

Designing P4 - Predictive, Preventive, Personalised and Participative - Healthcare Interventions for Managing Cognitive Decline and Dementia: Where are we at?

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Designing P4 Healthcare Interventions For Managing Cognitive Decline And Dementia: Where Are We At?

3 This paper presents a systematic literature review aimed at assessing how well current 4 technology-based interventions that focus on dementia and other cognitive impairments align 5 with the principles of the P4 vision for healthcare: Predictive, Preventive, Personalised and 6 Participative. A search of the SCOPUS database yielded 887 articles, of which 48 were 7 ultimately selected for analysis. Looking at whether and how each intervention implements 8 each "P"-principle, our results suggest a partial and non-systemic embrace of the P4 vision. 9 Reasoning on possible explanations for this state-of-the-art, we propose that our findings 10 represent an opportunity for the engineering design community to engage with P4-based 11 healthcare delivery models through the development of design frameworks, new indicators for 12 assessing the success of such healthcare delivery models, as well as tools and methods.

Keywords: Engineering Design, Healthcare Design, Healthcare Improvement, P4 Healthcare,
Dementia

15 1. Introduction

16 Design for health is gaining attention. More specifically, design thinking and engineering methods 17 generate growing enthusiasm as means to improve our healthcare services and systems (Clarkson et 18 al. 2004; Craig and Chamberlain 2017; Doss 2014; Kim, Myers, and Allen 2017; Komashie and 19 Clarkson 2018; Clarkson 2018; Ku and Rosen 2016; Lamé 2018; Patou and Maier 2017). This 20 relatively recent realisation comes as process inefficiencies, budget limitations, increasing 21 technology-adoption costs, rising prevalence of chronic diseases, and the scarcity- and work overload 22 of care personnel continue to challenge the performance of our healthcare systems (Cutler, Rosen, 23 and Vijan 2006; Spillman and Lubitz 2000). Only recently promoted by leading voices in healthcare 24 organisational management and clinical practice, a call for design thinking and the adoption of 25 engineering methods in healthcare have emerged from large systematic investigations of healthcare systems at both the national and international levels (Christensen, Hasman, and Hunter 2010; WHO 26 27 2009; Clarkson et al. 2017). These studies have revealed the potential of design thinking frameworks 28 for improving value-effectiveness and cost-efficiency in healthcare, through interventions at various

scales: from guiding national policy-making to prescribing recommendations for the structural remodelling of healthcare organisations, to the reengineering of more confined, context-specific care services. The successful application of such frameworks has confirmed the validity of a design- and systems approach to healthcare engineering. Although currently convincing when applied to the traditional healthcare delivery model, systems thinking and engineering design methods face a new challenge: the to-date unfamiliar emergence of new models of healthcare delivery and the novel types of products and services these models are inspired by and potentially call for.

8 The vision of a more Predictive, Preventive, Personalised and Participatory (P4) medicine 9 is perhaps the most illustrative set of guiding principles both advocating and foreseeing the radical 10 remodelling of medical practice (Flores et al. 2013). Although Hood et al. (2004) originally 11 introduced his vision of a P4 medicine and did not elaborate on the implications of the 12 transformation of medicine on the forms and objectives of our healthcare systems, we see in P4 a 13 set of predictive and prescriptive principles with a transformative potential for the improvement of 14 healthcare delivery if and only if these principles are operationalised through appropriate P4 15 healthcare delivery models. We therefore extend the semantic use of P4 and will refer from now on 16 to P4 healthcare to relate to models of healthcare delivery founded on the P4 principles. We argued 17 elsewhere that these models were essential for achieving value-effectiveness, i.e. cost-efficiency, 18 clinical efficacy, equity of access to care, and economic sustainability our healthcare systems are 19 desperately in need of (Patou and Maier 2017). The present paper builds on this perspective and 20 seeks to highlight the need for specific engineering design frameworks, methods, tools, and metrics 21 to foster successful P4 healthcare models, materialised through healthcare policies, organisational 22 structures, services, and products.

In what follows, the fundamental principles at the core of P4 healthcare are drawn and a systematic review of the engineering design and relevant clinical research literature on complex medical interventions for the clinical management of Mild Cognitive Impairment (MCI) and

1 dementia covering the past decade is presented. Mild Cognitive Impairment and dementia are 2 chosen as the focus of this paper as they are of great concerns societally. More specifically, for each reviewed work, the contribution of the intervention at play to each 'P' of the P4 principles is 3 4 assessed and reported in detail. Similarly, we identify and discuss, for the same set of complex 5 interventions (Moore et al. 2015), the elements implementing principles antithetical to the P4 6 principles: those generally associated with the conventional care model, i.e. reactive, palliative, 7 passive, and mostly population-based, which we refer to as generic. Findings are then discussed 8 from an engineering design viewpoint. Following, we elaborate on the rationale that could explain 9 why to-date, P4 remains largely unattained. Finally, opportunities for engineering design research 10 and practice to support and lead developments towards Predictive, Preventive, Personalised and 11 Participatory (P4) healthcare service delivery are highlighted.

