# Dialysis water treatment systems and monitoring in Italy: Results of a national survey

**Article** *in* Journal of nephrology · April 2004

Source: PubMed

CITATIONS
18

READS
497

**5 authors**, including:

Francesco Pizzarelli
University of Florence
**152** PUBLICATIONS **2,522** CITATIONS

SEE PROFILE

# Dialysis water treatment systems and monitoring in Italy: Results of a national survey

*Francesco Pizzarelli[1], T. Cerrai[1], M. Biagini[2], M. Malaguti[2], R. Bargagna[2]*

[1] Nephrology and Dialysis Unit, SM Annunziata Hospital, Florence - Italy
[2] Nephrology Unit, Civitavecchia - Italy

**ABSTRACT:** ***Background:*** **The risks connected with dialysis fluid contamination are well established. Epidemiological studies have demonstrated just how difficult it is to obtain permanently satisfactory quality standards. Therefore, dialysis centers must have effective and regular quality control programs, particularly with the growing and widespread use of on-line convective dialysis treatments. Considering this, we conducted a national survey of water treatment systems and monitoring in Italian dialysis centers.**
***Methods:*** **Two independent questionnaires were prepared and distributed in 1999 and 2001. The questions were designed to acquire information on structural and procedural elements. Responses to similar questions from both questionnaires were analyzed together.**
***Results:*** **Responses to questionnaires were received from 148 centers (17% of dialysis centers in Italy). In accordance with the European Best Practice Guidelines (EBPG) published recently concerning dialysis fluid purity, in the majority of centers (97%) the water treatment system consisted of at least pre-treatment and reverse osmosis (RO) modules. However, only one stage RO module was implemented (71%), there was a water storage tank (65%) and with water pipe distribution loops made of sanitary polyvinyl chloride (85%). Analysis of procedural elements – the timing and type of disinfection procedures used for the waterline system and monitors, the timing and type of water treatment quality control procedures – revealed a striking variability among centers in terms of the types and frequency of checks performed.**
***Conclusions:*** **Taking into account the EBPG, this survey revealed both good and bad elements, calling for a national initiative aimed at defining a standard periodicity of loop disinfection, points in the water pipe line to be tested, and the frequency and type of tests.**

**Key words:** *Dialysis fluid monitoring, Dialysis fluid quality, Hemodialysis, Quality, Sterility, Water*

## INTRODUCTION

Epidemiological studies investigating the quality of the dialysate produced in dialysis centers in various countries (1-4) demonstrated just how difficult it is to achieve permanently satisfactory quality standards. The difficulty of maintaining adequate quality standards is more disturbing when we consider that the risks connected to dialysis fluid contamination are well-established and classified (5-10).
The problem broadens if we consider the growing development and widespread use of on-line convective dialysis treatments. In terms of the situation in Italy, following the initial experimentation in the late 1980s and early 1990s (11-14), recently in a significant number of Italian dialysis centers on-line convective methods have progressively replaced "conventional" convective therapies, for example, treatments with re-infusion fluid derived from commercial bags.
With the advent of on-line re-infusion, not only has there been an increase in the awareness of the risks associated with low quality liquid use, but experts have also started to consider dialysis liquid purity as one of the elements, in the overall biocompatibility of dialysis therapy. This has had an impact on the standards now in force: water for dialysis is a therapy administered to the patient like any other drug, and the preparation and distribution system is considered a medical device (15, 16).
In considering this, it seemed to us to be of primary

importance to conduct a national survey on water treatment systems and water treatment monitoring and maintenance in Italian dialysis centers.

## Material and methods

Two members of our team prepared a questionnaire and it was distributed in 2001 making use of logistic support from Fresenius Medical Care, Italy.
The questions were designed to acquire information on:
*Structural elements:*
- Technical design of water treatment systems.

*Procedural elements:*
- Timing and type of disinfection procedures used in the water line system and HD proportioning machines;
- Timing and type of water treatment quality control procedures.

In addition, we were able to use data from a similar study conducted by some of our team in 1999 aided, at that time, by logistic support from the Baxter company. Responses to similar questions from both questionnaires were analyzed together.
Unless otherwise indicated, the percentages reported for replies refer to the total sample analyzed, i.e. from both questionnaires.

