

Dealing with complex patients in pharmaceutical care research:

Research with Vulnerable People

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Complex → Vulnerable



Capability

- Limited communication skills
- Limited social contacts & capacity for quickly establishing new contacts
- Less adaptable to 'new' situations
- Low health literacy
- Poor self care
- Variable behaviour
- Multiple health needs
- Polypharmacy & excess polypharmacy
- Restricted access to & use of health care





Vulnerable people - this workshop



Inclusion

- Physical disability
- Sensory disability
- Cognitive disability
 - Communication
 - Understanding
 - Capacity to care for oneself
- Drug treatment

Exclusion

Children
Homeless
Prisoners
Non-english
speaking

- People with Intellectual Disability (PWID) as an example





People with Intellectual Disability



“a disability characterised by significant limitations in both intellectual functioning and in adaptive behaviour which covers many everyday social and practical skills. This disability originates before the age of 18.”

American Association of Intellectual and Developmental Disabilities. Definition of Intellectual Disability 2014





Complexity



- The patient, the condition & the drug & non-drug treatment may all contribute to the complexity of a patient case.
- Interaction – interdependency of these elements that creates complexity.
- Variable quality of evidence for treatments (singly or combined).
- Capacity of care staff to implement treatment & convenience of different forms of treatment influences use
- Confounding factors are both numerous & potent



Cognition & communication



- Adjusting communication, taking into account the patient's receptive & expressive verbal capacity
- Pictures, icons – Ipads, stickers & boards (Picture exchange communication systems)
- Types of sign language - www.makaton.org
- Non-verbal communication; looking/pulling/turning away, covering their head, scratching/picking at themselves
- Patients with intellectual disabilities were provided with patient-held information documents where they could record key information for the benefit of hospital staff, including likes and dislikes.
- Addressing the patient's ability to cope with different environments, changes in routine, unfamiliar procedures and unfamiliar staff – advance warning, continuity



www.rcpsych.ac.uk/mentalhealthinfoforall/problems/learningdisabilities.aspx

Leicestershire Partnership NHS Trust

Escitalopram

Antidepressant



Escitalopram



What is this leaflet for?

This leaflet is to help you understand more about your medicine.

Your medicine could look different to the pictures on this leaflet.



Escitalopram is also called Cipralex

Escitalopram is available as tablets and oral drops.



Your medication



What is Escitalopram used for?

Escitalopram is commonly used to treat depression.

It is also used in:

- People having repetitive thoughts or behaviours
- People feeling tense or angry





Research

- Extensive, but limited
- Populations under-represented in many types of clinical research
 - Particularly RCTs
 - Cohort & Public observatory studies increasing
- Few pharmacist-led studies
- Anti-psychotics most widely, intensively studied



Some questions to consider



- What makes them vulnerable?
- What health needs do they have?
- In which setting(s) do they live and/or receive care?
- What this means for provider-patient interaction?
- Which medicines do they use, what is the prevalence & why?
- How are their medicines-related needs assessed & responded to?
- Who else is involved with care of these patients?





Workshop Plan

Wednesday

- Session 1 15.00-18.30 Introduction, Studies, Consent & Settings

Thursday

- Session 2 10.00-13.00 Health Assess
Multiple meds
- Session 3 15.30-18.30 Communication
Side effects

Friday

- Session 4 10.00-13.00
- Session 5 14.00-16.00



Workshop Organisation



- Devise a project to improve care of complex patients - vulnerable people with medicines
- Divide up into two? groups
- You may wish to identify complex patients in another way – if there are enough like-minded people, then that is fine
- Details of the projects are up to you
- A series of short lectures to illustrate aspects that are worth considering





Care in the Community



- Independent
 - Live at home with parents or alone
 - Primary Care
 - Community Pharmacy = PWID or family/carer visit
- Community group home or Sheltered accommodation
 - Live with others and with carers
 - Own room, Opportunity to come and go
 - Nurse-led care staff; GP regular review schedule
- Residential care
 - Live with others – specialised facilities
 - 24h supervision with medical (specialist), psychiatric nursing & care staff





Workshop Tasks



Suggested project areas

- To empower community pharmacists to provide pharmaceutical care for PWID who live at home/independently
- Draw up guidelines for the use of psychotropic drugs for moderate-severe ID residents of community group homes
- Improve the use of drugs for gastro-intestinal symptoms & conditions in PWID living in residential care homes
- Draw up guidelines for the use of drugs with anti-cholinergic activity in PWID
- Develop a de-prescribing intervention for PWID receiving multiple psychotropic drugs