12 2. Background

13 2.1 Predictive, Preventive, Personalised and Participatory (P4) Healthcare

14 Today, healthcare systems are still predominantly tailored around the reactive, curative or palliative, 15 and population-based (i.e. generic) care delivery model of evidence-based medicine (Hood, Balling, 16 and Auffray 2012). Their main objective is to react promptly to solicitations from symptomatic patients, i.e. to diagnose, treat and rapidly dismiss patients suffering an acute condition, or to 17 18 provide episodic support for the chronically ill. The scientific and technological disruptions of the 19 past two decades are driving a paradigm-shifting change in this model, with a trajectory set towards 20 the advent of P4 medicine (Westont and Hood 2004; Hood, Balling, and Auffray 2012; Hood and 21 Auffray 2013; Sagner et al. 2017). Predictive, Preventive, Personalised and Participatory (P4) 22 medicine is deemed to emerge from the "confluence of a systems approach to medicine and from 23 the digitalisation of medicine that creates the large data sets necessary to deal with the complexities 24 of disease" (Hood, Balling, and Auffray 2012, p.992). In other words, P4 medicine promises 25 proactive health and care delivery, more focused on wellness and on the implementation of

1 anticipatory measures for predicting and preventing disease or adverse consequences. This vision 2 contrasts with the main objectives and strongholds of our present healthcare systems: reactiveness 3 and short-term efficiency of episodic care delivery. Conceptualised after the completion of the 4 Human Genome Project and related breakthroughs in DNA sequencing technologies, the vision of a 5 P4 medicine is as much relying on progress in the life sciences as it is dependent on the capabilities 6 offered by novel Information and Communication Technologies (ICTs), including smartphones, 7 wearables, virtual-reality, data science and artificial intelligence. The concept of digitisation that 8 Hood et al. (2012) refer to is central in discussions on P4 medicine and the future of healthcare: it 9 evokes the digital capture of health-related information and the algorithms and devices on which the 10 vision of personalised medicine relies (Swan 2012; Topol 2014). The emergence of this new paradigm has implications for the power of design- and systems 11 12 methods for healthcare, especially for those aimed at guiding the design of healthcare products and 13 services. 14 Let us consider the first of the four P's, namely *Prediction: Predictive* medicine aims to determine the odds in absolute or relative terms that an individual develops a disease, that her 15 16 condition worsens, that she responds to specific medication or develops treatment side effects. 17 Prediction means to anticipate diagnostic outcome or therapeutic efficacy most often to be able to 18 prevent or to prepare in cases where prevention is not possible. Prediction is made possible by the 19 identification, collection, fusion and analysis of personal data acquired from various and 20 multimodal sources. Importantly, prediction is tightly coupled with *personalisation*, given that 21 accurate and precise predictions require the availability of data of people's unique biology, 22 behaviour and environment. This digital phenotyping of the individual is at the core of the future of 23 healthcare and we can therefore anticipate that good healthcare service design will require relying 24 on theories adapted to this reality (e.g. data-driven design (Parraguez and Maier 2017)). As 25 predictive healthcare strategies better inform us on both the general and individual mechanisms of 26 health and disease, the design of targeted *preventive* strategies will become feasible. Targeted

1 preventive medicine requires a knowledge base of all the factors and causal mechanisms linking the 2 genome, the environment and behaviour to the onset and development of disease and to treatment 3 response. If predictive medicine grants us that knowledge, policy-makers and healthcare service 4 providers should have the capacity to plan and implement *preventive* strategies focused on eliminating disease factors, or on diminishing their effects. Whether they involve pre-emptive 5 6 exogenous care delivery measures or not, these strategies will certainly aim at changing endogenous 7 behaviours among individuals presenting an unacceptable risk of health deterioration. P4's 8 preventive medicine is, as its name indicates, particularly suited to the anticipation of preventable 9 diseases, a significant number of which are chronic. The initial development and further progression 10 of chronic diseases are often influenced by behaviour and lifestyle, suggesting that preventive 11 healthcare strategies should be heavily based on cognitive and behavioural theories. Successful 12 implementation of such strategies will thus depend on our ability to harness cognitive and 13 behavioural insights; in particular those that are related to motivation, ownership, and engagement, 14 so that we can design and actuate interventions reducing or limiting self-damaging behaviours in 15 individuals most at risk. This brings us to the fourth P of P4 medicine. Future medicine is hoped to 16 be *participatory* or collaborative: it is also expected that patients become much more involved and 17 self-empowered in their own health management. The rationale behind this proposition, as has been 18 argued e.g. in Topol (2015) is that our traditional healthcare delivery model is characterised by a 19 large asymmetry in information availability and capability to take action between patients and 20 clinicians, which has been said to be patriarchal, inefficient and unjustified. While the ill and weak 21 have historically been largely dependent on their care providers, healthy citizens and patients alike 22 are today empowered with tools to become prominent contributors of their own health management. 23 Mobile health, personal health records and on-demand genetic testing are examples of the large 24 spectrum of technology-derived empowerment tools that appear to make the vision of a 25 participatory care model possible today. As mentioned earlier, participation is particularly relevant 26 when it comes to preventable diseases, when asymptomatic citizens hold the key to remaining

