National Neurology Needs Assessment

Appendices and Technical Reports

Appendix 1.1

Comhairle na nOspideal Review of Neurology & Neurophysiology Services 2003

A review of Neurology Services was undertaken by Comhairle na nOspideal in 2003. Its terms of reference were:

> ***'To examine the existing arrangements for the provision of consultant-level neurology and neurophysiology services nationally and following consultation with the interests concerned, to make recommendations to Comhairle na nOspideal on the future organisation and development of neurology and neurophysiology services.***

The report focused on adult neurology, neurophysiology, neuro-rehabilitation and paediatric neurology. The main recommendations were:

1. **Neurology**

Neurology services should be developed around groups of neurologists based or linked to major neuroscience centres. The two neuroscience centres at Beaumont Hospital and at Cork University Hospital (CUH), and the neurological unit at University College Hospital, Galway should continue to be the focal point for neurology and neurophysiology services in Ireland.

The priority developments were to:

a. Establish neurology units in Waterford Regional Hospital, the Mid-Western Regional Hospital, Limerick and Sligo Regional Hospital, each to be staffed by two consultants, with regular outpatient clinics and inpatient consultations at other hospitals in their regions. Each of these new units would have links to their relevant neuroscience centre (Waterford and Limerick would link with CUH and Sligo would link with Beaumont).

b. Enhance the Neuroscience Centre at Beaumont with the appointment of four additional consultant neurologists to provide a complement of seven posts in total. Long term Comhairle envisaged an eight post at Beaumont. Consultant neurologists based at the Neuroscience Centre at Beaumont should provide regular formal consultant out-patient clinics and inpatient consultations at the hospitals in North-East (Drogheda and Cavan) and The Midlands (Tullamore).

c. Enhance the Neuroscience Centre at CUH with the appointment two additional consultant neurologists at, giving a total of 5 posts - with commitments to South Infirmary - Victoria Hospital and Tralee General hospital. When post at Mercy Hospital

becomes vacant, a post based at the Neuroscience Centre at CUH with formal commitments to the Mercy Hospital should replace it.

d. Continue the development of neurology services in Galway with the appointment of a third consultant at University College Galway. Each consultant should have sessions designated for provision of outpatient clinics and inpatient consultations at other hospitals in the region and should have formal links with Neuroscience Centre in Beaumont.

e. The existing neurology units in the Mater, St. Vincent's, St. James's and Tallaght hospitals should continue to be developed and each consultant should have a formal attachment to the Neuroscience Centre in Beaumont. Comhairle envisaged a complement of three consultant neurologists at each of these site in the longer term.

A ratio of one consultant neurologist per 100,000 population was considered appropriate for Ireland (The ratio at the time of the report was approximately 1/280,000, i.e. 14 consultants). This recommendation equated to 39 consultants in 2003 (42 in 2007). The committee recommended a short-term target of 29 consultants (1 consultant neurologist per 150,000 population by 2013)

2. <u>Neurophysiology</u>

The Comhairle Review recommended that clinical neurophysiology services, in particular the major laboratory infra-structure and consultant posts be based at the two existing Neuroscience Centres of Beaumont and CUH with the other major teaching hospitals in Dublin each sharing a consultant post with the Beaumont Neuroscience Centre.

1. There would be six clinical neurophysiologists based at Beaumont. One of the post holders should be Director of neurophysiology service.
2. A second consultant neurophysiologist for CUH should be appointed.
3. An initial appointment of one clinical neurophysiologist at UCH, Galway was considered necessary to establish a service, with a sessional link to Beaumont. A second post was envisaged as the service develops.

3. <u>Neuro-rehabilitation</u>

The Comhairle Review recognised that a variety of different specialities and agencies are involved in the care, treatment and support of neurologically disabled patients but the no one body or group has overall responsibility. Scarcity of facilities and access difficulties have been the subject of a number of reports. The Committee noted that this area would benefit from a review and referred to the expected DOH&C national rehabilitation plan.

4. Paediatric Neurology

The Comhairle Review recommended two consultant paediatric neurologists per million population. In 2003, there were 5 consultants giving a ratio of 1/800,000. The Committee recommended the appointment of an additional consultant in Cork, based at CUH with a sessional commitment to the Mercy Hospital.

Appendix 1.2

Terms of reference of Working Groups were:

1. Health Information and Epidemiology

- Compile information on demography and population projections in Ireland
- Assess / estimate the prevalence of neurological conditions in Ireland and forecast how the prevalence may change over the next 20 years
- Compile information on neurology service activity including bed utilisation, waiting lists, outpatient activity and allied health professional activity and waiting lists (where this is available).

2. Description and Assessment of Current Services and Proposed Model of Care

- Describe the structure and organisation of Ireland's neurology services including paediatric neurology and neurophysiology
- Examine the Literature in relation to the structure and organisation of neurology services in other jurisdictions (particularly countries of similar population and geography) and examine good practice in this regard
- Compare the Irish structure with other models of care and define priorities for development using the Comhairle no nOspideal Report (2003) as a guide.

3. Technology, Training and R&D

- Examine requirements and opportunities for research and development, training and technology development
- Examine the impact from these developments on the services.

4. Nataluzumab (Tysabri) Needs Assessment

- Estimate the proportion of patients with multiple sclerosis would meet the criteria for being prescribed Tysabri (now and in 20 years time)
- In relation to preparing the neurology service for the introduction of Tysabri to identify its impact on diagnostic services e.g. MRI, neurology personnel, hospital beds, and other services including pharmacy costs and psychological needs
- In relation to monitoring, evaluation and medication effectiveness develop a clinical governance framework for the use of Tysabri in Ireland including: Criteria and services needed by hospitals for them to be eligible to use Tysabri
- a patient pathway (including patient selection criteria)patient monitoring and evaluation criteria including the recording and management of complications criteria to estimate cost-benefits of Tysabri e.g. symptom progression, disability monitoring, hospital admission avoidance, opportunistic infection.

Appendix 2

Appendix 2.1

Issues of Health Information in the context of Neurology Services

1. Applying general prevalence and i.e. rates from one population to another does not take account of the age and gender structure, geography or ethnicity of the Irish population. Our population is young and prevalence figures from countries, such as the UK, will over estimate diseases that are prevalent in older age groups (e.g. dementia and Parkinson's disease). As our population ages, the same prevalence rates may underestimate these diseases. While it is preferable to use age and gender specific rates for individual ethnic groups in a population such detailed data are not generally available.

2. Population projections are based on assumptions around fertility, mortality and migration.

3. The definition of neurological disease varies between studies. For example, the UK National Morbidity Surveys group diseases of the nervous system and sense organs together.

4. The definition of incidence and prevalence can vary. The method of calculation of these statistics can vary (particularly the denominator used) and thus the results may not be directly comparable.

5. The vagueness of some neurological symptoms can lead to patients being treated by other specialities (especially if there are long waiting lists for neurologists) and the patient may not always receive a neurological diagnosis.

6. Some neurological diagnoses are very rare or particularly difficult to diagnose.

7. Individuals with a neurological condition, who do not present for diagnosis or treatment, may not be included in prevalence and incidence figures.

8. Disease prevalence rates, from the published literature, are based on an aggregation of studies, of varying diagnostic quality and population coverage.

Appendix 2.2

UK Trends in Annual Prevalence 2001-2005: Age standardised prevalence rates per 10,000 persons registered in the practices Error! Bookmark not defined.

Age standardised prevalence /10,000 persons registered with practices						
ICD 9	Disease	YEAR				
		2001	2002	2003	2004	2005
346	Migraine	87	85	88	82	74
345	Epilepsy	34	35	41	51	44
436, 437, 438	Cerebrovascular disease	31	30	35	35	29
354	Mononeuritis Upper Limb Mononeuritis Multi	29	28	35	32	28
290	Senile Pre-Senile Organic Psychotic condition	20	20	20	19	17
332	Parkinson's disease	14	13	14	14	13
333	Extra Pyramidal disease Abnormal Movement (Other) includes dystonia and Huntington's chorea.	13	12	15	14	13
350	Trigeminal nerve disorders	9	7	8	8	7
340	Multiple Sclerosis	8	8	9	9	8
331	Cerebral Degenerations other (includes Alzheimer's)	5	5	6	7	6
342	Hemiplegia	2	2	3		2

The conditions are defined according to the International Classification of Diseases (ICD9). The use of ICD9 guarantees standard definitions across the practices in the survey. However, it is not always easy for clinicians to recognise individual neurological conditions in these classifications.

Appendix 2.3

National Physical and Sensory Disability Database
Neurological Conditions only

Neurological condition	Number	Percentage of People Registered
Multiple Sclerosis	2047	9.1
Stroke hemiplegia	964	4.3
Epilepsy	615	2.7
Head Injury	491	2.2
Spina Bifida	375	1.7
Spina Bifida and Hydrocephalus	282	1.3
Muscular Dystrophy	245	1.1
Parkinson's Disease and related disorders	166	.7
Friedrich's ataxia or cerebellar ataxia	146	.7
Hydrocephalus	121	.5
Paralytic syndromes quadraplegia	96	.4
Neuropathy	58	.3
Motor Neurone	58	.3
Meningitis	39	.2
Myalgic encephalomyelitis	36	.2
Myasthenia Gravis	13	.1
Spinal Injury	14	.1
Migraine	0	
Unspecified nervous system diagnostic category	284	1.3
Paralytic syndromes Erb's palsy	Low numbers*	
Mononeuritis	Low numbers	
Myopathy	Low numbers*	
Other demyelinating diseases of the CNS	Low numbers*	
Alzheimers disease and other cerebral degenerations	Low numbers*	
Huntington's chorea	Low numbers*	
Encephalitis	Low numbers*	
Dystonia	Low numbers*	
Myelopathies		

* "Low Numbers" refers to a policy not to list very low numbers to protect against indirectly identifying individuals.

Appendix 3.1:

Medical Neurology Groupings based on the Principal Diagnosis in 2004 HIPE; Inpatient and Day-case episodes combined*

MAJOR NEUROLOGY GROUP	Ranking in order of Magnitude	Percentage Of Medical Neurological episodes	Percentage treated as day cases
Seizure & Headache	1	*29%*	8%
Specific Cerebrovascular disorders except TIA	2	*14%*	2%
Cranial & Peripheral Nerve disorders	3	*10%*	565
Other Disorders of Nervous System	4	*10%*	25%
Transient Ischaemic attack & Precerebral Occlusions	5	*9%*	2%
Degenerative nervous system disorders	6	*6%*	22%
Traumatic Stupor & Coma	7	5%	3%
Nervous System Neoplasms	8	4%	36%
Multiple Sclerosis & Cerebellar Ataxia	9	4%	39%
Concussion	10	2%	0%
Nervous System Infection except Viral Meningitis	11	2%	27%
Spinal disorders & Injuries	12	1%	33%
Non-specific Cerebrovascular disorders	13	1%	9%
Nontraumatic Stupor & Coma	14	1%	
Viral Meningitis & Other	15	0.5%	
TOTAL		100%	17%

*Data source: HIPE & NPRS Unit, ESRI

Appendix 3.2:

Neurology Diagnosis Related Groups based on Principal Diagnosis HIPE 2004; Mean & Median Length of Stay and total number of bed days used

DRG - principle diagnosis of neurological nature	Number of bed days used in 2004	Number of HIPE episodes	Mean Length of stay	Median Length of stay
Specific Cerebrovascular Disorders except TIA	132,126	5,484	24	11
Non-Specific Cerebrovascular Disorders	6,286	448	14	7
TIA & Precerebral Occlusions	30,187	3,518	9	6
Cerebro-vascular Total	***168,599***	***9,450***	***18***	
Degenerative NS Disorders	***46,159***	***1,985***	***23***	***10***
Seizure & Headache	***44,521***	***10,783***	***4***	***2***
Traumatic Stupor & Coma	20,419	2,111	10	3
Non-Traumatic Stupor & Coma	2,124	352	6	2
Stupor & ComaTotal	***22,543***	***2,463***	***9***	
Other Disorders of NS+Hypert Encephalopathy	***20,189***	***2,952***	***7***	***2***
NS Infection except Viral Meningitis	13,448	500	27	9
Viral Meningitis	1,537	209	7	5
Infections Total	***14,985***	***709***	***34***	
NS Neoplasms	***13,603***	***1,118***	***12***	***7***
Spinal Disorders & Injuries	***11,950***	***366***	***33***	***10***
Multiple Sclerosis & Cerebellar Ataxia	***11,823***	***1,017***	***12***	***6***
Cranial & Peripheral Nerve Disorders	***10,376***	***1,761***	***6***	***3***
Concussion	***2,333***	***948***	***2***	***1***
Total	**367,081**	**33,552**	**11**	?4

*Data source: HIPE & NPRS Unit, ESRI

Appendix 3.3:

Breakdown of HIPE Episodes in each Hospital Network (2004)
By the HSE Administrative Areas in which the case resides*

PERCENTAGES OF HOSPITALISATIONS FROM EACH OF THE HSE ADMINISTRATIVE AREAS BY HOSPITAL NETWORK OF TREATMENT								
HSE ADMINISTRATIVE AREA (Based on county of residence of case)	***HOSPITAL NETWORK OF TREATMENT****							
	Dublin North	**Dublin South**	**Dublin Midlands**	**South-East**	**South**	**Mid-West**	**West/ North-West**	**North-East**
West	7.8	7.9	3.2	1.7	7.6	**96.5**	**94.5**	<1.2
South	5.3	8.1	4.3	**95.1**	**91.0**	1.8	<1.0	<1.2
Dublin/Mid-Leinster	18.7	**72.8**	**86.3**	1.6	<1.0	<1.0	3.3	1.3
Dublin/North-East	***67.2***	10.6	5.9	0.5	<1.0	<1.0	<1.0	**96.3**
Other Areas	1.0	<1.0	<1.0	1.1	<1.0	<1.0	1.3	<1.2
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

*Data source: HIPE & NPRS Unit, ESRI
** Bold: Hospital Network within the HSE Administrative Area

Appendix 3.4:

Percentage of HIPE Episodes 2004, with Medical Neurological Condition as Principal Diagnosis, receiving treatment within their own HSE Administrative Area of residence*

Medical Neurology Diagnosis Related Group (DRG)	PERCENTAGE RECEIVING TREATMENT IN OWN HSE ADMINISTRATIVE AREA (Based on county of residence of case)				
	West	South	Dublin/ Mid-Leinster	Dublin/ North-East	Total
Spinal Disorders & Injuries	24.0	34.2	85.5	53.0	52.3
NS Neoplasms	64.3	73.6	78.0	58.0	69.7
Degenerative NS Disorders	91.5	94.3	85.2	96.5	92.2
Multiple Sclerosis & Cerebellar Ataxia	80.7	90.6	83.0	89.3	85.8
Specific Cerebro-vascular Disorders except TIA	89.2	95.4	89.2	94.4	91.9
TIA & Precerebral Occlusions	94.4	96.1	88.6	96.5	93.9
Non-Specific Cerebro-vascular Disorders	89.6	89.4	79.7	84.4	85.9
Cranial & Peripheral Nerve Disorders	74.7	92.6	86.0	82.3	84.9
NS Infection except Viral Meningitis	89.6	79.1	92.0	84.6	87.5
Viral Meningitis	100.0	97.2	100.0	91.2	97.6
Non-Traumatic Stupor & Coma	96.1	96.0	91.4	94.4	94.6
Seizure & Headache	93.2	94.2	85.3	92.0	91.3
Traumatic Stupor & Coma	76.5	93.9	83.7	75.8	84.9
Concussion	94.6	94.5	28.0	98.9	90.7
Other Disorders of NS	72.9	78.7	85.1	72.1	77.5
Total	***85.8***	***91.1***	***85.3***	***87.8***	***87.6***

*Data source: HIPE & NPRS Unit, ESRI

Appendix 3.5

Fourth National Morbidity survey from General Practice (UK)
Patient Consultation Rates per 10,000 person years at risk

1991-1992		Patient Consultation Rates per 10,000 person years at risk								
ICD 9	Neurological Conditions	Total	0-4	5 to 15	16-24	25-44	45-64	65-74	75-84	85 & over
346	Migraine	**115**	3	99	150	158	126	***58***	***36***	***13***
345	Epilepsy	**36**	16	24	45	37	38	***41***	***42***	***34***
436	Acute but ill-defined cerebrovascular disease	**27**	-	-	0	1	22	***91***	***194***	***336***
437	Other and ill-defined cerebrovascular disease	**7**	-	-	-	0	7	***21***	***50***	***80***
438	Late effects of cerebrovascular disease	**1**	-	-	-	0	1	***2***	***3***	***6***
354	Mononeuritis Upper Limb Mononeuritis Multi	**21**	-	0	7	27	37	***25***	***27***	***16***
290	Senile & presenile psychotic conditions	**18**	0	-	-	0	4	***26***	***176***	***434***
332	Parkinson's disease	**15**	-	-	0	1	12	***56***	***113***	***135***
333	Other extrapyramidal disease & abnormal movement disorders (includes dystonia, Huntington's chorea)	**12**	2	6	8	9	18	***31***	***21***	***22***
350	Trigeminal nerve disorders	**9**	1	1	3	7	16	***21***	***26***	***16***
340	Multiple sclerosis	**7**	-	-	1	10	15	***9***	***2***	-
331	Other cerebellar degenerations (includes Alzheimer's disease)	**5**	0	0	0	0	2	***12***	***43***	***68***
342	Hemiplegia	**4**	0	0	1	1	4	***11***	***21***	***43***

Appendix 3.6

Brief Description of the Disciplines in Neurology (Including voluntary groups) from Submissions Received

Audiologist

Dizziness

Dizziness is one of the ten principle diagnoses for neurological disorders and accounts for a high proportion of attendance at ED, Neurology and ENT clinics. According to the National Institute of Health, dizziness is currently the third most frequently presented patient complaint, behind headache and lower back pain[1]. It follows from this that dizziness is a common symptom, affecting c.30% of people over the age of 65[2]. From an epidemiological perspective, vertigo and dizziness remain relatively under investigated[3].

The role of the audiologist/audiological scientist in the management of patients presenting with dizziness involves the conduction of oto-neurological investigations, including examination of the vestibulo-ocular reflex, electronystagmography, auditory brainstem response testing, caloric irrigation and rotational testing.

Migraine

Migrainous vertigo is relatively common albeit under-diagnosed in the general population. It has a significant impact both at the patient level and on the healthcare system[4]. A significant body of literature exists demonstrating a relationship between migraine disorders and dizziness. Vestibular and balance rehabilitation programs have a role in treating both of the disorders, although differ in the overall management aspects[5]. Audiologists and physiotherapists specialise in the provision of rehabilitative care.

Considering the issues raised above, the number of patients that should undergo oto-neurological investigation and balance rehabilitation is unquantifiable. Due to resource limitations, hospitals frequently do not provide services concerning further investigation of dizziness. Due to the complexity of the systems that are involved in maintenance of postural control and balance, as well as the number of disorders that can cause dizziness a multi-disciplinary team approach is required.

Additional investigation

Audiological investigation is also required in other neurological groups including: stroke, facial palsy, meningitis, multiple sclerosis, central auditory processing disorders, cerebral palsy, neurofibromatosis type2, auditory ganglion and auditory brainstem implantation.

References

[1] *http://health.nih.gov*

[2] *Colledge N, Lewis S, et al.: Magnetic resonance brain imaging in people with dizziness: a comparison with non-dizzy people*
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[3] *Neuhauser H.K.: Epidemiology of vertigo*
Current Opinions in Neurology, 2007 Feb; 20(1):40-6

[4] *Neuhauser H.K. et al.: Migrainous vertigo: prevalence and impact on quality of life*
Neurology, 2006 Sep 26; 67(6):1028-33

[5] *Shepard N.T.: Differentiation of Meniere's disease and migraine-associated dizziness: a review*
Journal of American Academy of Audiology, 2006 Jan; 17(1):69-80

Dietician

Dieticians/Clinical Nutritionists are uniquely qualified to translate scientific information about food into practical dietary advice. As well as providing impartial advice about nutrition and health, dieticians also advise about food related problems and treat disease and ill health. Dietetic practise follows evidence based guidelines.

Most neurological conditions are chronic in nature and, as such, many have nutritional implications including:

- Weight loss & malnutrition
- Dysphagia
- Nutrition related co-morbidities (Obesity/Diabetes/Hypercholesterolaemia)

<u>As a key member of the Multidisciplinary Team the Dietician/Clinical Nutritionist:</u>

- Conducts a full nutritional assessment.
- Identifies disease related nutritional complications.
- Advises regarding appropriate symptomatic management of these nutritional problems.
- Liaises with other MDT members.
- Provides timely intervention & follow up.

<u>Reasons for Dietetic Intervention Include:</u>

- During acute episodes of disease which put the patient at risk of weight loss, malnutrition and dysphagia. e.g. Relapse of Multiple Sclerosis.
- Where there is progression of illness. e.g. Motor Neurone Disease.

- When Enteral Nutrition including Home Enteral Nutrition needs to be instigated. e.g. Motor Neurone Disease or Multiple Sclerosis where oral diet is insufficient or contraindicated.
- Where there is scientific evidence to support the use of a special diet with neurological conditions e.g. Ketogenic Diet for Intractable Epilepsy.
- Where there is difficulty in food preparation as part of the disease e.g. Poor manual dexterity/ access to food.
- If there are side effects to the disease/condition which can be aided by Dietetic Intervention e.g. Impaired Glucose Tolerance following treatment with steroids.
- When there is need to support normal growth & development into adulthood e.g. Muscular Dystrophy.
- Where nutritional assessment & intervention is required following use of Fad diets e.g. Gluten free diet for treatment of Multiple Sclerosis.
- Where there is need to make dietary changes due to nutrition related comorbidities. e.g. Obesity/Diabetes/Hypercholesterolamia.

Ideally the above should take place through a patient centred MDT setting (Salmaggi et al, 2005). A patient centred approach integrating community services with hospital based clinics should be advocated to achieve the above. (Rio et al, 2007).

Occupational Therapist

Occupational therapists working in neurology are concerned with how persons with neurological conditions engage in the performance of activities of daily living, work/productivity and leisure activities. Occupational therapists seek to work from a client centred philosophy and the approach is one which seeks to address the physical, psychological and social aspects of care. Intervention is a collaborative process between clients, their significant others and the healthcare provider in order to promote client participation in goal directed and meaningful activity.

Similar to other allied health professional disciplines, occupational therapy intervention is based on a clinical reasoning process which incorporates sound clinical evidence in addition to an appreciation of the individual concerns and abilities of clients with neurological disorders.

Neurological patients appropriate for occupational therapy services are those who present with physical and/or cognitive disability and which consequently impact on functional independence in activities of daily living. This includes persons with various types of neurological disorders irrespective of acute or chronic disability. Assessment and treatment may be multidimensional in its approach though it is primarily rehabilitative i.e. increase and/or restore functional independence, or compensatory i.e. skills and techniques to adapt to residual disability. Though occupational therapy intervention is broad and inclusive, it primarily focuses on the assessment

and treatment of clients' occupational performance in activities of daily living. The following provides a broad summary of the occupational therapist's role in neurology:

- Assessment and treatment in areas of occupational performance in everyday activity
- Advice, recommendations, and education on achieving optimal independence and occupational wellbeing.

Specific areas of interest in neurology include:

- Wheelchair mobility and seating
- Environmental access and mobility
- Aid and appliances
- Assistive technology
- Splinting
- Fatigue management and energy conservation
- Work simplification
- Vocational rehabilitation
- Occupational wellbeing
- Lifestyle, coping and adaptation.

Orthoptist

Orthoptists play a vital role in the multidisciplinary approach to assessment and treatment of visual acuity, visual fields and ocular motility conditions in neurological patients. They are an integral part of the Ophthalmology team treating both inpatients and outpatients.

Physiotherapist

Physiotherapy is an autonomous, person centred, health care profession qualified to assess, diagnose, treat and evaluate in:

- Restoring, developing, improving and maintaining optimum independence, physical performance, function and health related quality of life;
- Preventing onset, symptoms and progression of impairments of body structures and functions, limitations in functional activities and restrictions in participation of life situations (WHO, International Classification of Functioning, Disability and Health 2001). All of which may result from disease, disorders or injury;
- Preventing and managing pain, physical impairments, disability and limits to participation and expediting recovery; and
- Promoting, assessing, enabling and maximising individual and population health and well-being

Physiotherapy practice is characterised by systematic clinical reasoning and reflective thinking which are both underpinned by a problem solving approach to patient centred care. Physiotherapy practice is supported, directed and shaped by scientific evidence of clinical effectiveness.

The list below includes the most frequent physiotherapy interventions in the physiotherapy areas of *neuromuscular* conditions

- Assessment, evaluation and management in the following:
- Nocioceptive, peripheral neurogenic and central pain states
- Motor function and sensory integrity associated with congenital or acquired disorders of the central nervous system in infancy, childhood and adolescence
- Motor function and sensory integrity associated with acquired non-progressive disorders of the central nervous system in adulthood
- Motor function and sensory integrity associated with progressive disorders of the central nervous system in adulthood Motor function and sensory integrity associated with peripheral nervous system conditions, whether acquired as a result of trauma or disease.
- Motor function and sensory integrity associated with non-progressive disorders of the spinal cord.
- Motor function and sensory integrity associated with incontinence
- Impaired arousal, range of motion, sensory integrity, and motor control associated with comas, near coma, or vegetative state
- Gait, balance and locomotion
- Vestibular conditions.

Scope of Practice, Irish Society of Chartered Physiotherapists, September 2006

It must be noted that patients with neurological conditions may also have other related or unrelated non-neurological problems in which physiotherapy may have a role to play.

Speech and Language Therapist

The practice of speech and language therapy in neurology includes prevention, diagnosis and treatment of communication, swallowing and voice disorders as associated with neurological conditions. The aim is to maximise communicative and swallow function in the natural environment and thereby promote overall wellbeing.

