

# THE JOURNEY TOWARDS SUCCESSFUL RESEARCH IN A DIABETES CLINIC: EXPECTATIONS VS. REALITY

*Hayat Mushcab, B.Sc. M.Sc.*

*W. George Kernohan, PhD*

*Jonathan Wallace B.A., M.Sc.*

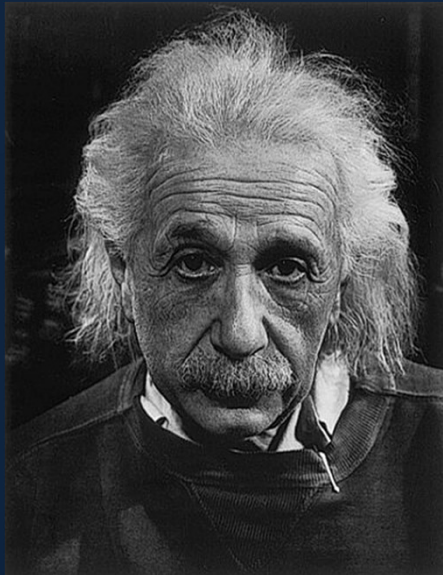
*Roy Harper, M.D, and*

*Suzanne Martin, PhD*

# PRESENTATION OUTLINE

- Background
- Challenges
  - Study Proposal and Design
  - Regulations and Ethics
  - Patient Recruitment
  - Data Collection and Management
- Conclusion

“IF WE KNEW WHAT IT WAS WE  
WERE DOING, IT WOULD NOT BE  
CALLED RESEARCH, WOULD IT?”



# DEFINITIONS

- **Interrupted Time-Series Design (ITS)** : is a collection of observations made consecutively in time and each study subject serves as their own control [10]
- **Connected health technology** : is the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for exchange of valid information [11]

# BACKGROUND

- Diabetes is one of the leading threats to health globally
- In 2010, 300 million people worldwide were living with diabetes, and 344 million others were at risk of developing T2D
- Robust research is focusing on the at-risk population to prevent or delay the development of their diabetes by lifestyle interventions
- Clinical trials are the key to scientific discovery and improvement in the medical field that deliver evidence to the healthcare systems worldwide

# EXPECTATION VS. REALITY

- A clinical researcher's long-term aim is to improve the healthcare provided by the clinicians and received by individuals
- Therefore, a proposal has to be well established and thoroughly documented with comprehensive methods for the study design and data analysis creating a clear and strong infrastructure
- A robust study design that delivers valuable results has to have sufficient sample size, statistical power and bias control
- It also has to be achievable in the proposed clinical setting.
- It is crucial to highlight and reflect upon challenges research faces to progress towards more successfully managed and completed trials

# THEORY



# REALITY





# OUR STUDY

- Aimed to determine the optimal use of connected health technology to achieve self-management of T2D
- Three-arm Interrupted Time Series (ITS) design was developed to
- The required sample size is 80
- Criteria :
  - Patients living with T2D
  - Undertaking insulin treatments
- District general teaching hospital in Northern Ireland
- Telemonitoring solutions are services currently provided by one Health and Social Care Trust

**WARNING**



**CHALLENGES  
AHEAD**

# CHALLENGE #1: STUDY DESIGN

- Having developed the research questions, the dilemma was how best to match this to a suitable study design
- Intervention studies in particular are often time consuming and require extensive planning and preparation
- Our study was conceived to be a five-armed RCT, testing four types of support against one control arm
- Interrupted-time series (ITS) design was most suitable to achieve our objectives.