healthy in their behaviour and lifestyle. Moreover, *participatory* care also applies to scenarios
 beyond the point of prevention, in cases where treatment and day-to-day clinical management of
 disease are required. *Participatory* care could then take many forms, involving shared decision
 making between patient and clinicians, e.g. on objectives and strategies for treatment.

5 2.2 P4 healthcare for cognitive impairment and dementia care

6 Dementia care and management of other forms of cognitive impairment represent a challenging yet 7 relevant use case for our investigation. Cognitive impairment in its milder forms often appears as an 8 abnormal, faster-than-normal, symptomatology of ageing. Although some individuals diagnosed 9 with a mild form of cognitive impairment remain stable, a significant number of them will see their 10 condition evolve towards dementia. The milder forms and slow progression from Mild Cognitive 11 Impairment (MCI) to dementia gives an opportunity for healthcare professionals, informal carer and 12 the person living with MCI to attempt and slow down or mitigate the apparition of symptoms, the 13 loss of autonomy, and the distress of both the person living with MCI and their entourage. Often 14 progressive, with adverse events (e.g. episodes of confusion, wandering, etc.) partly predictable and 15 to some extent preventable, it is reasonable to argue that cognitive impairment and dementia care 16 should be relevant to a P4-guided approach (Kivimäki and Batty 2016; Norton et al. 2014; Sabia et 17 al. 2017). It is worth noting that prevention may go beyond forestalling of the disease onset and 18 may also relate to strategies designed to delay further progression of the disease or to prevent some 19 of its adverse events. Also, people with dementia vary broadly in their functional capacity and 20 lifestyle, and pattern of symptoms and co-morbidities. A wide range of individual needs and 21 preferences can therefore be exploited to maintain wellbeing and autonomy as much and as long as 22 possible. Within the limits of prescribed "good-behaviours", personalisation ought to enable the 23 selection of the tailored health management measures that people suffering from cognitive 24 impairment are in great need of.

1 The current and expected impact of dementia worldwide is one of the most preoccupying 2 figures in society today. Worldwide, 50 million people were living with dementia in 2018 3 (Patterson 2018). This number is expected to rise to more than 152 million by 2050. Adding to an 4 incommensurate social and moral burden, the cost of dementia weighs heavy on our healthcare 5 systems, with more than 1 trillion USD spent worldwide in 2018 alone.

6 **3. Methods**

7 A systematic review of the literature addressing technology-based complex interventions for 8 dementia care and for managing cognitive impairment (Moore et al. 2015) was carried out 9 following the process depicted in **Figure 1**. For each reviewed paper, the objective was to assess 10 whether elements of the intervention implemented any of the 4 P's (predictive, preventive, 11 personalised and participatory), and to what extent. Interventions in this context would include 12 products, systems, services or a combination thereof, targeting actors in the care network, including 13 people with dementia or other form of cognitive impairment, their caregivers or healthcare 14 professionals such as nurses, general practitioners, gerontologists. The review process was 15 conducted by two researchers. Both reviewers carried out the search and filtered search results 16 according to the selection criteria. Papers included or rejected by only one of the reviewers were 17 discussed until a definite list of papers to review was agreed upon. Both researchers then separately 18 read and analysed each paper and reported their findings. Discrepancies in the evaluation were then 19 discussed in tandem and resolved. The table cells for which a disagreement was originally present 20 are marked with an asterisk* character in Table 2.

21

22 3.1 Literature search

We systematically searched, selected and analysed relevant papers, as outlined in Figure 1. The
SCOPUS scientific database was searched for papers with a title, keywords or abstract containing
the terms "design" + either "technology", "intervention" or "system"; + either "dementia" or "mild

1	cognitive impairment". Sources were limited to a collection of journals within the fields of
2	engineering design, technology, healthcare, and the clinical sciences (see Appendix A). To avoid
3	any anachronistic mismatch (interventions specified before the formulation of the P4 medicine
4	vision), we limited the timeframe of our search to papers published from 2007 onwards (Hood
5	2008; Price et al. 2008). As a reference point, this also coincides with the release of the first iPhone
6	in 2007. Finally, we excluded review papers to avoid double-counting.
7	

