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An e-Delphi Consensus Study

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International Consensus Recommendation Guidelines for Subcutaneous Infusions of Hydration and Medication in Adults

An e-Delphi Consensus Study

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ABSTRACT

Infusion of fluids and medications is traditionally performed intravenously. However, venous depletion in patients has led to the quest for vessel health preservation. A safe, effective, acceptable, and efficient alternative is the subcutaneous route. A lack of organizational policies may contribute to the slow uptake of this practice. This modified e-Delphi (electronic) study aimed to derive international consensus on practice recommendations for subcutaneous infusions of fluids and medications. A panel of 11 international clinicians, with expertise in subcutaneous infusion research and/or clinical practice, rated and edited subcutaneous infusion practice recommendations from evidence, clinical practice guidelines, and clinical expertise within an Assessment, Best Practice, and Competency (ABC) domain guideline model. The ABC Model for Subcutaneous Infusion Therapy provides a systematic guideline of 42 practice recommendations for the safe delivery of subcutaneous infusions of fluids and medications in the adult population in all care settings. These consensus recommendations provide a guideline for health care providers, organizations, and policy makers to optimize use of the subcutaneous access route.

Key words: consensus, e-Delphi, hypodermoclysis, infusion therapy, subcutaneous, subcutaneous therapy

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Medications and fluids are commonly delivered in the acute and home care settings as infusions, and this is gaining prevalence in the long-term care setting.¹ Traditionally, these parenteral therapies have been administered via the intravenous (IV) route, yet an alarming 19% to 69% of peripheral intravenous catheters (PIVCs) fail before the end of treatment.^{2,3} A failed PIVC may translate to patient discomfort, dissatisfaction, delays in treatment, and depletion of viable venous access.^{2,4} Patient pain and suffering, as well as health care professional frustration, are furthered by repeated attempts to gain venous access, potentially leading to more invasive vascular access devices and risk of patient harm.^{2,5} Patients, caregivers, and health care systems suffer the costs of these catheter failures.^{2,5} In the older population, especially those living in nursing homes and long-term care facilities, the subcutaneous route is a valuable alternative in case of delirium, agitation, or poor venous access. Moreover, subcutaneous infusion is easy to perform and may be removed in order to avoid functional decline.

Venous depletion (the deterioration of a patient's vasculature), coupled with inexperience and poor decision-making of clinicians inserting these catheters, has led to a movement to optimize the experience and outcomes of peripheral infusion therapy.^{6,7} There is a need for alternative drug and fluid delivery routes in patients with difficult-to-access vasculature, for oral intolerance, preservation of venous health, or clinical situations where there has been an inadequate therapeutic response to oral therapy.⁸ An alternative path is the subcutaneous route, a safe, effective, acceptable, and efficient mode of delivery of infusion therapy.^{1,8-11} In subcutaneous infusions, fluid is absorbed from the subcutaneous tissue to the circulation via the forces of diffusion and perfusion.⁴ The recommended change in practice from direct venous access to the subcutaneous route for many infusions serves to facilitate vessel health preservation for many patients. However, incorporating subcutaneous access as a viable option to be considered alongside peripheral venous access is a paradigm shift.

The Emergency Nurses Association Clinical Practice Guideline recommends subcutaneous rehydration as an alternative to peripheral IV insertion for the mildly to moderately dehydrated pediatric and elderly patients if oral hydration has been unsuccessful.¹² The recommendation was graded as a level B, moderate recommendation, reflecting moderate clinical certainty with some minor or inconsistencies in quality evidence, applicable to emergency nursing practice. In the palliative care setting, subcutaneous infusions are common practice, especially at the end of life when clinicians use the subcutaneous route as an alternative to other routes that are not appropriate or acceptable.¹³ A survey by Cabañero-Martinez et al¹⁴ demonstrated a lack of internationally agreed-upon practice guidelines to direct the safe delivery of both fluids and medications through the subcutaneous route.

