University of Nottingham
UK | CHINA | MALAYSIA

Understanding Gaps in Standards, Regulations and Training Needs for Healthcare Professionals working alongside Physically Assistive Robots

Praminda Caleb-Solly
Prof of Embodied Intelligence

Summary of Talk

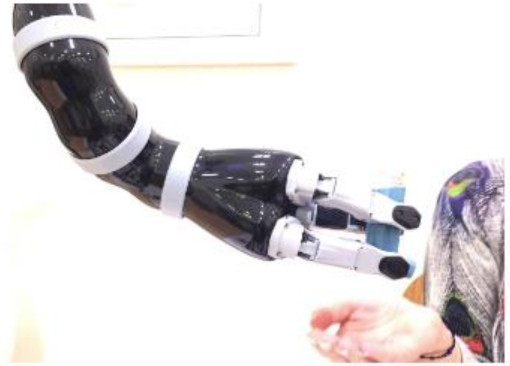
- Quick overview of the Cyber-physical Health and Assistive Robotics Technologies (CHART) research group
- Understanding the complexity
  - Diversity of robot platforms
  - Assistive Robots disrupting the dynamics within health and social care and Changing user needs
  - Examples of physically assistive robot use cases
- Gaps in standards and assessment methods
- Healthcare professional training needs for assistive robots
- Emerging challenges and opportunities

University of Nottingham
UK | CHINA | MALAYSIA

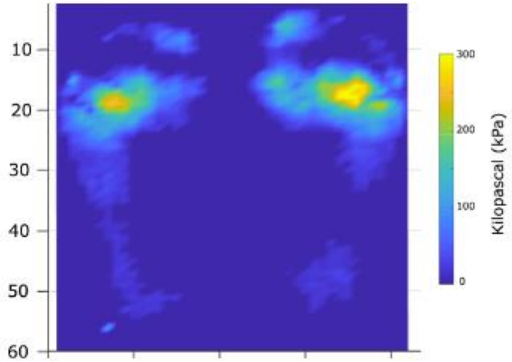
Cyber-physical Health and Assistive Robotics Technologies (CHART)

