Quality in Health Systems: How to Assess Clinical Effectiveness

Anuska Kalita

Webinar Series on Health Systems Assessment

September 2, 2021

HARVARD T.H. CHAN
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Objectives of this session

- Define clinical effectiveness
- Place clinical effectiveness within Quality in the Control Knob Framework
- Understand why clinical effectiveness is important for health system assessment
- Understand how to measure clinical effectiveness
  - Common methods
  - Pro and cons of each method
  - Role play to illustrate clinical vignette interview
- Evidence from India
  - Evidence from Odisha
- Group discussions on possible reasons behind low clinical effectiveness & potential policy solutions

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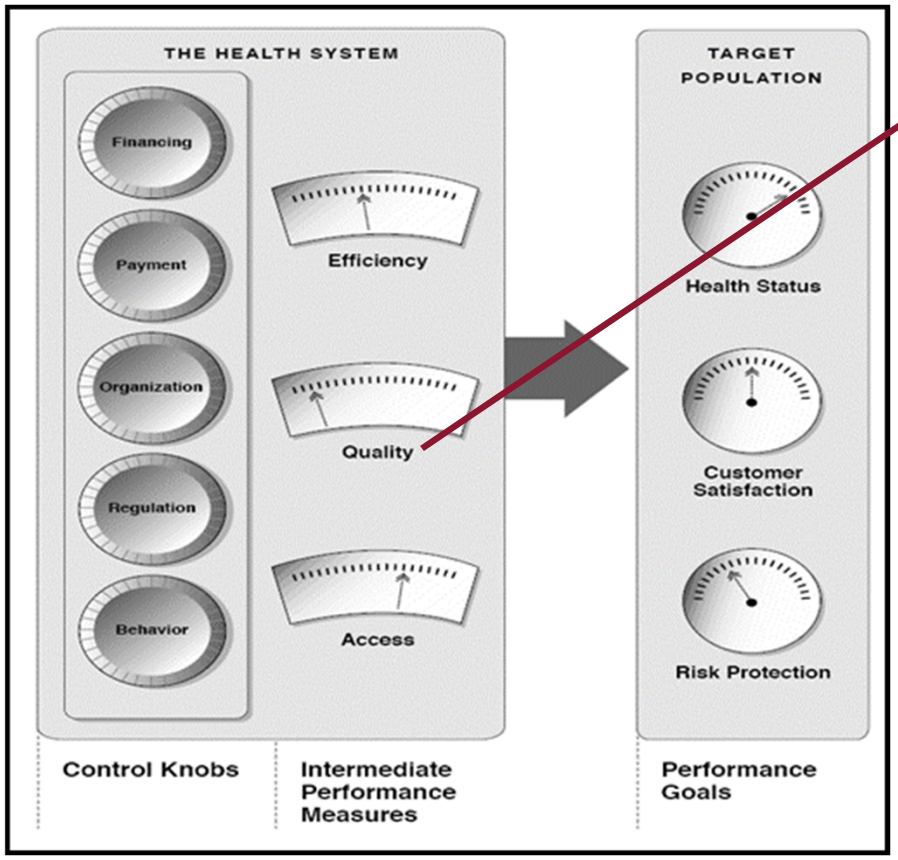
What is clinical effectiveness?

The competence of healthcare providers to make timely & correct diagnoses & advise correct treatment that is evidence-based



Health system is a means to an end.
Quality is one of the intermediate goals (ends) of a health system.
Clinical effectiveness is one of the aspects of quality

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Things to keep in mind about clinical effectiveness?

- It is only ONE aspect of quality
- It can indicate both knowledge and practice of providers
- It includes both underuse & overuse of care
- It can measure competencies of any healthcare provider (not just doctors)

Quality has 3 aspects	
Clinical Effectiveness	Do patients receive appropriate treatment when they seek care?
Patient Safety	When patients receive care, is the care safe/not harmful to patients?
Patient Centeredness	Are patients treated with respect & involved in decisions regarding their care?

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Why is clinical effectiveness important in a health system assessment?

Without quality, access to healthcare is meaningless

- Poor quality care / clinical ineffectiveness could lead to:
  - Delayed diagnoses/treatment, causing increase in severity, preventable complications, or preventable deaths
  - Irrational & low-value care, wastage both at individual & health system levels
  - Larger global health concerns e.g., anti-microbial resistance (overuse of antibiotics) or diseases like mucormycosis (overuse of steroids)
- Quality of care, especially clinical effectiveness, has been neglected in research & policies of LMICs, India & Odisha

POLL: Comparison of different clinical effectiveness measures

- According to you, which method of measuring clinical effectiveness is the best?
  A. Participant Observation
  B. Chart Reviews
  C. Clinical Vignettes
  D. Standardized Patients

- According to you, which method of measuring clinical effectiveness is the most suited for measuring provider knowledge in the Indian context?
  A. Participant Observation
  B. Chart Reviews
  C. Clinical Vignettes
  D. Standardized Patients

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How do we measure clinical effectiveness?

1. **Participant Observation**
2. **Chart Reviews**
3. **Clinical Vignettes**
4. **Standardized Patients**

Correct diagnosis

- Misdiagnosis as a less serious condition

Process of diagnosing

- Asking key questions for differential diagnosis
- Asking for right diagnostic tests

Correct treatment

- Unnecessary treatment
- Incorrect treatment

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How do we measure clinical effectiveness?

1. **Participant Observation**
   - 1-2 observers “observe” the provider’s interaction with the patient & record the observations. The provider’s diagnosis, treatment are compared against clinical guidelines
   - E.g., TB diagnosis and treatment in Mumbai (Madhukar Pai’s research)

How do we measure clinical effectiveness?

