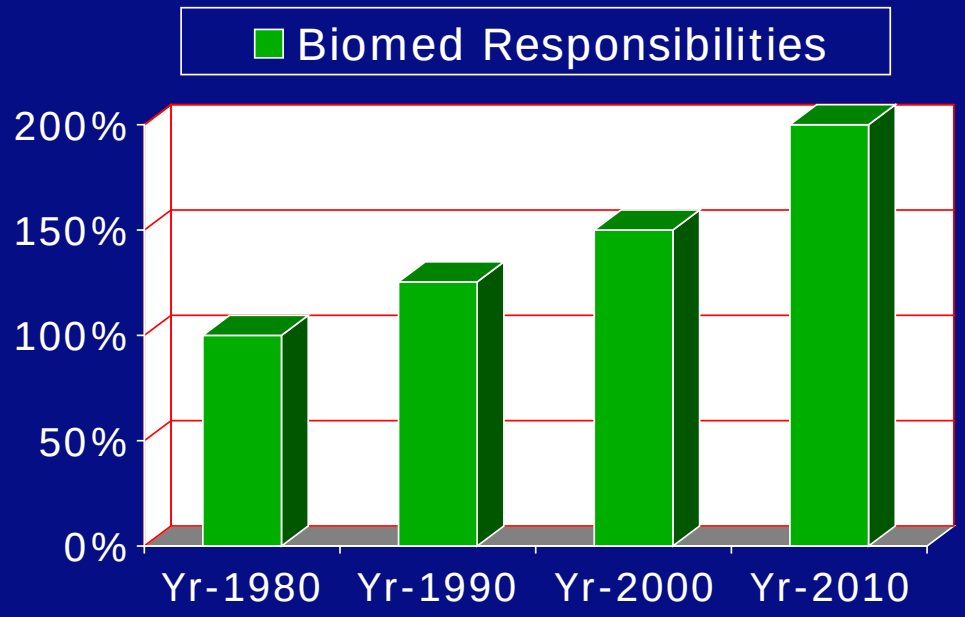
# Panel of Pioneers: Perspective and Predictions

*Speakers:*

V. Taaffe, J. Maltais, G. Rovegno, R. Ward

# Increasing Importance of Biomed Techs




# In a Changing Dialysis World

# Input from the Experts

Thank you to all who contributed comments:

- Danny Concepcion – St. Joe's., Orange, CA.
- Mark Rolston – FMCNA
- Chuck Weddle – IDF
- Bruce Fife - USRC
- John Dahlin – FMCNA
- Doyle Siglin – FMCNA
- Nick Grimley - RPC
- Mike Lorenson – RPC
- Dan Forde - RPC
- Multiple people (12) – RenalWEB

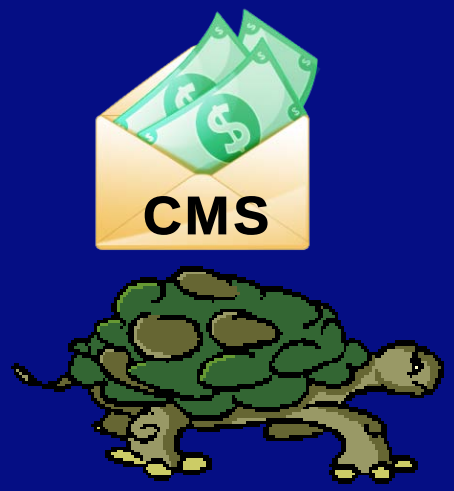
# Perspective on the Past

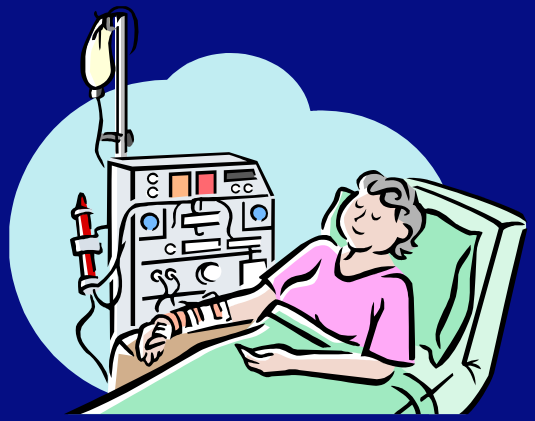
☑ One biomed for 1 or 2 clinics (common)
- Limited travel

☑ Responsibilities of biomed technicians
- Repair/maintain non-complex equipment
- Inventory control (informal) for 1 or 2 clinics
- Procedure management in relation to regulatory requirements of the time (for 1 or 2 clinics)
- Manage dialyzer reuse program (where applicable)
- In-service training & misc. support for staff

☑ Training of biomed technicians
- Education budget allowed outside training on a routine basis (e.g. equipment, professional development, etc.)

# Sluggish Reimbursement Rate



1980 1990 2000 2010

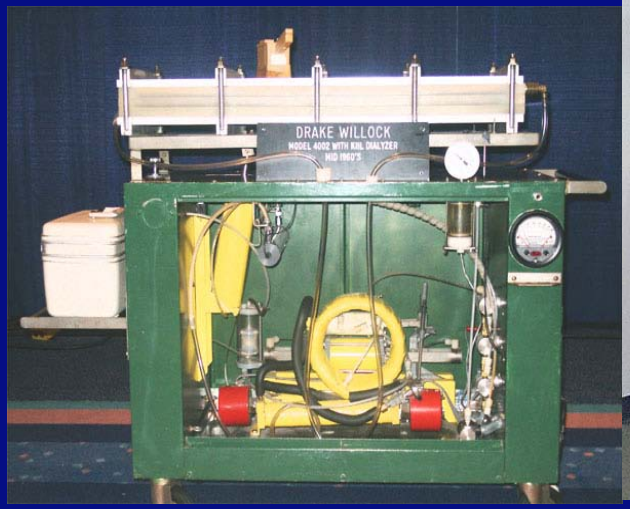
Year

# Consolidation

- RCG Acquires NNA
- DaVita Acquires Gambro
- FMC Acquires RCG
- RAI Acquires NRA

# Regulation

# Equipment Evolution




Drake-Willock
4002

Travenol
RSP

Fresenius
2008K

B. Braun
Dialog

Gambro
Phoenix

# Perspective on the Present

☑ One biomed for multiple clinics (common)
- Considerable travel

☑ Responsibilities of biomed technicians
- Repair/maintain complex equipment (software driven)
- Inventory control (formal) for multiple clinics
- Procedure management in relation to greatly increased regulatory requirements
- Manage dialyzer reuse programs (where applicable)
- Provide multiple clinics w/ training & misc. support

☑ Training of biomed technicians
- Education budget emphasizes receipt of training from within the dialysis provider organization

# Do You Agree?

- ☑ Sluggish reimbursement rate
- ☑ Consolidation
- ☑ Increased regulation
- ☑ Equipment evolution

… have all contributed to a critical need for Biomed Techs to take on a greater number of tasks and increased responsibility.

# Predictions for the Future

- Increased visibility
- Greater recognition
- Higher compensation rate for biomeds that have expanded responsibilities and certification.

# Make it a Bright Future

With:

- ☑ Confidence & positive attitude
- ☑ Certification
- ☑ Continuing education


**Training!**

... the critical need for Biomed Techs can be converted to an opportunity for advancement and career growth, for those that can adapt.

# Panel of Pioneers: Perspective and Predictions

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# Panel of Pioneers: Perspective and Predictions

## Infection Control & Equipment Disinfection Rhetoric, Reality & Future

Jo-Ann B. Maltais, Ph.D.

NANT 27th Annual National Symposium

Las Vegas, NV

March 3, 2010

Infection Control is the Responsibility of Everyone Involved in the Dialysis Treatment Process

# INFECTION CONTROL

# CHRONIC HEMODIALYSIS PATIENTS AT HIGH RISK FOR INFECTION

- Long-term vascular access; need for routine access to bloodstream for therapy delivery
- Immunosupressed state
- Concurrent treatment along with other patients
- Frequent hospitalization and surgery
- Exposure to infectious agents—bacteria & viruses
  - Person to person transmission
  - Contaminated devices, equipment, supplies
  - Environmental surfaces
  - Hands of personnel
  - Nosocomial infections in hospital & clinic environments
- Extended courses of antibiotic  treatment

# INFECTION CONTROL--RHETORIC

- Too many patients
- Too many regulations
- Too much paperwork
- Too little time
- Too few resources
- Need to focus on patient treatment
- No time for training
- We do the best we can!

# INFECTION CONTROL--REALITY

- Number of dialysis patients continues to rise
  - 309,269 patients were treated for ESRD in U.S. in 2004
  - Twice the number treated in 1994
- Infection is the 2nd most common cause of death
  - Accounts for 14% of mortality
- The number of new and resistant bacteria and viruses continue to rise (MRSA, VRE, H1N1)
- Clinics cited for Infection Control Non-Compliance
  - 58 clinics under TAG 110

# INFECTION CONTROL--REALITY

- Clinic resources continue to decline; training budgets reduced
- Compliance with vaccination, monitoring and hygiene requirements  is inconsistent
- Immunosuppressed  patients require higher vaccine doses, multiple dosing, frequent monitoring and limited exposure to infectious agents
- More time, More resources, More expense

# INFECTION CONTROL--FUTURE

- More Training Will Be Needed To:
  - Increase awareness of infectious agent sources & how transmitted
  - Focus on steps each person can take in their position to reduce the risk of transmission of infectious agents to patients
    - BioMed Techs
      - Water treatment systems—maintenance and control
      - Concentrate preparation and delivery--risks & responses
      - Hemodialysis system maintenance & disinfection
      - Monitoring and trending—respond to early warnings
      - Validation of control systems and frequency of disinfection
      - Periodic audits for regulatory compliance

# INFECTION CONTROL--FUTURE

- Better products and processes to make compliance with regulation & infection control practices more efficient will be forthcoming
  - Electronic patient records
  - More stringent bacterial & endotoxin limits
  - Improved system designs for bacterial, endotoxin & biofilm control and removal (e.g. ozone disinfection, heat disinfection)
  - Validation of systems & processes by manufacturers
  - Verification and control by BioMed Techs
- Work smarter, not harder!

