1) Audit title

Van Hout, MC. (2014) A Pharmacy Process Audit of compliance to the Royal Pharmaceutical Society (RPS) United Kingdom and Pharmaceutical Society of Northern Ireland (PSNI) guidelines for safe supply of non-prescription codeine containing products, and audit of training of pharmacy staff in how to comply with these guidelines. CODEMISUSED Project European Commission 7th Framework Programme, EU. Brussels.

2) Introduction

Medicines and Healthcare Products Regulatory Agency(MHRA) [1]: Practice Update: 03 SEPTEMBER 2009 Codeine Containing Products

Codeine containing analgesics have a potential for inducing dependency behaviour in those who take the drug inappropriately. Codeine containing over the counter (OTC) analgesics have been available for many years and are combined with paracetamol, aspirin or ibuprofen. In 2005 the pharmaceutical industry entered a voluntary agreement with the MHRA to reduce the pack sizes OTC medications containing codeine or dihydrocodeine (DHC) and add further warnings information provided with the product. The indications from patient groups show that this was not effective in reducing addiction to these products and that sale of larger pharmacy only packs were increasing. The Commission on Human Medicines (CHM) has now strengthened its advice to minimise the risk of misuse of these products. An advice bulletin was produced by MHRA and is available at: http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON057115

What the measures mean;

The new MHRA advice means sales of all medicines containing codeine/dihydrocodeine should:

• No longer be indicated for colds, flu, coughs and sore throats or other minor painful conditions;

• Only be indicated for use in acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone;

• Not be sold in effervescent formulation dispensary packs.

Additionally, the MHRA drew the attention of pharmacists to the following

When marketing authorisation changes have been made to OTC packs of codeine containing products by the end of 2009, all packs containing more than 32 capsules or tablets will be reclassified from Pharmacy Medicines (P) to Prescription Only Medicine (POM) status.

1. [1] The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all their work lie robust and fact-based judgments to ensure that the benefits to patients and the public justify the risks. They keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. They encourage everyone – the public and healthcare professionals as well as the industry – to tell them about any problems with a medicine or medical device, so that they can investigate and take any necessary action.

Patient information leaflets (PIL) in codeine containing analgesics were updated and positioned clearly and prominently on the front of the pack *'Can cause addiction. For three days use only'* to reinforce the message that they are for short term use only for the treatment of moderate, acute pain, and that the products can cause addiction or overuse headache if used continuously for more than three days. The PIL reinforced information about the warning signs of addiction, ie if the medicine is needed for longer periods and in higher doses than recommended, and if stopping the medicine makes you feel unwell but you feel better when you start taking it again. If treatment is required for more than 3 days then advice should be sought from a pharmacist or doctor.

The advertising and promotion code of practice for manufacturers and retailers was updated to reflect the new indications and warnings, and to remove references to painkilling power and strength. Also, all advertisements now include the statement '*Can cause addiction. For three days use only'*.

3) Rationale

The audit centres on pharmacy compliance of the RPS and PSNI guidelines for safe supply of non-prescription codeine containing products (I-VI). The rationale for the audit is as follows;

1) Professional concern

A variation in professional practice across different pharmacies has been noted (i.e. delivery of patient information around safe use of codeine, adherence to medical advice and labelling, awareness of dependence and harm, pharmacist decisions or refusal to supply the product, counter staff awareness of the guidelines for safe supply of non-prescription codeine containing products. An increase in the number of reported adverse events has been reported (for example customers reporting medication overuse headache associated with codeine withdrawal, and customer requests for over the counter codeine for symptoms, whilst unaware of actual withdrawal)

2) High risk procedures/situations

The issue of codeine misuse, both therapeutic and non-therapeutic is an area where pharmacy risk management requires focus. The cost of *`getting it wrong`* has major consequences for the patient (pharmacy risk management, impact of co-prescribing and use of OTC codeine)

3) Financial considerations

Given the focus on retail conflicting with customer care, not all pharmacies employ the same level of stringency and customer care.