The practice of speech and language therapy involves

1. Providing prevention, screening, consultation, assessment, diagnosis, treatment, intervention, management, counselling, and follow-up services for disorders of:

a. speech (e.g., articulation, fluency, resonance)
b. language (e.g., comprehension and expression in oral, written, and manual modalities)
c. voice production
d. swallowing
e. cognitive aspects of communication (e.g. attention, memory, problem solving, executive functions)
f. sensory awareness related to communication and swallowing

2. Establishing augmentative and alternative communication techniques and strategies including developing, selecting, prescribing and implementing of such systems and devices. The provision of continual support is also important for this population.

3. Using instrumentation (e.g., videofluoroscopy, stroboscopy) to observe, collect data, and measure parameters of communication and swallowing to assist in accurate diagnosis in accordance with the principles of evidence-based practice and in association with other relevant professionals.

4. Educating and counselling individuals, families, co-workers, educators, and other persons in the community regarding acceptance, adaptation, and decision making about communication and swallowing.

5. Advocating for individuals through community awareness, education, and training programs to promote and facilitate access to full participation in communication, including the elimination of societal barriers.

Practice settings

Speech and language therapists provide services to the neurological population in a wide variety of settings, which may include, but are not exclusive to: acute hospital settings, rehabilitation centres, community based centres and also domiciliary services in some areas.

References:
American Speech-Language Hearing association (2001) Scope of Practice in Speech-Language Pathology. Rockville MD

Social Worker

Currently many neurological services have little or no social work provision. Consequently there is a paucity of published information or local statistics relating to the work of social workers with neurology patients.

Clients with neurological conditions need appropriate information and support at the time of the diagnosis of their condition. This is a crisis point for the person as well as for their families and carers. Social workers work systemically to support the process of adjusting to an altered future with the entire social, practical, financial and emotional implications involved. Common experiences of clients and their families include long term isolation, high levels of stress, reduced employment options, financial strain, lack of appropriate information, the need to negotiate an ever increasing complex health care system and changes in family roles such as becoming a full-time carer.

Social Workers are trained in grief and loss work as well as Solution Focused Therapy and resilience building. Experience of long term case work, an ability to respond to crises and a thorough knowledge of community services are the skills needed to deliver professional services to families who are managing a chronic care condition.

Social workers play a key role in discharge planning from the hospital setting. Discharge planning is a multi-faceted process that not only addresses clinical needs but also considers psychosocial aspects. Discharge planning should be a collaborative process between the team, the patient, the family/carers and community service providers. In some areas the lack of adequate social work cover impedes this work.

Many neurological conditions become a chronic health care issue and clients/families need support and services throughout their lives. We would advocate seamless services between hospitals and communities allowing for a continuum of care. The First Patient Project in Tallaght Hospital is one such model in operation which is working well. This service has a hospital based Social Worker assigned half-time to the project and working with a number of clients with M.S. and other neurological conditions in the community.

One area that has been greatly neglected is the impact on children of parents with serious neurological conditions. Social Workers on the ground have found it difficult to link the child welfare aspects of these cases to disability services due to the services being funded from different budgets.

Care co-ordination is a now complex task involving numerous agencies and funding structures. Families need a case manager/key worker to co-ordinate person centred care in a manner that enhances the family's coping skills and life choices. People want to be involved in their care planning and delivery and want to have local accessible services.

Increased and adequate levels of community based services are vital. *The Person in Environment Perspective*- describes the domain in which Social Workers conduct their practice. When clients with complex care packages are admitted to hospital for lengthy periods, their care

structure can breakdown. It is vital that care services are based on a multi-systemic approach involving liaison with agencies providing housing, entitlements, personal social services, vocational programmes and respite/residential care. Often the barriers to living independently in the community centre on inaccessible housing or lack of physiotherapy for example. A return to work can lead to the withdrawal of a medical card which pays for expensive medical supplies.

A neglected group are those with dual diagnosis such as people with Acquired Brain Injury and Drug addiction or those with neurological conditions and psychiatric problems. These clients often fall between services and end up with a reduced rather than enhanced level of service.

The dismantling of larger residential institutions for the "young chronic sick" is to be welcomed but only if it is accompanied by community based assisted housing such as that provided by the Peter Bradley Foundation. Currently there are more and more people under 65 years (some as young as 18 years) being sent to Nursing Homes due to the unavailability of alternative resources.

There needs to be stronger carer entitlements and greatly increased in-home and residential respite facilities. Carers should also be able to avail of carer training and carer support groups such as those in oncology units. The National Rehabilitation Hospital has a two day Stroke Awareness for Carers programme and many Voluntary Agencies provide much needed support and advice services. These services need to be greatly expanded and carers need the respite back-up to even participate in such programmes.

Neurological Alliance of Ireland

The Neurological Alliance of Ireland was established in 1998 in response to the serious lack of development of neurological services in Ireland. The NAI represents a number of voluntary agencies working with a wide range of neurological conditions in children and adults. These agencies play a vital role in enabling people to manage their condition over their lifetime. NAI member groups provide a range of services nationwide including the following:

(a) Residential, home care and respite services and carer support programmes
(b) Rehabilitation assessment and structured training and education support programmes
(c) Supported employment and back to work training and assistance
(d) Specialised education and counselling in relation to diagnosis and management of a neurological condition
(e) Specialised support, education and counselling for family members
(f) Provision of neuropsychological assessment and rehabilitation
(g) A wide range of education programmes aimed at employers, health professionals, schools and community services aimed at promoting greater awareness of neurological conditions.
(h) Promoting, commissioning and funding research on neurological conditions and keeping up to date with developments in research and treatment.
(i) Specialist nurse-led helpline services.
(j) Improving accessibility through provision of transport services and social activities and groups
(k) Preparation and regular updating of publications such as websites, newsletters, leaflets and information booklets and manuals, videos, CD's, press releases etc.
(l) Support groups, seminars, conferences and other meetings
(m) One to one support services for people with neurological conditions around the impact of their diagnosis and ongoing management of their condition.

NAI member groups have developed close professional relationships with the neurology teams working in the hospitals ensuring that people are put in touch with their services at the earliest stage possible. It is important to note that these organisations are committed to achieving the highest standard of service provision for people with neurological conditions in Ireland as outlined in their Standards of Care documents published between 1999 and 2002.

Appendix 6

Appendix 6.1 Technical Report No. 1 June 2006

Health Technology Assessment – Deep Brain Stimulation

Introduction

In recent years there has been an increasing demand to refer patients with refractory Parkinson's Disease to the UK for Deep Brain Stimulation (DBS). The Health Intelligence Section in the Population Health Directorate was asked to provide guidance on best practice in relation to this emerging technology. This Health Technology Assessment was undertaken by Dr. Tessa Greally, Director of Public Health, HSE West with assistance from Dr Denise Mc Carthy, Specialist Registrar, Public Health Medicine and Ms Ruth Corcoran, Researcher, Public Health Department, HSE West.

Description

DBS is a surgical procedure indicated in patients with disabling movement disorders that are no longer adequately controlled with drug therapy. These movement disorders include conditions such as Parkinson's Disease, Essential Tremor and Primary Dystonia. DBS is considered a symptom therapy, and while its mechanism of action is not clear, it has been considered, thus far, as an adjunct to drug therapy.

It is a variation on an old surgery where parts of the brain, usually the thalamus or the globus pallidus were destroyed in order to prevent abnormal brain activity being passed onto the muscles and causing tremor. These procedures were known as thalamotomy and pallidotomy. However, though effective, these surgeries carried significant risks. DBS offers the opportunity to inactivate the thalamus, globus pallidus or sub-thalamic nucleus without destroying other parts of the brain. The surgical procedure consists of the implantation of an electrode in the thalamus, globus pallidus or sub-thalamic nucleus which is connected by a thin wire to an implantable programmable stimulator (IPG) which is placed under the skin over the chest. The IPG is a pacemaker-like device that generates a high frequency pulsed electronic current that blocks the tremor. The wearer passes a hand held magnet over the IPG to turn it on and off as required. The advantages of DBS include the fact that the amount of stimulation is adjustable, since the electrode has four metal contacts, which can be used in different combinations and can also be re- positioned. Also compared with destructive surgery like thalamotomy and pallidotomy, DBS does not reduce the patient's ability to benefit from future treatments such as brain cell transplantation and can reduce the level of medication required. Surgery can be unilateral or bilateral.

Indications for DBS

a. Advanced Levodopa-responsive Parkinson's Disease patients with movement related symptoms that cannot be controlled by drugs.
b. Essential tremor- where this is not adequately controlled with medication and where the tremor is disabling.
c. Dystonia – affects muscle contractions resulting in twisting or odd postures which may be refractory to drug therapy.

Contra-indications for DBS

a. Patients with concurrent medical illness e.g. brain atrophy, coagulopathies etc.
b. DBS is contraindicated in those undergoing diathermy procedures, (short-wave diathermy, microwave diathermy or therapeutic ultrasound diathermy.
c. Patients who will be exposed to MRI (magnetic field interferes with neurotransmitter signal).
d. Patients who are unable to operate the neurotransmitter
e. Patients with cognitive deficits or depression

DBS Implantation Requirements

The patient is assessed pre-operatively by members of a multi-disciplinary Movement Disorder Team to assess suitability for DBS surgery. These include a neurologist (who will out rule conditions similar to Parkinson's Disease which DBS will not benefit and ensure that medical treatment has been used to optimum effect) and a clinical neuropsychologist who carries out formal cognitive assessments which establishes both suitability for surgery and a baseline measurement for follow-up. The DBS system (electrode, extension and neurotransmitter) is implanted by a neurosurgeon using a special stereotactic head frame to guide the surgery, and imaging techniques such as MRI to map the brain and implant the electrode. A neurophysiologist assesses intra operative mapping of the subthalamic nuclei and placement of the electrodes. A Movement Disorder/Surgical Parkinson's Disease Nurse Specialist plays a pivotal role in the clinical assessment using established protocols and in coordinating all stages of the assessment, surgery and follow-up. Physiotherapy, occupational therapy, speech therapy and dietetic input are based upon the individual patient needs. The Parkinson's Disease Nurse Specialist in the patient's area of residence is a vital link between hospital and community care for the patient and liaises with the Surgical Movement Disorder Team regarding the ongoing care in the context of the Deep Brain Stimulator.

DBS Centres designated in the UK by the National Specialist Commissioning Advisory Group (NSCAG) to undertake DBS are required to meet certain standards in terms of staffing, skill-mix, training etc. Referral rates involve assessing at least 30 patients per year and undertaking at least 15 implants. (See *Standards required for a neurosurgical centre providing DBS in Appendix 1).*

Evidence basis for DBS

The evidence base supporting DBS has been critically appraised in recent years through several Health Technology Assessments as outlined in Table 1 which increasingly support the use of DBS for suitably assessed patients with Parkinson's Disease refractory to medical treatment, essential tremor and dystonia. Appendix 2 reviews this work and describes ongoing research. The most recent assessment in Ontario reached the following conclusions:

- There is level 1b evidence (from a large randomized controlled trial) that bilateral DBS of the subthalamic nucleus is effective in the short-term control of advanced parkinsonian symptoms.
- There is level 3a evidence that this effect in Parkinson's disease is sustained for at least 5 years, based on measures of motor function, activities in daily living, percentage of waking day spent in good function without dyskinesia, and reduction in daily drug intake.
- The use of DBS of the subthalamic nucleus for parkinsonian symptoms allows a patient's daily drug intake to be reduced by about 50%.
- There is level 3a evidence that DBS of the thalamus is effective in the control of tremor in patients with essential tremor and Parkinson's disease for at least 6 years.
- There is level 3a evidence that bilateral DBS of the globus pallidus is effective in controlling primary dystonia symptoms for at least 1 year.
- Accounting for improvements in motor function score (a mean of 22 points) in patients with Parkinson's, and using a 10-point improvement in motor function score as a clinically significant change, one possible calculation of the cost-effectiveness of DBS to treat patients with Parkinson's disease would be less than $11,650(Canadian dollars) per 10-point improvement in motor function score ([$25,620 / 22 points] x 10 points).
- Because complication rates are lower (approx 4%) if DBS is performed in specialized centres, the number of sites should be limited.

An evaluation with the objective of determining the best time to start treatment is being carried out under the auspices of the PD SURG trial, which is sponsored by the Medical Research Council and the Parkinson's Association(UK). Recruitment to the trial has been extended until the end of December 2006; as all patients enrolled require at least one year of follow-up. The first results can be expected in mid-2008.

Table1 – Recent Health Technology Assessments on DBS

2005	Ontario Health Technology Assessment Committee, Canada
2003	National Institute of Clinical Excellence, United Kingdom
2002	L'Agence Nationale d'Accreditation et d'Evaluation en Sante, France
2002	Blue Cross and Blue Shield, United States
2001	Medical Services Advisory Committee, Australia

Input from Stakeholder groups

a. Broad support exists for the establishment in an Irish setting of DBS as part of a spectrum of care for patients with movement disorders. The Neurological Alliance of Ireland (www.nai.ie) and the Irish Parkinson's Disease Association provide advice, information and mentorship from patients who undergo Deep Brain Stimulation and to those who are considering the procedure. Both stress that an Irish programme should be adequately resourced to provide a standard of care at least equal to that of the UK centres. They report that these centres, mainly Bristol, provide a highly satisfactory service to patients who are able to travel and that the current level of staffing of neurological and neurosurgical services in Ireland needs to be enhanced significantly before a comparable level of service is possible. Contacts with clinicians (including a neurologist referring patients to the UK services and a nurse specialist supporting patients in the lead-up and aftermath of surgery) are extremely positive about the benefits of the procedure for suitable patients.

b. The Irish Institute of Clinical Neurosciences (www.iicn.ie) who provide training for Neuroscience disciplines have arranged recent lectures from UK neurosurgeons undertaking DBS and support its introduction in a local context to provide greater access for patients and enhanced training for staff.

c. VHI are committed to covering Irish patients who have DBS procedures because of NICE approval and support establishing an Irish service of equivalent quality if cost economies can be achieved.

d. The Department of Health and Children has received representations from Medtronic, the makers of the DBS implantable equipment, urging the introduction of the service in an Irish setting.

Licensing of DBS as a medical device

As of 1993, all implantable medical devices sold within the European Economic Area are required to bear the CE mark in compliance to EU directive 90/385/EEC. DBS was granted the CE mark in Europe in 1998. Since then it has been established in a large number of European communities, Table 2. The medical device department of the IMB does not have a role in authorising the use of Deep Brain Stimulation in Ireland since it has received CE marking in Europe. The IMB acts as a vigilance reporting agency once a procedure/medical device has been introduced to the country.

Table 2

Country	No of DBS centres
United Kingdom	17
Austria	6
Turkey	5
Switzerland	2
Sweden	3
Norway	4
Italy	44
Netherlands	6
Germany	14
France	21
Denmark	2
Cyprus	1
Belgium	10

Current arrangements for DBS Referral in Irish Patients

E112: Since 1997 over one hundred patients have been referred to UK centres through the E112 Overseas Treatment Scheme for DBS assessment- an unknown number has undergone the procedure and the costs have amounted to over €2.5 million, Appendix 3.

Private Insurers: Voluntary Health Insurance(VHI) have referred 21 patients for the DBS procedure to UK centres since 1999 , mostly in the last 2-3 years.*

*The Irish Parkinson's Disease Association indicate that they are now recommending members to seek funding through E112 rather than through a private insurer because of the relative ease of financial arrangements.

Estimation of numbers of people eligible for DBS Surgery.

Table 3 uses epidemiological studies in other countries to estimate the numbers of people in Ireland who would be eligible for DBS – background data and references are provided in Appendix 3.

Table 3

	Parkinson's disease	Essential Tremor	Primary dystonia
Republic of Ireland	1515 *606* *likely to undergo surgery*	134	83
Northern Ireland	637 *255* *likely to undergo surgery*	57	36

Projected costs of DBS for 2007

Experience from other countries where DBS services are available indicates that between 700 and 800 people in this country (approximately 600 with Parkinson's disease, up to 130 with essential tremor and approximately 80 with dystonia) would be eligible for DBS and willing to undergo surgery. Accepting that 100+ have already had DBS a potential referral group of 600+ exists in the Republic of Ireland. This could be augmented with referrals from Northern Ireland if an Irish-based service was established. Detailed costs are provided in Appendix 3.

In the absence of a local service it is likely that the current trend of approximately 20+ new referrals per annum will be referred in 2007.

2007 DBS referral to UK Costing Projections	€		€
Surgical procedure (New referrals)	40,573	x 20	811,460
Travel for surgical procedure(x6 visits)	9,000	x 20	180,000
Battery replacement (Existing refs.@3 yrs.	15,782	x 20	315,640
Travel for battery replacement	1,500	x 20	30,000
Annual outpatient visits (All existing referrals)	575	x 40	23,000
Travel to OPD(All existing referrals)	1,500	x 40	60,000
Total Medical Cost			**€1,1150,100**
Total Travel Costs			**€270,000**
Total estimated costs 2007			**€1,420,100**

Conclusions and Recommendations

1. Evidence of the efficacy of Deep Brain Stimulation in defined conditions is growing with each Health Technology Assessment undertaken and further ongoing research is now focusing on the most appropriate application of the technology.

2. The level of Irish referrals, although rising sharply in the last 3 years, does not reflect expected numbers of patients, who would benefit from DBS and indicates a level of unmet need.

3. Overall costs can be expected to rise because of the increase in numbers of people post-implantation who require follow-up and battery replacement.

4. The estimated cost for patients receiving this intervention in the UK in 2007 is €1.42 million in 2007- this is an underestimation of overall population need.

5. Projections of need indicate that an Irish centre would reach the minimum referral level of 30 referrals and 15 procedures required for NSCAG Accreditation in the short to medium term. Consideration should be given to establishing a National Centre within the context of a Movement Disorder Service.

6. The E112 information systems do not have the capacity to project expenditure to future years as they are disparate and do not discriminate between patients at different stages of treatment. A centralized information system based on a common data set would allow for future expenditure planning.

References

Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat (2005). Deep brain stimulation for Parkinson's disease and other movement disorders. Health Technology Assessment. Toronto, ON: Ontario Ministry of Health and Long-Term Care

National Institute of Clinical Excellence, United Kingdom (2003). Interventional procedure overview of Deep brain stimulation for Parkinson's Disease.

Hittinger, M-C. (2002). Progress report: evaluation of deep brain stimulation in idiopathic Parkinson's Disease/ France. Saint –Denis La Paline (France): Agence Nationale d'Accreditation et d'Evaluation en Sante (ANAES).

Technology Evaluation Centre (2002). Bilateral deep brain stimulation (DBS) of the subthalamic nucleus (STN) or the globus pallidus interna (GPi) for treatment of advanced Parkinson's Disease. Washington, DC: Blue Cross Blue shield Association (BCBS).

Medical Services Advisory Committee (2001). Deep Brain Stimulation for the symptoms of Parkinson's disease. MSAC application 1301. Canberra (Australia).

Appendix 1 Standards required for a neurosurgical centre providing DBS

The following standards were developed in the UK as part of the Medical Research Councils Parkinson's Disease Surgical Trial (MRC PD-SURG). These standards include organizational and clinical standards, a description of the multi-disciplinary staff and facilities required (based on the UK national manual of cancer standards), and a clear description of clinical measures of service to support the monitoring of patients. They are broken down as follows:

Standard	Level	Description	Compliance Definition and information required	Standard met yes/no
Topic 1 Location				
1.1	A	DBS for PD will be undertaken within a neurosurgical centre that provides both surgical and medical neurology services	Description of neurosurgical centre including clinical organisation, academic and research responsibilities List key related specialties on site and providing support	
1.2	A	The DBS centre should have a catchment population with a defined clinical network large enough to provide at least 30 patients per year for assessment	Describe catchment; referring hospitals and clinical networks	
1.3	A	The centre will undertake at least 15 stereotactic movement disorder surgery procedures a year.	Numbers in each of last 5 years by disease and device/surgical intervention. Numbers by named clinicians.	
Topic 2 Facilities				
2.2	A	Staff experienced in caring for patients with movement disorders in particular patients with advanced Parkinson's disease.	See below re surgeons List other key staff including roles and WTE committed to DBS;include nursing,therapy,technical staff	
2.3	A	Neurosurgical operating theatre appropriately equipped to undertake functional stereotactic surgery.	Describe key equipment,. Theatre(s) dedicated or shared?	
2.4	A	Access to neurological imaging modalities including stereotactic MRI and CT	Detail access arrangements including emergency access; List and supply imaging protocols	
2.5	B	Intra-operative monitoring including microelectrode recording.	Available:describe the equipment Plans for supply if not available now/	
Topic 3 Personnel				
3.1	A	Neurosurgeon with training in stereotactic functional neurosurgery who will be able to undertake with his/her team approximately 15 such procedures per year.	Supply CVs and describe range of clinical experience in last 5 years	
3.2	A	If undertaking a new surgical procedure e.g. STN surgery it is expected that the surgeon would have obtained the necessary education at another centre.	Describe nature ,content and duration of training	
3.3	A	Neurologist with expertise in the management of movement disorders and training in the assessment and	Describe nature ,content and duration of training	

		long term management of patients undergoing movement disorder surgery.		
3.4	A	Movement disorder specialist nurse with training in the pre and post-surgical assessment and management of these patients.	Describe nature ,content and duration of training Current roles and responsibilities including DBS PD-SURG Trial	
3.5	A	Operating theatre personnel with experience in providing support during functional stereotactic procedures.	Describe numbers with relevant training and experience	
3.6	B but ? A	Access to neuropsychology services.	Current level and nature of support Describe preferred but unavailable support; plans to provide?	
3.7	A	Access to physiotherapy and occupational therapy services.	Current level of support WTE and nature of support	
3.8	B	Neurophysiologist with experience in intra-operative monitoring during movement disorder surgery.	Current level and nature of support Describe preferred but unavailable support; plans to provide?	
Topic 4 Patient assessment				
4.1	A	All patients undergoing surgery for movement disorder should be assessed pre -operatively using recognised rating scales.	Define clinical assessment measures and scales Quality of Life measures used	
4.2		All patients undergoing surgery for movement disorder should be assessed post-operatively using recognised rating scales.	Define clinical assessment measures and scales Quality of Life measures used	
Topic 5 Audit				
5.1	A	A database of all patients undergoing surgery should be maintained	Details of database, organisation , data fields	
5.2	A	Regular audit of activity, outcomes and complications should be undertaken.	Audit reports including Trust clinical governance standards and reports. Clinical outcome measures and results in last 5 yrs including mortality, morbidity and measures of complications (infection rates, device failure, re-admissions, repeat surgical interventions)	
Topic 6 Patient centred care				
6.1	A	Patients and carers should be provided with comprehensive information, time and support in order that they may make informed decisions about their treatment choices. This process should begin at first referral and continue throughout their care with the centre.	Review of process. Review of information documentation. Notes review. Patient consultation.	
6.2	A	In the process of assessment patients should be specifically informed of the consequences of failing to remain compliant with their treatment. This should be reiterated as part of the process of informed consent .	Documentation of verbal discussion. Review of written patient information.	
6.3	A	Information should be made available in a wide range of formats and on more than one occasion. It should be clear, understandable, and culturally sensitive and evidence based. When given verbally, information given should be precisely documented.	Review of information available. Notes review. Patient consultation.	
6.4	A	A range of psychological and social support services should be offered to meet the needs of patients and carers.	Availability and presence of suitable staff. Review of training. Take up rates for these services. Review of local links.	

		These should be made available at the specialist centre and links to facilitate this at a local level should also be developed.		
6.5	A	Patient and carers' self-help and support groups are encouraged and all patients referred to the centre should be provided with information about them. Involvement of these groups should be available early in the assessment process.	Discussion with support groups. Availability of information leaflets. Assess support from Tx centre.	
6.6	A	Patients should have immediate 24-hour access to a member of the Team for advice, information and support.	On Call rota. Information given to patients.	
6.7	A	Patients, carers and their General Practitioners should have access to all members of the multi-disciplinary team to discuss specific problems or concerns.	Take up rates. Patient satisfaction surveys. Suitable organisational arrangements in place.	
6.9	A	The views of patients, carers and staff will be regularly and formally sought and the results openly available.	Review patient satisfaction surveys. Review management minutes to confirm results discussed and acted upon if necessary.	
6.10	A	There should be formal arrangements for addressing complaints and other comments made by patients, carers and staff at other times.	Review complaint pathway.	
6.11	A	Staff in the multi-disciplinary team should have training and be supported in using communication skills. There should be a policy for breaking bad news.	Review policy. Review training.	
6.12	A	There should be written guidelines for the Centre agreed with local refering physicians, general practitioners and patient/carer groups covering communication between clinicians and patients.	Review guidelines. Confirm these are satisfactory with all involved.	
Topic 7 Research and Development				
		Research Strategy		
7.1	A	Each centre to have and regularly update a Research Strategy which documents: - current and planned activity - the resources needed to support (e.g. staffing) - -objectives for development	Research Strategy document. Progress against objectives in the Annual Report.	
7.2	A	Written into the strategy should be a commitment to working in partnership with other centres in research activity which is aimed at answering the research questions which are important to the further development and improvement of clinical practice, for the benefit of patients.	Examples of research collaborations with other centres.	
7.3	A	A documented Intellectual Property Policy and Procedures which will ensure that any IP arising from both service and research activity is protected and exploited to the benefit of future patient care.	IPR Policy and Procedures.	
7.4	B	Each centre should strive to continuously improve its research infrastructure; such improvements to be monitored regularly. Basic requirements include:	Progress against agreed objectives in the Annual Report.	

