

Ambulatory Clinic Standards — Full Guidance

Complete criterion-by-criterion guidance: worked examples, first steps, common mistakes, implementation plans, and Monitor verification methods for all 127 criteria.

26 standards · 127 criteria · Version 4.0

ASF STANDARDS · AMBULATORY CLINIC · STANDARD 9

Standard 9 — Aesthetic & Injectable Medicine

4 criteria · 3 non-negotiable · 1 core · Version 3.0

CRITERIA IN THIS STANDARD

9.1 — A Licensed Physician Oversees Every Injection, Even If Not the Injector

9.2 — Injectable Products Are Sourced From Verified, Traceable Suppliers

9.3 — Vascular Occlusion Is Recognised and Treated Within Minutes, Not Hours

9.4 — Patients Are Screened for Genuine Medical Suitability Before Treatment

9.1 A Licensed Physician Oversees Every Injection, Even If Not the Injector

NON-NEGOTIABLE

A licensed physician holds genuine, documented oversight of every injectable procedure performed at this facility, whether or not the physician personally administers each injection — not an arrangement where trained staff inject with no real physician accountability.

In plain terms: A licensed doctor genuinely supervises every injectable treatment — has assessed the patient, is reachable, and is accountable — even if a nurse gives the injection.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Botulinum toxin and dermal fillers are prescription medicines with serious complications: vascular occlusion causing tissue death or blindness, infection, migration, anaphylaxis. In many jurisdictions they may only be administered under the direction of a doctor who has assessed the patient. 'Under the direction of' does not mean a name on a certificate; it means the doctor has seen the patient (in person or by video), approved the treatment plan, is contactable during the procedure, and is accountable for the outcome. A clinic where the doctor's name is on the wall but the doctor has never seen the patient has no medical oversight.

WHAT GOOD LOOKS LIKE

- A specific, named physician holds genuine, documented oversight.
- Oversight is real-time and immediate when a non-physician injects.
- The physician can describe specific, real involvement in recent cases.

COMMON FAILURE MODES

- No specific physician is named; oversight is a vague, general claim.
- Oversight exists only as after-the-fact paperwork review.
- The physician cannot describe any specific recent involvement.

WORKED EXAMPLE

IN PRACTICE

An aesthetic clinic with two nurse injectors and a 'medical director' who visited monthly.

BEFORE

The medical director signed prescriptions in batches for patients he had not seen. Nurses assessed, planned, and injected. During a vascular occlusion event, the doctor was unreachable for 40 minutes. There was no documented prescriber assessment for any patient.

ACTION

The clinic adopted a supervision model: every new patient has a video or in-person consultation with the prescribing doctor before first treatment, recorded in the notes; the doctor approves each treatment plan in writing; the doctor is on call by phone during all injection sessions with a 10-minute response commitment; the doctor reviews all adverse events within 24 hours. A second doctor was contracted to cover absences.

AFTER

The Monitor reviewed 20 patient records: each had a documented prescriber consultation and plan approval. Reviewed the on-call rota and phone log showing three test calls answered within 10 minutes. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Pull ten patient records: did the prescribing doctor assess this patient before treatment? Is it documented?
2. Ask: if a vascular occlusion happened right now, how fast could you reach the doctor?
3. Write a supervision agreement: consultation before treatment, plan approval, on-call availability.
4. Arrange cover for the doctor's absence.

The most common mistake: Calling a doctor who signs batch prescriptions for unseen patients a 'medical director.'

SELF-ASSESSMENT QUESTIONS

1. Is there a specific, named licensed physician with documented oversight of injectable procedures here? — *A specific person and a real, checkable oversight relationship, not an assumed general affiliation.*
Evidence: Physician oversight documentation

2. If a non-physician performs the injection, is the physician's oversight genuine and immediate, not remote or after the fact? — *Real-time availability and accountability, not a signature reviewed days later.*
Evidence: Oversight protocol document

3. Can the physician describe their actual involvement in a recent case, specifically? — A real, specific example, not a general description of the arrangement.

Evidence: N/A — tested directly

COMMON REASONS FOR A PARTIAL ANSWER

- **A physician is named but is rarely physically present during procedures.** — Named oversight without genuine availability doesn't provide real protection during a complication.
- **Oversight is real for complex procedures but looser for routine ones.** — Complications can occur even in routine cases; the oversight standard shouldn't depend on perceived complexity.
- **The physician reviews cases in batches at the end of the week.**

IMPLEMENTATION PLAN

When	What
Week 1	Confirm and document the specific overseeing physician and their real availability.
Week 2	Establish a real-time oversight protocol for non-physician injectors.
Week 3	Brief all staff on the specific oversight arrangement and escalation process.
Ongoing	Review oversight genuineness periodically, including physician availability records.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Oversight documentation review	Reviews documentation naming the specific overseeing physician and the nature of their oversight.
ASK	Physician involvement interview	Asks the physician to describe their actual, specific involvement in a recent injectable case.
OBSERVE	Real-time availability check	Checks whether physician oversight is genuinely immediate during procedures, not remote.

SUPERVISOR TIPS

- **Ask the physician for a specific, recent case example, not a general description.** — Specificity reveals whether oversight is genuine or a formality.
- **Ask a non-physician injector how they'd reach the physician during a complication, right now.** — A confident, specific answer reveals genuine real-time oversight.

EVIDENCE BASE

[49] Goodman GJ, Liew S, Callan P, Hart S. Facial aesthetic injections in clinical practice: Pretreatment and posttreatment consensus recommendations to minimise adverse outcomes. *Australas J Dermatol*. 2020;61(3):217-225 — establishes physician-level clinical oversight, proper patient selection, and technique as core risk-reduction requirements for injectable treatment.

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9.2 Injectable Products Are Sourced From Verified, Traceable Suppliers

NON-NEGOTIABLE

Every injectable product used is sourced from a verified, traceable supplier, with batch and lot records retained — not purchased through unverified channels where authenticity cannot be confirmed.

In plain terms: Every filler, toxin, and injectable comes from a verified, licensed supplier with batch and lot numbers recorded — never from a website, a colleague, or an unverifiable source.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Counterfeit botulinum toxin and filler are a global problem. Fake products have caused botulism, blindness, and disfigurement. They are sold online at half price, in packaging indistinguishable from the real thing. The only protection is traceability: a supplier authorised by the manufacturer or the national regulator, with invoices, and the batch and lot number of every vial recorded against every patient. If a product is recalled or a patient has an adverse reaction, the clinic must be able to say exactly which vial from which batch was used. A clinic that buys from the cheapest source cannot.

WHAT GOOD LOOKS LIKE

- All products are sourced from verified, traceable suppliers.
- Batch and lot records are complete and linked to patient records.
- Staff describe genuine awareness of counterfeit product risk.

COMMON FAILURE MODES

- Sourcing channels cannot be verified or are informal.
- Batch and lot records are incomplete or not retained.
- Staff show no awareness of counterfeit product risk.

WORKED EXAMPLE

IN PRACTICE

An aesthetic clinic sourcing toxin and filler through several channels including an online marketplace.

BEFORE

Stock came from an authorised distributor when available, an online site when cheaper, and occasionally from another practitioner. No batch numbers were recorded in patient notes. A patient developed an unusual reaction; the clinic could not say which vial or source had been used.

ACTION	The clinic wrote a procurement policy: only manufacturer-authorised distributors, verified against the manufacturer's published list; every invoice filed; batch and lot number recorded in the patient record at every treatment; a stock register linking each vial to its supplier and patients. The online source was discontinued and remaining stock from it destroyed.
AFTER	The Monitor sampled ten vials in stock and traced each to an authorised distributor invoice. Reviewed 15 patient records with batch numbers recorded. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. List every source you buy injectables from.
2. Check each against the manufacturer's authorised distributor list.
3. Start recording batch and lot numbers in every patient record.
4. Destroy stock you cannot trace.

The most common mistake: Assuming a product is genuine because the packaging looks right — counterfeit packaging is near-perfect.

SELF-ASSESSMENT QUESTIONS

1. Is every injectable product sourced from a verified, traceable supplier, not an unverified or informal channel? — *A checkable, legitimate supply chain, not just a lower price.*

Evidence: Supplier verification record

2. Are batch and lot numbers retained for every product used, linked to the patient record? — *Traceability that would allow a recall or adverse event investigation to actually work.*

Evidence: Batch and lot tracking record

3. Can staff describe how they'd recognise a counterfeit or suspicious product? — *Genuine awareness, not an assumption that sourcing alone guarantees authenticity.*

Evidence: N/A — tested directly

COMMON REASONS FOR A PARTIAL ANSWER

- **Primary products are verified but occasional supplementary products are not.** — Every injectable product carries the same real authenticity risk, not only the primary ones.
- **Batch numbers are recorded but not consistently linked to the specific patient treated.** — Traceability requires the link to the patient, not just the product record alone.
- **Verification happened once at the start of a supplier relationship but isn't ongoing.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current suppliers for all injectable products against verification standards.
Week 2	Establish batch and lot tracking linked to patient records.
Week 3	Train staff on recognising counterfeit or suspicious product indicators.
Ongoing	Periodically reconfirm supplier legitimacy.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Supplier verification review	Reviews documentation confirming products are sourced from verified suppliers.
DOCUMENT	Batch tracking review	Reviews batch and lot records for completeness and linkage to patient records.
ASK	Counterfeit awareness interview	Asks staff how they would recognise a suspicious or counterfeit product.

SUPERVISOR TIPS

- **Ask to see the actual supplier verification and batch records, not a general assurance.** — Documented, specific records are the only real evidence of genuine traceability.
- **Ask staff directly what would make them suspicious of a product's authenticity.** — Genuine awareness reveals itself in specific, real answers, not a memorized policy line.

EVIDENCE BASE

[50] Counterfeit injectable products, including unapproved botulinum toxin and dermal filler formulations, are a recognised and actively monitored risk in aesthetic medicine, with regulatory bodies issuing specific warnings to both practitioners and patients about verifying product source and authenticity before use.

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9.3 Vascular Occlusion Is Recognised and Treated Within Minutes, Not Hours

NON-NEGOTIABLE

Staff performing filler injections are specifically trained to recognise the signs of vascular occlusion immediately, with hyaluronidase or the appropriate emergency treatment genuinely available on-site — not requiring the patient to be sent elsewhere before treatment can begin.

In plain terms: Everyone injecting filler can recognise the signs of a blocked blood vessel within minutes, and the antidote (hyaluronidase) is in the room, in date, with a protocol to use it.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

When filler enters an artery, the tissue it supplies dies within hours — and if the artery leads to the eye, the patient is blind within minutes. The signs — blanching, pain out of proportion, mottling, visual change — are subtle at first and easy to dismiss. The treatment is high-dose hyaluronidase injected immediately, repeated until circulation returns. A clinic without hyaluronidase in the room, without a protocol on the wall, and without staff who have rehearsed it, will lose the window. This is the single most serious emergency in aesthetic practice and the one most often unprepared for.

WHAT GOOD LOOKS LIKE

- Staff are specifically trained to recognise early signs of vascular occlusion.
- Appropriate emergency treatment is genuinely on-site and in date.
- A specific, known escalation process exists beyond initial treatment.

COMMON FAILURE MODES

- Training covers general complications without specific occlusion recognition.
- Emergency treatment isn't on-site or is expired.
- Staff are uncertain what happens if initial treatment isn't sufficient.

WORKED EXAMPLE

IN PRACTICE

An aesthetic clinic performing 50 filler treatments a week.

BEFORE

Hyaluronidase was kept in the fridge in a back room, one vial, expired. No written protocol existed. Injectors had read about vascular occlusion but never rehearsed a response. The clinic's plan was to 'send the patient to hospital.'

ACTION

A vascular occlusion kit was assembled for each treatment room: hyaluronidase (multiple vials, in date, expiry checked weekly), aspirin, warm compresses, the protocol card. The protocol was based on current consensus guidance: recognise, stop, flood the area with hyaluronidase, massage, reassess every 15 minutes, repeat, escalate to ophthalmology if visual symptoms. All injectors completed a course and a quarterly simulation drill.

AFTER

The Monitor found the kit in each room, in date, with the protocol posted. Asked an injector to describe the first three steps; she did without hesitation. Reviewed two drill records. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Where is your hyaluronidase right now? Is it in date? How many vials?
2. Print the consensus vascular occlusion protocol and put it in every treatment room.
3. Assemble a kit per room and check expiry weekly.
4. Run a simulation drill this month.

The most common mistake: Keeping one vial of hyaluronidase somewhere in the building — occlusion needs multiple vials, in the room, now.

