Disinvestment in Canada: The case of Fetal Fibronectin Testing

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Fetal Fibronectin Test

- Preterm birth is the single biggest cause of neonatal mortality and morbidity in many developed countries, affecting around 7 % of live births). About 75% of women delivering preterm do so after preterm labour (PTL)
- PTL is progressive cervical change in the presence of uterine activity (contractions) between 20 and 37 weeks of gestation.
- Difficult to assign risk of preterm delivery and diagnostic assessment of PTL is a challenge
- Especially important in rural and remote areas without access to speciality services (obstetrics and NICU)
- Timely diagnosis of PTL and and prediction of imminent preterm delivery at rural and urban clinical settings is a priority for health care providers

Fetal Fibronectin Test

- PTL is diagnosed by clinical history (including assessment of obstetric history, symptoms, and epidemiological risk factors) and physical examination (which usually begins with digital examination of the cervix).
- Absence of fetal fibronectin (fFN) and of phosphorylated insulin-like growth factor binding protein-1 (phIGFBP-1) in cervicovaginal secretions have shown potential to become clinically useful tests to aid in diagnosing PTL for symptomatic women with intact membranes.
- Several commercial point-of-care tests available

First HTA and Adoption

- HTAs (2006 and 2008) indicated fFN could reduce health care utilization and unnecessary treatment (ambulance transfers and/or length of hospital stay) by more accurately identifying women who were experiencing *false* PTL.
- Predicted that adopting fFN testing province wide would ensure women had equal access to fFN testing.
- fFN should be introduced as a publicly funded service available to all Alberta women and through all RHAs at the earliest possible date
- Ministry supported health regions in developing province-wide approach to quality assurance and clinical practice guidance and standards.

Post-Policy Implementation Review

After 5 years of implementation (2008-2012), Ministry asked IHE to perform a post-policy implementation review (PPIR) to determine whether the policy achieved its objectives

Updated Clinical Review

- Specificity and negative predictive value estimates were high for both tests at most clinical endpoints, meaning the tests performed well in predicting the majority of women who *were not at risk* for PTD.
- Sensitivity and positive predictive values were poor for all clinical endpoints of interest meaning they did not perform well in predicting the majority of women who *were at risk* of PTD.
- Clinical importance of positive PTL test results remains unclear

Post-Policy Implementation Review

Economic Evaluation

- Physicians placed greater significance on positive test results (inappropriate use of test) compared to negative test results (appropriate use of test), despite clinical utility of fFN being predicated on high specificity
- Analysis of provincial clinical data showed specificity of 98% compared to 90% reported in the literature
- fFN testing increased the number of *appropriate* ambulance transfer and admissions for preterm pregnancies in true labour.

Post-Policy Implementation Review

Economic Evaluation

- fFN testing did not reduce the number of unnecessary ambulance transfers or admissions for preterm pregnancies in false labour.
- Unnecessary ambulance transfers *increased* due to significance placed on a positive fFN.
- fFN testing did not reduce health system costs by reducing unnecessary resource utilization.
- In some cases, unnecessary utilization increased with fFN testing which was an unintended consequence.

Post-Policy Implementation Review

Conclusions

- Adoption of fFN testing in Alberta did not achieve its intended aims of reducing unnecessary utilization of health services to achieve health system savings.
- Physicians placing greater significance on positive test results produced an increase in health care utilization.
- Overall, total cost for the health system increased.
- If access to fFN testing services is to continue, it is *imperative that further education and training be provided to ordering physicians on how to interpret fFN test results along with a mechanism for ongoing management and assessment of fFN testing* that can feed back to these clinicians as well as health system managers.

BUT….

What Happened?

Explicit disinvestment/rationing decision: March 2016: Alberta Health Services mandated removal of publicly funding fFN

Specific directions:

- Inform clinicians that decision has been made and based on clinical, not financial considerations (not achieved the intended policy benefits)
- Provide practice support document for assessment and management of PTL in absence of test
- Provide protocol for transfer and consultation of patient with suspected PTL
- Inform clinicians why test is not longer being recommended
- Engage physician leadership to help support change
- Discontinue availability of test through provincial lab services
- Evaluate management of preterm labour after disinvestment

Reassessment of Utility of fFN

- Health care savings achieved through disinvestment, but not large (about $4 million)
- Some rural physicians (including influential rural physician) advocated for use of fFN based on potential harm to women in rural areas
- April 2017: IHE requested to develop workplan for evaluation of disinvestment to see if disinvestment has produced increase in inappropriate ambulance transfers, hospital admissions, and increase length of stay.
- How is clinical decision making affected by *not having* fFN test result?

Ethical Issues

- Improving maternal and newborn health
- Reducing unnecessary harms to pregnant women and families by inappropriate transfer and treatment

- Harms continued to significantly outweigh benefits
- HTA recommended educational campaign to foster appropriate use of test rather than disinvestment (in line with evidence)
- Needed strong physician leadership to drive change in either direction (educate and use appropriately OR disinvest)

- What should we say about the decision to frame disinvestment as a clinical issue rather than one about resource allocation and opportunity cost – preventing discussion about competing values?

Reflections

What ethical issues do you see in this case?

Is the fFN a case of the need for disinvestment or lack of will to invest in appropriate use/management? How do we prevent the second from becoming the first?

Haven't compared it with what happened in other countries, e.g., England. NICE Guidance 2015

Does you have an example of disinvestment in your country?

What ethical issues did it raise?

What do you think?

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