CHRONIC ILLNESS

IMPLICATIONS OF CHRONIC ILLNESS IN YOUNG CHILDREN

BIOLOGICAL
• Common sequelae ⇒ Short stature + pubertal delay
• Malnutrition is common
• Conditions such as eczema can cause significant scarring

PSYCHOLOGICAL ASPECTS
• ↑ likelihood of developing mental health disorders
• Parents feel exhausted, guilty, angry, depressed
• Siblings feel neglected
• Continuous nocturnal awakening can affect mental function

SOCIAL ASPECTS
• Visible signs of illness = Body image disturbance (Different from peers)
• Condition may impede developmental tasks of adolescence
• ↓ autonomy
• Repeat absenteeism ⇒ Poor performance at school
SKIN CANCER ➔ BEHAVIOURAL INTERVENTIONS

PRIMARY PREVENTION
1) Sun avoidance – hat, clothing, stay inside
2) Harm minimisation – wear sunscreen

SECONDARY PREVENTION (EARLY DETECTION AND TREATMENT)
1) Skin checks to detect lesions
2) Ablation of precancerous lesions (e.g. solar keratoses with cryotherapy, 5-FU creams)
3) Lesion removal – excisional biopsy/definitive excision with margins

TERTIARY PREVENTION (DECREASE SEQUELAE OF CONDITION)
1) Regional lymph node clearance
2) Chemotherapy
3) Radiotherapy
4) Immunotherapy

ETHICS OF BEHAVIOURAL INTERVENTIONS
• Beneficence
  ➔ Encourage behaviour modification which will be in their best interest because it decreases the risk of developing sun-related lesions
• Justice
  ➔ All patients deserve advice + management that will help them avoid skin cancers
• Autonomy
  ➔ Patient ultimately decides what risks they are willing to take in their sun exposure/protection measures
• Avoid paternalism
  ➔ Give info and encourage healthy behaviours

Considering all of this, doctors need to take a proactive role in educating and encouraging patients about the need for healthy behaviours, including opportunistic education (backed up by literature) and even opportunistic screening, all while respecting their lifestyle/work (autonomy) etc. This will maximise good to the patient while avoiding paternalism and allowing them to remain autonomous.
SKIN CANCER EPIEMIOLOGY IN AUSTRALIA

- Cancer registries do not routinely report non-melanoma skin cancers
  - exact incidence rates are unknown
- Most common form of cancer in Australia (BCC > SCC > Melanoma)
- QLD has highest incidence of skin cancers in the world
- Lifetime risk of melanoma has ↑ in QLD
  - BUT shift to more in-situ lesions ➔
    - 1/16 men + 1/24 women (QLD)
    - 1/60 men + 1/80 women (USA)
  - BUT mortality has stabilised
  - 10 year survival = 92%

PUBLIC HEALTH STRATEGIES

1) ↓ Sun exposure
   - Especially in early years (1st prevention)
   1. SunSmart Campaign
      - Public education, mass media, SunSmart school programs, training of doctors, allied health etc
      - Stay out of sun between 10am-3pm
   2. Sunsmart UV Aert
      - Reported in paper/weather forecasts to raise public awareness of the risk of exposure to UV radiation and to encourage them to adopt appropriate sun protection measures
   3. National skin cancer Action week
      - (November 13-19 in 2005) – initiative of the Cancer Council
      - Raises awareness at the start of the summer season
   4. Pamphlets/information brochures
      - produced by the Cancer Council
   5. School education

2) Early detection
   - Population screening (2nd prevention)
   - Education in clinical features of melanoma and advised to report changes
   - Self-examination every 6-8 weeks
   - Regular skin checks

EFFECTIVENESS OF PUBLIC HEALTH CAMPAIGNS
1. **Primary prevention**
   - **Short-term** ⇒ Improvement in sun-protection attitudes and knowledge of the harmful effects of sun exposure
   - **Medium-term** ⇒ Improvement in sun behaviours (i.e. ↓ incidence of sunburn)
   - **Long-term** ⇒ ↓ incidence & mortality expected
     - Incidence has actually ⇒ Most diagnoses are occurring in those aged 50 and older
     - People in these age groups did not have the benefit of education regarding the dangers of sun exposure during childhood and adolescence and therefore they incurred significant sun damage during these crucial years
     - In the next 20-30 years, skin cancer rates are expected to decline as those exposed to the SunSmart campaign during childhood & adolescence reach age groups which have traditionally been the most often diagnosed

2. **Early detection**
   - Has improved prognosis
   - > ½ of all melanomas are diagnosed when they are still <0.75mm
     - ∴ Even though incidence has increased mortality has remained stable at approx. 5% of men and 3% of women

**SHOULD WE HAVE A POPULATION SCREENING PROGRAM**

**Benefits**
1) Screening = ↑ detection
2) Melanomas detected at earlier stages

**Costs**
1) Doctors time
2) ↑ cost of excision and follow-up
3) Patient time and anxiety

- Population screening is **not** recommended ⇒ No evidence of proven effectiveness
- Screening is recommended in very high risk groups
  - Previous melanoma, strong family Hx, presence of dysplastic naevi
IMPROVING A POPULATION’S HEALTH

Mortality is Driven By:
1. Incidence: New cases / population
2. Case-fatality ‘rate’: % of cases who die

To improve a population’s health
1. ↓ Disease incidence = Prevent disease occurrence
   • Prevention = 1° Prevention ⇒ Health promotion
2. Treat disease more effectively

LEVELS OF PREVENTION

1. Primary Prevention
   ↓ ↓ incidence of disease ⇒ Prevent occurrence of disease
   • Social and economic improvements
     • Food availability, nutrition, general education, housing, water

2. Secondary Prevention
   ↓ ↓ prevalence of disease
   • Shortening duration of disease that has already developed
     • Early diagnosis
     • Screening

3. Tertiary Prevention
   ↓ ↓ number of complications of health conditions
   • Improving treatment and rehabilitation

POPULATION VS INDIVIDUAL RISK

• Tendency in medicine and epidemiology to divide people into high + low risk for targeted intervention
  ↓ BUT Risk for a disease is usually continuous (E.g. BP)
  • High and low risk is not always clear cut

• Should we target those in the high end of the distribution OR try to shift the whole population distribution down a little
  ↓ Benefit is greater if shift whole distribution but harder to do in practice

ESTIMATING THE CONTRIBUTION OF RISK FACTORS TO DISEASE BURDEN

⇒ Population Attributable Fraction (PAF)

• % reduction in disease or death that would occur if there was no exposure in the population
• Combines the relative risk and the prevalence of the condition in the population
• Can be used to prioritise areas for prevention
• Demonstrates that high risk of an outcome does not necessarily mean a large burden in the population due to that outcome

<table>
<thead>
<tr>
<th>'Mass' versus 'high risk' strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feature</td>
</tr>
<tr>
<td>Salience to patient</td>
</tr>
<tr>
<td>Appeal to doctor</td>
</tr>
<tr>
<td>Approach</td>
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<tr>
<td>Social reinforcement</td>
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<tr>
<td>Potential gain</td>
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<tr>
<td>Coverage</td>
</tr>
<tr>
<td>Efficiency</td>
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<tr>
<td>Impact</td>
</tr>
</tbody>
</table>
STRATEGIES FOR PREVENTION

1. HIGH RISK STRATEGY

- Common in clinical practice
- Intervention targets individuals at high risk in population (E.g. high BP)
- Control level of exposure to a cause of disease in high risk individuals
  - E.g. Introduction of strategies and treatments to bring BP below level deemed ‘high’

**Advantages**
1. Individual intervention can be identified and implemented. Cause and effect more reasonably evaluated
2. Avoids interference with those not at ‘high risk’ in population
3. Interventions for high risk individuals improves benefit to risk and benefit to cost ratios
4. ‘Magic bullet’ approach in a target group acceptable in a biomedical paradigm

**Disadvantages**
1. Prevention is limited to a medical and health care model (clinic / case focused)
2. Limited by a poor ability to predict future of individuals
3. Only small numbers of cases of disease prevented in a small number of people exposed to a high risk
4. Change population distribution but don’t affect risk of those with BP 160 and below

**Most Appropriate When**
1. Health problem confined to an identifiable minority
2. Health problem can be controlled in isolation

2. MASS STRATEGY

- Intervention aims to reduce health risks of entire population
- Acknowledges exposures and outcomes reflect behaviour and circumstances of society as a whole

**Advantages**
1. Interventions can effect large scale changes in health
2. Generally not restricted to immediate (proximate) causes and address underlying social, economic + political determinants
3. Addresses both health RFs and context in which these RFs are embedded

**Disadvantages**
1. Difficulties in persuading whole population that a health problem is a matter of concerted public action
   - People are reluctant to change what they do and enjoy
2. Large scale interventions are expensive
3. Interventions are often not in accord with unstated political and economic paradigms (E.g. poverty)

**Examples of Mass Strategies**
1. Legislated use of seat belts and motor vehicle accidents
2. Smoking and lung cancer (Pop health promotion, legislation, taxation)
3. ↓ CHD (Control of RFs through health promotion)
SCREENING

See MBBS1 Notes Week 25 “Screening For Disease”

PURPOSE
1) To detect disease before usual time of diagnosis
2) Based on a belief that earlier detection of disease will lead to improved outcome
   ▪ Morbidity, mortality, disability
3) Benefits to individual screened + also wider social benefits if health costs are ↓
4) Protect general population from exposure to disease
   ▪ E.g. Immigrant screening for HIV and Hep B

THE DISEASE PROCESS

SCREENING VS CASE-FINDING
⇒ Parallels with mass vs high risk approach

Screening: Refers (usually) to organised population-based approaches in the healthy (asymptomatic) population
   ▪ E.g. Breast cancer, cervical cancer

Case-finding: More opportunistic attempt at early detection when individuals present to health services
   ▪ E.g. GPs ➔ Cigarette smoking, high BP

REQUIREMENTS OF EFFECTIVE SCREENING
1) Right disease
2) Right test
   1. Accurate and reliable (i.e. sensitive and specific)
      ▪ Few false positives and false negatives
      ▪ Accurately identifies people with and without disease
   2. Safe and acceptable to population
   3. Simple to administer and inexpensive
3) Right program ⇒ Must be shown to confer sufficient net benefit to community

A SUITABLE DISEASE FOR SCREENING
1) Disease should be severe, relatively common and considered a public health problem
2) Good understanding of the natural history of the disease
   ▪ Early intervention must improve outcome
   ▪ E.g. Prostate cancer ⇒ Now a shift away from screening
3) Be confident that early detection will lead to a better outcome
4) High prevalence of pre-clinical disease
5) Long lead time between first detectable signs of disease and symptoms that would lead to clinical diagnosis
**IMPLICATIONS OF SCREENING IN THE POPULATION**

- Prevalence of most diseases is relatively low.
- Most negative screens will be true negatives
- Most positive screens will be false positives
- Large benefit for a small minority outweighs little or no benefit by majority
  - cf mass strategy

**ELEMENTS OF SCREENING PROGRAMS**

1) Suitable disease and valid screening test
- Will a screening program benefit population?
- Do benefits outweigh harms?
2) Program needs to be demonstrably effective (E.g. RCT)
3) Costs need to be acceptable
- Emotional and financial costs must be considered in relation to comparative costs of detecting disease at a later stage
4) Health care system is able to cope with additional cases of disease and diagnostic testing
- E.g. New bowel screening program
5) Effective treatment should be available that improves disease outcomes
6) Ongoing monitoring and evaluation of program process and outcome

**OUTCOME EVALUATION**

- Requires RCTs
- Compare long-term mortality rates in those randomised to screening vs those not
  - Positive benefits from screening for breast and large bowel cancer shown in RCTs
  - No trial of the effective cervical cancer screening program (Unethical)
  - Prostate cancer ⇒ Complex natural history
  - Lung cancer ⇒ Lead time too short

**HARM FROM SCREENING**

1) False positives ⇒ Unnecessary anxiety, work up, treatment, costs
2) Inconsequential disease
- Excessive treatment (Some true positives may never become symptomatic)
- Labelling (Calling those with risk factors diseased)
3) False negatives ⇒ ↑ in risky behaviour
POTENTIAL SOURCES OF BIAS IN SCREENING

1. **Volunteer Bias**

   - People who attend for screening may be different from the general population
     - E.g. Higher SES, more health conscious
     - \( \therefore \) Inherently more likely to have a better outcome regardless of screening
   - Avoid by pooling all volunteers + randomising subjects to screen or non-screen

2. **Lead Time Bias**

   - Lead-time = Period between point when disease is detected by screening and when it would have become symptomatic and diagnosed in usual way
   - Survival time is over-estimated in those screened
   - Unless we have some idea of the actual lead-time (E.g. previous studies) \( \rightarrow \) cannot use survival time to evaluate the effectiveness of a screening program
     - Instead should consider effects on age-specific morbidity or mortality rates

3. **Length Bias**

   - Screening is more likely to detect cases where disease progresses slowly
   - Disease that progresses quickly is more likely to be clinically detected
     - (i.e symptomatic)
   - Disease with slow progression is inherently more likely to have a better outcome
   - Effect of screening \( \therefore \) appears more favourable than it really is
   - Avoid by randomisation
GLOBAL BURDEN OF DISEASE

MEASURING HEALTH POTENTIAL

Area C: Years of Life Lost (YLL)
Weighted sum of deaths, using ‘lost’ life expectancy

Area B: Years of Life Lived with Disability (YLD)
Time-based measure incorporating incidence, duration and severity

Disability Adjusted Life Years = DALY = YLL + YLD

BURDEN OF DISEASE

- Incorporates premature deaths (age) and years lived with disability (ill-health)
- Massive exercise in descriptive epidemiology
  - Deaths by age, sex and cause
  - Common sequelae of diseases / injuries
  - Incidence / prevalence / duration of sequelae
  - Severity weights for years lived with sequelae

LEADING CAUSES OF YLL (AUSTRALIA, 2003)

<table>
<thead>
<tr>
<th>Cause</th>
<th>% of all YLL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischaemic heart disease</td>
<td>16.8</td>
</tr>
<tr>
<td>Stroke</td>
<td>6.6</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>6.5</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>4.0</td>
</tr>
<tr>
<td>Suicide and self-inflicted injuries</td>
<td>3.9</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease (COPD)</td>
<td>3.7</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>3.1</td>
</tr>
<tr>
<td>Road traffic accidents</td>
<td>2.8</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2.0</td>
</tr>
<tr>
<td>Nephritis and nephrosis</td>
<td>1.9</td>
</tr>
</tbody>
</table>

LEADING CAUSES OF YLD (AUSTRALIA, 2003)

<table>
<thead>
<tr>
<th>Cause</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety and depression</td>
<td>13.2</td>
</tr>
<tr>
<td>Type 2 diabetes</td>
<td>7.5</td>
</tr>
<tr>
<td>Alzheimer and other dementias</td>
<td>4.3</td>
</tr>
<tr>
<td>Adult-onset hearing loss</td>
<td>4.1</td>
</tr>
<tr>
<td>Asthma</td>
<td>4.0</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease (COPD)</td>
<td>3.5</td>
</tr>
<tr>
<td>Back pain (acute and chronic)</td>
<td>3.1</td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>2.8</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>2.3</td>
</tr>
<tr>
<td>Parkinsons</td>
<td>2.2</td>
</tr>
</tbody>
</table>
LEADING CAUSES OF DALYs (AUSTRALIA 2003)

<table>
<thead>
<tr>
<th>Cause</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ischaemic heart disease</td>
<td>9.4</td>
</tr>
<tr>
<td>2. Anxiety and depression</td>
<td>7.0</td>
</tr>
<tr>
<td>3. Diabetes</td>
<td>4.9</td>
</tr>
<tr>
<td>4. Stroke</td>
<td>4.2</td>
</tr>
<tr>
<td>5. Chronic obstructive pulmonary disease (COPD)</td>
<td>3.6</td>
</tr>
<tr>
<td>6. Lung cancer</td>
<td>3.3</td>
</tr>
<tr>
<td>7. Alzheimer and other dementias</td>
<td>3.2</td>
</tr>
<tr>
<td>8. Colorectal cancer</td>
<td>2.4</td>
</tr>
<tr>
<td>9. Asthma</td>
<td>2.3</td>
</tr>
<tr>
<td>10. Breast cancer</td>
<td>2.3</td>
</tr>
</tbody>
</table>

MAIN DRIVERS OF HEALTH CHANGE

1) Population ageing
2) HIV epidemic
3) Tobacco epidemic
4) Obesity epidemic
5) Declines in childhood communicable disease mortality
6) War / natural disasters
7) Education / economic growth
8) Good evidence-based health policy
**ASSESSING FITNESS TO DRIVE**

- Functional decline + disability affecting vision, cognitive + motor abilities ↑ with age

**ROLE OF THE GP**

1) Assist patients who drive to maintain mobility by driving for as long as is safe
2) Help drivers decide when to stop driving

- Doctors may be called on to submit reports about their patients’ driving ability
  1. When a condition is newly diagnosed or requires review
  2. To satisfy an employer’s screening requirements
  3. To assess a patient in relation to occupational health issues

- Essential that GP discusses a medical condition’s implications for driving with patient
  + Encourages the patient to self-report their condition to licensing authorities
- Age based reviews exist in some states

**REPORTING OBLIGATIONS**

- Not compulsory for health professionals to report drivers who have a medical condition that can affect driving (except SA)
- Decision on whether a person is fit to drive is ultimately made by licensing authority
- A patient’s failure to report can have adverse consequences for insurance and can lead to criminal charges if an MVC is found to be caused by an unreported medical condition

*Interaction between drivers, health professionals + driver licensing authority*

- Doctors should advise patients if a medical condition affects their ability to drive safely, whether in the short or long term
- Reports regarding fitness to drive are generally issued to the patient for communication to the driver licensing authority

- Legislation requires drivers with serious illnesses affecting driving ability to inform the driver licensing authority
- Driver licensing authority may request drivers to have a medical examination

- Doctors and driver licensing authority do not normally communicate directly with each other, which protects patient confidentiality
- Doctors may communicate directly with the driver licensing authority in extraordinary circumstances where patients who are known to be an imminent risk to road safety continue to drive contrary to repeated advice

**HIGH-RISK MEDICAL CONDITIONS ASSOCIATED WITH MVCs**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Prevalence in licensed drivers (%)</th>
<th>Overall MVC risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epilepsy</td>
<td>0.2% (1% of total population)</td>
<td>Higher (* to ***)</td>
</tr>
<tr>
<td>Alcohol abuse</td>
<td>2-3%</td>
<td>Higher (*)</td>
</tr>
<tr>
<td>Dementia</td>
<td>2-3%</td>
<td>Higher (*)</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>0.06-0.06%</td>
<td>Higher (*)</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>0.4% (25% of total population, at some time in life [includes substance abuse])</td>
<td>Higher (* to **)</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>1-2%</td>
<td>Higher (*)</td>
</tr>
<tr>
<td>Sleep apnoeai</td>
<td>0.3-4%</td>
<td>Higher (* to ***)</td>
</tr>
<tr>
<td>Cataracts</td>
<td>2-3% (40-50-year-olds)</td>
<td>Higher (*)</td>
</tr>
<tr>
<td>Young drivers, age &lt; 20 (compared with drivers aged 40-55)</td>
<td>5-6% (NSW, USA)</td>
<td>Higher (***)</td>
</tr>
<tr>
<td>Blood alcohol concentration</td>
<td>0.4% (Vic)</td>
<td>Higher (* [all crashes])</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Higher (*) [total crashes]</td>
</tr>
</tbody>
</table>
COMMON MEDICAL CONDITIONS AND FITNESS TO DRIVE

1) Epilepsy

2) Diabetes
   - Hypoglycaemia is greatest potential risk (Problem if treated with insulin)
     1. Test BGL before driving
     2. Have a low threshold for corrective action
     3. Keep sugary snacks in vehicle
   - End-organ damage affects systems important for driving

3) Cardiovascular disease
   - Sudden incapacity may be due to arrhythmias, syncope, stroke or MI

4) Syncope

5) Visual Function
   - Objective measurement of visual acuity, fields + colour perception is used to set standards for driving
     - Australian law = corrected acuity of 6/12 in better eye or with both together

6) Psychiatric Conditions (including behaviour disorders + drug abuse)

7) Sleep Disorders
   - Falling asleep behind wheel may be caused by OSA, narcolepsy, chronic insomnia + 2° causes such as drug effects and chronic fatigue syndrome
**COMMUNICATING WITH ELDERLY AND FRAIL PATIENTS**

Create a positive relationship with patient and family to assure optimal medical care, assuring emotional + cultural needs + expectations of geriatric patients

**FRAILTY**
- Failure to integrate responses in the face of stress
  - Functions that require integration of higher order cortical functioning (balance, walking) are more likely to fail, resulting in falls + delirium

**COMMUNICATING WITH THE ELDERLY + FRAIL PATIENT**
1) Find out how they feel about a given issue
   - There is a huge variation in how older people feel / view themselves and behave
2) Encourage patient to express needs, goals, values
3) Health care emphasis should increasingly **emphasise QOL** over length of life as primary goal
   - Functioning (Social, physical, emotional)
   - Perceptions (Patients life satisfaction)
4) Health care team approach is vital
5) Autonomy is an important theme in elderly care
6) Goals of therapy should be defined in a partnership between patient and doctor
7) Consultations may take longer
8) Use a hierarchy to deal with multiple problems

**Patients with Perceptual Problems**
1) Slow, clear, reasonably loud speech for those with hearing impediments
   - Don’t shout (Distorts speech, painful to patient + gives impression of anger)
   - Some people may find slow speech rather patronising
2) Make sure person can see your face for non-verbal cues + for lip reading

**Elderly Are Most Likely To Remember When:**
1) Info is presented reasonably slowly
2) They are not rushed into giving an answer
3) Questions test for recognition rather than recall
4) Retrieval cues are provided
5) Anxiety is reduced by support + encouragement

**THINGS THAT IRRITATE / CONFUSE THE ELDERLY**
1. Having a consulting room with slippery steps, poor lighting and inadequate handrails
2. Non-attention to simple courtesies by receptionist staff
3. Keeping them waiting
4. Having low soft chairs in the waiting room and surgery
5. Being overfamiliar, with addresses such as 'Pop' or first names for elderly females
6. Shouting at them on the assumption that they are deaf
7. Appearing rushed and keen to get the consultation over quickly
8. Forgetting their psychosocial problems and concentrating only on their physical problems, i.e. not treating the whole person
9. Forgetting that they have several things wrong with them and using a different priority list from theirs
10. Being unaware that they may have seen other practitioners or may be taking additional medication
11. Failing to ask patients to give their understanding of what is wrong
12. Omitting to give printed patient education handouts about their problems and meds
13. Omitting to explain how the medication will work
14. Treating them as though they would have little comprehension of their health and Tx
15. Failing to respect their privacy such as not knocking before entering the exam room
16. Failing to provide appropriate advice on various social services such as meals on wheels and other support groups
17. Failing to re-evaluate carefully their health and medication
18. Failing to take steps to reverse any deterioration in their health including reluctance to refer
GERIATRIC GIANTS

<table>
<thead>
<tr>
<th>Problem</th>
<th>Prevention</th>
</tr>
</thead>
</table>
| **Immobility** = physical/social/mental barriers | Maintain physical fitness  
Treat minor ailments before they become major |
| **Instability** = Falls, arthritis, osteoporosis  
↓ sensory acuity (Hearing, sight)  
↑ rates of chronic disease  
Spouse / peer loss  
Loss of meaningful activity / perceived contribution to society | Strength and balance exercises and weight bearing exercise  
Environment modification  
Medication assessment |
| **Incontinence** = Major cause of institutionalisation along with falls | Specific exercises  
Medication (use and assessment)  
Age-friendly environments |
| **Intellectual/cognitive impairment**  
Dementia, delirium, depression | **Dementia**: Higher cognitive level achieved seems to result in ↓ deficit  
**Delirium**: Is it drug/illness induced  
**Depression**: 10-20% prevalence in old people. → Encourage socialisation, increase autonomy etc, detect early |
| **Iatrogenic** = Mainly drug induced | Watch for POLYPHARMACY  
→ Regular medication review, minimise medications |

