ESPEN practical guideline: Home parenteral nutrition

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Abstract

This guideline will inform physicians, nurses, dieticians, pharmacists, caregivers and other home parenteral nutrition (HPN) providers, as well as healthcare administrators and policy makers, about appropriate and safe HPN provision. This guideline will also inform patients requiring HPN. The guideline is based on previous published guidelines and provides an update of current evidence and expert opinion; it consists of 71 recommendations that address the indications for HPN, central venous access device (CVAD) and infusion pump, infusion catheter and CVAD site care, nutritional admixtures, program monitoring and management. Meta-analyses, systematic reviews and single clinical trials based on clinical questions were searched according to the PICO format. The evidence was evaluated and used to develop clinical recommendations implementing Scottish Intercollegiate Guidelines Network methodology. The guideline was commissioned and financially supported by ESPEN and members of the guideline group were selected by ESPEN.

Keywords

Caregiver, Central venous access device, Home parenteral nutrition, Intestinal failure, Management, Monitoring, Multidisciplinary team, Parenteral nutrition admixture, Patient training

List of abbreviations

AIO, all-in-one parenteral nutrition admixture; CDC, Center for Disease Control and Prevention; CIF, chronic intestinal failure; CRBSI, catheter-related bloodstream infection; CVAD, central venous access device; CVC, central venous catheter; EN, enteral nutrition; HPN, home parenteral nutrition; NST, nutrition support team; PICC, peripherally inserted central venous catheter; PN, parenteral nutrition; QoL, quality of life; RCT, randomized controlled trial

Introduction

Parenteral nutrition (PN) is categorized as total (or exclusive) PN, where it meets the patient's nutritional needs in entirety, and as supplemental (partial or complementary) PN, where nutrition is also provided via the oral or enteral route. PN can be administered either in, or outside the hospital setting; the latter defined as home parenteral nutrition (HPN) [1].

HPN is the primary life-saving therapy for patients with chronic intestinal failure (CIF) due to either benign or malignant diseases [2-4]. HPN may also be provided as palliative nutrition to patients in late phases of end-stage diseases [1]. As HPN is sometimes used to prevent or treat malnutrition in patients with a functioning intestine, who decline medical nutrition via the oral/enteral route, HPN and CIF cannot be considered synonymous [2]. Thus, on the basis of underlying gastrointestinal function and disease, in tandem with patient characteristics, four clinical scenarios for the use of HPN can be identified [2-4]: (i) HPN as primary life-saving therapy for a patient with CIF due to benign disease; (ii) HPN for CIF due to malignant diseases, often transiently occurring during curative treatments; (iii) HPN included in a program of palliative care for incurable malignant disease, to avoid death from malnutrition; (iv) HPN used to prevent or treat malnutrition in patients with a functioning intestine, who decline other types of medical nutrition ('no-CIF scenario'). The goal and characteristics of the HPN program, as well as the specific needs of the patient, may differ among the four clinical scenarios.

The first European Society for Clinical Nutrition and Metabolism (ESPEN) guideline on HPN was published in 2009 [3]. It consisted of 26 recommendations, 10 were based on some evidence (grade B recommendations) but 16 were mostly based on expert opinion ('grade C recommendations'). In 2016, ESPEN guidelines for CIF due to benign disease was published, including 11 recommendations on HPN management, 17 on PN formulation and 22 on the prevention and treatment of central

venous catheter (CVC)-related complications [4]. The grade of evidence was very low for 31 recommendations, low for 14, moderate for 3 and high for 2, whereas the strength of the recommendations was weak for 18 and strong for 32. Most of the recommendations from both guidelines are still valid, particularly those covering nutritional requirements, metabolic complications and central venous access device (CVAD) management. Other guidelines and standards for HPN have also been provided by scientific societies and government bodies [5-14]; however, a systematic review revealed substantial differences among the recommendations published [10]. Furthermore, the management and provision of HPN differs among countries and among HPN centers within countries [15, 16], although HPN provision by different programs should be homogeneous in order to ensure equity of patient access to an appropriate and safe HPN service.

An updated version of ESPEN guidelines on HPN care was commissioned and finally published in 2020 in order to incorporate new evidence since the publication of the previous ESPEN guidelines, to highlight recommendations on safe HPN administration and to include the patient's perspective [17]. Based on this guideline, the present "ESPEN Practical guideline" comprising practical flow charts was created. The aim of this guideline is to provide recommendations for the appropriate and safe provision of HPN in a short and precise way clinical practice. This guideline does not include recommendations for the patient's nutrient requirements in specific conditions, for which the reader can refer to previous ESPEN guidelines [3, 4, 14].

Methods

The present practical guideline consists of 71 recommendations and five statements and is based on the European Society for Clinical Nutrition and Metabolism (ESPEN) guideline on home parenteral nutrition [17]. The original guideline was shortened by focusing the commentaries on the evidence and literature on which the recommendations are based on. The recommendations were not changed, but the presentation of the content was transformed into a graphical presentation. The original guideline was developed according to the standard operating procedure (SOP) for ESPEN guidelines and consensus papers [18].

This SOP is oriented on the methodology of the Scottish Intercollegiate Guidelines Network (SIGN). Literature was searched and graded 1-4 according to the evidence, and recommendations were created and graded into four classes (A/B/0/GPP).

All recommendations were agreed in a multistage consensus process, which resulted in a percentage of agreement (%). In brackets, the original recommendation/statement numbers (R1, R2, S1, S2…) and the grading is indicated. The guideline process was funded exclusively by the ESPEN society. The guideline shortage and dissemination was funded in part by the United European Gastroenterology (UEG) society, and also by the ESPEN society. For further details on methodology, see the full version of the ESPEN guideline [17] and the ESPEN SOP [18].

1. Indications for HPN

1.1 Indications

1) HPN should be administered to those patients unable to meet their nutritional requirements via the oral and/or enteral route and who can be safely managed outside of the hospital.

(R1, grade GPP, strong consensus 95.8%)

Commentary

PN is a life-saving therapy to those unable to meet their nutritional requirements by oral/enteral intake. No randomized controlled trial (RCT) can be conducted to compare HPN with placebo to confirm the life-saving efficacy of HPN therapy in this condition [3]. No absolute contraindications exist to the use of PN. The presence of organ failures and metabolic diseases, such as heart failure, renal failure, type 1 diabetes, may be associated with reduced tolerance to PN and may require careful and specific adaptations of the HPN program to meet the patient's specific clinical needs.

1.2 Criteria for effectiveness

2) HPN should be prescribed as the primary and life-saving therapy for patients with transient-reversible or permanent-irreversible CIF due to non-malignant disease.

(R2, grade B, strong consensus 94.7%)

Commentary

CIF is the chronic "reduction of gut function below the minimum necessary for the absorption of macronutrients and/or water and electrolytes, such that intravenous supplementation is required to maintain health and/or growth", in metabolically stable patients [2]. CIF can be due to either benign or malignant disease and may be reversible or irreversible [2].

Crohn's disease, mesenteric ischemia, surgical complications, chronic intestinal pseudo-obstruction and radiation enteritis are the main underlying diseases which can get complicate with CIF, whereas short bowel syndrome is the main pathophysiologic mechanism (around two-thirds of cases), the remaining cases due to intestinal dysmotility, enterocutaneous fistulas, intestinal mechanical obstruction and extensive mucosal diseases [19,20].

3) HPN can be considered for patients with CIF due to malignant disease.

(R3, grade 0, strong consensus 95.8%)

Commentary

A recent Cochrane review [21] concluded that they were very uncertain whether total HPN improves length of life in people with malignant bowel obstruction. However, the authors applied strict Cochrane methodology that may be appropriate for evaluating medication efficacy, but may be less applicable to assessing the role of essential nutrition [22].

Six prospective studies [23-28] on HPN-dependent patients for ≥ 1 month showed a benefit on health related quality of life (QoL) measured by validated tools (EORTC QLQ-C30 or FACT-G, or TIQ). Three RCT evaluating the impact of HPN in patient outcome reported an improvement in energy balance and, as-treated analysis, prolonged survival, increased body fat and fat free mass and maximum exercise capacity and improved QoL, one of the most important outcome indicators of HPN in cancer patients [29-32].

Contraindications for HPN support in cancer patients include [33]:

a) patients not adequately informed about the aims of HPN, of its limited benefits and potential complications

b) patients not informed of their predicted prognosis, or of the possibility of changing/withdrawing the treatment when it becomes futile

c) patients not sufficiently metabolically stable to be discharged home on PN

4) HPN should be prescribed to prevent an earlier death from malnutrition in advanced cancer patients with CIF, if their life expectancy related to the cancer is expected to be longer than one to three months, even in those not undergoing active oncological treatment.

(R4, grade B, consensus 90%)

Commentary

International guidelines [14, 33-35] generally advocate the use of PN in patients with malignancy who have failed oral and enteral nutrition (EN) and who have an expected survival longer than one to three months, which is the longest predictable survival in an individual unable to maintain adequate oral nutrition without artificial nutritional support.

A meta-analysis [36] reported that 45% of incurable cancer patients receiving HPN for malignant intestinal obstruction can survive more than three months [36]. These data are in keeping with those of a large prospective multinational case series [37].

The clinical challenge is to accurately identify those patients who are likely to survive long enough to benefit from HPN treatment. A nomogram has been developed from variables recognized as independent prognostic factors (Glasgow prognostic score, presence and site of metastases and Karnofsky performance status), aimed at estimating the 3-, 6-months and overall survival of incurable aphagic cachectic cancer patients considered for HPN [38].

5) HPN can be considered for patients without intestinal failure who are not able or do not want to meet their nutritional requirements via the oral/enteral route. The patient should be clearly informed about HPN benefits and risks.

(R5, grade GPP, consensus 89.5%)

Commentary

HPN surveys and registries report a percentage of cases who were not categorized as having either benign or malignant intestinal failure [39-44]. These may include patients needing artificial nutritional support who refused - or were not able to cope with - otherwise effective and clinically-recommended EN [45]. Such patients may have cancer and an indwelling CVAD for chemotherapy; alternatively, they may have dysphagia and elect not to have EN [46-48]. Since it is difficult to deny nutritional support in clinical practice, HPN can sometimes be prescribed in these settings. Patients without CIF who are not able or do not want to meet their nutritional requirements via the oral/enteral route should be fully informed about the risks of PN therapy, which will likely be higher (including life-threatening risks related to HPN) than EN in this setting [3, 4, 45].

1.3 Criteria for safety

6) For a safe HPN program, the patient and/or the patient's legal representative have to give fully informed consent to the treatment proposed.

(S1, strong consensus 95.7%)

Commentary

HPN is a complex, life-saving therapy that may result in serious harm if not properly prescribed, prepared and administered. The aims of an HPN program include provision of evidence-based

therapy, prevention of HPN-related complications, as well as ensuring QoL is maximized [3, 4]. The HPN program shall provide an individualized, safe, effective and appropriate nutrition support plan which should be supervised and evaluated on a regular basis [49, 50].

7) For a safe HPN program, the patient has to be sufficiently metabolically stable outside the acute hospital setting.

(S2, strong consensus 91.3%)

Commentary

The 'adequate' metabolic and clinical stability of a patient can be assessed by vital parameters, energy, protein, fluid and electrolyte balances and glycemic control; the term adequate means no immediate risk of acute imbalance after hospital discharge.

8) For a safe HPN program, the patient's home environment has to be adequate to safely deliver the therapy proposed.

(S3, strong consensus 95.7%)

Commentary

The home care environment should be assessed before the education program starts.

9) For a safe HPN program, the patient and/or the caregiver has to be able to understand and perform the required procedures for the safe administration of therapy.

(S4, strong consensus 95.7%)

Commentary

If the patient can achieve a stable HPN regimen and his/her overall clinical condition is acceptable, an education program for patients and/or caregivers should be initiated to teach correct and proper HPN care.

10) The patient and/or the caregiver should be trained by a nutrition support team (NST) to safely infuse the PN with appropriate monitoring and prompt recognition of any complications.

(R6, grade GPP, strong consensus 100%)

Commentary

Prescription, implementation and monitoring of an individualized HPN program shall be managed by a NST in centers with HPN management expertise [3, 10, 51-62]. Patients managed by such a dedicated patient-centered NST have better outcomes and possible lower overall costs of care [52, 63]. Besides involvement of the key-members of a NST (physician, dietician, nurse, pharmacist), specific patients will require input from physiotherapy, psychology and occupational therapy colleagues [3, 55-58].

11) The prescribed nutritional admixture and ancillaries required for safe and effective therapy should be delivered by an experienced/certified health care provider.

(R7, grade GPP, strong consensus 95.7%)

Commentary

The overall care plan includes a variety of pre-discharge and post-hospital care assessments that require coordination between several heath-professionals and care providers within and outside

the hospital (Table 1). An experienced and certified health care provider is also required for the appropriate delivery of nutritional admixture and ancillaries to patient's home.

12) The NST should provide appropriate monitoring and treatment for routine and/or emergency care, with appropriate contact details provided to the patient 24 hours per day, seven days per week.