Safety and Benchmarking

User-Centred Design Methods and Applications



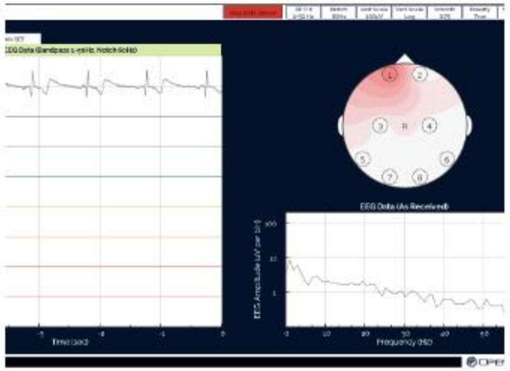
Ethics and Responsible Research



Smart Sensing and Embodied Intelligence

Autonomous and Human-Guided Manipulation

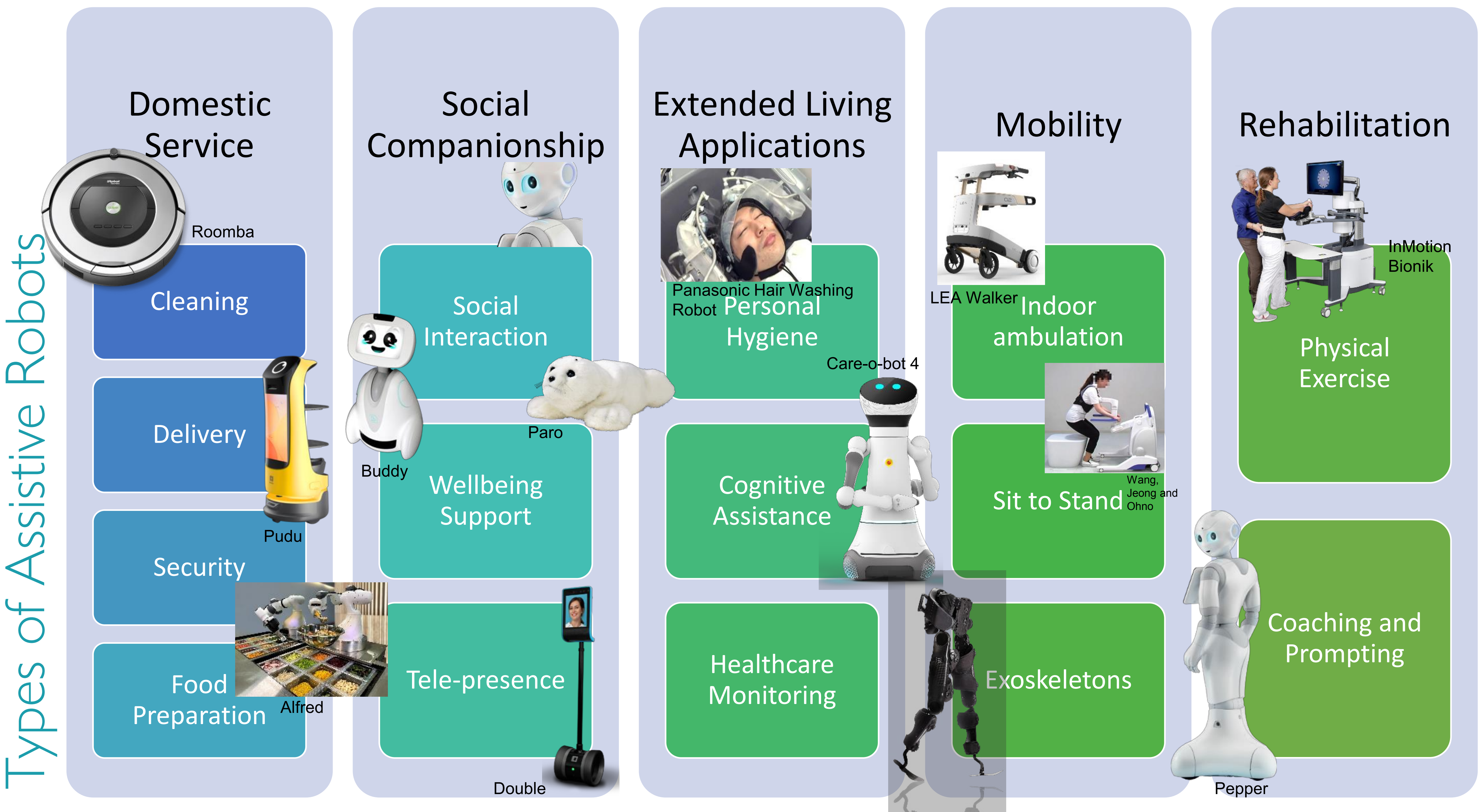
Telepresence and Teleoperation



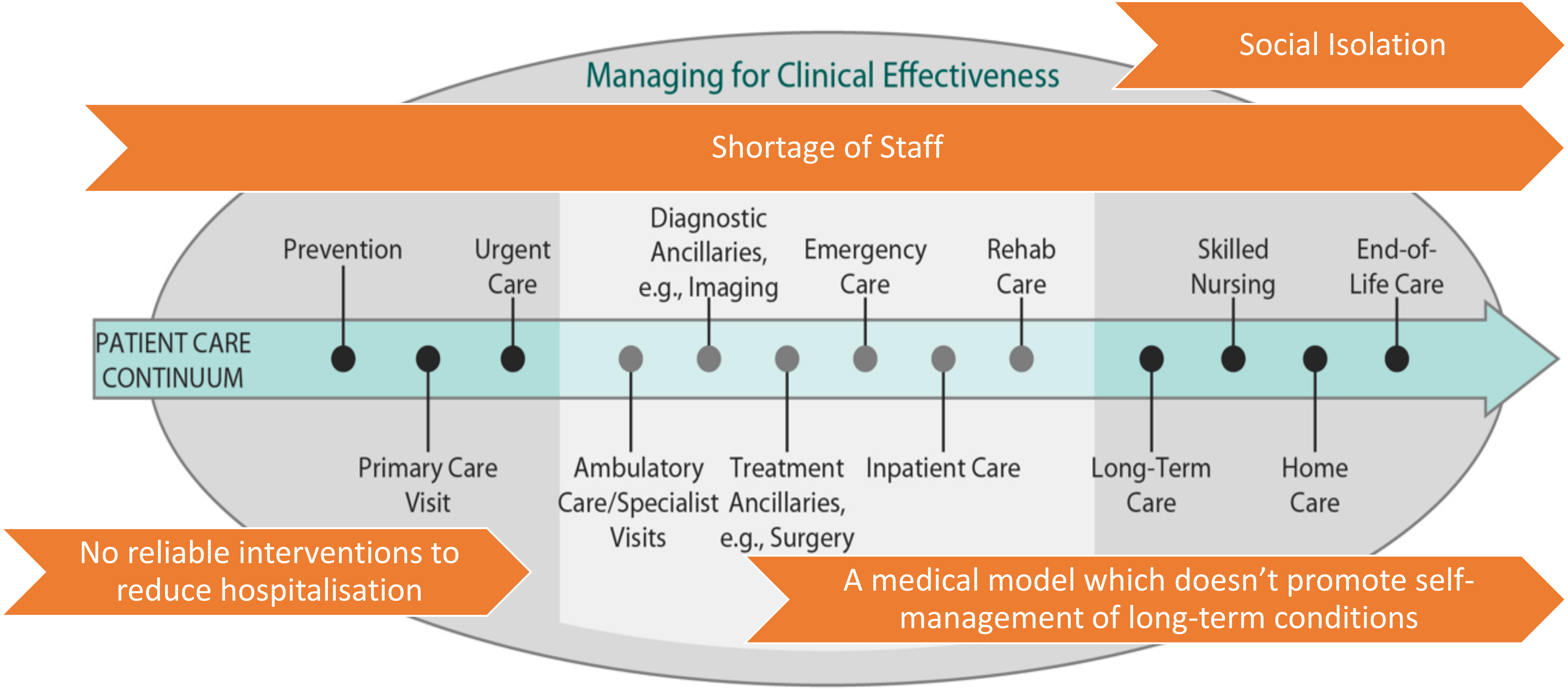
Accessible Human-Robot Interaction and Collaboration

Mobility and Navigation

CHART are conducting basic and applied research into cyber-physical systems and robotics technologies in health and social care https://www.chartresearch.org/


Types of Assistive Robots
Domestic Service
Roomba
Cleaning
Delivery
Pudu
Security
Food Preparation
Alfred
Social Companionship
Social Interaction
Buddy
Paro
Wellbeing Support
Tele-presence
Double
Extended Living Applications
Panasonic Hair Washing Robot
Personal Hygiene
Care-o-bot 4
Cognitive Assistance
Healthcare Monitoring
Mobility
LEA Walker
Indoor ambulation
Sit to Stand
Wang, Jeong and Ohno
Exoskeletons
Rehabilitation
InMotion Bionik
Physical Exercise
Coaching and Prompting
Pepper