Vulnerable people & research



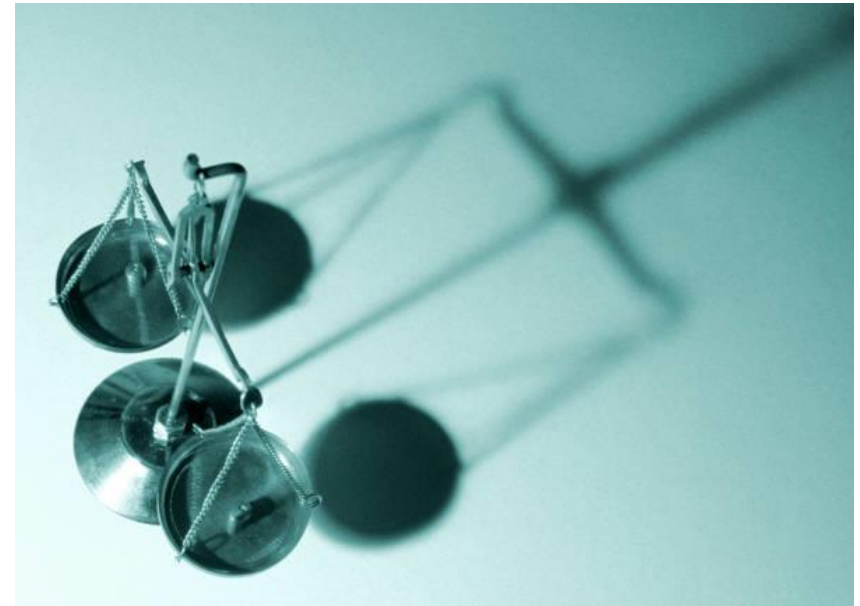
- Capacity
- Vulnerability
- Consent
- Legal status of Next of Kin, Carer
 - Person independent of the research & the research team
- Protection
 - Re-consent
- Law relating to Institutional care





Key Ethical Principles in Research

- Justice
- Respect of Persons
- Beneficence





Justice



- Equitable distribution of the burdens and benefits of research
 - Reasonable/appropriate to individual
- May not exploit vulnerable individuals or exclude without good reason eligible candidates who may benefit





Respect for persons



Respect

- Choices of autonomous individuals should be respected
- People incapable of making their own choices should be protected
- Voluntary subjects with adequate information

Threats to respect

- Inadequate information
- Inadequate voluntariness
 - Coercion
 - Undue Inducements
- *All of above applies also to carer or person acting on behalf of participant*





Beneficence

- Benefit vs Risk
 - Individual
 - Population of similar individuals
 - Both research process & outcome
- Value of Research must be clear
 - An evaluation that could lead to improvements in health or well being to the population relevant to the potential subject.
- Research without value
 - Question already fully answered
 - Results have no chance to be valuable to relevant population
 - Results will not be disseminated and thus cannot have an effect



Scientific Validity



- Feasible & practical
- Methodologically sound
 - Protocol subject to independent review
- Adequately powered
- Analytical plan pre-specified





Capacity



- In the UK, a person lacks capacity if,
- they have an impairment or disturbance (for example a disability, condition or trauma or the effect of drugs or alcohol) that affects the way their mind or brain works, and
 - that impairment or disturbance means that they are unable to make a specific decision at the time it needs to be made.



Ability to make a decision



Person must be able to,

- understand the information given to them that is relevant to the decision
- retain that information long enough to be able to make the decision
- use or weigh up the information as part of the decision-making process
- communicate their decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

Reference guide to consent for examination or treatment, second edition 2009.
Department of Health





Informed Consent



- Information
 - Research procedure and Purposes
 - Risks and benefits
 - Alternative procedures
 - Ask questions, withdraw, identified researcher
- Comprehension
- Voluntariness





Comprehension & Informed Consent



- Information must be tailored to the research subject
- Investigators must ascertain that the subject understood the information
- Surrogate consent if judgment is limited
- People with learning disabilities may be prone to suggestibility and acquiescence

Clare and Gudjonsson (1993)





Consent Process

- Adequate formulation
- Appropriate time
- Required support
- Subject's desired support
- Consent may be needed more than once
- Monitor vulnerability and take steps to protect subjects
 - Healthcare professionals may be providing care or treatment for a person who is taking part in a research project, and may be asked for their views about what the person's feelings are or need to advise the researchers if the person seems upset about any aspect of the research. Reference guide to consent for examination or treatment, second edition 2009.

Department of Health

- Reassess capacity



Application of Ethical Principles in Human Research



Principle	Aspect of Research
Respect, Resources	Social or scientific value
Respect, Resources	Scientific validity
Justice	Fair subject selection
Respect	Respect for subjects
Beneficence, Respect	Favorable risk/benefit ratio
Conflict of Interest; Professionalism	Disclosure/External review
Respect	Informed consent



Practice versus Research



A significant departure from standard practice -- innovation -- does not necessarily constitute research.

