Technical Specification

ISO/TS 9320

Health informatics — Standardized data set for transfer of hemodialysis patients

Informatique de santé — Ensemble de données normalisées pour le transfert des patients en hémodialyse

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Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

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Introduction

Globally, the population with end-stage renal disease (ESRD) has steadily increased. Haemodialysis, which provides rapid clearance of solutes, is the most popular renal replacement therapy for ESRD patients. However, haemodialysis has a high risk of serious complications for receivers of the treatment. Well-known complications of haemodialysis include hypotension, electrolyte imbalance, infection, fluid overload, and dialysis disequilibrium. Due to these side-effects, patients who receive haemodialysis have lower life expectancy than the general population.

Moreover, haemodialysis requires a patient to frequently visit a hospital and to go through complex and time-consuming dialysis procedures. This is because patients need to know how to care for the haemodialysis access or fistula, exercise, regulate diet and monitor their blood pressure and weight. In addition, haemodialysis patients are more likely to be depressed because they are limited in many areas of their daily activities.

Referral of haemodialysis cases occurs often due to complications of chronic kidney disease, such as myocardial infarction, heart failure, atrial fibrillation and cerebrovascular accidents. Recently, a notable change in these referral cases is the increase of referrals from abroad. One of the reasons behind this increase is that haemodialysis which is done outside of a person's residential area is covered by many payers in the United States. As a result, international travel for haemodialysis is growing fast in east Asian countries.

Since haemodialysis includes a complex procedure and requires attentive monitoring, it is imperative to share important and accurate information about a patient, dialysis setup and haemodialysis access to ensure safe and timely haemodialysis. This would also allow patients who are travelling abroad for a haemodialysis to experience smooth referral.

The purpose of this document is to define the data set for referral of haemodialysis patients. This data set will ensure continuity of haemodialysis-related care. The data set provides optimal dialysate parameters and individualized dialysis settings. Providing this information can reduce the occurrence of dialysis-related complications. The data set can be used for referring haemodialysis patients, for surgery or intensive care, and it can also support safe and timely haemodialysis procedures for ESRD patients from abroad.

Health informatics — Standardized data set for transfer of hemodialysis patients

1 Scope

The document defines a data set for the safe and timely transfer of haemodialysis procedure for end-stage renal disease (ESRD) patients. The necessary information for dialysis is provided through required, conditionally-required and optional data fields of the data set. Complicated use cases are also described in this document.

This document does not cover general quality requirements or system requirements for haemodialysis.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1.1
haemodialysis
dialysis
therapy where waste solutes from the blood are removed by diffusion across an artificial extracorporeal semipermeable membrane

3.1.2
haemodialysis interval
currently prescribed interval between *haemodialysis* (3.1.1) sessions

Note 1 to entry: The interval determines how effectively waste products and fluids are cleared from the body.

Note 2 to entry: A longer interval can lead to accumulation of harmful body products and water, resulting in complications such as oedema, electrolyte imbalance and increased blood pressure.

3.1.3
dry weight
optimal or target weight that a patient should achieve during or after a treatment

Note 1 to entry: Dry weight is measured without the excess fluid that builds up between dialysis treatments.

Note 2 to entry: Dry weight is an important concept because it helps clinicians determine how much excess fluid needs to be removed during each *haemodialysis* (3.1.1) session.

3.1.4
haemodialysis machine model
information about haemodialysis machine manufacturer and model used in recent *haemodialysis* (3.1.1) sessions

Note 1 to entry: The product name of *dialysate* (3.1.9) varies depending on the machine model (the manufacturer's product).

Note 2 to entry: The information helps clinicians prescribe dialysate in the receiving unit.

3.1.5
haemodialysis blood flow rate
rate at which a patient's blood is pumped through the dialysis machine during *haemodialysis* (3.1.1) treatment

Note 1 to entry: Haemodialysis blood flow rate is typically measured in millilitres per minute (ml/min) or litres per hour (l/h).

