Controversies conference on Novel techniques and innovation in blood purification: How can we improve clinical outcomes in hemodialysis ?

**Paris 14-15 October 2011**

# Hemodiafiltration: Where are we ? Where are we going ?


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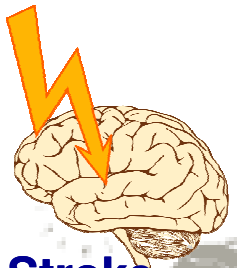
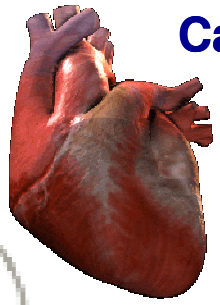
# Limits of conventional hemodialysis

## Maltolerance of dialysis sessions

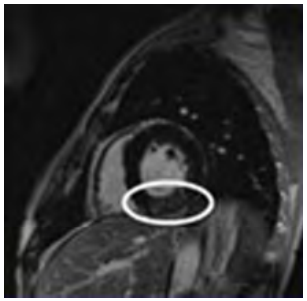
Intradialytic Hypotension



Stroke

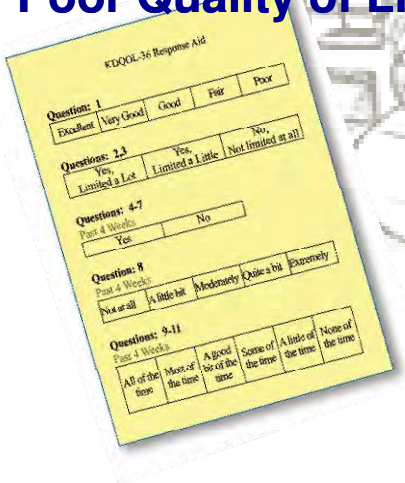


Cardiac Stunning

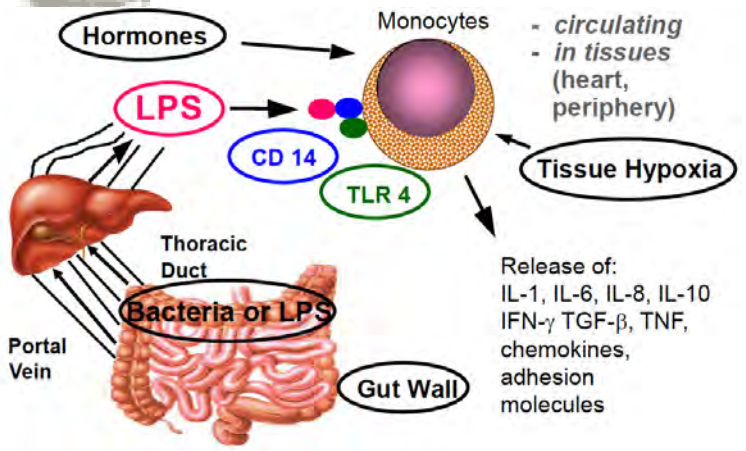




Poor Quality of Life




Gut ischemia - Translocation

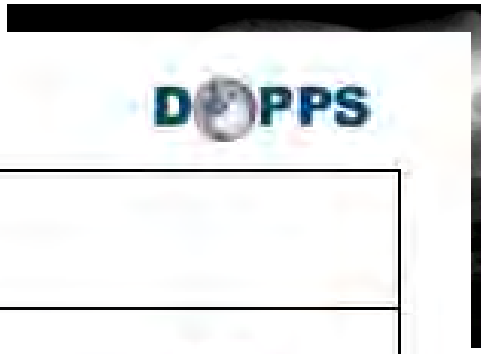


# Limits of conventional dialysis modalities

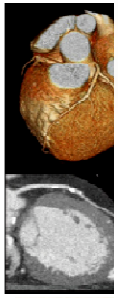
## Dialysis-related pathology

ß2-Amyloidosis

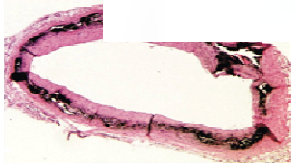
Tissular calcinosis

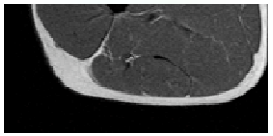




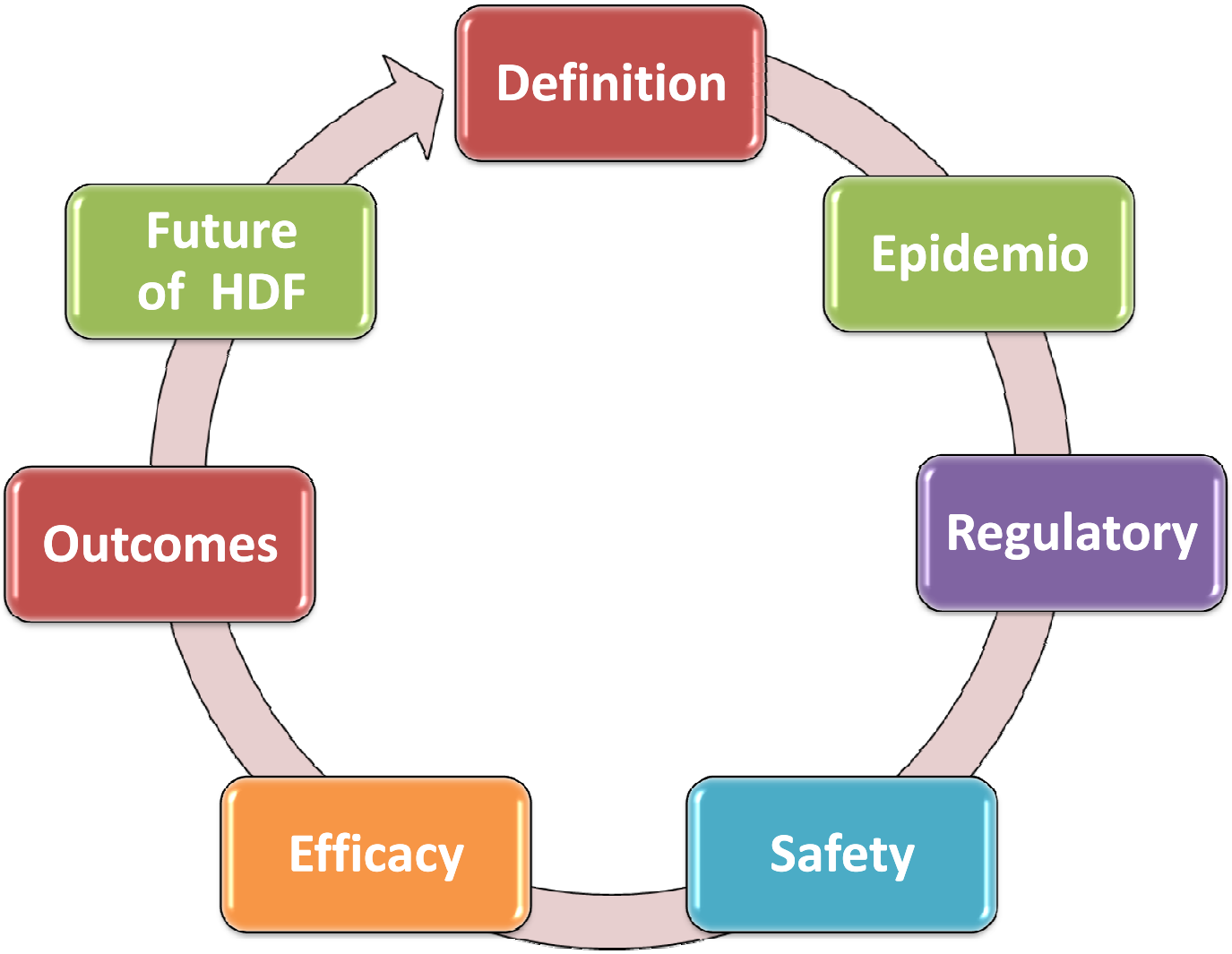



lasting





# Outline of the presentation



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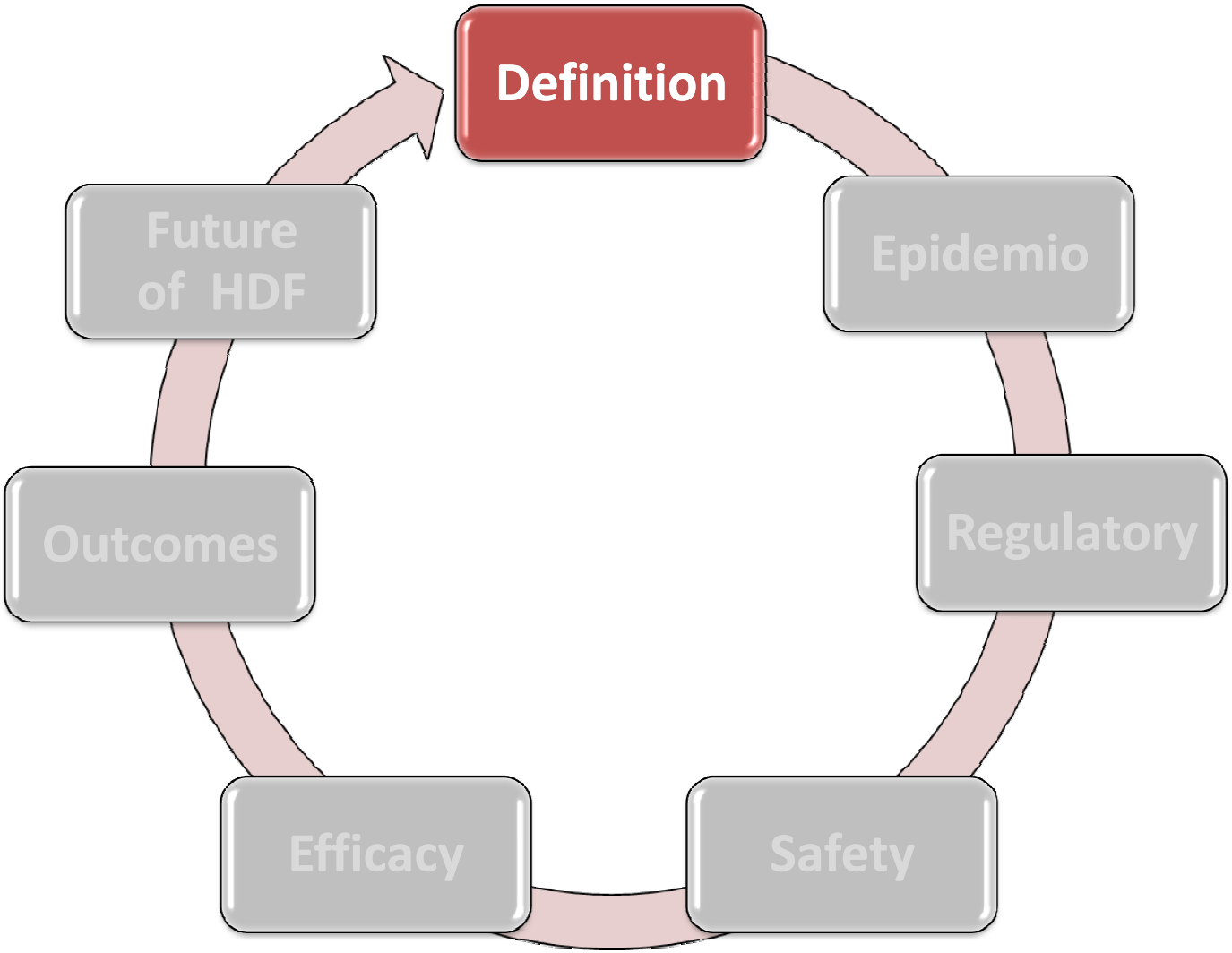
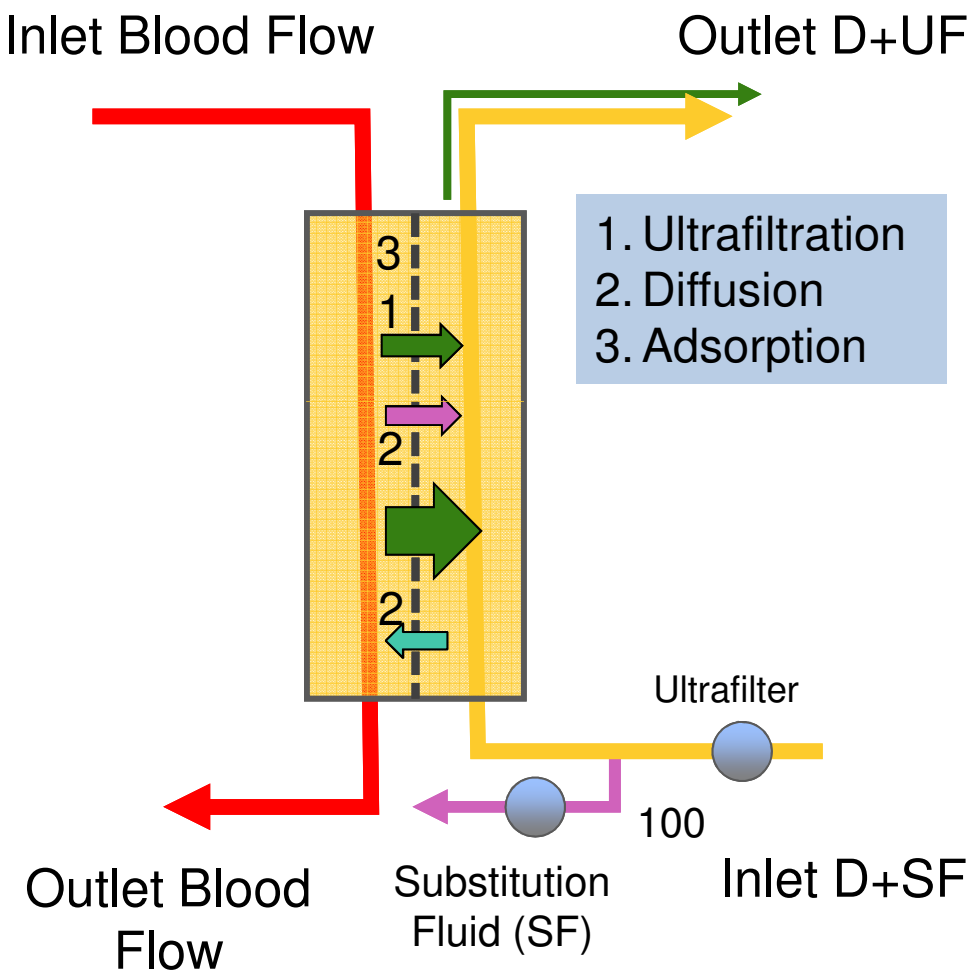
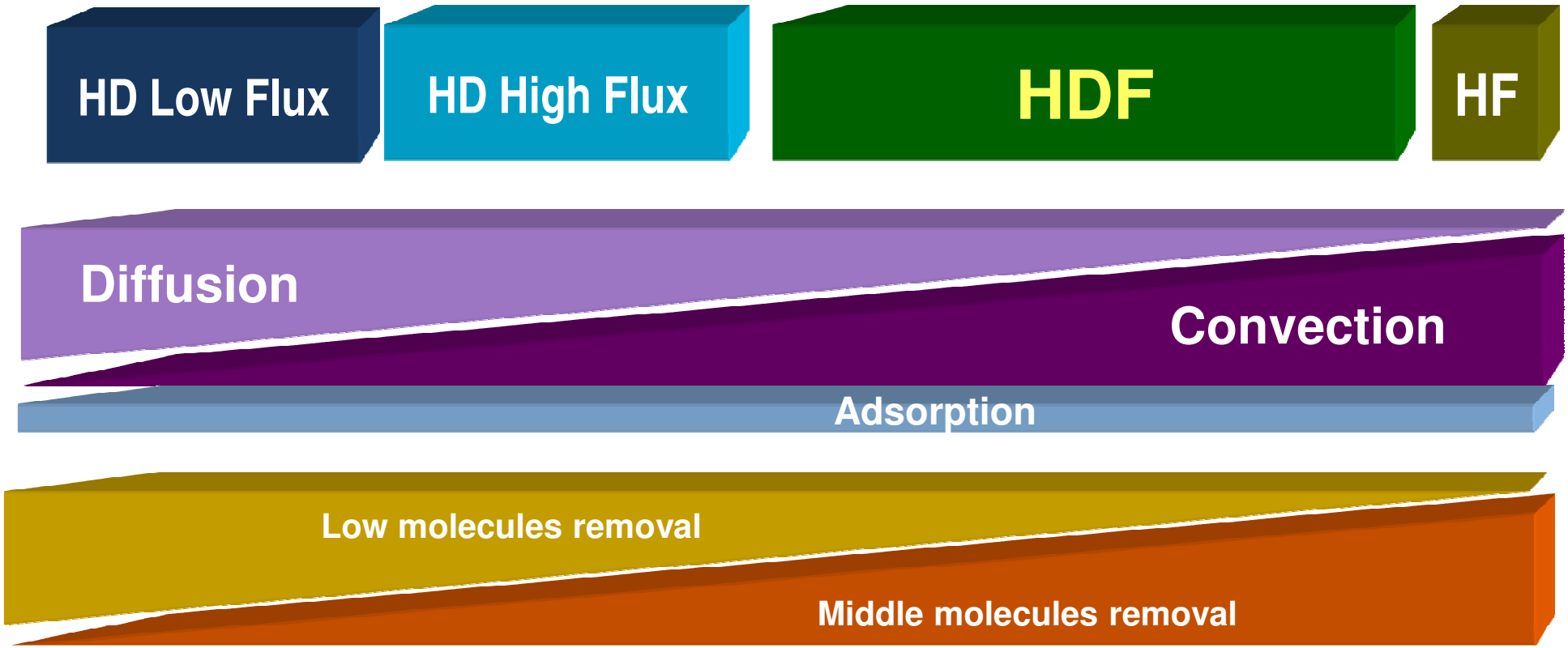


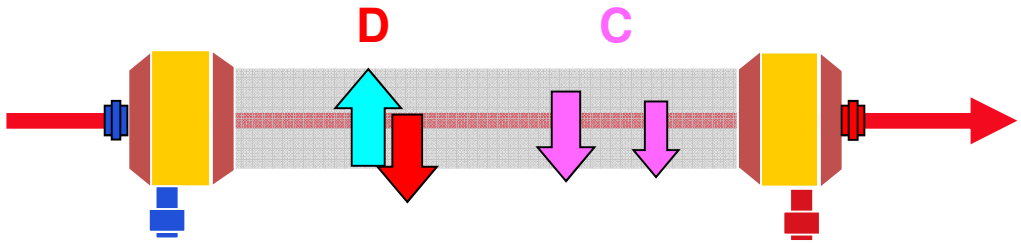
# HDF combines diffusive, convective and adsorptive clearances in the same module



