

**BUSINESS INFORMATION REQUIREMENTS FOR THE
PERFORMANCE MANAGEMENT OF
ASEPTIC DISPENSING IN THE NATIONAL HEALTH SERVICE**

ROBERT JOHN GANDY

A thesis submitted in fulfilment of the
requirements of the Liverpool John Moores University
for the degree of Doctor of Philosophy

May 2007

INDEX

| | <u>Page</u> |
|--|--------------------|
| Index | i |
| Abstract | ii |
| Acknowledgements | iii |
| Glossary of Abbreviations Used | iv |
| Details of Sections in Chapters | vi |
| List of Tables | xii |
| List of Figures | xiv |

CHAPTERS

| | | <u>Page</u> |
|-------------------|-------------------------------------|---------------------------------------|
| CHAPTER 1 | INTRODUCTION | 1 |
| CHAPTER 2 | LITERATURE REVIEW | 34 |
| CHAPTER 3 | METHODOLOGY | 74 |
| CHAPTER 4 | METHODS | 117 |
| CHAPTER 5 | RESULTS | 152 |
| CHAPTER 6 | DISCUSSION | 229 |
| CHAPTER 7 | FURTHER WORK | 256 |
| CHAPTER 8 | RECOMMENDATIONS | 260 |
| CHAPTER 9 | CONCLUSIONS | 263 |
| | BIBLIOGRAPHY | 270 |
| CHAPTER 10 | PUBLISHED WORK FROM RESEARCH | 295 |
| CHAPTER 11 | APPENDICES | Separate Document See Compact Disk |

Abstract

The purpose of this research is to determine the information to be collected for aseptic dispensing in NHS hospitals, and its use for management and business purposes in relation to capacity, demand, performance and efficiency.

Mixed methodologies were adopted on an exploratory basis. Qualitative methods included: regular expert input; workshops; out-turn questionnaires; Affinity Analysis; surveys; and structured interviews. Quantitative methods included: activity data surveys; targeted surveys; and Delphi methods.

The research systematised the collection and collation of the required data and determined novel ways of analysing and manipulating it to aid decision-making. These were used to evaluate the impact of major capital investment and variations in practices between different parts of the country.

A benchmarking approach should be applied in utilising the data and statistical indicators.

Nomenclature issues can influence data quality. Therefore clear, unambiguous guidance was developed for data collection. Existing pharmaceutical information systems will be the main sources of the data for the foreseeable future.

The research focused on the North West of England, with successful application in the West Midlands. Its transferability to non-NHS and foreign hospitals is inferred, as long as similar operational arrangements apply.

The research enables: the measurement of progress towards implementing the Breckenridge (1996) recommendations; the evaluation of performance for aseptic production and usage to inform capacity planning; and the presentation of the degree of collaboration between hospitals.

The research addresses the absence of set data for an important hospital support service, and applies relevant lessons from other fields and industries. It enables a systematic approach to capacity planning and performance evaluation, at a time when the contribution of the service to support clinical governance is being fully recognised.

Acknowledgements

I would like to give acknowledgement and thanks to the following:

Bob McClelland, Charles Morecroft and Graham Matthews for their friendship, advice, supervisory work and humour over the course of my time with the University.

Ian Beaumont for his friendship, support and advice throughout my research from the very beginning, and for acting as co-author for several pieces of my related published work.

My other co-authors in respect of my related published work.

The British Journal of Clinical Governance, Hospital Pharmacist, and Pharmacy Management for kindly providing electronic copies of my published work, so that they can be included in the thesis.

Those organisations that commissioned me on a consultancy basis to undertake work that has acted as the basis of the research.

Denis Adams and Peter Case-Upton for their various contributions and direct support and advice in respect of analytical and database requirements.

Those many health professionals in the North West, and elsewhere, who have provided expert input to the research and/ or acted as members of the various expert panels.

My family: Mom, Dad, Phil and Hilda, together with my three sons John, David and Christopher, for their continued love and support.

And last but by no means least, my wife Margaret, without whose love, patience and support this thesis would simply not have been possible.

Glossary of Abbreviations Used

| | |
|----------------|--|
| ADUH | Aseptic Dispensing Unit Hours |
| ADUHW | Aseptic Dispensing Unit Hours per Week |
| ADUHCW | Aseptic Dispensing Unit Hours per Week per Cabinet |
| AWTP | Average Weighted Time per Product |
| C&CP | Capital & Collaboration Programme (funded by NHS Executive North West) |
| CASfMM | Controls Assurance Standards for Medicines Management |
| CFH | Connecting For Health |
| CHWC | Cabinet Hours per Week per Cabinet |
| CIVAS | Centralised Intravenous Additives Service |
| CRP | Capacity requirements planning |
| DHSSPSNI | Department of Health, Social Services and Public Safety Northern Ireland |
| DoH | Department of Health |
| DHSS | Department of Health and Social Security |
| EPS | Electronic Prescribing Systems |
| EU | European Union |
| FCE | Finished Consultant Episode |
| FFCE | First Finished Consultant Episode |
| HEPA | High Efficiency Particulate Air |
| HSJ | Health Service Journal |
| ICT | Information and Communications Technology |
| IV | Intravenous |
| IM&T | Information Management & Technology |
| MA | Marketing Authorisation |
| MCA | Medicines Control Agency |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| MIP | Major Incident Plan |
| ML | Manufacturing Licence |
| MRP | Material Requirements Planning |
| MRP2 or MRP II | Manufacturing Resource Planning |

Glossary of Abbreviations Used (Continued)

| | |
|------|---|
| NHS | National Health Service |
| NPSA | National Patient Safety Agency |
| PAF | Performance Assessment Framework |
| PCA | Patient Controlled Analgesia |
| PL | Product Licence |
| RAWP | Resource Allocation Working Party of Department of Health |
| R&D | Research and Development |
| SHA | Strategic Health Authority |
| SMV | Standard Minute Value |
| STE | Staff Time Equivalent |
| TPN | Total Parenteral Nutrition |
| UTE | Unit Time Equivalent |

Details of Sections in Chapters

| Section | Title | Page |
|----------------|---|-------------|
| | Chapter 1 Introduction | 1 |
| 1.0 | Introductory Overview | 1 |
| 1.1 | Research background | 3 |
| 1.1.1 | Reason for research | 3 |
| 1.1.2 | Researcher's personal research interests | 3 |
| 1.1.3 | Background information | 4 |
| 1.2 | Hospital Pharmacy Departments | 5 |
| 1.3 | Aseptic Dispensing and Preparation | 7 |
| 1.4 | Medicines Act 1968 | 8 |
| 1.5 | Licensed and Unlicensed Units | 9 |
| 1.5.1 | Licensed Manufacturing Units | 10 |
| 1.5.2 | Unlicensed Manufacturing Units | 10 |
| 1.6 | Aseptic Practice and Technique | 12 |
| 1.7 | Managing Risk Associated With Ward-based Aseptic Practice and Techniques: National picture 1970s - 1997 | 12 |
| 1.8 | Information & Information Technology | 14 |
| 1.8.1 | NHS Information Systems & Electronic Prescribing | 14 |
| 1.8.2 | EPS and Data on Aseptic Preparation | 15 |
| 1.9 | Mainstream NHS Information & Data | 15 |
| 1.10 | North West Initiatives in respect of Aseptic Dispensing 1997 - 2005 | 16 |
| 1.10.1 | EL(96)95 & Original North West Survey | 16 |
| 1.10.2 | North West Working Party of Chief Executives and Chief Pharmacists | 17 |
| 1.10.3 | Outcomes from North West Working Party Report | 18 |
| 1.10.4 | Evaluation of Capital & Collaboration Programme | 19 |
| 1.11 | Clinical Governance and Medicines Modernisation: National Picture 1997 to date | 20 |
| 1.11.1 | Emphasis on Clinical Governance | 20 |
| 1.11.2 | Medicines Expenditure & Trends | 20 |
| 1.11.3 | Medicines Management | 21 |
| 1.11.4 | Risk Assessment | 21 |
| 1.11.5 | National Investment for Pharmaceutical Modernisation | 22 |

| | | |
|---------------|---|-----------|
| 1.11.6 | Monitoring Progress | 23 |
| 1.11.7 | Other Related Initiatives | 23 |
| 1.11.8 | Continuing Evolution of Services | 24 |
| 1.12 | Governmental Approach to Improving Performance in Healthcare since 1997 | 25 |
| 1.13 | Examples of Relevant Change Influences and Processes | 26 |
| 1.14 | Commercial Pharmaceutical Sector in respect of Aseptic Products | 28 |
| 1.15 | Aseptic Preparation in Private Hospitals | 29 |
| 1.16 | International Picture | 30 |
| 1.17 | Need for Information and Data to Support Aseptic Dispensing and Preparation in the NHS | 30 |
| 1.18 | Aim & Objectives of Research | 31 |
| 1.19 | Presentation of Research | 31 |
| 1.20 | Summary Outline of Steps in Research Process | 33 |
| | Chapter 2 Literature Review | 34 |
| 2.0 | Introductory Overview | 34 |
| 2.1 | Strategic Approaches to Literature Review | 35 |
| 2.1.1 | Background | 35 |
| 2.1.2 | Literature Searches | 36 |
| 2.1.3 | Scope of literature review | 36 |
| 2.1.4 | Available Pharmaceutical Literature Sources | 37 |
| 2.1.5 | Non-Pharmaceutical Literature Sources | 39 |
| 2.2 | Aseptic Technique, Best Practice and Clinical Governance | 39 |
| 2.3 | International and Regional Practices concerning Aseptic Preparation | 43 |
| 2.4 | Nomenclature for Aseptic Preparation | 44 |
| 2.5 | Metrics Surrounding Collaboration | 47 |
| 2.5.1 | Collaboration in Healthcare | 47 |
| 2.5.2 | Measuring Collaboration | 50 |
| 2.5.3 | Established metrics potentially applicable to Collaboration | 53 |
| 2.6 | Capacity and Workload Measurement | 54 |
| 2.6.1 | Definitions | 54 |
| 2.6.2 | Capacity Plans | 55 |
| 2.6.3 | Influence of Cancer Services Developments | 56 |
| 2.6.4 | Capacity and Workload Measurement | 57 |
| 2.6.5 | Unit Time Equivalents | 59 |

| | | |
|----------------|--|------------|
| 2.6.6 | Measuring the Aseptic Dispensing Process and Facilities | 60 |
| 2.7 | Information Systems & Data relating to Pharmacy and Aseptic Preparation | 62 |
| 2.7.1 | EPS | 62 |
| 2.7.2 | Complexity of Pharmaceutical Data | 63 |
| 2.7.3 | Information Systems relating to Aseptic Dispensing | 64 |
| 2.8 | Computerised Capacity Planning Software | 64 |
| 2.9 | Aseptic Skill Mix Issues, Skills Management & Quality | 66 |
| 2.9.1 | Skills Development in the NHS | 66 |
| 2.9.2 | Skills Management and Quality | 67 |
| 2.10 | NHS Data related to Patient Activity | 69 |
| 2.11 | Governmental Approach to Performance Management and Benchmarking since 1997 | 70 |
| 2.12 | Gaps in Literature | 73 |
| | Chapter 3 Methodology | 74 |
| 3.0 | Introduction | 74 |
| 3.0.1 | Philosophical Approach to Methodology | 74 |
| 3.0.2 | Overview of Methodological Approach | 75 |
| 3.0.3 | Relationship to Paradigms | 75 |
| 3.0.4 | Use of Expert Input | 79 |
| 3.0.5 | Qualitative and Quantitative Approaches | 80 |
| 3.0.5.1 | Questionnaires | 80 |
| 3.0.5.2 | Qualitative Interviews | 81 |
| 3.0.5.3 | Developing Definitions of Concepts | 82 |
| 3.0.5.4 | Delphi Techniques | 82 |
| 3.0.6 | Constraints | 83 |
| 3.1 | Data to Collect | 84 |
| 3.2 | Information Systems Data Audit | 86 |
| 3.3 | Baseline Survey | 88 |
| 3.4 | Baseline Survey Evaluation | 91 |
| 3.5 | Quarterly Surveys | 93 |
| 3.6 | Quarterly Surveys Evaluation | 95 |
| 3.7 | Data Available in Clinical Areas | 95 |
| 3.8 | Nomenclature | 97 |
| 3.9 | Collaboration | 98 |
| 3.10 | Work Study | 100 |
| 3.11 | Unit Time Equivalents | 103 |
| 3.12 | Concepts: Capacity and Workload | 104 |

| | | |
|---------------|--|------------|
| 3.13 | Statistical Indicators | 106 |
| 3.14 | Modelling | 107 |
| 3.15 | Acute Capacity Planning | 109 |
| 3.16 | Transferability | 111 |
| 3.17 | Evaluation of Programme | 113 |
| 3.18 | New Information Systems | 115 |
| | Chapter 4 Methods | 117 |
| 4.0 | Validation | 117 |
| 4.0.1 | Continual Validation | 117 |
| 4.0.2 | Original Expert Panel | 117 |
| 4.1 | Data to Collect | 118 |
| 4.2 | Information Systems Data Audit | 122 |
| 4.2.1 | Systems Survey | 122 |
| 4.2.2 | Availability of Research Data | 122 |
| 4.2.3 | EPS | 124 |
| 4.2.4 | Outline Data Collection Proposals | 124 |
| 4.2.5 | Validation Workshop | 124 |
| 4.3 | Baseline Survey | 125 |
| 4.4 | Baseline Survey Evaluation | 127 |
| 4.5 | Quarterly Surveys | 128 |
| 4.6 | Quarterly Surveys Evaluation | 129 |
| 4.7 | Data Available in Clinical Areas | 130 |
| 4.8 | Nomenclature | 133 |
| 4.9 | Collaboration | 135 |
| 4.10 | Work Study | 136 |
| 4.11 | Unit Time Equivalents | 137 |
| 4.12 | Concepts: Capacity and Workload | 140 |
| 4.13 | Statistical Indicators | 142 |
| 4.14 | Modelling | 143 |
| 4.14.1 | Capacity Planning Software | 143 |
| 4.14.2 | Capacity Modelling | 143 |
| 4.15 | Acute Capacity Planning | 144 |
| 4.15.1 | National Chemotherapy Simulation Model | 144 |
| 4.15.2 | Local Acute Capacity Planning Models | 144 |
| 4.15.3 | Analysis | 145 |
| 4.16 | Transferability | 145 |
| 4.17 | Evaluation of Programme | 147 |
| 4.18 | New Information Systems | 151 |

| | | |
|---------------|--|------------|
| | Chapter 5 Results | 152 |
| 5.1 | Data to Collect | 152 |
| 5.2 | Information Systems Data Audit | 154 |
| 5.3 | Baseline Survey | 156 |
| 5.4 | Baseline Survey Evaluation | 160 |
| 5.5 | Quarterly Surveys | 163 |
| 5.6 | Quarterly Survey Evaluation | 166 |
| 5.7 | Data Available in Clinical Areas | 167 |
| 5.8 | Nomenclature | 173 |
| 5.9 | Collaboration | 176 |
| 5.10 | Work Study | 182 |
| 5.11 | Unit Time Equivalents | 187 |
| 5.12 | Concepts: Capacity and Workload | 192 |
| 5.12.1 | Workshop | 192 |
| 5.12.2 | Final Workshop Conclusions | 193 |
| 5.12.3 | Views of Expert Panel | 194 |
| 5.12.4 | Validation by Regional Quality Control Pharmacists | 195 |
| 5.13 | Statistical Indicators | 196 |
| 5.13.1 | Developed Indicators | 196 |
| 5.13.2 | Calculating the Statistical Indicators Using Baseline Data | 197 |
| 5.14 | Modelling | 200 |
| 5.14.1 | Capacity planning software | 200 |
| 5.14.2 | Capacity Modelling | 201 |
| 5.15 | Acute Capacity Planning | 202 |
| 5.15.1 | Chemotherapy Simulation Tool | 202 |
| 5.15.2 | Leeds Teaching Hospital | 202 |
| 5.15.3 | North Manchester General Hospital | 203 |
| 5.15.4 | Conclusions | 203 |
| 5.16 | Transferability | 204 |
| 5.16.1 | West Midlands Analysis | 204 |
| 5.16.2 | West Midlands versus North West Comparisons | 208 |
| 5.16.3 | Overview | 212 |
| 5.17 | Evaluation of Programme | 212 |
| 5.17.1 | Coverage, consistency and presentation | 212 |
| 5.17.2 | Production and usage | 214 |
| 5.17.3 | Capacity issues | 218 |
| 5.17.4 | Collaboration between trusts | 219 |
| 5.17.5 | Scattergrams | 224 |

| | | |
|---------------|---|------------|
| 5.17.6 | Moving preparation from clinical areas | 225 |
| 5.17.7 | Trusts participating in Capital & Collaboration Programme | 226 |
| 5.18 | New Information Systems | 228 |
| | Chapter 6 Discussion | 229 |
| 6.0 | Aim and objectives and research process | 229 |
| 6.1 | Information Required and Data To Collect | 229 |
| 6.2 | Feasibility of Collecting Data | 231 |
| 6.3 | Nomenclature Issues | 233 |
| 6.4 | Feasibility of Collecting Data and Creation of Baseline | 236 |
| 6.5 | Baseline Survey Evaluation | 237 |
| 6.6 | Quarterly Surveys | 239 |
| 6.7 | Collaboration | 240 |
| 6.8 | Time Weightings | 242 |
| 6.9 | Quantifying the Concepts of Capacity and Workload | 244 |
| 6.10 | Statistical Indicators | 245 |
| 6.11 | Use of Data and Statistical Indicators to Evaluate Change | 247 |
| 6.12 | Transferability | 250 |
| 6.13 | Modelling | 251 |
| 6.14 | Acute versus Medium/Long-term Capacity Planning | 252 |
| 6.15 | Impact of New Information Systems | 254 |
| 6.16 | Use of Research Data and Statistical Indicators | 255 |
| | Chapter 7 Further Work | 256 |
| 7.1 | Connecting with Hospital Service Activity and Plans | 256 |
| 7.2 | Acute Capacity Planning | 258 |
| 7.3 | Linking Research in Skill Mix and Competencies to Support Capacity Planning Methodologies | 259 |
| 7.4 | Refinements of Research Data and Approach | 259 |
| 7.5 | Benchmarking Website | 259 |
| | Chapter 8 Recommendations | 260 |
| | Chapter 9 Conclusions | 263 |
| | Bibliography | 270 |
| | Chapter 10 Published Work from Research | 295 |

List of Tables

| Table | Title | Page |
|--------------|--|-------------|
| 1.1 | Comparisons of Key Issues Relating to Licensed Units & Those Operating Under Section 10 Exemptions of the Medicines Act 1968 | 11 |
| 1.2 | Constituent Components of Research: Purpose and Researcher's Role/Contribution | 32 |
| 3.1 | Basic Beliefs (Metaphysics) of Alternative Inquiry Paradigms | 76 |
| 4.1 | Trusts and Clinical Areas covered in Data Audit of Clinical Areas | 132 |
| 5.1.1 | Scores for Affinity analysis results as to relevance for clinical areas | 152 |
| 5.1.2 | Scores for common aseptic products as to relevance for clinical areas | 153 |
| 5.3.1 | Baseline Survey: Total volumes produced and used by each Trust/site | 158 |
| 5.3.2 | Baseline Survey: Total volumes produced and used by Product Type | 159 |
| 5.3.3 | Relationship between Size of Production and License Status | 160 |
| 5.4.1 | Illustration of data validation analysis | 161 |
| 5.5.1 | Trends in Production for Trusts participating in the Five Quarterly Surveys | 164 |
| 5.5.2 | Trends in Production for Product Types for Trusts participating in the Five Quarterly Surveys | 165 |
| 5.7.1 | Documentation Used Within Clinical Areas | 168 |
| 5.7.2 | In Patient Prescription Sheet | 169 |
| 5.7.3 | Blood and Intravenous Fluid Chart | 170 |
| 5.7.4 | Responsibility for preparation and administration of aseptic medicines | 170 |
| 5.7.5 | Variables/ Product Types used in the Audited Clinical Areas | 171 |
| 5.7.6 | Categories of Product Types | 172 |
| 5.7.7 | Random Count of Aseptic Preparations Administered | 172 |
| 5.7.8 | Local views of Frequency of Data Collection | 172 |
| 5.8.1 | Definitions of terms agreed for use within research | 173 |
| 5.8.2 | Numbers of words relating to specific terms | 174 |
| 5.8.3 | Words commonly used by professionals in clinical areas relating to specific terms | 175 |

| | | |
|---------------|--|------------|
| 5.9.1 | Aggregate Activity Over The Five Survey Quarters For Participating Trusts | 181 |
| 5.10.1 | Selected Process Timings: Minibag Plus (50 Ml; One Vial per Bag) – Batch of 50 (Flucloxacillin 1g) | 184 |
| 5.10.2 | Selected Process Timings: Minibag Solution (50 Ml) – Batch of 20 (Ranitidine); Syringe used in Assembly | 185 |
| 5.10.3 | Selected Process Timings: TPN – Neonatal (Time for one TPN Neonatal) | 186 |
| 5.11.1 | Summary of Progression of UTE Values | 188 |
| 5.11.2 | Summary Results from Survey of North West Aseptic Managers as to their agreement with the Proposed Average Production Times/UTES | 189 |
| 5.13.1 | Values of Statistical Indicators Using Baseline Survey Data | 198 |
| 5.16.1 | Total Volumes Produced in Aseptic Units and Used by Trusts by Trust in West Midlands (2000/01) | 205 |
| 5.16.2 | Total Volumes Produced in Aseptic Units and Used by Trusts by Product in West Midlands (2000/01) | 206 |
| 5.16.3 | Derived Usage of Aseptic Dispensing Units in West Midlands (2000/01) Using (Mean) Marker Unit Time Equivalents | 207 |
| 5.16.4 | Aseptic Production Rates in West Midlands and North West | 208 |
| 5.16.5 | Number of products produced at individual Trusts in the West Midlands, compared with the North West | 208 |
| 5.17.1 | Comparison of Distribution of Aseptic Dispensing Units in the North West by Licensing Type and Production Volume: Baseline versus 2003/04 | 214 |
| 5.17.2 | Changes in Production and Usage by Trust: Baseline to 2003/04 | 215 |
| 5.17.3 | Changes in Production & Usage by Product Type: Baseline – 2003/04 | 217 |
| 5.17.4 | Changes in Usage of Commercial Sources: Baseline – 2003/04 | 218 |
| 5.17.5 | Projected and Actual production levels for Aseptic Units at Trusts participating in the C&CP | 218 |
| 5.17.6 | Analysis of Changes in Collaboration for each Zone in North West: Baseline – 2003/04 | 223 |
| 5.17.7 | Estimation of Change in Aseptic Preparation Activity in Clinical Areas by Geographical Zone: Baseline – 2003/04 | 225 |
| 5.17.8 | Comparison of Actual & Planned Increases in Production for Trusts/Units that received Capital Funding (Anonymised) | 227 |

List of Figures

| Figure | Title | Page |
|---------------|---|-------------|
| 1.1 | Healthcare Commission Description of Pharmacy Services | 6 |
| 1.2 | Flowchart Outlining Steps in Research Process | 33 |
| 2.1 | Comparisons of Steps Measured in Aseptic Process used by Different Authors | 61 |
| 4.1 | Conceptual Model of Stock Process Within Clinical Area | 131 |
| 5.4.1 | Mapping of product types used in different research-related exercises | 162 |
| 5.9.1 | First Draft Collaboration Diagram By Trust Using Baseline Data | 177 |
| 5.9.2 | Import/ Export Collaboration Diagram By Trust Using Baseline Data | 179 |
| 5.9.3 | Import/ Export Collaboration Diagram for Baseline Quarterly Equivalent and each Quarterly Survey for Participating Trusts | 180 |
| 5.9.4 | Aggregate trends in Collaboration for Quarterly Survey Trusts | 181 |
| 5.11.1 | Regression Chart: Relationship between Minimum & Mean Production Times (Unforced) | 190 |
| 5.11.2 | Regression Chart: Relationship between Maximum & Mean Production Times (Unforced) | 190 |
| 5.11.3 | Regression Chart: Relationship between Minimum & Mean Production Times (Forced) | 191 |
| 5.11.4 | Regression Chart: Relationship between Maximum & Mean Production Times (Forced) | 191 |
| 5.13.1 | Scattergram of AWTP and ADUHC Values for Baseline Data | 199 |
| 5.16.1 | Comparison of Production in West Midlands and North West Regions by Product Type | 209 |
| 5.16.2 | Collaboration Diagram West Midlands (2000/01) | 211 |
| 5.16.3 | Collaboration Diagram North West (Baseline) | 211 |

| | | |
|---------------|---|------------|
| 5.17.1 | Inter-relationship between data collected for each Product Type within the single survey form (2003/04) and the survey design agreed by the expert panel | 213 |
| 5.17.2 | Percentage change in key indicators: Baseline – 2003/04 for each category of aseptic unit | 220 |
| 5.17.3 | Collaboration by Product Type for Baseline | 221 |
| 5.17.4 | Collaboration by Product Type for 2003/04 | 221 |
| 5.17.5 | Collaboration by Trust for Baseline | 222 |
| 5.17.6 | Collaboration by Trust 2003/04 | 222 |
| 5.17.7 | Collaboration by Geographical Zone: Baseline - 2003/04 | 223 |
| 5.17.8 | Scattergram of AWTP and ADUHC Values by Type of Aseptic Unit - Baseline | 224 |
| 5.17.9 | Scattergram of AWTP and ADUHC Values by Type of Aseptic Unit – 2003/04 | 225 |

Chapter 1 Introduction

1.0 Introductory Overview

The research covered by this thesis relates to the question of what information can and should be collected in relation to the production and preparation of aseptic products, primarily in National Health Service (NHS) hospitals in the United Kingdom (UK), and how it should be used for management and business purposes. The main focus of the work is in the North West of England.

Aseptic preparation involves sterile products being administered to patients by injection or irrigation, with the products being prepared in a hospital pharmacy or assembled in the clinical area, usually by a nurse. There is national guidance and legislation, in terms of production in pharmacies and clinical governance. It is likely that hundreds of thousands of such products are administered each day across the country. It is recommended that aseptic preparation should preferably be undertaken in pharmacies (Breckenridge, 1976) but hospitals do not have data that will confirm what the balance of aseptic preparation is between pharmacies and clinical areas.

This lack of set data relating to the production and usage of aseptic products prompted the research relating to this thesis, at a time when improvements and a more business-like approach were required for these services.

However, any data and analyses need to fit in with both the managerial and professional vocabulary. Therefore a research question that needed to be examined was how collected data should be used to support management discussions concerning key concepts such as “capacity”, “workload” and “collaboration”, in respect of business processes relating to aseptic production and preparation.

A further issue to be encompassed within the research was that of nomenclature. Different professions sometimes use the same words to mean different things, and sometimes they use different words to mean the same thing. With the range of professions involved in aseptic production and preparation this could have potential implications for the quality of any such data, when consistency and accuracy of interpretation are required. Consequently, nomenclature needed to be included in the research.

Chapter 1 therefore sets the scene, with Section 1.1 providing the main reasons and background for the research. Sections 1.2-1.6 describe: where Pharmacy sits within

hospital services, and how aseptic dispensing sits within a pharmacy; how aseptic dispensing, preparation and technique are defined, and the influence of legislation; and the different types of production facilities. Section 1.7 then outlines the national approach to managing the associated risks from the 1970s up to 1997.

The year 1997 represents something of a landmark in the approach and attitudes towards aseptic preparation, particularly in the North West. Therefore, before moving on to a more regional focus, Sections 1.8 and 1.9 outline the National situation in respect of both pharmacy and mainstream information systems, given their potential as the sources of required data.

Section 1.10 describes the history of aseptic dispensing work in the North West, from its initial response to national directives to the identification of the need to evaluate the impact of major capital investment. Section 1.11 places the North West in the national context, primarily in relation to clinical governance and modernising medicines management. The importance of clinical governance and managing clinical risk is central to why aseptic production and usage should be measured and monitored. Sections 1.12 and 1.13 then place these pharmacy-related initiatives within the context of the overall governmental approach to improving performance within the NHS, including the use of benchmarking.

It was important for the research to look outside the NHS, to see if there are lessons to be learned. Therefore Sections 1.14-1.16 consider the commercial pharmaceutical sector and private hospitals within the UK, before looking at the international picture.

The chapter then concludes by summarising the need for information and data to support the development and management of aseptic production and preparation in the NHS (Section 1.17), before describing the specific aim and objectives covered by this thesis (Section 1.18). Section 1.19 sets out a framework, which is used to present the research findings, breaking them down into 18 components, with the purpose of each and the researcher's role/contribution outlined. The framework is integral to Chapters 3, 4 and 5, ensuring correspondence for each component across them, e.g. Sections 3.8, 4.8 and 5.8 respectively detail the methodology, methods and results for Nomenclature.

Finally a flowchart is provided in Section 1.20 outlining the links between the various steps in the research process.

It should be noted that the author of this thesis is also known as the researcher throughout.

1.1 Research background

1.1.1 *Reason for research*

This thesis relates to aseptic dispensing and preparation, primarily in NHS hospitals in the UK. The activity is extremely common in acute clinical care within hospitals, and involves risks according to a range of factors (e.g. complexity and risk of preparation error, and chemical stability/shelf life) which point to whether preparation should take place within a pharmacy rather than in a clinical area (NHS Executive North West, 1997). Therefore the management of these risks is very important to support clinical governance. However, data has not been routinely collected in respect of aseptic production and usage. Consequently there has not been the development of measures and indicators to enable pharmacists, managers and other professionals to manage, plan, deliver and evaluate these services.

The modernisation of the NHS has driven improvements in care and support services, with a range of central and local initiatives to specifically improve aseptic dispensing and preparation. Yet without accepted relevant data, and agreed ways of utilising such data, it is not possible to evaluate the degree to which the aims and objectives of any initiatives have been met.

The research, to which this thesis refers, addresses this deficiency, by establishing: what data can and should be collected in respect of aseptic production and usage; how such data can be manipulated to provide statistical measures that are meaningful and useful to pharmacists, managers and others; and whether the findings can be successfully applied to actual initiatives, so as to evaluate their efficacy.

1.1.2 *Researcher's personal research interests*

The researcher has long been interested in examining how commonplace or specialised subjects/concepts might be measured or expressed statistically (see Section 11.1 for a list of publications not relating to this research). This research is an example of this: what is meant by terms used every day (in the NHS), such as “workload”, “capacity”, and “collaboration”, and how are they best measured for practical usage? The nature of such terms is that they are concepts that are open to interpretation, but which are used all the time for business and management purposes. Indeed, they will be interpreted differently in different arenas, and can evolve over time.

Because there are no absolute measures for the concepts, research approaches necessarily involve the (quantitative) development and use of proxy measures, integrated with testing the (qualitative) acceptability for their use to professionals, managers and others working within the field. Consequently, an iterative mixed methodological process is essential, as methods are continually refined/ upgraded in the light of developments in practice and data, and the constituency's responses to results. In each and all cases the research problem dictated the approach applied, taking into account any constraints (see Section 3.0.6).

1.1.3 *Background information*

To consider the research approach, methods and results it is first necessary to have background information of:

Aseptic dispensing and preparation, and where they feature in the overall role of pharmacy;

The environments of aseptic dispensing and preparation, and the associated risks;

How aseptic dispensing and preparation are organised and the rules that apply to them; and

The history of aseptic dispensing and preparation development in the NHS, and associated dynamics, together with an appreciation of the situation in the private sector and abroad.

It is also important to appreciate the role of information in connection with aseptic dispensing and preparation, and how this compares and relates to developments in information systems, data and performance measurement in the NHS, and the wider public sector. Suitable allowance will also need to be made (as far as possible) for changes in pharmaceutical services and information systems, as NHS modernisation unfolds (DoH, 2000d; Secretary of State for Health, 2002; NHS Executive, 1998).

This context is necessary in order to set out the aims and objectives of the research, and the reasons for pursuing them.

1.2 Hospital Pharmacy Departments

A full hospital pharmacy service has been described as providing patient-focused medicines management, in accordance with statutory requirements and the Code of Ethics of the Royal Pharmaceutical Society of Great Britain (Healthcare Commission, 2005). This service should also actively support education and research throughout the Trust (*ibid*). Figure 1.1 below provides an outline.

The main departments and functions relating to aseptic dispensing and preparation come under Preparative Unit Services, although nearly all other functions can have an important bearing, e.g. drug purchasing and supply. All aseptic preparation facilities should be commissioned by quality control and then monitored at regular intervals (Beaney, 2006).

“Asepsis” is defined as:

The state of being free of living pathogenic micro-organisms.

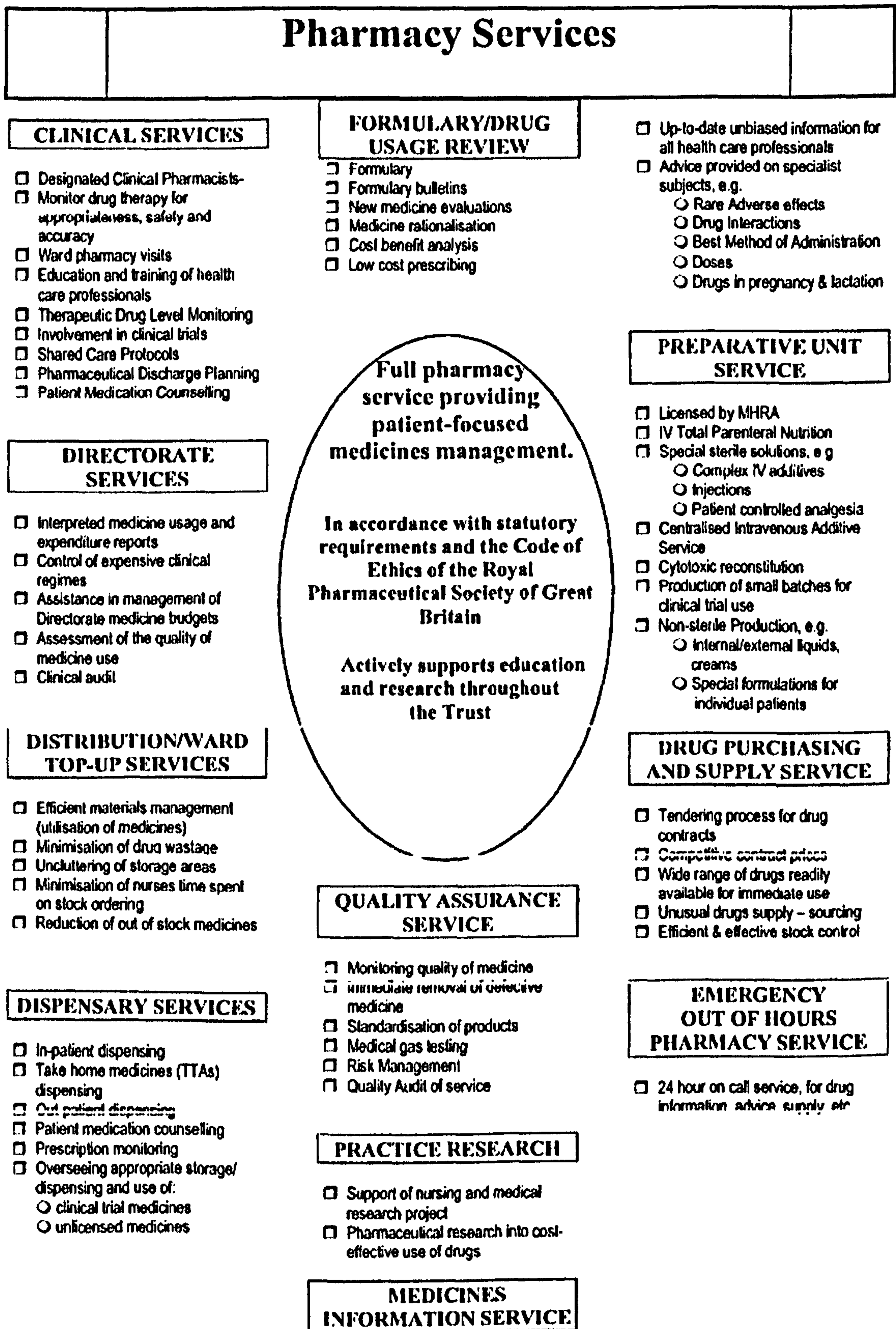
The process of removing pathogenic micro-organisms or protecting against infection by such organisms.

(Medical-dictionary.thefreedictionary.com, 2006)

Therefore, the word “aseptic” refers to working in a sterile environment, free from contaminating germs or bacteria, and using sterile techniques and instruments (Drugdevelopment-technology.com, 2006). Accordingly, aseptic dispensing is defined as the activity of supplying a sterile product in its appropriate form, using aseptic technique, to the patient pursuant to a doctor’s prescription (DoH, 2003a).

However, aseptic dispensing and preparation represent only one of the two main components of Preparative Unit Services. The other is classical/traditional manufacturing, which was not covered by this research. Classical manufacturing consists of terminally sterilised manufacture and non-sterile manufacture (*ibid*).

Figure 1.1 Healthcare Commission Description of Pharmacy Services



(Healthcare Commission, 2005)¹

¹ Available at: <http://www.healthcarecommission.org.uk/db/documents/04020127.pdf> Accessed 28th March 2007, 6.40pm

1.3 Aseptic Dispensing and Preparation

From the perspective of the Medicines Act 1968 (Medicines Act, 1968), aseptic dispensing should be seen as two separate but linked activities (Farwell, 1995). The first activity is dispensing, which is the supply or issue of a finished product to the patient or to the person responsible for its administration. The second activity is preparation, which is the manipulation of the product leading to this final presentation (*ibid*).

In order to achieve sterility, the facilities and performance requirements of aseptic preparation are necessarily very strict. The performance criteria of a facility should be established prior to building (Beaney, 2006), and adherence to the design specification should involve installation, operational and performance qualifications (British Standards Institute, 1999; Beaney, 2003).

With regard to performance requirements, all aseptic operations should be performed in a workstation sited within a controlled workspace environment conforming to EU Guide grade A (Medicines and Healthcare products Regulatory Agency, 2003). This may be provided by:

- A Laminar Flow Cabinet: situated in a clean room that is dedicated to aseptic preparation, with the room environment complying with EU Guide grade B.
- A Pharmaceutical Isolator: sited in a dedicated room used for the isolator and its ancillary equipment and related activities, with the room environment complying with EU Guide grade D.

(*ibid*)

There are many specific design and performance requirements that need to be adhered to in aseptic preparation facilities. These include: Clean rooms have associated changing rooms, designed as airlocks and used to provide separation of the different stages of change, thereby minimising microbial and particulate contamination of protective clothing (Beaney, 2006); Support rooms from which materials can be passed onto and out of the clean room through a hatch(es), with the doors of the hatch(es) interlocked (*ibid*); Ideally, clean air devices should run continuously; Pressure differentials across inlet high efficiency particulate air (HEPA) filters in cabinets, isolators and clean rooms, and between rooms of different classifications should be constantly indicated; All rooms and equipment used for preparation activities should be cleaned regularly and frequently in accordance with written procedure; All equipment should be operated in accordance with written operating instructions; Major equipment, including air-handling systems, should be subject to a suitable planned preventative maintenance schedule (*ibid*).

Such requirements must be met to ensure the quality of the aseptic products, irrespective of the volumes prepared, as long as safety is not jeopardised (see Section 11.38). Therefore creating and maintaining an aseptic environment represents a substantial fixed cost.

There is no standard design of an aseptic preparation unit, with variations across the country, to a greater or lesser extent (NHS Executive North West, 2001). Consequently there will always be limitations placed on any “standard solutions” recommended by any party.

Radiopharmaceuticals were initially included in the research, but subsequently excluded because they involve special units and have very specific requirements, different from other aseptic products (see Section 6.5). They have short shelf lives (generally less than 24 hours) that have been the subject of some controversy within pharmaceutical circles (Beaney, 2006), and especially since guidance questioned end-user dispensing in other departments by non-pharmacy staff (NHS Pharmaceutical Quality Assurance Committee, 2004).

1.4 Medicines Act 1968

The Medicines Act 1968 (Medicines Act, 1968) was introduced to regulate the manufacture, distribution and importation of medicinal products. This required the manufacture, wholesaling, importation and marketing of medicines to be controlled through a licensing system operated by the Department of Health’s (DoH) Medicines Control Agency (MCA). The objectives of the licensing provisions were to provide assurance on the safety, quality and efficacy of medicines via a system of product licenses (PL) and manufacturing licenses (ML).

Section 7 of the Act authorises the holder of a PL to: Sell, supply or export the product; Procure the manufacture or assembly of the product; and, Import the product. (Note: European Directives refer to marketing authorisations (MA) in preference to PLs; As a product approval, the two terms can be considered interchangeable).

Section 8 of the Act covers manufacturing licenses. Anybody who wishes to manufacture or assemble a medicinal product must hold a ML. Manufacture includes any process performed in the course of making the product. Assembly is the filling or labelling of the primary container. A ML covers the manufacture of broad classes or compounds (e.g. tablets, eye drops, ointments, etc.). A ML is only granted after an inspection of the premises has been made in the light of accepted criteria for good manufacturing practice.

The Act necessarily provided for some exemptions, given the practicalities of delivering healthcare at the time, and subsequently:

Section 9 enables Doctors and Dentists to be exempted from the licensing requirements of sections 7 & 8 (ML & PL), in the following circumstances: Products prepared to their prescription for administration to a particular patient of theirs; Products manufactured to their own prescription or that of another practitioner for a particular patient; When procuring the manufacture of stocks of products up to a maximum limit of 5 litres of fluid and 2.5 kg of solids; and, Products imported for administration to a particular patient.

Section 10 enables Pharmacists to be exempted from the licensing requirements of sections 7 & 8 (ML & PL), in the following circumstances: Preparing or dispensing a medicinal product in a hospital or health centre by or under the supervision of a pharmacist in accordance with a doctor's prescription; Assembling a medicinal product in a hospital or health centre by or under the supervision of a pharmacist; Preparing a stock of medicinal product in a hospital or health centre by or under the supervision of a pharmacist with a view to dispensing them.

Section 11 states that a registered Nurse or a certified Midwife does not require a manufacturer's licence in order to assemble medicinal products in the course of his/her profession.

A ML generally authorises manufacture or assembly of a product only if the licence holder also holds a PL in respect of that product or is manufacturing on behalf of the PL holder. Products may, however, be manufactured as part of a "specials dispensing service" (Specials) in response to special orders received from hospitals, retail pharmacists, wholesalers etc. A person providing these services is granted a ML (Specials) Licence that authorises the manufacture of medicinal products without a product licence.

1.5 Licensed and Unlicensed Units

There are essentially two types of manufacturing units within hospitals, *licensed* and *unlicensed*. These are described as follows:

1.5.1 *Licensed Manufacturing Units*

These units possess a ML (Specials) Licence under the provision of the Medicines Act (Medicines Act, 1968). A license is granted by the Medicines Control Agency (MCA) (now the Medicines and Healthcare products Regulatory Agency – MHRA) following an inspection of facilities, operating procedures, documentation and quality control procedures within a unit. A unit has to be audited against the Rules Governing the Manufacture of Medicinal products in the European Community (Commission of the European Communities, 1992).

This is normally seen as the most appropriate option for larger units that wish to provide a comprehensive local service and/or services to other hospitals.

1.5.2 *Unlicensed Manufacturing Units*

Unlicensed units do not hold a manufacturing licence. Preparation of medicines in anticipation of a prescription is exempted from the licensing requirements by virtue of conditions given in section 10 of the Act. MCA guidelines on the application of the Medicines Act to NHS hospitals advise that the units can undertake aseptic preparation providing set criteria are met (MCA, 1992). Activities should always be in accordance with the latest defined NHS guidelines (Medicines Act, 1968; Farwell, 1995; NHS Executive North West, 1997). For example, the conditions specified by MCA in 1992 were extended to cover preparation for dispensing directly to individual patients by Farwell (1995).

Preparation activities meeting the set criteria will nonetheless require an acceptable level of quality assurance together with regular external audit by quality assurance staff (Beaney, 2006).

Table 1.1 describes the main differences between licensed and unlicensed manufacturing units. It should be emphasised that the required standards for the facilities, operational procedures and documentation are the same for both licensed and unlicensed units.

Notwithstanding the above standards that aseptic units are required to meet, it is important to appreciate that the lack of consistency in the design of aseptic units across the country (NHS Executive North West, 2001), has always presented a major constraint when attempts have been made to make valid comparisons (Gandy and Beaumont, 2003a). This reflects many factors: whether a unit was “added on” to an existing hospital (which may be very old or modern), with associated space and functionality constraints, or

was an integral component of comprehensively designed building; the approach to hospital planning design prevailing at the time a unit was built; and, the local emphasis placed on aseptic services, which would influence the aseptic production size and capacity.

Table 1.1 Comparisons of Key Issues Relating to Licensed Units & Those Operating Under Section 10 Exemptions of the Medicines Act 1968

| SECTION 10 EXEMPT UNITS | LICENSED UNITS |
|--|---|
| Mainly in response to a prescription but can make in anticipation of demand | No formal request documentation required |
| Some small batch preparation may occur | Batch preparation is usual practice |
| Operates under Pharmacists' supervision | Operates with "Key Personnel" defined in license |
| Output restricted by MCA guidance | Output regulated, but not usually restricted by MCA |
| Shelf life restricted to a maximum of 7 days | Shelf life defined by validation work, normally well in excess of "Section 10" restrictions |
| Often a mixture of dedicated and rotational staff | Primarily dedicated, specialist staff |
| Needs high numbers of pharmacists and technicians | Skill mix allows for increased utilisation of support staff grades |
| Relatively high capital costs | Relatively high capital costs |
| High product costs | Relatively low product costs in spite of extra license and inspection fees |
| Internal audit system and inspection by Regional Quality Assurance specialists | Internal audit, external audit and inspection by MCA |

(NHS Executive North West, 1997)

1.6 Aseptic Practice and Technique

“Aseptic Technique” refers to the manipulation of sterile products by personnel so as not to introduce microbial and/or particulate contamination (DoH, 2003a).

Aseptic technique is the effort taken to keep the patient as free from hospital micro-organisms as possible (Crow, 1989). It is a method used to prevent contamination of wounds and other susceptible sites by organisms that could cause infection. This can be achieved by ensuring that only sterile equipment and fluids are used during invasive medical and nursing procedures.

1.7 Managing Risk Associated With Ward-based Aseptic Practice and Techniques: National picture 1970s - 1997

The first major published recognition of problems with aseptic practices and techniques in hospitals was in the 1970s, with the publication of the Breckenridge report (Breckenridge, 1976). The situation at that time was one where: there was a general lack of information regarding stability and compatibility of drugs in intravenous fluids; where pharmacists were rarely involved in advising doctors and nurses about these issues; nurses were in a “wasteland” due to poor training; labels showing that a drug had been added were often not attached to fluid bags; and, it was common practice, for example, to add drugs to inappropriate fluids (Graham, 2005).

The report recommended that drug-infusion mixtures ideally should be prepared in pharmacy-run facilities and not in wards, advice that was subsequently recommended by the British National Formulary. If this was not possible, the report went on to suggest that pharmacists should be at the forefront in giving advice about the addition of drugs to fluids in clinical areas, and should be heavily involved in training and educating doctors and nurses in this area of clinical practice (Breckenridge, 1976).

Given the huge number of such preparations in NHS hospitals, such a major change (*ibid*) could not hope to be implemented straightaway, and required an ongoing process. Consequently products were often prepared on an individual basis. In addition, the subsequent growth in chemotherapy, parental nutrition, nuclear medicine, etc expanded the range of special injections that, due to their complexity or hazards, had to be handled away from patients in special environments (Chief Pharmacist, 1994). Therefore, the focus of many national pharmacy initiatives since Breckenridge (1976) has been to increase patient safety by improvements in the preparation and usage of aseptic products,

primarily by risk management. The basic tenet is that it is preferable for aseptic preparation to be undertaken in pharmacies rather than in clinical areas, particularly for “high risk” products (Farwell, 1995; Chief Medical Officer and Chief Pharmacist, 1996; NPSA, 2006). Consequently data requirements have focused on audit and compliance.

Unfortunately, the early 1990s saw a number of fatal incidents. One involved the deaths of two children in April 1994 at the Royal Manchester Children’s Hospital following their injection of products that had been kept in proximity to a radiator (Anon, 1994), which resulted in the DoH undertaking a critical review of local practices for aseptic production. In addition, the Chief Pharmacist in 1994, highlighted the significant growth in the aseptic preparation of medicines in facilities managed by pharmacists. This was often done using Section 10 exemptions from full licensing available to pharmacists under the Medicines Act 1968. The evidence suggested that the standards of practice utilised did not always reach the levels of good practice recommended. This was seen as having the potential of increasing the significant risk regarding patient safety (Chief Pharmacist, 1994).

As a consequence, the Chief Pharmacist issued the Farwell report (Farwell, 1995) which described best practice and policies, and consolidating much of the guidance and requirements from Breckenridge (1976) and the Medicines Act 1968.

Moreover, the Secretary of State in 1996 asked the MCA to investigate standards of aseptic preparation in unlicensed NHS pharmacies in the UK (Chief Medical Officer and Chief Pharmacist, 1996). The survey involved a 10 per cent sample of all unlicensed aseptic dispensing units (i.e. 26), with advance notification of visits given. Widespread deficiencies were reported, and the MCA concluded that standards and guidelines were not being consistently met (*ibid*). Most of their concerns related to facilities, equipment and quality assurance. In over 60 per cent of the sample there were “significant failings” (against the standards required), although one in six of the units were considered to have standards comparable to those in licensed units (*ibid*).

This prompted the DoH to issue EL(96)95, which focused on the need for any unlicensed aseptic dispensing carried out within a Trust pharmacy to comply with published standards, and compelling all hospital Trusts to undertake an internal audit of all such facilities (*ibid*). The associated audit questionnaire enabled the evaluation of current practice, aiming at whether facilities, processes and resources met required standards, with proposed action to address any shortfalls. The deadline for completion was March 1997.

Importantly, the audit questionnaire did not collect data regarding levels of activity either in aseptic dispensing units or clinical areas. The whole exercise took place without any background data on the size and balance of aseptic dispensing and preparation taking place in these environments. Consequently, it was not possible for the DoH, or anyone, to have any appreciation of the relative volumes involved and the degree to which the Breckenridge (1976) recommendation to shift the balance of preparation away from clinical areas to pharmacies had been put into effect. Arguably this reflected a significant gap in knowledge.

1.8 Information & Information Technology

1.8.1 NHS Information Systems & Electronic Prescribing

The NHS has a relatively poor track-record in respect of investment and application of Information Management & Technology (IM&T) (NHS Executive, 1998). The publication of *Information for Health (ibid)* highlighted both existing shortcomings and future investment strategy. This resulted in a multi-billion pounds investment programme to improve IM&T systems and services across the NHS with a target that 4 per cent of total NHS spend should be on information technology by 2008 (Wanless, 2002), more than doubling the percentage at the time.

The Government intended IM&T investment to be at the heart of its overall modernisation programme for the NHS (Audit Commission, 2001). Electronic prescribing systems (EPS) (sometimes referred to as e-prescribing)² were a priority for reducing medical errors (Goundrey-Smith, 2004; HSJ, 2002), and pharmacy automation in respect of dispensing was a key factor in re-engineering hospital pharmacy services for a modern working environment (Audit Commission, 2001).

EPS reduce medicine errors significantly by providing timely, legible information (Wyatt and Walton, 1995; Schiff and Rucker, 1998; CFH, 2006b). This reduces transcription errors (a major source of medicine errors) and the loss of prescription sheets (Audit Commission, 2001). Therefore computer technology is not an optional extra but a fundamental part of the modernisation agenda for a range of changes, including clinical governance and pharmacy (DoH, 2000d; NHS Wales, 2001), creating the opportunity to release scarce pharmacy resources into direct patient care. Therefore the priority for pharmaceutical services within the *Information for Health* strategy was EPS. All Trusts would be expected to achieve the goal of having a Level 3 Electronic Patient Record by the target date of 2005 (NHS Executive, 1998).

² EPS is not Electronic Prescription Service

There were perceived problems at the outset of the national investment programme for EPS in 2002, in terms of slippage on procurement, and the impact on local support and actions of having a centralised approach to delivery (HSJ, 2002; Hoeksma, 2002; Bolton, 2002). Procurement and implementation should take place over the period 2008 – 2010 (CFH, 2006b).

1.8.2 *EPS and Data on Aseptic Preparation*

The focus of EPS is on clinical specialties, and improving clinical governance, and they do not include aseptic products/preparation per se although some such activity might be inferred (CFH, 2006b). (This situation was subject to review with the production of the formal functional specification (CFH, 2007a)).

Existing pharmaceutical information systems relating to aseptic dispensing support the operation of pharmacies (e.g. to produce labels), rather than generate detailed data for analysis (Gandy and Beaumont, 2003a). There are four main systems that have been established since the 1990s (*ibid*).

This situation in respect of limited relevant data being electronically available from NHS systems placed constraints on research methods. (A confirmatory check on progress was required towards the conclusion of the research, see Section 11.57).

1.9 **Mainstream NHS Information & Data**

The main measurements of hospital activity have traditionally focused on what is done by the medical profession, with the production of minimum datasets for patients attributed to whichever consultant is responsible for a patient for a given period of time. The Korner review of NHS data was undertaken in the mid-1980s (DHSS, 1984). Prior to this a patient's whole stay would be attributed to the consultant and specialty responsible immediately prior to discharge. This meant that specialties that were involved in the early stages of patients' stays did not get sufficient credit for their contribution, and arguably those that were involved in the latter stages got undue credit. The solution recommended by Korner was to break down the overall patient's spell into each episode under the care of a different consultant and specialty, where internal transfers were involved (*ibid*). This resulted in the creation of (inpatient) Finished Consultant Episodes (FCEs). These FCEs could be combined in different analytical ways to best answer a query. FCEs were used as the main activity currency in the early days of the "internal market" in the early 1990s.

However, it was suspected that some Trusts were more imaginative than others in how they recorded internal transfers: with increases in the number of FCEs being greater than the increases in the number of patient spells, resulting in apparent increases in patient throughput and apparent decreases in costs per case. FCEs are retained as a currency but these criticisms meant that First Finished Consultant Episodes (FFCEs) are now more generally used, because they are essentially the same as spells, i.e. a patient is only counted once.

The level of demand for aseptic products will naturally reflect the number and the related casemix of patients treated in a hospital, together with any local policies regarding aseptic preparation (Gandy et al, 2003; Gandy, 2005; Gandy and Beaumont, 2006; Hardy and Mellor, 2007). Therefore any analysis of aseptic preparation and usage for a hospital over a period of time, particularly where any movement in aseptic preparation between clinical areas and pharmacies is being investigated, should appropriately take into account changes in (inpatient) activity and casemix. FFCEs and FCEs in their different forms (e.g. inpatients, outpatients, A&E) are in practice the only readily available activity data for NHS hospitals. Therefore, along with their associated occupied bed-days, they are the main data used for quantifying changes in patient activity volumes and casemix over a period of time. Consequently FCEs, FFCEs/Spells and Occupied Bed-days are the only realistic data that can currently be used as proxy measures for hospitals' volumes and casemix (*ibid*).

1.10 North West Initiatives in respect of Aseptic Dispensing 1997 - 2005

1.10.1 EL(96)95 & Original North West Survey

When the DoH issued EL(96)95 (Chief Medical Officer and Chief Pharmacist, 1996), the Regional Pharmacist for NHS Executive North West commissioned the researcher to collate and analyse the local internal audit responses. In addition to the audit a survey was also commissioned which focused on all aseptic dispensing and preparation across the North West, in order to provide information on the types and volumes of aseptic products, characteristics of aseptic dispensing units, and expiry periods (Gandy et al, 1998a). This was because of concern at the lack of data for the production and usage of aseptic products (See Section 1.7) and to establish whether the amount of aseptic preparation taking place in clinical areas was sufficiently large as to suggest that the commercial sector might be interested in meeting requirements.

The results of the audit and the survey (*ibid*) demonstrated the diversity of services and facilities across the North West and raised a number of concerns. A particular concern was the range and volume of products being prepared in wards and clinical areas rather than in licensed and unlicensed aseptic facilities. At least 65 per cent were prepared in this way (*ibid*). (This figure was subsequently updated to 79 per cent (Gandy et al, 2003; Gandy, 2005)).

1.10.2 North West Working Party of Chief Executives and Chief Pharmacists

The North West survey also found that many units were considerably under-utilised (Gandy et al, 1998a). Given the financial constraints of that period this could be ill afforded. In the circumstances, the Trust Chief Executives in the North West set up a working party to identify best practice/guidelines, and look wider than just the use of the aseptic facilities themselves (NHS Executive North West, 1997; Gandy et al, 1998b; Gandy et al, 1998c). (The researcher acted as the project manager for the working party and chief author and editor of its report).

The working party report (NHS Executive North West, 1997) was circulated throughout the North West, with copies sent to the Chief Pharmacist at the DoH who circulated it throughout the UK as an example of "best practice". The report (*ibid*) sought to identify best practice and the actions necessary for Trusts to collaborate and develop local solutions that, importantly, would have local ownership (NHS Executive North West, 1997; Gandy et al, 1998b; Gandy et al, 1998c). It did not provide a blueprint for how future aseptic services should be organised in the North West.

Two factors emerged from the working party as being key to the approach: the need for local provision to provide a flexible, responsive service; and that a pharmaceutical aseptic unit should not necessarily be expected to deliver all the needs of a Trust (*ibid*).

Collaboration between Trusts was seen as key for the regionwide organisation of future aseptic services to operate successfully, and to maintain high standards on a cost-effective basis. It could also provide the infrastructure to facilitate staff training, skills assessment, manpower development and quality assurance (*ibid*). This begged the research question of how "collaboration" might be measured, which is an important component of this thesis.

1.10.3 *Outcomes from North West Working Party Report*

As a result of the working party report (*ibid*), Trusts in the North West were invited by NHS Executive North West to determine the most efficient, collaborative solutions locally, allowing for future trends in standards and demand. One obvious parameter for collaboration was geography, given that Trusts had historically worked on a geographical basis (Gandy et al, 1998b; Gandy et al, 1998c).

There was unanimity amongst the working party members that a significant increase in pharmaceutical aseptic dispensing was required to effect any real shift in the balance between pharmacies and clinical areas. Given the balance at the time, even allowing for data constraints (Gandy et al, 1998a), it was not be realistic to look to completely eliminate aseptic preparation in clinical areas, within existing resources and the prevailing culture, because it would have meant almost trebling pharmaceutical production from 1.1 million to 3.0 million per annum. To eliminate aseptic preparation in clinical areas would require a total review of current practices in clinical areas and would necessitate an extensive period of consultation, the outcome of which would be uncertain; whereas there were no objections from Trust Chief Executives to shifting the balance of aseptic preparation further towards pharmacies, particularly to appropriately deal with risk.

To generate momentum and facilitate the working party recommendations (NHS Executive North West, 1997), the NHS Executive North West provided £3 million capital funds to support capital developments in aseptic dispensing units across the North West that would markedly increase production capacity and enable collaborative arrangements. The underpinning assumption made by NHS Executive North West was that the resultant increase in production capacity across the region would enable a broadly equivalent reduction in the number of aseptic preparations taking place in clinical areas (Gandy et al, 1998b; Gandy et al, 1998c).

A competitive process was followed, with various Trusts in the North West presenting business cases and proposals for capital schemes in their aseptic dispensing units (supported by partner Trusts where appropriate). The process incorporated a “market management” component where production projections and usage projections from all Trusts were balanced (by the researcher) to ensure that there would be sufficient demand for any additional products (Beaumont, 1999). This allowed Trusts to provide new/improved data resulting in a revised total of 3.8 million aseptic preparations in clinical areas per annum across the North West (Gandy et al, 2003).

The NHS Executive North West approved eight schemes, of various sizes, from all the proposals submitted by Trusts. However, before awarding capital funds, Chief Executives of purchasing Trusts were required to commit to buying the numbers of aseptic products they had specified during the process for a minimum of two years, from the Trusts that received capital funding. This was to guarantee that there were customers for the additional production volumes, and avoid the danger of the schemes producing products that no-one wished to purchase (Gandy and Beaumont, 2006).

The potential contribution of the commercial sector was taken into account, although the limited availability of commercial aseptically prepared products at that time, was recognised (Gandy et al, 1998a).

1.10.4 Evaluation of Capital & Collaboration Programme

In addition to the above outcomes, the working party highlighted many issues relating to the lack of data regarding aseptic preparation (NHS Executive North West, 1997) these included, for example, the validation processes; physico-chemical stability data; environmental monitoring data in uncontrolled environments. A key concern was the lack of consistently defined and collected data for aseptic preparation in clinical areas (Gandy et al, 1998a). Data was required by pharmacists and managers that was relevant to the development of a definition of what constitutes the “capacity” of an aseptic dispensing unit (Gandy and Beaumont, 2003b). This would involve some form of time weighting for each type of product, given that different types of products take different amounts of preparation time.

Good (project) management requires initiatives to be monitored and evaluated, to determine the degree to which the aims and objectives have been realised. The NHS Executive North West needed to evaluate the £3 million Capital & Collaboration Programme (C&CP) (Beaumont, 1999) in respect of changes in: (weighted) workload; capacity and the use of facilities; collaboration between Trusts; the balance between pharmacies and clinical areas; etc. As the only available robust relevant data involved simple counts of the numbers of the different aseptic products dispensed by pharmacies, these requirements represented a large gap in knowledge. The NHS Executive North West endorsed the need for research into how aseptic production and usage should be measured.

The opportunity for the research covered by this thesis was born from these circumstances. However, it should be emphasised that this placed its own constraint on

the research because of its set deliverables. Consequently it was necessary for the research to establish the limits of usefulness and acceptability for relevant constituencies, and transferability to demonstrate its general efficacy.

1.11 Clinical Governance and Medicines Modernisation: National Picture 1997 to date

1.11.1 *Emphasis on Clinical Governance*

The DoH emphasised the importance of clinical governance with the publication of “The New NHS: Modern Dependable” (DoH, 1997) and subsequent guidance (DoH, 1998a; DoH, 1999a). Hospitals were required to develop comprehensive risk management strategies to ensure the safety and well-being of patients and staff. The continuing practice of preparing pharmaceutical products in clinical areas rather than in pharmaceutical aseptic facilities was readily perceived as a key risk, and therefore the North West report (NHS Executive North West, 1997) was very timely. Should problems occur in the preparation and administration of such products that lead to a major hazard for a patient, or even death, then the hospital concerned, and its staff, were open to litigation/prosecution and confidence in services would be damaged (Gandy et al, 1998b).

1.11.2 *Medicines Expenditure & Trends*

At the beginning of this decade, the NHS spent £1.5b on medicines per annum, which was 4.6 per cent of total costs, and pharmacy staff cost c. £270m (Audit Commission, 2002). Not surprisingly, pharmaceutical services and medicines management have been a continuing focus for a range of central initiatives, either specifically, or as part of more general guidance and directives from central government.

More specifically to this thesis, the DoH introduced the Controls Assurance Framework in 1999, which included a section devoted to reducing risk involved in the use of medicines (DoH, 1999b). The Controls Assurance Standards for Medicines Management (CASfMM) acknowledged that aseptic dispensing was an increasing and demanding activity for pharmacy services (NHS Executive, 1999), and that some NHS manufacturing capacity was needed to prepare medicines that were not commercially available. The CASfMM argued that Trusts should always consider whether collaboration with other trusts for the provision of common aseptically prepared items and manufacturing was a viable alternative to individual trusts investing in these services. An advantage of such collaboration was the possible release of pharmacy staff and capital for investment in other activities (Audit Commission, 2001).

1.11.3 Medicines Management

In 2000/01 the DoH required hospitals in England to assess their services against the DoH's Medicines Management Framework, highlighting priority action areas (DoH, 2001b). In addition, the Audit Commission encouraged the collection of baseline data regarding medicines management arrangements, to enable local auditors to work with hospitals, and chief pharmacists in particular, to improve services (Audit Commission, 2001). This baseline data involved indicators dealing with cost, uptake of processes, staffing and intensity of workload, and staff deployment, on a benchmarking basis. Performance was interpreted on a benchmarking basis, e.g. whether organisations were placed in the top or bottom quartile. Reference was made to the policy aim to minimise the administration of IV antibiotics on wards, compared to oral, because of higher costs and clinical risks (Audit Commission, 2002). Pharmacy staff were related to Trust activity using FCEs as the main indicator for activity. However, this examined all pharmacy activity, without separating out aseptic dispensing. The important point was highlighted that the local context could potentially provide reasons why values of indicators cannot be interpreted on their own (*ibid*), which is directly relevant to the question of how (benchmarking) analyses developed within this research should best be utilised.

In addition pharmacists were expected to apply more general modernisation guidance to medicines management, such as the "10 high impact changes for service improvement and delivery" (DoH, 2004b; Cooke, 2005).

1.11.4 Risk Assessment

In 1999, the DoH undertook a risk assessment survey of all 125 hospital pharmacy units in England holding a manufacturing licence. The questionnaire covered: workforce, facilities, products and capacity. The drivers for the exercise at the time were: unplanned closures of NHS Units (MHRA intervention) due to lack of investment; the role of production facilities in supporting supply chain/managing product shortages; and, the ageing facilities/poor local investment strategies (see Section 11.2 Reference 10).

The results of the risk assessment survey indicated that the current manufacturing service was uncoordinated, with no system of peer review of prescribing habits, and a duplication of effort across some units. Shortages of products arose which potentially put patients at risk, and the costs of products were variable (see Section 11.2 Reference 7). The results raised concerns regarding the continued viability of NHS manufacturing units and led the Government to commission a multi-disciplinary Advisory Group to undertake a UK-wide risk assessment of NHS pharmaceutical manufacturing.

1.11.5 *National Investment for Pharmaceutical Modernisation*

As a result of the Advisory Group's findings (DoH Advisory Group, 2002), in 2002, Ministers made available £4m capital to begin the process of modernising hospital manufacturing services, with a multi-disciplinary Implementation Board formed to lead the process in England. The following year, the DoH announced £42m capital was to be utilized (available across 2004/05 and 2005/06), to help deliver a cohesive, financially robust traditional NHS manufacturing service to provide medicines tailored to the specific needs of individual patients in circumstances where these needs cannot be met by the use of licensed medicines (DoH, 2003a). The processing of the bids was dealt with through four regional groups.

These capital initiatives meant that pharmaceutical manufacturing units within Trusts were faced with several options. These included to become a lead unit within the modernised hospital manufacturing service, a strategic support unit within the modernised service, or to opt out from the developing arrangements (e.g. local aseptics provision). A logical consequence of modernisation is the requirement to rationalise the products prepared, based upon: **standardisation; clinical desirability; technical assessment; and determining appropriate presentations (e.g. 'ready to use' v 'ready to administer' (ampoule/vial v syringe))** (see Section 11.2 Reference 10). There was a likelihood that "high risk" preparations would need to move to preparation in pharmacies (see Section 11.2 Reference 7), which was reaffirmed by Hardy and Mellor (2007).

Partnership working between the NHS and the commercial sector was emphasised where there was an advantage to the NHS and a clear benefit to patients (DoH, 2003a). The Association of Commercial Specials Manufacturers, working collaboratively with the Implementation Board, prepared general principles of working with the NHS which covered a variety of issues including business models, risk management and intellectual property rights. As is stated above in Section 1.10.3, the commercial sector's contribution to the NHS was limited in respect of aseptic dispensing (Gandy et al, 1998a), partly due to its need be able to produce standard products in sufficient quantities to be economically viable. The wide range of requirements of the NHS and the limited shelf lives of products, for example those used in the treatment of children (Aston University Business Partnership Unit, 2004) had militated against significant expansion of the commercial sector's contribution in the past.

In the event, just under 30 per cent of the total capital funds were allocated to aseptic dispensing schemes, but the figure varied considerably across the four regions of England: in the North it was less than 10 per cent (partly because of the past investment in the North West); in London it was just under 50 per cent; in the South of England (exc. London) it was broadly 67 per cent; but in Central it was zero (see Section 11.2 Reference 10).

However, no methodology has been established to fully evaluate whether the approved schemes will have met their stated goals (see Section 11.2 Reference 12).

1.11.6 *Monitoring Progress*

Building on the Audit Commission work (Audit Commission, 2001, 2002), the Acute Hospital Portfolio Medicines Management reviews in 2005/06 (Healthcare Commission, 2005), generated a benchmarking data set to inform on a hospital's progress against set Medicines Management initiatives. This enabled Trusts to compare their performance with one another. They could also re-use the tools involved to measure their progress over time.

The core questionnaire for the review broke down into nine sections (with an average of ten questions in each section) about different aspects of medicines management, including pharmacy staff and skill mix, and medicines management structures and strategies. Despite a wide range of questions, there was nothing that quantifies what was happening in terms of full aseptic production and usage. Indeed, there is reference to the fact that aseptic preparations are not all recorded in pharmacy systems (*ibid*), and that this has led to known problems with data completeness in relation to cancer medicines (*ibid*).

1.11.7 *Other Related Initiatives*

In addition to the above national programmes there have been other significant regionally based initiatives in recent years. These include a one-year project to develop a risk assessment tool for extemporaneous preparations, taking into account clinical risk, technical risk, a risk assessment of the current list of preparations, and the identification of the most risky products (see Section 11.2 Reference 9), and a two-year risk assessment of parenteral product preparation across North of England (Hardy and Mellor, 2007). The goals of the latter were to: Review the frequency, site of preparation and level of pharmacy control for recognised high-risk items; Collate information on a range of high/medium risk products to allow prioritisation for pharmacy preparation; Review current output of parenteral products from licensed and unlicensed units and compare with

information collated above; To identify and prioritise for pharmacy preparation those high/medium risk products which are not currently prepared in either licensed or unlicensed units.

The National Patient Safety Agency (NPSA) carried out a consultation exercise on proposals to carry out risk assessments of clinical area preparation activities throughout the NHS (NPSA, 2006), with a view to prioritizing the transfer of high-risk products to pharmacies. The NPSA subsequently issued a bulletin on injectable medicines (NPSA, 2007).

All these point to increased emphasis on moving aseptic preparation from clinical areas to pharmacies.

1.11.8 Continuing Evolution of Services

It is concluded from the above that the medicines and pharmaceutical services are fully recognised as priorities by the Government, not only in terms of their contribution to clinical governance and patient care, but also in terms of ensuring that the services and processes themselves are fit for purpose and cost effective. However, the sheer size of medicines consumption and the complexity of the associated requirements mean that a great amount of time and effort will be required to achieve the identified goals universally. For example, it has been pointed out that a lack of stability and compatibility data is a considerable barrier to preparing products that are ready-to-administer in pharmacy-managed aseptic units (Graham, 2005). Therefore, at least in the short term, practical strategies will involve targeting pharmacy production efforts towards “high risk products” (Beaney, 2005a; Hardy and Mellor, 2007).

The thrust and many details of the national and regional initiatives described above are consistent with the recommendations from work undertaken within the North West in the late 1990s, in respect of aseptic preparation (NHS Executive North West, 1997; Gandy et al, 1998a; Gandy et al, 1998b; Gandy et al, 1998c). Advice from the commercial sector is that the North West has always been seen as being clearly ahead of the rest of the country in respect of its aseptic dispensing services (see Section 11.2 Reference 5).

When Professor Breckenridge looked at progress to 2005 in addressing the issues raised in his report (Breckenridge, 1976), he noted that significant proportions of products were still prepared in wards and theatres, including those that are “high risk” because, for example, they include complicated dose calculations. However, the role of pharmacists had increased dramatically (Graham, 2005). Nevertheless, despite the importance of the

Breckenridge (1976) recommendations, hospitals' annual health check does not require data relating to aseptic dispensing and usage to be collected (Healthcare Commission, 2005). This suggests the timeliness of the research.

Aseptic production and preparation is clearly still evolving at the time that this thesis is submitted. Consequently it was important to ensure that the results of the research were suitably robust so as to maintain their validity for the foreseeable future.

1.12 Governmental Approach to Improving Performance in Healthcare since 1997

In 1989, the then Conservative Government introduced a market environment and competition into the NHS (Propper et al, 2003) where hospitals became sellers or "providers" of services, and health authorities (and some General Practitioners) acted as buyers or "purchasers". In 1997, the new Labour Government maintained this split of responsibilities but rejected the market management mechanisms of its predecessors (Laurance, 1997; Baggott, 1998; Webster, 1998; Paton, 1999). Market competition was replaced with a performance management regime relying on benchmarking standards (DoH, 1997). Improvements in performance and standards were to be achieved by sharing information and transparently comparing performance (*ibid*). Partnership would replace competition (*ibid*).

The new approach to performance management involved relative performance evaluation through key indicator benchmarking that ranked organisations in comparative league tables. As a result, hospitals competed in respect of comparative positioning through benchmarking on indicators, rather than in a market (Northcott and Llewellyn, 2005).

The Government reinforced its approach with a strategy of denouncing "failing" hospitals, which was a useful device for engaging public pressure against those Trusts with bad results (Trosa, 1997).

The next drive to identify best practice by Government was the establishment of Foundation NHS Trusts, which was available to three star Trusts (in 2003) (DoH, 2002a). The hope was that the freedoms Foundation NHS Trusts received would provide an incentive to others to improve (DoH, 2002b), although the King's Fund (2003) commented that being a top rated Trust does not guarantee innovation and responsive management. Foundation NHS Trusts were to remain subject to the annual performance rating.

The star ratings approach (DoH, 2002b, 2002d) was planned to end in 2005, and has since been replaced by a system developed by the Healthcare Commission (2006, 2007) that awards organisations one of five grades for overall performance, by focusing on an “annual healthcheck” which includes 472 “prompts” The emphasis is placed on every organisation declaring annually, in a statement checked by local partner organisations, whether it is compliant with standards. Evidence would be required, and there is the opportunity for unannounced “spot checks” (*ibid*). It is described as involving targets plus standards, and is a fundamentally different process to star ratings, with more co-operation between the Healthcare Commission and local partners (HSJ, 2004b).

In summary, the Government has been able to point to benchmarking as a new, collaborative tool for improving health processes and outcomes, while at the same time using it to reinforce standards, ensure centralised accountability and curtail provider power. Therefore, benchmarking has been a useful political instrument for driving performance, but as long as performance indicators are employed for political purposes, the more desirable attributes of benchmarking will be difficult to achieve.

1.13 Examples of Relevant Change Influences and Processes

Given the previous section, it is important to have an outline appreciation of some of the change processes that can impact on health and hospital services. The Prime Minister made no apologies for many reforms being driven from the centre (DoH, 2004), and whilst Local Delivery Plans, and similar, allow locally identified priorities, these are often subordinate to the achievement of national goals. This is partly due to the NHS Executive and Department of Health being organised in such a way that different parts/departments focus on specific areas, which leads to guidance being issued with its own (national) priorities and objectives. Examples are Payments by Results – Finance (DoH, 2007b), Connecting for Health - IM&T (CFH, 2007c), Agenda for Change - Human Resources (DoH, 2007a), and National Service Frameworks for categories of services such as Children, Young People & Maternity Services (DoH, 2003b) or specific conditions such as Cancer (DoH, 2000b) and Heart Disease (DoH, 2000c).

Therefore, NHS organisations deal with such parallel pressures by balancing them within their own local circumstances and resources. As a consequence of the fact that the nature and organisation of NHS services can vary due to historical and geographical reasons, collaboration between NHS organisations is essential to achieve results, and is a prerequisite (sometimes prescribed) for achieving results.

Payments by Results (DoH, 2007b) presents an overarching constraint, because it dictates that each Trust is paid a flat national tariff for a given type of care. The national tariff is in effect the average national cost for a type of care, calculated from the reference cost returns from each Trust across the country. This means that the cost of a treatment for commissioners will be the same wherever the patient is treated, be it within the NHS or in the independent sector. This is a way of opening up the market for the Government, and driving change. The rationale is that Trusts will have to become more efficient and improve quality to compete, and the reality of only receiving a set tariff will drive necessary changes.

Consequently the pressure for Trusts to review all of their services (including pharmacy) will be greatly influenced by the degree to which their total actual costs vary from what they are paid through tariff, and other income. Many will be considered to be already covered by the tariff, while others have specific allocations earmarked. Getting allocated funds to be fully spent on the target service(s) is not always straightforward (British Council, 2003).

One process used by the NHS to drive forward change in respect of new or priority initiatives is to allocate "targeted investment", where a given national sum of money is invested in specific priority services. Whilst this is nothing new, there has been particular emphasis to enable modernisation (and the modernising hospital manufacturing monies is that relevant to pharmacy (DoH, 2003a)). Such a funding mechanism has clear attractions as it enables Government to publicly state that it is making a particular service/client group a priority and is prepared to invest substantial resources accordingly. It also ensures that the money is invested in the specified area and that there is greater central control. However, a requirement for initiatives to be fully evaluated is not always specified.

If "targeted investment" money were spread evenly across the country then the amount available for each organisation is usually very limited and insufficient to support many of the individual schemes submitted. Consequently a competitive situation is created whereby only a selection of the bids will be approved. Few (relevant) organisations will want to be seen not to make a bid for such funding, which means that the effort put in to develop the rejected proposals will have been wasted, with the associated local disappointment. One effect can be that "targeted investment" influences organisations to be reactive, rather than proactive, and "chase the money", rather than developing a holistic approach locally, with locally set targets and priorities, such as that required by the European Foundation for Quality Management's (2007) Excellence model and Total Quality Management (Stark, 2007). Also, whilst collaborative/joint bids from organisations

would clearly be welcomed, and would probably be consequently given a high rating, the time involved, and logistical and competitive pressures can militate against their production, which in turn can mean that collaborative opportunities can be missed.

It can be seen that moving forward with modernisation and service improvement in the NHS is complex, and that medicines modernisation (DoH, 2003a) faces particular challenges because of the fact that pharmacy is primarily a support department, seeking to meet the requirements of a wide range of hospital services which will each be subject to their own, potentially divergent, pressures and trends. To manage this properly it is self-evident that pharmacists, managers and other professionals should require sound data on what pharmacies produce and how this is utilised by the various services.

1.14 Commercial Pharmaceutical Sector in respect of Aseptic Products

The commercial sector is a comparatively small player in the overall picture of aseptic production in the NHS. Gandy et al (1998a) identified that it accounted for only 2 per cent of all aseptic products used in the North West of England. This masked the fact that it accounted for 40 per cent of cytotoxics and 5 per cent of Total Parenteral Nutritions (TPNs), and 0.04 per cent of all other aseptic products combined (*ibid*).

