MINNESOTA BOARD OF PHARMACY

Safe Injectable Medication Practices

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Conflict of Interest Disclosure

• No conflict of interest to disclose

• Employed by the Minnesota Board of Pharmacy





- 1. Describe the objective, scope, and minimum practice standards for the preparation of compounded sterile preparations (CSP)
- 2. Explain the differences between a medication expiration date and beyond use date, and how each is used
- 3. List best practices for the safe use of singledose vials and multiple-dose vials
- Understand the risks and recommendations for safe practices associated with adult IV push injection preparation and administration

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Standards and Guidelines

- Association for Professionals in Infection Control and Epidemiology (APIC)
- Center for Disease Control and Prevention (CDC)
- Institute for Safe Medication Practices (ISMP)
- Joint Commission (JC) and related National Patient Safety Goals (NPSG)
- United States Pharmacopeia (USP)



Why are we concerned?

- Multiple exposures and outbreaks of viral and bacterial infections have occurred
- Unsafe injection practices include:
 - Reinsertion of used needles into multi-dose vials/solutions
 - Use of a single needle and syringe for multiple patients
 - Administration of medications from single-dose, single-use medication vials or IV bags to multiple patients
 - Failure to use aseptic technique and safe injection practices when preparing and administering injections
 - Inappropriate use of finger stick devices/glucometers



Compounding Legislation

Minn. Stat. 151.01 Definitions

- Subd. 35 Compounding
 - Preparing, mixing, assembling, packaging, and labeling a drug for an identified individual patient as a result of a practitioner's prescription drug order
 - Includes anticipatory compounding
 - Does not include mixing or reconstituting a drug according to the product's labeling or manufacturer's directions



Compounding Legislation

Minn. Stat. 151.01Definitions continued

- Subd. 36 Anticipatory Compounding
 - In the case of practitioners only, anticipatory compounding means the preparation of a supply of a compounded drug product that is sufficient to meet the practitioner's shortterm anticipated need for dispensing or administering the drug to patients treated by the practitioner



Compounding Legislation

Minn. Rule 6800.3300 Compounding Standards, subp. 1 and 2

- All licensed Minnesota pharmacies that compound nonsterile drug preparations must follow the USP, chapter 795, standards; and,
- Any licensed Minnesota pharmacy compounding a sterile product must follow the USP, chapter 797, standards



United States Pharmacopeial Convention (USP)

- Sets standards for the identity, strength, quality and purity of drugs, food ingredients and dietary supplements
- Standards are enforceable
- USP Compounding Expert Committee
- USP Compounding with Hazardous Drugs Expert Panel has developed new chapter 800 for the handling of hazardous drugs
 - Effective December 1, 2019



General Chapter <797> Pharmaceutical Compounding—Sterile Preparations

- Official in 2004
- Currently in revision to harmonize with USP 800
- Revision published in 2008 (currently enforceable)
- Minimum practice and quality standards for compounding sterile preparations



- Responsibilities of compounding personnel
- Personnel training and evaluation
- Compounded sterile preparation (CSP) microbial contamination risk levels
- Verification of compounding accuracy and sterility
- Environmental quality and control (facility design and equipment and air quality and flow)
- Finished preparation release checks
- Storage and beyond use dating (BUD)



http://www.usp.org/compounding/general-chapter-797

Scope:

- All persons who prepare compounded sterile preparations (CSP)
- All places where CSPs are prepared
 - Hospitals and other healthcare institutions
 - Patient treatment clinics, physician offices
 - Ambulatory surgery centers
 - Other locations and facilities in which CSPs are prepared, stored and transported
- Compounding practices only, not administration



http://www.usp.org/compounding/general-chapter-797

CSPs include any of the following

- Compounded biologics, diagnostics, drugs...
 - Aqueous bronchial and nasal inhalations
 - Baths and soaks for live organs and tissues
 - Injections (e.g. solutions, suspensions, etc.)
 - Irrigations for wounds and body cavities
 - Ophthalmic drops and ointments
 - Tissue implants
- Manufactured sterile products prepared according to the manufacturer's instructions or prepared differently



