

**THE EVOLUTION OF BIOMEDICAL SCIENCES IN EUROPE:
HISTORICAL EXPLANATION AND FUTURE PROSPECTS**

by

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ABSTRACT

This work seeks to identify those factors that have influenced the development of the professional group of workers associated with medical laboratory sciences. It has also examined the features that have both encouraged and impeded the trend towards European harmonisation within the profession. The study concentrates on the evolution of this occupational category with respect to four European Nations – the UK, Germany, Greece and Sweden. These countries have been selected on the basis that they have different financial systems for the delivery of health care. The thesis begins with an assessment of the significance of emergent medical sciences during the Renaissance and their impact on diagnostic pathology. This is followed by a consideration of the contribution of Twentieth Century medical advances, set against the background of the Industrial Revolution and the demands emanating from global conflict. The role of scientific and technological developments are seen as the most significant influences in forging European harmonisation within those professions concerned with biomedical sciences.

The next consideration concerns the attitude of medical laboratory technologists towards the notion of “profession”, together with their ability to identify the characteristics of such a concept. Results indicate that the ability of practitioners in such respect is not significantly different from that of other members of the professions allied to medicine, or the learned professions. The influence of health care systems on medical laboratory sciences is examined by identifying the political, economic, social and technological factors shaping health care delivery in the above countries. In all cases, diagnostic pathology services are financed by a mixture of public and private provision. The thesis also assesses the relationship between the various professional bodies and licensing authorities. Although practitioners in all

four countries require some form of licensure (i.e. are “regulated professions”), only those in the UK undergo State Registration on an annual basis.

The views of practitioners towards the mutual recognition of European professional qualifications has been sought using semi-structured interviews. There is some support for such a principle, but in practice little activity is taking place. A comparison has also been made of the views of undergraduates and tutors towards European exchange schemes such as SOCRATES. This is achieved using questionnaires aimed at assessing participation rates, identification of barriers to student mobility, levels of awareness regarding European current affairs, and language competencies. Student participation is relatively low and the main barrier to study in other European countries has been identified as lack of finance. Comparisons have been made with respect to curriculum content, student assessment strategies, course fees and other aspects of education. There is a requirement to increase levels of provision with respect to European studies and students need to be better informed regarding opportunities available to them. The influence of European Union policy on academic and professional harmonisation is assessed by considering aspects of student and staff exchange schemes, together with the possible affects of the Sorbonne and Bologna Declarations. The work concludes with some recommendations for increasing the role of education and training with respect to achieving closer European integration. These include a re-assessment of the affects of replacing Inter-University Collaborative Programmes with Institutional Contracts. There is also a need for greater tutor advocacy and further EU investment in student grant aid.

To my family

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CONTENTS

	Page
Abstract	i
Dedication	iii
Acknowledgements	iv
Contents	vii
List of Tables, Figures and Plates	xiii
List of Abbreviations	xxi
Introduction	1
SECTION A SCIENCE AND TECHNOLOGY – AGENCIES FOR HOMOGENEITY	8
Chapter 1 Pre-Twentieth Century Advances in Diagnostic Pathology	9
Introduction	11
Renaissance Medicine	11
The Influence of the Pure Sciences	16
The Birth of Medical Laboratory Sciences	23
The Foundations of Histopathology	24
The Advent of Medical Microbiology	28
The Emergence of Immunology	35
Early Attempts at Blood Transfusion	36
The Foundations of Haematology	37
Clinical Chemistry-The Early Years	40
Non-Scientific Influences	42
Conclusions	45
Notes	56

References	63
Chapter 2 Diagnostic Pathology in the Twentieth Century	67
Introduction	68
Histopathology-The Process of Modernisation	68
Microbiology and the Advent of Antibiotics	73
Immunology-the Emergence of a Dichotomous Science	78
Global Conflict and the Impetus for Developments in Blood Transfusion	88
Simple Microscopy to Advanced Automation-The Study of Blood Disorders	93
The Transformation from Chemical Physiology to Clinical Chemistry	99
The Emergence of New Disciplines	103
Conclusions	110
Notes	113
References	121
Chapter 3 Medical Laboratory Sciences-The Problem of Definition	127
Introduction	128
The Emergence of a New Group of Scientific Workers	128
Problems of Definition	136
The Issue of Profession	138
Task Related Autonomy	145
The Concept of "Profession"-Occupational Differences	152
(a). Method	153
(b). Results	155
(c). Statistical Analysis	165
(d). Discussion	166
Conclusions	171

Notes	174
References	178
SECTION B FOUNDATIONS FOR THE MODERN ERA.	181
Chapter 4 The Influence of Health Care Systems on Medical Laboratory Sciences	182
Introduction	183
Biomedical Sciences in the Context of Health Services in Europe	185
Developments within the UK	192
The UK National Health Service and the Expansion of Medical Laboratory Sciences	197
The Health Care Systems in Germany, Greece and Sweden	206
(a). Germany	206
(b). Greece	211
(c). Sweden	218
Conclusions	224
Notes	230
References	235
Chapter 5 The Professional Bodies and Licensing Authorities	237
Introduction	238
The UK	239
State Registration	241
Education and Training	248
Post-Basic Qualifications	251
Heads of University Centres of Biomedical Sciences (HUCBMS)	256
Continuing Professional Development (CPD)	257
Business and Technology Education Council (BTEC)	260

National Vocational Qualifications (NVQs)	263
Germany	265
Greece	269
Sweden	271
Conclusions	275
Notes	279
References	288
SECTION C THE INFLUENCE OF PRACTITIONERS	290
Chapter 6 The Practitioners' Perspective	291
Introduction	292
Methodology	292
Results – UK	294
Section A	294
Section B	295
Section C	303
Results – Germany	306
Section A	306
Section B	306
Section C	307
Results – Greece	308
Section A	308
Section B	309
Section C	310
Results – Sweden	312
Section A	312

Section B	313
Section C	315
Discussion	317
Notes	326
Chapter 7 The Education and Training Milieu	327
Introduction	327
Academic Programmes for Professional Qualification and Entry	329
UK	329
Germany	334
Greece	336
Sweden	339
The Student View	342
Methodology	342
Results	344
Section A	344
Section B	351
Section C	364
Section D	367
Survey of Course Directors	368
Discussion	376
Conclusions	379
Notes	381
SECTION D INTEGRATION IN EUROPE	382
Chapter 8 Scientific and Educational Cohesion	383

Introduction	384
Scientific and Technological Homogeneity	385
The Political Background in Relation to European Academic Exchange Programmes	386
European Exchange Schemes	387
(a) European Action Scheme for the Mobility of University Students (ERASMUS) (now SOCRATES)	387
(b) European Community Course Credit Transfer System (ECTS)	394
(c) Trans-European Mobility Programme for University Students (TEMPUS)	396
Mutual Recognition of Professional and Academic Qualifications	401
Barriers to Mobility	408
1. Definition of Status	408
2. Transferability of Grants	408
3. Qualifications	408
4. Information and Administration	409
5. Linguistic and Cultural Obstacles	410
The Sorbonne and Bologna Declarations	411
Conclusions	414
Notes	416
References	419
Chapter 9 Present Paradoxes and Future Challenges	421
Introduction	422
The Evidential Background	424
The Way Forward	437
Concluding Overview	442
References	447
Bibliography	448
Addenda	472

LIST OF FIGURES, PLATES AND TABLES

FIGURES	Page
1.1 External Factors Affecting the Early Development of Medical Laboratory Sciences	46
1.2 The Twelve Primary Causes of Death in London, 1665-% of Total	50
1.3 Causes of Death, United Kingdom, 1990	53
2.1 Immunophenotypic Differentiation of Acute Myeloblastic Leukaemia	97
2.2 Immunophenotypic Differentiation of Acute Lymphoblastic Leukaemia	98
2.3 Gene Assignments to Specific Chromosomes (1966-1992)	108
3.1 Institute of Biomedical Science (IBMS) Membership Grades (1945-1995)	133
3.2 Membership Grades of IBMS as Percentage Total (145-1995)	134
3.3 Organogram Showing the Inter-relationship between Pathology Departments and other Agencies (Typical District Hospital in the UK)	137
3.4 Regional Staffing Structures (Haematology)	144
3.5 Task Distribution by Percentage Workload and Degree of Autonomy	148
3.6 Total Percentage Workload per Degree of Autonomy	148
3.7 Percentage Respondents Quoting C1 (Prolonged Specialised Training in a Body of Abstract Knowledge)	157
3.8 Percentage Respondents Quoting C2 (A Collectivity or Service Orientation)	157
3.9 Percentage Respondents Quoting D3 (Determines own Standard of Education and Training)	158
3.10 Percentage Respondents Quoting D4 (Legislation is Designed and Influenced by that Profession)	158
3.11 Percentage Respondents Quoting D5 (Practitioners are free from Lay Evaluation and Control)	159
3.12 Percentage Respondents Quoting D7 (Practice is Recognised Legally by some form of Licensure)	159
3.13 Percentage Respondents Quoting ND8 (Compliance with Code of Conduct Expressly Designed for that Profession)	160

3.14	Percentage Respondents Quoting ND9 (The Practice of Expertise not available to the General Public)	160
3.15	Percentage Respondents Quoting ND10 (Attainment of Certain Minimum Qualifications for Entry)	161
3.16	Percentage Respondents Quoting ND11 (Self-Governance with Respect to all Aspects of Conduct, Practice, Ethics and Qualifications)	161
3.17	Percentage Respondents Quoting ND12 (Provision of Certain Minimum Standards Accepted by Society etc.)	162
3.18	Percentage Respondents Quoting Both Core Characteristics (C1 and C2)	162
3.19	Percentage Respondents Quoting Neither Core Characteristics (C1 and C2)	163
3.20	Percentage Respondents Failing to Quote Any of the Twelve Characteristics	163
3.21	Percentage Respondents Answering "Yes" to the Question: - "Are you a member of a Profession?"	164
3.22	Percentage Respondents Answering "No" to the Question: - "Are you a member of a Profession?"	164
3.23	Hierarchical Enclosure Typifying Semi-Professional Groups	168
4.1	Ideological Models of Health Care	187
4.2	Demographic Trends in Europe in Relation to the Industrial Revolution	190
4.3	Pattern of Real Expenditure in Pathology within the UK (1977/78-1987/88)	199
4.4	Number of Pathology Tests (Millions) in the UK (1970-1986)	199
4.5	Funding of Health Care Systems in England (Post 1999)	203
4.6	Application of PEST Model to Diagnostic Laboratory Services within the Context of the NHS (UK)	204
4.7	Finance Flows in German Health Care, 1995(Billion DM)	209
4.8	Application of PEST Model to Provision of Medical Laboratory Sciences in Germany	210
4.9	Organisational Structure of the Greek Health Care System	215
4.10	Health Care Finance Systems, Greece, 1999	216

4.11	Application of the PEST Model to Provision of Medical laboratory Sciences in Greece	217
4.12	Organisational Structure of the Swedish Health Care System	220
4.13	Financial Flows-Health Care System-Sweden, 1999	221
4.14	Application of the PEST Model to Provision of Medical Laboratory Sciences in Sweden	223
4.15	Determinants of National Health Systems	226
5.1	Schematic Structure Outline of CPSM Council and Associated Boards.	243
5.2	Constitution of Typical CPSM Board	244
5.3	Primary Areas of CPSM Activity, 1995	245
5.4	Total Number of IBMS CPD Registrations 1990-1996	259
5.5	Total Number of IBMS Accredited CPD Activities 1990-1996	259
5.6	Distribution of CPD Activities by Subject Area, 1994	260
5.7	Mainstream BTEC Course Pattern (16-18+ Years of Age)	262
7.1	Course Outline – BSc (Hons.) Biomedical Sciences (UK)	332
7.2	Diploma for Medical Technical Laboratory (Female) Assistants (Germany)	335
7.3	Course Outline – Diploma in Medical Laboratory Technology (Greece)	337
7.4	Course Outline – University Diploma in Biomedical Laboratory Science (Sweden)	340
8.1	UK ERASMUS Student Numbers, 1987/1988 – 1998/1999	392
8.2	UK ERASMUS Student Numbers (Thousands) – SAC 12 (Medical Sciences) 1987/1988 – 1998/1999	393
8.3	UK Average Student Period of Study (Months) by Host Country (SAC 12 – Medical Sciences – 1999-2000)	394
8.4	ECTS Student Numbers in SAC 12 (1992-93) in the UK, Germany, Greece and Sweden	396
9.1	Phylogenic Model of Professional Maturation	429

9.2	The Dichotomy of Professional Convergence in Medical Laboratory Sciences	430
9.3	Professional Harmonisation in Europe – the Confounding Variables	432
9.4	Academic Conflict and its Influence on the Evolution of Medical Laboratory Sciences as a Profession	435
9.5	Concordance Map of European Practitioners in Biomedical Sciences	436
9.6	European Harmonisation Strategies – Advocate and Resistant Influences in Education	438

PLATES

	Chapter 1 Front Piece: Anatomy Lecture given by Dr. Nicholas Tulp, 1632	10
1.1	Anatomical Theatre at Leyden from Peter Pauw (Paaw): <i>Succenturiatus anatomicus</i> , 1616	17
1.2	Anatomical Demonstration by Sebastius Christian a Zeidlern	19
1.3	Title Page and Front Piece: <i>De Sedibus Causis Morborum</i> , Morgagni, Venetia, 1761	21
2.1	Bacteriophage Ms2	75
2.2	Computer Generated Model of Mouse IgG2a Molecule	80
2.3	Human Immunodeficiency Virus Budding from a Cultured Lymphocyte	82
2.4	Fluorochrome Staining of <i>Plasmodium falciparum</i> Malaria	83
2.5	Female Mosquito (Unknown Species) Taking a Blood Meal from a Human	84
2.6	Anopheles Mosquito (<i>Plasmodium spp.</i>)	85
2.7	Factor VII a Docking with Tissue Factor	95

TABLES

1.1	The Twelve Primary Causes of Death in London, 1665	49
1.2	Causes of Death in the United Kingdom, 1990	52
1.3	Example of Synergistic Parallelism in Medical Laboratory Sciences	54

2.1	Vaccine Development - Successes and Challenges	86
3.1	Task Profile of MLSO Staff - Typical Haematology Department in the UK	146
3.2	Level of Autonomy Compared to Workload and Number of Tasks	149
3.3	Degree of Autonomy and Median Values of Skill Levels Attributed to MLSO Tasks	149
3.4	Percentage Responses Relating to Freidson's Characteristics of a Profession According to Occupational and Socio-Economic Categories	155
3.5	Percentage of Response Patterns Identifying Core, Derived and Non-Derived Characteristics	156
3.6	Percentage Responses Relating to Membership of a Profession	156
3.7	Statistical Analysis relating to the ability to identify the Characteristics of a Profession	165
4.1	<i>Per Capita</i> Health Care Expenditure in 1987 (\$ US)	224
6.1	Occupational Responsibilities identified by UK Respondents	295
6.2	Important Developments in Education and Training cited by UK Respondents	296
6.3	Important Professional Developments identified by UK Respondents.	297
6.4	Characteristics of a Profession identified by UK Respondents.	298
6.5	Areas representing Best Future Opportunities for Young Biomedical Scientists (identified by UK Respondents).	301
6.6	Perceived "Watersheds" in the development of the Profession (UK Respondents).	302
6.7	Factors identified by Greek Respondents as being Disadvantages to Biomedical Scientists working in European Countries other than their own	311
6.8	Areas identified by Swedish Respondents as representing the Best Future Opportunities for Young Biomedical Scientists	314
6.9	Advantages perceived to Students/Practitioners working in European Countries other than their own (Swedish Respondents)	315
7.1	Basis for Honours Classification in a Representative UK College	333

7.2	Grade Scale Descriptors – Representative Greek College	338
7.3	College Participation in Undergraduate and Course Director Questionnaires	343
7.4	Number of First and Final Year Student Participants	344
7.5	Mean Ages of Student Participants	344
7.6	Gender Distribution of Student Participants (both cohorts)	345
7.7	Nationality of Student Participants (both cohorts)	345
7.8	Permanent Residence of Student Participants (both cohorts)	346
7.9	Numbers of Students (both cohorts) having previously studied in Other Countries	347
7.10	Pattern of Previous Study Abroad for Both Cohorts of Participants	347
7.11	Purpose of Previous Study Abroad (both cohorts)	348
7.12	Main Subject Area Studied during Previous Periods Abroad (both cohorts)	349
7.13	Student Exchange Programmes Associated with Previous Periods of Study Abroad (both cohorts)	350
7.14	Sources of Funding Used to Support Previous Study Abroad (both cohorts)	350
7.15	Mean Levels of Non – Family Funding used to Support Previous Study Abroad (both cohorts)	351
7.16	Elements of Study Abroad Funded by Sources External to the Family (both cohorts)	351
7.17	Numbers of Students Wishing to Study in Europe as Part of Current Course (both cohorts)	352
7.18	Numbers of Students Wishing to Study in Europe Sometime in the Future (both cohorts)	352
7.19	Elements of Study identified by Students Wishing to Study in other European Countries (both cohorts)	353
7.20	Numbers of Students Willing to Make a Financial Contribution to Periods of Study in Europe (both cohorts)	354

7.21	Preferences for European Languages amongst Student Respondents (both cohorts).	355
7.22	Level of Interest in Working in other European Countries (both cohorts)	356
7.23	Perceived Advantages and Disadvantages of Participating in European Exchange Programmes (both cohorts)	357
7.24	Perceived Advantages and Disadvantages of Employment in other European Countries (both cohorts).	359
7.25	Level of Awareness Regarding CATS and ECTS Schemes at Home Institutions	361
7.26	Participation Rates in CAT and ECTS Schemes (both cohorts)	361
7.27	Subject Areas Identified by Students as representing the Best Career Opportunities (both cohorts)	362
7.28	Details Relating to European Studies in the Curriculum (both cohorts)	363
7.29	Student Perspectives on the inclusion of European Studies (both cohorts)	364
7.30	Numbers of Students correctly identifying the Date of the Advent of the Single European Market	365
7.31	Numbers of Students correctly identifying the date of the Maastricht Treaty	365
7.32	Numbers of Students correctly identifying the Country holding the Current Presidency of the Council of the European Parliament	366
7.33	Numbers of Students correctly identifying the Current President of the European Commission	366
7.34	Numbers of Students correctly identifying the Meaning of the Abbreviation "ECU"	367
7.35	Mean Student Proficiency Scores (Self-Assessed) in European Languages	368
7.36	Minimum Entry Qualifications to First-Level Courses cited by Course Directors	369
7.37	Average Intake of Students 1998-2000.	370
7.38	Linear/Modular Pattern of Courses.	371
7.39	Percentage Weighting of Project Work.	371
7.40	Stipulated Length of Project Work.	372

7.41	European Language Provision.	374
7.42	Numbers of Colleges Operating Quality Assurance Mechanisms at Different Levels.	375
8.1	All IC Approved Curricular Activities for SOCRATES within SAC 12 (Medical Sciences) for the UK, Germany, Greece and Sweden, 1999-2000. (Includes CDI, CDA, EM and ILC)	389
8.2	IC Approved IPs within SOCRATES for 1999-2000 for the UK, Germany, Greece and Sweden (SAC 12-Medical Sciences)	389
8.3	OSM Activity 1998-99 – UK Student Numbers by Host Country	390
8.4	Activity Pattern for SAC 12(Medical Sciences) within SOCRATES, 1999-2000	390
8.5	Number of TS Activities within SOCRATES, 1999-2000: SAC 12	391
8.6	TEMPUS Activities (Statistics for 1990-1995)	397
8.7	JEPs and Compact Projects within the PHARE Programme (1997-98) – Percentage of Host Country Projects with which the Selected Member States have been involved	399
8.8	Number of Member State Partners involved in TACIS JEPs and Compact Projects (1995-99)	400
8.9	Reciprocity Arrangements between European Member States with respect to Academic Entry Qualifications in MLS	407

Glossary of Abbreviations

ABC	Avidin – Biotin Complex
ACB	Association of Clinical Biochemists
ACP	Association of Clinical Pathologists
AIDS	Acquired Immune Deficiency Syndrome
AML	Acute Myeloblastic Leukaemia
APL	Accredited Prior Learning
APEL	Accredited Prior Experiential Learning
AWIC	Animal Welfare Information Centre
AWMF	<i>Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften</i> (Association of Scientific Medical Societies of Germany)
AZT	Azidothymidine (now Zidovudine)
B-ALL	B Cell Acute Lymphoblastic Leukaemia
BCG	<i>Bacillus Calmette Guerin</i>
BEC	Business Education Council
BIO	Biotechnology Industry Organisation
BLA	Blast (cell)
BMA	British Medical Association
BMS	Biomedical Science
BTEC	Business and Technology Education Council
CATS	Credit and Accumulation Transfer System
CD	Cluster of Differentiation
CDA	Curriculum Development at Advanced Level (under SOCRATES)
CDC	Communicable Disease Centre / Centres for Disease Control and Prevention (U.S.)

CDI	Curriculum Development at Intermediate Level (under SOCRATES)
CEEC	Central and Eastern European Countries
CEPES	<i>Centre Européen pour l'Enseignement Supérieur</i> (European Centre for Higher Education)
CFTR	Cystic Fibrosis Transcription Regulator / Cystic Fibrosis Transmembrane Conductance Regulator
CHP	Council for Health Professions
CI	Colour Index
CIHE	Cardiff Institute of Higher Education
CML	Chronic Myeloid (Myelogenous) Leukaemia
cMu	Cytoplasmic <i>mu</i> chain (of Immunoglobulin)
COMETT	Community Action Programme for Education and Training for Technology
COSHH	Control of Substances Hazardous to Health
CPA	Clinical Pathology Accreditation
CPD	Continuous Professional Development
CPSM	Council for Professions Supplementary to Medicine
CPVE	Certificate of Pre Vocational Qualification
CSTI	Council of Science and Technology Institutes
CUUPP	Canada/UK University Partnership Program
CVCP	(UK) Committee of Vice Chancellors and Principals (“Universities UK” as from 1 st December, 2000)
CVE	Continuing Vocational Education
CVU	Council for Validating Universities
DAAD	<i>Deutscher Akademischer Austauschdienst</i> (German Academic Exchange Service)
del	Deletion (cytogenetic)

DES	Department of Education and Science
DfE	Department for Education
DG	Directorate General
DHSS	Department of Health and Social Security
DMBS	Diploma in Managing Biomedical Science
DNA	Deoxy-ribo Nucleic Acid
DoH	Department of Health
DTI	Department of Trade and Industry
DVTA	<i>Deutscher Verband Technischer Assistenten in der Medizin</i> (German Professional Body for Medical Laboratory Sciences)
EAC	Education Advisory Council
EAIE	European Association for International Education
EC	European Community (Commission)
ECLM	European Confederation for Laboratory Medicine
ECSC	European Coal and Steel Community
ECTS	European Community Course Credit Transfer System
Ecu	European Currency Unit
ED	Employment Department
EDC	European Defence Community
EEA	European Economic Area
EEC	European Economic Community
EFTA	European Free Trade Association
EM	European Module (Related to SOCRATES)
EMS	Emergency Medical Service
EPBS	European Association for Professions in Biomedical Science
EPHLS	Emergency Public Health Laboratory Service

EPICS	Electronically Programmable Integrated Cell Sorter
EQA	External Quality Assurance
ERASMUS	European Action Scheme for the Mobility of University Students
ETF	ERASMUS Teaching Fellowship
EU	European Union
Euratom	European Atomic Energy Community
FAB	French-American-British (Collaborative Group)
FACS	Fluorescence Activated Cell Sorting
FETC	Further Education Teaching Certificate
FIBMS	Fellow of the Institute of Biomedical Science
FITC	Fluorochrome Isothiocyanate
FRG	Federal Republic of Germany
FST	Foundation for Science and Technology
GCSE	General Certificate of Secondary Education
GDP	Gross Domestic Product
GDR	German Democratic Republic
GKV	<i>Gesetzliche Krankenversicherung</i> (German Statutory Health Care Insurance)
GMC	General Medical Council
GNP	Gross National Product
GNVQ	General National Vocational Qualification
GSG	<i>Gesundheitsstrukturgesetz</i> (Health Care Structural Reform Act – Germany, 1993)
HCHS	Hospital and Community Health Services
HDN	Haemolytic Disease of the New-born
HE	Higher Education

HEFC	Higher Education Funding Council
HEFCE	Higher Education Funding Council England
HEFCW	Higher Education Funding Council Wales
HEQC	Higher Education Quality Council
HIV	Human Immunodeficiency Virus
HLA	Human Leucocyte Antigen / Histocompatible Leucocyte Antigen
HMI	Her Majesty's Inspectorate
HNC	Higher National Certificate
HND	Higher National Diploma
HUCBMS	Heads of University Centres for Biomedical Sciences
IAMLT	International Association of Medical Laboratory Technologists
IBL	<i>Institutet för Biomedicinsk Laboratorievetenskap</i> (Professional Body for Medical Laboratory Sciences in Sweden)
IBMS	Institute of Biomedical Science
IC	Institutional Contract (Relating to SOCRATES)
ICP	Inter University Collaborative Programme
IDS	Individual Development Skills
Ig	Immunoglobulin
IKA	<i>Idryma Kinonikón Asfaliseon</i> (Social Security Organisation of Greece/Social Insurance Foundation)
ILC	Integrated Language Course (Related to SOCRATES)
IMG	Individual Mobility Grant
IMLS	Institute of Medical Laboratory Sciences
IMLT	Institute of Medical Laboratory Technology
inv	Inversion (cytogenetic)
IP	Intensive Programme (under SOCRATES)

Ir	Immune response (gene)
ITE	Institute of Technological Education (in Greece)
JBL	Journal Based Learning
JEP	Joint European Project (under the TEMPUS Programme)
KEPE	<i>Kentro Npospammatiemy Kai OikonomikΩn EpeynΩn</i> (Greek Centre of Planning and Economic Research)
KMK	<i>Konferenz der Kultusminister der Lander Bundesrepublik Deutschland</i> (Conference of the Education and Cultural Affairs of the Lander in the Federal Republic of Germany)
LATSI	Laboratory and Associated Technical Standards Initiative
LEA	Local Education Authority
LFA	<i>Landstings Forbundets Antagningsnamnd</i> (Swedish County Council Association's Admission Committee)
MARS	Medical Access and Results System (in Sweden)
MBA	Master of Business Administration
MDS	Myelodysplastic Syndrome
MHC	Major Histocompatibility Complex
MLA	Medical Laboratory Assistant
MLS	Medical Laboratory Sciences
MLSO	Medical Laboratory Scientific Officer
MLT	Medical Laboratory Technician (Technologist/ Technology)
MLTB	Medical Laboratory Technician's Board
MPIfG	<i>Max-Plank-Institut fur Gesellschaftsforschung</i> (Max Plank Institute for the Study of Societies, Cologne)
MPO	Myeloperoxidase
MRC	Medical Research Council
MRC Path	Member of the Royal College of Pathologists

MTA	<i>Medizinisch Technische Assistent/in</i> (Medical Laboratory Assistant in Germany – Protected Title before 1972)
MTLA	<i>Medizinisch Technische Laboratorium Assisstant/in</i> (Medical Laboratory Assistant in Germany – Protected Title after 1972)
NARIC	National Academic Recognition Information Centre
NBA	National Blood Authority
NCVQ	National Council for Vocational Qualifications
NEQAS	National External Quality Assurance System (Scheme)
NHS	National Health Service
NHSCSP	National Health Service Cervical Screening Programme
NIS	New Independent States
NVQ	National Vocational Qualifications
OECD	Organisation for Economic Co-operation and Development
OGA	<i>Organismós Georgikon Aspheliseon</i> (Organisation for Agricultural Insurance in Greece)
OMS	[Support for] Organising the Mobility of Students (under SOCRATES)
ONC	Ordinary National Certificate
OND	Ordinary National Diploma
OPD	Out-Patients Department
PAM	Professions Allied to Medicine
PAP	Peroxidase – anti-peroxidase
PAS	Periodic Acid Schiff
PASOK	<i>Panhellinion Socialistiko Kinima</i> (Panhellenic Socialist Movement)
PBLAA	Pathological and Bacteriological Laboratory Assistants Association
PCC	Professional Conduct Committee

PCR	Polymerase Chain Reaction
PFI	Private Finance Initiative
PGC	Postgraduate Certificate
PGCE	Postgraduate Certificate in Education
PGD	Postgraduate Diploma
PHARE	Poland and Hungary: Action for the Rebuilding of the Economy (Sub-division of the EU TEMPUS Programme)
PHLS	Public Health Laboratory Service
PPC	Preliminary Proceedings Committee
PRF	Personal Record File
PROW	Protein Reviews on the Web
PSM	Professions Supplementary to Medicine
PUMLT	Panhellenic Union of Medical Laboratory Technologists
PV	Preparatory Visit (Related to SOCRATES)
QALY	Quality Adjusted Life Years
QCA	Quality and Curriculum Authority
R&D	Research and Development
RAE	Research Assessment Exercise
RFLPs	Restriction Fragment Length Polymorphisms
RHA	Regional Health Authority
RNA	Ribo-nucleic acid
SAC	Subject Area Code (Relating to SOCRATES)
SCARF	Serum, Cells and Rare Fluids (Exchange)
SCOTVEC	Scottish Vocational Education Council
SCP	Scottish Committee of Principals
SED	Scottish Education Department

SHDD	Scottish Home and Health Department
SHEFC	Scottish Higher Education Funding Council
SIg	Surface Immunoglobulin
SME	Small and Medium Sized Enterprise
SOP	Standard Operating Procedure
SQTF	Science Qualifications Task Force
STD	Sexually Transmitted Disease
STMC	Science, Technology and Mathematics Council
TAB	Typhoid/Paratyphoid A and B
TACIS	Technical Assistance to the Commonwealth of Independent States (Sub-division of the EU TEMPUS Programme)
T-ALL	T-Cell Acute Lymphoblastic Leukaemia
TdT	Terminal deoxy-nucleotidyl Transferase
TEC	Training and Enterprise Council / Technology (Technician) Education Council
TEI	ΤΕΧΝΟΛΟΓΙΚΟ ΕΚΠΑΙΔΕΥΤΙΚΟ ΙΔΡΥΜΑ ΑΘΗΝΑΣ Technological Educational Institution (in Greece)
TEMPUS	Trans-European Mobility Programme for University Students
TEVE	<i>Tameio Emporikon Viomihanikon Epihiriseon</i> (Small Business and Trades Insurance Fund in Greece)
TS	Teaching Staff mobility (under SOCRATES)
TZ NRW	<i>Technologie Zentren im Land Nordrhein-Westfalen e.v.</i> (Association of Technology Centres in North Rhine-Westphalia)
UETP	University Enterprise Training Partnership
UHÄ	<i>Univeritet Högskole Ämbetet</i> (National Board of Universities and Colleges in Sweden)
UKCC	United Kingdom Central Council for Nursing, Midwifery and Health Visiting

UNESCO	United Nations Educational Scientific and Cultural Organisation
UNICEF	United Nations International Children's Emergency Fund (Now United Nations Children Fund)
UWIC	University of Wales Institute, Cardiff
WHO	World Health Organisation
ZAB	<i>Zentralstelle für ausländisches Bildungswesen</i> (Central Office for Foreign Education-Germany)

Introduction

*Does the road wind up-hill all the way?
Yes, to the very end.
Will the day's journey take the whole long day?
From morn to night my friend.*

Christina Rossetti.

The purpose of this thesis is first to identify those factors that have either aided or obstructed the development of medical laboratory technologists as a professional group within certain European countries. The second aim is to identify common and disparate themes that have shaped the drive towards the European Union's vision of professional harmonisation, within the context of a unified Europe, predicated on a common and shared citizenship. Consideration is given to identification of barriers militating against the professional harmonisation of medical laboratory scientists within Europe, using four selected countries. The research has been carried out with the United Kingdom as the primary model concerning professional development, since much of the relevant information is more readily available to the author. This should not be interpreted that the British paradigm is axiomatic of European models, rather it is used as an analogy against which other continental systems can be compared.

The central hypotheses of this thesis are that: -

- (a). *The primary stimulus for professional homogeneity will stem from scientific and technological advances rather than any other factor(s)*
- (b). *There is conflict in relation to political (national) self-interest that has roots in the historical relationships between the selected countries. This militates*

against any impetus towards professional or academic harmonisation within Europe

(c). *The mutual recognition of academic and professional qualifications within biomedical sciences in Europe will be achieved by:*

(i) *An increased awareness by students of the threats and opportunities relating to graduate employment associated with various General Directives*

(ii) *The acceptance by colleges of credit transfer schemes*

(iii) *A willingness on the part of professional bodies, statutory authorities and employers to recognise academic and professional qualifications from other member states of the European Union.*

The evolution of this particular professional group in each country has been a dynamic process, and analysis of such a progression is made even more complex by the inclusion of a European dimension. National health organisations include a plethora of occupational groups referred to as health care scientists (approximately twenty-eight in the United Kingdom alone), and this research specifically addresses that category referred to as Medical Laboratory Scientific Officers (MLSOs) and their counterparts in Germany, Greece and Sweden. This selection is based on the funding mechanisms associated with the health care delivery systems in each country.

Medical science, and particularly pathology, is enigmatic. Predicated on biology, the art of linking cause and effect with respect to disease is based on examination of vital systems. These can be difficult to understand because disease processes can have unpredictable outcomes. This results in what can at best be described as an inexact

science. Diagnostic laboratory pathology is traditionally divided into four major specialist disciplines, namely haematology, medical microbiology, clinical chemistry and cellular pathology. This is an artificial division based on the requirement to analyse abnormal processes against a background of a need to learn, teach, and above all, understand the nature of disease. Such necessities have resulted in an approach towards diagnostic pathology that is reductionist in nature and false in relation to its tendency towards compartmentalisation of disease. The approach is also artificial with respect to a predilection for considering abnormal physiological mechanisms as anomalous entities that can be classified into discrete conditions, as defined by traditional Western medicine.

Problems with the delineation of terminology is an axiomatic characteristic of any treatise dealing with the development of professional groups, and this has proven to be the case with respect to this work. Definition is a difficulty associated with the occupational group under examination. As an example – there is some overlap between the terms “medical laboratory sciences” and “biomedical sciences”. The use of the former term tends to be restricted to the four specialist disciplines mentioned above, whilst the latter designation refers to a wider aspect of diagnostic medicine that includes immunology, molecular and cell biology, genetics, biotechnology, electron microscopy, gene replacement therapy and hybridoma technology. An additional confounding anomaly is the tendency towards the synonymous use of titles (such as “MLSO” and “Biomedical Scientist” in the UK, or “*laboratorie assistant*” and “*biomedicinsk analytiker*” in Sweden).

The current situation with respect to European harmonisation is confused, largely as a result of the complexities of medical science. Added to this are the historically wide ranging and conflicting factors that helped to shape the profession. The fact that MLSOs in the UK and their European counterparts have played a subordinate role to clinicians has further complicated the process of integration.

In an attempt to reflect the diversity of influencing factors, this thesis has been broadly structured into four sections (A-D). Section A (which includes Chapters 1,2 and 3) considers the influence of science and addresses the problem of definition with respect to “profession”. Section B (Chapters 4 and 5) examines how health care systems and the inter-relationships between professional bodies have laid the foundations for the modern era. Section C (Chapters 6 and 7) considers the influence of both current and future practitioners on professional harmonisation together with an academic perspective. Section D (Chapters 8 and 9) assesses future prospects against the background of European Union policy.

The profession under examination is concerned with the principles of science and many of the primary influences shaping its characteristics have been founded on the historical developments associated with medical advance. The first two chapters of this work relate to some of the most dominant scientific issues that have impacted on medical laboratory sciences. Although the chosen temporal interface between the chapters is the turn of the Nineteenth Century, this carries no particular historical significance since such selection was based primarily on convenience.

The development and maturation of medical laboratory sciences is typified by a convoluted momentum towards the goal of professional recognition - a process exemplified by characteristic occupational strategies aimed at achieving public, peer-group and governmental acceptance. The third chapter examines some of the issues centred on the issue of "profession", its primary characteristics and the relationship between profession and MLSOs.

Chapter Four considers the influence of national health service characteristics within the four selected countries and the ways in which these have influenced the development and funding of diagnostic pathology within the identified states.

Central to the maturation of any occupation that has claims towards being a profession is the role of the organisation(s) that represents such groups within the professional arena. An additional consideration related to the professions allied to medicine (including MLSOs) is the role of national statutory licensing authorities responsible for issues such as the state registration of practitioners within those particular professions. Chapter Five addresses such factors, examines the historical relationship between the relevant agencies involved in medical laboratory sciences, and their impact on the mutual recognition of professional qualifications.

Using a combination of taped face-to-face and electronic (e-mail) based semi-structured interviews, Chapter Six considers the views of practising biomedical scientists with respect to professional developments within Europe. The primary aim here is to assess the level of agreement concerning the mutual recognition of professional qualifications.

Chapter Seven consists of an assessment of data collected from questionnaires returned by undergraduate students and course tutors from within the four selected countries. The survey addresses concerns such as obstacles to student mobility, language competency and the European Credit Transfer Scheme (ECTS).

As with most other institutions, professional organisations operating within the European arena have been subjected to political, economic and social influences in the recent drive towards Europeanisation. Amongst the most significant of these are the measures adopted by the European Union in an attempt to achieve harmonisation within various spheres of activity. Chapter Eight briefly re-visits the contribution that science and technology have made towards European integration. There is then an examination of the influence of European Commission policy in relation to academic exchange programmes within the biomedical sciences sector. The need for pragmatism has resulted in the partial restriction of this particular debate to the most important programmes affecting education and training – namely SOCRATES and TEMPUS. This work does not address issues such as the Fourth and Fifth Framework Programmes concerned with Research and Development, nor does it consider the roles of various professional organisations within the stratum of international (including European) biomedical sciences e.g. the European Confederation for Laboratory Medicine (ECLM), European Association for Professions in Biomedical Science (EPBS) and International Association of Medical Laboratory Technologists (IAMLT).

The early part of Chapter Nine considers the weight of evidence in support of the hypotheses and testifies to the veracity of Oscar Wilde's observation that "the truth is rarely pure and never simple". The concluding passages suggest future strategies that may be adopted in order to facilitate greater European cohesion within medical laboratory sciences and considers some of the impending changes that are likely to shape the future of the profession.

The Bibliography is presented within nine sections designed to guide the interested reader to sources dealing with wider issues concerning this research. The citations are arranged in strict chronological order within each section and secondly in alphabetical order. The use of numerous acronyms and abbreviations is an unavoidable and unfortunate element of any treatise dealing with the European Union and in order to minimise any confusion the reader is directed to the list of abbreviations included in the early section of this work.

SECTION A

SCIENCE AND TECHNOLOGY

AGENCIES FOR HOMOGENEITY

CHAPTER 1

Pre-Twentieth Century Advances in Diagnostic Pathology

Chapter 1

Pre-Twentieth Century Advances in Diagnostic Pathology

“Since November the previous year (1700) the doctors in England had tried everything possible to get down the ...swelling: frictions with elderflower water: “spaw-water”, pills made of extract of gentian and lesser centary, powder of crab’s claw, huge pills made of salt of wormwood, crab’s eyes, tartar vitviate, steel prepared with sulphur. They fed him Epsom salt in chicken broth, purged him with rosin of jalap and extract of rhubarb, and dosed him with tincture of steel... his legs remained as swollen as ever and his cough got worse.”

Source: van de Zee, 1973.

Introduction

The annals of pathology, and ultimately laboratory science, are inextricably linked with the history of diagnostic medicine, anatomy, surgery and the pure and applied sciences. The development of medicine is itself characterised by contradictions, idiosyncrasies and false hopes interspersed by significant scientific advances. The seeds of today’s medical profession were laid during the Renaissance and nurtured by a revival in the arts as well as science. The practitioners of medicine had suffered a protracted period of doubt, conflict and contradiction, exemplified by the contention between adherents of the Greek and Arabist systems. This chapter examines the ways in which medical advances emanating from the Enlightenment have influenced the early development of diagnostic pathology.

Renaissance Medicine

It is commonly supposed that the Renaissance was characterised by a rapid expansion in intellectual creativity in sectors such as medicine - first in Italy but later in France, Holland and England. Such an augmentation represented the beginnings of modern scientific medicine and was to be characterised by the practice of dissection, the

formulation of hypotheses and the conduct of experimentation. The rebirth of medicine - beginning during the 14th Century - had been preceded by the establishment of the first organised medical school in Europe at Salerno (1).

External influences were also having an affect on the development and liberation of medicine and science. These included the invention of printing, the voyages of discovery, the Reformation and the new cosmology of Copernicus. All of these contributed to the freedom of scientific thought and removal from the constraints of mediaeval scholasticism. Some two hundred years earlier the fall of Constantinople had resulted in the scattering of Greek scholars throughout Europe. Such dispersion, accompanied by a propagation of precious manuscripts, was instrumental in the rise of Humanism (2).

The Middle Ages had witnessed a rule of authority with respect to European science, but from the 15th Century a radical change occurred. This period witnessed not only the continuation of Greek and Latin works, but also the study of medicine according to Hippocrates and physics according to Archimedes. Modern experimental science was gradually replacing personal experience and the scientific method was born. Based on observation and the maintenance of careful records, the system was founded on inventions such as the microscope and a renewed interest in the work of Galen.

The early years of the Renaissance saw a renewed interest in the study of anatomy. In order to better portray the human body, artistic drawings, such as those of Leonardo da Vinci, were prepared. In 1543, the Belgian anatomist Vesalius published his treatise *De Humani Corporis Fabrica* (On the Structure of the Human Body). This

highlighted many of Galen's anatomical errors. At the same time, Fallopius, also using drawings based on the dissection of human corpses, discovered the uterine tubes and tympanum and gave detailed descriptions of the eye muscles and tear ducts. Additional contradictions to Galen's work were made by the Spanish physician Servetus, who was the first to correctly describe the pulmonary circulatory system.

Contributions to medicine were also coming from other European countries. The Swiss physician and alchemist Paracelsus founded the practice of chemotherapy by discovering new chemical remedies. He also broke with tradition by lecturing in German and publicly burning Galen's classical treatises on medicine. The French surgeon Pare, using forceps and ligature, facilitated surgical amputation and provided a more humane alternative to cauterisation.

In addition to a revival of interest in Greek and Roman culture, the Renaissance represented a change of outlook: There was a desire to escape from the limitations of tradition and an eagerness for discovery. It was natural that the study of anatomy and physiology should be the first aspects of medicine to receive attention. Pollack and Underwood (1968) argue that the changes taking place in medicine during the Renaissance were a consequence of a general cultural revolution. The awakening of national feeling grew alongside increasing cosmopolitanism. The universities began to act as agencies effecting scientific and cultural ties between the European nations. German physicians travelled to Scandinavia while the English and Dutch physicians visited Russia. The art of medicine roamed the Mediterranean and Central Europe to the North and West. Medical men followed the explorers to Eastern Asia and America. European medicine was on the way to becoming world medicine.

The renewed interest in anatomy also laid the foundations for an increased understanding of human physiology. In 1616 the English physician Harvey characterised the circulation of the blood. Experimenting on live animals and dissecting the bodies of executed criminals his findings were published in his treatise of 1628 *Exercitatio Anatomica de Motu Cordis et Sanguinis* (An Anatomical Disquisition on the Movement of the Heart and Blood). Educated at Cambridge and trained in medicine at Padua, Harvey had been taught by Fabricius and was the first physician to simultaneously use quantitative and observational methods in medical investigations. Thus was furthered the cause of the scientific method (3). Harvey's important discovery had been founded on contemporary technology (such as the hydraulic pump) which assisted in his elucidation of cardiac valve function. Such a facility had been denied to his predecessors such as Galen. There are certain dangers in studying the body as a machine. Almost all who did so, convinced themselves that a complete explanation of its workings were within their grasp. Defeat resulted in specious theories and undefined terms, which became confused with spurious observed facts.

The Renaissance was dealing a fatal blow to the "authoritative principle" in science and philosophy. Rigid dogma gave way to observation and experiment, reason and logic replaced blind faith - and inductive reasoning (championed by the likes of Bacon) became pre-eminent. Now, for the first time in Europe, medical training was becoming properly organised (4).

Shortly after Harvey's discovery of the circulatory system, the Flemish chemist, van Helmont, furthered the cause of physiology by developing the concept of gases and

suggested that digestive disturbances could be treated by the use of alkalis. The Italian biophysicist Borelli publishing his studies on animal motion established the link between muscle fibres and muscle contraction. The Italian histologist Malpighi studied the physiology of the spleen, liver and kidney, and demonstrated the existence of blood capillaries. This was a time therefore of significant advances (5) – a period in history which defined the birth of contemporary diagnostic medicine.

The foundations for an integrated study of physiology were further cemented by the efforts of 18th Century scientists such as the Dutch physician Boerhaave and his Swiss pupil Von Haller. The latter was the first to establish that all living matter possessed irritability. The Italian physicist Galvani demonstrated that electric currents could be used to stimulate the contraction of frogs' legs, whilst his compatriot Spallanzani investigated the role of gastric juice in digestion.

During the 19th Century the French physiologist Bernard investigated carbohydrate metabolism in humans and studied the autonomic nervous system. Pointing out that living organisms are never at rest but constantly undergoing dynamic changes in order to maintain internal equilibrium, his expositions were to lay the foundations of modern concepts of homeostasis. Significant inroads were also being made into the understanding of the nervous system – once again characterised by contributions from across Europe (6).

Pathological anatomy was also witnessing important developments. Prior to its eventual decline as the great centre of learning, Padua was to produce one of the most pre-eminent researchers within the sector of human anatomy – Giovanni Battista

Morgagni. In 1761 he published his work entitled *De sedibus et causis morborum per anatomica indagatis* (On the Seats and Causes of Diseases Investigated by Anatomy).

For the first time the concept of the pathological lesion was introduced into the theory of disease. Morgagni had united anatomy, clinical medicine and pathology by correlating clinical symptoms with autopsy findings in approximately 700 cases (7).

Some 200 years earlier the Florentine Antonio Benivieni, practising medicine for over 30 years, had kept methodical records of autopsies. Following his death (circa 1502) his records were edited and published as *De Abditis Morborum Causis*. This work was to represent the forerunner of the great texts in pathology (See Plates 1.1: 1.2 and 1.3), pp 17, 19 and 21 respectively.

The Influence of the Pure Sciences

From 1500 onwards there was a transition from alchemy to chemistry which was to underpin modern concepts of this science. Represented by the work of the Belgian chemist Johann Baptista Van Helmont (8) and the Irish man Robert Boyle (9), this was an era characterised by an emphasis on experimental observation. Centres such as Leiden became pre-eminent by the mid 17th Century and attracted chemists such as

Franciscus de Boe (known as Sylvius) and Herman Boerhaave.

Following the discovery that different gases existed, four of these were quickly characterised by chemists of the 18th Century (10). Their work was to pave the way for the use of anaesthetics (see later). Partly resulting from Boyle's work it had become clear during the 17th Century that most "pure" substances were compounds rather than elements. It now became possible to synthesise compounds from their pure constituent elements. Many could then be broken down again and analysed. Such developments resulted in a rapid expansion of known pure compounds and represented the birth of synthetic chemistry and pharmacology (11).

Amongst the foremost contributions of the chemists towards medicine was the development of the dye industry. In 1845 the Royal College of Chemistry was established in London, primarily to provide education and research facilities modelled on those which had developed in Germany (previously British Universities had been entirely didactic). One of the College's primary areas of research related to the dyestuffs industry which had developed (primarily in Germany) into a highly efficient commercial industry - although essentially craft based. The staple dyes were red and blue and obtained from madder root and *Indigofera*. There was also a wide range of other natural dyes such as woad, weld, fustic, cochineal and logwood. In 1856 Perkin isolated mauve which proved to be the first of the aniline dyes widely used in areas such as cellular pathology (12).

Scientific research was now developing in both methodological and institutional senses. Later would come the establishment of the German research laboratories represented by Badische, Aniline and Agfa (also the Swiss company Ciba-Geigy).

Although chemists were providing novel investigative tools to medicine, some such as Cardwell (1994) have argued that surprisingly medicine, amongst the oldest of crafts and historically closely related to chemistry had shown the least evidence of progress towards systematisation or of the influence of science. The reason for this is cited as the fact that medicine is a biological science - more complex and obscure than the physical sciences.

The establishment of the Royal Society in London (1660) had also proven to be a significant stimulus for the advancement of chemistry. Formed specifically for the study of natural phenomena, it denoted the existence of a body of individuals committed to advancing scientific knowledge. It also provided the opportunity of exchanging views - science and medicine were becoming more interesting.

The physicists were also becoming increasingly involved in the scientific revolution. Notable amongst their contributions were the invention and further refinements of the microscope. For the first time it now became possible to study pathological changes at a cellular level, thus aiding the understanding of the aetiology and pathogenesis of diseases (13). The 17th Century was characterised by a growing trend towards the quantification of natural phenomena - in other words nature was becoming "mathematised".

Another significant invention was the thermometer. As early as 1575 there had been an interest in measuring heat, particularly amongst the Venetians. From about 1635, Santorio and Sagredo began to develop the thermoscope which was to become the first air thermometer (the former also adapted the pendulum to medical practice in an attempt to measure pulse rates). At the same time the "liquid in glass" thermometer was developed, although the definition of a universally accepted standard of temperature remained elusive. Some agreement was however reached in the early 18th Century when universal temperature scales based on fiduciary points (i.e. based on public confidence and trust) were developed. These involved the use of mixtures of ice and brine, ice and water, body temperature and the boiling point of water. The work was pioneered by Gabriel Fahrenheit, Anders Celsius and Rene-Antoine de Reamer.

By the mid 19th Century the imagination of Europeans had been captured by the astounding developments in areas of physics such as electro-magnetism. Progress included the work of Volta, Galvani, Ritter, Ampera, Orsted and Faraday. Linked to these advances were the observations of the effects of electric currents upon human muscles and nerves. These were to have a profound influence on medicine and psychology (Talmon, 1967).

The closing years of the 19th Century saw another important discovery in physics which was to have direct benefits to medicine. In 1895, Rontgen published his findings relating to the use of electro-magnetic radiation (X-rays) in penetrating solid substances. The use of X-ray photographs was quickly to become a widely used technique by surgeons during World War I (See Mantin and Pullen, 1997).

The Birth of Medical Laboratory Sciences

Although most historians of science would perhaps agree that modern medicine has its foundations in the 17th Century, laboratory based diagnostic medicine did not develop until the second half of the 19th Century. This was the period which witnessed an increasing interest in clinical microscopy, and between 1840-1890 such techniques were widely practised. This represented the foundations of contemporary specialist disciplines such as medical microbiology, haematology, blood transfusion science, clinical chemistry, histopathology and others. In most cases the work was being executed personally by medical practitioners who had an interest in scientific investigation. However some employed one or more individuals who assisted in the daily routine laboratory procedures. This early period of diagnostic laboratory pathology is associated with some of the most famous names in investigative medicine such as Koch and Virchow, many of whom were devoted to research. However it was their assistants who were to represent the predecessors of workers currently referred to as “medical laboratory scientific officers” or “biomedical scientists” (within the United Kingdom).

Many of the great scientific institutions were established during the 17th Century. These included the *Academie dei Lincei* (1603), the Royal Society for the Arts (1754), *Ecole Polytechnique* (1795), the Royal Institution (1799) and the British Association (1831). It was America however, which was to see the first exploitation of the newly emerging technologies. Such applications included the research activities of the Massachusetts Institute of Technology in 1865. Although essentially centred on the needs of industry, these activities were to influence the development of applied clinical science in Europe and elsewhere.

The Foundations of Histopathology

The emergence of medical laboratory sciences was heralded by dramatic developments in microscopy (13). In 1609, Galileo had invented the telescope and together with his assistant, Torricelli, had developed crude ground lenses. In 1879 the German mathematician Abbe introduced the oil immersion objective and apochromatic lenses, together with new mass manufacturing processes for precision built instruments. Six years earlier the American instrument maker Robert Tolles had devised the first 1/10th immersion microscope using Canada balsam. These developments resulted in an increased demand for – and a significant growth in methods for preparing specimens for microscopic examination. This led to the introduction of novel approaches such as the staining of tissues and bacteria. By 1886 high quality optical glass lenses were being manufactured by Zeiss in Jenna. It was during this time that some of the most significant developments in the study of tissues took place (14).

The founder of modern cellular pathology is regarded by many as being Rudolph Virchow. Born in Schwielbend (Germany) in 1821, he studied at the Friedrich Wilhelm Institut, Berlin, and had been a pupil of Muller. The word “cell” had first been coined by the 17th Century microscopist Robert Hooke, but it was Theodore Schwann (also working with Muller), who had discovered that animal organisms consisted of nuclear cell structures. Virchow’s “cellular pathology” was founded on the concept that no specific cells occurred in disease but that morbid processes arose in existing cells. It was he who first used microscopy in the study of cancerous tissue.

Many of the techniques developed in the latter part of the 19th Century are currently used in histopathology. In 1873 Camillo Golgi published his method for depositing metallic salts within cell structures. At this time the histological study of nerve cells was being stimulated by the introduction of new staining methods. Golgi cut sections of tissue by hand from material hardened in solutions of potassium bichromate or osmic acid. He later developed the first tissue impregnation techniques using chromate of silver in order to study the fine structure of nerve tissue. He is also remembered for discovering the fine cytoplasmic network in nerve cells (the Golgi apparatus), and it was he who first recognised *Plasmodium vivax* as a distinct species of malaria (15).

Other key figures who laid the groundwork for modern histopathology included not only Müller but his contemporary Purkinje (working first at Breslau and then Prague). Unlike the botanists the early histologists made little use of microscopy, but in the 1830s achromatic lenses began to appear which allowed closer examination of tissue. Using such lenses, Muller who had also studied at Bonn and Berlin, compiled a complete description of glandular and cartilaginous tissue. He also grouped various cells into connective tissues (16). In 1838 he wrote a major publication on tumours by which time improved methods of specimen preparation had been achieved using such reagents as potassium dichromate, glacial acetic acid and osmium tetroxide .

The Mid and Late 19th Century was a period rich in medical scientists and although many were bacteriologists, the discipline of pathological anatomy was also well represented. This was especially so within the medical centres of Germany. Typical of such men was Friedrich Von Recklinghausen, Professor of Pathology at

Strasbourg. Publishing his paper on neurofibromatosis in 1882, he became an authority on bone diseases, embolism, infarction and thrombosis. He was also one of the pioneers of metallic impregnation techniques.

The understanding of cellular reactions involved in disease was aided by the painstaking investigation of cell proliferation performed by Carl Weigert. He demonstrated the presence of bacteria in smallpox lesions in 1871 – his work representing the earliest record of the staining of micro-organisms.

Weigert also pioneered the use of differential staining and his histological methods in neuropathology formed the basis for modern procedures such as the preparation of serial sections of pathological tissue (17). Although studying initially at Breslau and Berlin, Weigert largely developed his histological methods at Leipzig and Frankfurt.

During the 1880s the microscopic examination of tissues remained relatively primitive, with only two stains being readily available. These were carmine and haematoxylin, both being natural dyes. Consequently all staining reactions were either red or blue in colour. When Weigert investigated smallpox lesions he used ammonium – carmine solutions differentiated with a mixture of glycine and dilute hydrochloric acid. This was an early example of “regressive” staining (18). He also experimented with aniline dyes such as methyl violet for examination of bacteria and later used acid fuchsin and Bismark brown. Weigert later developed “clearing” mixtures with dehydrating properties which represented a further advance in histopathology. The creator of neuropathological methods, he also published the resorcin – fuchsin method for elastic tissue in 1898, while the Weigert – iron

haematoxylin (with Van Gieson's counterstain) is still routinely used. Weigert is also credited with the first descriptions of the fine details of the nervous system – achieved by the use of the differential haematoxylin stain to illustrate myelin sheaths.

Another pioneer in the development of histopathological techniques was Ehrlich, who in 1881 first used methylene blue as a bacteriological stain. Later he extended its use to the staining of nerve endings – this probably representing the first “vital” stain (19). A year later Ehrlich reported his modification of the Ziehl – Neelson stain for tuberculosis to the Berlin Society of Internal Medicine. Using nitric acid as a decolouriser, fuchsin was employed as a primary stain and aniline water as a mordant. In 1886 Ehrlich solved the problems associated with unstable alum haematoxylin by developing acid – alum haematoxylin. This was achieved by adding acetic acid and glycerine in order to prevent oxidation. This represented one of the first examples of a “permanent” stain in histopathology. Later refinements in staining techniques are epitomised by the likes of Lorraine Smith, who in the early part of the 20th Century developed the Nile Blue sulphate method of staining fat in tissue sections.

Apart from the advances in staining, other techniques were also contributing to the development of the science of histopathology – most notably the construction of microtomes used for the cutting of tissue sections. In 1880 Deleoine was responsible for the adaptation of the carpenter's planing iron as a microtome knife. Together with Cooke he was later to develop the freezing microtome (20).

In the 1890s the Schanze microtome designed at Leipzig was to be modified by Sims – Woodhead to allow irrigation of celloidin blocks with spirit in order to facilitate

cutting of tissues. The design of the Cambridge rocking microtome by Horace Darwin in 1885 (see Chapter 2 regarding the development of microtomes), together with the use of paraffin embedding techniques by Krebs in 1869, represented further significant advances.

The foundations of histopathology were laid then, by developments in microscopy, the expanded use of staining techniques and advances in the applications of microtomes. The fact that thin, stained sections of tissues could be examined microscopically meant that for the first time pathological lesions could be assessed at the cellular level. This allowed the first tentative steps in relating cause and effect with respect to pathological processes. Technology was beginning to unravel the mysteries of disease.

The Advent of Medical Microbiology

The impetus for the development of investigative bacteriology had stemmed from the great epidemics which had ravaged Europe (21). In a practical sense bacteriology began when Van Leeuwenhoek first examined microscopic particles from the scrapings of teeth. During the Renaissance, Europe fell victim to another frightful disease given the name "syphilis" by Gorolamo Fracastoro, who recognised specificity of the disorder. He was also the first to establish the different methods of infection by typhus and the contagious nature of tuberculosis. Postulating the existence of invisible seeds of infection (*Seminaria contagionum*) his work began to displace the old humoral doctrine.

It was the second half of the 19th Century that saw an enormous increase in bacteriological discovery. Prior to the advent of the germ theory, disease was thought to be transmitted by a mysterious miasma (due to a host of tiny chemical particles in air) (22).

Foremost amongst the founders of clinical microbiology was Robert Koch. It was he who discovered the causative organisms of tuberculosis and cholera. Working also on anthrax at Breslau, Koch was the first to describe the phenomenon of phagocytosis. During the 1880s tuberculosis accounted for approximately 18% of deaths in Europe and it was Koch who evolved the first successful procedure for demonstrating the tubercle bacillus. Later the technique was to be modified by Ehrlich, Ziehl and Neelson. Using blood solidified by heating, Koch devised a special medium for growing tuberculosis and subsequently proved that the isolated bacillus caused the disease. Publishing his report in the *Berliner Klinische Wochenschrift* in 1882 he wrongly claimed that tuberculin was the cure for tuberculosis. In 1884 during the cholera epidemics in Alexandria and Calcutta he established the causative organism to be *Vibrio cholera*. Perhaps the greatest single contribution to the development of bacteriology was his technique for obtaining pure cultures using agar to solidify liquid growth media. Koch has also been credited for the current techniques of preparing and staining smears on glass microscope slides and it was he who was largely responsible for introducing the Abbe condenser (23) and Stephenson's high power oil immersion lens (24). His investigations into the efficacy of disinfectants and sterilising processes eventually led to the development of "Koch's steam steriliser".

Another important contribution made by Koch was the establishment of criteria for identifying the causative organisms of disease – later to be called “Koch’s postulates” (25). In 1885 Koch became Professor of Hygiene and Bacteriology at Berlin where he organised the first practical courses. As a direct result of the tension that existed following France’s defeat in the Franco – Prussian war of 1870–1871, an intense rivalry was to develop between Koch and Pasteur.

The last few decades of the 19th Century became the “golden years of bacteriology”. At this time Bruce discovered the cause of “Malta fever” (*Brucella melitensis*) and “sleeping sickness” (*Trypanosoma brucei*) by examining blood films. He also established the tsetse fly as the vector in the latter disease. Earlier in the 1850s the Irish physicist Tyndall (Professor of Natural Philosophy at the Royal Institution) had developed his process of sterilisation later to be known as “Tyndallisation”. For the first time spores could be destroyed by repeated heating. Having studied at Marburg he was a strong supporter of the germ theory of disease and also of Pasteur. Tyndall’s efforts were to finally destroy the fallacious doctrine of spontaneous generation.

Foremost amongst the bacteriological research institutions of this time was the *Institut Pasteur* – created by the French government and established in 1888. Pasteur’s researches had established that the fermentation of milk and wine was a result of the multiplication of bacteria and other micro-organisms. His findings were fundamental to the discovery of the role of micro-organisms in disease. Amongst his other major contributions was the development of immunisation by inoculation of attenuated microbes (*Varicella zoster*, cholera, diphtheria, anthrax and rabies), the process of pasteurisation, his work on asepsis and research in stereochemistry. There were also

other centres of research being established, e.g. in 1899 the Scot Patrick Manson, established the School of Tropical Medicine at the Albert Dock Hospital, later to become the London School of Hygiene and Tropical Medicine.

A direct outcome of Pasteur's fundamental bacteriological discoveries was the development of antiseptic surgery pioneered in Britain by Lister. Working on wound infection and abscess formation he devised a technique for obtaining pure cultures from a mixed growth in fluid medium. Lister had been profoundly affected by the high incidence of post – surgical sepsis at Glasgow and published his paper on the use of carbolic acid in 1867 (26).

Amongst many others, the 1870s saw three particularly significant developments in microbiology. First, Koch's assistant Loeffler co-discovered (with Klebs) the causative organism of diphtheria. An early pioneer of virology, he later demonstrated with Frosch that "foot and mouth" disease was due to a filterable virus. This was the first recognition of a virus causing animal disease. Loeffler's technical skills remain in evidence, e.g. his methylene blue stain is still widely used. He was also one of the earliest to appreciate the use of aniline dyes for staining bacteria and tissues. Loeffler also developed improved culture media such as the use of blood serum for growing diphtheria bacillus. He also introduced malachite green as a selective medium for *Salmonella typhi* together with his "meat–juice, peptone–gelatine" medium (27).

The second significant development was the discovery by Losch in 1875 that *Entamoeba histolytica* caused the amoebic form of dysentery. (In 1897 the Japanese bacteriologist Kiyoshi Shiga was to name *Shigella dysenteriae* as the causative

organism of bacillary dysentery). This allowed the differentiation of amoebic and bacillary forms of the disorder by means other than clinical grounds.

The third important discovery was made by the Norwegian, Hansen, in 1873. Working in Bergen he established the causative organism of leprosy to be *Mycobacterium leprae*. He was thus one of the first to establish an aetiological relationship between a specific micro-organism and a particular disease (28).

The 1880s were equally significant. Klebs, working at Prague and then Zurich, had been the first to filter bacteria successfully. At the Wiesbaden Medical Congress of 1883 he announced the discovery of a small bacillus using a rapid methylene blue stain. Claiming this to be the organism causing diphtheria the bacterium was called the "Klebs-Loeffler bacillus" (now known as *Corynebacterium diphtheriae*). Klebs was also the first to see the typhoid bacillus and also to produce experimental bovine tuberculosis.

A notable early example of joint European efforts in microbiological research was the unravelling of the mysteries surrounding malaria (29). Amongst others Laveran (French), Ross and Manson (British) and Grasi and Golgi (Italian), made significant contributions. It was Laveran who originally witnessed the parasite at the French Military Hospital, Algeria in 1880. He later established the Laboratory of Tropical Medicine at the Pasteur Institute in 1886.