		- sufficient research staffing/time, space and facilities to support the research strategy - a well regulated and documented internal funding system to support pilot/preliminary projects - a clinical information database which has written protocols for data entry and quality assurance - access to and support for independent statistical collaboration to assist in study design, analysis and interpretation of research findings		
		Research Governance		
7.5	A	Evidence of compliance in the specialities with the three MUST Dos: - systems are in place to ensure that an appropriate member of staff is notified of, and has approved, all research in the organisation - systems are in place to ensure all ongoing research has ethics committee approval - - arrangements are in place to ensure that someone acceptable is responsible for making sure that informed consent and procedures in the protocol approved by the ethics committee are being adhered to.	NHS Trust Research Governance Policy and Procedure in place, plus evidence of Trust and REC approval of all research activity.	
7.6	A	A research governance implementation plan must be in place by July 2002, in line with government policy for all NHS Trusts.	Implementation Plan	
7.7	A	The practice governing the use (i.e. collection, storage and use) of donated materials for research should be governed by Policy and Procedures which incorporate current national guidelines.	Uses of Biological Materials for Research Policy and Procedures.	
		Research Outputs and Outcomes		
7.8	A	Regular participation in national and international conferences	Summary of activity in Annual Report.	
7.9	A	Annual peer reviewed publications	Publications in Annual Report.	
7.10	A	Clinical practice is informed by regular review of research evidence derived from local, national or international research activity.	Examples documented in Annual Report.	
Topic 8 Education and Training				
8.1	A	Consultant core members of the MDT should attend one specialist meeting per year	CME log	
8.2	A	SAC recognised surgical trainees should perform/assist at a minimum of x supervised implants in 12 months	Surgeons Personal log	
8.3	A	Junior medical staff of the programme should be trained in relevant techniques and "signed off" by the relevant consultant as being permitted to carry out procedures unsupervised	Doctors procedure logs	
8.5	A	Nursing staff in dedicated areas should attend at least four relevant study days per year	Personal training record	

8.6	A	The nurse in charge of a dedicated area should have a post-basic clinical-base qualification in a relevant clinical area		
Topic 9 Management and organisation				
9.1		*Leadership and Accountability* There should be clear and accountable leadership of the service within each Centre with a named Director notified to NSCAG. There should be adequate time available to the lead clinician and manager to perform this role.	A management structure that clearly demonstrates lines of accountability within the service and within the Trust. Job plans and job descriptions outlining responsibilities and sessional time allocated.	
9.2		*Lead Clinician and Manager Responsibilities* Should have overall responsibility for ensuring staff are fully aware of the standards against which Centres will be assessed and that mechanisms are in place to achieve compliance with the standards. To take part in the Trust's clinical governance activities, which are of relevance to the service. To ensure effective communication with all members of the service and to facilitate multidisciplinary team working in the delivery of services. To meet regularly with colleagues from other Centres and with NSCAG to address regional and national service delivery issues	Clinical governance annual and other reports Attendance at national Advisory Group	
9.3		*Evidence Based Services / Protocols* There should be evidence based service protocols, which are reviewed and updated regularly covering all aspects of the service. These should be available to all new staff joining the service and should form part of a formal induction to the service.	Documented protocols made available. Record of induction of new staff	
9.4		*Workforce Planning* There should be effective and sustainable workforce planning covering all professional disciplines forming part of the multidisciplinary team. All staff should have regular appraisal and agreed professional development plans.	Published senior and junior staff rotas; demonstrable compliance with the New Deal and Working Time Directive wherever possible. Evidence that consultant surgeon establishment meets RCS guidelines. Record of appraisal and professional development plans.	
9.5		*Business Conduct* There should be regular (monthly/bi-monthly) business meetings within the Centre to address issues specific to the service. This should include financial reporting, activity reporting, education, audit, and clinical governance and research issues.	Record of attendance and minutes of meetings made available.	
9.6		*Resource Use* There should be clear accounting for all income to the Trust that is for the	Trust Financial Reports NSCAG Review	

		delivery of services in accordance with the fiscal guidance set out by NSCAG. This will include finance directly managed by the service and that, which is managed by the finance infrastructure within the Trust. Methods should be used to ensure there is equitable comparison of costs of the service between the Centres.		
9.7		*Data Collection* Robust arrangements should be in place for timely and accurate collection of data. Data should be made available to NSCAG under agreed reporting mechanisms.	Data transfer NSCAG monitoring	
Topic 10 Communication				
10.1		General practitioners and other referring physicians must receive adequate feedback after patients are assessed. If patients are turned down, the reasons should be made clear.	Audit of assessment letters	
10.2		When patients are discharged from hospital, primary care physicians must be provided with an information pack outlining details of medication, expected side effects and potential drug interactions.	Discharge 'packs' available	
10.3		Shared care protocols should be drawn up for key drugs.	Shared care protocol document	
10.4		After each visit to the follow up clinic, a letter with details of investigations and changes in medication must be sent promptly to the general practitioner	Audit of clinic letters	
10.5		Primary and secondary physicians with questions about any aspect of post DBS care should be encouraged to contact the physician for advice. A member of the team should be available at all times to receive calls.	Satisfaction survey of users of the service	

Appendix 2

Review of Evidence for Deep Brain Stimulation

Effectiveness & Safety Literature Review

Aim; Objective of review

To determine the effectiveness (efficacy) and adverse effects (safety) of DBS in the treatment of symptoms of idiopathic Parkinson's Disease, essential tremor and primary dystonia.

Methods of reviewing

The Ontario Health Technology Advisory Committee Recommendation on DBS in Parkinson's disease and other movement disorders was used as a baseline for evidence on the efficacy and safety of Parkinson's Disease (Ontario Ministry of Health and Long-Term Care, 2005). This review was published in March 2005 and the literature has been included in this review. They searched electronic databases such as OVID MEDLINE, EMBASE, OVID MEDLINE In-Process and Other Non-Indexed Citations, Cochrane Central Register of Controlled trials, Cochrane Database of systematic reviews and INAHTA.

We searched some of these databases for more recent studies on DBS and its use in Parkinson's Disease. In addition we searched the following databases: MDConsult and EBSCO.

Keywords for use in the literature review included:

Deep Brain Stimulation, brain stimulation, electrical stimulation of the brain, electric stimulation therapy, electrode, neurostimulation, thalamic, subthalamic, globus pallidal, activa, kinetra, soletra, Parkinson's disease, parkinsonian disorders, dyskinesa, dystonia, essential tremor, dystonic disorders, movement disorders

Inclusion Criteria

We included all those studies as included in the OHTAC study (English language articles and HTAs from January 1, 2001)
All English language articles and HTAs from January 1, 2005 until present

Intervention

Deep Brain stimulation for parkinsonian disorders, where the thalamic nucleus and/or subthalamic nucleus and/or the globus pallidus are stimulated.

Previous Health Technology Assessments

Year	Author, Country	Focus of Assessment
2005	Ontario Health Technology Assessment Committee, Canada	Effectiveness and adverse effects of DBS in the treatment of PD, essential tremor and primary dystonia.
2003	National Institute of Clinical Excellence, United Kingdom	Safety and efficacy of DBS-STN in patients with PD.
2002	l'Agence Nationale d'Accreditation et d'Evaluation en Sante, France	Safety and efficacy of DBS in PD patients refractory to medical therapy but remain sensitive to L-dopa.
2002	Blue Cross and Blue Shield, United States	Improved health outcomes associated with bilateral DBS of the STN or globus pallidus in advanced PD.
2001	Medical Services Advisory Committee, Australia	Effectiveness of DBS relative to ablative surgeries; effectiveness of DBS on its own

Summary of findings of previous Health Technology Assessments

Ontario Health Technology Assessment Committee, Canada, 2005

The objective of this study was to determine the effectiveness and adverse effects of DBS in the treatment of Parkinson's disease, essential tremor and dystonia and to do an economic analysis if evidence of effectiveness was established. It found that there was evidence from randomized controlled trials that bilateral DBS of the STN is effective in the short-term control of advanced parkinsonian symptoms. Non-randomised controlled trials in this study indicated that the effect is sustained for at least 5 years. There is non-RCT trial evidence that DBS of the thalamus is effective in the control of tremor in patients with essential tremor and PD for at least 6 years. There is evidence from non-RCT controlled trials that DBS of the GP is effective in the control of symptoms of primary dystonia for at least 1 year. The review concluded that there is a shortfall in the numbers of DBS being carried out in Ontario for drug resistant PD, essential tremor and dystonia. The review determined that the complication rates are lower if DBS is performed in specialized centres so it recommends that the number of sites where DBS is carried out be limited. This HTA ascertained that the cost per procedure in institutions with the expertise to carry out DBS and the associated human resource considerations are likely to be limiting factors in the development of the DNS procedure in Ontario,

National Institute of Clinical Excellence, United Kingdom, 2003: Interventional procedure overview of Deep brain stimulation for Parkinson's Disease

The objective of the NICE HTA was to determine the safety and efficacy of stimulation of the subthalamic nucleus in patients with PD who have become refractory to medical treatment (laterality [unilateral or bilateral] of surgery not specified). This review included 2 systematic reviews, an RCT, 6 non RCT, 8 case series and 9 small comparative studies. It found that DBS improved the motor skills, motor function and movement of patients with DBS. It found the safety and efficacy data from these studies to be adequate to support patients with PD who have become refractory to standard medical treatment. The review also concluded that patient selection be made by a multidisciplinary team and informed consent and clinical audit be provided for. It also recommended that the results of the PDSURG trial currently underway in the UK be reviewed upon completion.

l'Agence Nationale d'Accreditation et d'Evaluation en Sante (ANAES), France (Hittinger. 2002)

The objective of this review was to determine the safety and efficacy of DBS in patients with Parkinson's Disease who no longer respond to medical treatment but who remain responsive to L-dopa (laterality of surgery not specified). The review included 3 RCTs, 2 non-RCTs, 3 summary reviews and 5 case series. It was found that DBS of STN or GP is effective in the short-term for PD and that stimulation of thalamic DBS is effective for tremor. It concluded that DBS is a feasible treatment for PD and its related conditions but recommended that further assessment by expert centres is required. The lack of sufficient numbers of RCTs were found to hamper this technology assessment.

Blue Cross and Blue Shield, United States (Technology Evaluation Center, 2002)

The objective of this review was to determine whether bilateral (not unilateral) DBS of the STN or GP improves health outcomes in PD. The review included 1 RCT, 12 single centre studies and 1 large case series when assessing DBS for STN. It included 2 RCTs and 7 non-RCTs when assessing DBS of the GP. The review found that DBS of the STN relieved motor fluctuations, mobility and dyskinesias in PD. The magnitude of change in motor function and the reproducibility of the results of these studies demonstrate the effectiveness of DBS of the GP. The review found all this evidence to be compelling due to the consistency of the findings and clinical improvements demonstrated.

Medical Services Advisory Committee (MSAC), Australia, 2001

The objective of this study was to determine the effectiveness and safety of DBS (STN, GP or thalamus) relative to other surgeries, and on its own, in the control of parkinsonian symptoms in those patients for whom medical therapy no longer provides a sustained motor response. It included 1 RCT comparing DBS of the thalamus and thalamotomy; 1 RCT comparing DBS of the GP and pallidotomy; no studies comparing DBS of the STN and ablative surgery and 2 previous HTAs to compare DBS to medical treatment. It found that although these studies showed DBS to be significantly more successful than the other medical procedures more rigorous study is required. The review recommended funding for those centres with appropriate expertise.

In these reviewed assessments efficacy of DBS in relation to improving PD symptoms were determined. The following table details the summary data on adverse events as reported in these assessments.

Year	Author, Country	Adverse Effects
2005	Ontario Health Technology Assessment Committee, Canada	Expert opinion suggests that the rate of serious adverse effects may be as high as 8%, but that it falls to about 4% in multidisciplinary expert centers. These effects are as follows: • Haemorrhage:3-5% patients • Cognitive, behavioural effects • Neurological damage on sudden withdrawal of DBS. The study details all adverse effects specified for DBS for PD, for essential tremor and for dystonia
2003	National Institute of Clinical Excellence, United Kingdom	Complications: risk of stroke, confusion, speech disorders and vision problems. Risk of stroke found to be 3%
2002	l'Agence Nationale d'Accreditation et d'Evaluation en Sante, France	No safety data reported. Indication that medical device vigilance reports are suggestive of under-reporting of adverse events which are: surgical (haemorrhaging; medical device, infection, dysfunction) and stimulation

		parameters.
2002	Blue Cross and Blue Shield, United States	No analysis of adverse events
2001	Medical Services Advisory Committee, Australia	Adverse events related to the surgical procedure (e.g. lead dislodgement, hematoma); functional status (e.g. dystharia; transient paraesthesia) cognitive/behavioural functions. There are no certain estimates of incidence of these adverse events

The following list of efficacy studies 2005-present

1. Deep Brain Stimulation of the subthalamic Nucleus in Parkinsons Disease – A Clinical Study. Erola, T. 2006

Aims of study
• To evaluate clinical outcome after bilateral DBS STN • To assess the impact of bilateral DBS STN on health related quality of life • To evaluate the effect of DBS STN on tonic autonomic CV regulation

This study was carried out in the University of Oulu between the years 2001 and 2005. Forty-two patients were included in the study, all those who were operated on with bilateral DBS STN in Oulu University Hospital during the years of 2000-2003. The patients ranged in age from 44-74 years. This study was a RCT, a group of age-matched patients being used as controls. The following parameters were assessed in each patient both preoperatively and post operatively.

1. Clinical Evaluation and neuropsychological tests

The effects of the DBS STN on motor symptoms and activities of daily living were evaluated through intelligence tests (patients look for similarities in word pairs), trail making tests (time taken to combine numbers and letters), phonetic and semantic verbal fluency tests.

Results

- 12 months post surgery a significant improvement was seen in most subscales of the Unified Parkinson Disease Rating scale when the Stimulation was on.
- Dyskinesias and clinical fluctuation values reduced significantly by 53% ($p<0.01$ Friedman's test).
- Motor response values also improved significantly (31.4% improvement, $p<0.05$ Friedman's test) due to stimulation

- When comparing motor function during stimulator on and off situations there was an improvement in the severity of tremor ($p<0.05$), rigidity, gait ($p<0.05$) ($p<0.05$) and akinesia ($p<0.01$) when the stimulator was on.
- No change in verbal fluency ability

2. Evaluation of health-related quality of life (HRQoL)

Two HRQoL instruments were used to measure the HRQoL: PDQ-39 and NHP. The former instrument is a well-known measure of HRQoL in PD. It measures mobility, activity of daily living (ADL), emotional wellbeing, stigma, social support, cognitions, communication and bodily discomfort. The latter instrument assesses aspects of health namely pain, energy, sleep, physical mobility, emotional reaction and social isolation.

Results

- PDQ-39: Significant improvement in ADL ($p<0.001$), emotional wellbeing ($p=0.004$), stigma ($p=0.001$) and bodily discomfort ($p<0.001$).
- NHP: Significant improvements in those scales measuring energy, sleep, emotional reactions and social isolation. There was a non significant decrease in the scale measuring problems with physical mobility.

3. Autonomic Nervous System Evaluation

Cardiovascular parameters fluctuate from one beat to another under the control of the autonomic nervous system. Ambulatory EKGs were performed on all the patients before the operation and 12 months after.

Results

- No significant effects on cardiovascular autonomic function

This study concluded that DBS STN is an effective treatment of advanced PD.

2. Deep Brain Stimulation for the treatment of Parkinsons Disease: Overview and impact on gait and mobility. Piper, M., Abrams, G., Marks Jr. W. 2005

Aims of study	*Efficacy*
To evaluate impact of bilateral DBS on gait and mobility in patients with PD	Functional and quantitative gait analyses show sustained improvement in gait dynamics

3. Bilateral subthalamic stimulation improves gait initiation in patients with Parkinsons Disease. Liu et al. 2006.

Aims of study	*Efficacy*
To evaluate impact of bilateral DBS STN on gait and mobility in patients with PD	DBS significantly improved the performance of patients with advanced PD in gait initiation

4. Deep Brain Stimulation of the subthalamic nucleus reversibly deteriorates stuttering in advanced Parkinson's Disease. (Burghas et al. 2005)

Aims of study	*Efficacy*
To evaluate impact of bilateral DBS on stuttering in patients with advanced Parkinson's Disease	DBS significantly improved stuttering of patients with advanced PD

5. Normalising motor-related brain activity: subthalamic nucleus stimulation in Parkinson's Disease. Grafton et al. 2006

Aims of study	*Efficacy*
To test whether therapeutic unilateral deep brain stimulation of the subthalamic nucleus in patients with PD leads to normalization in the pattern of brain activation during movement execution and control of movement extent	DBS significantly leads to normalization in the pattern of brain activation during movement execution and control of movement extent

6. Clinical and economic results of bilateral subthalamic nucleus stimulation in Parkinsons Disease. (Fraix et al. 2005)

Aims of study	*Efficacy*	*Safety*
To assess the safety, clinical effects, quality of life and economic cost of STN stimulation.	• Motor score improved significantly by 57% • Activities of daily living improved significantly by 48% at 12 months follow-up	• Some patients developed a haemotoma during electrode implantation

This was s prospective multicentre study. Patients were assessed over 12 months following DBS. It concluded that STN stimulation has good outcomes with relatively low risk and little cost burden in PD patients.

7. ***Pallidal vs Subthalamic Nucleus Deep Brain Stimulation in Parkinson Disease. (Anderson et al. 2005)***

Aims of study	*Efficacy*	*Safety*
To extend our randomised, blinded pilot comparison of the safety and efficacy of STN and GPi stimulation in patients with advanced PD	• Off-medication Unified PD Rating Scale motor scores improved after 12 months of both GPi and STN stimulation (39% vs. 48%). • Bradykinesia improved more with STN than GPi stimulation. • Levodopa dose was reduced by 38% in STN stimulation patients compared with 3% in GPi stimulation patients ($P = .08$). • Dyskinesia was reduced by stimulation at both GPi and STN (89% vs. 62%).	• Cognitive and behavioural complications were observed only in combination with STN stimulation

This study concluded that stimulation of either the GPi or STN improves many features of advanced PD. It is premature to exclude GPi as an appropriate target for DBS in patients with advanced disease.

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Appendix 3

Economic Analysis

Since 1997 approximately 97 Irish patients were approved for referral to the U.K. for Deep Brain Stimulation assessment under the E112 Overseas Treatment Scheme. The total treatment cost paid to date under this scheme is €2,566,550. See Table 1.

The majority of patients are referred to Frenchay Hospital in Bristol U.K; . Radcliffe Hospital in Oxford U.K. and Hammersmith Hospital U.K. also receive referrals for Deep Brain Stimulation from Ireland under the E112 scheme.

Voluntary Health Insurance (VHI) have referred 21 patients for the DBS procedure to UK centres since 1999, mostly in the last 2-3 years. The Irish Parkinson's Disease Association indicate that they are now recommending members to seek funding through E112 rather than through a private insurer because of the relative ease of financial arrangements so the balance of costs may shift in favour of the E112 route. BUPA and VIVAS do not cover the costs of the DBS procedure

Medical Treatment Costs

Under the E112 scheme the total medical treatment cost paid to date since 1997 is approximately €2,566,550.*

*This does not include payments which have not been processed. These outstanding payments date back as far as 2002.In the South East region these outstanding payments were calculated at additional 33% of total treatment costs.

The 2006/2007 Frenchay Hospital Bristol cost for Deep Brain Stimulation	**(€)**
Pre-operative assessment/OPD visit	2,376
Surgery	13,945
Kinetra Stimulator	20,551
Follow-up in-patient Assessment	1,772
Follow-up OPD Appointment	757
Twelve Month Post Op. Assessment	1,172
Full medical costs for entire process	**€40,573**
Replacement battery (required every 3 – 5 years following surgery)	15,782
Annual Follow up Appointment	575

Travel and subsistence

Travel and subsistence data is not available from all regions. The total travel costs are grossly under estimated at €75,750 .See Table 1. All Parkinson's patients are accompanied and in most cases travel and subsistence is approved for them and their travel companion. The average cost for travel and subsistence per visit is

approximately €1,500 per trip. Some regions provide travel costs relating to flight/ ferry costs only. Community Welfare Officers may also contribute to other expenses incurred such as taxis, accommodation, subsistence etc. This expense data is not available for this report. All the above patients continue to have at least one out-patient assessment per year at a cost of €575 per visit and €1,500 per trip.

Estimation of cost of one patient who receives DBS Approval in 2006 following this patient forward 10 years.* (€)

Surgical procedure	40,573
Travel for surgical procedure(x 6)	9,000
Battery replacement (x 3 @4% inflation)	63,525
Travel for battery replacement (x 3 @4% inflation)	5,719
Annual outpatient visits(x10 @4%inflation)	7,120
Travel to OPD (x10 @4% inflation)	18,729
Total Medical Cost	**€111,218**
Total Travel Cost	**€33,448**
Total cost	**€144,666**

*** Please note in Primary dystonia follow up treatment may be required in excess of 50 years. Parkinson's disease mortality may reduce the quoted 10 year time period in some instances.**

Table 1. Referrals to UK for DBS for Ireland (E112 forms)

Region	Year	Number of Patients	Treatment Cost Euro	Travel Expenses Euro
Western Region				1192
	2002	1	957	
	2004	1	36,582	
	2005	1	33,656	
	2006	2	71,914	
	Total	**5 patients**	**€143,109**	**€1192**
North Western	**2000**	**1 Patient**	**€50,483**	
Southern Region	2001	2		
	2002	4		
	2003	1		
	2004	3		
	2005/2006	3		
	Total	**13 patients**	**€259,806**	**€29,623**

Midlands	**2002**	**1 Patient**	**€6,848**	
South Eastern				
	2002		9,956	364
	2003		49,710	2,212
	2004		52,296	618
	2005			108
	2006			133
	Total	**10 patients**	**€111,962**	**€3,435**
Region	**Year**	**Number of Patients**	**Cost of Treatment Euro**	**Travel expenses Euro**
Mid West	1997	1	25,953	2,000
	1999	2	50,000	3,000
	2001	2	53,000	3,500
	2002	2	53,000	3,500
	2003	3	96,000	4,500
	2004	6	192,000	9,000
	2005	2	123,616	8,000
	2006	2	156,000	8,000
	Total	**20 Patients**	**€749,569**	**€41,500**
North Eastern	2004	4	254,614	
	2005	1	73,165	
	Total	**5 patients**	**€327,779**	
Eastern	2001	4	99,504	
	2002	1	34,721	
	2003	14	365,120	

	2004	13	128,145	
	2005	8	218,523	
	2006	2	70,981	
	Total	**42 patients**	**€916,994**	
Ireland	**Grand Total**	**97 patients**	**€2,566,550**	**€75,750**

Incidence of Parkinson's Disease in Ireland

Republic of Ireland

There are no accurate figures for the number of people affected with Parkinson's Disease in Ireland. . Parkinson's disease occurs through out the world affecting all ethnic groups and affecting both sexes equally .The prevalence increases exponentially with age between 65 and 90 years, affecting 3% of people over the age of 65 years. Based on a population prevalence of 0.3% (1) and a population of 4.04 million in the Republic of Ireland , it is expected that there are 12,120 people with PD in the Republic of Ireland. The Parkinson's Association of Ireland estimates there are currently 5000 people with Parkinson's Disease presently in Ireland.

Of these only 10% to 15% are eligible for DBS (2). This narrows the estimate to 1,212 to 1,818 people. Given that about 5% (2) will consent to the procedure, this translates to 606 people in the Republic of Ireland with PD who are likely to under go DBS Surgery

Northern Ireland

Based on a population prevalence of 0.3% (1)

and a population of 1.7 million in the Northern Ireland , it is expected that there are 5,100 people with PD in Northern Ireland.

Of these only 10% to 15% are eligible for DBS . This narrows the estimate to 637(510 to 765) people. Given that about 5% will consent to the procedure, this translates to 255 people from Northern Ireland with PD who are likely to under go DBS Surgery.

Incidence of Essential Tremor in Ireland

Republic of Ireland

There are no accurate figures for the number of people affected with essential tremor in Ireland. Based on a population prevalence of 0.3% (3) and a population of 4.04 million in the Republic of Ireland, it is expected that there are 12,120 people with essential tremor in the Republic of Ireland. Of these 50%-60%, will seek medical care and 50% will these will have symptoms severe enough to be treated with drug therapy. Sixty percent of these will experience a

suboptimal response and/or adverse effects to drugs, and 5%to 10% will be eligible for DBS, resulting in an estimate of 134(90-109) people in the Republic of Ireland.

Northern Ireland

Based on a population prevalence of 0.3% (3) and a population of 1.7 million in Northern Ireland, it is expected that there are 5,100 people with essential tremor in Northern Ireland. Of these 50% will seek medical care and 50% will these will have symptoms severe enough to be treated with drug therapy. Sixty percent of these will experience a suboptimal response and/or adverse effects to drugs, and 5%to 10% will be eligible for DBS, resulting in an estimate of 57(38-76)-people in Northern Ireland.

Incidence of Primary dystonia in Ireland.

The prevalence of early onset dystonia (younger than 20 years) is 24 per million .The prevalence of late onset dystonia (primary dystonia older than 20 years) is 295 per million. (4)

Republic of Ireland

Based on PHIS tables the population under 20 years of age in the Republic of Ireland is 1,144,000. (5)The expected prevalence of early onset primary dystonia is 27 people. The expected prevalence for late –onset dystonia in people older than 20 years is 854. Accordingly the number of people with primary dystonia in the Republic of Ireland is 874. Of these 75% with early onset disease, and 5% to 10% with late onset disease may be eligible for DBS for a total of 62 to 105 people.

Northern Ireland

Based on NI DPH Core Tables the population under 20 years of age in Northern Ireland is 494,500 .(6)The expected prevalence of early onset primary dystonia is 12 people. The expected prevalence for late –onset dystonia in people older than 20 years is 373.

Accordingly the number of people with primary dystonia in Northern Ireland is 385. Of these 75% with early onset disease, and 5% to 10% with late onset disease, may be eligible for DBS for a total of 27 to 46 people.