Objective: Prevent harm that could result from

- 1. Microbial contamination
- 2. Excessive bacterial endotoxins
- 3. Variability in intended strength that exceed monograph limits
- 4. Unintended physical and chemical contaminants
- 5. Use of ingredients of inappropriate quality



Contamination risk levels of CSPs

 Low-risk level 	
 Medium-risk level 	Compounding must be
 High-risk level 	environment (e.g. hood)

Immediate-use

Contamination risk level is assigned to a type of CSP according to its potential for introduction of contamination during compounding



Immediate-use CSPs

- Emergency or immediate patient administration
- CSPs not intended for storage
- Low-Risk level CSPs only
 - Simple transfers of ≤3 commercially manufactured sterile nonhazardous products
 - Not more than 2 entries into any one container or package (e.g., bag or vial)
- Continuous compounding procedure not to exceed one hour



http://www.usp.org/compounding/general-chapter-797

Immediate-use CSPs continued

- Aseptic technique must be followed
- If not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix ups with other CSPs, and direct contact of outside surfaces



Immediate-use CSPs continued

- Administration begins not later than 1 hour following the start of preparation
- Unless immediately/completely administered by the person who prepared, the CSP shall be labeled (patient ID, names/amounts of all ingredients, name/initials of preparer, and the exact 1-hour beyond use date (BUD) and time)
- If administration has not begun within 1 hour of prep, the CSP shall be promptly and properly discarded



http://www.usp.org/compounding/general-chapter-797

Expiration Date

- Included in the FDA approved labeling for a drug
- Determined by the manufacturer based on testing
- Date after which an unopened vial should not be used
 Rubber



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Beyond-Use Date (BUD)

- The date or time after which a CSP shall not be stored or transported
- The date is determined from the date or time the preparation is opened or compounded
- Based on the microbial risk level and chemical stability, whichever is shorter



Single-Dose Containers

- Opened or needle-punctured singledose containers (e.g., bags, bottles, syringes, and vials of sterile products and CSPs) shall be used within 1 hour if opened in worse than ISO Class 5 air quality, and any remaining contents must be discarded
- Open single-dose ampules shall not be stored for any period of time



https://www.drugs.com/pro/fentanyl-injection.html



http://www.usp.org/compounding/general-chapter-797

Multi-Dose Containers

- Multi-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions
- Usually contain antimicrobial preservatives
- The BUD after initially entering or opening (e.g., needle-punctured multiple-dose containers) is 28 days, unless otherwise specified by the manufacturer





https://mms.mckesson.com/

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CDC Safe Injection Practices

- Included in Standard Precautions
- Apply to the use of needles, cannulas that replace needles, and, where applicable intravenous delivery systems

THINGS

you need to know about injection safety:

- Needles and syringes are single use devices. They should not be used for more than one patient or reused to draw up additional medication.

Do not administer medications from a single-dose vial or IV bag to multiple patients.

Limit the use of multiple-dose vials and dedicate them to a single patient whenever possible.



One and Only Campaign





http://www.oneandonlycampaign.org/

NPSG 03.04.01

NPSG.03.04.01 Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and procedural settings

- Ambulatory, Critical Access Hospital, Hospital, Officebased Surgery
- 1. Label medications that are not immediately administered
 - An immediately administered medication is one that a staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process



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NPSG 03.04.01

- 2. Label medications when transferred from the original packaging to another container
- 3. Labels include the following
 - Medication or solution name and strength
 - Amount of medication or solution*
 - Diluent name and volume *
 - Expiration date when not used within 24 hours**
 - Expiration time when expires in < 24 hours**

*If not apparent from the container

**The date and time are not necessary for short procedures, as defined by the hospital



NPSG 03.04.01 continued

- 4. Verify all medications or solution labels both verbally and visually
 - Verification is done by two qualified individuals whenever the person preparing the medication or solution is not the person who will be administering it
- 5. Label each medication as soon as it is prepared, unless immediately administered
- 6. Immediately discard meds found unlabeled



https://www.jointcommission.org/standards_information/npsgs.aspx

NPSG 03.04.01 continued

- 7. Remove/discard all labeled containers at the conclusion of the procedure*
- 8. All medication and their labels are reviewed by entering and exiting staff responsible for medication management

