

“We want to fundamentally change the way decisions are made about amputation surgery.

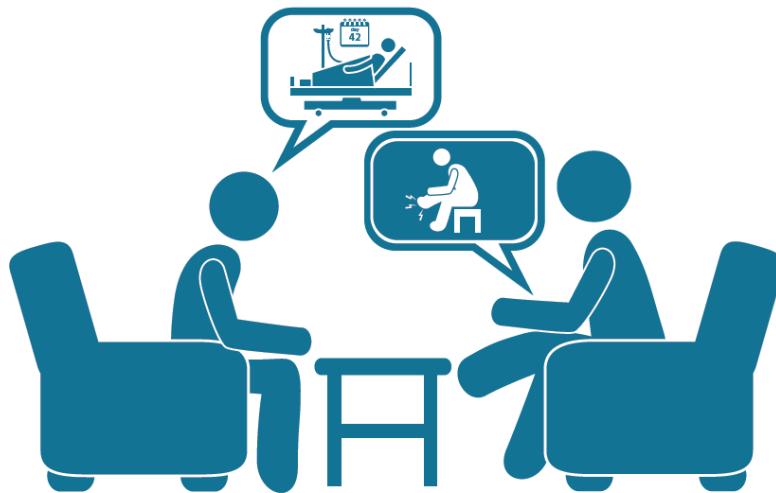
We want to ensure that all people have access to meaningful conversations with a health provider; conversations that include accurate and unbiased information about their treatment options, as well as the likely outcomes, and the risks of harms of each. We want to see people supported as they deliberate on such a difficult decision.

Only then can people make truly informed decisions about amputation surgery.”

Dillon et al., 2017 NIH grant application

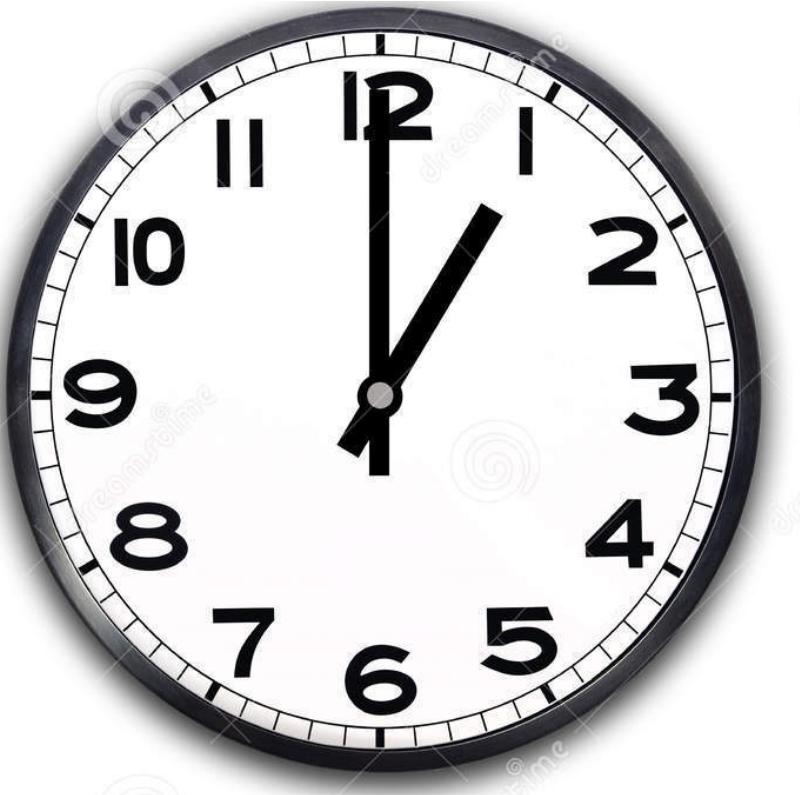
dysvascular

Informing decisions about ^ partial foot amputation using a shared decision-making approach



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In Australia, every hour, someone will undergo a lower limb amputation.

Dillon et al. 2017

Informed?

People facing prospect of partial foot amputation are often poorly informed



Surgery



Outcomes



Complications

Dillon et al. 2017, Ozturk et al. 2014, Pedlow et al. 2014

Informed?

People facing prospect of partial foot amputation are often poorly informed

Ozturk et al. 2014



“The overriding emotion was like, oh, wow, look how much they took off already... it was horrific, really confronting. I felt violated afterwards.” Sub 1

“After a week I was told they hadn’t taken enough off and I would need a debridement. I thought it would be like shaving Parmesan cheese off. They should just say, we’re going to chop off another inch or two...” Sub 3



Surprise!



40%

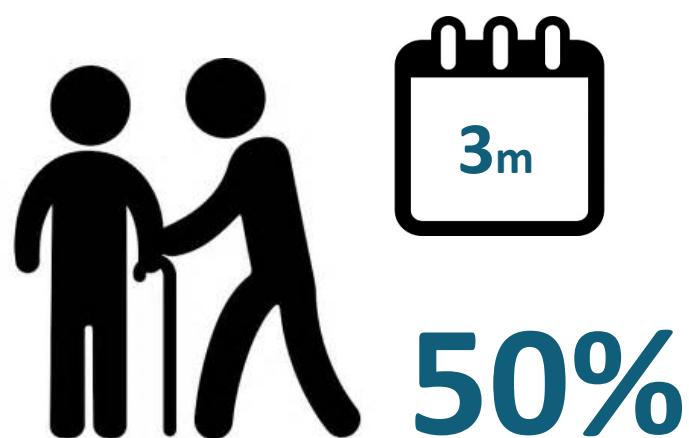
Experience significant complications after PFA; most in the first few weeks or months.

Dillon et al. 2017

Surprise!

Only half of all PFAs heal by 3 months

Dillon et al. 2017



Surprise!