Table 2.
Estimation of numbers of people eligible for DBS Surgery.

	Parkinson's disease	Essential Tremor	Primary dystonia
Republic of Ireland	1515 606 *(likely to undergo surgery)*	134	83
Northern Ireland	637 255 *(likely to undergo surgery)*	57	36

Summary

118 patients resident in the Republic of Ireland have been referred for DBS surgery to UK centres from 1997 to 2005 incurring costs of over 3 million Euros(€2,566,550 through E112 and an estimated €500000 through VHI). Approx 80% of this activity has occurred since 2003 indicating an increasing trend in referrals. 97 patients have been funded by the HSE via E112 and 21 through private insurance but the trend is towards referral through E112 which is seen to provide more direct funding.

Experience from other countries where DBS services are available indicates that between 700 and 800 people in this country (approx 600 with PD, up to 130 with essential tremor and approx 80 with dystonia) would be eligible for DBS and willing to undergo surgery. Accepting that 100+ have already had DBS a potential referral group of 600+ exists in the Republic of Ireland. This could be augmented with referrals from Northern Ireland if an Irish-based service was established.

In the absence of a local service it is likely that the current trend of approx 20-30 patients will be referred in 2007 and financial provision should be made for the 2007 estimates which include ongoing costs for an estimated 40 patients who have already been referred as follows:

2007 DBS referral to UK Costing Projections	€		€
Surgical procedure (New referrals)	40,573	x 20	811,460
Travel for surgical procedure(x6 visits)	9,000	x 20	180,000
Battery replacement (Existing refs.@3 yrs.)	15,782	x 20	315,640
Travel for battery replacement	1,500	x 20	30,000
Annual outpatient visits (All existing referrals)	575	x 40	23,000
Travel to OPD(All existing referrals)	1,500	x 40	60,000
Total Medical Cost			**1,115,100**
Total Travel Costs			**270,000**
Total estimated costs 2007			**€1,420,100**

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5. Ireland PHIS CD8 Table 01: Population Denominator Data by Sex and Age Group. Information Management Unit, Department of Health and Children

6.NI DPH Core Table 01a; Mid Year Population Estimates by Region. Ireland and Northern Ireland's Population Health Observatory (INIsPHO)

Appendix 6.2 Technical Report No. 2

Needs Assessment for Natalizumab (Tysabri)

1. Introduction

The management of Multiple Sclerosis (MS) has been considerably improved in the recent past with the advent of immunomodulatory therapy. To date, there are three major evidence-based therapies for MS – the interferons, glatiramir acetate ("Copaxone") and most recently, natalizumab ("Tysabri"). These evidence-based treatments have had a positive impact on the course of relapsing remitting disease. The interferons and copaxone reducing relapses by up to 33%, with an associated improvement in long term disability. The immunomodulatory treatments have reduced hospitalizations for acute relapses and have improved quality of life.

Natalizumab has recently been licensed in Ireland for the treatment of relapsing remitting MS, in cases where the other immunomodulatory therapies are ineffective. Early evidence suggests that natalizumab may be superior in efficacy to the other immunomodulatory agents, as relapse rates are reported to be reduced by up to 66% following natalizumab therapy. However, this agent is affected by the limited but real risk of severe opportunistic infections, particular progressive multifocal leukoencephalopathy (PML), caused by the JC virus. Natalizumab also differs from the other immunomodulatory agents as it requires monthly access to a day service for intravenous infusion.

Natalizumab is likely to be an important therapeutic agent in MS. The use of this agent is increasing by 25% per month across Europe since its reintroduction in February 2006. However, although the benefit of this infusion-based therapy is recognised, the rapid expansion has created major capacity difficulties for hospitals in Ireland.

The likely requirement for Natalizumab therapy in MS in Ireland is outlined in this document.

2. Estimating the Proportion of MS Patients in Ireland Suitable for Natalizumab

For the purposes of this assessment, a prevalence figure of MS which is the average of the lower figure from the GMS data, and the higher figure from the average of a 2004 prevalence study, i.e., the (5373 + 6776)/2 = **6075** was used. This is a prevalence rate of 143.4/100,000 rounded to 143/100,000.

Table 1 Population Projections to 2026

Year	2011	2016	2021	2026
Projected Population	4,504 900	4,854 200	5,140 100	5,398 900
Projected MS Sufferers	6442	6942	7350	7720

Proportion of patients suffering from relapsing-remitting MS (RRMS)

For the purpose of this assessment an approximate figure of 50% as the likely proportion of RRMS cases in Ireland was used. This gives a total estimated figure of 3,038 of cases of RRMS in the country.

Proportion of those patients with RRMS suitable for treatment with Natalizumab.

In the Irish situation the numbers of people suitable for treatment with Natalizumab using these figures can be calculated. Of the estimated 6075 MS sufferers, 20% would fulfil the criteria for DMD treatment, i.e. 1,215 people. Of these, between 20% and 40% may have disease progression while on DMD, i.e. between 243 and 486 people, or 4%-8% of the total MS population.

Projections to 2026

Some care needs to be taken when making these projections. As MS therapy improves, there may be increased survival in MS sufferers which may have the effect of increasing prevalence figures into the future. Also, as therapies are developed which are more effective, demand for treatment will increase and pressure to use newer drugs as first line therapies may increase. All these factors will increase the numbers projected.

Table 2 Projections of MS Patients who may be Suitable for Natalizumab treatment to 2026

Year	**2006**	**2011**	**2016**	**2021**	**2026**
Population	4,234,925	4,504 900	4,854 200	5,140 100	5,398 900
MS Sufferers	6,075	6,442	6,942	7,350	7,720
Numbers suitable for interferon treatment (20%)	1215	1288	1388	1470	1544
Numbers requiring Natalizumab @: 20% of those on interferon	243	258	278	294	309
35% of those on interferon	425	451	486	515	540
40% of those on interferon	486	515	555	588	618

3. Estimating The Financial Impact of Natalizumab

The costs of administering Natalizumab to the population of MS sufferers suitable for the drug is summarized in table 3.

Table 3 Costs of Nataizumab

	% needing Natalizumab = 20%	Those needing Natalizumab =35%	Those needing Natalizumab = 40%
Patient Numbers	243	425	486

Total cost Tysabri	8,118,894.87	14,199,713.2	16,237,789.7
Plus Cost of investigating PML	33,336	59,264	67,598
Less Savings for those discontinuing Rx	278,605.8	473,629.86	529,351.02
Less Cost of alternative DMDs	5,359,595.85	9,373,778.75	10,719,191.7
Less Cost of MS relapse	1,269,548.64	2,220,404	2,539,097.28
Total extra cost (net) Tysabri	**1,244,480.58**	**2,191,164.59**	**4922134.98**

Table 4 Estimate of costs of therapy in future years (Gross Costs)

	2007	2008	2009	2010	2011
Estimated total receiving treatment	413	418	423	428	432
Estimated costs of treatment for the year	13,808,886	14,004,728	14,171,783	14,299,947	14,473,409

Effects of differences in local protocol

The above estimates are based on patient follow-up as per the TOUCH protocol. However, given the high profile of safety concerns with the use of natalizumab, alternative protocols for monitoring patients have been proposed. The protocol in the Department of Neurology in Beaumont Hospital dictates that all patients receive MRI scans every three months while on the drug, as well as one scan in three months prior to starting therapy.

In trying to calculate the difference this would make to the overall cost of therapy, a number of assumptions have been made.

- In addition to the initial MRI scan prior to starting therapy, the patient will receive a total of 4 MRI scans in a twelve month period.
- The overall population number for treatment and the rates of discontinuation of therapy and investigation for PML remain as estimated above.
- For those discontinuing therapy, they are presumed to do so on the second administration of the drug. However, they are also presumed to do so prior to any other MRI scans being done, i.e., the only scan performed on these patients would be that prior to the start of therapy.
- For those being investigated for PML, they are presumed to require a separate MRI scan to the routine three – monthly follow-up scans under this protocol.
- Costs for other factors, e.g., CNS input, CSF analysis, hospital beds, etc., are presumed to be as outlined above.

Given these assumptions, the effect of this protocol on the overall cost of treatment would be

Minimum cost per twelve month period per patient (when follow-up as per TOUCH protocol)	33,411.09
MRI brain @ €255 per scan x 4	1,020.00
Cost per twelve month period per patient	34,431.09
Estimated total population receiving drug	x425.00
Estimated total cost in Ireland of therapy (if Beaumont protocol applied nationally)	14,633,213.20
Total amount not spent on those stopping therapy;	
Total not spent under TOUCH protocol follow-up	473,629.86
Total not spent on additional follow-up MRI scans	17,340.00
Total amount not spent on those stopping therapy	490,969.86
Total amount spent on investigating for PML	59,264.00
Total estimated cost of natalizumab per year	**14,201,507.30**

Based on the figures above, the need for natalizumab infusions per year may be calculated as (number of patients receiving therapy) x (number of infusions received per year). The most efficient manner by which this can be achieved will be the provision of infusion suites for each of the major neurology centres in the country.

4. Assessing the Wider Impact of Natalizumab

The exact requirements to meet this impact are dependant on the number of people receiving the drug. Based on the prevalence of MS in Ireland, a figure of 425 people is used for the following assessment, although this may represent an underestimate.

4.1 Required Diagnostic procedures

1) MRI

a) Pre-treatment scans

b) Routine follow-up scans

c) Urgent re-assessment scans

Although there is currently a waiting list of up to 5 months in some public hospitals for MRI, the necessity for an up-dated MRI scan prior to starting treatment does not represent a significant change in practice.

Difficulties arise in regards to the use of MRI for follow-up of these patients. Currently, as part of the TOUCH programme in the USA, MRI is not used routinely, but only for re-assessment as the physician feels is needed.

However, practices locally are physician-dependent, and MRI scans may be needed three-monthly for the first year and yearly after this. Each patient will require up to five scans in the first fifteen months or less of treatment.

Estimated rates of PML have been quoted at 1:1,000 for those on Natalizumab, but the AFFIRM data show that, of 3,116 patients, 44 were referred to a special committee for assessment of a possible diagnosis of PML – a rate of 14:1,000.

Given the population data previously presented, this gives a figure for the Irish group of an estimated 6 referrals (a number which is likely to prove an underestimate, in light of the marked safety concerns which have been associated with the drug).
These patients should all have MRI scans urgently.

The use of Natalizumab is likely to have a significant impact on the existing capacity to perform timely MRI scans.
Assuming that all 425 patients are treated with Natalizumab, it is estimated that at least 2000 extra scans will be required within the first 2 years of treatment.

As there is already a capacity problem with respect to neuroimaging in some hospitals, resources for personnel (radiographers and neuroradiologists) to facilitate the increase demand will be required.

2) CSF analysis

The impact on CSF analysis will be in the form of:

a) Increased numbers of lumbar punctures being performed

b) CSF analysis for the diagnosis of PML.

Lumbar punctures are common procedures, carried out on an in-patient and out-patient basis in hospitals in all HSE areas. The equipment needed is relatively inexpensive. As most public facilities are currently operating at capacity, extra space to undertake an increased number of lumbar punctures will be required. This would best be achieved in the context of a dedicated suite for infusions and related procedures (see below).

Analysis of CSF can be carried out by most hospitals, and by all centres where there is a Neurology service. PCR analysis for the presence of JCV DNA is carried out by the National Virus Reference Laboratory in UCD. Samples must be frozen at -70 degrees C for transport, and facilities must be available for storing a back-up sample. The procedures involved in freezing and storing the samples are within the scope of most laboratories in Neurology centres. However, the transport of samples to the NVRL is a matter which will have to be discussed with Laboratory services in each centre, to ensure that there are appropriate protocols in place for such transfer.

Allowing for a figure of at least 14 per 1,000 for suspected PML, this would translate to 6 assays in Ireland for PCR DNA in the Natalizumab-treated population, although it is worth pointing out again that this figure may be considerably higher.

4.2 Pharmacy

The impact on pharmacy services may be considered in regards to;

a) Drug storage

b) Drug preparation and administration

c) Drug cost (as documented above).

1) Drug storage

There are no special requirements for the storage of Natalizumab, compared to many other agents used. It is required that it be stored at 2 – 8 degrees C, and that it be protected form light, but no other special requirements are specified by the manufacturer. This is within the scope of hospital pharmacies. The shelf-life of the drug is 2 years.

2) Drug preparation and administration

There are no extraordinary precautions relating to the preparation and use of Natalizumab. The drug is prepared for intravenous infusion using aseptic technique, and infused over one hour. Any unused product or waste material is disposed of in accordance with local procedures.

3) Drug cost

Natalizumab has considerable expense attached to it. Each vial of 15 mls costs approximately €1,900. Given that each patient receives one vial every month, based on the previously calculated population data, this gives an estimated cost per year on a country-wide basis of €14million, allowing for 425 patients receiving one vial per month for 12 months. Given potential cases of intolerance of the drug, ineffectiveness in some people, savings due to the discontinuation of alternative treatments and due to the reduction in treatment costs for relapses this figure can be reduced considerably.

4.3 Hospital services

1) Equipment

The equipment for the administration of Natalizumab is available widely in all hospitals, and consists of IV access, an infusion set, an infusion pump which is capable of controlling the rate of infusion, and an appropriate flush for the IV access post infusion.

2) Environment

The requirements for drug administration state that patient must be able to stay in one area for a total of two hours (one hour infusion and one hour being observed for possible adverse effects). Furthermore, facilities for the treatment of adverse reactions must be on hand, including the treatment of anaphylactic reactions.

Most areas in hospitals are equipped with the appropriate resuscitation facilities and medications for such eventualities. The rate of infusion reactions in the administration of Natalizumab in the AFFIRM study was 24%, with 4% of patients having hypersensitivity reactions. A total of 5 anaphylactic or anaphylactoid reactions were reported (0.8%), for which adrenaline was required in only one case and supplemental oxygen in one case.
Based on current estimates, 17 patients will have hypersensitivity reactions, with 3 anaphylactic / anaphylactoid reactions.

3) Access to Hospital Capacity

Access to space in a day unit or transfusion unit which can supply the above facilities is limited in most hospitals. It is estimated that approximately 425 Irish patients might currently benefit from treatment with Natalizumab. However these numbers may expand as familiarity with the drug increases. Based on the figures above, the need for natalizumab infusions per year may be calculated as (number of patients receiving therapy) x (number of infusions received per year). As each of the 425 patients will receive 13 infusions in a twelve – month period (assuming no dicontinuations of therapy), the HSE needs capacity to carry out at least 5,525 natalizumab infusions per year.

This works out as approximately 115 infusions per week, allowing for public holidays, bank holidays, etc. This number is likely to expand incrementally over the coming years.

The currently necessary capacity (approximately 15-20 patients in each of the 7 Neurology centres) could be met if there were two dedicated spaces solely for Tysabri infusions in each of the major Neurology Hospitals, with two sessions per day in each. However, these spaces would have to be exclusively dedicated to Natalizumab, and will be inadequate to meet future demands.

A dedicated infusion facility is strongly recommended, with the capability to serve patients requiring infusions with Natalizumab and other intravenous therapies.

A suite comprising at least 9 recliners and 1 bed, with adequate resuscitation facilities, is recommended for each of the 7 Regional Neurology Centres.
This suite could also be used for lumbar puncture, counselling, monitoring and evaluation, and other infusion based neurological therapies.

4) Nursing Requirements

Management of patients treated with Natalizumab will require a substantial expansion of MS Nurse Specialists. It is estimated that a new Clinical Nurse Specialist post will be required for every 50 patients commencing Tysabri.

A total of 7-8 new MS Nurse Specialists will be required- one for each Neurology centre.

Their role can be summarised as follows:

Screening for Suitability for Tysabri

The MS Nurse Specialist assists in the identification of patients suitable for Natalizumab and completes a patient checklist to ensure the patient meets the requirements (Natalizumab physician booklet).

The MS Nurse Specialist liaises and provides patients GPs with all educational material (Natalizumab physician booklets, DVD's and information on PML) including a cover letter, and provides the patient with a 'patient alert card' instructs them to carry it at all times.

The MS Nurse Specialist completes a checklist to screen for symptoms of common side effects, serious infections, hypersensitivity reactions and progressive multifocal leukoencephalopathy (PML) prior to each infusion.

Infusions

The MS Nurse Specialist co-ordinates patient's admissions to a monitored bed or chair on a monthly basis. The MS Nurse Specialist ensures patients are having regular MRIs, orders and monitors patient's blood tests (FBC & LFTs) in conjunction with the Neurology Team, and ensures EDSS (Expanded Disability Status Scale) is done regularly.

Follow up

The MS Nurse Specialist ensures patients have follow-up outpatients to see their Neurologist, informs and advises patients to promptly report any continuously worsening neurological symptoms, and is available for patients to contact regarding worries or concerns for support and advice.

The MS Nurse Specialist maintains a database of MS patients receiving Natalizumab and liaises with hospital and community based Allied Health Care Professionals.

The recommended criteria for the administration of Natalizumab in Ireland are:

1. Natalizumab should only be given under the direction and monitoring of the neurologist.

2. Centres providing this treatment must have a neurology unit with multidisciplinary team and specialist neurology nursing, and treatment should be integrated with all parts of the patients care.

3. The hospital should have access to other specialties as required including MRI and access to specialist Neuroradiology.

4. Centres providing this treatment will require a dedicated infusion suite with access to resuscitation facilities and with resuscitation skills available on site.

5. Centres providing this treatment will require facilities to investigate complications such as PML. Mechanisms should be in place to record and report untoward events on a national basis.

Appendix 8

Appendix 8.1 Core Features of a Major Clinical Neurophysiology Department

- The department should be able to cater for adult and paediatric referrals
- There should be sufficient space allocated, including adequately constructed recording areas
- The consultants should be fully trained and appropriately accredited or certified consultants in CN. In some cases consultants may have full accreditation in Clinical Neurology with additional particular skills and full accreditation in a particular area of Clinical Neurophysiology, for example Video-EEG monitoring, or EMG studies.
- This department(s) should at all times be run by one of the full-time Consultants in Clinical Neurophysiology.
- Technicians should rotate between different areas, particularly early in their careers. Some would inevitably develop special interest and expertise in and responsibility for certain areas, for example EPs, NCS, monitoring etc. There should also be a place for occasional Clinical Scientist posts, to be filled by exceptionally skilled and motivated technicians who have a degree, for example PhD.
- Such a department should be able to provide a wide range of studies to international standards of data acquisition and interpretation, as well as an on-call service where appropriate. It should have a professional environment conducive to teaching and learning, and should be accessible to other neuroscience specialists to use the facilities where appropriate and collaborate on areas/projects of mutual interest. It should also have links with a university, and be able to conduct an active research programme.
- This department would also be able to provide an interpretive/reporting service for routine and standard investigation that could be carried out by appropriately trained technicians in other institutions not necessarily served by a department of adult or paediatric neurology. The investigations could be e-mailed to the main department or to consultants' homes for prompt assessment and reporting. These peripheral units would need to be monitored regularly by staff from the main department to ensure maintenance of standards of procedures and equipment. They would certainly help rural patients who currently have to make long arduous journeys to have routine investigations carried out.
- Other neuroscience clinicians, particularly neurologists, who have particular interest and expertise in areas of CN should be able to use the relevant recording and interpretative facilities at the department and should also be encouraged to have input into its administration if they wish.

Space / Accommodation

Apart from multidisciplinary personnel (medical, technical, nursing, secretarial), adequate space and equipment is a critical criterion for Clinical Neurophysiology.

There should be sufficient laboratory and office space with extra space for circulation and waiting areas where necessary. Extra space may be needed for additional special studies, for example sleep recordings. The department should be planned with the close co-operation of a designated consultant in Clinical Neurophysiology.

Recording rooms should be of adequate size. Ventilation, temperature and humidity should be controllable, in particular to avoid excessive heating and sweating with EEGs and excessive cooling with NCS/EMGs. EEG recording areas need to have dimmable lights, sound-proofing, and facilities where the technician can be separated from the patient to allow for full relaxation during the study. EP recording areas require total sound-proofing and the facility to shut out all light.

Appendix 8.1

C. D. Binnie et al – Setting up and Running a Department of Clinical Neurophysiology (See PDF addendum)

Appendix 8.2

HSE Primary, Community and Continuing Model of Health Care

The Primary Care model which is currently being developed within the HSE involves the provision of extra health professionals, reconfiguration of existing health professionals and the provision of services currently restricted to hospital, within local communities.

Each Primary Care Team will be part of a Primary and Social Care Network, which will link 3 – 5 teams, with responsibility for the community based health care needs of populations from 30,000 – 50,000 people.

Key roles of the Network will be to:
Facilitate the integration of Primary Care Teams within the Networks to support each other and patient journeys as needed
Provide and manage the pool of multiple specialist services required by complex patient pathways, through the Primary Care Teams
Facilitate the enhancement and development of services in the community setting.

The new Model of Service Delivery in the Community, based on Primary Care Teams and Primary and Social Care Networks, is the agreed strategic direction for the HSE.

Structural Model of Teams and Networks
Primary Care Teams need to be able to draw (pull to the client/patient) the necessary expertise from their PCCC network, to meet the needs of people in their enrolled populations. They also need to be able to draw on additional expertise and resources from the wider network of hospital and voluntary services. The person receiving the service is at the centre of this activity. Services will be provided by:

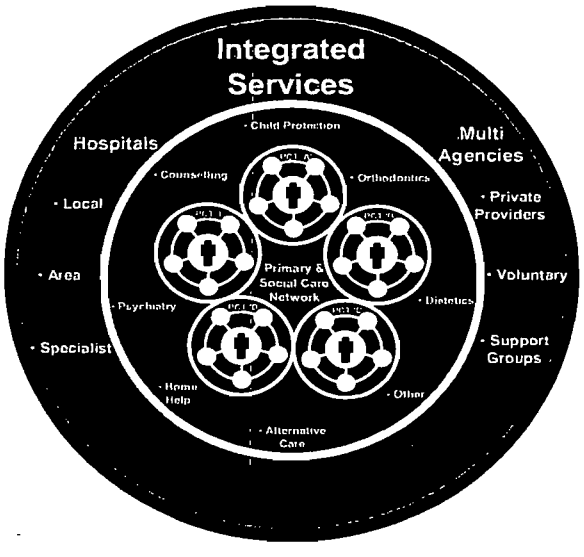
Primary Care Team: where the vast majority of services will be provided by core team members. This is why Teams are developing on the basis of agreed population focus and in partnership with local communities.

The Team and Network expertise: Based on a common assessment took, when the Team forms the opinion that a patient or client has a complex set of needs requiring input from more specialised staff, these are provided to the PCT (on behalf of the client) by the Primary and Social Care Network. The PCT Key Worker on behalf of the client navigates the system ensuring continuum of care. Intra and inter professional referrals are the responsibility of the PCT Key Worker not the client. The emphasis is on the role of a service or professional in the provision of care and their accountability in the care plan, not on complicated referral processes or boundaries between services.

The Hospital Network: Such services are usually of an investigative, acute or emergency nature. The sharing of resources between hospitals, Networks and Teams is part of a local operational plan.

Other Agencies and service Partners: All service providers are clear about their role in meeting need for a given population or cohort of population with particular needs, and they work in close cooperation with teams and networks.

This overall model is represented below:



Conclusion:

The National Clinical Network approach brings together the efforts and energies of the range of service providers involved to bring clarity to priorities for development, quality standards and geographical equity. Establishing clear strategic direction for neurology services will enable more effective engagement at national and regional level, across primary, secondary and tertiary care.

Appendix 8.1

C.D. Binnie, R. Cooper, F. Mauguière, J.W. Osselton, P.F. Prior, B.M. Tedman (Editors)
Clinical Neurophysiology, Volume 2
EEG, Paediatric Neurophysiology, Special Techniques and Applications

PART 7

Setting up and running a department of clinical neurophysiology

Appendix 8.1

C.D. Binnie, R. Cooper, F. Mauguière, J.W. Osselton, P.F. Prior, B.M. Tedman (Editors)
Clinical Neurophysiology, Volume 2
EEG, Paediatric Neurophysiology, Special Techniques and Applications

Chapter 7.1

Introduction

C.D. Binnie, C.J. Fowler, F. Mauguière and P.F. Prior

A modern department of clinical neurophysiology should offer all types of neurophysiological investigation: electroencephalography (EEG), evoked potentials (EP), nerve conduction studies and electromyography (EMG). For historical reasons, these subspecialties have developed separately in many centres. Some long established departments provide only EEG, much peripheral work was formerly carried out by physicians trained in physical medicine or neurology, and evoked response services have often been developed by clinical users, in audiology or ophthalmology. This division is happily disappearing. Clinical neurophysiologists are now trained in all three aspects of the subject and this has led to a unification of services with new departments of clinical neurophysiology replacing old 'EEG departments'. However, the unified specialty is still young in many countries and although most teaching hospitals may now have departments of clinical neurophysiology, many smaller local hospitals may not. Paradoxically, departments are also found in some specialised units (for learning disability for instance) without the medical or technical infrastructure to support a neurophysiology service. In some countries the scope of the specialty is taken to include a range of neurophysiological investigations wider than bioelectrical recording – Doppler ultrasound for instance. Provision of some subspecialties is open to competition between neurophysiology and other departments: polysomnography, MEG, EEG triggered fMRI, and electrical impedance tomography, for instance.

7.1.1 The basic unit

A department of clinical neurophysiology serving a general hospital should be able to offer a comprehensive neurophysiological service, including at least all the basic procedures of the three main subspecialties. However, smaller units are often set up, which are not capable of providing a full range of investigations. The reasons include financial constraints (as it is argued that a basic EEG department is economically more viable, or profitable), or a very reasonable demand for a local service to a small, geographically isolated unit, such as an institution for people with learning disabilities. There is, however, a minimum scale below which a department can neither be cost-effective nor provide a reliable, much less a comprehensive, service, or even provide much job satisfaction to its staff.