## Results

### *Representivity of the sample*

Responses to this questionnaire and the previous one came from, respectively, 87 and 61 centers. The 148 centers involved in the study comprised 17% of the 875 dialysis centers in Italy, while the percentage of patients dialyzed in the selected centers was much higher, approximately 30% of the Italian dialysis population.
The geographic distribution of the sample was 55 dialysis centers in the north, 40 in the center, and 53 in the south and islands, a distribution of, respectively, 37%, 27% and 36%. These percentages do not fully reflect the geographic distribution of Italian dialysis centers: 21% in the north, 26% in the center and 53% in the south of Italy. Private centers accounted for 29% of the sample, in accordance with the fact that 30% of Italian dialysis centers are privately run.

### Structural parameters

Figure 1 shows tap water treatment systems. Seventy-one percent of centers used a single system, in particular, reverse osmosis (RO) in the majority of cases. A double water treatment system (double RO or single RO combined with an ion exchange deionizer) was used in 28% of centers. A water storage tank was used by 65% of centers. Eighty-five percent of centers reported that their deionized water pipe distribution loops were made from sanitary polyvinyl chloride, while only 15% used more inert materials (Fig. 2).
Regarding the questions concerning structure, 133/148 centers (90%) responded.

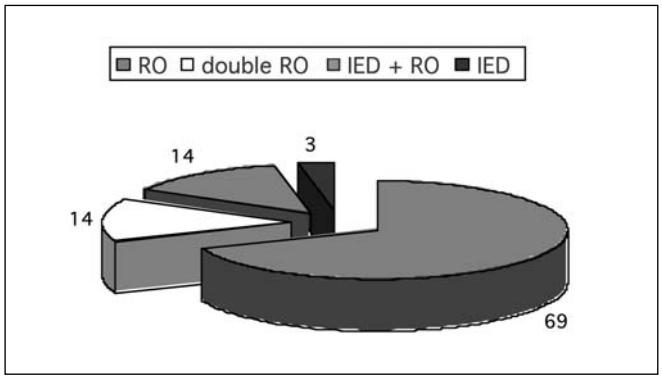


**Fig. 1 - Percentage of centers using different tap water treatment systems.**
**RO = reverse osmosis; IED = ion exchange deionizer.**

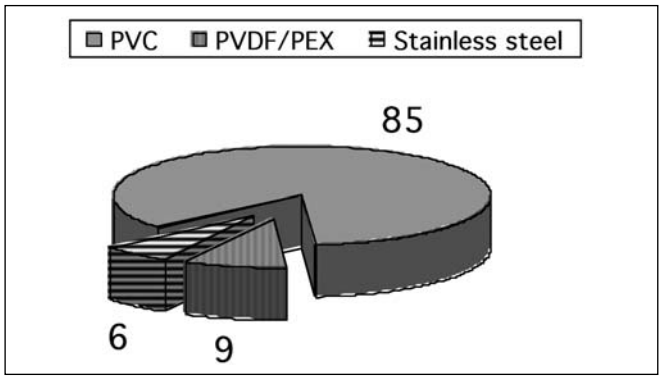


**Fig. 2 - Percentage of centers using different water pipe distribution loop materials.**
**PVC = sanitary polyvinyl chloride, PVDF = polyvinylidene fluoride.**

### Process parameters

#### *Disinfection of water storage tank and water pipe distribution loop*

Eighty-eight percent of those centers that used a water storage tank stated that they chlorinated the water in storage. Moreover, 72% stated that overnight the water in the water pipe distribution loop was stationary, and of these 74% (approximate-

ly 50% of the total sample), did not practice any form of daily disinfection of the overnight stationary water. The response rate to this question was 134/148 centers (91%). Table I shows the frequency of loop disinfection, based on 127 responses (86%).

### *Disinfection of monitors*

The vast majority (93%) of centers used sterile bicarbonate concentrate solution or powder, and 86% reported that they used disinfection protocols suggested by the manufacturers of the monitors, while the remaining 14% used internal protocols. Ninety-two percent of centers performed a complete disinfection at the end of every dialytic session, while 8% used washing only between dialytic sessions and disinfection only at the end of the day. These questions were asked only in our recent questionnaire, and 85/87 centers (98%) responded.

