Wearable Clinic: Safety Assurance

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(Safety) Benefits

- Digital health technologies matter for patient care
  - Core technology in healthcare

- AI, apps and wearables have a great potential for patient empowerment
  - Proactive care, self-monitoring, planning, real-time data, …

Safety Basics

- Digital health failures also matter!
  - Can compromise, under certain conditions, patient safety and lead to harm

- Need to identify and analyse these unsafe conditions
  - Manage them in a **Hazard Log**
- Justify that what we did is sufficient
  - Captured in a **Safety Case**

Safety Challenges

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Advantages

- Cheap(?)
- Commercially available
- Open source
- Reconfigurable
- Intelligent

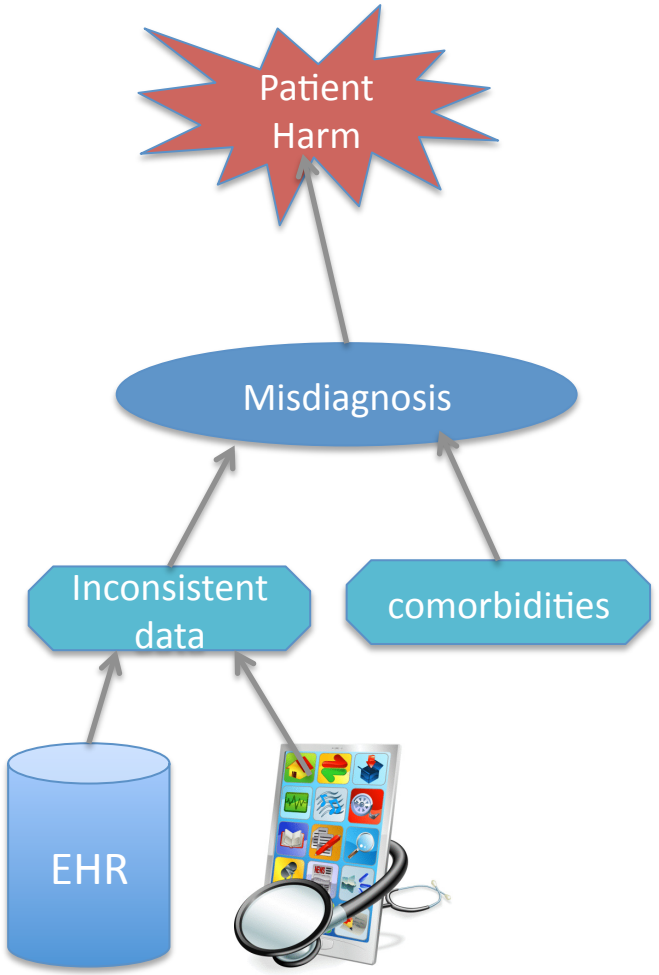
Safety Concerns

- Cheap(?)
- Commercially available
- Open source
- Reconfigurable
- Intelligent

New assumptions about the role of patient and carers

No agreement on regulations and standards

An Example

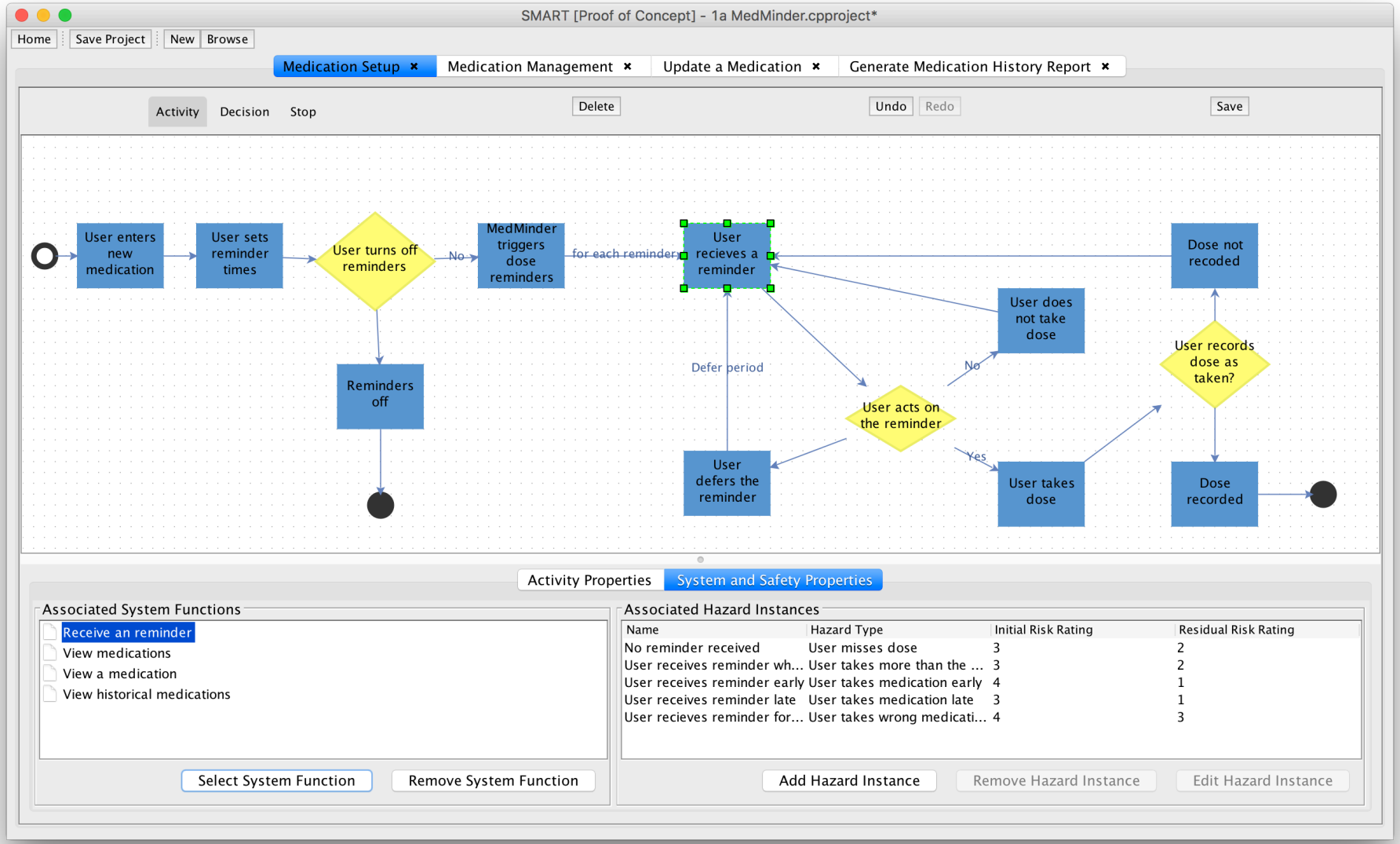


- Importance of:
  - Safety by design
  - Through-life assurance

Open Source safety Cases

- MediPi: open-source telehealth solution
- MedMinder: self management of medications
- Peripheral Arterial Disease (PAD): self-management and self-test app
- …

SMART


SMART [Proof of Concept] - 1a MedMinder.cpproject*
Home
Save Project
New
Browse
Medication Setup
Medication Management
Update a Medication
Generate Medication History Report
Activity
Decision
Stop
Delete
Undo
Redo
Save
User enters new medication
User sets reminder times
User turns off reminders
No
MedMinder triggers dose reminders
for each reminder
User recieves a reminder
Dose not recoded
User does not take dose
Defer period
No
User records dose as taken?
Reminders off
User acts on the reminder
Yes
User defers the reminder
User takes dose
Dose recorded
Activity Properties
System and Safety Properties
Associated System Functions
Receive an reminder
View medications
View a medication
View historical medications
Select System Function
Remove System Function
Associated Hazard Instances
Name
Hazard Type
Initial Risk Rating
Residual Risk Rating
No reminder received
User misses dose
3
2
User receives reminder wh...
User takes more than the ...
3
2
User receives reminder early
User takes medication early
4
1
User receives reminder late
User takes medication late
3
1
User recieves reminder for...
User takes wrong medicati...
4
3
Add Hazard Instance
Remove Hazard Instance
Edit Hazard Instance