



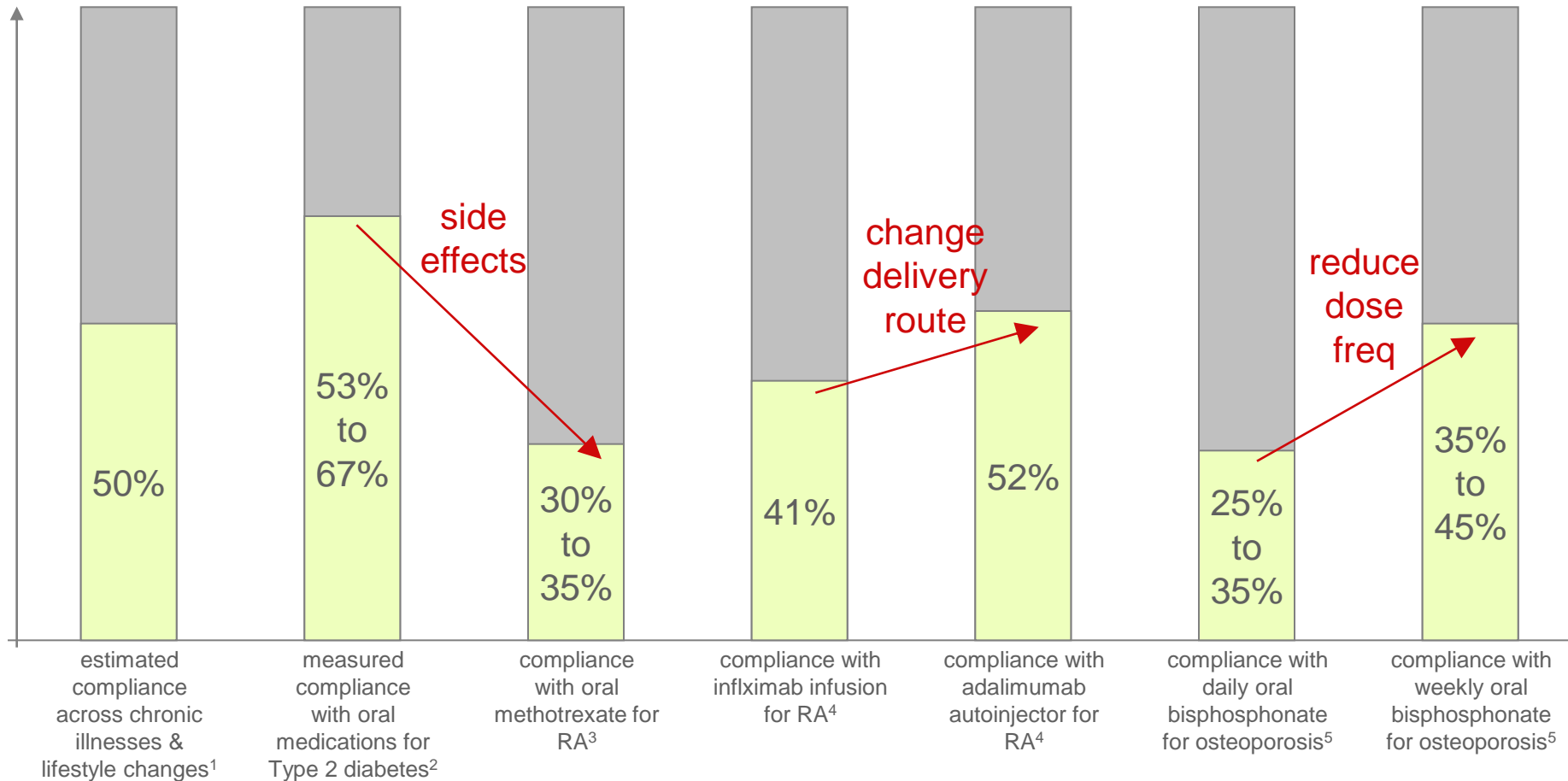
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that enhance lives

Device Usability and Compliance: The Implications, Opportunities and Requirements

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Compliance – some research data



1 - Haynes et al (1979) *Compliance in health care*. Johns Hopkins University Press, 1979

