

Investigation of the Impact of User Qualifications and Trainings on the Proper Use of Medical Equipment and Resulting Medical Error

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Outline

- Introduction
- Problem Statement
- Objective
- Existing Methods
- Methodology
- Conclusion



Introduction

Medical Technology:

- Facilitate Medicine and Diagnosis.
- Improved Care and Efficiency.
- Better and More Accessible Treatment.
- Software Improves Healthcare and Disease Control.



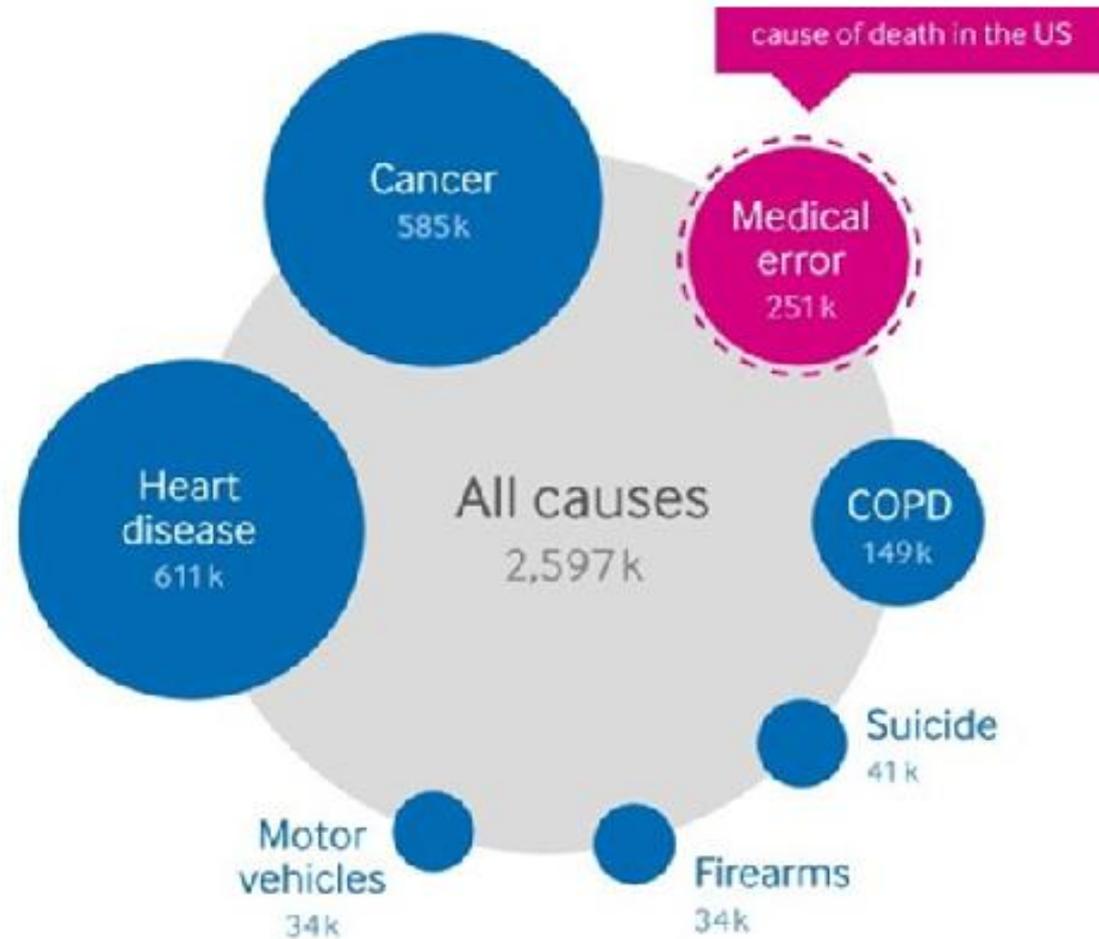
Problem Statement

Medical Errors: (In U.S)

- No. 3 killer
- High Cost
- 43 million Adverse Events
- Mean Rate of Death = 251,454



Problem Statement (cont.)



However, we're not even counting this - medical error is not recorded on US death certificates

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<http://bmi.co/mederr>

Medical Error Causes

- **Human Errors**
- **Absence/Lack of Training**
- **Equipment Failure**
- **Complexity of Technology**



Device-User Interface



Existing Methods

1. Evaluating and Predicting Patient Safety for Medical Devices with Integral Information Technology.
2. To Err Is Human: Building a Safer Health System.
3. Identifying, Understanding, and Communicating Medical Device Use Errors: Observation from an FDA Pilot Program.



