Patient Safety Action Network
Patient Driven, Patient Led
https://www.patientsafetyaction.org/

COMMENTS BY LISA MCGIFFERT
Request for Information on
Creating a National Healthcare System Action Alliance to Advance Patient Safety

Date: January 26, 2023
To: Department of Health and Human Services and Agency for Healthcare Research and Quality
PSActionAlliance@AHRQ.hhs.gov
Re: Request for Information on Creating a National Healthcare System Action Alliance to Advance Patient Safety

My name is Lisa McGiffert - I am a long-time patient advocate and a co-founder of the Patient Safety Action Network, a national patient focused organization.[1] This RFI fails to present relevant questions regarding what HHS and related health agencies can do for harmed patients and to help prevent future harm to patients. Simply put, they are not patient focused. The questions all focus on what HHS and related agencies can do for health care providers and facilities, without resources. The focus of any efforts to end medical harm must be on the patients and include patients meaningfully in solutions.

Secrecy has not worked. There is no evidence that it has worked and the claim that it will work should not be perpetuated. Safety improvement has been directly related to public disclosure - whether it be a news story, federal or state agency investigations, or mandated public reporting. Public transparency works because we cannot know where improvement is needed if we do not identify where preventable harm and infections are occurring. The only way to be sure that everyone can see results of prevention efforts is to measure them and make the results public. For example, we have seen significant improvements in specific hospital acquired infections that hospitals are required to report - this is a direct result of informing the public about these infections and motivating hospitals to reduce them through accelerated prevention activities. When these reportable hospital-acquired infections increased during the COVID-19 pandemic, (delayed) public reporting revealed a significant problem that we would not otherwise have known about.

The term “transparency” has many different meanings and whenever it is used, it should be well-defined. For example, “public transparency” is different than transparency shared only among or with providers. And “transparency to inform patients and their families” is another form of transparency that is personally connected to a harm event - patient advocates strongly support this kind of transparency. It is important for health care providers to be transparent about preventable medical harm events that occur within their facilities and among their staff - that transparency supports learning. Federal agencies have the duty to be publicly transparent. As this Alliance moves forward, we encourage the use of specific adjectives to avoid misunderstanding of the word “transparency” so providers, agencies, the public, patient advocates and policymakers have a common understanding of the topic.

The RFI contains much language about collaboration with private health care providers and facilities, but nothing about collaborating with local Public Health Departments and their front-line staff who have specific duties related to preventing harm in health care facilities. When implementing hospital acquired infection reporting and during the COVID-19 pandemic, these were critical federal agency partners. They should be considered active participants of the work of the Alliance and funding for their work should become considered a component of the common harm prevention infrastructure.

In addition to connecting prevention efforts with public transparency and regulatory actions, when needed, HHS needs to include specific goals that the Alliance participants are expected to meet. The results should be regularly measured and publicly reported to lead to more meaningful outcomes. This was done in the past with the HHS Strategic Action Plan to reduce hospital acquired infections.

The following comments will focus on how federal health agencies can advance patient safety through *public* transparency and accountability to *patients.* Most recommendations can be implemented by using the legal and regulatory tools that are already in place.

Public Transparency: In short, HHS and related health agencies should make the "public information" you possess more publicly accessible in more real time. By the time most information about medical harm is published, it is too old to be useful to consumers/patients or policymakers. Also, many of the reports by federal agencies are vague, giving national or state statistics rather than provider-specific information, which is what the public wants to see and should see. Specific measures, like hospital acquired infection information on Care Compare, do not include data from which the measures/SIRs are calculated. For example, CDC/NHSN claims some data, including the denominator data, is "protected" under an extremely broad federal law written long ago. Any specific data collected by NHSN should be publicly available for download for any researchers to analyze, with patient identifying data protected - for example, denominators, age, gender, race/ethnicity (if available), outcome (death, disability). This would create a more robust analysis of harm, beyond what the federal government can fund and produce. A 2016 OIG report indicated even CMS didn't have access to this NHSN data[2] and it is unclear if they do now. Finally, a good rule of thumb is that the public should not have to file a FOIA request to obtain information that is public by law. Other recommendations on improving public transparency:

- Aggregate all information available about each specific provider online in a way that makes it easy for the average person to find, look up and understand. For example, Nursing Home Compare includes a listing of recent inspections and reports of federal actions/penalties assessed for each facility (e.g. https://www.medicare.gov/care-compare/details/nursing-home/675733?id=70e86565-38de-430c-93b8-c0f22b80896e&city=Austin&state=TX&zipcode=78704), which gives the public significant information in addition to the "star" and quality measure rankings. These are easily found through tabs at the top. This gives the viewer more details for making their own assessments regarding whether they want their loved one to reside there. This is the purpose of Care Compare site. Contrast that with Hospital Compare, which does not provide any important inspection/penalty information. CMS should publish any 2567s and other inspection/penalty information under each facility's name on the Hospital Compare site. The number of consumer complaints and category type (e.g., standard of care, hazards, billing, etc.) received by CMS be included in these reports. CMS should require patient complaints submitted to hospitals to be sent to CMS and included on these websites.
- Require accreditation reports for hospital and other facilities to be public. These reports indicate when facilities are complying with federal law, yet they are hidden behind a wall of secrecy. HHS/CMS should have complete access to these reports, and the facility specific reports should also be available on Care Compare for each facility.
- Make information in the National Practitioner Databank Public (NPDB) Public. While making the NPDB public would require a change in federal law, HHS is encouraged to support such a change. Still, without a law change, there are options for HHS to add quality/safety information on the Physician Compare site. Most of the information in the NPDB is public elsewhere, but when aggregated, it is made confidential. This is a common problem with federal health care information -- disaggregated data is public but there are restrictions to access when the information is pulled together. This prohibits a broader look at a health care provider or facility safety. Making the NPDB public would increase the tools that patients and their families have to

make more informed health care choices, however, Physician Compare could and should include details such as Medicare, DEA and fraud actions that are now buried in the NPDB.

- Improve Data Collection Systems: We need efforts to bring the collection of health care data, including patient safety related events, into the 21st century. Certainly, finding ways to reduce the burden of reporting on health care providers is key, but more important is to find ways to collect accurate data that cannot be gamed by them. As recommended by the OIG in 2016 (https://oig.hhs.gov/oei/reports/oei-01-15-00320.pdf), HHS should audit the accuracy of reports using "analysis-based criteria, such as aberrant data patterns or rapid changes in reporting." HHS should also identify methods that will help in collecting and publicly reporting real time or close to real time data. For example, using lab reports could bring in more current infection data, just as they did during the COVID-19 pandemic.
- Rely on multiple sources to collect information about patient harm: Create a publicly supported platform for harmed patients and others to report infections and harm events, similar to the FDA's adverse events reporting system for drugs and devices (MedWatch and MAUDE). FDA has had this function for years - it needs some improvement (more on that below) but provides a platform for harmed patients to report what they have experienced and health care workers to report what they see happening and barriers to safety that their facilities are keeping quiet. Additionally, merging billing data with reported data could help to identify harm events.
- EHR data that is not manipulated and accurately reflect patient experiences should be used nationwide to report measures but also to calculate hospital-wide infection and medical harm rates. Most measures are collected with very specific details that will help the providers identify what went wrong (e.g., MRSA infections by hospital unit). That is all well and good, but patients who do not know to which unit they will be admitted want to know the likelihood of getting an infection or suffering a harm event at their local hospitals.

Use the Authority already granted to HHS agencies to protect the public and patients from harm.
Many laws and regulations address prevention of medical harm - either requiring that certain standards are met, prohibiting some actions or establishing fines and other actions. However, too often these laws fail to be enforced effectively or not at all.

