

Unit 2: Clinical Pharmacy Services

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2.1 Patient medication history interview

The medication history interview is the pharmacist's structured conversation with the patient, or with the patient's carer where the patient cannot be interviewed, to establish exactly what medicines the patient has been taking, and how, at entry to the present episode of care. Its standing is foundational: drug therapy review judges therapy against the patient, and the history supplies the allergies, the self medication and the adherence behaviour that charts alone rarely record. The components of a complete history are standard and should be listed in full: currently prescribed medicines, with dose form, frequency, duration and the indication as the patient understands it; over the counter medicines; herbal, traditional and complementary products, which patients often do not volunteer because they do not count them as medicines, and which the interviewer must ask for by name; medicines taken intermittently or as required, including inhalers, injections, eye preparations, topical products and contraceptives, all commonly omitted from an unprompted account; recent changes, and by whom; allergy and previous adverse reaction history, with the reaction described and not merely the drug named, since intolerance and true allergy carry different consequences; adherence, how medicines are actually taken against how they were prescribed, and the reasons for any difference; and practical context, including who administers medicines at home and any difficulty with swallowing, containers, labels or cost.

A complete medication history

WHAT IS TAKEN	HISTORY AND RESPONSE	HOW IT IS TAKEN
Prescribed medicines Over the counter medicines Herbal and traditional products, asked for by name	Allergy and previous reaction history, reaction described Recent changes and by whom Intermittent and non oral medicines	Adherence as actually practised, and its reasons Who administers medicines at home Difficulties: swallowing, containers, labels, cost

The parts an unprompted account misses are the parts the interview must ask for

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Figure: The components of a complete medication history. The products the patient does not count as medicines, and the way medicines are actually taken, are the parts an unprompted account most often misses.

2.2 Medicine and poison information services: the basic concept

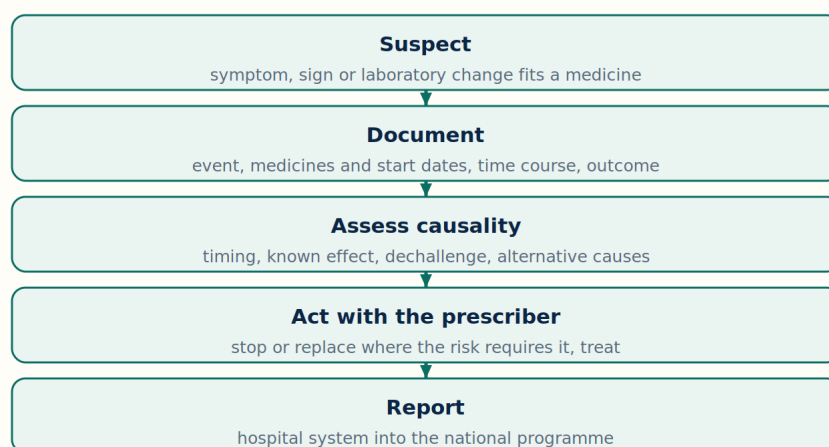
Unit 2 asks for the basic concept of the medicine and poison information services, and Unit 5 gives both their full treatment; this section fixes the concept and the reason the two are taught together. Both exist because medicines and poisons generate urgent, specific questions that general knowledge cannot answer safely: whether a medicine may be used in pregnancy, what to do after an extra dose, whether two products interact, what an ingestion is likely to do and how it is managed. Both answer from evaluated sources, by a systematic method, with the answer matched to the enquirer and the urgency, and both keep records that

make the service auditable. They differ in enquirer and tempo. The medicine information service, also called the drug information service, serves mainly healthcare professionals, and patients through them, with questions about medicines in therapeutic use, and its work is largely planned, researched and answered in writing or by considered verbal response. The poison information service serves professionals and the public in the emergency of an actual or suspected poisoning, where the first answer is immediate and verbal, and support continues while the patient is treated. A hospital commonly houses the two together, sharing sources, trained staff and documentation habits, which is why one subject teaches them as a pair.

