What kind of research and what scientific evidence are needed for decision-makers and clinicians?

Krešimir Dolić

KBC Split

- Health care delivery and outcomes can be improved by using innovations (i.e., new ideas, technologies, and practices) supported by scientific evidence
- well-documented evidence-practice gaps exist across healthcare settings, conditions, and jurisdictions

- Limited resources and limitless health needs require policy makers to choose amongst several treatment options and to prioritise technological innovations.
- Economic evaluation analysis in healthcare are consolidated practices in most countries and serve to support the decision-making process to formulate evidence-based guidelines, and adopt or reject recommendations.

CLINICAL DIAGNOSTICS

HEALTHCARE DECISION MAKERS & INFLUENCERS

Patient & Family Support

Patients make decisions in consultation with their doctors. But are influenced by their loved ones to seek more information and sometimes are encouraged to seek medical advice in the first place. Patients and their support groups play a strong role in healthcare decision making.

Doctors & Medical Groups

Doctors directly make and strongly influence medical decisions for their patients. However, medical groups often act in concert to provide improved patient outcomes and share learnings across the practice.

Clinical Practice Setting Bodies

Large clinical practice setting bodies such as the National Comprehensive Cancer Network serve to provide collective best practices among (for example) urologists as they seek to screen prostate cancer. These bodies strongly influence healthcare decisions.

Payors (Insurance)

Insurance companies are another strong influence in the healthcare decision making process. If patients are unable to afford medication, procedures or medical devices because they are not covered or don't offer great coverage - patents may not seek the medical solution they need.

Regulatory Bodies

Regulatory bodies set standards for how drugs and medical devices should behave and what should happen when it performs outside expectations. Regulatory bodies influence both payors and doctors in their decision making process.

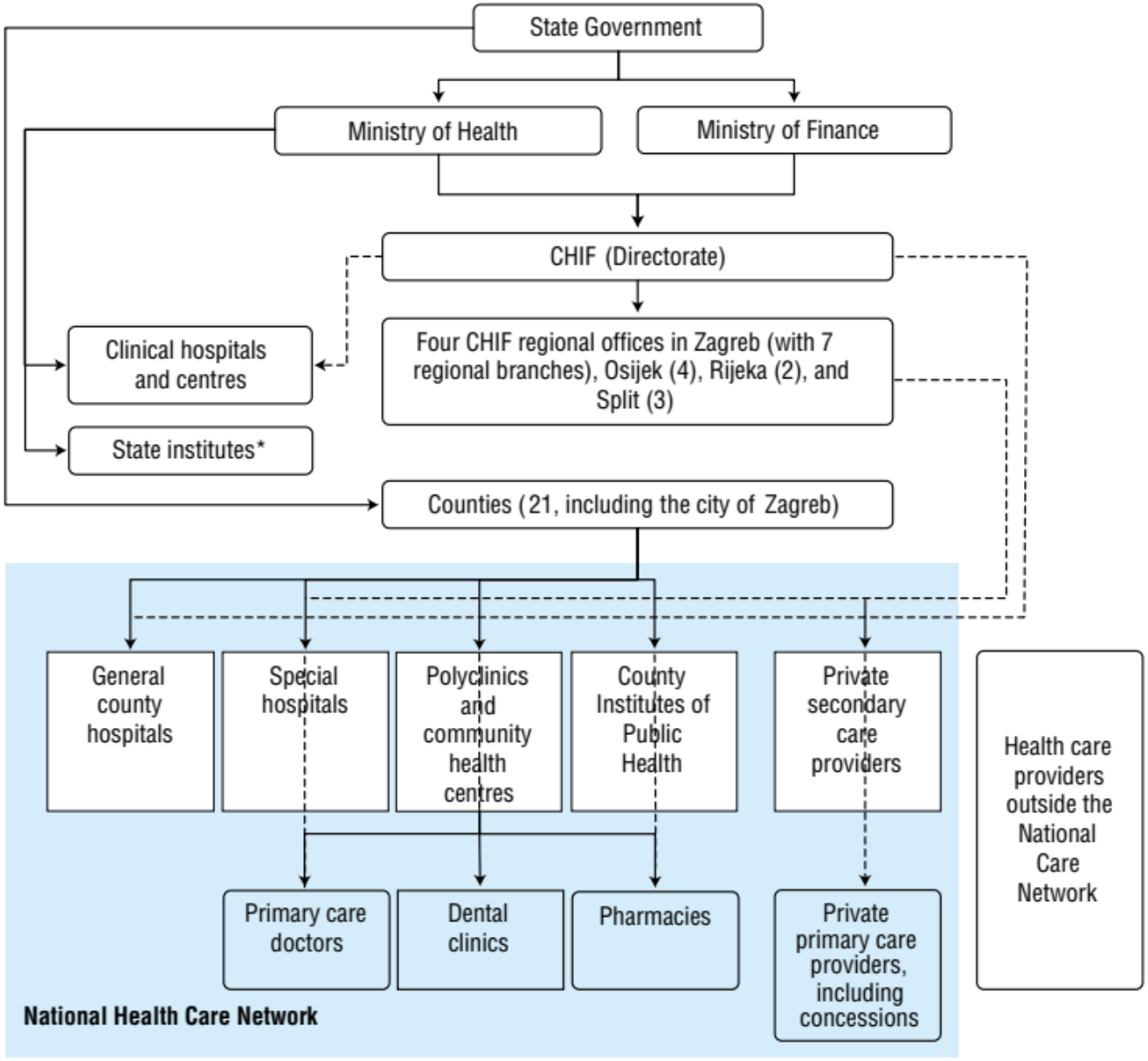
- There is increasing recognition that, in the case of medical devices, experimental clinical studies might be less relevant than real-world data to making policy decisions on, for example, reimbursement and coverage
- the questions therefore become, can we decide on coverage and reimbursement of new devices in the absence of randomised controlled trial (RCT) data? Are real-world data accumulated on the new device usable to inform decision making?

