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DEPARTMENT OF CLINICAL PHARMACY AND PHARMACY PRACTICE

PHARM D

600 LEVEL PRACTICAL MANUAL

DRUG INFORMATION SERVICES AND LITERATURE EVALUATION

PCP 617

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SCHEDULE ONE: PATIENT CONFIDENTIALITY (ETHICAL & LEGAL)

1. **Patient Confidentiality (Ethical & Legal)**
- Ethics: Uphold trust by protecting patients' private information.
- Legal: Protected under laws like HIPAA (in the US); in Nigeria, governed by professional codes and privacy laws.
- Example: A pharmacist must not disclose a patient's medication history without consent.
2. **Liability in Providing Drug Information**
- Ethics: Provide accurate, unbiased, and updated information.
- Legal: If incorrect or outdated info leads to harm, the provider (or institution) may be held liable.
- Example: Giving wrong dosage info that causes overdose could result in malpractice claims.
3. **Quality Assurance in DI Services**
- Ethics: Maintain high standards in sourcing, reviewing, and delivering information.
- Legal: Institutions may require standard operating procedures (SOPs) and documentation.
- Example: Using peer-reviewed references and updating databases regularly.

Summary:
Ethical and legal practices ensure:
- Patient safety and trust
- Professional accountability
- Accurate and evidence-based guidance

1. Patient Confidentiality

Case Example:
A hospital pharmacist receives a call from a patient's relative asking for details about the patient's medications. The pharmacist, without verifying consent, shares the medication list. Later, the patient complains about breach of privacy.

Ethical Issue: Confidentiality violation
Legal Implication: Breach of privacy laws or professional conduct

Sample Policy:

- Drug information personnel shall not disclose any patient-identifiable data without proper authorization.
- All DI requests involving patient details must include signed patient consent or approval from the treating clinician.

SCHEDULE TWO: LIABILITY IN PROVIDING DRUG INFORMATION

2. Liability in Providing Drug Information

Case Example:

A DI center provides outdated dosage information on a narrow therapeutic index drug (e.g., digoxin). The patient suffers toxicity, and investigation reveals the pharmacist used an old reference.

Ethical Issue: Failure to provide accurate, current info
Legal Implication: Possible negligence or malpractice claim

Sample Policy:
- All DI responses must be backed by current, peer-reviewed, evidence-based references.
- Pharmacists must document the source, version, and date of each reference used.

3. Quality Assurance in DI Services

Case Example:
An audit shows inconsistencies in DI responses across staff, leading to variability in clinical decisions.

Ethical Issue: Inconsistent patient care
Legal Implication: Institutional liability for harm due to poor-quality DI services

Sample Policy:
- Establish SOPs for responding to DI queries, including response time, documentation, reference use, and review.
- Conduct periodic peer reviews and training for DI staff.
- Maintain a logbook for all queries and responses.

Optional Additional Policies:
- Conflict of Interest Disclosure: DI providers must disclose if any financial or other relationships may influence their responses.
- Training & Competency: All staff must undergo annual training on medical literature appraisal, database use, and legal responsibilities.

Ethical Issue: Acting beyond professional competence
Legal Implication: If harm occurs, pharmacist may be held liable for practicing medicine without a license

Lesson: Refer dosage changes to prescriber unless within established protocol and collaboration.

7. Use of Unverified Sources

Case Example:

A DI officer copies content from a blog post (non-peer-reviewed) to respond to a query about off-label drug use in pediatrics.

Ethical Issue: Use of unreliable sources
Legal Implication: Patient harm from inaccurate advice; possible disciplinary action

Lesson: Use peer-reviewed, evidence-based, and updated references only.

8. Delay in Responding to Urgent Query

Case Example:
An ICU physician urgently requests an antidote dose for drug overdose. The DI center responds after 6 hours due to poor internal communication. The delay affects patient outcome.

Ethical Issue: Failure to prioritize patient safety
Legal Implication: Institutional responsibility for delay

Lesson: Triage and prioritization protocols must be in place for time-sensitive DI requests.

4. Incomplete Drug Interaction Information

Case Example:
A physician calls the DI center about potential interaction between a new antibiotic and a patient's existing anticoagulant. The DI staff, in a rush, checks only one database and fails to detect a major interaction. The patient is later hospitalized due to bleeding complications.

