Pioneering

Experienced

Rapid Reviews and Their Impact on Future Directions for Health Technology Assessment

Independent

Rapid Review Summit

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CADTH

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Evidence-based

ECRI Organizational Experience

▶ Nonprofit health services research institute with 45 years' experience in laboratory evaluation of healthcare technology (medical devices)

▶ 25 years' experience in health technology assessment, systematic review, comparative effectiveness reviews and forecasting of drugs, devices, procedures, including diagnostics

▶ 18 years' experience in rapid reviews

▶ Worldwide clients include: thousands of hospitals, health plans, national and regional governmental agencies (including CIHR), HTA agencies (including CADTH)

▶ For U.S. Agency for Healthcare Research and Quality (AHRQ): Evidence-based Practice Center, Patient Safety Organization, National Guideline Clearinghouse, National Quality Measures Clearinghouse, AHRQ Healthcare Horizon Scanning System

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Integrity

▶ Neither ECRI nor any of its staff has a financial interest in the sale of any medical technology. ECRI and its staff accept no royalties, gifts, finder's fees, or commissions from the medical device or pharmaceutical industries and are not permitted to own stock in or undertake consulting work for such industries.

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Rapid Reviews and Their Impact on Future Directions for HTA

▶ History of Rapid Reviews at ECRI

▶ How is a Rapid Review different from a full HTA?

▶ How have RR topics evolved over time?

▶ What infrastructure is needed for Rapid Reviews

▶ Challenges in conducting RRs

▶ Case example

▶ Lessons learned

▶ Conclusions

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History of Rapid Reviews at ECRI

▶ Why did we need Rapid Reviews?

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What We Know From Full HTAs/Systematic Reviews

▶ Provides critical input to payers, providers, policy makers and patients

▶ Largely based on evidence synthesis of published research

▶ Gaps in evidence common: few studies, poor study design and reporting, inconsistencies across studies, use of surrogate rather than patient-oriented outcomes, inadequate length of follow-up

▶ "Evidence is insufficient" – most decisions have to be made in the absence of good evidence

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Why We Needed to Develop Rapid Reviews

▶ Hospitals/clinicians offering many more technology-based services

▶ Manufacturers developing many more products

▶ Payers, governmental and private, asked to reimburse for all this

▶ Systematic review/full HTA output never enough

▶ Large number of topics means that some have to be evaluated in lesser depth

▶ Our clients demanding more information, faster delivery

▶ How to support their decision-making when the evidence isn't there?

▶ How to support their decision-making in a rapid or ultra rapid time frame?

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History of Rapid Reviews at ECRI*

▶ Full HTAs: 1992 – Health Technology Assessment Information Service debut

▶ First Rapid Review (Emerging Technology Reports): 1997 –

▶ First Ultra Rapid Review format (Hotline Responses): 1998 –

▶ Second Ultra Rapid Review format (Product Briefs): 2010 –

▶ Ultra Rapid Reviews are triggered by client requests

Does not pertain to the work performed by the ECRI Institute-Penn Medicine-AHRQ Evidence-based Practice Center

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How is a Rapid Review Different from a Full HTA/Systematic Review?

▶ Narrower scope

▶ Less extensive to no external review

▶ No meta-analysis

▶ For Ultra Rapid Reviews – no evidence synthesis

▶ Typical rapid to ultra-rapid time frame:

- Emerging Technology Reports – 3-5 months – 20 per year
- Hotline Responses – 10 to 20 business days – 100 per year
- Product Briefs – 5 to 15 business days – 200 per year

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HTA 13-Step Research Process:

1. Establish the HTA team, addressing potential for financial bias/other COI - no

2. Formulate the topic/define relevant PICOTS (based on prelim. literature searches) - yes

    1. Patient population
    2. Intervention
    3. Comparators
    4. Outcomes of interest
    5. Time frame
    6. Setting

3. Formulate and refine key clinical questions - yes

4. Create analytic framework - no

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HTA 13-Step Research Process:

5. Define study designs needed to address key questions - yes

6. Identify external reviewers of draft HTA - yes for ET

7. Refine search strategies - yes

8. Search for and retrieve evidence - yes, retrieve articles for ET, some PBs, but not usually for Hotline reports

9. Extract data, perform quality assessment of individual studies - yes for ET

10. Conduct evidence synthesis, rating of strength of evidence for each question yes for ET and meta-analysis as appropriate - no

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HTA 13-Step Research Process:

11. Evidence interpretation and drafting of HTA report - yes for ET

12. Internal and external review of draft report (including manufacturers) - yes for ET, internal review only for others

13. Address reviewers' concerns/finalize report - yes

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Emerging Technology Report

▶ Profiles and literature reviews of healthcare technologies (FDA cleared devices, drugs, procedures, and information systems)

▶ Each Emerging Technology Report provides a snapshot of the
Disease Incidence and Prevalence/Technology Description/ Care Setting/ Manufacturers/Regulatory Status/Reported Indications and Contraindications/Clinical Practice Guidelines/Other Evidence Reports/ Considerations for Hospitals /Credentialing and Training/ Complementary and Competing Technologies/ Phase of Diffusion/ Future Trends/ Costs/Procedure Charges/ Reimbursement/ Cost-effectiveness/ Methods /Evidence Base/ ECRI Institute Summary/ References/Meta-tagging/ Search Strategies

▶ 2-4 key questions

▶ Qualitative evidence synthesis

▶ Internal plus external review

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Hotline Response

▶ Topics include clinical issues as well as technologies

▶ Includes useful basic information on the technology (drug, device, procedure, behavioral health intervention, etc.) and the disease/condition/purpose for which it is used

▶ Review of abstracts only (usually)

▶ Abstracts may not accurately reflect the methods and findings of the full-length article

▶ No firm conclusions since no evidence synthesis, but comments on the types/designs of studies found

▶ Valuable as a roadmap to the literature based on our searches

▶ Provides search strategies, links to resources, curated bibliography

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Product Brief

▶ Focuses on a specific brand-name healthcare product safety and efficacy

▶ Searches of both gray and peer-reviewed literature (PubMed and Embase)

▶ Summarizes identified clinical literature from the past 5 years

▶ ECRI reviews selected full articles, article abstracts, FDA data summary of effectiveness, and/or conference abstracts

▶ Includes ECRI opinion statement on the technology's significance

▶ Originally created in collaboration with a health system client, but now very popular with payers as well

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How Have Rapid Review Topics Evolved Over Time?

▶ Client education necessary – many topics are too broad or too vague:

- ■ Does psychotherapy work?
- ■ Do pain management clinics work?
- ■ What mobile healthcare apps work for heart disease?

▶ Initially 2:1 Hotline Responses: Product Briefs; ratio now reversed

▶ Since 2013, increasing requests for genetic test topics

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Genetic Tests: Gaps in Evidence

▶ For new or emerging genetic tests, we often do not identify any published evidence to support analytic validity, clinical validity or clinical utility

▶ "We identified no published evidence…"

■ An important piece of information for policy makers

▶ Rapid Reviews are more than adequate in these cases

■ A thorough evidence search is crucial

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Infrastructure Needed for Rapid Reviews

► Dedicated team of masters' level medical librarians trained in searching for Rapid Reviews (different skill set from searching to support comprehensive HTAs/systematic reviews)

► Access to thousands of proprietary and free databases and journals (eg, Embase, Ovid, Ebsco)

► Automated alerts and current awareness searches to trigger updating

► Bibliographic database management system to track all search strategies, databases searched, references identified – to facilitate transparency and rapid updating

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Infrastructure Needed for Rapid Reviews

► Workflow tracking system to track requests, lit searching, review authoring, internal review, effort expended - all to be completed within days

► High level staff to author the reviews – scoping the topic with clients, distilling lit searches in a rapid time frame is nontrivial

► Need staff to both author and review reports: requires specific topic expertise (especially when crafting expert opinion statements)

► Written protocols and guidance documents to ensure replicability and transparency