- The gold-standard research designs, such as systematic reviews and meta-analysis, double-blind controlled trials, and cohort prospective studies, often cannot offer prompt information to decision makers.
- Real-world studies are increasingly recognised as a valuable source of clinical evidence: when clinical trials are either not available, difficult to realise, unethical or available but not providing a clear aid for decision making, lacking a deep understanding of a drug or device implications on current management in a specific real-life setting

- Real-world studies can monitor variations in clinical evidence over time, accounting for a learning curve, and across different users, with multicentre research designs.

- real-world studies might be preferred when: 1) the effectiveness of a technology is likely to differ largely from its efficacy due to use-specific effects,
- 2) the realisation of an experimental study does not grant the elimination of biases from selection or awareness (lack of blinding)
- 3) the RCT does not provide an acceptable representation of the economic consequences of use
- 4) the technology is constantly improving

Overview of the health system



Urquhart *et al. Implementation Science* (2019) 14:14
https://doi.org/10.1186/s13012-019-0859-5

Implementation Science

RESEARCH Open Access

The role of scientific evidence in decisions to adopt complex innovations in cancer care settings: a multiple case study in Nova Scotia, Canada

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- EVIDENCE-BASED DECISION MAKING INVOLVES ACTIVELY USING INFORMATION. Evidence-based decision making involves **combining the knowledge arising from one's clinical expertise, patient preferences, and research evidence within the context of available resources**.

- What is evidence-based research in healthcare?
- Evidence-based research means that **the information you use to make decisions about patient care is based on sound research, not opinion**. This means you must search several sources (published articles in medical journals or in electronic form) for data, results and conclusions of valid, reputable studies.

- What are the 3 components of evidence-based decision-making?
- Evidence-based practice includes the integration of best available evidence, clinical expertise, and patient values and circumstances related to patient and client management, practice management, and health policy decision-making. All three elements are equally important.

- How do clinicians make decisions?
- Clinical decision making is **a balance of experience, awareness, knowledge and information gathering, using appropriate assessment tools, your colleagues and evidence-based practice to guide you**. Good decisions = safe care. Good, effective clinical decision making requires a combination of experience and skills.

