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TITLE: Reconstructive Vascularized Composite Allotransplantation: Qualitative Approach to Enhance Patient Reported Outcome Metrics and the Candidate Screening Process

PRINCIPAL INVESTIGATOR: Scott M. Tintle, CDR MC USN

CONTRACTING ORGANIZATION: Henry M. Jackson Foundation, Bethesda MD

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Scott Tintle, MD, CDR MC USN
E-Mail: scott.m.tintle.mil@mail.mil

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Henry M. Jackson Foundation for the Advanced Military Medicine
6720 A Rockledge Dr. Suite 100
Bethesda MD 20817-1891

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Hand transplantation (also known as Vascularized Composite Allotransplantation, or VCA) can potentially restore function and improve quality of life (QOL) for affected individuals. Over the last two decades, science has focused on improving this treatment, and people are finding more success with this surgery. However, the science is less clear on who are the best candidates for this type of surgery. Also, so far doctors have focused mostly on the medical parts of the surgery but have focused less on how recipients feel about their QOL with their new hands. VCA is different from solid organ transplantation (e.g., kidney transplant). Patients who want hand transplants must be resilient, highly motivated, and determined to succeed in ways that are not required of solid organ transplant recipients. Psychological evaluation before the surgery is important, but scientists do not yet know the most important questions to ask patients. The proposed research intends to take what we know from studying amputees and other organ transplant patients to study people who receive hand transplants. This will also help doctors know what makes someone a good candidate for hand transplantation. The purpose of this project is to understand QOL before and after hand transplant, and to understand what factors make someone a good candidate for this surgery. This project addresses the FY17 Reconstructive Transplant Research Program (RTRP) Qualitative Research Award Focus Area: "Psychosocial considerations and challenges associated with VCA." To date, 13 focus groups with VCA stakeholders from a wide variety of specialties and backgrounds have been completed. Individual interviews have been completed with six patient participants, including both bilateral and unilateral hand transplant recipients. Qualitative analysis was used to identify the most important hand transplant outcome domains, which are similar to those reported in other trauma-related clinical groups. Several topics mentioned were unique to the hand transplant patient experience, such as sense of wholeness, expectations of transplant vs reality, satisfaction with new hand(s), and transplant complications. This research represents a vital first step in developing a qualitative framework for understanding QOL after VCA.

15. SUBJECT TERMS

Hand Transplant, Patient reported outcomes, quality of life, vascularized composite allotransplantation, amputation, upper extremity

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TABLE OF CONTENTS

1. INTRODUCTION

The psychosocial outcomes of hand transplantation remain elusive to clinicians and researchers. Little effort has been devoted to understanding these outcomes over the past 20 years. The purpose of this project is to understand quality of life (QOL) before and after hand transplant, and to understand what factors make someone a good candidate for this surgery. This project addresses the FY17 Reconstructive Transplant Research Program (RTRP) Qualitative Research Award Focus Area: "Psychosocial considerations and challenges associated with VCA." Through the use of focus groups and patient interviews, we are 1) actively determining the QOL domains most important to individuals involved in the VCA process, to enhance the creation and validation of standardized, psychometrically robust, and clinically useful patient reported outcome (PRO) measures for individuals with upper extremity amputation who have received or have been screened for hand transplantation; (2) evaluating the candidate screening process for reconstructive hand transplantation to identify the most important characteristics for successful transplantation.

2. KEYWORDS

Hand Transplant, Patient reported outcomes, quality of life, vascularized composite allotransplantation, amputation, upper extremity

3. ACCOMPLISHMENTS

What were the major goals of the project?

Note: on August 30, 2020, USAMRAA approved a modification to this project's Statement of Work (SOW), partly as a result of a second, complementary grant being awarded to the same team of investigators. All accomplishments and information provided in this annual report reflect this new SOW.