SELF-ASSESSMENT QUESTIONS

1. Are staff specifically trained to recognise the early signs of vascular occlusion during and immediately after injection? — *Specific, trained recognition, not general awareness that complications exist.*

Evidence: Vascular occlusion recognition training record

2. Is hyaluronidase, or the appropriate treatment for the products used, genuinely available on-site, not requiring off-site sourcing? — *Immediately available, not something ordered after a complication is recognised.*

Evidence: On-site emergency treatment stock record

3. Is there a defined, immediate escalation process if a suspected occlusion doesn't respond to initial treatment? — *A specific next step, not uncertainty about what happens if first-line treatment isn't enough.*

Evidence: Escalation protocol

COMMON REASONS FOR A PARTIAL ANSWER

- **Training happened once at hiring but hasn't been refreshed since.** — Rapid recognition under real pressure benefits from periodic reinforcement, not a single training session.
- **Hyaluronidase is stocked but its expiry date wasn't recently checked.** — Expired emergency treatment provides no real protection when actually needed.
- **Recognition training is strong for the injector but not for supporting staff who might notice symptoms first.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current vascular occlusion recognition training for specificity and recency.
Week 2	Confirm on-site emergency treatment stock and expiry dates.
Week 3	Establish and brief staff on a specific escalation protocol.
Ongoing	Refresh recognition training periodically, including for supporting staff.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Recognition training review	Reviews training records for specific vascular occlusion recognition, not general complication awareness.
OBSERVE	On-site treatment stock check	Physically confirms hyaluronidase or appropriate treatment is genuinely on-site and in date.
ASK	Escalation protocol interview	Asks staff what happens if a suspected occlusion doesn't respond to initial treatment.

SUPERVISOR TIPS

- **Ask to see the actual hyaluronidase stock and check its expiry date directly.** — Physical verification is the only real evidence of genuine on-site availability.
- **Ask a supporting staff member, not just the injector, how they'd recognise a complication.** — This reveals whether recognition training genuinely reaches everyone present, not just the injector.

EVIDENCE BASE

[51] Goodman GJ, Liew S, Callan P, Hart S. Facial aesthetic injections in clinical practice: Pretreatment and posttreatment consensus recommendations to minimise adverse outcomes. *Australas J Dermatol*. 2020;61(3):217-225 — identifies prompt recognition and treatment of vascular occlusion, including high-dose hyaluronidase availability, as critical to preventing permanent tissue damage.

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9.4

Patients Are Screened for Genuine Medical Suitability Before Treatment

CORE

Every patient undergoes a genuine medical suitability screening before treatment — relevant medical history, medications, prior reactions — not a booking process that moves directly from consultation to injection with no real screening step.

In plain terms: Before any aesthetic treatment, the patient’s medical history, medications, allergies, and previous reactions are genuinely assessed — not skipped because they only came for a 'small' procedure.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

The patient on blood thinners will bruise badly and may bleed. The patient with an autoimmune condition may react to filler. The patient with body dysmorphic disorder should not be treated at all. The patient who had a previous granuloma from a different filler needs a different plan. None of this is visible without asking. Aesthetic clinics often treat the consultation as a sales conversation and skip the medical screen — and then face a complication that a five-minute history would have predicted. A structured screening form, reviewed by the prescriber, is the minimum.

WHAT GOOD LOOKS LIKE

- Every patient undergoes genuine, structured screening before treatment.
- Screening specifically covers medications, prior reactions, and relevant conditions.

COMMON FAILURE MODES

- Screening is informal or skipped, moving directly to treatment.
- Screening content is generic and doesn't probe relevant risk factors.
- No example exists of screening ever changing a

- A real example exists of screening changing a treatment decision.

treatment decision.

WORKED EXAMPLE

IN PRACTICE

An aesthetic clinic where patients moved from a phone booking to treatment on the same visit.

BEFORE

The intake form asked for name, contact details, and treatment wanted. No medical history, medication list, or allergy question. A patient on warfarin had extensive bruising and a haematoma after filler; another with a history of cold sores developed a severe herpes outbreak after lip filler with no antiviral prophylaxis.

ACTION

A medical screening form was introduced: current medications, bleeding disorders, autoimmune conditions, allergies, previous aesthetic treatments and reactions, pregnancy, mental health history including body image concerns, and a body dysmorphia screening question. The prescriber reviews it before approving treatment. Patients on anticoagulants or with cold sore history follow specific protocols.

AFTER

The Monitor reviewed 20 patient records: all had completed screening forms reviewed and signed by the prescriber. Two showed treatment deferred based on screening. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Look at your intake form. Does it ask about medications, allergies, and previous reactions?
2. Add a one-page medical screen with a body image question.
3. Require prescriber review before any treatment.
4. Write protocols for anticoagulants and herpes history.

The most common mistake: Treating aesthetic patients as customers rather than patients — skipping the history because it might discourage the sale.

SELF-ASSESSMENT QUESTIONS

1. Does every patient undergo a genuine medical suitability screening before treatment, not just a booking conversation? — *A real, structured screening step, not an informal chat covering only what the patient happens to mention.*

Evidence: Screening documentation

2. Does screening specifically cover relevant medications, prior reactions, and medical conditions that change risk? — *Specific, relevant questions, not a generic intake form.*

Evidence: Screening content review

3. Where screening identifies a relevant risk factor, does this genuinely change the treatment decision? — *Screening that never changes an outcome isn't providing real protection.*

Evidence: N/A — tested directly

COMMON REASONS FOR A PARTIAL ANSWER

- **Screening happens for new patients but isn't repeated for returning ones.** — A patient's medical situation can change meaningfully between visits.
- **Screening covers medications but not prior reaction history specifically.** — Prior reaction history is one of the strongest predictors of future risk.
- **Screening identifies a risk factor but the decision to proceed anyway isn't documented with reasoning.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current screening practice for genuine structure and content.
Week 2	Build or strengthen a screening tool covering medications, prior reactions, and relevant conditions.
Week 3	Establish screening for returning patients, not only new ones.

When	What
Ongoing	Document reasoning whenever a screening-identified risk factor doesn't change the treatment decision.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Screening documentation review	Reviews a sample of patient records for genuine, structured screening before treatment.
DOCUMENT	Screening content review	Reviews the screening tool for coverage of medications, prior reactions, and relevant conditions.
ASK	Risk-factor response interview	Asks staff for a real example where screening identified a risk factor that changed the treatment plan.

SUPERVISOR TIPS

- **Ask for a real example where screening changed what was done for a patient.** — A real example reveals whether screening is genuine practice or a formality.
- **Check whether screening is repeated for returning patients.** — This is a common, specific gap — screening often concentrates only on new-patient intake.

EVIDENCE BASE

[52] Goodman GJ, Liew S, Callan P, Hart S. Facial aesthetic injections in clinical practice: Pretreatment and posttreatment consensus recommendations to minimise adverse outcomes. *Australas J Dermatol*. 2020;61(3):217-225 — identifies careful pretreatment patient selection as an essential risk-reduction step, distinct from general consultation.

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**Self-assess against these
criteria →**

**← Standard 8 — Dental
Practice**

**Standard 10 — Longevity &
IV Therapy →**

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Standard 10 — Longevity & IV Therapy

4 criteria · 3 non-negotiable · 1 core · Version 3.0

CRITERIA IN THIS STANDARD

- 10.1 — IV Line Insertion and Site Care Follow Recognised Infusion Standards
- 10.2 — Hormone and Peptide Products Are Sourced From Licensed, Regulated Suppliers Only
- 10.3 — Physician Oversight of Hormone and Peptide Protocols Is Genuine, Not Nominal
- 10.4 — Baseline Screening Happens Before Any Protocol Begins, Not After

10.1 IV Line Insertion and Site Care Follow Recognised Infusion Standards

NON-NEGOTIABLE

IV line insertion, site selection, and ongoing site care follow a recognised, evidence-based infusion therapy standard — aseptic technique, appropriate site selection, and defined site monitoring — not informal practice varying by whoever happens to be inserting the line.

In plain terms: IV drips and infusions are put in and looked after according to a recognised infusion standard — clean technique, the right vein, the site checked — not by whoever has done it before.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

A cannula placed without aseptic technique introduces bacteria directly into the bloodstream. A cannula in the wrong site — antecubital fossa in an ambulant patient, a vein that has been used repeatedly — fails and infiltrates. A site not monitored develops phlebitis nobody notices until the arm is red and swollen. Infusion therapy in wellness and longevity clinics is often delivered by staff whose training was informal and whose technique has drifted. The Infusion Nurses Society standards or an equivalent national standard define what good practice is; the clinic's job is to adopt one, train to it, and check compliance.

WHAT GOOD LOOKS LIKE

- Insertion technique is consistent and follows a recognised standard.
- Site selection is based on defined criteria, not convenience alone.
- Site monitoring happens on a defined schedule with a real response process.

COMMON FAILURE MODES

- Insertion technique varies significantly by individual staff member.
- Site selection has no defined criteria beyond ease of access.
- No defined monitoring schedule exists, or findings don't trigger any response.

WORKED EXAMPLE

IN PRACTICE

A longevity clinic delivering 30 IV infusions a day from four reclining chairs.

BEFORE

Cannulation was done by nurses and one non-nurse 'infusion specialist.' Technique varied. Skin was wiped with alcohol and cannulated immediately, without allowing to dry. Sites were not scored or monitored. Two patients had developed phlebitis in the previous month; one had a bloodstream infection requiring hospital admission.

ACTION	The INS Infusion Therapy Standards of Practice were adopted. Only registered nurses cannulate. A competency assessment was completed for each. The technique was standardised: hand hygiene, chlorhexidine-alcohol skin prep with 30-second dry time, sterile dressing, site labelled with date. A visual infusion phlebitis score is recorded every 30 minutes during infusion and at removal. Monthly audit of ten infusions.
AFTER	The Monitor observed three cannulations following the standard, reviewed competency records for all nurses, and reviewed the phlebitis audit (0 events in eight weeks). Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Watch three cannulations. Is skin prep allowed to dry? Is a sterile dressing applied?
2. Adopt a recognised infusion standard and train every cannulator to it.
3. Assess competency and record it.
4. Score every site at intervals and at removal.

The most common mistake: Wiping the skin and cannulating immediately — the antiseptic works only when it has dried.

SELF-ASSESSMENT QUESTIONS

1. Does IV insertion follow a recognised aseptic technique standard, applied consistently by every staff member who inserts lines? — *A recognised standard, applied consistently — not technique that varies by individual.*

Evidence: IV insertion protocol document

2. Is the insertion site selected and assessed against defined criteria, not simply whichever vein is easiest to access? — *Site selection based on vessel health and treatment need, not convenience alone.*

Evidence: N/A — tested directly

3. Is the IV site monitored on a defined schedule for signs of complication, with a specific response if found? — *A defined*

monitoring schedule and response, not informal checking.

Evidence: Site monitoring record

COMMON REASONS FOR A PARTIAL ANSWER

- **Technique is consistent for straightforward insertions but varies more for difficult access cases.** — Difficult access is exactly where technique consistency matters most for reducing complications.
- **Monitoring happens but isn't documented, relying on staff memory.** — Undocumented monitoring is difficult to distinguish from monitoring that didn't happen.
- **A response process exists for infection signs but not for infiltration or phlebitis specifically.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current insertion and site care practice against the recognised standard.
Week 2	Standardise technique and site selection criteria across all staff who insert lines.
Week 3	Establish a defined, documented site monitoring schedule.
Ongoing	Audit monitoring documentation and technique consistency periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Insertion technique observation	Observes an actual IV insertion for aseptic technique and site selection practice.
DOCUMENT	Monitoring schedule review	Reviews the defined site monitoring schedule and recent monitoring records.
ASK	Complication response interview	Asks staff what happens when site monitoring identifies a possible complication.

SUPERVISOR TIPS

- **Observe an actual insertion if timing allows, not just a description of policy.** — Real practice sometimes diverges

meaningfully from stated policy.

- **Ask about a specific difficult-access case and how it was handled.** — This reveals whether the standard genuinely holds under real, harder conditions.

EVIDENCE BASE

[53] Gorski LA, Hadaway L, Hagle ME, Broadhurst D, Clare S, Kleidon T, et al. Infusion Therapy Standards of Practice, 8th Edition. J Infus Nurs. 2021;44(suppl 1):S1-S224.

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→

This course teaches practical implementation of this standard. Free to enroll. ASF certificate on completion.

10.2 Hormone and Peptide Products Are Sourced From Licensed, Regulated Suppliers Only

NON-NEGOTIABLE

Every hormone, peptide, or compounded product used is sourced exclusively from a licensed, regulated compounding or manufacturing facility recognized by the relevant national medicines regulatory authority — never from research-use-only vendors, overseas suppliers, or any source without verifiable regulatory standing, regardless of cost or convenience.