MAJOR DISEASES OF THE ELDERLY

1) **Musculoskeletal disorders**: Osteoporosis, osteoarthritis, fractures
2) **CVD**: AF, HTN, CVA, AMI, angina, CCF, tachycardia, murmurs, PVD, ATH
3) **Respiratory**: COPD, asthma, chronic bronchitis, infection
4) **Malignancies**: Skin > Digestive organs > Breast
5) **Sensory loss**: Hearing and sight (macular degeneration, cataracts, glaucoma, loss of visual acuity), tinnitus/deafness
6) **Dementia**: Alzheimer’s disease, other mental/behavioural problems, depression
7) **Diabetes** and its complications
8) **Genitourinary problems**: Recurrent UTIs, incontinence, prostate disorders, impotence

CAUSES OF DISABILITY IN OLD AGE

1) Arthritis
2) Hearing Disorders
3) Hypertension
4) Heart disease
5) Stroke
6) Visual disorders
7) Back problems

**Burden of Disease in Elderly**

- Diseases are more likely to be **chronic**  
  ↦ Creating a greater burden of disease
- Take longer to recover from illness and require more medication, more consultation + longer hospital stays

CAUSES OF DEATH IN OLD AGE

<table>
<thead>
<tr>
<th>Males 85+</th>
<th>Males 45-64 yrs</th>
</tr>
</thead>
</table>
| Cardiovascular disease 46%  
Cancer 19%  
Respiratory disease 12%  
Genitourinary disease 3.5% | Cancer 43%  
Cardiovascular disease 27%  
Injury and poisoning 10%  
Digestive disorders 5% |

See MBBS1 Notes Week 28
EFFECTS OF AGEING

1. Home
   • Difficulties performing ADLs
     ⇐ E.g. Meal preparation, personal hygiene, household tasks, shopping, transport, communication, social + financial affairs

2. Work
   1) ↓ mobility to get to work (ill health, loss of licence, hospitalisation)
   2) ↓ ability to do work (physical + mental disabilities)
   3) ‘Outdated’ procedures + skills → Replacement by younger workers
   • Loss of work → Loss of social contacts + self-worth
     ⇐ Depression and further ill health
   • BUT many elderly people are able to function at home and work without assistance and are often unfairly discriminated against

MEASURES TO ACCOMMODATE EFFECTS OF AGEING

1) Community care services to help with ADLs
2) ↑ working life + encourage participation in volunteer work force once retired
   ⇐ ↓ risk of social isolation, ↑ self-worth ⇒ Keeps older people active
   ⇐ Volunteer work good for economy as well
3) Encourage participation in other organised community activities (sports, social)
4) Prevention of health deterioration
   ⇐ Improved primary health care accessibility (financial, geographical, social)
   ⇐ Promotion of improved diet and exercise programs
   ⇐ Treat and manage illnesses appropriately
MEDICAL OVERSERVICING

RESPONSIBILITIES OF MEDICARE AUSTRALIA
⇒ Formerly Health Insurance Commission ⇒ 1/10/05
⇒ Australia’s universal health insurance program

1) Administration of Medicare + the PBS under federal legislation
2) Pharmaceutical benefits scheme
3) Australian Childhood immunization register
4) Australian Organ Donor Register
5) Practice incentives program
6) Rural retention program
7) Department of Veteran’s Affairs (including Repatriation-PBS)
8) Family Assistance Office
9) Private health insurance rebate

Health expenditure is a big portion of GDP
⇒ Includes lots of medical services
⇒ 67.5% of all services have been bulk-billed
  ▪ Commonwealth government pays the bill at an agreed cost for service
  ▪ Different procedures and consults have different billing codes
  ▪ Patient makes a claim to Medicare to pay the doctor

Medicare does NOT exist to pay doctors
⇒ It is an insurance scheme to help patients pay for their health care

INAPPROPRIATE PRACTICE
Definitions
1) Conduct in connection with rendering or initiating services which would be unacceptable to the general body of members of that profession
⇒ Applies to all health practitioners who receive payment for services under Medicare or who can refer for Medicare funded services or prescribe PBS meds
  ▪ Doctors, dentists, optometrists, chiropractors, physios + podiatrists
2) Knowingly, recklessly or negligently causing or permitting a practitioner employed by a person or body corporate to engage in conduct that would be unacceptable to the general body of members of that profession

Medical Overservicing
• Medicare Australia refers to practice of overservicing as ‘inappropriate practice’ under HIA
  1. Seeing too many patients
  2. Ordering too many investigations
  3. Ordering inappropriate medications
  4. Accepting a benefit for a referral or recommendation to a health service provider
  5. Offering a benefit for a referral/recommendation
  6. Failure to disclose pecuniary interest in given referral/recommendation
  7. Poor record keeping
     ▪ Regard is given to whether the practitioner kept adequate patient records
     ▪ Poor records = Poor defence / No records = No defence
  8. Unnecessary medications (E.g. Vitamin injections)
  9. Unorthodox medicine

80/20 Rule: 80 consults on 20 days or more in a 12 month period is overservicing

Fraud vs Overservicing
Fraud: Knowingly making a false statement in writing in order to take a claim for payment by Medicare.
  ▪ Can be a criminal offence and is not dealt with by PSR
  ▪ Inappropriate practice is not fraud ⇒ Dr actually does see patients
**Nutrition and Cancer**

- Estimated that 30-40% of all cancers can be prevented by appropriate diets, physical activity and maintenance of appropriate body weight
- Most research on nutrition + cancer has been reductionist
  - Particular food or nutrient has been studied in relation to impact on tumour formation / regression or some other end point of cancer at particular site in body
- Epidemiological studies have positively associated use of micronutrients such as antioxidants in food as protective against oral and lung cancers
  - E.g. Lycopene in tomatoes
  - Selenium

### Specific Cancer Relationships Based on Epidemiological Studies

<table>
<thead>
<tr>
<th>Cancer Sites</th>
<th>Incidence Association</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic</td>
<td>Smoking; possibly meat, cholesterol</td>
</tr>
<tr>
<td>Esophageal</td>
<td>Alcohol, tobacco and combined use</td>
</tr>
<tr>
<td>Stomach</td>
<td>Salt-preserved foods; possibly bbq and grilling</td>
</tr>
<tr>
<td>Colorectal</td>
<td>Fat; possibly eggs, grilling, sugar</td>
</tr>
<tr>
<td>Liver</td>
<td>Hepatitis B or aflatoxins; alcohol</td>
</tr>
<tr>
<td>Lung</td>
<td>Smoking; possibly alcohol, fat and cholesterol</td>
</tr>
<tr>
<td>Breast</td>
<td>Obesity; early puberty; alcohol; possibly meat and fat</td>
</tr>
<tr>
<td>Endometrial</td>
<td>Obesity, estrogen therapy, fat</td>
</tr>
<tr>
<td>Cervical</td>
<td>Folate deficiency; smoking</td>
</tr>
<tr>
<td>Bladder</td>
<td>Smoking; possibly artificial sweeteners, coffee and alcohol</td>
</tr>
<tr>
<td>Prostate</td>
<td>High fat intake</td>
</tr>
</tbody>
</table>

**American Cancer Society Diet Guidelines**

1. 5-9 servings of a variety of fruits and vegetables / day
   - Vegetables better; fresh or frozen better than canned or dried
2. Choose whole grains over refined grains
3. Limit red meats, esp high fat, processed + preserved meats
4. Achieve / maintain a healthy weight
5. 30-45 minutes of movement / exercise per day
6. Limit alcohol consumption
## Healthy Male Check-up

### Healthy Male Check-up / Screening in Males Over 45

<table>
<thead>
<tr>
<th>Topic</th>
<th>Frequency of screening</th>
<th>Technique/test</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td>Normal: 2 yearly</td>
<td>Measure BP</td>
<td>140-159/90-99 – confirm in 2 months, give lifestyle advice</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>160-179/100-109 – evaluate and treat within 1 month, lifestyle advice</td>
</tr>
<tr>
<td></td>
<td>High risk: 6 monthly</td>
<td></td>
<td>&gt;180/&gt;110 – further evaluate and treat within 1 month</td>
</tr>
<tr>
<td></td>
<td>LRM: 1 yr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol and lipids</td>
<td>Normal: 5 yrs</td>
<td>Fasting blood lipids = total cholesterol LDL, HDL, triglycerides</td>
<td>Those at low/mod risk = dietary + lifestyle advice + monitor</td>
</tr>
<tr>
<td></td>
<td>High risk: 1-2 yrs</td>
<td></td>
<td>Higher risk = as above + cholesterol lowering therapy</td>
</tr>
<tr>
<td></td>
<td>Very high risk: 1 yr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 2 diabetes</td>
<td>Normal: ↑ 55yo – every 3 yrs</td>
<td>Fasting blood sugar</td>
<td>Dependent upon severity → dietary + lifestyle advice first → referral to dietician → treatment</td>
</tr>
<tr>
<td></td>
<td>Increased risk: ↑ 45yo–3 yrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High risk: 12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>Increased risk = 1 yr</td>
<td>Question re. Symptoms of TIA (dizziness, weakness, numbness)</td>
<td>If had TIA – should consider anticoagulant therapy (warfarin) or antiplatelet therapy (aspirin)</td>
</tr>
<tr>
<td></td>
<td>(55yrs + smoke/diabetes/HTN)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney disease</td>
<td>Increased/high risk = 1 yr</td>
<td>Urinalysis – proteinuria, BP, GFR, micro-albuminuria</td>
<td>Large range of disease = large range of intervention and treatment</td>
</tr>
<tr>
<td></td>
<td>Risk factors = ↑ 50, smoker, HTN, family hx</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin cancer</td>
<td>Opportunistically (if at ↑ risk, 1/yr)</td>
<td>Skin examination</td>
<td>Sun protection advice, biopsy, remove suspicious lesions</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>Dependent on risk of patient (varies with faecal occult blood every 2yrs above 50yrs for normal people + colonoscopy for high risk</td>
<td>Query symptoms → DRE/PSA</td>
<td>Remember test + treatment can do substantial harm – inform patients fully</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>Opportunistically – risk ↑ with age and family hx</td>
<td>Query symptoms → DRE/PSA</td>
<td>Remember test + treatment can do substantial harm – inform patients fully</td>
</tr>
</tbody>
</table>

At 45 yrs, the most important are:
- BP
- Type 2 diabetes
- Skin cancer

At almost every consultation, the big 5 should be thought about and queried and the appropriate advice/referrals offered when necessary:
- Smoking
- Weight
- Nutrition
- Physical activity
- Alcohol
<table>
<thead>
<tr>
<th>Disease or condition</th>
<th>What age</th>
<th>Test/examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary artery disease</td>
<td>People aged 45 and older</td>
<td>Cholesterol and triglycerides blood test, BP</td>
</tr>
<tr>
<td>Diabetes: type 2</td>
<td>People at high risk of type 2 diabetes</td>
<td>Fasting blood sugar level</td>
</tr>
<tr>
<td>Obesity</td>
<td>Adults aged 18 and over</td>
<td>Body mass index (BMI) and waist circumference</td>
</tr>
<tr>
<td>Skin cancer - melanoma</td>
<td>Everybody</td>
<td>Self skin examination</td>
</tr>
<tr>
<td>Testicular cancer</td>
<td>Men from puberty onwards.</td>
<td>Testicle self-examination</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>&gt; 40 (if have risk factors → &gt;35)</td>
<td>Eye examination</td>
</tr>
<tr>
<td>Dental health</td>
<td>Everyone</td>
<td>Dental check up</td>
</tr>
<tr>
<td>And when you are a bit older</td>
<td>→</td>
<td></td>
</tr>
<tr>
<td>Bowel cancer (colorectal cancer)</td>
<td>&gt; 50 OR increased risk</td>
<td>Faecal Occult Blood Test (FOBT) Colonoscopy</td>
</tr>
<tr>
<td>Visual impairment</td>
<td>People 50 years and over</td>
<td>Eye test</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>Population screening not recommended</td>
<td>DRE, PSA test</td>
</tr>
</tbody>
</table>
COST OF MEDICINES AND THE PBS

PHARMACEUTICAL BENEFITS SCHEME (PBS)

Costs of PBS in 2006-07

- $6.428 billion
- ($5.00 concession / $31.30 general, January 2008)
- ↑ costs > ↑ prescriptions
  - Doctors prescribing newer and more expensive drugs
  - 69% of govt funds on concession
- Average GP writes $50,000 in prescriptions for statins alone per year

Top 10 PBS Drugs by Cost to Govt: 2006-07

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>DDD/1000/day</th>
<th>Scripts x million</th>
<th>Cost (A$) million</th>
</tr>
</thead>
<tbody>
<tr>
<td>atorvastatin</td>
<td>Cholesterol</td>
<td>131.8</td>
<td>10.00</td>
<td>562.23</td>
</tr>
<tr>
<td>simvastatin</td>
<td>Cholesterol</td>
<td>58.0</td>
<td>6.23</td>
<td>309.23</td>
</tr>
<tr>
<td>clopidogrel</td>
<td>Prevent stroke</td>
<td>9.2</td>
<td>2.40</td>
<td>179.98</td>
</tr>
<tr>
<td>esomeprazole</td>
<td>PPI – ulcer/reflux</td>
<td>16.8</td>
<td>4.43</td>
<td>181.10</td>
</tr>
<tr>
<td>olanzapine</td>
<td>Antipsychotic</td>
<td>3.1</td>
<td>0.78</td>
<td>157.47</td>
</tr>
<tr>
<td>salmeterol + fluticasone</td>
<td>Asthma</td>
<td>-</td>
<td>2.79</td>
<td>157.24</td>
</tr>
<tr>
<td>omeprazole</td>
<td>PPI – ulcer/reflux</td>
<td>18.0</td>
<td>3.88</td>
<td>114.03</td>
</tr>
<tr>
<td>pravastatin</td>
<td>Cholesterol</td>
<td>13.5</td>
<td>1.87</td>
<td>93.39</td>
</tr>
<tr>
<td>venlafaxine</td>
<td>Antidepressant</td>
<td>12.0</td>
<td>2.32</td>
<td>93.33</td>
</tr>
<tr>
<td>tiotropium</td>
<td>COPD</td>
<td>5.3</td>
<td>1.30</td>
<td>91.22</td>
</tr>
</tbody>
</table>

- Statins = 1/6 of total cost of all subsidised drugs
  - Number of prescriptions for statins increased by 350% between 95 – 2006

PHARMACEUTICALS IN AUSTRALIA

1) TGA → Registration for use
  - Quality safety and efficacy
  - Once approved → May be prescribed without government subsidy

2) PBS: Public reimbursement

![Diagram of PBS and related agencies]
Questions in Subsidy Decisions
1) Is it effective
2) Is it MORE effective than treatment it is likely to replace
3) How much do people value the benefit
4) Is the additional benefit worth the additional cost
   ➔ How do benefits vs costs vary across different groups

Conditions For Listing on PBS
1) Acceptable cost-effectiveness
2) Needed for prevention or treatment of significant medical conditions not already covered, or inadequately covered by drugs in existing list
3) More effective and/or less toxic than drug already listed
4) At least as effective and safe

Resource Allocation ➔ Need to Look At
1) Size of problem (Public Health)
2) Evidence (EBM)
3) Value for money (Health economics)

Economic Evaluations
1) Cost Minimisation
   ➔ Equal benefits ➔ Which has lower cost?
2) Cost Effectiveness
   ➔ Cost per outcome
   ➔ E.g. Cost per one point reduction in HAM-D depression scale
3) Cost Utility
   ➔ Cost per quality adjusted life year (QALY)
     ▪ Combine quality + quantity of life (0.0 = dead / 1.0 = perfect health)
     ▪ Can have states worse than

Government
• Minister considers positive recommendations + determines whether listing occurs
  ➔ Minister cannot list without PBAC recommendation
• Drugs predicted to cost >$10 million annually must be taken to cabinet for discussion
  ➔ Estimated cost for Herceptin® in 1st year of listing >$100 million

Leakage
➔ Use outside subsidised indications
• Magnitude unknown but likely to be significant
• Opportunity cost (i.e. money can’t be spent on another drug)
• Need to identify reasons
  ➔ Intention (fraud)
  ➔ Lack of appropriate education
  ➔ Marketing
  ➔ Inappropriate media reports

Cost Containment Strategies
1) System Based
   ➔ Restrictions
   ➔ Capping, Risk sharing arrangements
   ➔ Generics ➔ Help spread health care dollar

2) Patient-based (? Equitable)
   ➔ Non-subsidy
   ➔ Co-payments (with safety nets)
   ➔ Brand price premiums
HEALTH FINANCING

OPPORTUNITY COST
⇒ Value of the best alternative that is foregone
⇔ E.g. $20 000 = 1 Rhinoplasty OR 10 000 fully immunised children

HEALTH FINANCING IN AUSTRALIA ⇒ MEDICARE
• Universal Health Insurance
• Principal objective ⇒ Remove all financial barriers to access to health care for all Australians
  ⇔ Free hospital care is provided to all
    • BUT Long waiting lists for nonessential surgery
  ⇔ Medical services are free if doctor bulk bills
    • GP: Rebate = 100% of MBS fee
      • About 75% are bulk-billed
    • Out of hospital specialists: Rebate = 85% of MBS fee
      • About 25% are bulk billed

• Safety net provided by Medicare
  ⇔ Protection against accumulating out-of-pocket costs
  ⇔ 100% of rebate when total rebate-MBS fees gap payments exceed ~$335 per family per year
  ⇔ Up to 80% of out of pocket costs when rebate-actual fee gap payments exceed
    • ~$500 for Family Tax Benefit A and concession card holders
    • ~$1000 for all other individuals

• Funded from general taxation which includes:
  1. Medicare Levy: 1.5% of taxable income
  2. Medicare Surcharge: Further 1% of taxable income applying to those uninsured
     • Family income > $100 000
     • Individual income > $50 000


**PRINCIPLES OF RADIATION THERAPY**

**BIOLOGIC BASIS OF RADIATION THERAPY**

- DS breaks of nuclear DNA $\rightarrow$ Irreversible loss of reproductive integrity of cell $\rightarrow$ Cell death
- Damage can be directly ionizing
  - BUT Damage is most commonly indirectly ionizing via free-radical intermediates formed from radiolysis of cellular water
- Cell survival is related to:
  - $O_2$ tension
  - Position of cell in mitotic cycle
  - Dose rate

**ACUTE EFFECTS**

- Occur during the course of therapy and during post-therapy period (~2-3 weeks)
- Patients are usually most bothered by acute effects
  - Can be quite uncomfortable but generally resolve
  - Chronic effects can be devastating, permanent + progressive

1) **Erythema** often evident after 1 week of treatment at conventional doses
   - Progresses over weeks through various stages of mucositis
   - Severe skin reactions uncommon

2) **Mucositis** represents caking of dead epithelial cells, fibrin + inflammatory cells
   - Ranges from small patches to confluent or ulcerated areas
   - Site of infection

3) **Loss of Taste**
   - Patients may report ↓ acuity, odd sensation, or complete absence of taste
   - Often accompanied by loss of appetite + weight loss
   - Recovery of taste is a slow + frequently incomplete process

4) **Xerostomia (Dry mouth)**
   - Radiation affects saliva volume, production + composition
   - ↓ salivary pH + volume are significant contributors to *altered mucosal flora* and predispose patients to caries
   - Patients frequently describe thickened, tenacious, ropy saliva which may make speech difficult in addition to affecting swallowing + taste

**LATE EFFECTS**

- Source of ongoing morbidity

1) **Fibrosis**
   - Limited neck movement
   - Masticatory muscles may be involved

2) **Lymphoedema**
   - Obstruction of cutaneous lymphatics

3) **Delayed wound healing**

4) **Telangiectasis**

5) **Xerostomia**
   - Artificial saliva substitutes
   - Pilocarpine 5 mg
   - Carry a bottle of water

6) **Ulceration + Bone exposure**
   - Osteoradionecrosis may follow but is uncommon
7) **Self-limited transversemyelitis** → With radiation to spinal cord

8) **Hypothyroidism**
   - Course of treatment often affects thyroid gland either directly or secondarily via hypothalamic-pituitary axis

9) **Damage to visual apparatus**
   - Dry eye syndrome – with irradiation of lacrimal gland
   - Cataract formation – with direct irradiation of lens

10) **Serous otitis / Possible sensorineural hearing loss**
    - With irradiation of auditory apparatus

11) **Radiation-induced cancers**
    - Uncommon following therapeutic doseses
    - Angiosarcomas with irradiation of breast
PSYCHOSOCIAL SUPPORT OF CANCER PATIENTS

- Directly affects 1/3 males and 1/4 females before 75 years

**IMPACT OF SERIOUS ILLNESS**
- Informed by 3 primary factors
  1. Developmental phase: of individual
  2. Intrapersonal factors: Individual’s personality style + coping capacity
  3. Interpersonal factors: Presence + nature of social resources

**Psychological impact of cancer**
- Depression
- Anxiety
- PTSD
- Sexual problems
- Long term distress

**PSYCHO-SOCIAL INTERVENTION**
- Reduce distress, anxiety and depression
- Improve mood, coping, self-esteem and sense of control
- Reduce physical symptoms – nausea, vomiting, pain
- Increased knowledge empowers the patient and allows participation in decision making

- **Group interventions:**
  - Mutual support
  - Reduce isolation and stigma
  - Sharing coping strategies
  - Evidence that it is efficacious (↓ psychological symptoms and pain)
    - Supportive and psycho-education groups

**OTHER COMMUNITY RESOURCES**
- Informal support – family and friends
- Telephone help line
- Online chat rooms
- Psychologists, psychiatrists, counsellors
- Allied health services
- Community based nurses
- HACC
- Meals on wheels etc.

**QLD CANCER FUND (QCF)**
- Largest cancer charity in QLD

**Cancer Council Helpline (13 11 20)**
- Confidential cancer information, support and referral services
- Database to refer people to
- Lots of printed literature they can send out

**QCF – Cancer Counselling Service**
- New service – extends the help line (can help those in more distress than help line)
- Contacts person within 2 working days after referral then a counsellor or clinical psychologist talks to the patient over several sessions
- “Triage” process – directs patient to find appropriate care for their needs
  - If insufficient care → refer to counselling service
- Phone based (so can overcome barriers of face to face services), ↑ flexibility for rural/remote
- Available for ANYONE in QLD distressed by cancer – patient, family, friends
**Other Activities**

- **Living with cancer program** – group education and support program for people coping with the diagnosis and treatment of cancer (sessions include information, stress management/relaxation, practical suggestions for diet, pain, activity etc.), information about complementary therapies
- **Healthy living seminars** – for cancer patients and their carers (topics include diet, exercise, complementary therapies like relaxation)
- **Cancer Connect** – telephone peer support service that puts people in touch with others who have a similar cancer experience. The volunteers talk through fears, concerns and give useful information

**CANTEEN**

- Four main groups that they provide support for:
  - Supports 12-24 y/o patients who have/have had cancer
  - Also support their **siblings**
  - **Parents or caregivers**
  - **Bereaved**
- Major events are **camps** – peer support model
- Also **skill based camps** – psycho-education based to cope with stress and lifestyle changes
- **Recreation days** and **café afternoons** to socialise
Learning Objectives
Explain the fundamental ethical arguments for and against active euthanasia (including considerations of medical practitioners' involvement), the distinctions between euthanasia and the withdrawal of medical treatment, and national and international developments including the legal status of euthanasia.