4) Practical considerations

The audit aims to measure practice compliance against national regulatory standards for safe supply. The audit is two-fold, auditing for compliance of standards and training audit of pharmacists and pharmaceutical assistants. Improvements included compliance, patient/customer care and evaluation of RPS/PSNI guidelines in operation.

4) The audit aim and objectives

The aim of the audit is ensure correct pharmacist compliance in adhering to the RPS/PSNI guidelines I-VI for safe supply of non-prescription codeine containing products, so that public awareness of correct use of codeine and safe supply occurs in UK and NI pharmacies.

The objectives are as follows;

1. To improve pharmacy practice with regard to supply of non-prescription products containing codeine occurs according to the RPS/PSNI guidelines for safe supply of prescription products containing codeine (RPS/PSNI standards I-VI).

2. To raise awareness among pharmacy staff (pharmacists, MCAs) that according to the RPS/PSNI standards I-III non-prescription products containing codeine can only be supplied when trained staff operating to written pharmacy procedures (SOPs) under supervision of the pharmacist are satisfied that, in the exercise of his or her professional judgement, the supply of such a medicine is the most appropriate therapy available at the time and that such supply is in the best interest of the patient. Non-prescription codeine containing products are not indicated for colds, flu, coughs and sore throats or other minor painful conditions.

3. To raise awareness among pharmacy staff (pharmacists, counter assistants) that according to the RPS/PSNI standards IV and V when a non-prescription product containing codeine is supplied, all sales are restricted to a single pack sold in any purchase, and products are not sold in effervescent formulation dispensary packs.

4 To raise awareness among pharmacy staff (pharmacists, counter assistants) that according to the PSNI standard VI non-prescription products containing codeine are only be supplied and used in accordance with the terms of their marketing authorisations, which all state that the product be used for short term use only for the treatment of moderate, acute pain, and that the products can cause addiction or overuse headache if used continuously for more than three days. It is also essential that patients be facilitated and encouraged to obtain medical assistance for any health problems related to their misuse that may arise.

5 To improve public awareness of safe use of codeine products, in terms of medical guidelines for safe use, potential for dependence and risk of adverse health consequences if misused[2]. All patients must be fully advised of the correct use of the product and these risks associated with its misuse.

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[2] Casati et al (2012) define 'misuse' of codeine as:
'The problematic consumption of codeine where risks and adverse consequences outweigh the benefits, and which includes use of codeine with or without prescription, outside of acceptable medical practice or guidelines, for recreational reasons, when self-medicating, with higher doses and for longer than advisable.'

5) The type of audit

The audit is a process audit and has two components, the compliance to the RPS/PSNI guidelines for safe supply of non-prescription codeine containing products (A), and the training of pharmacy staff in how to comply with these guidelines (B).

6) The audit team

The audit team consists of the Audit Facilitator responsible for running the audits and providing the training (Part B), expert consultation with the RPS/PSNI, and administration support (data input and administration support).

7) The standard statement

Audit Standard A: All customers requesting non-prescription medicinal products containing codeine will be consulted, advised and supplied the product according to the RPS/PSNI Guidelines (I-VI) for safe supply of non-prescription codeine containing products.

Audit Standard B: Staff will score 70% of above following training in how to supply non-prescription medicinal products containing codeine according to the RPS/PSNI Guidelines (I-VI) for safe supply of non-prescription codeine containing products.

8) Evidence base

The RPS/ PSNI guidelines for safe supply of codeine state that;

Sales of medicines containing codeine and dihydrocodeine.

I. Are only undertaken by trained staff operating to written pharmacy procedures (SOPs) under the supervision of a pharmacist.
II. Non-prescription codeine containing products are not indicated for colds, flu, coughs and sore throats or other minor painful conditions.
III. Non-prescription codeine containing products are only indicated for use in acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone.
IV. Sales of non-prescription codeine containing products are restricted to a single pack sold in any one purchase.
V. Products are not be sold as effervescent formulation dispensary packs.
VI. All customers requesting non-prescription codeine containing products are assessed for potential misuse. Pharmacists should be mindful that they are uniquely positioned to intervene where addiction is suspected and they should seek to refer any such patient to appropriate help or support services.