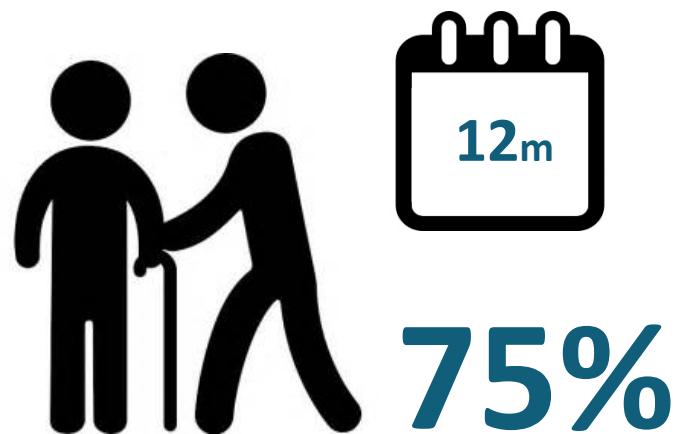


Many people spend months in-and-out of hospital

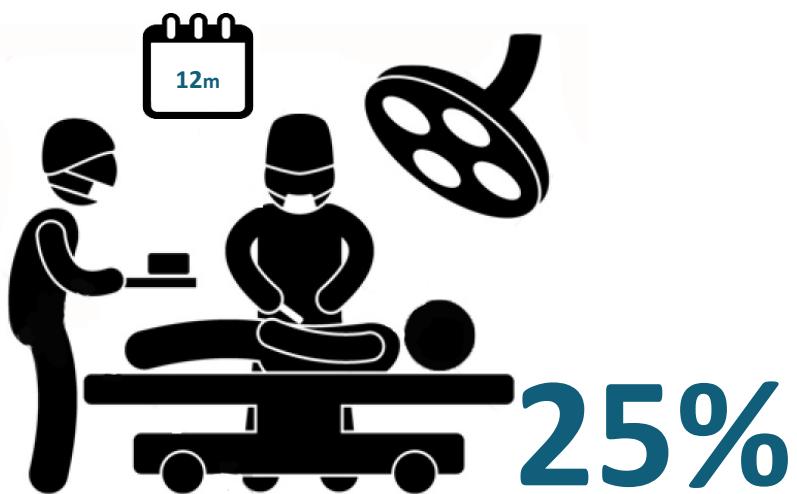
Surprise!

Three-quarters of all PFAs heal by 12 months

Dillon et al. 2017



Surprise!



In 12 months, one quarter
of all PFAs are revised

Dillon et al. 2017

Surprise!

In first 12 months, 12% of all PFAs revised 3+ times

Dillingham et al., 2005

12%

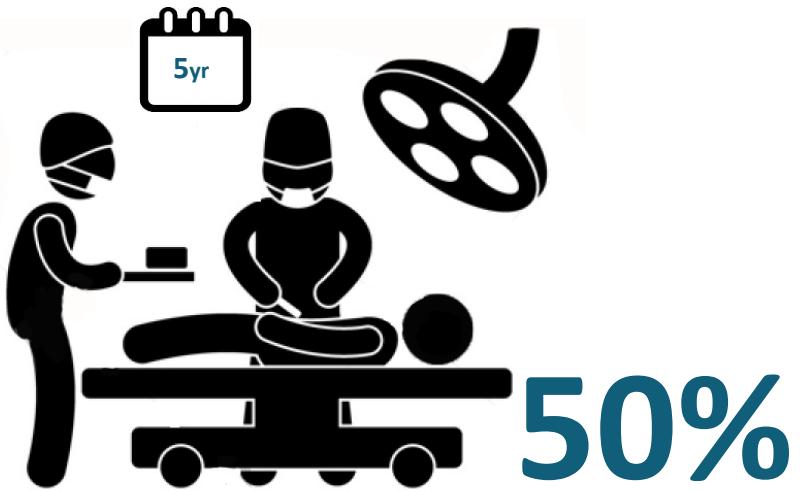


3+
revisions

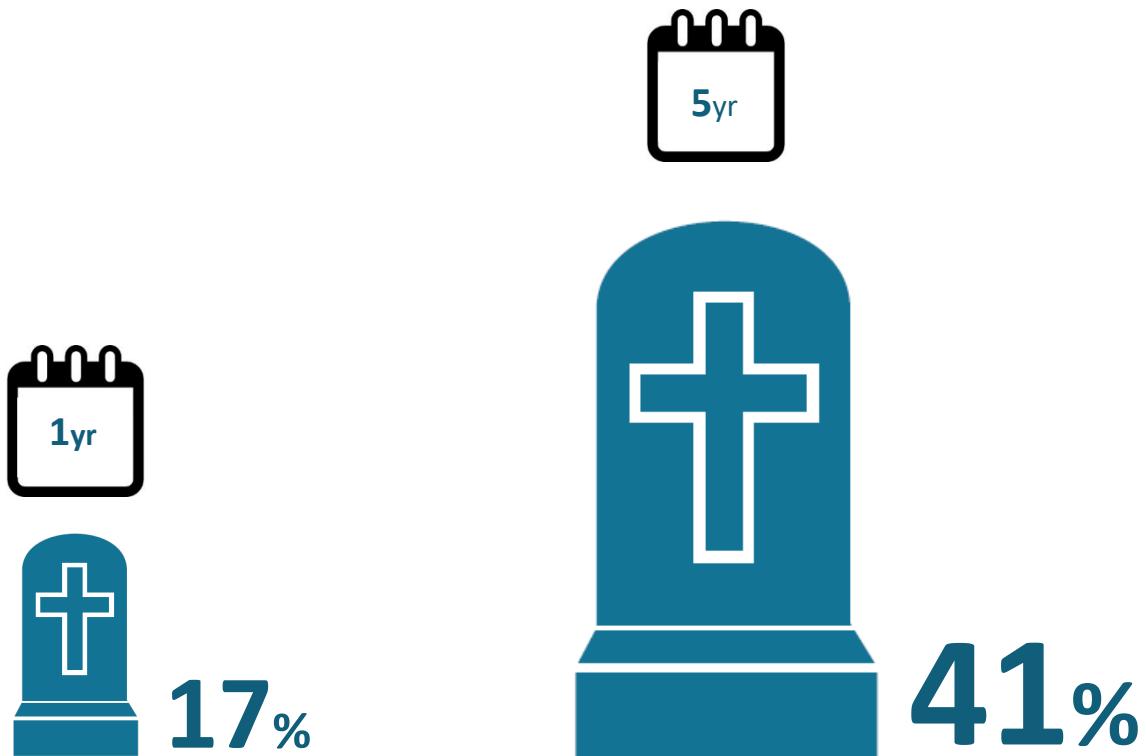
Surprise!