The *minimum viable department* should be directed by a full-time clinical neurophysiologist trained in all aspects of the subject, able to report EEGs and EPs, and perform nerve conduction studies and EMGs. It should be linked with a regional or academic department to promote quality assurance and clinical governance and for cover in the event of temporary staff shortages. Non-medical staff needed are three technologists, a secretary/receptionist, and possibly a nurse. Such a department will require two EEG machines (one portable or transportable), EP facilities and two EMG machines, one of them portable. A unit smaller than this will experience interruption of service due to failure or maintenance of equipment, staff holidays and illness, and suffer the disadvantages of medical cover being present only intermittently.

In most departments receiving referrals drawn from a general hospital, EEG currently represents the greater part of the workload in terms of recording time. Thus in the minimum unit, the EP and EMG equipment will be used less often than the EEG machines. If only in terms of maximum exploitation of the capital investment, a small department will therefore be less cost-effective than a larger unit.

Appendix 8.1

C.D. Binnie, R. Cooper, F. Mauguière, J.W. Osselton, P.F. Prior, B.M. Tedman (Editors)
Clinical Neurophysiology, Volume 2
EEG, Paediatric Neurophysiology, Special Techniques and Applications

Chapter 7.2

Siting and accommodation

C.D. Binnie, C.J. Fowler, F. Mauguière, R.C. Pottinger and P.F. Prior

7.2.1 Siting

Two major considerations in siting a neurophysiology laboratory are accessibility to users and the avoidance of environmental disturbances, both electrical and acoustic. The ideal location would be between the neurological and neurosurgical departments near the intensive care and special care baby units and medical wards, and accessible to neurological, neurosurgical, orthopaedic, rheumatological, paediatric and psychiatric outpatients. Where this is unachievable, it may be necessary to locate a main department in a neurosciences unit and maintain a satellite laboratory containing transportable equipment at a site accessible to the ITU, operating theatres, special care baby unit, and general medical wards. Such a facility can serve as a backup for routine investigation when the equipment is not being used for bedside recording. Both the main and satellite laboratories must be accessible to patients in wheelchairs and on stretchers or beds.

Improvements in design have made recording equipment less sensitive to electrical interference than formerly. However, any proposed site should be investigated by the medical physics service for interfering signals, most particularly if the proposed location is adjacent to an X-ray or physiotherapy department, operating theatre, air conditioning plant, lift switchgear, or the transmitter of a personal call system. Assurances by consulting engineers that interference can be eliminated by screening should be viewed with scepticism.

In view of the need for a quiet environment in which to perform sleep recordings and EP studies, it is desirable to avoid noisy sites (car park, children's ward, kitchens). Sound insulation is not an entirely satisfactory alternative; an unnaturally quiet, acoustically deadened environment provokes anxiety, particularly in children. A constant low level of background noise is more agreeable and masks sudden sounds which could arouse a sleeping patient; the hum of air conditioning may actually prove advantageous.

7.2.2 Accommodation

Any area for reception of patients should obviously present a friendly, not too conspicuously clinical or scientific environment. The success of the investigations performed in a department of clinical neurophysiology depends upon the patient's cooperation. Attention to creating pleasant, reassuring surroundings is therefore most important. The accommodation required by a typical small department of clinical neurophysiology is listed in Table 7.2.1.

Depending on work patterns, there is scope for combining some functions. EEG electrodes may be applied and removed in recording areas, but the provision of a separate preparation room permits greater exploitation of the available machines. Where this practice is followed, it is important to avoid a production line approach; the same technologist should be responsible for the entire procedure, from greeting the patient to arranging his departure. If there is no EMG clinic on some days, it may then be possible for the EMG accommodation (and apparatus) to be used for EPs. A view gaining support is that provision of separate accommodation for children, particularly while waiting, is mandatory. In any event there should be some small chairs, toys and children's books, and it is not difficult to make one room child-friendly, with posters, mobiles etc. If the department is near an outpatients' clinic there may be advantages in using common waiting and reception areas, and sharing such facilities as toilets and a playroom.

Lest the minimum requirements mentioned above should appear to be recommended as a norm, the specification is given in Table 7.2 for a recent, comprehensive department of clinical neurophysiology in an academic hospital in the UK – not a country noted for conspicuous expenditure on health care.

Floor coverings throughout the patient areas should be resistant to biological fluids, sterilising agents and solvents, but corridors should be carpeted and acoustically treated to avoid footsteps and conversation

Appendix 8.1

Table 7.2.1
Space allocation for a small department of clinical neurophysiology

	Function	Areas (m^2)
1	2 EEG recording areas	25–30 each
2	1 or 2 EMG areas	20
3	1 EP area	20
4	Administrative offices for filing and reception	20
5	Technologists' work area for electrode preparation, etc.	15
6	Offices for medical staff and chief technologist	15 each
7	Electronics workshop	15
8	Record storage and possible microfilming* area	30
9	Patient waiting area, visible from reception area	20
10	Accommodation for patients on stretchers, for those who become ill or are given sedative drugs, and for physical examination	15
11	Separate lavatories for staff and patients, including one accessible by wheelchair, and sluice	12
12	Preparation room for electrode application and removal	15
13	Secure storage for flammable chemicals, gases, drugs, etc., in conformity with local regulations	5
	Total space excluding corridors	ca. 300

*Depending on local policy and use made of paper or digital recording media.

being heard in the recording rooms. Similar considerations apply to the need to "contain" the sound of audio output of EMG which may alarm patients waiting to be examined. Each examination room should contain a laboratory type sink for hand washing and electrode cleaning. All clinical areas should be accessible to patients in wheelchairs or on stretchers or beds. There is also a need for adequate space for resuscitation equipment in the event that a patient collapses.

Signposts to the department should be clearly displayed; information and maps sent to patients should indicate arrangements for access and other facilities for the disabled.

7.2.2.1 Investigation areas for nerve conduction studies and EMG

The various investigations performed in a department of clinical neurophysiology require different types of accommodation. A feature of EMG and nerve conduction studies is the need for continuous or frequent physical contact with the patient in order to perform manipulations of electrodes throughout the test. A comfortable low bed appropriate for EEG recording, which may encourage a patient to fall asleep is totally unsuitable; the patient must lie on an examination couch which is accessible from all sides in the centre of a room of adequate size, and at a level convenient to the neurophysiologist who will be seated when applying electrodes and operating the EMG machine. A small, armless, office chair on wheels is particularly convenient from which to carry out tests, allowing easy movement between the machine controls and the patient.

The importance of getting the patient to relax for nerve conduction studies cannot be over-emphasised (see Section 2.5.1.1 of Volume 1), since continuous background EMG activity ruins all attempts to average minute sensory action potentials. The examination couch must therefore be comfortable and provided with pillows, both for comfort and to assist positioning of limbs. Optimal cooperation can be achieved by explaining the examination whilst it is in progress and demonstrating results on the screen to the patient as they appear. For this reason it is useful for the patient to be so positioned on the couch as to have a clear view of the screen of the EMG machine, and to be shown how to relax helped by the visual and audio feedback of the EMG potentials. To allow privacy for disrobing, there should be a screened area, or in a larger department, cubicles with secure clothes lockers.

Limb temperature has a significant effect on the results of peripheral nerve conduction. In some laboratories, infrared lamps, with or without feedback control from sensors on the patient, are used to maintain the skin temperature of the limb being studied. It is important to ensure a warm ambient temperature in both the waiting and recording rooms.

The room should be not only warm but also adequately ventilated. In the course of a clinic, seven or eight patients may pass through with only short intervals between them. To maintain hygienic conditions, it is important to have some method of rapidly changing the coverings on the examination couch. Disposable paper sheets and pillow cases are probably the best solution.

Table 7.2.2
Specification for a comprehensive department of clinical neurophysiology. This example typifies a department with an interest in treatment of patients with epilepsy; those in a general hospital would require adjustments to staffing and work pattern to cover monitoring in, for example, the neonatal unit, ICU and during surgical operations

Predicted annual workload	EEG (including non-routine procedures)	3000
	EMG & nerve conduction	1500
	EP	1500
	Polysomnography	100
	Telemetry	600
	ECoG	50
	Stereo-EEG	15
Establishment		
Medical staff		
Clinical neurophysiologists	Full-time specialists	2
	Half-time specialists	4
	Senior resident	1
Scientific and technological staff	Scientific officer (EPs and information technology)	1
	Physicist	1
	Top grade technologists	2*
	Senior grade	3
	Middle grade	4
	Basic grade	2
Other staff	Nurse (fully registered)	1
	Senior grade administrative	1
	Basic grade administrative	2
Space allocation (m^2)	1) 4 EEG recording suites	100
	2) 3 interchangeable EMG/EP areas	60
	3) 1 dedicated VEP/ERG lab	25
	4) Polysomnography suite	10
	5) Administration, filing, reception	20
	6) Technnologists' workshop	10
	7) Offices (7 medical staff, scientific officer, nurse, chief technologist)	150
	8) Electronics workshop	20
	9) Record storage and microfilming	50**
	10) Patient waiting area	20
	11) Examination/recovery room	15
	12) General staff office: preparing technologists' reports, reporting sessions, meetings and seminars, best combined in a single open plan area	20
	13) Staff coffee room	15
	14) Separate lavatories for staff and patients, including one accessible by wheelchair	10
	15) Secure machine room for computers, photocopier, video and other high value portable equipment	15
	16) Preparation room for electrode application and removal	15
	17) Secure storage for flammable chemicals, gases etc., and cleaning materials	5
	18) Telemetry suite: Equipment room, EEG lab and office for review of records (excludes patient accommodation within Department of Neurosurgery)	45
	19) Research accommodation:	
	– 2 interchangeable suites for EPs and psychophysiology	20
	– Suite for quantitative EEG and polygraphy	20
	– Waiting and electrode application area for subjects (normals requiring segregation from patients)	15

*One in charge of the general clinical service, the other responsible for special procedures. Research personnel are not included.
**20 m^2, if only paperless EEGs are to be stored.

7.2.2.2 Accommodation for evoked potentials

Environmental control is of especial importance for EP studies. Ideally, each suite should comprise two rooms, one for the patient and stimulators, and one for other equipment and the technologist. There should be a dividing door and observation window, both should be sound attenuating and it should be possible to black out the window. The rooms should be linked by a two way intercom (with an input to the head-phones for use during auditory evoked potentials (AEPs)). The entire suite should be acoustically insulated and electrical

screening may be required. The patient area should be well lit (avoiding fluorescent lighting) but easily darkened for visual evoked potential (VEP) recording with complete blackout for electroretinographic (ERG) studies. Sensitivity is required to ensure that, so far as possible, this highly controlled environment is not intimidating or claustrophobic – a large tank of tropical fish is a useful feature, soothing to both adults and children. There must be adequate space in the patient area for a wheel chair or stretcher trolley and the door must of course, be large enough to admit these. A double door, as used in a photographic darkroom, will allow staff to enter and leave without interfering with dark adaptation of the subject. There must also be sufficient space inside the patient area for the technologist to have access to the patient from all sides. To reassure or obtain the cooperation of the subject, the presence of a nurse or escort may be required, and there should be room for them to sit next to the patient.

For the patient, there should be a comfortable, and adjustable chair with a headrest (ideally a dental couch) to reduce myogenic and movement artefact, and to facilitate positioning, for instance to view a visual stimulator. One armrest should be removable to enable physically handicapped patients to be lifted from wheelchair to recording couch. It may be convenient for a headbox and sockets for head-phones and sensory stimulators to be mounted on the chair, and the cables taken under a false floor to the equipment room. Various switches for signalling responses during cognitive EP studies may need to be built into the armrests. There should be facilities for the technologist to measure electrode impedance in the patient area.

The screen or other stimulators used for VEPs should be located directly in front of the chair, and so mounted that the distance from the subject can easily be adjusted and measured. It should be possible to raise and tilt the screen to maintain the required distance and normal viewing angle, even if the subject is semi-recumbent.

Sometimes it may be necessary for the technologist to remain close to the patient, to obtain cooperation or to monitor ocular fixation. A slave monitor from the averager will then be required in the patient area, and also remote controls to start and stop the averager. Even in cooperative subjects, it is useful to have an infrared video camera over the visual stimulator screen to monitor ocular fixation during VEPs, with display in the equipment area. During SEP studies, the technologist may need access to the controls of the equipment whilst positioning electrodes and adjusting stimulus intensity. The apparatus used for this purpose should therefore be mobile, so that it can be wheeled into the recording area; again, this should be considered in allocating space.

7.2.2.3 Accommodation for EEG recording

To provide maximum flexibility it may be useful for the EEG recording areas to be of different types. One might be a large open-plan area of 30 m^2 accommodating both patient and recorder. This permits close observation, and ease of access to patients requiring medical and/or nursing attention, and possibly attached to intravenous infusion or other equipment. A second suite then could be divided into two smaller rooms, perhaps of 10 and 20 m^2, to provide separation of patient and recording equipment and to permit good environmental control, for instance during sleep studies. These two rooms should communicate through a door and a large glazed window, at least 1.5 m wide and 1 m high, with the sill low enough to ensure that the patient on a couch is visible to a technologist seated at the recorder. It is not acceptable for routine EEG recording to rely on communication through an intercom, much less to see the patient only by closed circuit television. There should be separate access doors to both rooms, so that the patient does not have to enter past the equipment, and is not disturbed by the comings and goings of personnel. There should be a work-bench or table near the recorder on which previous tracings can be spread out and examined.

Another layout worth considering, if there is no separate place for electrode application, is to site one machine area between two patient rooms, so that a recording can be made from one patient while the next is being prepared in the other room.

An uncommon, but useful, facility in the area used for electrode application and removal is a washbasin and reclining chair of the type used by hairdressers, so that a patient's hair can be properly cleansed and dried after the investigation. There should also be a mirror so that patients can tidy their hair before leaving the recording room.

7.2.2.4 Telemetry area

No provision is made in the above schedule of basic accommodation for video monitoring and EEG telemetry. Ideally, a telemetry unit, for instance in a special centre for epilepsy, should be self-contained, including separate bedrooms for each patient, a day room, toilets and bathroom. As such a unit will require continuous staffing and 'hotel' facilities, it may be more cost-effective to locate a telemetry facility on a neurological or neurosurgical ward in order to take advantage of the available nursing cover, catering etc. In any event, a control centre of, depending on the number of telemetry units, at least 20 m^2 will be needed for the equipment, and an office for replay, transcription and interpretation of recordings. This should be located close to the monitoring site, both to facilitate rapid

assessment of results and consequent modification of procedures, and also to provide feedback to the personnel involved in telemetry. Similar general considerations apply to facilities for polygraphic sleep monitoring, which may be carried out in sound-proofed rooms within the same unit.

7.2.3 Services

Electrical supplies must be free of interference, for instance from heavy switchgear used for lifts or air-conditioning plant. It may be necessary to provide the department with a separate mains supply or with filters to eliminate mains transients. Voltage stabilisers will be required only in those countries where mains supplies are grossly unreliable. Computers (and computerised electrophysiological equipment) need an non-interruptible power supply to avoid possibly catastrophic corruption of data and programs. This requirement is not met by most hospital emergency supplies, which cut in only after a significant drop of voltage has occurred. Suitable, self-contained units are available from suppliers of computer accessories.

It is easy to underestimate the number of socket outlets required and inconvenient to install them later. To take account of all possible ancillary equipment which may be used, each recording area needs at least six socket outlets near the intended site of the recording system, and another four sockets in the vicinity of the patient.

A sound earth connection is essential and may require that the department has a separate busbar and earth electrode in the ground. All socket outlets in the department should share a common earth and, so far as possible, blocks of multigang socket outlets should be used. It is currently a building practice to use plastic conduit for mains wiring and to run a separate earth lead, but there may be advantages in using steel conduit which is itself earthed as a further precaution against interference.

Fluorescent lighting is a potential interference source but rarely presents problems in practice, except possibly in EMG rooms. Interference from fluorescent tubes can be reduced by mesh screening, but it may be simpler to avoid any possible problem by using only tungsten lighting in the recording areas. For EMG and nerve conduction studies the part of the patient being examined needs to be well lit, and adjustable spotlights are useful; background illumination is not otherwise critical. In the EEG and EP recording rooms, there should be means of controlling the lighting independently in patient and machine areas using two-way switching, dimmers, spotlights and down-lighters, as appropriate. This too will dictate the use of tungsten lighting in many areas. It should be possible for the illumination of the entire recording environment to be controlled by a technologist in the vicinity of the EEG or EP machine.

A congenial background temperature is conducive to a sense of comfort and relaxation and the necessity for a warm waiting area has already been discussed in connection with EMG and nerve conduction studies. Shivering and sweating both produce EEG artefacts and appropriate arrangements for heating or air conditioning may be needed, depending on the climate.

The usual services expected in any clinical area will be required, hot and cold water, drainage, oxygen and suction. In addition, in areas where electrodes may be applied, there is a need for compressed air to dry collodion, and possibly for additional ventilation, to remove vapour from solvents. Note that metallic piping supplying these services or heating radiators may carry interference, and it may be necessary to isolate the department by the insertion of plastic tubing.

An alarm system should be available in every area to which patients have access so that a technologist can call for assistance, in the event of a seizure, cardiac arrest, other medical emergency, assault etc. If staff work alone out of hours (for example for all-night sleep recordings), the alarm must be connected to the switchboard or paging system. The site of the emergency must also be indicated.

7.2.4 Centralisation versus decentralisation

The principle of the minimal viable unit presents problems for the specialised user requiring a very limited service to patients who cannot readily travel from a particular site, for instance a learning disability hospital or maximum security prison. The ideal solution here will usually be found in the creation of a satellite department on site, small and self-contained but staffed and supported from a larger unit. Where urgent investigations are rarely needed, a more cost-effective alternative may be the use of portable equipment for regular sessions in suitable, dedicated accommodation. A complete mobile laboratory in a converted ambulance has also proved a suitable solution, where a regular but limited service has to be provided over considerable distances. It is now feasible to transmit signals from a satellite department back to a main unit for interpretation, usually by telephone or fax, and at the time of writing this technology is increasingly used in isolated regions. However, dangers inherent in this approach should be appreciated, particularly the possible lack of communication concerning important clinical information. Telephone transmission of EEGs for interpretation is never acceptable if the results may influence decisions about brain death.

C.D. Binnie, R. Cooper, F. Mauguière, J.W. Osselton, P.F. Prior, B.M. Tedman (Editors)
Clinical Neurophysiology, Volume 2
EEG, Paediatric Neurophysiology, Special Techniques and Applications

Chapter 7.3

Staffing and training

C.D. Binnie, C.J. Fowler and P.F. Prior

7.3.1 Staffing levels

As discussed earlier, the staff required for the minimum viable clinical neurophysiology unit comprise a full-time and appropriately trained physician, three technologists, a secretary, and possibly a nurse. Measurement of workload is discussed below but, as a guideline, such a team could be expected to perform approximately 2000 mixed EEG, EP and EMG investigations per annum. However, the output will depend very much on the work pattern; both the type of patients seen and the nature of the investigations undertaken. For instance, paediatric, learning disability or psychiatric EEG and EP referrals often require two technologists, effectively halving their output. Staffing levels must also be related to the wide range of complexity and duration of the procedures performed in different departments and the staffing requirements of a major department offering comprehensive neurophysiological services cannot be predicted without a detailed analysis of workload.

For a general clinical neurophysiologist, the most time-consuming aspect of his work in the laboratory is likely to be the peripheral studies, since these are either performed by the physician or, in the case of nerve conduction studies, may be carried out by technologists but require close medical supervision. For a neurophysiologist who specialises in EEG or EPs, an important consideration is the number of procedures requiring his presence during recording; insertion of sphenoidal electrodes, administration of intravenous drugs, investigations in the ITU, complex SEP studies, surgical monitoring, electrocorticography, etc., are obviously far more demanding of medical time than is interpretation of EEGs in the office. A two-bedded telemetry unit requires at least half the time of one physician, the duties possibly being divided between a senior and a junior. Stereo-EEG requires all the time of one physician.

Similarly, in determining staffing levels of technologists, extra weight needs to be given to specialised or portable investigations; a portable EEG in the ITU represents at least twice the workload of a routine recording (even assuming that there are no logistic problems), and the consequences for neurophysiological staffing should be taken into account when planning developments of services (renal, cardiothoracic, head injury, etc.) requiring intensive care. Electrocorticography will typically occupy a technologist for one to one and a half working days, including electrode preparation. Operating a one-bedded telemetry unit represents a task for one full-time technologist (exclusive of on-call arrangements), even assuming that nursing personnel are available to provide non-technical cover, document seizures, and change video tapes etc., outside office hours. A large self-contained telemetry unit should be staffed at all times by a technologist and one nurse per three patients, with a physician on call. The high staff/patient ratio is necessary so that when seizures occur both proper patient care and satisfactory recording are ensured.

From the above some impressions can be gained of the likely equipment and staffing needs of a typical larger unit in an academic hospital (as specified in Section 7.2.2). A basic workload of perhaps 3000 EEGs, 500 EPs and 1500 peripheral studies could under typical circumstances be supported by three EEG machines, two EMG suites and one EP unit. The staffing required for these routine investigations would be of the order of 4 full-time clinical neurophysiologists and 9 technologists, supported by 2 secretaries, a nurse and a physicist. However, these figures do not cover the more complex and labour-intensive procedures, the pattern of which is likely to vary from one unit to another. Additional equipment, and particularly staff, will be needed to meet any demand for investigations during intensive care, for intraoperative recording, or for polysomnography or epilepsy monitoring.

7.3.2 Measuring workload

Measuring the work involved in different investigations may be difficult, and indeed controversial. It is, however, necessary to establish guidelines, if only for purposes of negotiating staffing levels or costing services. Table 7.3.1 sets out a system of weighting factors for various procedures, taking as the basic units of medical and technical time the simplest investigations in each subspecialty: a routine EEG, a nerve conduction study, or the measurement of EPs in one modality. In these terms a reasonable annual output would be 600 units per technologist, 1800–2000 per physician, and from 900 to 2000 units per recording system. The large scatter in suggested annual workload per machine reflects variations in working practice and constraints of staffing, space, etc. A telemetry or monitoring system may run continuously by day and night, whereas, unless a production-line approach to patient preparation is adopted (which is not recommended), an EEG machine may actually record for only two or three hours per day. An EMG system, in a department with only one physician, may well be used for just two three-hour sessions per week. The guidelines suggested here are necessarily crude and will need to be modified to take account of local conditions.

Large units are more cost-effective: in the recent experience of one of the authors, the merger of three busy medium-sized units to form one large department allowed a 45% increase in productivity. It is, however, important that administrators and cost carriers are made aware that the various neurophysiological tests do not all represent the same workload, and that to base staffing, funding or charges on the basic investigations will deny patients access to the more complex procedures which, in clinical terms, are often the most cost-effective.

7.3.3 Training

7.3.3.1 Training of clinical neurophysiologists

International differences in the training and qualification of clinical neurophysiologists are considerable. The modern clinical neurophysiologist must combine an interest in technology with clinical expertise particularly in neurology, and be competent in the three quite dissimilar subspecialties of EEG, EMG and EPs. The application of EEG to the problems of neonatal intensive care has little in common with single fibre EMG, and yet a generalist is expected to be proficient at both. In larger departments there is understandably a reaction against the notion of the comprehensively competent generalist, and a tendency for individuals to concentrate on a particular subspecialty, often combined with direct patient care (for example EEG and epilepsy, EMG and neuromuscular disease, EEG telemetry and either presurgical assessment of epilepsy or a clinic for non-epileptic seizures).

In many countries neurophysiologists are registered neurologists, or psychiatrists, who devote only a part of their time to clinical neurophysiology. Formal training and certification in the specialty may be mandatory, optional, or non-existent. In an increasing number of countries all or most neurophysiological practice is carried out by full-time specialists. These will be accredited following a program of several years' training, including at least one year's full-time general neurology, and which will have covered not only the medical and interpretative aspects of clinical neurophysiology, but also the technology, including practical techniques, instrumentation and computer science. In some countries dual standards exist, with highly trained hospital personnel and unqualified private practitioners.

Training prior to entering clinical neurophysiology must include neurology, and experience of psychiatry, neurosurgery and paediatrics are valuable. However, a more general medical background is also necessary, and it could be argued that excessive specialisation in neuroscience disciplines is disadvantageous, in view of the expanding range of applications of clinical neurophysiology. Neurology is essential for the practice of EMG, and the interpretation of EEGs in seizure disorders requires more knowledge of epilepsy than is provided by most neurological training programs. However, an even much wider experience is needed by a neurophysiologist who works in neonatal intensive care, performs intraoperative monitoring during cardiac and spinal surgery, and provides EP services for ophthalmology and ENT, or EMG for a urological clinic.

The alternative systems of career neurophysiologists, or of neurologists with a part-time commitment to neurophysiology, both have certain advantages. Combining neurophysiology with neurological, or neuropsychiatric, practice helps to ensure the clinical relevance of the service provided. However, only full-time clinical neurophysiologists who have undertaken several year's training in the specialty are likely to acquire any interest or expertise in the underlying technology. Without this background they may be ill-equipped to train or supervise technologists, or manage complex, innovative services. The ideal may be a department headed by a career clinical neurophysiologist responsible for management and for maintaining technical standards, but with several neurologists, and possibly neuropsychiatrists, contributing on a part-time basis to the clinical workload.