Radically new procedures should be subjected to research to determine safety and effectiveness.

Participation in observational studies requires ethical approval





Standard of Care



- Health Service Regulations/Stipulations
- Institutional (where autonomous)
- Community of practice (norms) & professional judgment
- Professional Society Guidelines ?
- Published literature?





Health Needs



- Assessment of degree of cognitive impairment
 - Mild/Moderate/Severe
 - Activities of Daily Living (ADLs)
- Needs depend upon assessed health status
 - Self-assessed or Carer-assessed
 - Poor – Excellent
 - Morbidity varies with type of impairment
 - Neurological & Psychiatric
 - Behavioural
 - Endocrine





Health Needs



- assess a patient's symptoms is also a challenge





Health Assessment



- More difficult because of communication difficulties
- Atypical presentations
 - Depression may show as withdrawal
- Diagnostic overshadowing
 - the tendency for clinicians to overlook symptoms of mental and physical health problems in clients/patients with learning disabilities and attribute them to being part of the “having a learning disability”. Mason and Scior (2004)
- Associations
 - All - epilepsy
 - Downs syndrome – hypothyroidism, congenital heart disease, dementia



Health Needs



Causes of death

- Respiratory disease (pneumonia, aspiration, posture, swallowing and feeding problems and gastro-oesophageal reflux disease [GORD]).
- Cardiovascular disease (congenital heart disease rather than ischaemia)

Health Problems

- Epilepsy
- Mental health disorders
- Constipation (sometimes severe) which may require complex management
- Dysphagia and risk of aspiration pneumonia
- Respiratory infections
- Malnourishment or dehydration
- Hypothyroidism
- Obesity with associated risk of diabetes & cardiovascular disease
- Osteoporosis and osteomalacia
- Poor oral health
- Reduced or low mobility
- Sensory impairments
- Pain





Behaviour problems



Challenging behaviour – Emerson, 1997

- Culturally abnormal behaviours of such an intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit or deny access to and use of ordinary community facilities.



Health Needs



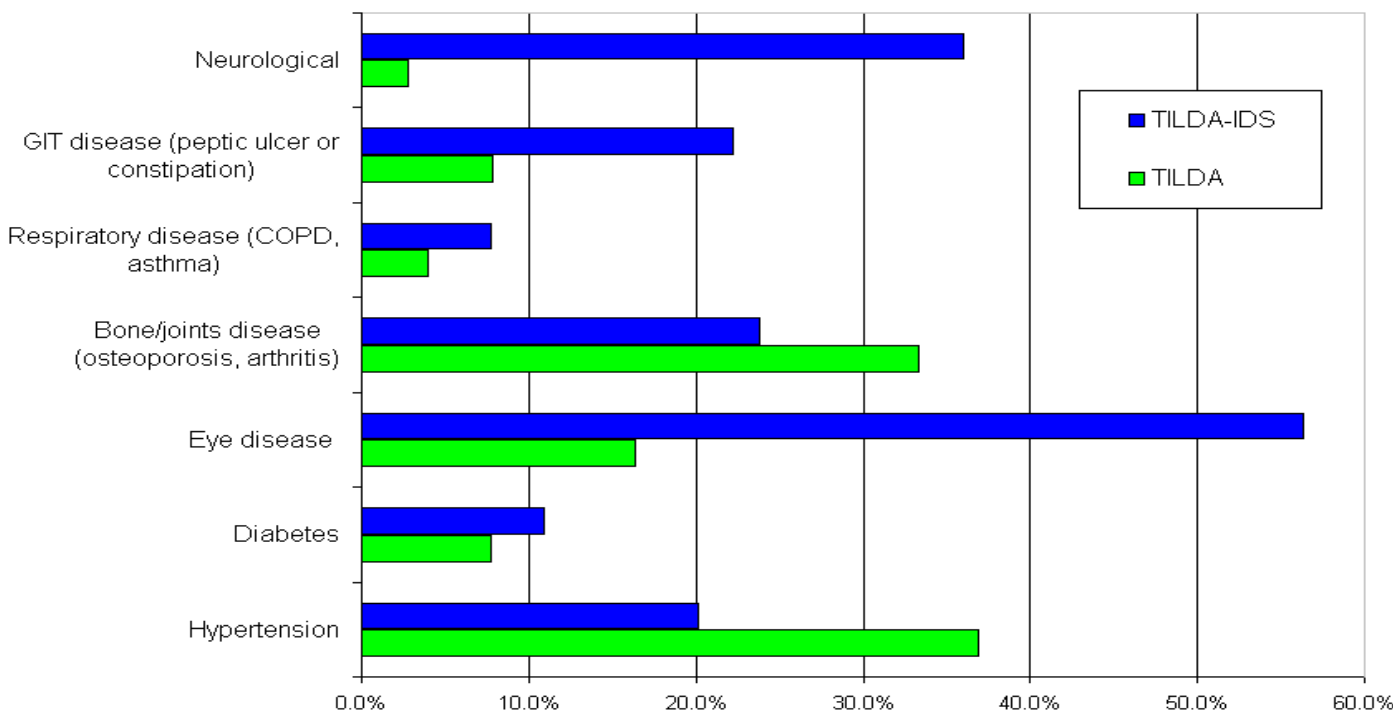
- Assessment of degree of cognitive impairment
 - Mild/Moderate/Severe
 - Health status
 - Self-assessed or Carer-assessed
 - Poor – Excellent
 - Morbidity varies with type of impairment
- | | |
|----------------------------|------------------------------|
| Neurological & Psychiatric | Dysphagia & Gastrointestinal |
| Behavioural | Vision problems |
| Endocrine | Hearing difficulties |



