Catheter lock solutions are instilled into central venous access systems to have certain effects in this location. These access systems can be either dialysis catheters, Hickman-type lines or port-a-cath systems. The latter are used mainly in parenteral nutrition and for the administration of medication in oncology patients. These access systems are approved as medical devices and are CE marked. The central venous access is inserted in the subclavian, jugular or femoral veins.

The use of Antimicrobial Lock Solutions has been recommended in the “Hygiene Guideline complementing the German Dialysis Standard” and in the Position statement of European Renal Best Practice (ERBP)". Pure heparin solutions containing no antimicrobial agent do not meet this criterion. Antibiotics are associated with the development of resistancy which is a major drawback. Highly concentrated citrate solutions and taurolidine-citrate solutions are therefore conceivably useful in this application.

Highly concentrated citrate solutions (30% and 46.7%) cause major adverse effects such as cardiac arrests and embolisms that are a significant risk for the patient. TauroLock™ as an antimicrobial lock solution has proven useful in dialysis, oncology and parenteral nutrition for many years and has meanwhile become established in the prevention of catheter-related infections.

TauroLock™ is safe: The concentration of 4% citrate in TauroLock™ is safe and efficient, according to the recommendation of the FDA [ref: FDA Warning Letter, April 2000]. No hypocalcaemic effects are observed in contrast to highly concentrated citrate solutions (30%, resp. 46.7%) e.g. arrhythmia, cardiac arrest, embolism, tingling fingers and metallic taste. TauroLock™ is biocompatible and non toxic. In contrast to highly concentrated citrate there is no protein precipitation if using TauroLock™.

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An introduction to the KHA-CARI guidelines

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Abstract

Increases in age, acuity and co-morbidities within the population of persons with kidney disease have made it essential that renal replacement therapies and associated treatments are evidence-based, effective and consistent. Additionally, the need exists to offer treatment option advice that is transparent and unbiased, for both consumers and health care professionals. These imperatives require guidance by principles that are recommended within a uniformly accepted framework. Written in notated point-form, this paper aims to explain why guidelines are important, and to highlight the advantages of referring to clinical guidelines, through an overview of the Kidney Health Australia — Caring for Australasians with Renal Impairment (KHA-CARI) Guidelines, as they stand within local and global contexts.

Keywords

KHA-CARI Guidelines, nephrology guidelines, evidence levels, end-stage kidney disease, dialysis.

Learning objectives

• To understand the imperative for using clinical guidelines, and the reasons why they have the potential to improve health care delivery.
• To identify international nephrology organisations who formulate guideline recommendations related to kidney disease.
• To appreciate the significance of differing evidence levels and grades as they relate to guideline recommendations.
• To develop an ongoing working knowledge of KHA-CARI guidelines and updates.

What are guidelines and why are they necessary?

Clinicians caring for people with kidney disease make frequent decisions about the best treatment option for delivering that health care. Every day more research is published contributing to the body of knowledge about the best way to provide care. It is impossible for each care-provider to review all of the literature and hence there is a risk of choosing a treatment based on past experience; a biased and possibly an out-of-date choice. Guidelines, which are basically a summary of recommendations for care, help to overcome this risk of bias and potentiate evidence-based practice, the gold standard for best outcomes. It is always important to remember, however, that clinician expertise and individual patient needs will always remain part of that decision-making process. The KHA-CARI Steering Committee is committed to developing reliable and trustworthy guidelines that follow practice recommendations from the best available evidence, with a high degree of transparency through all aspects of the process.

“Guidelines are sets of non-mandatory rules, principles or recommendations for procedures or practices in a particular field” (NHMRC, 2017, p. 1), which only become mandatory if adopted as policy, legislation or as codes of conduct. Various governmental agencies, (national and international) offer advice on the formulation and utilisation of guidelines.

In Australia, the National Health, Medical and Research Council (NHMRC) is the expert body responsible for the regulation of public and individual health care standards. They suggest Australian health care organisations ensure that guidelines meet international standards, and amongst other considerations guidelines should:

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be relevant to the population they represent, with respect to cultural, local, regional, and national specifications
- clearly state the purpose and context
- ethically reflect the community’s range of attitudes and concerns
- be well informed by research evidence and subject to peer review
- address the health care issue at hand
- have a clearly stated purpose
- be feasible to implement (NHMRC, 2017).

Specifically, KHA-CARI add that guidelines need to:
- enhance the appropriateness, consistency and cost-effectiveness of renal health care
- be reliable and trustworthy
- arise from current and appropriate research
- improve outcomes through improved quality of care for consumers
- improve benefits for health care providers
- minimise risk of harm
- bring about positive change (Howell, 2015).

What are evidence levels and grades?

Guidelines are strictly derived from evidence-based, published research literature. Evaluation and grading of the evidence is necessary to ensure quality and appropriateness for the findings to be applicable to clinical practice (NHMRC, 2017; Howell, 2015).

