

Central dialysis fluid delivery system

“Japanese experience, 40 years”

Hideki Kawanishi

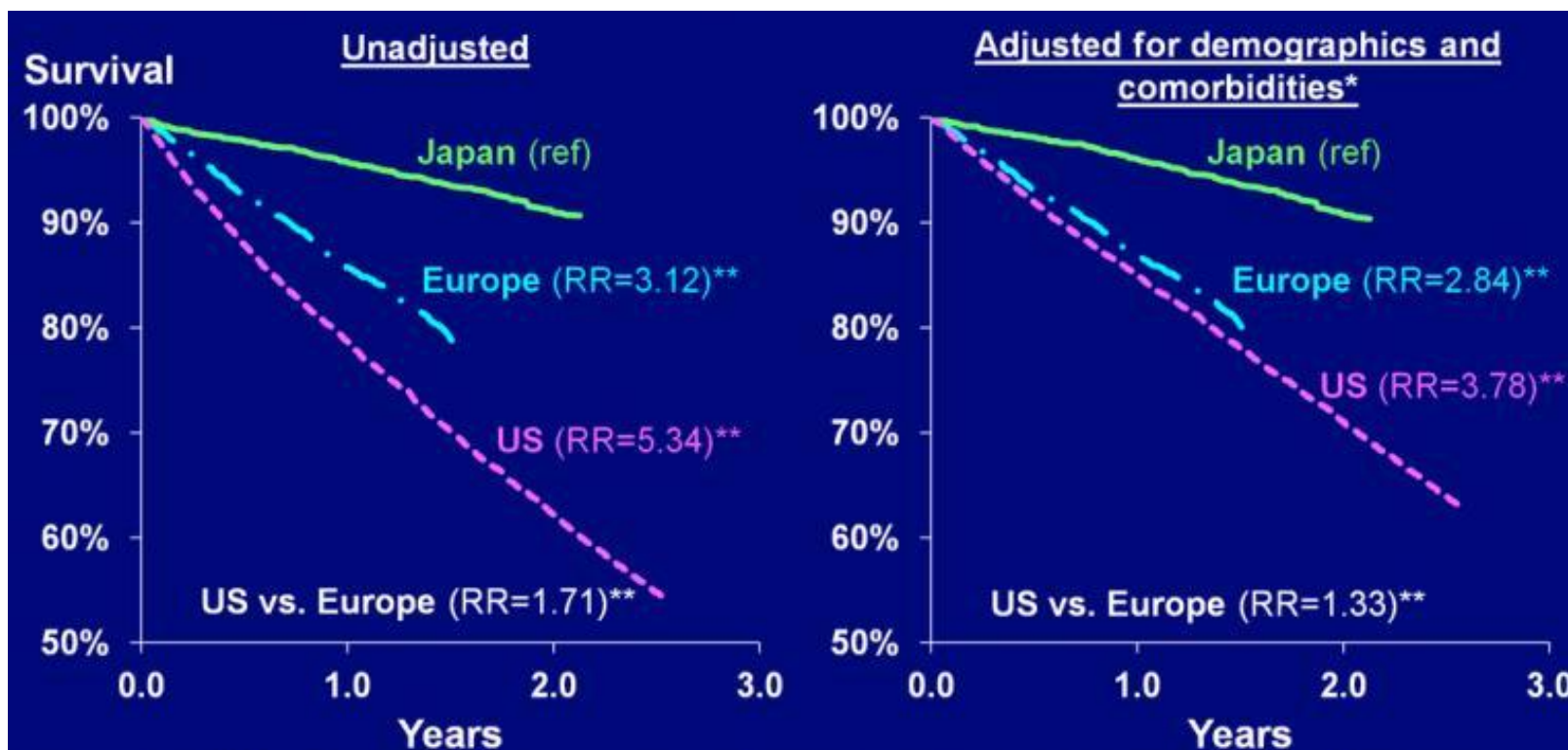
Tsuchiya General Hospital , Hiroshima

2011, in Beijing

Introduction

- It is widely known that the survival rate of Japanese HD patients is the highest in the world.
- This is mainly due to the development of dialysis and blood purification devices and preparation of the dialysis system.
- Cooperation among academic societies, the clinical engineering technologists, and industries has also played a significant role.
- Especially, the introduction of the central dialysis fluid delivery system (CDDS) in the 1960s realized the provision of stable dialysis conditions for all patients, which made a marked contribution.

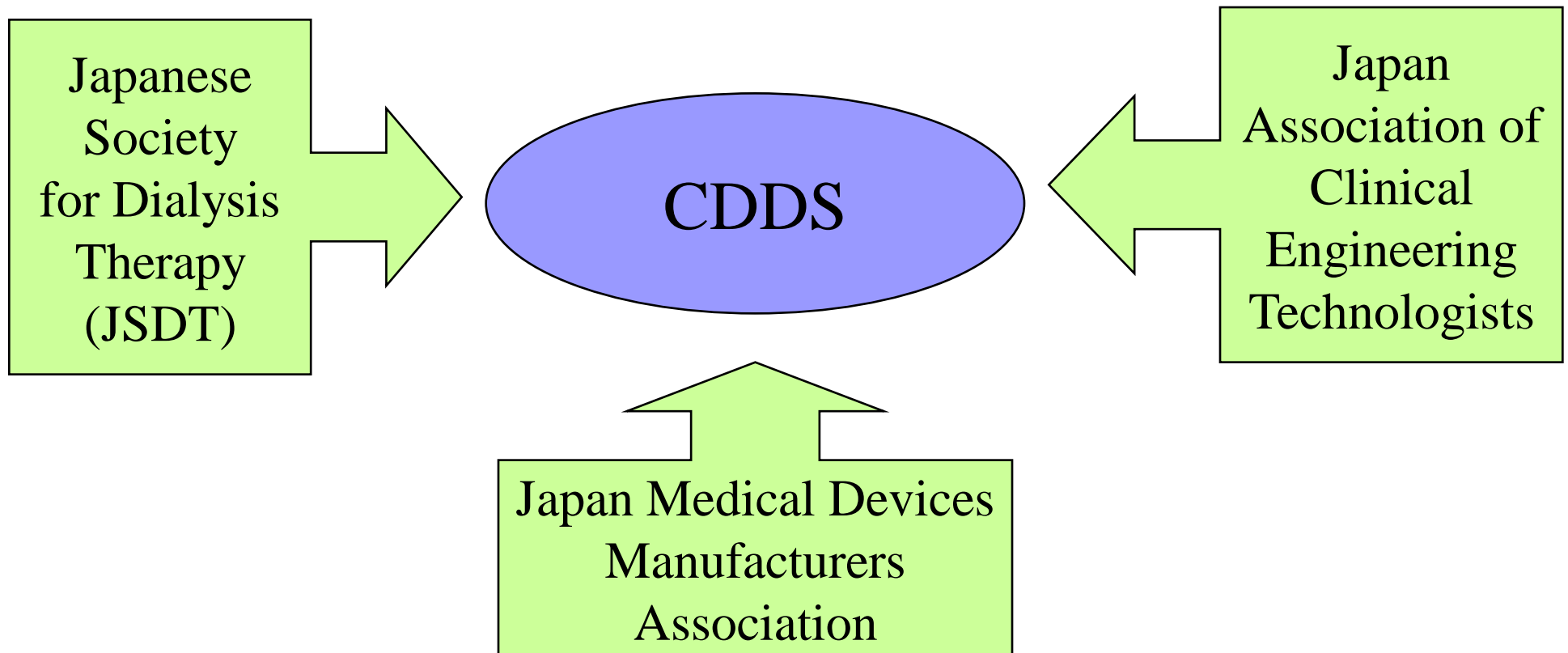
DOPPS; survival rate of HD



Data from DOPPS I (1997 through 2001). *Cox proportional hazards model adjusted for age, male gender, black race, coronary artery disease, congestive heart failure, other cardiac disease, left ventricular hypertrophy, cardiomegaly by x-ray, hypertension, cardiovascular disease, peripheral vascular disease, diabetes, lung disease, dyspnea, smoking, cancer, HIV/AIDS, gastrointestinal bleed, peptic ulcer disease, hepatitis B, hepatitis C, neurologic disorder, psychiatric disease, recurrent cellulitis or gangrene, and vision problems. ** $P < 0.001$.



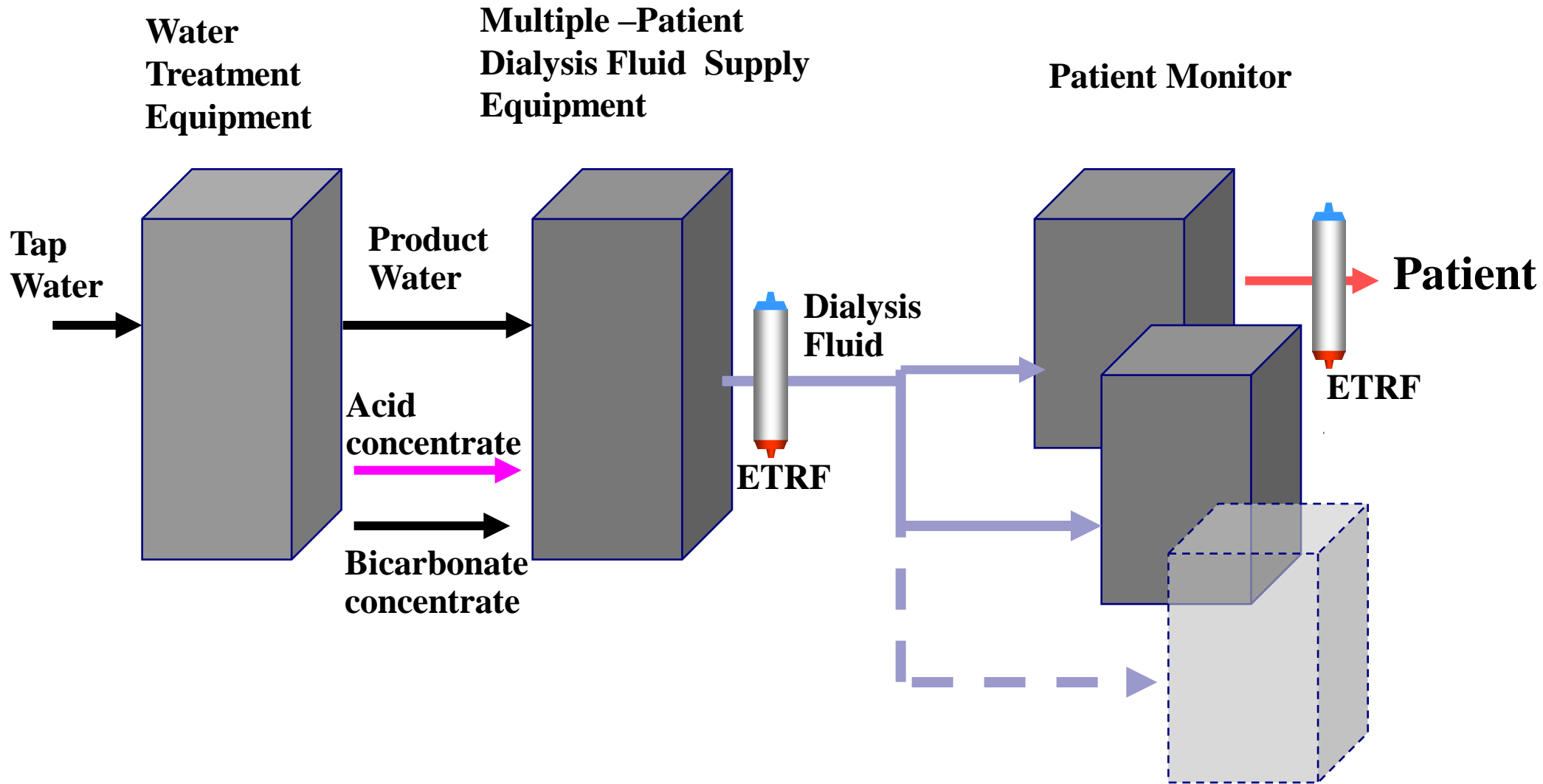
Joint; Physician, clinical Engineer & Industry in Japan