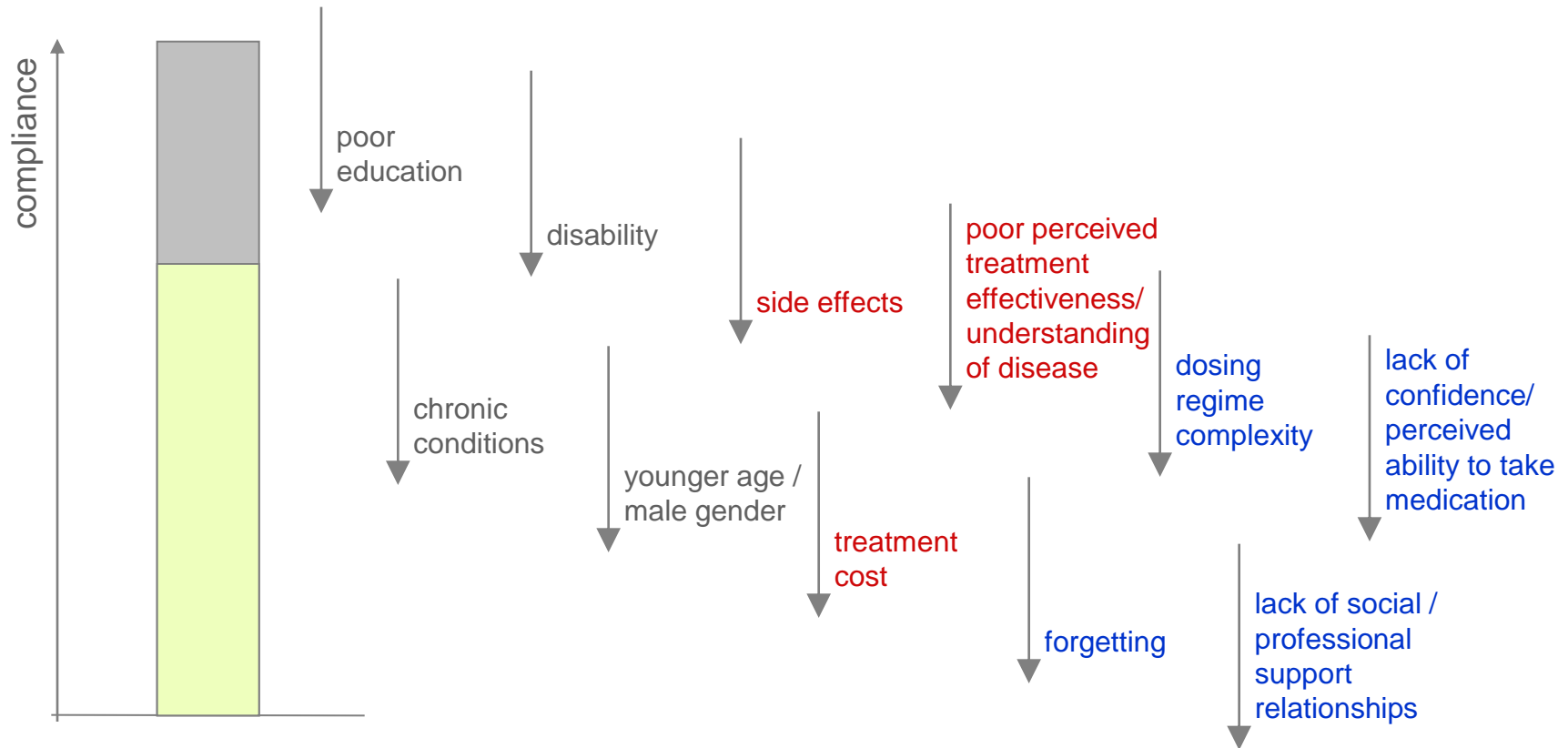
2 - Paes et al (1997) Impact of dosage frequency on patient compliance. *Diabetes Care* 20:1512 -1517

3 - Viller et al (1999) Compliance to drug treatment of patients with rheumatoid arthritis: a 3 year longitudinal study. *J Rheumatol* 10: 2114-22

4 - Hetland et al (2010) *Arthritis & Rheumatism* 62: 22–32

5 - Cramer et al (2007) A systematic review of persistence and compliance with bisphosphonates for osteoporosis. *Osteoporos Int* 18:1023–103

Compliance – influencing factors



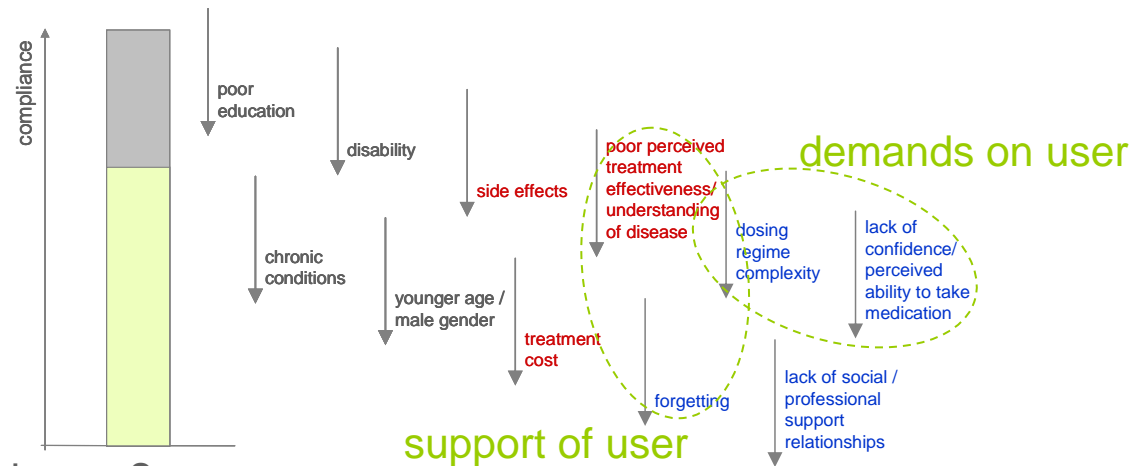
- driving wilful non-compliance
- driving unintentional non-compliance

1 - Paes et al (1997) Impact of dosage frequency on patient compliance. *Diabetes Care* 20:1512 -1517

3 - Viller et al (1999) Compliance to drug treatment of patients with rheumatoid arthritis: a 3 year longitudinal study. *J Rheumatol* 10: 2114-22

6 - Silvermann et al (2010) Oral bisphosphonate compliance and persistence: a matter of choice? *Osteoporosis International* 22: 21-26

Compliance – what can we device developers influence?



