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Validation Tools for Community Pharmacy

Practical Guidelines to Conduct a Validation Study

Practical Guidelines to Conduct a Validation Study

Definition sheets for:

Tool 01 The setting of the community pharmacy

Tool 02 Dispensing a prescription

Tool 03 Responding to symptoms

Tool 04 Communicating with the patient

Tool 05 Equipment and professional service available in community pharmacy

Tool 06 Clinical Governance

Gender: the use of him or he stands in all cases for him or her and he or she

Definition Sheet – Tool 1: Setting of the Community Pharmacy

For the purpose of this tool the following definitions apply:

Pharmacy premises: All the area covered by the premises i.e. dispensary, waiting area, clinics, perfumery, stores

Dispensary: The area within the premises where the pharmacist exercises his profession

Area for dispensing: Area within the dispensary where medicines are prepared for dispensing, including the preparation of labels

Section 1 to 15 covering the entire setting of a community pharmacy are described below:

1. The *first* section assesses the compliance to legal requirements. This section refers to pharmacy licenses and permits required by law at the time when the tool is used.

2. This section identifies the number of pharmacists working at the community pharmacy on a regular basis. As the number of pharmacists working in the pharmacy increases, there is more probability that there will be less uniformity in patient care unless the pharmacy has an established 'standard operating procedure' in place. To get the results pertaining to this section, information has to be obtained from the managing pharmacist or his representative.

3. Since the pharmacy should reflect a professional image, this section assesses the appearance of the pharmacy.

4. The pharmacy should be easily accessible with no obstructions at the doorways. If there is no merchandise and display stands near the doors, then option (i) applies. If the doors leading on to the pharmacy can be widely opened to allow entrance by pushchairs/wheelchairs score (ii) applies.

5. The environment within the pharmacy is assessed in this section. The pharmacy should not encourage sale of ordinary confectionery by impulse as this does not promote healthy eating habits. Patient counselling is a very important practice in community pharmacy and therefore should be given due importance. If the pharmacy holds a separate area for counseling option (ii) should apply. Also, communication between the patient and the pharmacist should not be obstructed.

Ordinary Confectionery: Sweets which are not sugar-free.

6. A role of community pharmacy is the promotion of healthy lifestyles including the provision of opportunistic advice. Distribution of health promotion leaflets either personally by the pharmacist or else through a free selection is assigned option (i). If health promotion material is displayed in the pharmacy (entrance door or on the counter), then option (ii) is assigned. Pharmacists will be expected to give opportunistic advice on specified public health topics to patients presenting prescriptions. This advice may be given verbally but could also be backed up with written information, if appropriate.

Health promotion material: written information on the prevention and treatment of health problems or ailments. Material which features only a specific product information is not considered as material for health promotion.

7. Pharmacists are expected to take part in national and local public health campaigns. This section assesses the number of campaigns the pharmacy has participated in and the number of patients who benefitted from advice.

Health Campaigns: Refer to strategies held by the Health Promotion Department and other public associations intending to increase health awareness among the general population, such as, smoking cessation campaigns and weight management campaigns.

8. In this section the professional image projected is assessed. The appearance of the pharmacist is assessed. If the pharmacist is wearing a lab coat then option (i) holds. If there exists a dress code where certain types of clothing (eg sports wear) are not used for the pharmacy option (ii) applies. If there is no music played in the pharmacy or if the sound is kept low so as not to interfere with communication then option (iii) holds.

9. In this section the toilet facilities which should be available to the public, are assessed.

10. The appearance from the outside is assessed in this section. The presence of a sign denoting the existence of the pharmacy is scored in option (i). If the main door leading to the pharmacy is not obscured with stickers option (ii) holds. The third option scores the shop window. If the shop window is organised with health promotion advertisements and other items particular to a pharmacy then option (iii) holds.

11. The size and area of the dispensary is assessed in this section. The dispensary should be large enough with minimal physical barriers. The dispensing area is assessed for layout in the pharmacy, clutter and cleanliness.

12. In this section facilities available in the dispensary, excluding toilet facilities accessible to the public, are assessed. The availability of a source of drinking water is scored in option (i). The facility of a wash hand basin with cold water with or without hot water is assessed in options (ii) and (iii) respectively. Facilities for waste disposal (waste bin) in the dispensary are assessed in option (iv).