Objectives

The aim of this study is to address this lack of practice guidelines by developing a formal consensus- and evidence-based guideline providing a structured approach to the care of adult patients receiving subcutaneous infusions of fluids and drugs in any care setting. The guideline for subcutaneous fluids and drugs will detail essential care components of this practice to promote consistency and continuity of care and to enhance documentation and communication.¹⁵ Practice recommendation guidelines were selected as the vehicle to provide a path and a solid reference for clinicians to follow confidently that will lead to safe subcutaneous infusion therapy practice.¹⁴ The goal of this work is to encourage wider adoption of subcutaneous infusions globally. The aim is to accomplish this through the development of tools to support clinical decision-making by health care professionals providing subcutaneous therapy to adult patients.

The objectives of the study were the following:

1. To reach consensus on practice recommendations in guideline domains of a) assessment and device placement; b) best practices in subcutaneous infusion management; and c) competency and quality assurance in subcutaneous infusion therapy.
2. To summarize the recommendations for subcutaneous hydration in an ABC guideline framework.
3. To validate the recommendation guidelines through consensus.

The recommendation guidelines will aim to standardize care so all adult patients requiring subcutaneous infusion receive the same high-quality care that is timely, safe, and cost-effective. This research is predicated on evidence identified in a systematic review of systematic reviews of subcutaneous infusions of hydration and medication¹ performed by this research team as the first of 2 phases of this research.

Scope

The scope of these recommendation guidelines includes infusion therapies that may be administered via the subcutaneous route, including hydration and medications. This work is guided by the research question, "What are the best practice recommendations for the assessment, device placement, and management of adult patients requiring subcutaneous infusion therapy?"

The recommendation guidelines are targeted toward clinical decision-making for adults requiring short-term or long-term infusion therapy. They are intended for use by health care professionals in generalized or specialized practice, including, but not limited to, the following: nurses, physicians, pharmacists, educators, administrators, and researchers. The clinical practice recommendations are targeted toward all care settings (eg, hospitals, home care, and residential care). Due to the limited data available,

the neonatal and pediatric populations are outside the scope of this research, although it is recognized that general recommendations (excluding infusion parameters, eg, rates and volumes) may apply to the pediatric population.

METHODS

Study Design

A formal consensus process was used, incorporating a 2-step modified e-Delphi (electronic) method, based on systematic review findings and clinical expertise.¹⁶⁻¹⁸ Formal systematic review-based consensus methodology was adopted to develop the international recommendation guidelines because the highly structured transparent process lends itself to explicit reporting.¹⁷ This study is underpinned by a systematic review recently conducted by the researchers¹ that formed the evidentiary foundation to determine the safety, efficacy, acceptability, and efficiencies of subcutaneous fluids and drugs.

The e-Delphi method is designed to achieve consensus through expert opinion gathered systematically through multiple rounds, particularly useful when participants are geographically dispersed.¹⁹ This method was selected because it is recommended for use when the research problem is not easily solved by analytical techniques but benefits from subjective judgments from a number of individuals across diverse locations and areas of expertise.²⁰

Ethics Approval Statement

Ethics approval for the study was obtained from Griffith University, Australia (2019/1040). A Study Information Sheet was provided to participants who indicated consent prior to completing the survey.

Participants

Expert panel selection targeted disciplinary representation, roles in the acute care and post-acute care settings, research expertise in the content area, and geographical continent representation.¹⁹ To ensure incorporation of key stakeholders' perspectives, experts from Australasia, North America, United Kingdom, and Europe were invited by email notification to participate, with an attachment of participant information and a consent form. Inclusion criteria required the following for participants: a) a minimum of 3 years of experience in the prescription or administration of subcutaneous hydration and medications (excluding specialized therapies, eg, insulin and immunoglobulin) for adults in any care setting; and/or b) evidence of professional productivity in terms of peer-reviewed or professional publications and research, participation in symposia, and/or teaching capacity in this field.²¹ The goal was to recruit a panel of 10 to 15 members of various disciplines, such as prescribers (eg, physicians, physician assistants, or nurse practitioners), pharmacists, and nurse educators/managers/front line nurses, with research expertise in the content area and international representation.¹⁹

These health care professionals were identified through purposive and snowball methods.²² Researchers practicing in this field were identified through authorship, and those recognized internationally as key opinion leaders were recruited by personal email invitation. Requests were also sent by email to relevant professional associations to forward the recruitment invitation to potential eligible members. Patients and the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Study Procedures

