Quality in Health Systems: How to Assess Clinical Effectiveness

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Webinar Series on Health Systems Assessment
September 2, 2021
**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
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.
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)

<table>
<thead>
<tr>
<th>Quality has 3 aspects</th>
<th>Do patients receive appropriate treatment when they seek care?</th>
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<tbody>
<tr>
<td>Clinical Effectiveness</td>
<td>Do patients receive appropriate treatment when they seek care?</td>
</tr>
<tr>
<td>Patient Safety</td>
<td>When patients receive care, is the care safe/not harmful to patients?</td>
</tr>
<tr>
<td>Patient Centeredness</td>
<td>Are patients treated with respect &amp; involved in decisions regarding their care?</td>
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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
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
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
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.
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

<table>
<thead>
<tr>
<th>Method of measurement</th>
<th>Pros</th>
<th>Cons</th>
</tr>
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</table>
| 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
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**

<table>
<thead>
<tr>
<th>Weight category</th>
<th>Number of tablets (FDCs)</th>
<th>Inj. Streptomycin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intensive phase</td>
<td>Continuation phase</td>
</tr>
<tr>
<td></td>
<td>HRZE</td>
<td>HRE</td>
</tr>
<tr>
<td>25-39 kg</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>40-54 kg</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>55-69 kg</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>&gt;=70</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

*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 0.75 gm. 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

Cases that prescribed only unnecessary drugs (all other antibiotics apart from the 5 recommended, INH/65, cough syrups, etc.)
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 pre-eclampsia, 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
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

- 35.55
- 40.00
- 24.55

- Providers with medical degrees (MBBS, MD, MS)
- Providers with AYUSH degrees (Ayurveda, Homeopathy)
- Providers without medical qualifications
### Key findings for provider-level correlates of competence - example from Odisha

<table>
<thead>
<tr>
<th>Independent variables</th>
<th>Differences in diagnostic competence</th>
<th>Differences in treatment competence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical qualification of providers</td>
<td>No significant difference between MBBS doctors, AYUSH &amp; unqualified</td>
<td>No significant difference in the competence to provide correct treatment</td>
</tr>
<tr>
<td>Education institution where provider was trained</td>
<td>Providers trained at government colleges were slightly more competent than those at private institutes</td>
<td>No significant difference in the prescription of incorrect &amp; irrational treatments</td>
</tr>
<tr>
<td>Rural v Urban Providers</td>
<td>Providers in urban areas were more competent than those in rural areas</td>
<td>No significant difference in the prescription of incorrect &amp; irrational treatments</td>
</tr>
<tr>
<td>Public v Private Providers</td>
<td>Private sector providers were more competent than public sector providers at PHCs</td>
<td>No significant difference in the prescription of incorrect &amp; irrational treatments</td>
</tr>
<tr>
<td>In-service training</td>
<td>There was no significant difference between providers who received in-service training versus those who did not</td>
<td>No significant difference in the prescription of incorrect &amp; irrational treatments</td>
</tr>
<tr>
<td>Time spent per patient</td>
<td>Diagnostic competence was not significantly correlated with the amount of time spent per patient</td>
<td>No significant difference in the prescription of incorrect &amp; irrational treatments</td>
</tr>
<tr>
<td>Work experience</td>
<td>No significant difference between providers with more or less years of work experience</td>
<td>No significant difference in the prescription of incorrect &amp; irrational treatments</td>
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Clinical guidelines - example of COVID-19 care in India using chart review

1. Recommendation to use Tocilizumab/Sarilumab in patients with severe or critical COVID-19 (published 6 July 2021)
2. Recommendation to NOT use Ivermectin in patients with COVID-19 except in the context of a clinical trial (published 31 March 2021)
7. Convalescent plasma has no benefits for the treatment of people with moderate to severe COVID-19 (May 21, 2021)


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**PATIENT'S NAME**: [Redacted]
**AGE**: 45 yrs
**SEX**: Male
**IP NO.**: 8954
**UHID NO.**: 1902663

**CLINICAL SUMMARY:**
A 45 yrs old male patient Mr [Redacted] got admitted to Sri Sarada Hospital 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, Antibiotics, Steroids, 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. Augmentin 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 tapered, Inj Clexane 0.6mL OD, 1 GeoD3 CZOD, Inj Remdesivir 200mg stat bd 100mg OD, Tab Dolo 650mg SOS, Syp Alex 2sp TDS, Inj Optineurin with iv NS, T. Dolo 650mg SOS, T. Ciplar OD, Inhaler Foracort 2 puffs BID.

**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 PANT 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 DAYS
- FORECORT INHALER 2PUFF PO 1-0-0 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- 18rpm, BP- 110/80mmHg, SPO2- 98% on RA.

**DIET**: Normal diet

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Harvard T.H. Chan School of Public Health
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?
Clinical guidelines - the importance of using evidence


1. Recommendation to use Tocilizumab/Sarilumab in patients with severe or critical COVID-19 (published 6 July 2021)
2. Recommendation to NOT use Ivermectin in patients with COVID-19 except in the context of a clinical trial (published 31 March 2021)
5. Strong recommendation for corticosteroids in patients with SEVERE and CRITICAL COVID-19
6. Recommendation to NOT use corticosteroids in patients with non-severe COVID-19
7. Convalescent plasma has no benefits for the treatment of people with moderate to severe COVID-19 (May 21, 2021)

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
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?

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/](https://sites.sph.harvard.edu/india-health-systems/2020/10/21/wp2-swasth/)
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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