8

Figure 1

9

10 3.2 Selection process

The literature search yielded 887 results from which 48 papers were ultimately included in the 11 12 analysis. In the first phase, all titles and abstracts were screened to filter out irrelevant search 13 results. Reasons for exclusion included no mention of a design process for the intervention (explicit 14 or implicit), the altogether absence of an intervention (such as in purely observational studies), 15 retrospective studies, interventions missing a technological element, or wrong target group. 16 Interventions lacking an appropriate technological element typically included pharmacology-only, 17 diet, physical activity, relaxation/stimulation activities, group therapy or other counselling 18 approaches, or archaic technology, e.g. a line telephone. The screening process filtered most of the 19 original search results, yielding 75 candidates for a detailed review. 20 In the second phase, full-text reviews were conducted to elicit the aim and implementation 21 details of each intervention. A further 27 papers were excluded in this process, mostly when an 22 insufficient level of detail prevented the confident delineation of modular aspects, i.e. elements of 23 the intervention realizing any of the P4 principles.

1 3.3 Review and analysis

2 A total of 48 peer-reviewed journal publications met our inclusion criteria for final review and 3 analysis. The goal of the analysis was to identify and describe interventions translating explicitly or implicitly to one or more of the 4 P's of P4 healthcare (predictive, preventive, personalised and 4 5 *participatory*) or, on the contrary, any antithetical principle to P4. We thus contrasted each of the 6 P's with their respective conceptual counterpart: reactive vs predictive, palliative/curative vs 7 preventive, generic vs personalised, passive vs participatory. 8 An overview of the characteristics we strived to identify and describe is provided in Table 1. 9 For each paper, an intervention with a technological element at its core, was identified along with 10 its primary purpose. The paper was then analysed to find evidence that the intervention included at 11 least one element representative of any of the characteristics listed in Table 1. A given intervention 12 could very well include several elements, each supporting conceptually contrasting, opposing 13 characteristics, e.g. reactive vs preventive, and generic vs personalised. In such a case, each element 14 would be detailed in the appropriate table cell. 15 16 17

18

Healthcare delivery	Characteristic	Description
Conventional Healthcare	Reactive	Care/treatment/intervention plan is determined and provided only after an adverse event, such as a trauma, or the appearance of or worsening of symptoms has occurred.
	Curative/ Palliative	Care/treatment/intervention aims to restore health after symptoms are already affecting the patient. In cases where recovery is not achievable, the objective is to accompany the individual (e.g. avoid discomfort) as the condition progresses.
	Generic	Care/treatment/intervention follows a one-size-fits-all: it is applied in the same way for all patients of a population meeting given criteria.

19 **Table 1.** Summary of characteristics of conventional and P4 healthcare used to review literature

	Passive	Care/treatment/intervention is administered unidirectionally by the healthcare professional to the patient without requiring active participation of the latter.
P4 Healthcare	Predictive	Care/treatment/intervention incorporates elements predicting the absolute of relative odds of health-related event to occur, e.g. disease onset or progression, or treatment response.
	Preventive	Care/treatment/intervention includes elements meant to prevent the onset or progression of disease, thereby avoiding or reducing the need for therapeutic measures.
	Personalised	Care/treatment/intervention is systematically tailored to each care recipient's individual health needs/disease profile and individual preferences.
	Participatory	Care/treatment/intervention is realized bidirectionally: it strongly encourages that the care recipient plays an active role in specifying, planning and implementing their treatment/intervention in collaboration with healthcare professionals.

1 4. Results

2 The literature search yielded 887 candidate papers before screening, of which 75 matched the 3 inclusion criteria for full text review. The in-depth full text-analysis of said 75 interventions targeting cognitive impairment or dementia led to the further exclusion of 27 studies, arriving at a 4 5 final selection of 48 papers, with the synthesis of results presented in what follows. Detailed results of the review are available as supplementary material (Patou et al. 2020). An abridged version is 6 7 provided in Table 2 where papers are presented in descending, chronological order. Markings in the 8 cells indicate whether elements translating a given characteristic could be identified or not (black 9 cell = yes, white cell = no). The cells for which the two reviewers were originally in disagreement 10 are marked with an asterisk * in Table 2, which was the case for overall 33 out of the 384 cells 11 (8.59%) of Table 2. Disagreements were resolved and reflected in the final colour of the cell. 12

Table 2. Abridged results relating articles to characteristics of conventional and P4 healthcare. Each
black cell represents the fact that the study reports an intervention including one or more elements
satisfying a given criterion of either conventional or P4 healthcare. Results are listed in descending,
chronological order. Abbreviations: R = Reactive, C/P = Curative/Palliative, G = Generic, Pa =
Passive, Pd = *Predictive*, Pv = *Preventive*, Ps = *Personalised*, Pt = *Participatorv*.