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Challenges in Conducting Rapid Reviews

▶ Need for frequent, proactive updating, especially for the Ultra Rapid Reviews

▶ Product Briefs focusing on a single technology are under extreme scrutiny by the manufacturer – increased liability

▶ Need for flexibility: our clients don't always follow the "one technology for a single indication" rule

▶ Comprehensive searching protocols are very important

▶ Managing the workload is tricky when so many reviews are underway at one time

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Case Example

▶ Cologuard Screening Test for Colorectal Cancer

▶ Not yet approved by Health Canada

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Cologuard Screening Test for Colorectal Cancer (Product Brief)

▶ Exact Science Corp (Madison, WI)

▶ Genetic test that detects methylated DNA derived from 2 genes and also 7 mutant alleles of the *KRAS* gene in CRCs and adenomas

▶ Also incorporates a fecal immunochemical test (FIT) to detect blood in patient stool samples

▶ Positive result is followed up with standard optical colonoscopy for confirmation and an opportunity for biopsy

Cologuard Screening Test for Colorectal Cancer

▶ Cologuard is the first test to be reviewed through a joint U.S. Food and Drug Administration - Center for Medicare and Medicaid Services (CMS) pilot program for parallel review

▶ 3 published studies on analytic and clinical validity

▶ Premarket approval received August, 2014

▶ Concurrent CMS proposed National Coverage Decision: colorectal cancer screening test for asymptomatic, average risk beneficiaries, aged 50 to 85 years

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What We Found

▶ As a noninvasive test that can be administered at home without the need for bowel preparation, Cologuard could improve CRC screening rates (based on 3 published studies of clinical validity)

▶ No studies evaluated Cologuard's clinical utility (eg, impact on cancer risk or overall survival); however, since all patients who receive a positive test result will be referred for optical colonoscopy, clinical outcomes would potentially be similar to those for optical colonoscopy alone

▶ Most private payers not yet reimbursing, although may change as their coverage policies are updated to reflect recent CMS National Coverage Decision that covers the test for Medicare enrollees

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Lessons Learned

▶ Rapid Reviews at ECRI are a major activity, not just a series of one-off reports – they require significant resources and commitment to updating

▶ Even ultra Rapid Reviews require systematic, replicable and transparent processes (124 page manual for Hotline/Product Brief authors/reviewers; 71 page manual for searchers)

▶ Rapid Reviews (Hotline Reports) can be used to provide quick updates to Full HTAs/Systematic Reviews if authored by a topic expert

▶ Rapid Reviews (especially ultra RRs) must be replaced by more in-depth HTAs when the body of evidence has accumulated

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Conclusions

▶ Diffusion of new technology often outpaces the evidence of its effectiveness (eg, genetic tests)

▶ Higher evidence bar for both adoption and reimbursement of new technology - identifying gaps in evidence is very important

▶ Rapid Reviews - very useful to decision makers in hospitals and health plans

▶ Through searching for both gray and peer-reviewed literature is necessary

▶ Findings are perishable - as new evidence emerges, Rapid Reviews must be updated frequently

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Conclusions - Future Directions

▶ Demand for RRs to support urgent decision making will increase (eg, hospital value analysis committees, payer reimbursement policies)

▶ Demand for full HTAs/systematic reviews will decrease

▶ Although viewed as very authoritative, full HTAs/SRs increasingly less relevant for providers and payers because of the time, cost , and resources needed

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Conclusions - Future Directions

▶ Full HTAs/ systematic reviews will remain essential for developing clinical practice guidelines (new requirement for inclusion in the National Guideline Clearinghouse)

▶ Full HTAs/systematic reviews absolutely essential for determining comparative effectiveness and evaluating topics with a significant body of evidence

▶ Although increased efficiencies in conducting systematic reviews are always possible, taking short cuts will create risks and tradeoffs

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Using Rapid Reviews for Assessing the Effectiveness of New Technologies

▶You can't always get what you want
But if you try sometimes you might find
You get what you need

<div align="right">Jagger/Richards 1969</div>

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