Health Needs & Multimorbidity comparison

Number of (mean+SD)	TILDA 50+y	TILDA-IDS 50+y
Chronic conditions	1.71 (1.45)	2.71 (1.55)

Comparison of prevalence of common conditions



Mental Health

High prevalence, but,

- Symptom identification
- Attribution
- Assessment

All difficult & comparison is inexact

- Behavioural problems



- Working with carers
 - Reliability of carer report
 - Practical aspects



Multiple Medicines Use



An Intellectual Disability Supplement to
The Irish Longitudinal Study on Ageing





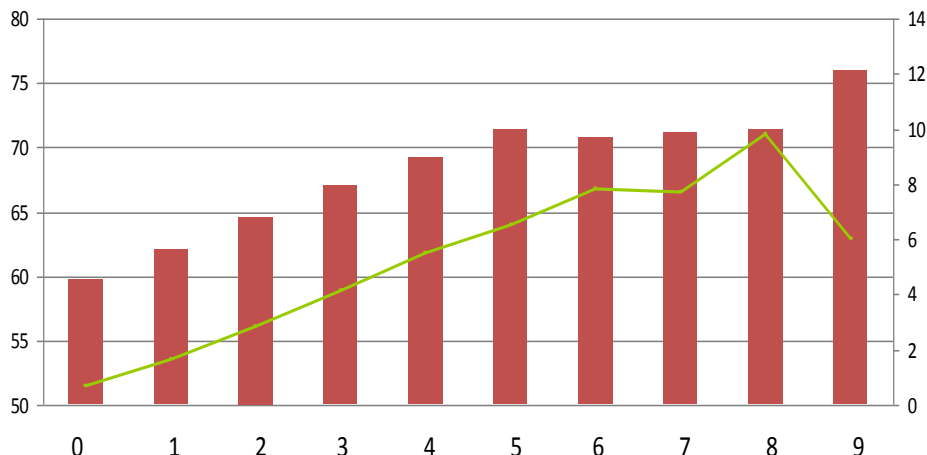
Multiple Medicines Use



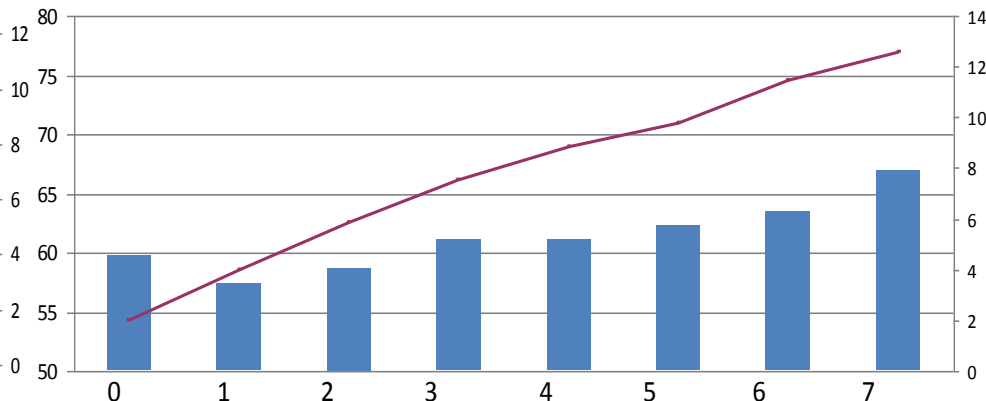
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	TILDA – general (mean+SD) or percentage pop'n	TILDA – IDS (mean+SD) or percentage pop'n
No of medicines	2.35 (2.55)	6.19 (4.43)
Polypharmacy 5-9 meds	19%	31%
XS Polypharmacy ≥ 10 meds	2%	21%
No of supplements	0.25 (0.64)	0.59 (0.81)