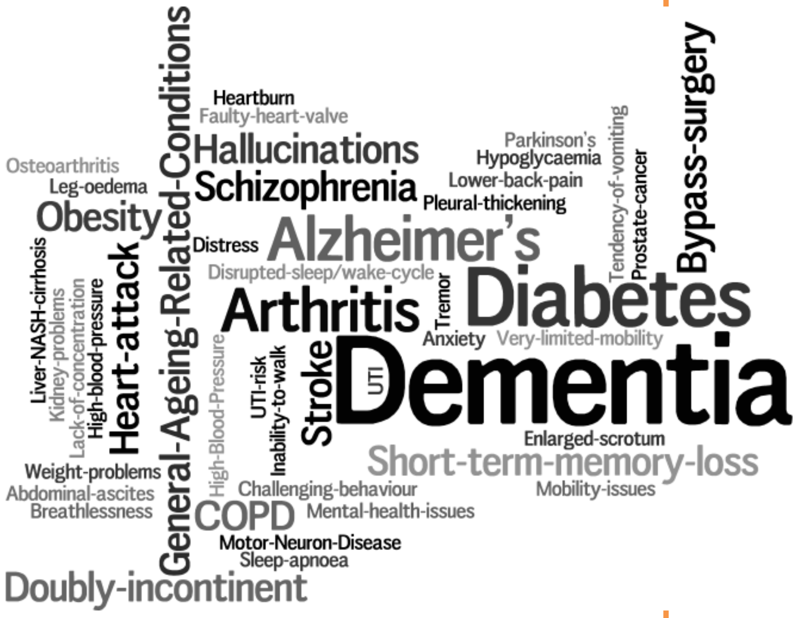
Changing the Dynamics Within Health and Social Care

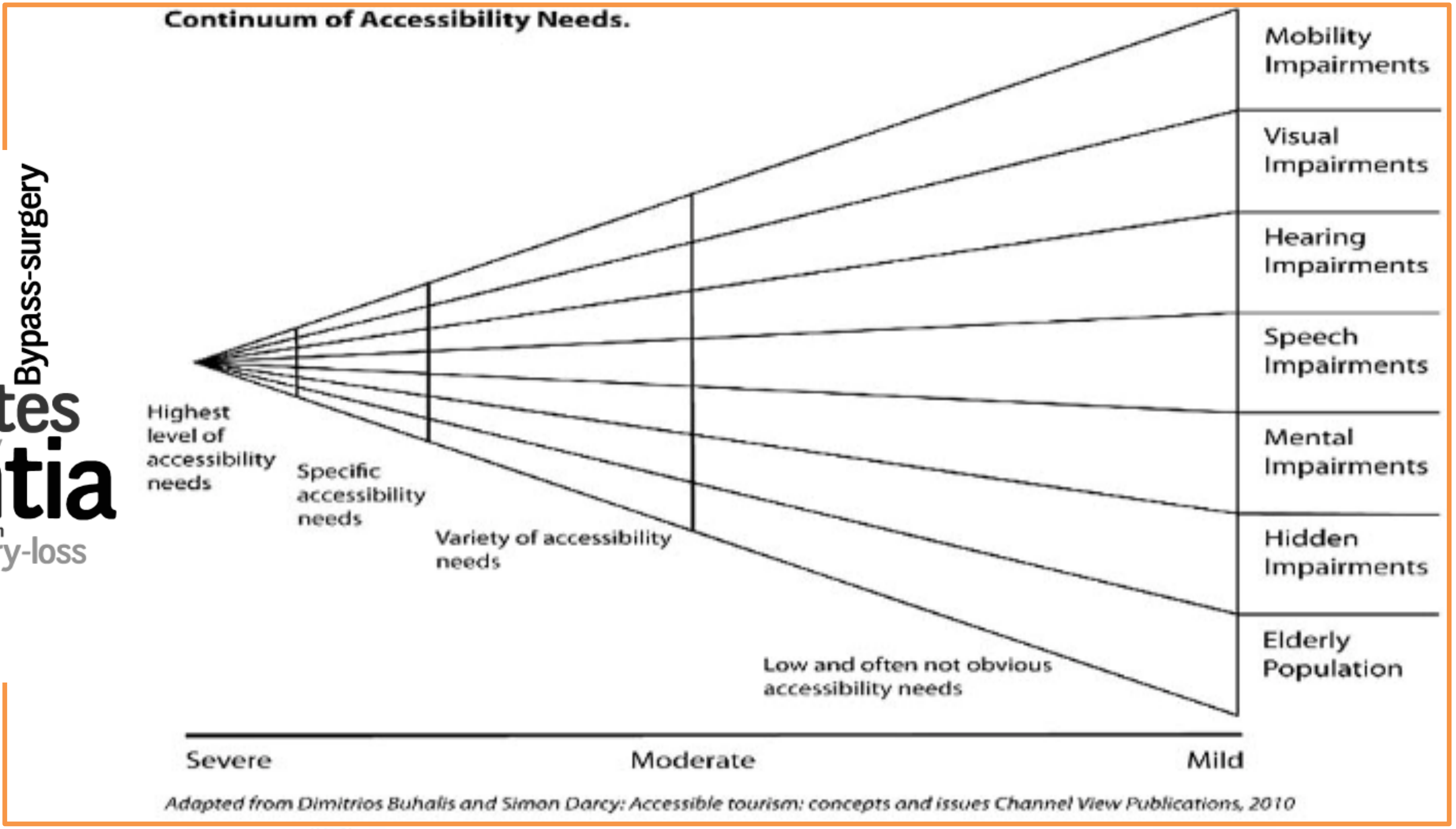


The Patient Care Continuum

Image Source: https://www.beckershospitalreview.com/hospital-management-administration/bringing-certainty-to-uncertain-times-6-imperatives-for-future-hospital-a-health-system-success.html