Half of all PFAs revised
within 5 years

Dillon et al. 2017



“Last drinks.”



High mortality in the years following PFA

Dillon et al. 2017

Defining moment.



So what does a cancer Dx and counselling have to do with difficult decisions about amputation surgery?

A truly informed choice.

Would people opt for a more invasive amputation surgery to reduce the risk of complications and reamputation if they were better informed?



Challenges

Helping older people make informed decisions can be challenging.



Age-related
cognitive
decline



Multiple
medications



Depression



Anxiety



Urinary tract
infection

Voice of experience

Many peoples' description of the experience highlight the challenges to informed decision making.



“Your on massive amounts of pain killers... Your decision making isn't as clear as it would normally be. Your emotions are all over the shop...” (Sub 1)

“It's very foggy you know. You'd take pain killers and two hours later you realise you're still looking at the fish tank. It made communication so hard.” (Sub 1)

Voice of experience

Upon reflection, knowing what to ask.



“Rather than ask how you would cut the toe of leg off, I’d ask how is it going to affect me?” (Sub 3)

“I would ask what the mobility comparisons would be between the two amputations... I probably should have asked more questions about being confined to the house, everything that was involved around the VAC machine... having to be on pain killers.. The quality of the time. If there were statistics on success rates, I’d point those out too.” (Sub 1)



Voice of experience

Many people suggest ways things can be better.



Sit down, have a cup of tea with them to get to know, get the feeling of them. Just let the conversation flow. (Sub 8)

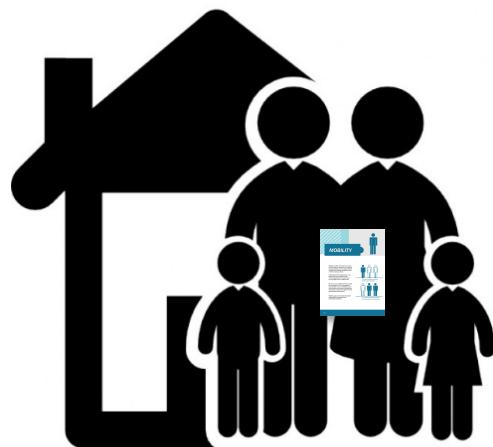
" You get information from doctors and nurses, but I find it easier to read something off paper... and let it really sink in, brochures you can take with you and read them in your room and read them whenever you feel like it in your own time."

(Sub 3)



How can we help?

Recognising these challenges, and the advice from the lived experience, we wondered whether a **shared decision making approach** might be helpful.



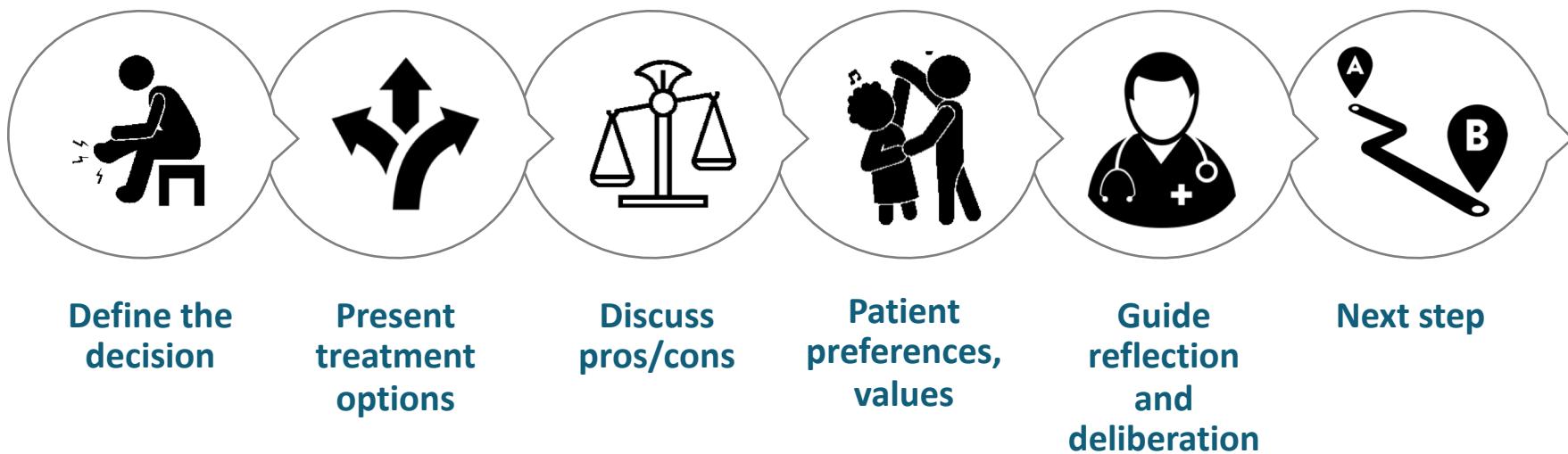
Shared decision making



Consultative process design to help clinicians and patients engage in meaningful conversations focused on decision making.