Agenda

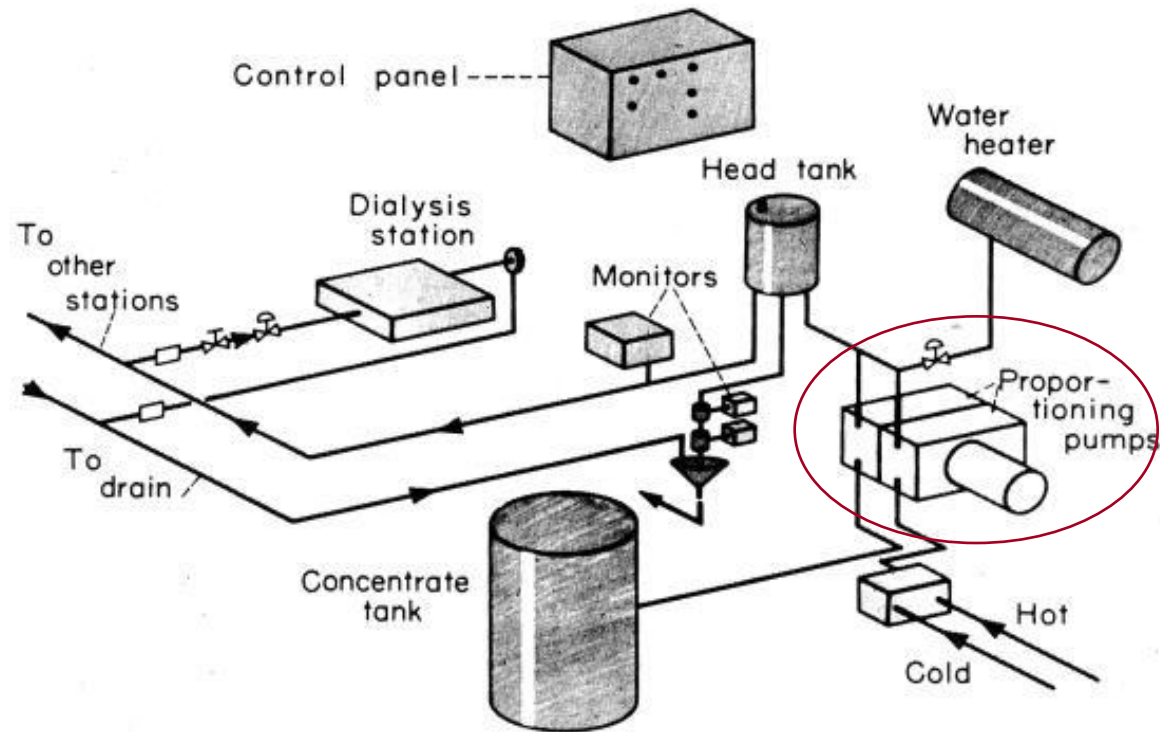
- Why we selected CDDS.
- Issues and benefit of CDDS
- Present status of CDDS in Japan
- Water quality standards for CDDS in Japan

Scheme of Central dialysis fluid delivery system (CDDDS)



Historical CDDS

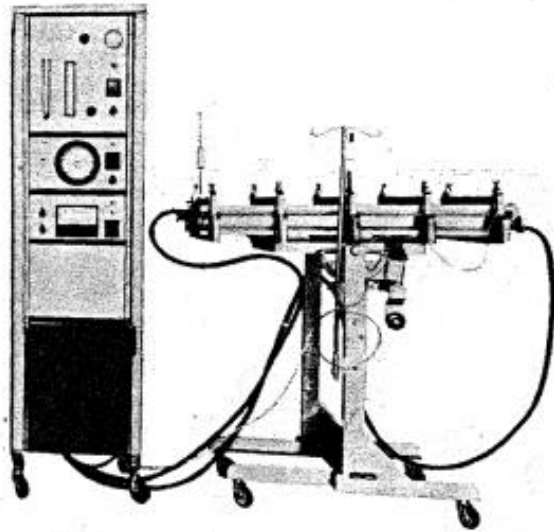
Grimsrud L, Cole J, Lehman G, Babb A, Scribner B. Trans Am Soc Artif Int Organs 1964



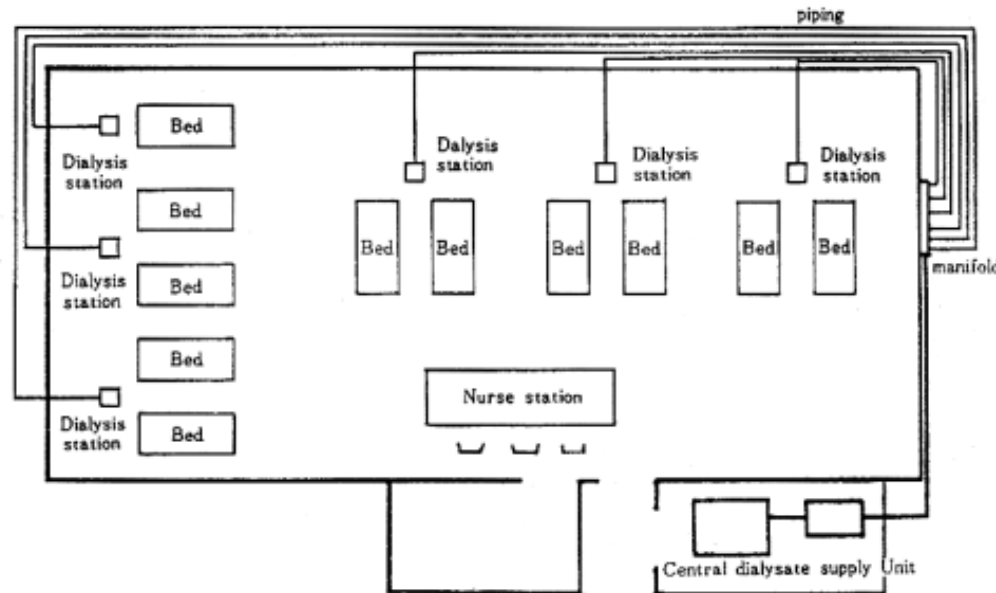
Central system for continuous preparation and distribution of dialysis fluid

CDDS was started in Japan at 1967 in Hiroshima

- We learned dialysis system from Dr Scribner & Seattle group
- 1967: First hemo-dialysis, 4 patients
- 1968: Central dialysis fluid delivery system, 6 bed-side monitor



Sweden Freezer console & Kiil dialyzer



Sweden Freezer central dialysate supply unit



Sweden Freezer bedside console & Kiil dialyzer



From 1967 to 1988 in Tsuchiya Hospital

1970 in Hiroshima

The hemodialysis center of Akanekai Tsuchiya Hospital in Hiroshima city is the biggest hemodialysis unit in Japan. Dialysis facilities in Akanekai Tsuchiya Hospital consist of a Sweden-Seattle Central Dialysate Supply System and ten hemodialysis stations. We have experienced 50 patients in total from December, 1967 through December, 1969. Thirty-six of them are in excellent or good condition, 8 are in fair or poor condition and 6 expired. Staff members of our dialysis center are two full time physicians, two part-time assistant physicians, thirteen nurses and three technicians. Dialysis is performed for 24 hours per day, six days per week.

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Dr. Tsuchiya



It is being planned in Japan to establish three hemodialysis centers on the same large-scale as that of Tsuchiya Hospital by the end of 1970. These will be located in the eastern, middle and western parts of Japan respectively. This project will serve many more patients with chronic kidney disease.

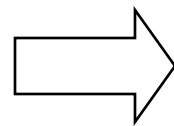
Japanese facilities mainly use CDDS

Dialysis map at 1968 data from JSDT

Total number of bedside console : 110 / 50 facilities

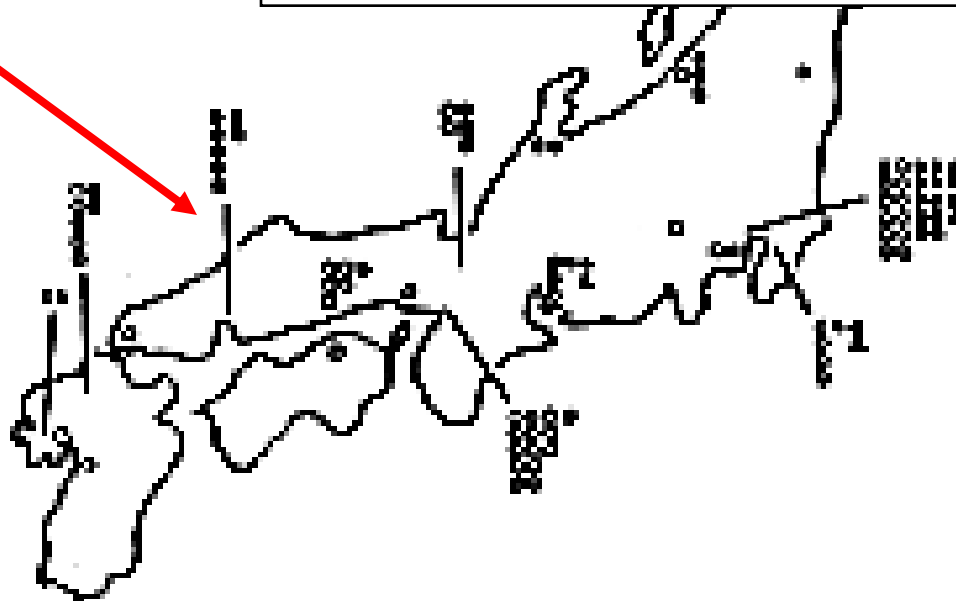
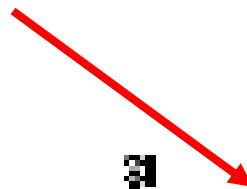
Central supply system 28 (56%) facilities