Mean age and mean No of drugs+FS vs. No of conditions



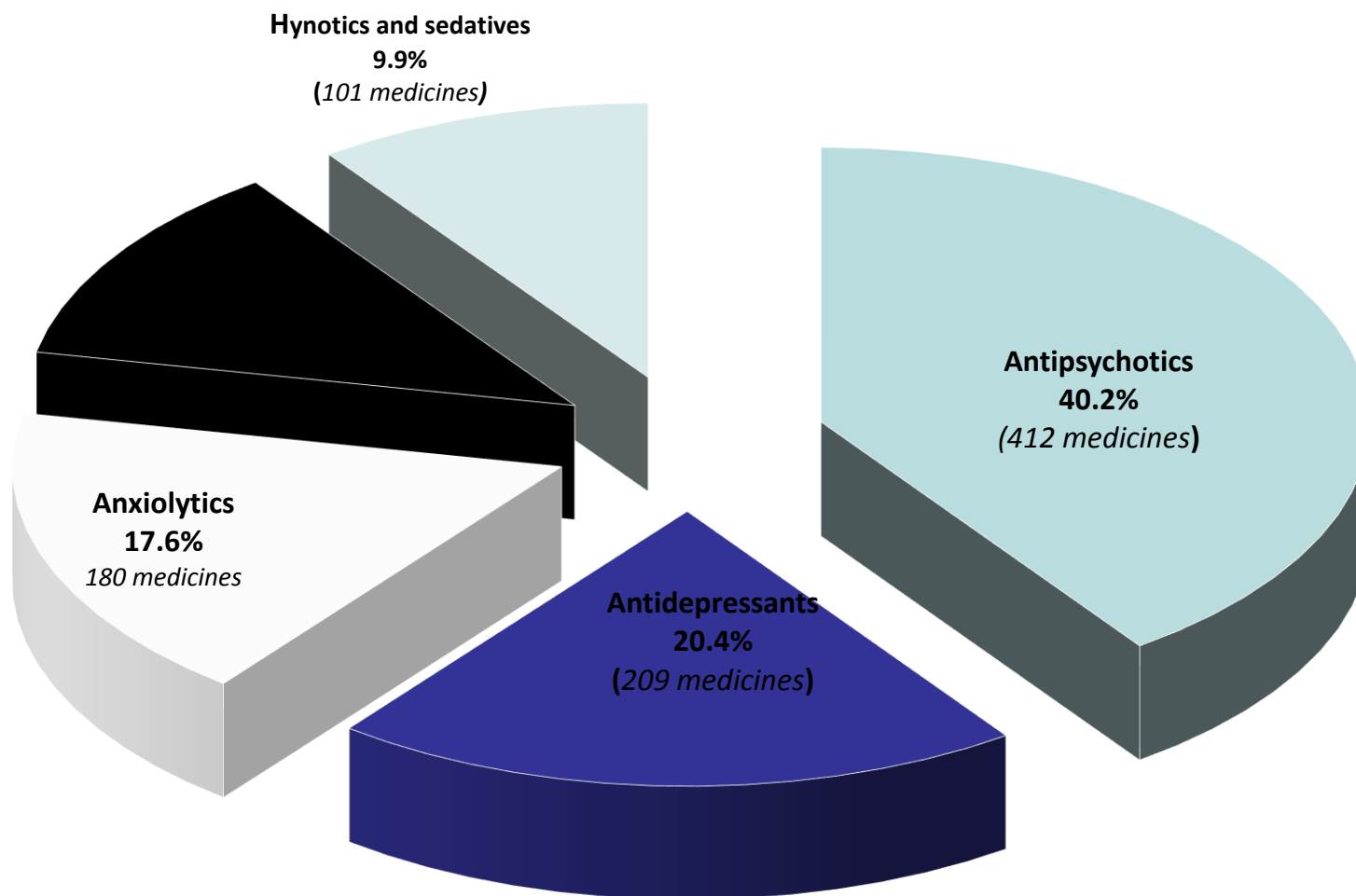
Mean age and mean No of drugs+FS vs. No of conditions





