## OpenAIR @RGU RGU RGU RGU RGU RGU RGU ROBERT GORDON UNIVERSITY ABERDEEN

This publication is made freely available under \_\_\_\_\_\_ open access.

AUTHOR(S):	
TITLE:	
YEAR:	
Publisher citation:	
OpenAIR citation:	t statement:
This is the	: statement:
in	
(ISSN; e	ISSN).
OpenAIR takedowi	i statement:
Section 6 of the "I students/library/lib consider withdraw any other reason s the item and the na	Repository policy for OpenAIR @ RGU" (available from <u>http://www.rgu.ac.uk/staff-and-current- grary-policies/repository-policies</u> ) provides guidance on the criteria under which RGU will ang material from OpenAIR. If you believe that this item is subject to any of these criteria, or for hould not be held on OpenAIR, then please contact <u>openair-help@rgu.ac.uk</u> with the details of ature of your complaint.
This publication is d	stributed under a CC license.

## 1 INTERNATIONAL JOURNAL OF CLINICAL PHARMACY

2 Lorna West, Maria Cordina, Lesley Diack, Derek Stewart

**3** A focus group based study of the perspectives of the Maltese population and healthcare

- 4 professionals on medication wastage
- 5

## 6 Background

According to the World Health Organization (WHO) global estimates published in 2004, 7 more than half of all medication is prescribed, dispensed or sold inappropriately with a 8 resultant "wastage of scarce resources and widespread health hazards".<sup>1</sup> Medication 9 wastage continues to be of paramount importance to public health in terms of safety, the 10 environment and the economy. A systematic review of the literature identified 42 published 11 12 papers, all employing a quantitative cross-sectional design. The main factors contributing to wastage were 'change in medication', 'patient's death', 'resolution of patient's condition' and 13 'medication passed expiry date'. There was a clear absence of qualitative research exploring 14 15 wastage from the perspectives of key stakeholders (members of the public, patients, healthcare professionals [HCPs] and policy makers), with no studies founded on behavioural 16 theories.<sup>2</sup> 17

18

There is an urgent need to develop, implement and sustain wastage reduction strategies. Such interventions are likely to be complex, defined by the United Kingdom Medical Research Council (MRC) as "*interventions with several interacting components*".<sup>3</sup> The MRC highlights several stages for development and evaluation of complex interventions, emphasising the need for a good theoretical understanding of how an intervention could bring about change. Developing processes which include behaviour change theories impacts significantly the positive implementation of evidence into healthcare practice.