Hiroshima



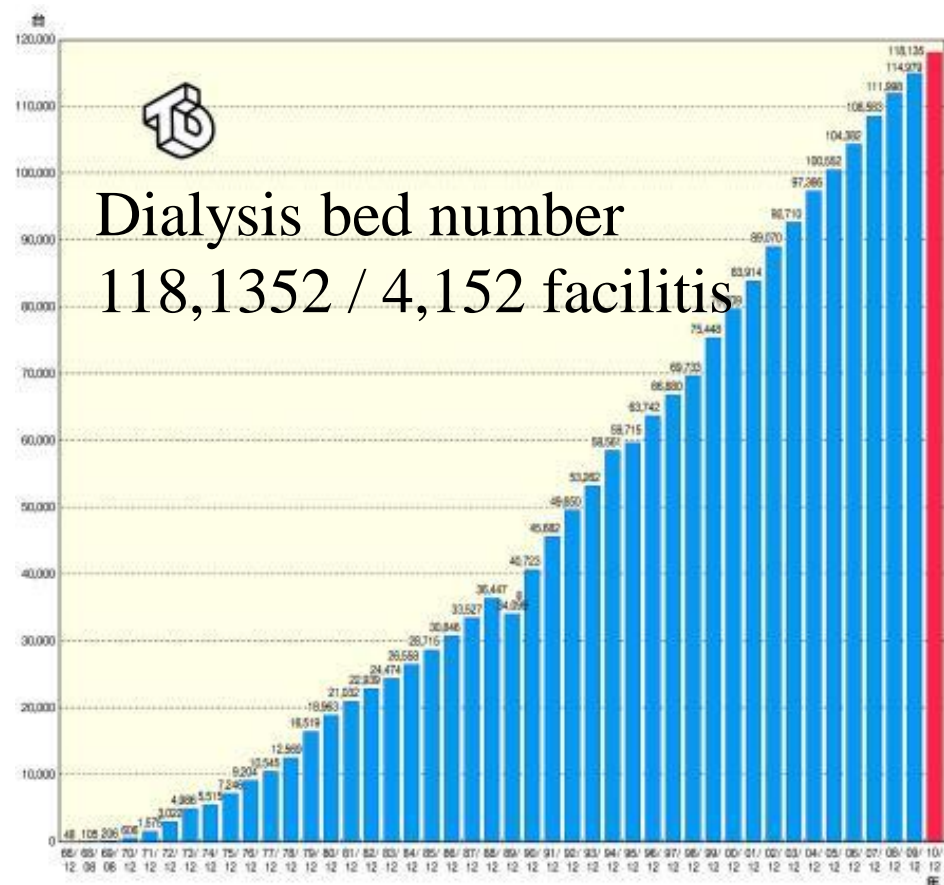
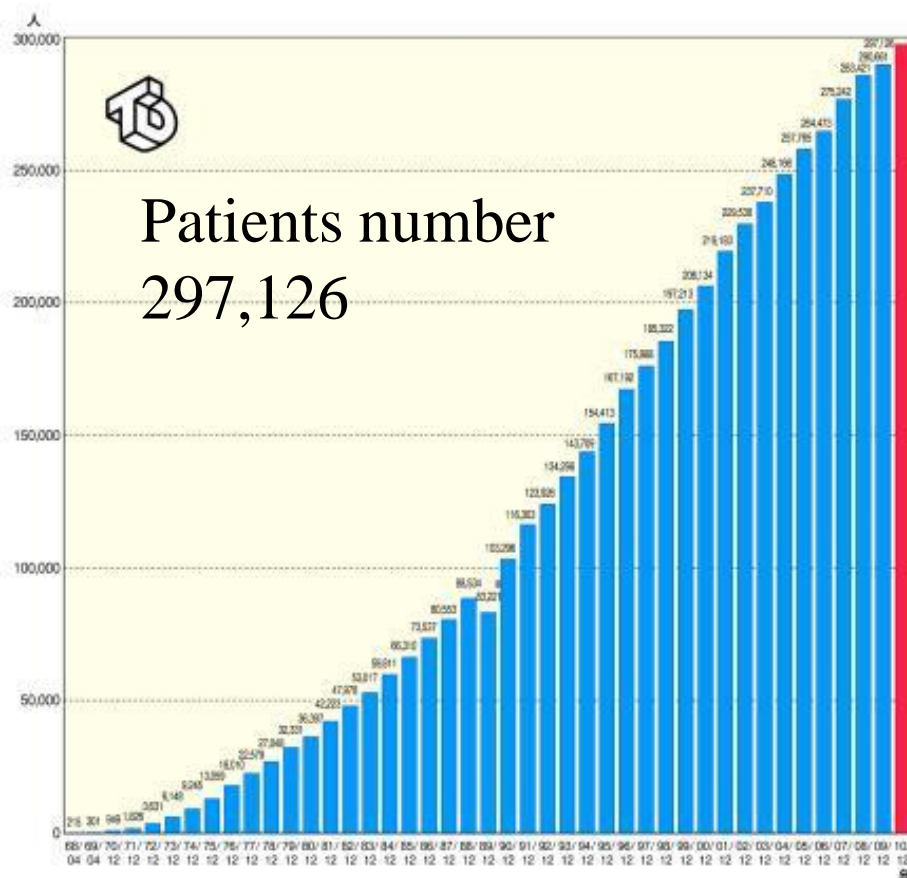
End of 2010

Dialysis bed 118,1352 / 4,152 facilities

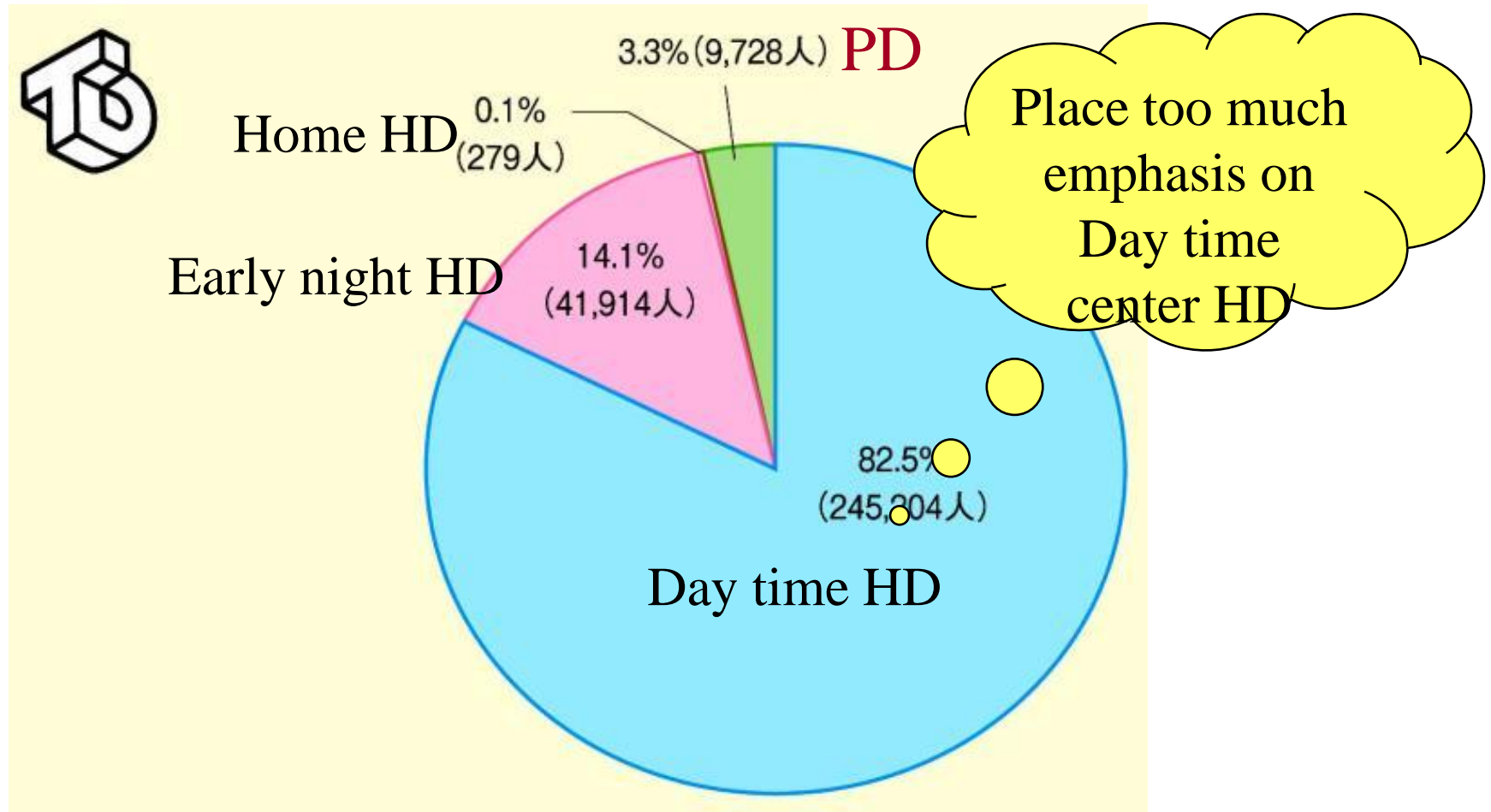


Dialysis population and bed number in Japan

Data from JSDT end of 2010



Type of modalities of dialysis population



Dialysis center used CDDS

Place too much emphasis on Day time center HD



Why we selected and able to select CDDS.

- Excessive number of dialysis patients in small islands.
- Place too much emphasis on center day time HD patients.
 - Space and cost effective to increase number of patients.

Issue of CDDS

- CDDS are usually more cost effective, but suffer from the disadvantage that a malfunction of the central proportioning unit will simultaneously affect several patients with discontinuation of dialysis at these patient station.
- Also, central systems do not allow for individualization of dialysis composition to meet unique patient needs.

By Keshaviah P, in Clinical Dialysis 1990



Advantage and disadvantage of CDDS compared single-patients system

■ Advantage

- Cost effective
- Maintenance is simple and easy, if the system is placed completely
- Labor saving of medical staff
- Automated operation system

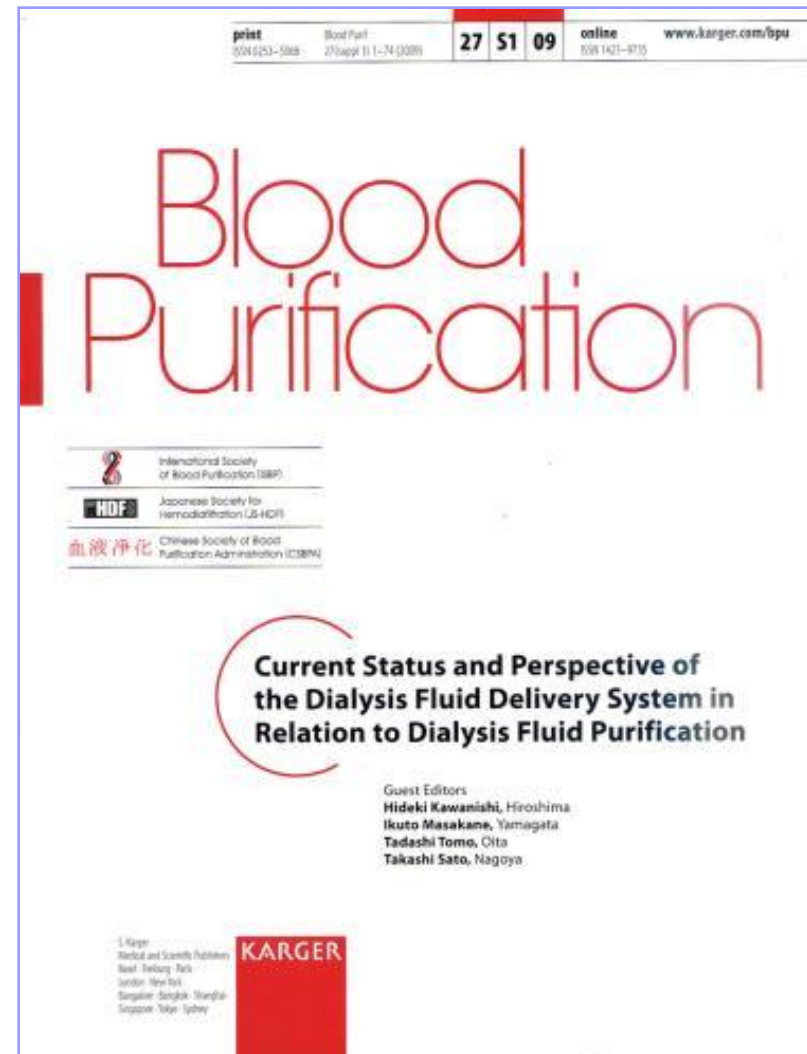
■ Disadvantage

- Dialysate composition; no permission to individual
- Machine dysfunction affects all patients
- Microbial: risk of long dialysis piping for contaminations