There are significant constraints in NHS pharmacy data in general, and aseptic dispensing in particular (Jackson and Walker, 1998; National Prescribing Centre, 1998; Jackson, 1999; Gandy et al 1998a). By comparison, the commercial sector regularly collects and utilises aseptic production data, as this is a clear necessity to enable it to achieve its business objectives. Data is generally collected on: product types manufactured; volumes of products; cabinet types and functions; and staff levels (see Section 11.2 Reference 6).

Clearly, the commercial sector does operate on a different basis than the NHS (companies need to make profits and returns on investment for their shareholders), and therefore the management of risk is very important (So, 2005).

The commercial sector prefers to focus on a limited range of products that can be mass-produced, preferably utilising as much automation as possible. Nevertheless, many processes are the same in principle, and it follows that the NHS can learn some lessons from it in respect of information (see Section 11.2 Reference 6).

To be able to justify any significant future engagement with the commercial sector it is essential that hospitals have some appreciation of the current and future demand for aseptic products in order to support the business case. This requires data and as has been demonstrated, there is insufficient data routinely collected to reflect either aseptic production within a hospital's aseptic dispensing unit or what is prepared in clinical areas (Gandy et al, 1998a).

(It should be noted that the commercial sector itself sees the North West as clearly ahead of the rest of the country in respect of aseptic dispensing services (see Section 11.2 Reference 6; NHS Executive North West, 2001) suggesting that undertaking the research primarily within the region, and utilising local references, could hardly have involved a more advantageous environment).

1.15 Aseptic Preparation in Private Hospitals

In terms of numbers of beds, private hospitals in the UK are general small and treat elective cases. Such cases can require aseptic preparations that are deemed to be of a sufficiently low risk that they can be undertaken in clinical areas. (More critical cases make greater use of aseptic preparations). Nevertheless, all private hospitals must meet accreditation standards for registration purposes, which cover policies and procedures for the control of infection (See Section 11.58).

They have pharmacies for classical dispensing, but because of their size they do not normally have aseptic dispensing units. Aseptic preparation takes place in clinical areas, with related fluids often bought in bulk. The control of the calculations for a drug mix remains with the pharmacist. Any requirement for pharmacy preparation is normally covered by contractual arrangements with the pharmacies of neighbouring NHS hospitals. (This situation was reflected in telephone enquiries to BUPA and Nuffield Hospitals).

It is inferred that private hospitals are not central to the research and can therefore be excluded.

1.16 International Picture

The literature review outlines the international picture in respect of how aseptic preparation is undertaken relative to pharmacies (See Section 2.3). There are many variations between countries with the UK being more advanced than other countries in Europe in respect of centralised additives intravenous services (CIVAS).

1.17 Need for Information and Data to Support Aseptic Dispensing and Preparation in the NHS

Pharmaceutical services, being a support service, are often “below the radar” for senior management in hospitals – unless something goes wrong (Anon, 1994). Therefore, whilst Trusts ought to routinely review and invest in these services, such priority has not always been forthcoming, with one of the reasons arguably being ignorance. The lack of routine data to demonstrate the use and production of aseptic products, and a means of linking these with the casemix of patients treated, leaves financial budgets as the only readily available related data, leading to a likely focus on the “bottom line” and “balancing the books”. There is also the vicious circle that means that: the information systems are not in place to provide the data to demonstrate the important role, contribution and potential of aseptic services and products; and because there is not the data to demonstrate the role, contribution and potential of aseptic services and products, there is not the case for improving information systems in this area to provide such data.

Therefore there is a clear need for the consistent, acceptable collection and usage of quality data in respect of aseptic dispensing and preparation in the NHS. This is so that this critically important area can be planned, managed and operated in such a way that its services can be optimised in their own right, and so that their contribution to clinical care and governance can be maximised within hospitals both individually and collectively.

This research is aimed at meeting this requirement by establishing: a realistic, robust specification of what data can and should be collected; how such data can be best used and manipulated to meet services’ needs; and whether such data and analyses can meet such needs.

1.18 Aim & Objectives of Research

The aim of the research is to identify the types of data and ways of measuring aseptic preparation and production required to evaluate changes in activity and performance over time.

The research will address the following questions:

- How should activity relating to aseptic preparation in hospital pharmacies and clinical areas be counted, collated and analysed?
- Can existing information systems readily provide such data?
- What statistical indicators can be developed to support collaboration and capacity planning for (NHS) aseptic production, and to evaluate related initiatives?
- How can such data and statistical indicators be best utilised?

The objectives of the research are:

- To establish sound, practical methods of collecting data which meet the needs of services;
- To establish (proxy) statistical indicators that relate to the concepts of “collaboration”, “capacity” and “workload”;
- To provide analyses of the data collected to hospital trusts to support them with collaborative arrangements and capacity planning;
- To evaluate the changes engendered by capital investment programmes.

1.19 Presentation of Research

Table 1.2 details the constituent components of the research, confirming the contribution of the researcher for each. This structure has been replicated within Chapters 3, 4 and 5 of this thesis to aid the reader. For example, Section 3.8, 4.8 and 5.8 respectively detail the methodology, methods and results for Nomenclature.

It also links the components to the research phases quoted in the original rd9r application to register for a PhD.

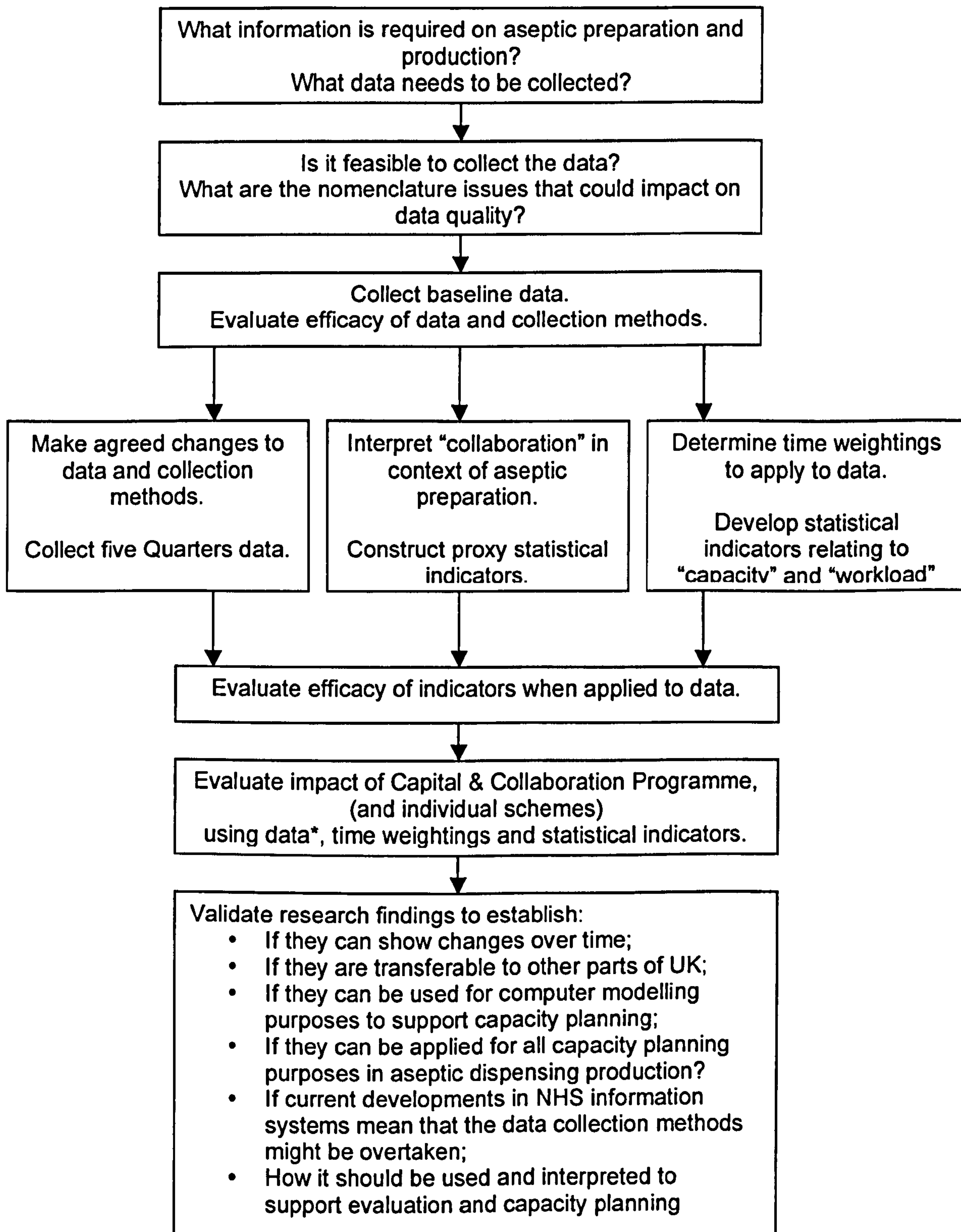
Table 1.2 Constituent Components of Research: Purpose and Researcher's Role/Contribution

| Ref | Research Component | Phase in rd9r | Purpose | Researcher's Role/Contribution |
|-----|---|---------------|--|--|
| 1 | Data to collect | 1 | Establish information, data and currencies required. | Lead Researcher |
| 2 | Information systems data audit | 2 | Evaluate capacity of existing information systems to provide required data | Developed specification/managed researcher/contributed directly |
| 3 | Baseline survey | 3 | Develop survey design; undertake baseline survey; analyse | Lead Researcher |
| 4 | Baseline survey evaluation | 5 | Evaluate survey design; determine required improvements | Lead Researcher |
| 5 | Quarterly surveys | 5 | Undertake five quarterly surveys; analyse | Lead Researcher |
| 6 | Quarterly surveys evaluation | 6 | Evaluate survey design for final recommendations | Lead Researcher |
| 7 | Data available in clinical areas | 2 | Evaluate what information can be acquired in respect of clinical areas | Developed specification/managed researchers/contributed directly |
| 8 | Nomenclature | 2 | Evaluate nomenclature issues | Lead/Co Researcher |
| 9 | Collaboration | 3 | Develop statistical indicators for "collaboration" | Lead Researcher |
| 10 | Workload Measurement: Work Study | 4 | Develop product weightings through work study methods | Developed spec/managed consultant/contributed directly |
| 11 | Workload Measurement: Unit Time Equivalents | 4 | Alternative approach to determining product weightings | Lead Researcher |
| 12 | Concepts: Capacity and Workload | 4 | Develop concepts of "capacity" and "workload"; determine implications for research | Lead Researcher |
| 13 | Statistical Indicators | 4 | Develop statistical indicators for "capacity" and "workload"; evaluate | Lead Researcher |
| 14 | Modelling | 4 | Evaluate potential for applying modeling software and techniques to aseptic dispensing | Lead Researcher |
| 15 | Acute Capacity Planning | 5 | Evaluate potential use of statistical indicators and data for daily/weekly capacity planning | Lead Researcher |
| 16 | Transferability | 6 | Evaluate transferability of approach; demonstrate usefulness of results | Lead Researcher |
| 17 | Evaluation of Programme | 6 | Evaluate capital programme, using research data and methods | Lead Researcher |
| 18 | New information systems | 7 | Test whether new hospital pharmaceutical systems might produce research data | Lead Researcher |

1.20 Linking the Steps in the Research Process

Figure 1.2 outlines the steps required to achieve the stated research goals. Section 4.0 describes the ongoing validation process applied throughout the research.

Figure 1.2 Flowchart Outlining Steps in Research Process



* Given delays in C&CP 2003/04 data was collected and used for final evaluation

Chapter 2 Literature Review

2.0 Introductory Overview

Having outlined the scope of the research in Chapter 1 it was essential that the Literature Review adequately covered the wide range of subjects relating to the components described in Section 1.19.

A strategic, systematic approach was required (see Section 2.1) which would cover both pharmaceutical and non-pharmaceutical references and databases, and take advantage of professional forums on the Internet. This built upon the professional advice and literature search techniques and results from earlier work (NHS Executive North West, 2001).

Sections 2.2 and 2.3 provide overviews of relevant literature relating to aseptic preparation and clinical governance within the UK and internationally, respectively. They include examples of problems, such as medication errors, that have required the various initiatives described to take place, and which arguably justify the requirement for research, as is covered by this thesis. Section 2.3 also describes where the UK sits within the international spectrum of pharmaceutical organisational arrangements.

The subsequent three main sections review literature with specific focus on three of the key research questions: Nomenclature (2.4), Collaboration (2.5) and Capacity and Workload Measurement (2.6). The latter two particularly examine the question of data and measurement. Section 2.7 therefore examines the situation in respect of the availability of data relating to pharmacies and aseptic preparation.

Section 2.8 (Computerised Capacity Planning Software) effectively links Sections 2.6 and 2.7, but within a modelling context. Section 2.9 then examines capacity modelling and its relation to skills availability, and the development of pharmacy skills within the NHS.

Sections 2.10 examines what NHS data is available on overall patient activity, as not all patient treatment involves aseptic preparation, and therefore activity relating to the research needs to be considered within a total NHS context. Section 2.11 then looks at how the UK Government has approached the question of performance management since the Labour Party was elected in 1997, with particular reference to its use of benchmarking. This is necessary to reflect the managerial culture within the NHS that applied during the course of the research.

2.1 Strategic Approaches to Literature Review

2.1.1 Background

From the outset the literature review needed to be set into some context of what were the likely issues that might arise during the course of the research, and where published literature would be beneficial. Given the potentially wide range of issues that could be interpreted as being relevant it was necessary initially to try and identify priority topics for the literature search. Set out below is a summary of the thinking applied to this question at the time, which helped shape the approach adopted.

The thrust of Breckenridge (1976) and Farwell (1995) was to move aseptic preparation from clinical areas to pharmacies, but it would be desirable to first clarify the issues and circumstances that brought about their recommendations. Therefore an appreciation of aseptic technique, best practice and clinical governance was required.

A central concern was what data can and should be collected to reflect aseptic production and preparation, and how this might relate to clinical practice. Literature was therefore required about pharmacies, pharmaceutical systems and aseptic preparation, together with any related information systems and data. Data quality was very important, and not specific to just pharmacy, often relying on how consistently and accurately definitions and nomenclature are interpreted.

As different types of product involve different production times, it was necessary to establish how production activity data could translate into aseptic unit workload. Evidence of the relationship between the different stages of the aseptic production process and available data needed to be taken into account, as did the potential impact on production of the availability of key equipment such as cabinets, and the licensing status of a unit.

Certain key words, regularly used by pharmacists and managers in respect of aseptic production, are conceptual by nature. These include *capacity*, *collaboration*, and *workload*. It was therefore necessary to evaluate their interpretation within the pharmaceutical and non-pharmaceutical literature, and examine how such words were interpreted statistically.

Even if relevant data and derived metrics are identified, they must be made available to pharmacists and managers in ways meaningful to them. Therefore it was necessary to evaluate how appropriate comparisons can be best effected, and whether they can be used for modelling purposes, having regard for the characteristics of aseptic dispensing units. A particular focus was required on benchmarking, given the emphasis placed on benchmarking by the Government in its efforts to improve public sector performance.

Finally, published influences concerning how the availability and skill mix of pharmacists and aseptic unit staff might impact on production were required.

2.1.2 *Literature Searches*

Standard methods of accessing Internet and NHSnet websites, and the LJMU library, were applied for keywords viz. Admixture, Aseptic Dispensing, Intravenous, Management, Parenteral, Statistics, Workload, and Work Study, were employed. These reflected professional advice used in earlier work (NHS Executive North West, 2001). Combinations were used, as follows:-

aseptic& dispensing& workload; aseptic& preparation& workload; aseptic& dispensing& statistics; admixture& workload; admixture& work study; parenteral& dispensing& workload; aseptic& dispensing& management& quantification; intravenous& dispensing& work study.

(Because of the limited results from "aseptic dispensing" the alternative of "aseptic preparation" was also used. Also, "quantification" was tried)

2.1.3 *Scope of literature review*

It should be emphasised that the results from these literature searches were very limited, and therefore the sole use of search terms was considered to be limited. Therefore, a literature review was undertaken to explore the wide range of publications relating to pharmacy to establish those of direct relevance, and where health and business metrics and information systems could be applied to the research. Journals/websites were identified during the earliest stages of the research and were broadly categorised in terms of their relevance to the research, as follows: *Directly Relevant*, *Partly Relevant* and *No/Minimal Relevance*. Section 11.3 lists those that were deemed as "No Relevance".

As the NHS is subject to governmental direction, many official sources were included, and these reflect the evolution of services in general and pharmacy in particular.

Gandy et al (1998a) broke ground in determining aseptic production and usage data across a significant number of hospitals. Analyses showed large volumes of aseptic products “made up on ward”, but this was an understatement as some Trusts recorded “data not available” (*ibid*). Concerns were expressed that existing information systems did not necessarily provide such data and at the lack of activity currencies (*ibid*). The subsequent North West risk management work was the first serious attempt to develop detailed guidelines for locations for aseptic preparation by product type (NHS Executive North West, 1997; Gandy et al, 1998b; Gandy et al, 1998c).

Coincidentally, the election of the Labour Party into Government in 1997 marked a change in the approach to how the NHS and other public services were managed (see Section 1.12).

Therefore, a timeframe was set for directly relevant (UK) literature. The review is pragmatic and includes direct professional knowledge and advice. Those journals/websites that were of relevance to the research were first thoroughly searched for appropriate publications back to the mid-1990s, with specific references to earlier publications obtained. Subsequently, published literature was surveyed regularly, generally quarterly given the publication cycle of many journals, with repeated use of keywords (see Section 2.1.2).

Advantage was taken of available opportunities that influenced the choice of methods: building upon existing relationships between the researcher and lead pharmacists in the North West, which included seeking direct views and advice; direct approaches to national initiatives and bodies; and, direct approaches for relevant lead experts and advisors in the UK and elsewhere, including Professor Breckenridge himself. The involvement with North West pharmacists also meant access to current initiatives and a great deal of unpublished, but relevant work, which is included in the Appendices where appropriate. Some research related to the researcher’s consultancy commissions.

2.1.4 Available Pharmaceutical Literature Sources

Pharm-line® (2007) is a well-established database for medicines management, pharmacy practice and prescribing, which started in 1978. It comprises more than 200,000 abstracts from major English language pharmaceutical and medical journals. All of the 27 journals covered were accessed electronically, with searches undertaken of each.

Journals/websites that were categorised as *Directly Relevant* to the research were:

- The American Journal of Health-System Pharmacy³
- Canadian Journal of Hospital Pharmacy;
- European Journal of Hospital Pharmacy;
- The Hospital Pharmacist;
- The Hospital Pharmacists Group Newsletter;
- Journal of Pharmacy Practice and Research (Australia);
- The Pharmaceutical Aseptic Services Group website;
- The Pharmaceutical Journal;
- The Pharmacy Management Journal;

The Pharmaceutical Journal and the Hospital Pharmacist are co-publications of the Pharmaceutical Society. The latter was established by the Royal Pharmaceutical Society of Great Britain for the publication of articles, reviews, reports and papers about any aspect of hospital pharmacy, and was found to be the most relevant of all journals, given the relative number of papers referenced.

Journals/websites that were categorised as *Partly Relevant* (with the area of research shown in brackets) were:

- American Medical Informatics Association (clinical decision making and electronic prescribing);
- Healthcare Pharmacy (electronic prescribing);
- Hospital Pharmacy (USA) (medication error);
- International Journal of Pharmacy Practice (USA) (prescription errors and decision support);
- Journal of American Pharmacists Association (pharmacists' work activities and electronic prescribing)
- Journal of Pharmacy Technology (USA) (pharmaceutical preparation mathematics and pharmacy skill-mix);
- Prescribing & Medicines Management (medicines management);

Official Governmental/NHS publications and guidance relating to pharmacy were clear sources to be referenced.

³ AJH-SPham covers a wide range: Website searched on admixture and other relevant key words, with some links to "similar articles in PubMed" used. PubMed is www.pubmed.gov, which is a service of the (American) National Library of Medicine and the National Institute of Health.

Pharmweb is a premier internationally-used website with a variety of forums for professionals to liaise with one another. This was interrogated using a structured key question (see Section 11.4 for details).

2.1.5 *Non-Pharmaceutical Literature Sources*

Non-pharmaceutical journals and publications reviewed were:

- Benchmarking: an International Journal
- British Journal of Healthcare Computing & Information Management
- British Journal of Health Care Management
- Health Service Journal (HSJ)
- Health Management
- Journal of the American Medical Association
- Private Hospital Healthcare Europe

As for Pharmacy relevant Official Governmental/NHS publications and guidance were included.

'Performance Measurement and Metrics' appeared relevant but its focus is library & information services. Similarly 'The Analyst' (published by the Royal Society of Chemistry) did not yield relevant references.

The Cochrane Library (2007) is an important source of reliable evidence about the effects of health care, dealing with clinical effectiveness, but this is not the focus of the research.

2.2 Aseptic Technique, Best Practice and Clinical Governance

Despite the recommendations to move aseptic preparation from clinical areas to pharmacies (Breckenridge, 1976; Farwell, 1995) problems continued to be observed in the clinical areas, with the outcome being death in the worst cases (Anon, 1994).

Patients have a right to be protected from preventable infection and nurses have a duty to safeguard the well-being of their patients (Crow, 1989; King, 1998). An aseptic technique should be implemented during any invasive procedure that bypasses the body's natural defences, e.g. the skin and mucous membranes, or when handling equipment such as intravenous cannulae and urinary catheters that have been used during these procedures.

Whilst it is difficult to maintain sterility, it is important to prevent contamination of sterile equipment. Poor aseptic techniques can lead to contamination. A 22 per cent syringe contamination rate has been observed for syringes prepared by intensive care unit nurses, compared to a 1 per cent rate for the syringes prepared by pharmaceutical technicians (Van Grafhorst et al, 2002). A study to establish nurses' actions whilst carrying out aseptic techniques suggested that not all nurses followed the same actions and that the rationale for the practice of aseptic techniques is not always research based (Bree-Williams and Waterman, 1996). Similar discrepancies were found amongst medical staff (Sellors et al, 2002). Nurses can feel uncertain about how to undertake an aseptic technique (Hallett, 2000). Unfortunately some routine infection control practices cannot be rigorously studied for ethical or logistical reasons, for example wearing versus not wearing gloves (Mangram et al, 1999).

Briggs et al (1996) suggest assessment of the individual patient's circumstances before each procedure: predicting and planning for potential problems can maintain asepsis.

The DoH (2000a) found that annually 10,000 hospital patients have serious adverse reactions to medicines, and one-fifth of clinical negligence litigation stemmed from hospital medication errors (*ibid*). Medication errors alone cost the NHS about £500 million a year in additional days spent in hospital (Audit Commission, 2001; DoH, 2001a). The upward trend in medication errors in the UK, similar to that in other countries, is probably due to the increasing pace of work in hospitals and greater toxicity of modern medicines. Consequently, Trusts were set a target to reduce serious medication errors by 40 per cent by 2005 (DoH, 2001a).

Medication errors account for 7 per cent of patients safety incidents reported by hospital, mental health and ambulance Trusts in 2004 (National Audit Office, 2005), and whilst these will not all relate to aseptic preparation a good proportion will. Day-to-day pressures can lead to acknowledged best practice being ignored (Toft, 2001), and it is believed that significant numbers of incidents still go unreported, particularly cases involving medicine errors or those "leading to serious harm" (National Audit Office, 2005). The continued blame culture in Trusts is a main reasons why staff are reluctant to report patient safety incidents (*ibid*). Nurses are perceived as the most common source of error, particularly where drugs are administered: fear of disciplinary action and admitting to a "silly" mistake stops them reporting errors if no ill effects on a patient (Audit Commission, 2002).

Medicines management is a very significant part of Trusts' clinical governance responsibilities (Audit Commission, 2001). It is central to the quality of healthcare, underpinning many specific objectives set out in The NHS Plan (DoH, 2000d). As hospitals do not always manage medicines to best effect, "A Spoonful of Sugar" (Audit Commission, 2001) addressed the main strategic challenges and issues, suggesting ways to meet and overcome potential obstacles and barriers, and improve the effectiveness of medicines' management.

The NHS Executive North West working party (1997) described "Best practice" in respect of aseptic dispensing as:

"All sterile medicinal products should be supplied by the pharmaceutical department to the practitioner in a form ready to administer and fit for their intended purpose".

It set guidance on standards, expiry periods and policies, to enable Trusts to ensure that the risk associated with aseptic preparation, and the protocols followed, were fully evaluated and acceptable (*ibid*). These included a matrix specifying where each main types of aseptic products should (not) be prepared (*ibid*). The options were:

- Pharmacy: Wards not acceptable even if pharmacy closed/not available;
- Pharmacy: Ward preparation is acceptable only if pharmacy closed/not available;
- Specialist clinic areas, e.g. ICU, operating theatres, maternity, coronary care areas, and in suitable designated aseptic facilities;
- All wards/departments.

Hardy and Mellor (2007) established current practice in 42 (82 per cent) of the 51 local secondary care acute in the North of England and calculated that the annual total aseptic preparation of high-risk drugs in clinical areas was 1,227,325. The largest group were Potassium solutions, which were of particular concern, with 108,197.

Farwell (1995) made implicit reference for best use to be made of available facilities and resources, whilst having appropriate regard to safety:

- Processes should be organised to make best use of facilities and equipment (Para 6.5) (*ibid*);

- Facilities for aseptic dispensing should be designed, constructed and operated in a manner appropriate to the activities undertaken and with respect to the equipment installed so that, by segregation and process control, maximum protection can be afforded to the product and, where necessary, the operator (Para 8.1) (*ibid*);
- Planned preventative maintenance programmes should exist, covering all key equipment, to standards agreed with the responsible pharmacist (*ibid*);
- A comprehensive quality assurance programme set up by the responsible pharmacist in conjunction with the Quality Controller is essential for all aseptic preparation activities. Individual product quality is generally not tested as would be the case in batch produced materials and therefore confidence that the patient will receive a medicine of suitable content, strength and purity is dependent on the controls built into the processes, the assessment of the raw materials and packaging components and the performance of staff and equipment (Para 15.1) (*ibid*);
- Quality assurance activity should particularly concentrate on those aspects of product manipulation and processing at which the integrity of the system is at greatest risk (Para 15.2) (*ibid*);

The four central pillars of modernisation of the NHS manufacturing service are (DoH, 2003a; Hardy and Mellor, 2007):

- *Clinical governance*: the application of clinical governance principles to the prescribing, manufacture, supply and administration of unlicensed medicines.
- *Capital investment*: to maintain and modernise the current NHS manufacturing capacity and to assist in planning for future service needs; Investment should be linked to change.
- *National co-ordination*: creating a cohesive national service that has robust communication networks and is responsive to changing patient need and to changes within the wider manufacturing industry.
- *Working with Industry partners*: so that good practice principles on ways in which the NHS and colleagues in the commercial sector should work in partnership can be agreed and promulgated.

In order of priority the NHS Manufacturing Service deliver traditional manufacturing and aseptic preparation, including cancer chemotherapy. Improvements in cancer chemotherapy services were required to support the implementation of the original Calman Cancer Plan that envisaged a significant expansion of oncology services (DoH, 2000b).

2.3 International and Regional Practices concerning Aseptic Preparation

The European Association of Hospital Pharmacists (2001) surveyed pharmacies in the 16 countries it covered in 2000. The response rate was 27 per cent (similar to its previous survey in 1995), with the UK's rate being 17 per cent. Public hospitals (i.e. owned by the government) accounted for 84 per cent of responses, with this being exclusively the case in the UK, Denmark, Slovakia & Greece, and almost the case in France, Slovenia & Sweden. Key points relevant to the research were:

- The survey showed that the UK is exceptional in its pharmacists visiting patient care areas at least once a day, with pharmacists spending at least 50 per cent of their time there. (This relates to all pharmacists not just those involved in the area covered by this thesis).
- More than 50 per cent of EU hospital pharmacies do not provide any additive services to the wards, and when it is, it mostly concerns cytotoxics, then TPNs. Even then the UK ranked 6th highest for the percentage of hospitals preparing cytotoxics, and 4th highest for TPN.
- There are hospitals in every EU country that do not provide any IV services. In some cases they are irrelevant (e.g. psychiatric hospitals), but Greece, Hungary, Finland, Slovakia & Slovenia such hospitals accounted for over 80 per cent.
- The UK appeared to be in "pole position" amongst EU countries for preparing nearly all IV admixture products for almost all patient care areas and special units within hospitals.

The survey results suggest that the UK arrangements for the preparation of aseptic products are at one end of the European spectrum in terms of decentralised pharmaceutical practice and the range/coverage of aseptic services. The lack of progress in developing CIVAS elsewhere in Europe was highlighted by Griffiths (2002).

The survey was repeated in 2005 covering 28 countries - EU member states plus Switzerland, Norway and Croatia (Results in press⁴: see Miharija-Gala (2007)).

In the United States most Total Parenteral Nutrition (TPN) and IV products are prepared in hospital pharmacies and predominantly the practice is moving to the preparation in clean rooms within pharmacy facilities for IVs, TPNs and of course cytotoxics (Rattinger, 2007).

⁴ The results of the EAHP 2005 survey were to be reported at the EAHP Congress at Bordeaux in late March 2007 although there is no indication when the full results will be published.

The management of local hospitals in the Middle East by Western companies, through contracts, has led to the adoption of "Western practice" for quality assurance (Saeed, 1995), which in terms of aseptic preparation means that the focus is on pharmacies, with products provided ready for injection. However, this is not always the case, with variations according to the type, size and locality of hospitals, with pharmacies often not undertaking aseptic dispensing (Al-Salti, 2001; Section 11.58). Also, over time the circumstances and practices at hospitals can alter according to managerial arrangements. At present, practice is generally moving forward towards CIVAS solutions, to support stringent control of infection policies (see Section 11.58).

It is noted that the World Health Organisation initiated a quality assurance programme as being a requirement for accreditation of hospitals worldwide (Saeed, 1995; Yousef et al, 1996; Al-Assaf, 1999), although the actual application is unclear (Al-Salti, 2001). However, these did not stipulate set arrangements and policies in respect of aseptic preparation.

None of the sources outlined above yielded pointers to how aseptic preparation is quantified and measured in the countries concerned.

Beaney (2006) highlights that although there is a general acceptance amongst pharmacists that variations exist in pharmacy and aseptic dispensing facilities and services across the UK, this has not been confirmed through, for example, a specific survey. For example, in the North East of England more Radiopharmaceuticals are delivered by Nuclear Medicine departments, compared to pharmacies, than elsewhere in the country (*ibid*). The DoH survey completed in 1997 required an audit of aseptic dispensing units against published standards but did not ask for details of the services provided (Chief Medical Officer and Chief Pharmacist, 1996).

2.4 Nomenclature for Aseptic Preparation

As stated in Section 2.1.1, the consistency and accuracy with which nomenclature is interpreted can impact on data quality, and therefore it was important to establish how this might relate to aseptic preparation. For illustration, dictionary definitions differ for one key word - "Parenteral". For example, Mosby's Medical and Allied Health Dictionary states: "Not in or through the digestive system" (Glanze et al, 1986), whilst On-line Medical Dictionary gives "Not through the alimentary canal but rather by injection through some other route, as subcutaneous, intramuscular, intraorbital, intracapsular, intraspinal, intrasternal, intravenous etc." (On-line Medical Dictionary, 1997).

The literature review sought references for the different uses of nomenclature, but found that the greater the number of sources referenced, the more complex matters became. Nomenclature in different publications reflects the professional background involved. No attempt was found in the literature to assimilate nomenclature across professional boundaries. This is not surprising given that any such venture would undoubtedly fail to achieve universal consensus; trying to establish consistent use of all nomenclature *within* any single profession across a country would be difficult in view of the inevitable variations in local custom and practice.

There can be differences in the use of nomenclature across countries. An American pharmaceutical company found that the use of specific terminology is different in the US compared to the UK (see Section 11.2 Reference 4). This had led to confusion, and still could not be ignored when people communicated across the Atlantic. Examples were: batch production; CIVAS; dispensing; multidose therapy; and patient specific.

Studies have referred to the problems associated with achieving clarity in the use of terms within health services (Advanced Life Support Group, 1995; Anderson, 1999; Brown, 1998; Gandy et al, 1998d).

Actually defining nomenclature can be problematical within different clinical contexts: Brown (1998) describes the use of terminology in "truth telling", stating that when truth is concealed or withheld, it may not be a lie so much as the suppression of information (which may be considered harmful to the patient); Anderson (1999) outlines the merits of generic versus branded prescribing, firstly in ensuring the patient actually receives what the prescriber intends, and secondly, that the patient clearly understands what their medicine is.

The Association of Accident & Emergency Consultants argued for national standards in the use of nomenclature within documentation supporting critical systems and processes relevant to Major Incident Plans (MIPs) (Advanced Life Support Group, 1995). Hospital emergency services each had their own form of MIP, developed in ad-hoc ways to reflect local circumstances and needs. There was no real consistency in the use of nomenclature within MIPs, with nomenclature differing, not only between hospitals, but also between emergency services likely to find themselves engaged in the operational management of the same major incidents. Questions such as "What is 'Major Incident Standby'?" and "How is a 'Major Incident' defined?" are examples. As a result, the handbook for Major Incident Medical Management and Support (*ibid*) was produced and MIPs were subsequently much more focused, and interrelated the plans of all local and regional

emergency services and agencies. Nomenclature relating to the key critical elements of the process was made clear (*ibid*).

Gandy et al (1998d) discussed nomenclature problems associated with integrated care pathways, care packages and care profiles and how they were often used interchangeably. In the absence of established, referenced definitions for these terms they defined their use of the nomenclature in respect of their study relating to cancer services.

Cancer services provide a good example of how nomenclature needs to be clear. The term "palliative care" was used very broadly in the past, which resulted in the published guidance (NHS Executive, 1996) to distinguish between "palliative interventions" and "specialist palliative care". Corcoran and Gandy (1997) discussed how these terms translated into data.

Nomenclature for staff can be loose or ambiguous. An example is "practitioner" which is commonly applied to nurses and operating department staff. Operating department practitioners do not have exemption under sections 9 & 11 of the Medicines Act (MCA, 1992) to prepare/manipulate medicines. As a result, Trusts seeking to integrate nursing and operating department policies for the administration of medicines found that they cannot make generic use of the term "practitioner" and had to be very specific throughout because to do otherwise could have serious results.

Similarly, the term "clinician" is commonly inferred to apply a medical practitioner, when it is now more widely understood to relate to all types of clinical professional - medical, nursing and other health care professions. This is still a cause of significant general confusion, particularly with the public.

Whilst on the surface it may not seem to matter if there are differences in use of nomenclature between professional groups, it can be seen from the above that it can be very important for inter-professional work, and work between the same profession in different organisations. There are clear benefits from appropriate, consistent use of nomenclature for staff moving between hospitals and between services, as there should be no requirement to re-familiarise themselves in the fundamentals of nomenclature within such documents as MIPs (Advanced Life Support Group, 1995).

For the purposes of data analysis, consistent nomenclature is of fundamental importance for processes and activity to be measured objectively. The increasing use of audit to compare services and organisations raises yet another level of complexity. Many questionnaires designed to elicit comparative data are flawed as they fail to define terms,

which have different meanings in different organisations or parts of the organisation. Results might be used in constructing league tables or for the application of corrective action.

Inevitably nomenclature and definitions evolve with language and knowledge. Sometimes this may be driven by the development of technology – computer terminology often takes everyday language and applies it to a new piece of hardware or software, rather than invent a new word that would mean nothing to the user. Also the definition of “death”, both medically and legally, has reflected experience and developments in medical science (Glanze et al, 1986; Fontana Dictionary of Modern Thought, 1988; Fortean Times, 2000).

What should be noted is that people will take words and terms, and interpret or abuse them for their own purposes, as was illustrated in the novel “1984” (Orwell, 1954). Consequently, whatever steps are rightly taken to address any problems associated with nomenclature, there will never be a final “right” answer. It is more important to appreciate the dynamics of nomenclature and language and always check that nomenclature is being used clearly and consistently within whatever context applies.

2.5 Metrics Surrounding Collaboration

2.5.1 Collaboration in Healthcare

As increased collaboration between pharmacies and Trusts was an objective of the C&CP, its evaluation should include whether collaboration had actually increased. In turn this raised the question “How can collaboration be measured?” to confirm it has taken place and its impact. But there is a danger that “collaboration” is interpreted in different ways. Three (relevant) definitions are:

- “When two or more people work together to create or achieve the same thing” (Cambridge Dictionaries Online)
- “The act of working together with another person or group to achieve something, especially in science or art” (Longman Web Dictionary)
- Work jointly on an activity or project (Oxford Concise English Dictionary).

The interpretation of the North West working party is reflected in the key recommendation that Trusts should “*liaise with each other to consider all models of collaboration to allow the development of aseptic services across a geographical area*” (NHS Executive North West, 1997). This was an imperative for bids for the subsequent C&CP (Beaumont 1999), as the capital and revenue investment required would be prohibitive if a totally

comprehensive aseptic preparation service was provided within each Trust. The working party argued that Trusts should not acquire equipment for specialist preparations if it will be under-utilised, and therefore a Trust should not necessarily expect to meet all of its needs locally (NHS Executive North West, 1997).

Local aseptic units need to provide ready-to-use aseptic preparations that cannot be provided in the appropriate form, and at the appropriate time by outside sources. These normally involve preparations with short shelf lives, particularly complex preparations, and any special requirements of the Trust (*ibid*). However, the range of products involved may be comparatively limited, and the volumes could be very large, and likely to increase should the desired shift in aseptic preparation from clinical areas to pharmacies take place (*ibid*). By comparison, there are considerable numbers of products for which demand from an individual Trust may be small, but which could benefit from efficient production processes were the volumes to be large enough. Such volumes could be created if Trusts collaborate (*ibid*).

No region-wide arrangements would deliver an appropriate solution for all such products due to logistics, although some specialist work may be appropriately centralised e.g. BCG. Therefore the degree to which the production of a particular aseptic preparation can and should be centralised was important, and the working party outlined three different models:

- *Hub and Spoke*: where a central facility is developed (optimising the use of resources for processing a range of items) whilst local facilities focus on those that necessitate local preparation. The central facility would be appropriately licensed;
- *Co-operative*: where a limited number of Trusts (with particular links of geography or specialist services) look to balance the workload between themselves. Processes would be optimised for selected items with each Trust focusing on an agreed range in such a way that they complement one another. One or all of the facilities could be licensed.
- *Network*: where it is accepted that local facilities are required, but the aim is to ensure that best use is made of all those available. For example, quality facilities that are comparatively under-utilised may be licensed for set items and serve the Trusts within the network for those items, through complementary arrangements. The aim would be to make maximum use of local facilities, thereby negating the need for a very large central facility and minimising the need for new capital investment. (*ibid*)

Examples of collaboration for NHS pharmacies involve links with the commercial sector, such as in the North West, where Christie Hospital, in Manchester, began a partnership relationship with Baxter Healthcare in the early 1990s (O'Connor, 2005; So, 2005). The partnership was reaffirmed with the signing of a 10-year repeat contract in 2005 (*ibid, ibid*). Baxter prepares 90 per cent of the chemotherapy drugs at Christie – 70,000 per annum, with more than 80 per cent being pre-ordered (*ibid, ibid*). Whilst other companies also prepare chemotherapy drugs for the NHS, Baxter is unusual in that it has three significant joint ventures with the NHS (the others being at Oxford Radcliffe Hospital and Mount Vernon Hospital in London) (O'Connor, 2005).

The measurement of collaboration is through the commercial Baxter-Christie contract, with inbuilt key performance indicators for monitoring purposes. These include: turnaround time for drug requests; the percentage of pre-ordered drugs; amount of wastage (*ibid*). There is also an annual financial review (*ibid*). The requirements of the contract itself make such data collection an imperative. The contract is based on risks that are acceptable to both sides, with the main risks for the private sector being: building facilities; installing adequate equipment to cater for current and future prescribing patterns; maintaining appropriate staffing levels and expertise; and meeting any changes in regulatory requirements (So, 2005). To manage such risk future income must balance risk and return (*ibid*). On average an 8 – 10 year contract allows enough time for sufficient income streams for a new build to be commercially viable and ensure value for money for the NHS (*ibid*).

The success of such joint ventures is likely to encourage similar initiatives, and the Government highlighted that where the extra capacity to improve the delivery of care is not available within the NHS, healthcare providers from the private sector should be considered (*ibid*). Breen (2004) states that the NHS as a customer already works with a plethora of suppliers and expects quality service at the right price, on time and fulfilled deliveries, with a need to monitor supplier performance and work with suppliers to develop their performance, particularly to develop the pharmaceutical supply chain. Such a contract-based model would not apply for NHS organisations collaborating with one another, because the NHS organisations operate with one another through service level agreements, that are not enforceable in law. They only hold contracts with non-NHS organisations (although this may change as Foundation Trusts mature).

In the NHS and public sector, collaboration is generally interpreted as organisations working jointly, or in partnership (Pollard and Noble, 2005; Summerton, 2004), sometimes through formal arrangements, such as 'virtual' care trusts between health and social services for specific care groups (Martin, 2004), and sometimes with vehicles such as

local area agreements (Shannon, 2005). Similarly collaboration can take place across organisations, on a professional basis, with clinical networks (Edwards, 2002; Smith, 2003). “Collaboratives” are also set up to enable NHS organisations to learn from one another and improve quality by disseminating best practice (Harvey, 2005; Cancer Services Collaborative, 2007).

2.5.2 *Measuring Collaboration*

Many references relate to collaboration and measurement, but few actually deal with measuring collaboration per se. Instead, they look at “collaboration to develop measures”, “measuring the outcomes from successful collaboration” and “evaluating social/interactive aspects of collaboration”.

Arbor (2001) and Bietz et al (2001) sought to evaluate the social underpinnings of collaboration, and discussed measures of collaborative success, but in an academic/research environment, i.e. it is aimed at people (researchers) working together. “Collaboratory” (sic) was defined as a:

“network-based facility and organizational entity that spans distance, supports rich and recurring human interaction orientated to a common research area, fosters contact between researchers who are both known and unknown to each other, and provides access to data sources, artefacts and tools required to accomplish research tasks”.

(ibid)

Illustrative measures that may reflect success, both in terms of process and product included: frequency and impact of publications; satisfaction of collaborators; level of interpersonal trust; degree of mutually consistent work practices; and level of public interest. Organisational and community consequences of collaboratory use were: expanded access; structural transformation; and increased production. Success measures for the latter included increased rates of publication (*ibid*).

Arbor (2001) and Bietz et al (2001) were unable to develop a universal measure of success for collaboratories (sic), but developed a framework, eliciting a number of possible measures of success, and pinpointing open issues and problems. This proposed a 3-dimensional framework, with any measures used to gauge success varying on each of three axes:

- Dimension 1 - Stakeholders (technologists, domain, users, scientists, sponsors/funders, corporations)
- Dimension 2 - Level of analysis (individuals, groups, organizations, fields, social policy)
- Dimension 3 - Time (short-term vs. long-term measures of success) (*ibid*)

South Carolina Commission On Higher Education (2004) looked at “Institutional co-operation and collaboration”, which involves the sharing and use of technology, programs, equipment, supplies, and source matter experts within the institution and with other institutions and with the business community. Benchmarking demonstrates effectiveness using compliance/performance data collected every 3 years. Institutional performance involved two indicators: 4A – Sharing and use of Technology, Programs, Equipment, Supplies and Source Matter within the Institution, with Other Institutions and with the Business Community; and 4B – Cooperation and Collaboration with Private Industry.

The Trillennium Corporation (2004) runs specific courses on how to profit from collaboration. This measures the gains and benefits of collaboration: measure the return on investment from substantial improvements in the ability to quickly solve multidisciplinary, cross-functional, and inter-divisional problems, and benchmarking.

De Jong and Jackson (2000) examined the measurement of inter-professional collaboration, through testing the reliability of the Mater Attitude Measure, which relates to understanding and implementing behaviour change in professionals. De Jong at al (1990) had previously aimed to develop and research the reliability and validity of a generic instrument to measure attitudes of health professionals towards integration, filling the void in validated instruments available for this purpose. Its methods involved the conceptual framework of Fishbein and Ajzen (1975), The Theory of Reasoned Action, which links attitudes, beliefs, intentions and behaviours. Its results from a series of focus groups, surveys and interviews with professionals elicited three categories of data: patient outcomes; resources (human, financial); and professional relationships.

The British Educational Communications and Technology Agency (Becta) (2006) set out collaborative criteria in respect of its Information and Communications Technology (ICT) in Practice Awards for 2006. The impact of their ICT collaboration was measured by:

- providing evidence of impact on practitioners' continuous professional development
- providing evidence of impact on practitioners' confidence and competence levels with ICT
- providing evidence of impact on learners' standards.

How collaboration has maintained high quality standards was demonstrated by:

- using training and/or support materials that promote effective collaboration using ICT
- modelling high quality teaching with practitioners
- demonstrating how the collaboration is tailored to individual needs and learning styles
- providing evidence that the partners value the collaboration
- providing evidence of how feedback is used to inform development of the collaboration.

Gariba (2003), indicated that development co-operation generally, and evaluation in particular are coming under considerable stress, as evidence is increasingly demanded with the increased competition for public resources in all countries. The functions of measurement, monitoring and evaluation were called to the task. He highlighted the need for accountability and set out five basic principles for co-operation in development evaluation. These included "Collaboration on what is measured or evaluated". As like many publications the aim is to *collaborate on what to measure* rather than to *measure collaboration* itself.

Wand (2003) highlighted that internal collaboration is the key to improved innovation in research for pharmaceutical companies. The study suggested that to optimise Research and Development (R&D) investments and create more sustainable value, pharmaceutical companies should focus on improving internal collaboration across traditional boundaries within the organisation. Once collaboration becomes a corporate priority, pharmaceutical firms will want to measure collaboration benefits against corporate business objectives. Outcome (or production-orientated) metrics are essential for assessing quantifiable benefits (*ibid*).

Collaboration is evaluated in the military environment. Noble and KirzI (2003) examined objective metrics for the evaluation of collaborating teams. They identified that there are two principle goals: to quantify changes in team performance, in order to determine the

extent to which new technology, process, or organization improves team effectiveness; and, to explain the reasons for changes in effectiveness. The need for objective performance measures is stressed, highlighting that many evaluations are based on subjective measures exclusively. These have an important part to play, but should not be the sole basis for evaluation, because a person's self-assessment does not always align with performance. Objective measures help document a credible audit trail to explain the reasons for the performance impact.

Noble (2002) also evaluated how collaboration and teamwork work from a cognitive perspective, with the goal of helping explain guidelines for effective collaboration processes and tool use. He indicated that collaboration and teamwork provide many benefits, but they also impose costs that can undermine a team if not managed well. Good teamwork maximises benefits while minimising costs (Evidence Based Research, 2001). There are three collaborative processes: Team set up and adjustment; Joint problem solving; and, Synchronize and act. Whilst then describing the various facets of collaboration and teamwork, there is no measure for "collaboration" itself.

Noble and Letsky (2002) similarly examine cognitive-based metrics to evaluate collaborative effectiveness, looking at effective collaboration within culturally diverse multinational coalitions, which are essential in many military operations. They define collaboration as "the mental aspects of joint problem solving for the purpose of achieving a shared understanding, making a decision, or creating a product." This emphasises the cognitive and problem solving aspects of collaboration, as opposed to other definitions that place greater emphasis on information sharing. For example, the Information Superiority Working Group (Alberts et al, 2001) defines collaboration as "actors actively sharing data, information, knowledge, perceptions, or concepts when they are working together toward a common purpose and how they might achieve that purpose efficiently or effectively."

2.5.3 *Established metrics potentially applicable to Collaboration*

It is inferred that there are no readily available metrics in respect of collaboration that can be directly transferred to the research area. In the circumstances it is necessary to examine valid, alternative possibilities to how "collaboration" is interpreted. One possibility was to see the degree of "collaboration" between Trusts and pharmacies as the amount of *interaction* between them, with the flows of aseptic products potentially forming the currency.

Gandy (1979) addressed a problem relating to NHS patient flows and the interactions between health authorities, i.e. two authorities could have similar catchment populations as a net result of widely different patient flow patterns. Catchment population calculations were very important to resource allocation at the time (DHSS, 1976), with various approaches and formulae developed to reflect this essentially abstract concept (Gandy, 1981a; Gandy, 1981b; Senn, 1981; Skidmore, 1981). The issues facing a health authority were very different if it treated all of its own patients, with minimal traffic of patients to and from neighbouring authorities, compared to a situation where there were very significant flows of patients into and out of the authority. Geography and traditional referral patterns were factors. The question was how to reflect such varying dynamics (Gandy, 1979). The solution was to create a diagram that plotted the percentage of residents that were treated in an authority against the percentage of patients treated within the authority who were residents (*ibid*). The nearer that an authority's co-ordinates were to the point (100,100) then the more independent that authority was of other authorities. Conversely, if neighbouring authorities were in the centre of the diagram then the greater their inter-dependence (*ibid*), or interaction with one another.

The requirement for such a diagram (*ibid*) ceased in 1989, with the introduction of a market environment into the NHS (Propper et al, 2003) with hospitals becoming "providers" of services, and health authorities acting as "purchasers". This was because the health authorities effectively undertook both such functions previously: providing local hospital services for local patients, and sending local patients for treatments in hospitals in other health authorities, where this made sense; and therefore they interacted with one another.

However, the diagrammatic approach was taken up by Public Health in Italy where it is referred to as the "Nomogramma di Gandy", and it continues to be generally used. It is incorporated in public health reports (3 references), publications (11), and books (1), as well as being taught on university Medical Statistics courses (2). See Section 11.5 for details of these specific references.

2.6 Capacity and Workload Measurement

2.6.1 Definitions

Capacity and Workload are essentially two concepts open to interpretation. The Compact Oxford English Dictionary defines them, as follows:

Capacity: the maximum amount that something can contain or produce.

http://www.askoxford.com/concise_oed/capacity?view=uk

(accessed 23/03/07, 10.15am)

Workload: the amount of work to be done by someone or something.

http://www.askoxford.com/concise_oed/workload?view=uk

(accessed 23/03/07, 10.16am)

2.6.2 Capacity Plans

Capacity planning is a requirement in both licensed and unlicensed aseptic units (Beaney, 2006)). Beaney (*ibid*) sets out a specimen format of a capacity plan.

Capacity planning is described as a system used to assess: volumes and types of workload to be undertaken within given timeframes; resources (staff, facilities, equipment) necessary to meet these workloads; and, potential strategies when available resources are inadequate. It includes indirect activities such as ordering, stock control, and product testing, as well as direct production. It should also be considered at two levels: medium to long-term (6/12+ months); acute (daily/weekly) (Lillywhite, 2000).

Capacity planning should ensure: response times are within agreed limits; quality and safety are not compromised; staff overtime is not excessive; staff do not suffer excessive pressure; and, error/defect rates do not increase (Beaney, 2006).

The key variables on aseptic processes and procedures are: whether automated or manual procedures are involved; whether individual prescriptions or batch processes apply; the size of any batches; type of preparation; shelf life; and the facilities themselves (NHS Executive North West, 2001).

Gandy et al (1998a) established that the types of (inter-related) additional resources that NHS units generally require to increase their capacity can include: increase in opening hours; increase in staff; increase in equipment; accommodation improvements; environmental monitoring.

In the commercial sector the elements of capacity planning are: capacity model; forecast; scheduling; "control mechanisms", with flexibility built into any model (see Section 11.2 Reference 6).

2.6.3 Influence of Cancer Services Developments

Cassidy and Glynne-Jones (2005) highlighted the lack of NHS capacity to deliver cancer services, with the demand for drug treatment increasing over 10 years, and likely to continue. New treatments may not be deliverable because of capacity constraints, and some perverse incentives created by Payments by Results (DoH, 2007c) might mean hospitals do not implement capacity saving measures (Pharmaceutical Journal, 2005).

Williamson (2006) describes how the continuing and accelerating rise in patient episodes for chemotherapy, created considerable pressure for pharmacies and demands for increased chemotherapy capacity. The local solution was to centralise services, with benefits in terms of collaboration, safety, increased efficiency in staff management and training, and increased production. The capacity planning model previously used enjoyed limited success in supporting business cases. Therefore other models were used (Low et al, 2003; Shield, 2004).

Low et al (2003) translated workload projections into staff requirements. Shield (2004) evaluated the methods of Trudeau (1980) and Matanin (1984) in respect of preparation times for cytotoxics, and highlighted that Low et al (2003) did not differentiate staff grades or complexity of preparation. Furthermore, although capacity planning is a requirement for aseptic units (Beaney, 2006), it was not undertaken in many departments. Where they were written, the varying methods resulted in significant variations in plans (Shield 2004). No published work had linked variable time requirements for different types of chemotherapy with the grades of pharmacy staff involved (*ibid*). Consequently “*uniform formula for calculating available capacity, (which) could then be used for staff bids*” were developed (*ibid*). This broke down the process with assigned average times, attributed to staff type/grade. Allowance could be included for audit, training, etc. All the sites in the related surveys were unlicensed.

The British Oncology Pharmacy Association (2001) linked staff shortages, capacity and patient safety, and emphasised the importance of getting staffing right. There were problems nationwide, but particularly in the South and London, with the two London Trusts with the worst vacancy levels reporting three chemotherapy associated Serious Untoward Incidents in two years (*ibid*).

The Shield model (2004) was adopted by the Modernisation Agency as the basis for its draft capacity planning model, part of an overall redesign toolkit for chemotherapy services (NHS Modernisation Agency, 2005).

2.6.4 Capacity and Workload Measurement

Measurement in aseptic preparation has focused on risk assessment (Beaney and Goode, 2003; Munro, 2003; Beaney et al, 2005), error rates (Bateman, 2003), and self-assessment in medicines management (Curtis, 2003; Chief Pharmacist, 2003; DHSSPSNI, 2005), rather than actually quantifying production.

Publications explicitly related to capacity planning used formulae to calculate the required (additional) staff to achieve projected outputs (Low et al, 2003; Purkis, 1997; Shield, 2004). Allowance was made for the time taken at each stage of preparation and the type of staff involved. Therefore, such capacity plans might be better thought of as *staffing* or *resource* planning (*ibid; ibid, ibid*).

Milne (2003) observed that recording workload statistics in aseptic units has always been determined by datasets and methods of counting established at local level, making it difficult to compile accurate comparisons. It was important that methods of recording activity and workload statistics comply with nationally agreed criteria so that the volumes, types and complexities of work carried out in aseptic units can be benchmarked. Once a standardised method was agreed and implemented it would provide a foundation for establishing a national capacity planning model for aseptic facilities. Otherwise any capacity model can only be a rough estimate (*ibid*).

To this end, Milne (*ibid*) recommended standard datasets, as follows:

- Daily patient treatment episodes (one daily patient treatment episode defined as “one patient receiving one or more items in a 24 hour period which are part of the same treatment”);
- Final containers prepared (e.g. syringe, infusion bag, disposable infusion device or reservoir pouch for an infusion device; more than one final container of the same drug may be dispensed to achieve the prescribed dose of a drug);
- Complexities (five bands A-E, based on number of aseptic manipulations performed during preparation).

NHS Pharmaceutical Production Committee (Lillywhite, 2000) suggested key quantitative indicators to assess whether available resources matched workload over a period of time: overtime worked; response/lead times; number “out of stocks”; error/defect rates; targets for “indirect” activities (percentage met); and numbers of complaints. It recommended benchmarking across hospitals to determine appropriate action (*ibid*).

In the commercial pharmaceutical sector data collected to support capacity planning includes product types manufactured, volumes of products, cabinet types & functions, and staff levels (see Section 11.2 Reference 6). Also, the industry has applied systematic mathematical programming for long-term, multi-site capacity planning under clinical trials uncertainty (Levis, 2004; Shah, 2004).

In industry, sizing and capacity are important to operate in a competitive market to avoid wastage and preserve the survival of the enterprise. Dealing with capacity is not easy because of a lack of clarity in decisional processes, large numbers of variables, the high correlation among variables, and high levels of uncertainty (Matta and Semararo, 2005). Having a flexible capacity enlarges the spectrum of possible future scenarios because many alternative strategies are viable, thus making risk evaluation more difficult. Many advantages of manufacturing systems are not easy to quantify and therefore they are seldom evaluated properly. Strong interactions amongst components of advanced manufacturing systems make it necessary to carry out evaluations considering the system as a whole (*ibid*).

“Manufacturing capacity” is defined as the set of human resources and equipments that a company can use to produce goods or services to sell in the market. Its dimensions are: type of manufacturing system (e.g. rigid/flexible, automated/manned); amount (quantity); and cost. The aim is to balance capacity with demand (*ibid*).

Main outputs of a capacity planning problem are: a capacity plan and products to market. To obtain these requires mechanisms for: decision models and tools for quantitative evaluation and appropriate (process and system) databases. Outputs include: “aggregate long term capacity”, which is the amount of production capacity required to produce the potential product mix at the established service level; and “service level” which is a definition of the minimum level of satisfaction of the market demand that is acceptable to achieve the strategic goals. “Product mix” is a key indication. To produce these outputs requires use of: mathematical programming, expert systems and process and systems database(s) (*ibid*).

2.6.5 Unit Time Equivalents

In assessing workload volumes and complexity, assessment could be simplified if standard work units (reflecting 'activity' time) are assigned to each product category or task (Lillywhite, 2000). Acute planning should use a capacity planning matrix, with pre-determined strategies to address identified shortfalls and surpluses: deferring production, overtime, transfer work elsewhere, etc (*ibid*). Beaney (2006) recommends the adoption of standard preparation time values and staffing times, but these should be determined locally for each unit. Shield (2004) applied standard times for each process step.

The commercial sector recognises the importance of defining a unit of currency for each product and service. This can involve either a full time and motion study or taking the simplest product as the basis for comparison (see Section 11.2 Reference 6). The former will determine standard minute values (SMVs), but to introduce these into the NHS would be impractical and arguably inappropriate because of the costs and the comparatively small volumes involved (NHS Executive North West, 2001). The latter approach involves agreeing unit time equivalents (UTEs), which act as a weighting system that can be applied to all products based on the most basic item. UTEs drive a clear understanding of current and future capacity (see Section 11.2 Reference 6). The key resources linked to this are numbers of cabinets and staff (*ibid*)

The values of UTEs need continual review as practices evolve. For example, dose banding is a system whereby doses of intravenous cytotoxics are calculated on an individual basis and rounded up or down within an agreed band to predetermined standard doses. A range of ready-to-use chemotherapy syringes or infusions, manufactured in-house or purchased as "specials", may be used to administer the prescribed dose (Plumridge and Sewell, 2001, MacLean et al, 2003). Dose banding still requires staff time for quality control, dispensing & checking, but removing the need to aseptically prepare the syringes, releases staff time (Williamson, 2006).

The above describes a situation where several principles are accepted within the NHS, but there has been no opportunity to define data, and metrics to interpret it, so that aseptic production and usage can be scrutinised and evaluated to support known objectives. The absence of agreed, consistent interpretations of concepts such as *capacity* and *workload* presents genuine constraints.

2.6.6 *Measuring the Aseptic Dispensing Process and Facilities*

In seeking to establish standard production times for aseptic products in pharmacies the NHS Executive North West (2001) chose to consider the period from the start of the aseptic process (i.e. receipt of request/prescription/order) to the end (i.e. product approval by supervising pharmacist), breaking it down into five common elements, with checks required between each stage:

- Assembly of components and documentation;
- Transfer into a controlled work zone;
- Manipulation and aseptic preparation of the products;
- Checking and labelling; and
- Product approval.

Several other authors broke the overall process into detailed constituent parts, but these differ from one another (Andrews, 2006; Benson and Longshaw, 1981; Shield, 2004). Figure 2.1 presents comparisons.

The NHS Executive North West (2001) identified that cabinets accounted for between 25 per cent and 40 per cent of the total time, according to the products. The latter was consistent with Shield's (2004) calculations for cytotoxics.

However, different units apply different methods of work and wide variations can occur even within the same unit in making similar products, e.g. one unit prepared 37 different types of syringes, where the number of ampoules required to make one syringe could be as many as 25. Also, the process time involved in making similar products can vary depending on the speed with which solutions mix (NHS Executive North West, 2001).

Importantly, aseptic dispensing units are nearly all different from one another in facilities and design, a point confirmed by quality assurance specialists from across the country (*ibid*). Even the size of a hatch can constrain the speed of production (Andrews, 2006).

Figure 2.1 Comparisons of Steps Measured in Aseptic Process used by Different Authors

| Benson and Longshaw (1981) General | Shield (2004) Chemotherapy | Andrews (2006) General | NHS Executive North West (2001) General |
|--|---|--|--|
| 1 Collect raw materials and worksheet | 1 Clinical check | 1 Clinical check | Not included as this is performed by clinical pharmacists outside the Unit (usually in the clinical area) prior to the aseptic process |
| 2 Weigh and check raw materials, fill in worksheet | 2 Prepare labels | 2 Prepare labels | 1 Assembly of components and documentation |
| 3 Prepare containers | 3 Prepare batch sheets | 3 Prepare batch sheets | |
| 4 Prepare equipment | 4 Set up ingredients | 4 Set up ingredients | |
| 5 Total time spent in unit - includes time to gown up, prepare and pack product, seal containers, leave unit | 5 First check | 5 First check | |
| 6 Prepare product for sterilisation | 6 Transfer decontamination | 6 Transfer decontamination | 2 Transfer into a controlled zone |
| 7 Leak test ampoules, view and check by pharmacist | 7* Manipulation and aseptic preparation of the products | 7 Manipulation and aseptic preparation of the products | 3 Manipulation and aseptic preparation of the products |
| 8 Label issue and preparation | 8 First check/release | 8 First check/release | 4 Checking and labelling |
| 9 Affix labels and put in final containers | 9 Packaging | 9 Packaging | 5 Product approval |
| 10 Final check and to quarantine | 10 Delivery | Not included | Not part of specified aseptic preparation process |

* This is calculated separately from the other stages, because it involves variable times, whilst the other stages are deemed to be fixed for each item of chemotherapy

The reason for such variability has been identified as lying

“in the general nature of the published guidance which give broad requirements in terms of general standards that a facility must meet but little help in terms of how to achieve those standards. As a result there have been a number of occasions when pharmacies and other similarly regulated areas have either been badly designed or inadequately constructed such that they offer little or no advantage over the old and sometimes decrepit facilities they are replacing”.

GRC Mott MacDonald (2006)

Such variability in facilities and how units operate means that logically each product in each unit needs to be individually timed and given it's own unique time, but this would involve a prolific amount of work. This serves to reinforce both the choice of UTEs as the means of weighting aseptically prepared products and the need for local knowledge. Industry often adopts a system based on informed opinion from qualified staff on how long a task should take (i.e. the values of UTEs) (see Section 11.2 Reference 6), where such a value is the same irrespective of production volume (*ibid*). Nevertheless, it is essential that there is clarity/agreement about what part(s) of the aseptic process any UTE covers.

2.7 Information Systems & Data relating to Pharmacy and Aseptic Preparation

2.7.1 EPS

The contribution of information systems to clinical governance in respect of pharmaceuticals is widely recognised. Computerised systems containing rules to prevent incorrect or inappropriate prescribing reduce the incidence of errors and increase the appropriateness of medicine treatment (Evans et al, 1994; Johnston et al, 1994; Pestotnik et al, 1996; Bates et al, 1998; Evans et al, 1998; Raschke et al, 1998; Shojania et al, 1998), although there are questions about the effectiveness of computer-aided prospective drug utilisation reviews (Chrischilles et al, 2002). Leape et al (1995) calculated that improved information systems could contribute to the prevention of 78 per cent of transcription errors leading to adverse medicine events. Using computers to generate worksheets and labels also helps efficiency within a pharmacy (Graham, 2005).

EPS are a priority (NHS Executive, 1998). A national functional specification was developed over 2006/07, with a view to procurement and implementation during 2008 – 2010 (CFH, 2000a; CFH, 2006b; CFH, 2007a). Its focus is clinical specialties, and it does not include aseptic products/preparation per se although some such activity might be inferred (CFH, 2006a).

A prototype (basic) specification was constructed for Trusts to use in 2002 (Walker, 2002). This described aseptic products such as cytotoxics, TPNs and CIVAS as “specialist functions” (*ibid*). Only one IM&T supplier (JAC) appeared to make significant progress with the development of electronic prescribing by 2004; the inference was that this was due to its specialist pharmacy knowledge, gleaned through its role as market leader in pharmacy systems (Goundrey-Smith, 2004).

Pharmacy Stock Control is outside the scope of the (formal) specification, and its specification/software development “is a considerable time off”, with links between them and EPS still to be specified (CFH, 2006a). Data on whether a patient had his/her drug delivered by prefilled syringe that had been made up on the ward or in pharmacy may be a requirement for a future generation of EPS, but at this stage it is not a primary focus for system development (*ibid*).

Notwithstanding the above, there is a question as to the degree to which EPS would be able to provide comprehensive, unambiguous data around aseptic products and preparation, because of a range of practical and process issues (Chief Pharmacist Wirral Hospitals NHS Trust, 1998). For patient care the data in EPS is vertically organised, and it can be difficult to get information that goes across systems (*ibid*), which means that a likely approach to investigating aseptic production and preparation would involve the transfer of identified data into a data warehouse for subsequent analysis (*ibid*).

From the perspective of actually implementing EPS, few hospitals have considerable experience of such systems (e.g. Wirral Hospitals NHS Trust has operated a system since before 1995), and most NHS hospitals made little progress by 2004 (Goundrey-Smith, 2004). Some hospitals introduced EPS within a single well-defined clinical specialty, or on a pilot basis (not always successfully), yet there is significant difference between this and implementing EPS throughout all clinical areas within a Trust, given the technical and training implications (*ibid*; Walker, 2002).

2.7.2 Complexity of Pharmaceutical Data

Even if EPS can provide data concerning (aseptic) medicines a patient receives, it cannot be automatically assumed that the data available will meet requirements. For example, the National Prescribing Centre’s Hospital Prescribing Information Project (Jackson and Walker, 1998; National Prescribing Centre, 1998; Jackson, 1999) examined the practicability of achieving an effective national database on hospital drug usage, broadly equivalent to that collected by the Prescription Pricing Authority’s Prescribing Analyses and Costs information system. It concluded that it was only feasible to record expenditure

rather than activity volumes for the identified purposes. The number of different measures and descriptions used for products was so great it presented major obstacles to the easy collection of data. Less than half of the hospitals involved had computer systems or configurations that met the minimum project criteria. Fitzpatrick (2001) subsequently reiterated that it was not possible to obtain data on drug volumes because of the lack of common drug identifiers and highlighted that reliance would have to be placed on manual acquisition of any data. Fitzpatrick also argued that medicines management should be studied by utilising outcome measurement (*ibid*).

2.7.3 Information Systems relating to Aseptic Dispensing

Evaluation of the four main information systems used specifically for aseptic dispensing established that Trusts can configure such systems differently to reflect local requirements. This gives potential for differences in product definition, coding systems, report formats and data export facilities, which means that any data collection needs to be at a suitably high level (e.g. product category) to ensure consistency and compatibility (NHS Executive North West, 2001) (See also Section 5.2).

2.8 Computerised Capacity Planning Software

Within industrial environments, material requirements planning (MRP) is a systematic method for determining the quantity and timing of dependent-demand items, but it is not sufficient to cope with balancing plant capacity with demand adequately, and therefore further development produced the so-called manufacturing resources planning system (MRP2) which consists of both material requirements planning and the capacity requirements planning functions (Wu, 1996). Capacity requirements planning (CRP) is the function of determining the capacity requirements needed to carry out production plans. MRP systems assume that capacity is available when needed unless told otherwise. CRP on the other hand takes material requirements from the MRP system and converts them into standard hours of load of labour and machine on the various workstations. By utilising the management information system, CRP attempts to develop loading plans that are in good balance with plant capacities. Thus CRP is an iterative process that first simulates loads on the workstations and then feeds back the necessary information to suggest changes if the plans are not feasible (*ibid*; OMNI 2005).

Consequently the development of capacity plans often involves the use of software models relating to MRP2 (Thacker, 2006a; Thacker, 2006b; Business Performance Improvement Consultancy, 2006; OMNI, 2005; McGuffie-Brunton, 1998). These deal with both aggregate/long term and detailed/short-term levels (Thacker, 2006b) and plan for the

utilisation of labour, materials, equipment and facilities. Flexible manufacturing systems allow for the specific mix of pieceparts to be produced in a given period (Parrish, 1993). Aggregate plans for production are translated into the individual steps necessary to realise those plans, with data generated to develop capacity plans (OMNI, 2005).

Computer modelling can determine the step points in production so that decisions can be made to optimise resources and outputs, taking into account the two main types of capacity constraint:

- *Hard ceiling*: where it is extremely difficult to add or remove capacity e.g. expensive plant or equipment working at full capacity, or a scarce skill. A change here would impute a step change in the fixed costs of the operation and consequently demand a compensating increase in mean and aggregate outputs.
- *Soft ceiling*: where it is relatively easy to flex capacity by overtime, sub contracting, etc.

(Thacker, 2006a)

Increased sophistication of capacity plans and capacity planning procedures can be reflected by an increased need for computer power (OMNI, 2005). MRP2 software has become extremely complex both in terms of functionality and visual presentation, making it impractical to write detailed requirements specifications, or invitations to tender (Business Performance Improvement Consultancy, 2006). Therefore, there is a reliance on purchasing available software packages, which can run the risks of software problems, or “bugs”, and inadequate support from the software vendor. It is essential to have a clear understanding and vision of what is to be achieved through using the software (*ibid*). Even then the success rate of MRP2 implementation can be poor, with consequences in time and cost (Thacker, 2006b).

Importantly, aseptic dispensing units are one part of a whole hospital pharmacy department. There will normally be interaction between the units and the rest of the department in the deployment of staff. Therefore, to be meaningful and effective, the whole of a pharmacy ought to be modelled and not just the aseptic preparation unit. Beer (1996) explores the utility and feasibility of modelling in depth.

The full cost of introducing capacity planning software is not inconsiderable, and the variation across the NHS in units and pharmacies (see Section 2.6.6) suggests that each Trust would need its own locally customised application. It is unlikely that the consequent

aggregate costs to the NHS would be countenanced, given the comparative marginal benefits that could be anticipated.

2.9 Aseptic Skill Mix Issues, Skills Management & Quality

2.9.1 Skills Development in the NHS

Skill mix and role diversification were introduced into the hospital pharmacy sector nearly two decades ago, in response to developments in clinical pharmacy and a shortage of pharmacists (Samuels and Hassell, 2004). Pressures on the recruitment of pharmacists and changes in university courses' structures emphasised the need to look at skill mix and link this to the amount of aseptic preparation that was produced on a licensed basis (NHS Executive North West, 1997; Gandy et al, 1998b; Gandy et al, 1998c) Therefore, whilst pharmacies in the NHS have not specifically adopted a skills-based quality management approach to their services, these pressures and modernisation initiatives mean that great emphasis has been placed on the development and application of competencies (Royal Pharmaceutical Society of Great Britain 2003a, 2003b, 2004; Samuels and Hassell, 2004; British Pharmaceutical Conference, 2004; McRobbie et al, 2005; McGuire, 2005; Cattell et al, 2005)

For example, the NHS Knowledge and Skills Framework is a key element of Agenda for Change (Foster, 2004) which will have lasting implications, and provides the opportunity to redefine the NHS pharmacy career and explore multidisciplinary working and re-engineer service deliverables (Cattell et al, 2005).

Skill mix has been the subject of review (DoH, 2002c; Samuels and Hassell, 2004; British Pharmaceutical Conference, 2004) although there are concerns that proposals might weaken the medicines safety net (Pharmaceutical Journal, 2002). In essence reviews seek to attribute tasks and responsibilities to the most appropriate personnel, taking into account all staff, including pharmacists, pharmacy technicians and pharmacy support workers. In Denmark, the role of pharmacy technicians have extended into "pharmaconomists", taking responsibility for many tasks traditionally associated with pharmacists, without their supervision (Samuels and Hassell, 2004).

Skill mix is seldom clearly defined and, as a result, the concept is poorly understood, which makes it difficult for pharmacists to engage with skill mix debates in any meaningful way (*ibid*). Skill mix can be defined as the "balance between trained and untrained, qualified and unqualified and supervisory and operative staff within a service area as well as between staff groups" (*ibid*).

Yet the progress could be undermined by the variety of methods applied to evaluate the competence of pharmacists in clinical practice (McRobbie et al, 2005). There is a lack of standardised performance criteria, and a lack of clarity of some roles. The concern is that the plethora of “competencies” being produced have no objective data to support them, and without a rigorous approach, the resulting competencies will not meet their aims. There needs to be a competence-based practitioner development framework (*ibid*).

2.9.2 Skills Management and Quality

Quality improvement has long been a priority across all sectors, and whilst there may have been successes in (industrial) manufacturing, the service sector has proved more difficult. This is because quality is generally interpreted as conformance to specification, or fitness for purpose or use, thereby equating quality with standardisation. As a consequence, quality levels are perceived as the inverse measure of deviation from a specification. Also, there is often no tangible product resulting in the service sector (Beckford, 2002).

The established industrial model of quality control involves a documented, procedure-based management approach. The complexities and variability of service provision in the service sector mean that quality improvement cannot be successfully modelled in this way (*ibid*).

The most successful approaches in the service environment are based on the premise that professions rely for service quality on the professionalism and judgement of the individual employee or partner. To maintain professional service quality such systems require explicit recognition of the nature of professionalism, and robustness in practice. Therefore, the only way to solve the problem of quality in the service sector is to employ trained, educated staff and grant them the freedom necessary to do the job. This requires an effective and manageable quality management system based on the development and recording of the skill base (*ibid*).

Using skills to assure quality is not a new idea. Section 6 of the ISO 9001:2000 standard deals with the effective management of skills, highlighting that to provide quality personnel it is necessary to both use competent staff and also support competence (International Organization for Standardization ISO9000, 2000). Nevertheless, good skills-based quality management explicitly uses skills as the basis of quality, with the organisational processes captured at a high, less detailed level. Therefore task and procedure descriptions are minimized or even done away with in many situations (Beckford, 2002).

A skills-based quality management system assures the quality of outputs through the determination of the abilities and competence needed to deliver the service, and then ensuring that only operators whose skills match those needed for a particular process are permitted to work on it (*ibid*).

It should always be remembered that services are delivered *by* people, and therefore process control is essentially the control of the behaviour of the people providing the service. Appropriate behaviour is assured by ensuring that the provider of the service has the skills, knowledge and competence deemed necessary to the provision of the service (*ibid*).

Services are also delivered *to* people, who vary, which is why complexities of service provision arise. The potential range of resultant situations is a key reason for the failure of the traditional process engineering approach to quality management (*ibid*). For example, doctors and nurses when determining their requirements for aseptic products will not only reflect evolving clinical practice and requirements, but also the potentially widely varying case-mix of patients that enter a hospital (*ibid*).

It is not possible to model all possible situations in advance, and therefore it is not possible to specify all activities and solutions in advance. It is not, then, possible to chart the process fully in advance (*ibid*).

People are extremely good at dealing with complexity, but when they are skilled, educated or trained for the task at hand. By defining the skills necessary to the fulfilment of the task:

The complexity of the procedural system necessary for its control is reduced, process definition is transformed into a statement of professional competence.

The level of managerial and supervisory intervention is reduced; tasks become owned by the front-line provider.

Organizations need to match the body of skills held by their personnel and the set of skills needed to deliver the service (identified through role analysis). It is relatively simple to construct a relational database to carry out this task and to extend its utility to the creation of personal development plans, pre-selection for internal promotions and the generation of job specifications for recruitment purposes (*ibid*). Computer software packages *do* exist to maintain and manage skill sets, once defined (Integra Management Systems©, 2006; VSSkillsManager©, 2006; VSDentist©, 2006).

The adoption of a skills-based quality management system would have a clear impact on any large organization, such as a hospital, as well as specific key services such as pharmacy. A particular challenge is to ensure that the skills match is in place all of the time. There are implications for training, recruitment, promotion and retention policies – but it is the key to consistent service quality. Strategic human resource development, as a sub-set of the wider strategic function, forms the link between current and future performance by managing the skills base of the organization (Beckford, 2002).

2.10 NHS Data related to Patient Activity

Gandy et al (1998a) identified the issues surrounding the acquisition of data on aseptic preparation in clinical areas, but even if it were readily available it would clearly be necessary to set it in the context of patient activity. Yet routinely available patient data has its own constraints. For example, minimum datasets' data only demonstrate (to a reasonable degree) what a medical consultant has done - they give no record of the contribution of all the other professions, such as nurses, therapists and pharmacists. The latter are effectively treated as overheads both in terms of activity and finances, and how overheads are dealt with in individual hospitals can vary considerably (see Section 11.11.2 Reference 11). Even where other medical consultants contribute to the care of a patient, in assisting the responsible consultant or even where there is joint care (such as for palliative care), this contribution is not recorded (Corcoran and Gandy, 1997).

Cox and Marriott (2002) highlighted the problems of linking medication-related deaths from adverse drug reactions and medication errors, with minimum datasets that use International Classification of Diseases (ICD) codes for patients' diagnoses, and how the media interpreted such analyses by the Audit Commission (2001).

Minimum datasets indicate the specialty but not the ward of a patient, and some specialties share wards (CFH, 2007b). This needs to be borne in mind if any cross-references are attempted with pharmaceutical data, so as to ensure consistency. If pharmacy data were to involve wards, then individual hospitals would need to use full data from their patient administration systems.

2.11 Governmental Approach to Performance Management and Benchmarking since 1997

A key aim of the 1999 NHS Performance Assessment Framework (PAF) was to increase the scope of benchmarking across all dimensions of performance, including efficiency and service quality. This benchmarking focus supported “culture change” to help the NHS to move from “acceptable to best practice” (DoH, 1999c).

The stated aim of the benchmarking approach was the identification, understanding, dissemination and implementation of best practice (Northcott and Llewellyn, 2005), although competitive league tables and performance standards are at odds with central notions of process improvement and learning outcomes (Kouzmin et al, 1999; Holloway et al, 1999; Hinton et al, 2000).

Benchmarking’s appeal in the context of health sector performance improvement is its avoidance of any need to pre-determine what best practice might comprise (Northcott and Llewellyn, 2003). Although the identification of best practice is recognised as problematic in benchmarking literature (Kouzmin et al, 1999), it is particularly complex in the public health sector (Northcott and Llewellyn, 2003). It is argued that benchmarking through league tables obfuscates this problem and then creates the paradox that the application of performance measurement becomes critical in defining performance itself (Ball et al, 2000).

