

Development and Pilot-Testing of Key Questions to Identify Patients' Difficulties in Medication Administration

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Supplementary data: Table 1

Development of exemplary key questions on patients' difficulties in medication administration (translated from German)

Potential difficulty	First draft of key question (Step 1)	Step 2	Change?	Step 3	Change?	Step 4	Change?	Step 5	Change?	Final Key Question
Inhalers (metered dose inhaler)	Many patients find it difficult to pull the trigger of their inhaler and to inhale simultaneously. Are you having any trouble using your inhaler?	x		x	x	x		x		Many patients find it difficult to pull the trigger of their inhaler and to inhale simultaneously. Are you having any trouble using your inhaler? For how many seconds after inhalation do you hold your breath?
Inhalers (Elpenhaler)	Do you always manage to insert and remove the blister strip without any problems?					x		x	x	Do you always manage to insert and remove the blister strip without any problems? For how many seconds after inhalation do you hold your breath?
Inhalers (nebulizers)	Many patients find it difficult to count the exact number of drops. Do you also have any problems with this?					x		x	x	Many patients find it difficult to measure the exact number of drops. Do you have any problems counting the right number of drops for your nebulizer?
Inhalers (capsule-based inhalers)	Many patients report difficulties in inserting the capsule. Do you also have any problems with this?			x	x	x		x		For how many seconds after inhalation do you hold your breath? Do the capsules contain powder residues after inhalation?
Inhalers (other inhalers)	For how many seconds after inhalation do you hold your breath?			x		x		x		For how many seconds after inhalation do you hold your breath?
Injection devices	How frequently do you change the injection site?			x		x		x		How frequently do you change the injection site?
Ophthalmic preparations (ointment/ creme/ gel)	Do you always succeed in inserting the right amount of ointment/cream/gel into the eyelid at the first attempt?					x		x	x	Do you always succeed in inserting the correct amount of this medication into the conjunctival sac at the first attempt?

Ophthalmic preparations (drops)	Do you always succeed in dripping directly into the eye or do you need several attempts?			x	x	x		x	x	Do you always succeed in inserting a drop into the conjunctival sac at the first attempt? Do you always keep both eyes closed after the drop?
Rectal preparations	Many patients report that they are uncomfortable with the rectal administration of a drug. Does the rectal application of your drugs also cause you problems?	x	x			x	x	x		Many patients have problems with the use of this drug. Does this equally apply to you?
Nasal preparations	Many patients have the feeling that they have to use more spray/drops than prescribed in order to achieve a sufficient effect. Does this reflect your experience?	x				x		x		Many patients have the feeling that they have to use more spray/drops than prescribed in order to achieve a sufficient effect. Does this reflect your experience?
Transdermal patches	Do you sometimes have to change your patch more often than prescribed, eg because it does not last or the effect wears off too quickly?					x		x		Do you sometimes have to change your patch more often than prescribed, eg because it does not last or the effect wears off too quickly?
Dermatological preparations	Many patients find it difficult to choose the right amount of cream or ointment. Do you equally have any problems using your cream or ointment?	x				x		x		Many patients find it difficult to choose the right amount of cream or ointment. Do you equally have problems using your cream or ointment?
Liquid oral dosage forms (with measuring device)	Many patients describe the measurement of a liquid drug as difficult. Do you have any difficulties with the measurement - for example when using the enclosed dosage device?	x		x		x		x		Many patients describe the measurement of a liquid drug as difficult. Do you have any difficulties with the measurement - for example when using the enclosed dosage device?
Liquid oral dosage forms (dry syrup)	Many patients report problems with the preparation of their liquids, eg because development of strong foam makes accurate filling difficult. Do you have any problems with the preparation?					x	x	x		Many patients report problems with the preparation of their liquids, e.g. because a lot of foam develops. Do you have any difficulties with the preparation?
Liquid oral dosage forms (Drops)	Many patients describe the measurement of a liquid drug as difficult. Do you also find it difficult to do the measurement - for example by counting the drops?			x		x	x	x		Counting drops is difficult for many patients. Do you have any difficulties concerning this?

