Maximizing the Long-Term Care Market Opportunity

Abbott Laboratories, Inc.

Abbott Laboratories

Orientation

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Long-Term Care Market Development

Maximizing Geriatric Healthcare Opportunities

REDACTED **offers a comprehensive training program to representatives of Abbott Laboratories who will serve the long term care (LTC) industry. This training program is designed to provide an overview of the LTC industry and familiarize each attendee with its associated components and terms. Additionally, the attendee will gain insight into how to favorably position Abbott Laboratories' core products, including Depakote ER, in the LTC environment.**

OBJECTIVE:

The complete training program takes place over a two-day period. The days are spent in classroom, long term care pharmacy, nursing facility and assisted living facility settings. Upon completion of the REDACTED LTC Training Program each participant will be able to:

1. Describe the roles of the various healthcare professionals who practice in long term care
2. Explain the meaning of common terms and abbreviations used in long term care
3. List the services provided by health care professionals practicing in long term care
4. Describe the role of a pharmaceutical manufacturer representative in the long term care environment
5. Describe the impact of state and federal regulations for the long term care industry in general and for long term care pharmacy in particular

PROGRAM SCHEDULE:

Day	General Description	Location	Time
Day 1	Program Orientation & Industry Review	Abbott Training	8:00a – 5:00p
Day 2	LTC Pharmacy & NF/ALF Site Visits	TBA	8:00a - 12:00n
Day 2	Reimbursement, Market Share, Partnering	Abbott Training	1:00p – 5:00p

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Program Components:

Day 1 (8am - 5pm) CLASSROOM

Long Term Care (LTC) Overview

1. The Aging of America
   a. Facts and figures
   b. Trends
   c. Projections
   d. Where aging Americans live (types of LTC facilities)

2. Long Term Care (LTC) Rules and Regulations
   a. Federal statutes & State laws
   b. Regulations specifically impacting LTC pharmaceutical care
   c. Quality Indicators and pharmaceutical opportunities

3. Key Decision Makers in Long Term Care
   a. Institutional LTC Pharmacy (operations and consulting)
   b. Nursing Facility Staff
   c. Medical Directors
   d. Communication skills workshop

Day 2 (8am - 12n) SITE VISITS

The Provider/Consultant Pharmacist

1. Specific Duties and Tasks
   a. Specialized medication packaging
   b. Medication Ordering and Dispensing
   c. IV and other "special" medications
   d. Staff
      Technicians, Medical Record clerks, Billing and Accounting staff, Customer Support staff, Medical Supply staff, Enteral Therapy, etc...

2. Special Services Provided - Dispensing Pharmacy
   a. Medical records (charting forms)
   b. Infusion therapy training
   c. Medical supplies
   d. Medicare Part B billing (enteral, wound care, urological)
   e. Specialized Billing (medicaid, medicare, insurance, capitated contracts, etc..)
   f. Emergency medication
   g. Drug information services (24hr/day)

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Day 2 (con't) SITE VISITS

3. Specific Duties and Tasks - Consultant Pharmacist
   a. Patient assessment
   b. Drug regimen review
   c. Med pass and treatment observations
   d. Med storage/cart reviews
   e. Review of procurement, receipt, storage, distribution & administration of medications in the long-term care facility
   f. Drug destruction and/or returns
   g. Inservice presentations
   h. Meeting attendance and presentations

4. Interaction with Pharmaceutical Manufacturer Representatives
   a. Setting up meeting with key decision makers
   b. Contracting
   c. Formulary issues
   d. Market share issues
   e. Lunch/dinner presentations

5. Special Services Provided
   a. Research (Phase IV and Outcomes)

Long-Term Care Facilities

1. Nursing Facility
   a. Interview with key staff
      i. Administrator
      ii. Director of Nursing
      iii. Staff Nurses
      iv. CNAs
   b. Medication administration observation
   c. Review of consultant pharmacist's activities
   d. Discussions with patients

2. Assisted Living Facility
   a. Interview with key staff
      i. Director
      ii. CAN
   b. Medication Observation (compare with nursing facility)
   c. Review of consultant pharmacist's activities
   d. Discussion with patients

3. Medical Director
   a. Role in the nursing facility
   b. Specific duties and responsibilities
   c. Interaction with key facility staff
   d. Interaction with the LTC pharmacists and consultants

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DAY 2 (1p - 5p) REVIEW & DISCUSSION

1. Review of Participant's Experiences

2. Reimbursement (Medicaid & Medicare) Challenges for the LTC Industry
   a. Prospective Payment System (PPS)
   b. Cost-Based Payment System
   c. Pharmacy reimbursement
   d. Contracting

3. Therapeutic Interchange
   a. How to select preferred products
   b. How to design therapeutic interchange programs
   c. Collaborative practice agreements
   d. Benchmarking and monitoring

4. Discussion of Applicability of LTC Experience to Sales
   a. Who are the decision makers
   b. How to conduct sales meetings
   c. What decision makers want to hear
   d. How to present your products

5. Summary & Conclusion

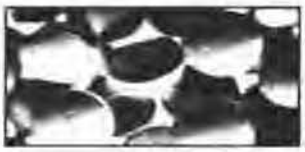
Maximizing the Long-Term Care Market Opportunity

Background

Abbott Laboratories

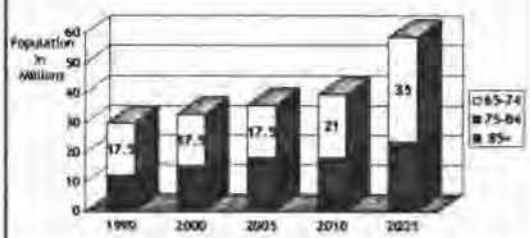
Purpose

As the fastest growing segment of health care, the long term care (LTC) market accounts for nearly $5.7 billion in total pharmaceutical purchases.



Source: DHS 2001

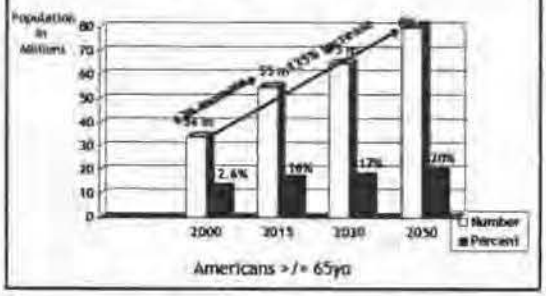
Graying of America



Quality of life

Frail Elderly

Graying of America



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Americans Over 50 Years Old

- 58% of all health care spending
- 61% of all OTC spending
- 74% of all prescription drug expenditures

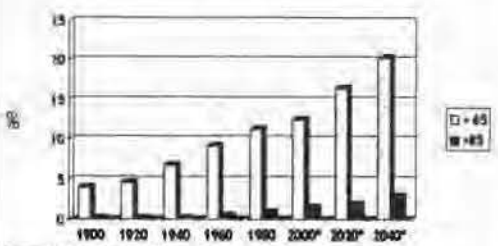
Source: Kan Dychtwald, Age Power: How the 21st Century Will Be Ruled By The New Old. (J.P.Tarcher Inc., Los Angeles 1999).

Elderly = 65yr & Older

- 34 million Americans who are currently 65 & over make up 12.6% of population but utilize
  - 44% of all hospital days
  - 40% of all visits to internists
  - 33% of the nation's personal health care expenditures
  - 40% of all medications
    - 2.8 billion prescriptions

Source: IMS 1999
Meszaros EC. The onslaught of the elderly: MCOs prepare for America's fastest growing demographic with special drug problems. Managed Healthcare. 1995;S13-S16.

% of US Population



Source: US Census Bureau 2000
* = estimated

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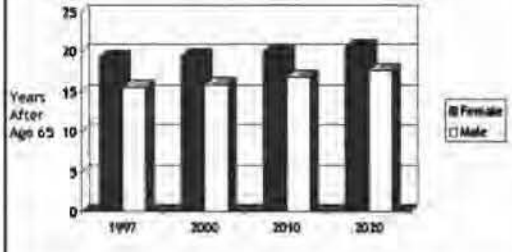
Elderly = 85yr & older

- 3 million Americans
  - 1.2% population
  - 3x the hospital resources
  - 2x the prescription drugs
- Fastest growing segment of elderly
- Will double by 2025 (5.2 million)
- 25% live in NHs

Age 65 Life Expectancy



Why All the Fuss?

"Medications are probably the single most important health care technology in preventing illness, disability, and death in the geriatric population."

Source: Avorn J. Medication Use and the Elderly: Current Status and Opportunities. Health Affairs 1995, Spring

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3

Objectives

Upon the completion of this program, the attendee will be able to:

- Define LTC
- Recognize LTC customers
- Identify key regulations
- List the key decision-makers who make up the LTC pharmacy & facility teams
- Describe a typical LTC pharmacy operation
- Identify the challenges facing the LTC industry
- Understand how Abbott Pharmaceuticals can partner with LTC pharmacies and facilities

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What is LTC ?

What Is Long Term Care?

Types Of LTC Customers

- Nursing facilities
  - ICF, SNF, ICF-MR, NF, NH
- Assisted living facilities
  - ALF, PCH, RCC, board & care, CCRC
- Sub-acute facilities
- Hospices
- Group homes
- Correctional facilities
- Small hospitals
- Out-patient surgery centers
- NORC's
- Employer groups
- ?
- ?

10%

If IMPDQ - ICFMR - NO OBRA/PASRR

OBRA/PASRR

Should have in-house Pharmacists

Sometimes Long-term Pharmacy

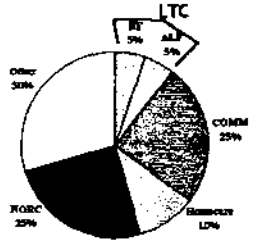
North Carol. says South Require a consultant Pharm. to Review every 3 mths.

Naturally Occurring Retirement Community

REDACTED contracting to manage retirement employees

Where Are the Elderly?

34.3 million individuals 65 & older



Long-Term Care Goal

To help people with disabilities to be as independent as possible. Focus is more on caring than on curing.

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Long-Term Care Patients

People who have functional limitations or chronic health conditions and who need **ongoing health care or assistance with normal activities of daily living (ADL).**

Activities of Daily Living (ADL)

- Eating
- Transferring (to and from bed, chair, etc...)
  - Ambulating
- Toileting
- Dressing
  - Grooming
- Bathing

Traditional Long-Term Care

- Takes place in Nursing Facilities (NF)
  - Subacute services,
    - IV therapy, ventilator pts, (hospital-like care)
  - Rehabilitative services,
    - Therapies that restore to prior functioning levels
  - Medical services,
  - Skilled nursing services,
  - Supportive social services

Adapted from The Managed Care Resource

CPR - Administers Medicine
P.P Adverse Events in
But side
Don't Realize Effects.
Teach how to
avoid Side
Effects.
$15 HR
CNA
6-8 HR

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2

90% occupancy is needed to be prof. table

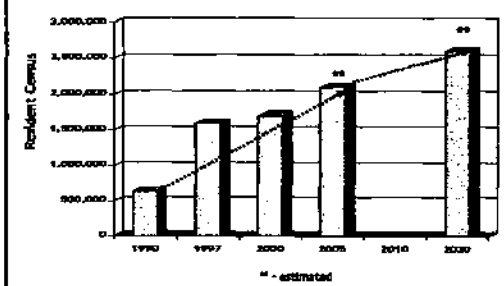
Nursing Facility (NF)

- State licensed
- Skilled nursing available 24hr/day
- Residents need frequent medical or nursing support
- Average size: 106 beds
- Average occupancy: 81%

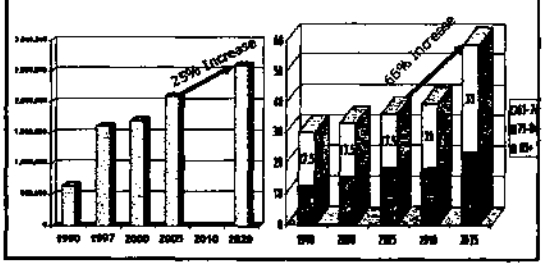
- Restorative or maintenance assistance with:
  - Medications
  - Eating
  - Dressing
  - Ambulating
  - Toileting
  - Bathing
  - Grooming

Called "residents"

Growth in Nursing Facility Residents



NF Beds vs Elderly Growth



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Traditional Nursing Facility Goal

- Rehabilitation
- Community involvement
- Encouragement of resident "living"
- Focus on resident's total needs

Adapted from Nursing Home Association Membership Directory

Nursing Facility – (Medicare A)

- Highest level of care
- Requires an RN available 24hr/day
- PT, OT, ST, RT
- 100 days per event
  - 3-day hospital stay
  - Qualifying illness
  - 20 days-100%, 80 days-80%

Medicare Part A Costs

- 1999 - $9.6 billion
  - 5 % of total national Medicare expenditures
- PPS reimbursement
  - MDS
  - RUGs
  - Capitated

Source: HCFA Review, Summer 2001

Nursing Facility – Subacute (Medicare/Insurance)

- Merges intensity of hospital services with operation of a nursing home
- Reduces cost of care for seriously ill patients
- May be a wing of the hospital or a SNF
- 35,000 – 45,000 beds in USA dedicated to Subacute care
- Goal: To stabilize seriously ill patients (cardiac, pain, extensive wounds, or other labor intensive problems) so they can be moved to less care-intensive facilities

Nursing Facility (Medicaid/Private/Insurance)

- Lower level of care
- No requirement for 24hr RN monitoring
- Medical, nursing, and social services provided ... but little PT,OT, ST
- Room and board of persons not capable of independent living due to inability to perform ADL's
- Cost based
  - MDS – Case Mix

Medicaid / Private Costs

Medicaid	Private
▪ 1999 - $43 billion • 23% of total Medicaid expenditures	▪ 1999 – $ 38 billion

Total NF Costs 1999 - $90 billion
2000 - $92.2 billion

Source: HCFA Review, [illegible] 2001

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Long Term Care Costs

- Average NF stay costs:
  - $46,000/yr
  - $120/day
- Daily rates include:
  - Room,
  - Board,
  - Nursing care,
  - Therapeutic activities,
  - Social services
- Other services are charged separately:
  - PT,OT,ST (therapy)
  - Supplies
  - **Pharmaceuticals**
  - Telephone
  - Cable TV

Source: American Council of Life Insurer's Report 2000

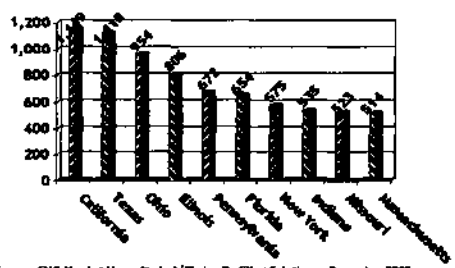
Pharmacy bills drugs directly to Medicaid, Private Pay, Insurance Company. The facility only pays for drugs on the 10% of patients who are on Medicare.

Top 10 NF Chains

Chain	Beds	Facilities
REDACTED	51,054	466
REDACTED	41,613	299
REDACTED	39,293	305
REDACTED	38,700	326
REDACTED	34,797	300
REDACTED	28,226	213
REDACTED	27,954	229
REDACTED	25,821	240
REDACTED	16,490	157
REDACTED	15,772	250

Source: Provider Magazine, July 2002 — 11.5% of Total US NF Beds

Top 10 States by # of Nursing Facilities



Source: SNG Nursing Home Market/Chains Profiling Solutions - December 2000

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Hospitals

- Approximately 20% of hospitals are in the LTC market
- Skilled beds for short-term care to sub-acute patients
  - Stroke
  - COPB
  - Orthopedic
- Average stay 100 days
- DRG debate
- Going away?

Called "patients"

ICF - MR

- Mentally retarded patients
- Slightly different regulations
- Usual age 5 - 25
- May also be cared for in:
  - Group residences
  - Semi-independent living facilities
  - State Institutions
- High emphasis on education and social programs
- Average stay 15 years

Called "clients"

Home Health Care

- Fastest growing sector of health care
- Nursing care provided in the patient's home
- Medicare and insurance is usual payor
  - Durable medical equipment (DME)
  - IV therapy
  - Ostomy/wound care
  - Nutritional supplements
  - Skilled nursing

Called "patients"

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Home Health Care Costs

- Average Medicare home health visit costs $85/visit in 1996
- Costs 1999: $34.5 billion
- Home care costs
  - 44% paid by Medicare
  - 14% paid by Medicaid
  - 42% paid by private insurance

HCFA Review, Summer 2001

Correctional Facilities

- Growth in prison population is leading to more elderly prisoners
- Similar physical problems seen in other LTC settings
- Average stay 5 yrs

Called " ???"

Hospice

- Care for the terminally ill (home or institution)
- Medicare and private insurance pays
- Typical patient
  - Cancer
  - AIDs
  - Alzheimers (end stage)
  - COPD, emphysema
- Average stay 2 months (6 mo limit)
- Primary emphasis is PAIN MANAGEMENT

Death with Dignity

Keeping Patient Calm -less agitated

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Assisted Living Facility

- Social model
- Residents similar to unskilled NF residents
- Private pay
- Less regulation
- No requirement for RN or LPN care *
- Med administration &/or assistance by CNAs
- No medical care provided by facility *
- Average size: 40 beds
- Average occupancy: 85%

* May differ by state

Called "resident"

Top 10 ALF Chains

Chain	Beds	Facilities
REDACTED	20,182	430
REDACTED	14,637	151
REDACTED	14,241	186
REDACTED	11,967	132
REDACTED	8,981	90
REDACTED	7,115	184
REDACTED	6,774	58
REDACTED	6,200	60
REDACTED	5,940	34
REDACTED	5,434	49

NH / ALF Chains

Chain	SNF Beds	ALF Beds
REDACTED	6,992	5,298
REDACTED	41,613	4,668
REDACTED	25,821	4,040
REDACTED	28,226	2,687
REDACTED	16,490	1,912
REDACTED	15,772	1,501

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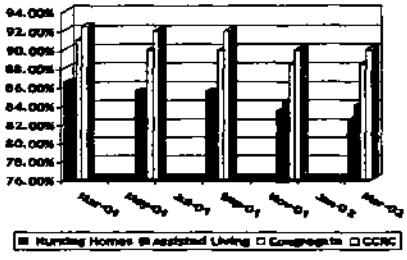
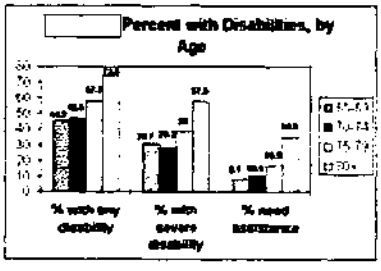
Senior Housing Occupancy Rates



Accessed 7/02: National Investment Center for the Seniors Housing and Care Industries

Disabilities Can Lead to Institutionalization



Source: CMS Report, April 2002

Same Patient - Different LTC Facility

Nursing Facility		Assisted Living
75% female	→	75% female
Average age – 85	→	Average age – 85
Average # meds – 9	→	Average # meds - 9
Medical model	→	Social model
Medicaid/Medicare	→	Private pay
CON (bed control)	→	No or limited CON
Highly regulated	→	Little regulation
Average stay – 1.5yr	→	Average stay – 3yr

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Who Lives in a Nursing Facility ?

- Americans with a nursing home address ...
  - 5.3% over age 65
    - 2% Americans age 65-74
    - 6% Americans age 75-84
    - 23% Americans age 85+

Who Uses NF Care?

- 89.3% over age 65
- 75% are women
- 10.7% ages 1 - 64

* Nursing Home Association Data

- Average NF resident - 4 ADLs
- Average home health patient - 2.5 ADLs
- Average ALF resident - 1 ADLs

Who Uses NF Care?

- 70 - 80% of USA facility population is disoriented or memory impaired
  - 34.5% Depression
  - 6.9% Psychiatric Dx

Source: CMS MDS Report Jan 2001

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ABC: The Key Symptom Domains of Alzheimer's Disease

Behavior Disturbances Exhibited in Dementia

- **DEPRESSION**
  - Depressed Mood
    - Irritable mood
  - Diminished interest or pleasure
  - Significant weight loss or anorexia
  - Insomnia or hypersomnia
  - Psychomotor agitation or retardation
  - Fatigue
  - Delusions of worthlessness or extreme guilt
  - Diminished ability to think, concentrate, or make decisions
  - Suicidal ideation
- **DEMENTIA**
  - Wandering
  - Poor self care/resisting care
  - Anxiety
  - Insomnia
  - Nervousness
  - Fidgeting
  - Uncooperativeness
  - Restlessness
  - Unsociability
  - Agitated behaviors
  - Impaired memory
  - Indifference to surroundings

Behavior Disturbances Exhibited in Dementia

- **PSYCHOSIS**
  - Delusions
  - Hallucinations
  - Disorganized speech
  - Grossly disorganized behavior
  - Catatonic behavior
  - Flat affect, alogia, avolition
- **DEMENTIA**
  - Wandering
  - Poor self care/resisting care
  - Anxiety
  - Insomnia
  - Nervousness
  - Fidgeting
  - Uncooperativeness
  - Restlessness
  - Unsociability
  - Agitated behaviors
  - Impaired memory
  - Indifference to surroundings

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Factors Leading To NF Care

- Absence of family
- Exhaustion of financial resources
- Burden on existing family members
  - Traditional care givers (women) are increasingly in the work force
  - Family size is decreasing
  - Rising life expectancies find children caring for very old parents while they themselves are elderly and lacking stamina

Factors Leading To NF Care

- Women are more likely than men to enter a nursing facility.
  - Lifetime risk of being in a NF at age 65: 52% women - 30% men
- Lack of children
  - 37% of NF residents lack children
  - 19% of community dwelling elderly lack children
- Lack of spouse
  - 84% of NF residents lack spouse
  - 45% of community dwelling elderly lack spouse

NF - ADL Total Dependency

Eating	34.2%
Transferring	68.4%
• Ambulating	26.6%
Toileting	75.2%
Dressing	81.2%
• Grooming	79.8%
Bathing	50.6%

Source: CMS MDS Reports, Jan 2001

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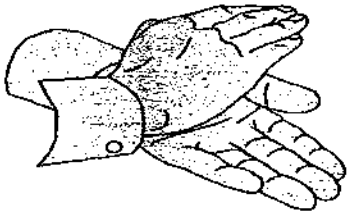
CONGRATULATIONS !!



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14

The LTC Regulatory Environment

Objectives

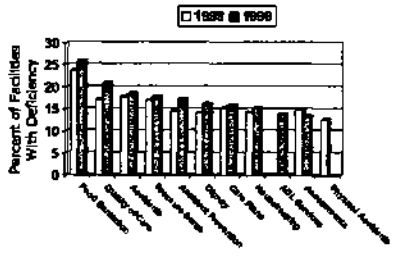
Upon completion of this section, the attendee will be able to:

- Recognize key legislative actions that have impacted the LTC industry
- Identify specific regulations that effect medication use in the LTC industry
- Differentiate how Abbott Laboratories' products can offer a benefit to the facility by improving compliance with regulations

Government Involvement In LTC - NF

- LTC (Nursing Facilities) is the most heavily regulated industry
  - CMS (Center for Medicaid and Medicare Services)
    - Formerly called: HCFA (Health Care Finance Administration)
  - State or Federal agencies have authority to:
    - impose monetary fines up to $10,000/day
    - suspend admissions to the facility
    - cut off Medicaid funds
    - place monitors in NF
    - hire temporary managers for the NF if the NF is having difficulty complying
- Over 300 pages of regulations (188 regs)

Top 10 Deficiencies



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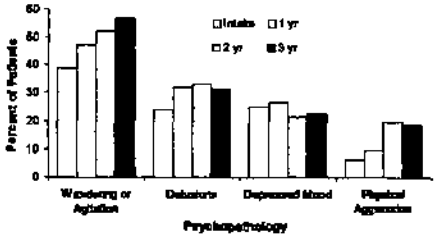
Omnibus Budget Reconciliation Act (OBRA) 1987

- Introduced "chemical restraint" regulations
- Required dose reductions & behavior monitoring on psychotropic medications
  - Antipsychotics
  - Anxiolytics
  - Sedative/Hypnotics
- Specified medication administration observation (med pass) procedures

Why Be Concerned With "Chemical Restraints"?

- 70-80%% of NF residents suffer from dementia
- Dementia mimics psychosis in many domains

Frequency of Patients With AD–Related Psychopathology During 3 Years of Follow-Up



Balanced Budget Amendment (BBA) 1997

- Cost control effort
- Introduced Prospective Payment System (PPS)
- Introduced Medicare "managed care" – Medicare + choice

Reimbursement NF = SNF + ICF

SKILLED CARE
(10% Medicare)
- Medicare
- Private Pay
- Insurance & Managed Care
- Capitation
- Maximum stay 100 days (Avg stay 60 days)
- DRUGS INCLUDED

UNSKILLED (ICF)
(47% MCD/43% Other)
- Medicaid
- Private Pay
- Insurance
- Capitation
- Maximum stay indefinite (Avg stay 1.5 years)
- DRUGS BILLED SEPARATELY

Medicare vs Medicaid

Medicare
- Administered federally
- Persons 65+ or disabled
- Rx meds not included w/few exceptions
- Part A - hospitalizations and SNF
- Part B - MD visits, DME

Medicaid
- Administered by states w/federal matching funds
- Medically "indigent"
- Rx meds included (voluntarily)
- Hospitalizations, NF, MD visits

State & Federal expenditures for NF = $54 billion in 2001

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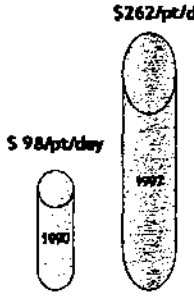
The Quest for Medicare PPS



Medicare PPS vs Cost Based

MDS

PPS Reimbursement

- Capitated Rate
- Requires 5 MDS evaluations (adm,14,30,60,90 days)
- Rate can change w/o MDS (RUGS)
- Encourages less spending
- Encourages less acute patients
- *Fluff has "gone with the wind"*

Cost Based Reimbursement

- Cost-Based Rate
- Cost + Overhead mark-up
- Encourages more spending
- Encourages more acute patients
- Room for fluff

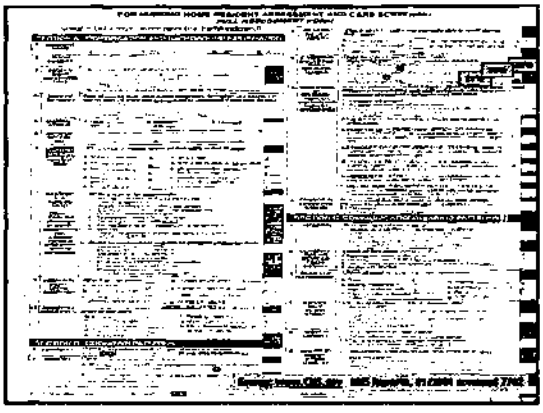
Minimum Data Set (MDS)

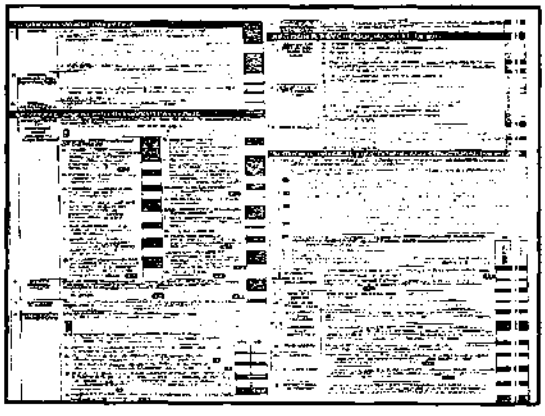
- Over 500 items assessed
- 22 Categories
- 10 pages
- All NF patients
  - On admission, quarterly, significant change
- Drives Medicare payment (PPS)
- Drives Quality Indicators
- Drives Medicaid payment-some states (Case Mix)

REDACTED

2002

4





HCFA Regulation Update 1999

- Added "Drugs Potentially Inappropriate in the Elderly" to "unnecessary drug" regulation
- Expanded medication administration requirements
- Required assessment and treatment of pain
- Focused attention on dialysis patients
- Quality Indicators

REDACTED

2002

5

Quality Indicators

- 24 Items
- Calculated from data elements that are included on the Minimum Data Set (MDS).
- Five of the 24 indicators are based upon Section O of the MDS. These five indicators are:
  - prevalence of symptoms of depression without antidepressant therapy
  - prevalence of residents who take 9 or more different medications
  - prevalence of antipsychotic use in the absence of psychotic or related conditions
  - prevalence of antianxiety/hypnotic use
  - prevalence of hypnotic use more than two times in last week

24 Quality Indicators

1. New fractures
2. Falls
3. Behavior symptoms affecting others
4. Symptoms of depression
5. Symptoms of depressed mood without treatment
6. Use of 9 or more medications
7. Cognitive Impairment
8. Bladder or bowel incontinence
9. Incontinence without a toileting plan
10. Indwelling catheters
11. Fecal Impaction
12. Urinary tract infections
13. Weight loss
14. Tube feeding
15. Dehydration
16. Bedfast
17. Decline in late loss ADLs
18. Decline in ROM
19. Anti-psychotic use, in absence of psychotic or related conditions
20. Anti-anxiety/hypnotic use
21. Hypnotic use more than 2x / week
22. Daily physical restraints
23. Little or no activity
24. Stage 1-4 pressure ulcers

29
20
10

Dep w/o
Bowel
0 - 17.4
1, 5.8
22. 8
24. 9

French roast

Lorazepam and Divalproex in Nursing Facilities

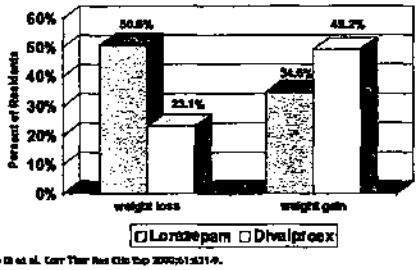
- 146 patient charts reviewed
- 81 patients (55.5%) received lorazepam; 65 patients (44.5%) received divalproex
- 37 patients (56.9%) treated with divalproex showed improvement
- 25 patients (30.9%) treated with lorazepam showed improvement

REDACTED

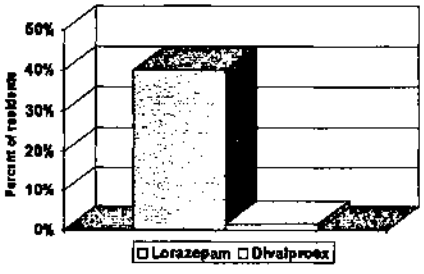
2002

6

Residents Experiencing Weight Gain or Loss



Residents Experiencing Falls



Sentinel Events- facility is flagged if only 1 resident triggers

- Fecal impaction
- Dehydration
- Acquired pressure ulcers

Anticholinergic Cause

REDACTED

2002

7

Additional considerations

- Hospice care
  - Plan of care must include directives for
    - Pain management (big JCAHO issue!)
    - Other uncomfortable symptom management
  - Drugs & supplies must be provided as needed for palliation & management of terminal illness & related conditions
    - Depression, Anxiety

Additional Considerations

- Dialysis services
  - Medication must be given at times for maximum effect

Additional New Investigative Protocols

- Unintended weight loss (diuretics, laxatives, cardiovascular meds)
- Dining & food services
  - Do not give meds at meals unless patient requests or necessary for optimal medication effect
  - Pain meds given prior to meals to allow eating in comfort
  - Do not use meal foods as med vehicles
- Nursing services, sufficient staffing

REDACTED

Nursing Staff Averages

	Nat'l	GA	MI	S.CA	WY
Avg # beds	80	100	97	77	64
Avg # RN FTE	9	6	12	8	9
Avg # LPN FT	12	19	15	76	14
Avg # C.N.A FTE	33	40	42	53	25
Avg # Total Nsg Staff FTE	54	65	69	137	48
Avg # Nsg FTE/ Resident	0.7	0.6	0.7	1.8	0.8

Source: HCFA OSCAR data 1999

F329 Unnecessary Drug

- Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used ...
  - Without **diagnosis or reason** to support drug use
  - Without **adequate monitoring**
  - In the presence of **side effects** or **adverse consequences** which indicate the dose should be reduced or discontinued
  - In the presence of **duplicate therapy or excessive dose**
  - For **excessive duration**

Medications Potentially Inappropriate in the Elderly

- Beers,M MD, *Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly*, Arch Intern Med/Vol 157. July 28, 1997
  - High Potential for Severe ADR ... F329, Unnecessary Drugs
  - High Potential for Less Severe ADR ... F428/429, Drug Regimen Review

REDACTED

Go to SLUD

The Problem

Cholinergic System Effects	Anticholinergic Effects
• Salivation	• Dry Mouth
• Lacrimation	• Dry Eyes
• Urination	• Urinary Retention
• Defecation	• Constipation
S L U D	

F329 - Potential for Severe ADR

- Pentazocine (Talwin)
- Long-Acting Benzodiazepines (Valium, Dalmane, et al)
- Amitriptyline (Elavil)
  - Except for neuropathic pain when benefit is greater than risk
- Doxepin (Sinequan)
- Meprobamate (Equanil)
- Disopyramide (Norpace)
- Digoxin > 0.125mg/day ** (Lanoxin)
- Methyldopa ** (Aldomet)
- Chlorpropamide (Diabenese)
- GI Antispasmodics (Levsin)
- Barbiturates (Phenobarb) *OK for seizures
- Meperidine ** (Demerol)
- Ticlopidine (except for ASA intolerant post CVA pts) (Ticlid)

[redacted]

F329 - Drug/Disease Combinations

- BPH
  - Anticholinergic antispasmodics
  - Anticholinergic antiparkinson meds
  - GI antispasmodic
  - Anticholinergic antidepressants
- Arrhythmias
  - Tricyclic Antidepressants

REDACTED

F329 - Drug/Disease Combinations

- COPD
  - Long Acting Benzodiazepines
    - Short Acting Benzos are OK PRN for anxiety
  - Barbiturates
  - Hypnotics/Sedatives
- PUD, GERD, GASTRITIS
  - NSAIDS
- SEIZURES/ EPILEPSY
  - Metoclopramide
- BLOOD CLOTTING DISORDERS
  - Aspirin, NSAIDs, dipyridamole, ticlopidine

F429 - Potential for Less Severe ADRs

- Phenylbutazone
- Trimethobenzamide (Tigan)
- Indomethacin (Indocin)
- Dipyridamole (Persantine)
- Reserpine (Serpasil)
- Diphenhydramine (Benadryl)
- Ergot Alkaloids (Hydergine)
- Muscle Relaxants (Soma, Flexeril, Robaxin)
- Antihistamines (Vistaril, Atarax, Anthvert, etc...)

F429 - Drug/Disease Combinations

- Diabetes
  - Corticosteroids - if started within 30 days
- PUD, GERD, GASTRITIS
  - Aspirin > 325mg/day
  - Potassium supplements (unless benefit outweighs risk)
- SEIZURES/ EPILEPSY
  - Antipsychotic Drugs (unless used for </= 72hr for acute psychosis)
- BPH
  - Narcotics (unless use is periodic, 1x per 3months for < 7 days)
  - Incontinence meds (flavoxate, oxybutynin, bethanechol)
  - *interesting point: other Anticholinergic Drugs are listed as F329 !!!*

REDACTED

2002

11

Relevance of ADR Regulations

- Average NF of 106 beds
  - 24 ADR events/yr
  - 8 "near misses"/yr
- 350,000 ADRs/yr for US NF's
- Nearly 50% of ADRs are preventable
- 80% of "near misses" associated with warfarin
- Cost of ADR's was $4 Billion in 1996.

Source: NIH Press release 8-9-2000

Causes of Preventable ADR

- Ordering Errors
  - Wrong dose
  - Harmful interactions
  - Wrong drug choice
- Monitoring Errors
  - Inadequate lab monitoring
  - Failure or delay in responding to s/s of drug toxicity

Most common ADR causes:

- Medications
  - Psychoactive meds:
    - **Anti-psychotic**
    - Anti-depressant
    - Sedative
  - Anti-coagulants
- Preventable ADR:
  - **Neuropsychiatric events**

REDACTED

2002

12

F330 Antipsychotic Drugs (APD)

- Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed & documented in the clinical record

Allowable APD"conditions"

- Schizophrenia
- Schizo-affective disorder
- Delusional disorder
- Psychotic mood disorders
  - mania
  - depression w/psychotic features
- Acute psychotic episodes
- Brief reactive psychosis
- Schizophreniform disorder
- Atypical psychosis
- Tourette's disorder
- Huntington's disorder

Allowable APD "Conditions"

- Organic Mental Syndromes – OMS (delirium, dementia, amnestic/cognitive disorders) w/ associated psychotic &/or agitated behavior, which:
  - are quantitatively & objectively documented
  - persistent
  - not caused by preventable reasons, and ...
  - which are causing resident to:
    - present a danger to self or others
    - continuously scream, yell, or pace if these behaviors cause functional impairment
    - experience psychotic symptoms which cause resident distress or functional impairment

REDACTED

2002

13

Depakote Read for Antipsy.
- reduce need
- can take at as whole

F331 APD Dose Reductions

- Must be gradual
- Must be attempted twice in one year
- Is "clinically contraindicated" IF:
  - resident has a specific condition (1-10), has a hx of recurrence of psychotic symptoms, is stable w/o significant side effects
  - resident has OMS, but had return of symptoms after 2 attempted dose reductions
  - MD has justified why continued use of drug and dose are clinically appropriate

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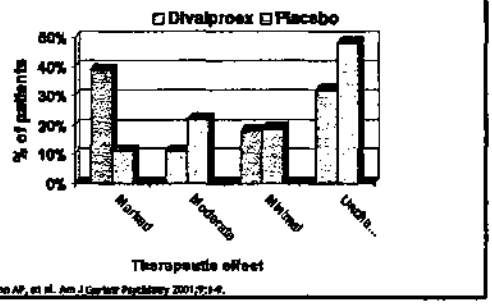
Divalproex For Agitation In Dementia

- Fifty-six patients randomized (28 divalproex, 28 placebo)
- Mean dose at Week 6 = 826 mg/d; mean serum concentration = 45.4 µg/mL
- Improvement in BPRS agitation score; divalproex vs placebo (ANCOVA: $P=0.05$)
- Change in CGI showed trend for improvement (ANCOVA $P=0.06$)
- The average dose and serum levels were low compared with reports in younger subjects
- Larger follow-up study indicated

REDACTED

Clinical Global Impression: Therapeutic Effect

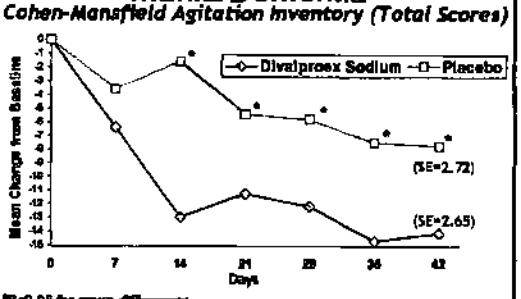


Divalproex in Elderly Mania/Dementia

- 173 randomized patients (87 received divalproex, 85 received placebo
- Divalproex group had a statistically significant decrease from baseline on CMAI score, compared to placebo (p=0.035)
- 47 patients in divalproex group withdrew prematurely due to somnolence (related to aggressive dosing and titration schedule)
- Somnolence generally rated as mild to moderate
- Further study of divalproex at a slower titration and daily doses below 15 mg/kg for agitation is warranted

Divalproex in Elderly Mania/Dementia

Cohen-Mansfield Agitation Inventory (Total Scores)



Stopped due to forced titration

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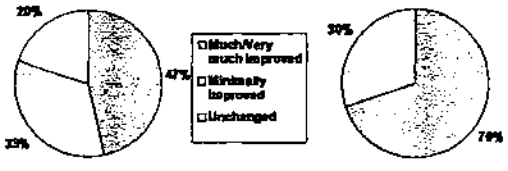
2002

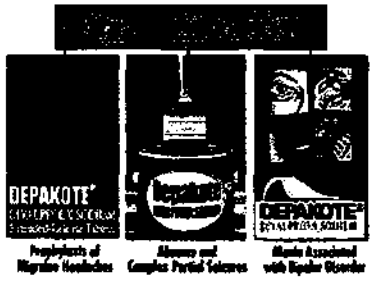
15

Divalproex Alone or In Combination with a Neuroleptic
Results



Narayan M. & Nelson JC. J Clin Psychiatry. 1997;58:351-4.

The Depakote Advantage



F329 Sedative/Hypnotic Drugs

- Overused (unless not paid for by Medicaid)
- High potential for side-effects
  - Sedation
  - Confusion
  - Amnesia
  - Anticholinergic
  - Falls
- Dose reduction required after 10 days of continuous use

REDACTED

F329 Anti-anxiety Drugs

- Overused
- High potential for side effects
- PRN vs Routine
- Dose reduction required after 4 months of continuous use
- Generalized anxiety vs Organic Mental Syndromes

Sedative Effect.