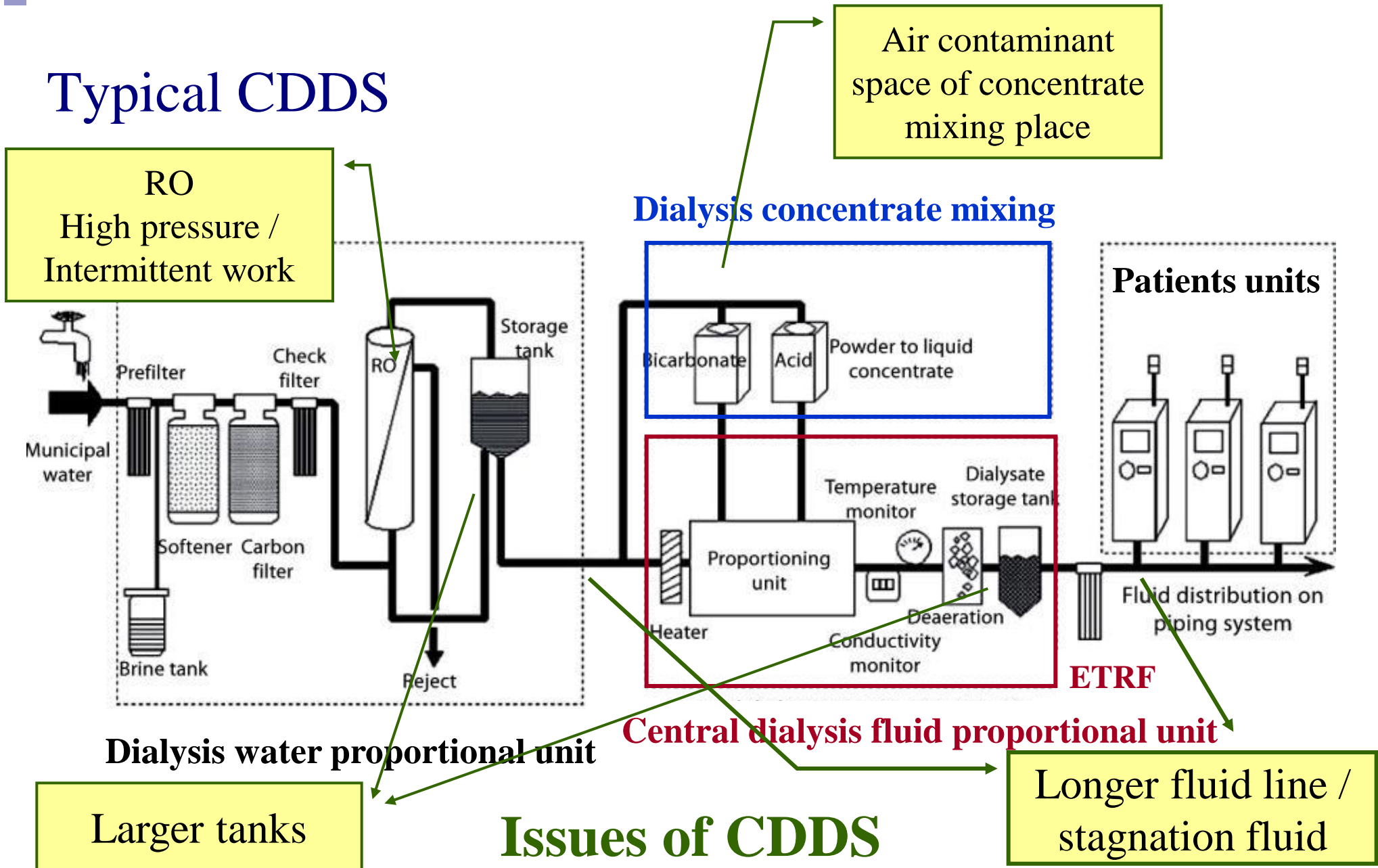
Current status and preparation of the dialysis fluid delivery system,

Kawanishi H et al., Blood purif 2009 (suppl 1)