Changes in impairments through a person's life course





Physically Assistive Robots

Example Applications:

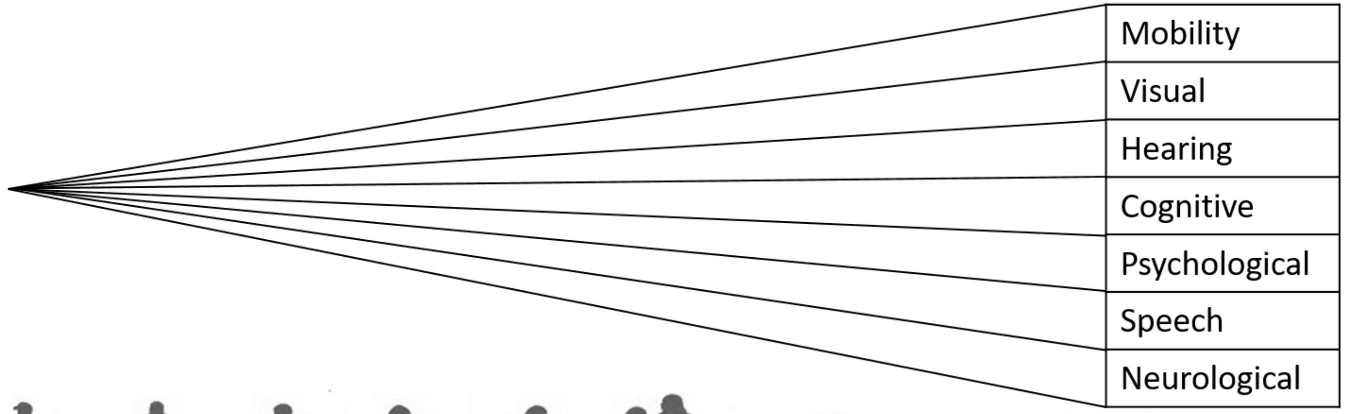
- ❑Walking assistance
- ❑Sit-to-stand and mobility assistance

Functional Support for:

Maintaining independence for ADLs	Physical support for tasks such as dressing, walking, food preparation
Enabling Rehabilitation	Supporting frequent and guided practice of exercises
Addressing care staff shortages	Reduction from two carers to one, or even zero for mundane tasks
Alleviation of physical workload for carers	Reduces injuries such as back strain, reduces sickness absence
Providing diagnostic information for carers	Sensor data recording, trend analysis, detection of emerging conditions

Challenges for Healthcare Professionals: Ensuring Physical Safety

- Hazard Analysis and Safety Assurance
- Risk assessment is not a straightforward process for Autonomous Systems
- Particularly given the:
  - the technical complexity of robotic devices and adaptation over time
  - the lack of sufficient data with respect to the potential risks
  - vulnerable users in the loop + cats



Types of Impairments

Rockwood K, Song X, MacKnight C, Bergman H, Hogan DB, McDowell I, Mitnitski A. A global clinical measure of fitness and frailty in elderly people. *CMAJ.* 2005 Aug 30;173(5):489-95

Real-world operational conditions

Hazard Analysis and Safety Assurance

- Hazard Identification / Risk Assessment / Safety Analysis
  - ❑ Internal, human factors and mission-related functional hazards can be identified by conventional techniques: HAZOP, FMECA, SHARD, HEART, FHA
  - ❑ Complex system architecture effects can be addressed by newer methods: STPA
  - ❑ Ethical Hazards (BS 8611:2016)
- Environmental Survey Hazard Analysis (ESHA)
  - ❑ Aimed at identification and assessment of external environmental features including non-mission hazards
- Ecological Interface Design
  - ❑ Considers unexpected events
  - ❑ Skills, Rules, Knowledge (SRK) framework

Towards an Ontological Framework for Environmental Survey Hazard Analysis of Autonomous Systems

Harper, C. and Caleb-Solly, P., 2021. Towards an Ontological Framework for Environmental Survey Hazard Analysis of Autonomous Systems. *SafeAI@ AAAI*. CEUR Proceedings (CEUR-WS.org, ISSN 1613-0073)

A possible safety argument strategy: where the claim is that the risk has been reduced ”so far as is reasonably practicable” (SFAIRP).

A safety case/argument will need to demonstrate objectively the following characteristics:
• that exhaustive coverage of potential hazards has been achieved
• that the analysis of a system’s scope of operation is systematic and complete
• that the identification of safety measures to resolve any potential hazard has been exhaustive
• that the costs vs. benefits of each identified safety measure have been analysed systematically

ESHA Guide-words (original version, informal model)

The environment itself (the background) [terrain areas/regions]

- Surfaces, geographic features
- Ambient Conditions
  (e.g. light levels, temperature, pressure, acoustic noise, EMI/RFI)