International Standard Organization

- **ISO 13485:2016:**

- ✓ Focusing on the Personal Performing Work
- ✓ Healthcare Organizations Determine the Needed Training

- **ISO 14971:2007:**

- ✓ Qualification of Personal
- ✓ Special Trainings

- **ISO 16142-1:2016**

- ✓ Understanding the Users' Needs
- ✓ Delivery of Safety Information

International Electronic Commission

- **IEC 62366-1:**

- ✓ Usability Engineering Process

- ✓ Personal Trainings for Specific Medical Devices

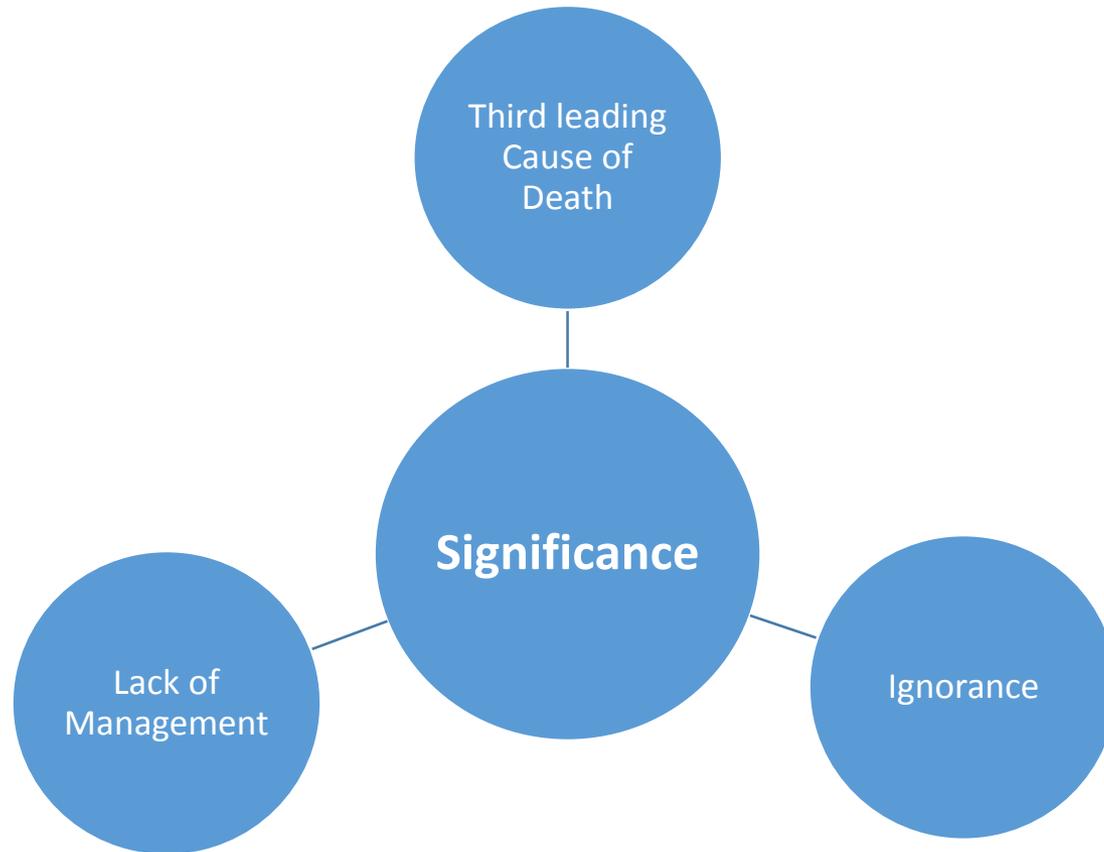
- ✓ Training Materials

- ✓ Risk Control Measure

Methodology



Methodology (cont.)



Methodology (cont.)

- Objective:

- High Education Levels

- Intensive Trainings

- Standardization

- Motivational Tools



Methodology (cont.)

- Certificates for the trainee.
- Forms to be filled.
- Updates for the trainings every period of time.
- Rewards for the participants.



Methodology (cont.)

Cost-Benefit

Save Time

Improve Quality



Conclusion

- Exceeding Expectations
- Sharing Knowledge and Experience
- Improve Care
- Patient Safety