- what can't we change?
 - the disease condition
 - the drug: side effects, symptomatic relief
 - the patient's age / gender / disabilities / socioeconomic status

- what can we influence?
 - the formulation: e.g. dosing frequency
 - the delivery route: e.g. from IV to SC, depot implants, wearable devices/patches
 - the **demands on the user** associated with dose delivery
 - the **support** provided to the patient to help them adhere to dosing regime
 - the patient's perceptions of and attitudes to their treatment

Improving Compliance through Usability - Reducing Demands on our Users

- what do we need to do to **minimise the core physical and cognitive burden of delivering a dose?**
- target - eliminate the negatives
 - perfect device reliability / consistency of performance in hands of users
 - no significant use-related risks
 - accommodate to full range of user input (e.g. grip styles, operation styles) & maximise ease of use
 - minimise delivery pain / anxiety
- but there are some conflicts
 - e.g. clarity of feedback vs. discretion/privacy
 - e.g. some users want to be in ‘control’, others want ‘distance’
- excellent usability = zero “delivery task” burden ...
.... but cannot address the “self-management task” burden



Improving Compliance through Additional Functionality – Supporting Users

- what can we do to **reduce the cognitive and emotional burden of managing their treatment?**
- on-board electronic features:
 - reminders
 - dose logging / memory
- wearable / implantable devices
- links to other devices:
 - smartphone self-management apps
 - diagnostic devices – theranostics – improved patient awareness of therapeutic effectiveness
 - integration – physical and communications – of these devices
- links to social networks
 - e.g. www.patientslikeme.com/



Health Economics and Related Issues

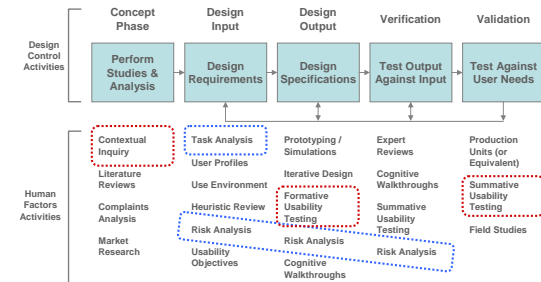
- compliance = improved clinical outcome
 - improved clinical outcome means
 - improved patient wellbeing
 - improved ability for gainful employment
 - better return on cost of treatment
 - i.e. better health economics overall

- a compliance-enhanced delivery device
 - offers health economics benefits
 - becomes the device of choice by patients, prescribers and payers
 - hence increases product loyalty
 - this is further enhanced for a retained device which
 - offers desirable additional features (alarms, aids to use etc) which may not be possible with a disposable device
 - the retained device can be designed to accept only the 'official' refills, thus ensuring product loyalty and hence continued revenue



Discussion Point 1 – Delivering Excellent Usability

- follow usability engineering / human factors process with passion and creativity
 - FDA guidance
 - ISO/IEC 62366 (incl. ANSI/AAMI HE74)
 - ANSI/AAMI HE75:2009
- regulatory necessity ...
- ... and improve compliance



Discussion Point 2 – Realising the Potential of Reusable Injectors (1/2)

Electronically Enabled Delivery Devices (EEDDs)

- don't spoil the opportunity!
- there is a perception that re-usable devices are clunky, awkward to use and undesirable....
- IT DOESN'T NEED TO BE LIKE THIS!

- well designed devices *should* be easy to use and *can* support additional functionality ...
 - ... remember that different patient groups have different needs/viewpoints;
 - seniors with a regular, but infrequent dosing regimen need reminders
 - children may respond well to simple compliance “rewards”
 -different strokes for different folks



Discussion Point 2 – Realising the Potential of Reusable Injectors (2/2)

Electronically Enabled Delivery Devices – Cost Comparison

- for prolonged/chronic treatment, cost per shot with an EEDD can be very competitive compared to a single use mechanical device;
 - mechanical single-use device ~ \$3
 - ‘limited’ functionality
 - if weekly therapy, device cost per shot (excluding drug and primary pack) = \$3

 - electro-mechanical multi-use reloadable device ~ \$40
 - ‘unlimited’ functionality
 - if weekly therapy and device replaced after 3 years (156 shots), hence device cost per shot (excluding drug and primary pack) = \$0.25

 - so maybe it’s not the expensive option after all...
 -especially if repeat prescriptions are unlikely to be filled with a substitute product!
-



Discussion Point 3 – Changing Perceptions of Injection

- what do we expect the injection experience to be like?
- what might a new generation of patients expect?
- why not see how we can improve the experience for the patient (and for us as well!)?



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