27       Aim         28       The aims of this research were to describe and understand the beliefs and behaviours         29       regarding medication wastage of the Maltese public and HCPs and to explore potential         30       solutions.         31       Ethical approval         32       Ethical approval         33       The study was approved by the School of Pharmacy and Life Sciences Research Ethics         34       Committee, Robert Gordon University and the University of Malta Research Ethics         35       Committee.         36       Design         37       Method         38       Design         39       This was an interpretative study based on a theoretical basis using focus groups of         40       participants.         41       Setting         42       Setting         43       This study was conducted in Malta, an island in the middle of the Mediterranean sea with a         44       population of 416,110. <sup>4</sup> The healthcare system in Malta is based mainly on taxation with a         45       centrally organized health service provided mainly by public health providers. <sup>5</sup> Medication         46       Malta is either purchased by the patient or supplied to the patient free of charge by the         47       government, based on entitlement criteria.      <	20	
The aims of this research were to describe and understand the beliefs and behaviours         regarding medication wastage of the Maltese public and HCPs and to explore potential         solutions. <b>Ethical approval</b> The study was approved by the School of Pharmacy and Life Sciences Research Ethics         Committee, Robert Gordon University and the University of Malta Research Ethics         Committee.         Method <i>Design</i> This was an interpretative study based on a theoretical basis using focus groups of         participants.         Setting         This study was conducted in Malta, an island in the middle of the Mediterranean sea with a         population of 416,110. <sup>4</sup> The healthcare system in Malta is based mainly on taxation with a         centrally organized health service provided mainly by public health providers. <sup>5</sup> Medication         Malta is either purchased by the patient or supplied to the patient free of charge by the         government, based on entitlement criteria.         Inclusion criteria, sampling and sample size	27	Aim
<ul> <li>regarding medication wastage of the Maltese public and HCPs and to explore potential</li> <li>solutions.</li> <li>Ethical approval</li> <li>The study was approved by the School of Pharmacy and Life Sciences Research Ethics</li> <li>Committee, Robert Gordon University and the University of Malta Research Ethics</li> <li>Committee.</li> <li>Method</li> <li>Design</li> <li>This was an interpretative study based on a theoretical basis using focus groups of</li> <li>participants.</li> <li>Setting</li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li>Inclusion criteria, sampling and sample size</li> </ul>	28	The aims of this research were to describe and understand the beliefs and behaviours
<ul> <li>solutions.</li> <li>solutions.</li> <li>Ethical approval</li> <li>The study was approved by the School of Pharmacy and Life Sciences Research Ethics</li> <li>Committee, Robert Gordon University and the University of Malta Research Ethics</li> <li>Committee.</li> <li>Committee.</li> <li>Method</li> <li>Design</li> <li>This was an interpretative study based on a theoretical basis using focus groups of</li> <li>participants.</li> <li>Setting</li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li>Inclusion criteria, sampling and sample size</li> </ul>	29	regarding medication wastage of the Maltese public and HCPs and to explore potential
<ul> <li>Ethical approval</li> <li>The study was approved by the School of Pharmacy and Life Sciences Research Ethics</li> <li>Committee, Robert Gordon University and the University of Malta Research Ethics</li> <li>Committee.</li> <li>Committee.</li> <li>Method</li> <li>Design</li> <li>This was an interpretative study based on a theoretical basis using focus groups of</li> <li>participants.</li> <li>Setting</li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li>Inclusion criteria, sampling and sample size</li> </ul>	30	solutions.
32       Ethical approval         33       The study was approved by the School of Pharmacy and Life Sciences Research Ethics         34       Committee, Robert Gordon University and the University of Malta Research Ethics         35       Committee.         36       Committee.         37       Method         38       Design         39       This was an interpretative study based on a theoretical basis using focus groups of         40       participants.         41       Setting         42       Setting         43       This study was conducted in Malta, an island in the middle of the Mediterranean sea with a         44       population of 416,110. <sup>4</sup> The healthcare system in Malta is based mainly on taxation with a         45       centrally organized health service provided mainly by public health providers. <sup>5</sup> Medication         46       Malta is either purchased by the patient or supplied to the patient free of charge by the         47       government, based on entitlement criteria.         48       Inclusion criteria, sampling and sample size	31	
<ul> <li>The study was approved by the School of Pharmacy and Life Sciences Research Ethics</li> <li>Committee, Robert Gordon University and the University of Malta Research Ethics</li> <li>Committee.</li> <li>Method</li> <li>Design</li> <li>This was an interpretative study based on a theoretical basis using focus groups of</li> <li>participants.</li> <li>Setting</li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li><i>Inclusion criteria, sampling and sample size</i></li> </ul>	32	Ethical approval
Committee, Robert Gordon University and the University of Malta Research Ethics Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committee. Committe	33	The study was approved by the School of Pharmacy and Life Sciences Research Ethics
<ul> <li>Committee.</li> <li>Kethod</li> <li><i>Design</i></li> <li>This was an interpretative study based on a theoretical basis using focus groups of</li> <li>participants.</li> <li><i>Setting</i></li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li><i>Inclusion criteria, sampling and sample size</i></li> </ul>	34	Committee, Robert Gordon University and the University of Malta Research Ethics
36       Method         37       Method         38       Design         39       This was an interpretative study based on a theoretical basis using focus groups of         40       participants.         41       .         42       Setting         43       This study was conducted in Malta, an island in the middle of the Mediterranean sea with a         44       population of 416,110. <sup>4</sup> The healthcare system in Malta is based mainly on taxation with a         45       centrally organized health service provided mainly by public health providers. <sup>5</sup> Medication         46       Malta is either purchased by the patient or supplied to the patient free of charge by the         47       government, based on entitlement criteria.         48       Inclusion criteria, sampling and sample size	35	Committee.
<ul> <li>Method</li> <li>Design</li> <li>This was an interpretative study based on a theoretical basis using focus groups of</li> <li>participants.</li> <li>Setting</li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li>Inclusion criteria, sampling and sample size</li> </ul>	36	
<ul> <li>Design</li> <li>This was an interpretative study based on a theoretical basis using focus groups of</li> <li>participants.</li> <li>Setting</li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li>Inclusion criteria, sampling and sample size</li> </ul>	37	Method
<ul> <li>This was an interpretative study based on a theoretical basis using focus groups of</li> <li>participants.</li> <li><i>Setting</i></li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li><i>Inclusion criteria, sampling and sample size</i></li> </ul>	38	Design
<ul> <li>participants.</li> <li><i>Setting</i></li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li><i>Inclusion criteria, sampling and sample size</i></li> </ul>	39	This was an interpretative study based on a theoretical basis using focus groups of
<ul> <li>Setting</li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li><i>Inclusion criteria, sampling and sample size</i></li> </ul>	40	participants.
<ul> <li>Setting</li> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li><i>Inclusion criteria, sampling and sample size</i></li> </ul>	41	
<ul> <li>This study was conducted in Malta, an island in the middle of the Mediterranean sea with a</li> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li><i>Inclusion criteria, sampling and sample size</i></li> </ul>	42	Setting
<ul> <li>population of 416,110.<sup>4</sup> The healthcare system in Malta is based mainly on taxation with a</li> <li>centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li><i>Inclusion criteria, sampling and sample size</i></li> </ul>	43	This study was conducted in Malta, an island in the middle of the Mediterranean sea with a
<ul> <li>45 centrally organized health service provided mainly by public health providers.<sup>5</sup> Medication</li> <li>46 Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>47 government, based on entitlement criteria.</li> <li>48</li> <li>49 Inclusion criteria, sampling and sample size</li> </ul>	44	population of 416,110. <sup>4</sup> The healthcare system in Malta is based mainly on taxation with a
<ul> <li>Malta is either purchased by the patient or supplied to the patient free of charge by the</li> <li>government, based on entitlement criteria.</li> <li><i>Inclusion criteria, sampling and sample size</i></li> </ul>	45	centrally organized health service provided mainly by public health providers. <sup>5</sup> Medication in
<ul> <li>47 government, based on entitlement criteria.</li> <li>48</li> <li>49 Inclusion criteria, sampling and sample size</li> </ul>	46	Malta is either purchased by the patient or supplied to the patient free of charge by the
<ul><li>48</li><li>49 Inclusion criteria, sampling and sample size</li></ul>	47	government, based on entitlement criteria.
49 Inclusion criteria, sampling and sample size	48	
	49	Inclusion criteria, sampling and sample size