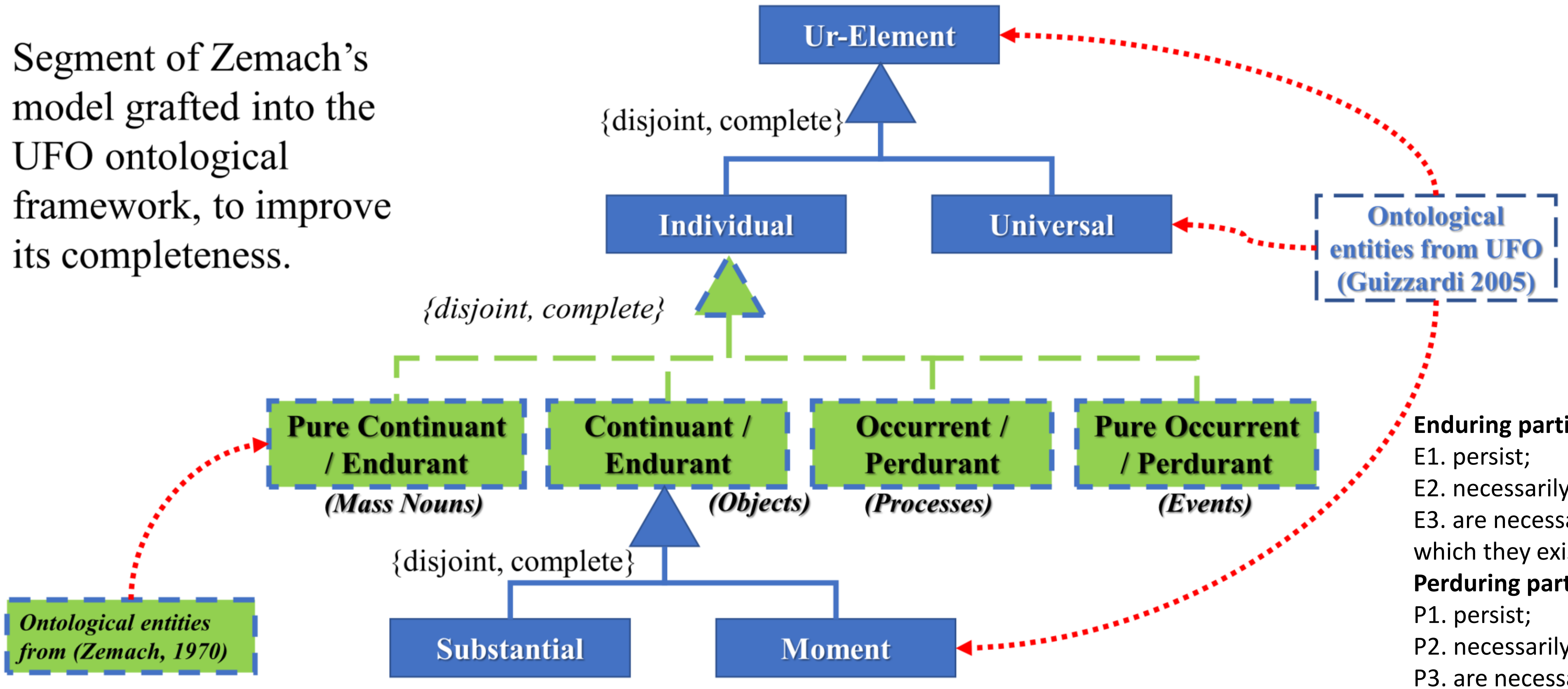
Objects situated within the environment

- Perceived Motion:
  - Things that don’t move (Obstacles)
  - Things that move without purposeful behaviour (Simple Moving Objects)
  - Things that move purposefully (Agents)
  - Biological (Living) Agents
    - Sentient Agents (Human, generally speaking)
    - Non-sentient Agents (Animals, generally speaking)
  - Non-biological Agents
    - Unintelligent Systems (performing only mission tasks)
    - Intelligent Systems (performing mission and non-mission tasks)

Towards an Ontological Framework for Environmental Survey Hazard Analysis of Autonomous Systems

Harper, C. and Caleb-Solly, P., 2021. Towards an Ontological Framework for Environmental Survey Hazard Analysis of Autonomous Systems. *SafeAI@ AAAI*. CEUR Proceedings (CEUR-WS.org, ISSN 1613-0073)

