

Danish Guidelines 2023 for Percutaneous Dilatational Tracheostomy in the Intensive Care Unit

Christina Sørensen, David Buck, Jonathan White, Pia Lawson-Smith

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Correspondence: Jonathan White, Consultant Intensive Care Unit 4131, Rigshospital, Copenhagen.

Jonathan.oliver.white@regionh.dk

Summary:

Percutaneous dilatational tracheostomy is a common procedure in intensive care. This updated Danish national guideline describes indications, contraindications and complications, and gives recommendations for timing, anaesthesia, and technique, use of fiberoptic bronchoscopy and ultrasound guidance, as well as decannulation strategy, training, and education.

Limitation: Applicable only for patients aged ≥ 15 years

Last literature review: January 2015

Next update: January 2027

List of abbreviations:

ICU = intensive care unit

PDT = percutaneous dilatational tracheostomy

ST = surgical tracheostomy

RCT = randomized controlled trial

PICO = population, intervention, comparator, outcome

DASAIM = Danish Society of Anesthesiology and Intensive Care Medicine

DSIT = Danish Society of Intensive Care Medicine

OR = operating room

1. INTRODUCTION

Tracheostomy is one of the most common surgical procedures performed in critically ill adults on intensive care units in patients requiring long term ventilation. The percutaneous procedure has been practiced and refined over the last 35 years, after having been described by Ciaglia in 1985¹, and has become the preferred procedure in the ICU.

2. CONTRIBUTORS, METHODS, SEARCH STRATEGY, AND LEVEL OF EVIDENCE

Contributors

A group of Danish ICU doctors with special interest and expertise in PDT was constituted.

Research questions

Where possible formal research questions were formulated, all concerning tracheostomy in mechanically ventilated adult critically ill patients in the ICU:

Which indications, contraindications, and complications should be appreciated?

What is the optimal timing of tracheostomy?

Should PDT be preferred as standard method over ST?

Should fiberoptic guidance be used?

Should ultrasound guidance be used?

Which form of anaesthesia is preferable?

How is training and education for PDT best organized?

PICO questions

Subtopics and PICO questions² were formulated and delegated to individual authors within the group, who in turn handed in a draft for internal peer review.

Population: Ventilated adult critically ill patients in the ICU

Intervention: PDT

Comparator: Any

Outcome: Mortality, morbidity, bleeding, pneumonia, length of mechanical ventilation, length of stay and serious adverse events

Search strategy

PubMed and Cochrane Library were searched for literature. In addition, we hand-searched reference lists of relevant publications. No study designs were per se excluded but emphasis was put on RCTs and well performed recent meta-analyses.

Inclusion criteria

Adult critically ill patients in the ICU undergoing mechanical ventilation.

Exclusion criteria

Age less than 15 years. Studies conducted in a non-ICU setting.

Validation and grading of evidence

We evaluated trial data using the GRADE approach (www.gradeworkinggroup.org). The GRADE system does not grade the quality of single studies but sequentially assesses the quality of evidence from the best available data for the outcomes of interest followed by assessment of the balance between benefits versus risks, burden, and cost. Literature identified by the search strategy was considered to represent the best-quality evidence. The quality of the evidence was quantified (high, moderate, low or very low) and potentially downgraded in the domains 1) risk of bias, 2) inconsistency of results, 3) indirectness of the evidence, 4) imprecision of results, and 5) other considerations including suspicion of publication bias, and was downgraded based on the number of domains with concerns (Table 1).

Recommendations

The recommendations were agreed upon in the group, and if total agreement could not be obtained, the group voted; 3/4 of the votes were needed to issue a strong recommendation. Strong recommendations (marked 1) were given the wording 'we recommend' and weak recommendations (2) 'we suggest'. The level of evidence was graded high (marked A), moderate (B), low (C) or very low (D) based on the number of domains that were downgraded in adherence to GRADE.