# BIOMED TECHS MAKE A DIFFERENCE

- Water Treatment System
- Concentrates & Dialysate
- Dialysis Machines
- Dialyzer Reuse

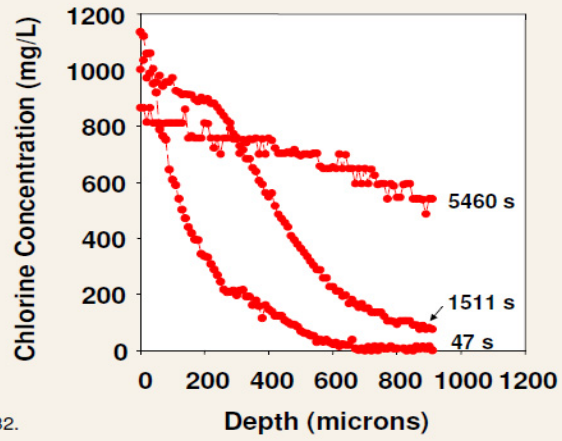
# DISINFECTION WATER TREATMENT SYSTEM WHAT MATTERS

- Design of System
- Disinfectant Used
- Concentration
- Dwell Time
- Residuals
- Frequency

Ryder, M. Medical Biofilm Research
TargetBSI.com Webinar 7/28/09

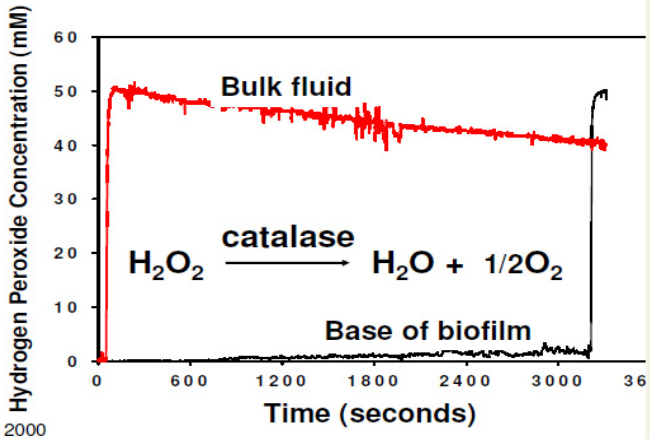
# Disinfectants and Biofilm

## Hypochlorite Penetrates Biofilm Slowly



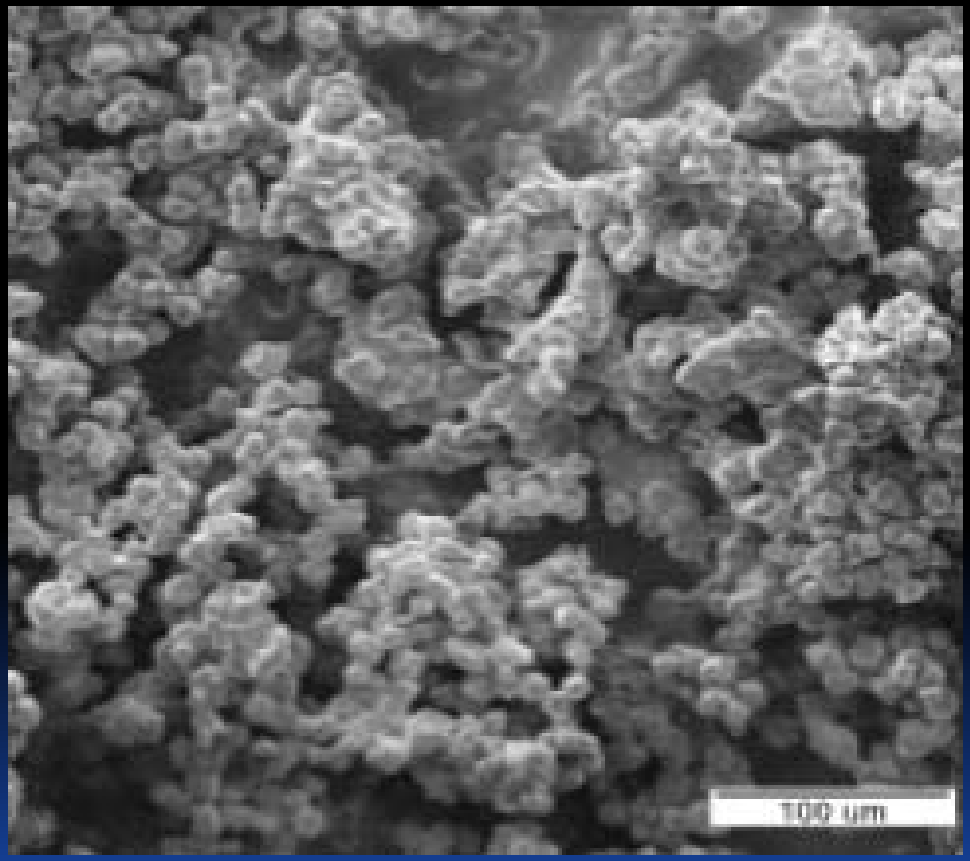

2. Stewart et al., 2001
Appl Microbiol 91:525-532.

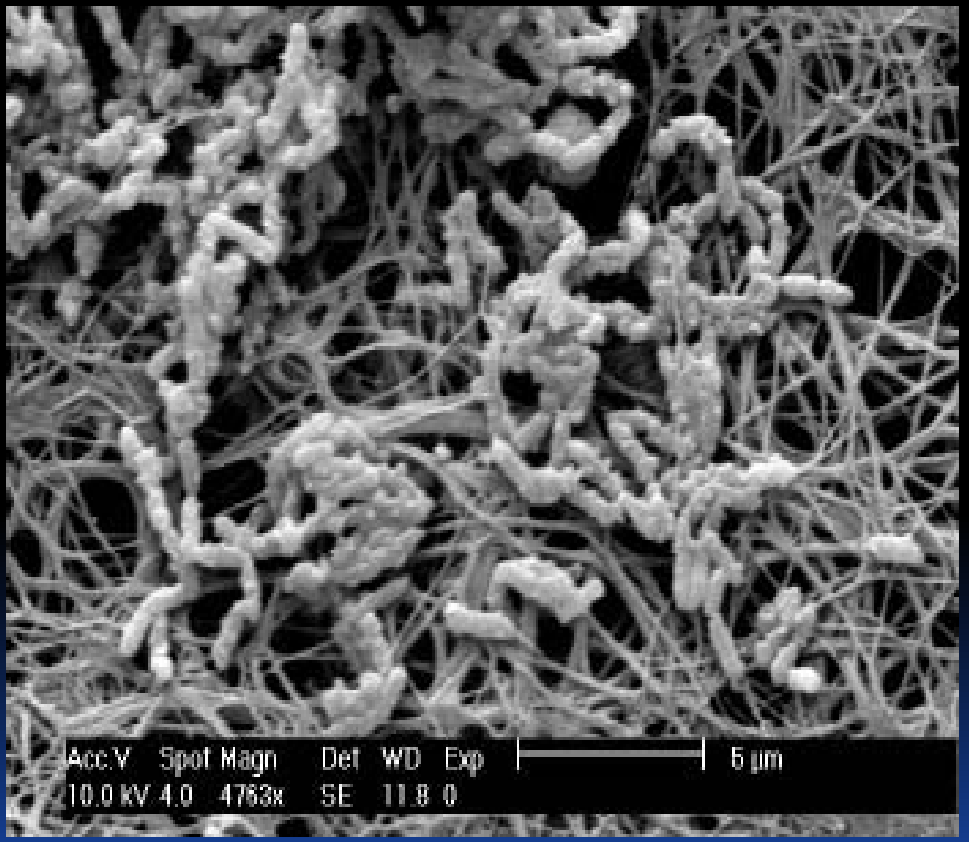
## $H_2O_2$ fails to Penetrate Biofilm




3. Stewart et al., 2000
Appl Environ Microbiol 66:836-838.

# BIOFILM IN WATER SYSTEMS AND MEDICAL DEVICES






Ryder, M. Medical Biofilm Research
TargetBSI.com Webinar 7/28/09

Donlan, RM. Biofilm Laboratory. CDC

# WATER TREATMENT SYSTEM--RHETORIC

- Once monthly disinfection adequate for all water treatment systems
- No detectable bacteria and/or acceptable levels of endotoxin = No Biofilm
- Turbulent flow in the loop prevents any biofilm formation
- Filters only need to be changed at manufacturer recommended intervals