### *Types of testing*

Table II shows the number and the percentage of centers that performed testing at each of the four major points of the water pipe line. Note that 32/148 centers (22%), did not respond to this question and that if we break the data down by center only 25% of centers analyzed the water at all four points, while 13% reported analyzing it at one point only: either deionized water (8%) or dialysis fluid at the dialyzer inlet (5%).
Figure 3 shows the typology of the testing performed. A summary of the data demonstrates that 118 centers (94%) checked the microbiology, 74 centers (59%) checked the chemistry, and 71 centers (56%) performed an endotoxin check by LAL testing.
Finally, Table III shows the frequency (%) in which the centers performed the various checks. This question was asked in our current questionnaire only, and 84/87 centers (96%) responded.

## Discussion

It is now well established that dialysis fluid quality depends on a complex chain of devices and procedures, which includes the water treatment system, the deionized water pipe distribution loop, the HD proportioning machine characteristics, the electrolyte concentrate characteristics, the dialyzer biocompatibility and, last but by no means least, the quality control procedure implemented.
According to the European Best Practice Guidelines (EBPG) on dialysis fluid purity published recently (17), "Success in achieving dialysate purity on a

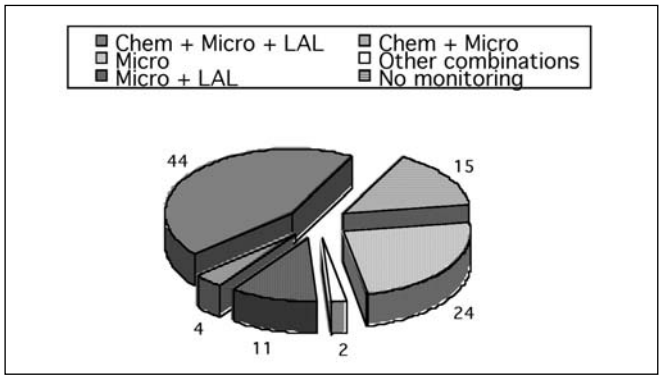


**Fig. 3 - Percentage of centers performing different typology of monitoring.**
**Chem = chemistry, Micro = microbiology, LAL = endotoxin check by limulus amoebocyte lysate assay.**

**TABLE I** - FREQUENCY OF DISINFECTION OF THE DEIONIZED WATER PIPE DISTRIBUTION LOOP

| Frequency | No. centers | % |
|---|---|---|
| <1 month | 27 | 18.2 |
| <2 months | 45 | 30.4 |
| <3 months | 19 | 12.8 |
| <6 months | 22 | 14.9 |
| >6 months | 14 | 9.5 |
| No reply | 21 | 14.2 |

**TABLE II** - NUMBER AND PERCENTAGE OF CENTERS THAT PERFORM TESTING AT EACH OF THE FOUR MAJOR POINTS OF THE WATER PIPE LINE

| | No. centers | % |
|---|---|---|
| Tap water | 57 | 39 |
| Treated water | 101 | 68 |
| Dialysate IN | 94 | 64 |
| Dialysate OUT | 38 | 26 |

**TABLE III** - PERCENTAGE OF CENTERS ACCORDING TO THE FREQUENCY OF THE VARIOUS CHECKS

| Frequency | Chemistry | Microbiology | LAL test |
|---|---|---|---|
| 1 month | 17 | 25 | 9 |
| 2 months | 9 | 12 | 3 |
| 3 months | 27 | 27 | 25 |
| 4 months | 4 | 3 | 3 |
| 6 months | 11 | 7 | 12 |
| 12 months | 5 | 2 | 3 |

long-term basis relies on a quality assurance process that involves all dialysis staff members, requires strict protocols, a permanent documentation of results and quick corrective actions when results deviate from their norm."

This study reports the results of two independent investigations concerning the impact these aspects have on Italian dialysis centers.

Overall, our study covered only 17% of Italian dialysis centers with centers in the north and south overestimated and underestimated, respectively. Therefore, the question arose as to what extent our survey was representative of the Italian situation. We filed two independent questionnaires administered 2 yrs apart with a balance of public and private dialysis centers. This should minimize, but not avoid, a positive selection bias. Moreover, the questionnaire was mainly distributed to nephrology units and not to small satellite, dialysis facilities. Accordingly, the number of patients on dialysis in the centers surveyed was approximately 9500, i.e. nearly 30% of the Italian dialysis population, a much higher figure and a more representative one.