As part of a related study 1,920 randomly selected members of the general public and 1,680
HCPs (all dentists, doctors and pharmacists) were invited to complete a questionnaire on
medication wastage.<sup>6</sup> As part of this mailing, they were invited to participate in a focus group
study. Those interested were requested to complete and return an 'expression of interest
form' indicating the most preferred time of the day to attend. Only the data from the focus
groups is included in this manuscript.

56

Five focus groups each containing six participants were planned, three with HCPs and two
for the general public. Purposive sampling was used to select participants of different ages,
gender and education levels (public); and HCP professions.

60

61 *Topic guide development* 

The topic guide was based on the key findings from the questionnaire study<sup>6</sup> and the 14 domains of the Theoretical Domains Framework (TDF). The topic guides for HCPs and general public were similar; the public one also translated into Maltese. The use of a theoretical basis, the TDF and associated domains were used to aid the construction of the topic guide and coding framework, to ensure that the research and outputs were grounded in a behavioural theory which focuses on change.

68

*TDF* The TDF was developed by psychological theorists, health psychologists and
researchers to simplify and integrate 33 theories and 128 into a 12 stage TDF (now extended
to 14) of: knowledge; skills; social/professional role and identity; beliefs about capabilities;
optimism; beliefs about consequences; reinforcement; intentions; goals; memory, attention
and decision processes; environmental context and resources; social influences; emotion;

74	behavioural regulation. <sup>7</sup> TDF has been used in several studies to explain implementation
75	problems and inform implementation interventions. <sup>8,9,10</sup>
76	
77	Focus group process
78	The focus groups were of approximately 90 minutes duration, were conducted by the
79	principal researcher in a conference room of a centrally located hotel, audiorecorded and
80	transcribed verbatim, with Maltese statements translated into English.
81	
82	Main outcome measures
83	Beliefs and behaviours regarding medication wastage and potential solutions to reduce
84	medication wastage.
85	
86	Data analysis
87	Analysis was carried out using the framework approach, <sup>11</sup> with the coding frame developed
88	and applied independently by two researchers to promote confirmability, and mapped to TDF
89	domains.
90	
91	Results
92	Participant demographics
93	Tables 1 and 2 provide a description of the participants' demographics.
94	Insert Table 1 here.
95	Insert Table 2 here.
96	

*Key themes identified within TDF domains* 

98	Key themes emerged from the focus groups, namely: practitioner effects, patient effects,
99	political effects and societal effects. An overlap of these four key themes was noticed when
100	mapped to the different TDF domains listed in the first column of Table 3. A wide range of
101	sub-themes emerged from these four key themes, with several of these sub-themes mapped to
102	one domain also aligned to other TDF domains, such as the healthcare system and medication
103	unavailability emerging under different domains.
104	
105	Insert Table 3 here.
106	
107	Behavioral regulation was the TDF domain which emerged most strongly with both HCPs
108	and members of the public. Implementation of solutions to minimise medication wastage
109	requires behavioural change. In terms of potential solutions to reduce wastage, these were
110	described under the domain of behavioural regulation in terms of facilitators to alter
111	behaviour; therefore the findings of the domain 'Behavioural regulation' will be presented
112	below.
113	
114	Domain: Behavioural regulation
115	1. Practitioner effects
116	Several noted the need to engender a culture of accountability in HCPs,
117	
118	" so if we are going to invest in an IT system and we are not going to make anybody
119	accountable for the cost, we are just going to spend money on an IT system".
120	(Female, hospital pharmacist, part-time community pharmacist, 9 years in practice)
121	

122	Medication use reviews (MURs) were discussed as a potential for HCPs and patients to
123	optimise medication and reduce wastage,
124	
125	"In the UK patients are even reviewed by the pharmacist, the MURs. And that has reduced a
126	great deal of costs for the NHS. Reviews are then every year for example".
127	(Male, hospital pharmacist, part-time-community pharmacist, 12 years in profession)
128	
129	A standardised patient review template was suggested, which would be mandatory and
130	updated regularly following patient assessment prior to prescribing,
131	
132	"together with the prescription, every 6 months they have to show something given to the,
133	by the doctor, of what the examination found. Maybe the blood pressure, the treatment they
134	are on. Maybe every 6 months something is filled in as proof that the patient was examined".
135	(Female, hospital doctor, 4 years in profession)
136	
137	The nurse within the public focus group discussed prescribing guidelines,
138	
139	"More guidelines if for example a patient is on certain medication, you can prescribe for
140	certain amount, for certain time".
141	(Male, Nurse, 34 years, post-graduate qualifications)
142	
143	while others stressed the need for better communication between the private and public health
144	sector and at all levels of the medication supply chain,
145	