# WATER TREATMENT SYSTEM--REALITY

- Water Quality is clinically relevant and a patient safety issue
- Consolidation has increased BioMed Tech responsibilities
  - Increased number of clinics to service
  - Mix of system designs to maintain
  - Older water treatment systems not being replaced due to cost constraints
    - Technology can be the same as 25 years ago
    - Larger diameter piping, long distance loops, storage tanks and system shut down times increase risk of biofilm formation
    - Additional effort  is needed to keep systems operational and in compliance with regulatory requirements
- Less training time & budgets available

# WATER TREATMENT SYSTEM--REALITY

- Regulations and documentation requirements are increasing
  - Old Medicare Regs = 4 TAGS related to water and dialysate
  - 2008 CFC = 64 TAGS related to water
- Top deficiencies related to water—

| # | TAG # | TAG Description | # Cited | % of Surveys |
|---|---|---|---|---|
| 11 | V196 | Carbon adsorption—Monitoring, testing, frequency | 96 | 10.1% |
| 39 | V187 | Environment—Schematic diagrams/labels | 55 | 5.8% |
| 49 | V260 | Personnel—Training program/periodic audits | 45 | 4.7% |
| 53 | | Softeners—Testing hardness/log | 41 | 4.3 % |

Source: Glenda M Payne, ESRD Technical Advisor, Centers for Medicare & Medicaid Services, Dallas & Atlanta Regions
Surveys completed: 948 of 5477 providers

# WATER TREATMENT SYSTEM--FUTURE

## GREATER EFFICIENCY, LOWER OPERATING COSTS

- Distribution loop velocity readouts
- RO membranes with higher rejection rates, lower operating pressures
- Electrodeionization
- Old systems replaced with new designs with lower operating costs
- New piping materials—less bacterial adhesion, tolerance to more aggressive disinfection (e.g. ozone or heat)
- Comprehensive automated daily sanitization/disinfection

# WATER TREATMENT SYSTEM--FUTURE

## GREATER EFFICIENCY, LOWER OPERATING COSTS

- More stringent bacterial and endotoxin level requirements
- In-line monitoring systems to detect biofilm and bacterial/endotoxin levels
- Better methods of removing biofilm
- Ultrapure dialysate requiring ultrapure water
- Validated process and process controlled systems

# THE GOAL

Standard Dialysis Quality Water → Ultrapure Water



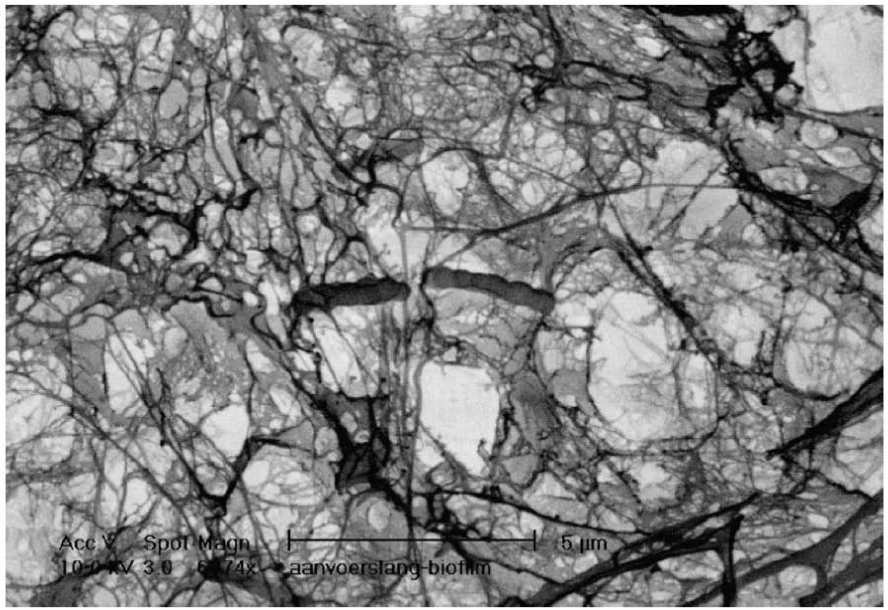



Fig. 2. Tubing segment, showing extensive biofilm formation, from a standard water treatment system.

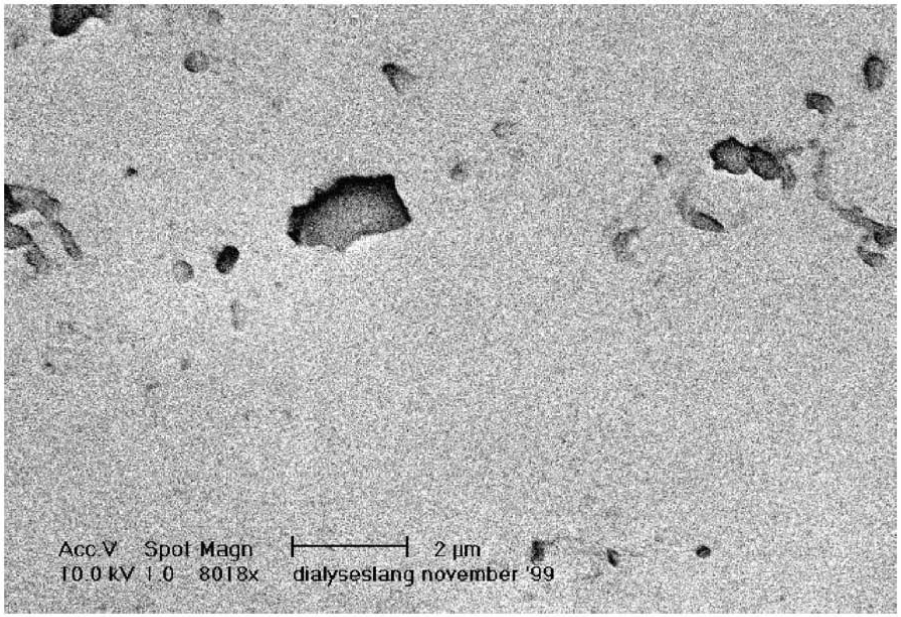



Fig. 1. Tubing segment, showing complete absence of biofilm, from a water treatment system delivering ultrapure water.

# CONCENTRATES & DIALYSATE--RHETORIC

- It is OK to  mix old and new batches of bicarbonate concentrate
- Biofilm doesn’t form in bicarbonate concentrate
- Containers don’t need to be disinfected once emptied of bicarbonate concentrate
- Water quality doesn’t matter for Acid Concentrate
- Dialysate contaminants don’t cross dialyzer membranes

# CONCENTRATES & DIALYSATE--REALITY

- Old Medicare Regs = 4 TAGS related to water & dialysate
- 2008 CFC = 28 TAGS related to dialysate
- Bicarbonate concentrate can form biofilm on the inside of containers
  - Disinfect with high level disinfectant/sterilant frequently and dry completely
- Mixing old and new batches of bicarbonate concentrate can result in changes in pH and concentration
- Acid concentrate if prepared with water containing large numbers of bacteria can result in endotoxin contamination
- Dialysate contaminants bacterial debris and endotoxin can cross dialyzer membranes by diffusive backfiltration

# CONCENTRATES & DIALYSATE REALITY—CFC CITATIONS

| TAG # | TAG Description | # Cited | % of Surveys |
|---|---|---|---|
| V250 | Dialysate proportioning—monitor pH/conductivity | 87 | 9.2% |
| V175 | Water & Dialysate Quality | 32 | 3.4% |

Source: Glenda M Payne, ESRD Technical Advisor, Centers for Medicare & Medicaid Services, Dallas & Atlanta Regions
Surveys completed: 948 of 5477 providers

# CONCENTRATES & DIALYSATE--FUTURE

- On-line generation of bicarbonate concentrate
- More stringent bacterial and endotoxin limits
- Increased use of ultrafilters to meet more stringent requirements
- Ultrapure dialysate production at point of use or via central delivery systems

# DIALYSIS MACHINES--RHETORIC

- The dialyzer prevents transmission of bacteria and endotoxin to patient so water and dialysate levels are irrelevant
- Post disinfection sampling tells me the machine meets AAMI acceptable levels
- As long as my monthly monitoring results are OK on a % of the dialysis machines, all of them are within limits and I don't need to be concerned or have to trend my data

# DIALYSIS MACHINES--FUTURE

- AAMI Standards likely to move closer to European (ISO) Standards—lower bacterial and endotoxin limits
- Validation and process control required
- On-line convective therapies may increase—Ultrapure dialysate, sterile substitution fluid
- Increased use of in-line ultrafilters for ultrapure dialysate as standard of care

# DIALYSIS MACHINES--REALITY

- Both low & high flux dialyzers can allow transfer of bacteria & endotoxin from dialysate to patient by backfiltration
- Pre-disinfection sampling of  a % of the dialysis machines/month gives a snapshot, it doesn't tell you what is happening in all machines all of the time
- Post disinfection sampling only tells you whether the disinfection procedure is effective or not

# BRIGHT FUTURE FOR BIOMED TECHS

## YOU CAN MAKE A DIFFERENCE!

- Employment expected to grow 27% over the next 9 years
- Faster growth than the average for all occupations
- The aging population puts more people at risk for developing ESRD
  - Growth of this segment of the population is expected to be faster than that of the total population
- Dialysis patient population is expected to increase (doubled in the UK over past 10 years)

Patient Safety and Delivery of Quality Therapy is--

# THE BOTTOM LINE

# YOU CAN MAKE A DIFFERENCE

# BIO MED TECHS ROCK!

# Panel of Pioneers: Perspective and Predictions

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# Perspective and Predictions: EMRs

