CITY
UNIVERSITY OF LONDON
EST 1894

Academic excellence for
business and the professions

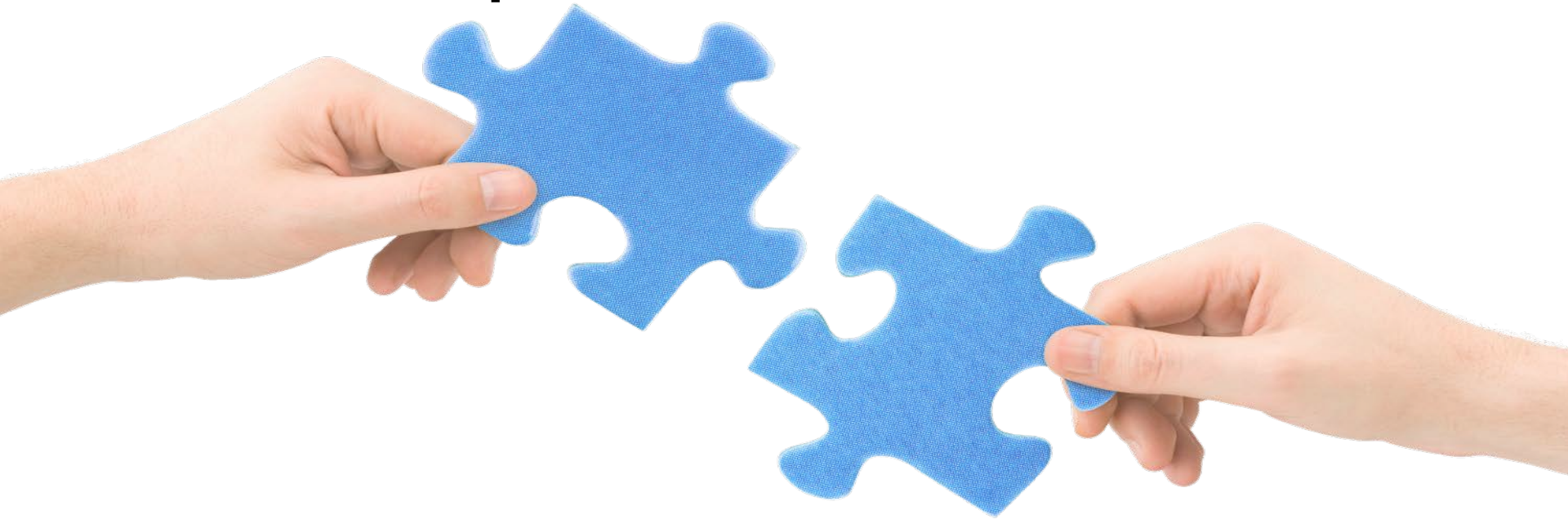
Fidelity and Implementation Science

Dr. Fabiana Lorencatto
Health Services Research, School of Health Sciences
Implementation Science in Health Research: IMPRNT Workshop
19.06.2016, NUI Galway

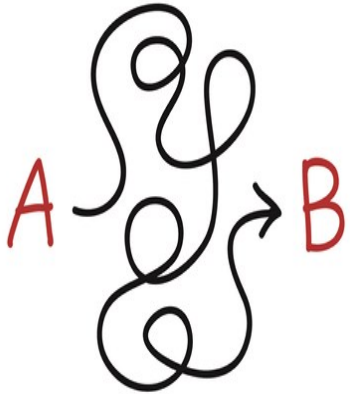
This talk….

- What is fidelity and why is it important?
- What do we know about fidelity?
- Example of a multidimensional fidelity assessment: the AFFINITIE program
- Challenges/future directions

What is fidelity and why is it important to Implementation Science?