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#	Paper	R	C/P	G	Р	Pd	Pv	Ps	Pt
1	(McCreedy et al. 2019)								
2	(Thorpe, Forchhammer, and Maier 2019)								
3	(Law et al. 2019)								
4	(Bekrater-Bodmann et al. 2019)								
5	(Jeon et al. 2019)								
6	(Helal and Bull 2019)		*						
7	(Tang et al. 2019)						*		
8	(Gelonch et al. 2019)						*		
9	(Moyle et al. 2019)								
10	(Gustafson et al. 2019)								
11	(Oksnebjerg, Woods, and Waldemar 2019)							*	
12	(Hooper et al. 2019)								*
13	(Enshaeifar et al. 2019)			*	*				*
14	(Wijma et al. 2018)								
15	(Moyle et al. 2018)				*				
16	(Killin et al. 2018)							*	*
17	(Soellner et al. 2015)						*	*	
18	(Barbera et al. 2018)			*		*			
19	(Burton and O'Connell 2018)								
20	(Lindauer et al. 2017)								
21	(Duggleby et al. 2017)								
22	(Elfrink et al. 2017)				*				
23	(Bahar-Fuchs et al. 2017)								
24	(Lazarou et al. 2016)								
25	(Jekel et al. 2016)					*			
26	(van de Weijer et al. 2016)			*					
27	(Mirelman et al. 2016)	*							
28	(van Knippenberg et al. 2016)								
29	(Gaugler, Reese, and Tanler 2016)	*							
30	(Matthews et al. 2015)								
31	(Tak et al. 2015)								
32	(Moreno, Elena Hernando, and Gomez 2015)								
33	(Baker et al. 2015)								
34	(Schaller et al. 2015)			*					
35	(Cristancho-Lacroix et al. 2015)								*
36	(Boman et al. 2014)								*
37	(Grindrod et al. 2014)	*							

#	Paper	R	C/P	G	Ρ	Pd	Pv	Ps	Pt
38	(McKechnie, Barker, and Stott 2014)								
39	(Aloulou et al. 2013)				*				*
40	(Blom et al. 2013)								
41	(García Vázquez et al. 2012)	*		*					
42	(Meiland et al. 2012)								
43	(van Hoof et al. 2011)						*		
44	(Van Der Marck et al. 2011)						*		
45	(Van Der Roest et al. 2010)						*		
46	(Hilbe et al. 2010)								
47	(Mihailidis et al. 2008)						*		
48	(Shoval et al. 2008)					*			

- 1
- 1
- 2

3	Results of the analysis indicate that none of the interventions we reviewed presented all four
4	characteristics of the P4 healthcare model simultaneously. Furthermore, we do not observe any
5	clear trend reflecting either a moving-away or a moving-towards a generalisation of the P4
6	principles. Noticeably though, elements of preventive and personalised care are generally
7	observable over the entire timespan covered by this study, whereas aspects of participatory care
8	seem to have appeared more recently. Predictive care remains very scarce. As mentioned earlier,
9	complex technology-based interventions are not monolithic blocks: they are generally composed of
10	several elements aggregating in a product-service system. It is at the lower element level that the
11	characteristics of conventional or P4 healthcare appear, and it is therefore not incompatible to see
12	conceptually-opposite characteristics fulfilled simultaneously by any given intervention. Many of
13	the works reviewed are based on interventions that do present characteristics of conventional care,
14	mirroring the opposite trend of that observed for the 4 P's. Overall, however, analysis results do not
15	suggest trends towards P4 healthcare or away from conventional care models.

1 5. Discussion

2 5.1 P4 in managing cognitive impairment and dementia

3 Our results suggest that *predictive* care may be the weaker point among interventions targeting 4 cognitive impairment or dementia. We conclude that only six out of the forty-nine papers reviewed 5 presented tangible element representative of *predictive* care. Prediction is arguably one of the 6 foundational building blocks of P4 healthcare, often an enabler of the other three P's. Yet, building 7 predictive models for diagnosis, prognosis or therapy efficacy is generally difficult, especially for 8 syndromes such as forms of cognitive impairment or forms of dementia where both complex 9 multigenic influences and numerous environmental and behavioural factors are at play. Moreover, 10 we need to also see this against the background of a population mostly consisting of elderly 11 individuals among whom co-morbidities are common which may complicate the issue of 12 predictability further. Yet, prediction is overall becoming more achievable, thanks to increasing 13 affordability, portability, pervasiveness and connectedness of multimodal data acquisition 14 modalities and thanks to the increasing efficacy and efficiency of computational techniques for 15 identification and validation of predictive models (Andreu-Perez et al. 2015; Topol 2014). Several 16 of the articles reviewed here describe the collection of data with potential predictive power, such as 17 cognitive impairment evaluation scores (Lindauer et al. 2017), performance in cognitive training 18 exercises or functional tasks (Bahar-Fuchs et al. 2017; Jekel et al. 2016; van de Weijer et al. 2016), 19 and behaviour, including sleep and physical activity patterns (Lazarou et al. 2016). 20 Examples of *preventive* care are more represented in the result table. It may seem somewhat 21 surprising to see prevention without prediction for a number of the studies reviewed, since the 22 former to some degree often depends on the latter: probabilistic knowledge about a likely future can 23 assist the design of *targeted* prevention. Without predictive models, *preventive* care can still be 24 pursued, though following a more generalised rather than targeted approach. Preventive 25 interventions here included the use of cognitive/motor training exercises to mitigate the risks of 26 disease progression or falls (Mirelman et al. 2016; van de Weijer et al. 2016). Similarly, wandering

could be prevented by detecting door-exits and confirming intent with the patient at each occasion
 (van Hoof et al. 2011), or by detecting and responding to every bed-exit to prevent falls (Hilbe et al.
 2010).