Appendix 8.1

Table 7.3.1
Clinical neurophysiological procedures and weightings

Investigation	Comment	Weighting	
		Physician	PMT*
Peripheral studies			
Nerve conduction	Simple measurement of nerve velocity, by PMT under medical supervision, using surface electrodes.	1	1
Electromyography	EMG examination by physician of 45 min duration. Assistance is provided by PMT or nurse. Extra for complex investigation or additional nerves/muscle groups	3	1
EP			
Simple EPs	Record of cerebral responses to one sensory modality. 0.5 extra for additional modalities.	1	1
Cognitive EPs	Record of cerebral responses during complex cognitive tasks	2	3
EP monitoring during surgical operations		6	4
EEG			
Routine EEG	Waking record of at least 30 min duration with overbreathing and photic stimulation.	1	1
Sleep	Sleep induced in daytime by sleep deprivation, or hypnotic drug.	2	2
Sphenoidal	Recording with special wire electrodes inserted by physician. Cost does not include intravenous anaesthetic given by a second doctor, Nursing help required.	2	2
Bedside	Recording from patient who cannot come to laboratory due to clinical state: unconscious, continuous seizures, depth electrodes, etc. Includes neurophysiologist's attendance at bedside during part of recording. Non-linear for multiple or prolonged records: maximum in 24 hr is:-	3	2
EEG monitoring during surgical operations		6	4
Carotid amytal test	Psychological testing under EEG control with intra-carotid injections of sodium amytal. Additional costs of neuroradiology and psychology.	5	2
Polysomnography	All night sleep EEG with various transducers. Medical cost depends on whether or not sleep staging is required, and whether this is automated.	4–8	6
Multiple sleep latency test	Repeated brief sleep recordings during one day	4	4
Ambulatory monitoring	24 h recording with portable tape recorder. Costs for medical time up to four times greater if problem requires examination of entire tape, for example for sleep staging or to count spikes.	4	2
Telemetry	24 h recording by radio or cable with simultaneous video registration. Clinical assessment by physician required at least once daily during procedure. See comment on costs of ambulatory monitoring.	4	3
Video-EEG	Conventional EEG with video recording of events	2	1
Electrocorticography	Recording from exposed surface of brain at operation. PMT cost includes preparation of special electrodes.	5	5
Record assessment	Assessment of EEG record loaned from another department.	2	
Intracranial electrode insertion	Insertion and preliminary recording from electrodes in the brain or subdural space. Includes consultation and attendance of physician during surgical implantation and stereotaxy, and setting up the investigation. Subsequent recording costs as for monitoring technology used. Additional cost of medical physics to prepare electrodes.	10	2
Psychological test	Psychological test, usually automated, under EEG control.	2	2
DNA	Patient did not attend or cancelled too late for the appointment to be given to another.		1

*PMT = Physiological Measurement Technologist.

7.3.3.2 Training and role of physiological measurement technologists

International practice as regards to the training and status of electrophysiological technologists is yet more varied. Formal training may be available with nationally recognised qualifications up to honours degree standard, or may be totally lacking. In some countries a nursing qualification is regarded as the starting point for technologist training. This is a useful background, provided it does not lead to selection of people with little aptitude for the technical aspects of the work. A post in the EEG department is sometimes viewed as an undemanding part-time job, requiring no special training, and suitable for married nurses who do not wish to work on a shift system. A recent development is the politically expedient assumption by some European politicians that all electromedical procedures are similar and that all branches of physiological measurement (neurophysiology, audiometry, cardiology, respiratory function, etc.) can conveniently be incorporated within a training program for radiographers. There are now helpful recommendations for minimal standards from the International Organisation of Societies for Electrophysiological Technology (OSET) (1996).

The task of an electrophysiological technologist is unusual in that it combines clinical involvement with patients, manual and visual skills, and applied technology. Where training programs and formal qualifications exist, there may be a tendency to concentrate excessively on the technology which lends itself to formal teaching and examination, and to underestimate the clinical skills required for good electrophysiological practice. A welcome development in some countries is competency-based training. The tasks performed by technologists are analysed and broken down into 'elements of competence'. These are then defined in terms of performance criteria which in turn determine the required knowledge base and skills. Both theoretical and practical training can thus be precisely matched to the actual work of the technologist, and is both comprehensive and relevant. Such an approach should help to achieve a balance between the economic pressures to neglect training and the possible vested interest of teachers and professionals in overtraining.

An important but controversial issue is the extent to which the exercise of clinical judgement by the technologist is considered to usurp the functions of the physician. We have put forward the view that the best approach to clinical electrophysiological recording is an interactive one, in which the technologist assesses both the clinical problem and the electrophysiological data, and adapts the investigative procedure appropriately. Inflexible adherence to formal technical protocols, however meticulous, can be no substitute for such a problem-solving approach. This necessarily involves an element of clinical decision-making and consequent responsibilities. It has proved difficult to achieve even national, much less international, agreement concerning the extent of the clinical responsibility to be exercised by technologists.

We can only advance the personal view that subject always to the need to seek medical advice when appropriate, a 'competent' technologist should have been trained at least to such a level that they can properly and reliably:

(1) Accept or refer back requests for EEG or EP investigation.
(2) Determine the appropriate type of investigation (wake versus sleep EEG, modalities of stimulation for EPs, etc.).
(3) Perform EEG and simple EP examinations, without supervision, modifying the procedures as above in the light of additional clinical or electrophysiological data.
(4) Perform nerve conduction studies under medical supervision.
(5) Prepare factual descriptions of the findings of investigations, to accompany an interpretative report by a physician.
(6) Issue reports of strictly objective results (amplitudes and latencies of EP components, sleep staging, etc.), without offering any opinion concerning possible clinical relevance.
(7) Review long-term EEG recordings (ambulatory cassettes, etc.) and identify significant events to be assessed by a physician.

The situation may well change with improving educational programs but the levels of training currently available in those countries with the highest standards does NOT generally equip the technologist to:

(1) Provide either written or verbal reports on EEGs, EPs, nerve conduction studies, electrocorticography or monitoring studies (including intraoperative monitoring), without medical interpretation. The issuing of a non-interpretative factual report with obvious clinical implications, is a common malpractice used to circumvent legal restrictions intended to prevent unqualified persons from performing medical functions.
(2) Carry out ECN investigations in terminal coma or suspected brain death without the attendance of a physician during part of the investigation.
(3) Perform EMGs for clinical purposes.

Whatever formal training programs may exist, regular departmental reporting sessions play an important role in basic and post-basic training of

both technical and medical personnel and contribute to quality control or clinical audit of the work.

7.3.3.3 *Training of other scientists*

Non-medical graduates played an important role in the development of clinical neurophysiology but in recent years have tended to be supplanted in clinical service provision by medical graduates, not least because of concerns about the legal implications of clinical responsibility. EEG interpretation not only requires medical knowledge, but arguably demands a greater degree of clinical acumen than face-to-face patient management, because of the limited information available; EMG also requires practical neurological skills. These are generally the exclusive province of the physician. However, there are some neurophysiological investigations which produce objective results without an intermediate step of clinical interpretation. There would seem to be no reason why non-medical scientists should not for instance be trained to run a sleep laboratory. There may also be an interpretative role in a very circumscribed subspecialty in which the scientist has special expertise, neonatal EEG for instance.

Brain-mapping is being represented in some quarters as an objective test requiring no clinical skill which can properly be interpreted by non-medical personnel – it is not.

Currently, the main role of the basic scientist in a clinical neurophysiology team is to provide complex technological services and to carry out developments in bioengineering, telemetry or data processing. However, as technologist training improves and increasing numbers of technologists are proceeding to masters degrees and doctorates, a new generation of senior graduates is emerging, trained not through academic basic sciences but through clinical neurophysiological practice. The division of roles between these new clinical scientists and medically qualified clinical neurophysiologist has yet to be determined.

C.D. Binnie, R. Cooper, F. Mauguière, J.W. Osselton, P.F. Prior, B.M. Tedman (Editors)
Clinical Neurophysiology, Volume 2
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Chapter 7.4

Equipment and servicing

C.D. Binnie, R. Cooper, C.J. Fowler, F. Mauguière, R.C. Pottinger and P.F. Prior

Minimal technical standards of equipment are indicated in the various relevant sections; there follows an account of the level of provision required.

7.4.1 EMG equipment

The minimal clinical neurophysiology department will need two EMG machines so that a clinical service can be maintained in the event of failure of one of them. At least one of the machines should be highly mobile or truly portable so that it can be taken to the ITU, outlying wards and if necessary, satellite hospitals.

EMG clinics can be conveniently run with two machines, one of which is mainly used by technologists to perform nerve conduction studies under the supervision of the clinical neurophysiologist in the adjacent suite. This gives greater flexibility so that a patient whose investigation takes an unpredictably long time can be accommodated as well as giving leeway to examine the ward patients who are added to the outpatient clinic list.

7.4.2 EP equipment

There should be at least one static and one mobile EP system for use at the bedside. The latter requires stimulators for brainstem auditory evoked potential (BAEP), somatosensory evoked potential (SEP) and flash VEP, while static systems should include pattern VEP stimulators in addition. ERG requires also a Ganzfeld and should ideally be performed in a dedicated suite, equipped of course for other types of VEP studies, and for perimetry and visual acuity measurements.

7.4.3 EEG equipment

In the notional minimal department with two EEG machines and three technologists, each electroencephalograph will produce up to 900 EEGs per annum. A greater throughput can be achieved by the employment of more technologists, by the rationalisations of scale possible in larger units, and by the provision of separate areas for recording and for electrode application and removal. Assuming an 8-hour working day, each EEG or EP machine could then, in theory, produce some 40 records per week. However, a satisfactory service must be sufficiently flexible to provide emergency investigations at a few minutes' notice. This implies that one machine should generally be held in reserve; often this will be a mobile equipment suitable for taking to the wards, ITU, etc.

Where a truly mobile service is required at a location remote from the base laboratory, it may be necessary to use portable equipment. There were few 'portable' paper EEG machines produced which were small and light enough to be carried more than a few metres, but digital machines are now available as laptop computers, weighing as little as 2 kg with the headbox. For a mobile service within a hospital site, most modern equipment is sufficiently easy to transport. The important consideration is usually not overall size but manoeuvrability and the provision of large rubber wheels. Lack of space at the bedside, particularly in the ITU or SCBU, is often a greater problem and it is useful to have one system based on a laptop rather than a PC for recording on the wards.

Various types of EEG monitors may be required, for use in theatre or the ITU, and/or equipment for telemetry and ambulatory recording. It should be noted that various methods of long-term EEG monitoring, by ambulatory cassettes or telemetry, may also make demands on

EEG machines for purposes of review and transcription. In the case of telemetry, the same apparatus can be used both for recording and playback. However, to avoid interruption of the recording during playback, it is preferable that a separate review station be provided close to the site where telemetry is performed.

7.4.4 Machine checks

In many countries there is a statutory obligation on employers, delegated to the head of department, to ensure safety of patients and in the workplace. Tests of electrical safety should be performed on all new equipment before use, and at regular intervals thereafter. They should be fully documented and are the responsibility of a qualified physicist. Calibration should be checked before every investigation (Section 4.2.7.4 for EEG equipment and Section 3.2.1.5 of Volume 1 for averagers), and more extensive tests, and adjustment as necessary, should be performed at regular intervals. The frequency of testing required will depend on the observed reliability of the particular apparatus.

The development of integrated circuitry has diminished the scope for user maintenance and servicing of electrophysiological equipment. Apart from adjustment of pen recorders, replacing circuit boards and mending broken cables, there are now few repairs which can be carried out without the support of the manufacturer's agents. Most digital machines run self-checking routines at startup to diagnose malfunction. This generates error messages which will generally require the attention of the manufacturer, who will supply the necessary replacement chip or circuit board. There is, therefore, a decreasing role for on-site maintenance by local personnel. However, preliminary investigation by the hospital's medical physics department is worthwhile, if only to identify easily corrected faults such as defective fuses or unplugged connectors. Similarly, the local Information Technology (IT) staff's help may resolve simple problems such as the need to defragment a disc, or reinstall a driver.

Contract maintenance, typically at an annual cost of 10% of purchase price, is claimed to be rarely profitable for the manufacturer's agent but may seem over-priced to the user. The decision whether or not to take out a contract will depend on the local availability of electronic support, the reliability of the apparatus in question, and the cost of site visits and spare parts on a non-contractual basis. Software updates for digital machines may be available on more favourable terms to holders of a maintenance contract. The quality and cost of technical support should be a major consideration in the selection of equipment and, particularly in developing countries, may limit the choice to a single manufacturer which might not otherwise be the first preference. Even where a choice from a full range of supported equipment is available, there may be advantages in having a "single manufacturer" department if this leads to better maintenance or other preferential treatment. Indeed, since the advent of digital machines, it has become difficult to mix the products of different manufacturers within a department because of problems of compatibility. Changing supplier is now a major decision, often implying re-equipment of the entire department.

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Chapter 7.5

Referrals and appointments

C.D. Binnie, C.J. Fowler, F. Mauguière and P.F. Prior

7.5.1 Establishing a referral policy

Referral policies have been discussed in Section 4.2.7.1 for EEG and in Section 2.1.2 of Volume 1 for EMG and nerve conduction studies; they are implicit in the considerations of the various applications of EPs (Chapter 3.6 of Volume 1). Implementation of such policies may prove difficult and requires close, interactive contact between the clinical neurophysiologist and senior colleagues. The practice of requesting unnecessary laboratory tests either to avoid possible litigation or as a substitute for clinical diagnosis is generally deplored. The dangers of misuse are particularly great where the applications and limitations of the investigation are poorly understood by the users, as is often the case for neurophysiology. Senior clinicians must be persuaded to monitor the work of their juniors in making referrals; otherwise they tend all too readily to think in terms of standardised protocols: '... the routine diagnostic work-up of condition x.' Education of colleagues on the uses and limitations of clinical neurophysiology is important and the neurophysiologist should attend Grand Rounds or case conferences whenever possible and take responsibility for teaching medical students and junior medical staff.

A deterrent to misuse may be the use of a detailed referral form and insistence that it be completed (examples of such forms for general ECN referrals or specifically for EEG are shown by way of illustration in Fig. 7.5.1). It is useful for the report of the investigation to be typed and returned on the reverse side of the referral form, and to refer specifically to the problems stated or to any deficiencies of the referral. Someone reading the case notes in the future may find it helpful to know why a particular investigation was requested. It may also be advisable to file a photocopy of the referral in the ECN department, to leave no doubt as to what question the neurophysiologist was asked to answer and what clinical information was provided or omitted.

7.5.2 Appointments

7.5.2.1 Appointments for 'EMG clinics'

An appointment system for 'EMG Clinics' at which many patients must be seen in 3–4 h presents problems which rarely arise when arranging EEGs or EPs at 1–2 hourly intervals. The question as to how many patients can reasonably be dealt with in one EMG session is a personal one and will depend very much on what type of referrals are expected, the level to which their neurological problems have been worked out beforehand and the detail of examination required. In a 3-h session it should be possible to see 6–8 patients, including referrals both for simple nerve conduction studies and for complex EMG investigations. Time should be reserved for referrals of inpatients at short notice, although the unpredictable numbers make booking difficult. Fortunately, there are few indications for urgent EMG investigation requiring attention on a time scale of less than a day or two. This workload allows an average of about 25 min for studying each patient and so gives the necessary flexibility to cope with the unexpected.

Peripheral neurophysiological tests are inevitably uncomfortable and a patient's limits of tolerance will often have been reached by the end of half an hour. It can also be said that the neurophysiologist has to spend longer if the problem was not properly formulated in the first place. However, some studies, such as single fibre EMG, are predictably longer and should be booked accordingly.

A common experience is to find the most fascinating electrophysiological problems in what appear to be unpromising referrals. Amongst six patients, all accompanied by requests for carpal tunnel studies, the chances are high that at least one will have a much more complex and time-consuming disorder to be investigated. At this point it is convenient to have two operational EMG rooms, so that a technologist can

proceed with 'routine' nerve conduction tests on the next waiting patient.

An attempt for a single individual to deal with more than seven new patients in a session will result in some patients having inadequate studies. This is a serious problem since, if the waiting list is long, the patient is unlikely to be sent back for further investigation and peripheral nerve surgery, etc., may be arranged on inadequate evidence.

7.5.2.2 EP appointments

For simple studies of EPs in a single modality, half an hour per test is usually sufficient, and therefore one and half hours for all three, exclusive of a half hour for electrode application and removal. However, when any sophisticated use is to be made of EPs for detailed analysis of a neurological problem, advance planning may be difficult. Thus, during VEP recording, it may become evident from the full field EPs, that to identify particular components other techniques will be required, such as half fields, foveal stimulation or flash; these require much more time to allow the patient to rest between each run. SEP studies are often highly interactive, requiring stimulation at multiple sites and with various montages; the conduct of the investigation is far from routine and is determined by the findings. It is therefore advisable to leave a generous margin of time between EP appointments.

7.5.2.3 EEG appointments

An appointments system must take account of the availability of personnel and equipment, including staff leave and machine maintenance schedules. Where a wide range of different investigations are offered, each referral should be assessed before an appointment is made. It is important to check that the most appropriate investigation has been requested, and to ensure that sufficient time is allowed, and that the most suitable equipment, personnel and recording site are allocated. For instance, if a sleep EEG has been suggested following a previous negative investigation and a further request for a waking record is received, this should be queried with the referring physician. If a mentally handicapped or disturbed patient is referred, it may be advisable to ensure that two technologists will be available, one of them senior or experienced in dealing with such patients. If urgent clinical decisions or medical intervention such as administration of intravenous drugs may be required during the investigation, the availability of medical staff must be checked.

It is currently perceived as good practice for appointments to be made immediately when the investigation is proposed by the referring physician. However, except where the referrer is known to be experienced in the use of neurophysiological investigations, or the procedure requested is simple and clearly appropriate, some form of triage is necessary as suggested earlier. This requires consideration by experienced personnel and possibly consultation with more senior staff, imposing inevitable delay. This may be addressed by 'partial booking', agreeing with the patient that they will contact the department after a specified interval, so that a definitive appointment at a time convenient to them and to the department can then be negotiated after full consideration of what is required. This approach is particularly helpful when there is a long waiting list. It ensures that the patients know where they are in the system, but delays the definitive booking until a short time before the appointment. This is convenient for the patients who may have difficulty planning time off work, childcare etc., weeks ahead, and enables the department to make optimal use of the resources available.

Sleep EEGs may be booked at certain times of day and possibly on a particular machine, or in a suite which is quieter than the others. If the purpose of the investigation requires special facilities, such as simultaneous video recording, the appropriate facility should be chosen.

Investigations of unpredictable duration are especially difficult to plan, EEG telemetry for capture of seizures being the worst case. In this instance, it may be helpful to keep a standby list of patients, who are available at short notice, and can be called in when a vacancy arises unexpectedly, for instance if an investigation is completed earlier than planned.

7.5.2.4 Waiting lists

A mismatch between referrals and capacity may result in a lengthy waiting list. No investigative specialty should have too long a waiting list since patients' conditions can seriously deteriorate whilst awaiting a test. A long waiting list, however caused, is evidence of mismanagement; either it is stable, and could be reduced by a brief spurt of increased productivity, or it is growing, and indicates a mismatch between referrals and resources. A long waiting list often serves as a substitute for a referral policy; it precludes investigation of acute problems, where neurophysiology has most to contribute, deters detailed investigation of complex questions, and reduces the clinical utility of the service. If available resources cannot meet the demand, the interests of patients are better served by restricting referrals than by providing a second rate service after an excessive delay.

7.5.3 Preparation of patient

Preparation of the patient for the investigation is essential, and it should not be assumed that referring physicians are familiar with the procedures to be performed or will send properly instructed patients. The less well-informed patient may have expectations based on seeing EEGs recorded in films, most probably in a context of brain-washing or science fiction, and may know nothing of 'EMG' except that it is painful and involves needles and electric shocks.

All outpatients should be sent an appointment letter which, in addition to basic administrative details, indicates: the nature of the test, who has requested it, any special preparation required (for example ensuring hair is clean and not lacquered, or otherwise dressed, for EEG or EPs), the likely duration of the investigation, and any special arrangements for travelling

(a)

THIS IS A PERMANENT RECORD
PLEASE COMPLETE LEGIBLY —
Preferably by typewriter

DEPARTMENT OF CLINICAL NEUROPHYSIOLOGY
REQUEST FOR ELECTROENCEPHALOGRAM

NAME DOB Consultant Hospital

ADDRESS Sex M F Hospital No. Ward/OPD

Phone Handedness L R Amb?

WARNINGS (e.g. drug sensitivities)

REASON FOR REQUESTING E.E.G. EXAMINATION

DIAGNOSIS

RECENT HISTORY *(NB — if the patient has seizures give a description of the fit pattern and the age of onset, frequency and last occurrence)*

FINDINGS/COMMENTS *(e.g., clinical, psychological, laboratory and radiological examinations)*

TREATMENT *(Give present drug regime and note if change within last two weeks. Give dates of last E.C.T. or of relevant surgical operations)*

PREVIOUS HISTORY *(Infantile Convulsions, Head Injuries, Intracranial disease, etc.)*

FAMILY HISTORY *(Epilepsy, Neurosis, Psychosis, Psychopathy, etc.)*

REMARKS

DATE SIGNATURE
Print or type name beneath signature

Fig. 7.5.1. (a) An EEG request form. (b) A general referral for EEG, EMG and EP studies. Neither is offered as a standard to be followed, but as an illustrative example.

Appendix 8.1

(b) **KING'S NEUROSCIENCES CENTRE**
DEPARTMENT OF CLINICAL NEUROPHYSIOLOGY

Appointments: _____

_____

Telephone:
For Departmental use: Test No ..... Test Type ..... Date .....

Please indicate test required: **EEG, Sleep EEG, Ambulatory EEG, Telemetry, EMG/NCV, MSLT, Polysomnography, VEP, ERG, EOG, BAEP, SEP, DSEP, Other:**.....

Use adhesive label if available	Consultant (Name, not initials) .....
Hospital No. ..... M/F.	Specialty ..... OP / IP: Ward .....
Surname ..... Title	Address for Report .....
Given Names	.....
Address	Patient's Tel. No. (Home) .....
.....	(Work) .....
.....	**Warnings** (e.g. drug sensitivity, HIV status, etc.):
Postcode ..... D.O.B ..../...../.....	.....

Provisional Diagnosis	Purpose of Investigation

Urgency (if claiming priority over other patients, give reasons) .....
.....
History of Present Complaint .....
.....
.....
Findings (physical examination & other investigations) .....
.....
.....
Suggested Nature & Site of Lesion .....
Previous Medical History .....
Relevant Family History .....
Mental State/Intelligence .....
Mobility, Transport Arrangements, & factors likely to affect ability to attend or cooperate:
.....

Treatment (All Medication, recent surgery etc.) .....
.....
.....

FURTHER DETAILS, IF NOT GIVEN ABOVE

FOR EEG:
Seizures: Description and/or Classification .....
.....
.....
Age at Onset ..... Frequency ..... Date of Last Attack .....
Head Injury ..... Birth Trauma ..... ECT .....

FOR EMG/NCV: Does patient have Diabetes Y/N
Special Tests Required .....
.....

FOR EPs/ERG:
Visual Acuity ..... Hearing .....
Visual Fields ..... Relevant Surgery .....

Signature ..... Date .....

SF4A (Revised 96)

Fig. 7.5.1. Continued

(for example, the need for transport and an escort after sleep EEG). A prepaid reply card and an informative brochure describing the specific test and including a map or plan of the hospital, showing access for the disabled, should be enclosed. Informed consent may have been obtained by the referring physician, or may form part of the appointments procedure (see Section 7.7.1.4).

7.5.4 Quality control and audit

To provide an objective basis for a referral policy and to improve procedures within the department, clinical audit and quality control are necessary. An important element in these may be the maintenance of a database concerning referrals (including both the clinical and administrative details) and results of investigation. Various measures of diagnostic utility can be used, such as the yield of clinically relevant new information from sleep EEGs, the numbers of abnormal EPs obtained, or the rate of seizure capture during telemetry. Breaking these measures down by sources and types of referral may highlight problems of referral policy. Does a very high yield from a particular test imply that it is being used only in selected patients, where the outcome is already predictable? Does a low seizure capture rate from telemetry performed for the child psychiatrists indicate that they are too readily referring children with episodic behavioural disorders for investigation of possible epilepsy?

Referral patterns themselves may be illuminating, particularly when combined with measures of diagnostic utility. For instance, one neurological practice may refer a smaller proportion of patients for EP studies than others and yet obtain a lower percentage of abnormal findings. Such a discrepancy is worth investigating in collaboration with the colleagues concerned. It would be naive to assume that the 'deviant' clinician is making less effective use of the investigation; on the contrary, he may show exceptional diagnostic acumen and require EP studies only for support of negative diagnoses. Such trivial statistics as the intervals between the dates on request forms and performance of the investigation may be of interest. Marked discrepancies may reflect the fact that one physician comes straight from his clinic to discuss problems in person and to make appointments, another merely sends a request form, while a third writes a detailed referral letter, imposing a week's delay before it is typed and signed. There may be merits in all three practices, but they are worth comparing and discussing with those concerned.

Feedback about individual investigations can be provided by members of the department and by referring physicians. Regular departmental reporting sessions allow individual records to be reviewed and provide an opportunity to discuss measures which might have improved their clinical value; should additional electrodes have been applied, or a different montage used to locate the focus? Should that full-field pattern EP have been followed up with half-field or foveal stimulation or flash? Perhaps with a hindsight that EMG should have included an assessment of other muscle groups. Feedback concerning diagnostic successes and failures is useful; did that EEG reported as normal in fact show a minor abnormality reflecting the tumour so obvious on the MRI; were ictal discharges wrongly reported as artefact in an ambulatory EEG of a patient, who now manifestly has epilepsy? Such departmental discussions can provide one basis for medical audit in clinical neurophysiology and keep a check on the validity, specificity and sensitivity of the tests used as well as on the quality of their performance, interpretation and reporting. They will not necessarily address the questions of the quality and cost-effectiveness of the investigations from the viewpoint of the patient or the referring physician. These issues require more formal investigation.