Major Tasks		Estimated % Complete
1.1	Obtain IRB approvals	100
1.2	Obtain HRPO approvals	100
1.3	Conduct focus groups at ASRT conference	100
1.4	Recruit and enroll patient participants for study inclusion from participating sites nationwide	33
1.5	Conduct initial interviews with transplant recipients and candidates (n = 30-35)	20
1.6	Conduct in-person focus groups with clinician participants from participating sites nationwide	100
1.7	Conduct thematic qualitative analysis from clinician and patient interviews	90
2.1	Develop new VCA-specific PRO items	100
2.2	Conduct 2nd telephone interviews with patient participants (n = 30-35) to administer PRO items	20
2.3	Analyze cognitive debriefing interview feedback	0
2.4	Revise new VCA-specific items as needed	0
2.5	Develop new VCA-specific PRO items to fill any identified domain gaps	0
2.6	Finalize VCA item pools	0
2.7	Analyze all PRO data to evaluate HRQOL of HT recipients	0

Major Tasks		Estimated % Complete
3.1	Discuss candidate screening process with clinician participants from participating sites nationwide as part of focus groups	100
3.2	Conduct Thematic Qualitative Analysis from focus group data on candidate selection process	0
3.3	Discuss screening process with investigators at each TORCH Consortium site; verify and systematically review procedures for candidate screening	0
3.4	Finalize screening process findings summary and recommendations	0
3.5	Disseminate best-practice recommendations for screening process	0

What was accomplished under these goals?

During year 3, major accomplishments were achieved in data collection and item development.

Major Tasks 1.4, 1.5, and 2.2

During year 3, regulatory approvals were finalized for two recruiting sites and data collection for patient interviews was launched. As of the end of this annual reporting period, we have completed both Major Task 1.5 and 2.2 interviews with six participants: four from the University of Pennsylvania (UPenn), including one candidate for transplant, and two from the University of Louisville (ULouisville). One additional recipient participant from ULouisville has been recruited and consented but has not yet been interviewed.

Major Task 1.7

During year 3, major progress was made on the thematic qualitative analysis of the focus groups and patient interviews. A manuscript reporting on these results is in preparation, nearing completion. We anticipate submitting this manuscript to a journal for peer review in fall 2021.

Major Task 2.1

During year 3, we completed a full internal review of new PRO items written specifically for hand transplant recipients, edited the items, and wrote several additional new items based on this review and initial input from patient interviews. This task is now completed, with 234 items written or selected across 7 topic areas.

What opportunities for training and professional development has the project provided?

Nothing to report

How were the results disseminated to communities of interest?

An abstract was published in the journal, *SAGE Open Medicine*, and is available online at https://doi.org/10.1177/20503121211003534. See section 6. Products below for additional information.

What do you plan to do during the next reporting period to accomplish the goals?

We have formally submitted notification or our plan to utilize a no-cost extension (NCE) to complete project major tasks. During our NCE year (year 4) of this project, we will continue data collection for Major Tasks 1.5 and 2.2. Results from these additional interviews will be analyzed as part of Major Task 1.7, and additional manuscripts will be prepared as relevant. We will amend our IRB protocol to add the newly finalized VCA-specific PRO items, so that we can administer these to participants to gather feedback through cognitive debriefing interviews. We will analyze this cognitive debriefing interview feedback for Major Task 2.3, and will then revise, supplement, and finalize the VCA item pools as needed (i.e., Major Tasks 2.4, 2.5, and 2.6). We have also been administering applicable PRO measures that assess patient participants' health-related quality of life and will analyze and report these data as part of Major Task 2.7. In a parallel effort, we will analyze and evaluate the data collected from sites regarding their candidate screening process, request any supplemental information from sites as needed, and then verify, review, and summarize our findings for Major Tasks 3.3, 3.4, and 3.5.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

To date, qualitative analysis of focus group and patient interview transcripts were used to identify 33 subdomains across the domains of physical function, physical symptoms, emotional well-being, and social participation were identified as relevant to the health-related quality of life (HRQOL) of individuals who have undergone UE VCA by VCA clinicians and recipients . In the physical/medical realm, hand function and satisfaction with hand function, sensation, and aesthetics are paramount, as are post-transplant challenges (e.g., rigor of post-transplant medication and therapy regimens), medical complications, and treatment compliance. The 14 emotional subdomains include positive and negative constructs, with several issues unique for this population, such as post-transplant expectations, fitting in, and integration and assimilation of the transplant (i.e., restoring "wholeness"). Major social themes included participation in social roles and activities, intimate relationships, independence and asking for help, and economic quality of life. This research represents a vital first step in developing a qualitative framework for understanding HRQOL after hand transplant.