- scientific evidence may not be the foremost factor in adoption decisions and is rarely sufficient
- The nature of evidence for health care improvement can be ambiguous and understandings of what constitutes sufficient and appropriate evidence (e.g., scientific evidence, clinical/professional experience, local data, patient values/preferences) differ across professional groups

- when making decisions about innovations, scientific evidence will have to be interpreted alongside local resources and constraints and clinical or policy priorities
- How evidence is identified and the role each type plays when individuals and teams decide to adopt innovations is often unclear

- The authors highlighted the need for empirical studies using novel methodologies to permit the identification and exploration of decision-making processes and how scientific evidence influences policy alongside other important factors, such as resources and the socio-political environment
- need for qualitative research to understand how and why different types of evidence are used during decision-making processes

	Innovation description	Main sources of evidence	Key resources and activities required for implementation	Decision process/length
Case 1: PET	Nuclear medical imaging technology, often combined with CT imaging, to provide additional functional imaging detail Supported by scientific evidence for better cancer diagnosis, staging, and/or response to therapy for certain cancer types	Scientific evidence Patient experience	• Capital equipment purchase • Access to isotopes* • Expertise in PET scanning • Policy pertaining to use (only to be used for certain indications)	Formal requests/proposals to successive levels of system, ending with government**; required approval at all levels Decision process lasted approx. 8 years with adoption occurring in 2008
Case 2: IMRT	Type of radiotherapy that delivers targeted radiation to tumors, with better sparing of surrounding normal tissue Supported by scientific evidence for certain cancer types and indications	Scientific evidence Clinical experience Local data Data from other jurisdictions	• Integration with existing imaging modalities • Policy pertaining to use (only to be used for certain indications) • Education/training for all members of multi-disciplinary team	No formal request; informally adopted at departmental level Decision process lasted approx. 2 years with adoption occurring in 2005
Case 3: MSI testing	Molecular biology technique to (1) identify Lynch syndrome and (2) provide additional prognostic/ predictive information in colon cancer Supported by scientific evidence	Scientific evidence Local data	• Expertise to perform testing • Policy pertaining to use (only to be used for certain indications) • Additional supplies (reagents)	Formal request/proposal to department; approved at departmental level Decision process lasted approx. 6 years with adoption occurring in 2012
Case 4: Barcoding	Technology in anatomic pathology to track cancer specimens from collection to reporting, and optimize patient safety Pre-post studies demonstrated significant error reduction	Scientific evidence Clinical experience Local data Data from other jurisdictions	• Capital equipment purchase • Education/training for all members of pathology team	Formal requests/proposals to successive levels of system, ending with government**; required approval at all levels Decision process lasted approx. 5 years with adoption occurring in 2014
Case 5: MRS	New staff position to optimize cancer patients' access to non-intravenous prescription medications Limited scientific evidence to support innovation, through some descriptive data regarding institutional experiences in the US	Clinical experience Local data Data from other jurisdictions	• Social worker with expertise or willingness to develop expertise in medication access • Referral form/process • Evaluation framework and infrastructure	Ad hoc committee struck to address problem; recommendation approved at program level Decision process lasted approx. 2 years with adoption occurring in 2005

- The documentary and interview data revealed the adoption process played out on a continuum, from someone's initial conviction the innovation should be implemented (typically someone at the frontline of care delivery), to advocating for the innovation (by an individual or small group of individuals at the frontline), to the decision to adopt the innovation at the departmental, organizational,and/or healthcare system levels.