Other principal advances at this time were made by the Scot, Alexander Ogston, who in 1881 clearly established the clinical and bacteriological role of staphylococci in

septic infection. Also Ross and Yersin demonstrated the existence of diphtheria exotoxins in 1888. The latter discovery was to have important implications in the development of an immunising serum. In 1894 Roux and Martin established the value of von Behring's anti-toxin serum (produced in horses) – their findings being presented at the International Congress of Medicine, Budapest.

As the 20th Century approached, discoveries in laboratory bacteriology continued unabated. Amongst these was the detection of the causative organism (*Clostridium welchii*) of gas gangrene. This was achieved by the American Henry Welch in 1882. Previously working in New York, Strasbourg, Leipzig, Breslau, Berlin and Gottingen, he later introduced the first course in Pathology in America (at the Bellevue Hospital Medical College, New York).

In 1892 Pfeiffer, working with Koch at Berlin, performed some of the earliest experiments to determine the specific nutritional requirements of bacteria, thus inaugurating the study of microbial nutrition. Pfeiffer wrongly claimed the causative agent of influenza to be *Haemophilus influenzae*. (In 1933 Smith, Andrews and Laidlaw established it to be a virus). However, Pfeiffer's procedure for the differentiation of *Vibrio metchnikovi* from *Vibrio cholerae* was to lay the foundations of clinical diagnostic serology. Using guinea pig inoculations he established that vibrios failed to grow in the peritoneal cavities of guinea pigs previously infected, i.e. that the micro-organisms were being agglutinated. These findings became known as "Pfeiffer's Phenomenon" and were to have a profound influence on the theory of immunity (30). A year later (1893) Haffkine used the first anti-cholera inoculation during the Indian epidemic and it was he who pioneered the production of the anti-

plague (*Yersinia pestis* at the time called *Pastuerella pestis*) vaccine during the Bombay epidemic of 1896.

The final contributions towards the scientific advancement of bacteriology in the 19th Century were made by three Frenchmen. In 1895 Calmette, working at the Lille branch of the *Institut Pasteur*, researched the efficiency of vaccines against tuberculosis and also developed Pasteur's work on attenuated live vaccines (31). His assistant Guerin eventually produced an attenuated strain of the bovine tubercle bacillus grown in a culture medium consisting of potato, glycerine and bile salts. This became known as the "Bacillus Calmette Guerin" (BCG) and its use as a vaccine represented a fundamental advancement in prophylaxis. In 1896 Vincent, an army major based at the military hospital in Algiers, discovered the causative organisms of Vincent's angina (*Borrelia vincentii* and *Fusobacterium fusiforme*). In the same year Widal developed a diagnostic agglutination test for typhoid fever.

Despite the fact that laboratory science was unravelling the mysteries of infectious disease there were those who were sceptical of the efforts of the early bacteriologists. Notable amongst these were Nightingale and Chadwick, who during the cholera outbreak of 1871 demonstrated hostility towards scientific research. They argued that there was an urgent need "not to know but to do". Improvements were required to water supplies and domestic habits and not to the development of laboratory investigations. By the mid 1880s Nightingale and her associates were demanding reliable statistics on the costs and benefits of hospital and "out-patient" services, and contended that it was hospitalisation which damaged the chances of cure. Such institutions were seen as being unsanitary, carelessly run and as beds of infection.

Even today there are those who argue that the successes of modern medicine are an illusion in terms of epidemics (Illich, 1990) (32).

The Emergence of Immunology

The important discoveries being made in bacteriology were providing an impetus for new advances in the field of immunology. During the late 18th Century Jenner worked on the protective effect of cowpox against smallpox. This, together with Pasteur's research on anthrax and rabies, eventually clearly demonstrated the value of vaccination. Jenner's famous paper of 1797 led to thousands benefiting from vaccination and this became a common practice within Europe by the beginning of the 19th Century.

At the time (1890) of von Behring's discovery of anti-toxic immunity (diphtheria antitoxin) there were two schools of thought within Europe regarding the nature of immunity. The "solidists" led by Metchnikoff believed that phagocytes played a leading role, while the "humoralists" maintained that substances evolved within the body were mainly responsible for biological defence (33).

Metchnikoff is regarded by some as the founder of cellular immunology (Haworth, 1999) (Pascoe and Webb, 1986). In 1877 he developed the first system for classifying leucocytes in which two forms of motile cells were included. These were referred to as "microphages" (now called neutrophils) and "macrophages" – both considered by Metchnikoff to be professional phagocytes (34).

Von Behring had proven that the serum of an animal recovering from an attack of a certain disease, could be injected into a second animal and confer protection – this he called “anti-toxin”. Anti-diphtheria toxin was later further developed by Loeffler, Roux, Yersin, Kitasato and Koch. Von Behring went on to develop the commercial manufacture of anti-toxins and worked with the German company, Farbwerke Hoechst. By 1895, diphtheria anti-toxin was also being produced at the Lister Institute, London. Other aims of early pioneers included the understanding of antigen-antibody (immune complex) reactions and evaluating methods of serological diagnosis.

Early Attempts at Blood Transfusion

Although important advances were being made in the late 19th Century, basic immunological principles were largely lost on the growing band of medical practitioners seeking to develop safe blood transfusion. Prior to Landsteiner’s discovery of the ABO blood groups in 1901 and the subsequent establishment of the discipline of blood group serology, transfusion of blood between individuals was often fatal (35).

The first recorded suggestion (in 1628) of treating humans with the blood of others is credited to Johanne Colle at Padua, although no evidence exists that the procedure was ever undertaken at this time (Keynes, 1947). Almost 40 years later the Journal of the Royal Society (May 17th and 24th, 1665) attested to the first organised attempts at blood transfusion by Lower, Wilkins, Cox, Croon, Boyle and others. These experiments were largely restricted to the use of dogs as experimental models. Pepys,

in his diary entry of November 21st 1667 records an attempt by Wilkins to transfuse the blood of a sheep to a man. Some 150 years later Walker and Doubleday were using blood transfusions in childbirth and in 1869 Braxton-Hicks, an obstetrician at Guy's Hospital became the first to use phosphate of sodium as an anticoagulant.

A significant step in the development of blood transfusion occurred in 1880 when Golgi, experimenting with endoperitoneal blood, concluded that homologous blood infused into the peritoneal cavity increased the haemoglobin content of circulating blood (36). However, little real progress was made until the beginning of the 20th Century when the discovery of the ABO, Rhesus and other blood groups systems, allowed blood to be safely transfused. The demands of the World Wars were to provide a major impetus for further advances (See Chapter 2).

The Foundations of Haematology

The wider study of blood and its diseases has its origins in the Mid 17th Century when Swammerdam and Malpighi observed corpuscles in the blood vessels of animals. Later, Leeuwenhoek reported his work on human blood cells in a series of papers to the Royal Society between 1674 – 1706. The first recorded cell count was reported in 1851 by Vierordt. Using a capillary tube method, the procedure took approximately three hours. In 1855 the Dutch physiologist Cramer devised the first counting chamber consisting of two parallel glass rods cemented into a glass slide. He also designed a squared ocular micrometer.

One of the founders of modern haematology was Georges Hayem. Studying at Paris he had several distinguished French predecessors. These included de Bordeau, Anderal (who first recognised the different forms of anaemia) and Donne (the discoverer of platelets in 1842). Hayem was the first to consider haematology as a specialist subject in its own right. His contributions fell into three areas - namely blood coagulation, red cell morphology and the development of basic haematological techniques. He was the first to publish a method for counting platelets and suggested that they played a key role in blood coagulation. At this time only limited techniques such as the "bleeding time", "clotting time" and "clot retraction" measurement were in use (37).

The study of blood coagulation was in the so-called "pre-classical" period, stemming from the Mid 17th Century when Malpighi had observed fibrin strands in clotted blood. At the beginning of the 20th Century, Morawitz was to postulate his "classical" theory of blood coagulation (38). The study of red cell morphology was also limited and confused with very little knowledge regarding the distinction between artefacts and actual changes resulting from disease. It was Hayem once again who classified anaemias caused either by haemopoietic disturbance, blood loss, toxemia and lesions of haemopoietic tissue. He introduced his red cell diluting fluid - universally used until the 1930s. He was also responsible for the introduction of the "colour-index", used in the study of anaemia.

Another at the forefront of early haematology was Ehrlich. Now famous for his discovery of Salvarsan (Ehrlich 606) used in the treatment of Syphilis and his "side-chain" theory of immunity, Ehrlich through his discovery of the triacid stain played an

important part in the development of the differential leucocyte count. This remains a fundamental aspect of haematology (39). Containing orange G, methyl green and acid fuchsin, this first example of a neutral stain made possible the structural differentiation of leucocytes from 1879 onwards. Ehrlich also discovered the basophil and first identified the presence of nucleated red cell in the peripheral blood of patients with anaemia. Although the clinical aspects of pernicious anaemia had been well defined since 1822, it was Ehrlich who defined its association with megaloblasts (40).

The widespread practice of air drying blood smears above a Bunsen Burner flame (for fixation purposes) had developed from such practice at the *Kaisierliche Gesundheitamt* in Berlin. The enumeration of blood cells was further facilitated in 1877 by an improved method devised by Gower. Using a ruling device engraved on a chamber, the counting of erythrocytes became practicable for the first time and the apparatus was the forerunner of later haemocytometers (41). Prior to this, cell counting was not practised in Britain and only infrequently in France and Germany.

Between 1850 and 1875 several experimenters (most notably Cramer, Potain, Malassez, Hayem and Nacet) were developing eye-piece micrometers, each being calibrated for particular microscopes. Gower also invented a simple clinical haemoglobinometer, which became the basis for Haldane's carboxyhaemoglobin instrument. This was later widely used for the estimation of haemoglobin (prior to the arrival of the photo-electric colorimeter). A further contribution to the counting of blood cells was made in 1872 when Postain invented the Melangeur diluting pipette. Early evidence for the interface between the emerging disciplines of haematology and

immunology became apparent in the 1880s with Von Recklinghausen's discovery of the amoeboid movement of leucocytes in the blood stream.

Two contemporaneous developments now occurred which significantly advanced the understanding of haematological disease. The first related to Ehrlich's staining mixture. As its use grew in popularity as a diagnostic reagent, the value of applying synthetic organic dyes to the study of blood cells became increasingly apparent. Peripheral blood smears and bone marrow aspirates could now be examined and different forms of leukaemia and anaemia could be distinguished (42). The second development was the accelerating growth of the German optical industry linked to improved glass manufacturing. This resulted in more precisely engineered microscope lenses.

Clinical Chemistry – The Early Years

Advances in clinical chemistry closely followed developments in medicine, biochemistry and physiology, and were also facilitated by the growth of chemical analytical techniques. (Although the earliest publications dealing with biochemistry appear from 1832, at the time such studies were more akin to the homeopathic treatment of disease. In the mid 19th Century the range of analyses available to physicians was largely restricted to the measurement of hydrochloric acid in gastric juice, together with a limited range of tests on urine. The latter included Fehling's test for sugar, estimation of proteins by boiling with acidification and the measurement of bile using nitric acid. The classical "Lectures on Chemical Pathology" given by Bence Jones in 1847 were based on quantitative analyses of

urine. Although sugar, uric acid and urea had been respectively demonstrated in the blood of patients with diabetes mellitus, gout and chronic renal failure, there were no methods available for easy estimation. For the remainder of the 19th Century little further development was seen, although the foundations of the subject were being laid by the work of pioneers such as Thudicum and Garrod in Britain.

In Germany, von Frerichs, the leading exponent of clinical medicine at Breslau in the latter decades of the Century, was becoming more active in biochemical research. His contributions included observations dealing with digestion, hepatic disorders and diabetes. It was he who discovered “leucin” and “tyrosin” in the urine. In France Bernard discovered glycogen and defined the *Milieu interieur*, thus paving the way for the discovery of numerous hormones.

Other early pioneers of what was termed chemical physiology included Liebig of Giessen who made advances in organic chemistry and in the study of metabolism. Meanwhile Naunyn at Berlin worked on diabetic acidosis. An indication of the comparatively slow growth of clinical chemistry is the fact that the first edition of Panton’s textbook “Clinical Pathology” (published in 1913 and which represented standard practice at the time) contained no satisfactory chemical tests on blood – except for microscopy (Jones, 1999). Kike’s “Physiology” – first published in 1848, had to await its 35th edition of 1937 before the term “biochemistry” appeared in the title.

There was now a rising expectancy that the chemical analysis of body fluids would add a degree of objectivity to the largely subjective practice of medicine. History

shows that the most significant advances in clinical chemistry had to await developments in microchip technology – originally designed for the American defence industry. It was not until the second decade of the 20th Century that other advances in instrumentation provided the first truly expansive phase in the history of this particular discipline.

Non-Scientific Influences

The relationship between science and religion has often been uncomfortable. The Reformation of the 16th Century witnessed a search for the discovery of fundamental truths. With some exceptions (e.g. Galileo), most of the great scientists of the period were Protestants from Northern Europe. During the Enlightenment, the Church, increasingly viewed as being intolerant and linked with superstition, was subjected to fierce criticism. As religion became regarded as being an obstacle to progress, writers such as Voltaire and Rousseau became increasingly anticlerical. Amongst religious influences on medicine was the Jesuit movement. Considered by some to have been the “schoolmasters of Europe” the order was established in 1540. One of the movement’s members, Athanasius Kircher, examined the blood and urine of bubonic plague victims using primitive microscopy. Speculating that a living organism (*Contagium animatum*) might play a role in the infection, he stopped short of propounding an actual germ theory of disease.

Having made significant strides since the 17th Century, science was increasingly seen as a better political guide than religion. In addition various governments were criticised – politics should not encroach on individual freedom (43). The spirits of

laissez faire and economic liberalism were on the ascendancy (44). Science (and medicine) was benefiting from an atmosphere of social, economic, political and religious emancipation. Modern Europe was becoming shaped by the ideas characterised by the 17th Century. The intellectual revolution associated with the Renaissance engendered a critical attitude towards traditional authority. Although it was essentially secular, its strength was derived from faith in reason and research. Humans would be guided via the scientific method towards a better understanding of the material universe and of their place in it. The insecurity of the late 16th Century would be replaced by a more humane society founded on the benefits of social and scientific reform amongst which medicine was expected to play its part (45).

The new-found freedom was to result in a European International Community – represented by the Grand Tour. The upper classes of all nationalities visited the great centres of European Culture and scientists began working without reference to frontiers. The new scientific advances were displayed in exhibitions amongst which electricity figured prominently. The Paris Exhibition of 1889 also saw optical sciences being given pre-eminence. Serious science however was represented by chemistry – the discipline most directly affecting daily life. The efforts of the German chemists (most notably von Liebig) transformed not only agriculture and food processing but also public health.

Improvements in travel and communication also resulted in the dissemination of scientific and medical information – both of which are predicated on the distribution of shared ideas. Amongst the most notable advances were the development of steam driven presses in 1814 and the introduction of regular cheap postal services

throughout most of Europe in the 1840s. (Approximately one hundred years earlier it had taken a minimum of 4 weeks for letters to reach Venice from Lisbon. Venice – at the heart of the Mediterranean economy was therefore a month away from its periphery).

Originating within the Ruhr district (the first industrial boom area on mainland Europe) the railway system began to expand during the 1840s (46). A decade earlier, the first telegraphs had been introduced (by Morse in America; Gauss and Webber in Germany; Wheatstone and Cooke in England). The second half of the 19th Century witnessed a direct benefit in communications as a result of the Industrial Revolution (47). The contributions made by advances in communications and chemical processes were impressive.. Not only was there a profound affect on commercial life (e.g. synthetic dyes, soaps and fertilisers) but also the introduction of new drugs and an increase in medical research. Such developments led to a better understanding of tuberculosis, cholera and malaria.

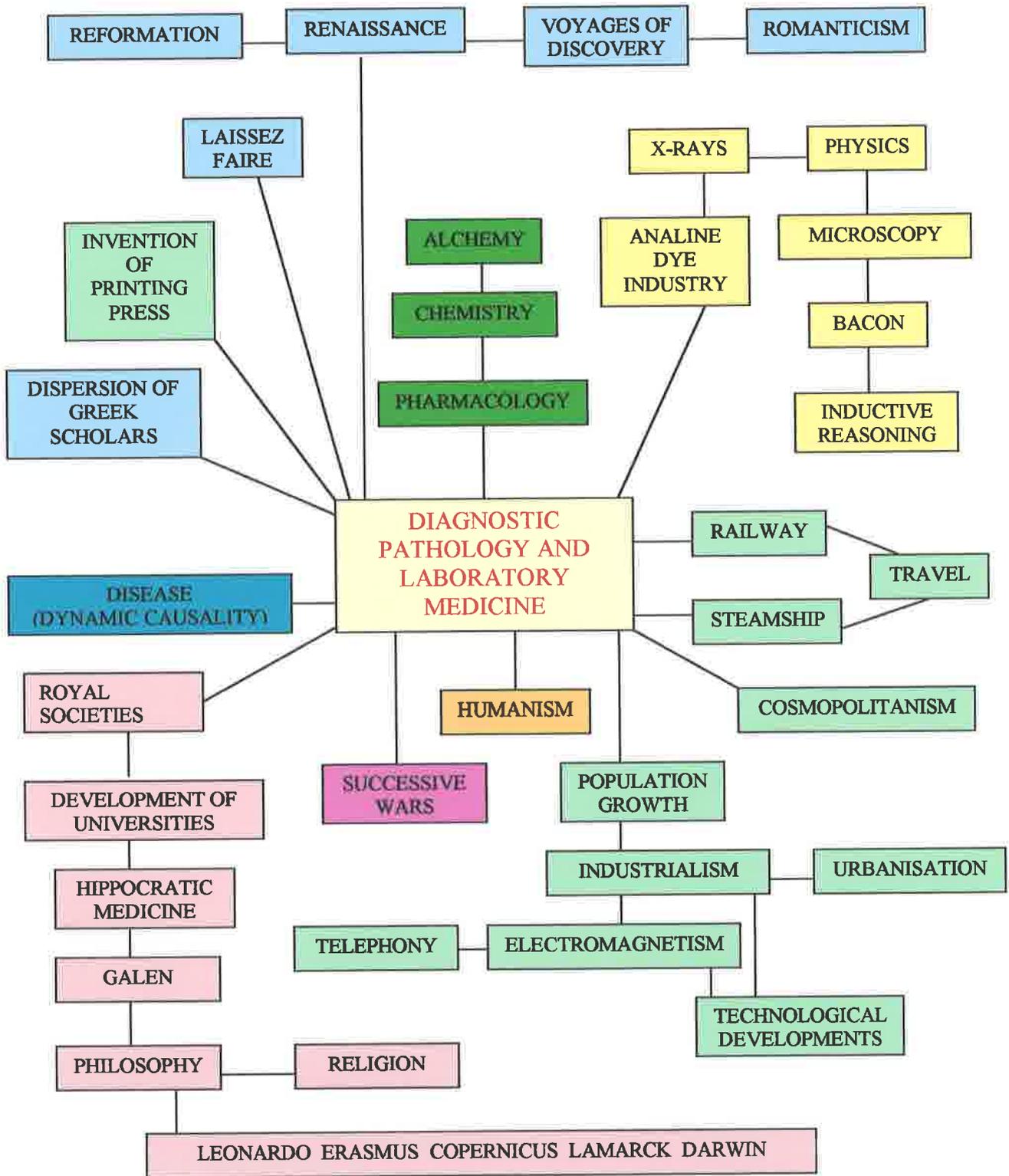
Important as these developments were to the spread of medical knowledge, there can be little doubt that the most fundamental contribution to the dissemination of such information was the invention of printing. Arguably described as the most significant technological advance in the history of civilisation, the ability to (comparatively) rapidly duplicate copies by using printing presses had a profound effect on the dissemination of knowledge (48).

Conclusions

The medical Renaissance, with its roots in the 14th Century, and inspired by the likes of Erasmus and Leonardo da Vinci, initiated profound changes in diagnostic medicine and pathology. The following centuries were to see medicine becoming more scientific, objective and systematised. By the beginning of the 20th Century, medical laboratory sciences had evolved into distinct disciplines such as haematology, histopathology, clinical chemistry and medical microbiology.

This Chapter has identified some of those factors (both scientific and non-scientific) which have influenced the early evolution of laboratory medicine. Such a maturation process has been characterised by several features. The first of these may be termed “Instrumental Externality” which involves those influences that are extrinsic to scientific medicine (See Figure 1.1). For the purpose of clarity only some of the more significant elements have been included (e.g. the development of Universities was a direct result of the dis-empowerment of monasteries - not shown in the relevant Figure). An additional consideration is the fact that some of the elements indicated are more closely associated with scientific medicine than are others (Hippocratic and Galenic medicine *cf. laissez faire*).

Figure 1.1: External Factors Affecting the Early Development of Medical Laboratory Sciences



The inter-relationship between some of these factors with both science and medicine is complex. Porter (1997) maintains that the discovery of America was “the most momentous event to affect human health”. Whilst the voyages of discovery were leading to the dissemination of medical knowledge, the human species was becoming increasingly exposed to novel pathogens.

Renaissance humanism was also proving to be something of an enigma. Galen and Hippocrates were being newly translated from the Greek and the discovery of new classical texts pointed towards the truths of Aristotelian natural philosophy and Galenic medicine (Debus, 1999). At the same time however such re-awakenings were being challenged by Paracelsus, Vesalius and Servetius. The fact that medicine (and pathology) were becoming systematic was eventually to lead to yet another paradox. It may have taken 500 years, but by the latter stages of the 19th Century, the basic principles of medical science were essentially analytical and reductionist in nature.

In some respects the advancement of medical laboratory sciences had mirrored the earlier progress in biology as exemplified by Linnaeus (taxonomy), Cuvier (comparative anatomy), Lamarck (inheritance) and Darwin (evolution) (Weiss and Mann, 1971). The tendency was towards a compartmentalisation of disease. As earlier enunciated by Galileo, Newton and Descartes, the pathophysiological basis of biological disorder could only be investigated, taught and understood by the categorisation of causal chains or units. Here the contradiction lies in the fact that Western medicine tends to categorise disease into somewhat artificial units. There are very few (if any) examples of specific pathological conditions where the resultant effects are restricted to medical microbiology, haematology or clinical chemistry.

Gregory (1999) points out that the conflict between Romanticism and science illustrated another contradiction. The Romantic reaction of the 17th Century opposed the idea that all things could be explained by science. There were some things in Nature which could only be described by artistic expression and not by a reductive analysis, notion or mathematics.

The second process influencing the development of laboratory medicine was the dynamic causality of disease. Advancement in medicine is shaped as a result of individuals or groups reacting to current or past diseases that have afflicted the human race. The rapid advance of medical microbiology during the 18th and 19th Centuries was largely a response to the historical lessons of plagues. Table 1.1 and Figure 1.2 illustrate the 12 primary causes of death in London during the great plague (49). Of a total of 97,306 deaths – 85,725 (88%) resulted from microbial causes. Plague accounted for 70.5% of mortalities. Even discounting these, 59.6% of deaths remain attributable to microbial disease. As a result of improved methods of microbial culture and identification, the advent of antibiotics, public health improvements and social reform, the pattern of microbial induced mortality and morbidity has since radically altered.

Some (such as Illich 1990) would argue that such improvements are but false hopes, based on the belief that medical intervention will provide the means to rid the human race of disease and pestilence.

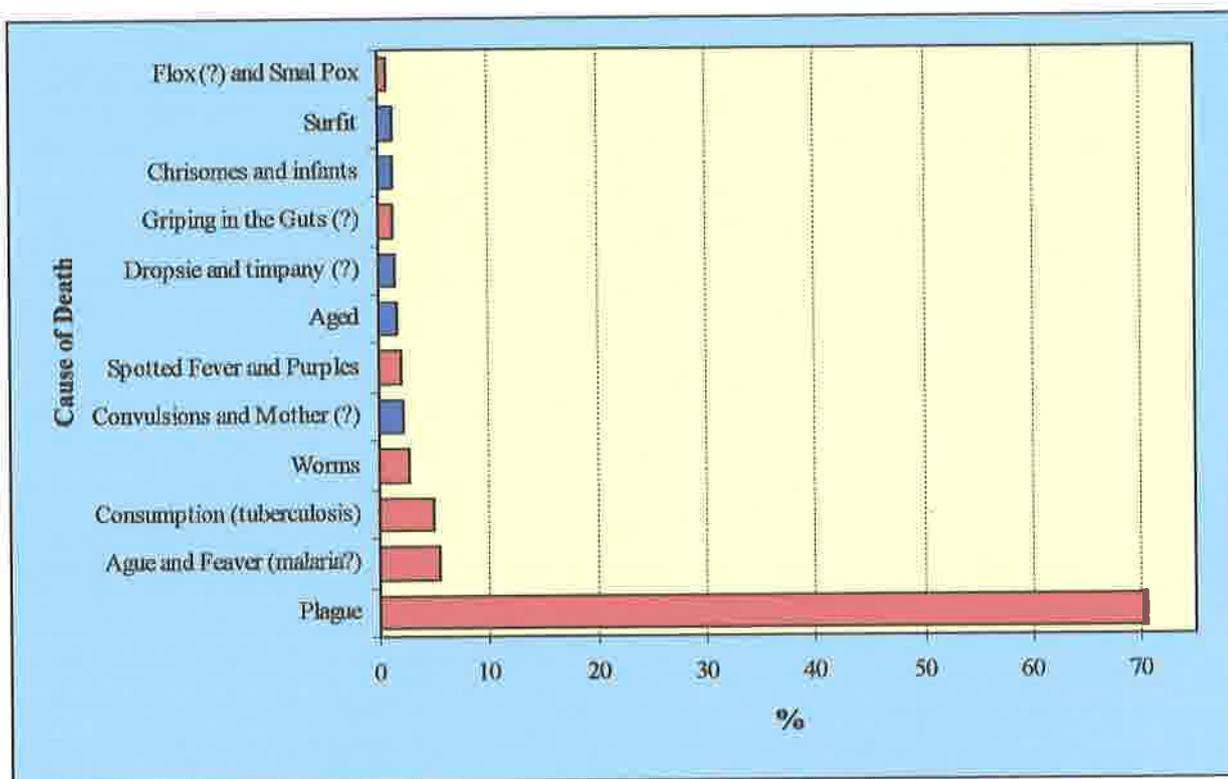
Table 1.1 The Twelve Primary Causes of Death in London, 1665

Cause of Death	Numbers	%
Plague (<i>Yersinia pestis</i>)*	68,596	70.5
Ague and fever (malaria?)*	5,257	5.4
Consumption (tuberculosis)*	4,808	4.9
Worms*	2,614	2.7
Convulsions and Mother (?)	2,036	2.1
Spotted fever and Purples*	1,929	2.0
Aged	1,545	1.6
Dropsie and timpany	1,478	1.5
Griping in the guts*	1,288	1.3
Chrisomes and infants	1,258	1.3
Surfit	1,251	1.3
Flox (?) and Small Pox*	655	0.7

*Indicates microbial origin of disease

Source:- Hammonds, 1999.

Figure 1.2: The Twelve Primary Causes of Death in London, 1665 - % of Total



■ Indicates microbially induced disease.

Adapted from Hammonds, 1999.

Table 1.2.and Figure 1.3. indicate the 12 primary causes of death within the United Kingdom in 1990.

Circulatory disease and cancer accounts for 71.5% of deaths while infections and parasitic illnesses result in only 0.4% of total mortalities (Some deaths within the “Respiratory Disease” category will be due to bacterial pneumonia. Even assuming that all 61,018 cases are microbial induced, the total microbe – mediated causes of death amount to 11.2%). The emergence of the Human Immunodeficiency Virus and antibiotic resistant strains of bacteria (*Staphylococcus aureus* and tuberculosis) may, ironically, reverse the above trend.

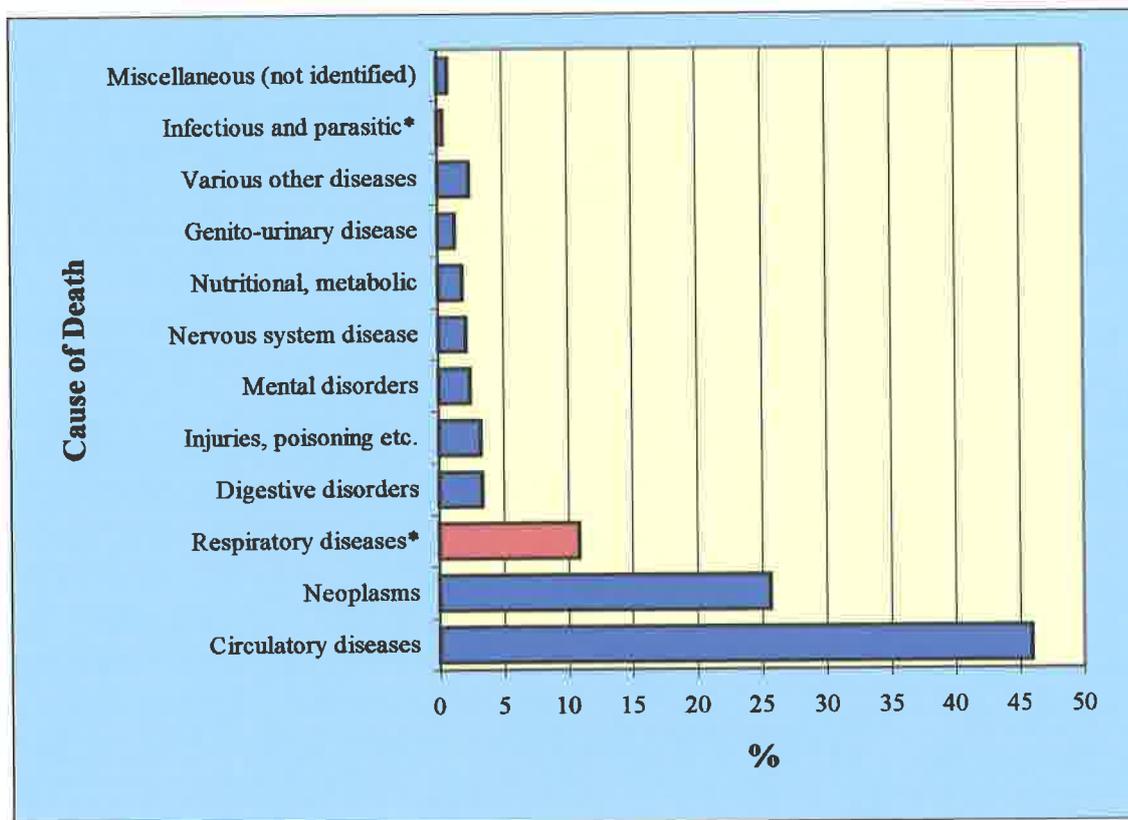
Table 1.2 Causes of Death in the United Kingdom, 1990

Cause of Death	Numbers	%
Circulatory diseases	259,247	45.9
Neoplasms	144,577	25.6
Respiratory diseases*	61,018	10.8
Digestive disorders	18,429	3.3
Injuries, poisoning etc.	17,943	3.2
Mental disorders	13,395	2.4
Nervous system disease	11,644	2.1
Nutritional, metabolic	10,249	1.8
Genito-urinary disease	7,317	1.3
Various other diseases	13,905	2.4
Infectious and parasitic*	2,446	0.4
Miscellaneous (not identified)	4,676	0.8

***Indicates microbial origin of disease**

Source: Hammonds, 1999.

Figure 1.3: Causes of Death, United.Kingdom, 1990



■ Indicates microbially induced disease.

The third influential process is that of synergistic parallelism (or vertical augmentation). These are essentially intrinsic to medical science and have a direct influence on its development. The advancement of scientific knowledge is incremental but it also has a synergy in that historically simultaneous scientific discoveries have resulted in an amplification of benefit to humans. Examples of such a phenomenon have occurred with respect to the development of medical laboratory sciences. Table 1.3 illustrates examples where simultaneous or chronologically approximate advances have resulted in synergistically improved diagnostic tests.

Table 1.3 Example of Synergistic Parallelism in Medical Laboratory Sciences

Date	Microscopy	Use of Dyes	Use of Microtomes	Consequences
1609	Galileo Invents Telescope			Impetus to the Spirit of Enquiry
1690	Van Leeuwenhoek, Simple Microscope			
1830	First Achromatic Lenses			
1856		Perkin isolates Mauve		Study of Pathology begins to shift to Cellular Level
1859		Verguin discovers Magenta		
1862		Verguin uses Azo Dyes		
1869			Paraffin Embedding	Tissue Processing leads to improved Specimen preservation
1873	Tolles uses Immersion Microscopy	Gogi Silver Impregnation		Development and spread of Medical Schools
1879	Abbe uses Apochromatic Lenses			
1880			Deleoine first Microtome Knife	High Resolution Microscopy
1881		Ehrlich uses Methylene Blue		Identification and Localisation of Cellular Components
1885			Darwin designs Rocking Microtome	
1886	Zeiss High Quality Lenses	Ehrlich uses Alum Haematoxylin		Increased understanding of Pathophysiology

The resultant effect of the parallel development of microscopy, the dye industry and microtomy, was the ability to examine pathological lesions at a cellular level. This occurred earlier than would have been the case if all three strands had developed in sequential order.

History is characterised by inevitabilities - the advent of the industrial revolution; the demand for social reform and the advancement of science were bound to result in a medical dividend. The 18th and 19th Centuries were characterised by global, regional and local reforms that were to prove to be the architectural pre-determinants of scientific and medical revolution. One of the resultant phenomena was the establishment of diagnostic pathology - which was to prove to be the forerunner of today's clinical laboratory. Chapter 2 will explore the issues which shaped the development of laboratory medicine within the 20th Century – an age influenced by the demands of global conflicts, the establishment of further social and welfare reforms, the advent of National Health Services and a second technological revolution with profound implications for health care and diagnostic medicine.

Notes

1. Salerno represented the confluence between classical, Arab and Jewish medicine. Situated near Monte Casino this ancient health resort had gained an increasing reputation during the 9th and 10th Centuries as a recognised centre of medical learning. By the 11th Century teaching was primarily practical and secular in tone with an emphasis on personal hygiene and diet. Latin translations from Arabic and Greek medical classics were prepared by Benedictine monks. During the 12th Century, medical instruction, which became increasingly scholastic and theoretical, was disseminated to medical schools at Montpellier and later to the Universities of Bologna, Oxford and Paris.
2. Developed during the Fifteenth and Sixteenth Centuries, this was a movement which aspired to re-animate the influences of classical antiquity – as opposed to the degraded scholasticism of the late Middle Ages. Such ambitions were to be achieved by a revival of the philosophy, language and literature of ancient Greece and Rome. The movement purported to advocate universally human (as opposed to utilitarian) science. Political strivings and religious dogma were also rejected (Watson, 1968).
3. This essentially involves four stages:
 - (i) Observation of fact.
 - (ii) The formulation of an appropriate theory or paradigm.
 - (iii) The testing of such theory by experimentation.
 - (iv) The recording of the results obtained (i.e. “conclusions”).
4. Such developments were epitomised in 1575 when William of Orange recommended Leyden for its successful defence against the Spaniards. Given the choice between a university and the remission of taxes, the burghers chose the former. Amongst the foremost of its scholars was Boerhaave. Trained first in divinity and then in medicine, he practised Hippocratic methods. His pupils were later to dominate British medicine and profoundly influenced the development of the Edinburgh medical school (See Carr, 1997 a).
5. Amongst other notable discoveries and advances were:-
 - (a) The first description of erythrocytes and spermatozoa by the Dutch microscopist van Leeuwenhoek.
 - (b) The initiation of the study of glands by the English physician Wharton, who first demonstrated salivary secretion. His work was further clarified by the Danish anatomist Steno (who identified secretions of the tear ducts and salivary glands) and the Dutch physician de Graaf (who discovered the ovarian follicles and performed studies on the pancreatic juices and the bile) (See Root, 1997).
6. Contributions included the work of:-
 - (a) Bell, the Scottish anatomist who described the functions of both sensory and motor nerves.
 - (b) Weber, a German physiologist who first recognised that the autonomic nervous system was composed of two processes.
 - (c) The French physiologists Magendie and Flovrens. The first described the functions of the spinal nerves and investigated the mechanisms of swallowing and regurgitation. The second investigated cerebellar function and pioneered the study of animal psychology.
 - (d) The German physiologist Muller, who showed that perceptions were determined only by the sensory organ that received the sensory impulse and Wundt, who established the first laboratory for investigating the physiological basis of psychology.

7. "Lesion" – a change in the structure of an organ or tissue resulting from injury or disease, and commonly giving rise to impaired function. The relationship between disease and tissue change has been the subject of study since ancient times including those of the Mesopotamians *circa* 3000 BC. However, prior to the mid 16th Century there had been considerable reluctance to the dissection of human bodies. This had primarily been for religious reasons. Although isolated autopsies had been performed as early as 1302 (for forensic purposes), it was not until 1556 that this reluctance was dissipated. This was the result of the decision of the Faculty of Theology at the University of Salamanca which declared that:-

"The dissection of human corpses serves a useful purpose, and is therefore permissible to Christians of the Catholic Church".

The most significant advances in understanding the lesion were achieved in the late 18th Century. Contributions included those made by: -

- (a) The Scot John Hunter who described the various stages of the inflammatory response in his publication of 1794 entitled "A Treatise on blood, inflammation and gunshot wounds".
 - (b) Hunter's compatriot and nephew – Matthew Baillie, who published clear illustrations of lesions as seen at autopsy. His book "The Morbid Anatomy of some of the most important parts of the Human Body" was first published in 1793 and the accompanying illustrations "The Series of Engravings" were published separately between 1799 and 1803.
 - (c) The English surgeon Astley Paton Cooper who described both inflammatory and innocent tumours of the breast in his work of 1829 - "Illustrations of Diseases of the Breast Part I". Using surgically removed lesions he pointed out the differences between benign and malignant lesions of the breast.
 - (d) The Frenchman Francis Xavier Bichat who first conceived the idea of "tissues" existing in various organs. He also classified membranes into "mucous", "serous" and "fibrous".
 - (e) Carl Von Rokitansky – alleged to have performed 30,000 autopsies, he was a descriptive pathologist and gave detailed accounts of arterial diseases, hepatic necrosis and congenital cardiac lesions.
 - (f) The Pomeranian Julius Cohnheim, whose contributions to experimental pathology included the first description of leucocyte diapedesis.
 - (g) Rudolf Virchow – the "father of Cellular Pathology", who first postulated that pathological reactions involved cellular changes (see later). By the advent of the Georgian Era (1714 – 1830) the practice of anatomical dissection had reached its peak. With approximately 700 medical students each year in London alone (each requiring three bodies per year for dissection) the demand for corpses was outstripping supply. Dissection was becoming fashionable – with even Harvey dissecting his own father and sister following their deaths. The practice of body snatching became rife with adult bodies sold at 2 guineas each and children at six shillings for the first foot and 1 pence per inch thereafter. Market forces prevailed and within a short time adult bodies were fetching 20 guineas each with body parts being sold separately (a possible derivation of the term "costing an arm and a leg") (See Richardson, 1999).
8. Van Helmont, a medical chemist, was an ardent follower of Paracelsus. Described as "the last alchemist and the first chemist" he was the first to recognise that there were different kinds of gases, each with different properties. He also pioneered the use of balances for precise weightings. Van Helmont's work on gases was later to be expatiated by John Mayow, Joseph Priestley and Antoine Lavoisier. These were to establish the relationship between oxygen, combustion and respiration (See Root, 1997).
9. Boyle is best known as the discoverer of the Law, which relates the pressure upon a sample of gas to its volume. He was also the first to define an element as "a pure substance which cannot be broken down into any simpler substance by chemical means"

10. Carbon dioxide was the first gas to be truly characterised. This was achieved by Joseph Black in 1750. Working as a clinician in Edinburgh he named the gas "fixed air" and presented his studies four years later as a doctoral thesis entitled "On the Acid Humour Arising from Food, and Magnesia Alba". The discovery of hydrogen is credited to the English chemist Henry Cavendish. The gas was described in his work "On Factitious Airs" published in 1766. Oxygen was first discovered and prepared by Joseph Priestley in 1774. He produced the gas by heating the red oxide of mercury (HgO). It has been established that Scheele had independently discovered oxygen in 1773 (prior to Priestley), but his work was not published until 1775 (Newth, 1895). Although nitrogen was clearly distinguished around 1772, the credit for its discovery remains unknown. The gas was extensively studied by Cavendish, Priestley, Scheele and Rutherford in the 1770s (See Plambeck, 1995).
11. In Sweden, Scheele investigated chlorine, hydrofluoric acid, manganese, oxalic and citric acids and barium. Priestley worked on hydrochloric acid, sulphur dioxide, ammonia and nitric oxide, while Black researched the relationships between a number of basic or alkaline substances – including magnesia, soda, lime and magnesium carbonate (See Williams, 1972).
12. Perkin was a student of Hofmann (the Head of the Royal College of Chemistry) who had requested his pupil to attempt the synthesis of quinine. Using aniline dyes derived from coal tar, Perkin found a black residue from which he extracted a purple substance (mauve) having the property of a dye. In 1859, Verguin discovered magenta and three years later Griess isolated the first of the azo dyes (See Cardwell, 1994).
13. Credit for the first microscope is usually given to Zacharias Jansen. In 1595 he elaborated the work of his father at Middleburg, Holland, and having given versions of their new inventions to Prince Maurice of Orange and Archduke Albert of Austria their instruments became popular with many of their contemporary scientists, including Galileo (See Jones, 1999). Approximately 100 years later the Dutch draper and amateur scientist Antoni van Leeuwenhoek described experiments using simple microscopes. Using basic drawings he recorded the first descriptions of protozoa, bacteria and spermatozoa (which he called "animalicules"). Using single, high quality, high power lenses, he was also able to provide the first detailed accounts of red blood cells. His microscopes had magnifications between 50x and 200x with resolutions of 2 microns.
14. Although most microscopists worked without the benefit of dyes, the ability of biologists to study disease processes at a cellular level for the first time led to advances in the understanding of a variety of diseases. Eventually the use of the microscope was to transform diagnostic pathology and the classification of disease from an anatomic – pathological approach (based on pragmatism) towards an aetiological approach (based on logic).
15. Golgi's approach to histological study exemplified the attitude of many of his contemporaries. Spurred on by advances in staining techniques scientists were experiencing a spirit of enquiry – promulgated most notably within the teaching centres of Germany.
16. The ability to recognise patterns of morphological features is a fundamental part of traditional histopathology. Such recognition is largely dependent on the staining of tissue components. However, the examination of such tissue sections can at best be described as the study of gross artefacts with little if any resemblance to the state of living tissues.
17. Occasionally the cutting and preparation of sections of a piece of tissue is required in order to elucidate the three-dimensional topography or anatomical architecture of an organ. For example this practice (which is referred to as "serial – sectioning") is employed when studying the tracking of malignant cells along neural sheaths or lymphatics.
18. Different tissue groups have varying affinities for dyes. These are reflected by the degree to which the dye is taken up by a particular tissue or by the stain avidity (i.e. a combination of the speed and binding power between the dye and the tissue). Regressive staining is a technique where tissue sections are over-stained after which the different avidities of various tissue groups for the dye are exploited. That is, the dye is selectively removed from unstained tissue groups.

19. "Vital" stains are those which are taken up by some living cells. The dye will selectively colour certain elements of the cell. These staining methods can be achieved via a variety of techniques, which may be *in vivo* (intravital) or *in vitro* (supravital).
20. Under normal circumstances, tissues, which require microscopic examination, are embedded in paraffin wax and cut into thin sections using a device called a microtome. This is always a time consuming process. In some situations requiring urgent results (e.g. the investigation of a possible malignant lesion of the breast – while the patient is under anaesthetics) tissues can be rapidly frozen in liquid carbon dioxide. These can then be subsequently sectioned, stained and examined under the microscope. This allows vital diagnostic information to be relayed to surgeons within minutes.
21. It has been estimated that approximately 33% of Britain's medieval population died from repeated outbreaks of bubonic and pneumonic plagues. During the 14th Century, the "Black Death" killed about 77 million individuals. Plagues remained the scourge of Europe for Centuries since in 1665 an outbreak claimed the lives of some 65,000 Londoners. Prior to Jenner's pioneering work, smallpox was also a major threat to Europeans. Unlike other epidemics, it did not disappear or lose virulence and during the 18th Century alone killed over sixty million people. In the 19th Century, new epidemics were seen. These included the cholera epidemics in Russia (1830) and London (1832 and 1865), together with the typhus (1838) and typhoid (1896) outbreaks in Southeast England (See Derry and Williams, 1973; Halsey and Friedman, 1984; Mantin and Pullen, 1997).
22. In 1843 Holmes showed that puerperal fever was transmitted by health workers and in 1847 the Hungarian obstetrician Semmelweis came to the same conclusion whilst working at the Vienna Maternity Hospital. The incidence of fever was markedly increased on those wards where students had frequented post-mortem rooms.
23. Using microscopy the objects to be examined are placed on a platform or stage. Below this is positioned a sub-stage condenser which is used to focus light onto the object. Such a condenser should form a perfect image of the light source. Although the Abbe condenser is commonly used, it is somewhat inefficient – forming only an imperfect image of the light source.
24. The use of immersion oil in microscopy allows an increase in resolution (i.e. the smallest distance between the closest two lines or dots that can be defined separately) by optimising the numerical aperture. (This is dependent on the refractive index of the medium between the object and the lens). Theoretically, the maximum possible numerical aperture when a lens is used in air is 1.0 whereas with immersion oil it is 1.51.
25. In order that an organism can be unequivocally proven to be an aetiological factor, the following criteria should be met :-
 - (a) It must be found in all cases of the disease.
 - (b) It must be isolated from the host and grown in pure culture.
 - (c) It should reproduce the original disease when introduced into a susceptible host.
 - (d) It must be found present in the experimental host so infected.
 (See Webster, 1993)
26. In 1865, Lister was Professor of Surgery at Glasgow. Using phenol or carbolic acid as a disinfectant he swabbed wounds and instruments in cases involving compound fractures. The mortality rates were reduced following the use of carbolic sprays. Carbolic acid is a derivative of benzene and first described by a group of Manchester chemists (Calvert, McDougall and Smith) as a means of suppressing the stench associated with sewage.
27. Such was the significance of Loeffler's technical contributions as Koch's assistant that it could be argued that he represents one of the earliest predecessors of today's Medical Laboratory Scientific Officers.

28. The terms “aetiology” and “pathogenesis” require careful distinction. The first refers to the causal factor(s) of disease whereas the second signifies the mechanism(s) by which the disorder arises.
29. Prior to the establishment of non-governmental scientific organisations in the latter part of the 19th Century, the “internationalisation” of science was epitomised by contributions from the individual researcher. The sum total of such efforts represented an “invisible college” of scientists. Important modes of contact were the personal visit and private letter (See Rose and Rose, 1971 Chapter 9, pp 179 – 197).
30. Pfeiffer found that live cholera vibrios could be injected into previously immunised guinea pigs without ill effect. He then withdrew a drop of the animal’s body fluid and examined it microscopically. He observed that the vibrios became motionless and gradually disintegrated. Other organisms that resembled vibrios in appearance were not similarly affected. Pfeiffer called this action “bacteriolysis” and showed that it also took place *in vitro*. Furthermore it was demonstrated that the power of the injected animal’s serum to produce lysis was abolished following heat treatment. This was “Pfeiffer’s phenomenon” (See Williams, 1998).
31. Attenuate – “*to cause a reduction in virulence by repeated culture or prolonged storage in the laboratory. The phenomenon is exploited in order to produce live vaccines, which generally have a more prolonged effect than killed vaccines, yet do not cause the serious disease for which the parent strain is responsible. An example is immunisation against tuberculosis by BCG*” (See Farr, 1988).
32. Illich contends that the progress of modern medicine has had little effect on the increased life expectancy. Contemporary clinical care is seen as being incidental to the curing of disease. He supports his argument with the following observations:-
Tuberculosis reached a peak over two generations. In New York the 1812 death rate was 700 per 10,000. This had declined to 370 per 10,000 by 1882 when Koch isolated and cultured the bacillus. A further reduction to 180 per 10,000 had already been achieved by the year 1910 when the first sanatorium was established. Finally, the rate was only 48 per 10,000 in the 1920s, i.e. prior to the advent of antibiotics. He also points out that cholera, typhoid and dysentery, similarly peaked and dwindled independently of medical intervention. The combined death rates of scarlet fever, diphtheria, pertussis and measles (up to the age of 15 years) showed that 90% of the decline in mortality (between 1860 and 1965) occurred before the use of antibiotics and mass immunisation. While Illich recognises that improved housing and reduction in virulence were important factors in this decline, he maintains that the most significant influence stemmed from increased resistance due to better nutrition.
33. Humoral – “*(Med) of the bodily humours; relating to body fluids esp. As opp. cells*”. Modern theories of immunity use the term “humoral immunity” to refer to the synthesis and secretion of antibodies into body fluids such as plasma (See Sykes, 1976).
34. Working at Messina in 1882, Metchnikoff conducted microscopic observations on *Daphnia*, the water flea, infected by the fungus *Monospora bicuspidata*. Once inside the *Daphnia* gut, the fungal spores were absorbed by amoeboid cells in the coelomic cavity. Such observations were later supported by work he undertook using cells in frog skin. These demonstrated the ability to take up anthrax bacilli prior to destroying them. This work led to Metchnikoff’s theory of phagocytosis supported by the likes of Virchow and Claus. It was the latter who provided the name “phagocyte” (Greek: *phagein*, to eat; *kytos*, cell). The destructive events of the 1870s and 1880s forced Metchnikoff to leave Russia and he joined the Pasteur Institute when it opened in 1888.
35. Based on current U.K. genotype frequencies within the ABO blood group system, approximately 40% of previously untested blood transfusions would result in some degree of incompatibility between donor and recipient. There exists some confusion as to who should be credited with the discovery of the A, B, AB and O blood groups. Some authors (Kirk et al, 1975) claim that the discovery was made by Landsteiner in 1900 while others (Williams, 1981) give credit to the Hungarian Jansky. His discovery in Prague during 1907 is said to have been confirmed by Agote (Buenos Aires) and Lewisohn (New York) in 1914.

36. The word “homologous” has different connotations in biology. In blood transfusion science the term “homologous blood” refers to blood of the same group – usually restricted to mean “of the same ABO group”.
37. These represented fairly crude attempts to measure the physiological (haemostatic) response of patients to minor injury such as pin-pricks or estimating the time for blood clots to form on pierced skin or using *in vitro* tests at 37°C.
38. Morawitz postulated that when blood clots are formed, a soluble protein in the blood called fibrinogen is converted to insoluble strands of fibrin. This is the result of an enzyme called thrombin. The latter is not normally present in the blood in an active form, but as a precursor substance called prothrombin. He also suggested that conversion of prothrombin to the active enzyme thrombin only takes place when another enzyme, “thromboplastin”, is released from injured tissues. Later research was to show that although the latter part of the theory was correct, the formation of thromboplastin is much more complex than was originally suggested and that there were other stimulants for the conversion of prothrombin.
39. The “differential” count is a common technique in haematology in which stained blood films are examined microscopically and the leucocytes categorised into five major groups. In certain blood disorders there are characteristic changes in the distribution patterns of white cells.
40. Megaloblasts are abnormal red cells recognised in bone-marrow and peripheral blood films because of distinct morphological abnormalities. They usually result from a deficiency of either vitamin B12 and/or folic acid.
41. Before the advent of automated electronic cell counters, blood cells were enumerated by preparing a solution of the blood and placing the liquid on to a ruled metal platen covered by a glass cover slip. Using conventional light microscopy, the cells lying within a defined area could be visualised and counted. The apparatus used for this purpose is known as a “haemocytometer”.
42. In 1891 Romanowsky first described a modified methylene blue stain for demonstrating malarial parasites. The mixture was observed to impart a differential colouration to white blood cells. In the same year, Malachowski obtained similar results using a polychrome methylene blue solution. The original Romanowsky stain was further modified by Jenner, Leishman, MacNeal, Giemsa and Wright. The result was a complex formulation consisting of methylene blue, eosin, azure and unstable eosinates. The compound dye gave vivid coloration to blood cells, which could now be distinguished on the basis of size, shape and chroma.
43. Championed by the likes of the English physician and philosopher John Locke, liberalism was being popularised alongside a growing trend towards female emancipation as exemplified by the efforts of Mary Godwin. The latter was also an ardent defender of the French Revolution and alongside her husband (William) believed in social anarchism.
44. Loosely translated from the French language, the term “laissez-faire” means “leave be”. Pioneered by French economists (known as the “physiocrats”) and lasting from about 1830 to 1880, this theoretical concept paradoxically resulted in a delay to much needed public reform, e.g. the introduction of public health and welfare changes advocated by Chadwick and others. The policy of non-intervention also extended to economic life. Favouring capitalist self-interest, competition and free trade, the philosophy was championed by Adam Smith.
45. The late 16th Century was a period of uncertainty extending even to the supply of life’s basic needs. Life was short and precarious. Survival at birth was uncertain with 200 out of 1000 babies dying before the age of 12 months. 50% of the population would not reach 20 years of age.

46. Although the first public passenger line was introduced in Darlington in 1825, it was Continental Europe which saw the greatest expansion of railway networks during the following three decades. Having achieved independence in 1830, Belgium constructed a network of State railways radiating from Brussels. In Germany, the first locomotive to be constructed (in 1839) ran on the Dresden to Leipzig line. Cologne became an important railway centre with links to Antwerp, Minden and Basel. Berlin also had lines connected to Hamburg, Stettin, Breslau, Magdeburg and Leipzig. In France, railway construction was retarded for political reasons (largely relating to who should finance the required infrastructure) but in 1842, legislation was introduced providing for railway construction between Paris, Rouen, Le Havre, Lille and Calais. Links to London and Brussels were to follow. By 1870, a web of steel ran across Europe including Spain and Italy.
47. The most important developments included :-
- (a) Brunel's iron steam ship built in 1858. Called the 'Great Eastern' it lay the first transatlantic cable.
 - (b) The invention of the first filament lamps used for electric lighting in 1878 – by Swan in England and Edison in America.
 - (c) The introduction of electric trams – first used by Siemens in the Berlin suburbs
 - (d) The invention of the telephone by Bell and Edison.
 - (e) The first use of electromagnetic waves to send messages by the Italian Marconi. Similar experiments in the use of wireless telegraphy were conducted by Popova in St. Petersburg.
 - (f) The production of the first internal combustion engines. The earliest gas engines were built in the 1860s in Germany and France by Lenoir, de Rochas, Hugon and Otto. The first engineering plant to produce small petrol models was built at Deutz near Cologne by Otto and Langen. In 1872, the latter was joined by Gottlieb, Daimler and Manbach. A decade later Daimler and Manbach built a factory at Cannstatt while Benz independently built petrol engines at Mannheim.
48. Prior to the advent of printing presses, medical knowledge had been disseminated by word of mouth, the laborious copying of manuscripts or by letter writing. Although the first developments in printing took place in China from as early as the 2nd Century, the spread of technological knowledge was slow to reach Europe. However by 1500, several European towns had printing houses (including Strassburg, Bamberg, Cologne, Subiaco, Rome, Venice, Milan, Florence and Naples). In France the Sorbonne had seen the introduction of printing in 1470, two years after the Swiss had established a press at Basle. Presses were also found at Valencia and Bruges (both established in 1474).
49. For the purposes of clarity, the other remaining causes are not shown. These included:-
- Childbed (625), Abortive and stillborn (617), Rickets (557), Rising of the lights (397), Stopping of the Stomack (332), Impostume (abscess) (227), Bloudy flux (185), Collick and winde (134), Apoplex and suddenly (116), Canker and thrush (111), Jaundies (110), Scurvy (105), Stone and Strangury (98), French Pox (syphilis), Kings evil (tuberculosis) (86), Broken, bruised limbs (82), Cold and cough (68), Cancer, fistula (56), Vomiting (51), Drowned (50), Accidents (46), Various others (452) (See Hammonds, 1999).

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CHAPTER 2

Diagnostic Pathology in the Twentieth Century

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"... we know [nothing] concrete about most of the medical encounters there have ever been. The historical record is like the night sky: we see a few stars and group them into mythic constellations. But what is chiefly visible is the darkness".

Source: Porter, 1997.

Introduction

This Chapter explores the emergence and development of medical science against the background of technological advances made during the Industrial Revolution. With the advent of antibiotics, the first half of the Twentieth Century witnessed a significant improvement in the ability of medicine to counteract many of the infectious diseases that had plagued the human race. These scientific tools together with technical improvements were to further public expectations in relation to clinical medicine. The demands of wars also acted as a spur to the development of novel techniques in areas such as blood transfusion science. The establishment of national health systems and the expansion of diagnostic pathology further provided the impetus for the introduction of a structured professional entity. This was to be the birth of the formal occupational group concerned with medical laboratory sciences.

Histopathology – The Process of Modernisation

History takes no heed of temporal boundaries. The advancement of medical science into the 20th Century witnessed a growing expectation of medicine. Diagnostic accuracy was not considered to be a problem until technological advances were to show that the classification of disease could be achieved on a more rational basis.

Cellular pathology was now being used to establish the relationship between disease causality and clinical manifestation. Previously it had been sufficient to recognise cell components and the organisational aspects of cells within tissues, but now the study of the form and function of cellular organelles was adding valuable information to the understanding of disease processes. Added to this, the recognition of cell types, not only according to morphological criteria but also in relation to their biochemical and immunological properties, was becoming more common.

Techniques originally introduced over a century ago remain the basis for many current procedures used within cellular pathology, e.g. microincineration was first introduced by Raspail in 1833 (1). The first half of the 20th Century saw several significant developments including the introduction of autoradiography by London in 1904 (2). The technique of microradiography (3) has been applied to the study of the dry mass of cells and sometimes to demonstrate the arrangement of blood vessels in tissues following their injection with radio-opaque material. Substances used to demonstrate the structure of blood vessels and anatomical regions such as the bronchial tree have included colloidal solutions. These are allowed to solidify so that permanent casts can be prepared. Gelatine injections containing coloured substances such as carmine, carbon or Prussian Blue have also been used, together with neoprene latex and cold-setting plastics. Specimens prepared using such techniques have been successfully employed as museum demonstrations.

A significant problem associated with the processing of tissues prior to histological examination has been the requirement to preserve cells and tissue constituents in a condition as near as possible to that existing during life. This must be achieved in

such a way as to allow the preparation of thin, stained sections suitable for microscopic examination. Such preservation is a primary objective of the process of "fixation" (4). Many of the difficulties associated with the preparation and cutting of histological sections were solved during the early decades of the 20th Century and several of the fixatives introduced at this time are commonly used in current diagnostic work. Notable examples include Helly's fluid (1903) and Susa fixative (1916). Improvements were also being achieved in the use of embedding media (5) and since the 1960s commercially available mixtures have been added to paraffin waxes in order to improve consistency (e.g. microcrystalline-wax mixture and synthetic rubbers).

In the late 1950s experiments were being undertaken on the feasibility of automatic tissue processing and examples of early instruments include the "Histette" (Hendrey Relay Ltd. Slough) and "Histokinette 2000" (Reichert-Jung Ltd.). These had the advantage of allowing tissues to be processed overnight. Ultrasonic vibration methods to improve tissue processing were also being developed at this time and advances were also being made in microtomy (6).

Development of the aniline dye industry had originated in the late 1850s and these stains, together with haematoxylin, still comprise the commonest true dyes in histology (7). Techniques developed since the Second World War have largely been histochemical methods - giving coloured reactions for the identification of specific chemical structures and enzymes. These, together with the hundreds of synthetic dyes being manufactured (principally in Britain and Germany) resulted in an explosive expansion of histological staining techniques between 1900 and 1965 (see Addendum

2.1 for a representative list of dye applications developed during this period). Histological staining had come of age – but developments in immunocytochemistry were to carry the science (and art) of cellular pathology to even greater heights during the second half of the 20th Century (see later).

Since many of the dyes were complex organic chemicals (the extracts of naturally occurring substances), their composition tended to vary from batch to batch and from manufacturer to manufacturer. Added to this, the nomenclature used to identify such stains led to confusion (8). Measures then taken in Britain and America, principally involving the establishment of a unified classification system for dyes, led to a more rational system of stain nomenclatures. By 1951, automated techniques for tissue staining had been introduced - one of the first examples of a machine which performed automatic staining being that devised by Davidson at King's College Medical School. There now quickly followed a plethora of commercially made apparatus, the American manufacturers "Technicon" being the primary providers of such equipment.

Since the early 1970s, immunocytochemical techniques have become established adjuncts to routine histopathological practice. The bases for immunocytochemistry had first been laid in the 1940s when Coons attempted to localise antigens and antibody responses related to pathogenic micro-organisms. This represented another example of scientific disciplines (namely histopathology, immunology, microbiology and chemistry) transcending traditional boundaries and thus reflecting scientific synergism. However, several conceptual and technical barriers had to be conquered before the full potential of immunocytochemistry could be recognised. Essentially

these related to the requirements of labelling each antibody with different fluorochromes, fading of the fluorescent signal from the stored tissues and an unsatisfactory degree of clarity of morphological detail. In 1966 however the advent of cell-lineage specific markers revolutionised the histopathological analysis of neoplastic lesions (9).

Between 1940 and 1987, several contributions were made to the development of immunocytochemical technology as aids to diagnosis. (10). Such was the popularity of these techniques that according to one survey (Angel *et al*, 1989), approximately 80% of histopathology laboratories in the United Kingdom were using histochemical methods in the later stages of the 20th Century.

Other immunologically based applications in histopathology were advanced between 1960 and 1990. These included the Peroxidase-antiperoxidase (PAP) procedure introduced by Sternberger in the late 1960s. The technique involved a three-layer bridge antibody system and demonstrated exquisite specificity in relation to antigen detection. The Avidin-Biotin Complex (ABC) procedure was a method introduced by Hsu *et al* in the early 1980s and allowed antibodies from a variety of animal species to be used in investigative histopathology.

Following the turn of the Century, advances in histopathology were centred on four principal developments. These were the increased availability of synthetic dyes and a standardised nomenclature, improvements in the processing of tissues (fixation, embedding etc.), the introduction of immunologically based chemical staining reactions and improvements in microtomy. These advances led to the production of

high quality uniform tissue sections available for microscopic examination. Histopathologists of the 20th Century were reaping the benefits of the efforts of Virchow, Schwann, Golgi, Muller and others.

Microbiology and the Advent of Antibiotics

Whereas the early years of the 20th Century are noted for the emergence of chemotherapeutic agents, there were also further advances in the identification of micro-organisms. In 1905, Schaidinn and Hoffman discovered the causative organism of syphilis (*Treponema pallidum*) and a year later von Wassermann, working at the University of Berlin, developed his serological tests for the causative spirochaete (11). It was also in 1906 that Bordet discovered *Bacillus pertussis* – the cause of whooping cough. Another notable advance occurred in 1923 when George and Gladys Dick established that scarlet fever was caused by a *Streptococcus* species (they later developed an effective antitoxin). In the same year Calmette and Guerin succeeded in manufacturing the “BCG” vaccine for tuberculosis (See Addendum 2.2).

Greater awareness was now growing of the effects of environmental and social factors on the epidemiology of infectious diseases. Amongst the early pioneers of reform was Sims-Woodhead who, in 1916, became the second President of the Pathological and Bacteriological Laboratory Assistants Association (PBLAA) of Great Britain. His interest in tuberculosis intensified during employment at Edinburgh Children’s Hospital and he became a member of the Royal Commission, which during the first decade of the 1900s investigated the transmission of tuberculosis from cattle to Man.

