Meeting 5 – 15/06/21

Welcome

The co-chair ran through the agenda for the group, with special mention to the policy teams for compiling the information at short notice.

Traverse then reminded the group of the ground rules and victim support service.

Matters arising from session 4 and DHSC update

Traverse noted that the previous meeting's policy teams have been asked to feedback their responses by the end of the week.

Traverse also confirmed that there will be a further follow up meeting with MHRA. By a majority vote, the 29th of July was agreed upon as the date for this session.

The department confirmed that they have continued drafting the government response and are speaking to the minister about the structure. Timelines are still being finalised. The department have also been spending time on publishing parliamentary handling. Parliament go to recess on the 22nd July so the team will make sure they get it out before that date.

Recommendation 2 Discussion:

The policy team for recommendation 2 introduced themselves and gave a short presentation on their work to consider recommendation 2, *The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices.*

This was followed by a whole group Q&A, and then two breakout group discussions. This followed the format of previous meetings.

The key points which arose from the group were:

The appointment of the Patient Safety Commissioner (PSC)

- There was group consensus that having a PSC is important to ensure patients are treated fairly and with respect, and have somewhere to go for various issues.
- Transparency of the appointments process is key for patients to have faith in the PSC. The public needs to have input all the way along, including in the recruitment process. Patient representatives should be involved in recruitment.

- PSC candidate must have expertise and experience in engaging with patients for patient safety. Patients need to trust them to speak on their behalf.
- The group stressed that an opportunity for public comment on the candidate is important as there may be people nominated that are not seen as independent by patients. They also noted that Ministers were clear that for this role to be successful the commissioner needs to be independent.
- The group agreed that a 3-year term is a sufficient minimum as it is a new role that needs to establish multiple strategies and relationships through UK-wide liaisons. Agree with a 6-year maximum term to avoid complacency.
- Patient Safety Learning's response to the PSC Scotland consultation was given as an example for the policy team's use. Describes powers and resources the PSC will require to effectively influence change and improve patient safety. https://www.patientsafetylearning.org/blog/patient-safety-commissioner-for-scotland-consultation-response Team members agreed with the usefulness of this response, especially as it highlighted human and financial cost.

The functions and powers of the Patient Safety Commissioner

The PSC needs to be truly independent. The PSC should not merely be a sounding board but should have the power to make changes. The group questioned whether the PSC would have powers to make organisations implement its recommendations, rather than only being required to respond to them. The group saw benefit in in making the PSC's recommendations mandatory.

- The group felt that the PSC should be able to investigate historic/ retrospective issues as well as current issues. They felt that without this the process would be deeply unfair.
- Some group members suggested that he PSC's role should be expanded to encompass a broader range of issues beyond medicines and medical devices. They felt that the PSC could be a great driver for cultural change across the whole system, but it currently seems limited. Members understood this would take time but stressed that patients need a voice across the whole system. DHSC officials noted that the scope of the Medicines and Medical Devices Act 2021, which legislates for the Commissioner, did not allow consideration of a Patient Safety Commissioner with a broader remit.
- The PSC should have the ability to work with other ministers outside of health, like the education minister for example
- The group wanted appropriate support for the PSC e.g. staffing.
  They said that the Cumberlege Review had a limited scope but patient safety concerns on medicines and medical devices were much broader and this work could not be done alone.

Progress and accountability

- There needs to be a way to check the business plan has been achieved at the end of the given time period. The PSC will need to set a strategic plan as well as a business plan when in office, with the tools to measure success for instance. Cited Fiona Caldicott as an example of someone who took a position and created a model thereafter.

- This role regarding systematic change needs to work in conjunction with tackling individual cases in order to see true change.
- The commissioner needs to organise their remit with the NHS, and how they work with other organisations in the system. They should be very clear on what they can actually do and then be held accountable.
- The group questioned how the team will ensure adequate resources and support can be provided when it won't be clear what the role will entail and what will come out of yearly report? How do ensure independence and financial independence?