Table 1. Rating the quality of evidence according to GRADE.
Source: Balshem et al.³

Study design	Quality of Evidence	Lower if	Higher if
Randomized trial →	High (A)	Risk of bias -1 Serious -2 Very serious	Large effect +1 Large +2 Very large
	Moderate (B)	Inconsistency -1 Serious -2 Very serious	Dose response +1 Evidence of a gradient
Observational study →	Low (C)	Indirectness -1 Serious -2 Very serious Imprecision -1 Serious -2 Very serious	All plausible confounding: +1 Would reduce a demonstrated effect or
	Very low (D)	Publication bias -1 Likely -2 Very likely	+1 Would suggest a spurious effect when results show no effect

Table 2. Key recommendations

We suggest that optimal timing of tracheostomy be determined on an individual patient basis. There is insufficient or conflicting evidence to make a general recommendation of early versus late tracheostomy (2B)

We recommend bedside PDT as the standard method for tracheostomy in intensive care patients (1B)

We recommend that surgical tracheostomy in the operating room remains the back-up method in difficult cases (ungraded best clinical practice)

We recommend that 2 doctors participate in the procedure of PDT (1D)

We suggest that anaesthesia for PDT should consist routinely of intravenous general anaesthesia and neuromuscularblockade (2D)

We suggest that PDT can also be safely carried out in local analgesia (2D)

We suggest the laryngeal mask airway as a safe alternative to retracting an endotracheal tube during PDT (2B)

We recommend bronchoscopic guidance for PDT (1D)

We suggest ultrasound as a possible adjunct to PDT (2C)

We recommend that the Surgical Safety Checklist, as developed by WHO, and with local modifications, should be routinely applied to the surgical procedure of PDT (1B)

We recommend capnography should be used in cases of suspected tracheal tube displacement (1D)

We suggest that all clinical staff who work in ICU should be trained in interpretation of capnography (2D)

We recommend the presence of a difficult airway trolley in close proximity to the unit (1D)

We suggest the establishment of an algorithm to be used in the clinical scenario where there is suspicion of a displaced tracheostomy (2D)

We suggest that all ICU doctors receive ongoing training in the use of supraglottic devices and are familiar in the techniques of advanced airway management (2D)

We suggest that an individual plan for tracheostomy management and decannulation should be presented at patient discharge from ICU to the general ward with a tracheal cannula in place (ungraded).

We recommend an active training and education strategy for PDT, with local modifications (ungraded).

3. PDT – INDICATIONS AND CONTRAINDICATIONS

Indications for PDT:

Prolonged/expected prolonged mechanical ventilation
Facilitate weaning from mechanical ventilation
Airway protection against pulmonary aspiration (e.g. laryngeal incompetence due to critical illness, polyneuropathy, or bulbar dysfunction)
Prolonged need for intratracheal suction
Upper airway obstruction (e.g. tumor, bilateral recurrent laryngeal palsy)
Trauma or infection in oral cavity, pharynx or larynx.
Minimisation of sedation
Improved patient comfort

Contraindications against PDT:

Informed refusal to the procedure
Unstable fractures of the cervical spine
Severe local infection of the anterior neck
Uncontrollable coagulopathy

Relative contraindications:

Controlled local infection
Coagulopathy
High PEEP or FiO₂ requirements
Difficult anatomy (e.g. morbid obesity, short thick neck, reduced neck extension, excessive goiter, tracheal deviation)
Proximity to extensive burns or surgical wounds
Elevated intracranial pressure
Haemodynamic instability
Previous radiotherapy to the neck

No randomized, controlled trials concerning indications or contraindications for PDT were found. In experienced hands, PDT seems to be a safe procedure. The risk/benefit and timing of PDT should be evaluated on an individual patient basis. Usually PDT is an elective procedure, and all reversible risk factors (e.g. severe coagulopathy or excessive PEEP/FiO₂ requirements) should be corrected in advance.

The number of relative contraindications to PDT declines with increasing operator experience. A case series with 207 patients showed that PDT can even be performed safely as an emergency procedure by experienced clinicians⁴. Also PDT has been performed safely at high PEEP/FiO₂ requirements⁵, and with few complications in spite of coagulopathy⁶ and even though patients with severe thrombocytopenia (platelet count <50,000/microL) has a five-fold risk of persistent stomal bleeding PDT can be performed safely after administration of platelets in experienced hands⁷. With respect to patient receiving antiplatelet therapy and anticoagulants, the evidence is sparse but PDT seems to be safe even though the risk of bleeding is increased^{8,9}.