2. Chart Reviews

- Patient's charts/discharge summaries are collected from providers. The provider's diagnosis, treatment are compared against clinical guidelines
  - E.g., Kumar S, Chaudhary S. Medical errors and consequent adverse events in critically ill surgical patients in a tertiary care teaching hospital in Delhi. J Emerg Trauma Shock. 2009 May;2(2):80-4.
  - Adil MS, Sultana R, Khulood D. PRIME study: Prescription review to impede medication errors. Int J Risk Saf Med. 2020;31(2):67-79. - Prescription errors accounted for the majority (87.1%) of errors.

How do we measure clinical effectiveness?

3. Clinical Vignettes

- 2 interviewers use clinical vignettes to conduct provider interviews. One interviewer plays the patient with specific symptoms & responds to the provider's questions. The other interviewer records all the questions and responses made by the provider against the vignette.
- Provider knows that it is NOT a real patient, and that it is a hypothetical case.
- Provider is asked to treat these cases as though these are real patients.
- IF and only if a provider says s/he would conduct a test/examination provide the results.
- The provider's diagnosis, treatment are compared against clinical guidelines
- E.g., Childhood diarrhea by Mohanan et al. TB by Das et al. 5 common conditions by Kalita et al.

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How do we measure clinical effectiveness?

4. Standardized Patients

- 1 patient actor visits the provider with specific symptoms & responds to the provider's questions.
- Provider DOES NOT know that it is not real patient.
- Patient avoids physical exams.
- The provider's diagnosis, treatment are compared against clinical guidelines
- E.g., Childhood diarrhea & pneumonia, TB by Mohanan et al. Different conditions by Das et al.

Comparison of the different methods to measure clinical effectiveness

Method of measurement	Pros	Cons
Participant Observation	• Measures practice • Relatively low cost • Can be conducted in most care settings	• Does not measure knowledge • Not possible to know the actual condition & whether the patient was diagnosed correctly • Possible Hawthorne Effect
Chart Reviews	• Measures practice • Low cost • Can be conducted in settings that have charts	• Does not measure knowledge • Not possible to know the actual condition & whether patient was diagnosed correctly • Not feasible for India (esp. OP care)
Clinical Vignettes	• Measures knowledge • Possible to know/control the actual condition Relatively low cost • Can be conducted in all settings • Useful for comparing competence across different providers	• Does not measure practice • Is a higher estimation of competence
Standardized Patients	Measures practice Possible to know/control the actual condition is Useful for comparing competence across different providers	• Does not measure practice • Very high costs/resources • Not applicable for all settings

ROLE PLAY: How to conduct clinical vignette interviews?

- Clinical vignette interview for a TB case

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ROLE PLAY: How to analyze clinical vignette interviews?

Process of diagnosis

Right diagnostic tests

- Tuberculin Skin Test (TST)
- Sputum test
- Chest X-Ray
- Temperature

Key questions

- Have you taken DOTS before?
- Patient's weight, height, age
- Has the cough been continuous for 1 mth?
- Is there mucous/blood in sputum?
- Pattern of the fever?
- Anyone in household/neighborhood with similar cough

Correct diagnosis

Tuberculosis

Correct treatment

Advice on spread, preventive measures
Patient counseling
Importance of treatment compliance and continuing treatment
Follow-up

RNTCP Guidelines for TB treatment regimen

Drug Dosage for Adult TB

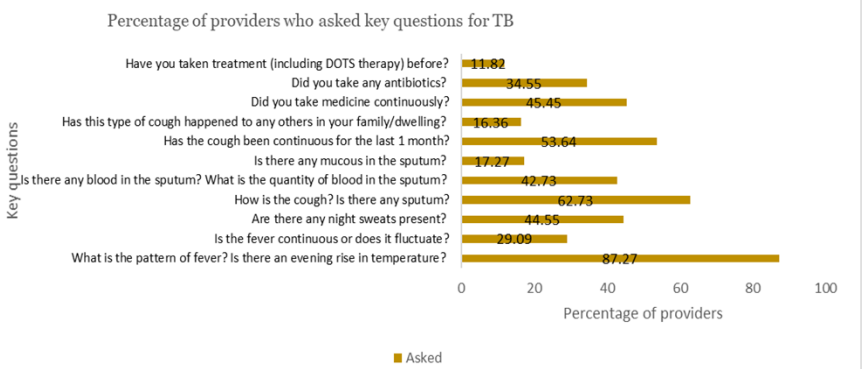
Weight category	Number of tablets (FDCs)		Inj. Streptomycin
	Intensive phase	Continuation phase	
	HRZE	HRE	
	75/150/400/275	75/150/275	gm
25-39 kg	2	2	0.5
40-54 kg	3	3	0.75
55-69 kg	4	4	1
>=70	5	5	1

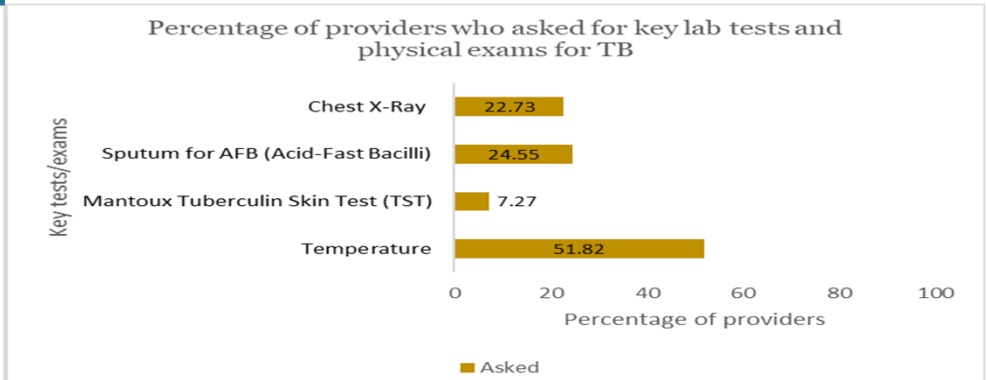
H = Isoniazid
R = Rifampicin
Z =Pyrazinamide
E = Ethambutol

