by the shaded area in Figure 2.2.

2.5.1 INITIAL MODELS

2.5.1.1 Initial Data Flow Diagrams

Initial Data Flow Diagrams were constructed showing:

a. the data flow within a hospital pharmacy department and to other disciplines both within pharmacy, within the Health Authority and without the Authority, Figure 2.3.

b. the data flow around the existing computer systems both within and without the Health Authority, Figure 2.4.

Figure 2.3 illustrates data flow within a hospital pharmacy department. The area within the dot-dashed line indicates the flows within pharmacy, while outside are the flows to and from other disciplines.

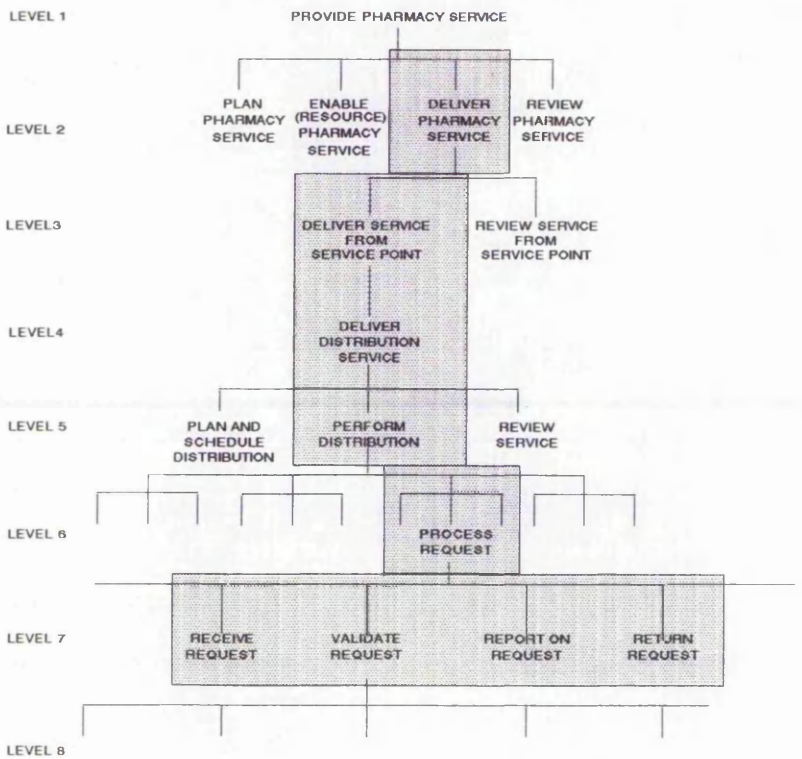


Fig. 2.2 The levels of analysis undertaken

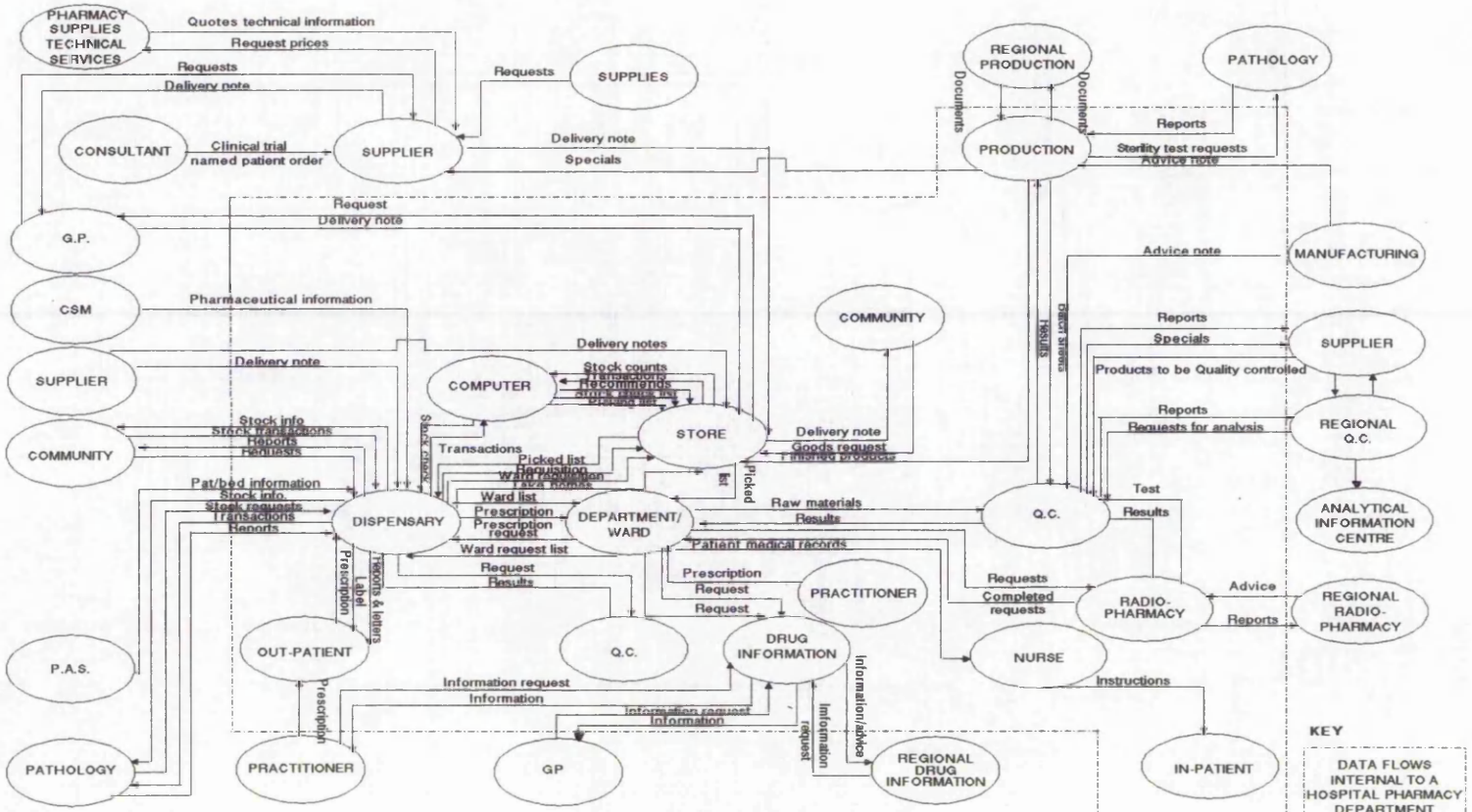


Fig. 2.3 Data flow diagram The data flows internal and external to a hospital pharmacy department.

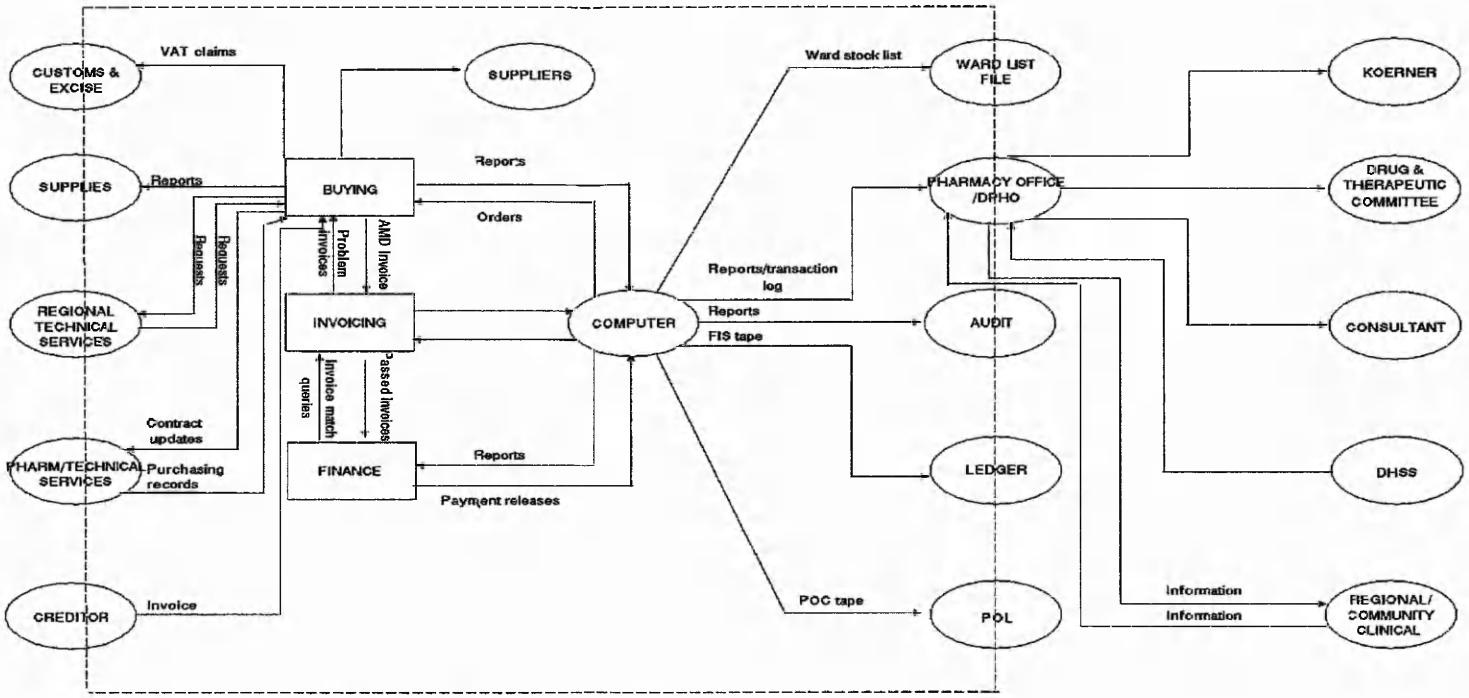


Fig. 2.4 Data Flow Diagram Comp ..ter information flows

Activities included in project Processes common to many activities

Figure 2.4 represents the data flow around the computer system. It illustrates the processes involved in servicing external units, e.g. Audit, which could be applied to monitoring of standards to and from the relationships illustrated in Figure 2.3.

It was envisaged before the project began that there were likely to be many external factors affecting hospital pharmacy. Therefore, a decision was taken to limit the study to data flows internal to a hospital pharmacy department, Figure 2.3, and similarly to data flows around the computer in Figure 2.4.

There would inevitably be some systems that straddle the bounds of the project, e.g. supplies, ledgers etc. It was concluded that if entities could be identified for the included areas, they could be related to entities of the disciplines outside the boundaries.

2.5.1.2 Initial Business Activity Models (BAMs)

These were drawn up for all activities. However, to illustrate the method used for this part of the project, a vertical slice through the PERFORM DISTRIBUTION section of DELIVER PHARMACY SERVICE (Figure 2.2), it is important to have an overview of the "top structure", PROVIDE PHARMACY SERVICE, at its second level (Figure 2.5): PLAN, ENABLE, DELIVER AND REVIEW PHARMACY SERVICE. Further analysis provides the next level - DELIVER PHARMACY SERVICE (Figure 2.6).

This diagram illustrates some of the services that a hospital pharmaceutical service may be expected to provide, depending on local circumstances or policy, from selected service points including and

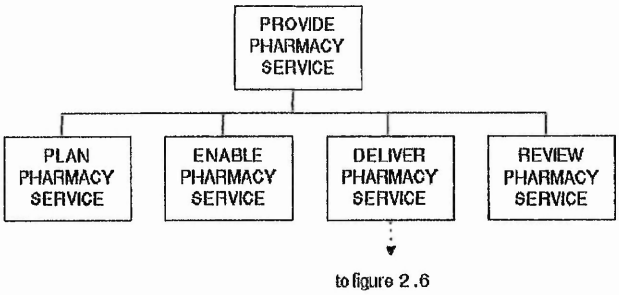


Fig. 2.5 Initial Business Activity Model
PROVIDE PHARMACY SERVICE

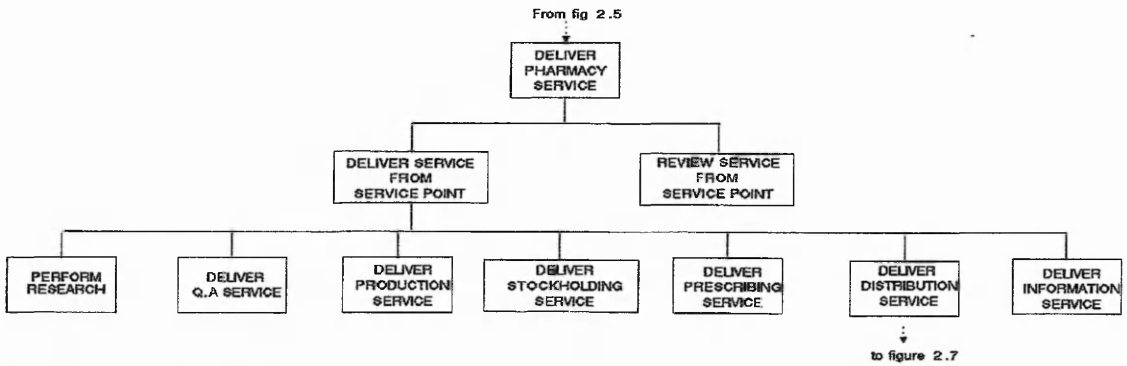


Fig. 2.6 Initial Business Activity Model
DELIVER PHARMACY SERVICE

down to - DELIVER DISTRIBUTION SERVICE.

Further analysis of DELIVER DISTRIBUTION SERVICE is illustrated in Figure 2.7.

It was reasoned in this case that since hospital pharmaceutical departments provide products to many points within a hospital, district, region and sometimes nationally, to deliver a distribution service, it is necessary to plan and schedule distribution, perform distribution and review distribution service, using the principle of plan, enable, do and review.

2.5.1.3 Logical Data Flow Diagrams (LDFDs)

These consist of a series of activities taken from the Business Activity Models of the activities at each level.

In considering the logical data flow diagrams for DELIVER PHARMACY SERVICE - PERFORM DISTRIBUTION, it is necessary to obtain a complete picture of the logical data flow diagrams of PROVIDE PHARMACY SERVICE, (Figure 2.8).

PLAN PHARMACY SERVICE

ENABLE PHARMACY SERVICE

DELIVER PHARMACY SERVICE

REVIEW PHARMACY SERVICE

The logical data flow diagram - DELIVER DISTRIBUTION SERVICE - PERFORM DISTRIBUTION is included for information (Figure 2.9).

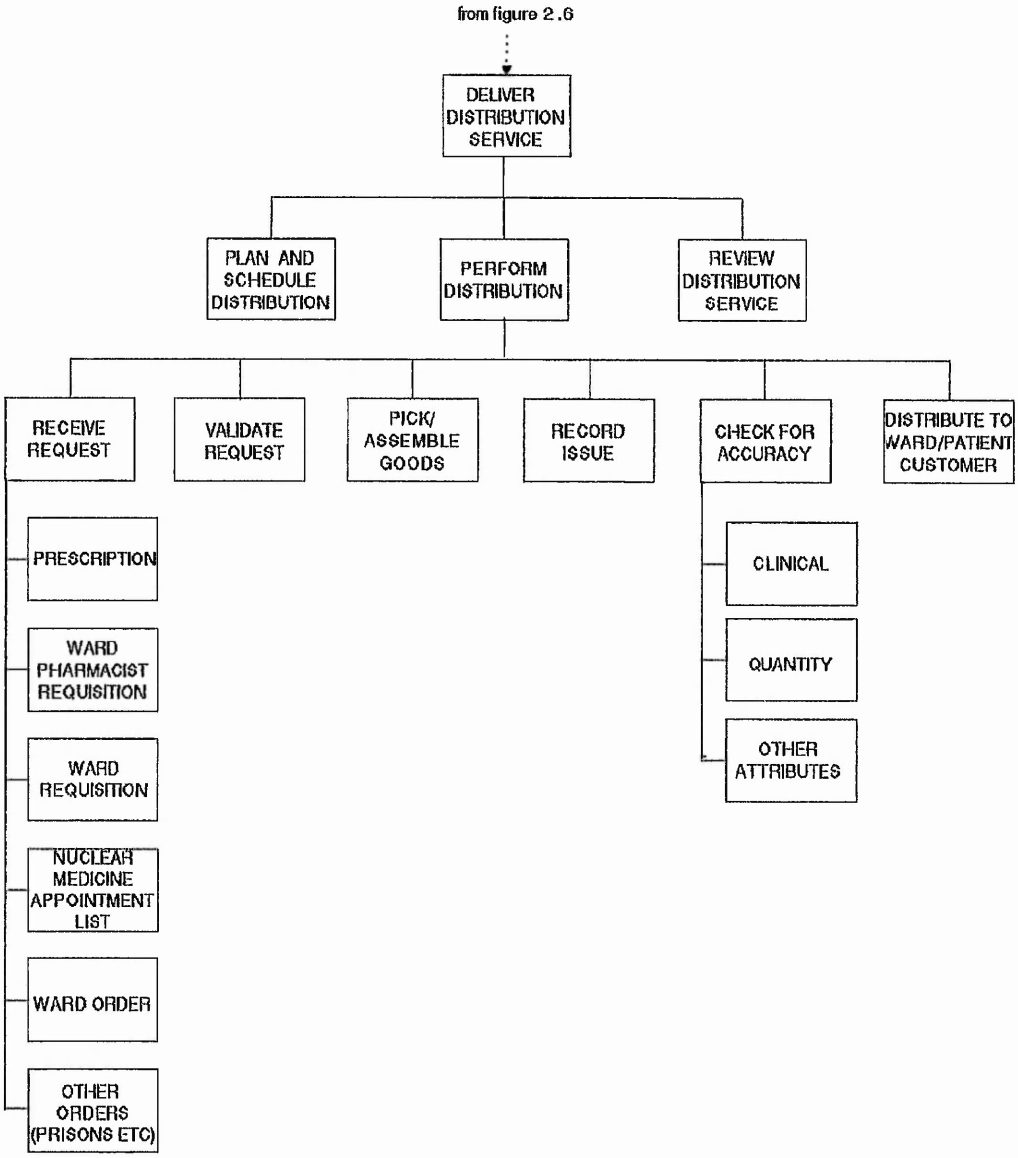


Fig. 2.7 Initial Business Activity Model
DELIVER DISTRIBUTION SERVICE

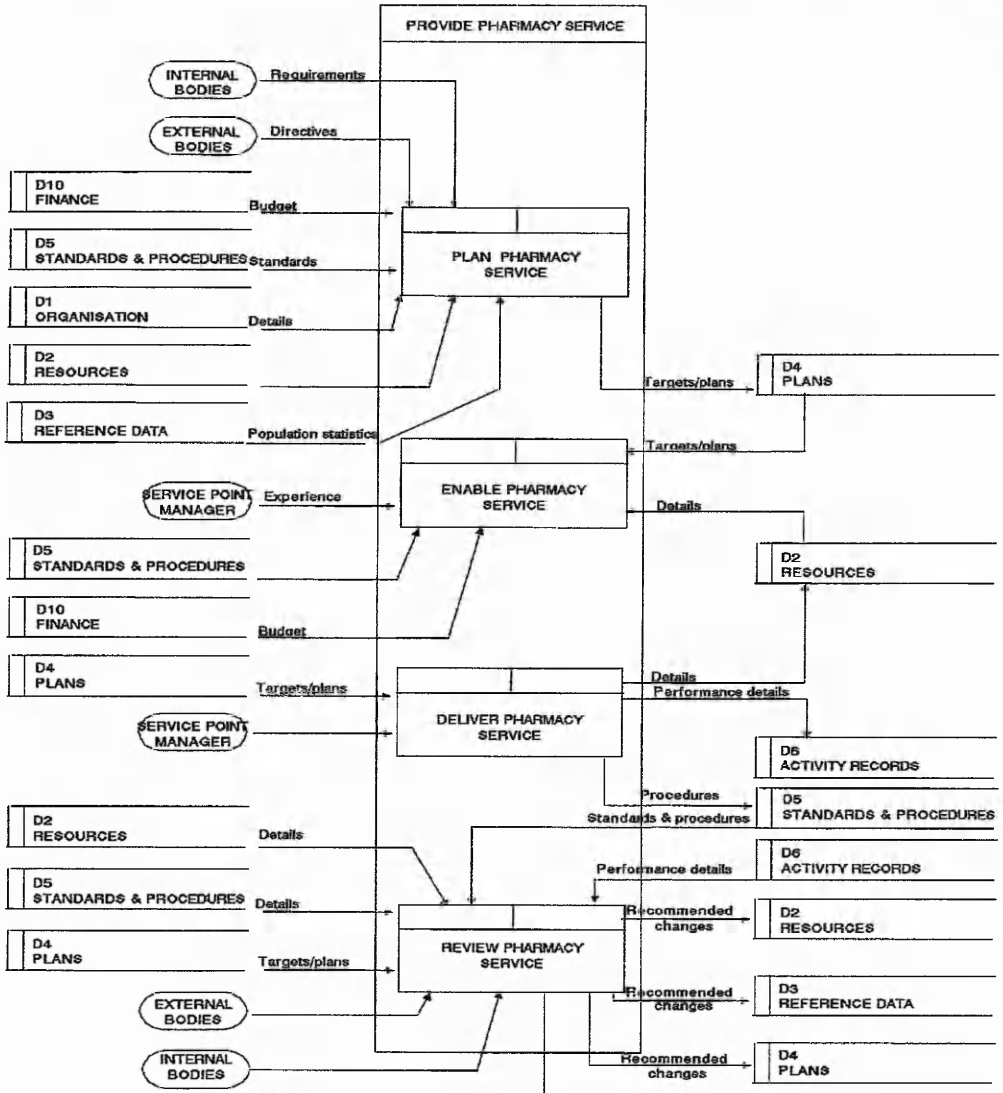


Fig. 2.8 Initial Logical Data Flow Diagram
PROVIDE PHARMACY SERVICE

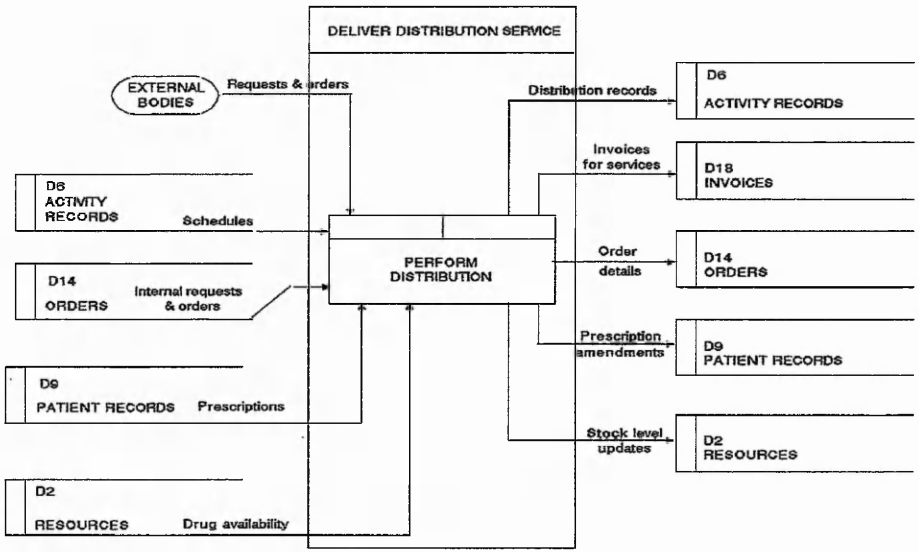


Fig. 2.9 Initial Logical Data Flow Diagram
DELIVER DISTRIBUTION SERVICE – PERFORM DISTRIBUTION

2.5.2 Modification of Models

As a result of quality assurance and testing, modifications were made to the original BAMs on a top down basis.

DELIVER PHARMACY SERVICE - (Figure 2.6 is now modified to Figure 2.10) and includes CONFIRM THE LEVEL OF SERVICE TO BE PROVIDED, and IDENTIFY RECIPIENT as new activities and modifications to DELIVERY SERVICE FROM SERVICE POINT.

CONFIRM THE LEVEL OF SERVICE TO BE PROVIDED was included, since in the initial BAM, Figure 2.6, there was no assessment of the standards required or resources required to service them.

IDENTIFY RECIPIENT was included, since in the initial BAM, Figure 2.6, only the services to be provided were identified with no identification of the recipients or their status.

(1) CONFIRM THE LEVEL OF SERVICE TO BE PROVIDED.

To do this it is necessary:

(a) to assess the resources required - ASSESS RESOURCES

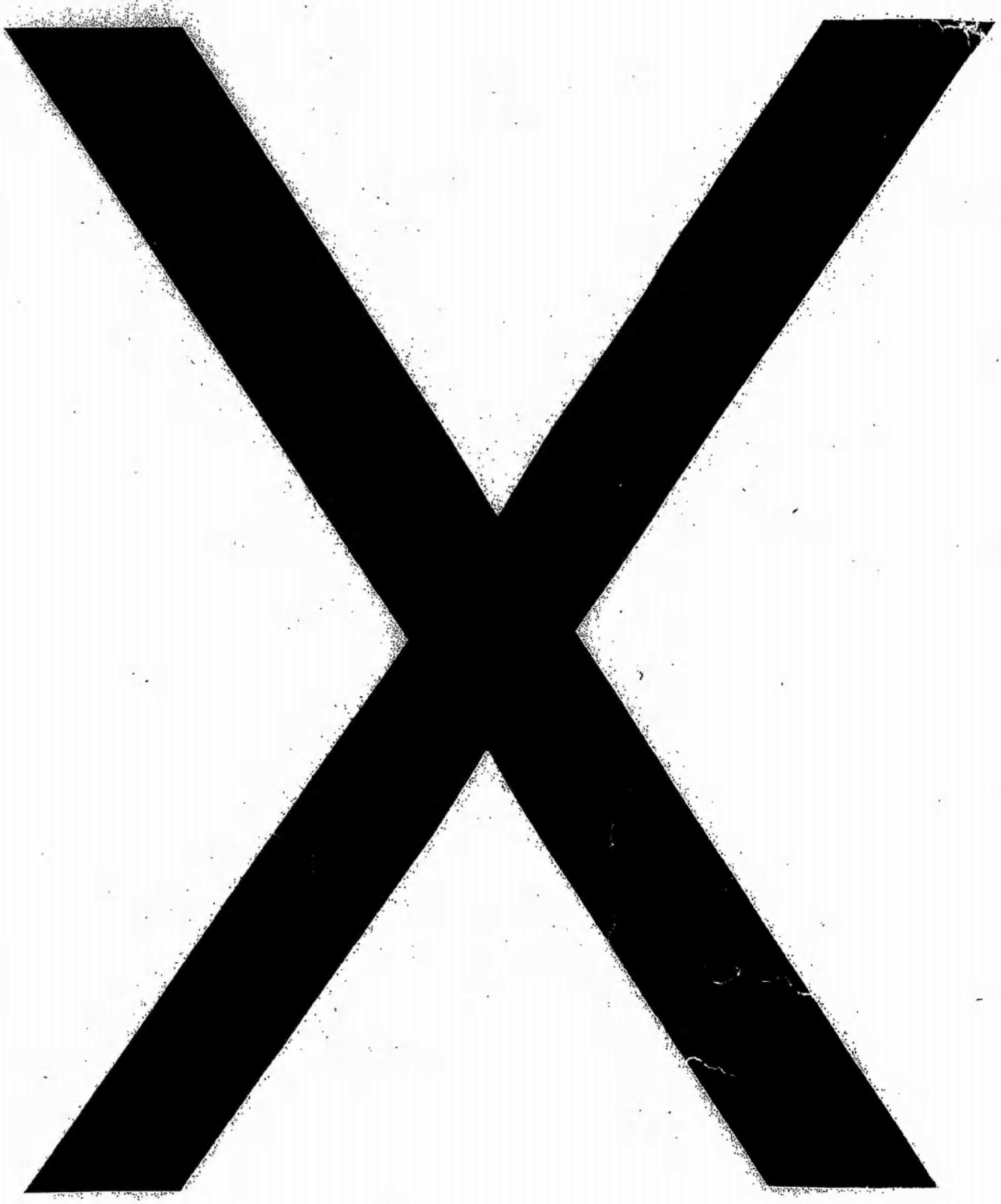
(b) to distribute those resources - DISTRIBUTE RESOURCES

(c) to alter the service if necessary to meet the agreed service level - ALTER SERVICE

(d) to inform customers of the service level - INFORM CUSTOMERS.

(2) IDENTIFY RECIPIENT

There was confusion in identifying the recipient of the service, as GPs



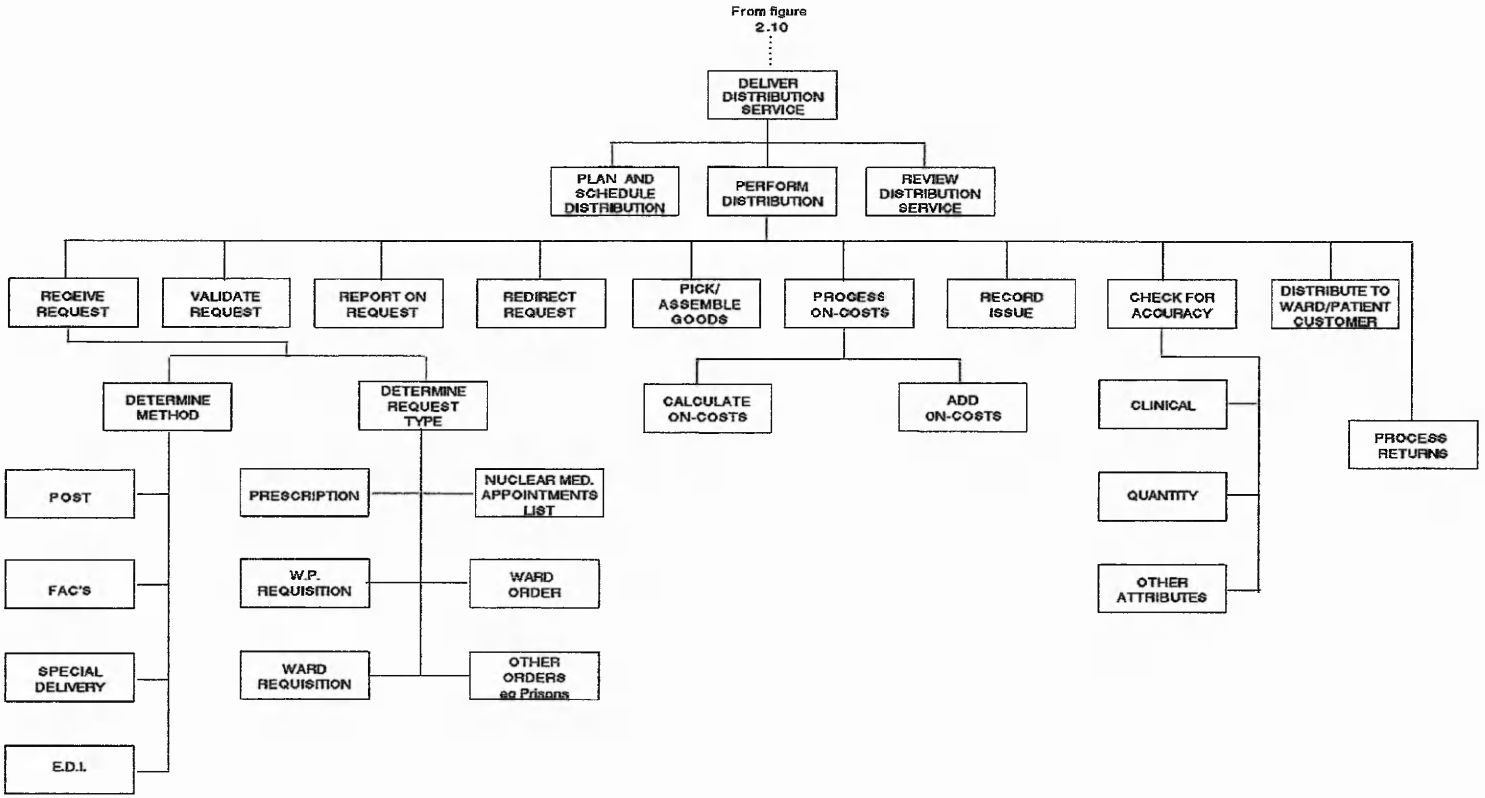


Fig. 2.11 Modified Business Activity Model
DELIVER DISTRIBUTION SERVICE

(a) REPORT ON REQUEST

(b) REDIRECT REQUEST

These are needed since receipt of request is not the appropriate place for distribution to be activated. Requests may be received at a point remote from the distribution source.

(c) PROCESS ON-COST

This being the area in which on-costs can be decided for things such as extemporaneous stock items.

For this activity there is a further level.

C1. CALCULATE ON-COSTS

C2. ADD ON-COSTS

RECEIVE REQUEST activity has also been modified to a further level.

1. DETERMINE METHOD

2. DETERMINE REQUEST TYPE

2.5.3 Final Models

The model now needs to follow a logical system rather than a physical system. Revision allows final BAMs and LDFDs to be drawn up. This is shown for DELIVER PHARMACY SERVICE, Figure 2.10, which was modified to Figure 2.12 and quality assured.

The activities in PROCESS REQUEST logically encompass the activities previously listed under CONFIRM SERVICE LEVEL TO BE PROVIDED and

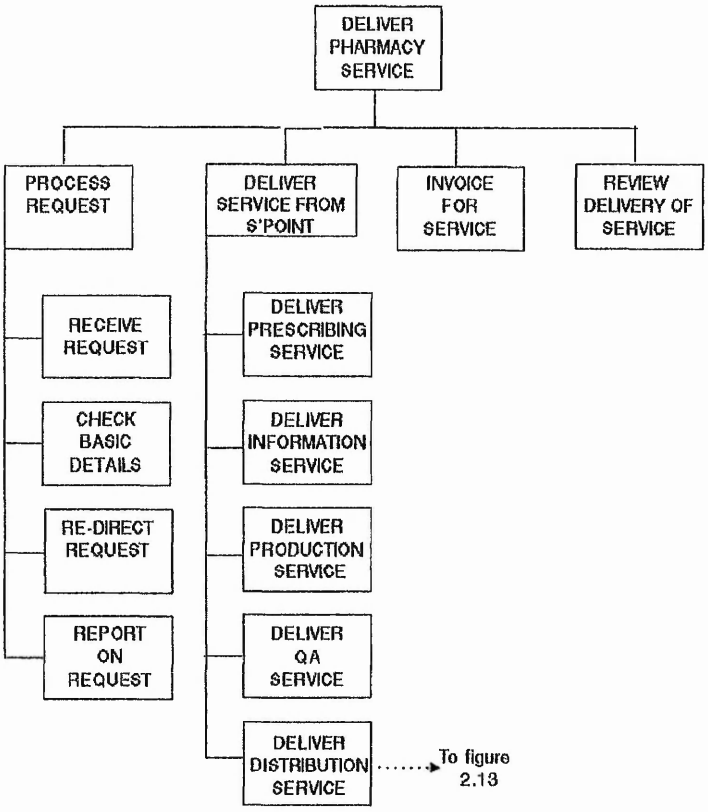


Fig. 2.12 Final revised Business Activity Model
DELIVER PHARMACY SERVICE

IDENTIFY RECIPIENT, which were part of the physical system.

The activity IDENTIFY RECIPIENT is now incorporated in the individual activities and is therefore removed, and incorporated within the activity CHECK BASIC DETAILS.

Several activities contained in the modified BAM are not unique to pharmacy and only pharmacy specific activities have been retained. Thus, research, EDUCATION AND TRAINING have been removed. It was reasoned that as these activities were not product orientated, e.g. ordering, they would have no implication on the area of this project.

Clinical activities previously identified, e.g. DELIVER PRIORITY SERVICE and DELIVER CLINICAL SERVICE, have been incorporated within DELIVER PRESCRIBING SERVICE as they are both associated with clinical and prescribing activities, e.g. ward pharmacy and therapeutic drug monitoring, Figure 2.12.

Since DELIVER STOCKHOLDING SERVICE is essentially an enabling (resourcing) service, which enables distribution to occur, it has been incorporated within ENABLE PHARMACY SERVICE.

The Radiopharmaceutical service has been incorporated within the DELIVER PRODUCTION SERVICE since it was reasoned that, although it is a valid pharmaceutical service, it varies little, apart from its radioactivity, from a normal pharmacy manufacturing aseptic service. It will therefore be treated as a specialised production service.

No activities, except those specifically mentioned, have been reallocated although some may have been combined or renamed.

DELIVER DISTRIBUTION SERVICE, previously shown in Figure 2.11, has been modified and now consists of five activities instead of the previous three and is shown as Figure 2.13. The activities have been renamed because the stimulus to provide a distribution service is due to the provision of a request. Hence the activities are now named requests. It covers the distribution of all goods from the pharmacy with respect to the departments served.

The PLAN AND SCHEDULE DISTRIBUTION activity (Figure 2.12) has now been separated into three parts: VALIDATE REQUEST, PLAN REQUEST, and SCHEDULE REQUEST.

VALIDATE REQUEST identifies the goods to be distributed, their quantities and any special handling procedures. This activity also incorporates REPORT ON REQUEST.

PLAN REQUEST identifies suppliers and stimulates the supply chain.

SCHEDULE REQUEST schedules requests in line with existing controls and procedures and has a possible variant due to urgency, which may modify existing schedules.

ACTION REQUEST covers the activities in PERFORM DISTRIBUTION in determining the processing of goods from the pharmacy, e.g. method of picking, goods allocation, recording of delivery details. It

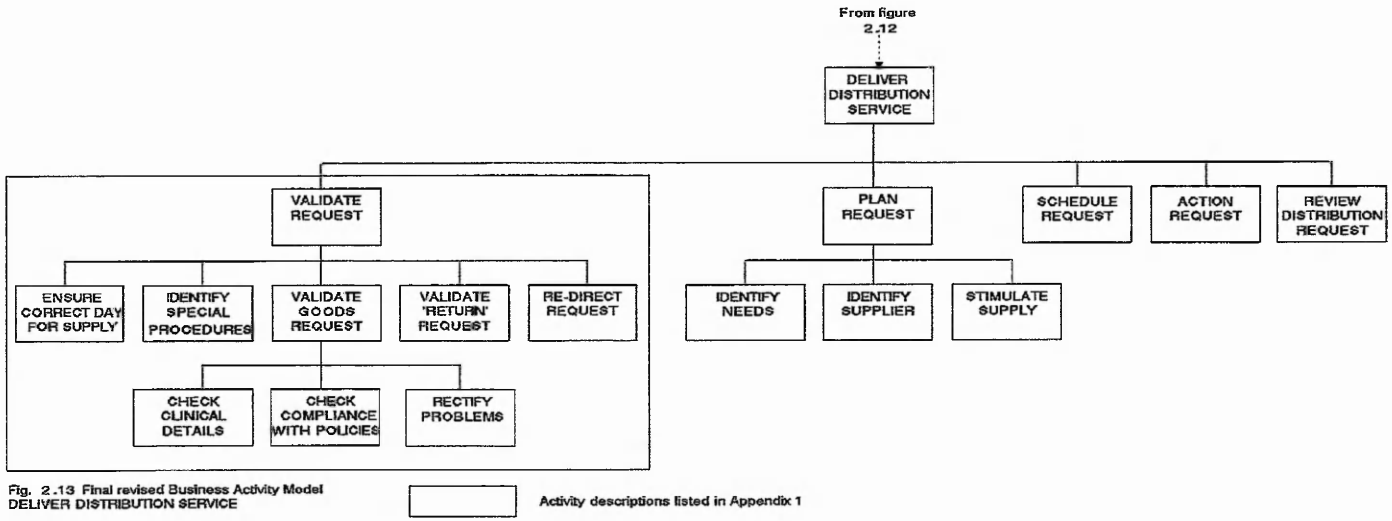


Fig. 2.13 Final revised Business Activity Model
DELIVER DISTRIBUTION SERVICE

incorporates PROCESSING OF RETURNS.

REVIEW DISTRIBUTION REQUEST reviews the way in which the request for distribution was dealt with according to predetermined standards.

Figure 2.14 illustrates the final levels of analysis undertaken and, when compared with Figure 2.2, shows the effect of modifications to reach the final BAM - DELIVER DISTRIBUTION SERVICE, Figure 2.13.

2.5.4 Activity Description

In order to complete this vertical slice, the activity descriptions related to activities within the rectangle of Figure 2.13 are listed in Appendix 1.

The logical data flow diagram for DELIVER DISTRIBUTION SERVICE, Figure 2.15, overlays Figure 2.13 and its Data Stores for this vertical slice are listed in Appendix 2. However, the contents of all the Data Stores are listed in Appendix 4 as these are necessary for the evolution of entities.

2.6 DATA STORES AND ENTITY EVOLUTION

Analysis of the business requirements for a particular environment permits documentation of the whole range of activities that take place. This documentation, whilst textually describing the activities, also identifies the data elements upon which the function acts and those which the function produces. Initially, these data requirements are represented in aggregated form as Data Stores.

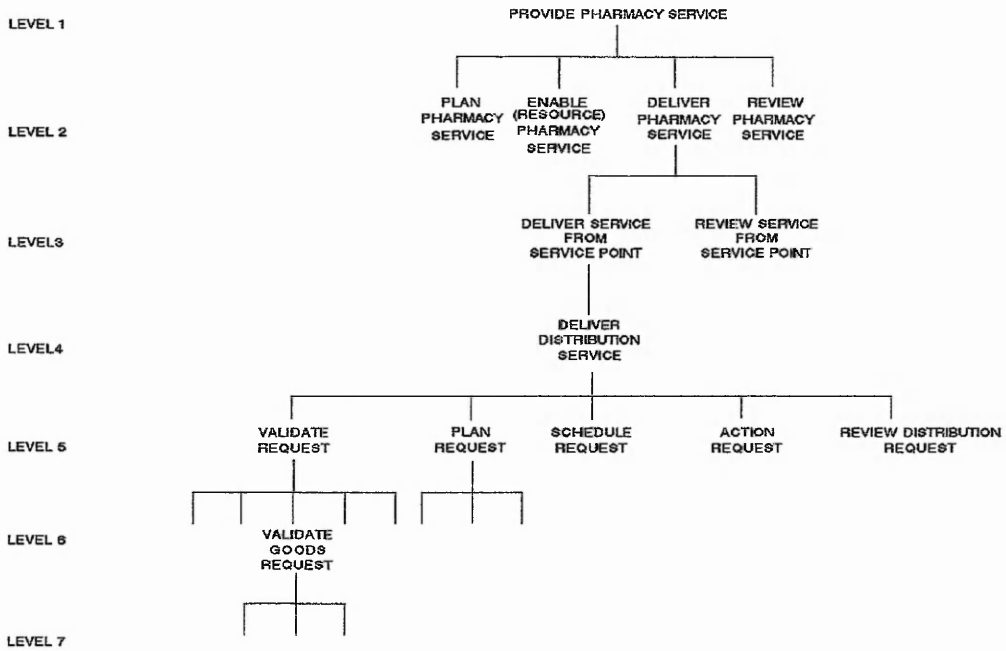


Fig. 2.14 Final diagram - the levels of analysis undertaken

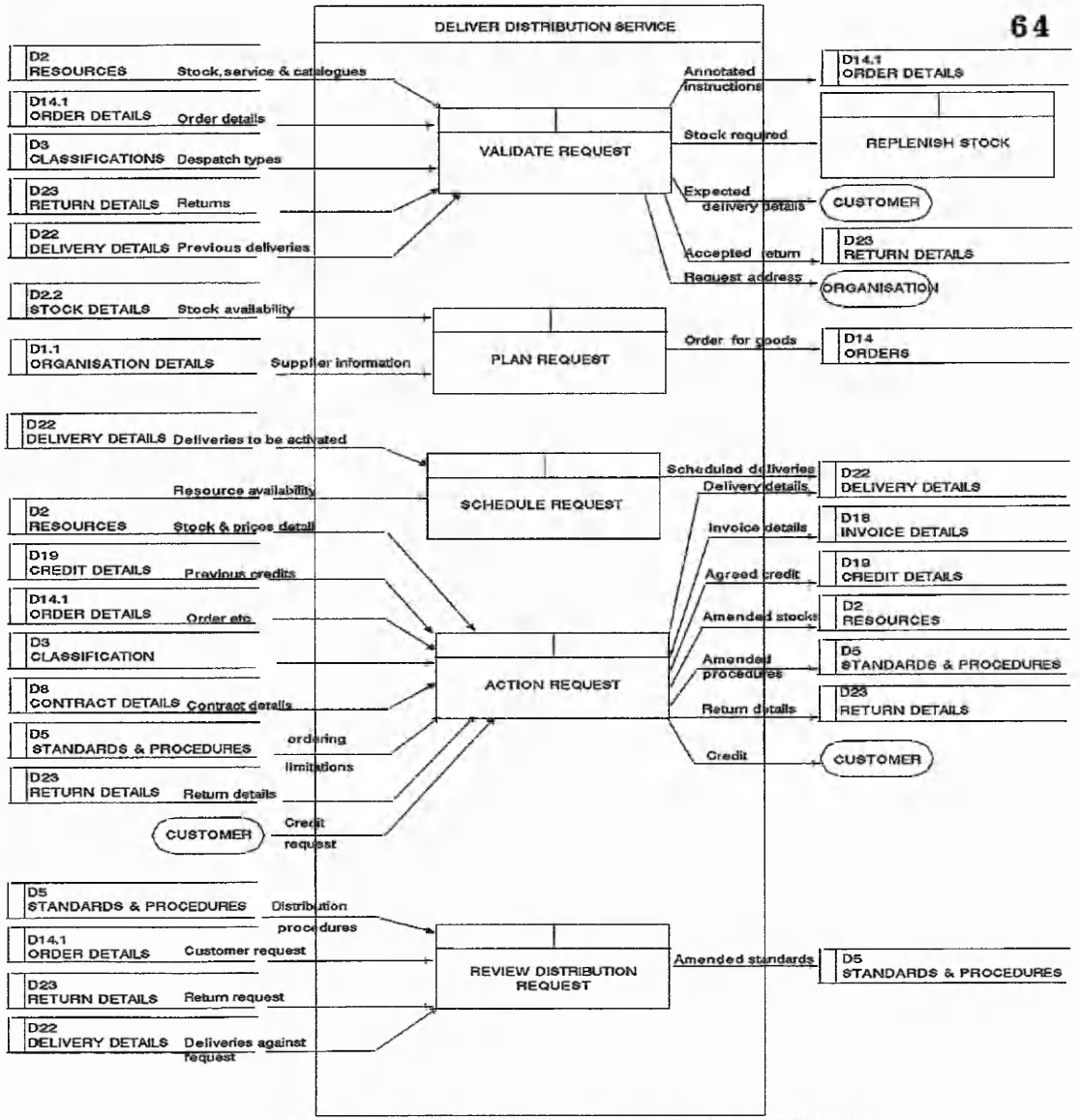


Fig. 2.15 Final Logical Data Flow Diagram DELIVER DISTRIBUTION SERVICE

As the analysis progresses, two aspects of the data are clarified. Firstly, the specific data elements input to and output from the processes are clarified and secondly, this provides the specific content requirements of each Data Store.

The development of the logical model (entity types and their associated attributes) from the Data Store contents used techniques that are identified within the Structured System Analysis and Design Method (SSADM, 1990). Broadly speaking, there will always be some obvious 'things of interest' or entity types, for example, PERSON, ORGANISATION etc. The attributes for these entity types are gleaned from the Data Store contents. Each data element within the Data Stores is examined relative to the entity types which are identified. If necessary, other entity types are created to accommodate each data element.

The result of this Data Store examination is a draft logical data model. In order to make the transition from this draft to a final logical data model other techniques are employed (SSADM, 1990) and combining this with the business analysis, a matrix of activity and data can be created.

This is illustrated by the following example. Activity analysis identified that a data store called LICENCE DETAILS contains

licence number

date of licence

product for licence

organisation licence given to

Because of the existence of ORGANISATION and MEDICINAL PRODUCT then these are identified as entities associated with the data store. Licence number and date of licence would be attributes of licence. Examination of the Data Stores helped to define some common entity types, e.g. PRODUCT which was present in many other entity types (57%), whilst entities of PRODUCT TYPE were present in many other entity types: a further 28% giving a total of 85%.

Defined entities for the project are listed in Appendix 3.

2.7 DISCUSSION

The necessity for workshops and interviews was confirmed since the information generated from them contributed greatly to the modification of original diagrams, to the defining of activity descriptions and the gradual compilation of data stores. The latter were compiled, using at first the top level BAMs as indexes for logical data flow diagrams and gradually expanding these as low level BAMs and LDFDs were developed.

The method of investigation has provided a specification for a complete system but importantly, from this project's point of view, has defined 200 entities. Many of the entities are common to many different processes, which when further developed will provide the basis for progression to the next stage. Some common entity types were identified, e.g. PRODUCT, which was present in many other entity types (57%):

Product and organisation

Product and route

Prescription detail

Whilst entities of PRODUCT TYPE were present in many other entity types: a further 28%. The remaining entity types were comprised of organisations, licence, rule etc., although some of them were peripherally associated with PRODUCT, e.g. CREDIT CAUSE etc.

The results so far show that objective (a) has now been attained since all the activities of a hospital pharmaceutical service have been investigated. Business Activity Models, Data Flow Diagrams and Logical Data Flow Diagrams have been constructed. These, in turn, have led to the identification of entity types (objective b) and their associated structure that constitute the service, the majority of which (85%) contain the entity type PRODUCT or one of its associated entities. This achieved objective (c), which was to identify whether MEDICINAL PRODUCT is a major entity type in the activities of a hospital pharmacy and other associated activities, e.g. wholesaling and prescribing.

Therefore by modelling and validating a comprehensive model for MEDICINAL PRODUCT the final part of general objective (c), namely, to model the entity type MEDICINAL PRODUCT on a theoretical basis, and objective (d), to develop and validate a model and product code based on practical experience, can now be researched.