Dosage forms for oropharyngeal use	This drug should be used in the oral cavity. Have you ever swallowed this drug by mistake?					x	x	x		This drug should not be swallowed but should be applied to the oral cavity. Have you ever swallowed this drug by mistake?
Otological preparations	Patients often find it difficult to use ear drops - for example, the unassisted instillation with a tilted head. Does the application also cause problems for you?	x				x		x		Patients often find it difficult to use ear drops - for example, the unassisted instillation with a tilted head. Does the application also cause problems for you?
Vaginal preparations	Many patients are insecure about the vaginal application of drugs. Does the vaginal application of the medication also cause you any difficulties?	x				x		x	x	Many patients are insecure about the vaginal application of drugs. Does this also apply to you?
Total number of drugs	When taking a multitude of drugs simultaneously, many patients feel overburdened. Is it hard for you to keep track of your drugs?	x				x	x	x		When taking a multitude of drugs simultaneously, many patients feel overburdened. Do you have difficulties keeping track of your drugs?
Once weekly administration	This drug should be used once a week. Is it difficult for you to use this drug always at the same day of the week?	x				x		x		This drug should be used once a week. Is it difficult for you to use this drug always at the same day of the week?
Administration more than two times daily	Is it a problem for you to take your medication several times a day in everyday life?					x		x		Is it a problem for you to take your medication several times a day in everyday life?
Administration at lunch time	According to your medication schedule, you should use this drug at noon. Particularly at this time of day, many patients have difficulty adhering to their therapy in everyday life. Have you found it difficult to take your drugs at noon?	x				x	x	x		According to your medication schedule, you should use this drug at noon. Many patients find it difficult to actually do this in everyday life. Have you found it difficult to take your drugs at noon?
Tablet splitting	Do you always have difficulties splitting your tablets into uniform pieces?			x		x		x	x	Do you find it difficult to split your tablets consistently into pieces that have the same size?
Pro re nata (as needed) medication	In your medication schedule it is specified that you can use this medication if necessary.	x				x		x	x	In your medication schedule it is specified that you may use this medication if necessary.

	Do you know what symptoms you can use this drug for and what dose you can use?								Do you know the medical condition that is treated with this drug? Do you know what dose you can use?
Administration every two days or less frequently	Is it hard for you to remember this drug because it is not used every day?	x				x	x	x	Is it difficult for you to remember taking this drug because it is not used every day?
Fixed dosing interval	In your everyday life, are you able to keep the exact intervals between the administrations of this drug?	x				x		x	In your everyday life, are you able to keep the exact intervals between the administrations of this drug?
Use of multiple doses concurrently	You should use this drug X times at this time. Is it difficult for you to actually use this amount each time?	x				x	x	x	This drug should be used more than once at the same point in time. Do you find it difficult to use this drug repeatedly each single time?
Different doses of the same active ingredient at different times of day	You have to use different doses of this drug during one day. Do you sometimes accidentally mix up these doses?	x				x		x	You have to use different doses of this drug during one day. Do you sometimes accidentally mix up these doses?
Variable dosing	No exact dose is indicated for this drug. Does this make you insecure about how to take this drug?					x		x	No exact dose is indicated for this drug. Does this make you insecure about how to take this drug?
Only one drug at a specific point in time	Your medication schedule specifies that you should use this drug at a specific point in time, separate from all other drugs. Is it hard remembering using this drug?	x				x	x	x	Your medication schedule specifies that you should use this drug at a specific point in time, separate from all other drugs. Do you ever forget to take this drug?
The same active ingredient in different preparations	These two drugs contain the same active ingredient. Is there a risk of you confounding these drugs?					x		x	These two drugs contain the same active ingredient. Is there a risk of you confounding these drugs?
Occasional, episodic drug treatment	This drug is used for a limited time only. Is it hard for you to integrate this drug into your daily routine?	x				x	x	x	This drug is used for a limited time only. Are you able to integrate this drug into your daily routine?
Meal-dependent administration	Is it hard for you to coordinate the daily intake of your medication with your meals?	x				x	x	x	Do you find it difficult to coordinate the daily intake of your medication with your meals?