*Note: This does not apply to multiuse vials that are handled according to infection control practices.



https://www.jointcommission.org/standards_information/npsgs.aspx

ISMP Guidelines and Tools

ISMP Safe Practice Guidelines for Adult IV Push Medications



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- Key elements of the medication use system
 - Patient information
 - Drug information
 - Communication of drug information
 - Drug labeling, packaging, and nomenclature
 - Drug storage, stock, standardization, and distribution
 - Device use
 - Environment, staffing, and workflow
 - Staff education and competency
 - Risk management, quality improvement challenges



- Risks associated drug labeling, packaging, and nomenclature, examples
 - IV medications prepared in empty syringes, left unlabeled
 - IV push medications prepared in 0.9% sodium chloride flush syringes and remain mislabeled as 0.9% sodium chloride
 - Pre-labeling empty syringes prior to use
 - Misleading/confusing pharmacy/manufacturer labeling or packaging



- Risks associated with drug storage, stock, standardization, and distribution
 - IV push drug dosages that need to be manipulated (e.g., vial-to-syringe or syringe-to-syringe transfer, dilution, use of a partial vial or ampule, more than one vial or ampule to prepare a dose)
 - Reconstitution of a medication on the unit using the incorrect type and/or amount of diluent, random choice of diluent type or amount
 - Use of 0.9% sodium chloride flush syringes to prepare (dilute, reconstitute) a med, then administer



- Risks associate with drug storage, etc. continued
 - Use of prefilled syringes as single- or multiple-dose vials from which to withdraw a dose
 - Preparation of IV flush syringes multiple patients from a common-source IV infusion bag of 0.9% sodium chloride outside of the pharmacy
 - Limited incentive for manufacturers to provide common concentrations in ready-to-administer packaging, often due to lack of standardization



- Risks associated with environment, staffing and workflow
 - Lack of dedicated locations for aseptic IV medication preparation that must be performed outside of the pharmacy
 - Lack of financial resources, human resources, or technology for safe pharmacy preparation of IV medications and/or purchase of commercial ready-toadminister products



- Risks associated with staff education and competency
 - Wide variability in preparation and administration procedures and lack of practice standards for IV drug preparation and administration
 - Learned workplace practices for IV push medications without sound scientific evidence
 - Limited knowledge and understanding as to how medications may be manipulated or administered by clinical staff



- Risks associated with staff education continued
 - Lack of training and experience with the IV push route of administration for undergraduates in professional nursing programs
 - Lack of a detailed review of safe IV injection practices during new hire orientation


- Risk management and quality improvement challenges
 - IV push medications selected, prepared, and administered by a single practitioner with limited or no safeguards to protect the patient/caregiver
 - Failure to follow appropriate infection control standards associated with IV injection preparation and administration
 - At-risk behaviors associated with IV push medications (e.g., unlabeled syringes)
 - Lack of a defined process to monitor IV injection practices or associated adverse effects after IV push drug administration



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Guidance Statements

- 1. Acquisition & distribution of adult IV push medications
- 2. Aseptic Technique
- 3. Clinician preparation
- 4. Labeling
- 5. Clinician administration
- 6. Drug information resources
- 7. Competency assessment
- 8. Error Reporting



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Guidance 1: Acquisition and Distribution of Adult IV Push Medications

1.1 To the greatest extent possible, provide adult IV push medications in a ready-to-administer form (to minimize the need for manipulation outside of a pharmacy sterile compounding area)

1.2 Use only commercially available or pharmacy-prepared prefilled syringes of appropriate IV solution to flush and lock vascular access devices



Guidance 2: Aseptic Technique

2.1 Use aseptic technique when preparing and administering IV push medications, flush/locking solutions, and other parenteral solutions administered by direct IV injection.

