What do you know about Patient Engagement in research or medical guidelines?

I don't know anything

I know a bit

I know a lot

Obstetric Internal Medicine

University of Calgary - Department of Medicine

UNIVERSITY OF CALGARY

CMV Infection in Pregnancy

Approach to Patient Engagement in Clinical Practice Guidelines

Lisa Robinson cCMV Parent, SLP
Rob Tetrault cCMV Parent, Founder CMV Canada
Eliana Castillo Parent, MD

Session Objectives

- Explain why patients should be engaged in clinical guideline development
- Share our roadmap to patient engagement in the Revision of the Canadian CMV Infection in Pregnancy Clinical Practice Guideline for OB care Providers

- Canada N= 2,300 Obstetricians
- SOGC N= 4,000 members

Midwifes, Nurses, Family Doctors and Obstetricians

- Guidelines French & English

SOGC CLINICAL PRACTICE GUIDELINE

No. 240, April 2010

Cytomegalovirus Infection in Pregnancy

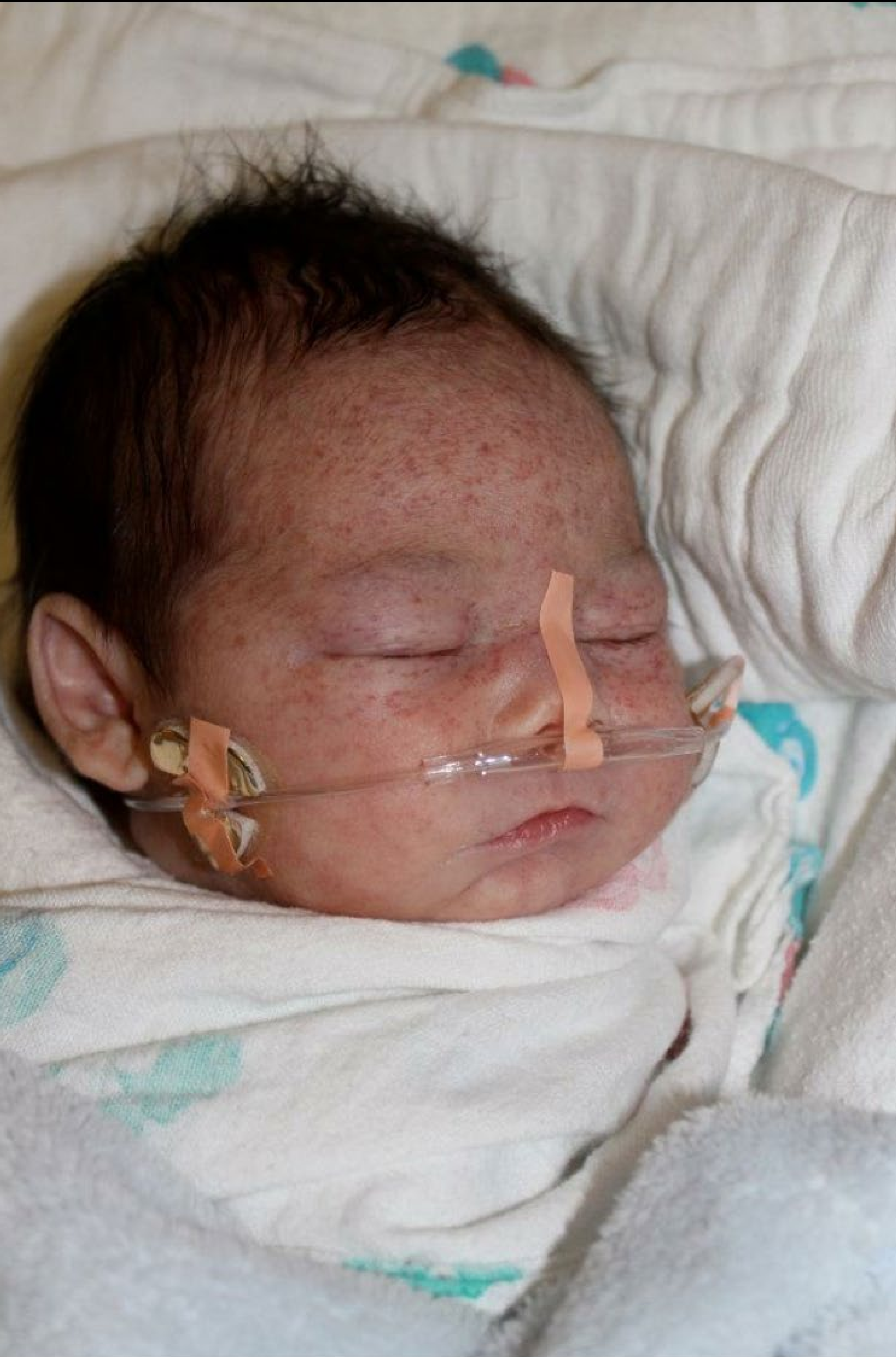
This guideline has been reviewed by the Maternal Fetal Medicine Committee and approved by Executive and Council of the Society of Obstetricians and Gynaecologists of Canada

