Meeting 4 – 27/05/21

Introduction and Welcome

The co-chair welcomed the group and went through the agenda for the session. Traverse reminded the group of the ground rules and the victim support line details.

The Recommendation 7 team introduced themselves.

Matters arising from meeting 3 and DHSC update

The department informed the group that they are still waiting for the MHRA team to come back on all comments and issues raised by members at the previous meeting, and that once they have received them they will be sent out to group members. Group members asked if they would have the opportunity to collectively discuss the MHRA's responses to questions that were raised, Traverse noted that they will put time in the next meeting to go through it and will think of the most appropriate way to address this.

Traverse informed the group that the summary notes from Meeting 3 have now been published on the Traverse website.

The co-chair and Traverse informed the group that they met with the *First Do No Harm* All-Party Parliamentary Group (APPG) to give updates on recruitment, the priorities identified, the nature of these meetings, and the timeline for reporting.

The department also noted that they have started drafting the government response and explained the process of publication. They are also meeting with devolved administrations monthly to collaborate where there are overlaps in their work.

Recommendation 7 Discussions:

The team for recommendation 7 (DHSC, NHSX, NHSD, NHSEI-GIRFT) gave a short presentation on their work in relation to recommendation 7, *A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures.*

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:

Engaging patients in the development of the Medical Device Information System (MDIS)

- Patient engagement is key for all devices. Engagement must be opened up to a broad range of patients who have had medical devices as patients are the experts.
- There needs to be real partnership and enabling of patients, with many patients feeling they have not been listened to in the past. Mechanisms need to be put in place to engage people of all backgrounds and consider factors such as informed choice and co-production etc.
- There should be additional understanding of particular needs of those with disabilities.
- Patients need to be more informed and involved. Those who are able to research medical devices before procedures may do so, but it should not be their responsibility. Some are unable to do this or may not understand what they are reading. They should be informed by clinicians of their choices, the risks, potential updates or recalls etc of devices.
- Some systems offer patients support through a buddy system. Using people who are more of an expert with patient experience to help people from across communities.
- Engagement should not be tokenistic. It is okay to not act on what you hear as long as you explain why with good evidence. Be open about the consultation process to improve trust and encourage patient confidence. From the start it should aim to improve the patient's life.
- Consult patients and patient groups throughout the process to encourage and gather a range of feedback from people with differing circumstances

Key principles for how the Medical Device Information System (MDIS) should operate

- Having a free text box option within the MDIS is essential, with artificial intelligence mechanisms to spot trends and track data. There should also be an alert sent to somebody to highlight the pattern/issue.
- MDIS should analyse and use data efficiently. Data needs to be publicly searchable, and submitting data needs to be mandatory and not only include basic patient details. In accessing data, patients must be supported to ensure usability.
- Patients should be provided with a variety of means to give feedback including a feedback form that can accurately capture what has gone wrong. Feedback needs to capture conditions that might not have been initially recognised.
- Reasons for policy decisions should be clearly evidenced through documentation and process.
- There needs to be a commitment to long term data capture. Devices need to be tracked for life, 'from the cradle to beyond the grave', particularly higher risk ones. The data must be gathered and kept safely. Long term data

capture is also essential to pick up unexpected and delayed complications. This includes linking into secondary issues.

- The group placed strong emphasis on transparency and what data it is collected. This could include clarity surrounding data input from the consultants implanting devices which is currently not fit for purpose, due to their own opinion on these issues.
- The MDIS should interact with existing registries here and abroad. Use existing data from a range of systems to contribute to a global network of learning.
- Policy makers must ensure both new and existing patients know that this resource is available to them. Advertise and increase publicity of the opportunity to feedback. Existing users must be informed about the database and any updates or changes.
- Policy makers should feedback information to the industry who are making the devices to create improvements.
- Expand on existing systems e.g. policies that force companies to share their data or they will suffer a monetary penalty.

Engaging patients in the public consultation process:

- Policy makers must consult lots of sectors and patient groups throughout the process to create genuine co-production. Consider how you are selecting patients to hear from in the most appropriate way.
- The process should not be rushed, and the government should be transparent about timelines for consultation. After consultation,
- Don't rush the process and be transparent with timelines for consultation. After consultation, close the feedback loop by providing timely feedback.
- Simplify language and explanations to cater to those from varied backgrounds and enable all to report accurately.
- There was repeated emphasis on advertisement of the consultation
- There was a suggestion that policymakers could meet with people in various locations as part of the consultation process. Sometimes it is easier for people to come in and speak to share their views.
- The government must truly listen and take patient views on board or patients will lose faith in you.

The co-chair stated this session was positive as the policy team wanted to listen and learn from the group and gave immediate and positive feedback for almost all questions.

Recommendations 3 & 4 Discussions:

Note: the position on recommendation 3 – that the government has no plans to establish an independent redress agency - was set out in the Government's Written Ministerial Statement of 11 January 2021: https://www.gov.uk/government/speeches/update-on-the-governments-response-to-the-independent-medicines-and-medical-devices-safety-review

Traverse informed the group that more time has been held to discuss recommendation 4 than 3 as that is where there is more opportunity for members to influence decisions. However, the group were welcome to use the chat to make comments or ask questions about recommendation 3.

