



ROLES AND RESPONSIBILITIES OF THE MEDICAL DIRECTOR OF A DIALYSIS FACILITY

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18th Asian Colloquium
in Nephrology

 **SOTANC**

Best Practices in Kidney Care in Asia

19 – 21 July 2019

Incorporating: SOTANC - State-Of-The-Art Nephrology Course (Nursing)
Singapore Society of Nephrology Annual Scientific Meeting
Asia Renal Association - Asian Nephrology Conference

Disclosures

- Ministry of Health Singapore – Auditor for Dialysis Facility Licensing
- Medical Director for NUH Dialysis Center @ Alexis
- Medical Director for FMC Dialysis Center @ Bukit Merah
- Chair of Hospital Tender Committee for Dialysis Equipment & Consumables
- Attended Advisory Board Meetings: Fresenius Medical Care, Baxter-Gambro, NxStage, Advent-Access
- Previous appointments with National Kidney Foundation (NKF) Singapore and Kidney Dialysis Foundation (KDF) Singapore

- **No conflict of interest to declare related to this presentation**

Definition of a Dialysis Facility

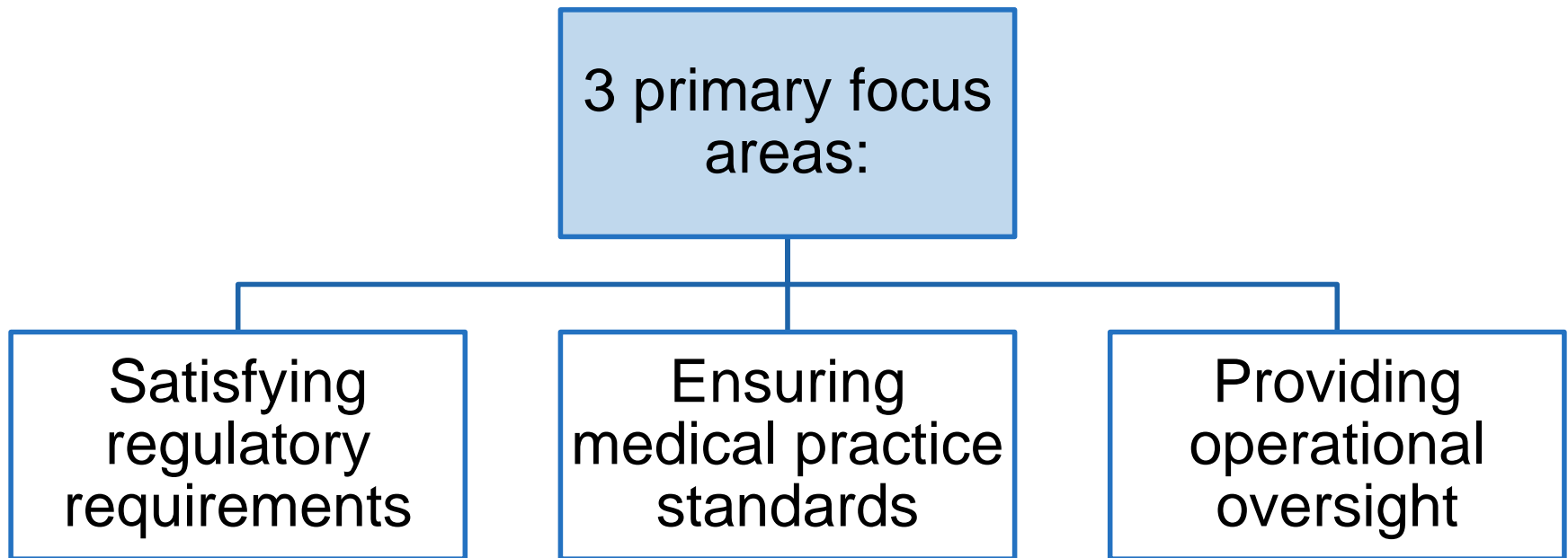
- *Dialysis facility* means an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit, that includes a self-care dialysis unit that furnishes only self-dialysis services.
- *Home dialysis* means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training (Home HD and PD).