(R8, grade GPP, strong consensus 100%)

Commentary

Communication with the caregivers at home (especially the home care nurse) and in the hospital seems to be a key-factor for patients [49, 58]. See Table 1.

Table 1. Items to be included in the assessment at patient discharged on HPN [50, 62]

- Medical, physical, psychological and emotional suitability/stability of the patient
- Stability of the PN regimen (dosage and admixture)
- Level of home care and support required
- Lifestyle/activities of daily living
- Rehabilitative potential
- Potential for QoL improvement
- Potential for learning self-management of HPN (patient/caregivers)
- Knowledge and experience of the home nursing team (if no self-management)
- Basic home safety, facilities and general cleanliness instruction
- Need for extra equipment (e.g. backpack, infusion pump, hospital bed, extra drip stand)
- Home care provider of nutritional admixture, equipment and ancillaries
- Reimbursement for bags, services and supplies
- Around the clock (on-call) availability of an experienced home care provider
- Post-discharge monitoring necessities/possibilities (including scheduled laboratory tests)
- Medication prescription with administration details

2. CVAD and infusion pump

2.1 CVAD Choice

13) The choice of CVAD and the location of the exit site shall be made by an experienced HPN NST, as well as by the patient.

(R9, grade GPP, strong consensus 100%)

Commentary

The process of choosing a CVAD for HPN must involve the patient and the NST, including the specific professional (e.g. anesthetist, radiologist or surgeon) responsible for placing the CVAD [63,64].

14) The exit site of the CVAD should be easily visualized and accessible for self-caring patients.

(R10, grade GPP, strong consensus 100%)

Commentary

The patient should be involved in choosing the location of the cutaneous exit site which should, or course, also facilitate optimal self-care [65]. Proximity to wounds, prior exit sites, tracheotomies, stomas or fistulae should be avoided.

2.1.1 Long-term HPN (>6 months)

15) Tunneled CVAD or totally implanted CVADs shall be used for long-term HPN.

(R11, grade GPP, strong consensus 90.9%)

Commentary

Tunneled CVAD (such as Hickman, Broviac or Groshong) or totally implantable devices (port) are usually chosen for long-term HPN (>6 months) [3]. A single lumen CVAD is preferred, as infections have been reported to occur more frequently with multiple lumen CVAD [61, 66, 67 68].

16) Access to the upper vena cava should be the first choice for CVAD placement, via the internal jugular vein or subclavian vein.

(R12, grade B, strong consensus 100%)

Commentary

The literature search did not add any new information relating to this question when compared to the previous ESPEN guideline for CIF in adults [4].

17) Right-sided access should be preferred to the left-sided approach to reduce the risk of thrombosis.

(R13, grade B, strong consensus 95.2%)

Commentary

The risk of venous thrombosis is reduced with right vs. left-sided CVAD insertion [68].

2.1.2 Short-term HPN (< 6 months)

18) Peripherally inserted central venous catheters (PICCs) can be used if the duration of HPN is estimated to be less than six months.

(R15, grade B, strong consensus 100%)

Commentary

ESPEN and ASPEN guidelines [3, 69] for CIF do not recommend PICCs for long-term HPN. However, many series have reported successful use of PICCS for up to four years [40, 43, 69-78]. The results indicate that:

a) PICCs seem to be associated with a lower risk of catheter-related bloodstream infection (CRBSI) and a possible higher risk of catheter-related venous thrombosis

b) the time to the occurrence of the first catheter-related complication seems to be shorter with PICCs

c) better description of the reasons for placement and outcomes of long-term PICC use in routine clinical practice is required

19) The tip of the CVAD should be placed at the level of the right atrial-superior vena cava junction.

(R14, grade B, strong consensus 100%)

Commentary

Regardless of the type of catheter used and the insertion side, the location of the CVAD tip at the superior vena cava-right atrium junction reduces the risk of venous thrombosis [69, 79,80].

2.2 Infusion control devices

2.2.1 Overnight only

20) HPN should be administered using an infusion pump for safety and efficacy reasons.

(R16, grade GPP, strong consensus 91.3%)

Commentary

An infusion pump is a medical device that delivers fluids, such as nutrients and medications, into a patient's body in controlled amounts [81, 82]. The use of an electronic (ambulatory) infusion pump with compatible delivery sets is considered as good practice [6, 83]. It is strongly recommended to use this device to manage and monitor the delivery of HPN [3, 4, 6, 12, 51, 84, 85].

2.2.2 Overnight and overday or overday only

21) A portable pump can improve the patient's QoL when compared to stationary pumps.

(R18, grade GPP, strong consensus 95.7% agreement)

Commentary

Portable infusion pumps enabled HPN patients to gain independence [86, 87]. Benefits included maintaining desired flow, low noise, long battery life as well as increased probability of social and working rehabilitation and of good QoL.

22) In exceptional circumstances a flow regulator can be temporarily used for HPN;

administration sets with only a roller clamp should not be used.

(R17, grade GPP, strong consensus 100%)

Commentary

Because of the (large) fluid volume, the hypertonicity of the PN admixture and the amount of glucose and potassium delivered, rapid administration or 'free flow' can potentially cause serious harm [84].

3. Infusion line and catheter site care

3.1 CVAD exit site

23) Either a sterile gauze or sterile, transparent, semipermeable dressing should be used to cover the CVAD exit site.

(R19, grade B, strong consensus 90.9%)

Commentary

Different kinds of dressings can be used for protecting the CVAD site from microbial colonization and infection, including (semi-permeable) transparent polyurethane dressings and gauze and tape. Transparent dressings permit continuous visual inspection of the CVAD site and require less frequent changes. If there is visible pus exuding from the exit or the site is bleeding, it is better to use a gauze dressing (may be replaced every two days or sooner) until the problem is resolved [61].

A systematic review including studies on hospitalized patients reported no clear difference between gauze and tape and polyurethane dressings on the incidence of CRBSI, but l included studies were of low-quality evidence [88]. A systematic review came to the same conclusion but the quality of the included studies was also low [89]. Another systematic review, showed that the use of transparent dressings was significantly associated with an elevated relative risk of catheter tip infection (RR = 1.78; 95% CI, 1.38 to 2.30) compared with gauze dressings [90].

24) When transparent dressings are used on tunneled or implanted CVAD exit sites, they can be replaced no more than once per week (unless the dressing is soiled or loose).

(R20, grade 0, strong consensus 95.5% agreement)

Commentary

The frequency of dressing change remains a question of debate. A multicenter study, on bone marrow transplant patients with a tunneled randomly allocated to CVAD polyurethane dressing changes at different time intervals showed no difference in the rate of local infection but more skin toxicity was reported in the group with shorter interval dressing changes [91]. A systematic review concluded that there is currently inconclusive evidence as to whether longer intervals between CVAD dressing changes are associated with more or less CVAD-related infections [92].

25) A tunneled and cuffed CVAD with a well healed exit site might not require dressing to prevent dislodgement.

(R21, grade GPP, strong consensus 100%)

Commentary

After the healing period (±3 weeks), it remains unclear if a dressing is necessary [61]. The recent ESPGHAN/ESPEN/ESPR/CSPEN guideline for pediatric parenteral nutrition access states that a tunneled CVAD with a well-healed exit site does not require dressing to prevent dislodgement (GPP); however, in children it is useful to have CVADs looped and covered [93].

26) Tubing to administer HPN should be replaced within 24 hours of initiating the infusion.

(R22, grade B, strong consensus 100%)

Commentary

PN is considered as a medium where several factors may influence microbial growth leading to CRBSI risk [94]. Currently there is no evidence that it is safe to extend the period of administration sets that contain lipids beyond an interval of 24 hours and this is generally accepted as best practice

[95-98]. The Center for Disease Control and Prevention (CDC) consider PN as an independent risk factor for CRBSI and recommend infusion set replacement after 24 hours [61]. Given that HPN patients are very often on cyclic PN, infusion sets normally will be replaced every 24 hours.

3.2 Antisepsis technique

27) Strict aseptic technique for the care of home CVAD shall be maintained.

(R23, grade A, strong consensus 100%)

Commentary

Even though a recent systematic review revealed that there is not enough evidence to confirm whether patients receiving PN are more at risk of developing CRBSI that those who did not receive PN therapy [99], CRBSI is a common complication in patients receiving HPN [100-102].

A systematic review in adult patients receiving HPN showed an overall CRBSI ranged between 0.38 and 4.58 episodes/1000 catheter days (median 1.31). Gram-positive bacteria of human skin flora caused more than half of infections [103].

28) Hand antisepsis and aseptic non-touch technique should be used when changing the dressing on CVADs.

(R24, grade GPP, strong consensus 100%)

Commentary

Hand antisepsis is the most important measure to prevent contamination. Using gloves does not obviate the need for hand antisepsis. Gloves can be used when contact with blood, body fluids, secretions and excretions can be anticipated. The CDC leaves the choice of using gloves to local or

federal regulations, rules, or standards [61]. There is only indirect evidence demonstrating the use of non-sterile gloves is not inferior to sterile ones even in more invasive procedures such as minor skin excisions and outpatient cutaneous surgical procedures, [104, 105].

29) A 0.5 - 2% alcoholic chlorhexidine solution shall be used during dressing changes and skin antisepsis; if there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol shall be used as an alternative.

(R25, grade A, strong consensus 95.2%)

Commentary

The incidence of CRBSI is significantly reduced in patients with CVAD who receive chlorhexidine gluconate versus povidone-iodine for insertion-site skin disinfection [61, 106-110]. This is also the reason why chlorhexidine is mentioned in most checklists for CVAD insertion [111].

30) Hand decontamination, either by washing hands with soap and water but preferably with alcohol-based hand rubs, should be performed immediately before and after accessing or dressing a CVAD.

(R26, grade B, strong consensus 95.2%)

Commentary

Hand decontamination is a key factor in the prevention of health-care related infections which includes CVAD-related infections [61]. Several products are available: alcohol-based decontamination, non-alcohol-based decontamination, antimicrobial/antiseptic hand-washes or agents or liquid soap and water. Before using a hand-rub solution, hands should be free from dirt

and organic material. The solution must come into contact with all surfaces of the hand. The hands must be rubbed together vigorously, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers, until the solution has evaporated and the hands are dry. This should be done immediately before and after direct patient care or contact and after removal of any gloves [112].

Results from a systematic review supported the use of alcohol-based hand rubbing: it removed microorganisms effectively, required less time and irritated hands less often than did handwashing with soap or other antiseptic agents and water [113]. Furthermore, the availability of bedside alcohol-based solutions increased compliance with hand hygiene among health care workers [113]. Other randomized trials also favored the use of alcohol-based solutions [114, 115].

3.3 Connector management

31) A needle-free connector should be used to access intravenous tubing.

(R27, grade B, strong consensus 100%)

Commentary

Needleless connectors are an easy access point for infusion connection, which prevent needlestick injuries and reduce the risk of transmission of blood-borne infections to healthcare personnel [61]. Compared to the use of standard caps or 3-way stopcocks, they can reduce internal microbial contamination and so the incidence of CRBSI, but they have to be properly disinfected [116-118].

32) Needle-free systems with a split septum valve may be preferred over some mechanical valves due to increased risk of infection with mechanical valves.

(R28, grade 0, strong consensus 100%)

Commentary

Split septum connectors should be preferentially used instead of mechanical valves [61, 119]. The risk of (tip) occlusion due to negative displacement or blood reflux is to be taken into account, depending on the type of connector used [120]. Needleless connectors have to be changed no more frequently than every 72 hours or according to manufacturers' recommendations [61].

33) Contamination risk shall be minimized by scrubbing the hub connectors (needleless connectors) with an appropriate antiseptic (alcoholic chlorhexidine preparation or alcohol 70%) and access it only with sterile devices.

(R29, grade A, strong consensus 100%)

Commentary

Infection guidelines strongly recommend proper disinfection of access ports [121]. A systematic review revealed that the greatest risk for contamination of the CVAD after insertion was the needleless connector, with compliance with disinfection as low as 10%, but the optimal technique or disinfection time were not identified [122]. Another systematic review recommended scrubbing with chlorhexidine-alcohol for 15 seconds [123]. If the membranous septum of a needleless luer-activated connector is heavily contaminated, conventional disinfection with 70% alcohol does not reliably prevent entry of microorganisms [124].

34) For passive disinfection of hub connectors (needleless devices) antiseptic barrier caps should be used.

(R30, grade B, strong consensus 90.9%)

Commentary

Since compliance with a time-consuming manual disinfection process is low, the use of an antiseptic barrier cap (placed on a luer needleless connector), which cleans the connection surface by continuous passive disinfection, was associated with a decrease in CRBSI [123, 124].

3.4 CVAD protection

35) If HPN is delivered via an intravenous port, needles to access ports should be replaced at least once per week.