# Hemodiafiltration enhances clearances of middle and large molecular weight solutes



# Total solute clearance in HDF is not the algebraic sum of solute transfer component




$$K_T = K_D + K_C + K_{Ads}$$

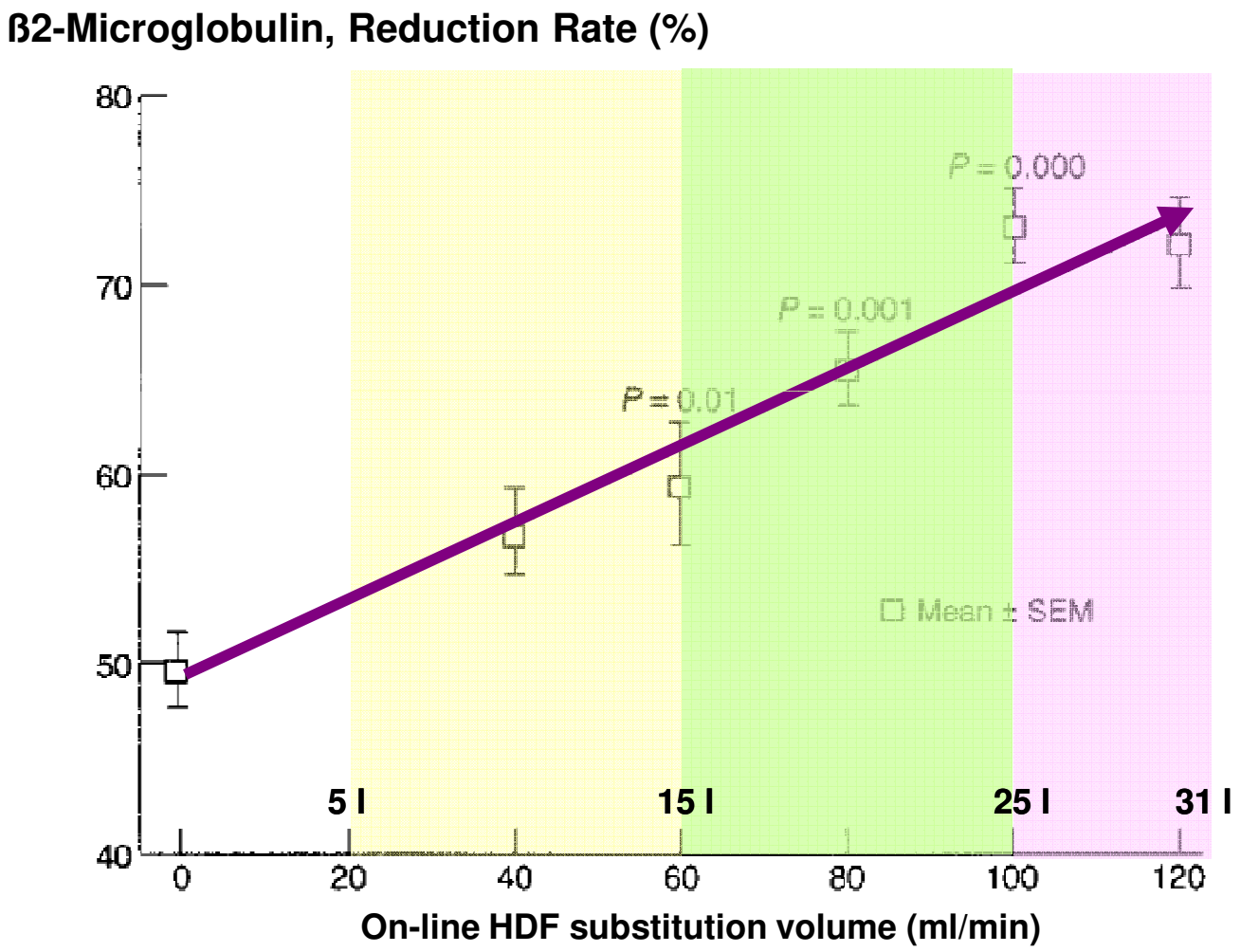
Total Diffusive Convective Adsorptive

$$K_T = K_D + 0.43\ Q_{UF} + 8.3.10^{-3}\ Q^2_{UF} + ?$$

$$K_T = K_D + 0.50\ Q_{UF}$$

Jaffrin M et al. *Artif Organs* 1995; 19:1162

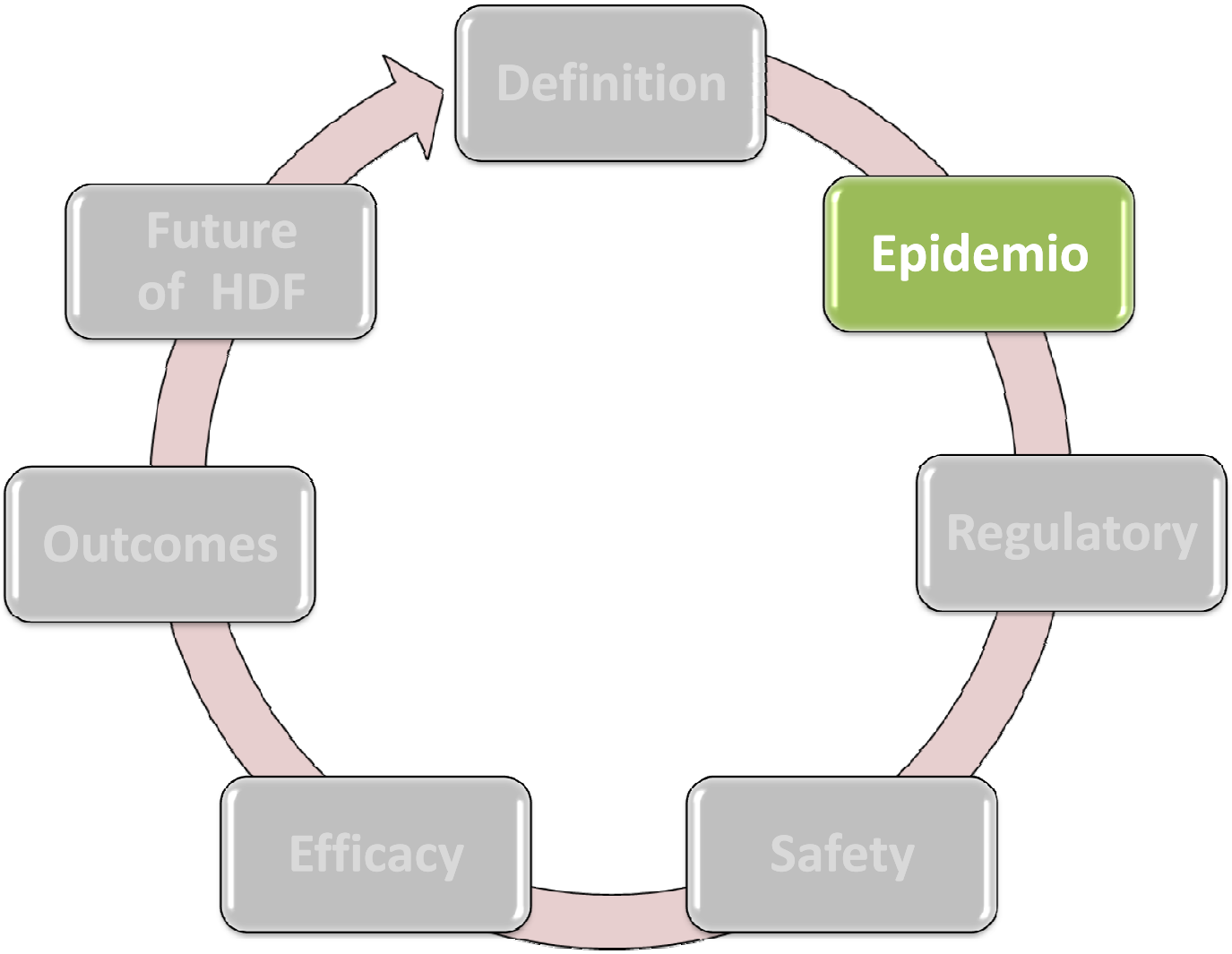
# Convective dialysis dose is a linear function of substitution volume



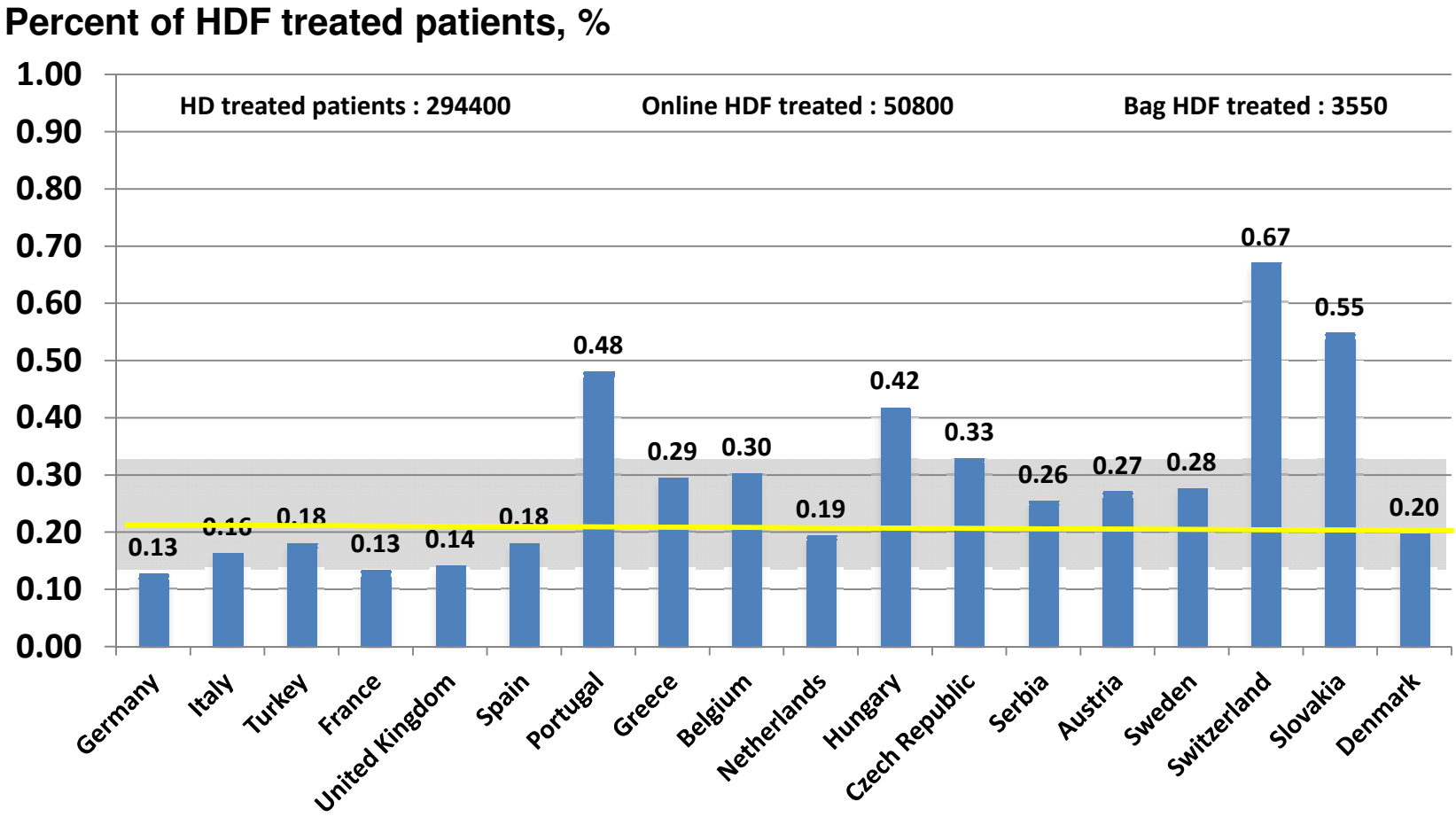

**Postdilution HDF**

Lornoy W et al, *Nephrol Dial Transplant.* 2000: 15: 49-54

# Outline of the presentation

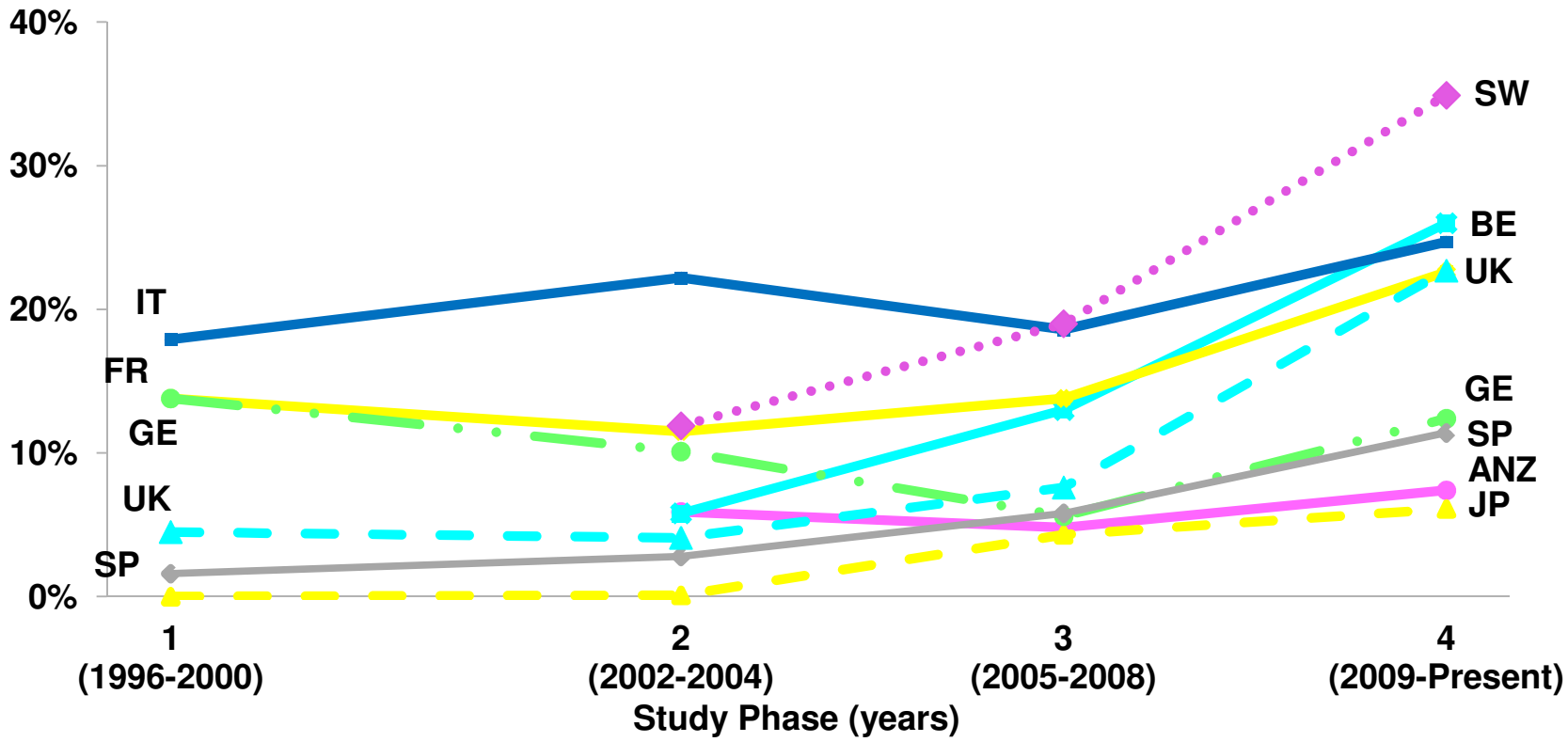


# Prevalence of HDF in Europe in 2010



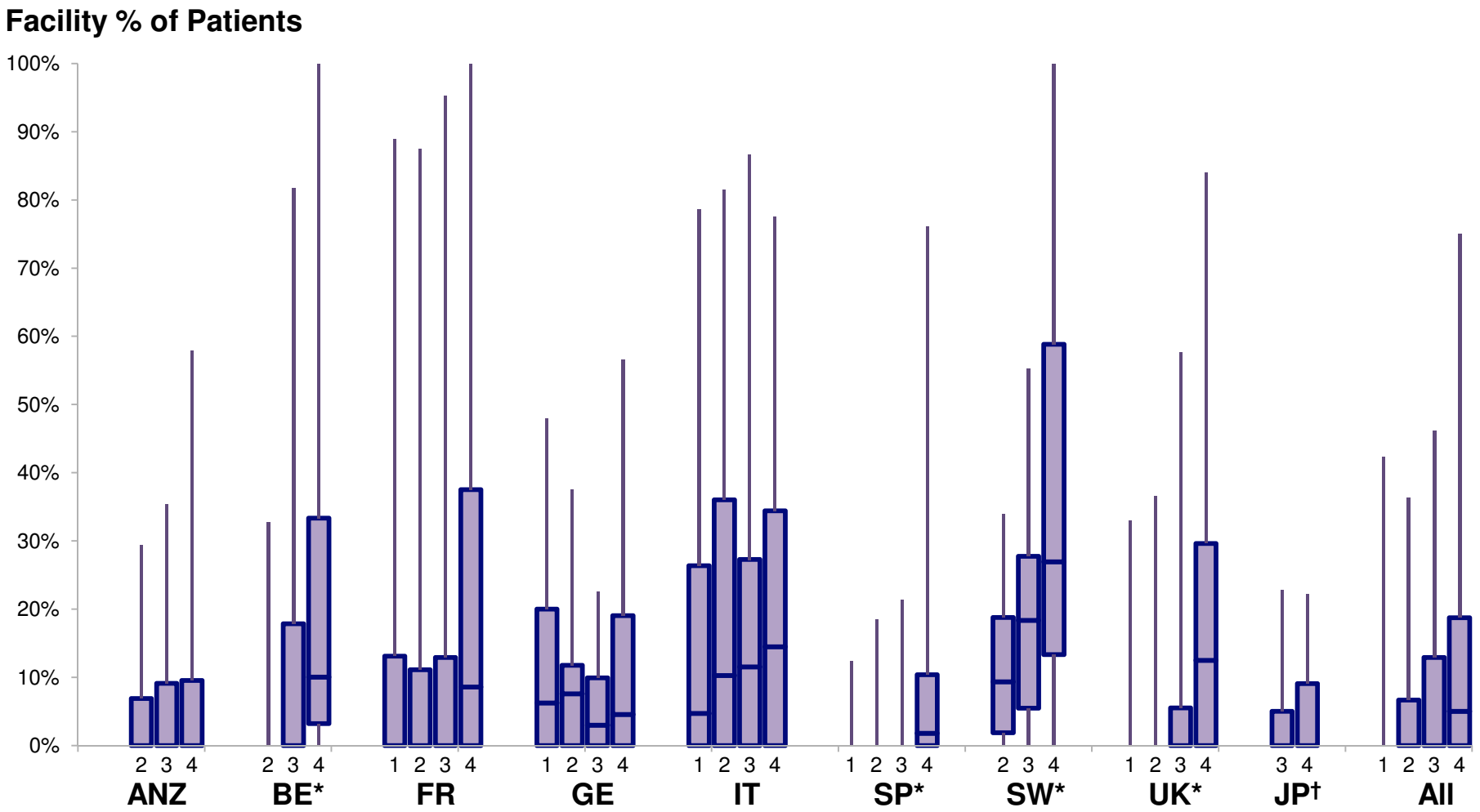
# Hemodiafiltration Trends by Country

## DOPPS 1-4 Sample Patients* (1996-2010)




*Initial prevalent cross-sections who dialyzed 3 times/wk with vintage ≥3 months; DOPPS 4 data are preliminary; ANZ, BE and SW did not participate in DOPPS phase 1

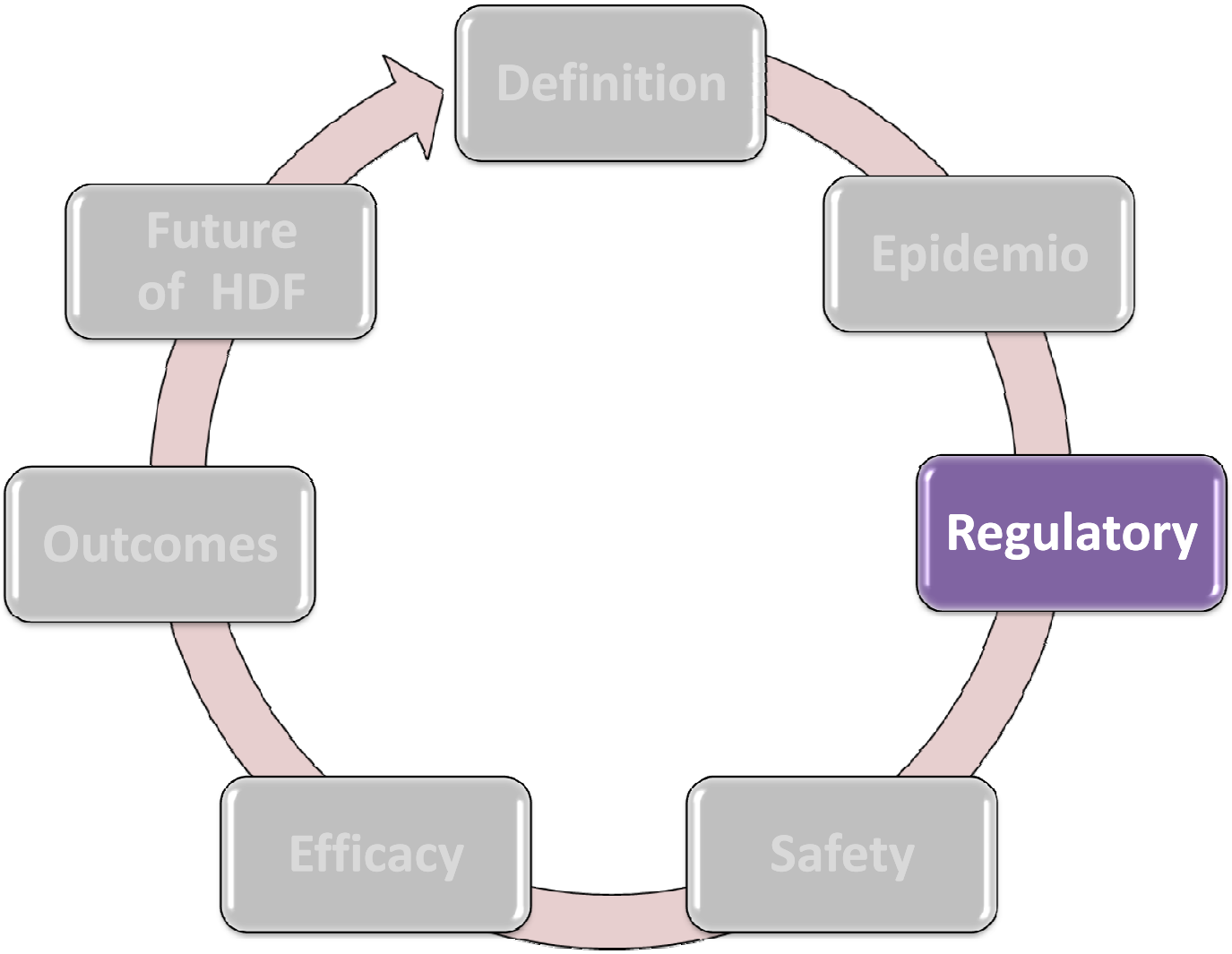
# Facility % of Patients on HDF, by Phase and Country



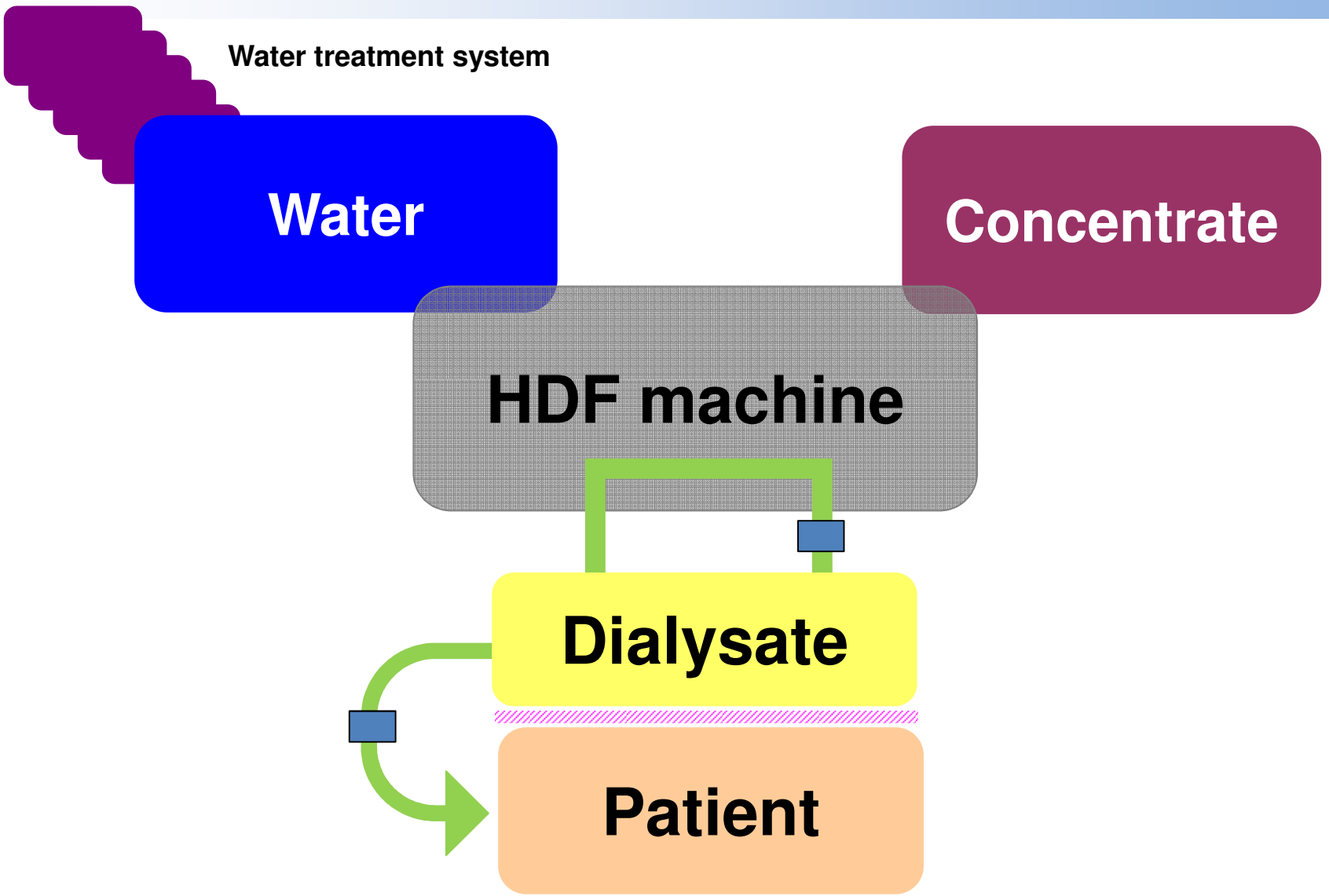

Initial prevalent cross-sections who dialyzed 3 times/wk with vintage ≥3 months

* p-value <0.05 for test for trend for HDF use over time; †HDF was not used in Japan during DOPPS phases 1 and 2