The results of our study revealed both good and bad elements in the structural characteristics of the standard Italian dialysis center. In almost all centers (97%), the water treatment system consists of at least pre-treatment and RO modules, in accordance with the EBPG. However, in the majority of centers:

- only one stage RO module was implemented;
- there was a water storage tank;
- water pipe distribution loops consisted of sanitary polyvinyl chloride.

This profile reflects the fact that the majority of Italian centers were designed and the service implemented many years ago; therefore, not in accordance with the EBPG advice to avoid water storage tanks and obtain ultra-pure water by double-stage RO modules (17).

However, we should stress that there is no reliable data in the literature indicating the necessity of these measures. It is fact that for years, extensive use has been made of high-flux dialysis in Italy, which includes significant backfiltration and backdiffusion (18), with no reports concerning the high percentage of pyrogenic reactions typical of the US (1). In Italy, it is likely that the increasingly extensive use of monitors incorporated with an ultrafilter for cold dialysate filtration has contributed significantly to this good result. Moreover, the recommendation that "storage tanks should be avoided" (17) should be reconsidered taking into account the Italian and European water crisis in the summer of 2003, and, in particular, since the future outlook for the planet's water resources is far from rosy.

We did not enquire about when the water treatment systems were implemented; therefore, we cannot stratify some of the results according to this parameter.

Concerning procedures, which are much easier to change than structures, the responses to the questionnaire provided serious considerations. It emerged that approximately 8% of Italian centers did not disinfect the water held in the storage tank, and that in about half of the centers, deionized water remained stationary in the distribution loop overnight and on weekends, with no sterilization, contrary to recommended practice (17).

Errors of this kind are easily corrected. It is preferable that water preparation systems in Italian centers should be fitted with pumps that allow disinfectants to be easily infused into the tank and the loop, and to take measures to ensure a continuous or intermittent water flow in the distribution loop overnight and at weekends.

It is possible that the internal protocols for the sanitation of the monitors used in 14% of centers were superior to those suggested by the manufacturers. However, it is desirable that the protocols proposed by the providers be used, especially because monitors and dialytic procedures are devices (15, 16); and therefore, insurance coverage in cases of accidents is guaranteed only if there has been rigorous compliance with the procedures advised by the manufacturer.

We believe that non-sterile concentrates should be abolished and that monitors should be sterilized after every dialysis session, procedures that were not applied in approximately 8% of centers. On these grounds, it should be kept in mind that no disinfectant has simultaneous optimum bactericidal, fungicidal, sporocidal and virocidal actions.

Last but by no means least, the variability in terms of the types and the frequency of checks performed is striking. It is particularly disturbing that approximately 40% of Italian centers reported that they did not perform any chemical or limulus amoebocyte lysate (LAL) testing of the water treated. The remarkable disparity in the frequency of testing, from 1 month to 1 year, does not indicate good quality.

This situation calls for the urgent definition of national guidelines concerning:

- standard periodicity of loop disinfection;
- points in the water pipe line to be tested;
- frequency and type of tests.

This study did not collect data on outcomes; and therefore, we are not in a position to correlate structural and procedural characteristics with outcome parameters. However, a recent study of dialysis centers in Uruguay (19) demonstrated that just the implementation of a monitoring system resulted eventually in a significant improvement in the microbiological quality of the dialysis fluid produced. The Uruguayan study was, it should be noted, an observational and not an interventional study, demonstrating that the simple awareness of a problem is the first step towards its solution.

In conclusion, dialytic therapy is becoming an ever more complex treatment administered to patients with constantly increasing comorbidity. Therefore, it is an area in which outcomes heavily depend on the correct synthesis of purely technological aspects with more specific sanitary aspects. The cooperation between the various professional stakeholders is a means to achieve quality control and assurance, and this is increasingly true, the more on-line re-infusion fluid becomes the standard for convection-based treatments.