(R31, grade GPP, strong consensus 100%)

Commentary

The port is placed just underneath the skin, usually in the chest. A catheter is attached to a subcutaneous pocket (made of titanium). To gain access, a needle is inserted through the skin and the rubbery self-healing membrane of the port. The CDC guideline considers the timeframe to replace needles as an 'unresolved' issue [61]. Because there is no clear evidence, we suggest replacing port needles at least once-a-week with the use of PN. This also gives the opportunity for some patients to safely take a bath or shower when the needle has been removed and replaced afterwards.

36) The CVAD or CVAD site should not be submerged unprotected in water.

(R32, grade B, strong consensus 95.2%)

Commentary

The ESPGHAN/ESPEN/ESPR/CSPEN guideline for pediatric PN access allows swimming (GPP) when a water-resistant dressing is used to cover the whole catheter and, after swimming, the exit site should be cleaned and disinfected [93]. Using a closed-hub system and waterproof catheter hub connections significantly reduces the incidence of CRBSIs (particularly infections caused by gram-negative pathogens) [126-128].

The CDC guidelines (recommendation B) allow showering if precautions can be taken to reduce the likelihood of introducing organisms into the catheter (e.g. if the catheter and connecting device are protected with an impermeable cover during the shower) [61].

37) Sodium chloride 0.9% instead of heparin should be used to lock long-term CVAD.

(R33, grade B, strong consensus 95.5%)

Commentary

A retrospective study [129], a randomized prospective study [130] and two systematic reviews [131, 132] demonstrated that normal saline flushing is not inferior to heparin flushing regarding CVAD occlusion, reflux dysfunction and flow dysfunction.

ESPEN guidelines for CIF do not recommend heparin because it promotes intraluminal biofilm formation and therefore potentially increases the risk of CRBSIs [129,133]. A grade B recommendation for the use of saline instead of heparin to flush and lock the CVAD is appropriate,

given that this approach does not increase the risk of CVAD occlusion and has a lower risk of biofilm formation in the CVAD lumen.

38) As an additional strategy to prevent CRBSIs, taurolidine locking should be used because of its favorable safety and cost profile.

(R34, grade B, strong consensus 100%)

Commentary

For the primary prevention of CRBSI they are recommended [4]:

a) education of staff and patients/caregivers; hand washing and disinfection before touching CVAD and after CVAD care; hub connector disinfection before accessing; single-lumen tunneled catheters; chlorhexidine 2% for antisepsis, IV administration sets regular change.

b) performing site care, catheter hub cleaning and changing CVAD dressings at least once weekly; avoiding CVAD care immediately after changing or emptying ostomy appliances.

c) avoiding in-line filters, routine replacement of CVAD, antibiotic prophylaxis and heparin lock.

Two RCTs [134, 135] and one retrospective analysis [136] investigated antimicrobial CVAD locking with taurolidine in the setting of HPN support for adult benign CIF. in adult benign CIF. No CRBSIs occurred in patients who received the taurolidine 1.4%-citrate-heparin formulation in contrast to CRBSIs in 7 out of 21 controls who received heparin 100 IE/mL ($p< 0.05$) [134].

Taurolidine 2% lock was compared to saline 0.9% in patients stratified in a new catheter group and a pre-existing catheter group [135]. CRBSIs/1000 catheter days were significantly lower in either the new catheter group, (0.29 vs 1.49) and in the pre-existing catheter group (0.39 vs 1.32).

A retrospective study on 270 patients who used taurolidine during 338.521 catheter-days . CRBSIs, catheter-related venous thrombosis and occlusions occurred at rates of 0.60, 0.28, and 0.12 per 1000 catheter-days, respectively [136]. Taurolidine was discontinued in 24 (9%) due to mild to moderate adverse events. The switch to 0.9% saline resulted in an increased CRBSI rate (ratio 4.01, p=0.02).

3.5 PICC management

39) If a PICC is used for HPN, a sutureless device should be used to reduce the risk of infection. (R35, grade B, strong consensus 100%)

Commentary

A prospective study and a meta-analysis found that use of sutureless devices for CVAD securement decreased the risk of CRBSI and dislocation [87, 101].

40) For the securement of medium– to long-term PICCs (> 1 month) a subcutaneously anchored stabilization device can be used to prevent migration and save time during dressing change. (R36, grade 0, strong consensus 100%)

Commentary

For the securement of PICCs, a subcutaneously anchored stabilization device seems safe and cost-effective , because time sparing during dressing and preventing migration of the tip, but training on correct placement and removal is critical to minimize pain [137-140].

3.6 CVAD lumen use

41) In multilumen catheters, a dedicated lumen should be used for PN infusion.

(R37, grade GPP, strong consensus 95.5%)

Commentary

A previous ESPEN guideline recommended use of a single-lumen CVAD or of a dedicated lumen on a multilumen CVAD for PN administration [9] The CDC guidelines gave no recommendation regarding the use of a dedicated lumen for PN [61]. There is lack of evidence for the use of a dedicated lumen to reduce infections, most likely due to the poor way study results were reported with a high risk of bias [141], Therefore, the panel of the present guideline strongly agreed to confirm the recommendation made by the earlier ESPEN guidelines [9].

42) Routine drawing of blood samples from CVAD should be avoided if possible due to an increased risk of complications.

(R38, grade B, strong consensus 95.2%)

Commentary

Obtaining blood from the CVC has been reported to be a risk factor for CRBSI occurrence [140, 141].

4. Nutritional admixtures

4.1. PN admixture bag choice

43) The HPN-admixture shall meet the patient's requirement.

(S5, strong consensus 95.7%)

Commentary

PN admixtures can be compounded in single bags, dual chamber bags or three in one/all-in-one (AIO) bags (these contain separate compartments for lipid emulsion/glucose/amino acids to be opened and mixed before infusion). Vitamins and trace elements can be added prior to infusion in the home setting, if appropriate compatibility and stability [3, 4]. German guidelines advocate the use of "all-in-one nutrient mixtures" and advise that multi-bottle systems should not be used because of increased risks and more difficult handling [11, 144].

44) Either commercially available ready-to-use admixtures or customized and tailored to the individual patient's requirements admixtures can be used for HPN.

(R39, grade GPP, strong consensus 95.7%)

Commentary

Published data did not support definitive recommendations on the clinical advantages or disadvantages of individually compounded ("tailored" or "customized") PN admixture in comparison with commercially available ready-to-use ("premade" or "premixed") PN admixture adapted to the patient's requirements [3, 4, 145]. The controlled clinical trials do not directly compare the use of commercial ready-to-use bags with customized PN systems for patient outcomes, efficacy or safety and focus instead on evaluations following conversion from one

delivery approach to another system [145]. An evaluation of clinical outcomes, safety and cost should be considered before making the final determination.

45) Customized and tailored HPN admixtures can be prepared either by individual compounding or by ready-to-use prepared and adapted commercial multi-chamber bags, according to the manufacturer instructions and using aseptic admixture technique preferably in a laminar flow cabinet.

(R40, grade GPP, strong consensus 100%)

Commentary

The literature search for this guideline provided eleven articles that were considered to have some relevance to the question of comparison of commercial ready-to-use and customized PN admixture in non-critically ill patients [146-156]. Only one of the eleven articles, a conference abstract, compared different types of PN bags in the homecare setting, with all other articles evaluating the use of PN in hospital inpatients [146]. The results suggested that customized PN may be associated with a lower microbiological risk than commercial ready-to-use bags for patients with CIF; however, differences were not-statistically significant and this paper has not been published in full [146].

Given the paucity of data in the HPN setting, further studies are clearly needed to investigate the cost implications, safety and clinical outcomes of using commercial ready-to-use PN-admixtures for patients with benign and malignant CIF.

4.2 Critical steps for the preparation and delivering of PN admixtures

4.2.1 Stability

46) Customized AIO admixture stability should be documented for the individual admixture based on checks by appropriate lab methods.

(R41, grade B, strong consensus 100%)

Commentary

AIO stability has to be documented for the individual admixture based on checks by appropriate lab methods. Electrolytes are prone to incompatibilities (precipitations, multi-valent cations and negative charged lipid emulsifier leading to emulsion destabilization). Their correct admixing into the appropriate macro-element component is crucial; in selected cases with a high calcium need, organic instead of inorganic components might be preferable [157]. Easy to use and validated methods may be used to check for stability like for the Oil/Water stability of AIO admixtures [158, 159]

47) Customized AIO admixture stability shall not be extrapolated from the literature.

(R42, grade GPP, strong consensus 95.2%)

Commentary

Literature extrapolation for stability is not adequate due to the complexities of the admixtures [11, 157, 158].

48) AIO admixture shall be completed immediately before infusion by adding trace elements and vitamins according to stability and compatibility data.

(R43, grade GPP, strong consensus 91.3%)

Commentary

AIO admixture shall be completed by adding trace elements and vitamins in aseptic conditions according to stability and compatibility data. For structural/and or organizational reasons, the addition may also be performed immediately before infusion through appropriately trained persons [11, 160, 161].

49) Drug admixing into AIO admixture shall be avoided, unless specific pharmaceutical data are available to document compatibilities and stability of the AIO.

(R44, grade GPP, strong consensus 100%)

Commentary

AIO admixtures show a high potential of drug interactions leading to incompatibilities or stability issues. They are normally not suited for drug admixing and, when necessary, the specific pharmaceutical data have to be provided and documented as this final product represents an individual drug product; the product performance and reliability after interaction with drugs is not covered by the manufacturer [159, 162].

4.2.2 Labelling

50) AIO admixtures shall be labelled for the individual patient indicating the composition (dose) of the individual components according to standards, the date, the patient's name and indication for handling such as storage, admixes to be made, infusion rate.

(R45, grade GPP, strong consensus 100%)

Commentary

AIO admixtures have to be labelled for the individual patient. Labels shall indicate the patient's name, the composition (dose) of the individual components according to standards, the date of manufacturing and expiring, instructions for handling like storage, admixes to be made, infusion rate, as well as avoidance of medication errors [160, 162, 163]. Specific pharmaceutical support within the NST is required and efficacious [164].

4.2.3 Delivering

51) For customized AIO admixtures, the cold chain should be guaranteed during transport and at the patient's home.

(R46, grade B, strong consensus 100%)

Commentary

Pharmaceutical safeguards must be applied for PN delivery, storage and administration at home throughout the patient's therapy. For customized AIO PN admixtures, the cold chain has to be guaranteed [157].

4.3. HPN admixture time and rate of infusion

52) The hanging time for an HPN-admixture should be no longer than 24 hours.

(R47, grade GPP, strong consensus 100%)

Commentary

The generally accepted maximum hanging time for a ready-to-use admixture are 24 hours. The giving set has to be changed upon each new PN dosing [11, 157, 161, 162].

53) At the end of cyclic PN administration, the infusion rate can be reduced to avoid rebound hypoglycemia (e.g. half of the infusion rate over the last half an hour).

(R48, grade GPP, strong consensus 93.8%)

Commentary

At the end of a (cyclic) PN-infusion, the infusion rate has to be reduced to tamper insulin need and to avoid rebound hypoglycemia. Glucose administration determines the maximum rate of PN infusion rate: (max. 5-7 mg glucose/kg/min; corresponding to about a maximum of 200 g glucose over twelve hours in 70 kg adult [157, 162] or 3-6 g glucose/kg per day [3].

5. Program monitoring

5.1 Patient monitoring

5.1.1 Timing

54) Patients receiving HPN shall be monitored at regular intervals, to review the indications, the efficacy and the risks of the treatment.

(R49, grade GPP, strong consensus 100%)

Commentary

The purpose of monitoring is to "secure and improve QoL" of persons on HPN by assessing the nutritional efficacy of the HPN program, preventing and timely diagnosing and treating HPN-related complications and measuring QoL and quality of care [3, 4].

After hospital discharge, the HPN NST has contact with patients and caregivers on a regular basis, initially every few days, then weekly and eventually monthly as the patient gains confidence. The clinician who is in contact should be prepared to clarify confusing issues and also to follow weight, urine output, diarrhea or stoma output, body temperatures (before and within an hour of starting the HPN infusion when required by clinical feature), and general health.

Incidence of CRBSI, incidence of rehospitalization and QoL have been identified as the three major indicators of quality of care HPN patients with either a benign [59] or malignant [51] underlying disease. Survival rate was also considered important when patients with benign disease were considered [165].

55) The time between reviews should be adapted to the patient, care setting and duration of nutrition support; intervals can increase as the patient is stabilized on nutrition support.

(R50, grade GPP, strong consensus 100%)

Commentary

Evidence-based guidelines for monitoring are not available due to the lack of published data [3-12, 166, 167]. Only one study has been published reporting monitoring practices for HPN across Europe [15]. The results showed that the majority of centers performed a 3-month monitoring interval for stable patients and emphasized that responsibility for monitoring should be assigned to a designated person on the hospital HPN specialist NST [15].

5.1.2 Modalities

56) HPN monitoring should be carried out by the hospital NST in collaboration with experienced home care specialists, home care agencies and/or general practitioners.

(R51, grade GPP, strong consensus 100%)

Commentary

Monitoring of HPN patients should also involve the general practitioner. Healthcare professionals should review the indications, route, risks, benefits and goals of nutrition support at regular intervals.