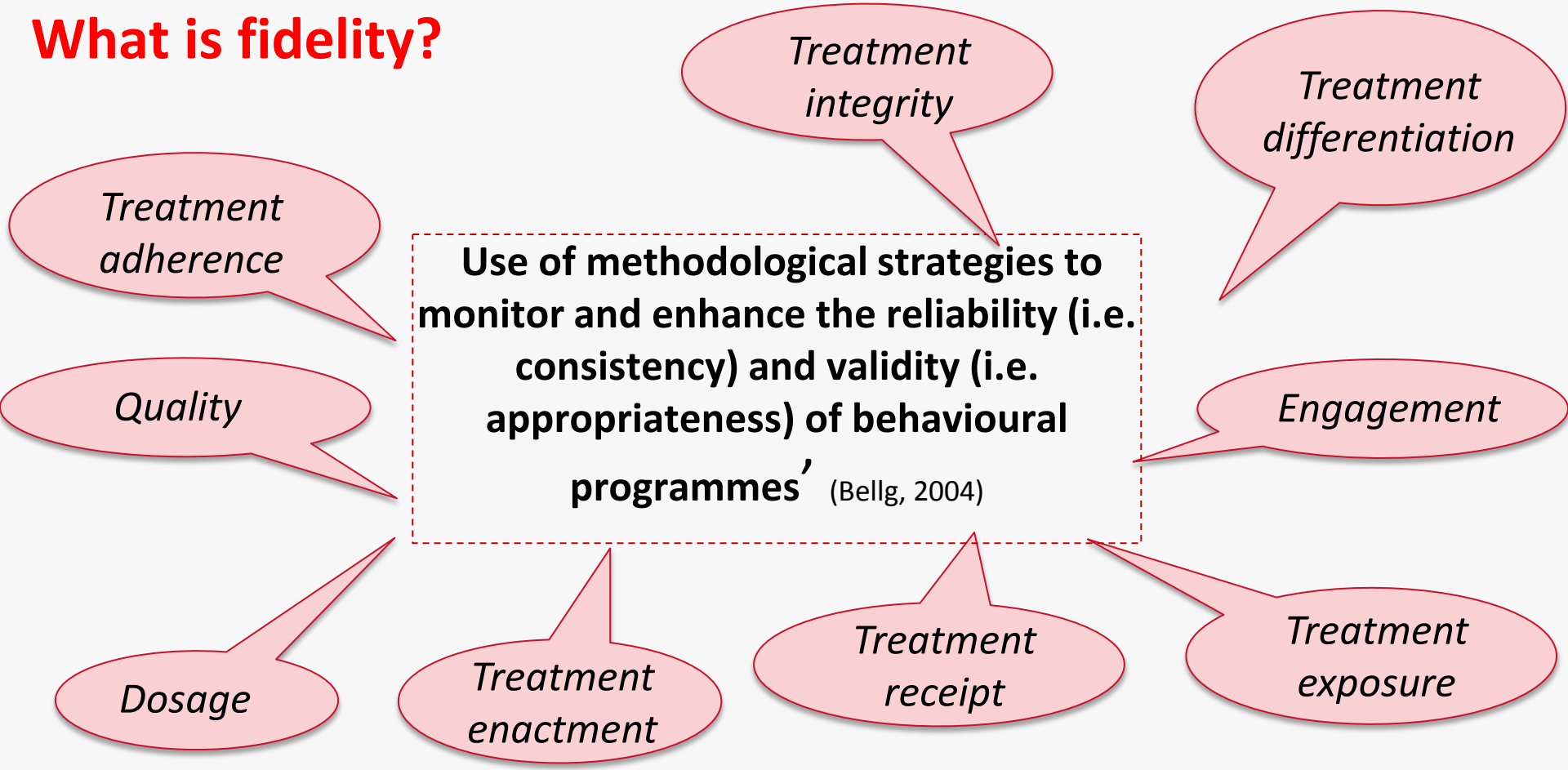



IMPLEMENTATION
EVIDENCE
PRACTICE

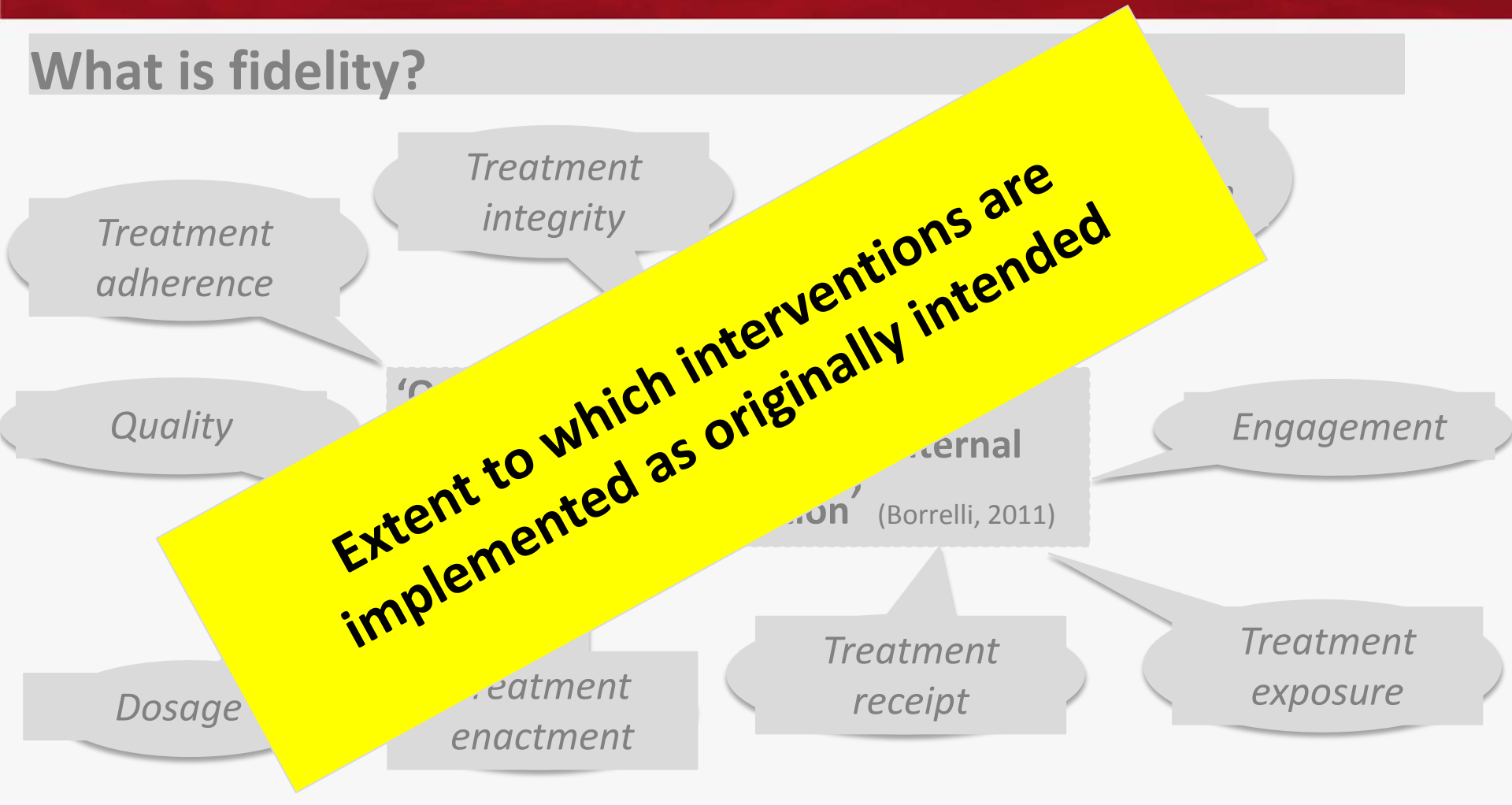


- Interventions delivered across multiple sites, by multiple providers to multiple recipients….
- Difficult, *impossible*, to ensure consistency in implementation!
- **Fidelity = understanding and measuring (in)consistency in implementation**

What is fidelity?



What is fidelity?



Why is it important to measure fidelity?

- Identify **deviations** and **inconsistencies** in implementation
- Increase **scientific confidence**/ accurately **interpret outcomes**

(i.e. reduce risk of Type III errors)

- Enhance **theoretical understanding** as to how interventions 'work'
- Identify **training needs** + areas for **improvement**
- Inform **feasibility** of intervention, **replication**, **scalability**


IMPLEMENTATION SCIENCE
FIDELITY

How should we measure fidelity?

- Various fidelity models to date
- Consensus: Fidelity = **multidimensional,** relevant at intervention designer, provider, recipient levels
- Differ in number + nature of dimensions argued to represent fidelity, + recommended assessment strategies.

NIH **BCC Fidelity Framework**

-Synthesises existing fidelity models/frameworks

-Comprehensive fidelity framework tailored to health behaviour change trials