The first NHS benchmarking indicators used by the Labour government related to costs (DoH, 1998). The subsequent PAF applied a balanced-scorecard approach to performance management across six key areas for continuous development in healthcare delivery (Kouzmin et al, 1999). The NHS Plan emphasised the importance of comparative performance measurement, whilst highlighting the historic lack of standards and the deficit of clear incentives (or levers) to improve performance (DoH, 2000d). In order to address this the NHS Executive introduced “rating systems” based on stars”, ranging from three star (for the highest level of performance) to zero star (for the poorest level of performance) (Wait and Nolte, 2005). Acute hospitals were judged on 45 criteria including length of time patients wait for operations, and cleanliness. (Other types of Trusts had different criteria relevant to their services) (Northcott and Llewellyn, 2005). Through this means, the Government sought to enable delegated authority within healthcare whilst ensuring that such devolved powers did not result in high variability in terms of results (*ibid*). However, relative rankings rather than any clear standard of acceptable

performance say little of the scale and significance of performance variations between categories (Northcott and Llewellyn, 2003).

Responses from within the NHS to the Government's strategy of denouncing "failing" hospitals were mixed (Trosa, 1997), and there was widespread criticism (Seddon 2003, 2004; Edwards, 2004; HSJ, 2004a; BBC Online, 2003). Variations were often interpreted as artefacts of fundamental incomparability between benchmarking organisations (Bullivant, 1996), and hospital managers would seek to justify, rather than modify, their position on indicator league tables (Northcott and Llewellyn, 2003; Jones, 2002). It appeared that providers responded to identified variations in performance either by seeking to discredit the ratings system in its entirety or by arguing that their less than highly rated performance was justified by factors that the rating scheme did not fully take into account (Northcott and Llewellyn, 2005). An unintended consequence is that managers are drawn to focus on the management of reported performance, at the expense of the management of performance itself (Ball et al, 2000). This highlights the importance of indicators being acceptable, or accepted as valid, by the organisations to which they are applied.

NHS also sought other, arguably "softer", measures to enable improved performance. The Modernisation Agency actively promoted good practice and innovations, and trained facilitators to help deliver local change (NHS Modernisation Agency, 2007a). It was set up in 2001 and ceased in 2005 when it was superseded by the NHS Institute for Innovation and Improvement (NHS Modernisation Agency, 2007b). Linked to this was the concept of "beacon" NHS Trusts, where selected exemplars of best practice in specific areas of health care service and innovation were publicised on a special NHS website (now defunct). There were 371 such beacon sites covered (Northcott and Llewellyn, 2005) but the scheme ceased in 2003 (NHS Beacons, 2004). The Healthcare Commission introduced the annual healthcheck in 2005 (Healthcare Commission, 2005).

The DoH established the Information Centre in April 2005 to centralise the collection and dissemination of information across the NHS. It recognised the need to develop information products and services, which would encourage senior, strategic NHS staff to make effective use of information. On the basis of negotiations through 2005, and Ministerial approval, the formation of a joint venture company 'Dr Foster Intelligence' was announced by the Secretary of State for Health in February 2006 (National Audit Office, 2007). Dr Foster has developed products, many of which are of a benchmarking nature, such as guides comparing services and standards in NHS and private hospitals throughout the UK answering: Who will treat me? How long will I have to wait? Which facilities and services are available - and when? How well does the hospital follow

guidelines / meet targets? (Dr Foster, 2007). It has also redeveloped the Key Indicators Graphical System, relating to Local Authorities' PAF (*ibid*). In December 2005, Dr Foster was identified as one of the top ten fastest growing companies in Britain in the Sunday Times Virgin Atlantic Fast Track 100 league table (Dr Foster, 2005), which suggests that the organisation will play a major role in future NHS benchmarking. However, a search of its website yielded no reference to aseptic dispensing (Dr Foster, 2007).

The NHS Benchmarking Club, founded in 1996, presents a voluntary opportunity to enable the sharing of ideas and information on processes. One of its aims is to "promote the use of benchmarking as a means of securing improvement and recognition that managerial effectiveness must support clinical effectiveness" (Northcott and Llewellyn, 2005). It is essentially a networking forum (NHS Benchmarking Club, 2006). At June 2006 there were 90 members of which 80 were English Primary Care Trusts (PCTs) (or their Welsh and Scottish equivalents), four Strategic Health Authorities (SHAs), and 6 were classed as "Other organisations". Of the latter only two were acute hospitals, i.e. acute Trusts have not joined the club, and therefore the Club's contribution to improving services in acute hospitals is questionable (*ibid*). The impact of mergers of PCTs and SHAs in 2006, can only be conjectured, but it is reasonable to infer that there will be a significant reduction in the number of members.

Acute hospitals do exchange benchmarking information on a voluntary basis (Llewellyn and Northcott, 2002), often via a private sector benchmarking agency (Northcott and Llewellyn, 2005). Results from such sources are usually private and anonymised, and it is inferred that they are used to inform Trusts of their own current position compared to similar organisations (*ibid*). This serves to reflect how important confidentiality can be in benchmarking, with this being a precondition of the original North West aseptic dispensing survey (Gandy et al, 1998a).

2.12 Gaps in Literature

The above sections point to gaps in the literature about what data should be collected in respect of aseptic dispensing and usage, not only in the UK but across the world. The varying emphasis on pharmaceutical aseptic dispensing is one reason, and the UK appears to be amongst the most advanced in centralising services.

Similarly no established metrics and statistical indicators used to describe “capacity”, “workload” and “collaboration” were identified in the literature in a hospital aseptic production context, although there is a great deal of literature that would suggest that benchmarking is the most appropriate means of utilising such metrics to evaluate and monitor performance once determined.

The consultancy work of the researcher initiated information and data to be collected in respect of aseptic preparation and production, to address the fact that none was available for pharmacists and managers to make important decisions about how the related services should be planned and developed.

It is apparent from all available literature that timely information is critical to the management of aseptic services. The identification and collation of such information is usually based on reactive, non-systemised responses from NHS management.

The literature surrounding the appropriate information for this type of decision-making is usually linked loosely to commissioned consultancy work for the NHS. The increased emphasis on nationwide initiatives that has taken place, as opposed to local initiatives, means that there is a need for such information to be systematised consistently across the NHS, which in turn requires publication so that it can be embedded in operational and planning processes.

Chapter 3 Methodology

3.0 Introduction

3.0.1 *Philosophical Approach to Methodology*

Students differ greatly in the way they learn (Kolb, 1984; McCarthy, 1990). Therefore, in an attempt to rationalise identity, professional standpoint and ideology in relation to the research, this researcher examined his strategic approach to learning. Kolb (1984) linked theory to practice and developed a 'cycle' to describe these phenomena. The Kolb cycle infers that learning processes undergo transitions involving Concrete Experience (feelings), Reflective Observation (watching), Abstract Conceptualisation (thinking) and Active Experimentation (doing). In utilising this model to evaluate the researcher's learning style it was anticipated that this would point to the preferred research style.

Honey and Mumford (1992) developed a learning styles inventory. This researcher was subjected to a styles assessment, administered at Liverpool John Moores University: the scoring and the test determined a learning style of "converger". Thus this researcher, according to the adaptation of Kolb's Learning Styles inventory, combines Active Experimentation (AE) and Abstract Conceptualisation (AC) attributes as a preferred style. The AE mode of learning has a tendency to be experience based and test things in practice. The AC mode relates "knowledge about" something, which is theoretical, and perhaps comprehensive. The combination of CE and RO placed this researcher into a quadrant of the model titled "converger".

Convergent knowledge brings to bear a number of facts or principles on a single topic: problems have "right" and "wrong" answers (Hudson, 1967). Convergent learners tended to be more highly valued (in school) because most assessment approaches focus on convergent skills (*ibid*).

An evaluation of the researcher's research style (undertaken at the same time) indicated the researcher is a positivist. Anecdotally, it is unusual for a positivist to have a learning style of a "converger". The difference between positivists who are "accommodators" and those who are "convergers" is that the former relate to 'concrete experience' and the latter relate to 'abstract conceptualisation'.

3.0.2 Overview of Methodological Approach

The methodological approach was shaped by the original proposals for research funding (NHS Executive North West, 2001) which required specific details, including costs, plans and project management arrangements. The researcher was the lead applicant, with a specific role in relation to the information aspects. The research was effectively submitted for and on behalf of the professional pharmacist and managerial communities within the North West. Therefore the relationship between the researcher and the subjects of the research (i.e. the professionals) was necessarily close and inter-related, and this consequently constrains the paradigms and methodologies. The involvement of experts was also predetermined (see Section 3.0.4).

The research undertaken for this thesis is one of iterative exploration: seeking to establish information requirements and data availability; evaluating how concepts might be measured/interpreted using the data and derived statistical indicators; testing whether the data can be collected and used in ways that meet the information requirements; improving methods and indicators until it is considered that potential has been maximised or specific boundaries reached; and so on. As Alexander (1964) indicates it is not a case of "get it right first time" but as an evolutionary process of adaptation and learning.

Box (1996) argues that the domination of Statistics by Mathematics rather than by Science has greatly reduced the value and the status of the subject, with the mathematical "theorem - proof paradigm" supplanting the "iterative learning paradigm" of scientific method; a misunderstanding affecting university teaching, research, the granting of tenure to faculty and the distributions of grants by funding agencies.

What the research for this thesis does not attempt to do at any point is to test a given hypothesis, because there was no substantive hypothesis to test. Therefore Popper's (1981) falsification of theory has no relevance, and the relationship with particular paradigms is influenced accordingly.

3.0.3 Relationship to Paradigms

The paradigm relating to any research is very important. A paradigm may be viewed as a set of basic beliefs (or metaphysics) that deals with ultimates or first principles. It represents a worldview that defines, for its holder, the nature of the "world", the individual's place in it, and the range of possible relationships to that world and its parts (Guba and Lincoln, 1994). A paradigm is based on ontological, epistemological and methodological assumptions (*ibid*). Examples of major paradigms are given in Table 3.1.

Guba (1990) describes: Ontology as addressing what is the nature of knowledge or reality; Epistemology as addressing what is the relationship between the researcher and the knowledge; and Methodology as addressing how the inquirer should go about finding out knowledge.

In relation to the research for this thesis, the ontological question (Guba and Lincoln, 1994) is that the nature of reality is that of professional (mainly pharmaceutical) practice, primarily within the UK.

The epistemological question (*ibid*) is that the researcher (as the knower/would-be knower) necessarily works closely with professionals and managers. This was because of the technical nature of many issues and the fact that the research was essentially *for* them. The researcher's role was clear and explicit.

Table 3.1 Basic Beliefs (Metaphysics) of Alternative Inquiry Paradigms
(Guba and Lincoln, 1994, p109)

| Item | Positivism | Postpositivism | Critical Theory et al | Constructivism |
|--------------|---|---|---|---|
| Ontology | Real "reality" but apprehendable | Critical realism – "real" reality but only imperfectly and probabilistically apprehendable | Historical realism – virtual reality shaped by social, political, cultural, economic, ethnic, and gender values; crystallised over time | Relativism – local and specific constructed realities |
| Epistemology | Dualist/objectivist; findings true | Modified dualist/objectivist; critical tradition/community ; findings probably true | Transaction/subjectivist; value-mediated findings | Transaction/subjectivist; created findings |
| Methodology | Experimental/manipulative; Verification of hypotheses; chiefly quantitative methods | Modified experimental/manipulative; critical multiplism; falsification of hypotheses; may include qualitative methods | Dialogic/dialectical | Hermeneutical/dialectical |

Therefore, analyses of the four alternative paradigms in Table 3.1 in relation to the research serve to exclude three of them:

- Positivism assumes that the investigator and the investigated “object(s)” are independent entities, and that questions/hypotheses are stated in propositional form and subjected to empirical test to verify them. None of these apply to the research.
- Critical Theory has ontology of historical realism, which does not apply to the research area. Although there are links between investigator and investigated “object(s)” the approach prevented any values of the former influencing inquiries, and so the value mediation of its epistemology is not relevant. Dialogic and dialectical methods are also not relevant because there is no transforming ignorance and misapprehensions into informed consciousness.
- Constructivism has a relativist ontology where realities apprehendable in the form of multiple, intangible mental constructions, socially and experientially based, local and specific in nature, and dependent for their form and content on the individual persons or groups holding the constructions. The epistemology links the investigator and investigated object so that “findings” are literally created as the investigation proceeds. Neither of these apply to the research given the practical NHS environment and processes involved.

This leaves Postpositivism: for the epistemology dualism is largely abandoned as not possible to maintain, but objectivity remains a “regulatory ideal”; special emphasis is placed on external “guardians” of objectivity such as critical traditions and the critical community (*ibid*), with this being maintained within the research by the existence of an expert panel of professional peers, and similar. (They also addressed the danger of the researcher’s “subjectivity” (Deetz, 1992, 1996)). The research methodology involves discovery as an element in inquiry, and emic viewpoints are solicited throughout to assist in determining the meanings and purposes that people ascribe to their actions. These aims are accomplished largely through the increased utilisation of qualitative techniques. All apply to the research approach.

Given the research’s use of statistics within an “iterative learning paradigm” rather than a “theorem – proof paradigm” (Box, 1996), it follows that both quantitative and qualitative methodologies need to be applied as required, according to the existing research requirements, i.e. a mixed methodological approach is essential.

A mixed methodological approach is in line with Guba and Lincoln’s (1994) inference that methodological questions are secondary to the choice of research paradigm. They suggest:

'From our perspective, both qualitative and quantitative methods may be used appropriately with any research paradigm'

(Guba and Lincoln, 1994 p105)

They go on to question why quantitative methodologies are privileged over the insights "of creative and divergent thinkers" suggesting how qualitative inputs can readdress the balance.

The appropriateness of such an approach within the NHS is reflected in Hill-Bailey's (1997) suggestion that post modern healthcare researchers (i.e. nurses) readily mix the quantitative experimental model, and natural inquiry qualitative perspectives in their design, knowledge existing in both areas with the resultant need for a mixed methodology.

Polit and Hungler (1995) defined the concept of triangulation as: "The use of multiple methods or perspectives to collect and interpret data about some phenomenon to converge an accurate representation of reality". Certainly the use of a variety of data sources, or a mixed methodology would be an example of the process of triangulation. Both Playle (1995) and Duffy (1985) recognised the importance of multi-faceted data collection methods, suggesting that such an approach "minimises distortion" and provides assurance that the data is representative of the phenomenon being studied, thereby adding rigour to the design.

Alvesson and Deetz (2000) make reference to the characteristics of an ethnography, which is a method, but for some "it is even a paradigm". This uses both quantitative and qualitative methods, and commonly involves the researcher establishing close contact with one or a few key informants who then guide the researcher and help him or her with crucial information. It is defined as a study of an exploratory nature, working with unstructured data and being case orientated and interested in meanings. Alvesson and Deetz (*ibid*) think that the term serves best if reserved for studies involving a longer period of field-work in which the researcher tries to get close to the community (organisation, group) being studied, relies on their accounts as well as on observation of a rich variety of naturally occurring events (plus other material, for example documents or material artefacts) and has an interest in cultural issues.

Whilst ethnography is generally used in relation to anthropology and related subjects, it is interesting that the research covered by this thesis exhibits several of the characteristics described, particularly in respect of mixing methods, the relationship between researcher and the subjects of the research, the exploratory approach, working with unstructured data, and timescales.

3.0.4 Use of Expert Input

Expert input was a “given” for the research from the outset given its origins and nature (see Section 3.0.2) and offered many opportunities without which the value of the research would have been limited.

The relevance of expert input to new systems or where insufficient information is available, was emphasised by Matta and Semeraro (2005).

“Analytical models are based on assumptions that characteristic parameters are either deterministic (static allocation) or probabilistic (queuing network/simulation). They are valid when historical datasets are available to describe the way the parameters are distributed, but they become less and less significant when it comes to developing a new system or when no or insufficient information is available on an existing system. In the latter case, experts on the system analysed are asked to provide useful indications concerning the variables involved”.

(Matta and Semeraro, 2005, p234-5)

Guba and Lincoln (1994) illustrate the inherent complexity in an inquiry a researcher may undertake, in the *etic/emic* dilemma. The etic perspective (outsider view of a cultural group) is brought to bear on an inquiry. This etic perspective, which may be hypotheses to be tested, may have little or no meaning within the emic perspective (the way members of a cultural group view themselves, an insider view). Guba and Lincoln (1994) suggest that qualitative data are useful for revealing and “uncovering” emic views. The qualitative researcher is likely to have a very different relationship with informants and data than that of quantitative researcher. This relationship is likely characterised by a researcher immersed in the subjective condition or state of his/her sample, with a flexible approach to data collection.

The research necessarily balanced the etic and emic perspectives, given that it required the respective skills and knowledge of the researcher and the professionals to come together to form a whole. Each had limited knowledge of the others' field(s) but knew that their requirements, disciplines and practices had to be respected and suitably accommodated if the research was to be successful. This required ongoing dialogue and interaction, the simplest means of achieving this was by the creation and maintenance of an expert panel (managed through a series of structured, regular and ad hoc meetings, together with reports circulated for comment).

Not only did this provide a means of triangulating the findings of the research to establish rigour, but it had a number of advantages:

- Consistency over the period of the research.
- Ready advice on variations between different geographical zones and types of hospitals.
- Enabling pre-notification to fellow professionals of what was to be covered in any local interviews, to clarify expectations.
- The minimisation of what Guba and Lincoln (1994) refer to as “context stripping”, where precise quantitative approaches focus on selected variables necessarily “strip” other variables that exist on the context that could alter findings.
- The researcher could provide personal opinions and engage in “real” conversation, thereby making interviews more honest, morally sound and reliable (Fontana and Frey, 1994).
- Minimising inconsistencies from interviews and identifying (potential) anomalies in data and analyses.
- Validating interview results.
- Validating whether the research was on course to achieve its aims and objectives.
- Enabling triangulation with the wider professional community, as appropriate.

In a similar way appropriate use was made of relevant experts providing direct advice on an ad hoc basis, particularly where there were no published references or it was necessary to be as “up-to-date” as possible. These do not represent academic references and have therefore been separately referenced in Section 11.2 as Expert Inputs Statements.

3.0.5 Qualitative and Quantitative Approaches

Given the mixed methodological approach care was exercised in which specific qualitative and quantitative methods were applied.

3.0.5.1 Questionnaires

The principles outlined by Polit and Hungler (1995) as the main strengths of using questionnaires as a design in research were applicable to the research:

- The ability to administer to groups
- Distribution in clinical settings is often inexpensive, efficient, and usually results in high yield

- A large geographically spread sample can be obtained
- Greater anonymity can enable candid response
- The lack of an interviewer creates a lack of interviewer bias

(see Polit and Hungler 1995 p289)

Polit and Hungler (1995) and Parahoo (1997) identify problems with self-report questionnaires, such as a respondent wishing to present a favourable image of him or herself, and their design being formulated on the basis of a researcher's own experience, as opposed to formulation based on the literature or an evidence base. Yet the use of self-report questionnaires in the research is limited to anonymous out-turn questionnaires evaluating the outcomes of workshops. All other questionnaires involve factual data (e.g. number of products, times, type of computer software). Therefore the problems of self-report data are not relevant. In practice, all questionnaires and survey designs were initially piloted with professionals and endorsed by the expert panel.

The out-turn questionnaires largely involved closed questions, which readily yields data to compare respondents, and quick and easy analysis through the use of pre-coded responses (Parahoo, 1997). As there was limited time for the questionnaires to be completed at the end of a workshop this type of design was suitably expeditious (Polit and Hungler, 1995).

3.0.5.2 Qualitative Interviews

Qualitative interviews (i.e. unstructured and semi-structured, as opposed to "talking questionnaires") are relatively loosely structured and open to what the interviewee feels is relevant and important to talk about, within the remit of the research questions. Interviewees are less constrained by the researcher's pre-understanding and preferred language (Alvesson and Deetz, 2000). The researcher may get perspectives, information and ideas that he or she has not thought of before. Such an approach was regularly applied to obtain "richer" accounts (*ibid*), given the need to coalesce the researcher's perspective, expertise and knowledge with those of the (professional) interviewee, their positions often being complementary to one another.

Getting close personal links between the researcher and the respondents – who are then seen as 'participants' may minimise potential problems of saying what the researcher was thought to want to hear (*ibid*) (although there is always a possibility of a Hawthorne effect (Olson et al, 2004)). Responses were peer-reviewed by the expert panel.

3.0.5.3 *Developing Definitions of Concepts*

Alvesson and Deetz (2000) highlight the problems caused by trying to establish a common definition of a particular concept. The diversity of interpretation and the associated variables means that a coherent definition with universal aspirations may say relatively little in terms of the richness and complexity of the quite varied phenomena it supposedly refers to. The impossibility of fixing a concept is partly related to the ways in which words are informed by the root metaphors for the phenomenon being studied. Researchers, like other people, structure worlds metaphorically (Alvesson, 1993; Brown, 1977; Morgan, 1980, 1986). Words get their meaning through the metaphorical context in which they are employed. This means that words work in an imaginative and associative rather than analytically clear-cut manner (Alvesson and Deetz, 2000). Adding the fact that words can have different meanings in different cultures (see Chapter 11.2 Reference 4), there is a strong case for a move to a more local/ emergent approach (*ibid*).

In addition, there is a danger that the reader (or in the case of the research, the professional community) “knows” in advance what the concepts are and can separate them from ‘culture’ and ‘strategy’ due to commonsensical cultural conventions. This can result in prejudices, biases and taken-for-granted assumptions that can lock the research into closed, conservative and uncreative modes of thinking. (*ibid*).

To address the above the research used workshops to explore and debate the concepts and related issues, using Affinity Analyses (Brassard, 1996) and dissemination to ensure that the potential problems did not arise, although nomenclature was fully recognised as a key issue (see Section 3.8). This approach being driven by participants, or jointly by participants and researchers, with allowance for cultural and institutional context and meaning creation patterns is seen as preferable to one that is one-sidedly, indeed authoritarily, decided upon by the researcher (Alvesson and Deetz, 2000). Nowhere in the research was there any aspiration to develop a “grand theory”, with all the connotations that that might involve (*ibid*).

3.0.5.4 *Delphi Techniques*

Delphi techniques are methods for obtaining forecasts from independent experts over two or more rounds. Experts are asked to predict quantities. After each round, an administrator provides an anonymous summary of the experts' forecasts and their reasons for them. When experts' forecasts have changed little between rounds, the process is stopped and the final round forecasts are combined by averaging. Delphi is based on well-researched principles and provides forecasts that are more accurate than

those from unstructured groups (Rowe and Wright 1999, Rowe and Wright, 2001). They are used where there is little or limited knowledge (Linstone and Turoff, 1975; Linstone, 1984; Surowiecki, 2004), a situation which applied in the research. They are increasingly being used in healthcare to obtain professional consensus and information (Medix, 2007).

Their advantages include: inexpensive; free of social pressure, personality influence and individual dominance; reliable; allows sharing of information and reasoning among participants. Disadvantages include: the selected group of people may not be representative; tendency to eliminate extreme positions; requires adequate time and participant commitment (Michigan State University Extension, 1994).

3.0.6 Constraints

Because the research involved such a large constituency as the North West of England, this placed constraints on what methods could be pursued, irrespective of the methodological options. These included:

Organisation: The research needed to allow for and operate within existing NHS and pharmaceutical organisational structures, and their associated communications and working arrangements. In respect of aseptic dispensing, the aseptic managers and pharmacists in the North West Region (co)operate through three geographical zones, viz. Cheshire & Merseyside, Greater Manchester, and Lancashire, each with their own group and zonal co-ordinator.

Practicality: Pharmacists, and other NHS professionals, are very busy and making time to provide contributions to the research would always be in competition with other priority demands; hence how realistic methods were in their demands on professionals' time was a major consideration.

Precedent: Where pharmacists had successfully utilised a specific method previously, there was an implicit assumption that this should be used again. This particularly applied to the decision relating to surveys for activity data, which had the precedent of the researcher having undertaken the original survey of activity in aseptic dispensing units and clinical areas (Gandy et al, 1998a).

Terms of Reference: For some components of the work associated with the research the researcher's role was one of commissioned consultant. Therefore the methods to be applied were (sometimes) predetermined, and strict deadlines were usually applied.

3.1 Data to Collect

The first research question was what data should be collected? This is inherently both qualitative and quantitative.

The expert panel interpreted this as what information is required by pharmacists, nurses, doctors and managers, in respect of their respective related roles. Varying interests within professions needed to be accommodated, e.g. Chief Pharmacists, Purchasing Pharmacists, Aseptic Managers. Therefore the range of information needs had to be determined. The options were:

1. Survey personnel with questionnaire for proposals/suggestions about their needs, and the data required to meet them; analyse results; make recommendations.
2. The researcher to draw lessons from literature; disseminate proposals; seek views through questionnaire about needs, and the data required to meet them; analyse results; make recommendations.
3. Structured interviews with all relevant players to achieve goals.
4. Gather key players from relevant professions and disciplines to debate requirements, evaluate literature, and make recommendations.

Whichever options were to be applied the resulting outcomes/recommendations would need to be validated.

The surveys in options one and two require piloting to ensure efficacy, and involve two stages: the first to determine agreed "needs" and the second to determine the data required to meet them. Undertaking such a process involves a considerable amount of time, which was not available within the commissioned plan timetable and resources.

Professional ownership of the research and its findings is essential, and both options one and two would not allow interaction between key players and professions. Surveys can suffer from poor response rates, unless there is ownership.

Option three was not realistic given the number of Trusts and professions to be involved. The creation of the expert panel negated the need, with key players inputting quality advice.

Option four was chosen (as a workshop) because it: creates ownership by involving key players; enables interactions between them, allowing consensual recommendations; makes best use of time. It also allowed for a collective evaluation of the lessons from the "original survey" (Gandy et al, 1998a), which had important local influence.

To determine "information needs" the expert panel chose Affinity Analysis (Brassard, 1996) as a robust, qualitative research and development method that yields significant findings: it involves all participants, establishes links between different needs, and prioritises them. Its advantages are that it is inclusive and non-directive, with no constraints, enabling the rapid identification of issues of relevance to the question asked. Its disadvantages are that it is usually time-limited and it can be mentally tiring, leading to passivity in some participants. The process needs validation to ensure full participation takes place.

The NHS can be insular and ignore approaches applied in other sectors. Therefore the private sector was invited to present how it quantifies production activity. Baxter's was approached as the main private producer in the North West, whose people were well known to members of the expert panel.

Given the objective to weight aseptic production, particular attention would be paid to the private sector approaches:

1. Consensus categorisation of product type, allocating weighting according to complexity ("unit time equivalents" (UTEs)); and
2. Consensus categorisation of product type with measured time standards allocated to each group ("standard minute values" (SMVs))

The workshop should (qualitatively) evaluate these, in the context of their applicability/transferability to the NHS, through discussion and debate of the advantages and disadvantages, and the associated practicalities.

The Affinity Analysis results would need triangulation. The clock diagram analysis stage would give a whole hospital overview, but aseptic preparation requirements vary between different hospital services. Therefore syndicate groups should focus on predetermined clinical areas, applying multidisciplinary expertise to validate the results in relation to each

clinical area, thereby establishing the degree of consistency of the identified information needs, together with any priorities. There should be sufficient groups to cover all types of main areas, whilst balancing the numbers and mix of the workshop attendees.

To address the gap in knowledge about the types of aseptic products used in different hospital services, the opportunity could be taken to ask the syndicate groups about the degree of usage of the most common aseptic products in their hospital service.

There were two basic options for managing the syndicate groups: unstructured discussion; and, a predetermined structure targeted at the workshop objectives. The expert panel chose the latter because of the time constraints, and because it was necessary to score the identified information requirements. It was anticipated that this would provide the best outcomes.

The efficacy of the workshop needed validation to assure its findings. The options were for a structured out-turn questionnaire of participants and an (unstructured) evaluation by expert panel members at its subsequent meeting. The panel agreed that combining both would triangulate the outcomes, with the survey results being available to the panel at its meeting.

The expert panel then needed to translate the findings into firm proposals for the next stage of the research.

3.2 Information Systems Data Audit

Identifying data requirements becomes largely academic if it is not feasible to (readily) collect/acquire such data. Pharmacists on the expert panel advised that existing (pharmaceutical) information systems could produce data similar to that identified by the workshop, but it was essential to confirm that the systems could actually deliver the research data.

It was necessary to identify the (commercial) systems used across North West hospitals so that they could be tested against the required data, together with how they were used. With no central database holding such information, the most straightforward approach was to survey all units to establish the systems used, together with relevant details (quantitative). Alternatives made little sense to pursue. Trusts will have acquired their systems at different times. Therefore any survey needed to establish the systems' place in local information strategies.

Using the survey results, the expert panel identified a representative sample of units to audit, because details for a particular system should be the same wherever used. The sample covered all systems, geographical zones and types of hospitals (specialist and non-specialist). All identified Trusts were approached to agree to participate.

The expert panel prepared a draft specification for the data audit, but it needed validation, which could only be achieved by an exploratory, pilot visit to an aseptic unit to establish the data and systems information available for one main system (qualitative and quantitative).

Options for the main exercise were: (a) to visit each of the sample units, undertake interviews and scrutinise systems outputs and documentation; and (b) to pursue a "desktop" approach whereby operational manuals, print-outs and other relevant documentation from units were provided and reviewed (backed up by a questionnaire, telephone calls and correspondence to deal with queries).

Both options involved a mix of qualitative and quantitative methods. The expert panel decided that whilst visits could be made to each unit, this would add little to what could be achieved by option (b) and would involve more time (which was at a premium). The reasoning was that systems are defined by their documentation and their standard print-outs, and interviewing local pharmacists on site about these would not add value.

Where automatically generated data did not appear to fully meet identified requirements, local pharmacists were asked how data shortfalls could be addressed (qualitative).

With developments in electronic prescribing systems (EPS), it was important to ascertain whether they might provide the required data within the foreseeable future. Three national sites piloted EPS and therefore a (qualitative) semi-structured interview with one of their chief pharmacists was appropriate, with further action taken if the expert panel considered it necessary.

With pieces of the research moving in parallel with one another, the opportunity presented to collate preliminary (qualitative) ideas and outline proposals for the collection of the main research data, using lessons from the initial workshop and the Data Audit pilot visits. These were presented for validation to the expert panel, and adapted in line with advice given, before presentation to a Data Audit workshop⁵ as potential next steps in the

⁵ For practical reasons, including timing, the Data Audit workshop's scope was broadened to cover issues relating to Nomenclature (see Section 3.8), as they were identified in the initial workshop, and could potentially impact on data.

research; the workshop itself acting as further validation. The expert panel considered this expeditious, as the alternative would involve developing proposals *after* the workshop, thereby requiring a further workshop (or other means) to validate them. Getting professionals together from across the North West for a third workshop on a similar theme would have been difficult.

Again, the efficacy of the workshop required validation, with an out-turn questionnaire and the full expert panel considering the outcomes. A "participants evaluation" was deemed unnecessary because the workshop was not to 'brainstorm' ideas and views (which requires confirmation that everyone contributed); its focus was validating the Data Audit work's findings and confirming the way forward.

Opportunities for placing findings on a website and inviting comments were not really viable at that point in time, and were arguably not as desirable as a workshop, because of the lack of direct interaction between professionals.

3.3 Baseline Survey

Having confirmed the identified data should be capable of being collected by survey, it is necessary to: test/confirm data *can* be collected, and is of suitable quality; and, to use the collected data as the research baseline.

The two main (quantitative) options to collect the data were:

1. To request preset analyses from local aseptic/pharmacy information systems, and collate them. However, Section 3.2 determined that this was not feasible because not all systems provide such preset analyses; it was impractical to request the software companies to develop these because of negotiation time, with no guarantee about the outcome, and the likelihood of financial charges.
2. To collect the data through a survey. This was supported by the expert panel and the discussions at the workshops, and replicated the approach of the original survey (Gandy et al, 1998a) i.e. it was proven to be acceptable and practical.

A full year's data was required to have validity as a baseline, and avoid seasonal variations. All reasonable means of ensuring data quality should be applied, e.g. figures that should correspond do correspond, column and row totals are correct.

The expert panel (qualitatively) translated outputs from the first and second workshops with care, to establish the main survey design principles and ensure guidelines were clear

and complete. The better this was done the better the completion of the survey forms should be, so as to help maximise data quality.

To minimise potential errors/mistakes, the (draft) design and associated guidelines required (qualitative) validation. The ideal option was to pilot the design and guidelines – with actual data recorded - and receive advice on whether: what was required was clear; the data was obtainable; and, any necessary changes were required. The expert panel would then evaluate comments and agree any amendments, before final (qualitative) checks prior to distribution.

The main alternative was for the expert panel and selected aseptic managers to consider the design and guidelines and give the same advice, but without actually providing data (as with a pilot), using their knowledge of local systems. This is not as thorough as a pilot, but the expert panel pharmacists were satisfied with the draft design and guidelines, and felt that a pilot would not add (significantly) to such consideration. It was acknowledged that a pilot would involve several weeks to arrange, undertake and feed back, and time was critical. In the circumstances the alternative course of action was agreed.

The survey was developed on the basis of three complementary forms (see Section 11.24 for details of each):

Form one dealt with the production of aseptic products within a pharmacy, with an indication of the customers involved (the categories were mutually exclusive and covered the full range of possibilities):

- Individual patients (within Trust)
- Use as Ward Stock (within Trust)
- Use in Other NHS Trusts
- Use by Non-NHS Users

Form two dealt with the usage of aseptic products, with an indication from where they were sourced (the categories were mutually exclusive and covered the full range of possibilities):

- Within Trust
- Other NHS Trust Licensed Unit
- Other NHS Trust Unlicensed Unit
- Commercial
- Other

Form three required one figure for each product category: the number of commercially acquired licensed products used in Trust without further manipulation in a pharmacy aseptic unit prior to administration to a patient. These products were excluded from Forms one and two to avoid any double counting.

The mutually exclusive list of product categories included in the baseline survey, on each of the three forms, is set out below. The expert view was that these represented distinct, recognisable categories, which would be homogeneous *within* each category in terms of the amount of pharmaceutical aseptic preparation time and effort that would be required:

- Cardioplegia Solutions
- Cytotoxics – *Infusions*
- Cytotoxics – *Syringes*
- Cytotoxics – *Devices*
- Epidural Injections
- Eye Drops/ Eye Irrigations
- Irrigations (exc. ophthalmic)
- Minibag Plus
- Minibag/ Infusion
- Injection Devices (inc. Elastomeric Infusor)
- Prefilled Syringe
- TPN - Adult: *Compounded*
- TPN - Adult: *Simple Additions*
- TPN - Neonatal/ Paediatric
- Radiopharmaceuticals
- Other

All acute hospital Trusts in the North West needed to be included, given that the C&CP covered the whole of the region. One option for survey distribution was to send it to *all* North West Trusts and ensure complete coverage. The alternative was to target Trusts using aseptic products in the original survey (*ibid*) and check directly that other Trusts had not changed in the interim. The former had disadvantages: Trusts that did not use or produce aseptic products could complain about time being wasted, and some would probably not reply; causing difficulties in determining whether non-respondents were not relevant or late responding. The latter course was chosen, because it was the most reliable option, and only added a little to the researcher's time and effort.

The survey guidance allowed Trusts flexibility on the number of sets of forms completed to allow for local circumstances: separate hospitals, with their own aseptic units, could be considered in their own right if the Trusts wished, to allow for NHS reorganisation where sometimes geographically disparate hospitals are part of the same Trust, even though they operate independently of one another for many operational purposes, e.g. Morecambe Bay Hospitals NHS Trust covered separate hospitals at Barrow, Kendal and Lancaster, each of which has had aseptic dispensing units.

Trusts/sites were allocated confidential survey numbers to identify themselves in the results analyses, and retain anonymity. This was partly to help maximise the response and partly in recognition that Trusts were autonomous organisations within the NHS and “commercial confidentiality” could apply. (Some Trusts *were* in competition with one another for certain of the services).

However, to enable the expert panel to qualitatively validate the data and analyses using local knowledge members had to have the full list of Trust/site codes.

To ensure expeditious analysis, all data was held in a central database.

3.4 Baseline Survey Evaluation

A key research question was whether the baseline survey design was optimal, or could improvements be applied? No matter how good the prior testing, some changes would inevitably be required. Therefore the baseline survey was effectively a first step towards achieving the objective of determining 'definitive' recommendations.

Accordingly, it was essential to (qualitatively) evaluate the baseline survey's efficacy and incorporate any necessary changes into the design for subsequent surveys, maintaining appropriate consistency to enable valid comparisons between results.

To ensure the efficacy of any evaluation it had to be assumed that there would be problems and criticisms, and ensure they would all be identified and notified to the researcher and the expert panel.

The evaluation covered the questions:

- (a) Were the survey forms and guidelines clear and unambiguous, so that pharmacists and aseptic managers could understand what was required and recorded?

- (b) Could this data be acquired from local information systems?
- (c) Was the data collected “fit for purpose” in the context of the research?

To address (a) there had to be (qualitative) opportunities/channels for the pharmaceutical constituency to record any problems and suggest improvements. The simplest means was to highlight that notifying problems/suggestions was welcomed. This involved either direct communication or face-to-face discussion (with the researcher attending zonal meetings of aseptic managers, or meeting local zonal co-ordinators). Both opportunities were made clear in survey correspondence, and stressed to the lead zonal co-ordinators for dissemination.

As (b) was also a local issue, such problems and issues were to be notified through the same (qualitative) opportunities as (a). In addition, the researcher validated submitted survey forms, discussing anomalous data with the hospital concerned, ascertaining whether simple errors or the design and/or guidelines were involved.

It was essential for data audit purposes to record all different types of queries and issues as they arose, because the data held on the database would have all such queries already addressed. A simple (qualitative) log was all that was required.

Clearly, responses through (a) & (b) could not be accepted automatically, and had to be (qualitatively) evaluated themselves to determine whether they would justify amendments to the survey design and/or guidelines. There were only two options. The first was for the expert panel (in line with its role) to receive the feedback, together with potential responses, to undertake its evaluation, before then disseminating to the pharmaceutical community. The second was to simply collate the feedback - without the expert panel's comments - throughout the pharmaceutical community for its own comments, and for these in turn to be collated and considered by the expert panel. The latter was dismissed as impractical: pharmacists would expect to see the expert panel's views/comments on the feedback as part of any dissemination, together with having sight of the results and comments in respect of (c); and it would take considerable time and process.

Evaluation (c) could only be (qualitatively) performed on the survey's completion and analysis. The main means would be for the expert panel to give critical (qualitative) consideration of whether the data and analyses were of appropriate quality and relevance to support the research objectives, whilst taking into account the feedback from (a) & (b).

The expert panel would then propose changes in design and guidelines for subsequent surveys, disseminating the reasons for changes and responses to the feedback received,

along with the baseline survey results and commentary, to North West pharmacists and aseptic managers.

This process was an additional means of (qualitative) validation, as it gave the first opportunity within the research for individual Trusts to benchmark themselves against each other, and the opportunity was both implicitly and explicitly open for them to review and revise their data if they thought, having made comparisons, that they had submitted (significantly) incorrect data.

One important part of the evaluation was to ensure that references to product types were consistent throughout the research, to avoid confusion and misunderstanding. Lists of product types were quoted by the Regional working party (NHS Executive North West, 1997) the baseline survey and the work-study exercise (see Section 3.10). It was not essential for the lists to be identical, because they had different purposes, but it was essential that the relationships between the lists were clear and understood. The straightforward method was to map the lists with one another and (qualitatively) scrutinise it for inconsistencies.

3.5 Quarterly Surveys

With the expert panel having agreed the survey design and guidelines for future data collection, it was necessary to determine the approach to evaluating the impact of the C&CP. The baseline data described the pre-programme situation, so data was required to describe the post-programme situation – the differences informing the (quantitative and qualitative) evaluation. Therefore it was necessary to determine: when and how such data should be collected; ensure that the data was consistent over the period, so that comparisons were legitimate; and that the data could be used to describe trends in activity.

The methodological arguments for collecting the data were exactly the same as for the baseline survey, and therefore the conclusions as to the approach were the same. This was reinforced by the fact that the pharmacists expected a survey approach, its having been adopted for the baseline data (and original survey (Gandy et al, 1998a)).

An important question was for what period(s) should data be collected to effect comparisons (bearing in mind that Trusts and partner organisations would wish to see the results as soon as possible)? It was envisaged that all capital schemes would complete within 15 months of the programme starting.

The main options were to take a full year that began after the end of the programme, thereby having clear pre and post programme sets of data, or to take a series of monthly, quarterly or 6-monthly surveys that ran from the start of the programme through to, and beyond its completion. (The first period within the latter option would start immediately after the end of the baseline financial year).

To wait a whole year after the last scheme's completion before collecting data, would mean the results not being available until 15-18 months after the programme finished, allowing for data collection and analysis, which would likely be unacceptable to Trust managers and pharmacists. It would not lend itself to trend analyses, as there would only be two sets of data.

Six-monthly surveys would not neatly cover a 15-month period, and 15 monthly surveys would triple the amount of data collection and validation, for limited advantage over five quarterly surveys. Five quarterly surveys would allow pre and post programme comparisons and trend analyses. The efficacy of the latter would present further means of validating the value and robustness of the data and any associated measures. Therefore the expert panel endorsed the collection of five quarters' data beginning immediately after the end of the baseline year.

It was expected that units with capital schemes would have data for whole quarters before and after their start and completion. Where this was not the case (because a scheme completed in the last quarter) it would be reasonable to ask for projections of being fully operational, post-scheme, and make appropriate allowance with the data. (NB Resource constraints relating to the commission meant that it was not possible to go beyond five quarters).

Given baseline data was for a full year, some appropriate adjustment would be required to provide equitable comparisons with quarterly data. The simplest method was to divide the annual figures by four, which is what was done to calculate a "baseline quarterly equivalent".

To encourage and enable reliable data collection by aseptic managers the quarterly surveys were designed to be user-friendly. Suitably designed computer disks were suggested to enable pharmacists to enter data routinely daily/weekly/monthly with totals automatically generated. This would give the potential for data to be emailed directly for transfer to the database. The most practical software to use was Excel, as it was sufficient to deal with requirements, and it was the spreadsheet software which Trust staff were most familiar with. The expert panel supported the proposal.

As with the baseline survey, the quarterly survey design and guidelines were (qualitatively) tested prior to issue to ensure they worked. The most practical option was for the draft data entry software to be piloted with the three Chief Pharmacists on the expert panel, as they readily volunteered.

3.6 Quarterly Surveys Evaluation

As for the baseline survey, the efficacy of the revised quarterly survey design and guidelines required (qualitative) evaluation, including the electronic means of data submission. The basic methodological principles were the same as for the baseline survey. Therefore great use was made of the established communication channels with pharmacists and managers.

In addition a (qualitative) evaluation of whether the quarterly surveys' data was consistent and comparable with the baseline survey was required. This was essential for measuring changes from the baseline, trend analyses and the impact of the C&CP. Appropriate allowance would need to be made where data had been removed following the evaluation of the baseline survey.

The expert panel determined that the best means of pursuing such evaluations was to undertake the analyses and then (qualitatively and quantitatively) scrutinise them for consistency over time, with any (significant) activity changes being matched against known plans/circumstances. Any perceived problems and issues were checked with the unit concerned, with either the local pharmacist's explanation recorded or correction to the data. The researcher gave preliminary scrutiny, followed by the expert panel. Disseminating the results throughout the North West pharmaceutical and managerial networks further supported such validation (by offering the opportunity to provide feedback).

3.7 Data Available in Clinical Areas

Given the clinical governance objective to move the balance of aseptic preparation away from clinical areas to pharmaceutical aseptic units, can data be collected about aseptic preparation in clinical areas, which is of sufficient quality and robustness, for the purposes of the research? Pharmaceutical information systems show stock allocation, but do not record how stock is assembled and administered to patients (see Section 3.2). Consequently data on aseptic preparation within pharmacies and clinical areas is not strictly comparable. This is clearly important when considering activity volumes that may move from clinical areas to pharmacies.

The options for researching what data can be collected for clinical areas, and its robustness were essentially: a questionnaire survey; structured interviews; unstructured interviews; or a combination of these. Each would contain quantitative and qualitative aspects, to gain factual data and subjective opinions. The main participants would be nurses.

There are many different types of clinical areas in any one hospital (e.g. adult medical wards; adult surgical wards; children's wards; critical care; theatres) that will have different usage of aseptic products. This means that the methods would need to ensure representative coverage.

Given the numbers of hospitals across the North West it was recognised that custom and practice might vary between different geographical areas, reflecting that different hospitals across the country exhibit different local practices (Zavery et al, 2005; Hardy and Mellor, 2007), together with historical reasons, such as relationships to different medical and nursing schools.

Therefore it was important to attach meaning to the systems and processes involved in a given hospital, which cannot really be achieved by questionnaire (alone), and hence some form of interpretivism was essential. Structured interviews were clearly preferable to unstructured interviews, given that the requirement to glean information on target issues, and the latter could not guarantee that they would all be sufficiently and appropriately covered.

It was impossible to have structured interviews with staff in all clinical areas of all the hospitals in the North West. This means that the methods would need to ensure representative coverage.

To ensure that the structured interviews had been planned properly, a pilot visit was made to one major hospital to test the efficacy of the questions and the programme.

Data from the interviews needed to be triangulated. As a workshop approach had been determined to validate the information systems data audit (see Section 3.2), the expert panel decided the same logic applied for the clinical areas data audit. Covering both at the same workshop would add value because it set the findings of these complimentary exercises alongside one another - one focused on production and the other focused on usage.

3.8 Nomenclature

As highlighted in Section 1.0, nomenclature is of fundamental importance in healthcare, as different professionals interpret different terms in different ways. This has implications for measurement, clinical governance, risk management and any comparative studies where clear definitions are not predetermined.

The issue arose at the initial workshop when pharmacists' and nurses' use of words in different ways created some confusion. Therefore, to ensure that the collection and interpretation of data were as consistent as possible, it was necessary to establish and evaluate the differences in use and understanding of nomenclature in systems, processes and practice within and between clinical groups.

The aim was therefore to determine for the purposes of the research covered by this thesis:

- Agreed definitions for key terms that could be applied consistently in the research, so as to ensure robustness of interpretation and data quality; and
- The full range of (alternative) words that can be applied for particular terms so as to appreciate the risk of the variable use of nomenclature in clinical areas.

The nature of the issue required an interpretive approach, as the personal views and experience of professionals were involved. The method options were essentially: a questionnaire survey; structured interviews; unstructured interviews. These were the same as those for investigating the data available in clinical areas (see Section 3.7). Similarly, the issue of different types of clinical areas utilising aseptic products was important, as nomenclature might vary between them. Including nomenclature as part of the structured interview visits dealing with the data available in clinical areas, made sense in terms of time and resources.

The next question was what structure should be applied? Time was a constraint for both interviewers and staff, and to simply ask staff what words they used, without any prior preparation, would involve much time and not guarantee the outcome. Therefore to address (1) above, the expert panel considered it best to prepare draft definitions of key terms for local staff to (qualitatively) scrutinise and either endorse or suggest amendments/improvements. The expert panel would then receive responses and qualitatively evaluate them with a view to a "final decision". To ask local staff to propose

their own definitions was considered wasteful of time and effort, as there would be inevitable variations, which would then in turn have to be evaluated and reconciled.

To address (2) above, the panel applied a broadly similar approach for the same reasons. It determined a list of key terms and phrases, and then set out the most commonly used (alternative) words, so as to prompt responses from staff. Staff were asked to confirm whether they had heard of all the words on the list, to ensure that none were inappropriate. They were also invited to add new words to the list. In this way the goal of establishing a complete list of alternative words for each listed term should be achieved. The number of alternative words identified would provide some representation of the relative risk that different nomenclature could be used in clinical areas. However, it would be impossible to establish the frequency with which the terms/words were used in local everyday conversations without recording them and then analysing them, which would not have been acceptable.

The process of interviewing followed that described for Data Audit in Clinical Areas (see Section 3.7). Details of the lists sent to Trusts as part of the planned agenda are provided in Section 11.19.

3.9 Collaboration

For collaboration, the literature review represented the first key stage, highlighting the different approaches to defining and measuring "collaboration" in a range of fields (see Section 2.5). The expert panel qualitatively considered these and debated their merits. None was a good fit for the aseptic dispensing situation. This meant that either established techniques, ostensibly unrelated to collaboration were somehow suitably translated for the purpose, or measures had to be developed from scratch. The former had to be exhausted first because the latter would be a last resort.

The researcher had developed a graphical methodology for illustrating the inter-relationship between Health Districts (Gandy, 1979) which had been further developed in Italy as the Nomogramma Di Gandy (Franci and Belbusti, 1979; Zanetti and Montaguti, 1983; Pavarin, 2001; See Section 11.5 for further references). Therefore the logistics underpinning it were understood and there was potential for it to be translated to the aseptic dispensing situation.

This could not be accepted at face value and therefore a brief was provided to the expert panel describing the background and what was involved, and how it might translate to aseptic dispensing, so that it could qualitatively consider whether it was worth taking things further. Such scrutiny was essential for any proposed method, to minimise any abortive quantitative work applying data to a model.

Scrutiny included a check as to whether the identified research data (see Section 3.5) included data necessary for the model, and whether their application made sense in the aseptic context. Any model could not go further unless both applied. If necessary, a check could include whether some adaptation to a model might enhance the applicability for aseptic dispensing.

Should a model pass this first check then it was necessary to further confirm its validity using data on a prototype basis. This quantitative application would need to qualitatively demonstrate patterns that could be usefully interpreted and give insight within the aseptic dispensing context, i.e. pharmacists and managers could see how they would inform their work and plans. The options (at the time) were to use actual baseline data or "dummy" data. The former was chosen as it was clearly preferable, and the timing coincided with the availability of the baseline survey data. Therefore its qualitative evaluation would include how well it sat alongside the baseline survey analyses.

If a model passed the main evaluation, it would be necessary to validate whether it could be used to demonstrate trends over time. Such an evaluation would be made by qualitatively judging whether or not the model showed meaningful time patterns. This in turn required data to be available over time. Consequently relevant analyses could only be undertaken on completion of the quarterly analyses.

The evaluation of any model was essentially twofold: first it had to be endorsed by the expert panel, and then it had to be accepted by the pharmaceutical community. This was not something to be done separately from the main dissemination routes prepared for the evaluation of the baseline and quarterly surveys, as the model needed to be considered alongside the survey results. Therefore its evaluation process was integral to those described in Sections 3.4 and 3.6.

An experimental, iterative process was added to test if the use of a model could be expanded beyond what was initially envisaged, with similar evaluatory principles applied to those outlined above.

3.10 Work Study

An important research objective was to establish how to weight aseptic production activity to inform capacity planning and performance measurement. The means of applying weighting was debated at the initial workshop, with a qualitative analysis of the two main established approaches from industry, viz. UTEs and SMVs. (See Section 3.1). The clear consensus was for UTEs (see Section 6.1).

The consequent research question was how to set values for the UTEs? There were two basic options: direct, empirical observation; and, estimates using professional advice. The former involved explicit quantitative methods, whilst the latter involved a qualitative approach to quantitative matters. The expert panel chose empirical observation because this should be more robust a method than relying on professional advice, and the results were likely to be more acceptable to pharmacists and managers alike.

An advantage was that direct observation might yield pointers to efficiency improvements in the processes involved, which could in turn influence UTE values. In principle, it would be inappropriate to use weightings based solely on current practice, because they may include inefficiencies. Therefore empirical observation offered the possibility of both current UTE values and improved UTE values.

To undertake empirical observation there were again options: the local Trust pharmacists themselves; pharmacists observing in aseptic units other than their own; and, an independent observer such as a work-study professional.

The expert panel rejected the first option because pharmacists did not necessarily have the time and full range of skills required, and it would not be independent; the second was rejected by the expert panel because pharmacists did not necessarily have the time and full range of skills required. This left the third option, and so a work-study professional was commissioned, who thereby had the requisite skills and was independent. This implicitly involves direct observation, which required visits to aseptic units in hospitals.

As with earlier components of the research, it would be impractical to visit all aseptic units in the North West. Therefore a sufficiently representative sample of units was agreed.

To ensure research objectives were achieved, a specification for the work-study commission was drafted and then validated through a pilot visit to a main aseptic unit, where its completeness and practicality were examined. The key components of the specification are set out below (See Section 11.27 for full details):

- A Projected 30 days consultancy, including writing up report;
- B The five common elements to the aseptic preparation of medicines in a pharmaceutical unit. Those to be covered, were:

- 1 Assembly of components and documentation;
- 2 Transfer into a controlled work zone;
- 3 Manipulation and aseptic preparation of the products;
- 4 Checking and labelling; and
- 5 Product approval.

(Checks were required to be made between each stage).

- C The variables to be taken into account, given their influence on processes and procedures were:

- Whether there are Automated or Manual processes involved;
- Whether there is Individual Prescription or Batch Processes, and where the latter applies, the Size of the Batches (e.g. 1 - 100);
- The Type of Preparation involved - the following to be targeted:

Minibag Plus
Minibag/Infusion
Prefilled Syringes
PCA Devices
TPN

(Eyedrops, Radiopharmacy and other products are excluded);

- Shelf Life : this links with whether a Licence is involved;
 - Facilities
- D How the "Start" and "End" of any process was defined locally.
- E Each of the identified Trusts were to be visited, with a series of observations of the processes involved with the aseptic preparation of medicines that will cover all of the variables and types of preparation indicated above. There would need to be sufficient repeat observations to ensure the validity of the results. The following were to be incorporated:

- Definition of the processes undertaken and each of their constituent components;
- Comparisons of the written processes/work programmes with those actually performed. Any variances should be noted and, where appropriate, quantified;
- The duration of each of the constituent components should be measured and recorded;
- As checks were required to be made between each of the key stages in the process, it will be necessary to quantify the associated delays/waiting times;
- Classification of the processes in such a way that will enable analysis of the data to achieve the objectives of the research;
- Classification of appropriate characteristics of staff involved in the processes;
- The collection of basic information on the facilities and workload of the participating Trusts (see Questionnaire in Section 11.27.8).

As with any commissioned piece of work it was necessary to monitor and manage the exercise, to ensure that it was on course. The researcher undertook this.

Given the links to other aspects of the research, i.e. capacity and workload measurement, it was important to ensure that the (interim) findings of the work-study consultancy commission were consistent with what was required by them, as a qualitative validation that the commission had been specified correctly and would support the overall research aim. Given the plans for a workshop on Capacity and Workload (see Section 3.12) the expert panel decided that it made sense for the work-study professional to attend the workshop to present findings and contribute.

In the event, the work-study exercise ran into significant practical problems, making it impossible to continue through to planned completion. A qualitative evaluation was required, and so a report was produced by the work-study professional for the consideration of the expert panel, which included available results, lessons learned and recommendations (see Section 11.28).

Therefore the expert panel had to revise its methodological approach. It decided to apply the alternative approach initially rejected, viz. develop estimates using professional advice (see Section 3.11).

3.11 Unit Time Equivalentents

The previous section describes how the chosen methodology to determine UTE values was direct, empirical observation. Its failure to achieve objectives left the second of the two original options to be pursued, viz. estimates using professional advice.

Seeking professional advice can be done in a number of ways:

1. Face-to-face, qualitative interviews with all pharmacists (which would need to be structured rather than unstructured to achieve the tightly defined objectives);
2. Circulate a questionnaire to all Trusts/units asking them to indicate the times taken to prepare different types of products. Analyses showing the mean values and distribution of the received data are then disseminated giving the opportunity for Trusts/units to confirm or revise their advice. The mean values from the final data form the basis of the UTEs. This approach would be qualitative, but could also include quantitative elements if pharmacists chose to actually time the production process;
3. Use a group of (expert) pharmacists to make preliminary estimates for each type of product, and then circulate them (as a survey questionnaire) to aseptic managers for comment and (qualitative) endorsement, with the opportunity to suggest alternative UTE values where the preliminary estimates were considered to be wrong, or different to local times.

(2) and (3) are iterative processes that test the consistency of expert advice. They embrace multiple perspectives and Delphi approaches (Linstone and Turoff, 1975; Linstone, 1984; Surowiecki, 2004) which can seek expert opinion, analyse it and feed the results back to the experts, with the opportunity for them to revise their original advice if they so wish, in light of the results. The revised data is then analysed to provide the final results. Approach (2) is closest to this, with (3) being a pragmatic adaptation.

The expert panel qualitatively evaluated these options, determining that (1) was too impractical, given the number of units. The main difference between (2) and (3) was that the latter would use a specific group of pharmacists with acknowledged skills and experience as the "expert group", whereas the former used the whole pharmaceutical community itself as the "expert group".

The expert panel chose (3) ahead of (2), because it was more practical, and was likely to get a quicker and faster response; it is easier to consider a value and judge whether it is reasonable and applicable locally, compared with having to make local observations and estimates from scratch. The pharmacists on the expert panel also considered that it would curtail potentially extreme estimates being submitted.

For the purposes of validation and ownership it would be necessary to take the analysed results and share them with senior pharmacists and aseptic managers across the North West (after the consideration and approval of the expert panel). This could be done by circulating the analytical report and then making a presentation for validation, via discussion, debate and comment. This was the methodology pursued with a view to establishing a single UTE value for each product type

In the event, the North West pharmacists highlighted that there should not be one set of UTE values but two: one for licensed and one for unlicensed. This was accepted by the expert panel, which meant that a means of determining them was required.

The view of the expert panel was that it would be unacceptable to repeat the whole process undertaken to determine the first UTE values (which would have been the ideal option). Time was a constraint and it considered that North West pharmacists were unlikely to be receptive to such an approach. The main alternative was to take the data and analyses from the survey and have them reviewed by the original "expert group" to (qualitatively) assign licensed and unlicensed values that were appropriately consistent with the data and analyses, and appropriately in balance with one another. The available data included responses from both licensed and unlicensed units and it was desirable to highlight any patterns that were relevant. Regression analyses were the clear option given the need to interpolate set/mean values, and upper and lower limits from a set of data.

For the purposes of validation and ownership it would be necessary to again share the new UTE values with the North West pharmacists (after the consideration and approval of the expert panel).

3.12 Concepts: Capacity and Workload

It was necessary to determine how UTEs should relate to the concepts of "Capacity" and "Workload".

The literature search gave no immediately obvious, clear, specific definitions that could be applied. This meant that definitions within the context of the research were required. A qualitative methodology needed to be applied. The options were effectively the same as the four considered before the initial workshop (see Section 3.1) and the expert panel made the same choice for the same reasons: Draw together key players (in a workshop) to debate requirements, evaluate literature, identify and evaluate options, and make recommendations.

The advantages were the same: it ensures ownership by involving key players; it enables interactions between them, which allows consensual recommendations to be made; it makes best use of time both in terms of the event itself, and it is speedy to arrange and complete.

In addition, a workshop approach best allowed for the inclusion of an evaluation of the lessons from the work-study exercise and the results of the baseline survey.

The expert panel agreed that the attendance at the workshop needed to be different from that at the first two workshops, because it focused very much on pharmacy issues. It would be important to aim for a full range of types of pharmacies to be represented, to triangulate the results. The only nurse to be invited was from the expert panel, which was for continuity purposes and to be able to identify where nurse-related issues might need to be highlighted.

There was a need to draw out what "Capacity" and "Workload" might involve, and what the associated issues might be. As with the initial workshop, Affinity Analysis (Brassard, 1996) was chosen (See Section 3.1), and for the same reasons, i.e. it is a robust, qualitative research and development method that can yield significant findings. Another reason for such an exercise was to ensure that the workshop did not start with preconceived ideas and views. This was a genuine danger given that the pharmacists invited had expertise and interest in the subjects considered, and they could therefore have strong views influenced by local experience.

The expert panel decided not to validate the Affinity Analysis process for full participation from attendees, as in the initial workshop, because the number attending was smaller and focused on people who had a genuine interest.

It was not possible to predict all options, points and issues that might arise about the concepts being discussed, but they would need to be fully explored and evaluated. Therefore it was planned that the workshop would use syndicate groups to develop ideas

and proposals, which were identified following collective discussion on the Affinity Analysis and any other preliminary presentations. The syndicate groups would work independently of one another, with discussion being unstructured (rather than structured) given the aforementioned uncertainty. Their feedback to the whole workshop would be qualitatively evaluated against each other, with overall conclusions and recommendations being derived. Such triangulation should ensure the validity of the outputs.

A key objective was to validate whether the data identified for the baseline survey was sufficient to deal with "Capacity" and "Workload". This was one of the issues included in the discussions and the evaluation of the syndicate groups' findings.

A validation of the efficacy of the workshop was required to assure its findings, and as for the first two workshops a structured out-turn questionnaire was agreed.

In turn, the recommendations arising from the workshop needed to be validated. The expert panel would do this first, but sharing them with relevant staff from across the country would provide triangulation of the subjects and data.

3.13 Statistical Indicators

Given that no specific, singular definitions could be determined for "Capacity" and "Workload" (See Section 3.12), it was not possible to develop a single all-encompassing statistical indicator to describe each of them. The only alternative is to develop a range of statistical measures, which can inform pharmacists about key aspects of aseptic dispensing production, from which they can infer (relative) performance to inform (local) capacity planning.

Such statistical indicators could only use the identified data. (The possibility of extending the range of collected data could not be ignored if during the process it became clear that a valid and valuable indicator could be created with additional data, and that data was agreed to be both robust and readily collectable; however, this would be treated as an exception). Any measures must be meaningful to pharmacists and managers, both conceptually and in their application i.e. by applying actual data across all aseptic units and Trusts.

In circumstances where there is little or limited knowledge an iterative approach is required: qualitative views sought from relevant stakeholders; analyses undertaken of responses; with results fed back for validation; the views then revised if necessary, and

the cycle repeated until there is a consensus. No real alternatives are available to such a Delphi methodology (Linstone and Turoff (1975), Linstone (1984) Surowiecki (2004)).

The qualitative options were to use the expert panel and/or the North West pharmacist community for triangulation. The approach could be to develop the statistical measures conceptually first and then apply data to the finally agreed measures, or to apply the available data to the statistical measures at each stage of their development, thereby enabling the stakeholders to see the associated results. The expert panel decided that the researcher should develop (draft) statistical measures, apply the data to them, and present the results to them as the initial stakeholder group. This was consistent with the researcher's skills and expertise and the expert panel's role.

Once the expert panel was satisfied that the statistical measures were valid and usable, they would be disseminated to the North West pharmacist community for triangulation. The expert panel would receive any responses and further validate the statistical measures in their light, repeating the process as necessary to achieve the objective.

As part of the validation process, established quantitative techniques such as sensitivity analyses would be applied to test the robustness of the statistical measures against variations in data and/or assumptions.

3.14 Modelling

Despite the conclusion that it is not possible to define a specific 'capacity' value, because aseptic units are very different from one another, and that a benchmarking approach be adopted so that pharmacists and managers can interpret and justify the scope for effecting local improvements (see Section 5.12), there will continue to be the desire to optimise levels of activity within given resources, with the most cost-effective solutions being sought.

There might be variations in how this is applied: one Trust might seek to maintain (or even reduce) preparation and rationalise resources, whilst another might wish to switch as much aseptic preparation as it can afford, away from clinical areas into pharmacies. Yet the principle of cost-effectiveness (without compromising standards and safety) will remain. Therefore there will always be an interest in the scope to achieve this goal using sophisticated computer/statistical models. This makes it important to evaluate the potential for such modelling techniques to be applied within NHS aseptic units.

There are essentially two main opportunities:

- (a) To acquire relevant software models used in industrial environments for capacity planning, and evaluate their applicability for NHS aseptic dispensing units.
- (b) To evaluate the potential utilisation of proven capacity modelling techniques in the environment of NHS aseptic dispensing units.

The software models in (a) usually relate to manufacturing resources planning (MRP2) (See Section 2.8), or similar systems. The main qualitative methods available for evaluation are:

- i. Obtain a copy of such software and try and introduce it to a NHS aseptic dispensing unit; and
- ii. Interview a senior pharmacist who has tried to introduce such software into a NHS aseptic dispensing unit, to establish the degree of success and any problems.

In either approach there would need to be qualitative validation as to the general applicability of the findings.

There are clear differences between the options in terms of time, effort and cost. Option (i) would first require a process to determine which of the available software models was “best” (however that might be measured). It would then require one or more chief pharmacists to agree to try and apply such software to their unit(s). Evaluation criteria and processes would need to be initiated, with the attempt to apply the software undertaken and findings recorded. The evaluation itself could then take place. The costs that would be involved would be considerable in terms of (senior) staff time, and the software itself would have to be bought. The total amount of time involved can be projected as at least six months. By comparison, Option (ii) involves minimal cost and could be undertaken quickly, if a suitable senior pharmacist is available.

The expert panel chose (ii) because the arguments for it were overwhelming, and one of the chief pharmacists on the panel had actually attempted to apply MRP2 software to his unit, and was happy to be interviewed. In addition, there was concern that it would be difficult to recruit chief pharmacists to participate unless there were real incentives, and they would have to be persuaded that introducing the software had clear benefits. This presents something of a dilemma because it would not be possible to demonstrate clear benefits until after the software was introduced. The (financial and time) costs/risks associated with Option (i) were deemed unacceptable by the expert panel.

Question (b) required a different approach. Capacity modelling techniques had been successfully applied to other NHS services that might superficially be seen as similar to pharmacies, e.g. theatre & sterile supplies, radiological equipment (Gandy et al, 2006). Therefore it was necessary to first qualitatively examine whether the characteristics of, and processes associated with the aseptic dispensing were consistent with what was required to apply the techniques.

Such an examination required “experts” in the related fields to qualitatively compare their knowledge in order to determine the degree to which the requirements for capacity modelling are fulfilled within aseptic dispensing environment. This is best done by a face-to-face interview, so as to enable questions to be immediately answered, and for issues to be discussed in depth. This “expert panel” approach (see Section 3.0.4) would establish the main points and issues, which would then require a critical review of published work, to confirm and expand upon them, with a view to determining a fully informed analysis. The research question, using the literature review and analyses, would then be further considered by the expert panel both for validation purposes, and to agree any findings.

3.15 Acute Capacity Planning

The focus of the research is to determine how the production and usage of aseptic products can be measured, in order to infer performance and inform capacity planning. Yet pharmacists and aseptic managers face capacity planning at two levels (Lillywhite, 2000):

- Medium to Long-term (6/12+ months); and
- Acute (daily/weekly)

The work-study professional highlighted the problems of acute capacity planning (see Section 11.28): the ongoing aseptic production cycles/patterns over a week need to be balanced with day-to-day demands on staff that can be predicted (e.g. training) or ad hoc (e.g. sickness). Hospitals often prepare week-end requirements in advance, for when aseptic dispensing units are closed.

It is clear that the prime focus of the research relates to medium to long-term capacity planning. Nevertheless, it is necessary to determine how far the research can and cannot relate to acute capacity planning, to establish boundaries to the research and ensure clarity. Specific features of acute capacity planning include:

- Indirect activities such as ordering, stock control, and product testing, as well as direct production (*ibid*) i.e. tasks outside the measures identified by the research;
- A need for standard preparation time values and staffing times to be determined locally for each unit (Beaney, 2006);
- Local facilities design, given the lack of consistency (See Section 5.12)

To attempt to encompass all such issues, utilising methodologies similar to those already applied, would involve significant additional research, because of the need to acquire considerable amounts of detailed data from each hospital that might participate: collecting daily data would be far more demanding than collecting annual or quarterly data, and collecting local standard time values for each stage of the overall aseptic process for each product type would require much greater effort than determining licensed and unlicensed UTEs (see Section 3.11). The amount of effort involved was anticipated by Syndicate Group B at the Capacity workshop (see Section 5.12) and rejected as not being practical, and because pharmacists would not be prepared to provide such amounts of data. Also, there would need to be a large number of participants to allow for variations in local circumstances, which would again add to the amount of effort.

In the circumstances a literature review was undertaken to ascertain what might have been published. The main relevant initiative was the development of the capacity planning tool for chemotherapy that had been prompted by the NHS Modernisation Agency (2005) to enable the expansion of chemotherapy services, and was consulted on in early 2005 (*ibid*). It used a published capacity planning model for chemotherapy (Shield, 2004), which applied standard times for each preparation step. The researcher critically reviewed the proposals and submitted a response as part of the consultation (See Section 11.45.2).

The next stage of the national process was to commission the creation of a simulation tool to enable Trusts and Cancer Networks to plan what resources are required within their local chemotherapy and oncology networks. A.T. Kearney Management Consultancy developed the tool, entitled "C-Port" (Concentra, 2006), which was being rolled-out across the country when this research was concluding.

Therefore it was necessary to establish whether C-Port could offer insights for the research. However, as chemotherapy represents a single and quite distinct strand of aseptic dispensing, with the cytotoxics cabinets generally dealing with all and only such products (See Section 5.17), there would need to be checks whether such a model might be transferable to general aseptic dispensing. The main option for doing this was to obtain the details of C-Port and to qualitatively interview key personnel at national and local level to get both perspectives.

Capacity planning is a requirement for aseptic dispensing units (Beaney, 2006) although there is no prescribed way of doing it. It was understood from contacts within the pharmaceutical community that individual aseptic dispensing units were developing local approaches to modelling acute capacity planning. Therefore direct contact was made with two that were known to have their own "in-house" methods, which were quite different from one another, and arguably represented different ends of the spectrum, so as to ensure reasonable balance.

Whilst it may have been possible to consider other methods to establish local approaches to (modelling) acute capacity planning, such as a qualitative questionnaire survey, this would have involved considerable time and effort, which was not feasible at that stage of the research. Equally, it would be unreasonable to make such investment in an area that was not central to the research. Pharmacist advice was that a critical review of the two units' approaches should be sufficiently representative of the range of approaches available.

A critical review would look to establish key commonalities and differences, determine lessons for the future of acute capacity planning, together with how they might relate to the research. Appropriate cross-reference would need to be made to the cytotoxics model. In order to test the validity of such a review it would first be necessary to ensure that the local pharmacists agreed with the analysis and findings. Following this it would be desirable to disseminate findings to a broader audience for further validation. The options would be to circulate the findings to key pharmacists (preferably their having been previously involved in the research, so as to readily appreciate the relevance) and/or to prepare a paper for publication.

3.16 Transferability

It was important to confirm the general applicability of the research findings in the wider NHS. The expert panel saw this point as being once the data requirements, survey methods and associated benchmarking analyses had been established (for the North West) (NHS Executive North West, 2001).

Therefore, testing the transferability of the research findings and methods necessarily required the replication of the survey and analyses outside the North West. The degree of success would represent the results.

There were two options for undertaking a survey outside the North West. Either a whole Region (or Regions) is surveyed (i.e. all of the hospitals within the Region are included), or a disparate range of hospitals across different Regions is used.

The problem with the latter option is how would the hospitals be chosen? It would be likely that only enthusiastic hospitals would volunteer to be involved, and this would be unlikely to be random: they would probably be larger hospitals with ambitious local agendas. It could also be difficult to recruit hospitals, given the associated logistics and the commitment that would be involved (see Section 6.16).

By comparison, surveying another Region - if fully participating - would have the advantage of all sizes of units and varying interests, i.e. it would be arguably random within itself. Therefore it was concluded that the best methodology was to apply the research methods to another Region in the country.

The opportunity to actually test the transferability of the research methods arose from an approach made to the researcher by chief pharmacists in the West Midlands Region. They specifically commissioned him to replicate the research methods locally, on a consultancy basis, given that they wanted information to enable them to plan services across the area. Therefore the expectation on the part of the commissioners was that a survey would be involved. (This also represented the most cost-effective approach in terms of consultancy time and costs).

Whilst the successful application of the survey to the West Midlands would demonstrate transferability and general applicability, it also offered the potential to make comparisons between local results and those for the North West. This would indicate the value of the methods for making inter-Regional comparisons (or any comparisons between different groups of hospitals). The chief pharmacists in the West Midlands were keen to see such comparisons, so that their own results were not seen in isolation. The North West expert panel readily agreed to its data being used for such purposes.

However, making inter-Regional comparisons raised the question of how to appropriately allow for the respective sizes of the Regions. The North West research and analyses had not had to deal with this. Therefore, it was necessary to identify suitable currencies for which data was available, and then make comparisons using them. A critical evaluation of the comparisons would then follow.

The key question was what proportion of aseptic preparation was undertaken in pharmacies compared with clinical areas. The North West research had confirmed the

difficulty of collecting such data, and therefore it had not been collected for the West Midlands. This meant that the only option was to try and determine an appropriate proxy measure for comparative purposes. Taking available data, exploring the potential options for developing such proxy measures, and then evaluating them to see which has the most and sufficient value to meet requirements, would do this.

3.17 Evaluation of Programme

An objective of the research was to measure the impact of the C&CP when completed. This would serve two purposes:

- To quantify the change in the production and usage of aseptic products prepared in pharmacies, across the North West; and
- To (qualitatively) validate the efficacy of the measures and methods developed by the research.

The (significant) delays in some capital schemes had prevented a full evaluation, because this was not possible until the last scheme completed.

The methodology was in effect predetermined by the earlier methodological decisions: a repeat of the (quantitative) survey design would be expected by the North West pharmaceutical and managerial constituency. Data needed to be collected for the most recent full year, post-programme activity (i.e. 2003/04). The baseline survey data already provided the pre-programme activity and performance levels.

It was ascertained that since the last of the quarterly surveys, North West pharmacists had derived a single sheet survey format from the two survey forms determined by the research, and successfully used them to collect (local) ad hoc data. (The same guidance had applied). Qualitative pharmacist advice was that this single sheet format was likely to be better received for the survey. Therefore, before proceeding further, it was necessary for the researcher to validate that the revised format provided all of the data required to calculate all of the analyses and statistical indicators identified by the research. This required a qualitative and quantitative comparison of the two sets of survey forms.

For similar validation purposes, the analytical methods identified through the research would need to be appropriately augmented by the techniques and lessons of the subsequent work/research. For example, by comparing the pre and post programme situation in the North West, rather than two different Regions (see Section 3.16). This

would be necessary to gauge the shift of aseptic preparation from clinical areas to pharmacies, and allow for changes in pharmacies, hospitals and organisations during the intervening period.

Applying the methods to different years also offered the opportunity to quantitatively evaluate their robustness over time, and for demonstrating change per se, which would be an essential criterion to meet.

The reorganisation of the North West Region into three separate and distinct Strategic Health Authorities (SHAs) during the period meant that an emphasis needed to be placed on how the methods could show quantitative and qualitative differences between different areas in terms of how local activity and performance had changed. This would go further than what had been achieved with the West Midlands exercise.

The above could only be addressed by producing many different comparisons over time for the many activity data and performance measures broken down for each of the key characteristics: size of hospital; size of aseptic unit; geography; whether an aseptic unit was licensed or not; etc., and then qualitatively interpreting the value and/or significance of the results.

The only data that would not be updated by the post programme survey concerned the UTE values. Therefore it was necessary to determine whether those used in the past were valid to apply to the most recent data. The two qualitative options for doing this were to repeat the original method or seek the views of senior pharmacists (mainly those who had been on the expert panel) as to whether they were still valid. The latter was right to pursue in the first instance, because if the professional advice was that the UTE values were still valid, i.e. there had been no changes, then the former was not required. This proved to be the case. (It was questionable whether the former would have been feasible within the timeframe).

The original expert panel no longer existed, as such. Therefore the North West senior group of chief pharmacists filled this role, with the Regional Quality Controller acting as the main communications link and advisor to the researcher. The fact that this was not a multidisciplinary group did not present any problems because all of the focus of this stage of the research was on pharmacy matters.

Specifically for those units that had received capital funds, it was necessary to quantitatively compare the changes in activity and performance with what had been planned in their business cases (Beaumont, 1999), not least for accountability purposes.

In the event, several of the units did not reach their targets. Therefore it was necessary to qualitatively determine why, and the most straightforward means was to contact them directly to ask the question through a telephone interview. To qualitatively validate the accuracy of the interviews, they were followed up by written confirmation of the stated reasons and circumstances, which were then agreed as correct.

It followed that there was spare capacity in these units, and therefore it was desirable to quantitatively establish the potential impact of what would happen if all such spare capacity were utilised. This was so that pharmacists and managers could appreciate how much further they could go in shifting aseptic preparation away from clinical areas, using the capacity of existing aseptic facilities.

The results from the repeat survey, including the changes over time, needed to be qualitatively validated and owned. The previous method had been to circulate them to all pharmacists for information and validation. This was therefore the natural choice, but there was an ad hoc opportunity for validation, presenting the results to a North West workshop of all pharmacies.

3.18 New Information Systems

Section 5.2 identifies that existing pharmacy information systems can provide the research data automatically, or at worst with further manual or other processing. Section 5.7 shows that whilst there is data on stock issued to clinical areas, there is no readily available data on the numbers and types of aseptic preparations undertaken there, and hence some form of estimation is required (See Section 11.23). In both cases this involved the evaluation of contemporary information systems. In light of the significant investment in new information systems in the NHS, following the publication of *Information For Health* (NHS Executive, 1998), and the emphasis placed on EPS, the question has to be asked whether any new systems might yield new data that could transform the situation.

To confirm the situation for the pharmacy information systems the options were to: repeat the survey of the North West (See Section 11.14); (qualitatively) survey a representative selection of Trusts; and (qualitatively) survey the systems suppliers. Initial contact was made with lead pharmacists for their views on the current situation. They confirmed that there was little or no change and therefore a repeat survey would probably be inappropriate. They also felt that suppliers were unlikely to respond in the context of the

research. Therefore a survey of representative Trusts was chosen as it was practical and did not preclude going back to one of the other options if the results so merited.

Clearly, if EPS can provide quality data on the numbers and types of aseptic preparations undertaken in both pharmacies and clinical areas, then it could be possible to take a further step with the research. For example, the balance of aseptic preparation between pharmacies and clinical areas might be directly quantifiable, rather than having to rely on estimates, and establishing the number of aseptic products consumed by each specialty could enable capacity planning to (better) reflect changes in projected patient activity.

Although the inference made as part of the research was that EPS will not provide such data in the foreseeable future (see Section 1.8) it is essential to confirm the latest situation in case of recent changes.

Improvements in hospital systems in the NHS are being taken forward through the Connecting For Health initiative (CFH, 2007c). This involves the country being divided into five areas, each served by a Local Service Provider (LSP) commissioned to provide all relevant systems for hospitals in its area (CFH, 2007d). The systems commissioned include EPS. Therefore the only real option was to approach CFH and make direct enquires.

It was also desirable to gain insights into any developments “on the ground” in hospitals where EPS were being used, in case of related local developments. The (qualitative) options were to undertake interviews with hospitals that had established experience of using EPS, or to send a structured questionnaire. Contact with CFH indicated that the number of such hospitals was limited, and the main candidates were the three national pilot sites (Burton, Winchester & Wirral). Using questionnaires was ruled out because insufficient time was available at the stage of the research. As the initial evaluation of EPS in a hospital environment had involved Wirral Hospital NHS Trust (See Section 3.2), a structured interview with lead personnel there would have the advantage of establishing any specific changes over time. Therefore the latter course of action was decided.