57) Patients and/or caregivers can be trained to monitor nutritional status, fluid balance and the infusion catheter.

(R52, grade 0, strong consensus 95.7%)

Commentary

In long-term HPN, patients and caregivers should be trained in self-monitoring of their nutritional status, fluid balance and infusion catheter, as well as in recognizing early signs and symptoms of complications and responding to adverse changes in both their well-being and management of their nutritional delivery system.

5.1.3 Parameters to be monitored and frequency of monitoring

58) Monitoring should comprise of nutritional efficacy, tolerance of PN, patient/caregiver management of infusion catheter, QoL and quality of care (e.g. CRBSI rate, readmission rate etc.).

(R53, grade GPP, strong consensus 95.7%)

Commentary

Parameters to be monitored, frequency and setting of monitoring are indicated in Table 2.

59) In clinically stable patients on long-term HPN, body weight, body composition and hydration status, energy and fluid balance and biochemistry (hemoglobin, ferritin, albumin, C-reactive protein, electrolytes, venous blood gas analysis, kidney function, liver function and glucose) should be measured at all the scheduled (e.g. every three to six months).

(R54, grade GPP, strong consensus 100%)

Commentary

The time between reviews depends on the patient, care setting, duration of nutrition support as well as the expected speed with which the impairment of a parameter is likely to occur. Monitoring should be more frequent during the early months of HPN, or if there is a change in the patient's

clinical condition. Intervals may increase as the patient is stabilized on nutrition support. Fluid balance requires the most frequent monitoring, especially in the first period after discharge and in patients with short bowel syndrome with a high output stoma or with intestinal dysmotility with recurrent episodes of vomiting. Frequent acute dehydration episodes are responsible for kidney failure and re-hospitalization [168,169].

60) In patients on long-term HPN, clinical signs and symptoms as well as biochemical indexes of vitamin and trace metal deficiency or toxicity should be evaluated at least once per year.

(R55, grade GPP, strong consensus 95.7%)

Commentary

Vitamin and trace metal deficiency may take more time to develop and to present clinical signs and symptoms, so that a six to twelve month interval of assessment is appropriate. Monitoring of micronutrients is important especially in patients on long-term HPN and in those who are undergoing intestinal rehabilitation and weaning from HPN. In the latter case, while intestinal rehabilitation is associated with maintenance of energy, protein, fluid and electrolyte balance without PN support, this is not necessarily the case for micronutrient balance, because decreasing or totally stopping PN infusion decreases micronutrient supplementation, thus creating a risk for deficiency [4].

61) In patients on long-term HPN, bone metabolism and bone mineral density should be evaluated annually or in accordance with accepted standards (e.g. DXA at max. every 18

months).

(R56, grade GPP, strong consensus 100%)

Commentary

See Table 2.

Table 2. Parameters, frequency (after baseline assessment) and setting of monitoring on patients on HPN.

Parameter	Frequency	Setting
General condition Body temperature	Daily if unstable, twice weekly to once a week if stable	Nurse at home Patient and/or caregivers
Body weight	Daily if unstable, twice weekly to once a week if stable	In the hospital (outpatient visit) Nurse at home Patient and/or caregivers
Body mass index	Monthly	In the hospital (outpatient visit) Nurse at home
Fluid balance - Urine output - Stoma output - Number or consistency of stools - Presence of edema	The frequency and type of parameters will depend on etiology of CIF, and stability of patients In case of high stool output (end jejunostomy), the monitoring after the first discharge should be daily, then twice weekly to once a week when stable	Nurse at home Patient and/or caregivers only in case of training program
Catheter cutaneous exit site	Daily	Nurse at home Patient and/or caregivers only in case of training program
Full count blood C-reactive protein Serum glucose Serum and urine electrolytes and minerals (Na, Cl, K, Mg, Ca and P) Serum Urea and Creatinine Serum bicarbonates Urine analysis	The frequency and type of parameters will depend on etiology of the underlying condition requiring HPN and the stability of patients Weekly or monthly, then every three to four months when stable	At home Verify at each visit
Serum albumin and prealbumin	Monthly, then every three to four months when stable	At home Verify at each visit
Serum liver function tests including INR	Monthly, then every three to four months when stable	At home Verify at each visit
Liver ultrasound	Yearly	In hospital
Serum Folate, vitamins B12, A and E	Every six to twelve months	Dosage at home or in the hospital
Serum ferritin iron,	Every three to six months	Dosage at home or in the hospital
Serum 25-OH Vitamin D	Every six to twelve months	Dosage at home or in the hospital
Serum zinc, copper, selenium	Every six to twelve months	Dosage in the hospital
Serum Manganese	Yearly	Dosage in the hospital
Bone densitometry (DEXA)	Every twelve to eighteen months	In the hospital

6. Management (nutrition support team, training, emergency, travelling)

6.1 Local and personnel preconditions for HPN

62) The suitability of the home care environment should be assessed and approved by the HPN nursing team before starting HPN, wherever possible.

(R57, grade GPP, strong consensus 91.3%)

Commentary

The management of PN in the home care setting differs from hospitalized patients because there is a shift in primary responsibility from health care professionals to patients and caregivers. The general goals in the education process are promoting independence with the infusion, (self-) monitoring of HPN, preventing complications and improving or maintaining QoL [3, 4] (Table 3). The HPN center NST plays a key role in the individualized decision-making process and guides all the necessary measures or steps which have to be taken [3, 10, 51-62].

63) A formal individualized HPN training program for the patient and/or caregiver and/or home care nurses shall be performed, including catheter care, pump use and preventing, recognizing and managing complications; training can be done in an in-patient setting or at the patient's home.

(R58, grade GPP, strong consensus 91.3%)

Commentary

Guidelines on core components for (catheter) infection control and prevention, give strong recommendations about the provision of education and training [60, 61]. Besides preventing CRBSI and assessing QoL, the overall teaching program has many aspects to deal with and is very often

driven by an experienced (nutrition support) nurse who takes the lead and responsibility for this program [3, 57]. See Table 3.

Table 3. Content of a teaching program for patients/caregivers discharged on HPN [3, 10, 50, 62]

- Indication for HPN: short and/or long-term goals and HPN-regimen
- Issues around informed consent
- Role of the home care provider to provide parenteral formulations, equipment, supplies, and eventually nursing care
- Determine learning abilities and readiness to self-management and self-monitoring
  - If applicable: make a checklist for competencies achieved
- Reviewing evidence-based written policies and procedures complemented with oral instructions
- Home care environment
  - General cleanliness (for example: Is there a clean area for aseptic/sterile procedures?)
  - Presence of animals
  - Basic home safety (telephone access, clean storage for supplies, dedicated refrigerator, toilet-bathroom, sanitary water supply,…)
- Catheter care
  - Principles of infection control and prevention (including aseptic techniques)
  - Preventing, recognizing and managing catheter related complications
  - Site care
- Storage, handling, inspection of admixtures (e.g. leaks, labels, precipitates, color), ancillaries and (medication) supplies
- If applicable:
  - Safe addition of vitamins, trace elements or other additives
  - Safe administration of HPN
  - Connecting and disconnecting IV tubing to the vascular access device
  - Pre/post infusion flushing
  - Periodically assessment of performance/compliance with aseptic techniques
- Pump use, programming, pump care and troubleshooting
- Preventing, recognizing and managing non-infectious related complications or problems
- Most common mistakes
- Available contact resources and post discharge support from the HPN center as well as the home care provider
- Self HPN monitoring
- Concomitant drug therapy and administration mode (total regimen management)

Training for HPN may be carried out in an in-patient setting or at patient's home and may take several days to weeks depending on patient skills, duration of HPN and underlying condition. [3, 4, 62].

Patient/caregiver education at home reduces hospital length of stay and may be preferable for some patients [170]. Multiple education interventions are possible including one-on-one counselling,

teach-back method, written handouts, computer-assisted learning and interactive presentations (videotapes, CDs/DVDs and internet education). [50, 56, 62].

6.2 Requirements for the hospital centers caring for HPN patients

64) Patients on HPN should be cared for by specialized, dedicated and a clearly identifiable hospital unit, normally termed "HPN center or IF center or intestinal rehabilitation center". (R59, grade GPP, strong consensus 100%)

Commentary

Key issues are the identification of the persons, structures and procedures responsible for the HPN care process [4, 12, 167], such as:

- Professionals who coordinate and manage the different phases of HPN management
- Place of initial care (center of intestinal failure, gastroenterology, surgery, other)
- Place and methods of training programs (on hospital beds, in day hospital, at home)
- Pathways of care in case of complications (example: emergency room, direct access to hospital beds, link with local hospitals of the patient residency)
- Place and procedures for CVAD positioning and managing of complications

The HPN center needs to estimate the time that each professional has to dedicate to the single patient, in order to define the number of human resources required for managing their total number of HPN patients.

65) The HPN unit should have offices for outpatient visits and dedicated beds for patients who need hospitalization.

(R60, grade GPP, strong consensus 91.3%)

Commentary

Hospitalization is required to monitor patients and/or evaluate intestinal function in order to better adapt treatments as well as to timely and appropriately treat complications according to the NST procedures. Hospital beds under the responsibility of the NST is essential for initial care as well as for managing of complications. These beds may be within an independent structure of nutrition/intestinal failure or within a more general structure, such as department of gastroenterology, oncology, surgery or other.

6.3 Requirements of the NST

66) All HPN patients should be cared for by a NST with experience in HPN management, independent from the underlying disease leading to intestinal failure.

(R61, grade GPP, strong consensus 100%)

Commentary

Only experienced NST should provide HPN treatment [3-7, 9-12, 164, 165], because it has been shown that experience in HPN support had a positive impact on patient survival [169] and CRBSI rates, which are considered a proxy for the quality of HPN support [64,65]. Key tasks of the NST include establishing (contra)-indications for HPN support, development and implementation of individualized training and treatment programs, treatment of complications (vascular access related, metabolic derangements) and organization of home care [171].

67) The NST consists of experts in HPN provision. This can include a physician, specialist nurses (including in catheter, wound and stoma care), dietitians, pharmacists, social worker, psychologist, as well as an appropriate practitioner with expertise in CVC placement. Surgeons with expertise in intestinal failure should also be available for structured consultation.

(R62, grade GPP, strong consensus 100%)

Commentary

The appropriate composition and size of a NST that provides HPN care to some extent depends on the number of patients under the team's care, which mostly also relates to the patient volume and scope of the hospital [172].

The team that provides HPN support should be multidisciplinary in nature and include physician specialists with a background in surgery and gastroenterology, specialized nurses, dieticians and pharmacists [54, 55]. Psychologists and social workers should also form part of the team. This latter issue was highlighted in studies showing that many HPN patients experience the lack of attention for their psychosocial problems as a shortcoming [173,174].

Concerning patients with active cancer, HPN support is challenging and discussion with the treating oncology specialist seems prudent before HPN initiation [14].

Caregivers closer to the home, such as the general practitioner and homecare nurses, although not direct team members, should be kept informed of patients' clinical course after discharge from hospital [49, 50, 56, 58].

6.4 Travelling with HPN - organization

68) For a patient to travel safely, he/she shall receive a sufficient supply of PN and relevant ancillaries during the journey and at the destination and the NST responsible for the patient's care shall endeavor to establish contact with a skilled NST at the patient's destination, in case medical support is required.

(R70, grade GPP, strong consensus 100%)

Commentary

Patients on long-term HPN need to learn how to adjust to lifestyle events such as bathing, showering, swimming, sports and travel [167, 175].

Travelling patient/caregivers should discuss their travel plans with their healthcare professionals/NST to ensure that they/their child are fit to travel and to ensure that PN bag and any required facilities and ancillaries for a safe HPN therapy are provided during the travel period.

The doctor should issue a letter/medical certificate for the patient/caregivers confirming that they are aware they are travelling, along with a brief overview of their condition and need for PN. Medical cover/travel insurance should be arranged prior to travelling to ensure that any medical treatment needed while travelling will be possible. Usual healthcare professionals should consider establishing local medical support or a contact for the patient should medical support be required. In case of an emergency situation, a plan of action should be prepared beforehand and all important (doctor, family) contact numbers should be easily accessible.

6.5. Criteria to monitor the safety of HPN program provision

69) Incidence of catheter-related infection, incidence of hospital readmission and QoL should be used as criteria to assess the quality of care of HPN program.

(R71, grade GPP, strong consensus 100%)

Commentary

Three multicenter international studies have identified and ranked the interventions determined to be essential for good quality of care (also called 'key interventions') [51, 59, 165].

The top three outcome indicators identified by healthcare professionals were incidence of CRBSI, incidence of rehospitalizations and QoL for CIF due to either benign [59] or malignant [51] disease. The top three desired outcomes of patients with benign CIF were incidence of CRBSI, survival rate, and QoL on HPN [165].

The key interventions identified should be measured annually in current practice, along with questionnaires on patients' satisfaction, to identify and address any areas for further improvement. [4].

