Veterans Health Administration
Research & Development
Improving Veterans' Lives — www.research.va.gov

Applying the PARIHS Framework to Implementation of a Complex Evidence-Based Practice

Christian D. Helfrich, MPH, PhD

Disclosures

- Funding – VA Health Services Research & Development grant number IIR 15-362
- Reviewed and approved by the VA Central Institutional Review Board (#VA CIRB 14-12)
- Trial Number Registry: https://doi.org/10.1186/ISRCTN66341299

Acknowledgements

Study investigators & analysts
- **Valentina Petrova**
- **Diana Naranjo**
- **George Sayre**
- Kristine Beaver
- Jake Doll
- Chuck Maynard
- Leslie Taylor

Study Administrators
- Emily Neely
- Christine Sulc

CART team
- Madhura Gokhale
- Meg Plomondon
- Stephen Waldo

Advisory Board
- Cathy Clark
- Richard Schofield

Coaches
- Jack Gootee
- Sara Jensen
- Samir Pancholy
- Arnold Seto
- Adhir Shroff
- Raj Swaminathan
- Javier Valle
- Mladen Vidovich

Acknowledgements

In memory of Christopher L. Bryson, MD, MS

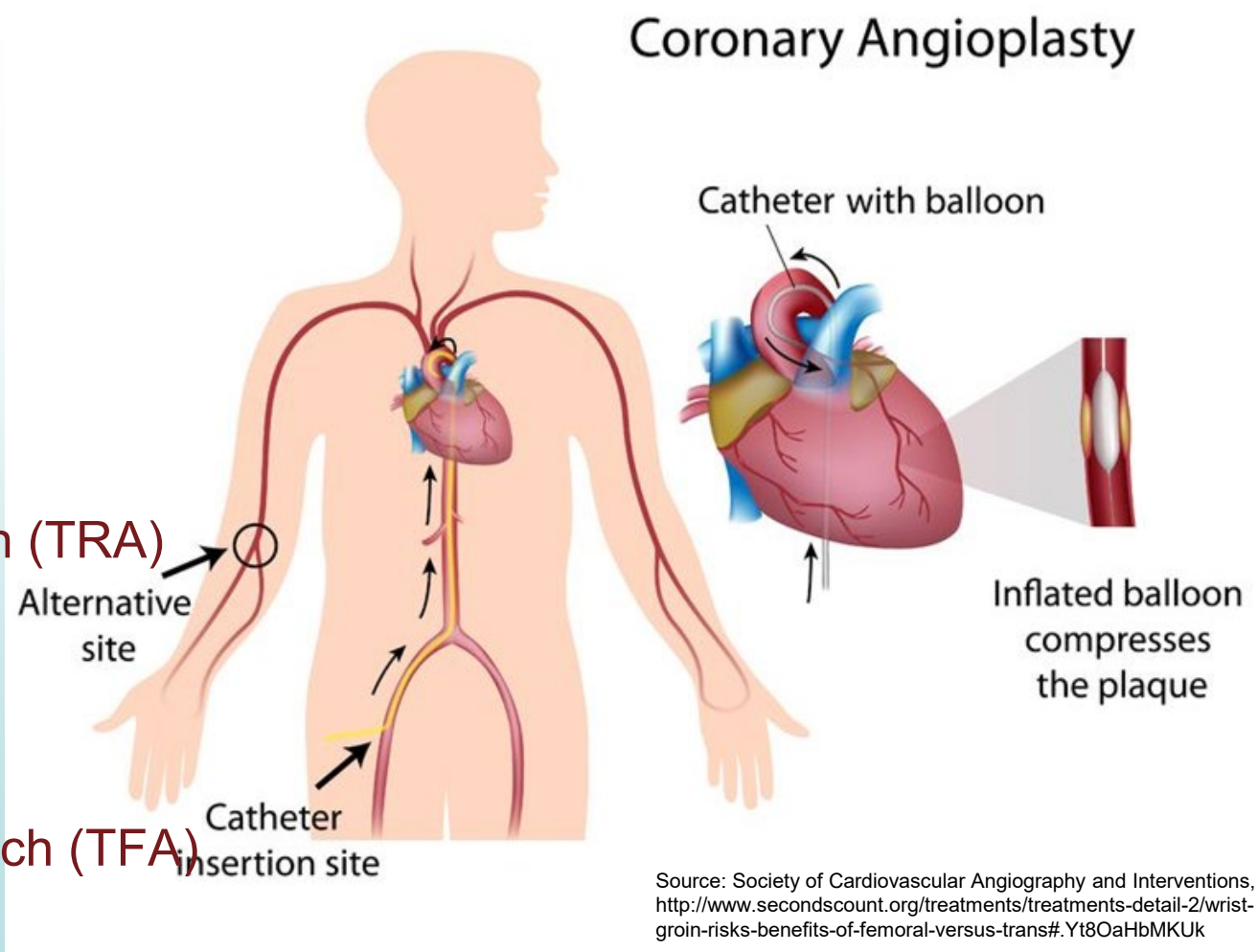
Background

Catheterization

TRA technically more complex, smaller-diameter artery, tortuous path; logistical requirements

Trans-radial approach (TRA)

Trans-femoral approach (TFA)

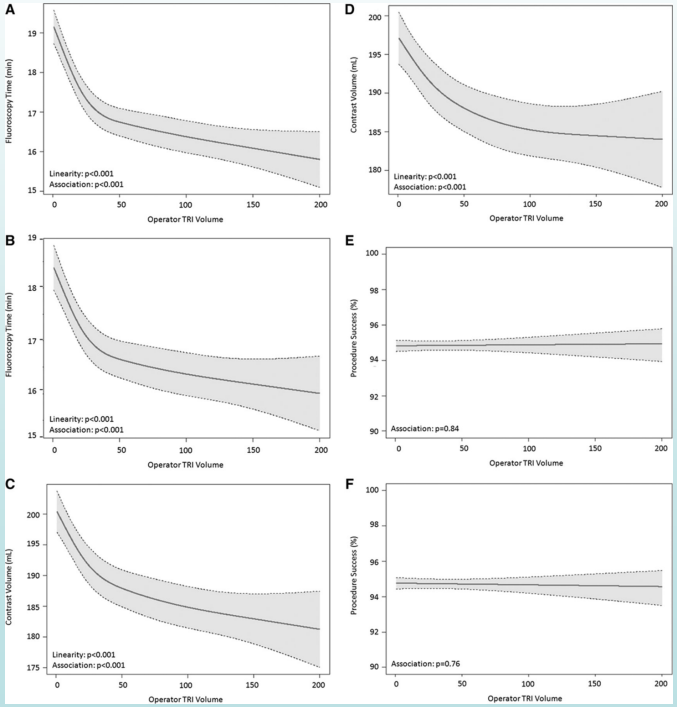


Source: Society of Cardiovascular Angiography and Interventions, http://www.secondscount.org/treatments/treatments-detail-2/wrist-groin-risks-benefits-of-femoral-versus-trans#.Yt8OaHbMKUk

Learning curve

- Well-documented learning curve (Elgharib et al 2009; Stolker et al 2016)
- Operators achieve proficiency ~ 50 cases (Hess 2014)

Fig., Operator TRI volume & procedural outcomes: Fluoroscopy time, contrast volume & procedure success (Hess 2014)



Barriers to TRA in VA

Tertiles of cath labs by TRA %	Top tertile (N = 20)	Middle (N = 19)	Bottom (N = 26)	Total (N = 65)
Long learning curve for radial access	**55.0%**	26.3%	46.2%	43.1%
Increased radiation exposure to the operator	**45.0%**	**63.2%**	**69.2%**	60.0%
Increased radiation exposure to cath team	40.0%	36.8%	**61.5%**	47.7%
Lack of support from other interventional cardiologists at my facility	15.0%	15.8%	**30.8%**	21.5%
Lack of support from the catheterization lab staff	5.0%	**21.1%**	**30.8%**	20.0%
Lack of support from clinical leadership	5.0%	0%	**19.2%**	9.2%

Source: Helfrich, C. D., Tsai, T. T., Rao, S. V., Lemon, J. M., Eugenio, E. C., Vidovich, M. I., ... & Bryson, C. L. (2014). Lessons learned from a qualitative evaluation of advantages and barriers to radial-access percutaneous coronary intervention in VA cardiac catheterization laboratories. Cardiovascular Revascularization Medicine, 15(6-7), 329-333.