Chapter 4 Methods

4.0 Validation

4.0.1 *Continual Validation*

Throughout the research the efficacy of the methods required validation. This was rigorously addressed by a variety of means:

- The early period of research involved an expert panel, with the report (NHS Executive North West, 2001) peer-reviewed;
- Subsequently the Chair of the original expert panel facilitated the North West Chief Pharmacists Group to fulfil this role;
- Findings at key stages were presented to practising pharmacists across a region, as part of dissemination and to validate methods and recommendations; this involved a combination of circulating reports and presentations at meetings;
- Papers were written for publication in peer reviewed journals and conferences.

The use of experts and the continual engagement with professionals was particularly important to ensure the triangulation of many of the qualitative results. These validation methods were applied throughout, tailored to circumstances.

4.0.2 *Original Expert Panel*

The expert panel maintained an important qualitative function for the research: agreeing the efficacy of next steps (e.g. workshop arrangements, work study specification) and evaluating the resultant outcomes. The membership covered those professions with an interest and the three North West geographical zones, given how pharmacists organised themselves and the associated channels for communications. Any differences in circumstances, approach and experience across the North West needed to be highlighted immediately. The membership was as follows:

- Director of Quality Control, North West Region (Chairman);
- Head of Laboratories & Licensing, Medicines Control Agency.
- Director/ Senior Pharmacist from each zone (3);
- Primary Care Pharmaceutical Advisor;
- Healthcare Information expert (also acting as project manager) (the researcher)
- Senior Hospital Nurse

- Senior Hospital Doctor (Consultant Microbiologist)
- Academic input from Liverpool Business School, Liverpool John Moores University (LJMU)

Individual contributions were on a professional/advisory basis; the panel was not a representative forum. Members were provided with full briefing packs of relevant documentation and reports from the outset.

There was regular communication and dissemination with Trusts and Health Authorities to ensure their engagement, and that the process was transparent. Dissemination included professional networks (by various panel members). Letters were written to the Pharmaceutical Journal and Microbiological publications to inform wider professional networks and enable interested parties to contribute should they wish.

The research was project managed using standard project management techniques, such as Gantt charts, milestones (and milestone reports), and reports to the expert panel for guidance, advice and agreement on further action.

The expert panel agreed the key words that should be used in the literature search. The researcher, as project manager, undertook the searches.

4.1 Data to Collect

A multidisciplinary workshop was arranged to establish the information required for the purposes of the research. Its specific aims and objectives were:

- To review the lessons from the original survey (Gandy et al, 1998a);
- Identify the information needed;
- Identify relevant data and currencies;
- Test these across a range of clinical scenarios;
- Compare the situations in pharmacy and clinical areas;
- Comment on how easy it is to collect such data;
- Develop and agree recommendations; and
- Ensure good practice in terms of research and development.

Five members from the expert panel facilitated the workshop, with another five acting as a "control" group to objectively consider the findings.

The main thrust was qualitative. Therefore, the workshop was carefully structured to include appropriate, proven qualitative techniques, augmented by selected information. Its structure was:

- Introduction and Aims & Objectives of Workshop
- Affinity analysis (Brassard, 1996) to explore relevant information required within aseptic/pharmacy context
- Prioritise requirements and determine provisional recommendations
- Commercial Sector presentation on data collection and usage
- Syndicate Groups to test and evaluate the findings from the Affinity analysis against predetermined clinical areas
- Feedback from Syndicate Groups (suitably triangulated)
- Main Conclusions and Recommendations

The Affinity analysis used the question: "What information is required by professionals and managers in respect of aseptic preparation: how is it used, for what purposes, and what are the key issues?" (See Section 11.8)

The commercial sector representatives presented how they approached relevant issues covered by the research, including how UTEs and SMVs relate to capacity. This was followed by questions and answers, and a (qualitative) debate about the relative merits of these measures for weighting aseptic production in a NHS context. A (qualitative) recommendation was then made. (A summary of the private sector presentation, the discussion and conclusions is provided in Section 11.10).

To assure the Affinity analysis a (qualitative) process audit was applied to ensure all participants made meaningful contributions and the results were comprehensive and representative. Two of the five facilitators acted as process auditors: a Nurse and a Pharmacist. They used a structured audit form and specifically did not actively contribute to the exercise, as their role was to observe participants. It was essential that participants did not realise they were being observed, and therefore the auditors masked their real roles. The auditors recorded observations independently of one another, and handed in their completed forms at the end of the exercise.

For the syndicate groups, the expert panel determined what it considered to be a sufficiently wide and representative selection of clinical areas from an acute hospital: General Medicine; Surgery/Theatres; Specialist Diagnosis Group – Cancer; and Specialist Clinical Area - Intensive Care Units (ICUs). The planned syndicate group membership dictated the overall attendance. Each had a chief pharmacist, a purchasing pharmacist, an

aseptic manager, a nurse and one "other", facilitated by expert panel members. The spread of pharmaceutical interests was necessary to ensure a full picture was obtained, particularly with regard to available information and data. The "others" enabled (indirectly) relevant interests and expertise to be included, such as Health Authority pharmaceutical advisors and Trust managers.

Each syndicate group attached (qualitative) "importance scores" to the issues and items from the Affinity analysis for its clinical area. These scores ranged from 1 = "No importance" to 5 = "Very important". The groups determined views independently, so collating results informed the consistency of views across clinical areas.

The syndicate groups then went through a predetermined list of questions, designed to establish key information about the clinical process in relation to the aseptic preparation of medicines, and how this might relate to information and data (qualitative). The list of questions was as follows:

- What are the processes and key activities in the clinical area?
- What are the activity categories and methods of counting?
- How does clinical activity and counts relate to what is issued and counted to the clinical area by the pharmacy?
- What determines production and assembly on wards?
- What documents record the production and assembly of ward activity?
- What further processing takes place of such records?
- What other relevant data sources exist?
- Consideration of any future developments that may require modifications to the above?

A final question was to assign the same scores to a set list of (the most common) aseptic products, in relation to the clinical area (qualitative). These were: minibag plus; minibag/infusion; prefilled syringe; PCA devices; and TPN. This was to confirm the relevance of each product to each clinical area. Given that current practice may not be what is ideally required, the syndicate groups assigned scores for the 'Current' situation and the 'Ideal' situation, so as to address any constraints imposed by current circumstances and examine potential future dynamics. In the event the Surgery/Theatres group adapted this question by distinguishing between the importance of products in surgical wards and operating theatres (rather than 'current' and 'ideal').

Again, because groups answered questions independently, collating the results informed the degree of consistency in practices across clinical areas.

Syndicate groups' results were fed to the whole workshop, collated and final recommendations developed.

The workshop was evaluated through Out-turn questioning (qualitative), which is standard practice for such events (see Section 11.11). The 26 questions were designed to ascertain views in a number of areas:

- Was adequate information provided ahead of the workshop? (1 question)
- The purpose of the project (3 questions)
- The purpose of the workshop (8 questions)
- Syndicate groups (4 questions)
- R&D Capacity (5 questions)
- The contribution of the Commercial Sector (2 questions)
- Location, accommodation & facilities (3 questions)

Responses were anonymous, but people were asked to indicate their profession, to enable comparisons between the different professionals' perceptions. There was always potential that (primarily) pharmacists and nurses would view matters differently from one another.

Questions were kept as simple as possible, as they were answered at the end of a long day. Each person tick an appropriate box against whether (s)he "Strongly Agreed", "Agreed", "Disagreed" or "Strongly Disagreed" with the statement/question, with an option to record "No View".

Not all of the questions required "Strongly Agreed" or "Agreed" to be ticked for the interpretation to be deemed positive. Three questions (3g, 3h & 4b) were negatively structured questions, which would mean that "Strongly Disagreed" or "Disagreed" would represent a positive view. Also, two questions (5a & 6b) were neutral.

The expert panel considered the outcome reports covering the different components of the workshop (see Sections 11.12 and 11.13), as a final validation of its outcomes and to made specific recommendations for the next stage.

4.2 Information Systems Data Audit

4.2.1 *Systems Survey*

A survey was undertaken of aseptic dispensing-related pharmaceutical information systems used in all North West Trusts (see Section 11.14).

The questions were:

1. Name of pharmaceutical information system
2. Version of pharmaceutical information system
3. Year current version acquired
4. Are there up-to-date versions of the User Guide?
5. Are there up-to-date versions of the System Documentation?
6. Is system in place Year 2000 compliant?
7. If not then will Trust replace ahead of Millennium?
8. Is Trust pursuing acquisition of new pharmacy information system through procurement process?
9. If "Yes" then in which year will it be in place?
10. Is Trust actively pursuing electronic prescribing system through procurement process?
11. If "Yes" then in which year will it be in place?
12. If either Q8 or Q 10 is "Yes" then is it part of a comprehensive IM&T procurement (for the Trust)?
13. Hospitals (within Trust) that use pharmaceutical information system.

The results were analysed and presented to the expert panel (see Section 11.15).

4.2.2 *Availability of Research Data*

The survey results were used to inform the selection of the hospitals/units to be included in the data audit exercise. Those chosen were: Aintree (JAC); Bolton (MDIS); Blackpool (MDIS); Burnley (Ascribe); Clatterbridge Centre for Oncology (CCO) (JAC); Manchester Children's (Ascribe); Mid Cheshire (HORIS); Stockport (Ascribe); and Wirral (JAC). CCO and Manchester Children's were included as specialist cancer and children's hospitals.

A selection was made of the major aseptic products for which research data would be required, so as to assess the suitability and provision of data on the quantity by volume

produced. These were: minibag plus; minibag/infusion; prefilled syringes; PCA devices; and TPN; with scope for units to highlight other products of particular relevance locally.

The tasks to be completed by the audit were:

- Confirm system type and version
- File content and structure
- Documentation available
- Assess relevance of data stored to target variables
- Report generation and cycle times
- Actual data storage and retrieval
- Sample data quality and validation
- Extent of data history
- Major changes made to system & practice that may affect data history
- Confirmation of nomenclature
- Identify/ascertain any routine data quality processes

The pilot visit was undertaken by the researcher to the Royal Preston Hospital using a structured template to explore the capabilities of the local system (MDIS) with regard to the target data and products.

For the desktop work, computer manuals were obtained for the JAC (Aintree) and MDIS (Preston) systems and checked for functionality. Discussions and multiple system reports were obtained for the other two systems, Ascribe (Stockport) and HORIS (Mid Cheshire), to confirm their actual functionality. Discussions included the possible contributions of pharmaceutical information system data, such as clinical stock usage, to various models for measuring clinical aseptic activity.

Telephone discussions took place with the remaining sample trusts that had not submitted 'demonstrator' system reports, supplemented with a structured questionnaire. The questionnaire included three factors: target product presentations; target data requirements; and evidence of difficulties and additional work required to meet the data requirements (see Section 11.16).

The results generated were collated and presented to the expert panel for the purposes of preliminary validation. It was then important to validate the findings with personnel from across the North West, to confirm whether the identified data requirements were feasible to collect, and (if not) then check whether suitable amendments could be made to the

stated requirements so that appropriate, valid data is available and collectable for the purposes of the research.

4.2.3 *EPS*

In respect of EPS, one of three national pilot sites was local to the research (Wirral Hospitals NHS Trust), and therefore the opportunity was taken to undertake a (qualitative) structured interview with its chief pharmacist to establish (potential) relationships between such systems developments and research requirements (see Section 11.17).

4.2.4 *Outline Data Collection Proposals*

Following this visit the researcher developed preliminary ideas and outline proposals for how the main research data might be collected, taking on board the findings of the initial workshop and the lessons from the visit. These were first considered by the expert panel, and amended in the light of comments made.

4.2.5 *Validation Workshop*

The options available for validation were the same as the four identified for Section 4.1, and the analysis was the same, i.e. a workshop approach was adopted with syndicate groups to enable multi-professional input. Detailed discussion and debate was essential, something that could not really be achieved via the alternative options of questionnaire surveys and structured interviews.

Therefore the results from both Data Audit exercises (see also Section 4.7) and the Nomenclature work (see Section 4.8) were fed into a multidisciplinary workshop. This offered the opportunity for the preliminary conclusions and recommendations to be tested out with professional colleagues prior to their submission to the expert panel. The aims and objectives were to:-

- Receive the results of the Data Audit exercise
- Validate the results and develop ideas
- Further develop the Nomenclature issues
- Develop proposals for the way forward
- Ensure good practice in terms of research and development
- Develop a survey design and approach

Invitations to participate in the workshop were issued to people involved in the initial workshop, to ensure continuity. It also avoided the need to repeat what the research was about. Moves were made to increase the number of nurses, following some concern about limited numbers.

The structure involved presentations on the pharmacy information and clinical area elements of the Data Audit exercise, plus presentations on nomenclature issues and preliminary ideas/ proposals on how the main research data might be collected (to prompt discussion). There followed two multi-professional syndicate groups discussing each of the two elements of the Data Audit exercise in detail, together with the associated nomenclature issues. Comments from the syndicate groups were fed into a plenary session at the end of the workshop to debate and recommend the way forward.

An out-turn questionnaire (qualitative), was completed, with the same approach and methods as that for the initial workshop (see Section 11.21). Questions were appropriately adapted to reflect the differences in coverage. The questionnaire for the Data Audit workshop had 26 questions designed to ascertain views in a number of areas:

- Was adequate information provided ahead of the workshop? (1 question)
- The purpose of the workshop (8 questions)
- Syndicate Groups (3 questions)
- R&D Capacity (6 questions)
- Research progress (5 questions)
- Location, accommodation & facilities (3 questions)

The expert panel considered the outcome reports covering the different components of the workshop (see Sections 11.18 and 11.22), as a final validation of its outcomes and to make specific recommendations for the next stage.

4.3 Baseline Survey

As described in Section 4.2, the expert panel (qualitatively) developed preliminary ideas/proposals for how research data might be collected, which were debated at the Data Audit workshop. The resultant comments and advice were used by the expert panel to (qualitatively) agree definitive survey design principles and guidelines, from which the researcher prepared draft survey forms and guidelines.

The forms and guidelines were (qualitatively) validated by the expert panel and lead aseptic managers from each zone, to confirm whether: it was clear what was required; the

data could be obtained from local systems; and, any changes were necessary. Advice was (qualitatively) fed to the next expert panel meeting, where minor amendments were agreed, and the survey design and guidance confirmed (see Section 11.24).

Copies of the (paper) survey forms and guidance were distributed with a covering letter explaining the purpose, context and requirements of the survey. These were sent to all senior aseptic managers in the North West by the co-ordinators of the zonal aseptic managers groups; the expert group advised this as the most effective route. Six weeks were allowed for completion.

Similar letters and copies of the forms and guidance were sent to all Trust Chief Executives and chief pharmacists in the North West, to ensure that Trust management was aware of, and supported the exercise.

The original survey (Gandy et al, 1998a) confirmed that community, mental health and ambulance Trusts did not produce aseptic products and their usage was nil (or minimal). These Trusts were asked to confirm that this was still the case and that this situation was unlikely to change within the foreseeable future. If aseptic products were used or produced, a Trust would contact the researcher so that survey documentation could be sent.

Data was to be collected for the last fully completed financial year.

Completed returns were sent to the researcher for initial validation, which included:

1. Activity totals in each row and column were the same as the sums of the activity recorded in the relevant cells;
2. For each product category the total of the number of products produced for "Individual Patients" and "Use as Ward Stock" on Form one should be the same as the number recorded as the number for that product category on Form two which were sourced from "Within Trust";
3. Comparisons were made with the original survey (*ibid*) results for any major differences that might suggest an error;
4. Logical checks, wherever possible: cancer centres are expected to produce/use cytotoxics.

Where a query arose from validation, the researcher directly contacted the person who completed the form concerned to seek advice, with revised data being entered by

agreement. (The forms required the person who completed them to give their name and contact details for this purpose).

When a form was validated and the data accepted the details were input to the database. (Checks were made to ensure that there had been no data input errors).

Once all forms were returned, validated and entered on to the (Excel) database, a series of analyses were undertaken and incorporated into a draft results report to the expert panel. Allowing for the panel's suggested amendments, a copy of the analysis was then circulated to trusts for information (and comment).

4.4 Baseline Survey Evaluation

The timing of the survey forms and guidance distribution was such that all zonal aseptic managers groups met within the survey period. Therefore the researcher could attend any or all of these meetings and give advice/deal with queries, and there still to be time for the survey forms' completion. Alternatively the researcher met with the zonal co-ordinator for the same purpose. The choice was left to each zone.

Any comments on survey design and guidance submitted directly to the researcher, were discussed with the correspondent to ensure complete understanding of the point(s) made.

With no Trust Chief Executives on the expert panel (their commitments and responsibilities made this impossible) the researcher met with one of those from the regional working party (NHS Executive North West, 1997) who retained an interest, to further validate the research approach and methods. This involved a (qualitative) structured interview, with comments and advice fed to the expert panel (see Section 11.32).

During the early stages, some queries arose about where certain data should be recorded. For the small number where this was not clarified by reference to the guidelines, the researcher collated them and sought advice from the expert panel. As a result a small update on the guidance was issued (See Section 11.24.3).

The researcher maintained a log of queries/issues that arose during data validation, and those from zonal meetings. When the survey completed, the researcher presented analyses of the queries/issues to the expert panel, with suggested actions for each (see Section 11.26).

The validation was a qualitative process undertaken by the expert panel. It was presented with a comprehensive analysis that covered:

1. Copies of the survey forms and all guidance issued (inc. update)
2. Analysis of the relationship between product types quoted by the Regional Working Party (*ibid*), the baseline survey and the work-study exercise (see Figure 5.4.1).
3. Detailed analysis of the different types of queries/issues that arose in respect of the survey forms.
4. A summary of what were perceived as the key points:
 - The list of product categories needed reduction;
 - The future of Form three;
 - The inclusion/exclusion of terminally sterilised products.

Expert panel members could add issues not covered by the researcher. In this way all actual and potential issues were evaluated.

5. Potential future arrangements.

The researcher undertook the comparisons described in (2) above by simply lining them up alongside one another and then mapping the relationships

The analytical report on the baseline survey (see Section 11.25) itself acted as further qualitative evaluation of the survey design and guidance: did the analyses and comparative figures make sense, given the subjective experience of professionals "on the ground"? Perceived constraints and limitations with analyses could suggest improvements for the next stage of research, such as additional data.

4.5 Quarterly Surveys

The software disk and associated instructions were developed using Excel spreadsheet methods, with links established to readily populate the main database; file names were automatically generated to ensure each file was unique to a unit and period, minimising the possibility of data getting mixed up (see Section 11.39).

Following the successful piloting, the software disks were distributed to all chief pharmacists at North West Trusts along with instructions and the guidelines (see Section 11.39). Anonymity was maintained through continued use of the baseline confidentiality codes. Only participants in the baseline survey were included, as no other Trusts were relevant (see Section 4.3). Trust Chief Executives were copied into appropriate correspondence to keep them briefed.

Use of the software was not compulsory. If Trusts wanted to submit data by means other than email, then they could print off the forms from the software, complete them manually, and submit them for entry to the database. Data validation used the same methods as the baseline survey data (see Section 4.3).

A full response could not be engineered from Trusts. Therefore, a "baseline quarterly equivalent" was calculated for trusts/units fully participating in the quarterly surveys by aggregating their baseline data and then dividing by four; including baseline data for non-respondents would skew analyses. Production and usage data for the three cytotoxics categories in the baseline data were added together.

Once all received returns had been validated and analysed, a draft results report was presented to the expert panel. Emphasis was placed on trends over the five quarters. A copy of the report, incorporating the panel's suggested amendments, was circulated to trusts for information (and comment).

4.6 Quarterly Surveys Evaluation

The quarterly survey methods reflected the principles of the baseline survey, with design changes arising from its evaluation (see Section 4.4). Therefore few, if any, problems with design and guidance were anticipated. Nevertheless it was made clear that the researcher was readily accessible, keeping a log should issues arise. The survey was a standing agenda item for the various regular pharmacists' meetings.

The opportunity was taken to update the pharmaceutical community about progress with the quarterly surveys when presentations were made to selected meetings, primarily about other components of the research. Feedback was always welcomed.

By the end of the five quarterly surveys the focus of evaluation was more on how the quarterly surveys' data, in concert with relevant baseline survey data, could be used to support the calculation of the various statistical indicators. At that stage the efficacy of the quarterly survey design was something of a given.

As for the baseline survey, the validation was a qualitative process undertaken by the expert panel, on similar lines to the process outlined in Section 4.4.

The expert panel endorsed a report summarising the key analyses, with commentary, for circulation to Trusts for information and comment (see Section 11.40).

4.7 Data Available in Clinical Areas

The expert panel agreed to a programme of hospital visits for structured interviews to investigate the question of available research data in clinical areas (plus nomenclature issues – see Section 4.8).

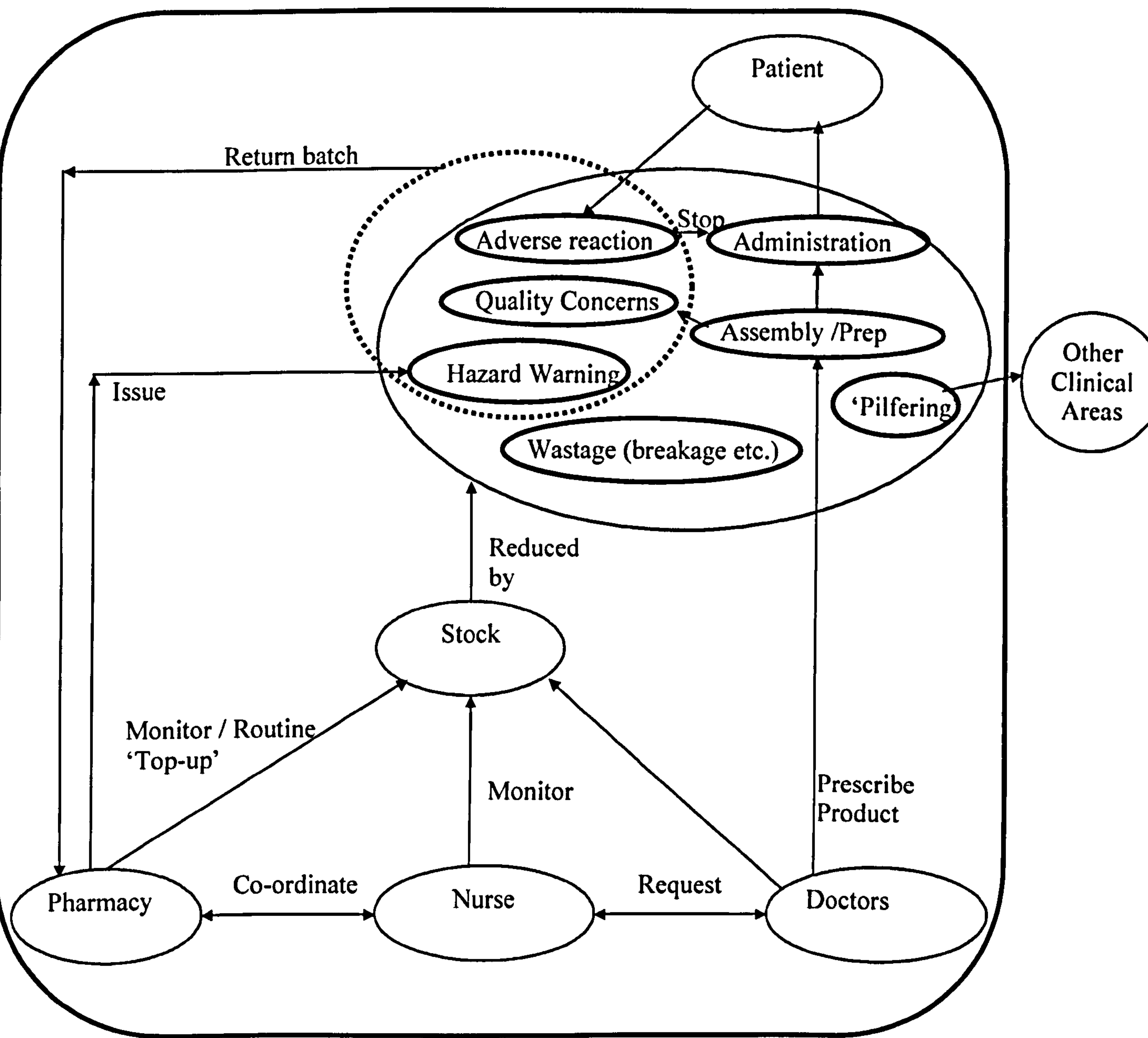
Visits entailed investigating ward stocks, prescribing and associated processes, existing documentation and recording methods. To make best use of time on the day, an agenda, including the questions and issues to be covered, was sent for prior consideration by local staff (see Section 11.19). The main questions/ issues covered were:

1. Stock processes.
2. Review of documentation in association with:
 - Methods of prescribing
 - Recording of administration
3. Ascertain which clinicians are involved within the process of assembly, preparation and administration.
4. Alternative data collection methods.
5. Approaches to the timing of data collection.

In order to gauge the amount of recording that might be involved with data collection, the audited clinical areas were invited to randomly select an individual patient and establish the number of aseptic preparations administered over a 24-hour period.

To assist in the fact finding within the clinical area, a conceptual model (Figure 4.1) was developed.

Figure 4.1: Conceptual Model of Stock Process Within Clinical Area



Key: Process / Activity



Direction of Information Flow →

Ref: Co-researchers Karen Kershaw & Gwen Dawick (2001)

The questions and approach were piloted with two hospitals, prior to the arrangement of the programme of visits, with little or no amendments identified as being required.

The researcher drafted a programme of visits to nine hospitals, covering different types of hospitals and clinical areas, and covering the North West. Table 4.1 provides details. The expert panel agreed this as a sufficiently representative coverage.

Table 4.1 Trusts and Clinical Areas covered in Data Audit of Clinical Areas

| ID Number | Trust | Clinical Area Visited |
|------------------|---|-------------------------------------|
| 8b | Aintree Hospitals NHS Trust | Theatre |
| 2b | Bolton Hospitals NHS Trust | Theatre |
| 7a | Stockport Acute Services NHS Trust | Theatre |
| 4a | Wirral Hospitals NHS Trust | Surgical - Colon rectal and general |
| 8a | Aintree Hospitals NHS Trust | Surgical |
| 5a | Mid Cheshire Hospitals NHS Trust | Surgical |
| 1b | Burnley Health Care NHS Trust | Paediatric Surgical |
| 1a | Burnley Health Care NHS Trust | Paediatric Medicine |
| 6a | Manchester Children's Hospitals NHS Trust | Paediatric Medicine |
| 6b | Manchester Children's Hospitals NHS Trust | Paediatric ITU |
| 3a | Blackpool Victoria Hospital NHS Trust | ITU |
| 5b | Mid Cheshire Hospitals NHS Trust | ITU |
| 9a | Clatterbridge Centre for Oncology NHS Trust | Oncology - Radiotherapy |
| 9b | Clatterbridge Centre for Oncology NHS Trust | Oncology - Chemotherapy |
| 3b | Blackpool Victoria Hospital NHS Trust | Medicine and Haematology |
| 4b | Wirral Hospitals NHS Trust | Medicine - Stroke and haematology |
| 2a | Bolton Hospitals NHS Trust | Medicine - General |
| 7b | Stockport Acute Services NHS Trust | Medicine - Care of the Elderly |

Practicalities meant one site could be visited in one day, but it was possible to have two sets of structured interviews (morning and afternoon) allowing for travel, face-to-face discussions, visits to facilities, and note taking. Therefore, two different types of clinical areas were selected for each hospital, with a balance being struck between geography and clinical areas. The number of hospitals was considered sufficient.

The visits were all involved the lead nurse of the expert panel and a colleague with a nursing background. They transcribed interviews, subsequently confirming their content with the staff interviewed, so as to ensure accuracy.

Data and notes from visits were collated and analysed, with conclusions/recommendations fed into the Data Audit workshop along with those from the desktop exercise (see Section 4.2.5 for details of the whole workshop, which are not repeated here). Conclusions and recommendations were validated with professional colleagues prior to submission to the expert panel.

The expert panel considered the outcome reports covering the different components of the workshop, as a final validation of its outcomes, and made specific recommendations for the next stage.

The workshop identified an outstanding research question: How best to collect data on aseptic preparation in clinical areas? Whilst relevant, it was not central to the research. The expert panel deemed it sufficient to develop specification proposals for supplementary projects to this end (see Section 11.23). If funded, they could be pursued separately.

4.8 Nomenclature

The initial workshop established that nurses and pharmacists use nomenclature in different ways (see Section 3.8) and that the issue needed addressing to underpin the research.

Structured interviews were arranged with nurses in clinical areas for data audit (see Section 4.7), and researching nomenclature required a similar approach. The expert panel pragmatically decided to incorporate nomenclature questions into the same visits and interviews (see Table 4.1 for programme of visits). The purpose was to explore local views and practices for comparison.

The expert panel determined eight terms requiring explicit definition for the purposes of the research:

| | |
|-----------------------|-------------|
| Administration | Ingredients |
| Administration begins | Parenteral |
| Administration ends | Preparation |
| Assembly | Product |

The expert panel's lead nurse and lead clinician produced (draft) definitions of each term, which were validated first by the expert panel and secondly at the two pilot data audit site visits (see Section 4.7). Interviewed nurses were to be asked their views on their efficacy, with the opportunity to propose amendments/improvements.

The expert panel also produced a list of words that might be used as alternatives to nine commonly used words/terms:

| | |
|-------------------------|-------------|
| Acquisition and Custody | Ingredients |
| Administration | Preparation |
| Container | Product |
| Dosage | Route |
| Equipment | |

Hospital nurses were to add to the list based on local and personal experience; the aim being to establish as full a range as possible of alternative terms for each.

To give nurses the opportunity fully respond in interviews and make best use of time, an agenda was sent in advance, with the above lists of words and (draft) definitions (see Section 11.19).

The interviews' details were collated and validated at the Data Audit workshop, where syndicate groups critically examined the use of key terms (see Section 4.2.5).

Recommendations were made to the expert panel taking into account comments and views from the workshop, and literature searches, so that a final list of terms and definitions could be agreed for consistent use for the purposes of the research.

The interview programme focused on nurses in clinical areas, with no guaranteed input from local pharmacists. Pharmacists were not precluded from participating in interviews; the expert panel did not require their attendance primarily because of time constraints. The expert panel overcame this limitation by ensuring strong pharmaceutical input in the preparation of the lists planned for site visits, and in the final evaluation (the largest group on the expert panel were senior pharmacists). The involvement of a full range of pharmacists at the workshop also ensured that the inter-professional balance was appropriate. The workshop importantly set the nomenclature results alongside those for the data available in clinical areas, given their inter-relationship.

It was clear that the research could not address universal issues associated with nomenclature. All that could be done was ensure consistency within the research itself, and highlight issues for wider discussion and debate.

4.9 Collaboration

The availability of methods of measuring “collaboration” was tested through a literature search, with the (negative) results qualitatively evaluated by the expert panel for their applicability to aseptic dispensing (see Section 2.5).

Next, an iterative approach was applied to establish whether methods not directly related to “collaboration” could be translated for the purposes of the research. This involved identifying a potential method and testing it; only moving on to further methods if the results were negative. There were two stages to testing:

1. A qualitative appraisal of whether the method appeared to have potential, i.e. it could be applied conceptually to aseptic dispensing, and the data required was fully covered by the research data or the collection of any additional data was feasible;
2. If the first stage was successful, research data was applied to the model to produce results, which were qualitatively evaluated by the expert panel as to whether they were both statistically and conceptually robust. If so endorsed, they were disseminated to the pharmaceutical community for consideration, and implicit validation, with responses invited.

Adaptations to a method could be made in response to the evaluation, with the process repeated, until a method was confirmed as valid.

The method subsequently used baseline and quarterly surveys data to test if it suitably reflected trends over time, applying the established evaluation processes.

The later stages of the research enabled further exploration of the method’s potential for:

- Comparing patterns of collaboration in different areas;
- Comparing trends in collaboration between different areas;
- Comparing how collaboration in respect of individual products had changed over time.

The researcher undertook this on an iterative basis, applying the above principles and processes.

4.10 Work Study

The researcher drafted a specification for a work-study professional to be commissioned. This was considered by the expert panel, amended in line with discussion and then approved (see Section 11.27).

A professional with considerable experience of hospital work was recruited following established processes. The professional attended the pilot visit to a major Trust to validate the efficacy and practicalities of the specification. This allowed opportunity for questions to local pharmacists and aseptic staff, and confirmation of how particular tasks might be best approached.

The expert panel prepared a representative list of aseptic units for the professional to visit, balancing a variety of factors, including geography, equipment, individual and batch preparation, types of units and products, and units that do and do not have licences. Units chosen were:

- Burnley Health Care
- Central Manchester Healthcare
- Clatterbridge Centre for Oncology
- Manchester Children's Hospitals (Pendlebury)
- Morecambe Bay Hospitals (Lancaster)
- Stockport Acute Services (Stepping Hill)
- Wirral Hospitals (Arrowe Park)

Chief Executives and chief pharmacists of the selected Trusts were asked to agree to the work-study professional visiting their aseptic unit to undertake interviews and observations. This was essential to reassure local staff that the exercise was for research purposes and that the results would not be used to amend local practices. Otherwise their willingness to accept the visits and fully contribute would be put in jeopardy. The letters enclosed a questionnaire asking for basic details about the local unit, so that the professional would have some appreciation of the unit and its work in advance (see Section 11.27.8). These included:

- The availability of different types of cabinet (horizontal and vertical laminar flow cabinets, and isolators);

- Confirmation of which aseptic products were prepared locally, together with (approximate) annual figures;
- Details of the ranges of batch sizes, where batch production took place;
- An indication was requested of details of any automated filling equipment.

The work-study professional began the programme of visits, but experienced difficulties that placed the overall exercise in jeopardy. Ways of addressing them were discussed with the researcher, but in the event they could not be overcome, and the termination of the commission was recommended. A report was written describing the work undertaken, the problems experienced and the efforts to address them, and any lessons/recommendations on the basis of the observations made. This report (see Section 11.28) was presented to the expert panel, which accepted the findings and recommendations.

Prior to writing the report the work-study professional attended the Capacity and Workload workshop (see Section 4.12) and described the lessons learned to date.

4.11 Unit Time Equivalents

Having agreed that a group of (expert) pharmacists make preliminary estimates of UTEs for each type of product, the expert panel decided that this group should consist of the three lead chief pharmacists and the two Quality Controllers from within its membership. This ensured that practices from all three zones would be taken into account. The expert panel also determined that for the purposes of the research the UTE would cover the period of time from the receipt of instructions to the final check/booking off of the product.

The work-study professional had recommended that it was reasonable to make estimates of UTEs by applying a standard unit value of one and a half minutes to the values from previous work done in Lancashire to relatively weight product types (primarily for cost purposes) (North West Aseptic Task Group, 1998). The expert panel endorsed this as a sensible starting point for the expert group of pharmacists.

The researcher identified too many inconsistencies between the list of product types used in Lancashire and that developed for the research. Comparisons of the two lists were made, with consistent (“best estimate”) values (qualitatively) estimated for the research product types by a chief pharmacist from the expert panel, with the degree of confidence clearly recorded (see Section 11.29). The researcher circulated these to other members of the expert group for consideration, together with chief pharmacists external to the North

West, in order to act as a form of validation. Responses were received from East Anglia and Yorkshire.

In the event the preliminary UTE values were endorsed by the expert group of pharmacists, and then by the expert panel.

In order to validate the preliminary UTE values with North West pharmacists, a (qualitative) questionnaire was prepared setting out the values for each product type and asked the person completing it to record (see Section 11.30):

- (a) A tick to confirm agreement that the proposed average time is reasonable;
- (b) Suggest an alternative average time if that proposed is not considered reasonable;
- (c) The shortest possible average time; and
- (d) The longest possible average time.

The researcher drafted the questionnaire, which was validated by the pharmacists on the expert panel. (c) & (d) were to provide data on the range of average production times. The expert panel did not consider it appropriate to identify the potential longest and shortest production times per se, because UTEs themselves are viewed as statistical means, which can be applied to large volumes of activity, rather than single values.

The researcher and Chair of the expert panel were to give a progress report to an Aseptic Managers Study Day planned for the near future. Given time constraints the expert panel took the opportunity to distribute the questionnaire to all aseptic managers, via the event organisers. The managers could complete it anonymously, or record their name and position. They were invited to hand in completed questionnaires to reception at the event, where the researcher quickly collated responses, so that feedback could be included within the progress report for triangulation purposes, with any wide variations being debated.

Returned questionnaires were quickly analysed, to show the numbers that (dis)agreed with the proposed UTE values, and the variations quoted as alternative mean values. These were presented on an overhead projector, and debated.

An important point raised was that the mean time of many product types would vary between licensed and unlicensed units, because the former include more batch work and the latter more individual work, which necessarily took longer. Therefore, it was agreed

that each product type needed two UTE values: one for licensed units and one for unlicensed units.

Following the Study Day, thorough analysis of all completed questionnaires was undertaken, including late submissions. The expert group of pharmacists agreed there was sufficient consistency to determine final UTE values.

To determine final values for the UTEs a meeting was held of the Chair, researcher and the three chief pharmacists on the expert panel. Ahead of the meeting the pharmacists were asked to independently determine their own views of the UTE values covering both licensed and unlicensed situations, together with the likely degree of variation. The researcher prepared a questionnaire to this end (see Section 11.31). In doing this they took into account the findings of the survey of aseptic managers, together with other responses received. Their respective views for each product type were compared and a consensus formed of the final UTE values.

To determine the likely variation, minima and maxima values for the UTEs were set using regression analysis relating the mean times to minima and maxima indicated by the aseptic managers in the survey. Regression formulae were established (including if the line went through the origin).

Differences between the values produced by the formulae, when the line did and did not pass through the origin were marginal for the higher values. For the lower values the differences could be inferred as due to where units were or were not licensed. Therefore the minima and maxima were set utilising whichever formula best reflected such circumstances. The values were rounded to the nearest whole number except for the lowest values.

The expert panel (qualitatively) considered these UTEs (and their ranges) and endorsed them for use in the research, i.e. they were to be applied to the baseline and quarterly surveys data. They would be further validated when presented alongside the results by the North West pharmacists. The expert panel considered this preferable to circulating them again for comment, in isolation of such results.

Note: The draft UTEs produced by the expert group were applied to the survey data before validation, in order to develop an understanding of how they could be used, and spreadsheet links effected; they were to be superseded with the finally agreed UTE values.

4.12 Concepts: Capacity and Workload

The aims and objectives of the half-day Capacity and Workload workshop were to:-

- Answer the question of what constitutes an optimal workload, or capacity, for an aseptic preparation unit;
- Develop the concept and definition of "Capacity" for aseptic preparation;
- Develop practical target workloads to allow for different circumstances;
- Receive an update from the work-study exercise - key issues & pointers;
- Consider how best to utilise survey data & what additional data might be required.

Invitations to participate were accepted by fourteen people (in addition to the researcher, who was the main facilitator, and the work-study professional). These were not the same as those who had been involved in earlier workshops.

Thirteen of the 14 were pharmacists, or worked in pharmaceutical departments. Four pharmacists were from the expert panel, and five were from a single Trust that had undertaken substantial work in the subject area. Pharmacists were invited who had specific expertise in respect of the situations for radiopharmacy, oncology, children and the commercial sector. No nurses attended (the Nurse from the expert panel was unable to attend).

The thrust of the workshop was qualitative. Therefore, it was carefully structured to include appropriate, proven qualitative techniques, augmented by selected information. Its structure was:

1. Introduction and Aims & Objectives of workshop
2. Presentation of simple analyses from original survey (Gandy et al, 1998a) illustrating variations in intensity of use of North West aseptic dispensing units
3. Presentation on lessons and findings from work-study exercise
4. Presentation on lessons from known initiatives to improve throughput and efficiency in aseptic dispensing units
5. Affinity analysis (Brassard, 1996) to explore what influences performance
6. Syndicate groups to develop proposals around definitions and potential solutions
7. Feedback from syndicate groups (suitably triangulated)
8. Main conclusions and recommendations

(1) & (2) were delivered by the researcher, with the work-study professional presenting (3). The chief pharmacist from the Royal Preston Hospital (a member of the expert panel) presented (4).

The Affinity analysis (Brassard, 1996) used the question: “What issues and practicalities influence the performance of work in a pharmaceutical aseptic dispensing unit?” (see Section 11.33).

The workshop itself then determined that there should be two syndicate groups to develop proposals as to definitions for “capacity” and “target workload”, with one group of six people and one of seven – it was agreed that having a third syndicate group (i.e. two groups of four and one of five) would be less effective.

The groups worked completely independently of one another. Their results were then fed back to the whole workshop, collated and final recommendations developed (see Section 11.34).

An out-turn questionnaire (qualitative) was completed, with the same approach and methods as that for the two previous workshops (see Sections 11.11 and 11.21). Questions were appropriately adapted to reflect the differences in coverage, with 21 questions designed to ascertain views in a number of areas (see Section 11.35):

- Was adequate information provided ahead of the workshop? (1 question)
- The purpose of the workshop (8 questions)
- Syndicate Groups (3 questions)
- R&D Capacity (3 questions)
- Research progress (3 questions)
- Location, accommodation & facilities (3 questions)

The expert panel considered the outcome reports covering the different components of the workshop, and the out-turn survey (see Section 11.36), as a final validation of its outcomes. The respective merits of the approaches were (qualitatively) evaluated and specific recommendations made for the next stage (see Section 11.37).

The opportunity was taken to validate the findings with Quality Control pharmacists from across the whole country, at an Audit Training Course in Birmingham. The researcher and Chair from the expert panel presented progress and key findings. They recorded the comments and views, with accuracy checked by the pharmacist who chaired the session (see Section 11.38).

4.13 Statistical Indicators

The expert panel qualitatively evaluated the findings from the work-study exercise, the capacity/workload workshop, the Regional Quality Control Pharmacists, and available literature. Reference was made to the types of statistical indicators used in the commercial sector (see Section 4.1).

Additional data requirements were confirmed: the numbers and types of cabinets in each aseptic dispensing unit. Such data was obtained from the Regional Quality Controllers, who kept records on them, and validated by circulating it to Trusts for confirmation or correction. The numbers of cabinets were “at a point in time” – rather than the average availability over a given period. Advice from the expert panel chief pharmacists was that the latter is too difficult to collect accurately.

A series of prototype statistical indicators was identified, utilising the available data. In each case, the researcher sought initial preliminary views from the expert panel Chair for validation purposes.

Licensed aseptic dispensing units had licensed UTEs applied to all of their activity, even though some products would inevitably be prepared on an unlicensed basis. The expert panel advised this, inferring that known constraints of existing information systems (See Section 4.2) would mean such a split of data was not feasible to collect on a comprehensive basis.

Results were qualitatively validated by the expert panel as to how conceptually meaningful and useful they were to pharmacists and managers. Outlier figures were evaluated to determine how this had come about and whether this meant that an indicator was insufficiently robust. Sensitivity analyses were undertaken for relevant indicators to test their robustness, with results validated by the expert panel. (This involved a cyclical iterative process: analyse – present results – feedback – (re)analyse).

When the expert panel considered statistical indicators as both valid and robust, the analyses and results from applying the indicators to the baseline and quarterly data were disseminated to North West pharmacists and aseptic managers to both inform them of relative performance and to validate the indicators.

4.14 Modelling

4.14.1 *Capacity Planning Software*

To evaluate the applicability of capacity planning software to NHS aseptic dispensing units, the following methods were applied:

- A representative example of the software was chosen for scrutiny. This was MRP2 software (McGuffie-Brunton, 1998).
- A chief pharmacist on the expert panel, whose unit was the largest in the North West (and one of the largest in the country) in terms of annual numbers of products, had tried to introduce this software locally to improve efficiency.
- The pharmacist collected files and notes from the exercise, and was interviewed by the researcher, who drafted a summary of the key points (see Section 11.42), which were subsequently endorsed by the pharmacist.
- The expert panel evaluated the agreed summary and developed a consensus.

4.14.2 *Capacity Modelling*

To evaluate the applicability of capacity modelling to NHS aseptic dispensing units, the following methods were applied:

- The researcher identified leading experts in the fields of capacity modelling and aseptic dispensing production: the Professor of Managerial Cybernetics at Liverpool John Moores University) and the Principal Pharmacist, Production and Aseptic Services Manager for Stockport Pharmaceuticals, Stepping Hill Hospital, Stockport, who was a past Chair of the NHS Pharmaceutical Production Committee.
- The researcher facilitated a meeting between the two experts and himself, where the practicality and feasibility of applying capacity modelling techniques to aseptic dispensing production were fully explored.
- The researcher recorded details of the meeting and shared them with the experts for validation and accuracy (see Section 11.43).
- Given the findings, the researcher undertook a literature search and critically reviewed relevant publications in relation to the research question.
- The researcher collated the experts' views and critical review to develop conclusions that the experts validated for dissemination (Gandy et al, 2006).

4.15 Acute Capacity Planning

4.15.1 *National Chemotherapy Simulation Model*

A literature review was undertaken, and in relation to the national chemotherapy capacity model, the researcher directly contacted the national manager responsible for the consultation process. The proposals were critically reviewed and comments submitted (see Section 11.45).

Details of the subsequently developed simulation tool (C-Port) (see Section 3.15) were kindly provided by the national manager. (N.B. Access to the references can only be obtained via a password-protected website). These were critically reviewed from the research's perspective. A semi-structured telephone interview was undertaken with the national manager to: clarify points and issues in respect of relevant detail and how C-Port might be utilised; confirm C-Port's roll-out; and confirm the likely local effort required (see Section 11.46). The interview notes were confirmed as accurate.

A structured interview was undertaken of the lead manager responsible for implementing C-Port for Clatterbridge Centre for Oncology and the Merseyside & Cheshire Cancer Network. This involved: an overview of C-Port and the associated training process; requirements to begin using the tool; and observations about how it would be utilised locally (see Section 11.47). Questions included:

- What is C-Port and how does it work?
- What are its purposes?
- What are its main features, components and structures?
- What are its outputs?
- What is required of the user, particularly for inputs?
- How is it being rolled-out?
- How is it managed and operated?
- What are the strengths and weaknesses?

4.15.2 *Local Acute Capacity Planning Models*

The researcher contacted lead pharmacists to enquire where particular progress had been made in the development of local acute capacity planning models. The advice gave two hospitals: North Manchester General Hospital and Leeds Teaching Hospitals. These appeared very different from one another, with the former using primarily manual methods and the latter developing computer-based spreadsheets.

The researcher contacted the respective lead pharmacy personnel responsible for the local approaches, and undertook semi-structured telephone interviews (see Sections 11.48 and 11.49). Both leads readily provided details and advice. Neither were aware of any general approach, or software, that could be taken and used for local acute capacity planning: this was a reason why they had developed local solutions. Interview notes were confirmed as accurate.

4.15.3 Analysis

A preliminary critical review was undertaken to establish the key similarities and differences between the local models (and C-Port), and determine lessons for the research.

A more detailed critical review is being undertaken, with the co-operation and collaboration of the lead personnel, to include:

- Comparisons of the steps of the overall aseptic process covered by both local models and published work;
- Comparisons and validation of any formulae applied;
- Comparisons of the overall approach and the data required;
- Comparisons of how the models are used locally.

(Gandy, 2007 in progress)

4.16 Transferability

The fact that a consultancy commission was involved acted as a constraint on methods. Only one survey was commissioned, which was for the most recently completed full financial year (2000/01). (A series of quarterly surveys would have involved more data, more analyses and therefore more consultancy time and costs).

The finally agreed survey forms and guidance were used (see Section 5.6)⁶, tailored for the West Midlands. Again, disks were provided for recording the data so that they could be emailed and efficiently entered in to the survey database, where data validation and checks were undertaken. Any queries were taken up directly with the hospitals concerned. The disks were circulated to pharmacists and aseptic managers with covering letters.

⁶ Chief pharmacists in the West Midlands asked for additional data to be collected on the times that their aseptic dispensing units were open on average each day. This data was collected separately from the Trusts and used in certain analyses. The collection of this data was not required in the North West because of the concerns about its robustness for use in analyses (see Section 5.12).

The researcher linked with the West Midlands Regional Quality Controller as the local focal point for dealing with queries and issues concerning the commission. The Quality Controller and his staff gave support and advice to local pharmacists.

All Trusts in the West Midlands were invited to send representatives to an initial workshop that served to launch the survey. The purpose of the workshop was to maximise data quality by ensuring all participants understood the nature of the survey and associated guidance. This involved appraising everyone of the North West research and its findings, before confirming the survey requirements, particularly in respect of guidance. All questions were answered/clarified.

As for the North West, Trusts determined the basic local unit for data collection, allowing for geography and organisation structures. Each Trust/unit was allocated a confidential code, so as to maintain anonymity in the presentation of results.

Data for the survey was submitted and validated. The Quality Controller provided the data in respect of the numbers of cabinets in each aseptic dispensing unit. The research analyses for activity, statistical indicators and UTEs (see Section 4.11) were applied to the submitted data to give local results for the West Midlands.

To make comparisons between the two Regions' results, it was decided to use the North West baseline data because although the quarterly surveys' data was more up-to-date, they were incomplete for the Region.

A search of national data published on the DoH's website identified the data available for all Trusts in both regions, that might be used as proxies for all Trusts' activity (of relevance to aseptic dispensing usage) as FCEs and admissions. (The advice of the respective Regional Quality Controllers was sought on these and other possible currencies before deciding to use these two). In addition population figures for each region were available. Consequently, the aseptic production figures for each region were translated into rates for each of: population; FCEs; and admissions; and comparisons made.

As aseptic preparation activity in clinical areas was not collected as part of the commission, it was necessary to estimate whether the balance of aseptic preparation in clinical areas (compared to pharmacies) varied between the regions. This involved taking the results of work undertaken in the North West, in preparation for the C&CP, which gave locally accepted estimates of c. 3.8 million products aseptically prepared in clinical areas (Gandy et al, 2003). Combining this with pharmaceutical production meant 4.8 million

products were used in clinical areas annually. Dividing this number by the total of acute admissions in the North West gives a rate of usage of aseptic products per admission. Making the key assumption that this rate of usage should be similar for the West Midlands (or any other region), then enabled an estimate to be calculated of the total usage of aseptic products in the West Midlands. The percentage of such products supplied by pharmacies was then readily calculated, and comparisons made between the two regions.

The consultancy report, including commentary and analyses, was first shared with the two Regional Quality Controllers to validate, to ensure no errors or inappropriate inferences were made, prior to the report being formally disseminated. In the event, only minor amendments were required.

The report (see Section 11.50) was circulated to relevant personnel, with presentations made to chief pharmacists and to aseptic managers. The report was warmly welcomed and accepted as a basis for building future plans.

The variations between the two regions' practices were suitably disseminated (*ibid*; Gandy, 2005).

4.17 Evaluation of Programme

Given the advice to the researcher to try and use the single survey form developed for ad hoc purposes to collect post programme data, it was essential to validate this form against the forms established by the research.

To this end the researcher liaised with the Chair of the Greater Manchester Aseptic Managers Group, who also acted as the lead Chair across the three zonal groups. The Chair provided copies of the single form that had been completed by four local Trusts for 2002/03 (see Section 11.51). The researcher compared the single survey form with the two forms from the previous research, to:

- Identify differences in the data collected;
- Confirm whether the analyses and statistical indicators identified by the research could still be produced; and
- Advise on whether the differences would compromise the value and validity of any comparisons between the baseline data and the post-programme data, if the latter were collected using the single survey form.

The data categories to be recorded were:

1. Prepared within pharmacy for use within own Trust (Production);
2. Outsourced from other Trusts (Usage);
3. Acquired from commercial sources (unlicensed products) (Usage);
4. Prepared within pharmacy for other NHS Trusts and other users (Production)
5. Prepared at ward level (best estimate)

(It should be noted that data relating to (5) was not considered by the researcher to be part of the research, given the experience of the original survey (Gandy et al, 1998a); however, chief pharmacists had included it within their single survey form design, and had asked for its retention, on the basis that if sound data was provided then this would be useful).

The conclusion was that with a number of small amendments, the 2002/03 single survey form could provide sufficient valid data to enable consistent comparisons with the baseline data and the associated main analyses and statistical indicators. The form included all of the product types that had been previously collected (see Section 11.39) except Cardioplegia Solutions. This was because the numbers were so low (709 across the North West in the baseline). Any such activity would need to be included under "Other", which would ensure that all products were still being covered.

Accordingly the suitably revised single survey form was agreed with the Chair of the Greater Manchester Aseptic Managers Group and the Regional Quality Controller, and distributed by the former to all chief pharmacists/aseptic managers across the North West. Completed forms were to be submitted directly to the researcher.

The researcher undertook data validation on the returns, and raised any queries with the persons who completed them directly. Data validation included ensuring: the survey forms were fully completed; any additions of figures had been correctly undertaken; and, there was sufficient consistency with the baseline data (and the planned expansion of production in the case of the units that received capital funds) to suggest that inadvertent errors had not been recorded.

Several organisational changes had taken place since the baseline. In respect of Trusts, all of these involved mergers, and therefore baseline data for the constituent Trusts/hospitals was aggregated to ensure valid matches for the 2003/04 organisations. In terms of regional boundaries, whilst all of Cheshire & Merseyside SHA and Greater

Manchester SHA had been within the pre-existing North West Region, and therefore covered by the C&CP, Cumbria & Lancashire SHA covered Trusts from both Lancashire (North West Region) and Cumbria (Northern & Yorkshire Region). The decision was taken to only collect data from the Lancashire Trusts to be consistent with the baseline cohort of organisations, and because Cumbria had not been a part of the C&CP.

Planned increases in production for aseptic dispensing units receiving capital funds were obtained by reference to the agreed business cases (Beaumont, 1999).

The researcher questioned if the continued validity of the UTEs with the Regional Quality Controller, who raised it with colleagues on the (new) expert panel. They confirmed their validity. In addition up-to-date details of the licensing status and cabinet numbers were provided for aseptic dispensing units across the North West.

Research analyses and statistical indicators were produced using the 2003/04 data, with aggregated baseline data used for organisations that had undergone mergers, so that comparisons were valid. As with previous research results, confidential codes were used to ensure appropriate anonymity. The same codes were used as previously, but with codes of the main site/Trust used where mergers occurred.

Comparisons were made between the data, analyses and statistical indicators for the two years, to determine actual and relative values of any changes. Three categories of aseptic dispensing units were used for aggregating Trusts/units in respect of licensing status. They usefully delineated where changes occurred in licensing status, and also enabled clarity around which UTEs to apply to the different years' data. These were:

- Units that were Licensed for both the baseline and 2003/04 surveys;
- Units that were Unlicensed for the baseline survey and Licensed for 2003/04 survey;
- Units that were Unlicensed for both the baseline and 2003/04 surveys;

Having two separate years' data also enabled an iterative approach to exploring the potential/validity of further analyses and indicators. Some had previously appeared to not have potential when considered for a single year, but taking two years' data showed there was comparative value. For example, the application of the collaboration diagram for product types (see Section 5.9). Also, fresh angles were suggested for some analyses: national developments in respect of chemotherapy activity (NHS Modernisation Agency, 2005) suggested there would be merit in exploring the impact of separating out chemotherapy activity and dedicated chemotherapy cabinets from other activity and

cabinets to establish the impact on the overall analyses/indicator values. Their validity was evaluated by reference to the expert panel and the pharmacist community, as with the earlier stages of the research.

The same methods applied to compare the North West and West Midlands in respect of the percentage of aseptic preparation performed in pharmacies and clinical areas (see Section 4.16), was used to estimate changes that had taken place over the period of the C&CP. This time, the number of beddays was added to the numbers of admissions and FCEs. Advice from the expert panel was that the use of aseptic products probably varied more in line with beddays than with either admissions or FCEs.

Comparisons were made between the actual and planned increases in production for the aseptic dispensing units included in the C&CP. Where targets had not been met direct contact was made with the chief pharmacist or aseptic manager to establish why variations had occurred. The reasons were recorded, and validated by the person quoted.

Projections were made of the potential impact for the overall balance of preparation between pharmacies and clinical areas if all of the unused spare capacity in the aseptic units that were part of the C&CP were to be utilised and replace aseptic preparation in clinical areas on a one-to-one basis. This was to set out how much further the balance could be further enhanced within existing capacity.

A draft of the report presenting the findings was validated by first inviting the Regional Quality Controller to make comments and give advice. The finally agreed version (see Section 11.52) was given relevant circulation across the North West.

The researcher also produced a specific report focusing in detail on the performance of the aseptic dispensing units included in the C&CP. This was kept separate and given restricted distribution, due to the sensitivity of the findings (see Section 11.53).

A formal presentation was made to a workshop of North West pharmacists, with further validation through dissemination (Gandy and Beaumont, 2006).

4.18 New Information Systems

A check was required to establish if new, better pharmacy information systems were available for aseptic dispensing units, or existing systems had improved.

Contact was made with five chief pharmacists at sites where each system (see Section 5.2) was in place, and (semi-structured) telephone interviews undertaken. Any changes in one system would apply across all its users. This meant that a full survey was not required.

In respect of EPS, email contact was made with the Clinical Lead for ePrescribing at CFH in June 2006. A semi-structured telephone interview was undertaken aimed at whether new EPS would address research data requirements, and relevant timescales. It was noted that consultation was to begin on a draft functional specification for EPS in Summer 2006 (CFH, 2006a) and that definitive comments could not be given until the process concluded. The researcher scrutinised the draft specification for relevant references to research data (*ibid*).

The final functional specification for EPS was published in February 2007 and the Clinical Lead again contacted (CFH, 2007a). It was confirmed that consultation had not materially impacted on advice given in the interview. The researcher scrutinised the final specification for relevant references to research data (*ibid*).

A structured interview was arranged with the Lead Pharmacist IT responsible for the EPS at Wirral Hospitals NHS Trust to establish local and other developments. Comparisons were made with the earlier situation when the Data Audit took place (See Section 11.17) so that advice could be given on any changes since that time.

Chapter 5 Results

5.1 Data to Collect

The Affinity analysis exercise determined the main information requirements in respect of aseptic preparation are: Assess Demand, Activity, Human Resources, Risk, Service, Cost, Cost, Primary/ Community Care, Standards, and Information Management & Technology (IM&T) (see Section 11.8 for full results).

Table 5.1.1 shows the collation of the syndicate groups' scores for how the Affinity analysis results related to different clinical areas:

Table 5.1.1 Scores for Affinity analysis results as to relevance for clinical areas

| Syndicate Group/ Affinity Analysis Heading | Medicine | Surgery/ Theatres | Specialist Diagnostic Group: Cancer | Specialist Clinical Area: ICU | Aggregate Score |
|---|-----------------|------------------------------|--|--|----------------------------|
| Assess Demand | 5 | 5 | 5 | 5 | 20 |
| Activity | 5 | 5 | 4 | 2 | 16 |
| Human Resources | 5 | 4/5 | 5 | 4 | 18/19 |
| Risk | 5 | 5 | 5 | 5 | 20 |
| Service | 5 | 4 | 4 | 5 | 18 |
| Cost | 3 | 1 | 5 | 2 | 11 |
| Cost | 1 | 4/5 | 3 | 1 | 9/10 |
| Primary/ Community Care | 1 | 1 | 4 | 1* | 7 |
| Standards | 4 | 5 | 5 | 5 | 19 |
| IM&T | 4 | 2/4 | 4 | 3 | 13/15 |

* The minimum score of "1" was assigned although the group and heading do not relate to one another

Table 5.1.2 shows the collation of the syndicate groups' scores for how common aseptic products relate to different clinical areas:

Table 5.1.2 Scores for common aseptic products as to relevance for clinical areas

| Aseptic Product/ Syndicate Group** | Minibag Plus | Minibag/ Infusion | Prefilled Syringes | PCA Devices | TPN |
|---|-----------------|----------------------|-----------------------|----------------|-----|
| Surgery | 5 | 5 | 5 | 5 | 5 |
| Theatres | 2 | 2 | 5 | 5 | 5 |
| Specialist Diagnosis Group: Cancer - Current | 1 | 5 | 5 | 1 | 3 |
| Specialist Diagnosis Group: Cancer - Ideal | 2 | 5 | 5 | 3 | 3 |
| Specialist Clinical Area: ICU – Current | 2 | 5 | 3 | 4 | 4 |
| Specialist Clinical Area: ICU - Ideal | 1 | 4 | 5 | 4 | 4 |

Note: The Medicine syndicate group considered that local variations would be very high in the sense that neighbouring hospitals could have very different patterns for general medical activity. Therefore it did not complete this exercise.

The data established as of most relevant to the research are:-

- Product Presentation (e.g. minibag plus, prefilled syringes);
- Ingredients (e.g. ampoules, vials);
- Patient Type (e.g. child versus adult);
- Administration (of product to patient)
 - Site
 - Route (e.g. intravenous, intramuscular)
 - Rate
- Place of preparation Whether product was manufactured (licensed), prepared in local aseptic unit or prepared in a clinical area;
- Assembly (by whom, e.g. nurse, pharmacist)

The currencies that should be considered within the project were identified as:-

- Dose / Administration / Product (delivered to a patient)
- Ingredients

One unanticipated result was that different professionals (nurses and pharmacists in this case) can use the same words for different things and different words for the same thing. Examples include: Administration, Assembly, Ingredients and (Product) Type. This could

have consequences for the recording, analysis and interpretation of data, making it very important, with the evaluation of Nomenclature being incorporated into the overall project (see Section 5.8 for Nomenclature results).

The out-turn questionnaire survey results (see Section 11.12) were that the workshop was a success for how it was organised and its influence on participants. There was a strong positive response in respect of Research and Development capacity.

5.2 Information Systems Data Audit

A full response was received to the survey of pharmacy information systems, which showed there were four main computer information systems/packages used in aseptic dispensing departments. These are: Ascribe, JAC Pharmacy Systems, HORIS and MDIS (previously McDonnell Douglas Information Systems). Some hospitals had more than one of the systems. The number of units where each was used was:

- Ascribe 13
- HORIS 2
- JAC 12 (Including one about to be installed)
- MDIS 13

(See Section 11.15 for full results)

The Data Audit exercise established:

- (a) One feature of the packages is the latitude provided to the user to configure the system to reflect local views of situations. In the absence, and even in the presence, of wider standards this freedom can lead to differences in product definition, coding systems, report formats, data export facilities etc.
- (b) These difficulties only have a limited impact on the research if it quantifies activity on a broad product basis, and not at a detailed level.

All the issues in (a) were evident to the National Prescribing Centre's Hospital Prescribing Information Project. It determined that it was impractical to try and collect data below a certain level of detail (Jackson and Walker, 1998; National Prescribing Centre, 1998; Jackson, 1999), so it concentrated on activity by economic/financial value rather than by volume, as was the original aim. Although the Data Audit focused on activity volumes, the principles involved were the same and conclusion (b) was drawn.

A full response to the audit questionnaire was received, with responses falling into two categories:

- The computer system can provide all target data on the target products currently identified automatically
- The computer system can provide base data relating to the target data and target products, but some manual or other processing would be required to meet the project data requirements

For the latter, the additional collation work appeared achievable within the staff capacity of the aseptic dispensing unit, if sufficient notice of requirements was given.

The systems were designed to support the aseptic production process (e.g. production of labels, batch numbers) rather than analysis of overall production. Such systems would not hold data on what aseptic preparation took place in clinical areas.

The assessment of the impact of EPS, following the visit to Wirral Hospitals NHS Trust, was that they could have an impact on data availability, but their rate of adoption will not materially affect the achievement or outcome of the research.

The workshop was evaluated as successful. It validated the main elements of the Data Audit exercise. The results included:

- A survey of pharmacy-based aseptic activity is realistic, but needs to take into account the need for clear guidance notes to ensure consistent data;
- Not all of the required survey information can be obtained from computerised pharmaceutical information systems;
- An expanded range of product types should be used in the survey (to be consistent with the list in Table 9.1 of the North West report on maintaining asepsis during the preparation of pharmaceutical products (NHS Executive North West, 1997). Some product types need to be divided into subcategories to reflect differentials in the amount of preparation (e.g. cytotoxics);
- Clarification of how data might be used is needed to ensure any survey is sufficiently comprehensive (e.g. the recording of unaltered TPN bags).

The out-turn questionnaires' results confirmed the workshop as a success (see Section 11.22). The report on the Data Audit exercise was amended to take into account its findings, and submitted to the expert panel for consideration. Its recommendations were endorsed (see Section 11.18).

This presented the problem that to expand the list of product types would mean that the additional products had not been scrutinised as part of the Data Audit. This could not be ignored, otherwise the research methodology could be criticised, if the issue was not formally addressed. Two options available: (a) approach the Trusts again to ask for equivalent information for the extra products, and update the exercise and its results; and (b) make an informed judgement as to whether similar results would apply to these additional items (which were considered minor in terms of volume).

The expert panel decided upon option (b) and determined that it was reasonable to expect the same results would have applied to the additional product types if they had been included in the Data Audit. In response to the workshop's advice, the expert panel decided that activity should be quantified by product presentation category, with specific breakdowns for cytotoxics, CIVAS products and TPN products, because the different types of presentations/manipulations make (substantially) different demands on resources in aseptic dispensing units.

The expert panel also identified that some commercially acquired licensed products, such as TPN, can be used in clinical areas without having passed through the hospital's aseptic dispensing unit. This was considered a gap to be addressed, so that a full picture of the use and/or acquisition of aseptic products could be measured. Consequently, it was agreed that three types of data should be collected:

1. Data about products prepared or manufactured in pharmacy aseptic preparation units
2. Data about the source of aseptically prepared unlicensed products used in a Trust
3. Data about the use of commercially acquired licensed products used in a Trust without further manipulation in a pharmacy aseptic unit before administration to a patient

5.3 Baseline Survey

All 37 trusts in the North West that produced or used aseptically prepared products participated in the survey. All other Trusts confirmed that they did not use them (or their use was minimal) and were excluded.

Of the Trusts that had not produced or used aseptic products in the original survey (Gandy et al, 1998a) all but two responded to the research letter in the affirmative and were therefore excluded. Two community Trusts said they did use aseptic products, but upon enquiry, both indicated that their volumes were very small and were provided by neighbouring Trusts' pharmacies. One was an ad hoc situation. Therefore it was agreed that they too would be excluded.

Table 5.3.1 details the total volumes produced and used by each Trust/site, and Table 5.3.2 provides details of total volumes produced and used by product type. Table 5.3.3 summarises the relationship between size of unit and license state. Section 11.25 provides full details of analyses.

Key points include:

- In broad terms, the situation in the baseline was similar to that in the original survey (Gandy et al, 1998a): the total number of products produced in North West aseptic dispensing units dipped from approximately 1.1 million to just under 1.0 million, while the total number of products used increased from c. 1.0 million to c. 1.1 million.
- The most popular items produced were minibag plus, minibag/infusion and prefilled syringes, which together totalled 767,745 products and accounted for 78 per cent of all the products produced.
- The seven units that each produced over 50,000 products accounted for 57 per cent of all the products produced. The absence of any units having a workload in the range 9,000 to 18,000 products naturally divided units into "low" and "high" volume.
- Seventeen of the aseptic units produced products for use outside the Trust. The total number of such products was 114,161 (12 per cent).
- The total number of commercial unlicensed products used was 122,753 (11 per cent) - almost double that in the original survey (*ibid*). Cytotoxics accounted for 94 per cent of such activity in the latter, but the number only increased by a little over 3,000. The main increases were in other types of products, with over 20,000 irrigations and prefilled syringes bought in.

Note: Some data and analyses from the baseline survey were used in respect of other aspects of the research. These are shown in the appropriate section.

Table 5.3.1 Baseline Survey: Total volumes produced and used by each Trust/site

| Code | No. of Products Produced Within Aseptic | | | | No. of Products used from each Source:- | | | | | | |
|-------------------|---|---------------------------|-------------------------------|----------------------------|---|--------------------|-------------------------------------|---------------------------------------|--------------------------------------|-------------|------------------|
| | Individual Patients Total | Used as Ward Stock* Total | Use in Other NHS Trusts Total | Use by Non-NHS Users Total | Total | Within Trust Total | Other NHS Trust Licensed Unit Total | Other NHS Trust UnLicensed Unit Total | Commercial UnLicensed Products Total | Other Total | Total |
| 111 | 19,794 | - | 375 | 15 | 20,184 | 19,794 | 1,804 | 102 | 19 | - | 21,719 |
| 112 | 4,871 | - | - | 30 | 4,901 | 4,871 | 20,212 | - | 2 | - | 25,085 |
| 113 | 4,869 | 435 | - | - | 5,304 | 5,304 | - | - | 1,705 | - | 7,009 |
| 114 | 3,642 | 32,506 | 10,783 | 1 | 46,932 | 36,148 | 4,239 | - | 71 | - | 40,458 |
| 115 | 55,206 | - | - | 4,735 | 59,941 | 55,206 | - | - | - | - | 55,206 |
| 116 | - | - | - | - | - | - | 12,580 | - | 290 | - | 12,870 |
| 117 | 37,385 | - | - | 2,190 | 39,575 | 37,385 | 10 | - | - | - | 37,395 |
| 118 | 18,488 | - | - | - | 18,488 | 18,488 | 342 | - | 2,800 | - | 21,630 |
| 120 | 8,389 | - | - | - | 8,389 | 8,389 | 4,492 | - | - | - | 12,881 |
| 121 | 3,730 | - | - | - | 3,730 | 3,730 | 100 | 1,300 | 65,000 | - | 70,130 |
| 122 | 11,873 | 15,700 | 600 | - | 28,173 | 28,173 | 1,000 | - | - | - | 29,173 |
| 123 | 2,561 | - | - | - | 2,561 | 2,561 | 2,803 | 26 | 443 | - | 5,833 |
| 124 | 449 | - | - | - | 449 | 449 | 1,678 | - | 685 | - | 2,812 |
| 125 | 1,969 | - | - | - | 1,969 | 1,969 | 5,730 | 99 | - | - | 7,798 |
| 126 | - | - | - | - | - | - | 1,695 | 4,720 | - | - | 6,415 |
| 127 | 3,550 | - | - | - | 3,550 | 3,550 | 2,703 | - | 4,850 | - | 11,103 |
| 128 | 3,437 | - | - | - | 3,437 | 3,437 | - | - | - | - | 3,437 |
| 129 | 17,972 | 1,600 | - | 72 | 19,644 | 19,572 | 8,900 | - | 2,500 | - | 30,972 |
| 130 | 7,520 | - | - | - | 7,520 | 7,520 | 3,470 | - | - | - | 10,990 |
| 131 | - | - | - | - | - | - | 2,670 | - | - | - | 2,670 |
| 132 | 40,055 | - | - | 728 | 40,783 | 40,055 | 207 | - | - | - | 40,262 |
| 133 | 4,755 | - | - | - | 4,755 | 4,755 | 2,612 | - | 11 | - | 7,378 |
| 134 | 14,981 | 50,596 | 38,271 | 245 | 104,093 | 65,067 | - | - | 510 | - | 65,577 |
| 135 | - | - | - | - | - | - | 236 | - | 156 | - | 392 |
| 136 | 68,512 | - | 2,948 | - | 71,460 | 68,512 | 292 | - | - | - | 68,804 |
| 137 | 88,105 | 5,646 | 4,743 | - | 98,494 | 93,751 | 107 | - | - | - | 93,858 |
| 138 | 33,377 | - | - | - | 33,377 | 33,377 | 584 | - | 21,744 | - | 55,705 |
| 139 | 64,814 | - | - | - | 64,814 | 68,092 | 8,999 | - | 87 | - | 77,178 |
| 140 | 3,278 | - | 2,969 | 10,830 | 17,077 | - | - | - | - | - | - |
| 141 | 8,719 | - | - | - | 8,719 | 8,719 | 1,066 | - | 126 | - | 9,911 |
| 142 | 45,516 | - | 866 | - | 46,382 | 45,516 | 1,084 | - | 66 | - | 46,666 |
| 143 | 6,585 | 537 | 637 | 27 | 7,786 | 7,122 | 146 | - | 21,420 | - | 28,688 |
| 144 | 21,858 | - | - | 30 | 21,888 | 21,858 | 1,278 | - | - | - | 23,136 |
| 145 | 7,190 | 51,623 | 4,455 | 11 | 63,279 | 58,813 | 4 | - | 141 | - | 58,958 |
| 146 | - | - | - | - | - | - | 3,962 | - | - | - | 3,962 |
| 147 | 18,903 | - | - | - | 18,903 | 18,903 | 1,162 | - | 31 | - | 20,096 |
| 148 | 2,167 | - | - | - | 2,167 | 2,167 | 1,473 | 44 | - | - | 3,684 |
| 149 | - | - | - | - | - | - | 20 | 375 | - | - | 395 |
| 150 | 791 | - | - | - | 791 | 791 | 3,262 | - | 96 | - | 4,149 |
| 151 | 16,286 | 1,800 | - | - | 18,086 | 18,086 | - | - | - | - | 18,086 |
| 152 | 9,686 | 47,690 | 27,713 | 887 | 85,976 | 57,376 | 1,310 | - | - | - | 58,686 |
| Total | 661,283 | 208,133 | 94,360 | 19,801 | 983,577 | 869,506 | 102,232 | 6,666 | 122,753 | - | 1,101,157 |
| % of Total | 67.2% | 21.2% | 9.6% | 2.0% | 100.0% | 79.0% | 9.3% | 0.6% | 11.1% | 0.0% | 100.0% |

Table 5.3.2 Baseline Survey: Total volumes produced and used by Product Type.

| Products | No. of Products Produced within Aseptic Preparation Unit for: | | | | | No. of Products Used from each Source: | | | | | |
|-----------------------------------|---|------------------|-----------------------|---------------------|---------------|--|------------------------|--------------------------|-------------------------|-------------|----------------|
| | Individual Patients Total | Ward Stock Total | Other NHS Trust Total | Non-NHS Users Total | Total | Within Trust: | Other, Licensed Trust: | Other, Unlicensed Trust: | Commercial, Unlicensed: | Other: | Total |
| Cytotoxics | 107906 | 0 | 456 | 2454 | 110816 | 107906 | 2295 | 149 | 62759 | 0 | 173109 |
| Epidural Injections | 42 | 8959 | 0 | 0 | 9001 | 9001 | 8474 | 0 | 3285 | 0 | 20760 |
| Eye Drops/Eye Irrigations | 3908 | 556 | 0 | 5 | 4469 | 4464 | 2942 | 0 | 2502 | 0 | 9908 |
| Irrigations | 14144 | 0 | 637 | 28 | 14809 | 14144 | 153 | 102 | 21821 | 0 | 36220 |
| Minibag Plus | 101950 | 135889 | 69573 | 23 | 307435 | 237839 | 52590 | 0 | 0 | 0 | 290429 |
| Minibag/Infusion | 185945 | 49481 | 5359 | 0 | 240785 | 235426 | 14186 | 0 | 1863 | 0 | 251475 |
| Injection Devices | 2294 | 3200 | 7 | 480 | 5981 | 5494 | 0 | 0 | 3000 | 0 | 8494 |
| Prefilled Syringe | 199628 | 9736 | 4296 | 5865 | 219525 | 209364 | 11543 | 3293 | 24116 | 0 | 248316 |
| TPN-Adult:Compounded | 15842 | 0 | 4192 | 10491 | 30525 | 15558 | 3955 | 1453 | 387 | 0 | 21353 |
| TPN-Adult:Simple Additions | 13523 | 0 | 484 | 48 | 14055 | 12980 | 227 | 0 | 2703 | 0 | 15910 |
| TPN-Neonatal/ Paediatric | 13375 | 312 | 8756 | 364 | 22807 | 14004 | 3075 | 1625 | 0 | 0 | 18704 |
| Other | 2726 | 0 | 600 | 43 | 3369 | 3326 | 2792 | 44 | 317 | 0 | 6479 |
| Total | 661283 | 208133 | 94360 | 19801 | 983577 | 869506 | 102232 | 6666 | 122753 | 0 | 1101157 |
| % of Total | 67.2% | 21.2% | 9.6% | 2.0% | 100.0% | 79.0% | 9.3% | 0.6% | 11.1% | 0.0% | 100.0% |

Table 5.3.3 Relationship between Size of Production and License Status

| Total Products Produced* | No. of Licensed Units | No. of Unlicensed Units |
|--------------------------|-----------------------|-------------------------|
| 50,000 + | 6 | 1 |
| 25,000 - 50,000 | 3 | 3 |
| 18,000 - 22,000 | 1 | 5 |
| 9,000 - 18,000 | 0 | 0 |
| < 9,000 | 1 | 14 |

5.4 Baseline Survey Evaluation

There was a full response from Trusts for Forms one and two. Variable responses were received in respect of Form three (see below).

Only one Trust submitted forms with absolutely no queries. Most others had small queries that were quickly addressed (see Table 5.4.1 for illustration of data validation analysis, and Section 11.26 for full summary overview)

The mapping of product types used in the different exercises was showed that relationships were clear, and there were no conflicts to prejudice the research (see Figure 5.4.1.

Data about commercially-acquired licensed products (Form three) caused problems and necessitated updated guidance to be issued. The main problem with the guidance as originally written was that it opened the way for a wide range of products to be included which were superfluous to the research. Only 12 completed forms were received and 10 of these included comments that suggested that there was limited confidence in the data.