The Position of Medical Director

- Is not just an “honorary” position
- Is not an entitlement

- It is an essential role with clearly defined responsibilities and performance expectations
- It is a position that is mandated, funded, given protected time and recognized by the authority / higher management

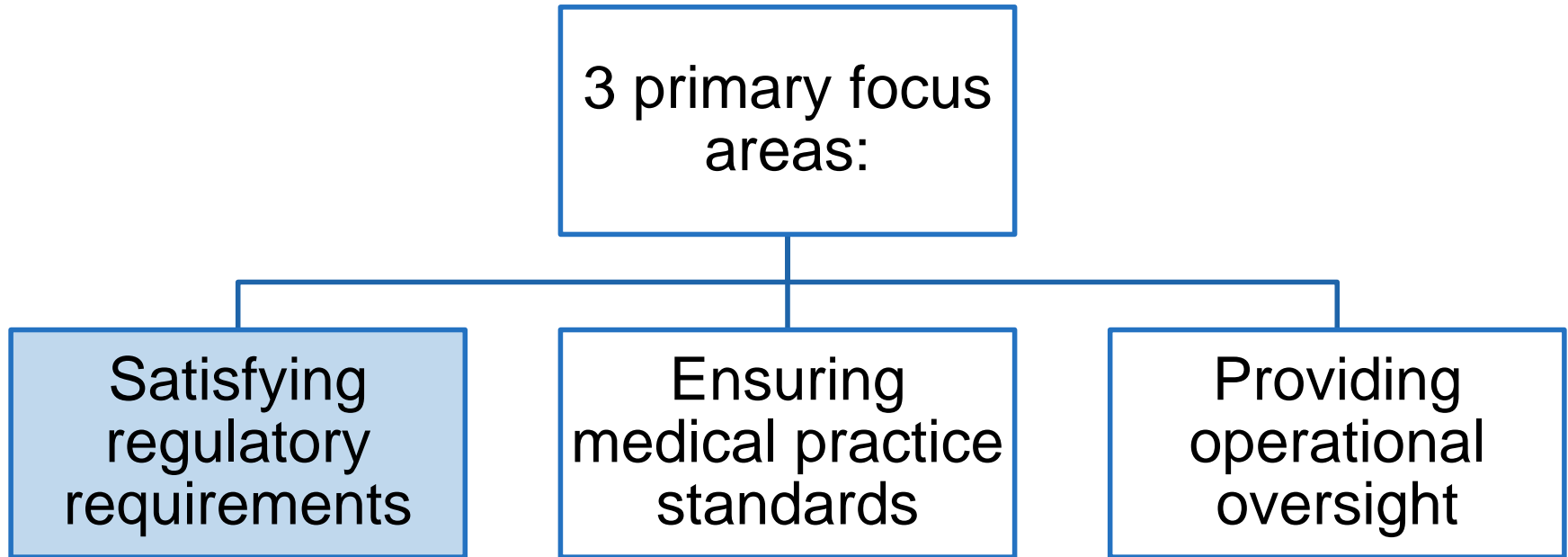
The Medical Director of a Dialysis Facility



Regulatory requirements of a dialysis facility

- Different countries have different considerations and hence, mandate different requirements to be met
- It will evolve and hopefully the nephrology community (including patients) plays a significant part in shaping these regulatory requirements
- The intent of these requirements is to make the delivery of care better and safer

The Medical Director of a Dialysis Facility



Regulatory requirements: Facility / Structure

Location / Size of center

Space for clinical work / toilet facility / safe storage of medical records

Number of treatment stations / examination room

Environmental aesthetics / Waiting area / Human traffic movement / Temperature

Adequate storage for consumables and pharmacy items / “dirty” utility room

Transport and ambulance accessibility

Infection control

Stairs / Elevator / Wheelchair access

Water and electricity supply system

Fire safety / Evacuation

Hazard discharge

Is this a well-designed center?



Regulatory requirements: Staff

Physician in-charge / Medical Director (Qualification)

Nurse in-charge / Nurse Manager (Qualification)

Dialysis staff to patient ratio

Level of nursing grade (Staff nurse, Nurse Asst., Dialysis Technician)

Staff roster / Contingency

Training and competency (Renal, Dialysis, BCLS)

Requirement for an attending physician to be present at all times (some)

Staff safety

Language requirement

Immunization

“Covering” physician (vacation, training, illness)

Staff welfare (work hours, meal breaks, place to rest)

Regulatory requirements: Medical

Acuity of patients

Distance from a general hospital

Time taken for ambulance assistance

Emergency care in free-standing facilities

Medical records (safe storage and confidentiality)

Clinical rounds (frequency)