**Unreasonable Ambitious**

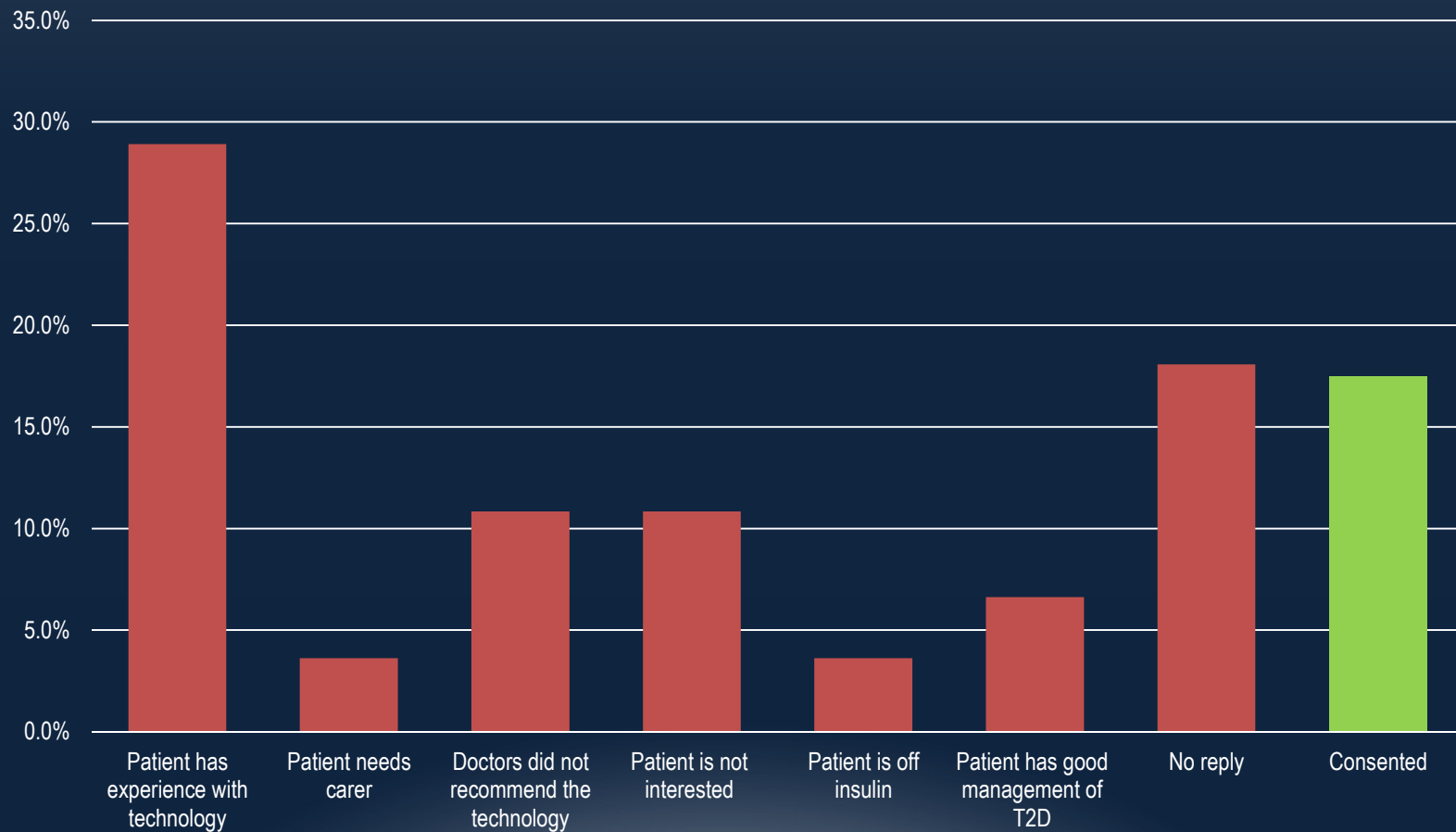
# CHALLENGE #2: REGULATIONS & ETHICS

- It takes the R&D department 114 days, Ethics 91 days and Regulatory 77 days to provide approval from the day of submission
- had to obtain four different regulatory governance approvals
  - University Research Governance “filter” committee (for preliminary screening),
  - ORECNI (for ethical approval),
  - AccessNI (for staff clearance) and
  - HSC R&D (for Trust approval)
- Whilst completing the IRAS for NHS permissions
- The task took 10 Months to complete

# CHALLENGE #3: RECRUITMENT

- Often the most challenging aspect of conducting a trial
- Patient recruitment and retention in a clinical trial depend on three factors:
  - **Patient-related** (Lifestyle adaptation, Age group, Cost, Time, Knowledge, Paperwork, Socioeconomic Status, Research Preference)
  - **Healthcare provider-related** (Time, Research Resources, Overloaded Staff)
  - **System-related** (Contracts, Database access, EMR, Funding)

# RECRUITMENT STATS



*Figure 1: This pie chart explains the status of patients screened in the recruitment process. Of 166 potential participants (100%) only 28 (17%) took part in the study after 13 months of recruitment.*

# CHALLENGE #4: DATA COLLECTION

- Study protocol as a map for data collection
- Our tools:
  1. The hospital patient records to collect their clinical outputs on every visit including (HbA1c, Blood Glucose, Body weight and Cholesterol Levels),
  2. Questionnaires that were already developed and validated by experts in the field of telemonitoring and diabetes



# CONCLUSION

- Clinical research in the field of type 2 diabetes is facing many challenging scientific issues
- **In theory**, conducting a clinical trial is an interesting, exciting and essential mission that is likely to provide new knowledge and improve evidence-based practice and healthcare delivery nationwide.
- **In reality**, conducting a clinical trial is not an easy task, and it can be extremely frustrating.



# CONCLUSION

- It is a major responsibility to deal with patients and be able to meaningfully describe people's lives, minds, feelings and realities with the data they have provided
- Asking the research question is important, but getting the clinical team and patients on board all the way to the end is essential
- Clinical trials need constant dedication from physicians and patients who are willing to participate for the sake of enriching the knowledge and providing better healthcare opportunities for future patients

Thank you