Retrospective data has indicated that obese patients (BMI > 27,5) have a 5 times higher risk of severe perioperative complications with respect to PDT than normal-weight patients¹⁰. Whereas a larger cohort study found PDT to be just as safe as surgical tracheostomy (ST) in 143 morbidly obese patients (BMI ≥ 35)¹¹ with an overall complication rate comparable to non-obese patients (5,6% vs 4%)¹². Some small studies and case reports have reported fewer laryngeal complications with tracheostomy as compared with prolonged translaryngeal intubation¹³.

Potential advantages with tracheostomy compared to prolonged translaryngeal intubation:

Less sedation needed for tube acceptance
Higher patient comfort (mobilisation, oral hygiene, phonation)
Reduced risk of laryngeal damage in long-term intubation
Reduced airway resistance and respiratory work
More efficient cough
Faster weaning from mechanical ventilation
Shorter ICU-stay

4. TIMING OF TRACHEOSTOMY IN THE CRITICALLY ILL - EARLY VERSUS LATE?

Population: Mechanically ventilated adult critically ill patients in the ICU

Intervention: Early tracheostomy

Comparator: Late or no tracheostomy

Outcome: Mortality, pneumonia, duration of mechanical ventilation and ICU or hospital stay

Recommendation: In prolonged mechanical ventilation, we suggest that optimal timing of tracheostomy be determined on an individual patient basis (2B).

The definition of what constitutes early vs. late tracheostomy has not been categorically defined and there is hence no 'gold standard'. The latest Cochrane review (2012) defined early as < 10 days and late > 10 days, trial authors have been free to use any arbitrary definitions.

All RCTs so far have been underpowered to detect a possible small yet clinically relevant benefit of early timing of this widespread procedure in the ICU. A host of meta-analyses^{14 15 16 17 18 19 20 21 22} have returned non-significant results on outcomes such as mortality, pneumonia, duration of mechanical ventilation, and length of intensive care or hospital stay and the two most recent have given conflicting results²³.

On this background, we find insufficient evidence to support a firm recommendation of early versus late tracheostomy in routine clinical practice. Optimal timing of tracheostomy should be determined individually with daily clinical assessment.

5. PDT VS. ST

Population: Mechanically ventilated adult critically ill patients in the ICU

Subject: PDT vs ST

Outcome: Early and late complications. Resource utilization.

Recommendation:

We recommend bedside PDT as the standard method for tracheostomy in intensive care patients (1B)

- bedside PDT is logistically simpler and has fewer or equally few complications compared to ST (1A)
- bedside PDT is less expensive than ST in the operating room (1B)

	Advantages	Disadvantages
Percutaneous Dilatation Tracheostomy	<ul style="list-style-type: none"> • Less postprocedural complications such as accidental decannulation, bleeding and wound infection. • Less bleeding risk (smaller hole) • Lower incidence of tracheal stenosis • Lower incidence of tracheal infection • The cosmetic effect is better • No transfer, thus no risks of transfer • Cheaper • Faster (10-15 minutes) • More easily available in the ICU • Decreases length of stay in ICU (if early tracheostomy) 	<ul style="list-style-type: none"> • Inadequate backup for major complications or difficult anatomy • Much of the technique is essentially blind. • Diathermy is not available • Bronchoscopy is required for safety • The bronchoscope may get damaged • Disposable percutaneous kits cost more than a bedside surgical tracheostomy • There is a greater risk of death and cardiac arrest • Some intraoperative complications are unique to percutaneous technique (eg. knotted guide wire)
Surgical Tracheostomy	<ul style="list-style-type: none"> • Gold standard for difficult anatomy • Better control of bleeding • Fewer intraoperative complications 	<ul style="list-style-type: none"> • More postprocedural complications • Higher incidence of tracheal stenosis • Higher incidence of stomal infections • Expensive; requires the operating theatre to be fully staffed • Takes longer to roganise • Exposes patients to risk of transfer

Table 3

We recommend that surgical tracheostomy in the operating room remains the back-up method in difficult cases (ungraded best clinical practice)²⁴
When :

- Anatomical landmarks are difficult to palpate
- Blood vessels at the site of insertion
- Malignancy at site of insertion
- If emergency tracheostomy is required

Background:

In controlled studies, clinically important complications are infrequent following both PDT or ST. Most serious or fatal complications such as uncontrollable bleeding or irreversible loss of airway have only been published in case reports. Table 3 shows the advantages and disadvantages in PDT and ST.