Radial vs femoral

Tertiles of cath labs by TRA %	Top tertile (N = 20)	Middle tertile (N = 19)	Bottom tertile (N = 26)	Total (N = 65)
More comfortable for your patients	100%	89.5%	69.2%	84.6%
Allow your patients to go home sooner	100%	63.2%	69.2%	76.9%
Faster to complete the procedure	**30.0%**	**0%**	**0%**	**9.2%**
Superior technical results	10.0%	0%	3.8%	4.6%
Fewer bleeding complications	100%	94.7%	88.5%	93.8%
Few vascular access complications	90.0%	78.9%	80.8%	83.1%
Easier to monitor your patients following the procedure	95.0%	63.2%	57.7%	70.8%

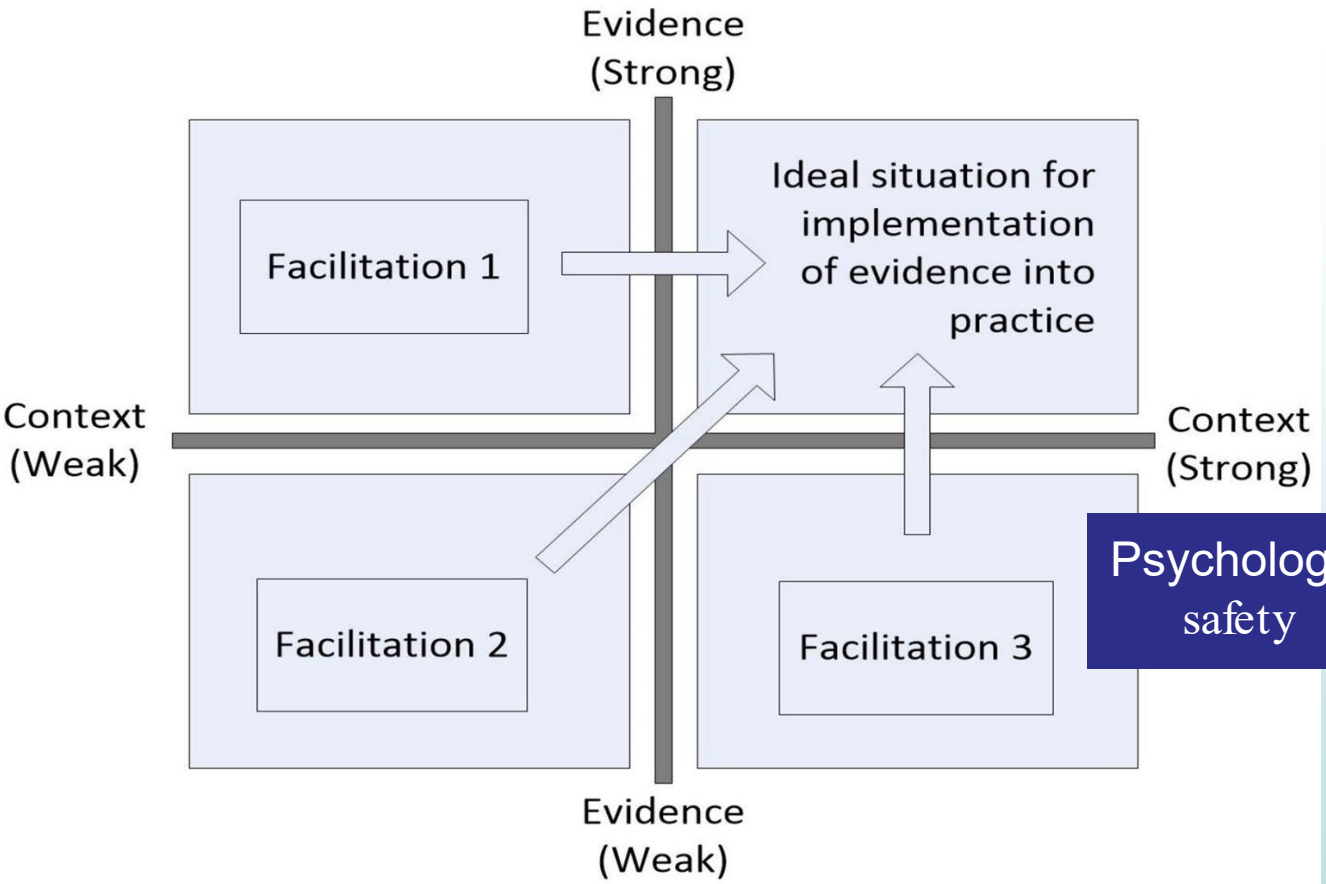
Source: Helfrich, C. D., Tsai, T. T., Rao, S. V., Lemon, J. M., Eugenio, E. C., Vidovich, M. I., ... & Bryson, C. L. (2014). Lessons learned from a qualitative evaluation of advantages and barriers to radial-access percutaneous coronary intervention in VA cardiac catheterization laboratories. Cardiovascular Revascularization Medicine, 15(6-7), 329-333.

PARIHS framework

- Challenge of the learning when trans-femoral is always an option
  - Internalizing that femoral was always going to be faster
- Challenge in cath lab context with peer and team support

- Theory: Promoting Action on Research Implementation In Health Services (Kitson et al 2008)
  - Support from trusted, knowledgeable peers who can make the new practice easier
  - Research evidence important, but so is practical, lived experience of the new practice
  - Critical to create a supportive context around the clinician implementing the new practice

PARIHS



Psychological safety

F_1-F_3 = Facilitation tailored to teams' situation in terms of Evidence and Context

Source: Kitson *et al. Implementation Science* 2008 **3**:1 doi:10.1186/1748-5908-3-1

Essence of our hypothesis

"…But for somebody who's done femorals all of their life, and then you tell them to switch to radial, **it's like having a stroke and learning how to walk again** ." – (cardiologist, 6mo interview +9mo due to Covid - excluded from findings)

Except for cath lab teams, they can bail to femoral *any time they want*

Coaching Intervention

- One-day TRA training course w/ cases
  - Hosted at high-TRA sites where coaches located
  - Mix of interactive, educational sessions & viewing live cases, including set-up & post-procedure care
- Coaching visit
  - Cardiology & nurse coaches visit participant site
  - ~1-2 months after the training course
  - Coaches meet with participants & non-participant members of lab; go over key lessons from training; observe cases performed by participants; debrief & review of TRA fidelity checklist

Coaching key ingredients

Veterans Health Administration
R&D
www.research.va.gov

Coaching

- Evidence
  - Not about TRA safety, comfort
  - About dispelling notions of TRA as slower, limited to low-risk cases
- Learning curve mental representations (Ericsson 2015)
- External support
  - Accountability
  - Counteract unsupportive context/pressures- psych safety

Coaching key ingredients vs. facilitation

Veterans Health Administration
R&D
www.research.va.gov

Coaching

- Evidence
  - Not about TRA safety, comfort
  - About dispelling notions of TRA as slower, limited to low-risk cases
- Learning curve mental representations (Ericsson 2015)
- External support
  - Accountability
  - Counteract unsupportive context/pressures- psych safety

Facilitation

- Transformational change
- Learning how to learn

PARIHS vs. i-PARIHS

Veterans Health Administration
R&D
www.research.va.gov

Original PARIHS framework	i-PARIHS framework
SI = ƒ(E,C,F) SI = successful implementation ƒ = function (of) E = evidence C = context F = facilitation	SI = Fac^n(I + R + C) SI = successful implementation Achievement of agreed implementation/project goals The uptake and embedding of the innovation in practice Individuals, teams and stakeholders are engaged, motivated and 'own' the innovation. Variation related to context is minimised across implementation settings Fac^n = facilitation I = innovation R = recipients (individual and collective) C = context (inner and outer)

Source: Harvey, G., & Kitson, A. (2015). PARIHS revisited: from heuristic to integrated framework for the successfu
implementation of knowledge into practice. Implementation Science, 11(1), 1-13.

Aims

- Test the effectiveness of team-based, peer-coaching intervention to increase use of TRA
- **Assess application of PARIHS:**
  - **Does coaching promote TRA implementation, in part, by improving evidence & context ?**
    - **Is psychological safety a salient part of context for TRA implementation?**
  - **What does this test of coaching tell us about PARIHS?**
- Cost analysis of coaching intervention

Methods

Methods - Design

- Cluster-randomized, stepped-wedge trial
  - 3 cohorts, 4 months apart
- Enrolled teams of intervention or invasive cardiologist + 1-2 cath lab nurse &/or tech
  - Unit of analysis cath lab
- Eligibility: cath labs $\geq$ 100 catheterizations & < 50% TRA per year

Methods

- Data coded in ATLAS.ti
  - Deductive/inductive approach to qualitative content analysis
  - Sequential coding of all 34 transcripts by DN, then VP
- Comparisons by…
  - Pre-/Post-/6-month follow up interviews
  - Role - Cardiologists vs. Nurses & Techs

Human Subjects

- Waiver of documentation of consent for participants
- TRA content taught considered within standard of care
- Reviewed and approved by the VA Central Institutional Review Board (#VA CIRB 14-12)

Veterans Health Administration

R&D

www.research.va.gov

Results

Intervention

- Cohort 1 – Chicago, August 2018
- Cohort 2 – Chicago, December 2018
- Cohort 3 – Chicago, April 2019

Completed Interviews

	Cohort 1	Cohort 2	Cohort 3	Total
Pre-training	8/8	3/3	3/4	14
Post-training	6/8	3/3	3/4	12
6-month follow-up	6/8	2/3	2*	8 (10)
Total	20	8	6 (8)	34 (36)

**This data was originally scheduled for collection in March 2020, but the COVID-19 pandemic delayed the interviews as many cath lab staff were caught up in the response to the pandemic at their respective VAs. The two interviews were eventually completed in November/December 2020, 9 months later than intended; a year and 3 months after the intervention instead of a 6-month follow-up. Methodological decision: Exclude this data from the overall analysis due to recall bias and COVID-19 impact on the participants' perspective.*