PRINCIPAL AUTHORS

Abstract

Objectives: To review the principles of prenatal diagnosis of congenital cytomegalovirus (CMV) infection and to describe the outcomes of the affected pregnancies.

Outcomes: Effective management of fetal infection following primary

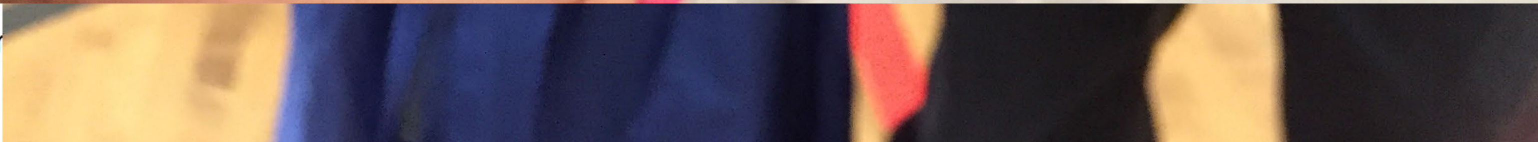


Georgia James Eliana

- Dx’d cCMV 23 weeks gestation: fully symptomatic
- Highly abnormal MRI at birth
- Polymicrogyria
- Moderate Hemiplegic Cerebral Palsy
- ADHD
- Global Developmental Delay
- Cognitive Differences

Georgia James Eliana

- 6yo old
- Attends regular class grade 1
- Highly verbal (and bossy)
- Highly affected AND highly functional: she walks unaided, can climb at play ground
- FANTASTIC QUALITY OF LIFE



Please tell us about you

If you care about cCMV!

What do you know about Patient Engagement in research or medical guidelines?

I don't know anything

I know a bit

I know a lot

Key Terms

- **Patients**: Individuals with personal experience of a health care issue, informal caregivers, including family & friends
- **Engagement**: The process of encouraging and enabling individuals and teams to participate
- **Clinical Practice Guidelines**: Institute of Medicine (IOM) defines clinical practice guidelines as "statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options"

What makes a CPG a good one?

- **Recommendations are ACTION statements describing what to do**

- Recommendations are NOT...

  - ”Treatment X leads to these complications...”

  - “Clinicians should use evidence based treatments...”

What makes a CPG a good one?

Recommendation

Summary statements

Detailed summary of evidence

For residents who are at high risk of fractures, we suggest that etidronate not be used (conditional recommendation; moderate-quality evidence).

There is moderate-quality evidence for little to no reduction in fractures (in particular, hip fractures) with etidronate. The cost of this drug is high, given the lack of important benefits.

Summary of the evidence

There is moderate-quality evidence for pharmacologic therapies from network meta-analyses of randomized controlled trials involving more than 100 000 people at high risk of fractures.[27,38,45] There was risk of bias in some studies and uncertainty when the effects in postmenopausal women were applied to long-term care residents.

What else makes a CPG a good one?

RESEARCH ARTICLE Open Access

Patient involvement in guidelines is poor five years after institute of medicine standards: review of guideline methodologies

Melissa J. Armstrong[1*] and Joshua A. Bloom[2]

VICTOR M. MONTORI,[4] JASVINDER A. SINGH,[5] AND W. BENJAMIN NOWELL[6]

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University of Calgary - Department of Medicine

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Existing CPGs for CMV Infection in Pregnancy

Guidelines

Recommendations in this document reflect national and international guidelines related diagnosis and antenatal management of cytomegalovirus infection[42,46-48]

Publi

PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN–GYNECOLOGISTS

NUMBER 151, JUNE 2015 *(Replaces Practice Bulletin Number 20, September 2000)*

Cytomegalovirus, Parvovirus B19,

SOGC CLINICAL PRACTICE GUIDELINE

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Outcomes: Effective management of fetal infection following primary

DIRECTIVE CLINIQUE DE LA SOGC

Jan-Mar 2018
n=1,359 downloads

N° 240, avril 2010

Infection à cytomégalovirus pendant la grossesse

La présente directive clinique a été analysée par le comité de médecine fœto-maternelle et approuvée par le comité exécutif et le Conseil de la Société des obstétriciens et gynécologues du Canada.