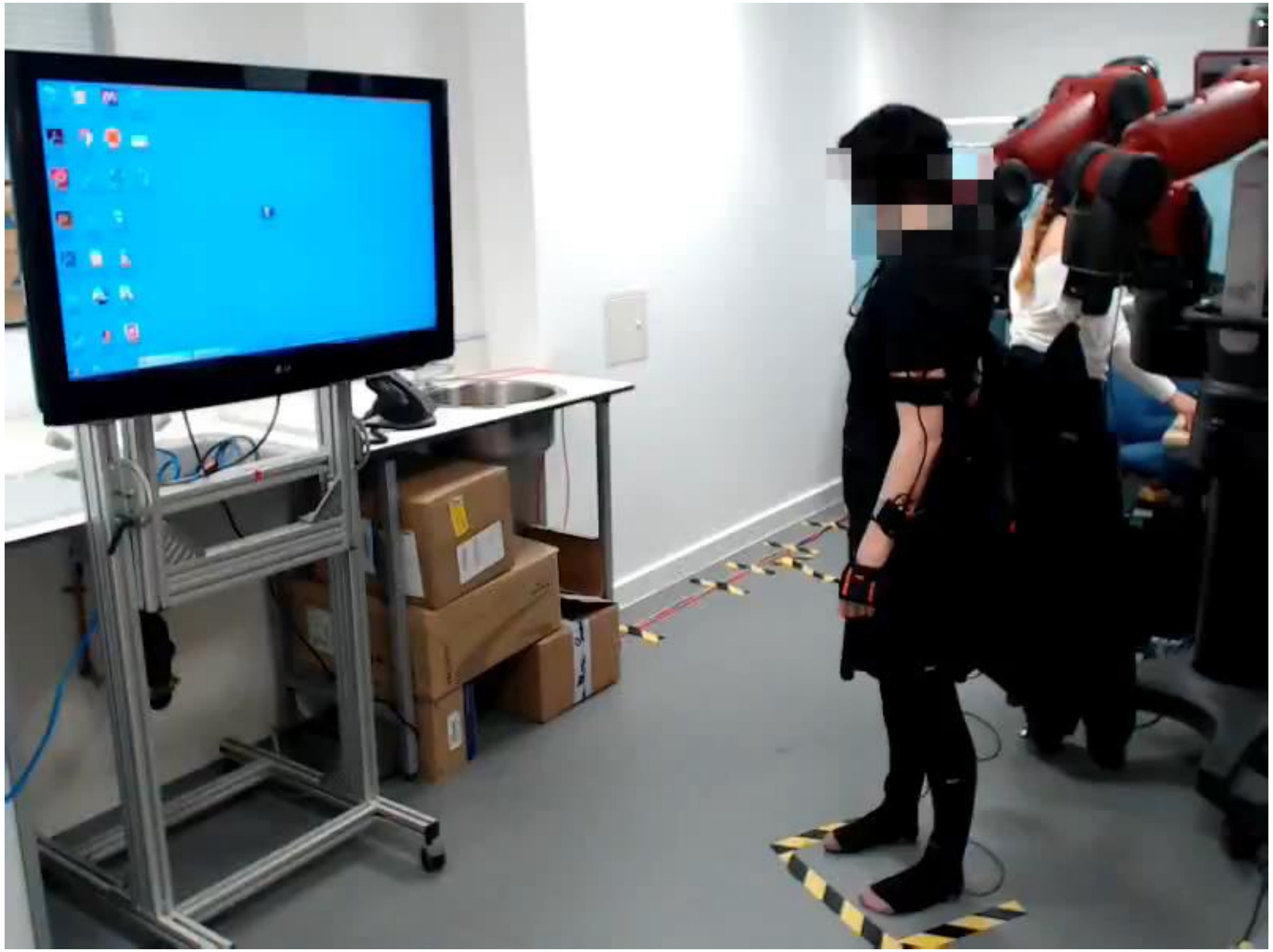
Segment of Zemach's model grafted into the UFO ontological framework, to improve its completeness.



Enduring particulars:
E1. persist;
E2. necessarily lack proper temporal parts;
E3. are necessarily wholly present in each time interval at which they exist.
Perduring particulars:
P1. persist;
P2. necessarily have proper temporal parts;
P3. are necessarily not wholly present in each time interval at which they exist.

- Zemach's "Four Ontologies" (Zemach 1970)
- Unified Foundational Ontology (UFO) (Guizzardi 2005)

Example: Human Factors Issues in a Physical Robot Assistance Dressing Support Task



Safety Related Human Factors issues to note:

1. **Attention/Distraction** and potential for mishaps
2. Impact of **Cognitive Load and Stress** on the interaction

Chance, G., Camilleri, A., Caleb-Solly, P. and Dogramadzi, S., 2016, June. An assistive robot to support dressing-strategies for planning and error handling. In *2016 6th IEEE International Conference on Biomedical Robotics and Biomechatronics (BioRob)* (pp. 774-780). IEEE.

Example: Human Factors Issues in a Physical Robot Assistance Dressing Support Task

Human Factors Safety Related issues to note:

1. **Attention/Distraction** and potential for mishaps
2. Impact of **Cognitive Load and Stress** on the interaction

Example: Human Factors Issues in a Physical Robot Assistance Dressing Support Task

Safety Related Human Factors issues to note:

1. **Attention/Distraction** and potential for mishaps
2. Impact of **Cognitive Load and Stress** on the interaction

Human Factors in Robot Assisted Dressing:

Impact of Cognitive Overload

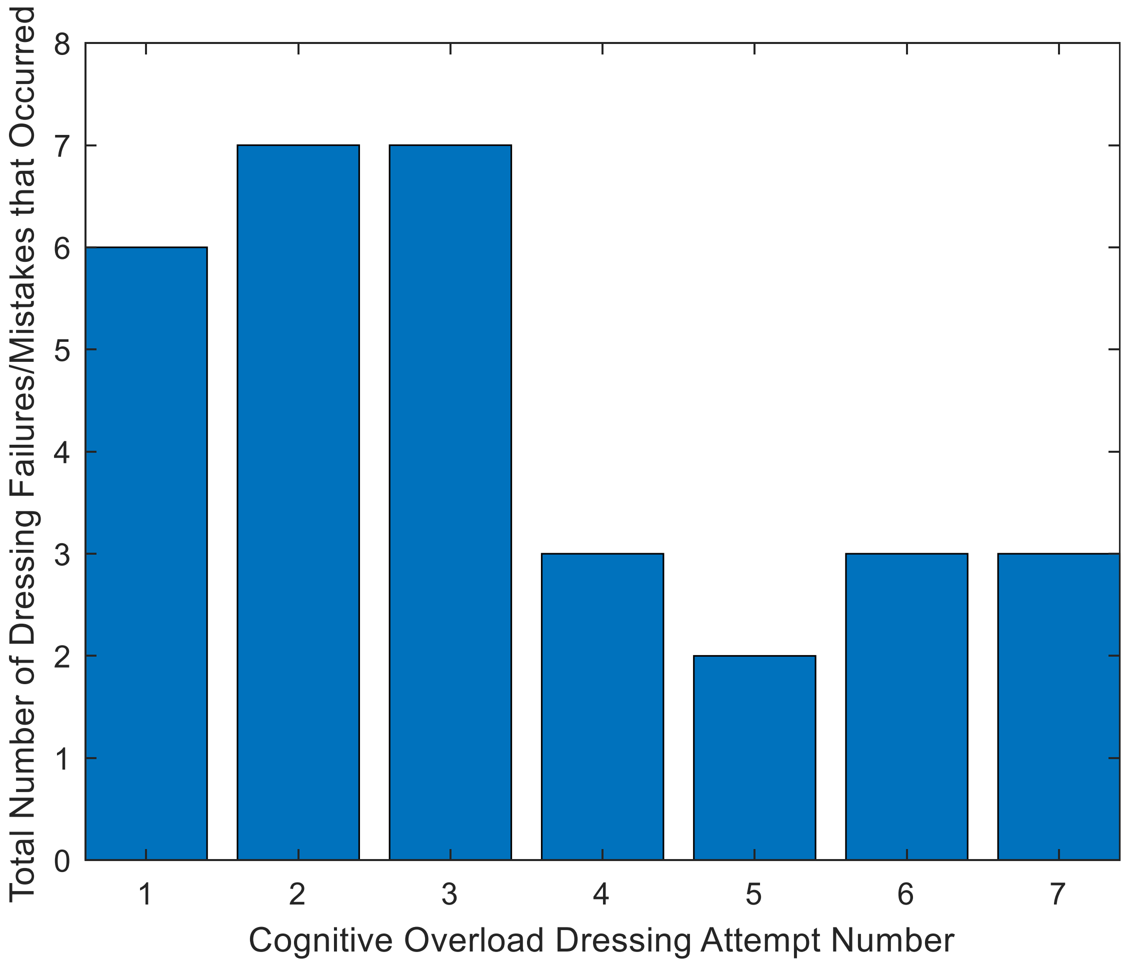
Chance, G., Jevtić, A., Caleb-Solly, P., Alenya, G., Torras, C. and Dogramadzi, S., 2018. “elbows out”—predictive tracking of partially occluded pose for robot-assisted dressing. *IEEE Robotics and Automation Letters*, *3*(4), pp.3598-3605.