**Inj. Streptomycin to be added in IP phase for 2 months in the previously treated regimen of drug sensitive patients. In patients above 50 years of age, maximum dose of streptomycin should be 0.75gm.*
Adults weighing less than 25 kg will be given loose drugs as per body weight. Dosages of loose drugs are given in appendix

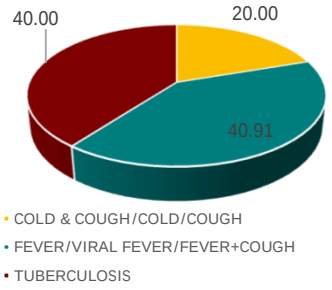
Clinical vignette analysis - example of TB case in India

Diagnostic Process – key questions and tests

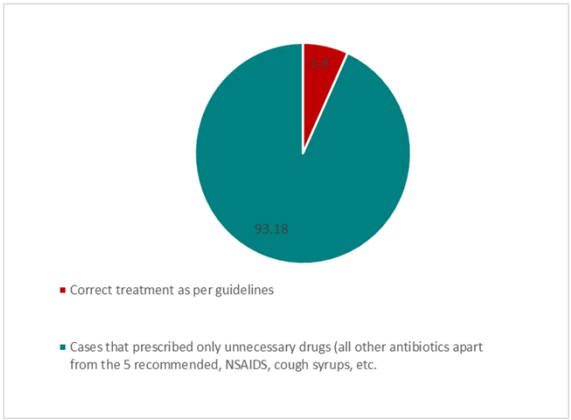




Correct Diagnosis



Correct Treatment



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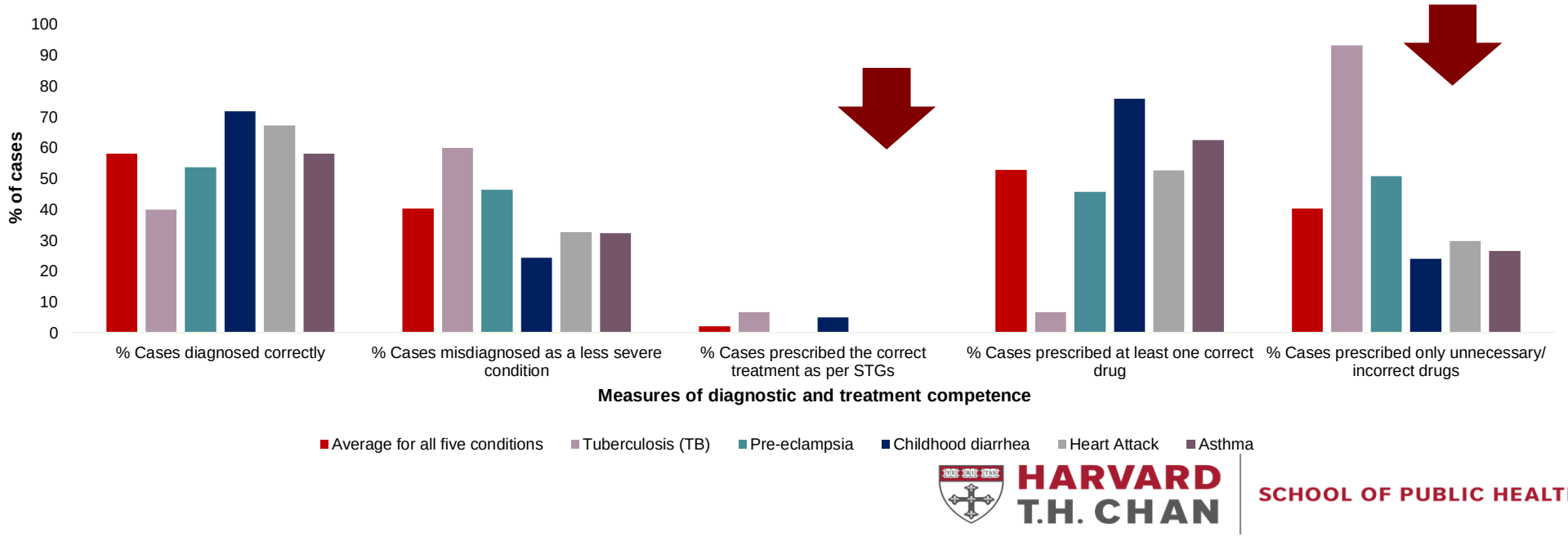
Measuring clinical effectiveness – example with clinical vignettes in Odisha

- **Incorrect diagnoses** - ~60% cases diagnosed correctly
  - Providers wrongly diagnosed as a less serious illness (E.g., cold, fever for TB, headache for preeclampsia, acidity & body ache for heart attack)

- **Incorrect treatment** - Only ~2% providers advised correct treatment. Although ~50% prescribed at least one correct drug. ~40% prescribed **only** unnecessary (sometimes harmful) drugs/antibiotics – raising concerns of low-value care, anti-microbial resistance