Ethical Issue: Inadequate review of evidence
Legal Implication: Professional liability for harm due to incomplete information

Lesson: Always consult multiple reliable sources and document responses.

5. Misuse of Personal Data

Case Example:
A pharmacist conducting a drug use evaluation includes patient initials and full hospital numbers in a public presentation.

Ethical Issue: Breach of confidentiality
Legal Implication: Violation of data protection regulations (e.g., NDPR in Nigeria, HIPAA in the U.S.)

Lesson: Patient data must be anonymized or excluded unless consent is obtained.

6. Providing Drug Info Outside Scope of Practice

Case Example:

A community pharmacist gives detailed advice about adjusting insulin dosage over the phone without full patient history.

Policy A: Patient Privacy & Confidentiality

- All patient-identifiable information must be kept confidential.
- No patient data may be disclosed outside clinical decision-making without explicit consent or authorized request from treating clinician.
- Data used for audits, presentations, or teaching must be de-identified or anonymized.

Policy B: Evidence-based Information & Source Documentation

- DI staff must use peer-reviewed journals, validated drug databases, standard textbooks, and latest clinical guidelines.
- For every response, record the source, date, version.

Outdated or non-validated sources are not acceptable for clinical advice.

Policy C: Scope-of-Practice & Referral

- Pharmacists or DI staff should advise or inform, not prescribe or adjust therapeutic regimens, unless part of a formal collaborative care agreement and with full clinical context.
- For dosage adjustments or therapy changes, refer to the prescribing clinician or multidisciplinary team.

Policy D: Urgent Request Protocol

- Establish a triage system: flag time-sensitive (e.g. overdose, paediatric dose, severe interaction) requests as “urgent”.
- Ensure dedicated on-call or standby DI officer, or prioritized workflow for urgent queries.
- Set maximum response time, e.g. within 30 min to 1 hour for critical queries.

Policy E: Quality Assurance & Continuous Training

- Maintain a logbook/database of all DI queries and responses (date, requester, content, sources).
- Conduct monthly or quarterly peer-review audits to check consistency, appropriateness, and currency of responses.
- Provide regular training to DI staff on literature evaluation, ethical standards, data privacy, and new drug information tools/databases.

SCHEDULE THREE: ETHICS AND LEGAL ASPECTS OF DRUG INFORMATION

What are the ethics and legal aspects of drug information including evidence-based medicine, principal and application in clinical practice, PICO framework for framing clinical questions, applying literature to patient care

Ethics and Legal Aspects of Drug Information

1. **Ethical and Legal Foundations.**

   Ethical practice in drug information centers on principles such as **beneficence**, **non-maleficence**, **autonomy**, and **justice**. Legally, providers must ensure **informed consent**, especially when prescribing medications with significant side effects or experimental use. Physicians are obligated to assess risks versus benefits and disclose relevant information, aligning with the principle of "do no harm." Regulatory agencies like the **FDA** enforce evidence-based drug approval processes and labeling to ensure safety and efficacy. Additionally, laws governing controlled substances (e.g., DEA regulations) and national standards for safe medication administration further underscore the legal responsibilities in drug information dissemination.

2. **Evidence-Based Medicine (EBM).**

   EBM integrates the best available research evidence with clinical expertise and patient values to guide safe and effective care. It is a systematic, lifelong learning process involving asking targeted questions, efficiently retrieving evidence, critically appraising it, applying it to practice, and evaluating outcomes. In pharmacy, EBM supports accurate drug information provision, helps scrutinize orders, and promotes rational medication use—reducing misuse, overuse, and underuse.

3. **Principles and Application in Clinical Practice.**

   The core EBM cycle—**Ask, Acquire, Appraise, Apply, Assess**—guides clinical decision-making. For pharmacists, this means framing clinical questions, conducting comprehensive literature searches, evaluating study design and validity, and applying findings tailored to individual patient contexts. Educational tools like the **Education Rx**, used in pharmacy training, reinforce this process by helping learners translate clinical uncertainties into structured questions and evidence-based answers.

4. **PICO Framework for Framing Clinical Questions**
   The PICO model (Population, Intervention, Comparison, Outcome) offers a clear structure for formulating answerable clinical questions. It enhances search precision and relevance when retrieving evidence.
   Example: “In patients with congestive heart failure (P), does an ACE inhibitor (I) compared to an ARB (C) result in better blood pressure control (O)?”

