

**TECHNOLOGY AND
PHARMACOVIGILANCE: THE
CODEINE CARE INITIATIVE**

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OUTLINE OF PRESENTATION

- 1) Need for effective pharmacovigilance in detecting drug-related problems
- 2) Role that technology can play in developing mechanisms to effectively monitor and evaluate drug use
- 3) The Codeine Care Initiative as a case study: benefits and weaknesses

1) NEED FOR EFFECTIVE PHARMACOVIGILANCE

IRRATIONAL DRUG USE

- Irrational drug use is a major problem.
- Can lead to drug-related problems (DRP), which can cause patient morbidity and/ or mortality
 - Ernst and Grizzle's (2001) study: the cost of DRP for ambulatory patients in the USA in 2000 was greater than \$177.4 billion
- Can occur due to errors on the part of prescribers, pharmacists, patients and others who may be involved (e.g. nurses, family members of patients)

RATIONAL DRUG USE

- Is medication (prescription/ OTC/ complementary) appropriate for a specific patient?
- In terms of:
 - Drug-disease interactions?
 - Drug-drug interactions (with other medication, including OTC and complementary medicine)?
 - Drug-food interactions?
 - Allergies/ hypersensitivity reactions?

RATIONAL DRUG USE

- Dosage?
- Frequency of administration?
- Dosage form?
- Duration of therapy?
- Age?
- Weight?
- Pregnant or breastfeeding? Or other special-risk population (e.g. elderly, renal failure)?
- Possible effects of excipients?

PHARMACEUTICAL CARE

- Pharmaceutical care is “a practice for which the practitioner takes responsibility for a patient’s drug therapy needs and is held accountable for this commitment” (Cipolle, Strand & Morley, 1997 cited in van Mil, Schulz & Tromp, 2004: 303)
 - Could decrease the potential for DRP
 - Involves taking responsibility for a patient’s health outcomes
 - Not just the domain of pharmacists! Doctors and other health-care professionals can and should play an invaluable role in the provision of pharmaceutical care.

PHARMACEUTICAL CARE

- The Good Pharmacy Practice (GPP) standards published by the South African Pharmacy Council (SAPC) outline various standards for the provision of pharmaceutical care – pharmaceutical care is not just the technical function of processing a prescription and issuing medication.
- These standards include (SAPC, 2010):
 - Ensuring that pharmacotherapy is appropriate
 - Detecting drug interactions
 - Detecting adverse effects of drugs

PHARMACEUTICAL CARE

- Assessing whether patients are compliant with their pharmacotherapy
- Counselling patients (providing information and advice) so that medication is used correctly and safely
- Counselling patients about possible dietary modifications
- Liaising with other health-care professionals (such as doctors) when necessary

PHARMACEUTICAL CARE

- Performing a medication review (includes assessment phase, development of a care plan and a follow-up evaluation to assess patient outcomes)
- Generic substitution (unless not permitted to do so in terms of the Medicines and Related Substances Act 101 of 1965)
- A recent study (Cassim and Dlodlu, 2012) found that one retail pharmacy, from the perspective of patients, was always compliant with only 2 out of 10 GPP standards

PHARMACOVIGILANCE

- Defined as “the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines. The ultimate goal of this activity is to improve the safe and rational use of medicines, thereby improving patient care and public health” (Standard Treatment Guidelines, 2012)
- Adverse drug reaction is “a response to a medicine which is noxious and unintended, including lack of efficacy, and which occurs at any dosage and can also result from overdose, misuse or abuse of a medicines (Medicines Control Council, cited in the Standard Treatment Guidelines, 2012)

PHARMACOVIGILANCE

- Is an important component of rational drug use and pharmaceutical care – to monitor adverse effects and efficacy of pharmacotherapy
- Systems and structures need to be in place in order to monitor effectively
- Pharmacovigilance is often just occurring informally by individual pharmacists – not integrated (between pharmacies and between public and private sector), so patients can “pharmacy hop”