- Death Certificate Accuracy. Require information about errors and infections to be indicated as contributing factors on death certificates. This has been done by CDC for COVID-19, opioid related deaths and maternal deaths. Why not for medical harm - a leading cause of death in the US? Requiring such documentation would lead to more accurate records and officially put preventable patient harm on the list with other leading causes of death, which in turn would lead to more focus, more activity and funding for patient safety.
- Inappropriate use of anti-psychotics with residents of nursing homes. This problem has repeatedly been studied by Congress. In 1976, the Senate Committee on Aging issued a report, "Drugs in Nursing Homes: Misuse, High Costs, and Kickbacks" and held a workshop on reducing misuse of drugs and the need for staff to see residents' behaviors as communication, not problems. In 2012 testimony before Congress provided that "Federal Nursing Home Reform Law, since 1990, has limited the use of pharmacological drugs. Implementing regulations and CMS guidance to surveyors are very strong, but they are inadequately and ineffectively enforced." Also, Section 6121 of the Affordable Care Act mandated dementia care training for certified nurse aides working in nursing homes. In 2011 this program was called "hand in hand" and looks more like a friendly collaboration than a regulatory mandate.[3] Just recently, the administration/CMS spoke out against nursing home abuse of patients through inappropriate use of antipsychotics. The agency will begin audits, but explicitly no actions. The audits will be made public, which is good. This may be an appropriate action to a new problem, but not for one that been prevalent since at least the mid 1970s. Until federal regulators become serious

about using their authority to enforce the law, this kind of abuse will continue. Owners and administrators who repeatedly lead abusive facilities should be held responsible for unlawfully drugging elder residents; at the very least, they should never be able to lead a facility with which the federal government does business.

- Federal agencies should actively use the information in the National Practitioner Data Bank. While regulation of physicians is a state authority, CMS has access to the information held by the NPDB as an agency administering federal health care programs and as an agency responsible for certification of health care practitioners, providers and suppliers. The NPDB should be used as a resource to CMS to more actively identify and investigate health care providers who have caused significant harm to patients as well as prevent health care providers with records of medical harm from participating in Medicare or Medicaid. Hospitals and other organizations that are required by federal law to report to the NPDB should comply with that duty; when they do not, federal actions should be taken. There are well-known efforts to avoid reporting to NPDB and this should be monitored and prevented.
- Medical Device safety is not typically addressed in discussions organized by HHS, but FDA is not an island and the products regulated by the FDA are a major component of health care to tens of millions of people. These include joint implants, cardiac devices and countless other equipment used in the delivery of health care.
    - CMS appropriately uses its authority through national coverage determinations, Conditions of Participation or other means to ensure that products without sufficient evidence of safety and effectiveness are not covered by federal health care programs. Recently, CMS did the same, under great pressure from special interests, with regard to Aduhelm, an Alzheimer's Disease that failed to provide sufficient evidence of safety. CMS approved coverage for clinical research but not for national coverage. This is a good example of CMS appropriately using its authority to prevent patient harm.
    - HHS could help to enforce the FDA requirement for hospitals to report adverse device events to manufacturers that in turn are supposed to report publicly to FDA MAUDE system. The Medical Device Reporting regulation requires a facility or manufacturer to self-report an adverse event within 30 days,[4] or within 5 days if the "reportable event necessitates remedial action to prevent unreasonable risk of substantial harm to the public health."[5] When a facility contacts a device manufacturer to report a serious device-related concern, injury, or death, a manufacturer is mandated to file an adverse event report with the FDA.[136]
    - HHS could require FDA to provide more transparency of medical device adverse event information reported to MAUDE and provided to the public. Currently, for no valid reason, FDA redacts information relating to age, race/ethnicity when known, gender and the state in which the harm occurred. We presume this information was initially redacted years ago when the platform was launched as an effort to protect patient identities, but the current volume of reports is high enough to protect privacy. For example, information regarding race may have alerted the FDA and HHS earlier regarding the significant problems with the inaccuracies of pulse oximeters based on skin color, as well as inaccuracies with women and children for whom this device often reports flawed information due to size of their fingers. This specific demographic information is important to make public in light of efforts to identify disparities due to age, race/ethnicity and gender. The state specific information is also important for obvious reasons, including purchasing decisions, oversight and alerting health care personnel checking on the safety of devices and state-based regulators.