13. In this section the presence and upkeep of a formulary is assessed. The frequency of updating per year is at the discretion of the managing pharmacist.

A formulary: A list of products that are readily available in the pharmacy.

14. The criteria followed for inclusion of a pharmaceutical product in the stock list is assessed in this section. This section is irrespective of whether a formulary exists or not. The inclusion of products following, the requests by clients, prescriptions or after discussions with the prescribers is assessed.

15. This section assesses the procedure generally followed when a request for a prescription medicine which is not kept in stock is made. If the patient is told to come again and the medicine is ordered, then option (i) holds. If the requested product is

taken note of and the product is not ordered, option (ii) holds. If the product is not ordered and no further action is taken, option (iii) applies.

Definition Sheet – Tool 2: Dispensing a Prescription

The tool is performed 10 times in the same pharmacy

For the purpose of this tool the following definition applies:

Patient: The person for whom the medication is prescribed or his representative

Section 1 to 10 covering the procedure of dispensing a prescription are described below:

1. The *first* section examines at what stage the pharmacist gets involved during the dispensing process. No scores are deducted if during the dispensing process an assistant gets the medication(s) for the pharmacist and /or handles the cash register. If this is the case, score from option (i) or (ii).

2. In the *second* section the tool aims to confirm the patient's details available to the pharmacist. If the pharmacist asks for whom the prescribed medication is, and upon receiving the answer, the pharmacist shows that the patient is familiar to him, option

(i) holds. Options from (ii) are selected if on the other hand the pharmacist indicates that the patient is not a regular customer. After the transaction the monitor may ask the pharmacist whether the pharmacist knows the patient. This may help the monitor for the scoring process.

If the prescription prescribed is a repeat prescription one should go to section 4 otherwise, one should continue with section 3.

3. This first section (3a) analyses whether the pharmacist probes the patient to check the knowledge of the patient about the prescribed medication. Sometimes it is the pharmacist who referred the patient to the prescriber. A full score (both i and ii) is given, if during dispensing the pharmacist shows that this was the case. In the second section (3b) the pharmacist is assessed for commitment shown to confirm that the information conveyed is understood by the patient.

4. In the case of a repeat prescription being prescribed, the first part of the section assess whether the prescription is dispensed in due time. Half the score is given if pharmacist uses personal judgment to determine when a prescription should be dispensed instead of following specific directions on the prescription. The second section analyses whether the pharmacist assesses medication safety. Full score is given if the pharmacist checks appropriateness of use of treatment by patient (i), prevalence of side effects (ii) and appropriateness of treatment including changes in dosage regimen or changes to the overall health of the patient (iii). If a problem is

identified (iv) is selected if the pharmacist refuses to dispense the prescription and (v) is selected if patient contact or refers patient to the prescriber.

5. The decision taken by the pharmacist to continue the dispensing process is scored in section 5. If a problem is identified, continue scoring on this tool once it is solved by choosing option (i). If the pharmacist decides to proceed but the medication is not available at the pharmacy, scoring depends on the action the pharmacist takes in such a situation. The scores from (ii) to (vi) scan through the levels of assistance offered by the pharmacist:

Score (vi), the pharmacist does not take any action and informs the patient that the request cannot be met with;

Score (v), the pharmacist tries to get the medication and discusses with the patient a convenient arrangement for collection at a later time;

Score (iv), the pharmacist informs the patient to go to another pharmacy;

Score (iii), the pharmacist refers the patient to another pharmacy that has the medication (may be after phoning the other pharmacies in the locality);

Score (ii), the pharmacist contacts the prescriber.

6. The pharmacist selects the product and this section assesses the degree of rechecking performed by the pharmacist. A final glance by the pharmacist at the prescription to compare the product against the prescription is scored as (i). Assign score (ii) if the pharmacist looks at the product to check its expiry date.

7. The type of information provided by the pharmacist is scored in this section. A common practice is for the pharmacist to write the dose on the packet. This is assigned as score (iii). It is not a label because for the purpose of this tool the minimum information for a label includes the name of the medication and instructions on how to take the medication.