F329 Anti-anxiety Drugs

- Overused
- High potential for side effects
- PRN vs Routine
- Dose reduction required after 4 months of continuous use
- Generalized anxiety vs Organic Mental Syndromes

Depakote Pearl - reduce need for Anti-anxiety and sedative/hypnotic drugs

Antidepressants

- Underused
  30 - 80% of NF residents may be depressed 34.5%
- Difficult to diagnosis depression
  - Co-existing diseases (dementia)
- AD drug selection is based on
  - Safety profile
    - Drug interactions
  - Cost

REDACTED

2002

17

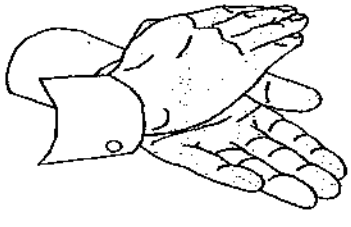
F333 Medication Administration

- Medication Error - the observed preparation or administration of drugs or biologicals which is not in accordance with:
  - MD orders
  - Manufacturer's specifications
  - Accepted professional standards

HCFA Med Error List

- Failure to "shake well"
- Failure to mix insulin by "rolling"
- Crushing meds that should not be crushed
- Giving meds without adequate fluids 4-8oz (bulk laxatives, potassium supplements, NSAIDS)
- Giving meds without food or antacids when manufacturer recommends (NSAIDS)
- Proper enteral feeding precautions
- Eye Drops – wait 3-5 min
- Swallowing sublingual meds
- MDIs – wait 1 minute

CONGRATULATIONS !!



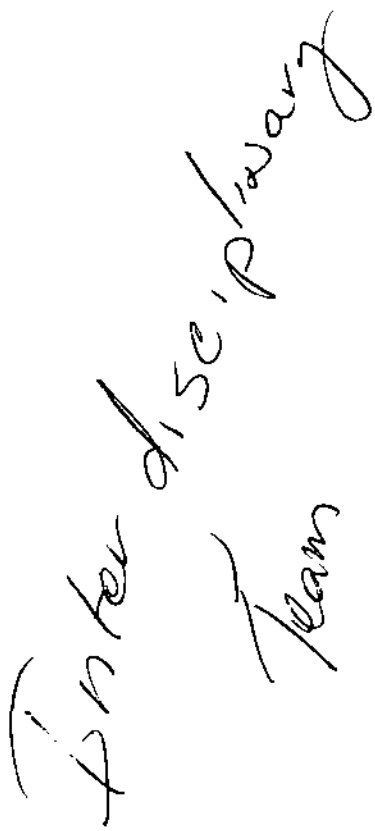
Depakote Pearl Can be given with food Sprinkles for pts who can't swallow and minimize GI side effects Can be Draw Back large amounts of water can

REDACTED

2002

18

Key Decision Makers


Interdisciplinary
Team


LTC Key Decision Makers
Administrator
Physician
Consultant Pharmacist
Dispensing Pharmacist
Technician
Nurse Practitioner
Charge Nurse
Certified Nurse Assistant
Dietician
Director of Nurses
Physician's Assistant

Objectives

Upon completion of this section, the attendee will be able to:

- Define LTC pharmacy
- List the health care practitioners who make up the LTC pharmacy team
- Identify services offered by the LTC pharmacy
- List the key decision-makers encountered in the LTC industry
- Recognize 3 different communication techniques to use when presenting information to the physician

Types Of LTC Customers

- Nursing facilities
  - ICF, SNF, ICF-MR, NF, NH
- Assisted living facilities
  - ALF, PCH, RCC, board & care, CCRC
- Sub-acute facilities
- Hospices
- Group homes
- Correctional facilities
- Small hospitals
- Out-patient surgery centers
- NORC's
- Employer groups
- ?
- ?

What's the Quickest Way to Reach All These LTC Customers??

- Long Term Care Pharmacists

REDACTED

2002

LTC Pharmacy

- Evolved over 30 ye
- Specialty practice
  - Products
  - Services
- High-tech systems
- Efficiency & accura expert
- Retail license
- Retail reimbursement

LTC Pharmacy

- Product
  - Dispensing pharmaceuticals
    - Specialized packaging
    - Delivery
  - Medical supplies/DME
  - Infusion therapy
  - Medical record production

LTC Pharmacy

- Services
  - Clinical consultative services
  - Education & training
  - Pharmacokinetics
  - Report generation/analysis

REDACTED

2002

LTC Pharmacy

- Consultant only 32%
- Consultant/Provider 61%
  - Retail 27%
  - Institutional Rx 33%
  - Nursing Home Rx 10%
  - Hospital Rx 5%
  - No Response 25%
- Provider only 3%

Provider vs Consultant Activities

- Provider:
  - Purchasing and distribution of drugs,
  - Billing,
  - Clinical review and therapy changes
- Consultant:
  - On-site clinical review of patient
  - Therapy recommendations,
  - Evaluation of facility compliance with regulations

What LTC Pharmacists Want ...

- Better understanding of disease states
- Knowledge of new pharmacological entities
- Improved communication skills
- Assistance with documentation of services

REDACTED

2002

3

LTC Pharmacy Team

- Consultant pharmacist
- Pharmacist manager
- Pharmacists
- Technicians
- IV Nurses
- Education Coordinators
- Inventory techs
- Med records techs
- Billing clerks
- Delivery personnel

DL VS
Te program
everyone needs
to know

Ancillary Staff

- Medical Records Technician
  - Corrects MAR/POF
  - Alerts pharmacist when TS drug is "un-corrected"
- Billing Clerk
  - Interacts with family members
  - Transfers inquiries to pharmacist when family questions why a TS drug appears on bill
- Driver
  - Delivers and checks-in order with nurse
  - Communicates TS issues with recommendation to contact pharmacist for full explanation

explain why
the switch

LTC Pharmacy Technician

- Inventory Tech
  - Controls ordering
- Order Entry Tech
  - Discovers order for incorrect product.
  - Alerts pharmacist to call MD for substitution
- Dispensing Tech
  - Catches labels for incorrect product
  - Reminds pharmacist to call for switch
  - Places alert/monitoring labels on product

REDACTED

2002

4

Punch card 90 b/o

Medication Distribution Systems

- Packaging
  - Unit dose
    - 24hr, 7day, 30day cycles
  - Bingo card
    - 30/31 day
  - Compliance packaging
    - Customizable cycle

Medication Distribution Systems

- Labeling
  - Only resident name, and medication name required
  - Most use modified retail prescription label format
  - Piggy back/peel off for re-ordering
  - Label placement for ease-of-use
  - Bar-coding

Medication Distribution Systems

- Unit Dose & Punch Card Packaging
  - Improves nursing staff efficiency & accuracy
- Multiple Dispensing/Month
  - Limit quantities of controlled substances
  - Limit quantities of large/bulky items
- Timely Delivery
  - 24 hour on-call
  - Emergency back-up 24hr/7day

REDACTED

2002

5

Equipment

- **Medication carts**
  - $2000 ea x 3/NF
- **Treatment carts**
  - $1000 ea x 1/NF
- **Fax machines**
  - 1 per station $250 ea
- **Computers ?**
  - Internet access
  - Direct on-line access
- **Software ?**
  - MDS, order/receipt

F426 Pharmacy Services

- The facility must provide routine & emergency drugs and biologicals to its residents or obtain them under an agreement ...
  - A drug, whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met.

Delivery

- Daily Mon-Fri
  - And Saturday 85%
  - And Sunday 5%
- Same day delivery
  - Multiple deliveries/day
- Courier vs employee drivers
  - Cost
  - Customer service
  - Consistency
  - Convenience

REDACTED

2002

6

Consult Pharm
Dispatch the need to be in there

Emergency Boxes

- First dose box
  - After hours re-admissions
  - Antibiotics
- True emergencies
  - Cardiac
  - Respiratory
  - Behavior
- Limitations on contents in some states

Medical Records

- Medical records
  - POF - 30day physician order summary
  - MAR - 30day medication administration record
  - TX record – treatment record
  - ADL record – nursing assistant documentation
  - Phone orders
  - Q/A reports
- In-house vs pharmacy production

Medical Supplies

- Medical supplies
  - OTC drugs
  - Wound care
  - Nutritionals
  - Urologicals
  - DME

REDACTED

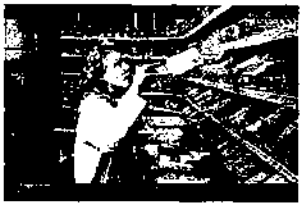
2002

7

Infusion Therapy

- Infusion therapy
  - IV products & supplies
  - IV training for staff
  - 24hr IV nurse support
  - 24hr emergency service

LTC Pharmacists



LTC Pharmacist

Consultant Pharmacist

- Problem solvers
- Clinical Skills
- Administrative Skills
- Organizational Skills
- Communication Skills
- Persuasive
- Self Motivated
- Intuitive

REDACTED

2002

8

LTC Pharmacist

Consultant	Provider
Problem solvers ←	Problem solvers
Clinical Skills ←	Clinical Skills
Administrative Skills ←	Administrative Skills
Organizational Skills	
Communication Skills ←	Communication Skills
Persuasive ←	Persuasive
Self Motivated	
Intuitive	

LTC Pharmacists

- Consultant Pharmacist's Oath
  - *"I take responsibility for my patient's medication-related needs and am held accountable for this commitment."*
  - *"I ensure my patient's medications are the most appropriate, most effective available, safest possible, and are used correctly."*
  - *"I identify, prevent, and resolve medication-related problems that may interfere with goals of therapy."*

Consultant Pharmacist

- F 428 The drug regimen of each patient in a nursing home must be reviewed at least once a month by a licensed pharmacist.
- F 429 The pharmacist must report any irregularities to the attending physician and the director of nursing and ...
- F 430 ... these reports must be acted upon.

REDACTED

2002

9

Consultant Pharmacist

- Clinical component
  - Therapeutic drug review
  - Economic drug review
  - Improve patient care
  - Improve functional ability of patient
- Suggestions to physician, nurses, administration, support staff

Consulting is the business of selling solutions

Clinical Activities

- Drug regimen review (DRR)
- Resident assessment and care planning
- Drug utilization review (DUR)
- Drug use evaluation (DUE)
- Therapeutic drug monitoring
- Facility staff education and training
- Formulary development and management
- Nutritional support services
- Geriatric research

Compliance Activities

- Policy and procedure development
- Committee participation
- Medication administration observation
- Medication storage, accountability, destruction
- Participation in state survey process
- Quality assurance (QA)
- Infection control

REDACTED

2002

10

Therapeutic Drug Review

- "Any symptom in an elderly patient should be considered a drug side effect until proved otherwise"

Source: J Gurwitz, M Monane, S Monane, J Avorn, Brown University Long-term Care Quality Letter, 1995

Medication Therapy Management Services

- Diagnosis appropriate
- Duplicate therapy
- Dosage appropriate
- Length of therapy
- Outcome appropriate
- Adverse reactions
- *Improve functional ability*
- *Improve quality of life*

Assessment of Drug Related Needs

- Initial Clinical Review of Medication Order
  - Best drug for condition
    - Anticonvulsant vs Antipsychotic
  - Best drug in category
    - Depakote vs Carbamazepine, Gabapentin
  - Best route
    - Liquid, tab/cap, topical
  - Medicaid / Insurance formulary coverage
    - Tiered co-pays, PDLs

REDACTED

Economic Drug Review

- Product expense
  - Depakote vs Zyprexa, Risperdal, Seroquel, Geodon
- Preparation expense
  - Ability to crush tablet
  - Prepackaged punch cards
- Outcome expense
  - Treatment failure, treatment duration
- Adverse reaction expense
  - CYP450 vs NOT

Consultant Pharmacist Recommended Changes

Acceptance frequency by type of recommendation

- Discontinue drug 82%
- Change dosage/route 73%
- Switch agents 65%
- Add drug 38%

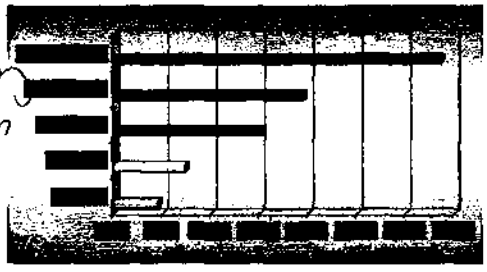
Source: SMG, TCP membership survey

NF Resident Drug Use

9.30 medication orders/resident

Source: Tobias,D.,et al, The Consultant Pharmacist, 2000

NF Resident Drug Use by Category



Consultant Pharmacist Value

- Consultant Pharmacist-conducted drug regimen review
  - Improves therapeutic outcomes - 43%
  - Saves $3.6 billion annually (DRP).

Source: Bootman, J., et al: The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities; Arch Intern Med/Vol 1997; 157:2089-2096

LTC Facility Personnel

REDACTED

2002

13

- wants to know what's going on

LTC Facility Personnel

- **Nursing Facility Administrator**
  - Licensed by board of examiners of nursing home administrators
    - Requires supervisory experience in nursing facilities
    - Requires CE
  - Responsible for the operation of facility
    - Financial, regulatory,
  - Planning of services
  - Compliance with state and federal regulations
  - Coordination of staff

Complaint of Profitable 30+0 hrs of CEUs
= Breakdowns

- RN Normally -

LTC Facility Personnel

- Director of Nurses (DON)
  - Registered Nurse (RN)
  - Supervisory position managing nursing staff
    - Certified nursing assistant (CNA)
    - Licensed practical nurses (LPN)
    - Registered nurses (RN)
  - Responsible for patient care
  - Responsible for financial performance of nursing department

Half time Administering meds.

9 1 5 9
8 8 1 4

LTC Facility Personnel

- Charge Nurse
  - RN or LPN
  - Responsible for care of up to 50 residents
    - Med administration
    - Documentation, progress notes, evaluations and assessments
    - Physician orders
    - Ordering and receiving meds and supplies
  - Supervises certified nursing assistants

REDACTED

2002

LTC Facility Personnel

- Certified Nursing Assistant (CNA)
  - High school diploma or GED
  - Certification by examination at facility or trade school
  - Performs direct resident care & assistance with ADLs
    - Bathing, grooming, eating, mobility, toileting
  - Requires 24hrs of CE yearly

The CNA is the most knowledgeable about the resident's behavioral and mental status

Pictures 3rd Grade Education
Deal with Behaviors

LTC Facility Personnel

- Nurse Practitioner & Physician's Assistant
  - Physician extender
  - Higher access
  - Frequent drug therapy changes
  - Authority varies by state
  - Operates under "physician protocol"

& Consultant Pharmacist TD

LTC Facility Personnel

- Medical Director
  - Usually attending MD for majority of residents (> 40%)
  - Oversees activities of other attending MD's
  - Provides educational and clinical support to patients & healthcare providers
  - > 45% are Medical Directors at 3 or more facilities

REDACTED

Attending Physician

- **Responsible for:**
  - Patient's total program of care
    - Medical, nutritional, psychosocial
  - Medical assessment
  - Disease prevention / treatment
  - Charting progress notes each visit
  - Acting on the Consultant Pharmacist's recommendations
- **Works cooperatively with interdisciplinary team**
- **Must visit patient at least every 30 days**

Probably doesn't care about Regs.
90% - Are Done by Phone
Docs Don't See

Communication

Communication: LTC Pharmacist

Consultant

- Clinical information on all entities in class
  - Efficacy
  - Metabolism
  - Administration
  - ADR profile
- Differentiation of products
- Outcomes data
- Sample "comment" language

Dispensing

- Clinical information
- Reimbursement information
  - Medicaid formulary
    - Prior approval
    - MAC'd competitors
  - Managed care formulary
- Packaging options
- Good business practices

REDACTED

Communication: Physician

- Part of the team (although may not realize it)
- Responds to clinical & financial information
- Ask don't tell
  - Have you considered...?
  - What do you think about...?
  - Would you please....?
- Define conditions leading to request
- Ask for definite actions
- Support statements with references

Communication: Director of Nursing

- Improving resident care
- Time savings for nursing staff
- Improving accuracy of nursing staff
  - Documentation
  - Administration

Communication: Administrator

- Cost effective solutions
- Regulatory compliance
- Public relations
- Patient care
  - Some ADMs are RNs

REDACTED

2002

17

Communication: Charge Nurse

- Patient care
- Time savings

Case Study

- 87yo, Caucasian female
- Diagnosis: Alzheimer's Disease w/psychotic agitation, CHF, Depression, Osteoarthritis,
- Labs/Vital Signs – WNL
- MMSE – 10
- Drugs:
  - Aricept 10mg qd for Alzheimer's
  - Celexa 20mg po qd for Depression
  - Enalapril 10mg po BID for CHF
  - Vioxx 25mg po qd for Osteoarthritis
  - Risperdal 1mg po BID for psychotic agitation
  - Alprazolam 0.25mg po TID for anxiety
- Problem: Increasingly agitated with recent episode of hitting roommate. Nurse has asked to increase Risperdal dose.

Normal / Dementia

Sample Comment: Physician

REDACTED

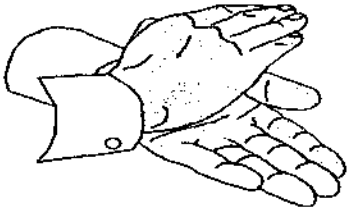
CMS.GOV

Sample Comment: Administrator

Sample Comment: DON

Director of Nurses

CONGRATULATIONS !!



REDACTED

Site Visits

REDACTED

LONG TERM CARE FACILITY VISIT

The LTC Facility Visit is designed to allow the attendee to experience the typical Nursing Facility (NF) and Assisted Living Facility (ALF) and participate in a routine consultant pharmacist visit.

OBJECTIVE

Upon completion of this section, the attendee will be able to:

- List the primary activities performed by the consultant pharmacist
- Prioritize the consultant pharmacist's role in both the NF and the ALF
- Recognize the importance of the consultant pharmacist in the care of the elderly and compliance with regulations in the NF and ALF
- Identify the health care professionals who make up the NF or ALF team
- List the primary activities performed by the NF and ALF team
- Identify the role of other professionals in the NF and ALF team

EXPERIENCES TO INCLUDE:

- Entrance interview with ADM and DON (approx 15 min)
- Tour of Facility (approx 30min)
- Introduction and Explanation of other Health Care Team Members
  - ADON
  - Charge Nurse
  - Med Nurse/Treatment Nurse
  - Certified Nursing Assistant
  - Medical Director / Attending Physician (if available)
  - Social Worker
  - Activity Director

RE [redacted]

- Meeting with ADM (approx 15min)
  - Role of ADM
  - What ADM expects from LTC Pharmacy and Consultant
  - Reimbursement Issues
  - Regulatory Issues
  - Challenges

- Meeting with DON (approx 15min)
  - Role of DON
  - What DON expects from LTC Pharmacy and Consultant
  - Staffing Issues
  - Patient Care Issues
  - Regulatory Issues
  - Challenges

- Medication Administration (approx 30min)

- Med Room and Med Cart Check (approx 15min)

- Chart Reviews (approx 15-30 min)
  - Inappropriate medication
    - Beer's Criteria
    - HCFA Regs
  - Therapeutic monitoring
  - Therapeutic interchange
  - Economic recommendation
  - Documentation review
  - Patient Assessment
  - Psychotropic Monitoring

- Preparation of Reports (approx 15min)

- Exit Interview with DON & ADM (approx 15 min)

REDACTED

REDACTED

LTC PHARMACY VISIT

The LTC Pharmacy Operations Visit is designed to allow the attendee to rotate through the various departments of the pharmacy and experience the type of activities performed.

OBJECTIVE

Upon completion of this section, the attendee will be able to:

- Identify the departments that make up a typical LTC pharmacy
- List the activities performed by each department
- Recognize the relationship of each department's activities to the LTC customer
- Identify the challenges LTC Pharmacy incurs in the operation of its business

ROTATIONS

The attendees will start in one of the 4 rotations. They will spend approximately 30 minutes in each rotation and should experience the listed activities. At the end of 30 minutes, the group will move to the next rotation.

Rotation 1 PRESCRIPTION PROCESSING

- Order taking (fax vs phone)
- Order entry
- Pharmacist Intervention
  - Preferred Product List
  - Medicaid Coverage
  - Allergy, Inappropriate Dose, Inappropriate Drug, etc.
  - Refill too early or too late
- Phone call to Nurse and/or Physician
- Automatic Stop Order Policy (ASOP)
- Challenges
  - Illegible Orders
  - Foreign Nurses
  - Orders coming late
  - Lack of communication

R
E

Rotation 2 **PRESCRIPTION FILLING**

- Emptying and Setting up Totes
- Filling Baskets
- Filling Automed Cassettes
- Ordering and Receiving
- Checking and Refilling Emergency Boxes
- IV Admixture

Rotation 3 **MEDICAL RECORDS**

- Order Entry
- MAR/POF Production
- QA Report Production
- Interaction with Nursing Staff

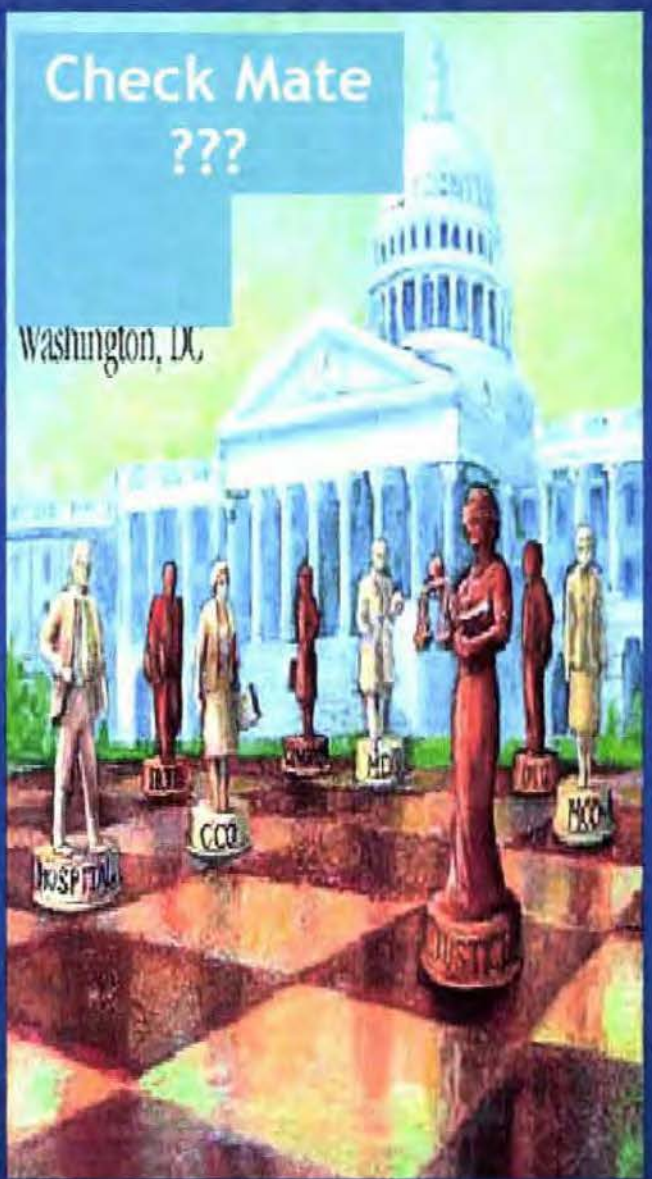
Rotation 4 **BILLING & MEDICAL SUPPLIES**

- Types of Billing (Understand how we bill)
  - Medicaid
  - Medicare
  - Private Pay
  - Insurance
- Challenges of Reimbursement and Billing
  - Manual manipulation
  - Medicaid denials and rebills
  - Length of Time for reimbursement
  - Low Rates with Insurance
- Medical Supply Department Processes
  - Order Taking
  - Order Delivery
  - Types of Products
  - Inventory Control
  - Challenges
  - Benefits

REDACTED

LTC Challenges

LTC Challenges

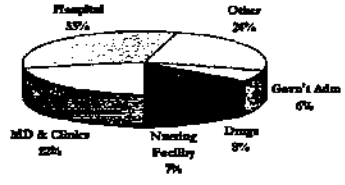


Objectives

At the completion of this section, the attendee will be able to:

- Identify reimbursement issues affecting LTC
- Discuss how consolidation of industry impacts LTC pharmacy
- Identify the primary competitors in LTC pharmacy

The Nation's Health Care Dollar



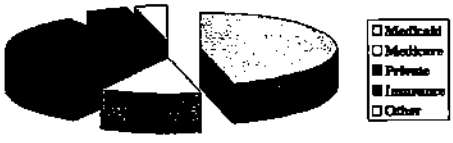
Who Owns Nursing Facility Beds?

REDACTED

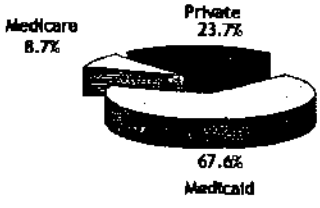
2002

1

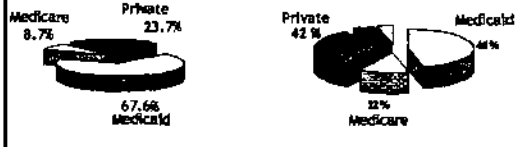
NF Reimbursement



NF Population Pay Type



NF Population Census vs Reimbursement



REDACTED

2002

National Medicaid Expenditures

- Medicaid cost 1999: $187 billion
- Federal government's share: $103 billion
- Federal & State Medicaid spending on nursing home care: $54 billion

1999

PPS vs Cost Based

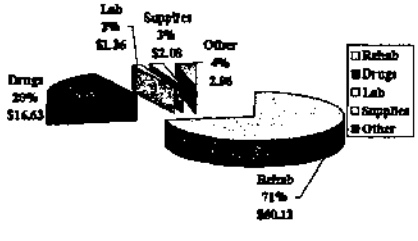
PPS Reimbursement

- Capitated Rate
- Requires 5 MDS evaluations (adm,14,30,60,90 days)
- Rate can change w/ea MDS (RUGS)
- Encourages less spending
- Encourages less acute patients
- *Fluff has "gone with the wind"*

Cost Based Reimbursement

- Cost-Based Rate
- Cost + Overhead mark-up
- Encourages more spending
- Encourages more acute patients
- Room for fluff

Average Cost of Ancillary Services per PPS Day = $83.16



REDACTED

2002

3

Two-Level Strategy to Manage Drug Costs

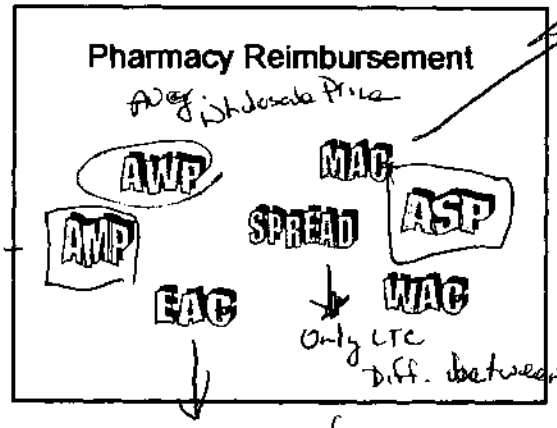
- FACILITY
  - Pricing strategies
  - Develop formulary
    - Preferred and non-preferred
    - Flexibility required
  - Physician practice patterns
  - Practices to reduce med errors and DRPs
- PATIENT
  - Pre-admission costing
  - New admission drug review
  - On-going clinical and cost monitoring
  - "Episode of care" case review

Forecast Of The Future

2000	2030
Adult day care $50/day $12,981/yr	Adult day care $220/day $56,100/yr
Home health aide $61/visit $15,743/yr	Home health aide $260/visit $68,000/yr
Assisted living facility $25,300/yr	Assisted living facility $109,300/yr
Nursing home care $44,100/yr	Nursing home care $190,600/yr

Source: American Council of Life Insurer's Report 2000

Pharmacy Reimbursement



Maximum Allowable Cost

MAC 134
AAC .03
.31

Avg. Selling Price

Avg Manu. Price

Whole Agu. Cost

Spread

⇒ = (reimbursement − AAC) + rebates

- Discounts are recognized in AAC
- Rebates must be added into spread

- Spread = Gross Profit (GP)

REDACTED

2002

Medicaid

STATE	INGREDIENT REIMBURSEMENT	DISPENSING FEE	LTC ADD-ON
Illinois	WAC + 8%/12%	$4.17	No
Minnesota	AWP – 9%	$3.65	Yes $0.30
Tennessee	AWP – 13% (MFN)	$2.50	No
North Carolina	AWP – 10%	$5.60(G) $4.00(B)	No
Rhode Island	WAC + 5%	$3.40 (OP) $2.85(LTC)	No

Medicaid

- No additional reimbursement for extra services (delivery, packaging, etc...)
  - PA study $2.87/rx for LTC services
- Pilot projects for reimbursing for MTMS
  - Washington
  - Wisconsin
  - Mississippi

Medicaid

- Capitation
  - South Carolina $7.00/day
  - New York
- Limits therapeutic choices
- Promotes 2nd class medicine
- No input/control in patient selection

Depakote ER Advantage

Depakote ER 500mg — Depakote DR 500mg
- AWP 1.77 — 1.85
- ACQ 1.41 — 1.48
Spread .36 — .37

ER Disadvantage = .01

OFP – Opportunity for Profit when the preferred product offers a

OFP = ((PP AWP – ACQ) + Rebates) – ((OP AWP – ACQ) + Rebates)

PP – Preferred Product

OP – Other Product in therapeutic class

OFP = (GP of PP) – (GP of OP)

GP = Gross Profit

REDACTED

2002

5

LTC Docs - Exempt from co Pay & Amount of Med Restrictions.

Medicaid

- Maximum # of Rx/month
- Prior Approval (PA)
- Favored Nations (MFN)
- No additional reimbursement for extra services (delivery, packaging, etc...)
- Maximum Allowable Cost (MAC) on generics

Maximum Allowable Cost (MAC)

MAC

- Federal MAC
- State MAC
  - Available from 3 sources
  - Average of WAC

Medicare

- Bill direct to facility
- Prospective pay
- Case mix (RUGS III)
- Capitated rate

REDACTED

2002

6

Insurance

- Pays even worse than Medicaid and Medicare
- AWP - 30% + 1.50

...somebody's gettin' rich ... and it ain't the provider!!

"Helping keep our customers in business in one of our major challenges"

- Profits were Medicare based
- Couldn't stop the spending in time for PPS
- Heavy debt to earnings ratio

Verdict

BANKRUPTCY

Litigation

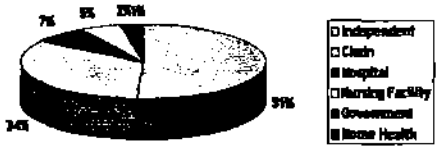
REDACTED

Consolidation

- Predators
- Large providers buy up the competition
  - Driving
    - Pricing
    - Services
    - Contracting

LTC RX

LTC Pharmacy Ownership



LTC Pharmacy Market Share: Nursing Facility Beds

	% of NF	# NF beds	# Total beds
REDACTED	29%	493,684	729,500
REDACTED	16%	274,134	310,000
REDACTED	10.5%	178,206	250,000
REDACTED	9%	153,400	153,400
REDACTED	4%	65,788	65,500
REDACTED	2.5%	45,000	45,000
Everyone else	29%	489,788	7

Source: ASCP data on file, based on 1.8 million NF beds 2001

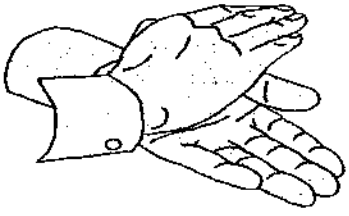
REDACTED

2002

Total Pharmacy LTC Market Share

- Institutional LTC Pharmacy 50%
- Retail drug store 50%

CONGRATULATIONS !!



REDACTED

2002

9

Market Share

Therapeutic Interchange and Market Share

Abbott Laboratories

Objectives

Upon completion of this session, the attendee should be able to:

- Identify 5 steps for a successful therapeutic interchange program
- List 4 considerations for selecting a preferred product for therapeutic switch
- Describe 3 methods of notifying physicians of a preferred product
- Define "Opportunity for Profit" and its role in monitoring for successful therapeutic switch programs

Advantages of Controlling Market Share

- Contracting
- Rebates
- Reduced Inventory Investment
- Control of Variables in Disease Management

Contracting & Rebates

- Price discounts limited by federally mandated rebates
- Discounts are acceptable for volume purchasing
- Rebates are acceptable if market share goals are attained

REDACTED

2002

1

Price Discounts & Rebates

- Pharmaceutical Manufacturers must rebate back to state Medicaid an amount = to lowest price anywhere in market
  - Limits amount available to pharmacies
  - Includes rebate amounts
  - Includes incentives if $$ value can be assigned
- OIG is looking at discounts & rebates as inducement (Fraud & Abuse) - no decision yet ... whew!!

Reduced Inventory Investment

- Standardize on 1 or 2 choices within a therapeutic class
- Lower inventory costs
  - Consignment,
  - Improved returns,
  - Special packaging
- *Select product with BEST VALUE*

Value

- Value = What you get for your investment
- Value ≠ Price
- Value = Price x Efficacy x Risk

REDACTED

2002

2

Cost of Drug Therapy

- Total drug cost = (PC+DC) x U +DRP
  - PC = product cost
  - DC = distribution cost
  - U = utilization
  - DRP= drug related problems

Source: Penny, I.R. Total Drug Therapy Cost Control, The Consultant Pharmacist, May 1996

Ambulatory Care Total Drug Cost

PC + DC x U = $84 billion

Source: IMS, 1994

1:1

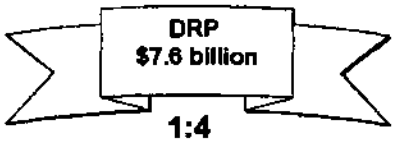
Source: Bootman L, et al, Arch Int Med 1995

(Without Consultant RPh Involvement)

Nursing Homes: Total Drug Cost =

(PC + DC) x U = $2 billion

Source: Nursing Home Drug Sales Audit 1995



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Source: J.Lyle Bootman et al. The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities. Arch Intern Med, 157, 10/1997

REDACTED

2002

3

(With standard Consultant RPh activity)
Nursing Homes: Total Drug Cost =
(PC + DC) x U = $2 billion

Source: Nursing Home Drug Spend Audit 1998

1:2

Source: J Lyle Bootman et al, The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities, Arch Intern Med, 157, 10/1997

Consultant Pharmacists are Responsible for ...

LTC Pharmacists's Role

- Assurance of proper drug utilization
- Minimization of adverse drug related problems
- Reduction of therapeutic failures
- Assurance that the chosen therapy (& associated costs) produces the desired outcome !!

REDACTED

2002

4

The most expensive drug is the one that doesn't work!

Control of Variables in Disease Management

- Choose the best therapeutic alternative
  - metoclopramide vs cisapride
  - escitalopram vs fluoxetine
  - quetiapine vs risperidone
- Outcome data is easy to obtain and manage
  - only 1 set of SE
  - only 1 set of outcome endpoints
- Formulary choices can compliment one another to obtain better outcomes
  - escitalopram(no cP450) & quetiapine (cP450 3A4)

Disadvantages of Controlling Market Share

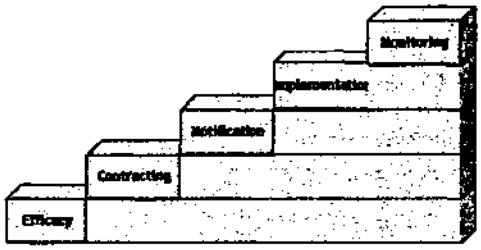
* Alienate physicians
* Irritate nurses (with repetitive order changes)
* Safe-harbor regulations
* Labor Intensive

REDACTED

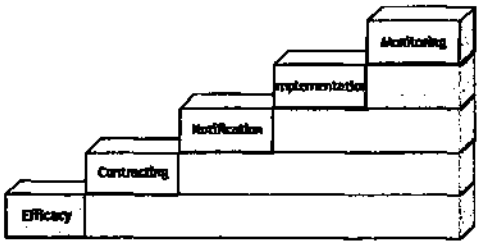
2002

5

5-Step Method for Successful Therapeutic Interchange



5-Step Method for Successful Therapeutic Interchange



Evaluating Therapeutic Efficacy

- Buy-in from clinical pharmacy staff
- Buy-in from physicians
- Must benefit the patient's health outcome and/or quality of life

Best Value doesn't mean Best Price

REDACTED

2002

6

Consultant Pharmacist's Oath

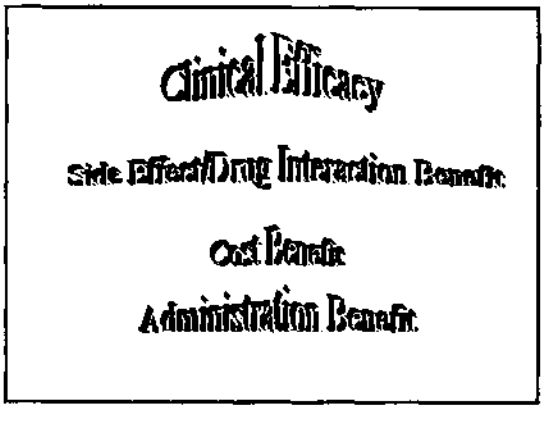
- *"I take responsibility for my patient's medication-related needs and am held accountable for this commitment."*
- *"I ensure my patient's medications are the most appropriate, most effective available, safest possible, and are used correctly."*
- *"I identify, prevent, and resolve medication-related problems that may interfere with goals of therapy."*

Clinical Efficacy

Side Effect/Drug Interaction Benefit

Cost Benefit

Administration Benefit



REDACTED

2002

Clinical Efficacy

Summary of Valproic Acid and Divalproate Efficacy in Agitation and Aggression

	N	Design	Outcome (No. improved)
Porsteinsson et al 2001	28*	Placebo controlled trial	Decreased aggression (17)
Frenchman, 2000	146*	Chart review	Decreased agitation (97)
Sival et al. 1994	23	Chart review	Decreased aggression (6)
Lott et al. 1995	10	Open label	Decreased agitation (9)
Narayan et al. 1997	25*	Chart review	Decreased agitation (13)
Porsteinsson et al. 1997	12	Open label	Decreased agitation (10)

Safety / Drug Interactions

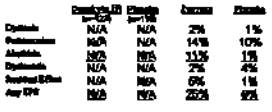
REDACTED

2002

8

Depakote DR and ER Adverse Events

Depakote DR and ER Adverse Events



Divalproex Sodium

Side Effects

- More Common
  - Sedation
  - Gastrointestinal distress (less severe then with other forms of valproate)
  - Tremors (mostly at higher doses)
  - Ataxia (usually dose related)
  - Weight gain
  - Thrombocytopenia (usually mild and dose related)
- Rare
  - Hepatotoxicity
  - Pancreatitis

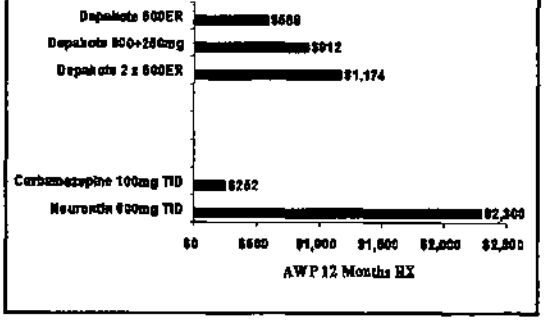
REDACTED

COST

Economic Drug Review

- Product expense (from payor perspective)
  - Depakote ER vs Valproic Acid, Depakote, Neurontin, Carbamazepine
- Preparation expense
  - Ability to open capsule and sprinkle vs crushing
  - Once daily vs multiple administration
- Outcome expense
  - treatment failure, treatment duration
- Adverse reaction expense
  - interactions w/cytochrome P450 system

Annual Cost of Therapy



REDACTED

2002

10

Administration

Dosing Considerations

- 30% of NH residents require some dosage form adjustment for administration
- 1999 new HCFA regs re-define medication error to require adherence to manufacturer's specifications (F 332, F333)

Depakote Dosing Information

Dosage Form	Depakene® (valproic acid)	Depakote® (divalproex sodium)	Depakote ER® (divalproex sodium)
Capsules (250 mg)	X		
Syrup (250 mg/5 mL)	X		
Delayed-release tablets (125 mg, 250 mg, 500mg)		X	
Sprinkle capsules (125 mg)		X	
Extended-release 500 mg tablets; QD Dosing			X

* Depakote may be preferable to liquid valproate because of its improved gastrointestinal tolerability and dosage flexibility

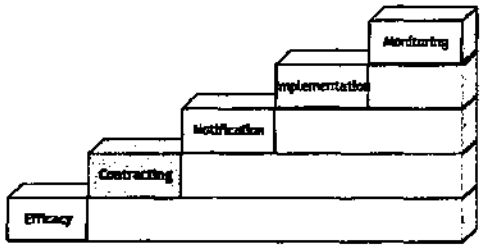
REDACTED

2002

Initiating Divalproex Therapy

- Initiate 125-250 mg qhs or 125 mg BID
- Increase by 125-250 mg every 3-7 days or until desired clinical response
- Usual range 375-2000 mg/day
  - Usual serum concentration 40-100 µg/mL
- Divalproex is an enteric-coated formulation to minimize gastrointestinal side effects
- Sprinkle capsules for patients who have difficulty swallowing pills

5-Step Method for Successful Therapeutic Interchange



Contract Evaluation

- Purchase Price
  - Spread
    - (AWP - purchase price)
  - MAC'd competitors
  - Return on Investment

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2002

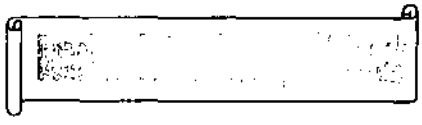
12

Contract Evaluation

- Rebates
  - Market share goals realistic ?
  - Single item market share ?
  - Bundled with other items ?
  - How often are rebates checks provided?
  - Does contract have a ramp-up period?