-Best practice recommendations + guidelines for **assessing, monitoring, enhancing** fidelity across five dimensions

Health Psychology
2004, Vol. 23, No. 5, 443–451

0278-6133/04/$12.00 DOI: 10.1037/0278-6133.23.5.443

Enhancing Treatment Fidelity in Health Behavior Change Studies: Best Practices and Recommendations From the NIH Behavior Change Consortium

Albert J. Bellg
Appleton Heart Institute

Belinda Borrelli
Brown Medical School

Barbara Resnick
University of Maryland

Jacki Hecht
Brown Medical School

Daryl Sharp Minicucci
University of Rochester

Marcia Ory
National Institutes of Health

Gbenga Ogedegbe
Cornell University

Denise Orwig
University of Maryland

Denise Ernst
University of New Mexico

Susan Czajkowski
National Institutes of Health

(For the Treatment Fidelity Workgroup of the NIH Behavior Change Consortium)

Fidelity elements	Questions
Design	• Operationalise the underlying **theory**? • Intervention **specified** in detail (i.e. conten • Treatment **differentiation**
Training	• Providers **acquire + maintai** • **Training** standardise
Delivery	• **Provider** • If **alysis?**
Recei	**stand** intervention? **ed** during intervention?
Enactment	**ts actually use** behaviours/skills/cognitive strategies developed **l-life settings**?