In plain terms: Every hormone, peptide, or compounded product comes only from a pharmacy or manufacturer licensed by the national medicines regulator — never from a supplement website or a 'research chemicals' supplier.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Peptides sold as 'research chemicals' are unregulated: their content, purity, sterility, and dose are unverified. Growth hormone and testosterone from grey-market sources are frequently counterfeit or contaminated. Compounded hormones from an unlicensed compounder may be sub-potent, super-potent, or non-sterile. Injecting these into patients is injecting an unknown. The only acceptable source is one the national regulator licenses: a registered pharmacy, a licensed compounding pharmacy, or a manufacturer with marketing authorisation. Every product must carry a batch number that can be traced to that source.

WHAT GOOD LOOKS LIKE

- Every product is sourced from a specifically named, licensed, verifiable supplier.
- Research-use-only and overseas sourcing are genuinely excluded.
- Certificates of analysis are retained and available for review.

COMMON FAILURE MODES

- Sourcing cannot be verified, or "we have a supplier" is the only answer given.
- Research-use-only products are used under a different clinical framing.
- No certificates of analysis or equivalent verification exist.

WORKED EXAMPLE

IN PRACTICE

A longevity clinic offering peptide and hormone protocols.

BEFORE

Peptides were purchased from an online supplier selling 'for research purposes only.' Testosterone came from a pharmacy in another country without verification of its licence. Batch numbers were not recorded. A patient developed a sterile abscess at an injection site; the product could not be traced.

ACTION

The clinic wrote a sourcing policy: only products from suppliers holding a current licence from the national medicines regulator, verified annually against the regulator's register; only compounded products from a licensed compounding pharmacy with a certificate of analysis per batch; batch

numbers recorded in every patient record. All research-chemical stock was destroyed. Protocols requiring unavailable licensed products were discontinued.

AFTER

The Monitor sampled eight products in stock and traced each to a licensed supplier with a current licence. Reviewed 15 patient records with batch numbers. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. List every hormone and peptide product you use and its supplier.
2. Check each supplier's licence on the national regulator's website.
3. Destroy anything marked 'research use only' or from an unlicensed source.
4. Record batch numbers in patient records from today.

The most common mistake: Buying peptides labelled 'not for human use' and using them on humans — the label is not a formality.

SELF-ASSESSMENT QUESTIONS

1. Is every hormone or peptide product sourced from a licensed, regulated compounding or manufacturing facility, verifiable by name? — *A specific, named, licensed source — not "we have a supplier."*

Evidence: Supplier licensing verification

2. Are research-use-only or overseas-sourced products genuinely excluded, not used under a different label? — *Genuine exclusion, not the same product relabelled or described differently.*

Evidence: N/A — tested directly

3. Does documentation retain certificates of analysis or equivalent verification for products used? — *Real, retained verification, not assumed from the supplier's reputation alone.*

Evidence: Certificate of analysis records

COMMON REASONS FOR A PARTIAL ANSWER

- **Primary hormone products are properly sourced, but a newer peptide offering was added without the same verification.** — Sourcing verification needs to apply to every product offered, not only the established ones.
- **A licensed source is used but certificates of analysis aren't consistently retained.** — A legitimate source doesn't eliminate the value of retaining the actual verification documentation.
- **Staff know the practice sources responsibly in general but can't name the specific supplier.**

IMPLEMENTATION PLAN

When	What
Week 1	Audit every hormone and peptide product currently offered against supplier licensing status.
Week 2	Discontinue or replace any product without a verifiable, licensed source.
Week 3	Establish retained certificate-of-analysis documentation for all products.
Ongoing	Verify supplier licensing status periodically, not only at first sourcing.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Supplier licensing verification	Reviews documentation confirming every supplier's specific, current regulatory licensing status.
DOCUMENT	Certificate of analysis review	Reviews retained certificates of analysis or equivalent verification records.
ASK	Sourcing awareness interview	Asks staff to name the specific licensed source for a product currently in use.

SUPERVISOR TIPS

- **Ask staff to name the specific supplier for a product currently in use, not describe sourcing generally.** — Specificity is the real test of whether sourcing is genuinely verified versus assumed.
- **Ask directly whether any product offered is sourced as "research use only."** — A direct, specific question often surfaces

what a general policy question won't.

EVIDENCE BASE

[54] Unregulated peptide and hormone sourcing, including research-use-only vendors and overseas suppliers, is documented to carry real risks of incorrect product identity, contamination, and dosing error, with licensed, regulated compounding and manufacturing facilities recognized by the relevant national medicines regulatory authority representing the only verifiable, regulated sourcing channel.

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10.3 Physician Oversight of Hormone and Peptide Protocols Is Genuine, Not Nominal

NON-NEGOTIABLE

A licensed physician genuinely evaluates and prescribes each patient's specific hormone or peptide protocol, based on that patient's actual results and history — not a standardised protocol applied uniformly with a physician's name attached after the fact.

In plain terms: A doctor genuinely designs each patient's hormone or peptide protocol from that patient's own blood results and history — not a standard package applied to everyone who pays.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Testosterone therapy for a man with normal testosterone is not treatment; it is harm — raised haematocrit, suppressed fertility, cardiovascular risk. Growth hormone for a person without deficiency is the same. A 'longevity protocol' sold as a package, with the same drugs at the same doses regardless of the patient's results, is a product, not medicine. Genuine oversight means: the doctor reviews

the baseline results, decides whether treatment is indicated at all, sets the dose for this patient, and reviews monitoring results to adjust. Every decision is documented. The patient is not a customer buying a package; they are a patient receiving a prescription.

WHAT GOOD LOOKS LIKE

- Physician evaluation is genuinely individual, reflected in real, patient-specific documentation.
- Protocols are adjusted based on this patient's own monitoring results.
- The physician describes specific, real clinical reasoning for individual cases.

COMMON FAILURE MODES

- A standardised protocol is applied to all patients with a physician's name attached.
- Protocols never change regardless of individual monitoring results.
- The physician cannot describe specific reasoning beyond a general standard approach.

WORKED EXAMPLE

IN PRACTICE

A longevity clinic offering three tiered 'optimisation packages.'

BEFORE

Patients chose a package from a menu. The medical director signed prescriptions for the package contents without reviewing individual results. A patient with a haematocrit of 54% was prescribed testosterone; another with no growth hormone deficiency received GH. The doctor's involvement was a signature.

ACTION

The package model was discontinued. Every patient now has a doctor consultation reviewing baseline results; a written treatment decision (treat, do not treat, or refer) with reasoning; individually specified doses; and a monitoring schedule. The doctor sees monitoring results and documents adjustments. Patients with normal results are told treatment is not indicated.

AFTER

The Monitor reviewed 20 patient records: each showed a documented doctor decision

referencing that patient's results, individualised dosing, and monitoring reviews with adjustments. Three records showed treatment declined. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Pull ten patient records: does the doctor's note reference this patient's specific results?
2. Look at your treatment menu. If everyone on a package gets the same drugs at the same doses, that is the gap.
3. Require a documented, individualised doctor decision before every protocol.
4. Decline treatment for patients without an indication — and document it.

The most common mistake: Having a doctor sign prescriptions for a package the patient has already bought — the decision was made by the sales process.

SELF-ASSESSMENT QUESTIONS

1. Does a licensed physician genuinely evaluate each patient individually before prescribing a hormone or peptide protocol? — *A real, individual clinical evaluation, not a standard protocol applied to everyone.*

Evidence: Individual evaluation record

2. Is the protocol adjusted based on this specific patient's actual monitoring results, not applied uniformly regardless of results? — *Genuine responsiveness to this patient's data.*

Evidence: Protocol adjustment record

3. Can the physician describe their specific reasoning for a particular patient's protocol? — *Real, individual clinical reasoning, not a general description of the standard approach.*

Evidence: N/A — tested directly

COMMON REASONS FOR A PARTIAL ANSWER

- **Initial evaluation is genuinely individual but follow-up adjustments become more standardised over time.** — Ongoing responsiveness to patient data matters as much as the initial evaluation.

- **Monitoring results are collected but don't consistently change the protocol when they should.** — Data collected but not acted on doesn't provide the protection genuine oversight is meant to offer.
- **The physician is involved for complex cases but less so for routine ones.**

IMPLEMENTATION PLAN

When	What
Week 1	Review a sample of patient protocols for genuine individual evaluation versus standardisation.
Week 2	Establish a consistent process for adjusting protocols based on individual monitoring results.
Week 3	Brief the physician on documenting specific, individual clinical reasoning.
Ongoing	Audit protocol individualisation periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Individual evaluation review	Reviews records for evidence of genuine, individual patient evaluation before prescribing.
DOCUMENT	Protocol adjustment review	Reviews whether protocols are adjusted based on individual patient monitoring results.
ASK	Physician reasoning interview	Asks the physician to describe their specific reasoning for a particular patient's protocol.

SUPERVISOR TIPS

- **Compare two different patients' protocols and documented reasoning.** — Genuinely different content reveals real individualisation; near-identical text reveals a standardised template.
- **Ask the physician to explain a specific protocol decision in detail.** — Real clinical reasoning is specific and detailed; a formality reveals itself in vague or general answers.

EVIDENCE BASE

[55] Physician-supervised prescribing, based on individual patient evaluation and monitoring rather than standardised protocols, is identified as the defining distinction between legitimate hormone and peptide therapy and unregulated wellness-market practice.

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10.4 Baseline Screening Happens Before Any Protocol Begins, Not After CORE

Every patient undergoes genuine baseline laboratory and clinical screening before a hormone or peptide protocol begins, with monitoring continuing at defined intervals — not a protocol started based on symptoms alone, with testing added only if a problem later emerges.

In plain terms: Baseline bloods and a clinical assessment happen before any hormone or peptide protocol starts, and monitoring bloods continue at set intervals — not started on a questionnaire and never re-checked.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

You cannot know whether a patient needs testosterone without measuring it — twice, in the morning. You cannot safely give it without knowing their haematocrit, PSA, and liver function first. You cannot continue it without re-checking those at three months and then regularly. Protocols started on symptoms alone, or on a questionnaire, or on a single afternoon blood test, are protocols started on inadequate evidence. Protocols continued without monitoring are protocols that will eventually cause polycythaemia, prostate disease, or liver damage that nobody sees coming.

WHAT GOOD LOOKS LIKE

- Baseline screening is genuinely completed before every protocol begins.

COMMON FAILURE MODES

- Protocols begin based on symptoms or patient request, without baseline screening.

- Monitoring continues at defined, followed intervals throughout.
- A real example exists of monitoring results changing a protocol decision.

- No defined ongoing monitoring schedule exists beyond the initial visit.
- Monitoring results are collected but never lead to any protocol change.

WORKED EXAMPLE

IN PRACTICE

A longevity clinic that started hormone protocols after an online questionnaire.

BEFORE

Patients completed a symptom questionnaire; if they scored above a threshold, treatment was offered. Some had a single blood test at any time of day. Monitoring was 'when the patient came back.' The Coordinator found patients on testosterone for over a year with no repeat bloods.

ACTION

A pre-treatment protocol was written: two morning testosterone levels on separate days, plus haematocrit, PSA, lipids, liver function, and a clinical examination before any androgen; equivalent panels for other protocols. Monitoring at 3 months, then every 6 months, with defined action thresholds (e.g. haematocrit >54% → stop and review). Patients who miss monitoring have their prescription paused.

AFTER

The Monitor reviewed 20 records: all had complete baselines before starting; all on treatment over 3 months had monitoring results with documented review. Two showed dose reduction after monitoring. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Pull ten hormone patient records: what bloods were done before starting? What time of day?
2. Write a baseline panel per protocol and require it before any prescription.

3. Set monitoring intervals with action thresholds.
4. Pause prescriptions for anyone who misses monitoring.

The most common mistake: Starting testosterone on a single afternoon blood test — afternoon levels are lower and a single test is unreliable.

SELF-ASSESSMENT QUESTIONS

1. Does every patient undergo genuine baseline screening before any protocol begins, not after starting? — *Testing before the first dose, not added only if a concern later arises.*

Evidence: Baseline screening record

2. Is monitoring continued at defined intervals throughout the protocol, not only at baseline? — *A specific, followed monitoring schedule, not a one-time check.*

Evidence: Ongoing monitoring schedule

3. Are monitoring results actually reviewed and acted on, not just filed? — *Genuine review that can change the protocol, not passive data collection.*

Evidence: N/A — tested directly

COMMON REASONS FOR A PARTIAL ANSWER

- **Baseline screening happens but the specific panel doesn't match what the protocol actually requires.** — Generic baseline testing may miss the specific markers relevant to this particular protocol.
- **Monitoring intervals are followed initially but lapse as treatment continues.** — Ongoing risk doesn't diminish just because a protocol has been running without incident so far.
- **Results are reviewed by staff but not consistently by the prescribing physician.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current screening practice against genuine pre-protocol baseline testing.
Week 2	Establish the specific baseline panel appropriate to each protocol offered.