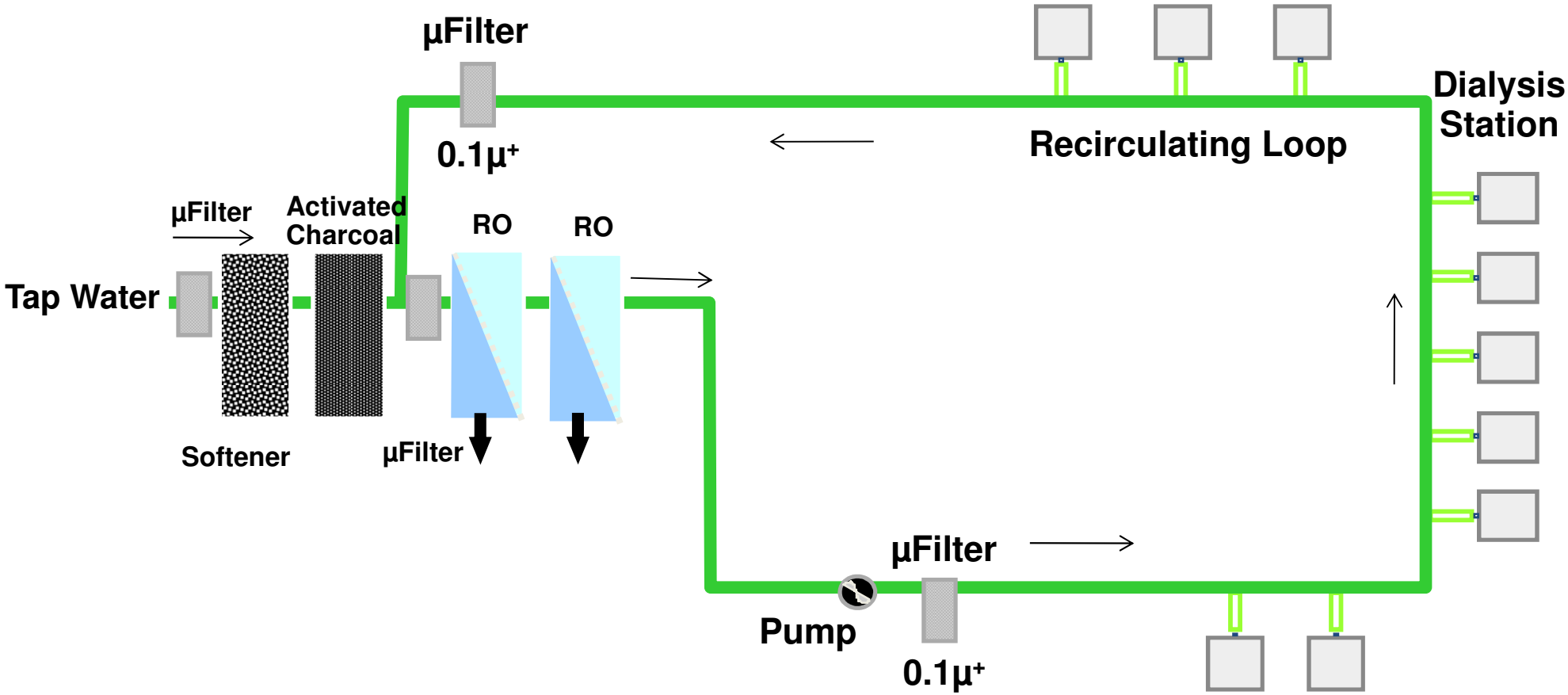
# Outline of the presentation



# Hemodialysis/Patient Interaction



# Water treatment system to produce ultrapure water



# Ultrapure dialysis fluid is now recognized as a new standard of contemporary dialysis

NDT Nephrology Dialysis Transplantation

SECTION IV: Dialysis fluid purity

Nephrol Dial Transplant 2002; 17 [Suppl 7]

European Best Practice Guidelines for Haemodialysis

2002

AAMI Association for the Advancement of Medical Instrumentation

**Water treatment equipment for hemodialysis applications**

**AAMI TIR34:2007**

American National Standard

ISO International Organization for Standardization

ISO 26722:2009

Water treatment equipment for haemodialysis applications and related therapies

The Japanese Society for Dialysis Therapy

**The New Standard of Fluids for Hemodialysis in Japan**

Blood Purification

2009

Blood Purif 2009;27(suppl 1):5–10

# International Standard ISO 2009

INTERNATIONAL STANDARD

**ISO/FDIS 11663**

**Quality of dialysis fluid for haemodialysis and related therapies**

*Qualité des fluides de dialyse pour hémodialyse et thérapies annexes*

International Organization for Standardization

# Non-pyrogenic - Sterile vs Ultrapure

**3.18**
**non-pyrogenic**
less than 0,03 EU/ml

NOTE Historically, the threshold pyrogenic dose of 5 EU/kg/h (the minimum dose that produces fever) has been used to set endotoxin limits of devices and injectable medications.

**3.19**
**sterile**
free from viable microorganisms with a sterility assurance level (SAL) of 6

NOTE 1 "sterile" can be used to describe a packaged solution that was prepared using a terminal sterilization process that has been demonstrated to achieve a $10^{-6}$ microbial survivor probability, i.e., assurance of less than one chance in one million that viable microorganisms are present in the sterilized article.

NOTE 2 Alternatively, "sterile" can be used to describe a solution prepared for immediate use by a continuous process that has been validated to produce a solution free from viable microorganisms with a SAL of at least 6. This SAL applies to the total volume of solution used in a single application.

ISO International Organization for Standardization

**ISO/FDIS 2009-11663**

# Ultrapure dialysis fluid – Substitution fluid

**3.21**
**ultrapure dialysis fluid**
highly purified dialysis fluid that can be used in place of conventional dialysis fluid or as feed solution for possible further processing to create fluid intended for infusion directly into the blood

NOTE A widely accepted specification of ultrapure dialysis fluid is < 0,1 CFU/ml and < 0,03 EU/ml.

**3.20**
**substitution fluid**
fluid used in haemofiltration and haemodiafiltration treatments which is infused directly into the patient's blood as a replacement for the fluid that is removed from the blood by filtration

NOTE 1 Substitution fluid is also referred to as substitution solution or replacement solution.

NOTE 2 Substitution fluid may also be used for bolus administration, for priming of extracorporeal blood circuit and for returning blood to the patient at the end of a treatment.

International Organization for Standardization

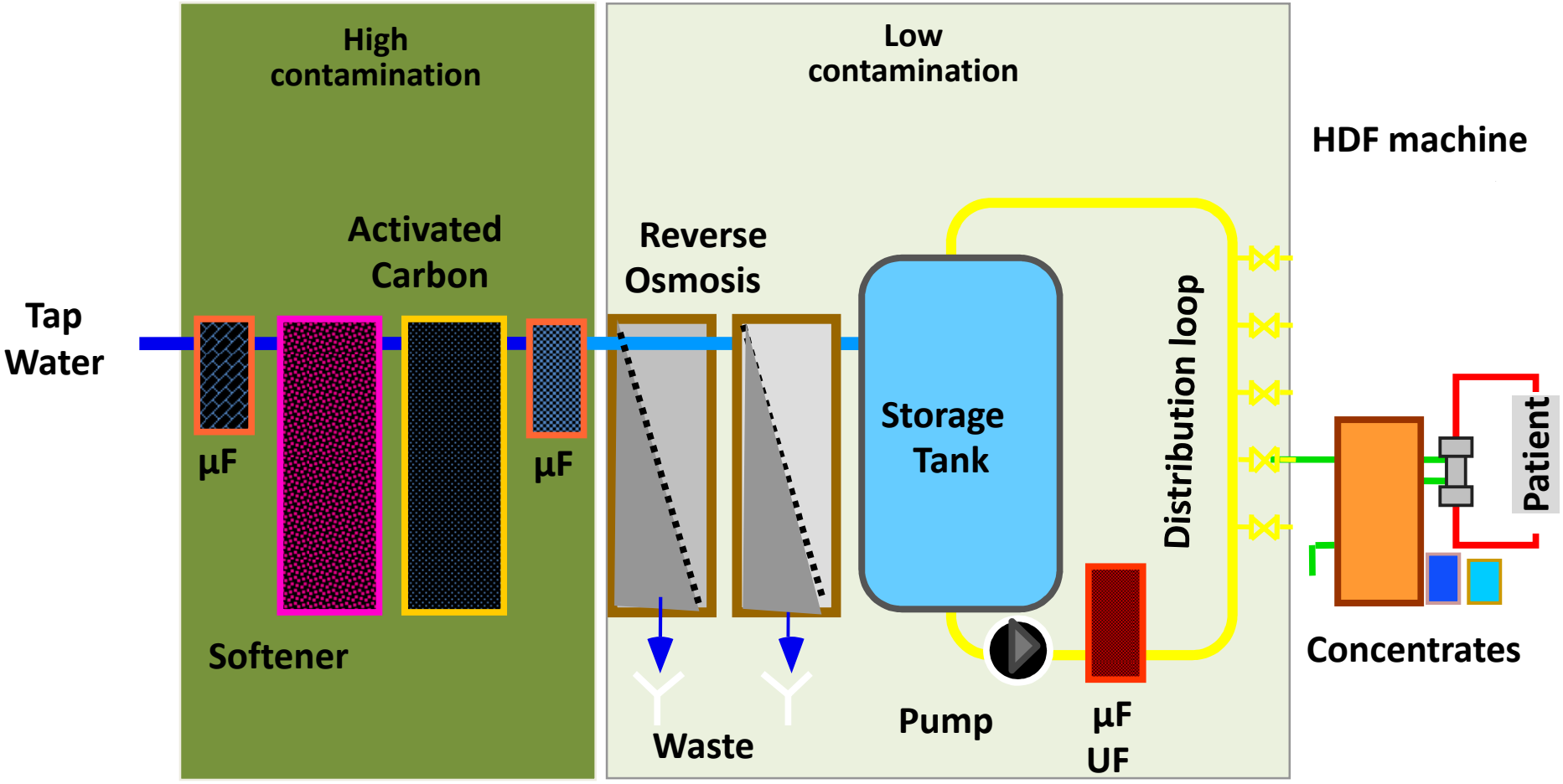
**ISO/FDIS 2009-11663**

# Water and dialysis fluid tend to the same degree of microbiological purity

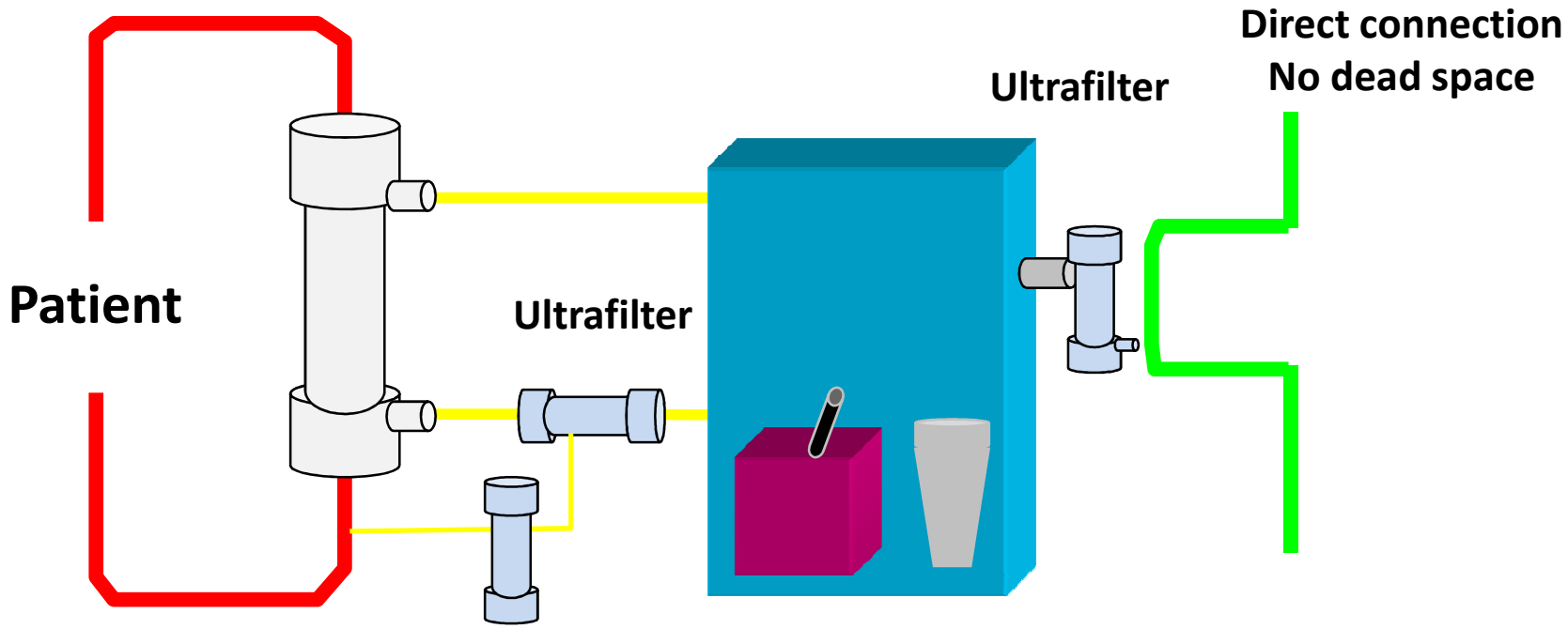
| International standards of water and dialysis fluid | | | |
|---|---|---|---|
| Maximum levels | Regular Water | Ultrapure Water | Ultrapure Dialysis Fluid |
| Microbial contamination (CFU/ml) *Sensitized methods* | <100 | <0.1 | <0.1 |
| Bacterial endotoxins (IU/ml) *LAL* | <0.25 | <0.03 | <0.03 |

Nephrol Dial Transplant (2002) 17 [Suppl 7]: 45–62

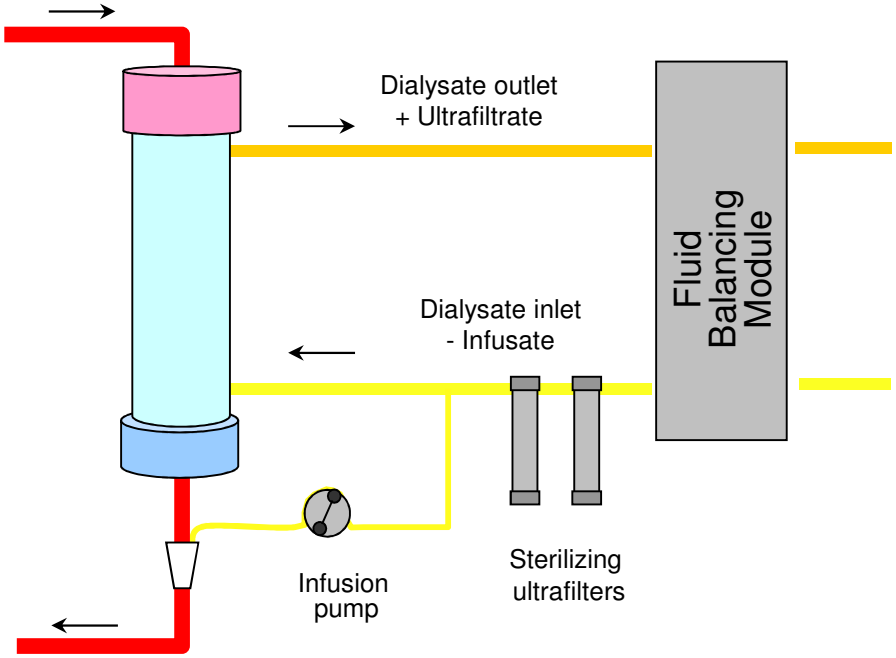
# Water Treatment System, Contamination Levels