Important to assess fidelity across all five dimensions!

What do we know about fidelity?

1. Fidelity is **under-evaluated and reported** (MRC complex intervention guidance, 2008)

2. Where fidelity has been measured, **almost always shown to be poor** (i.e. **50%** delivery) (Hardeman et al. 2008; Lorencatto et al. 2013, Lorencatto et al. 2014)

3. **Not comprehensively assessed:** n=342 studies, 10 year period, 5 key behaviour change research journals → **54% reported no strategies to assess fidelity!**

- **Not improving over time:** Review of 17 fidelity evaluations of smoking cessation behaviour change interventions (Lorencatto & Yada, *Under review*)
  - Just **1 study assessed all five BCC fidelity dimensions**; Only **4 assessed +1**
  - Most frequent: Delivery **(94%);** Least frequent: Enactment **(6%);** Receipt (11%)
  - Just **1 study** based on a **fidelity model/framework**

Affinitie

NHS Blood and Transplant

- NHS Blood & Transplant (NHSBT)'s **National Comparative Audit Programme (NCA)**
- Runs national audits looking at **appropriate + safe use of main blood components** across clinical specialties
- High % unnecessary transfusions persist

AFFINITIE Programme structure:

Workstream 1 (WS1: Intervention development and piloting) [Months 1-24]
Development, **piloting** and **refinement** of two enhanced feedback interventions: 'enhanced *feedback reports*' and 'enhanced *follow on support*'

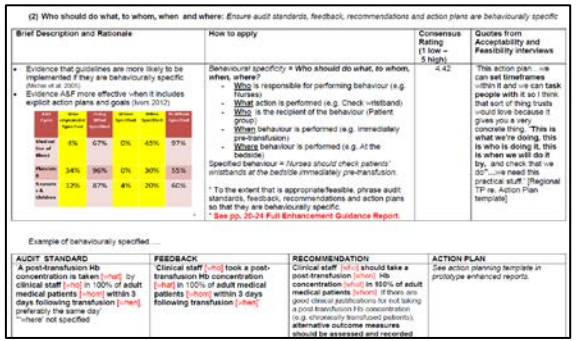
Workstream 2 (WS2: Evaluation) [Months 5-52]
Two, 2x2 Cluster-randomised trial to **evaluate effectiveness** of enhanced feedback interventions compared with usual feedback, with a decision analytic modelling analysis for **cost-effectiveness**

Workstream 3 (WS3: Fidelity) [Months 25-54]
Parallel process evaluation to investigate **fidelity** of interventions as **delivered, received, enacted**

Workstream 4 (WS4: Implementation) [Months 6-60]
Development of **general recommendations** and **tools**

Intervention 1 ‘enhanced CONTENT’

Enhancement guidance manual + template reports:
audit writing group

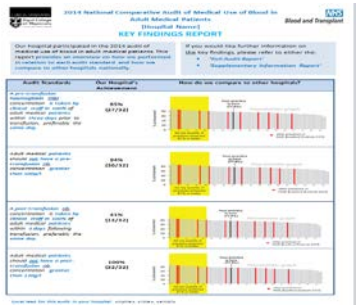


(2) Who should do what, to whom, when and where: *Ensure audit standards, feedback, recommendations and action plans are behaviourally specific*

Brief Description and Rationale	How to apply	Consensus Rating (1 low – 5 high)	Quotes from Acceptability and Feasibility interviews
• Evidence that guidelines are more likely to be implemented if they are behaviourally specific (Michie et al. 2009) • Evidence ASF more effective when it includes explicit action plans and goals (Ivers 2012)	*Behavioural specificity = Who should do what, to whom, when, where?* - Who is responsible for performing behaviour (e.g. Nurses) - What action is performed (e.g. Check wristband) - Who is the recipient of the behaviour (Patient group) - When behaviour is performed (e.g. immediately pre-transfusion) - Where behaviour is performed (e.g. At the bedside) Specified behaviour = *Nurses should check patients' wristbands at the bedside immediately pre-transfusion.* * To the extent that is appropriate/feasible, phrase audit standards, feedback, recommendations and action plans so that they are behaviourally specific. * See pp. 20-24 Full Enhancement Guidance Report.	4.42	This action plan …we can set timeframes …within it and we can task people with it, so I think that sort of thing trusts …would love because it gives you a very concrete thing. This is what we're doing, this is who is doing it, this is when we will do it by, and check that we do"…..we need this practical stuff." [Regional TF re. Action Plan template]

Example of behaviourally specified ….