When	What
Week 3	Establish a defined ongoing monitoring interval and physician review process.
Ongoing	Audit monitoring adherence and evidence of results genuinely influencing protocol decisions.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Baseline screening review	Reviews patient records for genuine baseline screening completed before protocol start.
DOCUMENT	Ongoing monitoring schedule review	Reviews the defined monitoring interval and adherence to it.
ASK	Result review interview	Asks staff for a real example where a monitoring result changed a protocol decision.

SUPERVISOR TIPS

- **Ask for a real example where a monitoring result changed what was done.** — A real example reveals whether monitoring is genuine practice or a formality.
- **Check whether monitoring intervals are still being followed for patients further along in treatment.** — This is where monitoring discipline most commonly erodes over time.

EVIDENCE BASE

[56] Baseline laboratory assessment followed by monitoring at defined intervals — for growth hormone secretagogues, typically IGF-1 at baseline, six weeks, and every three to six months thereafter — is identified as a standard safety practice distinct from symptom-triggered testing alone.

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Standard 11 — Oncology & Infusion Therapy

4 criteria · 4 non-negotiable · 0 core · Version 3.0

CRITERIA IN THIS STANDARD

11.1 — Cytotoxic Drug Handling Follows a Verified Safe-Handling Standard

11.2 — Chemotherapy Dose Is Verified by Independent Two-Person Check

11.3 — Extravasation Is Recognised and Managed Immediately

11.4 — Infusion Reaction and Anaphylaxis Response Is Rehearsed, Not Theoretical

11.1 Cytotoxic Drug Handling Follows a Verified Safe-Handling Standard

NON-NEGOTIABLE

Preparation, administration, and disposal of cytotoxic and other hazardous drugs follows a defined, verified safe-handling standard — appropriate personal protective equipment, engineering controls, and disposal procedures — not informal practice that varies by individual staff member.

In plain terms: Chemotherapy is prepared, given, and disposed of following a verified safe-handling standard — closed systems, PPE, spill kits — protecting staff as well

as patients.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Cytotoxic drugs damage the people who handle them: nurses and pharmacists exposed to chemotherapy over years have higher rates of miscarriage, cancer, and chromosomal damage. Exposure happens through skin contact, inhalation of aerosols during preparation, and contaminated surfaces. Safe handling means a defined standard — USP 800, ISOPP, or national equivalent — with engineering controls (biological safety cabinet or closed-system transfer devices), correct PPE (chemotherapy gloves, gown, eye protection), a spill kit in every area, and staff trained and competency-assessed. A clinic preparing chemotherapy on an open bench is poisoning its staff slowly.

WHAT GOOD LOOKS LIKE

- PPE is used consistently and correctly at every handling stage.
- Required engineering controls are documented and in place.
- A defined, compliant hazardous waste disposal pathway is followed.

COMMON FAILURE MODES

- PPE use is inconsistent or limited to administration only.
- Standard pharmacy equipment is used without required hazardous drug controls.
- Hazardous waste is disposed of as general medical waste.

WORKED EXAMPLE

IN PRACTICE

An oncology day unit administering chemotherapy from six chairs.

BEFORE

Chemotherapy was reconstituted in a side room with a standard laminar flow hood (which protects the product, not the operator). Nurses wore single latex gloves. No spill kit existed. Waste went in yellow bags. Surface contamination had never been tested.

ACTION	The unit adopted ISOPP standards. A closed-system transfer device was introduced for all preparations. Chemotherapy-rated nitrile gloves (double), gowns, and eye protection became mandatory. Spill kits were placed in the preparation room and at the chairs. Cytotoxic waste was segregated into purple-lidded containers. All staff completed a safe-handling course with competency sign-off. Annual surface wipe testing was scheduled.
AFTER	The Monitor observed a preparation using the CSTD with correct PPE, found spill kits in place, reviewed training and competency records for all staff, and reviewed the first wipe test results (below detection limit). Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Where is chemotherapy prepared? Is the cabinet designed to protect the operator or the product?
2. Check gloves: are they chemotherapy-rated? Double?
3. Find your spill kit. If none, order one for each area today.
4. Adopt a recognised standard and train every handler to it.

The most common mistake: Using a laminar flow hood for chemotherapy — it blows the drug toward the operator.

SELF-ASSESSMENT QUESTIONS

1. Is appropriate personal protective equipment — including chemotherapy-rated gloves and gowns — used consistently for every stage of handling? — *Consistent use at every stage, not only during administration.*

Evidence: PPE protocol and observation record

2. Are hazardous drugs prepared and stored using the required engineering controls, not standard pharmacy equipment? — *Specific, required controls, not general pharmacy practice assumed to be sufficient.*

Evidence: Engineering control documentation

3. Is hazardous waste disposed of through a defined, compliant pathway, not general medical waste? — A specific, separate disposal pathway matched to the actual risk.

Evidence: Waste disposal record

COMMON REASONS FOR A PARTIAL ANSWER

- **PPE is used correctly during administration but less consistently during preparation.** — Every handling stage carries real exposure risk, not administration alone.
- **Engineering controls exist but staff weren't specifically trained on their correct use.** — Correct equipment without correct training doesn't provide the intended protection.
- **Waste disposal follows the correct pathway for most hazardous drugs but not all categories on the hazardous list.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current handling practice against required PPE, engineering controls, and disposal standards.
Week 2	Address any gaps in PPE use or engineering controls.
Week 3	Establish or verify a compliant hazardous waste disposal pathway.
Ongoing	Train staff periodically and audit handling practice.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	PPE and handling observation	Observes actual handling practice across preparation, administration, and disposal stages.
DOCUMENT	Engineering control review	Reviews documentation of required engineering controls for hazardous drug preparation and storage.
DOCUMENT	Waste disposal pathway review	Reviews the defined hazardous waste disposal pathway and compliance records.

SUPERVISOR TIPS

- **Observe preparation and disposal, not only administration.** — Attention often concentrates on administration, leaving earlier and later stages less consistently observed.
- **Ask to see the actual hazardous waste disposal pathway and its documentation.** — A specific, verifiable pathway is the real evidence of compliant disposal.

EVIDENCE BASE

[57] Established hazardous drug handling standards, recognized in various forms across many countries' pharmacy and occupational safety guidance, require defined personal protective equipment, engineering controls, and procedures for the receipt, storage, compounding, administration, and disposal of hazardous drugs.

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11.2 Chemotherapy Dose Is Verified by Independent Two-Person Check

NON-NEGOTIABLE

Every chemotherapy dose, drug, route, and infusion rate is independently verified by two qualified individuals before administration, each forming their own judgement separately — not a single check followed by a second signature.

In plain terms: Every chemotherapy dose is checked by two qualified people independently — each calculating on their own, then comparing — before it is given.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

A tenfold chemotherapy overdose is fatal. A dose calculated from last month's weight, or an outdated body surface area, or a protocol for the wrong cancer, kills or harms. The independent double-check is the last barrier: two people, each separately verifying the patient, the drug, the dose calculation from current parameters, the route, the rate, and the cumulative dose against the protocol. Then they compare. If either has any discrepancy, the dose is not given until it is resolved. One person checking and the other initialing is not independent.

WHAT GOOD LOOKS LIKE

- Every dose undergoes genuine, independent two-person verification.
- Each verifier forms their own separate judgement.
- Verification covers drug, dose, route, and infusion rate together.

COMMON FAILURE MODES

- Verification happens for some doses but not consistently for all.
- The second check simply confirms the first person's conclusion.
- Verification covers dose alone, missing route or infusion rate.

WORKED EXAMPLE

IN PRACTICE

An oncology day unit where a pharmacist prepared doses and a nurse administered them.

BEFORE

The pharmacist calculated and prepared. The nurse checked the label against the prescription and gave it. Neither independently recalculated. A patient received a dose based on a weight recorded three months earlier, before 12 kg of weight loss; the overdose caused a prolonged admission.

ACTION	An independent double-check was implemented: pharmacist and nurse each separately verify patient identity, current weight and height (measured that day), BSA, protocol, drug, dose calculation, cumulative dose, route, and rate — on separate forms — then compare. Any discrepancy stops administration. Both sign. Weight is measured at every cycle.
AFTER	The Monitor observed two administrations with genuinely independent calculations and comparison. Reviewed 20 records with double signatures and same-day weights. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Watch a chemotherapy check. Does the second person calculate, or just look?
2. Require current-day weight and height for every dose.
3. Create two identical check sheets — one per checker — and compare before giving.
4. Write the rule: any discrepancy stops the dose.

The most common mistake: Using the weight from the first cycle for all subsequent cycles — chemotherapy patients lose weight.

SELF-ASSESSMENT QUESTIONS

1. Does every chemotherapy dose undergo independent verification by two qualified individuals before administration? — *Two people, every dose, without exception for perceived routine cases.*

Evidence: Independent double-check record

2. Does each person form their own separate judgement, not simply confirm the first person's check? — *Genuine independence, not sequential confirmation of the same conclusion.*

Evidence: N/A — tested directly

3. Does verification specifically cover drug, dose, route, and infusion rate together, not dose alone? — *All four elements, since an error in any one carries real risk.*

Evidence: Verification checklist content

COMMON REASONS FOR A PARTIAL ANSWER

- **Independent verification is strong for new regimens but becomes routine and less rigorous for familiar ones.** — Familiarity can quietly erode the genuine independence the check depends on.
- **Verification happens together, side by side, rather than separately before comparing.** — Checking together risks one person's read of the order influencing the other's, undermining genuine independence.
- **Infusion rate verification is inconsistent compared to drug and dose verification.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current verification practice for genuine independence between checkers.
Week 2	Retrain staff on separate, independent verification before comparing conclusions.
Week 3	Confirm the verification checklist covers drug, dose, route, and infusion rate together.
Ongoing	Audit verification records and observe practice periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Independent check observation	Observes an actual double-check for genuine independence between the two verifiers.
DOCUMENT	Verification record review	Reviews records confirming two-person verification for a sample of recent administrations.
ASK	Verification content interview	Asks staff what specifically gets verified during the double-check.

SUPERVISOR TIPS

- **Observe an actual double-check, watching specifically for separate, independent review.** — Genuine independence is visible in practice in a way records alone cannot confirm.

- **Ask two different verifiers separately what they checked.** — Consistent, specific answers from both reveal genuine independent verification.

EVIDENCE BASE

[58] Neuss MN, Gilmore TR, Belderson KM, Billett AL, Conti-Kalchik T, Harvey BE, et al. 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. J Oncol Pract. 2016;12(12):1262-1271 — mandates independent verification by two qualified individuals of chemotherapy drug, dose, route, and infusion rate prior to administration.

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11.3 Extravasation Is Recognised and Managed Immediately

NON-NEGOTIABLE

Staff administering vesicant or irritant chemotherapy agents are specifically trained to recognise early signs of extravasation, with a defined, immediate management protocol and appropriate antidotes genuinely available on-site.

In plain terms: Staff giving vesicant chemotherapy can spot leakage into tissue immediately, and the antidotes and protocol are at the chair — because minutes matter.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Vesicants — anthracyclines, vinca alkaloids, taxanes — cause tissue death when they leak from the vein. Left unrecognised for an hour, the result is a wound that needs surgery, months to heal, and can end limb function. The signs — pain, swelling, loss of blood return, slowed drip — appear early and are easy to attribute to 'a bit of discomfort.'

Management is drug-specific: dexrazoxane for anthracyclines within six hours; hyaluronidase and warm compresses for vincas; specific antidotes stored, in date, at the point of care. Staff must be trained to stop, aspirate, and act — not to wait and see.

WHAT GOOD LOOKS LIKE

- Staff are specifically trained on extravasation recognition for the actual agents used.
- A defined, immediate management protocol exists.
- Appropriate antidotes are genuinely on-site and in date.

COMMON FAILURE MODES

- Training is generic, not specific to the agents actually administered.
- No defined protocol exists beyond general awareness that extravasation can occur.
- Antidotes aren't on-site or are expired.

WORKED EXAMPLE

IN PRACTICE

An oncology day unit giving vesicant chemotherapy daily.

BEFORE

No extravasation kit existed. Dexrazoxane was not stocked. When a patient complained of pain during doxorubicin, the nurse slowed the infusion and continued. The extravasation was recognised the next day; the patient required surgical debridement.

ACTION

An extravasation kit was assembled and placed at the nurses' station with drug-specific antidotes, cold and warm packs, and a laminated protocol. Dexrazoxane was stocked with the pharmacy. All chemotherapy nurses completed extravasation training including a simulation. The rule: any pain, swelling, or lost blood return during a vesicant → stop, aspirate, do not remove the cannula, call the doctor, start the protocol. Every event is logged and reviewed.

AFTER

The Monitor found the kit stocked and in date, the protocol posted, and training records complete.