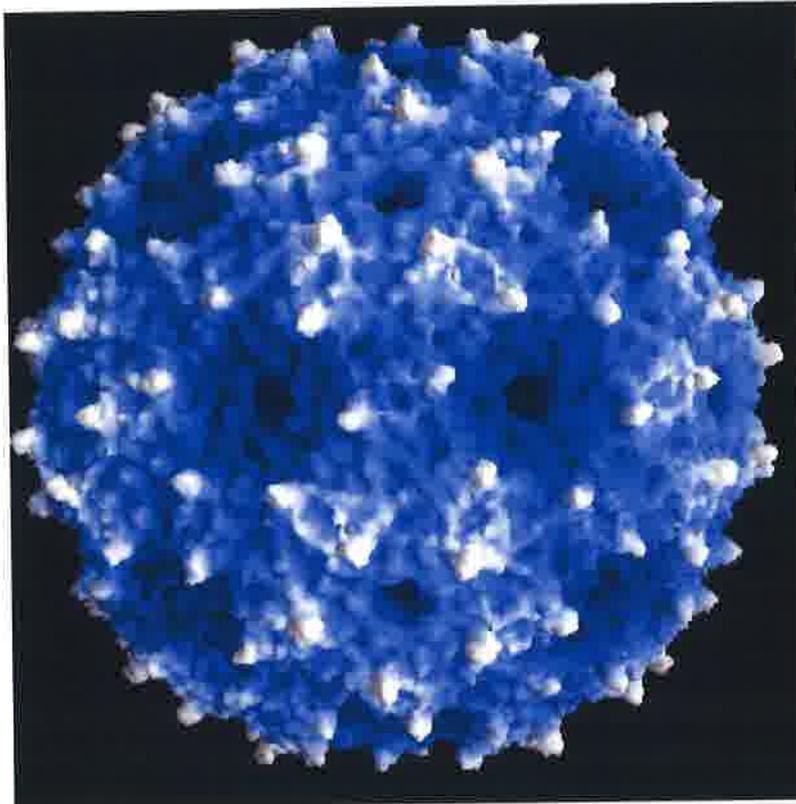
He was also a strong advocate of sanatorium treatment and also pioneered the practice of chlorinating water supplies.

Concomitant with the work of the Royal Commission, laboratory research on novel growth media was advancing. At Liverpool, MacConkey evolved a medium consisting of peptone water with an agar base and containing neutral red and carbolic acid. This was a significant advance since it allowed for the specific growth of Gram negative organisms but suppressed those that were Gram positive (12). Other typing methods developed at this time included those of the Canadian D'Herelle. During the 1920s he worked on the possibility of using bacteriophage (see later) as a therapeutic agent (See Plate 2.1). Although this never materialised, bacteriophage became an essential aid in the typing of *Salmonella typhi* and *Staphylococcus aureus*. Having practised at Yale he was later to establish the *Laboratoire du bacteriophage* at Paris in 1933 and also its peripheral research centres at Tifles (former Yugoslavia), Kiev and Kharkow (Ukraine).

Slightly earlier Felix (who had collaborated with Weil in the Austrian Army Medical Service during World War I) had begun to investigate Typhus. In 1916 they developed the Weil-Felix agglutination test for the organism (13). Felix had studied chemistry in Vienna and between 1927-1954 had worked at the Lister Institute and also for the Public Health Laboratory Service (PHLS) during World War II. It was as a result of his efforts that the Central Enteric Reference Laboratory and Bureau were established at Colindale, London.

Plate 2.1 Bacteriophage Ms2

X-ray structural determination using radial depth cue rendering with Grasp (A. Nicholls) on silicon graphics.



Reproduced with Permission: Dr. Jean-Yves Sgro, Institute for Molecular Virology,
University of Wisconsin

PDB Entry IM S2Code

Original Reference: Valegard, K, Jas, L.I, Fridborg, K. and Unge, T. (1990) Nature,
345, (36). (Not cited in Reference Section)

Although the beginnings of modern chemotherapy are attributed to Ehrlich's discovery of the anti-syphilitic agent Salvarsan (Arsphemamine or Ehrlich 606) in 1910, the chemical sulfanilamide had been isolated in 1908. Its bactericidal property was not known until after 1936, when it was discovered to be the active constituent of the first "wonder drug" Prontosil (see below and Addendum 2.2). Coincidentally, 1910 saw the introduction of tincture of iodine as a wound disinfectant by Woodbury – a major in the USA Army Medical Corp. In the meantime Fleming was researching other possible sources for substances that would destroy bacteria. In 1922 he isolated lysozyme from tears (14) but failed to establish any medical application. In 1928 came his famous discovery of penicillin in mould growing in cultures of *Staphylococcus*. His paper "On the antibacterial action of cultures of *Penicillium*" published in 1929 demonstrates his appreciation of the bacterial killing powers of penicillin and also that the substance was non-toxic. He did not pursue this line of research and it was not until the advent of World War II that Florey and Chain were to revisit the subject.

Spurred on by the need to discover substances for the treatment of war wounds, Florey had researched the biochemistry of mould (working with Raistrick's research group at the London School of Hygiene and Tropical Medicine). In 1940 he published his paper "Penicillin as a Chemotherapeutic Substance". Later at Oxford he actively pursued methods of purification, preservation and mass production of the drug. He successfully demonstrated the absence of toxicity and showed its effectiveness against haemolytic streptococci, staphylococci and *Clostridium septicum*. These efforts represented important milestones in the development of cell culture techniques and the birth of biotechnology - since improved culture procedures

and freeze drying applications were established (15). The new drug was eventually to abolish gas gangrene during World War II.

Between 1932-35 the German chemist Domagk obtained the first chemotherapeutic agent (Prontosil) which was strongly active against bacteria. The substance is degraded in the liver to sulphanilamide and this fact led to the discovery of sulphonamides. This group of drugs had a significant impact between 1935-37 and were used to combat pneumonia and puerperal fever (caused by *Streptococcus pyogenes*). Three other 'sulfa' drugs were soon discovered (Sulfapyridine in 1937, Sulfathiazole in 1939 and Sulfadiazine in 1941). The first effective antibiotic against Gram negative bacteria was discovered in 1943 when Waksman isolated Streptomycin from moulds growing in soil. A year later the first of the tetracyclines (Aureomycin) was discovered by Duggar and at the same time Erythromycin was isolated from the *Actinomycetes* mould. Davies (1999) maintains that the development and use of antibiotics, unlike vaccines, have not eliminated any of the infectious diseases. The bacterial infections causing human suffering prior to 1950 remain within the population and the inappropriate use of chemotherapeutic agents have resulted in the emergence of new antibiotic resistant organisms.

Significant developments in virology and tissue culture were also taking place. Although Harrison had earlier (1907) demonstrated outgrowths of nerve fibres from neurons embedded in lymph clots, the first true advances in tissue culture and virology had to await the 1950s. As early as 1928 Maitlands had shown that *vaccinia* virus would multiply in fragments of tissue suspended in liquid nutrient medium, but the use of such techniques was sporadic for the next three decades. In 1949 Enders

published his discovery that the poliomyelitis virus (highly tissue specific *in vivo*) could be grown in tissue cultures of non-neural origin.

Various refinements in technique followed, e.g. the use of cell monolayers. These allowed the application of tissue culture not only for virus isolation but also for cancer research, vaccine production and anti-viral chemotherapy. Enders, Webber and Robbins achieved significant results when growing mumps virus in chick tissue and using penicillin to prevent bacterial contamination. The early 1940s also saw the birth of microbial genetics (see later) when Avery *et al* (in 1944) showed that DNA was responsible for the transformation of pneumococci. Lederberg and Tatum also demonstrated genetic recombination in *Escherichia coli* in 1946.

Medical microbiology was becoming inextricably bound to the scientific disciplines of cellular and molecular biology, microbial genetics, biotechnology and molecular immunology. Biomedical sciences was therefore experiencing a conflicting exigency – i.e. the requirement to reconcile convergent scientific paradigms with divergent intimations in respect of emerging disciplines such as molecular biology and biotechnology.

Immunology – the Emergence of a Dichotomous Science

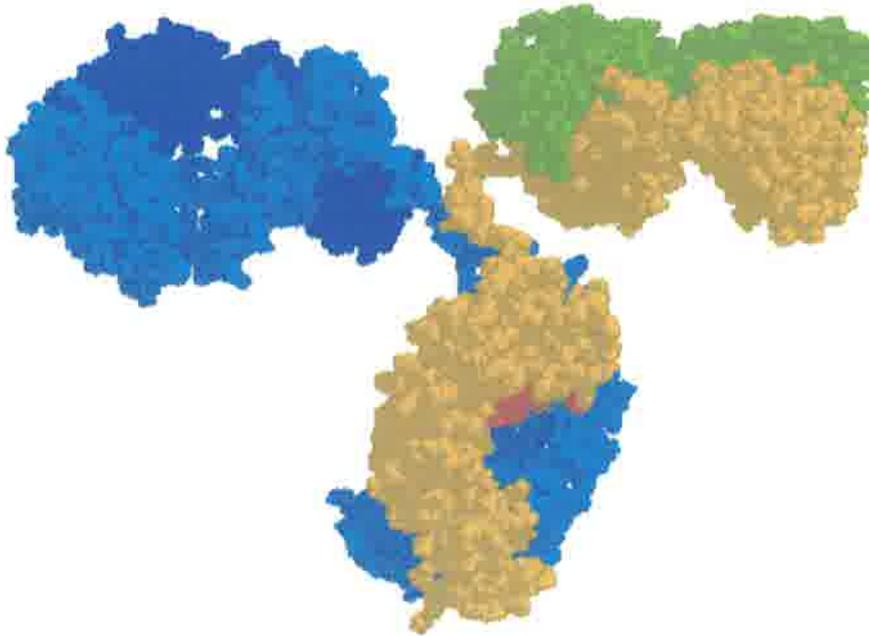
Immunity to infectious agents depends on the production of antibodies (which will react with the antigen) and cell-mediated immune reactions. Historical developments in the discipline reflect advancing knowledge of both “arms” of the immune response. It was not until 1903 when Wright demonstrated that antibodies (opsonins) aided the

cell-mediated phagocytosis of bacteria and that a compromise was reached between the two hypotheses of immunity.

The study of antibodies had begun in 1890 when von Behring established that bacterial toxins could be neutralised by horse anti-toxin antibodies. Ehrlich was also pioneering immunocytochemistry by attempting to quantify the precipitation reaction between toxin and anti-toxin. His work prompted the physical chemist Arrhenius to coin the word “immunochemistry” in a series of lectures published in 1907. It was not until the 1940s that significant advances regarding the chemical nature of antibodies were made. At this time Tiselius and Kabat, using electrophoresis, demonstrated that antibody activity in serum was associated with the gamma-globulin fraction (16). Another significant immunological breakthrough was accomplished in 1945 when Landsteiner and van der Scher, working with isomers of aminobenzene sulphonic acid, first demonstrated the exquisite specificity of antigen-antibody interactions.

The first attempts to investigate the structure of antibodies were made by Porter in 1959. Using several proteolytic agents (e.g. papain) he found that antibody molecules could be cleaved into different constitutional parts depending on the enzyme being used. Employing sulphhydryl reagents, Edelman then demonstrated that the constituent chains of immunoglobulins could be isolated. These observations formed the basis on which Porter postulated a four-polypeptide chain configuration for immunoglobulin (Ig) G (17) (See Plate 2.2). Elucidation of antibody structure and the generation of immunoglobulin diversity represented two of the most important immunological problems during the first half of the 20th Century. Theoretical

Plate 2.2 Computer Generated Model of Mouse IgG2a Molecule



Source: Clark, 2000.

Reproduced with permission

Note: Heavy chains of the antibody molecule are shown in yellow and light blue

Light chains are shown in green and dark blue

Carbohydrate is shown as red

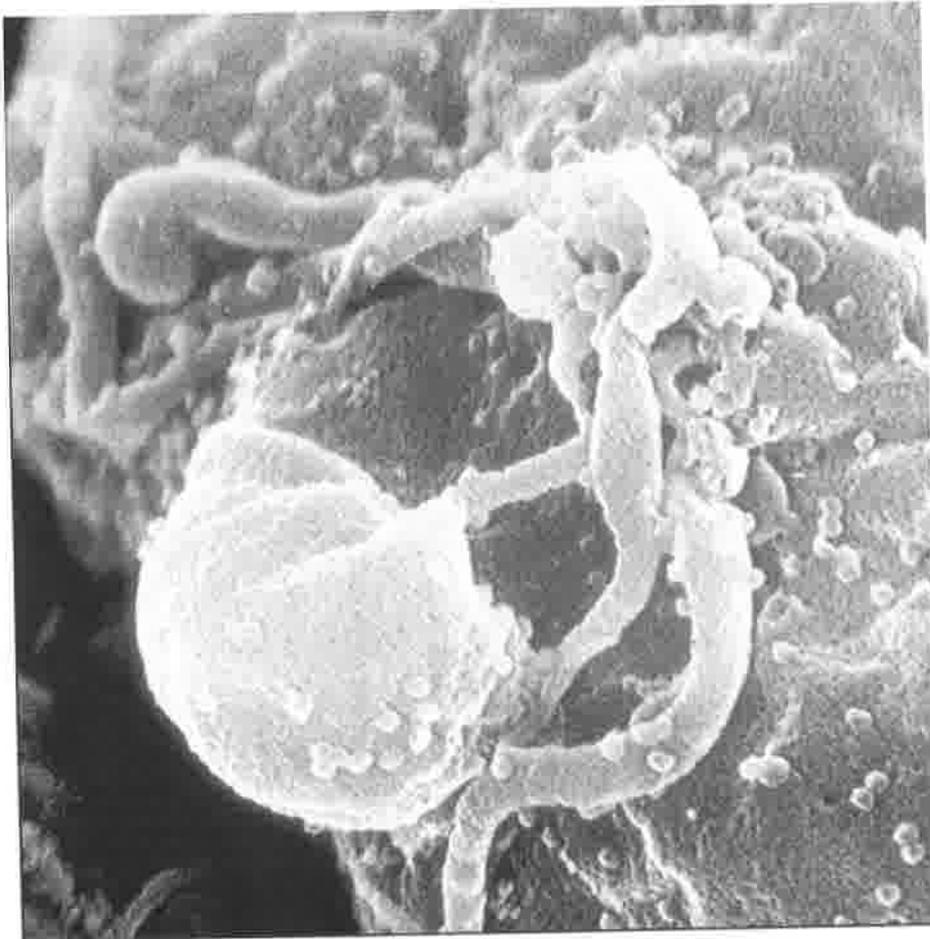
immunology became embroiled with the task of explaining how an apparently infinite number of antibodies could be produced using a finite number of lymphocyte clones (18).

Human necessities were to mother immunological inventions during the global conflicts that occurred at this time in history. Although vaccines using live attenuated organisms or bacterial filtrates had been previously used, the use of heat killed organisms (e.g. typhoid/paratyphoid A and B or TAB) became popular during the conflict. Striking prophylactic results were being recorded in the third and fourth decades of this century against diseases such as enteric fever, cholera and staphylococcal infections. By the close of the century, humanity was reaping profound benefits from vaccine development. Challenges remain with respect to diseases such as H.I.V (See Plate 2.3), malaria (See Plates 2.4, 2.5 and 2.6), enteric fevers and acute respiratory disorders (See Table 2.1). Tuberculosis also remains a major problem despite the availability of an effective vaccine. Ironically, although much is known regarding the transmission and pathogenesis of plagues such as malaria (See Plates 2.5 and 2.6), these continue to represent unresolved challenges to medicine. Pharmaceutical prophylactic treatment (e.g. with quinine) is not absolute and is at best relative (B.N.F., 1998).

Amongst other fundamental contributions was Nuttall's publication in 1904 of his paper "*Blood, Immunity and Blood Relationships*". He demonstrated that phyla, classes, orders and genera of organisms could be distinguished using serological methods. The following year, Carrel, working at the Rockefeller Institute developed a technique for rejoining severed blood vessels. This was to pave the way for organ

Plate 2.3 Human Immunodeficiency Virus Budding from a Cultured Lymphocyte

(Scanning Electron Micrograph)



Source: C.D.C., 2000.

Reproduced with permission

Note: Image shows H.I.V. 1 attached to a lymphocyte (large cell in background). This is the site for assembly and budding of free viral particles or virions (seen as small light-grey particles towards the front of the image).

Plate 2.4 Fluorochrome Staining of *Plasmodium falciparum* Malaria



Source: Caramello, 2000.

Reproduced with permission of the Editor, Atlas 2000 Project, Carlo Denegri Foundation.

Note: Image shows “cygnet-ring” form of *P.falciparum* inside erythrocytes.
The parasites are visualised using rapid fluorochrome staining using the
DAPI-PI * technique.

* 4', 6-diamidino-2-phenylindole (DAPI) and propidium iodide (PI)

Plate 2.5 Female Mosquito (Unknown Species) Taking a Blood Meal from a Human



Source: BIODIDAC, 2000.

Reproduced courtesy of University of Ottawa.

Note: There are approximately 400 species of *Anopheles*, approximately 25 of which serve as vectors for malaria (*Plasmodium spp.*) in humans. The image shows the female's gut engorged with blood.

Plate 2.6 **Anopheles Mosquito (*Palmodium spp.*)**



Source: **Curtis *et. al.*, 2000.**

Reproduced with permission of the Editor, Atlas 2000 Project, Carlo Denegri Foundation.

Note: The adult mosquito is in the characteristic position with the proboscis (biting part), the head and abdomen in a straight line. This is set at an angle of 45° with the surface on which it rests. The efficiency of Anopheles as a vector of malaria depends on their biting behaviour, fertility, survival and ability to adapt to their breeding habitats. The most efficient (*A. gambiae*) are widely distributed in tropical Africa.

transplants and by the late 1960s transplant immunobiology had been established as a multidisciplinary science.

Table 2.1: Vaccine Development - Successes and Challenges

(Figures reported in millions)

Disease	Annual Deaths (if not immunised)	Numbers Prevented	Numbers Occurring	% Prevented
Smallpox	5.00	5.00	None	100
Diphtheria	0.26	0.22	0.04	86
Pertussis	0.99	0.63	0.36	64
Measles	2.70	1.60	1.10	60
Neonatal Tetanus	1.20	0.70	0.50	58
Hepatitis B	1.20	0.40	0.80	33
Tuberculosis	3.20	0.20	3.00	6
Polio	0.64	0.55	0.09	86
Parasites e.g. malaria	2.20	None	2.20	0
H.I.V./Other STDs *	1.30	None	1.30	0
Diarrhoea etc.	3.00	None	3.30	0
Acute Respiratory Infections	3.70	None	3.70	0

* Sexually Transmitted Diseases

Source: UNICEF, 2000.

Immunologists were demonstrating one of the hallmarks of modern science, i.e. the disappearance of sectarian loyalties and the abandonment of isolationism (19). Such a phenomenon is compatible with the biomedical paradigm of disease which emerged from the Renaissance (20). Others (Bloom, 1994) have pointed to the innate reciprocity of immunology which, it is argued, provides significant opportunities for a reciprocal interaction between science and the real world (21).

Whilst knowledge of humoral immunity was advancing, it became increasingly apparent that antibodies could have harmful as well as beneficial effects. Ehrlich had first suggested the possibility of autoimmunity in 1900, referring to it as "*horror autotoxicus*" (22). Two years later Richet and Porter coined the term "anaphylaxis" to describe a type of allergy often associated with a lethal state of shock (23). In 1948 Fagraeus demonstrated that antibodies were synthesised in plasma cells, however by now research related to humoral immunity was being superseded by the rebirth of cellular immunology. Using the new technique of immunofluorescence, Coons demonstrated antigens and antibodies inside cells and at the same time (1941-42) Chase and Landsteiner discovered that delayed hypersensitivity could be transferred by cells but not serum (24). Other notable advances relating to cell mediated immunity included Gowans' discovery (in the late 1950s) that lymphocytes recirculate from blood to lymph fluid (called "lymphocyte trafficking"). This led to an understanding of the role of organised lymphoid tissue in cell mediated immunity (25). By the early 1970s the Americans (Benacerraf at Harvard and McDevitt at Stanford) were establishing the role of T lymphocytes with respect to antigen recognition (26). Another significant development included the discovery of the co-operative mechanisms between "T" and "B" lymphocytes by Claman, Chaperon and

Triplett in 1966. Described by Talmage (1994) as the period denoting the advent of molecular immunology, the 1960s and 1970s saw the separation and identification of several important molecules. These included complement components, cell receptors and interleukins. The introduction of hybridoma technology by Kohler and Milstein in 1975, and the subsequent use of monoclonal antibodies, greatly enhanced diagnostic immunology and haematology (See Figures 2.1 and 2.2). The use of such techniques later allowed King to describe the first T-cell subset in 1979 and the isolation of the T-cell receptor by Allison and Haskins in 1982-83.

(See Addendum 2.3 for a selected review of immunological developments).

These developments in immunology are indicative of a trend seen in other sectors of biomedical sciences, i.e. the replacement of *ad hoc* advances by an evolutionary theoretical sophistication – almost what might be termed a Darwinian conceptualisation of medical laboratory sciences.

Global Conflict and the Impetus for Developments in Blood Transfusion

History demonstrates that ironically medicine eventually benefits from human conflict - the development of blood transfusion science is no exception. The foundations for a rapid understanding and progress in this discipline were laid in the United States and Europe during the opening years of the 20th Century. The discoveries of Landsteiner, Levine and Wiener allowed for an expansion in the knowledge of blood groups. In 1900, Landsteiner (working at the Pathological Institute, Vienna) conducted experiments during which he mixed the red blood cells and sera of twenty-four individuals (mostly colleagues). His results led to the discovery of the A, B and O

blood groups. A year later, von Decastello and Sturli discovered the AB blood group. Despite these advances the medical world remained largely unconcerned until the needs of battle casualties in World War I provided a startling demand for blood transfusion. In 1928 Landsteiner, together with Levine, discovered the MN and P blood group antigens and also the Rhesus antigen with Wiener in 1940 (See Addendum 2.4 for details relating to the discovery of blood group systems).

Prior to 1914, direct transfusion of blood from donor to recipient had been dogged by the problem of blood clotting. The use of sodium citrate as an anticoagulant pioneered changes in the technique which substantially reduced the associated risk. This allowed one unit of blood (approximately 540 ml) to be transfused in 20 minutes (previously this had to be completed in 5-6 minutes). The advent of refrigeration and the acceptance of anticoagulants in the 1920s paved the way for storage of blood and therefore the birth of the "blood bank" (the first recorded being established in Leningrad in 1932) (American Association of Blood Banking, 2000). Within Britain the organisation of blood donor panels was originally undertaken in London by the Red Cross in 1921. The need for a separate service had become apparent by 1925 and consequently the London Blood Transfusion Service was inaugurated. This trend was replicated in other regions of Great Britain and a National Blood Transfusion Service was established.

Elsewhere the ravages of war were leading to creative inventions. Russia pioneered the use of cadaver blood for transfusion purposes. At the Sklifosovsky Institute 30,000 transfusions of blood taken from victims of sudden cardiac arrest (resulting from hypertensive heart disease, myocardial infarction and electric shock) were used

between 1930-60. The blood from individuals who have suddenly died can be recovered by venesection and flows out in the fluid state. After 20-30 minutes however it clots, but 30-90 minutes later it becomes liquid again (27). Normally 2-4 litres of blood can be obtained from the jugular veins of the corpse within 6-8 hours of death. If the blood is stored at 4°C it can be used for transfusions for a period not exceeding 25 days.

In 1910, Fleig experimented with plasmapheresis (28) in an attempt to remove toxic substances from blood. In these early experiments the donor red cells were suspended in isotonic spa water such as those from Kreuznaasch Elizabeth Quelle and Kissingen Schönbornsprudel. The procedure was significantly facilitated following the introduction of plastic transfusion equipment by Walter and Murphy in 1952.

The exchange of large volumes of plasma became possible with the introduction of cell separators. The first of these, introduced by Cohen in 1951, allowed the harvesting of particular fractions of blood, e.g. red blood cells, leucocytes, platelets and plasma. Plasma exchange has since been used successfully in a number of pathological conditions, e.g. the removal of harmful antibodies in haemolytic disease of the newborn.

The storage of blood prior to transfusion had been facilitated by the work of Rous and Turner in 1918. Working with the Allied Expeditionary Forces in France, they experimented with the use of dextrose as a nutrient for stored red cells. Following World War I, interest in the storage of blood waned until it was revived in the 1940s. The first large-scale blood bank was established at the Central Institute of

Haematology and Blood Transfusion in Moscow, where by 1937 some 6,000 transfusions had been successfully given.

The Spanish Civil War saw the first attempts to supply the transfusion needs of an army on the battlefield and during the period 1936-39 over 9,000 litres of blood were supplied from a centre in Barcelona. Further improvements to red cell preservation were made during the 1950s and 1960s and included the use of acid-citrate-dextrose, citric-phosphate-dextrose and adenine. The possibility of freezing red cells was realised in the 1970s by the use of solid carbon dioxide, dimethyl sulphoxide, glycerol and liquid nitrogen. Because of the technical advances being achieved it was becoming apparent that the use of fractionated blood products could optimise the benefits of transfusion. Consequently the advocacy of blood component therapy increased as the Century progressed.

The therapeutic value of transfused platelets had first been demonstrated by Duke in 1911, but it took 70 years and the advent of plastic filters and closed transfer systems before platelet transfusions became routinely used for the treatment of conditions such as leukaemia and haemorrhagic disorders. Such was the pace of advance that by the late 1980s the clinical management of haematological disorders was benefiting from a comprehensive range of blood products. (See Addendum 2.5 for examples of such products and their applications).

Of primary concern to blood transfusion scientists was the safety of both recipients and donors. During World War I there had been a tendency to use blood group O (the “universal donor” group). Since cross-match testing (29) was not always possible,

recipients were first challenged with small volumes of donor blood. If no untoward clinical reactions were observed, then the entire unit of blood was transfused. Between 1940-60 several refinements in cross-matching techniques were introduced (30), thus facilitating safer transfusions. Pre-transfusion protocols were further enhanced with the introduction of automated processing including grouping and antibody screens (31). The advent of computerised optical character recognition systems in 1981 represented additional safety features in relation to sample identification.

Fundamental to the development of blood transfusion science as a distinct discipline was the growing awareness that the biological applications of transfusion were largely based on immunological principles. Such a relationship was exemplified by four major advances in blood group serology. The first relates to the growing understanding of the biochemistry of erythrocyte membrane antigens through the use of lectins (32). The red cell agglutinating activity of Ricin (obtained from the castor bean) had first been described in 1888, but it was not until 1948 that Renkonen established that plant extracts had blood group specificity.

The second area of development involved the investigation of how the behaviour of blood group antibodies *in vivo* were related to their physiochemical characteristics. Immunologists were elucidating the basis of the immune response with respect to antibody class (isotype), structure, thermal amplitude and complement fixation. Such features were found to affect the ability of antibodies to cause haemolytic transfusion reactions (33).

The third advance came from the introduction of the “anti-human globulin” reaction (Coombs’ test) for the detection of red cells which had been sensitised with IgG antibody (34). This facilitated the understanding, investigation and treatment of auto-immune haemolytic anaemia, haemolytic disease of the newborn (HDN) and haemolytic transfusion reactions. The test also advanced techniques of antibody screening and cross matching.

Finally, the introduction of the blood product “Rhogam” in the late 1970s greatly reduced the incidence of HDN due to Rhesus (anti-D) antibodies (35). This represented a primary example of a practical clinical benefit in blood group serology stemming from a concept based on immunological theory. Perhaps nowhere else in medical sciences is there a better example of a biological peace dividend.

Simple Microscopy to Advanced Automation – The Study of Blood Disorders

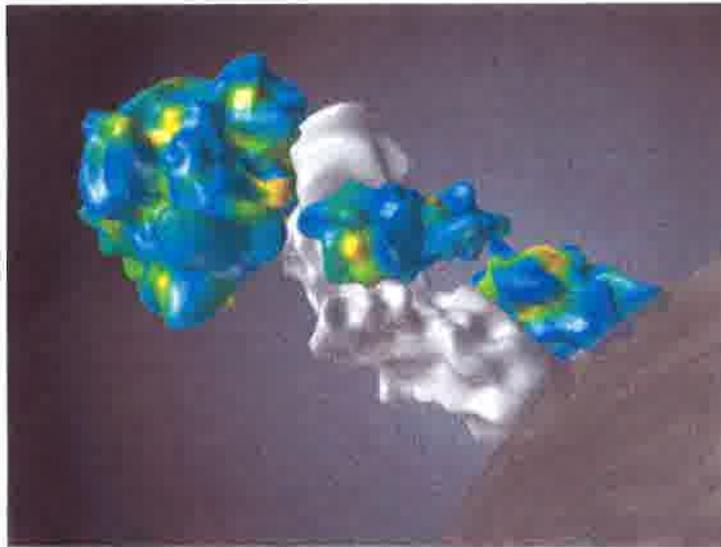
Some of the most notable achievements in haematology were coincidental with the advent of the 20th Century. Working with Haldane at Oxford, Lorraine-Smith investigated the respiratory pigments in blood. In 1900, he showed that the oxygen carrying capacity of the blood was directly related to its colour. This work later led to the introduction of Haldane’s carboxyhaemoglobin method for estimating haemoglobin. Based on a simple visual colorimetric technique, this remained the principal method of haemoglobin estimation for the next four decades. At the same time, Leishman introduced his modification of Romanowsky’s stain for the study of blood cells. Originally developed for identifying malaria and other parasites (especially intra-corpuseular forms) the incorporation of methylene blue and eosin,

supplied by the famous manufacturer Grubber & Co. at Leipzig, was to revolutionise the examination of blood cells. The first decade also saw the efforts of Price-Jones on the measurement of red cell diameters, both in health and a variety of pathological conditions. His work was of fundamental importance to the development of haematology since he showed that red cell size and shape exhibited characteristic deviations associated with different types of anaemia. While at Guy's Hospital in 1910, he published the first authoritative account of statistical variations of erythrocyte morphology in various diseases (36). These observations later led to the differential diagnosis of haematological disorders (most notably the anaemias) on the basis of erythrocyte morphology.

Progress was also being made in the study of blood coagulation. Although the original classical theory of Morawitz (1905) remains the foundation of modern concepts, he recognised only two (prothrombin and fibrinogen) of the many clotting factors necessary for blood coagulation. Techniques for investigating haemostatic mechanisms began to appear after 1935 when Quick introduced the "prothrombin time" test (37). In the following decades other proteins were discovered including Factor V by Owren in 1947, Factor VII by Aexander *et al* in 1951 (See Plate 2.7) and Factor X by Telfer *et al* in 1956.

It was in the area of automated blood cell analysis that the most significant advances were made. These were based largely on the "Coulter" principle. The original cell counter utilised electronic devices for counting different types of blood cells and represented the prototype for more advanced automated methods (38). These included instruments using the principle of continuous flow analysis as represented by

Plate 2.7 Factor VIIa Docking with Tissue Factor



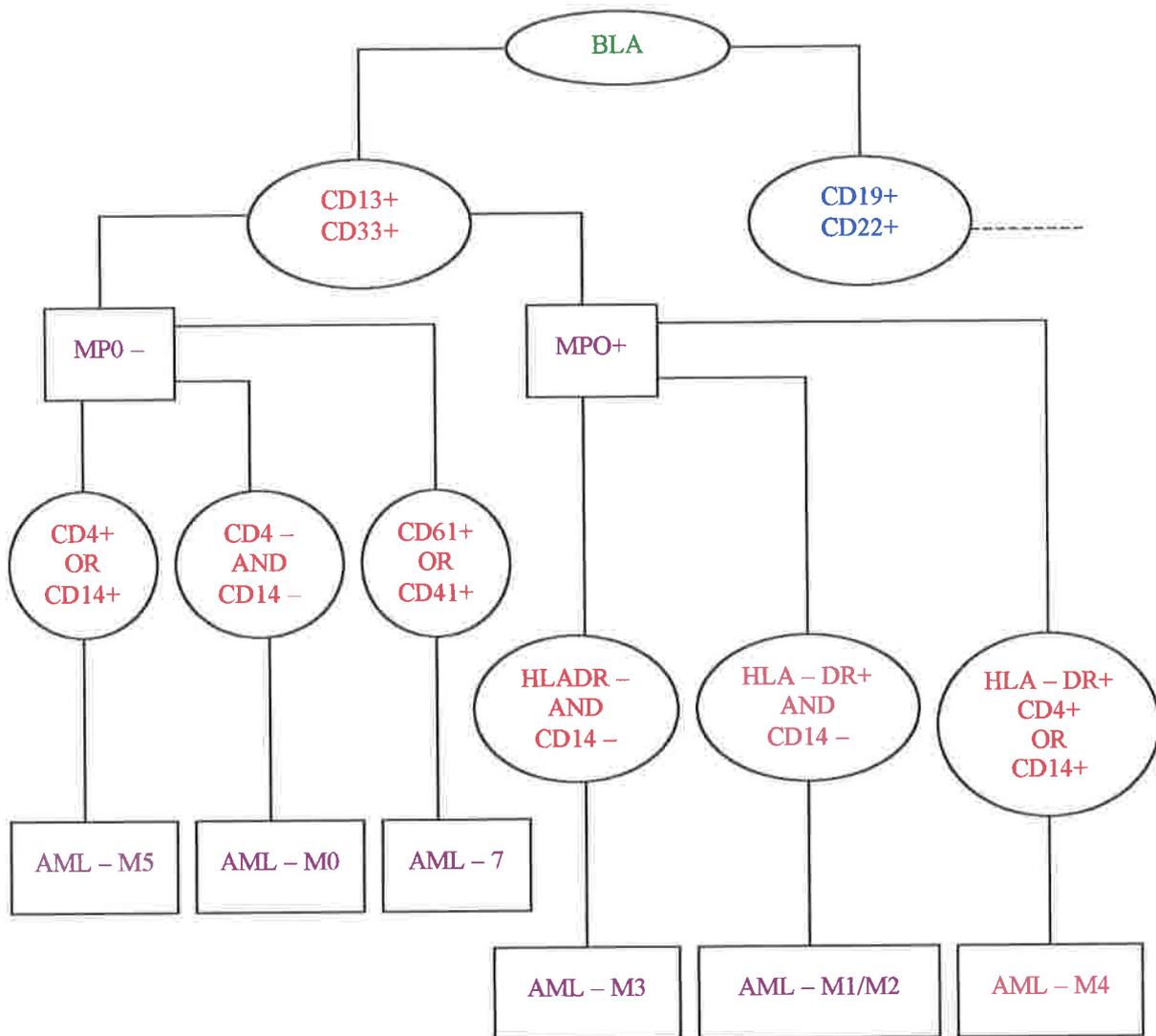
Source : **Rao and Duncan, 2000.**

Image courtesy of Arthur Olson, The Scripps Research Institute,
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Note: The image is a computational prediction of the docking sequence between soluble coagulation Factor VIIa (multicoloured) and tissue factor (white), the latter being bound to cell membranes. The sequence represents the beginning of normal secondary haemostasis. The structures of Factor VIIa were derived from related proteins and that for tissue factor determined by X-ray crystallography.

the American manufacturers Technicon Corporation (see earlier). These analysers allowed as many as eleven haematological parameters to be measured automatically and some had integrated cytochemical reactions that allowed the counting of specific types of leucocytes. Increasing sophistication in electronics and instrumentation has led to the development of advanced techniques. Perhaps the foremost amongst these is the application of fluorescence activated cell sorting (FACS analysis) (39) which has revolutionised the diagnosis of haemoproliferative disorders (See Figures 2.1 and 2.2). Using fluorescently tagged monoclonal antibodies and cell sorting, it is now possible to categorise the majority of leukaemias and lymphomas. These are conventionally classified into the French American British (F.A.B.) categories originally delineated according to cell lineage, morphological characteristics and degree of maturation/differentiation (See Addendum 2.6 (a)). This technology and its applications in diagnostic pathology reflect a disciplinary convergence of sectors such as immunology, molecular and cell biology, biochemistry and biotechnology.

Figure 2.1: Immunophenotypic Differentiation of Acute Myeloblastic Leukaemia



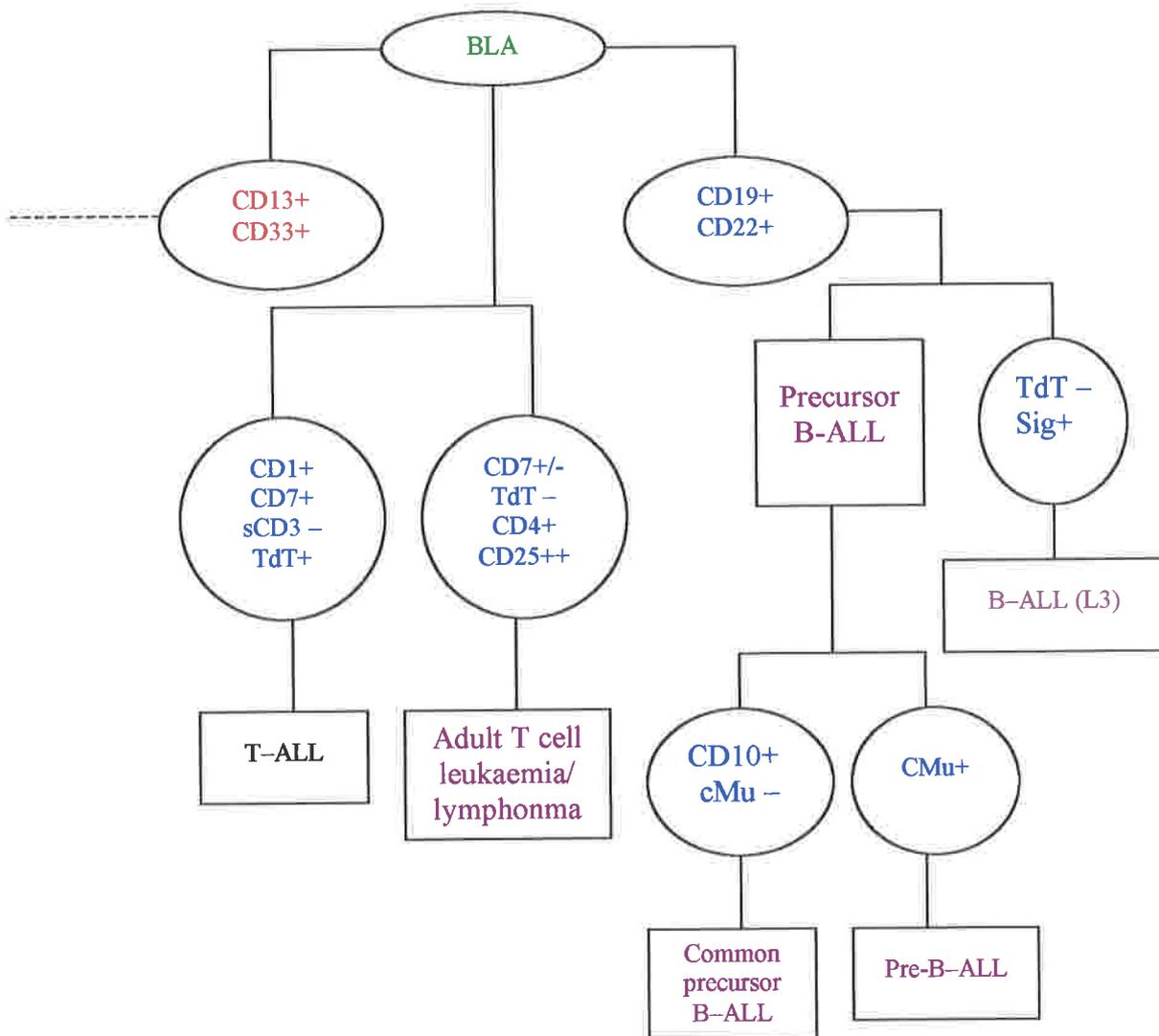
Abbreviations:-

- AML Acute Myeloblastic Leukaemia
- BLA Blast Cells
- CD Cluster of Differentiation (Myeloid) (Lymphoid)
- HLA - DR Human Leucocyte Antigen-DR
(Histocompatibility Leucocyte Antigen-DR)
- MPO Myeloperoxidase (Cytochemical Staining Reaction)

Adapted from Uthman, 1997.

See Addendum 2.6 (a) for F.A.B. Categories of Leukaemia.

Figure 2.2: Immunophenotypic Differentiation of Acute Lymphoblastic Leukaemia



Abbreviations:-

B-ALL	B cell-Acute Lymphoblastic Leukaemia
BLA	Blast Cell
CD	Cluster of Differentiation (Myeloid) (Lymphoid)
cMu	cytoplasmic mu heavy chain (ie. IgM immunoglobulin)
sig	surface immunoglobulin
T-ALL	T cell-Acute Lymphoblastic Leukaemia
TdT	terminal deoxynucleotidyltransferase

Adapted from Uthman, 1997.

See Addendum 2.6 (a) for F.A.B. Categories of Leukaemia.

Current understanding of disease processes is increasingly based on awareness of pathology at the molecular level. To some extent this exemplifies the dichotomous nature of modern science. On the one hand “*science.....[including medical science] is so specialised and fragmented that no synthesis is possible and therefore any advance for which synthesis would be required cannot now take place*”, while on the other “*if biologists and physicists could communicate only in dumbshow, there would be no molecular biology today. Sciences [are] becoming more unified, not less*” (Medawar, 1994).

The Transformation from Chemical Physiology to Clinical Chemistry

A thorough knowledge of physiological chemistry is a basic requirement for the proper understanding of medicine. The study of chemical pathology, aimed at elucidating the biochemical basis of disease, is promulgated on the premise that changes in biochemical parameters are both a reflection of, and the root causes of, pathological disorder. As an applied science, chemical pathology seeks to aid diagnosis and treatment by analysing body fluids and tissues. The emphasis on analysis is sometimes referred to as “clinical chemistry”.

Amongst the early 20th Century developments was the discovery of tryptophan (the first known essential amino-acid) by Hopkins in 1900. In 1901 Takamine and Bell concomitantly, but independently, isolated and synthesised adrenaline. At the same time there was a significant advance in the understanding of diabetes mellitus when Opie elucidated the role of the islets of Langerhans in this disorder (40). Shortly afterwards Bayliss and Starling first established the role of hormones when, in 1902,

they discovered “secretin” – a substance released by the walls of the small intestine. Another significant advance is attributed to the Russian botanist Tsvett, who in 1906 developed paper chromatography as a means of separating dyes. This was to become an important means of studying organic molecules in the 1960s. Three intrinsic elements were therefore shaping the development of chemical pathology – these were the practice of medicine, increasing knowledge of biochemical pathways and an expansion in the availability of chemical analytical techniques. Increasingly, correlations between biochemical tests and clinical manifestations were providing key information on the basic aetiology of human illness (41).

Other advances in the understanding of diabetes were achieved in the early part of the Century (42) and by 1922 Banting, Best, McLeod and Collip had successfully extracted insulin from human pancreas and used it experimentally to treat diabetes in dogs. In 1920 the English biochemist Astbury discovered that wool had different x-ray diffraction patterns when stretched – this eventually led to the use of x-ray diffraction techniques in the study of the three dimensional structures of proteins. Contemporaneously the Swede Tiselius developed electrophoresis – later to become a widely used method for separating proteins in solution. In 1932 Krebs discovered the “urea cycle”, the biochemical pathway which transforms ammonia to the waste product urea in mammals.

The foundations of clinical chemistry had been laid by Berzelius, Liebig and others in Continental Europe, while in Britain Bence-Jones had introduced a “physiological mentality” into clinical medicine during the latter half of the 19th Century. Against the prevailing tenets of classical pathology, Bence-Jones had attempted to apply the

principles of physiological chemistry (based on both diagnostics and therapeutics) to clinical practice. As a prominent physiologist he was one of the founders of chemical pathology, paving the way for quantitative clinical chemistry. Such a development can be delineated into five modern phases.

The first occurred between 1910-1920 when advances were made in methodology. Notable pioneers at the time were Bang in Sweden and Folin and Van Slyke in the U.S.A. By the 1920s, venepuncture had become routine practice, visual colorimeters were widely available and analytical methods requiring only one millilitre of blood were adopted. This led to the second phase during the 1920s when the number of analyses increased to approximately twenty, with 50% of these being in constant use. During this decade, the number of hospital laboratories performing biochemical analyses had increased ten-fold with the performance of such tests being transferred from the clinician to chemically trained staff in specialist laboratories. From 1930-1949 there was a slow but steady increase in investigative work. New methodologies included the introduction of flame photometers permitting the analysis of blood electrolytes such as sodium and potassium. Other instrumentation was also being pioneered, e.g. photoelectric colorimeters (affording greater speed and precision) and also micro-analytical techniques such as those adopted by King in Britain. These allowed a greater number of analyses to be performed on a single venous blood sample and also permitted the use of capillary blood. These developments preceded the third phase of growth – associated with a steep increase in the numbers of requests by clinicians who were becoming more scientifically minded. From 1950 the increase in demand in most large laboratories has been of the order of 10-15% per annum. More complex analytical procedures e.g. enzymic rate reaction studies, were being

introduced and analytical procedures became possible on “ultra-micro” samples of blood (0.01 microlitres). This allowed a more intensive biochemical study of paediatric and neonatal disease.

The fourth involved the introduction of automated analytical equipment using continuous flow or discrete systems (see earlier with reference to haematology analysers). This technology enabled the simultaneous measurement of approximately twenty parameters on a single plasma sample and two hundred or more samples could be processed per hour. The final phase involved the development of large computers during the 1980s. These were essentially designed to maintain sample identification, to control analytical machinery and to calculate, store and deliver the results of tests. At the same time, the first “simple to operate” machines for bedside or “near-patient” testing were being evaluated. The advent of computerised technology was eventually to lead to the establishment of multiple profiling.

Since there are relatively few chemical constituents in blood which can be measured directly, quantitative techniques using indirect means have been designed by clinical biochemists. Many of these rely on the production of coloured reaction products that can be measured using photoelectric absorbance devices, e.g. colorimeters and spectrophotometers. Using both light and ultraviolet spectroscopy it is possible to determine substances such as bilirubin, proteins, cholesterol, urea, acid phosphatase, calcium, creatinine, uric acid, glucose, albumin and lactate dehydrogenase (Rocks, 1998). Other common methods based on light measurement include turbidimetry, nephelometry and fluorimetry. Instruments using combinations of these techniques have now been developed, e.g. fluorescence polarization analysers can be used in

therapeutic drug monitoring. Other current techniques in clinical chemistry include the use of atomic absorption and emission spectrometry (e.g. to measure minerals and trace elements), high performance liquid chromatography (H.P.L.C.) (e.g. for analysing biogenic amines, vitamins, porphyrins and carbohydrates) and gas chromatography (e.g. for measuring alcohols, drugs, organic acids, steroids and bile acids). Clinical chemistry, then, has undergone a significant degree of technocratic divergence, a trend associated with a de-humanisation of diagnostic pathology.

Dry reagent chemistry techniques are also now widely used in clinical biochemistry. Emanating from the mid-1950s the first applications involved the development of reagent strips for the measurement of urinary glucose. The advent of such technology carried the advantage that comparatively untrained personnel could obtain semi-quantitative measurements in a relatively short time. This could be achieved by dipping the strip into a urine sample and following a stipulated interval – making a comparison of the colour developed with a pre-printed colour chart. More accurate quantification became possible with the development of simple photometers (glucose-meters) and in the 1970s photographic film technology was introduced into such systems. Using complex systems involving “support”, “reflective” and “analytical” layers, it is now possible to apply the techniques to measure hundreds of analytes including alanine transferase, creatinine, electrolytes (sodium and potassium) and human chorionic gonadotrophin.

The Emergence of New Disciplines

The advent of the new Century coincided with the first challenges to traditional approaches within diagnostic pathology. During 1915-1916, Twort in England and

D'Herelle in Canada discovered "bacteriophages" – a group of viruses that appeared to prey on bacteria (43). The discovery was to lead to advances in virology and bacterial genetics (See Addendum 2.2). Other achievements in virology were gained between 1940-1965 when Luria obtained the first good electronmicrograph of a bacteriophage in 1942 (See Plate 2.1) and also Enders, Webber and Robbins grew the mumps virus in chick tissue in 1948. They used penicillin to prevent bacterial contamination – a development that led to advances in tissue culture techniques. Further achievements in virology followed, including Blumberg's discovery of the "Australian antigen" in 1964 – a key stage in the development of a vaccine against Hepatitis B.

Genetics was also developing as a discipline and the necessity for a new nomenclature soon emerged. The word "gene", originally introduced by Johannsen in 1909, is derived from the term "pangen" originally coined by the Dutch researcher de Vries (44). It was the latter who, together with the German Correns and the Austrian von Seyssenegg, independently re-discovered Mendel's work on genetics in 1900. In 1902, Stanborough in New York established that chromosomes occur in pairs and were the carriers of heredity. In 1905, Chargraff suggested that the bases adenine and cytosine were paired with thymine and guanine respectively. This proved to be an important clue to the structure of DNA. McClung then established that the female karyotype contained two "X" chromosomes while males carried one "X" and one "Y" chromosome. In 1907, the American Thomas Morgan, working on the fruit fly *Drosophila melangaster*, proved that chromosomes had a distinct function in heredity and established his mutation theory – later leading to the fundamental understanding of the mechanisms of heredity.

It took almost forty years before DNA was established as the hereditary material for almost all living organisms. In 1944 this fact was established by Avery, Macleod and McCarthy. The birth of genetic engineering was to occur some eight years later when Luderberg discovered that viruses that alter bacteria could transmit genetic material from one bacterium to another. These bacterial structures (called plasmids) were shown to contain extra-chromosomal genetic material. The following year (1953) saw two further advances in genetics - Franklins and Wilkins conducted x-ray studies of DNA whilst Watson and Crick developed their famous double helix model of the same molecule.

Six years later the discipline of cytogenetics was given an impetus following the identification of specific karyotype disorders (involving sex chromosome defects) in Turner's and Klinefelter's syndromes (by Ford and Jacobs respectively). The 1970s saw further gains including the first appearance of gene technology (45), followed by additional advances in genetic research applied to both the diagnosis and treatment of inherited disorders (46).

Prior to the "molecular era" of genetics, the 1970s and 1980s had been associated with advances in chromosome banding techniques (47). These allowed karyotyping to be used in the study of cytogenetic disorders and in the elucidation of specific cytogenetic abnormalities associated with malignant conditions e.g. translocation events in leukaemia (See Addendum 2.6 (b)).

More recent developments are the use of DNA probes, which have allowed cytogeneticists to hybridise such probes to chromosomes and determine if a specific DNA sequence is present on the target chromosome. Several reviews have been carried out in relation to the historical development of human genetics and its importance in the treatment of disease (Connor and Ferguson-Smith, 1993) (Higgins, 1993) (See Addendum 2.7 for review of other developments in biotechnology and genetics).

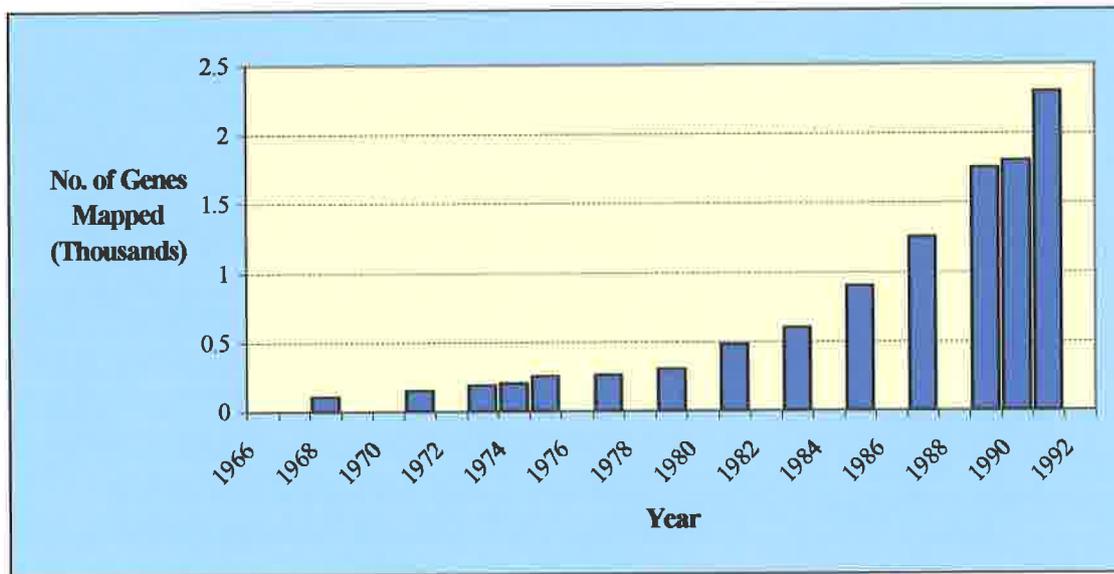
Although the genetic components inherent in many types of cancers have been studied since the 1920s, only comparatively recently has the involvement of specific genes been demonstrated at the molecular level. Elucidation of the role of oncogenes and tumour suppresser genes has yielded useful information on tumorigenesis, its treatment and control of cell cycles. Such studies once again represent the interface between disciplines such as genetics, immunology and molecular biology and have also aided the understanding of the relationship between cause and effect, i.e. how events occurring at a molecular level are eventually manifested at the macroscopic (or organ/tissue) level.

The advent of new technologies revolutionised diagnostic pathology – a prime example being the introduction of the polymerase chain reaction (P.C.R.). Developed at the Cetus Corporation in California (1985), the technique “*allows the rapid production of large amounts of a specific target DNA sequence of defined length and from as little starting material as a single molecule*” (Rapley *et al.* 1992). The protocols can be used to identify differences (e.g. genetic mutations) in both RNA and DNA. Undoubtedly the technique will have an impact in fields such as medical,

developmental and forensic pathology. Assays already developed have permitted the rapid detection of several disease markers such as tumour cell antigens, inherited gene defects and indicators of bacterial and viral infections as well as the translocations associated with leukaemia (see above and Addendum 2.6 (b)) (48).

In-situ hybridisation has also achieved significant success. Since its introduction in 1990, the technique has been extensively used to demonstrate nucleic acid sequences in cells that could represent gene component coding for particular proteins. By using *in-situ* hybridisation in combination with conventional immunophenotyping, accurate diagnosis of specific tumours can be achieved. These developments have been achieved in parallel with an impressive increase in gene mapping associated with the human genome project (See Figure 2.3). The acceleration of gene assignment has been facilitated by a combination of recombinant DNA technology, family studies and improved banding and sorting analysis. Launched in 1990, at an estimated cost of \$13 billion, the project aims at mapping and sequencing all human DNA by the year 2005 (See also Addendum 2.7).

Figure 2.3: Gene Assignments to Specific Chromosomes (1966-1992)



Adapted from McKusick, 1991.

Selection of the year 1900 as a demarcation line carries no particular significance in relation to the development of medical science. It is no more than an historical idiosyncrasy that the turn of the Century saw the confluence of two factors which brought the public to the altar of scientific medicine. The first relates to the perception of the medical benefits that could be reaped from the “fast-dye” industry, including drugs and antiseptics. The second concerns the appearance of the first effective analgesic – aspirin, the realistic replacement to alcohol and opium. European belief began to be based on the supposition that “altering nature” held the key to personal well being. Religious faith could be replaced by a financial investment in terms of intellect and money. At the same time the debate continued as to the acceptability and rationality of Darwinism – could it be possible that the higher forms of intellect were based on chance mutations of “lower” forms of life? This debate, centred around “emergent evolution”, was to pre- occupy scientists and lay-

persons for much of the 1920s and 1930s. In addition to biology, physics and chemistry were also contributing to the increased public perception of the value of science and medicine.

One of the most urgent problems facing the World at the turn of the Century was the need to increase the supply of nitrogen fertilisers. Global population was beginning to outstrip the capacity of wheat-growing countries. Chemistry provided the solution in the shape of the German firm, Harber-Bosch, at Oppau near Ludwigshafen. By 1909 the company had succeeded in combining nitrogen with hydrogen to produce synthetic ammonia – a fixed form of nitrogen which could be used as a fertiliser (and explosive!). Another German priority was the production of synthetic gasoline from coal by a process of hydrogenation, thus solving the Country's oil shortage and literally fuelling the road to war. In France, the production of medicines (and perfumes) was an important branch of the chemical industry - exports of these products amounting to approximately 53.5 million francs by 1913.

In physics, Russia, America and Germany were the first to experiment with rocketry, the government of the latter country undertaking such research for military purposes. It was nuclear physics which was to capture the public imagination. The 1930s saw a plethora of physical discoveries culminating in the control of nuclear processes. The splitting of the uranium atom was accomplished by 1938 and the eve of war coincided with the discovery of nuclear fission. Lichtheim (1974) argues that the first half of the 20th Century reaped the harvest of four centuries of modern science (49). Not the least of these was the development of electron microscopy which, together with

computerised technology, has allowed exquisite visualisation of biological subjects (See cover plate of phagocyte) (50).

Scientific achievement was now becoming more visible. By 1914 Trans-Atlantic radio messages were possible, city streets were becoming crowded with petrol-driven cars, aeroplanes were becoming more common and the educated people of Europe were appreciating telephones, anaesthetics, specialised steels and steam turbines. Science and the seeming mastery of nature, whilst boosting the confidence of civilisation was also contributing to *“an ill-defined sense of strain. This showed most obviously in the problems posed to traditional religion ... it also operated in the determinism its discoveries often encouraged, or through the relativism suggested by anthropology...science was itself a force sapping confidence in the values of objectivity and rationality so important to science itself”* (Roberts, 1996).

Despite intense research, many of the fatal diseases of humanity remain unconquered. Increasing in incidence and largely incurable, cancer, vascular and cardiac disease and chronic degenerative illnesses, all remain the most important challenges to medicine. Diagnosing medical conditions is one thing, curing them is another.

Conclusions

An inherent characteristic of diagnostic pathology is that it, like most branches of science, moves forward by incremental advances in human understanding. On the one hand this leads to an (ultimate) holistic approach to the understanding of disease. However there remains a reductionist tendency which is inherent in modern

laboratory medicine. This, it could be argued, is at best spurious. Western medicine categorises disease using artificial compartmentalisation and is based on pragmatism rather than logic. Parasitic disease may be regarded as one of the primary concerns of medical microbiologists - but the detection and identification of malaria has traditionally been ascribed to haematologists, presumably because the parasite is found within red cells during part of its life cycle. Similarly, enzymes are an important aspect of the work of clinical chemists, but the functional characteristics of blood clotting factors (serine proteases) are consigned to the haematologist. Similar idiosyncrasies are to be found in disorders such as leukaemia and lymphoma – almost identical in terms of their pathogenesis and affected tissues, and yet are the responsibility of haematologists in the first instance and cellular pathologists in the second. This demarcation is perhaps a reflection of the complexity of pathology – a requirement to categorise disease so that its aetiology, pathogenesis and manifestations can be more easily taught, learned and understood.

Such then, were the contributions that science and technology were making towards human health and well-being. The benefits were being shared by most people in Western European and elsewhere. The instinct of scientists to communicate their discoveries and inventions to others was creating a collective dividend and the beginnings of a vision of a united Europe.

The next chapter focuses on the problem of definition and the extent to which the concept of “profession” is shared between occupational groups. This is an important element of any consideration of professional harmonisation since the status of MLSOs within the hierarchy of health care scientists has always been problematic. Arguably,

many of the strategies adopted by the “professional” bodies representing this group of workers have spent much effort over the past few decades in attempting the transition from a predominantly “technical” vocation into a “scientific” métier.

Notes

1. A section of tissue is mounted on a slide and heated in an electric furnace. By slowly increasing the temperature, all the organic matter is burnt off – leaving a mineral skeleton of the tissue on the slide. This is then examined by reflected light or dark-ground illumination. The sites of mineral deposition are compared with control sections that have not been incinerated.
See Drury and Wallington, 1967.
2. In order to generate sufficient energy for cell division and continued survival, certain chemical substances have to be metabolised by cells. If radioactive elements are “labelled” and then fed or injected into an animal, the label may be incorporated into those tissues and cells which are metabolically active. Autoradiography can then be used to demonstrate the sites of radioactive isotopes in tissues by their ability to reduce the silver salts in a photographic emulsion.
See Doniach and Pelc, 1950.
3. The absorption of x-rays by histological sections can be used in order to study the structure of tissues. Information can also be gained regarding the chemical composition of tissues. Microradiography can detect mineral material (hydroxy apatite) which is responsible for virtually all the absorption of x-rays. Thin sections of bone for example can be placed in close contact with a fine grain photographic emulsion and then exposed to a beam of soft x-rays. The resultant picture will show the distribution of mineral material.
4. As soon as material for histological examination is removed from the body, it begins to decay. Consequently the primary aims of fixation can never be completely achieved. Methods now available for the preparation of tissue sections are essentially a compromise between the limitations of the technique and the need to preserve and demonstrate tissue components in a life-like manner. In practice the purposes of fixation are to:-
 - (i) Minimise autolysis (i.e. the “self-destruction” of cells by the action of intracellular enzymes). This results from the breakdown of proteins leading to the eventual liquefaction of cells. Bacterial decomposition and putrefaction are also minimised.
 - (ii) “Coagulate” the tissue in order to prevent loss of easily diffusible substances.
 - (iii) Protect the tissue from the deleterious effects associated with its processing (involving procedures such as dehydration, clearing and wax impregnation).
 - (iv) Leave the tissues in a condition which allows differential staining with dyes and other reagents.
See Cruickshank, 1911, for a review of autolysis.
5. In order to prepare tissues for sectioning they usually require impregnation with an embedding medium to provide support for microtomy (cutting). The most commonly used media are paraffin wax, ester and polyethylene waxes, cellulose nitrate and synthetic nitrates.
6. Prior to staining, ultra thin sections of tissues impregnated with wax are prepared using microtomes. Several types of instruments exist and all have separate firm supports for the knife and tissue blocks. There are also feed mechanisms designed to advance the specimen onto the cutting edge. The thickness of sections cut in this way range from a fraction of one micron (ultra-microtomy) to several hundred microns, but are usually 5-10 microns. Historically, the most common instruments have been the “Cambridge Rocking” (first introduced in the 1880s), “Rocking”, “Sliding”, “Base Sledge”, “Freezing” and “Ultra” microtomes.
See Culling *et al*, 1985, Chapter 5, pp 86-89.
7. In 1856 Perkin had discovered “mauve” which quickly made an enormous number of new dyes available. Two years earlier the German chemist von Hoffman had realised that benzene could be derived from coaltar. When benzene is treated with nitric acid it forms an oily yellow substance called nitrobenzene. If this is reduced it yields aniline – so called because it was first prepared from indigo (for which the French and Portuguese name is “anil”). Von

Hoffman developed a method for the mass manufacture of aniline and Perkin produced the aniline purple dye with its characteristic brilliant mauve colour.
See Derry and Williams, 1973.