Legare et al. 2006, Hoffman et al. 2014

SDM process



Resources



A decision aid for people facing partial foot amputation due to peripheral arterial disease

Authors:

Michael Dillon, PhD, BPO (Hons)
Stefania Fatone, PhD, BPO (Hons)
Matthew Quigley, MCPO (Hons)

Graphic design:

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2. Northwestern University Prosthetics-Orthotics Center, Feinberg School of Medicine,
680 N Lake Shore Drive, Suite 1100, Chicago, IL 60611



A discussion guide for healthcare professionals to support decision making about partial foot amputation due to peripheral arterial disease

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Decision aid

Resource to support **patients** to make a decision:

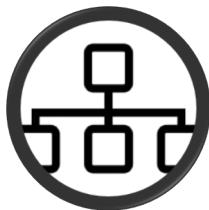
- Focused on a very specific decision
- Clear and easy to understand language
- Explains different options
- Risks and benefits w/out bias
- Figures/infographics aid understanding
- Include prompts to guide reflection



Quality SDM resources

International Patient Decision Aid Standards (IPDAS)

Elwyn et al. 2006; Coulter et al. 2013; Volk et al. 2013



Process



Reading level



Evidenced



Visual appeal



Patient stories



User tested

Need for evidence

Systematic review covering topics important to inform decision making:

- level of partial foot amputation
- partial foot vs transtibial amputation

Dillon et al. 2017



Complications

Quality of life

Psychosocial

Mortality

Wound healing

Reamputation

Mobility

Pain

Need for evidence

Systematic review covering topics important to inform decision making:

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Dillon et al. 2017



Complications

Quality of life

Psychosocial

Mortality

Wound healing

Reamputation

Mobility

Pain

Mortality



Guiding questions

- What is the risk of dying in the years after amputation?
- Does the choice of amputation level matter?

