OBRA REGS REVISITED
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"Unnecessary" Medications: The Never-Ending Pandemic

Plus ça change, plus c’est la même chose. (The more things change, the more they stay the same.)—Jean-Baptiste Alphonse Karr (1849)

The ongoing events related to COVID-19 have, among other things, once again brought the issue of medications—especially indications, and adverse consequences and interactions—to the forefront. This month I discuss a widespread, long-standing problem: How can we address a non-infectious pandemic of adverse medication consequences by revamping the way we think about and provide care? (“Patient Safety Primer,” Agency for Healthcare Research and Quality, Sept. 2019, https://bit.ly/2zwYjUT).

Nothing New Here
Almost 60 years ago, Dr. Louis Lasagna, a pioneer in clinical pharmacology, pointed out “The Diseases Drugs Cause” and detailed the positive and negative impacts of the pharmacologic revolution since the 1940s (Percept Biol Med 1964;7:457–470). He cited data showing an increasing incidence of iatrogenic complications (those due to medical care). Many of those complications were identified as being drug reactions—for example, gastrointestinal bleeding induced by anticoagulants and salicylates, excessive sedation from barbiturates, and osteoporosis due to steroids. Dr. Lasagna noted that a popular journal of the time had been calling these “Diseases of Medical Progress.” Despite warnings about drug-related adverse consequences, he wrote, “the publicized cases constitute merely the floating tip of an iceberg, with much of the difficulty remaining hidden beneath the surface of our awareness.”

Does this sound familiar? This is not a nostalgia trip, but a serious reality check. As noted six decades ago, all medications are associated with 60 years ago, far more drugs (over 20,000) are available now (Food and Drug Administration, “Fact Sheet: FDA at a Glance,” Oct. 2019, https://bit.ly/2Z0FGcO). Many more licensed health care disciplines have sought and received legal authorization to recommend and prescribe medications. There are far more patients, each presenting far more opportunities to order medications. There also is intense pressure to manage symptoms aggressively—to reduce hospitalizations, prevent alterations among nursing home residents, and address pain.

Despite the awareness campaigns and intensified survey scrutiny for specific medications such as antipsychotics, the same principles have not been applied to all medications. Therefore, many serious medication-related issues (e.g., excessive and inappropriate prescribing of valproic acid and anticholinergic medications) go largely unnoticed and unattended. It is questionable how many internal or external reviewers really look, recognize, or understand the significance of what they see. The fact that consultant pharmacists must review every resident’s medication regimen monthly in no way guarantees that they identify actual adverse consequences or that definitive action ensues (Ther Adv Drug Saf 2011;12:110–12).

Relatively few practitioners are well versed in the indications, interactions, and adverse consequences of commonly prescribed medications. Attending physicians may not adequately oversee their patients’ diagnostic and treatment decisions. Often no one else who is managing the patient will seek or receive sufficient guidance when a patient continues to experience problems, despite multiple medications or medication adjustments.

What to Do About the Drug Problem
For over half a century, the mass media and medical literature have chronicled the drug issue and have admonished practitioners that it represents a cause of substantial human suffering—especially, but not solely, among the frail elderly. Various initiatives such as medication “reconciliation” and “de-prescribing” have been developed and described (JAMA Intern Med 2015;175:827–834), all with relatively modest success (Cochrane Database Syst Rev 2018;9:CD008165; JAMA Netw Open 2019;2:e1910756).

What will we do about the medication problem? Will it continue to be more of the same? Or will we change course? This month I propose that the answer is not to initiate yet more special projects to deal with medications, but rather to build a different way of thinking about all aspects of care—including medications—into our everyday clinical practice and facility operations in all settings. To this end, we have spearheaded approaches that incorporate key principles and facilitate proper medication use.

An Essential Thought Foundation
As a key part of quality assurance and performance improvement (QAPI), every nursing home needs a thought foundation for the appropriate care of all residents/patients. As the Omnibus Budget and Reconciliation Act (OBRA) ‘87 surveyor guidance identifies, all medication use is “based in the care process and includes recognition or identification of the problem/need, assessment, diagnosis/cause identification, management/treatment, monitoring, and revising interventions” (§483.25[i]).