How the Patient Safety Commissioner works with patients and the public

- Patients or members of the public should be able to participate in the advisory board, and it needs to include a broad range of experience. The voices of those who have been affected are important and must be included. There should be a consultation on what kind of experts should be included in that team. The PSC needs to be accountable. The need for some type of engagement process for decision making.
- There is a difference between an advisory board and a board which the PSC would answer to. It should be advisory rather than a board the PSC had to answer to, as that would in turn have a chair that would hold power and confuse independence. The policy team highlighted that they would feedback this difference. They clarified that the group would prefer the board to be advisory and the commissioner ultimately accountable and that this would be achieved by the Commissioner appointing their own panel.
- The system should response rapidly when reports of harm are made, patients should not have to wait for issues to be reported to the PSC.
- The first commissioner would need to set out a long-term strategic plan spanning perhaps 3-5 years that would outline their vision and the legal frame they'll be working within. There needs to be more regular quarterly reporting, perhaps some form of dashboard, as there were fears a year-by-year plan could become task orientated.
- There needs to be a proper pathway of consultation and reporting. Both from the patients to PSC, and from the commissioner to everyone else. Need to work out what would help different types of patients. Being heard in the first instance and having somewhere to go is good but need to make sure the system works and it has the right tools.
- The group expressed optimism regarding the role. They noted their appreciation at being involved in the process rather than being expected to give their approval once all decisions has already been made.

Recommendation 8b Discussions:

The recommendation 8b team gave a short presentation on their work in relation to recommendation 8, part b, *In addition, there should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians.*

This was followed by a whole group Q&A, and then two breakout group discussions.

The key points which arose from the group were:

Key principles for industry reporting

- The group felt strongly that industry reporting of payments should be mandatory. Voluntary reporting is not good enough, it doesn't work at all for devices, and doesn't demonstrate enough commitment. Mandatory reporting would ensure patients can be assured they have quality, complete and reliable information on which to make an informed decision on their care.
- Group members suggested that reporting should be expanded beyond the recommendation in the IMMDS review, for example by also placing a requirement on payments to healthcare charities. Industry should have to report payments to all sectors to build trust and to deter re-classification with the aim of avoiding reporting duties.
- The group felt that for industry reporting to be effective, there needs to be an open, mandatory database. One participant said it should be one resource for devices and medicines.
- There needs to be accountability through penalties in order to create change. Some group members noted that in the USA they have already started to penalise drug companies who are not reporting payments properly. Patients need to know there is intent to make it mandatory and enforce penalties. There needs to be a commitment in government that says how we will fix it.
- Within industry, accountability could sit with boards. However, it is difficult to reach the board level because there are complexities in the layers of companies. Group member suggested speaking to the CQC who have worked on this.
- Transparency is essential for patient safety. Patients need to know about their options and all the devices or medicines available through education and support.
- Transparency also ensures a long-term positive impact on the quality of care by involving teaching hospitals etc and contributing to training better scientists and clinicians coming through those institutions. It is not good enough to only ensure safety from the manufacturer if it is then put into the hands of inattentive or inexperienced staff. Necessary to prevent flaws/bias in the scientific evidence and practice.
- One group member emphasised the importance of the broader issue of trust. Transparency of reporting payments and financial incentives is essential if the pharmaceutical and medical devices industries are to regain patients' trust that they put patient safety at the core of what they do. There should be industry-wide values and ethics that patient safety is not negotiable - organisational culture, systems and processes should ensure there is no avoidable harm, now and forever.

Industry reporting – medicines

- The reporting must be mandatory and transparent, and the resulting data must be accessible. If patients are being asked for their consent in treatment, they must be able to find out, via a user-friendly platform, about the financial incentives that led to the involved medicines and/or devices being

chosen. The group cited the databases from the US as a key reference for accessibility in UK development.