9) The sample

Part A: A process audit of pharmacy compliance in the safe supply of non-prescription codeine containing products according to the RPS/PSNI guidelines (I-VI)

All pharmacies registered in the United Kingdom (total 11,495 http://www.rpharms.com)and Northern Ireland (total 549 http://www.psni.org.uk/) will be advised that during one calendar month, a test shopper may visit their site, and request to purchase codeine using various scenarios in their pharmacies. These test shoppers will complete the data collection sheet to audit compliance. A stratified random sampling of every 10th pharmacy in each county will be audited by a test shopper requesting to purchase over the counter codeine. Test shoppers will present with a variety of scenarios to request codeine and inclusive of legitimate requests, inappropriate use, requesting codeine products by name, suspected misuse for intoxication purposes, suspected misuse for therapeutic purposes, suspected misuse for opiate withdrawals, suspected pharmacy hopping, lack of patient awareness of other forms of pain management and lack of patient awareness of codeine related harm.

Part B: A process audit of increase in knowledge around the safe supply of non-prescription codeine containing products according to the RPS/PSNI guidelines for safe supply (I-VI)

A stratified randomised listing of pharmacists (43,665) and pharmaceutical assistants (20,000) registered in the UK and NI (male/female/county) A stratified randomised listing of pharmacies will partake in 1 day training provided by the Audit Facilitator and requested to complete the data collection sheet to assess knowledge of the RPS/PSNI guidelines for safe supply of non-prescription codeine containing products at Time 1 before training, and Time 2 after training. Stratification will occur via job type (pharmacist/pharmaceutical assistant), gender and county, with every 10th case per subgroup sampled.

9) Data collection

The audit instruments will be piloted with a group of pharmacists (n=10) not partaking in the audit.

10) Ethical considerations

All participants will be provided with an information sheet outlining the purpose of the audit, will provide written consent to partake in the audit and be assured complete anonymity, that neither they nor their pharmacy be identified in the final report. Data will be stored on a password protected computer and only accessed by the author. Dissemination of the findings will be approved by the Lead Audit Facilitator and the PSNI prior to release.

11) Dissemination of findings

The findings will be collated and presented in a report. Findings will be presented to a group of pharmacists to see if they are surprised or dispute findings. It is envisaged that two journal publications will present data relating to Part A and B respectively.

12) Timetable

Month	1	2	3	4	5	6	7	8	9
	Design and piloting of instruments Circular Email advising of the audit Sampling frame finalised.								
Audit A	Recruitment and training of test shoppers	Audit Test Shopper	Audit Test Shopper	Analysis of data					Report Dissemination
Audit B				Audit Time 1	Delivery of Training	Delivery of Training	Audit Time 2	Analysis Of data	Report Dissemination

13) Resources required

Administration support, travel and subsistence for logistics.

Part A: A process audit of pharmacy compliance in the safe supply of codeine according to the RPS/PSNI guidelines for safe supply of non-prescription codeine containing products (I-VI)

Standard A: All customers requesting non-prescription medicinal products containing codeine will be consulted, advised and supplied the product according to the PSNI Guidelines (I-VI) for safe supply of non-prescription codeine containing products.					
Criteria	**Target**	**Allowable exceptions**	**Definitions**	**Evidence base ***	**Location**
Criterion 1) Non-prescription medicinal products containing codeine are only supplied when trained staff operating to written pharmacy procedures (SOPs) under supervision of the pharmacist are satisfied that, in the exercise of his or her professional judgement, the supply of such a medicine is the most appropriate therapy available at the time and that such supply is in the best interest of the patient. Non-prescription codeine containing products are not indicated for colds, flu, coughs and sore throats or other minor painful conditions.	100%	None.	N/A	Royal Pharmaceutical Society (UK) and Pharmaceutical Society of Northern Ireland guidelines (I-VI) for safe supply of non-prescription codeine containing products.	In the test customer's record sheet for each pharmacy.
Criterion 2) Every time a non-prescription medicinal product containing codeine is supplied, sales are restricted to a single pack sold in any purchase, and products are not sold in effervescent formulation dispensary packs.	100%	None.	N/A	Royal Pharmaceutical Society (UK) and Pharmaceutical Society of Northern Ireland guidelines (I-VI) for safe supply of non-prescription codeine containing products.	In the test customer's record sheet for each pharmacy.
Criterion 3) Every time a non-prescription medicinal product containing codeine is supplied, all patients are fully advised of the correct use of the product	100%	None.	N/A	Royal Pharmaceutical Society (UK) and Pharmaceutical Society of Northern	In the test customer's record sheet for each pharmacy.