Draft Recommendation Development

Data variables (in the form of practice recommendations) and response options were developed by the research committee (consisting of a pharmacist, infusion clinical specialist, nurse academic, and senior research assistant), based on evidence derived from their systematic review,¹ stakeholder interviews, review of international guidelines (eg, *Infusion Therapy Standards of Practice* [the *Standards*]²³) and grey literature. The framework for this research is structured as an ABC Guideline for Subcutaneous Infusion Therapy, underpinned by the Vessel Health and Preservation Model.²⁴ It provides a simplified approach, summarizing recommendation guidance in the domains of the following: a) assessment and device planning and placement; b) best practices in subcutaneous infusion management; and c) competency and quality.

The research committee graded the evidence for each recommendation (Tables 2-4), using the following scale adapted from the Oxford Centre for Evidence-Based Medicine (OCEBM) Level of Evidence Scale²⁵: level I, systematic review of randomized controlled trials; level II, randomized trial or observational study with dramatic effect; level III, non-randomized controlled cohort/follow-up (post-marketing surveillance) study; level IV, case series, case-control studies, or historically controlled trials; level V, single descriptive and qualitative studies, mechanism-based reasoning (pathophysiologic rationale), expert opinion from clinicians or authorities; and level [C], consensus by research committee.

e-Delphi Survey Rounds

Sequential surveys were administered online via Lime Survey™. The survey, with recommendation questions, was divided into 4 sections, representing the domains of the ABC framework. It also included supporting material such as the Participant Information Sheet, instructions on how to complete the survey, and the link to the systematic review. Members of the expert panel received the survey via a web-link using their provided email address.

Members of the expert panel were asked to rate agreement with each practice recommendation, on a 9-point Likert scale, ranging from strongly agree to strongly disagree (higher score corresponding with agreement). Options were included for open text comments at the end of each domain

for participants to suggest modified statements (if possible) with rationale and possibly “Not applicable-exclude,” to propose amendments to the included recommendation or suggest new definitions that were not included in the survey. No attempts were made to force consensus. The 2-round process was designed to determine “whether discrepant ratings are due to real clinical disagreement over the use of the procedure (‘real’ disagreement) or to fatigue or misunderstanding (‘artifactual’ disagreement).”²⁶ A third round of using an e-Conference Consensus was planned to address any remaining significant discord and obtain consensus. Upon achievement of consensus, this third round was not necessary.

Round 1 e-Delphi Survey: Review of Recommendations

The link to the survey was emailed to the participants. Respondents were asked to use the evidence from the systematic review and their clinical judgment to rate their agreement with the proposed clinical practice recommendation. Survey responses were collected and analyzed by the researchers. Recommendations ranked with a median score of 7 or higher were considered “strong” agreement and, thus, complete, while median scores ranked 4 to 6 were considered “weak” agreement, and median scores ranked 1 to 3 were considered “disagreement” and not to be included in round 2.^{26,27}

Round 2 e-Delphi Survey: Review of Ratings and Recommendations

A summary report prepared by the researchers describing round 1 group responses was sent to participants via email, with the link for the round 2 of the e-Delphi process. Recommendations that achieved a median score of 7 or higher in round 1 but had some rankings from individual experts from 1 to 6 or had qualitative comments were considered. As a result, either no changes were made to the recommendation and a rationale was provided in the report of results, or minor changes to wording (9 items) were made for panelists to vote on in a second-round survey.

Panel members were asked to review the revised recommendations and give their agreement with a “yes/no” response (“yes” indicating agreement with the revised standard and inclusion in the consensus recommendations and “no” indicating exclusion from the consensus recommendations). Minor editing (eg, grammar and structure) would be allowed by the researchers, but no change to intent would be made.

Statistical Analysis

Quantitative data were analyzed using SPSS version 26.0 (IBM, Armonk, NY), which included descriptive statistics to summarize respondents’ characteristics and demographic details. For each recommendation in round 1, the median, interquartile ratio, and range were calculated.¹⁸ Descriptive statistics were calculated for round 2 of the e-Delphi process.