2.8 CONCLUSION

The method of investigation with quality assurance has proved satisfactory in investigating the activities of a hospital pharmacy department and the whole project has identified links with external bodies, e.g. - wholesalers and prescribers. Importantly, it has established that the entity type MEDICINAL PRODUCT is contained in, or

its entities are associated with, 85% of the entities defined, as well as being peripherally associated with other entities, e.g. CREDIT CAUSE.

3. DEVELOPMENT OF A THEORETICAL DATA MODEL FOR MEDICINAL PRODUCTS

3.1 INTRODUCTION

The investigation into the activities of a hospital pharmaceutical department defined 200 entities, 85% of which are associated with entities of the entity type PRODUCT directly or indirectly.

This chapter describes the development of a theoretical data model for the entity type MEDICINAL PRODUCT, which is a sub-type of the entity type PRODUCT, based on the information required for Data Sheets (Medicines (Data Sheet) Regulations, 1972). By basing the model on legal requirements, by which all manufacturers and users must abide, it was reasoned this would provide an ubiquitous basis for the model. Additions to which could be made in the light of the research findings.

In order to facilitate the understanding of the modelling processes used in this project, guidance notes are given in Appendix 6.

3.2 DEVELOPMENT OF THE ENTITY TYPE PRODUCT

The entity type PRODUCT was developed as follows.

At the highest level any product may be classified into its highest class. This model is derived because PRODUCT has a many to many relationship with CLASS, i.e. PRODUCT must be associated with many CLASS(ES) and CLASS may be associated with many PRODUCT(S), Figure 3.1. Whilst this model is valid, it is limiting the ability to record information about the relationship. PRODUCT contains information about a product, and CLASS about classes. But where can the data about the relationship between the two be held? In the method used, data can

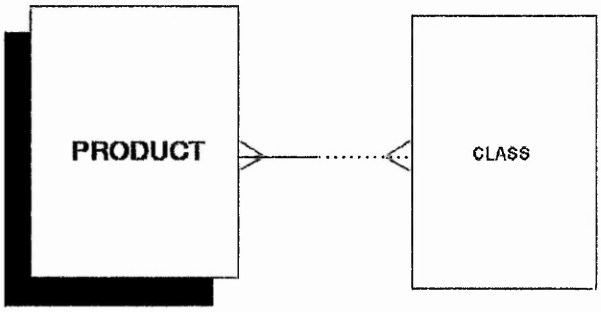


Fig. 3.1
The relationship between PRODUCT and CLASS.

only be retained within entity types. Therefore, to retain details of, for example, when a CLASS started to classify a PRODUCT and when it ended, we need to introduce an entity type which bridges the gap: PRODUCT CLASS. One PRODUCT CLASS is MEDICINAL PRODUCT, Figure 3.2.

Decomposition of this model to the next level would be by relating the entity MEDICINAL PRODUCT to the entity CHARACTERISTIC TYPE in order to determine the characteristics of a medicinal product, which again is a many to many relationship, Figure 3.3. That is, MEDICINAL PRODUCTS must have many CHARACTERISTIC TYPES and these CHARACTERISTIC TYPES can be found in many MEDICINAL PRODUCTS. By applying similar reasoning as the product/class relationship, a further entity is required to resolve this situation, in this case MEDICINAL PRODUCT CHARACTERISTIC, Figure 3.4.

In order to develop a model for medicinal products, it is necessary to understand the details in terms of the entities associated with MEDICINAL PRODUCT CHARACTERISTIC.

It was reasoned that by using the legal definitions and legal information required to produce a Data Sheet that medicinal products granted a Product Licence must have (Medicines (Data Sheet) Regulations, 1972), a model would be produced containing the minimum of information required by law. This would be a sound basis on which to compare any models developed later, since they must at least contain this basic information. These conditions being satisfied, other entities could be added in order to establish a comprehensive model, which would be, at least, compatible with pharmacy activities.

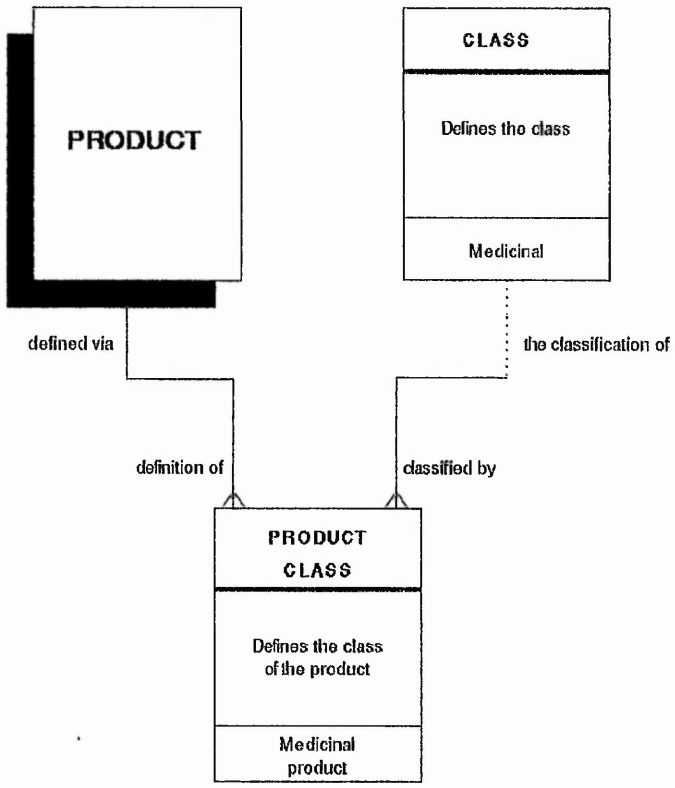


Fig. 3 .2
Defines the relationships of the entity PRODUCT CLASS.

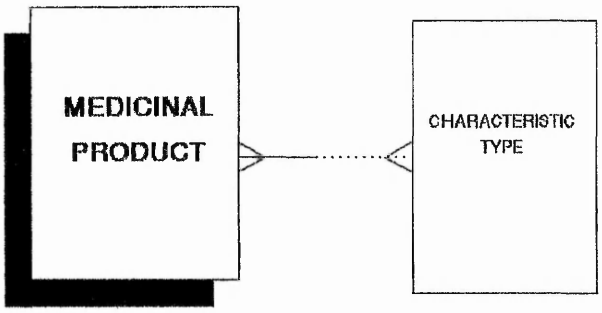


Fig. 3.3
The relationship between MEDICINAL PRODUCT and CHARACTERISTIC TYPE..

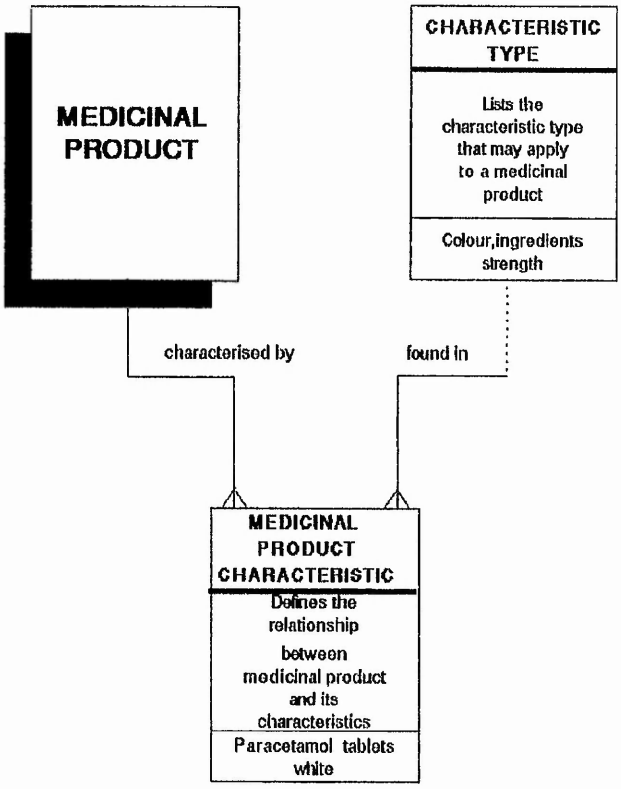


Fig. 3.4
Defines the entity MEDICINAL PRODUCT CHARACTERISTIC.

At each stage in the production of the product model, it is essential that it is validated. One route to achieving this is to populate it with real data. This will show up any discrepancies within the model and will identify the attributes associated with the entities, e.g. appearance, colour and shape. Only by populating the entities with real data can the full range of attributes and their variants be established, e.g. colour: red, pink, peach, beige etc.

3.3 DEFINITION OF A MEDICINAL PRODUCT

"ITALIC LETTERS INDICATE LEGAL STATEMENTS"

Medicines Act (1968) defines a medicinal product as:

"ANY SUBSTANCE OR ARTICLE (NOT BEING AN INSTRUMENT, APPARATUS OR APPLIANCE) WHICH IS MANUFACTURED, SOLD, SUPPLIED, IMPORTED OR EXPORTED FOR USE WHOLLY OR MAINLY IN EITHER OR BOTH OF THE FOLLOWING WAYS, THAT IS TO SAY -

(A) USE BY BEING ADMINISTERED TO ONE OR MORE HUMAN BEINGS OR ANIMALS FOR A MEDICINAL PURPOSE;

(B) USE, IN CIRCUMSTANCES TO WHICH THIS PARAGRAPH APPLIES, AS AN INGREDIENT IN THE PREPARATION OF A SUBSTANCE OR ARTICLE WHICH IS TO BE ADMINISTERED TO ONE OR MORE HUMAN BEINGS OR ANIMALS FOR A MEDICINAL PURPOSE. "

For the purpose of this research, a MEDICINAL PRODUCT is defined as a unique physical object, e.g. tablet, capsule, powder, cylinder of gas, ampoule etc., that complies with the legal definition of a medicinal product.

3.4 DATA SHEET REQUIREMENTS

A study of Data Sheet Requirements shows that general particulars are required by law for each medicinal product. Each of those is discussed in detail and modelled later.

Schedule 1, parts I and II of the Data Sheet Requirements, refer only to size and type-settings of the Data Sheet and do not form part of this study.

Schedule 2 of the Data Sheet Requirements details the particulars required in Data Sheets relating to medicinal products for human use namely:

Name of Product

Presentation

Uses

Dosage and Administration

Contra-indication and Warnings

Pharmaceutical Precautions

Legal Category

Package Quantities

Further Information

Product Licence Number, Names and Addresses

Data preparation or last review.

3.4.1 NAME OF PRODUCT

"NAME OF THE MEDICINAL PRODUCT AND, IF THE MEDICINAL PRODUCT HAS AN APPROVED NAME, THE APPROVED NAME."

This part of the model deals with the very complex naming structures of medicinal products. The names may be chemical, approved or proprietary.

Chemical names, e.g. acetic acid 6% irrigation, ferrous sulphate tablets etc., may overlap into approved names if they occupy a monograph in an official publication, e.g. British Pharmacopoeia, 1983.

Approved names are published by Ministers on the recommendation of the Medicines Commission. They are intended to aid prescribing by providing an approved name for manufacturers' proprietary names. Most new products are now issued with approved names on release. Proprietary names are owned by the product manufacturer and usually have approved names. Some, however, have only the names assigned to them by their manufacturers, e.g. Mucaine suspension. The entity NAME BY WHICH A MEDICINAL PRODUCT IS KNOWN is needed to ensure that in the eventuality of a manufacturer changing the product's name, stocks may exist under two names. It is the common name by which a product is known, e.g. paracetamol tablets. The naming structure can be modelled in the following way, Figure 3.5.

3.4.2 PRESENTATION

"DESCRIPTION OF APPEARANCE AND PHARMACEUTICAL FORM OF THE MEDICINAL PRODUCT TOGETHER WITH THE FOLLOWING INFORMATION THAT IS TO SAY -

(A) WHERE THE MEDICINAL PRODUCT CONTAINS ACTIVE INGREDIENTS ALL OF WHICH CAN BE DEFINITIVELY IDENTIFIED -

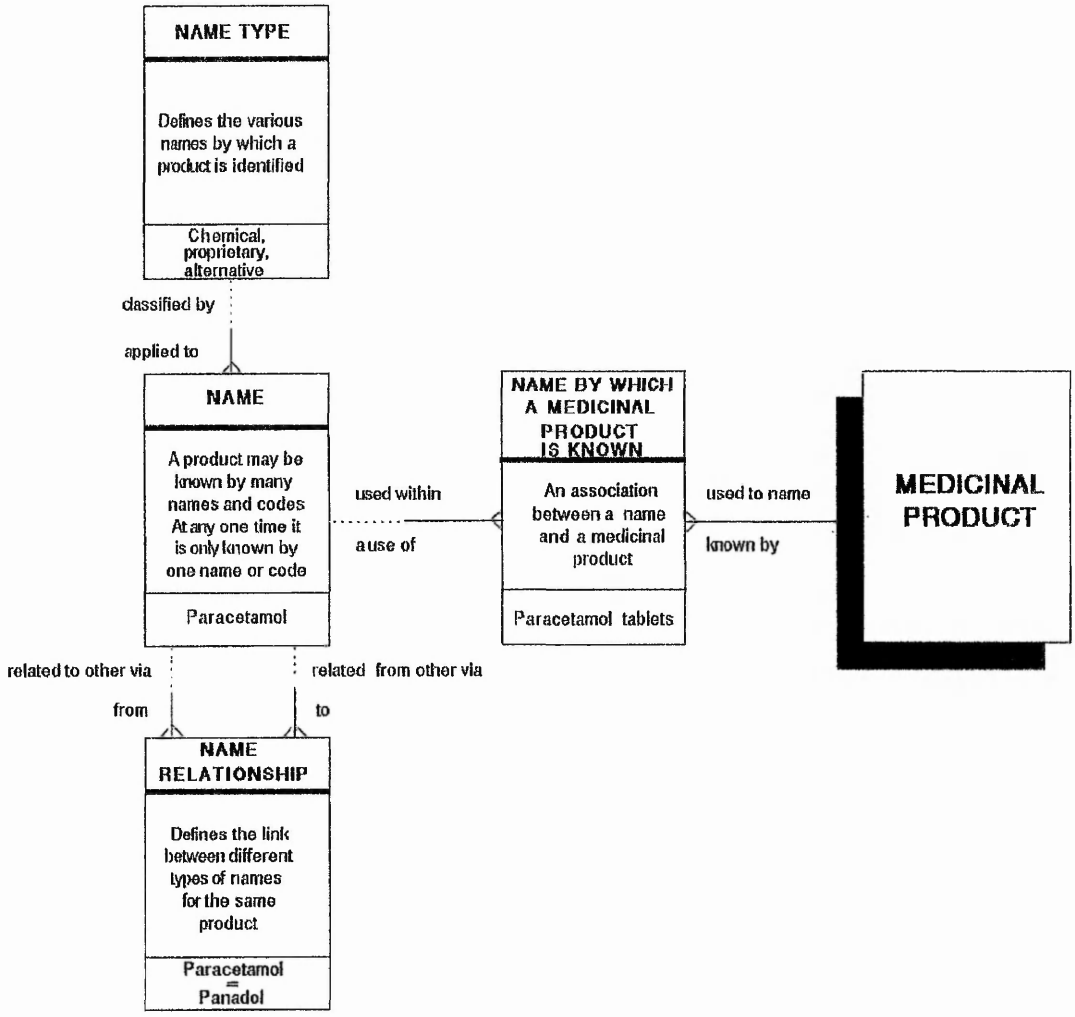


Fig.3.5
The name relationships of the entity type MEDICINAL PRODUCT.

(I) A LIST OF SUCH INGREDIENTS, EACH DESCRIBED BY ITS APPROVED NAME OR MONOGRAPH NAME OR, WHERE IT HAS NO APPROVED NAME OR MONOGRAPH NAME, ANY OTHER DESCRIPTIVE APPELLATION, AND

(II) THE QUANTITY OF EACH SUCH INGREDIENT CONTAINED IN EACH UNIT OR DOSE OF THE MEDICINAL PRODUCT OR, WHERE THERE IS NO SUCH UNIT OF DOSE, THE PERCENTAGE OF EACH SUCH INGREDIENT CONTAINED IN THE MEDICINAL PRODUCT;

(B) WHERE THE MEDICINAL PRODUCT CONTAINS ANY ACTIVE INGREDIENT THAT CANNOT BE DEFINITIVELY IDENTIFIED -

(I) THE INFORMATION AS REQUIRED UNDER (A) ABOVE IN RESPECT OF EACH IDENTIFIABLE ACTIVE INGREDIENT (IF ANY), AND

(II) A DESCRIPTION OF THE MATERIAL TO WHICH THE ACTIVITY OF ANY OTHER INGREDIENT IS ASCRIBED AND, WHERE APPROPRIATE, A STATEMENT OF THE ACTIVITY OR POTENCY OF THE MEDICINAL PRODUCT;

(C) WHERE THERE ARE NO ACTIVE INGREDIENTS IN THE MEDICINAL PRODUCT, A STATEMENT INDICATING THE MATERIAL OF WHICH THAT MEDICINAL PRODUCT CONSISTS."

This section of the model deals with appearance, form, ingredients and strengths of the medicinal product. Each of which will be discussed separately.

3.4.2.1 Form and Appearance

MEDICINAL PRODUCTS may occur in many FORMS, e.g. tablets, capsules, ampoules, liquids, cylinders of gas etc., Nationale Raad Voor Volksgezonheid, (1989b).

Medicinal products may have many varying appearances, e.g. powders may be granulated, smooth or coloured. Tablets may be coloured, varying in shape, coated or scored. The appearance of a product may be related to its manufacturer, e.g. proprietary markings on tablets or packaging. Figure 3.6 shows the relationship between MEDICINAL PRODUCT, FORM and APPEARANCE.

The model shows that a MEDICINAL PRODUCT may have many APPEARANCE attributes that contribute to its overall physical presentation PRODUCT APPEARANCE. However, for each PRODUCT APPEARANCE there will only be one APPEARANCE, e.g. the medicinal product may be smooth, round and coloured. According to the definition of MEDICINAL PRODUCT, there will be one and only one relationship to FORM, although the entity FORM may be applicable to many MEDICINAL PRODUCT entity types. The entity PRODUCT APPEARANCE is related to the entity FORM through the entity type MEDICINAL PRODUCT, since a medicinal product may have many appearances, e.g. tablet or capsule. It may be, for example, that a product may have a FORM tablet which has an identical appearance to a product having a FORM implant. Since they are completely different products the relationship of FORM to APPEARANCE is through MEDICINAL PRODUCT and not through FORM and APPEARANCE. For each occurrence of PRODUCT APPEARANCE, it will be related to one and only one MEDICINAL PRODUCT defined by the entity FORM.

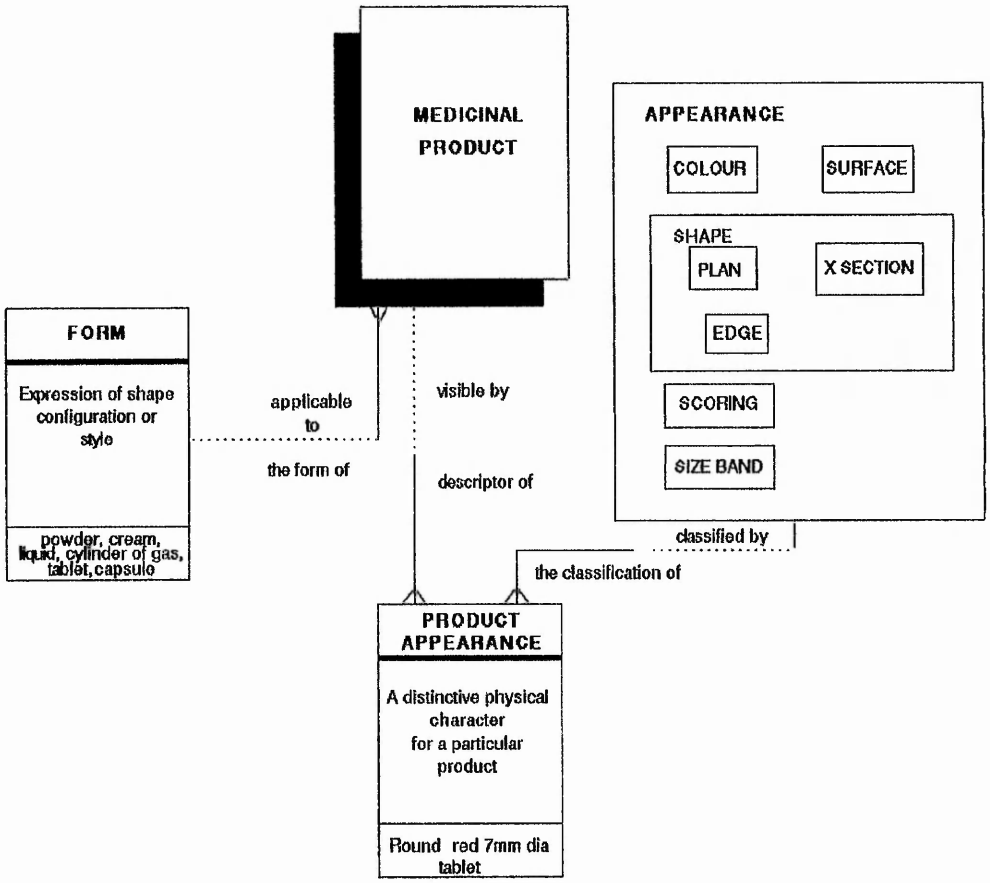


Fig. 3.6
The relationship between MEDICINAL PRODUCT, FORM and APPEARANCE.

3.4.2.2 Ingredients

Medicinal products are designed by means of their ingredients to produce or assist in producing an effect on patients. It is also necessary to know the inactive ingredients in a product for clinical reasons.

The ingredients of most products have approved names or monograph entities in approved reference publications. Importantly, an ingredient of a medicinal product is defined as a medicinal product (MEDICINAL PRODUCT) in its own right. In addition, a medicinal product may be a composite of two or more other medicinal products, e.g. Migraleve Duopack is a composite of migraleve pink and migraleve yellow.

Figure 3.7 models the ingredient relationship of a medicinal product.

Starting at MEDICINAL PRODUCT and reading the model anti-clockwise depicts a medicinal product made up of ingredients. Thus, a MEDICINAL PRODUCT must be 'made up of' one or many PRODUCT INGREDIENTS, and each PRODUCT INGREDIENT must be 'identified' as one MEDICINAL PRODUCT in its own right. Reading the model clockwise from MEDICINAL PRODUCT depicts a medicinal product as a component of a composite medicinal product. Thus a MEDICINAL PRODUCT may be identified as a component of another as a PRODUCT INGREDIENT, and one or more such PRODUCT INGREDIENTS may be a composite of one MEDICINAL PRODUCT.

A MEDICINAL PRODUCT is defined by many properties - name, strength, form etc. In the same way, any PRODUCT INGREDIENT ought to be

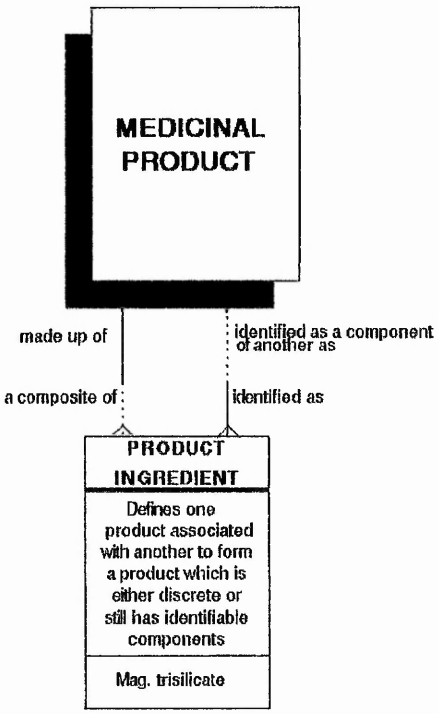


Fig. 3.7
The relationship of PRODUCT INGREDIENT to MEDICINAL PRODUCT.

similarly defined. In fact, a PRODUCT INGREDIENT has the same qualities as a MEDICINAL PRODUCT. Therefore a PRODUCT INGREDIENT must always identify a MEDICINAL PRODUCT. This can be illustrated by example.

A MEDICINAL PRODUCT - Co-proxamol is made up of one PRODUCT INGREDIENT linked to the MEDICINAL PRODUCT 'Paracetamol' and another PRODUCT INGREDIENT linked to the MEDICINAL PRODUCT 'Dextropropoxyphene'.
While Co-proxamal itself has no strength units the ingredient paracetamol as a MEDICINAL PRODUCT has a strength 325mg and dextropropoxyphene as a MEDICINAL PRODUCT has a strength 32.5mg. In this way not only can the set of MEDICINAL PRODUCTS that make up Co-proxamol be identified, but the amount of each ingredient per unit can be recorded.

Another way in which the model can be used is to identify all those MEDICINAL PRODUCTS of which a specific MEDICINAL PRODUCT is the component or ingredient.

For example the MEDICINAL PRODUCT 'Paracetamol' may be linked to PRODUCT INGREDIENT, which identifies the MEDICINAL PRODUCT Co-proxamol. This in turn is linked to another PRODUCT INGREDIENT that is identified as the MEDICINAL PRODUCT Dextropropoxyphene. Repeating the process allows the products of which Paracetamol is a component to be identified.

3.4.2.3 Strength

In general, most ingredients are easily identified qualitatively and

quantitatively. Some ingredients, however, consist of a mixture of components that have a total effect. These components are, therefore, referred to generically, e.g. Senokot tablets contain standardised senna, equivalent to 7.5mg total sennosides.

Quantitative identification is easy in many products, e.g. Paracetamol 500mg. However, the ingredients of some products are more difficult to measure, e.g. High Potency Pancreatin; the minimum activity of each gram is shown in Table 3.1.

Free Protease	1400	BP units
Lipase	25000	BP units
Amylase	30000	BP units

Table 3.1 - The strength and ingredients of high potency pancreatin

Some products have no active ingredients in a clinical sense and may be used as vehicles in the preparation of other products, e.g. water for injections. From a legal viewpoint however, they are active ingredients because they are specified in the product's product licence.

The entity STRENGTH defines the strength of the ingredient according to defined rules (Nationale Raad Voor de Volksgenzonheid, 1989). A medicinal product may or may not have a strength, e.g. Water for Injections BP and bandages. For each occurrence of a MEDICINAL PRODUCT that has a STRENGTH, there may be one and only one STRENGTH of that product. STRENGTH and PRODUCT INGREDIENTS are modelled in Figure 3.8.

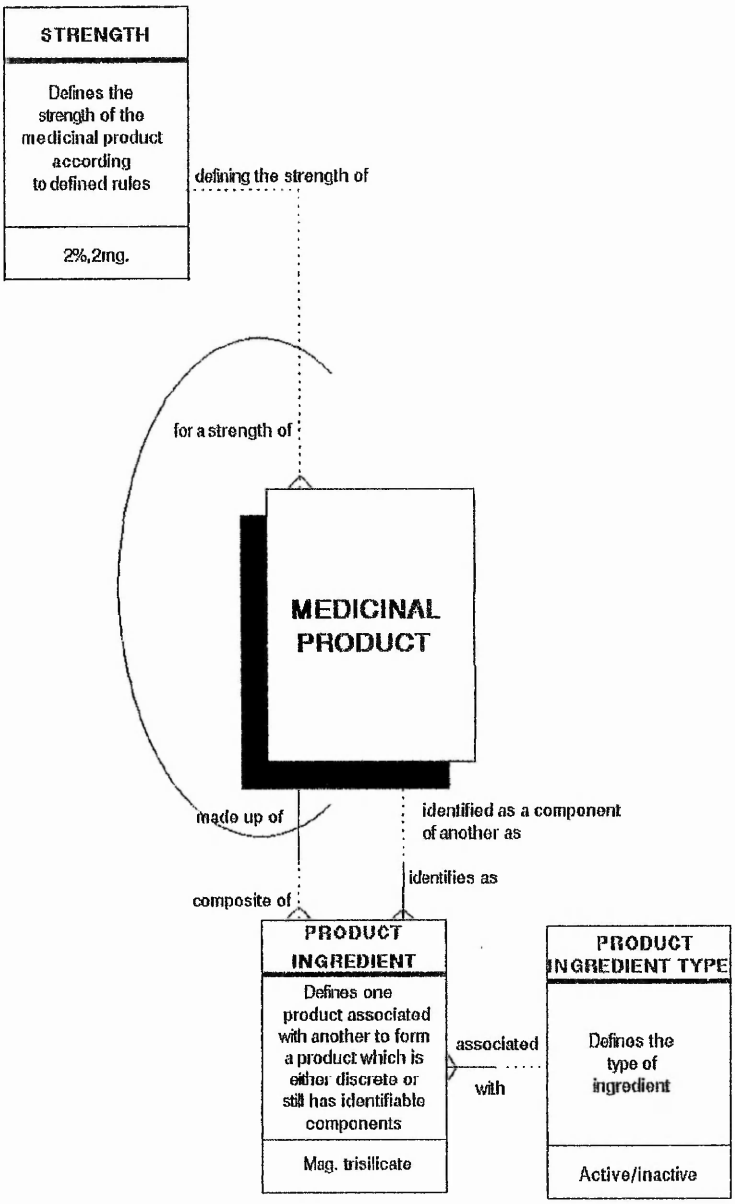


Fig. 3.8
The relationships of STRENGTH, and PRODUCT INGREDIENT to MEDICINAL PRODUCT

STRENGTH is associated through the entity type MEDICINAL PRODUCT with PRODUCT INGREDIENT, since only in this way can calculations be made for dose, total dose, and cumulative doses. Co-proxamol means nothing in strength terms but the strengths of its components Paracetamol 325mg and Dextropropoxyphene 32.5mg are essential for dosage calculations. MEDICINAL PRODUCTS will have a direct relationship with a strength, but those that have PRODUCT INGREDIENTS will have the strength defined by the strength of its ingredients. One and only one of these conditions must apply, hence the mutually exclusive arc from MEDICINAL PRODUCT.

To summarise, MEDICINAL PRODUCT may have a strength. However, in some cases it does not have, e.g. a multi-ingredient tablet. In this case some of the ingredients may have a strength. Thus, using the above reasoning, if a tablet contains 300mg Paracetamol the PRODUCT INGREDIENT will relate to the multi-ingredient tablet and Paracetamol, the latter being defined by strength of 300mg. Thus, by identifying the entity PRODUCT INGREDIENT, the model automatically defines the strength of the component.

PRODUCT INGREDIENT TYPE defines whether or not a product ingredient is active from a therapeutic view point.

Strength and ingredients can be modelled as shown in Figure 3.8.

3.4.3 USES

"PRINCIPAL ACTION (IF ANY) OF THE MEDICINAL PRODUCT AND THE PURPOSES FOR WHICH IT IS RECOMMENDED TO BE USED".

The use of a medicinal product depends on the indication for a product, i.e. the conditions that it is intended to treat or diagnose as recommended by the medicinal product's Data Sheet. The uses of a medicinal product also depend upon the route by which the product is administered, e.g. Diclofenac orally as a non-steroidal anti-inflammatory agent and parenterally for the treatment of colic. There is thus a valid route of administration of a medicinal product for a given indication. The indication for using a medicinal product also depends upon the patient's characteristics, e.g. age or sex, and other conditions from which a patient may be suffering, and for which they may be receiving treatment, i.e. patient's syndrome.

The indications for using the medicinal product, as defined by the entity INDICATION, are dependant on the entity MEDICINAL PRODUCT and the characteristics of the patient PATIENT CHARACTERISTIC TYPE. During the development of the model, it was argued that since some patients may be suffering from more than one condition, the choice of drug should depend on an entity SYNDROME, which provided a description of the patient's conditions, of which there may be several, which at a particular point in time influences the choice of medicinal product, Figure 3.9.

However, it can be argued that the entities SYNDROME and PATIENT CHARACTERISTIC TYPE are one entity PATIENT CHARACTERISTIC TYPE, since DISEASE TYPE and SYNDROME all contribute to the PATIENT CHARACTERISTIC TYPE, Figure 3.10. The entity INDICATION FOR PRODUCT, Figure 3.9 becomes the entity INDICATION, Figure 3.10, defining the relationship of MEDICINAL PRODUCT to PATIENT CHARACTERISTIC TYPE already discussed.

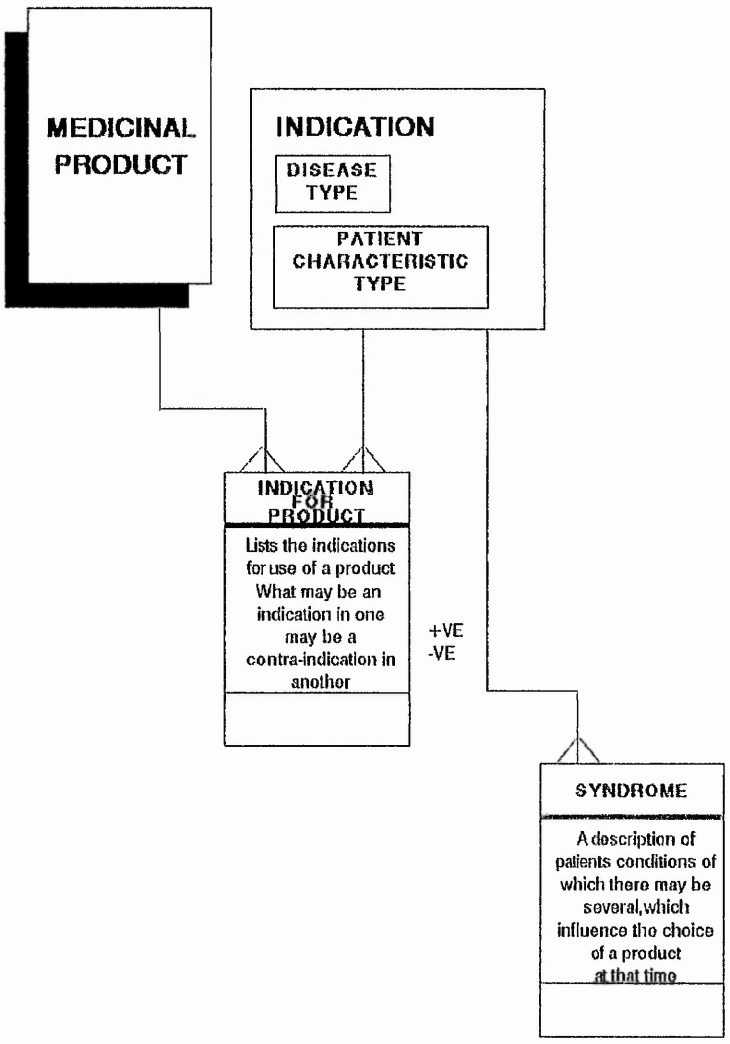


Fig. 3.9
Original model illustrating the relationship between INDICATION, SYNDROME and MEDICINAL PRODUCT.

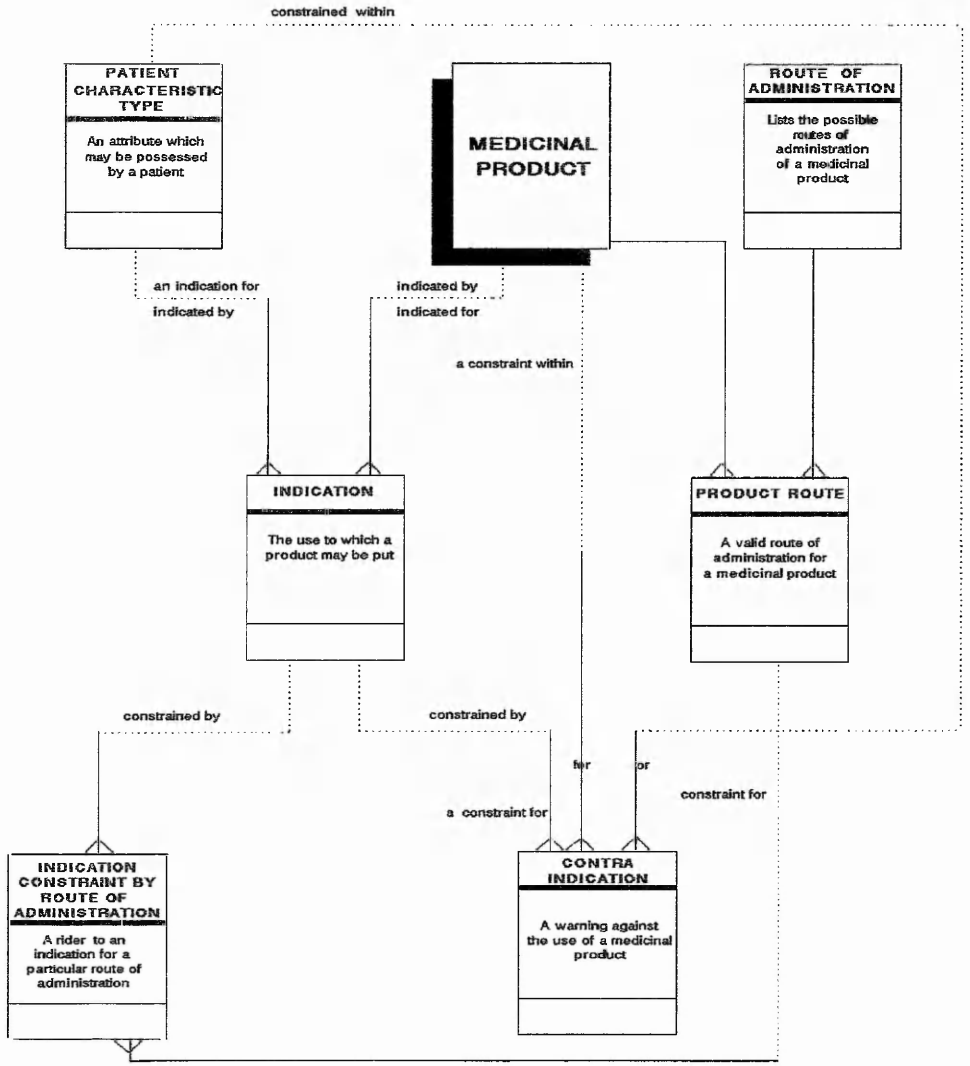


Fig. 3.10

The effects of indications and contra-indications on MEDICINAL PRODUCT.

In the use of a medicinal product the ROUTE OF ADMINISTRATION needs to be considered, since formulation is for a particular route.

MEDICINAL PRODUCT has a many to many relationship with ROUTE OF ADMINISTRATION. In order to satisfy this relationship, the entity PRODUCT ROUTE is added. Thus MEDICINAL PRODUCT may have many PRODUCT ROUTE(S) and ROUTE OF ADMINISTRATION may have one or more PRODUCT ROUTE(S). However, for each occurrence of PRODUCT ROUTE there will be only one ROUTE OF ADMINISTRATION and one MEDICINAL PRODUCT applicable.

Products may be constrained in their use by the route through which it is administered, e.g. Diclofenac may be used orally as a non-steroidal anti-inflammatory agent and parenterally for the treatment of colic. This is illustrated by the presence of the entity INDICATION CONSTRAINT BY ROUTE OF ADMINISTRATION, which may be a constraint for the entity PRODUCT ROUTE. Also INDICATION may be constrained by the fact that in certain conditions the product may be contra-indicated, CONTRA-INDICATION.

3.4.3.1 Contra-indications

These are modelled here, since the model (Figure 3.10) incorporates contra-indications. If a product is indicated for a therapeutic purpose, it may be contra-indicated for another purpose, e.g. steroids used to reduce inflammation in the presence of a viral infection. Similarly, it may also be contra-indicated because of its pharmacological effects on other conditions from which a patient may be suffering, PATIENT CHARACTERISTIC TYPE. For example, dihydrocodeine tartrate is used for the treatment of pain. However, because it may

bring about histamine release, it should not be given during an attack of asthma and should be administered with care to patients liable to such attacks, (ABPI,1993: p. 1055).

The action of a drug may also be potentiated in the presence of certain conditions, e.g. renal impairment.

A medicinal product may also be contra-indicated in the presence of another medicinal product, e.g. warfarin and aspirin.

The entity PATIENT CHARACTERISTIC TYPE, through some disease type of a patient, e.g. Hepatic or renal impairment, may be a constraint within the entity CONTRA-INDICATION. In turn the entity CONTRA-INDICATION must be for a specific PATIENT CHARACTERISTIC TYPE.

3.4.4 DOSAGE AND ADMINISTRATION

"WHERE THE MEDICINAL PRODUCT IS RECOMMENDED FOR ADMINISTRATION ONLY TO ADULTS, THE DOSAGE (IF ANY) FOR ADULTS STATING, UNLESS IT IS OTHERWISE APPARENT, THAT THE MEDICINAL PRODUCT IS NOT RECOMMENDED FOR ADMINISTRATION TO CHILDREN AND, WHERE THE MEDICINAL PRODUCT IS RECOMMENDED FOR ADMINISTRATION ONLY TO CHILDREN, THE DOSAGE (IF ANY) FOR CHILDREN STATING, UNLESS IT IS OTHERWISE APPARENT, THAT IT IS NOT RECOMMENDED FOR ADMINISTRATION TO ADULTS AND, WHERE IT IS RECOMMENDED FOR ADMINISTRATION TO BOTH ADULTS AND CHILDREN, BOTH SUCH DOSAGES (IF ANY) AND IN EACH CASE THE METHODS AND ROUTES OF ADMINISTRATION AND, WHERE APPROPRIATE, RECOMMENDATIONS AS TO DILUENTS".

This section of the requirements relates to the dosage and routes of

administration.

3.4.4.1 Dose

The dose of a medicinal product is intimately concerned with many factors, e.g. route of administration, age, patient's condition and surface area. It may also be related to other drugs being administered concurrently, e.g. the dose of some cytotoxic preparations is reduced when given in conjunction with other cytotoxic preparations. It may also vary with target results expected after pathology test, e.g. INR times.

For drugs, except those with target areas, there is an approved drug regime dependent upon the syndrome for which the product is being used. These can be found in standard reference books, e.g. British National Formulary and Data Sheets. In certain circumstances the dose may not be accurately specified; 'to be used sparingly' for ointments and creams. Within the approved drug regime there is a prescribed dose and its associated timeframe, any variation from which may result in the approved regime being breached.

The drug regime is only valid for products when they are used for their licensed purposes. Drugs may be used outside their licensed purposes. Therefore the entity APPROVED DRUG REGIME would in this case not be officially approved. However, the model allows recognition of non-approved use by the alterations invoked through the entity APPLIED DRUG REGIME.

There are medicinal products that are given as variable doses over

varying time frames, since their doses are related to the patient's characteristics, e.g. warfarin and insulin. These dosages are determined by the levels at the time of the patient's test. The entity REGIME ALGORITHM contains the target level for the results of the treatment.

For some other drugs, e.g. Cytotoxics, the dose depends on the patient's surface area. Others that are proportional to weight are, like the previous drugs, subject to dosage units that are encompassed in the entity REGIME ALGORITHM. The entity APPLIED DOSE REGIME defines the doses prescribed according to the dosage rules.

A PATIENT may be the exhibitor of a PATIENT CHARACTERISTIC, which itself must be exhibited by a PATIENT. The entity PATIENT CHARACTERISTIC must be classified by a PATIENT CHARACTERISTIC TYPE, e.g. poor renal function, weight etc. The PATIENT CHARACTERISTIC TYPE may, due to its nature, have the entity REGIME ALGORITHM applied. The entity REGIME ALGORITHM is also affected by the entity INDICATION, which determines the entity APPROVED DOSE REGIME for the product. The effects of these entities may be implemented in the entity APPLIED DOSE REGIME. Should it not be necessary to apply the model in this way, a clinician may assess the entity PATIENT and may apply the entity APPLIED DRUG REGIME that is applicable to only that patient, taking into account the APPROVED DOSE REGIME and INDICATION.

These entities can be modelled as shown in Figure 3.11.

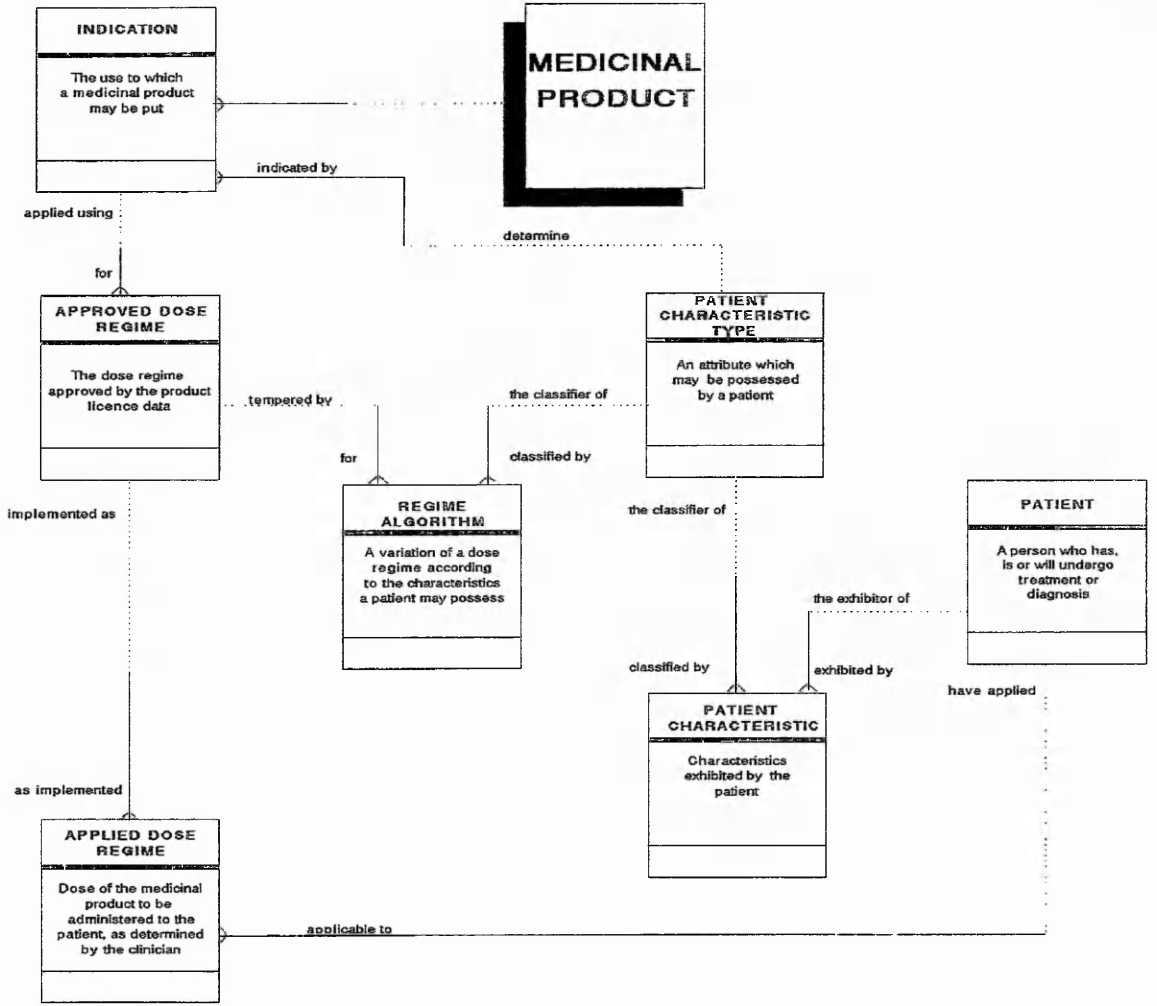


Fig. 3.11
The entities related to dose.

3.4.4.2 Route of Administration

Medicinal Products may have many routes by which they can be administered (Nationale Raad Voor de Volksgezonheid, 1988), e.g. prednisolone can be administered parenterally, either by the intravenous or intramuscular route.

This can be resolved by the inclusion of the entity ROUTE FOR FORM to form an appropriate model. The entity ROUTE OF ADMINISTRATION may have many levels of description (Nationale Raad Voor de Volksgezonheid, 1988).

MEDICINAL PRODUCT has a many to many relationship with ROUTE OF ADMINISTRATION. In order to satisfy this relationship the entity ROUTE FOR FORM is added. Thus MEDICINAL PRODUCT must have many ROUTE(S) FOR FORM and ROUTE OF ADMINISTRATION may have one or more ROUTE FOR FORM. However, for each occurrence of ROUTE FOR FORM there will be only one ROUTE OF ADMINISTRATION and one MEDICINAL PRODUCT applicable.

These entities can be modelled in Figure 3.12.

3.4.5 CONTRA-INDICATIONS, WARNINGS ETC.

"CONTRA-INDICATIONS, WARNINGS, PRECAUTIONS AND ACTION TO BE TAKEN IN THE EVENT OF OVERDOSAGE, RELATING TO THE MEDICINAL PRODUCT AND MAIN SIDE-EFFECTS AND ADVERSE REACTIONS LIKELY TO BE ASSOCIATED THEREWITH AND, WHERE THERE ARE NO SUCH PARTICULARS TO BE GIVEN, A STATEMENT TO THAT EFFECT SHALL BE MADE; WHERE REQUIRED IN THE INTERESTS OF SAFETY, THE ANTIDOTE OR OTHER APPROPRIATE ACTION TO BE TAKEN."