■ CDDS condition in Japan



Typical CDDS



Air contaminant space of concentrate mixing place

RO
High pressure / Intermittent work

Dialysis concentrate mixing

Patients units

ETRF

Central dialysis fluid proportional unit

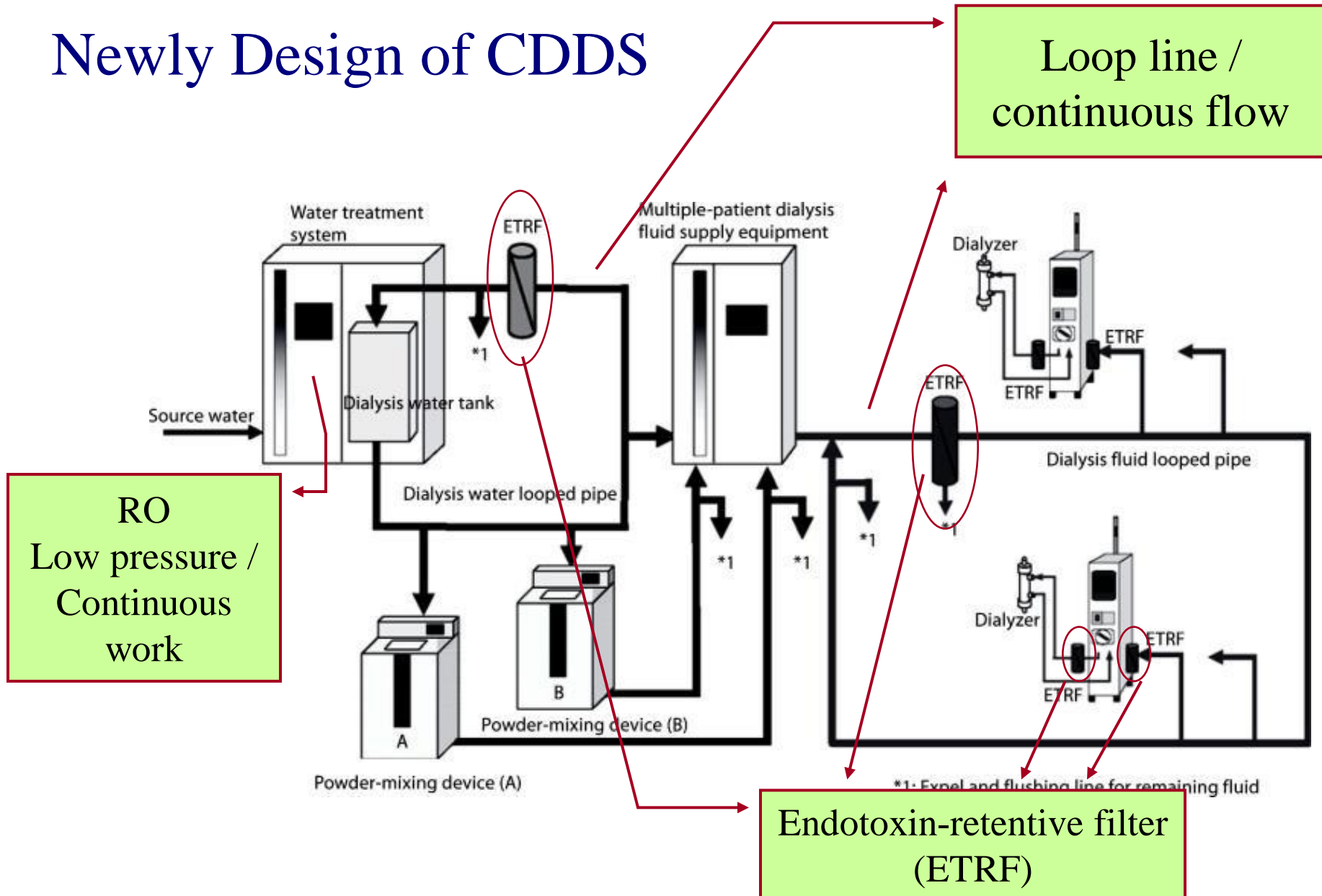
Dialysis water proportional unit

Longer fluid line / stagnation fluid

Larger tanks

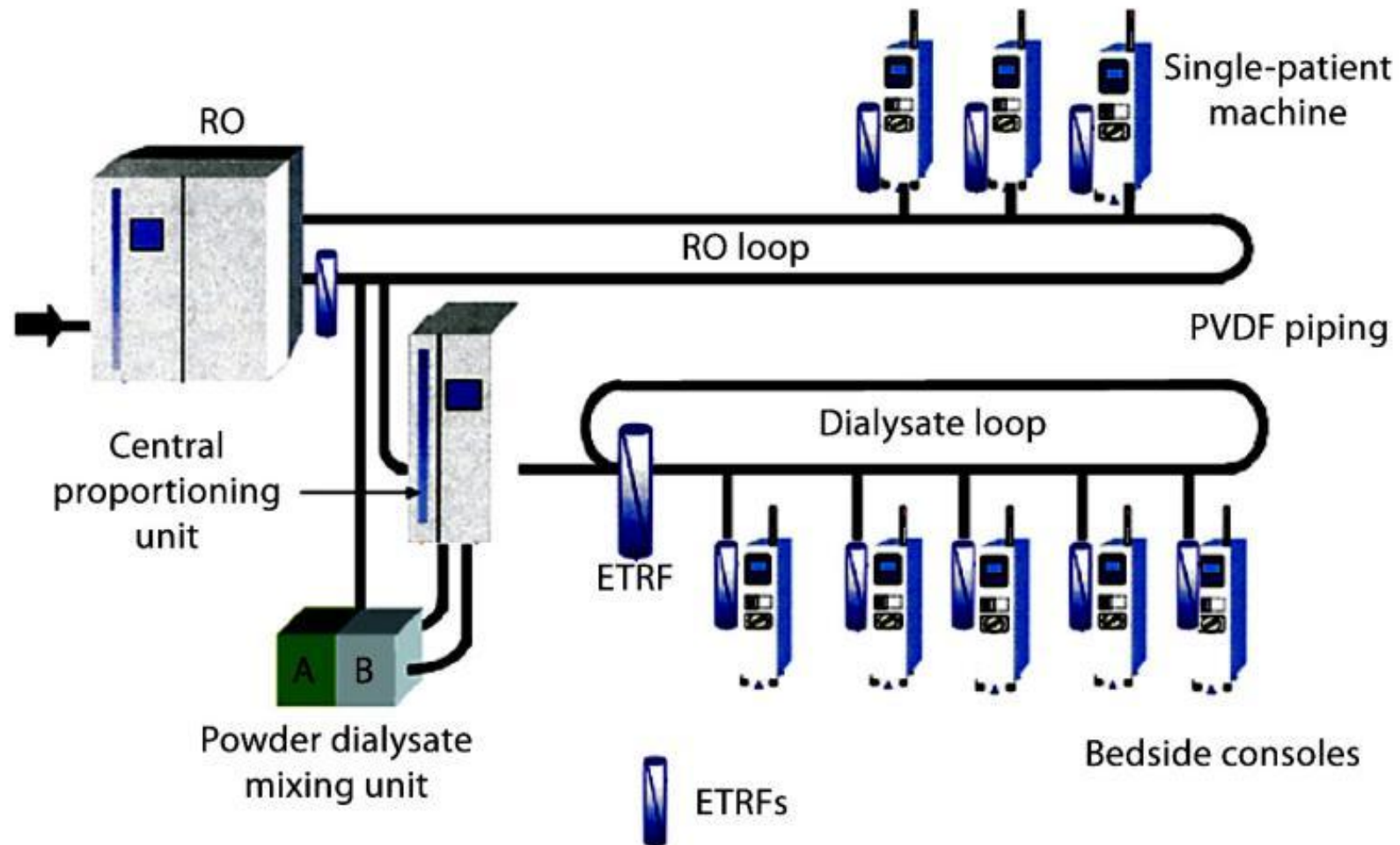
Issues of CDDS

Newly Design of CDDS



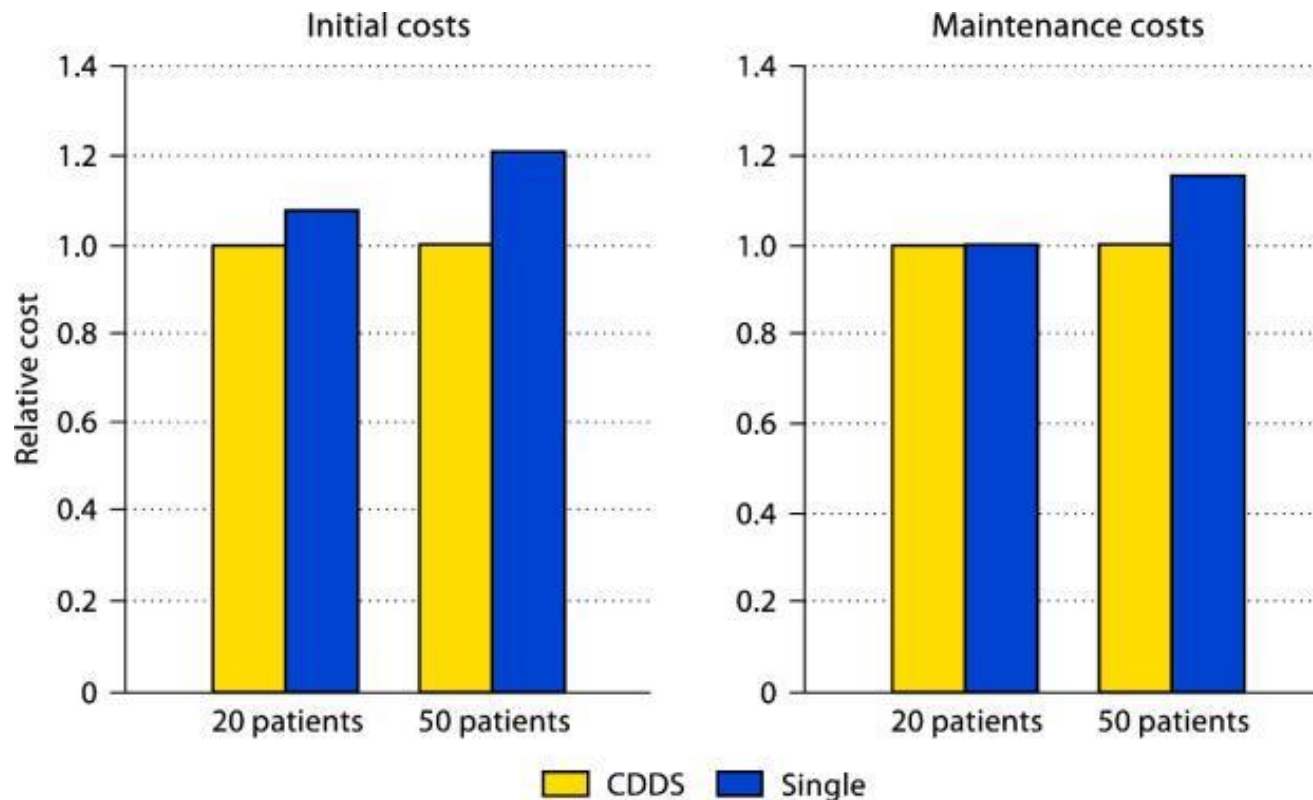
Newly Design of CDDS

Loop piping & continuous flow



Cost effective of CDDS

- Initial cost and maintenance cost is lower than SPS
- Cost benefit is depended on the number of patients



Disinfection of CDDS

- Chemical disinfection
 - Commercially available disinfectant
 - I.e. sodium hypochlorite, acetic acid, peracetic acid, acidic electrolyzed water
 - Disinfection is a daily programmed practice interlocked with the whole system; RO loop, bicarbonate mixing line to peripheral consoles.
 - All lines should be packed with disinfectant when not in use,
 - high concentration in a short period (300–1,000 ppm, bleach)
 - low concentration with overnight dwelling (dialysate line: 10–50 ppm, bleach)

Chemical disinfection, one example

- ◆ Monday, Wednesday, Friday (Sodium hypochlorite :600PPM)

RO flush 30min



Na hypochlorite 45min



RO flush 60min

- ◆ Tuesday, Thursday, Saturday (Peracetic acid)

RO flush 30min



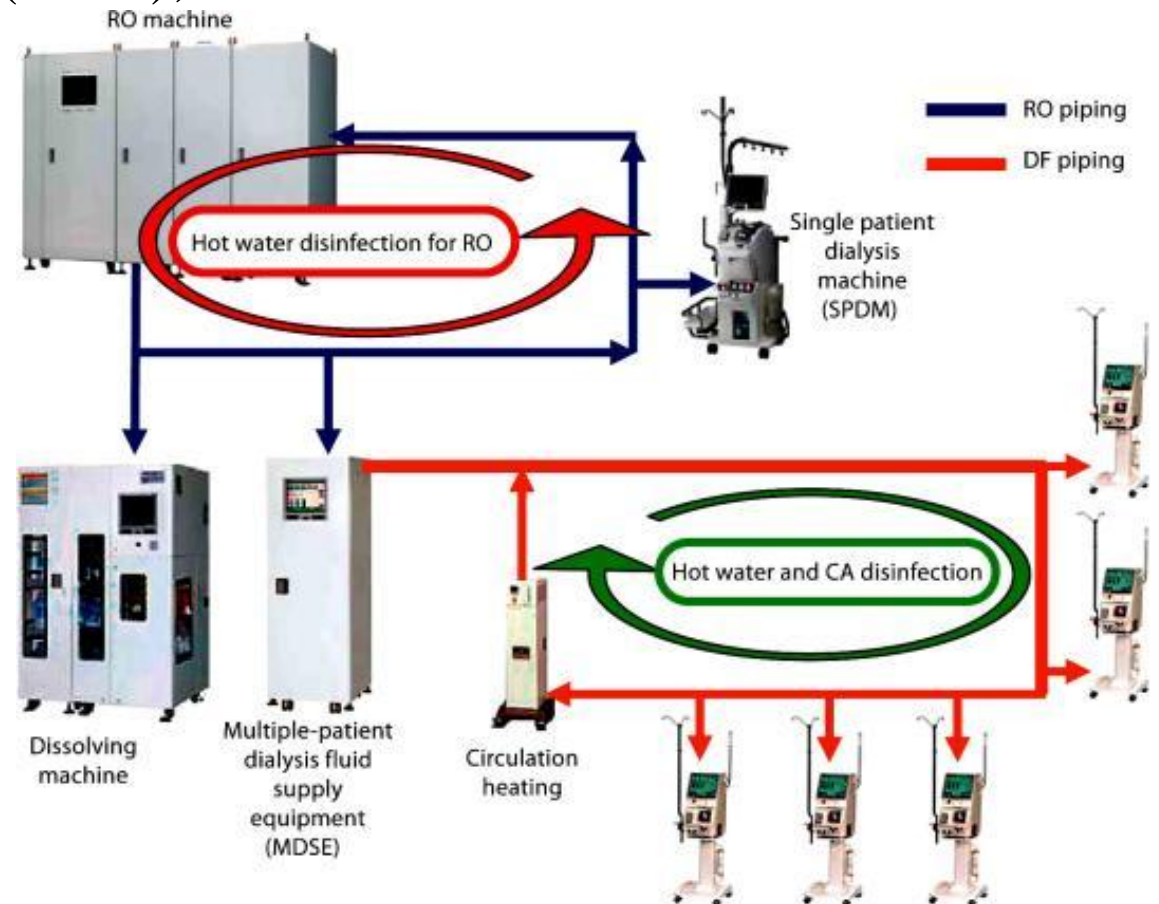
Peracetic acid 20min



Packed over night

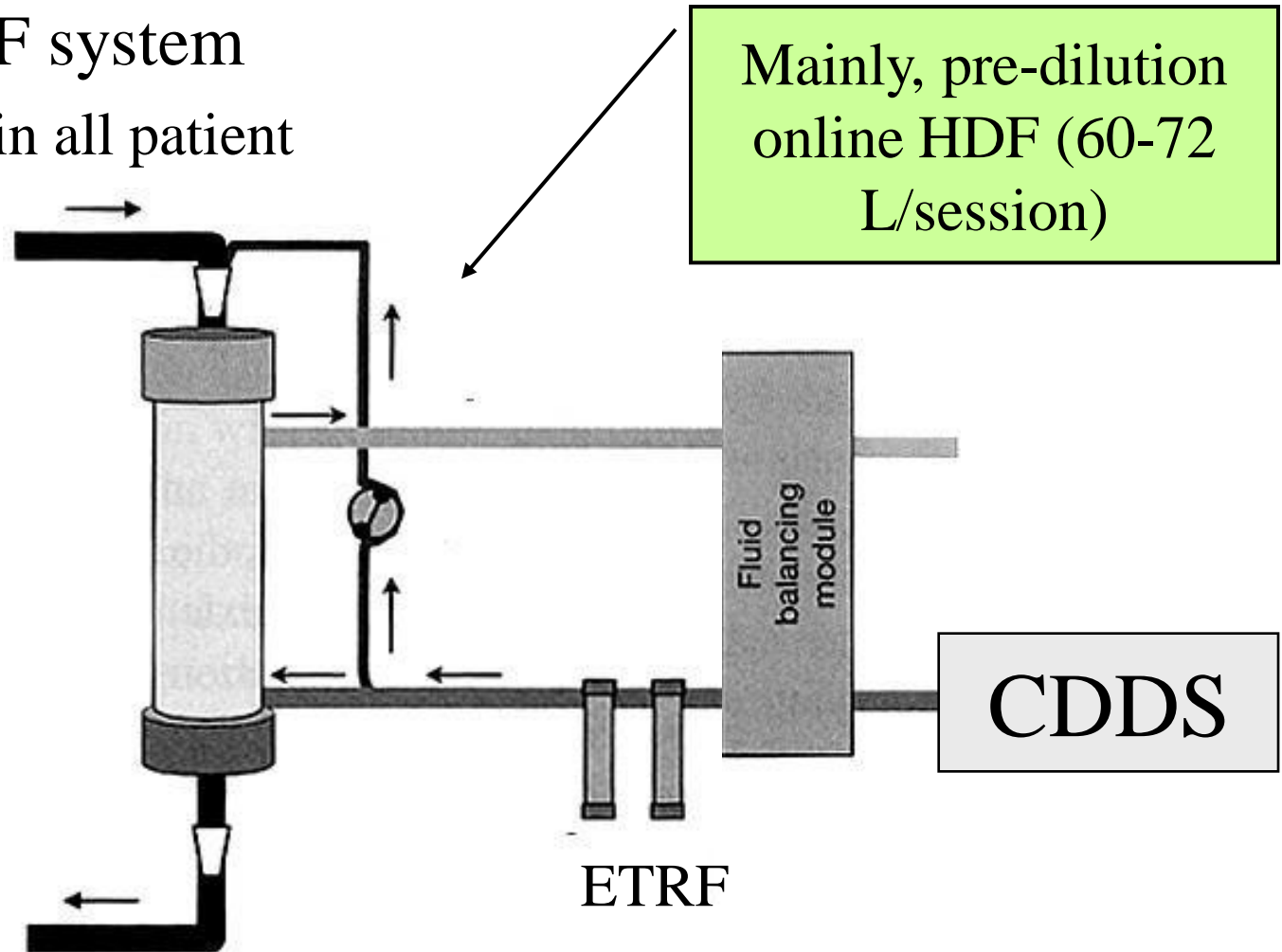
Disinfection of CDDS

- Hot water disinfection
 - Small number of facilities (0.5%),
 - New system developing