Hours of operations and medical coverage

Free and informed choice to choose (modality and center)

Standards of care / Protocols

Type of IV therapeutics offered

Other types of treatment offered (Dialysis catheters, AV access, Ultrasound)

Treatment chart / Monitoring chart / Medication chart

Resuscitation equipment / cart / supplemental oxygen

Regulatory requirements: Equipment / Products

Machines / Product used are all registered / licensed locally

Safe storage and condition of storage

Maintenance schedule for all equipment

Water processing unit (central or portable)

Water quality (frequency of testing, action taken, technical support)

Documentation

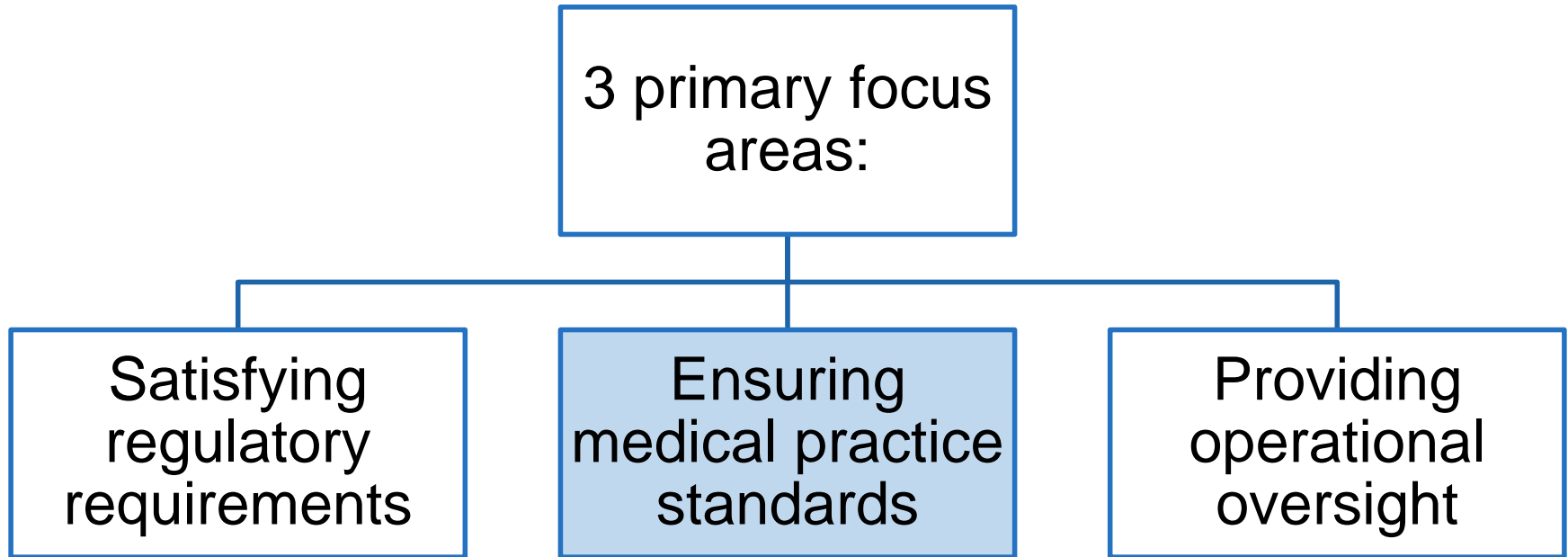
Cleaning / Disinfection protocol (Machines, RO, Loop)

Clinical waste management (bio-hazard)

Separation of machines for hepatitis patients

Spare machines (contingency)

The Medical Director of a Dialysis Facility



Ensuring Standards of Care

MEDICARE'S CONDITIONS FOR COVERAGE FOR END STAGE RENAL DISEASE FACILITIES

Overview:

The Centers for Medicare and Medicaid Services (CMS) new rules, the Conditions for Coverage (CfCs) for End Stage Renal Disease Facilities, went into effect October 2008. Dialysis facilities must meet these requirements to be certified under the Medicare program. These new CfCs focus on (1) improving the quality of care for patients; (2) establishing performance measures; (3) encouraging patient participation in their care and treatment and (4) eliminating outdated requirements. The rulemaking reflects advances in dialysis technology and care since 1976, when the first regulations were issued.

Why:

Individuals who receive dialysis treatment depend on quality care and staffing in dialysis facilities to survive.