Aseptic technique includes:

- a. Hand hygiene prior to and after preparation and administration of the medication or solution
- Disinfection of the medication access diaphragm on a vial or the neck of an ampule prior to accessing the medication or solution



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Guidance 2: Aseptic Technique continued

- 2.1 Aseptic technique continued:
- c. Disinfection of the IV access port, needleless connector, or other vascular access device (VAD)
- d. The use of personal protective equipment (PPE) if contact and exposure to blood or bodily fluids are possible



Guidance 3: Clinician Preparation

3.1 Withdraw IV push medication from glass ampules using a filter needle or straw

3.2 Only dilute IV push medications when recommended by the manufacturer, supported by evidence, or in accordance with approved institutional guidelines

3.3 If dilution or reconstitution of an IV push medication becomes necessary outside of the pharmacy sterile compounding area, perform these tasks immediately prior to administration, in a clean uncluttered, and separate location, using approved drug information resources and sterile equipment and supplies



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Guidance 3: Clinician Preparation continued

3.4 Provide instructions and access to the proper diluent when reconstitution or dilution is necessary outside of the pharmacy sterile compounding area

3.5 Do not withdraw IV push medications from commercially available, cartridge-type syringes into another syringe for administration

3.6 Do not dilute or reconstitute IV push medications by drawing up the contents into a commercially-available, prefilled flush syringe of 0.9% sodium chloride



Guidance 3: Clinician Preparation continued

3.7 When necessary to prepare more than one medication in a single syringe for IV push administration, limit preparation to the pharmacy

3.8 Never use IV solutions in containers intended for infusion (e.g. mini bags) as common-source containers (multiple-dose product) to prepare IV flush syringes or to dilute or reconstitute medications for one or more patients



Guidance 4: Labeling

4.1 Appropriately label all clinician-prepared syringes of IV push medications or solutions, unless the medication or solution is prepared at the patient's bedside and is immediately administered to the patient without any break in the process

CMS ASC Survey observation: BUD and time must be on the label

SYRINGE N	IEDICATION
PATIENT	
DRUG	1
AMT	/
PREPARED DATE	TIME
PREPARED BY	
EXPIRES DATE	TIME

https://www.unitedadlabel.com/irrigation-solution-syringe-medication-label-3-x-1



Guidance 4: Labeling continued

- a. If the clinician needs to prepare and administer more than one syringe of medication or solution to a single patient at the bedside:
 - Prepare each medication or solution separately, and immediately administer it before preparing the next syringe **or**,
 - If preparing several IV push medications at a time for sequential IV push administration, label each syringe as it is being prepared, prior to the preparation of any subsequent syringes



Guidance 4: Labeling continued

- Alternatively, if a practitioner prepares one or more medications or solutions away from the patient's bedside, immediately label each syringe, one at a time, before preparing the next medication or solution
- c. Bring only one patient's labeled syringe(s) to the bedside for administration



Guidance 4: Labeling continued

4.2 Provide clinical units with blank or printed, ready-to-apply labels, including sterilized labels where needed, to support safe labeling practices

4.3 Immediately discard any unattended, unlabeled syringes containing any type of solution

4.4 Never pre-label empty syringes in anticipation of use



Guidance 5: Clinician Administration

5.1 Perform an appropriate clinical and vascular access site assessment of the patient prior to and following the administration of IV push medications

5.2 Unless its use would result in a clinically significant delay and potential patient harm, use barcode scanning or similar technology immediately prior to the administration of IV push medications to confirm patient identification and the correct medication



Guidance 5: Clinician Administration continued

5.3 Administer IV push medications and any subsequent IV flush at the rate recommended by the manufacturer, supported by evidence, or in accordance with approved institutional guidelines. Use an appropriate volume of the subsequent IV flush to ensure that the entire drug dose has been administered



https://i0.wp.com/www.aliem.com/wpcontent/uploads/2011/04/SalineSyringe.jpg?fit=400%2C253&ssl=1