# Basic concept of online production of substitution fluid (infusate)

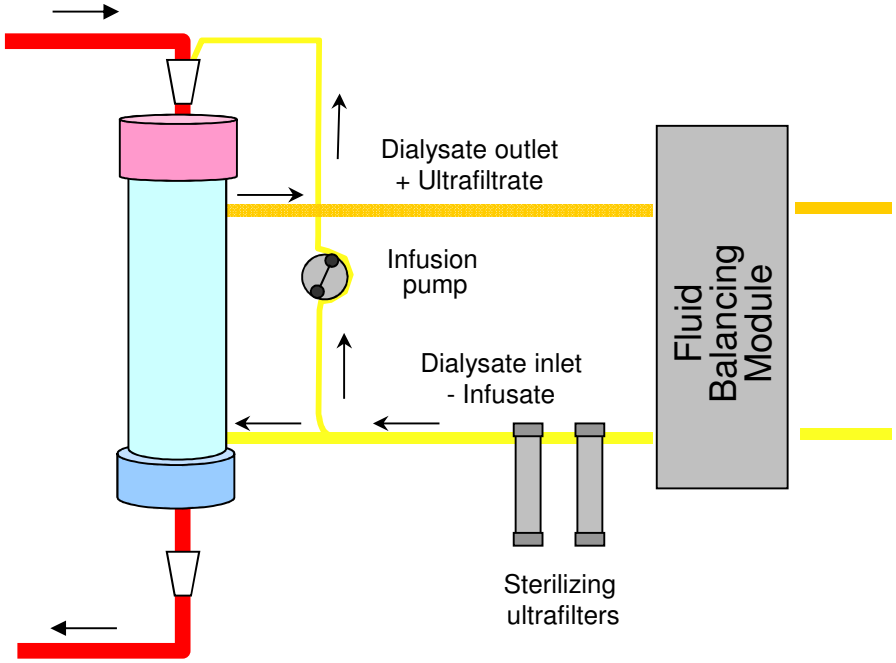


# Online HDF, Modalities of substitution




**Post-dilution on-line HDF**

Volume of substitution ≈ 25l/ses




**Pre-dilution on-line HDF**

Volume of substitution ≈ 50l/ses

# On-Line HDF machines approved and labeled with CE mark

Nikkiso DBB-05

Bellco Formula

B.Braun Dialog+

Gambro AK 200S/ Ultra ™

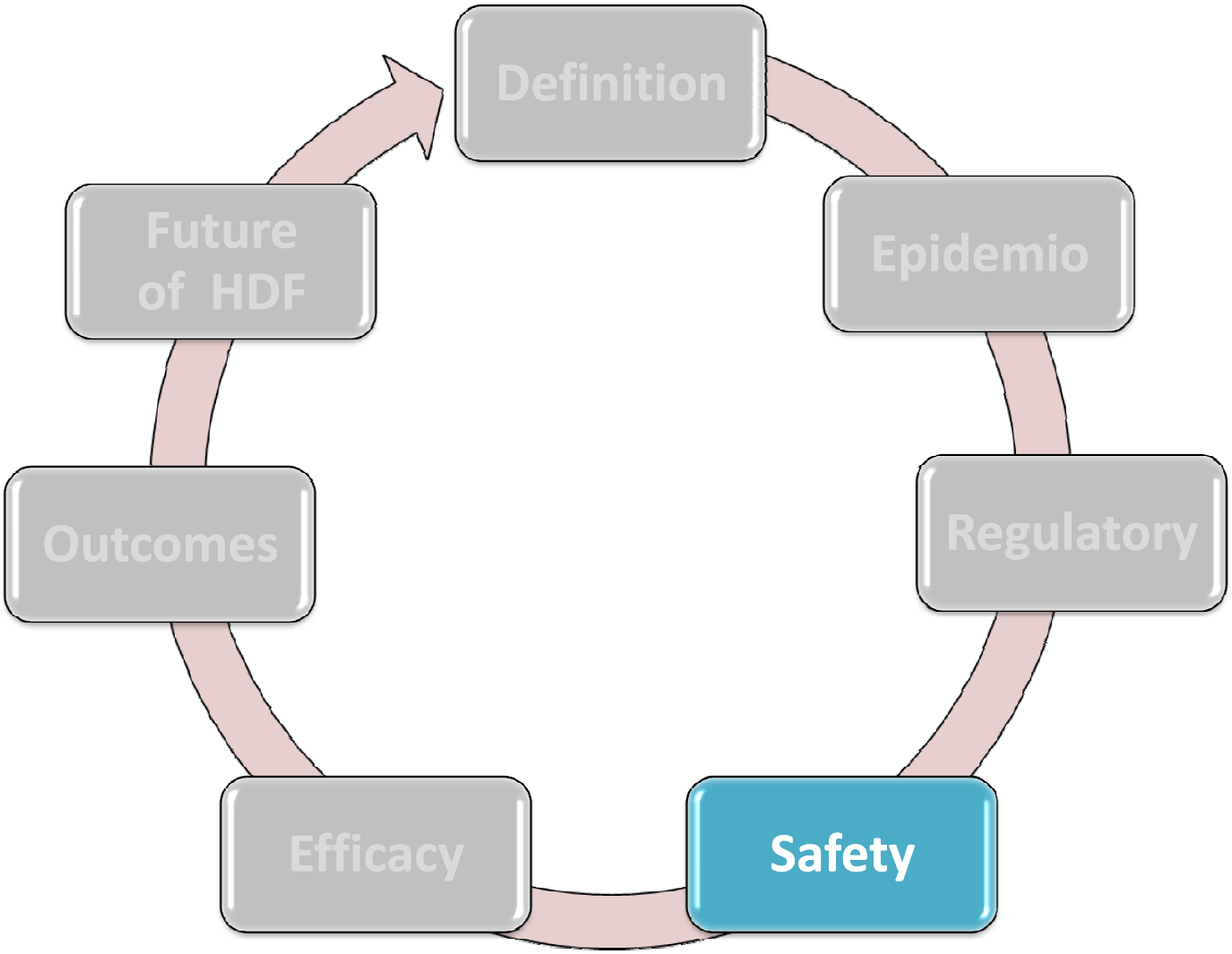
FMC 4008

FMC 5008

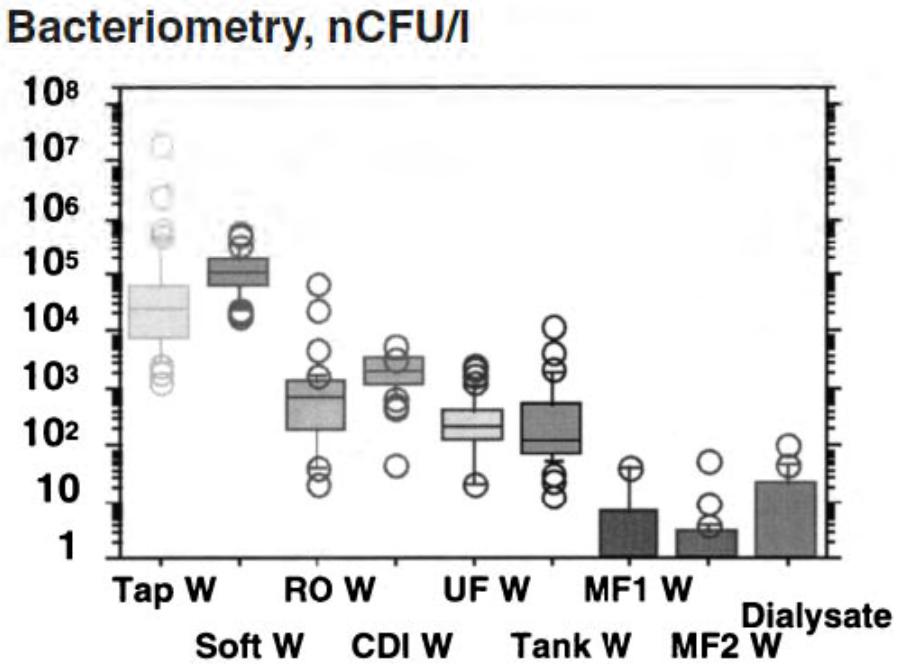
Gambro Innova

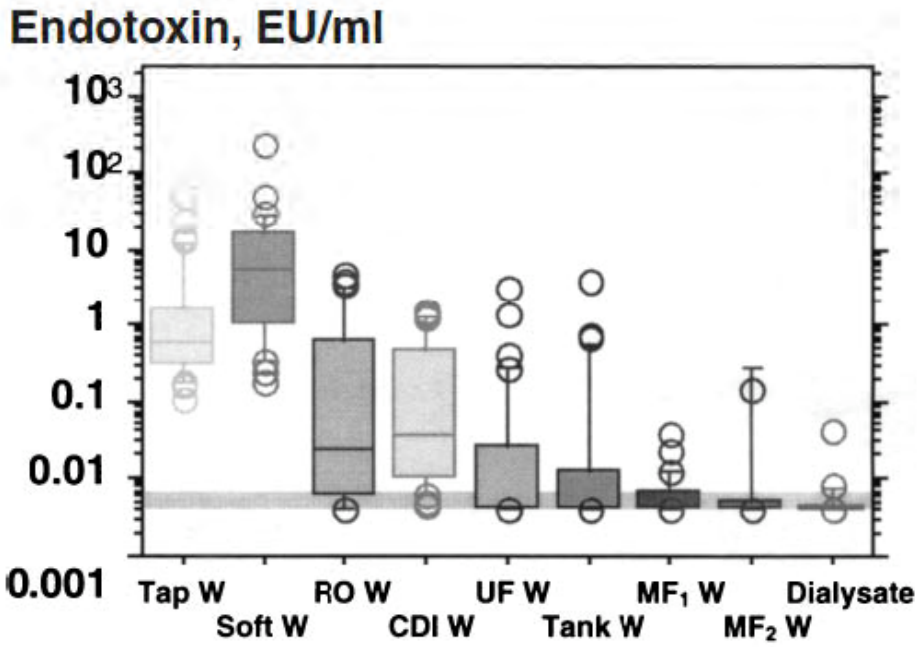
IEC ISO

# Outline of the presentation



# Safety and efficacy on long term use (1994-1997)




19200 HDF sessions
Total production of substitution fluid 533 594 liters

Canaud B et al, *Nephrol Dial Transplant* 2000; 15[S1]:60-67

# Infusate bacteriometry (1994-1997)

| Lapeyronie and UDSA, 1994–1997 | *n* | % |
|---|---|---|
| Membranes cultured | | |
| HDF sessions | | |
| Negative | 18 465 | 96.2 |
| Positive | 735 | 3.8 |
| Total | 19 200 | 100.0 |
| Positive membranes | | |
| n cfu | | |
| 1–9 | 663 | 90.2 |
| 10–99 | 48 | 6.5 |
| 100 | 24 | 3.3 |
| Total | 735 | 100.0 |

19200 HDF sessions – Mean volume filtrate 24 liters
Total production of substitution fluid 533 594 liters

Canaud B et al, *Nephrol Dial Transplant* 2000; 15[S1]:60-67

# Microbiological quality of purified water and ultrapure dialysis fluids for online HDF in clinical routine practice

- Subgroup analysis after enrolment
- 10 centers  - One year follow-up
- 97 patients - 11258 HDF sessions
- 3961 samples

**CONTRAST** Dutch Convective Transport Study

Penne EL et al, *Kidney Int.* 2009 ; 76: 665-672

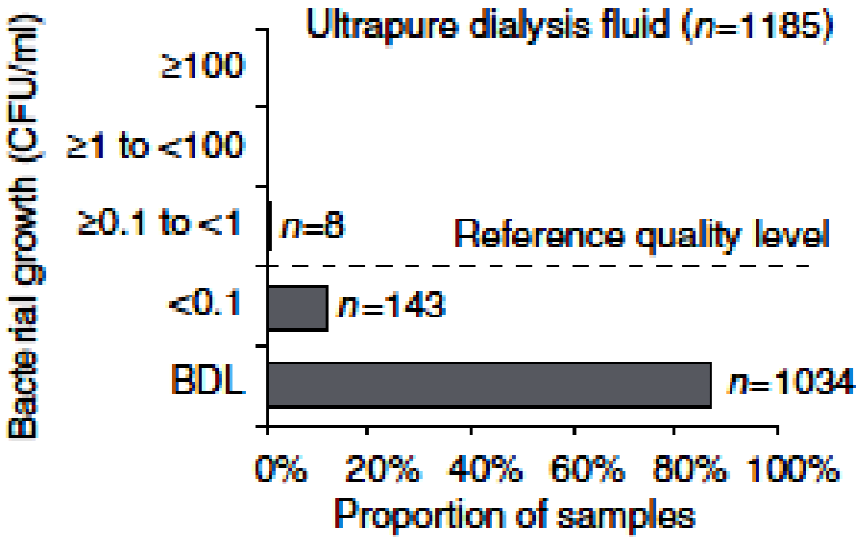
# Clinical safety is confirmed on a routine basis and large scale

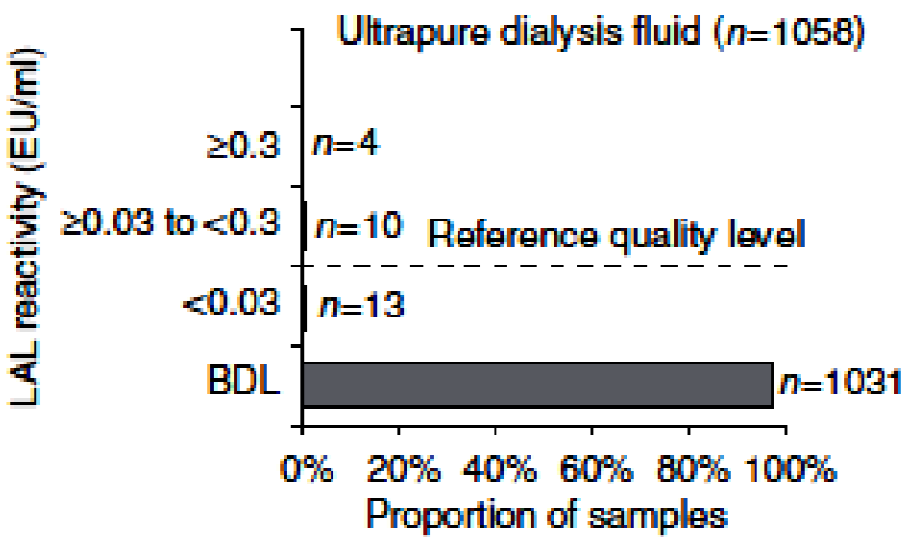
- One year follow-up
- 97 patients
- 11258 HDF sessions
- No febrile reactions
- No clinical adverse events

**CONTRAST** Dutch Convective Transport Study

Penne EL et al, *Kidney Int.* 2009 ; 76: 665-672

# Ultrapurity of dialysis fluid is confirmed in 85 to 98% of samples




10 centers
One year follow-up
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97 patients – 3961 samples

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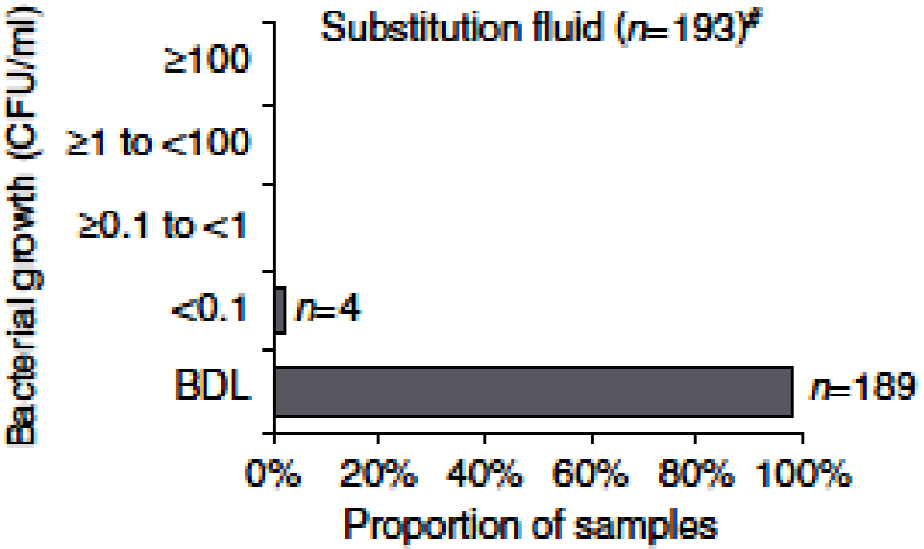
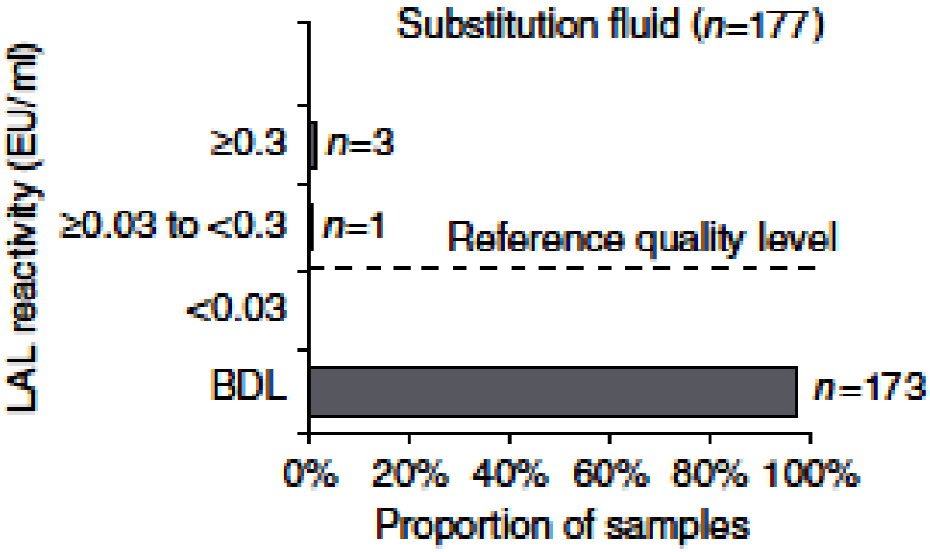
# Ultrapurity of infusate is confirmed in 99 to 100 % of samples



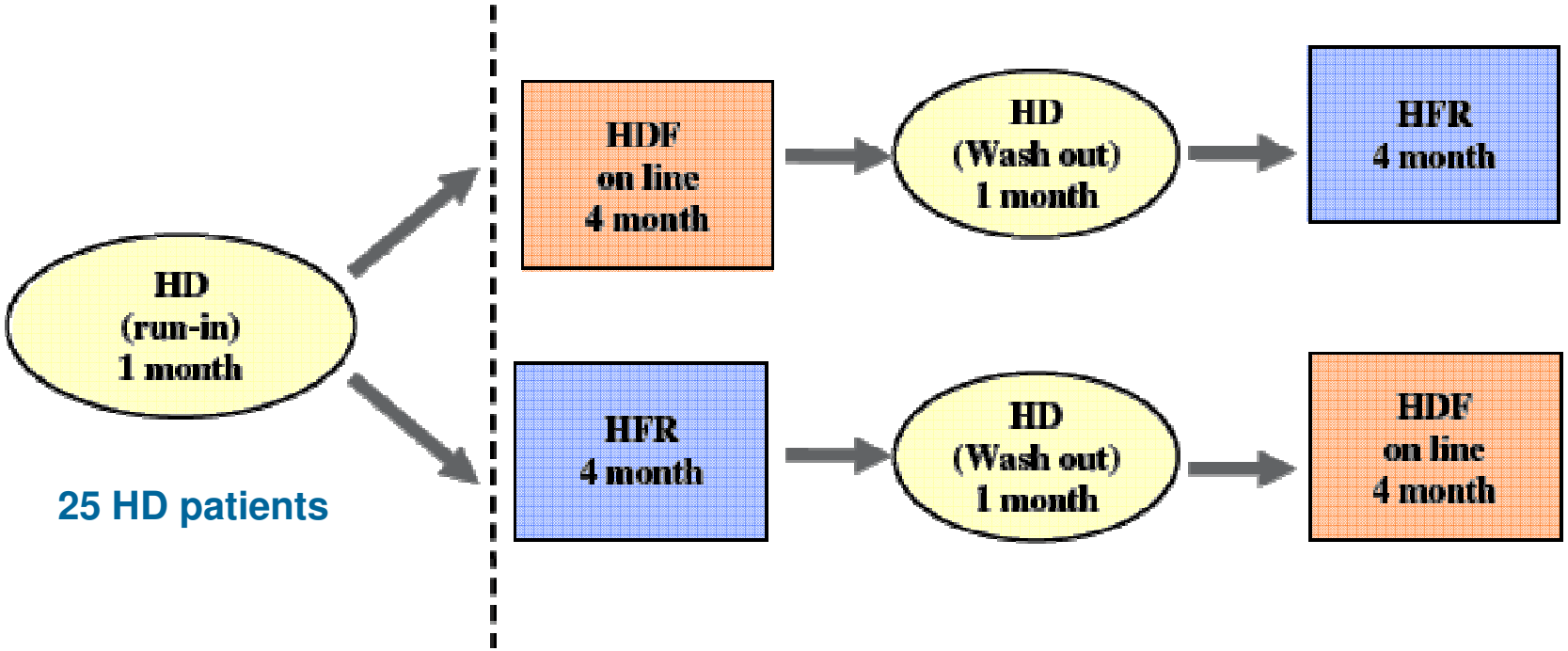




**CONTRAST** Dutch Convective Transport Study

Penne EL et al, *Kidney Int.* 2009 ; 76: 665-672

# Effects of OL-HDF & r-HDF on inflammatory & nutritional markers

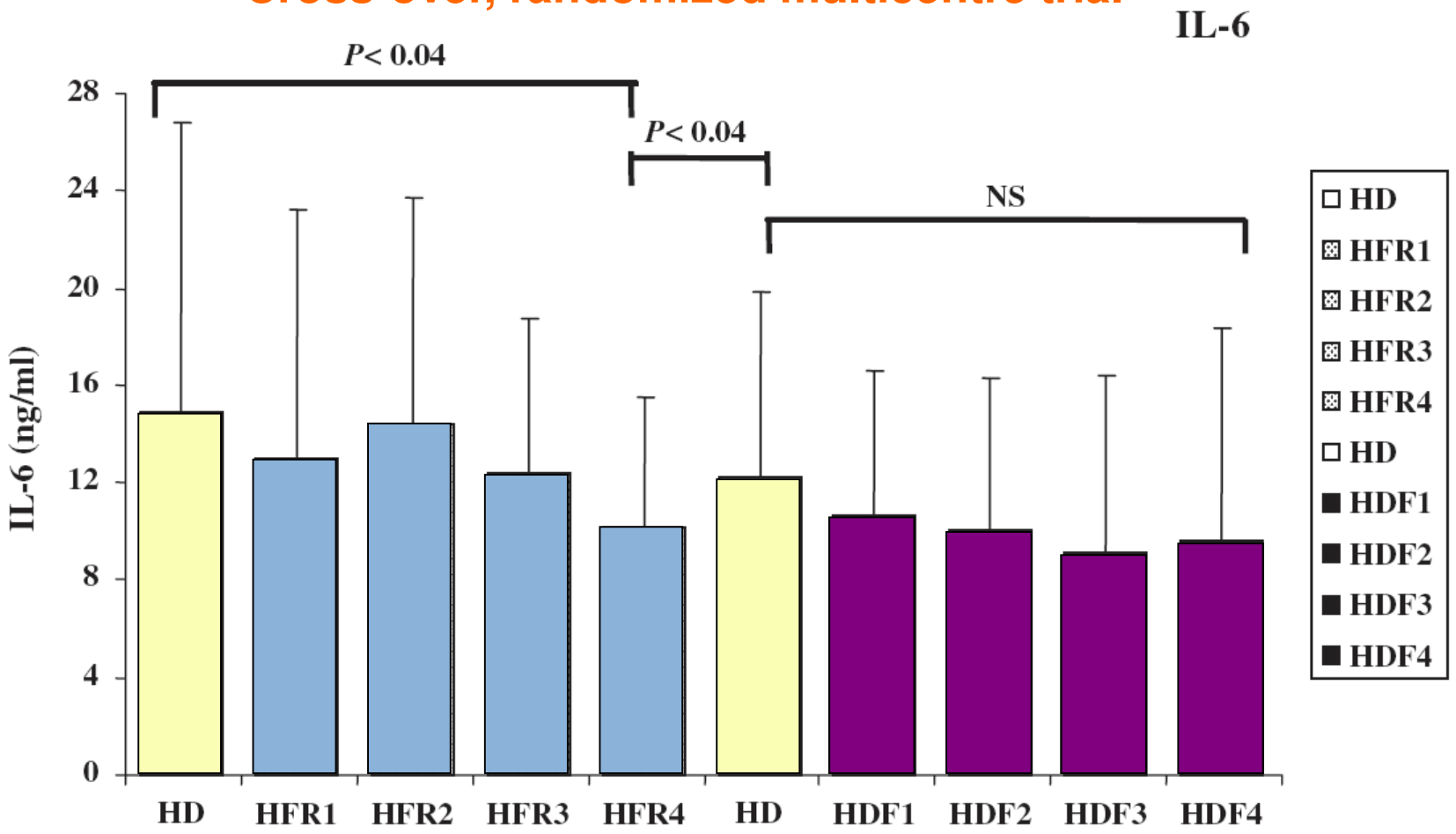
## Cross-over, randomized multicentre trial




Panichi V et al, *Nephrol Dial Transplant* 2006; 21: 756-762

# Effects of OL-HDF and r-HDF on inflammatory and nutritional markers

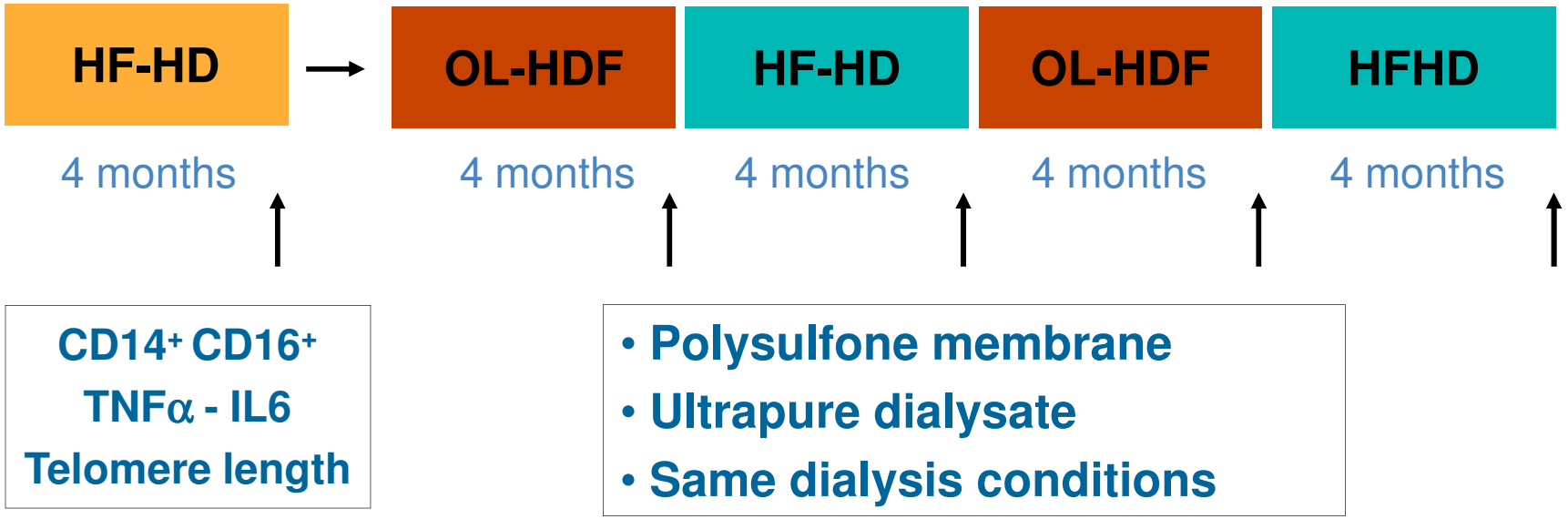
## Cross-over, randomized multicentre trial