Keywords
- The right to die
- The good death
- Quality of life
- Death with dignity
- Futility
- Burdensomeness
- Ordinary & extraordinary means
- Killing & letting die
- Active & passive euthanasia
- Voluntary, non-voluntary & involuntary euthanasia
- Physician-assisted suicide

INTRODUCTION
Euthanasia is the single most serious challenge to the Hippocratic tradition that has nurtured doctors for well over 2000 years
- Medical, professional, social, ethical, religious, legal, political + possibly economic issue
  cf abortion

TERMINOLOGY + DEFINITIONS
- Terms are difficult to define objectively

Physician Assisted Suicide:
- A person takes his own life, having been assisted by a doctor in one or more of a number of possible ways
  - E.g. Advice concerning lethal drugs + doses
  - Prescriptions for drugs to take in overdose
  - Setting up equipment which the person activates to deliver a fatal dose

Euthanasia:
- Good death, mercy killing

Active Voluntary Euthanasia:
- An action such as a lethal injection by someone, usually a doctor, at the request of and consented to by a competent person, sufficient for and intended to cause the death of that person, in order to end the person's suffering

Non-Voluntary Euthanasia:
- An action by someone else, which leads to the death of an incompetent person, who can express no preference for or against the action

Involuntary Euthanasia:
- An action by someone, which leads to a competent person's death, against the expressed wish of that person.
  - Misleading to use the word 'euthanasia' at all in this context
  - Involuntary euthanasia is equivalent to murder
Passive (voluntary or non-voluntary) euthanasia:

- Difficult concept which many people think is best avoided as it causes more confusion than clarity
- Withdrawal or withholding of life-sustaining treatment, leading to death of person
  - E.g. Removal of respirator → Debate as to whether such an action constitutes an action or an omission (does this cause death or let nature take its course?)
- Best to use active euthanasia for clearly direct actions, (as described above) and to simply use terms withdrawing and withholding treatment where these occur

Commonly Held Beliefs → Euthanasia Includes

1) Withholding or withdrawing ineffective life support systems, including advance directives to this effect
2) Giving increasing amounts of pain medication, which may also incidentally shorten the person’s life
3) Respecting a patient’s right to refuse further treatment
4) Providing a person with the means, or the knowledge, to end their own life

History
- Hippocratic oath outlaws active assistance to die
- After development of ether, physicians began advocating the use of anaesthetics to relieve pains of death
- 1870: Samuel Williams first proposed using anaesthetics + morphine to intentionally end a patient’s life
- 1906: Bill to legalise euthanasia presented in Ohio → Subsequently defeated
- 1935: 1st meeting of Voluntary Euthanasia Legalization Society in London
  - Leaders were all prominent physicians
- D Rodney Syme = Current vice-president of Dying with Dignity Victoria

Recent Worldwide Developments
- 1995: NT legalised active voluntary euthanasia + PAS
  - (Rights of the Terminally Ill Act 1996)
  - 1st legalisation in world
  - 4 people were assisted to die under the legislation before it was overridden by Commonwealth government (Euthanasia Laws Act 1997)
- 1997: PAS legalised in Oregon, USA
  - Other states have attempted legalisation in recent years
- 1997: Legalisation in Columbia
  - Implementation of guidelines is incomplete
  - Uruguay’s criminal code allows mercy killing to go unpunished under certain conditions
- 2001: Legalisation in Netherlands after many years of toleration of strictly illegal practice
  - Previously, Drs who performed voluntary euthanasia in accordance with strict conditions were able to employ the defence of necessity to avoid prosecution
- 2002: Euthanasia + PAS legalised in Belgium
- Switzerland tolerates assisted suicide by non-physicians, although PAS has recently received restricted approval by Swiss Academy of Medical Sciences
  - A number of British subjects + 1 Australian have travelled to Switzerland to take advantage of the law there
- Germany allows PAS but not active euthanasia
• Parliamentary bills have been presented to the legislatures of TAS, SA, NSW, WA, ACT, Luxembourg and New Zealand

• 2004/2006: UK House of Lords considered a bill to allow euthanasia
  ➔ 2 of UK’s royal medical colleagues dropped their opposition to bill
  ➔ BMA changed position to a neutral stance ➔ Agreeing that any decision on euthanasia is a political one which should occur through parliamentary process
  ➔ Rescinded in 2006 ➔ BMA now opposes euthanasia

• 2008: Bob Brown (Australian Greens) announced intention to introduce a private member’s bill into Federal parliament
  ➔ If passed ➔ Would have effect of lifting ban on euthanasia and PAS in NT
  ➔ Rights of Terminally Ill Act 1996 (NT) while overridden was never rescinded by NT parliament

**AMA STATEMENT**

• AMA line is anti-euthanasia
• While Drs have an ethical obligation to preserve health, death should be allowed to occur with dignity and comfort.
• When death is inevitable and when Tx which might prolong life is futile ➔ withholding / withdrawing Tx may be in patients best interests
  ➔ Assuming Dr is acting within boundaries of established medical practice
• Endorses right of a patient to refuse Tx
• Endorses right of severely + terminally ill patient to have pain relief medication even though it may hasten death

**WHO STATEMENT**

• PAS is unethical and must be condemned by medical profession

**QUEENSLAND**

**Law**

• QLD Criminal Code 1899, s300 on unlawful homicide
  ➔ Any person who unlawfully kills another is guilty of a crime, which is called murder or manslaughter, according to the circumstances of the case

• S311 ➔ Any person who:
  ➔ Procures another to kill himself or herself; or
  ➔ Counsels another to kill himself / herself + thereby induces other person to do so;
  ➔ Aids another in killing himself / herself
  is guilty of a crime, and is liable to imprisonment for life

**Community Opinion**

• Community strongly supports legalising active voluntary euthanasia + PAS
  ➔ Majority of nurses support legislation
  ➔ Medical practitioners more evenly divided (Significant % say not sure)
• Some recent surveys report 80% support

• Some people believe that this response by community has come about because many people have witnessed less than optimal end-of-life care for parents, partners + other family
Apparent Inconsistencies in QLD Law Concerning Events Which Could Lead to Death

1) Under common law every competent person has a right to refuse treatment, inc. life-saving treatment. In addition, if a competent person refuses treatment and their wishes are not respected, the person giving the treatment can be charged with assault under s245 of the Queensland Criminal Code, and/or may be the subject of a civil action for assault.

2) However, s296 of the Code says that anyone who, by any act or omission, hastens the death of another person, when that person is “labouring under some disorder or disease arising from another cause” shall be deemed to have killed that person.

3) Under s285, a person who has a duty to provide the necessaries of life for another person who, by virtue of age, ill health or disability cannot provide them for themselves, is criminally liable if they don't provide them.  
   ↓ Only an unreasonable failure would be sanctioned  
   - In cases where there is no apparent benefit in continuing medical interventions, it would be regarded as offence to discontinue treatment.

4) Under s284, it is no defence to a charge of criminal responsibility for causing another person’s death, that the other person consented to their death.
   - Is failure to treat an omission, which could be seen as criminally hastening the death of another person?
   - What is a necessary of life, whose absence would constitute a criminal failure?
   - Is it a ventilator? Or tube feeding?
   - Are there obligations to prolong life implied in these sections, which go against the spirit of not prolonging life when there is no point to it, even apart from the issue of euthanasia?

282A Palliative Care

- Protects from criminal liability a doctor or someone authorised by a doctor, who provides reasonable palliative care and skill, even if an incidental effect of providing the care is to hasten the death of the other person.

- Euthanasia supporters criticise distinction between intended and foreseen effects
  - If treatment which “incidentally” brings about death is acceptable, then so should treatment which is “intended” to bring about death in appropriate circumstances.

Doctrine of Double Effect

⇒ Giving sufficient pain relief to control a person’s pain but which also hastens death
  - Many argue that important factor relating to causation of death is intention
  - In many cases of palliative care ⇒ Intention is to relieve pain
    - Fastening death is claimed to be a foreseen but unintended consequence
    - BUT if an effect is foreseen, the fact that it was unintended may not constitute adequate protection in law.

“Slow Euthanasia”

⇒ In a small percentage of cases, symptom relief requires that patient be rendered permanently unconscious (Terminal sedation)
  - Dubbed ‘slow euthanasia’ by those who believe that it is hypocritical to claim that this process is morally different from active euthanasia.

Case

- Kelly Taylor (UK) → Patient with Eisenmeger’s syndrome + Klippel-Feil syndrome argued in court that she should be rendered unconscious and then not fed as the only available treatment for her symptoms, including pain
  - Opposed by doctors + BMA as amounting to illegal euthanasia
WITHDRAWAL OF LIFE-SUSTAINING TREATMENT
• E.g. Withdrawal of respirator leading to death of patient
  ➔ Euthanasia supporters argue that withdrawal does bring about death
    ▪ At least in sense of patient’s death at a particular time being the responsibility of those who decide to withdraw treatment
    ▪ Tend to morally equate such action with action to cause death of someone who is not dependent on life support
  ➔ Those who oppose euthanasia describe withdrawal as something which then allows nature to take its course,
    ▪ In active euthanasia it is not nature but another person who directly causes death

RECENT AUSTRALIAN DEVELOPMENTS
• Over recent decades, a small number of elderly “mercy killers” have not been required to serve custodial sentences

• Several years ago, 7 Victorian doctors admitted performing active voluntary euthanasia, but the police and the medical board took no action

• Dr Rodney Syme admitted in 2007 that he gave terminally ill man Steve Guest medication that may have helped him die in 2005, leaving him open to prosecution for assisting suicide.
  ➔ He said in making the admission he was testing the law and highlighting what he said were "inadequate and opaque laws" that did not protect doctors
  ➔ No prosecution has eventuated.

• Nancy Crick committed suicide in Queensland in 2002, witnessed by 21 people
  ➔ After two years of waiting, these people were finally told that they would not be prosecuted for assisting Mrs Crick commit suicide
  ➔ BUT one of the witnesses, John Edge, has written a book on the events, and this is currently being scrutinised by the Qld police, in order to determine whether there are grounds to lay any charges

• Australia’s well known euthanasia campaigner, Dr Philip Nitschke, runs clinics for people wishing to learn more about the law and options for dying
  ➔ Has developed a suicide machine, and conducts research into a “peaceful pill”
  ➔ Actions are in clear contrast to the more mainstream political lobbying of the Voluntary Euthanasia societies, and are grounded in the belief that political action is unlikely to be successful in the foreseeable future

• The Crimes Legislation Amendment (Telecommunications Offences and Other Measures) Act 2004 was recently enacted by the Federal parliament
  ➔ Aims to outlaw a number of practices utilising carriage services (eg the internet) to promote eg child pornography.
  ➔ The promotion of suicide is included in the legislation, so it is an offence for a person to use a carriage service to access, transmit, make available, publish or otherwise distribute material that directly or indirectly counsels or incites suicide.
  ➔ The proposals have been strongly criticised by the Voluntary Euthanasia societies, who perceive the legislation as a sneaky way of stifling discussion of the issues, rather than simply preventing actual incitement to commit suicide
    ▪ Some critics have also claimed that the legislation was primarily intended to shut down the activities of Dr Nitschke.
RESEARCH
- Opinion polls have shown increasing public support for legalising voluntary euthanasia
  - BUT have been criticised for using biased questions, which arguably discount available care options and result in a "false positive" level of support.
- Australian research revealed (unbiased surveys):
  - Significant, although not majority support, amongst medical and other health professionals, for legalisation of voluntary euthanasia.
  - Strong majority support in community for the legalisation of voluntary euthanasia
- Concerns expressed that allowing active voluntary euthanasia in the Netherlands would be a "slippery slope" leading to non-voluntary and involuntary euthanasia
  - Recent study showed that, while the number of reported active voluntary euthanasia deaths had increased in the previous five years, the percentage of deaths without specific request had, in fact, decreased.

ETHICAL AND PROFESSIONAL ISSUES
- Some who think that individual cases of euthanasia are morally permissible may still object to legalisation on other grounds
- Some euthanasia supporters favour situation where illegality of euthanasia reinforces the strength of society’s commitment to value of life, while at same time, extreme cases are accepted as exceptions based on extreme necessity
  - Principle has been utilised in Australia where juries have refused to send elderly “mercy-killers” to jail

ARGUMENTS FOR EUTHANASIA
1) A right to die is based on autonomy & freedom of choice
2) Death with dignity is based on the subjective determination of quality of life
3) Compassion requires that we relieve suffering, and sometimes this is only possible through a compassionate act of assisted death
4) Difference between active assistance to die and allowing a person to die is morally irrelevant (emphasis on consequences)
5) If suicide is permissible (ie it is not illegal in Australia and other western countries), then assisted suicide should also be permissible, especially for those physically incapable of doing this
  - Failure to make assisted suicide available implies an inequity between those who can and those who cannot bring about their own deaths
6) Procedural safeguards of active assistance to die are achievable
7) Euthanasia is occurring already, but often in dangerous and poorly managed circumstances
  - Gay communities’ euthanasia practices
8) Palliative care cannot relieve the suffering of all patients
  - Euthanasia and palliative care are compatible, not alternatives
ARGUMENTS AGAINST EUTHANASIA

1) Life is sacred, and it is wrong to intentionally kill
   ⇣ This view is usually religiously based, but can also be grounded in a secular position on the sanctity of life

2) There is a moral difference between killing and letting die, which lies in the difference between one person killing another, and a disease being the cause of a person's death

3) If we legalise PAS and voluntary euthanasia, this will lead to the spread of killing practices beyond those who can voluntarily consent to the practice (the slippery slope argument)

4) Legalisation will threaten vulnerable members of society, some of whom will feel pressured into requesting assistance to die from a perception that they are burdens to their families or to society

5) The motivation to save health care resources will tempt us to broaden the scope of euthanasia practices, and to persuade some people to request assistance

6) Procedural safeguards against abuses are impossible to guarantee

7) Agreeing to requests for assistance forecloses the opportunity to respond to what are often cries for help, expressions of depression, or attempts to exert control over desperate situations, and these can be responded to in better ways

8) Adequate palliative care services obviate the need for assisted death

9) No one can or should proclaim when someone else's life is not worth living
   ⇣ Although we might say that if a person requests assistance to die then it is that person making the judgement about the value of his life to him
   ⇣ Critics of euthanasia will claim that to agree to his request is to endorse the view that his life is not worth living, and that this is an illegitimate move to make

10) Even if euthanasia were legalised, doctors should not be involved, since medicine's primary goals concern the healing of patients, treatment of disease, and relief of suffering, not the bringing of life to an end.

11) The involvement of doctors would lead to a lack of trust by patients of their doctors
   ⇣ Supporters claim that trust would be strengthened by Dr's willingness to support

ARGUMENTS CAN BE COMBINED IN AN ILLOGICAL, ALTHOUGH STRATEGIC WAY

• E.g. An opponent of euthanasia may argue both that killing is morally wrong, and that if euthanasia were legalised, it would be abused
   ⇣ This is a combination of a moral argument and an empirical one (or at least an empirical prediction) BUT these are incompatible
   ⇣ If someone says we should oppose euthanasia because its legalisation would be abused, this presupposes that euthanasia in itself is morally acceptable.
   ⇣ Conversely, if euthanasia itself is morally wrong, then there should be no reason or need to argue about abuses, since its moral wrongness should be the end of argument for that person
**PUBLIC HEALTH AND MALARIA**

- Enormous cause of ill health in Africa and PNG
- Malaria is often what maintains the cycle of ill health and poverty
- Estimated that a country’s GDP growth is retarded 1%/year by malaria

**IMPACT**

- Substantial percentage of childhood deaths due to malaria
- Endemic areas have chronic ill health
- Epidemic areas can be massively disrupted during outbreaks
- Malaria and misery tend to congregate ⇒ post-disaster epidemics
  - Refugee – Kenya/Sudan, Rwanda, Border Armed conflicts
  - Vietnam-China 1979
  - Thai-Burma 1990s

**MALARIA EPIDEMICS**

- Occur in areas of **MARGINAL TRANSMISSION** (Where usually don’t see disease)
  - Highland areas due to temp
  - Desert areas due to few mosquitos
  - Disaster areas due to congregation of non-immune people
- Sudden upsurge of malaria when transmission favoured (E.g. Desert flooding)
- Refugee movement
  - **Rwanda**: Poorly prepared population thrown into endemic area with little medical care
    - More died of cholera and then malaria than in country of civil unrest

**TROPICAL ACCUMULATION OF LABOUR AND MALARIA:**

- Large diverse groups of workers brought together with varying parasite and varying resistance to malaria
- Labour stress increases recrudescence infections and infective mosquitoes
- Epidemic malaria outbreak occurs within work force

**MAJOR CAUSE OF PERINATAL MORTALITY**

- Preferentially infects the placenta
- Acrbates anaemia of mother and is leading cause of intrauterine growth retardation
- Malaria fever can trigger premature onset of labour

**EFFECT OF BLOOD TRANSFUSION**

- Leading cause of transfusion in the developing world
- Iatrogenic malaria outbreaks from blood transfusion occur usually from asymptomatic people
- Lab test to detect malaria in donated blood are suboptimal
MALNUTRITION IN THE DEVELOPING WORLD

WHO DEFINITION

Cellular imbalance between supply of nutrients and energy and the body’s demand for them to ensure normal growth, maintenance, and specific tissue functions.

- Can occur in all age groups
  - BUT most important in children, where it is implicated in more than 50% of all child deaths in developing countries.

SEVERE MALNUTRITION

Presence of at least one of the following:

1. Oedema of both feet
2. Severe wasting
   - <70% weight-for-height
   - OR <-3 standard deviations
3. In order to exclude children who are stunted, signs of wasting must accompany their measurements
   - Severe wasting of shoulders, arms, buttocks, thighs, visible rib outlines
4. Clinical signs of severe malnutrition (see below)

Aetiology

1) Breastfeeding ⇒ Absent or prolonged and exclusive
2) Single staples
3) Infections ⇒ Diarrhoea, TB + HIV

Kwashiorkor Malnutrition

- 60-80% of expected body weight, plus oedema
- Due to insufficient protein intake
  - Hypoalbuminaemia ⇒ ↓ Colloid osmotic pressure ⇒ Ascites
  - Generally occurs after weaning, as the child loses the supply of proteins delivered in the breastmilk, and is instead started on a diet high in carbohydrates
  - Changes in skin pigmentation

Marasmus Malnutrition

- <60% of expected body weight, without oedema
- Due to low energy intake
  - Accounts for the generalised wasting seen in marasmic children

- There is no distinct separation between the terms clinically, as the treatment is approached in a similar way
  - Kwashiorkor is technically a subset of marasmus (i.e. protein counts as energy),
  - Both presentations can be seen in one child
    - Marasmic kwashiorkor: <60% of expected body weight, plus oedema

VITAMIN AND MINERAL DEFICIENCIES

- All severely malnourished children have vitamin and mineral deficiencies
- Although anaemia is common, iron should not be given until some weight has been regained
  - Can worsen infections
- Vitamin A seems to be the most important vitamin for clinical signs (eye-related)
  - Presents with Bitot spot + xerophthalmia ⇒ Can lead to corneal scarring (Blindness)
  - Treated with multi-vitamin
- Zinc, copper, magnesium, and potassium are also targeted in treatments
  - Zinc deficiency appears to be the reason for the kwashiorkor dermatosis.
OHCA SURVIVAL CHAIN

- Out of Hospital Cardiac Arrest (OHCA) is commonly caused by arrhythmias
  - Usually VF
  - Definitive Tx is defibrillation

1) Early recognition and access to emergency medical services (EMS)
   - Public education campaigns to raise public awareness & emphasise need for
     witnesses of collapse to call EMS

2) Early cardiopulmonary resuscitation
   - Only performed in 22% of OHCA, often performed poorly

3) Early defibrillation
   - New technology has allowed defibrillators to become more user friendly
   - Automated external defibrillators (AEDs) can analyse patients' electrical rhythm
     and deliver pre-programmed shocks without further decisions by the rescuer
   - AEDs are simple to operate and are ideal for use by unskilled first responders
   - Technology is suitable for health clinics & GP surgeries & is becoming
     increasingly available in public areas eg sporting venues, public buildings, police

4) Early advanced cardiac life support
   - Defibrillation, endotracheal intubation and intravenous medications

COMMUNITY EDUCATION INTERVENTIONS

Strategies to improve survival from OHCA in Australia
1) Improved education of public and healthcare providers in recognizing cardiac arrest and
   accessing EMS
2) Improved training of laypersons in CPR
3) Increased deployment of automatic external defibrillators
4) Public access defibrillation
5) Improved ambulance response times
6) Improved data collection by the EMS throughout Australia
7) Improved communication between units researching pre-hospital resuscitation
8) An evidence-based approach to allocating resources for pre-hospital early advanced cardiac
   life support protocols

Educational interventions
1) Heart Foundation publications
2) Cardiac arrest events (fund-raisers held in Tassie)
3) National Heart week
4) Project HeartStart – St John’s ambulance campaign for automated defib in public places
5) Red Cross offers AED training programs

FACTORS TO CONSIDER WHEN IMPLEMENTING AEDs

Disease factors
- Incidence:
  - 1/1000/yr (US); 10 000 lives lost/yr in Aust
  - 75% occur in private residences
  - 12% on road/public places
  - 3% in nursing homes
  - 2.5% sporting facilities
- Consequences: hypoxic brain injury at 4min, death after 12min (OHCA = 95% mortality)
- Potentially high salvage rate (see Tx below)
**Treatment factors**

1) Effectiveness
   - Survival is TIME-critical: 10% ↓ chance of success w each min
   - Defibrillation within 1 min → 90% survival
   - AEDs at Melb cricket ground → 70% survival following VF

2) Cost:
   - $5000-$12000 for AED machine, small maintenance costs
   - Cost of roll-out – St John’s volunteers = $0

3) Ease of use:
   - Voice prompts and programmed algorithms mean no operator training required
   - Machine recognizes convertible rhythm and will only shock if this rhythm present
     (∴ cannot use as weapons or shock collapse pt inappropriately)

4) Maintenance issues:
   - Servicing & equipment maintenance
   - Adequate recording of incidents/usage

5) Alternatives:
   - ↑ ambulance service (attempts in Vic to ↓ response times still saw ~6min
     response to cardiac arrest & 9min before defib + cost = ~ $1million/life saved)
   - Implantable defibrillators – but most cardiac arrests are unexpected & in ppl with
     no apparent risk factors

6) Support from relevant bodies
   - St Johns
   - Aust Resuscitation Council
   - Heart Foundation
REASONS FOR PATIENT DELAY IN SEEKING EARLY INTERVENTION
1) Lack of knowledge regarding symptoms
2) Appraising symptoms as “not serious”
3) Worry about troubling others
4) Embarrassment about seeking help
5) Denial and vulnerability
6) “Too busy”

CHARACTERISTICS OF PATIENTS WHO DELAY SEEKING MEDICAL ASSISTANCE
1) Low income
2) Less than 12 years of education
3) People who have not had any health training/CPR
4) Diabetes mellitus
5) A history of hypertension
6) Location (rural)
7) Indigenous patients (in both rural and urban areas)
8) NESB patients

CONSEQUENCES OF DELAY IN SEEKING MEDICAL CARE FOR CHEST PAIN
- Chest pain can be the sign of serious disease or a warning of serious complications to come
  1. Acute, potentially life-threatening condition that warrants immediate hospitalization & aggressive evaluation
  2. Chronic condition likely to lead to serious complications
  3. Acute condition that warrants specific treatment
  4. Another treatable chronic condition

E.g. Timeline of heart problems due to CAD
1) Myocardial necrosis begins about 30mins after coronary occlusion
2) Classic acute MI with extensive damage occurs when perfusion of the myocardium is ↓ severely below its requirements for an extended period of time (usually about 2-4 hours) ↓ This causes profound, prolonged ischaemia and results in permanent loss of function of large regions
   - Can lead to arrhythmias, mechanical failure
3) If however, reperfusion follows briefer periods of flow deprivation (<20 minutes), loss of cell viability can be prevented
## DEFINITIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Variable</th>
<th>Equation</th>
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</table>
| CER          | Control Event Rate | \[
\text{CER} = \frac{\text{Events}}{\text{subjects in control group}}
\] |
| EER          | Experimental Event Rate | \[
\text{EER} = \frac{\text{Events}}{\text{subjects in experimental group}}
\] |
| ARR          | Absolute Risk Reduction (or increase) | \[
\text{ARR} = \text{CER} - \text{EER}
\] |
| RRR          | Relative Risk Reduction (or increase) | \[
\text{RRR} = \frac{\text{CER} - \text{EER}}{\text{CER}}
\] |
| NNT          | Number Needed to Treat / Number Needed to Harm | \[
\text{NNT} = \frac{1}{\text{ARR}}
\] |
| OR, RR       | Odds Ratio, Relative Risk | \[
\text{OR, RR} = \frac{\text{CER}}{\text{EER}}
\] |

### RELATIVE RISK REDUCTION + ABSOLUTE RISK REDUCTION

- Media reports Relative Risk Reduction (E.g. Drug reduces breast cancer risk by 50%)
  - **BUT This gives no indication of prevalence or baseline risk**
    - Drug may reduce prevalence of breast cancer from 2% to 1%
    - Absolute Risk Reduction = 1%

- ARR + NNT are far more useful measures of clinical significance of an intervention
COMMUNICATING RISK

1. Describe approaches to management of risk + uncertainty in medical care + public health practice
2. Explain, with examples, absolute versus relative risk

RISK IN THE CONTEXT OF A MEDICAL CONSULTATION
1. Probability of something happening (or not happening)
2. Feeling of dreadfulness of that event (which is very personal)
3. Context of the event