Table 5.4.1 Illustration of data validation analysis

| | No Queries/ Points | Small cross form/ calculation error | No / limited Totals | Form Two Cross link with Form One not made | Form Three Blank | "Other" not named | "Other" named but not split | Merging of categories | Missing data | Data Issue | Qualification on data |
|-------|--------------------|-------------------------------------|---------------------|--|------------------|-------------------|-----------------------------|-----------------------|--------------|--|---|
| TRUST | | | | | | | | | | | |
| 111 | | | | | | | X | | | | Cyto bladder irrigations inc. in Cyto Devices |
| 112 | | | | X | | X | | | | | Oral Cytotoxics counted as "Other" |
| 113 | | X | | | | | | | | Form Three: Interpretation query | |
| 114 | | | | | | | | | | No scope to highlight which products produced on site under "specials" | Neonatal TPN = 1 comp bag + 1 prefilled syringe |
| 115 | | X | X | | | | | | | GP care = Non-NHS user; Split of data for batches | Excludes terminally sterilised products |
| 116 | | | X | | | | | | | | |
| 117 | | | X | | | | | | | | |
| 118 | | | | | | | | | | Form Two Commercial Comp. TPNs purchased to use in simple addition TPNs - both recorded on form. | Cyto bladder irrigations inc. in Cyto Infusions; Irrigations = BCG - moved to "Other" |
| 120 | | | | | X | | | | | | |
| 121 | | X | | | X | | | | | | |
| 122 | | | | | | | | | | No split on Cytotoxics categories: manual record keeping would be required | |
| 123 | | | | X | | | | | | | |
| 124 | | | | X | | | | | | | |

Figure 5.4.1 Mapping of product types used in different research-related exercises

| WORK STUDY EXERCISE (See Section 4.10) | BASELINE SURVEY (See Section 4.3) | REGIONAL WORKING PARTY (NHS Executive North West, 1997) |
|---|--|--|
| Cytotoxics | <p>Cardioplegia Solutions</p> <p>Cytotoxics - Devices</p> <p>Cytotoxics - Infusions</p> <p>Cytotoxics - Syringes</p> | <p>Cardioplegia solutions</p> <p>Cytotoxics</p> |
| Epidural Injections | Epidural Injections | Epidural injections |
| Eye Drops/ Eye Irrigations | Eye Drops/ Eye Irrigations | Eye Preparations |
| Injection Devices** | Injection Devices** | Elastomeric devices |
| Irrigations (exc. ophthalmic) | Irrigations (exc. ophthalmic) | Infusors, syringe drivers, pumps/ PCA |
| | | Inhalations* |
| | | Irrigations (exc. ophthalmic) |
| | | Irrigations (exc. ophthalmic) for immediate use* |
| | | Preparation of doses from part of a container |
| | | Products ready for Administration* |
| Minibag Plus | Minibag Plus | Infusions |
| Minibag/ Infusion | Minibag/ Infusion | Syringes, Minibags (stored <3 hrs etc) |
| (Infusions <250 ml) | | |
| (Infusions >=250 ml) | | |
| Prefilled Syringes | Prefilled Syringe | Syringes, Minibags (stored >3 hrs etc) |
| Radiopharmaceuticals | Radiopharmaceuticals | Radiopharmaceuticals |
| TPN - Adult: Compounded | TPN - Adult: Compounded | TPN Solutions |
| TPN - Adult: Simple Additions | TPN - Adult: Simple Additions | |
| TPN - Neonatal | TPN - Neonatal/ Paediatric | |
| TPN - Paediatric | Other | Others |
| Exclusions: | | KEY |
| Eyedrops | | * Wards / Depts or Specialist clinical areas only |
| Radiopharmaceuticals | | ** Includes Elastomeric Infusor |
| | | Not included |

5.5 Quarterly Surveys

Table 5.5.1 shows the trends in production for participating Trusts over the five quarters, in comparison with the baseline. These were mixed with 13 increasing activity and eight reducing. The increase was 13 per cent over the five quarters, having peaked at 25 per cent after Quarter 3. This was largely due to Trust 152 reducing production by 82 per cent; this was one of the Trusts having a C&CP capital scheme and the unit had to close to enable the scheme to proceed.

Table 5.5.2 shows the trends in the total production of each product type, in comparison with the baseline. The picture of what happened in respect of the individual product types show:

- Two of the most used products from the baseline survey – minibag plus and prefilled syringe – increased by around a third and a fifth respectively over the period, whilst the other most commonly used product (minibag/infusion) fell by about a quarter. This may represent some switch of usage between the products, with the aggregate for the three types of products increasing by only 12 per cent.
- TPN usage fluctuated over the period, although the numbers for each category were not large. Those for adults with simple additions increased most (by over half in the last quarter), but neonates/paediatrics fell by around 20 per cent.
- Cytotoxics usage per quarter was generally between 13,000 and 14,000, which was up by over 10 per cent from the baseline activity, with a peak in Quarter 3 of 17,516.
- The category “Other” was broadly consistent over each of the five Quarters, but this level was about four times that in the baseline.
- The other products demonstrated the fluctuations that often arise from small numbers.

Table 5.5.1 Trends in Production for Trusts participating in the Five Quarterly Surveys

| Trust | Total Produced (All Product Types - Unweighted) | | | | | % Trends Using Baseline Quarterly Equivalent as base | | | | | |
|------------------|---|---------------|---------------|---------------|---------------|--|----------|----------|-----------|-----------|-----------|
| | Baseline Quarterly Equivalent | Qtr 1 | Qtr 2 | Qtr 3 | Qtr 4 | Qtr 5 | Qtr 1 | Qtr 2 | Qtr 3 | Qtr 4 | Qtr 5 |
| 111 | 5046 | 4618 | 4940 | 3789 | 3878 | 3267 | -8 | -2 | -25 | -23 | -35 |
| 112 | 1225 | 1066 | 1160 | 1261 | 1199 | 1248 | -13 | -5 | 3 | -2 | 2 |
| 113 | 1326 | 1521 | 1851 | 2536 | 2676 | 3004 | 15 | 40 | 91 | 102 | 127 |
| 114 | 11733 | 16635 | 15546 | 17604 | 28505 | 27790 | 42 | 32 | 50 | 143 | 137 |
| 118 | 4622 | 5019 | 5658 | 5392 | 5683 | 5975 | 9 | 22 | 17 | 23 | 29 |
| 120* | 2097 | 0 | 1020 | 11724 | 11816 | 13691 | -100 | -51 | 459 | 463 | 553 |
| 122 | 7043 | 6522 | 4869 | 7016 | 7083 | 6537 | -7 | -31 | 0 | 1 | -7 |
| 123 | 640 | 702 | 743 | 885 | 1345 | 1315 | 10 | 16 | 38 | 110 | 105 |
| 127 | 888 | 1730 | 1796 | 2162 | 2018 | 2018 | 95 | 102 | 144 | 127 | 127 |
| 128 | 859 | 1241 | 1343 | 1364 | 1544 | 999 | 44 | 56 | 59 | 80 | 16 |
| 132 | 10196 | 9608 | 10848 | 12197 | 12009 | 11722 | -6 | 6 | 20 | 18 | 15 |
| 134 | 25135 | 29513 | 29709 | 29973 | 27435 | 35896 | 17 | 18 | 19 | 9 | 43 |
| 138 | 8344 | 5831 | 8123 | 9602 | 8414 | 8137 | -30 | -3 | 15 | 1 | -2 |
| 139/140 | 20473 | 8840 | 5495 | 11767 | 12134 | 10580 | -57 | -73 | -43 | -41 | -48 |
| 141 | 2180 | 1622 | 1457 | 1316 | 1141 | 1159 | -26 | -33 | -40 | -48 | -47 |
| 142 | 11596 | 12793 | 13716 | 14420 | 15309 | 14212 | 10 | 18 | 24 | 32 | 23 |
| 144 | 5472 | 8788 | 8980 | 7189 | 8489 | 7869 | 61 | 64 | 31 | 55 | 44 |
| 145 | 15820 | 15989 | 17172 | 18585 | 21317 | 14918 | 1 | 9 | 17 | 35 | -6 |
| 148 | 542 | 303 | 302 | 417 | 404 | 372 | -44 | -44 | -23 | -25 | -31 |
| 150 | 198 | 193 | 309 | 291 | 222 | 295 | -2 | 56 | 47 | 12 | 49 |
| 152 | 21494 | 30125 | 33448 | 36127 | 10668 | 6493 | 40 | 56 | 68 | -50 | -70 |
| Aggregate | 156928 | 162659 | 168485 | 195617 | 183289 | 177497 | 4 | 7 | 25 | 17 | 13 |

* Unit 120 reopened as a licensed facility following refurbishment, having previously been unlicensed.

Table 5.5.2 Trends in Production for Product Types for Trusts participating in the Five Quarterly Surveys

| | | Total Produced (All Trusts - Unweighted) | | | | | % Trends Using Baseline Quarterly Equivalent as base | | | | |
|--------------------------------|-------------------------------|--|---------------|---------------|---------------|---------------|--|----------|-----------|-----------|-----------|
| | Baseline Quarterly Equivalent | Qtr 1 | Qtr 2 | Qtr 3 | Qtr 4 | Qtr 5 | Qtr 1 | Qtr 2 | Qtr 3 | Qtr 4 | Qtr 5 |
| Cardioplegia Solution | 177 | 142 | 158 | 166 | 246 | 227 | -20 | -11 | -6 | 39 | 28 |
| Cytotoxic | 11958 | 13,155 | 13489 | 17516 | 14667 | 13770 | 10 | 13 | 46 | 23 | 15 |
| Epidural Injections | 1313 | 1,155 | 993 | 1406 | 1466 | 1561 | -12 | -24 | 7 | 12 | 19 |
| Eye Drops / Eye Irrigations | 968 | 926 | 1074 | 1189 | 1495 | 1253 | -4 | 11 | 23 | 55 | 30 |
| Irrigations (exc. Ophthalmics) | 129 | 247 | 250 | 1085 | 1321 | 115 | 91 | 93 | 739 | 922 | -11 |
| Minibag Plus | 63100 | 74,645 | 78756 | 93063 | 81185 | 83927 | 18 | 25 | 47 | 29 | 33 |
| Minibag / Infusion | 39004 | 30,498 | 32169 | 34343 | 33517 | 28868 | -22 | -18 | -12 | -14 | -26 |
| Injection Devices | 1294 | 1,194 | 1269 | 1212 | 1128 | 1105 | -8 | -2 | -6 | -13 | -15 |
| Prefilled Syringe | 26865 | 26,588 | 28769 | 30177 | 33630 | 31975 | -1 | 7 | 12 | 25 | 19 |
| TPN-Adult: Compounded | 6474 | 6,324 | 3871 | 7559 | 7223 | 6863 | -2 | -40 | 17 | 12 | 6 |
| TPN-Adult: Simple Additions | 2322 | 2,451 | 2440 | 3057 | 2726 | 3510 | 6 | 5 | 32 | 17 | 51 |
| TPN-Neonatal / Paediatric | 2659 | 2,602 | 2550 | 2224 | 1764 | 2131 | -2 | -4 | -16 | -34 | -20 |
| Other | 665 | 2732 | 2697 | 2620 | 2921 | 2192 | 311 | 306 | 294 | 339 | 230 |
| Total | 156928 | 162,659 | 168485 | 195617 | 183289 | 177497 | 4 | 7 | 25 | 17 | 13 |

5.6 Quarterly Survey Evaluation

Not all of the capital schemes completed within the planned timeframe. Therefore, it was not possible to use the five quarterly surveys' data to evaluate the whole capital programme.

The expert panel's evaluation of the efficacy of the revised survey design and associated guidelines was that:

- The quarterly survey design, guidance and processes represented a sound, practical method of collecting data on aseptic production and usage;
- The quality of data was good;
- The structured approach to data collection meant that, for the first time, there was a good picture of practice and activity in the aseptic units across the North West.

5.7 Data Available in Clinical Areas

Table 5.7.1 summarises the types of documentation used in each Trust and clinical area covered.

Tables 5.7.2 & 5.7.3 illustrate the variations in documentation amongst the participating Trusts.

Table 5.7.4 shows the views of the nursing staff interviewed, as to the proportioning of shared responsibility of who carries out the preparation and administration of aseptic medicines.

Table 5.7.5 provides details of the types of variables/ product types used in each of the audited clinical areas.

Table 5.7.6 highlights that product types fall into two categories within the clinical area:

- Category one implies that a currency of one unit dose may be used, as the product is recognised as being in its final product presentation state.
- Products in Category two are those where more than one type of presentation can apply. If products are manufactured or pharmacy prepared, again a 1 to 1 relationship is implied. However, some product presentations may be interchangeable for the delivery of a particular drug dependent on the preferences of the individual clinician or local custom and practice. This would reflect the types of ingredients used. It would require individual assessment of the product as to the relationship, 1 to n , where n is the exact number of ingredients required to produce the final product.

Table 5.7.7 provides an insight to the amount of recording that would be involved with a clinical survey.

Table 5.7.8 summarises the responses to the alternative options for data collection, if continuous data collection did not take place.

The other main results were the proposals for supplementary projects to address research questions identified through the process (see Section 11.23).

Table 5.7.1 Documentation Used Within Clinical Areas

Documentation used within Clinical Areas

| ID Number | Trust | Clinical Area Visited | Documents |
|-----------|---|-------------------------------------|------------------------------|
| 2b | Bolton Hospitals NHS Trust | Theatre | 1, 3, 4, 5, 10 |
| 7a | Stockport Acute Services NHS Trust | Theatre | 1, 3, 10 |
| 8b | Aintree Hospitals NHS Trust | Theatre | 1, 3, 6, 10 |
| 4a | Wirral Hospitals NHS Trust | Surgical - Colon rectal and general | 2, 3, 7, 12 (1 if necessary) |
| 5a | Mid Cheshire Hospitals NHS Trust | Surgical | 1, 2, 3, 6, 11 |
| 8a | Aintree Hospitals NHS Trust | Surgical | 1, 2, 3, 5, 6, 14 |
| 1b | Burnley Health Care NHS Trust | Paediatric Surgical | 1, 2, 3, 4 |
| 1a | Burnley Health Care NHS Trust | Paediatric Medicine | 1, 2, 3, 4 |
| 6a | Manchester Childrens Hospitals NHS Trust | Paediatric Medicine | 1, 2, 3 |
| 6b | Manchester Childrens Hospitals NHS Trust | Paediatric ITU | 1, 2, 3, 8 |
| 3a | Blackpool Victoria Hospital NHS Trust | ITU | 1, 2, 3, 7, 8, 9, 11 |
| 5b | Mid Cheshire Hospitals NHS Trust | ITU | 1, 2, 3, 8, 11 |
| 9a | Clatterbridge Centre for Oncology NHS Trust | Oncology - Radiotherapy | 1, 2, 3, 7 |
| 9b | Clatterbridge Centre for Oncology NHS Trust | Oncology - Chemotherapy | 1, 2, 3, 7, 13 |
| 3b | Blackpool Victoria Hospital NHS Trust | Medicine and Haematology | 1, 2, 3, 7, 11 |
| 4b | Wirral Hospitals NHS Trust | Medicine - Stroke and haematology | 2, 3, 12 (1 if necessary) |
| 2a | Bolton Hospitals NHS Trust | Medicine - General | 1, 2, 3, 7 |
| 7b | Stockport Acute Services NHS Trust | Medicine - Care of the Elderly | 1, 3, 6 |

Key

- 1 = In Patient Prescription Sheet;
- 2 = Blood & Intravenous Infusion Fluid Chart;
- 3 = Controlled Drug Book;
- 4 = PCA Form;
- 5 = Epidural Form;
- 6 = Diabetic Prescription Sheet;
- 7 = Cytotoxic Prescription Form;
- 8 = 24 Hour Chart;
- 9 = Haemofiltration Form;
- 10 = Anaesthetic Form;
- 11 = TPN;
- 12 = Computer System;
- 13 = Day Case prescription chart;
- 14 = Heparin Chart.

Table 5.7.2 In Patient Prescription Sheet

(Also known as Wardex, medicine kardex/sheet, script, medicine chart etc.)

| Specified Areas | Trust Identification Number | | | | | | | | |
|---|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| | 1 | 2 | 3 | 5 | 6 | 7 | 8 | 9 | |
| Prescribing Information (Instruction for use) | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Patient Details | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Non administration coding | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | |
| Drug Allergies/Sensitivity | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Other Charts in use | <input checked="" type="checkbox"/> | | | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | | |
| Once only (and pre anaesthetic) | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| As required | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Regular | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Continuous infusion pumps | <input checked="" type="checkbox"/> | | | | | | | | |
| Drugs prior to admission | | | | | | | <input checked="" type="checkbox"/> | | |
| Medical Gases | <input checked="" type="checkbox"/> | | | | | | | | |
| Variable dose and time | | | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | | |
| Fluids - (Regime for fluid replacement) | | | | | | <input checked="" type="checkbox"/> | | | |
| PCA and S/C infusion | | | | <input checked="" type="checkbox"/> | | | | | |
| Epidural | | | | <input checked="" type="checkbox"/> | | | | | |
| Controlled drugs | | | | | | | | <input checked="" type="checkbox"/> | |
| IV Additive administration 'Pharmacy Prepared' IV additive labels placement | | <input checked="" type="checkbox"/> | | | | | | | |
| Nurse Prescribing | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | | | |
| Pages found within document | 6 | 4 | 2 | 6 | 6 | 6 | 4 | 4 | |

Note: Trust No. 4 was omitted from table as it uses a computerised system.

Table 5.7.3 Blood and Intravenous Fluid Chart

(Also known Infusion Chart, Continuous Running Fluids, 24 Hr Fluids Chart etc.)

| Required information (other than standard) | Trust Identification Number | | | | | | | |
|--|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|---|-------------------------------------|-------------------------------------|-------------------------------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 8 | 9 |
| Allergies / Sensitivities | | | | <input checked="" type="checkbox"/> | | | | |
| Affix Label or Enter Batch Number | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Given and Witnessed Signature | | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | | <input checked="" type="checkbox"/> |
| Drip set changed | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | | | | |
| IV site changed | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | | | | |
| Infusion Device Number | | <input checked="" type="checkbox"/> | | | | | | |
| Intragastric | | | | | | | <input checked="" type="checkbox"/> | |

Note: Trust No. 7 was omitted from table as the two documents are combined within the in patient prescription sheet.

Table 5.7.4 Responsibility for preparation and administration of aseptic medicines

| Preparation & Administration | Clinical Area Type | Number of Trusts |
|------------------------------|--|------------------|
| 50/50 (Doctor / Nurse) | Paediatric | 1 |
| 80/20 (Anaesthetist / Nurse) | Theatre | 3 |
| Mainly nurses | Medical, Surgical, Oncology, Paediatric and Intensive Care | 8 |

Note: All nursing staff undergo, (internal to individual NHS Trusts), training and assessment of the preparation and administration of aseptic medicines.

Table 5.7.5 Variables/ Product Types used in the Audited Clinical Areas

| Variables | Licensed | CIVAS | Clinical Area |
|-----------------------------------|---|-------------------------------------|-----------------------------------|
| Radiopharmaceuticals | | | |
| Eye drops | 1, 2, 3, 4, 5b*, 6a, 7, 8, 9 | | |
| Irrigation (excluding ophthalmic) | 2, 3, 4a*, 4b, 5b*, 7a, 7b*, 8a*, 8b, 9a, 9b* | | |
| Minibag Plus | 2, 4, 7 | | |
| Cytotoxic | 9b | 1*, 2a, 3, 4b, 7b*, 8a*, 9 | |
| TPN | 3 | 1*, 2a*, 3, 4a, 4b*, 5, 6a, 8a, 9a* | |
| Minibag/Infusion | 1, 2, 3, 4, 5, 6, 7, 8, 9 | 1, 4b, 5a, 6a, 7b, 8 | 1, 2, 3, 4, 5, 6, 7, 8, 9 |
| Epidural | | 2b, 5a*, 9a | 2b, 3a, 4a, 5b*, 7a, 8 |
| PCA Devices | | 1*, 2b, 4a, 5a*, 5b | 2b, 3a*, 5a*, 5b, 7a, 7b*, 8, 9a* |
| Prefilled Syringe | 1, 2, 3, 4, 5, 7, 8, 9 | 1, 3b, 4b, 5a, 6a, 8a | 1, 2, 3, 4, 5, 6, 7, 8, 9 |

* Indicates very rare usage

See Table 5.7.1 for details of the hospitals and clinical areas the ID Numbers refer to.

Table 5.7.6 Categories of Product Types

| | | |
|---|---|---|
| <p>Category One</p> <ul style="list-style-type: none"> • TPN • Eye drops • Radiopharmaceuticals • Cytotoxic • Minibag Plus | } | <p>Single product administration, Supplied Ready for Administration within clinical area.</p> |
| <p>Category Two</p> <ul style="list-style-type: none"> • Minibag/Infusion • Prefilled syringes • PCA (devices) • Epidural | } | <p>Either single product administration, Ready for Administration or Requiring preparation within clinical area. May require the combining of more than one ingredient.</p> |

Table 5.7.7 Random Count of Aseptic Preparations Administered

| Clinical Area | Number of Administrations |
|----------------|---------------------------|
| Theatre | 4 |
| Chemotherapy | 12 |
| Haematology | 30 |
| Surgical | 21 |
| Paediatric ITU | 99 |

Table 5.7.8 Local views of Frequency of Data Collection

| ID No | Beds | Data Collection | | ID No | Beds | Data Collection | |
|-------|------------|---------------------|---|-------|------------|-----------------|---|
| 2a | 27 | Historical 1 x 4 | 1 | 7a | 4 Theatres | 1x4 or 2x2 | 1 |
| 2b | 7 Theatres | 1 x 4 | 4 | 3b | 18 | Month | 7 |
| 3a | 8 | 1 x 4 | | 4a | 24 | Month | |
| 5b | 7 | 1 x 4 | | 5a | 28 | Month | |
| 9a | 33 | 1 x 4 | | 6a | 24 | Month | |
| 1a | 26 | 2 x 2 | 3 | 7b | 19 | Month | |
| 1b | 21 | 2 x 2 | | 8a | 23 | Month | |
| 4b | 29 | 2 x 2 | | 9b | 28 | Month | |
| 8b | 5 Theatres | Historical 2 x 2 | 1 | 6b | 6 | Unable | 1 |

See Table 5.7.1 for details of the hospitals and clinical areas the ID numbers refer to.

5.8 Nomenclature

Table 5.8.1 sets out the final definitions of key terms agreed for use within the project. Six of the definitions showed little or no variation from the original ones presented to local staff. Any changes recommended for these by the workshop involved simple refinements of detail. The definitions of “Parenteral” and “Product” required most debate before conclusions were reached.

Table 5.8.1 Definitions of terms agreed for use within research

Administration

Administration is the act of delivering the medicine in the right dose, in the right form, via the right route to the right patient at the right time according to both the patient’s prescription sheet and the administration of medicines policy.

Administration Begins

Administration begins with preparing the patient which includes preparing the site / line of access for administration, checking the identification of the patient against the prescription sheet in accordance with the administration of medicines policy and within clinical guidelines for the correct use of equipment (e.g. infusion devices / syringe drivers / PCA devices)

Administration Ends

Administration ends either when the medicine has been delivered (given to the patient) in its entirety and has been recorded; or can end before all of the prepared medicine has been given to the patient should any problem or unwanted effect occur (within either the patient or with any equipment used). In either event, the final act of administration is ensuring the comfort of the patient and recording that the medicine has or has not been given, stating reasons and initiating any necessary action in the latter case.

Assembly

Gathering together on a cleaned tray, trolley or appropriate work surface, all of the items of equipment and pharmaceutical agents required for the aseptic preparation and administration of a medicine to a patient, whatever the form, route, and method / technique of administration.

Ingredients

The collection of pharmaceutical agents, including diluents, infusion fluids and / or devices, required in order to achieve the final medicinal product, as defined on the patient’s prescription sheet. Ingredients can vary according to the strength required.

Parenteral

The administration of medicine(s) by injection. Parenteral methods are identified by a variety of routes including Intravenous, Intramuscular, Subcutaneous and Intradermal. Less common are: Intrathecal, Intrapleural, Intraperitoneal, Epidural, Intra-articular and Intraventricular.

Preparation

Preparation follows assembly. It is the procedure of using all of the assembled items in drawing up, mixing, combining or reconstituting the pharmaceutical agents, diluents and/ or infusion fluids into the right form, combination and strength according to the patient's prescription sheet, and via the correct delivery vehicle/ administration device. Preparation includes following clinical guidelines for the correct use of equipment.

Product

Is the whole or a constituent part of a medicine to be delivered to a patient. A product can be supplied in it's final form by the pharmacy department or can be supplied as individual (licensed) products which are drawn up / combined / reconstituted / mixed in the clinical area into the form required immediately prior to delivery to a patient.

Table 5.8.2 summarises the numbers of words that were established as being used or interpreted in different ways, where alternatives were sought for commonly used words by professionals in clinical areas. For each term, the number of words included in the initial list is shown, together the numbers of words added by local staff during the visits. All of the words on the initial list were recognised by local staff, although particular ones may not have been generally used locally. It was not feasible to try and establish the relative frequency of usage of the different words, and no attempt to do this was made.

Table 5.8.2 Numbers of words relating to specific terms

| Words relating to: | No. of words on initial list | No. of words added by hospitals visited | Total words |
|----------------------------------|-------------------------------------|--|--------------------|
| "Acquisition and Custody" | 3 | 5 | 8 |
| "Administration" | 14 | 4 | 18 |
| "Container" | 9 | 3 | 12 |
| "Dosage" | 5 | 4 | 9 |
| "Equipment" | 12 | 5 | 17 |
| "Ingredients" | 11 | 2 | 13 |
| "Preparation" | 8 | 7 | 15 |
| "Product" | 13 | 4 | 17 |
| "Route" | 18 | 3 | 21 |
| Total | 93 | 37 | 130 |

Table 5.8.3 provides details of the words relating to each term. The words shown in italics are those suggested by local staff, with the others being those on the initial list.

Table 5.8.3 Words commonly used by professionals in clinical areas relating to specific terms

| | | | | |
|---|-----------------------------|-------------------------|-------------------------------|------------------------|
| Words relating to "Acquisition and Custody": | | | | |
| Requisition | Supply | Issue | <i>Storing</i> | |
| <i>Order</i> | <i>Stock</i> | <i>Non-stock</i> | <i>Storage</i> | |
| Words relating to "Administration": | | | | |
| Drug delivery | Single nurse administration | | Manipulation | |
| Reconstitution | Drug administration error | | Self administration | |
| Drug administration | Untoward incident | | Route of Administration | |
| Single administration | Sliding scale | | Clinical Incident | |
| Additive | PCA | | <i>Titrate</i> | |
| <i>Stat</i> | <i>Bolus</i> | | <i>Infusion</i> | |
| Words relating to "Container": | | | | |
| Vial | Package | | Ampoule | Medicine container |
| Syringe | Prefilled syringe | | Minibag | Minibag plus |
| Bag | <i>Medication cassette</i> | | <i>Box</i> | <i>Infusion device</i> |
| Words relating to "Dosage": | | | | |
| Dosage units (mgs etc) | Single dose | | International Units | |
| Stat dose | Single administration | | <i>Rate</i> | |
| <i>Amount given</i> | <i>Titration</i> | | <i>Calculation</i> | |
| Words relating to "Equipment" : | | | | |
| Giving set | Gloves | Drug Administration Set | | |
| Infusion device | PCA device | | Syringe driver | |
| Needles | Syringes | | Dressing products / materials | |
| Apron | Gauze swabs | | Alcohol swab | |
| <i>Cannula</i> | <i>Butterfly</i> | | <i>Pump</i> | |
| <i>Venflon</i> | <i>Line</i> | | | |
| Words relating to "Ingredients": | | | | |
| Substance | Particles | Suspension | Solution | Treatment |
| <i>Solids</i> | Powder | Diluent | Additives | |
| Intravenous fluids | Prescription | Drugs | <i>Component parts</i> | <i>Vehicle</i> |
| Words relating to "Preparation": | | | | |
| Assembly | Expiry date | | Batch | Diluent |
| Expiry time | Compatibility | | Aseptic | Mixing |
| <i>Preparation date</i> | <i>Preparation time</i> | | <i>Prepared by</i> | <i>Checked by</i> |
| <i>Witnessed by</i> | <i>Reconstitution</i> | | <i>Dilution</i> | |

| Words relating to "Product" | | | |
|------------------------------------|------------------------|-----------------------------------|-------------------|
| Substance | Stock / non-stock item | Solution | Treatment |
| Powder | Form | Diluent | Presentation |
| Solids | Generic Name | Particles | Drug |
| Regime | <i>Infusion</i> | <i>Bag</i> | <i>Trade name</i> |
| <i>Injection</i> | | | |
| Words relating to "Route": | | | |
| Parenteral | Intrapleural | Epidural line | |
| Subcutaneous | Intraperitoneal | Pitcath | |
| Intravenous | Intra-articular | Infusion device | |
| Intradermal | Central Line | Syringe driver | |
| Intramuscular | Arterial line | PCA device | |
| Intrathecal | Hickman Line | Urinary Catheter into the bladder | |
| <i>Long lines</i> | <i>Porta Cath</i> | <i>P.I.C.C. line</i> | |

5.9 Collaboration

The reasons for testing the researcher's established graphical methodology for illustrating the inter-relationship between Health Districts (Gandy, 1979) are set out in Chapter 2. It allowed for measures of the volumes of patients treated within autonomous NHS organisations and the traffic between them, and described the degree of self-sufficiency. This passed the first test for methods not directly related to "collaboration" in that the Trusts could be seen as equivalent to Health Districts and volumes of aseptic products could be seen as equivalent to patients. The degree of self-sufficiency could be deemed a measure of "collaboration" because the greater the self-sufficiency of each organisation the less collaboration was in place.

The first results were to define the collaboration measures in a similar way to those used between Health Districts, viz.

Indicator A Percentage (of products) Locally Produced (that were used within Trust)

$$= \frac{\text{Number of Products Produced for Use within Trust} \times 100}{\text{Total Products Produced}}$$

Indicator B Percentage (of products) Locally Used (that were produced within Trust)

$$= \frac{\text{Number of Products Produced for Use within Trust} \times 100}{\text{Total Products Used}}$$

It was confirmed that the data required to support the calculation of these indicators was all included in that that finally agreed to be collected. Details of the results for each Trust in tabular format are shown in Section 11.25.

Figure 5.9.1 First Draft Collaboration Diagram By Trust Using Baseline Data

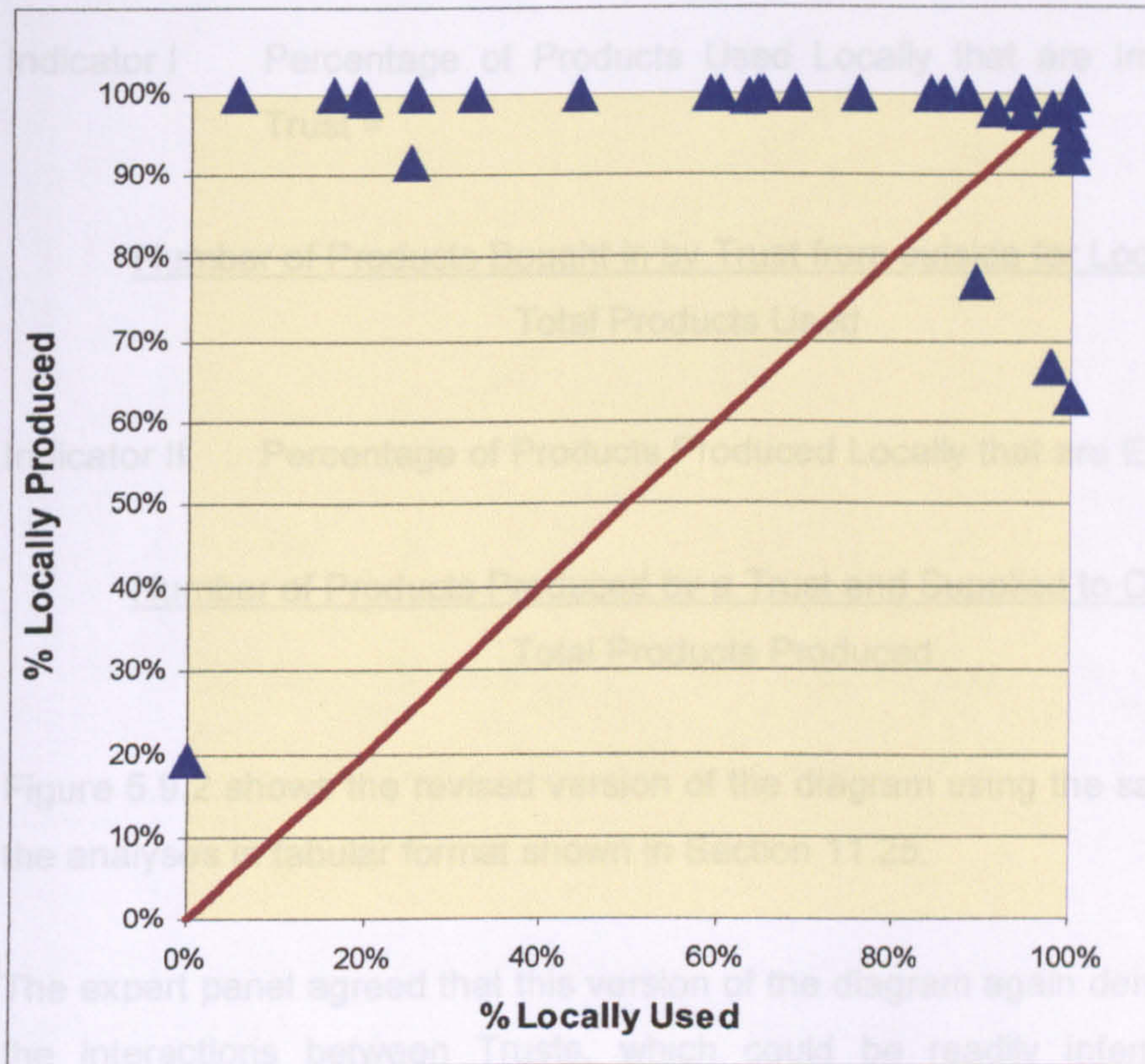


Figure 5.9.1 shows the results in the diagrammatic format: many Trusts were almost self sufficient in their production, with many not providing products for other Trusts, but receiving products in from others. The expert panel agreed that the diagram clearly demonstrated variations in the interactions between Trusts, which could be readily inferred as a measure of collaboration: the more Trusts gathered towards the (100 per cent, 100 per cent) point the more Trusts that were (virtually) self-sufficient, and the less collaboration was taking place. Therefore increased collaboration would be inferred from more Trusts moving away from the (100 per cent, 100 per cent) point. However, the panel felt uncomfortable with the measures themselves, in that they were quite difficult to describe and conceptualise. This was borne out from pharmacists' feedback. Accordingly consideration was given to whether the approach could be modified in some way that would be fully acceptable.

The process yielded measures that were effectively the inverse of those tried first, and used vocabulary that could be readily understood. Products that one Trust to another were described as being “exported” by the former Trust and “imported” by the latter. Therefore the second indicators tested were as follows:

Indicator I Percentage of Products Used Locally that are Imported from outside a Trust =

$$\frac{\text{Number of Products Bought in by Trust from outside for Local Use} \times 100}{\text{Total Products Used}}$$

Indicator II Percentage of Products Produced Locally that are Exported from a Trust =

$$\frac{\text{Number of Products Produced by a Trust and Supplied to Other Trusts} \times 100}{\text{Total Products Produced}}$$

Figure 5.9.2 shows the revised version of the diagram using the same baseline data, with the analyses in tabular format shown in Section 11.25.

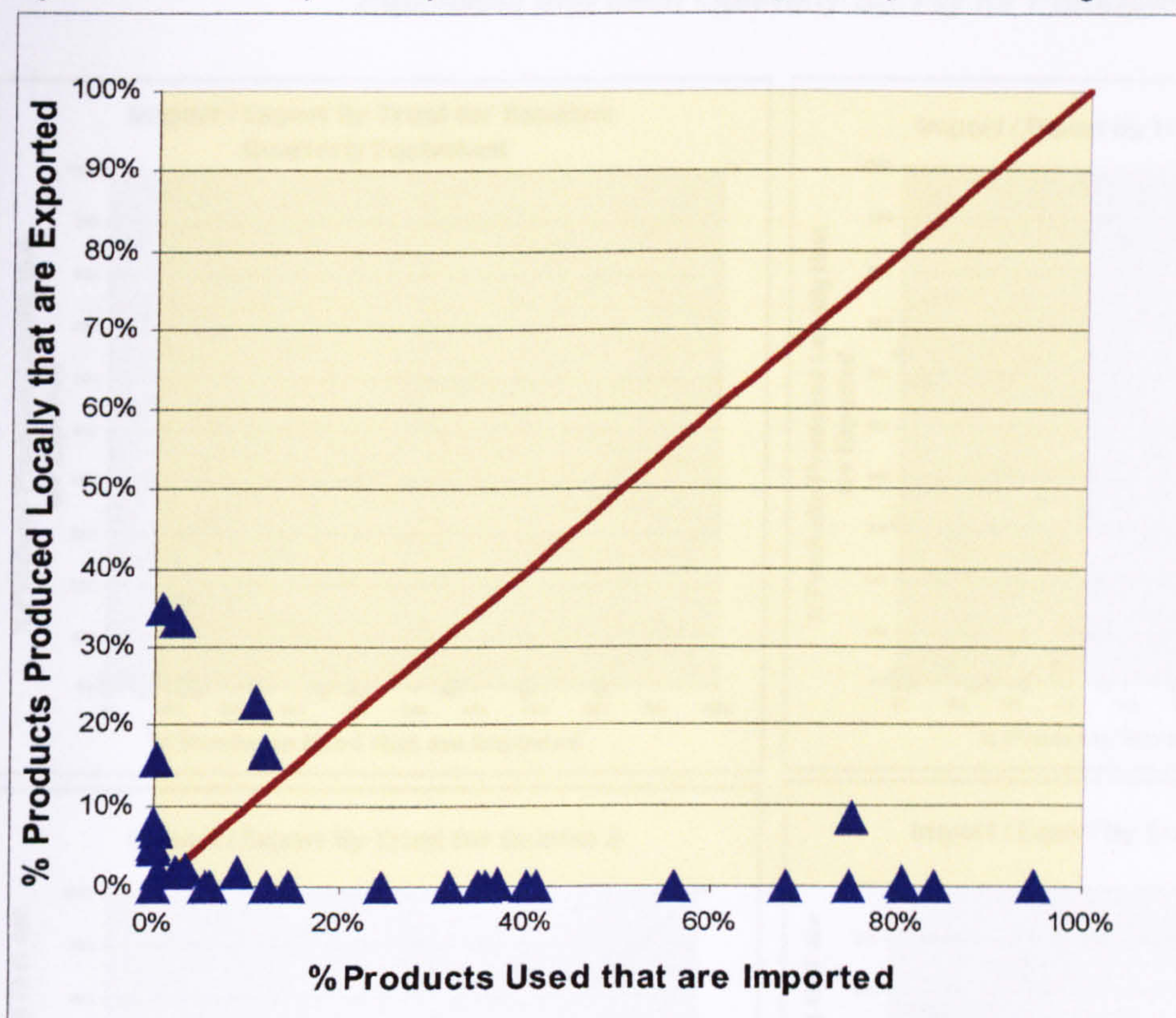
The expert panel agreed that this version of the diagram again demonstrated variations in the interactions between Trusts, which could be readily inferred as a measure of collaboration. More importantly, it was able to be readily comprehended by pharmacists and managers, a view which was endorsed following dissemination.

Key results included:

- Aggregating the data across all Trusts indicated that there were a total of 231,651 products sourced from outside the trust where the product was used (imported).
- There were a total of 114,161 products produced within Trusts for use by outside parties (exported).
- The difference between the two is largely attributable to the former including commercial unlicensed products, of which there were 122,753.

(The data used for Figures 5.9.1 and 5.9.2 are provided in Section 11.25).

Figure 5.9.2 Import/ Export Collaboration Diagram By Trust Using Baseline Data



Application of the model to the quarterly data showed that the evolution of collaboration over time could be demonstrated in two different ways. The first is illustrated in Figure 5.9.3, which is to apply the model to data for each point in time and then place the resultant diagrams alongside one another so that the eye can detect changes in the patterns. This is supplemented by the actual values of the two indicators for each point in time, which can be set in tables and trends quantified using traditional statistical techniques, e.g. percentage change from baseline.

The second way is to calculate the aggregate values of the indicators and then apply them to a single diagram, with the sequence being highlighted by arrows linking the points in turn, as in Figure 5.9.4. Table 5.9.1 shows the data behind the values.

The results relating to how the model compared patterns and trends in different areas, and for individual product types are shown in sections 5.16 and 5.17.

Figure 5.9.3: Import/ Export Collaboration Diagram for Baseline Quarterly Equivalent and each Quarterly Survey for Participating Trusts

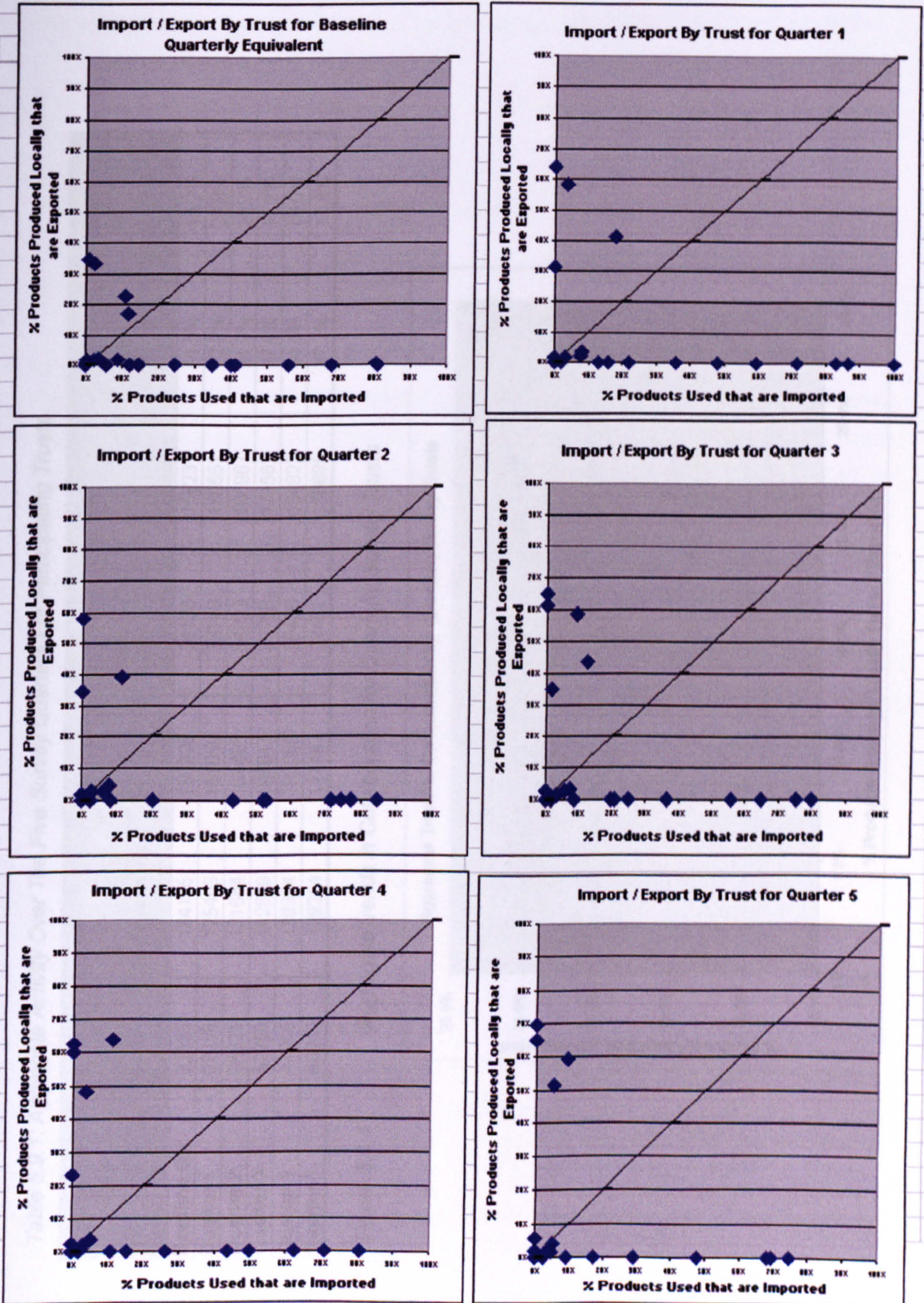
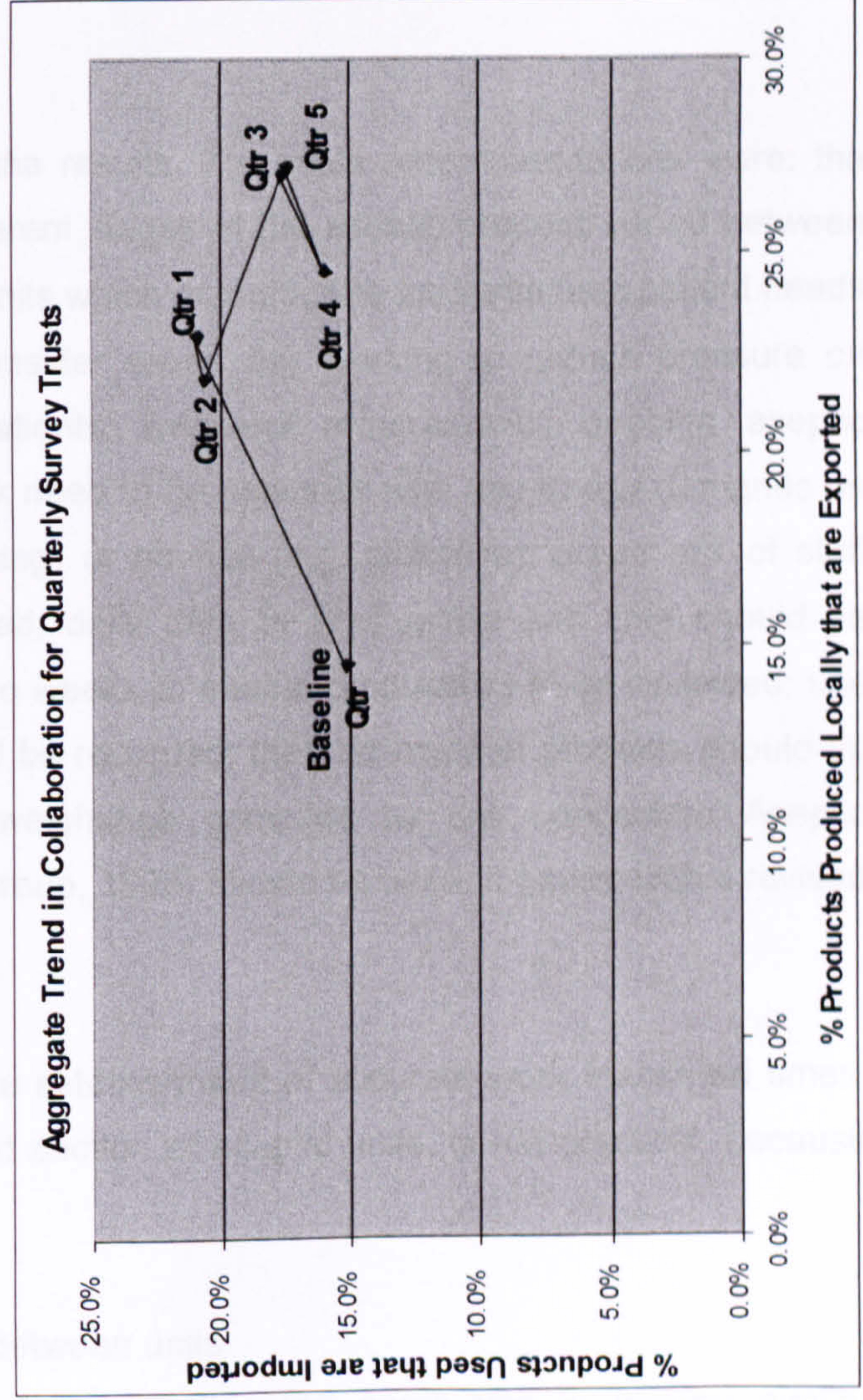


Table 5.9.1: Aggregate Activity Over The Five Survey Quarters For Participating Trusts

| Quarter | Produced Within Trust for use Elsewhere (Exported) | Produced for use within Trust | Total Produced | Obtained from Source Outside Trust (Imported) | Total Usage | % Produced Locally that are Exported | % Products Used that are Imported |
|--------------|--|-------------------------------|----------------|---|-------------|--------------------------------------|-----------------------------------|
| Baseline Qtr | 22823 | 134105 | 156928 | 24126 | 158231 | 14.5% | 15.2% |
| Quarter 1 | 37256 | 125403 | 162659 | 33148 | 158551 | 22.9% | 20.9% |
| Quarter 2 | 36821 | 131664 | 168485 | 34303 | 165967 | 21.9% | 20.7% |
| Quarter 3 | 52758 | 142859 | 195617 | 30708 | 173567 | 27.0% | 17.7% |
| Quarter 4 | 44905 | 138384 | 183289 | 26438 | 164822 | 24.5% | 16.0% |
| Quarter 5 | 48243 | 129254 | 177497 | 27431 | 156685 | 27.2% | 17.5% |

Figure 5.9.4 Aggregate trends in Collaboration for Quarterly Survey Trusts



5.10 Work Study

The work-study professional visited six aseptic units:

- Burnley General Hospital
- Manchester Children's Hospital
- Royal Preston Hospital
- Stockport Acute Services (Stepping Hill)
- Whiston Hospital
- Wirral Hospitals (Arrowe Park)

See Section 11.28 for full details of the results. The main recommendations were: the involvement of pharmacists in the different stages of the aseptic process varied between hospitals, and was often not optimal; units which manufacture for immediate patient needs and work a five day week should consider seven day working to reduce pressure on Thursdays and Fridays to meet patients' weekend requirements; ongoing aseptic production cycles/patterns over a week need to be balanced with day-to-day demands on staff that can be predicted (e.g. training) or ad hoc (e.g. sickness); grade mix of staff should be reviewed to reflect workload; daily data by staff grade and time should be collected by units for a minimum of two weeks to enable productivity to be reviewed; use and non use times for cabinets should be recorded; the true costs of products should be used for pricing products; activity weightings compiled by the Lancashire Aseptic Managers (North West Aseptic Task Group, 1998) should be used, together with a revised recording system.

A key conclusion reached was that the establishment of accurate work measured times, which could be applied across a broad section of aseptic units, is not practical, because of:

- (a) The different methods of work between units.
- (b) The wide variations that occur even within the same unit in making similar products. For example, one unit visited prepare 37 different types of syringes, where the number of ampoules required to make one syringe can be as many as 25.
- (c) The process time involved in making similar products can vary depending on the speed with which solutions mix.

In terms of when aseptic units were operational, the professional stated that “most units actually start to use their cabinets at about 9.30 a.m. and finish at about 3.30 p.m. with a stoppage of an hour or so for lunch”.

To illustrate the results of timings undertaken in respect of processes, the consultant provided examples for different product types. These are shown in Tables 5.10.1 –5.10.3 below. On the basis of these and his other studies, the consultant considered that the in aggregate cabinet time accounted for approximately one third of the total aggregate activity time, varying between 25 per cent and 40 per cent for observed products.

Table 5.10.1 Selected Process Timings
Minibag Plus (50 Ml; One Vial per Bag) – Batch of 50
(Flucloxacillin 1g)

| ELEMENT No. | ELEMENT DESCRIPTION | BASIC MINUTES |
|--------------------|--|----------------------|
| 1 | Receive Instructions | 1.00 |
| 2 | Obtain Worksheets, Batch Nos., Complete Batch No. Book | 3.00 |
| 3 | Obtain Tray, Tote Box, Vials & Minibags | 4.00 |
| 4 | Spray Tray, Tote Box, Vials & Minibags | 3.00 |
| 5 | Set up Computer and Print off 51 Labels | 2.50 |
| 6 | Obtain Finger Plates & Labels, Attach & Complete Label | 1.50 |
| 7 | Load Hatch (3 occasions); Unload Hatch (3 Occasions)* | 6.00 |
| 8 | Gown Up (Suit, Hat, Gloves, Mask, Boots) | 3.00 |
| 9 | Strip off Outer Wraps of Minibags | 3.00 |
| 10 | Spray Minibags after Stripping | 2.50 |
| 11** | Gown Up - Put on Additional Outer Garments | 1.00 |
| 12** | Clean Cabinet using Spray & Wipes | 2.00 |
| 13** | Finger Plates, Wipe and put into Cabinet | 1.00 |
| 14** | Snip off Tops of Vials and Wipe | 2.50 |
| 15** | Spray Minibags into Cabinet | 2.00 |
| 16** | Assemble Minibags to Vials | 3.00 |
| 17** | Clean Cabinet after Use | 2.00 |
| 18 | Remove Protective Clothing | 3.00 |
| 19 | Wipe Minibags Dry and Label | 5.00 |
| 20 | Put into Plastic Bags and Seal, Aside | 5.00 |
| 21 | Book off Computer | 3.00 |
| | TOTAL | 59.00 for 50 |
| | Personal Needs /Rest & Fatigue + General Allowances - ADD 30 per cent | 76.70 |

* Depending on layout of Aseptic Unit. In most Units this would be 8 occasions in total.

** Element used in calculation of Cabinet Capacity

Percentage of total Process time relating to Cabinets: 23 per cent

Table 5.10.2 Selected Process Timings

Minibag Solution (50 MI) - BATCH OF 20 (Ranitidine); Syringe used in Assembly

| ELEMENT No. | ELEMENT DESCRIPTION | BASIC MINUTES |
|-------------|--|---------------|
| 1 | Receive Instructions | 1.00 |
| 2 | Obtain Worksheets, Batch Nos., Complete Batch No. Book | 3.00 |
| 3 | Obtain Tray, Tote Box, Vials & Minibags | 4.00 |
| 4 | Spray Tray, Tote Box, Vials & Minibags | 3.00 |
| 5 | Set up Computer and Print off 51 Labels | 2.50 |
| 6 | Obtain Finger Plates & Labels, Attach & Complete Label | 1.50 |
| 7 | Load Hatch (3 occasions); Unload Hatch (3 Occasions)* | 6.00 |
| 8 | Gown Up (Suit, Hat, Gloves, Mask, Boots) | 3.00 |
| 9 | Strip off Outer Wraps of Minibags | 1.20 |
| 10 | Spray Minibags after Stripping | 1.00 |
| 11** | Gown Up - Put on Additional Outer Garments | 1.00 |
| 12** | Clean Cabinet using Spray & Wipes | 2.00 |
| 13** | Finger Plates, Wipe and put into Cabinet | 1.00 |
| 14**) | Snap off Tops of Vials, Fill Syringe, Insert Syringe to Minibag, | |
| 15**) | Complete Assembly and Aside | 15.00 |
| 16**) | | |
| 17** | Clean Cabinet after Use | 2.00 |
| 18 | Remove Protective Clothing | 3.00 |
| 19 | Wipe Minibags Dry and Label | 5.00 |
| 20 | Put into Plastic Bags and Seal, Aside | 2.00 |
| 21 | Book off Computer | 1.00 |
| | TOTAL | 58.20 for 20 |
| | Personal Needs /Rest & Fatigue + General Allowances - ADD 30 per cent | 75.70 |

* Depending on layout of Aseptic Unit. In most Units this would be 8 occasions in total.

** Element used in calculation of Cabinet Capacity

Percentage of total Process time relating to Cabinets: 36 per cent

Table 5.10.3 Selected Process Timings:

TPN – Neonatal (Time for one TPN Neonatal)

| ELEMENT No. | ELEMENT DESCRIPTION | "ONE OFF" BASIC MINUTES | BATCH OF 5 BASIC MINUTES |
|----------------|--|----------------------------------|-----------------------------------|
| 1 | Receive Instructions | 1.00 | 1.00 |
| 2 | Obtain Worksheets, Batch Nos., Complete Batch No. Book | 0.40 | 2.00 |
| 3 | Obtain Tray, Vial, Minibag etc. (13 Items on Tray) (Est.) | 10.00 | 35.00 |
| 4 | Spray Tray to Hatch (3 Occasions, 2 Sprays each) | 1.20 | 6.00 |
| 5 | Set up Computer, Enter Baby's Name, Amend & Print off Labels/Worksheet | 4.80 | 24.00 |
| 6 | Obtain Finger Plates | 1.50 | 1.50 |
| 7 | Load Hatch (1 occasion); Unload Hatch (3 Occasions) 0.20 x 3 | 0.60 | 3.00 |
| 8 | Gown Up (Fully Gowned) | 5.00 | 5.00 |
| 9 | - | - | - |
| 10 | - | - | - |
| 11 | - | - | - |
| 12** | Clean Cabinet etc. | 2.00 | 2.00 |
| 13** | Finger Plates to Cabinet | 1.00 | 1.00 |
| 14 | - | - | - |
| 15 | - | - | - |
| 16** | Assemble in Cabinet (Inc. Wipe Cabinet between Ass.) | 11.60 | 58.00 |
| 17** | Clean Cabinet after Use | 2.00 | 2.00 |
| 18 | Remove Protective Clothing | 3.00 | 3.00 |
| 19 | - | - | - |
| 20 | Put up Plastic Bag, put in TPN, Seal and Aside | 0.40 | 2.00 |
| 21 | Book off Computer | 0.40 | 2.00 |
| | TOTAL | 44.90 | 147.50 |
| | Personal Needs /Rest & Fatigue + General Allowances - | | for 5 |
| | ADD 30 per cent | 58.40 | 191.80 |
| | | | for 5 |
| | TIME FOR ONE | 58.40 | 38.40 |

In addition, there is work undertaken by a Pharmacist that not included in the above for 5 Neonatal TPNs. This is summarised as follows:

- (A) Calculate requirements for 5 babies = 11.00 minutes;
- (B) Check all parts of tray preparation before 2nd room = 22.00 minutes;
- (C) Check each tray after completion = 2.50 minutes per tray;
- (D) Balance residue of vials = 6.00 minutes. Average time for Tray = 10.30 minutes

**** Element used in calculation of Cabinet Capacity**

Percentage of total Process time relating to Cabinets ("One-Off"): 37 per cent

Percentage of total Process time relating to Cabinets ("Batch"): 43 per cent

5.11 Unit Time Equivalents

Table 5.11.1 provides summary details of the progression of the UTE values through the process described in Section 4.11. The finally agreed UTE values were ascribed the title of "Marker UTEs" by the expert panel, because they are for benchmarking purposes, and are not fixed performance targets (see Section 6.8 for discussion)

Twenty questionnaires were received from aseptic managers across the North West, which represented a 69 per cent response. Eighteen of these were handed in at the Aseptic Managers Study Day (see Section 4.11).

Table 5.11.2 provides a summary analysis of the responses. A full analysis is in Section 11.30.

The degree of agreement was substantial, with over half of the product categories getting an agreement level of at least 70 per cent. The remaining product categories had agreement levels of between 40 and 60 per cent.

The aseptic managers advised that the differences highlighted by the survey seemed largely attributable to whether aseptic preparation was licensed or unlicensed. It was realised that the preliminary UTE values had actually been set for unlicensed production, and UTEs for licensed production had been inadvertently ignored. Therefore it was decided that each product should have two UTE values – one for where production is licensed and one for where it is not.

The finally agreed Marker UTEs for licensed and unlicensed units can be seen in Table 5.11.1, together with the minima and maxima values set by using regression analysis. There were strong relationships for both: R² values of 0.93 & 0.85 when the regression line was forced through the origin, and 0.94 & 0.88 respectively when the regression line was unforced (see Figures 5.11.1 – 5.11.4).

When the mean UTE values had been finalised it was realised that the values for unlicensed products were broadly 50 per cent higher than the licensed equivalent. This was not predetermined, but the expert panel agreed that in retrospect it was a reasonable reflection of the difference between the circumstances.

Table 5.11.1 Summary of Progression of UTE Values

| Product Categories Used In Research | Preliminary View considered by Expert Group | Expert Group View tested with Aseptic Managers | Finally Agreed Marker UTE: Licensed | | Finally Agreed Marker UTE: Unlicensed | |
|-------------------------------------|---|--|-------------------------------------|-----------------|---------------------------------------|-----------------|
| | Mean Time (in minutes) | Mean Time (in minutes) | Mean Time (in minutes) | Minima & Maxima | Mean Time (in minutes) | Minima & Maxima |
| Cardioplegia Solutions | 15 | 15 | 10 | 7.5 & 15 | 15 | 12 & 23 |
| Cytotoxics | 15 | 15 | 6 | 4.8 & 10 | 10 | 7.5 & 15 |
| Epidural Injections | 7.5 | 7.5 | 5 | 4 & 8 | 7.5 | 6 & 12 |
| Eye Drops/Eye Irrigations | 7.5 | 7.5 | 5 | 4 & 8 | 7.5 | 6 & 12 |
| Irrigations (Exc. Ophthalmic) | 7.5 | 7.5 | 5 | 4 & 8 | 7.5 | 6 & 12 |
| Minibag Plus | 1.5 | 1.5 | 1 | 0.8 & 2 | 1.5 | 1.2 & 7 |
| Minibag/Infusion | 3 | 3 | 3 | 2.4 & 3 | 5 | 4 & 8 |
| Injection Devices | 12 | 12 | 12 | 9 & 19 | 18 | 14 & 26 |
| Prefilled Syringes | 6 | 6 | 6 | 4.8 & 10 | 10 | 7.5 & 15 |
| TPN – Adult: Compounded | 45 | 45 | 20 | 15 & 29 | 30 | 24 & 41 |
| TPN – Adult: Simple | 15 | 15 | 10 | 7.5 & 15 | 15 | 12 & 23 |
| TPN – Neonatal/Paediatric | 45 | 45 | 30 | 24 & 41 | 45 | 36 & 60 |
| Other* | 7.5 | 7.5 | 5 | 4 & 8 | 7.5 | 6 & 12 |

* It was appreciated that “Other” covered a wide range of products. The figure shown was thought to strike a balance across the types of products involved.

Table 5.11.2 Summary Results from Survey of North West Aseptic Managers as to their agreement with the Proposed Average Production Times/UTEs

| Product Type | Proposed Average Time | No. Agreed with Proposed Average Time | No. Disagreed with Proposed Average Time | % Agreement | Mean of Stated Alternative Average Times | Difference | Lowest Minimum Ave Time | Highest Maximum Ave Time |
|--------------------------------------|------------------------------|--|---|--------------------|---|-------------------|--------------------------------|---------------------------------|
| Cardioplegia Solutions | 15 | 19 | 1 | 95% | 40 | 25 | 10 | 50 |
| Cytotoxics | 15 | 14 | 6 | 70% | 27 | 12 | 5 | 60 |
| Epidural Injections | 7.5 | 15 | 5 | 75% | 23 | 16 | 10 | 45 |
| Eye Drops/Eye Irrigations | 7.5 | 14 | 6 | 70% | 16 | 8 | 2.5 | 40 |
| Irrigations (exc. Ophthalmic) | 7.5 | 18 | 2 | 90% | 21 | 14 | 5 | 40 |
| Minibag Plus | 1.5 | 16 | 4 | 80% | 15 | 14 | 0.5 | 35 |
| Minibag/Infusion | 3 | 8 | 12 | 40% | 14 | 11 | 3 | 45 |
| Injection Devices | 12 | 11 | 9 | 55% | 23 | 11 | 5 | 50 |
| Prefilled Syringes | 6 | 9 | 11 | 45% | 17 | 11 | 3 | 45 |
| TPN - Adult: Compounded | 45 | 12 | 8 | 60% | 41 | -5 | 17.5 | 90 |
| TPN - Adult: Simple | 15 | 12 | 8 | 60% | 31 | 16 | 5 | 90 |
| TPN - Neonatal/Paediatric | 45 | 10 | 10 | 50% | 53 | 8 | 17.5 | 90 |
| Other | 7.5 | 18 | 2 | 90% | 20 | 13 | 20 | 60 |

Figure 5.11.1

Regression Chart: Relationship between Minimum & Mean Production Times (Unforced)

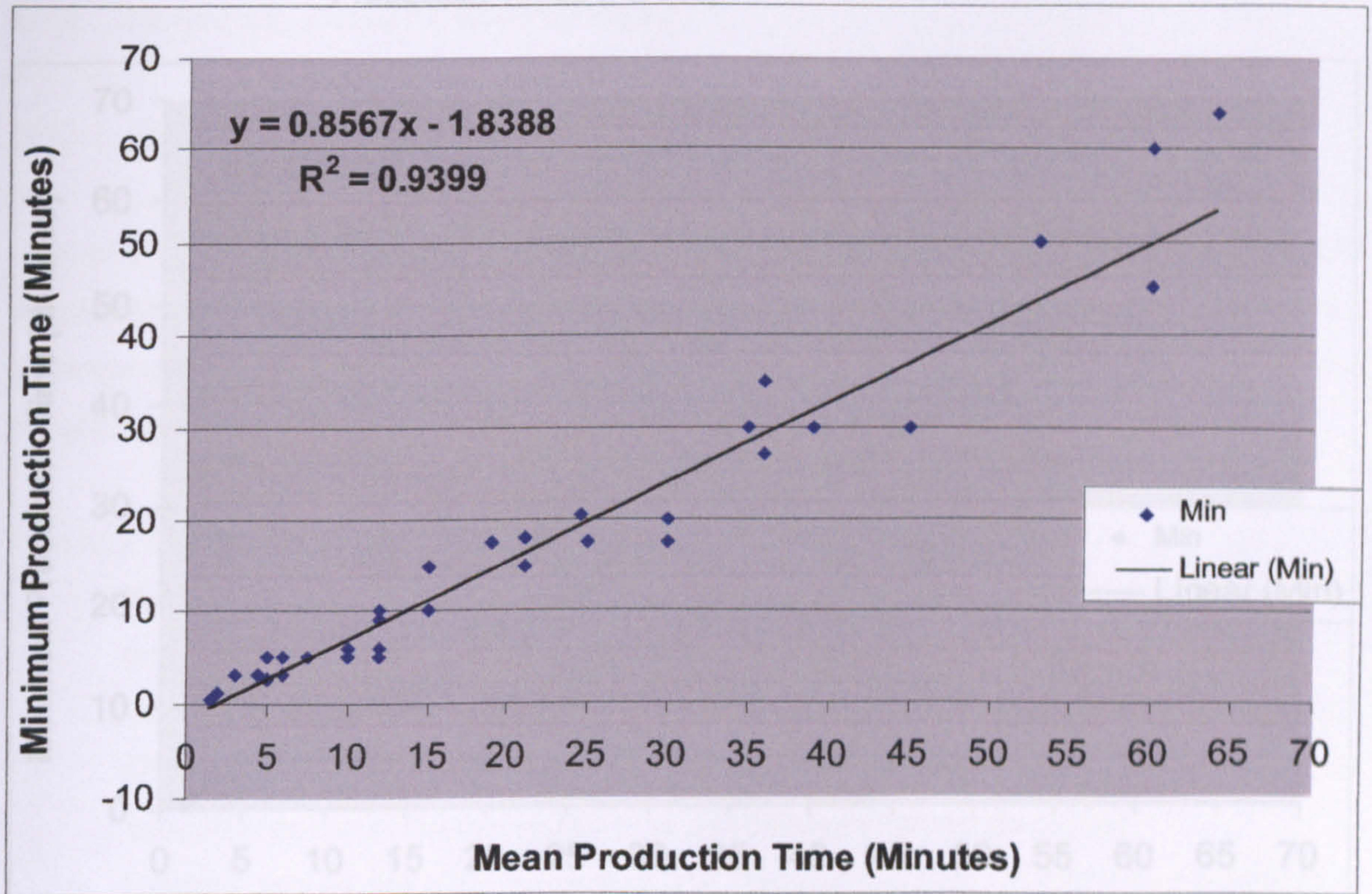


Figure 5.11.2

Regression Chart: Relationship between Maximum & Mean Production Times (Unforced)

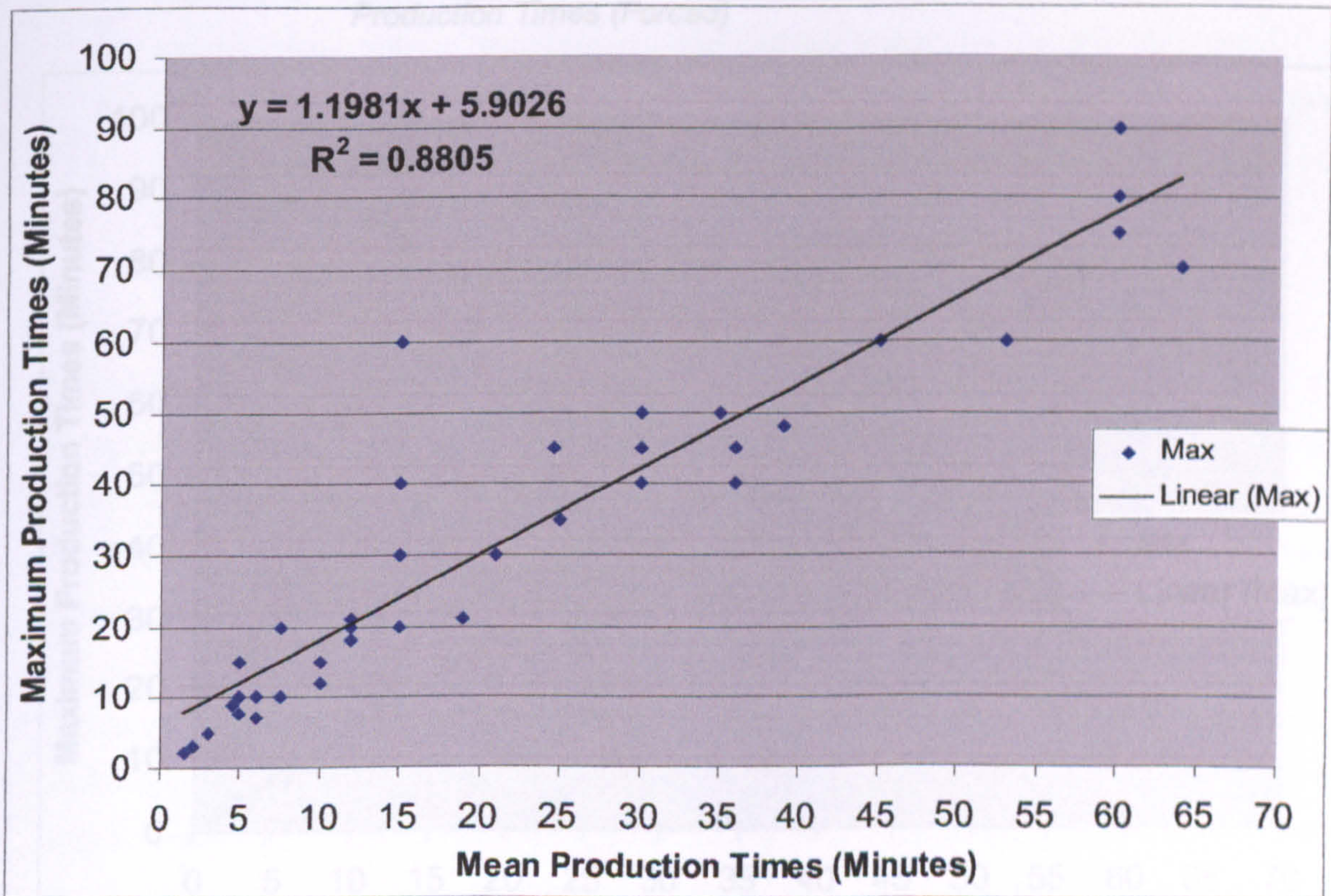


Figure 5.11.3

Regression Chart: Relationship between Minimum & Mean Production Times (Forced)

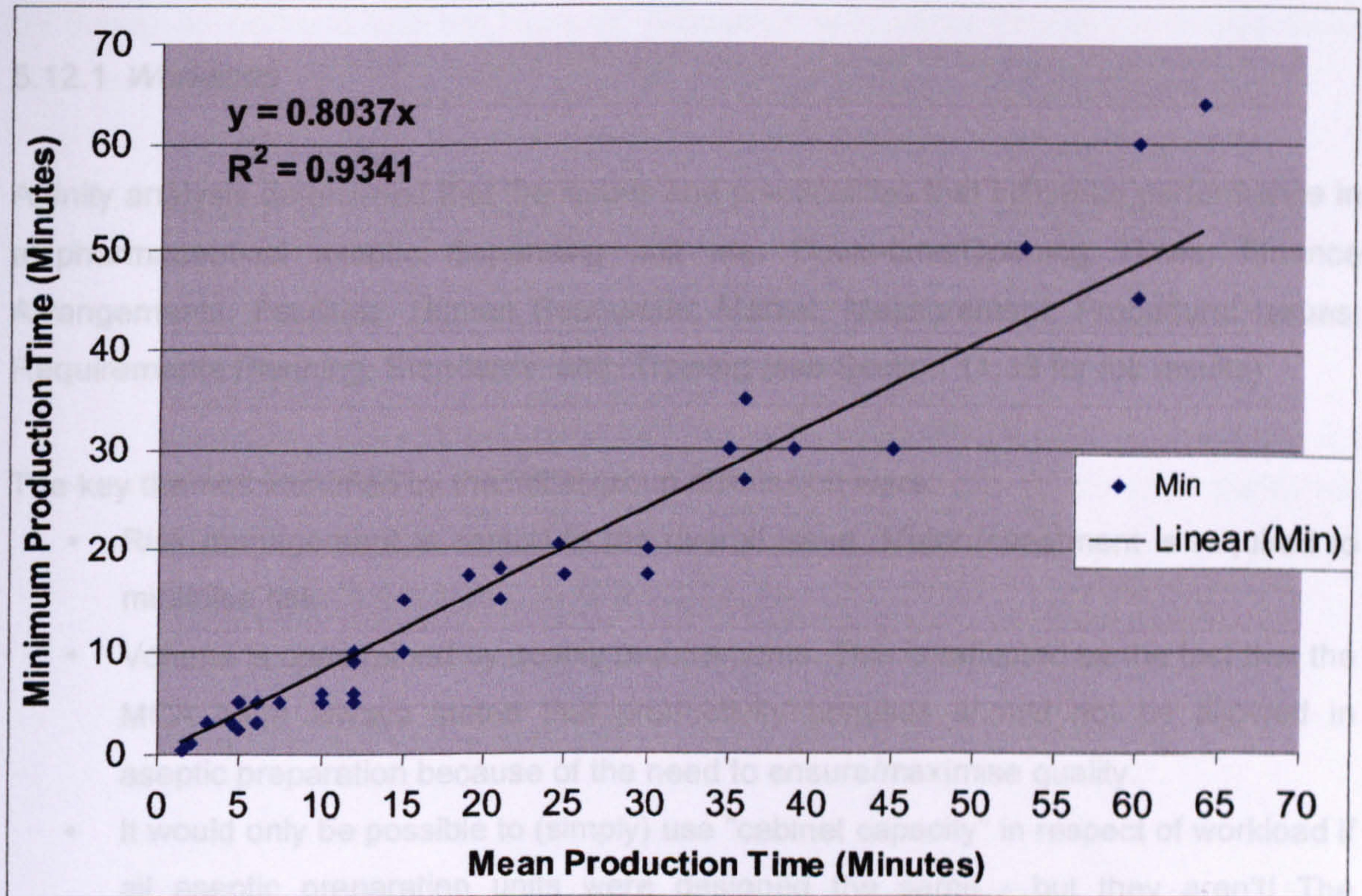
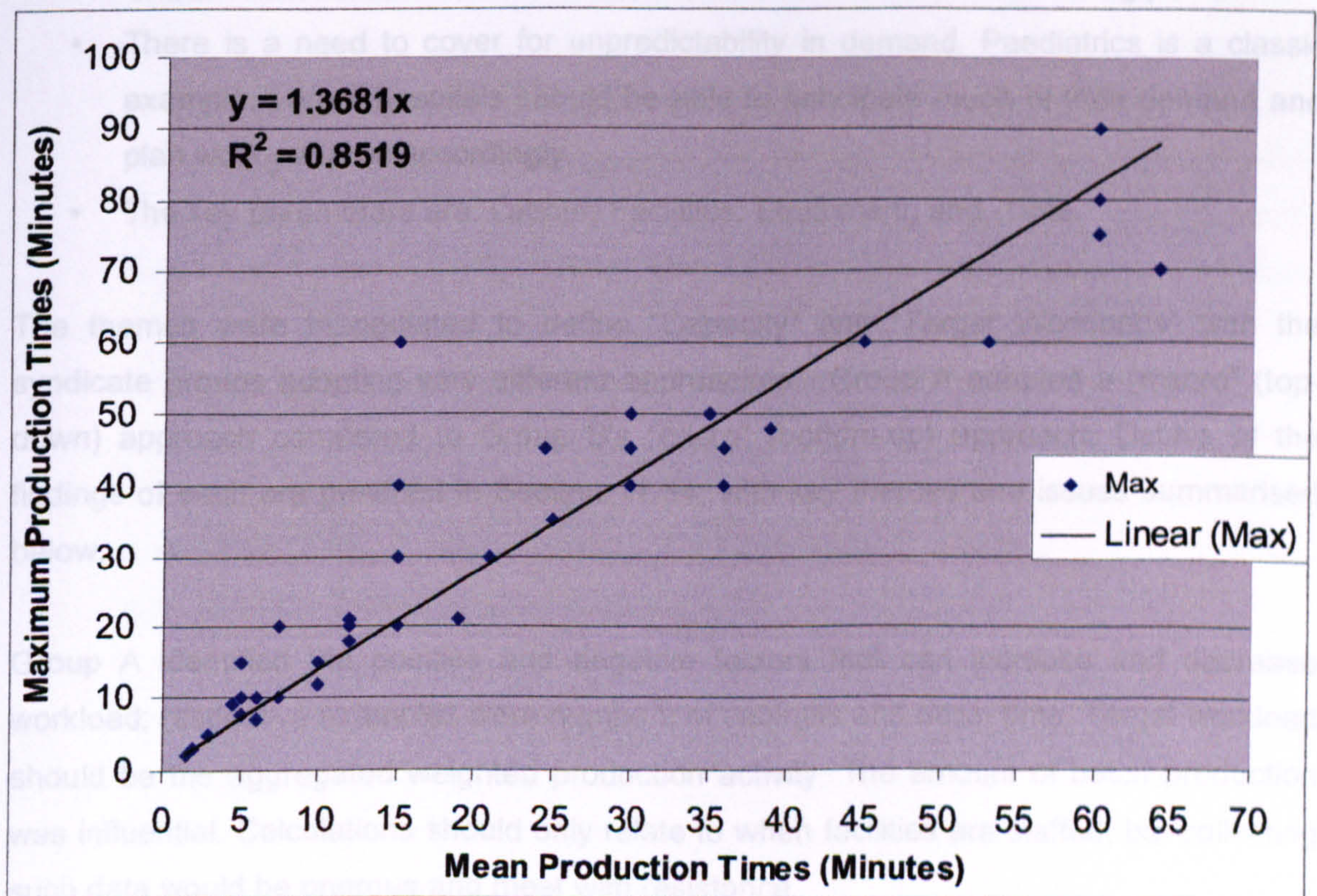


Figure 5.11.4

Regression Chart: Relationship between Maximum & Mean Production Times (Forced)



5.12 Concepts: Capacity and Workload

5.12.1 Workshop

Affinity analysis determined that the issues and practicalities that influence performance in a pharmaceutical aseptic dispensing unit are: Down-time/Opening Times; Finance Arrangements; Facilities; Human Resources; Market; Measurement; Procedural Issues; Requirements Planning; Standards; and, Training (see Section 11.33 for full results).

