



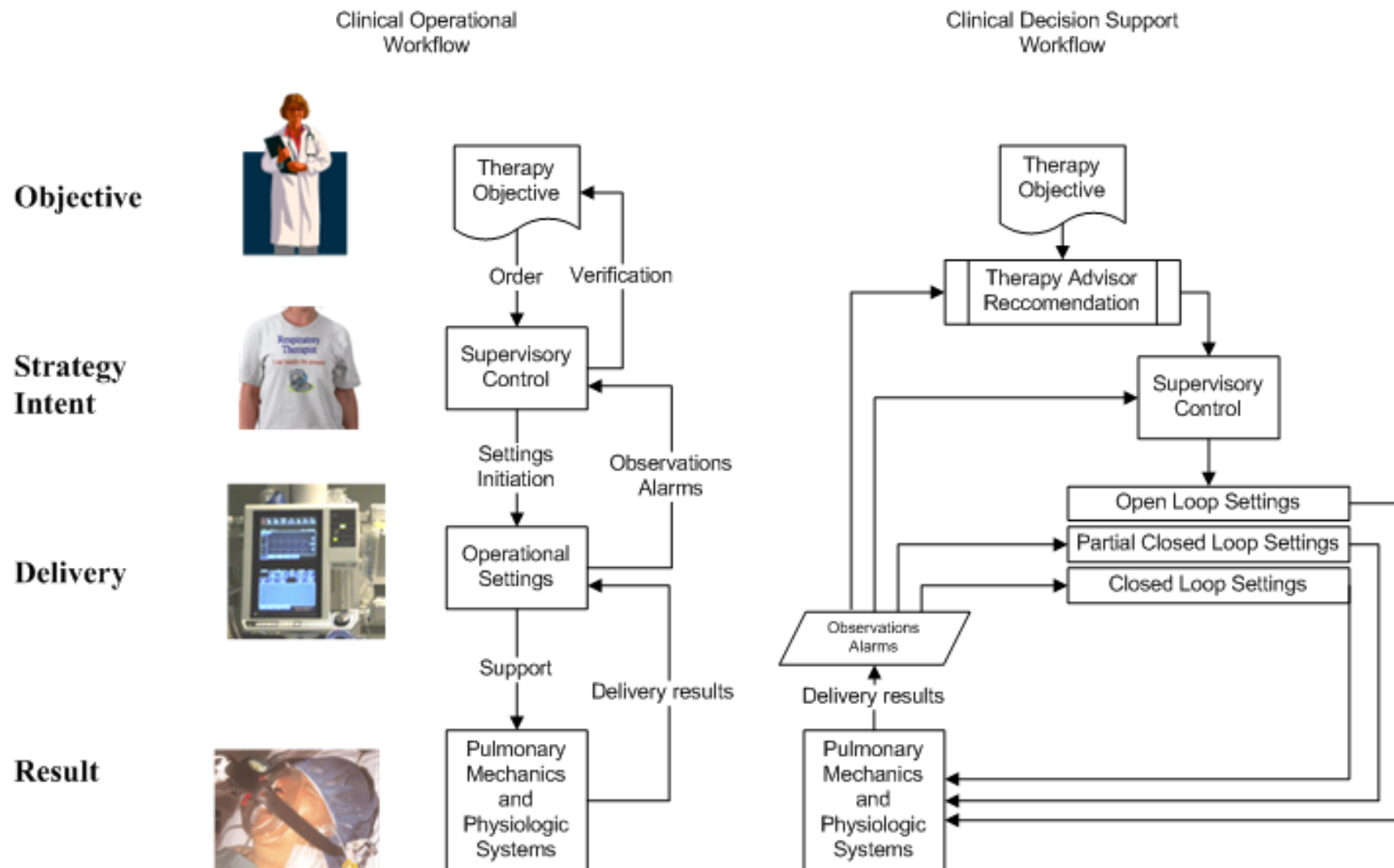
# FiO2 Control in Preterm Infants – A Case for Device Interoperability

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## Clinical Problem

Preterm infants on ventilator support may experience both hyper and hypoxemia events when insufficient attention is given to the adjustment of the inspired oxygen fraction ( $FiO_2$ ) to maintain the pulse oxygenation ( $SpO_2$ ) within a target range.



<u>Variables</u>		<u>Typical Safety and Effectiveness Issues</u>						
Ventilation Mode	Mode	Improper Mode @ Order	On/Off Interlock Failure	Improper Setting				
Interface		Disconnect or faulty attachment						
Metrics		<u>Units</u>	<u>Calculations</u>	<u>Settings</u>	<u>Alerts</u>			
<u>Ventilation</u>		Mis-selection of optional units, e.g. mbar vs. CMH20 vs. mmHg; or L vs. ml		Improper setting @ patient type, condition, or per Orders	High or Low values			
Compliance	C							
Resistance	Raw							
Peak End Expir. Press.	PEEP							
Peak Inspir. Press.	PIP							
Tidal Volume	Vt							
Minute Volume	Ve							
Leakage	Vleak							
Ventilation Rate	f							
<u>Oxygenation</u>								
Fractional Inspired O2	FiO2							
Inhaled NO	InNO							
Arterial O2	PaO2							
Transcutaneous O2	PtcO2 (SpO2)							
Arterial CO2	PaCO2							
Transcutaneous CO2	PtcCO2							
Mean Airway Pressure	MAP							
<u>Cardiography</u>								
Ultrasound CTG		Improper Lead Placement or Leads Off						
Fetal ECG								

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Patient not in transduction loop without notification to Calculation or User Interface (false positive)

SpO2 lead improperly attached causes measurement or derived calculation misprecision.

Lack of or faulty time synchronization among medical devices causes calculation or interpretation misprecision.

Alarm limits improperly or inappropriately set causes false positive or negative.

Improper use of adult vs. neonatal-specialized medical devices or interfaces

## Related Standardization Initiatives

- Clinical workflow and medical device interaction
  - IEC 80001
  - IHE (ITI, PCD)
  - IHE PCD DPI ICE-PAC
- Medical device specific safety and effectiveness
  - ICE; IEC
- Common semantic interoperability
  - IHTSDO
  - IHE PCD RTM
  - IEEE 11073
- Common interoperability profiles
  - HL7 HCD
  - IEEE 11073