Asked a nurse the first four actions; she listed them. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Ask: where is your extravasation kit? What antidotes are in it?
Are they in date?
2. Stock drug-specific antidotes for every vesicant you give.
3. Post the protocol at every chair.
4. Train and drill every chemotherapy nurse.

The most common mistake: Slowing the infusion when the patient reports pain instead of stopping it — the drug is still going in.

SELF-ASSESSMENT QUESTIONS

1. Are staff specifically trained to recognise early signs of extravasation for the agents actually used here? — *Specific to the actual agents administered, not generic infusion complication awareness.*
Evidence: Extravasation recognition training record
2. Is there a defined, immediate management protocol for suspected extravasation? — *A specific, known protocol, not improvisation in the moment.*
Evidence: Extravasation management protocol
3. Are appropriate antidotes for the specific vesicant agents used genuinely available on-site? — *Immediately available and in date, matched to the actual agents in use.*
Evidence: On-site antidote stock record

COMMON REASONS FOR A PARTIAL ANSWER

- **Recognition training happened at hiring but hasn't been refreshed as new agents were introduced.** — Training needs to stay current with the actual agents in use, not reflect an earlier point in time.
- **A protocol exists but doesn't specify agent-specific management steps.** — Different vesicant agents may require different specific management approaches.
- **Antidote stock exists but expiry dates weren't recently verified.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current extravasation training against the specific agents administered.
Week 2	Update or establish an agent-specific management protocol.
Week 3	Confirm on-site antidote stock and expiry dates for all vesicant agents used.
Ongoing	Refresh training whenever new agents are introduced.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Recognition training review	Reviews training records for extravasation recognition specific to agents actually used.
DOCUMENT	Management protocol review	Reviews the defined immediate management protocol for completeness.
OBSERVE	Antidote stock check	Physically confirms appropriate antidotes are on-site, matched to agents used, and in date.

SUPERVISOR TIPS

- **Ask about a specific agent used here, not extravasation in general.** — Specificity reveals whether training genuinely reflects current practice.
- **Physically check antidote stock and expiry dates.** — Physical verification is the only real evidence of genuine on-site availability.

EVIDENCE BASE

[59] Extravasation recognition and immediate management protocols, including agent-specific antidote availability, are established as a distinct and essential component of safe chemotherapy administration, separate from general infusion site monitoring.

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11.4 Infusion Reaction and Anaphylaxis Response Is Rehearsed, Not Theoretical

NON-NEGOTIABLE

Staff are trained and drilled — not only briefed — on recognising and responding to infusion reactions and anaphylaxis, with emergency medications and equipment genuinely available at the point of infusion, verified through a real, practiced response, not a written plan alone.

In plain terms: Staff have practised — not just read about — recognising and treating infusion reactions and anaphylaxis, and the emergency drugs and equipment are at the chair.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Infusion reactions to monoclonal antibodies, platinum agents, and taxanes range from flushing to fatal anaphylaxis within minutes. The first-line response — stop the infusion, give adrenaline for anaphylaxis, oxygen, fluids, antihistamine, steroid — must be immediate and reflexive. Staff who have been briefed but never drilled hesitate; staff who have drilled act. Emergency drugs must be at the chair, not in a cupboard down the corridor. A unit that has never run a simulation does not know how its staff will respond.

WHAT GOOD LOOKS LIKE

- Staff have genuinely rehearsed the response, with dated drill records.
- Emergency medications and equipment are immediately available at the point of infusion.

COMMON FAILURE MODES

- Only written protocol review has occurred, with no actual drill.
- Emergency equipment requires retrieval from another location.
- Staff are aware a protocol exists but can't describe their specific role.

- Staff can describe their specific, assigned role in a response.

WORKED EXAMPLE

IN PRACTICE

An oncology day unit administering monoclonal antibodies.

BEFORE	Staff had attended a lecture on infusion reactions. Adrenaline was in the emergency drawer at the nurses' station. No drill had ever been run. When a patient developed anaphylaxis to rituximab, the nurse called for help and waited; adrenaline was given after seven minutes.
ACTION	An anaphylaxis kit was placed at each infusion bay: adrenaline, antihistamine, hydrocortisone, salbutamol, oxygen, and the protocol. A quarterly simulation drill was introduced, alternating scenarios, with a debrief. Every nurse is competency-assessed annually on the response sequence. Pre-medication protocols per drug were standardised.
AFTER	The Monitor found kits at every bay, reviewed three drill records with debrief actions, and observed a mock reaction drill in which adrenaline was 'given' within 90 seconds. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Time how long it takes to get adrenaline from where it is kept to the furthest infusion chair.
2. Put a kit at every bay.
3. Run a simulation drill this month and debrief it.
4. Make drills quarterly.

The most common mistake: Keeping emergency drugs in one central location in a unit where reactions happen at the chair.

SELF-ASSESSMENT QUESTIONS

1. Have staff actually rehearsed an infusion reaction and anaphylaxis response, not only reviewed a written protocol? — *A genuine drill, not a policy document read once.*

Evidence: Drill record, date and participants

2. Are emergency medications and equipment genuinely available at the point of infusion, not in a separate location requiring retrieval? — *Immediately at hand, not requiring travel to another room during an emergency.*

Evidence: Emergency equipment location and stock record

3. Do all staff present during infusions know their specific role in a reaction response, not just that a protocol exists? — *Specific, assigned roles, not general awareness.*

Evidence: N/A — tested directly

COMMON REASONS FOR A PARTIAL ANSWER

- **A drill was conducted once but hasn't been repeated since.** — Rehearsed response capability fades over time without periodic repetition, particularly given staff turnover.
- **Emergency equipment is nearby but not genuinely at every point where infusions actually happen.** — A reaction can occur at any infusion chair, and equipment needs to be immediately reachable from all of them.
- **Clinical staff know their role clearly but support staff present during infusions are less certain.**

IMPLEMENTATION PLAN

When	What
Week 1	Assess current response readiness against genuine rehearsed practice, not policy review alone.
Week 2	Conduct an actual reaction response drill with all relevant staff.
Week 3	Verify emergency equipment is genuinely accessible from every infusion point.
Ongoing	Repeat drills periodically, particularly after staff changes.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Drill record review	Reviews records of actual rehearsed drills, not only protocol review sessions.
OBSERVE	Emergency equipment location check	Confirms emergency medications and equipment are genuinely at the point of infusion.
ASK	Role assignment interview	Asks staff present during infusions to describe their specific role in a reaction response.

SUPERVISOR TIPS

- **Ask for the date of the last actual drill, not the date the protocol was written.** — A specific, recent drill date is the real evidence of rehearsed readiness.
- **Ask a support staff member, not just a nurse, about their role in a response.** — This reveals whether readiness genuinely extends to everyone present, not only clinical staff.

EVIDENCE BASE

[60] Infusion reaction and anaphylaxis response protocols, including rehearsed drills rather than written policy alone, are identified as essential to safe ambulatory infusion practice given the narrow time window in which effective intervention determines patient outcome.

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← **Ambulatory Clinic Standards — all standards**

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← **Standard 10 — Longevity & IV Therapy**

Standard 12 — Dialysis & Renal Replacement Therapy



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ASF STANDARDS · AMBULATORY CLINIC · STANDARD 12

Standard 12 — Dialysis & Renal Replacement Therapy

4 criteria · 4 non-negotiable · 0 core · Version 3.0

CRITERIA IN THIS STANDARD

12.1 — Dialysis Water Treatment Meets a Verified Quality Standard

12.2 — Vascular Access Site Care Follows Recognised Core Interventions

12.3 — Patients Are Monitored for Intradialytic Complications Throughout

12.4 — Reuse or Single-Use Policy for Dialyzers Is Explicit and Followed

12.1 Dialysis Water Treatment Meets a Verified Quality Standard

NON-NEGOTIABLE

Water used to prepare dialysis fluid meets defined chemical and microbiological quality requirements, verified through regular testing against a recognised international standard — not assumed safe because it passes through a treatment system.

In plain terms: The water used to make dialysis fluid is tested regularly against a recognised standard for chemicals and bacteria — not assumed safe because it comes from a reverse-osmosis unit.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

A dialysis patient's blood is exposed to 120 litres of water per session. Chloramine in the water haemolyses red cells. Aluminium causes dementia and bone disease. Endotoxin from bacterial contamination causes fever, hypotension, and chronic inflammation. The reverse-osmosis system removes these — when it is working. When a membrane degrades, a carbon filter exhausts, or biofilm forms in the distribution loop, contaminated water reaches the patient invisibly. ISO 23500 and AAMI standards define the limits; monthly chemical and microbiological testing against them, with action levels, is the only way to know.

WHAT GOOD LOOKS LIKE

- Water is tested against the specific dialysis water quality standard consistently.
- Testing happens on a defined, regular schedule with genuine review.
- A specific, followed response exists for any out-of-limit result.

COMMON FAILURE MODES

- Testing, if it happens, isn't matched against dialysis-specific limits.
- Testing is occasional or reactive rather than scheduled.
- No defined response exists for an out-of-limit result.

WORKED EXAMPLE

IN PRACTICE

A 12-station dialysis unit with an RO plant installed five years earlier.

BEFORE

Water was tested 'when the engineer came' — roughly annually. The carbon filters had not been changed in 18 months. No endotoxin testing had ever been done. Patients had experienced unexplained febrile episodes for several months.

ACTION

The unit adopted ISO 23500 limits. Monthly testing was contracted: chemical analysis (chloramine, aluminium, fluoride, heavy metals) and microbiology (total viable count and

endotoxin) at defined sample points. Action and alert levels were set. Carbon filter change was scheduled per manufacturer with chloramine testing weekly at the point of use. The distribution loop was disinfected monthly. Results are reviewed by the unit lead and filed.

AFTER The Monitor reviewed six months of test results (all within limits after month two), the filter change log, and the loop disinfection log. Febrile episodes had ceased. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Find your last water test result. If it is more than a month old, that is the gap.
2. Check when your carbon filters were last changed.
3. Contract monthly chemical and microbiological testing against ISO 23500.
4. Set action levels and a response plan.

The most common mistake: Trusting the RO unit because it was expensive — RO membranes and filters degrade silently.

SELF-ASSESSMENT QUESTIONS

1. Is dialysis water tested against the specific chemical and microbiological limits set by the recognised standard, not general water safety limits? — *Dialysis-specific limits, which are meaningfully stricter than general drinking water standards.*

Evidence: Water quality testing record against ISO 23500-3 limits

2. Is testing conducted on a defined, regular schedule, with results reviewed and acted on? — *Regular, scheduled testing with genuine review, not occasional or reactive testing.*

Evidence: Testing schedule and review record

3. Is there a defined response if a test result exceeds the allowable limit? — *A specific action, not uncertainty about what happens when a limit is exceeded.*

Evidence: Out-of-limit response protocol

COMMON REASONS FOR A PARTIAL ANSWER

- **Chemical testing happens consistently but microbiological testing lapses periodically.** — Both chemical and microbiological contamination carry genuine, distinct risk.
- **Testing happens on schedule but results aren't reviewed by anyone with authority to act on them.** — Testing without genuine review provides limited real protection.
- **A response protocol exists but hasn't actually been used or tested.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current water testing practice against the specific dialysis water quality standard.
Week 2	Establish or correct a defined, regular testing schedule.
Week 3	Define a specific response protocol for out-of-limit results.
Ongoing	Review testing consistency and result trends periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Water quality testing review	Reviews testing records against the specific ISO 23500-3 chemical and microbiological limits.
DOCUMENT	Testing schedule review	Reviews the testing schedule for consistency and genuine review of results.
ASK	Out-of-limit response interview	Asks staff what happens when a water quality result exceeds the allowable limit.

SUPERVISOR TIPS

- **Ask for actual test results against the specific numeric limits, not a general assurance of water safety.** — Dated, specific records are the only real evidence of genuine compliance.
- **Ask what happened the last time a result was concerning.** — A real example reveals more than a policy description.

EVIDENCE BASE

[61] International Organization for Standardization. ISO 23500-3:2024 — Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies. Geneva: ISO; 2024 — specifies minimum chemical and microbiological quality requirements for dialysis water, with mandatory ongoing monitoring.

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12.2 **Vascular Access Site Care Follows Recognised Core Interventions**

NON-NEGOTIABLE

Vascular access care and catheter accessing follow a defined set of core infection prevention interventions — aseptic technique, hub disinfection, and structured surveillance — verified through periodic direct observation, not assumed from staff training alone.

In plain terms: Fistula, graft, and catheter care follow a defined set of infection prevention steps — clean technique, hub disinfection, surveillance — checked by audit, not assumed.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Vascular access is the dialysis patient's lifeline and their greatest infection risk. Catheter-related bloodstream infections kill. Fistula infections cost the access. The CDC Core Interventions — hand hygiene, catheter hub scrub with antiseptic before every connection, antiseptic skin prep before cannulation, dressing changes with sterile technique, monthly surveillance of infections — reduce infections by half when consistently applied. 'Consistently' is the word: audit shows that without observation, hub scrubs are skipped when the unit is busy.