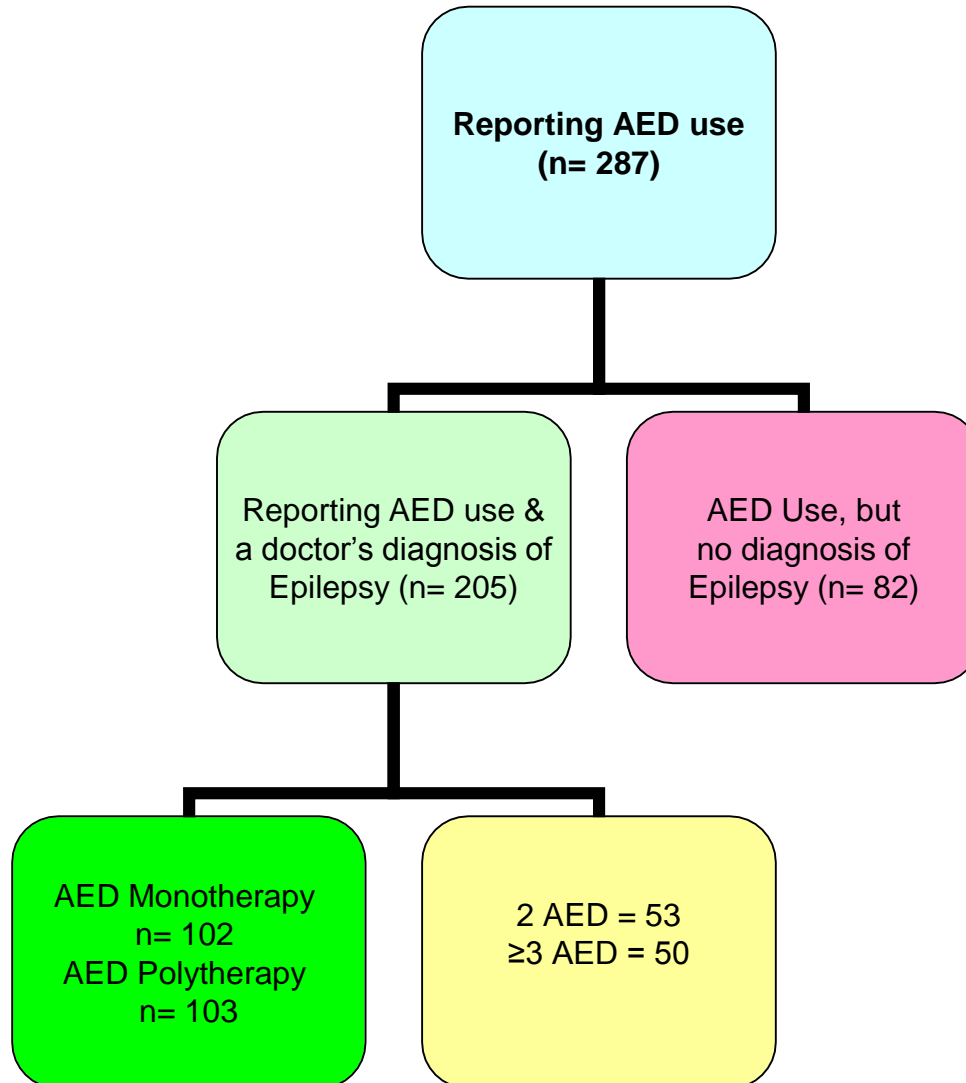
Classes of Psychotropic drugs

- **Psychotropic Use : 57.7% (434)**
- **Psychotropic Polypharmacy (2+ psychotropics): 66.4% (288)**
- **1025 Psychotropic Medicines used (57 different drugs)**





Epilepsy: complex treatment



- Only 42.6% were seizure free for past 2 years
- 24.5% experienced more than one seizure each month

Concomitant drugs

Antipsychotics = 79
Antidepressants = 50
Benzodiazepines + Z drugs = 100
Opioids = 0
Anticholinergics = 35
Analgesics = 89
Laxatives = 110
Agents for PUD/GORD = 58
Thyroid = 41



Multiple medicine use, over- or under-treatment

- Physical symptoms vs subjective
 - Interpretation by Health Care Professional or carer
 - Impact of patient's symptoms/response

Condition	No reporting	No relevant medicines	Ratio
Eye disease	386	50	0.13:1
Mental Health	359	885	2.5:1
Neurological	273	746	2.7: 1
Gastrointestinal	201	827	4.1: 1
Joint	164	154	0.9: 1
Pain	229	371	1.6: 1



Meeting Needs, Responsible use of medicines - Medication Review



- Assumption of appropriate assessment at outset
 - Who prescribed & when?
- Documentation
- Assessment of efficacy
 - Whose perspective?
- Assessment of side effects
 - How?