and the risks associated with its misuse, and facilitated and encouraged to obtain medical assistance for any health problems related to their misuse that may arise.				Ireland guidelines (I-VI) for safe supply of non-prescription codeine containing products.	
Criterion 4) Non-prescription medicinal products containing codeine shall only be supplied and used in accordance with the terms of their marketing authorisations, which all state that the product be used for short-term use, i.e. no longer than three days.	100%	None.	N/A	Royal Pharmaceutical Society (UK) and Pharmaceutical Society of Northern Ireland guidelines (I-VI) for safe supply of non-prescription codeine containing products.	In the test customer's record sheet for each pharmacy.

Data Collection Sheet

Standard A: All customers requesting non-prescription medicinal products containing codeine will be consulted, advised and supplied the product according to the RPS/PSNI Guidelines (I-VI) for safe supply of codeine. **Test Shopper Scenario** Legitimate use Inappropriate use Requesting codeine products by name Suspected misuse for intoxication purposes Suspected misuse for therapeutic purposes Suspected misuse for opiate withdrawals Suspected pharmacy hopping

Lack of patient awareness of other forms of pain management Lack of patient awareness of codeine related harm					
Criteria					**Comments** (these are for the data collector to add notes on each criterion if they think clarification is required)
Criterion 1) Non-prescription medicinal products containing codeine are only supplied when trained staff operating to written pharmacy procedures (SOPs) under supervision of the pharmacist are satisfied that, in the exercise of his or her professional judgement, the supply of such a medicine is the most appropriate therapy available at the time and that such supply is in the best interest of the patient. Non-prescription codeine containing products are not indicated for colds, flu, coughs and sore throats or other minor painful conditions.	Y	N	DK	NA	
Criterion 2) Every time a non-prescription medicinal product containing codeine is supplied, sales are restricted to a single pack sold in any purchase, and products are not sold in effervescent formulation dispensary packs.	Y	N	DK	NA	
Criterion 3) Every time a non-prescription medicinal product containing codeine is supplied, all patients are fully advised of the correct use of the product and the risks associated with its misuse, and facilitated and encouraged to obtain medical assistance for any health problems related to their misuse that may arise.	Y	N	DK	NA	

Criterion 4) Non-prescription medicinal products containing codeine shall only be supplied and used in accordance with the terms of their marketing authorisations, which all state that the product be used for short-term use, i.e. no longer than three days.	Y	N	DK	NA	
Criterion 5) Patient is refused to supply.					

Part B: A process audit of increase in knowledge around the safe supply of codeine according to the RPS/PSNI guidelines for safe supply of codeine (I-VI) after training.