WHAT GOOD LOOKS LIKE

- All core interventions are actively implemented together.
- Direct observation of vascular access care happens on the recommended schedule.
- Surveillance data is genuinely shared with and visible to front-line staff.

COMMON FAILURE MODES

- Only some core interventions are followed, with others informally skipped.
- No direct observation happens beyond initial staff training.
- Surveillance data, if collected, isn't shared with clinical staff.

WORKED EXAMPLE

IN PRACTICE

A 10-station dialysis unit with a catheter-related bloodstream infection rate it did not calculate.

BEFORE

Catheter care varied by nurse. Hub disinfection was 'quick.' Skin prep before fistula cannulation was a single alcohol wipe. No infection surveillance existed. When the Coordinator reviewed records, seven bloodstream infections had occurred in six months among 20 catheter patients.

ACTION

The CDC Core Interventions were adopted as unit policy. Hub scrub for 15 seconds with chlorhexidine-alcohol before every connection. Chlorhexidine skin prep with 30-second dry time before cannulation. Sterile dressing changes per protocol. Monthly infection surveillance with rates per 100 patient-months. Quarterly observational audit of ten access procedures with feedback.

AFTER

The Monitor observed three catheter connections with correct hub scrubs, reviewed audit results (compliance 92%), and the surveillance data (bloodstream infections down to 1 in the following six months). Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Watch three catheter connections. Time the hub scrub. Under 15 seconds fails.
2. Adopt the CDC Core Interventions as written policy.
3. Start counting access infections monthly.
4. Audit ten procedures a quarter and feed back.

The most common mistake: Not measuring access infections — the unit with no data believes it has no problem.

SELF-ASSESSMENT QUESTIONS

- 1.** Are the specific core interventions — surveillance, hand hygiene observation, vascular access care observation — all actively followed, not only some of them? — *All core interventions together, not a partial selection.*
Evidence: Core intervention implementation record

- 2.** Is vascular access care and catheter accessing technique directly observed on a defined schedule, not assumed from training? — *Direct observation, at least quarterly, not reliance on initial training alone.*
Evidence: Direct observation record

- 3.** Is infection surveillance data calculated and actively shared with front-line clinical staff, not filed without review? — *Genuine sharing that could influence practice, not passive record-keeping.*
Evidence: Surveillance data sharing record

COMMON REASONS FOR A PARTIAL ANSWER

- **Hand hygiene observation happens consistently but vascular access observation is less regular.** — Each core intervention addresses a distinct part of the same real infection risk.
- **Observation happens but findings aren't fed back to the specific staff observed.** — Observation without feedback provides less real improvement than genuine feedback.
- **Surveillance data is calculated but shared only with management, not front-line staff.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current practice against the full set of core interventions.

When	What
Week 2	Establish or correct a quarterly direct observation schedule for vascular access care.
Week 3	Establish a process for actively sharing surveillance data with front-line staff.
Ongoing	Track infection rates and adjust practice based on trends.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Core intervention implementation review	Reviews evidence that all core interventions are actively implemented, not a partial selection.
DOCUMENT	Direct observation record review	Reviews records of direct vascular access care observation against the recommended schedule.
ASK	Data sharing interview	Asks front-line staff whether they've seen recent infection surveillance data for this facility.

SUPERVISOR TIPS

- **Ask for actual observation records, not a description of the training staff received.** — Dated observation records are the real evidence of ongoing verification, not one-time training.
- **Ask a front-line staff member whether they've seen recent infection rate data for this facility.** — This reveals whether data sharing is genuine practice, not just collected and filed.

EVIDENCE BASE

[62] Established infection prevention guidance for dialysis settings, recognized in various forms internationally, recommends monthly infection surveillance, regular hand hygiene observation, and quarterly direct observation of vascular access care and catheter accessing technique.

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12.3

Patients Are Monitored for Intradialytic Complications Throughout

NON-NEGOTIABLE

Patients are actively monitored throughout the dialysis session for signs of intradialytic complications — hypotension, cramping, access-related bleeding — on a defined schedule, not checked only at the start and end of the session.

In plain terms: During dialysis, patients are monitored on a schedule for low blood pressure, cramps, and bleeding — not just checked at the start and the end.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Intradialytic hypotension causes cardiac ischaemia, stroke, and access thrombosis. It develops over minutes, mid-session, when the patient is quietly reading. Cramps signal excess fluid removal. Bleeding at the needle site can be silent under a blanket. A defined monitoring schedule — blood pressure and pulse every 30 minutes at minimum, more often for unstable patients, with a visual check of the access — catches these before harm. A unit where monitoring is 'when the alarm goes off' is relying on the machine to notice what a nurse should have seen.

WHAT GOOD LOOKS LIKE

- Monitoring happens at defined intervals throughout the entire session.
- Monitoring covers blood pressure, access site, and symptoms together.
- A specific, immediate response protocol exists and is known to staff.

COMMON FAILURE MODES

- Monitoring is concentrated at session start and end, with gaps during the session.
- Monitoring covers only one element, such as blood pressure, without the others.
- Staff are uncertain what to do if a complication is

WORKED EXAMPLE

IN PRACTICE

An 8-station dialysis unit with two nurses per shift.

BEFORE	Vital signs were taken at the start, mid-session if the nurse was passing, and at the end. A patient became hypotensive to 70/40 for an unknown period before it was noticed; she suffered a TIA. Monitoring was not scheduled or documented at intervals.
ACTION	A monitoring protocol was written: blood pressure and pulse every 30 minutes, every 15 minutes for patients with a history of intradialytic hypotension, recorded on a session chart; visual access check with each set of observations; defined thresholds for intervention (e.g. systolic <90 → reduce ultrafiltration, position, fluid bolus per protocol). Staffing was reviewed to make this achievable.
AFTER	The Monitor reviewed 20 session charts showing 30-minute observations, observed a session with monitoring performed on schedule, and reviewed two hypotension interventions documented and managed per protocol. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Pull ten session charts: how often were observations recorded?
2. Write a monitoring schedule — every 30 minutes minimum.
3. Add intervention thresholds to the chart.
4. Check that staffing allows it.

The most common mistake: Relying on the machine's alarms to detect patient deterioration — the machine monitors the circuit, not the patient.

SELF-ASSESSMENT QUESTIONS

1. Are patients monitored at defined intervals throughout the entire session, not only at start and end? — *Monitoring spread across the full session duration, not concentrated at the edges.*

Evidence: Intradialytic monitoring schedule and record

2. Does monitoring specifically include blood pressure, access site, and patient-reported symptoms together? — *All three together, since each can reveal a different type of developing complication.*

Evidence: Monitoring content documentation

3. Is there a defined, immediate response if monitoring identifies a possible complication? — *A specific, known response, not improvisation in the moment.*

Evidence: Complication response protocol

COMMON REASONS FOR A PARTIAL ANSWER

- **Monitoring is thorough during quiet periods but abbreviated when the unit is busy.** — Complications don't occur only when staff have time available to notice them.
- **Blood pressure is checked regularly but access site and symptom checks are less consistent.** — Each element of monitoring reveals a genuinely different type of developing complication.
- **A response protocol exists for hypotension specifically but not other complication types.**

IMPLEMENTATION PLAN

When	What
Week 1	Observe current monitoring practice for consistency throughout actual sessions.
Week 2	Establish a defined monitoring interval covering the full session duration.
Week 3	Ensure monitoring content covers blood pressure, access site, and symptoms together.
Ongoing	Observe monitoring practice periodically, particularly during busy periods.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Intradialytic monitoring observation	Observes actual monitoring practice during a dialysis session for consistency throughout.
DOCUMENT	Monitoring content review	Reviews whether monitoring covers blood pressure, access site, and symptoms together.
ASK	Complication response interview	Asks staff what happens when monitoring identifies a possible complication.

SUPERVISOR TIPS

- **Observe during a genuinely busy period, not a quiet one.** — Monitoring discipline is most likely to erode exactly when the unit is under real pressure.
- **Ask about a specific complication type beyond hypotension, such as access-related bleeding.** — This reveals whether response readiness extends beyond the most commonly discussed complication.

EVIDENCE BASE

[63] Structured intradialytic monitoring at defined intervals throughout the dialysis session, rather than only at session start and end, is established practice in dialysis safety literature for early detection of hypotension and other acute complications.

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12.4 Reuse or Single-Use Policy for Dialyzers Is Explicit and Followed

NON-NEGOTIABLE

The facility has an explicit, written policy on whether dialyzers are single-use or reprocessed for reuse, with the actual practice matching the written policy, and any

reprocessing following a defined, verified protocol — not an informal practice that varies without a stated policy.

In plain terms: The unit has a written policy stating whether dialysers are single-use or reprocessed, practice matches the policy, and any reprocessing follows a defined, monitored procedure.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Dialyser reuse can be safe when done to a rigorous standard: automated reprocessing, integrity testing, performance measurement, germicide residual testing, and patient-specific labelling. It is dangerous when done casually: manual rinsing, no integrity test, dialysers mixed between patients. The first requirement is honesty — a written policy that says what the unit actually does. The second is that practice matches it. The third, for units that reuse, is a validated reprocessing protocol with records for every dialyser, every reuse. A unit that claims single-use but reuses under pressure is lying to its patients.

WHAT GOOD LOOKS LIKE

- An explicit, written policy exists and is clear.
- Actual practice consistently matches the written policy.
- Any reprocessing follows a defined, verified protocol.

COMMON FAILURE MODES

- No written policy exists, only informal, undocumented practice.
- Practice diverges from what's actually written in the policy.
- Reprocessing, if it occurs, has no defined or verified protocol.

WORKED EXAMPLE

IN PRACTICE

A 14-station dialysis unit that officially used single-use dialysers.

BEFORE

The written policy said single-use. In practice, when supplies ran low, dialysers were manually

	rinsed and reused — sometimes for a different patient. No reprocessing procedure existed. Two patients had cross-infection events that were never explained.
ACTION	The unit lead and management decided: genuinely single-use, with a supply chain review to prevent shortages. Stock levels and reorder points were set. The policy was rewritten and posted. Staff were briefed that reuse under any circumstances is prohibited and must be reported if pressured. A monthly stock audit checks dialyser consumption against sessions.
AFTER	The Monitor reviewed the policy, the stock records showing dialysers consumed matching sessions performed, and interviewed two nurses who confirmed no reuse. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Read your dialyser policy. Now ask a nurse what actually happens when stock is low.
2. Decide: single-use or reuse. Write it down honestly.
3. If single-use: fix the supply chain so shortage never forces reuse.
4. If reuse: adopt a validated protocol with records per dialyser.

The most common mistake: Having a single-use policy on paper and reusing when supplies are short — the policy exists to be broken.

SELF-ASSESSMENT QUESTIONS

1. Does the facility have an explicit, written policy stating whether dialyzers are single-use or reprocessed? — *A specific, written policy, not an informal, undocumented practice.*
Evidence: Written reuse policy document
2. Does actual practice match the written policy, verified directly, not assumed? — *Genuine consistency between stated policy and real*

practice.

Evidence: N/A — tested directly

3. Where reprocessing occurs, does it follow a defined, verified protocol, including water quality specific to reprocessing? — *A specific, verified protocol, not informal reprocessing practice.*

Evidence: Reprocessing protocol and verification record

COMMON REASONS FOR A PARTIAL ANSWER

- **A policy exists but hasn't been updated to reflect a practice change made some time ago.** — A stale policy no longer reflects genuine current practice, creating exactly the mismatch this criterion checks for.
- **Practice matches policy for most patients but exceptions are made informally without documentation.** — Undocumented exceptions undermine the reliability of the stated policy.
- **Reprocessing follows a protocol but water quality verification specific to reprocessing wasn't recently checked.**

IMPLEMENTATION PLAN

When	What
Week 1	Confirm current actual practice and compare against any existing written policy.
Week 2	Write or update the policy to genuinely reflect current practice.
Week 3	If reprocessing occurs, verify the protocol and water quality requirements specific to it.
Ongoing	Periodically confirm practice continues to match the written policy.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Written policy review	Reviews the facility's explicit, written reuse or single-use policy.
OBSERVE	Practice-policy consistency check	Checks whether actual practice matches the written policy.

Method	What	Detail
DOCUMENT	Reprocessing protocol review	Where reprocessing occurs, reviews the defined protocol and water quality verification specific to reprocessing.

SUPERVISOR TIPS

- **Ask to see the actual written policy, not a verbal description of practice.** — A specific, written document is the real evidence of an explicit policy.
- **Ask a front-line staff member to describe current practice, and compare it against the written policy.** — This reveals whether policy and practice genuinely align, or have quietly diverged.