AUDIT STANDARD	FEEDBACK	RECOMMENDATION	ACTION PLAN
A post-transfusion Hb concentration is taken [what] by clinical staff [who] in 100% of adult medical patients [where] within 3 days following transfusion [when] preferably the same day* *'where' not specified	Clinical staff [who] took a post-transfusion Hb concentration [what] in 100% of adult medical patients [where] within 3 days following transfusion [when]	Clinical staff [who] should take a post-transfusion [when] Hb concentration [what] in 100% of adult medical patients [where]. If there are good clinical justifications for not taking a post-transfusion Hb concentration (e.g. chronically transfused patients), alternative outcome measures should be assessed and recorded	See action planning template in prototype enhanced reports.



Enhanced feedback reports:
transfusion clinical staff

Intervention 2 ‘enhanced FOLLOW ON SUPPORT’

Web-Toolkit

Telephone Support

Fidelity elements	ASSESSMENT IN AFFINITIE
Design	• Specify interventions using **logic models, BCT Taxonomy, TIDieR reporting guidelines**→ publish in intervention development papers • **Expert consensus panel** review • Differentiation: **dose** of **BCTs** in Int 1 vs Int 2 vs control
Training	• Standardised **training manuals** and sessions • Int 1: Review **draft feedback reports** (verify BCT delivery) • Int 2: Content analysis **audio-recorded role play** telephone support scenarios (verify BCT delivery)
Delivery	• **Log** report/ toolkit **upload** + telephone support according to trial arm allocation • Int 1: **Content analysis** enhanced + standard **template feedback reports** (verify BCT delivery + additional components + ***contamination***) • Int 2: **Content analysis audio-recorded** telephone support **sessions** + web Toolkit (verify BCT delivery + additional components)

RECEIPT/ENACTMENT

- AFFINITIE: Can control delivery, not what hospitals do with interventions!

- BCC Checklist:
  - Assess participant **exposure** to intervention
  - **Understanding** of intervention
  - **Performance** of intervention skills in settings in which intervention might be applied

- **38-item questionnaire** all participating sites (n=174 Trial 1; n=164 Trial 2)
- **45 minute semi-structured interviews** with sub-sample (~12 sites, 36 participants per trial; n=72 total)
- Items + topic guide based on **Theoretical Domains Framework** (Michie et al. 2005)
- Assess **extent of implementation** of intervention….
- ….and range of **contextual barriers and enablers** to implementation