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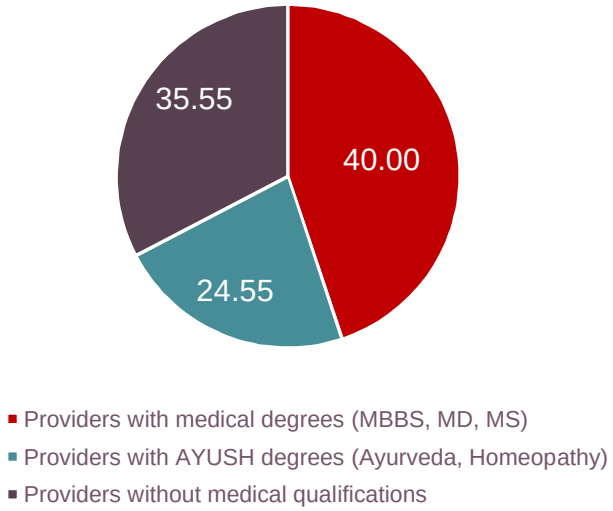
Possible provider-level correlates of competence – data from Odisha

- **Medical qualification** - Most primary-level care was provided by non-physicians. ~10% public providers had MBBS degrees
- **Educational institution** – 58.18% of providers were trained in govt colleges, 41.82% in pvt colleges. Higher number of pvt providers were trained in govt colleges versus



- **Work experience – ~**20 years avg
- **Poor training** - 19% providers had undergone any in-service training
- **Poor supervision** - ~40% public providers had supervisory visits
- **Work load** – Mean 185 patients/wk; private providers saw fewer patients
- **Time spent** – Mean 10 mins/pt; private providers spent more time per patient than public providers; no significant differences in number of work hours
- **Provider payment** - Private providers earned fee-for-service & almost double the salaries of public providers

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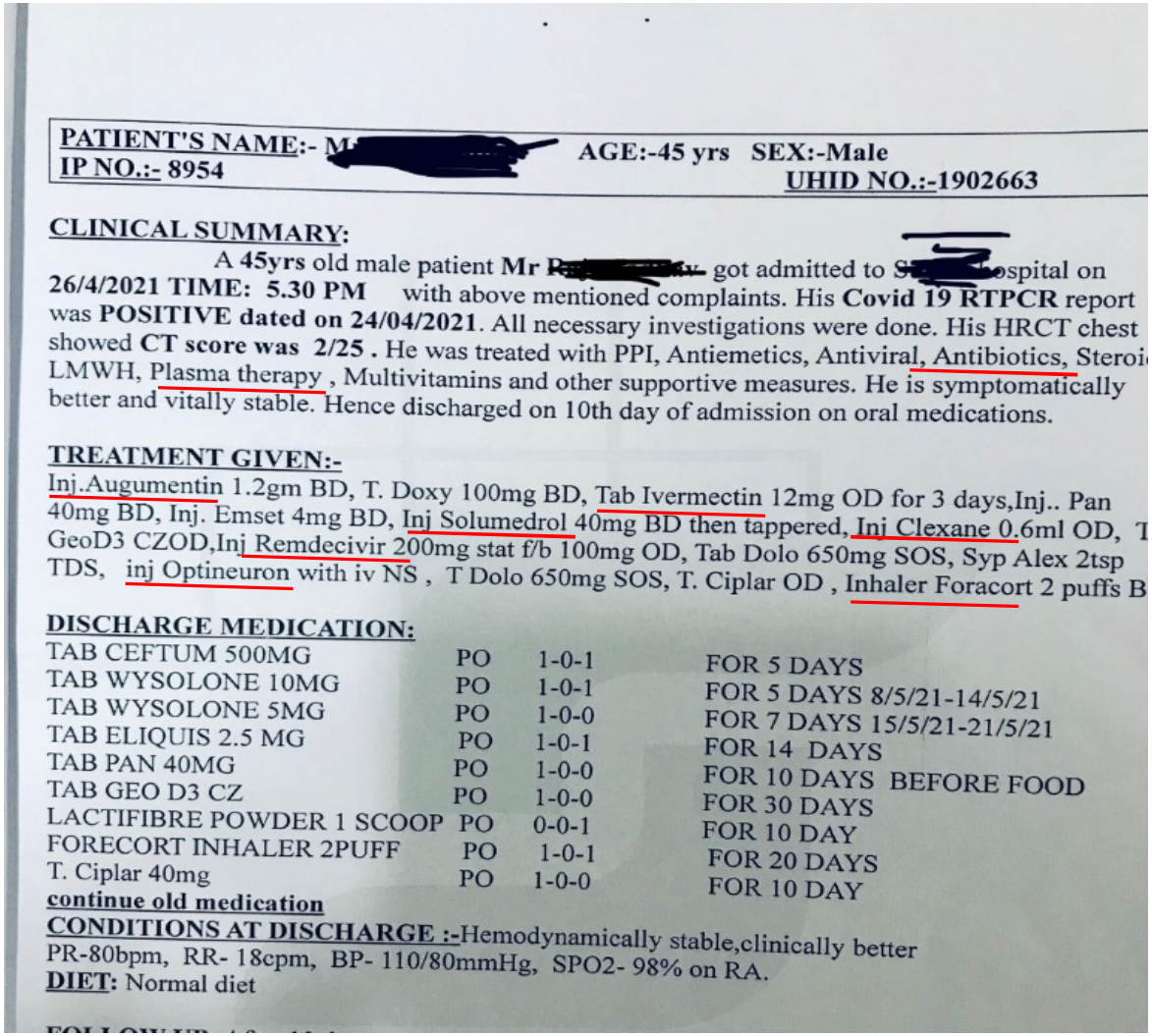
Key findings for provider-level correlates of competence – example from Odisha