PHARMACOVIGILANCE

- The Medicines Control Council has a programme called the National Pharmacovigilance Programme, which has a unit called the National Adverse Drug Event Monitoring Centre (NADEMC) in Cape Town
- NADEMC is a reporting mechanism for health-care professionals. All reports of adverse drug reactions are entered into a national database
- Form for reporting adverse drug reactions is given at the end of the Standard Treatment Guidelines and South African Medicines Formulary

PHARMACOVIGILANCE

- A report could result in the following (Standard Treatment Guidelines, 2012):
 - Further investigation into the use of that drug in South Africa
 - Educational initiatives to improve safe use
 - Changes in the product package insert
 - Changes in the scheduling of the drug
- But reporting takes time, requires individuals making an effort. Focuses more on the drug rather than the patient

2) ROLE OF TECHNOLOGY

ROLE OF TECHNOLOGY

- Some drug products have bar codes that can be scanned by cell phones and give further information to patients about the drug – but what about accessibility? Assuming literacy (including how to use the device)?
- Use of social media, Internet?
- How can we use technology to create a structure and systems that allow for optimal pharmacovigilance – monitoring and evaluation of drug use?
 - Not just about the technology, but how is it used? Processes?

3) THE CODEINE CARE INITIATIVE

(based on Cassim, 2014)

THE CODEINE CARE INITIATIVE

- South Africa is one of the few countries in which codeine-containing products can be purchased over-the-counter
- South Africa is 49th out of 193 countries internationally and the top country in Africa with regard to the average consumption of defined daily doses of narcotic drugs (PSSA, no date)
- A 2006 study by the Medical Research Council found that 5-8% of patients were abusing codeine-containing analgesics or benzodiazepines, and that codeine is the most commonly abused non-prescription drug (Grange, 2007)

THE CODEINE CARE INITIATIVE

- Possibility that the MCC may up-schedule OTC codeine-containing products
 - This could have major financial implications for the pharmaceutical industry
 - In 2012, 32 million units of codeine were sold in South Africa (Danetteb, 2013)
- To show the MCC that the profession can control codeine abuse without up-scheduling, the Community Pharmacist Sector (CPS) of the PSSA has launched the Codeine Care Initiative

THE CODEINE CARE INITIATIVE

- Consumers will provide their ID/ passport number when purchasing a codeine-containing product
- Dispenser puts this into a national database (Misused Substances Database)
- Can then access the consumer's purchase history of codeine-containing products over the last 6 months from different pharmacies
- Database will later be expanded to include other commonly abused drugs, e.g. sedatives
- Consumer education and counselling about rational use of codeine is also a key feature

THE CODEINE CARE INITIATIVE

- Sounds very promising and can hopefully identify and curb codeine abuse
- However, there are a number of concerns:
 - Consumers can choose whether or not to participate
 - Pharmacies have to voluntarily sign up to the Initiative, in order to access the database and allow their data to be made available
 - Many pharmacies do not yet have the software (cost?)
 - What about public sector pharmacies that may not have computer facilities?

THE CODEINE CARE INITIATIVE

- If a pharmacist identifies a consumer has been getting codeine too often, it is still up to the pharmacist to decide whether or not to dispense it. What mechanisms of accountability are there to ensure pharmacists do not ignore the history? Will the SAPC going to be inspecting this? What about dispenser's putting in a family member's ID?
- What is the role of the pharmacist's assistant? Are pharmacist's assistants and pharmacists going to make a judgement on what constitutes irrational codeine use? Have we been trained to do so?

THE CODEINE CARE INITIATIVE

- So this is an important initiative, but these issues need to be addressed in order for it to be effective
- For further information on the Codeine Care Initiative:

http://www.pssa.org.za/D_SectorsCPS_N.asp

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THANK YOU VERY MUCH FOR YOUR TIME!

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