Veterans Health Administration

R&D

www.research.va.gov

Baseline

Evidence - Baseline

"They're [TRA] supposed to be good. I've heard all of the literature, the data is good, there's less bleeding complications. There can be higher radiation time in operators not as experienced. … I think it's a good procedural approach for people who are very good at it. I think for certain patient populations, it's definitely beneficial." - (cardiologist, pre-)

Evidence - Baseline

"Because it's so common, it's just like any other procedure that we do, it's not any more difficult. We like it also just because the patients can sit up immediately after. It's a lot more comfortable for them, easier on them, lower risk of bleeding." – (nurse, pre-)

Context - Baseline

"… when I first started working in this lab, we probably only did about 10% of our cases radially. **What helped a lot is that we had gotten a new attending from somewhere else**. And he was newer, he hadn't been an attending for 20 years or anything, only for a year or two, and when he came to our facility, he liked to go radial. So, he really helped that process." – (nurse, pre-)

Context (& evidence)- Baseline

Veterans Health Administration
R&D
www.research.va.gov

"The cath lab perceived it to be a longer and more complex procedure, so they were generally a little more reluctant in prepping the patient, also keeping the arm on an arm board, and things like that. **Those have generally gone away now** , because the cath lab staff are all so used to radial access." – (cardiologist, pre-)

Context, (not) psych safety - Baseline

Veterans Health Administration
R&D
www.research.va.gov

"We aren't based upon money, yet everybody likes to be as efficient as they possibly can. So when that was slowing people down, they naturally were more resistant to it [TRA], because it was easier for everybody to do it the other way. (…) And just, in general, **they're a little apprehensive** to come here because they aren't sure what they're going to get themselves into, and they feel more comfortable with the femoral approach, because of that reason." – (nurse, pre-)

Veterans Health Administration

R&D

www.research.va.gov

Post-coaching & 6-month follow-up - evidence, context, facilitation

Evidence (& context) - Post-coaching

Veterans Health Administration
R&D
www.research.va.gov

"And when they say that it's being done at another VA and how happy the patients are after the procedure, that probably adds to the satisfaction for the patients and the nurses (…) And a new technique, when they find out it's been done at other VAs without any issues and complications, it got them (our supporting staff) excited about it." – (cardiologist, post-)

Evidence & context - Post-coaching

Veterans Health Administration
R&D
www.research.va.gov

"It took me 2 years, literally 2 years to get these people to accept and understand that this is the standard of care. And that we should be doing it. I had to meet over and over with Nursing Clinical Practice Committees, and we'd write SOPs over and over and over, and order sets and go through all of those pains. I'll say I was quite frustrated because this is not a new evidence-based practice. I mean, my mom had radial access in the 90s." – (nurse, post-)

Evidence & context - Post-coaching

Veterans Health Administration
R&D
www.research.va.gov

"They [leadership] approach this like this is some new evidence-based practice, I'm not sure why. So I basically just had to literally ask my Nurse Exec and the Chief of Medicine to walk with me here, and show them for their own self, why this was better for the patients. And once I did that, they actually said that I could have 2 bays, but that we could get our patients ready and recover them ourselves." – (nurse, post-)

Context - Post-coaching

"They [leadership] refused to allow us to participate [in the study]. It took weeks, if not months, of me urging them to try to accept our participation. As far as why, I can't understand why. I wish I could see into their minds, but this has kind of a hard place to be in to get things to move forward." – (cardiologist, post-)

Context, Psych safety - 6-mo post

Veterans Health Administration
R&D
www.research.va.gov

"I would say that a lot of our staff are still, we're definitely resistant with high-risk PCIs, of course. We do most of those through the femoral. We do all of our CTOs through the femoral. But I don't think any of our staff are scared of radial access." – (nurse, 6-mo)

Veterans Health Administration

R&D

www.research.va.gov

Post-coaching & 6-month follow-up - TRA implementation

Facilitation - Post-coaching

"I think our coaches did what I would seek to do if I were coaching, and that's to reinforce practices that make sense and are best practices. (…) Instead of trying to find something additionally to criticize about or build on, they reinforced the fact that those are all best practices and that our lab and our cardiologists were doing a good job." – (cardiologist, post-coaching)

Facilitation, mental model

"We had trouble getting the catheter to advance, so then the coaches, Dr. [name redacted] stepped in and gave us a few pointers there on how to fix that." – (tech, post-coaching)

Facilitation - mental model

"…[new] board was causing a shadow underneath the patient… Sometimes it would end up under the patient's heart, making it more difficult to see the images. **So they had a suggestion on how to flip the board in the opposite direction and move it down away, so that the extra shadow would be underneath the hips instead of under the heart."** (nurse, post-coaching)

Facilitation - mental model & repetition

Veterans Health Administration
R&D
www.research.va.gov

"And I learned a little bit about doing right heart caths from the brachial, antecubital vein, and some tricks and tips. I kind of stopped doing that because I wasn't overly familiar with it. But at the [training site name], I watched someone do a right heart cath there, and they went over the technique. So it was useful, the repetition of going over it was useful, once watching somebody and then once actually doing it, over there, and then over here, watch and then do… **The time that I watched the cases to the time that I actually did the cases was less than a month. So the information was relatively fresh in my mind** ." (cardiologist, post-coaching)

Facilitation, accountability - Post-coaching

Veterans Health Administration
R&D
www.research.va.gov

"Normally I would've just crossed over to femoral immediately, but because they were there, I decided to use ultrasound, which is just a new technique to have under your belt. So, I think it was sort of useful in a discovery manner for all of us I would say. We were sort of co-discovering." – (cardiologist, post-coaching)

Effect on implementation

Veterans Health Administration
R&D
www.research.va.gov

"I don't think my use of transfemoral has increased, I don't know if it's decreased though . I think what I am doing is I'm picking better patients to do radial cases so that the radial cases that I do are more successful, if that makes any sense. (…) I'm better at triaging; I think I'll be able to complete the case so I'm having less crossovers, for femoral." (cardiologist, 6mo)

Effect on implementation

Veterans Health Administration
R&D
www.research.va.gov

"I think that it's been a success story, and not **only has there been adoption for radial first as the approach for most operators**, but there have been no complications that I know of, and I keep track of that closely." – (cardiologist, 6-mo)

Effect on implementation

Veterans Health Administration
R&D
www.research.va.gov

"I used to be a femoral first operator because I wasn't that experienced with doing radials. But now, you know, I'm looking at everybody, but again, **I'm not a radial first operator** , I don't look at people and say that I'm going to do radial first and then switch over to femoral for every case." – (cardiologist, 6-mo)

Main trial findings

- Coaching strategy did not increase TRA implementation for diagnostic catheterizations or PCIs
  - Associated with significant decline in TRA in the as-treated analysis
- Strong secular trend
  - Several participating sites exhibited high rates of TRA at baseline
  - Non-participating eligible sites made substantial increases to TRA

Why did sites regress?

"There was one operator in particular, I look at cases at the end of every week and I noticed him, he did several leg cases, I couldn't figure out why, because they weren't valve cases, they were graft cases, **I wondered in the period of time of [month] and [month] if he was sliding a little bit,** but I've not noticed that recently." – (cardiologist, 6-mo)

Why did sites regress?

Veterans Health Administration
R&D
www.research.va.gov

"Since we spoke last it increased, but I will admit that we hired on a new physician and there's been a little bit of a learning curve because he isn't as familiar with doing the radial approach. (…) I would say we're doing more like 75%, 80%, after you all had left, but we have reached more of a decline recently. Because he got hired on in basically [month] and has been ramping up, he's more familiar with the femoral approach." – (nurse, 6-mo)