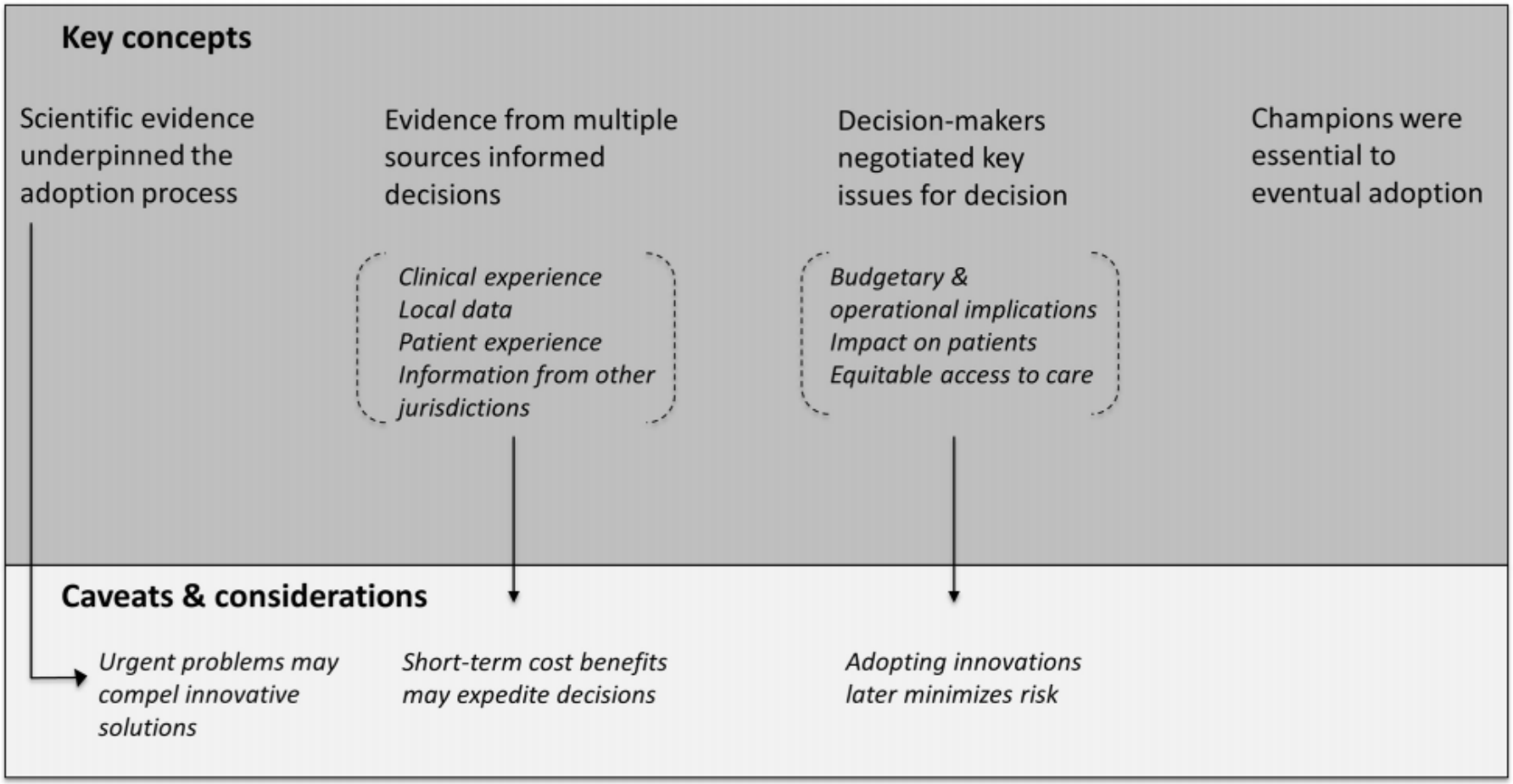


Fig. 1 Key concepts and caveats and considerations in decision-making processes around adopting innovations in cancer care settings

- During subsequent decision-making (which occurred at the department, organization, and/or system levels), scientific evidence played a limited explicit role in decision-making processes, with decision-makers typically trusting the individuals who brought the innovation forward

- „ We relied on the expertise of the Diagnostic Imaging professionals … I cannot speak to the evidence, I cannot point to the studies, except to say that it was confirmed with us, by both the hospital executive and DI, that there was ample evidence that this was the standard for technology.”
- most individuals at these levels felt the innovation would not be under consideration unless there was scientific evidence to support its adoption
- both documentary and key informant data revealed issues related to capacity and costs dominated decision-making processes

- In addition to scientific evidence, the data showed evidence from multiple sources informed decision-making, including clinical experience, local data, patient experience,and information from other jurisdictions.

- „local data were key to influencing decision makers to approve microsatellite instability (MSI) testing in Nova Scotia Specifically, data demonstrating high accuracy and reproducibility of the test locally was paramount to the adoption decision
- … to see whether we have this ability or capacity in Nova Scotia and to see whether the technique is really robust … it's just showing local data to convince [the] committee you know, yes, [we] can do it. It can work here."

- … Patient representatives, speaking at town hall meetings and with government officials and media, described the benefits of positron electron tomography (PET) and shared their experiences with having to access this technology outside the province.
- "Even though[PET] had all these implications for research, you know, and … patient care and all these sorts of things … the part that really resonated with people was the story [patients]told"

- the role of scientific evidence appeared less pertinent to adoption decisions when the innovation had been extensively adopted elsewhere, with the data suggesting real-world evidence and experience gained from others'adoption was more highly valued

"This really is an innovative approach, but I'm afraid we can't consider it. It's never been done before."