EVIDENCE BASE

[64] International Organization for Standardization. ISO 23500-1:2024 — Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements. Geneva: ISO; 2024 — addresses water used in dialyser reprocessing as a distinct, covered aspect of dialysis fluid quality management.

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← **Standard 11 — Oncology & Infusion Therapy**

Standard 13 — Fertility & IVF
→

Standard 13 — Fertility & IVF

5 criteria · 3 non-negotiable · 2 core · Version 3.0

CRITERIA IN THIS STANDARD

- 13.1 — Embryology Lab Quality Control Is Verified, Not Assumed
- 13.2 — Hormone Stimulation Protocols Have Real, Documented Physician Oversight
- 13.3 — Multiple-Pregnancy Risk Is Explicitly Discussed Before Transfer
- 13.4 — High-Stakes Consent Reflects the Real Emotional and Financial Weight of the Decision
- 13.5 — A Witnessing Protocol Prevents Gamete and Embryo Mix-Up

13.1 Embryology Lab Quality Control Is Verified, Not Assumed

NON-NEGOTIABLE

Embryo and oocyte assessment follows a recognised international consensus standard, with laboratory conditions — temperature, air quality, incubator calibration — verified through defined, regular quality control, not assumed stable because equipment appears to be functioning.

In plain terms: The embryology laboratory follows an international consensus standard for assessing embryos, and its incubators, air quality, and temperatures are checked and recorded on a schedule.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

An embryo's survival depends on a stable environment: temperature within 0.2°C, CO2 within tight tolerance, pH constant, air free of volatile organic compounds. An incubator that drifts, an air handler that fails, or a workstation that cools kills embryos that would have become children. Laboratory quality control means continuous monitoring with alarms, daily recorded checks, calibrated instruments, and validated procedures for every step. Embryo assessment must follow a consensus standard (Istanbul, Vienna, or ESHRE) so grading is consistent and meaningful. A lab that cannot show its incubator logs cannot show its embryos were safe.

WHAT GOOD LOOKS LIKE

- Assessment consistently follows the recognised international standard.
- Laboratory conditions are verified through defined, regular quality control.
- A specific, followed response exists for any out-of-range reading.

COMMON FAILURE MODES

- Assessment practice varies by individual embryologist without a consistent standard.
- Laboratory conditions are assumed stable without regular verification.
- No defined response exists for an out-of-range reading.

WORKED EXAMPLE

IN PRACTICE

A fertility clinic with an embryology lab and two incubators.

BEFORE

Incubator temperatures were checked 'daily' by reading the display — which had never been calibrated against an external thermometer. CO2 was not independently verified. No VOC monitoring existed. Embryo grading was by the

	embryologist's judgment without reference to a published scheme. Success rates had declined over 18 months with no explanation.
ACTION	Independent calibrated probes were installed in each incubator with continuous logging and alarms to a mobile phone. Daily checks of temperature, CO ₂ , and pH are recorded on a log. Quarterly external calibration is contracted. VOC filtration was installed and air quality tested. The lab adopted the ESHRE Vienna consensus for embryo assessment with all embryologists trained. A monthly KPI review tracks fertilisation, cleavage, and blastocyst rates.
AFTER	The Monitor reviewed six months of incubator logs, calibration certificates, air quality results, embryologist training records, and the KPI dashboard showing recovery of blastocyst rate. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check your incubator temperature with an independent calibrated thermometer. Compare to the display.
2. Find your incubator logs. If they are display readings only, that is the gap.
3. Install continuous monitoring with alarms.
4. Adopt a consensus embryo assessment standard and train to it.

The most common mistake: Trusting the incubator's own display — it can be wrong by a full degree without any alarm.

SELF-ASSESSMENT QUESTIONS

1. Does embryo and oocyte assessment follow a recognised international consensus standard, applied consistently? — *A named, recognised standard, applied by every embryologist consistently.*

Evidence: Assessment protocol documentation

2. Are laboratory conditions — temperature, air quality, incubator calibration — verified through defined, regular quality control? —

Regular, scheduled verification, not assumed from equipment appearing to function.

Evidence: Laboratory quality control log

3. Is there a defined response if quality control identifies conditions outside acceptable range? — A specific action, not uncertainty about what happens when a reading is out of range.

Evidence: Out-of-range response protocol

COMMON REASONS FOR A PARTIAL ANSWER

- **Temperature is monitored consistently but air quality checks are less regular.** — Each laboratory condition can independently affect embryo development.
- **Quality control happens but results aren't reviewed by someone with authority to act on them.** — Monitoring without genuine review provides limited real protection.
- **The assessment standard is followed for routine cases but applied less consistently for complex ones.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current assessment practice against the recognised international standard.
Week 2	Establish or verify a defined, regular laboratory quality control schedule.
Week 3	Define a specific response protocol for out-of-range conditions.
Ongoing	Review quality control logs and assessment consistency periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Assessment standard review	Reviews assessment protocols against the recognised international consensus standard.
DOCUMENT	Quality control log review	Reviews laboratory condition quality control logs for consistency and regularity.

Method	What	Detail
ASK	Out-of-range response interview	Asks laboratory staff what happens when a quality control reading is outside acceptable range.

SUPERVISOR TIPS

- **Ask for actual quality control logs, not a general assurance conditions are stable.** — Dated, specific records are the only real evidence of consistent verification.
- **Ask two different embryologists to assess the same case criteria.** — Consistent answers reveal genuine standardisation; differing answers reveal informal, individual practice.

EVIDENCE BASE

[65] Alpha Scientists in Reproductive Medicine, ESHRE Special Interest Group of Embryology. The Istanbul consensus update: a revised ESHRE/ALPHA consensus on oocyte and embryo static and dynamic morphological assessment. Hum Reprod. 2025 — establishes internationally recognised, evidence-based criteria for oocyte and embryo assessment.

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13.2 Hormone Stimulation Protocols Have Real, Documented Physician Oversight

NON-NEGOTIABLE

Ovarian stimulation protocols are individually determined and monitored by a licensed physician based on this specific patient's response, following recognised clinical guidance — not a standardised protocol applied uniformly regardless of individual monitoring results.

In plain terms: A doctor personally sets and monitors each patient's stimulation protocol based on her response — with ultrasound and hormone results

reviewed — not a standard protocol given to every patient.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Ovarian stimulation done wrong causes ovarian hyperstimulation syndrome — a condition that can hospitalise, thrombose, and occasionally kill. Done cautiously in a poor responder, it produces no eggs and a wasted cycle. The dose must be individualised from the start (based on AMH, antral follicle count, age, BMI, and previous response) and adjusted during stimulation based on follicle growth and oestradiol levels. This requires a doctor reviewing every monitoring scan and blood result and making a documented decision. A clinic where nurses run 'the standard protocol' and the doctor sees the patient only at egg collection has no medical oversight of the most dangerous part of IVF.

WHAT GOOD LOOKS LIKE

- Protocols are genuinely individualised, reflected in real, patient-specific documentation.
- Protocols are adjusted based on this patient's own monitoring results.
- A specific, known OHSS recognition and management process exists.

COMMON FAILURE MODES

- A standardised protocol is applied uniformly regardless of individual patient profile.
- Protocols don't change despite individual monitoring results suggesting they should.
- No specific process exists for OHSS risk beyond general awareness.

WORKED EXAMPLE

IN PRACTICE

A fertility clinic running 300 cycles a year.

BEFORE

Patients received one of three standard protocols based on age. Monitoring scans were done by nurses; results were noted but not reviewed by a doctor until egg collection. Three patients had

	been hospitalised with OHSS in the previous year. Dose adjustments were rare.
ACTION	A stimulation protocol policy was written: individualised starting dose from a documented assessment of AMH, AFC, age, BMI, and prior cycles; every monitoring scan and E2 result reviewed by the treating doctor the same day with a documented decision (continue, adjust, trigger, cancel); OHSS risk assessed at every visit with a defined trigger and freeze-all protocol for high-risk patients. Doctors sign every monitoring review.
AFTER	The Monitor reviewed 20 cycle records: each had an individualised starting dose with rationale, same-day doctor review of every monitoring visit, and OHSS risk documented. Three cycles showed dose adjustments; one a freeze-all decision. OHSS hospitalisations: 0 in six months. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Pull ten cycle records: was the starting dose individualised with a written rationale?
2. Check whether a doctor reviewed each monitoring scan the same day. Is it signed?
3. Write an OHSS risk protocol with freeze-all criteria.
4. Require doctor sign-off on every monitoring decision.

The most common mistake: Choosing the protocol by age band alone — a 32-year-old with an AMH of 40 and one with an AMH of 2 need completely different treatment.

SELF-ASSESSMENT QUESTIONS

1. Is the stimulation protocol individually determined for this specific patient, not a standard protocol applied uniformly? — *A real, individual clinical decision, reflecting this patient's own profile.*
Evidence: Individual protocol determination record

2. Is the protocol adjusted based on this patient's actual monitoring results during stimulation? — *Genuine responsiveness to real-time monitoring data, not a fixed plan followed regardless.*

Evidence: Protocol adjustment record

3. Is there a defined process for recognising and managing ovarian hyperstimulation syndrome risk specifically? — *A specific, known process for this specific serious risk, not general awareness alone.*

Evidence: OHSS risk management protocol

COMMON REASONS FOR A PARTIAL ANSWER

- **Initial protocol determination is individualised but adjustments during stimulation become more standardised.** — Ongoing responsiveness to monitoring matters as much as the initial individualised decision.
- **Monitoring happens but isn't consistently reviewed by the physician in time to adjust the protocol meaningfully.** — Delayed review limits the ability to actually respond to what monitoring reveals.
- **OHSS risk is recognised for high-risk patients but the process isn't consistently applied to lower apparent risk.**

IMPLEMENTATION PLAN

When	What
Week 1	Review a sample of stimulation protocols for genuine individual determination.
Week 2	Establish a consistent process for adjusting protocols based on real-time monitoring.
Week 3	Define and brief staff on a specific OHSS recognition and management process.
Ongoing	Audit protocol individualisation and OHSS management readiness periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Individual protocol review	Reviews records for evidence of genuine, individual protocol determination.

Method	What	Detail
DOCUMENT	Adjustment record review	Reviews whether protocols are adjusted based on individual monitoring results during stimulation.
ASK	OHSS management interview	Asks the physician to describe the specific process for recognising and managing OHSS risk.

SUPERVISOR TIPS

- **Compare two different patients' protocols and documented reasoning.** — Genuinely different content reveals real individualisation; near-identical protocols reveal standardisation.
- **Ask the physician to describe a specific OHSS case, real or hypothetical, in detail.** — Specific, detailed knowledge reveals genuine readiness rather than general awareness.

EVIDENCE BASE

[66] European Society of Human Reproduction and Embryology. ESHRE guideline: ovarian stimulation for IVF/ICSI — an update. Hum Reprod. 2025 — establishes individualised, response-based protocol adjustment as core to safe ovarian stimulation practice.

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13.3 Multiple-Pregnancy Risk Is Explicitly Discussed Before Transfer CORE

Before every embryo transfer, the patient has a genuine, documented conversation about multiple-pregnancy risk specific to the number of embryos being considered, including the option of single embryo transfer — not a generic consent form covering "embryo transfer" without this specific discussion.

In plain terms: Before every embryo transfer, the doctor talks with the patient about the risk of twins or triplets for the number of embryos proposed, and offers single embryo transfer — and this is documented.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

Twin pregnancy is the most common serious complication of IVF: preterm birth, low birthweight, cerebral palsy, maternal haemorrhage, and neonatal death are all several times more likely than in singleton pregnancy. Transferring two embryos to increase the chance of pregnancy trades a small gain in pregnancy rate for a large increase in harm. International guidance recommends single embryo transfer for most patients. The patient must understand this and decide — and the decision must be documented. A clinic that routinely transfers two 'because patients want the best chance' has not had this conversation.

WHAT GOOD LOOKS LIKE

- Every patient has a specific, documented multiple-pregnancy risk conversation.
- Single embryo transfer is genuinely presented as a real option.
- Patients can explain back the risk relevant to their own decision.

COMMON FAILURE MODES

- Multiple-pregnancy risk is folded into general consent without specific discussion.
- Multiple-embryo transfer is presented as the default with no genuine alternative offered.
- Patients cannot describe the specific risk relevant to their transfer.

WORKED EXAMPLE

IN PRACTICE

A fertility clinic with a 35% twin rate — more than double the national target.