Résumé

Objectifs : Analyser les principes du diagnostic prénatal de l'infection congénitale à cytomégalovirus (CMV) et décrire les issues des grossesses affectées.

Issues : Prise en charge efficace de l'infection fœtale à la suite d'une

Do Obstetric care providers follow guidelines?

SOGC N= 4,000 Obstetric Care Providers

SOGC CLINICAL PRACTICE GUIDELINE

Jan-Mar 2018
n=821 downloads

No. 240, April 2010

Cytomegalovirus Infection in Pregnancy

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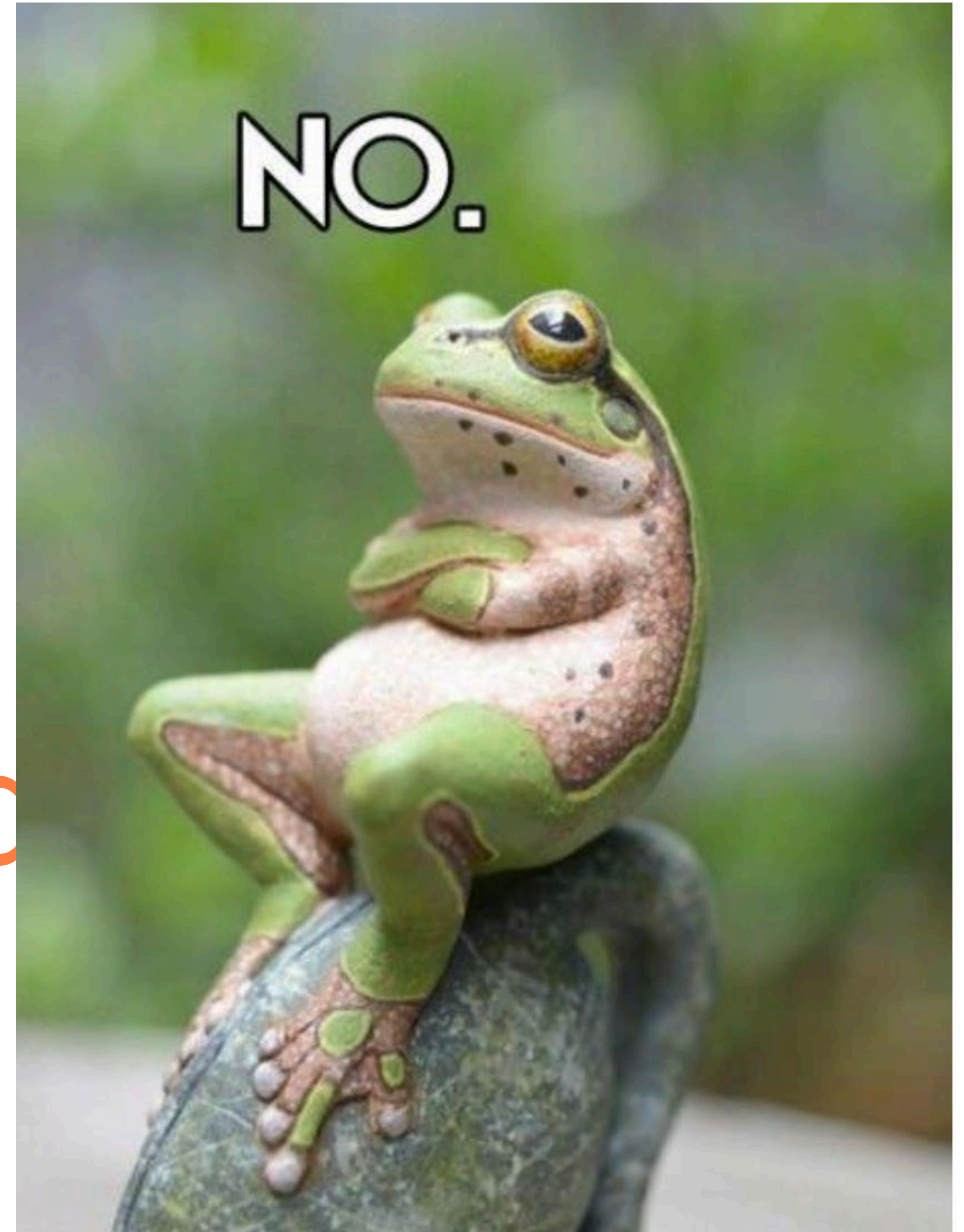
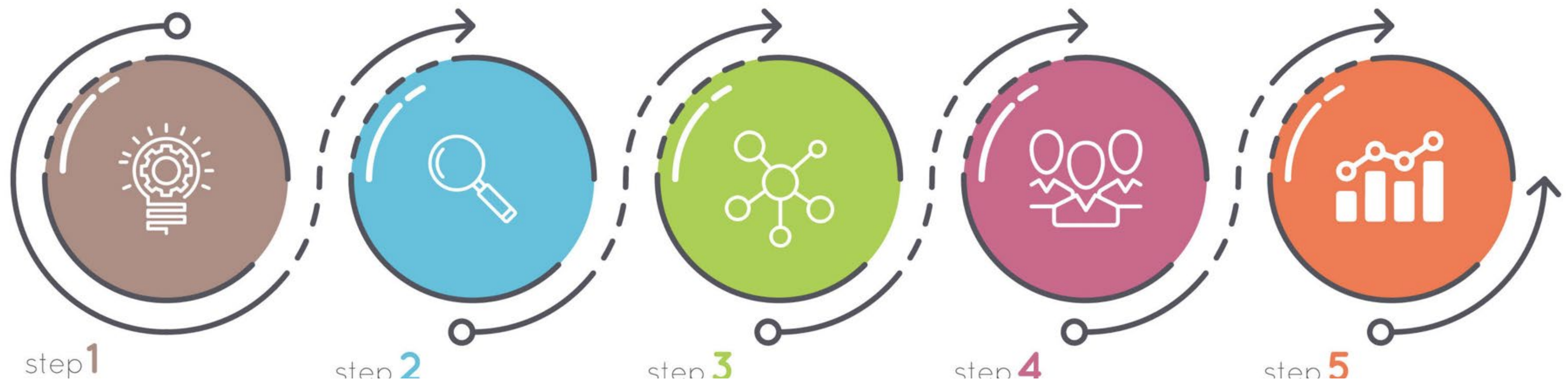
Have CMV in CPG involved