Panichi V et al, *Nephrol Dial Transplant* 2006; 21: 756-762

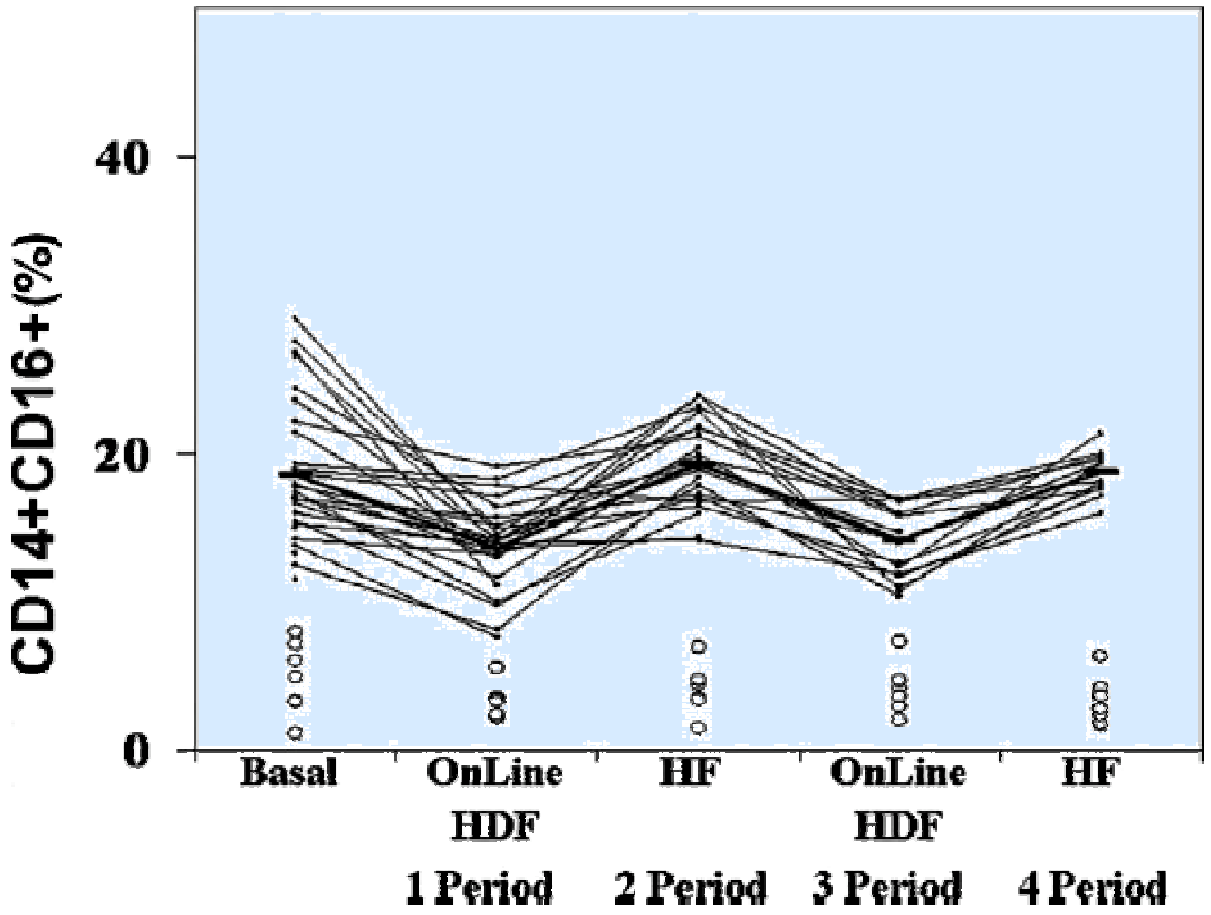
# Effect of HD and HDF on $CD14^+CD16^+$ monocytes, TNFα, IL6 and inflammatory markers

**Cross-over, randomized study (*31 HD patients*)**



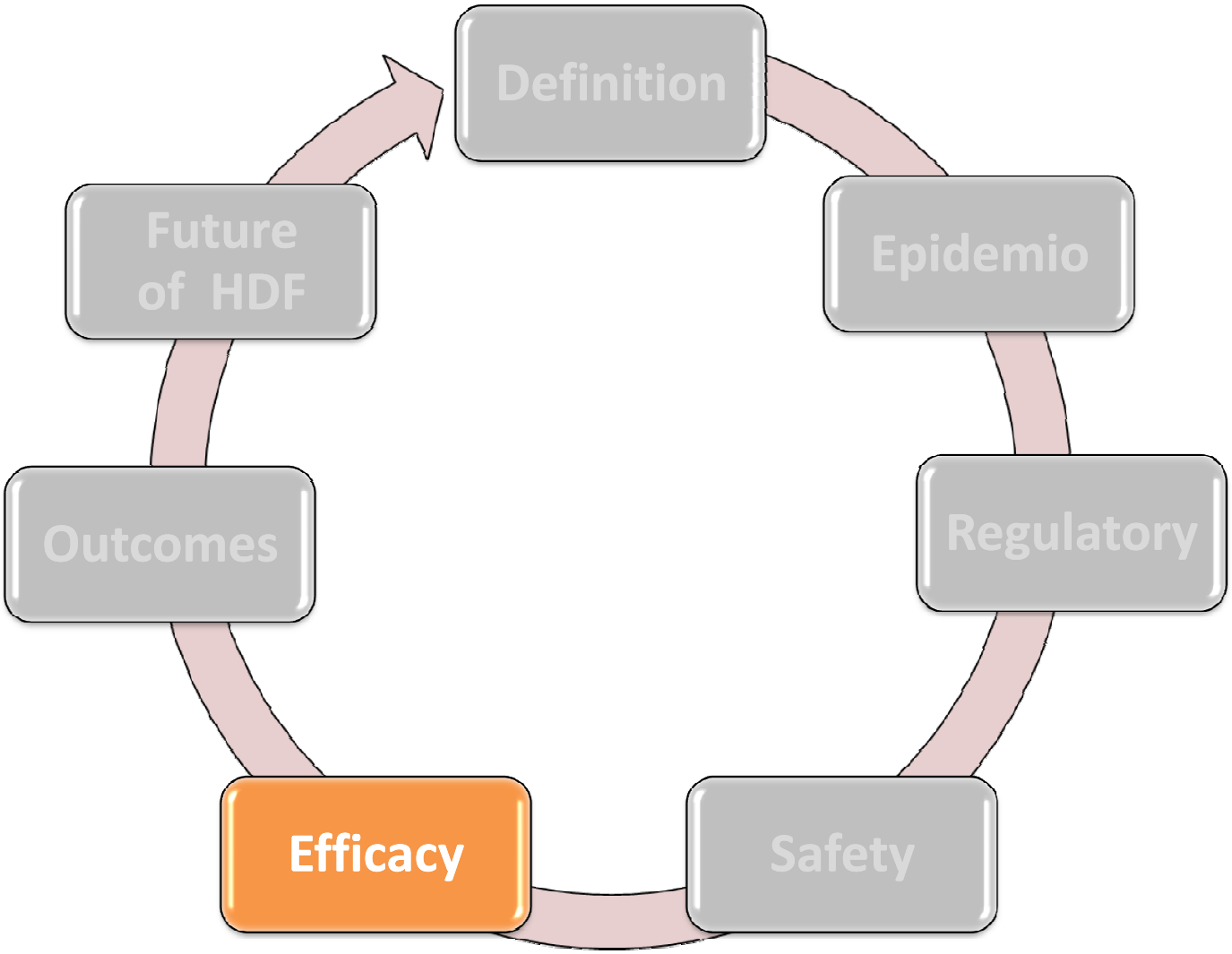

Carracedo J et al, *J Am Soc Nephrol.* 2006; 17: 2315

# OL-HDF reduces proinflammatory $CD14^{+}CD16^{+}$ monocyte-derived dendritic cells




Carracedo J et al, *J Am Soc Nephrol.* 2006; 17: 2315

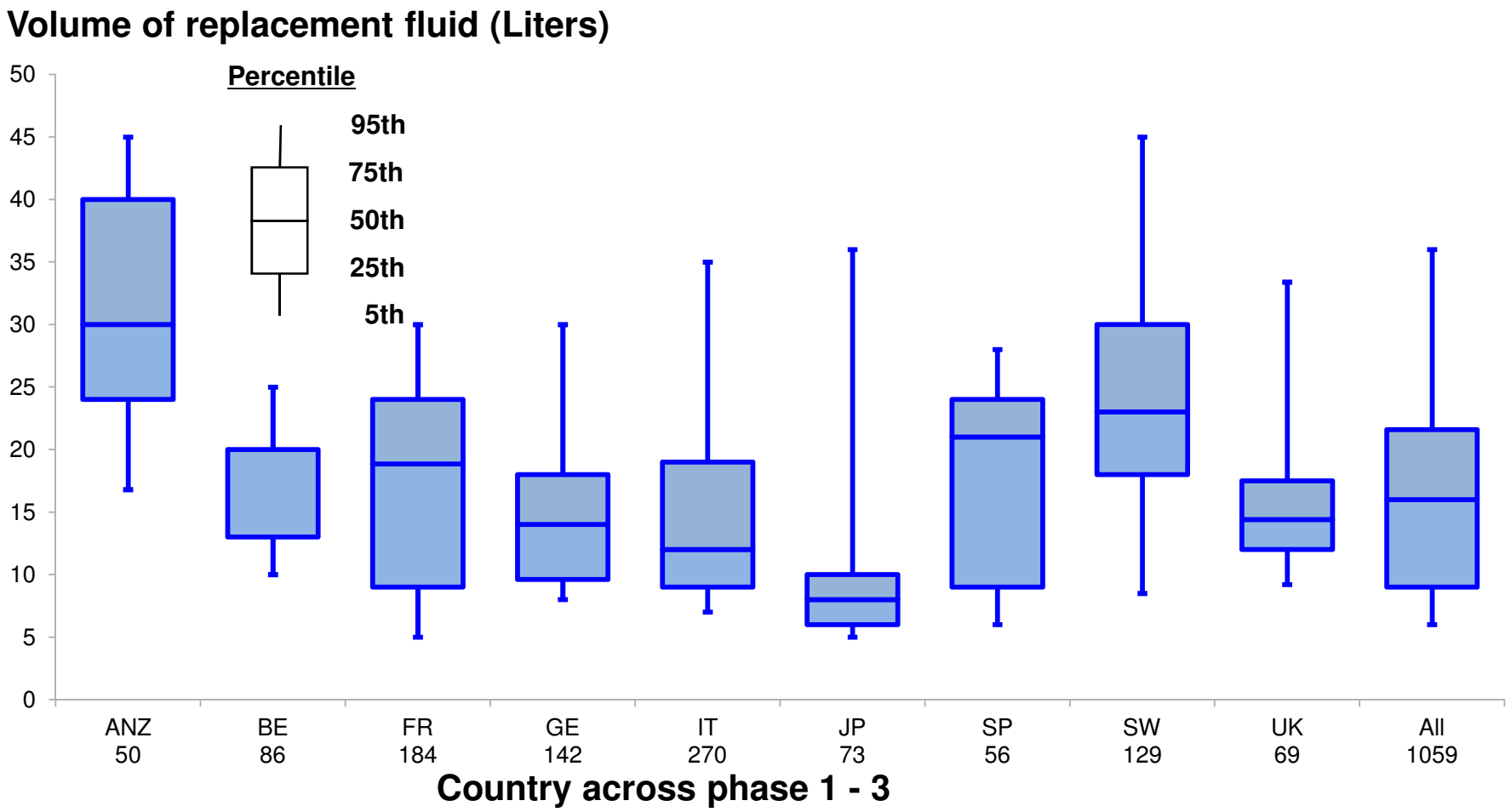
# Outline of the presentation



# High-Efficiency on-line HDF. What does it means?

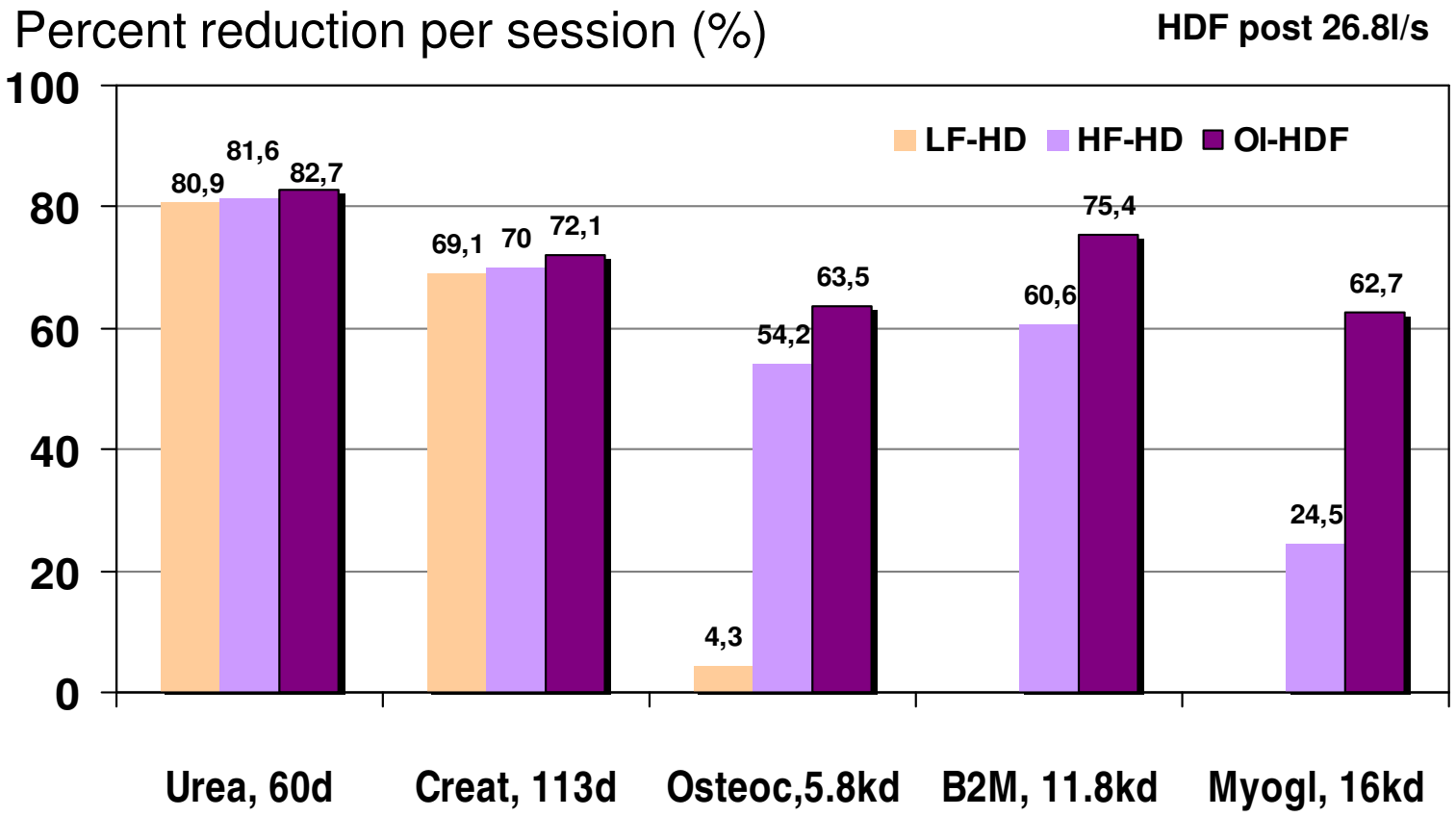
- Treatment schedule
  - ☐ 3 sessions of 4 hours weekly (minimum)
  - ☐ Longer or more frequent (possible)
- Highly permeable synthetic membrane
- Large surface area > 1.8 m2
- Ultrapure bicarbonate dialysis fluid
- High blood flow (effective QB: 350 - 400 ml/min)
- **High dialysate flow (500-700 ml/min) ⇨ diffusive dose**
- **Large volume of substitution ⇨ convective dose**
  - Post-dilution (Qsub : 100 ml/min, 24 l / session)
  - Pre-dilution (Qsub : 200 ml/min, 48 l / session)
  - Mixed dilution (Qsub : 150ml/min, 36 l/session)

# Distribution of Mean Replacement Fluid Volume for Patients on HDF, by Country



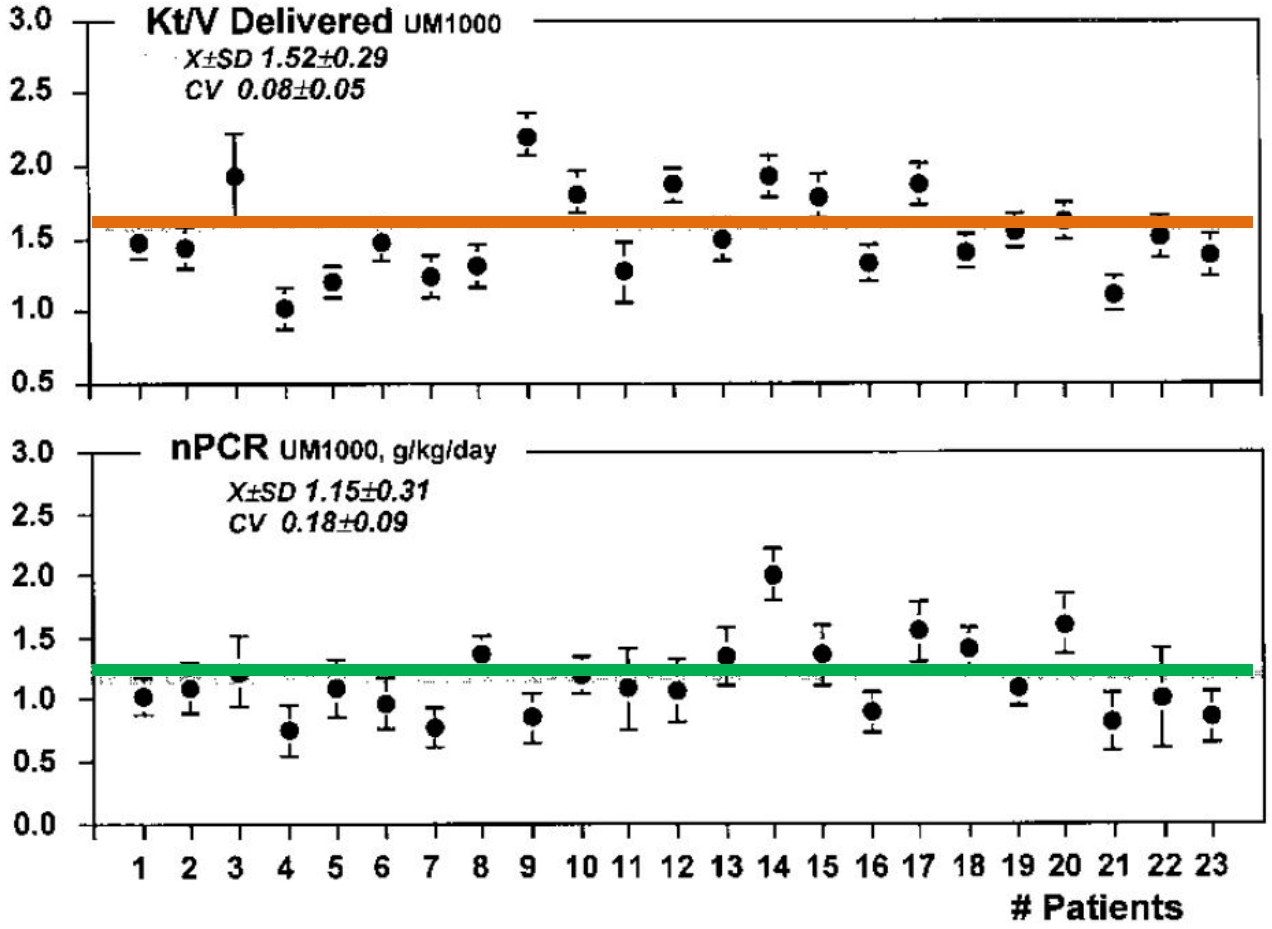

Initial prevalent cross-sections who dialyzed 3 times/wk with vintage ≥3 months;
HDF not used in the US and Canada