The key themes identified by the initial group discussion were:

- Risk management is central to the overall issue. Major investment is required to minimise risk.
- Volume is constrained by quality requirements. This is reflected by the fact that the MCA have always stated that productivity bonuses should not be allowed in aseptic preparation because of the need to ensure/maximise quality.
- It would only be possible to (simply) use "cabinet capacity" in respect of workload if all aseptic preparation units were designed the same - but they aren't! The introduction of an extra cabinet would not mean a proportional increase in the capacity of a unit, because there would need to be similar improvements to the overall infrastructure. Nevertheless, the Cabinet should be the starting point.
- There is a need to cover for unpredictability in demand. Paediatrics is a classic example. Larger hospitals should be able to anticipate much of their demand and plan work patterns accordingly.
- The key parameters are: Labour; Facilities; Equipment; and, Time.

The themes were triangulated to define "Capacity" and "Target Workloads" with the syndicate groups adopting very different approaches. Group A adopted a "macro" (top-down) approach compared to Group B's "micro" (bottom-up) approach. Details of the findings of each are provided in Section 11.34, with key themes and issues summarised below.

Group A identified the positive and negative factors that can increase and decrease workload; respective examples were numbers of cabinets and down time. Target workload should be the aggregated weighted production activity. The amount of batch production was influential. Calculations should only relate to when facilities are staffed, but collecting such data would be onerous and meet with resistance.

Group B determined that there are constraints in the process flows, particularly cabinets: the capacity of a unit is the maximum throughput of the cabinets. Target workload should be based on demand and not capacity. Allowance is required for non-production tasks such as training.

5.12.2 *Final Workshop Conclusions*

The two syndicate group approaches were complementary to one another, although this view was not unanimous. The main overall results are:

- The research data could be used with Group A's approach although additional information would be necessary: Time a Unit was open, Numbers and Types of Equipment, and Unit Weightings for Products.
- Group B's approach required more detailed information than the research data, which would be hard to collect, allowing for the fact that no two units are designed or resourced the same.
- Staffing and staff mix are key (see Section 5.14) but even where existing information systems provide related data it is not necessarily of a quality or detail that would be directly helpful. Pharmacists are reluctant to keep providing more and more data, particularly if there is no practical feedback (and the potential "threat" of how figures might be (ab)used).
- The only additional data required for the research is the number of cabinets (i.e. laminar air flow cabinets and pharmaceutical isolators), as it effectively describes the size of an aseptic dispensing unit. The number of cabinets is required rather than the number of associated workstations, because, in practice, in NHS aseptic units, only one operator would carry out aseptic manipulation in multiple-workstation cabinets at a time.
- How any figures are used is clearly important. The research (at this point) envisaged a benchmarking approach to inform Trusts of their relative position to one another, and allow for their different circumstances. To try and specify exact workloads and capacities based on the comparatively limited data would be very difficult and probably counterproductive.

The results of the out-turn questionnaire survey were that the workshop was a success from the perspective of how it was organised. There were mixed responses about whether the workshop and syndicate groups achieved their objectives (see Section 11.36).

5.12.3 Views of Expert Panel

In response to the workshop's advice, the expert panel (upon triangulation) decided that:

- No consensus could be reached about definitions for capacity and workload. The lack of consistency in aseptic unit design was a major constraint. Capacity was generally viewed as a measure of a unit's ability to maximise its workload.
- Each unit or Trust should develop its own capacity plan. Although capacity plans should be developed locally, they should be open to external scrutiny, particularly where collaborative arrangements are in place.

The expert panel also evaluated the relative merits of the approaches adopted by the syndicate groups and that described in the Work Study report (See Section 11.28) and concluded that:

- Group A's approach is unlikely to be used more than as a theoretical background.
- Group B's approach requires considerably more information than in the baseline survey, to take full account of all the factors (especially on staffing and staff mix) that influence capacity. Collecting such a large amount of information for all trusts would be difficult in terms of ensuring data quality and consistency. Even if the data could be collected, there would still be issues about how it should be used. Clarity about the benefits and use of additional data is essential to be able to justify requests for data from pharmacists.
- The approach from the Work Study report was the most practical and acceptable choice for utilisation within the research, as its only additional data requirements are the number (and types) of cabinets in each aseptic dispensing unit, and whether any are used for specialist purposes. The former would be available centrally (with Regional Quality Controllers) and the latter represents a reasonable "one-off" request.

5.12.4 Validation by Regional Quality Control Pharmacists

The presentation to the validation session at the Audit Training Course in Birmingham endorsed and added to the findings, which were all triangulated (see Section 11.38):

- There is little or no consistency in the design (and some other factors) of aseptic units across the country.
- The mix of units varies in different parts of the country: there are over 30 Radiopharmacy units in Northern region but only four in the whole of Scotland.
- There is no general clinical homogeneity across hospitals.
- "Capacity" is the point beyond which production is "safe".
- The period against which capacity is measured is key. Friday afternoons are particularly busy, compared to the rest of the week. If activity were to be measured across the whole of the week (or a longer period) then the "peak" periods would be submerged in the statistics, and the aggregate activity level may appear "safe". Such detail can only be dealt with locally.
- The use of the term "capacity" is important: whilst the capacity for a single (half day) period from a safety perspective is X, then the capacity for the unit over a year could be argued as $X \times 10 \times 52$. However, this is an academic figure because allowance should be made for training, leave, etc. Continued "flat out" performance would be unacceptable.
- It would not be realistic to have a situation where production had achieved its capacity target for the day (ahead of the end of the day) with the staff then refusing to do any more even if there is time and the request is urgent.
- There is a need to be clear and consistent about any calculations.
- Each Trust should develop its own capacity plan.

5.13 Statistical Indicators

5.13.1 Developed Indicators

The statistical indicators that were developed focused on measuring the work actually done (which by definition is staffed) utilising available data, including the agreed Marker UTEs. The finally determined indicators followed the following stream of logic, based on a year's data:

- A** Take the number of each of the products produced within the aseptic dispensing unit/trust for the period.
- B** Weight the number of products by the associated Marker UTE value, allowing for whether or not a license is involved.
- C** Aggregate the weighted numbers to give a total *Aseptic Dispensing Unit Hours (ADUH)*. This represents the total (staffed) time involved in production.
- D** Divide the total in (C) by 52 to establish the average total staffed time involved in production per week. This is called *Aseptic Dispensing Unit Hours per Week (ADUHW)*, and it can be compared locally with the amount of time that a unit is normally open, which can vary considerably (Gandy *et al* (1998)* 1) .
- E** The *ADUHW* is then divided by the number of cabinets in an aseptic unit to give *Aseptic Dispensing Unit Hours per Week per Cabinet (ADUHWC)*, to allow for the simple assumption that a unit that has twice the number of cabinets as another unit should be able to produce twice as many products.
- F** The work study exercise established that of the order of one third of the total process involves the cabinets, aggregating across all product types. Therefore dividing *ADUHWC* by three gives a reasonable estimate of the average number of *Cabinet Hours per Week per Cabinet (CHWC)*, which gives a perspective of how intensively these important pieces of equipment are actually used.
- G** Clearly the mix of types of products will vary between units and this will impact on the way the units operate. In order to gauge the balance between the products it is straightforward to divide the aggregate total production time (C) by the total number of products produced for the period. This gives *The Average Weighted Time per Product (AWTP)*.

5.13.2 Calculating the Statistical Indicators Using Baseline Data

To validate the statistical indicators, their values were calculated for each Trust/unit using the baseline data. The results are set out in Table 5.13.1.

The results demonstrate the wide variation in the use made of the aseptic dispensing unit facilities:

- ADUHW figures ranged from 7 hours to 114 for licensed units and from 2 hours to 348 for unlicensed units.
- The number of cabinets was a clear factor, as ADUHC showed greater consistency, although variations were still marked: the indicator ranged from 7 hours to 38 for licensed and from 1 hour to 69 for unlicensed. The unit with the highest figure for licensed units only produced TPNs (which have high Marker UTEs). The highest figures for unlicensed units were all for high volume units.
- CHWC values showed only seven units appeared using each of their cabinets for more than two hours per day (with only one being licensed). This assumes that cabinet time is one third of the overall aseptic dispensing time. Work- study advice was that the range was from 25 per cent to 40 per cent according to the type of product prepared. Uplifting the percentage to 40 per cent across the board (i.e. a 20 per cent increase in the figures shown in Table 5.13.1) would mean that only one more unit would meet this level. (It should be appreciated that the statistic is by definition an average over a week and that there are necessarily variations in the workload, with Thursdays and Fridays generally being highest in preparation for the week-end, which would point to the cabinets being used very sparingly at other times).
- The values of AWTP varied between 1.7 and 20.7 minutes for licensed units, with a mean of 3.9. However, the higher figure related to the specialist TPN unit, and if this was ignored the upper limit was only 6.2 minutes, and the mean reduced to 3.4.
- For unlicensed units the AWTP varied between 3.5 and 25.5 minutes, with a mean of 9.2.

Table 5.13.1 Values of Statistical Indicators Using Baseline Survey Data

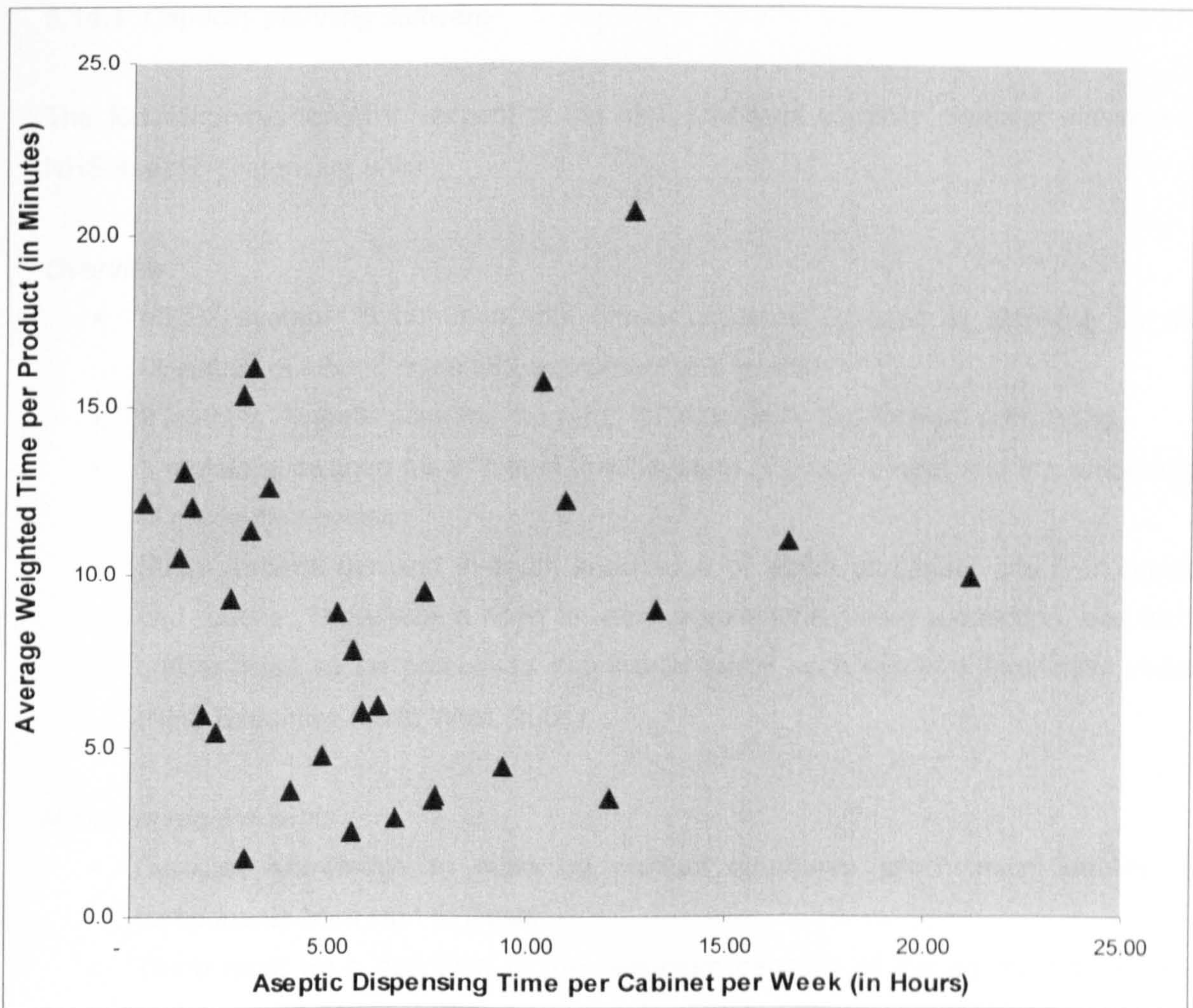
| Category | Trust Code | Total Products | Aseptic Dispensing Unit Hours Per Week | Number of Cabinets | Aseptic Dispensing Unit Hours Per Week Per Cabinet | Cabinet Hours Per Week Per Cabinet | Average weighted time per product |
|------------|------------|----------------|--|--------------------|--|------------------------------------|-----------------------------------|
| Licensed | 114 | 46,932 | 26.1 | 3 | 8.70 | 2.90 | 1.7 |
| Licensed | 115 | 59,941 | 84.3 | 3 | 28.1 | 9.37 | 4.4 |
| Licensed | 121 | 3,730 | 6.5 | 1 | 6.5 | 2.17 | 5.4 |
| Licensed | 122 | 28,173 | 56.1 | 3 | 18.7 | 6.23 | 6.2 |
| Licensed | 132 | 40,783 | 46.0 | 2 | 23.0 | 7.66 | 3.5 |
| Licensed | 134 | 104,093 | 114.7 | 5 | 22.9 | 7.64 | 3.4 |
| Licensed | 136 | 71,460 | 85.4 | 7 | 12.2 | 4.07 | 3.7 |
| Licensed | 140 | 17,077 | 113.5 | 3 | 37.8 | 12.61 | 20.7 |
| Licensed | 145 | 63,279 | 50.1 | 3 | 16.7 | 5.57 | 2.5 |
| Licensed | 151 | 18,086 | 35.1 | 2 | 17.5 | 5.84 | 6.0 |
| Licensed | 152 | 85,976 | 79.9 | 4 | 20.0 | 6.66 | 2.9 |
| Unlicensed | 111 | 20,184 | 50.4 | 3 | 16.80 | 5.60 | 7.8 |
| Unlicensed | 113 | 5,304 | 27.4 | 3 | 9.14 | 3.05 | 16.1 |
| Unlicensed | 117 | 39,575 | 126.8 | 2 | 63.4 | 21.14 | 10.0 |
| Unlicensed | 120 | 8,389 | 16.0 | 3 | 5.3 | 1.78 | 6.0 |
| Unlicensed | 127 | 3,550 | 13.7 | 3 | 4.6 | 1.52 | 12.0 |
| Unlicensed | 139 | 64,814 | 72.4 | 2 | 36.2 | 12.07 | 3.5 |
| Unlicensed | 141 | 55,101 | 158.9 | 4 | 39.7 | 13.24 | 9.0 |
| Unlicensed | 112 | 4,901 | 17.8 | 2 | 8.9 | 2.97 | 11.3 |
| Unlicensed | 118 | 18,488 | 92.8 | 3 | 30.9 | 10.31 | 15.7 |
| Unlicensed | 123 | 2,561 | 10.3 | 1 | 10.3 | 3.45 | 12.6 |
| Unlicensed | 124 | 449 | 1.8 | 2 | 0.9 | 0.29 | 12.2 |
| Unlicensed | 128 | 3,437 | 16.9 | 2 | 8.4 | 2.81 | 15.3 |
| Unlicensed | 129 | 27,164 | 77.5 | 5 | 15.5 | 5.17 | 8.9 |
| Unlicensed | 137 | 98,494 | 348.0 | 7 | 49.7 | 16.57 | 11.0 |
| Unlicensed | 138 | 33,377 | 130.9 | 4 | 32.7 | 10.90 | 12.2 |
| Unlicensed | 143 | 12,541 | 37.5 | 5 | 7.5 | 2.50 | 9.3 |
| Unlicensed | 144 | 21,888 | 66.6 | 3 | 22.2 | 7.40 | 9.5 |
| Unlicensed | 147 | 18,903 | 28.9 | 2 | 14.5 | 4.82 | 4.8 |
| Unlicensed | 148 | 2,167 | 7.3 | 2 | 3.7 | 1.22 | 10.5 |
| Unlicensed | 150 | 2,760 | 11.6 | 3 | 3.9 | 1.29 | 13.1 |

Sensitivity analyses were applied to the indicators to establish the effects of variations in the Marker UTE values (See Table 5.11.1). When the Minimum UTEs were applied, the indicators showed reductions of between 20 per cent and 24 per cent for licensed units and between 20 per cent and 25 per cent for unlicensed units. For the Maximum UTEs the licensed unit indicators increased by between 44 per cent and 78 per cent, whilst for unlicensed units they increased by between 38 per cent and 144 per cent. The mix of products was the main cause for the variations. For example, the figure of 144 per cent

was somewhat skewed by the fact that the unit concerned was a large producer of minibag plus, the maximum value of which was 7 minutes compared to a mean of 1.5 minutes. This range was proportionately the largest for any single product category. Otherwise the next largest increase was 88 per cent.

There is a research question as to whether the mix of products influence how much time units are used for. However, a scatter diagram (Figure 5.13.1) linking the two relevant statistics clearly shows that this is not the case.

Figure 5.13.1 Scattergram of AWTP and ADUHC Values for Baseline Data



The expert panel concluded that the results demonstrated the value of both the data collected and the way it was analysed. The statistical indicators highlighted the diversity of how aseptic dispensing units are used across the North West. The derivation of the statistics was valid, and whilst there was inevitably a degree of statistical "noise" by the very nature of the Marker UTEs, the differences identified were too large to be attributable to this.

The expert panel advised that the indicators should be used to provide a profile of the workload for each unit, thereby enabling comparative performance to be benchmarked and interpreted locally to inform the development of capacity or workload. All required data is available from the baseline and quarterly surveys, and the Marker UTEs, with the number of cabinets readily obtained.

The response from North West pharmacists, through the zonal networks and reported to the expert panel, was positive to the statistical indicators and their usage, illustrating that they were readily understood in the field.

5.14 Modelling

5.14.1 Capacity planning software

The following was found in respect of the applicability of capacity planning software to NHS aseptic dispensing units:

Overview

- MRP2 system, in common with similar systems, is used in planning for the utilisation of labour, materials, equipment and facilities.
- It leads to dynamic planning, applying finite capacity and forward scheduling.
- It makes allowance for a "just-in-time" system of procurement and the smoothing of production cycles.
- Such systems demand in-depth knowledge of which processes are both robust and routine. There was a need to remove variations during production, and for a critical mass to be processed that would make such systems financially viable (NHS Executive North West, 2001).

Minimum requirements

- Complex knowledge to build up product structures which must identify all components from start to finish.
- There must be a definition of the maximum capacity of the equipment and the facilities available, including down time for maintenance and cleaning.
- Staffing capacity must also be taken into account, with an 80 per cent capacity allowance generally made.
- Allowance is made to ensure that external factors such as transport, quality control and suppliers' lead-time are included.
- Any restrictions in the processes must be clearly identified (e.g. bottlenecks). The use of critical path analysis is helpful in most cases.

Constraints

The systems also require:-

- Complex routine processes to have little variation from day to day.
- Production processes to take place over relatively long timescales to enable pay back time for the planning processes.
- Product ranges must normally be routine and limited, with minimal non-stock output.
- Large-scale production.

Evaluation

The expert panel agreed that little or none of the constraints listed above fit the normal NHS hospital aseptic dispensing situation. This is because the planning of such services is not routine, there is a lot of variation, and plans cannot be made well in advance. In comparison to industry, batch sizes are relatively small, non uniform, and there are relatively short timescales involved due to the problems of product stability and storage (*ibid*).

Given the above it was concluded that such computer models were not easily applicable to the NHS hospital aseptic dispensing situation. Therefore this type of approach to establishing capacity planning requirements was not really relevant to the research.

5.14.2 Capacity Modelling

The evaluation of the applicability of capacity modelling to NHS aseptic dispensing units found:

- Capacity modelling is most easily applied where the main capacity issue is the use of (expensive) equipment and manpower is comparatively plentiful or low cost. Industry often has expensive equipment that needs to be used as intensively as possible, and relatively low cost staff – where the skills required can be acquired in a very short time.
- NHS aseptic dispensing units have relatively low-cost equipment but scarce and expensive specialist/professional staff – it can take years to develop staff to fulfil all requirements, and when they leave it can have a very disruptive effect, unless there has been appropriate succession planning.
- The wide range of products and specific drug regimens that can be required to be provided by a hospital aseptic dispensing unit means that the scope to produce a small number of very specific items in very large volumes does not exist. The skills have to be in place to accommodate the full range of patient requirements.

- Capacity planning for an aseptic unit is primarily a skills management issue, rather than one of (solely) process management. Therefore it is not best suited to capacity modelling techniques that require detailed statistical, process data.

5.15 Acute Capacity Planning

The emerging themes from the interviews (see Sections 11.46 – 11.49 for full details) and literature are:

5.15.1 *Chemotherapy Simulation Tool*

The web-based chemotherapy simulation tool enables Trusts and cancer networks to input local data and assumptions to understand current and future processes on a “what if” basis, down to individual sessions if necessary. Given the complexity – nursing requirements are included as well as pharmaceutical – a management consultancy was commissioned to construct it, and training is very important. Local data includes 52,000 different combinations of regimens/cycles/tasks/resources. One aim is to benchmark data from the tool’s application across the country to inform “best practice”. By February 2007 it had been rolled-out to six cancer networks.

5.15.2 *Leeds Teaching Hospital*

Pharmacists developed Excel spreadsheets using the national capacity planning tool for chemotherapy (NHS Modernisation Agency, 2005), applying local timings. An iterative approach was applied to separate and self-contained work:

- A Daily Planner;
- A Clinical Trials Planner;
- A Haematology Clinic Planner; and
- A Chemotherapy Clinic Planner.

The amount of data required is limited to a practical level, e.g. the Daily Planner only covers four product types, viz. TPN (Adult), TPN (Neonatal/Paediatric), Restricted Items (Cytotoxics) and “CIVAS”. The latter therefore covers nine product types identified in the research, and each would need its own addition to the spreadsheet for it to be comprehensive.

The spreadsheets require a lot of data, which is feasible and necessary for long-term/strategic capacity planning. However, far too much data is required to be used to

determine daily/weekly staffing and production, which would not be cost-effective. Therefore, a more qualitative approach is applied, using local knowledge, skills and experience to make practical judgements to balance available staff, and their grades, with the planned/anticipated workloads. This involves moving staff and work around to get a “best fit”. This is far less scientific than using the spreadsheets, and involves more of a “feel”.

5.15.3 North Manchester General Hospital

The local approach uses weekly schedules of each member of staff's daily commitments, divided into morning and afternoon, with their time availability for aseptic production on each day of the week calculated. The number of hours per week/day is then assigned set percentage factors for each person to reflect a combination of the available 'hands on' time and the person's competence. By multiplying these together a number of minutes availability is determined, before being divided by 4 to give a number of “Staff Time Equivalents” (STEs) availability for each person (local practice is that one STE equals 4 minutes). The percentage factors for competencies for new staff are re-evaluated each week.

The figures for individual personnel are then aggregated, with allowances for pre-registration, housekeeping and other duties, to provide a total number of available STEs for each day's production, to give a final figure against which production workload targets can be judged.

Daily production projections are made weighting each product type for the number of STEs required to make it and then aggregated. A matching process between staff availability and production requirements then follows with a suitable reallocation of staff and/or workload between days to get an equitable balance.

5.15.4 Conclusions

Triangulating the above it is evident that to construct an Acute capacity planning model that will cover all product types and circumstances requires significant commitment in time and resources that is beyond any single hospital. It would involve a considerable amount of local data. In its absence, pharmacists develop practical local solutions where data requirements are manageable and the results meet their needs.

Ideally a standard Acute capacity planning model should be developed, so that it is optimal and can enable benchmarking. Given variations in local approaches it would be

necessary to establish a consensus about the scope and detail first, before commissioning the work. The likelihood of this taking place in the foreseeable future is remote, and therefore this represents a boundary to the research.

5.16 Transferability

5.16.1 *West Midlands Analysis*

Twenty-four Trusts from West Midlands submitted data to the survey. Only one was unable to do this, but as it involved a Radiopharmacy (which was not part of the survey), this represented a 100 per cent response. The one Trust that used aseptic products but did not have a local unit submitted data. Full details of the results are provided in Section 11.50.

The number of products produced and used in the West Midlands, by trust and by each type of product, during the financial year 2000/01 are shown in Tables 5.16.1 and 5.16.2 respectively.

The derived usage of the aseptic dispensing units in the West Midlands, applying the "Marker UTEs" is set out in Table 5.16.3. (This table also includes data on how long each unit was open, which was included in the consultancy specification, together with an indicator of how long each cabinet was in use as a percentage of the time the unit was open).

At first sight the figures for Trust 222 may appear strange. This is because they relate to a specific Sterile Fluids Manufacturing Unit (SFMU) which is a specific facility on a major hospital site in Birmingham, but which operates as a business and only sells aseptic products. The recording of the data is therefore consistent with this situation and with the survey guidance.

It can be seen that the "Aseptic Dispensing Unit Hours Per week Per Cabinet" varies considerably across the region. The figures range from 2.41 (Trust 213) to 38.88 (Trust 212). The latter unit is somewhat exceptional and is influenced by the large number of Neonatal/Paediatric TPNs produced.

Table 5.16.1 Total Volumes Produced in Aseptic Units and Used by Trusts in West Midlands (2000/01)

| Trust/ Unit Code | No. of Products Produced Within Aseptic Preparation Unit For: | | | | | No. of Products used from each Source:- | | | | | |
|-------------------|---|---------------------------|-------------------------------|----------------------------|---------------|---|-------------------------------------|---------------------------------------|--------------------------------------|-------------|----------------|
| | Individual Patients Total | Used as Ward Stock* Total | Use in Other NHS Trusts Total | Use by Non-NHS Users Total | Total | Within Trust Total | Other NHS Trust Licensed Unit Total | Other NHS Trust Unlicensed Unit Total | Commercial Unlicensed Products Total | Other Total | Total |
| 211 | 2879 | 0 | 0 | 0 | 2879 | 2879 | 4150 | 0 | 11 | 25 | 7065 |
| 212 | 15450 | 0 | 900 | 0 | 16350 | 15450 | 0 | 0 | 0 | 0 | 15450 |
| 213 | 848 | 0 | 0 | 1 | 849 | 848 | 18 | 0 | 0 | 0 | 866 |
| 214 | 13541 | 1748 | 0 | 0 | 15289 | 15289 | 989 | 0 | 0 | 0 | 16278 |
| 215 | 2080 | 0 | 0 | 0 | 2080 | 2080 | 5496 | 0 | 8 | 0 | 7584 |
| 216 | 7473 | 40 | 0 | 0 | 7513 | 7473 | 3791 | 0 | 3847 | 0 | 15111 |
| 217 | 3014 | 0 | 0 | 0 | 3014 | 3014 | 735 | 0 | 0 | 0 | 3749 |
| 218 | 4171 | 0 | 0 | 0 | 4171 | 4171 | 0 | 0 | 2830 | 0 | 7001 |
| 219 | 4943 | 0 | 0 | 0 | 4943 | 4943 | 2200 | 0 | 1546 | 0 | 8689 |
| 220 | 12511 | 0 | 0 | 0 | 12511 | 12511 | 3611 | 0 | 1476 | 0 | 17598 |
| 221 | 2172 | 0 | 0 | 703 | 2875 | 2172 | 0 | 0 | 0 | 0 | 2172 |
| 222 | 0 | 0 | 4783 | 553 | 5336 | 0 | 0 | 0 | 0 | 0 | 0 |
| 223 | 7732 | 0 | 0 | 0 | 7732 | 7732 | 0 | 0 | 0 | 0 | 7732 |
| 224 | 11874 | 0 | 0 | 0 | 11874 | 11874 | 0 | 0 | 0 | 0 | 11874 |
| 225 | 7542 | 0 | 52 | 0 | 7594 | 7542 | 0 | 0 | 0 | 0 | 7542 |
| 226 | 14492 | 0 | 0 | 0 | 14492 | 14492 | 485 | 0 | 0 | 0 | 14977 |
| 227 | 4939 | 0 | 0 | 0 | 4939 | 4939 | 1238 | 0 | 298 | 0 | 6475 |
| 228 | 1583 | 0 | 2515 | 0 | 4098 | 1583 | 1955 | 0 | 480 | 0 | 4018 |
| 230 | 32556 | 12260 | 1417 | 219 | 46452 | 44556 | 462 | 0 | 250 | 0 | 45268 |
| 231 | 25347 | 0 | 5942 | 292 | 31581 | 25347 | 1889 | 3115 | 1084 | 0 | 31435 |
| 232 | 25395 | 0 | 0 | 56 | 25451 | 25395 | 156 | 0 | 0 | 0 | 25551 |
| 233 | 14808 | 532 | 2238 | 1411 | 18989 | 15340 | 1854 | 0 | 961 | 0 | 18155 |
| 234 | 0 | 0 | 0 | 0 | 0 | 0 | 1070 | 0 | 0 | 0 | 1070 |
| 235 | 1852 | 15801 | 12693 | 2854 | 33200 | 17653 | 1643 | 0 | 6 | 0 | 19302 |
| Total | 217202 | 30381 | 30540 | 6089 | 284212 | 247,283 | 31,742 | 3,115 | 12,797 | 25 | 294,962 |
| % of Total | 76.4% | 10.7% | 10.7% | 2.1% | 100.0% | 83.8% | 10.8% | 1.1% | 4.3% | 0.0% | 100.0% |

Table 5.16.2 Total Volumes Produced in Aseptic Units and Used by Trusts by Product in West Midlands (2000/01)

| Products* | No. of Products Produced Within Aseptic Preparation Unit For: | | | | | No. of Products used from each Source:- | | | | | | |
|------------------------------------|---|------------------|-----------------------|---------------------|---------------|---|------------------------|--------------------------|-------------------------|-----------|---------------|--|
| | Individual Patients Total | Ward Stock Total | Other NHS Trust Total | Non-NHS Users Total | Total | Within Trust: | Other, Licensed Trust: | Other, Unlicensed Trust: | Commercial, Unlicensed: | Other: | Total | |
| Cardioplegia Solutions | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Cytotoxics | 148446 | 3178 | 7624 | 2062 | 161310 | 151624 | 8263 | 0 | 7950 | 25 | 167862 | |
| Epidural Injections | 658 | 3243 | 1649 | 60 | 5610 | 3901 | 3748 | 0 | 220 | 0 | 7869 | |
| Eye Drops/Eye Irrigations | 1194 | 100 | 4783 | 553 | 6630 | 1294 | 5037 | 0 | 11 | 0 | 6342 | |
| Irrigations (exc Ophthalmic) | 565 | 0 | 298 | 0 | 863 | 565 | 45 | 298 | 0 | 0 | 908 | |
| Minibag Plus | 0 | 0 | 0 | 0 | 0 | 0 | 200 | 0 | 0 | 0 | 200 | |
| Minibag/Infusion | 18108 | 6015 | 6543 | 954 | 31620 | 24123 | 2112 | 262 | 0 | 0 | 26497 | |
| Injection Devices ** | 5099 | 821 | 1154 | 908 | 7982 | 5920 | 967 | 374 | 0 | 0 | 7261 | |
| Prefilled Syringe | 16680 | 16984 | 3987 | 956 | 38607 | 33664 | 1070 | 4 | 3921 | 0 | 38659 | |
| TPN-Adult:Compounded | 7654 | 0 | 1798 | 589 | 10041 | 7654 | 329 | 1417 | 0 | 0 | 9400 | |
| TPN-Adult:Simple Additions | 2824 | 0 | 1468 | 7 | 4299 | 2824 | 850 | 0 | 0 | 0 | 3674 | |
| TPN-Neonatal/Paediatric | 15081 | 0 | 1076 | 0 | 16157 | 15081 | 498 | 600 | 0 | 0 | 16179 | |
| Other-Arteriograms | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Other-BCG Vaccines | 233 | 0 | 0 | 0 | 233 | 233 | 0 | 0 | 318 | 0 | 551 | |
| Other-Complex haemofiltration | 100 | 0 | 0 | 0 | 100 | 100 | 0 | 0 | 0 | 0 | 100 | |
| Other-Dialysis Fluids | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Other-Morphine for PCA syringes | 0 | 40 | 116 | 0 | 156 | 40 | 8171 | 116 | 0 | 0 | 8327 | |
| Other-Nebuliser solutions | 0 | 0 | 44 | 0 | 44 | 0 | 0 | 44 | 5 | 0 | 49 | |
| Other-Nose drops | 0 | 0 | 0 | 0 | 0 | 0 | 45 | 0 | 72 | 0 | 117 | |
| Other-Potassium Chloride infusions | 117 | 0 | 0 | 0 | 117 | 117 | 0 | 0 | 240 | 0 | 357 | |
| Other-Topicals | 443 | 0 | 0 | 0 | 443 | 443 | 247 | 0 | 60 | 0 | 490 | |
| Other - Not Stated from NW Survey | 0 | 0 | 0 | 0 | 0 | 0 | 160 | 0 | 0 | 0 | 160 | |
| Totals | 217202 | 30381 | 30540 | 6089 | 284212 | 247283 | 31742 | 3115 | 12797 | 25 | 294962 | |

* List of products used in North West Aseptic Dispensing R&D project

** Includes Elastomeric Infusers

Table 5.16.3 Derived Usage of Aseptic Dispensing Units in West Midlands (2000/01)
Using (Mean) Marker Unit Time Equivalentts

| Category | Code | Hours Unit Open per Working Day* | Hours Unit Open per Working Week** | Aseptic Dispensing Unit Hours Per Week | Number of Cabinets | Aseptic Dispensing Unit Hours Per Week Per Cabinet | Percentage Usage per Cabinet*** | Cabinet Hours Per Week Per Cabinet | Total Products Produced | Average weighted time per product |
|------------|------|----------------------------------|------------------------------------|--|--------------------|--|---------------------------------|------------------------------------|-------------------------|-----------------------------------|
| Licensed | 214 | 7.00 | 35.00 | 19.22 | 3 | 6.41 | 18 | 2.14 | 15,289 | 3.9 |
| Licensed | 221 | 8.50 | 42.50 | 9.58 | 2 | 4.79 | 11 | 1.60 | 2,875 | 10.4 |
| Licensed | 222 | 8.00 | 40.00 | 8.55 | 2 | 4.28 | 11 | 1.43 | 5,336 | 5.0 |
| Licensed | 230 | 8.50 | 42.50 | 102.84 | 6 | 17.14 | 40 | 5.71 | 46,452 | 6.9 |
| Licensed | 231 | 9.00 | 45.00 | 60.73 | 7 | 8.68 | 19 | 2.89 | 31,581 | 6.0 |
| Licensed | 232 | 7.53 | 37.65 | 74.87 | 4 | 18.72 | 50 | 6.24 | 25,451 | 9.2 |
| Licensed | 233 | 8.50 | 42.50 | 49.64 | 2 | 24.82 | 58 | 8.27 | 18,989 | 8.2 |
| Licensed | 235 | 9.00 | 45.00 | 56.56 | 3 | 18.85 | 42 | 6.28 | 33,200 | 5.3 |
| Unlicensed | 211 | 7.50 | 37.50 | 9.34 | 2 | 4.67 | 12 | 1.56 | 2,879 | 10.1 |
| Unlicensed | 212 | 8.00 | 40.00 | 116.63 | 3 | 38.88 | 97 | 12.96 | 16,350 | 22.3 |
| Unlicensed | 213 | 8.00 | 40.00 | 4.81 | 2 | 2.41 | 6 | 0.80 | 849 | 17.7 |
| Unlicensed | 215 | 8.25 | 41.25 | 5.76 | 2 | 2.88 | 7 | 0.96 | 2,080 | 8.6 |
| Unlicensed | 216 | 8.00 | 40.00 | 30.68 | 4 | 7.67 | 19 | 2.56 | 7,513 | 12.7 |
| Unlicensed | 217 | 8.50 | 42.50 | 9.74 | 1 | 9.74 | 23 | 3.25 | 3,014 | 10.1 |
| Unlicensed | 218 | 7.50 | 37.50 | 13.37 | 2 | 6.68 | 18 | 2.23 | 4,171 | 10.0 |
| Unlicensed | 219 | 8.00 | 40.00 | 18.79 | 2 | 9.40 | 23 | 3.13 | 4,943 | 11.9 |
| Unlicensed | 220 | 8.25 | 41.25 | 45.28 | 5 | 9.06 | 22 | 3.02 | 12,511 | 11.3 |
| Unlicensed | 223 | 8.00 | 40.00 | 24.00 | 1 | 24.00 | 60 | 8.00 | 7,732 | 9.7 |
| Unlicensed | 224 | 6.50 | 32.50 | 42.10 | 3 | 14.03 | 43 | 4.68 | 11,874 | 11.1 |
| Unlicensed | 225 | 8.33 | 41.65 | 24.34 | 2 | 12.17 | 29 | 4.06 | 7,594 | 10.0 |
| Unlicensed | 226 | 9.00 | 45.00 | 34.28 | 4 | 8.57 | 19 | 2.86 | 14,492 | 7.4 |
| Unlicensed | 227 | 8.00 | 40.00 | 14.66 | 3 | 4.89 | 12 | 1.63 | 4,939 | 9.3 |
| Unlicensed | 228 | 8.50 | 42.50 | 16.03 | 4 | 4.01 | 9 | 1.34 | 4,098 | 12.2 |

* The number of hours a Unit was open each day (on average) - figures supplied by Trusts

** The number of hours a Unit was open each 5 day week

*** This figure simply takes "Aseptic Dispensing Unit Hours Per Week Per Cabinet" as a percentage of the number of hours a Unit was open, based on a 5 day week.

Robert Jones & Agnes Hunt Hospital Oswestry is not included because it does not have an aseptic dispensing unit.

5.16.2 West Midlands versus North West Comparisons

The results that follow compare the two regions, and include several analyses that can be considered for the West Midlands alone. However, they are only shown here to avoid repetition.

The total number of products produced in West Midlands units was 284,212 for 2000/01 – which was roughly 30 per cent of the North West baseline production. The sizes of the two regions were a little different – the West Midlands population is 81 per cent of that of the North West (5,335,598 and 6,595,330 respectively in 1999). Also, the in-patient workload for West Midlands was approximately two-thirds that of the North West (using both FCEs and Admissions). Calculating aseptic production as a rate against each of these parameters shows that there is clearly a different emphasis between the two regions (see Table 5.16.4).

Table 5.16.4 Aseptic Production Rates in West Midlands and North West

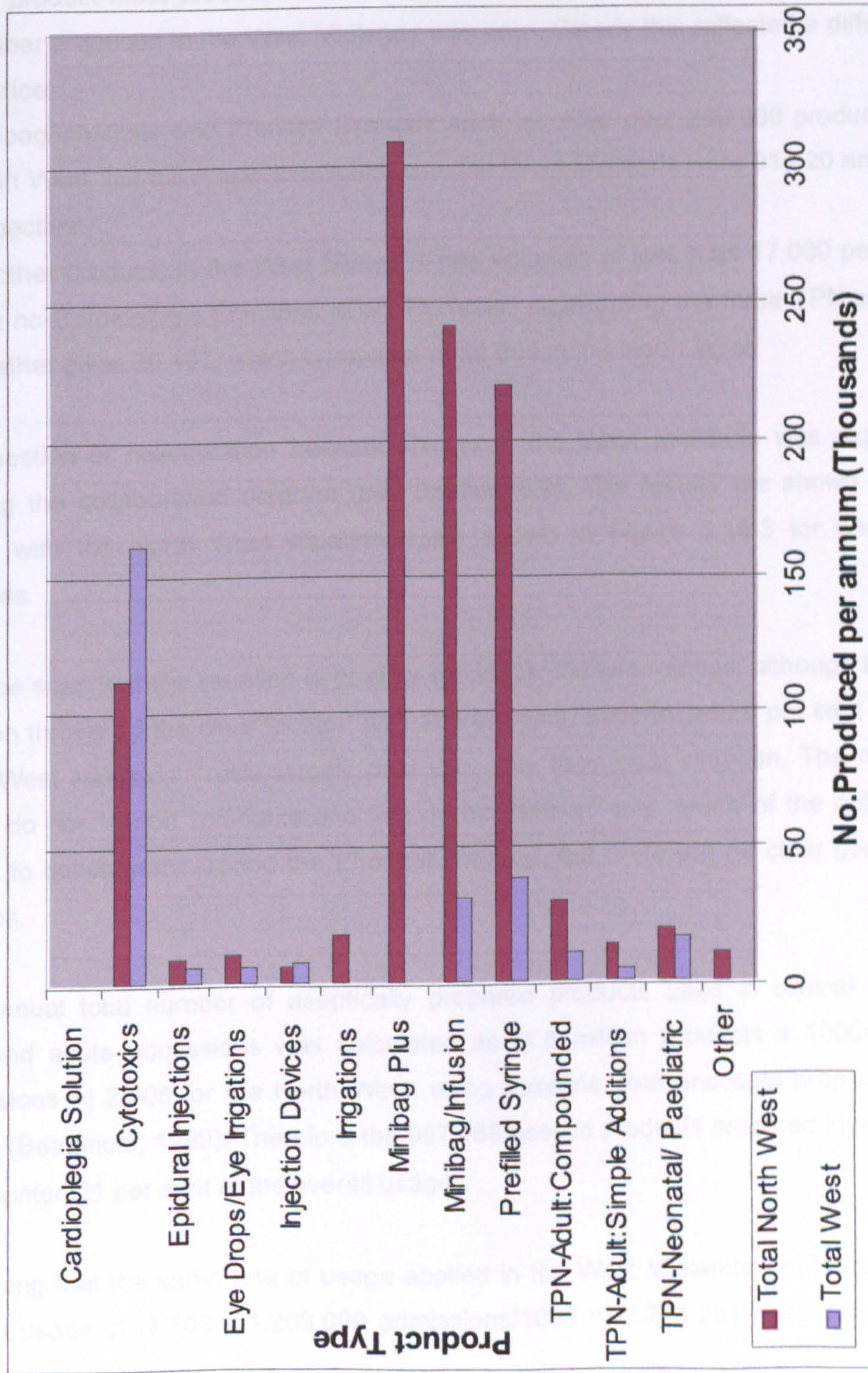
| Aseptic Products Produced In Trust Units per Thousand:- | West Midlands Region 2000/01 | North West Region Baseline |
|--|-------------------------------------|-----------------------------------|
| Resident Population | 53 | 151 |
| Finished Consultant Episodes | 216 | 506 |
| Admissions | 235 | 562 |

This situation is further illustrated by the sizes of the aseptic dispensing units in the two regions, in terms of production volumes (see Table 5.16.5). The size of production in individual units in the West Midlands is comparatively small. The North West analyses talked about units dealing with less than 15,000 products per annum as being “small”. Only four West Midlands units would register amongst the “large” units of the North West, and the largest West Midlands unit with 46,452 units has eight North West units producing more products (two were more than double).

Table 5.16.5 Number of products produced at individual Trusts in the West Midlands, compared with the North West

| Number of Products | Number of Units producing that number of products in Trusts in the West Midlands | | Number of Units producing that number of products in Trusts in the North West | |
|---------------------------|---|-------------|--|-------------|
| More than 50,000 | 0 | 0% | 7 | 21% |
| 25,000 – 49,999 | 4 | 17% | 6 | 18% |
| 18,000 – 24,999 | 1 | 4% | 6 | 18% |
| 9,000 – 17,999 | 5 | 22% | 0 | 0% |
| Fewer than 9,000 | 13 | 57% | 15 | 44% |
| Total | 23 | 100% | 34 | 100% |

Figure 5.16.1 Comparison of Production in West Midlands and North West Regions by Product Type



The most significant result was that the product profiles in the two regions are totally different, as is illustrated in Figure 5.16.1. Key points to note are:-

- Cytotoxics accounted for 57 per cent of all products in the West Midlands, with a total of 161,310. The total for the North West was about 111,000, which represented 11 per cent of all products. (However, the actual *use* of Cytotoxics was almost identical for the two Regions, because a substantial volume in the North West is acquired from a commercial source).
- The product most produced in the North West was Minibag Plus (307,000), but the number produced in the West Midlands was zero. Clearly this reflected a difference in practice.
- Minibag/Infusions and Prefilled Syringes each involved over 200,000 products in the North West, but the respective volumes in the West Midlands were 31,620 and 38,607 respectively.
- All other products in the West Midlands had volumes of less than 17,000 per annum, with no Cardioplegia Solutions at all. However, aggregating the three TPN categories together gives 30,497, which compares to 64,000 in the North West.

The question of collaboration between Trusts in the West Midlands was explored by applying the collaboration diagram (see Section 5.9). The results are shown in Figure 5.16.2, with the North West situation again shown in Figure 5.16.3 for comparative purposes.

It can be seen that the situation is broadly similar for the two regions, although the SFMU situation throws up the clear “outlier” with 100 per cent “exports” and 0 per cent “imports”. Many West Midlands Trusts largely deal with only their local situation. The majority of Trusts do not “export” products and five do not “import” any. Much of the collaboration seems to concentrate around the Birmingham area, but there are no clear geographical patterns.

The annual total number of aseptically prepared products used in clinical areas per thousand acute admissions was calculated as (4.8 million products x 1000/1,774,000 admissions =) 2,706 for the North West, using baseline data and data prepared for the C&CP (Beaumont, 1999). Therefore the 997,188 aseptic products prepared in pharmacies represented 21 per cent of the overall usage.

Assuming that the same rate of usage applied in the West Midlands would mean a total annual usage of (2,706 x 1,209,000 admissions/1000 =) 3,271,251 aseptically prepared

products in clinical areas in the West Midlands. Therefore the 284,212 products prepared in pharmacies represents 9 per cent.

Figure 5.16.2 Collaboration Diagram West Midlands (2000/01)

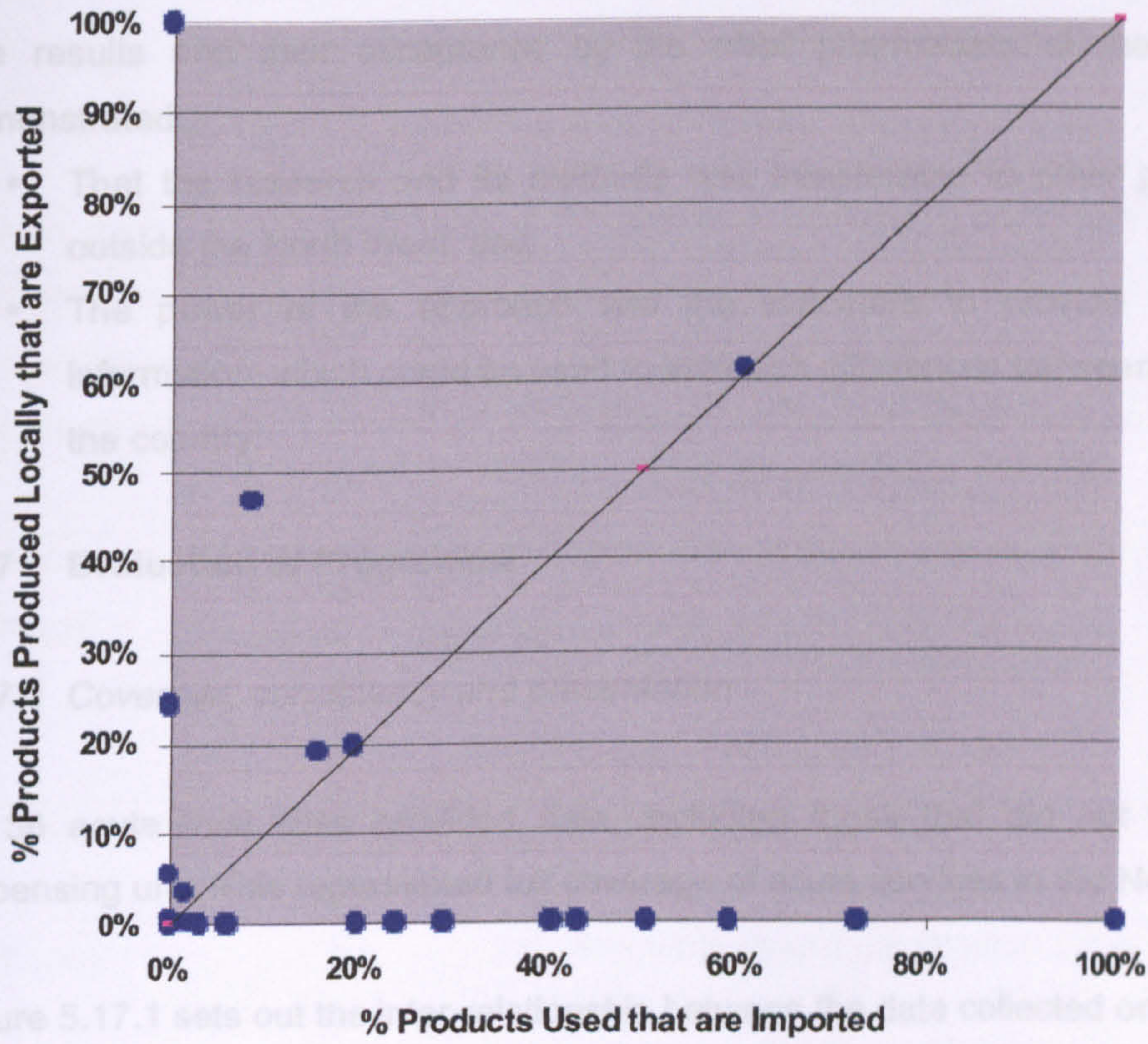
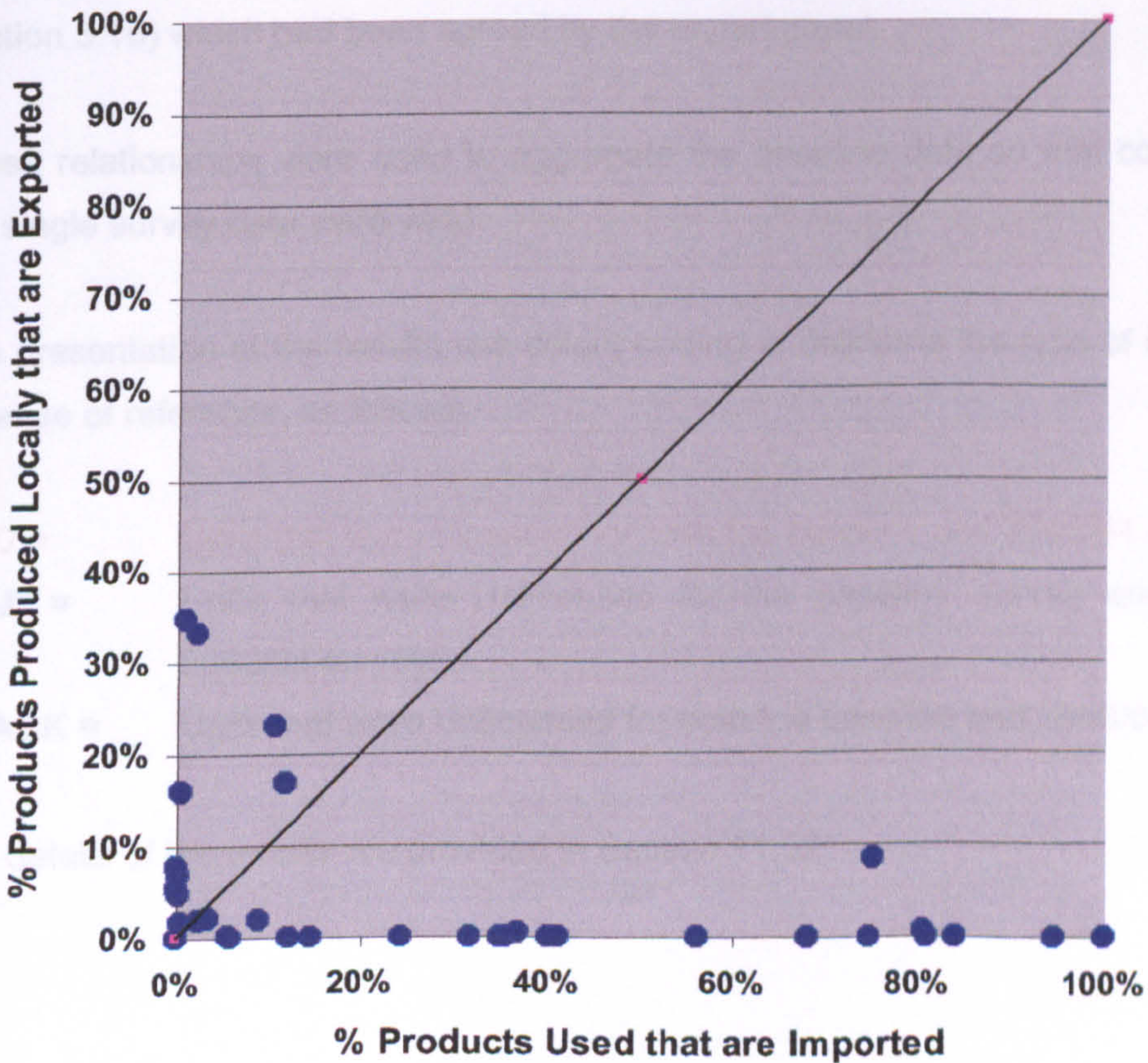


Figure 5.16.3 Collaboration Diagram North West (Baseline)



5.16.3 Overview

Figure 5.17.1 Inter-relationship between data collected for each Product Type within the

The results and their acceptance by the chief pharmacists of the West Midlands demonstrated:

- That the research and its methods was transferable to other parts of the NHS outside the North West; and
- The power of the approach and the indicators to provide genuinely useful information, which could be used to establish differences between different parts of the country.

5.17 Evaluation of Programme

5.17.1 Coverage, consistency and presentation

All 36 acute trust sites provided data, including those that did not have an aseptic dispensing unit. This represented full coverage of acute services in the North West.

Figure 5.17.1 sets out the inter-relationship between the data collected on the single survey form used for this part of the research, and the previously data collected for the baseline and quarterly surveys (see Sections 5.3 & 5.5), and the West Midlands (see Section 5.16) which had been agreed by the expert panel.

These relationships were used to aggregate the baseline data so that comparisons with the single survey data were valid.

The presentation of the results use colour coding to delineate the type of unit(s) involved, for ease of reference, as follows:

- RED =** Units that were Licensed for both the baseline and 2003/04 surveys;
- BLUE =** Units that were Unlicensed for the baseline survey and Licensed for 2003/04 survey;
- BLACK =** Units that were Unlicensed for both the baseline and 2003/04 surveys;

Full details of the results are provided in Section 11.52.

Figure 5.17.1 Inter-relationship between data collected for each Product Type within the single survey form (2003/04) and the survey design agreed by the expert panel

| Single Survey Form (2003/04) | Baseline, Quarterly & West Midlands Surveys |
|--|---|
| Prepared within Pharmacy for use within own Trust (Production); | Produced within Aseptic Preparation Unit for Individual Patients (Form one)* |
| | Produced within Aseptic Preparation Unit for Use as Ward Stock (Form one)* |
| Outsourced from other Trusts (Usage); | Products used from Source: Other NHS Trust Licensed Unit (Form two) |
| | Products used from Source: Other NHS Trust Unlicensed Unit (Form two) |
| Acquired from Commercial Sources (unlicensed products) (Usage); | Products used from Source: Commercial Unlicensed Products (Form two) |
| | Products used from Source: Other (Form two)** |
| Prepared within Pharmacy for other NHS Trusts and other users (Production) | Produced within Aseptic Preparation Unit for Use in Other NHS Trusts (Form one) |
| | Produced within Aseptic Preparation Unit for Use by Non-NHS Users (Form one) |

* Products used from Source: Within Trust (Form two) is the sum of these two pieces of data.

** It should be noted that the number of such products in the baseline data was zero; its inclusion is to ensure that no unforeseen sources are inadvertently excluded.

5.17.2 Production and usage

Table 5.17.1 compares the distribution of aseptic dispensing units in the North West by licensing type and production volume in the baseline and for 2003/04. There were eight more licensed units than there had been in the baseline, increasing the proportion of such units from 35 to 59 per cent. Licensed units accounted for 55 per cent of the products produced in the baseline and 84 per cent in 2003/04 (see Table 5.17.2). This demonstrates that the recommendations from the North West Chief Executives' and chief pharmacists' report (NHS Executive North West, 1997) for greater emphasis on licensed production were being progressed across the region, and not just focused on those units that received capital monies.

Table 5.17.1 Comparison of Distribution of Aseptic Dispensing Units in the North West by Licensing Type and Production Volume: Baseline versus 2003/04

| | Baseline | | 2003/04 | |
|--------------------------------|-----------------------|-------------------------|-----------------------|-------------------------|
| | No. of Licensed Units | No. of Unlicensed Units | No. of Licensed Units | No. of Unlicensed Units |
| Total Products Produced | | | | |
| 55,000+ | 5 | 3 | 9 | 1 |
| 25,000 – 49,999 | 3 | 3 | 4 | 3 |
| 18,000 – 24,999 | 1 | 4 | 3 | 0 |
| 9,000 – 17,999 | 1 | 1 | 2 | 3 |
| < 9,000 | 1 | 9 | 1 | 6 |
| TOTAL | 11 | 20 | 19 | 13 |

Table 5.17.2 shows the number of products produced and used by trusts in the North West. From the baseline to 2003/04, overall aseptic production in pharmacy facilities increased by 48 per cent and clinical use also increased by 45 per cent. At SHA level, production more than doubled in Lancashire, increased by two-thirds in Greater Manchester and increased by five percent in Cheshire and Merseyside.

The number of products acquired from commercial sources increased by 89 per cent between the baseline and 2003/04, with such products accounting for 14 per cent of all products used in 2003/04.

Table 5.17.2 Changes in Production and Usage by Trust: Baseline to 2003/04

| | Total No. of Products Produced Within Aseptic Preparation Unit | | | | Total No. of Products Used from All Sources | | | | |
|-----------------------|--|----------------|---------------|------------|---|----------------|---------------|------------|----------|
| | Code | Baseline | 2003/04 | Difference | % Change | Baseline | 2003/04 | Difference | % Change |
| 111 | 20184 | 10972 | -9212 | -46% | 21719 | 63729 | 42010 | 193% | |
| 112 | 4901 | 10087 | 5186 | 106% | 25085 | 15389 | -9696 | -39% | |
| 113 | 5304 | 11171 | 5867 | 111% | 7009 | 23095 | 16086 | 230% | |
| 114 | 46932 | 95260 | 48328 | 103% | 40458 | 78132 | 37674 | 93% | |
| 115 | 59941 | 87716 | 27775 | 46% | 55206 | 97459 | 42253 | 77% | |
| 116 | 0 | 0 | 0 | - | 12870 | 38290 | 25420 | 198% | |
| 117 | 39575 | 62746 | 23171 | 59% | 37395 | 59271 | 21876 | 58% | |
| 118 | 18488 | 27137 | 8649 | 47% | 21630 | 29837 | 8207 | 38% | |
| 120 | 8389 | 86104 | 77715 | 926% | 12881 | 36224 | 23343 | 181% | |
| 121 | 3730 | 4670 | 940 | 25% | 70130 | 74870 | 4740 | 7% | |
| 122 | 28173 | 32168 | 3995 | 14% | 29173 | 32090 | 2917 | 10% | |
| 123 | 2561 | 2938 | 377 | 15% | 5833 | 22300 | 16467 | 282% | |
| 124 | 449 | 2305 | 1856 | 413% | 2812 | 10597 | 7785 | 277% | |
| 126 | 0 | 0 | 0 | - | 6415 | 2759 | -3656 | -57% | |
| 127 | 3550 | 27202 | 23652 | 666% | 11103 | 29015 | 17912 | 161% | |
| 128 | 3437 | 6815 | 3378 | 98% | 3437 | 35204 | 31767 | 924% | |
| 129 | 27164 | 17688 | -9476 | -35% | 41962 | 78204 | 36242 | 86% | |
| 131 | 0 | 39292 | 39292 | - | 2670 | 41396 | 38726 | 1450% | |
| 132 | 40783 | 72387 | 31604 | 77% | 40262 | 74508 | 34246 | 85% | |
| 134 | 104093 | 210867 | 106774 | 103% | 65577 | 86260 | 20683 | 32% | |
| 135 | 0 | 0 | 0 | - | 392 | 1520 | 1128 | 288% | |
| 136 | 71460 | 24712 | -46748 | -65% | 68804 | 95931 | 27127 | 39% | |
| 137 | 98494 | 70389 | -28105 | -29% | 93858 | 66844 | -27014 | -29% | |
| 138 | 33377 | 41241 | 7864 | 24% | 55705 | 41441 | -14264 | -26% | |
| 139 | 64814 | 38534 | -26280 | -41% | 77178 | 117028 | 39850 | 52% | |
| 140 | 17077 | 21530 | 4453 | 26% | 0 | 9977 | 9977 | - | |
| 141 | 55101 | 63018 | 7917 | 14% | 56577 | 62572 | 5995 | 11% | |
| 143 | 12541 | 9579 | -2962 | -24% | 36066 | 9547 | -26519 | -74% | |
| 144 | 21888 | 36490 | 14602 | 67% | 23136 | 36490 | 13354 | 58% | |
| 145 | 63279 | 183352 | 120073 | 190% | 62920 | 86352 | 23432 | 37% | |
| 147 | 18903 | 5874 | -13029 | -69% | 20096 | 27731 | 7635 | 38% | |
| 148 | 2167 | 1645 | -522 | -24% | 3684 | 3216 | -468 | -13% | |
| 149 | 0 | 0 | 0 | - | 395 | 764 | 369 | 93% | |
| 150 | 2760 | 1304 | -1456 | -53% | 11947 | 18196 | 6249 | 52% | |
| 151 | 18086 | 23292 | 5206 | 29% | 18086 | 22950 | 4864 | 27% | |
| 152 | 85976 | 126378 | 40402 | 47% | 58686 | 68232 | 9546 | 16% | |
| Total | 983577 | 1454863 | 471286 | 48% | 1101157 | 1597420 | 496263 | 45% | |
| | | | | | | | | | |
| Zonal Split | Total No. of Products Produced Within Aseptic Preparation Unit | | | | Total No. of Products Used from All Sources | | | | |
| | Baseline | 2003/04 | Difference | % Change | Baseline | 2003/04 | Difference | % Change | |
| Cheshire & Merseyside | 387611 | 407183 | 19572 | 5% | 407342 | 515765 | 108423 | 27% | |
| Greater Manchester | 382737 | 617232 | 234495 | 61% | 482658 | 709820 | 227162 | 47% | |
| Lancashire | 213229 | 430448 | 217219 | 102% | 211157 | 371835 | 160678 | 76% | |
| Total | 983577 | 1454863 | 471286 | 48% | 1101157 | 1597420 | 496263 | 45% | |

Table 5.17.3 shows changes in production and usage by product type, which were not uniform. In the baseline, the three product types with the largest production values were Minibag Plus (307k), Minibag/Infusion (241k) and Prefilled Syringes (220k), which collectively accounted for 78 per cent of North West production. They accounted for 80 per cent of North West production in 2003/04: production of Minibag Plus more than doubled; Prefilled Syringes production was up by half; and Minibag/Infusions was down by almost a quarter.

It is notable that Cytotoxics production was up by over half, presumably reflecting the implementation of the National Cancer Plan (DoH, 2000b).

All the other product types increased in volumes produced, except TPN (Neonatal/Paediatric) and Irrigations, which reduced by 10 per cent & 85 per cent respectively. However, care should be exercised because of the comparatively small numbers that are involved for each. In terms of usage, the patterns were similar in terms of direction to those of production, although the percentages were usually different. It can be seen that usage went down for Eye Drops/Eye Irrigations, Injection Devices and TPN Adult (Compounded) despite (NHS) production increasing. The reverse was the case for TPN (Neonatal/Paediatric).

A factor in this picture is the use of Commercial Sources (see Table 5.17.4), which went up from 123k products for the baseline to 232k in 2003/04 – an increase of 89 per cent. However, there were dramatic variations between the Product Types: numbers increased for six types and numbers decreased for six types. Although the numbers were often limited, the percentage swings were all quite large. Cytotoxics had accounted for 51 per cent of commercial products in the baseline, but now accounted for only 32 per cent, despite an increase of 19 per cent in their use. This was due to the main change, which was the acquisition of over 100k Minibag Plus from commercial sources - almost the same as the overall increase in itself. From none being acquired from commercial sources in the baseline, Minibag Plus was 44 per cent of all commercial products purchased.

Table 5.17.5 summarises the aggregate increases in production for each product type, for the eight aseptic units that received monies from the capital programme, and compares them with the increases originally planned. The increased production in units that did not have such schemes was 239,000 products. Six of the eight units did not achieve their individual targets, with undershoots ranging from 1,000 to 165,000 for 2003/04. The other two units each exceeded their targets by 50,000 products.

Table 5.17.3 Changes in Production & Usage by Product Type: Baseline – 2003/04

| Product Category | Total No. of Products Produced Within Aseptic Preparation Unit | | | | Total No. of Products Used from All Sources | | | |
|----------------------------|--|----------------|---------------|------------|---|----------------|---------------|------------|
| | Baseline | 2003/04 | Difference | % Change | Baseline | 2003/04 | Difference | % Change |
| Cytotoxics | 110816 | 171569 | 60753 | 55% | 173109 | 243849 | 70740 | 41% |
| Epidural Injections | 9001 | 16622 | 7621 | 85% | 20760 | 31409 | 10649 | 51% |
| Eye Drops/Eye Irrigations | 4469 | 5082 | 613 | 14% | 9908 | 8338 | -1570 | -16% |
| Irrigations | 14809 | 2184 | -12625 | -85% | 36220 | 2225 | -33995 | -94% |
| Minibag Plus | 307435 | 646720 | 339285 | 110% | 290429 | 678878 | 388449 | 134% |
| Minibag/Infusion | 240785 | 191657 | -49128 | -20% | 251475 | 236289 | -15186 | -6% |
| Injection Devices | 5981 | 8685 | 2704 | 45% | 8494 | 6042 | -2452 | -29% |
| Prefilled Syringe | 219525 | 328506 | 108981 | 50% | 248316 | 316996 | 68680 | 28% |
| TPN-Adult:Compounded | 30525 | 30558 | 33 | 0% | 21353 | 18471 | -2882 | -13% |
| TPN-Adult:Simple Additions | 14055 | 23157 | 9102 | 65% | 15910 | 23843 | 7933 | 50% |
| TPN-Neonatal/ Paediatric | 22807 | 20466 | -2341 | -10% | 18704 | 21364 | 2660 | 14% |
| Other | 3369 | 9658 | 6289 | 187% | 6479 | 9717 | 3238 | 50% |
| Total | 983577 | 1454863 | 471286 | 48% | 1101157 | 1597420 | 496263 | 45% |

Table 5.17.4 Changes in Usage of Commercial Sources: Baseline – 2003/04

| Product Category | Baseline | 2003/04 | Difference | % Change |
|----------------------------|-----------------|----------------|-------------------|-----------------|
| Cytotoxics | 62759 | 74389 | 11630 | 19% |
| Epidural Injections | 3285 | 10740 | 7455 | 227% |
| Eye Drops/Eye Irrigations | 2502 | 1209 | -1293 | -52% |
| Irrigations | 21821 | 0 | -21821 | -100% |
| Minibag Plus | 0 | 102978 | 102978 | |
| Minibag/Infusion | 1863 | 33754 | 31891 | 1712% |
| Injection Devices | 3000 | 350 | -2650 | -88% |
| Prefilled Syringe | 24116 | 6555 | -17561 | -73% |
| TPN-Adult:Compounded | 387 | 941 | 554 | 143% |
| TPN-Adult:Simple Additions | 2703 | 21 | -2682 | -99% |
| TPN-Neonatal/ Paediatric | 0 | 650 | 650 | |
| Other | 317 | 0 | -317 | -100% |
| Total | 122753 | 231587 | 108834 | 89% |

Table 5.17.5 Projected and Actual production levels for Aseptic Units at Trusts participating in the C&CP

| Product Type | ACTUAL INCREASE (Difference between Final & Baseline Surveys) | PLANNED ADDITIONAL ACTIVITY | ACTUAL INCREASED ACTIVITY LESS PLANNED ADDITIONAL ACTIVITY |
|--------------------------|--|------------------------------------|---|
| Cytotoxics | 2547 | 4000 | -1453 |
| TPN (All Types Combined) | 1770 | 5750 | -3980 |
| Epidural injections | 4770 | 0 | 4770 |
| Eye drops/irrigations | -5138 | 100 | -5238 |
| Irrigations (ex Opthal) | -3313 | 200 | -3513 |
| Minibag Plus | 223820 | 155000 | 68820 |
| Minibag/Infusion | -43753 | 129000 | -172753 |
| Injection devices* | 795 | 0 | 795 |
| Prefilled syringes | 56856 | 163000 | -106144 |
| Other | -6290 | 3000 | -9290 |
| TOTAL | 232064 | 460050 | -227986 |

5.17.3 Capacity issues

Figure 5.17.2 shows the percentage change in the key indicators used for workload measurement for each category of aseptic unit from the baseline to 2003/04. The total number of cabinets (laminar flow cabinets and pharmaceutical isolators) at trusts in the

North West increased from 100 to 106. Eight licensed units installed new cabinets (12 cabinets in total) and four units closed cabinets (six cabinets in total).

All but five units had dedicated cabinets for preparing cytotoxic products. In 67 per cent of the units with dedicated facilities, the intensity of use of the general (i.e. non-cytotoxic) cabinets increased by between 4 and 97 per cent. In the other 33 per cent of units, the intensity of cabinet use decreased by between 1 and 49 per cent. Excluding a specialist TPN unit, all licensed units had average weighted time per product values below 8.0, and all unlicensed units had values above 8.0.

5.17.4 *Collaboration between trusts*

Figures 5.17.3 and 5.17.4 provide diagrammatic presentations of the collaboration indicators, setting out collaboration for individual product types in total for the baseline and 2003/04. Overall collaboration between trusts increased over the period. The proportion of products exported (indicator II) increased from 12 per cent in the baseline to 27 per cent in 2003/04. The proportion of products imported (indicator I, which includes commercially acquired products) increased from 21 per cent to 33 per cent over the same period. Regarding individual trusts, in 2003/04, five trusts exported more than 25 per cent of production, with one trust exporting nearly 60 per cent.

Figures 5.17.5 and 5.17.6 apply the collaboration diagram for individual Trusts for the two periods respectively, showing changes in patterns, with Trusts generally moving away from the origin: five Trusts exported more than 30 per cent of products in 2003/04 (with three over 50 per cent), compared with two in the baseline; twelve Trusts imported over 45 per cent of products used in 2003/04, compared with seven in the baseline.

Table 5.17.6 and Figure 5.17.7 demonstrate the changes in the collaboration patterns when the focus is the three geographic (and operational) zones in the North West. Lancashire has become a significant nett exporter of products with big increases in both the percentage exported and imported. Greater Manchester is still a nett importer, despite major increases in the percentage products exported, and small increases in the percentage imported. By way of comparison, Cheshire & Merseyside is still a nett importer, and has more than doubled its percentage imported with a limited increase in its exports. The key factor in the situation in Cheshire & Merseyside is the significant increase in the acquisition of commercial products.