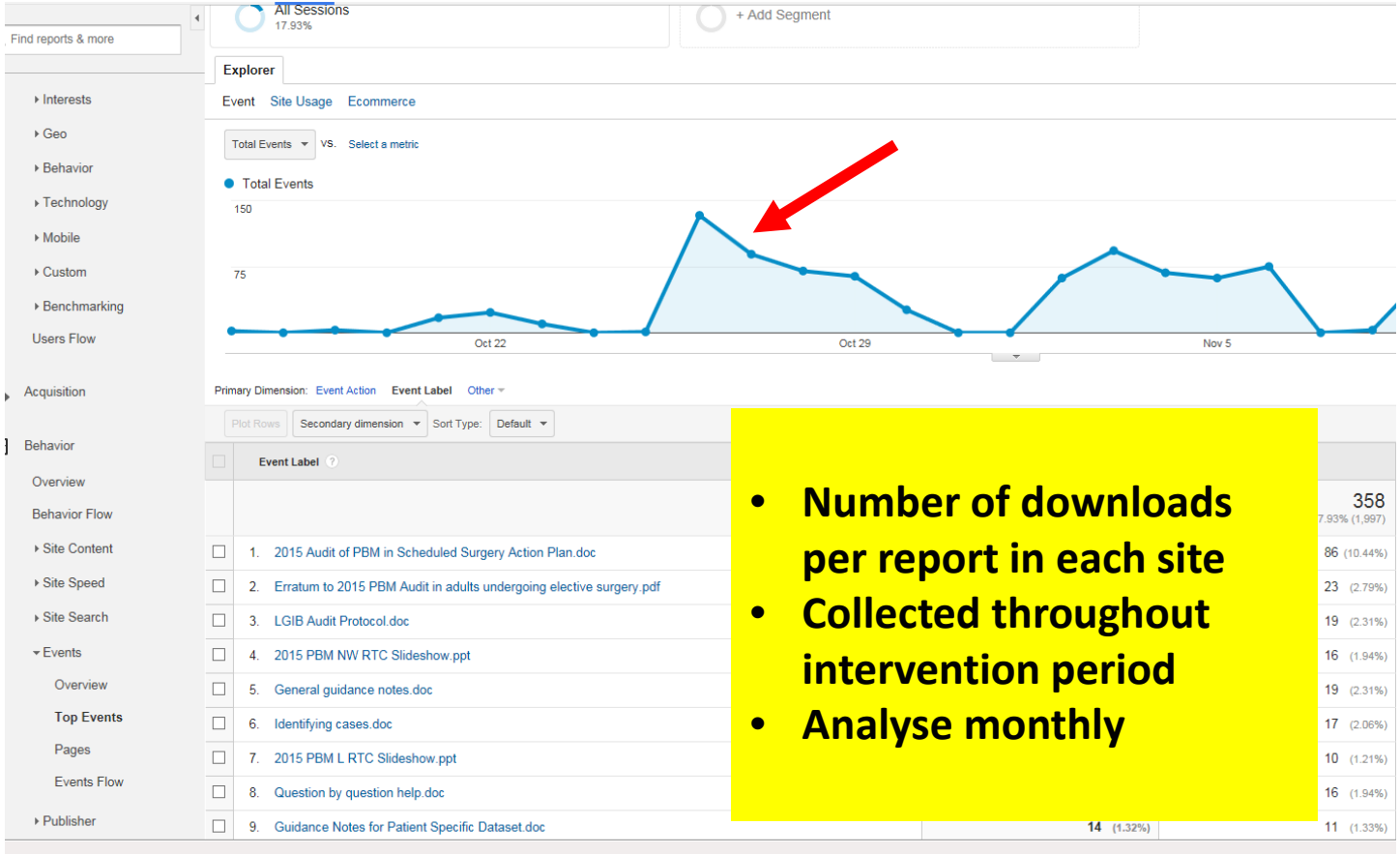
▪Do you think the feedback materials showed that your hospital was doing well in relation to the audit standards? *(UNDERSTANDING/RECEIPT)*

To what extent have any other policies or guidelines influenced your response to the audit? (BARRIERS/ENABLERS)

▪Which colleagues (if any) in your hospital did you share the feedback materials with? Any colleagues EXTERNAL to your hospital? (ENACTMENT/CONTAMINATION)