The outcome indicators should be measured with quality indicators related to structure, process and outcome of health care, where 'structure' refers to general administrative standards of the organization and people providing care, 'process' refers to the manner in which care is actually provided and administered and 'outcome' refers to a set of expected or desirable results for patients [176]. Therefore, the outcome indicators reported should be monitored along with the linked process as well as structure indicators which will help to drive quality improvement.

6.6 Emergency management

6.6.1 Mandatory organizational features

70) The NST for HPN/CIF shall have clear written pathways and protocols in place for the management of patients with complications relating to HPN.

(R63, grade GPP, strong consensus 100%)

Commentary

Complications relating to CIF should be demarcated into those relating to HPN, those relating to the patient's underlying disease leading to CIF (including any underlying oncological condition) and those unrelated to CIF. The CIF team should ensure that patients and caregivers are aware of the roles and responsibilities of the health care professionals involved in each component of their condition.

Two studies have demonstrated patient-education programs aimed at minimizing hospital admissions for complications associated with CIF, concerning protocol to treat dehydration at home for HPN patients [168] and patients' abilities to resolve problems and adequately respond to CVC-related emergency situations [174].

71) The NST for HPN/CIF shall provide patients and caregivers with written information relating to the recognition and subsequent management of HPN-related complications, including details (e.g. telephone number) of an appropriate NST member to contact in the case of an emergency, available 24 hours per day.

(R64, grade GPP, strong consensus 91.3%)

Commentary

The NST should be responsible for the emergency management of any HPN-related issues 24 hours per day, seven days per week. Patients and carers must be provided with clear written information

relating to the recognition and management of HPN-related complications, including contact details of the NST in case of any emergency.

72) The NST for HPN/CIF shall disseminate clear protocols relating to the recognition, investigation and initial management of HPN-related complications to hospital emergency departments, where patients are likely to present; where appropriate and available, written protocols can also be carried by the patient or accessed electronically via a secure web-portal.
(R65, grade GPP, strong consensus 100%)

Commentary

The NST should generate written protocols for the management of HPN-related complications.

6.6.2 Actions at time of hospital admission

73) When patients are admitted to hospital with HPN-related complications, their care shall be delivered by the NST for HPN/CIF; if patients are admitted to a hospital where such expertise does not exist, then clinical guidance should be provided by the NST for HPN/CIF, until the time when the patient can be transferred to the HPN/CIF center, as required.
(R66, grade GPP, strong consensus 100%)

Commentary

The NST should have systems in-place such that specialist advice from the NST is available at all times.

74) Written protocols for the management of HPN-related complications shall be developed and shared with the patient's local hospital, if it is likely that the patient will be admitted first to that hospital rather than to the HPN/CIF center in the event of an emergency; these should include contact details for the NST for HPN/CIF to advise on treatment and/or possible transfer to the HPN/CIF center. Where appropriate and available, written protocols can also be carried by the patient or accessed electronically via a secure web-portal.

(R67, grade GPP, strong consensus 95.5%)

Commentary

Where patients cannot attend the CIF center with emergency issues (for example, if distance and/or clinical need mandates immediate care at a local hospital), the NST should ensure that shared cared-protocols have been disseminated to local hospitals in advance.

75) Patients shall carry details relevant to their condition, and/or have access to a secure web-portal containing relevant clinical information, when travelling away from home, in order to aid clinical teams at other hospitals should emergency treatment be required.

(R68, grade GPP, strong consensus 100%)

Commentary

The NST should provide patients with relevant details of their clinical condition.

76) The NST for HPN/CIF shall ensure that patients, caregivers and general practitioners are aware of the roles and responsibilities of the health care professionals involved in aspects of the patient's condition that are unrelated to HPN, including any complications relating to the

patient's underlying disease and other non-IF related conditions.

(R69, grade GPP, strong consensus 100%)

Commentary

Patients and caregivers should be aware that the NST may not be responsible for all aspects of their health, including the underlying disease leading to CIF (e.g. Crohn's disease, malignancy), As soon as a patient is established on HPN, he/she and his/her general practitioner should be made aware of the relevant roles and responsibilities of the health care professionals involved in aspects of the patient's condition that are unrelated to HPN [3,11,14].

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Conflicts of interest

The expert members of the working group were accredited by the ESPEN Guidelines Group, the ESPEN Education and Clinical Practice Committee, and the ESPEN executive. All expert members have declared their individual conflicts of interest according to the rules of the International Committee of Medical Journal Editors (ICMJE). If potential conflicts were indicated, they were reviewed by the ESPEN guideline officers and, in cases of doubts, by the ESPEN executive. None of the expert panel had to be excluded from the working group or from co-authorship because of serious conflicts. The conflict of interest forms are stored at the ESPEN guideline office and can be reviewed by ESPEN members with legitimate interest upon request to the ESPEN executive.

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Figure Legends

Figure 1. Main structure of the ESPEN practical guideline: Home parenteral nutrition (HPN). The guideline consists of six chapters presented in Figures 2-9. For details see text.

Figure 2. Indications for HPN. In blue letters at the end of each recommendation, three items are indicated: (i) Rx, the original numbering of the recommendations in reference [17], (ii) A or B or 0, the grade of evidence, and (iii) x%, the consensus grade.

Figure 3. Central venous accesses device (CVAD) and infusion pump.

Figure 4. Infusion line and catheter site care.

Figure 5. Infusion line and catheter site care (continued).

Figure 6. Nutritional admixtures for HPN.

Figure 7. HPN program monitoring.

Figure 8. HPN management

Figure 9. HPN emergency management

Figure 1

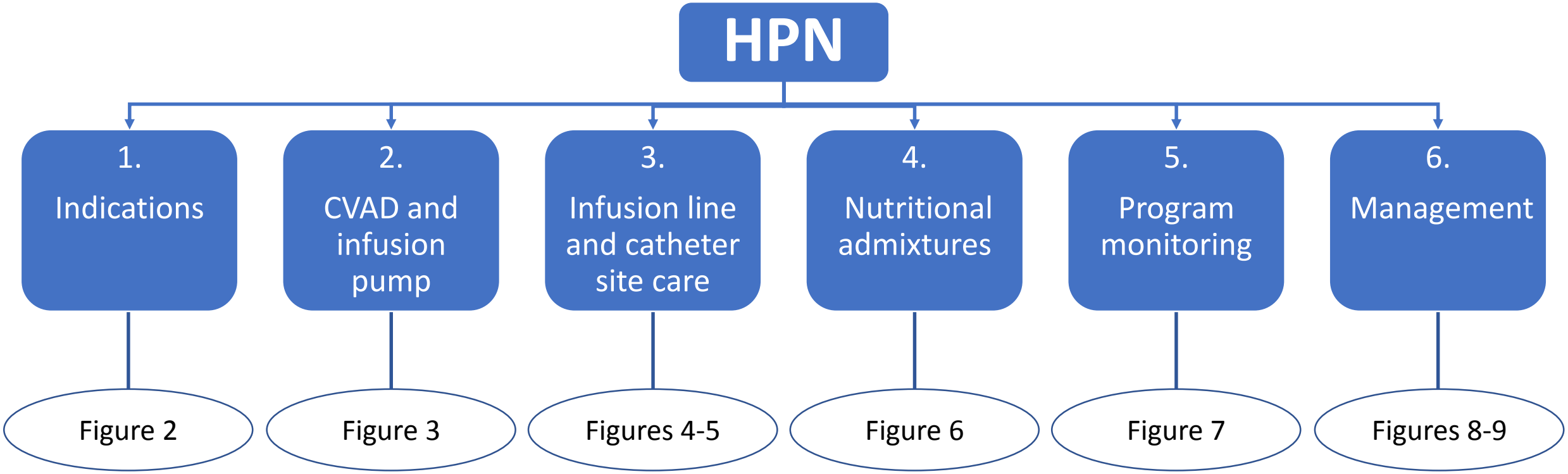


Figure 2

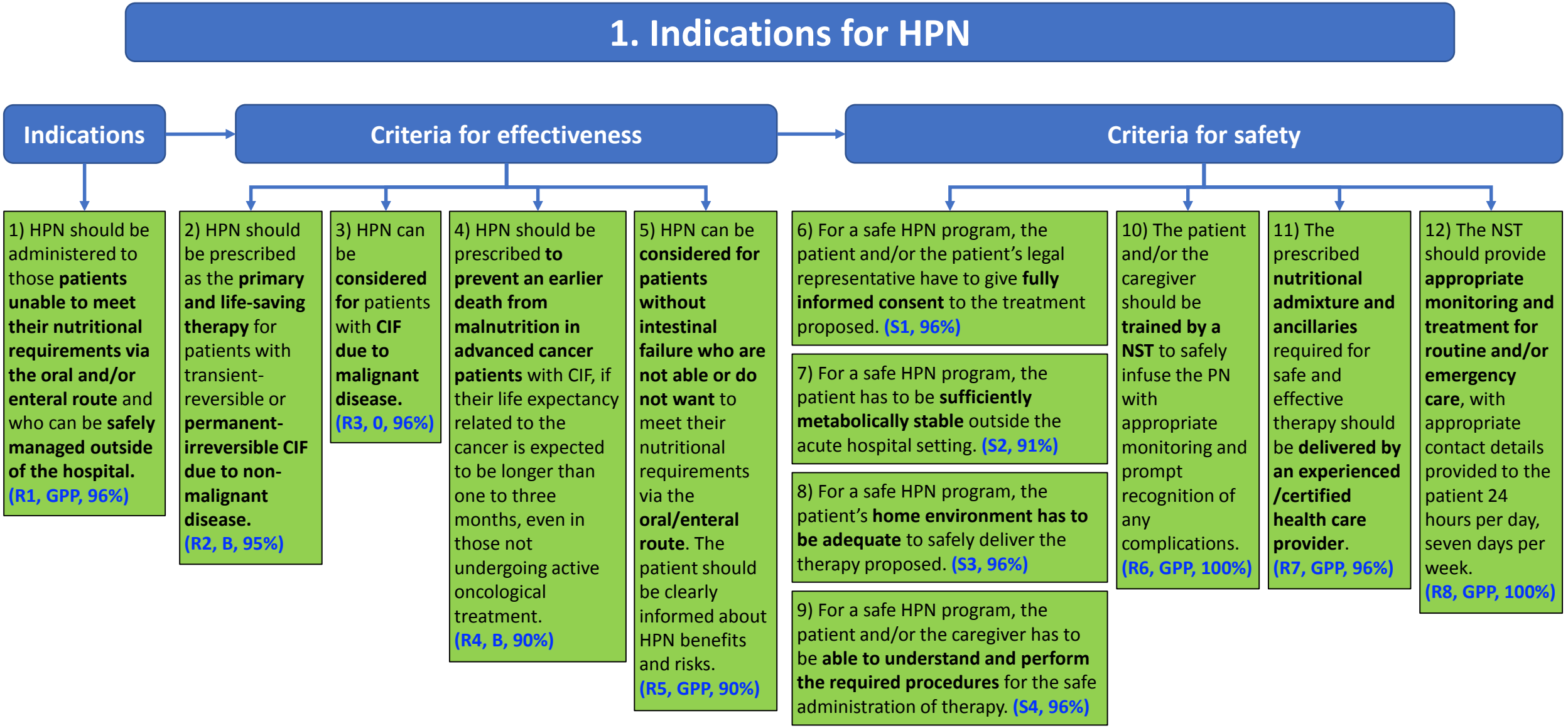

1. Indications for HPN
Indications
Criteria for effectiveness
Criteria for safety
1) HPN should be administered to those **patients unable to meet their nutritional requirements via the oral and/or enteral route** and who can be **safely managed outside of the hospital.** **(R1, GPP, 96%)**
2) HPN should be prescribed as the **primary and life-saving therapy** for patients with transient-reversible or **permanent-irreversible CIF due to non-malignant disease.** **(R2, B, 95%)**
3) HPN can be **considered for** patients with **CIF due to malignant disease.** **(R3, 0, 96%)**
4) HPN should be prescribed **to prevent an earlier death from malnutrition in advanced cancer patients** with CIF, if their life expectancy related to the cancer is expected to be longer than one to three months, even in those not undergoing active oncological treatment. **(R4, B, 90%)**
5) HPN can be **considered for patients without intestinal failure who are not able or do not want** to meet their nutritional requirements via the **oral/enteral route**. The patient should be clearly informed about HPN benefits and risks. **(R5, GPP, 90%)**
6) For a safe HPN program, the patient and/or the patient's legal representative have to give **fully informed consent** to the treatment proposed. **(S1, 96%)**
7) For a safe HPN program, the patient has to be **sufficiently metabolically stable** outside the acute hospital setting. **(S2, 91%)**
8) For a safe HPN program, the patient's **home environment has to be adequate** to safely deliver the therapy proposed. **(S3, 96%)**
9) For a safe HPN program, the patient and/or the caregiver has to be **able to understand and perform the required procedures** for the safe administration of therapy. **(S4, 96%)**
10) The patient and/or the caregiver should be **trained by a NST** to safely infuse the PN with appropriate monitoring and prompt recognition of any complications. **(R6, GPP, 100%)**
11) The prescribed **nutritional admixture and ancillaries** required for safe and effective therapy should be **delivered by an experienced /certified health care provider**. **(R7, GPP, 96%)**
12) The NST should provide **appropriate monitoring and treatment for routine and/or emergency care**, with appropriate contact details provided to the patient 24 hours per day, seven days per week. **(R8, GPP, 100%)**