The Recommendation 4 team then gave a short presentation on their work in relation to recommendation 4, *Separate schemes should be set up for each intervention – HPTs, valproate and pelvic mesh – to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim.*

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:

Views on the current system

- Litigation is not an effective route in many cases. Group members cited examples of cases being dropped or in Northern Ireland where no-win-no-fee agreements to bring claims are not available.
- Group members felt that litigation was often unsuccessful due to there not being enough clear evidence on causation of harm e.g. there are no specific tests for harm for some devices, very few autistic children are correctly diagnosed, there is not enough knowledge surrounding FVS etc.
- The current system creates adversaries between the medical world and the NHS; the medical system should work for patients. Litigation and patient safety are not binary, you can improve patient safety and have redress whilst still having litigation.

What redress means to patients

- Financial costs are one consideration:
    - redress should take into account the financial costs that come from needing to pay for care, disability aids, mortgages etc. There are also differences between disabilities and devices.
    - there also needs to be an acknowledgement that children need a care plan and that disabled carers is a further layer of complexity
- However, redress is not just about meeting financial needs:
    - There is a huge emotional cost which is not supported sufficiently by the NHS.
    - Group members emphasised impacts to mothers whose children have been harmed and that this physical and psychological effect is not compensated.
- Redress must be accessible – individuals must be able to access redress payments easily, there should not be extra barriers such as going through

certain banks or risking losing entitlement to your benefits (due to benefits having income thresholds.
- Many group members felt that decisions on public spending should not frame discussions on redress. The discussion should be about addressing the financial and emotional harm to patients. Some group members suggested that a levy on industry would be a better way to fund redress.

Other factors to consider:
- There are systems abroad with specific agencies that put patients first. Group members cited schemes in Scandinavia, New Zealand, the States.
- MacLeod says: "Evidence from other nations and other sectors within the UK indicates that these outcomes can be achieved by replacing clinical negligence litigation with redress delivered via an administrative scheme." Litigation is a barrier to learning from patient safety failings due to the way data is captured and it not being shared.
- The government needs to change the fundamental structure and that will reduce pay-out as they will catch mistakes earlier. If they don't do this, it will never change.
- One group member suggested looking at Patient Safety Learning's A Blueprint for Action.

Recommendation 3: independent redress agency

- The Government needs to change the fundamental structure of responding to incidents of harm so that they will catch mistakes earlier which will in turn reduce pay-outs.
- The purpose of the redress agency is not to improve safety. However, financial redress and patient safety are not mutually exclusive.
- A redress agency would help those who cannot handle the claims process or those that it is not available for.
- A redress agency should be funded by industry through a levy – this will create incentives for industry to improve safety. Without redress, they will not change their behaviour or practice. Penalties must be enforced.
- As there should be a levy, using public money for redress should not be used as an argument. If not industry, MHRA should foot the bill.
- Many group members expressed disappointment and anger that the government had decided not to take forward the recommendation for an independent redress agency.

Recommendation 4: redress schemes

- Redress is more than financial compensation, it shows regret and willingness to accept responsibility.
- There are systems abroad with specific agencies that put patients first. Group members cited schemes in Scandinavia, New Zealand, the States

which have replaced clinical negligence litigation through administrative schemes.

- There will be great anger from patient groups if there is no redress scheme or ex gratia payments:
- Many group members felt that decisions on public spending should not frame discussions on redress. The discussion should be about addressing the financial and emotional harm to patients.
- Whilst the cost to the government is being considered, redress schemes could save money on litigation cases and deter initial poor practice, saving money in the long term.
- Group members felt that discussions of causation should be left to the courts, and that looking at redress for historic cases through a causation lens is impractical as the evidence does not exist

Whole Group Reflection

The Recommendations 3 and 4 team thanked the group for their contributions and reiterated that they are still in the decision-making process so all comments will be fed back into the ministerial advice. They noted the sense of responsibility and collective voice with regards to group members advocating on behalf of many others.

Some group members emphasised they fear nothing will come from these discussions. They stated they do not want to have to continuously campaign because the government will not provide redress. The group noted that, if the government accepts the recommendation for redress schemes, there should not be eligibility requirements that exclude some patients and then need to be amended in the future.

Wrap up and close:

Traverse encouraged the group to send in more comments or questions by email. Policy teams will be sent the notes, the chat and any emailed responses from the group. The meeting notes will be published online, and the teams will respond with answers to the group as soon as possible.

On June 15th, we will hear from Recommendations 2 *(patient safety commissioner)* and 8b (*mandatory reporting of payments from industry)*. Papers will be sent to the group a week in advance. On June 24th we will have the Minister of State Nadine Dorries joining us for an hour. During that session we will also cover patient experience and patient engagement more generally.

Traverse are preparing an independent report of the findings of the Patient Reference Group on the group's behalf considering each of the responses and comments on patient engagement.

The co-chair personally thanked the group for their engagement and robust feedback. Some group members also gave quick updates on other information they are aware of and noted to share relevant links or documents with the group.