Independent variables	Differences in diagnostic competence	Differences in treatment competence
Medical qualification of providers	No significant difference between MBBS doctors, AYUSH & unqualified	No significant difference in the competence to provider correct treatment No significant difference in the prescription of incorrect & irrational treatments
Education institution where provider was trained	Providers trained at government colleges were slightly more competent than those at private institutes	
Rural v Urban Providers	Providers in urban areas were more competent than those in rural areas	
Public v Private Providers	Private sector providers were more competent than public sector providers at PHCs	
In-service training	There was no significant difference between providers who received in-service training versus those who did not	
Time spent per patient	Diagnostic competence was not significantly correlated with the amount of time spent per patient	
Work experience	No significant difference between providers with more or less years of work experience	

Clinical guidelines - example of COVID-19 care in India using chart review



PATIENT'S NAME:- M[redacted] AGE:-45 yrs SEX:-Male
IP NO.:- 8954 UHID NO.:-1902663

CLINICAL SUMMARY:

A **45yrs** old male patient **Mr** [redacted] got admitted to S[redacted]ospital on **26/4/2021 TIME: 5.30 PM** with above mentioned complaints. His **Covid 19 RTPCR** report was **POSITIVE dated on 24/04/2021**. All necessary investigations were done. His HRCT chest showed **CT score was 2/25 .** He was treated with PPI, Antiemetics, Antiviral, Antibiotics, Steroi LMWH, Plasma therapy , Multivitamins and other supportive measures. He is symptomatically better and vitally stable. Hence discharged on 10th day of admission on oral medications.

TREATMENT GIVEN:-

Inj.Augumentin 1.2gm BD, T. Doxy 100mg BD, Tab Ivermectin 12mg OD for 3 days,Inj.. Pan 40mg BD, Inj. Emset 4mg BD, Inj Solumedrol 40mg BD then tappered, Inj Clexane 0.6ml OD, T GeoD3 CZOD,Inj Remdecivir 200mg stat f/b 100mg OD, Tab Dolo 650mg SOS, Syp Alex 2tsp TDS, inj Optineuron with iv NS , T Dolo 650mg SOS, T. Ciplar OD , Inhaler Foracort 2 puffs B

DISCHARGE MEDICATION:

TAB CEFTUM 500MG	PO	1-0-1	FOR 5 DAYS
TAB WYSOLONE 10MG	PO	1-0-1	FOR 5 DAYS 8/5/21-14/5/21
TAB WYSOLONE 5MG	PO	1-0-0	FOR 7 DAYS 15/5/21-21/5/21
TAB ELIQUIS 2.5 MG	PO	1-0-1	FOR 14 DAYS
TAB PAN 40MG	PO	1-0-0	FOR 10 DAYS BEFORE FOOD
TAB GEO D3 CZ	PO	1-0-0	FOR 30 DAYS
LACTIFIBRE POWDER 1 SCOOP	PO	0-0-1	FOR 10 DAY
FORECORT INHALER 2PUFF	PO	1-0-1	FOR 20 DAYS
T. Ciplar 40mg	PO	1-0-0	FOR 10 DAY

continue old medication

CONDITIONS AT DISCHARGE :-Hemodynamically stable,clinically better
PR-80bpm, RR- 18cpm, BP- 110/80mmHg, SPO2- 98% on RA.
DIET: Normal diet

World Health Organization

https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2021.2

1. Recommendation to use Tocilizumab/Sarilumab in patients with severe or critical COVID-19 (published 6 July 2021)
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BREAKOUT SESSIONS: Group discussions

GROUP 1: Evidence from studies in Odisha, Chhattisgarh, Madhya Pradesh, Bihar, Delhi show that there is no difference in clinical effectiveness of providers with & without medical qualifications. What could be the possible explanations? What are the implications for reforms?

GROUP 2: Evidence from Odisha shows that private sector providers have higher diagnostic competence than public sector providers, but treatment competence was the same in both groups. What could be some possible explanations? What are some of the implications for future reforms?

GROUP 3: Evidence from India (and other LMICs) shows that providers' treatment advice differs from clinical guidelines? What could be the possible reasons? Discuss the formulation/updation, relevance & availability of guidelines. What are the implications for reforms?

GROUP 4: Keeping in mind the Indian context, what are 3 policy reforms would you recommend for improving clinical effectiveness at the primary care level? Are there existing policies/programs that you could leverage for these reforms?

GROUP 5: Have you come across any innovations/pilot programs trying to improve clinical effectiveness? If yes, state their key features. If not, share some key ideas. What are the potential challenges to their implementation & scale up?

Diagnosing reasons behind low clinical effectiveness – implications for medical education & training? (Discussion of Group 1)

GROUP 1: Evidence from studies in Odisha, Chhattisgarh, Madhya Pradesh, Bihar, Delhi show that there is no difference on clinical effectiveness of providers with & without medical qualifications. What could be the possible explanations? What are the implications for reforms?

- Medical education reforms
- Integrating evidence-based medicine
- Re-certification & professional regulation for medical doctors
- Involvement of professional bodies to self-regulate, given low state-capacity
- Investing in non-MBBS providers
- In-service training, supervision, monitoring, use of technology across all providers
  - Training alone is not sufficient
- What are providers' incentives?

Diagnosing reasons behind low clinical effectiveness – implications for public vs private sectors? (Discussion of Group 2)

- **GROUP 2:** Evidence from Odisha show that private sector providers have higher diagnostic competence than public sector providers, but treatment competence were the same in both groups. What could be some possible explanations? What are some of the implications for future reforms?

