

# A novel instrument to measure **Medicines-Related Quality of Life**

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# Why MRQoL?

- Patient-related outcome measures (PROMs) are increasingly recognised as important
- Relatively little research looking at impact of medicines from the patient perspective
- No existing tools are designed to detect changes in the overall impact of using medicines on quality of life, from the patient perspective.



# Could it help pharmacy studies?

- Pharmacists provide advice and review medicines
- This is likely to result in only small improvements in medicines-taking
- Potential impact of medicine review for patients:
  - Ordering
  - Administration
  - Symptom control
  - Adverse effects
  - Understanding
- Standard generic QoL tools, used in most published studies of medicine reviews, are not sufficiently sensitive to detect such small changes



# Aim

To develop a standardised tool to measure the impact of long-term medicines use on quality of life from the patient perspective



# Based on themes identified through in-depth interviews with 21 patients

- Relationships/communication with health professionals
- Practicalities in obtaining and using medicines
- Information about medicines
- Control over medicines use
- Efficacy
- Side effects
- Attitudes towards medicines
- Impact on daily life



# Method: Patient population

- NHS ethics approval obtained
- Inclusion criteria: Adults, living at home, with repeat prescription records for at least four medicines (not restricted to oral formulations or systemic treatments) for chronic medical conditions for at least one year
- Exclusion criteria: under 18 years, any patients whom the responsible GP felt were unsuitable for any reason, such as physical, mental or cognitive impairment
- Patients identified from medical records by practice pharmacists



# Method: Instrument Development

- 56-item questionnaire with 5-point Likert scores for each statement, scored 1 to 5  
(*strongly agree, agree, mostly agree, disagree, strongly disagree*)
- Tested for face and content validity and ease of completion using cognitive interviews with 11 patients
- Pilot postal distribution to 87 patients
- Responses assessed for:
  - poor discriminatory ability (interquartile range of 0)
  - possible ceiling effects (median of 1 or 5)
  - full coverage of all domains



# Method: Final questionnaire

- Contained 60 items plus demographic details:
  - Age, gender, employment, number of regular medicines
- Distributed to two cohorts of patients:
  - A** - confirmed as regularly collecting at least four repeat prescription medicines in the last year
  - B** - eligible for medication review because they used any medicines long-term
- Data entered into SPSS database for analysis
  - random 10% sample of entries checked for quality assurance





# Methods: Analysis

- Data from the two cohorts were compared for responses to individual statements, theme scores and overall score.
  - Combined datasets
  - Respondents completing fewer than 50 statements removed from analysis
- Internal consistency assessed using Cronbach's alpha
- Age, gender, number of regular medicines correlated with theme and overall scores.



# Results: response rates and demographics

## Cohort A

Distributed:	828
Returned:	189 (22.8%)
Female (%):	97 (51%)
Age 65 or over (%):	103 (54%)
Retired (%):	129 (68%)
At least 4 medicines(%):	166 (88%)