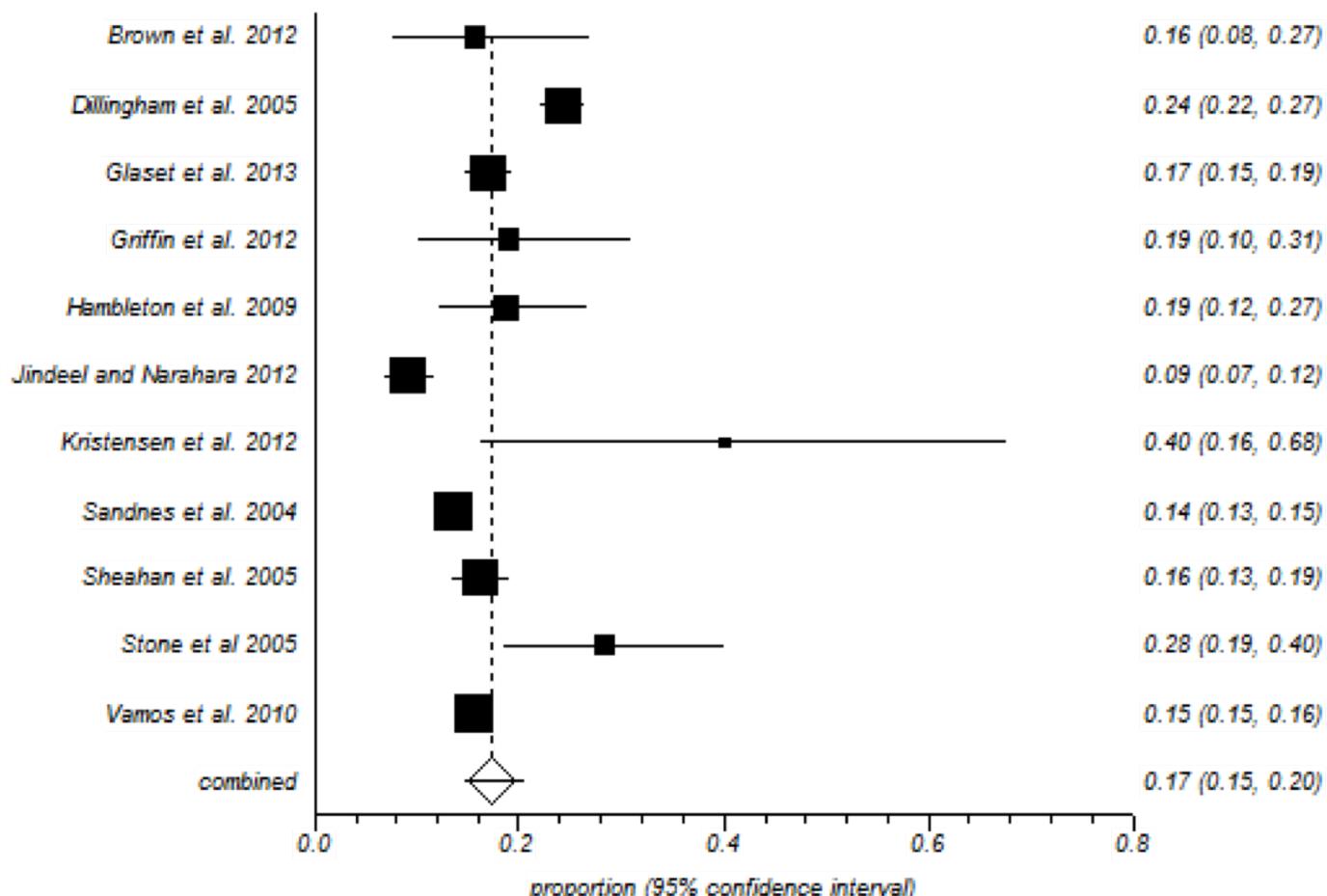
18 articles

All-cause proportionate mortality, at discrete time points
after PFA

Mortality



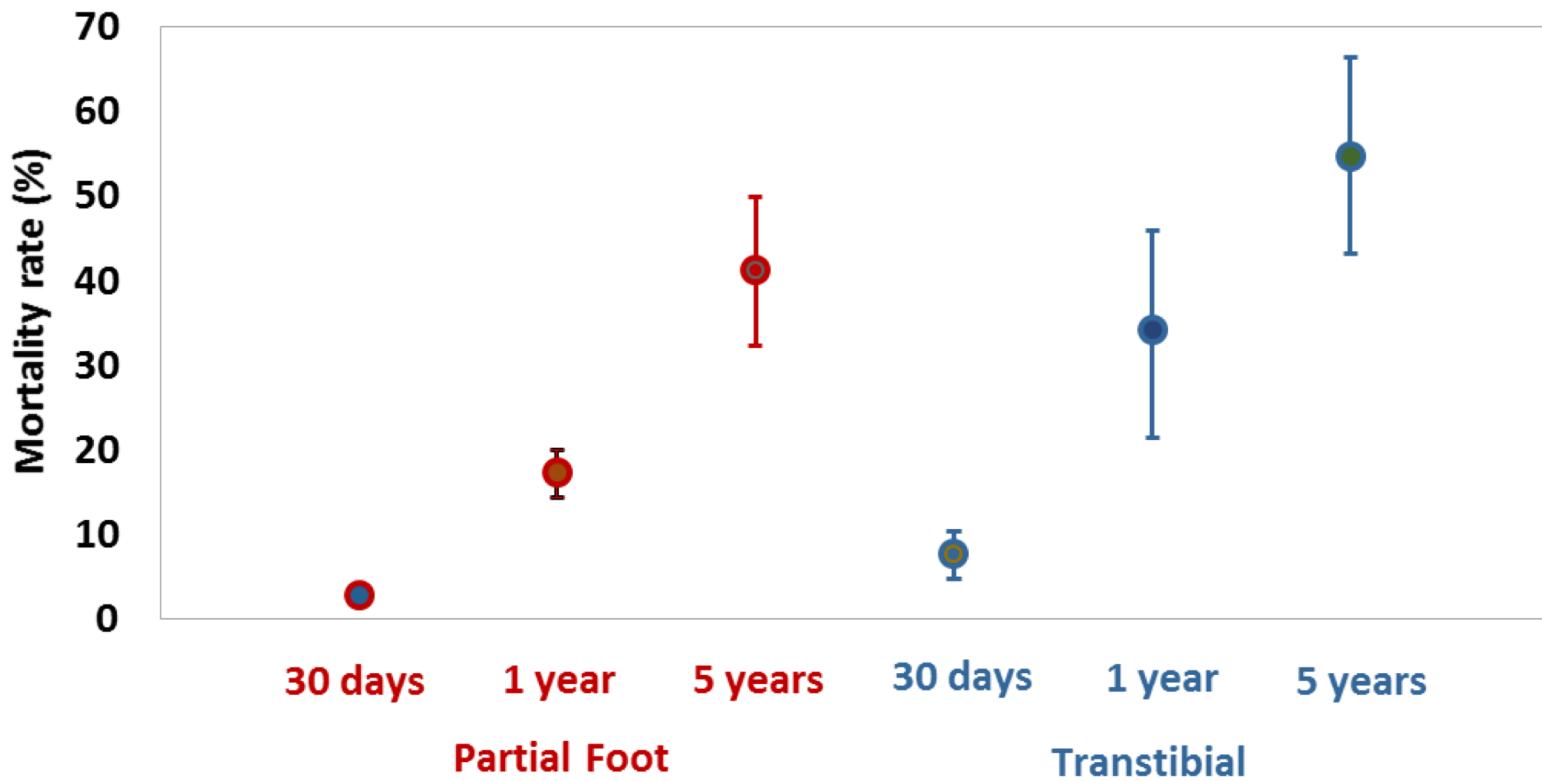
Proportion meta-analysis (random effects), 1-year mortality post partial foot amputation



Mortality



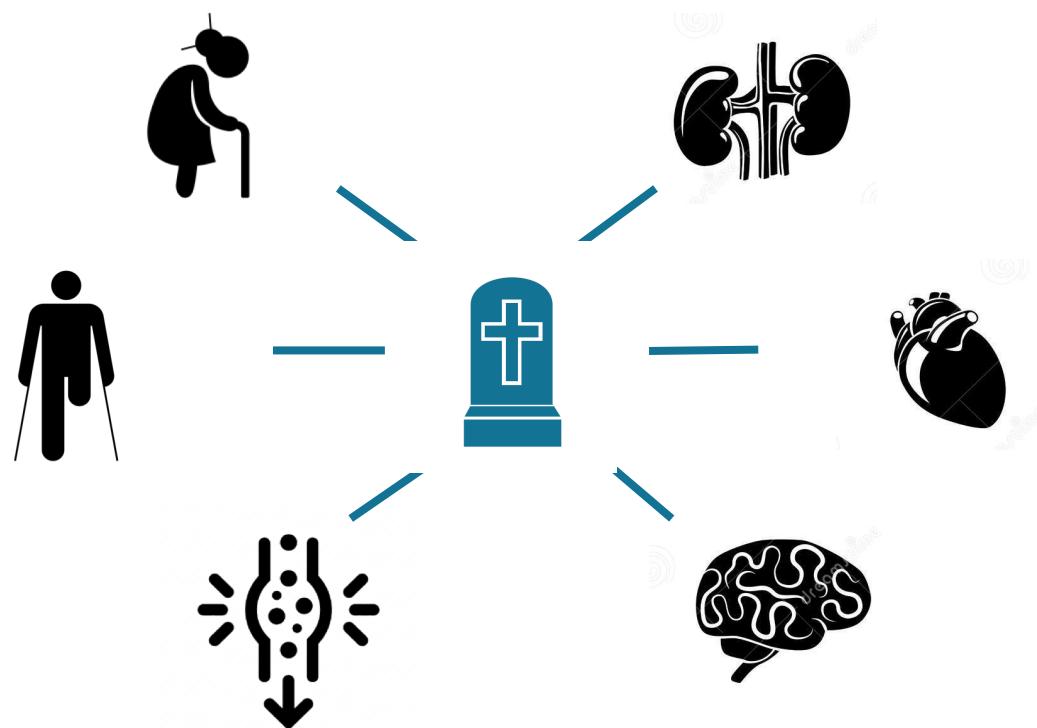
Mortality rates after partial foot and transtibial amputation



Mortality



Complex interactions between factors make it difficult to assess the effect of amputation level on mortality