This thought foundation requires that every nursing home and all practitioners adopt the following policy: Recommending and prescribing medications is just as serious a responsibility as recommending or performing surgery. It should never be done casually or taken lightly.

For decades, OBRA surveyor guidance has incorporated standard definitions of unnecessary drugs as any drug when used (1) in excessive dose (including duplicate therapy), or (2) for excessive duration, or (3) without adequate monitoring, or (4) without adequate indications for its use, or (5) in the presence of adverse consequences, which indicate the dose should be reduced or discontinued, or (6) for any combinations of the foregoing. Fast forward three decades, and all of this still applies today.

• Require close adherence to the care delivery process to ensure safe and appropriate prescribing. Deciding whether any resident’s current medications might meet these criteria requires a review of the thinking behind the prescribing. Quality improvement efforts in nursing homes and via regulatory oversight must expect and review for care process adherence. The interdisciplinary team (IDT) and surveyors should question prescribing that lacks evidence of adequate and pertinent underlying reasoning.
• Expect all practitioners to prescribe based on clinically pertinent reasoning that they can explain and document. A capable practitioner can always explain the thinking behind the prescribing, even if it is somewhat empirical or tentative. Guesswork typically lacks such a foundation and is not an acceptable basis for prescribing. Practitioners who cannot or will not provide clinically pertinent thinking underlying their medical decision making and medication selection should have their prescribing authorization limited and/or have their orders reviewed closely.

• Resist the pressure to prescribe on demand. As Dr. Lasagna stated, “Drugs should not be given for trivial reasons—not to mention wrong reasons—and ought never to be prescribed casually. It is quite obvious that in many cases the less the patient is treated the better off he is... The physician must avoid the temptation to overprescribe. There is a great tendency on the part of patients to expect or demand medication, and there is unfortunately a fervor therapeuticus in many physicians which demands that every symptom be treated (almost at the spinal reflex level) by administration of a drug.”

We should hear about resident and family concerns and acknowledge their requests for specific medications and treatments, but recognize they are unlikely to understand causation or know the indications and risks for various medications. The Centers for Medicare & Medicaid Services State Operations Manual (SOM) states, “the regulations do not require the facility to provide specific medical interventions or treatments requested by the resident, family, and/or resident representative that the resident’s physician deems inappropriate for the resident’s medical condition” [11/17, Guidance §483.10(c) (2)–(3)].

• Encourage IDT members to share objective resident data with medical practitioners. The IDT should focus on collecting, organizing, documenting, and reporting objective details that can help define the issues and identify causes. Requests from staff for specific medications are often premature and invariably not based on meaningful consideration of the underlying causes of symptoms, including side effects of existing medications.

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The consultant pharmacist can be helpful to prescribers by including information that is relevant to medication selection (J Am Med Dir Assoc 2007;8:55–64). However, knowing about medications (e.g., psychopharmacologic medications) is not the same as knowing how to manage specific conditions and symptoms with specific medications in light of all relevant considerations.

- **Strictly limit prescribing in silos.** In all human beings, all organ systems are closely linked, and all dimensions (physical, functional, and psychosocial) closely interact (Caring for the Ages 2020;21[2]:10,11). Contraindicated combinations and adverse interactions among medications are common. Someone has to oversee and coordinate all the medications.

  Naturally, different practitioners will see the same patient at different times. But prescribing in “silos” (attending physician, nurse practitioner, consultants, hospices, pain clinics, psychiatric consultant, etc.) is never a sound practice — it is a recipe for likely harm. We must expand the notion of medication “reconciliation” to include scrutinizing the relevance of all prescribing. Consultations are sometime necessary and helpful, but they also may be excessive and lack coordination. While collaboration among various practitioners is desirable, ultimately a practitioner must ensure that every medical order is relevant, effective, and safe.