Depakote ER ADVANTAGE

Depakote ER 500mg		Depakote DR 500mg	
AWP	$ 1.77	AWP	$1.85
ACQ	$ 1.41	ACQ	$1.48
SPREAD	$ 0.36	SPREAD	$0.37



Pricing shown is fictitious and does not reflect actual contract price or

Opportunity for Profit

- *"When the preferred product offers a greater spread between acquisition cost and selling price including rebate than other products in that therapeutic category"*

- OFP = (PP AWP - ACQ - Rebates) - (OP AWP - ACQ - Rebates)
  - OFP = Opportunity for Profit
  - PP = Preferred Product
  - OP = Other Products in therapeutic class

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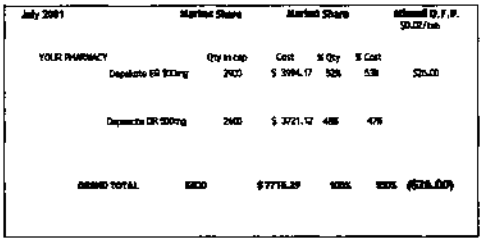
2002

13

Missed Opportunity for Profit



Capturing the Missed Opportunity for Profit

- Missed OFP = $ 26.00/mo
- Missed OFP = $ 312.00/yr
- Cost of RPh x 1wk = $ 2500.00

NET LOSS/yr = $2812.00

Set Benchmarks

- Evaluate regional market share expectations
- Compare to national/regional standards
- Set Goals & Expectations

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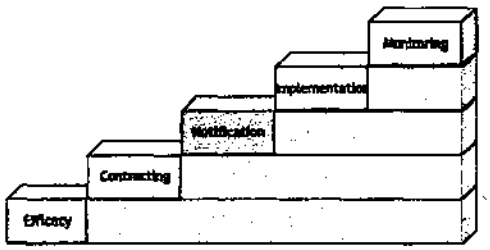
2002

5-Step Method for Successful Therapeutic Interchange



Notification

- Consultant DRR Recommendation
- Informative Mailing
  - Physicians
    - Introductory Letter
    - Patient Listing Letter
  - Facility
    - Administrative Introductory Letter
    - Copy of Physician's Letter

Consultant Pharmacist

- Determine appropriate patients prior to notification
- Set up monitoring parameters (GDS, B/P, MMSE, SOB, Dyspepsia, CBC, etc...)
- Provide inservice education to staff & physicians
- Monitor patient for response to therapeutic interchange

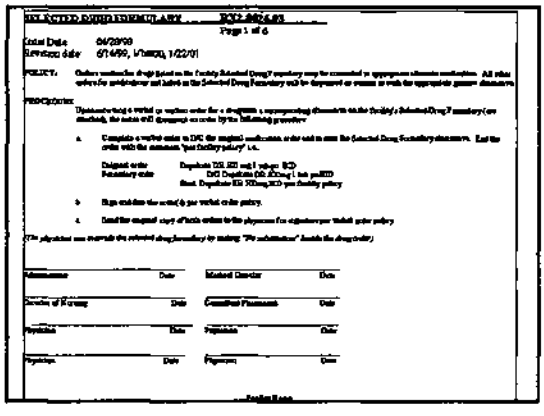
REDACTED

Preferred Product List

- Collaborative practice agreement
  - 35 states allow
  - Each state's requirements /allowances may differ
- Facility policy
  - Signed by:
    - Medical Director
    - DON
    - ADM
    - Consultant Pharmacist
    - Attending MD
- Assures compliance
  - Reduces time
  - Captures re-admits

Therapeutic Substitution Formulary

- Improves GM significantly
- Reduces time necessary for formulary maintenance
- Can be used with or without Collaborative Practice Legislation
- Captures new orders and re-admit orders automatically



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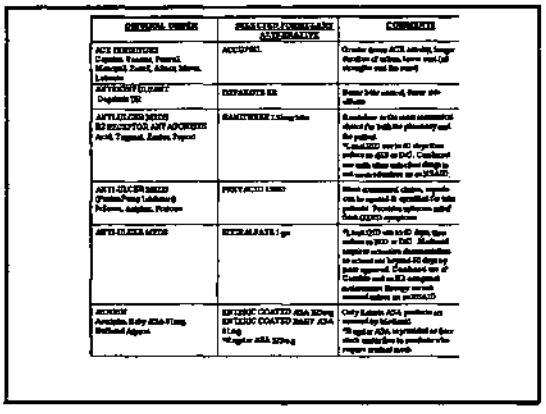

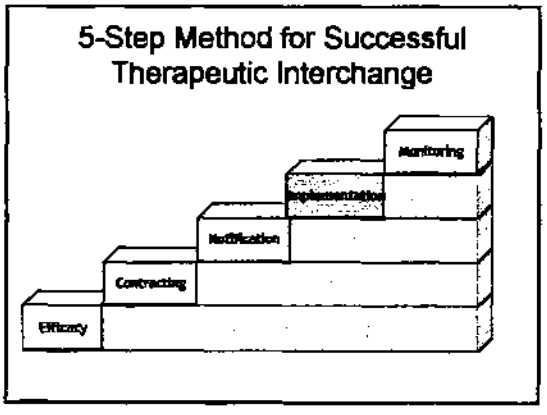

Implementation

- Conversion letter faxed to pharmacy
  - Target date for switch
  - Order change "when current supply is used"
- Consultant drug regimen review
- Notify facility of order change
  - Reminder memo
  - Conversion letter (signed)
    - copy letter for chart
    - write telephone order
    - CHANGE MAR !!

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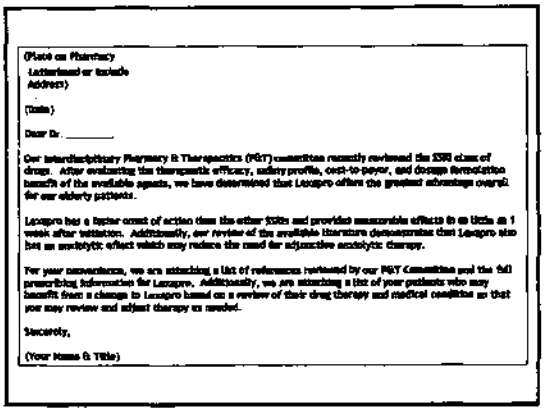
2002



(Place on Pharmacy
Letterhead or Include
Address)

(Date)

Dear Dr. _____

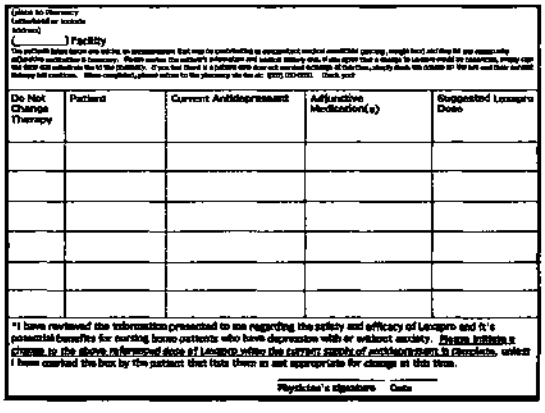
Our Interdisciplinary Pharmacy & Therapeutics (P&T) committee recently reviewed the SSRI class of drugs. After evaluating the therapeutic efficacy, safety profile, cost-to-payor, and dosage formulation benefit of the available agents, we have determined that Lexapro offers the greatest advantage overall for our elderly patients.

Lexapro has a faster onset of action than the other SSRIs and provides measurable effects in as little as 1 week after initiation. Additionally, our review of the available literature demonstrates that Lexapro also has an anxiolytic effect which may reduce the need for adjunctive anxiolytic therapy.

For your convenience, we are attaching a list of references reviewed by our P&T Committee and the full prescribing information for Lexapro. Additionally, we are attaching a list of your patients who may benefit from a change to Lexapro based on a review of their drug therapy and medical condition so that you may review and adjust therapy as needed.

Sincerely,

(Your Name & Title)



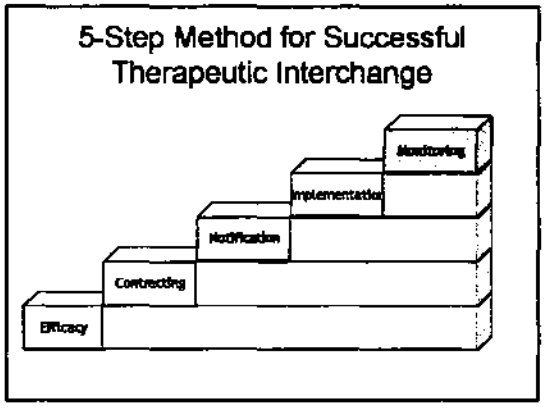
(Place on Pharmacy
Letterhead or Include
Address)

(_____) Facility

Do Not Change Therapy	Patient	Current Antidepressant	Adjunctive Medication(s)	Suggested Lexapro Dose

*I have reviewed the information presented to me regarding the safety and efficacy of Lexapro and it's potential benefits for nursing home patients who have depression with or without anxiety. Please initiate a change to the above referenced dose of Lexapro using the current supply of antidepressant in Physicians, unless I have marked the box by the patient that lists them as not appropriate for change at this time.

Physician's Signature Date



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Monitoring

- Incorporate monitoring parameters for therapeutic switch into order
- Usually labs or vital signs
  - B/P, Dyspepsia, H/H, Behavior Monitoring, INR, MMSE, GDS
- Have facility report any values outside of acceptable range to MD and Consultant Pharmacist
- Act on information to maintain optimal patient care

Monitoring

- Monthly tracking
  - By facility
  - By pharmacy
  - By consultant
- Prescriptions vs DOT vs Dollars vs Units
  - Rx's from dispensing system
  - Pharmacist's Interventions
  - Consultant Comments

Monitoring

- Audit wholesaler purchases vs rebate data
- Audit market share vs rebate data
- Provide feedback to clinical and dispensing staff
- *Take Action !!!*

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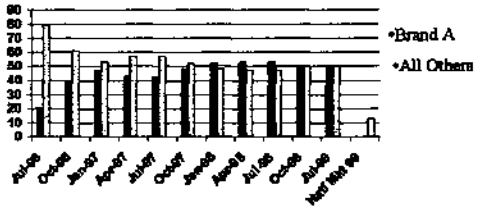
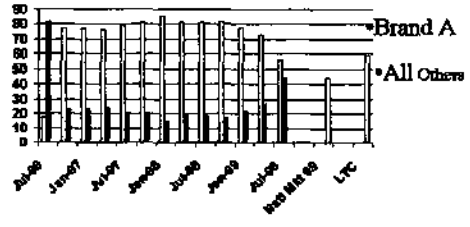
2002

ACE Inhibitor Market Share



H2 Antagonist Market Share



Extended Release Theophylline Market

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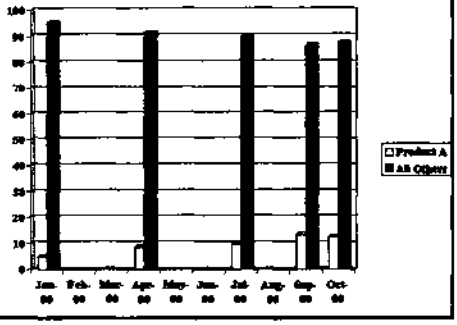
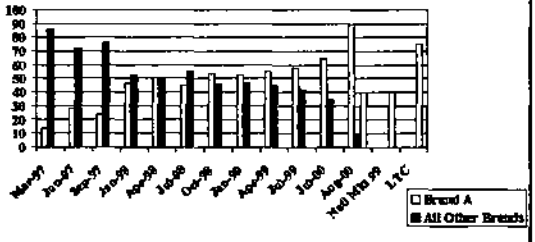
Atypical Antipsychotics



Proton Pump Inhibitors



Success Tips

- Products are therapeutically equivalent or selected product is superior
- Product offers a cost savings to payor
- Pharmacists and Physicians have trusting relationship
- High acceptance rate for pharmacist recommendations
- Good tracking methods
- **Primary concern for Optimal Patient Care**

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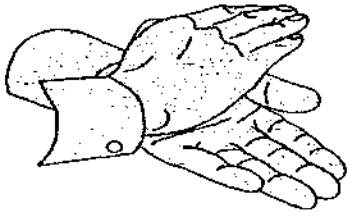
2002

21

CONGRATULATIONS !!



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22

Partnering

LTC Partnering

Abbott Laboratories

Objectives

Upon completion of this section the attendee will be able to

- Identify areas where Abbott Pharmaceuticals can assist LTC pharmacies in the performance of their services.
- List the primary factors affecting LTC pharmacy decisions regarding pharmaceuticals.
- Create a plan for marketing Abbott Laboratories' products to the LTC industry.

Partnering

Consultant Pharmacists

- Emphasis on the clinical aspects of pharmaceuticals
- Differentiation of product
- Outcomes data

Partnering

Provider pharmacists

- Information concerning good business strategies and policies
- Profitability of product
- Coverage by payors
- And outcomes data

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2002

1

DM → Medical Liaison

Partnering

- Value added services
  - CE programming for LTC employees
  - CE programming for LTC customers
  - Phase III/IV studies
- Co-marketing

Partnering

LTC Pharmacy and Abbott Laboratories working together to bring optimal patient outcomes to the LTC patient

Abbott Laboratories

REDACTED

2002

2

Thinking Outside the Box Exercise

1. Split into groups of 3 or 4. Discuss specific partnering options and value-added services. List below:

2. Outline your individual action plan for account calls and market development.

REDACTED 2002

References

Numeric Identifier _____

MINIMUM DATA SET (MDS) — *VERSION 2.0*

FOR NURSING HOME RESIDENT ASSESSMENT AND CARE SCREENING

BASIC ASSESSMENT TRACKING FORM

Form # CP6038H | Reorder From: MED-PASS, INC. 800-439-8884

SECTION AA. IDENTIFICATION INFORMATION

1.	RESIDENT NAME ⊙	a. (First) b. (Middle Initial) c. (Last) d. (Jr/Sr)
2.	GENDER ⊙	1. Male 2. Female
3.	BIRTHDATE ⊙	Month — Day — Year
4.	RACE/ ETHNICITY ⊙	1. American Indian/Alaskan Native 2. Asian/Pacific Islander 3. Black, not of Hispanic origin 4. Hispanic 5. White, not of Hispanic origin
5.	SOCIAL SECURITY ⊙ AND MEDICARE NUMBERS ⊙ [C in 1st box if non med. no.]	a. Social Security Number b. Medicare number (or comparable railroad insurance number)
6.	FACILITY PROVIDER NO ⊙	a. State No. b. Federal No.
7.	MEDICAID NO. ["+" if pending, "N" if not a Medicaid recipient] ⊙	
8.	REASONS FOR ASSESSMENT	[Note—Other codes do not apply to this form] a. *Primary reason for assessment* 1. Admission assessment (required by day 14) 2. Annual assessment 3. Significant change in status assessment 4. Significant correction of prior full assessment 5. Quarterly review assessment 10. Significant correction of prior quarterly assessment 0. *NONE OF ABOVE* b. *Codes for assessments required for Medicare PPS or the State* *1. Medicare 5 day assessment* *2. Medicare 30 day assessment* *3. Medicare 60 day assessment* *4. Medicare 90 day assessment* *5. Medicare readmission/return assessment* *6. Other state required assessment* *7. Medicare 14 day assessment* *8. Other Medicare required assessment*

9.	SIGNATURES OF PERSONS WHO COMPLETED A PORTION OF THE ACCOMPANYING ASSESSMENT OR TRACKING FORM		
I certify that the accompanying information accurately reflects resident assessment or tracking information for this resident and that I collected or coordinated collection of this information on the dates specified. To the best of my knowledge, this information was collected in accordance with applicable Medicare and Medicaid requirements. I understand that this information is used as a basis for ensuring that residents receive appropriate and quality care, and as a basis for payment from federal funds. I further understand that payment of such federal funds and continued participation in the government-funded health care programs is conditioned on the accuracy and truthfulness of this information, and that I may be personally subject to or may subject my organization to substantial criminal, civil, and/or administrative penalties for submitting false information. I also certify that I am authorized to submit this information by this facility on its behalf.			
	Signature and Title	Sections	Date
a.			
b.			
c.			
d.			
e.			
f.			
g.			
h.			
i.			
j.			
k.			
l.			

QUALITY INDICATORS

- 1 - Incidence of new fractures
- 2 - Prevalence of falls
- 3 - Prevalence of behavioral symptoms affecting others
- 4 - Prevalence of symptoms of depression
- 5 - Prevalence of symptoms of depression without antidepressant therapy
- 6 - Use of 9 or more different medications
- 7 - Incidence of cognitive impairment
- 8 - Prevalence of bladder or bowel incontinence
- 9 - Prevalence of occasional or frequent bladder or bowel incontinence without a toileting plan
- 10 - Prevalence of indwelling catheters
- ⚑ 11 - Prevalence of fecal impaction
- 12 - Prevalence of urinary tract infections
- 13 - Prevalence of weight loss
- 14 - Prevalence of tube feeding
- ⚑ 15 - Prevalence of dehydration
- 16 - Prevalence of bedfast residents
- 17 - Incidence of decline in late loss ADLs
- 18 - Incidence of decline in ROM
- 19 - Prevalence of antipsychotic use, in the absence of psychotic and related conditions
- 20 - Prevalence of antianxiety/hypnotic use
- 21 - Prevalence of hypnotic use more than two times in last week
- 22 - Prevalence of daily physical restraints
- 23 - Prevalence of little or no activity
- ⚑ 24 - Prevalence of stage 1 - 4 pressure ulcers

⚑ - Identifies QIs that are associated with a sentinel health event.

GENERAL INSTRUCTIONS

Complete this information for submission with all full and quarterly assessments (Admission, Annual, Significant Change, State or Medicare required assessments, or Quarterly Reviews, etc.)

XFM QS1639

⊙ - Signifies "answers" that could impact QI items identified by a number in a blue box (e.g., 3).

1 - Numbers (1-24) indicate the specific QI(s) that may be impacted.

Items shaded in GREEN are included in the Medicare PPS RUG-III Grouper. It is recommended that these items be verified for accuracy. *(RUG-III key developed in cooperation with Survey Solutions, Inc., Columbus, Ohio)*

⊙ = Key items for computerized resident tracking

☐ = When box blank, must enter number or letter

a. ☐ = When letter in box, check if condition applies

Resident _____ Numeric Identifier _____

MINIMUM DATA SET (MDS) — *VERSION 2.0*

FOR NURSING HOME RESIDENT ASSESSMENT AND CARE SCREENING

BACKGROUND (FACE SHEET) INFORMATION AT ADMISSION

SECTION AB. DEMOGRAPHIC INFORMATION

1. DATE OF ENTRY
Date the stay began. Note — Does not include readmission if record was closed at time of temporary discharge to hospital, etc. In such cases, use prior admission date
Month ___ Day ___ Year ___

2. ADMITTED FROM (AT ENTRY)
1. Private home/apt. with no home health services
2. Private home/apt. with home health services
3. Board and care/assisted living/group home
4. Nursing home
5. Acute care hospital
6. Psychiatric hospital, MR/DD facility
7. Rehabilitation hospital
8. Other

3. LIVED ALONE (PRIOR TO ENTRY)
0. No
1. Yes
2. In other facility

4. ZIP CODE OF PRIOR PRIMARY RESIDENCE

5. RESIDENTIAL HISTORY 5 YEARS PRIOR TO ENTRY
(Check all settings resident lived in during 5 years prior to date of entry given in item AB1 above)
- a. Prior stay at this nursing home
- b. Stay in other nursing home
- c. Other residential facility—board and care home, assisted living, group home
- d. MH/psychiatric setting
- e. MR/DD setting
- f. *NONE OF ABOVE*

6. LIFETIME OCCUPATION(S) [Put '/' between two occupations]

7. EDUCATION (*Highest Level Completed*)
1. No schooling
2. 8th grade/less
3. 9-11 grades
4. High school
5. Technical or trade school
6. Some college
7. Bachelor's degree
8. Graduate degree

8. LANGUAGE
(*Code for correct response*)
a. Primary Language
0. English 1. Spanish 2. French 3. Other
b. If other, specify

9. MENTAL HEALTH HISTORY
Does resident's RECORD indicate any history of mental retardation, mental illness, or developmental disability problem?
0. No 1. Yes

10. CONDITIONS RELATED TO MR/DD STATUS
(Check all conditions that are related to MR/DD status that were manifested before age 22, and are likely to continue indefinitely)
- a. Not applicable—no MR/DD (Skip to AB11)

MR/DD with organic condition
- b. Down's syndrome
- c. Autism
- d. Epilepsy
- e. Other organic condition related to MR/DD
- f. MR/DD with no organic condition

11. DATE BACKGROUND INFORMATION COMPLETED
Month ___ Day ___ Year ___

SECTION AC. CUSTOMARY ROUTINE

1. CUSTOMARY ROUTINE
(In year prior to DATE OF ENTRY to this nursing home, or year last in community if now being admitted from another nursing home)
(Check all that apply. If all information UNKNOWN, check last box only)

CYCLE OF DAILY EVENTS
- a. Stays up late at night (e.g., after 9 pm)
- b. Naps regularly during day (at least 1 hour)
- c. Goes out 1+ days a week
- d. Stays busy with hobbies, reading, or fixed daily routine
- e. Spends most of time alone or watching TV
- f. Moves independently indoors (with appliances, if used)
- g. Use of tobacco products at least daily
- h. *NONE OF ABOVE*

EATING PATTERNS
- i. Distinct food preferences
- j. Eats between meals all or most days
- k. Use of alcoholic beverage(s) at least weekly
- l. *NONE OF ABOVE*

ADL PATTERNS
- m. In bed/clothes much of day
- n. Wakens to toilet all or most nights
- o. Has irregular bowel movement pattern
- p. Showers for bathing
- q. Bathing in PM
- r. *NONE OF ABOVE*

INVOLVEMENT PATTERNS
- s. Daily contact with relatives/close friends
- t. Usually attends church, temple, synagogue (etc.)
- u. Finds strength in faith
- v. Daily animal companion/presence
- w. Involved in group activities
- x. *NONE OF ABOVE*

- y. **UNKNOWN**—Resident/family unable to provide information

SECTION AD. FACE SHEET SIGNATURES

SIGNATURES OF PERSONS COMPLETING FACE SHEET:

a. Signature of RN Assessment Coordinator — Date

I certify that the accompanying information accurately reflects resident assessment or tracking information for this resident and that I collected or coordinated collection of this information on the dates specified. To the best of my knowledge, this information was collected in accordance with applicable Medicare and Medicaid requirements. I understand that this information is used as a basis for ensuring that residents receive appropriate and quality care, and as a basis for payment from federal funds. I further understand that payment of such federal funds and continued participation in the government-funded health care programs is conditioned on the accuracy and truthfulness of this information, and that I may be personally subject to or may subject my organization to substantial criminal, civil, and/or administrative penalties for submitting false information. I also certify that I am authorized to submit this information by this facility on its behalf.

b. Signature and Title — Sections — Date

c. — Date

d. — Date

e. — Date

f. — Date

g. — Date

___ = When box blank, must enter number or letter

a. ___ = When letter in box, check if condition applies

Resident _____ Numeric Identifier _____

MINIMUM DATA SET (MDS) — *VERSION 2.0*
FOR NURSING HOME RESIDENT ASSESSMENT AND CARE SCREENING
FULL ASSESSMENT FORM

(Status in last 7 days, unless other time frame indicated)

SECTION A. IDENTIFICATION AND BACKGROUND INFORMATION

1. RESIDENT NAME — a. (First) b. (Middle Initial) c. (Last) d. (Jr/Sr)

2. ROOM NUMBER

3. ASSESSMENT REFERENCE DATE
a. *Last day of MDS observation period* — Month / Day / Year
b. Original (0) or corrected copy of form (enter number of correction)

4a. DATE OF REENTRY — Date of reentry from most recent temporary discharge to a hospital in last 90 days (or since last assessment or admission if less than 90 days) — Month / Day / Year

5. MARITAL STATUS — 1. Never married 2. Married 3. Widowed 4. Separated 5. Divorced

6. MEDICAL RECORD NO.

7. CURRENT PAYMENT SOURCES FOR N.H. STAY — (*Billing Office to indicate; **check all that apply in last 30 days***)

a. Medicaid per diem	a.	f. VA per diem	f.
b. Medicare per diem	b.	g. Self or family pays for full per diem	g.
c. Medicare ancillary part A	c.	h. Medicaid resident liability or Medicare co-payment	h.
d. Medicare ancillary part B	d.	i. Private insurance per diem (including co-payment)	i.
e. CHAMPUS per diem	e.	j. Other per diem	j.

8. REASONS FOR ASSESSMENT — [*Note— If this is a discharge or reentry assessment, only a limited subset of MDS items need be completed*]

a. ***Primary reason for assessment***
1. Admission assessment (required by day 14)
2. Annual assessment
3. Significant change in status assessment
4. Significant correction of prior full assessment
5. Quarterly review assessment
6. Discharged—return not anticipated
7. Discharged—return anticipated
8. Discharged prior to completing initial assessment
9. Reentry
10. Significant correction of prior quarterly assessment
0. *NONE OF ABOVE*

b. ***Codes for assessments required for Medicare PPS or the State***
1. *Medicare 5 day assessment*
2. *Medicare 30 day assessment*
3. *Medicare 60 day assessment*
4. *Medicare 90 day assessment*
5. *Medicare readmission/return assessment*
6. *Other state required assessment*
7. *Medicare 14 day assessment*
8. *Other Medicare required assessment*

9. RESPONSIBILITY/ LEGAL GUARDIAN — (***Check all that apply***)

a. Legal guardian	a.	d. Durable power attorney/financial	d.
b. Other legal oversight	b.	e. Family member responsible	e.
c. Durable power of attorney/health care	c.	f. Patient responsible for self	f.
		g. *NONE OF ABOVE*	g.

10. ADVANCED DIRECTIVES — (*For those items with supporting **documentation** in the medical record, **check all that apply***)

a. Living will	a.	f. Feeding restrictions	f.
b. Do not resuscitate	b.	g. Medication restrictions	g.
c. Do not hospitalize	c.	h. Other treatment restrictions	h.
d. Organ donation	d.	i. *NONE OF ABOVE*	i.
e. Autopsy request	e.		

SECTION B. COGNITIVE PATTERNS

1. COMATOSE — (*Persistent vegetative state/no discernible consciousness*) 0. No 4, 5* 1. Yes (**If yes, skip to Section G**)

2. MEMORY — (*Recall of what was learned or known*)
a. Short-term memory OK—seems/appears to recall after 5 minutes 0. Memory OK 1. Memory problem 2, 7
b. Long-term memory OK—seems/appears to recall long past 0. Memory OK 1. Memory problem 2

3. MEMORY/ RECALL ABILITY — (***Check all that resident was normally able to recall during last 7 days***)

a. Current season	a.	d. That he/she is in a nursing home	d.
b. Location of own room	b.	e. *NONE OF ABOVE* are recalled	e.
c. Staff names/faces	c.		

4. COGNITIVE SKILLS FOR DAILY DECISION-MAKING — (*Made decisions regarding tasks of daily life*)
0. *INDEPENDENT*—decisions consistent/reasonable
1. *MODIFIED INDEPENDENCE*—some difficulty in new situations only 2 7
2. *MODERATELY IMPAIRED*—decisions poor; cues/supervision required 2 7
3. *SEVERELY IMPAIRED*—never/rarely made decisions 2, 5B 7

5. INDICATORS OF DELIRIUM—PERIODIC DISORDERED THINKING/ AWARENESS — (*Code for behavior in the **last 7 days.**) [**Note: Accurate assessment requires conversations with staff and family who have direct knowledge of resident's behavior over this time**].*
0. Behavior not present
1. Behavior present, not of recent onset
2. Behavior present, over last 7 days appears different from resident's usual functioning (e.g., new onset or worsening)

a. EASILY DISTRACTED—(e.g., difficulty paying attention; gets sidetracked) *1, 17**
b. PERIODS OF ALTERED PERCEPTION OR AWARENESS OF SURROUNDINGS—(e.g., moves lips or talks to someone not present; believes he/she is somewhere else; confuses night and day) *1, 17**
c. EPISODES OF DISORGANIZED SPEECH—(e.g., speech is incoherent, nonsensical, irrelevant, or rambling from subject to subject; loses train of thought) *1, 17**
d. PERIODS OF RESTLESSNESS—(e.g., fidgeting or picking at skin, clothing, napkins, etc; frequent position changes; repetitive physical movements or calling out) *1, 17**
e. PERIODS OF LETHARGY—(e.g., sluggishness; staring into space; difficult to arouse; little body movement) *1, 17**
f. MENTAL FUNCTION VARIES OVER THE COURSE OF THE DAY—(e.g., sometimes better, sometimes worse; behaviors sometimes present, sometimes not) *1, 17**

6. CHANGE IN COGNITIVE STATUS — Resident's cognitive status, skills, or abilities have changed as compared to status of **90 days ago** (or since last assessment if less than 90 days)
0. No change 1. Improved 2. Deteriorated *1, 17**

SECTION C. COMMUNICATION/HEARING PATTERNS

1. HEARING — (*With hearing appliance, if used*)
0. *HEARS ADEQUATELY*—normal talk, TV, phone
1. *MINIMAL DIFFICULTY* when not in quiet setting. 4
2. *HEARS IN SPECIAL SITUATIONS ONLY*—speaker has to adjust tonal quality and speak distinctly. 4
3. *HIGHLY IMPAIRED*/absence of useful hearing. 4

2. COMMUNICATION DEVICES/ TECHNIQUES — (***Check all that apply** during last 7 days*)

a. Hearing aid, present and used	a.
b. Hearing aid, present and not used regularly	b.
c. Other receptive comm. techniques used (e.g., lip reading)	c.
d. *NONE OF ABOVE*	d.

3. MODES OF EXPRESSION — (***Check all used by resident to make needs known***)

a. Speech		d. Signs/gestures/sounds	d.
b. Writing messages to express or clarify needs	a. b.	e. Communication board	e.
c. American sign language or Braille	c.	f. Other	f.
		g. *NONE OF ABOVE*	g.

4. MAKING SELF UNDERSTOOD — (*Expressing information content—**however able***)
0. *UNDERSTOOD*
1. *USUALLY UNDERSTOOD*—difficulty finding words or finishing thoughts. 4
2. *SOMETIMES UNDERSTOOD*—ability is limited to making concrete requests. 4
3. *RARELY/NEVER UNDERSTOOD* 4

5. SPEECH CLARITY — (*Code for speech in the **last 7 days***)
0. *CLEAR SPEECH*—distinct, intelligible words
1. *UNCLEAR SPEECH*—slurred, mumbled words
2. *NO SPEECH*—absence of spoken words

6. ABILITY TO UNDERSTAND OTHERS — (*Understanding verbal information content—**however able***)
0. *UNDERSTANDS*
1. *USUALLY UNDERSTANDS*—may miss some part/intent of message. 2, 4
2. *SOMETIMES UNDERSTANDS*—responds adequately to simple, direct communication. 2, 4
3. *RARELY/NEVER UNDERSTANDS* 2, 4

7. CHANGE IN COMMUNICATION/ HEARING — Resident's ability to express, understand, or hear information has changed as compared to status of **90 days ago** (or since last assessment if less than 90 days)
0. No change 1. Improved 2. Deteriorated *17**

☐ = When box blank, must enter number or letter
a. ☐ = When letter in box, check if condition applies
17 - refer to a RAI manual for clarification*
4, 5* - N1a + N1b + N1c ≤ 1 and B1 = 0

Resident _____ Numeric Identifier _____

SECTION D. VISION PATTERNS

1. VISION

(Ability to see in adequate light and with glasses if used)

0. *ADEQUATE*—sees fine detail, including regular print in newspapers/books
1. *IMPAIRED*—sees large print, but not regular print in newspapers/books. *3*
2. *MODERATELY IMPAIRED*—limited vision; not able to see newspaper headlines, but can identify objects. *3*
3. *HIGHLY IMPAIRED*—object identification in question, but eyes appear to follow objects. *3*
4. *SEVERELY IMPAIRED*—no vision or sees only light, colors, or shapes; eyes do not appear to follow objects

2. VISUAL LIMITATIONS/ DIFFICULTIES

a. Side vision problems—decreased peripheral vision (e.g., leaves food on one side of tray, difficulty traveling, bumps into people and objects, misjudges placement of chair when seating self). *3*

b. Experiences any of following: sees halos or rings around lights; sees flashes of light; sees "curtains" over eyes

c. *NONE OF ABOVE*

3. VISUAL APPLIANCES

Glasses; contact lenses; magnifying glass
0. No 1. Yes

SECTION E. MOOD AND BEHAVIOR PATTERNS

1. INDICATORS OF DEPRESSION, ANXIETY, SAD MOOD

(E1a - E1p = 1,2) *8*
(E1n = 1,2) *17**
(E1o = 1,2) *7*

(Code for indicators observed in last 30 days, irrespective of the assumed cause)

0. Indicator not exhibited in last 30 days
1. Indicator of this type exhibited up to five days a week
2. Indicator of this type exhibited daily or almost daily (6, 7 days a week)

VERBAL EXPRESSIONS OF DISTRESS

a. Resident made negative statements—e.g., *"Nothing matters; Would rather be dead; What's the use; Regrets having lived so long; Let me die"* 4,5

b. Repetitive questions—e.g., *"Where do I go; What do I do?"*

c. Repetitive verbalizations—e.g., calling out for help, *("God help me")*

d. Persistent anger with self or others—e.g., easily annoyed, anger at placement in nursing home; anger at care received

e. Self deprecation—e.g., *"I am nothing; I am of no use to anyone"*

f. Expressions of what appear to be unrealistic fears—e.g., fear of being abandoned, left alone, being with others

g. Recurrent statements that something terrible is about to happen—e.g., believes he or she is about to die, have a heart attack 4,5

h. Repetitive health complaints—e.g., persistently seeks medical attention, obsessive concern with body functions

i. Repetitive anxious complaints/concerns (non-health related) e.g., persistently seeks attention/reassurance regarding schedules, meals, laundry, clothing, relationship issues

SLEEP-CYCLE ISSUES

j. Unpleasant mood in morning 4,5

k. Insomnia/change in usual sleep pattern

SAD, APATHETIC, ANXIOUS APPEARANCE

l. Sad, pained, worried facial expressions—e.g., furrowed brows

m. Crying, tearfulness

n. Repetitive physical movements—e.g., pacing, hand wringing, restlessness, fidgeting, picking 4,5

LOSS OF INTEREST

o. Withdrawal from activities of interest—e.g., no interest in long standing activities or being with family/friends 4,5

p. Reduced social interaction 4,5

2. MOOD PERSISTENCE

One or more indicators of depressed, sad or anxious mood were not easily altered by attempts to "cheer up", console, or reassure the resident over last 7 days

0. No mood indicators 1. Indicators present, easily altered. *8,* 4,5 2. Indicators present, not easily altered. *8,* 4,5

3. CHANGE IN MOOD

Resident's mood status has changed as compared to status of 90 days ago (or since last assessment if less than 90 days)
0. No change 1. Improved 2. Deteriorated *1, 17**

4. BEHAVIORAL SYMPTOMS

(A) ***Behavioral symptom frequency in last 7 days***
0. Behavior not exhibited in last 7 days
1. Behavior of this type occurred 1 to 3 days in last 7 days
2. Behavior of this type occurred 4 to 6 days, but less than daily
3. Behavior of this type occurred daily

(B) ***Behavioral symptom alterability in last 7 days***
0. Behavior not present OR behavior was easily altered
1. Behavior was not easily altered

	(A)	(B)
a. WANDERING (moved with no rational purpose, seemingly oblivious to needs or safety) *9, 11*		
b. VERBALLY ABUSIVE BEHAVIORAL SYMPTOMS (others were threatened, screamed at, cursed at) *9,* 3		
c. PHYSICALLY ABUSIVE BEHAVIORAL SYMPTOMS (others were hit, shoved, scratched, sexually abused) *9,* 3		
d. SOCIALLY INAPPROPRIATE/DISRUPTIVE BEHAVIORAL SYMPTOMS (made disruptive sounds, noisiness, screaming, self-abusive acts, sexual behavior or disrobing in public, smeared/threw food/feces, hoarding, rummaged through others' belongings) *9,* 3		
e. RESISTS CARE (resisted taking medications/ injections, ADL assistance, or eating) *9,* 4,5		

5. CHANGE IN BEHAVIORAL SYMPTOMS

Resident's behavior status has changed as compared to status of 90 days ago (or since last assessment if less than 90 days)
0. No change 1. Improved *9* 2. Deteriorated *1, 17**

SECTION F. PSYCHOSOCIAL WELL-BEING

1. SENSE OF INITIATIVE/ INVOLVEMENT

a. At ease interacting with others
b. At ease doing planned or structured activities
c. At ease doing self-initiated activities
d. Establishes own goals 7
e. Pursues involvement in life of facility (e.g., makes/keeps friends; involved in group activities; responds positively to new activities; assists at religious services)
f. Accepts invitations into most group activities
g. *NONE OF ABOVE*

2. UNSETTLED RELATIONSHIPS

a. Covert/open conflict with or repeated criticism of staff 7
b. Unhappy with roommate 7
c. Unhappy with residents other than roommate 7
d. Openly expresses conflict/anger with family/friends 7
e. Absence of personal contact with family/friends
f. Recent loss of close family member/friend
g. Does not adjust easily to change in routines
h. *NONE OF ABOVE*

3. PAST ROLES

a. Strong identification with past roles and life status 7
b. Expresses sadness/anger/empty feeling over lost roles/status 7
c. Resident perceives that daily routine (customary routine, activities) is very different from prior pattern in the community 7
d. *NONE OF ABOVE*

SECTION G. PHYSICAL FUNCTIONING AND STRUCTURAL PROBLEMS

1. (A) ADL SELF-PERFORMANCE—*(Code for resident's PERFORMANCE OVER ALL SHIFTS during last 7 days—Not including setup)*

0. *INDEPENDENT*—No help or oversight —OR— Help/oversight provided only 1 or 2 times during last 7 days
1. *SUPERVISION*—Oversight, encouragement or cueing provided 3 or more times during last 7 days —OR— Supervision (3 or more times) plus physical assistance provided only 1 or 2 times during last 7 days
2. *LIMITED ASSISTANCE*—Resident highly involved in activity; received physical help in guided maneuvering of limbs or other nonweight bearing assistance 3 or more times —OR—More help provided only 1 or 2 times during last 7 days
3. *EXTENSIVE ASSISTANCE*—While resident performed part of activity, over last 7-day period, help of following type(s) provided 3 or more times:
   — Weight-bearing support
   — Full staff performance during part (but not all) of last 7 days
4. *TOTAL DEPENDENCE*—Full staff performance of activity during entire 7 days
8. *ACTIVITY DID NOT OCCUR* during entire 7 days

(B) ADL SUPPORT PROVIDED—*(Code for MOST SUPPORT PROVIDED OVER ALL SHIFTS during last 7 days; code regardless of resident's self-performance classification)*