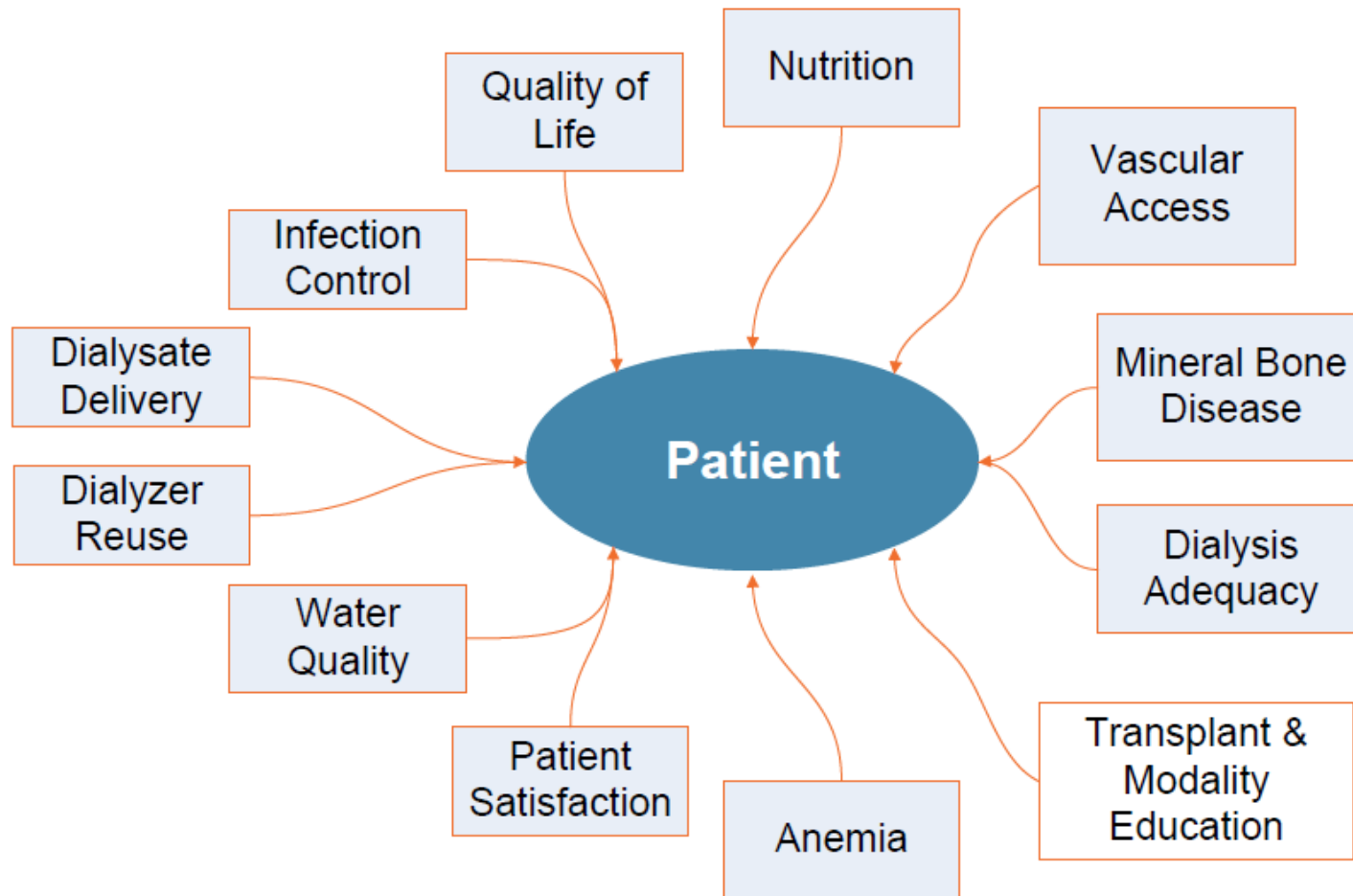
“The medical director is accountable to the governing body for the quality and safety of care provided...”