8. This section is aimed to assess the type of interaction between the pharmacist and the patient.

9. This section is aimed to assess the type of relationship which is built up between the pharmacist and the patient.

10. This section assesses the contribution of the pharmacist towards the therapeutic management of the patient.

Score (i), the pharmacist discusses with the patient how he can combine medication dosing with work, sleep or other medication.

Score (ii), the pharmacist gives advice on health condition.

Score (iii), the pharmacist advises on common drug interactions and reassures patient on the use of medications that may be taken safely with the medication prescribed.

Definition Sheet – Tool 3: Responding to Symptoms

In the validation tool 'responding to symptoms' a list of all the symptoms presented and all medications dispensed in relation to the symptom are presented.

Sections 1 to 10 covering the procedure of responding to symptoms are described below:

1. The *first* section scores the pharmacist for the commitment made to identify the patient. If the pharmacist asks for whom the medication is or is aware who the patient is (for example because of a repeated request), then score (i) applies. If the pharmacist knows the patient and so is aware of the patient's age, medications taken and allergies, score (ii) applies.

2. In the *second* section the tool aims to assess the information gathered by the pharmacist to establish a profile of the symptoms of the patient. If the pharmacist asks the patient to describe the symptom(s), score (i) applies. If the pharmacist asks the patient when did the symptom(s) start and how long has the patient been experiencing the symptom(s), score (ii) holds. If the pharmacist asks the patient whether he is experiencing any other symptoms, score (iii) holds. If the pharmacist asks whether there is anything which makes the symptom(s) worse or makes the patient feel better, score (iv) holds.

If during the conversation the patient starts describing the profile of the symptom(s) and all information is presented to the pharmacist without the need for the pharmacist to ask the question(s) then the scores should still be assigned.

3. This section assesses the procedure carried out by the pharmacist to establish a treatment history of the patient. If the pharmacist asks the patient whether he has already used a medication to treat the symptom(s), score (i) holds. If the pharmacist asks the patient whether a medical doctor was consulted for the symptom(s), score (ii) holds. If the pharmacist asks the patient whether the symptom(s) occurred previously and if this was the case, what medication was prescribed or used, score (iii) holds. If the pharmacist checks with the patient what medications are being taken, score (iv) applies.

4. This section assesses the intervention of the pharmacist to check whether there are any risk factors. If the pharmacist asks the patient whether he suffers from chronic conditions such as hypertension, diabetes, asthma, cardiovascular disease, score (i) applies. If the pharmacist asks the patient whether he suffers from any allergies (food, medicine) score (ii) holds.

5. In this section the detection of symptoms suggestive of serious disease and the subsequent course of action are assessed.

If any of the symptoms listed and defined as suggesting the presence of a serious disease are present, scoring is continued at section 25. If no such symptoms are detected then scoring should be continued in sections 6 to 23 depending on the symptom(s) presented (follow the subsections).

Definition of Symptom Suggestive of Serious Disease

Ankle swelling	swelling at ankle excluding swelling after a long distance flight
Anorexia	when it is a long standing symptom and patient is not following a diet
Blood loss from any orifice	excluding minor bleeds and loss due to minor cuts and bruises
Difficulty in swallowing	patient presents inflammation of throat
History of severe injury	patient is experiencing a symptom related to a past occurrence of severe injury
Increasing breathlessness	patient complains of continuous, unusual breathlessness
Loss of weight	unexplained i.e. when the patient is not dieting and symptom is long standing
Menstrual abnormality	recurrent abnormality: missed periods, frequent periods, heavy flow
Persistent or recurrent pyrexia	infection occurring without indication of bacterial infection

Pain in chest, abdomen, head or ears	excluding headache
Spontaneous bruising	over large areas
Swelling or lumps of any size	any location throughout the body
Tenderness over the blood vessels	pain over blood vessels
Urinary symptoms	incontinence, excluding cystitis
Yellow or green discharge from penis or vagina	bacterial or fungal infection
Yellow or green sputum	bacterial infection