- three key issues when making decisions: expected budgetary and operational implications, expected impact on patients, and equitable access to care.

- decision-makers recognized that once an innovation is implemented, it is difficult to maintain boundaries around its use, particularly in a complex clinical care environment where evidence continues to emerge and evolve “We couldn’t open the floodgates”.
- We couldn’t overload the system with a whole range of indications that could be treated, even though many, it seemed at that time, would benefit from this technology”

- expectations about the nature and magnitude of patient impact were important criteria when considering a particular innovation given competing priorities
- “there has to be a benefit somehow to patient care. The cost is something, probably the next thing we look at”

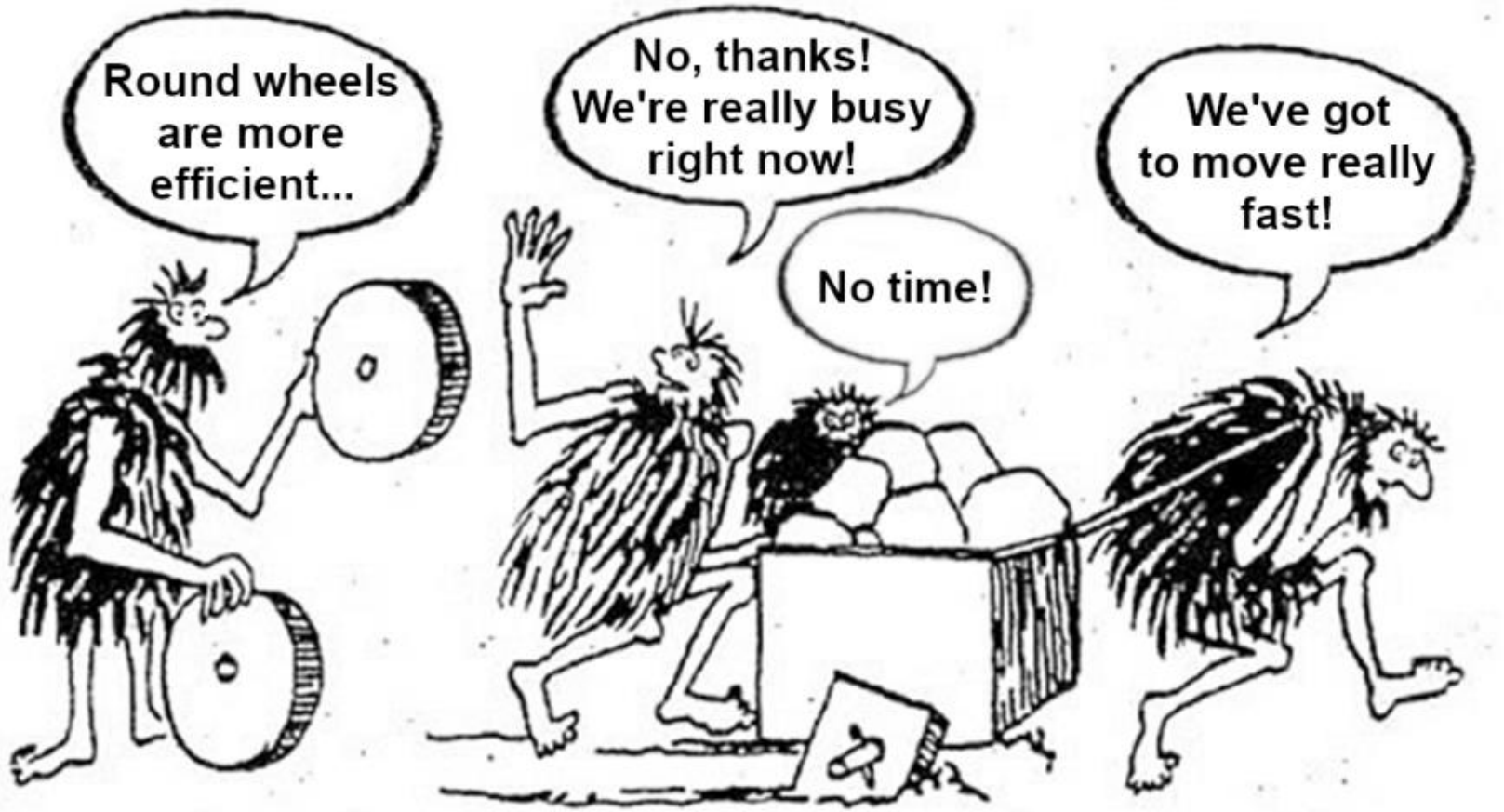
- The third issue in the decision-making process was whether or not a particular technology or service was standard of care elsewhere—specifically, equitable access to care was viewed as an important value, and if other Canadians had access to a particular technology/service, then patients in Nova Scotia should as well