8. Conventionally, commonly used dyes are identified by name only but the labelling of less familiar stains was confused by the existence of several synonyms. For example "Sudan IV", (a stain for lipids) has the synonyms "Oil Red IV", "Scarlet Red", "Fat Ponceau", "Scharlach R", "Fat Ponceau R or L.B" and "Ceratine Ponceau 3B". In order to avoid confusion the Society of Dyers and Colourists (based in Bradford) introduced a system of dye indexing in 1924 called the Colour Index (C.I.). With the collaboration of the American Association of Textile Chemists, a second edition of the C.I. was prepared in 1956 together with a supplement in 1963. The system uses a C.I. number as well as the name of the stain in order to identify dyes. Further progress towards standardisation of dyes was achieved in the early 1960s when the American Biological Stain Commission began testing dyes and publishing information in the journal "Biological Stains".
See Drury and Wallington, 1967, Chapter 6, pp 99-111.
9. Whenever malignant diseases are investigated, antibodies may be used to identify specific antigens on the surfaces of cancerous cells. Following the work of Koller and Millstein (see Immunology section), "monoclonal" antibodies could be used to detect highly specific molecules or "markers". These are referred to as "clusters of differentiation" (CDs) and are expressed on the surfaces of malignant cells. Identification of such markers can aid in the diagnosis and classification of malignancies such as leukaemia and lymphoma. The antibodies are usually attached to fluorescent dyes which can be detected using fluorescence microscopy.
10. The most notable of these were:-
 - (i) Invention of immunofluorescent techniques by Coons in 1940.
 - (ii) Development of the immunoperoxidase method by Nakane in 1967.
 - (iii) The diversification of immuno-enzyme technology by Avrameas in 1969 followed by Sternberger a year later.
 - (iv) The application of the immunoperoxidase method in diagnostic analysis by Taylor and Nayak in 1974.
 - (v) The promotion of the widespread use of immunocytochemical techniques in diagnostic pathology by Polak in 1986 and Mason in 1987.

See Jasani and Schmid, 1993, p 7.
11. In syphilis and other treponemal diseases, three distinct types of antibodies can be detected. One of these is known as a "reagin" (no relationship to those antibodies of the same name associated with allergy) and can be detected using the Wassermann reaction. This test utilises a cardiolipid antigen obtained from bovine heart muscle with added lecithin and cholesterol. The technique is an example of a "complement fixation test" and is based on the fact that when an antibody (i.e. reagin) combines with its corresponding antigen (i.e. the *T. pallidum*), then proteolytic enzymes belonging to the "complement" series are activated.
12. Gram stain: - "*A method of staining bacteria so that they are more easily seen by light microscopy. They can also be divided into Gram positive and Gram negative organisms based on the final staining reaction and this, together with observation of their morphology, provides valuable data for preliminary identification purposes. The method, developed by Hans Christian Gram in 1884, entails staining a fixed preparation of bacteria on a glass slide with crystal violet, followed by treatment with aqueous iodine solution. All bacteria in the preparation will then be stained blue-black. The slide is then treated with ethanol or acetone and the stain is removed from those bacteria which are Gram negative. The Gram positive bacteria retain the stain. The decolourised bacteria are counterstained with a suitable stain such as neutral red or safranin. In Gram positive bacteria the cell wall prevents elution of the crystal violet-iodine complex by the solvent, but the Gram negative cell wall is unable to do this.*"
Verbatim from Farr, 1988.

13. The Weil-Felix reaction is used for detecting rickettsial infection. The test relies on the fact that some *rickettsiae* share antigens with some serotypes of *Proteus* and involves agglutination of a strain of *Proteus vulgaris* (*Proteus* OX19) by serum of patients with typhus.
14. Found in tears, saliva, mucus and egg white, lysozyme is an enzyme that catalyses the destruction of the cell walls of many bacteria by hydrolysing mucopeptide. This renders the bacteria more susceptible to osmotic lysis (i.e. the cells burst when exposed to solutions in which the salt concentrations are slightly lowered).
See Martin, 1979.
15. Following Florey and Chain's success at isolating penicillin, scientists at the U.S. Northern Research Laboratory in Peoria, Illinois, discovered strains of penicillin mould that could be grown in large tanks.
16. First developed by Tiselius in 1937, electrophoresis is a technique for separating mixtures of charged particles (e.g. antibody protein) by using differences in their rates of migration through a stationary gel or liquid when subjected to an electric field. When treated in this way, antibody proteins (globulins) move towards the anode and separate into five bands according to their iso-electric points. These can be visualised by appropriate staining. In order of increasing migration speeds these bands are called "gamma" (γ), "beta" (β), "alpha 2" (α_2), "alpha 1" (α_1) and "albumen".
17. Immunoglobulins (antibody proteins) can be divided into five major classes. These are identified as "IgM", "IgG", "IgD", "IgE" and "IgA". Classes differ from each other in respect to their physiochemical characteristics and biological functions.
18. These were:-
 - (i) The "Instructive" or "Template" theory - proposed by Haurowitz and Pauling in 1930. According to this theory, antibodies were flexible molecules that could be moulded into the shapes (i.e. mirror images) of their corresponding antigens. The hypothesis however could not adequately explain immunological "memory".
 - (ii) The "Somatic Mutation" hypothesis – postulated by Lederberg in 1959. The model suggested that genetic modifications (point mutations) occurring in somatic cells could generate all necessary antibody conformations. The theory relied on the fact that cells producing antibodies had exceedingly high mutation rates.
 - (iii) The "Germ Line" theory – based on Ehrlich's Side-Chain theory (1898). The model proposed that all information for producing antibody diversity was genetically transmitted from one generation to the next. The argument was teleological since it assumed that all species had pre-existing "knowledge" of all antigenic molecules.

The debate relating to generation of antibody diversity was resolved by Burnet's "Clonal Selection" hypothesis (1957-59) which suggested that the antigen selected the clone of lymphocytes carrying the appropriate receptor and induced the cell to undergo clonal proliferation. The work of Tonegawa (1987) at the Basel Institute for Immunology later provided additional support for the basic principles of Burnet's hypothesis. In relation to the genetic principles for antibody synthesis Tonegawa showed that antibody diversity could be achieved via a combination of genetic mechanisms including not only somatic point mutations, but also meiotic cross-over and variable-diversity-joining (VDJ) genes (See Addendum 2.3).
19. Medawar (1996) argues that instead of scientists becoming more specialised, the opposite is the case. In the biological sciences, today's graduates have wider sympathies than their predecessors. It may be that such an holistic approach to biological sciences comes about as a matter of necessity since our understanding of molecular biology, genetics, microbiology, blood transfusion science etc. is amplified by advances in other sciences such as immunology.
20. In the 19th Century, what Medawar calls the monoclausal subtype of the medical paradigm, attempted to find one cause or one class of biomedical determinants of disease. However, contemporary science tends to think of disease in terms of multi-factorial causation. He

argues that this development follows “the growth of diverse new academic disciplines (medical psychology, psychotherapy, medical anthropology, medical sociology etc.)”.

21. Bloom suggests that basic knowledge of immunity is required for informing the understanding of tumour rejection, the amelioration of allergies and the resistance to infections. In this sense immunology complies with one of the classical paradigms of science, i.e. its unidirectionality - proceeding from the “basic” to the “applied”.
22. Referred to as “loss of tolerance”, the formation of antibodies against self-antigens was the subject of research by Owen (who studied consanguineous cattle twins). His efforts assisted Burnet (and later Medawar) to formulate theories of immunological tolerance. The concept of self-nonsel self discrimination was to become a central issue in immunology for over 40 years.
23. Synonymously known as “Type I hypersensitivity” or “antibody mediated mast cell degranulation”, this form of allergy can have localised or systemic symptoms. Such reactions are associated with “allergens” such as penicillin, the consumption of strawberries and bee-stings. Symptoms and signs include vasodilation and bronchio-constriction. These are mediated by substances such as histamine which are released from leucocytes called mast cells or basophils.
24. Also referred to as “Type IV “ or “cell mediated” hypersensitivity, this form of allergy usually takes more than twelve hours to develop. The effect can be transferred from an allergic individual to another person by infusing T lymphocytes (which have been previously sensitised to the allergen). This type of allergy forms the basis of the mantoux reaction used for testing immunity to tuberculosis.
25. Within ten years the roles of separate T and B lymphocytes as distinct functional units were being elucidated. Miller, examining the relationship between neonatal thymectomy and infection with the leukaemogenic murine retrovirus (Gross virus), discovered that absence of the thymus led to immunosuppression in new-born mice.
26. These researchers demonstrated that T cell responses were being controlled by linear peptides coded by an important set of genes called the Major Histocompatibility Complex (M.H.C.). Such immune response (Ir) genes (associated with the so-called “I” region) were known to code for a class of glycoproteins called “class II M.H.C” molecules.
27. Whenever the blood clotting process is activated, a major proteolytic process known as “fibrinolysis” is triggered. This mechanism eventually results in the dissolution or lysis of the fibrin clot originally produced to stem the flow of blood loss from an injury. The final result is that blood which clots (usually after about 11 minutes following injury) will turn into the liquid phase again. This process is called “haemostasis” – defined as the “maintenance of blood in the fluid state”.
28. The term “plamapheresis” can be translated as “taking away plasma”. First described by Abel in 1914, the technique involves removing blood from a donor and centrifuging it in order to separate the red cells from the plasma. The erythrocytes are then returned to the donor while the toxic substances in the plasma can, if necessary, be removed and discarded. Currently the technique has applications in a wide variety of disorders e.g. the procedure can be used to remove abnormal antibody proteins in a malignant disorder called multiple myeloma. The procedure is also used in blood fractionation.
29. In addition to establishing the blood groups of both donor and recipient and performing an antibody screen on the recipient’s serum, there is a requirement for a further cross-match. This entails mixing donor red cells with patient’s serum and incubating the mixture at room temperature and 37°C. Several techniques (see below) can then be used to seek evidence of incompatibility – usually signified by agglutination or haemolysis of the donor erythrocytes.
30. Although Ottenberg (working with Weil in New York in 1907) has been credited with first cross-matching donor and recipient bloods, there were other contributions to the development of such a procedure. Minot and Rous first used citrated samples on tiles, also Diamond and

Denton first used albumin in the 1940s in order to detect "incomplete" antibodies (see below). The use of proteolytic enzymes soon followed and test-tube methods were adopted in the 1950s together with centrifugation in order to augment agglutination. In 1974, Löw and Messeter introduced low ionic strength saline in order to further increase the test sensitivity. See Zeleski *et al.*, 1988.

31. The first automated systems fell into three broad categories:-
- (i) Those utilising discrete analysis in which serological analyses were conducted in individual cuvettes (e.g. the "Groupamatic" systems employed by Kontron AG).
 - (ii) Continuous flow techniques (as used by the American company Technicon).
 - (iii) Systems based on the use of microplates (introduced by Gamma Biological Inc., Houston)
- See Wagstaff, 1988.
32. These are sugar binding proteins or glycoproteins of non-immune origin and which can agglutinate red cells. First discovered in plants, they have been found in many organisms ranging from bacteria to mammals. Some lectins that react with human erythrocyte antigens have been isolated from the albumin glands of snails and from certain fungi. Some plant seeds contain more than one lectin, e.g. *Bandeiraea simplicifolia* contains three lectins. In blood group serology notable examples include the fact that the sugar N-acetylgalactosamine (found in the A1 blood group antigen) reacts with the lectin from *Dolichos biflorus*, while L-fucose (found in the H antigen) reacts with a lectin from the common gorse *Ulex europaeus*.
33. Of the antibody classes, the two most important with respect to blood group serology are probably IgM and IgG. The ability of such antibodies to activate (or "fix") complement and agglutinate cells *in vivo* results in different degrees of red cell haemolysis (destruction). Therefore the severity of transfusion reactions varies. The most severe reactions are caused by IgM antibodies of the ABO system.
34. IgG antibodies are relatively small molecules and cannot agglutinate red cells suspended in isotonic saline. They are therefore referred to as "incomplete" antibodies. In order to establish whether red cells have been coated or "sensitised" with such antibodies, the blood is "washed" prior to the addition of anti-human globulin reagent to the red cell suspension. This reagent can now agglutinate erythrocytes that have antibody protein attached to their membrane antigens. The test was introduced by the English immunologist Robert Coombs who adapted the 1908 antiglobulin concept of Moreschi. There are two versions of the technique – the "Direct" Coomb's test which is used to detect red cell sensitisation *in vivo*, and the "Indirect" test which involves incubating the patient's serum with test red cells *in vitro*. This is performed in order to detect IgG antibodies in the patient's serum.
35. HDN occurs because of blood group incompatibility between a mother and her foetus. Although antibodies from several blood group systems have been implicated, the most clinically significant cases arise from Rhesus incompatibility - most notably due to "anti-D" antibody. The "D" antigen is the most immunogenic within the Rhesus system. When a Rh (D) Negative mother becomes pregnant with a Rh (D) Positive foetus, some of the foetal cells will enter the maternal blood circulation (usually at delivery) and immunise the mother. As a result, she produced anti-D. If she subsequently becomes pregnant with a second Rh (D) Positive foetus then the maternal anti-D can cross the placental barrier and destroy or haemolyse the Rh (D) Positive foetal red cells. This is because the antibody is primarily of IgG class and therefore relatively small. Destruction of the foetal erythrocytes can lead to a spectrum of clinical signs, ranging from mild anaemia and jaundice to brain damage (kernicterus), heart failure and death. As a result of investigations carried out by Freda in 1964, it was discovered that sensitisation of a Rh (D) Negative mother could be avoided by the administration of small amounts of anti-D immunoglobulin. This has to be given by intramuscular injection within 72 hours of delivery. The anti-D coats any D-positive foetal cells in the maternal circulation and these are then consequently removed by phagocytes of the maternal immune system. As a result, the foetal red cells cannot be recognised as foreign and therefore the mother is not stimulated to produce her own anti-D.

36. Using specialised equipment, Price-Jones projected cells onto a screen at a magnitude of $\times 1000$. The peripheries of 100 cells were measured across their greatest and smallest diameters and the average distances calculated. The cell diameters were then grouped at intervals of 0.25 microns and plotted on a graph. The data obtained provided information for the means, standard deviations and coefficient of variation of normal and abnormal cells.
37. The test measures the efficiency of the latter stages of blood clotting – known as the “common pathway”. It was to prove to be one of the most important contributions to the understanding of the final phases of the haemostatic system.
38. Using a Coulter counter, the blood cell or particle suspension flows through a small orifice across which is passed an electric current. Each cell or particle gives rise to a resistance to the current. This will then result in a brief voltage pulse - the amplitude of which is proportional to the size of the particle. By pre-setting “electronic gates”, both the numbers and sizes of different types of blood cells can be measured with increased speed, accuracy, precision and reproducibility.
39. Automated blood cell analysis can be achieved using one or more of three basic techniques. The Coulter principle (see earlier) relies on electrical impedance technology whilst most of the analysers manufactured by the Technicon Corporation are based on light-scattering technology. These use dark-field optics to detect single cells passing a detection point. The cell suspension is introduced into a stream of fluid and this is known as the “sheath flow” or “hydrodynamic focusing”. The cells are drawn into a single file and a laser light source is used to illuminate the sheath. The angle of light scattering depends on the optical density of the cell and the detection of “wide angle” light is used to estimate the haemoglobin concentration of the cells. The third technique involves fluorescence activated flow cytometry. This is currently utilised in instruments such as the FACScan (Becton Dickinson) and EPICS (Coulter) analysers. Cells are stained or labelled with a fluorochrome dye and using sheath-flow technology the cells are struck by a focused laser beam. The cells then emit both scattered and fluorescent light, which can be separated according to wavelength by a series of mirrors and filters. In the more advanced analysers three fluorochrome detectors and two scatter measurements are incorporated. Fluorochromes used for marking the cells include phycoerythrin, thiazole orange and fluorescein isothio-cyanate. Monoclonal antibodies can be conjugated to the fluorochromes and are used to detect cell surface markers or antigens specific for certain cell types. The technique is now widely used in the study of diseases such as leukaemia and lymphoma (Figures 2.1 and 2.2).
- See Harmening, 1992, for an account of the applications of automated blood cell differential counters and Hall and Malia, 1991, for a succinct account of FACS analysis. Thom, 1990, provides an interesting appraisal of both electronic and optical methods of automated red cell analysis.
40. In 1869, Langerhans described unusual clusters of cells scattered throughout the pancreas. Later to be called the “islets of Langerhans” they were found to secrete the peptide hormone insulin (isolated in 1922). Two forms of diabetes mellitus are now recognised. Type I or “insulin dependent” diabetes mellitus is seen in individuals who lack insulin-secreting cells, whilst those with Type II (the majority) have “non-insulin dependent” diabetes mellitus. Usually these latter individuals have normal or slightly elevated levels of insulin but their cells have a reduced sensitivity to the hormone. The islets of Langerhans actually produce two hormones – insulin and glucagon, which interact to control blood glucose levels. See Raven and Johnson, 1990.
41. The authors argue that “most [if not all].....diseases originate from an impairment of biochemical or molecular mechanisms of the organism” and further that “biochemical processes affected by the disease and manifested through pathological lesions may be revealed by clinical biochemical tests.....normal cell function is based at several organisational levels”:-
- (i) Connected with the catalytic activity of simple or complex proteins and the activity of cells dependent on the transfer of genetic information – any fault in the genetic system leads to abnormality of enzyme or failure of enzyme synthesis.

- (ii) Related to structural complementation of the functional inter-relationships that exist between various enzyme activities – there being hundreds of enzyme catalysed biochemical reactions in the cell that do not operate independently. They are ordered into sequences of connective reactions through common intermediates. At the same time the enzyme systems are separated from each other by compartmentalisation. Sub-cellular structures are responsible for different cellular activities modulated by various reactions including energy transfer.
 - (iii) Various organs and inter-related systems. Cells are organised into more complicated multicellular tissues (a view which tends to support the arguments promulgated in Chapter 1 in relation to the reductionist nature of Western diagnostic pathology).
42. Amongst the most notable were:-
- (i) The use of picric acid as an oxidant in the estimation of blood sugar (See Pascoe and Webb, 1984).
 - (ii) The development of methods for measuring the specific gravity of urine (See Pascoe and Webb, 1985).
43. Bacteriophages can infect not only bacteria but also fungi. Having complex structures they are composed of a head containing DNA (or less commonly RNA) and a tail with a contractile sheath. The virus can attach to receptors on the surface of the host micro-organism and then infect its nucleic acid. This induces the host to manufacture more bacteriophage components. The bacterium may then be disrupted or lysed.
- See Farr, 1988.
44. In 1868 Darwin had postulated his “provisional hypothesis of pangenesis” in an attempt to provide a theory of heredity. In the hypothesis, the leading characteristics are represented by minute granules. Too small to be seen with a microscope, these multiply and are transmitted during cell division to the daughter cells. According to Darwin every cell gives off gemmules which then accumulate and are collected in buds or in the germ cells. Like Darwin, de Vries postulated that every heritable characteristic of the organism is represented by a minute entity, but to distinguish them from Darwin’s circulating gemmules he called these entities “pangenes”.
45. In 1970, Khorma, at the University of Wisconsin, achieved the first complete synthesis of a gene (analine-transfer RNA). In the same year Temin and Baltimore discovered reverse transcriptase. The discovery of this enzyme (used by retroviruses to transcribe RNA to DNA) was to prove to be another key step in the development of genetic engineering. The emergence of this new technology received a further boost in 1973 when Cohen and Boyer showed that DNA molecules could be cut with restriction enzymes, then joined together with other enzymes and reproduced by injecting them with *E. coli*.
46. Amongst the most important achievements were:-
- (i) The use of umbilical cord blood by Dafos in the diagnosis of foetal disease (1983).
 - (ii) The finding of the genetic marker for Duchenne muscular dystrophy by Davis and Williamson and that for Huntingdon’s chorea by Gusella (1983).
 - (iii) The development of the first genetically modified vaccinia virus to protect animals from Hepatitis B, herpes simplex and influenza (1984).
 - (iv) The discovery of the technique for genetic fingerprinting by Jeffreys (1984).
 - (v) The mapping of the gene markers for cystic fibrosis to chromosome 7 and that for polycystic kidney disease to chromosome 16 (1985).
 - (vi) Approval of the first genetically engineered hepatitis B vaccine by the U.S. Food and Drug Administration for use in humans (1986).
 - (vii) The discovery by Kunkel of the first defective gene in Duchenne muscular dystrophy (1986).
 - (viii) The finding of the first growth inhibition gene (in retinoblastoma) by Weinberg.
 - (ix) The successful implantation by Jaenisch of the genes for several hereditary diseases into mice, thus leading to better prospects for human treatment.

(x) The elucidation by Kim, Nishimura and Ohtsuka of the complete physical structure of a protein produced by the oncogene c-H ras. This led to clinical applications in the treatment of cancer.

47. Pioneered by Seabright – chromosome banding relies on the fact that areas of genetic material (called heterochromatin) on chromosomes are relatively resistant to proteolytic digestion by enzymes such as trypsin. Following treatment, the chromosomes are stained and the heterochromatin shows as dark bands. These are characteristic for each pair of chromosomes – an attribute that can be used in the counting and identification of chromosomes. This latter procedure is known as “karyotyping”.

48. Applications of P.C.R. include :-

<u>Genetic Disorder</u>	<u>Gene Studied</u>
Cystic fibrosis	Regulator Protein CFTR*
Muscular dystrophy	Dystrophin
Huntingdon’s disease	Huntingdon Gene Locus
Sickle cell anaemia	β Globin Gene
Thalassaemias	α and β Globin Genes

*Cystic fibrosis trans-membrane conductance regulator.

In addition, several infectious agents can also be studied. These include viruses (cytomegalovirus, Epstein Barr virus, human immunodeficiency virus and human papilloma virus), bacteria (*salmonella*, *klebsiella*, *legionella*, *pseudomonas*) and fungi (yeast, *Pneumocystis carinii*).

49. In 1897, Thomson identified the first structural component of the atom (the electron), and shortly afterwards the proton was discovered. Rutherford in 1911 demonstrated that alpha rays, emitted during radioactive disintegration, were positively charged helium atoms. Two years later, Soddy discovered isotopes and in 1919 Rutherford succeeded in obtaining hydrogen by using alpha particles to bombard certain light elements. These discoveries were eventually to lead to the atomic pile, the cyclotron and to Chadwick’s discovery of the neutron in 1932.

See Lichteim, 1974.

50. During the first quarter of the 20th Century, fundamental physical research had suggested that electrons (i.e. cathode rays) could, in some way, be utilised to increase the resolution of microscopes. In the 1920s the French physicist de Broglie suggested that electron beams could be utilised as a form of wave motion and in 1926 the study of electron optics was initiated when it was demonstrated that electrostatic or magnetic fields could be used as lenses for charged particles or electrons. In 1935, the first commercial electron microscope was constructed in England and by the end of the Century these were capable of resolutions of less than 0.2 nanometres.

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CHAPTER 3

Medical Laboratory Sciences – The Problem of Definition

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Medical Laboratory Sciences – The problem of Definition

“There are men and classes of men that stand alone above the common herd: the soldier, the sailor and the shepherd not infrequently; the artist rarely; rarer still, the clergyman; the physician almost as a rule. He is the flower (such as it is) of our civilisation”.

Robert Louis Stevenson
Underwood’s Foreword, 1887.

Source: Caplan *et al*, 1981.

Introduction

In assessing the professional harmonisation of any vocational group, there is an explicit assumption that the cohort in question is a discreet, easily identifiable cluster of workers. This is not necessarily the case with respect to medical laboratory workers in Europe. Health care scientists represent a heterogeneous category and include a wide range of personnel. Throughout Europe there are differences in qualifications, responsibilities, levels of education, employment rights, terminology (e.g. protected titles) and licensure. In addition there is confusion regarding the inclusion of such disparate groups within the heading “profession”. This chapter explores the perception of UK based practitioners with respect to this aspect, and a comparison is made with similar occupational categories.

The Emergence of a New Group of Scientific Workers

Discoveries in diagnostic pathology, the demands of global conflicts and the establishment of health services fuelled an increased call for laboratory services in the 1940s. The advent of microscopy had allowed investigators to examine tissues, thus the pioneers of pathological anatomy had inadvertently laid the foundations of cell biology. Increased understanding of nutrition, digestion and respiration – brought

about by developments in organic chemistry, also paved the way for new specialities such as endocrinology. By the 1960s, genetics, molecular biology and other disciplines were beginning to have an impact.

The earlier scientific medicine of the 19th Century had made greater contributions to knowledge than to health. Not until the advent of scientific drugs, antibiotics and anaesthetics in the 20th Century did the first significant breakthroughs in curative medicine occur. Social, economic and political changes stemming from the 19th Century “age of revolutions” had placed increasing demands on medicine. In Britain both the natural and human environments had been transformed through industrialisation and technical innovations such as the printing-press, steam engine and the “iron-horse”. These inventions were followed by the advent of electricity, the motor car and powered flight. Demographic changes associated with industrial boomtowns in Europe and America were leading to population growth. Because of acute industrial competitiveness, opportunities for work and wealth went hand in glove with poverty, disease and high mortality. Appeals from the bloody battlefields of Europe and elsewhere added to the pressures on the practitioners of medicine, which itself was undergoing a process of transformation (1).

Amongst the most important European centres of medical reform was Paris. Novel concepts of disease and research practices had been introduced in the 1860s. Characterised by scientific observation coupled with pathological anatomy, vast new teaching centres based within Parisian hospitals had promulgated the concept of the corpse as the new textbook of medicine. Autopsies were increasingly being used to corroborate diagnoses made at the bedside. The patterns of pathology were becoming

fashionable paradigms amongst both students and elite practitioners. From the end of the Napoleonic Wars, the city became a magnet for medical students from Europe and North America. Here they were encouraged to learn medicine through dissection and as a result medical education universally became more systematic and scientific (2). Other major seats of learning such as Vienna, Edinburgh and London were also embracing the “new medicine”.

In London the *1815 Apothecaries Act* had specified that all medical practitioners must possess a license to practice (3). Increasingly the hospital (a traditional focus of medical discovery) was becoming supplanted by the laboratory as the seat of learning. The concept of controlled scientific investigation was taking hold, and as a result of technical improvements the focal point for pathological advancement moved in the direction of German laboratories. These were exemplified by Liebig’s Institute of Chemistry at Giessen where an emphasis was placed on the study of organisms in terms of physico-chemical systems (4).

In Bonn and Berlin, Müller encouraged the systematising of laboratory inquiry whilst his protégé Ludwig continued the argument that physiological science must be quantitative and analytical. The latter’s work at Marburg, Zurich, Vienna and Leipzig championed positivist materialistic science. Romanticism and vitalism he argued no longer had a place in the study of physiological medicine. By the 1890s instruments such as the stethoscope, thermometer, sphygmomanometer and spirometer had established the phase of “low-technology” scientific testing. Measuring and counting the components of blood were becoming recognised as having diagnostic value. The laboratory was seen to have a role in both diagnostic medicine and basic research.

Thus were born the forerunners of today's pathology departments – clinical laboratories became the vehicles by which physiological measurements could be applied to both the diagnosis and treatment of disease. Increasingly, ward laboratories were becoming established, technological instrumentation was becoming more complex and by the turn of the Century, the first medical laboratory technicians were being employed within the Western European countries.

To some extent, Northern America had been setting the pace of laboratory expansion particularly within the context of public health initiatives with a bacteriological approach destined to spearhead the control of communicable diseases in most developed countries (5). Developments in Europe tended to be slower. The overwhelming majority of those engaged in pathological sciences held medical full-time posts in pathology. These were often seen as stepping-stones to more prestigious positions in medicine and surgery.

In Britain, laboratories were not numerous towards the close of the 19th Century and at this time the majority were attached to the larger university hospitals. Unlike America most towns lacked laboratory facilities, but from 1890 onwards concern for public health began to grow. Laboratories now began to be established under the direction of Medical Officers of Health. With them came the need for assistants with the necessary technical skills. The first recorded example of an employed assistant in Britain was in April, 1865, at St. Thomas' Hospital, London, at which Jenner worked. At this time the laboratory assistants were self-taught and often used relatively crude techniques, e.g. histological sections were shaved off using hand-held knives and

there were no solid bacteriological culture media. All microscopic observations on tissues had to be hand drawn.

In Britain the first organised classes for laboratory assistants took place at the University of Edinburgh in 1877, but there was little encouragement given to scientific research or teaching. The duties of assistants in many of the early laboratories were largely menial, many of the recruits were unskilled and there was little opportunity for personal advancement with no Trade Union representation. As increasingly higher standards and more skills were required of staff, the situation became more difficult. It became apparent that an organisation was required that could help to improve standards and conditions of employment.

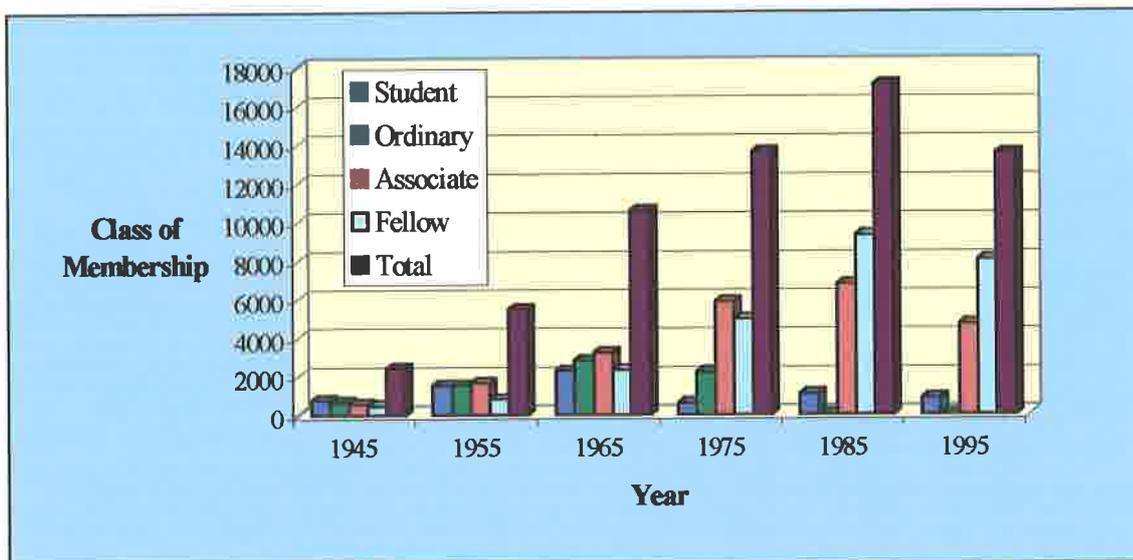
In 1896, John McLean at University College, Birmingham made the first (unsuccessful) attempt to form an organisation of all assistants in pathology laboratories. It was not until 1912 that Albert Norman, working at the Department of Obstetrics and Gynaecology in Liverpool, established the Pathological and Bacteriological Assistants Association (PBLAA). Operating closely with the Pathological Association of Great Britain and Ireland, the PBLAA's objectives were to form a means of communication amongst the assistants, to supply information regarding appointments and to assist in the general advancement of its members.

A new "professional" group was emerging – one which was to witness numerous developmental changes, undergo a profound expansion in later years (See Figures 3.1 and 3.2), participate in political conflicts and experience a continued struggle for professional recognition. Such tensions were exacerbated because of two

contributory factors. These related firstly to the fact that the science being practised was trans-disciplinary and secondly to the dichotomy between professionalism and vocationalism.

Figure 3.1 Institute of Biomedical Science Membership Grades (I.B.M.S.) (1945-1995)

(Ten Year Increments)



Note:- The grade of “Ordinary Member” was abolished in 1979 and individuals transferred to “Student” or “Associate” grades dependent on their qualifications.

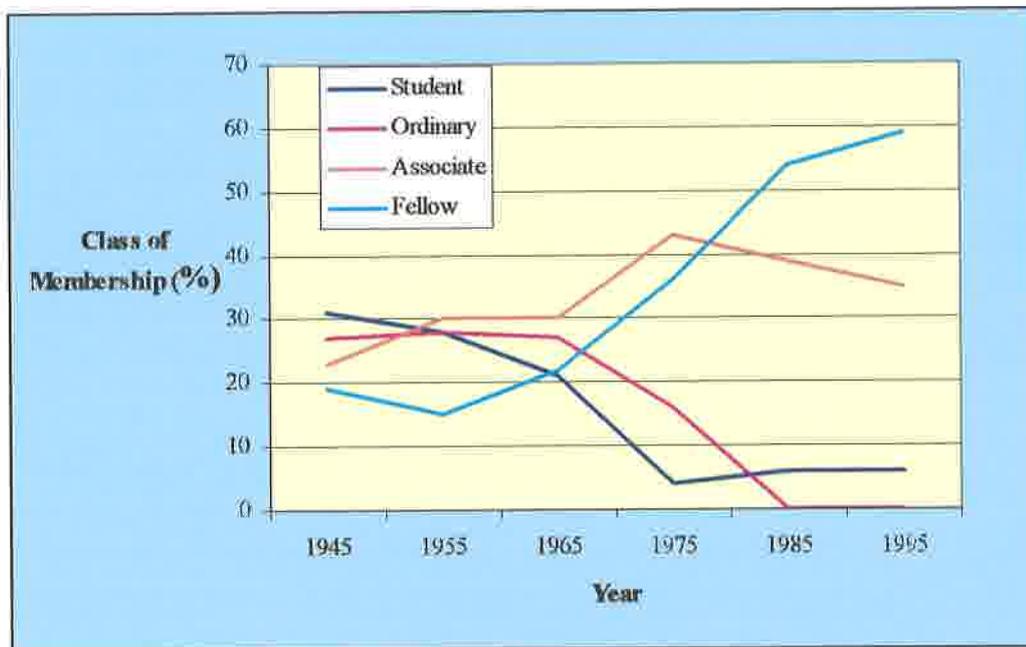
(The year 1989 saw the first decrease in total membership. This occurred at a time when the advent of “black-box” technology and increasing automation were changing the roles of MLSOs. There was also a drive for increased cost-effectiveness against a background of expanding demand for laboratory tests. Paradoxically the decrease occurred despite attempts by the I.B.M.S. to open membership to graduates in physics, chemistry and other scientific subjects

Source:- IBMS Annual Reports 1945-1997 (See Bibliography).

IBMS Central Office, Coldbath Square, London.

See also Farr, 1982, Chapter 15, p 167.

Figure 3.2 Membership Grades of I.B.M.S as Percentage Total (1945-1995)



Source :- IBMS Reports 1945-1997 (See Bibliography).

As with any other branch of science, medicine (including pathology) requires a systematic approach in order to reach a level of understanding. As mentioned earlier (See Chapter 2) medical researchers tend to set (sometimes) artificial boundaries to a given problem. Some would argue that such an approach can be represented by two distinct paradigms (Ratcliffe, 1993).

Reductionism and universality form the basis of the “analytic” or “Newtonian” paradigm in which an emphasis is placed on objectivity and analysis. Based on the assumption that the most effective way to generalise is from the parts to the whole, reductionism suggests that the comprehension of natural laws (i.e. those which govern the Universe and human behaviour) can best be achieved by understanding the fundamental building blocks of Nature. There is a conscious attempt to dismantle

problems into smaller “sub-problems” and thus reductionism is complemented by analysis. By treating each component as independent entities they become more manageable and if each is independently solved, the whole problem can be solved. The relationship of the parts to the whole (or indeed to other parts) is irrelevant

The “integrative” paradigm is based on the doctrines of relativity, value-critical subjectivity and expansionism. The doctrine of relativity maintains that there are no universal laws or truths – but only context dependent processes. This implies some semblance to reductionism in that an attempt is made systematically to connect problems with each other in order to better understand their relationship. Value-critical subjectivity suggests that all human practice, including that of science is “normative and value-laden”. Neither the problem under study or the applied methodology is independent of the researcher’s values. Expansionism holds that a better understanding of the problem is best achieved by conceptualising it as an interdependent part of a larger problem and is best explained in terms of its functional role in that larger system.

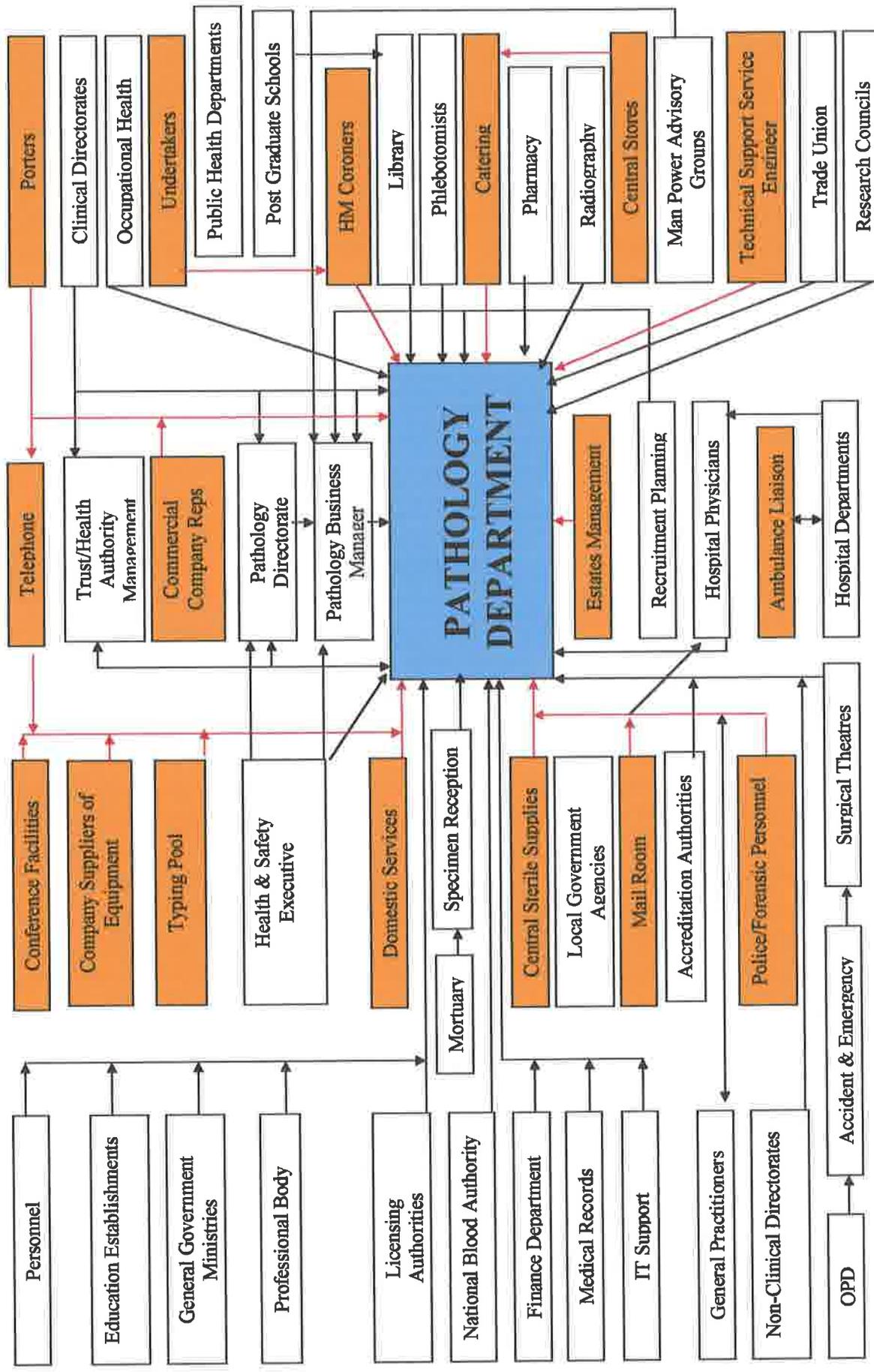
There is therefore within the study of medicine, a conflict between these paradigms, i.e. the tendency to reduce disease processes to their simplest discrete boundaries in order to better understand the mechanisms, but also the requirement to adopt a more holistic approach on the other. After all, disease is not simplistic with regard to cause, mechanism or effect. Such inherent conflict has influenced the evolution and practice of medical laboratory sciences and has been instrumental in shaping the organisational context of contemporary pathology departments.

Problems of Definition

Medical practitioners have a history of conflict with allied occupations, one area being the issue of “profession”. The question as to whether today’s biomedical scientists are members of a profession is complex, not least because they form a disparate group. The term “profession” may be variously defined (6) (7) (8) and used synonymously with other designations (9). With respect to those currently employed as Medical Laboratory Scientific Officers (MLSOs) in Health Service laboratories, the debate continues as to whether, as a group, their role and responsibilities reflect those criteria which characterise a profession in the traditional sense or whether labels such as “occupation” (10) or “vocation” (11) (12) (13) are more appropriate.

Since the emergence of semi-specialised diagnostic services at the start of the 19th Century, pathology departments have evolved into complex organisations within the hospital setting (See Figure 3.3). They now provide a comprehensive range of services for patients and other users concerned with the delivery of health care.

Figure 3.3 Organogram Showing the Inter-relationship Between Pathology Departments and other Agencies (Typical District Hospital in the U.K.)



The Issue of Profession

An assessment of whether MLSOs represent members of a profession requires consideration of both the criteria that characterise a profession and the occupational activities of this particular group. Freidson (1970) argues that professions have two “core” features from which other frequently cited characteristics are “derived”.

(Note: For the purposes of analysis (see later), each characteristic has been allocated a reference number).

The core characteristics are:-

- (a) a prolonged specialised training in a body of abstract knowledge (C1).
- (b) a collectivity or service orientation (C2).

Both are seen as fundamental criteria in that they form the basis of professional autonomy. Amongst the derived characteristics are several that refer to autonomy.

These include:-

- (c) the profession determines its own standards of education and training (D3).
- (d) most of the legislation concerned with the profession is designed and influenced by that profession (D4).
- (e) those that practice the profession are relatively free of lay evaluation and control (D5).
- (f) both licensing and admission boards are formed from members of the profession (D6).
- (g) the practice of the profession is usually recognised legally by some form of licensure (D7).

In addition other non-derived but equally fundamental criteria would include the following:-

- (h) compliance with a code of conduct expressly designed for that particular profession (ND8).
- (i) the practice of specific areas of expertise not available to members of the general public who at the same time recognise the value and significance of such work (ND9).
- (j) the attainment of certain minimum qualification criteria necessary for entry into that particular profession (ND10).
- (k) self-governance in respect that all aspects of conduct, practice, ethics and qualifications are controlled by the practitioners of that profession (ND11).
- (l) the provision of certain minimum standards of service as expected by society, government and individual members of the public (ND 12).

Also, peculiar to the “para-medical” professions (i.e. those “allied to medicine”):-

- (m) the subjection during their historical development to a common process, i.e. the re-formalising of a new order in the medical division of labour (Larkin, 1983).

Freidson (1970) maintains that a major occupational (professional?) problem of groups such as MLSOs stems from their “paramedical” status. This obliges them to work under the direction of clinically qualified practitioners. Only via a relationship with the physician’s work can the activities of such groups be given a degree of legitimacy. Historically, the formal organisation of the division of labour within medicine is such that the physician has the primary, and sometimes the only authority and licence to perform or order diagnostic tests, drugs and therapeutic procedures. However given the increasing complexity and proliferation of paramedical technologies, this traditional model is being challenged more frequently. Structural

distinctions have led to a pyramidal organisational hierarchy in health care groups. Within this complex division of labour, paramedical occupations hold a subordinate position. To many, this is unpalatable – a fact which leads to the adoption of certain strategies on the part of groups (including MLSOs) seeking professional status. Such approaches have involved attempts to create institutions similar to those already possessing professional standing and the development of formal standard curricula for training (preferably within an university). Other strategies include the creation of the abstract theory used in the teaching of new recruits and the establishment of a code of ethics. Such efforts are often pursued alongside attempts to gain the support of government, the public and other interested parties for the establishment of licensing and registration. These occupations (which are specifically and generically organised around the profession of medicine) may therefore be referred to more appropriately as “para-professional occupations”. Since the groups fall under the control of physicians, the occupations may also be termed “para”. Organised around diagnosis, treatment and healing, these occupations may, in some respects, be distinguished from established professions by a relative lack of authority, autonomy and prestige.

An additional stratagem employed by para-medical occupations in their quest for the status of “profession” is their claim to “professionalism” (14) (15). The collection of attributes defining such a characteristic, e.g. the commitment to a career, an emphasis on public service, a spirit of ethicality and so on, can only be measured with a degree of subjectivity. The structural differences between medicine and the paramedical occupations are, however, more definite and absolute. It is the relationship between one occupation and another within a social structure that establishes the status of a profession. The question as to whether “professionalism” does or does not exist within a given occupation is a separate issue and one that can only be assessed by

studying the individual members of that occupation. The crucial distinction between a profession and other occupations is that of autonomy – a legitimate control over work. Self-regulation granted by the state and society is the outcome of interaction between economic and political powers. Autonomy is the true criterion of professional status – a special privilege of freedom from the control of outsiders (16).

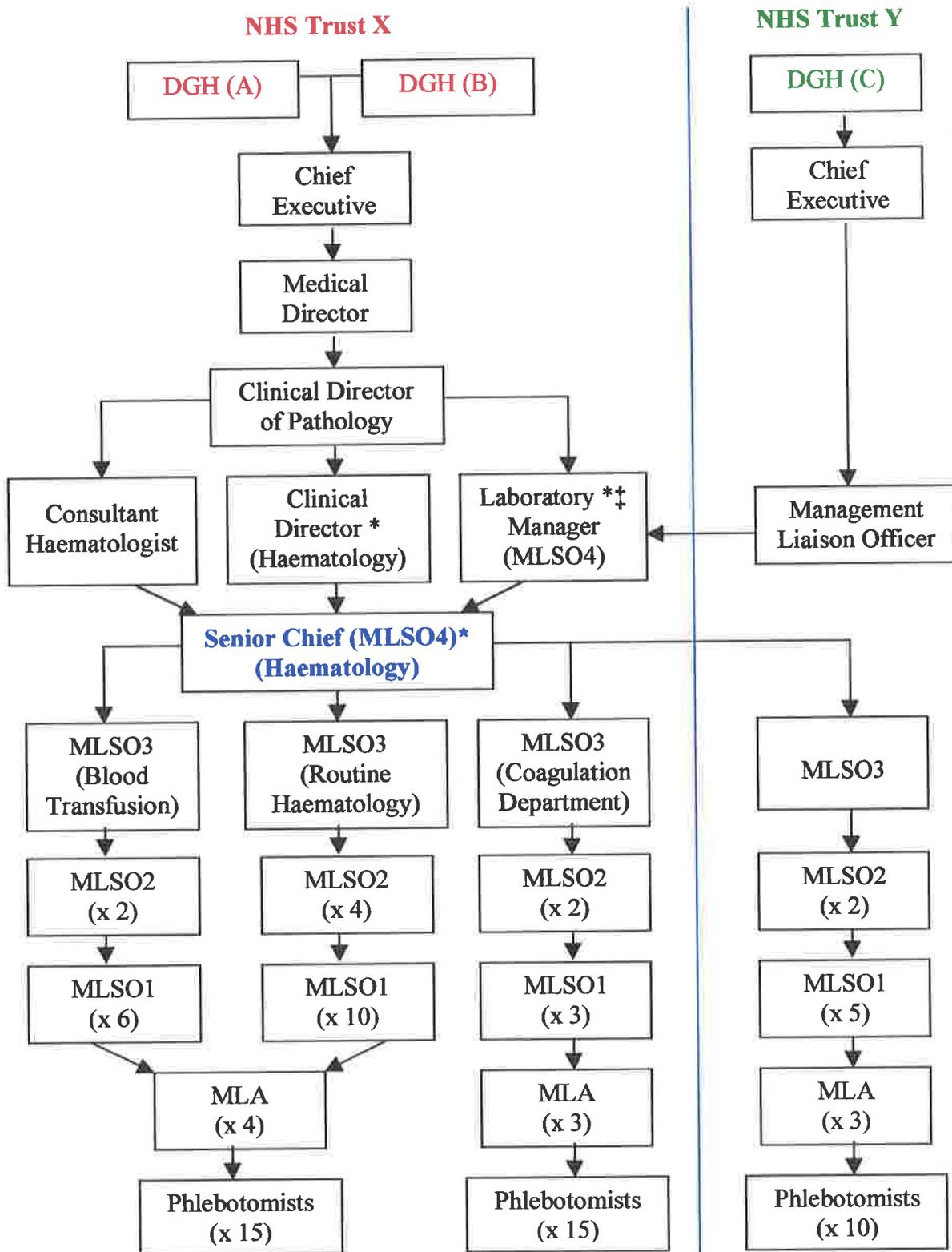
In an attempt to assess the degree of autonomy associated with the work of MLSOs, an analysis of the relevant job descriptions, career structures, service provision and responsibilities is required. Addendum 3.1 shows details of job descriptions for all grades of MLSOs within a typical Haematology department. Analysis shows that the duties performed by MLA grades are generally mechanistic in nature – many of the tasks being routine, prescribed by Standard Operating Procedures (SOPs) and requiring little expertise. Entry qualifications to this grade are below graduate level. With respect to competency, assessment is carried out either by the MLSO3 or Business Manager, however the declaration of proficiency has to be signed by the Pathologist – reflecting a lack of autonomy on the part of senior MLSO grades. Entry into Basic Grade posts requires an appropriate degree and while some of the duties (e.g. “cleaning”) are menial, others (e.g. “supervising MLAs”) carry greater responsibility. Recruits into this grade are required to show commitment to Continuous Professional Development (CPD), e.g. “education towards attainment of Fellowship of the Institute of Biomedical Science” (FIBMS). There is also a degree of interpretative work with a requirement for problem-solving skills (e.g. interpretation of “flagging” systems) together with some expertise (e.g. “performing haemoglobin electrophoresis”).

More senior grades such as MLSO2 are associated with a requirement for management skills. Duties include supervision, work planning, training and competency assessments, critical evaluation of new techniques and provision of “back-up” serology reference services. Such posts also require the possession of FIBMS qualifications or an appropriate higher degree, e.g. a MSc in Biomedical Sciences. Responsibility and accountability are to MLSO3 grades while the latter are in turn responsible to the **Medical Head of Department for Scientific Services** and are accountable to the **MLSO4 for technical work**. This is somewhat paradoxical since Senior Chief MLSO posts are increasingly held by PhD holders.

MLSO3 staff (or Chief Biomedical Scientists) have a supervisory role and are responsible for allocation of scientific work, together with the “establishment and maintenance of education and training programmes”. It may be argued that this reflects a greater degree of autonomy - reflected by responsibilities such as “the facilitation of operational policies” and to “effectively manage”. Such freedom is counterbalanced by the fact that even at this level of supervision, they are effectively answerable to other Professions Allied to Medicine (PAMs), e.g. Nurse Practitioners (See Addendum 3.1, (E), item “s”). The organisational relationship between the most senior grade of MLSO (Senior Chief) to other managerial staff within Pathology is illustrated in Figure 3.4. Analysis of the relevant job description (Addendum 3.1, (F)) indicates that their roles and responsibilities reflect some degree of autonomy. These include participation in business planning on a corporate basis, pursuance of research and development, responsibility for financial performance, implementation of Intellectual Property Rights, planning of education and training, and operational management etc. Autonomy is undermined by the fact that he/she is accountable to

the Consultant Haematologist and also to the Business Manager with respect to administrative issues. Figure 3.4 further illustrates the weakness of the Senior Chief MLSO in terms of organisational hierarchy in that the position is relatively subservient.

Figure 3.4 Regional Staffing Structure (Haematology)



Note:-

DGH = District General Hospital

(n) = Full Time Equivalent Members of Staff

* = Members of Laboratory Executive Committee

‡ = Appointment usually associated with additional discretionary salary points

Task Related Autonomy

In order to further evaluate the degree of autonomy associated with the work of MLSOs, an inventory of roles and responsibilities was identified by the author. Six senior members of a Haematology department (two Senior Chief and four Chief MLSOs) were asked to independently ascribe a grade of “low”, “intermediate”, “moderate” or “high” autonomy to each of the twenty-four tasks (See Table 3.1 for ranked results). These grades were originally recorded as a numerical score ranging from 1-4 respectively. The results obtained are based on the median value of each of the six scores. The percentage time spent on each task is indicated in brackets.

For the purpose of this exercise the term “autonomy” is defined as “the degree to which a task is performed to completion by departmental MLSO staff without recourse to members of another profession”.

Table 3.1 Task Profile of MLSO Staff - Typical Haematology Department in the UK

Task Number	Description
Low Autonomy (Score = 1)	
1	Delivery of a full diagnostic service including clinical reports from consultant Haematologists, e.g. bone-marrow and peripheral blood smears (10).
2	Advising on the clinical interpretation of results such as coagulation screens on patients with suspected haemorrhagic disorders (1).
3	Provision of mortuary and post-mortem services including pathological reports on the cause of death and also liaison with the police and coroner's office (0.5).
Intermediate Autonomy (Score = 2)	
4	Delivery of treatment and/or therapeutic services as in the monitoring and control of parameters relating to bone-marrow transplants. These may include the assessment of relapse in patients with leukaemia and can involve the identification of malignant cells in bone-marrow aspirates as an indication of relapse (1).
5	Problem solving such as the blood grouping tests required in cases of disputed paternity (5).
Moderate Autonomy (Score = 3)	
6	Provision of an "analytical results only" service where the laboratory simply feeds back data to the client (e.g. hospital clinician, general practitioner, research department or a commercial company) (38).
7	Storage and provision of blood products used in the treatment of disorders such as haemophilia and other conditions necessitating large volume blood transfusions (9).
8	The organisation of specialist (clinics e.g. outpatient coagulation sessions) where blood tests are performed in order to monitor the affect of warfarin therapy in patients with thrombo-embolic conditions (9).
9	Provision of phlebotomy services involving teams of personnel who take blood specimens requested by physicians and nurse practitioners. These include out-patient clinics as well as daily "ward-rounds" (5).
10	Providing an input into and preparation of hospital-wide policies, e.g. systems for the protection of blood transfusion recipients (1).
11	The design of health education services through publications, seminars and open-days with specific reference to the role of pathology services in the context of health care provision (1).
12	The active encouragement of Research and Development (R&D) programmes (1).

Task Number	Description
13	The monitoring of “near-patient” testing including the scrutiny of equipment purchase, maintenance of quality control/assurance and staff training (0.5).
14	The selection and provision of appropriate sample containers best suited for specific tests. This may include offering advice on sample volumes, the use of appropriate anti-coagulants and storage conditions (1).
15	Offering advice regarding transport, postage and labelling of hazardous specimens (0.5).
16	Development of communication systems for test requests and results, e.g. postal, transport, fax, telephone and computer lines between the laboratory, peripheral departments, health centres and hospital wards (1).
17	Provision of data processing services to assist communication systems and to include reformatting of reports, design and production of report forms (1).
18	Participation in internal quality control and external quality assurance schemes (3.5).
19	Assessment of new technology (e.g. the evaluation of auto-analysers) either for internal purposes or at the request of commercial companies as part of pre-marketing assessments (3).
20	Development of new techniques and diagnostic services (2).
21	Participation in hospital-wide committees and working groups, e.g. health and Safety Committees, Marketing groups etc. (1).
22	Provision of in-house training for staff and visiting students together with involvement in CPD programmes and education/training schemes for users of pathology services (3).
High Autonomy (Score = 4)	
23	Providing information to managers with respect to work-load statistics e.g. data used in man-power planning, human resource management, financial planning etc. (1).
24	Provision of inputs into the local community, e.g. talks to local groups, work placements, liaison with local schools and colleges, attendance at careers evenings etc. (1).

Figure 3.5 shows the relative distribution of these tasks in relation to departmental workload. They are ranked according to degree of autonomy.

Figure 3.5 Task Distribution by Percentage Workload and Degree of Autonomy

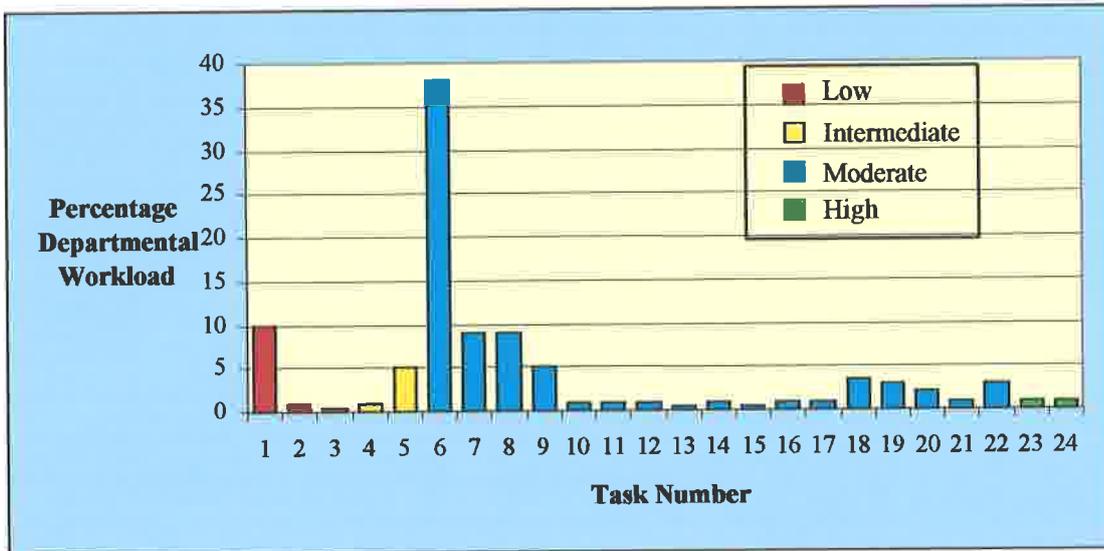
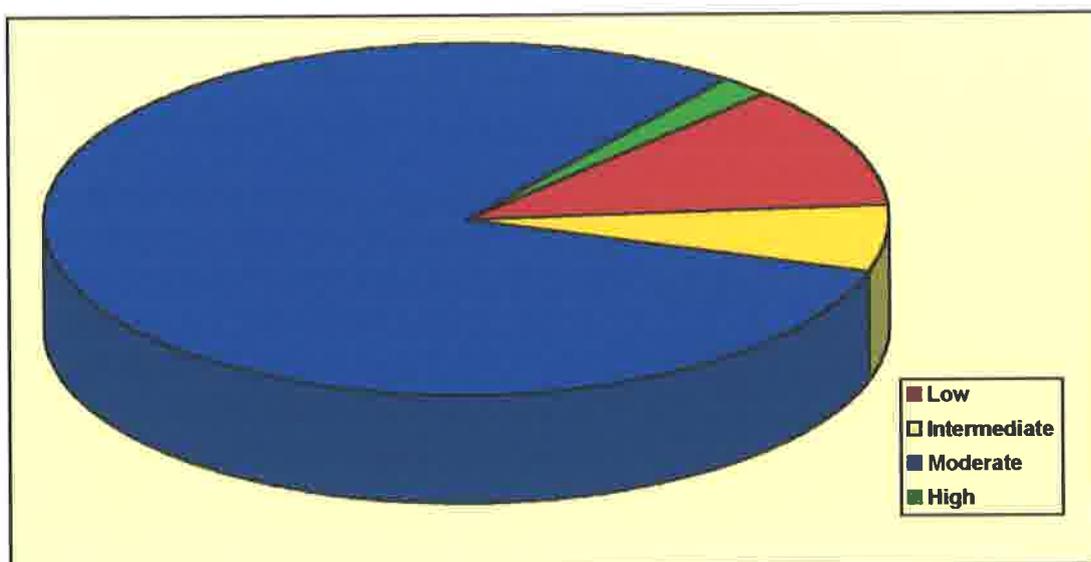


Figure 3.6 illustrates the total percentage workload segregated into the four categories of autonomy.

Figure 3.6 Total Percentage Workload per Degree of Autonomy



Analysis of this data yields the following results:-

Table 3.2 Level of Autonomy Compared to Workload and Number of Tasks

Level of Autonomy	% Workload	Number of Tasks
Low	11.5	3
Intermediate	6.0	2
Moderate	80.5	17
High	2.0	2

The greatest number of tasks are associated with a moderate degree of autonomy. This requires careful interpretation since many of these duties need little expertise. In an attempt to show the relationship between autonomy and skill, the members of senior staff previously used were requested to allocate a numerical value (1 = low; 10 = high) to each of the skills required to complete each of the tasks. Table 3.3 illustrates the mean values obtained for each task:-

Table 3.3 Degree of Autonomy and Median Values of Skill Levels Attributed to MLSO Tasks

Task Number	Degree of Autonomy	Median Skill Level
1	1	9
2	1	9
3	1	8
4	2	8
5	2	8
6	3	7
7	3	2
8	3	5
9	3	2
10	3	6

Task Number	Degree of Autonomy	Median Skill Level
11	3	5
12	3	9
13	3	8
14	3	3
15	3	3
16	3	7
17	3	7
18	3	8
19	3	8
20	3	9
21	3	5
22	3	7
23	4	3
24	4	6

Using the Spearman's Ranked Correlation Coefficient a significant negative correlation was found between the degree of autonomy and the median skill level ($p = 0.005$; $r = - 0.005$). With respect to the workload of MLSOs therefore, a greater degree of skill is associated with a lower degree of autonomy.

Elston (1977) argues that "developments in medical technology and changes in morbidity have led to a proliferation of [not only] new branches of medicine but also health related occupations". The latter, through greater political strength, have increasingly challenged the dominance of the medical profession. Added to this there have been increasing tensions within the ranks of Clinical Pathologists regarding the ramifications of recent White Papers relating to clinical autonomy. It has also been claimed (Harrison and Pollitt, 1994) that despite (or because of) such tensions, the

medical profession attempts to strengthen and protect its position via widespread involvement in the training and state registration of other health professionals. Such a strategy is based on the claim that "medical knowledge is all encompassing of health services, other professions therefore being totally subordinate".

Most of the non-medical professions have attempted to counteract this strategy by successfully constructing exclusive managerial hierarchies, thus ensuring that practitioners were not managed by persons from outside that particular profession. This trend, reaching its climax in 1974 is exemplified by the Zuckerman Report relating to scientists and technicians in the NHS. To this day the best career prospects for MLSOs lie mainly within the realms of management. Nelson (1988) points out that in the PAMs, the more senior managers have become increasingly distanced from the practice of their profession or trade. This in itself causes tensions since scientists by disposition have innate organisational scepticism (Munro, 2000). Harrison and Pollit (1994) have also maintained that in order to avoid conflict regarding clinical autonomy, non-medical professions have sought to pursue their own management arrangements – a strategy aimed at furthering occupational self-control.

Salaman (1980) asserts that "professions are those occupations which have had the greatest success in disseminating their occupational ideologies". If this is the case then MLSOs have made little progress, with members of the profession claiming that the IBMS had been ineffective in championing the cause of its membership (17).

With respect to autonomy, Elston (1977) maintains that a distinction should be made between self-determination with respect to content (i.e. the technological aspects of

the work) and the terms (i.e. the social and economic organisation) of that work. The former, it is argued is critical to the power of any profession. Potter (1996) asserts that professional autonomy has been partly gained as a result of the establishment of Biomedical Sciences as “a discrete faculty/discipline within higher education” – thus creating its own dynamic. Esland (1980) argues that professions can be separated from other occupational groups by making the distinction between “conception” and “execution”, an analogy perhaps with the differentiation between the “scientist” and the “technician”.

The Concept of “Profession” – Occupational Differences

As part of the process of their socialisation, education and training, members of any profession should be provided with explicit and implicit information regarding their roles, responsibilities, identities and the characteristics of “profession”. The acquisition of such knowledge is viewed as part of the obligations owed by members of a profession towards Society. The collective perception of any group within a given profession with respect to their roles, duties and attributes contributes towards that body’s view of what a profession is or is not. This perception is therefore likely to influence the standing of that group within Society and to determine the significance of that corpus with respect to other occupational groups. Measurement of the perception of “profession” is therefore central to the understanding of the place that groups such as MLSOs have within social and occupational hierarchies.