Note 2 to entry: Clinicians need to determine the appropriate blood flow rate for each individual undergoing haemodialysis to balance the benefits and potential risks.

3.1.6
haemodialysis access type
method or route by which blood is withdrawn from the patient's body, filtered through the dialysis machine, and then returned to the patient

Note 1 to entry: Common types of haemodialysis access are arteriovenous fistula, arteriovenous graft and central venous catheter.

3.1.7
haemodialysis access site
anatomical location of *haemodialysis* (3.1.1) access

Note 1 to entry: The preferred access site for an arteriovenous fistula is usually in the forearm.

3.1.8
haemodialysis access status
condition and functionality of the access site through which *haemodialysis* (3.1.1) treatments are performed

Note 1 to entry: Monitoring and assessing access status is necessary to ensure that the access site remains functional, safe and free from complications.

Note 2 to entry: Haemodialysis access status usually refers to patency, infection, maturation and functionality.

3.1.9
dialysate
fluid used in dialysis to exchange solutes with the blood

Note 1 to entry: Dialysate is used to draw fluids and toxins out of the bloodstream and supply electrolytes and other chemicals to the bloodstream

3.1.10
initial dialysis date
date on which a patient with end-stage renal disease (ESRD) begins *haemodialysis* (3.1.1) treatment for the first time.

Note 1 to entry: Initial dialysis date is a significant event for patients, as it marks the beginning of a lifelong or long-term commitment to regular dialysis treatments.

3.1.11
blood haemoglobin concentration
concentration of haemoglobin in whole blood

Note 1 to entry: Anaemia is a common complication in patients with chronic kidney disease.

Note 2 to entry: Haemoglobin is an important determinant for iron supplementation, blood transfusion or nutritional assessment.

3.1.12
blood sodium concentration
concentration of sodium in serum or plasma

Note 1 to entry: Sodium is key for electrolytes in the body.

Note 2 to entry: *Haemodialysis* (3.1.1) patients are at risk of fluid and electrolyte imbalance due to impaired kidney function and haemodialysis process.

3.1.13
blood potassium concentration
concentration of potassium in serum or plasma

Note 1 to entry: Potassium is key for electrolytes in the body.

3.1.14
blood calcium concentration
concentration of calcium in serum or plasma

Note 1 to entry: Calcium is key for electrolytes in the body.

3.1.15
blood phosphate concentration
concentration of phosphate in serum or plasma

Note 1 to entry: Phosphate is key for electrolytes in the body.

3.1.16
venereal disease research laboratory
nontreponemal test result for screening of syphilis

3.1.17
pre-dialysis vital sign
vital sign measured before *haemodialysis* (3.1.1) session

Note 1 to entry: Vital signs can be subcategorized in "blood pressure", "heart rate", "body temperature" and "respiration rate."

Note 2 to entry: Pre-dialysis vital signs help ensure patient's safety and provide information about their readiness for haemodialysis.

3.1.18
post-dialysis vital sign
vital signs measured after *haemodialysis* (3.1.1) session

Note 1 to entry: Vital sign can be subcategorized in "blood pressure", "heart rate", "body temperature" and "respiration rate."

Note 2 to entry: Post-dialysis vital signs are needed to assess haemodialysis response and to ensure patient's safety.

3.1.19
interdialytic weight gain
amount of weight gain between two *haemodialysis* (3.1.1) sessions

Note 1 to entry: Interdialytic weight gain is the result of salt and water intake.

Note 2 to entry: Interdialytic weight gain helps clinicians assess how effectively the patient is managing fluid intake and output between dialysis sessions.

Note 3 to entry: Interdialytic weight gain is used to determine the target fluid removal for each dialysis session.

3.1.20
remark note
note containing information or precautions regarding *haemodialysis* (3.1.1), disease management and general patient-care

Note 1 to entry: A remark note is usually provided in plain text.