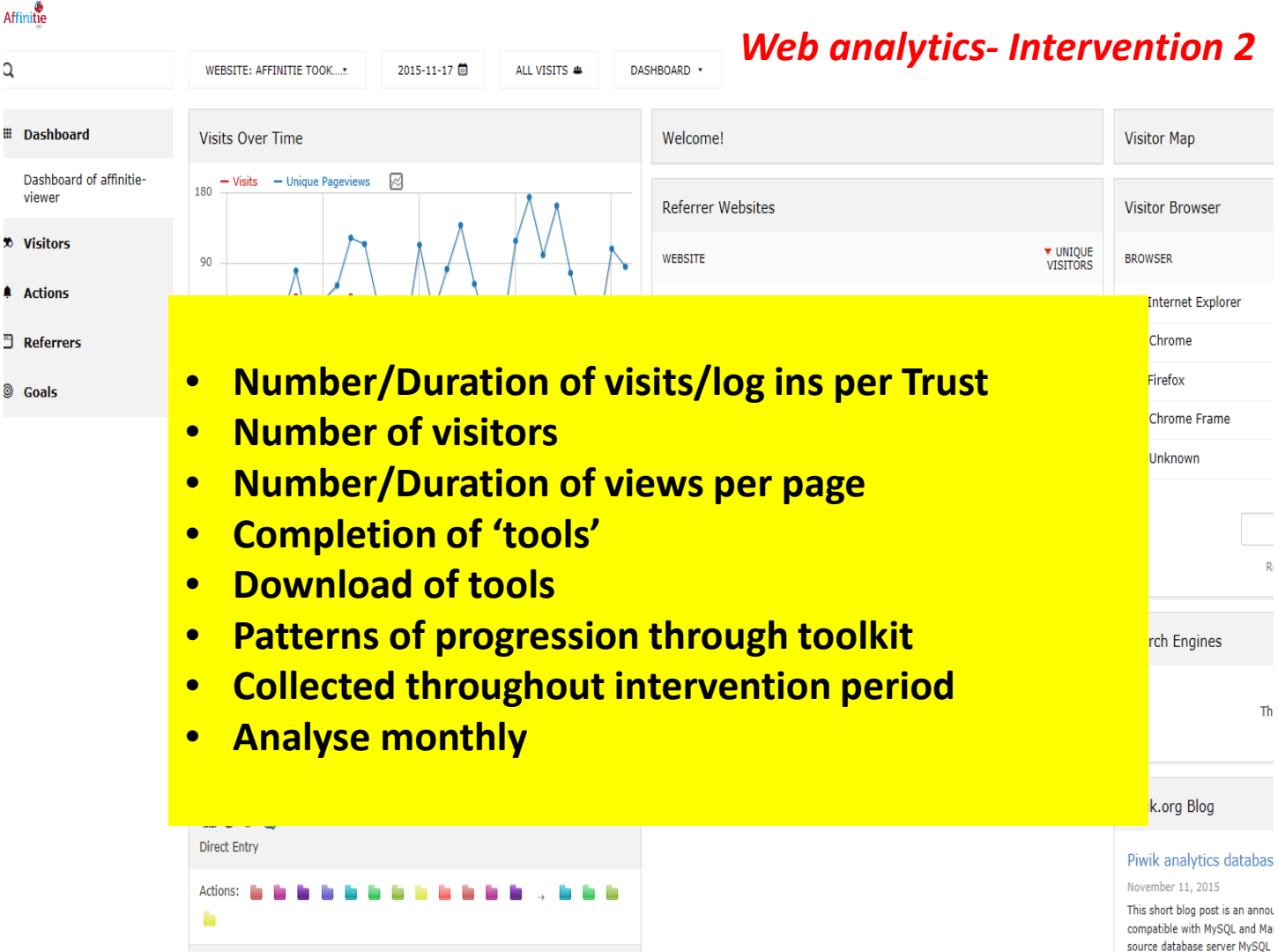
To what extent do you think your team/hospital has the necessary resources to change practice in light of feedback? (BARRIERS/ENABLERS)

RECEIPT/ENACTMENT: *Web analytics- Intervention 1*



- **Number of downloads per report in each site**
- **Collected throughout intervention period**
- **Analyse monthly**

Web analytics- Intervention 2



- **Number/Duration of visits/log ins per Trust**
- **Number of visitors**
- **Number/Duration of views per page**
- **Completion of ‘tools’**
- **Download of tools**
- **Patterns of progression through toolkit**
- **Collected throughout intervention period**
- **Analyse monthly**

- **Mediation analysis**: fidelity + outcomes (% unnecessary transfusions)

- Inform interpretation trial outcomes + feasibility/scalability:

1. Target **outcomes achieved** + **fidelity high** = *interventions effective*? Scale up? Feasible?

2. Target **outcomes not achieved** + **fidelity poor** = *premature to dismiss intervention as unsuccessful?*

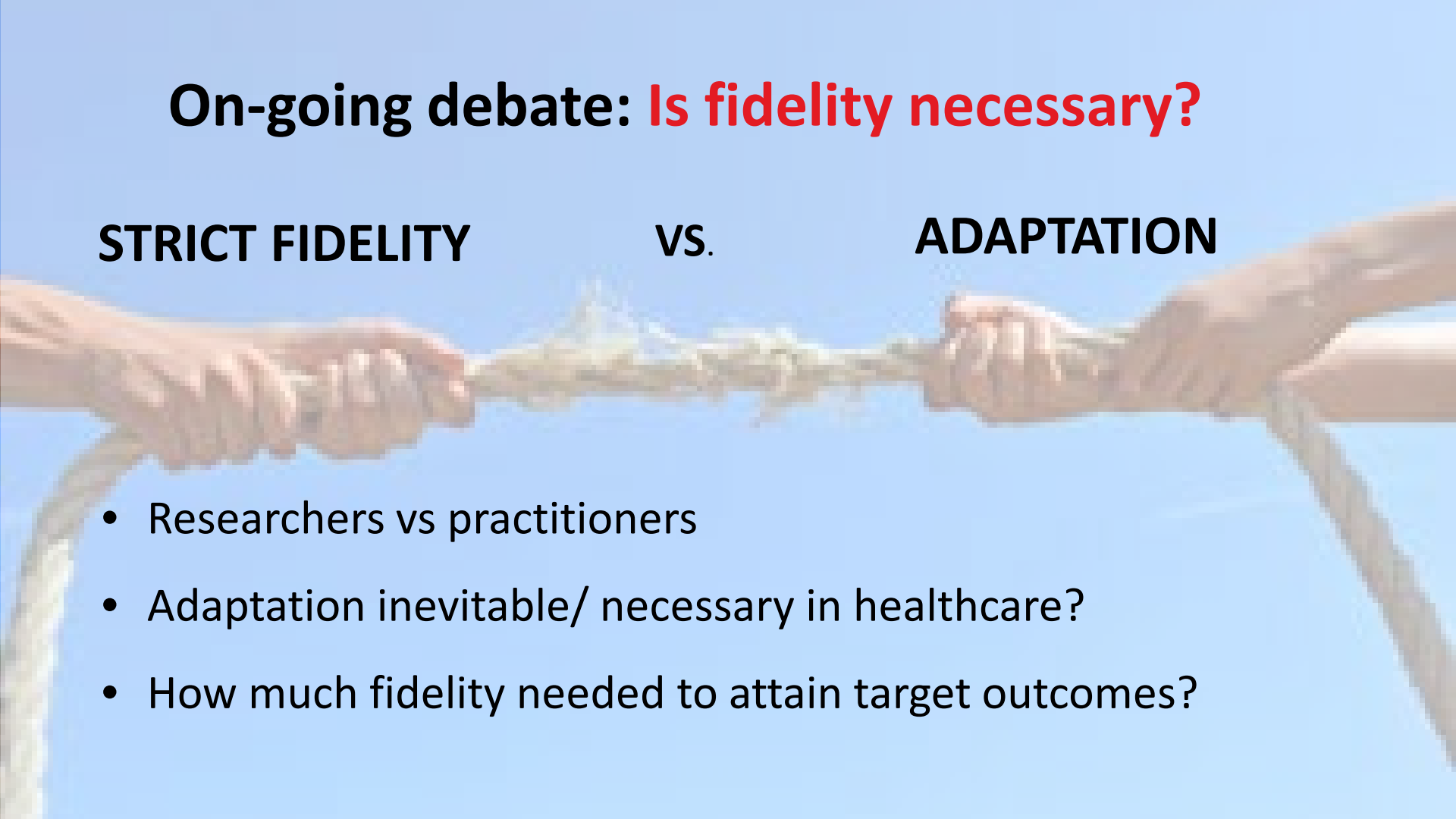
3. Target **outcomes achieved** + **fidelity poor** = *unexpected contextual factors influences? Delivery additional unintended BCTs*?

4. Target **outcomes not achieved** + **fidelity high** = *Interventions ineffective? Do not scale up? Refine interventions? Unexpected contextual influences?*


CHALLENGES
AHEAD

On-going debate: Is fidelity necessary?

STRICT FIDELITY **VS.** **ADAPTATION**



- Researchers vs practitioners
- Adaptation inevitable/ necessary in healthcare?
- How much fidelity needed to attain target outcomes?

- Some preliminary evidence that **better fidelity → better health related outcomes** (Lorencatto et al. 2015, Durlak et al. 2008, Burns et al. 2002)
  - Not clear how much more is better….

- However, field very much in its infancy

  - Limited studies **(6%)** examine association between fidelity and outcomes (Lorencatto & Yada, *Under Review*)

- Fidelity studies need to **move beyond description** to examining association with outcomes

- To build science of fidelity need:
  - Universal definitions/ terminology
  - Reliable and standardised methodologies
  - Better reporting of fidelity methods and results
  - Draw on fidelity theory/ models/frameworks
  - *More than 'was it delivered or not?'*

- Promoting fidelity evaluations
  - MRC Process Evaluation Guidance (Moore et al. 2015)
  - TIDieR checklist (Hoffmann et al. 2014)
  - Funders? (comprehensively assessing fidelity takes time and £$€ !)
  - Journal editors/ reviewers?

for listening!

Funded by the National Institute for Health Research

Further information:

- Fabiana.Lorencatto.2@city.ac.uk
- affinite@leeds.ac.uk

AFFINITIE Collaborators:

Jill Francis, ***Robbie Foy***, Simon Stanworth, Natalie Gould, Camilla During, Stephen McIntyre, Jon Bird, John Grant Casey, Rebecca Walwyn, Liz Glidewell, Amanda Farrin, Robert Cicro, Suzanne Hartley, Lauren Moreau, Steve Morris, Susan Michie, Jeremy Grimshaw

Funding:

National Institute for Health Research

This presentation summarises independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Grant Reference Number RP-PG-1210-12010). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.