5. **Applying Literature to Patient Care**
   After identifying relevant studies (e.g., systematic reviews, RCTs), clinicians must appraise validity—considering study design, sample size, inclusion/exclusion criteria, and statistical methods. Then, they evaluate whether the findings apply to the specific patient’s characteristics and context.
   Finally, clinicians implement recommendations thoughtfully and monitor outcomes, adapting as necessary.

In summary, the ethical and legal dimensions of drug information are grounded in safeguarding patient welfare, ensuring transparency, and adhering to professional and regulatory standards. Evidence-based medicine and structured frameworks like PICO are essential tools that support accurate, ethical, and patient-centered decision-making. Let me know if you'd like real-world examples or deeper exploration into any of these areas.

SCHEDULE FOUR: EVIDENCE-BASED MEDICINE (EBM), PICO FRAMEWORK, AND APPLICATION OF LITERATURE TO PATIENT CARE

Concise overview of ethics and legal aspects of drug information (DI), specifically in the context of evidence-based medicine (EBM), PICO framework, and application of literature to patient care:

3. PICO Framework for Framing Clinical Questions

- PICO helps formulate focused clinical questions:
  - P – Patient/Problem
  - I – Intervention
  - C – Comparison
  - O – Outcome

- Ethical Importance: Asking the right question ensures relevant, accurate answers, improving patient safety.

- Example:
  In adults with hypertension (P), is amlodipine (I) more effective than lisinopril (C) in reducing blood pressure (O)?

4. Applying Literature to Patient Care

- Use systematic approach:
- Search high-quality sources (e.g., PubMed, Cochrane, NICE, guidelines).
- Evaluate levels of evidence (RCTs > observational > expert opinion).
- Tailor findings to individual patient needs (renal function, comorbidities, preferences).

- Ethical Application:
- Present balanced, unbiased information.
- Inform clinicians of uncertainties, risks, or evidence gaps.
- Respect shared decision-making with the patient.

Examples for each ethics and legal aspect of drug information and evidence-based medicine application:

1. Patient Confidentiality
Example: A pharmacist receives a drug information request from a nurse asking whether a specific antiepileptic can be used in a “25-year-old pregnant woman with liver disease.” The pharmacist must avoid including patient name or hospital ID when consulting references or discussing with colleagues.

2. Liability in Providing Drug Information
Example: A pharmacist recommends combining two medications without checking for interactions. The patient suffers adverse effects, and it's found the pharmacist didn't consult a reliable database. This could result in professional liability if proven negligent.
3. Quality Assurance in DI Services
Example: A hospital sets up a policy where all responses to DI queries are reviewed by a senior pharmacist before being sent out. This improves accuracy and protects the institution from error-related liability.

4. Evidence-Based Medicine Application
Example: A physician considers using a new anticoagulant. The pharmacist conducts a literature review of randomized controlled trials and uses clinical guidelines to advise that the new drug may not be better than the standard therapy for the patient’s condition.

SCHEDULE FIVE: PRACTICAL QUESTIONS

PRACTICAL QUESTIONS

1. Cardiology Example
- P: Adults with heart failure
- I: Use of beta-blockers
- C: No beta-blockers
- O: Reduction in mortality

PICO Question: In adults with heart failure, does using beta-blockers compared to not using them reduce mortality?

2. Infectious Disease Example
- P: Hospitalized patients with COVID-19
- I: Remdesivir
- C: Standard care
- O: Time to recovery

PICO Question: In hospitalized COVID-19 patients, does remdesivir compared to standard care reduce recovery time?

3. Pediatrics Example
- P: Children with otitis media
- I: Antibiotic treatment
- C: Watchful waiting
- O: Symptom resolution within 48 hours

PICO Question: In children with otitis media, does immediate antibiotic use compared to watchful waiting improve symptom resolution within 48 hours?

4. Public Health Example
- P: Adolescents in rural areas
- I: Health education program
- C: No health education
- O: Improved contraceptive use

PICO Question: Among adolescents in rural areas, does a health education program improve contraceptive use compared to no intervention?

5. Endocrinology
- P: Adults with type 2 diabetes
- I: GLP-1 receptor agonists
- C: Sulfonylureas
- O: Better glycemic control (HbA1c reduction)

PICO Question: In adults with type 2 diabetes, do GLP-1 receptor agonists improve glycemic control compared to sulfonylureas?