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS

Changes in approach and reasons for change

As noted in section 3 above, the SOW for this project was changed during the previous reporting period, in consultation with the project's Science Officer. The SOW change was approved on August 30, 2020, by USAMRAA. All reporting herein is based on this revised SOW.

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to Report

Changes that had a significant impact on expenditures

Nothing to Report

Significant changes in use or care of human subjects.

Nothing to Report

Significant changes in use or care of vertebrate animals.

Nothing to Report

Significant changes in use of biohazards and/or select agents.

Nothing to Report

6. PRODUCTS

Publications, conference papers, and presentations

Journal publications. Nothing to Report

Books or other non-periodical, one-time publications. Nothing to Report

Other publications, conference papers, and presentations.

One conference presentation was accepted during the reporting period, although the conference was postponed due to the COVID-19 pandemic. This presentation has been rescheduled for November 2021.

> Tintle, SM, Tyner, CE, Slotkin, J, Tulsky, DS, Dearth, C, Horan, A, Dooley, M, Kisala, P, Levin, LS (*accepted*). Transplantation Outcomes Research Collaboration for the Hand: Toward the Development of Patient-Reported Outcome Measures for Vascularized Composite Allotransplantation of the Hand. Presentation accepted for the American Society of Reconstructive Transplantation conference. Abstract published online: https://journals.sagepub.com/doi/full/10.1177/20503121211003534

An abstract for this presentation is provided in Appendix A.

Website(s) or other Internet site(s)

Nothing to Report

Technologies or techniques

Nothing to Report

Inventions, patent applications, and/or licenses

Nothing to Report

Other Products

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Walter Reed National Military Medical Center (WR)

Name:	**CDR Scott Tintle, MD**
Project Role:	Initiating PI at WR
ORCID ID:	none
Nearest person month worked:	3
Contribution to project:	CDR Tintle oversaw all aspects of the project-related activities, including weekly team teleconferences, facilitation of the recruitment of patient participants, data analyses and manuscript preparation.

Name:	**Christopher L. Dearth, PhD**
Project Role:	Co-Investigator at WR
ORCID ID:	none
Nearest person month worked:	1
Contribution to project:	Dr. Dearth participated in the weekly team teleconferences and assisted CDR Tintle with efforts related to recruitment and manuscript preparation.

Name:	**Heidi Mahatan, MA**
Project Role:	Project Manager at WR
ORCID ID:	none
Nearest person month worked:	1
Contribution to project:	Ms. Mahatan participated in the weekly team teleconferences and assisted CDR Tintle with efforts related to recruitment and manuscript preparation.

University of Delaware (UD)

Name:	**David Tulsky, PhD**
Project Role:	Collaborating PI
ORCID ID:	none
Nearest person month worked:	1
Contribution to Project:	Dr. Tulsky oversaw all aspects of the project-related activities at UD, including weekly team teleconferences, supervision of data collection, data analyses and manuscript preparation

Name:	**Jerry Slotkin, PhD**
Project Role:	Co-I
ORCID ID:	none
Nearest person month worked:	1
Contribution to Project:	Dr. Slotkin participated in weekly team teleconferences, oversaw project planning, data collection, analyses, and manuscript preparation.

Name: **Callie Tyner, PhD**
Project Role: Co-I
ORCID ID: 0000-0003-2945-392X
Nearest person month worked: 2
Contribution to Project: Dr. Tyner participated in weekly team teleconferences, contributed to overall project planning, trained and supervised call center staff, oversaw data collection, and participated in data analyses and manuscript preparation.

Name: **Pamela Kisala, MA**
Project Role: Co-I
ORCID ID: 0000-0003-3234-795X
Nearest person month worked: 1
Contribution to Project: Ms. Kisala completed qualitative analyses of interviews and spearheaded manuscript preparation.

