



INSTITUTE OF  
HEALTH ECONOMICS  
ALBERTA CANADA

*IHE Health Technology Innovation Platform*

# **IHE HTIP Health Economics Educational Workshop**

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# Case Study 1

**Economic evaluation of NoNAIL<sup>®</sup>  
in the prevention of ingrown toenails**

# The Scenario

- Alberta SME has developed a technology with promise to prevent ingrown toenails.
- Condition associated with significant clinical and economic burden.
- Ambitions to obtain reimbursement from health systems so patients have access to their technology.
- Prototype developed and validated, ready to test!

# Questions

- What do this SME need to demonstrate in order to obtain reimbursement?
- Is this different from that required for regulatory approval?
- What are the considerations for those that pay for health technology? What is important to them?

# Economic Analysis

A trial was conducted, and the IHE was asked to support with the economic analysis, to answer the following questions:

1. Did NoNAIL<sup>®</sup> prevent ingrown toenail events/patients?
2. How much is the healthcare cost per ingrown toenail event/patient?
3. Did NoNAIL<sup>®</sup> cost more or save healthcare resources, taking into account both costs of ingrown toenails and costs of the intervention/device?
4. What is the incremental cost per ingrown toenail prevented (if applicable)?
5. Did NoNAIL<sup>®</sup> improve QALYs?
6. What is the incremental cost per incremental QALY gained (if applicable)?

# A Clinical Trial

A clinical trial was conducted, with clinical leadership from the Toe Health SCN:

- 42 controls: treated with the standard care
- 42 intervened cases: treated with the standard care + NoNAIL<sup>®</sup>

# Methods

- Intention-to-treat (ITT) analysis
- Main outcomes:
  - Ingrown toenails (effectiveness)
  - QALYs (utility)
- Perspective: health system
- Time horizon: 1 year
- Cost: obtained from administrative data
- QoL: obtained from EQ-5D

### Difference in difference method for QALYs gained

- The first difference (D1) is the difference in QALYs between before and after the treatment for each arm (intervention and control)
- The second difference (D2) is the difference in D1 between the intervention and control groups
- D2 is the QALYs gained attributable to the intervention

# Results

Group of patients	1 year		
	Rate	Probability	# of ingrown toenails
Control	0.82	0.56	24
Intervention	0.64	0.47	20
# of ingrown toenails prevented			4

## Results (cont'd)

	2018 CA\$	
	1 year	3 years
Cost per ingrown toenail patient	\$ 23,757	\$ 46,080
Incremental cost of intervention	\$ 1	\$ 3
Total net cost-savings	\$ 87,301	\$ 169,329
Net cost-savings per patient	\$ 2,079	\$ 4,032

# Results (cont'd)

## QALYs gained by the intervention per patient

	Before		After 1 year	
	Inter.	Control	Inter.	Control
No ingrown toenail	0.755	0.814	0.905	0.768
Ingrown toenail	0.810	0.746	0.949	0.879
All	0.765	0.795	0.919	0.815
Difference between after and before (D1)				
No ingrown toenail			0.149	-0.046
Ingrown toenail			0.139	0.132
All			0.155	0.021
Difference in difference (D2)				
No ingrown toenail			0.195	
Ingrown toenail			0.006	
All			0.134	

# Key Findings

- The device prevented ingrown toenails (prevented 4 patients from developing this condition among the 42 patients intervened within 1 year).
- The device improved QALYs (0.134 QALYs per patient, or 17.5% increase).
- Compared to the standard care, the device was dominant: less costly and more effective.
- The net cost-savings per patient was about \$2,000 per year and about \$4,000 per three years.

# Discussion

- How can we consider a timeframe longer than the trial period (1 year)?
- Do we need to extrapolate the study population to the population served by a health system?
- How do we capture the budget impact?
- Do we need to consider costs outside of the health care system (e.g., time off work)?
- Could these results have been modelled earlier in the development of the technology to inform decision-making?



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