4 Personalised care was slightly more prominent in the literature reviewed here. Yet, again, across all 5 reviewed works, the elements of any intervention that offered personalised – that is individualised -6 features generally accounted for few of the elements composing the intervention. Furthermore, the 7 elements that did offer options/variants required for the satisfaction of individual needs or 8 preferences did not appear to result from an explicit and systematic design process including 9 analysis, concept definition, implementation, and evaluation. Still, some of the works reviewed did 10 rely on prior user input for the definition of one or a few of their functional blocks. Examples 11 include a web portal offering caregiver support with sections in which users can upload background 12 information and patient-specific characteristics (Duggleby et al. 2017); or an online "life story 13 book" for users such as people with dementia and their caregivers to complete with personal files 14 and anecdotes (Elfrink et al. 2017). The conversion of possible design variants to a patient-specific 15 interface or interaction could in principle take various forms. For instance, some of the 16 interventions investigated here offer end-users to choose, that is essentially turning on/off various 17 software functionality. This is the case for the CogKnow Day Navigator in which users may opt for 18 a combination of features such as calendar, reminders, activity assistance (Meiland et al. 2012); and 19 a home safety system offering adjustable features and security levels (van Hoof et al. 2011). These 20 "user-master" implementations are both powerful and risky as they theoretically offer combinatorial 21 numbers of individualised solutions at the cost of requiring sustained user-engagement in utilising 22 the solution over time. Some works averted this issue altogether by setting up and fixing a set of 23 personalised features during the initialisation (design) or kick-start of an intervention, e.g. based on 24 the definition of personal goals (Burton and O'Connell 2018), or demographics, illness-related, 25 functional and psychosocial characteristics (Tak et al. 2015). Others circumvent the challenge of 26 user-master personalisation strategies by leveraging automated, algorithmic personalisation using

1	behavioural data gathered via a home sensor network as part of an assisted living environment
2	(Lazarou et al. 2016). Others describe similar approaches whereby an intervention continuously
3	adapts to changes in users' needs based on pervasive processing of behavioural data. Examples
4	include adjusting the difficulty level of training exercises based on user performance (Bahar-Fuchs
5	et al. 2017; van de Weijer et al. 2016), or adapting computer-based guidance for activities of daily
6	living based on user performance, responsiveness and feedback (Mihailidis et al. 2008). Other
7	strategies for <i>personalised</i> , adaptive care that responds to changes in users' needs do not require
8	automation, or in some instance should or could not be automated, such as when personalisation
9	targets a feature of critical nature for the end-user's well-being (e.g. pharmacology). An example of
10	this latter scenario is given in the case of caregiver support adapted based on face-to-face user-
11	feedback sessions (van Knippenberg et al. 2016). Van Knippenberg's intervention, however, still
12	leverages digital data acquired continuously in between user-carer meetings, feeding each
13	personalisation session with relevant clinical and behavioural data.
14	Finally, Participatory care seem to enter the scene more recently in our results (2013) and with a
15	seemingly dense concentration of works thereafter. Again, the extent to which participatory care is
16	achieved varies, opening critical questions about the objectives, strategies and concrete
17	implementations. Collaboration is at the core of <i>participatory</i> care, relying on patient engagement
18	and on clinicians' involvement of their patients for the assessment, planning and execution of
19	strategies to prevent or manage disease or otherwise improve their health and wellbeing (Valentin-
20	Hjorth et al. 2018). For dementia care, collaboration may extend to include primary caregivers
21	(typically a spouse or other close relative). In its current format and based on the results of the
22	literature review, participation is mostly limited to a subset of (or single) decisions and activities.
23	Several works reviewed here implement variants of a common strategy where healthcare
24	professionals and caregivers partner to assess the burden of disease and agree on care strategies
25	(Gaugler, Reese, and Tanler 2016; Matthews et al. 2015; Schaller et al. 2015). Once again, data
26	relative to patient's cognition, functional capacity, behaviour or other health-related information can

1 be harnessed to better assess and adjust care delivery (Bahar-Fuchs et al. 2017; Mirelman et al. 2 2016). Allowing the patient to define how and when they employ an intervention instead of relying 3 solely on instructions from the healthcare professional prescribing its use also constitutes an 4 essential element of *participatory* care, namely shared-decision making (Griffioen et al. 2017). One 5 single work reviewed here combined all aforementioned elements relevant to *participatory* care, 6 wherein the user participated in defining the care strategy and intervention goals and was able to 7 access her own data to follow her progress. Communication with a healthcare professional was 8 encouraged and facilitated by a messaging function incorporated into the system (Lazarou et al. 9 2016).