NO



How to engage?



doi: 10.1111/hex.12467

Framework for enhancing clinical practice guidelines through continuous patient engagement

Melissa J. Armstrong MD, MSc,*† Juan-David Rueda MD,‡ Gary S. Gronseth MD§ and C. Daniel Mullins PhD¶

*Assistant Professor, Department of Neurology, University of Florida College of Medicine, Gainesville, FL, †Assistant Professor, Department of Neurology, University of Maryland School of Medicine, Baltimore, MD, ‡PhD Student, ¶Professor and Chair, Pharmaceutical Health Research Department, University of Maryland School of Pharmacy, Baltimore, MD, §Professor, Department of Neurology, University of Kansas Medical Center, Kansas City, KS, USA

IAP2 Patient Engagement Spectrum

LEVELS of PATIENT and RESEARCHER ENGAGEMENT in HEALTH RESEARCH

GOALS	LEARN / INFORM	PARTICIPATE	CONSULT	INVOLVE	COLLABORATE	LEAD / SUPPORT
PATIENT	To ask questions and learn about how to get more involved	To act as a subject or participant in a research study	To provide feedback and advice on specific research activities	To work directly with a research team throughout the project	To partner on equal footing with researchers in all aspects of research	To make decisions and lead research activities
RESEARCHER	To provide information, listen, and answer questions honestly	To act ethically and respectfully in the conduct of research	To seek your input on an ad hoc basis	To include you as standing members of an advisory group	To partner equally with you as team members	To follow your lead and support your decisions
HOW CAN THIS BE DONE	Through orientation and information sessions, and media campaigns in an open atmosphere for sharing)	Through quantitative, qualitative, or mixed methods research	Through scientific cafes, focus groups, priority-setting activities, and as members of ad hoc working groups or expert panels	Patients as members of standing working groups and research advisory committees	Patients as co-investigators and research partners, and as members of research steering committees	Through patient or community steering committees and patients as principle investigators

− Time and Knowledge Needed +

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Step 1: WHY?

Why is Patient Engagement Important?