1. GOOD COMMUNICATION
   • Essential to shared decision making
   • Improves outcomes

   Essential for:
   1. Patient-centred medicine
   2. Informed consent
   3. Medico-legal climate
   4. Ethics, Hippocratic oath (first do no harm)

   Complex task ⇒ Requires skills from:
   1. Clinical experience
   2. Recent evidence
   3. Understanding patient’s perspective, autonomy
   4. Self-awareness (of own personal opinions)

   Patients benefit from good communication:
   1. Greater participation in healthcare
   2. Improved adherence (compliance?)
   3. Remember more info ⇒ Save time later
   4. More realistic expectations
   5. More satisfied with care
   6. Effective ‘motivational interviewing’
   7. Greater ‘self-efficacy’

   Informed Consent:
   ⇒ Necessary even when prescribing a medication for a patient
   • Document in notes
   ⇒ Amount of info commensurate with seriousness and context
   ⇒ Written or verbal
   ⇒ May occur over multiple consultations

   Informed Decision Making:
   1. Describe nature of the decision
   2. Establish patient-centred consultation
   3. Discuss alternatives
   4. Discuss risks and benefits
   5. Related uncertainties
   6. Assess patient’s understanding
   7. Elicit patient’s preference

2. PATIENT’S DESIRE FOR SHARED DECISION MAKING
   • 467 patients attending for invasive diagnostic or therapeutic interventions
   ⇒ 68% preferred shared decision making
   ⇒ 21% wanted doctor to decide
   ⇒ 10% for patient to decide
   ⇒ 93% wanted their doctor to disclose risk info to them
      • Trends show younger people wanting more involvement in decision making
Skills Needed for Doctor in Shared Decision Making Process

1) Explicit clarification of roles
   - Dr: ‘Jim, today I need to explain your results and discuss treatment options. Then, I’d like to hear from you what you would like to do’

2) Partnership building
3) Responsiveness to patient’s ideas, concerns + expectations
4) Avoidance of arguments and debates
5) Info giving that is patient centred
   - Tailored to personal characteristics and preferences for the mode of communication
6) Awareness of own biases, beliefs + personality style (optimist, risk-taker) and those of patient
   - Drs tend to over-estimate risk if they have experienced a recent adverse outcome in another patient
7) Provision of time for patient to make a decision
   - E.g. Arrange follow-up visits

3. PATIENT AND CULTURAL FACTORS
   - Good communication depends on doctor and patient being able to understand one another
   - Obstacles to understanding
     - Age, gender, social, cultural + educational background, health literacy
     - Failure to address obstacles may lead to
       - Patient not understanding medical condition
       - Undue anxiety
       - Unable to discuss condition with health professionals

Effective Communication
1) Build rapport
2) Present info clearly
3) Demonstrate and ask for feedback
4) Check understanding
5) Respect and take account of cultural values and beliefs
6) Provide and interpreter if necessary

4. PERCEPTION OF RISKS AND BENEFITS IS COMPLEX
   - Doctor and patient priorities may conflict
     1. Scientific Concept of Risk
        - Mathematical objective
        - Impersonal
        - Deals with populations rather than individuals
     2. Lay Concept of Risk
        - Individual’s concerns
        - Anxieties and fears about the future
        - Influenced by personal priorities
        - Over-assess low probability, high consequence (E.g. Train crash)
          - Under-assess common causes (E.g. DM)
        - Fear of the unknown
        - Fear of not being in control

Over- or Under-Estimations of Risk
   - Individuals are likely to be more sensitive to and over-assess likelihood of low probability or high consequence risks (E.g. train crash)
     - Underestimate risk of harm from more common causes (E.g. cancer or DM)
   - Individuals are more likely to be more sensitive to a risk if it is involuntary, inescapable, poorly understood by science, or subject to contradictory statements
   - Gain in short term (E.g. avoidance of Dr advice) is often an attractive choice
     - Even if it comes with later loss (E.g. disease has progressed)
5. PROVIDE COMPREHENSIVE RISK AND BENEFIT INFORMATION

1) Credible source of info
   - Respected organisation (NHMRC) or opinion leader (known specialist)
2) Knowledge of facts and figures
3) Provide option to patient of expressing risk in words of frequency / probability; numerically or graphically
4) Positive and negative ‘frames’, similarly loss and gain framing
   - Loss framing (E.g. potential losses from not having mammogram) influences screening uptake more than gain framing
   - Positive framing (chance of survival) more effective than negative framing (E.g. death) in persuading people to take risky treatments
5) Present both sides of story
   - “For 5% risk, 5 in 100 will experience side effect and 95 in 100 will not”
6) Provide qualitative and/or quantitative information
7) Use decision aids to individualise risk
8) Be aware of the multiple and conflicting sources of risk info that patients access
9) Provide more time and info for more important decision or greater risk

**Probabilities for Expressions**

**Presenting Balanced Information ➔ Communicating the Numbers**

1) Use consistent denominator
2) Provide both absolute and relative risk
3) Maybe also number needed to treat (NNT) and number needed to harm (NNH)
4) Use frequencies as well as percentages
   - Natural frequencies (E.g. 8 out of 1000) vs percentages (E.g. PPV)
5) Use a mix of visual aids to present the data
**Computerised Decision-Aids**
1) More realistic expectations of options, benefits + harms
2) People feel more comfortable with their decisions (↓ decisional conflict)
CLINICAL TRIALS

STUDY DESIGN HEIRARCHY

BEST STUDY TYPES

Diagnostic: Cross sectional compared with reference standard
Therapeutic: RCT
Prognostic: Inception cohort
Risk factor / Aetiology: RCT
Coastal or Case-control study
Prevalence / Frequency: Random sample / Cross sectional

PURPOSE OF CLINICAL TRIALS

1) Show with maximum certainty whether new strategies are better than best already available
2) Show that new strategies are not worse than those already available

SEQUENCE IN MODERN CLINICAL TRIALS

1) In vitro studies
2) Animal in vivo studies
3) Human Phase I ➔ Toxicology and pharmacokinetics
4) Human Phase II ➔ Evidence of efficacy
5) Human Phase III ➔ Randomised Controlled Trial(s)
6) Human Phase IV ➔ Post-marketing surveillance

RANDOMISED CONTROLLED TRIALS

- Special kind of prospective cohort study where conditions are specified by investigator
- Involves an intervention
- At least 2 groups
  - Experimental
  - Control or comparison
- Individuals followed to ascertain effects of intervention

Diagram:

- Defined Population
- Randomised
- New Treatment
- Placebo or current treatment
- Disease
- No Disease
- Disease
- No Disease

Time
Direction of Inquiry
<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>1) Randomisation</td>
<td>1) Difficult to conduct and design</td>
</tr>
<tr>
<td>2) Unbiased distribution of confounders</td>
<td>2) Expensive ⇒ Time and costs</td>
</tr>
<tr>
<td>3) Blinding of subject and/or investigator possible</td>
<td>3) Problems related to ethics + feasibility</td>
</tr>
<tr>
<td>4) Establishment of timing and event direction</td>
<td>4) Generalisability may be limited</td>
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<tr>
<td>5) Best evidence on which to make a judgement about the existence of a cause-effect relationship</td>
<td>5) Potential for loss-to-follow-up</td>
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**BIAS AVOIDANCE IN RCTs**

1) **Confounding** ➔ **Randomisation**
   - Deals with unknown confounding as well as known prognostic factors
   - Random allocation to study groups should balance known + unknown confounding variables
   - Differences in outcome then can (mostly) be confidently ascribed to differences in management, not differences in the make-up of the groups

2) **Measurement** ➔ **Blinding + Objective Measures**
   - Patient, treating staff, outcome measurement

3) **Selection** ➔ **Avoid losses to follow-up**
   - Eligible patients are those for whom all strategies under test are equally suitable
   - Patients who are lost to follow-up are not a random subset
     - Rapidly advancing disease
     - Sensitivity to side effects
     - Non-compliance with Tx

4) **Chance** ➔ **Confidence intervals, p-values**

**POTENTIAL ENDPOINTS (CVD)**

1) Death from any cause
2) Death from the target condition
3) Resolution of symptoms
4) Non-fatal CV events
5) Death or 1st major CV event

**Judging Endpoints**

1) Reduce **systemic** errors
   - Single blind
   - Double blind
2) Reduce **random** errors
   - Strict, reproducible criteria
   - Dual, independent assessments
3) Document **adverse outcomes**

**MEASURES OF TREATMENT EFFECT**

- **Case fatality at 5 yrs** = 4.0% (surgical) , 16.3% (medical)
  (cumulative incidence, risk, event rates [FER, CER])
- **Relative risk** (RR) = 7.6/16.3 = 0.47 (0.3 – 0.7)
  (risk ratio, case fatality ratio [CFR])
- **Absolute risk reduction** [FER-CER] = 16.3% - 7.6% = 8.7%
  (ARR, risk difference)
- **Number needed to treat (NNT)** = 100/8.7 = 12

ie, to save one extra life over 5 years, 12 patients with angina will need to be offered initial surgical intervention rather than medical therapy.
SURROGATE ENDPOINTS

Discuss the use and dangers of surrogate outcome measures in clinical trials

ENDPOINTS
- Outcomes that are measured during clinical trials
- Ideally trials should measure outcomes that are clinically important for patients
  - E.g. Impact of Tx on mortality or aspects of morbidity (Functional status, pain relief)

SURROGATE OUTCOME MEASURES / ENDPOINTS (SEP)
- A laboratory or physical sign that is used in trials as a substitute for a clinically meaningful endpoint that is a direct measure of how a patient feels, functions, or survives and that is expected to predict the effect of the therapy
  - Biomarkers serving as an endpoint of clinical effects because their changes show a statistical + mechanistically plausible association with the clinical endpoint
- Surrogate endpoints are useful when they can be measured:
  - Earlier
  - More conveniently
  - Or more frequently than endpoints of interest (referred to as “true” endpoints)

USES FOR SURROGATE ENDPOINTS
1) Replace distal endpoint with a more proximal one
   - Protein in urine as a marker for future renal failure
2) Can be measured more easily or frequently than clinically important endpoints (E.g. mortality)
   - HR, BP, RR, Temperature, instead of “sepsis”
3) Can be measured with higher precision, or less subject to competing risks
   - Change in the reproducible GCS as a marker for neurological state
4) Less affected by other treatment modalities
5) Reduced sample size requirements and faster decision making.

EXAMPLES OF SURROGATE ENDPOINTS
1) CD4+ Count: Effectiveness of HIV treatment or disease progression
2) BMD: Surrogate outcome for long-bone fractures
3) BP: Surrogate outcome for stroke
4) Ventricular Ectopic Beats (VEBs)
   - SEP for reduction in mortality post-MU when looking at effectiveness of ttx for arrhythmias

ADVANTAGES + DISADVANTAGES OF SURROGATE ENDPOINTS
- Effect of drugs could be thought to lead to clinical benefits but may ignore other effects
  - COX-2 inhibitors (Vioxx) have great effects on inhibiting COX and PG synthesis (markers) but they failed to pick up on the increased CVS adverse effects
  - Recombinant tPA is good at re-establishing blood flow (marker) following thromboemobolic stroke, but also increases the risk of haemorrhagic strokes

Hypertension:
- Only Thiazides have been shown to reduce mortality and morbidity
- Efficacy of other anti-HTNs are based on surrogate endpoint of ↓ing BP

Arrhythmias:
- Flecainide approved based on ability to settle irregular heart beats
- Post market trials showed ↑ed risk of death due to cardiac arrests
CD4 count and AIDS in HIV:
- Treatment with anti-viral although maintained higher CD4 count did not affect survival rates (CONCORDE trial)

<table>
<thead>
<tr>
<th>Potential advantages of surrogate outcomes</th>
<th>Potential disadvantages of surrogate outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Allow for reduced sample size, duration, and, therefore cost of clinical trials → fast track drug marketing + approval</td>
<td>• Very few surrogate endpoints have been introduced into routine clinical practice</td>
</tr>
<tr>
<td>• Allow estimation of effect of new tx under investigation → helpful in understanding MOA of drugs (e.g. phase II trials)</td>
<td>• True endpoints are usually complex and multi-factorial → rare to be wholly reflected by a surrogate endpoint</td>
</tr>
<tr>
<td>• May be more conveniently or more frequently measured than true endpoints</td>
<td>• Generally underestimate toxic effects and may not detect potential side-effects of a treatment which would render the new treatment unacceptable</td>
</tr>
<tr>
<td>• Used in situation where competing risks or true-end points are complicated by use of other tx e.g. CA tx</td>
<td>• Surrogate may not be in direct pathway between treatment and true endpoint or may be on the same pathway but insensitive to tx</td>
</tr>
<tr>
<td>• Allow TX to be assessed in situation when the use of primary outcomes would be excessively invasive or unethical</td>
<td>• TX effects may be mediated by a number of pathways only one of which includes surrogate endpoint.</td>
</tr>
<tr>
<td></td>
<td>• Often developed in animal models of disease (controlled conditions) → extrapolation to human disease?</td>
</tr>
</tbody>
</table>
APPLYING RESULTS OF CLINICAL TRIALS TO PATIENTS

WHICH TRIALS ARE MOST USEFUL
1) Practical clinical question
2) Good randomisation, blinding (x2 or x3)
3) All participants accounted for
4) Clinical and statistical significance considered
5) Clinically relevant outcomes
6) Adverse as well as positive outcomes reported
7) Participants described adequately (generalisability)

CLINICAL TRIAL FACTORS
1) Study objective
   - Competing interest
2) Methodology
   - Inclusion/exclusion criteria
   - Sample size
   - Blinding, controls, treatment arms
   - Definition of outcomes – true endpoints vs. surrogate endpoints
   - Biases, confounding issues
3) Statistical analysis
   - Confidence intervals
   - P-values (significance of results)
   - Null hypotheses
4) Results
   - Interpretation of results including precision + biases
   - Summary of limitations + strengths
   - Comparing results in context of previous studies
   - Absolute risk reduction
   - Number needed to treat (NNT)
   - Clinically worthwhile benefit of the intervention

PATIENT FACTORS
1) Safety
   - Short + long-term follow up
2) Efficacy
   - Vs. current ‘gold standard’ or Vs. no tx (if none exists)
3) Costs
   - PBS subsidy?
   - More or less expensive than current tx?
4) Compliance
   - Route of administration – oral, injections, rectal, inhalation etc.
5) Impact on quality of life/Clinical practice decisions:
   - Does it ↑ patient function, ↓ mortality or ↓ morbidity (True endpoints)
   - Or were outcomes surrogate endpoints?
6) Representation of study population to real patients
**SYSTEMATIC REVIEWS AND META-ANALYSES**

**REVIEW HIERARCHY**

**Narrative:**
- Traditional; based on expert opinion

**Systematic:**
- Research paper / explicit methods / data presented
  - Combining studies rather than data points

**Meta-analysis:**
- Data combination / summary

**Pooled analysis:**
- Combines original data

---

**Standard Narrative Scientific Review**

- Personal and idiosyncratic
- Incomplete survey
- Qualitative analysis
- Open to bias
  - Intellectual prejudice
  - Conflict of interest
- Recommendations often ‘go beyond the data’

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**SYSTEMATIC REVIEW**

**Process**
1) Formulate question(s)
2) Find all studies
3) Assess
4) Synthesise
5) Apply

**Structure**

**Introduction:** Sets research question

**Methods:** Search, exclusions, abstraction

**Results:**
- Pattern, differences explored
  - Summary if appropriate (Meta-analysis)

**Discussion:** Synthesis and interpretation, conclusions

---

**Presentation**

- ODDS RATIOS IN SYSTEMATIC REVIEW / META-ANALYSIS
  - If 2 interventions have an equal frequency of outcomes
    - OR = \( \frac{I_c}{I_o} \) (EER/CER) = 1
  - If new intervention has a lower frequency of outcomes
    - OR <1 (Left of the line)
  - If new intervention has a higher frequency of outcomes
    - OR >1 (Right of the line)
CONFIDENCE LIMITS IN META-ANALYSIS
• 95% CI limits define the range in which 95 of results would fall if the meta-analysis was repeated 100 times
• If this range excludes the value of the OR predicted by the null hypothesis ($I_e/I_o = 1$)
  ➔ Result is statistically significant at $p < 0.05$
• Practical rule ➔ CI limits that do not cross vertical line are statistically significant

ARE THE STUDIES CONSISTENT?
• Are variations in results between studies consistent with chance
  ➔ Test of heterogeneity: has low power
  ➔ If results studies differ greatly, may not be appropriate to combine results
• Inconsistent studies
  ➔ Variation in study methods (biases)
  ➔ Variation in intervention
  ➔ Variation in outcome measure (e.g. timing)
  ➔ Variation in population

ADVANTAGES OF SYSTEMATIC REVIEWS
1) Provide evidence of robustness and generalisability of the results
  ➔ Similar effects across a wide variety of settings and designs
2) Increased statistical power
  ➔ Many individual studies too small to detect modest but important effects
  ➔ Meta-analysis may reduce probability of false negative results

APPRAISING A REVIEW ARTICLE
Primary Guides
1) Did the overview address a focused clinical question?
2) Were the criteria to select articles for inclusion appropriate?

Secondary Guides
3) Is it unlikely that important relevant studies were missed?
4) Was the validity of the included studies appraised?
5) Were assessments of studies reproducible?
6) Were the results similar from study to study?
INFORMED DECISION-MAKING AND NEGLIGENCE

NEGLIGENCE
A duty of care
B breech of the standard of care (including failure to provide information)
C causal relationship between breech and damage (Legally caused the harm)
D damage

INFORMED CONSENT
- Phrase arose in the US, when failure to disclose risks + alternative counted as negating consent
  ➔ BUT, for Australia the phrase is misleading as it rolls two concepts that are two legal processes into one
    1. Consent/trespass
    2. Disclosure/negligence

- To avoid legal suits for battery, doctors need to advise patients of the nature, benefits & risks of procedures in broad terms only
- BUT to avoid suits in negligence, they need to advise patients in greater detail, since risks of a specific nature may persuade a particular patient not to undergo a procedure

CLAIMS FOR DAMAGES FOR MEDICAL MALPRACTICE
- Different factors which will be taken into account in determining the requisite standard of care depend upon whether case involves
  1. **Provision of information and advice**
     - No special medical standards or practice is involved
     - Skill is communicating the relevant information
     - In terms which are adequate for that purpose
     - Having regard to the patient’s apprehended capacity to understand that information
  2. **Diagnosis and treatment**
     - Responsible medical opinion will have an influential, often a decisive role
     - Re-emphasised in Civil Liability legislation: Modified Bolam test

THREE STANDARDS OF DISCLOSURE
1. Professional standard (Bolam: UK)
2. Reasonable (objective person standard (US))
3. Particular (subjective) person standard ➔ i.e. what particular patient deems relevant or material

1. **BOLAM PRINCIPLE (1957)**
- Professional determined standard
  - English and Australian courts for a long time accepted that:
    - Standard of care is that widely accepted by peer professional opinion by a significant number of respected practitioners in the field as competent professional practice
  - Known as Professional Practice Standard
    - Applies to all areas of practice ⇒ Diagnosis, treatment + disclosure of risks
    - Doctors needed only to indicate serious or frequent risks, or risks specifically asked about by the patient
  - Displaced by Rogers v Whittaker (1992) ➔ High Court of Australia

Australia ➔ RvW combines both notions


2. **ROGERS V WHITAKER (1992)**

- Mrs Whitaker was nearly blind in one eye and wanted corrective surgery to improve appearance in other eye
  - Procedure carried 1 : 14 000 risk of blindness in good eye ⇒ Subsequently occurred
  - Patient was not informed of risk despite repetitively inquiring about risks
  - If risk occurred it would impact significantly on her life
  - Court held that had she been informed of risk she would not have gone ahead with procedure

- **Court-determined standard for information disclosure**
  - Expert medical testimony is not relevant to issue of what should be disclosed to a patient to facilitate his or her decision making
    - Medical expertise per se does not extend to knowing what is significant to each and every individual
    1. *Dr has a duty to warn a patient of a material risk inherent in proposed treatment*
    2. *A risk is material if in the circumstances of the particular case:*
      - A **reasonable person** in the patient's position, if warned of the risk, would be likely to attach significance to it
      - OR The medical practitioner *is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it*
    3. *This duty is subject to the therapeutic privilege*
    4. *It is for the court and not “a reasonable body of opinion within the profession” to decide what risks are material*

- Australian courts began to move away from Bolam principle in 1980s
  - General rejection of medical paternalism
- Current professional practice still applies to standard of care (Diagnosis and treatment)
  - BUT does not apply to standard of disclosure (extent to which patient desires info)

**Results of RvW**

1) Rejection of Bolam principle
2) Distinction made between diagnosis + treatment cases and disclosure cases
3) Standard for disclosure would not be professional standard, and not just the reasonable person standard, but extended to include both reasonable person standard AND particular person standard

- Perception by some commentators that pendulum swung too far:
  - Courts readily making judgements in favour of patients + giving excessive damages
  - May have contributed to medical indemnity crisis

**MEDICAL INDEMNITY CRISIS + REFORMS TO MEDICAL NEGLIGENCE**

- Medical indemnity undergoing significant changes in response to:
  1. Perceptions of excessive premiums
  2. Excessive medical litigation
  3. Over-generous damages awards

- QLD passed legislation in 2002 that restricted damages awards in personal injury cases
- AMA pressured commonwealth government to reform medical indemnity system for:
  1. Capped damages awards
  2. National scheme for financing catastrophic injury claims
  3. Redefinition of medical negligence (according to perceptions of unfairness)

**Commonwealth → Ipp Review of Medical Negligence (2002)**

⇒ To propose law reform aimed at limiting liability + level of damages arising from personal injury + death

- **Recommendations**
  1. Keep rules for disclosure essentially the same as those given in RvW
  2. BUT swing pendulum back towards centre by changing the rules for determining standard of care in other areas (diagnosis + treatment)

Some elements incorporated into QLD’s Civil Liability Act 2003
CIVIL LIABILITY ACT 2003

- 2 different standards
  1. Disclosure (proactive + reactive duties)
  2. Diagnosis and treatment cases (Modified Bolam principle)

- A professional does not breach a duty provided that the professional acted in a way that was widely accepted by peer professional opinion by a significant number of respected practitioners in the field as competent professional practice (s22)
  ⇨ Peer professional opinion does not have to be universally accepted

Exceptions

1) If peer opinion irrational or contrary to written law (Don’t rely on idiots for back up)
2) Liability arising from the giving or failing to give a warning, advice or info in relation to the risk of harm to a patient (Peer professional opinion does not apply)

- Return to Bolam Principle in its wordings EXCEPT it includes an irrationality condition
  ⇨ Doctors + medical bodies have expressed general satisfaction with this outcome of the reform process
    - BUT it remains to be seen how courts interpret “widely held“ + “irrational”

Duty to Warn (s21)

- Recommendations of the Ipp Review ⇒ Restating RvW requirements
- No breach of duty to warn if patient is informed of the risk that:
  1. A reasonable person in patient’s circumstance would require to enable the person to make a reasonably informed decision about whether to undergo the treatment or follow the advice
     - Proactive duty
  2. The doctor knows (or reasonably ought to) the patient wants to be given before deciding
     - Reactive duty

- May weaken the test in RvW in respect of provision of info in some cases by imposing a greater level of objectivity on the patient’s position
  ⇨ “what the patient wants to know“ (Civil Liability Act)
  ⇨ Cf Rogers case ⇒ “what the particular patient would attach significance to”
    - E.g. unreasonable requests

<table>
<thead>
<tr>
<th>Time</th>
<th>Diagnosis + Treatment</th>
<th>Disclosure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bolam</td>
<td>Bolam</td>
</tr>
<tr>
<td>Rogers v Whittaker</td>
<td>Court (medical opinion)</td>
<td>Court (material risk)</td>
</tr>
</tbody>
</table>
| Civil Liability Acts | Bolam (modified) | Proactive duty
                          Reactive duty
                          (∼ = RvW) |

CAUSATION

- Successful negligence action requires that breach of standard of care legally caused harm
- Purpose of an award of damages is to restore the person, insofar as money can do so to the position they would have been but for the relevant breach
- Causation must be established on the balance of probabilities

1. US
  ➤ Reasonable Patient (Objective) Standard for Causation

- Negligence actions seldom succeed against procedures which are generally agreed to be necessary and important for patient welfare
  ⇐ Difficult for patient to persuade court that they would not have had the procedure, had they been better informed
  ⇐ Won’t hold that → but for the failure to warn, damage would not have occurred
2. High Court of Australia