RESULTS

Eleven expert panel members were selected, as per the inclusion criteria, for the consensus panel in the e-Delphi process. Five members were recruited from their authorship of significant subcutaneous infusion therapy research. Fourteen responses were received from members of professional organizations, and 6 of these met inclusion criteria. The final panel included physician, nurse, and nurse practitioner experts from Australasia, North America, and Europe practicing in subcutaneous infusion therapy in the pediatric and/or adult population (Table 1). All 11 expert panel members completed both consensus rounds.

Round 1 Survey Results

All recommendations (42/42) reached consensus and, thus, were included, with 100% of median scores between 7 and 9, indicating strong agreement. There were no missing

TABLE 1
Panelists Demographic Summary

Demographic	Frequency, n (%) (n = 11)
Age (years)	
30-39	3 (27.3%)
40-49	6 (54.5%)
50-59	1 (9.1%)
60	1 (9.1%)
Gender	
Female	8 (72.7%)
Male	3 (27.3%)
Country of practice	
Italy	1 (9.1%)
United States	4 (36.4%)
Denmark	1 (9.1%)
Spain	1 (9.1%)
France	1 (9.1%)
Australia	1 (9.1%)
Singapore	1 (9.1%)
Ireland	1 (9.1%)
Patient population	
Adult	8 (72.7%)
Mixed	3 (27.3%)
Discipline	
Nurse	5 (45.6%)
Nurse practitioner	1 (9.0%)
Physician	4 (36.4%)
Clinical nurse specialist	1 (9.0%)

items reported in the survey, with 11 valid responses from the consensus panel members for each item.

The research committee reviewed all recommendations that received a score of 1 to 7 by any panelist and/or had qualitative comments of issue. Of these, 9 recommendations required minor changes by the research committee (eg, identification of applicable setting or populations), as these were significant to content and, as such, consensus agreement from panelists was required. Following revision, these recommendations accompanied by the research committee's rationales for changes were advanced to round 2 (Supplemental Table 1, available at <http://links.lww.com/JIN/A106>).

Round 2 Survey Results

Recommendations revised by the research committee were assessed by the expert panel members. The original recommendation and first round-related qualitative comments accompanied the revised recommendations in the survey. All 9 revised recommendations gained consensus agreement by panel members. Three recommendations had an agreement rate of 10 (91%) of 11. The research committee reviewed the 3 responses and made a minor change to the wording of 1 recommendation. The final recommendations are presented in Tables 2-4. A third consensus round planned as an e-conference consensus panel was not required due to the strong agreement among panelists in rounds 1 and 2.

Synthesis of Results

Recommendations for safe and effective delivery of subcutaneous infusion therapy are summarized in the framework for this research, the ABC Model for Subcutaneous Infusion Therapy (Figure 1). Elements of the key recommendations are presented for each domain. The model is designed to depict practice considerations to guide the safe delivery of therapy from the assessment and planning phase through management of infusions. All of these phases require multidisciplinary health care providers competent in the field of subcutaneous therapy to ensure high-quality care of adult patients requiring subcutaneous administration of fluids and medications.

DISCUSSION

This international e-Delphi study resulted in the development of 42 practice recommendations designed to support the safe and effective delivery of subcutaneous infusion of fluids and medications. Patients and clinicians are facing significant challenges with venous access based on patient characteristics or health care setting.^{57,58} This study aimed to provide recommendations to support the uptake of the less invasive subcutaneous access route.⁵³ These consensus recommendation guidelines present a comprehensive approach to evidence-based subcutaneous infusion therapy as an alternative to IV access.

The ABC Model of Subcutaneous Infusion Therapy presents a systematic framework to describe key practice considerations. These recommendations were based on evidence synthesized by a systematic review completed by the researchers.¹ The recommendations were also compared to published practice guidelines and evaluated in context of clinical practice experience of the researchers and other experts in practice. Achieving 100% consensus in the first consensus round and from a geographically diverse and multidisciplinary panel was unexpected. This may, however, reflect the strong evidentiary underpinning of the recommendations. Despite the lack of high-level studies, the high level of consensus suggests a strong agreement with these practice considerations around the globe. Expertise of the panelists and their qualitative feedback led to only minor verbiage changes of 9 of the 42 recommendations.