146	"From the manufacturer, to the agent, to the wholesaler, to the pharmacy and eventually to
147	the patient. And between the pharmacy and the patient there is the doctor prescribing. Now if
148	there is more communication between each level, maybe on consumptions, prescribing
149	trends, etc., I think that wastage could be reduced at each level".
150	(Male, hospital pharmacist, part-time-community pharmacist, 12 years in profession)
151	
152	2. Patient effects
153	Participants described the patients' fear of unavailability of medication as a major obstacle to
154	their desire to reduce wastage, and thus the need for reassurance of medication availability. In
155	fact one of the pharmacists pointed out that patients explicity expressed concerns,
156	
157	"We see it, I mean quite frequently, people you know, they just tell us outright 'cause I don't
158	really need this medication, I have at home you know. But will it be available the next time I
159	collect my medicines?'".
160	(Male, hospital pharmacist, 12 years in profession)
161	
162	A hospital pharmacist suggested that patient groups and organisations could support,
163	encourage and reassure patients around appropriate medication ordering and use,
164	
165	"And the coeliac association had created a system they had like a support group, they
166	could meet or there was a liaising person and you know that you could go there and maybe
167	they could spare you a packet of gluten free flour. And I used to feel that that system was a bit
168	of like a reassurance to those patients".
169	(Female, hospital pharmacist, part-time-community pharmacist, 13 years in profession)
170	

171	Patient empowerment, specifically the need to empower patients to improve non-adherence
172	was also discussed. Non-adherence leading to wastage was attributed to issues such as poor
173	education and adverse effects,
174	
175	"Yes because their education is low, so they won't take their medication properly".
176	(Female, hospital pharmacist, 24 years in profession)
177	
178	"I think patients get side effects from medicines and they decide to stop them because of
179	side effects in the initial period".
180	(Female, hospital pharmacist, 24 years in profession)
181	
182	3. Political effects
183	The need to reduce political interference in the organisation and delivery of health services,
184	assigning strategy and decision making to HCPs, was discussed at length. As a member of the
185	public commented,
186	
187	" health is a sector that needs to be separated from politics. The administrative side of it is
188	one thing, the medical side of it is another thing, the regulating is another thing. So I think
189	the health sector needs to be separate. I don't know how it can be done; it needs to be
190	separated from the Government. If we need to get anywhere I mean".
191	(Female, Assistant Director, 32 years, post-graduate qualifications)
192	
193	However, numerous solutions to medication wastage that could be implemented by
194	politicians and policy makers, particularly in relation to the free healthcare system in Malta,

195	were discussed. HCPs and the public described the importance of stock management and
196	forecasting of medication requirements,
197	
198	"So we need to have a simple system which is continuously updated by the healthcare
199	professionals and even GPs who are seeing trends coming, at the general practice and even
200	at hospital, and this system is being updated by the doctors and even by professionals who
201	are reading papers about upcoming medicines ".
202	(Male, accountant, 24 years, post-graduate qualifications)
203	
204	Focusing attention around highly prevalent medical conditions when budgeting was
205	suggested,
206	
207	"We are talking about cardiovascular; it's a huge chunk of our budget, cardiovascular
208	medications and diabetes. I think if we are more selective in the medications we use in those
209	two groups; the cost savings will be quite significant".
210	(Female, hospital pharmacist, part-time-community pharmacist, 13 years in profession)
211	
212	A member of the public suggested the introduction by policy makers of a patient specific
213	pharmaceutical identity card containing all medication history for both privately purchased
214	medication and those obtained for free to prevent re-dispensing,
215	
216	"I thought if they had an ID card, sort of pharmaceutical ID with what you've been
217	prescribed, on a chip so that you can see what they've been prescribed previously as well
218	and even for repeat prescription abuse or over, you know people, over, stock piling. Because
219	you can see, look, they just came in and had this".