2.3 Pharmacovigilance: the basic concept, and adverse drug reaction monitoring

Pharmacovigilance is the science and the activities concerned with the detection, assessment, understanding and prevention of adverse effects and other drug related problems. The basic concept begins with the reason the activity exists: medicines reach the market on trials in limited numbers of selected patients for limited durations, so effects that are rare, delayed, or confined to groups the trials excluded, including older patients, pregnant patients and patients with several diseases, can only be learned after marketing, from use in the whole treated population. An adverse drug reaction, in the standard definition, is a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function; it is distinguished from an adverse event, any untoward occurrence during treatment whether or not the drug caused it, the distinction on which causality assessment works. The clinical pharmacist's part, the adverse drug reaction monitoring of ward practice, runs in a chain: suspect, from a symptom, sign or laboratory change that fits a medicine the patient is receiving, the newest medicine and the medicine whose effects match the event being the first candidates; document the event, the medicines with start dates, the time course and the outcome; assess causality in the structured way the standard methods require, considering temporal relationship, whether the event is a known effect, whether it improved when the drug was stopped and recurred if given again, and whether the disease or another medicine explains it better; act, with the prescriber, to stop or replace the medicine where the risk requires it, and to treat the reaction; and report, through the hospital's system into the national pharmacovigilance programme, because a reaction protects other patients only when it enters the pooled record from which signals are detected.

Adverse drug reaction: from suspicion to signal



A reaction protects future patients only when it enters the pooled record

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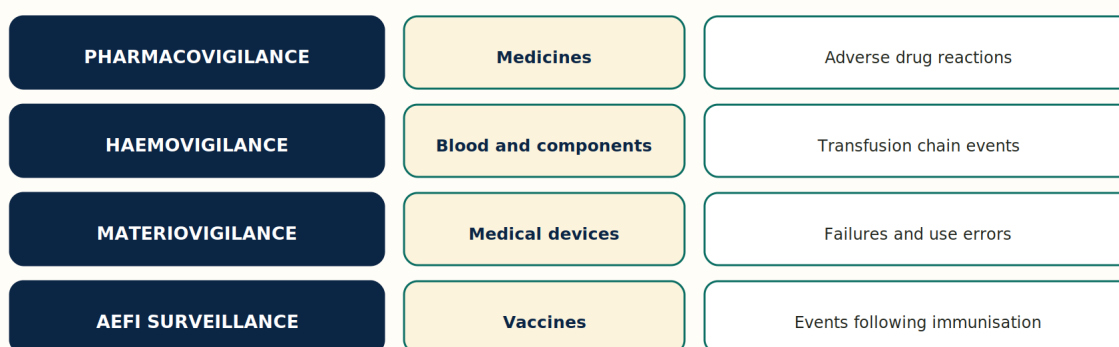
Figure: From suspicion to signal. A reaction helps future patients only when the bedside chain ends in a report that enters the pooled national record.

2.4 Haemovigilance, materiovigilance and AEFI

The syllabus names three companion vigilance activities beside pharmacovigilance, and the student should be able to place each precisely, because together they show that vigilance in modern Indian practice is a family of systems matched to the product involved. Haemovigilance is the system for blood and blood components: surveillance procedures covering the whole transfusion chain, from collection from donors through processing, storage and issue to transfusion and follow up of recipients and donors, concerned with adverse reactions, incidents, errors and near misses. Its clinical point is traceability: every unit must be traceable from donor to recipient and back, so a reaction or later discovered risk can be followed to every patient it touches, and the pharmacist meets it in transfusion committees and in the investigation of transfusion reactions. Materiovigilance is the system for medical devices: monitoring of adverse events and problems associated with devices in use, from implants and instruments to in vitro diagnostics, reported and analysed so that defective or unsafe devices can be corrected, recalled or withdrawn. Its characteristic events are device failures and use errors rather than pharmacological effects, and the pharmacist encounters it wherever devices and medicines meet, as in delivery devices and infusion equipment. AEFI, adverse events following immunisation, is the vigilance activity of the immunisation programme: an AEFI is any untoward medical occurrence which follows immunisation and does not necessarily have a causal relationship with the vaccine, and such events are reported, investigated and causality assessed through the programme's own system, which must separate events caused by the vaccine product, by an immunisation error, or by anxiety, from coincidental events, a separation on which public confidence in immunisation depends.