  - Mixed health systems have intersecting public & private sectors, need to consider both sectors when designing reforms for delivering primary care
  - Linkages between the public and private sectors are not black & white
    - Is the public sector not able to attract & retain qualified providers? (only 10% public providers at PHCs reported having medical degrees)
    - Provider incentives and payment methods
    - Sunshine Act

Diagnosing reasons behind low adherence to clinical guidelines? (Discussion of Group 3)

- **GROUP 3:** Evidence from India (and other LMICs) show that providers' treatment advice is very different from clinical guidelines? What could be the possible reasons? Discuss the formulation/updation, relevance & availability of guidelines. What are the implications for reforms?

  - Who knows about the guidelines and who uses them?
  - Having guidelines is not enough
    - How are guidelines enforced?
  - What do guidelines recommend & how evidence-based are they?
    - What is the process for updating them based on new evidence?
    - Responsibility of health and professional institutions to update clinical guidelines
  - Do inertia and politics affect scientific organizations?

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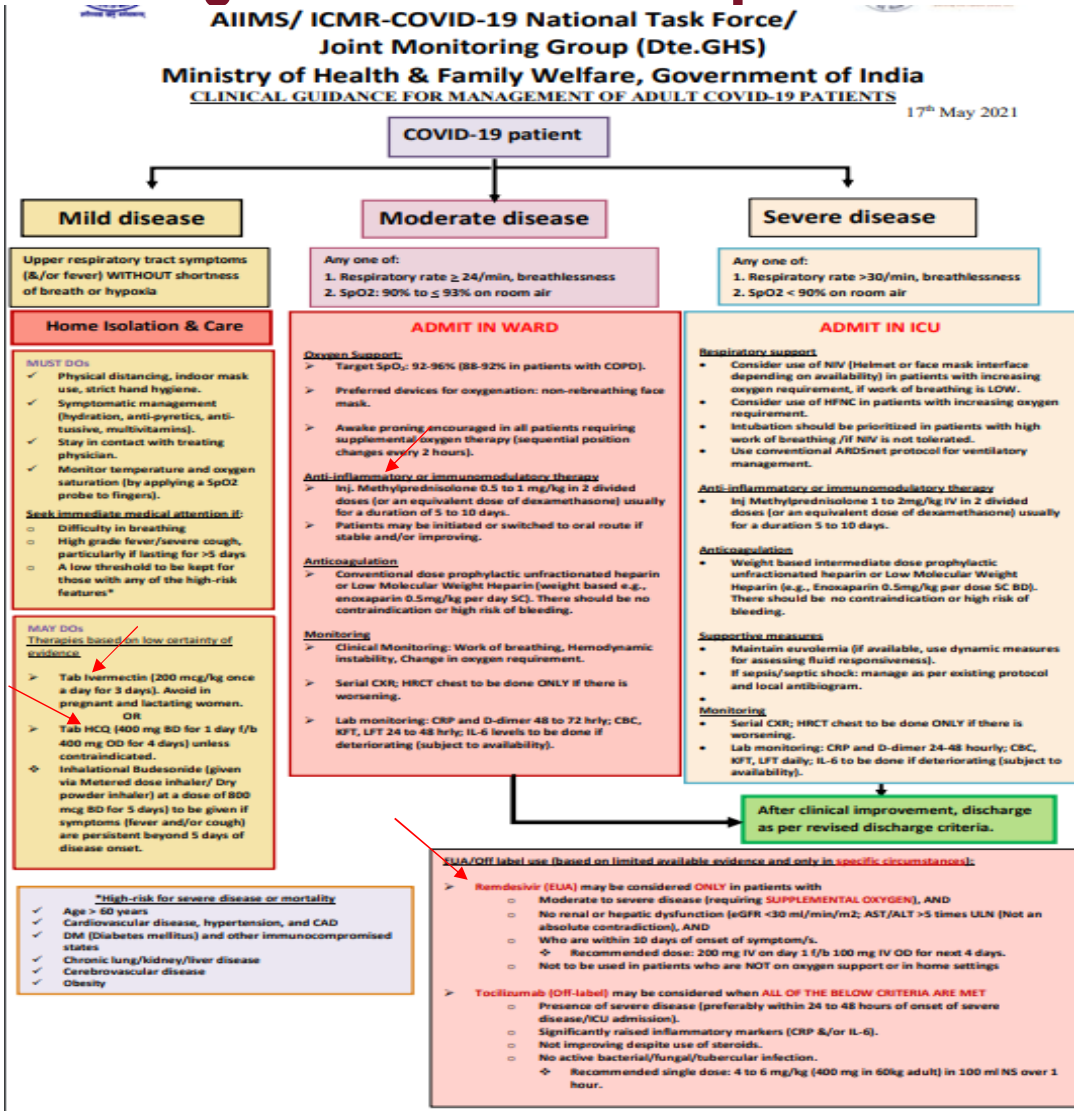
Clinical guidelines – the importance of using evidence



AIIMS/ ICMR-COVID-19 National Task Force/ Joint Monitoring Group (Dte.GHS)

Ministry of Health & Family Welfare, Government of India

CLINICAL GUIDANCE FOR MANAGEMENT OF ADULT COVID-19 PATIENTS

17th May 2021

COVID-19 patient

Mild disease

Upper respiratory tract symptoms (&/or fever) WITHOUT shortness of breath or hypoxia

Home Isolation & Care

MUST DOs
- ✓ Physical distancing, indoor mask use, strict hand hygiene.
- ✓ Symptomatic management (hydration, anti-pyretics, anti-tussive, multivitamins).
- ✓ Stay in contact with treating physician.
- ✓ Monitor temperature and oxygen saturation (by applying a SpO2 probe to fingers).