Conditions for Coverage 494.150

Conditions of coverage

- **Defines 16 conditions which must be met in order for ESRD facilities to receive Medicare coverage**
- **Failure to meet one or more of the conditions may lead to closure of a facility**
- **Medical Director accountability is defined in multiple conditions**
 - Conducting Quality Improvement
 - Infection Control
 - Governance
 - Medical Directors

Quality of care: common domains



Mandate #1: Infection Control

- The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.
- Standard Precaution according to International CPG recommendations
- Availability of PPE (personal protective equipment)
- Adequate wash basins / soap / hand sanitizer
- Disposable items
- Clean area to prepare iv medications
- No sharing of iv medications - discourage use of multi-dose vial
- Medication tray / cart
- Handling of hazardous waste

Infection control - BBV

- Prevention of BBV (blood-borne virus) transmission
- HD machines – disinfection / surface cleaning / transducer protector
- Virology screening – as mandated by local guidelines
- Separation of HBV POS patients / designated machines
- Immunization of staff and patients
- HCV and HIV as per local national guidelines

Infection control - others

- Pneumococcal and Influenza vaccinations
- Care of dialysis catheters and dialysis related blood-stream infection
- Reduction in use of dialysis catheters

Mandate #2: water quality for a HD facility

- Maintaining quality of dialysis water and dialysis fluid
- Microbial purity and chemical accuracy
- Recommended standards by ISO or AAMI (or local authorities)
- The details are given in a separate lecture

Mandate #3: Clinical outcome assessment and monitoring

- Regular and ad hoc assessment - acute symptoms
- Adequacy of dialysis dose / dialysis prescription
- Volume assessment and dry weight target
- Anemia
- CKD-MBD
- Nutrition
- CV Disease
- Psycho-social assessment
- Access care / monitoring
- Physical functioning / frailty

- **Plan of care must be clearly documented**

Mandate #4: patient education

- Dialysis modality selection
- Coping with dialysis
- Overall requirement as a ESRD patient on long term RRT
- Appropriate dietary plan
- Burden of disease and treatment
- Advanced Medical Directives
- Withdrawal from RRT program
- Opportunity for kidney transplant
- Has the right to choose to be treated in another facility

Mandate #5: quality and performance improvement

- This Condition looks at facility aggregate data and requires facility-based assessment and improvement of care, while the Plan of care Condition expects patient-based improvement of care.
- Compliance with this Condition is determined by review of clinical outcomes data and the records of the quality assessment performance improvement activities of the facility, and by interviews of responsible staff including the Medical Director.
- Non-compliance and deficiency defined by:
 - *Absence of an effective QAPI program;*
 - *Failure to recognize and prioritize major problems that threaten the health and safety of patients;*
 - *Failure to take action to address identified problems*