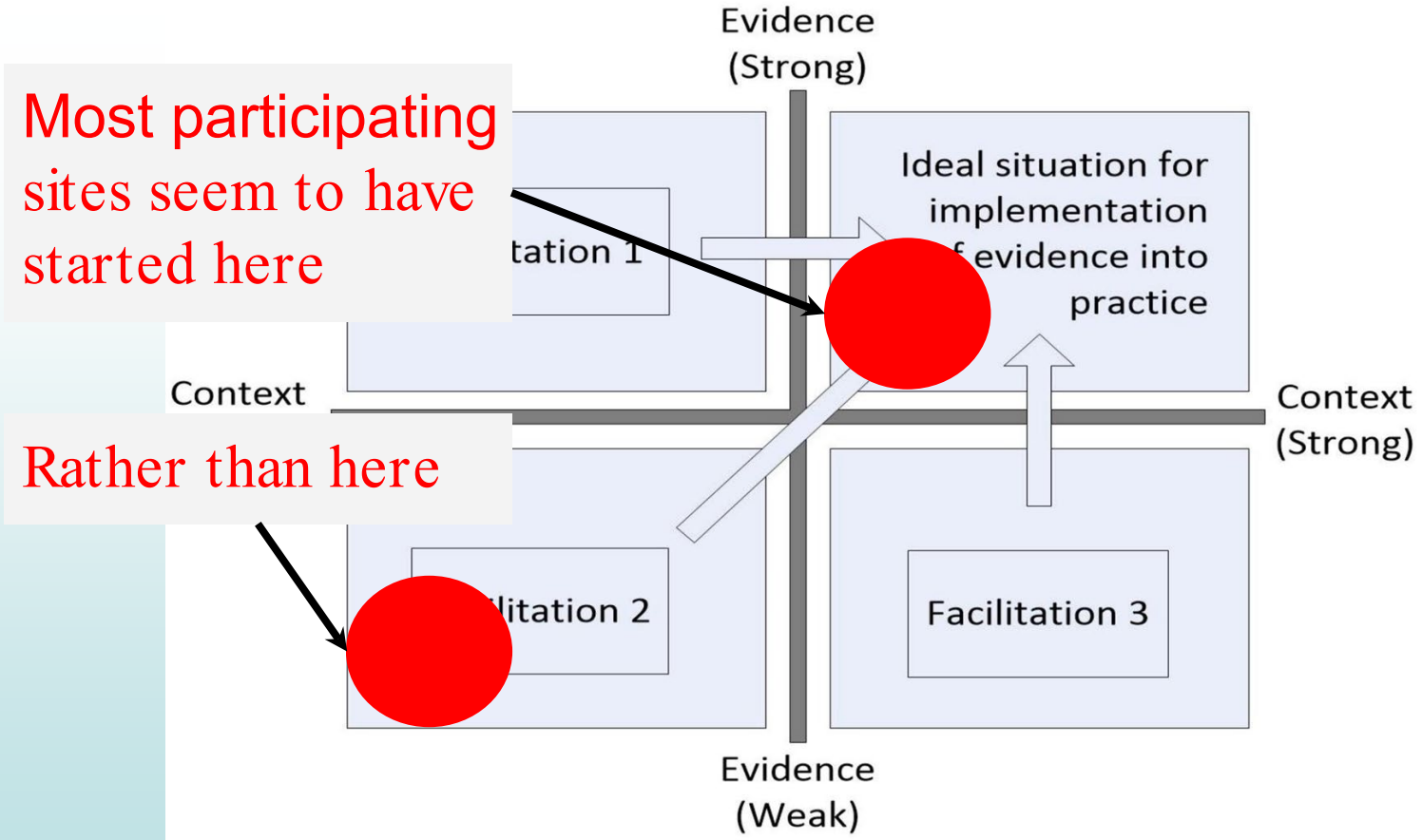
Veterans Health Administration

R&D

www.research.va.gov

Discussion

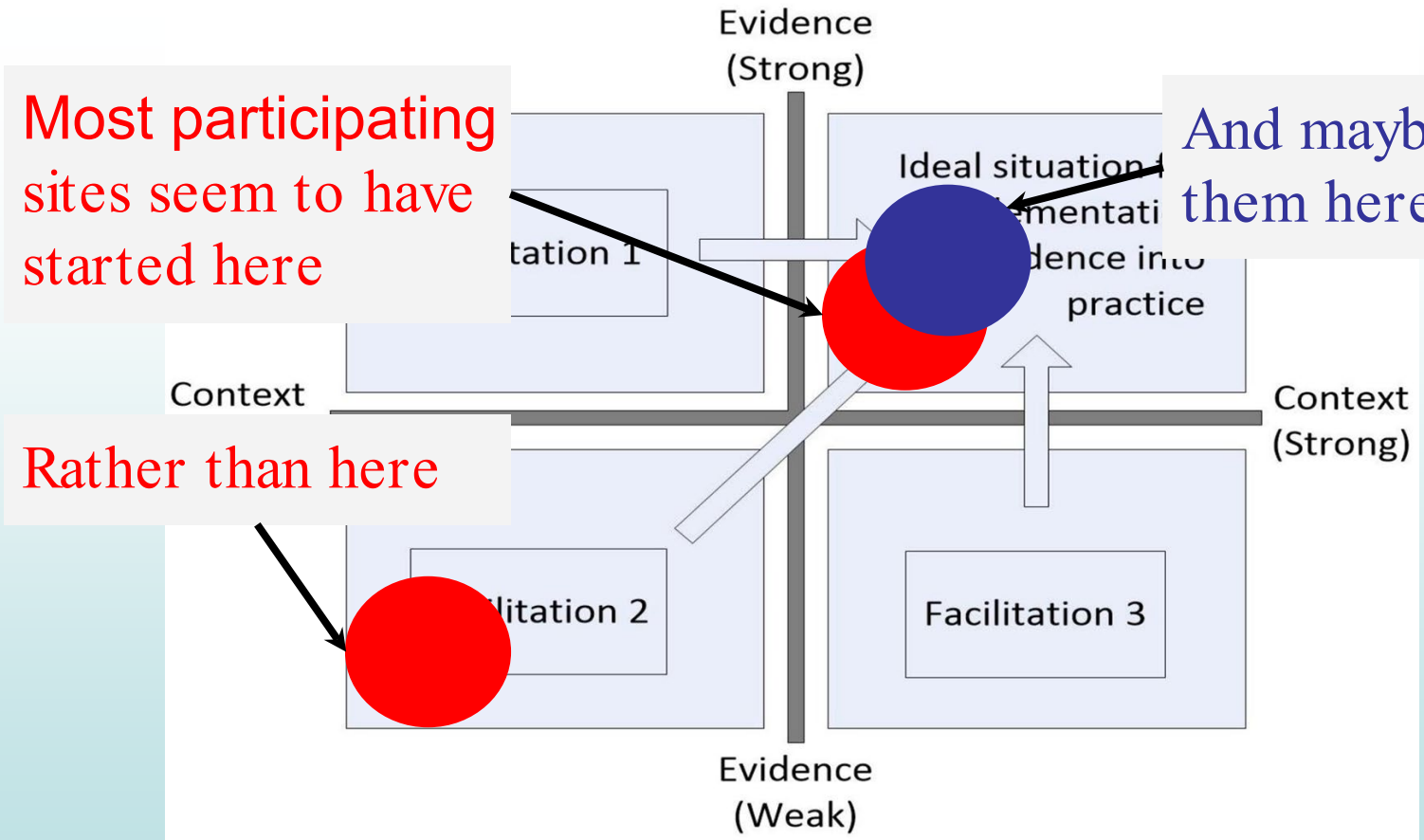
Discussion



F_1-F_3 = Facilitation tailored to teams' situation in terms of Evidence and Context

Source: Kitson *et al. Implementation Science* 2008 **3**:1 doi:10.1186/1748-5908-3-1

Discussion



F_1-F_3 = Facilitation tailored to teams' situation in terms of Evidence and Context

Source: Kitson *et al. Implementation Science* 2008 **3**:1 doi:10.1186/1748-5908-3-1

Discussion

- So limited change in evidence & context
- Selection bias likely
  - Probably inherent to this type of implementation trial
    - Limit to generalizability

Discussion - Context

- Context - Psychological safety
- Comfort ("you don't want to get in over your head") but not exactly psychological safety
  - Similar in sense of anxiety
  - Comfort about fearing negative outcomes, uncertainty about outcome
  - Psychological safety = fearing judgement of colleagues/supervisors

Discussion - Facilitation

- Stronger findings related to facilitation
  - Variety of specific learnings
    - Inferential: examples of mental models changing
  - Some indication of importance of timing & repetition (training followed by visit)

Limitations

- Response bias from declining interview participation 14/15 baseline 8/15 at 6mo
- Possible experimenter effect in interviews
  - E.g., self-censoring about where coaching failed to help
- Study exposure not delivered as planned
- Likely self-selection bias among those that enrolled, e.g., evidence, context

Conclusions

- Coaching intervention did not increase TRA implementation
  - Little to suggest effect on evidence or context, but may be due to type of site that enrolled
- Interesting/perplexing examples of concrete learning - negative trial in spite of evidence that type of learning occurred we hoped for

Veterans Health Administration

R&D

www.research.va.gov

Thank you!

Questions?

References

Ball, W. T., Sharieff, W., Jolly, S. S., Hong, T., Kutryk, M. J., Graham, J. J., ... & Cheema, A. N. (2011). Characterization of the learning curve for transradial coronary interventions. *Circulation: Cardiovascular Interventions*, *4*(4), 336-341.

Barbash, I. M., Gallino, R., Lager, R., Badr, S., Loh, J. P., Kitabata, H., ... & Waksman, R. (2014). Operator learning curve for transradial percutaneous coronary interventions: implications for the initiation of a transradial access program in an established practice. *Cardiovascular Revascularization Medicine*, *15*(4), 195-199.

Basavarajaiah, S., Brown, A., Naganuma, T., Gajendragadkar, P., McCormick, L., & West, N. (2018). Should technical difficulties discourage operators from embarking on transradial access for percutaneous coronary intervention?. *Journal of Invasive Cardiology*, *30*(3), 341-7.

Beaver, K., Naranjo, D., Doll, J., Maynard, C., Taylor, L., Plomondon, M., ... & Rao, S. V. (2021). Design and baseline results of a cluster randomized controlled trial of a multifaceted coaching intervention for implementation of transradial access in percutaneous coronary intervention. *Contemporary Clinical Trials*, *111*, 106606.

Berta, W., Cranley, L., Dearing, J. W., Dogherty, E. J., Squires, J. E., & Estabrooks, C. A. (2015). Why (we think) facilitation works: insights from organizational learning theory during a knowledge implementation intervention. *Implementation Science*, *10*(1), 1-13.

Bertrand OF, Bélisle P, Joyal D, et al. Comparison of transradial and femoral approaches for percutaneous coronary interventions: a systematic review and hierarchical Bayesian network meta-analysis. *Am Heart J*. 2012;163(4):632-648.