despite all records showing  $\geq 4$  regularly collected medicines

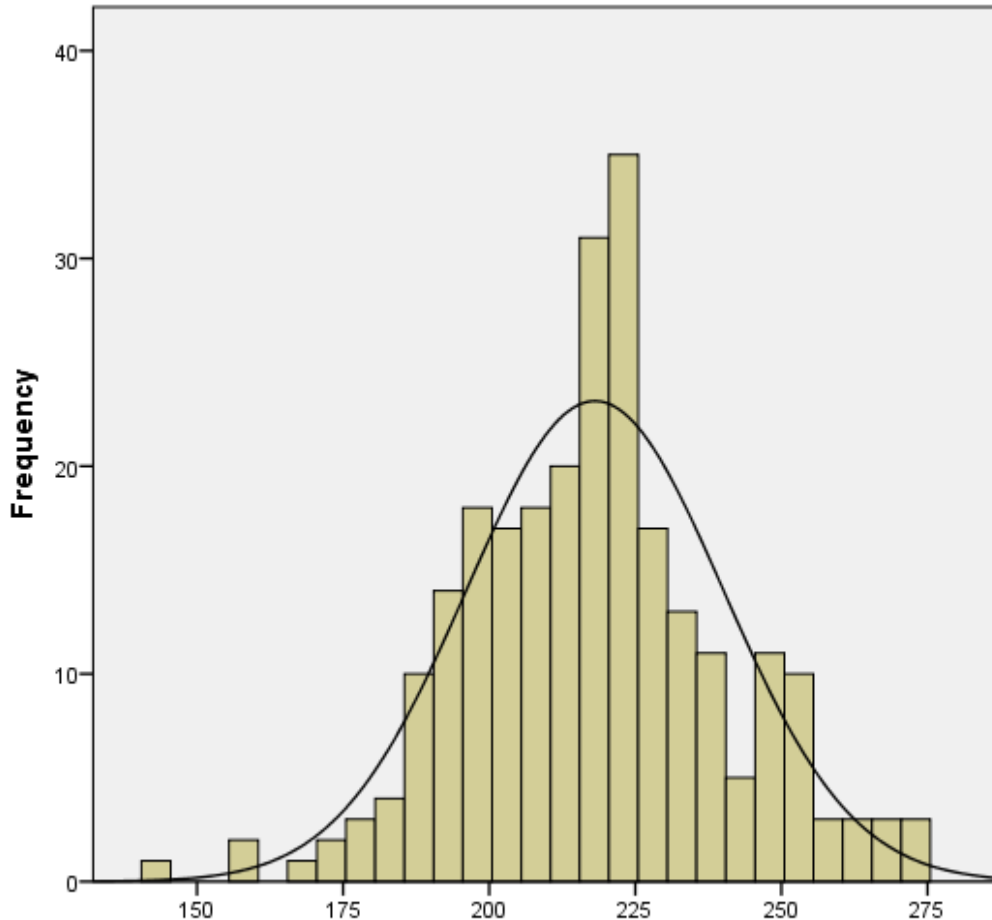
## Cohort B

Distributed:	529
Returned:	160 (30.2%)
Female (%):	78 (49%)
Age 65 or over (%):	82 (51%)
Retired (%):	97 (61%)
At least 4 medicines(%):	63 (39%)*

\* Significant difference between cohorts ( $p < 0.01$ )



# Results: Score distribution (n=255)



Median = 218  
Mean = 218.1  
Std Dev = 22.0

Mid-point = 180

Minimum = 143  
(Lowest possible = 60)  
Maximum = 274  
(Highest possible = 300)  
IQR = 203 - 230



Increasing quality of life



# Theme scores and internal consistency

Theme	Mean Score	Range (min – max)	Cronbach's alpha
Relationships with HCPs	39.5	19 – 50 (10 – 50)	0.891
Practicalities	40.1	28 – 50 (10 – 50)	0.698
Information	23.1	12 – 30 (6 – 30)	0.665
Side effects	13.2	6 – 20 (4-20)	0.352
Efficacy	20.0	10 – 25 (5-25)	0.778
Attitudes	31.8	14 – 45 (9 - 45)	0.591
Impact	27.3	12 – 44 (9 – 45)	0.762
Control	21.3	11 – 35 (7 – 35)	0.546



# Relationships with health professionals

Statement	Proportion agree/strongly agree (n)
I am confident about speaking to my doctor about medicines	89.5 (290)
I am confident speaking to my pharmacist about medicines*	78.8 (231)
I understand what my doctor tells me about medicines*	85.2 (276)
I understand what pharmacist tells me about medicines	81.3 (258)
My doctor spends enough time discussing medicines with me	69.9 (227)
My doctor listens to my opinions and concerns about medicines	77.4 (247)
My doctor takes my concerns of side effects seriously	81.5 (256)
There is enough sharing of information about my medicines between professionals providing my care	66.9 (209)
I trust my doctor's judgement in choosing medicines	84.6 (275)
Health professionals providing my care know enough about me and my medicines	69.5 (224)

Up to 30% of patients don't get enough time, aren't listened to or not taken seriously

\* Does not apply was an option



# Practicalities

Statement	Proportion agree/strongly agree (n)
I find opening the packaging of my medicines difficult	10.2 (31)
I have to put a lot of planning and thought into taking medicines	15.2 (27)
It is difficult to identify which medicine is which	4.3 (14)
I find getting prescriptions from the doctor difficult	5.9 (19)
I find getting medicines from the pharmacist difficult	3.1 (10)
It is easy to keep my medicines routine	84.2 (272)
The instructions on my medicines are easy to follow	92.3 (298)
I find using my medicines difficult	2.2 (7)
I sometimes run out of medicines	19.6 (63)
Taking medicines is routine for me	84.3 (273)

Up to 15% of patients have practical problems or need to make great effort to use medicines



# Information

Statement	Proportion agree/strongly agree (n)
I find the patient leaflet in my medicines containers useful	78.5 (252)
Information my doctor gives me about my medicines is useful	85.5 (277)
Information my pharmacist gives me about my medicines is useful*	82.4 (238)
I know enough about my medicines	57.9 (188)
I sometimes feel I need to get more information from other sources	20.4 (66)
I get too much information about my medicines	1.9 (6)