- 50% of patients do not get treatments of proven effectiveness
- Up to 25% get care that is not needed or potentially harmful
- This care is expensive.
  - In 2013, Canada spent approximately $211 billion on health care, or close to $6,000 per person.
- Patients and health care professionals have a right to expect that important health decisions are made on the basis of solid evidence

CFHI (2011) Canada's Strategy for Patient-Oriented Research: Improving health outcomes through evidence-informed care Retrieved at: http://www.cihr-irsc.gc.ca/e/44000.html; SPOR Overview, retrieved at: http://www.cihr-irsc.gc.ca/e/47473.html

What is the benefit of engaging patients in research?

- Patients are experts!: unique understanding of problem, context, environment & results
  - Identify facilitators & barriers
  - Tailor messages & interventions
  - Develop & execute dissemination plan

(Parry, D. Salsberg, J., & Macaulay, A. C., n.d.)

Step 2: WHO?

Who to engage?

POLICY MAKER/ GOVERNMENT

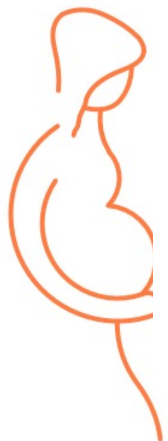
RESEARCHER

CAREGIVER

PROVIDER

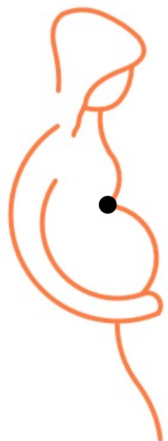
PERSON WITH LIVED EXPERIENCE

COMMUNITY



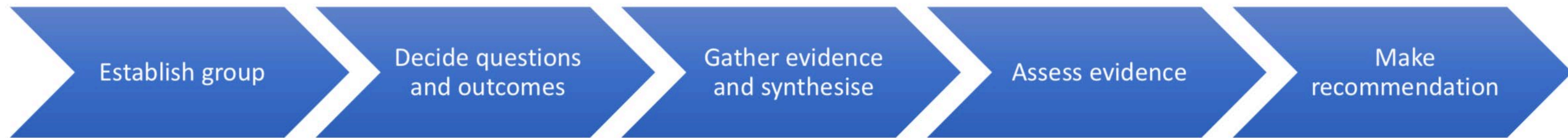
Where do you find patients?

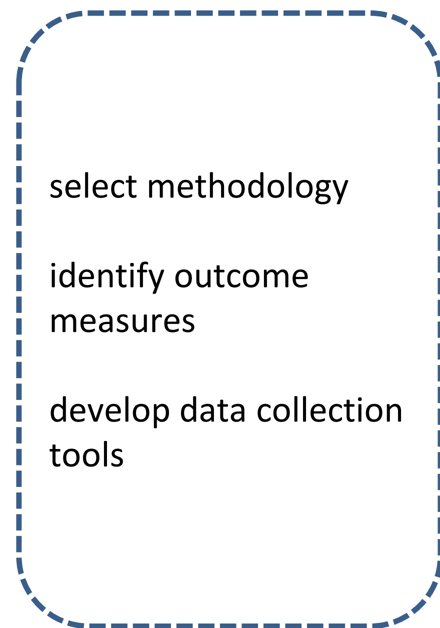
- Social Media
- Engage Doctors and Pharmacists to spread the word
- Patient support groups and offices
- Disease specific non-profits (e.g. CMV Canada)
- Use established communication mechanisms