# Middle molecules removal in ol-HDF vs LF-HD vs HF-HD




Maduell F et al, *Am J Kidney Dis* 2002; 40: 582-589

# Mean dialysis dose and nPCR in HDF treated patients with direct dialysis quantification method




**Urea Monitoring, BioStat 1000**

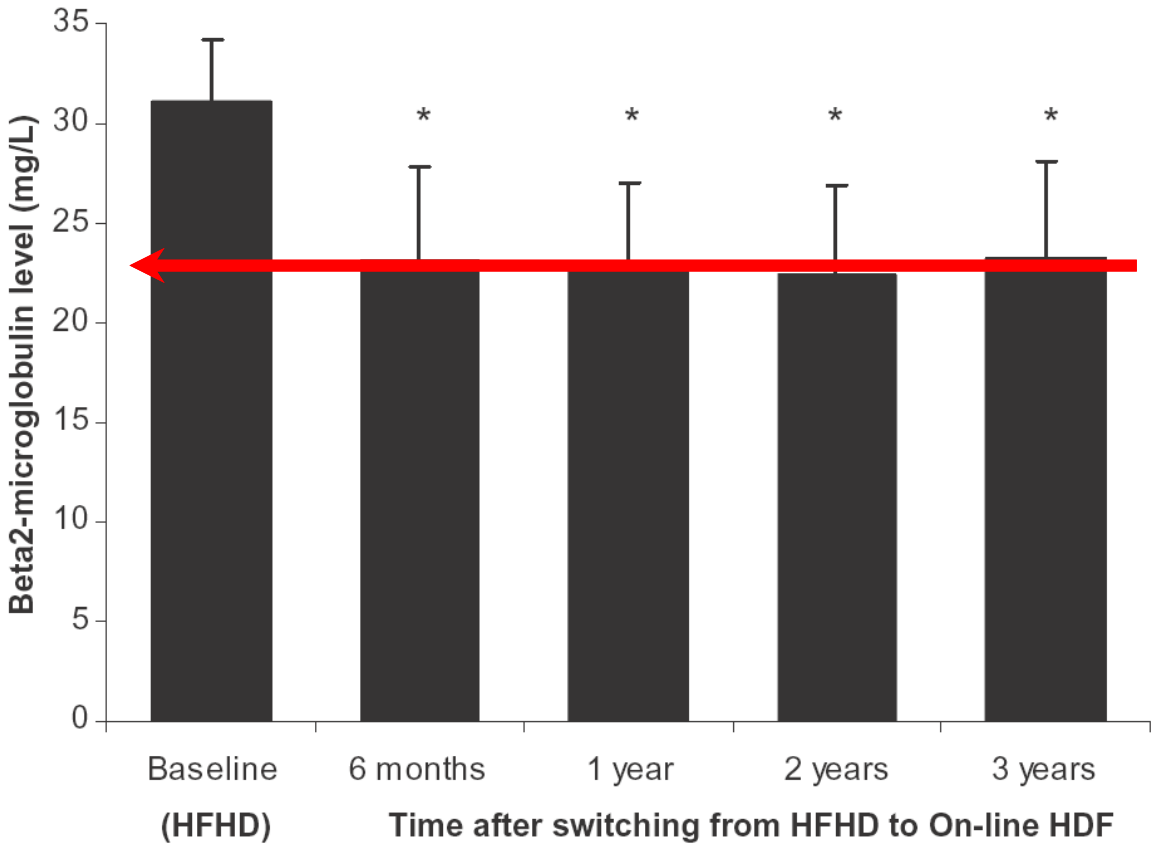
Canaud B et al, *Am J Kidney Dis* 1998; 31:74-80

# HDF vs HFHD: modest increase of urea Kt/V but significant reduction of circulating β2M

| | Baseline | 6 months | 12 months | Period 1<br>p: baseline versus 6 months | Period 2<br>p: 6 months versus 12 months |
|---|---|---|---|---|---|
| Study group: $n = 30$ ol-HDF | | | | | |
| eKt/V | 1.20 ± 0.08 | 1.21 ± 0.08 | 1.34 ± 0.11 | NS | <0.0001 |
| $Beta_2$ microglobulin (mg/dL) | 35.0 ± 9.6 | 34.9 ± 9.2 | 24.5 ± 9.0 | NS | <0.0001 |
| Controls: $n = 35$ LFHD | | | | | |
| eKt/V | 1.22 ± 0.06 | 1.23 ± 0.07 | 1.22 ± 0.06 | NS | NS |
| $Beta_2$ microglobulin (mg/dL) | 36 ± 12 | 37 ± 13 | 37 ± 11 | NS | NS |

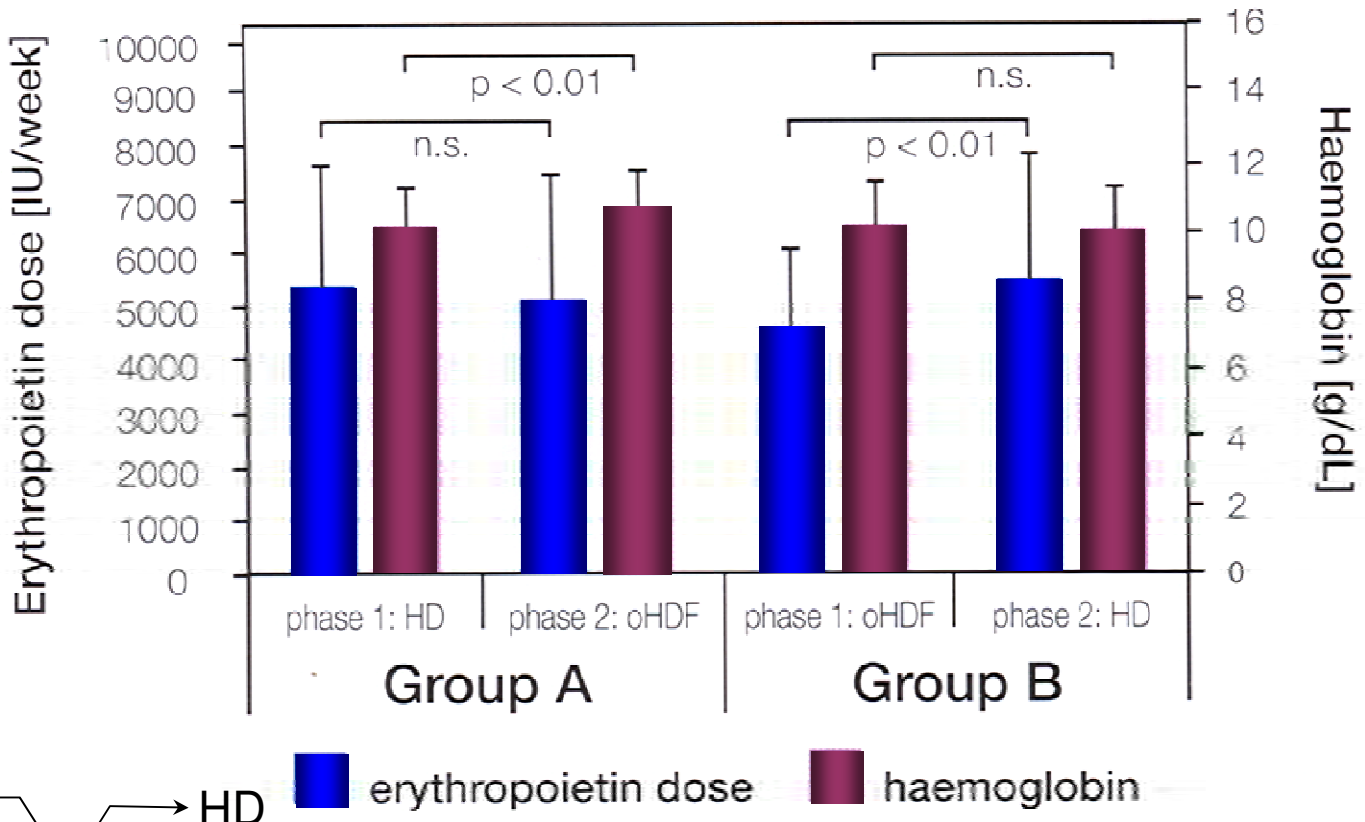
Movilli E et al, *Nephro Dial Transplant*. 2011; 0:1-6 ePub May2011

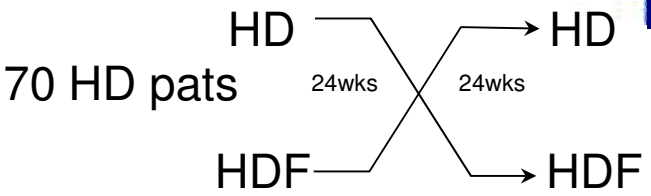
# ß2-M concentrations is reduced after switching from HFHD to ol-HDF




Tiranathanagul K et al. *Ther Apher Dial* 2009; 13: 56-62

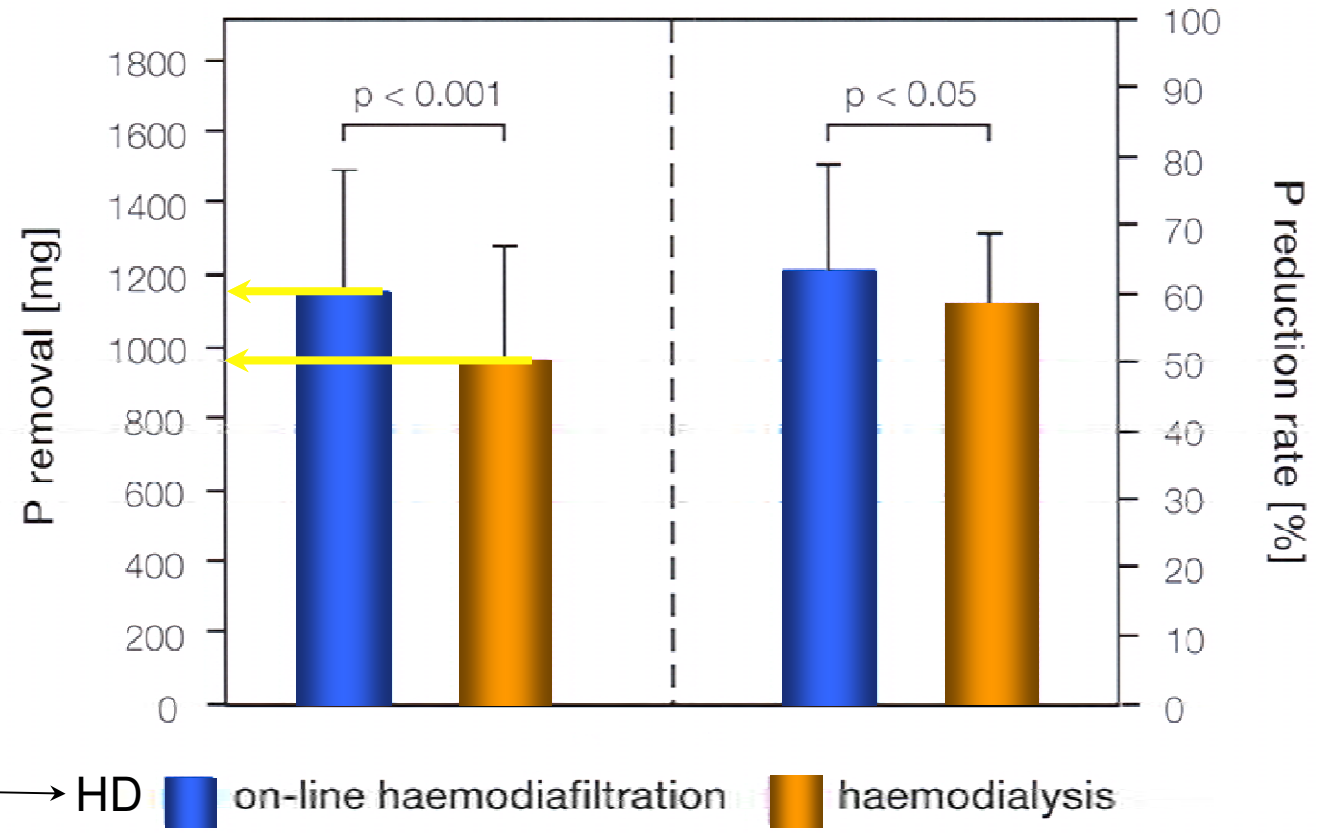
# High efficiency HDF increases the erythropoietic response to ESA



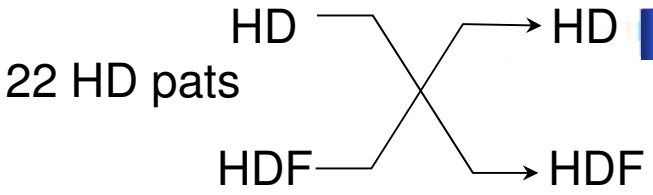




Vaslaki L et al, *Blood Purif* 2006; 24: 163-173

# High efficiency HDF increases the phosphate mass removal




4hrs x 3wk
HF80 - QD800
Direct dialysate quantification




Lornoy W et al, *J Ren Nut* 2006; 16: 47-53

# Hemodynamic tolerance is improved in HDF

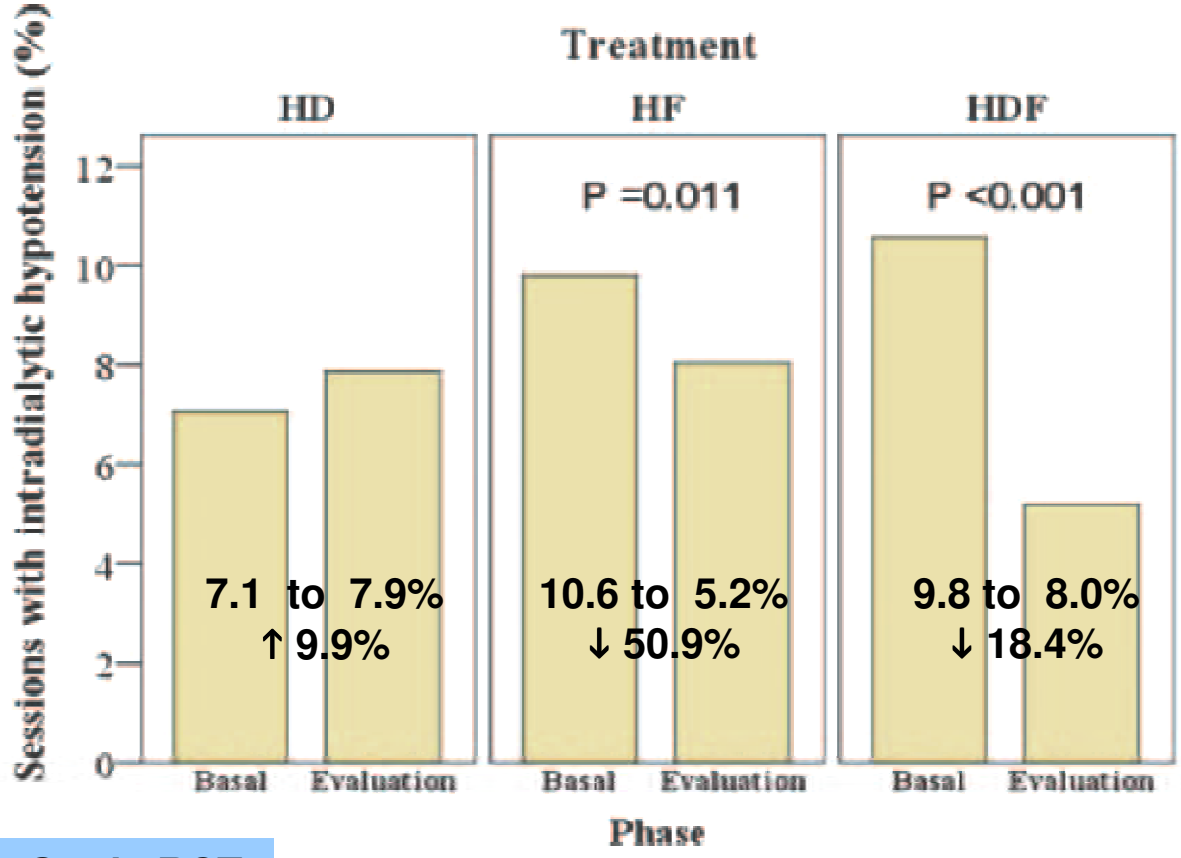
| Condition | HFHD (Baseline) | On-line HDF | | | |
|---|---|---|---|---|---|
| | | 6 months | 1 year | 2 years | 3 years |
| Hypotension | 20.2 ± 17.1 | 10.4 ± 17.6 | 11.8 ± 16.1 | 10.0 ± 13.8 | 12.4 ± 16.1 |
| Hypertension | 2.9 ± 4.7 | 2.2 ± 7.7 | 2.4 ± 5.7 | 0.1 ± 0.4 | 0.9 ± 2.1 |
| Muscle cramp | 7.8 ± 9.5 | 5.3 ± 7.7 | 2.0 ± 2.1 | 3.0 ± 3.7 | 1.9 ± 2.3 |
| Headache | 1.7 ± 2.6 | 1.3 ± 3.2 | 0.4 ± 1.1 | 0.4 ± 1.1 | 0.3 ± 0.9 |

ol-HDF in Southeast Asia: 3 years experience
22 HD patients HFHD → ol-HDF

Tiranathanagul K et al. *Ther Apher Dial* 2009; 13: 56-62

# Convective therapies (HF, HDF) reduce intradialytic symptomatic hypotension (ISH)

Total incidence of ISH 7.5% 28950 sessions




**Italian Multicentric Study RCT**
**LFHD, HF, HDF Ratio 2/1/1**

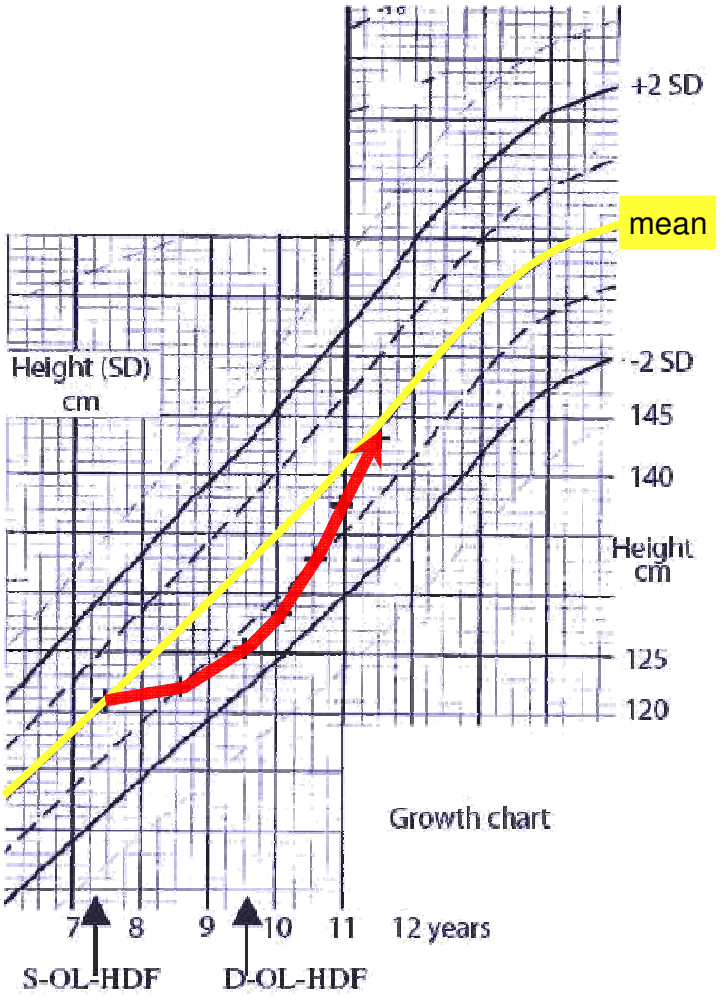
Locatelli F et al, *J Am Soc Nephrol* 2010; 21:1798-1807

# Daily online HDF promotes catch-up growth in CKD children

| Patient ($n$ = 15) | Mean ± SD | |
|---|---|---|
| Height (SDS) | | |
| Start of D-OL-HDF | − 1.5 ± 0.3 | |
| End of D-OL-HDF (1) | + 0.2 ± 1.1* | |
| Mid-parental target height (2) | − 0.3 ± 0.7 | |
| (1) − (2) (SDS) | + 0.3 ± 0.7 | |
| Growth velocity (centimetres per year) | | |
| The year before daily | 3.8 ± 1.1 | |
| First year of daily | 14.3 ± 3.8° | |
| Mean over daily | 8.9 ± 2.2°° | |
| BMI | $kg/cm^2$ | % |
| At start of daily | $16.5 \pm 2.0^{+}$ | $48 \pm 24^{++}$ |
| End of daily | $18.0 \pm 2.4^{+}$ | $65 \pm 26^{++}$ |

Fischbach M et al, *Nephrol Dial Transplant.* 2009;