Brown, C. H., Curran, G., Palinkas, L. A., Aarons, G. A., Wells, K. B., Jones, L., ... & Cruden, G. (2017). An overview of research and evaluation designs for dissemination and implementation. *Annual review of public health*, *38*, 1-22.

Brown CA, Lilford RJ. The stepped wedge trial design: a systematic review. *BMC Med Res Methodol*. 2006;6(1):54.

Brown ER, Davidson PL, Yu H, et al. Effects of community factors on access to ambulatory care for low-income adults in large urban communities. *Inquiry*. 2004;41(1):35-56. doi:10.5034/inquiryjrnl_41.1.39

Cooper CJ, El-Shiekh RA, Cohen DJ, et al. Effect of transradial access on quality of life and cost of cardiac catheterization: a randomized comparison. *Am Heart J*. 1999;138(3):430-436.

Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. 2012;50(3):217.

Elgharib NZ, Shah UH, Coppola JT. Transradial cardiac catheterization and percutaneous coronary intervention. *Coron Artery Dis*. 2009;20(8):487-493.

Ericsson, K. A., & Smith, J. (Eds.). (1991). *Toward a general theory of expertise: Prospects and limits*. Cambridge University Press.

Goldberg SL, Renslo R, Sinow R, French WJ. Learning curve in the use of the radial artery as vascular access in the performance of percutaneous transluminal coronary angioplasty. *Cathet Cardiovasc Diagn*. 1998;44(2):147-152.

Grimshaw J, Campbell M, Eccles M, Steen N. Experimental and quasi-experimental designs for evaluating guideline implementation strategies. *Family Practice*. 2000. 1;17(suppl 1): S11-6.

Harvey, G. and Kitson, A., 2015. PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. *Implementation science*, *11*(1), pp.1-13.

Helfrich, C. D., Tsai, T. T., Rao, S. V., Lemon, J. M., Eugenio, E. C., Vidovich, M. I., ... & Bryson, C. L. (2014). Perceptions of advantages and barriers to radial-access percutaneous coronary intervention in VA cardiac catheterization laboratories. *Cardiovascular Revascularization Medicine*, *15*(6-7), 329-333.

Hemming, K., Taljaard, M., McKenzie, J. E., Hooper, R., Copas, A., Thompson, J. A., ... & Grimshaw, J. M. (2019). Reporting of stepped wedge cluster randomised trials: extension of the CONSORT 2010 statement with explanation and elaboration. *BMJ*, *363*.

Hemming, Karla, and Monica Taljaard. "Reflection on modern methods: when is a stepped-wedge cluster randomized trial a good study design choice?." *International journal of epidemiology* 49, no. 3 (2020): 1043-1052.

Hess, C. N., Peterson, E. D., Neely, M. L., Dai, D., Hillegass, W. B., Krucoff, M. W., ... & Rao, S. V. (2014). The learning curve for transradial percutaneous coronary intervention among operators in the United States: a study from the National Cardiovascular Data Registry. *Circulation*, *129*(22), 2277-2286.

Hillegass, William B. "The many radial access learning curves." Catheterization and Cardiovascular Interventions: Official Journal of the Society for Cardiac Angiography & Interventions 89.5 (2017): 865-866.

Hooper R, Eldridge SM. Cutting edge or blunt instrument: how to decide if a stepped wedge design is right for you. BMJ Qual Saf 2020. doi:10.1136/bmjqs-2020-011620

Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials*. 2007;28(2):182-191.

Kitson, A. L., Rycroft-Malone, J., Harvey, G., McCormack, B., Seers, K., & Titchen, A. (2008). Evaluating the successful implementation of evidence into practice using the PARiHS framework: theoretical and practical challenges. *Implementation science*, *3*(1), 1-12.

Louvard Y, Lefèvre T, Morice M. Radial approach: what about the learning curve? *Cathet Cardiovasc Diagn*. 1997;42(4):467.

Maclure M, Carleton B, Schneeweiss S. Designed delays versus rigorous pragmatic trials: lower carat gold standards can produce relevant drug evaluations. *Med Care*. 2007;45(10):S44-S49.

Maddox TM, Plomondon ME, Petrich M, et al. A national clinical quality program for veterans affairs catheterization laboratories (from the veterans affairs clinical assessment, reporting, and tracking program). *Am J Cardiol*. 2014. doi:10.1016/j.amjcard.2014.08.045

Maynard, C., Bradley, S. M., & Bryson, C. L. (2013). The practice of transradial percutaneous coronary intervention in the Washington State Clinical Outcomes Assessment Program. *American Heart Journal*, *165*(3), 332-337.

Mazzucca, S., Tabak, R. G., Pilar, M., Ramsey, A. T., Baumann, A. A., Kryzer, E., ... & Brownson, R. C. (2018). Variation in research designs used to test the effectiveness of dissemination and implementation strategies: a review. *Frontiers in public health*, *6*, 32.

Rao S V, Cohen MG, Kandzari DE, Bertrand OF, Gilchrist IC. The transradial approach to percutaneous coronary intervention: historical perspective, current concepts, and future directions. *J Am Coll Cardiol*. 2010;55(20):2187-2195.

Rao, Sunil V., Jennifer A. Tremmel, Ian C. Gilchrist, Pinak B. Shah, Rajiv Gulati, Adhir R. Shroff, Van Crisco et al. "Best practices for transradial angiography and intervention: a consensus statement from the society for cardiovascular angiography and intervention's transradial working group." *Catheterization and Cardiovascular Interventions* 83, no. 2 (2014): 228-236.

Rosenthal, R. (2009). Interpersonal expectations: Effects of the experimenter's hypothesis. Artifacts in behavioral research, 138-210.

Spillane, Valerie, Mary C. Byrne, Molly Byrne, Claire S. Leathem, Mary O'Malley, and Margaret E. Cupples. "Monitoring treatment fidelity in a randomized controlled trial of a complex intervention." *Journal of advanced nursing* 60, no. 3 (2007): 343-352.

Stetler CB, Legro MW, Rycroft-Malone J, et al. Role of" external facilitation" in implementation of research findings: a qualitative evaluation of facilitation experiences in the Veterans Health Administration. *Implement Sci*. 2006a;1(1):23.

Stetler CB, Legro MW, Wallace CM, et al. The role of formative evaluation in implementation research and the QUERI experience. *J Gen Intern Med*. 2006b;21(2):S1.

Stolker JM, Hadid M, Hussain ZM, et al. Training the next generation of invasive cardiologists: Feasibility of implementing a trans-radial access program at an academic hospital. *Cardiovasc Revascularization Med*. 2016;17(7):431-437.

Traynor O. Surgical training in an era of reduced working hours. *Surg J R Coll Surg Edinburgh Irel*. 2011;9:S1.

Tremmel JA. Launching a successful transradial program. *J Invasive Cardiol*. 2009;21(8 Suppl A):3A-10A.

Valle, Javier A., et al. "Variation in the adoption of transradial access for ST-segment elevation myocardial infarction: insights from the NCDR CathPCI Registry." JACC: Cardiovascular Interventions 10.22 (2017): 2242-2254.

Waldo SW, Gokhale M, O'Donnell CI, et al. Temporal Trends in Coronary Angiography and Percutaneous Coronary Intervention: Insights From the VA Clinical Assessment, Reporting, and Tracking Program. *JACC Cardiovasc Interv*. 2018. doi:10.1016/j.jcin.2018.02.035

Wallace CM, Legro MW. Using formative evaluation in an implementation project to increase vaccination rates in high-risk veterans: QUERI series. *Implement Sci*. 2008;3(1):22.