See also Canadian Consensus guidelines: Sullivan et al Can Fam Physician 2011



Use of medicines with anti-cholinergic activity



An Intellectual Disability Supplement to
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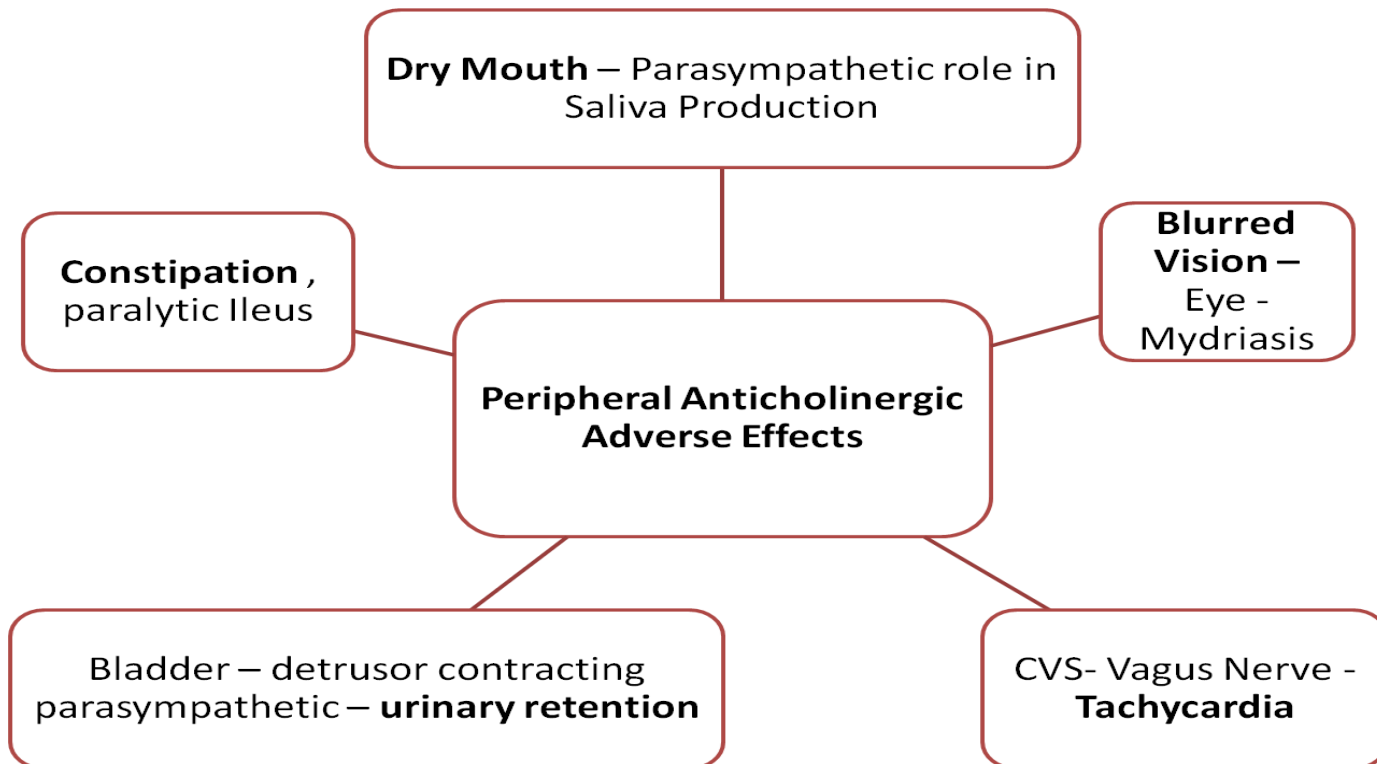


Anticholinergic Adverse Effects

Central effects: Sedation, Hallucinations, Amnesia, Agitation, Delirium, Excitation (Toxic Dose).

But, inconsistent results in published studies – integrity of the Blood Brain Barrier & ‘functional reserve’ vary

Peripheral effects:





Measurement of Anticholinergic activity

❑ Rating Scales

- Anticholinergic Risk Scale (*Carnahan et al., 2006*)
- Anticholinergic Drug Scale (*Rudolph et al., 2008*)