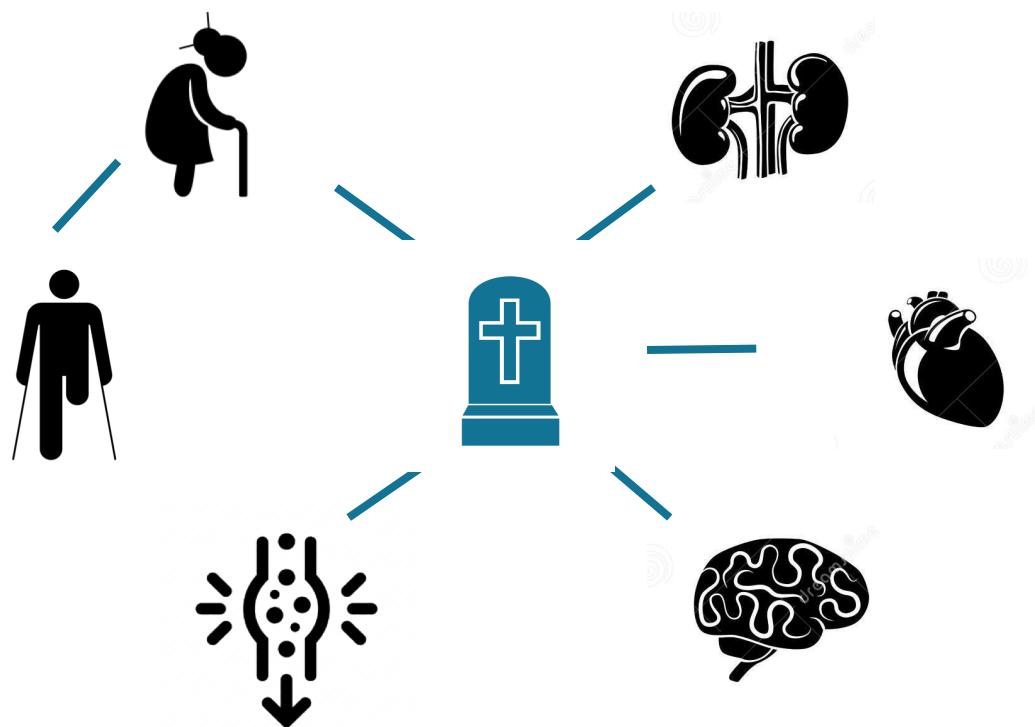


Mortality



Studies that control for the confounding effect of age, show that amputation level has no effect on mortality.

Tseng et al. 2008



Bringing it all together

Showcase how these SDM resources:

- In keeping with the patient experience
- IPDAS guidelines have been applied
- Evidence from systematic review



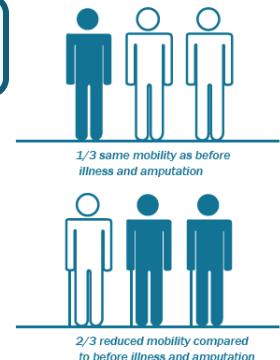


Mobility describes how easily you can get around using your prosthesis in a variety of everyday activities such as walking indoors, outside in bad weather, going down stairs or while carrying an object.

Following partial foot amputation, most people lose some mobility but still remain independent. You may need to use a mobility aid, like a walking stick.

We do not know if different levels of partial foot amputation (e.g., toe amputation) result in better or worse mobility because most research has focused on people with amputation through the middle of the foot (transmetatarsal amputation).

Mobility appears to be similar for people with partial foot and below knee (transtibial) amputation.



Simple definitions. Lay language.

Mobility describes how easily you can get around using your prosthesis in a variety of everyday activities such as walking indoors, outside in bad weather, going down stairs or while carrying an object.