Particular Patient (Subjective) Standard for Causation

- Patient sues Dr for inadequate disclosure of info leading to harm which could have been avoided
  - Patients cannot recover damages in “failure to warn” cases on the basis of the loss of a chance to make an informed decision
    - Must “positively establish” that they would NOT have undergone the operation had the warning been given.
    - Don’t have to demonstrate that any reasonable person would not have proceeded

Civil Liability Act 2003

- Judges issues subjectively, in light of all relevant circumstances
- Excludes post accident statements by person injured about what s/he would have done, unless against his/her interest
  - Rules out possibility of hindsight bias arising

Berger v Mutton

- A 48 year old nurse suffered recurring pain and bleeding → 2 years.
- Several procedures without negligence, but plaintiff’s bowel was perforated
- Plaintiff claimed she was not warned of the risk of perforation of the bowel
- As a result of the perforation, she suffered injury and damage
- Plaintiff claimed if she had been warned she would not have undergone the procedures
  - Plaintiff had seen devastating effects of cancer as a result of her professional experience.
  - The reason the plaintiff contacted the doctor was she feared she might have cancer.
  - Even if the defendant had informed her of the risks, the plaintiff would have had the exploratory procedures anyway.
    - i.e causation not established
    - ∴ no negligence

Therapeutic Privilege

RvW → High Court stated that the duty of disclosure was subject to “therapeutic privilege”
- Exception to general duty to disclose
  - Profession has a right NOT to disclose info in circumstances where the Dr considers on reasonable grounds that the disclosure itself would lead to significant harm to the physical or mental health of an unusually nervous, disturbed or volatile patient
  - Right demands a high threshold probability of significant harm
    - Given current views on patient autonomy + empirical evidence suggesting that patients usually benefit from knowledge + participation in decision-making
    - Anxiety + stress are insufficient harms to invoke therapeutic privilege
  - Justification may also exist for not imparting info when Dr reasonably judges that a patient’s emotional state is such that he would be unable to make the info a basis for rational decision

Withholding Information

- Information may be withheld in very limited circumstances:
  1. Medical emergency
  2. If the doctor judges on reasonable grounds that the patient’s physical or mental health might be seriously harmed by the information
- If patient expressly directs the Dr to make decisions and does not want the offered info
  - Dr should still give patient basic info about illness + proposed intervention
    - Document that patient didn’t want information
    - Also document that information given
NHMRC GUIDELINES ON PROVIDING INFORMATION TO PATIENTS

Content
1) Nature of illness
2) Proposed approach to investigation, diagnosis and treatment
3) Expected benefits
4) Common side effects
5) Material risks
6) Who will undertake procedure
7) Other options
8) The degree of certainty of any diagnosis or outcome
9) Likely consequences of not proceeding
10) Any significant long-term effects
11) Time involved
12) Cost involved (informed financial consent)

- Recommend disclosure of risks especially those which will influence the decision
- Information should be provided of known risks
  - Common though slight
  - Rare though severe

Presenting Information
1) Communicating info and opinions in a form the patient is able to understand
2) Allow sufficient time to reflect, ask questions and consult with significant others
3) Repeat key information to help patient understand and remember
4) Give written information or use diagrams where appropriate
5) Pay careful attention to patient’s responses to help identify what has/has not been understood

DEVELOPING AREAS OF INFORMED CONSENT

Informed Financial Consent
- AMA + commonwealth government are cooperating to ↑ provision of info regarding fees in relation to procedures and prostheses in order to ↓ incidence of patients discovering after the event that they may may be considerably more out of pocket than they anticipated
CONSENT TO MEDICAL TREATMENT

KEYWORDS
- Consent
- Competence
- Informed decision-making
- Disclosure
- Trespass
- Negligence
-Advance directives
- Research

ETHICAL BASES OF CONSENT
- Authorisation by a competent person of an action which affects the authorising person
  - Authorisation / Author / Autonomy
- Consent goes beyond agreement
  - Agreement usually concerned with belief
  - Consent has to do with a sense of acting
- Acting without consent is an infringement of a person freedom, bodily integrity and inviolability

ELEMENTS OF LEGALLY VALID CONSENT
- Consent must be obtained whenever medical Mx involves invasive procedures or risks

1. Voluntariness / Uncoerced
   - Decision must be made voluntarily and free from coercion
   - Doctors have a duty to refrain from influencing patients and to prevent patients from being coerced by family members or authority figures (police, lawyers)

2. Competence
   - Patient needs to be able to:
     1. Understand their condition
     2. Reflect on it in terms of their own values and beliefs
     3. Communicate a decision to others
     4. Accept decision
   - Patient must be sufficiently competent to make a reasoned, conscious, free and autonomous choice
     - NOT whether patient makes the absolute best choice possible
   - If a patient is found to be incompetent, any reversible causes should be treated.
     - If no reversible factors are found then decisions need to be reached through considerations of the patient’s advance directives or by surrogates (eg. family, doctors, the state)

3. Information Disclosure
   - Adequate information must be provided to enable the patient to make an informed decision
     - Current standard of disclosure is to tell each individual patient exactly what that patient would wish or need to know to make an informed decision that is congruent with his or her own life-goals
     - Patient should be allowed adequate time to make decisions and to seek alternative options or opinions

4. Comprehension
   - Dr must be satisfied that the patient appreciates and understands info provided
     - Many barriers to understanding (eg. time, terminology, emotions)

5. Other Legal Requirements
   1. Consent must cover actual procedure
     - Exception ⇒ Clause in most consent forms about necessary lifesaving actions in emergencies
   2. Procedure must be legal in itself (Eg. Euthanasia)
   3. Consent given to specific doctor
     - Except in public hospital situations where consent is given to a Mx team

Exceptions?
CAPACITIES THAT DEFINE A COMPETENT PATIENT

- Patient’s capacity to make autonomous decisions

1) Comprehend nature of situation (E.g. Rx)
   - Receive, comprehend, retain + recall relevant info
2) Integrate the info received and relate it to one’s situation
3) Evaluate risks / benefits in light of values
4) Ability to foresee consequences of decision
5) Decide / Choose / Persist
6) Act
7) Communicate / account for choice

CONSENT IN EMERGENCY SITUATIONS

- Where consent cannot be obtained (e.g. unconscious), consent may not be required if:
  1. Not offering treatment may cause great harm to the patient
  2. Treatment is urgent in terms of hours or day NOT weeks or month
  3. There are NO specific prior instructions against treatment (E.g. AHD)
- In these cases the Dr is protected by common law defence of “necessity”

CONSENT AND THE LAW OF TRESPASS

- Performing a procedure without valid consent is an invasion of the person’s body = trespass
- Trespass is a tort (civil wrong) involving a wrongful direct interference with another person

Trespass can be:

1. Assault: Intentional or reckless act causing someone to be put in fear of harm
   - Not necessarily causing harm
2. Battery: Intentional or reckless application of physical force without consent
   - With or without damage
- Medical assault/battery via fraud, deception or force may be punished in criminal law
  - E.g. Dr sedates patient to indulge in sexual activity with them
- More commonly medical assault/battery are dealt with under the CIVIL tort of trespass
  1. Most cases are unintentional
  2. Primary aim is for compensation

Trespass is actionable per se

- Even if life saved (E.g. Jehovah’s witness life saved ⇒ Malette v Schumann)
- Patient does NOT have to prove damage has occurred
  - cf negligence where patient has to prove damage was done

TRESPASS VERSUS NEGLIGENCE

- Can ONLY sue for trespass where no valid consent was given
  - Blood transfusion despite AHD (intentional)
  - Dr operates on right arm when patient consent operation on left arm (reckless)
- BUT consider a case where a patient develops complications of which she was not adequately informed following a procedure the patient consented to
  - Patient CANNOT successfully sue for trespass
    1. Patient had a general understanding of proposed operation
    2. Dr did not do anything that patient did not authorise

Negligent failure to disclose relevant risks

- Consent ⇒ But reduced quality of consent (Dr failed to disclose relevant risks)
- Patient can sue Dr for NEGLIGENCE
  - Inadequately informed in terms of what’s relevant to patient
  - Dr failed to satisfy legal standard of care relevant to disclosure
  - Patient must demonstrate to court that had they been warned of risks, they wouldn’t have had procedure
- Generally less blameworthy than trespass
Insufficiently informed decision making ➔ Actions in NEGLIGENCE
 lorsque Requires a more extensive disclosure of risks / benefits

Invalid consent ➔ Actions in TRESPASS
 lorsque Requires only a broad indication of natures and consequences

SUBSTITUTE DECISION MAKING
A number of laws provide for substituted decision making:
1. Power of Attorney Act 1998 (Qld)
   - Allows AHD, Enduring Power of Attorney, Statutory Health Attorney
     - Automatically next of kin if haven’t appointed one

2. Guardianship and Administration Act 2000 (Qld)
   - Establishes Guardianship & Administration Tribunal
     - Appoints adult guardians
     - Settle disputes
     - Consent Special Health Care (Tissue Donation, research, psychosurgery, ECT, sterilisation)

   • Special Health Care can only be consented to by a competent person (directly or Advanced Health Directive) or by the Tribunal
     lorsque NOT attorneys
     lorsque Withdrawal of life-sustaining Tx is NO longer Special Health Care
       • ∴ attorney can approve

HEIRARCHY OF GIVING CONSENT
1) Competent patient
2) AHD
3) Guardian
4) EPoA
5) Statutory health attorney ⇒ Spouse, carer, close friend
6) Adult guardian
7) Guardianship and Administration tribunal
8) Mental Health Act

WAYS TO GIVE CONSENT
1) Current (Given at time) or Advance (AHD)
2) Written or Verbal
3) Expressed (formal, explicit) or Implied (rolling up sleeve for injection)
   • Generally more serious interventions require formal consent
     lorsque E.g. BM transplant
       • An example where both explicit + implied consent are utilised
       • Expressed consent will be obtained at the outset after the patient is appraised the broad nature of the procedure
       • During transplant, which involves a number of separate events, consent is implied for the less significant interventions (E.g. taking temperature)
       • Separate consent form may be completed for more invasive procedures
         • Crucial aspect is the continuing communication between health professionals + patients for the duration of the process

WHO IS RESPONSIBLE FOR CONSENT?
• Clinician responsible for patient’s care is responsible for obtaining consent for interventions
   lorsque This responsibility is often delegated to junior staff
     • Often been poorly performed through no fault of those staff but often as a result of time constraints and procedural inadequacies

• If junior staff obtain consent from patients ⇒ they must be aware of all requirements of task
• Senior staff must be aware of their responsibilities to both patients and their junior colleagues in the matter of consent
COMPLIANCE

FACTORs INFLUENCING COMPLIANCE AND NON-COMPLIANCE

• Non-compliance is very common ➔ up to 50% of patients
  ➔ Difficult to estimate whether a patient is compliant

IMPACTS OF NON-COMPLIANCE
1) Underlying condition remains untreated
2) Increases the risk of over-medication
3) Increases financial burden of health care on the community
4) Distort conclusions of research about best practice for specific illnesses (EBM)

PREDICTING PATIENT ADHERENCE
• There are 4 factors related to the health belief model that help predict whether a person is likely to be adherent:
  1. Degree to which the patient is concerned about health issues
  2. Perceived susceptibility to an illness or adverse outcome
  3. Seriousness of the consequences of an adverse outcome through nonadherence
  4. Benefits and costs of the recommended actions, including emotional costs, inconvenience to the patient, or possibility of adverse effects

CAUSES OF NON-COMPLIANCE IN PATIENTS WITH A CHRONIC ILLNESS

Patient Related
1) Misunderstanding of prescribing instructions
2) Lack of understanding of the condition, its significance and importance of treatment
3) No faith in the drug’s effectiveness
4) Concern about taking drugs
   ➔ E.g. adverse-effects, addiction
5) Financial concerns
6) Physical and cognitive disabilities
   ➔ E.g. swallowing tablets or opening containers, poor memory
7) Mental illnesses (E.g. Psychosis, depression)
8) Difficulty with access to health care services
   ➔ E.g. distance + time
9) Social stigma with using ‘drugs’

Drug-related
1) Unpleasant adverse effects
2) Complex regimen
   ➔ E.g. frequent dosing, many drugs
3) Unpleasant taste or smell
4) Interference with lifestyle
   ➔ E.g. Driving, alcohol
STRATEGIES TO INCREASE COMPLIANCE

**INTENTIONAL**

⇒ When the patient rejects the diagnosis or treatment

**Patient Centred Care**

1) Adopt a partnership approach and involve the patient in their own care/decision making
   ⇧ Movement to **concordance** instead of compliance

2) Important to develop open, communicative, **non-judgmental** relationships with patients

3) Communication with patient is essential in order to understand their health beliefs, feelings about their condition and medications, barriers to adherence and any conflicting priorities.
   ⇧ Patients follow physician advice more often when they think the encounter was long enough and allowed for them to deal with their agenda as well as that of the physician

4) Ensure that the patient understands their condition and treatment.
   ⇧ Educate and discuss treatment options and the risks vs benefits of treatment
   ⇧ Educate about possible adverse effects of treatment and what to do if they occur

**NON-INTENTIONAL**

1) Simplify treatment where possible
   ⇧ E.g. Fewer drugs, doses and easier to use dosage forms

2) Tailor treatment plans to patient’s preferences, needs and capabilities
   ⇧ E.g. fitting treatment into daily activities

3) Use basic communication skills to facilitate understanding and improve recall
   ⇧ Brief, explicit, personal instructions repeated at the end of the encounter
   ⇧ Printed instructions and education material
   ⇧ Encourage patient to ask questions and express confusion
   ⇧ Ask patient to verbalise their understanding of the disease and treatment plan
      • Correct misunderstandings

4) Use dosing aids (e.g. Webster packs) to organise multiple medications and minimise the risk of medication errors

5) Encourage regular reviews and ongoing monitoring of adherence levels
   ⇧ Encourage patients to see a GP even when they are feeling well

6) Develop systems (e.g. reminders) to prompt patients on long-term treatment programs
   ⇧ Telephone reminders, individualised reminder charts, diaries

7) Enlisting the help of family members and other health care professionals (including pharmacists, case managers)

| C | Communicate with patient to identify and address any issues and misconceptions |
| O | Optimise recall and understanding with good communication techniques |
| M | Make it easy - simplify treatment regime, use dosage aids |
| P | Partnership - get patient involved in their own care (concordance) |
| L | Longterm review and evaluation should be done regularly |
| I | Inform the patient about their condition, treatment, benefits and side effects |
| A | Adopt treatment plan to individual needs and habits |
| N | Nag the patient - develop system of reminders (e.g. Telephone reminders) Don’t say nag in exam |
| C | Collaborate with family and other health workers |
| E | Encourage the patient and provide positive feedback |
STEREOTYPING AND COUNTER-TRANSFERENCE

TRANSFERENCE
Phenomena where patient unconsciously transfers feelings and attitudes from a past relationship onto their current doctor

- Positive or negative feelings about the doctor
- Some overlap with alliance

- Characterised by development of irrational + intense emotions disproportional to anything the doctor has said or done
  - E.g. Patient begins to unconsciously see therapist as a parent and transfer emotions of real parent onto doctor
  - Patients will treat doctor as though they are playing the complementary role (parent) and unconsciously “nudge” doctor to take on these feelings and behaviours

POSITIVE TRANSFERENCE
- Usually helpful or productive
  - More likely to accept recommendations
  - Get involved in health care
  - Return for follow-up

- Can be problematic when transference is positive engagement to Dr rather than Tx process
  - Dependent patient ⇒ Constantly returns for visits when unnecessary

Strategies for Responding to Positive Transference
1) Idealising Transference
   - Recognise underlying need for positive identification
   - Do not collude by hiding personal faults and failures
   - Acknowledge achievements and responsibility of the patient (E.g. lifestyle changes)

2) Erotic Transference
   - Maintain professional but not aloof or cold approach to patient
     - I.e. no collusion
   - If persists + depends ⇒ Refer patient to a colleague

NEGATIVE TRANSFERENCE
- Usually problematic
  - Failure to continue treatment
  - Failure to follow advice

POSITIVE TRANSFERENCE AND ALLIANCE
- Positive alliance maximises the ‘placebo effect’ in any treatment
  - E.g. Alliance strongly predicts treatment response in depression

- Positive alliance means
  1. Expectation of a successful outcome
  2. Shared goals and shared understanding of treatment process
  3. Experience of the doctor as competent and caring
COUNTER-TRANSFERENCE

- Unconscious, irrational + powerful feelings **doctor develops for patient**
  - Intense emotional response to a person without obvious basis
  - Activated in clinical or other close interpersonal situations
  - Positive or negative feelings
    - Positive feelings usually favourable but may lead to boundary problems
    - Negative feelings create risk of deficient clinical care

- Can be in response to:
  1. Patient’s transference ⇒ Adopt complementary role
  2. Patient’s characteristics remind doctor of a previous relationship
    - Independent of transference

- Sometimes counter-transference is used very loosely to refer to any feelings the doctor develops in response to the patient
  - E.g. Response to perceived negative non-verbal cues (Expression, posture etc)

**Positive Counter-Transference + Alliance**

- Effective alliance requires something approximating “unconditional positive regard”
- Positive regard must be genuine rather than contrived
- Positive regard must not be eroticised

**Negative Counter-Transference + Alliance**

- Maintaining alliance depends on ‘containing’ negative transference
- Negative emotional reactions to patients cannot be avoided or ‘denied’
  - Need to be acknowledged (but not necessarily shared with patient)

STEREOTYPING

- Attribution of a global set of characteristics on the basis of one or more observed characteristics
  - Pre-existing negative attitudes + behaviours to particular group (E.g. fat people)
- Culturally based
- May be positive but often negative
- Can result in failure to properly diagnose because of operating assumptions
  - People with mental illness less likely to have physical health problems diagnosed and treated
- Form of prejudice
  - When prejudice is widespread, a group of people may become **stigmatised** and an individual may internalise the stigma as part of their personal identity

**STEREOTYPING, COUNTER-TRANSFERENCE AND ETHICS**

1) Stereotyping + counter-transference can impact on key cognitive processes essential to medical practice
   - Observation
   - Clinical reasoning
   - Formulation

2) Stereotyping and negative counter-transference are threats to beneficence
3) Stereotyping and negative transference are threats to non-maleficence
4) Positive counter-transference may threaten professional boundaries
SITUATIONS WHERE DOCTORS ARE SUSCEPTIBLE TO NEGATIVE COUNTER-TRANSFERENCE

1. Feeling Helpless
- When doctor has no effective treatment to offer
  - Unable to channel emotional distress into treatment
  - Have to deal with patient expectations and feeling inadequate
  - May lead to patient blaming

2. Non-compliance
- May attribute non-compliance to negative patient characteristic (e.g. passive-aggressive)
  - Transference ➔ Patient feels doctor is pressuring them to perform and unconsciously tries to fail as an expression of anger and an attempt to defeat

3. Feeling Disrespected
- Doctors may feel their status is not respected when patients try to take charge of the interview by asking for specific treatments or querying recommendations
- Patient seen as “manipulative” & “controlling”
- Negative feeling expressed as submitting to demands even if they’re not optimal
  - “let them stew in their own juices”
  - OR refusing even when demands are clinically sound (“show them who is boss”)

COUNTER-TRANSFERENCE IN OBESITY
- Obesity is generally better understood within the frameworks of prejudice and stigma because it concerns a whole class of people
  - BUT classical counter-transference may occur with a doctor who has had an obese parent or has obesity issues
- E.g. Patient may become so preoccupied with their weight that they believe all their problems would go away if they lost weight
  - Dr may become frustrated by the pt’s pervasive negative appraisal of themselves or be tempted to agree with the patient
- Patients who lose weight and then frustrate doctor by binging may produce counter-transference responses of anger, helplessness & ineffectiveness

DEALING WITH COUNTER-TRANSFERENCE
1) Reflect and scrutinise own feelings and motives and be aware that we all have “blind spots” and can be affected by patients
2) Be willing to acknowledge prejudice and counter-transference if they occur
3) Discuss with team to clarify what a patient is transferring and use a psychotherapist to help understand what the patient is unconsciously communicating

BALINT GROUPS
- Meetings in which doctors (especially GPs) explore the emotional experience of patient care
- Facilitated by people trained generally in psychotherapy and specifically in working in group settings with doctors
- Assist with identification of stereotyping + counter-transference as well as with development of capacity to respond effectively to the cognitive and emotional consequences
IMPACT OF SOCIOECONOMIC FACTORS ON RURAL HEALTH OUTCOMES

GENERAL DETERMINANTS OF HEALTH
1) Socioeconomic Status
2) Demographics
   - Ageing populations
   - Geographic location / isolation
   - Climate
   - Access to information
   - Attitudes towards health
   - Illness and disability
3) Environmental and lifestyle factors
4) Ethnicity
5) Employment
6) Industry base of rural communities
7) Others
   - Risk-taking behaviour
   - Poor uptake of health promotion + self care messages

FACTORS CONTRIBUTING TO RURAL HEALTH DISADVANTAGE
1) Geographic isolation and problems of access to care
2) Shortage of health care providers and health services
3) Socioeconomic disparities
4) Greater exposure to injury ➔ especially farmers + miners
5) Lower road quality
6) Small, sparsely distributed populations
7) Indigenous health needs
   - Insufficient indigenous health care workers
   - Inappropriate health care services (not tailored to meet needs of indigenous community)
8) Lack of support for community health programs + government initiatives
   - Also lack of support for health care workers

RURAL/REMOTE VS METROPOLITAN

Sociodemographics
- ↓ life expectancy for male + female living in capital cities compared to RR areas
- Female life-expectancy: 81.2, 80.8 + 77.4 years (metropolitan, rural + remote respectively)
- Male life-expectancy: 75.6, 74.6 + 71.5 years (metropolitan, rural + remote respectively)
- ↑ fertility rates in rural and remote compared to capital cities
  - 2.2 children / woman compared to 1.7 children for women living in capital cities
- ↑ socioeconomic disadvantage with ↑ing distance from a major urban centre indicated by:
  - Economic resources
  - Education and occupation
  - Disadvantage
- ↓ SES: Means less likely to have private health insurance, less likely to own a car

Health Status
- Death rates in capital cities 6% lower than large rural centres + 20% lower than remote
  - ↑ mortality from injury with ↑ remoteness ⇒ particularly males
  - ↑ road vehicle accidents with ↑ remoteness
- Hospitalisation
  - ↑ hospitalisation rates in rural and remote injuries, falls (>65 years) and burns
- Higher rates of high alcohol consumption + ↑ smokers outside of metropolitan areas
- No significant differences seen in breast cancer screening and Pap smear testing
REFUSAL OF TREATMENT

KEYWORDS
- Refusal of treatment
- Consent
- Autonomy
- Rationality
- Competence
- Duty of care
- Emergency
- Resource allocation

LEARNING OBJECTIVES
1) Explain the ethical bases for
   - Patients’ right to refuse treatment
   - Need to interpret treatment refusals
2) Explain difference between over-riding a patient’s refusal of treatment and treating a patient without consent
3) Describe legal provisions supporting patients’ rights to refuse treatment

AUTONOMY, CONSENT + REFUSAL
- Decision to refuse treatment is a personal one NOT a medical one
  - Although it must be informed by medical knowledge
  - We should be able to determine our future according to our own interests, desires + values

- Common law upholds a straight rule of “negative liberty” which applies to health care:
  1. You have no right to treat me if I have refused to authorise that treatment
  2. If I am treated against my will, I may pursue an action in battery against the treating doctor;
  3. “Competent patients are entitled to refuse treatment, even though such refusal may lead to death”

- There is SYMMETRY between refusal of treatment and consent to treatment
  - Valid refusal of treatment requires the satisfaction of the same conditions as consent to treatment. Decision must be:
    1. Voluntary
    2. Informed
    3. Made by a competent person
    4. For a specific procedure

- There are some challenges to this symmetry, especially concerning the standard of competence required for refusal of treatment as opposed to consent

- ALSO There is asymmetry between the rights of minors to consent to or refuse treatment

INTERPRETING TREATMENT REFUSALS
1. DUTY OF CARE + QUESTIONS OF COMPETENCE
- Common law + specific Acts protecting patient’s right to refuse treatment AND protecting doctors from being prosecuted when they act in accordance with treatment refusals, depend on the link between competence and personal autonomy
- Medical duty of care motivates doctors to act in the patient’s best interests
  - Ethical difficulties arise when competent patients refuse treatment which appears to be in their interests (assessed from an objective medical point of view)

In Medical Law:
⇒ All adults presumed to be competent until & unless that presumption is rebutted
  - Doctors must show positively that someone lacks decision-making capacity
  - Not up to patients to prove that they are competent
    - Onus is on doctor to demonstrate incapacity
    - Must demonstrate some deficiency in the cognitive functions which constitute competence
Assessing Competence
1) Comprehend + retain relevant information
2) Understand nature and effects of decisions
3) Evaluate information + predicted consequences in relation to one’s situation, goals + values
4) Offer reasons for one’s decisions (justification)
5) Communicate one’s decisions to others
6) Ability to follow through with decision

Factors Affecting Competence
1) Patients change their minds
2) Medical conditions, both transient and chronic, may affect decision-making capacity
3) Depression may reduce competence
   - Major depression in elderly is associated with a ↑ number of life-saving treatment refusals, which is reversed significantly where the depression is treated
     - More respectful of a patient’s autonomy to treat a condition which is reducing their decision making capacity than to agree to a treatment refusal without exploring its possible causes/motivations.