0. No *setup* or physical help from staff
1. Setup help only
2. One person physical assist
3. Two+ persons physical assist
8. ADL activity itself did not occur during entire 7 days

			(A) SELF-PERF	(B) SUPPORT
a.	BED MOBILITY	How resident moves to and from lying position, turns side to side, and positions body while in bed 1,2,3,4 = *5,4* 2,3,4,8 = *16* 17		
b.	TRANSFER	How resident moves between surfaces—to/from: bed, chair, wheelchair, standing position (EXCLUDE to/from bath/toilet) 1,2,3,4 = *5,4* 17		
c.	WALK IN ROOM	How resident walks between locations in his/her room 1,2,3,4 = *5,4*		
d.	WALK IN CORRIDOR	How resident walks in corridor on unit 1,2,3,4 = *5,4*		
e.	LOCOMOTION ON UNIT	How resident moves between locations in his/her room and adjacent corridor on same floor. If in wheelchair, self-sufficiency once in chair 1,2,3,4 = *5,4*		
f.	LOCOMOTION OFF UNIT	How resident moves to and returns from off unit locations (e.g., areas set aside for dining, activities, or treatments). If facility has only one floor, how resident moves to and from distant areas on the floor. If in wheelchair, self-sufficiency once in chair 1,2,3,4 = *5,4*		
g.	DRESSING	How resident puts on, fastens, and takes off all items of street clothing, including donning/removing prosthesis 1,2,3,4 = *5,4*		
h.	EATING	How resident eats and drinks (regardless of skill). Includes intake of nourishment by other means (e.g., tube feeding, total parenteral nutrition) 1,2,3,4 = *5,4* 17		
i.	TOILET USE	How resident uses the toilet room (or commode, bedpan, urinal); transfer on/off toilet, cleanses, changes pad, manages ostomy or catheter, adjusts clothes 1,2,3,4 = *5,4* 17		
j.	PERSONAL HYGIENE	How resident maintains personal hygiene, including combing hair, brushing teeth, shaving, applying makeup, washing/drying face, hands, and perineum (EXCLUDE baths and showers) 1,2,3,4 = *5,4*		

17 - refer to a RAI manual for clarification

Resident _____ Numeric Identifier _____

2. BATHING — How resident takes full-body bath/shower, sponge bath, and transfers in/out of tub/shower (EXCLUDE washing of back and hair.) *Code for most dependent in self-performance and support.* (A) BATHING SELF-PERFORMANCE codes appear below

0. Independent—No help provided
1. Supervision—Oversight help only *K4*
2. Physical help limited to transfer only *K4*
3. Physical help in part of bathing activity *K4*
4. Total dependence *K4*
8. Activity itself did not occur during entire 7 days
(Bathing support codes are as defined in Item 1, code B above)

(A) (B)

3. TEST FOR BALANCE (see training manual)

(Code for ability during test in the last 7 days)
0. Maintained position as required in test
1. Unsteady, but able to rebalance self without physical support
2. Partial physical support during test; or stands (sits) but does not follow directions for test
3. Not able to attempt test without physical help

a. Balance while standing
b. Balance while sitting—position, trunk control *17**

4. FUNCTIONAL LIMITATION IN RANGE OF MOTION (see training manual)

(Code for limitations during last 7 days that interfered with daily functions or placed resident at risk of injury)

(A) *RANGE OF MOTION*: 0. No limitation; 1. Limitation on one side; 2. Limitation on both sides
(B) *VOLUNTARY MOVEMENT*: 0. No loss; 1. Partial loss; 2. Full loss

(A) (B)

a. Neck 18
b. Arm—including shoulder or elbow 18
c. Hand—including wrist or fingers 18
d. Leg—including hip or knee 18
e. Foot—including ankle or toes 18
f. Other limitation or loss 18

5. MODES OF LOCOMOTION

(Check all that apply during last 7 days)

a. Cane/walker/crutch
b. Wheeled self
c. Other person wheeled
d. Wheelchair primary mode of locomotion
e. *NONE OF ABOVE*

6. MODES OF TRANSFER

(Check all that apply during last 7 days)

a. Bedfast all or most of time *16* 16
b. Bed rails used for bed mobility or transfer
c. Lifted manually
d. Lifted mechanically
e. Transfer aid (e.g., slide board, trapeze, cane, walker, brace)
f. *NONE OF ABOVE*

7. TASK SEGMENTATION

Some or all of ADL activities were broken into subtasks during last 7 days so that resident could perform them
0. No 1. Yes

8. ADL FUNCTIONAL REHABILITATION POTENTIAL

a. Resident believes he/she is capable of increased independence in at least some ADLs *K4*
b. Direct care staff believe resident is capable of increased independence in at least some ADLs *K4*
c. Resident able to perform tasks/activity but is very slow
d. Difference in ADL Self-Performance or ADL Support, comparing mornings to evenings
e. *NONE OF ABOVE*

9. CHANGE IN ADL FUNCTION

Resident's ADL self-performance status has changed as compared to status of 90 days ago (or since last assessment if less than 90 days)
0. No change 1. Improved 2. Deteriorated

SECTION H. CONTINENCE IN LAST 14 DAYS

1. CONTINENCE SELF-CONTROL CATEGORIES
(Code for resident's PERFORMANCE OVER ALL SHIFTS)

0. *CONTINENT*—Complete control *[includes use of indwelling urinary catheter or ostomy device that does not leak urine or stool]*
1. *USUALLY CONTINENT*—BLADDER, incontinent episodes once a week or less; BOWEL, less than weekly
2. *OCCASIONALLY INCONTINENT*—BLADDER, 2 or more times a week but not daily; BOWEL, once a week
3. *FREQUENTLY INCONTINENT*—BLADDER, tended to be incontinent daily, but some control present (e.g., on day shift); BOWEL, 2-3 times a week
4. *INCONTINENT*—Had inadequate control BLADDER, multiple daily episodes; BOWEL, all (or almost all) of the time

a. BOWEL CONTINENCE — Control of bowel movement, with appliance or bowel continence programs, if employed 1,2,3,4 = *16* 3,4 = 8 2,3 = 9*

b. BLADDER CONTINENCE — Control of urinary bladder function (if dribbles, volume insufficient to soak through underpants), with appliances (e.g., foley) or continence programs, if employed 2,3,4 = *6* 3,4 = 8 2,3 = 9*

2. BOWEL ELIMINATION PATTERN

a. Bowel elimination pattern regular—at least one movement every three days
b. Constipation *17**
c. Diarrhea
d. Fecal impaction *17** 11
e. *NONE OF ABOVE*

3. APPLIANCES AND PROGRAMS

a. Any scheduled toileting plan
b. Bladder retraining program
c. External (condom) catheter *6*
d. Indwelling catheter *6* 10
e. Intermittent catheter *6*
f. Did not use toilet room/commode/urinal
g. Pads/briefs used *6*
h. Enemas/irrigation
i. Ostomy present
j. *NONE OF ABOVE*

4. CHANGE IN URINARY CONTINENCE

Resident's urinary continence has changed as compared to status of 90 days ago (or since last assessment if less than 90 days)
0. No change 1. Improved 2. Deteriorated

SECTION I. DISEASE DIAGNOSES

Check only those diseases that have a relationship to current ADL status, cognitive status, mood and behavior status, medical treatments, nursing monitoring, or risk of death. (Do not list inactive diagnoses)

1. DISEASES *(If none apply, CHECK the NONE OF ABOVE box)*

ENDOCRINE/METABOLIC/NUTRITIONAL
a. Diabetes mellitus
b. Hyperthyroidism
c. Hypothyroidism

HEART/CIRCULATION
d. Arteriosclerotic heart disease (ASHD)
e. Cardiac dysrhythmias
f. Congestive heart failure
g. Deep vein thrombosis
h. Hypertension
i. Hypotension *17**
j. Peripheral vascular disease *16*
k. Other cardiovascular disease

MUSCULOSKELETAL
l. Arthritis
m. Hip fracture
n. Missing limb (e.g., amputation)
o. Osteoporosis
p. Pathological bone fracture

NEUROLOGICAL
q. Alzheimer's disease
r. Aphasia
s. Cerebral palsy
t. Cerebrovascular accident (stroke)
u. Dementia other than Alzheimer's disease
v. Hemiplegia/Hemiparesis
w. Multiple sclerosis
x. Paraplegia
y. Parkinson's disease
z. Quadriplegia
aa. Seizure disorder
bb. Transient ischemic attack (TIA)
cc. Traumatic brain injury

PSYCHIATRIC/MOOD
dd. Anxiety disorder
ee. Depression *17**
ff. Manic depression (bipolar disease)
gg. Schizophrenia

PULMONARY
hh. Asthma
ii. Emphysema/COPD

SENSORY
jj. Cataracts *3*
kk. Diabetic retinopathy
ll. Glaucoma *3*
mm. Macular degeneration

OTHER
nn. Allergies
oo. Anemia
pp. Cancer
qq. Renal failure
rr. *NONE OF ABOVE*

2. INFECTIONS *(If none apply, CHECK the NONE OF ABOVE box)*

a. Antibiotic resistant infection (e.g., Methicillin resistant staph)
b. Clostridium difficile (c. diff.)
c. Conjunctivitis
d. HIV infection
e. Pneumonia
f. Respiratory infection
g. Septicemia
h. Sexually transmitted diseases
i. Tuberculosis
j. Urinary tract infection in last 30 days *14* 12
k. Viral hepatitis
l. Wound infection
m. *NONE OF ABOVE*

3. OTHER CURRENT OR MORE DETAILED DIAGNOSES AND ICD-9 CODES

a. _____ •
b. _____ •
c. _____ •
d. _____ •
e. _____ •

276.5 = 14, 15

SECTION J. HEALTH CONDITIONS

1. PROBLEM CONDITIONS *(Check all problems present in last 7 days unless other time frame is indicated)*

INDICATORS OF FLUID STATUS
a. Weight gain or loss of 3 or more pounds within a 7 day period. *14*
b. Inability to lie flat due to shortness of breath
c. Dehydrated; output exceeds input *14* 15
d. Insufficient fluid; did NOT consume all/almost all liquids provided during last 3 days. *14*

OTHER
e. Delusions
f. Dizziness/Vertigo *11,17**
g. Edema
h. Fever *14*
i. Hallucinations *17**
j. Internal bleeding *14*
k. Recurrent lung aspirations in last 90 days. *17**
l. Shortness of breath
m. Syncope (fainting) *17**
n. Unsteady gait *17**
o. Vomiting
p. *NONE OF ABOVE*

17 - refer to a RAI manual for clarification* 9* - H3a or H3b not checked

Resident _____ Numeric Identifier _____

2. PAIN SYMPTOMS (*Code the highest level of pain present in the last 7 days*)

a. **FREQUENCY** with which resident complains or shows evidence of pain
0. No pain (*skip to J4*)
1. Pain less than daily
2. Pain daily

b. **INTENSITY** of pain
1. Mild pain
2. Moderate pain
3. Times when pain is horrible or excruciating

3. PAIN SITE (*If pain present, check all sites that apply in last 7 days*)

a. Back pain
b. Bone pain
c. Chest pain while doing usual activities
d. Headache
e. Hip pain
f. Incisional pain
g. Joint pain (other than hip)
h. Soft tissue pain (e.g., lesion, muscle)
i. Stomach pain
j. Other

4. ACCIDENTS (*Check all that apply*)

a. Fell in past 30 days *11,17** ❷
b. Fell in past 31-180 days *11,17**
c. Hip fracture in last 180 days *17** 1
d. Other fracture in last 180 days 1
e. *NONE OF ABOVE*

5. STABILITY OF CONDITIONS

a. Conditions/diseases make resident's cognitive, ADL, mood or behavior patterns unstable—(fluctuating, precarious, or deteriorating)
b. Resident experiencing an acute episode or a flare-up of a recurrent or chronic problem
c. End-stage disease, 6 or fewer months to live
d. *NONE OF ABOVE*

SECTION K. ORAL/NUTRITIONAL STATUS

1. ORAL PROBLEMS

a. Chewing problem
b. Swallowing problem *17**
c. Mouth pain *15*
d. *NONE OF ABOVE*

2. HEIGHT AND WEIGHT *Record (a.) height in inches and (b.) weight in pounds. Base weight on most recent measure in last 30 days; measure weight consistently in accord with standard facility practice—e.g., in a.m. after voiding, before meal, with shoes off, and in nightclothes*

a. HT (in.) _____ b. WT (lb.) _____

3. WEIGHT CHANGE

a. **Weight loss**—5 % or more in **last 30 days**; or 10 % or more in **last 180 days**
0. No 1. Yes *12* 4,5,13

b. **Weight gain**—5 % or more in **last 30 days**; or 10 % or more in **last 180 days**
0. No 1. Yes

4. NUTRITIONAL PROBLEMS

a. Complains about the taste of many foods *12*
b. Regular or repetitive complaints of hunger
c. Leaves 25% or more of food uneaten at most meals *12*
d. *NONE OF ABOVE*

5. NUTRITIONAL APPROACHES (*Check all that apply in last 7 days*)

a. Parenteral/IV *12,14*
b. Feeding tube *13,14* 14
c. Mechanically altered diet *12*
d. Syringe (oral feeding) *12*
e. Therapeutic diet *12*
f. Dietary supplement between meals
g. Plate guard, stabilized built-up utensil, etc.
h. On a planned weight change program
i. *NONE OF ABOVE*

6. PARENTERAL OR ENTERAL INTAKE (**Skip to Section L if neither 5a nor 5b is checked**)

a. Code the proportion of total calories the resident received through parenteral or tube feedings in the **last 7 days**
0. None
1. 1% to 25%
2. 26% to 50%
3. 51% to 75%
4. 76% to 100%

b. Code the average fluid intake per day by IV or tube in **last 7 days**
0. None
1. 1 to 500 cc/day
2. 501 to 1000 cc/day
3. 1001 to 1500 cc/day
4. 1501 to 2000 cc/day
5. 2001 or more cc/day

SECTION L. ORAL/DENTAL STATUS

1. ORAL STATUS AND DISEASE PREVENTION

a. Debris (soft, easily movable substances) present in mouth prior to going to bed at night *15*
b. Has dentures or removable bridge
c. Some/all natural teeth lost—does not have or does not use dentures (or partial plates) *15*
d. Broken, loose, or carious teeth *15*
e. Inflamed gums (gingiva); swollen or bleeding gums; oral abscesses; ulcers or rashes *15*
f. Daily cleaning of teeth/dentures or daily mouth care—by resident or staff. Not ✓ = *15*
g. *NONE OF ABOVE*

SECTION M. SKIN CONDITION

1. ULCERS (Due to any cause) (*Record the number of ulcers at each ulcer stage—regardless of cause. If none present at a stage, record "0" (zero). Code all that apply during last 7 days. Code 9 = 9 or more.) [Requires full body exam.]* — Number at Stage

a. Stage 1. A persistent area of skin redness (without a break in the skin) that does not disappear when pressure is relieved.
b. Stage 2. A partial thickness loss of skin layers that presents clinically as an abrasion, blister, or shallow crater.
c. Stage 3. A full thickness of skin is lost, exposing the subcutaneous tissues - presents as a deep crater with or without undermining adjacent tissue.
d. Stage 4. A full thickness of skin and subcutaneous tissue is lost, exposing muscle or bone.

2. TYPE OF ULCER (*For each type of ulcer, code for the highest stage in the last 7 days using scale in item M1—i.e., 0=none; stages 1, 2, 3, 4*)

2,3,4 = *12*
1,2,3,4 = *16*

a. Pressure ulcer—any lesion caused by pressure resulting in damage of underlying tissue 0 - 24
b. Stasis ulcer—open lesion caused by poor circulation in the lower extremities

3. HISTORY OF RESOLVED ULCERS Resident had an ulcer that was resolved or cured in **LAST 90 DAYS**
0. No 1. Yes *16*

4. OTHER SKIN PROBLEMS OR LESIONS PRESENT (*Check all that apply during last 7 days*)

a. Abrasions, bruises
b. Burns (second or third degree)
c. Open lesions other than ulcers, rashes, cuts (e.g., cancer lesions)
d. Rashes—e.g., intertrigo, eczema, drug rash, heat rash, herpes zoster
e. Skin desensitized to pain or pressure *16*
f. Skin tears or cuts (other than surgery)
g. Surgical wounds
h. *NONE OF ABOVE*

5. SKIN TREATMENTS (*Check all that apply during last 7 days*)

a. Pressure relieving device(s) for chair
b. Pressure relieving device(s) for bed
c. Turning/repositioning program
d. Nutrition or hydration intervention to manage skin problems
e. Ulcer care
f. Surgical wound care
g. Application of dressings (with or without topical medications) other than to feet
h. Application of ointments/medications (other than to feet)
i. Other preventative or protective skin care (other than to feet)
j. *NONE OF ABOVE*

6. FOOT PROBLEMS AND CARE (*Check all that apply during last 7 days*)

a. Resident has one or more foot problems—e.g., corns, callouses, bunions, hammer toes, overlapping toes, pain, structural problems
b. Infection of the foot—e.g., cellulitis, purulent drainage
c. Open lesions on the foot
d. Nails/calluses trimmed during **last 90 days**
e. Received preventative or protective foot care (e.g., used special shoes, inserts, pads, toe separators)
f. Application of dressings (with or without topical medications)
g. *NONE OF ABOVE*

SECTION N. ACTIVITY PURSUIT PATTERNS

1. TIME AWAKE (*Check appropriate time periods over last 7 days*) Resident awake all or most of time (i.e., naps no more than one hour per time period) in the:

a. Morning ❷ *10B* 4,5*
b. Afternoon 4,5*
c. Evening 4,5*
d. *NONE OF ABOVE* 4,5

(**If resident is comatose, skip to Section O**)

2. AVERAGE TIME INVOLVED IN ACTIVITIES (**When awake and not receiving treatments or ADL care**)

0. Most—more than 2/3 of time ❷ *10B*
1. Some—from 1/3 to 2/3 of time
2. Little—less than 1/3 of time *10A* 23
3. None *10A* 23

3. PREFERRED ACTIVITY SETTINGS (*Check all settings in which activities are preferred*)

a. Own room
b. Day/activity room
c. Inside NH/off unit
d. Outside facility
e. *NONE OF ABOVE*

4. GENERAL ACTIVITY PREFERENCES (adapted to resident's current abilities) (*Check all PREFERENCES whether or not activity is currently available to resident*)

a. Cards/other games
b. Crafts/arts
c. Exercise/sports
d. Music
e. Reading/writing
f. Spiritual/religious activities
g. Trips/shopping
h. Walking/wheeling outdoors
i. Watching TV
j. Gardening or plants
k. Talking or conversing
l. Helping others
m. *NONE OF ABOVE*

17 - refer to a RAI manual for clarification* ❷ = Two items required to trigger

4, 5* - N1a + N1b + N1c ≤ 1 and B1 = 0 MDS 2.0 September, 20

Resident _____ Numeric Identifier _____

5. PREFERS CHANGE IN DAILY ROUTINE — *Code for resident preferences in daily routines* 0. No change 1. Slight change *104* 2. Major change *104*
- a. Type of activities in which resident is currently involved
- b. Extent of resident involvement in activities

SECTION O. MEDICATIONS

1. NUMBER OF MEDICATIONS — (*Record the number of different medications used in the last 7 days; enter "0" if none used*) 0-6

2. NEW MEDICATIONS — (*Resident currently receiving medications that were initiated during the last 90 days*) 0. No 1. Yes

3. INJECTIONS — (*Record the number of DAYS injections of any type received during the last 7 days; enter "0" if none used*)

4. DAYS RECEIVED THE FOLLOWING MEDICATION — (*Record the number of DAYS during last 7 days; enter "0" if not used. Note—enter "1" for long-acting meds used less than weekly*)
- a. Antipsychotic 1-7= ✱17* 0-1=19
- b. Antianxiety 1-7= *11*, ✱17* 0-1=20
- c. Antidepressant 1-7= *11*,✱17* 0=5
- d. Hypnotic 0-1=20 >2=21
- e. Diuretic 1-7= *14*

SECTION P. SPECIAL TREATMENTS AND PROCEDURES

1. SPECIAL TREATMENTS, PROCEDURES, AND PROGRAMS — a. SPECIAL CARE—*Check treatments or programs received during the last 14 days*

TREATMENTS
- a. Chemotherapy
- b. Dialysis
- c. IV medication
- d. Intake/output
- e. Monitoring acute medical condition
- f. Ostomy care
- g. Oxygen therapy
- h. Radiation
- i. Suctioning
- j. Tracheostomy care
- k. Transfusions
- l. Ventilator or respirator

PROGRAMS
- m. Alcohol/drug treatment program
- n. Alzheimer's/dementia special care unit
- o. Hospice care
- p. Pediatric unit
- q. Respite care
- r. Training in skills required to return to the community (e.g., taking medications, house work, shopping, transportation, ADLs)
- s. *NONE OF ABOVE*

b. THERAPIES - *Record the number of days and total minutes each of the following therapies was administered (for at least 15 minutes a day) in the last 7 calendar days (Enter 0 if none or less than 15 min. daily)* [Note—count only post admission therapies]
(A) = # of days administered for 15 minutes or more
(B) = total # of minutes provided in last 7 days

	DAYS (A)	MIN (B)
a. Speech - language pathology and audiology services		
b. Occupational therapy		
c. Physical therapy		
d. Respiratory therapy		
e. Psychological therapy (by any licensed mental health professional)		

2. INTERVENTION PROGRAMS FOR MOOD, BEHAVIOR, COGNITIVE LOSS — (Check all interventions or strategies used in last 7 days—no matter where received)
- a. Special behavior symptom evaluation program
- b. Evaluation by a licensed mental health specialist in last 90 days
- c. Group therapy
- d. Resident-specific deliberate changes in the environment to address mood/behavior patterns—e.g., providing bureau in which to rummage
- e. Reorientation—e.g., cueing
- f. *NONE OF ABOVE*

3. NURSING REHABILITATION/ RESTORATIVE CARE — *Record the NUMBER OF DAYS each of the following rehabilitation or restorative techniques or practices was provided to the resident for more than or equal to 15 minutes per day in the last 7 days (Enter 0 if none or less than 15 min. daily.)*
- a. Range of motion (passive)
- b. Range of motion (active)
- c. Splint or brace assistance

TRAINING AND SKILL PRACTICE IN:
- d. Bed mobility
- e. Transfer
- f. Walking
- g. Dressing or grooming
- h. Eating or swallowing
- i. Amputation/prosthesis care
- j. Communication
- k. Other

4. DEVICES AND RESTRAINTS — (*Use the following codes for last 7 days:*) 0. Not used 1. Used less than daily 2. Used daily

Bed rails
- a. — Full bed rails on all open sides of bed
- b. — Other types of side rails used (e.g., half rail, one side)
- c. Trunk restraint 1,2 = *11,18* 2 = *16* 22
- d. Limb restraint 1,2 = *18* 22
- e. Chair prevents rising 1,2 = *18* 22

5. HOSPITAL STAY(S) — Record number of times resident was admitted to hospital with an overnight stay in last 90 days (or since last assessment if less than 90 days). (*Enter 0 if no hospital admissions*)

6. EMERGENCY ROOM (ER) VISIT(S) — Record number of times resident visited ER without an overnight stay in last 90 days (or since last assessment if less than 90 days). (*Enter 0 if no ER visits*)

7. PHYSICIAN VISITS — In the LAST 14 DAYS (or since admission if less than 14 days in facility) how many days has the physician (or authorized assistant or practitioner) examined the resident? (*Enter 0 if none*)

8. PHYSICIAN ORDERS — In the LAST 14 DAYS (or since admission if less than 14 days in facility) how many days has the physician (or authorized assistant or practitioner) changed the resident's orders? *Do not include order renewals without change.* (*Enter 0 if none*)

9. ABNORMAL LAB VALUES — Has the resident had any abnormal lab values during the last 90 days (or since admission)? 0. No 1. Yes

SECTION Q. DISCHARGE POTENTIAL AND OVERALL STATUS

1. DISCHARGE POTENTIAL
- a. Resident expresses/indicates preference to return to the community 0. No 1. Yes
- b. Resident has a support person who is positive towards discharge 0. No 1. Yes
- c. Stay projected to be of a short duration— discharge projected within 90 days (do not include expected discharge due to death) 0. No 1. Within 30 days 2. Within 31-90 days 3. Discharge status uncertain

2. OVERALL CHANGE IN CARE NEEDS — Resident's overall self sufficiency has changed significantly as compared to status of 90 days ago (or since last assessment if less than 90 days) 0. No change 1. Improved—receives fewer supports, needs less restrictive level of care 2. Deteriorated—receives more support

SECTION R. ASSESSMENT INFORMATION

1. PARTICIPATION IN ASSESSMENT
- a. Resident: 0. No 1. Yes
- b. Family: 0. No 1. Yes 2. No family
- c. Significant other: 0. No 1. Yes 2. None

2. SIGNATURE OF PERSON COORDINATING THE ASSESSMENT:

a. Signature of RN Assessment Coordinator (sign on above line)

b. Date RN Assessment Coordinator signed as complete ___ Month ___ Day ____ Year

✱ = One of these three items, plus at least one other item required to trigger

17 - refer to a RAI manual for clarification*

Resident _____ Numeric Identifier _____

SECTION T. THERAPY SUPPLEMENT FOR MEDICARE PPS

1. SPECIAL TREATMENTS AND PROCEDURES

a. RECREATION THERAPY—*Enter number of days and total minutes of recreation therapy administered (for at least 15 minutes a day) in the last 7 days (Enter 0 if none)*

	DAYS (A)	MIN (B)
(A) = # of days administered for 15 minutes or more (B) = total # of minutes provided in last 7 days		

Skip unless this is a Medicare 5 day or Medicare readmission/return assessment.

b. ORDERED THERAPIES—*Has physician ordered any of following therapies to begin in FIRST 14 days of stay—physical therapy, occupational therapy, or speech pathology service?*
0. No 1. Yes

If not ordered, skip to item 2

c. Through day 15, provide an estimate of the number of days when at least 1 therapy service can be expected to have been delivered.

d. Through day 15, provide an estimate of the number of therapy minutes (across the therapies) that can be expected to be delivered?

2. WALKING WHEN MOST SELF SUFFICIENT

Complete item 2 if ADL self-performance score for TRANSFER (G.1.b.A) is 0,1,2, or 3 AND at least one of the following are present:
- Resident received physical therapy involving gait training (P.1.b.c)
- Physical therapy was ordered for the resident involving gait training (T.1.b)
- Resident received nursing rehabilitation for walking (P.3.f)
- Physical therapy involving walking has been discontinued within the past 180 days

Skip to item 3 if resident did not walk in last 7 days

(FOR FOLLOWING FIVE ITEMS, BASE CODING ON THE EPISODE WHEN THE RESIDENT WALKED THE FARTHEST WITHOUT SITTING DOWN. INCLUDE WALKING DURING REHABILITATION SESSIONS.)

a. Furthest distance walked without sitting down during this episode.

0. 150+ feet
1. 51-149 feet
2. 26-50 feet
3. 10-25 feet
4. Less than 10 feet

b. Time walked without sitting down during this episode.

0. 1-2 minutes
1. 3-4 minutes
2. 5-10 minutes
3. 11-15 minutes
4. 16-30 minutes
5. 31+ minutes

c. Self-Performance in walking during this episode.

0. *INDEPENDENT*—No help or oversight
1. *SUPERVISION*—Oversight, encouragement or cueing provided
2. *LIMITED ASSISTANCE*—Resident highly involved in walking; received physical help in guided maneuvering of limbs or other nonweight bearing assistance
3. *EXTENSIVE ASSISTANCE*—Resident received weight bearing assistance while walking

d. Walking support provided associated with this episode (code regardless of resident's self-performance classification).

0. No setup or physical help from staff
1. Setup help only
2. One person physical assist
3. Two+ persons physical assist

e. Parallel bars used by resident in association with this episode.

0. No 1. Yes

3. CASE MIX GROUP

Medicare [ ][ ][ ][ ][ ] State [ ][ ][ ][ ][ ]

Resident _____ Numeric Identifier _____

SECTION U. MEDICATIONS – CASE MIX DEMO

List all medications that the resident **received** during the last 7 days. Include scheduled medications that are used regularly, but less than weekly.

1. Medication Name and Dose Ordered. Record the name of the medication and dose ordered.
2. Route of Administration (RA). Code the Route of Administration using the following list:

1 = by mouth (PO)	5 = subcutaneous (SQ)	8 = inhalation
2 = sub lingual (SL)	6 = rectal (R)	9 = enteral tube
3 = intramuscular (IM)	7 = topical	10 = other
4 = intravenous (IV)		

3. Frequency. Code the number of times per day, week, or month the medication is administered using the following list:

PR = (PRN) as necessary	2D = (BID) two times daily (includes every 12 hrs)	QO = every other day
1H = (QH) every hour		4W = 4 times each week
2H = (Q2H) every two hours	3D = (TID) three times daily	5W = five times each week
3H = (Q3H) every three hours	4D = (QID) four times daily	6W = six times each week
4H = (Q4H) every four hours	5D = five times daily	1M = (Q month) once every month
6H = (Q6H) every six hours	1W = (Q week) once each wk	2M = twice every month
8H = (Q8H) every eight hours	2W = two times every week	C = continuous
1D = (QD or HS) once daily	3W = three times every week	O = other

4. Amount Administered (AA). Record the number of tablets, capsules, suppositories, or liquid (any route) **per dose** administered to the resident. Code 999 for topicals, eye drops, inhalants and oral medications that need to be dissolved in water.
5. PRN-number of days (PRN-n). If the frequency code for the medication is "PR", record the number of times during the last 7 days each PRN medication was given. Code STAT medications as PRNs given once.
6. NDC Codes. Enter the National Drug Code for each medication given. Be sure to enter the correct NDC code for the drug name, strength, and form. The NDC code must match the drug dispensed by the pharmacy.

1. Medication Name and Dose Ordered	2. RA	3. Freq	4. AA	5. PRN-n	6. NDC Codes

Numeric Identifier _____

SECTION V. RESIDENT ASSESSMENT PROTOCOL SUMMARY

Resident's Name:	Medical Record No.:

1. Check if RAP is triggered.
2. For each triggered RAP, use the RAP guidelines to identify areas needing further assessment. Document relevant assessment information regarding the resident's status.
   - Describe:
     - — Nature of the condition (may include presence or lack of objective data and subjective complaints).
     - — Complications and risk factors that affect your decision to proceed to care planning.
     - — Factors that must be considered in developing individualized care plan interventions.
     - — Need for referrals/further evaluation by appropriate health professionals.
   - Documentation should support your decision-making regarding whether to proceed with a care plan for a triggered RAP and the type(s) of care plan interventions that are appropriate for a particular resident.
   - Documentation may appear anywhere in the clinical record (e.g., progress notes, consults, flowsheets, etc.).
3. Indicate under the Location of RAP Assessment Documentation column where information related to the RAP assessment can be found.
4. For each triggered RAP, indicate whether a new care plan, care plan revision, or continuation of current care plan is necessary to address the problem(s) identified in your assessment. The Care Planning Decision column must be completed within 7 days of completing the RAI (MDS and RAPs).

A. RAP PROBLEM AREA	(a) Check if triggered	Location and Date of RAP Assessment Documentation	(b) Care Planning Decision—check if addressed in care plan
1. DELIRIUM			
2. COGNITIVE LOSS			
3. VISUAL FUNCTION			
4. COMMUNICATION			
5. ADL FUNCTIONAL/ REHABILITATION POTENTIAL			
6. URINARY INCONTINENCE AND INDWELLING CATHETER			
7. PSYCHOSOCIAL WELL-BEING			
8. MOOD STATE			
9. BEHAVIORAL SYMPTOMS			
10. ACTIVITIES			
11. FALLS			
12. NUTRITIONAL STATUS			
13. FEEDING TUBES			
14. DEHYDRATION/FLUID MAINTENANCE			
15. DENTAL CARE			
16. PRESSURE ULCERS			
17. PSYCHOTROPIC DRUG USE			
18. PHYSICAL RESTRAINTS			

B.

1. Signature of RN Coordinator for RAP Assessment Process

2. ☐☐ — ☐☐ — ☐☐☐☐ (Month — Day — Year)

3. Signature of Person Completing Care Planning Decision

4. ☐☐ — ☐☐ — ☐☐☐☐ (Month — Day — Year)

Sample **Exhibit 269**

Run Date: 1/7/1999 2:53:52 pm

Report 2
Facility Quality Indicator Profile

Report Period: 1/1/1998 to 12/31/1998

Data Submitted By: 1/5/1999

Facility: REDACTED

Facility Login ID: T44

Domain/Quality Indicator	# in Num	# in Denom	Facility Percent	Comparison Group Percent	Percentile Rank
Accidents					
1. Incidence of new fractures	1	159	0.6	0.9	27
2. Prevalence of falls	47	177	26.6	20.4	92
Behavior/Emotional Patterns					
3. Prevalence of behavioral symptoms affecting others	29	177	16.4	19.9	8
High risk	24	100	24.0	26.0	6
Low risk	5	77	6.5	7.4	51
4. Prevalence of symptoms of depression	19	177	10.7	20.7	8
5. Prevalence of symptoms of depression without antidepressant therapy	5	177	2.8	10.0	0
Clinical Management					
6. Use of 9 or more different medications	82	177	46.3	34.6	100
Cognitive Patterns					
7. Incidence of cognitive impairment	6	47	12.8	9.1	89
Elimination/Incontinence					
8. Prevalence of bladder or bowel incontinence	60	163	36.8	39.6	13
High risk	19	37	51.4	47.6	62
Low risk	41	126	32.5	36.3	14
9. Prevalence of occasional or frequent bladder or bowel incontinence without toileting plan	22	64	34.4	22.6	81
10. Prevalence of indwelling catheter	10	177	5.6	7.4	14
11. Prevalence of fecal impaction	1	177	0.6	0.8	31
Infection Control					
12. Prevalence of urinary tract infections	32	177	18.1	9.7	100
Nutrition/Eating					
13. Prevalence of weight loss	29	177	16.4	10.6	100
14. Prevalence of tube feeding	5	177	2.8	2.7	70
15. Prevalence of dehydration	0	177	0.0	0.5	50

Designed and Implemented by the Center for Health Systems Research and Analysis. U.W. - Madison
for the HCFA Standard Automation System Analytic Reporting System (beta-test)

Sample **Exhibit 269 (continued)**

Run Date: 1/7/1999 2:53:52 pm

Report 2
Facility Quality Indicator Profile

Report Period: 1/1/1998 to 12/31/1998

Facility: REDACTED

Facility Login ID: T44

Data Submitted By: 1/5/1999

Domain/Quality Indicator	# in Num	# in Denom	Facility Percent	Comparison Group Percent	Percentile Rank
Physical Functioning					
16. Prevalence of bedfast residents	11	177	6.2	2.1	100
17. Incidence of decline in late loss ADLs	18	108	16.7	17.5	61
18. Incidence of decline in ROM	72	120	60.0	14.3	95
Psychotropic Drug Use					
19. Prevalence of antipsychotic use, in the absence of psychotic or related conditions	19	169	11.2	11.2	61
High risk	5	22	22.7	29.9	50
Low risk	14	147	9.5	7.4	77
20. Prevalence of antianxiety/hypnotic use	37	169	21.9	15.2	100
21. Prevalence of hynotic use more than two times in last week	12	177	6.8	2.6	100
Quality of Life					
22. Prevalence of daily physical restraints	7	177	4.0	8.7	13
23. Prevalence of little or no activity	64	177	36.2	18.0	93
Skin Care					
24. Prevalence of stage 1-4 pressure ulcers	17	177	9.6	7.5	82
High risk	8	68	11.8	11.5	7
Low risk	9	109	8.3	4.0	100

Designed and Implemented by the Center for Health Systems Research and Analysis, U.W. - Madison
for the HCFA Standard Automation System Analytic Reporting System (beta-test)

REDACTED

Glossary

Activities of Daily Living (ADLs)
Functions required to be able to live independently, which include: Eating, Bathing, Grooming, Transferring, Toileting, and Transferring.

Acute Care
Care for a person with a single episode of a short-term illness or with an exacerbation of a chronic condition.

Administrator
Person responsible for the overall operation of a health care facility. A term most associated with hospitals and nursing homes. May be called the *Program Director* in community based facilities.

Adult Foster Home (AFH)
Private residence where up to 5 non-related elderly or disabled people may live in order to receive room, board, and personal care. Care provider must live in the residence full time. Care providers are not required to be medically licensed or certified.

Alzheimer's Unit
Provides medical and custodial care for individuals suffering from Alzheimer's disease.

American Association of Homes and Services for the Aged (AAHSA)
An organization representing nursing homes and assisted living facilities. Membership is primarily made up of not-for-profit facilities.

American Health Care Association (AHCA)
An organization representing nursing homes. Membership is primarily made up of for-profit facilities.

American Society of Consultant Pharmacists (ASCP)
An organization representing pharmacists who provide prescription services and consulting services to the long-term care industry.

American Medical Directors Association (AMDA)
The organization representing physicians who are medical directors of nursing homes.

American Geriatrics Society (AGS)
An organization comprised of any healthcare professional who is engaged in providing care and/or services to the long-term care environment. Includes physicians, nurses, social workers, and pharmacists.

Ancillary Services
Hospital services other than room, board, and professional services. They may include x-ray, laboratory, or anesthesia.

Assisted Living Facility (ALF)
Facility with over 5 residents who live in individual apartments or room. Meals, organized activities, medication management, and some assistance with dressing and personal care provided by hired staff. Care staff not required to be licensed or certified. Minimal supervision by RN or non at all. Social model.

Assisted Living Federation of America (ALFA)
An organization representing assisted living facilities.

Balanced Budget Act (BBA) of 1997
A Congressional act that introduced Medicare + Choice, an option that was intended to reduce Medicare costs. The act allows beneficiaries who have Medicare A & B to choose risk-based HMO plans, fee-for-service plans, or Medical Savings Accounts.

Beds
Term used to describe the capacity of a facility. Used in hospitals and nursing homes. Not an acceptable term in community based facilities. (*See units*)

Beneficiary
A person designated by an insuring organization as eligible to receive insurance benefits.

Bingo Card
A form of modified unit dose packaging, also referred to as blister pack or punch card.

Bundling
A contractual arrangement in which a seller provides several products at a discount. The products may be related, possibly from another manufacturer or unrelated, such as drug and non-drug products.

Care Plan
A plan that identifies the resident's care needs, describes the strategy for providing services to meet those needs, documents treatment goals, and objectives, outlines the criteria for terminating specified interventions, and documents the resident's progress in meeting goals and objectives.

Care Staff
A loosely used term to refer to the staff providing physical care in all levels of care. May or may not be licensed or certified.

Case Manager
An experienced professional (e.g., nurse, doctor, or social worker) who works with patients, providers, and insurers to coordinate all services necessary to provide the patient with a plan of medically necessary and appropriate health care.

Client
Current term often used in place of the term patient, especially in community based care facilities, and facilities for the mentally retarded or developmentally disabled.

Closed Formulary
A formulary that restricts prescriptions exclusively to the approved drug list. Emphasis may be placed on generic substitutions and step therapy protocols.

REDACTED

Center for Medicare and Medicaid Services (CMS)
A Federal Agency under the Department of Health and Human Services (HHS), which administers the Medicare program and oversees the states' management of the Medicaid program. (Formerly Health Care Finance Administration-HCFA)

Certified Medication Assistant (CMA)
A person who has worked for a specified period of time as a CAN then completed and passed a standardized program in basic medication administration. May not administer injections or IVs. Not recognized in all the states.

Certified Nursing Assistant (CNA)
A person who has completed and passed a standardized certification program in basic care. Provides assistance with activities of daily living (ADLs).

Community
See *Facility*.

Community Based Care
Term used for facilities other than hospitals and nursing homes. Includes ALF, AFH, RCF.

Delegation
Allows non-licensed non-certified staff to perform some duties traditionally done by licensed nurses. Requires teaching and supervision by an RN.

Diagnosis Related Groups (DRGs)
A system of classification for inpatient hospital services based on principle diagnosis, secondary diagnosis, surgical procedures, age, sex, and presence of complications. This system of classification is used as a financing mechanism to reimburse hospital and selected other providers for services rendered.

Director of Nursing
The person who is responsible for all nursing care provided. Required in hospitals and nursing homes. Must be a registered nurse. Also know as a Director of Nursing Services (DNS).

Disease Management
An information based process that provides an integrated, multi-disciplinary approach to the prevention, diagnosis, management, and treatment of various diseases. The goal is to optimize the clinical and economic outcome of care for a specific disease state of diagnosis.