Medical Director of Home Dialysis Program

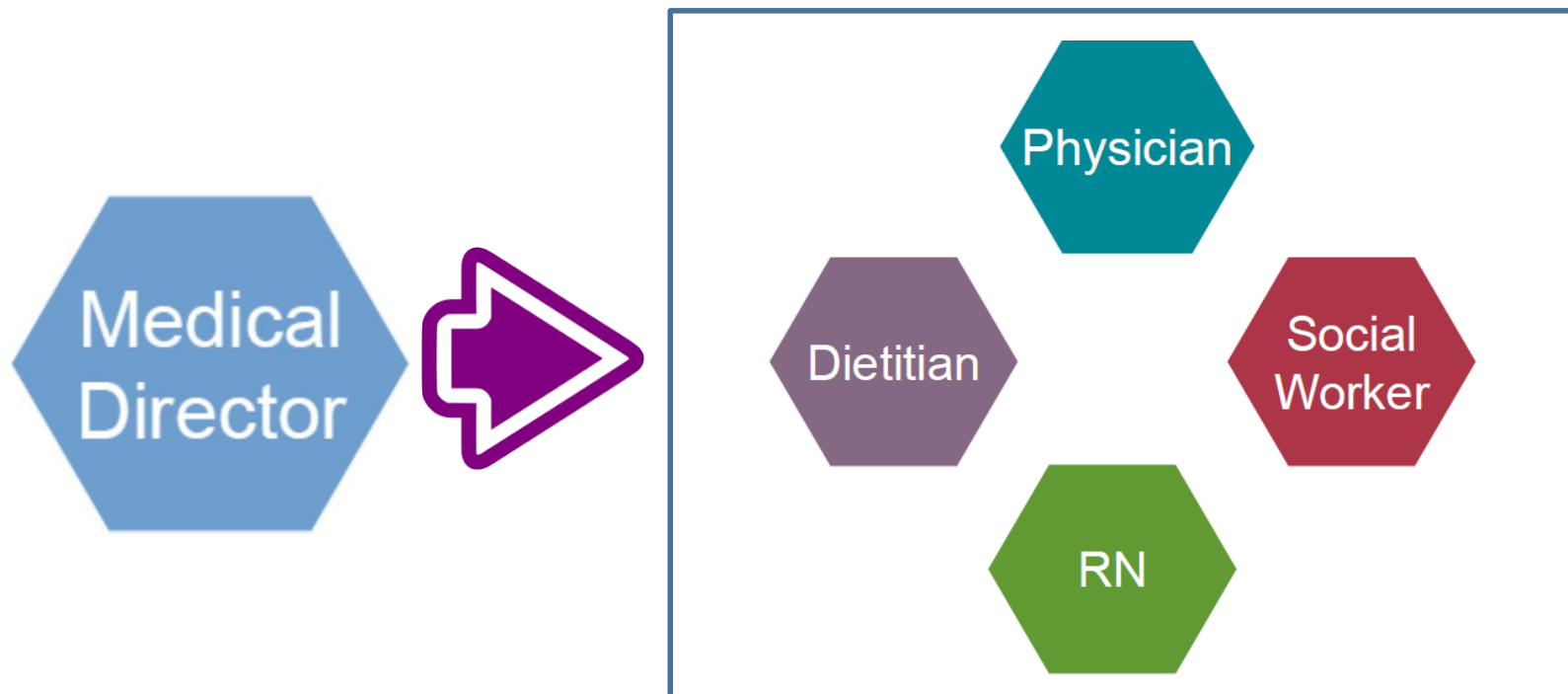
- **Peritoneal Dialysis and Home Hemodialysis**
- For a dialysis facility to provide a home dialysis program, the facility must be certified for home dialysis services including both training and support
- The nurse responsible for home dialysis training must be a registered nurse who meets the professional practice requirements
- The facility must provide home dialysis patients access to resources and assistance 24 hours/day, 7 days/week. This may be through a call system which can be reached by the patient/family/helper (HOTLINE)
- The dialysis facility must obtain and maintain records on all home patients including at a minimum, treatment records, flow sheets, medications administered, equipment and water treatment system checks, if applicable
- Documentation of home visits and assessment should be included in the medical record
- Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment
- For home HD, all standards that are applicable for in-center facility applies for home HD as well
- The dialysis facility is responsible for identifying a plan and arranging for timely emergency back-up dialysis whenever needed by the home dialysis patient

- **Coach to the Interdisciplinary Team (IDT)**

- Patient assessments and care plans
- Managing the disruptive patient

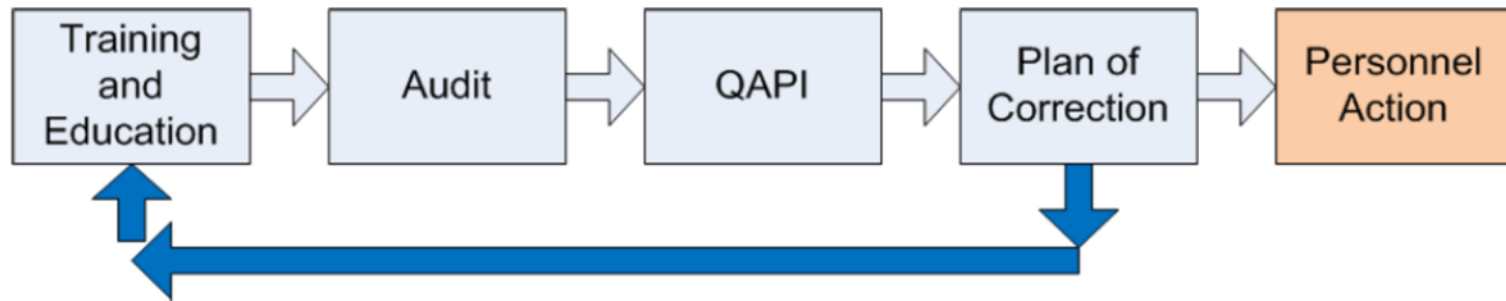
- **Clinical leader**

- Quality Assessment and Process Improvement (QAPI) Team
- Governing body



Role of Medical Director: governance and QA

- **Quality**
- **Safety**
- **Policy and procedure**
- **Training and education**