*The AA declare that they do not have a conflict of interest with the Fresenius MC Italia and Baxter companies, who lent support in the distribution of the questionnaires.*

**ACKNOWLEDGEMENTS**

The contribution to this survey of the nephrologists of the Vision club is greatly valued. The AA extends sincere thanks to Dr. Paolo Cogliati and Dr. Stefania Cortesi, of the Medical Division of FMC Italia, for their personal contribution to the accomplishment of the study.

Address for correspondence:
*Francesco Pizzarelli, MD*
*UO Nefrologia e Dialisi*
*Ospedale SM Annunziata*
*Via dell'Antella*
*Firenze, Italia*
*fpizzarelli@yahoo.com*

**REFERENCES**

1. Baurmeister U. Dialysate contamination and backfiltration may limit the use of high-flux dialysis membranes. ASAIO Trans 1989; 35: 519-22.
2. Bambauer R, Schauer M, Jung WK, Daum V, Vienken J. Contamination of dialysis water and dialysate. A survey of 30 centers. ASAIO Trans 1994; 40: 1012-16.
3. Laurence RA, Lapierre ST. Quality of hemodialysis water a 7-year multicenter study. Am J Kidney Dis 1995; 25: 738-50.
4. Arvanitidou M, Spaia S, Katsinas C et al. Microbiological quality of water and dialysate in all hemodialysis centers of Greece. Nephrol Dial Transplant 1998; 13: 949-54.
5. Keshaviah P, Luehmann D. The importance of water treatment in haemodialysis and haemofiltration. Proc EDTA-ERA 1984; 21: 111-31.
6. Bommer J, Ritz E. Water quality - a neglected problem in hemodialysis. Nephron 1987; 46: 1-6.
7. Lonnemann G, Krautzig S, Koch KM. Quality of water and dialysate in hemodialysis. Nephrol Dial Transplant 1996; 11: 946-9.
8. Cappelli G, Perrone S, Ciuffreda A. Water quality for on-line haemodiafiltration. Nephrol Dial Transplant 1998; 13 (suppl 5): S12-6.
9. Brunet P, Berland Y. Water quality and complications of haemodialysis. Nephrol Dial Transplant 2000; 15: 578-80.
10. Jochimsen EM, Carmichael WW, An J et al. Liver failure and death after exposure to microcystin at a hemodialysis center in Brazil. N Engl J Med 1998; 338: 873-8.
11. Rindi P, Pilone N, Ricci V, Cioni L. Clinical experience with a new hemodiafiltration (HDF) system. ASAIO Trans 1988; 34: 765-8.
12. David S, Caserta C, Cambi V. Preparazione estemporanea di soluzioni sterili ed apirogene di sostituzione. In Liquido di dialisi liquidi di sostituzione. Milan: Wichtig Ed 1989; 59-64.
13. Pizzarelli F, Cerrai T, Dattolo P, Neri V, Maggiore Q. L'emodiafiltrazione con preparazione on-line del reinfusato è fattibile e sicura. In La Greca G, Petrella E, Cioni A eds. I Liquidi nella dialisi. Milan: Ghedini 1992; 131-7.
14. Pizzarelli F, Cerrai T, Dattolo P, Tetta C, Maggiore Q. Convective treatments with on-line production of replacement fluid: a clinical experience lasting 6 years. Nephrol Dial Transplant 1998; 13: 363-9.
15. Pirovano D. Regulatory issues for on-line haemodiafiltration. Nephrol Dial Transplant 1998; 13 (suppl 5): S21-3.
16. D.L. 24.2.1997, n° 46. Attuazione della direttiva 93/42/CEE, concernente i dispositivi medici. G.U. 6.3.97 serie generale n° 54.
17. European Best Practice Guidelines for Haemodialysis (part 1). Section IV. Dialysis fluid purity. Nephrol Dial Transplant 2002; 17 (suppl 7): S45-62.
18. Ronco C, Brendolan A, Feriani M et al. A new scintigraphic method to characterize ultrafiltration in hollow fiber dialyzers. Kidney Int 1992; 41: 1383-93.
19. Zunino P, Beltran L, Zunino L et al. Microbiological quality of hemodialysis water in a three-year multicenter study in Uruguay. J Nephrol 2002; 15: 374-9.

*Received: 2004*
*Revised: 2004*
*Accepted: 2004*