- „The fact that we didn't have [PET] in Atlantic Canada was also a great motivation to bring it here because it said that the standards of care … were better frankly,everywhere else in Canada except here"
- Why should patients have to travel all that way to Toronto? They do not want to travel. Who wants to travel out of province for a treatment?
- E.g. Zadar - oncology

- Champions were instrumental in motivating others to support the innovation and overcoming barriers to its adoption and eventual implementation.
- These individuals undertook a number of activities, including gathering and disseminating multiple types of evidence to communicate benefits, formally and informally advocating for the innovation across levels of the organization/system, collecting local data to demonstrate need and/or value, and lobbying with external players (e.g., hospital foundations, policymakers, politicians) to garner moral and material support.
- E.g. MR Gospić

- adopting later in time (relative to peer institutions elsewhere) minimized risk and allowed managers/administrators to acquire valuable evidence from elsewhere to understand the resource implications and real-world patient/health system impacts of implementation.

- “Yes, it’s new, it’s great, it’s wonderful. But we’re not ready for that. And let’s let some other institution get the bugs out and then we’ll go forward”


Round wheels are more efficient...
No, thanks! We're really busy right now!
No time!
We've got to move really fast!

- Decision makers often relied on multiple types of evidence, which were necessary due to the multiple issues they considered as they made their decisions.
- The most relevant type of evidence for organizational-level decision-makers was information from other jurisdictions that had previously implemented the innovation since this evidence provided them with key insights into implementation challenges andreal-world impact.

- Research has shown that the strength or quality of scientific evidence does not always have a large influence on the decision to adopt innovations in health care
- For many decision-makers, experiential knowledge can feel more relevant and applicable than knowledge acquired through scientific inquiry
- local data and clinical/professional experience

- scientific evidence highly valued by frontline clinicians (mainly specialist physicians) who were advocating for the innovation, whereas non-scientific types of evidence were highly valued by the individuals making the adoption decisions (e.g., department/unit chiefs and managers, senior executives, policymakers)

- decision-makers must balance clinical effectiveness and need with budgetary, capacity, patient/public, and other considerations
- earlier adoption stages focus on assessments of efficacy and safety, with later stages focusing on issues related to implementation (e.g., acceptance, ease of use)

- Decision-makers across cases discussed acquiring such information from colleagues in other jurisdictions, gray literature sources, industry/vendors, and/or networking at meetings and conferences.
- Recent studies have shown that policymakers in public health report their most frequent source of evidence as "other people" (e.g., colleagues) and service payers in healthcare systems favor the evidence they receive from contact with colleagues or through professional networking over scientific evidence

- Research has shown that the scientific evidence does not always have a large influence on decisions to adopt innovations in health care. For many decision-makers, experiential knowledge can be more relevant and applicable
- Although we found scientific evidence typically underpinned the adoption process, the types of evidence most valued by strategic-level decision-makers were insights into real-world implementation challenges and impact obtained from other jurisdictions

- Future research should continue to examine how evidence is used in adoption decisions, including how different types of evidence are legitimized and why some types are prioritized over others.

- the evidence considered should be the best available!!!

What is Health Technology Assessment?

"A multi-disciplinary field of policy analysis that examines the medical, economic, social and ethical implications of the incremental value, diffusion and use of a medical technology in health care."

*Medical technology: "*Any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organizational systems used in health care."