Figure 3

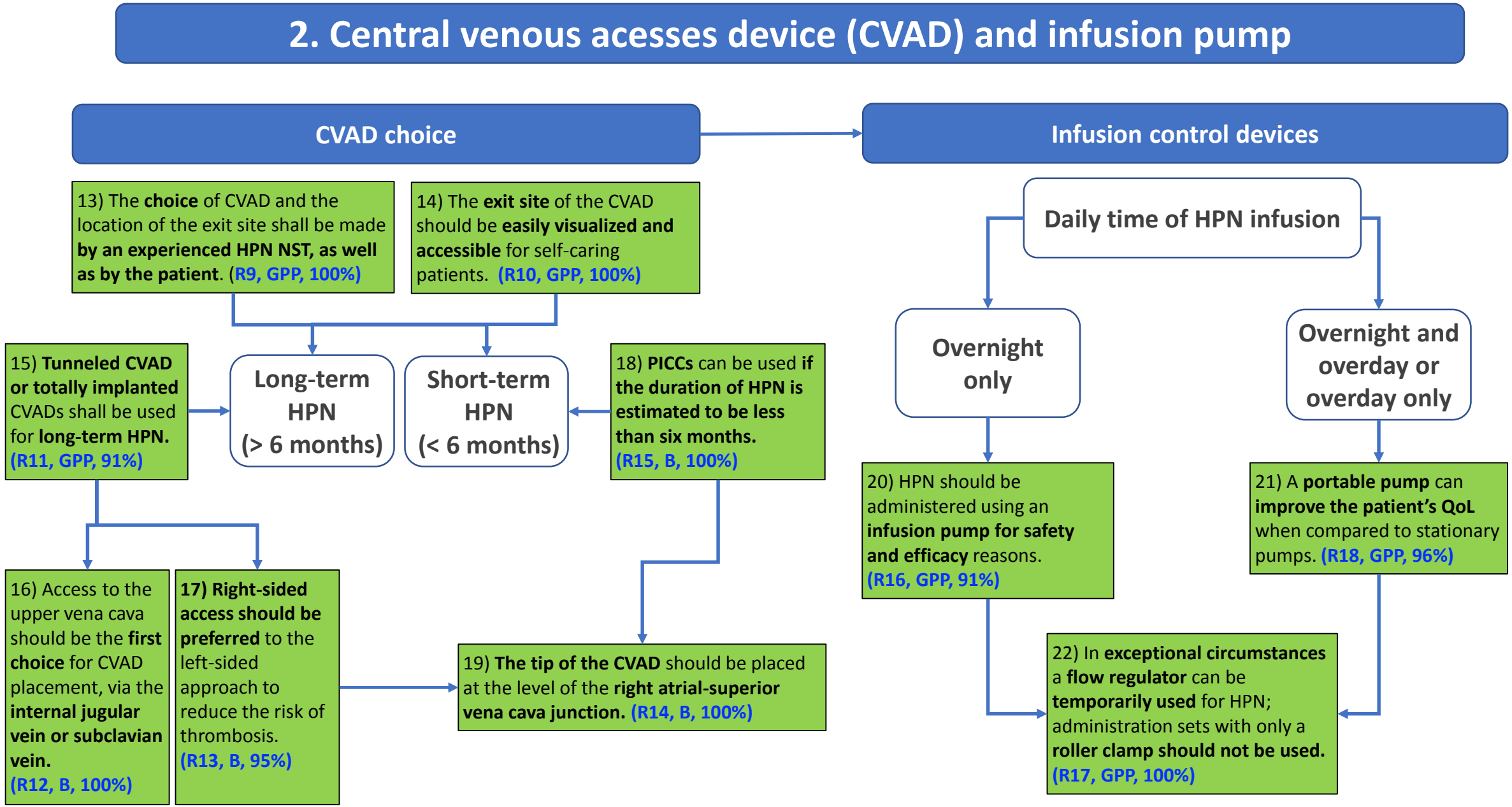

2. Central venous acesses device (CVAD) and infusion pump
CVAD choice
Infusion control devices
13) The choice of CVAD and the location of the exit site shall be made by an experienced HPN NST, as well as by the patient. (R9, GPP, 100%)
14) The exit site of the CVAD should be easily visualized and accessible for self-caring patients. (R10, GPP, 100%)
15) Tunneled CVAD or totally implanted CVADs shall be used for long-term HPN. (R11, GPP, 91%)
Long-term HPN (> 6 months)
Short-term HPN (< 6 months)
18) PICCs can be used if the duration of HPN is estimated to be less than six months. (R15, B, 100%)
16) Access to the upper vena cava should be the first choice for CVAD placement, via the internal jugular vein or subclavian vein. (R12, B, 100%)
17) Right-sided access should be preferred to the left-sided approach to reduce the risk of thrombosis. (R13, B, 95%)
19) The tip of the CVAD should be placed at the level of the right atrial-superior vena cava junction. (R14, B, 100%)
Daily time of HPN infusion
Overnight only
Overnight and overday or overday only
20) HPN should be administered using an infusion pump for safety and efficacy reasons. (R16, GPP, 91%)
21) A portable pump can improve the patient's QoL when compared to stationary pumps. (R18, GPP, 96%)
22) In exceptional circumstances a flow regulator can be temporarily used for HPN; administration sets with only a roller clamp should not be used. (R17, GPP, 100%)

Figure 4

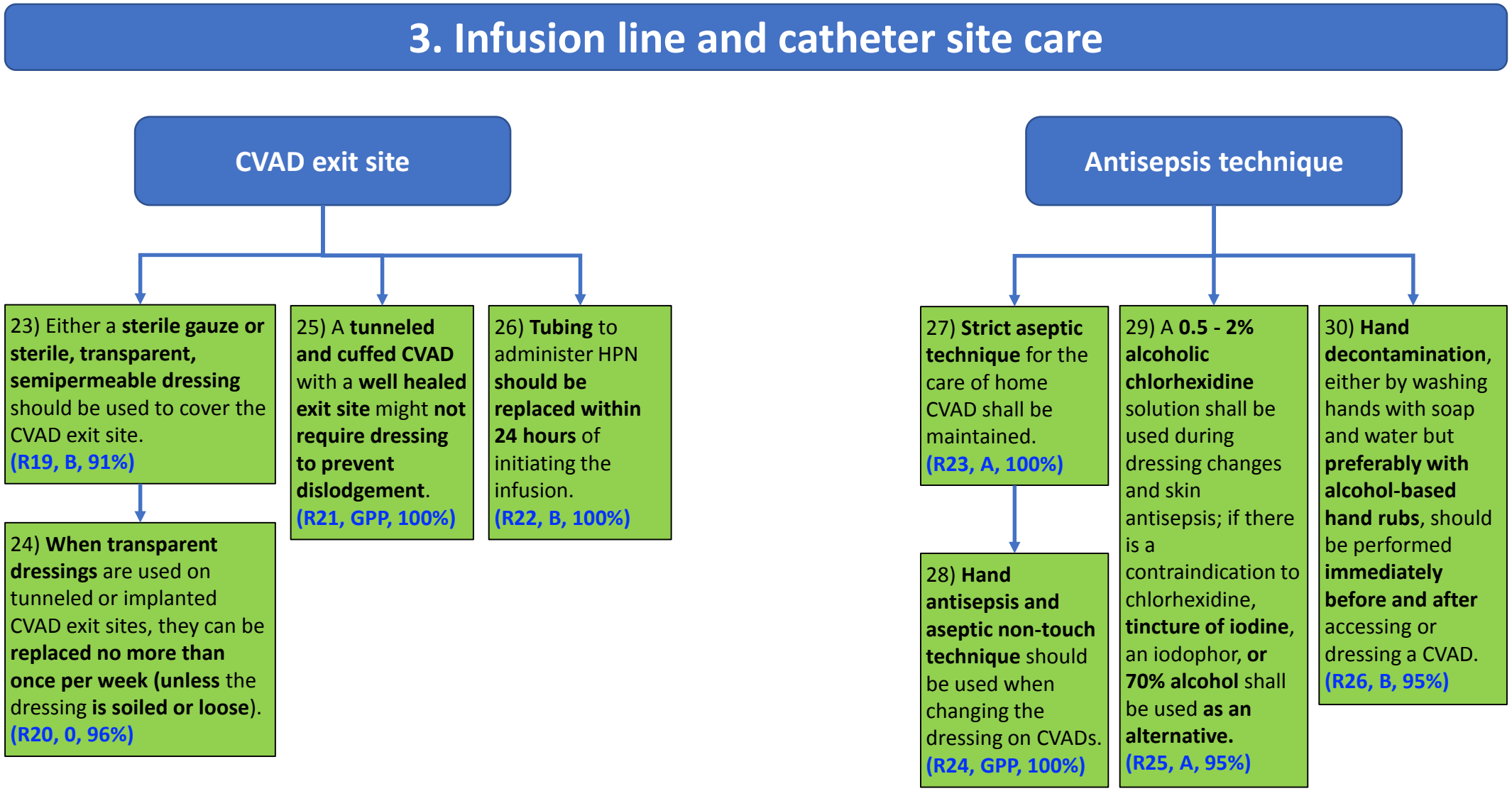

3. Infusion line and catheter site care
CVAD exit site
23) Either a sterile gauze or sterile, transparent, semipermeable dressing should be used to cover the CVAD exit site. (R19, B, 91%)
24) When transparent dressings are used on tunneled or implanted CVAD exit sites, they can be replaced no more than once per week (unless the dressing is soiled or loose). (R20, 0, 96%)
25) A tunneled and cuffed CVAD with a well healed exit site might not require dressing to prevent dislodgement. (R21, GPP, 100%)
26) Tubing to administer HPN should be replaced within 24 hours of initiating the infusion. (R22, B, 100%)
Antisepsis technique
27) Strict aseptic technique for the care of home CVAD shall be maintained. (R23, A, 100%)
28) Hand antisepsis and aseptic non-touch technique should be used when changing the dressing on CVADs. (R24, GPP, 100%)
29) A 0.5 - 2% alcoholic chlorhexidine solution shall be used during dressing changes and skin antisepsis; if there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol shall be used as an alternative. (R25, A, 95%)
30) Hand decontamination, either by washing hands with soap and water but preferably with alcohol-based hand rubs, should be performed immediately before and after accessing or dressing a CVAD. (R26, B, 95%)

