Digital Additional Risk Minimization Measures: An Exploratory Study Using Qualitative Feedback from Healthcare Professionals and Patients Across 6 Countries

Barbara Da Silva-Tillmann[2] Marie-Claire Wilson[1]· Hetal Doshi[2] Fabio Lievano[2]· Mark Perrott[1] Cheryl Renz[2]

[1] Axian Consulting Ltd., Cambridge, UK

[2] AbbVie Inc., North Chicago, IL, USA

Corresponding author: barbara.dasilva@abbvie.com

Supplementary Information for article

Supplementary Information

Screening / eligibility criteria

The screening questions for HCPs and patients are provided below. In addition, the authors provided the following general guidelines for Adept Field Solutions Ltd to help limit bias in the results and to help ensure respondents are suitable.

HCPs

- Ideally, no more than 2 HCPs working at the same institution
- At least 5 years' experience at specialist consultant level
- Per country, HCPs: 3-4 rheumatologists and 1-2 dermatologists
- Respondents should be fluent with reading and speaking English (except Switzerland where interviews will be conducted in German) and highly competent with using websites. Regular use of computers/smartphone/tablets

Patients

- A mix of genders and ages considering ankylosing spondylitis being much more common in men and RA in women
- Per country, 3-4 rheumatology (moderate-severe RA, PsA, AS) patients and 1-2 dermatology (AD) per country Patients must have used a disease-modifying anti-rheumatic drug (DMARD)
- At least 5 years living with the condition
- Minimum 6 AD patients across all countries
- Should be comfortable with reading and speaking English and with using websites. Regular use of computers/smartphone/tablets

HCP screening questions

1. How many years have you specialised in [Dermatology / Rheumatology]? Terminate if less than 5 years

2. What percentage of patients that you treat have the following conditions?

Moderate-severe rheumatoid arthritis.

Psoriatic arthritis.

Ankylosing spondylitis.

Atopic dermatitis [Dermatologists only]

Other

Terminate if none more than 50%, or if the sum of rheumatological diseases is less than 50%

On a scale of 1-5, where 1 = Not at all familiar and 5 = Very familiar: How familiar are you, in your clinical practice, with newer disease-modifying anti-rheumatic drugs (DMARDs) for rheumatological/dermatological diseases? Terminate if under 3

4. How familiar are you with the risk management materials intended to help reduce the risk of serious side effects of rheumatological or dermatological drugs (e.g., HCP and/or patient/caregiver risk minimization tools/educational brochures/guides/cards)? Terminate if under 3

5. Do you consent to the interview being audio-recorded for notetaking and quality-control purposes? Yes/No

6. Do you consent to be contacted after the survey and interview if the project team need to clarify any of my responses? Yes/No

Patient screening questions
1. Have you had one or more of the following conditions for over 5 years?

> Moderate-severe rheumatoid arthritis

> Psoriatic arthritis

> Ankylosing spondylitis

> Atopic dermatitis

> Terminate if No

2. Which medicines have you been prescribed for your condition(s)? Please provide a list of current and previous medicines Terminate if no DMARDs are listed.

3. Are you aware of the educational materials (e.g., brochures/guides/cards) that may be provided (in addition to the PIL) with medications to help reduce the risk of side-effects? Yes/No

4. Do you consent to the interview being audio recorded for notetaking and quality control purposes.? Yes/No

5. Do you consent to be contacted after the survey and interview if the project team need to clarify any of my responses? Yes/No

Survey questions (used during the interview sessions)

HCP survey

1. On average, roughly how many patients do you see per week?

• Less than 20

• 20-50

• 50-75

• 75-100

• 100+

2. Additional risk min tools are focused on certain targeted risks. They do not discuss all risks of a product. Which would be most useful for you in terms of a digital HCP resource for additional risk min tools?

• A website, usually accessed via PC or tablet

• An app accessed via a smartphone

• A website and an app

Please explain your answer

3. Additional risk min tools are focused on certain targeted risks. They do not discuss all risks of a product. What do you think would be most useful for your patients as an additional risk min tool?