George Rovegno
MIQS Software

# Perspective

- EMRs can improve quality, reduce costs
- EMRs make the necessary information readily available to the caregiver at the point of care
- EMRs manage workflow and prevent things from falling through the cracks
- EMRs are cheap and not much used

# Predictions

- Lack of skilled personnel will force IT solutions into healthcare. Substitute IT for people
- Accountability
- Quantification

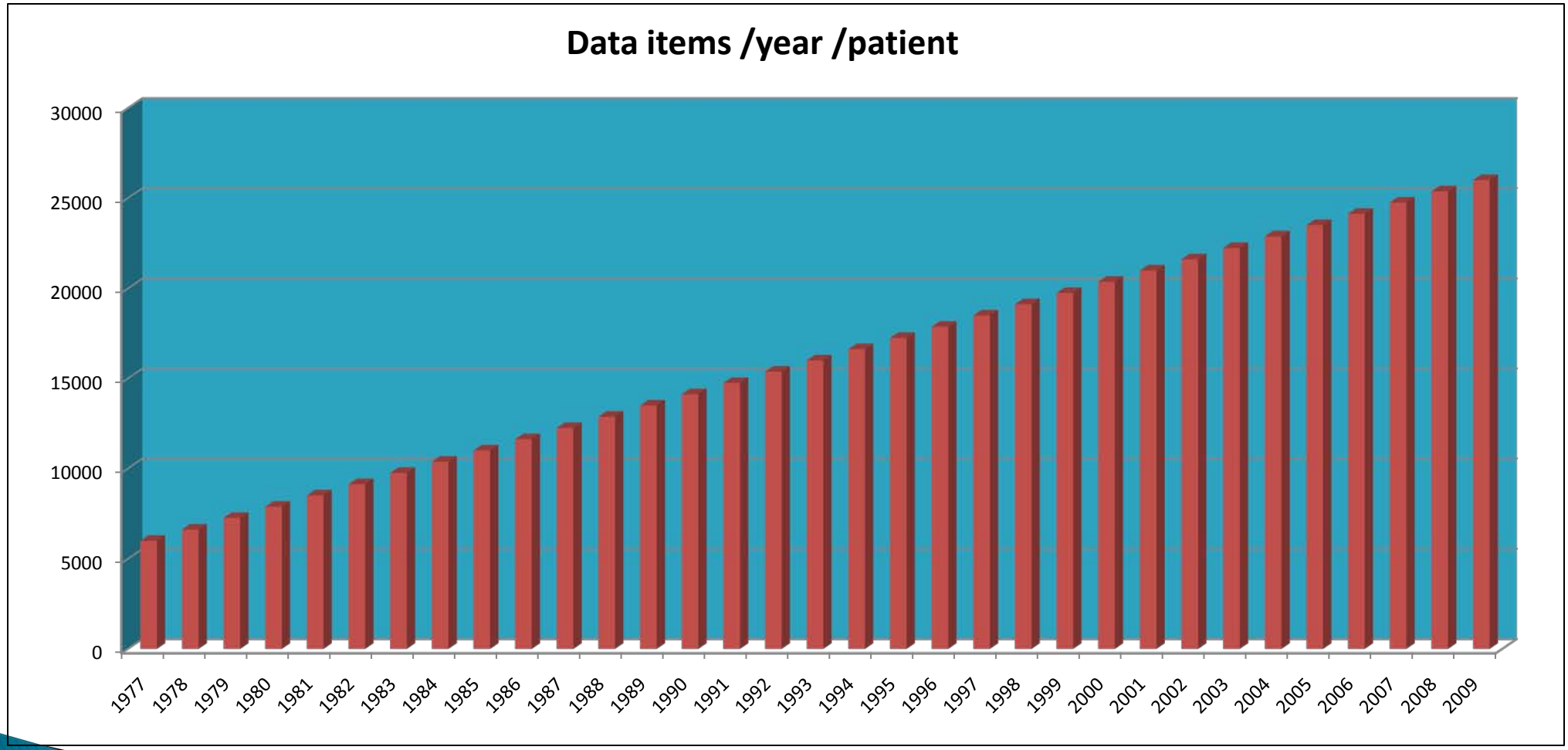
# The roles of EMRs

- Care implications
  - IT = Individualize Treatment
  - Managing huge volumes of data at the point of care – Amount of data – Reporting of data
  - Using the data
  - Quality of care–team approach–efficient delivery
  - Integral quality tools
- Financial implications
  - Quality rewards & penalties
  - Financial survival

# Individualize Treatment

- The CfCs require individualized care and the surveyors are enforcing this rule.
  - Regular (annual/monthly) assessments drive comprehensive care plans with mandatory follow-up and revision – teams of caregivers
  - Assessment & PoC must be data driven – this requires computers and relational databases.

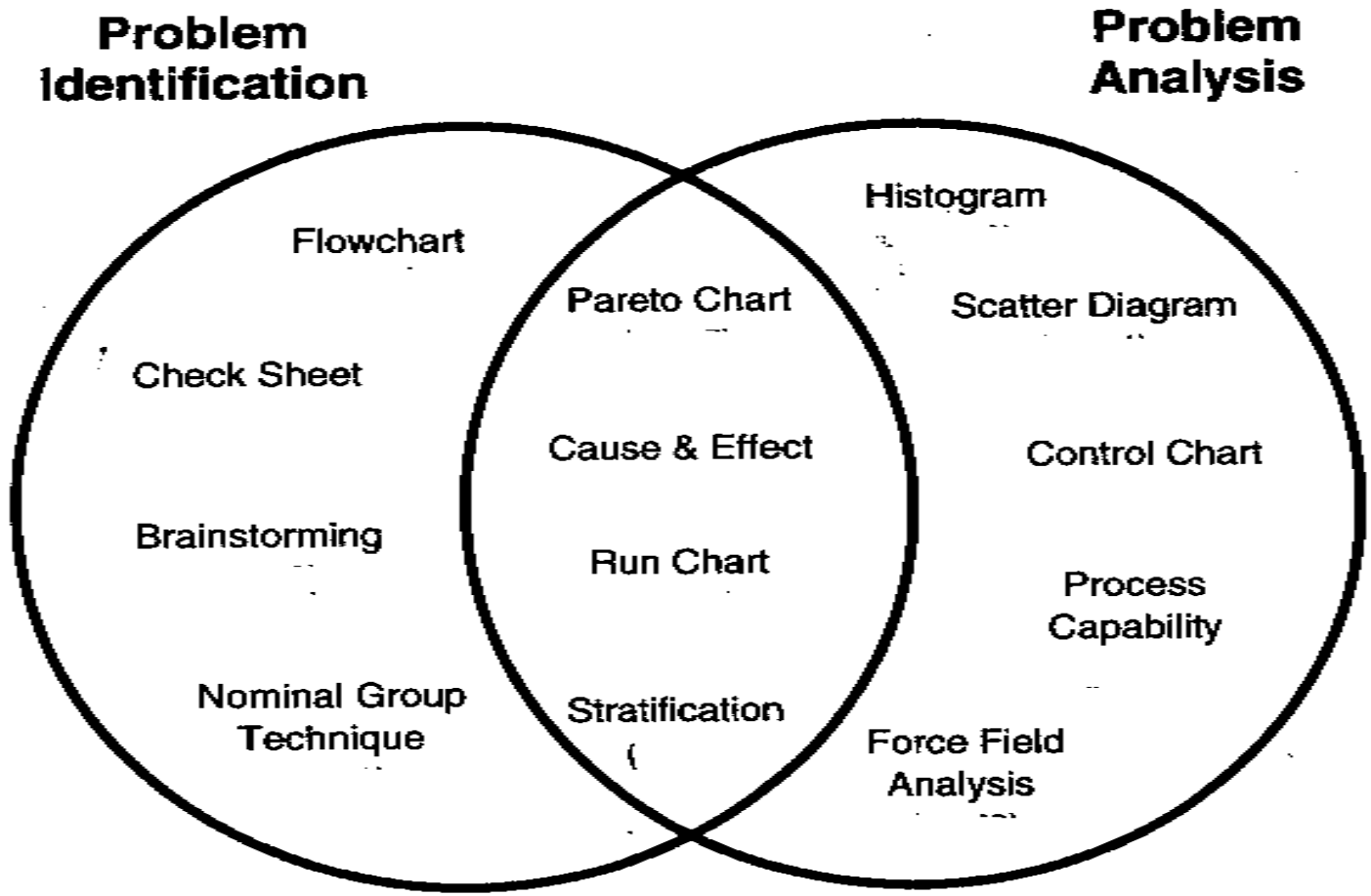
# Large amounts of data require EMRs



# Quality of Care

- Outcomes & Quality –evidence based medicine requires lab values
  - Whatever happened to CQI?
  - Outcomes vs. Process
  - Ratings and scores – like dialysis compare – public disclosure, more items
- Accountability – tech credentialing

# Process (CQI)


Problem Identification
Problem Analysis
Flowchart
Check Sheet
Brainstorming
Nominal Group Technique
Pareto Chart
Cause & Effect
Run Chart
Stratification
Histogram
Scatter Diagram
Control Chart
Process Capability
Force Field Analysis

# Documentation

- Pay for what you document not just what you do
- Time stamps, sign offs, P & Ps
- If you document it correctly you avoid trouble and are paid correctly the first time.

"Our professional staff has determined that the services were medically necessary and properly documented."