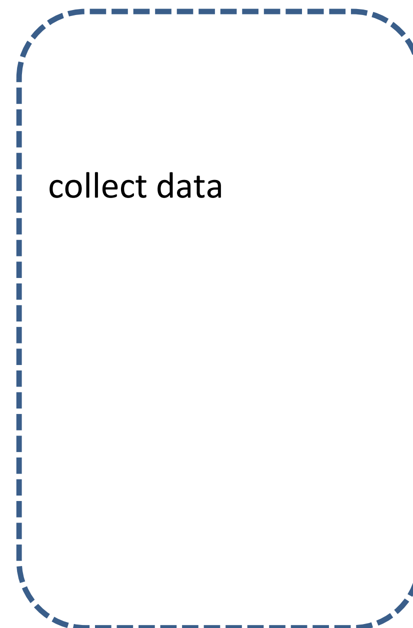


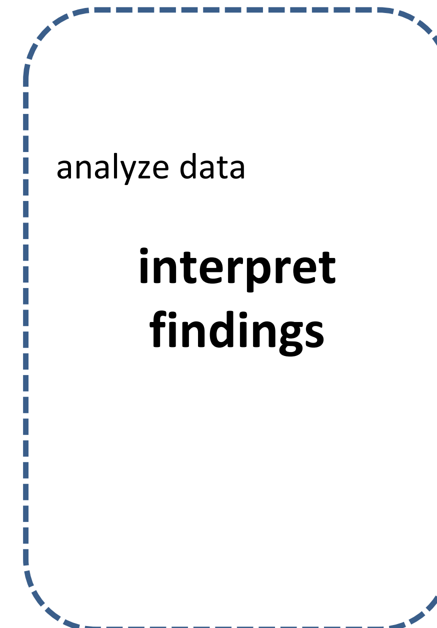
Step 3: HOW?

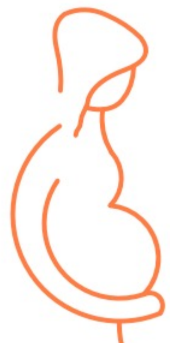
Standard guideline development process











Objective: To provide an update on cytomegalovirus infection and pregnancy so that obstetric health professionals improve their awareness about the consequences of maternal infection for the fetus and the infant, preventative strategies and new developments on newborn screening and treatment.

Patient Review of SOGC cCMV CPG Update (August 3rd, 2018 Draft)

Lisa Robinson: comments about draft in red; additional comments/questions in blue

Patient Priorities for CPG update:

1) Recognizing the prevalence & importance of cCMV, and creating consistency in Physician knowledge and practice.
2) Addressing the Nature, Quality and Consistency of Patient education about cCMV from pre-natal Physicians/Care providers.
3) Updating Recommendations for Screening and/or Diagnosis of cCMV during pregnancy and/or in neonatal period.
4) Updating Recommendations for Treatment and/or Management of cCMV during pregnancy and/or in neonatal period and beyond.

What's Changing?

4. CMV prevention strategies should be discussed with all pregnant women, regardless of serostatus, to reduce the risk of cCMV through maternal infection or reinfection

ABNORMAL ULTRASOUND

CMV Serology

30 social media groups general groups N = 38,178 & 5 "medical groups"

Criteria:

- levels of activity (e.g. freq of posts, number of posts)
- membership (e.g. 500+ for moms groups, 50+ for dads/parents).

CMV

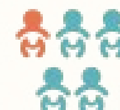
IF YOU'RE PREGNANT, ASK YOUR DOCTOR ABOUT CMV

WHAT IS CMV?

Cytomegalovirus (CMV) is a common virus that can infect almost anyone. Once infected, your body retains the virus for life. Most people don't know they have CMV because it rarely causes problems in healthy people. But if you're pregnant, CMV is cause for concern because the infection can be transmitted to your baby.

WHAT IS THE IMPACT OF CMV ON BABIES AND MOTHERS?

1 in 200 Canadian infants are infected with CMV during pregnancy.



1 in 5 children infected with CMV during pregnancy will have a permanent disability such as hearing loss or developmental delay.

Young children infected with CMV usually have no symptoms but easily spread the infection to others through saliva and urine. If a pregnant woman is living with a young child infected with CMV, her chance of developing the infection is 1 in 4.

HOW TO LOWER THE RISK OF CMV IN PREGNANCY

Wash your hands often with soap and water for 15-20 seconds

Do not share food, drinks, or eating utensils with young children

Do not put a child's pacifier in your mouth

Do not share a toothbrush with a young child

Avoid contact with saliva by kissing a young child on the forehead instead of the lips

Clean toys, countertops and other surfaces that come in contact with children's urine or saliva

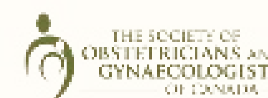
CMV is the leading cause of preventable hearing loss in children

If your newborn fails newborn hearing testing ask about CMV testing

Newborn CMV can cause learning disabilities

Talk to your healthcare provider about CMV today

FOR MORE INFORMATION



Do we need ethics to do this?

When patients are partners on the research team (Consult, Involve, Collaborate, Lead levels of engagement), they are not ‘human participants’ in the project as defined in the TCPS2. **No unique REB approval is required for their involvement in this capacity,** other than normal REB approval that may be required for the project itself.