Early complications

Johnson-Obaseki et al (2016)²⁵ concluded that with regard to rates of mortality, intraoperative hemorrhage, and postoperative hemorrhage there was no statistically significant difference between the two techniques. The same authors found that the post-procedure infection rate was lower with the percutaneous technique. This has been confirmed by Raymond et al²⁶.

Resource utilization

The above mentioned meta-analysis from Johnson-Obaseki et al²⁵ found that the procedure time was faster for the percutaneous technique, as well as requiring much less personnel.

Late complications

The risk of tracheal stenosis was found to be higher for surgical tracheostomy, though only as a trend, rather than a firm association²⁷. A meta-analysis from 2006²⁸ of 17 RCTs including 1212 patients found a significantly reduced wound infection rate of 2,3 % after bedside PDT versus 10,7 % following surgical tracheostomy either bedside or in the OR. A possible cause is the minimally invasive surgical technique with PDT.

Bleeding requiring transfusion or subsequent surgical haemostasis was seen in 5-6 % in both groups. A subgroup analysis of bedside PDT versus surgical tracheostomy in the OR revealed a significantly lower risk of bleeding and lower mortality with bedside PDT. This finding could reflect the risk of intrahospital transport of a critically ill patient.

Also the financial cost of bedside PDT is lower than that of surgical tracheostomy in the OR²⁹.

The most significant study³⁰ in the above-mentioned meta-analysis randomized 200 ICU patients to either bedside surgical or percutaneous tracheostomy. No significant difference was found in the combined primary endpoint (bleeding, infection, pneumothorax, accidental decannulation, other major operative complication, or death). The total complication rate was low: 3,5 %. However, there were fewer stomal infections in the PDT group at day 7. Also time from randomization to tracheostomy was shorter in the PDT group. The latter could reflect the logistical advantage of the intensivists themselves performing the procedure.

6. ANAESTHESIA FOR PDT

Recommendation:

We *suggest* that anaesthesia for PDT should consist routinely of intravenous general anaesthesia and neuromuscular blockade (2D)

We *suggest* that PDT can also be safely carried out in local analgesia (2D).

We *suggest* the laryngeal mask airway as a safe alternative to retracting an endotracheal tube (2B).

Usual fasting rules are applicable.

Prepare for a difficult airway (ungraded)

Randomised clinical studies of anaesthesia for PDT were not identified, so this recommendation relies primarily on expert opinion and case reports. Sedation to tube tolerance is not sufficient for surgical anaesthesia. Neuromuscular blockade optimises surgical conditions and facilitates controlled ventilation. Inhalational anaesthesia is avoided due to the inherent gas leakage during the procedure.

In this procedure, managing the airway is the anaesthesiologist's greatest challenge³¹.

To facilitate the surgical procedure, the upper part of the back is elevated and the neck hyperextended which makes laryngoscopy more difficult. Prior prolonged intubation constitutes a risk for airway oedema³². The orotracheal tube can be retracted under direct laryngoscopy until the cuff is just distal to the vocal cords, before the trachea is punctured³³. Still there is a risk that the introducing needle hits the tracheal tube if the tip of the tube is not proximal to the puncture site.

An alternative is to extubate the patient and insert a laryngeal mask, where the risks are pulmonary aspiration, air leakage and compromised ventilation.

However one randomized clinical trial concludes that the laryngeal mask airway has significant advantages over withdrawing an endotracheal tube³⁴.

The exact choice of method depends on clinical evaluation and personal preference. Equipment for managing the difficult airway should be available.

7. PDT: TECHNIQUE AND PROCEDURE

Recommendation, PDT technique:

We do not recommend any specific percutaneous technique. (grade 1B)

We suggest the choice of a percutaneous technique to be based on the operator's experience, clinical judgment, and local practice. (grade 2D)

Several commercial kits are available for PDT. Raimondi et al²⁶ in 2017 a review of comparative studies regarding different modalities of PDT. All included studies were randomized trials and compared different techniques;

PDT with multiple dilators

PDT with forceps

PDT with single dilator

Rotational PDT

Translaryngeal PDT

PDT with a balloon

There is no evidence to recommend one PDT technique over another. The method should be selected on the basis of clinical criteria, experience, availability and local practice

The following suggestions for PDT procedure are based on expert opinions and rules of thumb. (ungraded)

Staff:

We recommend that two doctors should participate, one of whom should be experienced in the technique of PDT. (1D)

Preparation:

If the patient has the capacity to give consent then this must be obtained directly from the patient.