Drug Regimen Review (DRR)
A review of the record of each patient in the long-term care facility to identify drug therapy problems or irregularities. DRRs are conducted by consultant pharmacists, and must be made in writing. (Also known as Drug Utilization Review-DUR).

Facility
The building or environment where residents live. A more acceptable term replacing the word *institution*. Now being replaced by the term *Community*.

Fee-for-Service Plan
A method of reimbursement in which providers are paid a "reasonable or customary" fee for a unit of service. Included are comprehensive first-dollar coverage, arrangements with deductibles and co-payments, or plans using utilization reviews and mandatory second opinions.

REDACTED

Formulary
An exclusive list of drugs for which a third-party payer will provide reimbursement. A formulary usually includes lower-priced entries in a multiple source category, and will often exclude higher-priced, branded products.

Health Care Coordinator
A loosely defined term often used in community based facilities to refer to the person responsible for overseeing the care provided to the residents. This person may or may not be licensed or certified.

Hospice
A facility or program engaged in providing palliative and supportive care of the terminally ill, and licensed, certified or otherwise pursuant to the law of jurisdiction in which services are received.

Intermediate Care Facility (ICF)
See Nursing Facility (NF)

Long-Term Care
Assistance and care of persons with chronic disabilities who require help with the activities of daily living or who suffer from cognitive impairment. Long-term care's goal is to help people with disabilities be as independent as possible; thus it is focused more on caring than on curing.

Long-Term Care Provider
Any organization that provides long-term health care. The description applies equally to a single nursing home or home health agency, a nursing home chain, or a large integrated system that contains a combination of long-term care services, including sub-acute care, skilled nursing care, and home care.

Managed Care
A system of healthcare delivery that influences utilization and cost of services and measure performance. The goal is a system that delivers value by giving people access to high-quality, cost-effective healthcare. A systemic approach, which seeks to ensure the provision of the right healthcare at the right time, place, and cost. (Also know as Managed Costs)

Medicaid
A federal program, partially funded by individual states, that provides medical benefits to certain low-income individuals. Each state under broad federal guidelines, determines what benefits are covered, who is eligible and how much providers will be paid.

Medical Director
A physician who assumes some administrative responsibilities in hospitals and nursing homes. Not required in community based facilities. Is paid for his role as medical director and must sign documents and attend quarterly meetings.

Medical Model
Refers to physician centered philosophy of care found in hospitals and nursing homes. All care is provided under the direct orders of a physician.

Medical Savings Account
A method of reimbursement in which the beneficiary is allotted a fixed amount of money to spend on health care. Allows the beneficiary to control the selection of providers and therapies.

Medicare
A federally funded program that uses tax dollars to reimburse providers for health care services rendered to the elderly, ages 65 and over. The major benefits of this legislation include physician services, hospital care, home care, and extended care facility coverage for a defined period of time. This program is voluntary and is financed through Social Security deductions from employee-employer payrolls. It is handled through nation trust funds. Part A covers hospital and skilled nursing facility costs. Part V, for which there is a monthly premium, covers physician services and certain outpatient procedures. While it is governed at the federal level, claims are processed through insurance companies that serve as fiscal intermediaries.

Medicare + Choice
An option introduced by the Balanced Budget Act of 1997 that was inteded to reduce Medicare costs. The act allows beneficiaries who have Medicare parts A & B to choose risk-based HMO plans, fee-for-service plans, or Medical Savings Accounts.

Minimum Data Set (MDS)
A CMS assessment tool containing more than 100 items that is filled out by nursing staff when a patient is admitted to a nursing facility. It is completed quarterly and upon a significant change in the resident's condition. It captures a patient's medical condition, functional status, sensory and physical impairment, nutrition, psychosocial status, dental status, activity level and rehabilitation potential. It is based both on staff observation and on previous written reports filed on the patient.

Morbidity (morbidity rate)
1. An actuarial determination of the incidence and severity of sickness and accidents in a well-defined class or classes of people. 2. The actual state of being diseased. 3. An actuarial determination of the death rate in a given population in a given period.

Open Formulary
A formulary that allows physicians to prescribe as they see fit, whether or not the drug is on the approved list.

Outcome
The result of a certain course of therapy, measured in terms of health impact and costs.

Patient
Consumer of health care. Term still used in some medical model facilities. Not an acceptable term in community based facilities (see *Resident or Client*).

Pharmacy and Therapeutics Committee (P&T)
An organized panel of consulting physicians, attending physicians, pharmacists, the director of nursing, and the long-term care administrator, who function as an advisory panel to the facility or plan regarding the safe and effective use of prescription medications.

Pharmacy Provider
A company that contracts to supply pharmacy services to a health care provider.

Prior Authorization (PA)
The process of obtaining approval to reimburse for a service or medication.

Program Director
A loosely defined term referring to the person responsible for the overall operations of a community based facility. (See *Administrator*).

Prospective Payment System (PPS)
The system for payment of Medicare Skilled Nursing Facility care. Pays for a day of care on an all-inclusive basis. The case mix adjusted payment includes all routine, pharmaceutical ancillary and capital related costs for each skilled day of care.

Residential Care Facility (RCF)
Facility with over 5 residents. Meals, organized activities, medication management, and some assistance with dressing and personal care provided by hired staff. Care staff not required to be licensed or certified. Minimal supervision or none by RN.

Resident
Person who lives in a health care fadcility. Term used in nursing homes and community based facilities. (See *Patient or Client*).

Resource Utilization Group (RUGs)
The classification system that is being used as part of the Prospective Payment System (PPS) for Skilled Nursing Facility care (SNF). The RUGs III classification system is based upon nursing and therapy resource use across 44 different patient categories.

Restricted Formulary
A formulary that restricts the number of drug choices in a particular class. May have lower co-pays for preferred products and higher co-pays for non-preferred drugs.

Retirement Facility
Facility providing individual apartment living with organized activities, meals, security, and limited or no health care services. No licensed nursing services.

Skilled Nursing Facility (SNF)
Facility providing skilled nursing care for elderly, disabled, and chronically ill patients.

Step Therapy
A procedure that requires physicians to use less expensive therapies in patient treatment before going on to more extensive interventions.

Social Model
Refers to client centered health care. Client directs his/her own health care and maintains the right to remain autonomous. Opposite of Medical Model.

Sub Acute Facility
Merges the intensity of hospital based services with the operation of a nursing facility to reduce the cost of caring for seriously ill patients., The goal of sub-acute care is to stabilize patients requiring cardiac care, pain management, extensive wound care or other types of labor intensive care so they can be moved to a less care-intensive facility.

Therapeutic Interchange or Substitution
The dispensing by a pharmacist of a therapeutically equivalent product without event-specific approval of the physician. This practice is common in hospitals and/or formulary- based programs for a limited number of selected rugs. Approval is generally provided by the P&T Committee. This practice will become more common in the long-term care facilities as PPS is enacted.

Third Party Payer
A public or private organization that pays for or underwrites coverage for healthcare expense4s or another entity, usually an employer (i.e. Blue Cross, Blue Shield; Medicare; Medicaid; commercial insurers).

REDACTED

Transitional Care Unit (TCU)
Provides high level skilled nursing care for more acutely ill patients transitioning from hospital setting. Also know as a "step-down unit".

Units
Apartments. Current term used to describe the capacity of an assisted living facility. (See *Beds*).

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Reference Guide For CMS F-Tags

Issue	F-Tag
Antianxiety Agents	F329
Antidepressant Agents	F329
Antipsychotic Agents	F329
Antipsychotics - initial therapy	F330
Antipsychotics - gradual dose reductions	F331
Chemical Restraints	F222
Consultant Pharmacist requirements	F427
Controlled Drug - record keeping	F427
Drugs Potentially Inappropriate in Elderly	F329/F429
Drug Regimen Review	F428
DRR - report to DON & Medical Director	F429
DRR - report must be acted upon	F430
Hypnotic Agents	F329

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Reference Guide For CMS F-Tags

Issue	F-Tag
Medication Change Notification	F157
Labeling of Medications	F431
Medication Errors	F332
Significant Medication Errors	F331
Medication Pass Observation	F331
Medication Storage	F432
Parenteral/Enteral Nutrition	F328
Pharmacy Services	F425
QAA Committee	F520
Sedative/Hypnotic Agents	F329
Self-administration of Drugs	F176
Side Effect Documentation	F272
Unnecessary Drugs	F329

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SPECIAL ARTICLE

Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly

An Update

Mark H. Beers, MD

This study updates and expands explicit criteria defining potentially inappropriate medication use by the elderly. Additional goals were to address whether adverse outcomes were likely to be clinically severe and to incorporate clinical information on diagnoses when available. These criteria are meant to serve epidemiological studies, drug utilization review systems, health care providers, and educational efforts. Consensus from a panel of 6 nationally recognized experts on the appropriate use of medication in the elderly was sought. The expert panel agreed on the validity of 28 criteria describing the potentially inappropriate use of medication by general populations of the elderly as well as 35 criteria defining potentially inappropriate medication use in older persons known to have any of 15 common medical conditions. Updated, expanded, and more generally applicable criteria are now available to help identify inappropriate use of medications in elderly populations. These criteria define medications that should generally be avoided in the ambulatory elderly, doses or frequencies of administrations that should generally not be exceeded, and medications that should be avoided in older persons known to have any of several common conditions.

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In 1991, researchers[1] at the University of California, Los Angeles published the first explicit criteria identifying inappropriate medication use in nursing home residents. Thus, the criteria were designed to apply to only the frailest and sickest elderly populations. Those criteria were meant to serve researchers evaluating the quality of prescribing, drug utilization review systems, and educational efforts. They were designed to evaluate medication use in the absence of clinical information on diagnoses because of the relative inaccuracy of such information in nursing home records. The criteria have now been used as the basis for several research studies.[2-4]

At the time they were created, the criteria filled a void in pharmacoepidemiological methods.[5] However, even when they were first published, the authors cautioned that updating and expansion would be needed. The growing need for such criteria has led to their application in ways that they were never intended to be used. For example, although the original criteria were developed for the frailest elderly—those residing in nursing homes—they have been used to evaluate prescribing in noninstitutionalized elderly populations.[6-8] Additionally, the original criteria have been modified by most who have used them. Some have selected a subset of the criteria that they believed identified the most serious prescribing problems, since the criteria did not rate the potential severity of outcomes. Since the creation of the criteria, new medications have come to the marketplace that were not considered during the original development process and new scientific information has become available about the effects and side effects of many medications in older populations. Finally, the availability of clinical information in drug utilization review and research databases has increased so that accurate information on concurrent diagnosis is sometimes available. For all these reasons, the criteria must be reevaluated.

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Table 1. Final Criteria: Independent of Diagnoses*

Summary of Prescribing Concern	Applicable Medications†	High Severity
Propoxyphene should generally be avoided in the elderly. It offers few analgesic advantages over acetaminophen, yet has the side effects of other narcotic drugs.	Propoxyphene and combination products	No
Of all available nonsteroidal, anti-inflammatory drugs, indomethacin produces the most central nervous system side effects and should, therefore, be avoided in the elderly.	Indomethacin (Indocin, Indocin SR)	No
Phenylbutazone may produce serious hematological side effects and should not be used in elderly patients.	Phenylbutazone (Butazolidin)	No
Pentazocine is a narcotic analgesic that causes more central nervous system side effects, including confusion and hallucinations, more commonly than other narcotic drugs. Additionally, it is a mixed agonist and antagonist. For both reasons, its use should generally be avoided in the elderly.	Pentazocine (Talwin)	Yes
Trimethobenzamide is one of the least effective antiemetic drugs, yet it can cause extrapyramidal side effects. When possible, it should be avoided in the elderly.	Trimethobenzamide (Tigan)	No
Most muscle relaxants and antispasmodic drugs are poorly tolerated by the elderly, leading to anticholinergic side effects, sedation, and weakness. Additionally, their effectiveness at doses tolerated by the elderly is questionable. Whenever possible, they should not be used by the elderly.	Methocarbamol (Robaxin), carisoprodol (Soma), orphenadrine (Norflex), chlorzoxazone (Parafon Forte), metaxalone (Skelaxin), and cyclobenzaprine (Flexeril)	No
Benzodiazepine hypnotic has an extremely long half-life in the elderly (often days), producing prolonged sedation and increasing the incidence of falls and fractures. Medium- or short-acting benzodiazepines are preferable.	Flurazepam (Dalmane)	Yes
Because of its strong anticholinergic and sedating properties, amitriptyline is rarely the antidepressant of choice for the elderly.	Amitriptyline (Elavil), chlordiazepoxide-amitriptyline (Limbitrol), and perphenazine-amitriptyline (Triavil)	Yes
Because of its strong anticholinergic and sedating properties, doxepin is rarely the antidepressant of choice for the elderly.	Doxepin (Sinequan)	Yes
Meprobamate is a highly addictive and sedating anxiolytic. Avoid in elderly patients. Those using meprobamate for prolonged periods may be addicted and may need to be withdrawn slowly.	Meprobamate (Miltown, Equanil)	Yes if recently started‡
Because of increased sensitivity to benzodiazepines in the elderly, smaller doses may be effective as well as safer. Total daily doses should rarely exceed the following suggested maximums:	Lorazepam (Ativan), 3 mg; oxazepam (Serax), 60 mg; alprazolam (Xanax), 2 mg; temazepam (Restoril), 15 mg; zolpidem (Ambien), 5 mg; triazolam (Halcion), 0.25 mg	No
Chlordiazepoxide and diazepam have a long half-life in the elderly (often several days), producing prolonged sedation and increasing the risk of falls and fractures. Short- and intermediate-acting benzodiazepines are preferred if a benzodiazepine is required.	Chlordiazepoxide (Librium), chlordiazepoxide-amitriptyline (Limbitrol), clidinium-chlordiazepoxide (Librax), and diazepam (Valium)	Yes
Disopyramide, of all antiarrhythmic drugs, is the most potent negative inotrope and therefore may induce heart failure in the elderly. It is also strongly anticholinergic. When appropriate, other antiarrhythmic drugs should be used.	Disopyramide (Norpace, Norpace CR)	Yes
Because of decreased renal clearance of digoxin, doses in the elderly should rarely exceed 0.125 mg daily, except when treating atrial arrhythmias.	Digoxin (Lanoxin)	Yes if recently started‡
Dipyridamole frequently causes orthostatic hypotension in the elderly. It has been proven beneficial only in patients with artificial heart valves. Whenever possible, its use in the elderly should be avoided.	Dipyridamole (Persantine)	No
Methyldopa may cause bradycardia and exacerbate depression in the elderly. Alternate treatments for hypertension are generally preferred.	Methyldopa (Aldomet); methyldopa/hydrochlorothiazide (Aldoril)	Yes if recently started‡
Reserpine imposes unnecessary risk in the elderly, inducing depression, impotence, sedation, and orthostatic hypotension. Safer alternatives exist.	Reserpine (Serpasil); reserpine hydrochlorothiazide (Hydropres)	No
Chlorpropamide has a prolonged half-life in the elderly and can cause prolonged and serious hypoglycemia. Additionally, it is the only oral hypoglycemic agent that causes SIADH. Avoid in the elderly.	Chlorpropamide (Diabinese)	Yes
Gastrointestinal antispasmodic drugs are highly anticholinergic and generally produce substantial toxic effects in the elderly. Additionally, their effectiveness at doses tolerated by the elderly is questionable. All these drugs are best avoided in the elderly, especially for long-term use.	Dicyclomine (Bentyl); hyoscyamine (Levsin, Levsinex); propantheline (Pro-Banthine); belladonna alkaloids (Donnatal and others); and clidinium-chlordiazepoxide (Librax)	Yes
All nonprescription and many prescription antihistamines have potent anticholinergic properties. Many cough and cold preparations are available without antihistamines, and these are safer substitutes in the elderly.	Examples include single and combination preparations containing chlorpheniramine (Chlor-Trimeton), diphenhydramine (Benadryl), hydroxyzine (Vistaril, Atarax), cyproheptadine (Periactin), promethazine (Phenergan), triprolidine/min, and dexchlorpheniramine (Polaramine)	No

(Continued)

Table 2. Final Criteria Considering Diagnoses*

Disease and Condition	Drug†	Alert	High Severity
Heart failure	Disopyramide	Negative inotrope. May worsen heart failure.	Yes
	Drugs with high sodium content (such as sodium alginate, bicarbonate, biphosphate, citrate, phosphate, salicylate, and sulfate)	Large sodium load, leading to fluid retention. May worsen heart failure.	No
Diabetes	β-Blockers (limited to people with diabetes taking oral hypoglycemics or insulin)	May block hypoglycemic symptoms in people with diabetes receiving treatment.	No
	Corticosteroids (limited to recently started use)	May worsen diabetic control.	No
Hypertension	Diet pills; amphetamines	May elevate blood pressure.	Yes
Chronic obstructive pulmonary disease	β-Blockers	May worsen respiratory function in persons with chronic obstructive pulmonary disease.	Yes
	Sedative/hypnotics	May slow respirations and increase carbon dioxide retention in persons with severe chronic obstructive pulmonary disease.	Yes
Asthma	β-Blockers	May worsen respiratory function in persons with chronic obstructive pulmonary disease.	Yes
Ulcers	NSAIDs	May exacerbate ulcer disease, gastritis, and GERD.	Yes
	Aspirin (>325 mg)	May exacerbate ulcer disease, gastritis, and GERD.	No
	Potassium supplements (all)	May cause gastric irritation with symptoms similar to ulcer disease.	No
Seizures or epilepsy	Clozapine, thorazine, thioridazine, and chlorprothixene	Lower seizure threshold.	No
	Metoclopramide	May worsen peripheral arterial blood flow and precipitate claudication.	Yes
Peripheral vascular disease	β-Blockers	May worsen peripheral arterial blood flow and precipitate claudication.	Yes
Blood-clotting disorders, limited to those receiving anticoagulant therapy	Aspirin	May cause bleeding in those using anticoagulants.	Yes
	NSAIDs	May cause bleeding in those using anticoagulants.	Yes
	Dipyridamole and ticlopidine	May cause bleeding in those using anticoagulants.	Yes
BPH	Anticholinergic antihistamines	Anticholinergic drugs may impair micturition and cause obstruction in persons with BPH.	Yes
	Gastrointestinal antispasmodic drugs	Anticholinergic drugs may impair micturition and cause obstruction in persons with BPH.	Yes
	Muscle relaxants	Anticholinergic drugs may impair micturition and cause obstruction in persons with BPH.	No
	Narcotic drugs (including propoxyphene)	Narcotic drugs may impair micturition and cause obstruction in persons with BPH.	No
	Flavoxate, oxybutynin	Bladder relaxants may cause obstruction in persons with BPH	No
	Bethanechol	Anticholinergic bladder relaxants may cause obstruction in persons with BPH.	No
	Anticholinergic antidepressant drugs	Anticholinergic drugs may impair micturition and cause obstruction in persons with BPH.	Yes
Incontinence	α-Blockers	α-Blockers relax the external bladder sphincter and may cause incontinence.	No
Constipation	Anticholinergic drugs	Will worsen constipation.	No
	Narcotic drugs	Will worsen constipation.	No
	Tricyclic antidepressant drugs	May worsen constipation.	Yes
Syncope or falls	β-Blockers	Negative chronotrope and inotrope. May precipitate syncope in susceptible persons.	No
	Long-acting benzodiazepine drugs	May contribute to falls.	Yes
Arrhythmias	Tricyclic antidepressant drugs	May induce arrhythmias.	Yes if started recently‡
Insomnia	Decongestants	May cause or worsen insomnia.	No
	Theophylline	May cause or worsen insomnia.	No
	Desipramine, SSRIs, methylphenidate, and MAOIs	May cause or worsen insomnia.	No
	β-Agonists	May cause or worsen insomnia	No

*It is important to note that most package circulars produced by drug manufacturers do not include language identical to the statements presented herein. Although the adverse effects that these drugs can produce are generally listed in the package circulars, these as well as warnings and contraindications must be approved by regulatory agencies and in general are not based on consensus or surveys. NSAIDs indicates nonsteroidal anti-inflammatory drugs; GERD, gastroesophageal reflux disease; BPH, benign prostatic hyperplasia; SSRIs, selective serotonin reuptake inhibitors; and MAOIs, monoamine oxidase inhibitors.

†Dose limits are total daily dose.

‡Panelists believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. In general, the greatest risk would be within about a 1-month period.

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ORIGINAL INVESTIGATION

The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities

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Background: Preventable drug-related morbidity and mortality within nursing facilities represent a serious problem urgently requiring expert medical attention. The health care costs of drug-related problems can be both immense and avoidable. However, the research to date has been narrow in scope, focusing on the drug costs avoided and failing to consider the wider range of possible negative outcomes and potential drug-related problems.

Objectives: To develop a model of therapeutic outcomes resulting from drug therapy within nursing facilities, to estimate the magnitude of the cost of drug-related morbidity and mortality within nursing facilities in the United States, and to assess the impact of pharmacist-conducted, federally mandated, monthly, retrospective review of nursing facility residents' drug regimens in reducing the cost of drug-related morbidity and mortality.

Methods: Using decision analysis techniques, a probability pathway model was developed to estimate the cost of drug-related problems within nursing facilities. An expert panel consisting of consultant pharmacists and physicians with practice experience in nursing facilities and geriatric care was surveyed to determine conditional probabilities of therapeutic outcomes attributable to drug therapy. Health care utilization and associated costs derived from negative therapeutic outcomes were estimated.

Results: Baseline estimates indicate that the cost of drug-related morbidity and mortality with the services of consultant pharmacists was $4 billion compared with $7.6 billion without the services of consultant pharmacists.

Conclusions: Drug-related morbidity and mortality in nursing facilities represent a serious economic problem. For every dollar spent on drugs in nursing facilities, $1.33 in health care resources are consumed in the treatment of drug-related problems. With the current federally mandated drug regimen review, it is estimated that consultant pharmacists help to reduce health care resources attributed to drug-related problems in nursing facilities by $3.6 billion.

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MEDICATIONS ARE prescribed to nursing facility residents for the treatment of disease with the intent of achieving an optimal therapeutic outcome. In the past, *optimal therapeutic outcome* has been defined as "the right drug, for the right patient, at the right time."[1] More recently, optimal therapeutic outcome implies the absence of drug-related problems (DRPs).[2] A *DRP* is defined as an event or circumstance involving a patient's drug treatment that actually or potentially interferes with the achievement of an optimal outcome.[2] Eight categories of DRPs have been identified (**Table 1**).[3]

Unresolved and/or unrecognized DRPs may manifest as drug-related morbidity and, if left untreated, may eventually lead to drug-related mortality. Although it is recognized that some drug-related morbidity and mortality is due to patient peculiarity and is therefore unavoidable, there is considerable evidence that a large proportion of drug-related morbidity is preventable.[2-7]

Preventable drug-related morbidity within nursing facilities may be the result of a number of factors, including inappropriate prescribing by the physician or inappropriate monitoring by the pharmacist.[2] Viewing the cause of drug-related morbidity and mortality within this context, Manasse[5,6] suggests that it be considered a "disease" whose clinical, epidemiological, and economic impact should be measured. Thus, drug-related morbidity and mortality within nursing facilities can be assessed using cost-of-illness methods, providing a baseline measurement against which new interventions may be evaluated.[8]

physician visits. The direct cost of drug-related morbidity and mortality within nursing facilities, both with and without the services of a consultant pharmacist, was estimated by multiplying the number of health services used as a result of negative therapeutic outcomes by the estimated unit cost of each service. All calculations were based on 41 million nursing facility physician encounters, which conservatively assumes 2 initial physician encounters per month for each of the 1.7 million nursing facility residents. This estimate was based on consultations with clinical faculty, consultant pharmacists, and physicians practicing in nursing facilities.

COST DEFINITIONS

The rising cost, frequency, and duration of nursing facility care is a major concern to third-party payers of health care. Therefore, the perspective taken in the study was that of a third-party payer and every attempt was made to obtain values reflecting this perspective. Monetary values were identified from previous published reports and available statistical reports (**Table 2**). A value of $27.01 was used as the average prescription cost.[19] The cost of both an initial and subsequent nursing facility physician visit was conservatively estimated at $61.00. This value represents the national average allowed by Medicare for reimbursement to physicians.[20] The cost of an ED visit was taken from a review of recent articles reporting an average cost of ED visit of $360.00.[11,21-23] The cost of a hospital admission ($5415.00) was estimated from the American Hospital Association's 1992 hospital statistics,[24] multiplying the average length of stay by the adjusted total expense per inpatient day and adjusted for inflation to 1995 dollars. Additionally, this method of calculation has been used in previous estimations of the cost of drug-related hospital admissions.[11,25] The average cost of an allied health care professional visit (eg, dietitian, physical therapist) was estimated as $75.00 based on a survey of local charges. For the purposes of this research, the average cost of a consultant pharmacist's services was based on a fee of $10.00 per health care encounter. It should be noted that consultant pharmacists are not reimbursed per patient encounter. However, failure to include some economic value of pharmacist services assumes that no cost is associated with such services, thus biasing our total cost estimates. The average cost per laboratory and radiology procedure ($100.00) was also estimated using the 1995 HealthCare Consultants' *Physicians' Fee Guide*.[26] For estimating the costs associated with the outcome of death, it was assumed that deaths were preceded by a hospital admission.[11,22] The indirect costs of lost productivity or intangible costs were not included in this analysis because of the perspective taken and the average age of the population.

The ultimate outcome or resolution of drug-related morbidity and mortality may require a series of health care encounters. Thus, the costs associated with the final pathway must reflect all previous health care encounters. For example, additional prescription therapy would imply a preceding prescriber contact. As such, the cost of managing a treatment failure due to a DRP may include the cost of an initial physician visit, an initial prescription for the offending drug, and then a revisit by the physician (which may or may not lead to an additional prescription, an ED visit, or a laboratory or radiology procedure). Alternatively, a new medical problem may require hospitalization for management, which includes not only the cost of the hospital stay but also the initial physician visit and prescription along with a revisit by the physician and an ED visit.

STATISTICAL ANALYSIS

Descriptive statistics were calculated for all items with the results used in estimating the probabilities associated with the various points of the pathway probability model. The Student *t* test was used to test for differences across probability estimates between the 2 groups of panel experts (consultant pharmacists and physicians). Panel responses were tabulated and statistical analyses performed using computer software (Microsoft EXCEL, version 7.0, Microsoft Corp, Redmond, Wash).

SENSITIVITY ANALYSES

The cost-of-illness model was evaluated for its sensitivity to key components of the model based on 3 sensitivity analyses. These sensitivity analyses were chosen because of their potential impact on the decision process, and the analyses target the key probability estimates of the decision process. The first 2 sensitivity analyses accounted for possible differences in the distribution of residents among the various outcomes provided by the 2 groups of expert panel members. Specifically, the first 2 sensitivity analyses used the different estimates of outcomes provided by physician and pharmacist panel members. The third sensitivity analysis increased the proportion of physician visits resulting in the initiation of drug therapy to 60%. We believed that this was a reasonable assumption, given the estimates provided by our panel members and information from the medical literature.[11]

cant economic consequences of preventable drug-related morbidity and mortality in nursing facilities. However, given the current emphasis on cost containment within the health care system, it is necessary to justify the economic outlay demanded by such services.

The pharmacy and medical literature is replete with the results of research pertaining to the impact of consultant pharmacists on inappropriate medication use in nursing facilities.[12-18] Although the contribution of these studies is recognized, most have been narrow in scope (ie, measuring only drug costs avoided), failing to consider the range of possible negative outcomes (therapeutic failure, new medical problem, or a combination of the 2) and the range of potential DRPs.[2,3] An analysis of the direct costs of illness associated with drug-related morbidity and mortality in nursing facilities requires that a wide range of possible negative outcomes and potential DRPs be incorporated.

Preventable drug-related morbidity and mortality represent a dire medical problem that urgently requires expert attention.[2] The extent to which negative therapeutic outcomes can be minimized within nursing facilities would then represent the value of that expert attention. This study uses cost-of-illness methods to estimate

Table 2. Cost of Health Care Resource Utilization*

Outcome	Cost, $								
	Health Care Visit	Prescription	Additional Health Care Visit	Additional Prescription	ED Visit	Hospital Admission	Laboratory or Radiology Procedure	Allied Health Care Professional Visit	Total
No additional treatment	61.00	27.01	...	...	...	...	...	...	88.01
Practitioner visit	61.00	27.01	61.00	...	...	...	...	...	149.01
Additional treatment	61.00	27.01	61.00	27.01	...	...	...	...	176.02
ED visit	61.00	27.01	61.00	...	360.00	...	...	...	509.01
Hospital admission	61.00	27.01	61.00	...	360.00	5415.00	...	...	5924.01
Additional laboratory or radiology procedure	61.00	27.01	...	...	...	...	100.00	...	188.01
Death	61.00	27.01	61.00	...	360.00	5415.00	...	...	5924.01
Allied health care professional visit	61.00	27.01	61.00	...	...	...	...	75.00	224.01
Optimal outcome	61.00	27.01	...	...	...	...	...	...	88.01
No drug therapy	61.00	...	...	...	...	...	...	...	61.00

*When calculating the cost of health care resource utilization with the services of consultant pharmacists, a $10 initial consultation fee was assumed and included. ED indicates emergency department; ellipses, no costs were incurred in particular scenario.

to occur in 4% to 7% of cases involving negative therapeutic outcomes. Finally, deaths attributed to negative therapeutic outcomes were estimated to occur in 2% to 4% of nursing facility residents.

COST OF DRUG-RELATED MORBIDITY AND MORTALITY

Using the estimated 41 million annual nursing facility encounters, the baseline estimate of the cost of drug-related morbidity and mortality without the services of consultant pharmacists is $7.6 billion ($3.2 billion, treatment failure; $2.3 billion, new medical problem; and $2.1 billion, both treatment failure and new medical problem) (**Table 6**). With consultant pharmacists providing the federally mandated retrospective review of each nursing facility resident's drug regimen, the estimated cost of drug-related morbidity and mortality is $4 billion ($1.6 billion, treatment failure; $1.3 billion, new medical problem; and $1.1 billion, both treatment failure and new medical problem).

With the services of consultant pharmacists, there will be an estimated 9.6 million optimal therapeutic outcomes compared with 6.7 million without consultant pharmacists. Conversely, with the services of consultant pharmacists, it is estimated that 6.4 million suboptimal outcomes (2.7 million, treatment failure; 2.4 million, new medical problem; and 1.3 million, both treatment failure and new medical problem) occur compared with 9.3 million (4.2 million, treatment failure; 3 million, new medical problem; and 2.1 million, both treatment failure and new medical problem) without the services of consultant pharmacists.

SENSITIVITY ANALYSES

Table 6 provides a comparison of the cost-of-illness estimates derived from the 3 sensitivity analyses, as well as the baseline estimate. The first 2 sensitivity analyses evaluated the sensitivity of the model to possible differences in the outcomes provided by the 2 expert panel groups. As Table 6 depicts, some variation in the cost-of-illness estimates exists between physicians and pharmacists and between physicians' and pharmacists' estimates and baseline. However, all 3 estimates provide similar or identical values for the difference in costs with and without consultant pharmacists ($3.6, $3.4, and $3.6 billion). Based on the outcome estimates provided by physician panel members, the estimated cost of drug-related morbidity and mortality is $3.3 billion ($1.4 billion, treatment failure; $1.2 billion, new medical problem; and $0.7 billion, both treatment failure and new medical problem) with the services of consultant pharmacists. Without consultant pharmacist services in nursing facilities, the estimated cost of drug-related morbidity and mortality is $6.7 billion ($2.8 billion, treatment failure; $2.2 billion, new medical problem; and $1.7 billion, both treatment failure and new medical problem).

Table 3. Expert Panel Demographics

Statistic	Responses, Mean (SD)		
	Pharmacist	Physician	Total
No. of nursing facilities	5.00 (5.44)	1.61 (1.24)	3.42 (4.22)
No. of total nursing facility beds	592.00 (616.67)	215.80 (221.83)	417.30 (495.72)
Years practicing in nursing facility	10.80 (6.17)	9.88 (4.89)	10.38 (5.53)
No. of nursing facility visits per month	1.60 (1.61)	9.78 (8.61)	5.40 (7.45)
Time devoted to nursing facilities, %	56.00 (34.63)	44.62 (39.85)	50.71 (36.49)
Health care encounters resulting in drug therapy initiation, %	45.53 (27.57)	30.38 (10.90)	38.50 (22.22)

ing to the initiation of therapy increases the estimated cost of drug-related morbidity and mortality. Specifically, the estimated cost of drug-related morbidity and mortality is $6 billion ($2.4 billion, treatment failure; $2 billion, new medical problem; and $1.6 billion, both treatment failure and new medical problem) with the services of consultant pharmacists. Without consultant pharmacist services in nursing facilities, the estimated cost of drug-related morbidity and mortality is $11.5 billion ($4.8 billion, treatment failure; $3.5 billion, new medical problem; and $3.2 billion, both treatment failure and new medical problem).

COMMENT

The cost estimates presented in this study of drug-related morbidity and mortality in nursing facilities represent a significant economic outlay of our nation's health care resources. The cost estimates of drug-related morbidity and mortality with the services of consultant pharmacists range from a low of $3.3 billion to a high of $6.0 billion. Without consultant pharmacists' services, cost estimates range from $6.7 billion to $11.5 billion.

The difference between the 2 baseline estimates, $3.6 billion, represents the drug-related morbidity and mortality costs that may be avoided with the services of consultant pharmacists through retrospective drug regimen reviews. This represents a 54% reduction in the cost of drug-related morbidity and mortality within nursing facilities, which is remarkably similar to the impact of pharmaceutical care on the cost of drug-related morbidity and mortality in the ambulatory setting estimated by Johnson and Bootman.[9,11]

To put these costs into perspective, however, the costs of DRPs should be compared with the total expenditure for drug products within long-term care nursing facilities. It is estimated that approximately $3 billion is spent annually for drug therapy in nursing facilities,[9] indicating that the estimated health care cost of drug-related morbidity and mortality exceeds the original outlay for drugs by $1 billion. In other words, for every dollar spent on drugs in nursing facilities, $1.33 is consumed in the treatment of drug-related morbidity and mortality. This ratio is higher than that reported by Johnson and Bootman[9,11] for the ambulatory setting (1:1). This higher ratio can be explained by a number of factors. First, nursing facility residents consume, on average, a greater number of prescription medications, thus increasing the potential for DRPs. Additionally, in contrast to their ambulatory counterparts, nursing facility residents are placed at higher risk of DRPs because of the physiological effects of aging that alter the ability to metabolize certain drug products. Finally, another factor leading to the greater cost of drug-related morbidity and mortality is that once a DRP has occurred in the nursing home patient, there is a greater intensity of care required to treat the DRP. This could be the result of a more severe reaction experienced by the frail elderly or the higher costs of care that occur within the institutional setting.

The results of the 3 sensitivity analyses demonstrated that the cost-of-illness estimates were relatively insensitive to variations in the estimates of the distribution of residents among the various outcomes used in this research. Estimates provided by physicians and pharmacists varied little from each other as well as from the overall estimate. However, variations in the number of physician visits resulting in the initiation of drug therapy had a significant impact on the cost-of-illness estimate as well as the number of optimal therapeutic outcomes attained. A modest increase in the proportion of visits resulting in drug therapy brought about a 50% increase in the cost-of-illness estimate. Finally, because the scope of this research was broad, the costs estimated are significantly higher than those in previous reports.[17,18]

There are significant limitations and assumptions involved in this research. Most importantly, this research is limited by the lack of empirical data concerning the clinical outcomes associated with drug therapy in the nursing facility setting. These data are essential in determining the true health care cost of DRPs in nursing facilities. Additional research is needed to provide these data. However, the use of clinical experts to gather data is considered acceptable.[24,25] Overall, the impact of this possible limitation is reduced because of the following: when the probabilities of negative therapeutic outcomes and DRPs were compared between groups of panel members (physicians and pharmacists), the responses were very consistent and no significant differences were detected; and the expert panel did not provide responses biased toward the consultant pharmacist alternative since the probabilities derived from the expert panel demonstrated only a modest effect for consultant pharmacists on the proportion of optimal therapeutic outcomes attained.

Additional limitations are that the model used to assess the 2 alternatives was conceptual and the probabilities attached to the outcomes as well as costs were estimations. Therefore, the results of this research represent estimations of the true costs of drug-related morbidity and mortality. However, the estimates were provided by a panel of experienced practitioners, including both pharmacists and physicians, with diverse backgrounds practicing throughout the country.

In conclusion, this research represents a significant advancement in the economic analysis of the cost of drug-related morbidity and mortality in nursing facilities and the impact of consultant pharmacists in reducing these costs. Previous attempts to evaluate the health-care cost of DRPs have been narrow in scope (ie, measuring only the drug costs avoided), failing to consider the range of possible negative outcomes (therapeutic failure, new medical problem, or a combination of the 2) and potential DRPs. This research represents an improvement over previous research endeavors in that it simultaneously incorporates clinical and economic effects of drug therapy in the nursing facility setting.

The serious nature of the provision of drug therapy in nursing facilities is highlighted by the results of this analysis. Under the current federally mandated drug regimen review, the cost of drug-related morbidity and mor-

OUTCOMES BASED THERAPEUTIC INTERCHANGE: AN ACE INHIBITOR INTERCHANGE PROGRAM

Dana Saffel
Richard A. Marasco
Sonya Sengson

Objective: To evaluate the impact of a consultant pharmacist therapeutic intervention program for ACE inhibitors on both patient outcomes and market share of preferred product.
Design: Data was collected retrospectively and included measurements prior to and following the therapeutic interchange.
Setting and Participants: Patients taking an ACE inhibitor who resided in long-term care facilities in Georgia that were consulted to by the staff of United Pharmacy Services.
Main Outcome Measures: Blood pressures were recorded at one week intervals for three weeks prior to and following conversions. Additionally, physician-recorded symptoms of CHF were recorded during one month post conversion. Percent market share of ACE inhibitors was measured prior to conversion and one month post conversion.
Results: Of the 131 patients included in the retrospective review, none of the patients had to stop therapy as a result of a change in clinical status. No patient in the data sampling had any symptoms of CHF documented during the month before or the month after conversion to quinapril. The mean blood pressure recordings did not change after conversion. Market share of the preferred ACE inhibitor, quinapril increased from 3% to 44% during the conversion period.
Conclusions: Pharmacist-driven voluntary therapeutic interchange of ACE inhibitors resulted in significant change in market share of preferred agent without noticeable change in blood pressure or symptoms of CHF in the residents of selected long-term care facilities.
Abbreviations: ACE = angiotensin-converting enzyme; CHF = congestive heart failure.
Consult Pharm 1999;14:65–71.

Two of the primary considerations in the selection of medications for patients are patient response (or outcome) and cost. These reasons are the driving forces behind many programs being developed to monitor and evaluate the outcomes of patient care interventions, especially those outcomes directly resulting from pharmacist interventions.[1] The long-term care environment, which focuses on cost-containment, places pharmacists in an ideal position to lead the health care team in both the selection and monitoring of the optimal medication for individual patients on the basis of their specific medical conditions.[2]

In the past, the availability (or non-availability) of a medication on a pre-determined formulary was usually the only strategy implemented to manage drug costs.[3] However, the management of drug costs in this manner provided only a limited degree of total cost control. When the primary focus is on product and distribution costs (with no consideration for costs associated with therapeutic failure and adverse events) any formulary will achieve only limited success (Figure 1). The focus of pharmaceutical care must be the management of appropriate utilization and the avoidance or reduction of therapeutic failures and adverse reactions. Traditional formularies also have failed to consider patient outcomes from therapy as part of the formulary (drug selection) process.[3] Consequently, fiscal savings in the pharmacy budget may likely be spent twofold or threefold in other departmental budgets.[4]

Preferred Medication Lists

In order to improve patient outcomes, many organizations, including United Pharmacy Services, Inc. (UPS), are changing from the rigidity of traditional formulary systems to a list of "preferred medications." Under this classification system, medications are identified as being preferred, acceptable, or unacceptable to the primary medication selected. This system is similar to a traditional formulary, as there is still a primary agent desired for utilization; however, the preferred agent's selection is not based on cost alone. Several clinical and economic factors

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Acknowledgment: The following article represents a therapeutic interchange program and preferred agent selection that was performed in the absence of pharmaceutical manufacturer sponsorship. The authors thank the following staff of United Pharmacy Services, Inc., who contributed to this article: Derek Osborne, RPh; Chris Bryson, RPh; Donna Ferrell, RPh; Marvinna Gabby, RPh; Cara Lee, PharmD; Cliff Walker, PharmD; and Sherry Williams, PharmD.