- Every recorded dressing issue occurred during cognitive overload section.

Dressing Issues	Stuck	Fail	Stuck or Fail
Total Number of users	11	6	17
% of total users	27%	15%	41%

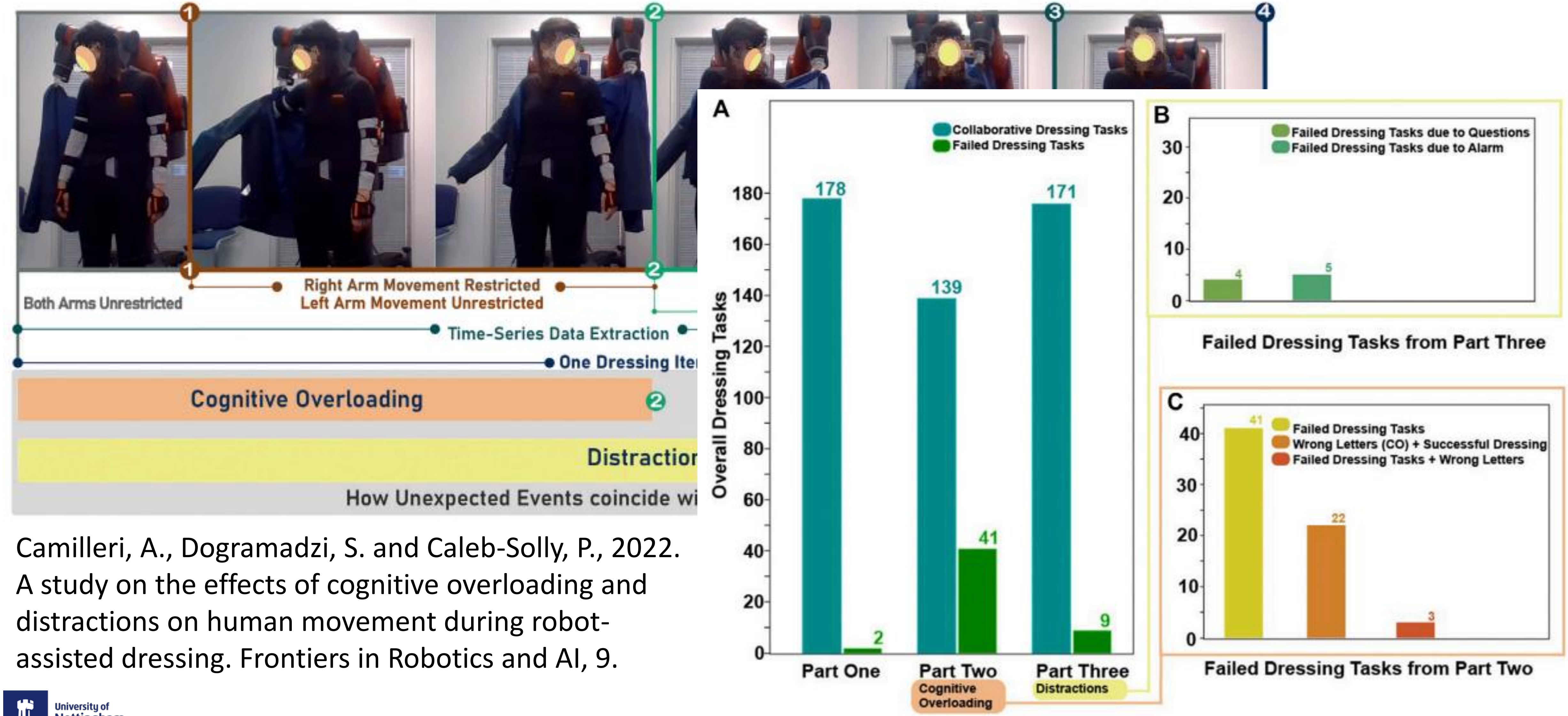
- Mistakes occurred most frequently after the new distraction stimulus was first introduced.