The goal of this research development was to provide a subcutaneous infusion therapy resource for use in a wide variety of settings and practices. Clinicians find guidelines to be more useful as a resource to support individualized practice than a specific instrument, as there are often many variables affecting informed decision-making.¹⁴ The recommendation guidelines present a holistic framework from assessment to quality evaluation applicable to multiple disciplines regardless of local practice variations. For this reason, specific recommendations for individual therapies or administration methods were avoided. As such, responsibilities were not delineated specific to a discipline, and language accommodating self-administration or caregiver administration were included. Scenarios specific to one therapy or one setting (eg, acute care, emergency care, chronic care) were avoided. Specific practice recommendations, such as indications and contraindications; fluid and hydration types, rates, volumes, and delivery devices; and subcutaneous access sites are described in a recent systematic review.¹

STRENGTHS AND LIMITATIONS

The strengths of this study include the efficiency of which consensus was met. All recommendations met the requirements for acceptance during the first round. Achieving consensus in round 1 for all recommendations enabled the researchers to focus in on those that had a larger spread in agreement to enhance acceptability of the recommendations. Additional strengths include the international scope of participants, varied disciplines, specialties (eg, complex care, gerontology, home infusion, medicine, pharmacology, and vascular access), and the types of practice settings represented in the panel and the researchers. This should facilitate a broader global uptake of the recommendations for organizations, policy makers, and clinicians seeking to expand the use of subcutaneous infusion therapy in vascular access device selection.

The recommendation guidelines were structured in the ABC model to be more comprehensive than specific