3.1.21
heparin concentration
concentration of an anticoagulant in *haemodialysis* (3.1.1) fluid required to prevent thrombosis in catheter, filter and circuit

Note 1 to entry: Heparin concentration usually refers to heparin bolus dose as initial and maintenance dose.

3.1.22
remnant kidney function
renal working capacity remaining after *haemodialysis* (3.1.1)

Note 1 to entry: Remnant kidney function is usually measured as daily urine output or *glomerular filtration rate* (3.1.29).

3.1.23
other laboratory results
laboratory examination of a blood sample other than those mentioned among required and conditionally-required data set

3.1.24
radiology report
text that represents the interpretation of a radiological study

3.1.25
allergy
altered bodily reactivity (such as hypersensitivity) to an antigen in response to a first exposure

3.1.26
presence of heart failure
presence of a condition in which the heart cannot pump enough blood to meet the body's needs

Note 1 to entry: *Haemodialysis* (3.1.1) patients are at an elevated risk of cardiovascular complications.

Note 2 to entry: Managing heart failure is important for fluid management, blood pressure control and dialysis procedure.

3.1.27
heart ejection fraction
measure of cardiac function reflecting the average fraction of emptying of the left ventricle with each contraction

Note 1 to entry: Heart ejection fraction is a crucial indicator of heart function and is commonly assessed using echocardiography.

3.1.28
haemodialysis access construction date
procedure date of current *haemodialysis* (3.1.1) access

Note 1 to entry: Haemodialysis access construction date helps clinicians check the duration of access use and complications that can arise over time.

3.1.29
glomerular filtration rate
calculated measure of renal function which is expressed by the total volume of fluid filtered through all renal glomeruli in a minute

Note 1 to entry: The glomerular filtration rate is usually corrected for estimated body surface area, and reported in ml/min/1,73 m^2.

3.2 Abbreviated terms

ESRD	end-stage renal disease
HD	haemodialysis
HBsAg	surface antigen of the hepatitis B virus
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
LOINC	Logical Observation Identifiers Names and Codes
FHIR	Fast Healthcare Interoperability Resources
VDRL	venereal disease research laboratory
GFR	glomerular filtration rate
NYHA	New York Heart Association

4 Significance of haemodialysis data set

4.1 General

Haemodialysis is one method of renal replacement therapy for ESRD patients. Since ESRD patients do not have functioning kidneys, patients experience symptoms such as water retention and accumulation of waste metabolites. Typically, ESRD patients require extracorporeal blood circulation that connects to the patient's vascular structures (vascular access), which are artificially constructed in the body.

The basic principle of haemodialysis is to remove unnecessary body water and toxic wastes, such as urea and creatinine, by extracorporeal filtration of patients' blood. Haemodialysis is conventionally performed and managed by highly trained staff. Furthermore, many clinics have specialized haemodialysis facilities such as high-quality water purification system and electricity system. The facility should apply additional measures to prevent microbial contamination.

Although the number of haemodialysis medical institutions and haemodialysis machines is steadily increasing, it is difficult to manage the quality of haemodialysis treatment for various reasons. Patients' lack of awareness of their dialysis data and their non-compliance to medical staff's instructions are obstacles to the improvement of patient's life quality and the reduction of mortality in ESRD patients. Additionally, ESRD patients usually suffer from severe anaemia, malnutrition, hyperparathyroidism, hyperphosphatemia, hypocalcaemia, metabolic acidaemia, hypertension and congestive heart failure at the start of dialysis. Hypoalbuminemia, anaemia and left ventricular hypertrophy are common side effects of dialysis treatment. Sometimes dialysis results in premature death. Details of these cases should be communicated through standardized data set so that this ultimately leads to improvement in dialysis treatment and better prognosis for ESRD patients.[8],[9]

4.2 Unique elements in the haemodialysis data set

There are unique data elements that exist only for haemodialysis and these elements are sometimes misleading. Procedural data is often misunderstood as observational data. Caution is required as the meaning of a specific data element can be conveyed inaccurately. Some data sets do not use standard medical terminology. Table 1 provides unique data elements which exist only in the haemodialysis domain and often lack standard terminology.