Name: **Aaron Boulton, PhD**
Project Role: Co-I
ORCID ID: none
Nearest person month worked: 1
Contribution to Project: Dr. Boulton participated in data collection platform (REDCap) design and oversaw data collection quality assurance.

Name: **Emily Forth, BA**
Project Role: Research Assistant
ORCID ID: none
Nearest person month worked: 1
Contribution to Project: Ms. Forth completed data collection interviews.

Penn Medicine (PM)

Name: **L. Scott Levin, MD**
Project Role: Collaborating PI
ORCID ID: 0000-0001-9108-5182
Nearest person month worked: 1
Contribution to Project: Dr. Levin oversaw all aspects of the project-related activities at PM, including weekly team teleconferences, facilitation of the recruitment of patient participants, data analyses and manuscript preparation.

Name: **Annamarie Horan, PhD**
Project Role: Co-I
ORCID ID: 0000-0003-3000-5841
Nearest person month worked: 1
Contribution to Project: Dr. Horan participated in weekly team teleconferences and oversaw project planning and execution at PM.

Name: **Mary Dooley, PhD**
Project Role: Co-I
ORCID ID: 0000-0002-0647-6187
Nearest person month worked: 1
Contribution to Project: Dr. Dooley participated in weekly team teleconferences and oversaw project planning and execution at PM.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

University of Delaware (UD)

David Tulsky, Ph.D.

New funding:

- Title: Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL)
  Funding Agency: NIH/NIGMS
  Project dates: 7/1/2021-6/30/2022; Effort: 0.60 academic
  Description: To adapt an existing, web-based "ehealth" symptom-monitoring/self-management system, iManage, to the needs of the general population in the wake of the COVID-19 crisis.Overlap: none
- Title: Relations between motor social and social communication impairments as well as repetitive behavior severity in children with autism spectrum disorder (ASD)
  Funding Agency: NIH
  Project dates: 6/1/2021-3/31/2024; Effort: 0.24 academic
  Description: We will determine the risk for motor impairment and how that changes with increasing social communication impairment, repetitive behavior severity, comorbidities, and levels of impairment using parent report measures.Overlap: none

Previous funding:

- Development of Psychosocial Symptom Monitoring and Self-Management System for individuals with SCI (CNF), ended 2/28/2021
- Stakeholder Determination of Patient-Reported Outcomes for Adults with Communication Disorders (NIH/NIGMS), ended 11/30/2020
- Women's Health & Disability: Building a Clinically Relevant Outcome Measure (Univ Mich/NIH), ended 5/31/2021

Jerry Slotkin, Ph.D.

New funding:

1. Title: Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL)
   Funding Agency: NIH/NIGMS
   Project dates: 7/1/2021-6/30/2022; Effort: 0.24 calendar
   Description: To adapt an existing, web-based "ehealth" symptom-monitoring/self-management system, iManage, to the needs of the general population in the wake of the COVID-19 crisis. Overlap: none

Previous funding:

- Development of Psychosocial Symptom Monitoring and Self-Management System for individuals with SCI (CNF), ended 2/28/2021

Aaron Boulton, Ph.D.

New funding:

- Title: Relations between motor and social communication impairments as well as repetitive behavior severity in children with autism spectrum disorder (ASD)

Funding Agency: NIH
Project dates: 6/1/2021-3/31/2024; Effort: 1.80 calendar
Description: We will determine the risk for motor impairment and how that changes with increasing social communication impairment, repetitive behavior severity, comorbidities, and levels of impairment using parent report measures. Overlap: none

Previous funding:

Nothing to report

Pamela Kisala, M.A.

New funding:

1. Title: Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL)
   Funding Agency: NIH/NIGMS
   Project dates: 7/1/2021-6/30/2022; Effort: 0.48 calendar
   Description: To adapt an existing, web-based “ehealth” symptom-monitoring/self-management system, iManage, to the needs of the general population in the wake of the COVID-19 crisis. Overlap: none

Previous funding:

- Development of Psychosocial Symptom Monitoring and Self-Management System for individuals with SCI (CNF), ended 2/28/2021

What other organizations were involved as partners?