220	(Female, Director, 36 years, post-graduate qualifications)
221	
222	A number discussed the importance of good infrastructure, with one participant adding the
223	introduction of a centralised patient medication record,
224	
225	"One thing I was going to mention is that in the community there should be an IT system
226	where you, where if I go to a doctor and maybe next month I don't find my own doctor, and I
227	have to go to another doctor, then there should be a record".
228	(Female, hospital pharmacist, part-time-community pharmacist, 5 years in profession)
229	
230	Incentives by politicians for HCP to reduce wastage were suggested,
231	
232	"If not, there should be steps that are taken where if they don't want to take that
233	responsibility, there is no incentive, they need to be incentivised somehow".
234	(Female, Director, 36 years, post-graduate qualifications)
235	
236	A hospital pharmacist mentioned the need to regulate use of high consumption, low cost
237	medication which could result in a higher total cost compared to low consumption, high cost
238	medication,
239	
240	"When you mention high cost medication, we tend to go see one tablet, how much that costs.
241	But really when you have high consumption items their cost might actually be higher than the
242	high cost".
243	(Male, hospital pharmacist, 12 years in profession)
244	

245	The aim of disease prevention with resultant decrease in the need for medication was
246	discussed. The employment of, for example, more nutritionists in hospitals was suggested,
247	
248	"Because this is like a chain, 'cause if I am eating for my health, I will not get high
249	cholesterol Even the Government would save a lot of money".
250	(Female, housewife, 56 years, secondary level of education)
251	
252	4. Societal effects
253	Making patients, HCPs, politicians and the society as a whole more aware of the cost of
254	medication, particularly those supplied free to the patient, was highlighted as a positive move
255	in regulating behaviour,
256	
257	" but I think if we make people aware, especially politicians and doctors, how much it is. I
258	think there will be much more awareness, as money, as pills. I don't know the exact amount
259	yes but especially politicians, I think they don't know the extent so they do not know if it is
260	a problem".
261	(Male, Nurse, 34 years, post-graduate qualifications)
262	
263	Several suggested more education on appropriate medication use, starting with the very
264	young and using different targeting strategies,
265	
266	"for example if you need the youngsters, there is the social media, Facebook, Twitter,
267	everything, computer".
268	(Male, Nurse, 34 years, post-graduate qualifications)
269	

and settings such as as the workplace,

271

"... so why shouldn't we educate people at the workplace?... You would tell me maybe not all 272 workers can attend. No, but we should try to do it even in their breaks, get someone who is 273 competent". 274 (Female, housewife, 56 years, secondary level of education) 275 276 A medication education campaign amongst patients was also proposed as a measure to 277 278 regulate behaviour, 279 "Launch a medication education campaign. You have to tell the patient that if they stop 280 wasting the medication... that money can go somewhere else which can end up helping 281 282 them". (Female, hospital doctor, 17 years in profession) 283 284 Discussion 285 Key findings 286 Four key themes (practitioner effects, patient effects, political effects and societal effects) and 287 a wide range of sub-themes were identified within the TDF domains. Focus groups conducted 288 289 with HCPs and the general public identified the following five key themes to address in proposing solutions to minimise medication wastage under the behavioural regulation 290 domain: system effects; practitioner effects; patients effects; political effects; awareness and 291 292 educational effects. 293 294 Strengths and weaknesses

To our knowledge this is the first interpretative study providing a detailed description of behaviours around medication wastage, with attention paid to solutions and facilitators of behavioural change. The use of a theoretical basis ensured that the research and outputs were grounded in behavioural theories of change.

299

However, there are limitations to the research and the data generated. Despite employing purposive sampling, a wider range of participants, such as unemployed or less educated members of the general public, and nurses may have impacted the findings. While it is possible that data saturation was not achieved, a number of important themes and potential solutions were identified.

305

## 306 Interpretation of study findings

307 This study confirms the usefulness of the TDF and has provided valuable in-depth description and understanding of a number of behaviours which may lead to medication wastage and in 308 doing so act as barriers or hindrances to all stakeholders striving to reduce wastage. 309 Implementation of interventions requires behavioural change and the success of 310 implementing proposed solutions to reduce medication wastage relies on the scrutiny of 311 barriers and facilitators of the behavior to be changed. There are multiple theories of 312 behaviour change and overlapping constructs which present a challenge on which theory 313 314 should be adopted in research. The TDF was applied in this research since it includes constructs from 33 behaviour change theories. Moreover, the TDF was used as it is an 315 integrative framework that allows for the systematic and comprehensive identification of 316 barriers to change, supports identification of target behaviors for change and informs 317 implementation strategies of proposed interventions.<sup>12</sup> Overlap in the four key themes in line 318 with the different TDF domains in this research demonstrates the importance of these four 319

major components and development of strategies for change should be targeted from theperspective of each of these components.

322

323 The Maltese (or any) free healthcare system as a possible major barrier to medication wastage reduction was a recurring sub-theme in this study and thus needs to be further looked into. 324 There is some evidence (albeit limited) that those patients entitled to free medication are 325 more likely to receive polypharmacy, traditionally defined as "the concurrent use of five or 326 *more medications*".<sup>14</sup> Whilst providing free medication could be viewed as a positive step in 327 328 terms of patient equality of care, there is a need to research the impact of no charge on patient request for and use of prescribed medication. It could be hypothesised that patients receiving 329 free medication are more prone to wastage. Hence the effects of the free healthcare system 330 need to be fully explored and recognised to fully inform policy debates.<sup>13</sup> Moreover, the 331 perspectives of participants in this study on disease prevention should also be considered as a 332 means of saving on limited resources, including HCPs' time and healthcare expenditures. 333 334 Notably, the EU Commission staff working document 'Investing in Health' very recently reported that only approximately three percent of the current health expenditure is earmarked 335 for public health and prevention programmes amongst Member States.<sup>14</sup> 336