Exploring Refusal
- It is a medical duty to explore motivations for refusing recommended treatment
  - In some cases, immediate agreement by doctor not to treat, or to withdraw/withhold treatment may amount to abandonment of the patient
  - Refusal may result from:
    1. Inadequate knowledge or understanding
    2. False beliefs concerning medical implications of treatment OR risks of treatment or medical conditions. Remember

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Doctors’ Bias in Interpreting Refusal
1) May tend to define a patient as incompetent, just because they refuse treatment
2) May interpret the scope and specificity of refusals of treatment through AHD differently from how things were intended by the patient (differing values between patient and doctor)
3) Tendency to think that “Presence of significant risks of treatment refusal should demand a higher level of competence of patients refusing treatment than that required of a patient consenting to having treatment”
   - ASSYMETRY between consent and refusal based on risk

Risk-Related Standard of Competence ➔ A Type of Assymmetry
- Seems appealing since it suggests that patients will be protected from dangerous decisions
  - BUT ⇒ Questionable whether or not there can be different levels of competence, according to seriousness of risk
- In serious cases, patients should be given high quality information and explanations and it should be clearly established that the patient is competent in relation to the situation and the information
  - Rather than insisting on some higher “level” of competence which makes no sense
2. COMPETENCE, RATIONALITY + AUTONOMY

Comptence: A capacity in terms of one’s own beliefs / values
Rationality: Reasons / grounds / content of beliefs and values

- In some cases, a doctor may consider a patient to be technically competent, BUT they are making an irrational decision
  - Someone may be competent in terms of their beliefs
  - BUT doctors may consider the beliefs themselves to be faulty
    - .: Will want to persuade them to a different view (perhaps by pointing to some evidence against the belief/inconsistency in the belief)
- Difficulty = There is a strong expectation that doctor’s respect patient decisions and that the ultimate grounds for decisions are the patient’s alone
  - BUT if patient desires are based on false or inconsistent beliefs/faulty reasoning, the is arguably false autonomy
  - To deeply respect autonomy, doctors should arguably interpret, educate & correct these beliefs/reasoning as far as possible, as well as exploring possible external influences on decision to refuse treatment

Two Kinds of Irrationality
1) Procedural: Inconsistent beliefs or faulty reasoning are prominent
   - Amounts to incompetence
   - Faulty reasoning → Does not satisfy conditions for competence
     - Can not clearly understand + evaluate information
     - BUT Consider continuum of rational persuasion → pressure → coercion
2) Substantive: Labelling a belief/preference as irrational because you don’t agree with it

3. LEGAL POSITION

1) In recent years, common law has attributed significant decision-making autonomy to patients
   - English case → “The patient’s right of choice exists whether the reasons for making that choice are rational, irrational, unknown or even non-existent”.
2) Schizophrenic patient won an injunction restraining doctors from amputating gangrenous leg
   - Accepted that he weighed in the balance the information given to him in light of his particular values (he preferred to die with 2 feet than live with 1) and that his mental condition did not interfere with this process
     - .: Legal competence or capacity, as defined in this case, is essentially procedural rather than a substantive matter
3) Another case involved refusal by a patient to a brain scan because she hated needles
   - Judged that she was unable to discuss the procedure reasonably and therefore to give valid refusal, due to her delusions + medical state
   - Judged that her mental condition DID interfere with her ability to weigh up options
     - .: Technically incompetent

4. INFORMED REFUSAL

- Refusal of treatment by a competent patient will be invalid if it is insufficiently informed

  - Legally valid consent → Requirement = Patient be broadly informed of nature of procedure
  - BUT for fully informed decision making, everything which is materially relevant to the patient should be disclosed, in order to follow a doctor’s duty of care
  - Refusal → While info provision would only need to indicate the broad nature of things, in order to be symmetrical with requirements for consent, a middle path is generally supported
    - I.e. “foreseeable consequences of undergoing or not undergoing Tx are elaborated”
    - Patient must not only understand what is involved (competence) but it is clear that they must understand things which are materially relevant to them
      - Especially in more serious cases

Competence doesn’t depend on the amount of information given the patient
- Greater or lesser amounts may be given + assessment of competence depends on whether patient understands the information that has been provided.
- Doctor’s failure to provide information sufficient for informed decision-making DOES NOT imply incompetence
FORMS OF REFUSAL
1) **Verbal:** Either for themselves or others  
   - E.g. refuse to take advised treatment OR have child vaccinated
2) **Action:** Illustrates unwillingness to undertake treatment and **constitutes refusal**  
   - E.g. leaving a hospital
3) **Statutory Provision:** More formal methods of indicating and documenting refusal

DEVELOPMENTS IN THE LAW & SPECIFIC LEGAL INSTRUMENTS
1) All Aust jurisdictions (except NT) have legislation **enabling substitute decision-makers to refuse medical treatment under certain conditions**  
   - QLD, Vic, SA, ACT + NT have legalised **advance health directives**  
     - Provide for treatment refusals in advance, to operate once a patient has lost his / her decision-making competence
2) **QLD Power of Attorney Act (1998)**  
   - Provides for the appointment of an attorney for health matters and the writing of advance directives
3) Various legal instruments support common law right to refuse treatment  
   - BUT they also provide for various **formal procedures** for refusal, and various obligations, restrictions & protections for those involved, including doctors  
   - ∴ Formalise and entrench the common law right to refuse treatment

REFUSING TREATMENT FOR CHILDREN
1. JW refusing blood transfusions
2. Refusing childhood immunizations
3. Refusing newborn screening tests

- Parental power to consent to treatment operates until child achieves mature minor status  
- Parents should make medical treatment decisions on basis of **best interests** of child  
  - Since child cannot make decisions autonomously  
  - Best interests made up of medical interests (physical + psychological) but also wider social considerations to some extent
- In emergency situations ➔ **medical interests legally predominate**  
  - Statutory provision in all states for provision of blood transfusion when child’s life is in danger ➔ Despite protest or refusal by parents
- In support of both mandatory screening where it exists, and of incentives to screening, are arguments, which appeal to the idea that children should be afforded an “open future”  
  - I.e. Values of the parents should not interfere with what the child may decide in the future, or prevent the child from developing into someone who can so decide
- Other arguments for screening are that failure to screen will commit the community to avoidable costs in supporting seriously disabled people

PROBLEM OF RESOURCES
- One concern of the London doctor who ordered his patient to hospital was his  
  "Responsibility towards the community nursing staff + other patients in locality not to allow scarce and valued resources to be consumed by a futile + irrational treatment strategy"
- **Do patients have the right to refuse treatment X, if alternative treatment Y is significantly more costly?**  
  - When there are no concerns about competence and rationality, we tend to accord what amounts to an absolute priority to autonomy, and respect a person’s right to refuse treatment  
  - Question of resources should make us think about this absolute priority  
  - To what extent should we respect someone’s competent preference if this contributes to an unjust distribution of resources
TREATING WITHOUT CONSENT

General rule is that consent must be obtained from someone for all medical treatment.

DIFFERENCES BETWEEN OVER-RIDING REFUSAL + TREATMENT WITHOUT CONSENT

- Over-riding a patient’s refusal of treatment when that patient has been deemed competent is not only over-riding their autonomy (strong paternalism), it is also illegal and may result in a charge of battery (assault).
- Treating a patient without consent (weak paternalism) most often occurs in the context of emergency treatment.
  - In this case treatment is legal under the doctrine of necessity (& proportion) + complies with the ethical principles of beneficence and non-maleficence.
- The law states that treatment can be administered without consent when there is an immediate danger to the person’s life or health.
  - Provided there is no knowledge of advance health directives etc.

EMERGENCIES

- Only reasonably clear cases where treatment without consent is generally accepted.
- May require treatment without the consent because consent cannot be given.
  - BUT is reasonably regarded as implied.
  - NOTE – in JW type cases, where an express refusal of treatment under certain conditions has been previously issued, consent cannot be automatically regarded as implied, despite the emergency nature of the case.

PATIENT NOT COMPETENT TO REFUSE

- Incompetence does NOT allow treatment to proceed without consent.
  - Must identify relevant decision-making person or authority in the circumstance.
  - E.g. May have an AHD, appointed substitute decision maker.

Case ➔ Victoria 2003

- Husband of a sufferer of Pick’s dementia who had been fed through a PEG tube for 3 years applied to have the tube removed.
- Was determined that, as medical treatment, the tube feeding could be removed under Victoria’s Medical Treatment Act 1988, and this was confirmed in Victorian Supreme Court.
  - In effect, consent for continuing treatment was withheld by the patient’s husband.

MINORS

- Some English courts have imposed an asymmetry between minor’s consent and refusal.
  - Higher standard of decision-making competence is required in cases of refusal (Esp. if it would lead to death or serious morbidity).
  - Arguably technically competent refusal (made by Gillick-competent minor) may be overridden by a court.

MENTAL HEALTH LEGISLATION

- In some cases ⇒ Patient who is mentally ill will refuse treatment.
  - Under certain defined conditions, such a refusal may be overridden by the provisions of the Mental Health Legislation.
  - ∴ A person who satisfies the requirements of competence may still be involuntarily detained under such conditions.

PATIENT’S BEST INTERESTS

- Best interests are accepted as part of the justification for treating without consent when consent cannot be given.
  - BUT in cases of competent refusal, the patient’s autonomy would be infringed by the imposition of somebody else’s view of their best interest.

WHERE REFUSAL DOES NOT COVER A NEW SITUATION OR IS TOO NARROW IN SCOPE ➔

Including advance refusal by way of AD.
- Both consent and refusal may be invalid when circumstances change.
- This will give rise to difficult cases of interpretation as to whether, for example, a particular advance refusal covers a particular situation.
MEDICAL CONDITIONS ASSOCIATED WITH CIGARETTE SMOKING

**GENERAL**

1) **Cancer:** Lung, lip, tongue, mouth, pharynx, oesophagus, pancreas, bladder etc
   - Smoking is associated with almost all cancers
   - May ↓ risk of endometrial cancer

2) **COPD**

3) **CVD:** Coronary heart disease, stroke, atherosclerosis

4) **Peripheral vascular disease (PVD)**
   - Diabetes mellitus & cigarette smoking are the 2 major risk factors for PVD & subsequent amputation of lower limbs

5) **Peptic ulcer disease**
   - Studies have found that cigarette smoking (nicotine in particular) is causally associated with PUD through alterations to gastric acid secretions & impairment of the protective mucosal stomach lining

6) **Lung Immunodeficiency**
   - ↓ functioning of lung immunity leading to serious infection (E.g. pneumonia)

7) **Chrn’s Disease**
   - Risk factor for developing Crohn's Disease & may also be a factor in recurrence of the disease following surgery
   - ~36% of Crohn's Disease in men & 40% in women is caused by smoking

8) **Surgery**
   - Smoking is a major risk factor relating to surgery & post-op period due to the effects of smoking on tissue oxygenation, heart rate, airways clearance, immune response, & circulation.

9) **↓ Wound healing**

10) **Cataract development**
   - Smokers of twenty or more cigarettes a day increase their risk of developing cataracts by up to three times compared to the risk of never-smokers or former light smokers
   - Former moderate to heavy smokers appear to carry some excess risk of developing lens opacity

11) **Back pain**
   - Smoking is among RFs for back pain + appears to be independent of other RFs
   - Dose-response relationship is evident between heavy smoking & severe pain
     - May be due to impaired blood flow to the spinal region, making it more vulnerable to injury, jarring from constant smoking-caused coughing or diminished bone mineral content

12) **Snoring**

13) **↑ abnormal spermatozoa**

**MATERNAL SMOKING**

1) ↓ birthweight of infant
2) ↑ foetal + neonatal mortality
3) ↑ asthma

**PASSIVE SMOKING**

1) ↑ risk of asthma, pneumonia, bronchitis in infants of smoking parents
2) ↑ cough + breathlessness in smokers and non-smokers with COPD + asthma
3) ↑ risk of cancer
PUBLIC HEALTH ISSUES RELEVANT TO SMOKING

- Smoking is the **LEADING** modifiable cause of premature mortality and morbidity
  - Most researched + clearest cause of disease in the history of biomedical research
- Causal relationships cannot be **DIRECTLY** evaluated due to ethical constraints on giving people cigarettes
  - **BUT** Smoking has been shown to meet **Bradford Hill criteria**
    1. Temporality
    2. Consistency
    3. Strength of Association
    4. Dose-response Relationship
    5. Biological Plausibility
    6. Specificity
    7. Experimental Evidence
    8. Analogy
    9. Biological Coherence

EPIDEMIOLOGY

- Australia ➔ 21% of male deaths + 8.8% of female deaths due to smoking-related causes
- Major cause of cancers, coronary heart disease, cerebrovascular disease & COPD
- ~25% of Australian smoke regularly (2001)
  - 25% of men over 14
  - ~20% of women over 14
- Prevalence of smoking has declined over the last 15 years **BUT** not among women
  - Prevalence is higher in lower SES

DOSE-RESPONSE RELATIONSHIP

- Risk of respiratory disease ↑ with
  1. Younger starting age
  2. Number of cigarettes smoked
  3. Duration of smoking
- If stop smoking ➔ After 10 yrs, risk of lung cancer is **1/2 to 1/3** of a continuing smoker
- Stopping before the age of 30 avoids 90% of risks associated with smoking
- COPD smokers can improve their lung function if they quit while young
  - Quitting when old ⇒ no improvement in function but further deterioration follows that of a non-smoker

**Slight LEFT shift of the mean (↓ %FEV1) with more pack years smoked**

↑ Pack Years ➔ ↑ Lung Disease

- Note that relationship relates to PACK YEARS
- Pack Years (PYS) = Packs/Day x Years of Smoking
- A person that continues to smoke a small amount for a number of years may be better off than someone who has smoked an enormous amount for a shorter time & has stopped smoking
- Even if a patient cannot be persuaded to stop smoking, it is helpful to encourage them to cut down on their numbers of cigarettes per day
- Also relevant to Policy Implementation
  - ↑ ‘Smoking age’ (for purchasing) = ↓ fewer PYS young starters will amass leading to better health outcomes even if they eventually start smoking anyway.

<table>
<thead>
<tr>
<th>Number of cigarettes smoked per day</th>
<th>Annual death rate per 100,000 men</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>1-14</td>
<td>76 (8 times that of non-smokers)</td>
</tr>
<tr>
<td>15-25</td>
<td>127 (13 times that of non-smokers)</td>
</tr>
<tr>
<td>25 or more</td>
<td>251 (25 times that of non-smokers)</td>
</tr>
</tbody>
</table>

See MBBS1 Notes Week 14
“Risk Assessment + Risk Reduction”
PASSIVE SMOKING
• Harmful health effects in unborn child
• Otitis media, bronchitis, pneumonia, asthma and other chest infections in children
• Linked to SIDS
• Equivalent to smoking ~1 cigarette per day

KEY FEATURES OF TOBACCO + OTHER SMOKING PRODUCTS ACTS (2002)
1) A ‘Sales to Children Prohibition’ sign and a ‘Quit Smoking’ sign MUST be displayed at the point of sale.
2) Restrictions on tobacco vending machines
3) A tobacco advertising and tobacco promotions ban
4) Displays of packets and cartons of tobacco products are regulated:
   ↦ Only one face of a ‘product line’ may be on display
   ↦ Only single cartons are visible to customers
5) Smoke-free enclosed places
6) Managers MUST provide training to their employees regarding shop advertising and sale to minors etc

BURDEN OF MORBIDITY AND MORTALITY ACCOUNTED FOR BY SMOKING-RELATED DISEASE
⇒ Australia’s Health 2004 (AIHW)
1. Tobacco smoking contributes to more deaths & drug-related hospitalisations than alcohol & illicit drug use combined.
2. Of all the health risk factors, smoking is responsible for the greatest disease burden in Australia
   ▪ ~12% of the total burden of disease in males & 7% in females
3. Globally, the WHO estimates that tobacco causes 8.8% of deaths & 4.1% of the total burden of disease (WHO 2002).
4. Cigarette smoking is estimated to have directly caused 10,807 new cases of cancer (57.2 per 100,000 persons) & 7,650 deaths (40.5 per 100,000 persons) in 2000
5. Cancers attributable to smoking are estimated to account for 16.8% of all new cases in males & 7.9% of all new cases in females
   ▪ Difference is mainly due to higher rates of smoking among males over the last several decades
CLINICAL AND PUBLIC HEALTH STRATEGIES AVAILABLE FOR REDUCING SMOKING RELATED MORBIDITY AND MORTALITY

1. LEGISLATION
   • State tobacco license fees & federal excise
   • Tobacco and Other Smoking Products Amendment Act 2004
     - No-smoking in most indoor public places (including indoor dining & bingo areas of liquor licensed premises)
     - Mandatory no-smoking and quit smoking signs
     - Restrictions on how tobacco products can be displayed at retail outlets
     - No tobacco advertising or competitions.

2. PUBLIC HEALTH CAMPAIGNS
   1. TV ads
   2. Anti-smoking advertisements
   3. Quitline

3. OPPORTUNISTIC PREVENTION
   • GP interventions are generally quiet successful
   • Simple interventions → describing negative effects of smoking & providing a pamphlet
     - (5% improvement in smoking cessation amount pts in general practice)
   • Complex interventions → contracts & follow up visits (up to 20% improvement)

4. PHARMACOLOGICAL INTERVENTION
   1. Nicotine replacement therapy (NRT):
      - Patches, gum, inhaler, sublingual tablet & lozenges
      - NRT = ↑ quit rates approximately two-fold at 12 months compared to placebo
      - No significant differences in effectiveness between forms
   2. Bupropion (Zyban ®)
      - Oral non-nicotine therapy to assist cessation
      - Affects neuronal re-uptake of NA & DA
        - ↓ cravings & other Sx of nicotine withdrawal
      - Approx doubles cessation rates at 12 months compared to placebo

   • In general, pharmacotherapy is not offered to people smoking less than 10 cigarettes / day as there is a lack of evidence for effectiveness below this level
**Smoking Cessation Guidelines for Australian General Practice**

**5As for smoking cessation in Australian General Practice**

** ASK **
- "Do you smoke?"
- If yes - take smoking history and record category and number per day.

** ASSESS **
- Review and record smoking history.
- Assess stage of change: "How do you feel about your smoking at the moment?" and "Are you ready to stop smoking now?"
- Assess nicotine dependence, past quit attempts, other health problems and special needs.

** ADVISE **
- All smokers should be advised to quit in a way that is clear but non-confrontational e.g. "While I respect that it is your decision, as your doctor I strongly suggest you stop smoking."

** ASSIST **
- Minimal intervention is to provide written information (e.g. Quit Pack) and offer referral (Quitline 131 846) and advice on pharmacotherapy as appropriate or offer general practice based assistance targeted to stage of change (see below).

** ASSIST - Not ready **
- Brief advice as above.
- Point out relevance of smoking for current and future health.
- Offer further help from practice and/or written information and referral.

** ASSIST - UNSURE **
- Motivational interviewing: "What are the things you like and don't like about your smoking."
- Other options:
  - Explore barriers to cessation.
  - Explore other mental or physical health issues of relevance.
  - Offer further help from practice and/or written information and referral.

** ASSIST - READY **
- Affirm and encourage.
- Help patient to develop a quit plan.
- Assist with advice on NRT or prescribe bupropion as indicated (see pharmacotherapy algorithm).
- Offer further help from practice and/or written information and referral.

** ASSIST - RECENTLY QUIT **
- Congratulate.
- Review and reinforce benefits.
- Offer further help from practice and/or written information and referral.

** SUCCESSFUL QUITTER **
- Congratulate and affirm decision to quit. Give relapse prevention advice.

** ARRANGE FOLLOW-UP **
- For patients attempting to quit schedule follow-up within 1 week and 1 month after quit day. At these visits, congratulate and affirm decision, review progress and problems, encourage continuation of pharmacotherapy, give relapse prevention advice, encourage use of support services.

** RELAPSE **
- Offer support and reframe as a learning experience. Explore reasons for relapse and reasons for future quit attempts. Offer on-going support. Ask again at future consultation.
ADVICE SHOULD BE

1) Clear
   ⇨ “I think it is important for you to quit smoking now and I can help you.”
   ⇨ “Cutting down while you are ill is not enough.”

2) Strong
   ⇨ “As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you.”

3) Personalized
   ⇨ Tie tobacco use to current health/illness, and/or its social and economic costs, motivation level/readiness to quit, and/or the impact of tobacco use on children and others in the household

4) Encourage all clinical staff to reinforce cessation message + support patient's quit attempt

ASSIST ➔ AID PATIENT IN QUITTING

➔ A patient’s preparations for quitting (STAR):

   1. Set a quit date, ideally, the quit date should be within 2 weeks
   2. Tell family, friends, and coworkers about quitting and request understanding and support.
   3. Anticipate challenges to planned quit attempt, particularly during the critical first few weeks; these include nicotine withdrawal symptoms.
   4. Remove tobacco products from your environment; prior to quitting, avoid smoking in places where you spend a lot of time (eg, work, home, car).
   5. Plus - Provide practical counseling (problem solving/skills training)

➔ Total abstinence is essential ⇒ Not even a single puff after the quit date
   • Past quit experience
     ⇨ Review past quit attempts including identification of what helped during the quit attempt and what factors contributed to relapse
   • Anticipate triggers or challenges in upcoming attempt
     ⇨ Discuss challenges/triggers and how patient will successfully overcome them
   • Alcohol
     ⇨ Drinking alcohol is highly associated with relapse; the patient should consider limiting/abstaining from alcohol during the quit process
   • Recommend the use of approved pharmacotherapy except in special circumstances

MOTIVATIONAL INTERVIEWING

1) ASK ➔ “What do you like about smoking?” + “What don’t you like about smoking?”
2) SUMMARISE ➔ Your understanding of the patient’s pros and cons
3) ASK ➔ “Where does this leave you now?”
4) Assess motivation and confidence in quitting (rate on a scale of 1 to 10)
   ⇨ “What would have to happen for your motivation score to increase?”
   ⇨ “How can I help to increase your confidence in quitting?”

WITHDRAWAL SYMPTOMS

1) Cravings ➔ Each one lasts a short time, but may be strong
   ⇨ ↓ frequency + intensity over time
2) Feelings of irritability, frustration, depression or anxiety
3) Feelings of restlessness and/or difficulty concentrating
4) Changed sleeping patterns
5) ↑ appetite + weight gain
**HEALTH BENEFITS OF QUITTING**

<table>
<thead>
<tr>
<th>Time</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 hours</td>
<td>almost all the nicotine is out of your body</td>
</tr>
<tr>
<td>24 hours</td>
<td>blood levels of carbon monoxide have dropped dramatically (\rightarrow) ability to have (\text{O}_2) in bloodstream</td>
</tr>
<tr>
<td>5 days</td>
<td>1. most nicotine by-products have been removed</td>
</tr>
<tr>
<td></td>
<td>2. sense of taste and smell improve</td>
</tr>
<tr>
<td></td>
<td>3. coughing up of phlegm as cilia regain function, improves as hypersecretion due to smoking</td>
</tr>
<tr>
<td>1 month</td>
<td>↓ bp, immune system begins to show signs of recovery</td>
</tr>
<tr>
<td>3 months</td>
<td>cilia continue to recover and lung function improves</td>
</tr>
<tr>
<td>1 year</td>
<td>risk of CHD is halved compared to continuing smokers</td>
</tr>
<tr>
<td>10 years</td>
<td>risk of lung cancer is less than half that of a continuing smoker and continues to decline</td>
</tr>
<tr>
<td>15 years</td>
<td>1. risk of coronary heart disease the same as a non-smoker</td>
</tr>
<tr>
<td></td>
<td>2. 10-15 yrs after quitting the all-cause mortality in former smokers = never smoked</td>
</tr>
<tr>
<td>Other</td>
<td>1. Women who quit before or in the early months of pregnancy have the same risk of having a low birthweight baby as women who have never smoked</td>
</tr>
<tr>
<td></td>
<td>2. slows the rate of loss of lung capacity in chronic airways disease</td>
</tr>
<tr>
<td></td>
<td>3. Improved appearance of skin and fitness</td>
</tr>
<tr>
<td></td>
<td>4. Saves money (-\text{$2000/yr if smoke 20 cigs/day})</td>
</tr>
</tbody>
</table>

**BEHAVIOURAL STRATEGIES \(\rightarrow\) 4 D’s**

**Delay:** Acting on urge to smoke
- Don’t open a pack or light a cigarette
- After 5 mins, urge to smoke will weaken if patient ...