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

Collaborative Awards

n/a

9. APPENDICES

See Appendix A for the attached abstract described in question 6.

See Appendix B for Quad Chart.

Appendix A: Presentation Abstracts

One conference presentation was accepted during the reporting period, although the conference was postponed due to the COVID-19 pandemic. This presentation has been rescheduled for November 2021.

> Tintle, SM, Tyner, CE, Slotkin, J, Tulsky, DS, Dearth, C, Horan, A, Dooley, M, Kisala, P, Levin, LS (*accepted*). Transplantation Outcomes Research Collaboration for the Hand: Toward the Development of Patient-Reported Outcome Measures for Vascularized Composite Allotransplantation of the Hand. Presentation accepted for the American Society of Reconstructive Transplantation conference. Abstract published online: https://journals.sagepub.com/doi/full/10.1177/20503121211003534

Abstract

Background: Vascularized Composite Allotransplantation of the hand offers the potential for significantly improved function and QOL for upper extremity amputees. Unfortunately, there is minimal patient reported outcome data available to confirm this ostensibly true statement.

Methods: This study uses a grounded-theory-based qualitative approach to better understand the QOL factors most important to individuals who are candidates for, or who have received, hand transplantation. Focus groups with transplant experts were held at the biennial meeting of The American Society for Reconstructive Transplantation (ASRT) in November 2018 in Chicago, IL, at the University of Pennsylvania, at the University of Louisville, The University of California at Los Angeles, and at the Brigham and Women's Hospital. The sessions were audio-recorded and transcribed for qualitative analysis. Analytic methods used are well-documented in prior qualitative research to develop new patient reported outcome measures for medical rehabilitation populations (Kisala & Tulsky, 2010). Results allow for development of a qualitative framework for understanding QOL in individuals involved in the VCA process, as well as to identify the most appropriate outcomes measures for a VCA population.

Results: 13 Focus group sessions with 60 participants total representing national and international VCA facilities were completed. The background/specialties of the participants were diverse, covering the key domains of the multi-disciplinary care team. Major themes that emerged from these focus group discussions included both the tangible and intangible benefits imbued to recipients, such as feeling "whole" or restored physically, socially, and emotionally. Embodiment and acceptance of the donor hand was brought up in each of the groups as an important milestone. Some challenges that patients face was also raised, primarily dealing with the extensive rehabilitation requirements post-surgery as well as the health complications that can arise due to long-term immunosuppression.

Conclusion: This research represents the first step in understanding how hand transplant surgery impacts QOL. The next vital step begins shortly with patient interviews at the major transplant centers in the United States and will further refine the understanding of hand transplant recipient quality of life.

Appendix B: Quad Chart. Reconstructive Vascularized Composite Allotransplantation: Qualitative Approach to Enhance Patient Reported Outcome Metrics and the Candidate Screening Process

Log Number: RT170101; Award Number: W81XWH18-2-0066

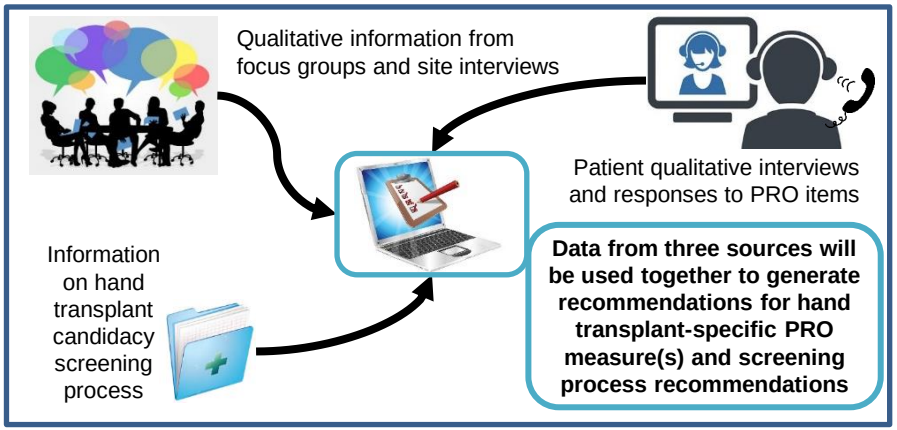
PI: Scott Tintle, MD **Organization:** University of Delaware **Award Amount: $146,586**