  - **Do not allow consultants (hospices, pain clinics, wound centers) to write orders directly.** Instead, their consultations should be overseen or pass through a capable medical practitioner who oversees and coordinates all prescribing. The attending physician should not abdicate all responsibility or assume that others are overseeing and coordinating all this care without reviewing carefully and confirming periodically that this is happening. It is all too common to see one specialist adding medications to chase the side effects of medications prescribed by a different consultant.

  - **Maintain very tight controls on “phantom” verbal orders.** Occasional protocols may allow various IDT members to write in the order sheet for limited reasons. However, the use of the order sheet for “phantom” orders for tests and medications (alleged verbal orders, to which someone applies a practitioner’s name but are not based on direct instructions from a practitioner) should be prohibited. As identified in a significant study by AMDA – The Society for Post-Acute and Long-Term Care Medicine (Caring for the Ages 2009;10[12]:1-14), this has become a disturbingly common practice and a thinly disguised route to misguided and inappropriate clinical decision making.

  - **Include medication-related adverse consequences in all differential diagnoses of all symptoms and problems.** Because all medications can potentially cause adverse consequences, we must maintain a high index of suspicion. As noted 60 years ago and repeatedly since then, many practitioners do not recognize or may deny that their patients’ symptoms may be related to or exacerbated by their medications (Washington Post, Aug. 28, 2007, https://wapo.st/3cFgbNa; Front Pharmacol 2016;7:358).

  We must include a careful review of every patient’s medication regimen as part of the required periodic care plan reviews under OBRA as well as for all new symptoms and changes of condition. We must integrate the medical plan of care with the IDT care plan. We must challenge and question situations where the drug regimen is left unchanged despite suspected or confirmed adverse consequences, without adequate pertinent justification.
M. G is ticked off. The 58-year-old man arrived at your facility about two days ago after a hospital stay for alcohol withdrawal and sepsis. Upon admission, you fielded several questions from him about how soon you would “let me out of here.”

“This is not a prison, Mr. G. You can leave anytime you want,” you tell him. “But your family was hoping that you would stay until you’re able to get around your apartment safely. You also need to finish your IV antibiotics for alcohol withdrawal and sepsis. Upon your discharge, we will need to check less frequently as most medications’ indications, doses, and risks rarely change significantly (Am J Med 2000;109:87–94)."

Autonomy

As a modern health care professional you are obligated to recognize patients’ rights to make decisions (good and bad) for themselves. Mr. G seems to be reacting to a situation in which his autonomy is being threatened. He’s being forbidden to practice a habit (smoking) that is a legal activity in all 50 states, he’s had his personal property confiscated, and he suspects you are trying to hold him against his will. It may seem counter-intuitive, but the one thing that could most convince Mr. G to stay is letting him know he can leave.

One of the primary things that drives people to leave AMA is the loss of control over their health (Acad Emerg Med 2014;21:1050–1057). Reassure Mr. G by telling him the truth: “You can leave anytime you want.” Then work to encourage him to stay by helping him regain control over his situation. How can you partner with Mr. G to maximize his autonomy? Perhaps there is some wiggle room in the center’s smoking policy. Can you allow him to smoke e-cigarettes? Can the facility designate a smoking area? (I do think that nonsmoking policies in nursing communities are one of the greatest violations of resident autonomy in the industry, but I digress.)

One caveat: Mr. G’s decision must be informed, and he must have medical capacity. He must be able to appreciate his disease and the risks and benefits of treatment. He must also be able to express his decision about his care. This is all involved in assessing his medical capacity. Learn how to use a tool like the Joint Centre for Bioethics’s Aid to Capacity Evaluation (ACE) (available for free at http://www.jcb.utoronto.ca/tools/documents/ace.pdf), and document that your patient is capable of an informed decision. You can do this in 10 minutes or less, and it’s really helpful in case you’re threatened with legal action in the future.