337

Both from practitioner and patient perspectives, medication shortages was discussed in depth during the focus groups as a key cause of unnecessary hoarding and stocking by patients and also recommended to patients at times by HCPs. Medication shortages are a global problem with all medication classes being affected<sup>15,16</sup> and have been described for more than a decade.<sup>17</sup> This issue has also been recognised as causing great distress to patients, their carers and families.<sup>15</sup> There are many and complex reasons for medication shortages including manufacturing quality problems, the increased demand of medication and changes in

regulatory standards of manufacturing plants, amongst others.<sup>18</sup> Following a reflection paper 345 on the issue of medication shortages by the European Medicines Agency (EMA), the 346 European Association of Hospital Pharmacists (EAHP)<sup>15</sup> issued a number of 347 recommendations. One key recommendation is the collaborative involvement of patients' 348 organisations, using their expertise to issue guidelines for patients and HCPs to promote 349 rationale medication use. Interestingly focus group participants were in accord with this 350 351 recommendation, proposing one solution involving collaboration with patient groups to provide guidance, support and reassurance. 352

353

Medication non-adherence was discussed at length during the focus groups and was 354 considered to be one of the key barriers hindering resolution of medication wastage. 355 356 Furthermore, medication non-adherence can lead to leftover unused medication in households which can be later used for an inappropriate indication or may expire and hence pose a public 357 health issue, including environmental implications through improper disposal. A very recent 358 review of 51 systematic reviews of the determinants of adherence identified 771 individual 359 factors for non-adherence to medicines for chronic conditions. These factors were grouped 360 into eight clusters, two of which were the patients (key issue in the elderly) and the medicine 361 (key issue with polypharmacy).<sup>19</sup> While this research does not focus exclusively on non-362 adherence, future research should pay attention to these factors could positively impact 363 364 medication wastage.

365

The lack of awareness and the existence of knowledge gaps in relation to medication wastage both amongst the public and HCPs emerged in focus group discussions. Future reseach aiming at the knowledge-behaviour gap through different programs designed to educate different age groups and different stakeholders was considered as the main goal to reduce medication wastage. However, this knowledge-behaviour gap cannot be seen as a standalone
barrier in the issue of medication wastage but has to be seen in the context of all the other
factors elicited by participants, such as psychological factors in terms of fear of medication
unavailability.

374

Political interference contributing to wastage and as a potential barrier to implementing 375 wastage reduction strategies was discussed in all groups and by almost all participants. 376 Undermining of HCPs and scientific experts by political influence has been described 377 elsewhere.<sup>20,21</sup> In a commentary, Rest and Halpern argue that public policy decisions need to 378 379 be informed by independent scientists rather than through political interference if one wants to ensure a good government and a functioning democracy.<sup>22</sup> Pham *et al.* describe the 380 381 importance of segregating 'macro-level decisions' generated at a political debate level from 'micro-level decisions'.<sup>23</sup> This is in line with participants' suggestions around the need to 382 redefine political will. 383

384

A comprehensive description of strategies to potentially reduce wastage was elicited. These 385 will require intervention at macro-contextual levels, meso-transactional level and at the 386 micro-organisational level. Recommended interventions and policies to change behaviour 387 within this study fit well with the 'Behaviour Change Wheel', which promotes uptake and 388 optimal use of strategies.<sup>24</sup> Implementation of any of these strategies is likely to be an 389 iterative process, especially since each and every strategy merits further consideration which 390 will generate its own multifaceted challenges. Nonetheless, implementation of some 391 392 strategies might not be as simple or straightforward as one might think. In a study employing photo-elicitation to identify different types of wastage, Goff et al. stated that whilst 393 attempting to reduce medication wastage one needs to be careful so as not to generate other 394

395	forms of wastage, such as the time and money invested in implementing a specific
396	intervention which may not always outweigh the benefits of introducing the intervention. <sup>25</sup>
397	
398	Future research
399	One of the benefits of this research is the linkage to practice developments. While there are
400	many future research areas and questions which emerge from this research, there are key
401	priority areas which need to be targeted: the effect of policy implementation on practice from
402	the HCP perspective; effects of education on different age groups and stakeholders; and the
403	overall impact of the interventions discussed within this paper on medication wastage.
404	
405	Conclusion
406	This study has employed a theoretical framework to identify key underlying medication
407	wastage related behaviours (such as system, practitioner and patient effects) which require
408	attention as part of strategic development.
409	
410	Acknowledgements
411	The authors acknowledge those who participated in the focus groups.
412	
413	Funding
414	The research work carried out was fully funded by the Malta Government Scholarship
415	Scheme.
416	
417	Conflict of interest