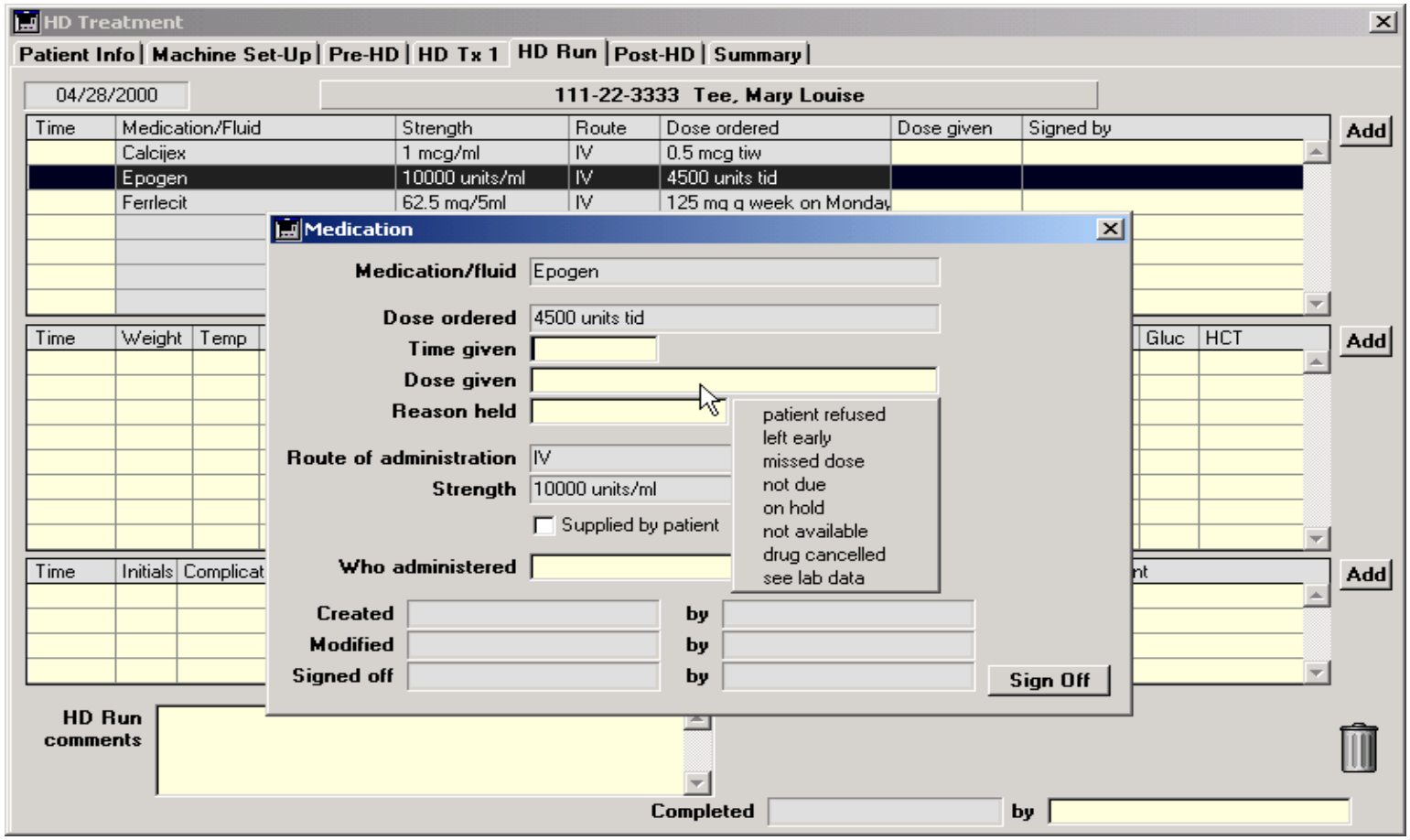
# Physician MCP: Some Early Results

Billing data on 243 patients treated by HD in a single Dialysis Unit in March 2004*
(In Feb 2004 <70% of possible was documented)

| | Recorded (#) | Maximum (#) | Percent of possible |
|---|---|---|---|
| Comprehensive encounter | 232 | 243 | 95.5% |
| Brief encounter | 709 | 729 | 97.3% |
| Billed G0317 (1 Comp & 3 Brief encounters) | 231 | 243 | 95.1% |
| Billed G0318 (1 Comp & 1-2 Brief encounters) | 10 | 243 | 4.1% |

- Used wireless laptop computer on rounds
- Major effort made to utilize the software to record encounters
- Major administrative feedback to ensure physician compliance

# MIQS: Giving EPO During HD Run

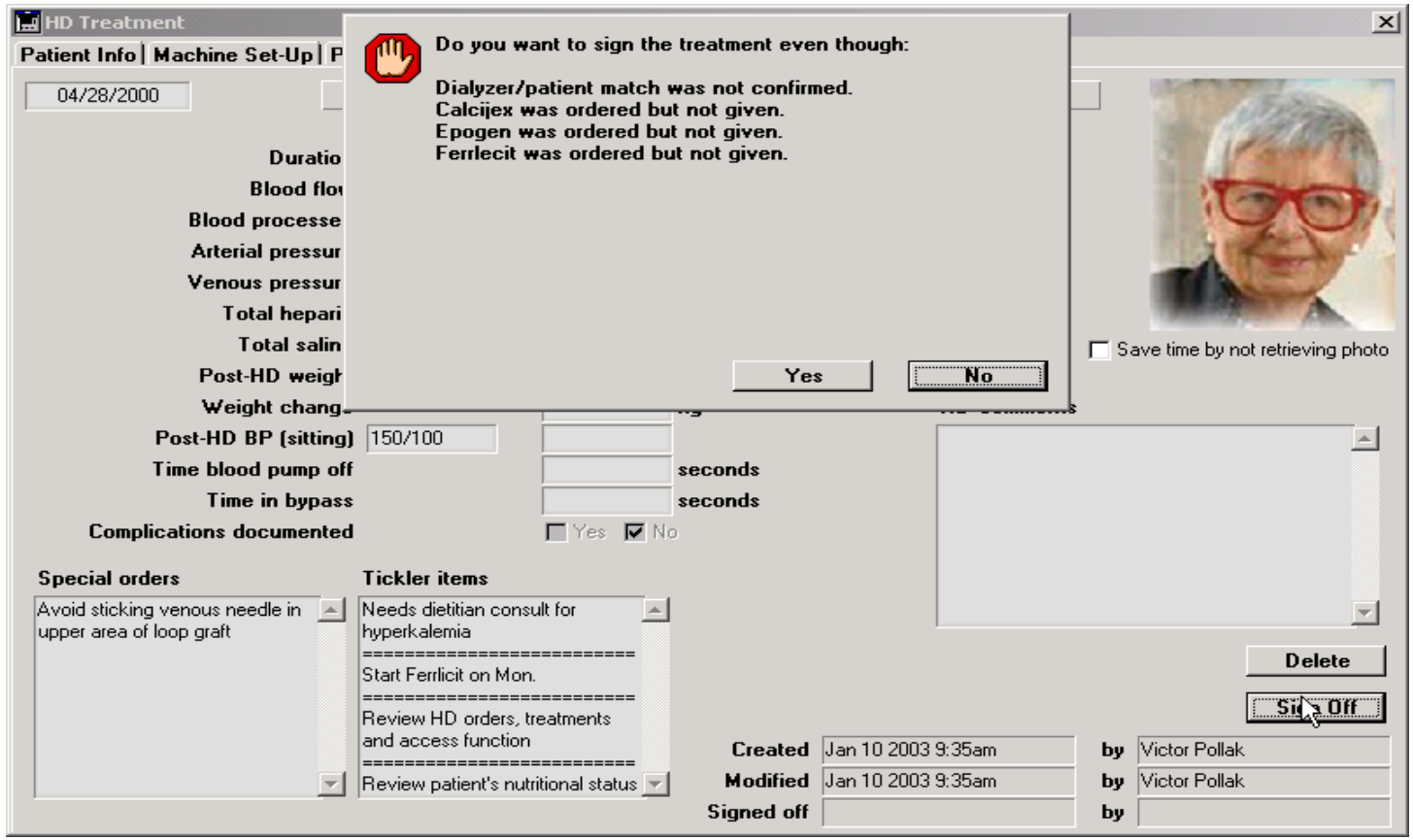



An EPO Order on the HD Run Screen must be addressed.

Nurse documents administration or NON administration and signs off

# MIQS: Checking EPO at HD Sign off

## Nurse Signs off at End of HD Treatment




A warning appears if the ordered EPO was not recorded as given- management tool

# Bundling CPMs

- ESRD QIP – reporting & quantification
- 9 Topic areas for 26 measures:
  - Anemia, Dialysis Adequacy (Hemodialysis and Peritoneal Dialysis), Vascular Access, Mineral Metabolism, Influenza Vaccination, Mortality, and Patient Education, Satisfaction, and Quality of Life.
- Will determine payments & penalties

# HCIT

- Healthcare is a major anomaly among information-intensive businesses – over $2T revenue business spending under 2% of revenue on IT. Not on EMRs
- least exploited is the core of the business, clinical operations and clinical data.
- cottage-industry nature, resistance of providers to be measured on their performance

# The Future

- More IT use
- Increasing scrutiny
- ESRD is a model for all healthcare
- Quantification of quality
- Global bundling
- Lower payments for more work

# Panel of Pioneers: Perspective and Predictions

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# CHLORAMINE REMOVAL:

## *Is carbon always the answer?*

**Richard A. Ward**

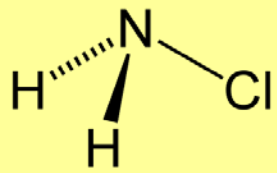

Kidney
Disease
Program

# FREQUENT CHLORAMINE BREAKTHROUGH

- Several dialysis units in the same geographical area obtain water from municipalities that draw their water supply from lakes.
- Units use exchangeable carbon tanks with an EBCT ≥ 10 minutes.
- Chloramine breakthrough occurs within a week of exchanging tanks.
- What's going on and what can be done to control chloramine levels without needing to constantly be changing carbon tanks?