# Normalization of growth curve in children treated by daily ol-HDF

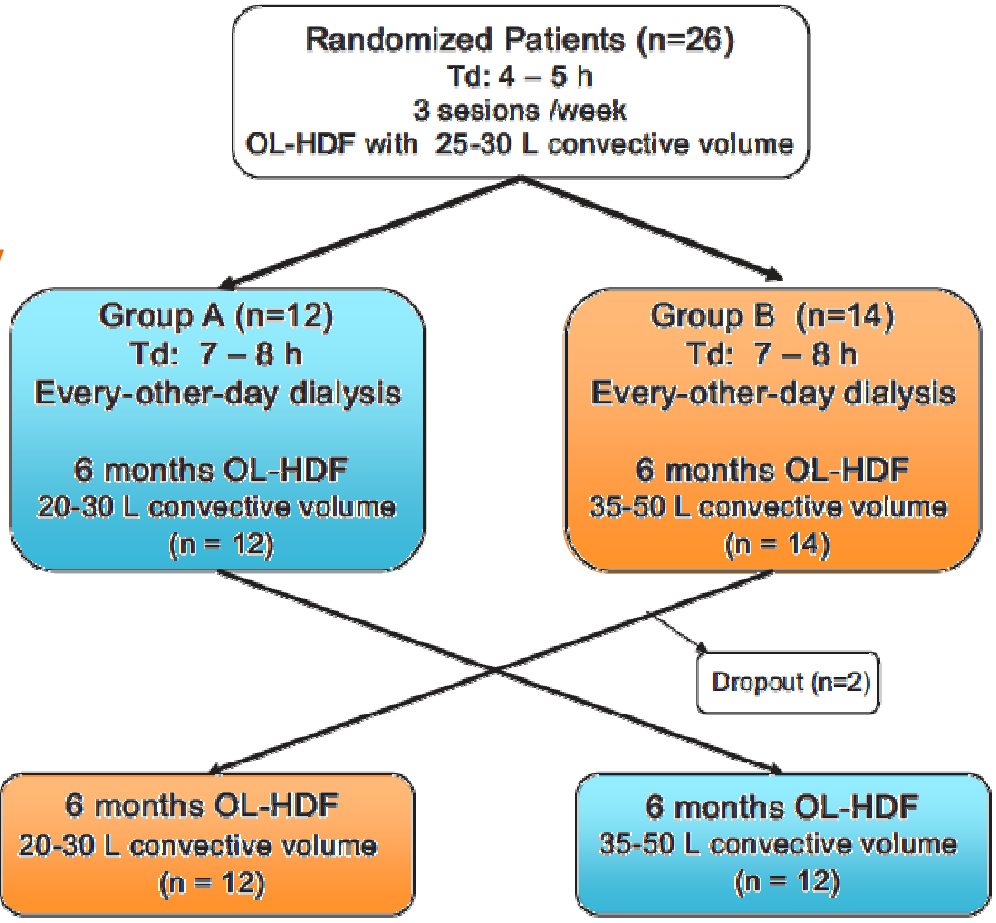



Fischbach M et al, *Nephrol Dial Transplant* 2004; 19: 2360-2367

# Nocturnal, every-other-day, ol-hemodiafiltration

**Time & Frequency**

**Intracorporeal resistance**

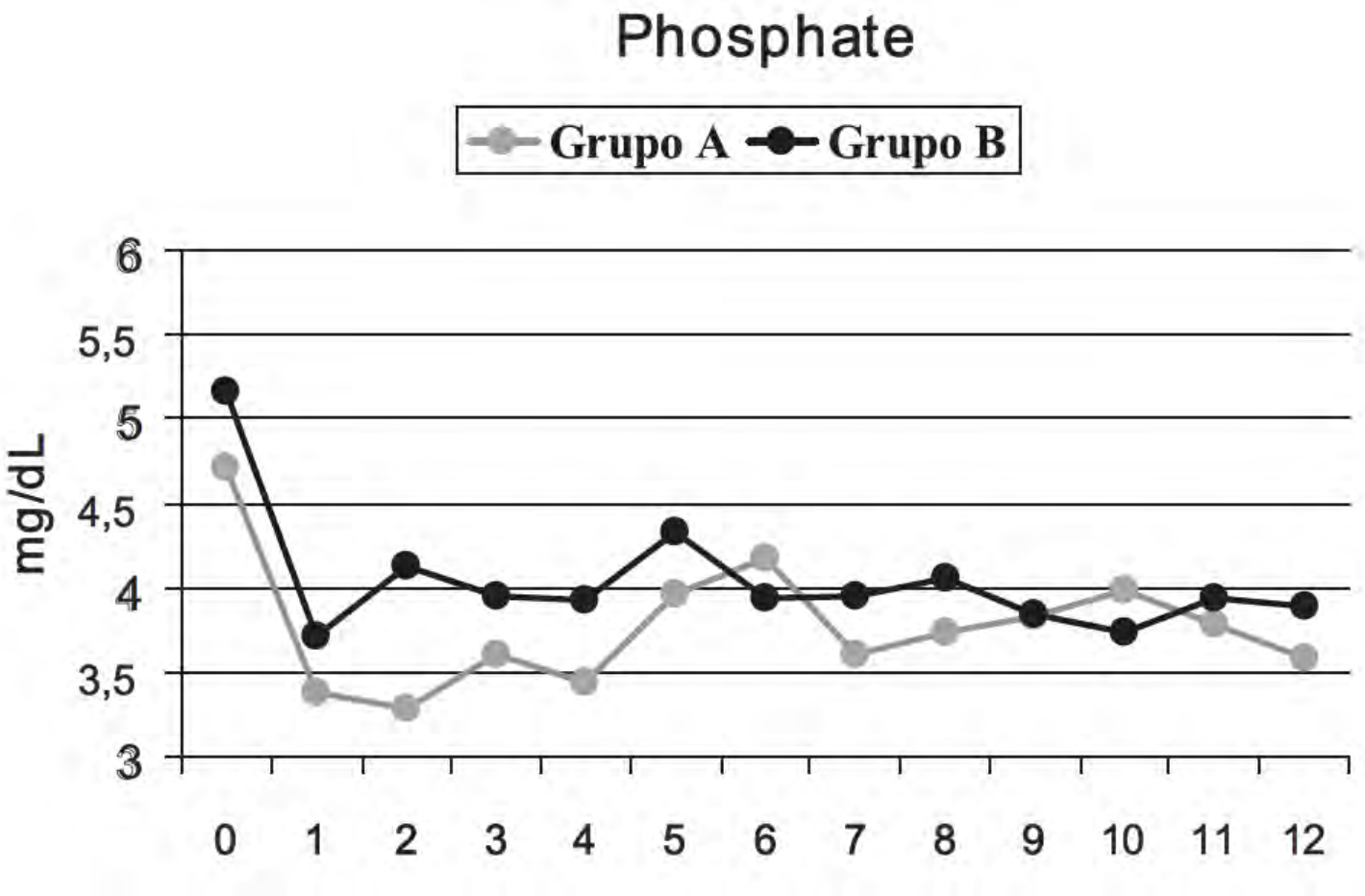



**Volume substitution**


**Convective dose**

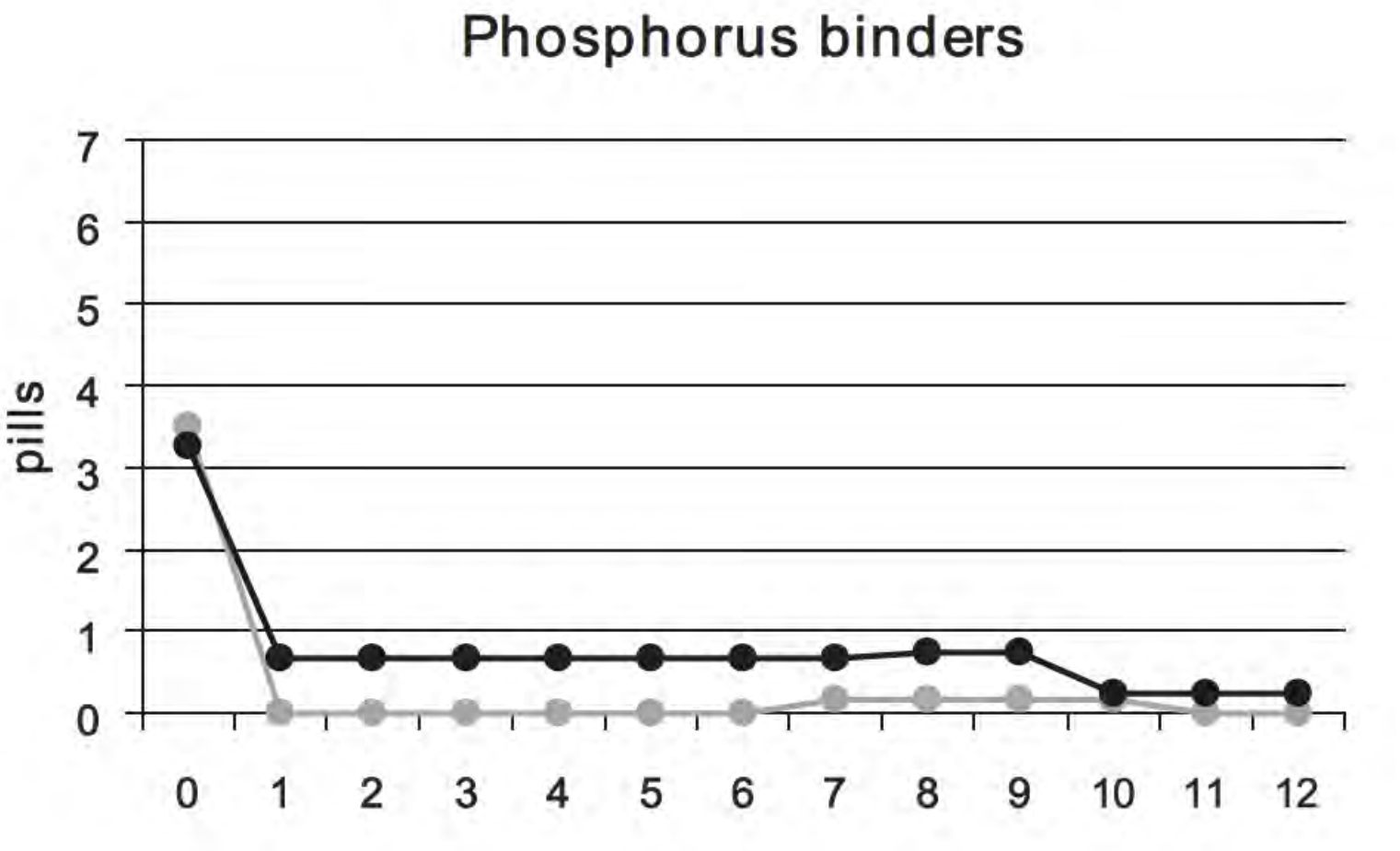
Maduell F et al, *Nephro Dial Transplant*. 2011; 0:1-13 ePub 13Sep2011

# Remarkable effect on phosphate control



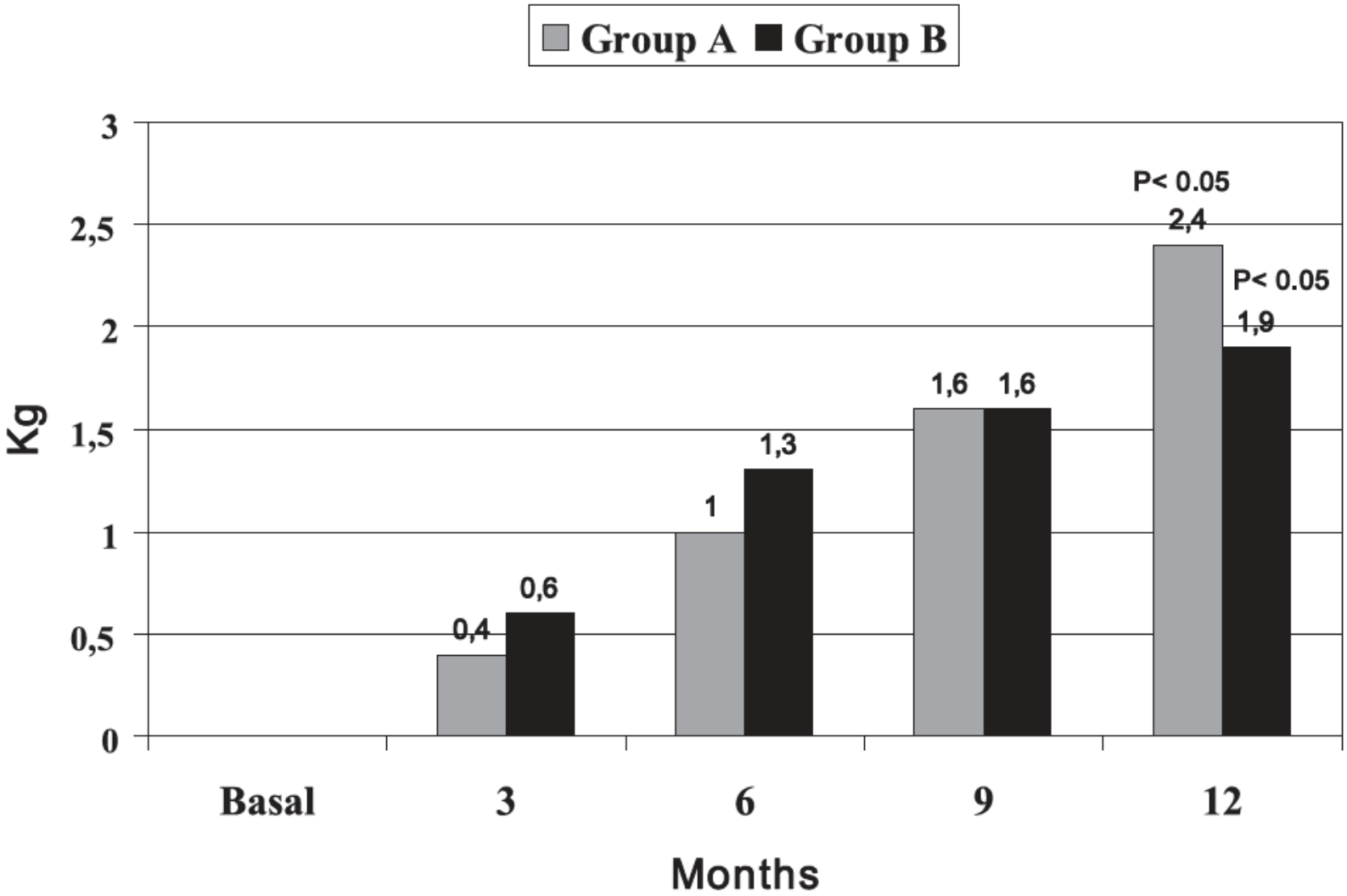

Maduell F et al, *Nephro Dial Transplant*. 2011; 0:1-13 ePub 13Sep2011

# Considerable reduction of phosphate binders consumption



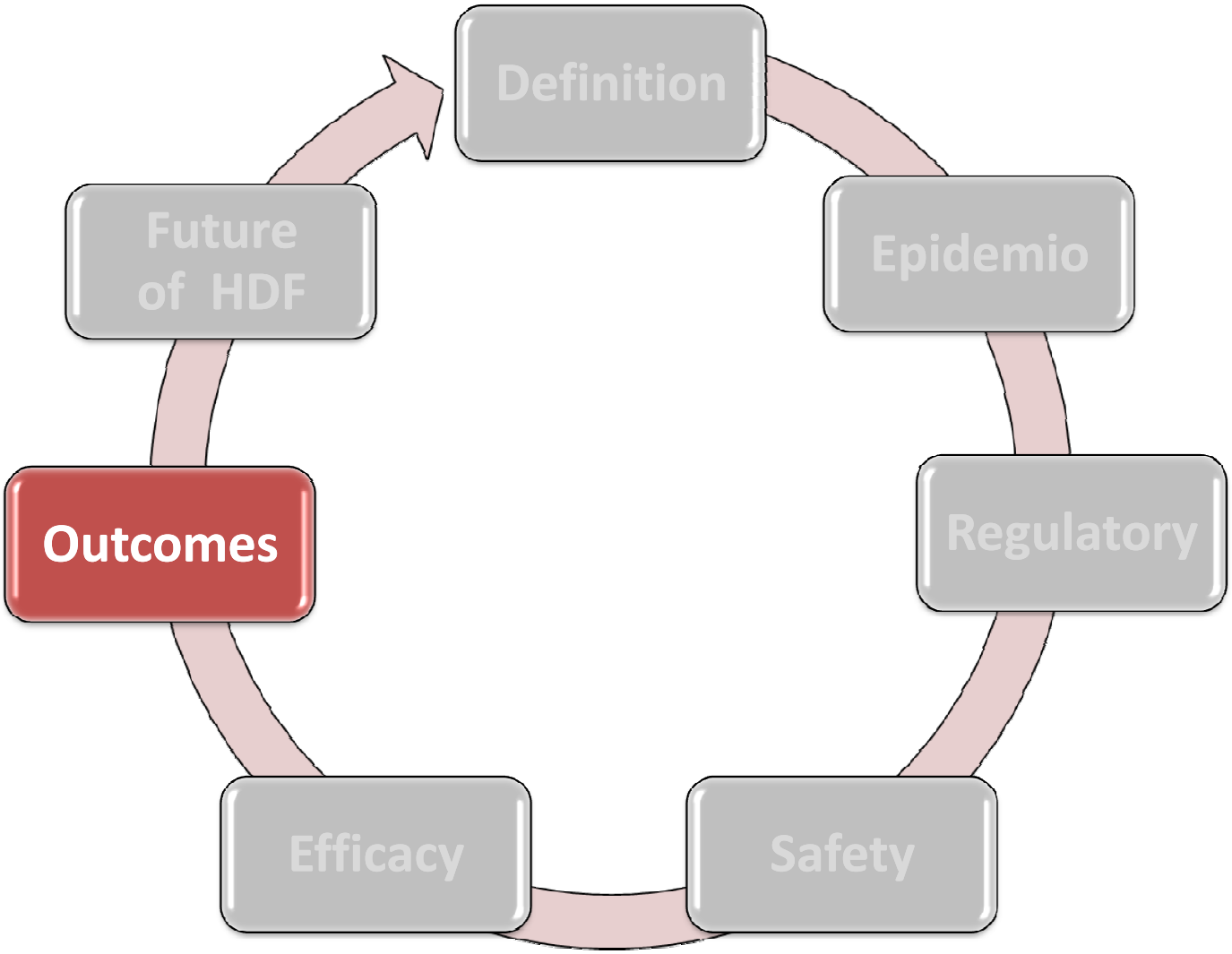

Maduell F et al, *Nephro Dial Transplant*. 2011; 0:1-13 ePub 13Sep2011

# Significant beneficial effect on nutritional status




Maduell F et al, *Nephro Dial Transplant*. 2011; 0:1-13 ePub 13Sep2011

# Outline of the presentation



# Outcomes of HDF versus HD

| Author, Year | HDF vs Comparator | Type of study | Grading |
|---|---|---|---|
| **Wizemann V et al, 2000** | HDF vs LFHD | RCT | Ia |
| **Bosch JP et al, 2006** | HDF vs LFHD vs HFHD | Historical prospective cohort | IIb |
| **Canaud B et al 2006** | HDF± vs LFHD vs HFHD | Historical prospective cohort | IIa |
| **Jirka et al, 2006** | HDF vs LFHD vs HFHD | Historical prospective cohort | IIa |
| **Schiffl H et al, 2007** | HDF vs HFHD + UPD | RCT | Ia |
| **Vinhas J et al, *2007*** | HDF vs HFHD | Prospective controlled study | IIb |
| **Panichi V et al. 2008** | HDF+/- vs LFHD | Prospective controlled study | IIa |
| **Santoro A et al, 2008** | HF vs HFHD | RCT | Ia |
| **Tiranathanagul K 2009** | HDF vs HFHD | Prospective controlled study | IIa |
| **Vilar E et al, 2009** | HDF vs HFHD | Historical prospective cohort | IIb |
| **Locatelli F et al, 2010** | HDF vs HD vs LFHD | RCT | Ia |

# Distribution of dialysis modality for prevalent patients

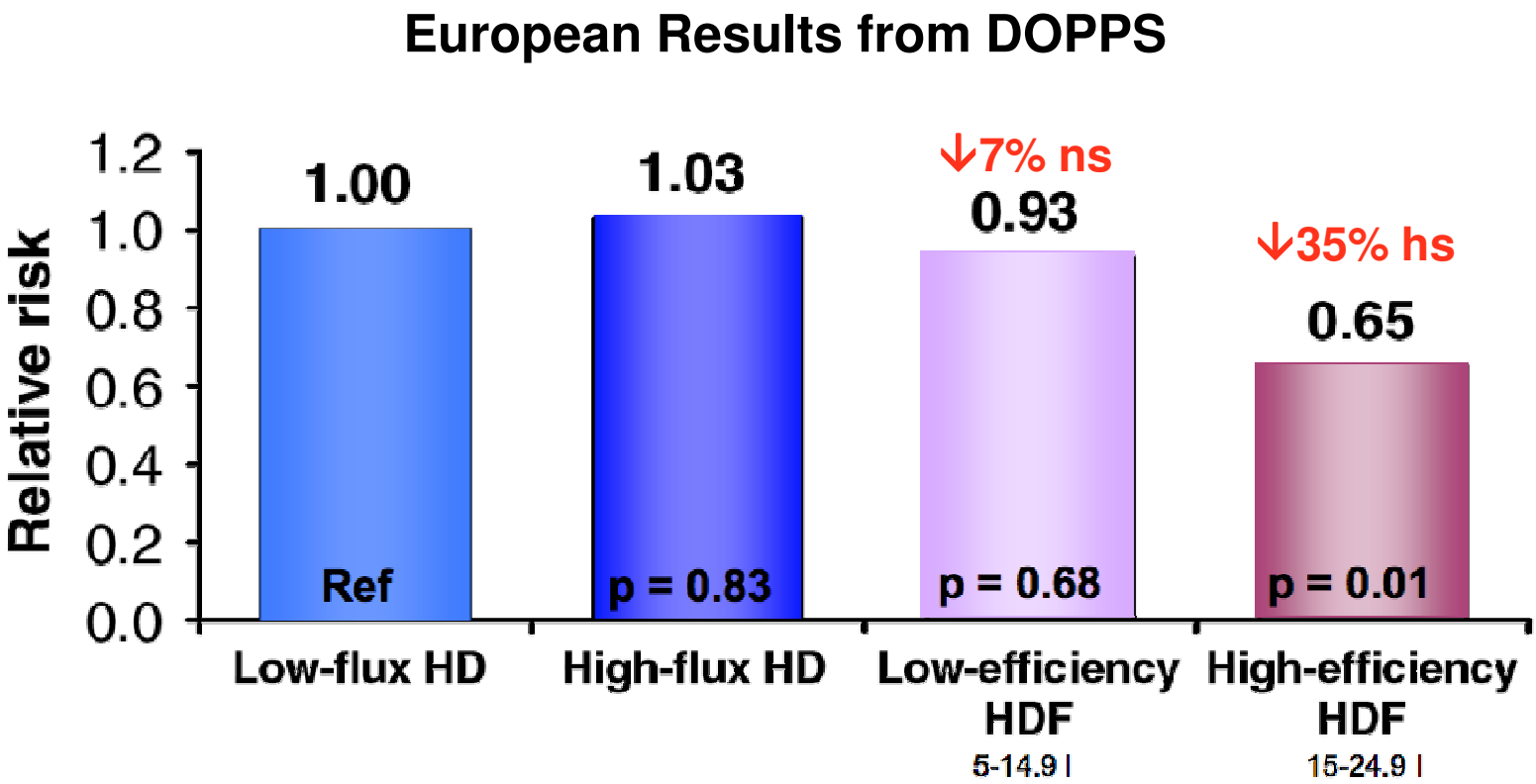
| Country | *n* | Patients (%) | | | |
|---|---|---|---|---|---|
| | | Low-efficiency HDF[a] | High-efficiency HDF[a] | Low-flux HD | High-flux HD |
| France | 460 | 5.4 | 8.9 | 45.9 | 39.8 |
| Germany | 440 | 11.1 | 4.8 | 50.5 | 33.6 |
| Italy | 443 | 14.7 | 5.4 | 74.9 | 5.0 |
| Spain | 383 | 1.8 | 0.0 | 61.4 | 36.8 |
| UK | 439 | 2.3 | 2.5 | 83.4 | 11.8 |
| All | 2165 | 7.2 | 4.5 | 63.1 | 25.2 |

[a]Low-efficiency HDF includes replacements of 5–14.9 l. while high-efficiency HDF includes replacement of 15–24.9 l.
HD, hemodialysis; HDF, hemodiafiltration.

