Technical Information Report

AAMI TIR72: 2017

Dialysis fluid chemical composition

AAMI
Advancing Safety in Health Technology

Dialysis fluid chemical composition

Approved 8 September 2017 by
Association for the Advancement of Medical Instrumentation

Abstract: This technical information report (TIR) addresses critical aspects of processes affecting the quality of fluids used to perform hemodialysis, including water, concentrates, and final dialysis fluid. It defines concentrates for hemodialysis, provides rationale for their use, and describes the major critical aspects of the quality process involved in the preparation, handling, and use of dialysis fluids. This TIR does not address peritoneal dialysis fluids.

Keywords: concentrate, dialysis, quality, water

AAMI Technical Information Report

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Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

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A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

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Comments on this TIR are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation
Renal Disease and Detoxification Committee

This technical information report (TIR) was developed by the AAMI Renal Disease and Detoxification Committee. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Renal Disease and Detoxification Committee** had the following members:

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NOTE Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Foreword

This technical information report was developed by the AAMI Renal Disease and Detoxification Committee. The objective is to provide dialysis practitioners additional background information related to the dialysis processes described in ANSI/AAMI 23500 (proposed ANSI/AAMI/ISO 23500-1), *Guidance for the preparation and quality management of fluids for hemodialysis and related therapies,* that affect the chemical composition of dialysis fluid.

As used within the context of this document, "should" indicates that among several possibilities one is recommended as particularly suitable without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the TIR. "Can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulations.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

NOTE This foreword does not contain provisions of AAMI TIR72:2017, *Dialysis fluid chemical composition,* but it does provide important information about the development and intended use of the document.

Introduction: Need for this AAMI TIR

Dialysis fluid (dialysate) is one of many components of a hemodialysis treatment. It can have both chemical and microbiologic impacts on patients. Responsibility for quality control of hemodialysis concentrate preparation has shifted from the medical device manufacturer to the clinic, with the move to "on-site" production of the concentrate products by clinic personnel. The quality of this solution can be affected by various inputs, from production to patient treatment.

ANSI/AAMI 11663 (proposed ANSI/AAMI/ISO 23500-5), *Quality of dialysis fluid for hemodialysis and related therapies,* establishes quality requirements for dialysis fluid used in hemodialysis and related therapies. Standard dialysis fluid is the minimum acceptable quality for routine hemodialysis, with ultrapure dialysis fluid recommended. ANSI/AAMI 23500 (proposed ANSI/AAMI/ISO 23500-1), *Guidance for the preparation and quality management of fluids for hemodialysis and related therapies*, outlines the quality program management requirements for ensuring the quality of fluids, mixers, distribution systems, and dialysis equipment used for hemodialysis. These quality standards reference specified range limits for the chemical constituents of prepared dialysis fluid and the maximum allowable levels of chemical and microbial contaminants.

The labeled content of hemodialysis concentrate describes the amount of each constituent delivered under ideal conditions in dialysis fluid during hemodialysis. Variation occurring at any of the process points in the manufacture, handling, distribution, and measurement of dialysis fluid can affect the actual delivered chemical content. Standards with performance limits are established for some, but not all, process steps. This technical information report (TIR) was developed to provide background information on process factors that could contribute to variability in the chemical content of the prepared dialysis fluid, and to review strategies helpful in controlling these variables.

This TIR is directed at healthcare professionals responsible for the final preparation of dialysis fluid (e.g., dialysis facility managers, technical staff, direct care providers).

Dialysis fluid chemical composition

1 Scope

This TIR addresses the roles of manufacturing, laboratory testing, and clinical processes in relation to the production and testing of dialysis fluid for hemodialysis.

1.1 Inclusions

The TIR includes discussion of the roles, processes and materials involved in the preparation and use of dialysis fluids for hemodialysis and strategies for managing the risk of failures occurring in related process steps.

1.2 Exclusions

This TIR does not cover peritoneal dialysis fluids, prepackaged fluids, such as those used in continuous renal replacement therapies (CRRT), or sorbent-based dialysis fluid systems that regenerate and recirculate small volumes of dialysis fluid. Although microbiologic contamination is a critical component of dialysis fluid quality, it is addressed in existing standards and therefore not included in this document.

2 Definitions

For the purposes of this TIR, the following definitions apply.

2.1
acid concentrate
"A" concentrate
mixture of salts which, when diluted with dialysis quality water and bicarbonate concentrate, yields dialysis fluid for use in hemodialysis

NOTE 1 The term "acid" refers to the small amount of acid (for example, acetic acid or citric acid) that is included in the concentrate.

NOTE 2 Acid concentrate might contain glucose.

NOTE 3 Acid concentrate can be in the form of a liquid, a dry powder, other highly concentrated media, or some combination of these forms.

2.2
action level
concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels

2.3
bicarbonate concentrate
"B" Concentrate
concentrated preparation of sodium bicarbonate that, when diluted with dialysis water and acid concentrate, makes dialysis fluid used for dialysis

NOTE 1 Sodium bicarbonate is also known as sodium hydrogen carbonate.

NOTE 2 Some bicarbonate concentrates also contain sodium chloride.

NOTE 3 Bicarbonate concentrate might be supplied in the form of a liquid or a dry powder.

NOTE 4 Dry sodium bicarbonate, without added sodium chloride, is also used in concentrate generators to produce a concentrated solution of sodium bicarbonate used by the dialysis machine to make dialysis fluid.