Developing Recommendations

Assist in translating evidence-based conclusions into meaningful, clear, and respectful recommendations

Assist in ensuring that recommendations foster partnership between physicians, patients and families

Describe variability in patient preferences

Help make recommendations easy to understand

Provide input when there are gaps in the evidence

Indicate which recommendations are counterintuitive (e.g. so that additional explanation can be provided)

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Abstract

Objectives: To review the principles of prenatal diagnosis of congenital cytomegalovirus (CMV) infection and to describe the outcomes of the affected pregnancies.

Outcomes: Effective management of fetal infection following primary

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Key Words: Hepatitis B, antiviral therapy, breast-feeding, chronic hepatitis, immuno- prophylaxis, vertical transmission, viral load, pregnancy

http://dx.doi.org/10.1016/j.jogc.2016.11.001

J Obstet Gynaecol Can 2016;■(■):■–■

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Abstract

Objective: To review the epidemiology, natural history, evaluation, and treatment of hepatitis B virus (HBV) infection during pregnancy. This will aid obstetric care providers in counseling their patients regarding perinatal risks and management options available to pregnant women with hepatitis B.

Outcomes: Outcomes evaluated include thresholds for HBV anti-viral treatment for prevention of perinatal transmission and for invasive procedures during pregnancy for women with hepatitis B infection.

Evidence: Medline, EMBASE, and CINAHL were searched for articles in English on subjects related to HBV infection, pregnancy, and perinatal transmission from 1966 to March 2016. Results were restricted to systematic reviews, randomized controlled trials/controlled clinical trials, and observational studies. Other (unpublished) literature was identified through searching the websites of health technology assessment and health technology assessment-related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical speciality societies.

Validation methods: The quality of the evidence is rated using the criteria described in the Report of the Canadian Task Force on Preventive Health Care (Table 1). Recommendations for practice are ranked according to the method described in this Report.

Guideline update: The guideline will be reviewed 5 years after publication to decide if an update is required. However, if important new evidence is published prior to the 5-year cycle, the review process may be accelerated for a more rapid update of some recommendations.

This document reflects emerging clinical and scientific advances on the date issued, and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the publisher.

Women have the right and responsibility to make informed decisions about their care in partnership with their health care providers. In order to facilitate informed choices, women should be provided with information and support that is evidence based, culturally appropriate, and tailored to their needs. The values, beliefs, and individual needs of each woman and her family should be sought and the final decision about the care and treatment options chosen by the woman should be respected.

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Disclaimer: Acknowledgement that CPGs should reflect most up-to-date information & evidence available AND that individual physicians/care providers may deviate from CPGs if more compelling evidence warrants amendment to a guideline or recommendation.
This is important as it sets the tone for trustworthiness and open information sharing within an individual doctor-patient relationship.

Disclaimer ct'd: "Women have the RIGHT and RESPONSIBILITY to make INFORMED decisions about their care in PARTNERSHIP with their healthcare providers....The values, beliefs and individual needs of each woman should be SOUGHT, and the final decision about the care and treatment OPTIONS CHOSEN BY THE WOMAN SHOULD BE RESPECTED"
This section states very well what patients should be able to expect from a relationship with their physician. Withholding of information about the risks of cCMV infection violates the fundamental trust that patients have in their professional care provider. If physicians believe the efficacy and ethics of this statement, then important steps need to be taken to foster truly informed partnerships between pregnant women and their care providers regarding the issue of cCMV across Canada.

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Assist in ensuring that recommendations foster partnership between physicians, patients and families

Describe variability in patient preferences

Help make recommendations easy to understand

Provide input when there are gaps in the evidence

Indicate which recommendations are counterintuitive (e.g. so that additional explanation can be provided)

2. In the context of abnormal US findings associated with cCMV, pregnant women with a low IgG avidity, documented seroconversion, >4 fold increase in IgG titres should be offered amniocentesis >6 weeks from suspected infection and >21 weeks GA

5. SOGC recommends against maternal CMV screening, as seropositive pregnant women remain at risk for cCMV and the message of being "CMV-immune" could be misleading and provide false reassurance.

208 The gold standard for diagnosis of primary CMV infection is documentation of a positive CMV IgG test in a person previously documented to be negative (seroconversion) (Rawlinson 2017, Revello 2002). Determining whether infection is primary is difficult in most cases because no pre-conception serum is available to confirm seroconversion. However, if access to stored sera is possible, comparative testing can help to determine the timing of infection.

For example describing positive confirmation of CMV IgG seroconversion as the "gold standard" for diagnosis of this incredibly common and impactful (primary) infection during pregnancy reads as counterintuitive or even contradictory to the conclusion that knowledge of a pregnant woman's initial CMV status is unimportant and not worth testing for. This section is clearly stating that early serum data may turn out to be very important indeed to both the patient and the physician.