(a) Method

In order to undertake a comparative assessment of the awareness of MLSOs with respect to such an issue, brief “face-to-face” interviews were carried out (See Addendum 3.2 (a) for *pro-forma*). The sample included :-

1. Members of the public selected at two city centres (Cardiff and Swansea, UK) over a three week period and on various days of the week (Monday p.m., Wednesday a.m. and Saturday a.m.). Selection was undertaken using a computer generated random number list. Volunteer respondents (representing a 53% return) were asked to answer the questions in the absence of time constraints and without consulting accompanying relatives or friends.
2. MLSOs and PAMs (also nurses) selected using a computer generated random number list from alphabetically ordered Personnel Department staff records in three District General Hospitals and one University Teaching Hospital. Once again volunteer respondents (representing a 69% return) were given the opportunity to provide answers without time constraints and with no recourse to consultation with colleagues or reading material.

The total sample group (n = 278) was then subdivided into eight occupational/Socio-Economic Categories (SECs) as follows:-

Group Number	Occupational Group/SEC	Key for Figures 3.7 to 3.22
1	MLSOs	
2	PAMs and Nurses	
3	Learned Professions	
4	SEC I (Excluding Learned Professions)	
5	SEC II (Excluding MLSOs and Nurses)	
6	SEC III	
7	SEC IV	
8	SEC V	

(See Adendum 3.2 (b) for details of SECs)

The responses were then matched against Freidson's characteristics of a profession (see pp 12-13). These replies are shown as percentages in Table 3.4 and graphically in Figures 3.7 – 3.17.

(b) Results

Table 3.4 Percentage Responses Relating to Freidson’s Characteristics of a Profession According to Occupational and Socio-Economic Categories

Occupational Group/SEC	n	Characteristics of a Profession											
		Core		Derived					Non-Derived				
		C1	C2	D3	D4	D5	D6	D7	ND8	ND9	ND10	ND11	ND12
MLSOs	70	17	13	31	0	3	0	14	4	14	41	4	13
PAMs and Nurses	40	13	13	0	0	0	0	25	13	25	63	0	13
Learned Professions	17	18	53	0	12	6	0	6	18	0	6	15	41
SEC I (Without Learned)	20	10	25	0	0	15	0	15	5	20	50	0	10
SEC II (Without MLSOs and Nurses)	31	0	16	0	0	0	0	0	3	10	45	0	6
SEC III	35	0	9	0	0	0	0	0	0	3	54	0	6
SEC IV	30	0	17	0	0	0	0	0	0	0	17	0	0
SEC V	35	0	0	0	0	0	0	0	0	0	57	0	0

The ability of occupational groups to name “both” and “neither” of the core characteristics (C1 and C2) together with their failure to name any of Freidson’s twelve features are shown in Table 3.5 and Figures 3.18 – 3.20.

Note: None of the respondents referred to characteristic D6 (both licensing and admission boards are formed of members of the profession).

Table 3.5 Percentage of Response Patterns Identifying Core, Derived and Non-Derived Characteristics

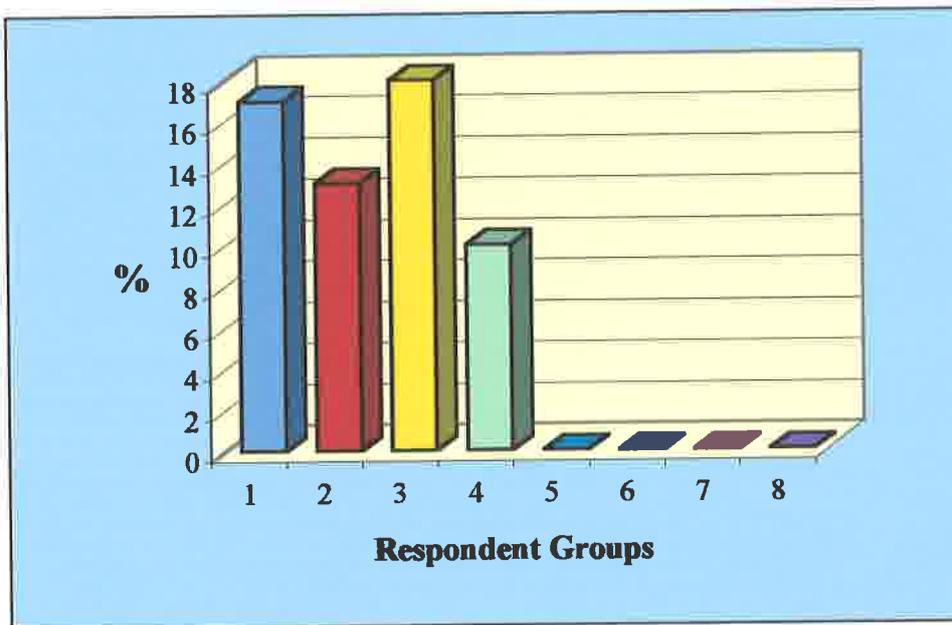
Occupational Group/NEC	Identifying Both Core (C1 + C2)	Identifying Neither Core (C1 + C2)	Identifying None of the Twelve
MLSOs	0	71	17
PAMs and Nurses	0	75	13
Learned Professions	12	47	18
SEC I (Without Learned)	25	65	15
SEC II (Without MLSOs and Nurses)	0	81	19
SEC III	0	91	40
SEC IV	0	67	83
SEC V	0	100	43

Table 3.6 together with Figures 3.21 and 3.22 illustrate the occupational group responses to the question relating to membership of a profession.

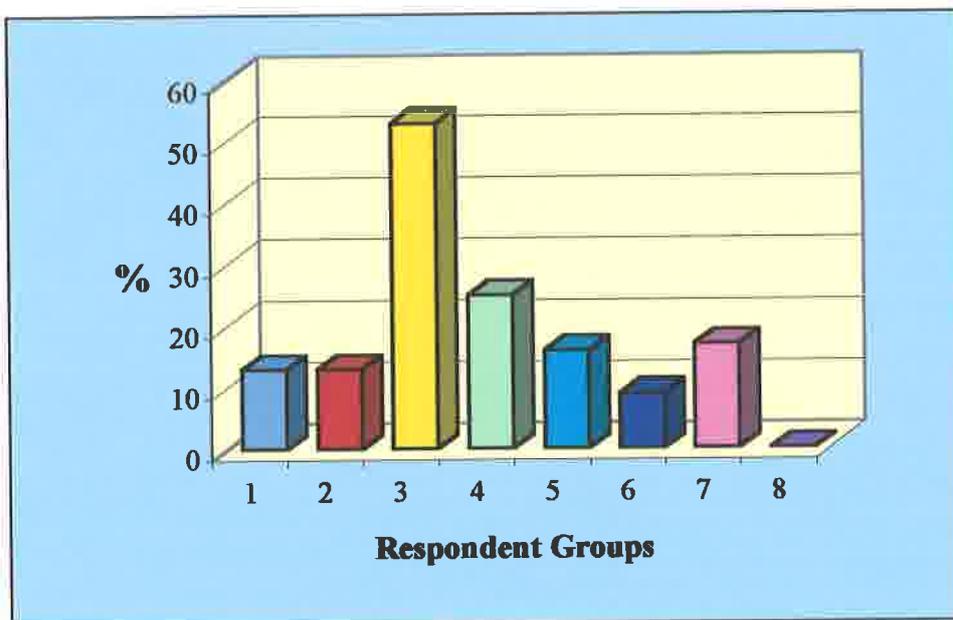
Table 3.6 Percentage Responses Relating to Membership of a Profession

Occupational Group/NEC	Yes	No
MLSOs	91	9
PAMs and Nurses	75	25
Learned Professions	94	6
SEC I (Without Learned)	75	25
SEC II (Without MLSOs and Nurses)	84	16
SEC III	57	43
SEC IV	50	50
SEC V	14	86

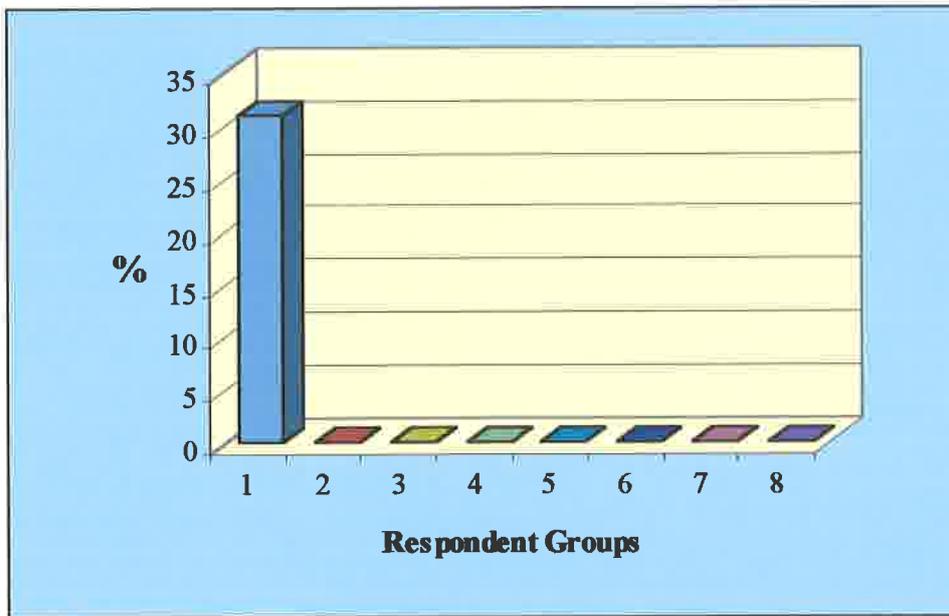
**Figure 3.7 Percentage Respondents Quoting C1
(Prolonged Specialised Training in Body of Abstract Knowledge)**



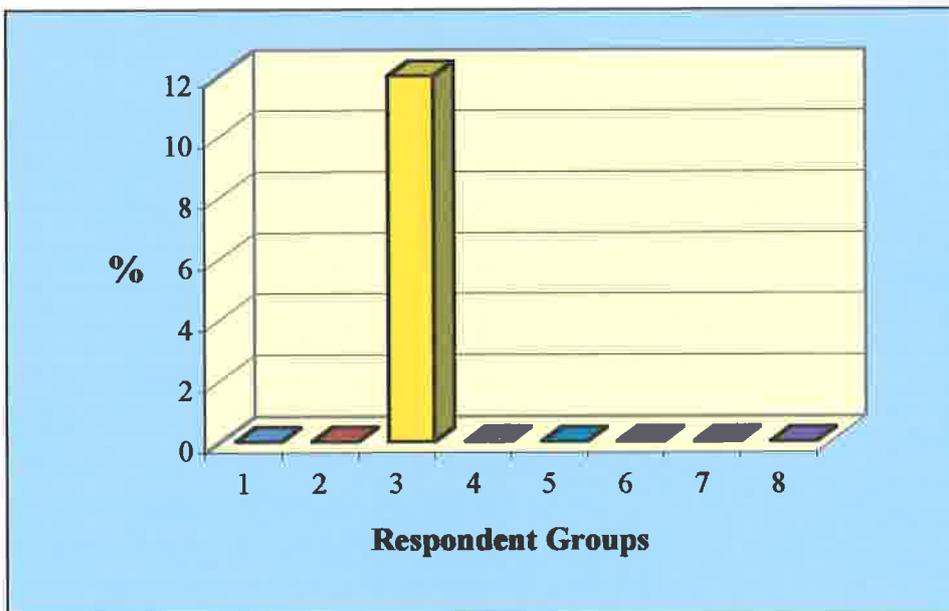
**Figure 3.8 Percentage Respondents Quoting C2
(A Collectivity or Service Orientation)**



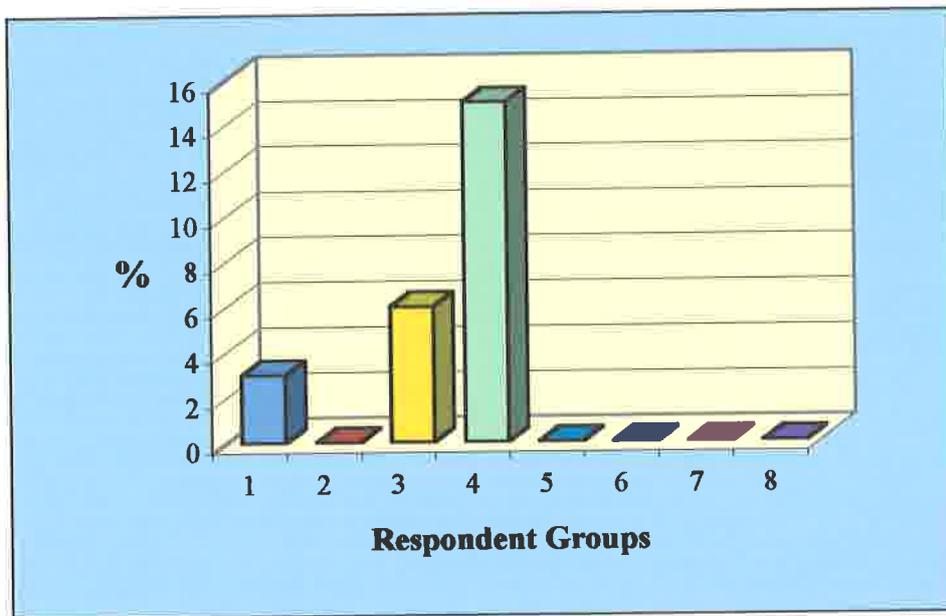
**Figure 3.9 Percentage Respondents Quoting D3
(Determines own Standard of Education and Training)**



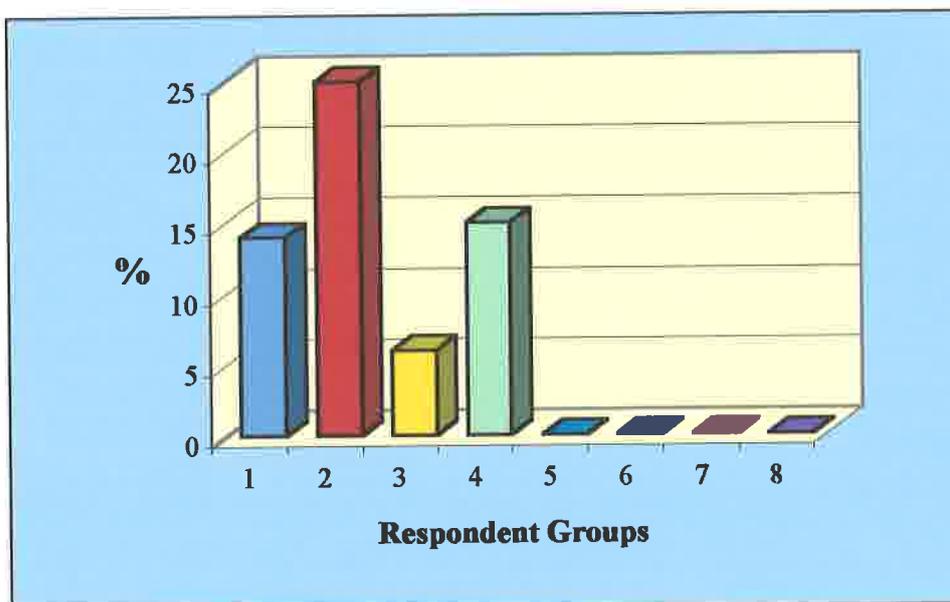
**Figure 3.10 Percentage Respondents Quoting D4
(Legislation is Designed and Influenced by that Profession)**



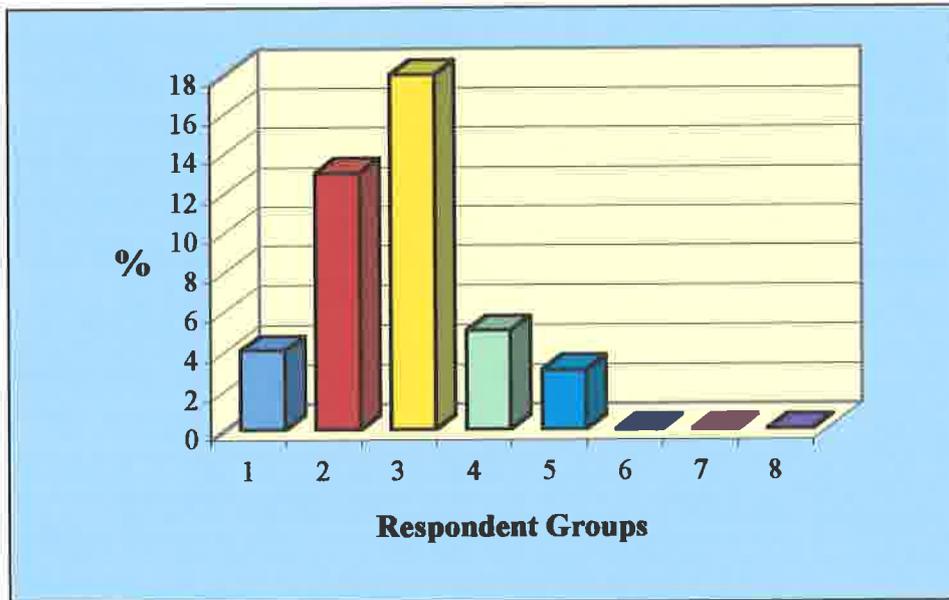
**Figure 3.11 Percentage Respondents Quoting D5
(Practitioners are Free from Lay Evaluation and Control)**



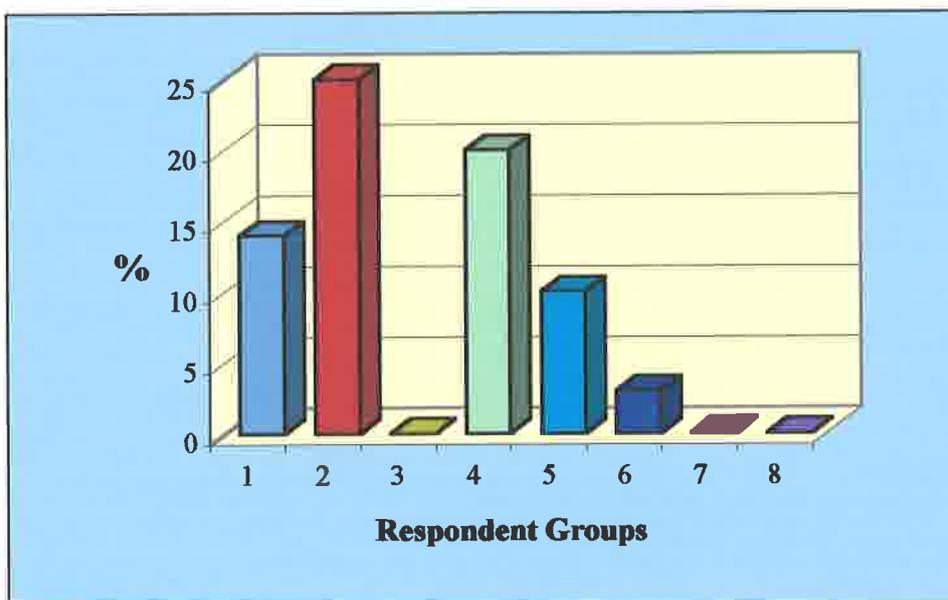
**Figure 3.12 Percentage Respondents Quoting D7
(Practice is Recognised Legally by some form of Licensure)**



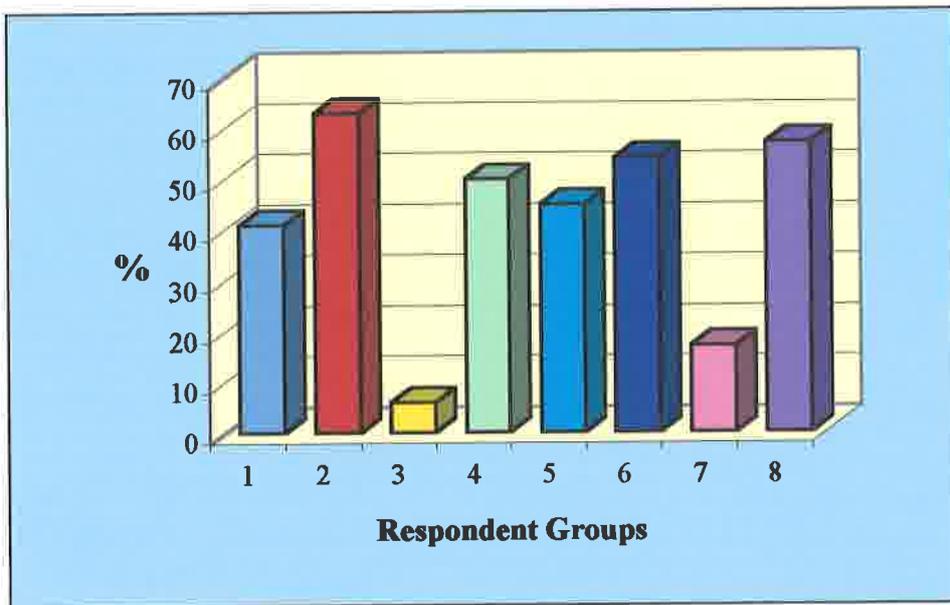
**Figure 3.13 Percentage Respondents Quoting ND8
(Compliance with Code of Conduct Expressly Designed for that Profession)**



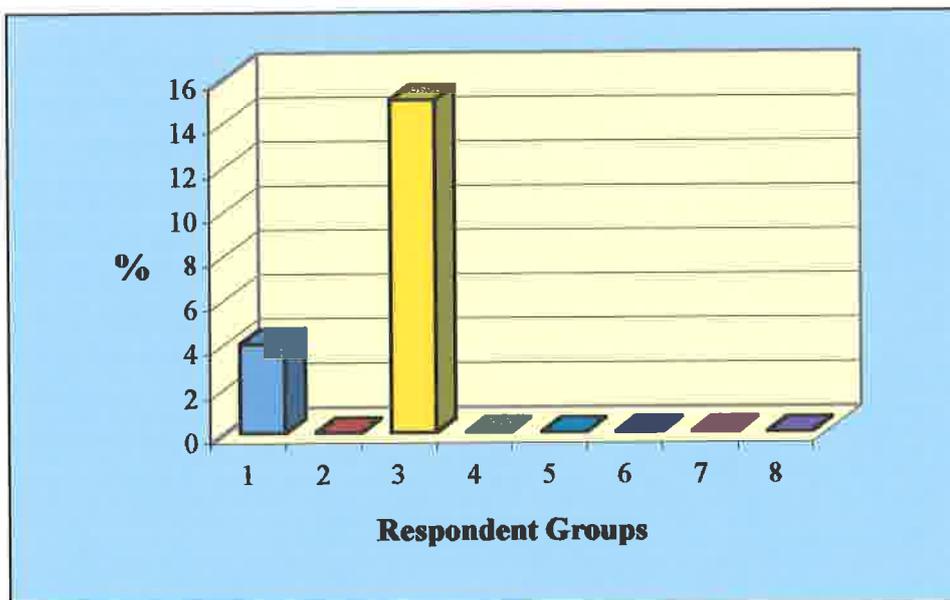
**Figure 3.14 Percentage Respondents Quoting ND9
(The Practice of Expertise not available to the General Public)**



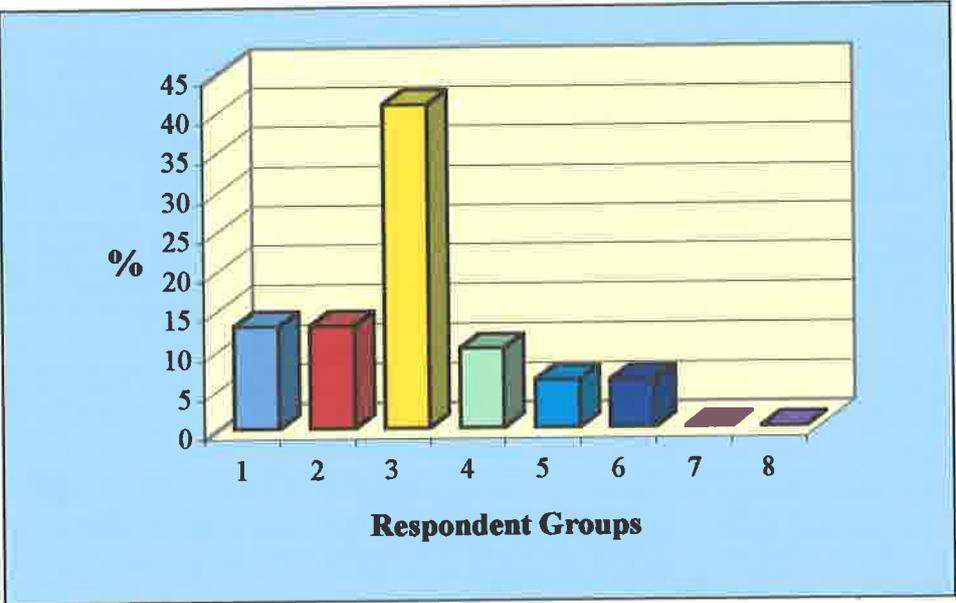
**Figure 3.15 Percentage Respondents Quoting ND10
(Attainment of Certain Minimum Qualifications for Entry)**



**Figure 3.16 Percentage Respondents Quoting ND11
(Self Governance with Respect to all Aspects of Conduct, Practice, Ethics and Qualifications)**



**Figure 3.17 Percentage Respondents Quoting ND12
(Provisions of Certain Minimum Standards Accepted by Society etc.)**



**Figure 3.18 Percentage Respondents Quoting Both Core Characteristics
(C1 and C2)**

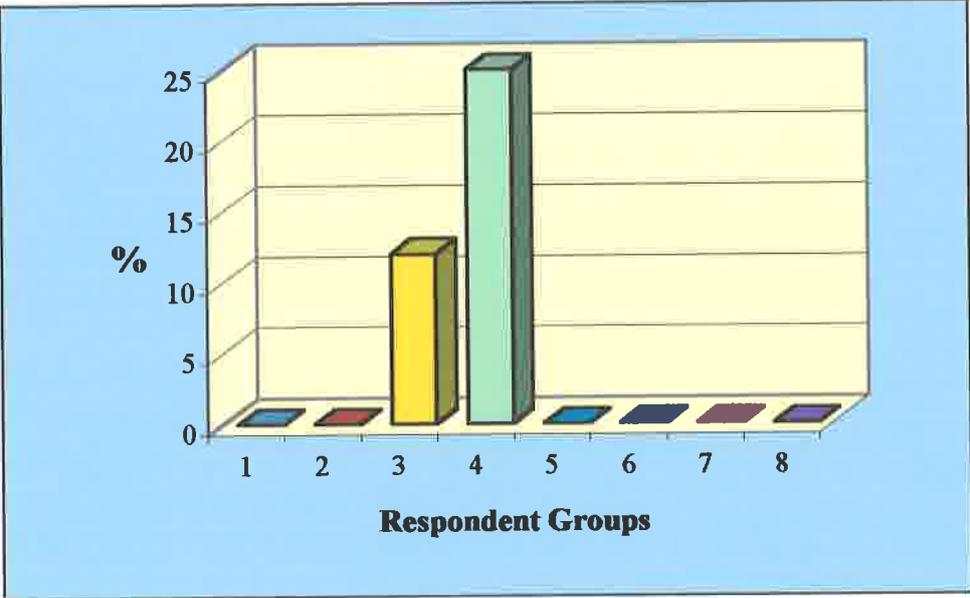


Figure 3.19 Percentage Respondents Quoting Neither Core Characteristic (C1 and C2)

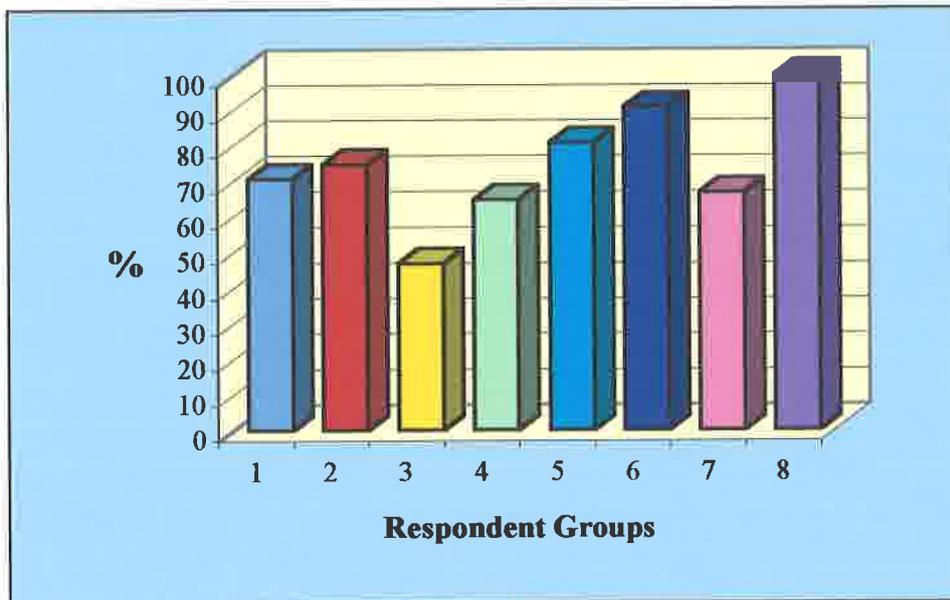


Figure 3.20 Percentage Respondents Failing to Quote Any of the Twelve Characteristics

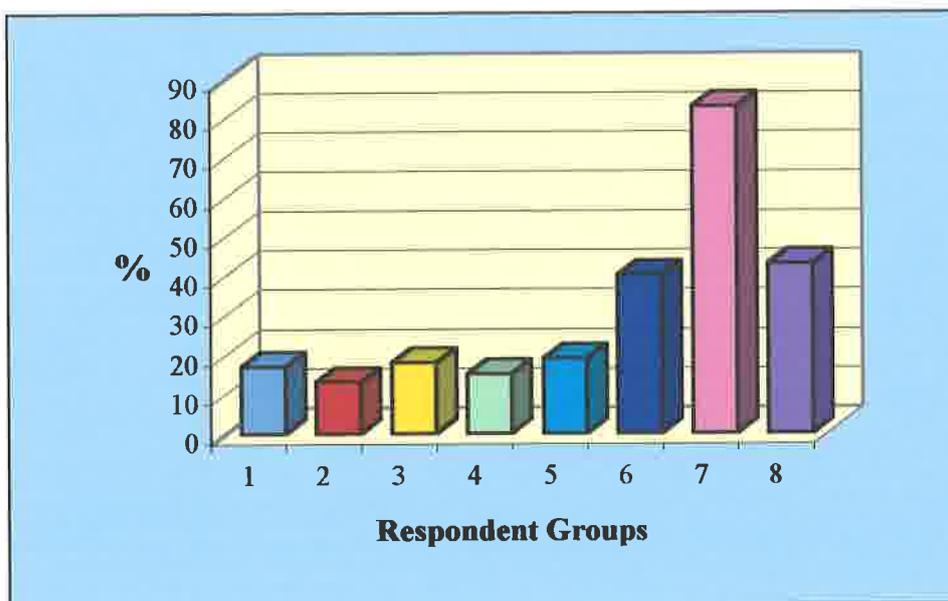


Figure 3.21 Percentage Respondents Answering “Yes” to the Question:-
“Are you a member of a Profession?”

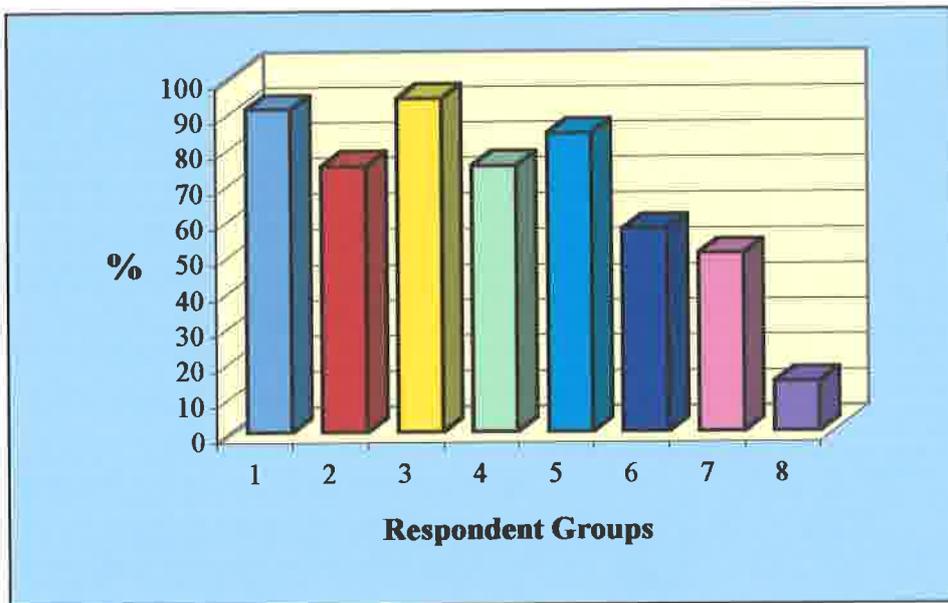
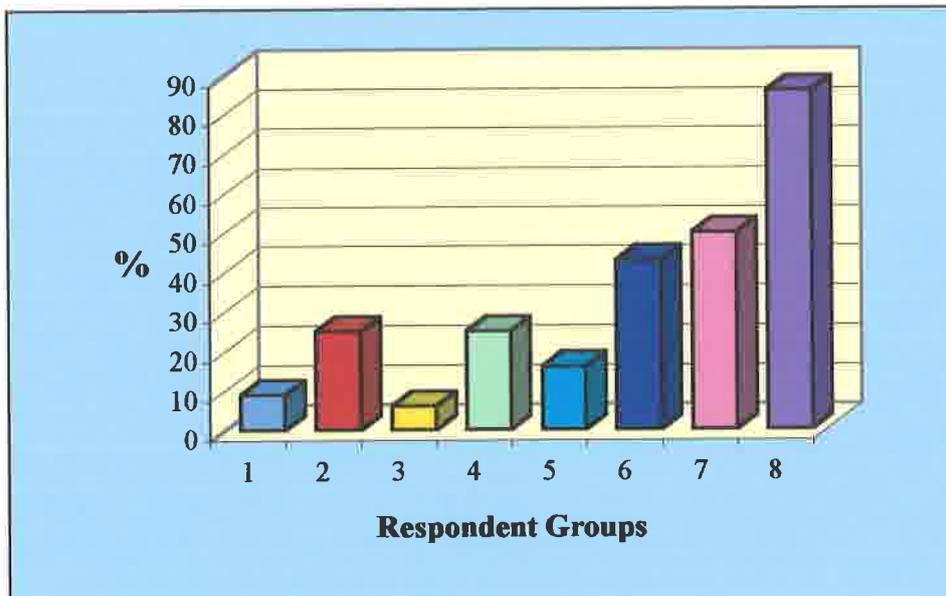


Figure 3.22 Percentage Respondents Answering “No” to the Question:-
“Are you a member of a Profession?”



(c) Statistical Analysis

Given that the Null Hypothesis (Ho) is that “There is no relationship between profession and the ability to name the characteristics of a profession”, Chi-Square test analysis was performed using the raw data (not percentages) between the following occupational categories:-

1. MLSOs
2. PAMs and Nurses
3. The Learned Professions
4. SEC II (excluding MLSOs and Nurses-and chosen because of the closest similarities to MLSOs)

The following results were obtained (the expected results being shown in brackets):-

Table 3.7 Statistical Analysis relating to the ability to identify the Characteristics of a Profession

	Failure to Identify Either Core Characteristic	Failure to Identify Any of the Twelve Characteristics	Ability to Identify Both Core Characteristics	Total
MLSOs	50	12	1	63
	(49.78)	(11.45)	(1.76)	
PAMs + Nurses	30	5	0	35
	(27.66)	(6.36)	(0.98)	
Learned Professions	8	3	2	13
	(10.27)	(2.36)	(0.36)	
SEC II	25	6	1	32
	(25.29)	(5.82)	(0.90)	
Total	113	26	4	143

$$\begin{array}{rcccccc}
 \text{Chi-Sq} = & 0.001 & + & 0.026 & + & 0.330 & + \\
 & 0.198 & + & 0.292 & + & 0.979 & + \\
 & 0.503 & + & 0.171 & + & 7.364 & + \\
 & 0.003 & + & 0.006 & + & 0.012 & = 9.885
 \end{array}$$

DF = 6 5 Cells have expected counts less than 5.0.

Ho is therefore accepted, i.e. the responses provided are not related to categories of profession.

(d) Discussion

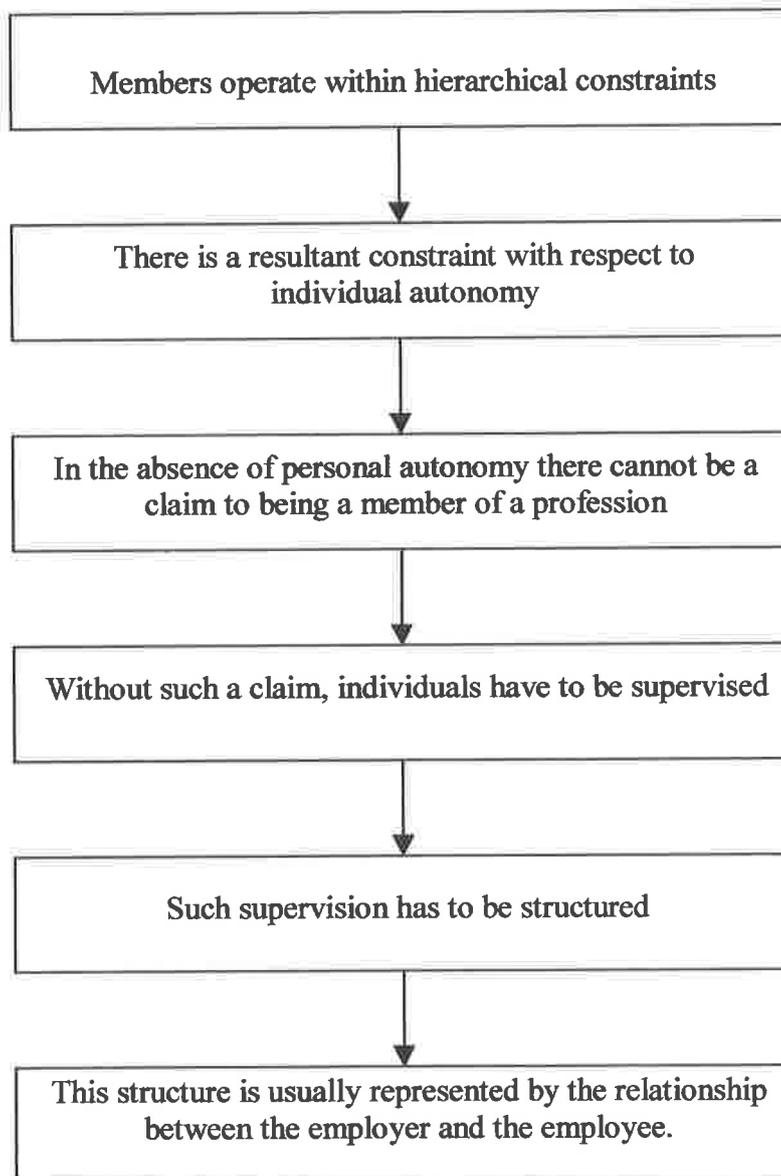
The results suggest that despite the relatively high claim (91%) (See Table 3.6 and Figure 3.21) of MLSOs to being members of a profession, their ability to name core, derived or non-derived characteristics does not significantly differ from other occupational or socio-economic classes. In common with other categories (with the exception of the learned professions) only a relatively small minority of Biomedical Scientists named “a collectivity or service orientation” (C2) as being a feature of professions (See Figure 3.8). That this is also true of PAMs and Nurses is somewhat surprising. MLSOs however were the only group citing the “determination of own standards of education and training” (D3) as a characteristic – approximately one-third of the respondents positively identifying this feature (See Figure 3.9). There was also a failure by all respondents (again with the exception of 12% of the learned profession) (See Figure 3.10) to recognise that “legislation is designed and influenced by that profession” (D4). This finding together with the fact that none of the respondents cited D6 (“both licensing and admission boards are formed of members of that profession”) is unexpected since many of the respondent groups require some form of licensure to practice and are periodically invited to elect membership of such boards (e.g. the MLT Board of the CPSM). Such failures are compounded by the fact that the MLSO and PAMs (and Nurses) groups were unable in the majority to identify “compliance with a Code of Conduct ...” (ND8) as a feature of their professions (See Figure 3.13 and Table 3.4).

Analysis of the responses provided by MLSOs suggests that many within the group identify “profession” as simply being related to personal advancement and the ability to carry out routine tasks. Typical responses included the following:-

- “associated with a good salary”
- “ability to follow standard operating procedures”
- “ability to assist clinicians to make a diagnosis”
- “being able to produce accurate results”
- “conforming to set procedures and protocols”
- “must have a good career structure”
- “can detect that which is abnormal”
- “ability to gain promotion”

The fact that members of a profession are expected to value performance above reward does not appear to be a factor significantly influencing the concept of “profession” amongst MLSOs. Therein lies a form of maturity deficit – an anomaly typifying this occupational group aspiring towards the status of profession. Recognition by members of other health care groups and the public is reliant on the perception that Biomedical Scientists not only exhibit the characteristics of a profession but also demonstrate professionalism. Historically the struggle on the part of Biomedical Scientists in the UK and other countries towards professional recognition has been characterised by a “circularity” more representative of semi-professional groups as outlined in Figure 3.23.

Figure 3.23 Hierarchical Enclosure Typifying Semi - Professional Groups



The fact that such an enclosure applies to MLSOs is evident from earlier considerations relating to job descriptions, levels of autonomy and staffing structures. Added to such considerations are the findings of several surveys over the past few decades that have highlighted the relative failure of medical laboratory technologists with respect to their aspirations towards professional status. Amongst such setbacks have been an apparent misconception of the value and relevance of MLSOs, the

relatively low esteem of Biomedical Scientists amongst fellow health professions (18) and the continuing frustration of MLSOs with respect to professional recognition (19).

Hugman (1991) describes a form of “exclusionary closure” by which occupational groups aspiring towards the status of a profession develop strategies such as:-

- (a) choosing who enters the profession and is allowed to practice
- (b) defining the boundaries of that particular profession and its relationship with other professions
- (c) providing the foundations for power exercised by that profession in relation to its users.

It may be argued that in respect of Biomedical Scientists (at least within the UK) there has been some success concerning the first of these strategies (i.e. CPSM regulations), but little if any achievements in relation to the others. Ellis (1991) maintains that the 20th Century has seen an increase in the number of hospital-based semi- or para-professions, each having attempted to “establish some control over a particular category of illness, its treatment and over a particular technological apparatus or process”. Such tensions inevitably lead to conflict, the degree of which is a function of the similarity between the occupational groups involved – a typical example being the struggles between MLSOs and Clinical Scientists within the UK (See Chapter 5).

Blane (1997) suggests that in addition to Friedson’s characteristics, an additional feature of the professions is that of status. He points out that professions are middle-class occupations, membership of which is usually assigned to Social Classes I and II.

It is further argued that as a result of this characteristic, members undergo a process of professional socialisation that involves not only the acquisition of knowledge but also the transfer of appropriate attributes towards clients and others. The characteristics of a profession are not obtained *en bloc* by any given occupation, but by a piecemeal process involving a series of specific historical situations and a protracted period of struggle. The battle for professionalisation by MLSOs (as in the case of other occupational groups such as radiographers, podiatrists and pharmacists) have been negotiated within a division of labour already dominated by the medical profession.

Baly (1984) points out that it is not only skill and esoteric language that distinguishes the professions but also characteristics that are difficult to define, e.g. the ability to inspire trust amongst members of the laity. The latter, it is argued is achieved by a process of voluntary subordination on the part of the professions - a submission by their members to a standard of exacting social morality. An additional feature of professions is a tendency towards increased specialisation, typified by occupations accountable to medicine. Baly suggests that by undergoing a continual prosecution of research, the nursing profession (*cf.* MLSOs) is attempting to establish a body of specialised knowledge.

Giddey (1995) refers to a long-established approach to the problem of defining the traits of a profession. The application of "trait theory", he maintains, involves the comparison of the characteristics of a particular profession to those of the learned professions. The extent of complementarity or equivalence then determines whether that occupation is seen as "non-profession", "semi-profession" or "profession". Occupations such as social work and nursing are classified as semi-professions

primarily because of a lack of a discrete body of scientific knowledge and a tendency to emphasise skills rather than knowledge.

Macdonald (1995) refers to the professions as “[those] *occupations based on advanced, or complex, or esoteric, or arcane knowledge*” and points out that Friedson’s “power approach” (i.e. organised autonomy) to characterising professions must be placed in the context of the latter author’s claim that “*one does not attempt to determine what a profession is in an absolute sense, so much as how people in Society determine who is a professional and who is not - how they make or accomplish professions by their activities*”.

Unlike Friedson who identifies autonomy as a central feature of the professions, Macdonald implies that it is possession of a theory of relatively esoteric knowledge that is the essential characteristic. Turner (1995) supports this notion, arguing that specialised knowledge represents the basis for prestige and social distance between the expert and client.

Conclusions

Originating from the medieval universities of Europe, professions were, at first, restricted to the three learned groups of medicine, law and the clergy. Dingwall and Lewis (1987) have suggested that these categories of “status professions” be differentiated from the more recent occupational professions that have arisen largely as a result of organised middle-class efforts. Baly (1984) points out that according to the 1841 Census, the only acknowledged professions were divinity, law and

“physics”. Forty years later the list had expanded to include nineteen occupations including surveyors, accountants, the higher Civil Service, but not teachers (except those in Higher Education). Since that time there has been a profound shift in relation to the concept of “profession”, in that, following World War II there has been a simultaneous emergence of successive occupational groups (including Biomedical Scientists) that have striven for recognition. Within the context of institutional hierarchies MLSOs have sought professional recognition by adopting several strategies. These include the creation of national bodies responsible for the representation of practitioners in relation to professional issues, e.g. personal development, education, training, quality issues, the political agenda and so on. Added to this has been the introduction within the UK of an “all-graduate” entry into the profession and the development of undergraduate and postgraduate academic programmes. The proliferation of CPD programmes including Management courses are attempts towards the attainment of acceptance within the health care professions and beyond.

These attempts have had little success since any occupational autonomy is associated largely with relatively low skill tasks. Senior managerial positions are subservient to administrators, clinical pathology directors and others, and there remains little public recognition (as witnessed during recent National Press Releases relating to MLSO recruitment and retention).

Knowledge and perception relating to the characteristics of “profession” amongst MLSOs are not significantly different from other occupational groups. Indeed, some

of the latter (e.g. the learned professions) show an ignorance of several features of professions (See Figures 3.14 and 3.15 relating to ND 9 and ND 10).

Currently there are additional developments taking place that are also aimed at promulgating Biomedical Scientists as being members of a profession. These include the introduction of the first professional doctorates and the proposed amalgamation of the IBMS with the Royal College of Pathology.

The following Chapter will address issues relating to the second section of this thesis i.e. the influence of health care systems in laying the foundations for modernisation of diagnostic pathology. This will largely be attempted by an analysis of the political, economic, social and technological influences that have impinged on the evolution of health care delivery systems within the selected countries.

Notes

1. The “new science” established by Newton, Descartes, Galileo, Harvey and Bacon had been popularised by the Enlightenment. However it was not until after 1800 that the public sciences were to receive significant levels of funding. Increased manpower, the advent of new institutions, teaching and training and the first patronage by the State were leading to new expectations across Europe. New scientific bodies were being established and medicine was being increasingly seen as “scientific” (See Porter, 1997 (pp 304-305)).
2. Even important figures such as Virchow and Bernard were influenced by the French approach to anatomical pathology. Inspired by the likes of Bichat and Broussais (the latter arguing that disease resembled a continuum between sickness and health), it became fashionable to measure physiological phenomena in terms of specific parameters. Such measurements included the absolute and relative numbers of leucocytes and erythrocytes, the concentration of chemicals in the blood and urine, blood pressure and body temperature. These were found to vary about a mean correlated by age, gender, body weight and so on. Thus was born the concept of the “normal reference range” – a basic tenet of modern practice in laboratory medicine.
3. The Act required compulsory attendance at lectures in botany, chemistry, anatomy, *materia medica* and the theory and practice of physic. Six months work at the hospital bedside was also mandatory. The period 1800-1840 saw the establishment of London University and its associated medical teaching centres – primarily “University” and “Kings”.
4. The approach used by centres such as Giessen relied heavily on microscopy. In 1826, Lister had produced a high magnification instrument capable of revealing the fine detail of tissues. The next fifty years were associated with the industrial supremacy of the lens makers Zeiss and Leitz. Amongst the pioneers of the microscopic study of anatomy was Henke, who held chairs at Zurich, Heidelberg and Gottingen. German (and Prussian) universities now began developing a research ethos that evolved alongside educational reforms. These included an increased investment in academic science (*Wissenschaft*), professional freedom to teach specialities (*Lehrfreiheit*) and the increased mobility of students (*Lernfreiheit*) (See Porter, 1997 (pp 321-322)).
5. Amongst the most significant developments in North America was the establishment of a bacteriological laboratory at Staten Island Marine Hospital in 1887. Achieved largely as a result of the efforts of Kinyoun (working for the Marine Hospital Service), the laboratory was later to be transferred to Washington D.C. to become the Hygiene Laboratory. A year later, the Public Health Laboratories were founded in Providence, Rhode Island. In 1890, Chapin launched a campaign to eliminate diphtheria in Providence. The major strategy included the isolation of bacteriologically tested victims and carriers. This eventually led to the introduction of a School of Public Health at John Hopkins University, Baltimore. In 1892 a Division of Microbiology and Disinfection at the New York City Health Department was opened. This was later to be developed into a diagnostic facility. Between 1894-1895, similar laboratories were established in Massachusetts and Philadelphia. By 1900, diagnostic laboratories had been established in every State and most major cities. The conversion of the Maine Hospital Service into the United States Public Health Service by Roosevelt occurred in 1912. Other government departments also acquired specific health responsibilities, e.g. the War Office took over management of the health of military forces. In 1929 there was an expansion of the Mayo Clinic, Rochester, Minnesota, to include the employment of 895 laboratory technicians, nurses and other workers within 21 laboratories.
6. “*Profession*:- the occupation which one professes to be skilled in and to follow:
 - (a) a vocation in which a professed knowledge of some department of learning or science is used in its application to the affairs of others or in the practice of an art founded upon it. Applied *spec* to three learned professions of divinity, law and medicine; also to the military profession.....1839 Maurice Lect. Educ. Mid. Classes 186 *Profession in our country...is expressly that kind of business which deals primarily with men as men, and is*

thus distinguished from a Trade, which provides for the external wants or occasions of Man.

- (b) in wider sense: Any calling or occupation by which a person habitually earns his living. Now usually applied to an occupation considered to be socially superior to a trade or handicraft, but formerly, and still in vulgar (or humorous) sense, including these.
- (c)
- (d) the body of persons engaged in a calling”.

(Source:- *verbatim* Murray et al., 1961).

7. “*Profession* :-

- (a) a calling requiring specialised knowledge and often long and intensive preparation including instruction in skills and methods as well as the scientific, historical or scholarly principles underlying such skills and methods, maintaining by force of organisation or concerted opinion high standards of achievement and conduct, and committing its members to continued study and to a kind of work which has for its prime purpose the rendering of a public service.
- (b) a principal calling, vocation or employment”.

(Source:- *verbatim* Gove, 1993, p1811).

8. “*Learned Profession*:-

n: one of the three professions, theology, law and medicine, traditionally associated with extensive learning or erudition: broadly any profession in the preparation for or practice of – of which academic learning is held to play an important part

learned (3) well informed, skilled or practised in a specific field”.

(Source:- *verbatim* Gove, 1993, p 1286)

9. “*Profession*:- business, calling, career, employment, line of work, occupation, office, position, sphere, vocation, walk of life” (See McLeod, 1987).

10. “*Occupation*”:- the principal business in one’s life: a craft, trade [profession] or other means of earning a living: employment, vocation (See Gove, 1993, p 1560).

11. “*Vocation*”: *vocare* – to call, summon

- (i) the action on the part of God of calling a person to exercise some special function, especially of a spiritual nature, or to fill a certain position, divine influence or guidance towards a definite (esp. religious) career, the fact of being so called or diverted towards a special work in life, natural tendency to, or fitness for, such work.
- (ii) (a) the particular function or station to which a person is called by God; a mode of life or sphere of action regarded as so determined (*cf.* calling).
(b) one’s ordinary occupation, business or profession.
(c) *collect.* those who follow a particular business or profession.

(See Murray et al., 1961, p 278).

12. fr. L. *vocation* – summons, bidding, invitation

- (b) (i) the work in which a person is regularly employed usually for pay: line of work: occupation
- (c) (i) the special function of an individual or group within a larger order (or society)
 - (ii)
 - (iii)
 - (iv)
- (v) the membership of a particular occupational group: the persons engaged in a field of business, profession or trade.

(See Gove, 1993, p 2561).

13. "Vocation": business, calling, career, employment, job, life's work, metier, mission, office, post, profession, pursuit, role, trade, occupation (See McLeod, 1987, p 1123).

14. "Professional":

1.
2.
3. Engaged in one of the learned or skilled professions, or in a calling considered to be socially superior to a trade or handicraft.
4. (a) That follows an occupation as his/her profession, life-work or means of livelihood, as a *professional soldier, musician or lecturer, spec*, applied to one who follows by way of profession or business, an occupation generally engaged in a pastime: hence used in contrast with *amateur*, as *professional cricketer*. Disparagingly applied to one who "makes a trade" of anything that is properly pursued from higher motives, as a *professional politician*.
- (b) Of play, sports etc. Undertaken or engaged for money, or as a means of subsistence, engaged in by professionals (as distinct from amateurs).
5. That is trained or skilled in the theoretic or scientific parts of a trade or occupation, as distinct from its merely mechanical parts: that raises [her]/his trade to the dignity of a learned profession.

"Professionalism"

Professional quality, character, method or conduct; the stamp of a particular profession. (See Murray *et al.*, 1961, p 1428).

15. "Professional"

- (a) (i) relating to or characteristic of a profession or calling
- (ii) concerned or occupied with the training of professionals.
- (b) characterised by or conforming to the technical or ethical standards of a profession or an occupation : manifesting fine artistry or workmanship based on sound knowledge and conscientiousness : reflecting the results of education, training and experience.

(See Gove, 1993, p 1811).

16. Such privilege is substantiated by three claims:-

- (i) "that there is such an unusual degree of skill and knowledge involved in professional work that non-professionals are not equipped to evaluate or regulate it."
- (ii) "that professionals are responsible, i.e. in the absence of supervision they can be trusted to work conscientiously."
- (iii) "that the profession itself may be trusted to undertake proper regulatory action."

(See Freidson, 1970, p 137)

17. Amongst other criticisms, the IBMS was criticised for the following:-

- (a) having little influence because of the low degree of esteem enjoyed by individual members
- (b) having a low profile both with the general public and its own membership
- (c) the fact that the professional body was suffering from a lack of identity, adopting a defensive strategy and having a tendency to "sit on the fence"
- (d) possessing little political effectiveness with no Parliamentary representation.

(See Surrey, 1991).

18. In an attempt to estimate the image and social status of Medical Laboratory Technologists amongst hospital colleagues and the general public of North America, the University of Texas used a rating scale comparable to that of the National Opinion Research Centre. Researchers compared the ranking of laboratory scientists with those of occupations outside health care. Asking respondents to rank 13 categories of health professionals with respect to their general social standing, Medical Laboratory Technologists were ranked 11th above Dental hygienists and Radiological Technologists. Occupational groups such as speech pathologists,

audiologists, physical therapists and social workers were rated higher. Using comparable rankings of prestige, Medical Laboratory Technologists were classed within the same rankings as carpenters and other manual workers and only marginally succeeded in entering the public's perception of the professional image of prestige (Winchell, 1986).

19. The frustrations experienced by Biomedical Scientists in their attempts to gain recognition as members of a profession were evidenced by the result of a survey undertaken in 1981 by Griffin and Klun. Sampling 150 Pathology Laboratories in the UK (with a return rate of 64%), researchers ranked the order of 22 stress factors quoted by MLSOs. Results indicated the following pattern (rank order in brackets) :-

- Failure to understand the laboratory on the part of doctors (1)
- Lack of recognition and/or appreciation by physicians and other hospital staff (10)
- Lack of authority to make decisions (14)
- Two years earlier a survey of 904 individuals using a 468 item questionnaire (with a response rate of 83%) and also identifying 22 stress sources resulted in the following findings (rank order in brackets):-
- Lack of recognition (12)
- Apathy on the part of peers and supervisors (13)
- Lack of professionalism amongst staff (17)

(See Ivancevich and Matteson, 1987).

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SECTION B

FOUNDATIONS FOR THE MODERN ERA

CHAPTER 4

The Influence of Health Care Systems on Medical Laboratory Sciences

Chapter 4

The Influence of Health Care Systems on Medical Laboratory Sciences

“Time in his course will bring us to endless successors in spirit of the Victorian pioneers of social advance – men and women with the conscience and industry of Shaftesbury, the strength of purpose of Elizabeth Fry, the courage and inventiveness of the Barnetts, the untutored fervour of William Booth, the exuberant humanity of Quintin Hogg, the pity and the anger of Benjamin Waugh. But who will restore the conditions in which these men and women did their work? When and how shall we replace the lost power of widespread religious belief, the material resources which must support the Philanthropic Motive as the body clothes the soul, and the sense of brotherhood in the human race? None of the Victorian powers dreamed of a world with dangers such as ours. None of them doubted that man could and would be master of his fate.

To restore the conditions in which these pioneers did their work will not be the work of any man. But restoration may come through one spirit breathing again through many men, as it did in the special field from which this study began. So at last human society may become a friendly society - an Affiliated Order of branches, some large and many small, each with its own life in freedom, each linked to all the rest by common purpose and by bonds to serve that purpose. So the night's insane dream of power over other men, without limit and without mercy, shall fade. So mankind in brotherhood shall bring back the day”.

Beveridge, 1948.

Introduction

Developments within the pure sciences have made a significant contribution to the advance of medicine. However, there are those who would argue that the most notable metamorphoses in the medical arena are founded within the socio-political domain. Alongside the scientific influences outlined in the previous chapters came demands for a different type of society, one in which nation states saw the need to develop new vestiges of a civic society within which health and well-being would be prioritised. Such a goal, perhaps, was largely achieved by the mid 1960s and this is the time when medical laboratory technologists were to find a home.

Whilst there existed amongst European governments a consensus regarding the requirement for collective health care provision, there was a debate on the extent of

such contribution and the form in which it should be supplied. The financial, social and political characteristics of health care systems within any nation state have influences on the supply of diagnostic (including pathological) services within that particular country.

The origins of the “European Welfare State”, (shaped by global conflicts, economic pressures and class struggles) stemmed from Germany in 1883 when Bismarck devised a comprehensive scheme of social security, offering workers protection (insurance) against old age, accident and sickness. This model of Bismarkian socialism was to form the foundation of welfare systems for many other European countries and represented a form of paternalism by the state. Health care systems within the broader concepts of welfare state development have their roots embedded deeply in the economic and political institutions of nation states. Within Europe they are, to a large extent, linked to social-democrat parties. Three broad categories of financing and organisation of healthcare have emerged within Europe. The dominant group is that associated with “Beveridge”-style health systems, exemplified by Sweden and Britain. Funded through earmarked general taxation and associated with mainly public providers, such systems use staff in the main employed directly by the state.

“Bismarkian” systems, as typified by those in France and Germany, are based on compulsory social health insurance. Here, there is a mixture of payroll deductions together with both public and private provision of health funds. The “Semashko” model, typical of the Soviet era, is associated with non-earmarked general taxation, total state authority and control, together with significant centralisation of

administration, planning and financing (1). In other (most notably Southern) European countries there is a current transition from Bismarkian systems to Beveridge models of healthcare provision, e.g. in Portugal, Spain, Italy and Greece.

As a reflection of these different models, the health care systems of Germany, Sweden, Greece and the UK will be considered alongside an examination of how technological advances together with social, political and economic factors have influenced the provision of diagnostic laboratory services. There will also be an assessment of the extent to which such factors have affected the impetus towards professional harmonisation.

Biomedical sciences in the Context of Health Services in Europe

Beveridge's Utopian vision of the Welfare State implicitly enshrines the concept that the well being of the human race is largely predicated on the provision of comprehensive and effective health care delivery. Jones and Moon (1987) maintain that the primary features shaping the provision of health care within a particular country include the social and politico-economic ideology of that nation, cultural factors and issues concerned with regional resource planning. Such an ideological model of health care organisation is illustrated in Figure 4.1.

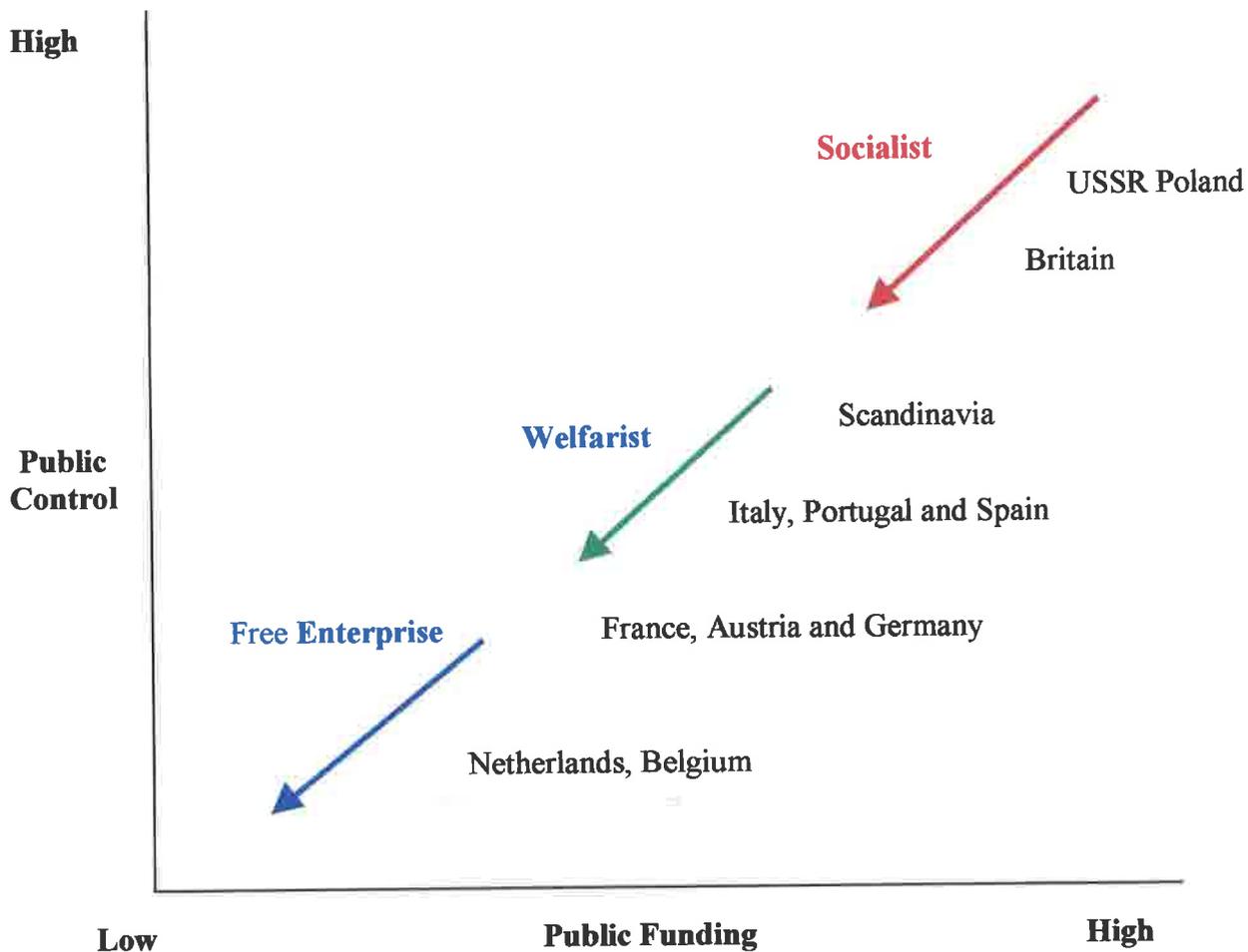
Whereas the early emphasis on health care provision in Britain had stemmed from concerns regarding environmental hygiene, Europe saw public health activities being centred on personal public health. The first free treatment for venereal disease had been introduced in Denmark as early as 1790, while in Germany six years later,

vaccination against smallpox became compulsory. State hospitals had been built in most European countries by the 1840s. By 1892 the French system of child welfare clinics was being widely imitated in Europe and the first midwives were being trained in Scandinavia and Holland.