System	Product covered	Characteristic events
Pharmacovigilance	Medicines	Adverse drug reactions and other drug related problems
Haemovigilance	Blood and blood components	Transfusion reactions, incidents, errors and near misses
Materiovigilance	Medical devices	Device failures, malfunctions and use errors
AEFI surveillance	Vaccines	Any untoward occurrence following immunisation, causal or not

The vigilance family: one method, four products



In all four: structured report, causality assessment, pooled signal detection

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Figure: The vigilance family. One method, event, report, causality assessment and signal, matched to four kinds of product.

2.5 Patient medication counselling

Patient medication counselling is the pharmacist's oral, and where useful written, communication with the patient or carer that ensures the patient understands the medicines and can use them correctly and safely after the consultation ends. It is a clinical service and not a courtesy conversation, because therapy reviewed perfectly in hospital fails at home if the patient takes the wrong dose, at the wrong time, by the wrong technique, or stops at the first side effect no one warned about. Its content, for each medicine, is

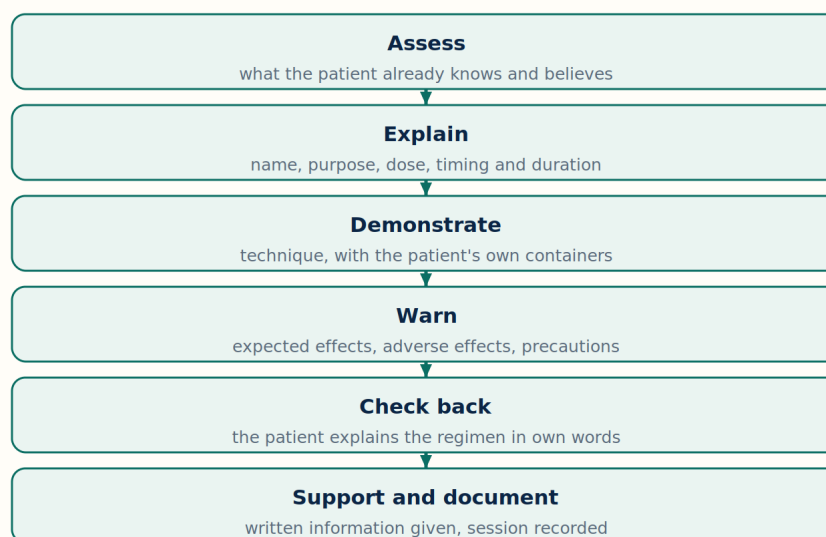
standard: the name of the medicine and what it is for, in the patient's own terms; how and when to take it, frequency, timing in relation to food and other medicines, and what to do if a dose is missed; how long to continue, rather than stopping when symptoms ease; technique where the medicine demands it, inhalers, injections, eye preparations and topical applications being the cases in which the method is half the therapy; expected effects and their time course; the important adverse effects, which are minor and transient and which require prompt medical advice; storage and safe keeping away from children; and precautions specific to the medicine and the patient, including alcohol, over the counter and herbal products the patient must now report rather than add silently. Counselling is prioritised where its absence is most dangerous: at discharge, when medicines are new or changed, for high risk medicines and complex regimens, for techniques, and for patients whose history showed adherence difficulty.