Table 1 — Unique data elements in haemodialysis

Elements	Element description and its significance
Dry weight	— Target weight of haemodialysis without fluid overload or hypovolemia. — It should not be misinterpreted as common body weight.
Haemodialysis blood flow rate	— Blood flow in haemodialysis machine. — It should not be misinterpreted as the blood flow in the patient's body. — It represents setting value in the haemodialysis machine.
Haemodialysis access	— Body site to reach the blood for haemodialysis.
Dialysate	— Kind of chemical bath used in dialysis to draw fluids and toxins out of the blood stream. — It is not considered as medication data.
Interdialytic weight gain	— Amount of weight gain as a result of salt and water intake between two haemodialysis sessions. — It is used as value to calculate target weight during haemodialysis. — It should not be misinterpreted as common weight gain.
Haemodialysis machine model	— Information of haemodialysis machine manufacturer and model. — Importance of model is often neglected. — Standard terminology not given.

4.3 Purpose of a standardized data set

Safe and timely haemodialysis requires a complex set of data and it is practically unfeasible for a patient to remember each element. Therefore, it has been a common practice to carry paper-based data when they are transferred (see Annex A). A standard haemodialysis data set benefits both patients and medical staff by electronically transferring relevant and accurate dialysis data.

Moreover, a standard haemodialysis data set can provide safe dialysis to patients by reducing the possibility of haemodialysis-related complications. Haemodialysis is a care-intensive process that requires the utmost attention to prevent various complications. For example, if haemodialysis parameters are set inappropriately, too much water can be removed from patients which can lead to hypovolemia, hypotension and fatigue. Therefore, it is critical to have data from previous dialysis about end-dialysis weight and dialysis speed. Such information can be accurately and electronically transferred from one medical institution to another using the standardized data set proposed in this document.

Timely haemodialysis is important, because delays in haemodialysis schedule can lead to worsening uraemia, increased infection susceptibility and other preventable complications. Sometimes, medical staff need to additionally contact the medical institution that issued the referral because patients did not know all the necessary information for their haemodialysis. Since the standardized data set proposed in this document provides basic parameters to start and monitor haemodialysis procedure, it can reduce the time for medical staff to prepare a haemodialysis session.

5 Use case

5.1 General

Haemodialysis transfer is a multidisciplinary process because it involves wide range of agenda, including educating a patient on diet and exercise and explaining inadvertent complications of haemodialysis to the patient's family members.

A transfer can be done for various reasons, for example if the patient needs a procedure unrelated to kidney issues or if they move to another state. It can also occur if the patient's family planned a family trip to a near-by country.

Reviewing the data elements in the proposed data set provides helpful information to medical staff, especially in the case of a haemodialysis patient who is planned to be transferred. For instance, the time between receiving the data and the patient's visit would help medical staff to evaluate risk factors for the upcoming transfer and to decide on appropriate transfer time. Sending the proposed data set to a recipient hospital is more than a simple data transfer because it helps a recipient hospital prepare for unexpected events that can occur at any step of the transfer process. Detailed information on the transfer process should be shared with the patient, and discussions can be necessary with patient's custodians.

Patients can have very different complication risks depending on their age, race and comorbidities. Some patients can develop repetitive complications by haemodialysis and can develop similar complications in the recipient hospital. Repetitive adverse events can be notified and can be prevented. Sometimes it is necessary to contact the recipient hospital to query whether all necessary medical equipment is ready for expected emergency.

5.2, 5.3 and 5.4 are intended to provide several use cases with different risks of complication.

5.2 Haemodialytic patient with no special problems

In this use case, the haemodialysis patient has had stable haemodialysis repeatedly. The patient is young. Vital signs are stable. No adverse event has been notable in repeated haemodialysis session. The patient can be transferred with only the required data set. Other fields are either conditionally-required or optional. The required, conditionally-required and optional field are further explained in Clause 6.