Newly develop of CDDS

- Central online HDF system
 - Selection of HDF in all patient

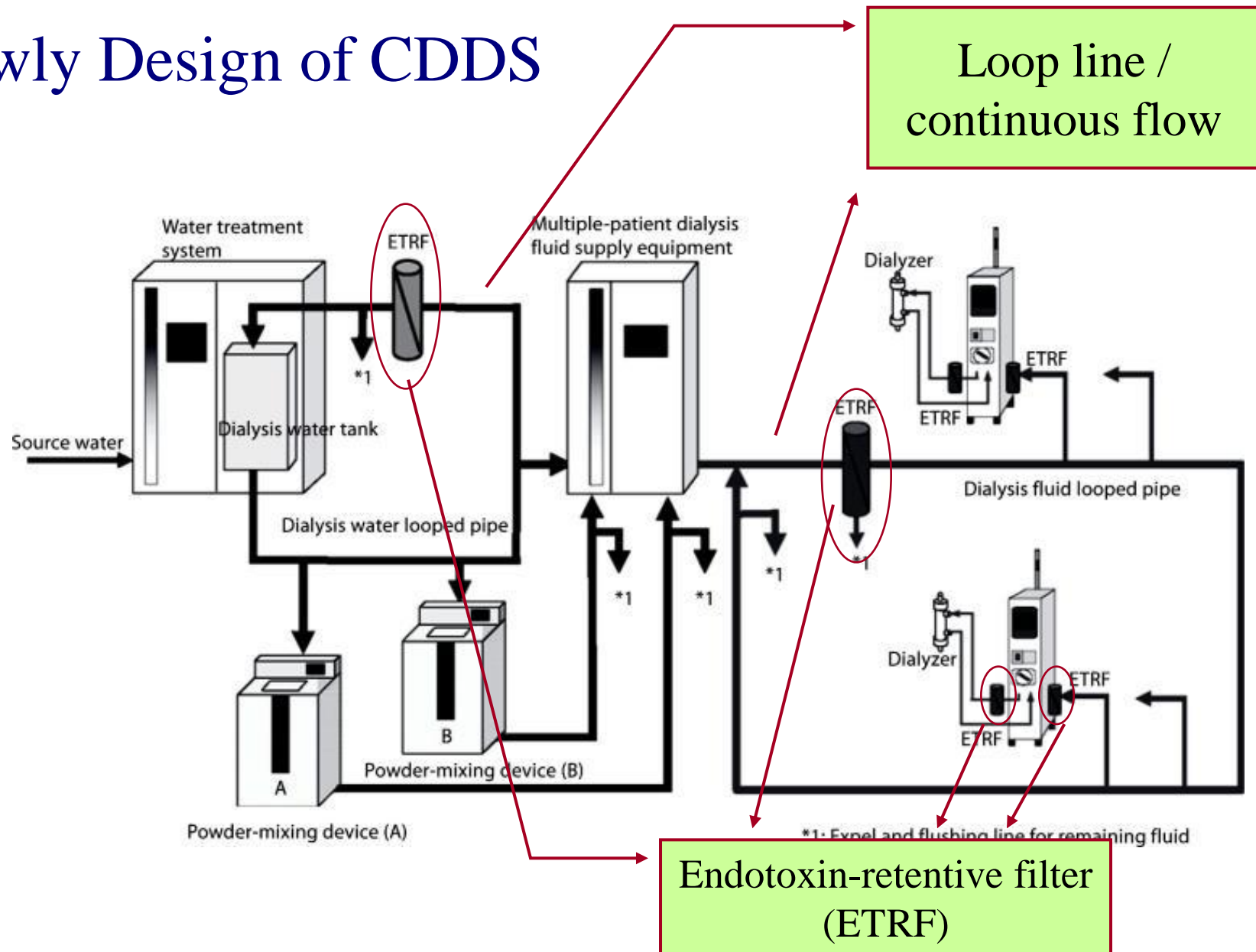


Newly develop of CDDS

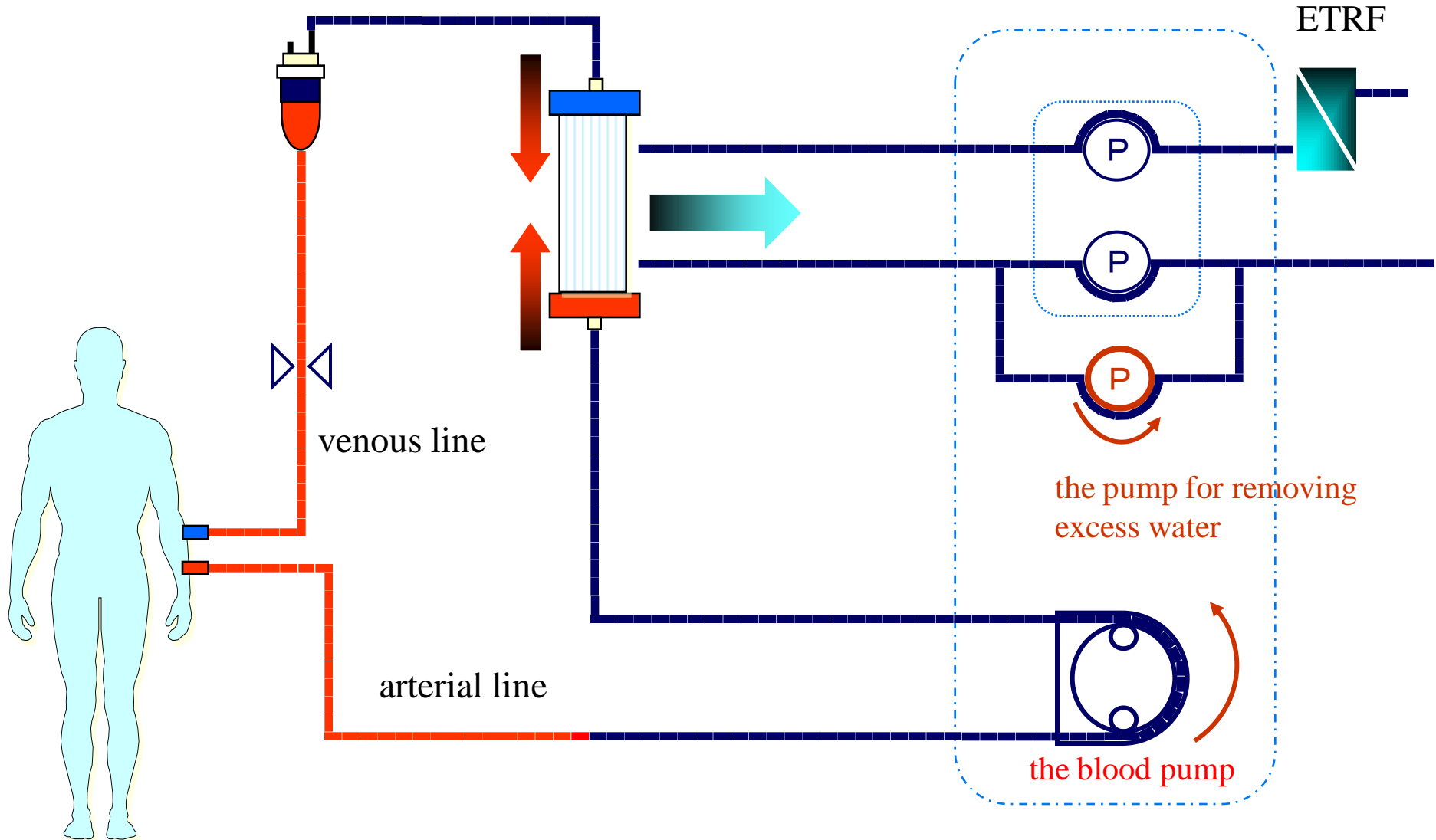
- Fully automated dialysis system (FADS) use by back-filtration (ASAIO J. 2003 ;49:547-53)
 - Ultra-pure dialysis water and fluid
 - Automated washing, blood guiding & returning used by (back)-filtration
 - This back-filtration occurs by reversing UF pump