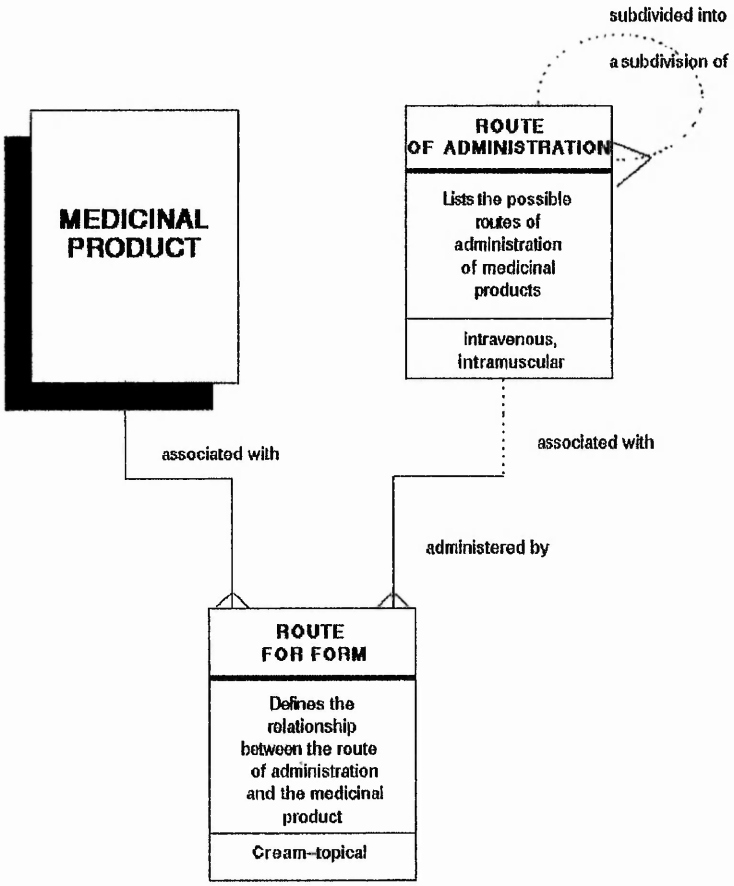


Fig. 3.12
The relationship of ROUTE OF ADMINISTRATION to MEDICINAL PRODUCT.

3.4.5.1 Contra-Indications

These were modelled under Uses Section 3.4.3.

3.4.5.2 Warnings

Some drugs require warnings to be issued, e.g. when there is insufficient evidence to support their use safely in certain conditions, e.g. pregnancy. In certain cases, absolute warnings may be necessary, e.g. because Isotretinoin is teratogenic, it should not be used by women of child bearing age unless very stringent conditions are accepted, Figure 3.13. The entity STATEMENT OF NO WARNING complies with the legal requirements and only comes into effect when the entity WARNING FOR PRODUCT is not applicable. This is represented by the mutually exclusive arc between the entities STATEMENT OF NO WARNING and WARNING FOR PRODUCT.

3.4.5.3 Effects

A MEDICINAL PRODUCT may have a variety of effects, some of which are the reason for use and some of which are side effects. Side effects in some products may be the reason for use in some instances, e.g. imipramine, normally used as an antidepressant, because it has the side effect of causing urinary retention is frequently used in the treatment of enuresis in children (ABPI, 1993: p. 563).

The entity type may be modelled in the following way, Figure 3.14. This figure illustrates that a MEDICINAL PRODUCT, through the entity MEDICINAL PRODUCT FOR INDICATION, depending on the entity PATIENT CHARACTERISTIC TYPE, may have either THERAPEUTIC EFFECTS or SIDE EFFECTS, which are subtypes of the entity PATIENT CHARACTERISTIC TYPE.

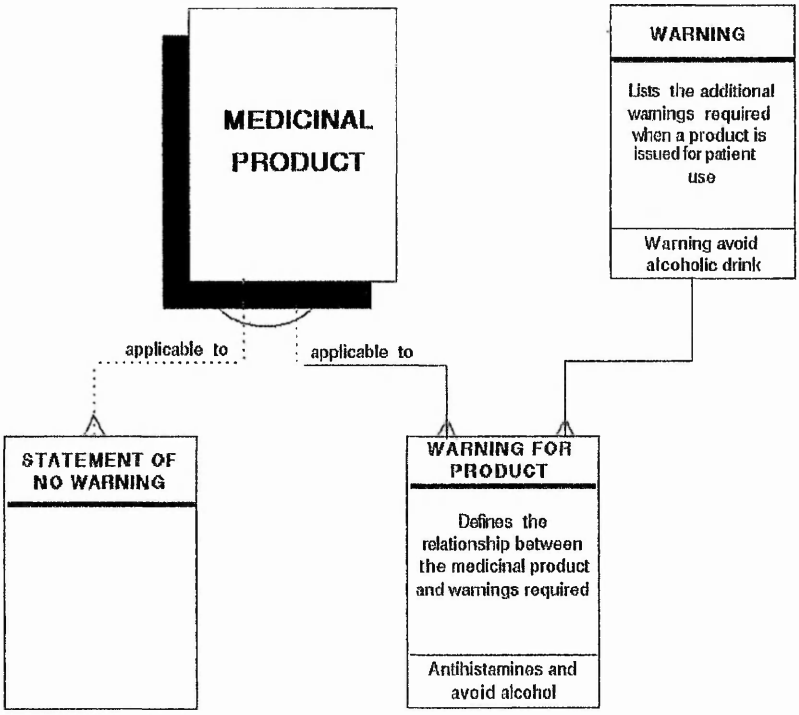


Fig. 3.13
The relationships of WARNING to MEDICINAL PRODUCT.

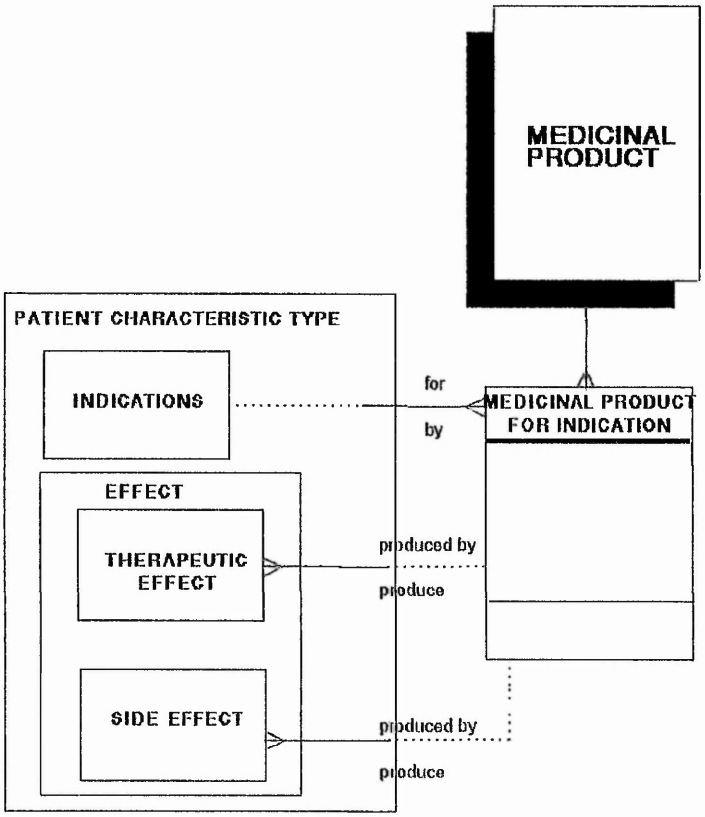


Fig. 3.14
The effects of a medicinal product.

The MEDICINAL PRODUCT FOR INDICATION may produce SIDE EFFECTS and a SIDE EFFECT must be produced by one and only one MEDICINAL PRODUCT FOR INDICATION.

3.4.6 PHARMACEUTICAL PRECAUTIONS

"SPECIAL REQUIREMENTS FOR STORAGE OF MEDICINAL PRODUCTS AND, WHERE APPROPRIATE, PHARMACEUTICAL PRECAUTIONS INCLUDING RECOMMENDATIONS AS TO EXCIPIENTS, DILUENTS AND OTHER ADDITIVES AND AS TO SUITABLE CONTAINERS, OR, WHERE THERE ARE NO SUCH REQUIREMENTS OR NO SUCH PRECAUTIONS, A STATEMENT TO THAT EFFECT SHALL BE MADE."

Medicinal products may have special requirements for labelling, (e.g. protect from light) for storage and containers (e.g. glyceryl trinitrate tablets). All of which are necessary to prevent degradation of the product.

During the manufacture, dispensing or administration of medicinal products it may be necessary to use certain excipients or diluents that must not react adversely with the medicinal product, e.g. Thioridazine syrup is to be diluted with water, syrup or sorbitol on dispensing. This action may also reduce the shelf life of the product.

This entity PRECAUTION TYPE lists the precautions necessary with regard to labelling, storage, containers, diluents, excipients etc. It does not include clinical precautions, e.g. this product may cause drowsiness.

These entities are modelled in Figure 3.15.

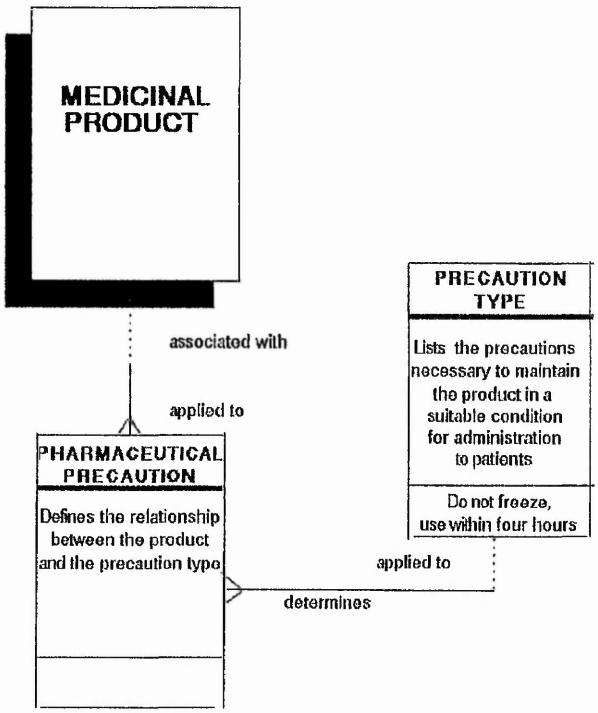


Fig. 3.15
The relationship of PRECAUTION TYPE to MEDICINAL PRODUCT.

The entity PRECAUTION TYPE as well as defining the relationship between the product and the precaution type for product protection, e.g. do not freeze, can also be used to determine precautions for personal protection, e.g. wear gloves, wear respirator etc. It, therefore, has a dual focus: product and personnel protection.

3.4.7 LEGAL CATEGORY

"REFERENCES TO STATUTORY PROVISIONS RELATING TO SALE OR SUPPLY OF THE MEDICINAL PRODUCT."

Medicinal products may belong to several categories, some of which are subsets of others, e.g. Controlled Drugs, which has its own subset, is a subset of Prescription Only Medicine (POM).

However, legal categories are influenced by other considerations. Paracetamol 500mg, for example, is available under General Sale List (GSL) in packs of 25 tablets. However, if the pack size is greater than 25 it is a Pharmacy Medicine(P).

3.4.7.1 Strength

There are restrictions on site of usage and strength, e.g. hydrocortisone cream 1% is a pharmacy medicine (P). The cream should not be used on children under 10 years of age, not more than twice a day for seven days or on the face or genital areas or broken skin. If these conditions are exceeded the product becomes a prescription only medicine, (POM).

3.4.7.2 Dose

Chloroquine used for the prophylaxis of malaria is a pharmacy medicine

(P), whilst for the treatment of malaria it is a prescription only medicine, (POM). The official wording being:
"Can be sold for use to the public provided it is licensed and labelled for the prophylaxis of malaria" (BNF, 1993: p 247). The dose for the prophylaxis being specific and different from that for the treatment for malaria.

The model thus needs to take all these variations into account and a suitable model would be Figure 3.16.

LEGAL CATEGORY FOR PRODUCT defines the legal status of the product. The category depends on either the MEDICINAL PRODUCT itself, the pack in which it is provided for retail sale PACK FOR MEDICINAL PRODUCT, or the dose in which it may be used DOSE REGIME FOR PRODUCT. Each of these are mutually exclusive as defined by the mutual exclusion arc. The latter two are however, related to the MEDICINAL PRODUCT by the relationships shown in Figure 3.16.

3.4.8 PACKAGE QUANTITIES

"QUANTITY OR AMOUNT OF THE MEDICINAL PRODUCT IN EACH SIZE OF PACKAGE OR CONTAINER FOR RETAIL SALE, OR SUPPLY IN CIRCUMSTANCES CORRESPONDING TO RETAIL SALE."

MEDICINAL PRODUCTS may consist of single medicinal products in a container, e.g. a bottle of 100 tablets, or of two or more products combined together to form MEDICINAL PRODUCT, e.g. Canesten cream and vaginal tablets comprise CANESTEN DUOPACK.

The entity STRENGTH defines the strength of the ingredient according to

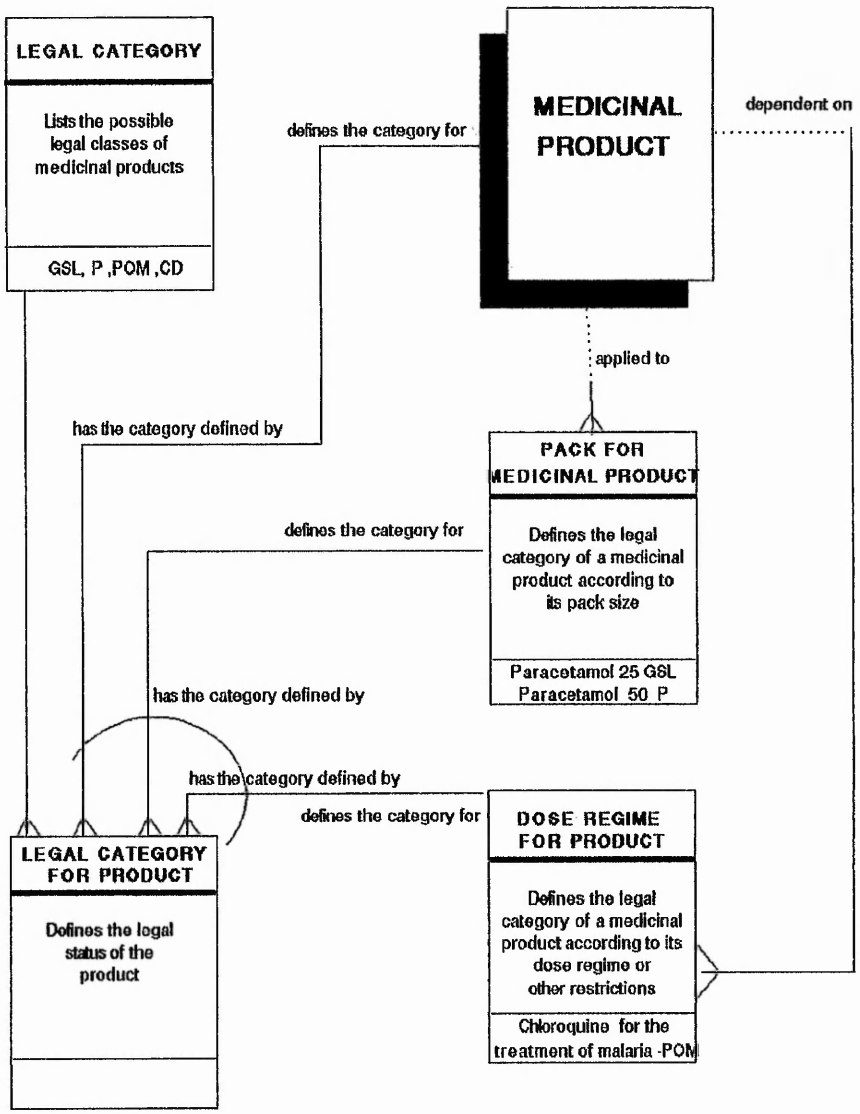


Fig. 3.16
The relationships of legal entities to MEDICINAL PRODUCT.

defined rules (Nationale Raad Voor de Volksgezonheid, 1989). However, a medicinal product may or may not have a strength, e.g. water for injections and bandages. It will in this case have a BASE UNIT SIZE.

Similarly, a MEDICINAL PRODUCT may consist of a bottle of 100 tablets. This is also identified in the entity BASE UNIT SIZE.

A suitable model to illustrate this is Figure 3.17. Taking the first example, 100 x 500mg Paracetamol tablets would be "made up" of PRODUCT ELEMENT bottle and PRODUCT INGREDIENT, Paracetamol tablets. These must be "identified as" a MEDICINAL PRODUCT, the STRENGTH of which would be 500mg and BASE UNIT SIZE 100.

This model also accommodates complex packages, e.g. Canesten Duopack composed of Canesten Cream and tablets.

3.4.9 FURTHER INFORMATION

"SUCH FURTHER INFORMATION (IF ANY) AS MAY BE NECESSARY TO ASSIST THE PRACTITIONER IN THE PROPER UNDERSTANDING, RECOGNITION, ADMINISTRATION AND USE OF THE MEDICINAL PRODUCT PROVIDED THAT SUCH INFORMATION SHALL NOT COVER MORE THAN ONE TENTH OF THE TOTAL SURFACE AREA OF THE DATA SHEET."

In order to comply with this section it is necessary to model

1) modified products, since these may have a bearing on the product prescribed in terms of length of action, e.g. modified action products, enteric coated, Human insulins etc., Figure 3.18.

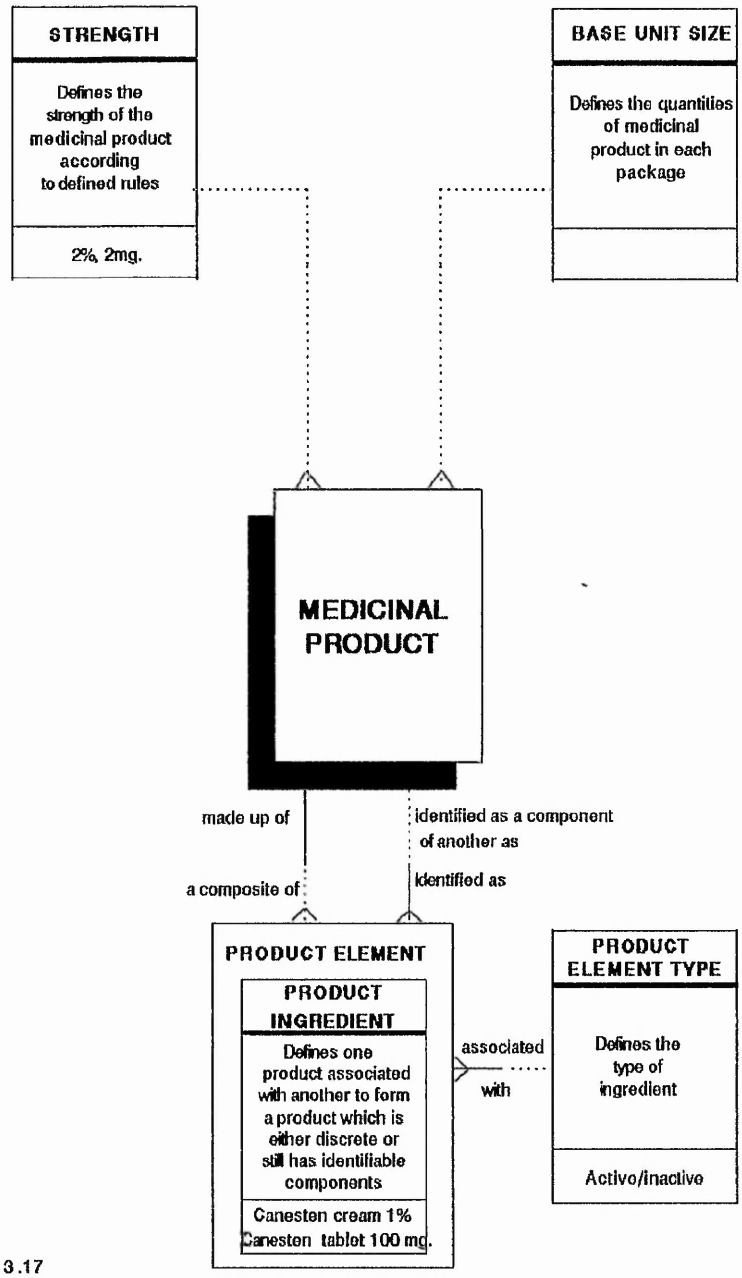


Fig. 3.17
The elements of a product pack.

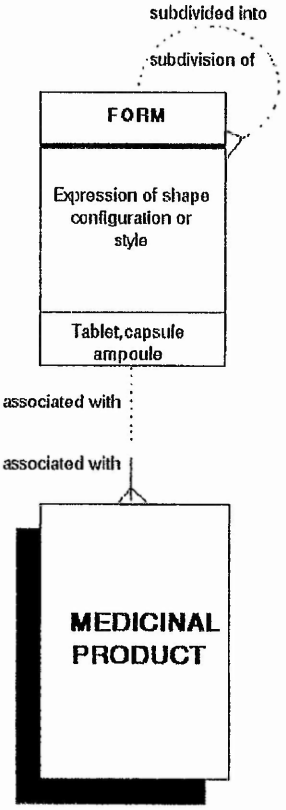


Fig. 3.18
The modified FORM relationships to MEDICINAL PRODUCT.

2) product interactions, since MEDICINAL PRODUCT may interact with other MEDICINAL PRODUCTS or other PRODUCTS, Figure 3.19.

3.4.9.1 Modified Products

Some medicinal products are modified forms of medicinal products, e.g. Enteric coated or chewable tablets, depot injections in oil etc.

This model shows that the entity FORM, e.g. tablet, capsule or ampoule, may be associated with many MEDICINAL PRODUCTS. Each occurrence of a MEDICINAL PRODUCT must be associated with one and only FORM. The FORM however, may be modified. This is contained within the recursive relationship shown in the entity FORM in Figure 3.18.

3.4.9.2 Interactions

Medicinal products may interact with each other to produce a variety of effects, e.g. potentiation or antagonism in effect. For medicinal products the antagonism may be pharmacokinetic or pharmacodynamic.

Pharmacokinetic interactions affect absorption, distribution, metabolism or excretion of medicinal products by another (BNF, 1993: p. 487).

Pharmacodynamic effects are interactions between drugs that have similar or antagonistic pharmacological effects or side effects. These are drugs which compete at receptor sites or act on the same physiological system (BNF, 1993: p. 487).

These effects were dealt with in the section dealing with CONTRA-

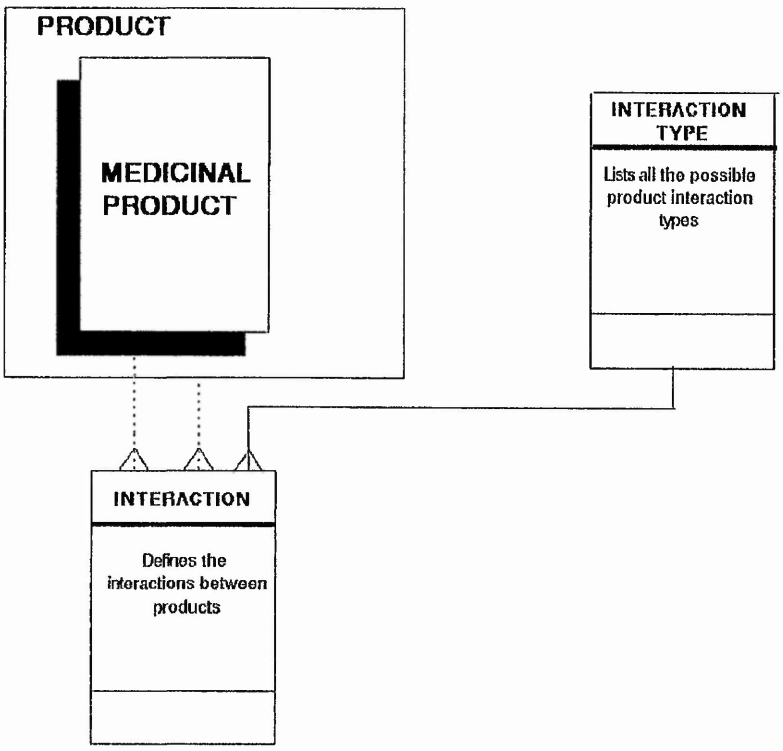


Fig. 3.19
The relationship of INTERACTION entities to MEDICINAL PRODUCT.

INDICATIONS (3.4.3.1)

There are other types of interaction which need to be considered.

1. chemical, e.g. Tetracycline and milk, iron and ampicillin, paraldehyde and plastic syringes,

2. interference reactions - with laboratory tests, e.g. methyldopa may affect blood cross-matching.

The latter two interactions cast doubt on the validity of the original definition of a medicinal product used in this study, viz. a medicinal product contains active ingredients that may be chemical or a substance specified in a product licence.

It is reasoned therefore that, at this point, the entity type MEDICINAL PRODUCT should be a group in another entity PRODUCT. Thus encompassing materials such as milk or other foods, which by definition are not medicinal products. However, they may interact with a medicinal product in any way to produce any effect that was not originally required, e.g. influence on laboratory tests, potentiation or antagonism of drug actions.

A PRODUCT may therefore consist of one or several components that may be medicinal in nature, any of which may react with one or several other medicinal or non- medicinal components.

The entity INTERACTION associates the effect with a particular

INTERACTION TYPE produced by a combination of ingredients.

The route of administration of an ingredient may have a decisive effect on the potential interaction of the ingredients, e.g. tetracycline orally and milk produce an interaction but tetracycline parenterally and milk would not.

A suitable model would be Figure 3.19.

3.4.10 PRODUCT LICENCE NUMBERS, NAMES AND ADDRESSES

"PRODUCT LICENCE NUMBER OF THE MEDICINAL PRODUCT AND (A) NAME AND ADDRESS OF THE HOLDER OF THE PRODUCT LICENCE, OR (B) THE BUSINESS NAME AND ADDRESS OF THE PART OF HIS BUSINESS THAT IS RESPONSIBLE FOR ITS SALE AND SUPPLY, OR (C) THE NAME AND ADDRESS OF A PERSON NAMED IN THE PRODUCT LICENCE AS BEING RESPONSIBLE FOR, OR PERMITTED TO PARTICIPATE IN, ITS SALE AND SUPPLY, OR (D) THE NAME AND ADDRESS OF A PERSON TO WHOM THE PROVISIONS OF ARTICLE 3 OF THE MEDICINES (EXEMPTION FROM LICENCES) (SPECIAL AND TRANSITIONAL CASES) ORDER 1971 ARE APPLICABLE UNLESS, AS RESPECTS THE NAME AND ADDRESS IN THE CASE OF A DATA SHEET COMPENDIUM, DATA SHEETS ARE GROUPED TOGETHER BY REFERENCES TO ANY NAME FALLING WITHIN EITHER (A), (B), (C) OR (D) OF THIS PARAGRAPH AND THE NAME AND ADDRESS APPEARS EITHER AT THE HEAD OF THAT GROUP OR IN THE FIRST DATA SHEET OF THAT GROUP."

Figure 3.20 describes the relationships of PRODUCT LICENCE to MEDICINAL PRODUCT.

A MEDICINAL PRODUCT must have a PRODUCT LICENCE, e.g. full, clinical

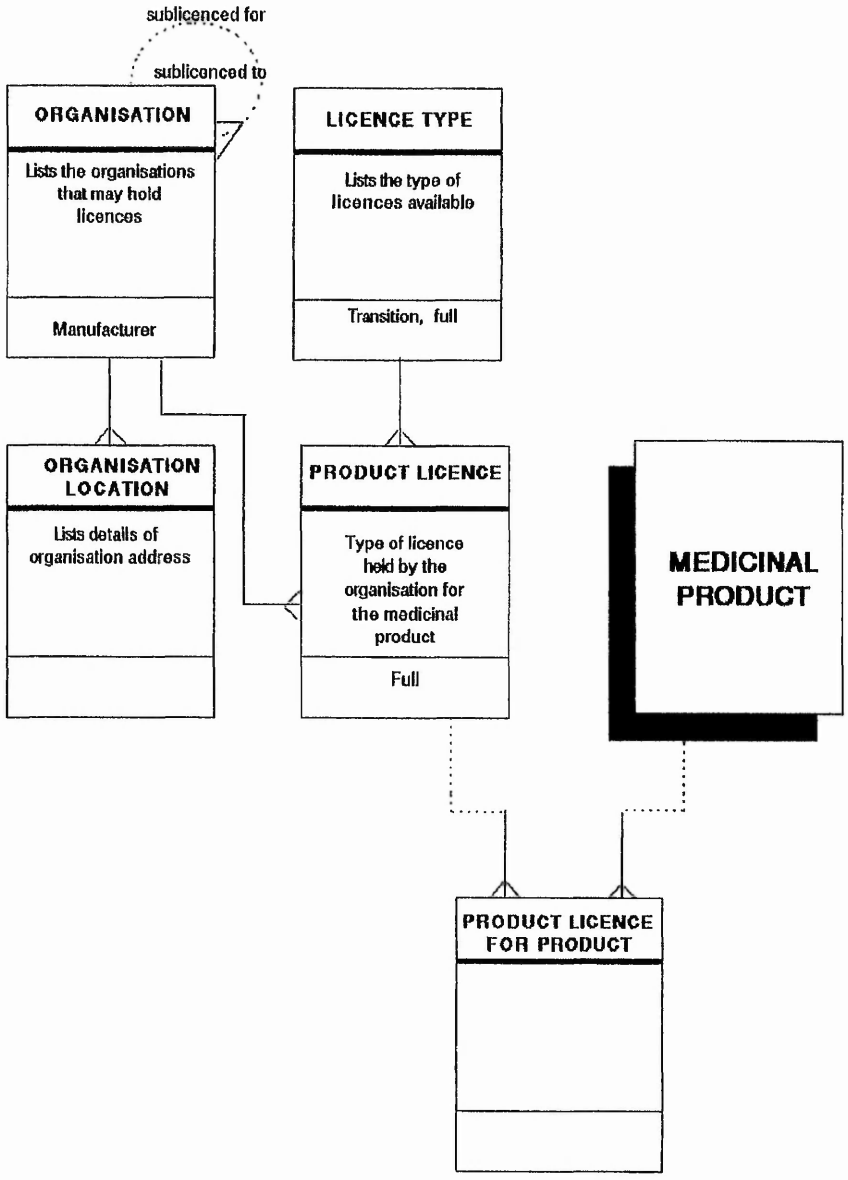


Fig. 3.20

The relationships of the entities affecting licencing to MEDICINAL PRODUCT.

trial, and the types of licence are listed in the entity LICENCE TYPE. A product licence can be held by only one organisation for a medicinal product, although they can license other manufacturers to produce or repack the medicinal product.

The recursive relationship on the entity ORGANISATION ensures that the activities of sublicensing the manufacture of products is included in the model.

A multi-ingredient product, e.g. Canesten Duopack, bears the product licence numbers of its constituents, i.e. Canesten cream 1% 0010/0016 and vaginal tablets 100mg 0010/0015, whilst Migraleve bears the product licence number 0232/5008R which is identical to that of its constituents, i.e Migraleve yellow and pink tablets. The entity PRODUCT LICENCE FOR PRODUCT gives these details.

The entity ORGANISATION LOCATION lists details of the organisation and their licences.

3.4.11 DATE OF PREPARATION OR LAST REVIEW

"DATE OF PREPARATION OF THE DATA SHEET OR, WHERE SINCE SUCH PREPARATION THERE HAS BEEN A REVIEW OR REVISION OF THE DATA SHEET, THE DATE OF THE LAST SUCH REVIEW OR REVISION."

This part of the Data Sheet Requirements is not modelled here as it forms no part of the structure of the entity type MEDICINAL PRODUCT.

3.5 DISCUSSION OF LEGAL MODEL

This completes the model from a Data Sheet requirement point of view and the model so far is illustrated in schematic form in Figure 3.21.

Examination of the schematic legal model showed that three entities namely FORM, PATIENTS CHARACTERISTIC TYPE and ROUTE OF ADMINISTRATION were found in more than one entity type. The models containing FORM, Figures 3.6 and 3.18, PATIENT CHARACTERISTIC TYPE, Figures 3.11 and 3.14, and ROUTE OF ADMINISTRATION, Figures 3.10 and 3.12, were inspected for redundant relationships: none were found and the models were not amended.

The model is in effect a "legal" description of a medicinal product. In order to be of practical benefit, there are several entities to be included and existing entities to be modified to include other essential information. Since the model is to be used for all aspects of medicinal product usage, it is essential they are included. Although they can be argued to be included under the further information section prescribed in the Data Sheet Regulations.

Importantly, the model does not contain a definition of a base unit. Without this entity, calculation on dosage, total dosage or stock control cannot be carried out.

These and several other entities will be modelled in the next section - non-legal requirements.

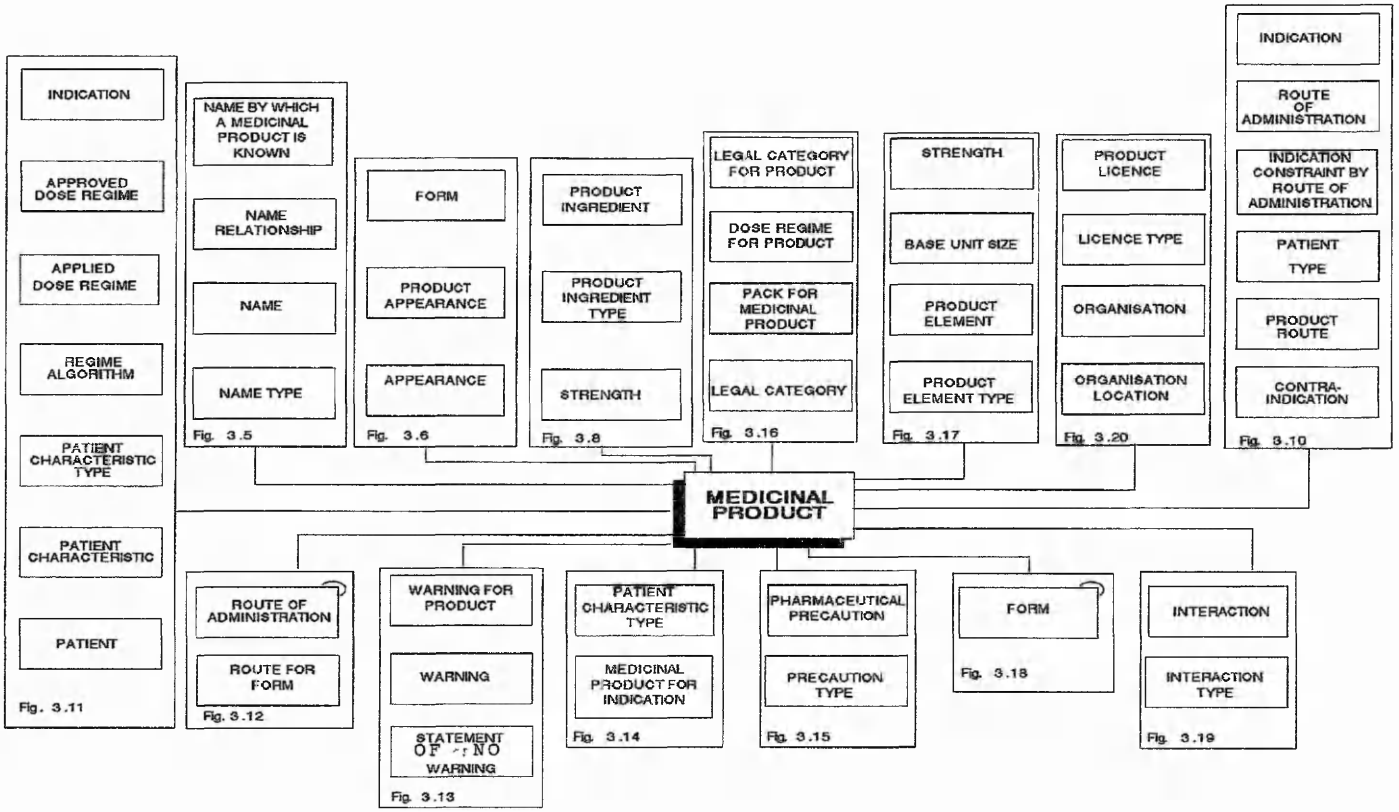


Fig. 3.21
Schematic model showing all the identified entities.

3.6 NON-LEGAL REQUIREMENTS

3.6.1 INTRODUCTION

It is intended to model here the non-legal requirements of a medicinal product that, although not required by law, may be required under practical circumstances. For example, a community pharmacist may need to know whether or not a product is prescribable on the NHS, i.e. whether it is on the blacklist, or is a borderline substance[1]. In other circumstances, special handling requirements may be required, e.g. cytotoxic preparations.

A prescriber may need information to support his prescribing, e.g. patients may require hydration before administration of cisplatin. This information would be covered by the "further information" section of the legal model.

A wholesale organisation may need information on pack sizes, storage, weights/volumes, stacking heights and transport.

To illustrate examples of non-legal requirements, the following entities, which are applicable to all products (base unit, product code, prescribable and non-prescribable products), are modelled.

3.6.2 BASE UNIT

It is essential to have an entity BASE UNIT, since this is the basis on which issue and costing quantities are calculated. Medicinal products may be powders, tablets, capsules, inhalers, ampoules etc. In such a diverse group, it is important to have a rule defining base units. A base unit is defined as the unit by which a medicinal product is

1. Black listed products are all proprietary products which cannot be prescribed either by brand name or generic on the NHS. or proprietary products that can only be dispensed at NHS expense in the form of a generic preparation. Borderline products are products. e.g. foods. toilet articles which may be prescribed only under certain specified conditions.

issued. The base unit will vary according to the environment in which the model is operating. For example, powders may be mg or g, tablets and capsules are supplied as tablets or capsules. Other products, e.g. inhalers, ampoules etc., even though they may contain powders because they are supplied as such, have base units of inhaler, ampoule etc. The deciding factor is that if they were broken down their integrity would be breached.

This is illustrated in model Figure 3.22.

3.6.3 PRODUCT CODE

Supplies may come from a manufacturer or supplier, each of whom will have their own product code, and/or product pack codes. The codes may be allocated by the manufacturer or supplier, or be allocated to a manufacturer or supplier in an unstructured form, e.g. EAN.

The manufacturer or supplier structures these codes to their requirements. The model has to accommodate these in such a way that they may be altered but do not affect, in any way, the body of the model. In this way, each "user" can use their own code to identify their products.

Figure 3.23 illustrates a model which supports such a system.

The entity ORGANISATION lists the organisation that maintains the code and must be involved with one or more of the codes contained with the entity PRODUCT CODE. The entity PRODUCT CODE must have the involvement of only one ORGANISATION.

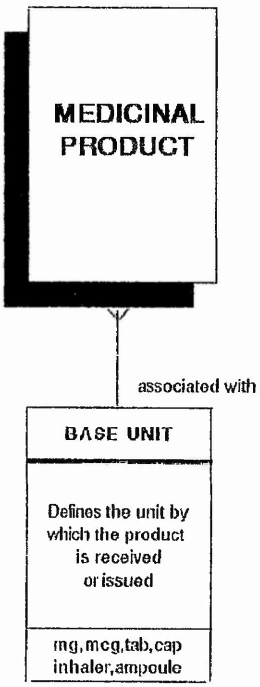


Fig. 3.22
The relationship of BASE UNIT to MEDICINAL PRODUCT.

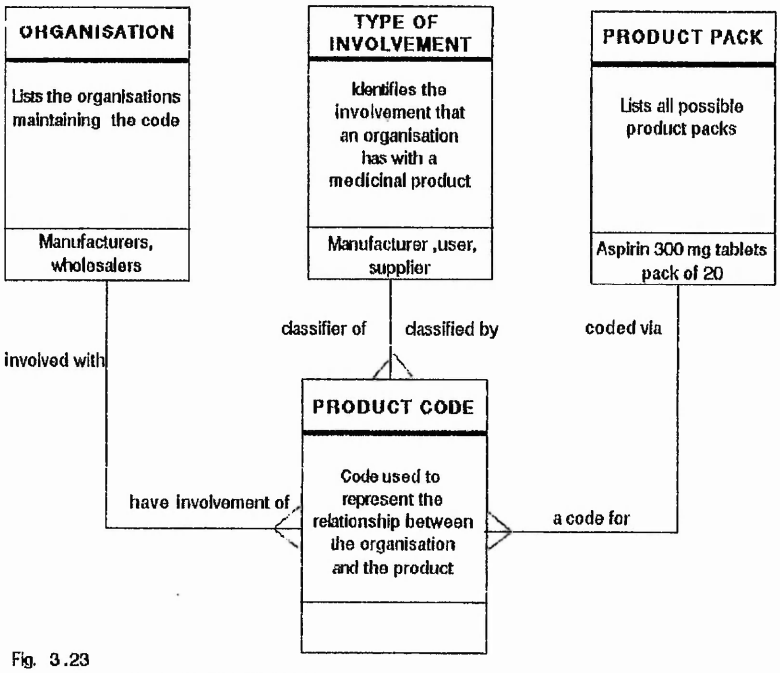


Fig. 3.23
The entities related to PRODUCT CODE.

For each occurrence of the entity PRODUCT CODE, there will be only one code for the entity PRODUCT PACK. Whilst the entity PRODUCT PACK may be coded by one or more of the entity PRODUCT CODE.

The entity TYPE OF INVOLVEMENT, which identifies the type of involvement an organisation has with a medicinal product, e.g. user, supplier or manufacturer, may be a classifier of one or many occurrences of the entities PRODUCT CODE, each of which will be classified by only one occurrence of TYPE OF INVOLVEMENT.

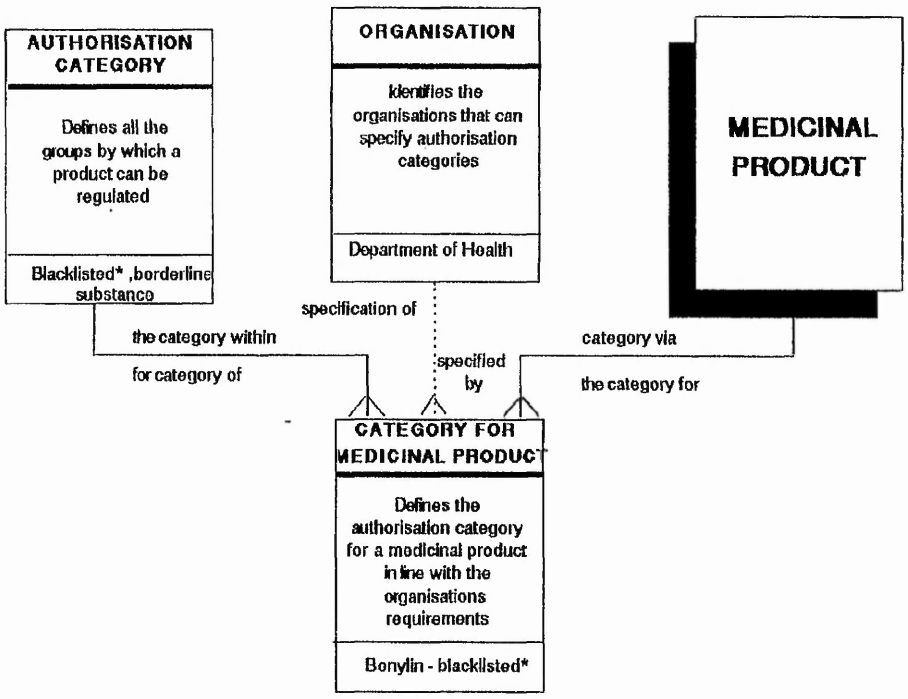
3.6.4 PRESCRIBABLE AND NON-PRESCRIBABLE PRODUCTS

From a community pharmacist's point of view, many products may be prescribed for the treatment of patients. However, only certain products may be prescribed under the NHS regulations. Certain products may be prohibited under the blacklisting regulations, MIMS, (1993) or may be prescribed only under certain conditions, e.g. borderline substances, Law on Medicines, (1986).

Figure 3.24 illustrates a model supporting such a system.

The entity AUTHORISATION CATEGORY defines all the groups by which a product may be regulated, e.g. blacklisted. For each occurrence of the entity AUTHORISATION CATEGORY there may be one or more occurrence of the entity CATEGORY FOR MEDICINAL PRODUCT. For each occurrence of this entity it will specify the category for a specific MEDICINAL PRODUCT.

The entity ORGANISATION may determine the specification of one or more of the entities CATEGORY FOR MEDICINAL PRODUCT.



* Proprietary products which are blacklisted and which cannot be prescribed either by brand name or generic name on the NHS.,or proprietary products which have been blacklisted and which can only be dispensed at NHS expense in the form of a generic preparation.

Fig 3.24 The relationships associated with authority to supply a medicinal product.

3.7 DISCUSSION

This completes the model from a non-legal point of view.

It now includes entities that affect manufacturer, wholesaler and suppliers and enables them to carry out their business. But more importantly, they can be used to produce a classification of medicinal products by using any of the identified entities or combinations thereof.

The method can also be used to produce a coding system; any portion of which can be used according to the needs of the user but could be understood by all users.

4. DEVELOPMENT OF UNIQUE MEDICINAL PRODUCT IDENTIFICATION CODE

When medicinal products are manufactured, sold, prescribed or dispensed, knowledge about the product needs to be transferred from one party to another. The knowledge may be product identification, appearance, strength, ingredient etc. The information transferred depends upon the need of the parties, e.g. a clinician will need to know a product's name, strength etc. Thus a coding system for medicinal products must be sufficiently comprehensive to accommodate the needs of all parties. It must, therefore, provide a unique identifier for each medicinal product but must be constructed in such a way that its components, when used separately, provide information for all the potential users according to their needs.

Currently, unique identification is achieved by descriptive text and/or by a reference code known to both parties. In addition, extra supporting text is always required. The ideal solution to this is some form of data transfer, accepted and understood by the relevant parties, that passes with the product. (Kneale, 1989; Sprince, 1990; Pharmaceutical Journal, 1990(a); Worling, 1990; Sesame, 1990b).

The code should, if used in its entirety, be able to identify all the characteristics of a medicinal product and its interactions with non-medicinal products. It should also be possible to use sections of the code to perform specific activities, e.g. calculate dose, or identify product characteristics.

Any code should be user friendly, flexible, easily convertible for computer usage and comprehensive. Its flexibility should be such that

it has nodes by which other branches or additions can be added in the future to ensure its usefulness and continuity.

Its components should be short enough to enable them to be used with the minimum of rules and in line with current medical, nursing, pharmaceutical, wholesaling and manufacturing practice.

This part of the project is to determine whether or not a medicinal product can be uniquely identified from product modelling principles and, if so, to model and validate a suitable coding system.

4.1 DEVELOPMENT OF CODE

The following is an account of the way in which a unique product identification code was modelled, populated, critically evaluated and modified. The resultant model was compared with the theoretical legal model already devised, in order to:

1 ensure completeness, and

2 ensure the theoretical model is robust enough to act as a complete medicinal product model.

4.2 OVERVIEW

The sequence and outline method of determining the code is illustrated in Figure 4.1.

4.2.1 Phase 1

In the light of experience gained over a period of five years, a single model and an algorithm to enable the generation of a code were produced and tested on a live pharmaceutical system. Codes for 3049 products

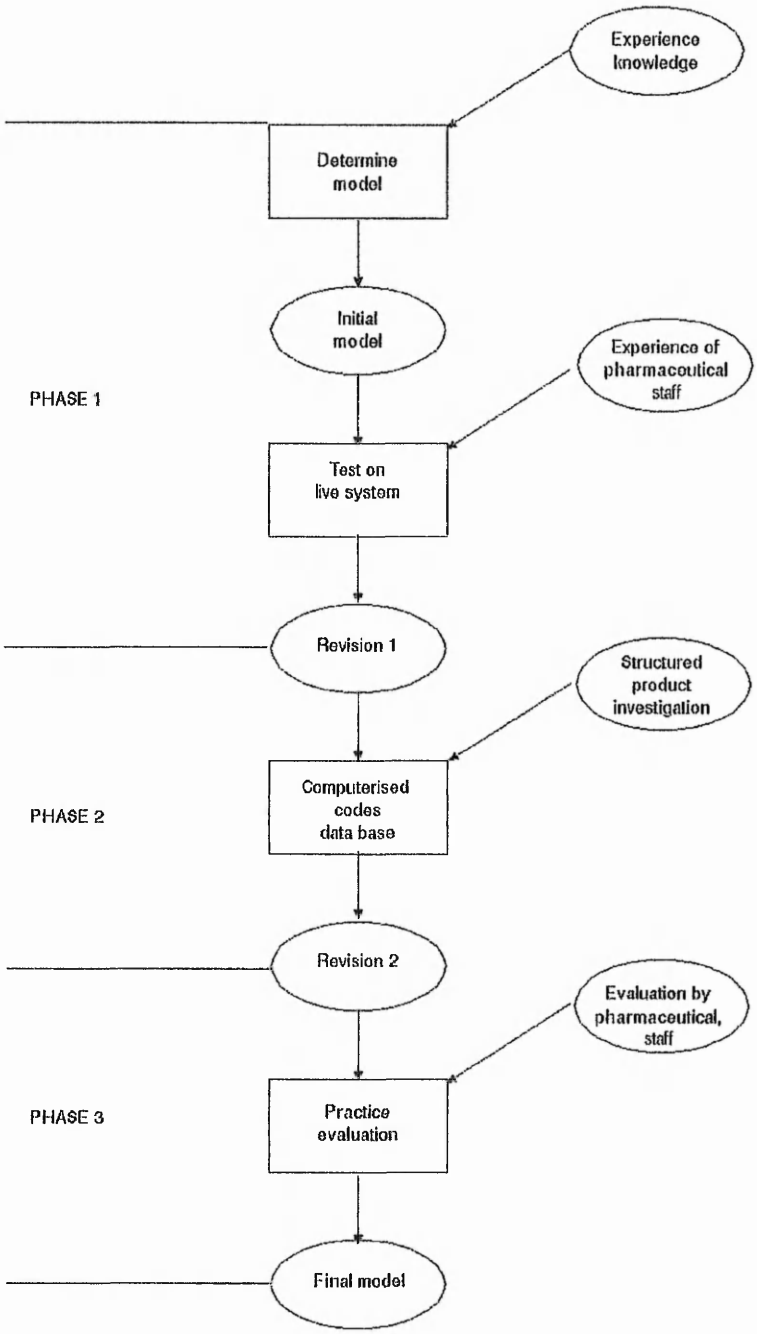


Fig. 4.1

The phases of this part of the project

were evaluated by pharmaceutical staff by using them for issue, ordering and reporting. The results were obtained by several methods: experience of personal inputting by the author, analysis of inputted codes, comment by staff members, inspection of orders forwarded to manufacturers, financial reports and drug usage reports. Results from this phase were analysed and the model, code and algorithm modified and entered into phase 2 of the study.