Specific Aims & Approach

Aim 1: Determine the psychosocial/QOL outcome domains most important to individuals involved in the VCA process. We will conduct focus groups with VCA clinicians and interviews with patients involved in the VCA process to identify the most critical psychosocial and QOL domains to be assessed in individuals at all stages of the VCA process (e.g., screening, candidacy, transplantation, rehabilitation).

Aim 2: Enhance the selection and validation of standardized, psychometrically robust, and clinically useful patient-reported outcome (PRO) measures for traits and symptoms that are of critical importance to VCA patients. Individuals currently or formerly involved in the VCA process will review items from the ExTrA-QOL measurement system to evaluate 1) the relevance/appropriateness of included constructs and 2) the wording, construct representativeness, and content coverage of the ExTrA-QOL items.

Aim 3: Optimize the VCA candidate screening process by identifying and standardizing the most important clinical and psychosocial characteristics to consider for successful transplantation. We will conduct another series of clinician focus groups and individual patient interviews to understand, evaluate, and optimize the current VCA screening process. We will utilize ExTrA-QOL and other current measures and variables as needed to recommend a standardized and data-supported method for screening.



Accomplishments: During year 3, data collection with patient participants was launched. Interviews have been completed with six participants, including four from the University of Pennsylvania and two from the University of Louisville. New hand-transplant-specific item writing is complete, with 234 items written or selected across 7 topic areas.

Timeline and Cost

Major Tasks	Sites	Year 1	Year 2	Year 3	NCE
1.1 Obtain IRB approvals	WR, UD, PM				
1.2 Obtain HRPO approvals	WR, UD, PM				
1.3 Conduct focus groups at ASRT conference	WR, UD, PM				
1.4 Recruit and enroll patient participants from sites nationwide	WR, PM				
1.5 Conduct initial interviews with transplant recipients and candidates	UD				
1.6 Conduct in-person focus groups with clinician participants	UD				
1.7 Conduct thematic qualitative analysis from clinician and patient interviews	UD				
2.1 Develop new VCA-specific PRO items	UD				
2.2 Conduct second round of interviews with participants	UD				
2.3 Analyze cognitive debriefing interview feedback	UD				
2.4 Revise new VCA-specific PRO items as needed	UD				
2.5 Develop new VCA-specific PRO items to fill any identified gaps	UD				
2.6 Finalize VCA item pools	UD				
3.1 Discuss candidate screening process with clinician participants	UD				
3.2 Conduct Thematic Qualitative Analysis from interviews	UD				
3.3 Discuss screening process with clinician participants, verify and review procedures for candidate screening	WR				
3.4 Finalize screening process findings summary and recommendations	WR, UD, PM				
3.5 Disseminate best-practice recommendations for screening process	WR, UD, PM				

Updated: 25-Oct-2021 NOTE: WR = Walter Reed, UD = University of Delaware; PM = University of Pennsylvania Medicine

Goals/Milestones

Year 1 Goals

- ☑ Obtain regulatory approvals (IRB & HRPO)
- ☑ Conduct focus groups at ASRT conference
- ☑ Engage with partnering sites for recruiting patients
- ☑ Identify most important domains for hand transplant outcomes

Year 2 Goals

- ☑ Conduct expert groups and interviews at participating transplant sites
- ☑ Develop new hand transplant-specific items

Year 3 Goals

- ☑ Enroll transplant recipients and candidates (n = 30-35) ***in progress***
- ☐ Finalize hand transplant-relevant item pools
- ☐ Finalize and disseminate screening process observations and recommendations

Comments/Challenges/Issues/Concerns

Timeline updated to reflect NCE; expenditure differential relates in part to timing.