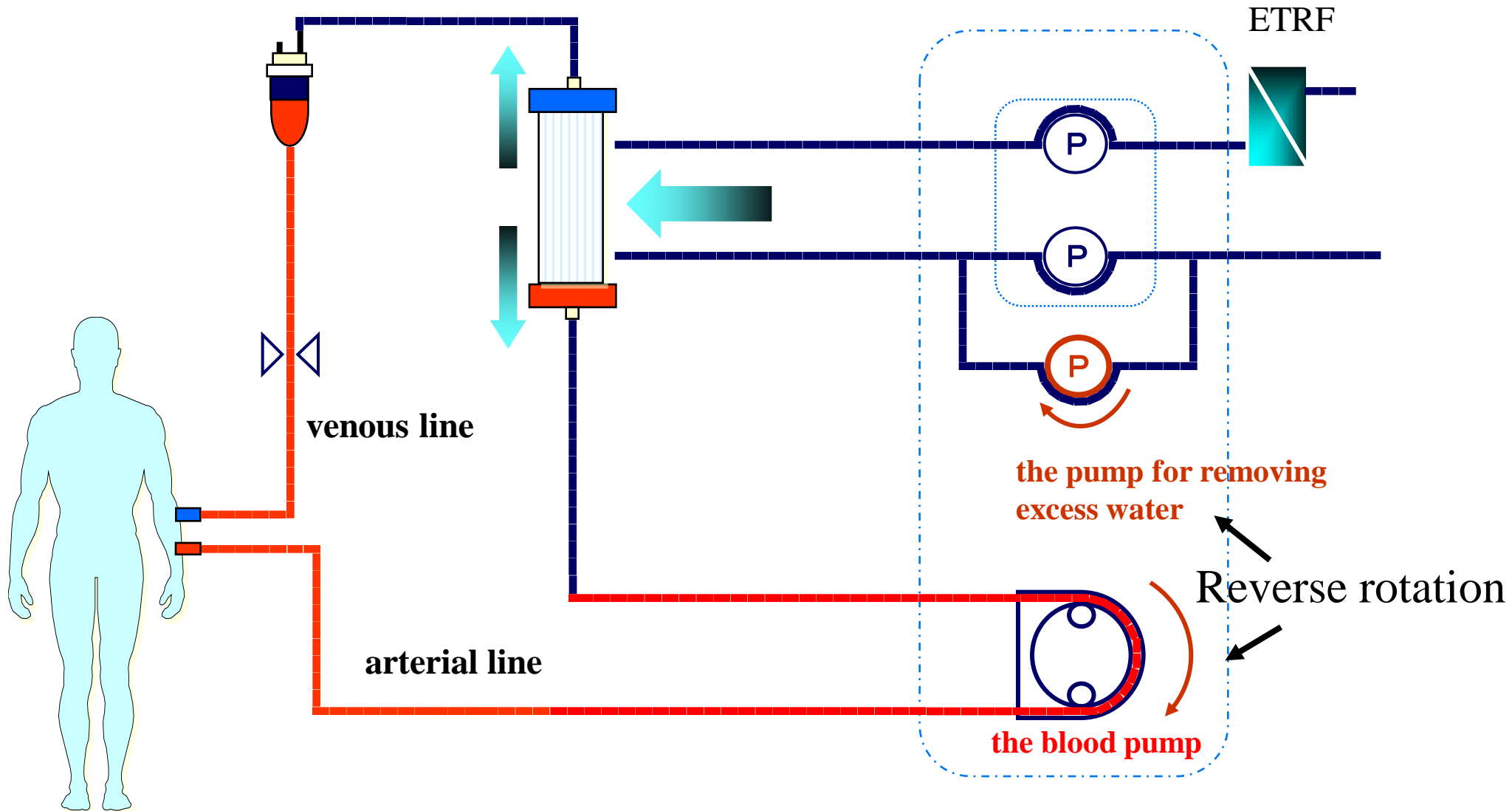
Newly Design of CDDS



Automated guiding blood into the dialyzer

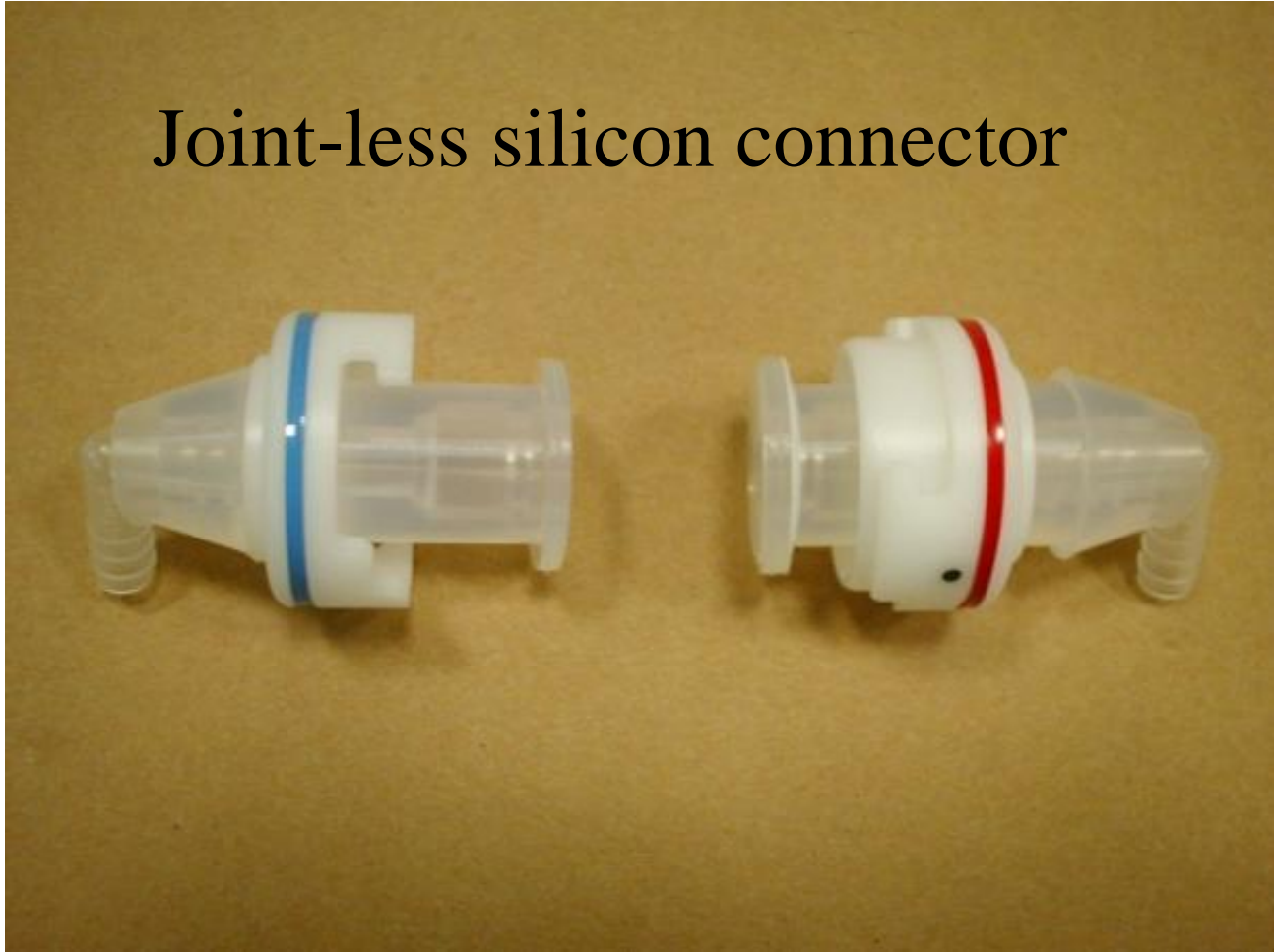


Returning blood and collecting



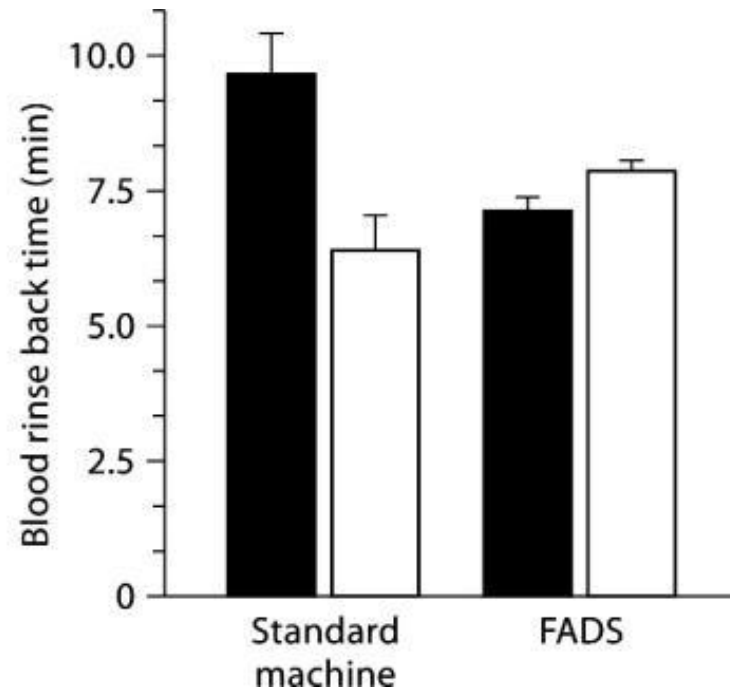
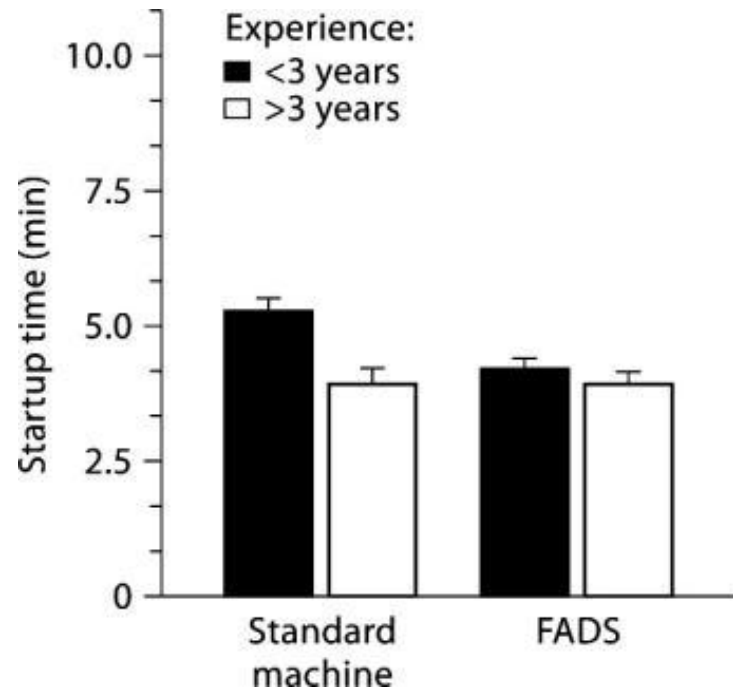
Newly developed ET free dialysate connector

Joint-less silicon connector



The comparison of setup and blood rinse back times by the degree of experience of dialysis staff in FADS

- The time required for startup and for blood rinse back were shorter for the FADS
- Splitting the subjects by their degree of experience (3 years) showed that there was no difference in the times required for startup/blood rinse back



The slide features five decorative circles. Two are solid light purple, one is a light purple outline, and two are solid light purple. They are arranged in two rows: the top row has three circles (outline, solid, solid) and the bottom row has two solid circles followed by one outline circle.

Water quality standard for hemodialysis in Japan

ISO standard for dialysis fluid quality

ISO standard for hemodialysis

- 13958 : Concentrates for HD and related therapies
- 13959 : Water for HD and related therapies
- 26722: Water treatment equipment for HD applications and related therapies
- 11663: Quality of dialysis fluid for HD and related therapies
- **23500: Guidance for the preparation and quality management of fluids for HD and related therapies**

Clinical dialysis



International
Organization for
Standardization

ISO meeting, Korea 2005 to USA 2010

Korea 2005, Austria 2006, China 2007, Germany 2008, Japan 2009, USA 2010

- Japanese Society for Dialysis Therapy (JSDT) [Physician]
- Japan Association of Clinical Engineering Technologists [Engineer]
- Japan Medical Devices Manufacturers Association [Industry]



Chaired by Dr Fischbach L



Chaired by Dr Ward R

Dialysis fluid quality standard in Japan

Therapeutics Apheresis Dialysis 2009;13:161-6

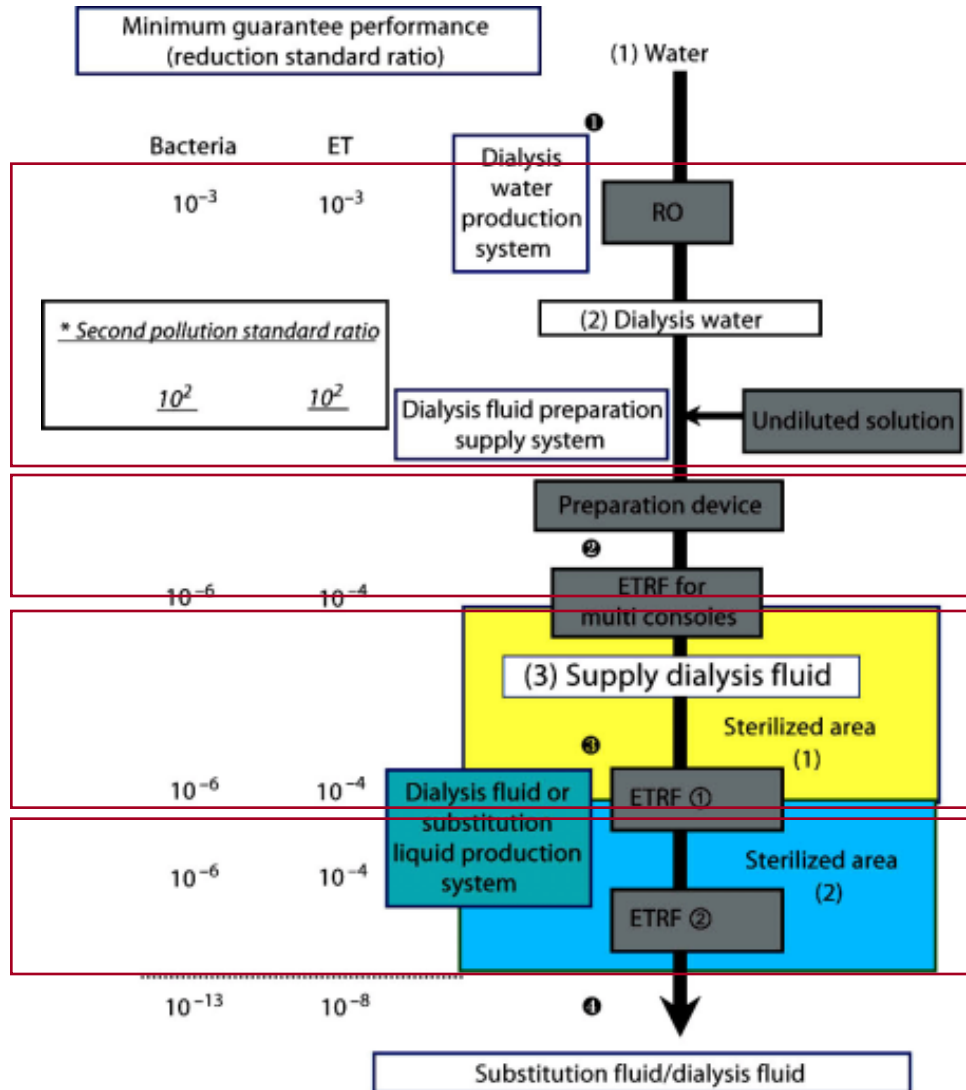
Standard on Microbiological Management of Fluids for Hemodialysis and Related Therapies by the Japanese Society for Dialysis Therapy 2008

Hideki Kawanishi,¹ Takashi Akiba,¹ Ikuto Masakane,¹ Tadashi Tomo,¹ Michio Mineshima,¹
Tadayuki Kawasaki,¹ Hideki Hirakata,¹ and Tadao Akizawa²

Concept of water quality standard for HD in Japan

- In Japan, the CDDS is used in many dialysis facilities, and dialysis fluids are prepared through multiple processes performed by various apparatuses connected in series.
- A dialysis facility functions as a dialysis fluid manufacturing facility, and is responsible for the final quality of the dialysis fluid.
- Therefore, a person responsible for manufacturing and managers of various processes must be appointed for dialysis fluid purification in the same manner as at manufacturing facilities.