Figure 5.17.2 Percentage change in key indicators: Baseline – 2003/04 for each category of aseptic unit

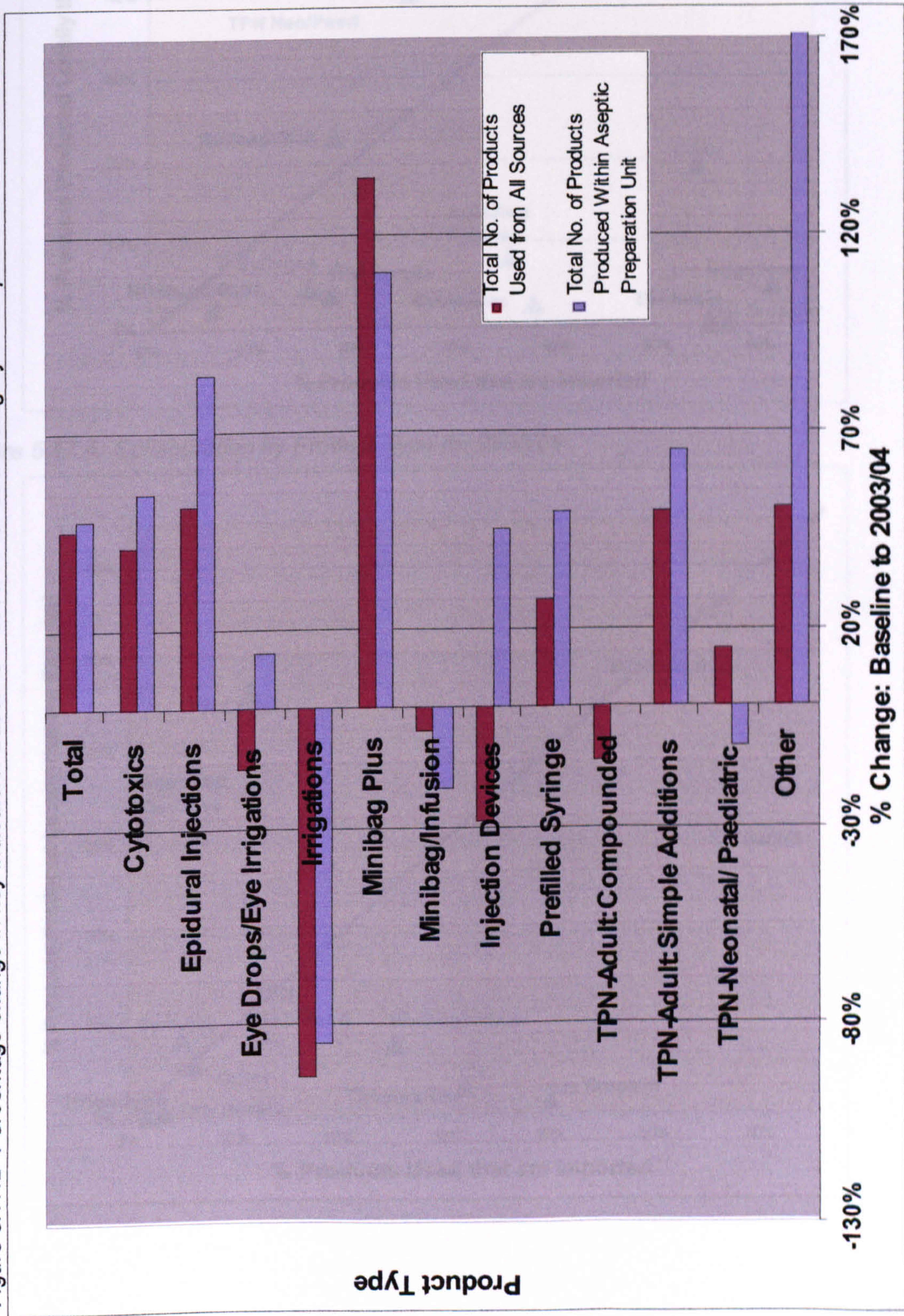


Figure 5.17.3 Collaboration by Product Type for Baseline

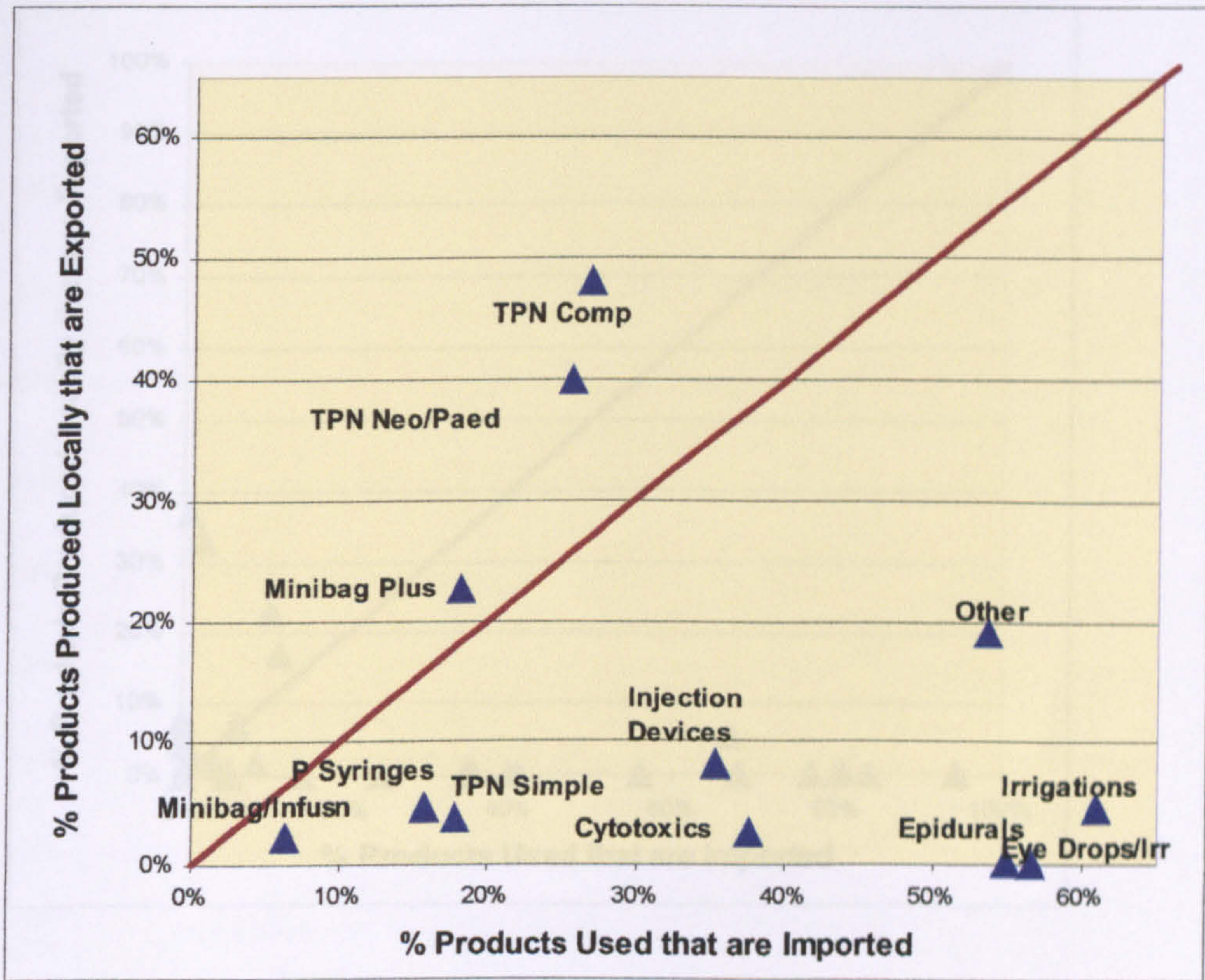


Figure 5.17.4 Collaboration by Product Type for 2003/04

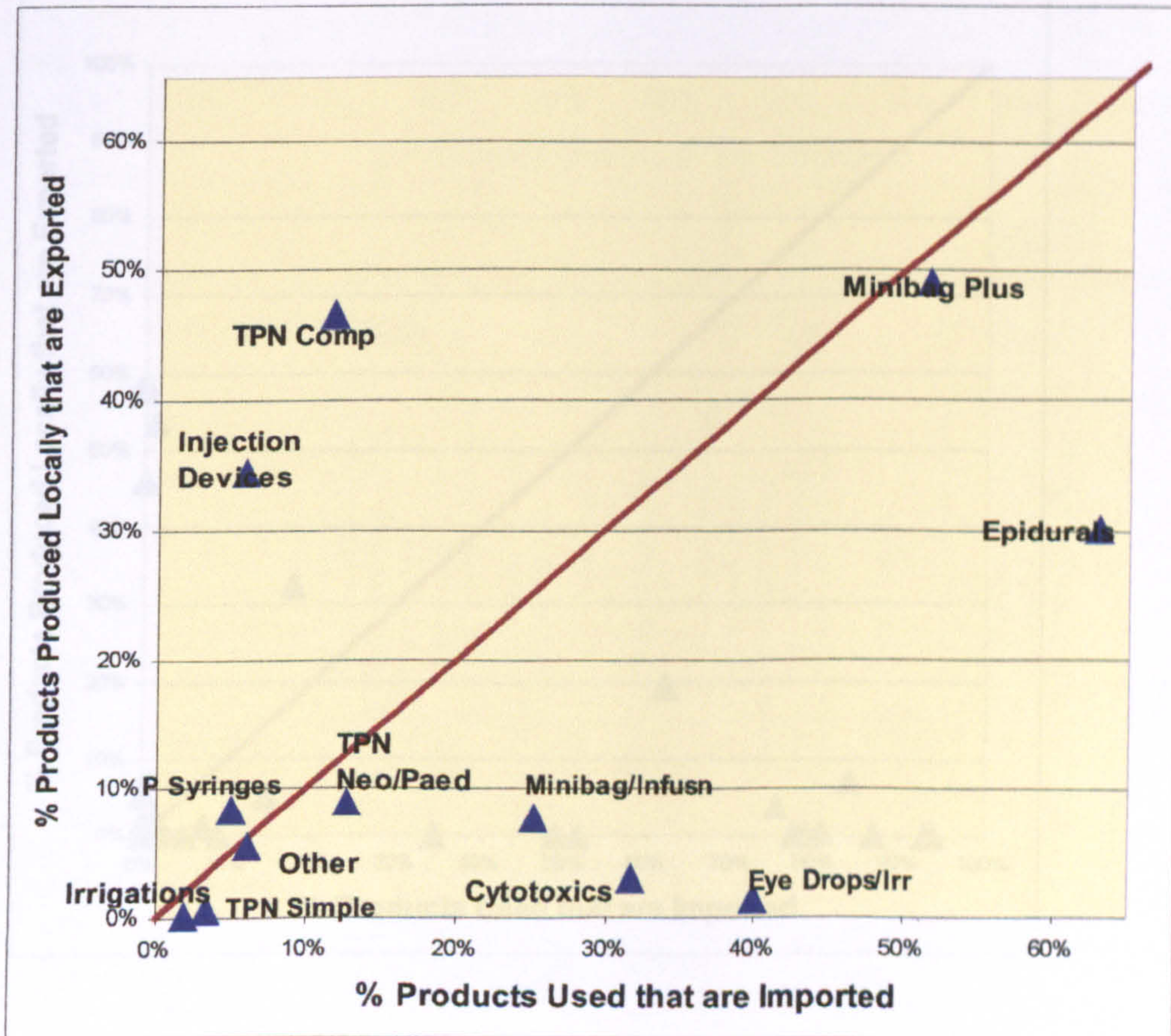


Figure 5.17.5 Collaboration by Trust for Baseline

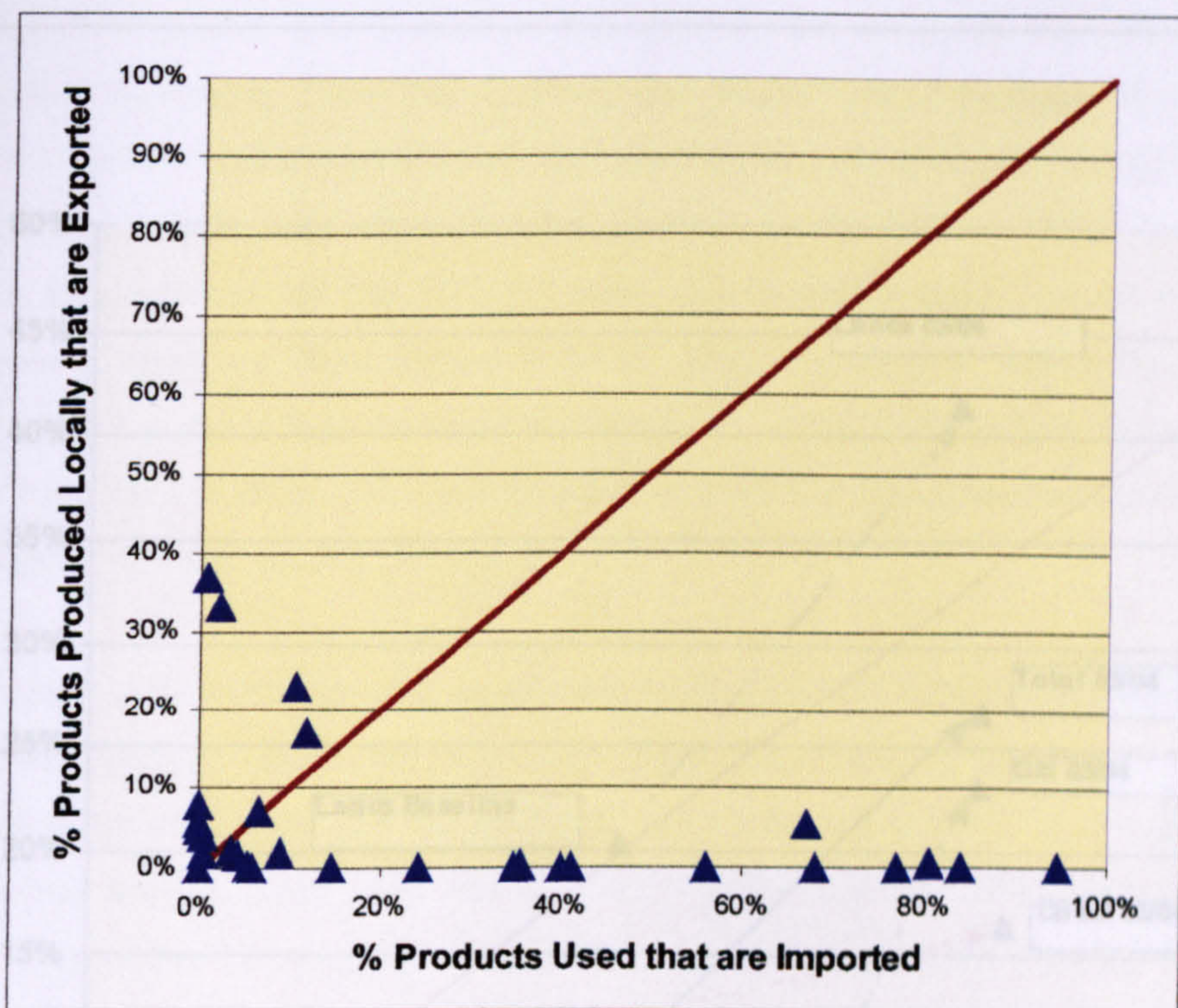


Figure 5.17.6 Collaboration by Trust 2003/04

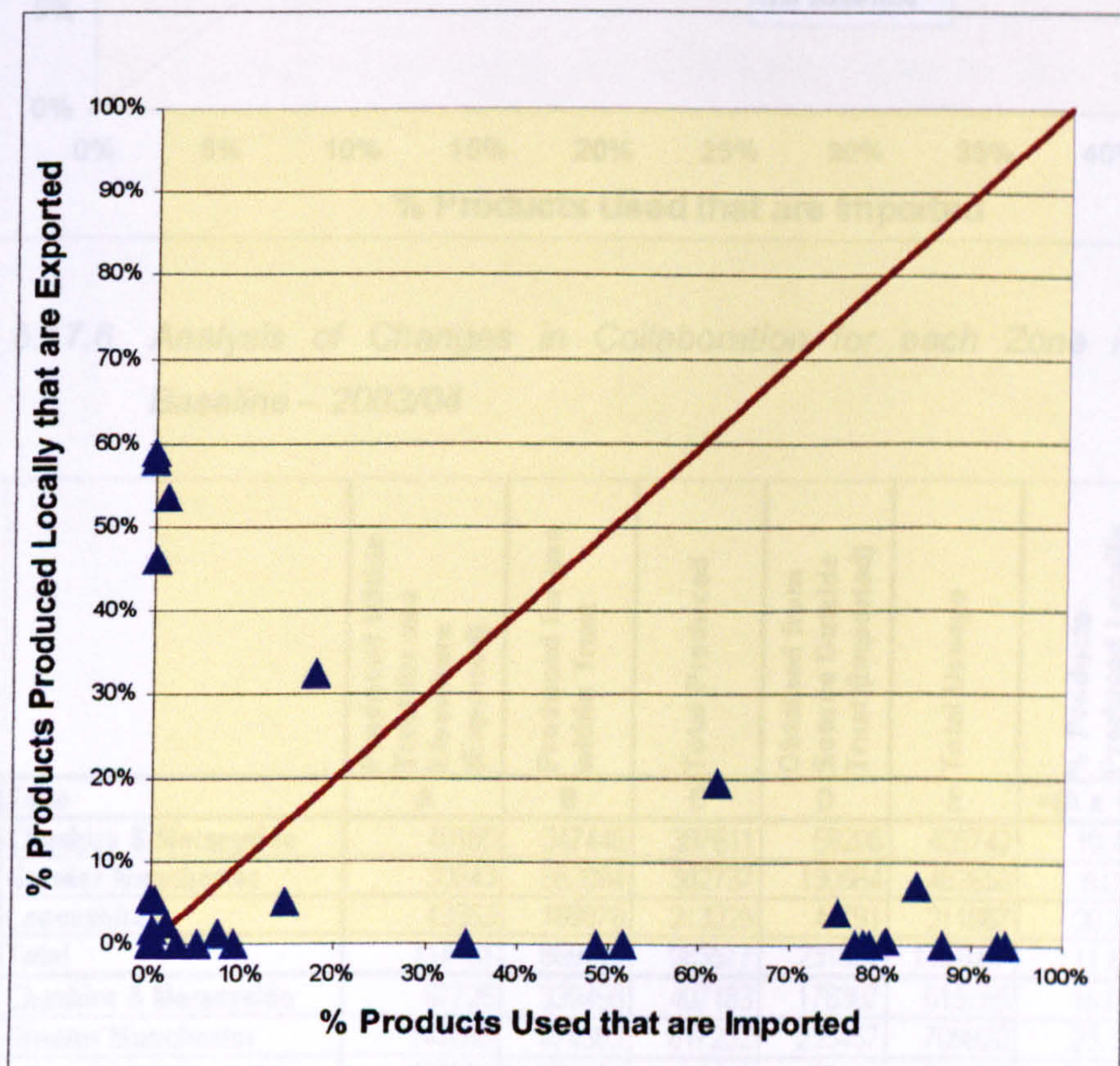


Figure 5.17.7 Collaboration by Geographical Zone: Baseline - 2003/04

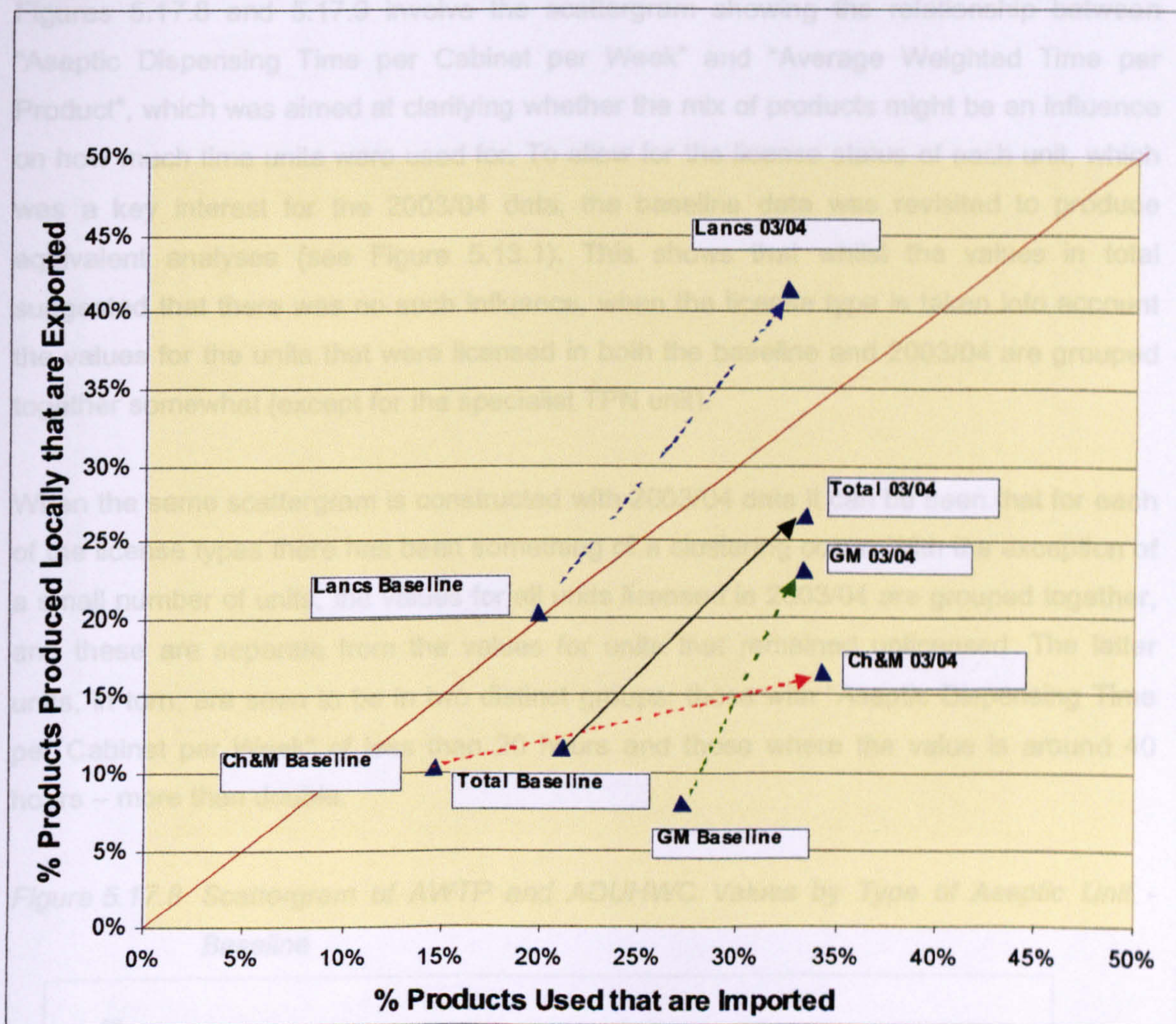


Table 5.17.6 Analysis of Changes in Collaboration for each Zone in North West: Baseline – 2003/04

| Period | Zone | Produced Within Trust for use Elsewhere (Exported) (A) | Produced for use within Trust (B) | Total Produced (C) | Obtained from Source Outside Trust (Imported) (D) | Total Usage (E) | % Products Produced Locally that are Exported $=(A \times 100)/C$ | % Products Used that are Imported $=(D \times 100)/E$ |
|----------|-----------------------|--|-----------------------------------|--------------------|---|-----------------|---|---|
| Baseline | Cheshire & Merseyside | 40165 | 347446 | 387611 | 59296 | 406742 | 10.4% | 14.6% |
| Baseline | Greater Manchester | 30643 | 352094 | 382737 | 130564 | 482658 | 8.0% | 27.1% |
| Baseline | Lancashire | 43353 | 169876 | 213229 | 41791 | 211667 | 20.3% | 19.7% |
| Baseline | Total | 114161 | 869416 | 983577 | 231651 | 1101067 | 11.6% | 21.0% |
| 03/04 | Cheshire & Merseyside | 67725 | 339458 | 407183 | 176307 | 515765 | 16.6% | 34.2% |
| 03/04 | Greater Manchester | 142869 | 474363 | 617232 | 235457 | 709820 | 23.1% | 33.2% |
| 03/04 | Lancashire | 179039 | 251409 | 430448 | 120426 | 371835 | 41.6% | 32.4% |
| 03/04 | Total | 389633 | 1065230 | 1454863 | 532190 | 1597420 | 26.8% | 33.3% |

5.17.5 Scattergrams

Figures 5.17.8 and 5.17.9 involve the scattergram showing the relationship between “Aseptic Dispensing Time per Cabinet per Week” and “Average Weighted Time per Product”, which was aimed at clarifying whether the mix of products might be an influence on how much time units were used for. To allow for the license status of each unit, which was a key interest for the 2003/04 data, the baseline data was revisited to produce equivalent analyses (see Figure 5.13.1). This shows that whilst the values in total suggested that there was no such influence, when the license type is taken into account the values for the units that were licensed in both the baseline and 2003/04 are grouped together somewhat (except for the specialist TPN unit).

When the same scattergram is constructed with 2003/04 data it can be seen that for each of the license types there has been something of a clustering occur. With the exception of a small number of units, the values for all units licensed in 2003/04 are grouped together, and these are separate from the values for units that remained unlicensed. The latter units, in turn, are seen to be in two distinct groups: those with “Aseptic Dispensing Time per Cabinet per Week” of less than 20 hours and those where the value is around 40 hours – more than double.

Figure 5.17.8 Scattergram of AWTP and ADUHC Values by Type of Aseptic Unit - Baseline

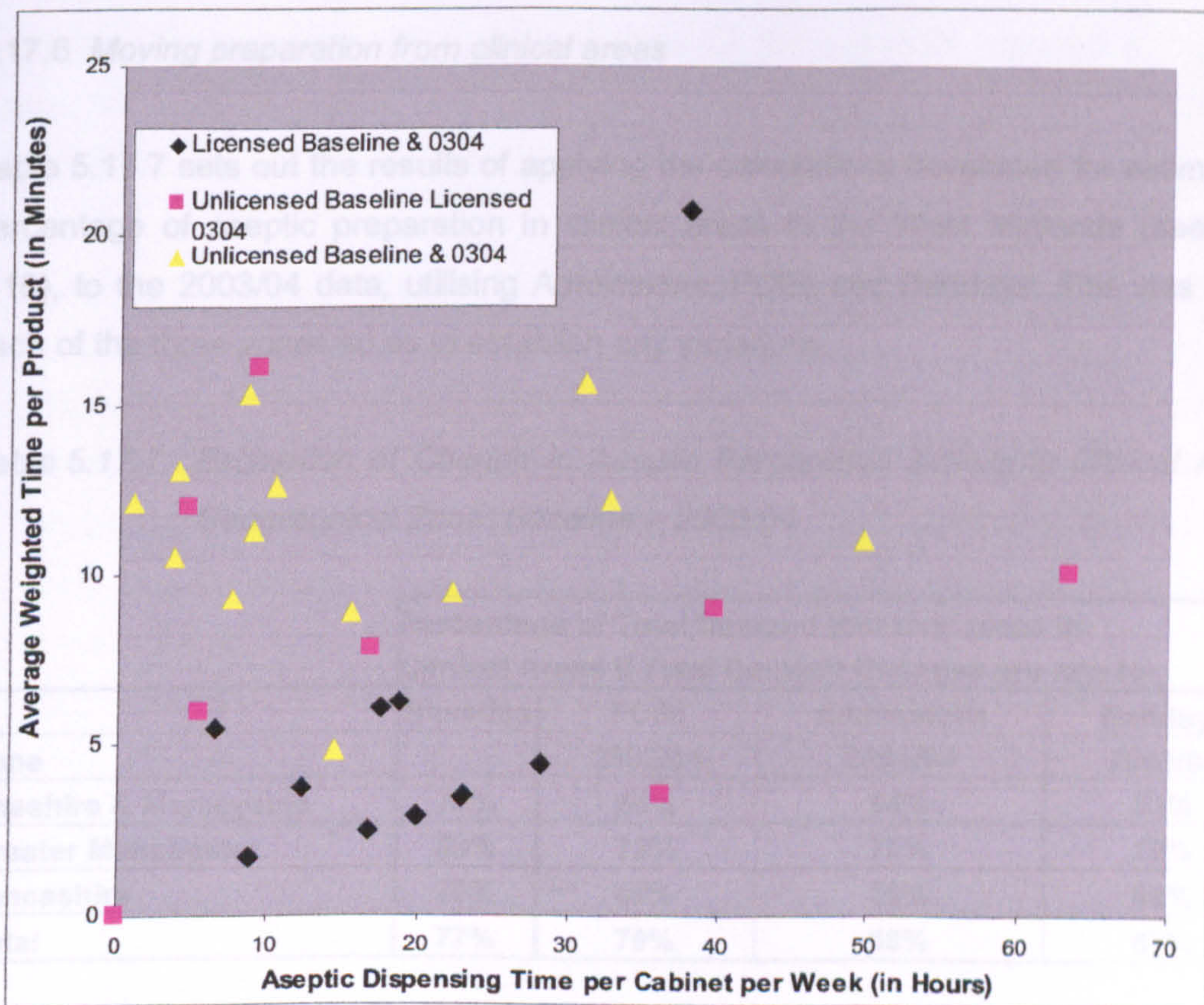
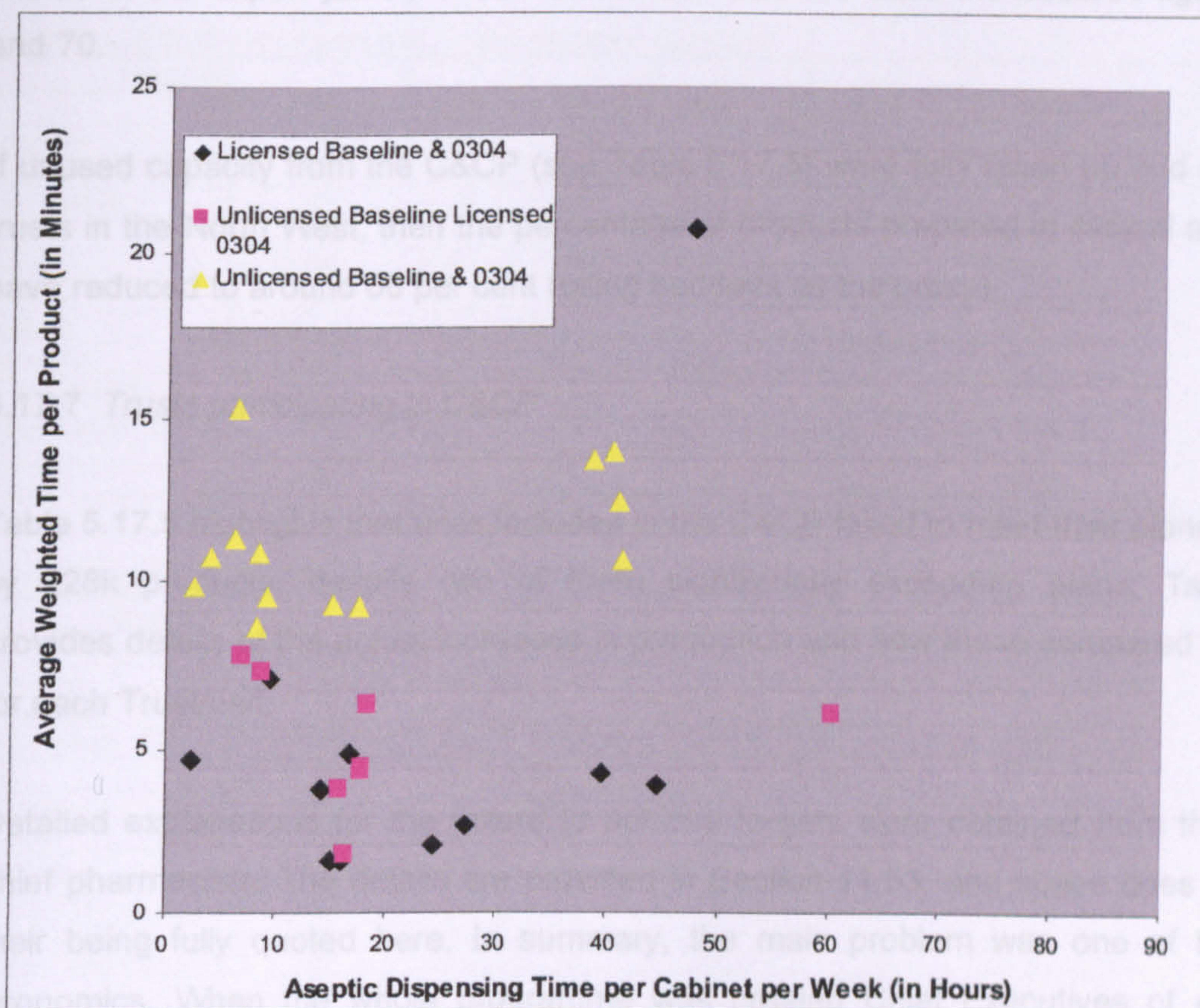


Figure 5.17.9 Scattergram of AWTP and ADUHC Values by Type of Aseptic Unit – 2003/04



5.17.6 Moving preparation from clinical areas

Table 5.17.7 sets out the results of applying the calculations developed for estimating the percentage of aseptic preparation in clinical areas in the West Midlands (see Section 5.16), to the 2003/04 data, utilising Admissions, FCEs and Beddays. This was done for each of the three zones so as to establish any variations.

Table 5.17.7 Estimation of Change in Aseptic Preparation Activity in Clinical Areas by Geographical Zone: Baseline – 2003/04

| Zone | Percentage of Total Demand that took place in Clinical Areas if Total Demand Changes pro rata to: | | | |
|-----------------------|---|-----------------|-----------------------|--------------------|
| | Baseline | FCEs 2003/04 | Admissions 2003/04 | Beddays 2003/04 |
| Cheshire & Merseyside | 72% | 66% | 64% | 63% |
| Greater Manchester | 80% | 72% | 70% | 70% |
| Lancashire | 79% | 69% | 69% | 66% |
| Total | 77% | 70% | 68% | 67% |

The percentage of aseptic preparation in clinical areas decreased from 77 per cent in for the baseline to around 67 per cent in 2003/04, when bed-days were used as proxy (the choice of the expert panel). If admissions or FCEs are used the 2003/04 figures are 68 and 70.

If unused capacity from the C&CP (see Table 5.17.5) were fully taken up and used within trusts in the North West, then the percentage of products prepared in clinical areas would have reduced to around 60 per cent (using beddays as the proxy).

5.17.7 Trusts participating in C&CP

Table 5.17.5 highlights that units included in the C&CP failed to meet their planned targets by 228k products, despite two of them significantly exceeding plans. Table 5.17.8 provides details of the actual increases in production and how these compared with plans, for each Trust/unit.

Detailed explanations for the failure to achieve targets were obtained from the relevant chief pharmacists. The details are provided in Section 11.53, and space does not permit their being fully quoted here. In summary, the main problem was one of timing and economics. When the whole programme was created Chief Executives of purchasing Trusts committed to (a minimum of) two years business for the additional production volumes. Unfortunately, the implementation of the schemes covered a 5-year period rather than the 18 months or so envisaged, which effectively negated the commitment to buy two years worth of products:

- The purchasing Trusts concerned had to acquire the products from somewhere, to support the treatment of patients;
- The climate of the NHS moved significantly more towards proper market conditions;
- Those units that had increased their capacity in the early stages, and which had established transport and supply links, therefore had increased numbers of buyers who they could not reasonably refuse (the two units that produced 50k more products than originally projected both fell into this category);
- Some purchasing Trusts were not necessarily realistic about what they should pay for products made in other NHS organisations. The producing Trusts were not going to produce more products without commitment: Boards will not approve the necessary investment in staff for increased production, unless there are guarantees.

In addition, there were some specific local problems (see Section 11.53).

Table 5.17.8 Comparison of Actual & Planned Increases in Production for Trusts/Units that received Capital Funding (Anonymised)

ACTUAL INCREASE (Difference between Final & Baseline Surveys)

| Trust/ Unit | A | B | C | D | E | F | G | H | Total |
|---------------------------|--------------|--------------|---------------|---------------|-------------|-------------|---------------|--------------|---------------|
| Cytotoxics | 2434 | -675 | -1152 | 964 | 0 | 196 | 416 | 364 | 2547 |
| Epidural Injections | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4770 | 4770 |
| Eye drops/Irrigations | -425 | 371 | -899 | -3889 | 0 | -30 | -338 | 72 | -5138 |
| Irrigations (ex Opthal) | -215 | 0 | 0 | -3098 | 0 | 0 | 0 | 0 | -3313 |
| Minibag Plus | 0 | 0 | 113603 | -40000 | 0 | 23420 | 109160 | 17637 | 223820 |
| Minibag/Infusion | -15318 | 4079 | -7214 | -16000 | 0 | -11732 | -12777 | 15209 | -43753 |
| Injection devices* | -483 | 569 | -52 | -8 | 0 | 53 | 0 | 716 | 795 |
| Prefilled syringes | 3012 | 17871 | 5807 | 8730 | 0 | -4309 | 22779 | 2966 | 56856 |
| TPN - Compounded | 216 | 460 | 34 | -237 | 4107 | 329 | -528 | -381 | 4000 |
| TPN - Simple Additions | -4 | 1059 | -275 | 498 | -1096 | -387 | 756 | -481 | 70 |
| TPN - Neonatal/Paediatric | -122 | -82 | 40 | -2300 | -194 | 223 | 605 | -470 | -2300 |
| TPN Total | 90 | 1437 | -201 | -2039 | 2817 | 165 | 833 | -1332 | 1770 |
| Other | 1693 | 0 | 437 | -8574 | 0 | 154 | 0 | 0 | -5576 |
| TOTAL | -9212 | 23652 | 110329 | -63914 | 2817 | 7917 | 120073 | 40402 | 232064 |

PLANNED ADDITIONAL ACTIVITY

| Trust/ Unit | A | B | C | D | E | F | G | H | Total |
|---------------------------|--------------|--------------|--------------|---------------|-------------|--------------|--------------|---------------|---------------|
| Cytotoxics | 0 | 0 | 0 | 2000 | 0 | 0 | 0 | 2000 | 4000 |
| Epidural Injections | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Eye drops/Irrigations | 0 | 0 | 0 | 0 | 0 | 0 | 100 | 0 | 100 |
| Irrigations (ex Opthal) | 0 | 0 | 0 | 0 | 0 | 0 | 200 | 0 | 200 |
| Minibag Plus | 0 | 0 | 30000 | 0 | 0 | 5000 | 20000 | 100000 | 155000 |
| Minibag/Infusion | 0 | 0 | 30000 | 45000 | 0 | 15000 | 35000 | 4000 | 129000 |
| Injection devices* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Prefilled syringes | 20000 | 40000 | 0 | 55000 | 0 | 30000 | 15000 | 3000 | 163000 |
| TPN - Compounded | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TPN - Simple Additions | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TPN - Neonatal/Paediatric | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TPN Total | 0 | 0 | 0 | 0 | 4250 | 1500 | 0 | 0 | 5750 |
| Other | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3000 | 3000 |
| TOTAL | 20000 | 40000 | 60000 | 102000 | 4250 | 51500 | 70300 | 112000 | 460050 |

ACTUAL INCREASED ACTIVITY LESS PLANNED ADDITIONAL ACTIVITY

| Trust/ Unit | A | B | C | D | E | F | G | H | Total |
|---------------------------|---------------|---------------|--------------|----------------|--------------|---------------|--------------|---------------|----------------|
| Cytotoxics | 2434 | -675 | -1152 | -1036 | 0 | 196 | 416 | -1636 | -1453 |
| Epidural Injections | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4770 | 4770 |
| Eye drops/Irrigations | -425 | 371 | -899 | -3889 | 0 | -30 | -438 | 72 | -5238 |
| Irrigations (ex Opthal) | -215 | 0 | 0 | -3098 | 0 | 0 | -200 | 0 | -3513 |
| Minibag Plus | 0 | 0 | 83603 | -40000 | 0 | 18420 | 89160 | -82363 | 68820 |
| Minibag/Infusion | -15318 | 4079 | -37214 | -61000 | 0 | -26732 | -47777 | 11209 | -172753 |
| Injection devices* | -483 | 569 | -52 | -8 | 0 | 53 | 0 | 716 | 795 |
| Prefilled syringes | -16988 | -22129 | 5807 | -46270 | 0 | -34309 | 7779 | -34 | -106144 |
| TPN - Compounded | 216 | 460 | 34 | -237 | 4107 | 329 | -528 | -381 | 4000 |
| TPN - Simple Additions | -4 | 1059 | -275 | 498 | -1096 | -387 | 756 | -481 | 70 |
| TPN - Neonatal/Paediatric | -122 | -82 | 40 | -2300 | -194 | 223 | 605 | -470 | -2300 |
| TPN Total | 90 | 1437 | -201 | -2039 | -1433 | -1335 | 833 | -1332 | -3980 |
| Other | 1693 | 0 | 437 | -8574 | 0 | 154 | 0 | -3000 | -8576 |
| TOTAL | -29212 | -16348 | 50329 | -165914 | -1433 | -43583 | 49773 | -71598 | -227986 |

5.18 New Information Systems

Triangulation of the five telephone interviews found that there was no new pharmacy (aseptic dispensing) information system, and in all cases the basic functionality and nature of the existing systems had not changed and no changes were anticipated. Therefore it is concluded that the situation described in the original audit still applied, and would still apply beyond the period of the research (see Section 11.57)

The emerging themes for EPS were triangulated through the interviews and scrutiny of the EPS functional specification (CFH, 2007). Summary details from the interviews are provided in Section 11.55.

The triangulated themes are that the planned EPS are output based and aimed at best use of medicines and risk reduction. They will not provide the data required by this research. For example, a prescription will state the required medicine but not how it is delivered (e.g. prefilled syringe, TPN, oral) or how the medicine originates (e.g. made up by pharmacy or by nurse on ward). The situation is basically the same as when the Data Audit exercise (see Section 5.2) took place, with aseptic preparation data insufficiently robust for the requirements of the research and analysing data not straightforward. Few hospitals have fully-fledged EPS in place, and rolling them out across all hospitals will take considerable time.

The conclusion is that the new EPS will not generate the data identified by the research in the foreseeable future. This suggests that the research conclusions and recommendations will remain valid for some time.

Chapter 6 Discussion

6.0 *Aim and objectives and research process*

The primary aim of the research was to identify the types of data and ways of measuring aseptic preparation and production required to evaluate changes in activity and performance over time. The research addressed the following questions:-

- How should activity relating to aseptic preparation in hospital pharmacies and clinical areas be counted, collated and analysed?
- Can existing information systems readily provide such data?
- What statistical indicators can be developed to support collaboration and capacity planning for (NHS) aseptic production, and to evaluate related initiatives?
- How can such data and statistical indicators be best utilised?

The objectives of the research were:-

- To establish sound, practical methods of collecting data which meet the needs of services;
- To establish (proxy) statistical indicators that relate to the concepts of “collaboration”, “capacity” and “workload”;
- To provide analyses of the data collected to hospital trusts to support them with collaborative arrangements and capacity planning;
- To evaluate the changes engendered by capital investment programmes.

The practical boundaries of the research also needed to be established, i.e. what is the point beyond which the acquisition of data and use of statistical indicators ceases to be practical, acceptable and useful to professionals?

The steps required to achieve these research goals have been outlined in Figure 1.2 in Section 1.20.

6.1 *Information Required and Data To Collect*

The first basic question was why professionals and managers require information and what data they require? The strength of a workshop approach (see Section 3.1) was that it could be structured to progress through linked processes to achieve desired outcomes, and enabled wide-ranging, relevant experience and expertise to come together and reach consensus: NHS & Industry; managers, pharmacists, nurses, doctors; different areas of

hospital care. Group work was carefully prepared to maintain professional balance whilst covering the full range of circumstances, with their independence meaning their results could be checked for consistency. Validation checks were integral to the structure and processes to assure quality outcomes.

The evaluation of the Affinity analysis (Brassard, 1996) was that it was very successful: all participants made contributions; the vast majority could be described as significant. Compared with other Affinity Analysis exercises the total ideas generated (216) were at the high end of what could be expected, and underwrote the value of the outcome.

The main outcome from the rest of the workshop was that key decisions were made that underpinned the whole of the research:

- The data relevant to the research was established (See Section 5.1);
- Data should be acquired by means of a survey;
- The main data currency should be the Dose /Administration /Product (delivered to a patient), which should be assigned to Product Presentation/Type;
- Product types were used differentially in different clinical areas;
- The data should be robust across different clinical areas;
- The importance of nomenclature issues was recognised;
- The decision was reached that UTEs should be used to weight aseptic production rather than SMVs.

The last point was of critical importance, and it is necessary to set out the reasoning:

- (a) UTEs allow for accurate comparison of total output, with analyses used for safety monitoring, long term business plans and strategic planning. Trend analyses use UTEs per cabinet, UTEs per person, UTEs per hour, etc. They are used irrespective of whether actual production (in any particular site) has the same time relationships. Therefore UTEs do not provide a quantitative measurement of efficiency.
- (b) The UTE approach was similar to that developed by Pharmacists in North West around costing and product assessment for the collaborative purposes (North West Aseptic Task Group, 1998).
- (c) SMVs consist of time studies, direct observations and interviews with aseptic personnel, and break down operations into their elements. They require the accurate breakdown and timing of all activities plus an understanding of complex formulae. Therefore, their calculation is a major exercise involving industrial engineers, and is normally only undertaken every five years or so, or when there is significant change.

The resources concerned can be considerable. SMVs will be different for each unit, and can therefore be used to calculate unit capacities and efficiencies.

- (d) Whilst in theory both approaches could be translated to the NHS, it was probably not feasible or practical to introduce SMVs throughout the NHS because of the amount of work (and consequent cost) involved. This conclusion was made because SMVs are different for each aseptic unit, and whilst Baxter's had four in the UK at the time there were over 40 in North West Trusts alone. Also, whereas Baxter's could focus on a comparatively limited range of products that are viable commercially (partly because of the comparatively large size of the facilities), the NHS has to deal with the full range of products and respond to prescriptions direct from clinical areas, often in small units.
- (e) The UTE approach allows the accurate comparison of total output between aseptic units and the monitoring of trends, once acceptable values had been determined. Their use involves little or no cost, which cannot be ignored within the NHS.
- (f) It was concluded that UTEs should be used as their use for comparing private sector aseptic units and monitoring trends is of direct relevance to the NHS and the research.

The evaluation of the workshop by the expert panel (i.e. including the 'control' members) was that all aims and objectives had been met. This was a consensus (qualitative) view based on the results and outcomes papers, and the collective discussion. The out-turn questionnaires' results confirmed the workshop as a success (see Section 11.12).

The chief impact was the multi-professional consensus about the data and time weightings to be collected to measure aseptic preparation and production activity. Although some individual aspects were not "new knowledge", linking them together and validating their potential for application was.

6.2 *Feasibility of Collecting Data*

Identifying the data required is of little use if it is not feasible to collect it and it is not robust. Different approaches were required for data from pharmacies and data from clinical areas (see Sections 3.2 and 3.7 respectively).

The basic premise was that (pharmacy) data should be a by-product of operational systems (NHS Executive, 1998). Therefore it was necessary to confirm the pharmacy systems used, and then whether they could provide the data. The first step was to survey all hospitals' systems, with the second step being to scrutinise them for the identified data. The nature of a system is that it is (virtually) the same in whichever hospital it is installed, and so it was not necessary to investigate the situation in all hospitals: it was sufficient to

ensure all systems were investigated, across the spread of the types of hospitals, in case the different environments impact. There was little benefit from actually visiting a computer, and so a desktop approach analysing manuals, print-outs and similar, backed up by a questionnaire covering key issues, represented a robust use of resource.

The results showed the required data could be acquired, sometimes with additional collation work. Data quality would be robust at product type level, but could not be guaranteed below this. Therefore, the research could continue. Also, as the systems examined were understood to cover practically the whole of the country, this pointed to the potential for research findings to be transferable. However, the systems did not hold data on aseptic preparation activity in clinical areas.

To investigate data in clinical areas, the expert panel agreed the research methods should involve visits with structured interviews; to investigate ward stocks, prescribing and associated processes, existing documentation and recording methods. The number and range of clinical areas in all (acute) hospitals in the North West is huge, with the strong likelihood of varying practices, policies and documentation. It was impossible to visit all clinical areas in all hospitals, and therefore care was taken to visit each type of clinical area at least twice, with all different types of hospitals and each geographical zone also covered, to ensure that results were robust. This was reinforced by the interviews being undertaken by experienced senior nurses.

It was found that within each NHS Trust, pharmaceutical management, i.e. stock control management issues, were managed according to the needs of the individual clinical area, within the constraints of budgeting, consultants' preferences, and available pharmaceutical resources. Documentation may be standard within a NHS Trust, but it was not standard throughout the North West. Whilst such standardisation is desirable, it would not be feasible.

Information was readily available on all stock issued to a clinical area, but stock not obtained directly from pharmacy may or may not be recorded, given that it was usually required in emergency. Given the small numbers involved, it was noted, but ignored for data quality purposes. Aseptically prepared medicines fall into two categories:

- Category one has a primarily one to one relationship (dose = product), a known currency of one single product dose.
- Category two requires the combination of two or more ingredients and therefore has a 1 to n relationship.

Should 'real-time' data be recorded the responsibility for data capture would fall to nursing staff. Historical data could be captured either by pharmacy or nursing staff. Concern was raised as to the consistency of data collated by nurses, where there was a heavy workload. Additional human resources may be necessary to undertake surveys in such circumstances.

Given the number of administrations carried out in clinical areas, careful consideration should be given to what data is actually required. Prudent selection of only the minimum necessary should improve the consistency of data capture. Information extracted from pharmaceutical systems could be used to support any clinical area surveys. A sampling approach would best determine the levels of activity within clinical areas, as it would be unrealistic to carry out data collection in all areas 365 days a year. Collecting data on product and product dose, over a period of one month per year, or four individual weeks, every three months, should provide sufficient and representative data. Selectivity in which clinical areas to survey may be required, due to workloads and available resources.

The importance of these findings is that they confirm the difficulty of acquiring standard, routine data for aseptic preparation in clinical areas. Although a negative result, it was positive in that it highlights a practical boundary for the research that might then be the subject of further work. The findings represent substantial new knowledge, as this is an area not previously explored. The principle of having to rely on "snapshots" to collect pharmacy data in clinical areas was reaffirmed by Hardy and Mellor (2007).

Having established the situation for both pharmacies and clinical areas, it was essential to validate the findings through a workshop, which included many professionals from the initial workshop for continuity. The results from the out-turn questionnaires confirmed the workshop as a success (see Section 11.22).

6.3 *Nomenclature Issues*

The initial workshop identified that there were nomenclature issues relating to aseptic preparation that could potentially influence data quality. Therefore it was essential to explore their extent and how they might impact on the research. As this was not anticipated when planning the research it was necessary to be pragmatic. As structured interviews would be required, primarily with nurses, the issues were included in the hospital visits, to explore local views and practices for comparison (see Section 3.8).

This was recognised as new ground from the outset, as was the need to keep focused on the needs of the research. Eight terms were key to the research which were known to have multiple interpretations, and which would require explicit definition to ensure their consistent use for the purposes of the research. Appropriate definitions were drafted and endorsed by the expert panel (which clearly understood the context) before being presented for validation to nurses interviewed. They could suggest amendments, which were considered by the expert panel to determine final definitions.

Whilst such specifics were required, it was also desirable to establish how wide-ranging nomenclature issues might be. It was decided to try and identify all alternative terms used (however frequently) for nine selected words (four of which were included in the definitions). To make best use of time at visits, and illustrate what was being sought, the expert panel produced an initial list of alternative words, which professionals were asked to confirm that they had heard, and then invited to add others. The initial list had 93 words for the nine terms and had 37 added – a 40 per cent increase.

The (interim) results were included in the Data Audit workshop for validation. There was debate about the sensitivity and objectivity of their use within and outside the scope of the research, and to the implications for the future. Examples of note were:

- 1 There is a wide range of *Routes of administration*, with the most routinely used being: Intravenous, Intramuscular, Subcutaneous and Intradermal. Less common were: Intrathecal, Intrapleural, Intraperitoneal, Epidural, Intra-articular and Intraventricular.
- 2 The term *Parenteral* was difficult to define explicitly, as it was used in several contexts by different professional groups.

Dictionary definitions of "Parenteral" also differed. For example Mosby's Medical and Allied Health Dictionary states: "Not in or through the digestive system" (Glanze et al, 1986) whilst On-line Medical Dictionary gives "Not through the alimentary canal but rather by injection through some other route, as subcutaneous, intramuscular, intraorbital, intracapsular, intraspinal, intrasternal, intravenous etc." (On-line Medical Dictionary)

Some definitions offered by expert panel and workshop members, for the purposes of the research, were:

- The administration of medicines by any route other than the mouth or bowel;
- The administration of medicines via the intravenous route;
- Administration by injection which may occur via a number of routes; and
- Administration by breach of the skin or mucous membrane.

Table 5.8.1 details the definition of "parenteral" finally agreed by the expert panel for use within the research.

- 3 In addition, some nursing staff associated the term "parenteral" with TPN only. A quote from the hospital visits was: "We don't prepare TPN on the ward, so this research is not relevant to our area."
- 4 *Assembly* had very different meanings for pharmacists and nurses. Pharmacists used the term when they *assembled* all of the materials and items together at the beginning of the aseptic preparation process in a pharmacy. Nurses used the term when they *assembled* the various components for administering a drug to a patient.
- 5 Pharmacists strongly believed that *Preparation* should exclude licensed products that required no aseptic manipulation (unless further manipulation took place once received from the licensed unit). Nurses disagreed, emphasising that most products, whether licensed or not, require some level of aseptic preparation in the clinical area prior to administration.
- 6 For pharmacists, the *Aseptic Process* began on receipt of a prescription. For nurses, the *Aseptic Process* began with hand washing prior to gathering together the items required for the preparation of the product in advance of administration.
- 7 The definition of the act of actually administering the medicine parenterally was debated. A process familiar to every clinician, there was disagreement in choice of the word(s) to explicitly describe it. For use within this project, nurses preferred to use either *Product Administration*, or *Product Dose*. It should be borne in mind that the process of giving medicines to patients can mean a number of medicines being given during one procedure. One approach to a patient does not necessarily count as a single administration.
- 8 The term *Dose* was often colloquially used as a generic term to cover several other specific terms. For example, it could be applied to each of the ingredients being combined in the (nurses') aseptic process, to the resulting combination, and to the actual administration itself. Also, for Patient Controlled Analgesia (PCA) devices, is a dose counted as the full content of the delivery vehicle, or one boost administered by the patient? Clearly, this term is ripe for confusion.
- 9 There are differences uses of nomenclature across countries. The use of some specific terminology is different in the US compared to the UK (see Section 11.2 Reference 4) sometimes leading to confusion when people communicate across the Atlantic. Examples include: batch production; central intravenous additives service (CIVAS); dispensing; multidose therapy; and patient specific.

There is no statistical validity in comparing the number of additional words suggested by local staff with the numbers on the initial list, as shown in Table 5.8.2 because the initial

list simply reflected the efforts of the expert panel. Nevertheless, despite an extensive initial list of 93 words being prepared, local staff still suggested 37 additional words – a 40 per cent increase. The key issue is the total number and variety of words - 130 words were identified as being used in relation to nine main terms: an average of over 14 words per term, with a range from 8 (Acquisition and Custody) to 21 (Route).

Clearly it would be impossible to try and get all staff in all hospitals in the North West (let alone the UK) to use just a single set of terms and definitions, which in theory would be one way to resolve the issue. The only practical way to address the issues for the research was to ensure that there was an explicit set of definitions for key terms, which might impact of data quality, for use and reference within the research itself, so as to ensure consistency within the research. The work demonstrated new knowledge (Gandy et al, 2002).

6.4 *Feasibility of Collecting Data and Creation of Baseline*

Having determined the research data required and ascertained that in principle it should be collectable it was necessary to test this in practice, and thereby create a baseline for the research. A survey had been agreed as the most practical means, and the structure and content agreed following pilot work (see Section 3.3). Validation checks were inbuilt which aided data quality.

Some data in the original survey (Gandy et al, 1998a) was not relevant to the research and excluded, or covered in other ways: expiry periods for “tracer” products; whether there is scope for increasing the capacity of a unit; whether “on-call” arrangements existed; and, times a unit was open. The workshops and expert panel considered these latter times of questionable use; given they did not fully reflect local circumstances and their use could be misleading. “Time” would be covered by the use of UTEs. Cross-reference to the original survey (*ibid*) enabled confirmation of (non-acute) organisations that were not relevant and could be excluded. Anonymous codes were used to encourage responses, with the outcome of a 100 per cent response from the 37 Trusts.

Form Three had been introduced comparatively late in the process to address the fact that some licensed aseptic products were being bought commercially and distributed directly to clinical areas without further manipulation in a pharmacy aseptic unit prior to administration to patients. TPNs were often used in this manner. The concern was that if Trusts show an increase in the production and usage of such a product over time, based on the analysis of data from Forms One & Two, it is not possible to establish whether this

represents a real increase or simply a switch in the use of such commercial products from the clinical areas. The list of products from the first two forms was used.

The overall size of baseline production and usage was in line with the original survey (*ibid*) but there was much greater detail. Details at organisation and product type level are shown in Section 5.3. The number of products produced varied considerably between aseptic units. Production was generally dictated by whether or not the unit held a “specials licence” from the Medicines Control Agency.

The success of the survey meant there was a robust baseline for the research, and useful analyses for immediate local, zonal and regionwide consideration, in the development of plans. Whilst the survey repeated some elements of the original survey (*ibid*) the greater detail and robustness of data represented new knowledge.

6.5 *Baseline Survey Evaluation*

However successful the baseline survey might be, it could not be assumed that no improvements could be identified. A thorough evaluation process was planned from the beginning, and included: interviews with lead pharmacists and managers, canvassing views at group meetings, and the opportunity to raise queries and comments, which were logged (see Section 3.5).

These were all summarised for the expert panel’s consideration (see Section 5.4), which took the view that queries and issues were inevitable because of the nature of the survey and the complexity of the subject matter. The main changes agreed were:

1. Radiopharmaceuticals were excluded from the research, following representations from the Regional Radiopharmaceutical Group, because of their special characteristics: there are (at least) two separate stages, where staff leave the facility and undertake other work in between, which is totally unlike general aseptic dispensing unit processes. A complication is that only a limited number of Trusts are involved and the departments are not always managed by Pharmacy – Medical Physics can have responsibility.
2. The distinction of whether a cytotoxic was an infusion, syringe or device was removed. Data available from pharmacy computer systems did not necessarily provide this level of detail, and so pharmacists estimated the split. The split had been proposed because pharmacists considered the amount of work involved varied between the categories, and allowance should be made. The data had to be robust, otherwise the benefits of subdividing the category are spurious. (If anything, the expert panel had

been guilty of trying to increase the amount of detail included in the survey beyond that dealt with by the data audit exercise (see Section 3.2) because it recognised/anticipated differentials in time and resource *within* certain product types, e.g. cytotoxics and TPN, which could be important in workload evaluation. The fact that such data could not always be acquired meant the survey had empirically tested the boundaries of feasibility).

3. The amount of work required to collect Form Three data was found to be prohibitive (and in some cases impossible). It was not possible to establish a clear definition of the commercially-acquired licensed products for which data was requested, and so the data received was inconsistent. The forms returned indicated that the number of these products used in the trusts was relatively small. Therefore it was agreed that Form Three be discontinued.
4. The question was asked whether terminally sterilised products should be included, but they were excluded because they do not really relate to the purpose of the research. This was relayed to Trusts to ensure that they had not included such products, with the opportunity for any data to be amended accordingly. (No Trusts submitted revised data as a result; however, when the final survey was undertaken (see Section 5.17) it transpired that one Trust had inadvertently included small numbers; the baseline data was retrospectively amended accordingly, but this is not reflected in the results in this section).
5. Other specific data issues and qualifications are summarised below, with the response indicated in brackets:
 - There was no scope to highlight which products were produced on site under a "specials" licence. (Noted)
 - On Form Two, where commercial compounded TPNs were purchased and subsequently used for simple additions then they appeared twice. Similar circumstances applied to cytotoxics syringes. (This was deemed acceptable because two separate processes were involved)
 - Oral products were not part of the survey or project and were therefore excluded. This was because they were not aseptic products.
 - Statements clarifying that a neonatal TPN might involve one compounded TPN plus a prefilled syringe were accepted.
 - BCGs should be classed under "Other" rather than be included in another category.
 - Cytotoxics eye drops should be included in "Cytotoxics" and not "Eye Drops".
 - Bladder installations should be classed as "Irrigations" and not "Prefilled Syringes".

Taking the above into account, and the quality of the data received, the expert panel deemed the survey had been a significant success, and should act as baseline for the

research. It had established that the basic currency for measuring activity is the number of products produced and used by product type. There was complete confidence that the amendments to the survey design and guidelines, agreed as a result of the evaluation, meant that future data collected would be totally robust.

This represented a major breakthrough and new knowledge, because for the first time there was clarity about data to be collected in respect of aseptic production and usage, together with comprehensive guidelines and definitions.

6.6 *Quarterly Surveys*

The five quarterly surveys were designed to collect the data necessary to evaluate the overall C&CP, and identify any short-term changes associated with capital schemes. The method of collecting data was developed so that pharmacists could record data with a frequency that suited them, before collating it and emailing it to the main database. (see Section 4.6).

In the event, ten of the 37 trusts did not submit any quarterly data or there were significant shortfalls in the data submitted. They included one trust that had received capital monies as part of the C&CP. Some “non-responding” trusts had closed their units, and trusts that did not have aseptic units generally did not respond. These trusts were excluded from the analysis. The trusts fully included in the quarterly surveys accounted for 71 per cent of all aseptic dispensing units and 63 per cent of the aseptic dispensing unit production activity across the region according to the baseline survey. They also accounted for 57 per cent of the total product usage.

Longstanding relationships existed between trusts that did and did not participate in the surveys, and based on local knowledge, senior pharmacists did not feel that the response was skewed, given the regionwide move for greater collaboration.

Activity and trends in the numbers of products produced at participating trusts throughout the survey period are shown in Section 5.5. Overall there was a 25 per cent increase in the number of products up until the end of quarter 3, followed by a dip. The fall in the last two quarters was largely due to production at one (major) trust being reduced as its aseptic unit was replaced with a new unit. If production in that aseptic unit were to return to its quarter 3 level when the new unit opened, the overall increase in production across the trusts would have been around 32 per cent. Such patterns highlight the important point that aseptic units may have to close (albeit temporarily) when changes, developments and problems occur.

Data from individual trusts fluctuated dramatically between quarters. A small number showed reductions in production (other than those being upgraded), but otherwise there were notable increases. This perhaps points to better use being made of the units, for example, by some moving of activity from clinical areas (Gandy and Beaumont, 2003a).

The capital schemes did not progress to the planned timetable, which complicated monitoring. Only two were completed during the period covered by the quarterly surveys, and one of these was right at the end. This meant that the overall impact of the C&CP could not be determined.

The evaluation by the expert panel confirmed the efficacy of the quarterly survey design, concluding that the data collection problems (which were outside the researcher's control) did not invalidate the research in any way. The analyses of the data over the five quarters demonstrated the key objective of establishing *how* changes/trends could be measured and monitored, had been achieved. Although circumstances had conspired against measuring the impact of the completed C&CP, the evaluation confirmed that the identified research data and how it could be analysed was fit for this purpose.

The response from the pharmacist community to this component of the research (*ibid*) reaffirmed new knowledge.

6.7 Collaboration

When the agreed collaboration model (see Section 3.9) was applied to the baseline data, the results (see Section 11.25) showed that the average import figure across trusts (i.e. indicator I) was 21 per cent, whilst the average export figure across trusts (i.e. indicator II) was 12 per cent. (Products acquired from commercial sources are deemed "imports", which means that indicator I will probably always be greater than indicator II). Trusts were described as nett importers or nett exporters according to whether the value of indicator II was lower/higher than that of indicator I respectively.

The majority of trusts did not produce many or any products for other trusts (i.e. indicator II was less than 10 per cent). Four of the trusts exported more than 15 per cent of their products (indicator II ranged 16 to 37), and were described as "high exporting units". These trusts would naturally produce the majority of products for local usage as well.

(Trusts without a local aseptic dispensing unit were excluded from collaboration diagrams as they necessarily import all products).

Figure 5.9.3 shows how the collaboration diagram demonstrates changing patterns over time: 4/5 units significantly increased their percentage exports over the period; the other Trusts are well distributed in their percentage imports, with a cluster of Trusts being largely self-sufficient (those grouped around the origin).

Table 5.9.1 and Figure 5.9.4 summarise the overall picture. The latter shows the way in which the percentage of exports has substantially increased whilst the percentage imports originally increased before falling back a little.

However, if the unit that had closed for capital work had continued at even its Quarter 3 level (i.e. ignoring any planned increases associated with the scheme), the total number of exported products at the end of Quarter 5 would have been 71,421, with a total production of 207,131. This would mean that the value of indicator II would have been 34 per cent.

This suggests that collaboration generally increased throughout the research period. It is inferred that this was the result of both the capital (and other) initiatives – one trust unit reopened as a licensed unit during Quarter 3 - and a consensus between trusts that collaboration should increase.

As the C&CP did not proceed according to plan, it was impossible to establish its full effect on collaboration, as intended. Nevertheless, the results clearly demonstrated how the indicators and diagrams could be used to measure/demonstrate “collaboration” both at a given point and over time.

The response from the pharmacist community and the expert panel was positive because, for the first time, they had clear and understandable means of describing “collaboration” for aseptic production and usage. The conceptual interpretation of “collaboration” in terms of “imports” and “exports” was consistent with the fact that hospitals trade with one another, and the statistical indicators were simple and used the research data. As a result “collaboration” was now measurable. This component of the research clearly represented new knowledge (Gandy and Beaumont, 2003b).

6.8 *Time Weightings*

A central objective of the research was to establish time weightings that could be applied to aseptic production activity figures, so that production time could be quantified and analysed. As seen in Section 6.1, UTEs would be the means of doing this. The expert panel decided that they should relate specifically to the production process: the period from the receipt of a request/prescription/order to the approval of the finished product by the supervising pharmacist. The question was how to determine their values?

The first methodological choice was for empirical observation, applying work-study techniques. This yielded some valuable results (see Section 5.10) but did not achieve full UTE values because of problems, mainly about the work-study professional being present in a unit when aseptic preparation was taking place. For example, in order to maintain an aseptic environment, the professional could not sit next to the pharmacist or technician preparing the products, and to be in the unit at all, the professional needed to “gown up” and appropriately cover his monitoring equipment (for example, stopwatch, clipboard, paper). In the few units where CCTV existed, the whole of the cabinet was not in view, and so UTEs could not reliably be obtained from reviewing the footage. (That the whole of the cabinet is not covered by CCTV is not a problem during normal use because operators are trained to hold objects up to the camera, for example, for checking).

Notwithstanding these problems, the work-study professional did identify wide variations in the time taken to make up items in a particular product category both between units (often depending on the method of work) and within units. For example, one unit visited prepared 37 different types of prefilled syringes, with the number of ampoules required to make one syringe varying considerably up to a maximum of 25. The process time involved in making similar products also varied depending on the speed with which solutions mix. It was clear that unless each item in each category was individually timed and unless each product category in each unit was given its own unique time, establishing UTEs by this method was not possible. Undertaking this work was not practical within the scope of the research.

Given this situation an alternative approach was essential, with an iterative process using statistical techniques of “multiple perspectives” and “Delphi” (Linstone and Turoff, 1975; Linstone, 1984; Surowiecki, 2004) with as much cross-checking as possible (see Section 3.11). The basis of the approach had been successfully used by pharmacists in the past and in industry (see Section 11.2 References 3 and 8).

Surowiecki (2004) describes how a crowd's views can be better than those of a small group of experts when there is: diversity of opinion; independence of members from one another; decentralisation; and a good method for aggregating opinions. The methods of validating expert opinion used the North West pharmacists as the "crowd", with these conditions applying as they work independently, are geographically separated and freely expressed their opinions at all stages of the research. The forms which invited confirmation of, or alternatives to experts' proposed UTE values were robust and enabled opinions to be aggregated. The adjustment to create UTEs for licensed and unlicensed products was effective.

There was considerable variation in UTE values between the different product categories (see Section 5.11). The products produced in high numbers (minibag plus, minibag/infusion and pre-filled syringes) all have low UTE values.

Yet the expert panel saw that the different circumstances and practices of units might mean aseptic managers not accepting the UTEs applicability to their local situation.

Consequently how UTEs were to be used was important. As the emphasis for developing capacity plans lay with local Trusts, informed by benchmarking data, it was essential for local pharmacists and managers to feel comfortable and confident in such data for them to use it. If the UTEs were presented as reasonable mean times which local units could compare with what was achieved locally then their threat would be minimised. Such units could then analyse what local circumstances or practices might account for any variation and act accordingly. However, if the UTEs were presented as fixed (performance) targets, say, then they would be viewed and used very differently. Consequently the expert panel proposed that the mean UTEs used in the benchmarking analyses should be described as "Marker UTEs".

It was important to appreciate that there will be dynamics in aseptic production which will mean that any UTE values will change over time, presumably to reduce. By adopting a professional judgement approach to setting Marker UTEs, backed up by empirical evidence wherever possible, it is easier to maintain and update a benchmarking database.

The Marker UTE values represent a major breakthrough because they mean that for the first time NHS aseptic production activity can be robustly weighted to reflect the actual time involved, which is central to measuring capacity and workload. The confidence intervals enable sensitivity analyses to review local performance (Gandy and Beaumont, 2003b).

6.9 *Quantifying the Concepts of Capacity and Workload*

As described in Section 3.12 “capacity” and “workload” are essentially concepts that do not have a single, measurable meaning. Therefore it was necessary to determine what they mean in the context of aseptic production, in a way that can be measured.

Section 3.12 sets out the reasons for, and the design of an initial workshop to explore this. Section 5.12 gives the main results. The Affinity analysis resulted in 91 post-its presented by the group (albeit with a small number of duplicates), which were arranged into ten Affinity groups. The average number of post-its was approximately 8 per person, above average for such exercises; reflecting well on the interest and commitment of the participants. The results underwrote the value of the outcomes.

Independently of one another, the syndicate groups explored very different approaches to defining and measuring capacity and workload, but the outcome was that no consensus could be reached about their definition. Neither of the models pursued was entirely satisfactory, and the lack of consistency in aseptic unit design was a major constraint. *Capacity* was generally viewed as a measure of a unit’s ability to maximise its workload.

Considerably more information would need to be collected than was collected in the baseline survey to take full account of the numerous factors (especially on staffing and staff mix) that influence capacity. Collecting this large amount of information for all trusts would be difficult in terms of ensuring data quality and consistency. Also, even if the data could be collected, there would still be issues about how it should be used. Clarity about the benefits and use of additional data is essential to be able to justify requests for data from pharmacists.

In light of the above, it was decided that the appropriate way forward was for each unit or trust to develop its own capacity plan. The model developed by the NHS pharmaceutical production committee was a good example (Lillywhite, 2000). The plan should make explicit, for example, a trust’s assumptions, resources and constraints. Although capacity plans should be developed locally, they should be open to external scrutiny, particularly where collaborative arrangements are in place.

The data collected in the research provide a basis for constructing such capacity plans through a benchmarking approach. It enables relativities between trusts to be highlighted, and can be used by trusts to inform and justify local capacity plans, taking local factors into account.

The only additional data specified was the number of cabinets (i.e. laminar air flow cabinets and pharmaceutical isolators) because the greater the number the greater the potential production. The number of cabinets is required rather than the number of associated workstations because, in practice, in NHS aseptic units, only one operator carries out aseptic manipulation in multiple-workstation cabinets at a time.

The workshop was a success in how it was organised, but the mixed responses about whether the workshop and syndicate groups achieved their objectives arguably reflected the complexity and nature of the subject (see Section 11.36).

There can be no doubt that this workshop dealt with the most difficult issues of the research to date. There were different approaches and viewpoints, generating considerable (healthy) debate, with no obvious solutions apparent. Yet such a negative outcome was actually positive because, for the first time, the whole issue had been formally investigated and any notions that there are straightforward definitions that can be readily measured were completely dispelled. This is critically important for pharmacists and managers to know so that they do not waste time.

Identifying that a specific statistical definition of capacity is not feasible and that individual capacity plans should be developed for trusts using a benchmarking approach was an important conclusion (Gandy and Beaumont, 2003b), which was triangulated at the Audit Training Course in Birmingham (NHS Executive North West, 2001).

6.10 *Statistical Indicators*

Without a single all-encompassing statistical indicator to describe *capacity* or *workload* a range of statistical indicators are required, which only use the identified data, from which (relative) performance can be inferred to inform capacity planning. The iterative process for doing this is described in Section 3.13, with the main results of applying them to the baseline data shown in Sections 11.40 and 11.52.

The baseline results showed there was wide variation in the use made of aseptic dispensing unit facilities. For example, ADUHW ranged from 7–114 hours for licensed units and from 2–348 hours for unlicensed units. The number of cabinets was a clear factor, and when this was taken into account (i.e. by using ADUHWC) there was greater consistency, although the variations were still marked (7–38 hours for licensed units and from 1–69 hours for unlicensed units). The highest ADUHWC figure was for a licensed unit that only produced TPNs (which have high marker UTEs). The highest ADUHWC figures for unlicensed units were for high volume units. This was not surprising because

producing a large number of products enables efficiencies in processes to be effected, and these efficiencies are not accounted for in the UTE values for unlicensed units. It may therefore be appropriate for high volume unlicensed units to use the marker UTEs for licensed units, but this is something for the units themselves to consider when assessing their performance.

When considering the time spent using the cabinets, only seven units seemed to use each of their cabinets for more than two hours per day. Even if the figure of 40 per cent (the top of the range of cabinet time observed by the work-study professional) was used to calculate CHWC, only one additional unit would meet this level of usage. It should be appreciated that the CHWC figure is by definition an average over a week and that there are necessarily variations in the workload, with Thursdays and Fridays generally having the highest workloads in preparation for the weekend. This points to cabinets being used sparingly at other times. It is arguably unrealistic for some smaller units to increase their workload significantly, because they essentially perform an “insurance” role – in other words, they are there to provide an essential but irregularly used aseptic facility and must be maintained in an operational state in case patient need arises.

It was reasonable to anticipate that the mix of products would influence how much time units were used for. However, a scatter diagram (Figure 5.13.1) linking the two relevant statistics clearly shows that this is not the case, as the R^2 value was 0.0002. (The R^2 value shows how good one term is at predicting another; if it is 1.0 then given the value of one term, the value of another term can be perfectly predicted, but if it is 0.0 then knowing one term does not help the prediction of another term at all).

The numbers of cabinets were “at a point in time” – rather than the average availability over a given period. Chief pharmacists on the expert panel advised that the latter would be too difficult to collect accurately. Nevertheless, in principle, where there have been changes (through expansion or rationalisation) the average available number of cabinets could be calculated for a period, and the related indicators would remain valid.

The results demonstrate the value of both the data collected and the way it has been analysed. The statistics highlighted the diversity of what happened in aseptic dispensing units across the North West. The derivation of the statistics is valid, and whilst there will inevitably be a degree of statistical “noise” by the very nature of the Marker UTEs, the differences identified are too large to be attributable to this. The view of the expert panel was that there can be no doubt that the statistics are genuinely capable of generating and informing local debate about the use and performance of the aseptic dispensing units.

The development of the statistical indicators and their application to the baseline (and subsequent) data was significant new knowledge that enabled aseptic production performance to be evaluated in detail (Gandy and Beaumont, 2003b).

6.11 *Use of Data and Statistical Indicators to Evaluate Change*

A primary purpose of the research was to identify data and means of measuring aseptic preparation and production to evaluate the outcome of the C&CP, i.e. to evaluate changes in activity and performance over time. The statistical indicators had been successfully applied to the baseline data, together with analyses of activity trends over the five subsequent quarters. The use of arrows had successfully been used to this end on collaboration diagrams.

The real test of the research findings' efficacy was therefore when survey data was available for all North West trusts following the last capital scheme's completion. Section 4.17 describes the methods, the allowances for organisational changes and the requirements of pharmacists relating to data collection.

Comparing the results from the baseline and final surveys raised many points. There were clearly major increases in aseptic production in the North West, with the three main objectives of the C&CP achieved:

- Aseptic production and production capacity significantly increased;
- Collaboration very much increased between Trusts; and
- The balance of aseptic preparation moved towards pharmaceutical units.

Chief pharmacists across the North West appear to have reviewed local practice and assessed risks, and worked collectively to make best use of available resources. More of the time-intensive products (which possibly involve most risk) were prepared in-house in the aseptic dispensing units.

The major increase in the number of licensed units reflected regional recommendations (NHS Executive North West, 1997), and available facilities (in terms of cabinets) were used more intensively. There appeared to be greater consistency in the relationship between how intensively cabinets are used and the mix of the products, in line with whether a unit is licensed or not.

There were major changes in (some of) the export/import patterns for different product types, with collaboration increasing, although the individual zones developed different emphases. Greater use was made of commercial sources, where appropriate.

There are clearly differentials between the zones, with Lancashire arguably moving ahead further than the others. Interestingly, Lancashire has almost had to “run to stand still”, given that patient activity greatly increased, and with it (it is inferred) the demand for aseptic products.

Reducing the aseptic preparation taking place in clinical areas to 67 per cent (with potential to further reduce it to around 60 per cent) represents a major achievement; the figure estimated for West Midlands Region was 91 percent (see Section 5.16).

Nevertheless, the fact that most of the units having capital schemes did not achieve their projected targets was a source of concern. Their chief pharmacists each gave reasons for this (see Section 11.53). They were not all the same, and included problems where an aseptic unit staff member suffered from repetitive strain injury and the local Occupational Health advice placed considerable constraints on how much work could be done. Production consequently fell below previous workload levels, although the situation subsequently improved.

The main problem appeared to be one of timing and economics. When the C&CP was created Chief Executives were required to sign up for two years business for the additional production volumes. Unfortunately, the implementation of the schemes covered a 5-year period rather than the 18 months envisaged. The reasons for the delays are not relevant to the debate, but such an extended period of implementation effectively negated the commitment to buy two years worth of products: purchasing Trusts had to acquire products from somewhere, to support patient treatment, and those units that had increased capacity in the early stages (which had established transport and supply links) therefore had increased numbers of buyers who they could not reasonably refuse. The two units that produced 50,000 more products than originally projected both fell into this category.

In addition, the NHS climate moved significantly more towards proper market conditions. The view was expressed that some/many of the ‘purchasing’ Trusts are not necessarily realistic about the price for products from other NHS organisations, and this is possibly a major hurdle. ‘Producing’ Trusts will not produce more products unless there is the business/commitment. Certainly, chief pharmacists will not get Board approval for the necessary investment in staff for increased production, unless there are guarantees.

If all the unused capacity from the C&CP were fully taken up and used within trusts in the North West, then a further 328,000 products would be made, and aseptic production would increase by 81 per cent instead of 48 per cent, with aseptic use increasing by 75 per cent instead of 45 per cent.

An evaluation of the individual capital schemes associated with the C&CP is in Section 11.53. The overall conclusions in respect of the C&CP are:

1. In the main it was a success, with two Trusts/units far exceeding projected volumes and another four significantly increasing production;
2. Local problems and issues affected the situation at the remaining two Trusts/units, but both look forward to increasing activity in the future;
3. The failure of the internal market arrangements, as originally agreed, impacted on several Trusts/units;
4. Practices at two Trusts in respect of the use of minibag plus need to be noted and included in any debate.

The issue referred to in (4) relates to where, following risk assessment, the view was taken that issuing minibag plus, without a vial attached, is a lower risk item for aseptic manipulation in clinical areas. Given the predicament at both the Trusts concerned - aseptic production was severely constrained at particular points in time - it made sense to acquire minibag plus commercially and then issue to a ward for subsequent addition of the vial. This led to both Trusts not manufacturing minibag plus themselves at the scale originally planned. These two Trusts were responsible for almost all the acquisition and supply of undocked minibag plus across the North West.

It is concluded that the overall Collaborative and Capital programme was a significant success. There were instances where ambitions have not been (fully) realised, primarily in respect of some of the capital schemes, but this did not detract from the major increases in aseptic production, usage and collaboration, and the reduction in aseptic preparation taking place in clinical areas.

The analytical methods developed within the research proved their worth, by enabling the analysis of change over time, when quite complex issues were at play. They were sufficiently flexible and robust to deal with the various organisational changes that had taken place.

This was the first complete evaluation of an aseptic dispensing initiative of this size and it demonstrated its worth by the lessons and impacts revealed. This provided a practical template for the monitoring and evaluation of such programmes as well as local performance.

6.12 *Transferability*

It was essential to demonstrate the research data and methods could be used outside the North West, to confirm their general applicability. The opportunity arose in respect of the West Midlands. In essence the methods involved simply applying the research survey methods to the region and then analysing the data (see Section 4.16 and Section 11.50).

The survey in the West Midlands was a success and provided useful data for local purposes. The main value was in how the results showed the very different profiles for aseptic preparation in the two regions. For example, it was inferred that many more products were prepared on the wards in the West Midlands: extrapolating North West figures, using admission data, suggested that circa. 3.2 million products were used by trusts in the West Midlands with only 9 per cent prepared under pharmacy control. Nearly 13,000 products were acquired from commercial sources in the West Midlands, accounting for just over 4 per cent of products used, which was much less than the North West. The most significant result was that the product profiles in the two Regions were totally different (see Figure 5.16.1).

There was limited collaboration in producing products between West Midlands trusts. The average export figure (indicator II) across the 23 trusts that produced aseptic products was 13 per cent, with the average import figure (indicator I) being 16 per cent. (These compare to 12 and 21 respectively for the North West baseline). It appeared that many West Midlands Trusts largely dealt with only their local situation. The majority of Trusts did not “export” products and five did not “import” any. Much of the collaboration seems to concentrate around the Birmingham area, but there were no clear geographical patterns.

Having confirmed the transferability of the research, it is worth noting that it has been successfully applied across two regions in the UK, the combined population of which is circa. 12 million (Gandy et al, 2003). To put this in perspective, this population is greater than that of the majority of countries in Europe. Only seven have a larger population, viz. France, Germany, Holland, Italy, Poland, Romania and Spain (United Nations Economic Commission for Europe, 2007). This suggests the methods could be applied outside the UK, in terms of time and effort, if aseptic preparation and pharmacy arrangements share relevant similarities.

The exercise represented new knowledge and pointed to the prospect that the profiles of aseptic preparation and production could be different throughout the UK.

6.13 *Modelling*

A natural step after identifying data and statistical indicators to enable activity and performance evaluation of aseptic production is to examine whether they can underpin modelling techniques. If this is possible and such techniques can be computerised then there would be the opportunity to optimise various projections.

It was shown that capacity planning software was not easily applicable to the NHS hospital aseptic dispensing situation (see section 5.13). A critical review of capacity modelling in relation to NHS aseptic dispensing units indicated (see Section 11.41): it is applicable where (expensive) equipment is used and manpower is comparatively plentiful or low cost - industry configures a factory/unit to produce very large numbers of a limited range of products, and equipment operators are semi-skilled or skilled as opposed to professional/specialist; the wide range of products and specific drug regimens provided in the NHS means the scope to produce a small number of very specific items in very large volumes does not exist - skills have to be in place to accommodate the full range of patient requirements; smaller aseptic dispensing units serve an "insurance" role; in effect, NHS aseptic units have relatively low-cost equipment but scarce and expensive specialist/professional staff, where their absence can have a potentially disruptive effect.

In terms of Schmenner's Service Classifications, described by Dotchin and Oakland (1993), this analysis arguably places (unlicensed) NHS aseptic units as a "Professional service", because of the high interaction and customisation and high labour intensity, where the latter is defined as a ratio of labour costs to capital equipment costs. By comparison, licensed production has low interaction and customisation whilst maintaining high labour intensity, which would place it as a "Mass service" (*ibid*).

It is concluded that capacity planning for an aseptic unit is primarily a skills management issue, rather than one of (solely) process management. Therefore it is not suited to capacity modelling techniques that require detailed statistical, process data.

NHS initiatives in respect of skill mix and competencies do not appear to be strongly linked with what might be required to support improvements in capacity planning methodologies, which could in turn benefit from a skills-based quality management approach. This connection must be made if capacity planning for aseptic preparation is to go on to the next level, which is necessary if preparation is to be appropriately and economically maximised, so that related risks are best managed and minimised (Gandy et al, 2006).

This establishes a clear boundary to the research beyond which it is not feasible for the researcher to proceed.

6.14 *Acute versus Medium/Long-term Capacity Planning*

The research data was collected for a quarter and a year. Therefore its efficacy, and that of the methods, has only been established for these, or longer periods. However, aseptic dispensing unit workload varies over a week for several reasons, often with peaks on Thursdays and Fridays to cover week-end requirements (see Section 5.10). Therefore it is important to determine whether the research can apply for acute capacity planning, i.e. daily/weekly.

The evaluation included a literature review and contacts with lead pharmacy personnel in respect of local approaches, followed by a critical review of the information (some is work in progress) (see Section 4.14).

The national chemotherapy simulation tool (Concentra, 2006) addresses acute capacity planning but required considerable resource to develop, great amounts of data (over 52,000 different regimens/cycles/tasks/resources combinations) and significant training. This suggests that acute capacity planning is more complicated than the use of the research data and statistical indicators. Yet there are similarities in that the emphasis is on local interpretation and data and there is the intention to benchmark data.

The tool utilises the approach from Shield (2004) for unlicensed situations. There is no batch processing/licensed model available. Inevitably some networks and Trusts will have licensed facilities, which will incorporate (some) batch production. Indeed, commercial organisations such as Baxter's use batch processes considerably and provide chemotherapy for major centres such as Christies in Manchester.

The complexity is also reflected by hospitals having to develop local means of projecting daily/weekly production requirements and matching them to staff (and skill) availability. The suggestion that the Excel spreadsheets developed at Leeds act as a basis for publication, despite limited coverage, highlights the lack of sophisticated, comprehensive models for acute capacity planning (see Sections 11.48 and 11.49).