5.3 HIV positive haemodialytic patient

When a haemodialytic patient is HIV positive, additional measures should take place to minimize the risk of spreading HIV to other patients and clinic staff. HIV test result shall be included in the data set. Clinic staff are also required to share the information because careless contacts with the patient must be avoided. Also, a recipient haemodialysis clinic must provide a haemodialysis machine which is dedicated to HIV patients. Before referral, a physician can contact the recipient hospital for the availability of HIV haemodialysis. Since an HIV dedicated machine is equipped in limited numbers, it is imperative to check that schedules are not overlapping and that those machines are ready for the next scheduled haemodialysis.

5.4 Haemodialytic patient with refractory heart failure

Heart failure and renal dysfunction can coexist. The number of comorbidities increases over time. A critical issue with this combination is that each disease can exacerbate another. ESRD can lead to retention of water which can cause cardiac dysfunction. ESRD can also exacerbate heart failure progressively and finally make it refractory to treatment. A possible treatment approach can be to address the treatable cause of valvular heart disease. Physicians should deal with the volume of excess fluid. Patients are requested to reduce the dietary intake of salt during the transfer process. The data set which is related to heart failure shall be transmitted before transfer process. The recipient clinic shall make a decision on whether they accept the transfer. Medication should be also monitored and approximated because renal dysfunction commonly limits the use of medication on cardiac problems.

6 Data sets for transfer of haemodialysis

6.1 General

In this document, data set types are categorized as required, conditionally-required and optional. Data sets are also categorized according to when they are needed, so they are defined as needed before, during or after the haemodialysis procedure. Data sets are also categorized according to the importance of the dialysis procedure, as the focus is on the dialysis procedure rather than general health. Therefore, they may differ from general healthcare data sets. Table 2 shows the overall data tabulated and accompanied by the necessary metadata, including a glossary of terms and brief examples with code and value property. Also, more detailed exemplary data are provided in Annex B.

Table 2 — data elements for haemodialysis

Attribute name/Data element name	Coding system	Code value	Data value type	Qualifier[a]
Last dialysis date	Applicable terminology		DateTime	R
Haemodialysis interval	LOINC	LOINC 50951-9 Interdialytic time (ESRD)	DateTime	R
Dry weight	LOINC	LOINC 8341-0 Dry body weight measured	kg, lb	R
Haemodialysis machine model			Text	R
Haemodialysis blood flow rate	LOINC	LOINC 99711-4 Blood flow rate Renal replacement therapy circuit	ml/min	R
Haemodialysis access type	LOINC	LOINC 72050-8 Dialysis access	LOINC Answer List LL2169-2 ESRD-dialysis access type	R
Haemodialysis access site	LOINC	LOINC 99715-5 Dialysis access site	SNOMED Body Structure	R
Haemodialysis access status	LOINC	LOINC 99716-3 Dialysis access site appearance	LOINC Answer List LL2150-8 Access site apperance	R
Hepatitis type B antigen / antibody	LOINC	LOINC 5195-3 Hepatitis B virus surface Ag (presence) in serum	LOINC Answer List LL3865-4 True|-False|Unknown	R
Hepatitis C virus infection	LOINC	LOINC 11259-9 Hepatitis C virus RNA (presence) in serum or plasma	LOINC Answer List LL3865-4 True|-False|Unknown	R
Human immunodeficiency virus infection	LOINC	LOINC 7917-8 HIV 1 Ab (Presence) in serum	LOINC Answer List LL3865-4 True|-False|Unknown	R
Dialysis duration	LOINC	LOINC 68489-4 Dialysis hours per session	Hours	R
Dialysate	LOINC	LOINC 99732-0 Dialysate fluid renal replacement therapy circuit	Text	R
Initial dialysis date	Applicable terminology		DateTime	C (6.3.2.2)
Last laboratory test date	Applicable terminology		DateTime	C (6.3.3.2)

[a] R = required; C = conditionally required; O = optional.