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Assessment Committee (QAAC). At that time the medical director and consultant pharmacist discussed any concerns and clarified questions about implementation. The list was then sent to attending physicians for their approval and signature. By signing the preferred agent list, each physician established a collaborative protocol agreement with the pharmacy care team so that the dispensing pharmacist can change the original order to the preferred agent. The pharmacist would then have the responsibility, acting as the agent of the physician, to notify the nursing facility staff of the interchange so that all records would be updated. This notification is through a verbal order form, which is also sent to the physician's office to be signed. In addition, monitoring parameters are also determined and procedures are implemented so that both the physician and consultant pharmacist are notified immediately if the monitored criteria fall outside the pre-determined parameters.

ACE Inhibitor Selection

Quinapril was selected as the preferred ACE inhibitor because no ACE inhibitor demonstrated a significant clinical advantage over the others and there was a significant cost savings derived from economy-of-scale buying incentives with this drug. The need for a preferred ACE inhibitor was initially determined by a desire to reduce the variety of agents being used (Figure 2) and the belief that this would increase the nurses' familiarity with medications, because there would be a fewer number of agents in this class. Another significant factor was the once-a-day dose schedule, which would reduce the total number of medication doses administered on a daily basis compared with the older ACE inhibitors dosed two or more times per day. By converting patients to quinapril, we anticipated that they would receive the same therapeutic response and clinical outcome as with their previous ACE inhibitor,[14] the nursing staff would have to administer fewer doses each day, and the pharmacy would have a lower investment in inventory. A table of equivalent ACE inhibitor conversions was developed for converting patients to quinapril (Table 4). The doses were based on initial dose recommendations adapted from *Facts and Comparisons* and the pharmacist's clinical experience and judgment.

Benchmarking and Program Implementation

Prior to the selection of quinapril as the preferred ACE inhibitor, the utilization of ACE inhibitors was examined (Figure 2) to establish a benchmark. This examination revealed that three agents accounted for 79% of the ACE inhibitor use, with enalapril accounting for the highest use at 35%. However, on further examination it was determined that 31% of the ordered ACE inhibitors were dosed multiple times a day. This was an important factor in our selection criteria. The reduction of doses may reduce nursing medication administration time in general and, in some cases, may eliminate entire medication passes for individual patients. This theoretical timesaving would be an important factor in obtaining nursing staff support for this conversion program. If successful, it would allow them to invest their time in other patient care activities, rather than simply administering medications to patients.

In April 1996, three UPS consultant pharmacists began requesting that physicians convert patients to once-a-day quinapril therapy in four long-term care facilities. This was done as a pilot program to obtain sample physician responses and to assess the overall comfort and acceptance of the conversion. During the pilot program, 79 recommendations were made to switch from the current ACE inhibitor to quinapril, of which 58 were accepted (73.4%). Of the 21 recommendations not accepted by physicians, 10 were refused without reason, nine expressed concern over change in disease control, and two were patients who were receiving high-dose enalapril therapy (40 mg/day) and the physician did not feel comfortable with the conversion.

However, since these facilities were selected because of good physician–pharmacist relationships and a higher-than-average physician acceptance rate in general, it was thought that a more modest overall conversion rate of approximately 60%–70% should be expected when the program was implemented on a larger scale. In July and August 1996, all UPS consultant pharmacists

basis of ease of access to retrospective data in the medical records. Data were collected for 131 patients, on the basis of convenience. This represented 16% of patients who were converted to quinapril. Thirteen of the 823 patients receiving an ACE inhibitor were receiving quinapril at start of the conversion, leaving 810 patients with the opportunity for the conversion.

Prior to being converted to quinapril, the 131 patients sampled had a mean length of ACE inhibitor therapy of 14.3 months. The range of treatment length extended from less than one month to 54 months at the pre-conversion dose and dose schedule. When converted, the mean starting dose of quinapril was 12.5 mg (range, 2.5–40 mg), with all doses being administered once a day; 40 (30.5%) were receiving ACE inhibitor therapy two or three times per day prior to conversion. One patient was receiving lisinopril on a twice-a-day schedule, and quinapril was initiated at an equivalent dose to lisinopril and at a twice-a-day schedule.

None of the 131 patients had to stop therapy as a result of a change in clinical status. No patient in the data sampling had any symptoms of CHF documented during the month before or the month following the conversion to quinapril. The mean blood pressure recordings, which were primarily collected by certified nursing assistants, also did not change after the conversion. The mean systolic pressure, for the sample of 131 patients, was 131.2 mmHG at three weeks before and 130.9 mmHG three weeks after the change. The mean diastolic blood pressure was 73.1 mmHG three weeks before and 72.7 mmHg three weeks after the change.

Discussion

This was one of the first outcomes projects conducted by UPS in which all consultant pharmacists were included in the intervention and data collection. As a result, one limitation in the process was that all consultant pharmacists were not proceeding at the same rate and at the same time. Each consultant implemented the conversion over a period of several months. While this allowed each one to reach a comfort level before aggressively proceeding, it increased the difficulties associated with retrospective data collection and record availability. Another limitation involved the actual data collection. Because the facility staffs were not actively participating in data collection, they did not strive to assure that records were complete and available. Also by collecting the data several months after the conversion, questionable or missing data could not be re-collected. Missing information was the primary reason that only a sampling of patients were selected for data analysis. The blood pressure readings used for calculating the mean values were those recorded on the

TABLE 3. ACE Inhibitor Conversion Guidelines

ACE Inhibitor	ACE Ratio	Other ACE Dosage Equivalent to 10mg of Quinapril*
Ramipril: quinapril	1:4	2.5 mg ramipril
Captopril: quinapril	5:1	50 mg captopril
Benazepril: quinapril	1:1	10 mg benazepril
Fosinopril: quinapril	1:1	10 mg fosinopril
Moexipril: quinapril	1:1.5	7.5 mg moexipril
Enalapril: quinapril	1:2	5 mg enalapril
Lisinopril: quinapril	1:1	10 mg lisinopril

Adapted from Facts and Comparisons: Angiotensin-Converting Enzyme Inhibitors, Initial Dose Recommendations.
*When appropriate, rounded to nearest available dosage strength.

TABLE 4. Indications for Use of ACE Inhibitor for Study Group of Patients

Indication for Use	No. of Patients (n=131)	% of Patients
Congestive heart failure	18	14
Hypertension	75	57
Hypertension and congestive heart failure	38	29

program is the key to a successful program. Clear and frequent communication between pharmacists and physicians, nurses, and the direct care staff, as well as an organized and well-planned process, is essential for a successful program.

While some physicians may object to programs such as this because of concern over prescribing authority or patient differences that they believe pharmacists may not be able to determine,[24] our experience is that this is not the case. Through this program of voluntary interchange of ACE inhibitors, pharmacists were able to determine therapeutic equivalence and manage the implementation of a conversion program in a clinical setting. Although patients in the data sampling did not have changes in blood pressure based on MAR recordings, physician-identified CHF symptoms, or ACE inhibitor dose adjustments within the first three weeks after the conversion, the program cannot assess whether the clinical outcomes observed were associated with the conversion. Further research will be needed to assess the impact of this program on clinical and economic outcomes.

While the future of long-term care pharmacy may significantly change under a prospective payment system, managed care, or any reimbursement model, the role of the pharmacist to assure the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life will not change. This is how the consultant pharmacist of the next millennium will survive—by implementing programs and treatment strategies that assure both clinical effectiveness and cost efficiency to both the patients and the payers.

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Special Report

The Pharmacy Benefit in the Year 2001: Experts See Problems and Discuss Solutions

Robert McCarthy, PhD, Valerie Ottarsh, MPH, CSW

The millennium has come and gone. We've had a presidential election and we've had the Supreme Court "legitimize" the appointment of a president. Now for the issues that hit home: Will there be a Medicare drug benefit? Will anything be done to abate the ever-increasing pharmacy spend? Is Big Pharma superseding the HMO in the "Big Book of Consumer Demonology"? These and other issues are weighed and considered by our panel of expert prognosticators. Here now are their predictions of things to watch—and to watch out for—during the coming year.

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More Tiers, More Therapeutic Substitution, More Red Ink?

I'm afraid I see a continuing trend of premium increases at managed care organizations. At the same time—and I'm sure payers aren't going to be happy to hear this—too many MCOs are operating in the red and cannot continue to do so for very long.

It's a question of survival. MCOs in the red that have to increase premiums are being confronted by MCOs in the black that see an opportunity to low-ball premiums. While the object of those in the black is plain old economic piracy, the effect may be deleterious across the industry. Obviously, those MCOs in the red will be in worse shape if they lose members and clients—but those currently in the black who play that game may find themselves squeezed between higher medical costs and lower revenues.

We're also seeing some pharmacy-risk arrangements being removed from physician-provider contracts. Physician groups are increasingly unwilling to go at-risk for pharmacy cost and utilization. This means risk travels upstream to the managed care organizations, whose pharmacy spend then goes up. We're already looking, as we did last year, at a pharmacy benefit cost increase of between 15% and 18%.

There will be an increasing pullback of managed care from Medicare and Medicaid products. Plans have been burnt; the reimbursements have been inadequate. Plans staying in those businesses will be increasingly conscious of the cost of pharmaceuticals. Here's a hint to the pharmaceutical companies: when introducing new products or when repricing old ones, please consider lower average wholesale prices (AWPs)—especially if your drug is in a crowded therapeutic class. Lower AWPs may be what it takes to get your drug prescribed.

Speaking of pharmaceutical companies, I look for more in the way of mergers and acquisitions. For us in the MCO business, such mergers are often equal to less competitive pharmaceutical pricing. I also am looking for more in the way of state-mandated coverage—for infertility, diabetes disease management, and so forth.

In addition, I expect drug companies to increase their spending on outcomes studies and pharmacoeconomics. In order to sell into a crowded therapeutic class, increase share, and increase profits, the pharmaceutical companies will have to supply data.

We're going to see more MCOs going to "legal" therapeutic substitution; that is, increased efforts to drive utilization toward specific drug class members in an effort to save dollars, whether via rebates or lower AWPs. Look for a lot more switching and a lot more working with physicians to prescribe the preferred product than ever before.

We'll see a fourth tier in formularies. There will be deductibles before you even get to the copays. You'll see bigger percentage deductions from AWP and more drugs not covered. If the plan member wants noncovered drugs, he or she must pay the entire cost. There'll be more NDC lockouts with drugs not covered. It's touchy, it gets to member satisfaction—but the big, big imperative is controlling the pharmacy spend.

There will be some very good, but very expensive, new biotech products. I think managed care organizations will

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ing will intensify during the next 12 months—especially in the face of likely political gridlock in Washington. Several states have tried to take some action on pricing—particularly, the border states, both north and south. What Maine, for instance, has been trying to do, while understandable from a political perspective, is unlikely to be successful enough to provide anybody any benefit; practical impact is extremely low. (See Legal Matters, page 17)

On the federal front, Congress has already passed the Medicine Equity and Drug Safety Act that authorizes the reimportation and resale of exported pharmaceuticals; however, the regulations needed to support it will probably take at least 2 years to write and implement. And I would surmise those regulations will be written in such a way as to prevent what the pharmaceutical industry would describe as the "worst excesses" of parallel trade into the United States.

From a practical point of view, I don't see any conceivable state or federal action posing any real threat to business as usual for the pharmaceutical industry. The new Congress won't change that, and given how politically wounded the new president will be, real radical change is implausible.

With regard to the pharmacy benefit, the continued thrust from managed care organizations will center on trying to control pharmacy costs by means of a multitier formulary strategy. Already 30% to 35% of managed care lives have a multitier formulary in place, and by next year, those figures will be well over 50%. I think we'll also see copay amounts increasing, with copay differentials increasing across the tiers in addition to the more expected increased differential between brand and generic copays. I'm not sure any of those strategies have had much impact on the pharmaceutical industry; they've impacted the consumer, who has so far opted to absorb the increased costs.

We'll also see some targeted action centered on particular therapeutic areas. The proton pump inhibitor (PPI) class will definitely see some cost-control action. With *Prilosec* going off patent, we can expect to see a major battle around MCOs struggling to switch patients to a generic version and AstraZeneca looking to switch those patients to its PPI. In fact, the MCO strategy now is to switch PPI patients to *Prilosec*, take a hit in the short term, and when *Prilosec* goes off patent, to drive those *Prilosec* patients over to the generic version.

Another possible battleground involves COX-2s. Pharmacia and Pfizer will be releasing their follow-up COX-2 product in 2002, which they think will be very big. But I think the managed care view is that there is a lot of inappropriate use of these agents. There are patients and conditions for which NSAIDs and even OTCs would do the job just as well and for far less cost.

With regard to the pharmacy spend, most of what the pharmaceutical companies say is true; it's mostly being driven by utilization, not pricing. The industry has told the truth on that issue, which is an important stake to put in the ground. But if you look from the payers' point of view, pharmacy costs have been increasing by 15% to 18% for several years now—and no one thinks that's going to change anytime soon. Some payers are about to reach a critical-mass moment: when their drug costs actually surpass their inpatient costs. That's going to be an important psychological milestone; it's going to concentrate minds. Will it concentrate them enough to enable MCOs to go to employers and say, look, let's really do something? That's another matter.

And yet I would think that pharmacy costs increasing at 15% to 18% per annum is simply not sustainable. What ultimately might result is employers throwing up their hands and getting out of the health care benefit business. But I don't see that happening in the short-term and, in the meantime, other things might occur to change the equation.

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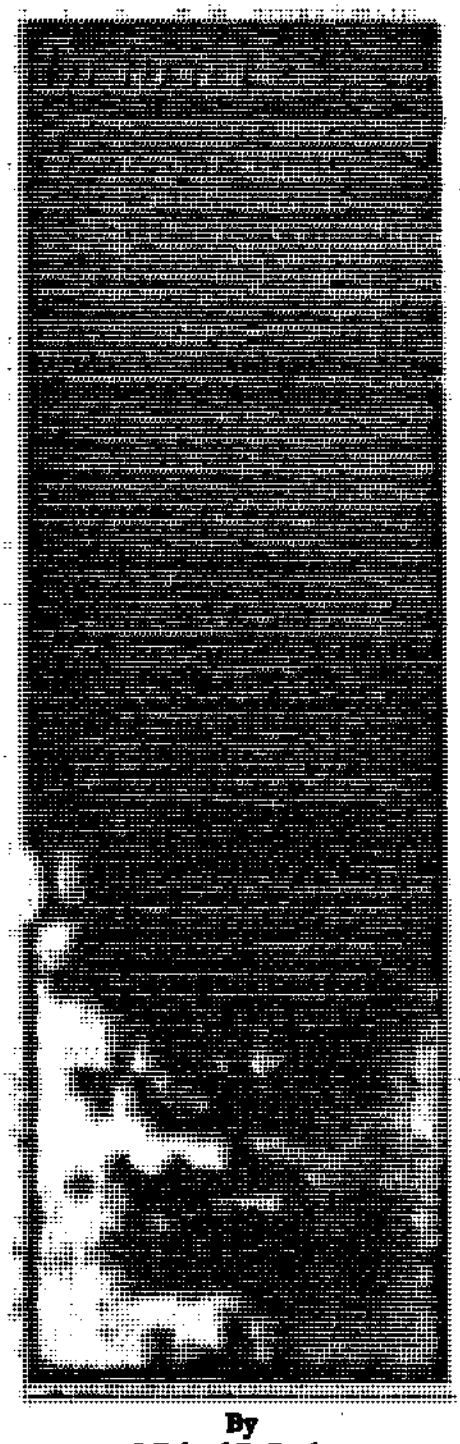
Injectables Get the Pharmacy Benefit Treatment

Bad press for pharmaceutical manufacturers is likely to remain because of the increasingly prevalent perception that prices are too high. The response from manufacturers has to be a demonstration of value: the price may be high, but look at what we're able to treat and to cure that wasn't treatable or curable just a short time ago. This message has to get to consumers. Consumers, not managed care or federal and state governments, are the ones now screaming the loudest about the price of medicines. I suspect we'll see some sort of direct-to-consumer messages concerning the value of particular drug products.

I also think the big push on the payer side will be how to implement the reimportation legislation. I think there will be more focus on reimportation as a strategy to help control the pharmacy spend, but there has to be an assessment of how, and whether, this legislation can be implemented. That's going to take a lot of time and energy.

As for a Medicare drug benefit, I believe we'll see something—regardless of who the president is. Something will

Nursing home ADEs: Largely preventable



By
Michael F. Conlan

There are about 20,000 fatal or life-threatening adverse drug events among the 350,000 ADEs that take place at the nation's nursing homes annually, according to a research team that called its estimates "likely to be conservative." The researchers said half of all the ADEs are preventable, including 80% of the most serious ones.

They based their conclusions on a study of 2,916 residents of 18 Massachusetts nursing homes. About three-fourths of residents were women; the

in 17,000 U.S. nursing homes. An average resident uses six different medications, and 20% take 10 or more.

R. Tim Webster, executive director of the American Society of Consultant Pharmacists (ASCP), called the study "valuable" and said that it "supports our assertion that adverse drug events and other medication-related problems are a significant national health policy issue. It's especially acute for the elderly, wherever they reside."

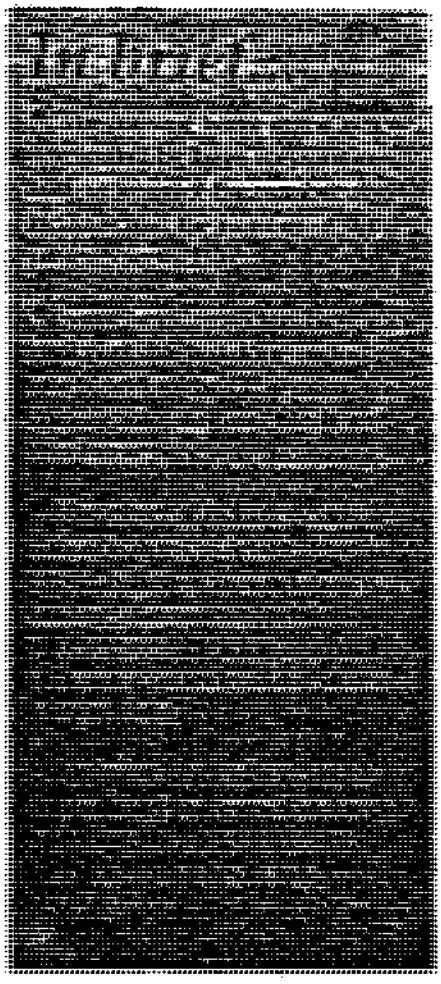
Webster called for research into medication problems associated with the growing number of seniors residing in assisted-living facilities. "Given the fact that nursing home residents are closely monitored and that well-established medication-use systems are in place in nursing facilities, it stands to reason that the scope of the problem among seniors in assisted-living and ambulatory populations is significantly higher," he told *Drug Topics for Consultant Pharmacists*.

The Massachusetts study findings were reported in the Aug. 1 issue of the *American Journal of Medicine*. The re-

Amy C. Edmondson, Ph.D.; and David W. Bates, M.D., of Harvard University.

"This study points out that it's not just a small list of so-called bad drugs in the elderly that we need to be concerned about. It's the whole range of drugs," Gurwitz said. "However, we have identified some drug categories that appear to cause more problems than others. We're not saying people shouldn't be on these drugs. We're saying that sometimes providers are not

Corporatization: Is it good for consultant pharmacy?



By
Joseph Breu
Based in Chicago, the author writes frequently on pharmacy-related issues.

Where once there used to be a lot of mom and pop consultant pharmacists, today corporatization through consolidation is the order of the day. It's a "fait accompli," in the words of R. Tim Webster, Sc.D., executive director of the American Society of Consultant Pharmacists (ASCP). The question is, What impact is it having on pharmacists and on nursing homes and patient care?

The answer varies depending on who is asked. Some will say it has cost some pharmacists their jobs and increased the pressure on consulting pharmacists to do more with less. Others claim there are several benefits, such as the greater information resources that the large companies can provide and some of the initiatives that they undertake.

And while a lot of small companies have been gobbled up by the large concerns, other small and medium-sized pharmacies are finding a niche and gaining business by responding to local conditions and offering some of the services that the big companies do not.

"There are quite a number of smaller, independently owned local or regional pharmacies that are getting their footing in the market, and they are growing quickly because of their entrepreneurial drive. And that's true not only with regard to nursing homes but in assisted living and in the ambulatory elderly market as well," noted Webster. Nonetheless, he added, it is true that the nursing home segment of the industry is now dominated by large, publicly held corporations, both in terms of the number of facilities and the number of patients served.

"Consolidation is a fact; it's extant; it exists today," Webster said. And it is having effects on consultant pharmacists and on the way they practice, say observers.

"One of the big impacts that I have seen from consolidation is stress on staff," observed Lynn Williams, R.Ph., v.p. of Learning Solutions in Boulder, Colo., a firm that provides educational services to pharmacists and other health-care personnel in long-term care (LTC).

"Staff is being asked to do more with less because the financial resources for pharmacy have been decreased," she said. "It takes a lot of financial resources for those companies to buy out pharmacies and the LTC facilities, and a number of them have gone bankrupt because they've gotten themselves into too much debt just when reimbursement from Medicare has decreased."

One of the reasons for that, according to Webster, was the implementation in 1998 of a prospective payment system (PPS) for nursing home care provided under Medicare. "When payment for drugs is wrapped in an all-inclusive per diem that's paid to the nursing facility, that focuses people's attention on managing the cost of that service component so the facility can live within the constraints of the finite per diem payment," he said. "That has led pharmacists to focus more on cost-containment rather than optimizing drug therapy."

One who believes that the companies and nursing homes should have foreseen the challenges of PPS is Gene Memoli Jr., R.Ph., v.p. of pharmaceutical care for The Medicine Center Pharmacies, a group of independent pharmacies in New England. "The large companies were not prepared properly for PPS," Memoli said. "They knew it was coming and they were generating huge profits before PPS, but they didn't put anything aside for it. So when it hit, they got hit financially. Now, they look at everything from a cost perspective. They're cutting their staffs and consolidating their pharmacies, in turn increasing the workloads of the consultant pharmacists."

Memoli is also critical of the large

Wanted: Consultants in geriatric health care

Consultant pharmacists are in demand. A shortage of geriatricians, the physicians who specialize in treating elderly patients, has led to a need for other health professionals with expertise in geriatrics.

"There is a shortage [of geriatricians], and it's severe," confirmed Kathleen DiGangi of the American Geriatrics Society's Foundation for Health in Aging. Currently, there are about 9,500 certified geriatricians in the United States, and that's less than half the number necessary to meet the needs of the elderly population.

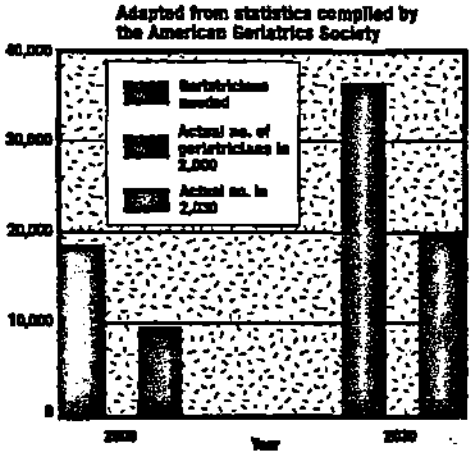
"There's going to be an unprecedented need for pharmacists with knowledge of [geriatric pharmacy]," said Jon Bernhoft, R.Ph., a consultant pharmacist and owner of Sequim Plaza Pharmacy in Sequim, Wash.

According to Tom Clark, R.Ph., M.H.S., director of professional affairs at the American Society of Consultant Pharmacists (ASCP), older adults have a decreased ability to metabolize and excrete drugs. Liver and kidney functions are often impaired, and altered protein binding and volume of distribution (becoming more hydrophyllic) may also occur. All of these changes can lead to increased susceptibility to drug interactions and adverse reactions. He explained that pharmacists fresh out of school, as well as established pharmacists looking for a career change, will most likely need additional training before entering consultant pharmacy.

Excellent communication skills, problem-solving skills, and knowledge of geriatric pharmacotherapy are essential for any consultant pharmacist, said Clark. Being able to communicate effectively is especially critical, he noted, because geriatrics is a highly interdisciplinary field. "It really takes a team of people to get [the elderly] the care that they need," he said. Consultant pharmacists "have to be able to present issues and problems in a nonthreatening way. Most of our members have generally developed pretty good relationships with physicians."

Bernhoft, who provides chart-review and drug-regimen review services to local long-term care facilities, agreed. He estimated that 80% to 90% of the physicians he consults with appreciate his help.

While knowledge of geriatric pharmacotherapy is essential for consultants, there are other issues they need to be familiar with as well. Clark pointed out that there are numerous regulations pharmacists should understand. These regulations vary from state to state and by type of facility.



A relatively recent development is the Minimum Data Set, or MDS, a comprehensive assessment instrument that has been in use for about 10 years. The MDS "has become increasingly more important," said Bernhoft.

The MDS is a tool upon which reimbursement is based, and an inaccurate MDS can result in Medicare fraud, Clark cautioned. As if all that weren't enough, he said, independent consultant pharmacists have to become proficient in marketing, contracts, pricing, and time management. Fortunately, there are several good references available, and many can be obtained through ASCP. The organization also offers an on-line review course to prepare for the Commission for Certification in Geriatric Pharmacy's certification exam. Pharmacists who pass the exam may use the title Certified Geriatric Pharmacist or C.G.P. Clark said there are now more than 500 pharmacists who have qualified for certification.

ASCP has developed several traineeships for consultants seeking further education in specific areas. These include wound care, Alzheimer's/dementia, Parkinson's disease, and psychiatric and behavioral disorders. The traineeships allow a small number of pharmacists to receive five days of intensive training at selected medical centers. While all of these educational programs are extremely valuable, Clark said, "the best way for someone to learn [how to consult] is to hook up with someone who's doing it." He recommended spending six to 12 months shadowing an established consultant.

Susan Klem, B.S., C.G.P., regional clinical director, Great Lakes and Great Plains Region, for Omnicare, echoed Clark's views. She added that some universities also have geriatric certification programs, including one that Omnicare helped create at Ferris State University in Big Rapids, Mich.

Klem believes some physicians are satisfied if patients are stable, and they may be reluctant to make therapy changes purely for improved quality of life. This age bias, which implies older adults stop living after a certain age, is unfounded, she said. "We have people getting married at 100 years old."

By
Jillene Magill-Lewis, R.Ph.
Based in Washington State, the author writes frequently on health-related subjects.

Studies: Crisis Looms in Long-Term Care

As more Americans grow older, the rate of increase for acute care services, primarily hospital care and physicians' services, will drop. At the same time, however, expenditures for long-term care will increase sharply, according to a recent study.

The study and other recent research into the issue of long-term care shows that America is heading for a crisis as the population ages. Providing health care for older Americans will become more costly and the burden will fall on all health care providers and public policy experts to develop solutions to the problem, experts say.

Americans who are 50 years and older are responsible for about 58% of all health care spending, 61% of all over-the-counter drug spending, and 74% of all prescription drug expenditures, says Ken Dychtwald, the president and CEO of AGE Wave LLC, a company in Emeryville, Calif., that advises corporations on age-related trends, and the author of *Age Power, How The 21st Century Will Be Ruled By The New Old*, (J. P. Tarcher Inc., Los Angeles, 1999).

What's more, baby boomers are demanding consumers. They will present in pharmacies and physician offices with heart disease, orthopedic impairments, diabetes, digestive disorders, and adult cancer, among other conditions, Dychtwald says. He believes the health care system is ill prepared to deal with the coming onslaught. Out of the 126 medical schools in the United States, only three have departments of geriatrics, and less than 2% of physicians graduating this year have taken a rotation in geriatric care, he says.

Among all Americans, 13% are currently over the age of 65. Within 30 years, 20% will be over age 65, according to population projections from the U.S. Census Bureau.

Health care for those in the last two years of life is particularly costly, according to a study, "Longevity Has Implications for Health Care Financing," published in *The New England Journal of Medicine*, May 11. Authors Brenda C. Spillman of the Urban Institute, in Washington, D.C., and James Lubitz of the federal Health Care Financing Administration (HCFA), in Washington, D.C., used data from Medicare and national surveys to estimate expenditures on health care according to age at death.

Spending increases with the age at death because of steep increases in nursing home care, and the costs of long-term care at the end of life are less likely to be covered by Medicare or private insurance than are the costs of acute care, Spillman and Lubitz report. The total expenditure for all health care services from age 65 until death is $164,505, in 1996 dollars, they say. Total spending from age 65 until death rises substantially with longevity, from $31,181 for people who die at 65 to more than $200,000 for those who die at age 90 or older.

"Our simulations show that increased longevity after the age of 65 may have a small effect on expenditures for acute care, if present trends continue, but will have a larger effect on expenditures for long-term care and, consequently, on total health care spending for the elderly," says Spillman.

The patterns identified in the study could result in a greater financial burden for elderly people and their families as well as for Medicaid programs as the population ages, says Judith Feder, dean of policy studies at Georgetown University in Washington, D.C.

The fact that nearly a third of long-term care costs are paid out of pocket by patients "reflects the absence of an insurance system, public or private, that spreads the financial risk of needing long-term care," Feder says. "In its place is a system that protects people only if they are impoverished." The average annual cost of nursing home care is more than $40,000, resulting in a substantial financial burden for people who need to purchase such care," she says.

Feder and others believe the financial dilemma implied in these figures should be addressed through a series of public policy initiatives, including increased public support of the financing of long-term care. "I don't believe these issues can be addressed through private long-term care insurance," she says, "because the people who need financial protection the most often cannot afford or even subscribe to this type of insurance."

"Long-term care matters to many Americans of all ages and affects spending by public programs. Legislative support is needed to enhance public financing of this service."

—Judith Feder, Georgetown University

Many financial planners believe that Americans should save money during their working years to pay for long-term care if needed. But Feder counters that the purpose of insurance is to pay for expensive and unpredictable costs. "That's what long-term care is, and that's why this is a public policy issue," she says.

Many seniors needing long-term care today do not have the money to pay for it, a public policy dilemma that could have catastrophic implications for millions of Americans as our society ages, says Feder.

(Continued on page 14)

D.C., and Marlene Niefeld, a research associate at the institute, describe an "imperative change (in public support for long-term care) to assure adequate services at an acceptable cost." Their findings also were published in *Health Affairs*, May 1.

Using public money to supplement private insurance is not the answer, says Feder. "Realistically, subsidizing private insurance just helps those people who are already capable of helping themselves," she says. "It would be better to use that money to provide care to people who need help the most."

Long-term care should be financed in the same manner as acute care, relying on insurance to spread risk, she says. Although 39% of people age 65 and over will need some nursing home care before they die, almost half will require less than a year of care, while about a fifth will require five years or more. "Public discussion all too often assumes that a need for long-term care is an inevitable part of aging and that saving is therefore the right strategy to address it," says Feder. "With costs so varied and unpredictable, savings will be inadequate and inefficient. Insurance makes more sense."

—Reported and written by Marian Sipkoff, in Gettysburg, Pa.

Experts Offer Ideas for Public Financing of LTC

Expanded public financing of long-term care would entail a major shift in how the costs of LTC would be shared by society, says David Kennell, a researcher with Lewin-VHI Inc., a health care research organization in Fairfax, Va. Kennell has studied the issue of long-term care for the federal Department of Health and Human Services in Washington, D.C. "In evaluating public insurance models, it is important to assess not only who benefits, but who pays," Kennell says. "The distribution of the cost burden will depend upon the specific taxes and financing mechanisms used to generate the revenue needed to pay for public benefits."

About 50% of all long-term care costs are borne privately by the individuals who use care, primarily through private payments for nursing home care, Kennell says. The remaining 50% of formal long-term care costs is borne by the public sector, in particular the Medicaid program, which pays 38% of the cost. Medicaid costs are paid out of federal and state general revenue, primarily income taxes.

A social insurance approach, modeled on Social Security and Medicare, would finance benefits for beneficiaries from payroll taxes on current workers. Under social insurance, workers would pay into the system during their working years, and draw benefits from the system when they need long-term care as they age. "Like Social Security and Medicare, a social insurance approach to financing long-term care would be built upon social pacts between successive generations of workers," Kennell says.

Broader-based financing mechanisms also have been proposed to finance a public insurance program for long-term care, Kennell says. Increased taxes on unearned income and increases in payroll taxes would distribute costs more evenly across all age groups, since individuals over age 55 hold the vast majority of the nation's financial assets and earn the majority of unearned income, he says. Also, the government might consider taxing the Social Security benefits of beneficiaries who have high incomes, he adds.

"Like private insurance, a public insurance program would reduce the costs to most individuals who needed long-term care services and increase costs to those who paid into the system, but never used benefits," Kennell says. "Unlike private insurance, however, participation in the insurance risk pool would be mandatory, not optional. In addition, a public program is likely to include an income redistribution component, in which premium costs are income related, while benefits for all eligible recipients would be equal."

The advantages of public financing for long-term care include the following, according to Kennell and others:

Universal access. All persons who needed long-term care would be provided access to care without regard to their ability to pay. Persons with long-standing chronic conditions would not be denied access to care simply because they were uninsurable, and discriminatory policies against poor patients would be minimized.

Equity. All persons would be entitled to the same standard benefit, regardless of their economic position. Under the current system, patients who pay for care themselves often receive better quality of care than Medicaid patients do, experts say. Wealthier individuals could still purchase additional services not covered under the public program, but the basic standard of care would be raised for everyone. Also, since the program would be federally financed, current differences in access and quality among states would diminish.

Protection against catastrophic costs. Since all persons would be covered under a public program, all individuals would be protected from the risk of being impoverished by catastrophic long-term care costs. This protection would be provided to all elderly individuals, not just those who can afford to buy insurance privately.

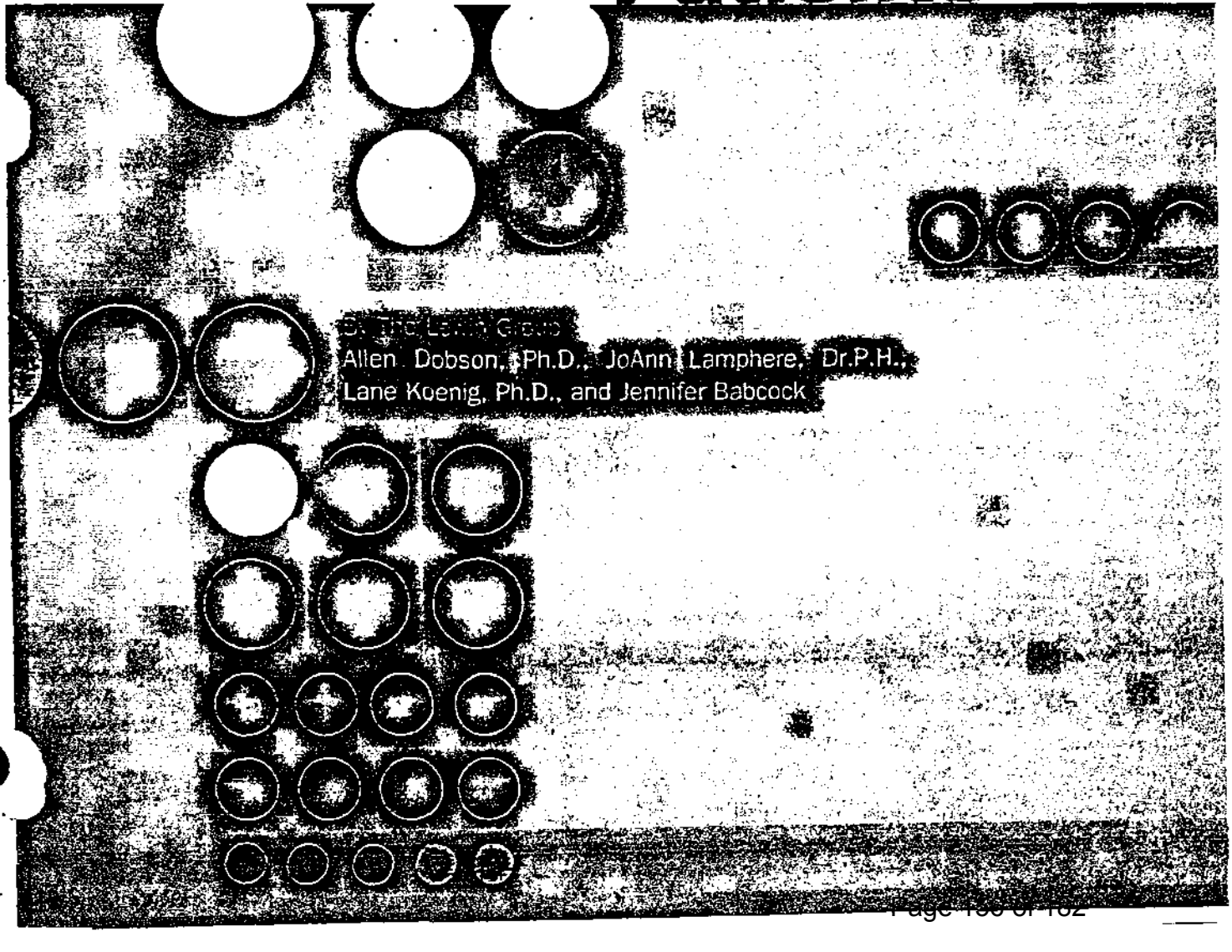
Dedicated financing. Since a public long-term care program would be financed by taxes devoted exclusively to the purpose of financing long-term care, the financial stability of the program would be increased.

Broad-based insurance. All taxpayers or workers would be required to pay taxes to finance the system. This universal insurance risk pool would mean that the costs of long-term care would be spread across a broad group of users.

Administrative efficiency. Compared with private insurance systems, public programs, such as Social Security and Medicare, are so large that they have low administrative costs relative to the amount of premiums paid.

—MS

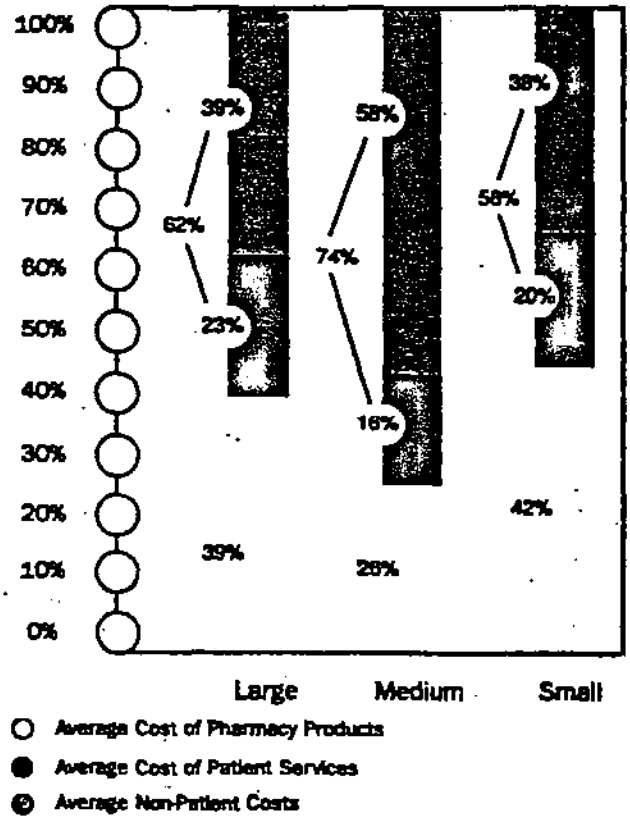
Impact of Proposed AWP Reductions on the Provision of Home Drug Therapies to Medicare and Medicaid Patients



Allen Dobson, Ph.D., JoAnn Lamphere, Dr.P.H.,
Lane Koenig, Ph.D., and Jennifer Babcock

Exhibit 1

Estimated Distribution of Average Total Cost of Providing Respiratory Therapy and Infusion Drugs in the Home to Medicare and Medicaid Patients, by Company Size



provide ongoing professional services integral to quality patient care under current payment arrangements.

The Department of Health and Human Services announced on May 31, 2000 that it is moving administratively to reduce Medicare payments for select drug therapies. For Medicare Part B claims, DHHS intends to pay the "average wholesale catalog price," compiled by the Department of Justice and recommended for state Medicaid programs. Although First Data Bank (FDB) recalculated wholesale drug prices for nearly 400 national drug codes, the method used by FDB has not been made publicly available. Resulting Medicare drug payment changes are scheduled to become effective October 1, 2000.

The Lewin Group has completed its analysis of data collected from mail and telephone surveys of providers. The following is a report of what was learned through this effort.