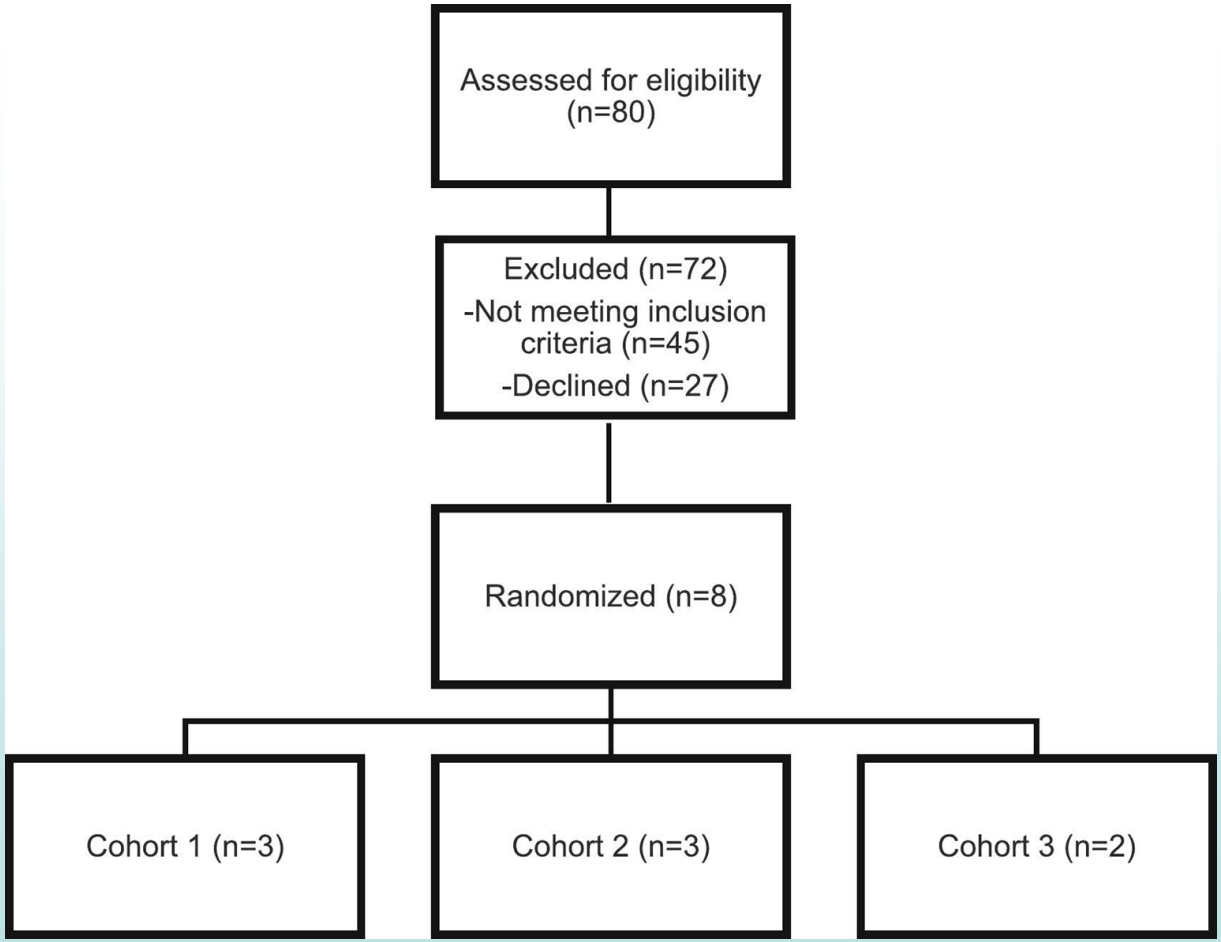
Extra slides

i-PARIHS context

Context

- Resources
- Culture
- Leadership
- Orientation to evaluation & learning
- Broader policy environment

Recruitment



Source: Beaver et al 2021

Baseline

Facility level	Cohort 1 (*n* = 3)	Cohort 2 (n = 3)	Cohort 3 (n = 2)
Facility bed size (mean, SD)	93.6 (48.0)	180.7 (83.5)	135 (96.2)
Diagnostic case volume (mean, SD)	559.3 (133.5)	500.3 (315.2)	685 (311.1)
% TRA (mean, min-max)	**42.0%** (13.5%–64.2%)	**25.4%** (14.5%–38.5%)	**32.2%** (14.0%–50.3%)
PCI volume (mean, SD)	241.3 (62.2)	154.7 (145.6)	267.5 (224.2)
% TRA (mean, min-max)	**31.3%** (12.6%–43.7%)	**28.3%** (22.6%–34.0%)	**25.3%** (7.5%–4.3%)

Source: Beaver et al 2021

Validity & Prediction

Veterans Health Administration
R&D
www.research.va.gov

Complexity & Prediction

Veterans Health Administration
R&D
www.research.va.gov

- Weather as metaphor
  - Complex, dynamic systems
    - Recursive loops, non-linearity
    - Small differences in initial conditions lead to wildly different outcomes
      - Butterfly effect
- Stock market as metaphor
  - Dynamic systems that react
    - E.g., Goodhart's Law

Published Results

- **Protocol paper with baseline findings**

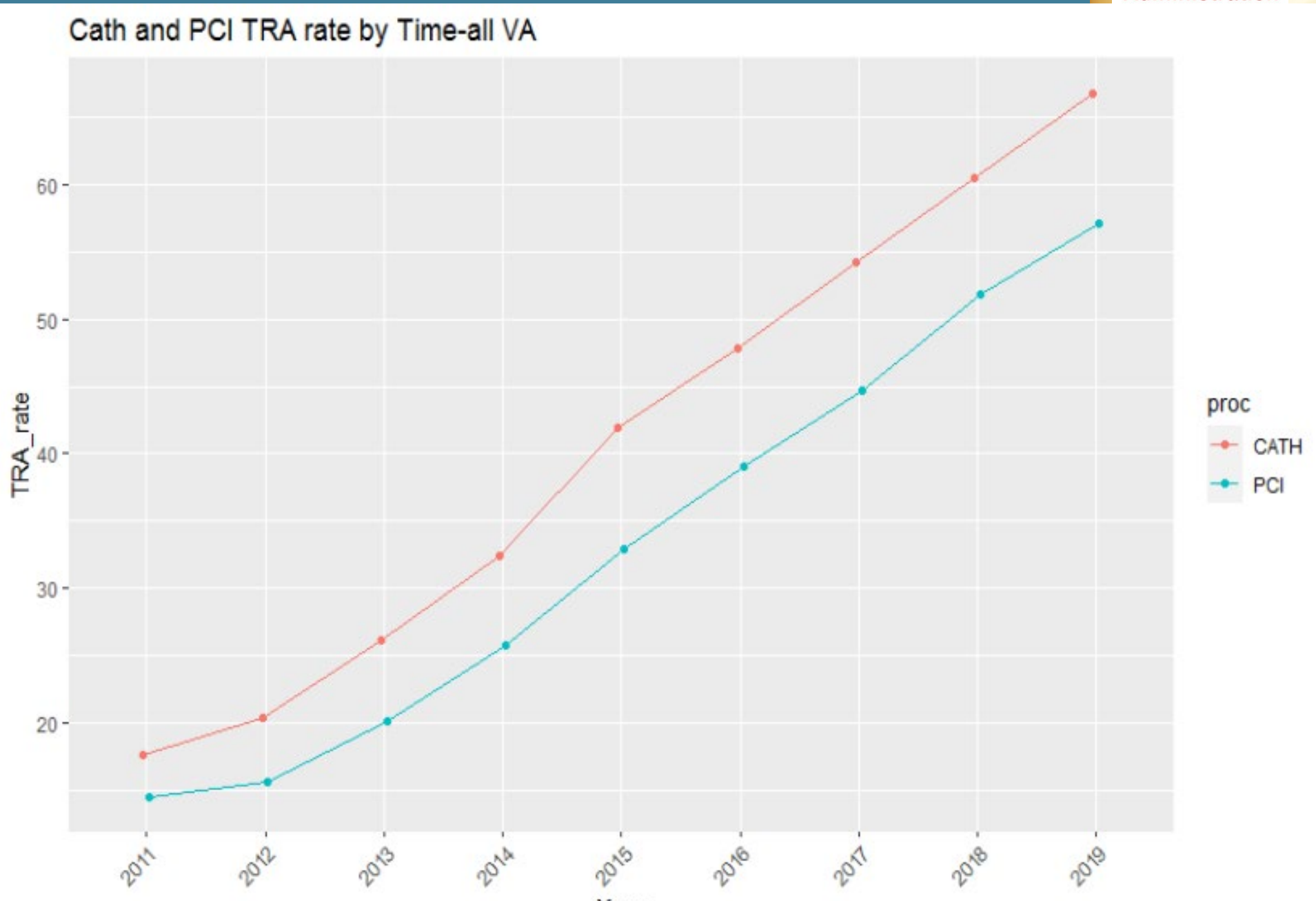
  Beaver, K., Naranjo, D., Doll, J., Maynard, C., Taylor, L., Plomondon, M., ... & Rao, S. V. (2021). Design and baseline results of a coaching intervention for implementation of trans-radial access in percutaneous coronary intervention. *Contemporary Clinical Trials*, *111*, 106606. https://doi.org/10.1016/j.cct.2021.106606

- **Cost analysis of coaching intervention**

  Duan, K. I., Helfrich, C. D., Rao, S. V., Neely, E. L., Sulc, C. A., Naranjo, D., & Wong, E. S. (2021). Cost analysis of a coaching intervention to increase use of transradial percutaneous coronary intervention. *Implementation science communications*, *2*(1), 1-11. https://doi.org/10.1186/s43058-021-00219-5

- **Comparison of bleeding complications for TRA vs TFA across VA over time**

  Doll, J. A., Beaver, K., Naranjo, D., Waldo, S. W., Maynard, C., Helfrich, C. D., & Rao, S. V. (2022). Trends in Arterial Access Site Selection and Bleeding Outcomes Following Coronary Procedures, 2012-2018. *Circulation: Cardiovascular Quality and Outcomes*, CIRCOUTCOMES-121. DOI: 10.1161/CIRCOUTCOMES.121.008359


Cath and PCI TRA rate by Time-all VA
TRA_rate
60
50
40
30
20
2011
2012
2013
2014
2015
2016
2017
2018
2019
proc
CATH
PCI

Risk paradox

- Bleeding complications ~ 2% of cases (Rao et al 2008)
  - Scary for patients
  - Costly: hospital stay, transfusions
  - Primarily related to access site (radial vs. femoral)
- Radial access = 50%-70% lower complications (Rao et al, 2010)
  - Benefit greater for women (Maynard et al, 2013)