Over 40% don't know enough about medicines and 20% want more information

\* *Does not apply was an option*



# Side effects

Statement	Proportion agree/strongly agree (n)
I am concerned about experiencing side effects	45.1 (146)
I am concerned about possible damaging long term effects of taking medicines	49.8 (162)
The side effects I get are worse than the problem for which I take medicines*	18.6 (60)
The side effects are worth it for the benefits I get from my medicines*	66.3 (211)

Roughly 50% of patients are concerned about side effects  
Many have side effects which may make medicines not worth taking

\* Does not apply was an option





# Efficacy

Statement	Proportion agree/strongly agree (n)
My medicines are important to me	92.6 (300)
I am satisfied with effectiveness of my medicines	71.6 (231)
My medicines live up to my expectations	66.0 (181)
My medicines prevent my condition getting worse	79.0 (256)
My medicines are working	72.6 (234)

Roughly 30% of patients don't feel their medicines are working well enough or are not really satisfied with their medicines



# Attitudes

Statement	Proportion agree/strongly agree (n)
I am concerned about running out of medicines	30.6 (99)
I would be concerned if I forgot to take my medicines	59.0 (191)
I am concerned I may forget to take my medicines	27.2 (88)
I am comfortable taking the medicines I have been prescribed	81.0 (263)
I am comfortable with the times I should take my medicines	88.3 (287)
I am concerned that I am too dependent on my medicines	24.9 (81)
I accept that I have to take medicines long term	90.5 (294)
I worry that I have to take several medicines at the same time of day*	25.3 (81)
I worry that my medicines may interact with each other*	24.8 (80)

Roughly 25% of patients are concerned about interactions  
 Up to 30% are concerned about not remembering medicines/running out

\* Does not apply was an option



# Impact

Statement	Proportion agree/strongly agree (n)
My medicines allow me to live my life as I want to	73.4 (238)
My life revolves around using my medicines	27.1 (88)
Taking medicines interferes with my social life	14.2 (46)
Taking medicines causes me problems with daily tasks	8.6 (28)
I am unhappy with the extent to which my medicines interact with alcohol*	8.6 (28)
Taking medicines affects my driving ability*	4.1 (7)
Changes in daily routine cause problems with my medicines*	13.6 (35)
My medicines have an adverse effect on my sexual life*	30.0 (57)
The medicines I use have an adverse effect on the holidays I can take*	7.5 (17)

Medicines adversely affect the social and daily lives of many patients

\* Does not apply was an option



# Control

Statement	Proportion agree/strongly agree (n)
I can choose whether or not to take my medicines	21.9 (70)
I am able to balance my day to day life with taking medicines	82.5 (267)
I have a say in the brands of medicines I use	10.5 (34)
I always follow my doctor's advice about my medicines	86.1 (279)
I can change the times I take medicines if I want to	31.9 (103)
I can adapt my medicine-taking to my lifestyle	72.6 (236)
I can vary the dose of the medicines I take	15.1 (49)

Roughly 20% of patients don't feel they have control of their medicines use



# Scores versus demography

Score	Gender	Age	Number of medicines
Relationships	>0.05	Decrease <0.05	None evident >0.05
Practicalities	>0.05	>0.05	Decrease <0.05
Efficacy	>0.05	>0.05	Decrease <0.001
Side effects	>0.05	>0.05	Decrease <0.001
Information	>0.05	>0.05	Decrease <0.001
Attitudes	>0.05	>0.05	Increase <0.001
Impact	>0.05	>0.05	Decrease <0.001
Control	>0.05	>0.05	Decrease <0.001
Overall	>0.05	>0.05	Decrease <0.001

Generally quality of life scores reduce with increasing numbers of medicines

# Factor analysis

- Showed no clear relationship between items within the dataset
- Identified 15 potential components, but 33 items loaded onto one component
- Factor analysis is used to confirm the constructs within a scale
  - Does not confirm our pre-determined constructs
  - Does not identify any constructs at all!



# Conclusions

Results are in line with existing knowledge about patients' experiences of medicines use.

Show that a significant proportion of patients have quality of life issues as a result of using regular medicines.

First attempt to quantify these experiences in a single tool as a PROM.

Further development and testing is required to validate the tool in larger populations.



# Ongoing work

- Revised version has *does not apply* options removed
- Replace *mostly agree* with *neutral opinion*
  - for use by respondents who consider statement does not apply to them
- Currently being tested in Ireland
  - Approximately 500 patients completed, analysis ongoing
- Seeking collaboration for further testing!
- Requires to be tested in intervention studies to assess sensitivity to change.





If you are interested,  
please contact me  
Thank you!

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