Administrative measures of service quality should also be regularly reviewed. The waiting list should be monitored and action taken before it gets out of hand. The various steps between completion of recordings and the dispatch of reports should be monitored, and sources of delay identified and corrected. If a patient is kept waiting after the time of the appointment, this should be recorded and the reasons for excessive or too frequent delays be investigated. Last minute cancellations or failure of patients to attend should also be documented and reviewed. They may be symptomatic of a deficient referral policy or appointments system, or may identify a physician who fails to discuss proposed investigations with his patients.

There is a place for regular surveys to ascertain the opinion of the users of the service. As well as, for example, the use of questionnaires which invite patients to indicate their satisfaction or dissatisfaction with the service, there should also be some mechanism for the referring clinician to indicate whether the clinical questions posed have been effectively answered. A regular formal external audit, for example on a quarterly basis between different departments in a particular region, should be undertaken to obtain an objective view of the overall quality and effectiveness of the service.

C.D. Binnie, R. Cooper, F. Mauguière, J.W. Osselton, P.F. Prior, B.M. Tedman (Editors)
Clinical Neurophysiology, Volume 2
EEG, Paediatric Neurophysiology, Special Techniques and Applications

Chapter 7.6

Storage of records and reports

C.D. Binnie, C.J. Fowler, F. Mauguière and P.F. Prior

7.6.1 Record storage

In many departments, storage of records, particularly of bulky paper EEGs, presents a major problem. There may be a legal requirement to keep all medical data for a specified period (see Section 6.8.3). Regulations will differ from one country to another, and may be complex. For instance, under English law a person may bring civil proceedings for injuries suffered in utero or at birth up to the age of 25 years. It may be a simple matter to keep obstetric records for a quarter of a century, but it is less easy to identify and preserve all EEGs performed on pregnant women or their offspring. A person of 'unsound mind' may bring an action for wrongful imprisonment up to six years after recovery; thus an EEG recorded on admission to a mental subnormality unit could be required for legal purposes 50 years later. The Department of Health for England and Wales requires (in Circular HC(89)20) that medical records should in general be kept for eight years 'after end of treatment', a point in time which may be difficult to define for potentially chronic or recurring disorders such as epilepsy. They offer, however, the rider that this is subject to 'consultation with the appropriate health professional'. The latter may argue that to preserve the neurophysiologists' reports, but not primary tracings, meets the same standards of documentation as are accepted in the case of doctors' notes of physical signs or case histories. See also Chapter 6.8.

Less contentious are the clinical considerations concerning preservation of records. Many neurophysiological procedures are performed to investigate potentially life-long diseases, and serial changes in the findings may be important. Further, the interpretation of various tests involves assumptions about the normal picture in the individual concerned, prior to the current illness. Thus the results of a previous investigation, possibly undertaken for a different complaint, may be valuable for assessing the present findings. Long-term storage of data is therefore dictated by good clinical practice, quite apart from any other considerations of saving material for retrospective research, preserving evidence which may be required in future litigation, or complying with local or national regulations.

It is not necessary, nor practical, in all cases to preserve records of the primary biological signals. Figures for latency and amplitude are the major information extracted from nerve conduction studies and so long as these are kept, original traces of waveforms are less important. By contrast, numerical descriptors of EEG phenomena give a poor indication of the findings and the traces need to be preserved. Although latency and amplitude are the parameters used to report EPs, some information is contained in the waveforms and the averages, but not the primary signals, should therefore be saved.

Printouts of averaged EPs and EMGs and nerve conduction studies may conveniently be stored together with reports in a conventional filing system and many modern recording machines have the facility to store traces along with patient data on disc. Paper EEGs however, are bulky, heavy, often of unequal size where different machines are in use, and easily become tattered.

After five decades of clinical EEG, those departments which have pursued a policy of storing EEGs indefinitely are having to reconsider. Options include:

(1) Automatic destruction after a fixed period, which may result in loss of clinically important data in patients with chronic disease or of valuable research material.
(2) Selective storage of illustrative sections of each record, which if done properly makes heavy demands on the time of skilled personnel. It may be the only practical method of handling prolonged records. After telemetric EEG investigations, hard copy of seizures is saved and video clips of the clinical events transcribed and archived, together with samples of interictal EEG. The magnetic media used for recording are recycled.

(3) Selective destruction after a fixed period with retention of particular categories of records; this requires good and readily accessible documentation to identify the records to be retained, for instance of people with chronic diseases such as epilepsy, or conditions in which there is a local research interest. This process is made much easier by marking the spine of bound records with colour coded indicators immediately after reporting.

(4) Microfilming, which involves the cost both of filming (which may be done inhouse or commercially), and of microfilm viewers and printers. The filming costs, however, are generally only of the order of 2–5% of the total cost of the original recording and as such appear justifiable. Particularly where reel or cassette film is used, the inconvenience of locating a required record (unless a very effective indexing and search system is used) may discourage review of past records. Microfiche has the advantages of greater accessibility, the possibility of logical filing of a patient's repeat recordings and the use of relatively simple viewing apparatus. These considerations justify the added cost of mounting the original film in jackets and make this method the most favoured option for long-term storage of paper tracings.

Problems of storage space have been eliminated by the development of low cost mass storage systems for digitised EEGs. The capacity of, for instance, optical discs and CDs is so great that storage space ceases to be an important consideration. Unfortunately, the long-term stability of these media is uncertain – after ten years it may be necessary to transcribe records to whatever medium is currently 'state-of-the-art'.

7.6.2 EEG archives

So long as paper records are kept, whether for short or long periods, some suitable archiving system must be devised. The most obvious perhaps is simple sequential storage of the tracings, numbered in order of production, on shelving. However, if a patient has had multiple investigations, this involves finding, and re-filing after use, records on several different shelves. This difficulty is overcome by filing together all the records of each patient indexed alphabetically or by hospital or a unique departmental number. This policy is, however, incompatible with effective utilisation of shelving, as empty space must be left for the reception of possible future records. EEGs are readily damaged during removal from the shelves and subsequent replacement. If stacked flat they may be difficult to extract and replace. If stacked on end they tend to collapse and become unfolded, particularly if they are bound into books by means of adhesive tape. The most satisfactory solution may be to stack EEGs on end after placing them between cardboard covers or in large envelopes. This last method is particularly useful when the records are not of equal size (uniform envelopes can be used to accommodate all types of neurophysiological recordings). It also has the advantage that, if desired, it is possible to record on both sides of the paper, a cost saving method which is not applicable if the records are to be bound with sticky tape.

The archiving of digital records on optical discs or CDs immeasurably reduces the storage problem, as discussed below and in Section 4.2.5.8.

7.6.3 Reports

Reports will be sent to the referring physician, preferably on the reverse of the request form, and duplicates should be stored with a copy (typed or photocopied) of the referral with the tracing and in a suitable index system. Where the requests themselves are received in digital form, they can easily be incorporated into an integrated archiving system. Even if they are hand-written, they can be scanned and incorporated into a digital archive. Circulating photocopies of EP or EMG traces or illustrative samples from EEGs may serve as an educational function and promote communication with referring physicians. Similar considerations may apply to brain maps. With the development of fully digital telemetry systems and the introduction of "paperless EEGs", graphic print-outs of ictal recordings and of salient EEG features are becoming readily available, automatically labelled with montages and in a format convenient for insertion in hospital records, and may usefully be supplied as part of the report. Windows™-based systems allow sections of EEG recording, EP traces, brain maps or graphics of equivalent dipoles to be elegantly inserted into the text report. Many digital EEG systems include facilities for archiving reports directly from the word-processor onto the same media as the digitised records themselves.

7.6.4 Filing results

As indicated above, the paperless neurophysiology laboratory has already arrived, but so long as conventional office practices persist, it may be most convenient to create a folder to cumulate all the reports of a particular patient, together with a summary sheet which may be updated in the light of new clinical information. The request form layout (as illustrated in Figs. 7.5.1a and b) can also be used as the front of a summary sheet, which is updated as more information

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becomes available. On the opposite side are listed the dates, types and index numbers of all investigations, together with the reasons for each referral, current clinical status, and changes in medication.

Some redundancy in the filing system is essential (unless this is computerised and safely backed-up). If records can be traced only by accession number and these numbers are listed only in the patient report files, the loss of a file immediately makes an entire series of records inaccessible. A solution may be either a simple alphabetical card index of patients or a database which can be searched by patient name or number.

7.6.5 Databases

Two reasons for maintaining a database have been considered above: quality control and recovery of records and reports. In many departments a more immediate concern may be generation of reports on work done and sources of referral, costing and possibly billing. If the stored data include clinical details and clinical neurophysiological findings, the possibility also exists of their being used for purposes of research.

Standard reports, generated possibly by several different interpreters using proformata, may not be sufficiently consistent to be used as primary research material. They will, however, generally be suitable for identifying patients or records meeting specified criteria for inclusion in a research study. Various types of database have been developed for documenting electrophysiological findings. EMG and EP studies result in mainly numerical data that can easily be stored. EEG findings, both qualitative and numerical but resulting from subjective visual analysis, present greater problems. Over many years, simple but reliable systems have been used to record the presence of items on a checklist of abnormal or uncommon EEG phenomena and clinical events (for example Schwab, 1951; Krauthammer et al., 1966; Scott and Prior, 1981, 1982). More sophisticated systems repay the time spent on coding EEG data by automatically generating textual reports suitable for sending, possibly after minor editing, to the referring physician. Both coding and subsequent retrieval of salient findings may be facilitated by integrating the data entry system with the manufacturer's EEG review software. Thus, Aurlien et al. (1999) describe a system that links the coding program to marked events in the EEG. These can be viewed and directly coded. For instance a previously marked epileptiform pattern can be viewed on screen, the waveform categorised, the amplitude measured by cursoring, the affected electrodes tagged, and the information entered in a database, from which will eventually be generated a report that describes the event in question.

It is not necessary to await the installation of a comprehensive hospital information system. In many departments, reports are generated on magnetic media by the use of word processing; it is then a small step to incorporate the text in a permanent record using a microcomputer implementation of one of the popular database programs. Such a simple approach not only serves as a means of archiving reports, but can easily be adapted to meet the basic requirements for production statistics, invoicing, quality control and clinical audit. A further sophistication is to add an appointments system, so that administrative, demographic and clinical information entered when a booking is made can be passed to the report-writing module and hence to the archive. When a patient returns for further investigation this information can be recovered, verified, updated and recycled, avoiding duplication of repetitious clerical tasks. Most large departments will have access to sufficient computer expertise to create such systems, and administrative packages for clinical neurophysiology are also commercially available.

As hospital information systems are introduced, a local departmental database could in time directly access administrative and clinical data in a central computer, saving duplication and errors in data entry and allowing referrals to be made digitally, so that clinical details can eventually be archived without further manual data entry. Ultimately, the establishment of such databases may provide the starting point for the development of expert systems for clinical interpretation.

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Clinical Neurophysiology, Volume 2
EEG, Paediatric Neurophysiology, Special Techniques and Applications

Chapter 7.7

Medico-legal considerations

P.C.B. Fenwick, C.D. Binnie, P.F. Prior and B.M. Tedman

In addition to their clinical and scientific responsibilities, clinical neurophysiologists need to be concerned about a range of medico-legal issues in their professional lives. These may be divided into:

(1) matters affecting safety of patients and staff;
(2) responsibilities for training and supervising staff to ensure a high quality performance of techniques;
(3) action to ensure proper reporting of results and that storage of material relating to investigations complies with legislation about confidentiality and data protection rights of the individual;
(4) specific medico-legal applications of neurophysiological techniques;
(5) broader areas where neurophysiology may assist indirectly in matters which may have medico-legal implications.

The last two of these are discussed in Chapter 6.8 which should be read in conjunction with this section.

7.7.1 Safety of patients and staff

The work of a department of clinical neurophysiology brings staff into contact with many aspects of legislation about safe practice with regard to electromedical equipment, drugs and dangerous substances and control of infection as well as the more general features of the safe and healthy environment for patients and staff, such as reduction of hazards from fire, slippery floors, excessive noise and extremes of temperature and humidity.

Every hospital has a statutory responsibility to ensure the safety of both patients and staff. In the UK, 'Crown immunity' no longer applies. Although they are defined by statute, heating and lighting requirements, and the number of windows that a room in which people are working continuously must have, are not always applicable to hospitals. However, hospitals would be held negligent in law if they did not provide satisfactory and safe working conditions for their staff. The clinical neurophysiologist in charge of a department would be expected to maintain a safe working environment for all the staff, and to be concerned about their health. However, in the final analysis, it is the hospital managers who take the ultimate responsibility. Again taking the regulations in England and Wales as an example, Health and Safety at work regulations may require that a specific individual is designated Safety Officer. The Safety Officer will be required to keep regular dated records pertaining to checking of electromedical equipment, drugs and lotions, fire fighting and escape equipment, infection control, first aid, personal security and risk avoidance. The Safety Officer will generally be responsible for informing staff of National and Hospital safety rules and procedures and for drawing up a local set of rules and ensuring that all staff receive, understand and comply with them.

The welfare of patients who use the department is also the responsibility of the hospital managers, but as an agent of the managers the clinical neurophysiologist would be expected to maintain the safety of the department and be satisfied that all the furniture, fittings, lighting, heating, safety and electromedical equipment are in good order. Clear sign-posting of exits, fire apparatus and departmental facilities should be provided. Staff should be identifiable by clear labels bearing their name and position. It is also helpful if a simple explanation of the tests that the patients are likely to undergo can be displayed in the waiting room. The department should have a notice board on which can be displayed hospital or national circulars relating to the safety of patients and staff. Many hospitals have a no smoking policy, and this, together with No Smoking notices, should be clearly displayed within the department.

A risk assessment should be carried out, to identify, before they cause actual harm, all possible risks within the department, whether electrical, chemical, microbiological, or related to fire hazards, possibility of

accidental injury, etc. This may be backed up by procedures for reporting all actually or potentially adverse incidents, from defective mains lead to prescribing errors or damaged floor coverings. Attention to risk assessment does not only protect those responsible from possible litigation but, more practically, avoids harm to staff and patients and motivates managers to fund necessary improvements in facilities, if for no better reason than avoidance of personal blame.

7.7.1.1 Electromedical equipment

Specific regulations exist about safety of electromedical equipment and are outlined in Section 1.2.1.6 of Volume 1. The physician in charge of clinical neurophysiology is expected, when buying equipment for the hospital, to recommend those machines which conform to the guidelines laid down by the government or appropriate national agencies. If substandard machinery were to be installed, and an accident was to occur, then although the managers would be held to be negligent, the clinical neurophysiologist nevertheless would have to carry some share of the responsibility. Proper documentation of safety checks, by appropriately trained personnel, on installation and at regular intervals thereafter are essential. In the event of inadequacies of equipment which have a bearing on the provision of the clinical service, the neurophysiologist should ensure that the hospital authorities are informed in writing of his or her professional opinion that there is a need for improved maintenance facilities or replacement of equipment. Risk of an erroneous result or equipment failure during a procedure, for example intra-operative monitoring, could well have medico-legal implications. Any report based on results, where equipment failure or artefacts make a recording inadequate should clearly state this fact.

7.7.1.2 Infection control

General guidelines about control of infection are given in Section 4.2.1.8 and in Section 1.2.3 of Volume 1. It is incumbent on the clinical neurophysiologist to keep abreast of current patterns of infection and of regulations designed to avoid risk to patients or staff. This may mean that changes in practice are required, for example in cleaning and sterilisation methods for electrodes and ancillary apparatus and in changing to exclusive use of disposable electrodes, where there is any form of invasive technique such as needle EMG, intracranial and epidural spinal monitoring. Regular review should be made of all procedures from an infection control point of view and changes documented in departmental safety manuals issued to all staff. The emphasis should always be on the risk of the procedure and not on trying to predict the risk that any individual patient might be carrying any specific infection.

Regular and specific advice should be given to staff about reduction of personal risks by proper use of techniques and on the advisability of immunisation against transmissible infections such as hepatitis B which might be considered an occupational hazard.

7.7.1.3 Drugs

A secure supply of drugs for resuscitation and other medical emergencies will be required in the department in addition to any used in conjunction with clinical neurophysiological examinations. The physician-in-charge will be expected to satisfy him or herself that the department complies with regulations concerning drugs liable to cause dependence or misuse (Controlled Drugs) for which there are legal requirements regarding prescription and safe keeping. National and local regulations should be checked regularly and the clinical neurophysiologist should ensure that all staff are familiar with them. In the UK, it is required that certain drugs be kept in a locked cabinet with a double locked inner compartment, whilst others can be kept in the outer locked cupboard. The drug cupboard must be firmly fixed to the wall so that it cannot be removed, and when the main lock is undone, a warning light must show above the cabinet. The keys for the drug cupboard may only be held by specifically designated and qualified people, for example the doctor, nurse, or chief technologist. No drug should be prescribed or administered for a test without checking with the patient about previous allergies or adverse reactions to drugs. Any such drugs must be recorded in the records of the patient. There must be an established procedure whereby any drugs given to patients are recorded correctly in the departmental drug book, together with the signatures of two persons, who both check the drug and witness its administration. Patients who are to return home after being given sedative or anaesthetic medication should arrange to be escorted by a relative or friend and should be checked for fitness to leave the department by a medically qualified member of staff. Relevant advice should be given for the avoidance of alcohol and driving or cycling, etc., after such medication. Prescription of drugs, the outcome of enquiries concerning contraindications, certification of administration, and assessment of fitness to leave should all be documented.

7.7.1.4 Identification of patients and consent to procedures

Clearly, it is essential to ensure that all investigations are carried out on the correct patient. Whilst inpatients are generally issued with identification bracelets, some outpatients may be confused as to person and place and careful checks are necessary before undertaking a test. It should hardly be necessary to point out that a patient who resists examination, arrives in a mentally disturbed condition, or in an intoxicated state from abuse of alcohol or other substances, or becomes violent, should be handled with caution and wherever possible in the presence of more than one member of staff. Patients known to have expressed suicidal thoughts should not be left unaccompanied. Chaperoning is prudent when investigations (for example those of the pelvic floor or sphincters) concern intimate examinations by a person of either sex. A written record of any untoward events or incidents should be kept and the hospital administration informed. This applies as much to incidents or accidents affecting staff as to patients.

Statute law and common practice in respect of obtaining consent will vary greatly between countries and is subject to continual review. Only general guidelines can be given here. Potentially hazardous procedures such as surgical operations may require a two stage process, of first providing information, then obtaining consent after the patient has had time to reflect and ask questions. For most neurophysiological procedures a single stage process of explanation and agreement should suffice. A legally competent adult may be presumed to be consenting, if he or she submits to a simple procedure such as application of EEG electrodes after adequate explanation. More invasive techniques and those that carry a risk of inducing seizures or involve administration of drugs may require formal information and consent, and this also applies to some types of innovative procedures carried out as part of the development of new techniques. When the patient after being informed needs to weigh up the possible risks and benefits of what it proposed, it is not good practice to confront him with this only a few minutes before the investigation. Information should ideally be provided, and consent elicited, by the referring physician – if competent to do so. As a further safeguard information should be provided, answers to possible questions offered, and consent invited, as part of the appointments procedure. Special considerations will apply to children and legally incompetent adults. In the UK, for instance, no-one can consent on behalf of an incompetent adult (although the informal agreement of carers or next of kin should be obtained, if at all possible); the responsible physician must certify that a proposed procedure is in the patient's best interest, and be prepared to defend that decision. The local ethical committee should be consulted on such matters and will generally wish to approve any consent forms before they are introduced. Obviously, the use of neurophysiological techniques during research studies will require the usual ethical evaluation and formal consent by the subjects involved.

The need to collect normative data for most neurophysiological techniques can also pose potential problems. For non-invasive techniques written consent is not usually required but consideration has to be given to the ethical dilemma posed by unexpected abnormal findings. It is generally wise to pre-empt the situation by having a standard procedure (preferably a tick sheet which can be filed with the test results) whereby all 'healthy' volunteers are asked to indicate their preference as to action to be taken if investigations reveal abnormality. Options might include no action unless the abnormality is serious, discussion with the clinical neurophysiologist, notification of their personal physician, or referral to an appropriate specialist.

Video monitoring that is to be used for presentation at meetings or as teaching material should be made with due sensitivity to the patient's privacy and considerations of confidentiality. Formal consent procedures are mandatory when videos which were made for investigation of specific clinical problems for the benefit of the patient, are then used for other purposes. Hospital policy may dictate written informed consent for all video recording. Recent UK guidelines have been given by the General Medical Council (1997).

7.7.1.5 Inherent risk of procedures

Certain investigations carry an implicit, albeit small, risk. For example any provocative procedure during an EEG, even the widely used routine hyperventilation or stroboscopic stimulation, may provoke an epileptic seizure in a susceptible patient. It would be irresponsible to continue with the provocative technique once warning signs were evident in the EEG or clinically, unless the investigation was specifically aimed at recording a seizure, for example during consideration of surgical treatment for intractable epilepsy when precautions to avoid damage or complications must be available. In any patient, risk of physical injury during a seizure, risk of impairment of the airway or oxygenation, or inhalation of vomit, must be the concern of the physician and technologists in charge. Appropriate resuscitation equipment and training must be available. Similarly, the use of needle

electrodes should be avoided in a patient with a bleeding diathesis. Most pitfalls can be avoided by a combination of well-understood codes of practice for each procedure and careful discussion and planning of the investigation with the referring physician or surgeon.

7.7.1.6 Security and insurance

Patients, staff and equipment require protection from assault by intruders and from theft. The department should be as secure as is consistent with a friendly welcome to patients and a reception area near the entrance should allow identification of unauthorised visitors. It may be possible to provide safe custody for valuables, particularly if patients are undergoing sleep tests or anaesthetics. Most hospital administrators can provide appropriate local guidelines. Hospitals may not carry an insurance policy as the management are deemed to carry their own insurance risks. This means that any damage or loss of property from the department will not be made good by insurance replacement. Any equipment requiring replacement will have to be bid for again. It is thus important to make sure that the department is secure. It is also good practice to ensure that an adequate and up-to-date inventory is kept recording serial numbers, models and purchase dates of all equipment.

7.7.1.7 Complaints

Preventative action should reduce the problems of complaints associated with the activities of the clinical neurophysiology department. Some aspects (such as transportation, lack of parking facilities, waiting lists) may not be in the control of departmental staff. However, care must be taken to ensure proper training of all staff, full explanation of any unavoidable delay and of every test, making full and objective notes at the time about any unusual aspects in the conduct of the test and the patient's reaction to it, avoidance of unduly noxious procedures without anaesthesia, and ensuring a safe and friendly environment. Many complaints are avoidable by timely explanation. If complaints are received, verbally or in writing, they must be carefully documented and reported to the hospital authorities. All relevant material must be retained. Good notes written at the time (and not subsequently amended!) always provide important evidence in the event of a complaint. The current culture of litigation is self-perpetuating, fear of admitting liability prevents admission of indefensible errors, which could themselves have been resolved by timely apologies to the satisfaction of all concerned.

7.7.2 Responsibilities in training and supervising staff

The neurophysiologist in charge of a neurophysiology department will be responsible for the standard of medical and technological practice within the department. In many countries, it is not yet a legal requirement for either technologists or medical personnel to attend post-graduate education in neurophysiology. However, regular (for example weekly) seminars within the department as part of post-basic training and for audit of the quality of technological and medical work, is good practice. Many departments also undertake or participate in training programs for junior medical staff and student technologists. The hospital would generally be responsible for fees for mandatory external courses, while the department will be responsible for in-service training. Although not a legal requirement in all countries, every clinical neurophysiology technologist is expected to take the appropriate qualifying examinations, where these exist. No technologist should work unsupervised before passing the relevant examinations and having demonstrated adequate understanding and practical competence to undertake the various types of neurophysiological recordings. By the same token no trainee doctor should undertake investigations unsupervised, for example with EMG techniques, until such time as observation by an experienced clinical neurophysiologist confirms his or her competence.

7.7.3 Responsibilities in respect of reports on investigations

The department will be expected to have an efficient record filing system. There must be a day-book in which every investigation carried out in the department is recorded. The department may have a statutory responsibility to indicate whether the patient was an insured or a fee-paying patient, or whether the investigation was carried out under a national or regional health service. The head of department is responsible, with the hospital managers, for collecting any fees owed to the hospital for private investigations.

The medical officer in charge of the department is entirely responsible for reports sent to other clinicians. Although it is usual practice for the technologist in the department to write some aspect of the report, usually a factual description of the recording, nevertheless, the departmental head remains responsible for the entire report. Good medical practice dictates that reports are concise, clear, and attempt to answer the questions asked by referring physicians. Reports by trainee neurophysiologists should be carefully checked against

the original recording and request information, and countersigned until competence is established.

It is essential that there is some system of quality control in the department so that errors in reports are detected before the report is sent out. It is good practice for EEG and EP reports to be read by both the technologist and physician concerned before they are issued.

Information stored about patients must be treated as strictly confidential and held in compliance with legislation about data protection rights of the individual. Since in many countries this includes the right of the patient to view information held, care must be taken to avoid irrelevant personal remarks in documentation. Difficulties may arise when unexpected information is revealed by a patient, for example about driving when disallowed because of epilepsy. Discussion between the clinical neurophysiologist and the referring physician may be the best approach.

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EEG, Paediatric Neurophysiology, Special Techniques and Applications

Chapter 7.8

The integrated digital clinical neurophysiology laboratory

E. Stålberg

7.8.1 The digital environment

It should be apparent from much of the above that in the modern department of Clinical Neurophysiology many functions are based on digital equipment. This will mainly be based on personal computers, either off-the-shelf or packaged as special-purpose electrophysiological equipment. This creates the possibility for digital communication between functions leading to a fully integrated laboratory.

Digital equipment is the basic requirement to build an integrated laboratory in the sense discussed here. It should be said that compatibility between equipment facilitates communication, but translation routines between different types of systems are now available, and continue to be developed. The main building stones of IT in Clinical Neurophysiology are given in Fig. 7.8.1. The use of the facilities offered by the digital environment varies depending on factors such as: the size of the laboratory (number of recording systems), homogeneity in level of digitalisation (mix of analogue and digital or fully digital), computer literacy of users, availability of technical knowledge and imagination. Certainly, a considerable initial investment, but it is to be expected that costs will be recovered through more cost-effective practice. Some functions are summarised in Fig. 7.8.2 and will be discussed below. This account is structured according to increasing complexity of functional integration.