5. SOGC recommends against maternal CMV screening, as seropositive pregnant women remain at risk for cCMV and the message of being "CMV-immune" could be misleading and provide false reassurance.

6. CMV prevention strategies should be discussed with all pregnant women, regardless of serostatus, to reduce the risk of cCMV through maternal infection or reinfection

Also, it is perfectly acceptable for physicians to tell patients that the data is imperfect or incomplete, and that there are complexities about CMV seroprevalence, serostatus and seroconversion that are not fully understood. Recommendations may recognize these gaps in evidence and reflect the need for ongoing discussion and individualized options to accommodate for the complexities of cCMV infection as well as inherent variability in patient values & preferences.

Developing Recommendations

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Assist in ensuring that recommendations foster partnership between physicians, patients and families

Describe variability in patient preferences

Help make recommendations easy to understand

Provide input when there are gaps in the evidence

Indicate which recommendations are counterintuitive (e.g. so that additional explanation can be provided)

1. CMV HIG for prophylaxis or treatment of cCMV currently should only be used as part of a research or investigational protocol (I-C)
2. The use of antiviral medications during pregnancy to decrease symptomatic disease among infants is not recommended (II-3C)

We understood then and do now that the evidence around HIG & oral antivirals as treatment options for cCMV during pregnancy is incomplete, imperfect, inconclusive and frankly not that great.

However having the data (slightly hopeful but still mostly crushing in terms of possible outcomes) explained to us by our physician with a high regard for our values & preferences was something that empowered us.

Disseminating & Implementing Recommendations

Endorse guidelines from patient perspective (either individually or in representation of patient groups)

Assist in developing patient- and family-level summaries of systematic review findings and guideline recommendations

Assist in developing patient decision aids

Identify barriers to implementation and possible solutions

Facilitate engagement of other patients in dissemination

Improve legitimacy and trustworthiness of guideline process such that recommendations are more likely to be implemented

Identify when public or stakeholder views have changed such that a guideline requires update

Principles of Patient Engagement

Inclusiveness

CoBuild

Support

Mutual Respect

CIHR SPOR Framework, 2011

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Tactics and Approaches

- James Lind Alliance
- Nominal Group Technique
- Key informant interviews
- Focus groups
- Survey/Questionnaire
- Research Team Members
- Citizen Jury
- World Café

Engage!

You moustache us a question?

Ethical Considerations

Power Dynamics

Benefits/Harms

Conflict of Interest

Confidentiality

Special Considerations

Patient Engagement Ethics Guidelines

http://www.aihealthsolutions.ca/initiatives-partnerships/spor/patient-engagement-platform/resources/

EVALUATE!

FIND OUT MORE

Patient and Public Engagement Evaluation Tool | McMaster University (Canada)
https://iap2usa.org/resources/Documents/Research/Evaluation%20Tool%20-%20PublicandPatientEngagementEvaluationTool.pdf

Researcher Surveys | Patients Canada (Canada)
https://www.patientscanada.ca/site/patients_canada/assets/pdf/researchersurveys_2016.pdf

Patient/Caregiver Surveys | Patients Canada (Canada)
https://www.patientscanada.ca/site/patients_canada/assets/pdf/patientsurveys_2016.pdf

Evaluation Framework | INVOLVE (UK)
https://www.involve.org.uk/knowledge-base/evaluation-framework/

Dissemination & Implementation Toolkit| PCORI (US)
https://www.pcori.org/sites/default/files/PCORI-DI-Toolkit-February-2015.pdf

RESOURCES

IPPOSI (Ireland)
http://www.ipposi.ie/

PCORI (USA)
*www.**pcori**.org/*

INVOLVE (UK)
www.invo.org.uk

SPOR

Strategy for Patient-Oriented Research

- SPOR is a coalition of federal, provincial and territorial partners – all dedicated to the integration of research into care:
  - patients and caregivers
  - researchers
  - health practitioners
  - policy makers
  - provincial/territorial health authorities
  - academic institutions
  - charities
  - private sector

Patient Engagement Platform

- Online: www.absporu.ca
- **Registry: www.bit.ly/peRegistry**
- Twitter: @AbSPORU_PEP
- Facebook: SPOR Patient Engagement Platform

References

- Alberta SPOR Support Unit, Patient Engagement Platform (2017). *A how-to guide for patient engagement in health research.* Document in preparation.
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