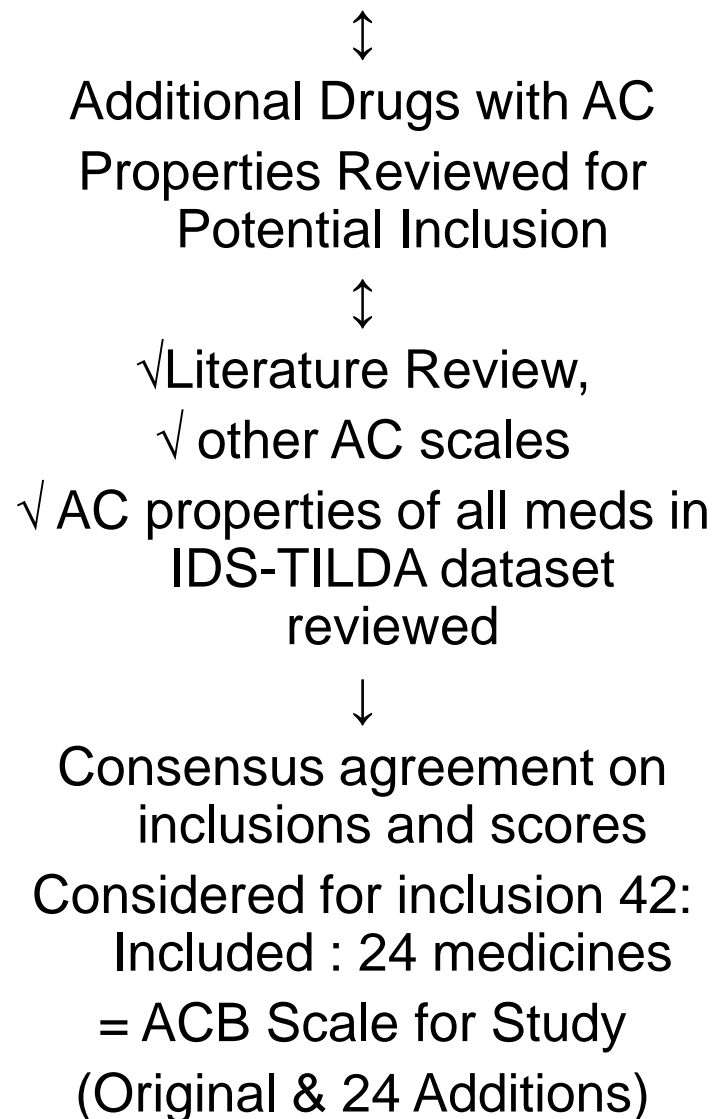
ABC Anticholinergic Cognitive Burden Scale (ACB)

(<http://www.agingbraincare.org/tools/abc-anticholinergic-cognitive-burden-scale>)

- ❖ Developed in 2008 – Update 2012
- ❖ Literature and Consensus Numerical Scoring (Total)

0 = no- Anticholinergic Activity
1 = low activity (potential AC properties)
2 = moderate Activity (definite AC properties)
3 = high / severe activity (definite AC properties)

ACB Scale (2012)





Anticholinergic Medicines

- Anticholinergic Cognitive Burden Scale;
0 = none.....3 = severe activity
- 306 participants (40.7%) reporting taking an ACB 3 Medicine

ACB 3 Therapeutic Classes	ATC Code	Number Medicines (450)
Antipsychotics	N05A	46%
Anticholinergics	N04A	27.6%
Antidepressants	N06A	9.6%
Antihistamines	R06A	5.3%
Urologicals	G04B	5.1%

- Participants with ≥ 2 ACB score 3 meds - 115 (max concurrent 4)
- No. receiving concurrent antipsychotic + anticholinergic -111



Peripheral Anticholinergic Adverse Effects by Cumulative Anticholinergic Burden Score

	Total	NO AC Exposure	ACB 1-4	ACB 5+	P-VALUE
Question Peripheral Adverse Effects	752	225	310	217	
“Is constipation a problem for you?” (n=740)	322 (43.5)	63	139	120	<0.001
Chronic Constipation, Doctor’s Diagnosis (n=751)	130 (17.3)	17	55	58	<0.001
Laxatives	276 (36.7)	65	120	116	<0.001
1	146 (19.4)	62	62	54	
2+ laxatives	130 (17.3)	3	58	62	<0.001



Side effects

- Levetiracetam - agitation and depression
- Valproate - increased bruising due to thrombocytopenia
- Lithium - polydipsia leading to possible investigations for diabetes



Side effects



- Medication side effects can require special tools





Pharmacists' views & experiences



- Role
 - We must ensure that the right dose is delivered at the right time for positive outcomes, and to follow up on it, to keep monitoring whether all that is happening properly.
 - Guess you've got to be able to educate them, to ensure they understand, like something you explain to someone else might seem obvious that they understand it, but you might need to look at how you're explaining things.
- Experience
 - I may not be able to understand what their level of understanding would be.
 - We've had a couple of these people that have really become good friends, and you can see the relationship grow, and you can see improvements in them, and even the staff feel good about it.
- Carers
 - . . . they're the conduit, they're the sort of supply line, they're the best person to actually convey some information because they have a better understanding of how to communicate with them.
- Collaboration
 - They're leaving us out of the loop. We don't know what their role is.
 - Trying to get a communication system working between doctors and us, and the carers can be a challenge.
 - We don't know what support mechanisms are out there . . . who do we communicate with?
- Needs
 - I guess a barrier too is experience or I don't have a lot of education on how to deal with customers that have an intellectual disability.
 - I think it's important for us in pharmacy, pharmacists, pharmacy staff... if you deal with a lot of intellectually disabled people, to actually have some formal education.