Standard B: Staff will score 70% of above following training in how to supply non-prescription medicinal products containing codeine according to the PSI Guidelines (I-IV) for safe supply of codeine.					
Criteria	**Target**	**Allowable exceptions**	**Definitions**	**Evidence base ***	**Location**
Criterion 1) Accurately describe when non-prescription medicinal products is the most appropriate therapy available at the time, supply is in the best interest of the patient and can be supplied to the patient. Refer to a) For pain relief, single ingredient medicinal products such as paracetamol, aspirin or ibuprofen, should be used first in line with pain protocols and current evidence-based practice. Refer to b) Non-prescription codeine-containing products are only supplied as 'second line' products for the treatment of pain relief, when the above products have not shown to be effective. Refer to c) Non-prescription codeine containing products are not	100%	None.	N/A	Royal Pharmaceutical Society (UK) and Pharmaceutical Society of Northern Ireland guidelines (I-VI) for safe supply of non-prescription codeine containing products.	End of test sheets at time One and Two

indicated for colds, flu, coughs and sore throats or other minor painful conditions.					
Criterion 2) Accurately describe when a non-prescription product containing codeine is supplied, the advice provided to patients of the correct use of the product and the risks associated with its misuse.	100%	None.	N/A	Royal Pharmaceutical Society (UK) and Pharmaceutical Society of Northern Ireland guidelines (I-VI) for safe supply of non-prescription codeine containing products.	End of test sheets at time One and Two
Criterion 3) Accurately describe when a non-prescription product containing codeine is supplied, how patients will be facilitated and encouraged to obtain medical assistance for any health problems related to their misuse that may arise.	100%	None.	N/A	Royal Pharmaceutical Society (UK) and Pharmaceutical Society of Northern Ireland guidelines (I-VI) for safe supply of non-prescription codeine containing products.	End of test sheets at time One and Two
Criterion 4) Accurately describe that non-prescription products containing codeine shall only be supplied and used in accordance with the terms of their marketing authorisations, which all state that the product be used for short-term use, i.e. no longer than three days.	100%	None.	N/A	Royal Pharmaceutical Society (UK) and Pharmaceutical Society of Northern Ireland guidelines (I-VI) for safe supply of non-prescription codeine containing products.	End of test sheets at time One and Two
Criterion 5) Accurately describe that all sales of non-	100%	None.	N/A	Royal Pharmaceutical Society (UK) and	End of test sheets at time One and Two

prescription codeine containing products are restricted to a single pack sold in any purchase, and products are not to be sold in effervescent formulation dispensary packs				Pharmaceutical Society of Northern Ireland guidelines (I-VI) for safe supply of non-prescription codeine containing products.	

Data Collection Sheet

Standard B: Staff will score 70% of above following training in how to supply non-prescription medicinal products containing codeine according to theRPS/ PSNI Guidelines (I-IV) for safe supply of codeine.				
Criteria				**Comments** (these are for the data collector to add notes on each criterion if they think clarification is required)
Criterion 1) Accurately describe when non-prescription medicinal products is the most appropriate therapy available at the time, supply is in the best interest of the patient and can be supplied to the patient. Refer to a) For pain relief, single ingredient medicinal products such as paracetamol, aspirin or ibuprofen, should be used first in line with pain protocols and current evidence-based practice. Refer to b) Non-prescription codeine-containing products are only supplied as 'second line' products for the treatment of pain relief, when the above products have not shown to be effective. Refer to c) Non-prescription codeine containing products are not indicated for colds, flu, coughs and sore throats or other minor painful conditions.	Y	N	No answer	

Criterion 2) Accurately describe when a non-prescription product containing codeine is supplied, the advice provided to patients of the correct use of the product and the risks associated with its misuse.	Y	N	DK	
Criterion 3) Accurately describe when a non-prescription product containing codeine is supplied, how patients will be facilitated and encouraged to obtain medical assistance for any health problems related to their misuse that may arise.	Y	N	DK	
Criterion 4) Accurately describe that non-prescription products containing codeine shall only be supplied and used in accordance with the terms of their marketing authorisations, which all state that the product be used for short-term use, i.e. no longer than three days.	Y	N	DK	
Criterion 5) Accurately describe that all sales of non-prescription codeine containing products are restricted to a single pack sold in any purchase, and products are not to be sold in effervescent formulation dispensary packs	Y	N	DK	

Funding Acknowledgement

The research leading to this clinical audit template has received funding from the European Community's Seventh Framework Programme FP7/2007-2013 under grant agreement no 611736.

This Clinical Audit should be referenced as follows:

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