TABLE 2**Recommendations for Assessment and Device Placement****Recommendation**

1. Assess patient to determine if subcutaneous access is appropriate for the infusion of medications and hydration as an alternative route to intravenous access. Subcutaneous access is a vessel health preservation strategy for adults in all health care settings.^{1,23,28-31} (III)
2. Assess intended duration of therapy, reason for parenteral route, properties of the solution/medication (eg, viscosity, pH, dose, volume, concentration and rate), available support and resources (if outside the hospital), patient's clinical and skin condition (including availability of appropriate tissue).³²⁻³⁴ (V)
3. For the management of mild-to-moderate dehydration, assess need for subcutaneous infusion of isotonic solutions if oral route not appropriate (alternate routes include enteral, intravenous, and intraosseous). Complete an interprofessional team hydration/nutrition/electrolyte assessment to determine patient's fluid and electrolyte needs.^{34,35} (V)
4. Review drug product monograph to determine labeling of medication for subcutaneous route. In the absence of marketing authorization for subcutaneous route, the organization/prescriber, including the pharmacy team, will determine if infusion of medications off-label meets organizational and/or regulatory requirements and is supported in the literature.^{8,34,36,37} (III)
5. Collaborate with the health care team and patient to perform a risk/benefit analysis with the patient/caregiver to determine appropriateness of subcutaneous infusions, establishing the goals of treatment. Ensure treatment is consistent with patient's plan of care; obtain consent as per organizational policy.^{1,33} (III)
6. Ensure subcutaneous medications and hydration prescribed are at rates, frequency, and volumes/dosage appropriate for the patient's age, weight, clinical condition, individual subcutaneous absorption, laboratory values, and as recommended by the drug manufacturers or supporting literature and generally not exceeding those used for IV infusions.^{23,32,34} (V)
7. Ensure prescriptions include medication/solution, dose/volume, route, rate, frequency (eg, once daily), duration of infusion (eg, over 8 hours), and end date.^{34,35} (V)
8. Avoid infusion rates >5 mL/h for medications (unless recommended by manufacturer, eg, subcutaneous immunoglobulin). Slow infusion rates and use of diluted solutions have been recommended in the literature for subcutaneous antibiotics.^{1,23,32,37} (III)
9. Select a site for subcutaneous access with intact skin and adequate subcutaneous tissue (eg, minimum 1.0-2.5 cm thickness), assessing and addressing patient comfort, needle fear, mobility, safety, and preference (to identify optimal position or location for the patient).^{1,32-35,38} (III)
10. Consider use of 2 or more sites as required for high-volume solutions (eg, up to 1 L/d per site).^{1,28-31,33} (III)
11. If multiple subcutaneous infusions are prescribed, determine if they are compatible and can be administered in the same infusion. If using more than 1 subcutaneous set simultaneously (or bifurcated needle sets), use a separate site for each set.³⁹ (V)
12. To aid in dressing adhesion, remove excess hair from insertion site with clippers or scissors (do not shave or use a depilatory).⁴⁰ (V)
13. Perform hand hygiene and don gloves. Perform skin antisepsis, preferably using chlorhexidine-based solution, using a single-use applicator, and allow to dry naturally (without wiping, fanning, or blowing on skin).^{23,32,34,40} (V)
14. Use a nonmetal cannula appropriate for the patient and infusate, preferably with a short length (to avoid intramuscular injection) and small gauge (eg, 24-27 gauge); larger gauges (eg, 22 gauge) may be required for higher flow rates.^{1,23,32,34,39-43} (III)
15. Prime the subcutaneous access device with either 0.9% sodium chloride or the prescribed medication/solution (to expel any air). For specific medications, such as immunoglobulins, which may be irritating to the intradermal space, consider partially priming the cannula, stopping prior to the tip of the cannula ("dry-priming approach").^{32,33,39,44} (V)
16. Using aseptic nontouch technique, insert cannula to establish subcutaneous access. Insert short cannula (<6 mm) at a 90° angle, using a skin fold lift in the slim patient to lift the skin away from the muscle fascia. To insert a longer cannula or cannula of any length in lean adults, arm or thigh sites (which have less subcutaneous tissue), use a 45° angle and/or use a skin fold lift to minimize the risk of intramuscular injection.^{1,33,34,39,40,42-45} (III)
17. Remove the metal stylet (if applicable) and dispose in sharps container.³⁹ (V)
18. If blood return is present during device placement, remove and insert new device at new site.³² (V)
19. Aseptically apply a transparent semipermeable membrane dressing (if not integrated with the cannula) over the site (to protect sites and devices, allow moisture vapor permeability, and allow for site assessment). Use skin injury mitigation strategies (eg, alternate dressings, skin barrier prep) when necessary.^{32,34,44} (III)
20. Document the patient assessment, patient consent, device placement (including cannula type, size, and site), patient response, complications, or missed attempts.³⁴ (V)

Abbreviations: (I), level I evidence: systematic review of randomized controlled trials; (II), level II evidence: randomized trial or observational study with dramatic effect; (III), level III evidence: non-randomized controlled cohort/follow-up (post-marketing surveillance) study; (IV), level IV evidence: case series, case-control studies or historically controlled trials; (V), level V evidence: single descriptive and qualitative studies, mechanism-based reasoning (pathophysiologic rationale), expert opinion from clinicians or authorities; (C), level [C] evidence: consensus by research committee.

TABLE 4

Recommendations for Competency and Quality in Subcutaneous Infusion Therapy

Recommendation

38. Organizations should establish systems to ensure that all health care professionals involved in prescribing and/or administering subcutaneous infusions are trained on the principles covered in these recommendations and are then formally assessed and reassessed at regular intervals to demonstrate competence (knowledge, skills, and judgment).^{31,34,35,38} (IV)
39. Organizations should consider designating clinician lead/resource for infusion therapy, responsible for training, clinical governance, audit and review of subcutaneous fluid prescribing, and patient outcomes.⁸ (V)
40. Organizations should monitor quality outcomes related to subcutaneous infusion therapy. [C]
41. Consider quality standards such as: i) infusion fluids clinical lead/resource; ii) health care professionals' competencies; and iii) identifying and reporting consequences of fluid mismanagement (eg, pulmonary edema or hypovolemia).⁸ (V)
42. Encourage and participate in research to promote evidence-based decision-making and clinical practice in the administration of subcutaneous infusions of hydration and medications.³⁸ (V)

Abbreviations: (I), level I evidence: systematic review of randomized controlled trials; (II), level II evidence: randomized trial or observational study with dramatic effect; (III), level III evidence: non-randomized controlled cohort/follow-up (post marketing surveillance) study; (IV), level IV evidence: case series, case-control studies or historically controlled trials; (V), level V evidence: single descriptive and qualitative studies, mechanism-based reasoning (pathophysiologic rationale), expert opinion from clinicians or authorities; (C), level [C] evidence: consensus by research committee.

parameters to be assessed. The final domain of the model includes recommendations around the practice of subcutaneous infusion, including the education and competency of staff, the quality controls, and application of research in practice.