6-22. In this section questions put forward by the pharmacist specific to the symptom(s) presented by the patient are assessed. If the information is already available to the pharmacist because the patient has given the information earlier on during the conversation with the pharmacist, then the scores should still be assigned.

a. This section assesses the pharmacist's assessment of accompanying symptoms presented. If any accompanying symptoms are detected, then these should be marked in the list provided in this section. If the accompanying symptom(s) are not included in the list it should be written down in the last row under the sub heading *Other*. If any of the listed accompanying symptoms is detected since these warrant referral, scoring should be continued at section 28. If no accompanying symptoms requiring referral are present then score (i) is assigned and scoring is continued at section *b*.

b. In this section the management recommended by the pharmacist is assessed.

23. This section is used when a patient presents with a symptom other than the above. In the first section the knowledge of the pharmacist about the presenting symptom is assessed. If the pharmacist is able to determine possible diseases by the characteristics described by the patient(i) while observing other signs suggestive of the possible diseases which are not complained of by the patient (ii) then both (i) and (ii) apply.

23a. In this section the pharmacist excludes any potential serious illness. If accompanying symptoms or signs of abnormality warrant referral then scoring should be continued at section 28.

23b. In this section the management recommended by the pharmacist is assessed.

24. In this section the information provided to the patient by the pharmacist on how to manage the condition is assessed. If no medication is recommended but the pharmacist explains home nursing and recommends supportive measures, score (i) holds. If a medication is supplied then scoring should be carried out choosing from scores (ii) - (iv) depending on the extent of information provided. If home nursing as well as a medication is supplied, then scoring should be carried out from (ii) to (iv).

25. This section assesses how the pharmacist ends the session. If the pharmacist gives some information about the patient's ailment, score (i) holds. If the pharmacist gives information and reassures the patient about symptoms so that the patient feels in control of the situation, score (ii) holds. If the pharmacist tells the patient to come again or seek medical advice if symptoms persist, score (iii) holds.

26. This section assesses documentation carried out by the pharmacist. If the pharmacist offers diagnostic tests such as BP monitoring, weight, blood analyses, score (i) holds. A list of diagnostic tests recommended according to the symptom(s) is presented below. If the pharmacist provides written information for the patient to pass on to the General Practitioner, score (ii) holds.

Recommended Diagnostic Tests

Ankle swelling	Blood pressure monitoring, heart rate, blood glucose, weight,
Anorexia	Weight, blood glucose
Blood loss from any orifice	blood pressure monitoring, heart rate
Difficulty in swallowing	body temperature
History of severe injury	examination of the area
Increasing breathlessness	heart rate, blood pressure monitoring

Loss of weight	weight, height
Menstrual abnormality	record of events of previous menstrual periods
Persistent or recurrent pyrexia	body temperature
Pain in chest	heart rate, blood pressure monitoring
Pain in abdomen	body temperature, test strip urinalysis
Pain in head	body temperature
Pain in ears	examination of outer ear, body temperature
Spontaneous bruising	examination of the area, blood glucose analysis
Swelling or lumps of any size	examination of lumps
Tenderness over the blood vessels	examination of the area
Urinary symptoms	test strip urinalysis, body temperature
Yellow or green discharge from penis or vagina	description of discharge
Yellow or green sputum	description of sputum, body temperature

27. This section assesses recommendation of referral.

If the pharmacist informs the patient about the need to seek medical advice immediately, score (i) holds. If the pharmacist indicates seriousness of symptom and suggests to the patient to seek medical advice if symptoms persist for more than 24 hours, score (ii) holds. If the pharmacist recommends a medication until the patient seeks medical advice, score (iii) holds.

28. This section assesses the procedure undertaken by the pharmacist before referring. If the pharmacist asks the patient or he is already aware that the patient has a family doctor, score (i) holds. If the pharmacist gives advice to the patient on the procedure to be followed and which actions should be avoided until medical advice is sought, score (ii) holds.

29. This section assesses the method of referral. If the pharmacist refers the patient to his family doctor, score (i) holds. If the pharmacist offers to phone and make an appointment for the patient who does not have a family doctor, score (ii) holds. If the pharmacist gives the telephone number, clinic times of a general practitioner or of another health professional to a patient who does not have a family doctor, score (iii) holds.