Seek immediate medical attention if:
- ○ Difficulty in breathing
- ○ High grade fever/severe cough, particularly if lasting for >5 days
- ○ A low threshold to be kept for those with any of the high-risk features*

MAY DOs
Therapies based on low certainty of evidence
- ➢ Tab Ivermectin (200 mcg/kg once a day for 3 days). Avoid in pregnant and lactating women.
  OR
- ➢ Tab HCQ (400 mg BD for 1 day f/b 400 mg OD for 4 days) unless contraindicated.
- ❖ Inhalational Budesonide (given via Metered dose inhaler/ Dry powder inhaler) at a dose of 800 mcg BD for 5 days) to be given if symptoms (fever and/or cough) are persistent beyond 5 days of disease onset.

*High-risk for severe disease or mortality
- ✓ Age > 60 years
- ✓ Cardiovascular disease, hypertension, and CAD
- ✓ DM (Diabetes mellitus) and other immunocompromised states
- ✓ Chronic lung/kidney/liver disease
- ✓ Cerebrovascular disease
- ✓ Obesity

Moderate disease

Any one of:
1. Respiratory rate ≥ 24/min, breathlessness
2. SpO2: 90% to ≤ 93% on room air

ADMIT IN WARD

Oxygen Support:
- ➢ Target SpO_2: 92-96% (88-92% in patients with COPD).
- ➢ Preferred devices for oxygenation: non-rebreathing face mask.
- ➢ Awake proning encouraged in all patients requiring supplemental oxygen therapy (sequential position changes every 2 hours).

Anti-inflammatory or immunomodulatory therapy
- ➢ Inj. Methylprednisolone 0.5 to 1 mg/kg in 2 divided doses (or an equivalent dose of dexamethasone) usually for a duration of 5 to 10 days.
- ➢ Patients may be initiated or switched to oral route if stable and/or improving.

Anticoagulation
- ➢ Conventional dose prophylactic unfractionated heparin or Low Molecular Weight Heparin (weight based e.g., enoxaparin 0.5mg/kg per day SC). There should be no contraindication or high risk of bleeding.

Monitoring
- ➢ Clinical Monitoring: Work of breathing, Hemodynamic instability, Change in oxygen requirement.
- ➢ Serial CXR; HRCT chest to be done ONLY if there is worsening.
- ➢ Lab monitoring: CRP and D-dimer 48 to 72 hrly; CBC, KFT, LFT 24 to 48 hrly; IL-6 levels to be done if deteriorating (subject to availability).

Severe disease

Any one of:
1. Respiratory rate >30/min, breathlessness
2. SpO2 < 90% on room air

ADMIT IN ICU

Respiratory support
- Consider use of NIV (Helmet or face mask interface depending on availability) in patients with increasing oxygen requirement, if work of breathing is LOW.
- Consider use of HFNC in patients with increasing oxygen requirement.
- Intubation should be prioritized in patients with high work of breathing /if NIV is not tolerated.
- Use conventional ARDSnet protocol for ventilatory management.

Anti-inflammatory or immunomodulatory therapy
- Inj Methylprednisolone 1 to 2mg/kg IV in 2 divided doses (or an equivalent dose of dexamethasone) usually for a duration 5 to 10 days.

Anticoagulation
- Weight based intermediate dose prophylactic unfractionated heparin or Low Molecular Weight Heparin (e.g., Enoxaparin 0.5mg/kg per dose SC BD). There should be no contraindication or high risk of bleeding.

Supportive measures
- Maintain euvolemia (if available, use dynamic measures for assessing fluid responsiveness).
- If sepsis/septic shock: manage as per existing protocol and local antibiogram.

Monitoring
- Serial CXR; HRCT chest to be done ONLY if there is worsening.
- Lab monitoring: CRP and D-dimer 24-48 hourly; CBC, KFT, LFT daily; IL-6 to be done if deteriorating (subject to availability).

After clinical improvement, discharge as per revised discharge criteria.

EUA/Off label use (based on limited available evidence and only in specific circumstances):
- ➢ Remdesivir (EUA) may be considered ONLY in patients with
  - ○ Moderate to severe disease (requiring SUPPLEMENTAL OXYGEN), AND
  - ○ No renal or hepatic dysfunction (eGFR <30 ml/min/m2; AST/ALT >5 times ULN (Not an absolute contradiction), AND
  - ○ Who are within 10 days of onset of symptom/s.
    - ❖ Recommended dose: 200 mg IV on day 1 f/b 100 mg IV OD for next 4 days.
  - ○ Not to be used in patients who are NOT on oxygen support or in home settings
- ➢ Tocilizumab (Off-label) may be considered when ALL OF THE BELOW CRITERIA ARE MET
  - ○ Presence of severe disease (preferably within 24 to 48 hours of onset of severe disease/ICU admission).
  - ○ Significantly raised inflammatory markers (CRP &/or IL-6).
  - ○ Not improving despite use of steroids.
  - ○ No active bacterial/fungal/tubercular infection.
    - ❖ Recommended single dose: 4 to 6 mg/kg (400 mg in 60kg adult) in 100 ml NS over 1 hour.

World Health Organization

https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2021.2

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Diagnosing reasons behind low clinical effectiveness – policy reforms? (Discussion of Group 4)

- **GROUP 4:** Keeping in mind the Indian context, what are 3 policy reforms that you would recommend for improving clinical effectiveness at the primary care level? Are there existing policies/programs that you could leverage for these reforms?