If the patient can not give consent then the patient's next of kin are informed (if possible).

If the patient has appointed a power of attorney then they should give consent to the procedure

Anti-coagulation should be paused according to institutional practice.

Instruments:

PDT-kit.

Tracheostomy tube

Laryngoscope, intubation tray and equipment for difficult airway management should be immediately available.

Flexible bronchoscope (preferably a video bronchoscope, since it allows all personal in the room to visualize the positioning of the oral endotracheal tube) and a bronchoscope attachment for the ventilator.

Optional: ultrasound machine.

The procedure itself:

Patient in supine position. Placement of a shoulder roll under the scapula for optimal presentation of anterior neck anatomy.

Identify anatomical landmarks; thyroid cartilage, cricoid cartilage and tracheal rings are palpated. The optimal site for tracheostomy is under the cricoid cartilage between the second and third tracheal ring. More proximal placement increases the risk of tracheal stenosis, whereas a more distal placement increases the risk of erosion of the great vessels in the mediastinum.

Palpate the neck to identify the pulse of any arteries in the area of planned incision.

The choice of tracheostomy site can be guided with flexible bronchoscopy (light through the anterior tracheal wall) and/or ultrasound.

Withdrawal of the tracheal tube under bronchoscopic guidance until the cuff is placed just under the vocal cords.

Antiseptic and sterile preparation according to institutional guidelines.

Local analgesia with a local anaesthetic containing adrenalin (to reduce bleeding) from skin to trachea.

Skin incision: 8-12 mm horizontal incision at the chosen level. The incision must be as short as possible to reduce risk of bleeding and infection and to provide a tight-fitting stoma.

Introduction of guidewire: The cuff of the tracheal tube is deflated, the trachea is punctured in the midline, and the guidewire is introduced. Bronchoscopic confirmation of intra-tracheal placement and visualization of distal guidewire placement

Stomal dilatation with one or more dilators, possibly with the use of a dilating forceps. Direct visualization of intra-tracheal placement (bronchoscopic confirmation through oral tube)

Finally appropriate fixation according to institutional practice to avoid cannula displacement.

Complications:

Loss of airway

A new airway must be established expeditiously by

- creating the tracheostomy
- or replacing the endotracheal tube

Perioperative bleeding:

- Minor bleeding (no transfusion requirement):
 - manual compression.
 - subcutaneous infiltration with adrenaline containing local analgesic circumferentially to the tracheal stoma.
 - compress soaked with adrenalin-solution (1 mg adrenalin, 4 ml sterile water) wrapped around the tube between the flange and the skin or with locally applied tranexamic acid.
- Major bleeding (transfusion requirement or continued bleeding despite the above measures)
 - consult an ENT specialist (exploration, suture, cautery).

8.BRONCHOSCOPIC GUIDANCE:

We recommend bronchoscopic guidance for PDT (1D)

Background: No RCTs of PDT with bronchoscopic guidance versus no bronchoscopic guidance were identified. A systematic review²⁶ and a meta-analysis³⁵ found no evidence of use of bronchoscopic guidance to decrease the number of complications.

The primarily rationale for using bronchoscopy during PDT is

- Correct tracheostomy site (midline placement, level at tracheal rings, light at the anterior tracheal wall).
- Intra-tracheal guidewire placement.
- Intratracheal dilator placement without tracheal damage.
- Position of tracheal cannula postprocedurally

9.ULTRASOUND GUIDANCE :

We suggest the use of Ultrasound prior to PDT to identify anatomical structures (2C)

Background:

A systematic review by Gobatti compared ultrasound guided PDT to bronchoscopic and landmark-guided PDT. They found no difference in complication rates. Neither did Raimondi²⁶

The prior rationale for using Ultrasound before PDT is

- Evaluation of the anatomy of major vessels and the thyroid gland in relation to tracheostomy site or small vessels anterior to the tracheostomy site
- the position of the tracheal rings and the midline (even in obese patients³⁶)
- Gauging depth of subcutaneous tissue
- Improving puncture accuracy

There is so far insufficient evidence to make recommendations of routine use of ultrasound before PDT to reduce complications