30. This section assesses the general advice provided by the pharmacist. If the pharmacist offers additional information (verbal advice, written literature) about the

symptom(s), score (i) holds. If the pharmacist does not alarm the patient to avoid creating a panic state but indicates the emergency of the situation score (ii) holds.

Definition Sheet – Tool 4: Communicating with the Patient

The tool is performed 10 times in each pharmacy

For the purpose of this tool the following definition applies:

Patient: Person who asks for advice from the pharmacist or his representative

Advice Given

This tool is used when the pharmacist gives advice to the patient in any circumstance i.e.

- when pharmacist gives advice to complement a prescribed medicine
- when advice is given upon dispensing an over-the-counter medication
- when patient presents the pharmacist with a symptom
- when patient asks for advice on a medication or on a nonpharmaceutical product

Sections 1 to 10 covering aspects of communication with the patient are described below:

1. The *first* section looks at the encounter stage when the patient and the pharmacist meet. When the pharmacist either gives immediate attention to the patient as soon as he walks to the dispensing counter if there are no other patients or the pharmacist gives immediate attention to the patient who is next at the dispensing counter, score (i) holds. If the pharmacist greets the patient by welcoming him to the pharmacy, score (ii) holds. Perhaps the pharmacist knows the patient and addresses him by name or surname and in that case score (iii) holds. If the pharmacist is known to the patient and if not, the pharmacist introduces himself to the patient, score (iv) applies.

2. Body language presented by the pharmacist to show skills of reception and encouraging two-way communication are assessed in this section. If the pharmacist faces the patient by keeping shoulders square to patient, score (i) holds. When the pharmacist keeps a good eye contact with the patient which is varied and consistent but not stare at a distant object, score (ii) holds. When the pharmacist tries to reduce the distance between himself and the patient by leaning towards the patient or moving towards the patient by going down from behind the dispensing counter score (iii) applies. When the pharmacist acts as an open communicator by keeping hands open in relation to torso and not crossed or at the side with palms of hands facing front, option (iv) holds. If the pharmacist maintains an interested facial expression and makes encouraging gestures such as nods, smiles, hand gestures, score (v) applies. If the pharmacist shows that he can understand the feelings of the patient from the body language used by the patient, then score (vi) applies.

3. The *third* section assesses the pharmacist's attending role. If the pharmacist allows the patient to talk about things that are of concern to him, score (i) applies. If the pharmacist is a good listener and interrupts the patient only to clarify points mentioned by the patient, score (ii) applies. If the pharmacist uses a pleasant and convincing tone by which he shows that the patient's experience is understood, score (iii) is assigned.

4. Section *four* assesses the establishment of trust and rapport in improving the pharmacist -patient relationship. When the pharmacist tries to understand the concerns, actions, perceptions, emotions and motivations of the patient, score (i) applies. If the pharmacist respects the dignity and privacy of the patient by speaking confidentially and acting professionally, score(ii) is assigned. When the pharmacist succeeds to establish a relationship built on trust and friendship, then score (iii) applies.

5. The probing carried out by the pharmacist to access relevant information from the patient is assessed in this section. When the pharmacist poses open ended questions which allow open expression from the patient and only few close ended questions, score (i) applies. If the pharmacist poses close ended questions, which can be answered with either a "Yes" or "No" response or with few words, and few open ended questions then score (ii) applies. If the pharmacist poses close ended questions only score (iii) holds. If the pharmacist adopts an excessive questioning technique (which results in a passive reaction from the patient), then score (iv) holds.

6. The commitment by the pharmacist to focus on the needs of the patient are assessed in this section. If the pharmacist asks the patient to repeat the major issues of the counselling session, score (i) applies. If the pharmacist provides concrete information which is specific information in clear terms score (ii) applies. If the pharmacist does not indulge in telling stories and past experiences, score (iii) applies.

7. In this section assertive behaviour expressed by the pharmacist is assessed. If when speaking the pharmacist speaks slowly and repeats key information to ensure that he is understood, then score (i) applies. If the pharmacist assumes a preaching, didactic style where he presents himself as an expert, score (ii) holds.