Logistical problems

- Of 8 randomized sites:
  - 3 withdrew due to turnover (2 from Cohort Two, 1 from Cohort Three)
  - 1 violated randomization (reschedule)
- Two sites were enrolled late & non-randomly assigned to rescheduled Cohort 2 (8/2019) and Cohort 3 (4/2019)

Logistical problems

- Coaching site unable to deliver two planned components
  - TRA simulator
  - Education credits

Logistical problems

- Cohort 2 (12/2018)
  - Two sites withdrew citing turnover
  - Third site didn't receive travel authorization until week before training & site declined to attend
    - Remained in study & rescheduled to August 2019, held in Durham
- Cohort 3 (4/2019)
  - One of the two sites withdrew citing turnover

Formative Evaluation

- Based on formative evaluation, two changes to in-person training after Cohort One:
  - Addition of training on ultrasound to guide access;
  - Example materials requested by nurses & technicians, e.g., example nursing note; example same-day discharge procedure
- No further revisions to coaching

As-Treated (n=5)

Type	Intervention Period	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Diagnostic	5-8 months post	1.09 (0.81-1.47)	1.11 (0.82-1.52) †
	9-12 months post	0.84 (0.69-1.01)	0.83 (0.68-1.01) †
PCI	5-8 months post	0.99 (0.66-1.40)	0.95 (0.62-1.43) ‡
	9-12 months post	0.71 (0.54-0.93)	0.71 (0.54-0.94) ‡

† Adjusted for patient's sex, age, race, CKD, PAD, and procedure status
‡ Adjusted for patient's sex, age, race, and procedure status

Secular trend

- Among 25 eligible non-participating sites, TRA rates for DX catheterizations
  - 42.9% equivalent pre,
  - 45.2% equivalent to 5-8 months post
  - 50.0% equivalent 9-12 months post
- TRA rates for PCI
  - 36.8% equivalent pre
  - 37.6% equivalent to 5-8 months post
  - 41.9% in equivalent 9-12 months post

Prior survey (Helfrich et al 2014)

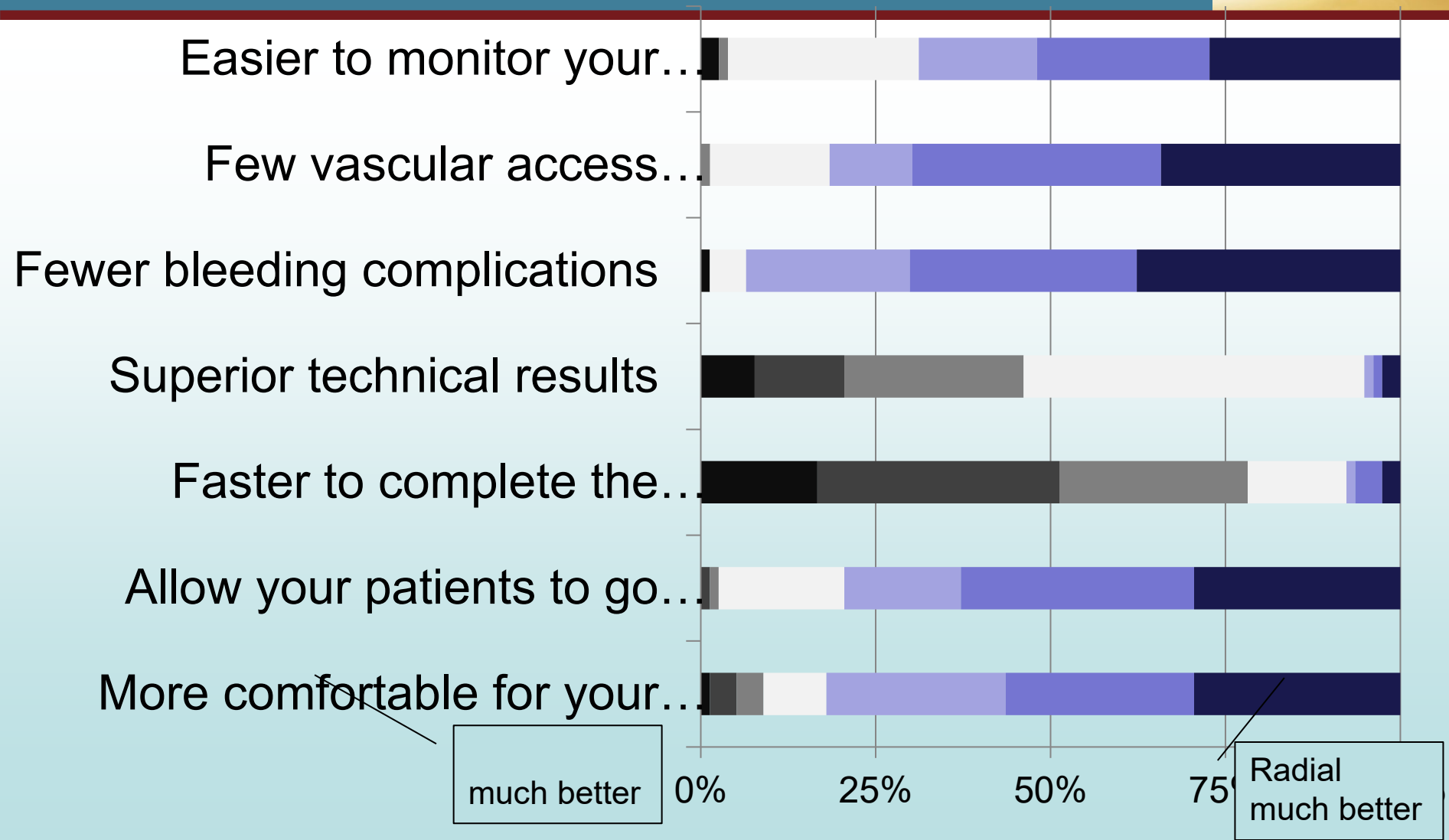
National survey of VA cardiologists

Survey

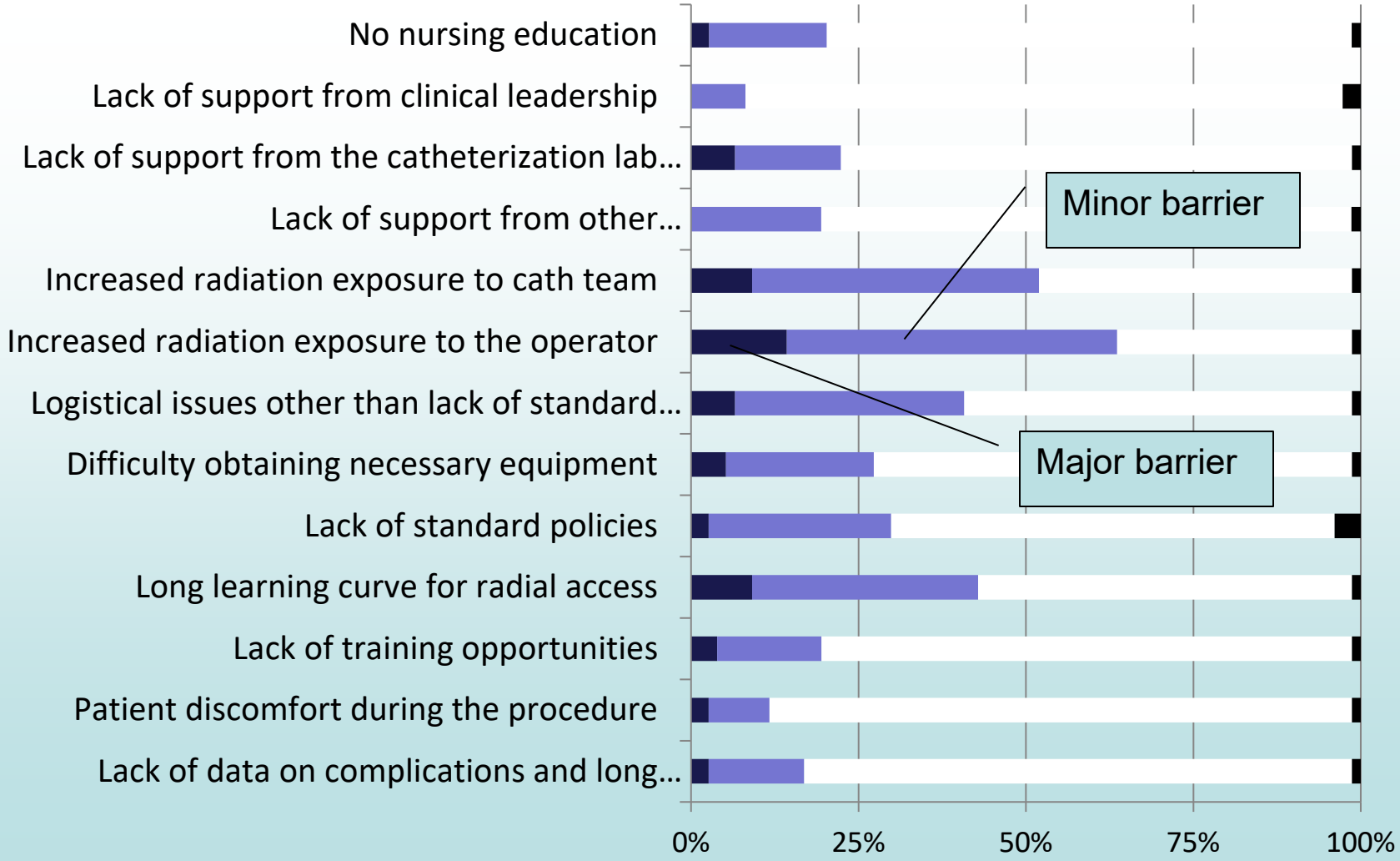
- Content developed from interviews:
  - Perceptions of rPCI vs. fPCI
  - Barriers to rPCI
  - Current use, experience w/ training
- Interventionalists identified via CART
  - 79 of 235 completed survey (33.6% response rate)
  - 48 of 66 cath labs (73%)