# USE OF CHLORAMINE TO DISINFECT WATER SUPPLIES

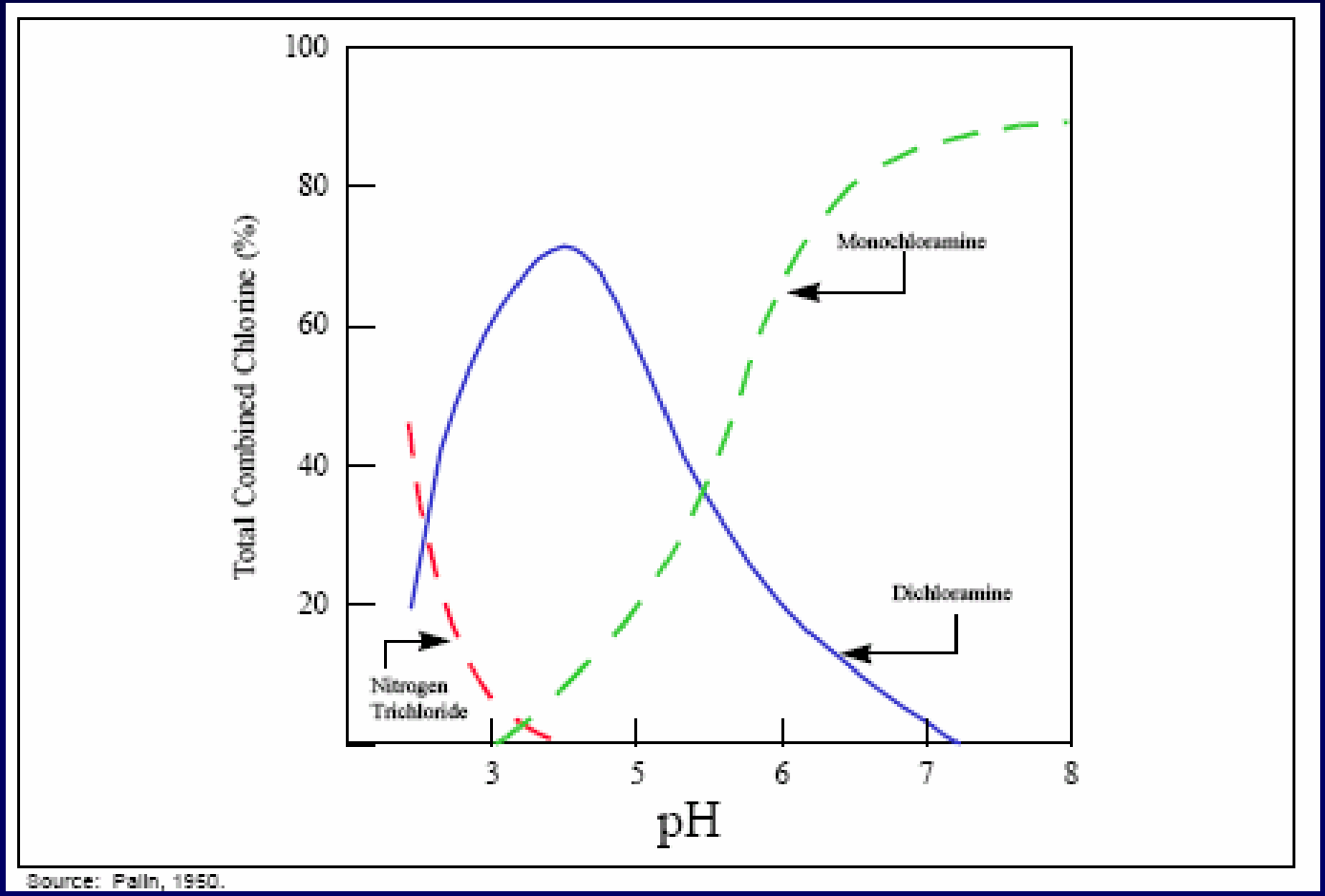
- Chloramines are formed by adding ammonia to chlorinated water.
  - $HOCl + NH_3 \rightarrow NH_2Cl + H_2O$ (monochloramine)
  - $HOCl + NH_2Cl \rightarrow NHCl_2 + H_2O$ (dichloramine)
  - $HOCl + NH_2Cl_2 \rightarrow NCl_3 + H_2O$ (trichloramine)




**MW = 51.5 Da**

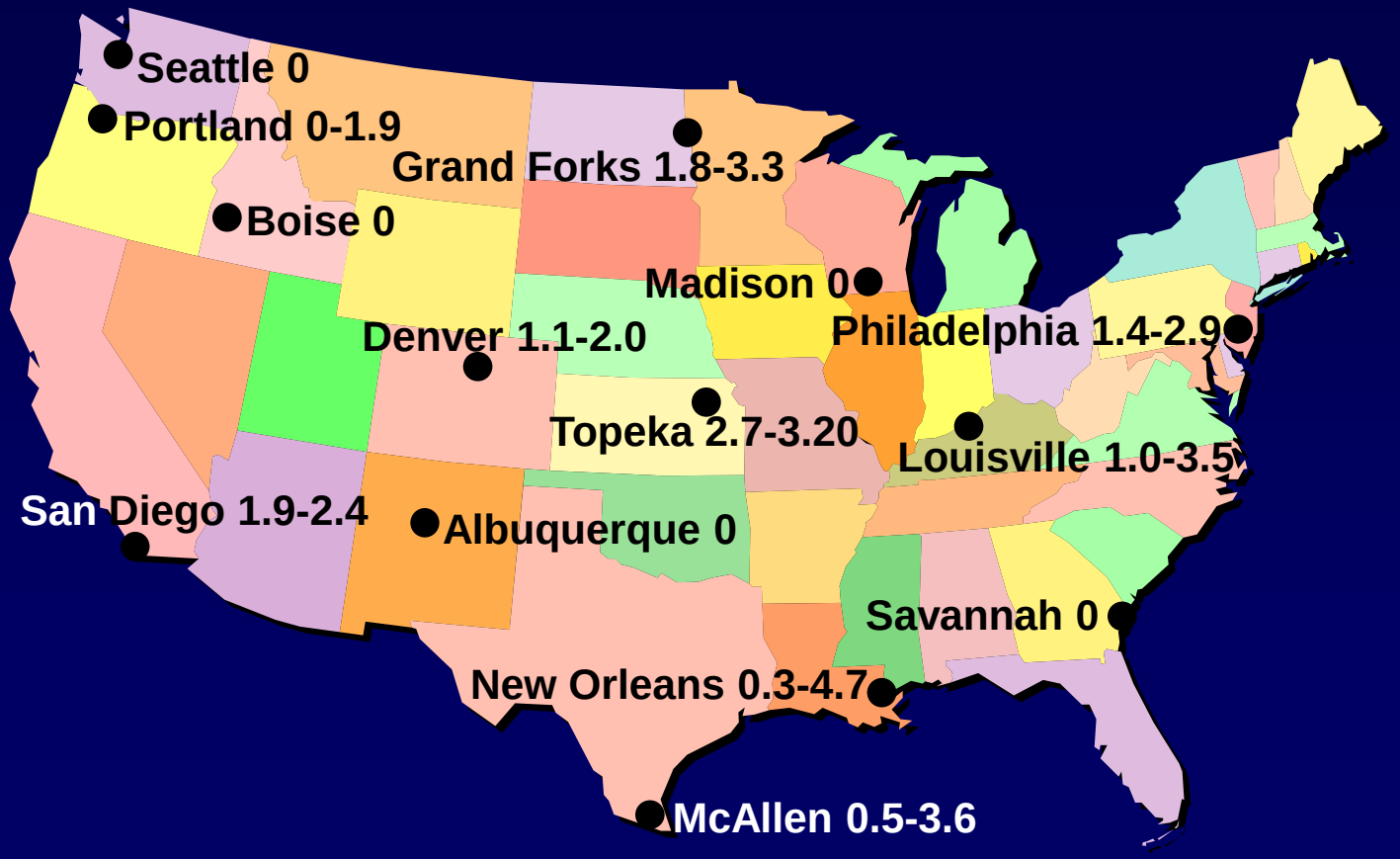
- The form of chloramine is pH dependent. At pH > 7, monochloramine is the most prevalent form.

# THE FORM OF CHLORAMINE DEPENDS ON pH



# CHLORAMINE CONTENT OF TAP WATER

Added to water as an alternative disinfectant to chlorine to reduce the formation of carcinogenic trihalomethanes



# REMOVAL OF CHLORAMINE

- Carbon adsorption with granular activated carbon is generally the most effective means of removing chloramines.
- Two beds are connected in series to give a total EBCT of ≥ 10 minutes.
- Testing for chloramine between the beds is used to prevent disruptions in operation following unanticipated breakthrough.