Local developments mean the aseptic production process may be broken down differently by different hospitals in their models, and innovations can apply, such as "Staff Time Equivalents" to allow for competencies (see Section 11.49). Approaches are pragmatic and been successfully applied to local circumstances. The technical efficacy of some might be questioned.

Such approaches use projected/planned workloads, which are prospective in nature, and which can be fairly readily set. To try and optimise production on a daily/weekly basis could be difficult because assumptions would need to be built in about what ad hoc requests might arise daily. Such demand would mean statistically analysing historic daily data and calculating means and ranges.

No doubt the research methods and Marker UTEs can be applied to retrospective and prospective daily and weekly data, if so desired. However, as the time covered by the UTEs does not cover all tasks and requirements, the resultant analyses would be of questionable value. To develop a sophisticated, comprehensive computer-based model that can automatically project the demand for aseptic production for each day of the next week, and match the necessary staff and other resources, whilst allowing for holidays, training, etc. in both licensed and unlicensed facilities, would require time and investment beyond the researcher. That there is a need for such a model for acute capacity planning is clear, but like some of the other issues raised, it is effectively a practical boundary to the research covered by this thesis.

6.15 *Impact of New Information Systems*

As information systems develop, they might include data previously unavailable. Section 5.2 indicates that pharmacy systems provide data for aseptic production, albeit sometimes with additional collation. The check in November 2005 confirmed that this situation is unlikely to change (see Section 5.18).

The acquisition of data relating to aseptic preparation in clinical areas requires surveys (see Section 5.7). The priority placed on introducing EPS throughout hospitals (NHS Executive, 1998) offers the potential for such data to be collected, in which case professionals could have the information they require to support clinical governance in this regard. It is therefore important to clarify the likelihood that current EPS plans will include a requirement for related data.

Section 4.18 describes how information about the new EPS was triangulated, confirming that they are required to interface with pharmacy stock control systems, for the foreseeable future they will not provide data for aseptic preparation in clinical areas relevant to this research. Therefore quantifying such activity will require surveys or other estimates. This is important new knowledge that sets a practical boundary for the research.

6.16 *Use of Research Data and Statistical Indicators*

It bears summary that the research has confirmed what data is required in respect of aseptic preparation and production, and has provided methods of collecting the latter. Applying the Marker UTEs to the activity data provides important analyses to support capacity planning. Because no two aseptic units are the same (NHS Executive North West, 2001) and because the research statistical indicators reflect, or are proxies for concepts such as “capacity”, “workload” and “collaboration”, the data and indicators should be used on a benchmarking basis.

Nevertheless, information can be a double-edged sword, and whilst some pharmacists are keen to obtain data and use it to explore issues and influence their plans, there can be no doubt that some will see making their local performance transparent as a threat. Therefore perverse incentives can apply (Gandy, 2004), which may reflect local politics and agendas, and the prevailing style of management.

Ideally there would be a nationwide benchmarking database using the research methods and findings, in order that consistent data can be collected across Trusts and pharmacies, with organisations set into appropriate categories so that like can be compared with like. This would enable objective comparisons to help inform capacity planning and clinical governance, and the evaluation of specific initiatives. The researcher did try to create a benchmarking club to this end (Aseptic Benchmarking Club©, 2002), but found that Trusts/pharmacies were not prepared to pay the economic cost (£395 + VAT in 2002) to participate. Therefore it is inferred that a database should be web-based to maximise accessibility and be free to users, i.e. governmental funds and/or advertising revenue would be required. Such a website should have a facility to enable the values of the Marker UTEs to be updated.

There could be no compulsion for Trusts to use the database, given the trend for them to operate in a competitive healthcare environment (Secretary of State for Health, 2005) but equally there are advantages in their collaborating with one another for aseptic dispensing and usage purposes. A national web-based database therefore would offer a practical third-party means of moving forward, with it anticipated that the major Trusts which see aseptic preparation as a key issue readily participating. Peer pressure would undoubtedly draw in other Trusts.

Chapter 7 Further Work

7.1 Connecting with Hospital Service Activity and Plans

Pharmacy is a critical support service within a hospital, with aseptic dispensing units a key component. The research identified how aseptic preparation should be counted, quantified and analysed for both production and usage, to support the capacity planning and evaluation of these services. But it must be emphasised that it is a support service and that the amount of aseptic preparation required in the future will be dictated by the size and nature of patient activity undertaken in hospitals at the time and will reflect clinical trends and related guidance, such as the publication of national advice on injectable medicines in late 2007 (Hardy and Mellor 2007). Therefore a priority area for further work is to make the connection between aseptic preparation and the different services provided by hospitals.

If hospital information systems will not provide data on the number of aseptic preparations then it is important to create some means of estimating this. One way is to undertake regular surveys to directly collect data on such activity, from which extrapolations can be made for set periods. The alternative is to determine the relationships between the use of aseptic products and particular hospital services and (types of) specialties, so that they can be used as proxy measures to translate stock issue data into reasonable estimates of the total number of aseptic preparations undertaken in clinical areas. (Section 11.23 describes supplementary projects for this purpose). By then identifying the number of pharmaceutically prepared products that have been used in the hospital, it would be possible to calculate, and therefore monitor for clinical governance purposes, the percentage of aseptic preparation undertaken in clinical areas and in pharmacies.

Hospital Trusts and Primary Care Trusts are required to have capacity plans for their patient services, so that any capacity gaps can be addressed to ensure that key targets such as the 18-week patient pathway are achieved (DoH, 2006). Details include the numbers of different types of cases (non-elective inpatients, elective inpatients and outpatients) for each specialty on an annual basis for future years (see Section 11.2 Reference 13). It would be desirable to match the capacity plans for aseptic preparation with Trusts' service capacity plans to ensure that they are as consistent. This would need to involve specialty and type of case-specific rates of aseptic preparation, given that the use of aseptic preparations varies between them. Set out below is an outline of the type of approach and further work that would be required:

- (a) Determine the number of aseptic preparations in relation to each specialty for each type of case (any sub-categorisation of specialties and types of case would need to be agreed);**
- (b) Calculate rates by dividing the resultant figures by relevant currencies (e.g. number of aseptic preparations per 100 Non-Elective General Medicine Admissions or number of aseptic preparations per 100 Non-Elective General Medicine beddays);**
- (c) Apply such rates to the (Trust) service capacity plans to calculate projections for the number of aseptic preparations, and determine the likely change over the period; make allowance for any anticipated changes in lengths of stay, for rates relating to beddays;**
- (d) Agree a target percentage for aseptic preparation to be pharmacy based, taking into account local clinical governance and risk policies, and apply this to the projections to give the planned number of pharmaceutically prepared products each year; the corollary is that such policies will need to be clear about where and in what circumstances continued aseptic preparation in clinical areas is acceptable; some phasing might be allowed;**
- (e) Compare the resultant planned number with the existing local usage of pharmaceutically prepared products to give the difference between the current and projected usage of pharmaceutically prepared products; meeting any (significant) shortfall would then be the focus of capacity planning for aseptic dispensing units, including the potential contribution of outside sources;**
- (f) A given drug can be delivered through different product types, and the research has demonstrated that the choice of product type can vary; therefore the projected usage of pharmaceutically prepared products needs to be translated into specific targets for each product type; this may be the subject of informed professional judgement apportioning the overall target number between the different product types, or it might involve the collection of data to establish any relationships that can then be applied.**
- (g) Suitable adjustments to the projections in (c) & (d) would be necessary if there are moves to reduce demand by using alternative routes of administration, such as switching from intravenous to oral antibiotics (Hardy and Mellor, 2007).**

The subsequent process(es) would be the subject of collaboration between Trusts, and possibly the commercial sector, to develop and appraise available options to meet aggregate requirements. This would take into account a wide range of factors, such as: the potential impact and acceptability of dose banding; the scope for individual aseptic dispensing units to expand production, and the implications of delivery; the condition of the existing estate and equipment; the need to retain a local aseptic dispensing capability; finances; skill-mix and workforce planning; transport links; etc. A key factor is the fact that Foundation Trusts (and the commercial sector) will be governed by legally enforceable contracts. This means that any plans for aseptic production and provision need to be as robust and accurate as possible, for business purposes, which serves to highlight the importance of the above.

It will be seen that steps (a) and (b), and the last element of (f) all involve further research work, probably involving surveys and Delphi techniques, or a combination.

From the above it will be seen that whilst the two areas of work have some similarities, they are complementary with one another: the first seeks to translate data on stock issued so that it can be used to monitor activity on an ongoing basis, whilst the second is strategic in scope.

A refinement of the above would be to aim for specific recommended targets for the percentage of aseptic preparation in pharmacies for each specialty and type of case combination, reflecting their relative risks. Applying these to projected activity and aggregating the results would produce hospital-specific targets for pharmaceutical preparation that reflect local casemix. The likely amount of detail required makes this more long term.

7.2 Acute Capacity Planning

The principles of Acute capacity planning are established. The problem appears to be one of time and resource to deal with the complexities, and produce a sufficiently sophisticated (computer) model that pharmacies can readily utilise and tailor to local needs, including recording local times. Given that most pharmacies work under pressure, it is unlikely that individual pharmacies will have an opportunity to achieve such a goal. The danger is that if different pharmacies produce local computer models, they will inevitably be different from one another. Therefore useful further work would be to develop a (standard) computer model.

7.3 Linking Research in Skill Mix and Competencies to Support Capacity Planning Methodologies

Section 6.13 identified that whilst progress is being made on a range of fronts within the hospital pharmacy sector of the NHS in respect of skill mix and competencies, these did not appear to be strongly linked with what might be required to support improvements in capacity planning methodologies, which in turn could benefit from a skills-based quality management approach. This connection must be made if capacity planning for aseptic preparation is to go on to the next level.

7.4 Refinements of Research Data and Approach

If local pharmacy information systems can be enhanced so that analyses can be readily undertaken to distinguish between production that is licensed and unlicensed (In licensed units) then the respective Marker UTEs could be applied to ensure more appropriate values for the statistical indicators produced by this research. (This would impact on the design of the data input).

7.5 Benchmarking Website

There should be a facility that enables hospitals to benchmark aseptic activity, using the research findings, to inform capacity planning and clinical governance. There could be no compulsion for Trusts to participate in such a facility, and therefore it would need to be made so easy and attractive to use that they would want to do this.

The proposed model would be to develop a benchmarking database which can be accessed via a website, and which would provide downloadable analyses and diagrams. There would need to be agreed processes and protocols to ensure the quality and timeliness of data.

The database should also have a facility for pharmacists to record local values of Marker UTEs, so that consideration can be given to whether they should be revised.

The benefit would be the accessibility to all Trusts across the country, thereby offering opportunities for (anonymised) regional, and other, comparisons that could inform national plans and policy.

Chapter 8 Recommendations

The research involves many recommendations:

Capacity

It was determined that a specific, single statistical definition of "Capacity" is not feasible. "Capacity" is related to available skill mix and therefore research should take place to link capacity planning with a skills-based quality management approach. Aseptic dispensing units should have locally developed capacity plans detailing their strategy, which are open to external scrutiny, particularly where collaborative arrangements are in place.

Benchmarking should enable relativities between Trusts to be highlighted. This should be used by Trusts to inform and justify their local capacity plans. The research data and the associated statistical indicators are viable and appropriate to be used to inform the development and maintenance of such plans. The survey methods and documentation are appropriate and sufficient to collect the required data, so that benchmarking can be developed.

Existing software packages for capacity planning are not appropriate for aseptic dispensing units in the NHS.

Nomenclature

Nomenclature is of fundamental importance to the research. Different terms are used or interpreted in different ways by different people, largely reflecting professional background. Therefore it was necessary to adopt a set of terms and definitions for consistent use for the purposes of the research, with definitions agreed for: "Administration"; (when) "Administration begins"; (when) "Administration ends"; "Assembly"; "Ingredients"; "Parenteral"; "Preparation"; and "Product". These definitions should continue to be used in any future surveys based on the research.

Measuring Workload

The data required to make workload calculations are: the period of time covered; the number of products produced during this period for each product type; standard times for the production of each product type; and, the number of cabinets (i.e. isolators and laminar flow cabinets) available for use.

Unit time equivalents represent the most appropriate form of standard time, and they are suitable for benchmarking. It is important that these should be acceptable to pharmacists and managers. Given variations in local circumstances or practices, these times should be described as "Marker UTEs" and not used as specific targets to be achieved. This is consistent with a benchmarking approach. It is desirable to ensure the values of Marker UTEs are kept up-to-date. The statistical indicators devised to enable workloads to be benchmarked utilising survey data and Marker UTEs are:

- "Aseptic Dispensing Unit Hours per Week" (which can be compared locally with the amount of time a unit is normally open);
- "Aseptic Dispensing Unit Hours per Week per Cabinet";
- "Cabinet Hours per Week per Cabinet"; and
- "The Average Weighted Time per Product" (which reflects the relative mix of products).

Pharmacists should separate out cytotoxics activity from the overall aseptic dispensing unit's activity where there are specialist cabinets that are used only for cytotoxics and for all cytotoxics. This is to avoid skewing the statistical indicator values for the other products. (The same applies to any situation where there is a cabinet used specifically for a given type of product).

In aggregate, cabinet time (i.e. that part of the process directly involving an isolator or laminar flow cabinet) accounts for approximately one third of total aggregate activity time, varying between 25 per cent and 40 per cent for observed products.

Variations in "performance" point to it being unrealistic for some smaller units to increase their workload significantly, as they essentially fulfil an "insurance" role. Whether this situation applies for an aseptic dispensing unit should be made clear, so as to support the development of capacity plans.

Collaboration

The definition of "Collaboration" within the research is appropriate and consistent with its goals. The results support collaboration between Trusts because they set out the respective levels of aseptic activity, relative performance and the degree of interaction. The collaboration diagrams can demonstrate trends over time by the use of arrows.

Ensuring Consistency of Data

Allowance needs to be made when comparing units' performance over time for any changes in license status. (A simple method of categorising units according to past and current status, using different colours, should be sufficient (see Section 5.17)). Comparisons over time require allowance for any organisational change. For example, where two hospitals merge, was there significant traffic between them previously in respect of aseptic products? A transparent decision should be taken about how to deal with this, giving reasons if necessary. The research is sufficiently flexible and robust to deal with this.

EPS

Future developments of specifications for EPS should take on board the findings of this research, with a view to the number of aseptic preparations taking place in clinical areas being readily identifiable from routine data.

Estimation of Aseptic Preparation in Clinical Areas

In the absence of readily available routine data from EPS, proxy measures/rates should be developed for aseptic preparation in clinical areas so that:

- (a) The actual number of aseptic preparations can be inferred from stock issue data; and
- (b) The projections can be made of to reflect the future likely demand associated with a Trust's capacity plan for its patient services.

Until (b) comes to fruition, the number of aseptic preparations per admission and per bedday calculated for the North West can be used as reasonable proxies for extrapolating overall activity.

Other Recommendations:

- A standard computer model for Acute capacity planning in aseptic dispensing units should be developed.
- A web-based nationwide benchmarking database should be developed, based on the research methods and findings, to enable Trusts to evaluate their performance. This should be free to Trusts and enable Marker UTE values to be updated.
- Every opportunity should be taken to undertake greater dissemination of the research findings.

Chapter 9 Conclusions

Section 1.18 states that the aim of the research is to identify the types of data and ways of measuring aseptic preparation and production required to evaluate changes in activity and performance over time, and that it will address the following questions:

- How should activity relating to aseptic preparation in hospital pharmacies and clinical areas be counted, collated and analysed?
- Can existing information systems readily provide such data?
- What statistical indicators can be developed to support collaboration and capacity planning for (NHS) aseptic production, and to evaluate related initiatives?
- How can such data and statistical indicators be best utilised?

The research achieved all of this aim: it identified how activity relating to aseptic preparation in pharmacies and clinical areas should be counted, collated and analysed. It determined what relevant data existing pharmacy information systems can provide and that these systems are unlikely to change soon. The main constraint is the current lack of systems to enable data on the activity in clinical areas to be collected, and the fact that no such systems are likely to be introduced in the foreseeable future.

This means that in order to establish the balance of aseptic preparation between pharmacies and clinical areas – a key issue highlighted by Breckenridge (1976) and subsequent reports (Farwell, 1995; NHS Executive North West, 2001; Audit Commission, 2001) – it will be necessary to apply proxy calculations for total aseptic preparation that use admissions and beddays figures (as the only relevant published currencies). Subtracting the number of products used that were pharmaceutically prepared then gives the number prepared in clinical areas.

The research has shown how such proxy calculations are undertaken, and demonstrated the usefulness of the results, both to compare different regions and to evaluate changes over time. These calculations implicitly took the total level of aseptic preparation in the North West per admission and bedday as being fixed at the point when the data and business cases were made for the C&CP (Beaumont, 1999; NHS Executive North West, 2001). Further work would be required to update such data and determine whether the total level has changed, with the opportunity taken to establish the degree of preparation involved in different clinical areas (see Section 7.1).

However, the overall balance is still very much towards aseptic preparation in clinical areas with considerable effort and investment required to effect further significant shifts towards pharmacies, as illustrated by the evaluation of the impact of the C&CP. It is therefore arguably sufficient, for the foreseeable future, to use the North West's total aseptic preparation rates for proxy calculations to estimate the percentage of preparation in clinical areas, as this figure is likely to remain high for some time (i.e. well over 50 per cent): it will be clinical governance and risk management issues and requirements that drive local decision-making processes. The proxy calculations will inform and support such decisions, and knowing the magnitude of the balance should be enough for these purposes, i.e. is aseptic preparation in clinical areas 60 per cent or 90 per cent? Whilst increased accuracy is always desirable, being able to say that the figure should be 62 per cent instead of 65 per cent will not influence a Trust's decision as to whether to make plans and investment available to shift the balance.

The research determined that the main level of data to be collected is that of product type. It is the product type that largely determines the amount of production time involved within an aseptic dispensing unit. The list recommended by the research covers all main product types.

Two different types of data are then required: production activity and usage activity. For production, data needs to show where products went (Individual Patients, Use as Ward Stock, Use in Other NHS Trusts, and Use by Non-NHS Users are the recommended categories). For usage, data needs to show from where products were sourced (Within Trust, Other NHS Trust Licensed Unit, Other NHS Trust Unlicensed Unit, Commercial Unlicensed Products, and Other are the recommended categories). In both cases the categories can be amended, as long as they are mutually exclusive and cover the full range (see Section 4.17).

The research provided a set of guidelines that supported the consistent recording and quality of data. These took on board real issues in pharmacies and dealt with them practically and clearly. In some cases the research forced the creation of definitions that reflected professional practice, e.g. making a distinction between "TPN – Compounded" and "TPN – Simple Additions".

The data identified by the research can be submitted in either paper or electronic format, with the latter being more efficient, and a precursor for any development of a web-based solution. The fact that the final survey used a modified and abbreviated version of the data agreed for collection for the quarterly surveys, which was endorsed by the expert group as the data required to be collected, shows that the data is robust and flexible. Pharmacists

and managers should decide what is most practical for their requirements, if they look to undertake such a survey.

The research determined weightings (viz. Marker UTEs) that can be applied to production activity (from the assembly of components/documentation to product approval) in aseptic dispensing units, whether they are licensed or unlicensed, so that production time can be aggregated and analysed. Their robustness was confirmed by a series of sensitivity analyses and other calculations. The Delphi methods applied in their derivation helped ensure their acceptability to pharmacists; without such acceptance the research would be of very limited value. Similarly, clarifying that the Marker UTEs were to be viewed as reasonable mean production times to be used for comparative purposes and local interpretation, rather than fixed performance targets, increased their acceptability.

The failure of the work-study exercise to deliver production time weightings demonstrated that genuine problems cannot always be overcome. The aseptic environment by its very nature militates against this type of empirical observation. In retrospect it may also have been more difficult to ensure the acceptability of any production times resulting from the exercise, given that work-study by its very nature can be, and often is used to set targets.

By applying Marker UTEs, the research created a series of statistical indicators that aggregated the activity data in a meaningful way for pharmacists. They were straightforward and were reasonably simple conceptually. Pharmacists found the results useful and informative, in that they showed variations between different units. The research also showed the impact on the indicators of separating out specific, identifiable subcomponents of units' production, i.e. cytotoxics.

There were two limitations to the statistical indicators. The first was that all production in a licensed aseptic unit was assigned the licensed Marker UTEs, although some production will inevitably take place on an unlicensed basis. This is because to try and distinguish licensed and unlicensed production from existing pharmacy information systems was considered impractical by pharmacists, and to do so would raise the prospect of significantly increasing the amount of data to be collected: it would be likely that the existing research data collection forms would need to have both a "licensed" and "unlicensed" version completed. Yet the fact that licensed work usually involves batch processing means that the weight of activity in licensed units will be for this type of product. Therefore it is inferred that the impact of collecting such detail and applying differential Marker UTEs would have a comparatively marginal effect on the overall values for the statistical indicators for the units concerned. (This research question needs testing if such data becomes available).

The second limitation was that certain units effectively operated as licensed units, but retained an unlicensed status. As a result of applying unlicensed Marker UTEs, it would appear that a unit was operating for far more hours in a week than could reasonably be expected: Trust 137 was the prime example in the baseline survey with production apparently involving 50 aseptic dispensing units hours per week per cabinet. It is reasonable in such circumstances to infer that their actual production times would be towards the minimum of the range for unlicensed Marker UTEs, because they are likely to function as a quasi-licensed unit with associated efficiencies in processes. The simple way to deal with this is either to apply minimum Marker unlicensed UTE values, or apply licensed Marker UTEs to illustrate the potential impact of such units becoming licensed.

Notwithstanding the above, the robustness of the statistical indicators was demonstrated by the way that they were used to show differences between regions, and trends over time within the North West, and be meaningful to the pharmaceutical and managerial audiences.

However, all data collected was for either a three-month or one-year period, and was retrospective. As confirmed by the work-study exercise, daily production varies in hospitals, often with increased production towards the end of the week to cover week-end requirements. The focus of such acute capacity planning is prospective – to balance the availability of staff and other resources with production demands. To do this properly, pharmacy managers have to take into account all (local) factors, which will include those outside what is covered by the Marker UTEs: cleaning, packaging, delivery, training, holidays, staff skill mix, and opening and closing times for the unit. Therefore, whilst the research methodology and the Marker UTEs can clearly be applied to daily data, it is questionable as to the worth of doing so, unless it is to undertake a retrospective audit and identify patterns that might be informative.

A related, critical point that shaped the scope and reach of the research is the fact that no two aseptic dispensing units are the same in their design and resources. This is generally recognised and accepted, and was highlighted in Section 5.12. Therefore the question arises as to the degree to which the research can and should try to cover all aspects of aseptic dispensing?

Given the uniqueness of aseptic dispensing units, it follows that the amount of data and other information required to fully evaluate their performance is considerable – for example, the times and resources associated with all the tasks and factors listed above that are outside what is covered by the Marker UTEs – and requires detailed local

knowledge for interpretation. Therefore, the only practical approach is to develop robust and transparent benchmarking information, that enables local pharmacists and managers to benchmark their activity and performance, and then use this to inform where there is the potential for improvements and/or increased production, taking into account local circumstances and knowledge. This can then form the basis for their local capacity plans.

Therefore it was essential to confirm that the research has gone as far as it reasonably could, by determining its realistic boundaries. These were as follows:

- The lack of robust sources of data for aseptic preparation activity in clinical areas meant that whilst the research could identify key points and suggest further work and opportunities, it could not fully encompass this area in detail (Sections 3.7, 4.7 & 5.7).
- Issues surrounding Nomenclature become more complicated if data goes to a more detailed level than that proposed by the research, with data quality being potentially compromised (Sections 3.8, 4.8 & 5.8).
- The prospect of developing the research to make firm proposals for specific capacity calculations was nullified by the identification that mainstream capacity planning software does not lend itself to aseptic dispensing in NHS hospitals, and that many “capacity planning” initiatives are actually aimed at workload and/or staffing. Accordingly capacity planning for an aseptic unit is primarily a skills management issue, rather than solely one of process management, and it is not best suited to capacity modelling techniques that require detailed statistical data. To pursue research into the skills management dimension would have moved well beyond the central focus of the research, and would involve a great amount of time and effort. (Sections 3.14, 4.14 & 5.14).
- A major point for Acute capacity planning is that the amount of data required is far greater than that identified by the research, involving factors outside the actual aseptic dispensing process. Given variations between hospitals’ aseptic dispensing units and associated resources, it would be difficult to determine and get agreement on standard data to be collected, and how this might be analysed. The requirement is for a sufficiently sophisticated (computer) model that pharmacies can readily utilise and tailor to local needs. The requirements for developing such a model would be beyond the scope of this research. (Sections 3.15, 4.15 & 5.15).

Capacity plans are required of hospitals, but the nature of how services currently work and how they are likely to evolve, is that capacity plans should be for groups of hospitals collaborating with one another (and possibly with the commercial sector). Therefore, the capacity of a given group of hospitals will not necessarily be the aggregate total of the activity specified in their respective capacity plans, if developed independently of one another. It would be expected that collaboration should enable further performance improvements. This serves to emphasise the need to measure collaboration. The research has identified how “collaboration” can be defined, in such a way that it can be measured and monitored in respect of time and area (with allowance for the commercial sector), utilising the research data (Sections 3.9, 4.9 & 5.9).

Nevertheless, the value of the research would be restricted if its only achievement was to provide a high-level descriptive comparison of Trusts in the North West of England. Its strength has been demonstrated by its transferability to other parts of the UK (Sections 3.16, 4.16 & 5.16), and that they can provide detailed, objective evaluation of a major change programme (Sections 3.1, 4.17 & 5.17):

- The research survey methods were successfully transferred for the West Midlands without difficulty, producing results useful to local pharmacists. The significant variation of the results from those in the North West, showed that practices vary in different regions, and these need to be identified and understood, so as to inform both capacity planning and clinical practice. It was inferred that there was no reason why this should not apply equally to other parts of the UK. The combined size of the two regions would suggest that, in principle, the methods could also be applied in other countries, where aseptic preparation and pharmacy arrangements share relevant similarities to those in the UK.
- The research survey methods were successfully applied to evaluate the North West C&CP (Beaumont, 1999; NHS Executive North West, 2001) identifying: changes in production and usage for each unit/Trust; whether or not units/Trusts receiving capital funds had achieved their business plans; the contribution of other units/Trusts to the overall changes; the relative situation in each zone; and the degree to which trends in hospital service activity were reflected.

The research methods are now considered a standardised approach contributing to the development of capacity plans for aseptic dispensing (Beaney, 2006).

The logical way that the NHS could build on the research would be to create/sponsor a nationwide benchmarking database that uses its methods and findings:

- This could enable consistent data to be collected across Trusts and pharmacies, with organisations set into appropriate categories, as to size and type, so that like can be compared with like.
- Such objective comparisons would inform capacity planning and clinical governance, and the evaluation of specific initiatives.
- The database should be web-based to maximise accessibility and be free to users, i.e. governmental funds and/or advertising revenue would be required.
- Such a website should have a facility to enable the values of the Marker UTEs to be updated.

(For other potential further work see Chapter 7)

The research necessarily involved an iterative and complementary application of both qualitative and quantitative methodologies and methods. Effectively it looked at how the evaluation of plans, practices and performance in the area of aseptic preparation, should itself be evaluated. A mixed methodological approach was required, with both quantitative and qualitative methods used on an iterative basis. The basic cycle of: develop concepts – produce (measurable) proposals – test/evaluate proposals - further develop concepts; reflected the fact that the research primarily involved the creation of data and the development of related quantitative indicators and analyses which had to be qualitatively assessed by the audience professionals in order to validate whether they represented suitable and appropriate interpretations of key concepts, such as collaboration and capacity, and whether their current and future needs were being met. A series of cumulative and sequential steps were involved, and validation was required at each and every stage, not least to ensure continuing support. The methods applied were sufficient and appropriate in each case.

There can be relatively few similar opportunities where there are important, established (health) services which are the subject of significant change and development, but where there is no (central) requirement for data to be collected and no standardised approach to measuring activity and performance. Consequently, it can be stated that the research and its findings represent new knowledge of what data is required in respect of aseptic preparation, and how this can be analysed for the purposes of planning, performance, monitoring, and evaluation. The research is substantial and robust, and acts as a platform for further work.

The value of the research is that it is readily usable and transferable, and has been actively used to support pharmacists and managers in their planning and evaluation of aseptic dispensing services.

Bibliography

Advanced Life Support Group (1995) *Major Incident Medical Management and Support*, BMY Books, London.

Al-Assaf, A. (1999) Introducing Quality in Health Care: an International Perspective, *Journal of Health Care Quality*, 21, 1, p.4

Alberts D., Garstka J., Hayes R. and Signori D. (2001) *Understanding information age warfare*. Command and Control Research Programme.

Alexander, C. (1964) *Notes on the Synthesis of Form*. Harvard University Press, Cambridge, Massachusetts & London, England. ISBN 0-674-62751-2

Al-Salti, F. (2001) *Jordanian Nurses Knowledge and Performance Concerning Quality Assurance and Infection Control: A Descriptive Survey within Ministry of Health Hospitals*. PhD Thesis. North East Wales Institute: University of Wales. ISBN/ISSN: 52-14055G5F.

Alvesson, M. (1993) *Cultural Perspectives on Organizations*. Cambridge: Cambridge University Press.

Alvesson, M. and Deetz, S. (2000) *Doing Critical Management Research*. Sage Publications. London. ISBN 0-7619-5333-7

Anderson, R. (1999) Responsibilities of prescribing, p.49-52. In Humphris, J.L. and Green, J. eds. *Nurse Prescribing*, Macmillan Press, London.

Andrews, K. (Kevin.Andrews@pat.nhs.uk), 13 June 2006, Re. *Draft Description of North Manchester Capacity Planning Approach*. Email to R.J. Gandy (rob.gandy@ntlworld.com)

Anon. (1994) Two children die after receiving infected TPN solutions. *Pharmacy Journal*, 252, p.596

Arbor, A. (2001), *Workshops: The Social Underpinnings of Collaboration: Final Summary*. Science of Collaboratories, University of Michigan

<http://www.scienceofcollaboratories.org/Workshops/WorkshopJune42001/index.php>

Accessed 16/05/07 at 4.10pm

Aseptic Benchmarking Club© (2002) Advert, *Pharmacy Journal*, 269, p.393

Aston University Business Partnership Unit (2004) News Release: *Aston University and pharmaceutical manufacturing giant sign for medical future of region.*

<http://www.aston.ac.uk/downloads/bpu/Aseptic%20aston%20release%202.pdf>

Accessed 07/05/07 at 4.05pm

Audit Commission (2001) *A Spoonful of Sugar - Medicines Management in NHS Hospitals*. ISBN: 1-86240-321-X

Audit Commission (2002) *Acute Hospital Portfolio: Guide to Indicators*.

Baggott, R. (1998), *Health and Health Care in Britain*, 2nd ed., Macmillan Press, London.

Ball, A., Bowerman, M. and Hawksworth, S. (2000), Benchmarking in local government under a central government agenda, *Benchmarking*, 7, 1, p. 20-34.

Bateman, R. (2003), Determining the rates and types of errors in pharmacy-managed aseptic preparation units. *Hospital Pharmacist*, 10, p.496-498.

Bates, D.W., Leape, L.L., Cullen, D.J., Laird, N., Petersen, L.A., Teich, J.M. et al (1998) Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. *JAMA*, 280, p.1311–1316

BBC Online (2003), *NHS star ratings slammed*, BBC Online, 21 August.

Beaney, A.M. editor (2003a) *Pharmacy Cleanroom Capital Schemes Edn 1*. On behalf of NHS Pharmaceutical Quality Assurance Committee. Newcastle.

Beaney, A.M., editor (2006) *The Quality Assurance of Aseptic Preparation Services 4th Edition*. Pharmaceutical Press. ISBN: 0-85369-615-2

Beaney, A.M., Black, A., Dobson, C., Williamson, S., and Robinson, M. (2005) Development and application of a risk assessment tool to improve the safety of patients receiving injectable medicines. *Hospital Pharmacist*, 12, p.150-154.

Beaney, A.M. and Goode, J. (2003) A risk assessment of the ward-based preparation of parenteral medicines. *Hospital Pharmacist*, 10, p.306-308.

Beaumont, I.M. (1999) *Implementation of the recommendations of the North West Regional working party on aseptic dispensing - Final report of North West Regional Aseptic Task Group*. Internal North West report to Chief Executives & Pharmacists.

Beckford, J. (2002) *Quality*. Routledge. ISBN 0-415-25919-3 (pbk)

Beer, S. (1966) *Decision and Control: The Meaning of Operational Research and Management Cybernetics*. John Wiley & Sons. ISBN: 0471062103

Benson, C. and Longshaw, R. (1981) Measuring workload in a hospital pharmacy. *British Journal of Pharmaceutical Practice*. December, p.4-15.

Bietz, M., Gergle, D. and Olson, G. (2001), *Notes on Measures of Collaboratory Success*. Science of Collaboratories, University of Michigan
<http://www.scienceofcollaboratories.org/Workshops/WorkshopJune42001/index.php?FinalSummaryMeasures> Accessed 16/05/07 at 4.12pm

Bolton, M. (2002) Down to the wire. *Health Service Journal*. 15 August. p.18

Box, G. (1996) *Scientific Statistics, Teaching, Learning and the Computer*.
<http://www.engr.wisc.edu/centers/cqpi/reports.html>: r146 Accessed 01/05/07 at 2.05pm

Brassard, M. (1996) *Memory Jogger Plus: Featuring the Seven Management & Planning Tools*. Goal/QPC. ISBN 1-879364-02-6

Breckenridge, A. (1976) *The report of the working party on the addition of drugs to intravenous fluids*. HC(76)9. (The Breckenridge Report). London: Department of Health and Social Security.

Bree-Williams, E.J. and Waterman, H. (1996) An examination of nurses' practices when performing aseptic technique for wound dressing. *J Adv Nurs*, 23, p.48–54.

Briggs, M., Wilson, S. and Fuller, A. (1996) The principles of aseptic technique in wound care. *Prof Nurse*, 11(12), p.805–808.

British Educational Communications and Technology Agency (Becta) (2006) *ICT in Practice Awards 2006: Collaboration criteria*.

<http://www.becta.org.uk/corporate/display.cfm?section=21&id=3265>

Accessed 22/03/07 at 3.15pm

British Oncology Pharmacy Association (2001) *The NHS Cancer Plan and The Pharmacy Contribution To Cancer Care*. January.

British Pharmaceutical Conference (2004) Skill mix and technician checking are key to many pharmacy developments. Editorial. *Pharmacy Journal*, 273, p.618

British Standards Institute (1999) *Clean Rooms and Associated Controlled Environments. Part 1: Classification of Air Cleanliness*. BS EN ISO 14644-1. London.

Brown, N. (1998) Truth telling in patient care. *European Journal of Oncology Nursing*, 2, 4, p.218-224.

Brown, R.H. (1977) *A Poetic for Sociology*. Chicago, IL: University of Chicago Press.

Bullivant, J. (1996), Benchmarking in the UK national health service. *International Journal of Health Care Quality*, 9, 2, p.9-14.

Business Performance Improvement Consultancy, The (2006) *Software Selection Guide for ERP & MRP (Enterprise and Manufacturing Resource Planning) systems*. <http://www.bpic.co.uk/erpsoft.htm> Accessed 27/06/06

Cancer Services Collaborative (2007)

<http://www.cancerimprovement.nhs.uk/View.aspx?page=/default.html>

Accessed 30/03/07 at 2.25pm

Cassidy, J. and Glynne-Jones, R. (Eds) (2005) *Optimising service capacity to meet demand for cancer drug treatment delivery*. Cancer Capacity Coalition. Report of a working party funded through a Roche educational grant.

Cattell, R., Thornton, D., and Mitchell, L. (2005) Competency frameworks – how they apply to hospital pharmacists. *Hospital Pharmacist*, 12, p.221 – 223.

Chief Medical Officer and Chief Pharmacist (1996)

Executive Letter EL(96)95: Aseptic dispensing in NHS hospitals

Chief Pharmacist (1994) *Pharmacist Letter PL/CPhO(94)2: Aseptic dispensing for NHS patients. Covering letter for Farwell Report*.

Chief Pharmacist (2003) *Medicines Management in NHS Trusts. Letter and attachment from Department of Health to NHS Trust Chief Pharmacists 19th September*
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4072184 Accessed 22/03/07 11.20am

Chrischilles, E.A., Fulda, T.R., Byrns, P.J., Winckler, S.C., Rupp, M.T. and Chui, M.A. (2002) The Role of Pharmacy Computer Systems in Preventing Medication Errors. *J Am Pharm Assoc*, 42, 3, p.439-448, 2002.

Cochrane Library (2007) <http://www.cochrane.co.uk/en/clibintro.htm>
Accessed 25/02/07 at 3.35pm

Commission of the European Communities (1992) *The rules governing medicinal products in the European Communities. Vol IV. Good manufacturing practice for medicinal products*. HMSO. Cambridge.

Concentra (2006) <http://ccpmt.concentra.co.uk> Accessed 01/02/07 at 1.15pm

Connecting For Health (2006a) *Draft ePrescribing Functional Specification*
<http://www.connectingforhealth.nhs.uk/eprescribing/news/eprescribing.pdf>
Accessed 19/02/07 at 11.05am

Connecting for Health (2006b), Email from Clinical Lead for ePrescribing, 5th June.

Connecting For Health (2007a) *ePrescribing Functional Specification for NHS Trusts*
http://www.connectingforhealth.nhs.uk/eprescribing/eprescribing_baseline_functional_specification.pdf Accessed 19/02/07 at 11.10am

Connecting For Health (2007b) *NHS Data Dictionary - Commissioning Data Sets*
http://www.connectingforhealth.nhs.uk/datadictionary/web_site_content/navigation/commissioning_data_sets_menu.asp Accessed 20/04/07 at 7.45pm

Connecting For Health (2007c) <http://www.connectingforhealth.nhs.uk/>
Accessed 21/04/07 at 11.05am

Connecting For Health (2007d) *Guide to the National Programme for Information Technology*

http://www.connectingforhealth.nhs.uk/all_images_and_docs/npfit_brochure_apr_05_final.pdf Accessed 21/04/07 at 11.10am

Cooke, J. (2005) Hospital Medicines Management and the 10 high impact changes for service improvement and delivery, *Pharmacy Management*, 21, 4, p.16-21

Corcoran, G. and Gandy, R. (1997) Skewed Statistics: Recording Palliative Care. *Br J Healthcare Comput Info Manage*. 14, 8, p.16-18

Cox, A.R., and Marriott, J.F. (2002) Take a spoonful of sugar with salt. *Hospital Pharmacist*, 9, p.90.

Crow, S. (1989) Asepsis: an indispensable part of the patient's care plan. *Crit Care Nurse Quart*, 11, 4, p.11–15.

Curtis, C., Langley, C., Marriott, J. and Wilson, K. (2003) A comparison of antibiotic prescribing indicators and medicines management scoring in secondary care. *Int J Pharm Pract*. 2003, 11, p.54

De Jong, I. and Jackson, C. (2000) *Measuring interprofessional collaboration: Reliability study of the Mater Attitude Measure*

<http://www.uq.edu.au/cgpmh/gp-research/gp-instrument.htm>

Accessed 20/08/2004 at 6.50pm

De Jong, I., Jackson, C. and McKernon, M. (1990) *Development and pilot of an instrument to measure interprofessional collaboration*

<http://www.uq.edu.au/cgpmh/gp-research/gp-instrument.htm>

Accessed 20/08/2004 at 6.55pm

Deetz, S. (1992) *Democracy in the Age of Corporate Colonization: Developments in Communication and the Politics of Everyday Life*. Albany. NY: State University of New York Press

Deetz, S. (1996) 'Describing differences in approaches to organizational science: rethinking Burrell and Morgan and their legacy', *Organization Science*, 7, p.191-207

Department of Health (1997) *The New National Health Service: Modern, Dependable*. HMSO, London.

Department of Health (1998a) *A First Class Service: Quality in the new NHS*. Department of Health. www.doh.gov.uk/newnhs/quality.htm Accessed 15/08/07 at 4.20pm

Department of Health (1998b), *The New NHS: 1998 Reference Costs*. HMSO, London.

Department of Health (1999a) *Clinical Governance: Quality in the new NHS*. Department of Health. www.doh.gov.uk/clinicalgovernance/hsc065.htm Accessed 15/08/07 at 4.30pm

Department of Health (1999b) *Controls Assurance Framework*. Department of Health

Department of Health (1999c), *The NHS Performance Assessment Framework*, HMSO, London.

Department of Health (2000a) *An Organisation with a Memory*, The Stationery Office

Department of Health (2000b) *NHS Cancer Plan*. www.doh.gov.uk/cancer/cancerplan.htm Accessed 07/08/05 at 4.15pm

Department of Health (2000c) *Coronary heart disease: national service framework for coronary heart disease - modern standards and service models*.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4094275 Accessed 16/05/07 at 5.55pm

Department of Health (2000d) *NHS Plan*, The Stationery Office

Department of Health (2001a) *Building a Safer NHS for Patients*, The Stationery Office

Department of Health (2001b) *Medicines Management Framework*.

http://209.85.165.104/search?q=cache:2WiPr4RI-28J:www.dh.gov.uk/prod_consum_dh/idcplg%3FIdcService%3DGET_FILE%26dID%3D10275%26Rendition%3DWeb+Medicines+Management+Framework+%2B+2001&hl=en&ct=clnk&cd=1&gl=uk Accessed 19/05/07 at 4.20pm

Department of Health (2002a) Press release: *NHS Foundation Hospitals to be Freed from Whitehall Control*. www.info.doh.gov.uk/doh/intpress.nsf/page/2002-0240?OpenDocument Accessed 16/05/07 at 6.15pm

Department of Health (2002b), *NHS foundation trusts: eligibility criteria and timetable*.
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4009559 Accessed 16/05/07 at 6.15pm

Department of Health (2002c) *Pharmacy Workforce in the New NHS*. London: The Department. <http://www.dh.gov.uk/assetRoot/04/06/83/54/04068354.pdf>
Accessed 27/06/06 at 6.32pm

Department of Health (2002d) *Press Release: Star ratings system for hospital performance has improved services for patients. Published date: 28 January 2002*
http://www.dh.gov.uk/en/Publicationsandstatistics/Pressreleases/DH_4024557
Accessed 20/04/07 at 8.30pm

Department of Health (2003a) *Modernising the NHS Hospital Medicines Manufacturing Service Implementation Plan: Allocation of capital funding for Financial Years 2004/05 & 2005/06*. London: The Department.
<http://www.dh.gov.uk/assetRoot/04/06/82/69/04068269.pdf>
Accessed 18/07/06 at 10.35am

Department of Health (2003b) *Getting the right start: The National Service Framework for Children, Young People and Maternity Services - Standard for Hospital Services*. Department of Health.
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006182 Accessed 27/07/06 at 8.45pm

Department of Health (2004a) *NHS Improvement Plan: Putting People At Heart of Public Services*. Department of Health.
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4084476 Accessed 16/05/07 at 6.35pm

Department of Health (2004b) *10 high impact changes for service improvement and delivery*. Department of Health. <http://www.wise.nhs.uk/cmsWISE/HIC/HIC%2BIntro.htm>
Accessed 16/05/07 at 6.40pm

Department of Health (2004c) *Making Partnership Work for Patients, Carers and Service Users: A Strategic Agreement Between the Department of Health, NHS and Voluntary and Community Sector Gateway Ref: 3703*. Leeds

Department of Health (2006) 18 Week Delivery Programme: 18 Week Patient Pathway Delivery Resource

http://www.18weeks.nhs.uk/cms/ArticleFiles/gm5hdlexqmhakbqwzzxfb32t19102005124130/Files/Delivery_Resource_Pack.ppt Accessed 18/05/07 at 7.45pm

Department of Health (2007a) Agenda for Change

<http://www.dh.gov.uk/en/Policyandguidance/Humanresourcesandtraining/Modernisingpay/Agendaforchange/index.htm> Accessed 18/05/07 at 7.50pm

Department of Health (2007b) Connecting for Health

<http://www.connectingforhealth.nhs.uk/> Accessed 18/05/07 at 7.55pm

Department of Health (2007c) Payment by Results

<http://www.dh.gov.uk/en/Policyandguidance/Organisationpolicy/Financeandplanning/NHSFinancialReforms/index.htm> Accessed 18/05/07 at 5.15pm

Department of Health Advisory Group (2002) *Risk Assessment of NHS Manufacturing - "Restricted-Commercial"*

Department of Health and Social Security (1976) *Sharing Resources for Health in England. Report of the Resource Allocation Working Party (The RAWP Report)*. London: HMSO. Crown Copyright. ISBN 011320227x

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4121873 Accessed 22/03/07 at 4.00pm

Department of Health and Social Security (1984) *Reports of the Steering Group on Health Services Information ("The Körner Reports") 6 Volumes, Chaired by Mrs E Körner*, London: HMSO

Department of Health, Social Services and Public Safety Northern Ireland (2003) *Controls Assurance: Medicines Management Standard (Safe and Secure Handling of Medicines)* www.dhsspsni.gov.uk/medicines_03.doc Accessed 22/03/07 10.55am

Dr Foster (2005) *Dr Foster in top ten fastest growing companies*

<http://www.drfoosterintelligence.co.uk/newsPublications/article.asp?articleid=1>

Accessed 18/05/07 at 8.05pm

Dr Foster (2007) <http://www.drfooster.co.uk/> Accessed 30/03/07 at 11.55am

Dotchin, J.A. and Oakland, J.S. (1994), Total Quality Management in Services, Part 1: Understanding and Classifying Services. *International Journal of Quality & Reliability Management*, 11, 3, p.9-26

Drugdevelopment-technology.com (2007)

<http://www.drugdevelopment-technology.com/glossary/aseptic.html>

Accessed 22/03/07 at 9.50am

Duffy, M.E. (1985) Designing nursing research: the qualitative – quantitative debate. *Journal of Advanced Nursing*, 10, p.225-232.

Edwards, B. (2004) Falling Stars, *Health Management*, March, p.11

European Association of Hospital Pharmacists (2001). *Survey Results 2000: Parts 1-4. (The results were presented at EAHP Congress 2001 and EAHP General Assembly 2001 in Amsterdam (Netherlands))*.

<http://www.eahponline.org/asp/survey.asp?m=7&s=2> Accessed 30/03/07 at 4.00pm

European Foundation for Quality Management (2007) <http://www.efqm.org/>

Accessed 20/04/07 at 8.30pm

Evans, R.S., Classen, D.C., Pestotnik, S.L., Lundsgaarde, H.P., Burke, J.P. (1994) Improving empiric antibiotic selection using computer decision support. *Arch Intern Med*, 154, p.878–884

Evans, R.S., Pestotnik, S.L., Classen, D.C., Clemmer, T.P., Weaver, L.K., Orme, J.F. et al (1998) A computer-assisted management program for antibiotics and other anti-infective agents. *NEJM*, 338, p.232–238

Evidence Based Research (2001) *Enabling effective collaboration in military operations. Workshop report*. Evidence Based Research, Vienna, VA. 2001

Farwell, J. (1995) *Aseptic dispensing for NHS patients (The Farwell report)*. London: Department of Health.

Fishbein, M., & Ajzen, I. (1975). *Belief, Attitude, Intention, and Behavior: An Introduction to Theory and Research*. Reading, MA: Addison-Wesley.

<http://www.people.umass.edu/aizen/f&a1975.html> Accessed 22/03/07 at 3.00pm

Fitzpatrick, R. (2001) Evaluating medicines management. Hospital Pharmacist Conference: Medicines management — what's new? Lambeth, London. November. *Hospital Pharmacist*, 8, 10, p.266-272

Fontana, A. and Frey, J. (1994) Interviewing: the art of science In: Denzin, N. and Lincoln, Y. (eds), *Handbook of Qualitative Research*. Thousand Oaks, CA: Sage.

Fontana Dictionary of Modern Thought (1988), 2nd Ed., Fontana, London.

Fortean Times (2000), Coming back from the dead, *Fortean Times*, 131, p.8-9.

Foster, A. (2004) Director of Workforce, Department of Health. Letter to NHS Chief Executives, 1 December 2004: Implementation of Agenda for Change from 1st December 2004. <http://www.dh.gov.uk/assetRoot/04/09/73/53/04097353.pdf> Accessed 27/06/06

Gandy, R. (1979) A Graphical Representation of the Inter-Relationship between Districts, *Hospital and Health Services Review*, 75, p.50–51

Gandy, R. (1981) The Calculation of Catchment Populations Within the National Health Service, *The Statistician*, 28, p.29-37

Gandy, R. (1981) The Calculation of Catchment Populations Within the National Health Service – Reprise, *The Statistician*, 30, p.297–302

Gandy, R. (2004) Perspectives on statistics & statisticians in the NHS, Royal Statistical Society Conference, Manchester, 7th – 10th September, *Royal Statistical Society*

Gandy, R. (2005) A Comparison of Aseptic Preparation and Usage in Different NHS Regions, Poster Presentation at Royal Statistical Society Conference, Cardiff, 18th – 21st July, *Royal Statistical Society*

Gandy, R., and Beaumont, I. (2003a) Analysing Aseptic Preparation – Survey design and data assessment, *Hospital Pharmacist*, 10, p.328-337

Gandy, R., and Beaumont, I. (2003b) Analysing Aseptic Preparation – Workload measurement and capacity planning, *Hospital Pharmacist*, 10, p.338-347

Gandy, R., and Beaumont, I. (2006) Evaluating the impact of major investment in aseptic preparation on capacity and collaboration, *Hospital Pharmacist*, 13, p.221-225

Gandy, R., Beaumont, I., and Norval, M. (1998a) Aseptic Dispensing in NHS Hospitals : A North West Survey. *Hospital Pharmacist* , 5, p.140-142

Gandy, R., Beaumont, I., Lee, G., and Cumming, I. (1998b) Risk management and the aseptic preparation of medicines. *Eur J Hosp Pharm*, 4, p.114-119

Gandy, R., Beckford, J., and Booth, M. (2006) Secondary care coalface: The challenge of capacity management in aseptic preparation. *Pharmacy Management*, 22, 4, p.17-23

Gandy, R., Cumming, I., Beaumont, I., and Lee, G. (1998c) Distilling solutions for pharmacists – managing contamination risks. *Br J Health Care Management*, 4, 12 (Clinical Governance Supplement), p.17-20.

Gandy, R., Jones, A., and Tanner, D. (1998d) Care profiles and contracts for cancer in the community, *European Journal of Oncology Nursing*, 2, 4, p.208-217

Gandy, R., Kershaw, K., and Beaumont, I. (2002) Nomenclature Issues in Aseptic Preparation of Medicines, *British Journal of Clinical Governance*, 7, 4, p.242-249

Gandy, R., Smith, J., and Beaumont, I. (2003) Aseptic Preparation and Use at Trusts in Two Different Areas of England, *Hospital Pharmacist*, 10, p.403–405

Gariba, S. (2003) Collaboration for development evaluation: "IDEAS" Shaping a new global effort. Presented during DAC-OECD Workshop on Partners in Development Evaluation: Learning and Accountability, Paris, 25-26 March 2003.

<http://www.uneval.org/docs/ACF4DD.doc> Accessed 22/03/07 at 3.25pm

Glanze, W.D., Anderson, K.N., and Anderson, L.E. (Eds) (1986) *Mosby's Medical and Allied Health Dictionary*, 3rd ed., Mosby, St Louis, MO, p.881

Goundrey-Smith, S. (2004) Is electronic prescribing a Holy Grail? *Pharm J*, 272, p.412

Graham, R. (2005) Revisiting Breckenridge. *Hospital Pharmacist*, 12, p.186

GRC Mott MacDonald (2006) It's the pharmacy that lets the process down. *GRC Mott MacDonald PFI Magazine*. <http://www.grc.mottmac.com/files/page/78024/PPR-0023.pdf>
Accessed 25/02/07

Griffiths, W. (2002) CIVAS in Switzerland 2002. Pharmacy des Hopitaux Universitaires de Geneva, Lugano, Switzerland, 13 September.

www.hcuge.ch/Pharmacie/ens/conferences/wg_gsasa02_civas.pdf

Accessed: 29th January 2007 at 6.35pm

Guba, E. (1990) *The paradigm dialog*. Sage. Newbury Park. CA.

Guba, E., and Lincoln, Y. (1994) Competing paradigms in qualitative research In: Denzin, N.K., and Lincoln, Y.S. (eds) *Handbook of qualitative research*. p. 105-117. Sage. Thousand Oaks. CA.

Hallett, C.E. (2000) Infection control in wound care: a study of fatalism in community nursing. *J Clin Nurs*, 9(1), p.103–9.

Hand, K. and Barber, N. (2000) Nurses' attitudes and beliefs about medication errors in a UK hospital, *Int J Pharm Pract*, 8, p.128-134

Hardy, L. and Mellor, L. (2007) Risk assessment of parenteral product preparation across secondary care acute hospitals in the north of England, *Hospital Pharmacist*, 14, p.58-64

Healthcare Commission (2005) *Assessment for improvement: The annual health check*. ISBN 1-84-562017-8

Healthcare Commission (2006) Acute hospital portfolio - medicines management 2005/6; http://www.healthcarecommission.org.uk/serviceproviderinformation/reviewsandinspection/s/acutehospitalportfolio/guidance.cfm?cit_id=439 Accessed 02/07/06 at 6.45pm

Healthcare Commission (2007) *The annual health check* <http://www.healthcarecommission.org.uk/serviceproviderinformation/annualhealthcheck.cfm> Accessed 20/04/07 7.55pm

Health Service Journal (2002) Editorial Comment. *HSJ*, 15 August, p.17

Health Service Journal (2004a) Comment: Stop the star-ratings rows, *HSJ*, 22 July, p.17

Health Service Journal (2004b) News: Commission unveils blueprint for star-ratings replacement, *HSJ*, 2 December, p.5

Hill-Bailey, P. (1997) Finding your way around qualitative methods in nursing research. *Journal of Advanced Nursing*, 25, p.18-22.

Hinton, M., Francis, G. and Holloway, J. (2000), Best practice benchmarking in the UK, *Benchmarking*, 7, 1, p.52-61

Hoeksma, J. (2002) Simple Minds. *HSJ*, 15 August, p.14-16

Holloway, J., Francis, G. and Hinton, M. (1999), A vehicle for change? A case study of performance improvement in the 'new' public sector, *The International Journal of Public Sector Management*, 12, 4, p.351-365

Honey, P., and Mumford, A. (1992) *The manual of learning styles* (3rd ed). Peter Honey. Maidenhead.

Hudson, L. (1967) *Contrary Imaginations; a psychological study of the English Schoolboy*. Harmondsworth: Penguin

Integra Management Systems©, www.doxarus.com Accessed 04/07/06 at 9:02pm

International Organization for Standardization ISO9000:2000

Jackson, C. (1999) Confirmed notes in respect of National Hospital Prescribing Information Project. Quoted in NHS Executive North West (2001)

Jackson, C., and Walker, D. (1998) Hospital Prescribing Information - can we achieve an effective National database? *Pharm J*, 261, p.205-208.

Johnston, M.E., Langton, K.B., Haynes, R.B., and Mathie, A. (1994) Effects of computer-based clinical decision support systems on clinician performance and patient outcome: a critical appraisal of research. *Arch Intern Med*, 120, p.135-142

Jones, C.S. (2002), The attitudes of British national health service managers and clinicians towards the introduction of benchmarking. *Financial Accountability and Management*, 18, p.163-188

King, S. (1998) Decontamination of equipment and the environment. *Nurs Stand*, 12(52), p.57-63.

King's Fund (2003), *Health and Social Care (Community Standards) Bill Second Reading Briefing, House of Commons*. www.kingsfund.org.uk/pdf/FoundationTrusts.pdf
Accessed 12/08/05 at 4.30pm

Kolb, D.A. (1984) *Experiential Learning: experience as the source of learning and development* New Jersey: Prentice-Hall ISBN: 0-13-295261-0

Kouzmin, A., Loffler, E., Klages, H. and Korac-Kakabadse, N. (1999), Benchmarking and performance measurement in public sectors: towards learning for agency effectiveness, *The International Journal of Public Sector Management*, 12, 2, p.121-144.

Laurance, J. (1997) New national checks after breast screening disgrace, *The Independent*, 4 November, p.5

Leape, L.L., Bates, D.W., Cullen, D.J., Cooper, J., Demonaco, H.J., Gallivan, T., Hallisey, R., Ives, J., Laird, N., Laffel G. et al, (1995) Systems analysis of adverse drug events. *JAMA*, 274, p.35–43

Levis, A., and Papegeorgiou, L. (2004) A hierarchical solution approach for multi-site capacity planning under uncertainty in the pharmaceutical industry. *Computers & Chemical Engineering*, May, 28, 5, p.707-725

Lillywhite, M. (2000) *Guidance Notes on Capacity Planning for Technical Services*, NHS Pharmaceutical Production Committee.

Linstone, H. (1984) *Multiple Perspective for Decision Making*, Elsevier North Holland

Linstone, H., and M., Turoff (1975) *The Delphi Method: Techniques and Applications*, Addison-Wesley.

Llewellyn, S. and Northcott, D. (2002), The average hospital. Conference, Barcelona, Spain, July, *EGOS Colloquium*. Quoted in Northcott, D. and Llewellyn, S. (2005)

Low, J., Macintyre, J., McIver, L., and Lannigan, N. (2003) The Development of a Capacity Planning Model for Pharmaceutical Services to Cancer Patients. *Pharm J*, 270, p.239-240

MacLean, F., Macintyre, J., McDade, J., and Moyes, D. (2003) Dose banding of chemotherapy in the Edinburgh Cancer Centre. *Pharm J*, 270, p.691-693.

Mangram, A.J., Horan, T.C., Pearson, M.L., Silver, L.C., and Jarvis, W.R. (1999) Guideline for prevention of surgical site infection. Centers for Disease Control and Prevention [CDC] Hospital Infection Practices Advisory Committee. *Am J Infect Control*, 27(2), p.97–132.

Matanin, D., Carlson, K., and Bonace, B. (1984) Determining staffing for pharmacy chemotherapy admixture programme. *Hospital Pharmacist*, 19, p.514-518.

Matta, A., and Semeraro, Q. (2005) editors. *Design of Advanced Manufacturing systems: Models for Capacity Planning in Advanced Manufacturing Systems*. Springer ISBN 1-4020-2930-6 (2005)

McCarthy, J. (1990). *Formalization of common sense, papers by John McCarthy edited by V. Lifschitz*. Ablex.

McGuffie-Brunton Impact System, Material Requirements Planning 2 Software, 1994-1998. Quoted in NHS Executive North West (2001).

McGuire, R. (2005) Competence frameworks – their purpose in the workplace. *Hospital Pharmacist*, 12, p.144–147.

McRobbie, D., Davies, J.G., Bates, I., and Webb, D. (2005) Competencies for pharmacists should be designed robustly and be evidence based. *Hospital Pharmacist*, 12, p.122

Medical-dictionary.thefreedictionary.com,

<http://medical-dictionary.thefreedictionary.com/asepsis> Accessed 18/07/06 at 6.45pm

Medicines Act 1968 HMSO 1968

Medicines and Healthcare products Regulatory Agency (2003). *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2002*. London: The Stationery Office, 2002. (Rev. to Annex I in operation September 2003).

Medicines Control Agency (1992). *Guidance to the NHS on the licensing requirements of the Medicines Act 1968*. London.

Medix UK (2007) http://ixdata.com/about_medix/index.html Accessed 29/03/07 at 1.45pm

Michigan State University Extension (1994) Delphi Technique: Issue Identification Information - III00006. <http://web1.msue.msu.edu/msue/imp/modii/iii00006.html>
Accessed 06/05/07 at 6.05pm

Miharija-Gala, T. (2007) Scientific Programme, Seminar 4: The EAHP 2005 Survey: trends of European hospital pharmacy in the new century. EAHP Congress, Bordeaux, France 21-23 March, *European Association of Hospital Pharmacists*.
<http://www.eahponline.org/asp/congress.asp?m=5&s=2&c=27>
Accessed 19/15/07 at 6.55pm

Milne, J. (2003) Aseptic Services Specialist Interest Group (ASSIG), Standardised workload statistics for aseptically prepared products dispensed from pharmacy. Unpublished.

Morgan, G. (1980) Paradigms, metaphors and puzzle solving in organization theory, *Administrative Science Quarterly*, 25, p.605-622.

Morgan, G. (1986) *Images of Organization*. Newbury Park, CA: Sage.

Munro, M., Millar, B., and Radley, A. (2003) A risk assessment of the preparation of parenteral medicines in clinical areas. *Hospital Pharmacist*. 10, p.303-305.

National Audit Office/ Department of Health (2005) A Safer Place For Patients – Report by the Comptroller and Auditor General, HC 456 Session 2005-2006, November. London: The Stationery Office

National Audit Office (2007) Press Notice: Dr Foster Intelligence: A joint venture between the Information Centre and Dr Foster LLP. Report by the Comptroller and Auditor General, HC 151 2006-2007. ISBN: 9780102944266 <http://www.nao.org.uk/pn/06-07/0607151.htm>
Accessed 30/03/07 at 12.05pm

National Patient Safety Agency (2006) *Medication practice stakeholder consultation*. The Agency; London; 2006.

National Patient Safety Agency (2007) *Improving medication safety in the NHS*.
<http://81.144.177.110/display?contentId=5807> Accessed 21/05/07 at 10.10am

National Prescribing Centre (1998) *Hospital Prescribing Information Project - Analysis for Health Authority Advisers and Senior Hospital Professionals/ Managers*.

NHS Beacons (2004) www.nhsbeacons.org.uk Accessed 21/12/04 at 6.30pm

NHS Benchmarking Club (2002) www.nhsbenchmarking.nhs.uk/
Accessed 22/03/07 1:15pm

NHS Executive (1996) *Executive Letter EL(96)85. A policy framework for commissioning cancer services: palliative care services*. Leeds: NHS Executive.

NHS Executive (1998) *Information for health. An information strategy for the modern NHS 1998–2005*. NHS Executive. Leeds Ref A 1103

NHS Executive (1999) *Controls Assurance Standards for Medicines Management*, Department of Health, 1999.

NHS Executive North West (1997). *Maintaining asepsis during the preparation of pharmaceutical products*. Available at: <http://www.aseptic-b-club.co.uk/report.pdf>
Accessed 18/07/06 at 4.45pm

NHS Executive North West (2001) *Quantification and optimisation of the aseptic preparation of medicines*.

Summarised as: Gandy R. Quantification and Optimisation of the Aseptic Preparation of Medicines. The Research Findings Register, Summary number 596; 2005
<http://www.refer.nhs.uk/ViewRecord.asp?ID=596> Accessed 31/05/06 at 7.35pm

Also:

http://www.info.doh.gov.uk/doh/refr_web.nsf/0570b366e8e90a0a802567e7004f3bb0/aca8f4c56f3fbcc300256ad9003fb495?OpenDocument&Highlight=0,gandy

Accessed 25/02/07 at 5.55pm

NHS Modernisation Agency (2005) *Letter to Chief Pharmacists from Modernisation Agency: Cancer Services Collaborative Improvement Partnership, Draft Chemotherapy Capacity Model: Consultation*. January.

NHS Modernisation Agency (2007a) <http://www.wise.nhs.uk/cmswise/default.htm>
Accessed 30/03/07 at 12.40pm

NHS Modernisation Agency (2007b)
http://www.modern.nhs.uk/scripts/default.asp?site_id=10 Accessed 30/03/07 at 12.30pm

NHS Pharmaceutical Quality Assurance Committee (2004). *Multiple Use Injections, 3rd edn*. London.

NHS Wales (2001) *Improving Health in Wales*, The Stationery Office

Noble, D. (2002) A Cognitive Description of Collaboration and Coordination to Help Teams Identify and Fix Problems, in *Proceedings of the 2002 International Command and Control Research Technology Symposium*, Quebec, Canada.

Noble, D., and Kirzi, J. (2003) Objective Metrics for Evaluation of Collaborating Teams, In *Proceedings of the 2003 Command and Control Research Technology Symposium*. Washington, D.C. National Defense University

Noble, D., and Letsky, M. (2002) Cognitive-Based Metrics to Evaluate Collaboration Effectiveness, *SAS Symposium: Analysis of Military Effectiveness of Future C2 Concepts and Systems, SAS 039 Symposium*, Den Hague, Netherlands

Northcott, D., and Llewellyn, S. (2003), The ladder of success in healthcare: the UK national reference cost initiative, *Management Accounting Research*, 14, 1, p.51-66

Northcott, D. and Llewellyn, S. (2005), Benchmarking in UK health: a gap between policy and practice? *Benchmarking: An International Journal*, 12, 5, p.419-435

North West Aseptic Task Group (1998) *Costing Working Party: A structure for the introduction and application of a mandatory Unified Costing System for Licensed Aseptic Services*. July. Quoted in NHS Executive North West (2001)

O'Connor, N. (2005) Hatched and batched. *HSJ*, 16 June, p.36-38.

Olson, R., Verley, J., Santos, L., and Salas, C. (2004) What We Teach Students About the Hawthorne Studies: A Review of Content Within a Sample of Introductory I-O and OB Textbooks, *The Industrial-Organizational Psychologist*, 41, 3, p.23-39

OMNI (2005) MRP (Material requirements planning) and MRP2 (Manufacturing resources planning), www.omni.bus.ed.ac.uk/opsman/oakland/oak22.htm

Accessed 18/11/05 at 6.55pm

Note: <http://www.intute.ac.uk/healthandlifesciences/medicine/> provides the service formerly known as OMNI.

On-line Medical Dictionary (Definition loaded 18 Nov 1997)

<http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=parenteral&action=Search>

Accessed 22/03/07 at 5.05pm

Orwell, G. (1954), 1984, Penguin Books, London. ISBN-10: 0451524934; ISBN-13: 978-0451524935

Parahoo, K. (1997) Questionnaires p.246-281. In: Parahoo, K. *Nursing Research. Principles, Process and Issues*. Palgrave Macmillan. Basingstoke. Hampshire.

Parrish, D. (1993) *Flexible Manufacturing*. Butterworth Heinemann ISBN 0-7506-1657-1 (Paperback edition 1993)

Paton, C. (1999) New labour's health policy: the new healthcare state, in Powell, M. (ed), *New Labour, New Welfare State*, The Policy Press, Cambridge, MA, p. 51-75.

Pestotnik, S.L., Classen, D.C., Evans, R.S., and Burke, J.P. (1996) Implementing antibiotic practice guidelines through computer-assisted decision-support: clinical and financial outcomes. *Arch Intern Med*, 124, p.884-890

Pharmaceutical Journal (2002) News: *Skill mix proposals may weaken the medicines safety net, warns the NPA*. *Pharm J*, 269, p.515

Pharmaceutical Journal (2005) News: *NHS needs to tackle lack of capacity to deliver cancer services*. *Pharm J*, 275, p.566

Pharm-line ® <http://www.pharm-line.nhs.uk/home/default.aspx> Accessed 25/02/07

Playle, J.F. (1995) Humanism and positivism in nursing: constructions and conflicts. *Journal of Advanced Nursing*, 22 (5), p.979-984.

Plumridge, R., and Sewell, G. (2001) Dose-banding of cytotoxic drugs: a new concept in cancer chemotherapy. *Am. J. Health Syst. Pharm.*, 58, p.1760-1764

Polit, D.F. and Hungler, B.P. (1995) *Nursing Research. Principles and Methods*, (5th ed.). J.B. Lippincott. Philadelphia, Pennsylvania.

Popper, K. (1981) The rationality of scientific revolutions p.80-106. In: Hacking, I. ed. *Scientific Revolutions*. University Press. Oxford.

Propper, C., Burgess, S., and Gossage, D. (2003) *Competition and Quality: Evidence from the NHS Internal Market 1991-1999*. CMPO Working Paper Series No. 03/077
<http://www.bristol.ac.uk/Depts/CMPO/workingpapers/wp77.pdf>
Accessed 05/04/07 at 9.05pm

Purkiss, R. (1997) How to get the staff you need. *Pharm Pract*, 7, p.393-396

Raschke, R.A., Gollihare, B., Wunderlich, T.A., Guidry, J.R., Leibowitz, A.I., Peirce, J.C. et al (1998) A computer alert system to prevent injury from adverse drug events: development and evaluation in a community teaching hospital. *JAMA* 280:1317–1320

Rattinger, G. (Gail.Rattinger@ucsf.edu) 23 February 2007, Re. *Advice Request*. Email to R.J. Gandy (rob.gandy@ntlworld.com)

Rowe, G., and Wright, G. (2001) Expert Opinions in Forecasting: Role of the Delphi Technique, In S. Armstrong (ed), *Principles of Forecasting: A Handbook for Researchers and Practitioners*, p.125-144. Norwell, MA.: Kluwer Academic Publishers

Rowe, G. and Wright, G. (1999) The Delphi technique as a forecasting tool: Issues and analysis, *International Journal of Forecasting*, 15, p.353-375.

Royal Pharmaceutical Society of Great Britain (2003a) *Competencies of the future pharmacy workforce Phase 1 report*. www.rpsgb.org.uk/pdfs/compfutphwfph1.pdf
Accessed 27/06/06 at 8.50pm

Royal Pharmaceutical Society of Great Britain (2003b) *Competencies of the future pharmacy workforce: Full report on the results of the consultation on Phase 1*. www.rpsgb.org.uk/pdfs/cfpwph1repfull.pdf Accessed 27/06/06 at 9.05pm

Royal Pharmaceutical Society of Great Britain (2004) *Competencies of the future pharmacy workforce: Phase 2 report*. <http://www.rpsgb.org/pdfs/compfutphwfph2s1.pdf>
Accessed 27/06/06 at 9.25pm

Saeed, K.S. (1995) Implementation of quality assurance programme in Saudi Arabia Hospitals, *Saudi Medical Journal*, 16, 2, p.139-143

Samuels, T., and Hassell, K. (2004) Do not let skill mix debate pass you by, *Pharm J*, 272, p.84

Schiff, G.D., and Rucker, T.D. (1998) Computerized prescribing: building the electronic infrastructure for better medication usage. *Journal of the American Medical Association*, 279, p.1024–1029

Schommer, J.C., Pedersen, C.A., Gaither, C.A., Doucette, W.R., Kreling, D.H., and Mott D.A. (2006) Pharmacists' Desired and Actual Times in Work Activities: Evidence of Gaps From the 2004 National Pharmacist Workforce Study, *J Am Pharm Assoc*. 46(3), p.340-347 <http://www.medscape.com/viewarticle/533490> Accessed 18/07/06 at 10.50am

Secretary of State for Health (2002), *Delivering the NHS Plan*, HMSO

Secretary of State for Health (2005) Annual health and social care lecture - Investment and reform: transforming health and healthcare; 13 December

http://www.dh.gov.uk/en/News/Speeches/Speecheslist/DH_4124484

Accessed 05/04/07 at 9.10pm

Seddon, J. (2003) *Freedom from command and control: A better way to make the work work*. Vanguard Consulting Ltd. ISBN-10: 0954618308; ISBN-13: 978-0954618308

Seddon, J. (2004) Missing the point. *Health Management*, December/ January, p.16-17

Sellors, J.E.I., Cyna, A.M.I. and Simmons, S.W.I. (2002) Aseptic precautions for inserting an epidural catheter: a survey of obstetric anaesthetists. *Anaesthesia*, 57(6), p.593–596.

Senn, S. (1981) Some comments on 'The Calculation of Catchment Populations Within the National Health Service', *The Statistician*, 30, p.73–75

Shah, N. (2004) Pharmaceutical supply chains and strategies for optimisation. *Computers & Chemical Engineering*, 28, 6/7, p929-941

Shield, K. (2004) Capacity Planning for Chemotherapy, *Pharm J*, 272, p.61-62.

Shojania, K.G., Yokoe, D., Platt, R., Fiskio, J., Ma'luf, N., Bates, D.W. (1998) Reducing vancomycin use utilizing a computer guideline: results of a randomized controlled trial. *J. Am. Med. Inform. Assoc.*, 5, p.554–562

Skidmore, S. (1981) Some comments on the 'Calculation of Catchment Populations Within the National Health Service' by Gandy, *The Statistician*, 30, p.69–72.

So, J. (2005) Going Private, *Healthcare Management*, Sept/Oct p.14-16

South Carolina Commission on Higher Education (2004)

http://www.che.sc.gov/Finance/Perf_Fund/Perform/Workbook_2nd_ed/Factor%204.html

Accessed 22/03/07 at 2.45pm

Stark, J. (2007) *A few words about TQM*. <http://www.johnstark.com/fwtqm.html>
Accessed 20/04/07 at 8.45pm

Surowiecki, J. (2004) *The Wisdom of Crowds*. Anchor 978-0-385-72170-7 (0-385-72170-6)

Thacker, S.M. (2006a) *Capacity Management*.
http://www.smthacker.co.uk/capacity_management.htm Accessed 27/06/06 at 7.05pm

Thacker, S.M. (2006b) *Manufacturing Resource Planning (MRP2)*
<http://www.smthacker.co.uk/MRP2.htm> Accessed 27/06/06 at 7.10pm

Toft, B. (2001) *External Inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham*, Department of Health.

Trillennium Corporation *Profit From Collaboration* (2004)
<http://www.trillennium.com/collasem.htm> Accessed 24/08/2004 6.35pm

Trosa, S. (1997) *Chairman's Summary in: Benchmarking, Evaluation and Strategic Management in the Public Sector: Papers Presented at the 1996 Meeting of the Performance Management Network of the OECD's Public Management Service, OCDE/GD(97)50, OECD, Paris, p.5-9.*

Trudeau, T. (1980) *A simple work measurement system that can aid in effective production planning*. *Hospital Pharmacist*, 15, p.229-233

United Nations Economic Commission for Europe (2007), *Trends in Europe and North America; The Statistical Yearbook of the Economic Commission for Europe 2005: Population*. http://www.unece.org/stats/trends2005/Sources/101_Population%20mid-year.pdf
Accessed 24th July 2007 at 5.35pm

Van Grafhorst, J.P., Foudraine, N.A., Nooteboom, F., Crombach, W.H.J., Oldenhof, N.J.J. and Van Doore, H. (2002) *Unexpected high risk of contamination with staphylococci species attributable to standard preparation of syringes for continuous intravenous drug administration in a simulation model in intensive care units*. *Crit Care Med*, 30(4), p.833-836.

VSDentist©, www.doxarus.com Accessed 04/07/06 at 9:05pm

VSSkillsManager©, www.doxarus.com Accessed 04/07/06 at 9:10pm

Wait, S., and Nolte, E. (2005) Benchmarking health systems: trends, conceptual issues and future perspectives. *Benchmarking: An International Journal*, 12, 5, p.436-448

Walker, D. (2002) Electronic prescribing – administration and pharmacy specification for NHS Trusts. *Hospital Pharmacist*, 9, p.102-104.

Wang, A. (2003) *Rx for pharmaceutical companies: Internal collaboration is the key to improved innovation*. IBM Institute for Business Value.

Wanless, D. (2002) *Securing Our Future Health: Taking a Long-Term View (Final Report)*. HM Treasury. http://www.hm-treasury.gov.uk/Consultations_and_Legislation/wanless/consult_wanless_final.cfm
Accessed 20/04/07 at 7.40pm

Webster, C. (1998) *The National Health Service: A Political History*, Oxford University Press, Oxford.

Williamson, S. (2006) Secondary Care Coalface: Creating capacity for cytotoxic preparation through centralisation, *Pharmacy Management*, 22, 1, p.16-21

Wu, B. (1996) *Manufacturing Systems Design and Analysis: Context and Techniques*. Chapman and Hall ISBN 0-412-58140-x 2nd Edition Reprinted 1996

Wyatt, J. and Walton, R., (1995) Computer based prescribing: improves decision-making and reduces costs. *British Medical Journal*; 311, p.1181–1182

Yousef, F., Nel, D. and Bovaird, T. (1996) Healthcare quality in NHS hospitals, *International Journal of Health Care Quality Assurance*, 9, 1, p.15-28

Zavery, B., Gurnell, P., and Wright, D. (2005) Risk assessment of ward parenteral drug preparation in two hospitals: a Controls Assurance evaluation. *Pharmacy Management*. 21, 2, p.15-20

Chapter 10 Published Work from Research

The researcher has had a number of papers published from the research, as at April 2007. Their details are as follows:

1. Gandy R., Kershaw K. and Beaumont I. (2002) "Nomenclature Issues in Aseptic Preparation of Medicines", *British Journal of Clinical Governance* (2002), 7, 4, 242-249.
2. Gandy R. & Beaumont I. (2003) Analysing Aseptic Preparation – Survey design and data assessment, *Hospital Pharmacist*, 10: 328 - 37.
3. Gandy R. and Beaumont I. (2003) Analysing Aseptic Preparation – Workload measurement and capacity planning, *Hospital Pharmacist*, 10: 338 - 47.
4. Gandy R., Smith J. and Beaumont I. (2003) Aseptic Preparation and Use at Trusts in Two Different Areas of England, *Hospital Pharmacist*; 10: 403 – 405.
5. Gandy R. (2005) Poster Presentation: A Comparison of Aseptic Preparation and Usage in Different NHS Regions, *Royal Statistical Society Conference*, 18th – 21st July, Cardiff
6. Gandy R. and Beaumont I. (2006) Evaluating the impact of Major Investment in Aseptic Preparation on Capacity and Collaboration, *Hospital Pharmacist*, 13: 221 – 225.
7. Gandy R., Beckford J. and Booth M. (2006) Secondary Care Coalface: The Challenge of Capacity Management in Aseptic Preparation, *Pharmacy Management*; 22.4; 17 – 23

Copies of the papers published from the research and listed on the previous page are provided on the following pages. The papers appear in the same order.

It will be appreciated that the papers were generally printed on A4 paper when published in the journals, and have page numbers relevant to the journals. The presentation of the papers has necessarily been reduced in size to accommodate the requirements of Liverpool John Moores University regarding this thesis. Thesis page numbers are not shown so as to avoid any potential for confusion with the page numbers in the journals.

The kindness of the British Journal of Clinical Governance, Hospital Pharmacist, and Pharmacy Management is again acknowledged for the provision of electronic copies of the published work so that they can be included in the thesis.

As the covers of the journals are provided, the following credits should be noted for the pictures on the *Hospital Pharmacist* covers for October 2003 and June 2006:

- Bryson Biomedical Illustrations/Custom Medical Stock Photo/Science Photo Library (October 2003)
- Biophoto Associates/Science Photo Library (June 2006)

SOME PARTS
EXCLUDED
UNDER
INSTRUCTION
FROM THE
UNIVERSITY

**THESIS
CONTAINS
CD**