10 5.2 Engineering P4 Healthcare

11 This systematic review of state-of-the-art in the implementation of P4 healthcare models to address 12 the management of cognitive impairment and dementia sheds light both on a number of opportunities and shortcomings. Attempts at proposing P4 models of care for managing cognitive 13 14 impairment seem to some extent already be founded on engineering design practices, as we have 15 seen here in several explicit or implicit uses of, for example, participatory-design, co-design or 16 inclusive design. These examples illustrate the relevance of research in engineering design to 17 support exploration, refinement, adaptation and widespread implementation of healthcare delivery 18 models based on the P4 principles (predictive, preventive, personalised and participatory). 19 Conversely, one can expect that engineering design research itself may benefit from embracing an 20 application domain that has until now been hesitant to look for solutions outside of the clinical 21 science community. One aspect in which research in engineering design and clinical- and healthcare 22 improvement research can especially benefit from one another is their common interests in human 23 behaviour. Clinical researchers already harness behaviouromic insights and theories from 24 psychology and the cognitive sciences to generate new hypotheses on and interventions for dealing 25 with chronic diseases. Engineering designers interested in the healthcare domain could build on

these disciplines to rationalise further design process research and, in turn, help generalise practices
 that would facilitate the design of interventions engaging patients more, harnessing multi-omics
 data throughout broader and more integrative product- and service systems, and thus supporting
 better clinical decision making.

5 5.2.1 Design frameworks

6 Although encouraging in that they show a partial embrace of the 4 P's (predictive, preventive, 7 personalised and participatory) in the management of cognitive impairment, our results also 8 suggest obvious improvement opportunities in the systematic practice of and research in 9 engineering design applied to healthcare. First of all, as mentioned earlier, none of the studies we 10 reviewed demonstrated the systematic implementation of a complex intervention addressing all 4 11 P's simultaneously. One can hardly think that this would be deliberate since the 4 P's are not 12 mutually exclusive. On the contrary, they were formulated with complementarity in mind: the 4 P's 13 should interact positively whenever implemented together. Perhaps more importantly, none of the 14 studies reviewed explicitly *claimed* an attempt to shape their complex intervention following the P4 15 principles. This simple observation suggests paradigmatic limitations in how complex healthcare 16 interventions are crafted and call for remedies this community is proficient in making: the 17 elaboration of holistic engineering design *frameworks* and *methodologies* to systematically design 18 comprehensive P4 interventions. One can anticipate some of the commonalities these frameworks 19 will exhibit: the comprehensive and iterative consideration of each of the 4 P's, each P 20 implementing specific features reflecting the particular scope and context of the challenge under 21 consideration.

22 5.2.2 Success indicators

Importantly, engineering design frameworks and the design models these frameworks will support
 will also need to adopt new or borrow existing outcome measures and *indicators* to assess the

1 success of a P4 intervention. These measures are likely to include – but may very well not be 2 limited to – metrics of clinical efficacy and health economics, i.e. *distal* clinical and economic 3 measures against which medical or cost benefits of an intervention should be evaluated. But 4 indicators of a different nature will be required to evaluate the *proximal* effects of a design process 5 and its supporting framework on achieving high subjective or objective degrees of *Prediction*, 6 Prevention, Personalisation and Participation. These indicators should allow us to answer the 7 questions such as: how might we measure Personalisation? The availability of these measures 8 should, in turn, help engineering designers and clinicians understand better which design principles, 9 mechanisms or methods foster the clinical or operational benefits observed distally. These measures 10 may well distinctly represent any of the P's but not necessarily: other conceptualisations of 11 healthcare systems, other novel models of care will become available pressuring us in deriving new 12 intermediary indicators of their success, e.g. to evaluate the degree of connectivity, stratification, personalisation, pervasiveness or decentralisation (Patou and Maier 2017) of a complex healthcare 13 14 intervention. Only then would one be capable of determining which combination of elements, and 15 in which forms, ought to lead to better health outcomes, including cost-reductions, and patient satisfaction. 16

17 5.2.3 Tools and methods

18 Although necessary, the availability of frameworks and design processes for P4 healthcare 19 will not guarantee the success of complex interventions. The benefit of engineering design for 20 improving healthcare systems' outcomes, whether clinical, economic, operational, organisational, 21 etc. will also depend on the availability of adequate tangible tools and methods. For instance, none 22 of data-centric approaches to prediction or personalisation reviewed in this work addressed the need 23 for scalability or interoperability that clinical systems often require, e.g. interfacing with Electronic 24 Health Records, Hospital Information Systems. One may attribute this shortcoming to several 25 reasons, the first being the deliberate setting aside of these issues, on the account they may not be