BEFORE

Double embryo transfer was the default. Multiple pregnancy risk was mentioned in a leaflet. The Coordinator interviewed ten patients post-transfer: seven did not know twins were a serious

	risk; four had not been offered single embryo transfer. Twin pregnancies had produced two preterm births with NICU admission in the previous year.
ACTION	A pre-transfer consultation was made mandatory: the doctor discusses this patient's likely pregnancy rate with one embryo versus two, the specific multiple pregnancy risks, and recommends single embryo transfer where prognosis is good. The conversation is documented with the patient's decision and reasoning. A clinic policy set single embryo transfer as default for patients under 38 with a good-quality blastocyst.
AFTER	The Monitor reviewed 25 transfer records: all had documented multiple pregnancy discussions and patient decisions. Single embryo transfer rate up from 30% to 78%; twin rate down to 9%. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Calculate your twin rate. Above 15% signals a problem.
2. Interview five post-transfer patients: do they know twins are a serious risk?
3. Make single embryo transfer the default for good-prognosis patients.
4. Document the conversation and the patient's decision every time.

The most common mistake: Treating twin pregnancy as a bonus rather than a complication — patients often do, and the clinic must correct that.

SELF-ASSESSMENT QUESTIONS

1. Does every patient have a specific, documented conversation about multiple-pregnancy risk before transfer? — *A specific conversation about this risk, not folded into general transfer consent.*
Evidence: Multiple-pregnancy risk discussion documentation

2. Is single embryo transfer genuinely presented as an option, not just multiple-embryo transfer as the default? — *A genuine choice presented, not a default the patient would need to actively push back against.*

Evidence: N/A — tested directly

3. Can the patient explain back the specific risk relevant to their own transfer decision? — *Tests genuine understanding, not just that a conversation occurred.*

Evidence: N/A — tested directly

COMMON REASONS FOR A PARTIAL ANSWER

- **The discussion happens for patients considering multiple-embryo transfer but not those already planning single transfer.**
— Even a patient inclined toward single transfer benefits from understanding why the choice matters.
- **Risk is mentioned but single embryo transfer isn't genuinely presented as an equally valid option.** — A mentioned risk without a genuine alternative doesn't provide a real choice.
- **The conversation happens once, early in treatment, and isn't revisited at the actual point of transfer decision.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current pre-transfer consent practice for specific multiple-pregnancy risk discussion.
Week 2	Build a specific discussion point into the pre-transfer consultation, distinct from general consent.
Week 3	Train staff to genuinely present single embryo transfer as a real option.
Ongoing	Spot-check patient understanding after pre-transfer consultations.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Risk discussion documentation review	Reviews records for a specific, documented multiple-pregnancy risk discussion distinct from general consent.

Method	What	Detail
OBSERVE	Transfer consultation observation	Observes an actual pre-transfer consultation for genuine discussion of single embryo transfer as an option.
ASK	Patient understanding check	Asks a patient to explain back the specific risk relevant to their own transfer decision.

SUPERVISOR TIPS

- **Ask the patient, not the clinician, to describe the risk discussion they had.** — This tests actual understanding, not staff confidence in their own explanation.
- **Ask specifically whether single embryo transfer was presented as a genuine option.** — A direct question often reveals what a general consent review won't.

EVIDENCE BASE

[67] Single embryo transfer, with explicit discussion of multiple-pregnancy risk as part of the transfer decision, is established international guidance for reducing avoidable multiple-pregnancy risk in IVF, distinct from general transfer procedure consent.

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13.4 High-Stakes Consent Reflects the Real Emotional and Financial Weight of the Decision CORE

Consent conversations for fertility treatment genuinely address the real emotional and financial weight of the decision — realistic success rates specific to this patient, not generic clinic statistics, and the real possibility of an unsuccessful cycle — not a form focused only on the physical procedure.

In plain terms: Consent for IVF honestly covers this patient's real chance of success, the emotional and financial cost, and what happens if it does not work — not generic clinic statistics and a signature.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

A 42-year-old with low ovarian reserve has a live birth rate per cycle of perhaps 5%. If she is shown the clinic's overall figure of 35%, she has been misled. Fertility treatment is one of the most emotionally and financially loaded decisions in medicine: patients spend savings, take loans, and endure repeated loss. Honest consent means age- and diagnosis-specific success rates from the clinic's own data, the cumulative cost of a realistic number of cycles, the emotional impact, the alternatives including stopping, and time to decide. A consent process designed to close the sale is not consent.

WHAT GOOD LOOKS LIKE

- Success rates discussed are specific to this patient, not generic clinic statistics.
- The real possibility of an unsuccessful cycle is genuinely, honestly discussed.
- Financial commitment, including possible multiple cycles, is discussed upfront.

COMMON FAILURE MODES

- Success rates cited are generic clinic marketing figures, not individualised.
- Consent implicitly assumes success, without genuine discussion of failure possibility.
- Financial discussion happens only as costs are being incurred, not upfront.

WORKED EXAMPLE

IN PRACTICE

A fertility clinic that quoted its overall live birth rate on its website and in consultations.

BEFORE

Patients were told the clinic's live birth rate (36% per cycle). Age-specific rates were not discussed. Financial counselling covered the cost of one

cycle only. A 43-year-old had spent her savings on four cycles with a realistic success rate under 4% per cycle; nobody had told her that figure.

ACTION

Consent was restructured: the doctor presents this patient's success rate by age and diagnosis from the clinic's own outcomes data; a financial counsellor presents the cost of one, two, and three cycles; the emotional impact and counselling access are discussed; the option of not proceeding is explicitly offered; a 48-hour cooling-off period is required before treatment begins; the patient signs a consent that records the specific success rate she was told.

AFTER

The Monitor reviewed 20 consents: each recorded a patient-specific success rate, multi-cycle cost, and the cooling-off period. Interviewed two patients who could state their own success rate. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Ask five patients what success rate they were told. Compare to their age-specific rate.
2. Calculate your own success rates by age band and diagnosis.
3. Present those — not the overall figure — in every consultation.
4. Add a cooling-off period and record the rate given on the consent.

The most common mistake: Quoting the clinic's overall success rate to a patient whose personal rate is a fraction of it.

SELF-ASSESSMENT QUESTIONS

1. Does consent include realistic success rates specific to this patient's own profile, not generic clinic-wide statistics? — *Individualised, honest expectations, not marketing-oriented general figures.*

Evidence: Individualised success rate discussion documentation

2. Is the real possibility of an unsuccessful cycle genuinely discussed, not treated as an unlikely exception? — *Honest*

acknowledgement, not an implicit assumption of success.

Evidence: N/A — tested directly

3. Does the conversation address the real financial commitment, including the possibility of multiple cycles? — *Genuine financial transparency, not deferred until costs are already being incurred.*

Evidence: Financial discussion documentation

COMMON REASONS FOR A PARTIAL ANSWER

- **Individualised success rates are discussed for the first cycle but not revisited for subsequent attempts.** — Each cycle's own realistic likelihood deserves its own honest discussion.
- **Financial discussion covers the immediate cycle cost but not the realistic possibility of needing further cycles.** — Genuine financial transparency includes the realistic full picture, not only the immediate cost.
- **The conversation is thorough at initial consultation but not revisited as treatment progresses.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current consent practice for individualised, not generic, success rate discussion.
Week 2	Build individualised success rate and unsuccessful-cycle discussion into the consent process.
Week 3	Establish upfront financial discussion covering realistic multiple-cycle possibility.
Ongoing	Spot-check patient understanding of both clinical and financial realities.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Individualised success rate review	Reviews consent documentation for patient-specific, not generic, success rate discussion.
OBSERVE	Consent conversation observation	Observes an actual consent conversation for genuine discussion of unsuccessful-cycle possibility.

Method	What	Detail
ASK	Financial discussion interview	Asks a patient whether the real financial commitment, including possible multiple cycles, was discussed upfront.

SUPERVISOR TIPS

- **Ask a patient what success rate they were told, and compare it to this patient's actual individual profile.** — This reveals whether figures given were genuinely individualised or generic.
- **Ask whether the possibility of needing more than one cycle was discussed before treatment began.** — This is where financial transparency most commonly falls short in practice.

EVIDENCE BASE

[68] Realistic, individualised success rate discussion, distinct from generic clinic-wide statistics, is identified as an essential component of genuinely informed consent in fertility treatment, given the significant emotional and financial stakes involved.

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13.5 A Witnessing Protocol Prevents Gamete and Embryo Mix-Up

NON-NEGOTIABLE

Every critical step involving gamete or embryo handling — collection, insemination, cryopreservation, thaw, transfer — is verified through a defined witnessing protocol, either double manual witnessing by a second qualified person or a certified electronic witnessing system, with every step traceable.

In plain terms: Every time eggs, sperm, or embryos are handled — collected, fertilised, frozen, thawed, transferred — two people or an electronic system confirm they belong to the right patient.

Facility category	Crisis	Transition	Small	Standard
Applicability	N/A	Full	Full	Full

WHY THIS MATTERS

An embryo mix-up is the catastrophe fertility clinics exist to prevent: a child born to the wrong parents, a genetic child lost, a family destroyed, a clinic closed. It happens through a moment's inattention in a lab handling dozens of samples with similar labels. The defence is witnessing: at every critical step, a second trained person (or an RFID/barcode electronic witnessing system) independently confirms the identity of the patient, the sample, and the destination — and records it. No step is skipped because the lab is busy. No witness is the person who did the step.

WHAT GOOD LOOKS LIKE

- Every critical step is covered by a defined witnessing protocol.
- Witnessing is genuinely independent, whether manual or certified electronic.
- Every witnessed step is traceable through a retained, specific record.

COMMON FAILURE MODES

- Some critical steps lack a defined witnessing protocol.
- Witnessing is not genuinely independent, or is skipped under time pressure.
- No retained record exists confirming witnessing actually occurred for a given step.

WORKED EXAMPLE

IN PRACTICE

A fertility clinic laboratory handling 20 patients' samples on a busy day.

BEFORE

Witnessing was done 'when possible.' On busy days, embryologists worked alone and signed the witness line themselves. Labels were handwritten. A near-miss occurred when two patients with the same surname had samples on adjacent workstations.

ACTION

A witnessing protocol was written listing every critical step: oocyte collection labelling, sperm

preparation, insemination/ICSI, embryo culture dish labelling, cryopreservation, thaw, and transfer. Each requires a second person to independently verify patient ID (two identifiers), sample ID, and destination, and sign. The witness cannot be the operator. Staffing was adjusted so a witness is always available. An electronic witnessing system was budgeted for the following year.

AFTER

The Monitor observed an ICSI procedure and a transfer with double witnessing performed and recorded. Reviewed 30 witness records with no self-witnessing. Verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Pull 20 witness records. Is any witness the same person as the operator?
2. List every critical step and require a witness for each.
3. Adjust staffing so a witness is always available.
4. Budget for electronic witnessing.

The most common mistake: Allowing the embryologist to sign as witness for their own work on busy days — the busy day is when the mistake happens.

SELF-ASSESSMENT QUESTIONS

1. Is every critical step — collection, insemination, cryopreservation, thaw, transfer — covered by a defined witnessing protocol? — *Every critical step specifically, not a general awareness of the importance of care.*

Evidence: Witnessing protocol coverage documentation

2. Is witnessing genuinely independent — a second qualified person or certified electronic system — not the same person self-confirming? — *Genuine independence, whether human or verified electronic system.*

Evidence: N/A — tested directly

3. Is every witnessed step traceable after the fact, with a retained record of who witnessed what and when? — *A real, retained record,*

not an assumption that witnessing happened because the protocol exists.

Evidence: Witnessing traceability record

COMMON REASONS FOR A PARTIAL ANSWER

- **Witnessing is rigorous for embryo transfer but less consistently applied to earlier steps like insemination.** — Every critical step carries the same real mix-up risk, not transfer alone.
- **An electronic witnessing system exists but isn't used consistently for every applicable step.** — A system that exists but isn't consistently used doesn't provide the intended protection.
- **Witnessing happens but records don't specify exactly which steps were witnessed by whom.**

IMPLEMENTATION PLAN

When	What
Week 1	Map every critical gamete and embryo handling step against current witnessing coverage.
Week 2	Close any gap in witnessing coverage for critical steps.
Week 3	Establish specific, retained traceability records for every witnessed step.
Ongoing	Audit witnessing consistency and traceability records periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Protocol coverage review	Reviews the witnessing protocol for coverage of every critical handling step.
OBSERVE	Witnessing independence observation	Observes an actual witnessed step for genuine independence between the operator and witness.
DOCUMENT	Traceability record review	Reviews records for retained, specific traceability of witnessed steps.

SUPERVISOR TIPS

- **Ask to see the traceability record for a specific, recent case.** — A specific, real record is the only genuine evidence witnessing actually happened as described.

- **Observe a witnessed step directly if timing allows.** — Genuine independence between operator and witness is best confirmed through direct observation.

EVIDENCE BASE

[69] Human Fertilisation and Embryology Authority. Code of Practice. 9th ed. London: HFEA; 2021 — mandates witnessing, either double manual witnessing by a second qualified individual or a certified electronic witnessing system, at every critical step of gamete and embryo handling.

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