Extensive use of infographics

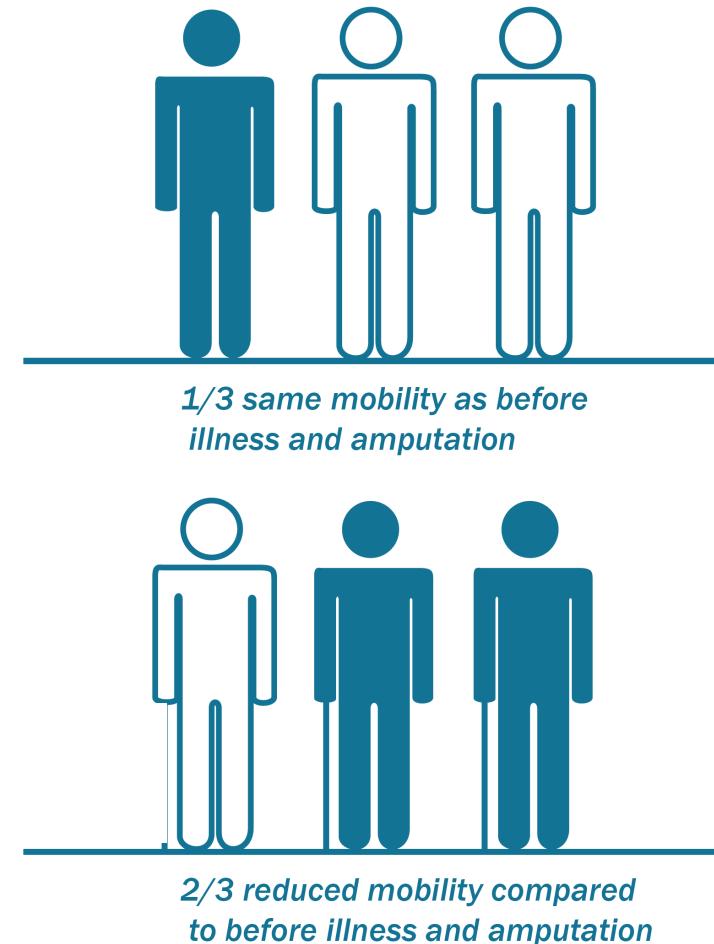
MOBILITY

- Mobility describes how easily you can get around using your prosthesis in a variety of everyday activities such as walking indoors, outside in bad weather, going down stairs or while carrying an object.
- Following partial foot amputation, most people lose some mobility but still remain independent. You may need to use a mobility aid, like a walking stick.
- We do not know if different levels of partial foot amputation (e.g., toe amputation) result in better or worse mobility because most research has focused on people with amputation through the middle of the foot (transmetatarsal amputation).
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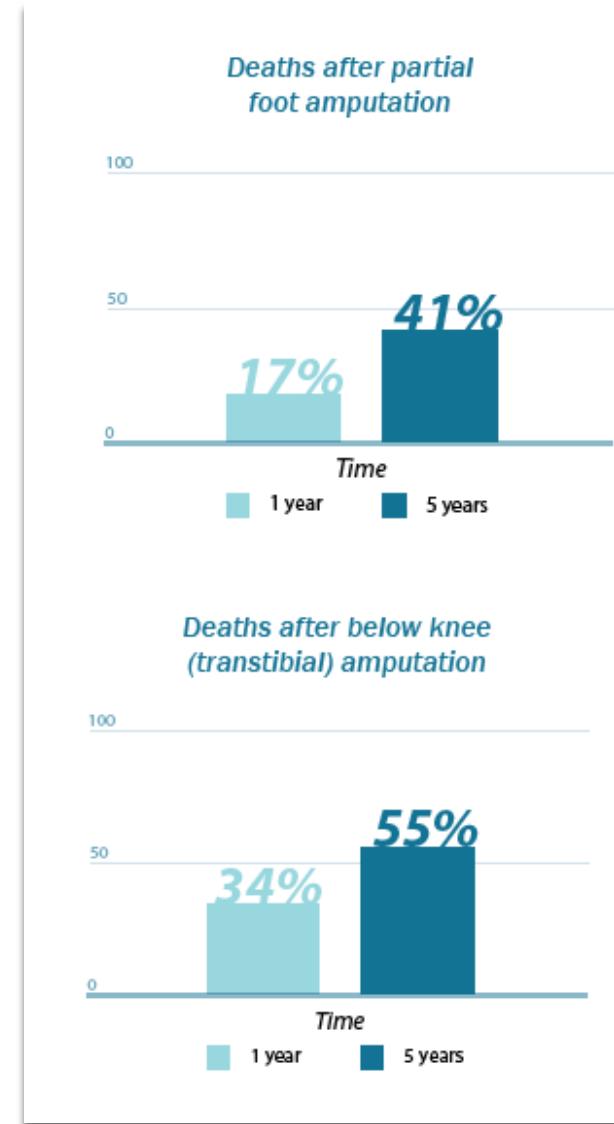
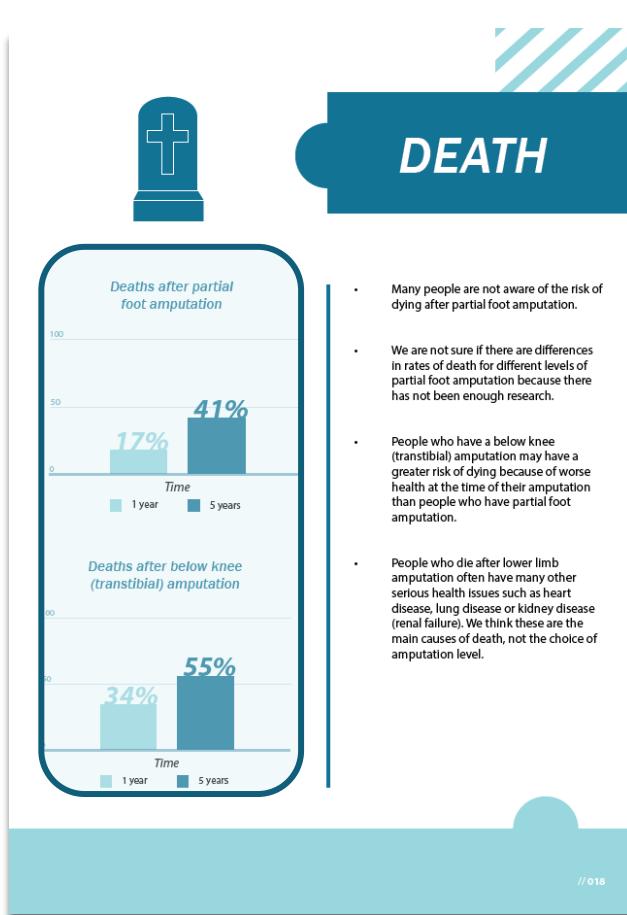
1/3 same mobility as before illness and amputation

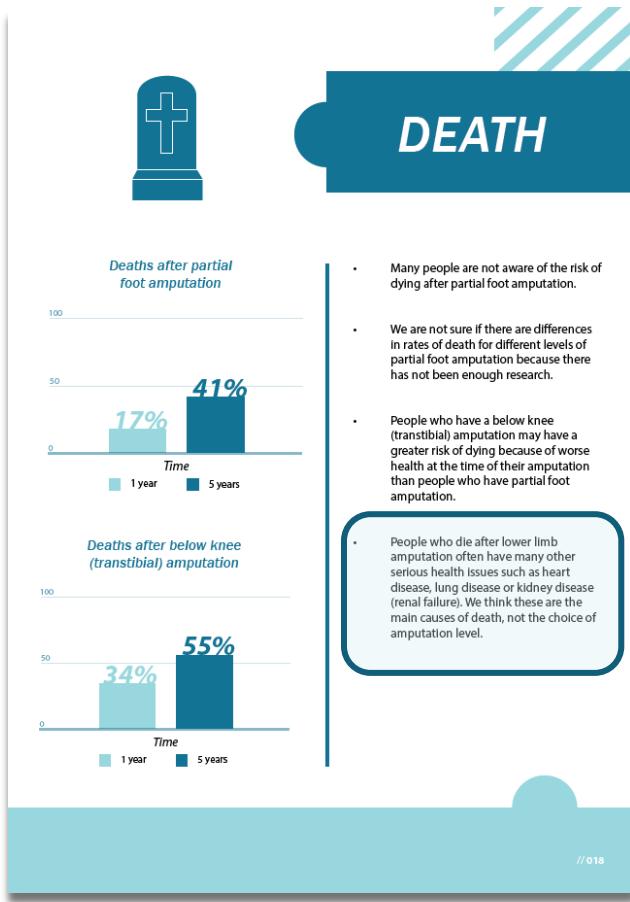
2/3 reduced mobility compared to before illness and amputation

// 015



Compare outcomes w/ simple statistics





Guide interpretation.