4.2.2 Phase 2

The modified codes were entered onto a computerised database that had been designed to prevent duplication of codes and accommodate the extra entities determined from phase 1. The results from this phase were analysed and further modifications to the model, codes and algorithm were made. This phase was repeated until all the products within the pharmacy were coded and accounted for within the model and algorithm.

4.2.3 Phase 3

Following phase 2, the modified product codes were entered onto a system database, designed to facilitate ordering, issuing, prescribing and administration and then evaluated in practice by pharmaceutical staff in the pharmaceutical environment.

At the completion of each phase, the practical model was critically compared with the theoretical legal model and the preceding practical models.

4.3 REASONING AND METHODOLOGY

In order to ensure ease of use, it was reasoned that the code components had to contain as few characters as possible and yet provide

an accurate identification of the medicinal product, while at the same time providing a user-friendly interface. However, it was evident that some rules, i.e. algorithms, would be necessary to ensure a structured approach, especially for personnel constructing the codes.

4.4 PHASE 1

The model, Figure 4.2, was postulated on the basis that a medicinal product could probably be coded uniquely by virtue of its name, its size or strength and its form. As few entities as possible were used on the basis that if coding could be carried out at a high level then the code would be simple in its form. If on investigation this proved not to be so then extra levels could be added as they proved necessary.

Comparison with the theoretical legal model, developed earlier, shows that this model is a composite drawn from the theoretical legal models in NAME, FORM and APPEARANCE (Figures 4.3 and 4.4). This would be expected as any unique code would have to embrace many and varied product characteristics, not simply those contained within a particular entity type.

The additional entities STRENGTH and SIZE need to be included because of the postulation that a medicinal product could probably be uniquely coded using its name, strength or size and form.

In order to test the model the following potential code system was evaluated, based on the model illustrated in Figure 4.2, in which each occurrence of MEDICINAL PRODUCT will only have one strength or size applicable to it, and one associated form.

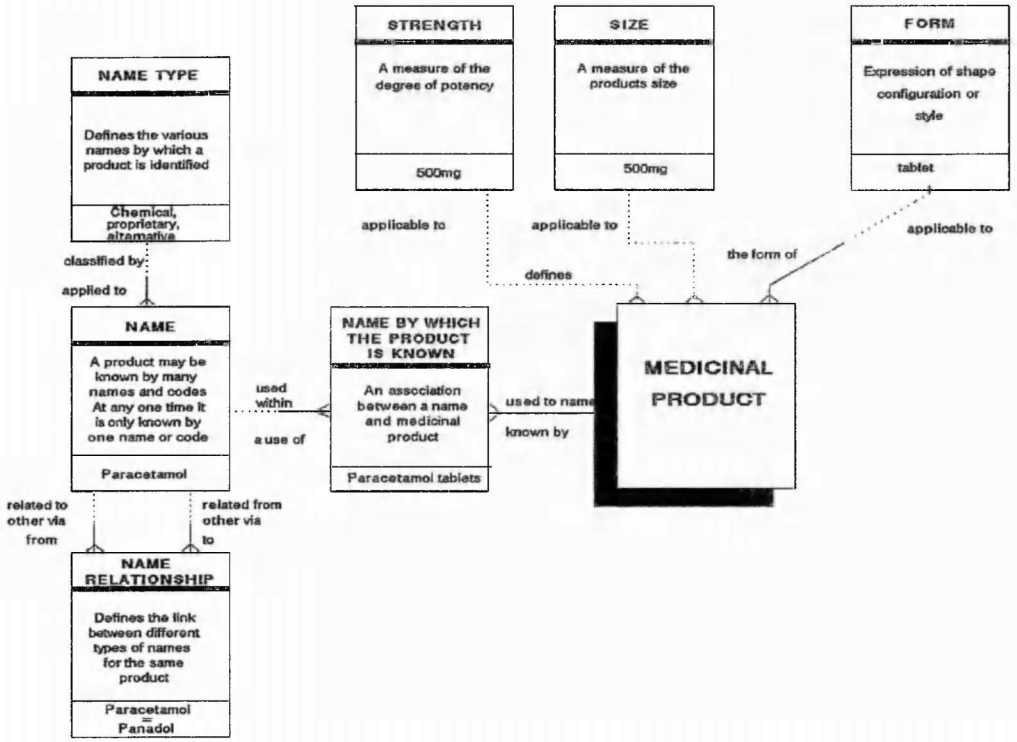


Fig. 4.2

The relationships between NAME,STRENGTH and FORM to MEDICINAL PRODUCT

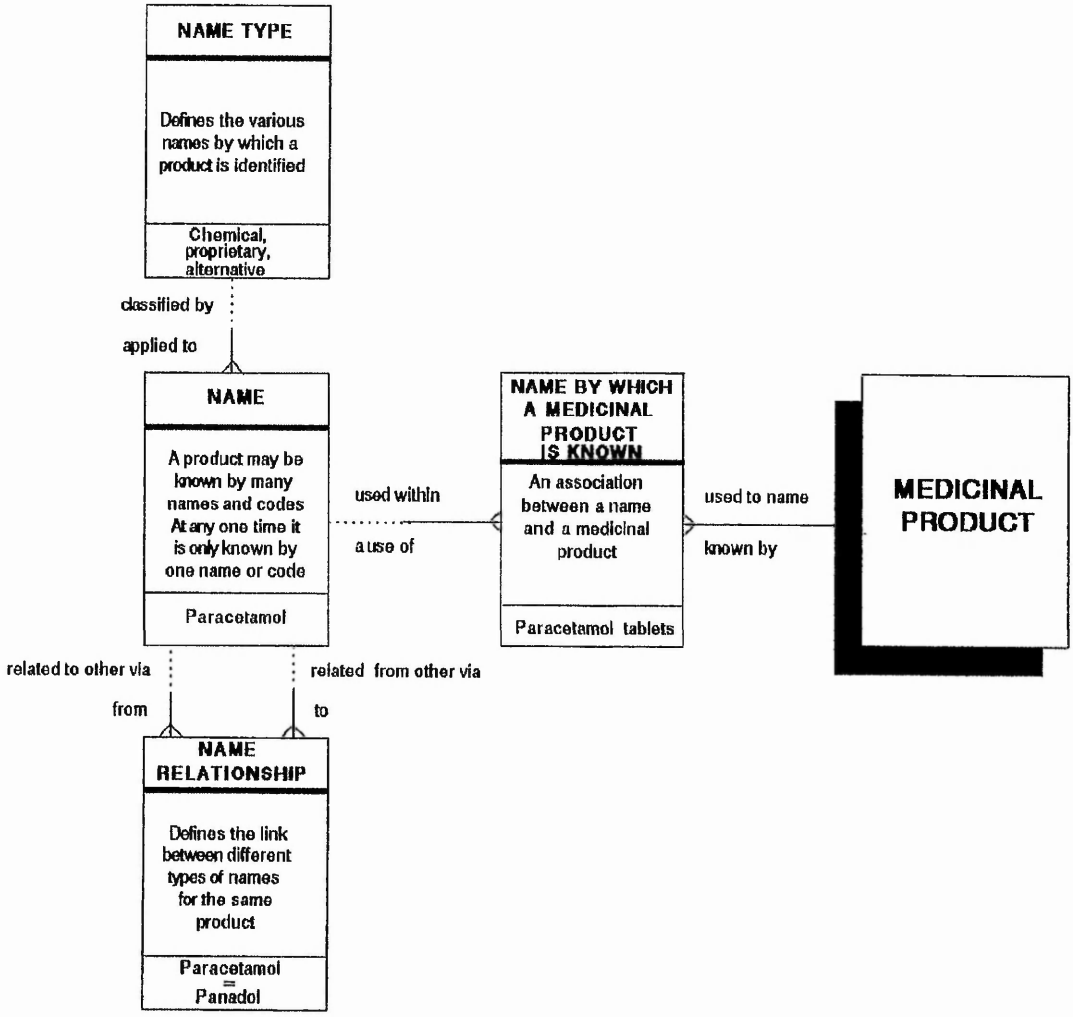


Fig. 4.3
The relationships of the entity NAME and MEDICINAL PRODUCT - legal model 3 5

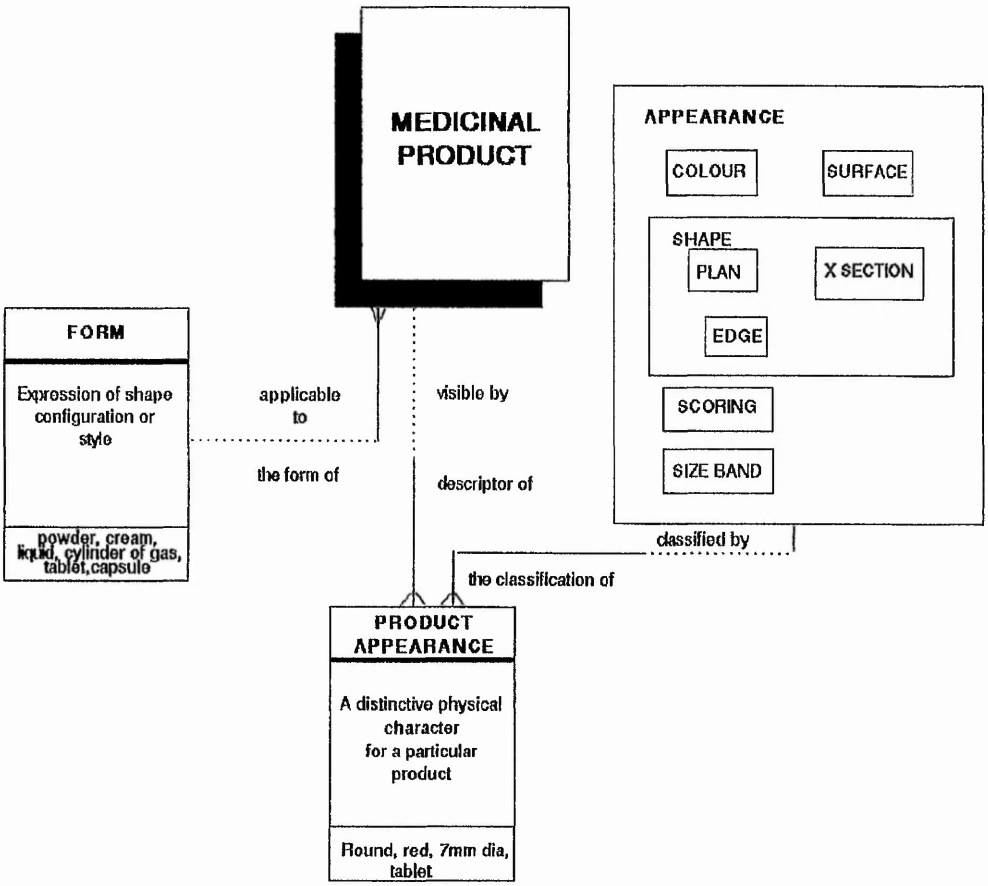


Fig. 4.4
The relationships of the entities FORM and APPEARANCE to MEDICINAL PRODUCT - legal model 3.6

Using the following model, the code was evaluated. The number of characters in the code was constrained by the nine characters available on the computer code field.

Table 4.1 illustrates the possible method of coding a medicinal product using nine characters, NAME being accommodated by 4 alpha characters, STRENGTH AND SIZE by 4 numeric characters and FORM by 1 alpha character, as illustrated in Table 4.1.

PRODUCT	STRENGTH/SIZE	FORM
AAAA	NNNN	A

A = ALPHA CHARACTERS
N = NUMERIC CHARACTERS

Table 4.1 - The possible coding method.

4.4.1 ALGORITHM

Figure 4.5 illustrates the algorithm used in phase 1, which consists of four sections. The objective of the algorithm is to provide a unique product code, combining name, strength or size and form characters.

The algorithm was designed to provide a different step to produce a unique code for the product, if the first pass did not produce a unique code.

4.4.1.1 Name Field

At this point it is important to distinguish between the unique identity of a name and the unique identification of a product by a unique product code. In this part of the research, which is concerned with the unique identification of a product, it does not matter if the

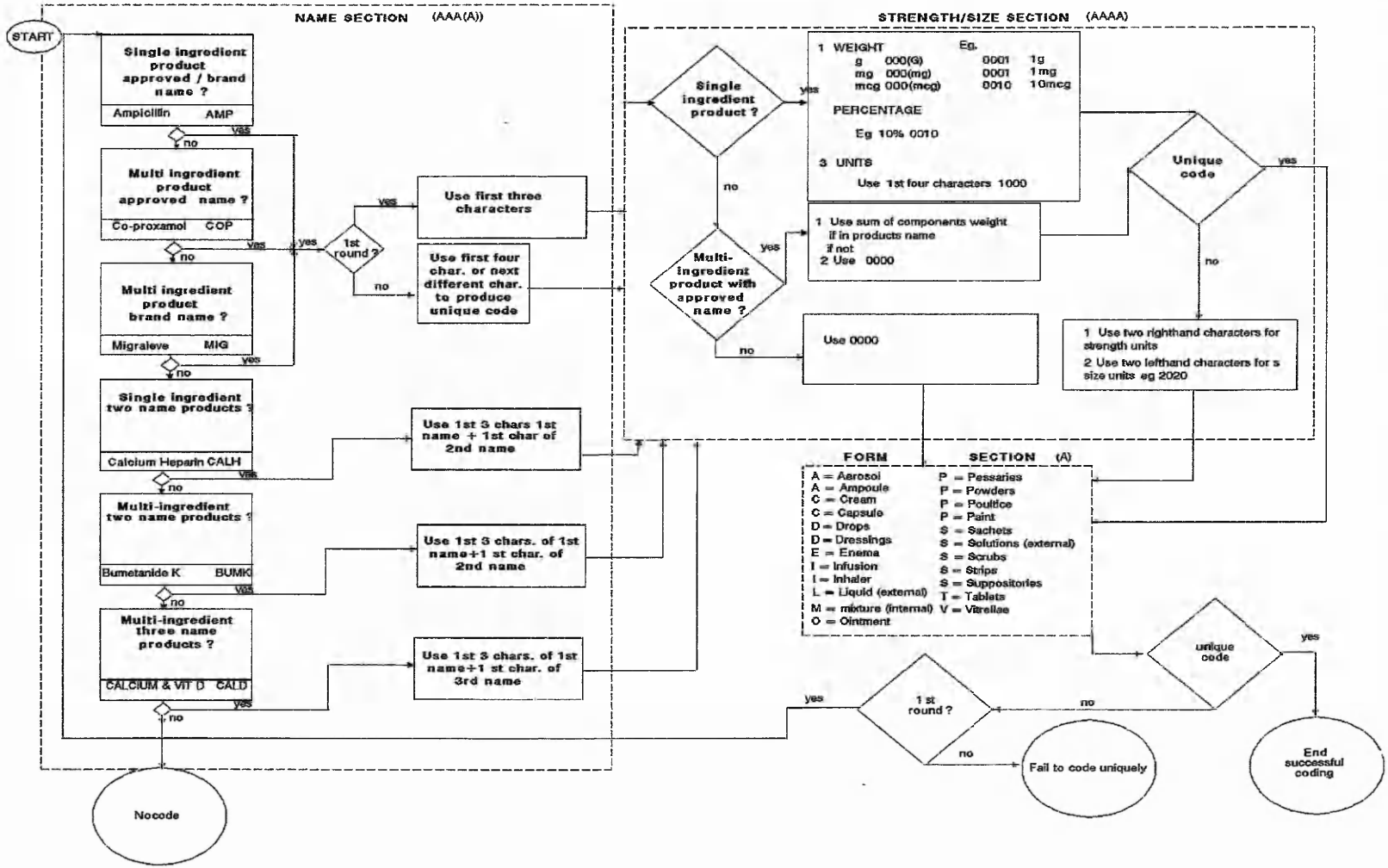


Fig. 4.5
The algorithm at the beginning of Phase 1

product cannot be uniquely identified by the name alone, since the characters used are combined with others to form a unique identifying code. Unique product identification is necessary for prescribing and dosage uses.

Since the code had to be simple in its nature, it was reasoned that by using as few characters as possible to produce the name portion of the code, a simple user-friendly code would be produced. It was, therefore, reasoned to begin the process by using three characters with an option, if necessary, to use a fourth by re-entering the algorithm if a unique combination was not found in the first pass.

Methods of determining the characters to be used for the differing types of names encountered in pharmacy are included within the algorithms. The abbreviated name characters are taken from the name by which a product is known, in preferential order of approved and proprietary names.

4.4.1.2 Strength

A protocol was drawn up within the algorithm, taking into account the various ways in which a product's strength can be identified.

The strength of products may be indicated by weight (e.g. g, mg, mcg) in a unit (e.g. tablet, capsule) or in volume or percentage terms.

This was accommodated within the weight section of the algorithm. The weight units are right justified. Products having their strengths indicated in percentage terms were accommodated in a similar way to weight.

Since only four characters are available for the strength field, it was reasoned that for products having strengths >9999 only the numeric characters having any relevance would be accommodated within the code in this section, i.e. 750,000 units would be truncated to the leading four digits.

Some multi-ingredient products with approved names have, by convention, the sum of their components included in their names, e.g. Co-trimoxazole 480. If this is the case, they were included within the strength section, in this case 0480. Other multi-ingredient products do not have their strength included in their names, e.g. Co-proxamol, in this case 0000 is used.

4.4.1.3 Size

Some products do not have a strength associated with them, e.g. Water for Injections. They do, however, have an associated size, e.g. 2 ml, 5 ml or 10 ml. In this case it was reasoned that they could be incorporated within the numeric characters to form part of the unique code, e.g. 0200, in a similar manner to weight and percentage.

It was reasoned that a combination of strength and size together may form part of a unique code, if strength and size used separately did not produce a unique identifier. In some cases different sizes are associated with single strengths, e.g. 2% 2 ml, 2% 5 ml, and in this case the entry 0202 and 0502 would accommodate these products to help provide a unique code.

4.4.1.4 Form

Medicinal products have a form, e.g. tablet, capsule etc. In order to

identify and distinguish products by using the numeric code for strength/size, it was reasoned that the addition to the code of a field for form with a single alpha character would possibly provide a unique identifier. The combination of the strength/size (numeric) and the form (alpha) fields are unlikely to have the same characters for example for creams and capsules.

Examples are: AMP 0250C = Ampicillin 250 Capsule

AMP 0250A = Ampicillin 250 Ampoule

4.4.2 OVERLAY OF ALGORITHM ON MODEL

Figure 4.6 shows how the hypothetical code overlays the theoretical model, Figure 4.2.

4.4.3 TESTING

Over three thousand medicinal products of all types were used to populate the code using the algorithms. They were entered into the hospital pharmacy computer database as the unique product identifier. The resulting printouts and reports were inspected for compliance with the algorithm. The addition of new products to the data base was monitored to confirm whether the code could be completed in line with the algorithm. In both cases, notes were made of non-compliance, which are reported in the results and analysis section.

The results were gathered over two years by reference to inspection of reports, issues, orders, and staff comment.

4.4.4 RESULTS AND ANALYSIS

Examination of printouts showed that it was possible on the first pass, by using three name characters together with four strength or size

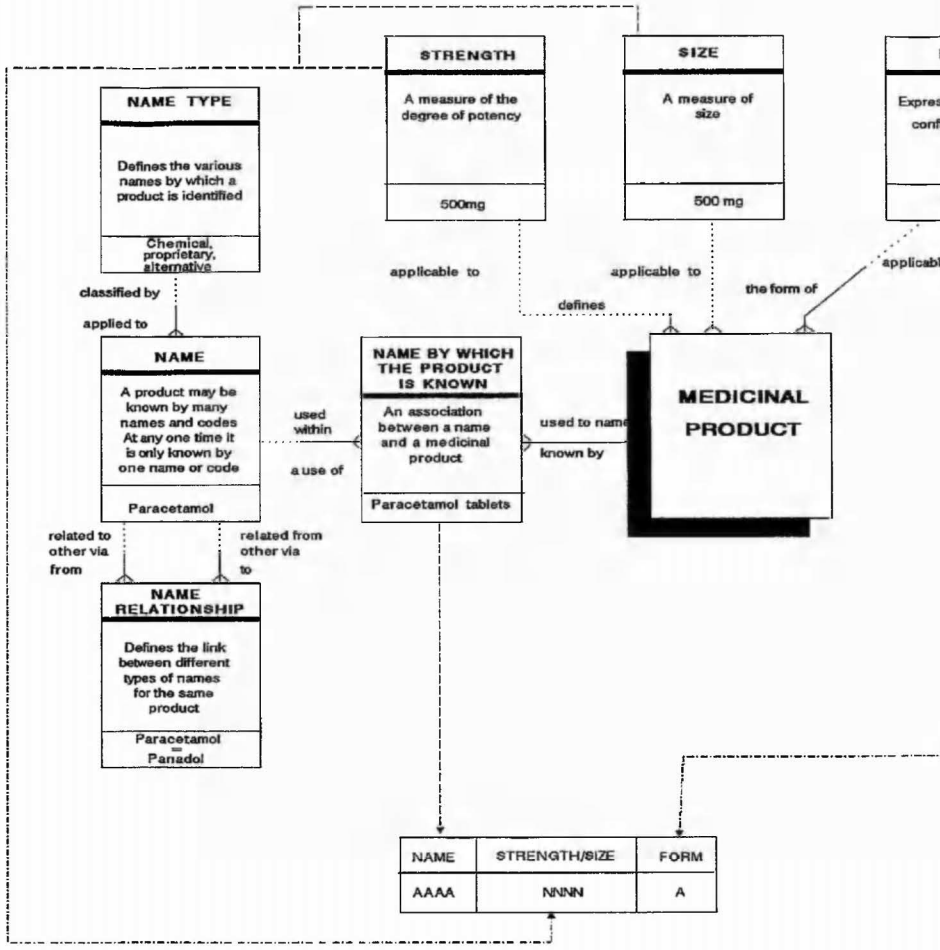


Fig. 4.6
The overlay of the code on the phase 1 model

characters and one form character, to uniquely identify 2033 products out of a total of 3049 (66.67%). These comprised mainly tablets, capsules and ampoules produced only in one strength and size.

On the second pass, a further 653 (21%) products could be uniquely identified using a fourth name character. These consisted of products with common beginnings to their names, e.g. CHLO.

A further 221 (7.24%) products could be uniquely identified by the use of three name characters and a combination of strength and size according to the algorithm. A further 142 (4.6%) products could be identified by four name characters and a combination of strength and size. These were injectables of varying sizes, e.g. lignocaine 1%, 2ml and 5 ml ampoules.

Thus by using this method, 2849 (93.4%) products could be identified, leaving 200 products to be fitted into the coding system.

An examination of the codes showed the following examples, which are illustrated in Table 4.2.

CODE	PRODUCT	STRENGTH CHARACTERS	SIZE CHARACTERS
PAR0500T	Paracetamol tablet	500	
GLU0505A	Glucose ampoule	5	5
DIT0001C	Dithranol cream	1	
WAT0002A	Water ampoule for Injections		2

Table 4.2 - The effects of coding in Phase 1.

For products produced in only one strength or size, the method produces a unique code, e.g. paracetamol tablets 500 = PAR0500T, water ampoules 2 ml = WAT002A. Although, in these cases, the addition of units are necessary to conveniently identify the product at this stage, i.e. mg or ml etc.

When a product is produced in one strength but many sizes (base unit sizes), this method of coding was not able to cope with many sizes of products and strengths, e.g. Glucose 5% 10 ml = GLU0105A and Glucose 5% 100ml = GLU1005A. This is, however, due to the few strength/sizes of products and strengths. However, Glucose 5% 1000 ml = GLU1005A is still a problem as it is the same code as for glucose 5% 100ml. It was in this area that the staff found problems and adopted unstructured and unofficial codes. For accurate identification, reference had to be made to a product description.

The use of the strength characters in this method does not facilitate the identification of decimal points, e.g. DIT0001C represents Dithranol cream 0.1% and the same code could be used for Dithranol cream 1%.

Another very important failing of this coding method is that since the numeric field consists of a mixture of strength and sizes it would not be possible to perform calculations on this field without appropriate look-up tables for dose purposes. In addition, the field is not large enough to accommodate large or small strengths, which are common in medicinal products, i.e. >9999 or <0001.

Using only one character in the form field has its limitations since

the characters available to represent form are not unique within the series. For example, the form represented by C could also be construed to read not cream but capsule. However, both the form and strength characters only matter if fields of the code are to be used to identify product forms in some process, e.g. prescribing.

Using this method of coding it was not possible to include certain medicinal products, which, although containing the same active ingredients, are modified to release their ingredients in a specific manner, e.g. long acting, chewable or soluble tablets or long acting capsules. It was therefore necessary to identify these products and their modifications in order to provide unique identification of each product. This is illustrated in Table 4.3.

NAME	NAME CHARACTERS	STRENGTH/ SIZE	FORM	FORM DETAIL
PREDNISOLONE	PRE	0005	T	
PREDNISOLONE	PRE	0005	T	ENTERIC COATED
PREDNISOLONE	PRE	0005	T	SOLUBLE

Table 4.3 - The effect on the entity FORM DETAIL.

Table 4.3 shows that the entity FORM DETAIL is necessary to separate products that have identical name characters, strength/size and form.

The computer system, which was designed not to allow code duplication, would not allow Prednisolone 5 mg enteric coated and Prednisolone 5 mg soluble to be entered without modification to the alpha codes. In practice the alpha characters were modified to PREE and PRES respectively. Whilst this was used as a "stop gap", it would have

prevented identification if four characters were required for identification.

The foregoing illustrated the results and failings within the initial coding hypothesis. However, a study of the individual code components is necessary to determine any necessary modifications and the validity of the algorithms in producing the code.

The results showed that more than 66% of products could be coded using three alpha characters and by using the fourth alpha character a further 21% could be coded.

However, using the algorithm, Figure 4.5, there were several failings. Throughout the exercise, approved names were used preferentially, where they were available. Dependent upon the order in which the products were coded, products with similar names and numeric characters are mixed, thus preventing accurate sorting into products by code. For example, CHL may be chlorpromazine, chlorpropamide, chlordiazepoxide. Even when the fourth character is used the problem is still apparent.

Paracetamol could be easily identified but problems were apparent with such products as Erythromycin Estolate and Erythromycin Stearate, which have different indications but similar forms and strengths, and must therefore be accurately identified.

Multi-ingredient products with brand names, e.g. Mucaine and Migraleve, were accommodated within the rules. There were many multi-ingredient products having no approved names but with brand names which consisted of alphanumeric characters, e.g. Glucoplex 1000, Eugynon 50 and Eugynon

30. These could not be accommodated within the rules.

Products with approved names consisting of words and figures that represented the strength of the product's ingredients, e.g. Co-careldopa 10/100 (Carbidopa 10mg, Levodopa 100mg), could not be accommodated either.

There was confusion over the definition of a "single ingredient product" and a "single ingredient product with a two-part name". It was originally considered that sodium chloride was a "single ingredient product" and Heparin Calcium a "single ingredient two name product". However, it was reasoned that since both were salts of sodium and calcium respectively, products of this type should be classified as "single ingredient products" following the name order in which the product was listed in the British National Formulary (BNF).

Following this principle, it was reasoned that where components were chemically distinct then they would be classed as "multi-ingredient two or three name products".

"Multi-ingredient three name products" proved impracticable to apply the rule of the first three characters of the first name and the first character of the third name since there was no indication of the second product's name. The code would cause confusion with a two ingredient product that had ingredients in common with the multi-ingredient one, e.g. SODK = Sodium Chloride and Potassium also SODK = Sodium Chloride, Glucose and Potassium.

Finally, a method had to be found for identifying modified products.

4.4.5 MODIFICATIONS TO CODING

In the light of the above findings, it was necessary, before proceeding to phase 2, to modify the method of coding, Table 4.1, and its associated model and algorithm, Figures 4.2 and 4.5. The modifications, which will be discussed, are summarised in Table 4.4, Figure 4.7 and Figure 4.8.

Modifications were necessary since the results showed that a combination of strength and size could not be used for any useful purpose. The combination also caused confusion in the coding stage of products. The entity BASE UNIT is, therefore, added for completeness and the entity STRENGTH is adapted to accommodate values outside the range of 1 to 9999.

i) The entity BASE UNIT was added to the model and the entity SIZE replaced by BASE UNIT SIZE. BASE UNIT is defined as the unit in which the product is usually received or issued, e.g. ampoule or cylinder of gas. BASE UNIT when associated with BASE UNIT SIZE provide the relationship necessary to define the characteristics of an issued product, e.g. Lignocaine 1% 2 ml and 5 ml, ampoules.

BASE UNIT in many cases will have the same identifiers as FORM, e.g. ampoule, tablet, capsule. However, this will not always be the case, e.g. FORM - gas, BASE UNIT - cylinder.

The entity BASE UNIT may not have an applicable relationship to FORM in all cases, e.g. FORM Powder has no base unit only a BASE UNIT SIZE, e.g. mg.

PRODUCT	STRENGTH			FORM	ROUTE FOR FORM	FORM DETAIL	BASE UNIT	BASE UNIT SIZE
	MAGNITUDE	MULTIPLIER	UNITS					
AAAA	NNNN	N	AAAAA	A	A	A	AAA	NNN

TABLE 4.4
The code at the end of phase 1 and beginning of phase 2

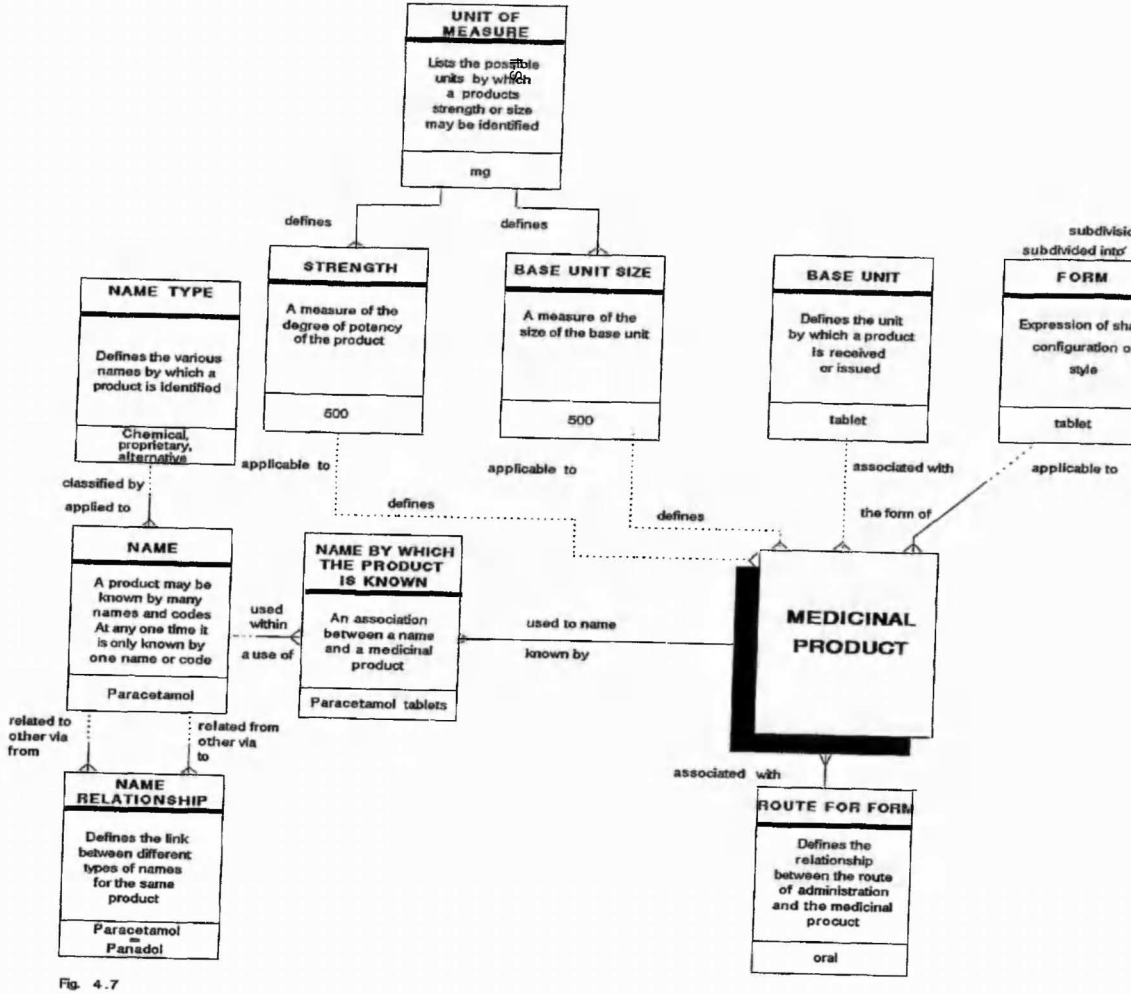


Fig. 4.7

The model at the start of phase 2

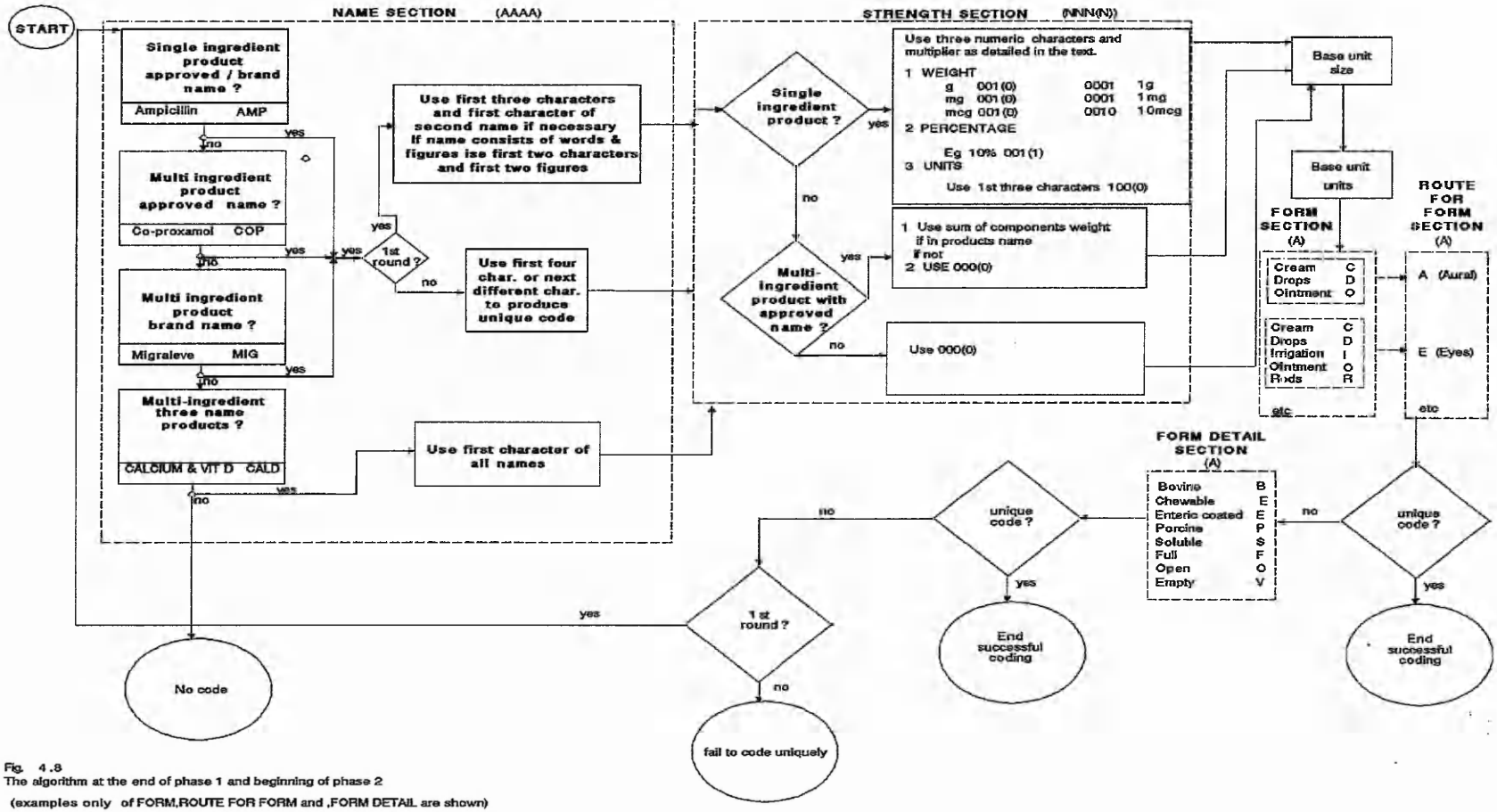


Fig. 4.8
The algorithm at the end of phase 1 and beginning of phase 2
(examples only of FORM,ROUTE FOR FORM and ,FORM DETAIL are shown)

BASE UNIT SIZE is qualified by the entity UNIT OF MEASURE.

ii) The entity STRENGTH is modified by the entity UNIT OF MEASURE. It was reasoned necessary to accurately identify identical products that may be known by more than one strength notation, e.g. % and mmols, units and mg.

Examples of this are tablets, which will not have a size relationship, unlike some ampoules, which will have a strength and size relationship, e.g. Lignocaine 1% in 2ml or 5ml ampoules. Ampoules of Water for Injections will only have a size relationship.

iii) In order to represent decimal points and to accommodate large or small strengths within the strength characters of the code, the following system was adopted.

A field width of four characters is retained but it is organised in such a way that the strength is stored in scientific notation, i.e. a mantissa and exponent. The first three characters are used to provide the mantissa as an integer between 1 and 999 with the fourth providing the exponent. This by itself now allows for representation of numbers greater than 9999 but not for those less than 1 nor those to three significant figures with a decimal point, e.g. 1.25.

This latter requirement can be achieved by the simple device of using the fourth field as a code rather than directly as the value of the exponent. The code is based on a principle used in binary arithmetic known as the "twos-complement", in which positive and negative numbers can both be represented by a positive number.

Using this principle, the exponent can be represented with a code base of 10. As only one digit is available 0 and 10 are both represented by 0. In other words only the value of the least significant figure is visible.

For positive exponents, the value is added to 10, so 1 could be coded as 11, but since only the least significant digit is visible it appears as 1 while 2 appears as 2 etc. For negative numbers, the value is also added to 10. Of course adding a negative number is equivalent to a subtraction, so -1 codes as 9, -2 as 8 etc. However, since only 1 digit is available, confusion could easily occur if there were no rules limiting the range of values that can be coded for. For example, does the code of value 5 represent an exponent value of 5 or -5? For the purpose of coding for medicinal products, an upper limit of 5 and a minimum of -4 is put on the exponent. This is illustrated in Table 4.5.

For strengths greater than 1:

CODE COMPONENTS			
ACTUAL CODE	STRENGTH CHARACTER	EXPONENT = x 10^n	ACTUAL STRENGTH
0010	001	0 = 10^0	1 or 1
0011	001	1 = 10^1	1 x 10^1 or 10
0012	001	2 = 10^2	1 x 10^2 or 100
0013	001	3 = 10^3	1 x 10^3 or 1,000
0014	001	4 = 10^4	1 x 10^4 or 10,000
0015	001	5 = 10^5	1 x 10^5 or 100,000

For strengths less than 1:

CODE COMPONENT			
ACTUAL CODE	STRENGTH CHARACTER	EXPONENT = x $10^{(n-10)}$	ACTUAL STRENGTH
0016	001	6 = 10^{-4}	1 x 10^{-4} or 0.0001
0017	001	7 = 10^{-3}	1 x 10^{-3} or 0.001
0018	001	8 = 10^{-2}	1 x 10^{-2} or 0.01
0019	001	9 = 10^{-1}	1 x 10^{-1} or 0.1

Table 4.5 - The effects of mantissa and exponents for coding of strength.

Extremely large or small strengths could be accommodated if a series of numeric characters were used for strengths greater than 1 and alpha characters for strengths less than 1. This would have the advantage that the range of the multiplier field could be extended without disruption.

However, if present practice is an indication, it is likely that the terms micro, mega, will be used. Therefore a very large series may not be necessary.

This method also gives flexibility, enabling strength characters to be used as an identification component in several ways, e.g. 001(0) = 1, 010(9) = 1.

Thus the strength characters still form part of a user-friendly code that now accommodates large or small strengths. This is particularly important with genetically engineered drugs or in homeopathy where it is likely to be necessary to accommodate lots of characters.

iv) In order to allow the continued use of a common code for two differing forms, e.g. C for cream and capsule, it was reasoned that this entity could be further qualified by the addition of the entity ROUTE FOR FORM, since medicinal products may have many routes by which they can be administered.

For example, tablets and capsules are usually administered by the oral route, thus the characters for FORM C and ROUTE FOR FORM O would indicate capsules oral and the characters FORM C and ROUTE FOR FORM T would indicate cream topical. Thus the characters used in FORM and ROUTE FOR FORM should produce a unique combination excluding unacceptable combinations, yet still allow user-friendly application. Acceptable characters for ROUTE FOR FORM are listed in the modified algorithm, Figure 4.7 and Table 4.6. It is the entity ROUTE FOR FORM that will allow prescribing to take place as it is usually carried out in the following sequence, e.g. Ampicillin 250 mg oral. By including ROUTE FOR FORM all products containing Ampicillin available for oral use will then be listed, i.e. capsules, syrups and drops.

This method also allows products with the same form to be used in other

ways, e.g. FORM C, ROUTE FOR FORM I would equate to capsules for inhalation, e.g. Sodium cromoglycate capsules.

So that the form of products can be identified, it is necessary that the characters representing FORM, e.g. C, T and A, are unique within ROUTE FOR FORM, Table 4.6.

Included in this section are some products, which strictly do not have a ROUTE FOR FORM but are stocked in pharmacies. These products, e.g. Sodium Chloride are used to prepare other products that have a ROUTE FOR FORM, or are used for diagnostic purposes, e.g. Dextrostix. These products need to be identified and as part of this research are included under the ROUTE FOR FORM in groups M (Manufacturing) and D (Diagnostic).

It is this entity, which together with FORM, produces a more focused identification of the product by reducing the possible number of duplications.

v) In order to identify modified products which could not be identified by name, strength/size and form alone, the field "Form Detail" has been added to the code. It was reasoned that, since the physical form of a modified product is the same as that of its unmodified form, an appropriate relationship would be a recursive one, as shown in Figure 4.7.

This field also accommodates products that are modified during use, e.g. gas cylinders or containers, (i.e. returnable containers). It is considered that when a cylinder or container is issued, it will be

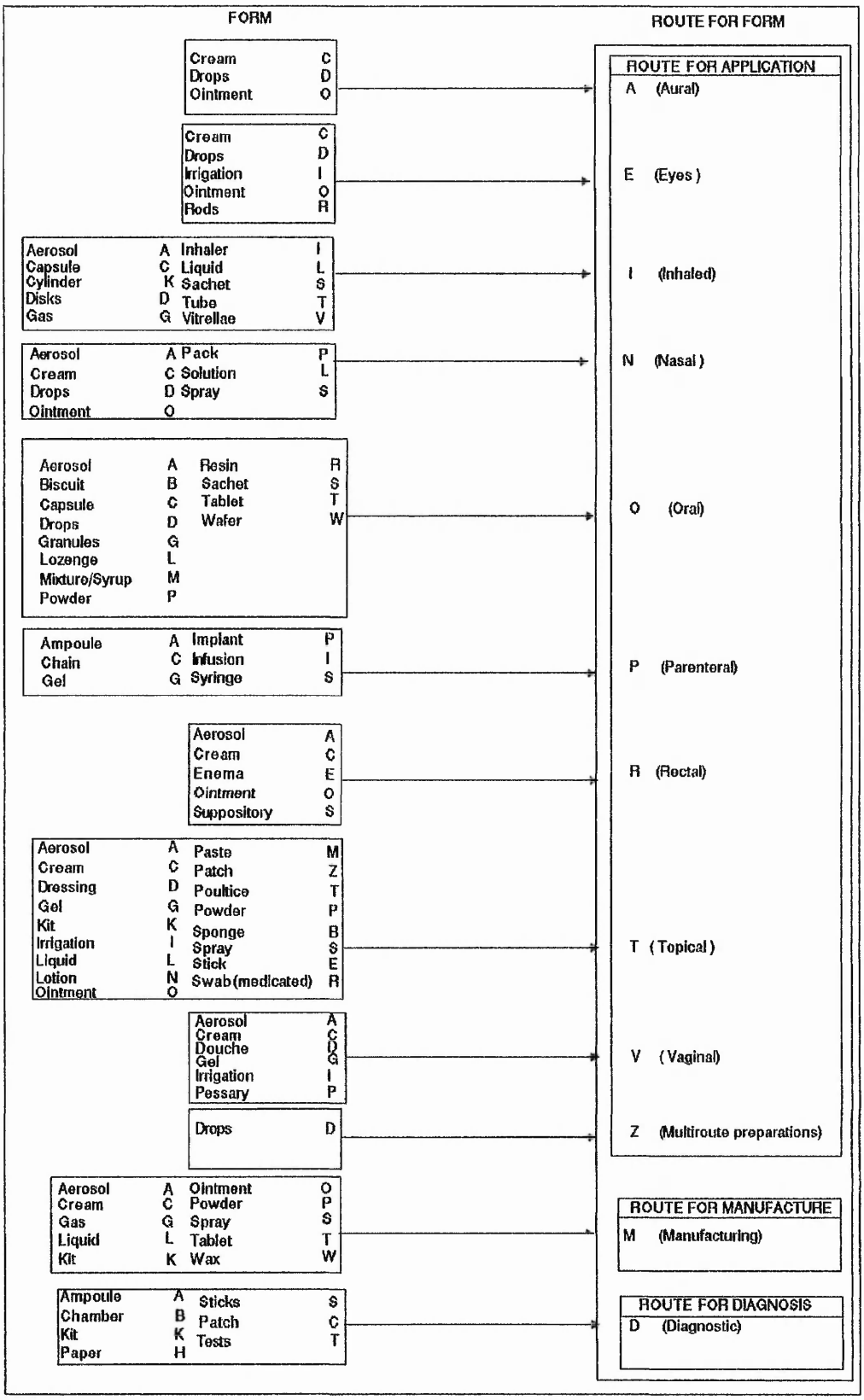


TABLE 4.6
Details the relationship between FORM and ROUTE FOR FORM

opened and its contents removed, although its form will not have changed. Thus the product has been modified, the code changes and so the number of full cylinders or other returnable containers in stock, those issued and empty returns can be accounted for.

vi) Only eighty-seven per cent of products could be identified by the use of a name field with four alpha characters. The majority of these were products having one or two names.

The results indicated that for an organised grouping of products it would be necessary for a structure to be applied that enabled products with identical names to be grouped together within identical alpha characters. This problem was only apparent within certain commonly used alpha characters, e.g. CHL, SOD, and TRI.

A possible method of resolving the problem would be to increase the size of the name field from four characters to enable a satisfactory identification of the products, e.g. Chlorprom, Chlorprop, Chloro. This, however, would not help in the case of some products, e.g. sodium, as it would need further extension to accommodate the salt field for identification. These options would conflict with the original premise of the code being as concise as possible and would not fit within the field.

It would however enable the code to be read without confusion from code to description. When coupled with the code components it would produce an accurate product description.

Products having different salts (the clinical reasons for use may vary)

can be accommodated by using the single ingredient product box in the algorithm, together with the first character of the second name.

Multi-ingredient products having brand names but no approved names and consisting of alphanumeric characters were resolved by using the first two alpha characters and the first two numeric characters of the product name, e.g. Eugynon 30 = EU30.

Multi-ingredient products having approved names consisting of alphanumeric and numeric characters were resolved by adding the strength characters, the precedent for which is the approved name Co-trimoxazole 480mg which is equivalent to sulphamethoxazole 400mg and trimethoprim 80mg. Thus co-careldopa 10/100 would be coded COC 110.

4.4.6 SUMMARIES OF MODIFICATIONS

4.4.6.1 MODEL

Comparison of the basic model, Figure 4.2, with the model modified in the light of findings, Figure 4.7, so far shows:

1. The entity UNIT OF MEASURE has been added. This lists the way in which strength, base unit and size can be qualified.

2. The entities BASE UNIT and BASE UNIT SIZE have been added since it was determined that a unique code could not be produced unless there was some indication of the base unit and its size when all the other entities were identical. In some cases the identifier of this entity may be identical with FORM, e.g. tablet, capsule, in others there will be a difference, e.g. gas with BASE UNIT cylinder.

The modified model, Figure 4.7, accommodates all products whether or not they have a size or strength, or size and strength relationship to the base unit.

In certain environments the base units may vary, e.g. in manufacturing the base units may be kg rather than grams or a bottle of tablets. This unit must be explicit since it is used in stock control and dosage systems.

3. Modifications to a product are identified through the recursive relationship illustrated in Figure 4.7. The details of the product are held in the lower level of FORM, e.g. live vaccine, chewable tablet, empty cylinder etc. In future this relationship may become very important with the increase in genetically and modified release products.

4. The entity ROUTE FOR FORM has been added since it is this entity that further focuses the entity FORM to exclude unacceptable combination of FORM and ROUTE FOR FORM, Table 4.4.