Bismark's state medical insurance system of 1884 was followed by similar schemes e.g. in Austria (1888), Hungary (1891), Luxembourg (1907) and Norway (1909). Meanwhile in Russia, programmes involving salaried doctors and hospital buildings had been introduced as early as 1861, but the country was completely lacking in sanitary science.

In some respects the European health care systems developed from a process of economic modernisation which had extended from developed countries such as Britain and Belgium southward to Northern Italy during the latter decades of the Eighteenth Century. While the Industrial Revolution continued to spread, those states with the most developed economies rapidly expanded their industrial systems and underwent further technological advances.

Figure 4.1 Ideological Models of Health Care



Adapted from Jones and Moon (1987) and modified to take account of more recent changes in Southern European Countries.

Predominant amongst the multi-factorial influences which shaped the European health care systems were:

- (a) The demographic revolution – characterised by a massive population increase between 1770 and 1950. Europe saw a rapidly falling death rate but a relatively constant birth rate. Figure 4.2 illustrates the complex interplay

between the relative rates preceding and succeeding the Industrial Revolution. Contributory factors included a reduction in disease mortality (in 1776 Jenner had established the efficacy of vaccination against smallpox) and the absence of any widespread famine in Europe after 1715. The advent of antibiotics would later add to the fall in death rates.

- (b) The pace of economic advance, the rise of industrial capitalism, technical advances, increased agricultural output, the trend towards imperialism and public health reforms, would all play a greater or lesser part in sculpturing the design of later health care provision.
- (c) The emergence of a new social class resulting from the profound social change associated with the Industrial Revolution. Described by Marx as “having nothing but their labour to sell”, the nineteenth century “proletariat” were subjected to the abuses of primitive capitalism. Originally living in appalling squalor, existing on starvation wages, exposed to child labour and experiencing utter poverty, the mass of wage earners in Europe slowly began to benefit from the emergence of the labour movement. Workers began to receive legislative or contractual guarantees against occupational disease, unemployment and accidents. Other benefits followed, e.g. minimum wages, invalidity pensions and paid holidays. The demands of social reformists were gradually being met and constraints were being placed on absolute *laissez-faire* liberalism.

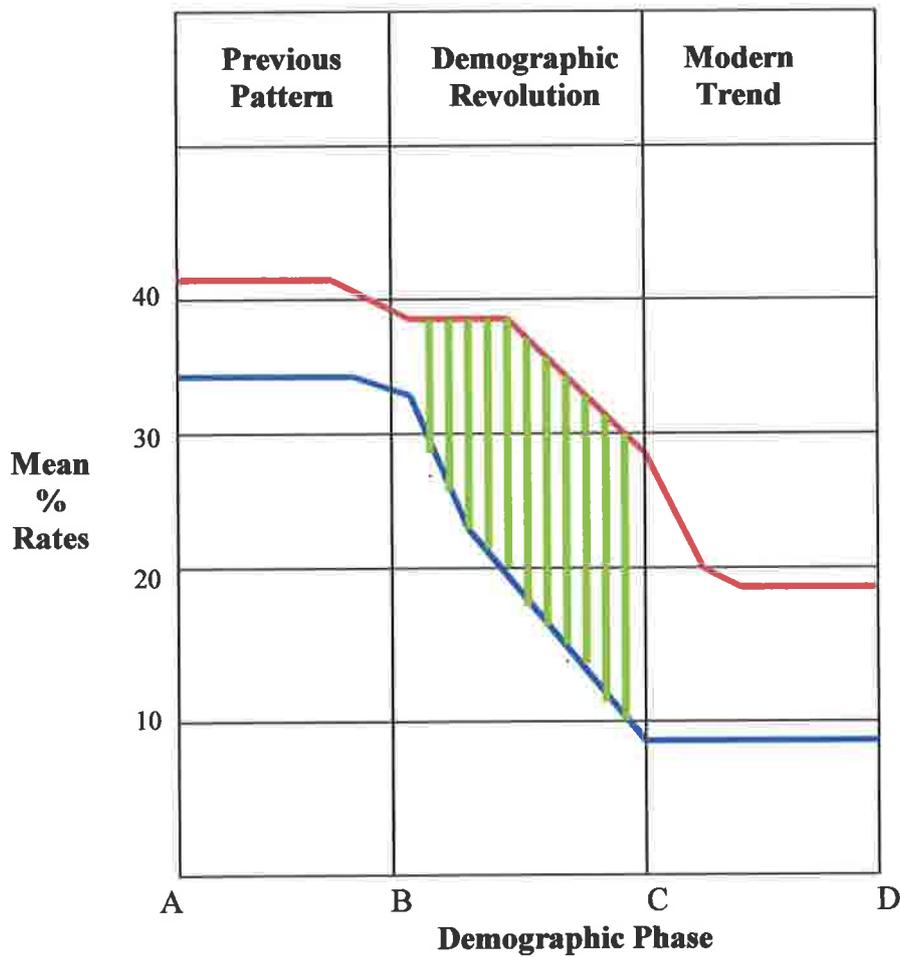
At the beginning of the Twentieth Century therefore, Europe was faced with not only a growing population, but also an ageing one (a tendency probably exaggerated by the emigration of younger people). Consequently greater numbers would be expected to

die from diseases of old age. Although notable successes had been achieved in controlling tuberculosis, pneumonia and influenza, medical science had made little progress against heart disease, mental and nervous disorders or cancer.

Since life-expectancy had at least doubled since the Middle Ages, the expectations of the ageing European population (dying from different diseases at later periods in their lives) were becoming more demanding of medicine and the state. Added to this was the growing realisation that the standard of living, economic growth and prosperity, could significantly influence both the quality and length of life. Europeans became less tolerant of deprivation and poverty and shared a vision of attainable happiness. The people were beginning to demand the benefits which social, economic and medical improvements could provide.

As in Britain, other European countries were making greater efforts to improve public health facilities such as urban sewerage, sanitation and water supplies, because of the dangerous levels of ill health in most larger towns and cities. Irrespective of the fact of whether national production was based on agriculture (e.g. Denmark) or industry (e.g. Germany, France, Norway, Sweden and Italy), employers were becoming more concerned about the health of their employees since efficiency diminished as a result of ill-health. Consequently, medical care was provided through the firm at least by some of the larger employers, while the smaller business owners either dismissed the chronically sick employees or advocated state and charitable health care.

Figure 4.2 Demographic Trends in Europe in Relation to the Industrial Revolution



Note:

1. — Birth Rate (Adjusted)
2. — Death Rate (Adjusted)
3. A, B, C and D represent different dates for different countries; e.g.

	B	C
France	1770	1850
Britain	1740	1870
Russia	1890	1950

Source: Modified from Duroselle, 1990 (2).

Following World War II, Europe, beginning a period of convalescence, started the task of reconstructing its economies, governments and administrations. Everywhere on the Continent the experience of Hitler's tyranny rekindled the candle of democratic ideals. There was a tide of political sentiment that promulgated the resurgence of social democratic and Christian socialist movements. The swing towards the left in political public opinion constituted in part a leaning towards Communism.

In Britain, Beveridge's paper of 1942, the "*Report on Social Insurance and Allied Services*" attracted wide international interest. Representing a practical vehicle for social reorganisation in the post-war world, and possessing a measure of visionary welfare reform, the principles of the report were adopted to varying degrees by France, Norway, Belgium and Spain (3).

Although the level of economic development was a major constraint in some countries, health provision became the centrepiece of the European Welfare State. Medical care was not free everywhere but whenever charges were expected to be met by individuals, they were kept to a minimum. There now followed a marked improvement in European health - average life expectancy steadily increased, there was a sharp decline in infant mortality and between 1930 and 1960 there was a 400% increase in health spending.

Developments within the UK

As in Europe, an increase in population growth in Britain (4) paralleled the advance of industrialisation and urbanisation – factors that were to emphasise the division between rich and poor and highlighted the features that contributed to higher morbidity and mortality. It may be argued that, despite advances in medicine and technology, these characteristics remain within contemporary society.

The *Poor Law Commission Act* of 1834 and its *Poor Law Amendment* had declared that all relief should be confined to the workhouse where conditions should always be “less eligible” to recipients than those outside. There was no unemployment benefit, sick pay, compensation or relief, except that provided by the workers themselves via friendly societies and trade unions. In the case of sickness – this had been on the periphery of the Poor Laws for centuries. Frequently the problem had been left to private enterprise where provision was often disordered and uncertain. There was a failure to appreciate the relationship between public health and the health of the people. *The Poor Law Act* of 1601 had instructed the parishes to obtain “competent sums of money” for the relief of the old, blind and lame. In towns there were voluntary hospitals (some dating from the Middle Ages) and the trend to minimise numbers inside workhouses now increased (5). Consequently out-door medical relief was encouraged and workhouse sick bays developed into something akin to general hospitals. Local authorities also began to provide hospitals for the destitute sick. By the end of the Nineteenth Century responsibility for the sick-poor was divided between local authorities, voluntary organisations, Poor Law guardians and District Medical Officers.

Public health now lay in the hands of approximately 1,800 local authorities with 1,000 isolation hospitals and other institutions, together with 1,380 full-time Medical Officers of Health and several thousand sanitary inspectors. There was an annual wastage of 30,000 lives and 60,000 unnecessary cases of sickness as a direct result of the prevailing sanitary conditions. The financial cost to society was estimated to be £15 million *per annum*. The *Public Health Act 1848* consequently proposed the establishment of a Central Board of Health. This emanated from Chadwick's report of 1842 to Parliament (6). Slowly the social reform movement gathered pace – the result of working class agitation and organisation together with the work of humanitarians such as the factory owners (e.g. Owen and Fielden), aristocrats and landowners (e.g. Shaftsbury) and medical practitioners and administrators (e.g. Simon and Chadwick).

During the period 1860-1880 Rumsey and Chadwick championed the cause for a united state medical service but their efforts were largely unsuccessful. Secure in their private practices, doctors scorned state medicine. By the turn of the Century state services had become confined to the comparatively lowly tasks of controlling infectious diseases and poisons. Other aspects such as sewage disposal, the protection of water supply and the prevention of food adulteration, were passing to the newly developing “paramedical” services – staffed by engineers and laboratory technicians. From 1860 and for the next sixty years, the medical profession became gradually wealthier, enjoyed higher status and adopted a more conservative ideology.

At the end of this period, Lloyd George's *National Insurance Bill* represented the direct forerunner of the health and unemployment legislation lying at the heart of the

welfare state. Part I of the Bill provided for a system of insurance against loss of health and unemployment (7). Hospital services were free in cases of real poverty, but entailed assessment of means and payment accordingly. Becoming law in December 1911, there was much opposition towards the Bill from the medical profession. There was final agreement to a capitation fee of 9 shillings for each insured worker (8). By 1930, 12 million people were insured and unemployment benefit cost £110 million with contributions amounting to only £30 million. Many had to revert to charity or the Poor Law, which was still governed by the harsh principles of the Nineteenth Century.

The Poor Law Board now became the Public Assistance Authority and applicants were expected to exhaust their personal savings prior to obtaining relief. They also had to undergo the rigours of a household means test (9). The restriction of welfare benefits to working heads of households (i.e. males) continued to be a source of aggravation. This state of affairs resulted in concerns being voiced in 1934 regarding the effects of prolonged economic depression. Avoidable ill health amongst housewives and other women workers were attributed to the lack of medical facilities and an absence of available treatment. It was further agreed that the provisions of the *National Health Insurance Act* should be extended to all insured women and that a national maternity service should be introduced.

Despite the efforts of the labour government in 1948 to provide health and welfare services free of the stigma of the Poor Law, there was much in the public perception which retained state aid within the concept of charity to the poor and needy. Inequality with respect to access to health care, distribution of health needs, quality of

medical care and morbidity persisted and exacerbated apathy on the part of the disadvantaged. There remained also the relationship between state contribution, capitalist production and collective consumption. The heaviest demand for NHS resources came from the non-working population – the old and the young (and still does). The NHS is therefore “consumption” rather than “production” orientated. Perhaps rather than searching for distant origins of the welfare state and health service and drawing conclusions about their relative success or otherwise, one should accept the philosophy expounded by Titmuss that there is no finality in the social process. After all, the likes of Chadwick, Booth, Hill, Rowntree, Beveridge, Bevan, the Webbs and Lloyd George, were not building a marble monument called “Society” - they were helping to create a legacy which sought to provide decency, health, citizenship and fairness.

The Act of 1929 had merged the Poor Law into local authority services. The merger had proven to be straightforward with respect to maternity and child welfare, special services and tuberculosis, but the hospitals were more problematical. Although the *Public Health Act, 1875* had empowered authorities to provide general hospitals, few had done so – most preferring to award grants to voluntary hospitals. The advent of war in 1939 represented a testing time for the Ministry of Health and by this time approximately 60,000 beds existed in 400 hospitals and institutions provided under the Poor Law, 70,000 in 4140 hospitals under public health control and some 77,000 in voluntary hospitals. Much of the accommodation was antiquated and of low standard and in 1937 the *Voluntary Hospitals Commission Report* paved the way for regionally organised hospitals under the NHS. (Half a century later, the hospital sector was to account for approximately 75% of health care expenditure).

Even as late as the 1930s, one in fifteen children died before reaching the age of eleven years. Life expectancy was only approximately sixty years. Poor housing and malnutrition persisted in contributing to fatal diseases such as diphtheria, polio and scarlet fever for which there were few effective treatments. For the poor there was little support except for the so-called “wise-women”. These administered home duties such as delivering babies and laying out the dead. Remedies at the very least were dubious – earache was thought to be remedied by placing a table-spoon of warm urine in the ear, children with *pertussis* were instructed to stand near to gangs tarring the roads and to breathe in the boiler fumes. The recommended cure for bedsores was the white of an egg, stirred until frothy, with two teaspoons of wine and applied with a feather. Very few people over the age of forty years had their own teeth!

Following the initial shock of World War I the Government, mindful of the recent depression, began to consider reconstruction. The blueprint detailing the proposed structure of the NHS was published in the 1946 White Paper – the architect of which was Aneurin Bevan (Labour’s post-war Minister of Health). The proposals were met with vehement opposition, primarily from the medical profession (10). By 1962 Enoch Powell’s *Hospital Plan* resulted in most of the NHS financial investment being made on district hospitals. Changes in clinical science were requiring changes in the design of Out-Patient Departments while radiology and pathology were increasing in importance. On July 5th 1948, the *National Health Service Act, 1946* was finally implemented. Of 3,040 voluntary and municipal hospitals some 2,688 were taken under state control and an enormous burden of worry was lifted from the sick.

The UK National Health Service and the Expansion of Medical Laboratory Sciences

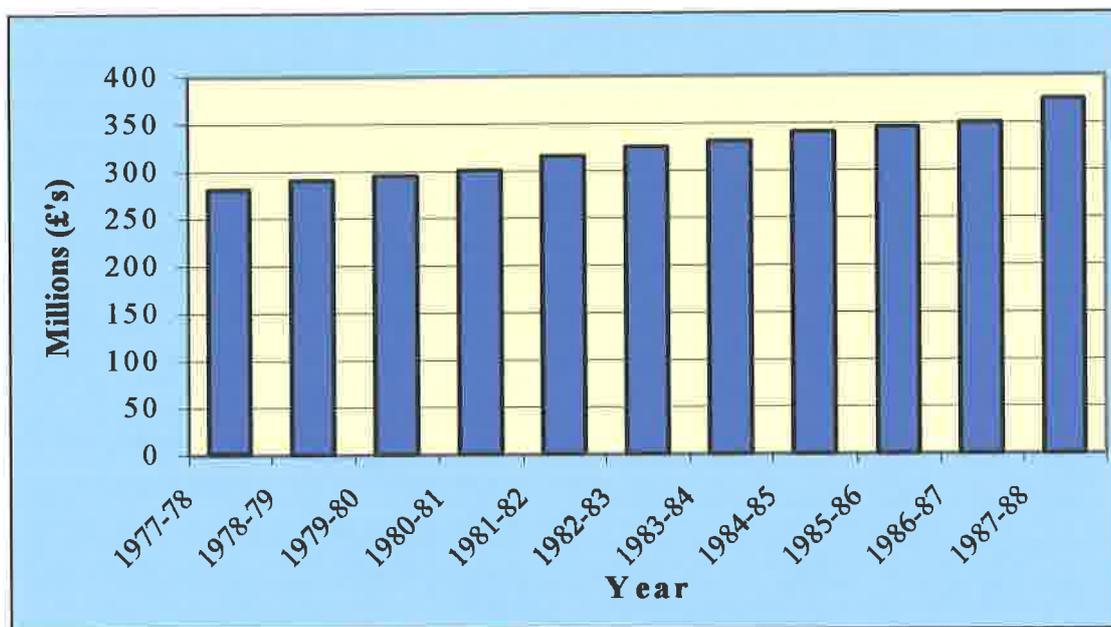
At the beginning of the Twentieth Century, preventative health care measures had become a focus of attention since losses in the Boer and Crimean wars had highlighted the poor health of soldiers. More had died from fevers and typhoid than through warfare. Later, the period following World War II witnessed the comprehensive reorganisation of social services in the UK. This included not only the local authority welfare services, but also the education system, housing and the Health Service. The principle of a comprehensive system of medical services, available to all and independent of national insurance was introduced by Aneurin Bevan in July, 1948.

Historically the organisation of the NHS reflected the development of the various branches of the medical services. In order to establish a unified hospital system both voluntary and local authority hospitals had to be integrated with Regional Health Boards responsible for their administration. By the early 1970s there were fifteen regions in England and Wales and five in Scotland. The daily management of groups of hospitals was the responsibility of Hospital Management Committees (the Boards of Management in Scotland). The GP medical, dental and ophthalmic services, together with the supply of subscription drugs, were managed by executive councils within each Local Health Authority. The latter were then to lose control over their hospitals but retained maternity and child welfare services together with midwifery, health visiting and home nursing services. They also kept responsibility for vaccination, care of the mentally ill, care of the blind, sufferers of tuberculous and ambulance services.

The separation of GPs from hospitals reflected the growing specialisation of medicine. Within the new Health Service the hospitals were the dominant element. At the outset the hospital sector absorbed 54% of available funds and this reached a peak of 70% by the mid-1970s. The birth of the NHS coincided with the advent of the golden age of high-technology medicine. The capacity of hospital medicine was being transformed in the late 1940s by the widespread availability of natural and synthetic antibiotics, more reliable blood transfusions, the development of anticoagulants and more refined techniques in diagnostic pathology (see Chapter 2).

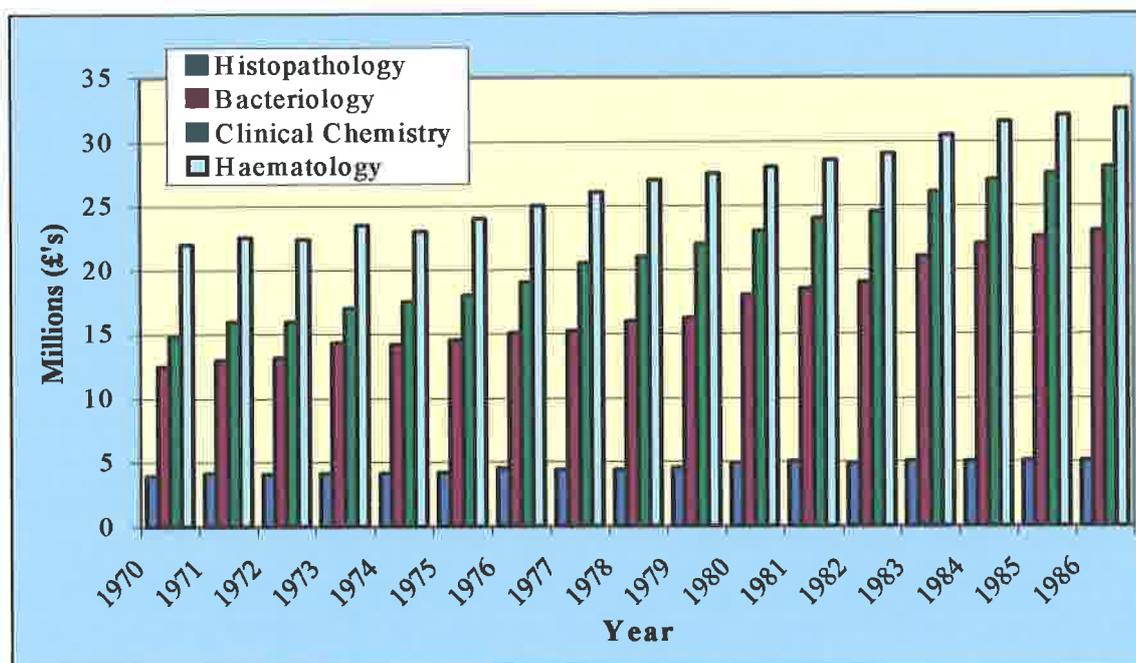
During the first decade of its conception, specialisms in support services such as pathology, radiology and anaesthetics had become an integral part of the NHS. Between 1949 and 1964 significant increases were being achieved in the quantities of blood supplied by the Regional Transfusion Services and there was a mushrooming of diagnostic tests (aided by innovations in automated testing procedures) in haematology, bacteriology, biochemistry and histopathology. This expansion continued into the 1970s and 1980s (see Figures 4.3 and 4.4). Following the advent of the NHS the quantity of blood issued to hospitals had increased by 265% in 1967, whilst the total population of England and Wales had increased by 12%. The next fifteen years saw a 66% rise in the numbers of consultant and nursing staff, hospital medical staff numbers doubled and professional and technical staff increased nearly three-fold.

Figure 4.3 Pattern of Real Expenditure in Pathology within the UK (1977/78 - 1987/88)



Source: Stocking, 1993.

Figure 4.4 Number of Pathology Tests (Millions) in the UK (1970-1986)



Source: Modified from Stocking, 1993.

The National Insurance Act, 1911 had made no provision for pathology tests and although “panel patients” had free access to GPs, pathological investigations carried a fee. The very poor were provided with some free services, (usually through the voluntary hospitals) and a few county councils established their own laboratories with each of the four major disciplines being represented. These were substituted by many private and commercial laboratories offering postal services but without consultancies. The net effect was the delay in the establishment of laboratories in large provincial hospitals.

In 1927 the Association of Clinical Pathologists (ACP) was formed largely in response to concern regarding the proliferation of commercial laboratories and a lack of supervision by qualified pathologists (11). The ACP promoted the establishment of hospital laboratories in every large town throughout the UK. The major impetus for this provision stemmed from fears regarding the possible outbreak of war. Anxieties regarding the need to combat possible bacterial warfare prompted the recommendation by the Medical Research Council (MRC) in 1934 for the establishment of an Emergency Public Health Laboratory Service (EPHLS).

Four years before the start of hostilities, the British government began planning for the treatment of war casualties and with the commencement of war the Emergency Medical Service (EMS) was established. For many clinicians this provided the first access to diagnostic pathology and increasingly blood transfusion became a concern for the ACP. Previously many members of the Association had organised independent services but the demands of casualties provided the impetus for a standardised national transfusion service. Initially because of official apathy,

facilities were restricted to the London area and organised by the MRC. By the summer of 1940 the first full-time Blood Transfusion Officers were appointed to regions outside the capital. At the same time a nation-wide pathology service, organised on a regional basis and sub-divided into specialities, was established under the supervision of "Group Pathologists".

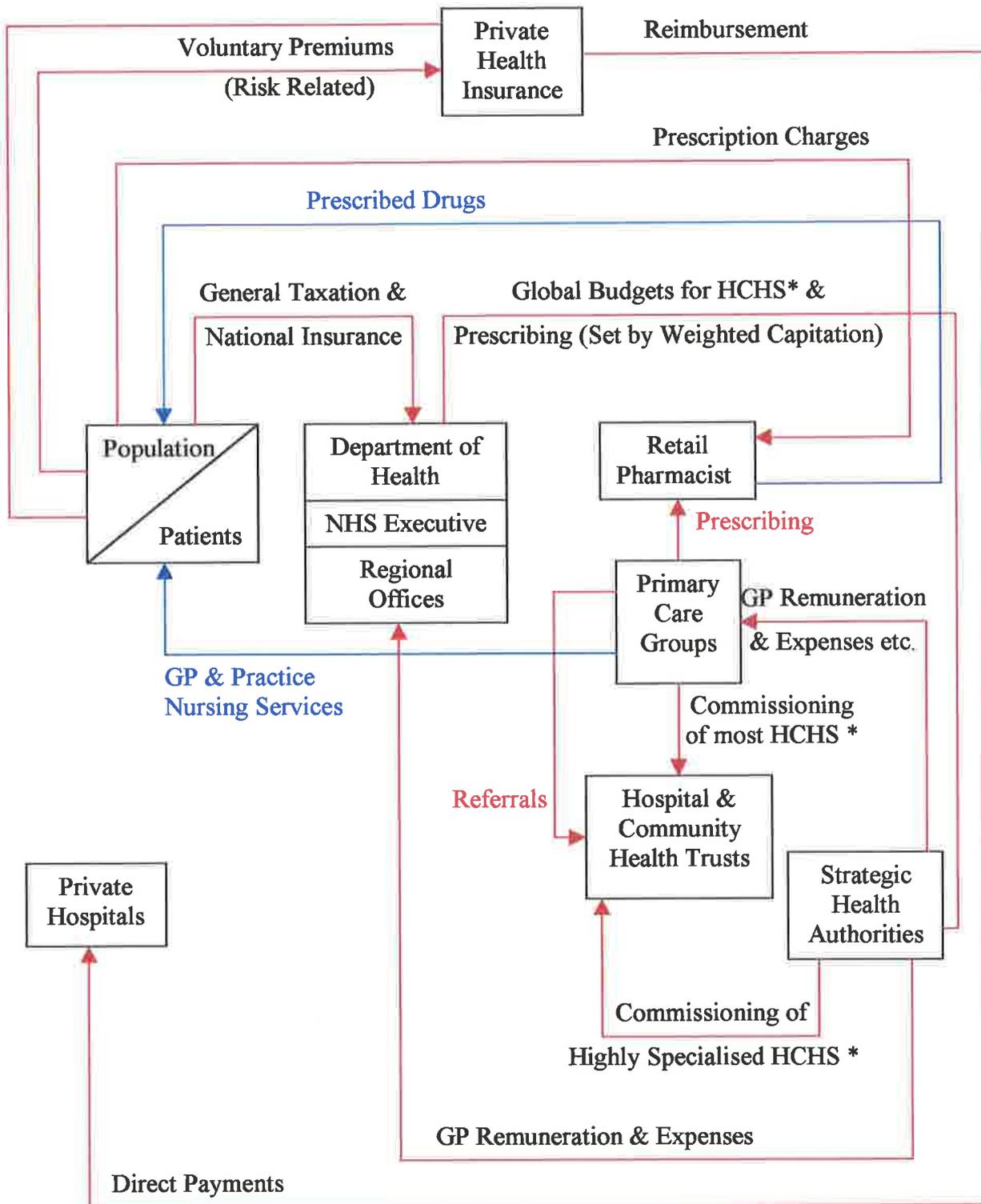
Practised in hospital laboratories, clinical pathology now included morbid anatomy and the provision of autopsies for coroners. Each region had a central laboratory, normally attached to a medical school with peripheral laboratories providing epidemiological work. These regional services were controlled by a committee of "Directors of Group Laboratories" with an elected chairman and a minority membership consisting of clinicians, public health officers and lay persons. Under the direction of the Ministry of Health the ACP also provided training programmes for personnel serving both in the EMS and the Armed Forces. The rapidly expanding laboratory service became increasingly dependent on the skills of technicians and scientists employed in the Health Service. On matters relating to their training and status, the ACP determined policy, rules and regulations and the curriculum content of courses. Between 1939-1948 the numbers of medical laboratory technicians had increased by 50% and during the period 1958-1968 the numbers of professional and technical staff in the NHS increased by 100% and by a further 70% in the decade 1971-1981. Despite this, hospital laboratories had a relatively low priority in relation to building and refurbishment, since houses, schools and wards were deemed to have priority. The strategic tiers introduced during the structural reforms of 1974 were partly an attempt to target funds towards local healthcare needs. This strategy was further developed in the government's "*Patients First*" report in December 1979. This

advocated the establishment of district health authorities, recommended the devolution of control and suggested concomitant improvements in accountability to the lowest possible levels. Two basic principles now formed the foundation for the functioning of the NHS – consensus management and strategic planning. Thereafter, inherent tensions resulting from the alleged undermining of strategy by the medical profession, together with demands for further funding, led to several additional reviews and reforms in the 1980s (12).

The NHS operates within a complex macro-environment, has intricate funding arrangements (see Figure 4.5) and is one of Europe's largest employers. The use of a Political, Economic, Social and Technological (PEST) model allows the identification of a broad range of influences that have shaped the demand and supply of medical laboratory sciences within the NHS during the 1990s (O'Hara, 1996) (see Figure 4.6).

A significant cultural change within the NHS followed the 1989 White Paper "*Working for Patients*" which was subsequently to become law under the "*National Health Service and Community Care Act 1990*". As a result of the Act, the first wave of 57 NHS Trusts were introduced in 1991 and four years later these were the sole providers of all healthcare within the public sector. Under the scheme many GPs became fund-holders and were able to purchase healthcare from the NHS Trusts. In May 1997 the election of a new Government saw a political commitment to abolish the internal market.

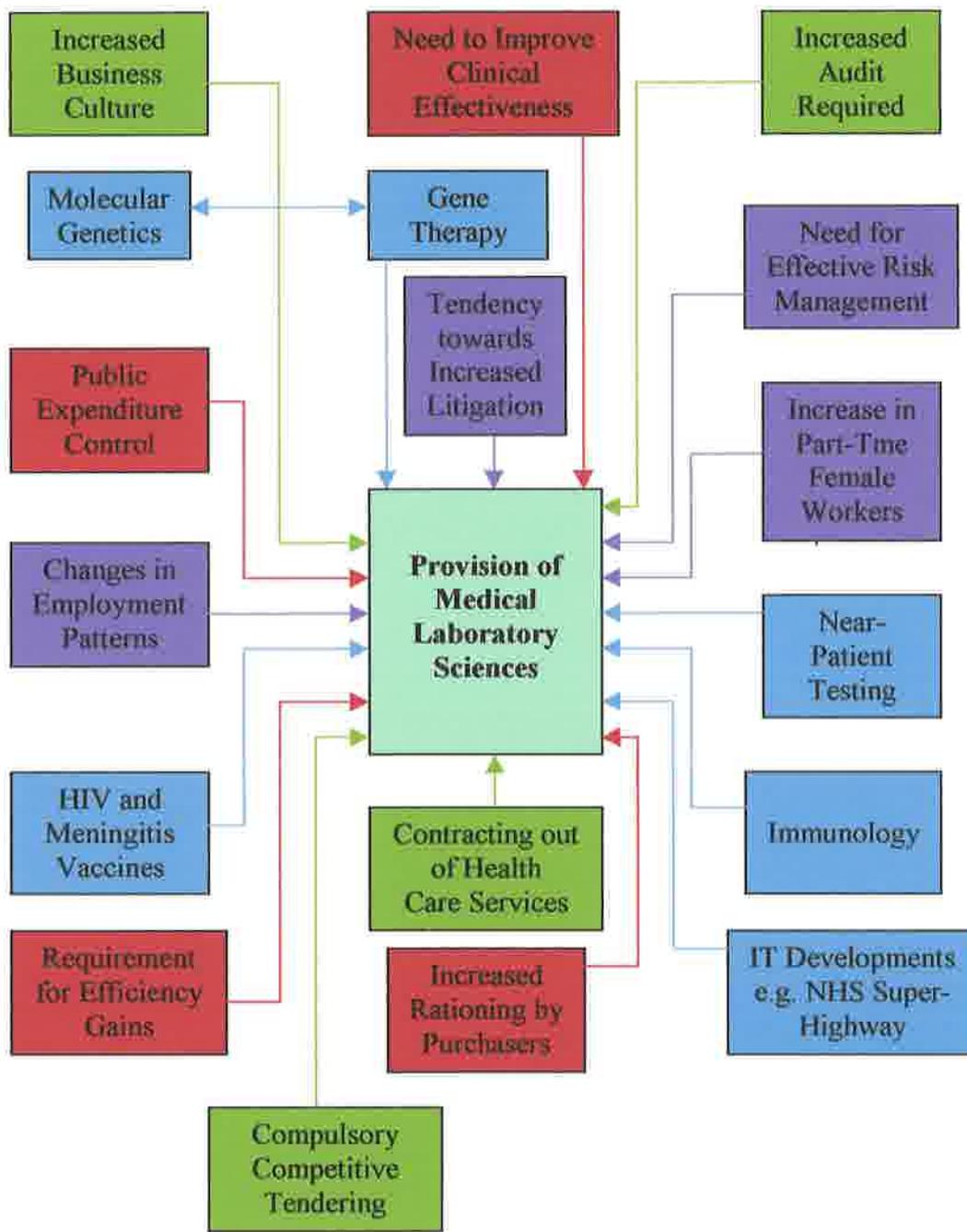
Figure 4.5 Funding of Health Care Systems in England (Post 1999)



* Hospital and Community Health Services

Source: Modified from Organisation for Economic Co-operation and Development (OECD), 2000.

Figure 4.6 Application of PEST Model to Diagnostic Laboratory Services within the Context of the NHS (UK)



Key to Influencing Factors: -



The White Paper "*The New NHS Modern, Dependable*" advocated the tenets of partnership and performance in the management of the NHS - competition was to be replaced by collaboration.

The introduction of the internal market was a result of the government's conviction that professions should be subject to managerial control and accountability and also that competition leads to efficiency. It was also a recognition of the structural plurality of the NHS. Consequently there was a move towards market testing, i.e. the contracting out of health care services including to some extent the tendering for a diagnostic pathology service (13). The inculcation of a business culture into the NHS also stemmed partly from curtailment of trade union power and the drive to make the professions conform to market economics. Such measures, together with increasing audit requirements, were attempts to ensure that local decision making processes could be compatible with increased public and political accountability. Private sector provision was also enhanced by changes in taxation policy. The granting of tax relief for private medical insurance and the introduction of the Private Finance Initiative (PFI) were further attempts to support NHS investment decisions.

Within the economic context, there has been an increasing trend towards the use of outcome research and health economics in order to measure the relative cost and clinical effectiveness of different treatments. Indicators such as "Quality Adjusted Life Years" (QALYs) have been used in an attempt to integrate quality, cost and outcome. In the UK such measures were taken against a background of political pressure to reduce taxes, high unemployment and demographic change, resulting in

increased dependency (see Addendum 4.1 for relative age changes in the elderly) and the need to service an insatiable demand for healthcare.

Following publication of the White Paper, the Labour government (faced with the prospect of Scottish and Welsh devolution) produced an additional White Paper for England called "*The New NHS*". This advocated the phasing out of fund-holding (and its two-tier healthcare provision), the devolution of budgetary responsibility to clinical teams, the establishment of contract negotiations between purchasers and providers and the introduction of quality initiatives (e.g. the National Institute for Clinical Excellence).

The Health Care Systems in Germany, Greece and Sweden

(a) Germany

With respect to health care, over 90% of Germany's residents receive services through the country's statutory health care insurance programme (*Gesetzliche Krankenversicherung*) (GKV) – with nearly universal access to comprehensive medical care and a choice of physicians. Membership of the programme is compulsory for all those earning less than a periodically revised income ceiling. The majority of the remainder receive health care via private (profit-making) insurance companies. All individuals use the same facilities irrespective of funding mechanisms.

Although national health care policies are largely specified by the federal government and the hospital sector is controlled by the *Länder* (see below), the health care system

is administered by national and regional self-governing associations of payers and providers (see Figure 4.7). These organisations have key roles in recommending policy details and negotiating the finance and provision of health care. Rather than being paid for through taxation, the system is largely financed by both compulsory and voluntary health care insurance premiums.

In 1993, the Health Care Structural Reform Act (*Gesundheitsstrukturgesetz*) (GSG) was introduced. Effectively this marked the end of a period that saw the ever-increasing provision of benefits and services under statutory public health insurance payments. The Act allowed an equalisation of contribution rates across all sickness funds by authorising payments to funds burdened with health risks associated with age and gender. It also allowed the development of a more sophisticated reimbursement method for hospitals (previously there had been a simple system of *per diem* payment rates) (14).

In 1986 the *Land* governments assumed sole responsibility for hospital policy making. The *Länder* own and partially finance medical school hospitals and accredited teaching hospitals. They also enforce accreditation and licensing of health facilities and of health professionals working in social services.

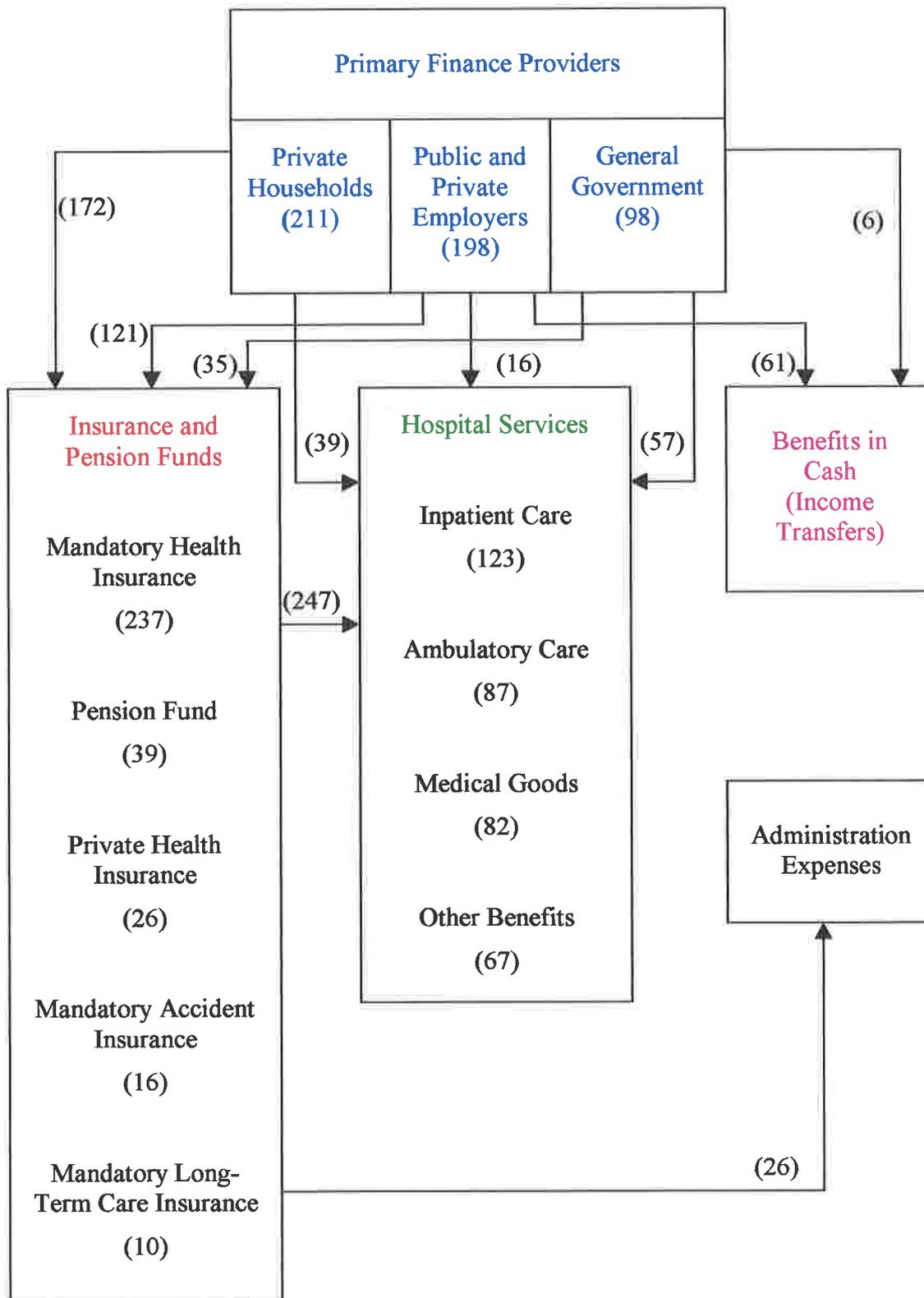
By the early 1990s there were 3,590 hospitals in Germany, 3,104 in the west and 486 in the East . These were of three types – public, non-profit and private for-profit – each accounting for about one-third of the total. There is a sharp distinction made between hospital-based and office-based physicians, the latter group acting as gatekeepers for specialist referrals and hospitalisation. In 1993 there were more than

266,000 physicians working in the German health sector (89,000 were office-based). Physicians were reimbursed on a fee-for-service basis according to a point value scale (German Uniform Evaluation Standard).

In 2000 the Federal Government introduced further reforms of the health care system primarily in order to ameliorate the growing costs. The most important aims and objectives of the reforms were to increase collaboration within the system, encourage new forms of care and treatment provision, promote counselling services, rationalise funding mechanisms, increase patient's rights and expand health promotion activities.

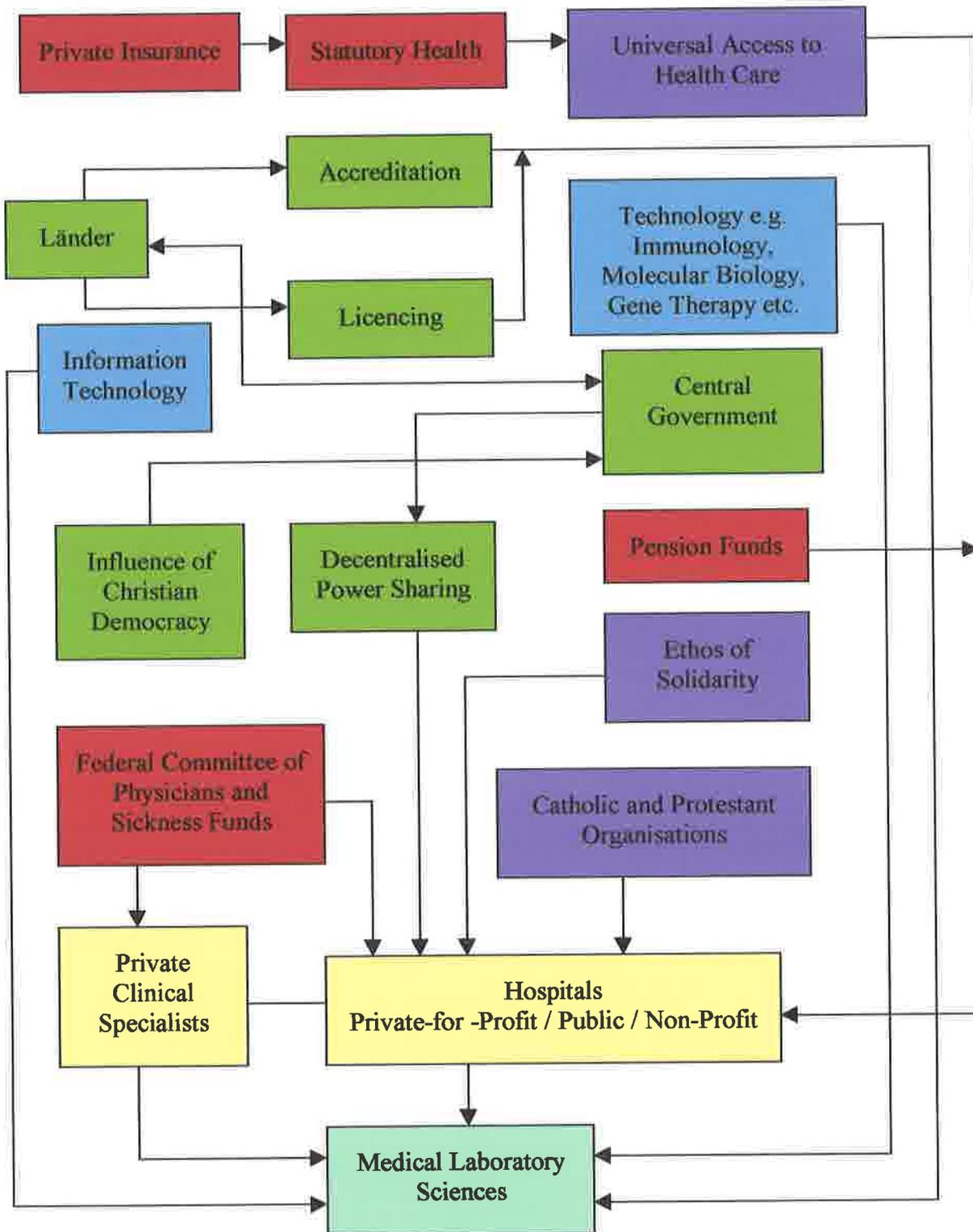
Diagnostic services for ambulatory patients, including laboratory tests, are largely defined and controlled currently by the "Federal Committee of Physicians and Sickness Funds". Between 1990 and 1998 there was a 38% increase in laboratory specialists amongst physicians contracted under the statutory health insurance scheme. An application of the PEST model to the provision of medical laboratory services is shown in Figure 4.8.

Figure 4.7 Finance Flows in German Health Care, 1995 (Billion DM)



Adapted from Federal Office of Statistics, 1998 (Not cited).

Figure 4.8 Application of PEST Model to Provision of Medical Laboratory Sciences in Germany



Key to Influencing Factors:-



(b) Greece

Having won their independence in 1830 the Greek population remained without any significant health care coverage for almost a century. Although the Ministry of Hygiene and Social Welfare was established in 1922, the level of care provided at the time remained rudimentary. Only a few municipal and community hospitals existed together with some state controlled larger institutions and some private hospitals. The year 1934 saw the first serious attempt by the government to increase coverage of the population with the establishment of the Social Security Organisation (*Ídryma Kinonikón Asfalíseon*) (IKA). Primarily aimed at protecting one third of the population (blue and white-collar workers), the scheme applied to organisations employing more than seventy persons. Temporary public hospitals were established in 1941 to serve the needs of war and in 1953 legislation was introduced to establish a National Health Service. The major aim was to decentralise health care to regional and local health councils and the legislation focused on providing a hospital and physician based system designed on the basis of a “needs-based” approach. In practice however the law was never implemented and the opportunity was lost.

The 1960s were associated with an expansion in the numbers of insurance funds coinciding with a period of rapid economic growth. Several financial institutions such as the banks established independent funds financed mainly by employer contributions. Public sector employees and the self-employed also gained access to social health insurance schemes. Approximately 50% of the Greek population were employed in the agricultural sector and in 1961 farmers and their families were provided with coverage for the first time when legislation established the Organisation for Agricultural Insurance (*Organismós Georgikon Asphelíseon*) (OGA).

But public health expenditure remained at less than 2.5% of the GDP. All insurance funds (with the exception of the IKA) continued to contract health services from private specialist clinics (in the case of primary care) and from private or public hospitals (in the case of secondary care). Private health care thus expanded significantly in terms of both physician and hospital numbers. The state continued to subsidise charity hospitals and only developed public sector hospitals in the larger cities.

Historically the development of the Greek health care system shows a continued loss of opportunities. During the dictatorship of 1967-1974 the first proposals for a National Health Service, aimed at harmonising the insurance fund regulations and the introduction of a single funding agency, were eventually abandoned. The need for health care reforms intensified following the restoration of democracy in 1974 and two years later a working party appointed by the Centre of Planning and Economic Research (*Kentro Npospammatiemy Kai Oikonomikōn Epeynōn*) (KEPE) identified the major problems and potential solutions relating to the Greek health care system (15). Once again – this time due to political and medical opposition – the plan was never implemented.

In 1981 conditions were ripe for a radical change. This coincided with the advent of the Socialist Party or the Panhellenic Socialist Movement (*Panhellinion Socialistiko Kinima*) (PASOK). Two years later the government introduced legislation to establish a National Health Service based on a comprehensive set of reforms (16) and in the early 1990s a new Conservative government introduced yet more changes.

These resulted in financial autonomy for primary health care centres and freedom of choice with respect to private practice for physicians employed in public hospitals.

The health care system then underwent a process of partial decentralisation. Although currently the lead institution in the development and financing of health policy is the Ministry of Health and Welfare, the structure of the NHS is based on the regional and district division of the country. In principle, the regions are responsible for planning and co-ordinating health care development but owing to lack of human resources (e.g. managers and scientists) the role of regional health councils has yet to be optimised. Figure 4.9 illustrates the organisational structure of the Greek health care system and the primary patterns of funding are shown in Figure 4.10.

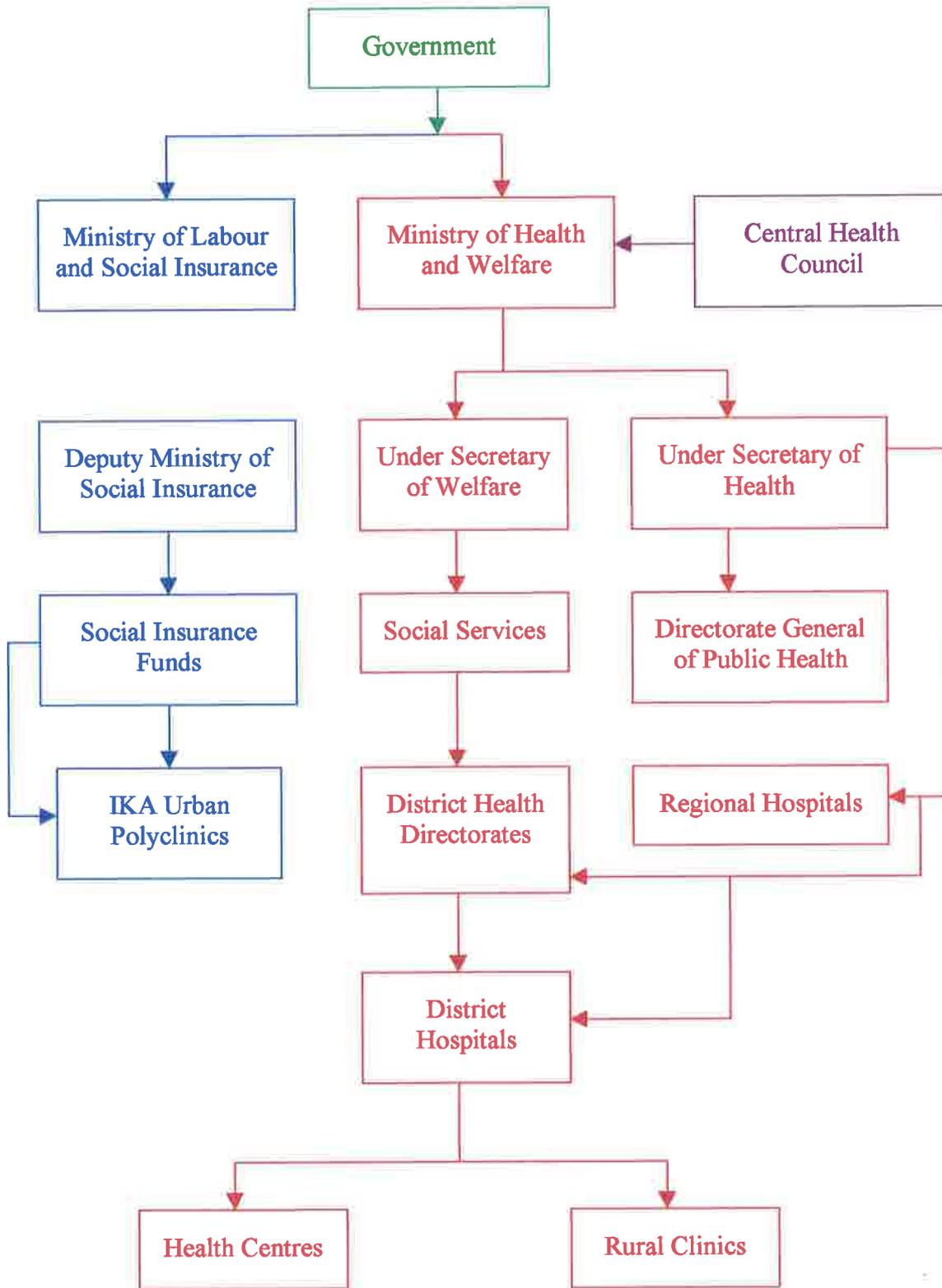
Under the current system, laboratory services are delivered by a combination of public and private sector provision. All three major insurance funds will pay towards the cost of diagnostic tests (e.g. TEVE contributes 75% of laboratory fees while the dependants of civil servants have 90% of their costs met). There is also a growing usage of private laboratories and medical clinics (currently approximately 200 exist) since there is a general dissatisfaction with public sector services. In addition there is an increasing tendency towards the use of voluntary health insurance (approximately 5-8% of the population) for meeting the cost of private laboratory tests. Most of the clinicians staffing the 176 rural health centres are either pathologists or paediatricians. Greece has received European Union (EU) structural fund finances for the upgrading or construction of 15 hospitals, a new National Blood Bank (the Greek blood transfusion system is the responsibility of the Directorate General of Health), together with the establishment of one central and five regional public health laboratories.

The Country's requirements for health care services are shaped by multi-factorial influences – some of which are specific to Greece. The nation has one of Europe's most rapidly growing ageing populations (see Addendum 4.1), a pattern likely to re-enforce the ethos of Southern Mediterranean welfare regimes based on the gender/family/work nexus.

There is also a growing proportion of immigrants from ethnic minorities who have specific patterns of disease, e.g. in the late 1980s it was estimated that 40,000 legal and illegal immigrants from Albania, Poland, Romania and Russia were resident within Greece. This factor has not yet however influenced statistics such as the incidence of AIDS within the country (24.8 new cases per million population in 1996 – a relatively low level) (WHO, 2000). The major causes of death are similar to those in Western culture and include malignancies, cerebrovascular disease, accidents and cardiac disease. With the exception of hepatitis, infectious diseases are no longer major health problems.

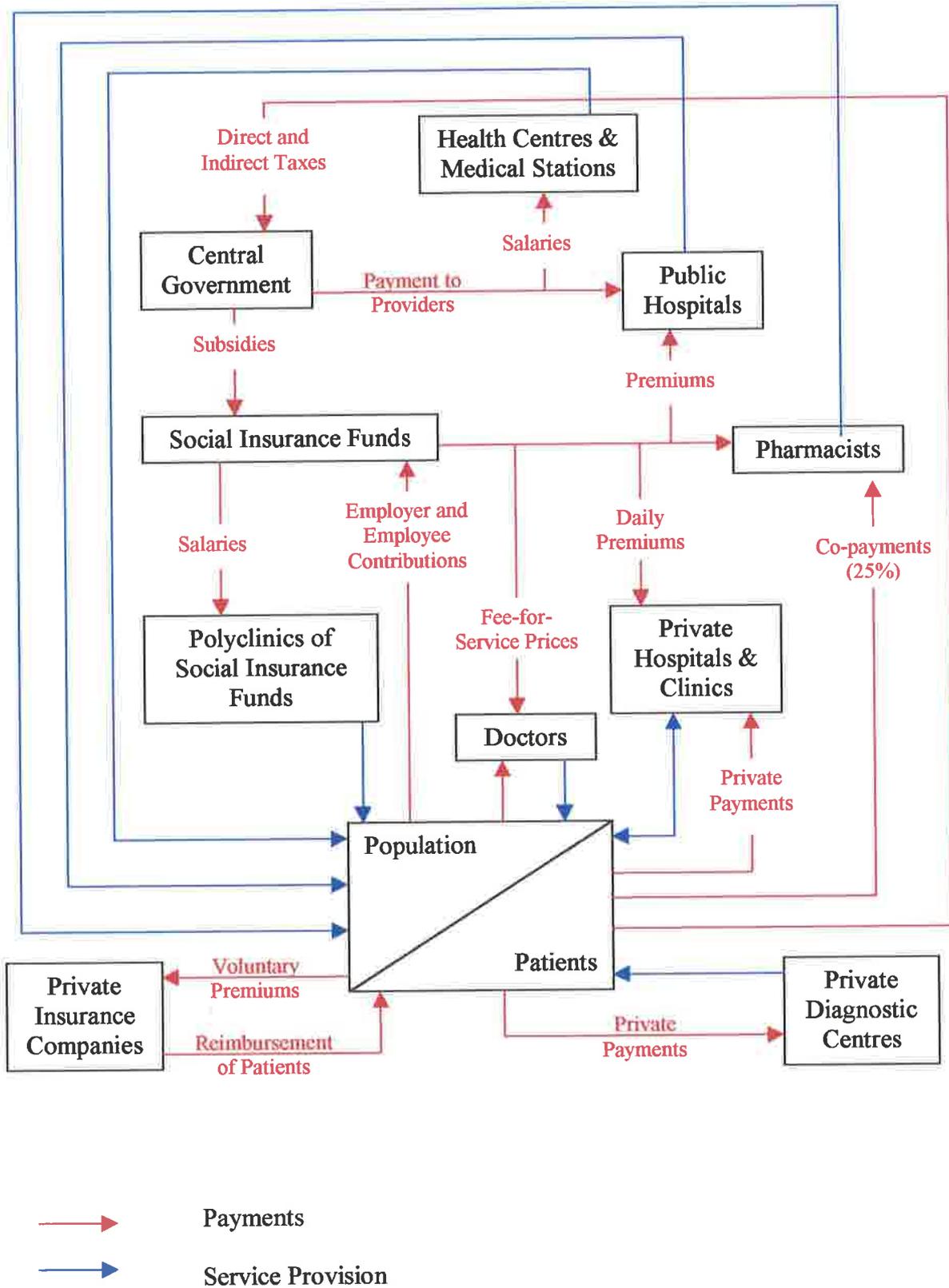
The main emphases of public health activities include public campaigns on nutrition, smoking, AIDS, diabetes and thalassaemia (5 prenatal screening centres exist for the latter). Seasonal health problems, most notably pulmonary conditions, are associated with air pollutants especially in Athens (17). Figure 4.11 illustrates the application of the PEST model to the provision of laboratory diagnostic testing in Greece.

Figure 4.9 Organisational Structure of The Greek Health Care System



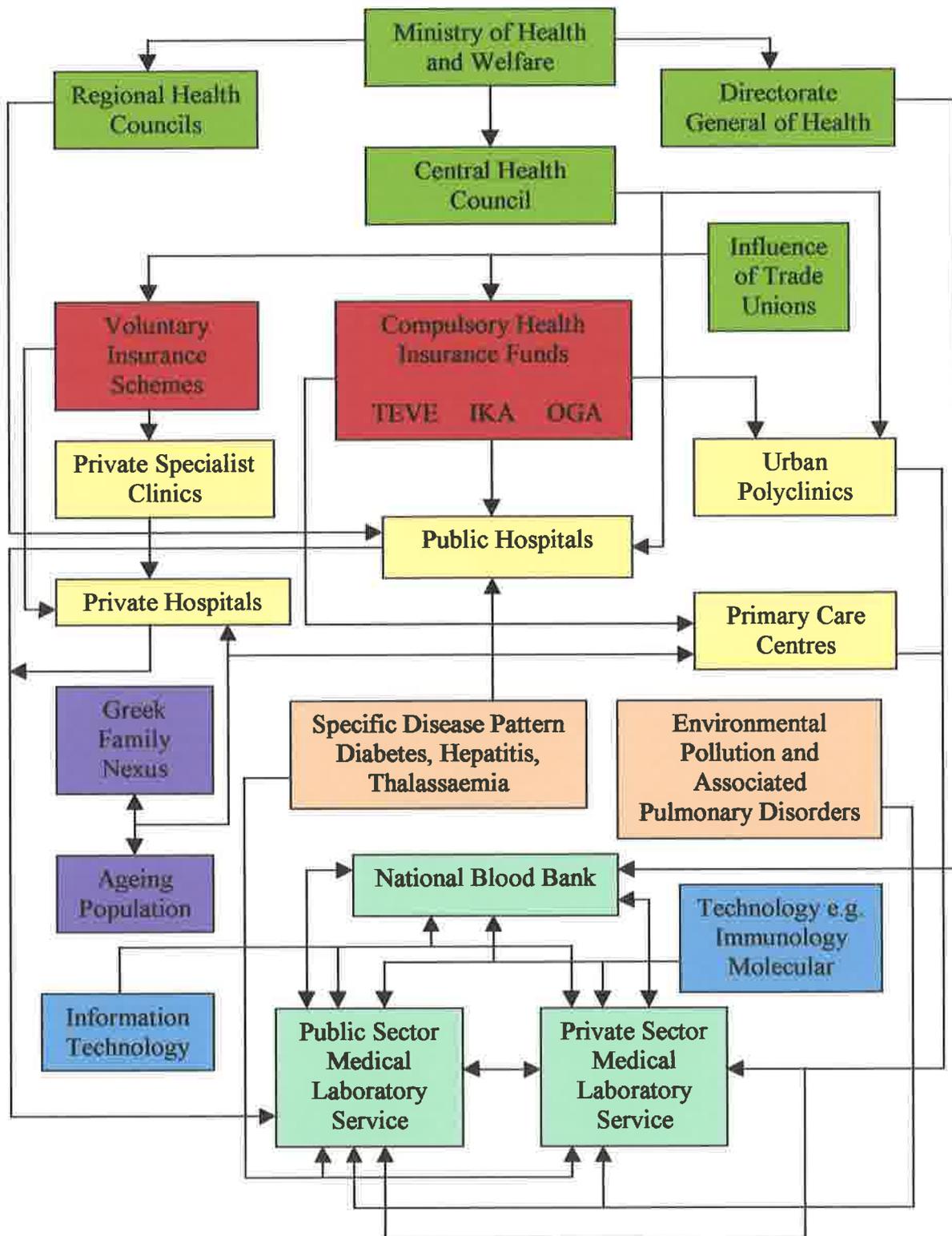
Adapted from WHO (2000).

Figure 4.10 Health Care Finance Systems, Greece, 1999



Source: Adapted from OECD, 1990.