8. Verbal information given by the pharmacist is assessed in this section. If the pharmacist explains the information given and offers valid reasons, for each issue mentioned, score (i) holds. If the pharmacist projects the image of having a sound background about medications and health-related issues, score (ii) applies.

9. The ability of the pharmacist to detect what is important to the patient is assessed here. The ability of the pharmacist to adjust to the patient's background (age, personality, educational level) is scored in step (i). When the pharmacist anticipates that the patient perceives issues discussed, differently from the pharmacist, score (ii) is assessed. When the pharmacist is able to detect the level of knowledge of the

patient about medications or a health condition, score (iii) applies. When the pharmacist is able to perceive the expectations of the patient from medications, score (iv) applies.

10. The process of conclusion of the counselling interaction is assessed in this last section. When the pharmacist asks for any questions on the part of the patient, score (i) holds. If the pharmacist offers any further advice to the patient whenever needed and encourages the patient to contact him if further information is needed, then score (ii) applies. If the pharmacist does not rush the patient through the counselling session score (iii) applies. Score (iv) applies when the pharmacist concludes the process by greeting the patient. If the pharmacist does not end the interview abruptly score (v) applies.

Definition Sheet – Tool 5: Equipment and Professional Services

Available in a Community Pharmacy

For the purpose of this tool the following definitions apply:

Pharmacist: The managing pharmacist

Controlled drugs: Narcotic and psychotropic drugs which are listed under the relevant legislation depending on the country or state where the study is being run.

Section 1 to 15 covering equipment and professional services available in a community pharmacy are described below:

1. The *first* section assesses the participation of the managing pharmacist in continuing education programmes and the contribution made by the managing pharmacist towards pharmacy practice research and development. To obtain the data pertaining to this section, information has to be obtained from the managing pharmacist. If the pharmacist regularly attends continuing education lectures organised by professional bodies or sponsored by the pharmaceutical industry, score (i) holds. If the pharmacist periodically reads through professional pharmacy journals such as *The Pharmaceutical Journal*, *Middle East Pharmacy*, score (ii) holds. If the pharmacist uses information technology such as the internet to access informative professional pharmacy-related web sites, score (iii) holds. If the pharmacist currently has or is willing to have pharmacy students attending for practice sessions in the community pharmacy, score (iv) holds. If the pharmacist collaborates with project supervisors in the collection of data for studies being carried out within the ambit of pharmacy practice research, score (v) applies.

2. In this section references and information sources available in the pharmacy are assessed. If a recent edition of an indexed drug reference such as the *British National Formulary*, *The Pharmaceutical Index* is available, score (i) holds. The availability of a current edition of a drug compendium such as *Martindale: The Extra Pharmacopoeia*, *Physician's Desk Reference* is assessed in score (ii). The availability of a reference book in pharmacology and therapeutics such as *Goodman and Gilman's The Pharmacological Basis of Therapeutics* is scored in step (iii). If an

updated copy of laws and regulations relevant to pharmacy is available, score (iv) applies.

3. In this section the availability of electronic and other resources is assessed. If the pharmacy has internet access, then (i) applies while if the pharmacy has access to electronic sources of information then (ii) applies. If the pharmacy has up to date copies of local GP formularies and local prescribing guidelines then, (iii) and (iv) apply respectively. If a system is available for dissemination of new information received, such as local prescribing guidelines then (v) applies.

4. This section looks into the dispensing equipment available in the pharmacy. If the dispensing equipment is stored in a clean place such as a cabinet and is kept in good condition and free from dust, score (i) holds. If the tablet and capsule counting aids are cleaned after use and kept clean to avoid cross contamination, score (ii) applies. If the dispensing balance is accurate and is checked periodically to be accurate, score (iii) applies.

5. In this section the refrigerator available in the pharmacy is assessed. If the refrigerator is kept in a cool place in the pharmacy away from direct sunlight, score (i) applies. If the refrigerator is cleaned and defrosted regularly, score (ii) applies. Score (iii) applies when the refrigerator is fitted with a thermometer and if the temperature of the refrigerator is kept between 20C and 80C then score (iv) holds. When only pharmaceutical items are stored in the refrigerator then score (v) applies.