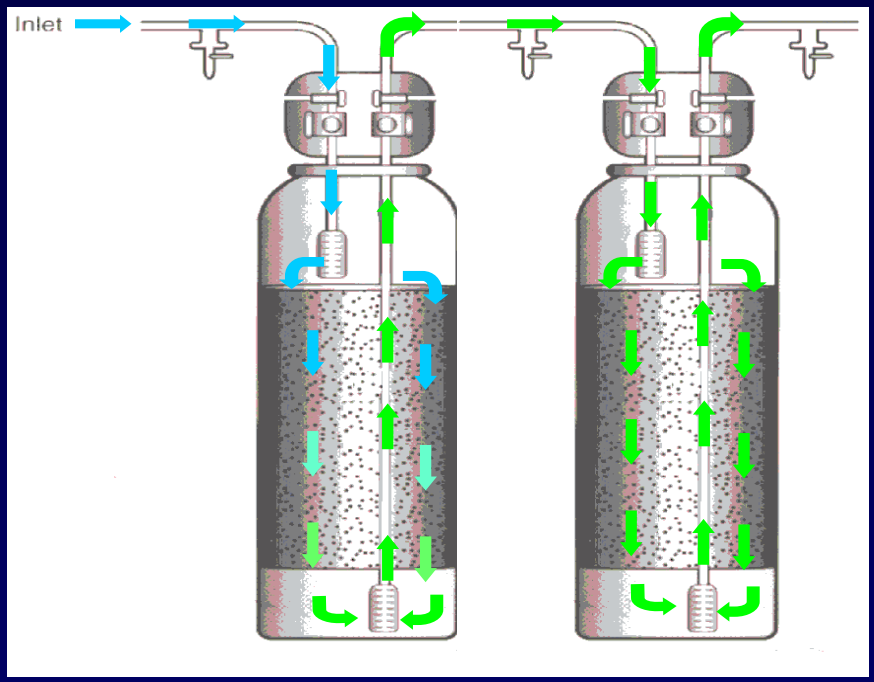



Image courtesy of FMS

# REMOVAL OF CHLORAMINE BY CARBON

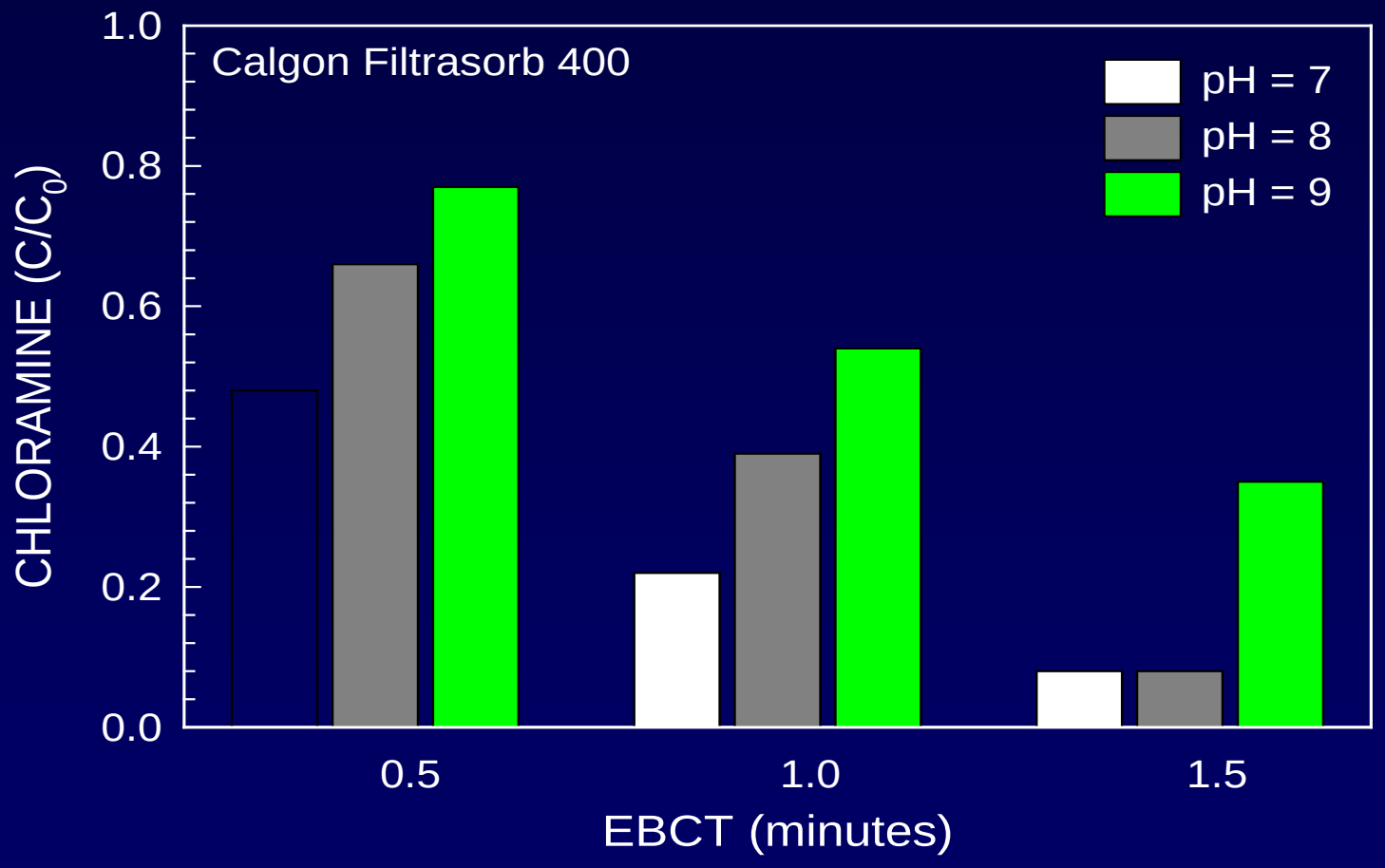
# CARBON REMOVES CHLORAMINE VIA AN OXIDATION REACTION

- Two reactions take place at the carbon surface:
  - $C^* + NH_2Cl + H_2O \rightarrow NH_3 + H^+ + Cl^- + CO^*$
  - $CO^* + 2NH_2Cl \rightarrow N_2 + H_2O + 2H^+ + 2Cl^- + C^*$

- The reaction rate for monochloramine oxidation of carbon is much slower than the rate for oxidation by hypochlorous acid/hypochlorite ion.

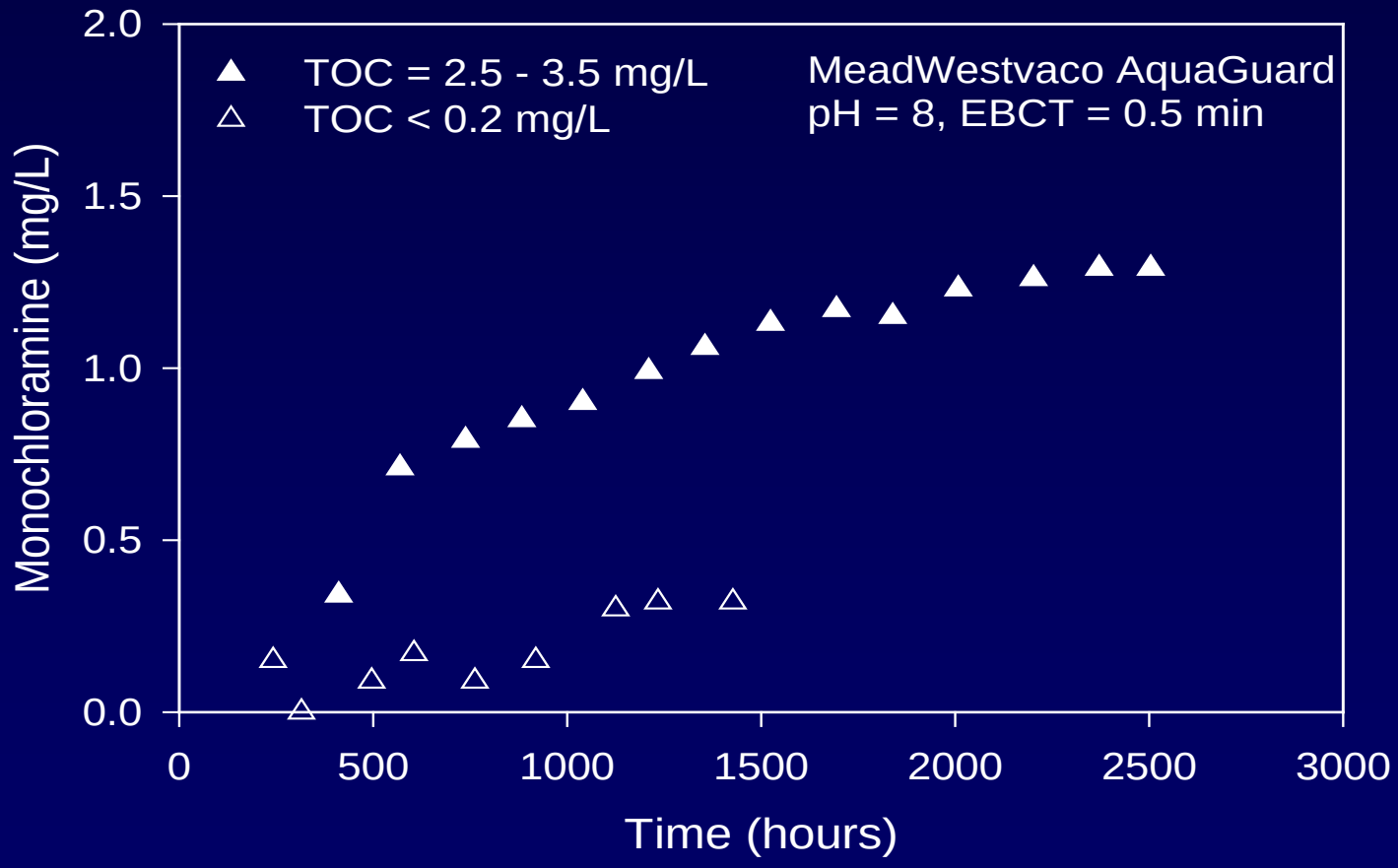
- Catalytic carbon is carbon that has been modified to have more surface reaction sites