Figure 4.11 Application of PEST Model to Provision of Medical Laboratory Sciences in Greece



Key to Influencing Factors:-



(c) Sweden

Sweden's health care system has its roots in the early 17th Century when physicians were employed by towns and cities to provide public primary care. Within the provinces such provision was delivered by physicians employed by central government. The country's first hospital (the *Serafimerhospital*) was established in Stockholm in 1752 and its eight beds were intended to meet the needs of the whole population of Sweden and Finland! Since then the provision of health care has been predominantly a public responsibility. Originally this was the remit of central government and its administration was carried out by the *Collegium Medicum*. In 1813 the Board of Health (*Sundhetscollegium*) took over responsibility. (In 1878 the *Sundhetscollegium* became the Royal Medical Board and in 1968 was transformed into the National Board of Health and Welfare. This remains the body responsible for supervision of health and social services). By 1865 there were 50 hospitals with a total of approximately 3,000 beds. No outpatient care was provided and each institution had only one physician with between 10-30 beds. By now County Council (*landsting*) administrative units had been established, given power to levy taxes and health care became one of their principal duties. This transition marked the beginning of the present strongly decentralised structure of the Swedish health care system (see Figure 4.12). With the *Hospital Act, 1928*, hospital care became the legal responsibility of the County Councils and during the 1930s these took over responsibility for the provision of services such as district nursing, midwifery, maternity and paediatric health care. Less than one in three physicians held a hospital post at this time and ambulatory care was offered mostly by private practitioners in their own offices. An important step towards universal coverage occurred with the

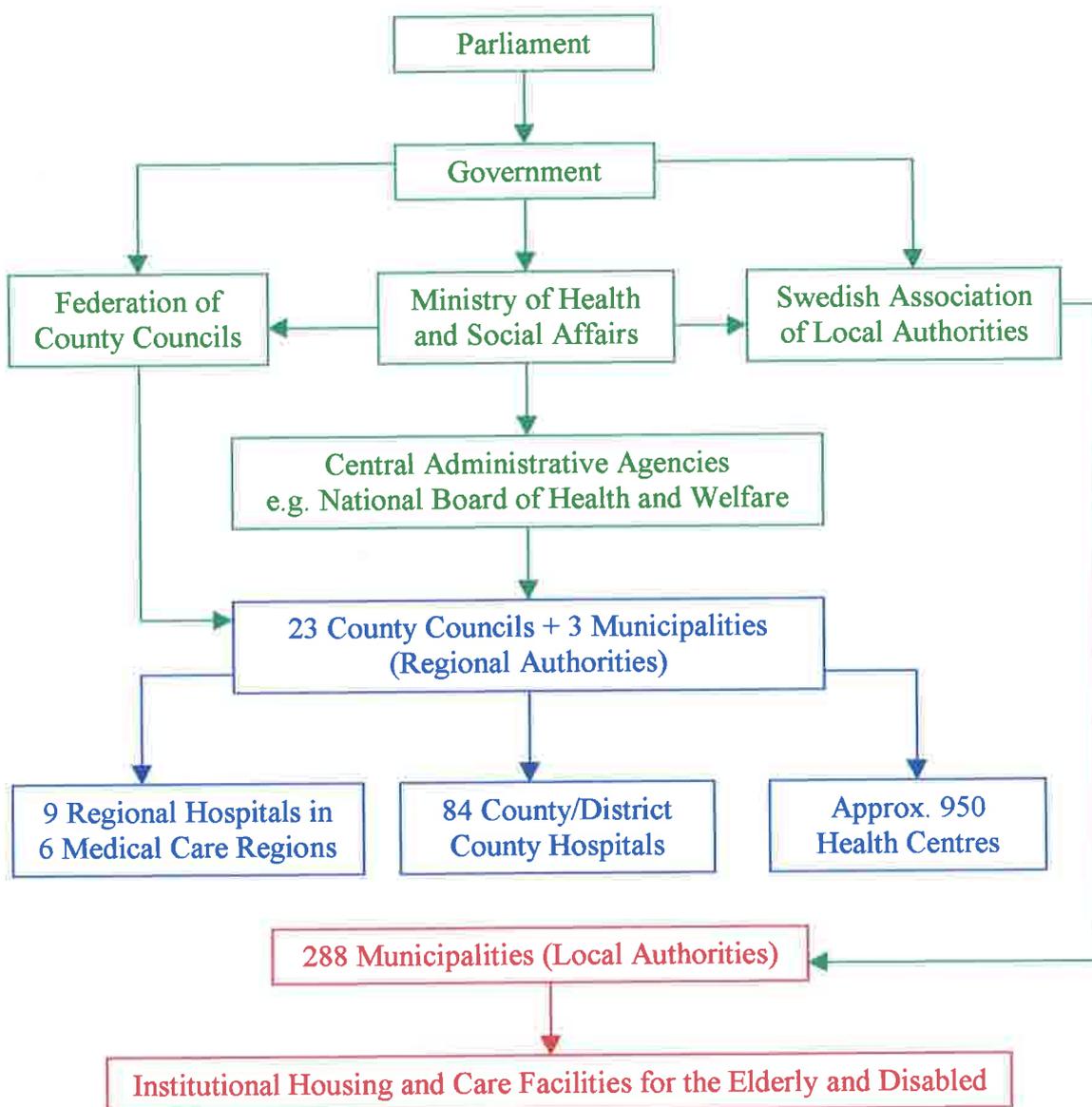
introduction of the *National Health Insurance Act, 1946*. This Act also provided for prescription drugs, sickness compensation and physician consultations.

Following World War II there was considerable expansion of the health sector and during the 1960s and 1970s the health care delivery system became more hospital based. Responsibility for all health care was decentralised to the county councils during the 1980s (as a result of the constitutional reform in 1974) and this included both university hospitals (the Academic Hospital of Uppsala and the Karolinska Hospital of Stockholm).

The current health care system is regionally based, publicly operated and organised on three levels (national, regional and local). Sweden's National Health Service is predominantly publicly financed through taxation – primarily involving proportional County Council income taxes levied by each of the 26 counties. Approximately 77% of such funds are used for financing health care and these are supplemented by state grants, the national social insurance system, private expenditure (out-of-pocket flat fee payments at points of service) and private insurance (see Figure 4.13). By 1970, 6% of public funding was being invested in the hospital sector compared to the 21% of total public consumption in health and medical care. Hospitals were classified into two categories – those handling emergency and other serious cases (general hospitals) and those providing chronic patient care (nursing homes). Each county had at least one general hospital - some specialities, e.g. neurosurgery, plastic surgery and radiotherapy, being organised by County Councils in co-operation with seven health and medical care regions. Of a total of 151,500 hospital staff, there were 2,800 laboratory technicians (representing 1.85% of the total staff). Over the next two

decades there was a shift towards profit centred management in many of the services including pathology, e.g. by the end of the 1980s some 40% of Sweden's clinical chemistry laboratories were being managed as profit centres.

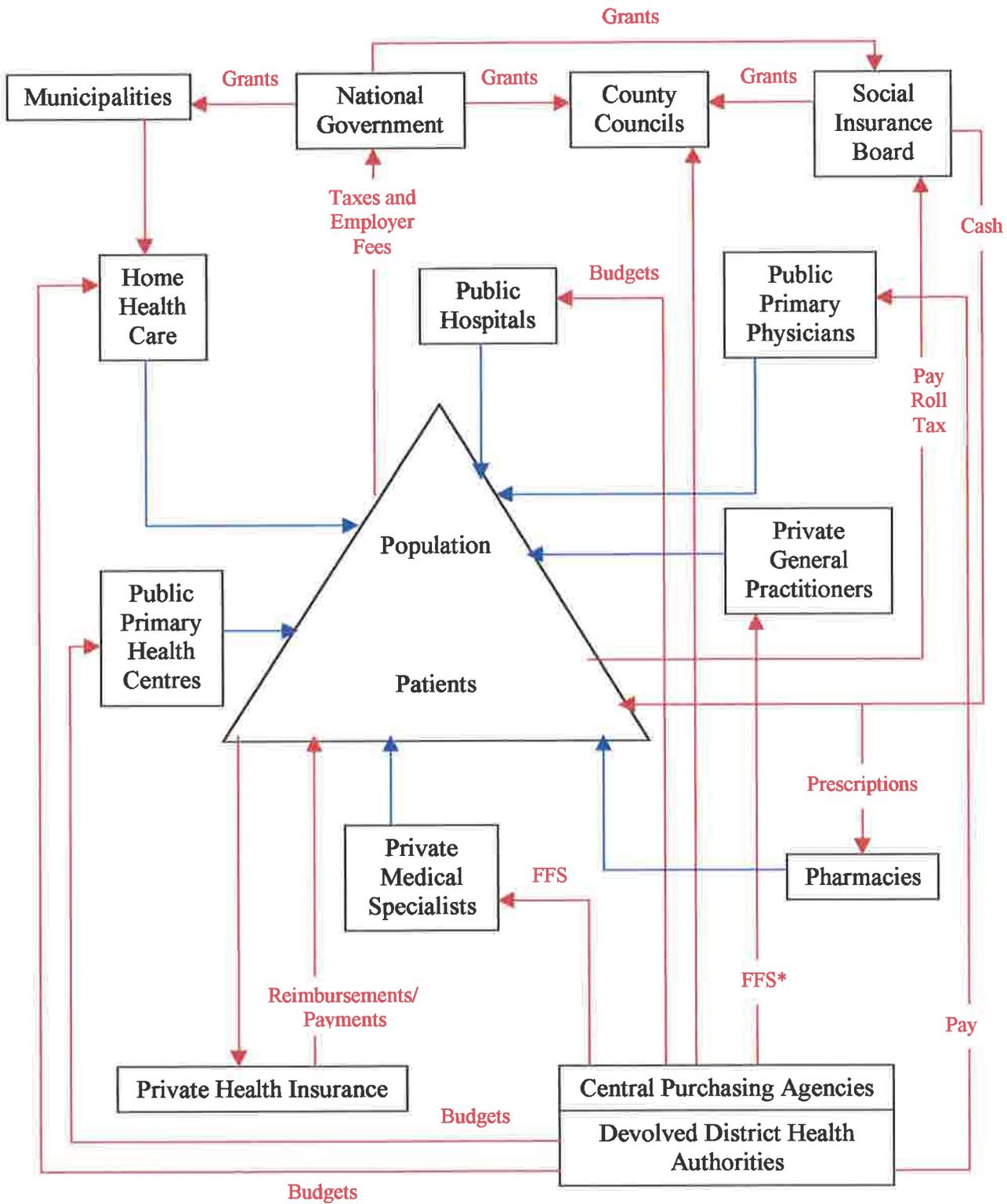
Figure 4.12 Organisational Structure of the Swedish Health Care System



Organisational Level:- **National** **Regional** **Local**

Adapted from WHO (2000).

Figure 4.13 Financial Flows-Health Care System -Sweden, 1999

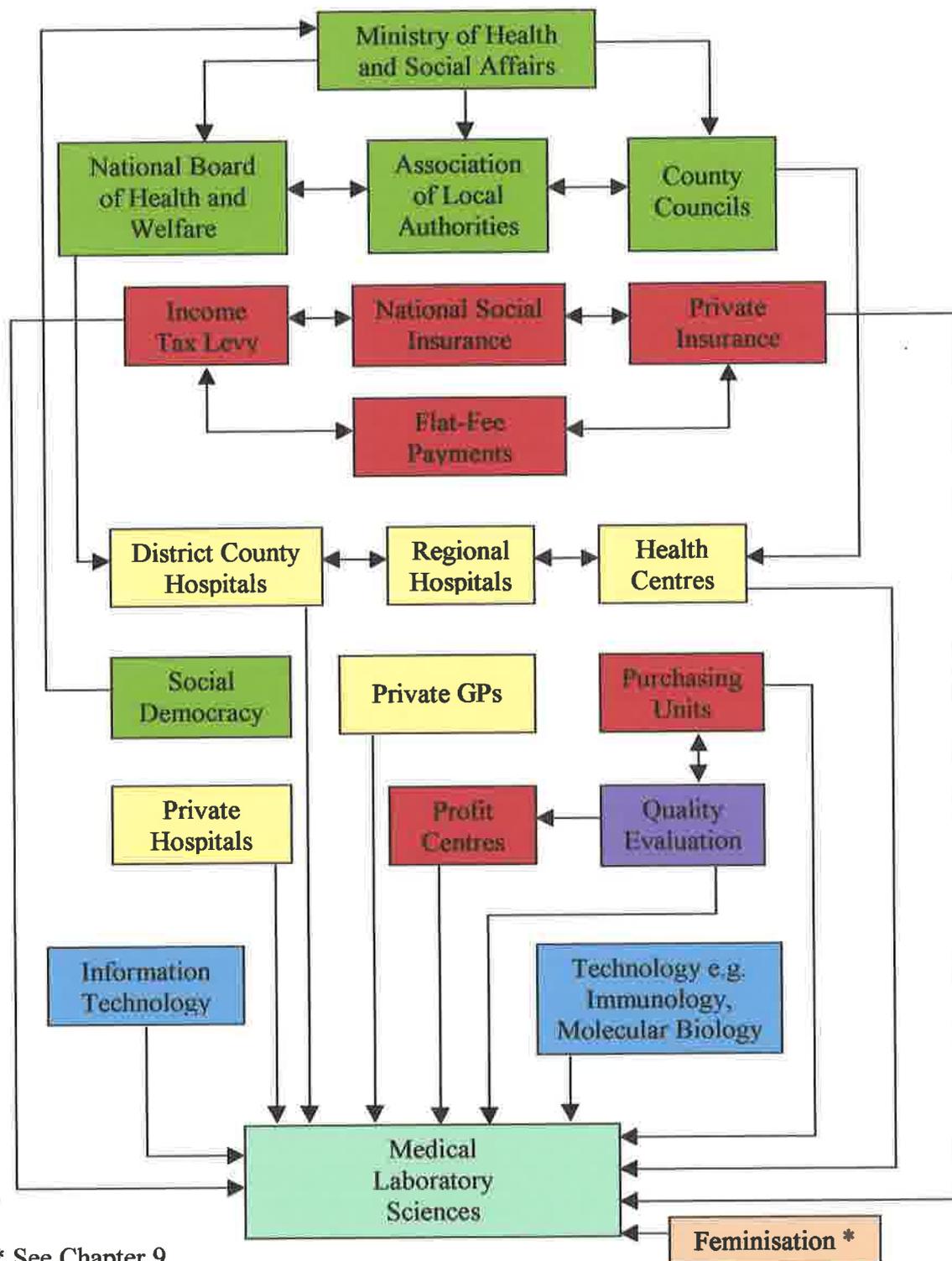


During the 1990s most County Councils introduced some form of purchaser-provider model into their medical services. Traditionally fixed annual allocations had been made to hospitals and primary care services – a system now partially abandoned. Performance related payments are currently made and competition with the private sector is encouraged in some Councils. The evaluation of quality and prices and the formulation of requirements are undertaken by purchasing units. Figure 4.14 illustrates the application of the PEST model to the provision of diagnostic laboratory services in Sweden.

Additional factors shaping diagnostic pathology services in Sweden include influences such as the growth of industrial capitalism and the feminisation of the profession. The MLS profession in Sweden has historically been dominated by females and this remains to be the case, with only approximately 6% of the workforce being male. The reasons for such a trend are predicated on political, economic and social grounds. Issues surrounding the influence of factors such as industrial capitalism, the role of the family nexus, the societal demands for the protection of women and the political requirements for economic constraint, will form the basis for some of the discursive elements of the concluding chapter of this work.

The fact that the profession of “medical laboratory technologist” is predominantly female orientated in many European countries is a reflection of the close alliance with the nursing vocation, the subordination of the technical aspects of diagnostic pathology to male dominated medical/clinical superiors and the division of labour characteristic of the professions allied to medicine.

Figure 4.14 Application of the PEST Model to Provision of Medical Laboratory Sciences in Sweden



Key to Influencing Factors:-



Conclusions

Irrespective of their type of health care service models, by the mid-1980s most of the countries within the European Community were spending between 7 and 10% of their GDP on health care. Greece (together with Spain and Portugal) was spending a significantly lower proportion. The health care *per-capita* expenditures for the four selected countries in 1987 are illustrated in Table 4.1 (Culyer, 1990) (Cochrane, 1994).

Table 4.1 *Per Capita Health Care Expenditure in 1987 (\$US)*

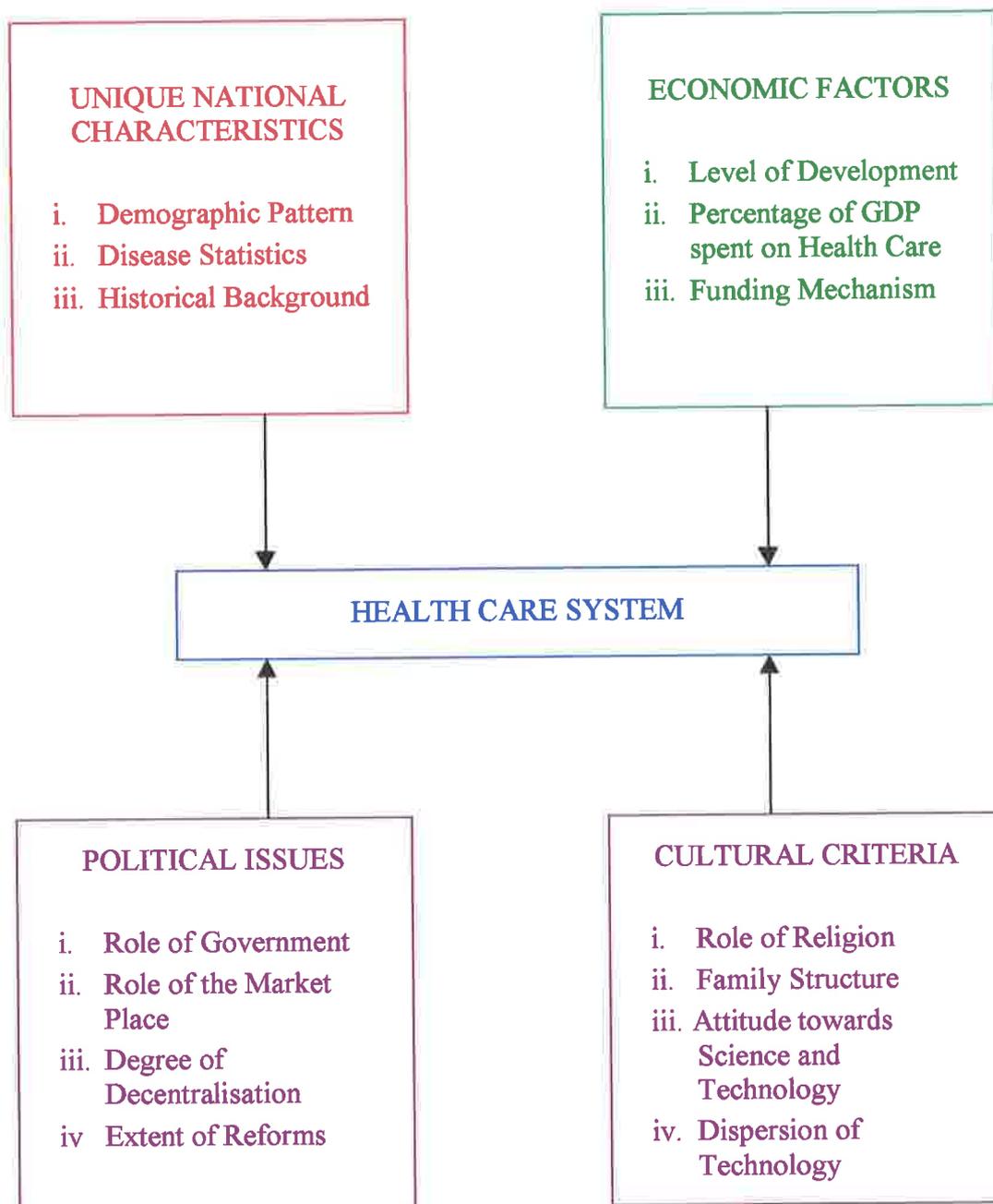
Country	Expenditure
Germany	1093
Greece	337
Sweden	1233
UK	758

Although there are diverse social and cultural conditions within each of the countries, a number of common factors can be identified. The population within each of the nations is ageing so that the proportion of “heavy users” of health services will increase (particularly in Greece). The cost of providing health care will, as a result, fall to a relatively smaller working population. There is generally a rising public expectation with respect to health care, while there is also a corresponding increase in costs (partly due to the use of increasingly sophisticated techniques). Cost containment is a shared concern and many of the reforms undertaken in each country have been attempts to curtail expenditure. Although health indicators are improving, there is likely to be intensified pressure on health services since there is little relationship between such indicators and health expenditure. Narad (2000) suggests

that the features influencing the shape of a country's health system are multi-factorial, some unique to a particular nation and others shared. Consideration of national patterns of health care described earlier allows the construction of a common model of health system determinants (see Figure 4.15).

Within the four countries considered there are differences with respect to the welfare models used and the mechanisms for both the provision and financing of health care. The UK, with a functionally "Liberal" welfare state, utilises a compulsory general taxation system and has a National Health Service characterised by structural plurality. Germany has a compulsory social health insurance scheme with a mix of payroll deductions and contributions from the private sector. Functionally described as "Corporative" its health care system has been influenced strongly by institutional factors and Christian Democracy. The country's principles of compulsory insurance, sickness benefits and free services are predicated on an ethos of solidarity and decentralised power sharing. Greece has a health care system financed by a mix of tax-based and insurance-based statutory financing, supplemented significantly by voluntary funding. The country may be considered to be in a transition phase from a predominantly insurance-based (Bismarkian) model to becoming a predominantly tax-based (Beveridge) system. The country's health care (and welfare) provisions have been shaped by influences (such as strong family tradition) peculiar to the Mediterranean nations.

Figure 4.15 Determinants of National Health Systems



Sweden has a functionally “Universal” health and welfare model and has been largely politically shaped by Social Democracy. Described as the “middle-way” the welfare system represents a mix of central planning and a free-market economy with the result that the country was severely affected by the economic crises of the 1970s. Sweden’s health care system is predominantly publicly financed through taxation.

The funding mechanisms for diagnostic pathology tests are reflected to some extent by such national differences, but in all cases there is a mixture of public and private provision. Recent developments within the UK have illustrated the influence of political, economic and social elements impinging upon diagnostic pathology services. Examples have included adverse publicity resulting from failings within the National Health Service Cervical Screening Programme (NHSCSP) (18) leading to the introduction of a national “Call and Recall” programme. It may be argued that, to some extent, this is an example of “expectational deficit” related to medical laboratory science. Cervical cytology screening is an inexact science frequently based on subjective assessment criteria – a weakening of public confidence in the ability of medical science to deliver accurate and reliable diagnostic tests will be an inevitable outcome. Additional adverse publicity such as the mis-diagnosis of cancer cases (Swindon), failure in cytology external quality assurance performance (Leicester), the issue of organ retention (Alder Hey) and poor recruitment and retention rates, has done little to champion the cause of pathology at the beginning of the new Millennium. The existence of a socio-scientific dichotomy results perhaps from a continuing failure of scientists to inform the public.

Analysis of the PEST models allows an evaluation of the extent to which the pattern of health care delivery systems are likely to affect the degree of harmonisation with respect to the provision of diagnostic pathology. The paradigms presented are relatively diffuse and reflect multi-factorial influences that shape health care provision and thus the delivery of medical laboratory sciences. Scientific and technological advances may be regarded as the delineators of public expectation with respect to diagnostic services, but the ability of governments to deliver health care are predicated on economic constraints. While there is little to separate the scientific/technological capabilities of the selected countries, it may be argued that with respect to the provision of diagnostic services, there is a degree of economic under-investment in the case of Greece (see Table 4.2). Within all countries the increasing financial burden of health care is forcing rationalisation of diagnostic services together with a requirement for efficiency gains. The introduction of a market economy (as in the case of the UK) and the need for improved clinical effectiveness will act as drivers towards increased selectivity of diagnostic provision.

A factor making against harmonisation difficult is the trend towards political decentralisation of health-care provision seen in countries such as Germany and Sweden – a pattern associated with an increased stratification of governmental control (see Figures 4.8 and 4.14). The influence of trade unions in countries such as Greece is shaped by peculiar national politics and may mitigate against greater harmonisation of working practices. The increased tendency towards near-patient testing adds an additional confounding tier to any attempt at greater cohesion of diagnostic pathology within Europe. The introduction and extension of internal and external (national) quality assurance measures (to encompass both central and peripheral laboratory

activities) will assist in the convergence of technical standards. Additional developments such as the accreditation of laboratories according to defined standards of practice and confirmed by peer review (19), will further assist in the construction of common standards of scientific and technical practice.

Having examined the influence of health care systems in shaping the past and future evolution of the profession, the next chapter will investigate the relationships between professional bodies and statutory authorities. The main aim will be to explore any degree of commonality that exists within the four countries, since such associations are likely to have a significant impact on professional harmonisation.

Notes

1. Developed in the USSR in the 1930s the Semashko system relied on relatively stable flows of state funds and provided free medical assistance at the point of delivery. With an emphasis placed on in-patient and specialised services, the principles of prevention and primary health care were often proclaimed. In practice however, little actual development took place within these areas. The emergence of dramatically new economic, political and social systems and the resultant economic crisis have had a significant negative impact on this type of healthcare system. Administration and central planning have collapsed, allocation of state funds is too small and there is an excess capacity (inherited over-investment) of acute care beds and personnel. In addition there is a critical shortage of drugs, diagnostic substances and vaccines, an inability to renew (and maintain) supplies and equipment, low salaries, poor morale and a lack of motivation.

2. The demographic revolution was associated with a surge in the European population, primarily during the 1800s. The total number of Europeans also expanded by approximately 50% to 450 million between 1870 and 1914. The primary reasons for this included an improvement in nutrition and a declining death rate from infectious diseases. At the same time the process of urbanisation quickened with cities such as London, Paris and Berlin seeing the sharpest increases. Despite this, most Europeans still lived in the country at the start of the Century, however the social influence of both the peasant classes and landed aristocrats diminished as European urbanisation and industrialisation increased. Concomitantly, urban middle classes gained political power in several Western European countries and the wealth of the *bourgeoise* increased. By 1880 the population of Europe was divided into states as small as Montenegro (population less than 250,000) and as large as Russia (population between 90-100,000,000). However 80% of Europe's population was to be found in six states - Russia, Germany, Austria-Hungary, England, France and Italy (Roberts, 1989). Between 1880 and 1940, Europe's population increased from approximately 320 million to 579 million (including the USSR) (Wood, 1972). Europe's population at this time represented approximately one quarter of the world's people, however there were geographical disparities - in fact in some countries the birth rate was declining and there were regional differences in fertility. Slower population growth was seen in wealthier countries and regions with an inverse relationship between natality and economic well being (see Roberts, 1989, p 23 for calculation formulae for natality rates). The overall increase in population occurred despite huge emigration, steadily dropping natality and enormous wartime losses. Additional factors helping to sustain population growth were:
 - (a) A sharp reduction in mortality rates largely as a result of decreasing infant mortality with more babies surviving their first twelve months - so that there was an excess of births over deaths.
 - (b) There was increasing wealth and consequently better feeding and housing, improvements in medical and sanitary science and advances against communicable diseases. Many of the great killers were mastered either by decreasing their prevalence or cutting down their case-fatality rates. Between 1901-1931, Germany had reduced its diphtheria rate from 39.1 to 6.4 per 100,000; England had reduced the typhoid and paratyphoid death rate from 15.5 in 1901 to 0.4 in 1941 (in other countries the reduction was slower e.g. in Spain the rate dropped only from 51.3 to 16.1 in the same period) and plague had virtually disappeared (apart from small outbreaks in Spain and Russia in 1899).
 - (c) Declining mortality rates meant people living longer - though again there were distinct regional differences e.g. in the 1880s the life expectancy of an Englishman was 43.7 years and for a Frenchman, a little over 40 years. By 1940 these had increased to 60.2 and 55.9 years respectively (compared to the underdeveloped countries this increase was significant e.g. in India life expectancy at birth was 23.6 years in 1881 and by 1910 had increased to just 26.9 years.

As a result of these factors, the populations of all six of the major European powers were getting bigger but at different speeds, e.g. between 1880 and 1910 population increases were:-

Country	% Increase
Russia	55
Germany	43
Austria-Hungary	35
Great Britain	26
Italy	24
France	5

3. Encapsulating the notion of comprehensive public protection (not only for the individual but also for the family) “from the cradle to the grave” against sickness, poverty, squalor, ignorance and unemployment, the report struck sympathetic cords across Europe. Only two years previously Britain had been struggling with the problems of Dunkirk. The fact that now the nation could countenance the provision of social services, public health, medical aid, pension and family allowances, unemployment insurance, improved public education and better housing caught the imagination of Europe.
4. Within the UK, population growth was influenced by a number of factors:
 - (a) An increased investment in capital together with a rising demand for labour.
 - (b) The expanding population led to an enlarged market for goods and supplying labour for their production itself stimulated capital investment.
 - (c) During the middle decades of the Eighteenth Century there had been an unexplained fall in the death rate, which had resulted in increased population trends in both urban and rural areas. Within the towns there was, for the first time, a substantial excess of births over deaths together with migration from the over-populated countryside.
 - (d) Economic factors resulted in an increased birth rate e.g. investment in industry, expansion of agriculture (into lighter soils for turnip and grain cultivation) and a boom in cottage building (associated with an increased size of farms). In addition, a premium was placed on large families by new industries.
 - (e) The balance of births over deaths was not punished by the high death rates associated with earlier epidemics – largely because of environmental factors. Most of these were associated with the new economy e.g. cotton clothes, cheap soap, (which killed typhus bearing lice), pottery and iron ware, houses of brick and tile, increased use of piped water, paving and draining and improved methods of inoculation against smallpox. Also, in addition to increased medical knowledge, there was the spread of hospitals, improved feeding of infants, and in nursing a changing age structure (i.e. the population was becoming younger – in 1791 individuals within the 0-29 year age group accounted for 56.7% of the population whereas by 1821 this had increased to 64.7%).
 - (f) The numbers reaching the age of marriage were getting larger in each successive generation. The high birth rate was being promoted by the Poor Law because it was a system of subsidising wages from the poor rates. In addition, increased medical assistance from the parish resulted in reduced infant deaths. Between 1801 and 1881 the population of Britain rose from 10.5 to 29.71 million. This rate of growth was to be maintained into the Twentieth Century and represented an average increase of 13.4% per decade.
5. In London, St. Bartholomew’s and St. Thomas’s had been founded in the Sixteenth Century whereas Guy’s was built in 1724 in order to relieve overcrowding at St. Thomas’s. By the end of the Eighteenth Century few towns were without voluntary hospitals, some with specialist functions e.g. the Middlesex was dedicated to smallpox and inoculation. Within the “lying-in” hospitals, the poor and Poor Law patients were subject to a fixed charge paid by the parish. These were occasionally associated with voluntary dispensaries where doctors saw their patients and dispensed medicines.
6. The report entitled “*The Sanitary Conditions of the Labouring Population of Great Britain*” was a damning indictment of living conditions in the larger towns and cities. As a result of

this, the *Public Health Bill* of 1848 required local health authorities to provide sufficient water for private and public use, public sewers and drainage systems, remove rubbish, control industrial smoke emissions and appoint inspectors of nuisance.

7. Relating specifically to health, Part I of the Act was based on the principle of compulsory contributions and included all males and females aged between 16-79 years of age and in normal employment. It also accommodated all those in non-manual employment earning more than £160 *per annum*. The Act also offered insurance on a voluntary basis to anyone else wholly or mainly dependent for their livelihood on some regular occupation and subject to an income limit of £160 *per annum*. Contributions from compulsorily insured workers were 4d per week, the employers contributing 3d and the State gave 2d. Voluntary contributions varied according to age of entry. Any contributor was entitled to enrol on the "panel" of any doctor who agreed to take part in the scheme. They were also eligible to receive free medical attention and sickness benefit (5-10s for men and 3-7s for women). The latter would run for 26 weeks followed if necessary by disablement benefit – normally 5s per week. Maternity benefit of 30s was also provided but apart from this, medical services and medicines were provided only to the insured worker and not his family.
Note:- Denarias (d = British penny; s = shilling)
8. Health insurance was extended by the Act of 1919 to those earning £250 or more per annum. This covered less than 14 million individuals while their dependants remained excluded. In the same year the Ministry of Health was established. Ten years later all hospital functions were taken away from the Poor Law and given to the major local health authorities. Part II of the Act was also extended in the following years and in 1920 the new *Unemployment Insurance Act* covered nearly 12 million workers. Eventually however the *National Insurance Act* failed largely because the temporary boom following World War I was succeeded by a severe depression. Overseas trade fell, profits declined, wages dropped and unemployment increased. By 1922 more than 1.5 million people were unemployed in the UK - many outside the scope of the *National Insurance Act*. By 1930 this had increased to 2 million and two years later to 3 million. The rate of unemployment rose to 20-30% in coal mining, iron and steel production, ship-building, cotton and textile manufacturing, public works and contracting.
9. The public mood became revolutionary, prompting demonstrations such as the Jarrow march there was increasing destitution and a total collapse of capitalist society with a backlash against life on the "dole", the indignity of the means test, the government's failure to provide homes and the squalor of slums. Thus were established the conditions for the General Strike of 1926. During the inter-War Depression the working classes in the Labour Party struggled for an increased share of national resources. The 1923 General Election had seen the introduction of the first Labour Government (a minority Party holding power by virtue of Liberal support) and the second Labour Government (now holding a majority) was brought down during the global financial crisis of 1931. Thereafter attention became increasingly focussed on Hitler's Germany and prior to the outset of War, the Labour leaders – for the first time in history – stood alongside the traditional governing classes. At this time of a national crisis with Labour sharing power, the whole concept of government and of the relationship between the working classes and the State underwent a significant change.
10. Cox, a former Secretary of the British Medical Association (BMA), perceived the proposals as something more suited to Nazi Germany, describing the White Paper as "uncommonly like the first step, and a big one, towards National Socialism". The BMA actively encouraged the storm of protest from its members and family doctors in particular thought that the proposals would "turn them all into state-controlled semi-civil servants at the beck and call of a medical Fuhrer". Bevan was vilified as a dictator and autocrat and called a "squalid nuisance" by Churchill. His plans to bring hospitals under state control were described as "the greatest seizure of property since Henry VIII confiscated the monasteries".
See Allen, 1998, p 240.
11. Instigated by Dyke and with approximately forty founder members, the stated aims of the ACP were to :-

- (a) Develop the application of pathology in relation to medicine and to protect the interests of those engaged in its study and practice.
 - (b) Secure clinical pathologists as being equal to other consultants.
 - (c) Encourage and assist medical schools and post-graduate education, so that suitably trained doctors could assume charge of hospital laboratories throughout the UK.
 - (d) Establish meetings where members could exchange views on their research etc. Members of the Association (originally called the British Pathologists Association) were motivated primarily by economic concerns. Recognising that the BMA had a fundamental role to play, a request was made to establish a Consulting Pathologists Group consisting of all BMA members practising pathology in institutional and private laboratories.
12. The most significant of these were:
- (a) The "*Griffiths Report*" published in October 1983. This advocated the introduction of general management into the NHS and the notion that professional groups should be subject to a similar degree of accountability and control as found within business hierarchies. However since clinicians retained their right of "clinical freedom", in practice managers still lacked influence regarding the spending decisions made by clinicians.
 - (b) The *National Health Service and Community Care Act 1990*. Resulting from a radical NHS review instigated by the Thatcher government, the Act introduced several internal market reforms from April, 1991. Essentially a "public contract" model of healthcare – this was similar to strategies being pursued within the global healthcare market. Within such a model, healthcare is funded nationally but delivered in a decentralised manner through a market economy.
13. Examples of private sector companies offering diagnostic pathology tests include "JP Diagnostics", the "Doctors Laboratory PLC", "SmithKline Beecham Clinical Laboratories" (involved in the joint co-ordination of blood transfusion and cytology services for the West Middlesex hospital) and "Unilabs" (participating in the automated analyses of clinical chemistry and endocrinology tests). Recently "Quest Diagnostics", together with KPMG (the accountancy and management consultancy company) have successfully introduced a PFI to supply pathology testing for the West Middlesex University Hospital Trust. The partnership is also bidding (March 2001) to supply pathology services to the Greater Manchester area (including the Rochdale, Bury, Oldham and North Manchester Trusts). An example of the enterprise culture within the NHS sector is the introduction of screening services (e.g. those offered by Queen's Hospital, Burton upon Trent) to assist Trusts struggling to clear cervical cytology backlogs.
14. The law required that four sets of costs be negotiated for each hospital:-
- i. Payments to diagnosis-related groups to cover the full treatment of any one case.
 - ii. Special payments for surgery including pre- and post-surgery treatment.
 - iii. Departmental allowances in order to reimburse the hospital for all medical and nursing procedures per patient per day.
 - iv. A basic allowance for all non-medical procedures (e.g. accommodation and food).
15. Amongst the major problems were:-
- (a) A lack of capital development within the public hospitals.
 - (b) Inequalities with respect to the geographical distribution of services - especially between urban and rural areas.
 - (c) Poor co-ordination between the Ministry of Health and other government institutions.
 - (d) A lack of harmonisation of finance and health care coverage.
 - (e) A system of payment that encouraged unethical practices and inefficiency.

As a result the report recommended the creation of a unified fund comprising the three major insurance schemes i.e. IKA, OGA and the Small Businesses and Trades Insurance Fund (*Tameio Emporikon Vionihanikon Epihiriseon*) (TEVE). This new fund was to provide cover for 85% of the Greek population.

16. These included:

- (a) A revised method of payment for health care providers with all staff being paid fully and exclusively by the National Health Service.
 - (b) A de-centralisation of the planning process and the establishment of a Central Health Council.
 - (c) The development of primary health care and a system of patient referral.
 - (d) The provision of universal and equal access to health services.
 - (e) A novel approach using a combination of public and private provision public health centres staffed by General Practitioners, together with public hospitals were to provide both primary and secondary health care. Public sector health care services, e.g. teaching hospitals, health centres, new technology and capital expenditure, were to be increased together with a modification of regional planning authorities. Doctors were required to choose between exclusively salaried employment in the public sector or totally private employment. In reality, only partial implementation of the proposals was achieved, e.g. the establishment of rural health clinics and the building of three large university hospitals at Crete, Patras and Ioannina.
17. The Athenian smog or "*nephos*" is caused by high levels of photochemical pollutants such as carbon monoxide, hydrocarbons, nitrogen oxides (primary pollutants), ozone and organic nitrates (secondary pollutant). Smog results from a series of chemical reactions driven by sunlight.
18. Examples of such systems failures have included changes to colcopy referral patterns at Inverclyde (Glasgow) following the appointment of a new consultant in cytology (1995) and screening errors at the James Paget Hospital, Great Yarmouth (1996) and at the Kent and Canterbury Trust (1997).
19. These developments include the activities of such organisations as "Clinical Pathology Accreditation (UK) Ltd" (CPA), the European Committee for Clinical Laboratory Standards (ECCLS) and the Western European Laboratory Accreditation Co-operation Organisation (WELAC). Increased use will be made of international kite-marks such as ISO9000 and the European Accreditation Standards EN 45001 and EN 45002.

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CHAPTER 5

The Professional Bodies and Licensing Authorities

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The Professional Bodies and Licensing Authorities

Introduction

This chapter seeks to examine the relationship between organisations having a significant influence in the shaping of medical laboratory sciences as a profession. These include not only the institutions representing the professional interests of MLSOs but also those authorities with statutory jurisdiction over the right to practice.

There is an inevitable emphasis on UK developments since countries such as Greece and Sweden do not have a requirement for periodically renewed state registration, neither do they have a formal institutionalised form of continuous professional development. There is also the historical actuality that the track of British professional body representation is significantly longer than those in the other selected countries. In selecting issues for discussion, one has had to exercise a certain degree of selectivity e.g. the development of management education programmes and “training the trainers” courses have been conscientiously excluded. The co-operation of both professional and statutory (licensing) authorities is central to the trans-national recognition of qualifications and is an essential pre-requisite to European harmonisation.

The UK

The year 1912 saw the establishment of the World's first organisation for non-medical staff of the newly emerging pathology laboratories – the Pathological and Bacteriological Laboratory Assistants Association (PBLAA). The organisation had been the vision of Albert Norman who had argued for a body to represent those who worked alongside pathologists in the embryonic disciplines of histopathology and medical bacteriology. Initially, the Association had limited aims (1), but by 1921 the founder members had established an examination structure providing a recognised qualification and status for laboratory assistants. The increasing importance of clinical laboratory investigations was leading to the engagement of additional staff to handle the technical aspects of the work – many of whom were being recruited directly from school or absorbed from associated jobs in the laboratory premises. The relationship between the head of the laboratory and the assistants was often paternalistic, the latter usually being paid directly by the pathologist and accompanying their chief to new posts as and when required (2).

In its early form the PBLAA was fortunate to survive the outbreak of war in 1914. Most of the laboratory assistants had joined the Armed Forces and since the nature of their work was held in low esteem, very few had the opportunity to continue their careers in the Army Medical Services. Following the cessation of hostilities the gradual expansion of healthcare provision during the 1920s and 1930s, together with the introduction of new disciplines such as haematology and chemical pathology meant that by 1945 the membership was approximately 1500. (The advent of World War II once again denuded the pathology laboratories of male staff and an increasing number of women had been recruited).

By 1939 plans were already in hand to restructure the PBLAA into a “professional” institute which would more properly reflect the high level of technical skill then being required in medical laboratories and, with most of its members away at war, the Institute of Medical Laboratory Technology (IMLT) was formed in 1942. As laboratory medicine underwent an expansive phase there occurred a matching growth in both the status and required skills of laboratory workers – and the laboratory assistants became technicians.

In the late 1940s the IMLT became responsible for representing the political views of its membership, primarily with respect to the government. Although forbidden by its Memorandum of Association to act as a trade union, the Institute found itself involved with issues such as wages and conditions of work. Being closely involved with the Pathological Society of Great Britain and Ireland, the PBLAA was to remain the only representative of medical laboratory technicians.

After the War, medical laboratory technicians grew not only in numbers but also in scientific knowledge, skill and status – such trends leading to tensions with older pathologists reflected in the relationship between the IMLT and the Association of Clinical Pathologists (ACP). However the formation of a Standing Joint Committee between the IMLT, ACP and Pathological Society maintained an uneasy peace. In 1963 all consultants in Pathology were invited to become members of the College of Pathologists, membership of which was occasionally extended to non-medically qualified IMLT members. In 1965, the Joint Standing Pathological Committee was to be replaced by a Joint Committee of the IMLT and the College of Pathologists, such a development representing a new era of mutual respect. Politically however the

Association of Clinical Biochemists (ACB) manifested an entirely different relationship with the IMLT.

Although numerically comparatively small, clinical biochemists were a group of mainly science (occasionally medical) graduates (3). Unlike clinical pathologists and medical laboratory technicians, clinical biochemists were free from any requirement for statutory registration.

Although accepted in principle by the government, the Zuckermann report was to receive a cool reception from both the IMLT and Council for Professions Supplementary to Medicine (CPSM). Partly perhaps as a result of this professional concern, the implementation of the Report's proposals did not materialise.

State Registration

This has been defined as "*that which is proper medical activity in a number of statutes*". [Further] *...it implies high ethical standards, educational and professional excellence, and a higher expectation of duties of care than from unregistered practitioners. It also regulates interaction with other medical professions and with patients and is the instrument of self-governance independent of educational, employment, governmental, or professional (in the sense of membership) interests*" (Burley, 1995).

Within the United Kingdom, the advent of the NHS necessitated governmental action in order to ensure that the interaction between the health professionals and the patients

should be properly regulated. Consequently, in May 1949, a number of committees were established by the Ministry of Health and the Secretary of State for Scotland, to enquire into the education, training and qualifications of various groups of staff (4).

The report of the Cope Committee was not well received by the professional bodies including the IMLT. Following further discussions with the Ministry of Health the *National Health Service (Medical Auxiliaries) Regulations, 1954* became the Statutory Instrument that set out the qualifications for NHS employment (5). Having been given the opportunity to debate the regulations and following consultations with its membership, the Council of the IMLT indicated to the Ministry of Health that the provisional scheme was unacceptable on three points (6). None of these were conceded.

Following its first House of Commons Reading in November 1959, the Bill to effect State Registration passed into law a year later as the *Professions Supplementary to Medicine Act, 1960*. The Act established a regulatory Council and Boards for each of these professions (with the exception of Speech Therapists) with responsibility for providing registration of members, regulating their professional education and professional conduct and for cancelling registration in cases of misconduct.

The Privy Council was to hold control over the machinery of registration. Initial membership of the Medical Laboratory Technicians Board (MLTB) was determined by the Minister of Health, the Secretary of State for Scotland and the Minister of Health and Local Government for Northern Ireland. Nomination by the Professional

Boards and subsequent election from amongst the regulated practitioners of each board was also possible (See Figures 5.1 and 5.2).

Figure 5.1 Schematic Structure Outline of C.P.S.M. Council and Associated Boards

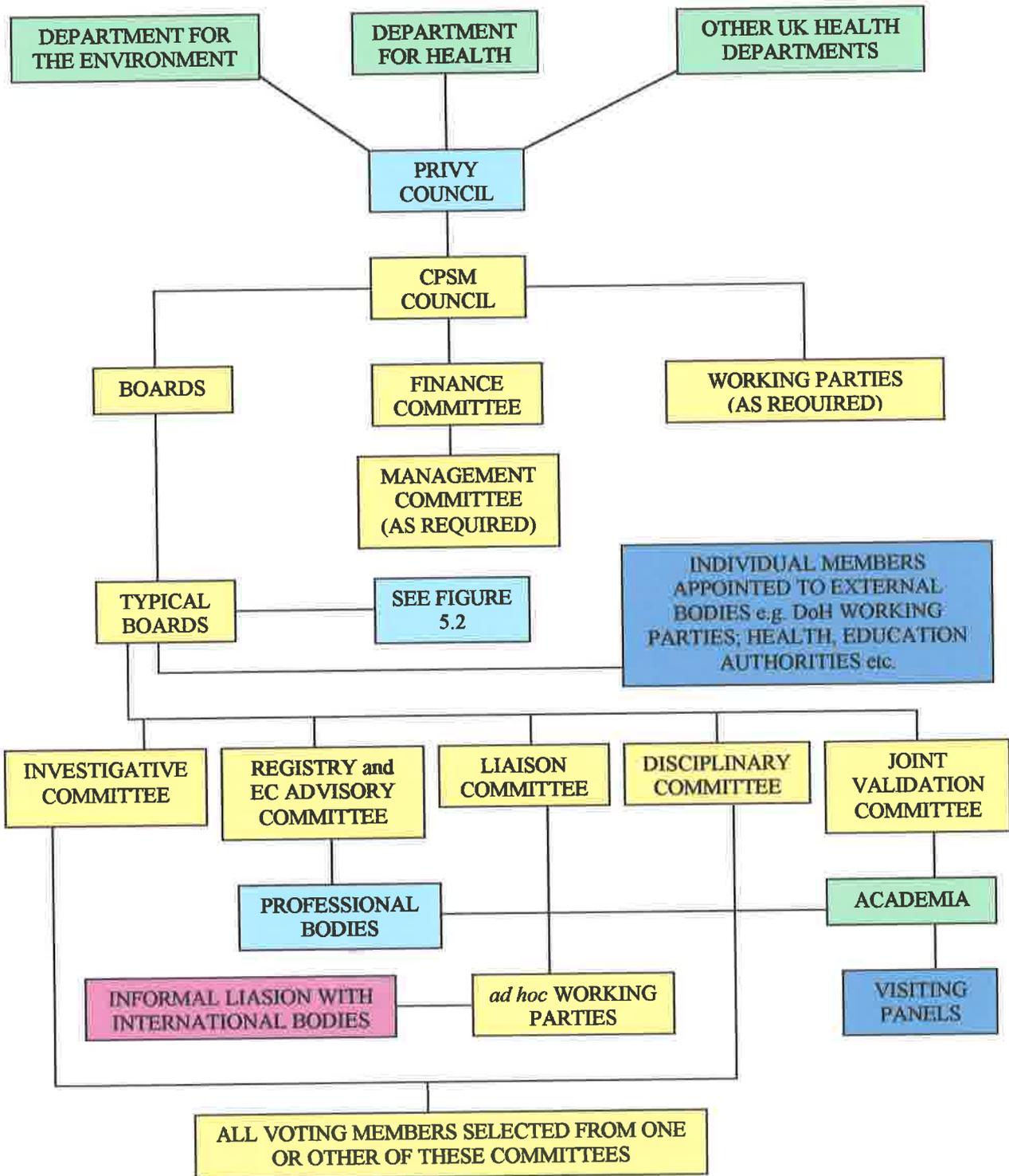
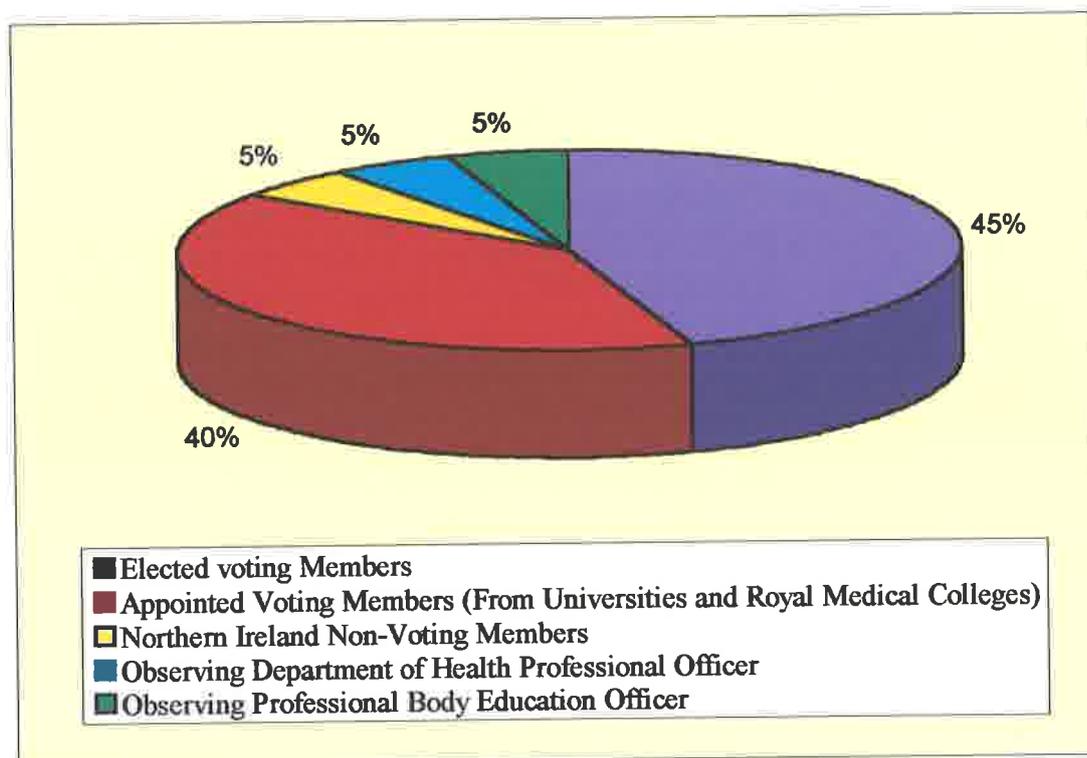


Figure 5.2 Constitution of Typical CPSM Board



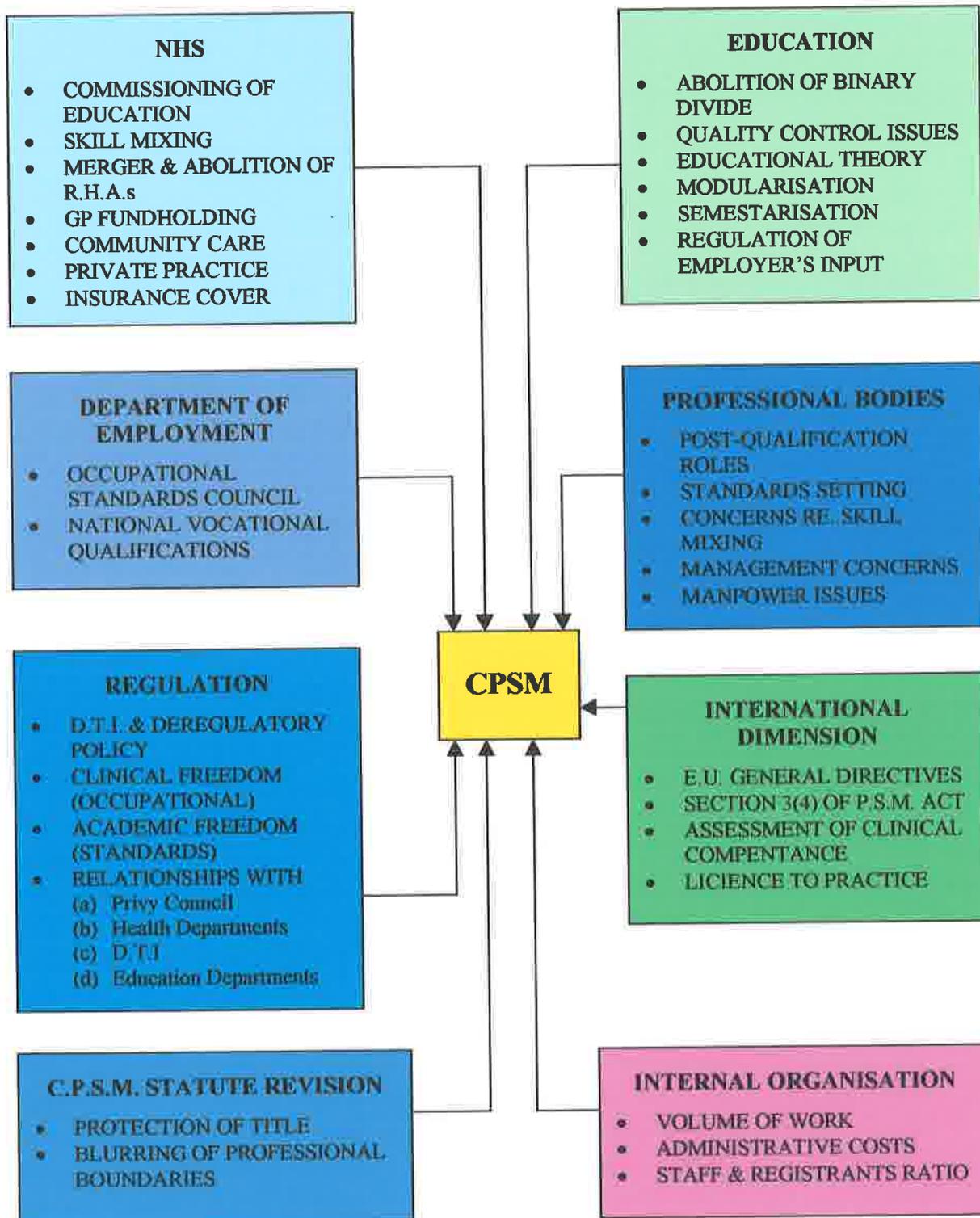
Modified from Burley, 1995.

As far as the public is concerned, State Registration represents a threshold of competence where both “omission” and “commission” are covered by a duty of care and professional discipline.

Within the current UK context, the primary concerns and responsibilities of the CPSM can be identified within several spheres of activities (see Figure 5.3). Since 1960 the environment within which medical laboratory technicians and other PSMs operate has radically changed for example with respect to public attitudes and expectations, reforms in Higher Education, professional development and reforms

within the NHS. The requirement for State Registration of MLSOs remains, together with the requirement to comply with certain criteria (7).

Figure 5.3 Primary Areas of CPSM Activity, 1995



Some three decades later, the PSM Act of 1960 had remained largely unchanged. With little prospect for its review and revision, attention was increasingly being given to mechanisms for dealing with overseas applicants. Little information was provided within the public domain - relating to either the criteria or the mechanisms for approving (or otherwise) the qualifications held by overseas applicants for state registration.

At the same time the CPSM announced its intention to undertake an internal review process involving both Parliamentary Agents and the Nuffield Institute (8) (9). In the 1990s the environment within which the CPSM was operating was becoming increasingly complex. Amongst the primary concerns of the Council were the continuing developments within the NHS, the requirements for education commissioning, the increasing trend towards skill-mix and the fact that Regional Health Authorities (RHAs) were merging (and some being abolished). Shortly there was to be a "U-turn", so that in early 1995 the Department of Health announced a review of the PSM Act.

There were also other issues to be considered - most notably the evolving relationship between public-sector and private practice, the emergence of GP fund-holding and its implications *vis a viz* state registration, the growing trend towards increased community care and also issues relating to insurance cover. By 1993 the predominant theme pre-occupying the Council was the development of a more coherent relationship with the Higher Education (HE) sector. The impetus for such a change stemmed from the NHS reforms and the implementation of *Working Paper 10* (the NHS's framework for commissioning and funding both education and training in

England from 1990) (10). The activities of CPSM Boards dealing with the education sector include the approval of courses and examinations – requiring final approval by the Privy Council. However the Boards alone approve institutions for training (see Figure 5.1).

The Spring of 1996 saw the publication of the independent review of the *PSM Act, 1960*. The Report's major recommendation was the establishment of a new Council for Health Professions (CHP) (See Addendum 5.1 for selected abstracts of recommendations submitted by review consultants). One of the clear disadvantages of the new Bill would be the loss of the MLTB and also therefore a certain degree of autonomy, together with a significantly reduced representation for practising biomedical scientists. Other major changes in the proposed Act are identified as those relating to protection of title (the preferred title being "Biomedical Scientist"), CPD and disciplinary procedures (with an expected increase in the numbers of misconduct cases being considered by the Council).

Educational reform was also increasingly occupying the attentions of the CPSM. The most important of these changes included the abolition of the binary divide, quality control issues, educational theory, the external pressures for standards in education, the trend towards modularisation and semesterisation and the question of employer input into courses. Also related to education were the concerns linked to the Occupational Standards Council (i.e. the National Vocational Qualifications (NVQ) movement) and its relevance to the regulated professions. The debate centred on regulation was another principal matter occupying the CPSM. First there was the tendency on the part of the Department of Trade and Industry (DTI) to deregulate and

second was the conflict between the requirement for occupational standards and academic freedom.

The CPSM then established a Bill Advisory Group (consisting of individuals drawn from the NHS Executive, CPSM and the Chief Executives of many of the professional bodies – including the IMLT). The group was charged with the task of formulating a document that would form the basis of a draft Bill prior to its presentation to both Houses of Parliament. Apart from its initiatives with respect to reforms, the MLTB has, in the late 1990s, continued its shared involvement with the IBMS in regards to several other developments. These have included the publication of a register of licensed practitioners, the re-enforcement of codes of conduct (see Addenda 5.2a and 5.2b) and the maintenance of a list of approved training laboratories.

Education and Training

An aspiration towards personal improvement is an enduring quality of human nature. Even in the early days of its development, members of the embryonic PBLAA were demanding some form of formal qualification by which their expertise could be recognised by both peers and supervisors. It soon became apparent that certification of technical ability could only be achieved by formal examination procedures. Such convictions were re-enforced by the Great War since the number of casualties resulting from infection and disease far outnumbered those resulting from battle wounds. War conditions in Europe were therefore to provide a powerful demand for trained laboratory assistants, so that by July 1921 a certification scheme had been jointly approved by both the PBLAA and the Pathological Society. The first

examinations were arranged in the same year and organised in London, Liverpool, Manchester, Bristol and Edinburgh.

In 1929 an expanded syllabus was introduced to include the addition of Pathological Chemistry. This represented the first acknowledgement by the PBLAA that the scope of medical laboratory science was expanding. Six years later a “two-stage” qualification structure was introduced with the inauguration of a “Part I” examination (11). The subsequent introduction of the “Part II” examination represented a significant watershed in the professional development of medical laboratory assistants. Farr (1982) argues that there are important reasons appertaining to such a claim and that the PBLAA examination scheme was “*abundantly justified in practise*”. This assertion is based on the argument that following its introduction, possession of the Part II certificate became a condition for employment in senior posts. Furthermore, holders of the certificate found themselves in a better position and with improved status within the laboratory. As a result, those who did not possess the certificate found it increasingly difficult to obtain any sort of laboratory post. More importantly, the introduction of a qualification in medical laboratory sciences was to be the “*pivotal development which resulted in a manual trade being elevated into an embryonic scientific profession*” (12).

Following the formation of the IMLT in 1943 the two-tier examination structure of the PBLAA was to be removed. Part I became the “Intermediate” and Part II the “Final” examination. Soon after the cessation of war, the Council of the PBLAA found its attention becoming increasingly drawn to the educational standards of entrants into the profession. As a broad principle, the Council decided that those

students intent on pursuing the study of medical laboratory technology should reach a standard *“equivalent to that of the University of London School Certificate”*. Subsequently the Educational Sub-Committee of the Council submitted a report which made several recommendations regarding changes to the education structure of those working in medical laboratory sciences (13).

Prior to World War II, the organisation of classes in medical laboratory technology was the sole responsibility of local branches of the PBLAA. This pattern was continued under the auspices of the IMLT and in 1944 the Council established a list of approved teaching institutions nation-wide, each of which were required to provide a detailed syllabus. Supervised by a Board of Studies, panels of approved tutors were appointed. Commencing in 1945 the first post-war tutorial classes under the aegis of the IMLT were conducted in 12 major cities. Following the establishment of a Joint Committee on Further Education and Training (consisting of representatives from the IMLT, Emergency PHLS and the Ministry of Health and Education) the first courses funded by Local Education Authorities (LEAs) were provided in the 1947-48 session. Conducted in the evenings all of the classes were taught either by practising medical laboratory technicians, biochemists or pathologists.

By the early 1960s the Institute's Council were becoming increasingly aware of the advantages of the national certificate system. The increasing demand for technicians with scientific as well as technical knowledge, the advent of day-release classes and the increasing demand for better career opportunities, were all cited as factors which supported the adoption of a new qualification system. Consequently in 1965 an advisory working group was established to examine the feasibility of introducing

national certificates for medical laboratory technicians (14). By the Autumn of 1966 Ordinary National Certificates (issued by the Business and Technology Education Council – BTEC) in medical laboratory technology were being offered in several colleges across the UK. Some have maintained that such developments in education and training were merely reflecting the realism of the post World War II years and that “*laboratory art was becoming subservient to medical laboratory science*” (Bennet, 1987). Others (Jones, 1987) maintained that the introduction of the National Certificates, coupled with the granting of day-release, were amongst the most significant events in medical laboratory science education. Previously courses had remained outside of the mainstream education provision and the qualifying system - isolated and uninfluenced by developments in the educational world. Now, for the first time, both courses and those who taught them were subjected to the pressures and effects of the Higher Education (HE) environment.

The Council next focussed its attention on the Higher National Certificate (HNC) as a suitable replacement for the Final examination for Associateship and the first of these HNCs were awarded in 1968 (See the later section relating to BTEC). In Scotland Ordinary National Certificate (ONC) courses were introduced in 1967 and HNC programmes in 1969.

Post-Basic Qualifications

Since the early 1940s, fellowship of the Institute had traditionally been achieved by the successful completion of a Final examination in a second specialist subject. The basic philosophy whereby a higher qualification was achieved by a mere extension of

breadth of knowledge (as opposed to in-depth acquisition) increasingly became of arguable relevance in a discipline undergoing increased specialisation. Further it was realised that the attainment of two Final examinations as a route to Fellowship was not suitable for those working in specialist departments. Consequently in 1944 the General Purposes Committee of the IMLT drafted the regulations permitting candidates to submit a thesis for the purposes of attaining Fellowship. This route to Fellowship was to prove unsatisfactory to those individuals who lacked the facilities to perform a research project, but whose work was too specialised to undertake a second Final examination. As a result a new form of examination was devised in 1955 – the “Dissertation and Examination”. In many respects this qualification route proved to be the most difficult of all options (15). Not surprisingly there were few candidates for this route to Fellowship (approximately 6 per annum) and consequently the programme was terminated in 1968 with only 48 candidates having obtained Fellowship by this route.

Four years earlier the Council had approved a new scheme for an advanced examination (in the same subject that candidates had obtained Associateship) as a route to Fellowship. Following dissent from the membership, the Council was forced to postpone introduction of the new “Special” examination until 1966.