**Deep Breathing**

**Drink Water**

**Do something else**
PHARMACOTHERAPY FOR QUITTING SMOKING

NOT NICOTINE DEPENDENT
Support quit attempt with non-pharmacological strategies
- Counselling
- Cognitive & behavioural coping strategies – Delay, Deep breathe, Drink water, Do something else
- Offer information (e.g., Quit Pack) and referral to support service.

ASSESSMENT FOR PHARMACOTHERAPY
Evidence of current nicotine dependence on withdrawal in previous quit attempt. Patient’s previous experience and views on pharmacotherapy.

ASSESS NICOTINE DEPENDENCE
Nicotine dependence can be assessed by asking:
1. Minutes after waking to first cigarette
2. Number of cigarettes per day
3. Cravings or withdrawal symptoms in previous quit attempts.
Smoking within 30 minutes of waking, smoking more than 15 cigarettes per day and history of withdrawal symptoms in previous quit attempts are all markers of nicotine dependence.

ASSIST WITH PHARMACOTHERAPY
Encourage patient to consider using pharmacotherapy to increase chance of successful cessation.
Explain options for pharmacotherapy (bupropion sustained release and nicotine replacement therapy).
Decide on pharmacotherapy based on clinical suitability and patient preference.

NOT WILLING TO USE PHARMACOTHERAPY
Support quit attempt with non-pharmacological strategies
- Counselling
- Cognitive & behavioural coping strategies – Delay, Deep breathe, Drink water, Do something else
- Offer information (e.g., Quit Pack) and referral to support service.

NICOTINE REPLACEMENT THERAPY (NRT)
Clinical suitability
Absence of contraindications such as pregnancy.
Caution with recent MI, unstable angina, recent CVA, recent MI, unstable angina, recent CVA, severe aneurysms (check P2).
Patient choice
Reasons to prefer NRT include concern about adverse effects of bupropion, over the counter availability of NRT.

Follow up within one week and 1 month after quit date (by GP, practice nurse or pharmacist).
Review progress and problems, common adverse effects – skin irritation, sleep disturbance.
Encourage completion of at least 10 weeks of therapy.
Consider increased dose of NRT if withdrawal not controlled e.g., add gum, lozenges or inhaler to patch therapy.
Encourage use of support services.

BUPROPION SUSTAINED RELEASE
Clinical suitability
Absence of contraindications such as current or past seizures, concurrent NAIDs, pregnancy.
Caution with other conditions or drugs that lower seizure threshold (check P1).
Patient choice
Reasons to prefer include PBS subsidy, oral non-nicotine preparation, relapse in past using NRT.

Follow up within one week and 1 month after starting treatment.
Review progress and problems. Common adverse effects include insomnia, headache, dry mouth, nausea. Look for allergy problems such as skin rash. Encourage completion of at least 7 weeks of therapy.
Consider combination treatment if nicotine withdrawal not controlled.
Encourage use of support services.

- Bupropion (zyban) / NRT quit rate is double placebo after 12 months
  ⇦ Start bupropion while still smoking ⇒ Set quit date in 2nd week of Rx

- Nortriptyline = Same quit rates as Bupropion
  ⇦ Anticholinergic side effects + risk of arrhythmias in patients with CVD
  2nd line
DISABILITY, IMPAIRMENT, HANDICAP

IMPAIRMENT

⇒ Anatomical or physiological abnormality
  ⇣ Reduction of body or organ function
  ⇣ Not all impairments lead to disability or handicap

Organic impairment:
  ⇣ An impairment explained on the basis of demonstratable abnormality, dysfunction or disease

Functional impairment:
  ⇣ An impairment not explained on the basis of demonstratable abnormality, dysfunction or disease

DISABILITY

⇒ Restriction of ability to perform an activity considered a normal part of life
  ⇣ Inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment/s
  ⇣ A person can be disabled but not necessarily handicapped

Permanent partial disability:
  ⇣ Disability at a level less than total disability that is not expected to improve

Permanent total disability:
  ⇣ Disability that prevents gainful employment and that is not expected to improve

Temporary disability:
  ⇣ Either total or partial disability that is thought to have a high probability of being short-term and thus can be expected to improve to a higher level of function

HANDICAP

⇒ Disadvantage for a given individual that limits or prevents fulfilment of a role that is normal for that individual
  ⇣ Depends on age, sex, social + cultural factors)
  ⇣ Results from an impairment or disability
PUBLIC WORKPLACE HEALTH AND SAFETY POLICY

- All QLD workers are protected by health and safety laws
- The legislation applies to all QLD workplaces and work activities (except mines)
- 3 main pieces of legislation are:
  2. Workplace Health and Safety Regulations
  3. Advisory Standards

WORKPLACE HEALTH AND SAFETY ACT (1995):
- Objective = Prevent anyone being killed, injured or contracting illness because of a workplace, workplace activities, hazardous substances or high-risk plant (machinery)
- Act provides a framework to prevent injury by:
  1. Imposing obligations on all persons at the workplace
  2. Providing information about management and exposure to hazards
  3. Promoting consultation through officers, representatives and committees
  4. Enforcement of the Act through inspectors, offences and penalties
- Act is Performance based legislation
  - Means that it seeks to improve workplace health and safety by requiring those people who create risks at workplaces to identify, assess and control them

WORKPLACE HEALTH + SAFETY REGULATIONS
- Regulations establish more specific legal requirements of work practices that must be followed
  - Outline how to identify, assess and control specific workplace habits
  - Controlling lead exposure, asbestos removal, hazardous substances
- Regulations also deal with:
  - Administration such as registering workplaces
  - Notifying or injury/dangerous event and
  - Training required for particular occupations
- Failure to comply with a regulation may constitute a breach of the WHSA

ADVISORY STANDARDS
- Advisory standards and industry codes of practice provide advice in the management of exposure and risks in the workplace
- Advisory standards are not legally binding
  - BUT following them provides substantial evidence that the employer has upheld their DOC for that particular hazard
  - If employer chooses an alternative risk management strategy, it must (at minimum) be equivalent to the advisory standard or code of practice.
- Examples of advisory standards: First Aid, Noise, Falling objects

OBLIGATIONS AND RESPONSIBILITIES
- QLD Workplace Health & Safety Act imposes obligations on every person to ensure their own health safety and that of others:

Employers:
1. Ensure health and safety of their workers, themselves and others such as customers
2. Provide safe systems of work and a safe environment
3. Provide properly maintained and safe machinery, equipment and substances
4. Provide health and safety training, information & supervision
5. Provide personal protective equipment (if it’s needed)
**Employees:**
1. Follow at H&S instructions/procedures
2. Wear personal protective equipment (if needed)
3. Not endanger themselves or others

**Other people:**
1. Self employed people must ensure their work activities do not compromise their own health and safety and that of others
2. Principal contractors must ensure a construction site is safe for all people on site, members of the public and others near the workplace
3. Designers, manufacturers, importers and suppliers of equipment (or substances) must ensure their products are safe for those who use them
4. Those who own machinery must ensure it is maintained and in a safe condition

**ENFORCEMENT**
- OH+S inspectors monitor compliance with the Act and may enter any workplace to investigate a workplace incident or conduct an audit

If a work process, activity or substance breaches the Act, an inspector may issue:
1. **Improvement notice**
   - Legally binding, states what’s wrong, what must be done to fix it and the deadline when it must be fixed

2. **Prohibition notice**
   - If a work process, activity or substance poses an immediate risk to people’s health and safety
   - Work must be stopped until the problem is fixed.
   - States what is causing the risk, which part of legislation has been breached and what must be done for work to resume

3. **On the spot fines** *(infringement notices)*
   - May be issued if certain Workplace Health and Safety Regulations are not complied with
     - Failing to record a dangerous event attracts a $240 fine
     - Failing to comply with an improvement notice can result in an infringement notice

- Breaches of the Act may also result in prosecution (last resort to gain compliance)

**COMMON LAW VS. STATUTE LAW**
- An injured Queenslander who can show his/her injuries resulted from the employer’s negligence can sue the employer under common law for damages
- Common law is **reactive** a person has to be injured before it comes into effect
- Statute Law (WHSA) is **pro-active** by preventing workplace injuries or work related illness.

**WORKER’S COMPENSATION**
- Benefits under the worker’s compensation scheme will be forthcoming to “workers” who suffer a **work-related injury or illness**.

**Who is a ‘worker’?**
- **Workers Comp Act** s11 ➔ Individual who works under a contract of service
- In Schedule 2 of the Act, it includes any person who works for another person under a contract unless the person performing the work is (i) paid to achieve a specified result or outcome, (ii) has to supply their own tools of trade, and (iii) would be liable for the cost of rectifying any defect in the work performed themselves. Note however that there is a lot of legal fine print.
- The Act expressly excludes certain people from being ‘workers’, including directors of corporations, trustees, partners of a partnership, professional sportsmen... (Schedule 2, Part 2 of the Workers Comp Act)
Definition of ‘Injury or Illness’

• s32 Workers Comp Act defines *injury* as ‘personal injury arising in the course of employment, if the employment was a significant contributing factor’
  - Includes contracting a disease, aggravation of pre-existing injuries, diseases, or medical conditions, loss of hearing, and death
  - **Does not include** psychiatric or psychological disorders arising out of reasonable management actions (e.g. demoting, disciplining or firing the employee).

When is an Injury ‘work-related’?

• Ss34, 35 Workers Comp Act extend the scope of ‘work-related injuries’ to include
  - injuries occurring
    - At or away from their place of employment while engaged in an activity for or in connection with the employer’s trade or business
    - While the worker is temporarily absent from the place of employment during an ordinary recess if the injury causing event is not due to the worker voluntarily subjecting themselves to an abnormal risk of injury. In this case the employment need not be a significant contributing factor to the injury.
    - On a journey between the worker’s home and place of employment
  - An injury on a journey will not be ‘in the course of employment’ if the worker in control of the vehicle contravenes the *Transport Operations (Road Use Management) Act* s79 or *Criminal Code* s328A (Dangerous operation of a vehicle), or unnecessarily delays or deviates from their journey, etc

What benefits do injured workers receive?

1) Income replacement
2) Hospital, medical and rehabilitation costs
3) Lump sum compensation et al
4) For all the details see Chapter 3 of the *Workers’ Comp Act*. 
NORMAL RANGE

NORMAL (OR REFERENCE) RANGE
 Values falling within some range, usually 95% (confidence limits) of some factor

What does this imply about sensitivity and specificity?

- **Can set specificity based on healthy population**
  
  - Range in which 95% of non-diseased people fall
  - Implies a specificity of 95% for non disease
  - Says nothing about diseased people (Sensitivity to disease unknown)
  - Does this mean all diseases have the same prevalence – 5%?

- Many ranges are dependent on analytical method, age, gender and other variables.
- Results collected also vary according to specimen collection & method used.

- The RCPA recommends that the **95% confidence interval be used** (within 2 standard deviations away from mean)

  - This means that the reference range will include 95% of the expected healthy population
  - This also means that by its own virtue, 5% of people who are normal (but are just outliers within the upper/lower range) will also be classified as ‘abnormal’.
    - This is why we have to remember only to use laboratory tests to confirm/disprove our preliminary differential diagnoses
    - **Treat PATIENT not the LAB RESULT**

---

**Normal Curve**

95% Confidence limit within 2 std deviations from the mean
**TYPES OF ABNORMALITY**
1) Unusual (Outside normal range)   E.g. 2.3m tall female
2) Associated with disease       E.g. ↑ blood glucose
3) High risk              E.g. High BP, cholesterol, or weight
4) Point beyond which specific treatments do more good than harm
   E.g. Diastolic BP

**SOURCES OF VARIATION**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Biologic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument</td>
<td></td>
</tr>
<tr>
<td>Observer</td>
<td></td>
</tr>
<tr>
<td>The means of making the measurement</td>
<td>The person making the measurement</td>
</tr>
<tr>
<td>Within Individuals</td>
<td>Between individuals</td>
</tr>
<tr>
<td>Changes in people with time and situation</td>
<td>Biologic differences from person to person</td>
</tr>
</tbody>
</table>

**SUMMARY**
1) Clinical observations fall on a continuum of values
2) Observations vary due to
   - Measurement error (instrument and/or observer)
   - Differences within individuals from time to time
   - Differences among individuals
3) If patients with extreme values are retested ⇒ Second set is likely to fall closer to mean
4) Values for normal and abnormal people often overlap
   - Cut-off point should be based on diagnostic probability or treatment effect
SECOND OPINIONS

REASONS FOR OBTAINING SECOND OPINIONS
1) Patient dissatisfied with initial diagnosis/treatment/decision
   - Patient anxious and uncertain
   - Difficulty in the doctor patient interaction
2) Specialist referral
3) Doctor may request a second specialist opinion if unhappy with the initial one or with current specialist management
4) Expert testimony in a case of medical negligence (requested by the court)

PATIENT’S RIGHTS
- Statements of patient’s rights (or health rights codes) explicitly describe a right to a second opinion
- There are also situations where second opinions are mandated by statute e.g. mental health legislation

PHYSICIAN’S RESPONSIBILITIES
- There are a range of purposes and motivations for obtaining a second opinion and it need not be an occasion for defensive behaviour
- Regard the situation as an opportunity for reflection and further considered management.
- Requests for referrals that can be competently delivered by GP’s are arguably unreasonable. Dealing with this requires patient education, tact and time
- If a patient requests a second opinion due to their perception of substandard care, often a second assessment may be what is in the patient’s best interests
- The doctor may take steps to initiate a second opinion. The thought that the avenue is available will often reassure the patient
- If a second opinion is sought and there is a break-down with the initial doctor patient relationship, the doctor is ethically obliged to facilitate optimum care – e.g. by the transfer of records/information
COMMUNICATING DIAGNOSIS, PROGNOSIS + MANAGEMENT

GUIDELINES
1. Ensuring privacy and allowing adequate time,
2. PEARLS to establish rapport
3. Assessing patients' understanding,
4. Giving information about diagnosis and prognosis simply, concisely and honestly,
5. Avoiding euphemisms,
6. Encouraging patients to express feelings,
7. Being empathic,
8. Giving a broad but realistic time-frame concerning prognosis,
9. Arranging a review
10. Discuss treatment options
11. Offer assistance to tell others
12. Provide information about support services
13. Document information given
14. Plan and follow-up

"BLOCKING BEHAVIOURS"
1) Telling patients that any distress is normal,
2) Switching the subject to neutral topics,
3) Giving information and advice before patients' concerns have been identified,
4) Focusing only on physical aspects of the condition,
5) Using leading, closed and multiple questions.
COMMUNITY SUPPORT GROUPS

Community support groups are important to provide holistic patient care.

- Medical treatment can solve most people’s biomedical problems, but not their psychosocial issues
  - It is important to refer patients to relevant community support groups
  - Don’t forget about carers either (Carers QLD)

4 BROAD CATEGORIES OF COMMUNITY-BASED SUPPORT SERVICES

- Other than domestic/voluntary carers at home

1) **Government or Public** (E.g. Community Health Centres, Commonwealth Rehabilitation Services)
2) **Non-profit organisations** (E.g. Meals on wheels, Bluecare, Blue Nurses, St Luke’s)
3) **Self-help groups** (E.g. Stroke association, Spina bifida association)
4) **Private** sector services (E.g. pharmacy, physios, psychologists)

**POTENTIAL BENEFITS**

- Type of care + support that the patients need may be outside the realm of doctor
  - E.g. emotional support, assistance with ADLs
- Many community-support services respond DIRECTLY to such needs:
  - In addition, long-standing members of chronic illness support groups can demonstrate that problems can be overcome
  - They can provide empathy and emotional support
  - Can supply info about both medical (usually researched and supported by doctors) and non-medical aspects of the condition (e.g. Ankylosing spondylitis provides evidence based news on treatment as well as info on how to cope with daily activities)

**GOALS OF PSYCHOSOCIAL INTERVENTION:**

1) Reduce feelings of alienation by talking to others in a similar situation
2) Reduce anxiety about treatments
3) Assist in clarifying misconceptions and misidentification
4) Help reduce feelings of helplessness and being neglected by others

<table>
<thead>
<tr>
<th>Providers</th>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health professionals</td>
<td>Individual</td>
</tr>
<tr>
<td>Education</td>
<td>Supportive psychotherapy</td>
</tr>
<tr>
<td>Crisis intervention</td>
<td>Supportive intervention</td>
</tr>
<tr>
<td>Combinations of above</td>
<td></td>
</tr>
<tr>
<td>Fellow and veteran patients</td>
<td>Hospital visits and education</td>
</tr>
<tr>
<td></td>
<td>Practical advice from personal knowledge</td>
</tr>
<tr>
<td></td>
<td>Coping models</td>
</tr>
</tbody>
</table>

**FOUR MAIN APPROACHES**

1) **Educational:** Seeks to replace helplessness with a sense of mastery and control
2) **Behavioural:**
   - Helps reduce psychological stress as well as complications of treatment (e.g. progressive muscular relaxation, hypnosis, meditation, biofeedback)
3) **Individual psychotherapy:**
   - Addresses the distress of diagnosis, provide support, facilitate anticipation and preparation (*includes a wide range of approaches from a variety of professionals*)
4) **Group therapies:** Generally assist the patient with coping
WHY PEOPLE DON'T ATTEND COMMUNITY SUPPORT GROUPS

1) Simply don’t know about the service or how to access the service
2) Reluctant due to fear of costs (most are quite affordable if not subsidised or free)
3) Some may have heard negative views on groups (clarify, dispel or investigate such claims)
4) Some are afraid that listening to others will make them sad/depressed (often the opposite, as they can empathise with others and realise that others are going through what they are)
5) “It’s just a whinging session” – most group therapy coordinators try to ensure a positive environment which aims to provide problem-solving skills (not just a complaint forum)
6) Some may not have the time/ability to access the organisation (some groups arrange off-site visits and even telephone counselling/info services)

WHAT CAN DOCTORS DO TO HELP?

Tell all patients about the services relevant to them

1) Look up telephone directory/internet
2) Look up MIMS “assist” directory
3) Lifeline has a directory of community based organisations
4) Call QLD Self-Help
   - Provides a service to healthcare providers in the form of a database of self-help organisations and an information/referral service

<table>
<thead>
<tr>
<th>Patient Issues</th>
<th>Doctors Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 1g dependency (“burden”)</td>
<td>- Breaking bad news</td>
</tr>
<tr>
<td>- Preoccupation with their “condition”</td>
<td>- Pt denial (of Dx &amp; worsening dis)</td>
</tr>
<tr>
<td>- Facing death</td>
<td>- Denial used as defence mechanism</td>
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<tr>
<td>- Trying to maintain QOL</td>
<td>- Chronic sorrow</td>
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<tr>
<td>- Effects of Sx on Social life (biopsychosocial)</td>
<td>- “Burden” for caregiver (make sure acknowledge &amp; ask if they’re going)</td>
</tr>
<tr>
<td>- Facing fears &amp; anxiety about death</td>
<td>- Ambiguity - Dx, Tx, Prognosis</td>
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Hints for Drs looking after Patients:

1. Treat the pt as a PERSON not a condition
2. Be aware of community gps & REFER for pt support & self-care
3. When caring - listen to & RESPECT requests of pts & carers (decision making triangle)
4. Remember that illness can ISOLATE the pt/carers & it can DOMINATE their lives

Decision Making:

DR —— PATIENT —— CARER

- Advanced health directives
- End of life & euthanasia debate
SELF-INDUCED DISEASE

KEYWORDS
- Self-induced disease
- Responsibility
- Abandonment
- Resources
- Lifestyle
- Autonomy
- Consequences

DETERMINANTS OF HEALTH
- Western disease patterns suggest that personal behaviours + lifestyles are primary determinants of health, given our knowledge of pathophysiology
- Organic, environmental, personal, social + financial factors implicated in disease causation
  - Individuals + public health practices presuppose some degree of reliance on individual responsibility as a factor in health status
    - Individual Mx plans raise expectations of adherence to advice / plan
    - Lifestyle counseling assumes patient’s application to task will align with self-interest

SOCIETY’S RELIANCE ON INDIVIDUAL RESPONSIBILITY
- ↑↑ emphasis on prevention + lifestyle implies significant responsibility for health status
  1) Many people willingly + knowingly damage their own + others’ health
  2) Many acute medical problems are thought to be preventable as they are considered to be strongly lifestyle-based
  3) Chronic medical conditions ⇒ Patient participation in therapy often appears to be more effective than other ‘passive’ treatments
  4) Awareness of limited resources encourages us to perceive, describe + condemn phenomena such as waste, recalcitrance in patients, non-compliance etc
    - Treating people whose actions and activities have contributed to their illness diverts funds and resources from other health needs
  5) Higher expectations of responsibility may be tied to greater recognition of patient autonomy
  6) Public + preventative health measures are crucial in advancing health status
    - High technology medicine often returns only marginal benefits by comparison

CHANGING VIEWS TOWARDS INDIVIDUAL RESPONSIBILITY FOR HEALTH
- Should we pay more attention to individual responsibility for health + even penalize those who fail to adopt certain practices?
  - This would change long-held Western welfare view that health is a right to:
    - “While certain health-related factors such as adequate housing, clean air and water remain rights, these should be complemented by certain responsibilities which do not sabotage the beneficial health effects of such factors”
  - Appeals to governments ⇒ Shifts responsibility away ⇒ Minimise or contain expenditure

RANGE + CONCEPT OF SELF-INDUCED DISEASE
1) Straightforward causal sense
  - Prior to attachment of any ethical or social attributions + sanctions

2) Sense of attributing responsibility which is penalized in some way
  - E.g. Denying CABG to smokers
    - BUT if there are good medical reasons to expect poorer results, then it is not necessarily a punishment to exclude them (Efficient use or resources)

3) Sense of attributing responsibility in a way which seeks some therapeutic advantage from understanding connections between self, society, behaviours, harms + disease
RESPONSIBILITY

1. Absolute Responsibility For Disease Status
   - Would require complete freedom to choose concerning causal factors leading to disease
   - Individuals bear total responsibility for health status
     ↦ BUT we do not 'choose' our genetic make-up OR most environmental experiences
       ▪ People are not responsible for the social conditions into which they are born + raised

E.g. Self-Mutilating Behaviour = Self-Induced
   ↦ Attribution of responsibility is much more complex when considering the extent that we can provide explanations for “irrational” and self-harming behaviour
   ↦ If we think there is a scientific explanation of anything (including behaviour), we are also saying that there were necessary and sufficient causal conditions for its occurrence
     ▪ This tends to minimize or even extinguish the place for personal agency and responsibility in the generation of the behaviour

→ It does not require an explicit attribution of absolute responsibility in order for some people to be disadvantaged
   ↦ Yoder: "Information can help people exercise responsibility for health, BUT greater control it appears to afford them can be exploited by governments who can blame them for being or becoming ill"

2. No Responsibility
   - We have tended to medicalise many problems which were previously described in ways which presupposed more personal responsibility
     ↦ E.g. Criminal behaviour ⇒ Deviance, psychopathology
     ↦ Having medical / scientific explanations for diseases tends to ↓ our perceived responsibility for them
     ↦ Extreme of continuum = Absence of any responsibility for health status
       ▪ Deterministic view ⇒ Rejected as being inconsistent with our experience of all kinds of responsibilities (People can think, try, decide)

3. Compatibilist Path (In-between view)
   - We want to understand diseases + behaviour BUT also want to continue to attribute some level of personal responsibility
     ↦ Challenge is to find + justify ways of attributing, but also encouraging, facilitating + utilizing a sense of responsibility for health status