Let’s say you have established that Mr. G has medical capacity, you’ve reminded him that you will respect his autonomy, and you’ve expressed your concern for his health, but he still plans on leaving — right now, with his Winstons and lighter in hand. Everyone’s in a bit of a panic — you huddle with the unit supervisor, director of nursing (DON), and the administrator. You’re all worried about Mr. G and his health, of course, but maybe everyone’s a little worried about something else: no one wants to get sued.

Beneficence

The DON suggests that you follow the typical procedure and sign the AMA form, avoiding any further involvement with Mr. G — you don’t want to be seen as enabling dangerous behavior, after all. Here’s the ethical conflict again: if you follow the advice of the DON, you’re stepping aside and letting autonomy take precedence over beneficence. But does it have to be? Here’s the good news: being a good, beneficent provider (and documenting it) is always the best protection against litigation.

Putting off the Uber driver, you use your Sanford guide to find an oral anti-biotic that at least has some of the same spectra of activity and prescribe it for him. You quickly put together a discharge summary and medication list and give it to him. Have the nurse call in any medications Mr. G might need to tide him over, and have the facility make an appointment with his primary care doctor. Following the advice of the DON and avoiding any role in Mr. G’s discharge may actually be seen as a violation of standard of care (J Fam Pract 2000;49:224–227).

As usual, document the steps you have taken not only to determine capacity but to express your concerns for a poor outcome, as well as the steps you have taken to mitigate harm to the patient. If you’re concerned about his safety at home, it wouldn’t hurt to call Adult Protective Services. Get buy-in from your DON and administrator to reassure Mr. G he can return to the facility within the

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All specialists and consultants (e.g., cardiologists, neurologists, urologists, gastroenterologists, psychiatric consultants, and surgeons) should be open to questions about the impact of the medications they recommend or prescribe. Primary care practitioners should assert themselves vigorously as needed.

• Make looking up information about medications mandatory. Everyone is expected to know basic details about the medications they recommend or prescribe. If we do not know what we are prescribing, we must look it up — including the indications, doses, duration, interactions, and adverse consequences. If we do not know this information and do not look it up, we should not prescribe the medication.

Today, just as stated by Dr. Lasagna in 1964, “It may be said without fear of error that many of the drugs now on the market have a potential for causing difficulty that is incompletely appreciated … The physician must have better knowledge about the relative efficacy and toxicity of the compounds available for treating a given condition.” Some of the problematic drugs he mentioned 60 years ago are still around, and even more have become available over the past three decades.

Of the 20,000 or so available medications, fewer than 100 are commonly problematic in PALT patients. Today, it is quick and easy to look up any medication in a minute, using sources such as the Beers Criteria (J Am Geriatr Soc 2019;67:674–694; Am Fam Physicst 2020;101:56–57; Med Lett, Dec 15, 2008, https://secure.medical-letter.org/w130l), and Medscape.com (or its equivalent). At any time we can get a well-organized, comprehensive snapshot of any medication by simply typing the name of the medication and the word “Medscape” into Google (e.g., “amiodarone Medscape”). Once we become familiar with a medication, we will need to check less frequently as most medications’ indications, doses, and risks rarely change significantly (Am J Med 2000;109:87–94).

The Time Is Now (No, Not Tomorrow)

Sixteen years ago, an editorial entitled “The Time Is Now” demanded we not wait any longer to address the huge medication problem in our care of the elderly (Arch Intern Med 2004;164:1603–1604). I am suggesting that we do not appear to be any closer to addressing this multi-generational medication pandemic than we were then — or 60 years ago.

Recommending and prescribing medications are solemn responsibilities that have a profound impact on people’s lives. Prescribing is not a right but a privilege. If prescribing is not based on the care process, it is nothing more than rote practice or guessing.

Any sustained and meaningful improvement in PALT requires a radically different approach across all settings, including every nursing home. However, fundamentally, the necessary approach isn’t “radical” at all. Instead of yet another separate project or initiative about medications, improvement requires the faithful application and oversight of the care delivery process, spearheaded by all AMDA members, with the full support and collaboration of all regulatory bodies and the entire PALTC industry. Otherwise, the problem of medications as a cause of widespread suffering will never end, and the regulatory process cannot fix it.

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