4.4.6.2 ALGORITHM

In view of the failings found in the implementation of the model in Figure 4.7 and the original algorithm, Figure 4.5, before implementing phase 2, the algorithm was amended as follows, Figure 4.8.

4.4.6.2.1 Name Field

1. The section dealing with "single ingredient two name product" was incorporated within "single ingredient approved/brand name product".

2. "Multi-ingredient two name products" were incorporated within the section, "Multi-ingredient product approved name" or "multi-ingredient product brand name" according to the nature of the product.

3. "Multi-ingredient three name products" had the naming structure altered to use the first characters of the three names rather than the first and last names.

4. A section has been added to accommodate products with names which consist of alphabetic and numeric characters.

5. A section has been added to accommodate products with names which consist of alphanumeric and strength characters.

4.4.6.2.2 Strength and Size

These have now been separated out and form two parts of the algorithm, each having their own rules for use.

4.4.6.2.3 Form

In the light of experience the number of form attributes was increased considerably and they are listed in Table 4.6.

4.4.6.2.4 Route for Form

A further entity ROUTE FOR FORM has been added in line with the findings. Its contents are listed in the algorithm, Table 4.6.

4.4.6.2.5 Form Detail

A listing of the modifications to products has been added in line with the findings. The path through the algorithm at this point is optional

since every product does not have modified activities, Figure 4.8.

4.4.7 OVERLAY OF ALGORITHM ON MODEL

This is shown in Figure 4.9 which depicts the code at the end of Phase 1 ready to enter phase 2 where it will be critically appraised.

4.4.8 COMPARISON WITH THEORETICAL MODEL

As in the earlier comparison the entities now added show the model to be a composite of entities from several parts of the theoretical (legal) model. Their definitions however are identical.

But, importantly, several entities have been added to the theoretical model to make it a practical product model.

4.5 PHASE 2

Three thousand and forty-nine products in the form of the modified code were then entered on to a database designed to prevent duplication and the results analysed.

4.5.1 TESTING

The testing of the codes was by a program in which if a unique code could not be produced then the product was excluded from entry to the data base.

The lists of unentered products were identified by manual inspection and the reason for exclusion identified.

4.5.2 RESULTS AND ANALYSIS

Examination of the print-outs showed it was possible using the modified

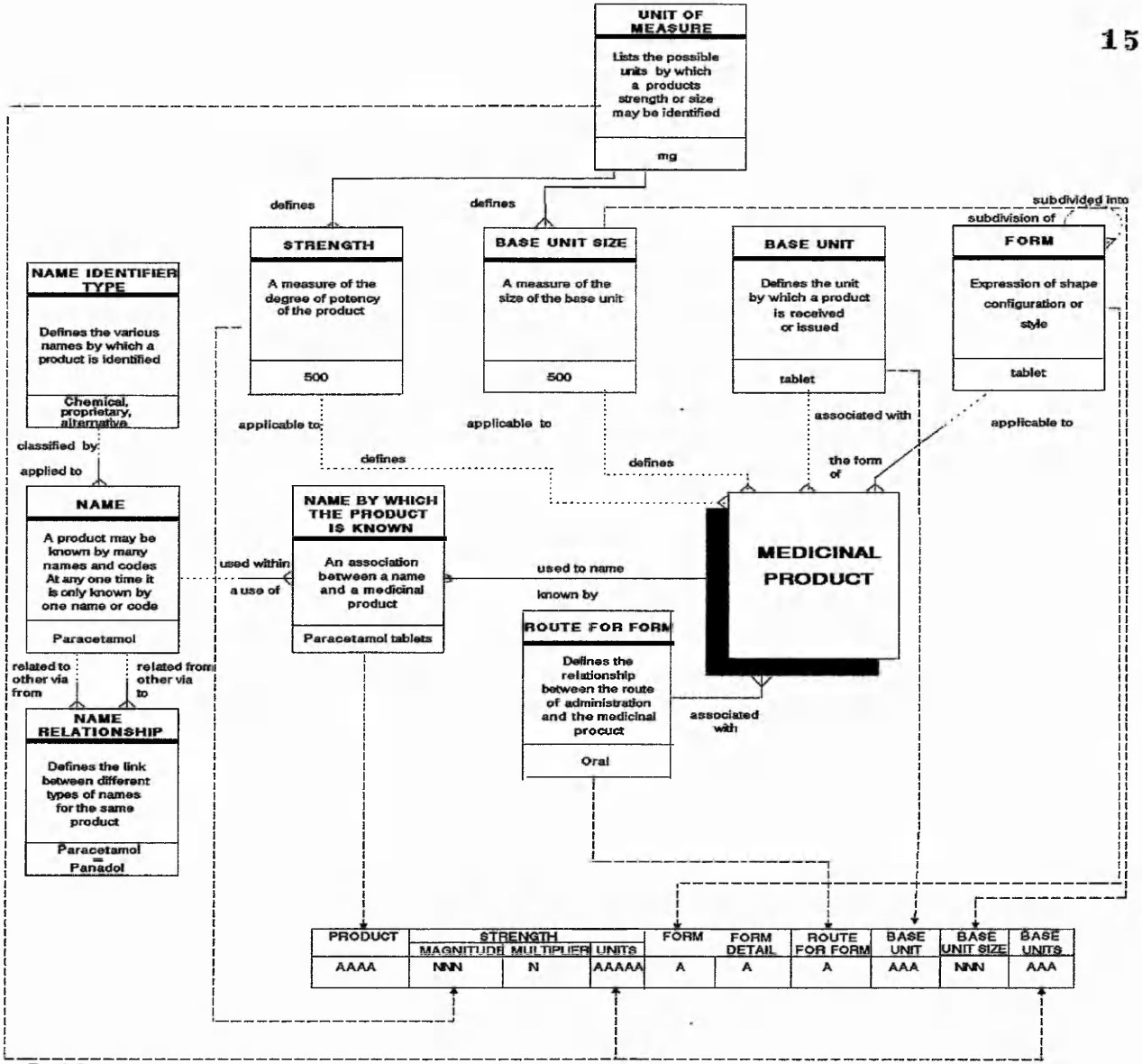


Fig. 4.9
The overlay of the code on the coding model.

code to uniquely identify 3017 products out of a total of 3049 (98.72%); this was an improvement on the previous phase (93.4%). Out of the uniquely identified products, 453 (14.2%) required four name characters, compared with 21% in phase 1. 13 (0.42%) products were identified by characters and figures in the name field.

The 39 products not uniquely coded were identified by inspection and consisted of four important groups of products, namely insulins, multi-route products, products identified by molecular weight, e.g. Dextrans, and some intravenous fluids.

4.5.3 MODIFICATIONS TO CODE

4.5.3.1 Insulins

Insulins, with the exception of biphasic insulins, are not a mixture of products. They are distinguished from each other by the nature of their constituents, which affect their type of action, e.g. crystalline, amorphous and protamine etc. They also are distinguished by the source of their preparation, e.g. porcine, bovine or human.

These are illustrated in Table 4.7.

PREPARATION	FINAL LOCAL CODE	SPECIES
NEUTRAL INSULIN INJECTION		
Neutral	INS1	Beef
Human Actrapid (pyr)*	INS2	Human
Velosulin	INS7	Pork
BIPHASIC ISOPHANE INSULIN INJECTION		
Human Actraphane (pyr)*	IND1	Human
Human Initard 50/50 (emp)*	IND2	Human
Human Mixtard 30/70 (emp)*	IND3	Human
Humulin M2 (prb)*	IND5	Human
Mixtard 30/70	IND9	Pork
Penmix 30/70 (pyr)*	IND12	Human
BIPHASIC INSULIN INJECTION		
Rapitard MC	INB1	25% Pork 75% Beef
INSULIN ZINC SUSPENSION (AMORPHOUS)		
Semitard MC	INA1	Pork
ISOPHANE INSULIN INJECTION		
Human Insulatard (emp)*	INI2	Human
Human Protaphane (pyr)*	INI3	Human
Humulin (prb)*	INI4	Human
Hypurin Isophane	INI5	Beef
INSULIN ZINC SUSPENSION (MIXED)		
Human Lente (prb)*	INM3	Human
Hypurin Lente	INM4	Beef
INSULIN ZINC SUSPENSION (CRYSTALLINE)		
Human Ultratard (pyr)*	INC1	Human
Humulin Zn (prb)*	INC2	Human
PROTAMINE ZINC		
Hypurin Protamine Zinc	INP1	Beef

* (prb) - produced from proinsulin synthesised by bacteria using recombinant DNA technology.
(pyr) - produced from a precursor synthesised by yeast using recombinant DNA technology.
(emp) - produced by enzymatic modification of porcine insulin.

Table 4.7 - The Insulin list.

In order to code insulins three methods were tried, bearing in mind that, with the exception of cartridges, all insulins have identical basic name characters, i.e. INS, strength, form and base unit sizes.

4.5.3.1.1 Method 1

This method was to accommodate insulins within the algorithm. Since it could be reasoned that they were all modified forms of insulin, the modifications could be accommodated within the form detail field: the form details being arbitrarily allocated according to the BNF classifications illustrated in Table 4.8.

	FORM DETAIL
Soluble insulin	S
Insulin zinc suspension (mixed)	M
Insulin zinc suspension (amorphous)	A
Insulin zinc suspension (crystalline)	C
Isophane insulin	I
Protamine insulin	P
Biphasic	B
Biphasic isophane insulin	D

Table 4.8 - Insulins arbitrarily coded from the BNF.

The code would therefore be as illustrated in Table 4.9.

NAME	NAME CHARACTER	FORM DETAIL
Insulin (Soluble)	INS	S
Insulin zinc suspension (mixed)	INS	M
Insulin zinc suspension (amorphous) etc	INS	A

Table 4.9 - Insulins coded in accordance with Method 1.

Previously the form detail field had been reserved for the source of the preparation, e.g. porcine, bovine, human etc. It could not, therefore, be used to include these modified forms, so this method of coding was not acceptable.

4.5.3.1.2 Method 2

This consisted of adding the code previously used above for the form detail to the basic prefix INS as illustrated in Table 4.10.

	NAME CHARACTER	FORM DETAIL
Insulin soluble	INSS	H
Insulin zinc suspension (mixed)	INSM	H
Insulin zinc suspension (amorphous)	INSA	H

Table 4.10 - Insulins coded in accordance with Method 2.

This, together with the FORM DETAIL, which indicates the origin of the insulin, allowed identification of all the insulins except biphasic isophane insulins. However, to accommodate a mixture of insulins, e.g. porcine and bovine, the form detail field would have to be increased to two characters.

Biphasic isophane insulins present a problem in that they consist of varying proportions of products and cannot be identified generically unless ingredients are taken into consideration. This is illustrated in Table 4.11.

It is apparent that, although INSD would allow entry into the system at the biphasic insulin level, it is inadequate to uniquely identify the product. In these cases, only the manufacturer's trade name uniquely identifies the product. As this is manufacturer-specific it will not allow for the inclusion of identical products from other manufacturers. It is likely in the future, in line with many other products, that an approved name will be given to these products. However, until then the local naming of these products would perhaps produce a satisfactory identifier, e.g.

INSB1 10% soluble 90% isophane
INSB2 20% soluble 80% isophane etc.

In this case, the name field would have to be expanded to five characters. However, this method of coding proved unsuitable for two reasons.

a) There were insufficient name characters to represent the product, i.e. INSB1 would be required to identify Biphasic Insulin number 1 using this system. There are seventeen insulins of this type at present, so all could not be accommodated even within five characters.

b) A study of all the available insulins showed that each varied by its method of production within its form detail. They could not, therefore, uniquely be identified, as form detail has its own subdivisions, e.g. Human (prb), Human (pyr), Human (emp), Table 4.7.

CODE	STRENGTH	FORM	ROUTE	FORM DETAIL	INGREDIENTS	STRENGTH	PACK SIZE
INSD	100	I	P	H	SOLUBLE ISOPHANE	10% 90%	10ML
INSD	100	I	P	H	SOLUBLE ISOPHANE	20% 80%	10ML
INSD	100	I	P	H	SOLUBLE ISOPHANE	30% 70%	10ML
INSD	100	I	P	H	SOLUBLE ISOPHANE	40% 60%	10ML

TABLE 4.11

Illustrates the coding problems associated with Biphasic Isophane Insulins

4.5.3.1.3 Method 3

This method was to allocate a local code to all insulin products according to their grouping, (e.g. soluble and biphasic) with arbitrary characters being given to each group, Table 4.8. In order to keep the number of name characters as low as possible, the abbreviation for insulin was reduced from INS to IN followed by the group identifier. This was followed by the number allocated locally to each insulin product within each group, e.g. INS1, INM1. However, to accommodate the number of insulins, especially the isophanes in each group the name character field needs to be enlarged by one character to five, e.g. IND17.

In order to provide the information of the source of the insulin (e.g. porcine, human etc), it was reasoned that as these were not modifications of a product, the information should not be contained in the form detail field but in a new field of two characters named SPECIES. Two characters are necessary since one insulin group, Rapitard MC, is a mixture of porcine and bovine insulins.

This field will also be useful in showing the source of other medicinal products of animal or human origins and especially with the increased production of recombinant DNA derived products.

The method of preparation will be implicit in the local code.

There will always be a need for local codes since some products will be prepared locally and the codes could be made "official" in specific circumstances.

4.5.3.2 Drug Identified by Molecular Weight

Certain products are identified by their molecular weight, e.g. Dextran 110 in saline. The present algorithm will not identify these as it will only accommodate four characters. To uniquely identify these products the molecular weight and the product vehicle have to be identified, e.g. Saline or glucose. At present the strength of the vehicles for these products is standardised as illustrated in Table 4.12.

10% Dextran 40 in 5% glucose intravenous infusion
10% Dextran 40 in 0.9% sodium chloride intravenous infusion
6% Dextran 70 in 5% glucose intravenous infusion
6% Dextran 70 in 0.9% sodium chloride intravenous infusion
6% Dextran 110 in 0.9% sodium chloride intravenous infusion

Table 4.12 - Products containing ingredients identified by molecular weight.

The algorithm was, therefore, modified to where the molecular weight is a two character number, e.g. Dextran 40, then the first two characters of the name would be used together with the molecular weight and one letter from the vehicle. However, if other strength vehicles are introduced this method of coding will not be satisfactory and local coding may be necessary.

DE40S = Dextran 40 in saline. Where the molecular weight is greater than two figures, the first character, the molecular weight and the vehicle would be used D110S.

Because of these particular products the name field had to be increased to five characters, which will be used in the next stage of coding development.

4.5.3.3 Multi-Route Products

These consist of single products that are designed for administration via several routes, e.g. eye, ear and nasal drops. If they are included in the coding system as separate products, they would undoubtedly corrupt a stock control system. If they are to be included as one product, some method needs to be determined to incorporate them, since the present model does not cope with them. The model, Figure 4.10, would allow for the inclusion of such products. The entity ROUTE FOR FORM has a relationship with the entity ROUTE OF ADMINISTRATION COMPONENT, which lists the possible routes for which a product may be used and relates them to a notional character in this case Z.

Study of the occurrence diagram, Figure 4.11, illustrates this process. In this diagram, a single product may have a compound ROUTE FOR FORM, e.g. ear, eye or nose. However, if this ROUTE FOR FORM has an arbitrary symbol Z, then Z may relate to any one of the ROUTES OF ADMINISTRATION COMPONENTS, which signifies a one to many relationship for ROUTE FOR FORM to ROUTE OF ADMINISTRATION COMPONENT.

4.5.3.4 Products normally Identified by two or more Ingredients and their Respective Strengths

These are illustrated in Table 4.13.

4%	Glucose + 0.18% Sodium Chloride
0.9%	Sodium Chloride + 0.2% Potassium Chloride
4%	Glucose + 0.18% Sodium Chloride + 0.2% Potassium Chloride

Table 4.13 - Some products identified by two or more ingredients and their respective strength.

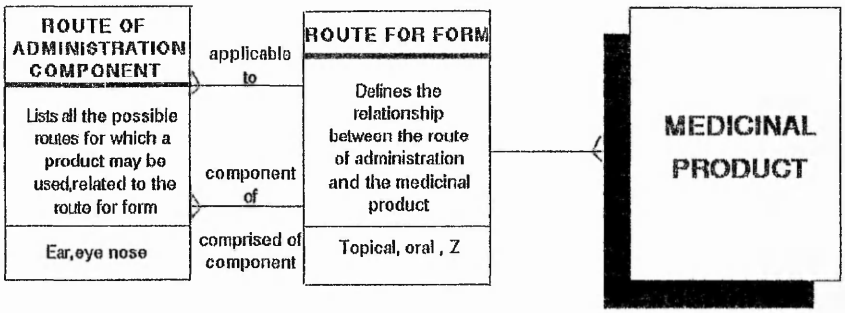
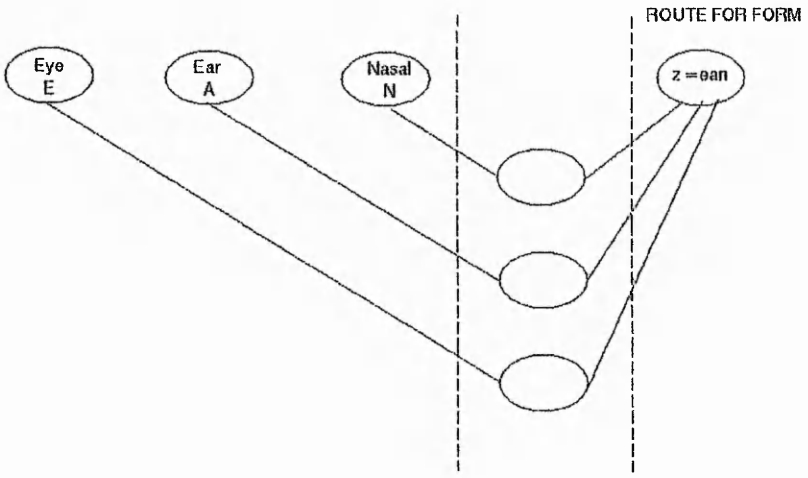


Fig. 4.10

The relationships between the ROUTE OF ADMINISTRATION COMPONENT and ROUTE FOR FORM to MEDICINAL PRODUCT.



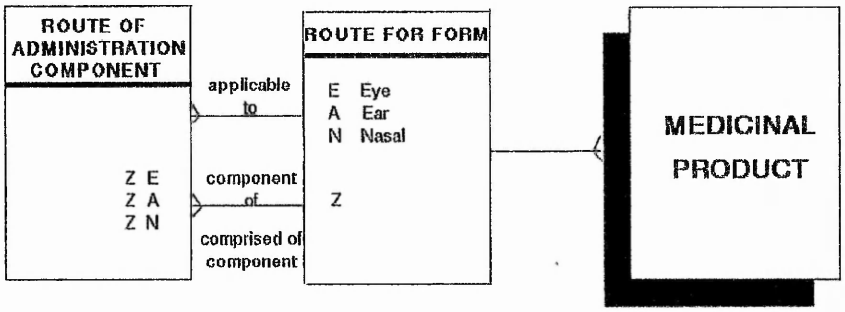


Fig. 4.11
Occurrence diagram illustrates Fig. 4.10 ROUTE OF ADMINISTRATION COMPONENT

Unlike medicinal products with approved names and strengths that can be added together, e.g. co-careldopa, the strength portions of this group cannot be summed.

The method chosen to identify these was similar to that of the insulin group, i.e. a locally allocated number. Table 4.13 therefore becomes Table 4.14.

GLUS1	4% Glucose + 0.18% Sodium Chloride
SODP2	0.9% Sodium Chloride + 0.2% Potassium Chloride
GSP2	4% Glucose + 0.18% Sodium Chloride + 0.2% Potassium Chloride

Table 4.14 - The method of identifying products identified by two or more ingredients and their respective strengths.

4.5.4 Comparison with Theoretical Models

The model at the end of Phase 2, Figure 4.12, contains the entities present in the original phase 2 model, Figure 4.7, with the exception of PRODUCT INGREDIENT, SPECIES and ROUTE OF ADMINISTRATION COMPONENT. The model now allows for a medicinal product to be identified either as a "single ingredient medicinal product" or a "multi-ingredient product", each of which needs to be ascertained for identification purposes, e.g. biphasic insulins and species.

ROUTE OF ADMINISTRATION COMPONENT identifies the possible routes for a product and relates them to notional characters.

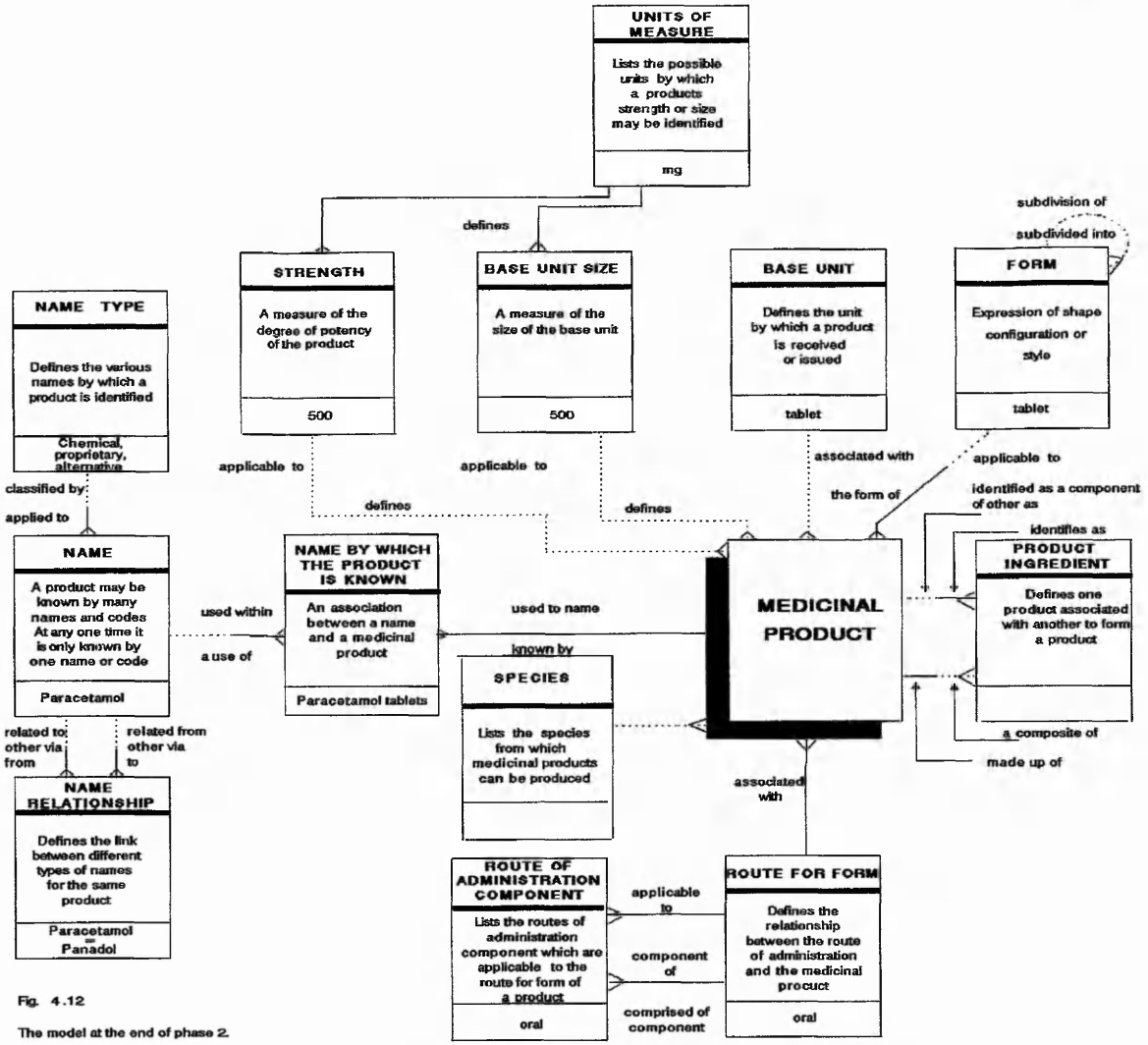


Fig. 4.12

The model at the end of phase 2.

SPECIES identifies the species from which a medicinal product is produced, e.g. salmon calcitonin.

4.5.5 Modification of Original Phase 2 Algorithm

The algorithm was modified to take into account the failings identified in the phase 2 testing. It was necessary to include the following sections, as shown in Figure 4.13.

(1) Products with local codes, e.g. insulins and some intravenous fluids, could not be accommodated elsewhere within the algorithm. This group links to strength in the same way as for other products.

(2) Products identified by molecular weight, e.g. Dextrans, could not be accommodated elsewhere in the algorithm as it is necessary to identify the product vehicle as well as the product for identification purposes. The group links to strength as for other products.

(3) Multi-route products were included in the form and route for form section of the algorithm to enable these products to be identified.

(4) A species field was included for use with suitable products, in order that the product's origins may be identified, e.g. calcitonin

(5) Importantly, the name character field has been increased from four to five characters. This allows the identification of locally coded Insulins and the identification of the products identified by molecular weight. This field also will allow the name characters of other products to be extended in the future should this be necessary.

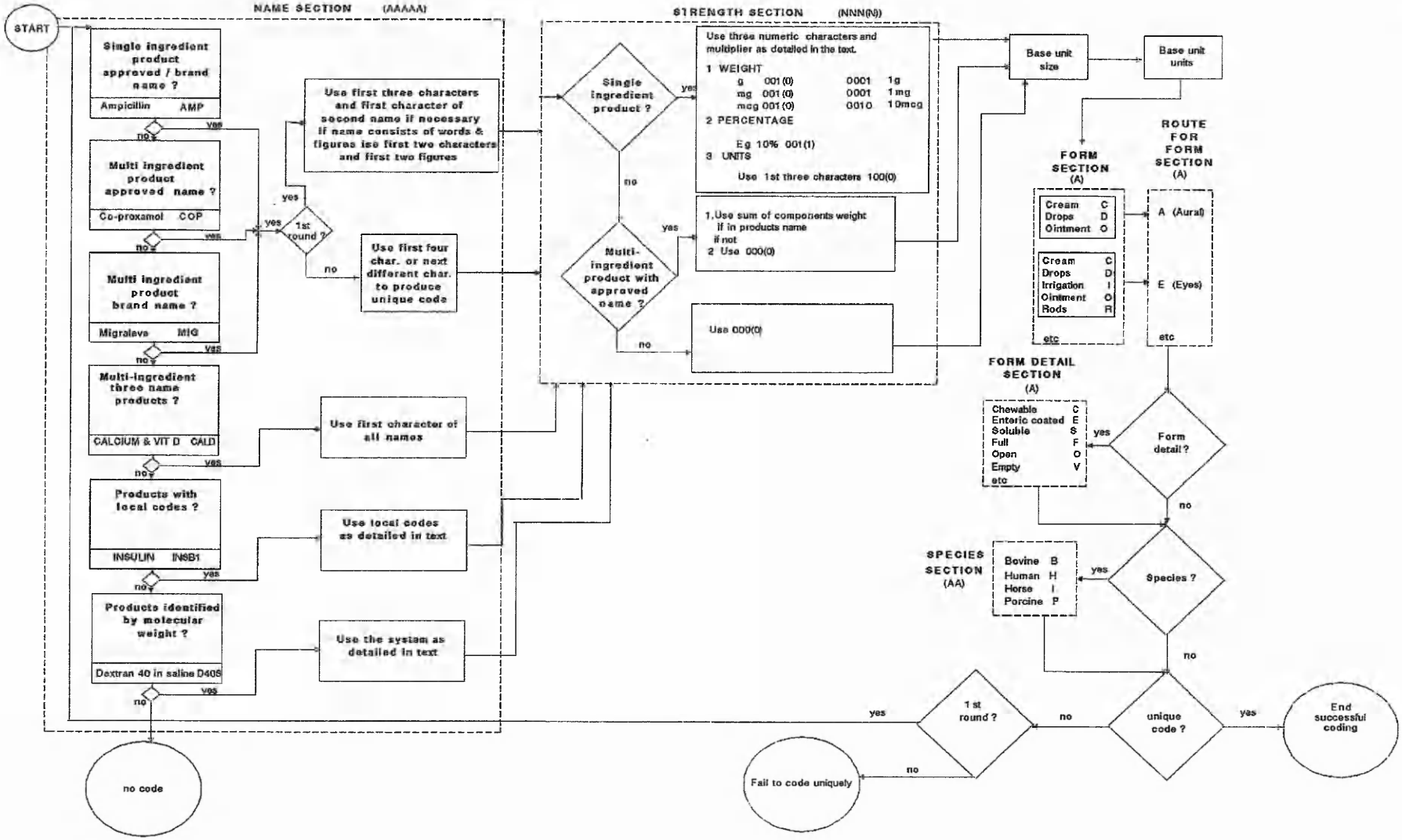


Fig. 4.13
The algorithm at the end of phase 2

(examples only of FORM,ROUTE FOR FORM , FORM DETAIL and SPECIES are shown)

4.5.6 Overlay of the Code on the Model

Figure 4.14 illustrates the overlay of the code on the model at the end of phase 2.

When compared with that at the beginning of Phase 2, Figure 4.7, the following modifications can be seen:

1. name characters are increased from 4 to 5

2. species is accommodated by 2 alpha characters.

4.6 PHASE 3

4.6.1 Methodology

The method of testing the system was by:

1. a report program, which verified uniqueness of the product code,
2. visual inspection of screens to ensure the code modules were correctly assigned to their respective fields,

3. pharmacists entering the prescribing module and entering a patient's treatment using the present treatment sheet as a model. Thirty-eight drugs for ten patients were added.

4.6.2 Testing

The codes generated from 3049 medicinal products were loaded on to the South Lincolnshire Prescribing and Administration System via a data transfer system.

In order to further validate the codes for non-duplication, a unit was written within the system to verify non-duplication. A further unit was

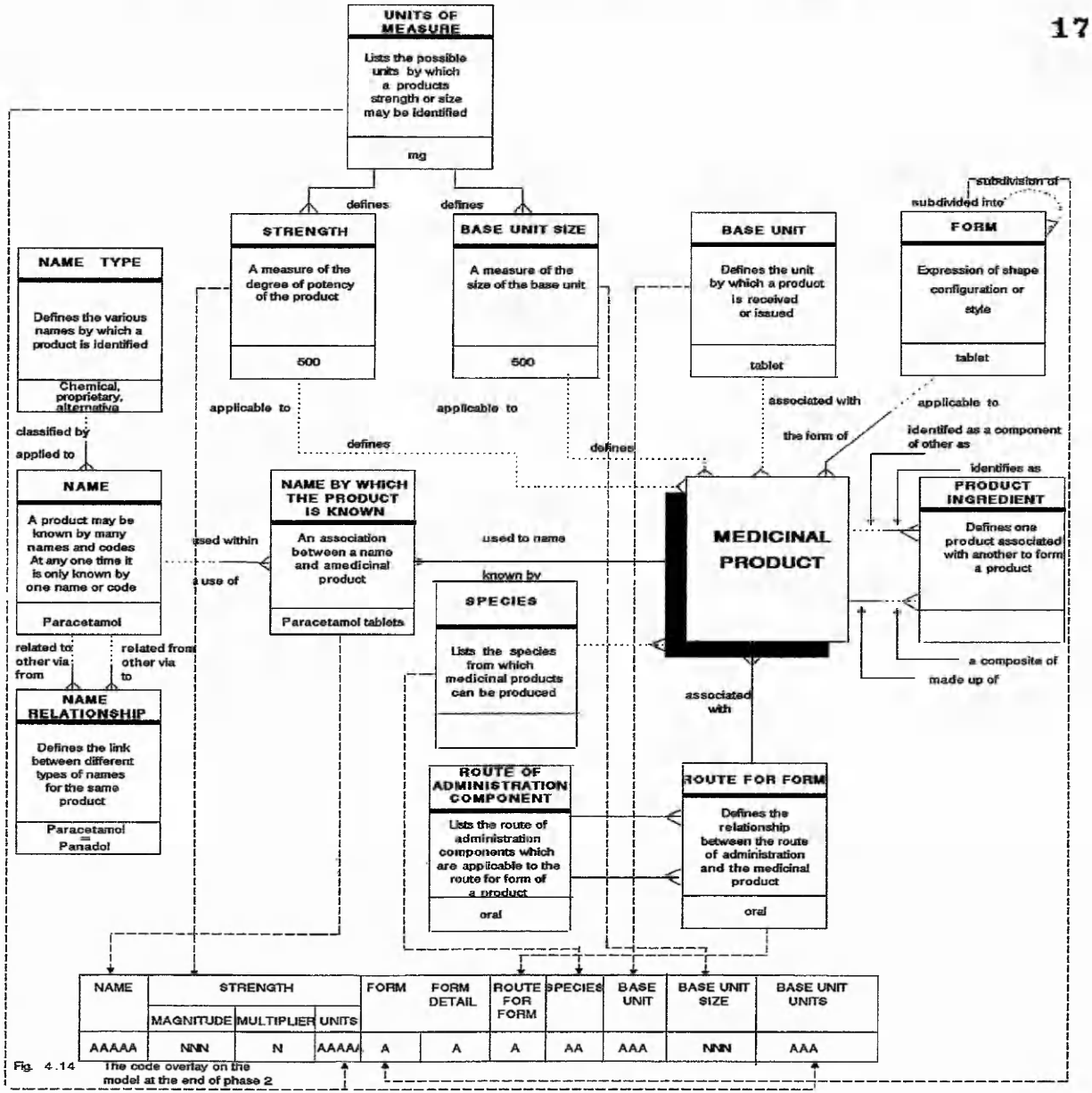


Fig. 4.14 The code overlay on the model at the end of phase 2

also written to split the codes into their component modules and to place them within the fields necessary to provide information to enable the functioning of the system.

An important part of the Prescribing and Administration System was to provide information on dosage related to patients' characteristics, and approved drug regimes to clinicians, pharmacists and nurses. A program was written based on the coding model, Figure 4.15, which took information for its function from the codes already entered, together with patient information entered manually.

It was reasoned that if this was successful, it would be a further validation of the modelling process.

Figure 4.15 illustrates the coding model for dose. MEDICINAL PRODUCTS are administered to patients in line with the INDICATION for the product, which is determined by the clinician's diagnosis. The APPROVED DOSE REGIME of the medicinal product is indicated by the product's Data Sheet. This may be affected by the entity PATIENT CHARACTERISTIC TYPE, e.g. age, weight or surface area, which are related to the PATIENT CHARACTERISTIC and to the PATIENT. It may be, however, that the clinician does not wish the patient to receive the APPROVED DOSE REGIME and prescribes the APPLIED DOSE REGIME.

This was carried out by the formulation of a dosage grid which took into account the entities included in the model, Figure 4.16.

The construction and population of the dosage grid proved difficult because:

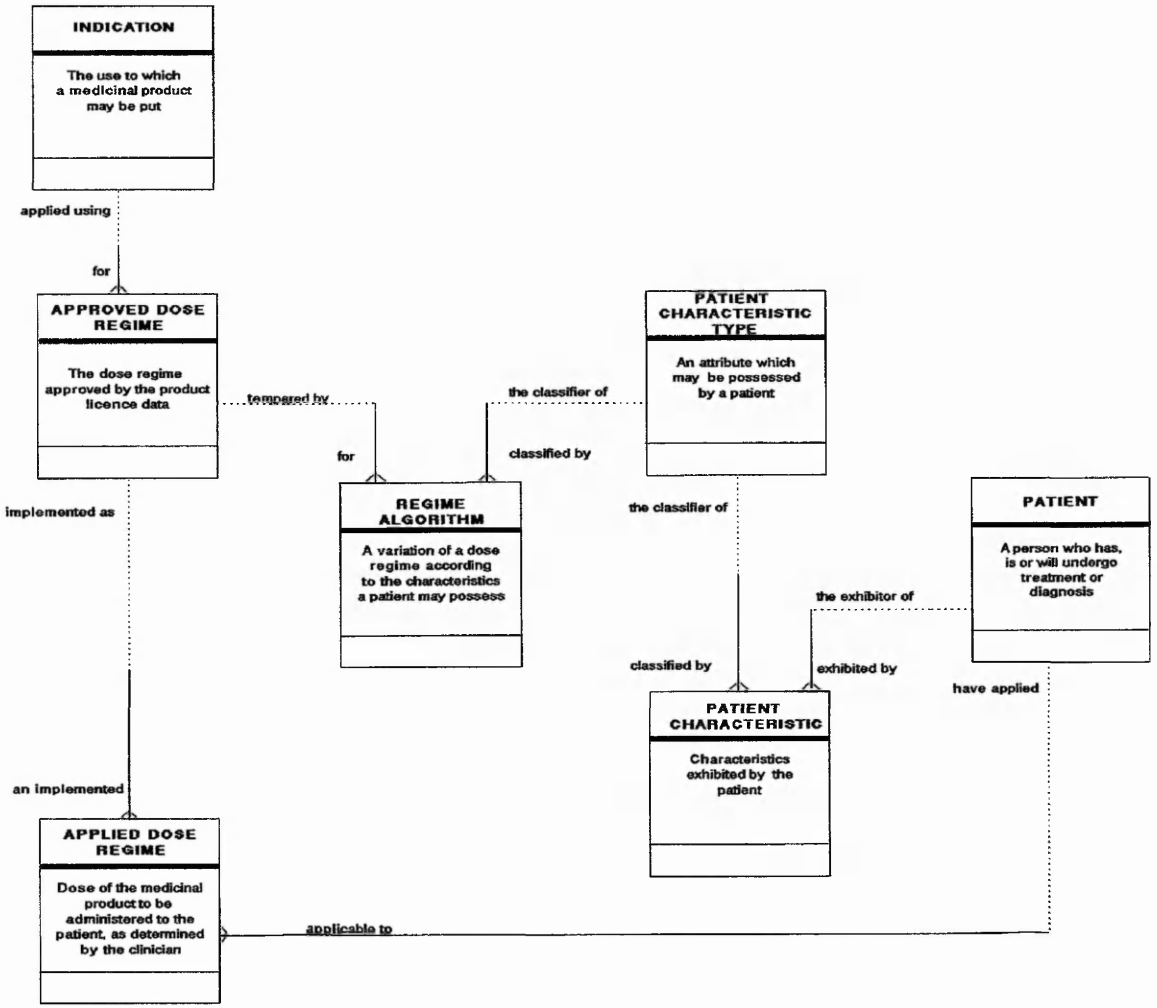


Fig. 4.15
The entities related to dose

Drug..... Route of Administration.....

Age	Max Doses	Loading Doses 1st	2nd	3rd	Daily Doses	Maximum Doses Daily	Course	Monthly	Lifetime
< 1 wk									
1-4wk									
1-12m									
1 yr									
2yr									
3yr									
4yr									
5yr									
6yr									
7yr									
8yr									
9yr									
10yr									
11yr									
<65yr									
>65yr									

Fig. 4.16
The dosage grid for use with the Prescribing and Administration system.

(a) information for drug doses by age proved variable and was unavailable for many products

(b) there was an extremely wide variation in the way in which drugs' doses could be administered to patients, not in terms of route of administration or form, but in terms of course, daily maxima, loading doses etc.

It was therefore decided to arrange the patients' ages in the manner shown in Figure 4.16. Pharmaceutical experience shows that these are the groups of ages for which drug doses are most critical.

The dose regimes entered were not related to the medicinal products' indication, since many products had several indications, each with its own dose. It was therefore reasoned that the maximum dose allowed for any of a product's regime would be entered on the assumption that whilst it may not be the correct maximum dose for the indication, it would be unlikely to harm the patient, especially if the prescriber's attention were drawn to the importance of matching doses according to the patient's characteristics.

In line with the grids, 38 drugs were added. These were for ten patients with differing complex problems requiring drugs. It was believed that some of the drugs would be difficult to enter in the grids.

Drugs with identical ingredients were used to determine the effectiveness of the product ingredients' model included in Figure 4.12. Other characteristics were added, although at present these were to warn the prescribers of potential problems, e.g. pregnant, breast feeding, liver

or renal malfunction.

4.6.3 Results

When the codes were added to the data base, there were no errors due to lack of uniqueness. Any errors were traced to coding errors, e.g. form detail being omitted or incorrectly assigned. When these were corrected, no further errors due to their effect on the other coded entries were noted.

Inspection of the screens showed that the code modules had been placed in the correct fields of the Prescribing and Administration System. Product and product ingredients and strength were accurately recorded, the latter being calculated fields.

When the patient's medication was "prescribed" by a pharmacist the following problems occurred. Ampicillin 250mg O (oral): when this operation was carried out, all the ampicillin products for oral administration were listed for selection by the prescriber. However, if ampicillin 250mg IM was prescribed, the ampicillin preparations available were not presented because the ROUTE FOR FORM field, in this case Parenteral, had been bypassed.

Medicinal product ingredients and their strengths were identified. Concurrent prescriptions containing identical ingredients were highlighted and their total strengths summed. Errors found here were due to inaccurate inputting of information, e.g. Heparin calcium and calcium heparin.

In order to test the accuracy of the dosage grids, two dosage tables were

completed for each route of administration of a drug by two pharmacists. It was found that the dosage grids produced by pharmacists were not identical. This was not because of the coding or programme but reflected the lack of available information. Therefore, in these cases professional subjective judgement was used.

Drugs modified by patient's characteristics were highlighted.

Drugs that needed the dose to be calculated, e.g. by surface area, were correctly calculated.

When drugs were prescribed that exceeded the maximum dose, this was highlighted.

4.6.4 Modifications

In line with the results, the following modifications were made.

1. The computer program was amended to allow the prescriber to omit the route for form field but to ensure the route of administration field is linked to the route for form field to allow only those products valid for the route for form to be listed. This is possible because all the necessary information is available within the product code.

2. To ensure the accurate identification of ingredients, a protocol will be established to ensure consistency.

3. To ensure conformity of dosage information the following protocol was established, as illustrated in Table 4.15.

0 - 12 months	Neonatal Vade-Mecum *(Neonatal Vade-Mecum)
2 months - 12 years	Paediatric Vade-Mecum * (Paediatric Vade-Mecum)
12 - 65	British National Formulary ** (BNF)
> 65	British National Formulary ** (BNF)

* If the information was not available then Alder Hey Book of Children's Doses Formulary was reviewed (Alder Hey).

** If the information was not available then the Data Sheet Compendium was reviewed (ABPI).

Table 4.15 - The dosage grid for use with the Prescribing and Administration System.

4. At the end of this phase the code has ten modules: most of which except strength units, base units, and base unit units, were themselves in a coded form. Commonly accepted SI abbreviations have been used to populate the relevant uncoded modules during testing. It was found that the abbreviations used varying amounts of space within the modules. It was reasoned that this was extravagant use of space and that these blocks could be replaced by a single character. Using the letters A-Z upper and lower case and figures 0-9 excluding I, i, O and o gives 58 possible codes, which can be used for the as yet uncoded modules. The product code would now consist of 20 characters organised in 10 modules.

4.7 DISCUSSION

The implementation of the Prescribing and Administration System showed that the unique product identification code together with some additional modules could be used to identify medicinal products. The additional modules, e.g. ROUTE OF ADMINISTRATION, PRODUCT INGREDIENTS, also proved satisfactory in providing accurate information used in prescribing of medicines.

The models that were used also proved satisfactory in providing the basis for codes and providing a basis for population and implementation of systems.

The number of characters which represent the code has been reduced to 20 in 10 modules.

Thus, the final phase of this part of the project, shown in Figure 4.1, the final model, was reached, tested and proved to be satisfactory.

The final project objective, (d), that of developing and validating a model and product code based on practical experience, was also attained.

5. DEVELOPMENT OF MEDICINAL PRODUCT IDENTIFICATION MODULE

5.1 INTRODUCTION

The project so far has concentrated on the production and validation of a unique product code. However, the models can be used to classify medicinal products according to any of the entities established, e.g. FORM, STRENGTH, ROUTE OF ADMINISTRATION etc. One very useful method of classification of solid form products, e.g. tablets, capsules, pessaries etc, may be by appearance in order to identify products. There have been several methods of identifying solid forms, ranging from printed sheets depicting tablets, capsules and their markings (Chemist and Druggist, 1993) to more sophisticated methods of measuring tablets and associating this with colour, markings, surface appearance etc (Tablident, 1988). A computerised data base (Tic Tac) has been established for the identification of medicinal products for toxicological reasons. However, none has been developed for medicinal products and ingredient identification that is suitable for use in the consulting room, or accident and emergency department.

Smolinske and Robertson (1992), writing in Veterinary and Human Toxicology, say

> "In 1992, identifying unknown tablets or capsules to help in managing a poisoning, with refilling a prescription, assessing an adverse reaction to an excipient, or in auditing the accuracy of a hospital's drug distribution program remains a problem."

It was reasoned therefore, that if the model for entity type APPEARANCE could be validated it would provide a suitable basis for such a system. More importantly, it would test the robustness of the model and its

development.

The objective of this section is to allow the input of limited information, based on the unknown products physical characteristics, in order to identify its name rather than to do the reverse.

The entity type APPEARANCE, evolved in the theoretical model section, Figure 5.1, was taken as the starting point and its validation follows Figure 5.2. The system was validated in several stages for the following reasons.

1) It would be difficult to capture all the attributes of appearance of all solid form medicinal products on the first trawl, e.g. colours, shapes and sizes.

2) The identification of colours is, to a large extent, subjective, e.g. pale red - pink - blue red etc.

3) The colours of products received in the consultation room or accident and emergency departments may not be the original manufacturing colours. They may have faded over time, or been contaminated by body fluids, e.g. sweat or gastric acid etc.

5.2 METHODOLOGY

5.2.1 Proforma Preparation

Approximately one thousand solid form products, tablets and capsules, were inspected to determine the spread of colours and shapes. As there

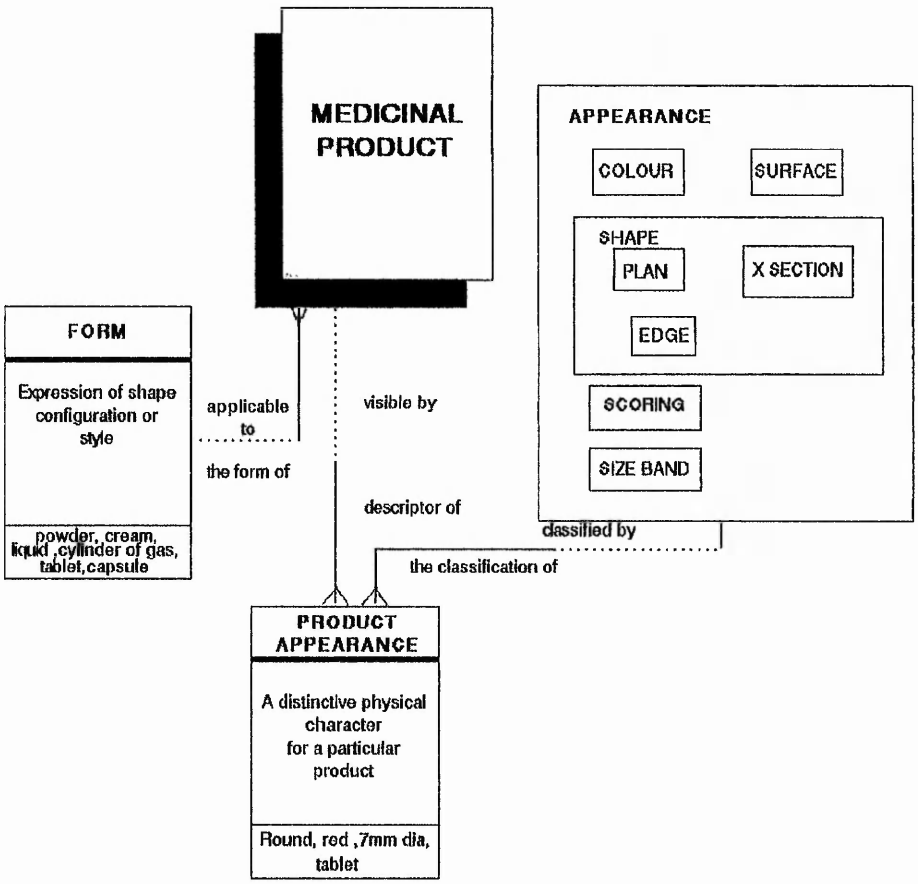


Fig. 5.1
The relationship of FORM and APPEARANCE to MEDICINAL PRODUCT

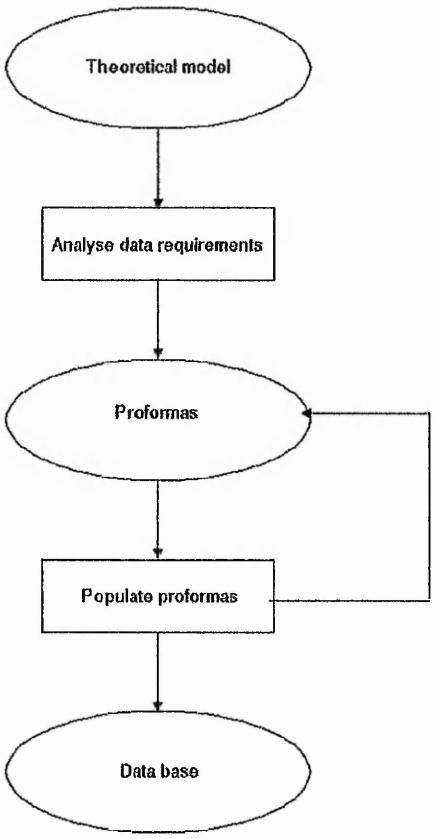


Fig. 5.2
The Medicinal Product Identification module

were many colours in use, it was decided to classify these into broad groups for tablets (proforma 1 - tablets (Figure 5.3)) and capsules (proforma 1 - capsules (Figure 5.4)).

Some tablets and capsules were composed of two or more colours and in the case of capsules the contents of the capsules had their own attributes, e.g. colour, powder, liquid, granules etc.