Limitations of this study identified at the start included the potential for a small number of participants who fit the inclusion criteria, limits in evidence available to support some recommendations, the language of the study, and that the recommendations are only suitable

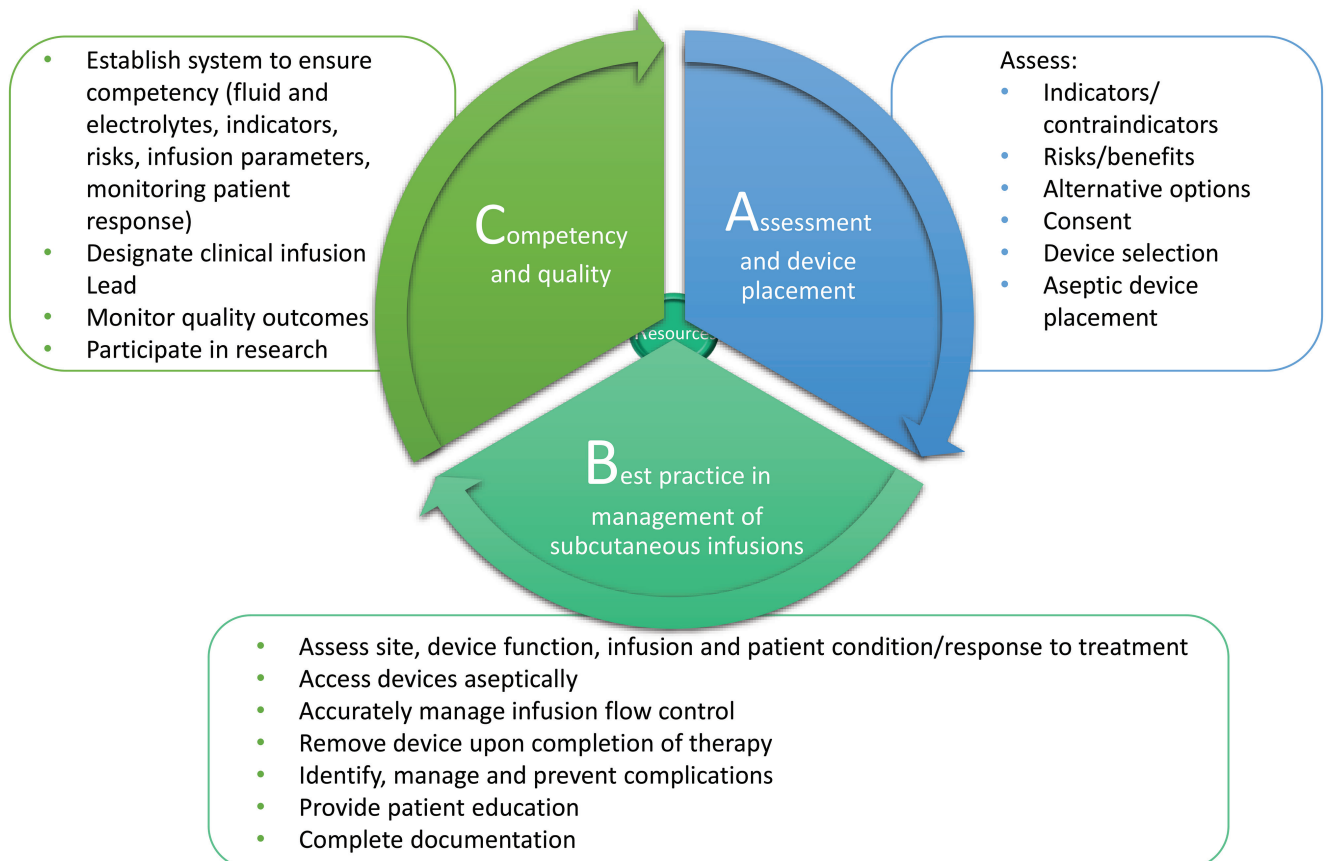


Figure 1 ABC Model of Subcutaneous Infusion Therapy.