Administration at fixed times of the day	Your medication schedule specifies that this drug should be used at a certain time of day. Are you able to integrate this into your daily routine?	x				x		x		Your medication schedule specifies that this drug should be used at a certain time of day. Are you able to integrate this into your daily routine?
Increasing doses	Can you tell me in your own words how you have to increase the dose?					x		x		Can you tell me in your own words how you should increase the dose?
Decreasing doses	Can you tell me in your own words how you should reduce the dose?					x		x		Can you tell me in your own words how you should reduce the dose?
Intake with advised liquid	Is it hard for you in everyday life to remember taking this medicine together with the special liquid or food?					x	x	x		Do you find it difficult in everyday life to remember taking this medicine together with the special liquid or food?
Crushing tablets	This drug is to be crushed. Is it hard for you to crush this drug in such a way that it is easier to take afterwards?					x	x	x		This drug is to be crushed. Do you have any difficulties crushing this drug in such a way that it is easier to take afterwards?
Opening capsules	These capsules are to be opened. Do you have any difficulties opening the capsules?					x		x	x	These capsules are to be opened before use. Do you have any difficulties opening the capsules?
Disintegrating tablets, capsules and powders	This drug should be dissolved before use. Is your drug always completely dissolved?	x				x		x		This drug should be dissolved before use. Is your drug always completely dissolved?
Patient-unfriendly nature of liquid oral dosage forms	Have you ever not taken your drug because the smell, taste or consistency disturb you?					x		x		Have you ever not taken your drug because the smell, taste or consistency disturb you?
Lack of training in dosage form use	Have you received any training on the use of your drug? Do you think that such training would make it easier for you to perform your therapy?	x		x		x	x	x		Have you been advised on how to use this drug? Do you think that an explanation of how to use your drug would make it easier for you to perform your therapy?
Complex measurements (self-performed)	Do you feel safe when adjusting your dose after blood glucose/ blood coagulation measurement?					x		x		Do you feel safe when adjusting your dose after blood glucose/ blood coagulation measurement?

Supplementary data: Table 2

Detailed results of pilot-testing

	Total	Metered-dose-Inhaler	Capsule-based/Other inhalers	Eye drops	Injection devices	Tablet splitting	Meal-dependent administration
Number of tests	43	6	5	8	7	8	9
Number of tests for which the key question indicated the patient was experiencing difficulties (%)	18 (41.9)	2 (33.3)	3 (60.0)	8 (100.0)	1 (14.3)	3 (37.5)	1 (11.1)
Number of tests for which the general questions indicated the patient was experiencing difficulties (%)	9 (20.9)	2 (33.3)	0 (0)	3 (37.5)	1 (14.3)	2 (25.0)	1 (11.1)
Number of tests for which patients answer to key question corresponds to actual administration (%)	35 (81.4)	6 (100.0)	4 (80.0)	8 (100.0)	1 (14.3)	7 (87.5)	9 (100.0)
Number of tests for which patients answer to general question corresponds to actual administration (%)	26 (60.5)	4 (66.7)	3 (60.0)	3 (37.5)	1 (14.3)	6 (75.0)	9 (100.0)
Number of tests with an error identified in actual administration (%)	24 (55.8)	2 (33.3)	2 (40.0)	8 (100.0)	7 (100.0)	4 (50.0)	1 (11.1)
... thereof confirmed via key question (%)	17 (70.8)	2 (100.0)	2 (100.0)	8 (100.0)	1 (14.3)	3 (75.0)	1 (100.0)
... thereof confirmed via general question (%)	8 (33.3)	1 (50.0)	0 (0)	3 (37.5)	1 (14.3)	2 (50.0)	1 (100.0)
Number of tests with an error identified in actual administration that was addressed directly by key question (%)	15 (34.9)	2 (33.3)	2 (40.0)	5 (62.5)	1 (14.3)	4 (50.0)	1 (11.1)
... thereof confirmed via key question (%)	14 (93.3)	2 (100.0)	2 (100.0)	5 (100.0)	1 (100.0)	3 (75.0)	1 (100.0)
... thereof confirmed via general question (%)	5 (33.3)	1 (50.0)	0 (0)	1 (20.0)	0 (0)	2 (50.0)	1 (100.0)

Supplementary data: Table 3

Description of errors observed in the pilot testing

Key question	Errors observed (number of observations)
Inhalers (Metered dose inhalers)	Wrong breathing technique before inhalation (2) Multiple doses in one inhalation (1) Incorrect orientation of inhaler (1) Mouthpiece not tightly enclosed (1) No holding of breath after inhalation (for at least 5 seconds) (2) No slow exhalation after inhalation (2)
Inhalers (Capsule-based/Other inhalers)	Wrong breathing technique before inhalation (1) No holding of breath after inhalation (at least 5 seconds) (2)
Ophthalmic preparations (drops)	Installation of multiple drops (4) No Eyelid closure (8) No nasolacrimal occlusion (8) Misdirection of the eye or conjunctival sac (6) Contamination of the dropper tip (3)
Injection devices (prefilled)	No Priming of Pen before injection (6) Dose Knob not pushed in fully (1) No waiting for at least 5 seconds before removing needle after injection (4) Replacement of inner and outer needle shield (1) No change of injection site for each injection (1)
Tablet splitting	Tablet not divided evenly with hands (2) Tablet not divided evenly with knife (1) Tablet not divided evenly with letter opener (1)
Meal-dependent administration	Time interval from taking the tablet to the meal is not adhered to (1)