DOPPS

Canaud B et al, *Kidney Int* 2006; 69: 2087-2093

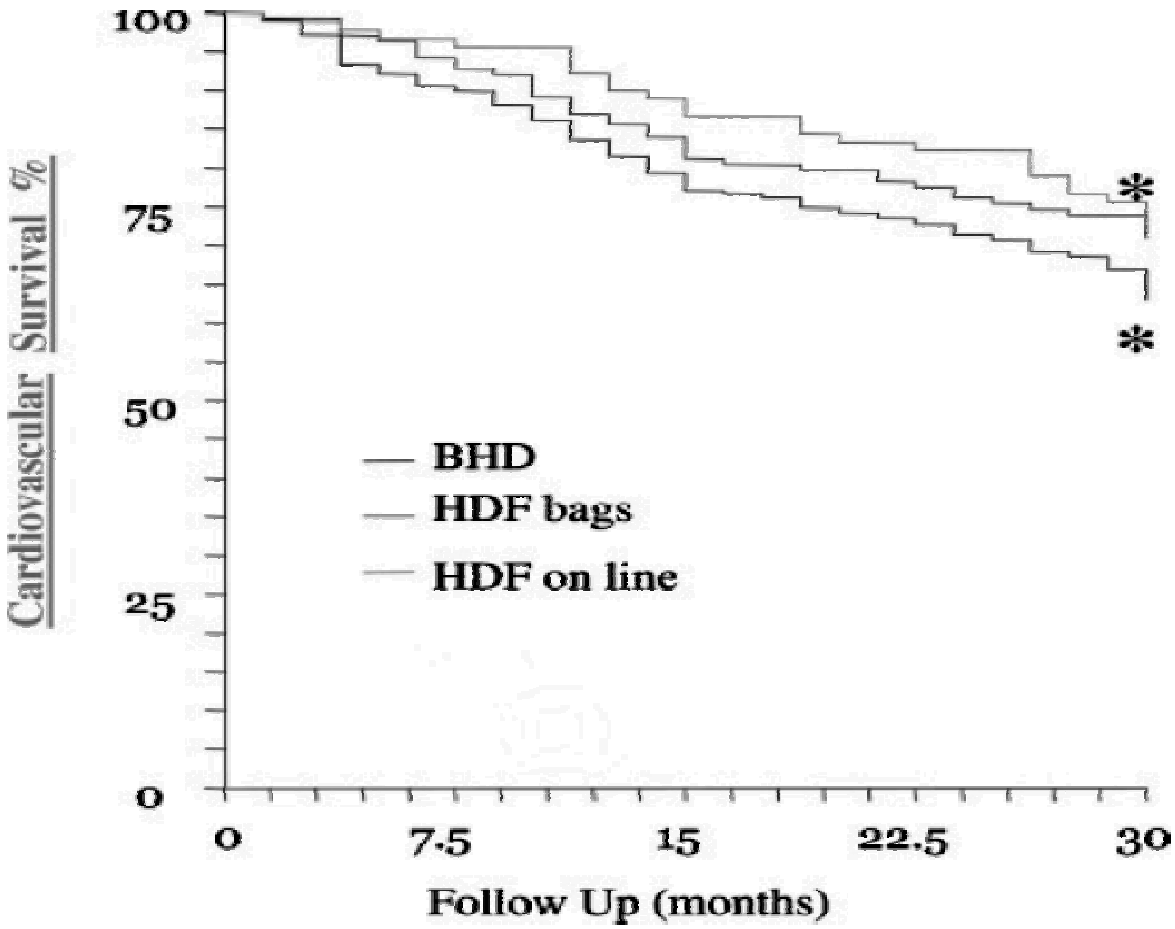
# Mortality risk for patients receiving high efficiency HDF *vs.* HD is reduced




DOPPS

Canaud B et al, *Kidney Int* 2006; 69: 2087-2093

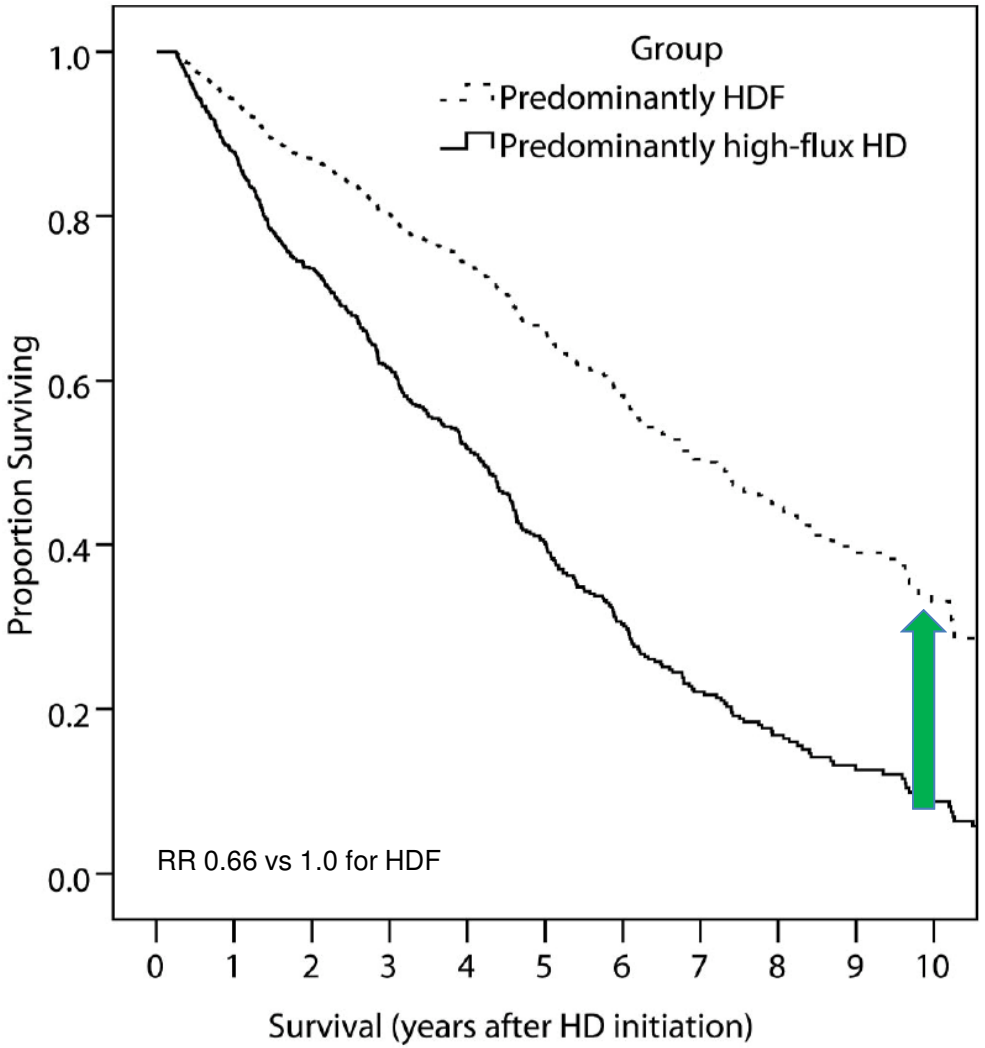
# Cardiovascular mortality is reduced in oI-HDF




**RISCAVID Study**

Panichi V et al. *Nephrol Dial Transplant.* 2008; 23:2337-2343

# Survival is significantly higher in HDF treated patients




Vilar E et al, *Clin J Am Soc Nephrol 2009*, ePub

# Outcomes of HDF versus HD up to 2011

| Author, Year | HDF vs Comparator | Type of study | β2-M | Annual Mortality HD/HDF | Survival Gain |
|---|---|---|---|---|---|
| **Wizemann V et al, 2000** | HDF vs LFHD | RCT | ↓ | **9.5/4.3** | = |
| **Bosch JP et al, 2006** | HDF vs LFHD vs HFHD | Historical prospective cohort | ? | | ↑ 45% |
| **Canaud B et al 2006** | HDF+/- vs LFHD vs HFHD | Historical prospective cohort | ? | **12.7/8.9** | ↑ 35% |
| **Jirka et al, 2006** | HDF vs LFHD vs HFHD | Historical prospective cohort | ? | **14.8/8.2** | ↑ 36% |
| **Schiffl H et al, 2007** | HDF vs HFHD + UPD | RCT | ↓ | **4.1/4.2** | = |
| **Vinhas J et al, *2007*** | HDF vs HFHD | Prospective controlled study | ? | **19.9/8.9** | ↑ 50% |
| **Panichi V et al. 2008** | HDF+/- vs LFHD | Prospective controlled study | ↓ | **13.2/10** | ↑ 15% |
| **Santoro A et al, 2008** | HF vs HFHD | RCT | ↓ | **13.3/12** | ↑ 18% |
| **Tiranathanagul K 2009** | HDF vs HFHD | Prospective controlled study | ↓ | | = |
| **Vilar E et al, 2009** | HDF vs HFHD | Historical prospective cohort | ↓ | **9/6** | ↑ 34% |
| **Locatelli F et al, 2010** | HDF vs HD vs LFHD | Prospective randomized controlled study | ? | | = |

# Randomized clinical trials in Europe evaluating HDF vs HD

**Dutch Trial**
CONTRAST
LFHD vs HDF
350/350
CV events
Mortality
36 months

**Completed**
**Reported at ERA-EDTA**

**Italian Trial**
LFHD vs HF/HDF
150/75/75
Tolerance
Morbidity
Mortality
24 months

**Reported & Published**

**French Trial**
HFHD vs HDF
> 65yo
300/300
Tolerance
CV events
Mortality
24 months

**Ongoing**

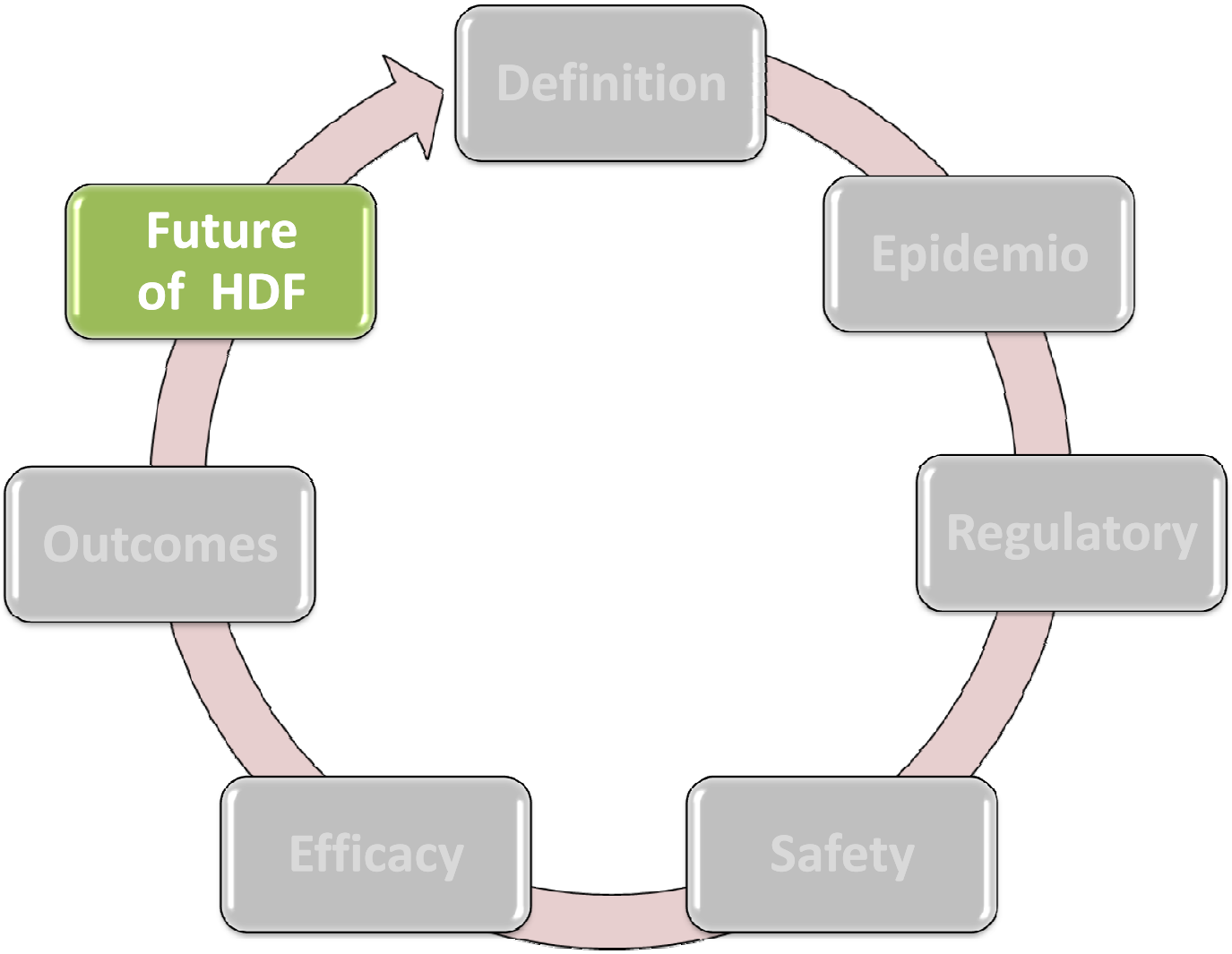
**Catalonian Trial**
HFHD vs HDF
300/300
CV events
Mortality
24 months

**Ongoing**

**Turkish Trial**
HFHD vs HDF
300/300
CV events
Mortality
24 months

**Completed**
**Reported at ERA-EDTA**

# Outline of the presentation



# Focusing on middle molecules…Convective dialysis dose

## Small water soluble solutes

- Asymmetric dimethylarginine
- Benzylalcohol
- ß-Guanidinopropionic acid
- ß-Lipotropin
- Creatinine
- Cytidine
- Guanidine
- Guanidinoacetic acid
- Guanidinosuccinic acid
- Hypoxanthine
- Malondialdehyde
- Methylguanidine
- Myoinositol
- Orotic acid
- Orotidine
- Oxalate
- Pseudouridine
- Symmetric dimethylarginine
- Urea
- Uric acid
- Xanthine

*CMPF is carboxy-methyl-propyl-furanpropionic acid

## Protein-bound solutes

- 3-Deoxyglucosone
- CMPF*
- Fructoselysine
- Glyoxal
- Hippuric acid
- Homocysteine
- Hydroquinone
- Indole-3-acetic acid
- Indoxyl sulfate
- Kinurenine
- Kynurenic acid
- Methylglyoxal
- N-carboxymethyllysine
- P-cresol
- Pentosidine
- Phenol
- P-OHhippuric acid
- Quinolinic acid
- Spermidine
- Spermine

## Middle molecules

- Adrenomedullin
- Atrial natriuretic peptide
- $ß_2$-Microglobulin
- ß-Endorphin
- Cholecystokinin
- Clara cell protein
- Complement factor D

**Middle molecules**

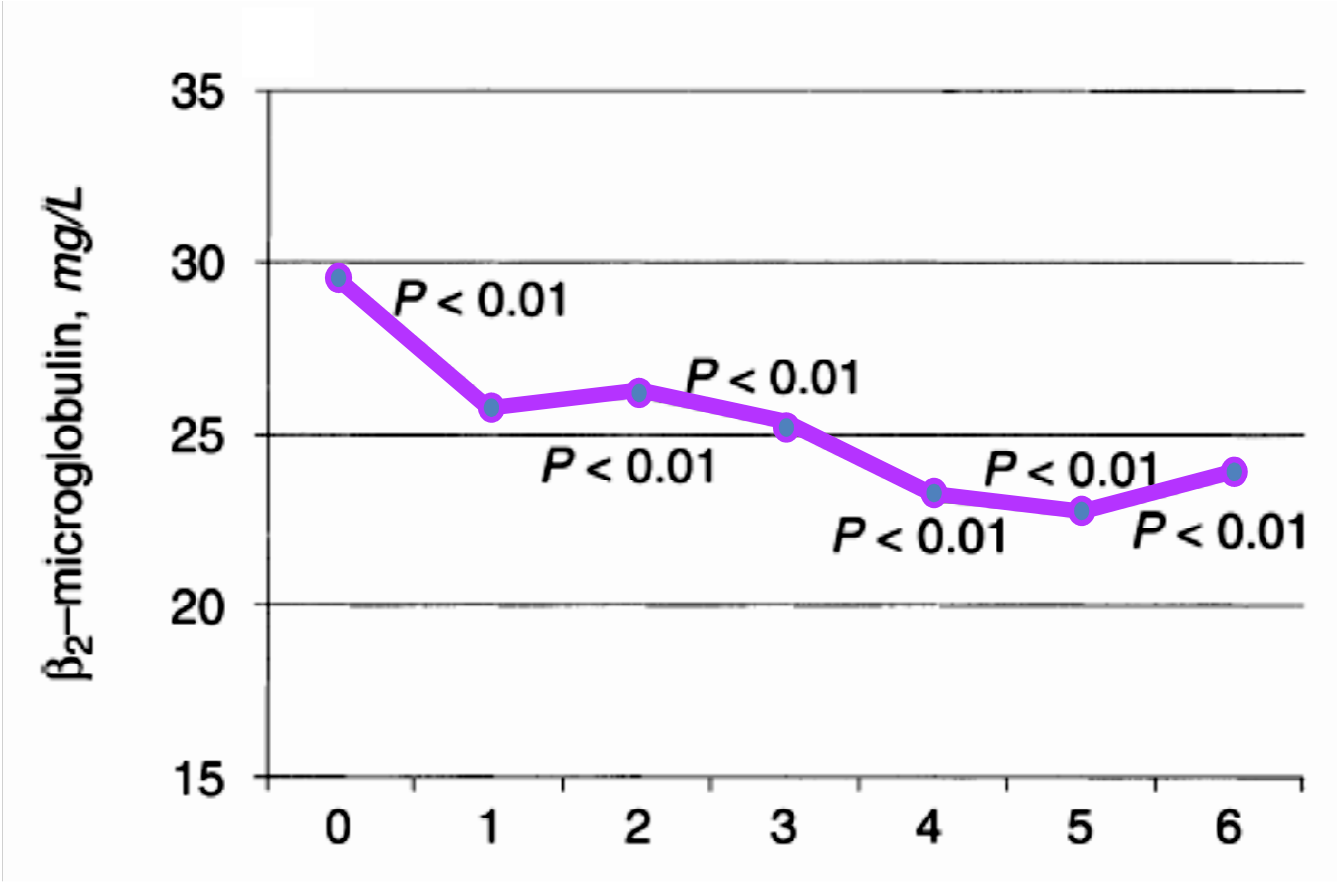
**β2 - Microglobulin**

- Hyaluronic acid
- Interleukin 1ß
- Interleukin 6
- Kappa-Ig light chain
- Lambda-Ig light chain
- Leptin
- Methionine-enkepahlin
- Neuropeptide Y
- Parathyroid hormone
- Retinol binding protein
- Tumor necrosis factor alpha

EUTox
European Uremic Toxin Work Group of the ESAO

Vanholder R. et al New insights in uremic toxins. *Kidney Int*, 2003, 63; 84: S6–S10

# HDF vs Daily HDF, ß2-M Kinetic



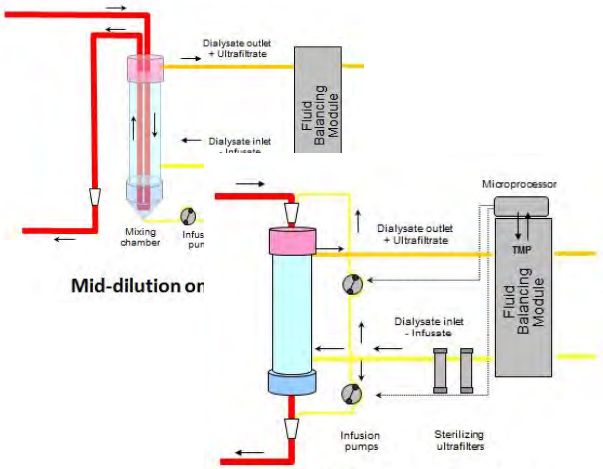

**8 patients (6M, 2F)**

**4-5 hrs x 3 to 2-2,5 hrs x 6 per week for 6 months**

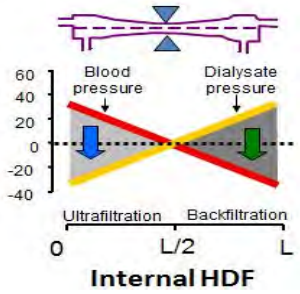
Maduell F et al, *Kidney Int.* 2003; 64:305

# Online HDF provides a platform for developing new RRT options

## Flexible HDF

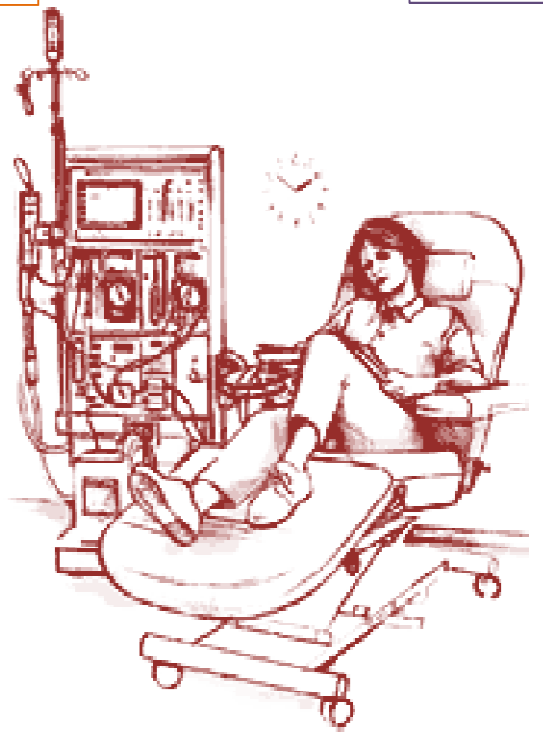



## Internal HDF




## Blood volume controlled machine

## Automated dialysis procedure



**Manual infusion**

**Biofeedback system**

**Cleansing**
**Priming**
**Rinsing**

**Suppressing saline requirement**
**Reducing manual handling**
**Save money**

**Self Care or Home therapy**

# If you want to know more register to eudial@era-edta.org

**Eu**ropean **Dia**lysis **W**orking **G**roup dedicated to improve dialysis outcomes focusing on online convective therapies

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EUROPEAN DIALYSIS AND TRANSPLANT ASSOCIATION
Registered Charity n° 1060134