Many varying shapes of tablets were noted, ranging from round to barrel shaped to triangular in plan whilst the cross sectional view differed from the edge view (Figure 5.5). Capsules ranged from rectangular to tear shaped (Figure 5.6).

The appearance of tablets was also variable, e.g. matt, speckled, shiny, coated etc.

Some tablets and capsules also had markings. On tablets, if they were present, they were associated with scorings. On capsules they were associated with the body and cap portions.

Proforma 1 - tablets (Figure 5.3) and Proforma 1 - capsules (Figure 5.4) were therefore drawn up to accommodate these parameters relying on textual descriptions of shape etc.

5.2.2 Population of Proformas

A data base was constructed that allowed the inputting of information based on the proformas and that could sort on one or more of the fields marked with an asterisk (proforma 1 tablets - Figure 5.3 and proforma

TABLETS

APPROVED NAME

MAIN COLOUR *

WHITE YELLOW RED PINK GREEN CREAM SILVER
GOLD ORANGE BLUE VIOLET BROWN BLACK GREY
BEIGE PEACH

SECONDARY COLOUR *

WHITE YELLOW RED PINK GREEN CREAM SILVER
GOLD ORANGE BLUE VIOLET BROWN BLACK GREY
BEIGE PEACH

APPEARANCE *

MATT SPECKLED SHINY

COATING

FILM SUGAR

SHAPE PLAN *

ROUND HEXAGONAL SQUARE TRIANGULAR PELLET
OCTAGONAL PENTAGONAL DIAMOND OVAL SPHERICAL BARREL

CROSS SECTION *

SPHERICAL CONVEX/CONVEX FLAT/FLAT CONCAVE/FLAT CONCAVE/CONCAVE CONVEX/FLAT OVAL

EDGE *

ROUND FLAT BEVELLED

SIZE *

LENGTH.....MM WIDTH.....MM

WEIGHT

GM

SCORING *

UNSCORED
1/2 SCORED, NO MARK
1/2 SCORED , MARK SAME SIDE
1/2 SCORE, MARK OTHER SIDE
1/2 SCORED, MARK BOTH SIDES
1/4 SCORED, NO MARK
1/4 SCORED, MARK SAME SIDE
1/4 SCORED MARK OTHER SIDE
1/4 SCORED MARK BOTH SIDES

MARKINGS *

SIDE 1 SIDE 2

PROPRIETARY NAME

MANUFACTURER

* SORTABLE FIELDS

Fig 5 .3 Proforma 1 tables.

CAPSULES

APPROVED NAME

BODY COLOUR	*	WHITE YELLOW RED PINK GREEN CREAM SILVER GOLD ORANGE BLUE VIOLET BROWN BLACK GREY
CAP COLOUR	*	WHITE YELLOW RED PINK GREEN CREAM SILVER GOLD ORANGE BLUE VIOLET BROWN BLACK GREY
BAND COLOUR	*	WHITE YELLOW RED PINK GREEN CREAM SILVER GOLD ORANGE BLUE VIOLET BROWN BLACK GREY
APPEARANCE	*	OPAQUE OPAQUE & CLEAR OPAQUE&TINTED TINTED & CLEAR CLEAR
CAPSULE CONTENTS	*	NOT VISIBLE PASTE LIQUID POWDER GRANULES
CONTENTS COLOUR	*	WHITE YELLOW RED PINK GREEN CREAM SILVER GOLD ORANGE BLUE VIOLET BROWN BLACK GREY MULTICOLOUR
SHAPE	*	CYLINDRICAL TEAR SHAPED OVAL OVOID SPHERICAL
SIZE	*	LENGTH .....MM... WIDTH .....MM. **WEIGHT** GM
MARKINGS	*	

PROPRIETARY NAME **MANUFACTURER**

* SORTABLE FIELD

Fig. 5.4 Proforma 1 capsules.

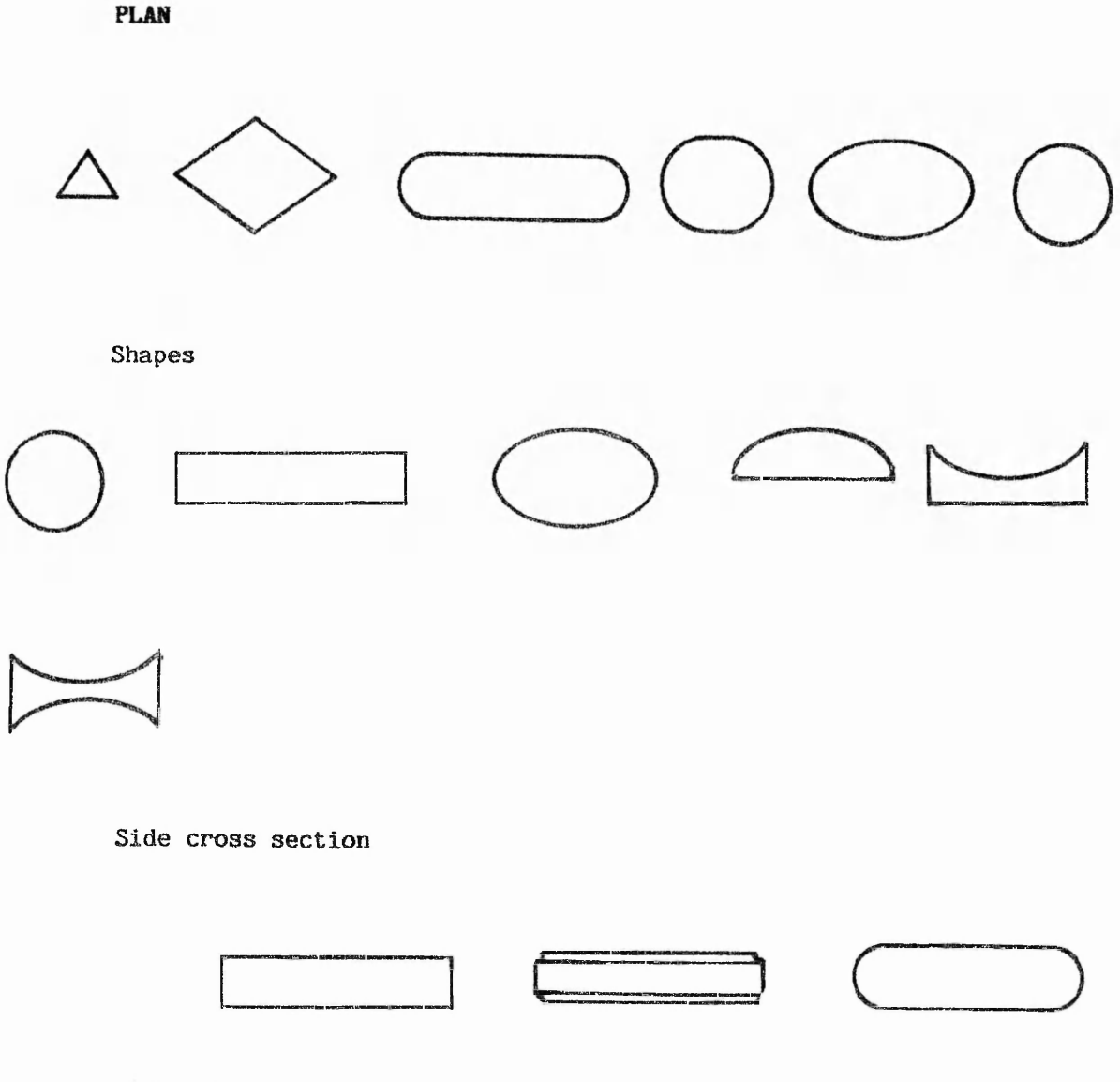


Fig 5.5 - The Plan, Cross Sectional and Side Views of Tablets

Capsules

Fig 5.6 - The Shapes of Capsules

1 capsules - Figure 5.4). Thus the greater the number of fields used for sorting the fewer final products are identified that show common characteristics. The occurrence diagram (Figure 5.7) illustrates the process.

The proformas were populated with two hundred and fifty tablets and capsules picked in alphabetical order of approved names from the shelves of a hospital pharmacy by pharmacists and inexperienced personnel. There were eight inputters.

5.3 RESULTS

5.3.1 INITIAL CONDITIONS

5.3.1.1 Tablets

5.3.1.1.1 Layered Tablets

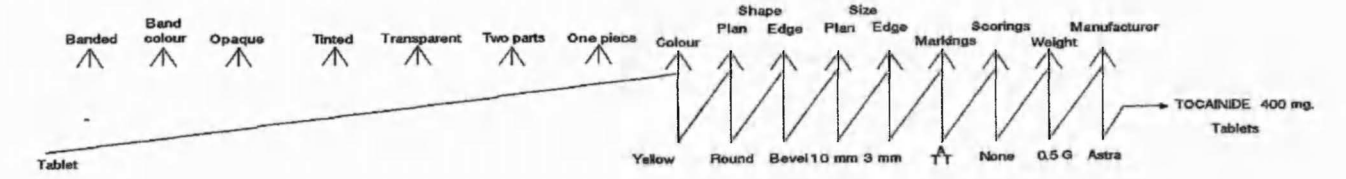
The majority of tablets were found to be of a single colour. There were, however, several that were layered, each layer having distinctive colours. One product had three layers, each of a distinctive colour.

There is, therefore, a need for more than two colours to be identified.

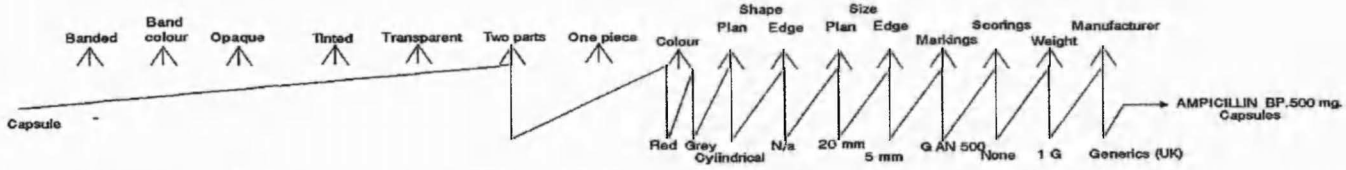
5.3.1.1.2 Appearance/Coating

These were two separate attribute fields but it soon became apparent that with modern production techniques it was extremely difficult to distinguish between shiny, film coated or sugar-coated products with certainty.

Matt products were easily identifiable, as were speckled products.



TABLET IDENTIFICATION



CAPSULE IDENTIFICATION

Fig. 5.7
Occurrence diagrams for the identification of tablets and capsules.

5.3.1.1.3 Size

In most cases size was easily measured, e.g. diameter of round tablets. However, some products, e.g. triangular, presented a problem of which dimension to measure and to enter first in the proforma, i.e. which was length, which was width.

It was decided to measure the tablets where it was applicable to measure the two biggest dimensions, Figure 5.8.

It was found that the size of products in individual batches did not vary greatly (0.1%) but the range of sizes over 250+ products was from 4 mm to 2.5 cm. Measurements were made by micrometer, to the nearest mm.

5.3.1.1.4 Scoring

Tablets were found to be unscored, half-scored or quarter-scored on either one or both sides. They may also be associated with markings in any combination.

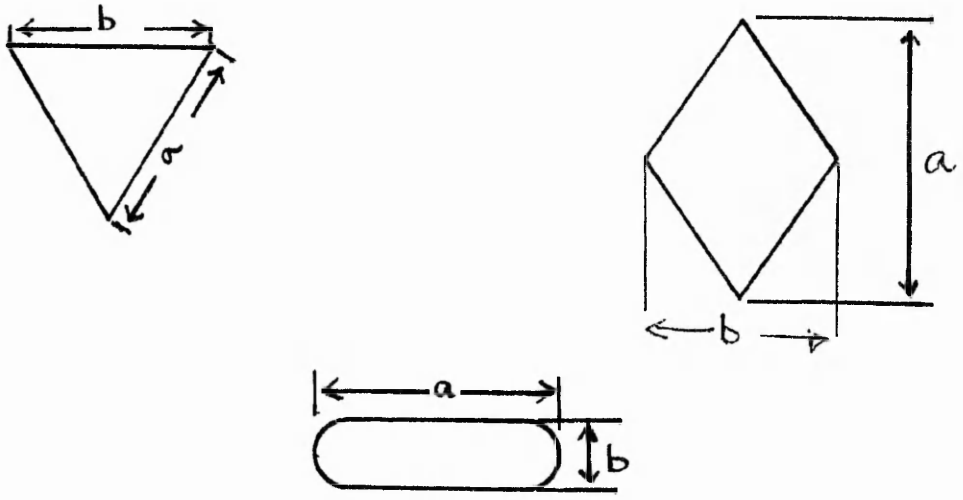
5.3.1.1.5 Shape

There was a very great variation in shape from round through oval, square through rectangular, barrel and triangular shaped.

It was difficult in some cases for the observer to allocate shapes in line with those on proforma 1 - tablets - Figure 5.3.

5.3.1.1.6 Cross Section

Like the plan, there was a great variation in shape from spherical



a and b are illustrations of the two longest sides that can be measured on a tablet

Fig 5.8 - The problem of measuring tablets

through flat to concave. There were combinations of types, e.g. flat/convex and flat/concave.

5.3.1.1.7 Edge

In the first trawl this was omitted from the proforma but it soon became apparent that edge was a most important identifier. It was omitted because at first it was reasoned that edge was a function of the cross section of a tablet, however it was included as it became obvious that edge was a separate elevation, e.g. flat, rounded, spherical (Figure 5.5).

5.3.1.1.8 Marking and Scoring Combination

This proved to be a very inaccurate way of trying to identify an attribute since the original proforma did not identify which was the "master side" of the product to associate it with markings. Neither did it distinguish between identification marks and trademarks and their association with the product's scoring and the side bearing the marks.

Identification marks were found to range from simple alphanumeric characters given to the product, as an aid to identification by their manufacturers, to elaborate trademark emblems or specialised signs, e.g. cardiac potential signs, ship etc, or combinations of these. The trademarks, when present, appeared together with or without identification marks on one or both sides of the product or in association with the product's score lines. The same applied to identification marks. There were no identification marks or trademarks on some products.

At this stage "markings" was being used as a sortable field. Some markings, identification marks and trademarks were difficult to describe accurately and were not easily reproducible by computer and could only be accommodated as accurately as possible by text fields. Its reliability as a sort field was therefore inadequate. There was also difficulty, because of the design of the scoring part of the proforma, designating the relationship of the markings to a particular side of the tablet.

5.3.1.1.9 Weight

At this stage, the weight field was not pursued as it was reasoned that it would be inaccurate because, for example, paracetamol produced by one manufacturer would be a similar size to that produced by another manufacturer, as the BP produces standards for weight and size. Therefore, weight could only be used as an additional field with which to confirm findings.

5.3.1.2 Capsules

5.3.1.2.1 Shapes

In the samples selected, there was a great variation in shape from rectangular to spherical, oval to tear shaped. Capsules could be moulded in one piece with or without seams. Some were also found to consist of two parts, cap and body: the cap overlapping the body, and may be sealed to it by a coloured band.

5.3.1.2.2 Colour

Unlike tablets, capsules were frequently found to be multi-coloured, i.e. body and cap of differing colours. Similarly, where bands were

present they may be of any colour.

Where capsules were clear, they may be tinted or they may be opaque and clear, or tinted and clear.

5.3.1.2.3 Contents

Where a capsule was clear or tinted its contents could be seen. The contents provided another attribute for identification, e.g. liquid, paste, powder or granules. There appeared to be no difficulty in identifying these.

5.3.1.2.4 Contents' Colour

The colour of the contents could also form a further identification attribute from a single colour to multicoloured granules.

The colour of the contents was judged to be that seen through the coloured or clear coating, i.e. the capsules were not opened to identify the contents colour.

5.3.1.2.5 Size

The size of capsules presented no problems, the length being easily measured and determined and the width being the maximum width of the product. Where a cap is present, the width over the cap, i.e. maximum width of capsule, was used. Care was necessary to ensure the micrometer did not distort soft capsules.

Measurements were made to the nearest mm.

5.3.1.2.6 Markings

Like tablets, markings consisted of identification marks and trade marks, either individually or in combination. Sometimes they were repeated on the body and cap. On some capsules there were no identification marks or trademarks.

Some trademarks and identification marks were difficult to describe accurately and are not easily reproducible by computer. These are best accommodated as accurately as possible by text fields. However, at this stage "markings" is a sortable field.

There was also difficulty because of the proforma 1 - capsules (Figure 5.4) design in designating the relationships of the markings to a particular portion of the product.

5.3.2 MODIFICATIONS

5.3.2.1 Capsules and Tablets

These were made after the results from the data base, populated from proforma 1 - tablets (Figure 5.3) and proforma 1 - capsules (Figure 5.4), were analysed.

5.3.2.1.1 Colour

It was apparent that after the first validation that colour was going to be a problem due to:

1) individual perception
2) fading of products' dyes
3) reaction with other products or body fluids.

These problems were confirmed on inspection of results in which, for example, browns, beiges and yellows were interpreted differently by up to eight persons completing the proformas. For the same reason, the conventional method of using standard colour strips for comparison was ruled out for the reasons of individual perception.

It was decided in the next validation phase to use a system of fuzzy matching. In this system the colours entered on to the proforma were matched by the computer program to a group of related colours from which the original may possibly be identified.
This is illustrated in Table 5.1

ORIGINAL COLOUR	Orange	Red	Blue	Brown	Yellow
FUZZY MATCH	yellow	orange	violet	yellow	cream
	red	pink	pink	black	brown
	gold			orange	green

Table 5.1 - The principle of "fuzzy match" colour

The program thus indicated exact and near matches. Thus, if a product did not have the exact matching attributes, e.g. markings, shape etc., the near match file could be inspected for these attributes.

This was applied to all attributes of tablets and capsules that were associated with colour, e.g. layers, contents and bands.

5.3.2.1.2 Weight

The results showed the majority of tablets that were difficult to identify were white and of similar sizes. A small batch of these 50

were measured and weighed and it was found that for a similar size the tablets were almost identical in weight. This would therefore be an unsatisfactory attribute on which to base identification. Similarly, the weight of a tablet or capsule could vary significantly on its contact with body or other fluids or on its storage conditions.

This field was, therefore, removed from subsequent proformas for both tablets and capsules.

5.3.2.1.3 Markings

Because of the difficulty of describing markings, e.g. cardiac action potential output sign, lion, ship etc, or identification being made to specially configure them, e.g. 200, 0404 it was reasoned that these would be put in as descriptive text. In order to overcome the difficulty of ensuring the same method of description for each product, the field was removed from the sort programme and used only to confirm the findings of the previously sorted fields.

5.3.2.2 TABLETS

5.3.2.2.1 Appearance

From the number of queries raised during the completion of proformas, it became obvious that this attribute was very difficult to identify accurately. This was due to modern manufacturing techniques as it was difficult to distinguish between film-coated and sugar-coated products. In some cases reference had to be made to the original containers or data sheets.

This would be unsatisfactory for product identification purposes where

these were not available. It was therefore decided to increase the number of possible entries in the modified proforma to four: matt, eggshell, shiny and speckled.

5.3.2.2.2 Shape

Accurately determining the shape of some tablets, which could be mistaken for other shapes, e.g. round and octagonal, presented a problem.

It was, therefore, reasoned that errors could be reduced by applying the fuzzy matching principle to shape by grouping similar shapes together (Figure 5.5). By using this method it should be possible to reduce errors caused by interpretation.

5.3.2.2.3 Size

The problems that were experienced in determining the size of tablets were overcome by formulating a rule.

The measurements would be taken at the two longest dimensions, in some cases they may be equal, e.g. equilateral triangles. No distinction would be made in the proforma of length and width. The computer program compared the dimensions with those held for other products in the data base.

5.3.2.2.4 Thickness

Thickness had been previously omitted from proforma 1 - tablets (Figure 5.3). It was now reasoned that, certainly in the case of tablets, it was an important identification attribute, especially of tablets of a

similar diameter and colour (proforma 2 - tablets - Figure 5.9).

5.3.2.2.5 Scoring and Marking Combinations

Scoring and marking combinations proved extremely difficult to input onto the original proforma for the reasons already discussed. Because of the large number of combinations available, it was reasoned that it was not practicable to list them all and to expect personnel to identify accurately every combination.

The proforma 2 - tablets (Figure 5.9) was therefore modified to include a section on categories associating scoring and marking on tablets as shown in Table 5.2.

SIDE 1	SIDE 2
Identification mark No score	Identification mark No score
Trademark. No score	Trademark. No score
Identification/Trademark No score	Identification/Trademark No score
Identification mark + 1/2 score	Identification mark + 1/2 score
Trademark + 1/2 score	Trademark + 1/2 score
Identification/Trademark + 1/2 score	Identification/Trademark + 1/2 score
Identification mark + 1/4 score	Identification mark + 1/4 score
Trademark + 1/4 score	Trademark + 1/4 score
Identification/Trademark + 1/4 score	Identification/Trademark + 1/4 score

Table 5.2 - The category associated with scoring and marking on tablets.

No distinction was made of sides bearing markings. The computer program compared the sides of products bearing markings to

TABLETS

APPROVED NAME

FIRST COLOUR *

WHITE	YELLOW	RED	PINK	GREEN	CREAM	SILVER
GOLD	ORANGE	BLUE	VIOLET	BROWN	BLACK	GREY
BEIGE	PEACH					

SECOND COLOUR *

WHITE	YELLOW	RED	PINK	GREEN	CREAM	SILVER
GOLD	ORANGE	BLUE	VIOLET	BROWN	BLACK	GREY
BEIGE	PEACH					

THIRD COLOUR *

WHITE	YELLOW	RED	PINK	GREEN	CREAM	SILVER
GOLD	ORANGE	BLUE	VIOLET	BROWN	BLACK	GREY
BEIGE	PEACH					

APPEARANCE *

MATT EGGSHELL SHINY SPECKLED

SHAPE PLAN *

ROUND	HEXAGONAL	SQUARE	TRIANGULAR		PELLET
OCTAGONAL	PENTAGONAL	DIAMOND	OVAL	SPHERICAL	BARREL

CROSS SECTION *

SPHERICAL CONVEX/CONVEX FLAT/FLAT CONCAVE/FLAT OVAL CONVEX/FLAT CONCAVE/CONCAVE

EDGE *

FLAT BEVELLED ROUNDED

SIZE *

SIZE 1.....MM SIZE 2.....MM THICKNESS.....MM

SCORING/MARKINGS RELATIONSHIP *

SIDE 1		SIDE 2	
IDENTIFICATION MARK	NO SCORE	IDENTIFICATION MARK	NO SCORE
TRADE MARK	NO SCORE	TRADE MARK	NO SCORE
IDENTIFICATION&TRADE MARK	NO SCORE	IDENTIFICATION&TRADE MARK	NO SCORE
IDENTIFICATION MARK	1/2 SCORE	IDENTIFICATION MARK	1/2 SCORE
TRADE MARK	1/2 SCORE	TRADE MARK	1/2 SCORE
IDENTIFICATION & TRADE MARK	1/2 SCORE	IDENTIFICATION & TRADE MARK	1/2 SCORE
IDENTIFICATION MARK	1/4 SCORE	IDENTIFICATION MARK	1/4 SCORE
TRADE MARK	1/4 SCORE	TRADE MARK	1/4 SCORE
IDENTIFICATION & TRADE MARK	1/4 SCORE	IDENTIFICATION & TRADE MARK	1/4 SCORE

MARKINGS

PROPRIETARY NAME

MANUFACTURER

* SORTABLE FIELDS

Fig. 5.9 Proforma 2 tablets

provide accurate matches.

No attempt was made at this stage to identify trademarks or identification marks.

If no identification marks were present then that tablet was classed as unmarked. Unmarked tablets were used as a positive attribute to distinguish them from products that may have been damaged by erosion or rubbing etc.

5.3.2.3 CAPSULES

Apart from the variation in colour due to the reasons already discussed for tablets, no alterations were made to proforma 1 - capsules (Figure 5.4) with the exceptions of fuzzy matching within the program for the colour section and the removal of the weight section. This led to proforma 2 - capsule (Figure 5.10).

5.4 CONCLUSION

The results show that the modelling appears to be satisfactory and can classify the entity type medicinal product according to its entities. However, the practicality of many products having similar size, colour, markings etc, will preclude a complete individual identification of all products.

Further testing is needed to fully validate this part of the project.

CAPSULES

APPROVED NAME

BODY COLOUR *
WHITE YELLOW RED PINK GREEN CREAM SILVER
GOLD ORANGE BLUE VIOLET BROWN BLACK GREY

CAP COLOUR *
WHITE YELLOW RED PINK GREEN CREAM SILVER
GOLD ORANGE BLUE VIOLET BROWN BLACK GREY

BAND COLOUR *
WHITE YELLOW RED PINK GREEN CREAM SILVER
GOLD ORANGE BLUE VIOLET BROWN BLACK GREY

APPEARANCE *
OPAQUE OPAQUE & CLEAR OPAQUE&TINTED TINTED & CLEAR CLEAR

CAPSULE CONTENTS *
NOT VISIBLE PASTE LIQUID POWDER GRANULES

CONTENTS COLOUR *
WHITE YELLOW RED PINK GREEN CREAM SILVER
GOLD ORANGE BLUE VIOLET BROWN BLACK GREY MULTICOLOUR

SHAPE *
CYLINDRICAL TEAR SHAPED OVAL OVOID SPHERICAL

SIZE *
LENGTH.....MM... WIDTH.....MM.

MARKINGS

PROPRIETARY NAME

MANUFACTURER

* SORTABLE FIELD

Fig. 5.10 Proforma 2 capsules

6. GENERAL DISCUSSION

The introduction showed that although there are many coding systems in use for medicinal products, they are each designed for a particular application. No existing coding system can be applied immediately to provide unique identification of a medicinal product and at the same time provide a comprehensive view of the attributes of that medicinal product. Some are ad hoc serial codes. Others are based on rational criteria but the medicinal product is the end-point of a process such as prescribing. Many dispensing-oriented systems, such as those available in community pharmacy computing systems, are limited in function, usually to the production of labels, stock control and maintenance of simple patient records. No code allows the facility of automatic checking for potential overdosage when two or more products are prescribed. Most codes are simply a link between the user and a look-up table, which is usually textual. This, therefore, relies on the user reading and interpreting the textual information. In this study a structured code has been developed which provides unique product identification, from which product attributes can be identified and, in particular, dosage calculations made, thus allowing for automatic checking during dispensing and prescribing.

Whilst there is nothing wrong with the premise of designing systems to meet users' perspectives, it does mean that different classifications and codes have to be designed for each user or existing codes modified for each user. As none of the systems satisfies the requirements of all users, the confusion will continue until a comprehensive system is adopted. Green (1990) states that if an existing code is modified to

meet a particular use, the code loses consistency and flexibility, adding to the confusion of codes available. The answer, therefore, is to determine a cohesive information architecture for medicinal products that encompasses the relevant pharmaceutical functions. The components of the information architecture can then be used as required. In devising a coding system it is then possible to contextualise it within the information environment of its use.

Modelling of information architectures is a technique gaining strong ground in the engineering and building spheres. In these areas, product models are being developed to encompass all the perceived information requirements, which can be used to produce flexible information systems suitable for computer applications (Björk, 1989, 1991; Sanvido, 1990; Wierda, 1991; Corrigall, Lee, Young and Bell, 1992).

Using product modelling as a method for developing a coding system has the advantage that the code is based on a more comprehensive or top-down view, rather than methods based on experience alone or from the narrow perspective of those codes developed for particular purposes.

The top-down view of product modelling is reflected in the objectives and hence the conduct of this project.

Objective (a) was to investigate all the activities of a hospital pharmaceutical service and their relationships with other disciplines within the service as well as their relationships with bodies outside the service (e.g. commercial suppliers, Department of Health, Royal

Pharmaceutical Society), in order to draw up Business Activity Models, Data Flow Diagrams and Logical Data Flow Diagrams.

The processes to achieve this objective were shown in Chapter 2, "Definition of Entities Associated with Pharmacy."

The method of investigation proved satisfactory in that the activities of a hospital pharmaceutical service and their relationships were identified. The Business Activity Models, Data Flow Diagrams and Logical Data Flow Diagrams were very detailed. These are, of course, high level product models. At these levels, an individual product and its data are invisible but the environment in which it exists is conceptualised. Even at these high levels, the comprehensiveness and accuracy of the models are essential. This was obtained from the in-depth contributions from workshops and interviews. The need for accuracy and comprehensiveness in product modelling is reiterated by Wright, Lockley and Wiltshire (1992), writing from the School of Architecture, University of Newcastle Upon Tyne.

Moving down a level focuses on objective (b) which was to determine the basic entities that constitute the pharmaceutical service.

This part of the project identified 200 entities, many of which are common to many different processes encompassing all the pharmaceutical activities investigated.

Objective (c) was to identify whether the entity type MEDICINAL PRODUCT was a major entity type in the activities of a hospital

pharmacy and other associated activities, e.g. wholesaling and prescribing. If so, to model the entity type on a theoretical basis, based on the legal requirements of the Medicines (Data Sheet) Regulations, 1972.

This part of the research showed that of the 200 entities identified, the entity type PRODUCT was present in 57% of the entity types. Entities of PRODUCT TYPE were also present in a further 28% of the entity types, producing a total of 85% of the entity types in which the product was represented. The methods also determined that medicinal products made up the majority of the products in the activities of a hospital pharmacy. It was, therefore, appropriate to continue with the second part of objective (c), i.e. to model the entity type MEDICINAL PRODUCT on a theoretical basis, based on legal principles.

As a starting point, it was reasoned that this was the correct way of proceeding with the modelling, since this would provide a basis of the minimum of information required by law (Medicines (Data Sheet) Regulations, 1972) to which other non-legal information could be added as the research progressed. This proved to be a satisfactory basis and the models were developed and discussed in Chapter 3 - "Development of a Theoretical Data Model for Medicinal Products."

The model is in effect a "legal" description of a medicinal product. One difficulty that presented itself in defining this model was the catch-all section, "Further Information". This information is likely to be unstructured and variable in content, thus rendering the type of

information unamenable to practical automated use. It could be argued that any further information to assist the practitioners could include all information about medicinal products. It was, therefore, decided to adhere to the specifically mentioned requirements of the Medicines (Data Sheet) Regulations, 1972, which were used as a basis for the legal model. The addition of entities under non-legal aspects provided a comprehensive model for all users, including practitioners defined under the Medicines Act, 1968.

At the outset, because "legal information" was used, there may have been a possibility of redundant information being included. However, this was found not to be the case. Björk (1989) of the Laboratory of Urban Planning and Building Design, Technical Research Centre of Finland and Sanvido (1990) of the Department of Architectural Engineering, Pennsylvania State University, agree that an important principle in product modelling is the identification of redundant information. This is essential so that there is no potential conflict of terminology.

The complete model at this stage provides a theoretical, comprehensive picture of the entities involved with the entity type MEDICINAL PRODUCT from manufacturer to final user of the product. It can also be used to classify medicinal products, using the identified entities either singly or in any combination, e.g. name, name and dose or name with form and strength etc.

Objective (d) was to develop a model based on practical requirements and out of this develop a product code. Throughout this part of the

project, the "practical" model was compared with the "legal" model to ensure comprehensiveness and adherence to the principles of the Medicines (Data Sheet) Regulations, 1972. Since the "practical" model requires adherence to legal principles then all the entities and their relationships in the "legal" model are inherent in the "practical" model.

During this part of the project it was found that to develop satisfactory models, many modelling sessions were required, together with "sounding sessions" with colleagues in the fields of systems analysis and pharmacology. This ensured the accuracy and comprehensiveness of the model. The "practical" model provides an information architecture for the entity type MEDICINAL PRODUCT. The entities comprising the information architecture for MEDICINAL PRODUCT are listed in Appendix 5. The uses of these entities in the various processes, e.g. prescribing, dispensing and wholesaling, are illustrated in Figure 6.1, which shows the elements used in many activities. The information for prescribing, ordering etc. is usually obtained from textual sources: prescribing via BNF or Data Sheets, ordering from catalogues, drug information, adverse reactions and interactions from Data Sheets.

Commonly used information was identified from the models and used to construct a coding system that not only uniquely identified a medicinal product without duplication but also carried the commonly needed information in its structure.

Populating the models and codes throughout their definition proved a

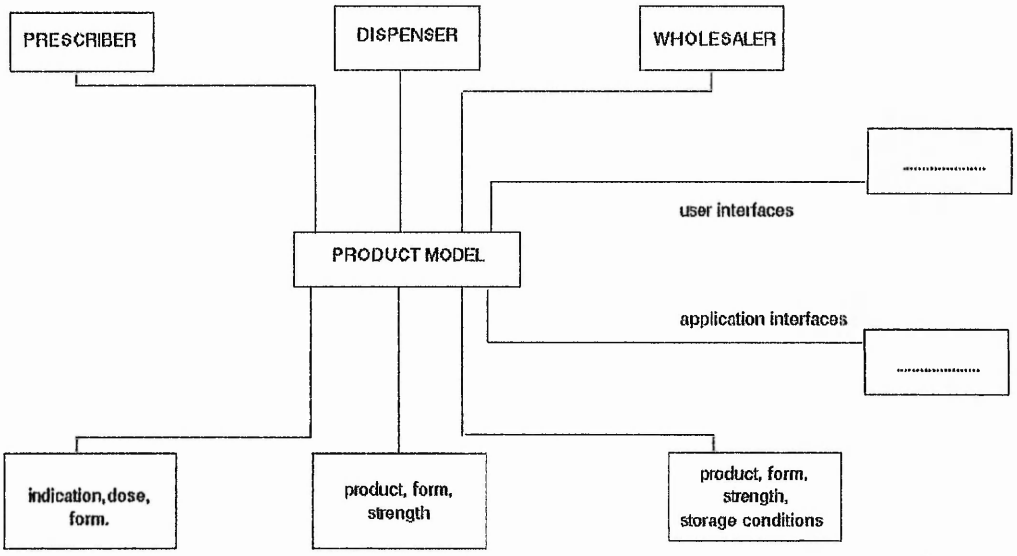


Fig 6.1
Feature-based product model as the central data base for several medicinal 'supply' disciplines and applications (adapted from Wierda, 1991)

valuable way of checking their validity. This was essential since any occurrence (and only one was needed) where data did not fit the models, codes or algorithms meant that the model or code was inadequate.

The researched code and the information architecture were validated by pharmaceutical and nursing staff using the Prescribing and Administration System designed for use in the South Lincolnshire Health Authority. The code, when input into the system, identified products uniquely and provided prescribing information on route, form, strength, base unit, modified product, species etc. When linked with other products containing identical ingredients, the system provided information on summed doses, thus alerting the prescriber to potential overdoses. Linkage of the code to other parts of the information architecture, e.g. PATIENT CHARACTERISTIC, provided dosage calculations related to a patient's surface area. Links were also validated to product warnings, interactions and labels.

The development of the "practical" models and product codes showed the importance of the validation step, as both needed to be amended until models and data were concurrent. It did highlight some problem areas, e.g. the problem of multi-route products where a single product form may have a multi-route application. This was discussed in chapter 4.

As part of the validation process, the concept of classifying products from the model was addressed. This was investigated in order to test the validity of those parts of the models not involved in the coding process.

To this end the model illustrating the relationship of the entities, FORM and APPEARANCE to MEDICINAL PRODUCT, was populated and a computer program written on the basis of the model - Chapter 5.

The results showed that the modelling was satisfactory and that it was possible, using the program developed from the model, to classify a medicinal product according to its characteristics. However, the practicality of several products having a similar size, colour, markings etc. precluded a complete individual identification of all products.

The objectives of the project having all been met, it is now necessary to discuss the implications of using product models to determine an information architecture and of using the architecture to determine a code for unique product identification and the implications and uses of the code.

6.1 Information Architecture and Product Models

Literature searches showed little has been published about medicinal product data modelling, except NETHRA (1989), SESAME (1990c), NHS IMC (1991) and Thompson (1991), although there are many published papers related to data modelling in other disciplines, such as those by Björk (1989 and 1991), Wix (1989), Sanvido (1990), Wierda (1991) and Corrigall et al (1992).

Ideally, modelling requires that for the product in question, in this case medicinal products, the way the product models and associated information are derived and structured is to encompass all the

attributes associated with the medicinal product. This view of completeness of product models is confirmed by Gielingh (1990) and Smith (1986). According to Wright, Lockley and Wiltshire (1992), the 'completeness', discussed by Smith and Gielingh, is only true for a closed system, that is, one in which the boundaries of the study are completely defined. It is always possible to find applications which require data that are not contained within a closed product model. This implies that if such data are required then a new model has to be developed to take account of the developments. Such an example is seen in the code in use at the Prescription Pricing Authority for the PACT coding system. This system was developed out of the BNF codes, which could be considered closed but not capable of unique identification of products. The PACT application required additions to the BNF codes to give individual product codes.

Whilst the PACT application itself can be considered closed, it is not global. The Prescription Pricing Authority is going to repeat the development process in producing systems to take account of Nurse Prescribing and Paperless Prescribing (Alexander, 1993; Ball, 1993). When the PPA's PCA system is taken into account, it can be seen that three or more coding systems, which are inconsistent, will soon be in use in one major pharmaceutical organisation.

Considering the diverse nature of pharmacy practice and its expansion due to the advent of computerisation (Calder, 1993), it is incongruous that this is happening. According to Love (1989),

> "Estimates suggest that 25% of a transaction cost can be data entry and re-entry, while 70% of all computer output is re-entered into other computers."

If a truly global model is developed, the information architecture should provide information from its modules that can be useful to many professionals, when user and application interfaces are designed and used, Figure 6.1. Ideally, compatible systems could be developed allowing the full potential of electronic data interchange to be met, accompanied by streamlining of data processing.

Björk (1989, 1991), Wright, Lockley and Wiltshire (1992) and Wierda (1991) state that a data model should be comprehensive. The "legal" model is complete from the Medicines (Data Sheet) Regulations, 1972 point of view. However, from a practical point of view, some extra areas had to be added. In addition, some areas of the total model have not been addressed in depth. The models could be considered to be comprehensive but incomplete. This is in line with the views of Spur, Krause and Armbrust (1986) of the Institute für Werkzeugmaschinen und Fertigungstechnik Technische Universität Berlin, who state

> "A product model must not necessarily contain all informations within all its possible information layers. Certain layers might be incomplete, because they are, for instance, still "under design"."

The data models could be extended beyond the bounds of this project to include manufacturing information for medicinal products, e.g. pressure in tableting machines etc., along the lines of mechanical engineering processes, which are well documented by Wierda (1991). Such an extension would be beyond the bounds of this project, which should be seen as an in-depth study of only one part of a much greater product model.

Throughout the project, the data models were constructed so that they could be easily updated. This accords with the view of Björk (1989),

> "A building product model should also be capable of smooth continuous growth, as new design decisions are made and recorded in the product model."

A similar view is held by Wix (1989). The models were constructed so that additional entities may be added to the information architecture without disruption to the total model. For example, sub-product models may also be added to provide manufacturing information (Spur, Krause and Armbrust, 1986; Wierda, 1991).

Wright et al (1992) refer to sub-product models as specialisation of data models in which more detailed models of specialist areas are produced from an overall data structure. In this project, it is considered that MEDICINAL PRODUCT is a sub-product model of the generic entity type PRODUCT. It has its own information architecture defined for a particular application. This process is supported by Wright, Lockley and Wiltshire (1992) who say:

> "For a given domain, increasing specialization results in a product model which, compared to the original data set:
> - is suited to a particular set of applications
> - has a compressed data set [i.e. the entities can be coded or labelled]
> - incorporates specific domain knowledge [in this case legal requirements and practical experience]
> - contains more assumptions."
> [B H Thompson's comments]

The way in which the product models were produced, together with their structure, allows not only additions of new sub-product models but also linkage to other systems via the entity types within the models. Thus a clinician could make a diagnosis coded to ICD-9 (1977), ICD-9-CM (1980), OPCS-4 (1987) etc. and through linkage of these to INDICATION would be able to access all the information in the information architecture. Links could also be extended to incorporate existing codes such as Read, BNF and ATC codes, thus allowing

continuation of current practices and systems but bringing in the advantages of a new code with its information architecture to facilitate prescribing and dispensing practice. A dispenser, to obtain the information necessary for the task, could link into the same information architecture at the unique product identification level by means of the information already defined, viz. name, strength, form, form detail, species, base unit, base unit size and associated units. The requirement for extending a product model and its linkages is confirmed by Björk (1989) and Sanvido (1990).

The fact that the entities or modules of the information architecture have no special spatial relationship to each other, provides the user with an information system in which the components can be used in any order or combination. This was illustrated in chapter 5 where the physical attributes of a medicinal product were modelled and the model tested. The aim of the test was to see if a product could be identified from its physical characteristics: the type of exercise performed when unknown tablets or capsules are submitted for identification. The model was validated in that the subsequent program identified products by appearance, size, colour etc. It may be assumed that the lower the level of the model, the more precise is the detail it will provide. This is perhaps true in the philosophical sense. In practice, it was found that because so many products were of a similar size, shape, colour and had similar marking characteristics, it was impossible to produce unique identification. The model itself was validated in that it could identify correctly the products with identical physical characteristics. In an exercise to get unique identification of an unknown tablet or capsule, further information

such as chemical analysis would be needed. The chemical techniques that could differentiate products could be incorporated into the product model, which is growth of the model as suggested by Björk (1989) and Wix (1989) for data models.

This implies, therefore, that in a product model of pharmacy, the information determined, together with its relationships, will form an information architecture. The 'bricks' of the architecture can be assembled or used in any combination, if the information is defined and is used on a 'global' basis. The entities of the "practical" MEDICINAL PRODUCT model are the bricks and are listed in appendix 5.

This then strengthens the argument for the use of product models in determining an information architecture from which modules can be selectively used or to which modules can be added when necessary, e.g. computer controlled manufacture as shown by Wright, Lockley and Wiltshire (1992).

One problem associated with many systems, manual or computerised, especially when the latter is used to communicate with other computerised systems, is that of information that is identical but with different names, i.e. there may be redundant information in the system or systems, e.g. uses and indications in prescribing.

Björk (1989) says,

> "Each item of information should be defined only once in the model. Because of this, many problems that occur in manual practice are avoided."

Sanvido (1990) confirms this problem by saying that in the construction industry, information includes design information,

business information and operating information that are used widely by dispersed disciplines and individuals on a project:

> "This information is not integrated, often uses different terms for similar items; and is typically developed and owned by different organisations. This leads to redundant [duplicated] information in the various systems."
> [B H Thompson's comment]

A similar situation exists in medicine. For example, what is the definition of a child for dosage purposes? Different reference books give varying views. There is no definition and, therefore, information may be duplicated under children's or adults' dose. There is also the interchangeability of commonly used terms, e.g. uses and indications. The plethora of computer and coding systems (Sprince, 1990; Maddock, 1992; Hurley and McNeil, 1989; Ball, 1993), which cannot interpret each other's information without the use of complex look-up tables to overcome the duplication of information, adds to the problem. The Read, BNF and ATC Codes have the problem of redundancy with respect to product entries. Careful definition of entities removed the likelihood of redundancies in this project. For example, the Data Sheet definition of a medicinal product refers to uses of a product. Throughout this project it has been defined as the INDICATION FOR PRODUCT then INDICATION after careful consideration (Chapter 3). Redundancies are common problems that the protocols of SSADM (1990), used in this study, try to prevent. In recognition of the redundancy problem in the UK, the Körner Committee Report endeavoured to set out basic definitions for the administrative part of the medical record, so that there would be unity of recording and interpretation nationally (Anderson, 1986; Körner, 1982). Spur, Krause and Armbrust (1986) confirm that product model concepts avoid redundancy.

The fact that the Prescription Pricing Authority has two incompatible codes, one for pricing and one for collecting PACT data, and are about to develop codes for nurse-prescribing and paperless prescribing (Alexander, 1993; Ball, 1993), strengthens the argument for using an information architecture to rationalise the system and allow interchange of data between functions. The relevant elements of the information architecture could be coded and used to provide any product information, thus eliminating the need for several codes.

6.2 Coding

Björk's (1991) definition of a product model as a conceptual description of a product, although in building terms, translated to medicinal products allows an information architecture to be established that provides all the information necessary to establish a medicinal product code. Some of the entities from the information architecture of the medicinal product data model were used to determine whether or not a modular code, carrying usable information in its structure and providing unique identification for medicinal products, was possible. Because of the nature of the product model, the researched product identification code can be linked to any of the other information available within the model (Wright, Lockley and Wiltshire, 1992). The code as designed, as well as giving unique identification, has most of the characteristics defined by Murray (1985), which are listed in the introduction. Green (1990), an archivist from the Somerset Record Office, and Williams (1990), an archivist employed by the Gwynedd Archives and Museums, confirm that Murray's characteristics are recommended. Importantly, other attributes of a product can be identified that may be of use, not just

for identification purposes, but to classify and manage recorded information (Sanvido, 1990).

Because a code represents reality, classification of information from it depends on the perspective of the user. For example, a prescriber may need only information on indications and doses whilst a dispenser will need strength and pack size information. Therefore, it makes sense to determine all the characteristics of a product that may be coded to form a product code irrespective of the user. Portions of the complete code can then be used by all the individual users according to their needs.

> "The coming of the automated system alerts us all to the need for more consistent data analysis and description: reference coding is one small but vital part of the challenge to be better information professionals." (Green, 1990).

Some of the characteristics, which are represented by the entities of the product model have been coded, i.e. given a compressed data set (Wright, Lockley and Wiltshire, 1992; Davies and Read, 1993), in order to research a product code that is suitable for a particular application, i.e. unique identification of medicinal products. To enable this, the experience and knowledge of the pharmaceutical profession have been essential and have been an important part of the project. This is the use of specific domain knowledge, referred to by Wright, Lockley and Wiltshire (1992).

The introduction showed that, apart from serial codes and the PACT codes giving unique identification, no existing pharmacy coding system dealt with all the requirements of a hospital pharmacy. So, what type of code would be suitable? It has already been shown, in the

Introduction, that there are basically only two types of code, hierarchic and linear: any others are hybrids of these types. An advantage of linear codes over hierarchical ones is that it is easier to classify data according to the value of elements of the code. In a block linear code, the meaning of the code depends only on the block it is in. In a hierarchical system the meaning of the code depends not only on the block it is in but often also depends on the meaning of the higher level data, in other words what branch it is on.

A hierarchical code that addresses this problem is the CI/SfB system used by the building industry. The CI/SfB system was designed to provide an indexing system and codes for building construction, referencing plans and documents (Ray-Jones and McCann, 1971; Ray-Jones and Clegg, 1976). This system is a coded hierarchical classification system with five levels of decomposition (Ray-Jones and Clegg, 1976). In order to avoid the problem of a code having a meaning that is dependent on the branch of the hierarchy, the CI/SfB system has a unique set of codes for each branch and is presented in a modular form. These factors allow classification of information according to the values of a segment of the code. However, the code does not allow the classification of individual products without the addition of local information. Inherently there is nothing wrong with local information, provided that all the users understand the additions (Green, 1990). In fact, the CI/SfB system, because it is primarily an indexing system, illustrates a fundamental philosophical difference between a simple code and a coded classification system. For example, a brick is a brick (disregarding the different types of brick for the time being). In product terms it does not matter where a brick is used. However, in CI/SfB terms, a brick used for an external wall is

not the same as a brick used for an internal wall. That is, the total code would be different and there would be more than one code for a product. Is it possible within the CI/SfB system to separate the brick characteristics from its use? Yes, but it has limitations. Within the CI/SfB system, level 0 identifies the physical environment, e.g. hospital, level 1 identifies the element such as building fabric, level 2 identifies the construction/form, and level 3 identifies the materials. These are classification criteria. Because the CI/SfB has a unique set of codes for each branch of the hierarchy, it is possible when coding for a brick to ignore levels 0 and 1. So, proceeding with the coding for a brick from level 2, the construction/form is brickwork/blockwork/bricks/blocks, (coded as F, and material is clay (dried, fired), coded as g2, so a brick = Fg2 (Ray-Jones and McCann, 1971; Ray-Jones and Clegg, 1976). However, this gives neither a size nor a type but, equally well, this codes for a brick wall. To define brick size or type, level 4 is needed, where size is coded (F4). However, (F4) is only a coded index heading not a code for an actual dimension. It is still necessary to add the dimensions locally, which is not recommended, for a good coding system (Green, 1990). In addition, adding the local codes can produce ad hoc lengthening of the code. In order to code for the appearance of a brick, a completely new code will be required. Since appearance, which is given the code (G1), like size, is a level 4 criterion, its code is not just an addendum to the code for a brick of a certain size. The data about appearance still has to be added locally. The two branches from brick to size and to appearance obviously lead to redundancy.

To overcome this, it is advocated by Ray-Jones and Clegg (1976) that

the two values are combined in the same code segment. For example, for a brick the two codes for size and appearance are respectively Fg2(F4) and Fg2(G1), which could be abbreviated to Fg2(F4:G1). Aggregating classes from the same level will alter the length of the code on an ad hoc basis. Aggregation of code segments to avoid redundancy produces, in effect, a linear code within an hierarchical structure. But the codes are only indexing values not coded data values. The data values still need to be added locally, further complicating the code. This may be satisfactory if the objective of the classification is to reference normal project information and for in-house use only. However, the authors state:

> "In some cases (e.g. for computer applications), a fixed code length will be needed."

A point that is also supported by Murray (1985).

Since the CI/SfB system is capable of coding for the characteristics of a building product, albeit after the addition of local codes, could it be used to code for the characteristics of medicinal products and produce unique product identification?