Guidance 5: Clinician Administration continued

5.4 Assess central line patency using at a minimum, a 10 mL diameter-sized syringe filled with preservative- free 0.9% sodium chloride. Once patency has been confirmed, IV push administration of the medication can be given in a syringe appropriately sized to measure and administer the required dose

5.5 When administering IV push medications through an existing IV infusion line, use a needleless connector that is proximal (closest) to the patient, unless contraindicated in current evidence-based literature, or if the proximal site is inaccessible for use, such as during a sterile procedure



Guidance 6: Drug Information Resources

6.1 Standardized, facility-approved IV push medication resources are readily available at the point of care to guide the safe practice of IV push medication administration

Resources should include any special considerations for the preparation and administration of IV push medications and for unique practice locations where medications may be administered IV push to ensure effective patient monitoring



Guidance 7: Competency Assessment

7.1 Competency assessments for IV push medication preparation and administration are standardized across disciplines within healthcare organizations and validated through an initial assessment and on an ongoing basis



<u>1. www.ismp.org</u> <u>2. https://3.bp.blogspot.com/-</u> HefpNKDCqbc/V4Uw6ZVKv6I/AAAAAABErw/mDJIsbw0ac4xBWxnmp_aqZ116pg3bXXHACLcB/w1200-h650-pnu/Exa_Diag.jpg

Guidance 8: Error Reporting

8.1 Report adverse events, close calls, and hazardous conditions associated with IV push medications internally within the healthcare organization as well as in confidence to external safety organizations such as ISMP for shared learning

8.2 Use internal and external information about adverse events, close calls, and hazardous conditions associated with IV push medications for continuous quality improvement







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- Store, access and prepare medications in a designated clean medication area, not adjacent to potentially contaminated items
- Never store needles and syringes unwrapped. Remove the needle/cannula, syringe from its sterile packaging immediately before use
- Perform proper hand hygiene



- Use aseptic technique during all steps of medication preparation and administration
- Draw up medication into a syringe as close to administration time as possible
- Disinfect the rubber septum of medication vials and the neck of glass ampules with 70% alcohol, allowing adequate time to dry before entry
- Always use a new sterile needle and new sterile syringe to enter a vial (SDV or MDV) or IV bag



- Use a filter needle or filter transfer device to draw up medications from an ampule
- Never leave a needle, cannula or dispensing device in the septum of a medication vial for multiple medication draws
- Do not use prefilled syringes to dilute medications for administration
- Do not transfer prepared medication in one syringe to another syringe (e.g., by removal of the plunger or injecting into the bevel), or withdraw medication from a manufacturer's prefilled syringe



- Label all syringes containing medication if not immediately administered (include pt. ID, names and amounts of all ingredients, name/initials of who prepared the CSP, date and time the CSP was prepared, and BUD date/time)
- Discard syringes, needles and cannulas in approved sharps container/receptacle after/at the time of use
- Only prepare one medication for one patient at a time



Single Dose Vials (SDV)

- Prior to use, check the manufacturer's label and expiration date
- Use SDVs for injectable medications whenever possible
- Use SDVs for a single patient during the course of a single procedure. Discard the vial after this single use
- Do not administer medications from SDVs or ampules to multiple patients
- Do not combine or pool the leftover contents of SDVs or store for later use



Multi-dose Vials (MDV)

- MDVs should be dedicated to a single patient, whenever possible
- If used for more than one patient, MDVs should be stored and labeled appropriately, and only kept and accessed in a dedicated medication preparation area (e.g., nurses station)
- Once a MDV enters an immediate patient treatment area, it must be dedicated for singlepatient use only, and discarded immediately after use



Multi-dose Vials (MDV)

- Prior to use, check the manufacturer's label and expiration date prior to use
- Always inspect an open MDV for signs of contamination, and check the manufacturer's expiration and BUD prior to use
- Discard any vial that is exposed to or placed on a contaminated surface
- Discard a MDV with a needleless access device after use with a patient



Conclusion

- Form a multidisciplinary team
- Review procedures, practices and products
- Determine when and where sterile compounding occurs
- Evaluate the use of vials (SDVs and MDVs)