In 1968, Council decided that a review was required of those courses leading to the examination for Fellowship. As a result of the deliberations of an *ad hoc* committee (including educationalists, members of the profession and Institute representatives), general agreement was reached that such courses should be aimed at the standard of an honours degree in science, following 3 years of part-time study and commencing at

the level of a good HNC in Medical Laboratory Subjects. Arranged to commence in 1969 at centres in Leeds, London and Bristol, the new 3-year course was to be named the Diploma in Medical Technology (Dip. Med. Tech.) (16). This drive towards honours degree (and later post-graduate) qualifications has been described by some (Jones, 1987) (Barrow, 1991) as “quality inflation” or “quality escalation”. The former author argues that such a phenomenon relates to three inter-related trends with respect to qualification systems. These include increases in the level of entry qualifications to [education and] training courses, a rise in the level of basic occupational qualifications and finally an increase in the minimum time taken to acquire such a qualification. Another phenomenon identified as being characteristic of medical laboratory science education is that of “academic drift” – resulting indirectly from the inclusion of such programmes into the national education system and therefore exposed to the politics and collective culture of the new environment.

From August 1987 the Special Fellowship course was further refined with most entrants requiring three years part-time study. The one year Part I course (later to become known as the course leading to “Primary Fellowship”) was designed to meet the needs of students with differing educational backgrounds. Catering both for graduates with little experience of medical laboratories as well as for holders of HNC/HND (Higher National Diploma) in Medical Laboratory Sciences (MLS) (with substantial experiential learning), the course was divided into “Section 1” (comprising 175 hours of Biology of Disease, Epidemiology and Statistics) and “Section 2” (with 75 hours of Biomedical Sciences for HNC/HND holders and any one of the specialist options for holders of CPSM approved but IBMS non-accredited degrees). Part II consisted of two years of part-time study (approximately 300 hours) and one of seven

specialist option subjects was chosen (Applied Histopathology/Applied Cytology, Clinical Chemistry, Haematology, Immunology, Transfusion Science, Microbiology and Virology). There were complicated rules for either partial or total exemption from Part I of the programme e.g. those graduates with accredited honours degrees, and current Fellows and holders of higher degrees from a UK university or polytechnic were given total exemption, whilst those with non-accredited degrees (e.g. in Biochemistry or Microbiology) may have been eligible for partial exemption. Prior to the commencement of the new programme, some sixteen institutions had applied for and received IBMS accreditation for the new courses. The programme was to survive for ten years with the final opportunity to sit the Part II Fellowship examination being provided in 1997. Subsequently the Two-Part Fellowship was to be replaced by higher degree programmes.

Amongst the limited opportunities for those with degrees or vocational qualifications obtained overseas (and intended primarily for those temporarily resident in the UK) was the Institute's "Scheme O" qualification. Designed for candidates wishing to obtain Associateship, the system was available for holders of appropriate science degrees awarded by approved overseas universities or those with qualifications obtained outside the UK or Republic of Ireland (and acceptable to the MLTB). Associateship could be gained through part-time study for the appropriate Higher Certificate or Higher Diploma in the UK or Republic of Ireland. A minimum of twelve months experience in an approved laboratory in either country was necessary, together with a prescribed registration period with the Institute and successful completion of an assessed theoretical examination in MLS. Examination topics

included Biochemistry and Physiology. The scheme was finally terminated in June 1993.

With the advent of the 1970s the requirement for a more academically based education and training for medical laboratory personnel had grown as the numbers of graduates entering the profession increased (by 1974 almost 10 % of the total annual intake had degrees) (17). The desirability of vocational degrees in MLS was now to become a contentious issue. Farr (1982) asserts that there were 3 major arguments relating to the controversies surrounding the debate. The first centred on the questionable validity of MLS as a degree subject in its own right, the second concerned the relevance of such degrees within the context of the NHS and the third related to problems linked to manpower planning. Such assertions were countered by claims, which formed the central focus of a wider debate (18). Others (Barrow, 1991) have asserted that courses in biomedical sciences were “recognised as appropriate” for both the first degree and Masters programmes. Following consultation with both the IBMS and external agencies and bearing in mind the arguments for and against “all graduate” entry, the Institute’s Council and MLTB agreed that the principle route for entry into the profession would be via specifically approved BSc Honours degrees in Biomedical Sciences. Consequently a Press Release was issued announcing the fact (See Addendum 5.3 for selected abstracts of the accompanying Annexe). The routes to State Registration were clearly defined (19).

As from 1st January 1995 therefore both the IBMS and CPSM adopted an all graduate policy. Thereafter prospective new recruits into the profession were advised to take a “broadly based biomedical science degree” accredited by the IBMS and approved by

the CPSM. In 1998 the MLTB sought Privy Council agreement to widen and increase the numbers of BSc (Hons.) degrees acceptable as preliminary qualifications. Accreditation of degree courses by the IBMS had now steadily expanded – as early as 1992, the Institute had accredited degree programmes at 18 centres throughout the UK and Ireland. A year later its portfolio of accredited Masters degrees expanded also to include the first centre outside the British Isles (the part-time MSc in Clinical Biochemistry at the Chinese University of Hong Kong).

Heads of University Centres of Biomedical Sciences (HUCBMS)

Formed in 1993 in association with the IBMS, this organisation was established to provide a focus for education issues within the Biomedical Sciences (BMS) sector. It also aimed to “*promote the discipline [i.e. BMS] in both teaching and research, to stimulate collaboration in such areas as teaching methodology, laboratory design, use of equipment and also to address semi-political matters crucial to the future of the subject such as funding.....*” (Baker, 1993) (20).

Since its inception the organisation’s influence on education policy within the UK BMS sector has been significant. During the 1996 Research Assessment Exercise (RAE) the Chair held membership of the Specialist Panel for BMS (and has subsequently been nominated as Chair of the next Panel for “Other Studies and PAMs” in the RAE planned for the year 2001), while two members of the executive committee were appointed as specialist advisors to the Panel. HUCBMS also nominates specialist assessors to the Funding Council’s Teaching Quality Assessments, maintains a register of External Examiners and an institutional database

for BMS courses. The organisation liaises with and advises the IBMS and CPSM in relation to professional education – exemplified in latter years by the issue of “top-up” qualifications (21).

This issue is centred on the fact that the MLTB had over-relied on the Primary FIBMS qualification as a suitable top-up qualification for those candidates aspiring to become state registered but who lacked an IBMS accredited and CPSM approved honours degree. Increasingly graduate entrants into the profession were holders of degrees in subjects such as Biochemistry, Physics and Chemistry. The IBMS insisted that such entrants should have longer training periods than those with accredited degrees in BMS. Such a strategy would maintain the advantage held by the latter group of candidates. HUCBMS maintained that the shortfall in recruitment of suitable holders of honours degrees in BMS was only temporary (advocating at the same time a salary increase for new recruits) and pointed out that while there was a need to provide appropriate education for those who lacked suitable degrees, the intention of the MLTB to extend work-based training periods for such candidates was untenable. HUCBMS later (in 1998) issued a policy statement advocating certain minimum educational attainments for MLTB registration (22).

Continuing Professional Development (CPD)

The IBMS launched its CPD Diploma scheme in May 1992 following a period of development and consolidation. At this time there had been approximately 134 activities accredited by the Institute. As the nature of the work of biomedical scientists changed the IBMS recognised the need for a formal and structured CPD

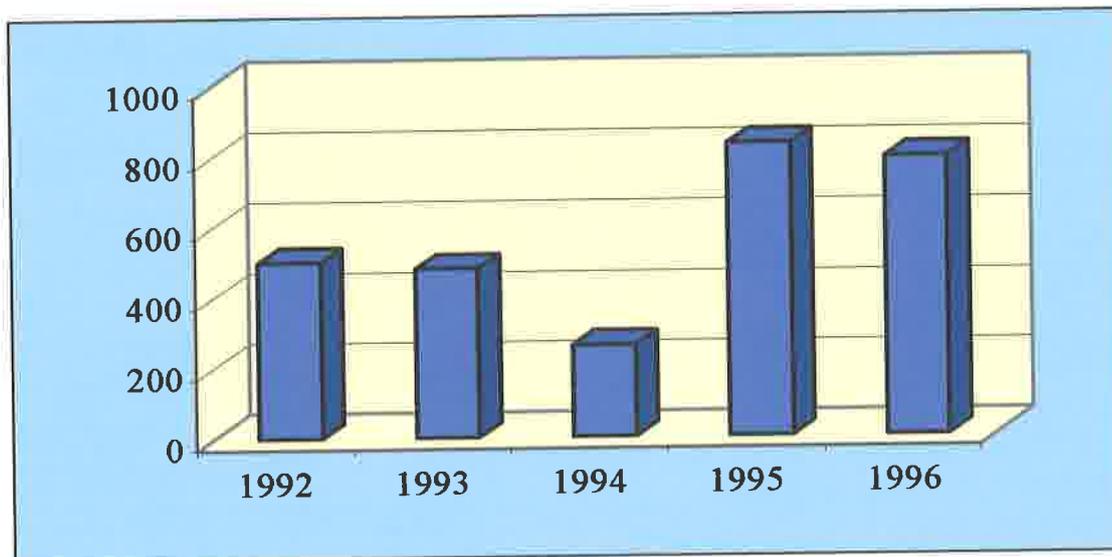
programme. Consequently the Institute had introduced a pilot scheme in 1989. Within its first five years the scheme had attracted 50% (5860 individuals) of those eligible for registered membership and since its inception the scheme has undergone a number of modifications. These have included the introduction of Personal Record Files (PRFs), the formation of a network of local CPD officers and the recommendation that members achieve a target of four credits *per annum*. Three of these must be in the “Educational” category (23).

Details of all members’ achievements are recorded in their PRFs which are validated annually either by the local CPD officer or the CPD section of the IBMS office. Activities involve distance learning exercises, structured reading (using given references in a new subject area), self-selected structured reading (with the option to choose one’s own topic for study) and Journal Based Learning (JBL). Introduced in 1995, JBL has proved to be the most popular activity (as a result of increasing demand the assessment of JBL is now computer marked) and involves answering two sets of questions requiring true/false answers. Recently the IBMS has begun drafting core competencies for inclusion in the CPD scheme. CPD registered programmes are now provided not only in NHS pathology departments and Medical Schools but also by universities, commercial companies and training consultants. Examples of CPD credit ratings for recognised activities are provided in Addendum 5.4.

There were critics of the scheme (Carr, 1992) who pointed out that opportunities for such advancement relied on geographical distance from the centres of provision, the granting of study leave, cost implications and that there were therefore inequalities of opportunity. Despite such criticisms the scheme continued to expand (see Figures 5.4

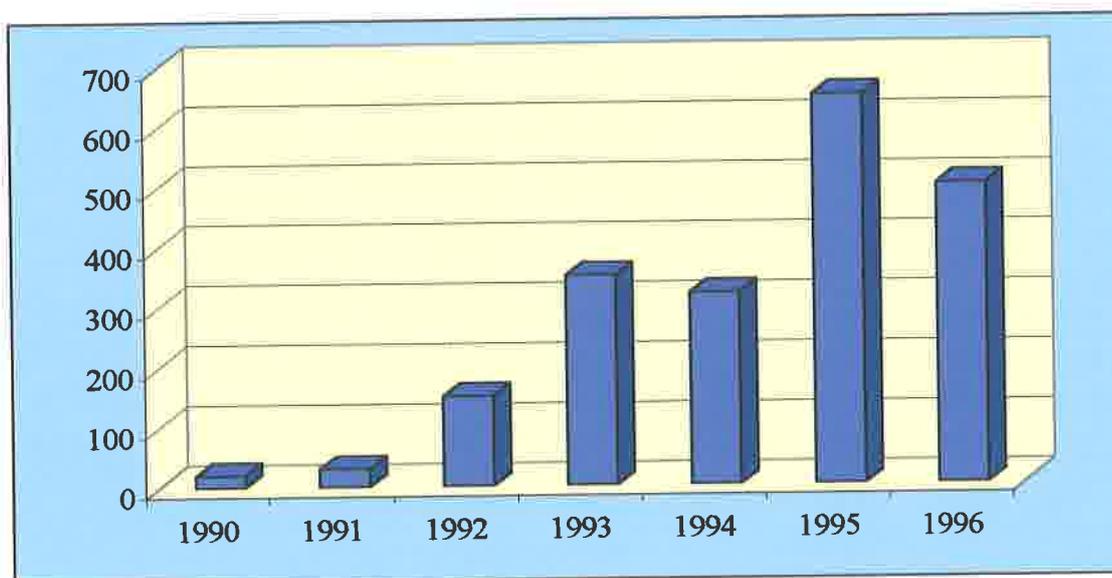
and 5.5) with activities involving a comprehensive range of subject areas. Surprisingly however, some disciplines (e.g. Immunology) were relatively under-represented (see Figure 5.6).

Figure 5.4 Total Number of IBMS CPD Registrations 1990-1996



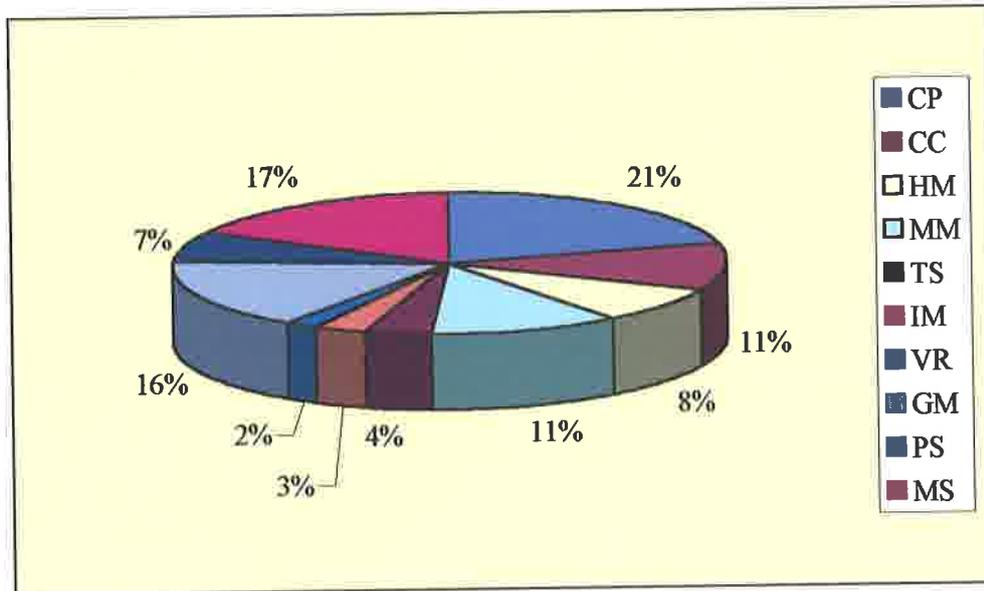
Source: Allison, 1996.

Figure 5.5 Total Number of IBMS Accredited CPD Activities 1990-1996



Source: Allison, 1996.

Figure 5.6 Distribution of CPD Activities by Subject Area, 1994



Key:

CP	Cellular Pathology
CC	Clinical Chemistry
HM	Haematology
MM	Medical Microbiology
TS	Transfusion Science

IM	Immunology
VR	Virology
GM	Management
PS	Parasitology
MS	Miscellaneous

Source: Adapted from Loaring, 1994.

Business and Technology (Technician) Education Council (BTEC)

Formed in 1983 this organisation sought to advance both the quality and availability of work-related education for those either in, or preparing for employment. The primary fundamental aim of the Council was that students on its courses should develop necessary competence in their own interests together with those of their employers and the Nation. Prior to this, the Technology (Technician) Education Council (TEC) had designed specific courses (e.g. its Higher Award Programmes in MLS) for those students intending to be trained as MLSOs. Within the context of

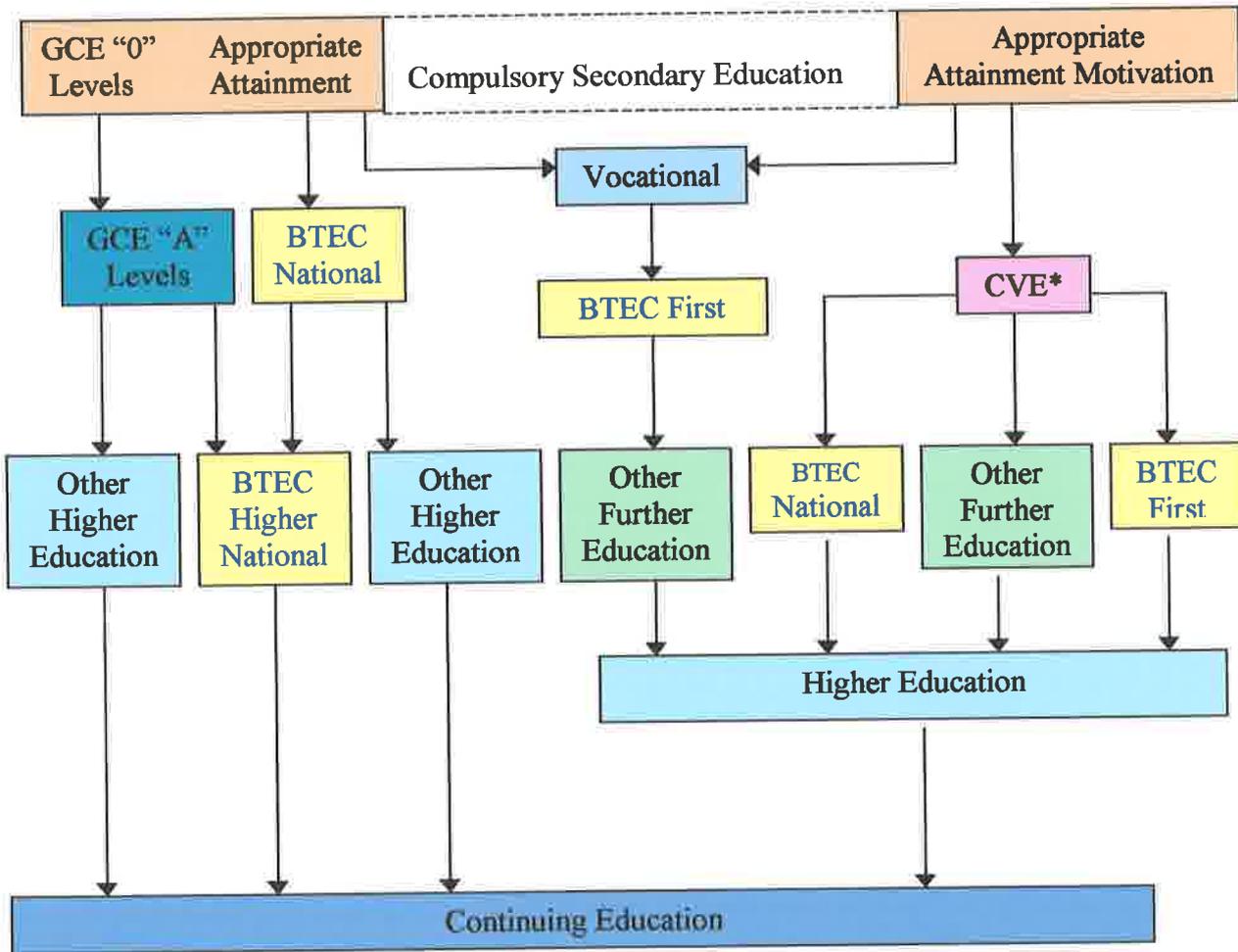
mainstream education, the BTEC course pattern was well-defined (see Figure 5.7) and designed to strengthen the relationship between education and training, colleges and employers.

Publishing its educational policy in 1984, BTEC consulted with representatives from industry, commerce, the education sector and professional bodies on a number of issues (24). Taking advice from its Education Advisory Committee, the IMLS made a pointed response (25).

In the same year (1984) relationships between the MLTB and the membership of the IMLS further deteriorated when the former issued a Press Release announcing the requirement for holders of BTEC and Scottish Vocational Education Council (SCOTVEC) Higher Certificates in MLS to undertake an "oral" examination. This, together with three years training was prescribed as a prerequisite in order to demonstrate competency to practice.

While HNC courses in MLS had been taken over by TEC in September 1982, the advent of BTEC saw Moderators appointed to every college. Concurrently the importance of Individual Development Skills (IDS) was emphasised with the introduction of common skills and core themes. IDS was considered to be a vital aspect of student ability and a central tenet of communication skills amongst developing MLSOs.

Figure 5.7 Mainstream BTEC Course Pattern (16–18+ Years of Age)



* Continuing Vocational Education

There now followed a fragmentation of the traditional pattern of teaching disciplines within MLS. A further confounding factor was the additional demands emanating from novel inter-disciplinary advances including those in immunology and DNA technology as well as the separation of BTEC HNC/D programmes into specialist disciplines. These factors represented additional strains on already limited resources.

Some argued that as the qualification spiral increased there was a concurrent demographic decline together with increased unemployment. This resulted in increased pressure for an all-graduate entry into the MLS profession (Oliver, 1990). Others maintained that the adoption of HNC schemes by the IMLS was a natural step in the progression towards an all-graduate entry and further that entry of the Institute into the National Certificate Scheme had been founded on well established grounds (26). By 1992, the IMLS was arguing (Seth-Smith, 1993) that the acquisition of an accredited degree represented the soundest foundation for aspiring young Biomedical Scientists. One of the primary factors in advocating replacement of the BTEC Higher courses was cited as the increasing complexity of work undertaken by MLSOs.

National Vocational Qualifications (NVQs)

The National Council for Vocational Qualifications was established in 1983 in response to the White Paper *Working Together – Education and Training*. Although not itself an awarding body, its role is to approve and accredit qualifications and the organisations which award them. In Scotland, SCOTVEC develops and accredits a parallel system, but unlike the NCVQ the former is an awarding body. Such was the uncertainty in the science community regarding the work of the NCVQ that the IMLS, the Foundation for Science Technology (FST), the Council for Science and Technology Institutes (CSTI), the Employment Department (ED) and other organisations established the Science Qualifications Task Force (SQTF) (27).

Because of the uneven distribution of qualifications in the scientific sector, the IMLS called for a more coherent framework of NVQs and urged the need for science to be

properly recognised within the networks. Consequently the IBMS was later to contribute to a “mapping” exercise of the science occupations and provided advice on proposals to establish an umbrella body to oversee the co-ordination and development of a national framework of occupational standards and vocational qualifications in science, technology and mathematics. Proposed by the CSTI, the national framework was established in 1993 (28). In pursuance of its interests in NVQs, the IBMS fostered collaboration with the Science, Technology and Mathematics Council (STMC) and the Laboratory and Associated Technical Standards Initiative (LATSI).

Such partnerships led to the conclusion that the development of NVQs for MLAs and other laboratory support staff should not hinder the affect of graduate status on the profession. In 1996 the IBMS established a working party to examine the feasibility of applying NVQ qualifications to “training the trainers” programmes and also to the training of cytology screeners. The possibility of the IBMS awarding NVQs to MLAs also precipitated action by the Institute with respect to the development of lead body standards as measures of assessor competency. This was the result of the insistence on the part of the Quality and Curriculum Authority (QCA) that any individual performing assessment of a NVQ candidate (e.g. a MLA) must hold the D32/33 assessor’s award (29).

The advent of NVQs and GNVQs represented a dilemma for the Institute as it did for many other professional bodies. This predicament related to the need to balance the requirements for academic recognition (all-graduate entry) against the pressures for transparent measurement of competency (government driven NVQs and GNVQs). Some (Ball, 1991) would contend that terms such as “academic” and “vocational”

courses of study are poorly defined and that the contrast made between academic (education) and vocational (training) is imprecise and that the perception that academic courses have a higher value is not necessarily true (30). In any event, at the time of writing (March, 1999) the Council of the IBMS have no intention of extending the national competency standards (applying to MLAs) to the introduction of NVQs for MLSOs.

Germany

The German professional body for MLS is *Deutscher Verband Technischer Assistenten in der Medizin* (DVTA). Within Europe, the country was amongst the first to have organised courses for medical laboratory assistants. These were provided in 1896 at the *Lettehaus* (a school for women) in Berlin. The first formal state examinations were established in 1912 by an association of former students (*Letteverein*) of the school, and this coincided with the legal establishment of the profession. At the same time there was a growing trend towards specialisation particularly in Clinical Chemistry and Bacteriology.

Clinical Chemistry however remained rather limited in scope (See Chapters 1 and 2) while an early course in Bacteriology was established at the Robert Koch Institute for Infectious Diseases in Berlin. The title "*Medizinisch-Technische/r Assistent/in* (MTA) became a protected title in 1940 (in 1972 this was changed to *Medizinisch-Technische Laboratorium Assistent/in* - MTLA). Following extensive educational reforms during the early war years, training became the responsibility of the *Berufsfachschulen* (vocational schools). Currently training takes place within MTA *schulen*, attached

either to universities, technical colleges or urban clinical centres. All training colleges have to be licensed by the appropriate Länder.

Laboratory training during the first year of studies was polyvalent until August 1993, when legislation allowed entrants into the profession to choose one of four disciplines (effective from January 1994). These include laboratory medicine (MTAL), radiology (MTAR), functional diagnostic (MTAF) (similar to a Physiological Measurement Technician in the UK) and veterinary medicine (MTAV). The generic title of MTA has in practice therefore been retained. In some cases the job title “medical technical laboratory female assistant” is used. This reflects the fact that during the early development of the profession, practitioners were almost exclusively female. Successful completion of the education and training programme entitles the graduate to apply for a national license to practice. In Germany such a licence permits the holder to establish her/his own private (and independent) laboratory.

College programmes are of three years duration and there is a legal requirement for a six-week practical training period in nursing during the first year. The first six months represent a probationary period after which students can elect to transfer from laboratory medicine into one of the other three professional categories. Following approximately 26 weeks of study there is a mandatory period of hospital laboratory rotation within the four specialist disciplines. This must represent at least 1,000 hours of study (a minimum 300 hours of which must be in clinical chemistry and 100 hours minimum in each of the haematology, medical microbiology and histopathology departments). In addition to the usual subject areas such as physiology, pathology,

anatomy and biochemistry, students are required to study English, law, hygiene and psychology.

On successful attainment of certain course requirements (relating to attendance and course work assessments) a college certificate is issued prior to a national final examination taken under the supervision of local supervisory organisations such as public health authorities. These examinations include theoretical, practical and oral assessment. The former consists of two examination papers (the first – of three hours duration, covers subjects such as mathematics, statistics, biochemistry and pathophysiology, the second – of four hours duration, is concerned with all four specialist disciplines).

Entry regulations are strict, perhaps reflecting the fact that many qualified practitioners will work independently of public sector and state quality assurance systems. Academic pre-requisites include possession of the “*Abitur*” (the German School Leaving Certificate) with passes in mathematics, physics, chemistry and biology being mandatory. Alternatively applicants may have at least two years of appropriate professional training. Copies of hand written personal records must accompany letters of application together with authenticated education certificates. A police certificate of good conduct is also required and this must include evidence of suitability to work in the sector. All applicants have to sit an entrance examination and be interviewed to assess suitability. Applications from Member States are subject to scrutiny by the German Academic Exchange Service (*Deutscher Akademischer Austauschdienst – DAAD*).

Qualified practitioners are employed in a variety of sectors including hospital and community pathology laboratories, the pharmaceutical industry, forensic pathology, material testing (quality control) and academic or industrial research departments. The larger university schools organise CPD programmes in areas such as multi-drug resistance, lymphocyte transformation testing, complement assays and Fluorescence Activated Cell Sorting (FACS).

Legislation (originally enacted in 1979) allows MLTAs to pursue courses of continuing education towards a higher level of qualification. These are usually organised under the auspices of the “German Institute for Further Education of Medical Technologists in Medicine” (*Deutsches Institut zur Weiterbildung technischer Assistenten in der Medizin*). Qualifications include:

- (1) ‘Teaching Technologist’ (*Lehrkraft*) requiring the MTLA qualification and 3 years professional experience as entry pre-requisites. Preference is given to applicants with the “specialist” qualification (See below).
- (2) ‘Manager’ (*Leitende/r Assistent/in*) requiring the MTLA qualification and 2 years professional experience. Students undertake work in psychology, law, sociology, health and safety, medical documentation and administration. Preference is again given to “specialist” applicants.
- (3) ‘Specialist’ (*Fachassistent/in*). There is a choice of specialist subject areas including clinical chemistry, haematology (with immunology), histopathology (also cytopathology) or medical microbiology. Each programme must include 600 hours of training (200 hours of which must be practically based). Applicants must possess the MTLA qualification and have a minimum of 3 years work experience.

Greece

The professional association within Greece is the Panhellenic Union of Medical Laboratory Technologists (PUMLT). The first formal programmes of study for MLTs were not established until 1973 and were taught over 2 years. These had been preceded by the Senior Technical High School Diploma for Microbiology Assistants. The new programmes were introduced because of shortages of appropriately qualified laboratory staff. This situation had arisen as a direct result of the National Health Insurance reforms (See Chapter 4) and the granting of free hospital services and laboratory tests. Currently the qualification to practice is the three-year Diploma in Medical Laboratory Technology.

Under legislation passed in 1983 ("Founding Law" 1404/83) these Diplomas were required to be supplemented with a 6 month period of paid practical training. Also stipulated was the fact that the theoretical components were to be taught at the Technological Educational Institutions (ΤΕΧΝΟΛΟΓΙΚΟ ΕΚΠΑΙΔΕΥΤΙΚΟ ΙΔΡΥΜΑ – ΤΕΙ). These Institutions form part of the Greek HE system but are independent of the university sector. The TEIs are self-governing and are controlled by the Minister of Education and Religion. Only three colleges provide Diplomas in Medical Laboratory Technology (at Athens, Larissa and Thessaloniki). Diplomates (referred to as "graduates") are entitled to certain "professional rights" as defined under Presidential Decree No. 163 of 5th June 1996 (examination of such rights reveals that these are in fact stipulated in the format of a job description).

Although there is a heavy emphasis on traditional subject areas, students are also required to study sociology, foreign languages, the history of medical sciences,

“laboratory animals”, “nutritional substrates” and first aid. There is also a requirement to complete a dissertation involving library research and which must be presented orally to a Faculty committee. The research does not involve laboratory work. Acquisition of the Diploma allows the individual to use the title “Technologist of Medical Laboratories” and they are able to practice in state hospitals and clinics (approximately 40%), blood transfusion centres, national pharmaceutical companies, health centres and private (licensed) doctor’s laboratories (approximately 40%). Graduates may also find employment within social security centres and as Laboratory Instructors in the Technical and Professional Senior High Schools. There is also the option of progression to continue studies at university level following successful completion of the entrance examination during the third semester of the Diploma (approximately 20%) – otherwise there are no formal opportunities for MLTs to gain higher academic or vocational qualifications (in such cases they must undertake periods of study abroad).

Laboratory supervisors must be licensed by the Ministry of Health and Social Services and have to hold either:

- (1) A medical degree with evidence of experience in a specialised area, together with publications in referred journals.
- (2) A Masters degree in an appropriate subject (e.g. biology, chemistry etc.) with evidence of experience in a specialised area.
- (3) A PhD in clinical chemistry, Biochemistry etc.

Although there is no requirement for laboratories to be accredited, there is a national external quality assurance system available (similar to the UK National External

Quality Assurance System or NEQAS schemes) for the technical aspects of diagnostic testing. Approximately 90% of laboratories choose not to participate in this scheme and only six laboratories have received accreditation since November 2000.

There is no formal career structure and practitioners tend to be organised into “working teams” within the larger departments e.g. staff may be divided into one group with responsibility for histopathology and clinical biochemistry (including haematology) while another may be concerned with microbiology (including virology and parasitology). Cytology is regarded as a separate subject from histopathology and all smears are checked by a second cytoscreener.

Sweden

The Swedish professional body for MLS is the *Institutet för biomedicinsk laboratorievetenskap* (IBL). Unlike the IBMS, this organisation has very little input into education. As in other European countries, the advances associated with experimental pathology provided the impetus for growth of the profession. During the latter part of the Nineteenth Century, Swedish laboratory medicine was centred on the disciplines of histology, chemistry, bacteriology and physiology. By 1880 there were a few laboratory assistants working primarily in histopathology and three years later the first clinical diagnostic laboratory was established at Uppsala. In 1888 a bacteriological laboratory was added to the Institute of Pathology in Lund, but at this time clinicians performing pathological tests had little assistance. Gradually however (and in contrast to the UK) women were becoming increasingly employed as laboratory aids. These were often unpaid wives, siblings or friends of the physicians

and benefited from personal tutoring in relation to the technical aspects of the work involved.

Although the IBL represents the profession, there is advocacy from the Swedish Association of Health Professionals (*Värdförbundet* or “Care Society”) – this acts in the capacity of a Trade Union. The Association offers guidance on both policy and structure in relation to professional competency (roles carried out by the CPSM and IBMS in the UK – the latter organisation having consistently refused to participate in Trade Union activities) but has no powers of licensure.

It was not until 1942 that national training programmes were introduced and three years later the first course in histopathology was organised (this representing two years of laboratory based training). The programme consisted of part time theoretical study (two evenings per week) centred not only on histopathology but also on laboratory experimentation, anatomy, photography, bacteriology and chemistry. Although the first central government funds were allocated for the training of “medical laboratorians” in 1947, it took another ten years before the first medical laboratory school (*Laborantskola*) was established. The first major reform to affect Swedish medical laboratory education was undertaken in 1977 and this resulted in the discipline being integrated into the HE sector (by this time the number of training schools had increased to thirteen).

By 1982 medical laboratory training was established at the university level and offered at institutions variously referred to as “Colleges of Health Caring Sciences” (*Vårdhögskolor*) or “Universities of Health” (*Hälsöhögskolan*). The basic training

programme for the title of “ Medical Laboratory Technologist” (MLT) (*Laboratorie-assistant*) lasted for two years and three months (and was equal to 100 points or *poäng*). Graduates of the Medical Laboratory Technology programmes were eligible to receive a college or university Certificate. Opportunities then existed for specialisation via short courses (e.g. 6 week programmes in Blood Transfusion Science) and longer periods of study (such as the 24 week programmes in Clinical Cytology). Such opportunities still exist.

Successful completion of such courses provided eligibility to proceed to first degrees in subject areas such as “Biotechniques” and Molecular Biology.

Prior to the educational reforms of 1993 the organisation responsible for validation of courses was the National Board of Universities and Colleges (*Universitet-Högskole Ämbetet* – UHÄ). This body also stipulated a national curriculum together with specific study aims and objectives. Since 1994 all programmes have consisted of 120 credit points (one credit point being equal to 20 hours of teaching plus 20 hours of student effort i.e. one week of study) plus an additional 10 credit points for a research project. Graduates exiting with a Bachelor of Science qualification are referred to as “*kandidatexamen*” and now carry the title of “*biomedicinsk analytiker*”. The national curriculum was also abandoned in 1994 with all decisions regarding programme content now being taken at local level. Quality Assessment is the responsibility of the University Chancellors who also have the power to grant examining rights to individual universities.

Following successful completion of a first degree there are opportunities to study for a Master's degree requiring two years of study within a Faculty of Medicine or a Faculty of Social Science. These equate to 80 credit points. Doctoral degrees require 4 years of full-time study (or 8 years of part-time study) following acquisition of the first degree. These equate to 160 credit points. Qualified Technologists are eligible to enrol on Teacher Training courses (of 18 months duration and carrying 60 credit points) or Health Administration programmes (ranging from 20-60 credit points).

Entry to all training programmes is co-ordinated via a central administration system controlled by the County Council Association's Admission Committee (*Landstings Förbundets Antagningsnamnd-LFA*). As for all higher education, the minimum basic entry requirement is successful completion of upper-secondary school or equivalent education. This means completion of at least 2 years (grade 11) of the upper secondary school programme and must include mathematics and natural sciences. Most candidates have however completed 12 years with 3 years in a technical curriculum or 13 years with 4 years in a "gymnasium" following a natural science curriculum.

Qualified MLTs work in health service sectors, medical and veterinary research, the pharmaceutical industry and in the food sector. There are five specialist options, which are: clinical chemistry (including haematology and blood banking), microbiology, morphological cell biology (previously histopathology), clinical physiology and biochemistry/molecular biology.

The career structure within pathology departments is relatively informal with most departments being directed by clinicians. (Within Sweden there approximately five laboratories that have MLTs as the senior manager but these carry no clinical responsibilities). In most cases the technical head/deputy director is an experienced MLT with “good personal qualifications – but not necessarily academic ones” (Morgan, 2001). Officially there is no hierarchical staffing structure and salary is negotiated separately between individual members of staff and the Director on an annual basis. This is usually accomplished as part of a staff appraisal exercise. As in the UK there is a requirement for Swedish laboratories to be accredited by the government (in the former case this function is performed by the governmental agency Clinical Pathology Accreditation (CPA) and in the latter by SWEDAC). Within Sweden there is a comparative form of CPD, since the accreditation system requires the allocation of a “körkort” (“driving licence”) before individuals are allowed to use new equipment.

Conclusions

The first professional organisation for technical (diagnostic) workers in medical laboratories was established within the UK early in the second decade of the Twentieth Century. However formal education and training provision had been provided within Germany prior to the close of the Nineteenth Century. Traditionally there has been a significant gender gap between practitioners within the selected countries - the UK workers being predominantly male (except during the War years) whilst Germany and Sweden were represented almost exclusively by female practitioners. There is also a disparity between the functions of the Trade Unions in

that within the UK the IBMS is prevented by its memorandum from involvement within Trade Union activities, but has a significant role in relation to education policies. The professional organisation also has a well established relationship with the licensing authority. In Sweden however the *Värdförbundet* is pre-eminent in relation to Trade Union activities, dictates the regulations regarding competency to practice and also has an important input into educational policy.

With respect to professional practice, medical laboratory technology personnel within all four countries require some form of state regulation in order to practice (i.e. they are “regulated professions”). Even so, neither Germany, Greece or Sweden have an equivalent organisation to the CPSM in that there is no requirement to become state registered on an annual basis. There are also disparities with respect to professional codes of practice. In the UK these are the responsibilities of the CPSM and the IBMS whilst in Greece it is the Laboratory Director (clinician) who is mandated to provide jurisdiction on matters of professional misconduct.

Within each of the countries there is a broad consensus regarding the entry qualifications to programmes of study, nevertheless following graduation there are marked differences in provision of higher qualification routes between Greece and the other countries. Germany, Sweden and the UK have well established routes for progression to management and teaching opportunities, with the former two countries having programmes designed specifically for laboratory instructors (the closest analogy in the UK are the short courses referred to as “training the trainers” programmes, although there are teaching courses now being developed for laboratory personnel in London).

There are variations in the requirements for laboratory training (e.g. six months in Greece and one year in the UK) and within the latter country the career/staffing structures appear to be far more formal. Only British students are required to complete a laboratory based research project as part of their studies. As in other Scandinavian countries the system for the allocation of credit points is more advanced than in other European countries and more clearly defined.

Employment patterns reflect the importance of private insurance schemes in health care systems with significant numbers of MLTs in Greece and Germany working in independent laboratories. Finally the professional designations are strictly protected titles in Germany and Greece while in the UK the exact generic title for state registered MLSOs is a subject under consideration by the shadow Health Professions Council. In Sweden there is dispute regarding the use of the title *biomedicinsk analytiker* between MLTs and scientific researchers.

Differences in employment patterns (such as the greater use of private laboratories in Germany and Sweden) together with disparities in the requirements for on-going State Registration are prime factors militating against professional harmonisation. More stringent approaches in the UK towards evidence-based competency to practice are likely to further widen the gap between the four selected countries (CPD may become mandatory with the introduction of the Health Professions Council). Within Germany and Sweden, clinical chemistry has traditionally been practised in combination with haematology (unlike the UK). In Greece there is a tendency to practice diagnostic pathology using a team-based approach – the specialist options being divided e.g. into

microbiology (bacteriology, virology and parasitology) and biopathology (cellular pathology, biochemistry and haematology). Amongst academic factors that complicate European accord are the differences in professional entry requirements together with contrasts in curricula (e.g. only in the UK are students required to undertake an Honours degree research project).

Having reviewed the relationship between those organisations responsible for the control and guardianship of professional standards, the next chapter seeks to gauge the practitioners' views with respect to European harmonisation . This investigation represents the beginning of the third Section of this thesis.

Notes

1. These were to :-

- (a) "Form a means of communication amongst the assistants.
- (b) Supply information regarding appointments.
- (c) Assist in the general advancement of its members".

2. Such paternalism gave rise to an ethos of dedication and enthusiasm coupled to curiosity in the work being carried out by the clinically qualified pioneers of pathology. These were the driving forces, which gave birth to a separate class of scientific worker. By the end of the Nineteenth Century it had become apparent that an effort must be made to consolidate this new strata and consequently an attempt was made by John McLean (assistant to Leith at University College, Birmingham) to form an association of laboratory assistants in 1896. Although unsuccessful this initiative was later to inspire the efforts of Norman in 1912.

3. In the Zuckerman Report of 1968 the role of such graduates was defined thus: "The Clinical Biochemist studies and advises on chemical and biochemical processes in the organs, tissues and fluids of the human body and the effect of disease and drugs on these processes. He [She] organises the routine services of analytical and functional tests; devises and tests new methods of investigating disease processes and applies to clinical problems all modern chemical techniques".

Having been established in 1967 under the Chairmanship of Sir Solly Zuckerman, the Committee was requested to "consider the future organisation and development of hospital Scientific and Technical services in NHS hospitals and the broad pattern of staffing required and to make recommendations". Having received evidence from over 170 individuals and organisations, including the IMLT, the Committee's report was published December 1968. The IMLT's evidence had emphasised the fact that:

- (a) Medical laboratory technology was a separate discipline although clearly related to the pure sciences and medicine.
- (b) Practitioners represented a distinct profession for whom the term "technician" would be more appropriately replaced by the term "technologist" (or otherwise "scientific officer" as exemplified within the nomenclature of the scientific civil service)
- (c) Existing hospital technical and scientific services were inadequate in scale, organisation and personnel, and that there was a requirement for a category of staff which had received basic training in the practical aspects of medical laboratory technology, these having then progressed at an academic level to an Institute qualification in a particular specialist subject area and to the standard of a science degree.

- (d) By creating a unified career structure accessible to all medical laboratory staff, open-ended employment opportunities would be available to the most able practitioners. Publishing its report in December 1968, the main proposal affecting medical laboratory technicians focussed on a proposed new staffing structure and emphasised the role of non-medical graduates in medical laboratories. The essential details included the following suggested grades:

Scientific Officer: Normally recruited from graduates with 1st or 2nd Class Honours degrees or equivalent qualifications. Chartered engineers and sometimes persons with medical qualifications will also belong to this class. There should be opportunity for direct appointment to higher grades for scientists with appropriate experience outside the NHS.

Technical Officer: Qualifications of the level the Higher National Certificate. Some members of the class may be graduates.

Technical Assistant: Training will normally include practical training, generally provided in-service, and complementary further education through courses for higher qualifications including those leading to promotion to the Technical Officer class.

Technical Aide: No age limits or special qualifications. The members of this class will have the qualities required for simple routine procedures, care of equipment and other work requiring

experience of hospital procedures. Training would normally be in-service and promotion by experience and length of service”.

(See Zuckerman, 1968)

4. Under the common chairmanship of Mr. V (later Sir) Zachary Cope eight committees each having two common members (one medical and one lay) and a common secretary examined the training and supply of workers in the Health Service known as “medical auxiliaries”. These included the professions of Almoner, Chiropodist, Dietician, Medical Laboratory Technician, Occupational Therapist, Physiotherapist (including Remedial Gymnast), Radiographer and Speech Therapist. Amongst their recommendations was the suggestion that all persons qualified for employment in the NHS should be eligible for inclusion on a State Register and further that no individual should be appointed to a post in the NHS who was not on the register.
5. From 1st April 1954 any individual employed as a medical auxiliary would have to attain an appropriate qualification approved by the Minister or be deemed to possess alternative appropriate qualifications or experience. In the case of medical laboratory technicians the requirements were possession of either the Final Examination of the IMLT, or a United Kingdom science degree, or Associate membership of the Royal Institute of Chemistry. The IMLT was designated as the “appropriate” qualifying body. Replying to the Cope Committee’s questionnaire in 1949, the IMLT Council recognised the fact that State Registration would be a probable outcome of the Committee’s deliberations. This naturally had serious implications for the role of the IMLT as the professional qualifying body for Medical Laboratory Technicians and there was a marked reaction against the Committee’s proposals. Consequently alternative procedures for State Registration of medical auxiliaries were to be encapsulated in the *National Health Service (Medical Auxiliaries) Registrations Act, 1954 (Statutory Instrument, 1954, No. 55, London, HMSO)*. The new regulations established the qualifications required for NHS employment from April 1st 1954. Those individuals without formal qualifications but who were already practising prior to enforcement of the Act were allowed to seek registration. Such applicants were subsequently eligible for “ordinary membership” of the IMLT and were allowed to progress to higher grades by examination. Initial qualifications accepted by the IMLT for registration were:-
 - (a) Associateship or Fellowship of the IMLT
 - (b) “Such university degrees as the Board may approve”The list of alternative qualifications was soon to expand to include:-
 - (c) Higher National Certificates or Diplomas
 - (d) Military service and certain overseas qualifications
6. These were that:-
 - (a) An increase was required in the representation of the various professions on the Registration Boards.
 - (b) There should be a mechanism for limiting (by guarantee) the financial liability of those whose names were to be included on the Statutory Register.
 - (c) There should be a change of designation from “technician” to “technologist”.
7. The requirements for MLSO State Registration are:-
 - an agreed period of training in a laboratory approved by the CPSM
 - possession of a preliminary qualification recognised by the CPSM
 - completion of the relevant (i.e. specialist option specific) CPSM logbook
 - satisfactory performance in an oral examination (i.e. following the preliminary qualification)
 - a minimum of one year in-service training

8. The key points for review were to include :
- better protection of title
 - introduction of "health powers" (mechanisms for dealing with registrants who become ill)
 - a requirement to replace the outdated definition of "infamous conduct" and its replacement by a formula of "professional misconduct" in relation to discipline
 - the issue of lay or consumer representation
 - a re-assessment of the proper role of the Privy Council
 - a re-appraisal of the level and structure of medical involvement with respect to the professions allied to medicine
 - a re-examination of the need for such professions to evolve in the light of recent educational developments such as Continuous Professional Development

9. The Nuffield Institute was commissioned to examine the issues raised by a review of the Act – more specifically those relating to public protection and "natural justice" during disciplinary procedures. The report was completed in 1996 concomitant with the Parliamentary Agent's internal review (largely centred on Osteopaths and Chiropractors).

10. The most important development resulting in increased dialogue between the CPSM and the HE sector were the following:-

- (a) a joint workshop (involving all Boards) organised by the Council for Validating Universities (CVU) - concerned principally with the respective values of a research-based as opposed to a clinically orientated approach to courses.
- (b) a convention on the implementation of educational developments related to the PSM Act, the outcome of which included a realignment of the Boards' previous relationship with the Department for Education (D of E) and Her Majesty's Inspectorate (HMI) with respect to the new higher education councils. These were the three Higher Education Councils for England, Wales and Scotland (HEFCE, HEFCW and SHEFC); the Northern Ireland Advisory Council and the UK wide Higher Education Quality Council (HEQC). Added to this, the non-statutory fora of the Committee of Vice Chancellors and Principals (CVCP) and the Scottish Committee of Principals also became more involved with the CPSM Boards. The result was a complex funding arrangement. In Scotland and Wales all funds for PSM courses were administered by the Funding Councils whilst health-funded courses (e.g. Physiotherapy and Occupational Therapy) fell outside the HEFCE's remit and were transferred to the Regional Health Authorities.

11. The examination was designed specifically for student members of the PBLAA. Entrants to the examination must have reached the age of 20 years and have had 3 years experience in an approved laboratory. The examination was designed for admission to full membership of the Association and represented an essential pre-requisite for entry to examination for "Certificate A" (which subsequently became known as the "Part II" examination). Responsibility for qualifying examinations was later to pass to the IMLT subsequent to its inauguration in January 1943.

12. In support of his argument, Farr quotes the following advertisement:-

MIDDLESEX COUNTY COUNCIL. Technician required for Redhill County Hospital, Edgware, Middlesex. Must hold the Association's certificate in bacteriological technique. Should also have some knowledge of haematology. Salary £5.0s. 6d. rising to £5.18s. 0d. – pensionable post.

(PBLAA *Monthly Bulletin*, April 1939)

Farr's contention is that the advertisement is significant on several counts, i.e.

- (a) the fact that reference is made to a specialist subject area (haematology).
- (b) the use of the title "technician" which at the time carried some prestige.
- (c) the fact that the post was pensionable and carried a comparatively generous salary.
- (d) the requirement for a formal qualification.

Such criteria he maintains were a reflection of "a substantial revolution in the status of the medical laboratory worker in the community" [and that] "without a recognised qualification

obtained by examination requiring a high standard of performance, this could never have come about”.

13. Adopted by the Council in 1944, the report made several recommendations relating to the basic education of students. Advocating the establishment of courses at both local teaching institutions and also the use of correspondence courses, subjects to be included were Physiology (to General Nursing Council standard), inorganic Chemistry, Biology and Physics. Additional recommendations (including a syllabus) were made regarding student preparation for the Intermediate examination. The course duration was to be approximately 2 years and assessment should include written, practical and oral tests. The minimum age for student members was also to be reduced to 16 years. Held twice yearly, the examination covered all 4 major disciplines. Candidates were required to attempt questions in all subjects and obtain a pass mark of 60% in the practical session as well as in the aggregate of the 3 sections. From November 1957, Blood Transfusion Techniques were included. The examination was also extended to overseas countries, these being primarily Nigeria (1956), Ghana and Hong Kong (1961), Uganda and Mauritius (1963). The last Intermediate examinations were held in the Autumn of 1970.

The Final examinations however were always held in the UK. The requirements for success were identical to those for the Intermediate. Originally the specialist subjects were Pathological Technique, Bacteriological Technique and Pathological Chemistry Technique. (With time these subject categories became known as Histopathology, Bacteriology and Chemical Pathology respectively). Haematology and Blood Transfusion Technique were introduced in 1948, Parasitology in 1950 and Virology in 1960. Medical practitioners were appointed as examiners and as with the PBLAA system, Fellows of the Institute were to be present as assessors. The last Final examination was held in 1975, during the final months of the Institute's own existence as the IMLT. Following the introduction of the new National Certificates in 1967 the Institute became increasingly concerned with post-basic qualifications – a change symptomatic of its changing role from a qualifying to a purely professional body.

14. The advisory group consisted of representatives from the Joint Committee for Ordinary National Certificates and Diplomas in Science, the newly established College of Pathologists, the IMLS, the Department of Education and Science (DES) and the Scottish Education Department (SED). Following the group's conclusions that the introduction of national certificates was both desirable and feasible, the Council made a formal application to the DES. As a result, agreement was reached that a variant of the Ordinary National Certificate (ONC) in Sciences be designed specifically for those training in medical laboratory technology.

15. Published in 1953, the regulations for Fellowship by Dissertation and Examination included the following:-

- (a) candidates were required to complete a dissertation of not less than 5,000 words which was to contain an “*ordered and critical exposition of existing knowledge of the subject*”.
- (b) the dissertation, ideally should contain original work although this was not a necessary pre-requisite.
- (c) candidates were also required to sit 2 papers of a written examination in a subject in which the candidate had previously qualified for Associateship.
- (d) all candidates were required to attend an oral examination.

In addition, the Examining Body reserved the right to require candidates to undertake a practical examination – a right which in practice was never exercised.

16. As a result of DHSS resistance to development of the course the new Diploma was only offered at the Sir John Cass College of the City of London Polytechnic. The first awards (Dip. Med. Tech.) were made in 1972 and eventually were to receive academic recognition. In 1973 the Burnham Further Education Committee accepted the qualification as the “equivalent of a good honours degree”. Two years later both the DHSS and Scottish Home and Health Department (SHHD) recognised holders of the Diploma as being eligible for appointment as Scientific Officers (under PTA regulations) within the NHS. In 1976 the Royal College of Pathologists, under the regulations referring to honours degree entrants, recognised the Dip. Med. Tech. as a suitable qualification for entry to the MRC Path. examination.

17. The substantial increase in graduate entry was a result of several factors:-
- unemployment was relatively high with approximately 1.5 million registered unemployed persons in the UK.
 - the nature and value of the work of personnel in Pathology Departments became more pre-eminent in the public's perception.
 - early in 1978 the introduction of the title "medical laboratory scientific officer" reversed the adverse image of the "unskilled technician".
 - at the same time, the number of UK university places was 3-4 times higher than it was in the late 1940s (the number of school-leavers proceeding to degrees had increased from 2% to 7% in the same period).
 - the increasing availability of courses leading to vocationally orientated degrees in the medical sciences (the first was to be in Portsmouth Polytechnic in 1974 and the second at the University of Bradford in 1975).
18. It was argued that the profession needed to consider its attitude to graduate entry, particularly with respect to:
- the traditional frustrations and irritations of older practitioners suffering from artificial (or perhaps real) class distinctions imposed by Whitley Council regulations.
 - the question as to whether medical laboratory sciences as a degree subject was either viable or relevant (the debate continues as to whether there should be multi-disciplinary or single subject programmes).
 - whether manpower planning forecasts justified the establishment of such degree courses.
 - the fact that those school leavers wishing to pursue an essentially vocational career should have access to an academic course relevant to that vocation, further – whether such graduates should possess vocational or traditional science degrees.
 - whether there should be graduate-only entry with uniform minimum requirements and common pathways of qualification, or a wider intake of recruits from various educational backgrounds.
19. Medical Laboratory Technicians Board – Routes to State Registration – From 27/9/93

Qualification	"Top-up" Qualification	Minimum Length of In-Service Training	Implementation Date
Specifically approved Degrees in Biomedical Sciences. MLS option. Vocational	None	1 Year	Immediate
Single Honours and Modular degrees in related Sciences, the major subject being Anatomy, Biochemistry, Biomedical Sciences, Biology, Genetics, Immunology, Microbiology, Molecular Biology, Pathology, Pharmacology, Physiology, Zoology, Pharmacy	Successful completion of Primary FIMLS*	1 Year	Immediate (Those already in training will have a choice of continuing their current programme or topping up their qualification, therefore reducing their training to 1 year)
Single Honours in less Related Sciences (Chemistry, Physics, Biophysics)	Successful completion of Primary FIMLS*	2 Years	Immediate (Those already in training can continue without a top-up qualification)
Higher degrees accepted by the IMLS for Fellowship	None #	2 Years #	Immediate #
BTEC/HNC in Medical Laboratory Sciences	None	2 Years	September 1993 to be the last cohort accepted as a preliminary qualification

* 1 year day release or specifically approved postgraduate diploma

under discussion at the time – applicants holding these qualifications were advised to contact the Board for more details

Source: Annexe to CPSM MLT Board, Press Release October 1993 (Not cited).

20. The organisation's roles and responsibilities are discharged through an elected Executive Committee (originally five in number) and there is an annual conference open to all members and associate members. Its stated aims are to:-

“promote the quality of Biomedical Sciences teaching and research in institutions offering degree courses in Biomedical Sciences accredited by the IBMS. Towards this end the organisation will:-

- make representations to relevant bodies and organisations on matters concerned with the organisation, funding and assessment of Biomedical Sciences, teaching and research
- advise on and promote relevant membership of panels, boards and committees concerned directly or indirectly with Biomedical Sciences teaching and research
- provide a forum for the collection and dissemination of information and exchange of views on matters of common interest to centres engaged in Biomedical Sciences teaching and research
- provide a reference point for bodies and organisations concerned directly or indirectly with Biomedical Sciences teaching and research
- provide co-operation and collaboration between centres engaged in Biomedical Sciences teaching and research”

The Executive Committee now consists of seven members, two of whom retire annually to be replaced via election. The Chair and Vice-Chair are elected by the Executive and hold office for two years. A nominee of the IBMS Council attends meetings of the Executive Committee. The IBMS also provides the secretariat and a financial accounting system. Membership of the organisation is drawn from centres world-wide, each being entitled to nominate one voting representative to attend the business meeting at the annual conference. Centres offering non-accredited degrees in BMS may obtain associate (non-voting) membership. The Executive Committee also invites affiliate membership from other relevant bodies and organisations (e.g. CPSM, learned societies and government departments) and these can attend at annual conferences.

21. The firm belief of HUCBMS was that it was not possible to provide the educational components of MLSO requirements simply by means of extended work-based training periods. The organisation argued that with the advent of modularisation and Credit and Accumulation Transfer Schemes (CATS), the provision of appropriate top-up qualifications for holders of non-accredited degrees would be further facilitated. HUCBMS further advocated that the requirements for appropriate top-up education could be met by one or more of the following routes:-

- A Graduate Diploma or freestanding Postgraduate Diploma (PGD) in BMS with entry by an appropriate first degree
- A PGD linked to a Masters qualification in BMS
- Credit-rating for the presenting qualification which would then be followed by an appropriate combination of modules (i.e. a defined “field of studies”) from existing accredited degrees. In this way sufficient CATS points could be gained for the award of an accredited degree (in some cases this would represent a second undergraduate degree for the individual concerned)
- A combination of existing programmes, e.g. the Biology of Disease module from the Primary FIBMS course, together with “specialist” subjects, including as appropriate, molecular biology and/or immunology. Such programmes would lead to a University Diploma accredited by the IBMS and MLTB

22. Selected abstracts from the Policy Statement include the following:-

“.....There are however, core subject materials which should form the basis (at least 50%) of an approved top-up course. These can be grouped under the heading ‘Biology of Disease’ (including Genetics, Molecular Biology and Immunology). The content of the Biology of Disease should be defined, laying emphasis upon human disease. Biology of Disease is also the core component of Biomedical Sciences undergraduate degree programmes.....The minimum credit points for an approved top-up course should be 60 at level D (undergraduate), or M1 or M2 (postgraduate) (this is equivalent to one academic year of part-time study). Courses should have a robust and transparent structure and should lead to a

named qualification e.g. (Postgraduate Certificate, Postgraduate Diploma, Graduate Diploma) and title e.g. (Biomedical Sciences). Only holders of CPSM-approved qualifications should be deemed to satisfy the requirements for State Registration (i.e. holders of approved biomedical sciences degrees or holders of acceptable Science degrees plus a top-up qualification)

23. Two categories of activities exist:-

- (a) "Educational" (including participation in IBMS CPD accredited courses, workshops, research presentations, seminars and refereed publications).
- (b) "Professional" (including teaching, lecturing, examining, attendance at journal clubs and other similar activities).

Members achieving 25 credits (60% of which must be in the Educational category) within a 5 year period are awarded a CPD Diploma.

24. These included:-

- whether the Council should develop standard BTEC requirements for its national level courses or retain a measure of diversity
- the exact requirements for entry qualifications to BTEC courses
- how to deal with the proliferation of awards, staff development requirements, transferable skills and the use of Regional Advisory Councils

25. The major comments were that:-

- (a) the discussion document appeared to suggest that BTEC was seeking to increase its role and influence.
- (b) BTEC should confine its activities to those of an examining or moderating body.
- (c) it was inappropriate for BTEC to adopt an additional influential role for which it was not properly qualified or staffed.
- (d) BTEC had placed an undue emphasis on the objective model as a means of achieving its stated intentions (particularly with respect to higher awards). The IMLS called for such an emphasis to be "questioned urgently and critically".
- (e) the introduction of a modular structure might lead to a fragmentation of knowledge.
- (f) consideration of policy should include the general and scientific education of students as well as "work-related" education.
- (g) courses of study should include reference to educational as well as to vocational objectives.

26. Reasons for entry of the IMLS into the National Certificate Scheme included:-

- (a) an increase in the national demand for better opportunities in further education.
- (b) advances in MLS resulted in a requirement for improved scientific knowledge on the part of MLSOs.
- (c) a growth in the demand for day-release facilities.
- (d) the lack of recognition of IMLT qualifications outside of the MLS/NHS sector (not until the early 1970s did most universities begin to recognise the Fellowship qualification as an appropriate entry qualification to higher degrees).
- (e) the likelihood that LEAs would no longer fund courses which were not supported by the DES.

27. The aims of the NCVQ were to meet the demands for more qualified employees. Targets (originally meant to be met by 1992) were that 80% of the population in 1000 occupations should be qualified to NVQ level 1-4. All NVQs fit into the NVQ Framework (according to occupational area and level). NVQ levels are defined thus:-

Level 1 Competence in the performance of a range of varied work activities, most of which may be routine and predictable, or provide a broad foundation, primarily as a basis for progression.

Level 2 Competence in a significant range of varied work activities, performed in a variety of contexts. Some of the activities are complex or non-routine, and there is some

individual responsibility or autonomy. Collaboration with others, perhaps through membership of a work group or team may often be a requirement. For setting national targets, qualifications equivalent to five GCSEs at grades A–C or better match this level.

- Level 3 Competence in a broad range of varied work activities performed in a wide variety of contexts – most of which are complex and non-routine. There is considerable responsibility, autonomy and control or guidance of others is often required (i.e. supervisory competency). Qualifications equivalent to the BTEC National Diploma or a portfolio of two “A” levels plus five GCSEs at grades A–C or better are the comparable levels for target–setting purposes.
- Level 4 Competence in a broad range of complex technical or professional work activities performed in wide variety of contexts and with a substantial degree of personal autonomy and responsibility. In addition to these, responsibility for the work of others and the allocation of resources is often present. In many areas competence in supervision or management will be a requirement. Qualifications at this level include BTEC Higher National Diplomas and the Diploma in Higher Education.
- Level 5 Competence, which involves the application of a significant range of fundamental principles and complex techniques across a wide and often unpredictable variety of contexts. Very substantial personal autonomy and often significant responsibility for the work of others and for the allocation of substantial resources feature strongly, as do personal accountabilities for analysis and diagnosis, design, planning, execution and evaluation. Qualifications at this level include BA/BSc Honours degrees and Postgraduate degrees.

Nationally, standards of competency are determined by over one hundred and fifty lead bodies, twelve of which cover 45% of the population. Approximately twenty thousand individuals are directly involved in drawing up competencies.

GNVQs were introduced in September 1992 and represented a third type of qualification in addition to NVQs and academic qualifications. These are available at “Foundation”, “Intermediate” and “Advanced” levels. Designed to be delivered via FT education, GNVQs are based on explicit standards and are of a modular structure to allow credit accumulation. Advanced level GNVQs (the new vocational “A” levels) are designed to prepare candidates for entry into higher education. Both NVQs and GNVQs include core skills (at five levels) which involve communication, Information Technology, working with others, modern languages and “application of number”.

28. The Framework divided occupations into “Main”, “Critical” and “Enhanced” categories. The total number of people employed in occupations in which science, technology and mathematics were the main function was approximately 0.6 million. In July 1993 the ED funded a working group to draft terms of reference for a body for science, technology and mathematics. Its main recommendations in terms of aims were as follows:-

Aims

To contribute to the development of a competent and qualified UK labour force through the provision of a comprehensive framework of occupational standards to:

- *enhance the wealth creating potential of UK industry*
- *protect, improve and maintain the quality of life in the wider community*
- *enhance career opportunities and flexibility of employment in the labour force*
- *underpin vocational qualifications and thus provide valid and challenging targets for those in education and training*

(Verbatim from Seth – Smith, 1993).

29. Research (Grigor, 1994) has shown that laboratory training officers have previously complained of lack of formal qualifications. In reality however, several qualification systems existed already to meet the requirements of such training officers. These included the City and Guilds (NVQ Level 3), Further Education Teaching Certificates (FETC) and Postgraduate Certificates of Education (PGCEs) offered by many FE and HE institutions.

30. Ball maintains that academic study is learning-related and theoretical, liberal (implying an open-ended purpose), norm-referenced (i.e. associated with competition rather than achieving specific objectives) and is general or broad in nature. Vocational training on the other hand is associated with learning that is work related (practical), instrumental (thus having specific objectives), criterion referenced (i.e. requiring the achievement of specific skills or knowledge) and is also specific or narrow in nature.

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