# EFFECT OF pH ON CHLORAMINE REMOVAL




Fairey JL, et al. *J AWWA* 99:110-120, 2007

# EFFECT OF NATURAL ORGANIC MATERIAL ON CHLORAMINE REMOVAL




Adapted from: Fairey JL, et al. *Environ Sci Technol* 40:4268-4273, 2006

# WHAT CAN REDUCE THE EFFECTIVENESS OF CHLORAMINE REMOVAL BY CARBON?

- Substances that prevent monochloramine from reaching the reactive sites on the carbon surface.
  - Corrosion inhibitors, such as orthophosphate.
  - Organic material in the water.
- Conditions that slow the rate of reaction.
  - Low temperature.
  - High pH.

## WHAT ARE THE OPTIONS WHEN CARBON PROVIDES INADEQUATE CHLORAMINE REMOVAL?

- Remove substances that mask reactive sites.
- Adjust the temperature and pH for optimal carbon performance
- Use alternative methods of removal

# ALTERNATIVES AND SUPPLEMENTS TO CARBON ADSORPTION

- **ANION EXCHANGE RESINS (ORGANIC SCAVENGER)**
  - Remove organic matter and other substances that may foul carbon.
- **CHEMICAL INJECTION SYSTEMS**
  - pH adjustment for optimal carbon adsorption.
  - Sodium bisulphite reduces chlorine species to chloride.
- **REDOX ALLOY MEDIA (KDF RESIN)**
  - Copper/zinc alloys that reduce chlorine species to chloride.
  - Limited pH range.
  - Not effective with orthophosphate and polyphosphate.
- **ULTRAVIOLET IRRADIATION**
  - Converts chlorine species to chloride (254 nm).
  - Breaks down organic species (185 nm).

# ALTERNATIVES AND SUPPLEMENTS TO CARBON ADSORPTION

- **ANION EXCHANGE RESINS (ORGANIC SCAVENGER)**
  - Remove organic matter and other substances that may foul carbon.
- **CHEMICAL INJECTION SYSTEMS**
  - pH adjustment for optimal carbon adsorption.
  - Sodium bisulphite reduces chlorine species to chloride.
- **REDOX ALLOY MEDIA (KDF RESIN)**
  - Copper/zinc alloys that reduce chlorine species to chloride.
  - Limited pH range.
  - Not effective with orthophosphate and polyphosphate.
- **ULTRAVIOLET IRRADIATION**
  - Converts chlorine species to chloride (254 nm).
  - Breaks down organic species (185 nm).

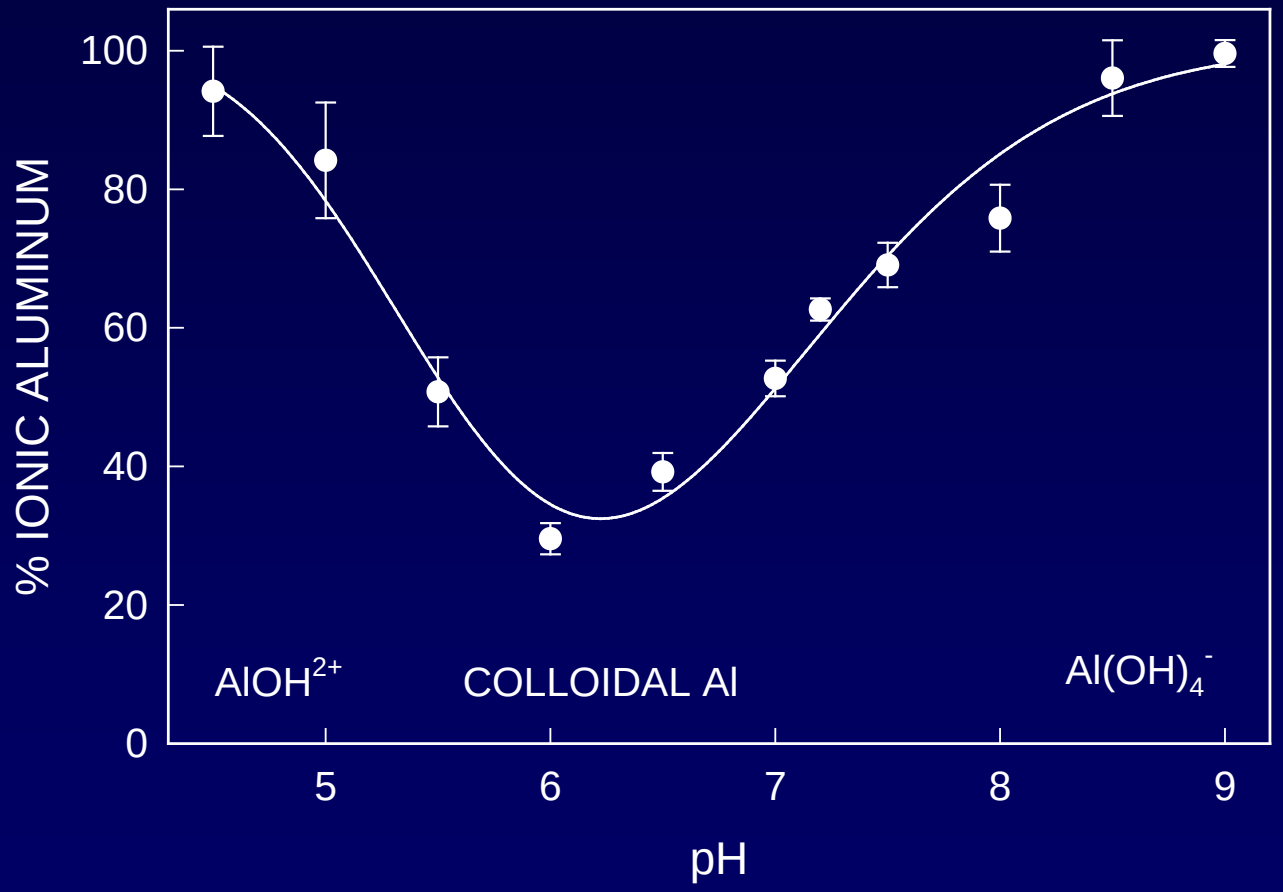
# INJECTION SYSTEMS

- **CONTROL THE RATE OF INJECTION**
  - Acid injection can be controlled by pH
  - Bisulfite injection can be controlled by oxidation- reduction potential (ORP)
- **FOR ACID INJECTION**
  - Use a mineral acid
  - Select a target pH consistent with proper operation of other purification processes

# EFFECT OF pH ON FLUORIDE REMOVAL

| DATE | pH | FLUORIDE (mg/L) | | | RO REJECTION (%) |
|---|---|---|---|---|---|
| | | FEED | POST-HCl | PRODUCT | |
| JAN 02 | 10 | 0.79 | | 0.005 | 99 |
| HCl INJECTOR INSTALLED IN PRE-TREATMENT | | | | | |
| MAR 02 | 7 | 0.79 | 0.77 | 0.011 | 99 |
| APR 02 | | 0.76 | 0.76 | 0.015 | 98 |
| JUL 02 | | 0.81 | | 0.005 | 99 |
| OCT 02 | | 0.86 | 0.81 | **0.073** | **91** |
| JAN 02 | 6 | 0.85 | 0.88 | **0.884** | **0** |
| NEW RO MEMBRANES INSTALLED | | | | | |
| FEB 02 | 6 | 0.81 | 0.81 | **0.158** | **80** |
| FEB 02 | 10 | 0.90 | 0.85 | 0.005 | 96 |
| MAR 02 | 8 | 0.86 | 0.87 | < 0.01 | 99 |

# EFFECT OF pH ON ALUMINUM IN WATER




Parkinson IS et al. *J Clin Pathol* 34:1285-1294, 1981

# TESTING FOR TOTAL CHLORINE

- *N*-chloramines (organic chloramines) will test positive in DPD-based assays.
- Other oxidizing agents (e.g., permanganate) will test positive in DPD- and MTK-based assays.
- Manganese oxides interfere with DPD-based assays, but not MTK-based assays

  - *N*-chloramines and permanganate are rejected by reverse osmosis.
  - If you suspect interference in the DPD assay, measure total chlorine after the RO.

# CHLORAMINE REMOVAL

- Levels in municipal water are a moving target.
- Establish communications with your water provider.
- Other changes in municipal water may impact on the ability of carbon to remove chloramine.
- When installing an alternative means for chloramine removal, think how it will impact the rest of the treatment system.
- If there is unexpected breakthrough, think about possible interferences with the chloramine assay.

# Panel of Pioneers: Perspective and Predictions

*Speakers:*

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