Analysis and Approach

STUDY OBJECTIVES

The Lewin Group conducted a study for the American Association for Homecare during July-August 2000 that estimated the cost structure of providing respiratory and infusion drug therapies in the home setting and the financial impact of adopting proposed reductions in Medicare Part B and Medicaid reimbursement for these drugs. As part of this study, The Lewin Group assessed the potential effect of these reimbursement changes on Medicare and Medicaid patients who receive drug therapies in the home.

SAMPLE

Data were obtained from 12 providers of home medical equipment and pharmaceutical services, specifically respiratory and infusion therapies, who completed a written survey instrument and a telephone interview. The sample is believed to be generally representative of home pharmaceutical companies nationally. Sampled companies range in size from less than $1 million to $1 billion annual net revenue and serve Medicare and Medicaid patients in all geographic regions throughout the United States.

The sample was stratified by size of companies' volume of business. Small firms were defined as those with less than $5 million total annual revenue; large firms were those with $30 million or more in total annual revenue; and mid-sized firms were in-between.

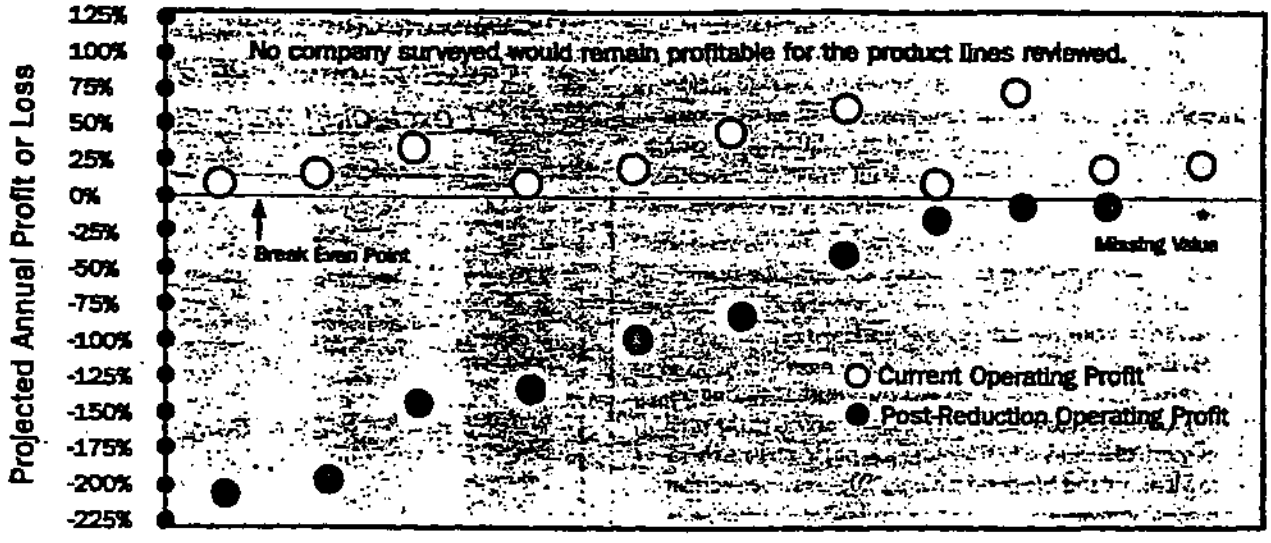
SURVEY DESIGN

The cost survey, designed in conjunction with industry financial experts, sought to calibrate the cost structure of the industry as it pertains to the provision of respiratory and infusion drug therapies in the home setting to Medicare and Medicaid patients. A chief financial officer (or designee) from each participating company completed the mail-in cost survey and participated in an extensive follow-up telephone interview.

The Lewin cost survey identified major categories of professional services that accompany the provision of drug therapies in the home (such as pharmacy, patient management, delivery, and others) and other corporate costs. Revenue and cost data were provided by surveyed companies and then proportionately allocated to the business unit providing respiratory and infusion services to patients whose care is covered by Medicare or Medicaid. Estimates of AWP reductions were derived for approximately 50 drug categories listed in First Data Bank's compilation of drugs that would be affected by new pricing data (as of June 2, 2000), as communicated in a Department of Justice letter to State Medicaid directors. In addition to financial data, the survey and follow-up telephone interviews posed open-ended questions concerning the provider's assessment of the business impact of proposed AWP reductions in the Medicare and Medicaid sectors for those drug therapies under review. Finally, participants provided their perceptions of the consequences in terms of

Exhibit 3

Estimated Initial Financial Impact of AWP Reductions for Respiratory and Infusion Drug Therapies to Medicare and Medicaid Patients at Home by Individual Company



- No company surveyed would remain profitable for the provision of home respiratory and infusion drug therapies to Medicare and Medicaid patients should the proposed AWP reductions be implemented. The estimated initial financial loss to companies as a result of proposed reductions ranges from 2 percent to 214 percent (Exhibit 3). If bad debt costs are excluded from financial loss estimates, only two companies expect to show any profit from Medicare and Medicaid services after AWP reductions (Exhibit 4). Note: in both Exhibits 3 and 4, sampled companies are arrayed in order of expected loss, not by size of company.
- The companies projecting the greatest percentage losses are those that are the largest and which have operations in many states. Two-thirds of the largest companies and three-quarters of mid-sized companies expect to experience a 50+ percent loss on studied services should proposed AWP reductions be adopted for the Medicare and Medicaid programs.
- Most of the companies with the greatest projected negative impact are those which serve a high proportion (>75 percent) of Medicare patients in their respiratory and/or infusion service areas.

IMPACT ON MEDICARE AND MEDICAID BENEFICIARIES

- Medicare and Medicaid beneficiaries' access to respiratory and infusion drug therapies is expected to diminish should AWP reductions be adopted. Firms indicate they will reduce exposure in certain public sector markets. Companies report that they will be forced to curtail accepting new Medicare and Medicaid patients. Several companies assert they will exit the Medicare and Medicaid markets altogether.
- Quality may be jeopardized as companies limit ongoing patient monitoring and reduce staff.
- Ironically, Medicare patient costs could increase should proposed AWP reductions be adopted. Said one pharmacist, "I could serve patients one whole year for what it will cost Medicare for a day when they end up in the emergency room" [because of reduced access to in-home services]. In addition, some companies report they may stop accepting assignment for Medicare patients, thus increasing costs to the patient.

It is important for public policymakers to grasp the financial realities of the health care industry that provides respiratory and infusion services to Medicare and Medicaid patients in the home. Companies in this study's sample serve Medicaid patients in 31 states. Due to revenue losses from Medicaid AWP reductions for respiratory and infusion drug therapies, companies report they have begun curtailing acceptance of new Medicaid referrals, not accepting

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ORIGINAL CONTRIBUTION

Adverse Events Associated With Prescription Drug Cost-Sharing Among Poor and Elderly Persons

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Context Rising costs of medications and inequities in access have sparked calls for drug policy reform in the United States and Canada. Control of drug expenditures by prescription cost-sharing for elderly persons and poor persons is a contentious issue because little is known about the health impact in these subgroups.

Objectives To determine (1) the impact of introducing prescription drug cost-sharing on use of essential and less essential drugs among elderly persons and welfare recipients and (2) rates of emergency department (ED) visits and serious adverse events associated with reductions in drug use before and after policy implementation.

Design and Setting Interrupted time-series analysis of data from 32 months before and 17 months after introduction of a prescription coinsurance and deductible cost-sharing policy in Quebec in 1996. Separate 10-month prepolicy control and postpolicy cohort studies were conducted to estimate the impact of the drug reform on adverse events.

Participants A random sample of 93 950 elderly persons and 55 333 adult welfare medication recipients.

Main Outcome Measures Mean daily number of essential and less essential drugs used per month, ED visits, and serious adverse events (hospitalization, nursing home admission, and mortality) before and after policy introduction.

Results After cost-sharing was introduced, use of essential drugs decreased by 9.12% (95% confidence interval [CI], 8.7%-9.6%) in elderly persons and by 14.42% (95% CI, 13.3%-15.6%) in welfare recipients; use of less essential drugs decreased by 15.14% (95% CI, 14.4%-15.9%) and 22.39% (95% CI, 20.9%-23.9%), respectively. The rate (per 10 000 person-months) of serious adverse events associated with reductions in use of essential drugs increased from 5.8 in the prepolicy control cohort to 12.6 in the postpolicy cohort in elderly persons (a net increase of 6.8 [95% CI, 5.6-8.0]) and from 14.7 to 27.6 in welfare recipients (a net increase of 12.9 [95% CI, 10.2-15.5]). Emergency department visit rates related to reductions in the use of essential drugs also increased by 14.2 (95% CI, 8.5-19.9) per 10 000 person-months in elderly persons (prepolicy control cohort, 32.9; postpolicy cohort, 47.1) and by 54.2 (95% CI, 33.5-74.8) among welfare recipients (prepolicy control cohort, 69.6; postpolicy cohort, 123.8). These increases were primarily due to an increase in the proportion of recipients who reduced their use of essential drugs. Reductions in the use of less essential drugs were not associated with an increase in risk of adverse events or ED visits.

Conclusions In our study, increased cost-sharing for prescription drugs in elderly persons and welfare recipients was followed by reductions in use of essential drugs and a higher rate of serious adverse events and ED visits associated with these reductions.

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RISING COSTS OF MEDICATIONS and inequities in access to medication have sparked calls for drug policy reform in the United States and Canada.[1,2] One of the most contentious issues is the introduction of cost-sharing to control drug expenditures. Cost-sharing is intended to deter the use of drug therapies that do little to improve health.[3-5] But cost-effectiveness rests on the assumption that individuals will have the capacity to pay for essential drugs and that they will make rational choices about which drugs to use and abandon. Otherwise, the use of essential drugs will be curtailed to control drug expenditures and short-term savings in the drug budget may be offset by downstream costs in the

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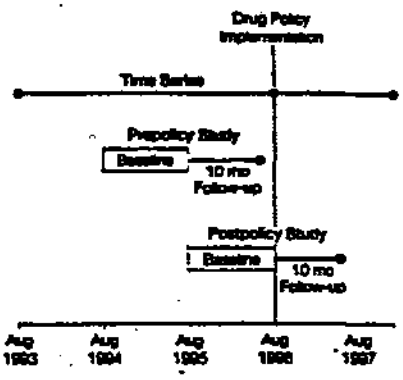
ies were conducted in comparable 10-month periods before (August 1995 to 1996) and after (August 1996-1997) policy implementation (FIGURE 1). The prepolicy control study provided an estimate of the expected rate of adverse events due to reductions in drug use prior to policy implementation. The estimation of an expected rate was important because even when drugs are free, individuals will experience adverse drug events due to injudicious reductions in needed therapy, because of forgetfulness, adverse effects, or misperceptions about the importance of drug treatment.[27] The difference in the rate in the prepolicy control study vs the postpolicy study was used to estimate the impact of the drug reform on adverse events. This approach had several advantages. First, it voided biases related to ecological fallacy[28] because changes in drug use were linked at the level of the individual with the occurrence of adverse events and ED visits. Second, it provided a means of isolating the effect of the drug policy from other health care policies that were implemented in the same 4-year period that may have reduced the rate of ED visits and hospitalizations, unrelated to prescription drug use (hospital closures and reallocation of service locations). Finally, the prepolicy and postpolicy cohort study approach verified the assumption that the primary impact of cost-sharing would be to increase the prevalence of reductions of drug use rather than changing the "biological risk" associated with rationing or stopping therapy. Thus, the studies were designed to estimate both the risk and the population attributable fraction or the share of adverse events and ED visits due to reductions in drug use, in the prepolicy and postpolicy periods.

For this analysis, study populations were limited to regular recipients of essential or less essential drugs, defined as persons who had a supply of the respective medication in each of the 12 months prior to the follow-up period or new users with a minimum of 6 months of continuous use.

Data Sources

Four provincial health databases, validated in previous research,[29-31] were linked by unique encrypted health numbers. The beneficiary demographic database provided data on drug plan eligibility, death, and beneficiary characteristics. The prescription claims database, which includes the drug, quantity, date, and duration for each prescription dispensed from community-based pharmacies, was used to measure medication use. The physician claims database, which includes the date, type, and location of service delivery (eg, inpatient, emergency, clinic), was used to measure ED visits and hospitalization-institutionalization. The hospitalization database was used to validate claims-based measures of hospitalization-institutionalization.

Figure 1. Time Series and Prepolicy Control and Postpolicy Cohort Design



The first 3 months of the time series and of an individual's enrollment in the public plan were excluded because prescriptions filled prior to these dates were unknown and created artificially low values for monthly drug use. The month immediately prior to policy implementation also was excluded because of possible prescription stockpiling.

Prescription Drug Use

The number of drugs available each day was calculated from prescription claims records using methods developed to convert the date, drug, and duration of prescriptions dispensed into a drug-by-day matrix.[32] In each of the 53 months of the time series, a matrix of monthly mean daily drug use was then constructed for each beneficiary (for all drugs and separately for essential and less essential drugs). The first 3 months of the time series and of coverage for newly eligible recipients were excluded to avoid artificially lower values for drug use in the first few months of available prescription information. The month immediately prior to policy implementation also was excluded because of possible prescription stockpiling, leaving 49 months for analysis.

For the prepolicy and postpolicy cohort studies, reductions in drug use were measured first by estimating an expected daily drug use for each person. The resulting expected values were then compared with observed use in the 10-month follow-up period. The expected use value was estimated as the level predicted for the last baseline month by a linear trend fit to each person's mean monthly daily drug use in the baseline year. This method conservatively assumed that expected drug use would remain constant rather than increase during follow-up. In addition, it was assumed that the impact of reductions in drug use would cumulate over time. Therefore, time-dependent measures were used to summarize differences between expected and observed use during the follow-up period. Time-dependent measures of drug use also provided a means of adjusting for unusual drug consumption patterns triggered by the features of the drug policy. For instance, the deductible and maximum ceilings instituted a pattern whereby reductions in one month may be compensated for by increases in the next when drugs were free for those persons reaching the spending ceiling. Cumulative mean monthly increases (observed > expected) and reductions (observed < expected) in drug use were calculated as the sum (from the first follow-up month) of the monthly difference in observed and expected drug use divided by the number of follow-up months. For example, an individual who had an expected value of 5 drugs per month and who filled prescriptions for 3 drugs in the first 2 months of follow-up and 8 in the third month would have a mean cumulative reduc-

showed a 9.12% (95% CI, 8.7%-9.6%) reduction in the number of essential drugs used per day (0.17 drugs; 95% CI, 0.16-0.18). Absolute and relative reductions were higher among welfare recipients (14.4%; 95% CI, 13.3%-15.6% and absolute reduction: 0.21; 95% CI, 0.19-0.23 essential drugs per day).

Relative reductions were greater in the use of less essential drugs by elderly persons and welfare recipients (15.14%; 95% CI, 14.4%-15.9% and 22.39%; 95% CI, 20.9%-23.9%, respectively) than for essential drugs (FIGURE 3). However, because fewer less essential drugs were used per day, the absolute size of the reduction was smaller for less essential drugs (elderly persons, 0.10 and welfare recipients, 0.15) than for essential drugs (elderly persons, 0.17 and welfare recipients, 0.21). Also, there was a significant decrease in the slope of less essential drug use over time in the postpolicy period (policy/time interaction) for the elderly persons ($\hat{\beta}$=−0.009; P<.001) and for the welfare recipients ($\hat{\beta}$=−0.008; P<.001).

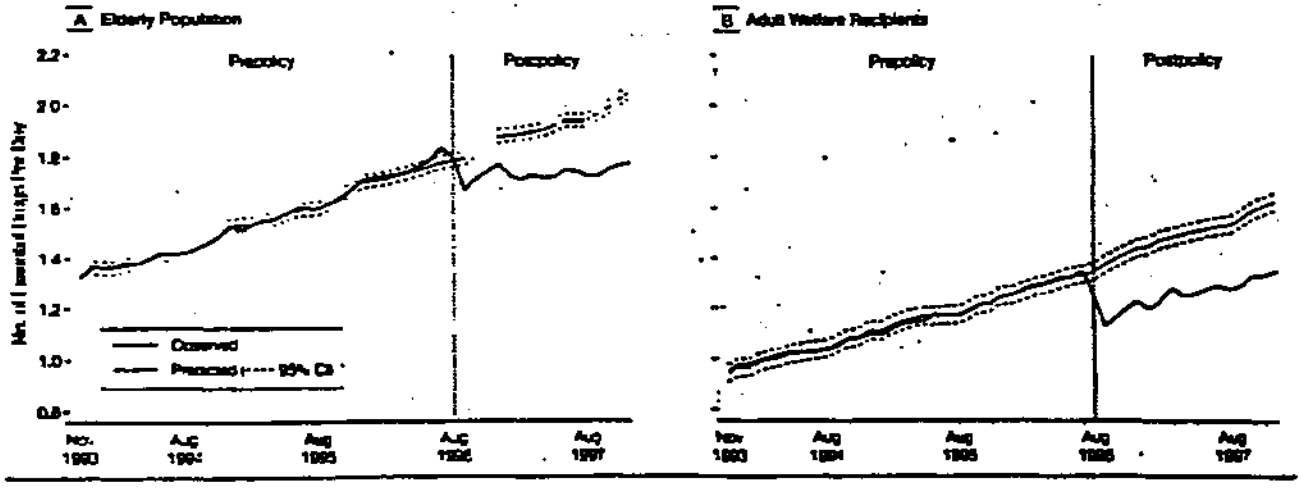
As expected, in both the prepolicy and postpolicy studies, there was a significantly higher rate of adverse events and ED visits in those individuals who reduced their use of essential drugs vs those who did not (TABLE 3). Dose-response relationships were evident between the magnitude of the reduction and the rates of both outcomes. For example, in the prepolicy control study, the rates of adverse events in those with no reduction (≤0.1 drugs/d), minor reduction (>0.1 to 0.5 drugs/d), and major reductions (≥1 drugs/d) were 256, 272, and 385 per 10000 person-months, respectively. Reduction of 1 medication would be equivalent to stopping 1 drug or rationing 2 drugs to half the expected use. Risks associated with reductions

Table 2. Characteristics of the Recipients of Essential and Less Essential Drugs in the Prepolicy Year (August 1995-July 1996)

	Elderly Persons		Adult Welfare Recipients	
	Essential Drugs	Less Essential Drugs	Essential Drugs	Less Essential Drugs
Total No. of medication recipients	93 950		55 333	
Medication recipients, No. (%)	70 801 (75.3)	38 065 (40.5)	25 820 (46.7)	14 888 (26.9)
Demographics				
Female, %	61.4	68.9	60.9	61.7
Age, mean (SD), y	73.1 (5.6)	73.4 (5.6)	43.4 (12.6)	44.7 (11.6)
Plan type for medication recipients by income-indexed ceiling, No. (%)*				
$200/y	4011 (5.7)	2387 (6.3)	25 820 (100)	14 888 (100)
$500/y	26 157 (36.9)	14 944 (39.3)	...	...
$750/y	40 633 (57.4)	20 734 (54.5)	...	...
Drugs used per day, mean (SD), No.				
Total†	3.1 (7.2)	3.4 (8.0)	2.4 (7.3)	2.6 (8.1)
Essential	1.7 (4.3)	1.5 (4.8)	1.2 (4.1)	1.0 (4.3)
Less essential	0.3 (1.6)	0.5 (1.6)	0.3 (1.8)	0.6 (1.8)
Monthly drug costs, mean (SD), $				
Total†	87 (272)	89 (292)	75 (332)	76 (339)
Essential	48 (154)	42 (163)	39 (184)	33 (173)
Less essential	3 (18)	7 (20)	4 (26)	8 (31)
Health service use, mean (SD)				
Emergency department visits/mo	0.1 (0.9)	0.1 (1.0)	0.2 (1.2)	0.2 (1.4)
Hospitalized per year, %	27.9	30.2	27.9	30.3

*Welfare recipients were subject to an annual maximum of $200.
†Also includes drugs other than those listed in Table 1 that were covered by provincial formulary.

Figure 2. Observed and Predicted Use of Essential Medication in the Prepolicy and Postpolicy Periods



likely to be related to the cost-sharing policy. Prescription claims files do not indicate what drugs were taken, only medication purchased. Although prescription refill rates provide a reasonably accurate measure of medication compliance,[42-44] reductions in drug use could have been overestimated if individuals received free samples or purchased equivalent over-the-counter preparations (eg, aspirin) after policy implementation. However, these individuals would be falsely classified as having reduced medication use, and as a result, the risk associated with reductions in drug use in the postpolicy studies would be underestimated.

Indications for therapy were unknown. Drugs classified as less essential may have been required therapy for some individuals (eg, benzodiazepines for panic disorder), whereas some essential therapeutic drugs may have been prescribed without adequate clinical indication (eg, diuretics for transitory elevation in blood pressure). This misclassification would likely lead to an underestimation of both the potential benefits of reducing the use of less essential drugs and the risks of reducing essential drug therapy.

Our study suggests that the primary mechanism by which cost-sharing affected the rate of adverse events was by increasing the proportion of people who made reductions in the use of essential drugs. We cannot confirm that reductions in essential drug use led to a deterioration in health status, but we believe that this is a plausible explanation for several reasons. First, there was a dose-response relationship between the magnitude of the reduction in the use of essential drugs and the risk of adverse events and ED visits. Second, reductions were associated with an increase in the risk of adverse events in the prepolicy and postpolicy period, a phenomenon that would be expected if reductions represented medication noncompliance. Finally, the risk associated with reduction was specific to essential drugs, for which there is clinical trial evidence of efficacy.

The challenge for insurers has been to craft health care policies that provide adequate access to drug therapy while simultaneously exercising fiscally responsible control over the drug budget. Consumer cost-sharing has been the principal method of fiscal control because it assumes that people will value what they pay for and as a result, they will reduce their use of unnecessary medication when they are required to contribute a portion of the payment.[4,6] While this reasoning may apply to many consumer goods, cost-sharing has been shown to have unintended effects in health care, such as increasing hospital admissions.[16,17,19,20,45-48] Consumers may not have the information needed to make wise decisions about necessary treatment. We estimate that for elderly persons alone, the drug policy reform in Quebec may result in 7000 additional adverse events per million annually. In light of the substantial impact that drug policy can have on the population's health, there is a need to redress the relative scarcity of scientific data on the outcomes of policy interventions. Our results suggest that more stringent cost-sharing pharmaceutical cost containment policies in other parts of Canada[48] and the United States[1,4] may contribute to avoidable illnesses.

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Dr Hanley participated in study concept and design, analysis and interpretation of data, critical revision of manuscript for important intellectual content, provided statistical expertise, technical support, and supervised study conduct.
Dr Abrahamowitz participated in analysis and interpretation of data, drafting of manuscript, and critical revision of manuscript for important intellectual content, and provided statistical expertise.
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Dr Hurley participated in acquisition of data and critical revision of manuscript for important intellectual content, and provided statistical expertise.
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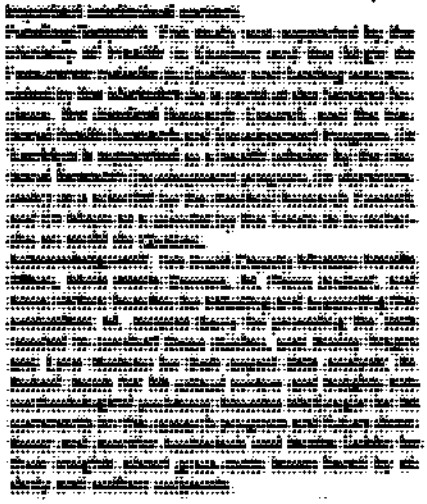
Dr Larochelle participated in analysis and interpretation of data and critical revision of the manuscript for



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Definition of Drug-Induced Cognitive Impairment in the Elderly

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Introduction

Drug-induced cognitive impairment can generally be categorized into 2 types: delirium and dementia. Drug-induced delirium refers to the development of an acute confusional state, whereas drug-induced dementia implies a more chronic alteration in mental function.[1] Drug-induced cognitive impairment is the most common reversible cause of confusion.[2] It can be either dose related or, in some cases of delirium, it may be idiosyncratic. Cognitive impairment secondary to nonpsychoactive medications may be more likely to result from an idiosyncratic mechanism. Compared with drug-induced delirium, less is known about the prevalence of drug-induced dementia.[1]

Nearly every drug class can cause either drug-induced delirium or dementia in older persons. The elderly may be especially prone to developing drug-induced cognitive impairment due to age-related changes in drug pharmacokinetics (eg, reduced oxidative metabolism, reduced renal function) and pharmacodynamics. The elderly may also be at greater risk of drug-induced confusion than younger people because of decreased functional reserve of the CNS and changes in brain perfusion. They may have alterations in neurotransmitter systems. Alzheimer's disease and vascular dementia are more common in this age group; dementia is a major predisposing risk factor for the development of drug-induced cognitive impairment. Polypharmacy, involving both prescription and over-the-counter medications, is also very common among the elderly and increases the risk of cognitive impairment. Electrolyte imbalances, which occur frequently in older persons, can predispose to cognitive changes.

Delirium

Diagnostic criteria for delirium in the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (DSM-IV), are divided into 5 categories based on the possible etiology of the syndrome, ie, whether it is thought to be attributable to: a general medical condition, substance intoxication, substance withdrawal, multiple etiologies, or not otherwise specified. For "Substance Intoxication Delirium," the criteria state that there is evidence from the history, physical examination, or laboratory findings of either disturbances in consciousness with reduced ability to focus, sustain, or shift attention OR that there is a change in cognition or the development of a perceptual disturbance that is not better accounted for by a preexisting, established, or evolving dementia AND that these symptoms develop during the substance intoxication AND that medication use is etiologically related to the disturbance. For "Substance Withdrawal Delirium," the symptomatology must present during or shortly after the removal of the drug. "Delirium due to Multiple Etiologies" considers the possibility that there may be more than 1 cause of the delirium, eg, drugs and the underlying medical condition. If the cause of delirium is not addressed by any of the above categories (eg, sensory deprivation), it is considered "Not Otherwise Specified."[3]

Criteria used to define drug-induced delirium in one study protocol included the following: the drug in question had central nervous system (CNS) effects; a toxic level was documented, or there was improvement with dose reduction or cessation; and the time course of mental status change coincided with the period of drug use. This definition excluded the presence of alcohol and drug withdrawal.[4]

Other terms that have been used synonymously with delirium are transient cognitive impairment, acute brain failure, exogenous psychosis, toxic confusional state, toxic delirious reaction, toxic encephalopathy, toxic psychosis, senile delirium, acute brain syndrome, pseudosenility, clouded states, neurotoxicity, reversible dementia, intensive care unit psychosis, postsurgery psychiatric syndrome, metabolic encephalopathy, psychosis associated with organic brain syndrome, postoperative delirium, and postoperative encephalopathy.[5-9]

Delirium, which is also known as an acute confusional state, is a syndrome characterized by disturbance in consciousness

(ie, reduced clarity of awareness of the environment), change in cognition including alteration in attention, disorganized thinking, disturbed psychomotor activity, and abnormal sleep-wake cycle.[1,6] According to DSM-IV, the essential feature of delirium is a disturbance of consciousness that is accompanied by a change in cognition that cannot be better accounted for by a preexisting or evolving dementia. This disturbance in consciousness results in altered awareness of the environment and the inability to focus, sustain, or shift attention appropriately. This change in consciousness is associated with cognitive abnormalities (which may include memory impairment, disorientation, or language disturbance such as inability to name objects or to write) or the development of perceptual disturbance (which may include misinterpretations, illusions, or hallucinations). Additional characteristic features of delirium are its development over a brief period of time and that it has a fluctuating course. Disturbances in orientation and thinking as well as bizarre psychomotor behavior are possible. These behaviors may manifest as stupor or as severe agitation with the patient trying to pull out intravenous catheters or trying to leave the facility.

Delirium is estimated to occur in 14% to 56% of hospitalized elderly patients.[10] About 15% of elderly have delirium upon admission to the hospital.[8] About 10% to 30% of hospitalized medical and surgical patients are experiencing delirium at any given time,[8,11] and 25% to 55% of elderly who are asymptomatic on admission develop confusion during their hospital course.[5] Once delirium develops, it is associated with a 10% to 75% mortality rate, although death may be related more to advanced age and severity of illness than to delirium per se. Unfortunately, 32% to 80% of delirious patients are not diagnosed properly. In the elderly, this may be an especially important problem since symptoms may falsely be attributed to dementia or senescence and because they may manifest as the hypoactive form of delirium, which is characterized by lethargy and decreased activity. Patients may also demonstrate a mixed form of delirium having elements of both the hyper- and hypoactive states. This mixed state may be the most common presentation of delirium.[10,12-14] Francis and associates[4] found that less than half of the delirious older patients in their study demonstrated disruptive behaviors, hallucinations, or delusions. Rather, somatic features such as incontinence were the problems most frequently associated with the onset of delirium.

Another problem that may occur in the elderly is the persistence of symptoms even once the underlying condition is addressed and the patient is discharged from the hospital. About one fifth of patients may have residual symptoms of the delirium present even 6 months postdischarge.[10] The risk for elderly patients of either dying or of being transferred to an institutional care setting may be especially high following the first 6 months after discharge from the hospital. Patients who succumb to these outcomes demonstrate more cognitive and functional impairment. Cognitive impairment may outlast the acute syndrome. Up to 55% of those who experience delirium may have permanent cognitive impairment, which may be a harbinger for the onset of dementia.[15] Delirium may serve as a marker of future cognitive and functional impairment.[13] The likelihood of developing delirium appears to be inversely related to a patient's physiological reserve capacity.

Delirium occurs in 25% to 40% of all patients with cancer and up to 85% of patients who are in the terminal phase of the disease. This alteration in mental status may be attributable to both the underlying condition as well as to the cancer treatment utilized. Yet, there is a paucity of data on the cognitive side effects of cancer treatments used among older adults.[5]

Surgical patients may be especially at risk for developing cognitive impairment. Postoperative delirium in the elderly occurs in 10% to 61% of those aged 65 or older. Orthopaedic patients are more likely to experience delirium than those undergoing general surgery. Delirium develops in 44% to 55% of hip surgery patients vs 10% to 14% of general surgery patients. Even patients undergoing cataract surgery are at risk. In the coronary and intensive care units, between 2% and 30% of patients experience delirium.[8,13,16]

Medications are the most common reversible cause of delirium. It is estimated that medications contribute to 22% to 39% of all cases of delirium.[10] A recent study involving older hospitalized adults found that the most likely primary cause of delirium in their study population was medication use.[17]

Dementia

According to DSM-IV, multiple cognitive deficits that occur with dementia only in the context of substance use are diagnosed as "Substance Intoxication" or "Substance Withdrawal." If the dementia results from the persisting effects of a substance (ie, a drug of abuse, a medication, or toxic exposure), "Substance-Induced Persisting Dementia" is diagnosed. Other causes of dementia (eg, "Dementia Due to a General Medical Condition") should always be considered, even in a person with substance dependence.[3]

The essential feature of dementia is the development of multiple cognitive deficits that include memory impairment and at least 1 of the following cognitive disturbances: aphasia, apraxia, agnosia, or a disturbance in executive functioning. The cognitive deficits must be sufficiently severe to cause impairment in occupational or social functioning and must represent a

decline from a previously higher level of functioning.[3]

Dementia is a chronic, insidious, progressive, and often permanent form of cognitive impairment that includes impaired thinking, memory, and learning abilities and difficulties in daily functioning, problem solving, and emotional control (Table 1).[5] Dementia occurs at age 60 in about 1% of the population; however, this increases to greater than 30% by age 85.[18] Starr and Whalley[19] make the following distinction: "Drug-induced dementias reversed by withdrawal of the offending drug are probably best thought of within the spectrum of delirious states, while dementias that are drug-related and persist when the drug is withdrawn are, *de facto*, drug induced." However, as they point out, a satisfactory definition of drug-induced dementia is lacking.

Drug-induced dementia may be a cause of cognitive impairment in about 12% of patients with a suspected dementia. In the elderly, this is distinguished from age-related cognitive impairment, where the decline in mental function is considered a part of the normal aging process. The relative odds of a drug-induced dementia increase as the number of medications consumed rises. The relative odds range from 1.0 with the use of 0-1 drugs to 9.3 with the use of 4-5 medicines.[18,20] Medication side effects accounted for 5% of reversible dementias in patients aged 60 or older in one study.[21] The prevalence of drug-induced dementia in the general population is unknown.[1]

Drugs may impair cognition indirectly by metabolic effects, such as hypoglycemia, by alterations of immunologic factors within the CNS, and by actions that interfere with synaptic transmission. Classes of drugs most often associated with the development of drug-induced dementia include benzodiazepines, antihypertensives, and anticholinergic agents.[19]

DSM-IV also recognizes research criteria for "Mild Neurocognitive Disorder." This condition is defined by the presence of 2 or more of the following impairments in cognitive functioning, usually lasting for a period of at least 2 weeks: memory impairment as identified by a reduced ability to learn or recall information; disturbance in executive functioning (ie, planning, organizing, sequencing, abstracting); disturbance in attention or speed of information processing; impairment in perceptual-motor abilities; and impairment in language (ie, comprehension, word finding). However, this condition should not be considered if a patient meets the criteria for "Substance-Related Disorder," including medication-related side effects. "Substance-Related Disorders" include disorders related to the taking of drugs of abuse (including alcohol), the side effects of a medication, and a toxic exposure. Medications that cause substance-related disorders include, but are not limited to, anesthetics and analgesics, anticholinergic agents, anticonvulsants, antihistamines, antihypertensive and cardiovascular medications, antimicrobial medications, antiparkinsonian medications, chemotherapeutic agents, corticosteroids, gastrointestinal medications, muscle relaxants, nonsteroidal anti-inflammatory medications, other over-the-counter medications, antidepressant medications, and disulfiram. Within this classification is "Substance Intoxication." This diagnosis requires the development of a reversible substance-specific syndrome caused by the recent ingestion or exposure of a substance and requires that the clinically significant maladaptive behavioral or psychological changes associated with the intoxication (eg, belligerence, mood lability, cognitive impairment, impaired judgment, impaired social or occupational functioning) are attributable to the direct physiologic effects of the substance on the CNS. In "Substance-Induced Persisting Amnestic Disorder," memory disturbance must not occur exclusively during the course of a delirium or a dementia, and it must persist beyond the usual duration of substance intoxication or withdrawal.[3]

Delirium may be superimposed on dementia. Approximately 22% of ambulatory demented elderly have concomitant delirium.[22] For any patient with a diagnosis of dementia who suddenly develops a change in mental status, delirium should be ruled out. The manifestation of delirium in a patient with dementia may be atypical. Even in demented patients, cognitive function may temporarily improve if an offending agent is removed. Delirium and dementia may be 2 places along a spectrum ie, if delirium is not reversed, it may evolve into dementia. Further, depression may mimic either dementia or the early stages of delirium.

Risk Factors for Drug-Induced Cognitive Impairment

Major risk factors that have been identified as predisposing to delirium include a diagnosis of dementia or other neuropsychological disorders, advanced age, and sepsis. Other predisposing factors include hypoalbuminemia, hospitalization, postoperative status, myocardial infarction, congestive heart failure, acute blood loss, stroke involving subcortical regions, severe chronic illnesses, total knee arthroplasty, cardiac and noncardiac thoracic surgical procedures, aortic aneurysm surgery, functional impairment, high blood urea nitrogen/serum creatinine ratio (azotemia), proteinuria, lymphocytosis, HIV disease, sensory impairment, untreated pain, fluid and electrolyte imbalances, acid-base disturbances, infection, hypoxia/ hypercarbia, Parkinson's disease, depression, abnormal glucose levels, acute urinary retention, nutritional deficiencies (vitamin B_{12}, folate), collagen diseases, blood dyscrasias, constipation/diarrhea, hypo- or hyperthermia, unfamiliar environment/ isolation, sleep deprivation, malignancies, alcohol or substance abuse, psychosocial factors or acute stress, disorders caused by hypersensitivity, injury by physical agents, male gender, fracture present on admission, family history of mental illness, history of serious brain trauma, and, of course, medications (eg, anticholinergic agents, psychotropic drugs).[2,5,6,8,10,11,13,15,17,22,24,25] Often, multiple causes and risk factors for the development of cognitive impairment are

present.

It is not known what causes delirium; however, among the theories proposed are: a reduction of cerebral oxidative metabolism; CNS dopamine and endorphin hyperfunction; brain acetylcholine-dopamine-serotonin-glutamate imbalances; increased CNS cortisol activity; damaged neuronal enzyme systems; decreased synthesis and function of neurotransmitters, namely acetylcholine; increased central noradrenergic activity; dysfunction of beta-endorphinergic neurons; disturbances of the normal ionic passage through excitable membranes; gross changes in the electrolyte and water content, osmolality, and pH of the internal milieu; presence of false neurotransmitters; impaired synthesis of macromolecules needed for renewal of the structural and functional integrity of neurons; mismatch of metabolic supply and demand; involvement of cytokines; and neuronal loss.[5,7] These proposed mechanisms point to a number of ways in which drugs may be involved in inducing delirium by affecting the function, supply, or use of substrates of CNS neurotransmitters or neuropeptides. Cerebrospinal fluid (CSF) somatostatin-like immunoreactivity and CSF beta endorphin-like immunoreactivity were found to be lower in delirious vs nondelirious patients, and these changes persisted even 1 year after the initiating event.[8,24,25]

In the elderly, polypharmacy may predispose patients to developing drug-induced delirium. However, there is a lack of data on this subject, because reports citing multiple causative agents are often not published. In the late 1970s, Summers[26] tried to estimate the risk of developing drug-induced delirium based on the propensity of a drug either to have anticholinergic effects OR to be associated with the onset of altered mental status AND its daily effective dose. The relative risk of developing delirium when 3 or more medications are added during the hospital course may increase 3-fold.[27]

Drugs Associated With Cognitive Impairment

Taking a thorough drug history is one of the first steps that should be performed when assessing an older patient with changes in cognitive function. This history should include prescription drugs, over-the-counter medications, illicit substances, alcohol use, herbs, vitamins, nutraceuticals, homeopathic products, and naturopathic remedies, including the use of home remedies as well as other forms of complementary or alternative medicine. In the elderly, an increased number of medications may have a greater negative impact on orientation and memory as opposed to concentration and judgment.[28] The more complex a drug regimen, the more difficult it may be to identify the specific drug(s) that may be causing cognitive impairment. It is important to note that in the elderly, drug-induced cognitive impairment may occur even in the presence of nontoxic or therapeutic levels of a drug. Further, there may be intraclass differences in the propensity to induce cognitive impairment.

Numerous drugs have been identified in *The Medical Letter on Drugs and Therapeutics* as causing a multitude of psychiatric symptoms, including hallucinations, fearfulness, insomnia, paranoia, depression, delusions, bizarre behavior, agitation, anxiety, panic attacks, manic symptoms, hypomania, depersonalization, psychosis, schizophrenic relapse, aggressiveness, nightmares, vivid dreams, excitement, disinhibition, rage, hostility, mutism, hypersexuality, suicidality, crying, hyperactivity, euphoria, dysphoria, lethargy, seizures, Tourette-like syndrome, obsessiveness, fear of imminent death, illusions, emotional lability, sensory distortions, impulsivity, and irritability, which can impact on mental capacity. Further, there are a number of medications that may be linked to causing cognitive impairment by inducing delirium, confusion, disorientation, memory loss, amnesia, stupor, coma, or encephalopathy. Among these drugs are: acyclovir, anticholinergics and atropine, anticonvulsants, tricyclic antidepressants, asparaginase, baclofen, barbiturates, benzodiazepines, beta-blockers, buspirone, caffeine, chlorambucil, chloroquine, clonidine, clozapine, cytarabine, digitalis glycosides, disulfiram, dronabinol, ganciclovir, histamine-2 antagonists, ifosfamide, interleukin-2, ketamine, levodopa, maprotiline, mefloquine, methyldopa, methylphenidate, metrizamide, metronidazole, pergolide, phenylpropanolamine, pilocarpine, propafenone, quinidine, salicylates, selegiline, sulfonamides, trazodone, and trimethoprim-sulfamethoxazole. Often these medications produce more than 1 type of psychiatric symptom.[29]

A simple mnemonic to help remember the drugs or drug classes that are associated with acute changes in mental status in the elderly is ACUTE CHANGE IN MS (Table 2).[30]

Many of these drugs have already been recognized as being potentially inappropriate for use in the elderly. In 1991, Beers and colleagues[31] published explicit criteria for determining inappropriate medication use in nursing home residents. These criteria were derived by expert consensus using the Delphi method. The risk-benefit profile of specific agents within various drug classes, including sedative-hypnotics, antidepressants, antipsychotics, antihypertensives, nonsteroidal anti-inflammatory agents, oral hypoglycemics, analgesics, dementia treatments, platelet inhibitors, H_2-blockers, antibiotics, decongestants, iron, muscle relaxants, gastrointestinal antispasmodics, and antiemetics, were examined. Many of the drugs were cited because of potential CNS adverse effects.[31] This list was later updated in 1997 to include drug-disease combinations that may also be inappropriate for use by the elderly.[32] In 1999, the Health Care Financing Administration drafted new nursing facility survey procedures and interpretative guidelines based on these 2 articles. Under these new guidelines, which went into effect on July 1, 1999, drugs that were considered to have a high potential for severe CNS adverse outcomes were pentazocine, long-acting benzodiazepines, amitriptyline, doxepin, meprobamate, disopyramide, digoxin, methyldopa, chlorpropamide (if

hypoglycemia results), gastrointestinal antispasmodic drugs, and barbiturates (Table 3).