418	The authors declare no conflict of interest. This study formed part of the author's submission		
419	for PhD. The scholarship had no influence on study design, conduction, analysis,		
420	interpretation or writing of this article.		
421			
422			
423			
424	Re	ferences	
425	1.	World Health Organization. Challenges in expanding access to essential medicines; 2004.	
426		http://apps.who.int/medicinedocs/en/d/Js5571e/2.html; 29 Apr 2016.	
427	2.	West LM, Diack L, Cordina M, Stewart, D. A systematic review of the literature on	
428		'medication wastage': causative factors and effect of interventions. Int J Clin Pharm.	
429		2014;36(5):873-881.	
430	3.	Medical Research Council. Developing and evaluating complex interventions: new	
431		guidance, 2008; http://www.mrc.ac.uk/complexinterventionsguidance; 2 Nov 2014.	
432	4.	Malta Tourism Authority. Tourism in Malta, 2013;	
433		http://www.mta.com.mt/loadfile.ashx?id=69b07385-93a7-4b05-89cb-db6a27fb95d3; 29	
434		Apr 2016.	
435	5.	PwC. Healthcare delivery in Malta, 2012;	
436		http://www.pwc.com/en_MT/mt/publications/healthcare/assets/healthcare_delivery_in_m	
437		alta_august_2012.pdf; 29 Apr 2016.	
438	6.	West LM, Diack L, Cordina M, Stewart D. A cross-sectional survey of the Maltese	
439		general public on medication wastage. Int J Clin Pharm. 2016; DOI: 10.1007/s11096-015-	
440		0233-x	

441	7.	Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use
442		in behaviour change and implementation research. Implement Sci. 2012;7(37). doi:

443 10.1186/1748-5908-7-37

- 8. Squires JE, Suh KN, Linklater S, Bruce N, Gartke K, Graham ID, et al. Improving
- physician hand hygiene compliance using behavioural theories: a study protocol.
- 446 Implement Sci. 2013;8(16). doi: 10.1186/1748-5908-8-16.
- 9. Duncan EM, Francis JJ, Johnston M, Davey P, Maxwell S, McKay GA, et al. Learning
- 448 curves, taking instructions, and patient safety: using a theoretical domains framework in
- an interview study to investigate prescribing errors among trainee doctors. Implement Sci.
- 450 2012;7(86). doi: 10.1186/1748-5908-7-86.
- 451 10. Bussières AE, Patey AM, Francis J, Sales AE, Grimshaw JM. Identifying factors likely to
- 452 influence compliance with diagnostic imaging guideline recommendations for spine
- disorders among chiropractors in North America: a focus group study using the
- 454 Theoretical Domains Framework. Implement Sci. 2012;7(82). doi: 10.1186/1748-5908-7455 82.
- 456 11. Bradley E, Curry LA, Devers KJ. Qualitative Data Analysis for Health Services
- 457 Research: Developing Taxonomy, Themes, and Theory. Health Serv Res.
- 458 2007;42(4):1758-1772.
- 459 12. Phillips CJ, Marshall AP, Chaves NJ, Jankelowitz SK, Lin IB, Loy CT, et al. Experiences
- 460 of using the Theoretical Domains Framework across diverse clinical environments: a
- 461 qualitative study. J Multidiscip Healthc. 2015;8:139–146.
- 462 13. Richardson K, Kenny RA, Bennett K. The effect of free health care on polypharmacy: a
- 463 comparison of propensity score methods and multivariable regression to account for
- 464 confounding. Pharmacoepidemiol Drug Saf. 2014;23(6):656-665.

- 465 14. European Commission. Investing in Health; 2013.
- 466 http://ec.europa.eu/health/strategy/docs/swd\_investing\_in\_health.pdf. 29 Apr 2016.
- 467 15. European Association of Hospital Pharmacists. Common position between patients',
- 468 consumers, and healthcare professionals' organisations involved in the activities of the
- 469 European Medicines Agency on: supply shortages of medicines, 2013;
- 470 http://www.geneticalliance.org.uk/docs/final\_common\_position\_supply\_shortages\_signat
- 471 ures.pdf; 29 Apr 2016.
- 472 16. Dill S, Ahn, J. Drug shortages in developed countries—reasons, therapeutic
- 473 consequences, and handling. Eur J Clin Pharmacol. 2014;70(12):1405–1412.
- 17. Charatan F. Prescription drug shortages plague US. BMJ. 2001;322(7279):130.
- 475 18. Gray A, Manasse HR. Shortages of medicines: a complex global challenge. Bulletin
  476 WHO. 2012;90:158–158A.
- 19. Kardas P, Lewek P, Matyjaszczyk M. Determinants of patient adherence: a review of
- 478 systematic reviews. Front Pharmacol. 2013;4(91). doi: 10.3389/fphar.2013.00091.
- 479 20. Check, E. Task force set up to combat threat of political interference. Nature.
- 480 2003;426(6964):218.
- 481 21. Baum NM, Gollust SE, Goold SD, Jacobson PD. Ethical Issues in Public Health Practice
  482 in Michigan. Am J Public Health. 2009;99(2):369-374.
- 483 22. Rest KM, Halpern MH. Politics and the Erosion of Federal Scientific Capacity: Restoring
- 484 Scientific Integrity to Public Health Science. Am J Public Health. 2007;97(11):1939-
- 485 1944.
- 486 23. Pham HH, Ginsburg PB, Verdier JM. Medicare Governance and Provider Payment
- 487 Policy. Health Aff. 2009;28(5):1382-1394.