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Patient medication counselling sequence
Assess what the patient knows and believes
|
v
Explain: name, purpose, dose, timing, duration
|
v
Demonstrate technique where the medicine demands it
|
v
Warn: expected effects, adverse effects, precautions
|
v
Check understanding: the patient explains the regimen back
|
v
Support with written information and document the session

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Patient medication counselling: the steps



Understanding is verified by the check back, never assumed from nodding

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Figure: Counselling as a sequence with a check at its end. Understanding is verified by the patient explaining the regimen back, not assumed from nodding.

2.6 Drug utilisation evaluation

Drug utilisation evaluation, also taught as drug use evaluation, is the structured, criteria based review of how a medicine or a class of medicines is actually used in an institution, conducted to improve the quality and economy of prescribing. Where drug therapy review examines one patient's therapy, drug utilisation

evaluation examines a pattern across patients. The method follows a fixed cycle the student should be able to reproduce. A medicine or problem is selected for study, usually because it is high risk, high cost, high volume, or suspected of misuse, and the selection is approved through the hospital's pharmacy and therapeutics structure. Criteria are written in advance, drawn from accepted evidence and guidelines, stating what counts as appropriate use: indications, patient selection, dose form, route and duration standards, the monitoring expected, and the outcomes to be counted. Data are then collected, prospectively or retrospectively from records, on a defined sample, and compared against the criteria, so the result is a measured gap between actual use and agreed standards rather than an impression. The findings are reported to prescribers and the committee with proposals for action, which may be educational, may revise the formulary or a guideline, or may restrict how the medicine is initiated; and after the action, the evaluation is repeated to confirm that use has moved toward the criteria. The pharmacist's role is central at every step: proposing topics, drafting criteria, designing data collection, analysing results and presenting them in a form prescribers can act on.

2.7 Documentation of clinical pharmacy services

Documentation is the written record of clinical pharmacy work, and the syllabus gives it the standing of a service in its own right because undocumented clinical work cannot be verified, handed over or improved. What is documented follows the service set: the medication history; the chart endorsement and review notes of Unit 1; each intervention, with the problem, the recommendation, the prescriber's response and the outcome; counselling given, with the aids supplied; adverse drug reactions suspected, assessed and reported; drug information queries and the answers given, by the records of Unit 5; and the department's activity record, the counts and summaries from which reports to hospital management are built. The standards are those of any clinical record: contemporaneous, written at the time of the activity and not reconstructed later; accurate and specific, naming the medicine, the problem and the action in terms another professional can act on; attributable, signed and dated by the pharmacist who did the work; held in the record systems the hospital uses; and confidential, under the same duties as every other part of the clinical record.

2.8 Quality assurance of clinical pharmacy services

Quality assurance of clinical pharmacy services is the systematic activity by which a department confirms that its services are delivered to the standard it claims, finds where they fall short, and improves them. It closes Unit 2 because it closes the loop on every other service in the unit: histories, counselling, review, vigilance and information work are each auditable, and quality assurance is the auditing habit organised. Its instruments are standard. Standards and procedures are written first, the department's service descriptions and standard operating procedures, against which performance can be measured at all. Indicators are chosen that reflect real risks and value: the proportion of charts reviewed and endorsed, the number and acceptance pattern of interventions, counselling coverage at discharge, the completeness and timeliness of adverse reaction reporting, the turnaround and quality of drug information answers, and the outcomes of drug utilisation evaluations. Performance is measured by audit, by peer review of records and answers, and by the feedback of prescribers, nurses and patients; gaps are analysed for their cause, which may be staffing, training, a defective form or a defective process, and the remedy is matched to the cause rather than to the person nearest the gap. Changes are then made and the indicator measured again, which is the audit cycle, quality assurance being a cycle and not an inspection event. Measurement must serve care and not replace it: a department that maximises counted activities while their quality thins has inverted the purpose, which is why peer review of content accompanies the counting of records. And quality assurance is prospective as well as retrospective: training, supervision of new staff, double checking of high risk work and current drug information sources prevent defects that audit would otherwise only count.

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