Conclusion

- Develop and implement evidence based policies and procedures
 - Complete training and competency assessments
 - Perform audits to determine compliance
- Identify locations for designated clean medication preparation where needed



Can a syringe of medication (typically, a pain med) be used to titrate small doses to a patient over time or must a new syringe be signed out and wasted for each dose? (e.g., fentanyl 50 mcg/ml, 2 or 5 ml ampule or SDV)

Answer: No. Fentanyl is available as an ampule or SDVs. Ampules must not be stored after opening. Use SDVs as single use. The manufacturer includes the following in the package insert "Contains no preservative. DISCARD ANY UNUSED CONTENTS"



https://www.drugs.com/pro/fentanyl-injection.html



Can a vial of propofol be used as a MDV?

Answer: No. Propofol is for single patient use only. Strict aseptic technique must always be maintained during handling



https://www.drugs.com/pro/propofol.html



Can you mix drugs like lidocaine with propofol into the IV line? Or is it better to give them separately?

- Answer: No, not unless you have a reference showing y-site compatibility with use of the same concentrations of each drug
- The manufacturer recommends administering IV lidocaine prior to administration of propofol or, alternatively, that lidocaine be added to propofol immediately before administration, in quantities not exceeding 20 mg lidocaine per 200 mg propofol



If a surgery suite is equipped with an automated dispensing cabinet, can a MDV be used and re-used for 28 days after opening?

Answer: Yes, but...best practice is to limit the use of a MDV to only a single patient, whenever possible

If you must use a MDV for more than a single patient, the MDVs must be kept in a dedicated medication prep area. Use a new needle and new syringe for each entry. Do not take the MDV into the immediate patient treatment area



Where should medications be drawn up (e.g. nursing unit, operating room, pre-inductions area)?

Answer: Medications should be drawn up in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed

Draw up a medication into a syringe as close to administration time as feasible. After drawing up the medication, inject within one hour (or as soon as feasible)

Label all syringes containing medication if not immediately administered



Is it acceptable to leave a needle or other device (e.g., needleless dispensing device) inserted in the septum of a medication vial for multiple medication draws?

Answer: No. A needle or other device should never be left inserted into a medication vial septum for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid. Use the vial and device only for one patient and discard

Spiking a bag, vial or bottle of sterile fluid with a dispensing device and leaving it in place to dispense medication for multiple patients puts patients at risk of infection and must be prohibited



How should medications prepared in perioperative and other procedural areas need to be labeled?

Do drawn up medications need to be labeled if immediately administered?

Answer: Per NPSG.03.04.01, immediately administered meds do not need to be labeled

Labeling includes:

- Medication or solution name and strength
- Amount of medication or solution, if not apparent
- Diluent name and volume, if not apparent
- Expiration date when not used in 24 hours
- Expiration time when expires in <24 hours



How far in advance can IV fluid bags be spiked prior to administration?

Answer: USP considers single dose containers (e.g., bags, bottles, syringes, and vials of sterile products and CSPs) opened or needle punctured in worse that ISO Class 5 environments as "immediate-use" and administration must begin not later than 1 hour following the start of preparation

Others recommend preparation as close to the time of administration, and completion of a risk assessment when considering extension of the 1 hour USP recommendation


Questions

Can bags of IV solutions be warmed?

Can they be left they be left in the warmer box until the next day or longer?

Answer: A manufacturer provides medication storage recommendations within product labeling or the package insert. For storage outside of the manufacturer's recommendations, a facility would need to obtain documentation from the manufacturer for that medication, stating the storage conditions and timeframes are acceptable. Accrediting bodies may request to see documentation from the manufacturer during inspection



Questions

Can the contents of a MDV vial be poured into a beaker and drawn up from it as needed?

Answer: No. Individual doses should be drawn up aseptically using a new needle and new syringe to enter the vial septum

For surgery, never use a decapping device to remove the top from a vial to pour the contents onto the sterile field (e.g., into a sterile basin) as vials are not designed for sterile pouring



Questions



http://modernmixing.com/wp-content/uploads/2011/01/questionmark.jpg



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