The evidence level or grade of evidence is an alphabetical or numerical value ascribed to a piece of information that intends to describe the overall quality of that evidence. Different grades have different recommendation strengths: Level 1: “we recommend …”, and Level 2: “we suggest …”. The evidence levels have specific, yet linked, implications for the patient, clinician and policy stakeholders. The higher or stronger levels of recommendation are based on the level of the evidence, which at the highest is based on randomised controlled trials and at the lowest is based on expert opinion. For example, the NHMRC Evidence Hierarchy designates levels of evidence according to the type of research question, in six evidence levels (NHMRC, 2009). This is similar to the Joanna Briggs Institute levels of evidence for effectiveness, which displays five levels of evidence for effectiveness in diagrammatical format (Joanna Briggs Institute, 2014). Over the past few decades, various scientific agencies have made recommendations regarding sourcing of the most appropriate quality of evidence for the research question, and these are similarly aligned.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) is a working group which suggests use of their internationally recognised approach to rate the quality of evidence and the strength of recommendations. GRADE is considered to be the standard in guideline development (NHMRC, 2017) and this approach is utilised in the KHA-CARI guidelines (Howell, 2015). Evidence levels and grades are given within each KHA-CARI guideline.

KHA-CARI guidelines
- Are accessible through the KHA-CARI website at http://www.cari.org.au/
- Writing of Kidney Health Australia (KHA) — Caring for Australasians with Renal Impairment (CARI) Guidelines were commenced in the 1990s, and the process is ongoing.
- It is envisaged that they be the front-line resource for Australasian clinicians and consumers in considering care options for persons with kidney disease.
- New guideline commentary and updates are frequently published in the journal Nephrology.
- Current KHA-CARI guidelines are sectioned into three areas, with subsections and dates:
  - Chronic kidney disease guidelines
    - Acute kidney injury: May 2014
    - Cardiovascular disease: May 2013
    - Diagnosis and treatment of urinary tract infection in children: Nov 2014
    - Early chronic kidney disease: May 2013
    - Nutrition and growth in kidney disease: Dec 2005
    - Vitamin D, calcimimetics & PO₄ binders: Apr 2006
  - Dialysis guidelines
    - Dialysis adequacy: Apr 2013
    - Peritonitis treatment and prophylaxis: Jan 2014
    - Vascular access: Jun 2012

For further information:
For detailed information on the KHA-CARI guideline development and writing process, including evidence level and grading descriptions: http://www.cari.org.au/docs/KHACARI_Guideline_development_%20manual.pdf
European Renal Best Practice (ERBP): http://www.european-renal-best-practice.org
Kidney Disease Improving Global Outcomes (KDIGO): http://kdigo.org
National Institute of Health and Care Excellence (NICE): http://www.nice.org.uk
Information about the GRADE approach: http://www.gradeworkinggroup.org/
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- Transplantation guidelines
  - Care of kidney transplant recipients Jan 2012
  - CMV disease Mar 2011
  - Recipient assessment for transplantation Mar 2013

- Archived guidelines:
  - There is an extensive list of guidelines from each of the three areas, which are out of date and have been archived to an accessible link on the website. Guidelines may be considered out of date if older than five years, but in some areas there is little new research, meaning a guideline may stay relevant for longer than this arbitrary period. The KHA-CARI steering committee oversees writing and updating of the guidelines, and decides if a guideline remains current or should be archived. Of note, some archived guidelines contain relevant information, but may have been archived because another guideline group has produced a more recent guideline.

- Guideline structure and content:
  - Individual guidelines are constructed of several sections (subtopics), to offer a sectioned, comprehensive and transparent overview of the evidence, as follows:
    - Guideline section title
    - Author(s)
    - Guideline summary
    - Ungraded suggestions for clinical care
    - Implementations and audit
    - Background
    - Search strategy
    - Overview of the evidence
    - Comment on what other guidelines say
    - Suggestions for further research
    - Conflict of interest
    - References

Which other international guidelines focus on persons with kidney disease?

- In parallel with most international health commentary, as directed by the World Health Organization (WHO), guidelines frequently link in, or take into account those written by other international authorities. The KHA-CARI guidelines make reference to these organisations within the guideline commentary.

- United States: The National Kidney Foundation (NKF) began developing guidelines which were published in 1997 as Dialysis Outcome Quality Initiative (DOQI). Since then, with other international nephrology specialist collaboration and commentary (Eknoyan et al., 2004), these have been further developed and now comprise 13 guidelines, under the auspices of the Kidney Disease Outcomes Quality Initiative (KDOQI). NKF publishes a list of topics under either chronic kidney disease or dialysis care (NKF, 2017). Their new guideline commentary and updates are frequently published in the American Journal of Medicine, Journal of American Society of Nephrologists, and American Journal of Kidney Disease.

- Europe: In 1999, the European Renal Association and European Dialysis and Transplant Association (ERA-EDTA) initiated the European Best Practice Guidelines (EBPG). In 2008, after a change in philosophy, these were adapted from “guidelines” to “recommendations” or “position statements” under the new term European Renal Best Practice (ERBP) (ERA-EDTA, 2017). Their new guideline commentaries and updates are frequently published in the journal, Nephrology Dialysis Transplantation.

- United Kingdom: The Renal Association (RA), founded in 1950, has contrived a list of 10 guidelines to date, covering care aspects of kidney disease, formulated into their Renal Association’s Clinical Practice Guidelines, as accredited by the National Institute for Health and Care Excellence (NICE) (Renal Association). They are informally allied with the British Association for Paediatric Nephrology (BAPN). Their new guideline commentaries and updates are published on their website.

- Canada: In 2008, the Canadian Society of Nephrology developed their guidelines which cover approximately ten areas of nephrology care. Specifically these align with guidelines as recommended by their national hypertension, cardiology and diabetes associations (Levin et al., 2008). Their new guideline commentaries and updates are frequently published in the Canadian Medical Association Journal.

References


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