1. **Focus on *access with quality*, rather than just physical access and utilization metrics**
   - Integrate quality metrics into key outcomes
   - NONE of the Indian policies have focused on clinical effectiveness
   - Initiatives like *Mera Aspatal* are NOT measures of clinical effectiveness – do not confuse patient experience/satisfaction with clinical effectiveness
2. **Think about the health system as a whole – not just public sector facilities**
3. **Change provider knowledge & behavior**
   - Medical education, professional, training reforms
   - Incentivize in the system for quality, provider incentives/payment methods are key to changing behaviors
   - Leverage technology to support providers
     - Up-to-date
     - AI-based decision tools

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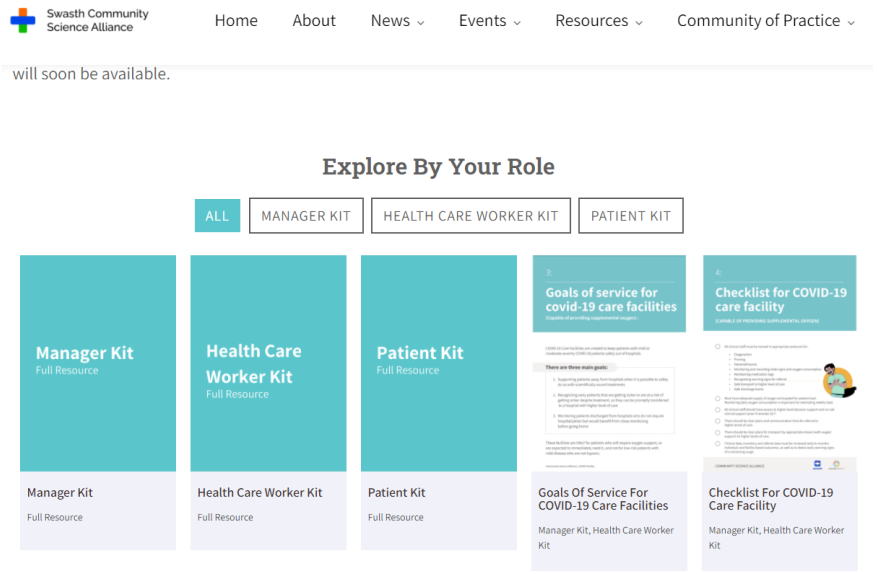
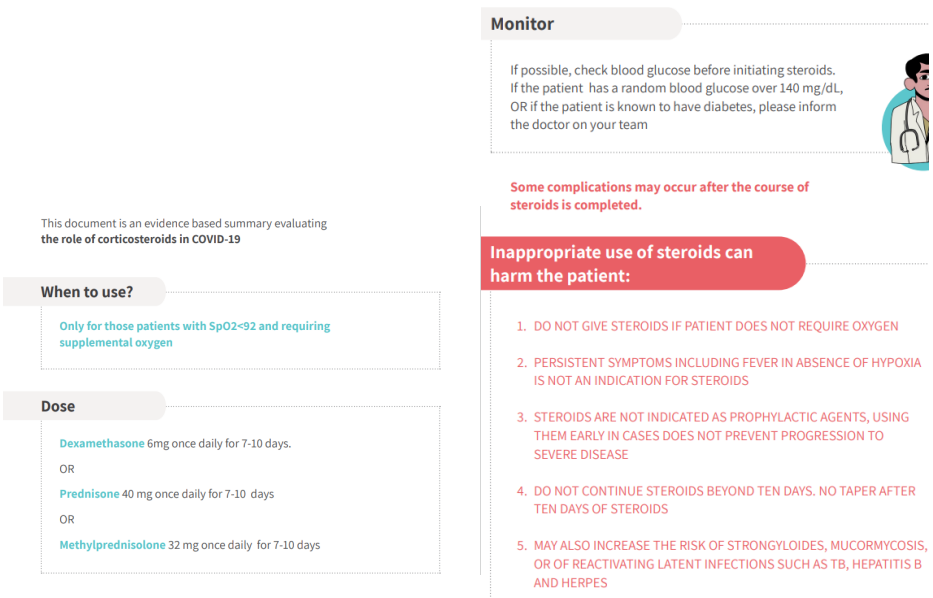
Diagnosing reasons behind low clinical effectiveness – ideas for innovations & implication for scale? (Discussion of Group 5)

- **GROUP 5:** Have you come across any innovations/pilot programs that are trying to improve clinical effectiveness? If yes, state their key features. If not, share some key ideas. What are the major challenges to their implementation & scale up?

1. **Swasth** - https://science.swasth.app/covid-19-care-centre/





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Diagnosing reasons behind low clinical effectiveness – ideas for innovations & implication for scale? (Discussion of Group 5)

- **GROUP 5:** Have you come across any innovations/pilot programs that are trying to improve clinical effectiveness? If yes, state their key features. If not, share some key ideas. What are the major challenges to their implementation & scale up?

2. Swasth Foundation - https://sites.sph.harvard.edu/india-health-systems/2020/10/21/wp2-swasth/

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To recap

- Clinical effectiveness is at the core of health systems – critical to achieve other health system goals (Health Status, Access, FRP, Satisfaction, Efficiency)
- Clinical effectiveness is only *ONE* aspect of quality
- There has been no focus on clinical effectiveness in Indian policies & very limited research
- There are 4 main methods of assessing clinical effectiveness. The main aspects to measure are correct diagnosis, diagnostic procedure, & correct treatment
- When choosing a method to assess clinical effectiveness, we need to keep in mind what we want to measure, among whom, the context, & available resources
- Diagnosing clinical effectiveness needs to keep in mind provider-level correlates + broader context in which providers operate. Provider behavior, incentives, medical education, evidence-based clinical guidelines & politics matter
- India needs to URGENTLY address the low level of clinical effectiveness across all providers, all levels of care

Thank you

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