- This is necessary information for the individual but also for campaigns, journalists and organisations as it will allow them to identify trends across the industry. Members suggested that campaigns and organisations should be able to voice to the team what data would be helpful for them spotting these trends.
- One member said that whatever scheme is put in, it needs to be reviewed regularly so it can evolve over time.
- The CMS Open Data system in America was given as an example of an easy to use system which enables patients to see conflicts of interest. The alternative UK system was said to look unprofessional and is incomplete as numerous names are not included. It was described by a group member as tokenistic and not building trust. It also only includes medicines rather than also medical devices.

Industry reporting – medical devices

- The industry has a historic tendency to rush releasing new devices without proper patient involvement throughout the development, and promote the device from the manufacturing side without providing sufficient information to the public because they wish to start making money as soon as possible. This leads to a lack of research in the public domain as patients are treated as outliers due to issues never having arisen in development because no one was consulted and promotion was handled by the manufacturer.
- Cases of motivation for profit influencing moral decisions were inherent in the system, but are currently impossible to identify due to the lack of a central database . There is a need to expand upon the work of Disclosure UK and look to US companies for examples of patient accessibility. The Sunshine model is not faultless however, and so should be used as a starting point, and improved for UK use.
- Data must be monitored continuously as trends emerge over time to identify those harmed and keep behaviours in check. This will in turn also benefit manufacturers as it will reduce litigation.
- The database should be highly promoted, unlike the yellow card system which is fairly unknown. This database needs to be much more open so anyone can find it not just those in the know.

Patient involvement in taking forward work on industry reporting

- Any changes to systems for industry reporting need to be made in consultation with patients, in particular those who have been affected.
- Lengthy public consultations don't always attract patients and the public. Patient voice is essential, these people are experts in their own care. The best feedback is from those with experience. This should be a transparent process which is publicised so that you access the appropriate people. Look beyond the usual consultation process.
- Policy team noted that they would need to reach out to patient groups as well as industry in any consultation process.

- Some group members felt that there should be continued patient engagement as work on recommendation 8 and other recommendations is taken forward, both to test ideas and to provide external accountability.

Connection to recommendation 8, part A, *lists of doctors' interests*

- Group members stressed that conflicts of interest need to be addressed in a coherent way across both parts of recommendation 8, with clinicians required to report their interest, and industry required to report payments.
- In order to address conflicts of interests clinicians must declare all information and it must be mandatory to do so. Otherwise, you may find that you have a clinician that isn't receiving payments, but they're tied to an organisation that is, or people may leave reviews who are on boards of institutions in other countries. Similarly, organisations may ask the same experts for advice each time already knowing and approving of their answers.
- Any individuals involved in decision making processes must report financial incentives, including perks such as pharmaceutical weekends for example. This relates to transparency at all levels, there should be no way to conceal interests or opt out of reporting or it will not work as intended. The policy team noted that they hear the point about voluntary vs mandatory.

Wrap up and close:

The next meeting is on Thursday 24th June, 1-3.30pm and the agenda will be sent to the group on Thursday. The Minister will join this meeting for an hour and there will be time for open discussion. The department are also working on getting representatives from Recommendation 5 to attend the discussion. Finally, we will discuss the patient journey and patient engagement more generally in that meeting.

Traverse noted that the group will be sent the draft report on Thursday and asked members to keep their comments focused on whether it captures their voice, views and key concerns, rather than formatting issues for example. Traverse also noted that they will anonymously include the questions made by group members from the chat or emails, summary notes, and Terms of Reference.

Group members were keen to understand the minister's intentions and hopes for the meeting. The department expressed that the minister is happy to be guided by the group, listening to and answering any questions the group might have.

Traverse acknowledged concern over the timing of the minister's attendance but expressed that this would be a further opportunity to put forward individual views and the report will in turn tie these together and situate within the group perspective. It was agreed that it would be useful for the minister to also receive the draft report beforehand.

Finally, the co-chair thanked policy teams for preparing so well and noted the receptiveness from both policy teams in today's meeting, stating that there appeared to be intent, progress and group success. If group members had any further comments or reflections for the teams they were asked to email these.