INAHTA (International Network of Agencies for Health Technology Assessment)

HTA

- **Multidisciplinary** proces
- **summaries** information in a **systematic, transparent, unbiased, robust manner**
- about **medical, social, economic and ethical issues** related to the use of a health technology
- **to inform** the formulation of **safe, effective, health policies** that are **patient focused** and seek to achieve **best value**

Domains of HTA

- Promote the **multidisciplinary** nature of HTA

Health problem and current use of technology
Technical characteristics
Safety
Clinical effectiveness
Costs and economic evaluation
Ethical analysis
Organisational aspects
Social aspects
Legal aspects

Aims

- To contribute to policy-making, strategic planning, management and the implementation of technologies in health care
- To contribute to decision on funding (reimbursement) and investment/planning
- Bridge between research and decision-making

HTA agencies and units in Europe:

Austria, Belgium, Denmark, Finland, France, Irland, Italy, Germany, Hungary, Latvia, Netherland, Poland, Spain, Sweden, UK, Norway, Switzerland

Country	Since	Annual HTA budget (US $ million)	Population served (million)	Permanent staff in HTA Department	Consultants
Finland	1995	2.0	5.1	18	65
Latvia	1995	0.05	2.3	8	variable
Denmark	1997	3.8	5.4	15	variable
Norway	2003	4.0	4.5	30	100
Croatia	**2007**	0.4 (for whole Agency in 2009)	4.4	1 (out of three planned in 2009)	

HTA is not yet sustainable and mandatory in the reimbursement/investment or disinvestment decision process in Croatia. There are still barriers to overcome.

To implement it fully, the support and commitment of government institutions (political decisions) with a full legal framework in place is needed. Capacity building (educated permanent, full- or part-time staff), appropriate stakeholders involvement, further sustainable national and international cooperation and collaboration (network), and appropriate funding are of utmost importance as well.

PREPLAĆENI UREĐAJ

Otkrivamo kako je mala tvrtka zaradila milijune: Kupnja uređaja je išla brzo i preko reda

Piše Ivan Pandžić, Martina Pauček Šljivak,
Četvrtak, 5.5.2022. u 20:03

Mala tvrtka Endomedic će samo na prodaji spornog uređaja ostvariti ukupno 4,1 milijun kuna dobiti

Engaging with Decision-makers:

Issue Briefs for policy and practice

5 week online Short Course: 26 Oct – 27 Nov 2020

Decision-makers, whether at the household, organizational, community or network level make decisions in complex environments. With the multitude of information that impacts their decisions, its critical for researchers to not only understand the complexities of the decision-making environment but also to appreciate the efforts and strategies that can be employed to contribute to those decisions with evidence.

The Centre for Evidence-based Health Care, Department of Global Health, Faculty of Medicine and Health Sciences, Stellenbosch University, offers this 5 week online short course to provide researchers with the knowledge, skills and tools to contribute meaningfully to evidence-informed decision-making (EIDM).

The course is predominantly focused around creating an issue brief for a key decision-maker that delegates seek to inform, provide clarity for, or compel to action. Majority of the time is spent intensely working with peers and facilitators to craft a well-designed and appropriately populated issue brief taking into consideration the key stakeholder participants seek to influence. Participants will leave the course with a penultimate version and a strategic dissemination plan.

25 hours total course time commitment over 5 weeks

Facilitators: Dr. Nasreen Jessani[1,2,3] and Ms. Lynn Hendricks[1,4]
[1]Stellenbosch University, [2]Africa Centre for Evidence-UJ, [3]Johns Hopkins University, [4]KU Leuven

After completion of this course, participants will be able to:

- Understand the nuances of engaging with decision-makers (including policymakers & practitioners)
- Appreciate the facilitators and barriers to engaging with decision-makers and how these can be managed
- Think strategically about how to engage effectively with various types of decision-makers
- Design and populate an issue brief relevant to a chosen decision-maker
- Identify strategies to disseminate and evaluate the research output (issue brief)

Upon completion participants will receive a Stellenbosch University short course certificate of attendance.

Attendance limited to 20 participants. Cost R1,050.

RESERVE YOUR SEAT: Contact Liesl Esterhuizen, lesterhuizen@sun.ac.za by 30 Sep 2020.

Course Pre-requisite:

Note that only applicants who have completed the prerequisite short course, **"The Art, Science and Complexity of EIDM: Introduction to Knowledge Translation"** will be eligible to enroll for this course. If you have not already taken the prerequisite short course, it is being offered immediately prior from 1 September to 2 October 2020 in a 5 week online short course format. Contact Liesel for details.

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FOURTH EDITION

ETHICS in Health Administration

A Practical Approach for Decision Makers

EILEEN E. MORRISON