If the overall organisation of the indexing system is taken into account, it is clearly an hierarchical system, which was devised not from the perspective of the product but from the perspective of building design. As such, it is the building equivalent of the BNF, Read and ATC codes. All have the problem of redundancy that is inherent in hierarchical systems. While the PPA for PACT purposes has used the BNF as the basis of its coding system, it has had to sort out the problem of redundancy by the use of ad hoc rules. Any attempts to produce a medicinal product code based on the CI/SfB would run into

the same difficulties as exist in current medical hierarchical codes. In designing a code, the type of structure and the code elements have to be rationally chosen. It is possible that the coding structure may resemble those in other fields. If the codes of other disciplines were to be used as a basis of a new code, unless they were considered in the context of pharmacy, the results may not be satisfactory. They would not have been designed originally for pharmacy and may have missing or surplus elements. Such modifications of an existing system to fit it for another purpose are not recommended (Green, 1990). If, therefore, an existing code would need modification to meet the requirements, it would be better to start ab initio. The code would be designed specifically to meet the profession's requirements rather than be one that may be non-rational in its organisation or possibly easily corrupted (Green, 1990). In considering the modifications that may be needed to amend an existing system, as much effort could be expended as in a custom design.

No existing code for medicinal products is based on a product model but several are based on hierarchical classification systems. Classification systems are often driven by semantics and as such are liable to change as the meanings of different classes are amended. Thus classifications alter to accommodate changes and are therefore not permanent. A code tied to such a system could produce ambiguity and is likely to alter as definitions alter. A code, therefore, should only embrace characteristics of a product that will not change, e.g. form, appearance, strength etc.

When considering a coding system, it was decided to choose a linear

code to avoid the problems inherent in an hierarchical one, particularly redundancy. The code is modular, based on the characteristics and properties of medicinal products that can be assessed objectively. These properties, by not being defined according to subjective criteria, are unlikely to be subjected to change in interpretation and are therefore likely to endure. Other entities are not easily coded, e.g. indications or patients' characteristics, but like those that were, are clearly defined in the model.

Briz-Kishore and Avadhanulu (1983) had a similar problem with hydrogeological data. They found that in order to produce an efficient computer code for monitoring hydrogeological data they required a block code based on objectively measured characteristics. They needed to identify uniquely a well's basin number, well number (and name) and also the serial number of the operation and the reference level of the well before they could analyse the observed level of the well. If the value of any of the characteristics changed then they had a "new well". They concluded that the characteristics needed to be assembled into a block code consisting of five modules.

Development and analysis of code structure for medicinal products (chapter 4) started with a three module code, based on name, strength and form, which are the basis of information provided by many pharmacy systems, including the textual fields in the Read Code Drug Dictionary. Unique identification was not obtained with 100% of the products until the code had been expanded to include ten of the commonly-used objectively-defined modules.

Having produced the product model and having used parts of it to generate a product code, does all of it need to be coded? The answer here is probably no, since some parts do not lend themselves easily to coding, e.g. indications. These are basically textual entities that are very difficult for computer software to interpret and where there is often a great deal of debate about meaning. In fact, a whole science of medical information has grown up around this area in which semantics form a large part (Markwell, 1993). Attempts have been made to classify and code these areas using systems such as the Read Clinical Codes (Davies and Read, 1993), the OPCS-4 (1987), ICPC (1987) and CEN/TC251/PT0025/N23 (1992) systems etc. It was previously argued that a product code should be based on only information which is unlikely to change. Other parts of the model not used in the product code may lend themselves readily to coding, while others may not. These parts, whether coded or not, can be linked easily to the product code, which form the "handles" to access them. In a global information architecture, the product model would cross-reference to the clinical classification systems. It is even possible that, for example, the Read Clinical Codes could provide codes for indications.

The modules of the information architecture that were found necessary to identify a medicinal product uniquely are illustrated in Figure 6.2.

The researched code consists of 20 characters grouped into 10 modules. Unlike other codes for medicinal products, part of the researched code is characterised by name characters. In fact the code is structured in such a way as to allow some user-significance to the name,

	NAME CHARACTERS	STRENGTH		FORM	FORM DETAIL	ROUTE FOR FORM	SPECIES	BASE UNIT	BASE UNIT SIZE	BASE UNIT UNITS
		MAGNITUDE	UNITS							
	AAAAA	NNNN	N	A	A	A	AA	.A	NNN	A
Number of characters	5	4	1	1	1	1	2	1	3	1

Figure 6.2 The structure and character numbers of the final product code.

strength, form and route for form modules, all or any of which may be used to access product information. Green (1990) holds the view that a short alphabetic-numeric sequence would provide the necessary simplicity and short-term memorability when accessing the complete code. This view was also expressed by Murray (1985) who states,

> "It should be **meaningful** (i.e. the code should convey to the user at least some information on the data item represented)."

If the code is meaningful (Murray, 1985) then the likelihood of mistakes is reduced and the user can associate part of the code with the product.

What, therefore, are the advantages of having some meaningful portions? Beckley (1967) looked at possible error types. The most likely error according to Beckley (1967) is transcription. The frequency with which errors occur depends on many varied factors. The results of one of these tests are shown in Table 6.1

Type of error	Percentage Total Errors
Transcription	86%
Transposition	8%
Double transposition and random	6%

Table 6.1 - Type of error by percentage, Beckley (1967)

Beckley (1967), however, did not define the total percentage of errors made. But, any method of reducing errors must be of use in improving accuracy (Murray, 1985; Green, 1990).

The design of keyboards is also of importance but the quality of input material is also of significance. Shneiderman (1980) reports a study carried out by Segal (1975). 70 undergraduates had to list 25 of the

50 states of the United States and list 20 permutations of 'abcde' such that 'c' occurs somewhere before 'd'. The results showed that, depending on whether the students were told of their errors either during input or at the end of input, the results were as follows, Table 6.2.

	States task		Permutation task	
	Error Correcting Method			
	Immediate	End	Immediate	End
Percent error keypresses	2.55	1.99	4.54	4.48
Total time (seconds)	234.00	300.00	408.8	546.4

Table 6.2 - Average performance results for user correction styles Segal (1975)

The results imply that if meaningful data are used, the input is considerably more accurate and faster than when the data are not meaningful. This confirms the views of Murray (1985) and Green (1990). Hirsch (1976) and Hart (1976) (both cited in Shneiderman (1980)) determined the error rate for each finger. From their results, can be determined an overall average of keypress errors of 0.62%. These results are similar to those reported by Longe (1992), who in her paper states that,

> "Studies have shown that there is usually 1 error for every 300 characters of information keyed into a computer."

Whilst the error rate may be modified by keyboard design, any effort to reduce errors by providing data information in a meaningful form must be advantageous. The advantages of having accurate information input are confirmed by Love (1989).

Personal and departmental experience showed that in the dispensary the number of errors that occurred when using the Manchester System (a non-structured, serially allocated numerical system) was great. It led to the employment of extra clerical staff and to stock-loss errors because staff could not remember the codes of some 4,500 lines. Transposition errors and typographical errors occurred in the dispensing situation. There were fewer errors in the ordering situation where the pressure of work was less. However, there were many in the stock-check situation where non-technical staff had constantly to use look-up tables to ascertain the correct product. This system was abandoned due to its high error rate.

6.3 Code Application

In the prescribing situation, a clinician on a ward needs information but does not necessarily need a code to access it. For example, the BNF contains structured information for therapeutic purposes and is a publication frequently used for this purpose.

The present trend for computerised prescribing systems (Calder, 1993), could be met by providing access to an information architecture. Access to the information architecture need not only be via clinical criteria but also could be provided by entering the code for a desired product. In a prescribing situation, the identification of a product either directly or through a code is at the end of the process, which may have involved a choice of products. In dispensing, the product is at the start of the process, so therefore needs to be identified uniquely.

Furthermore, if a product can be uniquely identified by a coding system, then any information the code carries must be definitive and not open to interpretation. The product code itself will be "the handle" to other information, which may be attributed to it and will be accurate on retrieval (Neeley, 1990).

The increased threat of litigation due to negligence requires a system that provides as much information as possible at the time of prescribing, dispensing and administration together with product information throughout the life of a product. This could be provided textually by documentation but would have to be read after searching for the information at each prescribing, dispensing and administration operation. The way forward is to be able to identify uniquely a medicinal product by a rationally designed code and use the information within the code to provide as much specific information as possible either directly from the code or from the information architecture at the time of prescribing, dispensing and administration to aid those processes. This aspect of getting data from the information architecture was successfully tested on the Prescribing and Administration system used during the validation stage for the product code.

Use of part of the proposed code that can fulfil the required functions is shown in Table 6.3. This product-search facility, based on an alphanumeric sequence, is possible because the code is not just a code per se but can have its modules used as a series of database search criteria.

SECTION	SEARCH ON NAME STRENGTH FORM ROUTE	PRODUCTS LOCATED
1	AMP	Amphotericin 10mg lozenge Amphotericin 50mg ampoule Amphotericin 100mg in 5ml suspension Amphotericin buffer for injection Ampicillin 125mg in 5ml suspension Ampicillin 250mg ampoule Ampicillin 250mg capsule Ampicillin 250mg in 5ml syrup Ampicillin 500mg ampoule Ampicillin 500mg capsule
2	AMP 250	Ampicillin 250mg ampoule Ampicillin 250mg capsule Ampicillin 250mg in 5ml syrup
3	AMP 250 C*	Ampicillin 250mg capsule
4	AMP 250 O**	Ampicillin 250mg capsule Ampicillin 250mg in 5ml syrup

* capsule
** oral

Table 6.3 - Shows the effects of searching on name strength, form, route characters.

Table 6.3 shows that if the database is searched using the meaningful (Murray, 1985) portion of the code, i.e. AMP, then the ten products listed in first section of the "Products located" column will be identified. These include all the products of varying strength and form available on the data base linked to the name character AMP. If the code used for searching is AMP250, which is still meaningful, then the three products of strength 250mg linked to AMP in the second section of the "Products located" column of Table 6.3 will be located, irrespective of their form and route for form.

If the code AMP250C, which is still meaningful, is used in a search, then only Ampicillin 250mg capsules are located, as shown in section three of the "Products located" column: this being the only product that fulfils the requirement listed in the first section of the "Products located" column.

When AMP250 - (blank) O, which is meaningful, is used, then only products with the characters AMP strength 250 and route for form O (oral) will be displayed. This combination of meaningful characters derived from the code is useful for prescribers who may wish to know the available products for a route.

Should the name characters not locate the required product, then the addition of extra characters in incremental steps up to a total of five characters, following the method illustrated in Figure 4.13, will locate the product. (Five being the minimum number of name characters that were found to accommodate unique product identification, as described in Chapter 4.) The only exceptions to this were those products that required defined codes, e.g. insulin products.

In a similar manner, the way in which a prescription is translated into a label via the modules is illustrated in Figure 6.3. The structure of the coding system together with its relationships to other elements of the information architecture could allow the checking of a patient's dose.

An integral part of the code is the strength module, which, when

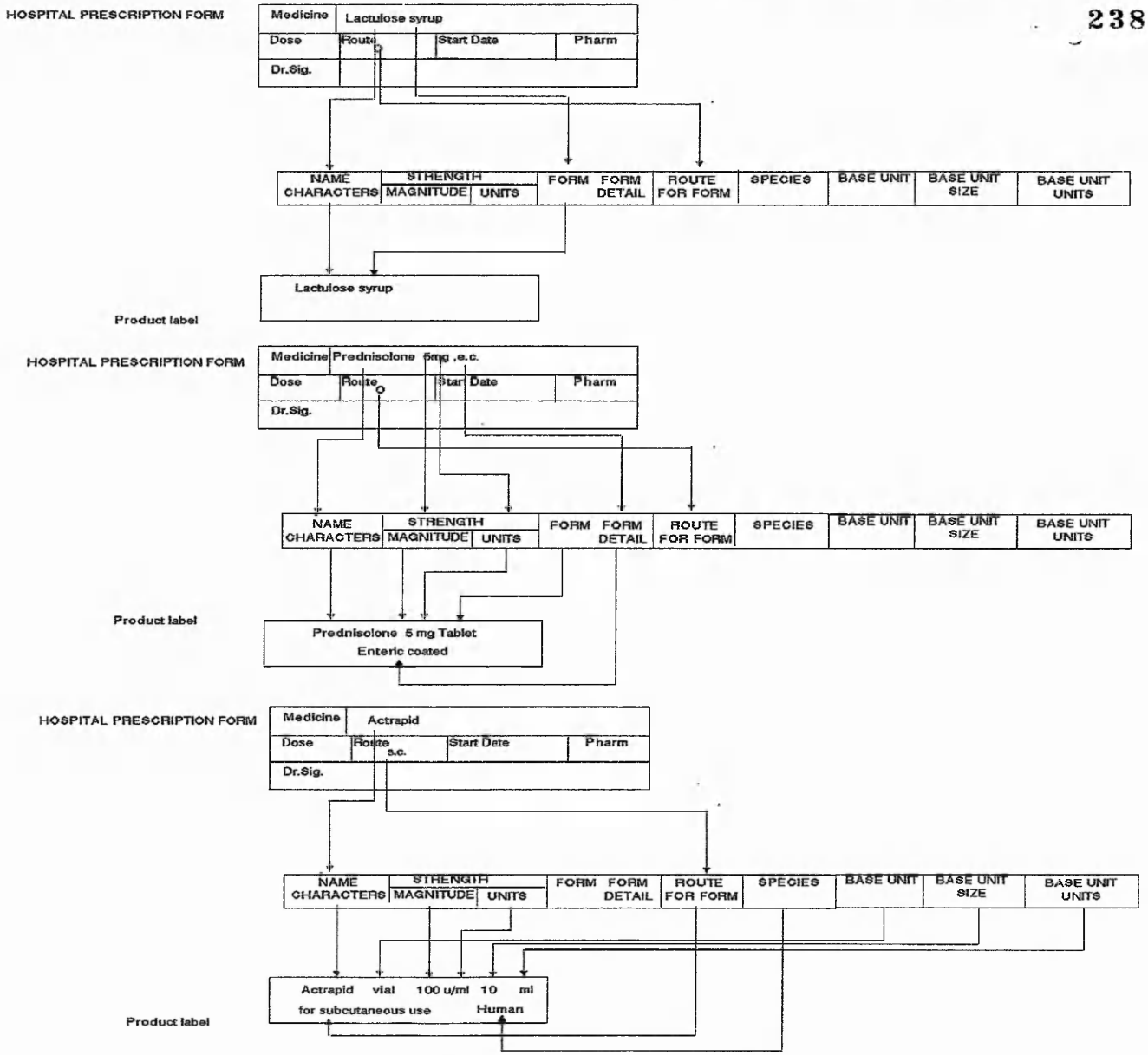


Figure 6. 3 The relationship between prescribing, the researched code and product labels.

interacted with base unit and base unit size, allows calculation of medicament quantities in any given amount. This, when linked via the model to PATIENT CHARACTERISTIC, allows linkage (Wright, Lockley and Wiltshire, 1992) to patient surface area for dosage calculations. The BNF, ATC, Read and PACT codes do not allow for direct extraction of drug strength so dosage calculations are not possible with these codes.

In translating from a prescription to the code and then to a label, some of the information in the modules of the code may need decoding into long form when the label is printed. Some decoding may be through a simple algorithm, e.g. strength, others may require translation tables, e.g. name. While this may seem extravagant use of processing time, the trade off is that the amount of database space would be smaller with the coded form plus translation table than having the same information about the same number of products stored in full form. The Read Code Drug Dictionary is an example of the latter state, which has a drug code of five characters plus a text field (at least thirty characters) for each product. This is made worse by redundancy where a product may have more than one code associated with it.

Clinicians in the United Kingdom may prescribe any medicinal product for the treatment of their patients. A medicinal product is licensed for the uses, the doses and the routes of administration that are detailed in its data sheet. These details are included in the documentation that led to the issue of a product licence for the medicinal product. Thus, clinicians may prescribe a licensed

medicinal product for a licensed use or, if they have reason to believe it may be effective, they may prescribe a product for unlicensed use.[1]

The BNF and Read codes, because they are based on licensed uses, will only identify a medicinal product licensed for the indication. It will not be possible to use these codes to identify a drug that may be suitable for treating a condition for which it is not licensed or by a dose or route of administration for which it is not licensed.

The situations in which unlicensed uses of a drug occur are not exceptional. Unless special procedures are instituted, then automated systems based on Read and BNF would not allow standard procedures to be followed. A system based on the researched code, where entry is at product level or through the product code, would accommodate unlicensed drugs in clinical trials or unlicensed use of drugs without disruption to standard procedures.

Thus some users, e.g. prescribers, would not come into contact with the code directly. As far as they are concerned, the code is an invisible link between the prescribing process and obtaining information about a medicinal product. Others, however, may require and be given direct access to information and for them it is more appropriate to enter the code or part of the code. For these users, the code is access to the information architecture either about a specific product or it could be more of a general database enquiry. In the latter case the modules form the elements of the enquiry.

1. In the National Health Service clinicians in the United Kingdom may prescribe any medicinal product not listed in Section XVIIIA of the Drug Tariff (the Black List).

The researched product code itself, because of its structure, could be considered as an abbreviated database for the commonly used elements of a medicinal product. The relationships of the product identification code to the activities in a hospital are detailed in Table 6.4. In this table, users of the researched code, its modules and their relationships with other parts of the information architecture are detailed against the activities for which they are required. Linking the code to information outside the code itself, but which is part of the information architecture from which the code is derived, will aid information awareness.

Hospital pharmacy goes beyond the bounds of simply prescribing and dispensing. It encompasses, for example, stock control in which pharmaceutical characteristics are of no importance. In any rational automated system, product codes that are used for stock control should be the same as those used elsewhere in the organisation. The coding system in this situation could be converted into a bar-code, or optical character code, which could be impressed on the product or its containers. These could be read directly by bar-code reader on issue or receipt of new stock, thus up-dating the inventory immediately and automatically. Using a common code for all functions could assist in the analysis and auditing of, for example, prescriptions against dispensed products. In a situation where the codes are entered directly, because they are constructed of meaningful modules, manual input should be less error prone than non-meaningful codes.

Having developed the code on a rational basis allows it to conform to the requirements of Markwell (1993) who says,

	PRODUCT CODE								
ACTIVITY	NAME CHARACTERS	STRENGTH	FORM	FORM DETAIL	ROUTE FOR FORM	SPECIES	BASE UNIT	BASE UNIT SIZE	BASE UNIT UNITS
THE PRESCRIBING PROCESS	+		C	C	+	C			
THE PRESCRIPTION	+		C	C	+	C		+	+
THE DISPENSING PROCESS	+	+	+	+	C	C	+	+	+
THE LABEL	+	+	+	+	+				+
PATIENTS REQUIREMENTS	+		+	C	+				
PRESCRIPTION PRICING AUTHORITY	+	+	+	C			+	+	+
WHOLESALER (SUPPLIER)	+	+	+	C			+	+	+
MANUFACTURER	+	+	+	+	+	+	+	+	+
CLINICAL DIRECTORATES	C	C	C	C	C	C	C	C	C
PATIENTS' DISCHARGE INFORMATION	+		C	C	+	+			
RESOURCE MANAGEMENT	C	C	C	C	C	C	C	C	C
MEDICAL AUDIT	C	C	C	C	C	C	C	C	C
DRUG INFORMATION	+	+	+	+	+	+	+	+	+

C= Information that may be needed.
+ = Information needed for activity.

Table 6.4 The uses of modules from the product code.

> "Messages composed of codes drawn from different coding schemes may be a recipe for chaos. In health care information there will be ever increasing demands to deal with this threat of chaos and restore a coherent meaningful order."

Since the product code is modular in nature, the modules can be used, either individually or in combination, to provide information tailored to the activity and perspective of the user. Importantly, these modules can be combined with other information detailed in the information architecture, again according to the perspective of the user. In addition, since the modules of the code are defined by rule (recommended by Murray, 1985), the data they contain is discrete, i.e. not in a free text form, and may be used as variables and placed in any position on labels or documentation, Figure 6.3. The fact that the modules of a code are defined and discrete is a feature also found by Briz-Kishore and Avadhanulu (1983). Working with hydrogeological data, they found it necessary, in producing a useful code, to define discrete modules. This view is also shared by Williams (1990).

6.4 Comparison with Other Codes for Medicinal Products

The proposed code is modular and, unlike the BNF, ATC, Read and PACT codes, does not have a hierarchical structure to descend. Thus, the code can be accessed from any point.

Green (1990) expresses the view that

> "It is enough to specify the terms of the search - the machine will select the matching items and allow the user to browse through the descriptions which match the request. In a similar way the links between related items and the groups of which they form part can remain concealed. There is no need to have an elaborate hierarchical code to guide the user up the fixed list to another level of description. Users only need to specify that they want to move forward (to the next item), back, up (to the next level) or down."

Comparison of the researched code with the BNF, ATC, Read, Pact and Serial codes is illustrated in Table 6.5.

The researched code complies with all Murray's criteria except compactness, whilst the BNF and ATC codes do not provide unique identification and the Read Codes have redundancy. The PACT code only provides unique identification when products that cannot be coded uniquely are allocated "randomly" to a BNF section. Unlike the researched code, none of the others are easily expandable. Most of the others are compact and of a fixed size but only the researched code is precise and meaningful, according to the criteria of Murray (1985) and Green (1990).

The codes of the Read Code Drug Dictionary consist of 5 characters including the delineator; the ATC code has 7 characters; the BNF code has 7 characters; the PACT code has 11 characters; while the researched code has 20 characters in 10 modules of 5, 4, 1, 1, 1, 1, 2, 1, 3, 1 characters, respectively. The Read Code Drug Dictionary has one product for each value of the code but the ATC and BNF codes, although longer than the Read Code Drug Dictionary, do not give unique product identification. The PPA needed to extend the BNF code to eleven digits to get unique coding for PACT purposes. None of these four coding systems provides a basis for the manipulation of data contained in the codes.

So how long does a non-serial code need to be to give unique coding? This is a difficult question to answer since it depends very much on the principles behind the code. The Read Code Drug Dictionary, with

	READ	ATC	BNF	PACT	SERIAL CODES	RESEARCHED CODE
UNIQUE (FOR IDENTIFICATION PURPOSES	YES	NO	NO	YES	YES	YES
EXPANDABLE	NO	NO	NO	NO	YES	YES
COMPACT (less than 10 chars.)	YES	YES	YES	NO	YES	NO
PRECISE	NO	NO	NO	YES	YES	YES
FIXED SIZE	YES	YES	YES	YES	NO	YES
MEANINGFUL	NO	NO	NO	NO	NO	YES
CAN MODULES BE USED IN ALL COMBINATIONS ?	NO	NO	NO	NO	N\A	YES
ENTRY POINT.	TOP LEVEL	TOP LEVEL	TOP LEVEL	TOP LEVEL	N\A	ANY POINT
CODE GENERATION.	← FOLLOWS ESTABLISHED PROTOCOLS →					
OUTPUT	TEXT	TEXT	TEXT	TEXT	TEXT	CODED TEXT MODULES OR TEXT
IS THE CODE BASED ON A SINGLE CLASSIFICATION SYSTEM?	YES	YES	NO	NO	N\A	CODE NOT BASED ON A CLASSIFICATION
CAN INGREDIENTS BE IDENTIFIED FROM CODE ?	NO	NO	NO	NO	NO	SINGLE INGREDIENT PRODUCTS
CAN CODE LINK TO OTHER ENTITIES ?	BY LOOKUP TABLES	BY LOOKUP TABLES	BY LOOKUP TABLES	BY LOOKUP TABLES	BY LOOKUP TABLES	BY MODEL
DUPLICATE CODES	YES	YES	YES	NO	NO	NO
DOES THE CODE PROVIDE FURTHER INFORMATION ?	← VIA LOOKUP TABLE →			NO	VIA LOOKUP TABLES	YES
CAN MODULES BE ADDED EASILY ?	NO	NO	NO	NO	N\A	YES
CAN MODIFIED PRODUCTS BE IDENTIFIED EASILY ?	ONLY BY TEXT	NO	NO	ONLY BY TEXT	NO	YES
CAN PRODUCT SPECIES BE IDENTIFIED EASILY ?	ONLY BY TEXT	NO	ONLY BY TEXT	ONLY BY TEXT	NO	YES
CAN STRENGTHS BE CALCULATED AUTOMATICALLY?	NO	NO	NO	NO	NO	YES
IS THE CODE SUITABLE FOR USE BY ALL USERS ?	NO	NO	NO	NO	YES	YES
SIZE (Chars.)	5 inc.delineator	7	7	11	VARIES	20

IDEAL IDENTIFICATION CODE ATTRIBUTES, (MURRAY,1985).

Table 6.5 Comparison of Read,ATC, BNF, PACT, Serial and Researched codes.

only four characters, one for each level of decomposition, is capable of coding over eleven million products: each code represents one product. The BNF code, on the other hand, has seven characters but is unable to give only one product for each code. The BNF only gives unique coding when extended to eleven characters as shown by the PACT Codes. The size of a code appears to be determined by what is required of that code. This is seen by the current re-appraisal of the Read Code Drug Dictionary (A. Davies, 1993, personal communication). Although the existing Read Code Drug Dictionary has more than enough capacity to code the current range of medicinal products, the Read Code Group is considering extending the Drug Dictionary Codes to five characters. This will allow the Read Code Drug Dictionary to provide some of the information that is necessary in pharmacy practice, which the Code does not currently provide. Therefore, codes appear to go beyond providing a simple label, which could be achieved by serial codes, but to their area of application. However, the classification systems on which these coding systems are based, are primarily associated with prescribing. The product is one of the last criteria to be considered. The product name is randomly assigned a code in the lower levels of the Read Code Drug Dictionary. With the PACT Code the product name is coded in the character at the eighth position. Even here, the code depends on an alphabetic list held in the relevant section of the BNF. In the researched code the name is held as a truncated alpha-numeric sequence in the first module. So the name is a primary criterion in the researched code not an ultimate one.

The problem of code length is not unique to pharmacy. Johnson (1988)

records that to accommodate extra information in the UPC code, needed to satisfy the requirements of the meat market, the 10 digit code had to be increased to 24 digits - Version D-3. Amending existing systems to accommodate their inadequacies in a particular field is not recommended by Green (1990), who states,

> "... that in a complex network of relationships, structural and functional clashes are bound to occur. If accruals are allowed it becomes impossible to use a single reference code system that gives all that is desirable in the way of consistency and flexibility in all areas of activity."

When determining a code, what has to be considered is whether the code performs the required function rather than its length. This is supported by Ray-Jones and McCann (1977) who state,

> "..., looking forward to mechanized sorting, machines are far less worried by long codes than humans. The more precisely an item is described the more easily it can be separated from the rest when required."

The code length is less of a problem for manual users than it may initially seem. Its modular structure has been shown to allow selected modules to be used as database selection criteria. Inputting a small number of the modules can provide a short list of definitive products or product codes from which the desired data can be chosen. A practical compromise would need to be found that balanced speed with accuracy.

It, therefore, makes sense to design a new code based on rational principles to provide the desired consistency and flexibility without the necessity for accruals, thus minimising structural and functional clashes. Williams (1990) confirms this view. Green (1990) also states,

> "If an old coding system that has outgrown its usefulness has to be retained, then the less work the code has to do the better."

The crux of the coding problem is not just the production of a code but producing one that meets the needs of the users. This is not to say the BNF, ATC or Read codes have outgrown their usefulness. They are useful for their original purpose but may not prove as useful when modified for purposes for which they were not originally intended.

The Read and ATC codes are each based on single classification systems, whilst the BNF and Prescription Pricing Authority's PACT code are based on two classification systems, thus allowing multiple entries of products in their systems. These codes provide a classification of products. The researched code is not based upon a classification but upon the characteristics of the product and therefore does not allow duplication of products. The BNF, ATC, Read and PACT codes, because they are hierarchies, must be entered at a high level and all the modules must be used to be most efficient; unlike the researched code, which is linear and can be entered at any point. It will be noted that modules of the researched code are formed by and adhere to predetermined rules as required by Green (1990). It can be argued that the BNF, ATC and Read codes adhere to and follow predetermined rules since the levels are coded according to a protocol and are of a defined length and character type. Apart from labelling the hierarchical level, the letters have none of the meaningful significance referred to by Murray (1985). These codes, on the other hand, can be split into the various levels giving varying degrees of information down to groups of products. In order to do this, a key is necessary to determine the significance of the

characters, the meaning of which depends on the branch of the hierarchy.

The researched code also has the advantage that its modules can be accessed in any order or combination (recommended by Green, 1990), unlike the BNF, ATC, Read and PACT codes. This also means that, unlike the others, because the modules and their information are discrete they can be used in any combination and manipulated to suit the needs of the user. This facility provides the user with a variety of classification systems, e.g. the number of chewable tablets of strength X. Importantly, other modules can be added without disturbing the integrity of the code (Green 1990) and manipulated to provide further classification systems. This is not available in the other systems.

The active ingredients from single ingredient products can be identified and their strengths calculated from the researched code, thus allowing calculation of doses and, when implemented through the defined information architecture, their relationships with patients' characteristics. None of the other codes allows this facility, neither can they calculate quantity per volume for dose purposes.

Modified products and species can be identified as part of the researched code and by only textual means in the other codes. These attributes can, therefore, be brought automatically to the attention of prescribers.

Linkage to other entities within pharmacy and medicine is only

possible with the Read, ATC and Pricing Authority Codes by means of look-up tables. The researched code, by means of its product model base, allows linkage to any part of the information architecture. The model with its information architecture are abstract representations of pharmacy information and their relationships. Thus, they are independent of hardware and software. As such, the product models can be used by modern Computer-Aided Software Engineering (CASE) tools to generate databases. Being abstract, the models can be used by existing and future generations of CASE tools to produce up-dated databases or databases customised for speed or economy of space. Thus, mapping of information through the model will be more efficient than that with the look-up tables used by the Read, ATC and PACT codes.

The access to BNF, ATC, Read and PACT codes and the researched code is by alphanumeric characters, all of which follow established protocols. The output of all except the researched code is textual in nature, in the case of the Read Code Drug Dictionary the text fields have 30, 60 or 198 characters. The contents of a textual field, whilst their meaning is likely to be obvious to a human, do not lend themselves easily to further automated use. While text is usually presented grammatically correct, most is not rigidly structured.

> "With manual systems humans can get by because experience and the human brain's pattern recognition ability enable staff to deduce that this string of characters should really be that one." (Green, 1990)

A computer system cannot easily distinguish between different forms of text having the same meaning. This is explained in the following example of the genitive case. "The boy's mother" and "the mother of the boy", both have the same meaning but would require a sophisticated text reading and searching program to convert them for use within an

identification system. The contents of the BNF, ATC, Read and PACT codes are not as extreme as this example but the principle of lack of structure applies, making automated extraction of information difficult.

The output from the researched code is discrete, coded modules, which can be converted to alphanumeric fields and used as required. Numerical output can be used for calculations, and all output can be used as variables in automated systems.

In an automated system the researched code could be used to replace the text fields of the Read Code Drug Dictionary. The researched code consists of 20 characters, whilst the Read Code Drug Dictionary consists of 30 characters in the smallest text field format (50% larger than the researched code). Thus, information not provided currently by the Read Code Drug Dictionary, e.g. pack size, could be incorporated through adding extra modules to the researched code to expanded it to fit into the current Read Code text field. Because the researched code is modular in form, it is structured and a data dictionary based on the code could be used as a database that could be entered through another process, e.g. dispensing. Personal Communication with Davies indicated that the Read Code centre is looking for a product that is more structured and could be slotted into the existing hierarchical structure.

The design of the researched code, since it is product specific and part of an information architecture, allows its use by all users, unlike the other codes which are designed mainly for prescribing

purposes.

6.5 Currency of the Codes

With any coding system, especially in a dynamic field such as pharmacy, there is a constant requirement for the codes of new products to be added to a product database. Similarly, codes for deleted products need to be removed. It is, therefore, essential to consider how the codes would be initially disseminated and up-dates promulgated. Both the Read and ATC Codes are up-dated on a regular basis (Davies and Read, 1993). The PACT codes are not only up-dated as a result of new or deleted products but also as a result of alterations to the BNF codes. In order to rationalise changes to the PACT codes, especially those resulting from BNF code alterations, they are reviewed and re-issued on an annual basis.

Most code producers up-date their customers by the provision of up-dated disks. The proposed code would be no different from up-dates to existing codes, being sent out at regular intervals. The main reason for up-dating would be to incorporate additional products and remove deleted ones. Unlike the PACT codes, once a code was designated for a product using the proposed code, it would remain unchanged during the product's life. What is important about promulgation of the proposed code is that it would have to be generated and maintained centrally. This is needed to maintain consistency throughout code users. This would obviously require commitment from a central source, i.e. the Department of Health or the NHS Centre for Coding and Classification. The most probable scenario, in which the code might be promulgated centrally, is if it were to be

adopted by the NHS Centre for Coding and Classification as an adjunct to the Read Codes.

Indirectly, the code is being disseminated as it is being used as a standard for the North East Thames Pharmacy Computer Project and is being included in the Generic Model for the Common Basic Specification (NHS, IMC, 1990a).

So far, the researched code follows the British legal requirements with some additional modules. There is no reason why the requirements of other countries could not be included (Blasius, 1991). In Britain the presentation of a product is taken to be the product form, e.g. tablet or capsule. In Holland the presentation is taken to be the product's form plus its container, outer and inserts. These variations, if it were required that a code should carry them, could be incorporated with the code or may perhaps be a combination of modules already included.

The extension of the code to include the requirements of other countries could be of use to companies based in one country and exporting to others and to the users of that information. The modular nature of the code would allow easy adaptation of the code to suit the requirements of different statutory requirements. It would mean, however, that the whole code would have to be transported on each occasion for the user to extract the parts necessary for their own use. This again shows the necessity for central control of the coding system.

It may be possible, although further research would be required, to use the work of Dvořák, Gotfrýd and Munz (1992) to develop the name characters for other languages. In this case, they matched up the English alphabet with the Czech and Slovak languages in order to provide information via a MUMPS language system. They found their method produced the correct sequencing of strings in Czech or Slovak and in alphabetical order where necessary.

The method could therefore produce name characteristics, providing the system with a wider use than just English speaking countries. This could also be true of other coding systems.

6.6 CONCLUSION

It has now been shown that the original hypotheses (1.6 Aims and Objectives) have been tested during the study with outcomes as follows. The method of modelling with BAMs and LDFDs determined the influence of medicinal products in hospital pharmacy. The models identified the entities associated with hospital pharmacy and their relative proportions. It was shown that the first hypothesis was true and that medicinal products are a major entity in hospital pharmacy.

It proved possible to model the Data Sheet Regulations and to identify the characteristics of a medicinal product, although the catch-all term "Other information" needed some definition. This was needed in order to determine the difference between legal and other practical information, which allows a more complete data model of a medicinal product (Chapter 2).

Having shown the first two hypotheses to be true, it was determined that data models can be used to structure a coding system allowing the generation of unique product codes. Originally it was thought that using the three characteristics of name, strength and form would be sufficient but this showed not to be adequate. Further development and testing determined that a unique code was possible using the characteristics of name, strength, form route for form, species, base unit, and associated units. Even then, because of the nature of medicinal products, some products, e.g. insulin, had to be allocated specific codes (Chapter 4). The third hypothesis was thus shown to be true but the proviso needs to be added that uniqueness of the code is dependent on the structure of each field.

The modelling of physical characteristics in order to identify a medicinal product showed that it was possible in some cases, but not all, to obtain unique identification. Identification was limited by the number of products that have identical physical characteristics but dissimilar ingredients. In this case, the fourth hypothesis was shown not to be true. To uniquely identify products by this means would require an extension to the models and the search criteria to encompass analytical techniques.

The way forward for computerised pharmacy systems that would assist in the seamless flow of information would be to have an information architecture based on data modelling techniques. The seamless flow would be further enhanced by further development of the product models to form "global" models covering all aspects of pharmacy and all the relevant activities of any organisation or personnel associated with

the manufacture or use of medicinal products. The use of global model would allow access to standard information. This will eliminate the need for look-up tables, ensuring comprehensive and non duplicated information. The output could be arranged in a suitable form for the user. Pharmacy access to the information architecture should logically be through a code based on an information architecture, incorporating what are perceived to be the most important elements of products. The characters which make up the code could be translated into the character sets of other languages. This is particularly important in today's climate of international co-operation and regulation, e.g. via the European Community (EC), where calls have already been made for standard coding and information systems for medicinal products. The use of a total information architecture for medicinal products based on the requirements of the EC would allow common coding and classification systems between trading partners. The translation of the researched information architecture and code into European and international architectures and codes would need to be researched to determine the precise requirements. This could form the basis of a further project.

The defined code is not necessarily the only unique code but it has been defined using rational pharmaceutical principles and has taken into account the experiences and requirements of users and researchers in the field.

The defined code not only provides useful information through its modules and structure, but also could be used as a handle to a much more comprehensive data set. This contrasts with other codes that

provide only textual information and the need for look-up tables to communicate with other code systems.

The code as an access to a database could be visible or invisible to the user, depending on the nature of the system in which it is used. If it is part of a prescribing and administration system it could be invisible to the user. For a dispenser or prescriber of a product for unlicensed use, it might be used directly. When used directly, it is possible for selected modules to be used as database searching criteria, reducing the need to enter the whole code. Operated in this way, it may need selection of the definitive product from a short list of similar ones. It could act as a node that brings together different users and different levels of use, while allowing access to the same information architecture from different perspectives.

However, the code is longer than the other codes evaluated. This was recognised by Murray (1985) who said,

> "There is a trade off between compactness and flexibility. Costs of data capture, transmission data entry, storage, and both human and computer processing increase as the length of code increases. However, categorization, statistical analysis, and other types of data studies become easier as the code length increases."

This trade off must be taken into account when designing and using codes. The purpose for which a code is to be used is paramount. If it can be used over a wide spectrum of users and for a wide spectrum of uses and can be easily and rationally amended, i.e. added to, then perhaps this is the way forward, rather than to amend "old" codes that were not designed for the user's needs and will never completely fulfil them, even with a lot of modification.

Perhaps the comment of Green (1990) is most apt, viz:

> "If an old coding system that has outgrown its usefulness has to be retained, then the less work the code has to do the better."

With the design of new systems and the increase in information requests (Green, 1990), the way forward will be to use a code designed on relevant rational principles that will provide the user with information that can be modified to accommodate new requirements and will be useful for many years.

APPENDIX 1

ACTIVITY DESCRIPTION

Validate Request

The request for distribution is assessed to ensure that it is full and correct, to ensure that it can be met and to determine the urgency.

Ensure correct day/time for supply

The time and day of request for goods are checked against the prevailing policies.

Identify special procedures

Any special handling or transport requirements are determined.

Validate goods request

Goods may be requested from a number of different places in a variety of ways. The requests may come in the form of in-patient charts, FP10(HP)s, ward pharmacist requisitions and orders from external clinics and homes.

Check clinical details

A clinical check is made of the requested goods to ensure that they are appropriate for their intended purposes.

Check compliance with policies

The goods requested should conform to the formulary and to the policies on quantities to be issued, amongst other local, regional and national policies.

Rectify problems

Any problems identified are rectified, if possible through discussions with the requester in accordance with the controlling standards and procedures.

Validate 'return' request

Goods may also be returned to the Pharmacy as a result of incorrect ones being distributed initially, stock expiring on the wards, etc. Such return requests must be validated to ensure that the details are correct and that the Pharmacy can or should deal with it.

Re-direct request

Having assessed the request, it may be re-directed to a more suitable department and/or a report sent to the requester.

APPENDIX 2

STORE	ENTITY TYPE	ENTITY
D2.1	ITEM	ITEM
	ITEM CHARACTERISTIC	
	ITEM CLASS	
	ITEM CODE	
	ITEM HELD AT LOCATION	
	PRODUCT CLASS	
	BUYING POINT FOR ITEM	
	USAGE POINT FOR ITEM	
	ITEM UNIT	
	DELIVERY POINT FOR ITEM	
D2.2	MANUFACTURER BATCH STOCK	STOCK
	Manufacturer Item batch	
D2.4	PRODUCT INGREDIENT	PRODUCT/
	PRODUCT COMBINATION	CONTENTS
	COMBINATION ELEMENT ROUTE OF ADMINISTRATION	
	COMBINATION ELEMENT	
D2.5	PRICE PROFILE	SUPPLIES
	SUPPLIER ITEM	
	SPECIAL TERM	
D2.6	DOSE DETAIL	DOSE
	DOSE REGIME	
	DOSE REGIME FOR PRODUCT	
	DOSE REGIME ROUTE	
D2.7	RESOURCE	RESOURCE
	RESOURCE HELD	
D2.8	MANUFACTURER PRODUCT IN SUPPLIER PRODUCT PACK	PRODUCT
	MANUFACTURER PRODUCT PACK	
	PRODUCT PACK	
	PRODUCT PACK CHARACTERISTIC	
	PRODUCT PACK COMPONENT	
	PRODUCT PACK FROM SUPPLIER	
	USE FOR PRODUCT PACK	
D2.9	EFFECT	EFFECT
	PRODUCT ROUTE OF ADMINISTRATION EFFECT	
	ROUTE FOR SPECIAL INSTRUCTION	
	PRODUCT ROUTE	

STORE	ENTITY TYPE	ENTITY
D2.10	MANUFACTURER PACK CODE	PRODUCT
	NAME RELATIONSHIP	
	SUPPLIER PACK CODE	
	PRODUCT	
	PRODUCT CHARACTERISTIC	
	PRODUCT ROUTE OF ADMINISTRATION	
	INDICATION CODE	
	INTERACTION EFFECT	
	SPECIAL INSTRUCTION FOR PRODUCT	
	PRODUCT FOR CONDITION	
	NAME IDENTIFIER	
	PRODUCT ELEMENT	
	PRODUCT ROUTE OF ADMINISTRATION INDICATION	

APPENDIX 3

ENTITIES

1 ADDITIONAL ITEM FOR INVOICE
2 ADDITIONAL ITEM FOR INVOICE LINE
3 ADDITIONAL ITEM FOR ORDER LINE
4 ADDITIONAL ITEM
5 ADDITIONAL ITEM FOR ORDER
6 ADDITIONAL ITEM TYPE
7 ASSESSMENT OF INVOCATION
8 ASSESSMENT RELATIONSHIP
9 BUYING POINT FOR ITEM
10 CHARACTERISTIC
11 CHARACTERISTIC TYPE
12 CLASS
13 CLASS STRUCTURE
14 CLASS TYPE
15 CLINICAL RESPONSIBILITY
16 CODE
17 CODE TYPE
18 COMBINATION ELEMENT
19 COMBINATION ELEMENT ROUTE OF ADMINISTRATION
20 CONDITION IN WORKING DIAGNOSIS
21 CONDITION TO BE TREATED
22 CONSTANT
23 CONTRACT
24 CONTRACT ASSESSMENT
25 CONTRACT CREDIT CAUSE
26 CONTRACT CREDIT EFFECT
27 CONTRACT INVOCATION
28 CONTRACT LINE
29 CONTRACT LINE DEPENDENCY
30 CONTRACT LINE USER
31 CONTRACT TERM
32 CONTRACT TYPE
33 CONTRACTED ORGANISATION
34 CONTRACTING ORGANISATION
35 CONTRACTUAL REQUIREMENT
36 COURIER FOR DESPATCH PACK
37 CREDIT CAUSE
38 CREDIT CAUSE USER
39 CREDIT EFFECT
40 CREDIT EFFECT TYPE
41 CREDIT LINE
42 CREDIT NOTE
43 CREDIT TYPE
44 DELIVERY CREDIT CAUSE
45 DELIVERY CREDIT EFFECT
46 DELIVERY LINE
47 DELIVERY NOTE
48 DELIVERY POINT FOR ITEM
49 DELIVERY POINT FOR ORDER LINE
50 DELIVERY TYPE
51 DESPATCH METHOD
52 DESPATCH PACK

ENTITY

53 DOSE DETAIL
54 DOSE REGIME
55 DOSE REGIME FOR PRODUCT
56 DOSE REGIME ROUTE
57 EFFECT
58 EFFECT TYPE
59 EXPRESSION
60 EXPRESSION COMPONENT
61 EXPRESSION TYPE
62 FORM
63 INDICATION
64 INDICATION TYPE
65 INPUT TYPE
66 INTERACTION
67 INTERACTION EFFECT
68 INTERACTION TYPE
69 INVOICE
70 INVOICE CREDIT CAUSE
71 INVOICE CREDIT EFFECT
72 INVOICE LINE
73 INVOICE LINE FOR DELIVERY LINE
74 INVOICE TYPE
75 ISSUE TRANSACTION
76 ITEM
77 ITEM CHARACTERISTIC
78 ITEM CLASS
79 ITEM CODE
80 ITEM HELD AT LOCATION
81 ITEM TYPE
82 ITEM UNIT
83 ITEM UNIT TYPE
84 LICENCE
85 LICENCE LOCATION
86 LICENCE TERM
87 LICENCE TYPE
88 LOCATION
89 LOCATION CHARACTERISTIC
90 LOCATION STRUCTURE
91 LOCATION TYPE
92 MANUFACTURER PRODUCT IN SUPPLIER PRODUCT PACK
93 MANUFACTURER BATCH STOCK
94 MANUFACTURER ITEM BATCH
95 MANUFACTURER PACK CODE
96 MANUFACTURER PRODUCT
97 MANUFACTURER PRODUCT PACK
98 NAME IDENTIFIER
99 NAME IDENTIFIER TYPE
100 NAME RELATIONSHIP
101 NAMED PATIENT
102 OPERATOR
103 ORDER
104 ORDER CREDIT CAUSE
105 ORDER CREDIT EFFECT
106 ORDER DESPATCH

ENTITY

107 ORDER LINE
108 ORDER LINE FOR DELIVERY LINE
109 ORDER LINE FOR INVOICE LINE
110 ORDER LINE INFLUENCE
111 ORDER LINE RELATIONSHIP
112 ORDER ORGANISATION TYPE
113 ORDER TYPE
114 ORDERING LIMITATION
115 ORDERING RULE
116 ORGANISATION
117 ORGANISATION DETAIL
118 ORGANISATION DETAIL TYPE
119 ORGANISATION LICENCE
120 ORGANISATION LOCATION
121 ORGANISATION STRUCTURE
122 ORGANISATION TYPE
123 OUTPUT TYPE
124 PARAMETER
125 PATIENT
126 PATIENT CHARACTERISTIC
127 PRESCRIBER RESTRICTION
128 PRESCRIBER TYPE
129 PRESCRIBING RULE
130 PRESCRIPTION
131 PRESCRIPTION INFLUENCE
132 PRESCRIPTION LINE
133 PRICE PROFILE
134 PRODUCT
135 PRODUCT CHARACTERISTIC
136 PRODUCT CLASS
137 PRODUCT COMBINATION
138 PRODUCT ELEMENT
139 PRODUCT FOR CONDITION
140 PRODUCT INGREDIENT
141 PRODUCT INGREDIENT TYPE
142 PRODUCT PACK
143 PRODUCT PACK CHARACTERISTIC
144 PRODUCT PACK COMPONENT
145 PRODUCT PACK FROM SUPPLIER
146 PRODUCT PACK STOCK LOCATION
147 PRODUCT ROUTE OF ADMINISTRATION EFFECT
148 PRODUCT ROUTE OF ADMINISTRATION INDICATION
149 PRODUCT ROUTE
150 REASON FOR RETURN
151 REASON FOR RETURN LINE
152 RELATIONSHIP
153 RESOURCE
154 RESOURCE CREDIT EFFECT
155 RESOURCE HELD
156 RESOURCE TYPE
157 RESTRICTION FOR CHARACTERISTIC
158 RESTRICTION ON PRODUCT
159 RETURN CREDIT CAUSE
160 RETURN ITEM BATCH

ENTITY

161 RETURN LINE
162 RETURN NOTE
163 RETURN OF DELIVERY
164 ROUTE FOR SPECIAL INSTRUCTION
165 ROUTE OF ADMINISTRATION
166 RULE
167 RULE DEPENDENCY
168 RULE EXPRESSION
169 RULE SET
170 SERVICE
171 SERVICE AT LOCATION
172 SERVICE AVAILABLE
173 SERVICE ELEMENT
174 SERVICE INPUT
175 SERVICE OUTPUT
176 SERVICE RELATIONSHIP
177 SERVICE TIMETABLE
178 SERVICE TYPE
179 SPECIAL INSTRUCTION FOR PRODUCT
180 SPECIAL INSTRUCTION FOR PRESCRIPTION LINE
181 SPECIAL INSTRUCTION
182 SPECIAL TERM
183 STORAGE ACTION
184 STORAGE LIST
185 STORAGE LIST LINE
186 STRENGTH
187 SUPPLIER ITEM
188 SUPPLIER ITEM ON CONTRACT
189 SUPPLIER PACK CODE
190 TERM CREDIT CAUSE
191 TERM CREDIT EFFECT
192 TRANSACTION DELIVERY POINT
193 TYPE OF ITEM HELD
194 UNIT
195 UNIT TYPE
196 USAGE POINT FOR ITEM
197 USE FOR PRODUCT PACK
198 WORKING DIAGNOSIS FOR PATIENT CHARACTERISTIC
199 WORKING DIAGNOSIS RELATIONSHIP
200 WORKING DIAGNOSIS