1 "central" or essential for proof-of-concept of the intervention. A second reason could be alternate 2 priorities of clinical researchers and emphasis lying elsewhere than proposing tools and methods for 3 the investigation of system properties, an activity usually the forte of engineering designers. Some 4 early attempts to systematise the considerations of data-centric interventions for managing cognitive 5 impairment, for instance, are presented in Thorpe and Forchhammer (2016) and Thorpe, 6 Forchhammer, and Maier (2019). The challenge of developing tools and methods for P4 or any 7 other new conceptualisation of healthcare delivery also comes from the fact that the ontology of the 8 *concepts* advocated in the clinical literature is often not consensual or is lacking precise definitions. 9 This invites preliminary attempts to clarify terms used, such as a recent work revolving around the 10 concept of Collaborative Care (Valentin-Hjorth et al. 2018).

11 6. Limitations

The systematic review was conducted using the SCOPUS database. Future work may cross-check 12 13 results using other research platforms. The two researchers, although individually conducting the 14 search, screening, reading, selection, and analysis of the selected papers, are from the same 15 institution inducing potential selection bias. Moreover, evaluating each intervention found in the 16 selected literature records based on the four P's – predictive, preventive, personalised and 17 *participatory* – is to some extent open for interpretation and translation as the principles may be 18 operationalised differently in different contexts. Finally, the scope of this paper's investigation is 19 arguably vast and aggregation of interventions related to cognitive impairment and dementia 20 without further clustering (e.g. depending on the clinical endpoints of the intervention, depending 21 on the clinical diagnosis, to, for example, maintain cognition, promote autonomy or else) makes it 22 impossible to judge whether some sub-group of references may have after all revealed a clear 23 pattern of implementation of the P4 principles. Further, the absence of an obvious pattern or 24 advancement towards an implementation of P4 principles in literature cannot be attributed with 25 certainty to a gap in design practice: P4 may simply not be a straightforward or applicable

framework for addressing cognitive impairment and dementia. Yet, as stated earlier, we believe P4 healthcare that embraces *predictive, preventive, personalised and participatory* principles to be an option to consider as cognitive impairment is in parts preventable, evolves over a long time span (prediction), and affects multiple stakeholders in the surroundings of those affected (participation).

5 7. Conclusions

This paper presents a systematic literature review aimed at assessing how well current technologybased interventions that focus on dementia and other cognitive impairments align with the P4 -*Predictive, Preventive, Personalised, Participative* - model of healthcare. We identified forty-nine
relevant studies and found that none of them demonstrated the simultaneous and systematic

10 application of all four principles. We argued that this presents an opportunity for the engineering

11 design community to engage with future models of healthcare delivery through the development of

design frameworks, new indicators for measuring the success of these models as well as tools andmethods.

14 In sum, awareness for the potential of engineering design for healthcare improvement (Clarkson,

15 2018) has previously been raised Griffioen et al. (2017). This paper builds on such calls. It is the

16 first paper to map extant design research on to the principles of P4 healthcare and, by extension,

17 shows the potential of design research in improving the path specifically towards P4 healthcare:

18 predictive, preventive, personalised and participative.

19

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1 Appendix A: Journals List

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4 Engineering Design

- 5 International Journal of Design
- 6 Systems Engineering
- 7 Journal of Engineering and Technology Management
- 8 Design Studies
- 9 Design Science
- 10 Research in Engineering Design
- 11 Journal of Engineering Design
- 12 Journal of Mechanical Design
- 13

14 Biomedical, Healthcare and Clinical Sciences

- 15 Advanced Engineering Informatics
- British Medical Journal (BMJ)
- IEEE journals: Transactions on Engineering Management, Journal of Biomedical and Health
- 18 Informatics, Systems Journal, Transactions on Biomedical Engineering, Transactions on
- 19 Systems, Man and Cybernetics, Transactions On Information Technology in Biomedicine
- International Journal of Medical Informatics
- Journal of Biomedical Informatics
- Journal of Medical Internet Research
- PLOS ONE

2	•	Age and Aging
3	•	Aging and Mental Health
4	•	Alzheimer's and Dementia
5	•	Archives of Gerontology and Geriatrics"
6	•	BioMed Central (BMC) Journals
7	•	BMC Geriatrics
8	•	Dementia and Geriatric Cognitive Disorders
9	•	Geriatrics and Gerontology International
10	•	Gerontechnology
11	•	Gerontology
12	•	Journal of Aging and Health
13	•	Journal of Aging and Physical Activity
14	•	Journal of Alzheimer's Disease
15	•	Journal of Applied Gerontology
16	•	Journal of healthcare engineering
17	•	Journal of Healthcare Management
18	•	Journal of the American Geriatrics Society
19	•	Journal of the American Medical Association (JAMA)
20	•	New England Journal of Medicine
21	•	The Gerontologist
22	•	The Journals of Gerontology
23	•	The Lancet