6. In this section the storage of control drugs is assessed. If the controlled drugs are kept in a locked cabinet then score (i) holds. If the key is kept by the pharmacist on duty, then score (ii) holds. If a stock control exercise is carried out periodically to check the stock of controlled drugs then score (iii) applies. If the required registers and documentation for controlled drugs is kept up to date then score (iv) holds.

7. This section assesses the containers used for dispensing other than original packs. If the containers are clean and free from contamination, score (i) applies. If the containers protect medicines from environmental factors such as light, moisture, score (ii) applies. If special containers are used for dispensing such as child resistant, score (iii) holds. If the containers are easy to open by elderly patients and patients suffering from disability such as arthritis, score (iv) applies. If the pharmacy uses different types of containers depending on the medicine dispensed, then the rating should be carried out based on the fact whether the containers are suitable for the specific medicines dispensed.

8. The labels attached to medicines dispensed are assessed in this section. If the label is clear, legible and suitable for elderly patients and those with eye sight problems, score (i) is assigned. The preparation of the label using a mechanical printer (typewriter or computerised system) is assessed in score (ii). If the label is prepared so as to be understandable by the patient (e.g. language), score (iii) applies.

9. The weighing scales available in the pharmacy are assessed in this section. A routine check carried out to ascertain that the weighing scales are properly calibrated is scored in step (i). If the weighing scales give the reading in the metric system, score (ii) applies. If weighing scales are available for infant weighing in an appropriate area, score (iii) applies. If in the pharmacy there is a reference chart of the average weight, score (iv) holds.

10. The diagnostic equipment used in the pharmacy is assessed in this section. The availability of blood pressure measuring equipment is scored in step (i). If the equipment is checked periodically, score (ii) applies. In step (iii) the availability of diagnostic test strips (urinalysis, blood testing) is assessed. In step (iv) the storage of the diagnostic test strips and their routine checking is assessed.

11. In this section documentation of diagnostic tests carried out in the pharmacy is assessed. Documentation sheet refers to documentation of the diagnostic test which is kept at the pharmacy for records and /or is given to the patient. Scores (i) to (iv) assess the data compiled within such a documentation sheet.

12. In this section the use of computer technology in the pharmacy is assessed. If a computer is available at the pharmacy this tool is filled in. If a system is maintained to ensure access to computer records is limited to authorized personnel then (i) applies. Score (ii) if all data is backed up according to a planned schedule. If the computer is maintained to reduce the chances for external attacks e.g. viruses,

worms and spyware then (iii) holds. Score (iv) assesses the security and safety of the computer system and its effectiveness in emergencies. The term emergencies imply *situational* emergencies which may crop up in a community pharmacy. In score (v), the computer system's set-up to support effective workflow and operations of the pharmacy and if the computer system contains the required software for the functioning of the pharmacy, score (vi) holds.

13. In this section the disposal of unwanted medicines is assessed. If a standard operating procedures in place to handle the receipt, storage, record keeping and disposal of unwanted medicine then (i) holds. The availability of suitable bins for unwanted medicines is assessed in (ii). Score (iii) applies if the unwanted medicines are collected frequently enough. If the staff members have the knowhow through training on how to protect themselves and the environment then score (iv) applies. The availability of protective equipment, including gloves, overalls and materials are assessed in (v).

14. This section assesses the services of signposting offered in the pharmacy. The availability of a list of other health and social care providers to whom patients may be referred to by the pharmacist is assessed in (i). If the pharmacy uses written referral forms when needed (ii) applies.

15. This section assesses the support for self-care offered by the pharmacy. If employees have the knowledge in providing advice in managing a medical condition

together with advice on treatment available (i) applies. The availability of a range of leaflets to support self-care is assessed in (ii). If a record of advice given is kept, score (iii) holds while if follow up care is offered by the pharmacist score (iv) applies.