Figure 5

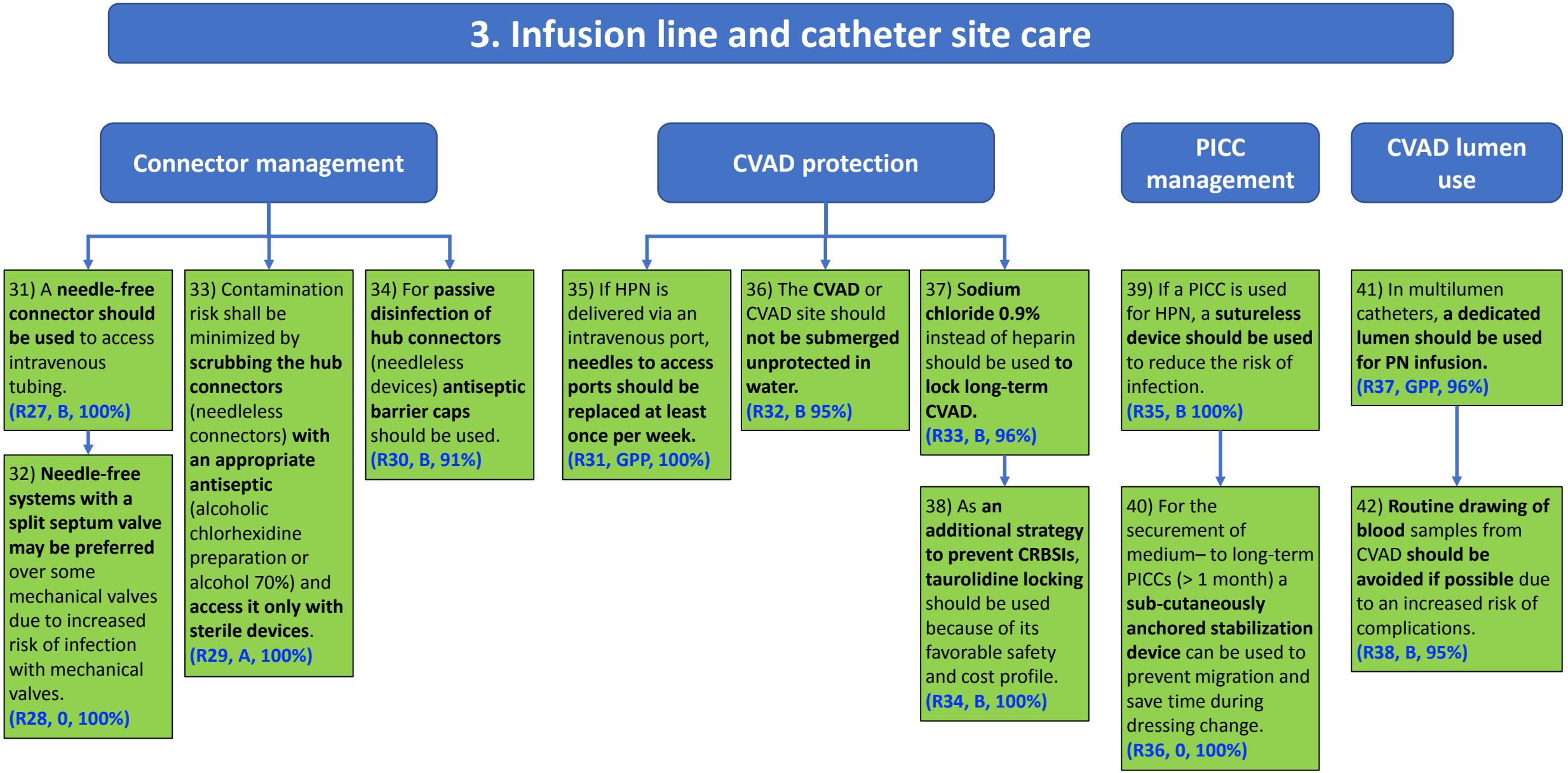

3. Infusion line and catheter site care
Connector management
CVAD protection
PICC management
CVAD lumen use
31) A needle-free connector should be used to access intravenous tubing. (R27, B, 100%)
32) Needle-free systems with a split septum valve may be preferred over some mechanical valves due to increased risk of infection with mechanical valves. (R28, 0, 100%)
33) Contamination risk shall be minimized by scrubbing the hub connectors (needleless connectors) with an appropriate antiseptic (alcoholic chlorhexidine preparation or alcohol 70%) and access it only with sterile devices. (R29, A, 100%)
34) For passive disinfection of hub connectors (needleless devices) antiseptic barrier caps should be used. (R30, B, 91%)
35) If HPN is delivered via an intravenous port, needles to access ports should be replaced at least once per week. (R31, GPP, 100%)
36) The CVAD or CVAD site should not be submerged unprotected in water. (R32, B 95%)
37) Sodium chloride 0.9% instead of heparin should be used to lock long-term CVAD. (R33, B, 96%)
38) As an additional strategy to prevent CRBSIs, taurolidine locking should be used because of its favorable safety and cost profile. (R34, B, 100%)
39) If a PICC is used for HPN, a sutureless device should be used to reduce the risk of infection. (R35, B 100%)
40) For the securement of medium– to long-term PICCs (> 1 month) a sub-cutaneously anchored stabilization device can be used to prevent migration and save time during dressing change. (R36, 0, 100%)
41) In multilumen catheters, a dedicated lumen should be used for PN infusion. (R37, GPP, 96%)
42) Routine drawing of blood samples from CVAD should be avoided if possible due to an increased risk of complications. (R38, B, 95%)

Figure 6

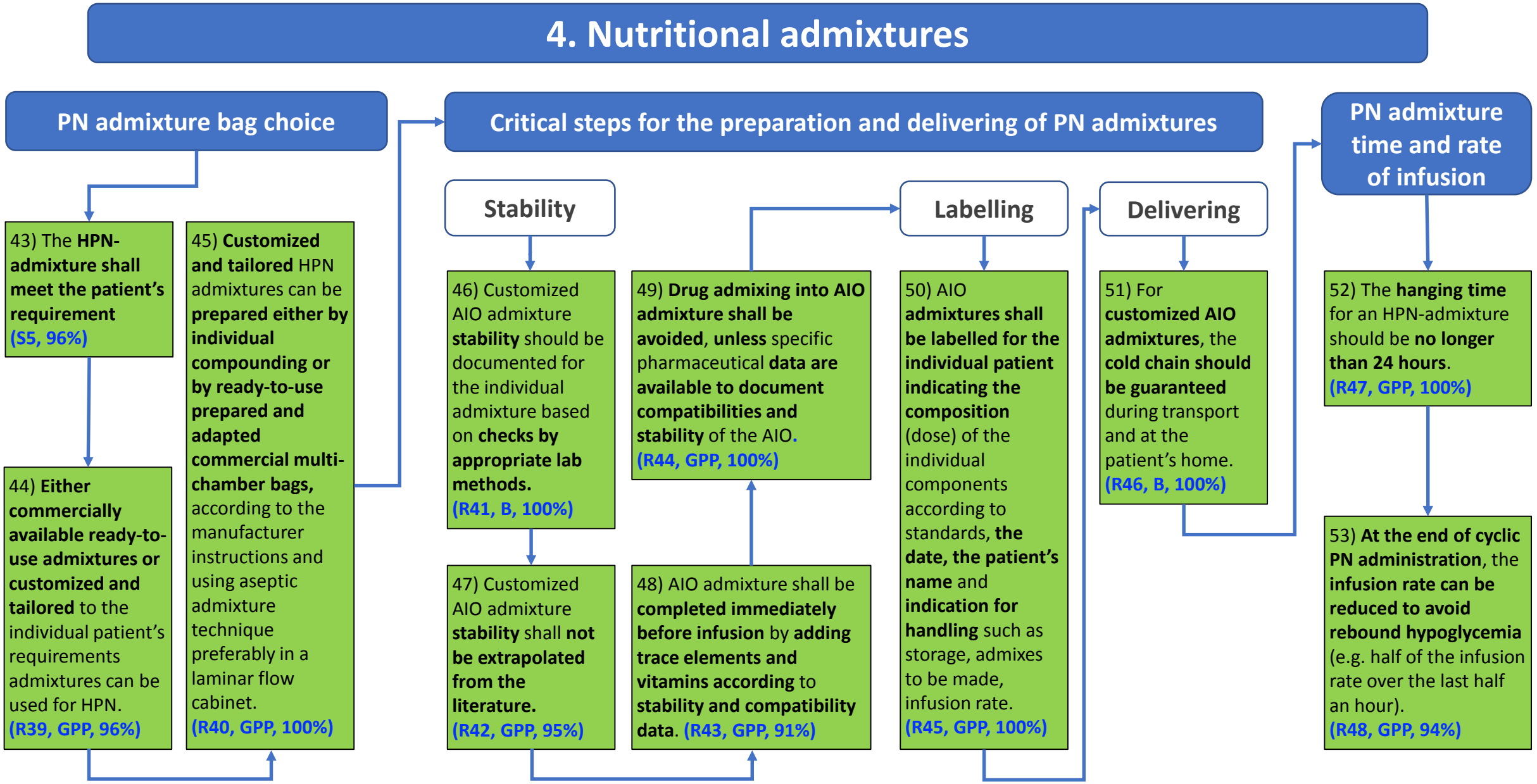

4. Nutritional admixtures
PN admixture bag choice
43) The HPN-admixture shall meet the patient's requirement (S5, 96%)
44) Either commercially available ready-to-use admixtures or customized and tailored to the individual patient's requirements admixtures can be used for HPN. (R39, GPP, 96%)
45) Customized and tailored HPN admixtures can be prepared either by individual compounding or by ready-to-use prepared and adapted commercial multi-chamber bags, according to the manufacturer instructions and using aseptic admixture technique preferably in a laminar flow cabinet. (R40, GPP, 100%)
Critical steps for the preparation and delivering of PN admixtures
Stability
46) Customized AIO admixture stability should be documented for the individual admixture based on checks by appropriate lab methods. (R41, B, 100%)
47) Customized AIO admixture stability shall not be extrapolated from the literature. (R42, GPP, 95%)
48) AIO admixture shall be completed immediately before infusion by adding trace elements and vitamins according to stability and compatibility data. (R43, GPP, 91%)
49) Drug admixing into AIO admixture shall be avoided, unless specific pharmaceutical data are available to document compatibilities and stability of the AIO. (R44, GPP, 100%)
Labelling
50) AIO admixtures shall be labelled for the individual patient indicating the composition (dose) of the individual components according to standards, the date, the patient's name and indication for handling such as storage, admixes to be made, infusion rate. (R45, GPP, 100%)
Delivering
51) For customized AIO admixtures, the cold chain should be guaranteed during transport and at the patient's home. (R46, B, 100%)
PN admixture time and rate of infusion
52) The hanging time for an HPN-admixture should be no longer than 24 hours. (R47, GPP, 100%)
53) At the end of cyclic PN administration, the infusion rate can be reduced to avoid rebound hypoglycemia (e.g. half of the infusion rate over the last half an hour). (R48, GPP, 94%)

Figure 7

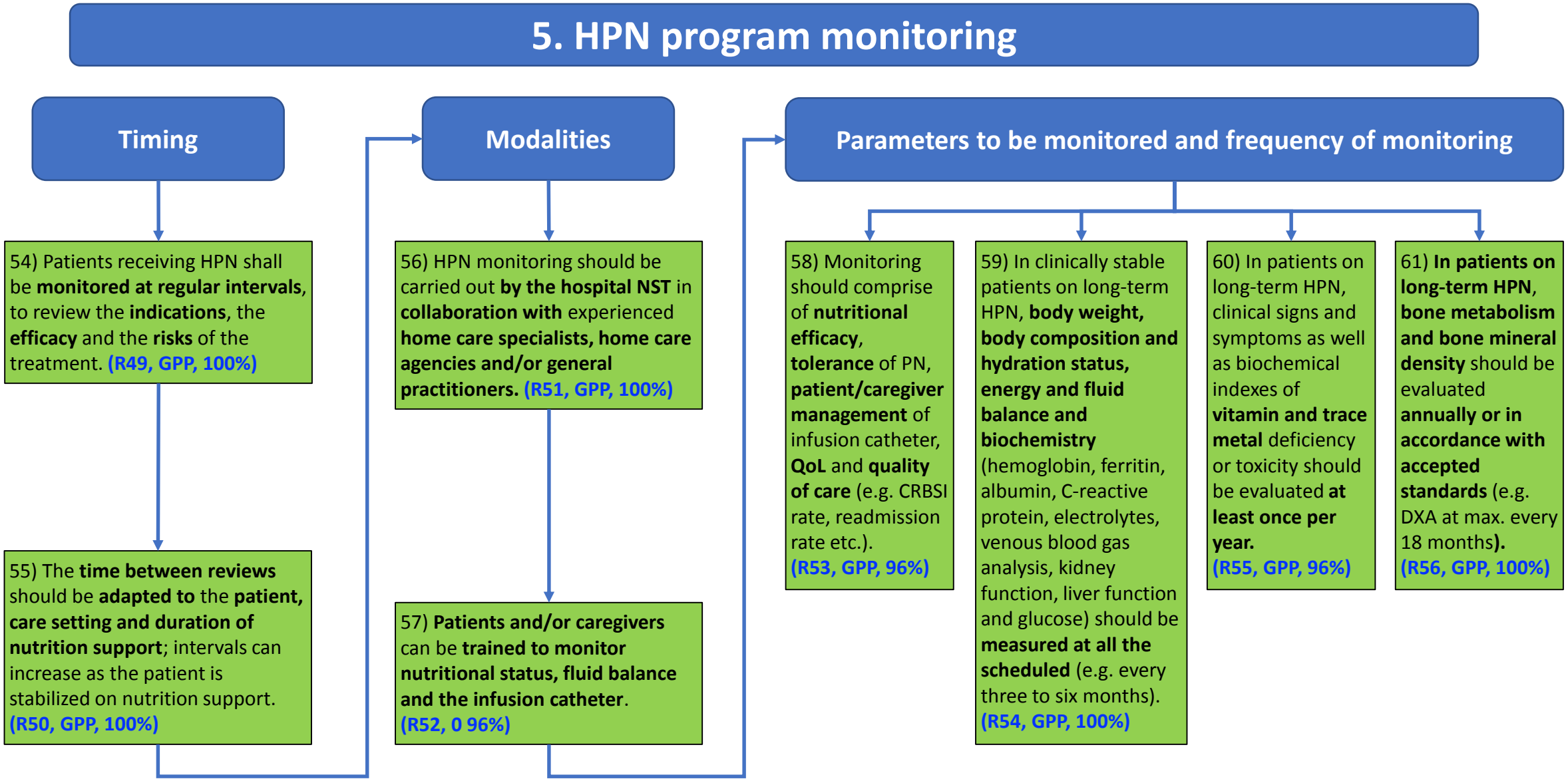

5. HPN program monitoring
Timing
Modalities
Parameters to be monitored and frequency of monitoring
54) Patients receiving HPN shall be **monitored at regular intervals**, to review the **indications**, the **efficacy** and the **risks** of the treatment. (R49, GPP, 100%)
55) The **time between reviews** should be **adapted to** the **patient, care setting and duration of nutrition support**; intervals can increase as the patient is stabilized on nutrition support. (R50, GPP, 100%)
56) HPN monitoring should be carried out **by the hospital NST** in **collaboration with** experienced **home care specialists, home care agencies and/or general practitioners.** (R51, GPP, 100%)
57) **Patients and/or caregivers** can be **trained to monitor nutritional status, fluid balance and the infusion catheter**. (R52, 0 96%)
58) Monitoring should comprise of **nutritional efficacy**, **tolerance** of PN, **patient/caregiver management** of infusion catheter, **QoL** and **quality of care** (e.g. CRBSI rate, readmission rate etc.). (R53, GPP, 96%)
59) In clinically stable patients on long-term HPN, **body weight, body composition and hydration status, energy and fluid balance and biochemistry** (hemoglobin, ferritin, albumin, C-reactive protein, electrolytes, venous blood gas analysis, kidney function, liver function and glucose) should be **measured at all the scheduled** (e.g. every three to six months). (R54, GPP, 100%)
60) In patients on long-term HPN, clinical signs and symptoms as well as biochemical indexes of **vitamin and trace metal** deficiency or toxicity should be evaluated **at least once per year.** (R55, GPP, 96%)
61) **In patients on long-term HPN**, **bone metabolism and bone mineral density** should be evaluated **annually or in accordance with accepted standards** (e.g. DXA at max. every 18 months**).** (R56, GPP, 100%)