6. Obstetrics
- P: Pregnant women at risk of preeclampsia
- I: Daily low-dose aspirin
- C: No aspirin
- O: Reduced incidence of preeclampsia

PICO Question: In pregnant women at risk of preeclampsia, does daily low-dose aspirin reduce its incidence compared to no treatment?

7. Psychiatry
- P: Adults with major depressive disorder
- I: Cognitive behavioral therapy (CBT)
- C: Antidepressants
- O: Symptom reduction

PICO Question: In adults with major depressive disorder, is CBT more effective than antidepressants in reducing symptoms?

8. Surgery
- P: Patients undergoing abdominal surgery
- I: Laparoscopic approach
- C: Open surgery
- O: Shorter hospital stay

PICO Question: In patients undergoing abdominal surgery, does laparoscopy reduce hospital stay compared to open surgery?

9. Pediatrics (Vaccination)
- P: Children under 5 years
- I: MMR vaccination
- C: No vaccination
- O: Prevention of measles

PICO Question: In children under 5, does MMR vaccination prevent measles better than no vaccination?

10. **Ethical & Legal: Duty to Warn**

Scenario: A dentist writes a prescription for 90 tablets of oxycodone for a patient with known suicidal ideation. The pharmacist notices the risk.

Question: What ethical and legal responsibilities does the pharmacist have, and how should they act?

11. Scenario: A clinician asks about using a newly approved drug for a rare condition, but evidence is limited.

Question: How should the drug information specialist apply EBM principles to provide a balanced recommendation?

12. **Principles & Application in Clinical Practice**

Scenario: A nurse considers offering a patient an unapproved compounded medication that has only anecdotal evidence of efficacy.

Question: Which ethical principles are relevant, and how should the nurse proceed?

13. **PICO Framework: Framing Clinical Questions**

Scenario: A physician asks whether acetylcysteine plus hydration protects kidneys better than hydration alone before contrast imaging in patients with renal failure.

Question: Construct this using PICO and explain the benefits of doing so.

14. Applying Literature to Patient Care

Scenario: A patient with renal impairment asks whether the standard dose of Drug Y is safe. The only available data are from pharmacokinetic studies—not clinical trials.

Question: How should the drug information specialist interpret and apply this information?

15. Cardiology

a. P: Adults with atrial fibrillation
b. I: Early initiation of direct oral anticoagulants (DOACs)
c. C: Warfarin therapy
d. O: Reduction in stroke incidence

16. Infectious Disease

a. P: Children aged 2–12 with acute otitis media
b. I: High-dose amoxicillin-clavulanate
c. C: Standard-dose amoxicillin
d. O: Clinical cure at 7 days

17. Endocrinology

a. P: Adults with type 2 diabetes inadequately controlled on metformin
b. I: Addition of GLP-1 receptor agonist
c. C: Addition of sulfonylurea
d. O: Improvement in HbA1c after 6 months

18. Pulmonology

a. P: Patients with moderate persistent asthma
b. I: Inhaled corticosteroid plus long-acting beta-agonist combination inhaler
c. C: Higher-dose inhaled corticosteroid alone
d. O: Frequency of asthma exacerbations

19. Orthopedics

a. P: Older adults with osteoarthritis of the knee
b. I: Structured land-based exercise program
c. C: Standard care without structured exercise
d. O: Improvement in pain and function at 12 weeks

20. Psychiatry

a. P: Adults with moderate major depressive disorder
b. I: Cognitive-behavioral therapy (CBT)
c. C: Pharmacotherapy with SSRIs
d. O: Remission rates at 12 weeks

21. Gastroenterology

a. P: Adults with Helicobacter pylori infection
b. I: Bismuth quadruple therapy
c. C: Standard triple therapy
d. O: Eradication rate

22. Oncology

a. P: Adults with advanced non–small cell lung cancer (NSCLC) harboring EGFR mutations
b. I: First-line EGFR tyrosine kinase inhibitor (TKI)
c. C: Platinum-based chemotherapy
d. O: Overall survival

23. Neurology

a. P: Adults with acute ischemic stroke within 3 hours of symptom onset

b. I: Intravenous tissue plasminogen activator (tPA)
c. C: Standard supportive care without tPA
d. O: Functional independence at 90 days

24. Nephrology

a. P: Patients with chronic kidney disease (stage 3–4)
b. I: Low-protein diet plus ACE inhibitor
c. C: ACE inhibitor alone
d. O: Slower progression to end-stage renal disease

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