• A website, usually accessed via PC or tablet

• An app accessed via a smartphone

• A website and an app, so all patient preferences are covered

Please explain your answer

4. Do you find the demo site easy to navigate?

Is it clear where you would need to click to get to various parts of the site? E.g., where to find the Safety information, or the resources section

Does the general layout of the site make sense? If not, what should be changed?

Are the parts of the demo that are important to you easy to find/prominent enough? If not, what should be changed?

5. Do you think it would be easy to use a website or app based on this demo? Please explain your answer.

6. Please rate the following features in terms of their usefulness to HCPs (Useful/Not Useful/Not Sure)

- Safety information section
- "Prescribing guidance" list
- Frequently asked questions (FAQs)
- Emergency treatment/ AE information
- Clinical scenarios
- Resources
- Videos of mechanism of action
- Graphical representation of data
- Information to discuss with your patients

7. In what circumstances would you use a website or app based on this demo?

- Instead of paper materials

- Alongside paper materials

- I would not use it at all – I prefer paper

Please explain your answer – if you wouldn't use it, what would change your opinion and bring you to use it?

8. Would you encourage your patients to use an app based on the demo?

- Yes, for some patient groups

- Yes, for all patients

- No

Please explain your answer

9. Do you think that HCPs like yourself would benefit from a digital risk minimization tool based on this demo?

- Yes

- No

- I'm not sure

Please explain your answer

10. Do you think your patients would benefit from having a digital risk minimization tool based on this demo?

- Yes

- No

- I'm not sure

Please explain your answer

11. Would a website/app based on this demo be more convenient to use than paper for additional risk min? Please explain your answer

12. What does the online tool do better than a paper version for additional risk min? (5 fields for answers)

13. What do paper materials do better than an online tool for additional risk min? (5 fields for answers)

14. What would be the best way to direct patients to the patient tool and to show that you have directed the patient appropriately?

• A hard copy material would have the link/QR code to the site

• There would be a link I could share by email/text

• Other

Please explain your answer

15. Which other features would you like to see in the HCP tool? (Free text)

16. Which other features would you like to see in the patient tool? (Where the patient tool has been demonstrated - free text)

17. Suggest one way in which the tool could be improved for HCPs

Patient survey

1. We are interested to get your feedback on materials / resources that would provide you with important information about certain risks associated with your medication. Which would be most useful for you personally in terms of a digital patient resource that provides information about product risk?

• A website, usually accessed via PC or tablet

• An app accessed via a smartphone

• A website and an app

Please explain your answer

2. Do you find the demo site easy to navigate?

Is it clear where you would need to click to get to various parts of the site? E.g., where to find the Safety information, or the resources section

Does the general layout of the site make sense? If not, what should be changed?

Are the parts of the demo that are important to you easy to find/prominent enough? If not, what should be changed?

For example, the resources section

3. Do you think it would be easy to use a website or app based on this demo? Please explain your answer.

4. Please rate the following features in terms of their usefulness to patients (Useful/Not Useful/Not Sure)

- Safety Information section
- Patient Alert Card
- Frequently asked questions (FAQs)
- "Confirm your knowledge"
- Reminders
- Resources
- Graphic representation of data
- Videos of how the drug works

5. In what circumstances would you use a website or app for information about risk, based on this demo?

- Instead of paper materials

- Alongside paper materials

- I would not use it at all – I prefer paper

Please explain your answer – if you would not use it, what changes could be made to bring you to use it?

6. Would you recommend that other people with your condition should use a website or app to get information about risk, based on this demo?

- Yes, for some patient groups

- Yes, for all patients

- No

Please explain your answer

7. Would a website/app based on this demo be more convenient to use than paper materials that provide information about risk? Please explain your answer

8. What does the online tool do better than paper materials that provide information about risk?

9. What do paper materials do better than a digital tool that provides information about risk?

10. What would be the best way for you to find out about a digital tool providing information about risk?

- A hard copy material that I get from my doctor would have the link/QR code to the site

- My doctor would give me a link via email or text

- Other

Please explain your answer

11. Which other features would you like to see in the patient app or website? (Free text)

12. Suggest one way in which the app or website could be improved for patients