Validation of management for microbial contamination in CDDS



Management of each area in CDDS

1. setting a sterilized area
2. decision of the sterilization level
3. confirmation of maximum bio-burden
4. performance of ETRF or RO module
5. checkpoint of purity of water in the system

Water quality standard for Hemodialysis in Japan, JSDT2008

- Standard dialysis fluid
 - ET level < 0.050 EU/mL, Microbial < 100 CFU/mL (*ISO ET*<0.5)
 - **Minimum standard**
- Ultra-pure dialysis fluid
 - ET level < 0.001 EU/mL (ND), Microbial < 0.1 CFU/mL
 - **Desirable for all dialysis modalities**
- Online prepared substitution fluid
 - Sterile and nonpyrogenic
 - **Can be used only after validation by the dialysis equipment safety management committee in each facility.**



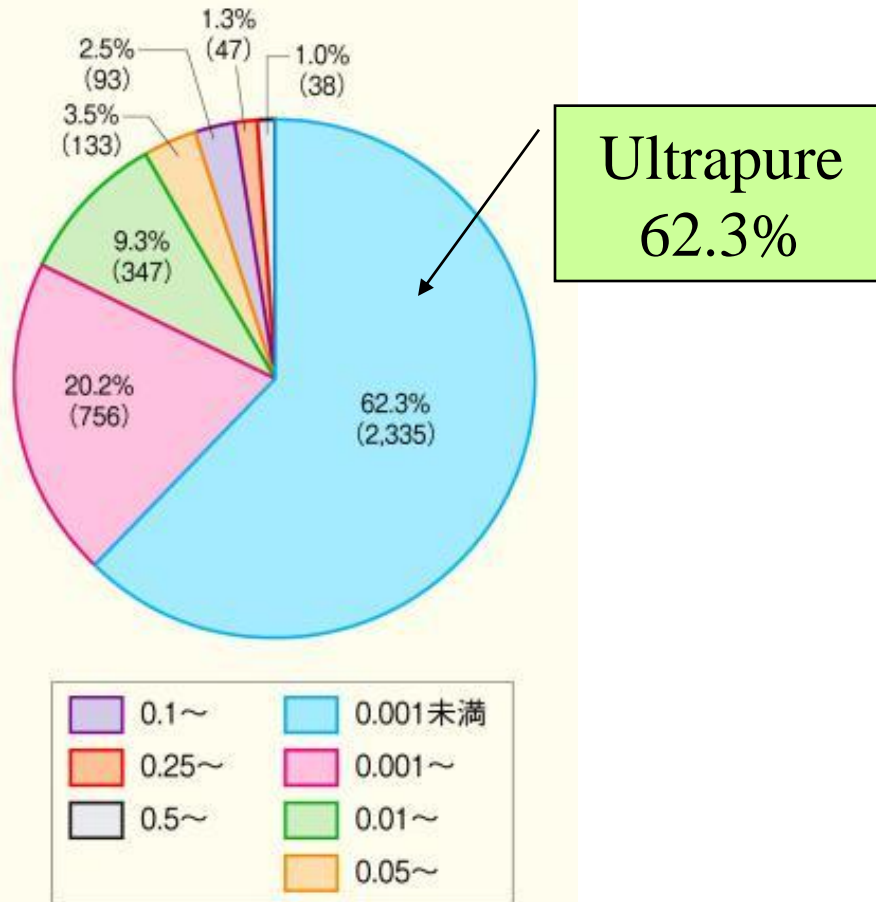
A dialysis equipment safety management committee

- **The dialysis equipment safety management committee** is appointed under the safety management of medical equipment committee, the establishment of which is required by the Ministry of Health, Labour and Welfare
- The each facility should be organized this committee of hemodialysis
- The committee;
 - Consist; physician, nurse, clinical engineering technologists
 - Responsibility to the quality of hemodialysis.
 - The position; same as a manufacturers

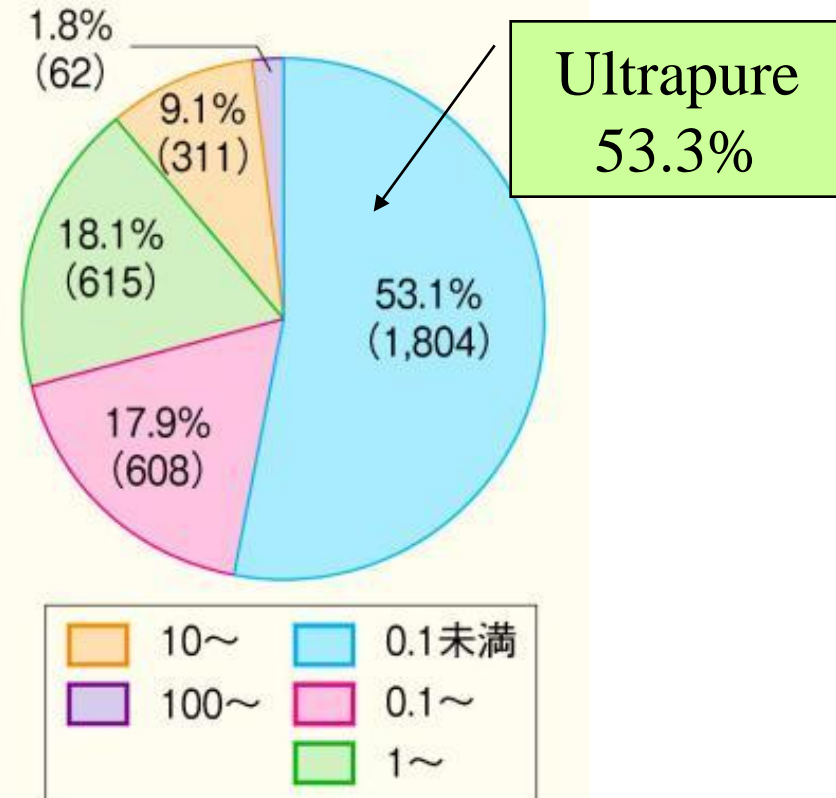
Bacteriological Qualities of Dialysis Fluid in Japan

JSDT data end of 2010

Endotoxin EU/mL



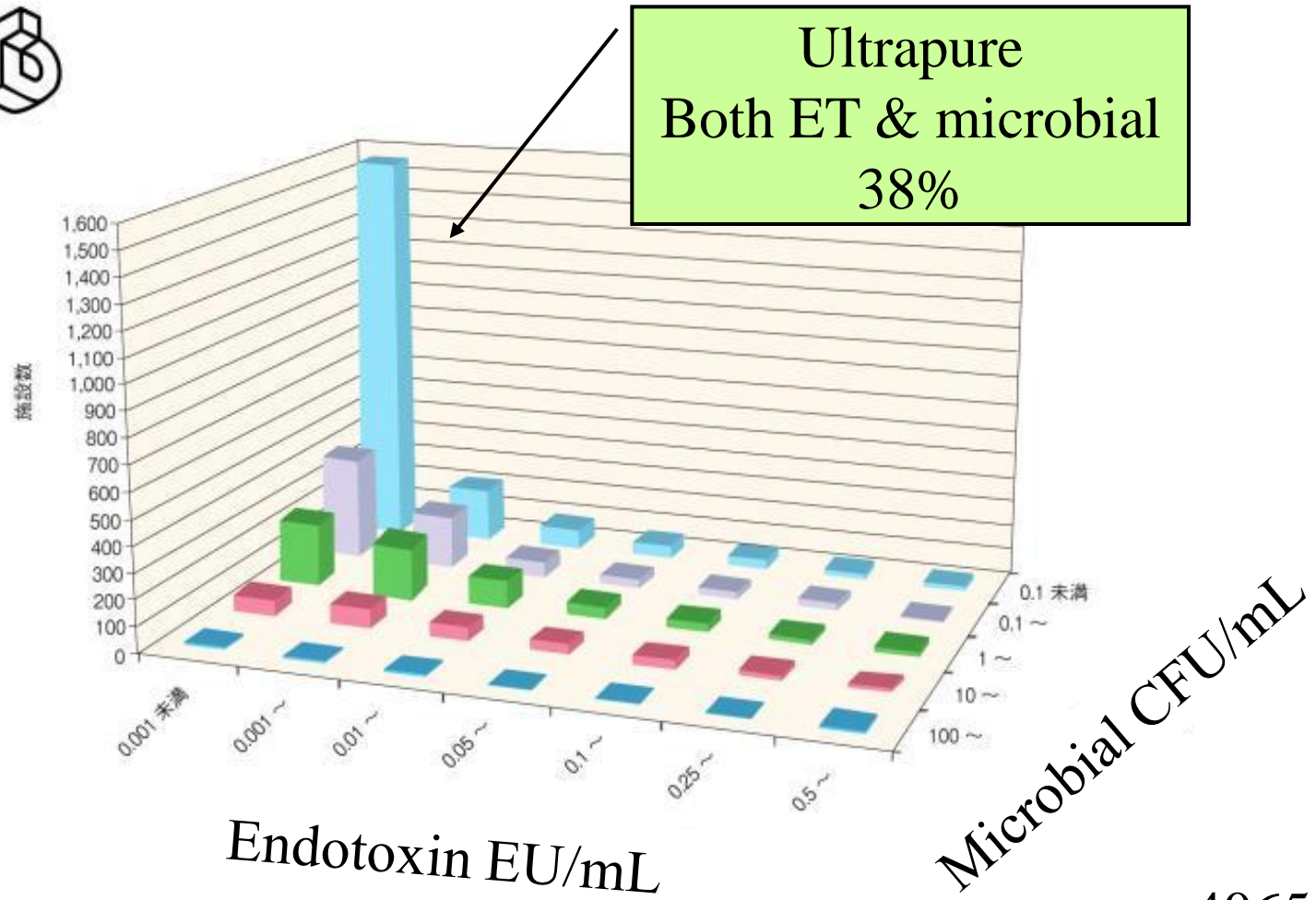
Microbial CFU/mL



4065 facilities

Bacteriological Qualities of Dialysis Fluid in Japan

JSDT data end of 2010



4065 facilities

Conclusion

- CDDS has been working exclusively in Japan since 1960s.
Approximately 88% of dialysis machines are bedside consoles with CDDS.
- It is a cost-effective, laborsaving, time-tested system and microbial safety with 40 years of experience.
- In many countries, especially in Asia, the number of ESRD patients is increasing. CDDS will contribute to such emerging situations with its easy handling and economical advantages.



Thank you for your attention