Other drugs that were considered to be potentially inappropriate, but were thought to produce less severe adverse outcomes, were identified. Among the medications that may produce adverse CNS effects are indomethacin, reserpine, diphenhydramine, muscle relaxants, sedating antihistamines, and trimethobenzamide (which can cause extrapyramidal effects). Lastly, drugs were identified that may exacerbate insomnia. This list of medications included decongestants, theophylline, desipramine, selective serotonin reuptake inhibitors (SSRIs), methylphenidate, monoamine oxidase inhibitors, and beta-agonists.[33]

Anesthetics

Both anesthetics and preoperative medications such as anticholinergic agents used to dry up secretions or sedative premedication (barbiturate or benzodiazepine) have been associated with the development of delirium postoperatively. Since it is thought that the residual effects of anesthetics on cognitive function may remain 48-72 hours after surgery, the choice of the anesthetic drug is important. Newer medications with shorter elimination half-lives may be preferred in the elderly.[16] The type of anesthesia (ie, general vs spinal) does not seem to affect the occurrence rate of postoperative delirium.[14]

Antibiotics/Anti-infectives

Although sepsis is one of the main risk factors for delirium, antibiotics and anti-infective agents may also produce changes in mental status. Among the agents that have been associated with delirium are aminoglycosides (eg, gentamicin, tobramycin, streptomycin), penicillins, cephalosporins, sulfonamides, and fluoroquinolones (eg, ciprofloxacin, ofloxacin).[10,34] Inhibition of GABA may be involved in fluoroquinolone- and penicillin-induced delirium. Penicillin can induce psychosis and encephalopathy. Risk factors for drug-induced delirium include renal impairment, increased permeability of the blood-brain barrier, high antibiotic dosage, intrathecal or intravenous administration of antibiotics, prior psychiatric illness, severe medical illness, slow acetylator status, and advanced age. Overall, however, this class of drugs has a low risk of inducing cognitive changes.[18] Other anti-infectives that have been associated with drug-induced cognitive impairment are erythromycin, clarithromycin, ketoconazole, amphotericin B, isoniazid, rifampin, quinacrine, chloroquine, quinine, trimethoprim/sulfamethoxazole, amantadine, acyclovir, and zidovudine.[2,30] Trimethoprim-sulfamethoxazole can cause acute psychosis and a catatonic depressive-like reaction.[30]

Anticholinergic Agents

This class includes drugs with known anticholinergic properties such as the first-generation, sedating antihistamines (eg, diphenhydramine, hydroxyzine, chlorpheniramine, meclizine), antispasmodics (eg, belladonna, diphenoxylate, clinidium, dicyclomine, hyoscyamine), oxybutynin, trazodone, ipratropium bromide, tricyclic antidepressants (which are discussed separately under antidepressants), phenothiazines (eg, thioridazine, prochlorperazine, promethazine, chlorpromazine, fluphenazine), muscle relaxants (cyclobenzaprine, orphenadrine), mydriatics (atropine, homatropine, tropicamide), diphenoxylate/atropine, antiparkinsonian agents (eg, benztropine, trihexyphenidyl), and antiarrhythmics (eg, disopyramide, quinidine, procainemide). Further, other drugs which may have possible anticholinergic effects include codeine, colchicine, warfarin, digoxin, furosemide, haloperidol, isosorbide dinitrete, meperidine, nifedipine, cimetidine, ranitidine, prednisolone, quinidine, and theophylline.[10,35-37] Many drug classes starting with the prefix "anti" have anticholinergic properties (eg, antihistamines, antidepressants, antipsychotics, antispasmodics, antiparkinsonian drugs, and some antihypertensives) and may help alert the practitioner to drugs that may be a source of confusion in their patients.[38]

Anticholinergic agents have been causally linked to the development of memory impairment in healthy subjects. Memory impairment may be associated with basal forebrain cholinergic pathways, whereas changes in consciousness seen in delirium may be attributable to alterations in pontine cholinergic pathways projecting into the frontal cortex and brain stem. Acetylcholine is also involved with attention, the sleep-wake cycle, and other aspects of cognitive functioning.[8,13]

In a study that was published in 1983, approximately 60% of nursing home residents and 23% of ambulatory patients were receiving drugs with anticholinergic properties. In some cases, patients may have received 3 or more anticholinergic medications concurrently.[39]

Tune and others[36] examined the anticholinergic effects of drugs commonly prescribed for the elderly as a potential means for assessing risk of delirium (Table 4). Using a standard concentration of 10^{-8} M of 25 compounds and en anticholinergic radioreceptor assay, they assessed these substances against an internal standard of atropine. Atropine equivalents represented in nanograms per milliliter of equivelent amounts of atropine were compared to the test drug. Of the 25 drugs tested, 14 produced detecteble anticholinergic effects with 10 of these 14 medications, resulting in anticholinergic levels that have been associated with significant deficits in memory and attention in normal elderly.

Medications that were not associated with anticholinergic effects in this study included hydrochlorothiazide, propranolol, salicylic acid, nitroglycerin, insulin, methyldopa, ibuprofen, diltiazem, atenolol, metoprolol, and timolol.[36]

In an earlier paper, Tune and colleagues[40] had found that postoperative cardiac surgery patients who had experienced delirium had high serum levels of anticholinergic drugs and that impairment in cortical function was related to this elevated level. This group later examined the cumulative anticholinergic effects of drug regimens among surgical intensive care unit patients.[41] They have since expanded their work to examine the anticholinergic effects of 48 commonly prescribed medications.[42]

Flacker and colleagues[35] analyzed the association of serum anticholinergic activity with delirium in medical patients aged 75 or older. Delirium was associated with a higher serum anticholinergic activity quintile. The number of symptoms of delirium were also associated with higher serum anticholinergic activity. Mach and colleagues[43] demonstrated the resolution of delirium in an elderly population upon discontinuation of medications, which resulted in a reduction of serum anticholinergic levels. Only 5 of 17 medications discontinued were known to have in vitro anticholinergic activity. Even topically administered anticholinergic ophthalmic preparations have been associated with the development of delirium.[44,45] Other investigators have reported the presence of high serum anticholinergic levels among patients who have not received a drug that blocks acetylcholine, which raises the possibility of an endogenous source of anticholinergic activity that may possibly increase during times of stress.[35,46] Among elderly nursing home residents, serum anticholinergic activity seems to increase during illness and declines upon recovery, regardless of medication changes.[47]

In the presence of central anticholinergic toxicity, the use of physostigmine (a 1- to 2-mg test dose) may rapidly improve mental status. However, this drug has many severe side effects, including increased secretions, bronchospasm, vomiting, aspiration, and bradycardia, so its routine use cannot be advocated in the elderly.[10] The value of acetylcholinesterase inhibitors such as donepezil in this setting is unclear. Often, removing the causative agent and offering supportive care may be sufficient.

In summary, the likelihood of developing delirium following ingestion of an anticholinergic is unpredictable and may depend on other concomitant medications that exert anticholinergic effects, baseline cognitive status, pharmacokinetic or pharmacodynamic effects, specific agent used, and the total anticholinergic burden.[18]

It should also be stated that despite all of this evidence, the association between anticholinergic drugs and the development of delirium is not universally accepted. Francis and coworkers [4] and Schor and colleagues[48] failed to demonstrate causality between the use of these agents and the development of delirium in elderly medical inpatient populations. Yet others have felt that the lack of association between delirium and anticholinergic drugs in epidemiologic studies is one of misclassification of drug effects rather than the inability of the anticholinergic effects of drugs not to produce delirium.[14]

Anticonvulsants

All anticonvulsants can affect cognition, even in the presence of therapeutic drug levels. They may cause drug-induced delirium or dementia. These effects appear to be dose related. Further, repeated episodes of uncontrolled seizures can adversely affect cognition. Phenobarbital, primidone, and clonazepam have a greater negative impact on cognition than do valproic acid, carbamazepine, or phenytoin. The mental status changes of phenytoin, phenobarbital, and primidone may be attributable to interference with normal folate mechanism.[30] In the elderly, it is important to check both serum albumin and serum creatinine when dosing phenytoin, because both hypoalbuminemia and an elevated serum creatinine necessitate lowering the dose administered. Newer anticonvulsants may also have a lower risk of cognitive impairment.[1,18] The Neurotoxicity Scale has been developed to help assess the adverse effects of anticonvulsants on cognitive function. The revised version of the Neurotoxicity Scale consists of 24 questions. Among the domains tested are fatigue, slowing, memory, concentration, language, and motor coordination. Although this scale may be useful for identifying the presence or absence of an antiepileptic drug-induced side effect, it is unsuitable for determining the type or severity of this event because it produces a global or "all or none" evaluation of whether a person on an antiseizure medication is experiencing cognitive impairment. This scale is self administered by the patient. Further, it has been tested primarily in younger patients (average 34.1 years). Therefore, it may have limited utility in assessing the drug-induced cognitive impairment of an elderly person who is already confused or delirious or who may be on a complex medication regimen.[49] Use of monotherapy and maintenance of serum concentrations within the therapeutic range (for older agents with therapeutic drug monitoring available) may help to minimize cognitive changes.

Antidepressants

It is important to note that in the elderly, depression may present as pseudodementia. Therefore, cognitive impairment can be induced by the disease process itself. However, tricyclic antidepressants are notorious for producing adverse CNS side

effects such as delirium, disorientation, and memory impairment in the elderly owing to their highly anticholinergic properties. The most common and specific feature of tricyclic-induced cognitive impairment in the elderly is impaired short-term recall memory.[50] Other types of impairment include reduced reaction time, impaired retrieval from secondary memory, and impaired information processing.[1]

Confusion or agitation developed in approximately 5% of elderly depressed patients who received either amitriptyline or imipramine.[51] The former agent has been associated with impaired cognitive performance. Preskorn and Jerkovich[52] found that 6% of patients administered tricyclics experienced CNS toxicity. Tricyclic antidepressants can also induce a Creutzfeldt-Jakob-like dementia.[19]

The use of tricyclic antidepressants has fallen out of favor for use among patients in this age group because of their side-effect profile and the availability of newer, safer classes of antidepressants. However, if tricyclic antidepressants are to be used in the elderly, 2 agents have been preferred because of their more favorable risk-to-benefit ratio. These drugs are nortriptyline and desipramine. Kutcher and Shulman[53] describe the first case report of desipramine-induced delirium in an elderly woman with a subtherapeutic serum desipramine concentration. This 68-year-old woman had initially been started on 25 mg of desipramine. After 1 week her dose was increased to 50 mg. Within 3 days of the dosage increase, this woman started experiencing bouts of confusion, demonstrated inattentiveness and hypoalertness, and had disorganized speech. Her serum desipramine level, which was drawn 13 hours after her last dose, was 112 nmol/L (therapeutic range: 500-1000 nmol/L). The drug was discontinued and 3 days later, she was back at her baseline mental state.

In general, risk factors for drug-induced delirium are high tricyclic antidepressant plasma concentration, advanced age, and female gender.[18]

Trazodone, a nontricyclic antidepressant, is also associated with impaired cognition.[1] Confusion is one of the most common side effects of nefazodone, a compound structurally related to trazodone.[30]

Fortunately, newer medications that are devoid of anticholinergic properties, such as SSRIs and reversible inhibitors of monoamine oxidase (not yet available in the United States) may actually improve cognitive function as witnessed by improved vigilance, attention, memory, and psychomotor performance in some studies. This effect may be unrelated to their antidepressant properties.[50] Yet, when these drugs are combined with other medications, caution may be advised.[54] Whereas the reversible monoamine oxidase inhibitors may have less effects on cognition, older monoamine oxidase inhibitors such as tranylcypromine have been associated with adverse CNS effects.[2] Fluoxetine has been associated with the development of acute organic brain syndrome.[55] Caution is also advocated in the face of antidepressant-induced electrolyte imbalances (eg, SSRI-induced hyponatremia). In the case of SSRIs, one also needs to be concerned about the development of serotonin syndrome, which is characterized by delirium, autonomic instability, hyperreflexia, ankle clonus, tremor, diarrhea, and rigidity.[9,18] Serotonin syndrome may occur when SSRIs are combined with tramadol.[30]

Antiparkinsonian Agents

Approximately 20% to 30% of patients with Parkinson's disease have a concomitant dementia.[1] As with patients with other neuropsychiatric conditions, Parkinson's patients may be especially prone to the development of drug-induced cognitive impairment. One of the drugs that is most often associated with changes in mental status is levodopa. About 5% of patients develop delirium from the use of this drug,[56,57] although cognitive symptoms may occur in up to 60% of patients.[30] Yet, not all mental status changes are delirium; patients may experience isolated hallucinations while maintaining a clear state of consciousness, and this would not be considered delirium. Early clues to possible worsening cognitive function may include abnormal dreaming and sleep disturbances.[30] If these signs occur, lowering the dose of medication may be helpful. A relative excess of dopamine has been proposed as a possible cause of delirium.[13] Risk factors for drug-induced confusion include increasing age, dementia, and high doses of antiparkinsonian drugs.[1] As mentioned earlier, anticholinergic drugs used in Parkinson's disease can cause cognitive impairment. If dementia is present, Parkinson's patients on anticholinergic agents may be more than twice as likely to develop delirium compared with nondemented Parkinson's patients.[58] Amantadine's adverse cognitive effects may be dose dependent. The dose needs to be reduced in the elderly because of decreased renal function. High-potency dopamine agonists, such as pergolide, may be associated with higher rates of delirium than levodopa, with altered mental function occurring in 11% to 33% of patients. Bromocriptine can induce mental status changes even when used in low doses. Drug-induced delirium is also common with selegiline. Psychiatric side effects to these medications may become more common as the disease progresses. If these medications were to be ranked by their potential to cause cognitive changes, anticholinergic Parkinson's drugs would have the highest propensity, whereas bromocriptine, levodopa, and selegiline would be associated with medium degree of risk.[18] If a patient develops drug-induced cognitive impairment while on multiple antiparkinsonian agents, it may be beneficial to slowly withdrew the anticholinergics, selegiline, and amantadine before removing other agents from the regimen.[1]

Antipsychotics

As with other psychoactive medications, the risk of developing drug-induced cognitive impairment may be dose related. However, age may also be a significant risk factor for the development of this condition. Many traditional antipsychotics possess anticholinergic properties (eg, thioridazine, chlorpromazine, trifluoperazine), which may partly explain the predisposition of this class of drugs to the development of delirium and accelerated cognitive decline. One of the newer atypicals, clozapine, is also highly anticholinergic. Other atypicals that are devoid of significant anticholinergic effects, such as risperidone, appear less likely to cause drug-induced delirium. Such drugs as thioridazine and chlorpromazine may have a medium potential to induce cognitive changes, whereas risperidone has a low risk of such an event. The possibility of neuroleptic malignant syndrome should also be ruled out in patients in whom delirium develops shortly after the administration of an antipsychotic. Neuroleptic malignant syndrome is characterized by delirium, fever, autonomic dysfunction, extrapyramidal syndrome, and recent history of antipsychotic use.[9,18] One flaw in some of the studies on delirium and major tranquilizer use is that they fail to distinguish whether antipsychotics were the cause of delirium or were used to treat the delirium.

Cardiac Medications/Antihypertensives

This category includes the antiarrhythmics (eg, digoxin, amiodarone, lidocaine, disopyramide, procainamide, quinidine, flecainide, mexiletine, propafenone, tocainide), dipyridamole, and antihypertensives such as beta-blockers (eg, propranolol), methyldopa, clonidine, reserpine, calcium channel blockers, and angiotensin-converting enzyme inhibitors (ACEIs).[5,10,18] It is important to keep in mind that hypertension itself is a risk factor for vascular dementia and that aggressive lowering of blood pressure may also have a deleterious effect on cognition. Uncontrolled blood pressure and plasma lipids may lead to vascular dementia.

Among the antihypertensives that historically have been associated with significant adverse CNS effects (both delirium and dementia) is methyldopa. This drug produces cognitive impairment and decreased visual motor performance.[4] Methyldopa acts like a false neurotransmitter being converted to alpha-methyl-noradrenaline. In general, centrally acting antihypertensives such as clonidine and guanabenz are associated with more adverse cognitive effects. Reserpine irreversibly damages noradrenergic storage granules, thereby inducing altered mental function.[19] Dipyridamole has been associated with decreased Mini-Mental Status Examination scores.[59] CNS effect may be the first and only manifestation of digoxin toxicity and may be even more common than cardiac effects.[60] Both delirium and dementia can be signs of digoxin toxicity.

Cognitive changes can occur even in the presence of therapeutic digoxin levels.[61] Amiodarone's long half-life may promote prolonged confusion. Diuretics can cause fluid and/or acid-base imbalances, which can result in confusion, especially in the postoperative patient. CNS toxicity is common with lidocaine. Beta-blockers can be associated with pseudodementia. The incidence of neuropsychiatric toxicity ranges from 1% to over 20%.[30] Although controversial, less lipophilic beta-blockers may be preferred over highly hydrophilic agents as a way to reduce possible CNS adverse effects. Topical beta-blockers used for glaucoma have also been associated with the development of delirium.[2]

For drugs such as ACEIs, calcium channel blockers, and amiodarone, drug-induced delirium may represent an idiosyncratic event. The risk of cognitive impairment remains low for such drugs as diuretics and ACEIs. Other drugs, including quinidine, digoxin, methyldopa, alpha-blockers, postganglionic blockers, and beta-blockers, may have a medium risk of inducing such changes.[2,18]

Chemotherapeutic Agents

Drugs, either alone or when combined with other treatment modalities in cancer in the presence of a compromised host, can cause adverse CNS effects. For example, cognitive impairment induced by methotrexate is enhanced when this drug is administered to a patient undergoing cranial radiation. Among the chemotherapeutic agents that have been identified as causing delirium are carmustine, vincristine, vinblastine, L-asparaginase, ifosfamide, intrathecal procarbazine, high-dose cytosine arabinoside, methotrexate, 5-fluorouracil, hexamethylmelamine, etoposide, nitrogen mustard, lomustine, dacarbazine, and cytarabine.[2,5] Adjunctive agents such as antiemetics, cyclosporin, biologic response modifiers (interferon, interleukins) and corticosteroids are causally related to the production of mental status changes. Interleukins (eg, IL-2) may produce drug-induced dementia by increasing the blood-brain barrier's permeability to neurotoxins; by activating inappropriate central neuropeptidergic systems that impair attention, registration and memory; or by a direct neurotoxic effect. Cyclosporin's adverse CNS effects may be attributable to similar mechanisms, as it inhibits IL-1 and IL-2.[19] The actual propensity for each drug to cause cognitive impairment is unclear because these medications are often used in combination as part of treatment protocols.[2,5]

Corticosteroids

One of the proposed theories of what causes delirium is increased CNS cortisol levels. Exogenously administered corticosteroids may produce a similar effect. Corticosteroids can induce both delirium and chronic cognitive impairment as well as psychosis. Use of high-dose steroids (> 80 mg/day of prednisone), long duration of use, or the abrupt discontinuation of these hormonal agents can induce mental status changes. Even brief exposure to high doses of steroids can reversibly affect neuronal activity in the hippocampus, the area of the brain associated with memory; with continued use, permanent injury occurs. Overall, there is a medium risk of cognitive-induced impairment secondary to this class of drugs.[18] In addition to high dose, female gender and concomitant neuropsychiatric disease are predisposing risk factors for drug-induced mental status changes.[30]

Herbal Products

There is a misconception among consumers that because a product is natural or herbal it is without toxicity. A recent report has linked the use of St. John's Wort to the development of mania.[62] In another report, 2 patients developed encephalopathy and neuropathy following the ingestion of a Chinese herbal broth that contained podophyllin.[63] Melatonin use may be associated with the development of confusion.[64-66] Most recently, the FDA has warned of the potential neurotoxic effects of GHB or gamma-butyrolactone, a substance whose uses include sleep induction, release of growth hormone, enhancement of sexual activity and athletic performance, relief of depression, and prolongation of life.[67]

H2 Antagonists

All histamine-2 (H2) receptor antagonists have been associated with acute CNS toxicity, including delirium.[18,68] The drug that has received the most attention as being associated with medication-induced delirium is cimetidine. Cimetidine is thought to possess anticholinergic properties. Whether or not this explains it, its association with the development of delirium is unclear. However, cimetidine-induced delirium has been reversed with the use of physostigmine.[1,69] Cantu and Korek[70] found that there was no difference among the H2-blockers in their propensity to cause CNS changes. Among hospitalized patients, about 1% to 2% develop drug-induced cognitive changes compared with 15% to 80% of intensive care unit patients.[18] Advanced age and impaired renal function may be risk factors for the drug-induced CNS changes. Nonetheless, the overall risk of H2-antagonist-induced cognitive impairment is low.

Hypoglycemic Agents

Insulin and oral hypoglycemic agents may cause both reversible and irreversible brain damage secondary to hypoglycemia, which may result in cognitive loss.[71]

Lithium

Lithium may impair memory and psychomotor performance. It is also associated with the development of delirium. Lithium has a high risk of inducing cognitive impairment. It may induce a Creutzfeldt- Jakob-like dementia. Its ability to produce dementia may be related to its inhibition of protein kinase C, which results in interference of regulatory processes of neuronal growth and differentiation. Lithium's toxicity is potentiated by drugs such as thiazide diuretic and nonsteroidal anti-inflammatory agents, which interact with this drug to produce higher lithium levels.[1,2,18,72,73]

Narcotic Analgesics

It is important to recognize that untreated pain itself can cause delirium. However, narcotics can also induce this condition, especially among postoperative patients. Narcotics are among the primary causes of delirium in the postoperative patient. The risk of drug-induced delirium may be highest with meperidine. In one study, among individual narcotic agents studied, only meperidine was significantly associated with the development of delirium (odds ratio 2.7) among postoperative patients aged 50 or older.[46] Meperidine has long been recognized as a drug that should not be given to older persons because this age group undergoes an age-related decline in renal function, which allows for accumulation of normeperidine, a neurotoxic substance. The delirium induced by meperidine has been characterized by fluctuations in levels of awareness, confusion, disorientation, illusions, visual and auditory hallucinations, persecutory delusions, and seizures. Further, both meperidine and normeperidine have anticholinergic properties. This drug was originally developed as an antispasmodic alternative to atropine during the 1930s. Meperidine's toxicity may be more pronounced when this drug is combined with the enzyme inhibitor cimetidine or with other drugs possessing anticholinergic activity.[74] Francis and colleagues[4] and Schor and others[48] also found a correlation between the use of narcotics and the development of delirium. The route of administration (eg, intramuscular vs patient-controlled analgesia) may also influence the risk of developing drug-induced delirium. Epidural and

intramuscular administration may be more problematic than patient-controlled analgesia.[1] Even tramadol has been associated with drug-induced confusion.[30]

Nonsteroidal Anti-Inflammatory Agents (Including Salicylates)

Aspirin use may pose a problem in the elderly because older patients may not even consider this substance a medication. This age group is more prone to having pains and aches and is therefore more likely to use this drug. Delirium is the major manifestation of salicylate toxicity. Confusion can also occur at therapeutic doses. Acetaminophen, while safe in usual doses, may also cause cognitive impairment in an overdose situation. Drug-induced cognitive effects from nonsteroidal anti-inflammatory agents range from delirium with indomethacin (medium risk for cognitive changes) and sulindac to disturbances in memory and concentration with naproxen and ibuprofen (low risk for cognitive changes).[18] However, in light of recent data that nonsteroidal anti-inflammatory agents may be protective against the development of Alzheimer's disease, the role of these agents in inducing cognitive impairment needs to be clarified. It may be that high doses (not therapeutic doses) of nonsteroidal anti-inflammatory agents have an adverse effect on cognition.[1]

Over-the-Counter Products

The elderly consume a large amount of over-the-counter medications. These medications, which are often less expensive than prescription drugs, may be used by older adults in an attempt to save money and to help maintain their independence. However, these medications, especially cough/cold products, sleep aids, and antinausea agents, contain potent anticholinergic substances that can induce delirium in older persons. Oral decongestants such as phenylpropanolamine and pseudoephedrine can also cause delirium in the elderly. Mental status changes associated with the use of decongestants may occur with low doses and topical administration.[30]

Promotility Agents

Metoclopramide has been associated with the development of drug-induced delirium.[75] This drug crosses the blood-brain barrier and effects both dopaminergic and cholinergic systems. Cisapride, a newer promotility agent, may have fewer CNS effects; however, it is associated with very serious drug interactions, so caution is advised when using this agent.

Proton Pump Inhibitors

Omeprazole may be associated with neuropsychiatric adverse effects, especially in older patients and in patients with liver disease.[30,76]

Sedative-Hypnotics

This class of drugs includes benzodiazepines such as flurazepam and diazepam, barbiturates, meprobamate, chloral hydrate, and sedating antihistamines, which are found in over-the-counter sleep aids. Long-acting benzodiazepines, such as flurazepam, especially if used in high doses, are the most likely drugs to cause or exacerbate dementia. Shorter-acting drugs, such as diazepam or temazepam, have a medium risk of causing drug-induced cognitive impairment.[18] CNS toxicity is often dose dependent.

In one study, exposure to long-acting benzodiazepines was significantly associated with the development of delirium (odds ratio 3.0) among postoperative patients aged 50 or older.[45] Another study found that 11% of older patients admitted to a general hospital developed cognitive impairment following benzodiazepine use.[77] Benzodiazepines have been associated with impaired learning of verbal and visual information,[1] immediate and delayed memory, and psychomotor performance.[78] The psychomotor and cognitive impairment may be persistent with long-term use of benzodiazepines. Anterograde amnesia occurs more commonly with higher potency and shorter-acting benzodiazepines, thereby limiting the usefulness of these medications.[1]

Barbiturates can cause chronic cognitive impairment, which may mimic Alzheimer's disease. The sedation produced by sedative-hypnotics may lower the elderly person's threshold for developing drug-induced delirium or dementia.[18] Even newer agents such as zolpidem are associated with adverse cognitive effects similar to those seen with triazolam. Zolpidem produces memory impairment that corresponds to its peak blood concentration.[79]

Theophylline

Although theophylline may be associated with drug-induced cognitive impairment, it is unlikely to occur when this drug is used in usual doses.[1] Most adverse cognitive effects ("theophylline madness") occur in an overdose situation. If overdose occurs, one must be very watchful for seizures, which may soon develop if they are not present already.[30]

Urinary Antispasmodics

These drugs (eg, oxybutynin, flavoxate) induce delirium either via their anticholinergic effects or by causing urinary retention ("cystocerebral syndrome"). This latter condition is thought to be related to an increase in adrenergic tone, which leads to increased peripheral and CNS catecholamine levels. Risk factors for this condition include benign prostatic hypertrophy, dementia, and diabetes associated with autonomic dysfunction.[30]

Withdrawal Effects

Delirium associated with the withdrawal of centrally active psychotropics such as benzodiazepines, barbiturates, or alcohol may be attributable to understimulation of the inhibitory neurotransmitter GABA, which leads to symptoms of hyperactivity.[13] In the surgical patient, withdrawal from alcohol resulting in delirium may not manifest until 12-48 hours after surgery.[16] In the elderly, mortality associated with alcohol withdrawal-induced delirium tremens may be as high as 27%.[60] It is important to keep in mind that although the discontinuation of anticholinergic drugs is encouraged, rapid withdrawal of these agents may result in cholinergic rebound. This has been noted with clozapine, among other drugs.[61]

Strategies to Prevent Drug-Induced Cognitive Impairment in the Elderly

Perhaps the single most important step one can take to minimize the risk of drug-induced cognitive impairment is to administer the least possible number of medications to older patients, thereby avoiding the problem of polypharmacy. Proper dose adjustments based on age and renal or hepatic function are also necessary. Elderly patients should be encouraged to discuss all of their over-the-counter drug purchases with either their pharmacist or physician. Having a high index of suspicion that a drug may be likely to cause cognitive impairment is also one of the main ways to help prevent this problem in the elderly. It is important to be familiar with the known risk factors for cognitive impairment. Whenever possible, every attempt should be made to avoid high-risk medications such as sedative-hypnotics and drugs with anticholinergic effects, as well as other drugs that may readily cross the blood-brain barrier.

Pain needs to be adequately controlled. In patients experiencing mild pain symptoms, drugs such as acetaminophen or the cyclooxygenase-2 nonsteroidal anti-inflammatory agents may be tried instead of narcotics. If a patient has already been receiving a psychoactive medication for a long time and discontinuation is desired, a gradual dose reduction should be employed, because abrupt cessation may lead to withdrawal symptoms and delirium. Maintaining adequate nutritional and fluid status is also helpful. Caution is especially advised in patients with dementia whenever a new medication is prescribed. It may be helpful to obtain a baseline mental status examination in all elderly patients so that subtle changes can be identified early. Should a problem arise, ascertaining the likelihood that a drug may be associated with cognitive impairment may help determine which drug or drugs to eliminate first from the regimen.

Tables

Table 1. Differential Diagnosis of Delirium and Dementia

Feature	Delirium	Dementia
Onset	Abrupt, acute (sometimes subacute) with an identifiable date	Gradual, chronic, insidious
Course	Fluctuates during day with worsening of symptoms at night	Consistent pattern—no diurnal variation; may develop sundowning in later stages of disease
Duration	Hours to weeks/months in elderly (some permanent residual effects may remain)	Progressive, continuous
Interaction with environment	Reduced awareness Fluctuating alertness	In early stages, no problem with awareness

	Impaired attention Orientation impaired and fluctuating	In early stages, normal alertness Relatively unaffected, especially in early stages Often impaired
Memory	Immediate and recent impaired	Recent memory initially impaired; as it progresses, remote impaired
Thought process and language	Disorganized, distorted, fragmented, incoherent speech, global cognitive impairment	Perseveration and confabulation, difficulty with abstraction, thoughts impoverished, judgment impaired, agnosia, anomia
Perception	Distorted with illusions, delusions, and hallucinations (visual and auditory) and difficulty distinguishing reality from misperceptions and psychomotor disturbances (hypo- or hyperalertness or mixed state)	Early stage minimally affected; later stages may be associated with delusions and hallucinations
Sleep	Always disrupted with reversal of sleep-wake cycle	Fragmented sleep
Mental status testing	Distracted, often unable to participate in testing	Usually tries hard; often tries to hide deficiencies

Adapted from Weinrich and Sarna,[5] Lipowski,[6,11,23] Flacker and Marcantonio,[14] Espino et al,[22] Dessonville et al.[24]

Table 2. Acute Change in MS

Initial	Drug Class
A	Antiparkinsonian drugs
C	Corticosteroids
U	Urinary incontinence drugs
T	Theophylline
E	Emptying drugs
C	Cardiovascular drugs
H	H2-blockers
A	Antimicrobials
N	NSAIDs
G	Geropsychiatric drugs
E	ENT drugs
I	Insomnia drugs
N	Narcotics
M	Muscle relaxants
S	Seizure drugs

Adapted from Flaherty.[30]

Emptying drugs: a class of drugs that stimulate motility of the upper gastrointestinal tract (eg, metoclopramide)

Geropsychiatric drugs: includes any drug that works in the brain and that can cause confusion (eg, tricyclic antidepressants, SSRIs, benzodiazepines, antipsychotics, anticholinergics)

ENT drugs: ear, nose, and throat; agents taken for ailments of the respiratory and sinus passageways (eg, decongestants, antihistamines, expectoranta, antitussives)

Table 3. Drugs Identified in HCFA's Revised Nursing Home Guidelines That Have CNS Adverse Effects

Drugs	Adverse Effects
Pentazocine	Confusion, hallucinations, dizziness, lightheadedness, euphoria, and sedation
Long-acting benzodiazepines	Sedation, drowsiness, ataxia, fatigue, confusion, weakness, dizziness, vertigo, syncope, psychological changes
Amitriptyline	Anticholinergic and sedating properties, which can result in confusion, delirium, or hallucinations
Doxepin	Anticholinergic and sedating properties, which can result in confusion, delirium, or hallucinations
Meprobamate	Highly addictive and sedating, which can result in drowsiness and ataxia
Disopyramide	Strongly anticholinergic properties, which can result in confusion, delirium, and hallucinations
Digoxin	Toxic signs include headache, fatigue, malaise, drowsiness, and depression
Methyldopa	May exacerbate depression
Chlorpropamide	Hypoglycemia, which can result in altered mental state (confusion, amnesia, coma)
GI antispasmodics	Highly anticholinergic properties, which can result in confusion, delirium, or hallucinations
Barbiturates	Highly addictive and sedative, resulting in drowsiness, lethargy, depression, severe CNS depression
Indomethacin	Headache, dizziness, vertigo, somnolence, depression, fatigue
Reserpine	Depression, sedation
Diphenhydramine	Highly anticholinergic, which can result in confusion, delirium, or hallucinations
Muscle relaxants	Anticholinergic properties, which can result in sedation, weakness, confusion, delirium, or hallucinations
Antihistamines	Anticholinergic properties, which can result in confusion, delirium, or hallucinations
Trimethobenzamide	Extrapyramidal side effects

Adapted from Health Care Financing Administration.[33]

Table 4. Anticholinergic Drug Level

Medication	Anticholinergic Drug Level (ng/mL of atropine equivalents)

Captopril	0.02
Cimetidine	0.86
Codeine	0.11
Digoxin	0.25
Dipyridamole	0.11
Dyazide	0.08
Furosemide	0.22
Isosorbide dinitrate	0.15
Lanoxin	0.25
Nifedipine	0.22
Prednisolone	0.55
Ranitidine	0.22
Theophylline	0.44
Warfarin	0.12

Adapted from Tune et al.[36]

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Collaborative Practice Agreements by State

STATE	CDTM	Year	S,R,G*		STATE	CDTM	Year	S,R,G*
Alabama	No				Missouri	No		
Alaska	No				Montana	No		
Arizona	YES	2000	S		Nebraska	YES		S
Arkansas	YES		S		Nevada	YES		S
California	YES	1995	S		New Hampshire	No		
Colorado	No				New Jersey	No		
Connecticut	No				New Mexico	YES	1978	S
Delaware	No				New York	No		
DC	No				North Carolina	Yes	1999	S
Florida	YES		S		North Dakota	YES		S
Georgia	YES	2000	S		Ohio	YES	1999	S
Hawaii	YES		S		Oklahoma	No		
Idaho	YES	1998	R		Oregon	YES	1998	R
Illinois	No				Pennsylvania	No		
Indiana	YES		S		Rhode Island	No		
Iowa	YES	1996	G		South Carolina	YES	1998	S
Kansas	YES	1996	S		South Dakota	YES		S
Kentucky	YES	1982	S		Tennessee	No		
Louisiana	YES	1993	S		Texas	YES	1997	S
Maine	No				Utah	No		
Maryland	No				Vermont	YES		R
Massachusetts	No				Virginia	YES	1999	S
Michigan	YES	1994	S		Washington	YES	1991	S
Minnesota	YES	1999	S		WestVirginia	No		
Mississippi	YES		S		Wisconsin	No		
					Wyoming	YES		R

CDTM - Collaborative Drug Therapy Management (also known as Collaborative Practice)
S - Statute
R - Regulation
G - Guideline

November 2000 - ASHP

ASCP ANALYSIS OF MEDICAID PHARMACY AWP CHANGES 1/02

State	Ingredient Reimbursement	Dispensing Fee	2002 Changes	LTC Add-on
Alabama	WAC+9.2%	$5.40		No
Alaska	AWP-5%	$3.45 - $11.46		No
Arizona	Managed Care: AHCCCS Program		Discount Card Legislation	No
Arkansas	AWP-10.5%	$5.51	Proposal (AWP-14%-B; AWP-25% or FUL-G,	No
California	AWP-5%	$3.80		No
Colorado	AWP-11%	$4.08		No
Connecticut	AWP-13%	$4.10		No
Delaware	AWP-12%	$3.65		No
Florida	AWP-13.2%	$3.15 - $4.23		Yes - $.50
Georgia	AWP-10% (MFN)	$4.63	Pharm Study - Commissioner not supportive	No
Hawaii	AWP-10.5%	$4.67		No
Idaho	AWP-11%	$4.54	PA after 4 drugs	Yes - $1.00
Illinois	WAC+8%/12%	$4.17		No
Indiana	AWP-10%	$4.00	Rule-AWP-13%, disp. fee $3.00/Pharm Study	No
Iowa	AWP-10%	$4.13 - $6.42		No
Kansas	AWP-10%	$4.82		No
Kentucky	AWP-10%	$4.51	Bud. Proposal-AWP-12%,exempt from disp. fee decrease	Yes - $.02 for manu un
Louisiana	AWP-15%/16.5% (tiered)	$5.77		No
Maine	AWP-10% (MFN)	$3.35 (extra fees for compounding)		No
Maryland	WAC+10% or AWP-10% (lowest of to fit E	$4.21	Proposal AWP-13%	Yes - $1.40
Massachusetts	WAC+10% (MFN)	$3.00		No
Michigan	AWP-13.5% (5+ stores=AWP-15.1%)	$3.77	Appealing Drug Formulary Program	No
Minnesota	AWP-8%	$3.65	AWP-14%, Disp. Fee $4.15	Yes - $0.30
Mississippi	AWP-10%	$4.91	Lowest State, Bud. Proposal - $2.50	No
Missouri	WAC+10%	$4.09		Yes - $0.15
Montana	AWP-10%	$2.00 - $4.20	Minus 2.6% from Medicaid	No
Nebraska	AWP-8.71%	$2.84 - $5.05		No
Nevada	AWP-10%	$4.64		No
New Hampshire	AWP-12%	$2.50		No

MFN = Most Favored Nation
OP = Outpatient
LTC = Long-Term Care
B = Brand
G = Generic

Prepared by ASCP

ASCP ANALYSIS OF MEDICAID PHARMACY AWP CHANGES 1/02

State	Ingredient Reimbursement	Dispensing Fee	2002 Changes	LTC Add-on
New Jersey	AWP-10%(G); AWP-15%(B)	$3.73 - $4.07		Yes - Varies
New Mexico	AWP-12.5%	$4.00		No
New York	AWP-10%	B: $3.50, G: $4.50	Bud. Proposal-AWP-15%-defeated	No
North Carolina	AWP-10%	$5.60(G); $4.00(B)		No
North Dakota	AWP-10%	$4.60		No
Ohio	AWP-11.2%	$3.70		No
Oklahoma	AWP-10.5%	$4.15	PDL Legislation	No
Oregon	AWP-13%	$3.80 for unit dose/ $3.50 for all others	Budget Proposal AWP-15 to AWP-20%	Yes - refer to disp. Fee
Pennsylvania	AWP-10%	$4.00		No
Rhode Island	WAC+5%	OP: $3.40, LTC: $2.85		No
South Carolina	AWP-13%	$2.05	JR - reverse disp. fee reduction	No
South Dakota	AWP-10.5%	$4.75		Yes - $0.40 - $0.80 (dep
Tennessee	AWP-13% (MFN)	$2.50		No
Texas	AWP-15% or WAC+12%	$5.27+2% of ingredient		No
Utah	AWP-12%	$3.90(urban); $4.10 (rural)	Gov's Prop. (AWP-15%-B; AWP-20%-G) - def	No
Vermont	AWP-11.9%	$4.25		No
Virginia	AWP-9%	$4.25	Budget Proposal (AWP-11%)	Yes - .0157/tablet
Washington	AWP-11%	$3.98 - $4.92 (based on annual # of Rxs)	Budget Proposal (AWP-20%-B; AWP-65%-G	No
Washington, DC	AWP-10%	$3.75		No
West Virginia	AWP-12%	$3.90 (extra fee for compounding)		No
Wisconsin	AWP-11.25%	$4.88 (minus .50 on claims to $4.38)		Yes - $0.0015/dose (wh
Wyoming	AWP-11%	$5.00		No

MFN = Most Favored Nation
OP = Outpatient
LTC = Long-Term Care
B = Brand
G = Generic

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