APPENDIX 4

DATASTORE - ENTITY CROSS-REFERENCE

ENTITY	STORE	ENTITY CONTENTS
ADDITIONAL ITEM FOR INVOICE	D18	Invoice details
ADDITIONAL ITEM FOR INVOICE LINE	D18	Invoice details
ADDITIONAL ITEM FOR ORDER LINE	D14.1	Order details
ADDITIONAL ITEM	D3.6	Transaction classes
ADDITIONAL ITEM FOR ORDER	D14.1	Order details
ADDITIONAL ITEM TYPE	D3.6	Transaction classes
ASSESSMENT OF INVOCATION	D8	Contract details
ASSESSMENT RELATIONSHIP	D8	Contract details
BUYING POINT FOR ITEM	D2.1	Item details
CHARACTERISTIC	D3.3	Resource classes
CHARACTERISTIC TYPE	D3.3	Resource classes
CLASS	D3.3	Resource classes
CLASS STRUCTURE	D3.3	Resource classes
CLASS TYPE	D3.3	Resource classes
CLINICAL RESPONSIBILITY	D9	Patient details
CODE	D2.10	Product details
CODE TYPE	D3.3	Resource classes
COMBINATION ELEMENT	D2.4	Product contents
COMBINATION ELEMENT ROUTE OF ADMINISTRATION	D2.4	Product contents
CONDITION IN WORKING DIAGNOSIS	D3.5	Effect classes
CONDITION TO BE TREATED	D3.5	Effect classes
CONSTANT	D3.1	Rules
CONTRACT	D8	Contract details
CONTRACT ASSESSMENT	D8	Contract details
CONTRACT CREDIT CAUSE	D19.2	Credit cause
CONTRACT CREDIT EFFECT	D19.3	Credit effect
CONTRACT INVOCATION	D8	Contract details
CONTRACT LINE	D8	Contract details
CONTRACT LINE DEPENDENCY	D8	Contract details
CONTRACT LINE USER	D8	Contract details
CONTRACT TERM	D8	Contract details
CONTRACT TYPE	D3.2	Business classes
CONTRACTED ORGANISATION	D8	Contract details
CONTRACTING ORGANISATION	D8	Contract details
CONTRACTUAL REQUIREMENT	D8	Contract details
COURIER FOR DESPATCH PACK	D22	Delivery details
CREDIT CAUSE	D19.2	Credit cause
CREDIT CAUSE TYPE	D3.6	Transaction classes
CREDIT EFFECT	D19.3	Credit effect
CREDIT EFFECT TYPE	D3.6	Transaction classes
CREDIT LINE	D19.1	Credit details
CREDIT NOTE	D19.1	Credit details
CREDIT TYPE	D3.6	Transaction classes
DELIVERY CREDIT CAUSE	D19.2	Credit cause
DELIVERY CREDIT EFFECT	D19.3	Credit effect
DELIVERY LINE	D22	Delivery details
DELIVERY NOTE	D22	Delivery details
DELIVERY POINT FOR ITEM	D2.1	Item details

DATASTORE DEFINITION

ENTITY	STORE	ENTITY CONTENTS
DELIVERY POINT FOR ORDER LINE	D14.1	Order details
DELIVERY TYPE	D3.6	Transaction classes
DESPATCH METHOD	D3.6	Transaction classes
DESPATCH PACK	D22	Delivery details
DOSE DETAIL	D2.6	Product dose details
DOSE REGIME	D2.6	Product dose details
DOSE REGIME FOR PRODUCT	D2.6	Product dose details
DOSE REGIME ROUTE	D2.6	Product dose details
EFFECT	D2.9	Route details
EFFECT TYPE	D3.5	Effect classes
EXPRESSION	D3.1	Rules
EXPRESSION COMPONENT	D3.1	Rules
EXPRESSION TYPE	D3.1	Rules
FORM	D3.3	Resource classes
INDICATION	D3.5	Effect classes
INDICATION TYPE	D3.5	Effect classes
INPUT TYPE	D3.3	Resource classes
INTERACTION	D3.5	Effect classes
INTERACTION EFFECT	D2.10	Product details
INTERACTION TYPE	D3.5	Effect classes
INVOICE	D18	Invoice details
INVOICE CREDIT CAUSE	D19.2	Credit cause
INVOICE CREDIT EFFECT	D19.3	Credit effect
INVOICE LINE	D18	Invoice details
INVOICE LINE FOR DELIVERY LINE	D18	Invoice details
INVOICE TYPE	D3.6	Transaction classes
ISSUE TRANSACTION	D22	Delivery details
ITEM	D2.1	Item details
ITEM CHARACTERISTIC	D2.1	Item details
ITEM CLASS	D2.1	Item details
ITEM CODE	D2.1	Item details
ITEM HELD AT LOCATION	D2.1	Item details
ITEM TYPE	D3.3	Resource classes
ITEM UNIT	D2.1	Item details
ITEM UNIT TYPE	D3.3	Resource classes
LICENCE	D21	Licence details
LICENCE LOCATION	D21	Licence details
LICENCE TERM	D21	Licence details
LICENCE TYPE	D3.2	Business classes
LOCATION	D1.2	Location details
LOCATION CHARACTERISTIC	D1.2	Location details
LOCATION STRUCTURE	D1.2	Location details
LOCATION TYPE	D3.2	Business classes
MANUFACTURER PRODUCT IN SUPPLIER PRODUCT PACK	D2.8	Product pack details
MANUFACTURER BATCH STOCK	D2.2	Stock details
MANUFACTURER ITEM BATCH	D2.2	Stock details
MANUFACTURER PACK CODE	D2.10	Product details
MANUFACTURER PRODUCT	D21	Licence details
MANUFACTURER PRODUCT PACK	D2.8	Product pack details
NAME IDENTIFIER	D2.10	Product details
NAME IDENTIFIER TYPE	D3.3	Resource classes

DATASTORE DEFINITION

ENTITY	STORE	ENTITY CONTENTS
NAME RELATIONSHIP	D2.10	Product details
NAMED PATIENT	D14.1	Order details
OPERATOR	D3.1	Rules
ORDER	D14.1	Order details
ORDER CREDIT CAUSE	D19.2	Credit cause
ORDER CREDIT EFFECT	D19.3	Credit effect
ORDER DESPATCH	D14.1	Order details
ORDER LINE	D14.1	Order details
ORDER LINE FOR DELIVERY LINE	D22	Delivery details
ORDER LINE FOR INVOICE LINE	D18	Invoice details
ORDER LINE INFLUENCE	D14.1	Order details
ORDER LINE RELATIONSHIP	D14.1	Order details
ORDER ORGANISATION TYPE	D3.2	Business classes
ORDER TYPE	D3.6	Transaction classes
ORDERING LIMITATION	D5	Standards and procedures
ORDERING RULE	D3.1	Rules
ORGANISATION	D1.1	Organisation details
ORGANISATION DETAIL	D1.1	Organisation details
ORGANISATION DETAIL TYPE	D3.2	Business classes
ORGANISATION LICENCE	D21	Licence details
ORGANISATION LOCATION	D1.1	Organisation details
ORGANISATION STRUCTURE	D1.1	Organisation details
ORGANISATION TYPE	D3.2	Business classes
OUTPUT TYPE	D3.3	Resource classes
PARAMETER	D3.1	Rules
PATIENT	D9	Patient details
PATIENT CHARACTERISTIC	D9	Patient details
PRESCRIBER RESTRICTION	D5	Standards and procedures
PRESCRIBER TYPE	D3.2	Business classes
PRESCRIBING RULE	D3.1	Rules
PRESCRIPTION	D14.2	Prescription details
PRESCRIPTION INFLUENCE	D14.2	Prescription details
PRESCRIPTION LINE	D14.2	Prescription details
PRICE PROFILE	D2.5	Supply details
PRODUCT	D2.10	Product details
PRODUCT CHARACTERISTIC	D2.10	Product details
PRODUCT CLASS	D2.1	Item details
PRODUCT COMBINATION	D2.4	Product contents
PRODUCT ELEMENT	D2.10	Product details
PRODUCT FOR CONDITION	D2.10	Product details
PRODUCT INGREDIENT	D2.4	Product contents
PRODUCT INGREDIENT TYPE	D3.4	Product classes
PRODUCT PACK	D2.8	Product pack details
PRODUCT PACK CHARACTERISTIC	D2.8	Product pack details
PRODUCT PACK COMPONENT	D2.8	Product pack details
PRODUCT PACK FROM SUPPLIER	D2.8	Product pack details
PRODUCT PACK STOCK LOCATION	D2.2	Stock details
PRODUCT ROUTE OF ADMINISTRATION EFFECT	D2.9	Route details

DATASTORE DEFINITION

ENTITY	STORE	ENTITY CONTENTS
PRODUCT ROUTE OF ADMINISTRATION INDICATION	D2.10	Product details
PRODUCT ROUTE	D2.9	Route details
REASON FOR RETURN	D23	Return details
REASON FOR RETURN LINE	D23	Return details
RELATIONSHIP	D3.1	Rules
RESOURCE	D2.7	Resource details
RESOURCE CREDIT EFFECT	D19.3	Credit effect
RESOURCE HELD	D2.7	Resource details
RESOURCE TYPE	D3.3	Resource classes
RESTRICTION FOR CHARACTERISTIC	D5	Standards and procedures
RESTRICTION ON PRODUCT	D5	Standards and procedures
RETURN CREDIT CAUSE	D19.2	Credit cause
RETURN ITEM BATCH	D23	Return details
RETURN LINE	D23	Return details
RETURN NOTE	D23	Return details
RETURN OF DELIVERY	D23	Return details
ROUTE FOR SPECIAL INSTRUCTION	D2.9	Route details
ROUTE OF ADMINISTRATION	D3.4	Product classes
RULE	D3.1	Rules
RULE DEPENDENCY	D3.1	Rules
RULE EXPRESSION	D3.1	Rules
RULE SET	D3.1	Rules
SERVICE	D2.3	Service details
SERVICE AT LOCATION	D2.3	Service details
SERVICE AVAILABLE	D2.3	Service details
SERVICE ELEMENT	D2.3	Service details
SERVICE INPUT	D2.3	Service details
SERVICE OUTPUT	D2.3	Service details
SERVICE RELATIONSHIP	D2.3	Service details
SERVICE TIMETABLE	D2.3	Service details
SERVICE TYPE	D3.2	Business classes
SPECIAL INSTRUCTION FOR PRODUCT	D2.10	Product details
SPECIAL INSTRUCTION FOR PRESCRIPTION LINE	D14.2	Prescription details
SPECIAL INSTRUCTION	D2.10	Product details
SPECIAL TERM	D2.5	Supply details
STORAGE ACTION	D22	Delivery details
STORAGE LIST	D22	Delivery details
STORAGE LIST LINE	D22	Delivery details
STRENGTH	D3.4	Product classes
SUPPLIER ITEM	D2.5	Supply details
SUPPLIER ITEM ON CONTRACT	D8	Contract details
SUPPLIER PACK CODE	D2.10	Product details
TERM CREDIT CAUSE	D19.2	Credit cause
TERM CREDIT EFFECT	D19.3	Credit effect
TRANSACTION DELIVERY POINT	D22	Delivery details
TYPE OF ITEM HELD	D3.3	Resource classes
UNIT	D3.4	Product classes
UNIT TYPE	D3.4	Product classes

DATASTORE DEFINITION

ENTITY	STORE	ENTITY CONTENTS
USAGE POINT FOR ITEM	D2.1	Item details
USE FOR PRODUCT PACK	D2.8	Product pack details
WORKING DIAGNOSIS FOR PATIENT CHARACTERISTIC	D9	Patient details
WORKING DIAGNOSIS RELATIONSHIP	D3.5	Effect classes
WORKING DIAGNOSIS	D3.5	Effect classes

APPENDIX 5

ENTITIES OF MEDICINAL PRODUCT

1 APPEARANCE
2 APPLIED DOSE REGIME
3 APPROVED DOSE REGIME
4 AUTHORISATION CATEGORY
5 BASE UNIT
6 BASE UNIT SIZE
7 CATEGORY FOR MEDICINAL PRODUCT
8 CONTRA-INDICATION
9 DOSE REGIME FOR PRODUCT
10 FORM
11 INDICATION
12 INDICATION CONSTRAINT BY ROUTE OF ADMINISTRATION
13 INTERACTION
14 INTERACTION TYPE
15 LEGAL CATEGORY
16 LEGAL CATEGORY FOR PRODUCT
17 LICENCE TYPE
18 MEDICINAL PRODUCT FOR INDICATION
19 NAME
20 NAME BY WHICH A MEDICINAL PRODUCT IS KNOWN
21 NAME RELATIONSHIP
22 NAME TYPE
23 ORGANISATION
24 ORGANISATION LOCATION
25 PATIENT
26 PATIENT CHARACTERISTIC
27 PATIENT CHARACTERISTIC TYPE
28 PATIENT TYPE
29 PHARMACEUTICAL PRECAUTION
30 PRECAUTION TYPE
31 PRODUCT CODE
32 PRODUCT ELEMENT
33 PRODUCT ELEMENT TYPE
34 PRODUCT INGREDIENT
35 PRODUCT INGREDIENT TYPE
36 PRODUCT LICENCE
37 PRODUCT PACK
38 PRODUCT ROUTE
39 REGIME ALGORITHM
40 ROUTE OF ADMINISTRATION
41 ROUTE FOR FORM
42 SPECIES
43 STATEMENT OF NO WARNING
44 STRENGTH
45 TYPE OF INVOLVEMENT
46 WARNING
47 WARNING FOR PRODUCT

APPENDIX 6

In order to facilitate the understanding of the modelling process used in this project the following notes are provided.

A6.1 Business Activity Models (BAMs)

These represent the activities taking place in an organisation and are structured in a hierarchal manner. They are collated under the headings PLAN, ENABLE (resource), DELIVER and REVIEW. Each of the activities is investigated to produce Business Activity Models.

Finally they produce the index for the Logical Data Flow diagrams.

A6.2 Data Flow Diagrams

These represent the flow of information within a system and between the system and the outside world.

The symbols used are **EXTERNAL ENTITY, DATA FLOWS, PROCESS BOXES** and **DATA STORES**

A6.2.1 External Entity Symbol

These receive data from sources within the system or are themselves sources of data that is transferred to the system, e.g. Department of Health circulars, Figure A.1.

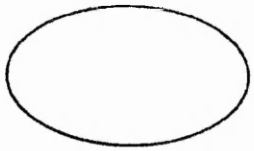


Fig. A.1
External entity symbol

A6.2.2 Data Flow symbol

These represent a data flow between two processes, the direction indicated by the direction of the arrow, Figure A.2. No alteration of the data can take place during the flow of data along the line.

Fig. A.2
Data flow symbol

A6.2.3 Process symbol

The symbol illustrated in Figure A.3 shows that some activity is being performed, which affects the data being handled. Each process can be further decomposed to the lowest level if necessary.

In Structured System Analysis and Design Method (SSADM, 1990) the top two rectangular areas are used for a reference number and the locations where the activity takes place. The latter is not required in the logical model.

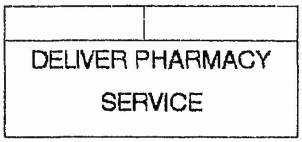


Fig. A.3
Process symbol

A6.2.4 Data Store Symbol

The symbol represented in Figure A.4 represents stores of data similar to a filing cabinet or computer file.

Information passes into and out of these stores either to form a master file or a transient storage file for use at a later date.

Normally the reference number is in the first part of the box and where a store appears more than once on a diagram then an additional bar is added. However, in this project for clarity the reference number is included within the box and no additional bars are attached.

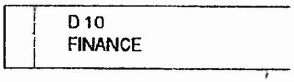


Fig. A.4
Data store symbol

A6.3 Entity Diagrams

A6.3.1 Entity, Entity Types

An entity or entity type is represented by a box in which the entity name or entity type is in capital letters. This is illustrated in Figure A.5.

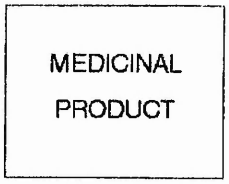


Fig. A.5
Entity symbol

In order to describe an entity, detail can be added to it in such a way that a relationship exists between the entity (or master) and the detail. The detail itself can be another entity. This is shown as two entity boxes joined by a relationship line.

A6.3.2 Relationship Lines

From the entity symbol a line extends to another entity symbol to recognise a relationship between the two entities. The relationship may be either a mandatory relationship, i.e. "must be", or an optional relationship, i.e. "may be". This is represented by the nature of the line; (Figure A.6) "must be" is represented by a solid line and "may be" by a dotted line. Relationships are needed from both directions. In circumstances where the relationship in one direction is definite but in the other direction it is optional the line will be part solid and part dotted. In this situation the nature of the relationship, by convention, is given by the type of line emerging from the entity box.

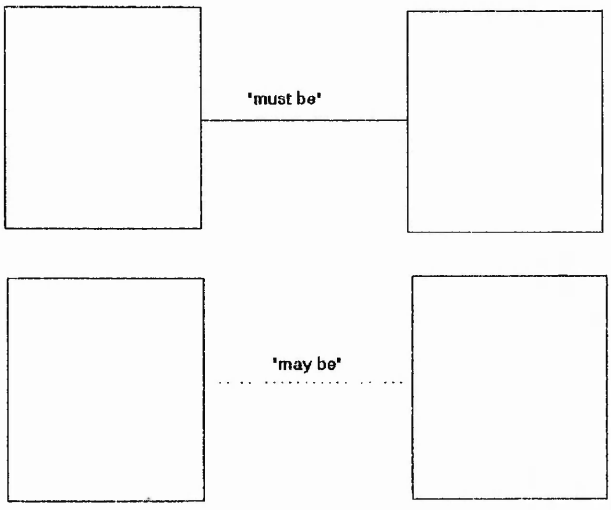


Fig. A.6
The nature of relationships between entities

A6.3.3 Constructed Phrases and Relationship to Entities

The words "must be" and "may be" form part of a constructed sentence. The relationship is further clarified by link phrases that form part of the constructed sentence, examples of which are illustrated in Figure A.7.

By convention the phrase above the line is read in conjunction with the left entity type and the phrase below the line is read in conjunction with the entity type on the right from right to left.

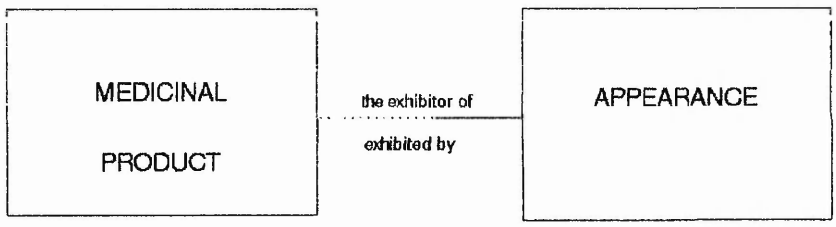


Fig. A.7
The use of link phrases between entities

In a vertical model the phrase nearest the entity type applies to that entity type. This is illustrated in Figure A.8.

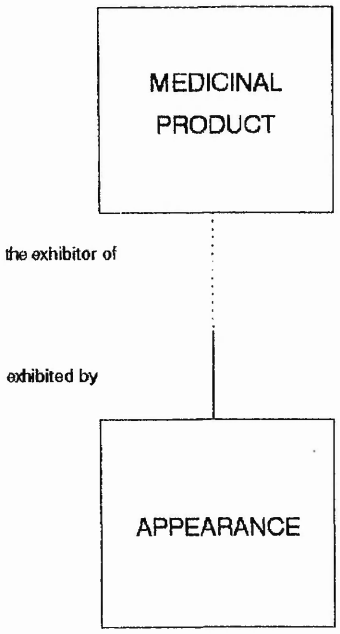


Fig. A.8

The vertical labelling convention of link phrases

In this case a MEDICINAL PRODUCT "may be" the exhibitor of APPEARANCE and APPEARANCE "must be" exhibited by a MEDICINAL PRODUCT.

A6.3.4 Relationship Line Endings

The end of a relationship line indicates the number of entity type occurrences which can be associated with each relationship. There are two main types:

(a) a "crow's foot" which indicates there may be one or many relationships with the entity

(b) a single line indicates only one relationship.

In some situations the conditions given in (a) or (b) may need to include the possibility of 0 relationships occurring, i.e. optionality. To accommodate this, the dotted line convention is coupled with (a), the "crow's foot", to give a relationship of 0, 1 or many or with (b), the single line, to give 0 or 1. This is illustrated in the example in Figure A.9.

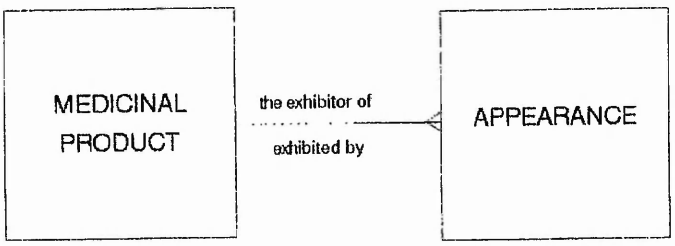


Fig. A.9
The end of line relationships

This relationship says that a MEDICINAL PRODUCT "may be" the exhibitor of 0, 1 or many APPEARANCES but for each occurrence of APPEARANCE there "must be" one and only MEDICINAL PRODUCT.

A6.3.5 Mutually Exclusive Relationships

Some relationships are mutually exclusive in that only one set of relationships exists. This is represented in the following way, Figure A.10.

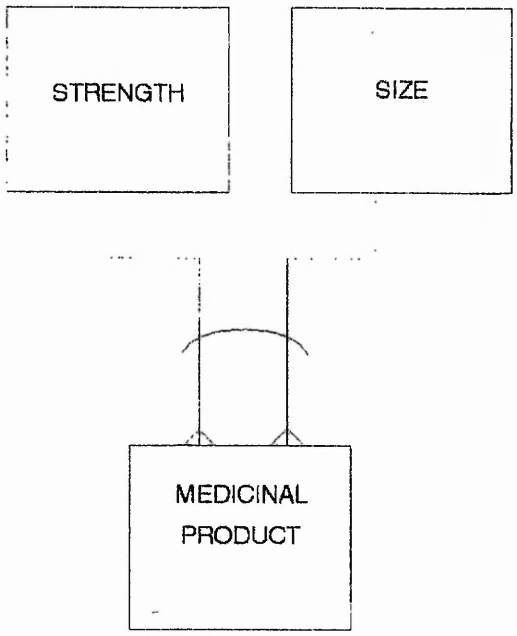


Fig. A.10
The mutually exclusive relationships between entities

An arc links the relationships that are mutually exclusive and the entity that "contains" the centre of the arc is the one to which this exclusivity applies.

This relationship says that a MEDICINAL PRODUCT must have either STRENGTH or SIZE.

A6.3.6 Recursive Relationships

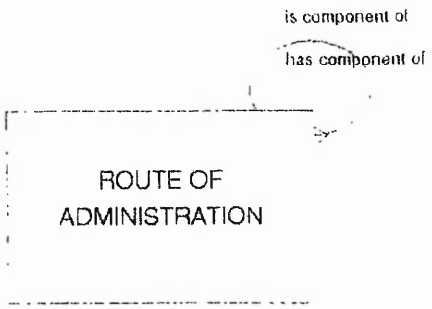


Fig. A.11
The recursive relationship

An hierarchal set of the same entity type can be represented by a single relationship starting and ending at the same entity. This is illustrated in Figure A.11. The relationship line is often referred to as a "pig's ear".

This relationship would allow, for example, for the ROUTE OF ADMINISTRATION "by injection" to be further subdivided into intravenous, intramuscular etc.

A6.3.7 Entity Subtypes

A sub-type has all the properties of the super type plus additional ones, which may be in the form of attributes or relationships.

Entity subtypes are represented as shown in Figure A.12 in which the sub-type is presented as a box within the entity box.

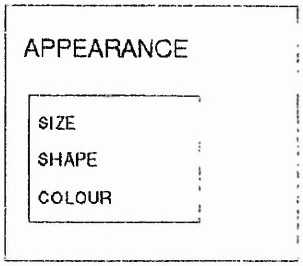


Fig. A.12
The modelling of entities and sub-entities

A6.3.8 Modified Entity, Entity Type Presentation

SSADM requires that entities should have accurate descriptions. These are usually given in separate tables.

Throughout this thesis, the entity boxes have been modified to include definitions and examples on the basis that it is easier to see and understand relationships in a "pictorial manner" rather than to refer to lists of definitions and examples. This is illustrated in Figure A.13.

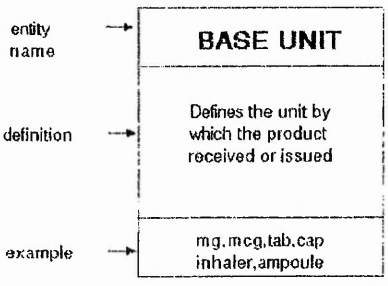


Fig. A.13
The modified entity
representation used in this project

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The construction of a classification and encoding system for drugs

BH Thompson

The presently available coding systems, e.g., EAN, are useful as point-of-sale codes but have little use as a coding system which accommodates the needs of industry, wholesalers, hospital/community pharmacists, drug prescribing, and administration.

The project presently being undertaken in the Pharmacy Department at the Pilgram Hospital, Boston, is to develop by means of data modelling and careful definition of entities, a coding and classification system which will be applicable for medicinal products from the raw material stage through manufacturer, supplier, wholesaler, to users and ultimately to the patient, in the case of drugs administration after prescription. It has been designed to be flexible enough to incorporate new developments or requirements as they develop, as well as present requirements, e.g., COSHH, labelling requirements, storage, and use of the British National Formulary Therapeutic Classification.

The product data model has been developed with links to other data models, e.g., prescribing, licensing, invoicing, manufacturing, etc. Other models are being developed. It also takes into account the special naming conventions of pharmaceuticals and has a facility of adding different coding systems without the need to alter the model.

In order to facilitate coding a four-alpha, four-numeric, and two-alpha code, has been arbitrarily assigned taking into account the diverse names of pharmaceutical products. To this further digits can be added which will allow the following portion of the code to be read, in order to identify the product attribute to which it is related, e.g., form, price, pack size, colour, storage conditions, legal category, special hazards, dose, dose range, stacking details, shipping details, etc. to be read by the appropriate personnel. For a given application, only certain parts of the code need to be printed on the product or its pack.

Similarly the model allows classification of products in any form for any purpose, e.g., those shown in the table.

Table 1

Form	Classified by form e.g., liquid gas, cream, ointment, etc.
Appearance	Colour, fluorescent, may include markings, taste, etc.
Ingredients	Quantity of product within a unit of product, e.g., 32.5 mg Dextropropoxyphene, 325 mg Paracetamol in Co-proxamol tablets
Product element	Number of products in a product pack, e.g., 100 tablets XYZ, 1 tube ointment ABC 50 mg, compriseproduct pack 123.
Ingredient	Active ingredient, inactive ingredient
Pharmaceutical	Do not use if cloudy or if a precipitate is present precautions
Medical precautions	Side effects, adverse reactions

Several portions of this coding and classification system have been in use at the Pilgrim Hospital for some time and they have proved satisfactory over some 4500 product lines.

It is intended to extend the research by incorporating many more codes which are currently being developed from the entities of further diagrams.

DATA MODELS FOR MEDICINES

By B. H. THOMPSON, MRPharmS

ANY system designed for managing pharmaceuticals from their manufacture to their administration has to be simple and usable across the full spectrum of activities. For example, a wholesaler or community pharmacist requires to identify the required product quickly and accurately. A prescriber requires to identify the product by the route of administration and perhaps needs to know its possible interactions and ingredients after having decided to use a particular drug. Both require the same information but in a different form. Similarly, a shipper or transport manager may need to know specialised transport or storage conditions, and all parties will need to know the legal requirements for the product as well as many other details.

It therefore appeared that if data models could be prepared taking into account the legal and the accepted product definitions of the countries of the European Community it would be possible to identify all the attributes of a medicinal product from raw material to administration to patient, providing the information is in a form to suit any professional as well as an audit route for a product. The system had, however, to be capable of linking to already accepted codes, eg, European Approved Names, pipcodes, etc, without altering the data model structure.

A data model is a graphic illustration of carefully defined pieces of data expressed in such a way as to show their relationship to the whole (see Figure 1).

A data model was therefore constructed, using a modified structured systems and design methodology technique, of a medicinal product to form the basis of other data models, eg, prescribing, route of administration, stock control, etc.

A data model illustrating the identification of paracetamol tablets is illustrated in Figure 2. It shows how a unique identifier can be constructed and arranged in a way suitable for the various ways in which health care professionals work.

For example, a doctor having decided the preparation would prescribe it by its route, in this case orally, but a manufacturing wholesaler or community pharmacist would recognise it from its form, in this case tablets.

Research has shown that, using a data base of 4,000 products and some basic rules, products can be uniquely identified by 10 characters: four letters, four numbers and two letters.

► *Mr Thompson is district pharmaceutical officer, South Lincolnshire health authority*

This work is an extension of a joint project between the information centre of the National Health Service and North East Thames regional health authority which sought to identify the elements of a pharmacy service and to match them if possible to the common basic specification written and updated by the Information Management Centre

By the addition of further data items a product can be identified to manufacturer, product ingredients (both active and inactive), legal category, transport, storage conditions, location, therapeutic groups, etc, by any or combination of which it can be classified. Examples are shown in Figures 3, 4 and 5.

By using occurrence diagrams of individual products and related data models an entire history of a medicinal product can be built up from raw materials to the administration of that product to the patient. For example, Figure 6 illustrates the preparation of morphine sulphate injection.

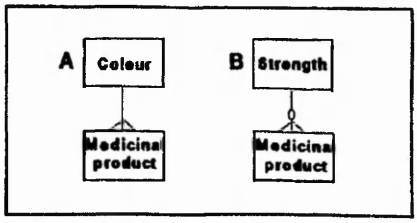

Figure 1: (A) In this data model there must be zero, one or many colours associated with the medicinal product, but for every occurrence of that product there will be only one associated colour. (B) In this data model, there may or may not be a strength associated with the medicinal product, but for every occurrence of the product there will be one and only one strength if one is associated with each product.

CONCLUSION

The data model produces a complete representation of a medicinal product which, when the entities are accurately described, can be used for classifying the product in any combination of entities

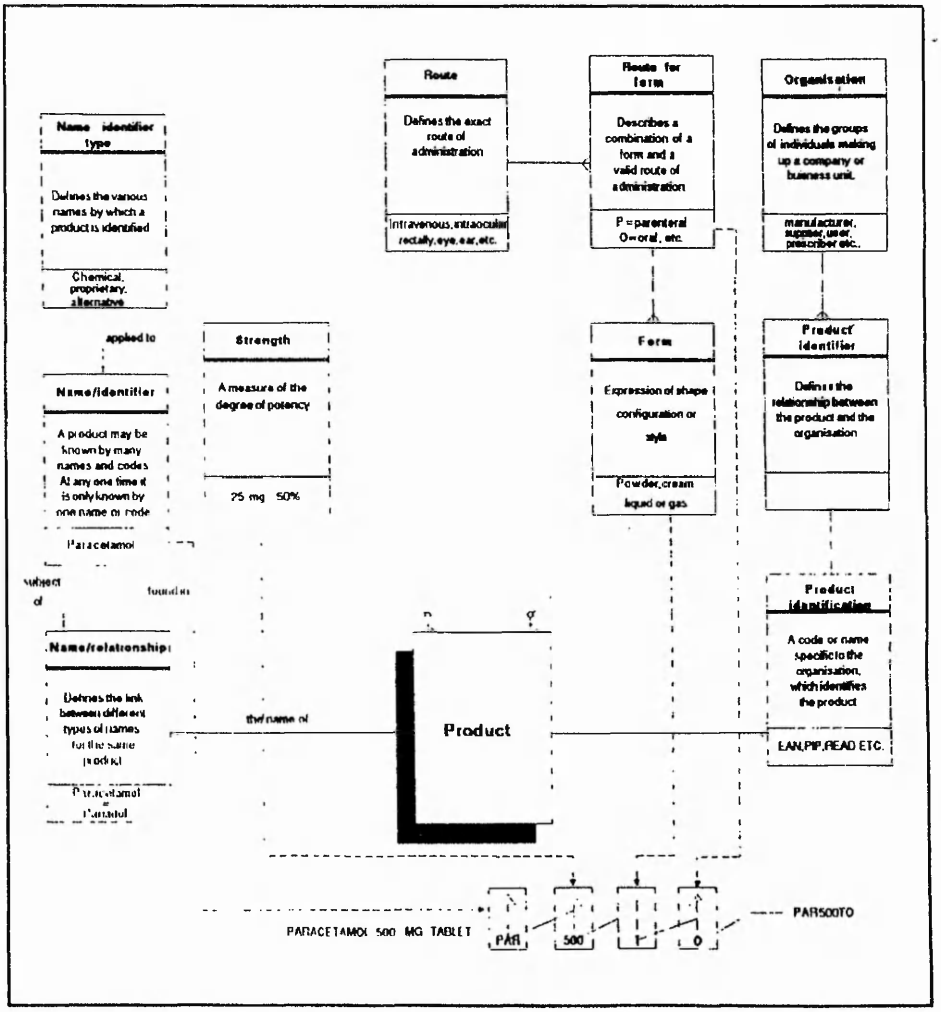

Figure 2: An example of a data flow diagram. See text for explanation.

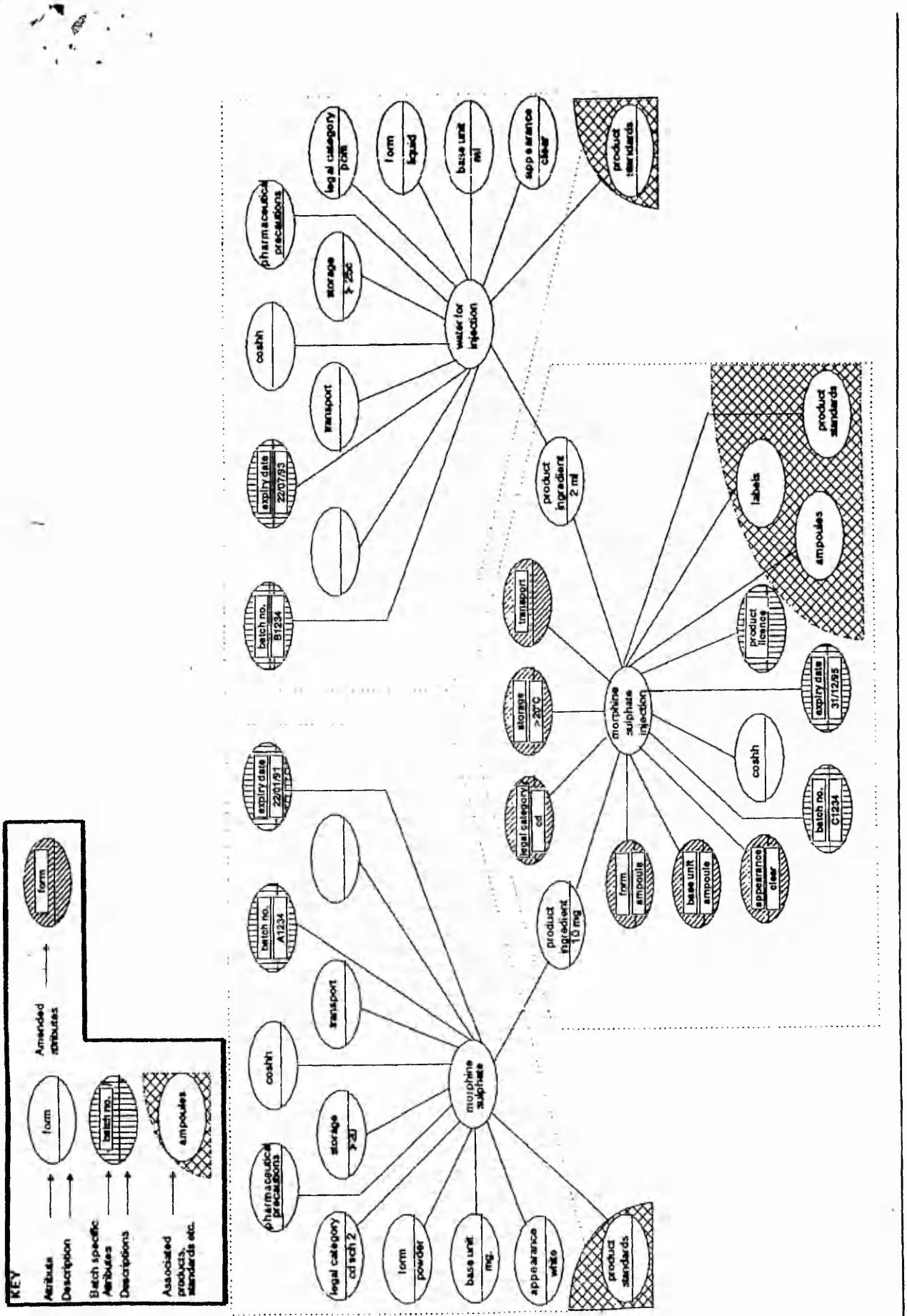

Figure 6: An occurence diagram illustrating the preparation of morphine sulphate injection.

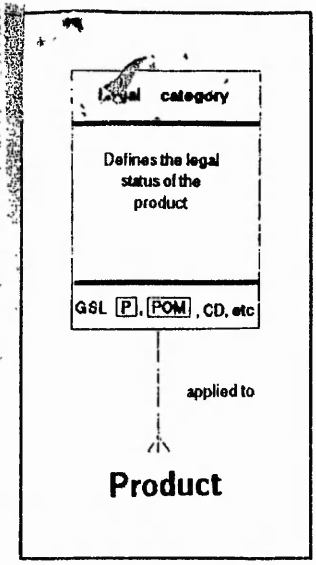

Figure 3: A data model identifying a product's legal category.

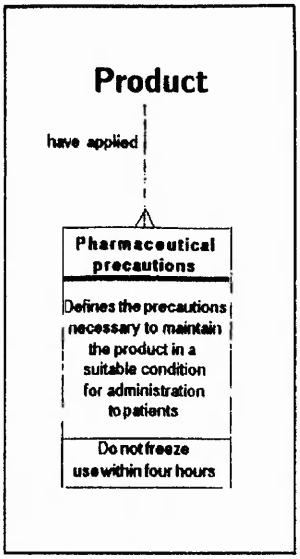

Figure 4: A data model identifying pharmaceutical precautions.

suitable for the required purpose. Similarly the model can be added to, in order to accommodate new developments, perhaps coding systems without interfering with the body of the model. It should thus be possible to use the model for the foreseeable future.

By ng the attributes associated with the entities, eg, batch number, expiry date, it is possible to trace the product from raw material to administration.

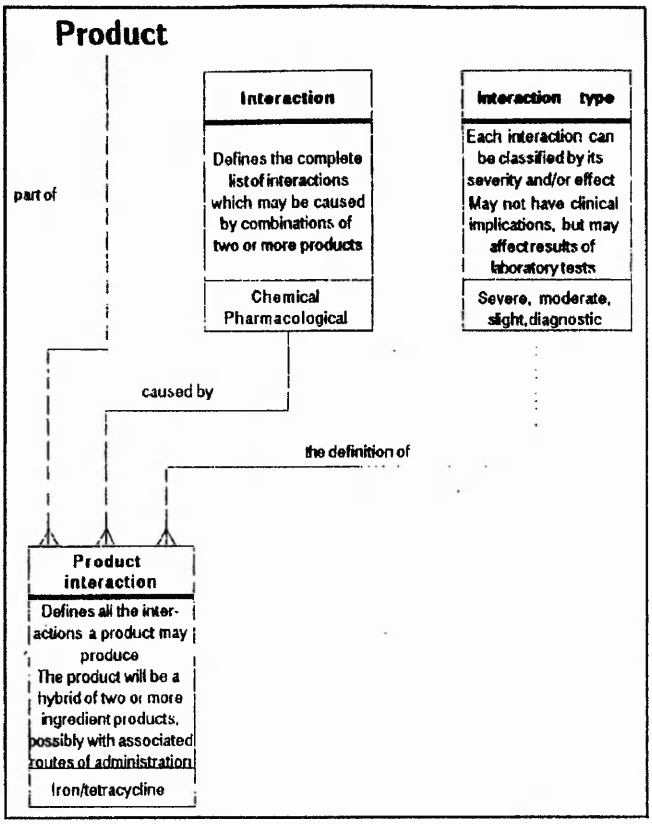

Figure 5: A data model identifying product interactions.

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IMPACT - Integrated MUMPS Prescribing, Administration and Cost Transfer System

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1. Introduction

This system is designed to facilitate the prescription, administration and costing of medicines within all hospital settings. It has been produced to replace a paper based method of working, the objectives being:

improved quality of patient care and safety
improved information and analysis
efficient, economic management of medicine stocks
streamlining of medicine supply
better use of professional time
increased job satisfaction for carers.

2. The Previous Paper-Based Approach

The general pattern of operation was as follows:

1. Clinicians used to handwrite prescriptions using eight different charts or forms.
2. The pharmacists had to read the charts, check the safeness of the medicine in terms of dose, frequency, route to be administered (e.g: some drugs must be given by injection into the muscle and others into the skin (epidermis)), and combination with other drugs prescribed, prior to dispensing the medicines.
3. Nurses had to interpret these charts to select the right medicines at the right time for the right patient having ensured that they were available from the pharmacist when required.

The handwriting of prescriptions is made with little or no reference material available. The manual system also requires either a visit by the nurse to pharmacy or regular visits by pharmacists to wards each time new drugs are required, to check for un-dispensed prescriptions.

Accurate stock levels of medicines were only known for those held in Pharmacy. Usage of drugs was only known per location and not per patient or consultant. The safety of medicines varied according to the knowledge and experience of the prescri-

ber, dispenser and nurse.

3. The New Computer-Based System

The automation of the process of prescription and administration of medicines has made it possible to achieve the above objectives. In addition to writing new software, this has been accomplished via two main initiatives:

1. Electronically linking relevant systems and users together in order to minimise physical movement and time taken to prescribe drugs, dispense new prescriptions and automatically re-order depleted ward stock.

2. Including on-line information and automatic checking to ensure drugs, their doses and preparations are safely prescribed.

4. The Design and Working of the New System

The new software resides on a 486/33Mhz PC SERVER (Fig 1: PATIENT FILE) running DataTree DT Max and networking MUMPS with a Netbios link to a SHADOWER.

It is also linked to PC clients also running DT Max networking MUMPS on the wards and departments, via the ethernet network. This enables the prescribers and nurses to access the system from the point of convenience.

5. Links to Sources of Information

The SERVER takes the basic demographic patient and bed state information from the Patient Administration System which is written in DSM11 and housed on a PDP 11/44. This gives the vital information required to identify the patient, their location within the hospital and their consultant.

The Patient History File, on a second PDP 11/44, provides details about physical state (age, weight etc - needed to calculate the appropriate drug dose and frequency), and medical history to check for allergies or diagnoses which would contra-indicate the prescription of certain drugs.

There is also a link via the network into the Pharmacy Management System, which also runs under DSM11 and is housed on another PDP 11/44. This provides all the drug information. There has been a thorough analysis and re-coding of the drugs to enable timely provision of information and warnings relating to medicines which have a similar therapeutic action, which have important interactions with other drugs or which are contra-indicated in the case of certain medical conditions. Optimum dosages, frequencies and routes for administering different drugs are also a feature of

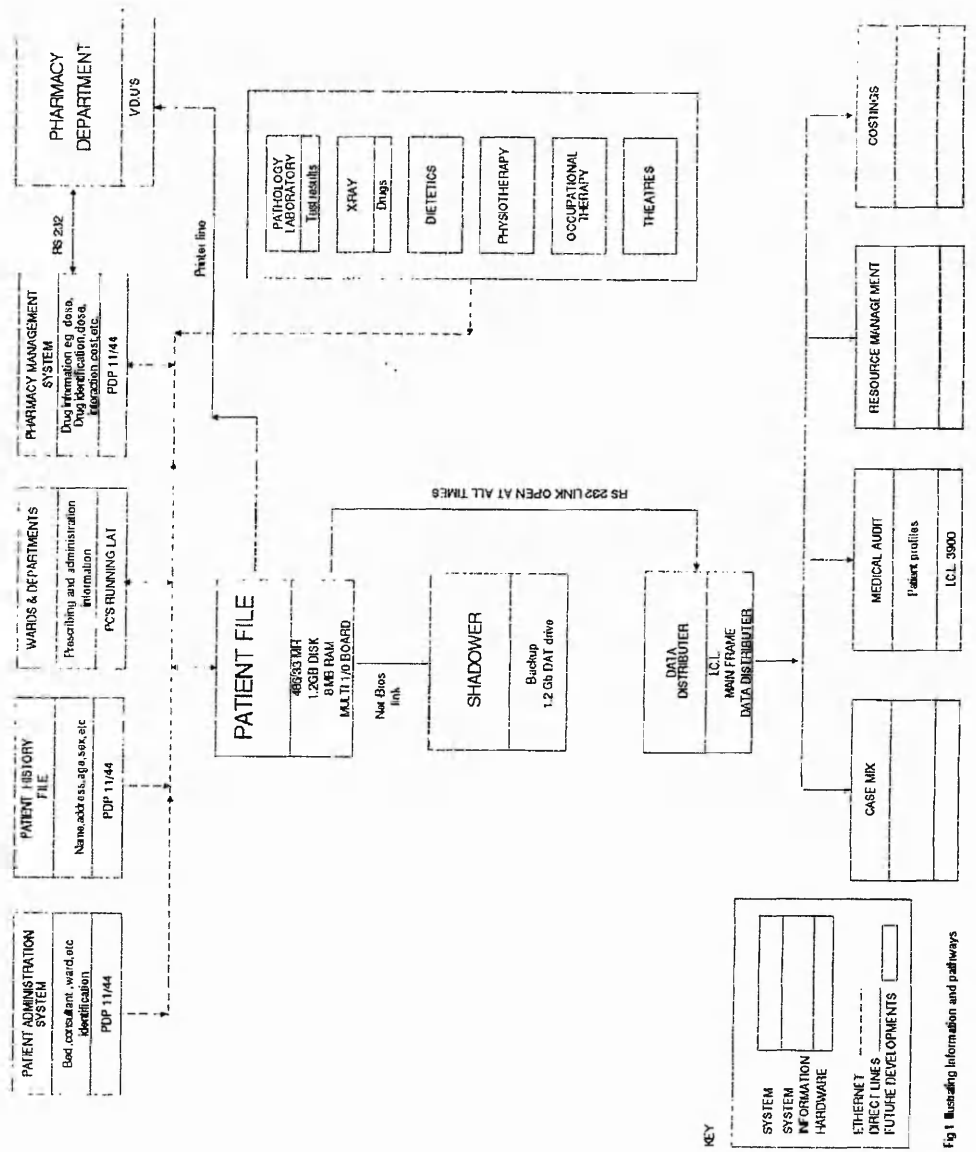

Fig 1 Illustrating information and pathways

the revised drug information. The Prescribing system also provides information on the drug stocks in wards and departments and automatically requests replenishment of stock. The pharmacist can keep track of drugs around the whole hospital and in emergency can request transfers of items, which are out of stock in Pharmacy, between wards.

There is a printer based in Pharmacy, which outputs new prescriptions as they are entered into the system from around the hospital.

6. Using the New System

Once the Doctors have identified the patients and prescribed the relevant drugs, the nurses can print a list of drugs due in time sequence, with patient names and bed numbers. This list is taken on the drug trolley and used as a single legible source of information of those drugs due. On completing the drug round the nurse can return to the ward terminal and at a single prompt, enter "Yes" or "No" to confirm whether all the drugs due have been administered. If "No", she is able to log the exceptions with reasons. The system will them remind her that those drugs are still due. Individual patient medicine charts can also be printed. Drugs can be discontinued and new ones added at any time, as with the paper system. The advantage now is that drugs cancelled cease to appear on the chart so there is no confusion. It is a lot clearer to interpret and hence safer.

The system is security controlled with two levels of access. The first security code or "ID" identifies the person and their status. Those who are qualified doctors, midwives etc., are able to prescribe. Those who are nurses are able to administer. The system recognises the state registered nurses who can give controlled drugs. The "ID" acts as an electronic signature. The system adds this and the date to each transaction the user makes. Hence there is effectively a signed record of all drugs prescribed and administered.

Consultants are able to establish protocols for administering medicines for particular medical conditions. The system will hold these and offer them to doctors prescribing for a patient with that particular consultant and medical condition. The protocols could be made mandatory if this is desired by the consultant. This needs to be considered carefully in case it should become proscriptive.

7. Links to Provide Information

Information is output via an RS232 link, which is open at all times, to four different systems:

1. to Medical Audit where analysis of patient drug profiles can be made in relation to standard disease classifications. This will assist in measuring the efficacy of treatment protocols and in deciding whether further refinements should be made.

2. to the Case Mix system where management can look at the overall case load of the hospital and analyse the work load and efficacy of treatments.

3. to the Resource Management system where analysis of the use of drugs and all other resources can be made.

4. to the Costing system where the information contributes to analysing the total cost per patient episode, per consultant and per course of treatment in relation to the effectiveness.

8. Conclusion

As mentioned in the Introduction, this system was introduced with certain objectives in mind.

1. Improved quality of patient care and safety

There are now safeguards to prevent the doctors from diagnosing drugs, doses or routes which are known to be less than optimum. The system has a lot of information in-built which is produced on screen at the relevant time. The consultants can also set up protocols to give their junior doctors the benefit of their expertise even when they are absent.

2. Improved information and analysis

Prior to the introduction of this system there was no means of collecting data necessary to costing and analysing the efficacy of medical treatments.

3. Efficient, economic management of medicine stocks

Pharmacists can see at a glance now which drugs are where in the hospital, which are no longer needed and could be brought back for re-issue.

4. Streamlining of medicine supply

In automating the prescribing, dispensing and administering of drugs, we have been able to streamline and speed up the supply from pharmacy to the patient.

5. Better use of professional time

In achieving 4. above we expect to demonstrate a saving of professional time in ordering drugs and in checking patient prescriptions and administering drugs but without risking, rather enhancing, patient safety.

6. Increased job satisfaction for carers.
In achieving 4. and 5. above we expect to improve the lot of the nurse, doctor and pharmacist. The doctor will be able to go to the nearest terminal in order to prescribe and no one will contact him to decipher his handwriting. The pharmacist will know immediately that more drugs are required without having to leave his workplace and the nurse will have a legible organised comprehensive drug list, an easy recording system and a reminder system for overlooked drugs.

Finally - the computer professionals have linked all relevant systems together and have the opportunity to demonstrate the speed and convenience of a well planned computer based system.