for adults in health care settings. The impact of these limitations was mitigated as much as possible in the study design and evaluation. No differences were observed in the acceptance of the recommendations or the comments by panelists based on international borders, health care systems, or practice settings.

Language and cultural variances did not appear to be as much of a limitation as feared when the recommendations and surveys were performed in English. Comments during round 1 of consensus did not indicate that there was confusion in any of the chosen verbiage; however, the application and integration into practice may be impacted.

There is no agreement on the number of participants in the e-Delphi consensus process⁵⁹; however, it has been reported that 10 to 15 participants is the norm.⁶⁰ Although the number was sufficient for consensus and did provide a wide geographical setting and demographic variance, the researchers had hoped to have more pharmacy representation (although one of the lead researchers is a clinical pharmacist) and participants representing South and Latin America. Representation from Canada, as well as further representation from the United States and Australia, was included within the lead investigator team. Due to the timing and the unexpected pandemic (COVID-19) affecting so many practices, potential panelists were burdened and slow to respond to original requests to participate. Some organizations did not respond to requests for panelist recommendations. Due to how quickly consensus was met, this may not have impacted the results.

The recommendation guidelines include reference to a larger scope of medications administered subcutaneously as an alternate to IV administration. Common subcutaneous infusions of analgesics, as well as the administration of antibiotics,^{36,60} antiepileptics, anxiety treatments, and newer biological therapies, are included based on the evidence from systematic review.¹ For these therapies, administration by the subcutaneous route can safely bring improved outcomes, especially for patients with safety concerns and limited venous access options. More research is needed to strengthen and expand recommendations regarding these therapies, including the bioavailability of medications appropriate for the subcutaneous route.

Future areas of research were identified during this study that could impact quality of life and economic outcomes, as well as health care resource utilization. More evidence is needed for the specific administration parameters for fluids and medications so specific care algorithms can be developed. During the systematic review used as a foundation for this research, it was found that there were limitations to the amount of evidence published on subcutaneous infusion as an alternative administration. More research is needed to increase the use of subcutaneous infusion practice, evaluate the reduction of negative outcomes by using this as an alternative to IV administration, and identify the populations

who will most benefit from this administration method. More data are needed to support the use of subcutaneous administration as a tool in venous access preservation for chronic illnesses, a means to allow for a safer alternate site of care or self-administration, reductions in negative outcomes from venous catheters, and reduction in infection rates related to catheter placement and use.

An additional area for research is the development of specific integrated care pathways for subcutaneous infusions. Although one of the original visions of the researchers was to pursue this, the evidence was unable to support it, especially in the face of multiple patient and infusate variables, limited research published using large patient populations, and variances in practice settings and health care systems; thus, developing specific pathways and decision trees was not possible. Using the ABC Model of Subcutaneous Infusion Therapy and the consensus recommendations, individual organizations or practice groups may be successful in developing and piloting these pathways. Although health information technology-supported clinical pathways have been shown to improve patient outcomes, quality of care and health care resource utilization, the study scope precluded this scope of work⁶¹; however, it may be considered by organizations implementing this guideline.

CONCLUSION

This e-Delphi study has produced international expert consensus-based recommendations for the safe and effective delivery of subcutaneous infusion of fluids and medications. The ABC Model of Subcutaneous Infusion Therapy presents a systematic approach to the care of adult patients receiving subcutaneous infusions of fluids and drugs in any care setting. This model addresses assessment and device placement, best practices for infusion management, and competency evaluation in a quality program. This framework offers a guide for health care providers, organizations, and policy makers in the safe delivery of infusion therapy via the subcutaneous route. Further research is required to develop algorithms incorporating subcutaneous access as a vascular access alternative.

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