488	24. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for
489	characterising and designing behaviour change interventions. Implement Sci. 2011;6(42).
490	doi: 10.1186/1748-5908-6-42.
491	25. Goff SL, Kleppel R, Lindenauer PK, Rothberg MB. Hospital workers' perceptions of
492	waste: a qualitative study involving photo-elicitation. BMJ Qual Saf. 2013;22(10):826-
493	835.
494	
495	
496	
497	
498	

499 Table 1: HCP demographics

Participant	Age	Sex	Profession	Years in	Main role	Other
				profession		experience
1	47	F	Pharmacist	24	Hospital	
					pharmacist	
2	23	М	Pharmacist	1	Hospital	Community
					pharmacist	pharmacist
3	31	М	Pharmacist	8	Community	
					pharmacist	
4	35	М	Pharmacist	12	Hospital	Community
					pharmacist	pharmacist
5	28	М	Doctor	5	Hospital doctor	
6	38	М	Pharmacist	15	Hospital	Medical
					pharmacist	representative

7	32	М	Pharmacist	9	Responsible	
					person/regulatory	
					affairs pharmacist	
8	27	F	Doctor	4	Hospital doctor	
9	28	F	Pharmacist	5	Hospital	Community
					pharmacist	pharmacist
10	43	F	Doctor	20	Hospital doctor	
11	35	М	Pharmacist	12	Hospital	
					pharmacist	
12	32	F	Pharmacist	9	Hospital	Community
					pharmacist	pharmacist
13	36	F	Pharmacist	13	Hospital	Community
					pharmacist	pharmacist
14	26	М	Doctor	4	Hospital doctor	
15	38	F	Doctor	17	Hospital doctor	
16	26	М	Doctor	4	Hospital doctor	
17	26	F	Pharmacist	3	Hospital	Community
					pharmacist	pharmacist

507			
508			
509			
510			
511			
512			
513			
514			
515			
516			

518 Table 2: General public demographics

Participant	Age	Gender	Profession	Level of education
1	34	М	PhD Nursing	Postgraduate
2	24	М	Accountant	Postgraduate
3	36	F	Director	Postgraduate
4	32	F	Assistant	Postgraduate
			director	
5	63	F	Housewife	Primary
6	56	F	Housewife	Secondary

524			
525			
526			
527			
528			
529			
530			
531			
532			
533			

535 Table 3: Key themes and sub-themes mapped to TDF domains

Theoretical Domain	Key themes (sub-themes)
Knowledge	1. Practitioner effects (knowledge of the consequences of
	medication wastage on economy, staff resources)
Skills	1. Practitioner effects (ability of practitioners)
	2. Patient effects (non-adherence to medication by patients)
Beliefs about capabilities and	1. Practitioner effects (HCPs as educators, time constraints.
their social/professional role	overstocking of medication by HCPs)
and identity	2. Political effects (failing system)
	3. Societal effects (social influences - global force)
Optimism	1. Practitioner effects (psychological influences - stress,
	obsessed, discouraged, optimistic)
Beliefs about consequences	1. Practitioner effects (consequences of medication
	unavailability to treat their patients)

	2.	Patient effects (consequences of medication unavailability for
		patients' conditions, patients' unawaress of consequences of
		unused returned medication)
	3.	Political effects (financial consequences of inappropriate
		prescribing/dispensing on country and tax payer)
Reinforcement	1.	Practitioner effects (HCP incentive - uphill battle,
		professionalism)
Intentions	1.	Political effects (the free healthcare system, unclear goals
		within the Government health system)
Environmental context and	1.	Practitioner effects (lack of patient review, lack of patient
resources		information, multiple prescribers, lack of patient registration,
		lack of treatment management guidelines)
	2.	Patient effects (selfish practices, confrontation, vulnerability)
	3.	Political effects (lack of resources, lack of harmonisation)
	4.	Societal effects (lack of education amongst certain social
		classes, abuse of free healthcare system)
Social influences	1.	Practitioner effects (mentality, communication, power,
		pressure by work colleagues, pharmaceutical lobbying)
	2.	Patient effects (pressure of HCPs by patients to prescribe or
		dispense)
Emotion	1.	Practitioner and patient effects (fear of medication
		unavailability)
Behavioural regulation	1.	Practitioner effects (correct prescribing and accountability,
		medication use reviews, improved documentation, improved
		communication)

	2. Patients effects (increase patient reassurance, patient
	empowerment)
	3. Political effects (reduce political interference, stock
	management, budgeting, independent body governing free
	healthcare system, pharmaceutical identity card,
	infrastructure, incentives, medication fee, reimbursement,
	compulsory private insurance, medication take-back scheme
	with cash card, high consumption medications, disease
	prevention)
	4. Societal effects (increase awareness, strategies and settings to
	deliver education)
Goals	1. Practitioner effects, patients effects, political effects and
	societal effects (need for education of all stakeholders
	including HCPs and patients)