10.PATIENT SAFETY

Recommendation: In intensive care units caring for tracheostomized patients:

- We recommend that the Surgical Safety Check-list, as developed by WHO, and with local modifications, be routinely applied to the surgical procedure of PDT (1B)³⁷
- We recommend capnography should be used in cases of suspected tracheal tube displacement (1D)
- We suggest that all clinical staff who work in ICU should be trained in interpretation of capnography (2D)
- We recommend the presence of a difficult airway trolley in close proximity to the unit (1D)
- We suggest the establishment of an algorithm to be used in the clinical scenario where there is suspicion of a displaced tracheostomy (2D)
- We suggest that all ICU doctors receive ongoing training in the use of supraglottic devices and are familiar in the techniques of advanced airway management (2D)

Background: Considering the results of the national audit project (NAP4) from the United Kingdom it seems prudent to implement the above measures ^[Citation].

11. DECANNULATION

Recommendations: (all ungraded best clinical practice)

The patient should be decannulated as soon as possible when

- Effective coughing
- Effective swallowing
- Inspiratory fraction of oxygen is reasonably low
- Suctioning is rarely needed
- Successful prolonged spontaneous breathing trial on a capped tracheostomy
- The airway is patent

At discharge from ICU to the general ward with a tracheal cannula in place:

- The tracheal cannula should be without cuff (to avoid risk of total airway occlusion) unless the ward is specialized in care of patients with cuffed tracheal cannulas.
- An individual plan for tracheostomy management and decannulation should be presented.

Background: Recommendations about decannulation suffer from lack of solid evidence and are largely based on expert opinions. Systematic reviews on the subject have identified the paucity of evidence and the need for³⁸ evidenced based decannulation protocols. They found that the decannulation is more often individualized than protocolized. They found some objective criteria to use in the clinical judgement of decannulation, but the criteria still need to be validated in daily practice. A prospective observational study showed that discharge from ICU to the ward with a tracheal cannula in place was an independent risk factor for mortality, especially in case of a high BMI³⁹. A survey in Denmark revealed inadequate post-ICU follow-up in non-decannulated patients on the ward⁴⁰. An intensivist led, post ICU tracheostomy follow-up team has been associated with earlier discharge from hospital⁴¹.

12. TRAINING AND EDUCATION

To minimise complications, PDT should be performed by doctors able to maintain their routine in this procedure, typically at a specialist level in intensive care medicine. In one study complication rates among residents performing PDT was found to be higher during their first five procedures than later⁴²(1).

Training a procedure, in this case PDT, involves both knowledge (indications, contraindications, complications), practical management (preparation, dexterity, technique) as well as communication and teamwork (consent, modesty, knowing when to call for senior assistance) .

When a colleague is training a procedure, the following steps are suggested (3):

- 1) Demonstration: The supervisor demonstrates the procedure at a normal pace, but without comments.
- 2) Deconstruction: The supervisor demonstrates and simultaneously describes the steps of the procedure.
- 3) Understanding: The supervisor demonstrates the steps of the procedure, but this time with the trainee talking the supervisor through the steps.
- 4) Management: The trainee demonstrates and describes the steps of the procedure.

In this way the procedure is split into manageable steps, and the trainee is asked to describe each step.

The repetition reinforces the learning process, and possible mistakes are corrected. Also, different learning styles are possible, because the trainee sees, hears, describes and performs the procedure.

We recommend that the supervisor and the trainee meet two times as a minimum to ensure that all 4 steps are carried out. Step 1 is demonstrated on a patient or a teaching video

Step 2-4 can be trained theoretically, but preferably on a mannequin, where promising results with producing low cost PDT simulators indicate potentials⁴³. The steps are repeated until the supervisor finds the trainee ready to perform the procedure on a clinical patient under supervision (step 4). It is individually decided when the colleague is ready to perform PDT without supervision.

We recommend the following structure for every learning session

- **Introduction:** The trainee's basic knowledge of PDT? Consider the placement of the trainee: Next to you or opposite? Left- or right-handed?
- **Dialogue:** Have you broken down the PDT procedure into clearly defined steps? Do you give positive feedback to the trainee? ("What went well?", "What would you do differently next time?") Avoid too much talk. Often too many details are given.
- **Conclusion:** Can the colleague safely perform PDT? How will he or she continue the learning process? Take home messages.

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