Perceptions of rPCI vs. fPCI

Veterans Health Administration
R&D
www.research.va.gov



Barriers to rPCI



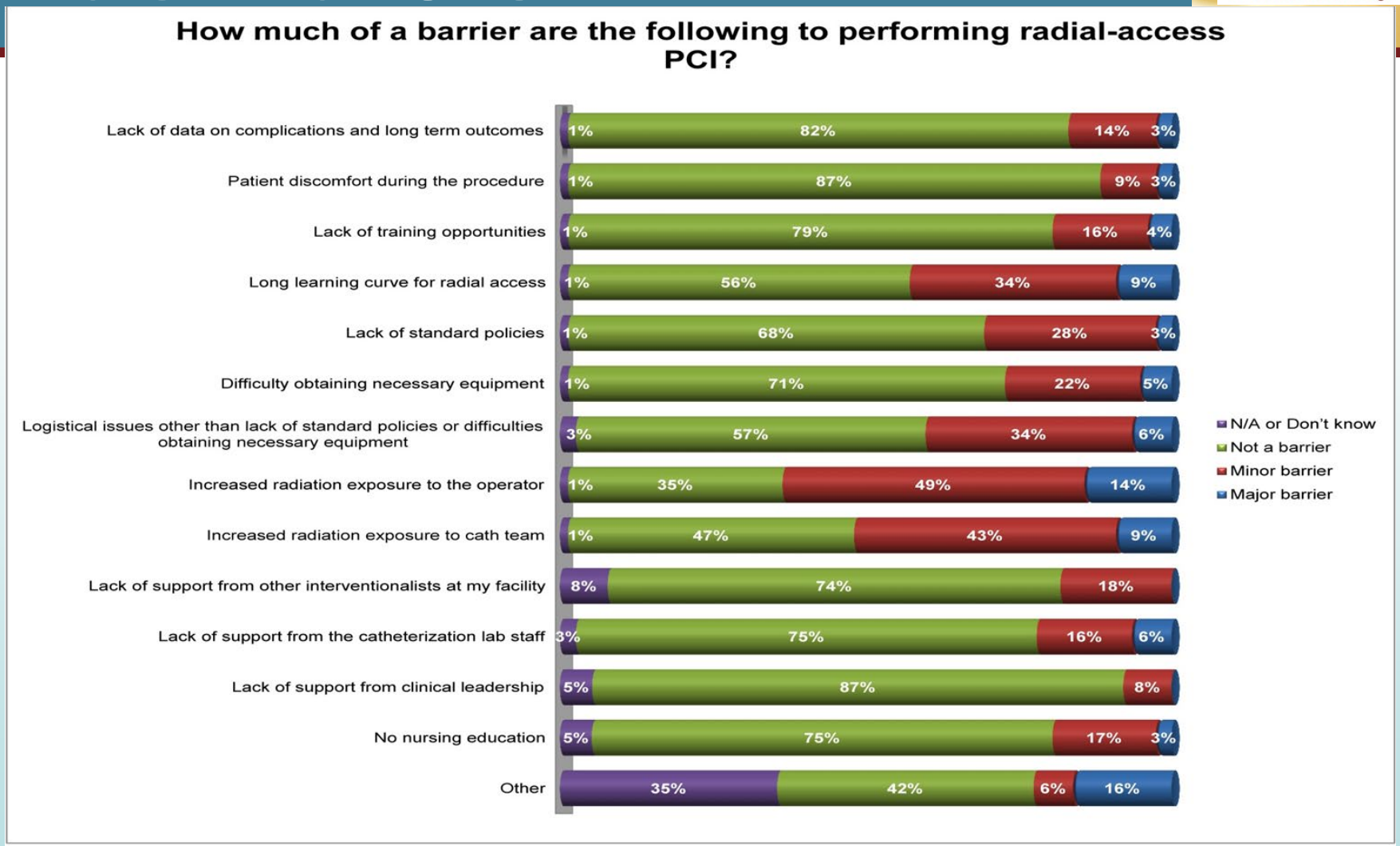
Site visit debrief & post-training interviews

Veterans Health Administration
R&D
www.research.va.gov

- Reverse site visit (Chicago training)
  - Addressed concerns over evidence for rPCI
  - Increased confidence among cath team members
- Site visit by trainers
  - Addressed un-recognized barriers
    - Arm board placement; radiation safety
    - rPCI-specific equipment; patient comfort
    - Dealing w/ arterial spasms; dealing w/ trouble
- Unclear if practice has changed as a result

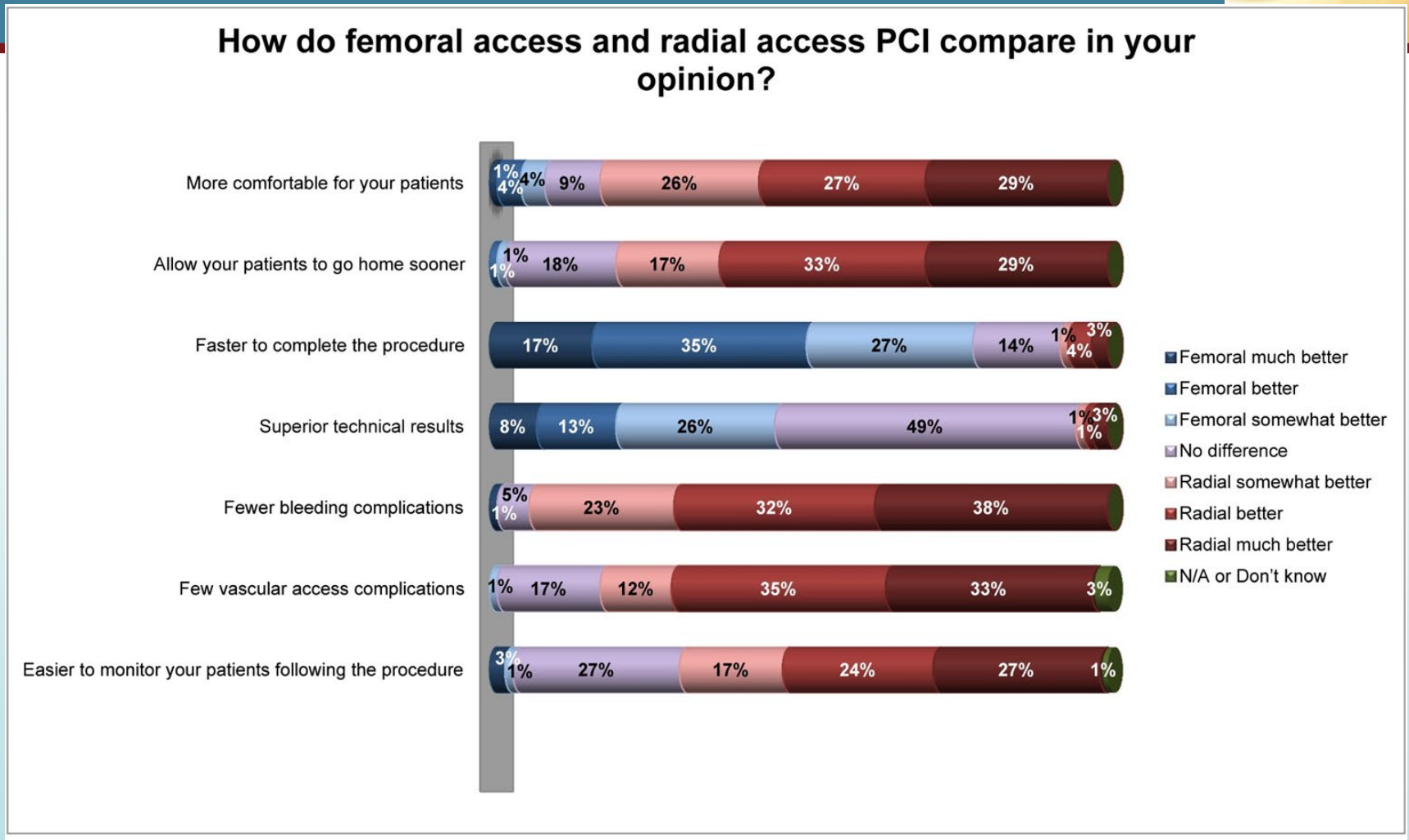
rPCI Barriers and Facilitators

Veterans Health Administration
R&D
www.research.va.gov



rPCI versus fPCI

Veterans Health Administration
R&D
www.research.va.gov



What proportion of your PCIs are the result of diagnostic caths that get converted ad hoc?