FACTORS THAT MODIFY ABSOLUTE VIEW OF RESPONSIBILITY

1) Social / financial status
   ↦ E.g. In lower SES groups, smoking is seen as relaxing and means of stying calm in face of stressful circumstances
2) Social / political structures
3) Deficiencies in competence
   ↦ Some diseases and disorders ↓ competence to deliberate + make decisions
4) Psychopathology

   • Many people willingly and knowingly damage their own and others' health
   • For a large number of diseases there causal factors which individuals could have done something about in order to prevent or delay onset.
   • Failure to adhere to treatment regimes, or observe a prudent lifestyle can also negatively affect outcomes.
   • Treating people whose actions and activities have contributed to their illness diverts funds and resources from other health needs.
PUBLIC POLICY RESPONSES TO SELF-INDUCED DISEASE

1. SANCTIONS

1) Costs, Insurance + Managed Care
   • Exclusions, coercions + premium differentials
   • Managed care schemes (US) are perceived by some to be replacing medical paternalism with managerial paternalism, with fiscal bottom lines threatening denial of care as a response to noncompliance
   • The open-ended nature of health as free enterprise risks abandonment of noncompliers under the cover of ostensible efficiency
     ↪ These mechanisms therefore encourage self-interest and self-responsibility by way of sanctions or negative reinforcement

2) Law and Responsibility
   • Legitimate areas in which law might sanction individuals in relation to health
     ↪ E.g. Contributory negligence ⇒ Damages awarded to an injured person are reduced in proportion to his/her causal contribution
   • BUT how legitimate would it be to limit care to smokers?
     ↪ It is often accepted that priority should not be given to those whose risk profile for surgery is high BUT smoking addiction could arguably be seen as a disability, and limiting treatment consequently seen as discrimination.
     ↪ In rich countries like Australia, there is arguably no need to establish different levels of priority
       ▪ This could be seen as disguising social discrimination by what appear to be more acceptable medical criteria

2. INCENTIVES

1) Macro-level
   • In Australia, positive incentives have been used by some private medical insurers
     ↪ E.g. Preventive health measures, gym membership attract annual rebates
     ↪ Certain welfare benefits are conditional on maintaining childhood vaccinations
     ↪ Doctors are also offered financial incentives for achieving minimal immunization rates for their practice populations

2) Micro-level (Doctor-Patient Interface)
   • Possibilities exist for both negative sanctions + positive inducements to increase responsibility for self-care
   • Patient-centred approach + principles of compassion, commitment and non-abandonment suggest that self-induced disease be understood rather than penalised
     ↪ Depends on respectful exploration ways in which patients can reasonably be said to be at least partially responsible for their health status, and the consequent ways in which they can be helped to use this insight to improve their health
   • Doctors should use motivational interviewing techniques to promote greater patient self-reliance and awareness of the consequences of behaviour
   • Simple measures including regular meals, moderate exercise, adequate sleep, moderate weight and alcohol, and no smoking should be encouraged

3. HARM REDUCTION / HARM MINIMIZATION
   ⇒ Deals with tension between patients’ values + capabilities, and the recommendations of EBM
   • Strategy accepts that in the real world, various levels of unhealthy behaviour are inevitable, but nevertheless tries to minimize the harm which results from the behaviour
     ↪ E.g. while lifestyle modification may be the optimum approach for many chronic diseases, some people who are unable to adopt lifestyle changes, or are resistant to the idea, may benefit from an earlier pharmaceutical intervention
       ▪ Controversial ⇒ As it would appear to suggest that we can diverge from “best practice” if the patient resists it
         • BUT this is often what happens in practice
PSYCHOSOCIAL ASPECTS OF FUNCTIONAL GI DISEASE

See MBBS2 Notes Week 8 “Psychosocial Aspects of Cardiac Disease”

PAIN

- Unpleasant sensory + emotional experience associated with actual tissue damage or is described in terms of such damage
  - Experienced in an emotional, cognitive & socio-environmental context
  - Psychological, social & cultural factors influence the perception, presentation & related behaviours of ALL pain
  - Experience of pain + the associated emotion & cognitive processing leads to behaviour
    - ‘Pain behaviour’
  - Chronic pain is associated with a high prevalence of psychological disorders among patients
  - Abdominal pain is v. common in the community:
    - Only a minority are presented to a doctor
    - ∴ Must think, “WHY HAS THIS PERSON COME?”

SOMATISATION

- ‘Presentation of psychological distress by way of somatic complaints’
  - Patient attributes symptoms to physical illness ➔ EVERYONE HAS THE POTENTIAL TO SOMATISE!
  - Illness (pain) behaviour is out of keeping with evident disease

Reasons Why People Somatise

- Better acceptance of physical symptoms than psychological ones – reinforced from early age
- Benefits of sick role

Risk Factors For Somatisation

1) Intellectual impairment
2) Immaturity – children & adolescents
3) Cultural
4) Lack of psychological mindedness
5) Developmental trauma & abuse (especially childhood sexual abuse)
6) Early experiences or Hx with significant illness (either themselves or in the family)

Look Out For The Following

1) Depression
2) Anxiety disorder
3) Somatization disorder
4) Substance abuse + dependence

PSYCHOSOCIAL FACTORS IN FUNCTIONAL GI DISORDERS

1) Effects on gut physiology
   - Gut responds to emotional and environmental stimuli
   - One hypothesis suggests that functional GI disease results from a dysregulation of brain-gut interactions (not an actual disorder of these organs)
   - Significant evidence that the CNS modulates gut motility

2) Modulation of the symptom experience
   - Health care seeking behaviour and ↑ pain are associated with anxiety, depression, and health anxiety

3) Influence on illness behaviour
   - Patients with anxiety tend to believe the worst explanation for their pain + disregard other information (eg. That offered by doctor)
     - Present more frequently to doctor than other patients, with a variety of non GI complaints as well

4) Impact on outcome
   - Psychosocial trauma, or poor coping style have a significant impact on symptom severity, daily function, and health outcome

5) Choice of the therapeutic approach:
   - Patients with health anxiety are less likely to see a link between their anxiety and GI pain, and may thus reject the potential role of psychotherapies in their treatment

- Biopsychosocial model is best way to understand and treat these patients
  - In some cases psychological treatments such as antidepressants + CBT are indicated
MANAGING UNCERTAINTY

- Medicine is an inexact science → Often may be uncertain about Dx, Tx etc
  - ↓ Need to balance risk of harmful investigations vs missing diagnosis

DIAGNOSTIC STRATEGIES

1. **Follow Murtagh’s Five-Step Diagnosis**
   - Consider these five possibilities when diagnosing

   1. **Probability diagnosis**
      - What are the most likely causes considering patient characteristics
        - (Age, gender, PMHx, FHx)
      - What are the most likely causes considering disease characteristics
        - (Natural Hx, signs & Sx, epidemiology, patterns in the community)

   2. **Serious disorders not to be missed**
      - Diseases that may be rare but would have serious consequences if missed
        - Should be considered until proven otherwise

   3. **Pitfalls (commonly missed)**
      - Simple non-life threatening problems that are often missed

   4. **Seven Masquerades:**
      - Seven conditions which present in a variety of ways
      - Consider these seven if examination is inconclusive
        - (ROYGBIV) – STUDIAD or STUD-DAD
          - Red: Blood → Anaemia
          - Orange: Fruit sugar → Diabetes
          - Yellow: Urine → UTI
          - Green: Plants → Drugs (iatrog)
          - Blue: Blues → Depression
          - Indigo: Iodine → Thyroid
          - Violet: Cloak over spine → Spinal dysfunction

   5. **Is the pt trying to tell me something?**
      - Patient has something to say but feels they can’t
        - E.g. depression, suicide, abuse
        - Presenting Sx used as excuse to see Dr

2. **Red Flag + Alarm Symptoms and Signs**
   - Red flag symptoms + signs are those that if absent rule out the diagnosis
   - Alarm symptoms + signs are those that raise the possibility of a serious diagnosis

3. **Probabilistic Reasoning**
   - Consider the diagnostic accuracy of ‘tests’ to rule in and rule out disease
     - Sensitivity + specificity

4. **Spot Diagnosis**
   - E.g. conjunctivitis, acne, perianal warts, croup

5. **Pattern Recognition → Look for Dissonance**
   - Look for inconsistencies between what is expected + observed history & facts
     - Listen to your “sixth sense”

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**E.g. Murtagh’s Five Step Diagnosis for:**
- Lower abdominal pain in 18yo female
  1. Period pain
  2. Appendicitis
  3. Ectopic pregnancy
  4. UTI
6. **Test of Treatment**
- E.g. Heart failure, fungal infection
  - What can go wrong? ⇒ Placebo effects, regression to mean

7. **Safety Netting**
- Consult with colleagues or more experienced specialists and have a **contingency** plan for the worse case scenario
  - E.g. tell patient to come back if Sx persists
  - "At this point it's hard to say... if it gets better, then OK, but give it 12 hours, if still bad then we need to see you"

8. **Know That Uncertainty is Common**
- Frequently diagnoses are NEVER found
  - It's easy to live with uncertainty when you know that presentations are often undiagnosed

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**Presentation**

- **Rule out disease**
- **Return if...**
- **Investigate/treat**

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**1. Disease knowledge base**
- Ability to recognise symptoms and signs as presentation of disease

**2. Communication skills**
- Ability to listen to patient and to determine patient's problems
- Ability to explain when patient should return for review

**3. Examination skills**
- Objective observations
- Ability to elicit clinical signs

**4. Diagnostic reasoning skills**
- Ability to assess baseline probability of disease
- Understanding of the diagnosticity of symptoms, signs and test information
- Ability to use diagnostic heuristics
- Ability to recognise new symptoms and signs and revise diagnosis

**5. Organisational skills**
- Adequate follow-up of patients
- Adequate communication between clinicians treating a patient
- Follow-up of test results
OPPORTUNISTIC HEALTH PROMOTION IN MEDICAL CONSULTATIONS

OPPORTUNISTIC HEALTH PROMOTION

Form of 1° prevention that involves promoting a healthy lifestyle

- Diet, leisure, age-relevant health checks and scheduling appointments for overdue screening etc
- Tailored to each patient

- Designed to benefit overall mental and physical well being
  - E.g. patient presents with a leg sprain, and after addressing the main issue, the doctors raise issues such as weight reduction, cholesterol, diabetes and how these affect wound healing etc, importance of regular exercise and building up muscle strength to avoid future sprains
  - Possible appointments for cholesterol testing

SPECIFIC OPPORTUNISTIC HEALTH PROMOTION ACTIVITIES

*Children*: Developmental milestones, height and weight, vaccinations

*Adolescents*: Vaccinations, height + weight, depression, drug use, sexual health, fertility

*Adults*: BP, cholesterol, tetanus, Fluvax, weight, pap smear, breast exam, skin exam, alcohol, drugs, risk factors for CAD, depression, exercise and diet (esp. for overweight or diabetic patients), asthma

*Elderly*: Memory, IHD, will, chronic disease, anaemia, osteoporosis

AREAS TARGETED FOR OPPORTUNISTIC HEALTH PROMOTION INCLUDE:

1) Osteoporosis.
2) Teenage health.
3) Sexual health.
4) Cardiovascular risk factors.
5) Exercise.
6) Weight reduction, over weight/obesity and diabetes.
7) Asthma.
8) Smoking cessation.
9) Hypertension.
10) Breast cancer.
11) Cervical cancer screening.
12) Alcohol Reduction.
13) And many more – review their history and see what is appropriate that may have been missed.

Again, virtually any stage of a disease from primary prevention to tertiary prevention may benefit from health promoting interventions.
PSYCHOSOCIAL IMPACT OF IBD

*** See MBBS1 Notes Week 10 "Lifelong Serious Disease / Chronic Illness" ***

PSYCHOSOCIAL IMPACT OF CHRONIC DISEASE

1) Changed concept of self
   - Major coping challenge
     ▪ Previous abilities, energy and ability to successfully engage in desired activities may be diminished
     ▪ Must avoid allowing disability or illness to become entire identity
     ▪ Activities that enhance ability thus self esteem should be sought

2) Altered social relationships
   - Chronic disease can cause isolation and loneliness. Can be due to:
     ▪ Low self-esteem
     ▪ ↓ energy levels
     ▪ Physically unable to participate in former social events etc

3) Feelings of grief, uncertainty and own mortality

4) Change of role (E.g. social, employment, family etc)
   - Individual must take on role of chronically ill, dependent help seeker, self-care agent and client of complex health-care system as well as loss of old roles

5) Feelings of loss of control
   - Intrusions of privacy by healthcare team
   - Lack of knowledge

6) Must learn how to manage condition
   - Handling physical discomfort
   - Modifying routines and lifestyle
     ▪ Changing routines to fit in treatment or altering lifestyle factors such as smoking, exercise etc
   - Complying with prescribed regime: altering habits for a lifetime
   - Obtaining knowledge and skills for continuing self-care
     ▪ E.g. awareness of body cues and physical changes

7) Normalisation (Striving to feel normal)
   - Keeping signs and symptoms under control or out of view of surrounding persons

8) Learning to deal with social stigma
   - Can react by ignoring, overreacting or using humour

STRATEGIES TO ASSIST PATIENTS ACCEPT AND MANAGE CHRONIC ILLNESS

- Communication and patient education are vital
- Refer to community support organisations (E.g. Australian Crohn’s + Colitis Association)
- Health Belief Commitment ▸ Patient must accept that:
  1. They do have the disease
  2. The consequences of the disease are serious
  3. It can be managed
  4. Advantages of treatment over the disadvantages
- Encourage collaboration
  ▸ Dr and patient working together to negotiate Mx – a therapeutic alliance
  ▸ Rather than compliance (Patient expected to follow regimen prescribed by Dr)
- Identify what patients goals are
- Identify hidden concerns and negotiate differences
  ▸ Medical best interests and patient’s best interests may not always be the same
  ▸ Explore alternative treatment options
    ▪ E.g. Minimize impact of disease on patient’s life by ↓ doses of meds per day
Encourage self-management

- Chronic disease patients usually become expert managers of their conditions
- Help patients to deal with the consequences of the illness, not the physiological disease
- Emphasize problem solving, decision making and patient confidence rather than prescription and adherence
- Encourage patient- HCP partnership
  - Health professionals primarily responsible for medical management
  - Patients responsible for the day-to-day management of the illness
Clinical Trials

Clinical Trial: Study involving humans to find out whether an intervention which it is believed may improve a person's health actually does so
- Method for objectively comparing 2 (or more) variables + their corresponding outcomes.

DESIGN OF CLINICAL TRIALS FOR DRUG THERAPY

1) Study objectives – what do we really want to know?

2) Comparator medication
   - Placebo:
     - Inert or dummy med that is formulated to match the real one in all external qualities, but without the presence of the drug
     - Supplied at the same interval, via same route, + in the same amt
   - Standard Drug Regime:
     - Active control
     - Patients receive the well-establish medication as the control
     - Used when determining if a drug is better than the current therapy

3) Trial designs
   - Prospective, retrospective, cross-sectional, cross-over or not?
   - Blinding or open?

4) Sample size – Calculate ‘power’ + no. of pts to show statistical significance

5) Patient selection
   - Inclusion + exclusion criteria
   - Patients or normal volunteers?
   - Demographics?
   - Age, gender, socio-economic status, genetics, co-morbidities, etc

6) Ethical issues
   - Can we ethically give a placebo or should we give the current gold std
     - E.g. in analgesic trials – you shouldn’t give patients in pain a placebo!
   - Do we have informed consent?
   - Do we have ethics committee approval for the trial design?

7) Dosage regimens
   - What dose?
   - How many times a day?
   - How should we monitor concordance?

8) Assessment & collection of data
   - How often?
   - Who’s in charge?
   - How many different investigators and how many different collection sites?

9) Analysis of results
   - Who? Blinded?
   - Conflicts of interest?
   - Biases?

10) $$$ - Clinical trials cost a fortune
    - Significant contributor to cost of final drug
**PHASES OF DRUG DEVELOPMENT**

**Pre-Clinic Drug Development Process**

**Phase 0:**
- Drugs that are candidates for clinical use must by law be tested on animals or their cells
- Specific + general pharmacodynamic, pharmacokinetic, metabolic & interaction studies
- Drug must demonstrate therapeutically relevant activity in animals
- Unwanted effects (& dose) are appraised in toxicity evaluation
- Mutagenicity, carcinogenicity & reproductive toxicology are specifically investigated
- Generates a therapeutic window & must have net benefit

**Clinical Trials Move Through 4 Phases**

**Phase I:**
- Researchers **test a new drug or treatment in a small group of people** (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects

**Phase II:**
- Drug or treatment is given to a **larger group of people** (100-300) to see if it is effective and to further evaluate its safety
  - Drug is compared to current available therapy
  - Clinical doses decided
  - Placebo controlled design

**Phase III:**
- Drug or treatment is given to **large groups of people** (1000-3000) to:
  - Confirm its effectiveness
  - Monitor side effects
  - Compare it to commonly used treatments
  - Collect information that will allow the drug or treatment to be used safely

**Phase IV:**
- Conducted **after the drug or treatment has been marketed**
- Continue testing the study drug or treatment to collect information about their effect in various populations and any side effects associated with long-term use
  - In Australia, we also use ADRAC (adverse drug reaction advisory committee) to ensure post-marketing surveillance of side effects, interactions, etc

**PSYCHOLOGICAL ISSUES**
- Healthy volunteers vs. patients vs. desperate patients (eg terminal cancer)
- Enrolment of participants for clinical trials can be a difficult process
- In early phase clinical trials, healthy volunteers are used to test the preliminary safety of the drug in humans
  - Usually there is a low risk to the patient & it can be quite easy to get volunteers
- On the other hand, particularly in cancer trials (patients used not volunteers), the vulnerability & sheer desperation of the patient may push them to eagerly participate in any new offerings of ‘hope’

**ETHICAL DOCTOR-PATIENT ISSUES**
- **Need “informed consent” prior to entry into a trial**
  - Requires: Voluntariness + Informed decision + Competence
- Failure to obtain informed consent = Assault (threat of harm) or battery (if physically harmed)
- At no time should there be any ‘coercion’
  - This can be a grey area ‘payment for participation’ is involved
  - Subject must VOLUNTEER while being fully aware of the justification for the trial + of the relevant risks & benefits
  - Consent gained must be WRITTEN & documented
'Declaration of Helsinki' protects the rights of trial participants & all trials approved by ethics committees will have fulfilled its recommendations.

Must also bear in mind:
1. Participant confidentiality (Dr-patient confidentiality)
2. Tell the participant that they may withdraw at any time without any threat of repercussions & without having to supply a reason
3. The participant must be given time to consult with family/friends prior to agreement
4. Information provided should be verbal & written (without jargon so that patient fully understands & has time to ask questions)
DECISION MAKING IN EMERGENCIES

DIAGNOSTIC AND MANAGEMENT PROCESSES OF CLINICAL DECISION MAKING

- Expert emergency physician utilizes all four diagnostic and management decision-making processes depending on the clinical situation
  - (1) Pattern-recognition,
  - (2) Rule-using,
  - (3) hypothetico-deductive,
  - (4) Naturalistic, or event-driven.

1. PATTERN-RECOGNITION PROCESS

- Memorisation of a critical number of facts, which over time can be grouped, together (i.e. disease-specific history & physical examination findings) that allow for pattern recognition or the “doorway diagnosis”
- For new pt, aim is to link to existing knowledge (i.e. the disease pattern), this facilitates recall of important disease entities and patient information.
- Disease-oriented patterns contain little knowledge about pathology or physiology but a wealth of clinically relevant information about the disease, its consequences, and associated signs and symptoms.
- Pattern-recognition process involves the lowest level of the clinical decision-making, as it’s without conscious effort
  \[ \text{Decision making is automatic, operates briefly, and processes information rapidly.} \]

Any departure from the routine clinical presentation where the disease pattern is recognized requires a rule-based or hypothetico-deductive solution

2. RULE-USING PROCESS

- Solutions to familiar problems are governed by previously memorized rules of the “if X then Y” variety.
- When clinicians are faced with atypical presentations or unusual symptom complexes not previously memorised, they may resort to using rules, heuristics, or algorithms to discriminate or classify symptoms, signs, or diagnostic study results into previously defined diagnostic or therapeutic groups.
- Heuristics can be grouped into algorithms, allowing the physician to use agreed-upon rules of action in critical or high-stress situations where higher levels of decision making are difficult

3. HYPOTHETICO-DEDUCTIVE PROCESS

- Highest on the clinical decision-making hierarchy
- Ability to make clinical decisions by problem solving using previous knowledge to create new solutions.
  - Hypothesis generation → Initial cues are perceived from pt & environment, & multiple diagnostic hypotheses are rapidly generated
  - Hypothesis evaluation → Data-gathering inquiry strategies are used to collect relevant hx, physical examination, & diagnostic study information are interpreted to confirm or reject the provisional hypotheses. This process may lead to additional diagnostic hypotheses being generated (hypothesis refinement).
  - Hypothesis verification → Finally, physician chooses & verifies most likely diagnosis (confirmed by data) from among the provisional diagnostic hypotheses and treats accordingly.
- Involves attending to relevant facts and conditions of the problem, such as pertinent positive and negative historical, physical examination, and diagnostic study findings and trying to avoid premature judgment or closure, such as labelling with a diagnosis that does not exactly “fit”
**NATURALISTIC OR EVENT-DRIVEN PROCESS**

- Dynamic process is utilized in emergency medicine more than any other specialty and involves treating pts’ signs or symptoms before definitive diagnoses have been determined.
- When presented with unstable patient, certain therapeutic actions are necessary to stabilize the patient long before the cause of the instability is known.
- In general, the number of available therapeutic or management options is smaller than the number of possible diagnoses.
- The emergency physician often uses a strategy of ruling out the worst-case scenario. This strategy, coupled with a focus on stabilizing actions and not diagnoses, can rapidly prune the decision tree.
- Once a satisfactory response to intervention is obtained, the search for the definitive diagnosis can often be truncated.
  - Physician must be willing to accept a good or likely presumptive diagnosis instead of the definitive diagnosis

**HEURISTICS FOR OPTIMAL DECISION MAKING IN EMERGENCY MEDICINE**

- A number of important heuristics (rules of thumb) guiding diagnostic and management decision making have been identified by emergency medicine decision-making experts.

1. Sit at patient’s bedside to collect a thorough history.
2. Perform an uninterrupted physical examination.
3. Generate life-threatening and most likely diagnostic hypotheses.
4. Use information databases and expert systems to broaden diagnostic hypotheses.
5. Collect data to confirm or exclude life threats first, then most likely diagnoses.
6. Avoid diagnostic testing whenever possible by using readily available decision-making algorithms.
7. Order only those tests that will affect disposition or that will confirm or exclude diagnostic hypotheses.
8. Include decision rules on diagnostic testing order forms.
9. Use guidelines and protocols for specific therapeutic decisions to conserve mental energies while on duty.
10. Allow 2 to 3 minutes of uninterrupted time to mentally process each patient.
11. Mentally process one patient at a time to disposition.
12. Avoid decision making when overly stressed or angry. Take 1 to 2 minutes out, regroup, and then make the decision.
13. Carry a maximum of 4 to 5 “undecided” category patients. Stop—make some dispositions.
14. Use EBM techniques to substantiate decisions with evidence, understand the limitations of the evidence, and to answer specific questions, such as usefulness of diagnostic testing, management plans, and disease prognosis.

1) **Rule out life or limb threats first** *(i.e., think the worst).* Upon identifying life or limb threats, the emergency physician must also decide if direct intervention is necessary to mediate or prevent patient deterioration.
2) **Determine if there is more than one active pathologic process present.**
3) **Try a diagnostic-therapeutic trial.** Administering a stabilizing therapy that also provides diagnostic information is an important decision-making strategy in the emergency department.
4) **Determine the bottom line.** *Close the disposition and follow-up loop.* Emergency physicians have a unique relationship with other physicians. This relationship is based on the concept of “our” patient. We share responsibility for the health and welfare of the patients in our care with other providers.
5) **Understand fully why the patient is in the ED, and then meet the patient’s expectation.**
6) **Use ED resources fully but understand that ED personnel and facilities cannot be all things to all people.** The emergency physician has a responsibility to maintain the highest level of quality in terms of staffing, equipment, and care. Recognizing what the ED is not and knowing the facility limitations are equally important.