People who die after lower limb amputation often have other serious health issues such as heart disease or kidney disease (renal failure). We think these are the main causes of death, not the choice of amputation level.

YOUR DECISION

What is important to you?

Q: What are your greatest concerns about surgery?

Q: What are your greatest concerns about life with amputation?

Q: Based on what you have read, do you have a preferred option?

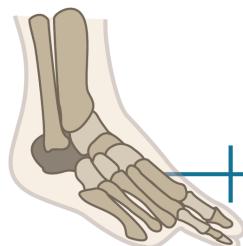


Supporting deliberation

- Open-ended questions for reflection
- Eliciting a preference to guide further discussion

Q: *Based on what you have read, do you have a preferred option?*

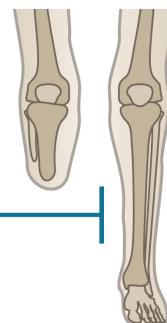
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Toes



Transmetatarsal



Below knee

In practice

How are these SDM resources incorporated into consults?



Decision aids used in
consult and taken home
to share with family



Decision aids provided
as part of referral



Decision aids available
online before consult



Myths

“The consultation will take too long.”

BUSTED

3 x systematic reviews show no systematic increase in consultation time.

Legare et al. 2010, Legare et al. 2012, Stacey et al. 2014



Myths

“Patients don’t want to be involved...”

BUSTED

Most patients are dissatisfied with the information provided and want more involvement in decisions

Keisler et al 2006



Myths

BUSTED
“Most people can’t participate.”

Vulnerable people receive less information, are less willing to participate and experience greater inequity.

Mc Caffery et al. 2010

Strategies can be learnt to facilitate meaningful conversations and improve participation.

Legare et al. 2011



Myths

“I already do shared decision making!”

BUSTED

Systematic review of studies that observe patient involvement in shared decision making report low levels of engagement.

Coulter et al. 2013

Will it work?



1. Effectiveness shown in other areas of healthcare

Prostate screening, breast cancer treatment etc.

Improves

- Knowledge of options
- Accurate perception of risks
- Communication between patients and clinicians
- Participation in decision making
- Clarity about what matters
- Body language in consult

Reduces

- Feeling uninformed
- Feeling unsupported
- Uncertainty about decision
- Decision regret
- Uptake of unnecessary or risky treatments

Stacey et al. 2014, Irwig et al. 2008

Will it work?



1. Effectiveness shown in other areas of healthcare

Prostate screening, breast cancer treatment etc.



2. Legislative change

State of Washington introduced legislation changing informed consent, and use of shared decision making



3. Reimbursement

CMS reimbursement for low-dose CT for lung cancer screening requires consent using shared decision making



4. Investment

CMS, AHRQ and NIH investment

What's ahead?



Real world testing required to ensure the approach works to make things better, and not cause harm

Elwyn et al. 2006

Real world testing

To comply with the IPDAS standards, and meet regulatory requirements for use in the United States:



1. Developed training

Clinicians need education to know how to use these resources and facilitate SDM.

The diagram illustrates three training course modules, each represented by a film strip frame:

- Reading level:** Shows a person reading a document. Text: "Simple definitions & lay language". "Mobility describes how easily you can get around using your prosthesis in a variety of everyday activities such as walking indoors, outside in bad weather, going down stairs or while carrying an object." Includes a magnifying glass icon over a mobility chart.
- Regular consult:** Shows a clinician and a patient. Text: "Bain bain portal day reservation possible detailed information required. Bain bain bain". Includes a speech bubble from the patient.
- A training course:** Shows a person working at a desk. Text: "We worked with a graphic designer to translate the evidence into SDM resources".

Each module is labeled "A training course" at the bottom. Traffic cones are placed in front of the first and third frames.

Real world testing

To comply with the IPDAS standards, and meet regulatory requirements for use in the United States:



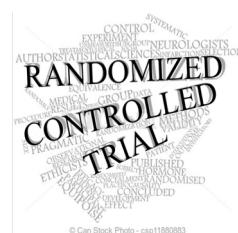
1. Developed training

Clinicians need education to know how to use these resources and facilitate SDM.



2. Seeking collaborators for beta testing in real world

Ensure SDM resources are clear, include all relevant topics to inform decision and cause no harm



3. Looking ahead to studies of effectiveness

RCT compare SDM to standard of care consult

With thanks



American Orthotic &
Prosthetic Association



NORTHWESTERN
UNIVERSITY

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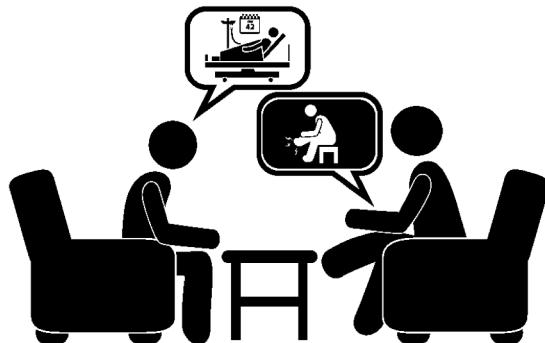
Publications

Final word



'For the clinician staff guiding the patient as to what surgical outcomes they can expect: give them the full options. Be prepared to provide a whole host of options and choice. You need to listen. Give the fact base and, um, give them time to contemplate. If that is at all feasible. Do not expect them to choose the one that you would choose as well. Be prepared that whatever that decision is for that person... needs to be made for that - the person needs to make their decision.' (Sub 5)

Discussion



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