- Internal audit: Medical Director directs and plan the audit
- External audit: Medical Director prepares team for audit

Internal auditing of your own facility:

Steps to Prepare the Audit

- Establishing audit objectives and scope of work
- Study of background information
- Selecting the audit team and other audit resources
- Preparing a preliminary audit program
- Informing the auditee and others
- Determining how, when, and to whom the audit results will be communicated
- Obtaining approval to do the audit

To promote safety culture: voluntary reporting

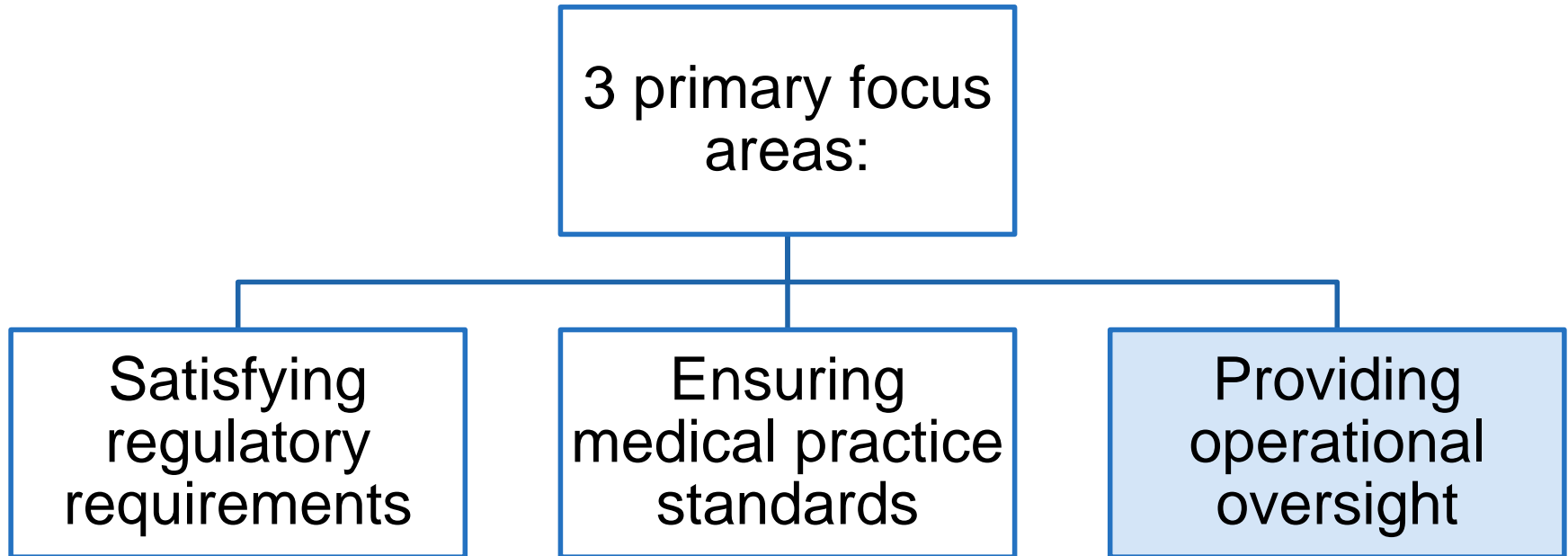


Do you investigate all incidents including near misses?

Do you have an effective process in place for ensuring all incidents are reported?

Incident reporting and investigation is a key method for correcting issues in the workplace to ensure the same incident never happens again. By understanding *why* an incident occurred, you can be confident you have the tools to correct it for the future.

The Medical Director of a Dialysis Facility



Operational oversight

- Business plan
- Service standards
- Customer (patient or potential patient enquiry) support
- Administrative / billing support
- Accounts / bookkeeping
- Profit and loss balance sheet
- Ensuring adequate supplies
- Payment of bills
- Contracts to update
- Lease agreement
- Purchasing / procurement (set your policies and priorities)

“ If you think you have the skills to make a good medical director, you have a moral obligation to put them to use. You can make a huge difference, not just to one group of patients but to the entire population you serve ”

Many medical directors did not actively pursue the role but found themselves stepping in when a post became vacant.

The medical director's responsibilities are varied and broadly defined, which can make it challenging for a new medical director to understand their role and be effective from day one.

Medical leadership is often learned by experience – there is no single pathway to becoming a medical director, so new medical directors' skills and knowledge will vary.