Definition Sheet – Tool 6: Clinical Governance

Section 1 to 15 covering clinical governance in a community pharmacy are described below:

1. In the first section advertising and promotional material is assessed. Scores (i) to (iv) assesses whether all advertising or promotional material complies with the code of ethics, is supported by reliable evidence, is unbiased and accurate and does not promote unrealistic expectations and excessive use of pharmaceutical products. If the price list compares with local standards (v) applies.
2. The second section assesses the use of patient satisfaction survey in the pharmacy. If the pharmacy makes use of such surveys then (i) applies while if action is taken as a result of the survey to improve the services provided by the pharmacy (ii) holds.
3. Section 3 assesses how the pharmacy deals with complaints. If a complaints procedure is in place then (i) holds while if the complaints are also recorded

(ii) also applies. Score (iii) assesses if investigations are carried out as a result of a complaint while (iv) evaluates if corrective action is recorded.

4. Section 4 assesses pharmacy based audits carried out in the pharmacy. If an audit is carried out at least every 12 months and action are carried out as a result of the audit then both (i) and (ii) applies.

5. This section assesses medication handling. Pharmaceutical items restricted for sale from a pharmacy should not be readily available for self-service to the public. If this is the case (i) applies. Score (ii) assesses the storage of medicines away from sunlight, excessive heat and humidity. Medicines for external use should be segregated from internal or injectable pharmaceutical products. If this is the case (iii) holds. Score (iv) assesses the availability of a system for handling different type of stock from a-c.

6. This section assesses medication quality. Score (i)a applies if a system is followed for dealing with damaged, faulty or out of date stock while (i)b deals with products subject to recall. If the system is an organized and systemic procedure (ii)a holds while if it is a random check (ii)b applies.

7. This section assesses policies and procedures for pharmacy stock. Score (i) – (iv) assesses the availability of systems used for monitoring out of stock items

(i), ordering stock (ii), price checking (iii)(iv). (v)a-d assess policies and procedures developed on handling pharmacy stock.

8. Section 8 deals with safety and security in the pharmacy. If a health and safety risk assessment and fire risk assessment is carried out routinely then (i) applies. The use of systems to ensure an effective response to emergencies is scored in (ii). If systems are in place to ensure both security and safety of staff and customers (iii) and (iv) hold. If pharmacists employed have a current First Aid qualification then (v) applies. If staff and locums are given an induction program including knowledge on safety and security in the pharmacy (vi) holds. The monitoring of effectiveness of these systems is assessed in (vii). The openings to the outside of the pharmacy must be securely locked when the pharmacy is closed. This is assessed in (viii).

9. This section assesses risk management in pharmacy. Scores (i) – (x) assesses the availability of written procedures for different areas in community pharmacy.

10. This section assesses child protection in community pharmacy. If child protection procedures are in line with national and local guidance then (i) applies while if the pharmacy has contact details of local child protection officers (ii) holds.

11. Clinical effectiveness is assessed in this section. (i) applies if a medicines use review service is being provided at the pharmacy. If the pharmacist reinforces advice especially during the dispensing of repeat prescriptions (ii) applies while if additional advice is given on the reduction of wastage (iii) applies.

12. This section evaluated the importance that the pharmacy gives to continuing professional development of employees. If a training plan is maintained for each member of staff (i) applies. If it is ensured that all staff have received both initial and ongoing training on products, services and procedures relevant to the position they hold (ii) holds. The maintenance of a training record for each member of staff is assessed in (iii).

13. Personal medication records (PMR) kept at the pharmacy are assessed. The PMRs can be kept manually or on computer. This section assesses the content and utility of PMRs.

14. The actual use of PMRs is assessed in this section. If prior to dispensing a medication, the pharmacist goes and checks the PMR, then option (i) holds. If the pharmacist checks the PMR prior to suggesting a medication over-the-counter and prior to giving any advice on medications, option (ii) holds. If before dispensing the pharmacist documents the medication in PMR then option (iii) holds.

15. The degree of confidentiality of patient information is assessed in this section.

If confidentiality is part of an induction program given to staff and locums then (i) holds. If confidentiality clauses are signed by all members of staff (ii) applies. The availability of a mechanism for disposal of confidential waste is assessed in (iii). Information includes that retained through memory or held in records. If the information is only available to pharmacists, then score (iv) applies. If on the other hand, the information is available or (in the case of information retained through memory) passed on to other personnel working in the pharmacy score (v) applies.