7.8.2 Analysis

The first obvious advantage of digital systems is the possibility for fast analysis, statistical post-processing, comparison to reference values, variations in display modes, reporting and storage (Fig. 7.8.3). The software for the recording system may be so flexible that layout of displays and some functions can be tailored for the user's needs. Great flexibility may, however, sometimes be demanding for the user and has usually not been used to its full extent.

7.8.3 Remote access to data

In the busy laboratory, it is necessary to have separate 'review stations' for offline analysis, for rounds with colleagues, and for education. The recording stations are then only occupied during the actual investigations. The review stations have access to data from all recording stations (usually from a server via a network, see below).

In the case of monitoring a remote recording, for example long term EEG, intraoperative recording, the office module should rather be an online slave-monitor or online active unit. In some instances a small video camera on the recording equipment may be helpful or even necessary for accurate understanding of the ongoing recording when observed at a distance.

7.8.4 Reporting

The integration of signals, analysis with comparisons to reference values, display of results in graphical or numerical form and a written report helps to convey the neurophysiological results to the non-expert neurophysiologist. Reporting is a very important part of the entire study (see Section 4.5.4) and an effective use of resources in a digitised laboratory may improve general report quality considerably.

7.8.5 Storage

An important feature of the digital 'paperless' laboratory is the ease by which data can be stored and retrieved. All biosignals, reports, related data (pathology reports, photos) are stored in databases. Memory capacity is no longer a concern, as the costs of digital memory are now so low. If data-handling is efficient, all previous

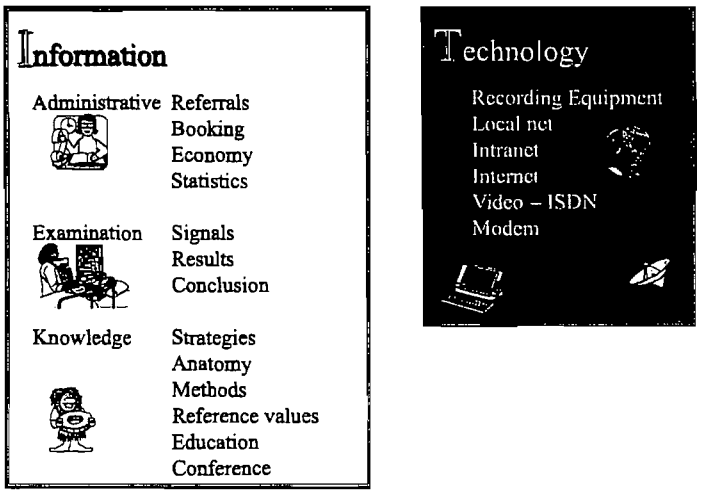

Fig. 7.8.1. Components of IT in Clinical Neurophysiology.

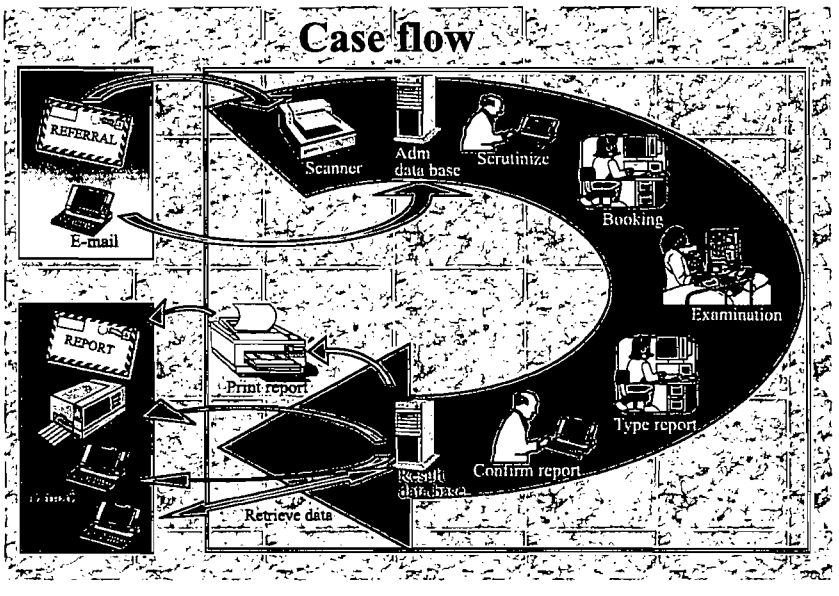

Fig. 7.8.2. A case flow in a routine EMG lab. The referral is received in as a paper copy and is scanned. After this the process is paperless. In some centres the referral is received in digital form. After administrative routines, investigation and data storage, a report is generated. This can be delivered as paper copy, security fax or less commonly in digital form. In some hospital systems, laboratory results can be retrieved from referring department via hospital net (modified from Stålberg, 2002). "Administrative data-base" and "Results data-base" are linked and stored in the same server (although indicated as two units in the figure).

information about a patient can be obtained immediately, a useful feature at followup. For research, such databases will be of unique value. One may now also fulfil legal requirements of the storage of raw data much more easily than before. The stored data are, of course, so vital to the operation of the department that rigorous backup procedures are essential. Regular backup every 24 h, or even every 6 h is reasonable. The

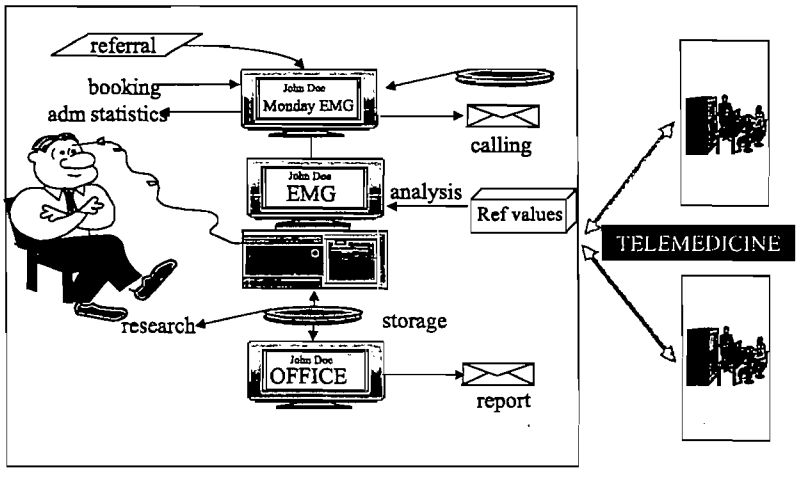

Fig. 7.8.3. A typical setup of an integrated EMG system. This setup may symbolise a stand alone system with administrative functions, analysis software, reference databases, report generator and storage capacity in one computer.

backup data must be physically separated from the server in case of disaster. Some backup systems are very sophisticated but also rather opaque, saving separately all changes since the previous backup, rather than single complete records. Make sure that you can in fact retrieve data from your backup discs.

7.8.6 Server

In the simplest case with a stand alone recording system, the recording workstation runs the analysis software and stores results, and a connected printer is used for reporting. If two or more recorders and other digital functions are part of the routine setup, a common server is recommended. This may be local within the laboratory or be connected to external nets. The advantages of a server are:

(1) Same program for all users.
(2) Easy to update, same data are available to all users, even when files have been revised by different people at different times.
(3) Easy backup.
(4) Integrity.

The main disadvantage may be:

(1) Vulnerable (breakdown, theft, etc.).

7.8.7 Networks

In the unusual situation of a single stand alone recorder with its own printer and storage capacity, a network will not be used (Fig. 7.8.4). As soon as more units or

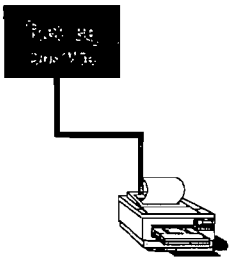

Fig. 7.8.4. Stand alone system with printer connected. No network is necessary.

functions of various kinds are routinely used, a network is required. A decision then has to be made as to whether this should be an independent local area network (LAN) or whether all equipment should be directly connected to a hospital-wide system (Fig. 7.8.5). The storage and transmission of large volumes of EEG, and particularly video data on the main Hospital Information System is not usually welcomed by IT managers. It is therefore usually better to have departmental LAN, that can communicate with the main system, as required, to export reports and import patient administration material, referrals, or clinical records. Within the laboratory, users of recording equipment or review equipment and administrators may share common resources such as server, backup system, laser printer, colour printer and scanner.

With increasing degree of integration, wider connections may be required. It gives the possibility to connect to systems within the same hospital or even to other hospitals connected on a wide area network (WAN) (Fig. 7.8.6). Finally, for general communication for

example to reach various databases, connection to Internet is nowadays commonly installed, also in smaller laboratories. Firewalls and other precautions are taken to secure medical data from intrusion.

The principle applications for networks may be:

(1) A LAN is a requirement for:

- Administration
- Appointments, activity statistics, data for audit, invoicing, etc
- Access to primary bioelectrical data from review stations for analysis
- Storing original bioelectrical data and reports from investigations
- Central reporting

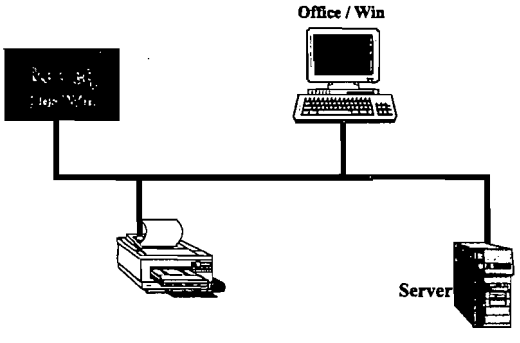

Fig. 7.8.5. Small local area network (LAN) when a few units should communicate or use common facilities for example a printer. A server is recommended to keep software, administrative data, reference values, data from recordings and a separate disc for backup.

(2) The connection to the hospital net (WAN and INTRANET) is used for:

- Referrals
- Circulation of reports (push or pull)
- General connection to hospital systems (economy, electronic medical records, radiology, etc.)

(3) Connection to wider telemedical nets or Internet can be used for:

- Description of the department, procedures, diseases to colleagues and the public
- Patient contacts (calling, billing and interactive homepage for booking)
- Telemedicine applications (biosignals from satellite units or videoconferencing)
- Joint audit or clinical governance with other departments
- Literature searches when unusual clinical conditions are seen

7.8.8 Risk management

It is important to be aware of weak points in the integrated CN lab. An action plan should be made for maintenance of security and for use in case of a vital computerised administrative or medical function breakdown due to network failure, robbery, hard disc crash, fire, flooding, etc. Complete hazard elimination is almost impossible to achieve and would be far too expensive. Therefore acceptance limits for data loss,

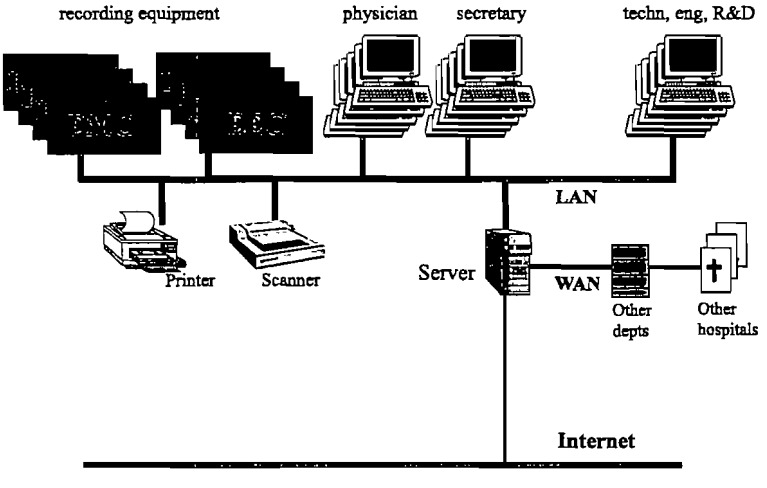

Fig. 7.8.6. The integrated laboratory with LAN, and external net (WAN, Internet) connecting equipment and functions within the laboratory and with external resources. Security measures such as firewalls are not shown in the figure.

time of breakdown and so on have to be defined and measures to meet corresponding criteria be implemented.

The hazard analysis may result in a number of safety precautions, for example:

- Automatic backup of all data every night for total system reconstruction
- Backup tapes and original discs are stored in a fire-proof safe on a separate site
- Mirror hard discs on the server for instant backup
- Star network instead of a circular chain
- Recording equipment shall be able to run locally without connection to server
- Data acquisition workstations need sufficient local storage to run for, say, 24 h without access to the server
- Servers in secure rooms
- Servers installed above the floor in case of flooding
- Uninterruptible power supplies for all critical equipment

7.8.9 Administration – booking, billing

With access to computer systems, a number of administrative functions can be included in the integration. Referrals are until now usually written on paper. It is likely that this will change to electronic form, a situation already seen routinely in certain centres. Until this is routine, the paper referral can be translated into digital form, for example via scanning, for efficiency in handling documents. The information is from then on treated in paperless mode. Booking of patients should be a part of the system. Usually the secretary makes appointments, but routines to open the booking from remote sites (for example from referring departments in the hospital) could facilitate administration for the laboratory and the service to the referring partner. The possible need for preliminary triage may however limit this (Section 7.5.2.3). The patient data should only be inserted once, preferably through the central patient administration system, where it can be validated and updated as necessary, and then automatically transferred to appointment and recording systems, report headers, bills and statistical summaries.

7.8.10 Telemedicine

Telemedicine comprises various types of remote communications. In neurophysiology we usually think of transmission of biosignals and of video-communication.

7.8.10.1 Biosignals

The department of the present author (ES) serves a number of satellite laboratories. Well-trained technologists perform EEG, EPs and neurography on a daily basis. Formerly, they transmitted the signals to our main department via modem or Internet. Now we use a web-based model using a national Telemedical net. Our department has access to certain segments in the servers of the remote hospitals (IP address giving access only to neurophysiological data). In our hospital the physician responsible for service to the remote laboratory can then, from his office, access recordings just performed and analyse and edit them, close the file and make a report. We have used this system linking us to four hospitals for some years on a daily basis and found that it reduces delay between recording and report time-saving from that recording to report, quality improvement and avoidance of a considerable amount of administration with surface mail. For consultations from other parts of the world we use the Internet. The data are sent from anywhere in the world as an attachment. Text has to be encrypted, and the signals need office software to be unpacked. This is used to obtain second opinions, for collection of reference values and for scientific collaboration.

7.8.10.2 Tele-EEG

The approach described above is ideal for the relatively small volumes of data generated by EMG and EP studies. Transmission of EEG files of some 40 mB is difficult, unless a dedicated fibre optic network is available. However, the problems have been addressed in various ingenious ways over many years, because the potential benefits are clearly considerable, for several reasons:

(1) In most countries, EEG facilities are widely dispersed.
(2) Patients may require investigation outside the laboratory, for instance in the operating theatre or ITU, or in the home, school, or workplace to monitor seizures in a natural environment.
(3) Expertise in some specialised applications such as neonatology is not widely available.
(4) Immediate interpretation may be required, for instance in status epilepticus, during electrocorticography and intensive care.
(5) EEG is a small discipline and its practitioners often work alone; audit, clinical governance, research, and continuing medical education therefore require collaboration and multicentre review of records.

EEGs for urgent reporting may be sent by fax (Gibbs and Gibbs, 1970), but this is applicable to only small

samples of the record and remontaging is impossible. Both routine and urgent reporting would be easily accomplished, with a minimum cost in time or expense, by electronic transmission over telephone lines. This is not trivial, as the volumes of data are considerable: typically some 40 mB/h. Off-line transmission of EEGs as complete files is surprisingly difficult without dedicated wide bandwidth facilities. An irrecoverable interruption of transmission is highly probable whilst sending a 40 mB file over standard telephone lines. On-line synchronous live EEG transmission would be preferable but is beyond the capacity of the public telephone system without data compression. The ideal is even more demanding: off-line EEG transmission at the data rates employed by experienced electroencephalographers reading EEGs, one or two 10 s pages per second, requiring the EEG display to be updated at 10–20 times recording speed.

All three approaches will doubtlessly be feasible when wide-band networks for telephony, video and other applications become the norm. In the meantime, a system that can support all these applications must function over the telephony links generally available, i.e., the public telephone network.

Biotelemetry, including EEG, was employed in the first manned space flights of the 1960s and Ray et al. (1965) describe its use over standard telephone and satellite links. Bennett and Gardener (1970) transmitted six-channel EEGs over two parallel voice lines from isolated small communities for remote interpretation, but noted that this greatly increased the cost of the clinical service. By 1974, Schear et al. had established a system for transmitting eight-channel EEGs with a bandwidth up to 65 Hz, over a single telephone line from 31 sites in the USA and Canada to a centre in San Francisco and had used this for remote review of some 6000 EEGs.

The combination of local radio telemetry in the home, with a telephone link to a central laboratory was used in a four-channel version by Hanley et al. (1969), and in an eight-channel configuration by Rosekind et al. (1978) for polysomnography.

All of the above were analogue systems and subject to degradation by noise. An eight-channel digital (PCM) system with a 30 Hz bandwidth was developed specifically for home monitoring of epilepsy by Kamp (Van der Weide and Kamp, 1984; Kamp, 1984). The local telemetry gave the patient freedom of movement and continuous display of the signals in the base laboratory allowed supervision, quality control and feedback by telephone.

Many manufacturers provide for digital EEG transmission but this is practical only over fast networks (Loula et al., 1997). One system, "TeleTrend" (Vespa et al., 1999), compresses individual pages for downloading. Other methods described for compressing the EEG (for example Hinrichs, 1991; Antoniol and Tonella, 1997), are intended to reduce storage requirements, not for telephonic transmission.

However, data compression algorithms are available to allow review of EEGs even over the public telephone network in approximately 20% of real time, i.e., at a presentation rate acceptable to the experienced reviewer (Holder et al., 2003). This is a facility particularly useful for obtaining expert opinion out-of-hours on emergency EEGs, for instance in neonates or intensive care patients.

7.8.10.3 Video-conferencing

A video-studio has been arranged within the department, but can naturally be elsewhere in the hospital (Fig. 7.8.7). It is used to allow colleagues outside our hospital to participate in rounds, consultations and meetings. We arrange training sessions for various personnel categories within our regional area or abroad. The use of video-conferences and lectures within medicine is increasing and will develop further with faster communication links, and smaller and less expensive equipment and traffic cost.

The same telemedicine system has also has been developed between the Baltic countries (Fig. 7.8.8). This collaboration is now in operation and contains elements of case consultations and education. During a three-year project we have had the opportunity to implement (by means of a project funded by the Swedish government) a total of seven EMG and one EEG machines in Estonia, Latvia and Lithuania. Video-conference units were also installed at five of the participating centres. The aim was to transfer knowledge in clinical neurophysiology and improve general standard in the specialty. For this it was important to build an infrastructure which can be used in future within the network of centres and beyond. From a situation of little or no clinical neurophysiology, the telemedicine resources have given us a chance to transfer knowledge in clinical neurophysiology, train physicians, introduce the specialty into the routine care and to give consultations. As an example, after initial preparations and basic training of staff, the new equipment was installed and during the second and third years of the project was used for 4200 EMG and neurography investigations, 800 EEGs (from the new equipment), 260 mail consultations, 18 video-conferences with teaching and the building of a valuable network of personal contacts. Considering the initial standard, such benefits would have been impossible to achieve within the allotted time without efficient communication media. At the end of this project, all partners were satisfied and well established on a promising path into the field. We suggest that our

Appendix 8.1

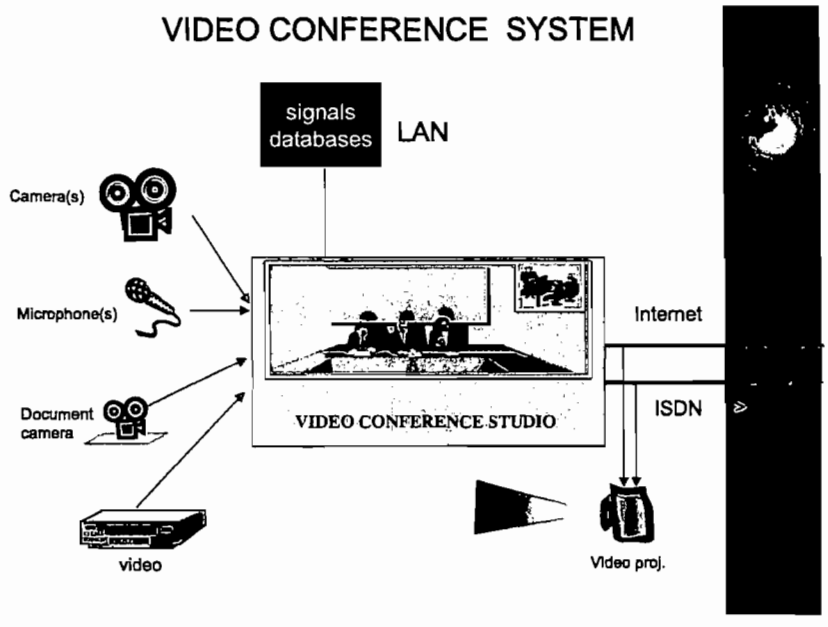

Fig. 7.8.7. Video studio used for communication with remote centres for rounds, consultations, lectures, administrative meetings. The video-transmission is either on Internet (dedicated Intranet for speed) or ISDN. A practical number of participants is less than 10. For larger number of simultaneous participants, streaming (one active studio and others receivers) is used.

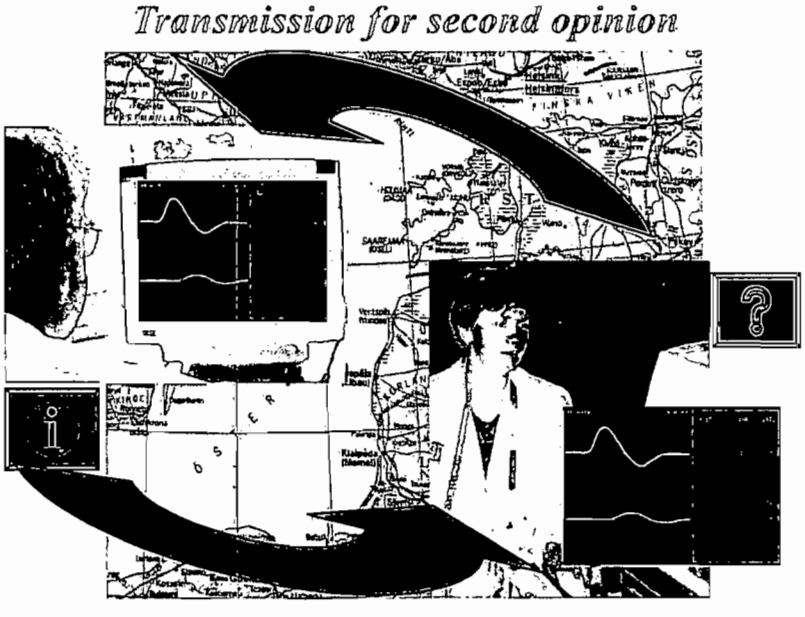

Fig. 7.8.8. Tele-neurophysiology, in this case from Estonia. Signals from an EMG investigation are transmitted as e-mail attachment to our department where the traces are "active". Gain and cursors can be changed. Feedback either via e-mail (indicated), or as video-conference (not shown in the figure).

experience may provide a model to use for transfer of knowledge to support colleagues in remote areas or in other countries, where clinical neurophysiology is not yet a fully developed service.

7.8.11 Conclusion

It is sometimes important to take a step back and look at the entire operation in a laboratory, or to visit some other laboratory of similar size to get ideas and inspiration. One may forget the advantages of integrating *all* functions in the department from referral, acceptance, calling patient, investigation, analysis, reporting, archiving, billing, monitoring activity to assessment of specific and general quality. Factors for a successful integration of IT in clinical neurophysiology are:

- The integration is driven by medical needs and by available technology.
- Ideas for solutions have been defined.
- Consensus among staff and partners.
- Defined plans for development and implementation.

The integration of the various functions in a neurophysiological laboratory can now be obtained with commercial software. It is important to remember that improvements can be achieved in *every* laboratory. Significant advantages are obtained by the use of easily available techniques, for example for connecting the different functions within the laboratory and outside. Modern equipment will contain software for quality control, easy access to previous data for comparison with current findings, and efficient and comprehensive reporting. The recording equipment may also be linked to larger databases, for example via the Internet for an immediate literature search and for contact with a particular colleague who may help with advice. Clinical neurophysiology lends itself for the use of various technical solutions. So many times in its history, clinical neurophysiology has made progress on the basis of new techniques which have allowed a better understanding of physiological functions. Now, we can also see advances in clinical neurophysiology due to factors such as sophisticated signal analysis, quality control of recording conditions and of the obtained signals, strategy planning, global consultations and collaboration. Such developments enhance the possibilities of using small dedicated units for some applications at bedside or in homes. Certain modules of recording equipment, e.g., connectors, amplifiers and stimulators may be linked via the Internet with the analysis and review units at a central location. What has been described here, are not visionary dreams for the future, but examples of practical possibilities that are already well-established in few pioneering centres today. Time will show how widely such approaches can be implemented and their more general usefulness in clinical neurophysiology.

It requires an open mind to formulate the medical and administrative needs, to see the possibilities, to analyse the advantages and interest among the entire staff in order to use the fascinating new facilities now available to enhance medical quality, efficiency, and security, all for the benefit of our patients.

Appendix 8.1

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Clinical Neurophysiology, Volume 2
EEG, Paediatric Neurophysiology, Special Techniques and Applications

Chapter 7.9

Combined references of Part 7

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