- Participants adapted to the distraction and became more experienced at the dressing process during the experiment.



University of Nottingham
UK | CHINA | MALAYSIA

Human Factors in Robot Assisted Dressing: Impact of Cognitive Overload and Distractions



Camilleri, A., Dogramadzi, S. and Caleb-Solly, P., 2022. A study on the effects of cognitive overloading and distractions on human movement during robot-assisted dressing. Frontiers in Robotics and AI, 9.

University of Nottingham
UK | CHINA | MALAYSIA

Potential Hazards
derived from consultation with care experts

User Related

- User collapsing or falling
- User lets go suddenly (e.g. distracted by ringing phone)
- User could rush towards their target in an uncontrolled way, once they are standing, which could lead to a collision or a fall.
- User has a bent posture, and hits their head on the robot
- User has wet hands and slips off (loses grip of) the robot handles
- User wants to stop but cannot let go, e.g. due to arthritis
- Loose clothing gets in the way and causes restriction/tripping
- User feels anxious and fails to transfer onto the robot properly, leading to a fall
- User wants to sit (or collapse) straight back down before completing the Sit-to-Stand action.

User Falling Modes

- Fainting from standing up too quickly.
- Tipping forward and getting caught up in the robot
- Falling backwards and hitting the chair that the user is standing up from, or hit his/her legs on the bed he/she is standing up from
- Falling into a small or narrow space, e.g. between furniture or between bed and wardrobe, where it is difficult for the user to get up with or without assistance from the robot.
- Falling forward and colliding with the robot
- Crumpling to the floor while still holding the handles resulting in injure, e.g. shoulder injury.
- Losing balance or having sudden pain or a muscle spasm, and fall over
- Foot/feet slippage forward during standing

Robot Related

- Equipment failure, leaving the user in a stranded position
- Speed mismatch between robot and User – robot moves too quickly and pulls the User across the room or off their feet (to fall down)
- Robot does not encourage good standing or sitting technique, which may either be dangerous (risk of strain injury) or counter-productive to rehabilitation.
- Robot **noise levels**: excessive or anxiety-inducing noise may have a negative impact on user behaviour.
- User might not find the robot behaviour or embodiment acceptable

Camilleri, A., Dogramadzi, S. and Caleb-Solly, P., 2022. Learning from Carers to inform the Design of Safe Physically Assistive Robots-Insights from a Focus Group Study. In *Proceedings of the 2022 ACM/IEEE International Conference on Human-Robot Interaction* (pp. 703-707).

Regulatory Considerations for Physically Assistive Robots

Safety Assurance Standards	
ISO 13482:2014	Robots and robotic devices – Safety requirements for personal care robots
BS EN 12182-2012	Assistive products for persons with disability – General requirements and test methods
IEC 61508	Functional safety of electrical/ electronic/ programmable electronic safety-related systems
ISO 12100	Safety of machinery – General principles for design – Risk assessment and risk reduction
EN ISO 11199	Walking aids manipulated by both arms — Requirements and test methods (Walking frames, Rollators, Walking Tables)
EN ISO 11334	Assistive products for walking manipulated by one arm – Requirements and test methods. Elbow crutches, Walking sticks
BS EN 21856	Assistive products — General requirements and test methods

Caleb-Solly, P., Harper, C. and Dogramadzi, S., 2021, March. Standards and Regulations for Physically Assistive Robots. In *2021 IEEE International Conference on Intelligence and Safety for Robotics (ISR)* (pp. 259-263). IEEE.

Regulatory Considerations for Physically Assistive Robots

UK Health and Medical Regulations	
LOLER (1998)	Lifting Operations Lifting Equipment Regulations
MHRA Guidance 2019	Assistive technology: definition and safe use
UK Care Regulations	
NICE Guidelines	Need logging and reporting of accidents and incidents and how and by who the maintenance and servicing would be performed
UK Health & Social Care Act 2008 (Regulated Activities)	UK legal regulations governing health and social care – incorporating service user's preferences

Caleb-Solly, P., Harper, C. and Dogramadzi, S., 2021, March. Standards and Regulations for Physically Assistive Robots. In *2021 IEEE International Conference on Intelligence and Safety for Robotics (ISR)* (pp. 259-263). IEEE.

University of Nottingham
UK | CHINA | MALAYSIA

Empowering the Future Care Workforce

Scoping Capabilities to Leverage Assistive Robotics through Co-Design

- Healthcare professionals
- Social care professionals
- Unpaid carers (family and friends)
- Informal assistants (volunteers)

https://www.tas.ac.uk/research-projects-2022-23/empowering-future-care-workforces/

Rethinking Assistive Robots

- **Assistive robots require deeper consideration of how they will be supported:**
  - ➢ Step change compared to existing ways of delivering care
  - ➢ Are autonomous systems so have the ability to self-adapt
- **Complex user conditions and needs are difficult to characterise:**
  - ❑ Need to determine how the health-care professional will be supported in
    - ➢ Initial system modelling to learn generalized solutions and then personalised to individual needs/context
    - ➢ Identifying required range of adaptability
    - ➢ Ensuring that the robot addresses specific clinical, cognitive and psychological care needs of their users, and the risks are assessed accurately.
- **There are still gaps in industry standards and design methods:**
  - ❑ Functional and non-functional requirements elicitation and representation
  - ❑ Safety analysis and risk assessment
  - ❑ Verification and validation

University of Nottingham
UK | CHINA | MALAYSIA

Thank You