Figure 8

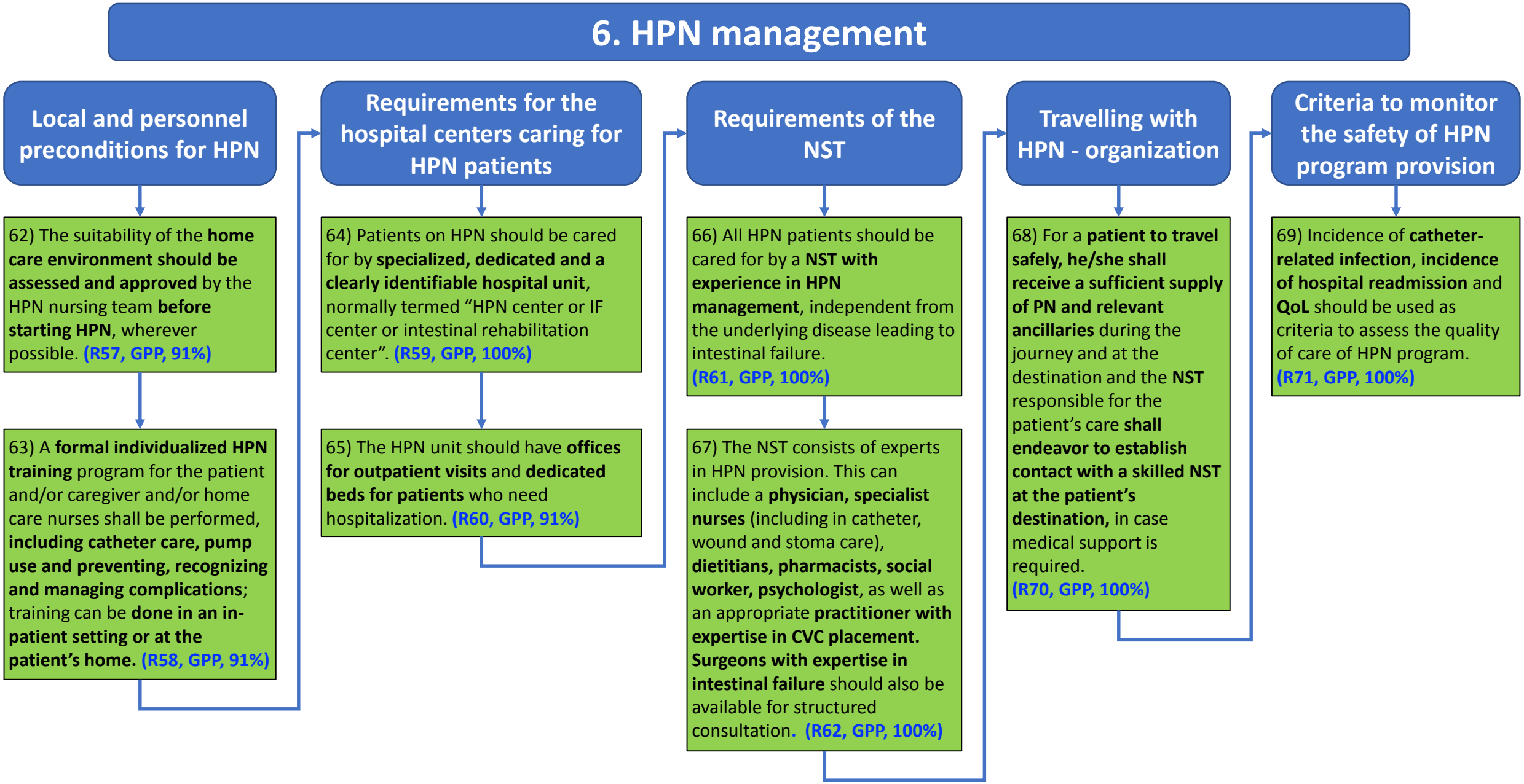
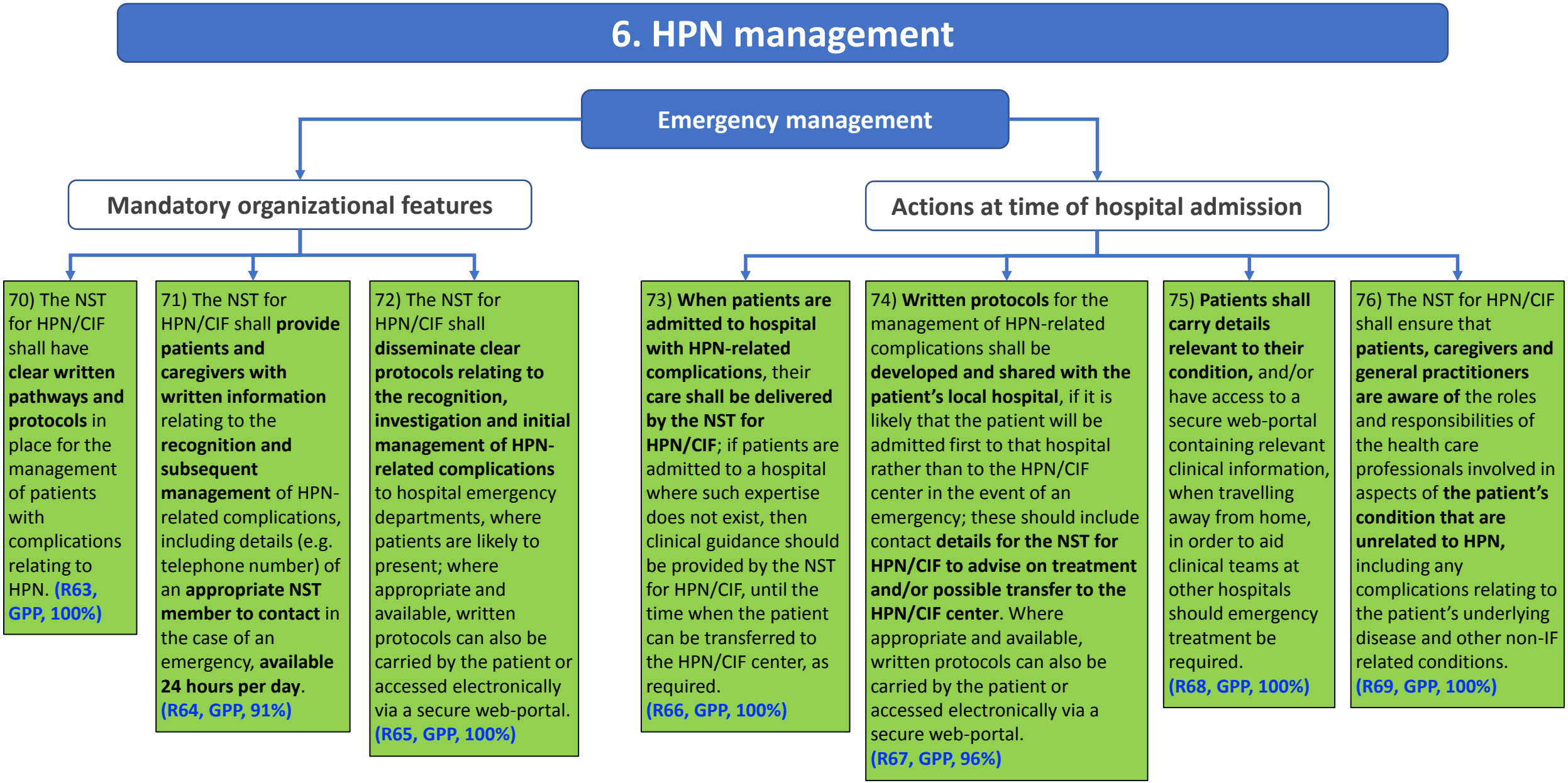

6. HPN management
Local and personnel preconditions for HPN
62) The suitability of the home care environment should be assessed and approved by the HPN nursing team before starting HPN, wherever possible. (R57, GPP, 91%)
63) A formal individualized HPN training program for the patient and/or caregiver and/or home care nurses shall be performed, including catheter care, pump use and preventing, recognizing and managing complications; training can be done in an in-patient setting or at the patient's home. (R58, GPP, 91%)
Requirements for the hospital centers caring for HPN patients
64) Patients on HPN should be cared for by specialized, dedicated and a clearly identifiable hospital unit, normally termed "HPN center or IF center or intestinal rehabilitation center". (R59, GPP, 100%)
65) The HPN unit should have offices for outpatient visits and dedicated beds for patients who need hospitalization. (R60, GPP, 91%)
Requirements of the NST
66) All HPN patients should be cared for by a NST with experience in HPN management, independent from the underlying disease leading to intestinal failure. (R61, GPP, 100%)
67) The NST consists of experts in HPN provision. This can include a physician, specialist nurses (including in catheter, wound and stoma care), dietitians, pharmacists, social worker, psychologist, as well as an appropriate practitioner with expertise in CVC placement. Surgeons with expertise in intestinal failure should also be available for structured consultation. (R62, GPP, 100%)
Travelling with HPN - organization
68) For a patient to travel safely, he/she shall receive a sufficient supply of PN and relevant ancillaries during the journey and at the destination and the NST responsible for the patient's care shall endeavor to establish contact with a skilled NST at the patient's destination, in case medical support is required. (R70, GPP, 100%)
Criteria to monitor the safety of HPN program provision
69) Incidence of catheter-related infection, incidence of hospital readmission and QoL should be used as criteria to assess the quality of care of HPN program. (R71, GPP, 100%)

Figure 9


6. HPN management
Emergency management
Mandatory organizational features
Actions at time of hospital admission
70) The NST for HPN/CIF shall have **clear written pathways and protocols** in place for the management of patients with complications relating to HPN. **(R63, GPP, 100%)**
71) The NST for HPN/CIF shall **provide patients and caregivers with written information** relating to the **recognition and subsequent management** of HPN-related complications, including details (e.g. telephone number) of an **appropriate NST member to contact** in the case of an emergency, **available 24 hours per day**. **(R64, GPP, 91%)**
72) The NST for HPN/CIF shall **disseminate clear protocols relating to the recognition, investigation and initial management of HPN-related complications** to hospital emergency departments, where patients are likely to present; where appropriate and available, written protocols can also be carried by the patient or accessed electronically via a secure web-portal. **(R65, GPP, 100%)**
73) **When patients are admitted to hospital with HPN-related complications**, their **care shall be delivered by the NST for HPN/CIF**; if patients are admitted to a hospital where such expertise does not exist, then clinical guidance should be provided by the NST for HPN/CIF, until the time when the patient can be transferred to the HPN/CIF center, as required. **(R66, GPP, 100%)**
74) **Written protocols** for the management of HPN-related complications shall be **developed and shared with the patient's local hospital**, if it is likely that the patient will be admitted first to that hospital rather than to the HPN/CIF center in the event of an emergency; these should include contact **details for the NST for HPN/CIF to advise on treatment and/or possible transfer to the HPN/CIF center**. Where appropriate and available, written protocols can also be carried by the patient or accessed electronically via a secure web-portal. **(R67, GPP, 96%)**
75) **Patients shall carry details relevant to their condition,** and/or have access to a secure web-portal containing relevant clinical information, when travelling away from home, in order to aid clinical teams at other hospitals should emergency treatment be required. **(R68, GPP, 100%)**
76) The NST for HPN/CIF shall ensure that **patients, caregivers and general practitioners are aware of** the roles and responsibilities of the health care professionals involved in aspects of **the patient's condition that are unrelated to HPN,** including any complications relating to the patient's underlying disease and other non-IF related conditions. **(R69, GPP, 100%)**