Patient-centered solutions to improve health care system response to medical harm. Rethink how harm events are treated right after they happen. The overarching culture within health care delivery

systems now is secrecy and it should be openness. This can be done collaboratively -- with patients engaged as equal partners in all aspects of care design, delivery, and operations -- to find solutions for preventing harm. Engaging harmed patients will improve safety, they have more to contribute beyond their stories.

- Better communication with patients/families about complaints. When complaints are being investigated, including the concluding actions, patients are often left in the dark. Those filing complaints with CMS may never find out what happened in the investigation or why CMS came to certain conclusions. The patients should be able to see those investigation details. If there are findings of violations related to specific complaints, the patient should receive a copy or a link to the 2567 report. If there is no action, patients should receive more than a brief letter indicating "the standard of care was met."
- Disclosure and apology. When medical errors and harm occur, health care providers should reveal what happened to patients and their families in actual real time. These disclosures should not be conditional, but honest discussions. These disclosure programs should be available to all harmed patients and there should be no strings attached to the patient/family in order to get this information. Patients/families should then be engaged in facility investigations and actions for change. A resource for what patient-oriented programs should include is here: https://www.patientsafetyaction.org/wp-content/uploads/2022/02/PSAN-Position-on-Disclosure-and-Apology-Policies.pdf
- HCAPS surveys should be revised to include specific questions asking patients about harm and infections that occurred during their hospital stay.

Health care acquired infection prevention. This is one area where there has been progress and subsequently, expansion of surveillance and documentation of health care acquire infections is warranted. CDC estimates that one in 31 patients contract infections while hospitalized. This is a critical safety area given the setbacks in prevention during COVID-19 pandemic peaks. These setbacks, well documented by CDC, have eliminated the many gains achieved over the last decade.

- Target facilities with significantly higher rates for improvement. Reportedly QIOs have targeted these poor performers in the past, but information about such work is not transparent to the public, so we have no idea whether the "help and support" actually made a difference. Further, as the QIOs work with these hospitals, regular reports should document progress. After that extra help from HHS is withdrawn, tell the public if those hospitals continue progress. These are all obvious methods to follow through and to move toward improving patient safety -- they can be applied for all measures and all types of facilities.
- Follow the VHA's lead. The VA system is a wholly integrated system focused on patients and not profits while the rest of our health care system that is totally driven by profits - this factor cannot be discounted but it should be *countered* with regulatory authority. At a time when precautions were heightened for PPE and very few surgical procedures were being done, we cannot completely pass off this increase in hospital acquired infections to COVID chaos. We must have a system that works at difficult times as well as easy times. The VHA did not have a rise in MRSA infections during this same time period and a recent study on the VHA's record states, "The difference may be explained not only by the VHA's use of uniform mitigating policies which rely on active surveillance and contact precautions, but also on the VAH's ability to maintain adequate staffing during the pandemic. Future research into MRSA mitigation is warranted and this data supports the need for healthcare system transformation."[7] At the least, HHS/CDC needs to evaluate how this rise in infections happened and tell the public about it.
    - Nursing home acquired infections need to be reported. It is commendable that many facilities signed up voluntarily to report COVID-19 infections. Now that needs to be

expanded and made public. Each day, an estimated one in 43 nursing home residents contracts an infection in association with their stay.8 This strongly underscoring the need for improvement in resident care practices in nursing homes. That should include facility reporting (preferably via electronic records) and public transparency of facility-specific rates of infection.

- Infection Outbreak Response. The Council for Outbreak Response Healthcare Associated Infections and Antimicrobial-resistant Pathogens (CORHA), a collaborative effort of Public Health professionals across the US funded by CDC, developed a framework on infection outbreak response and disclosure. The framework, which can be found at https://www.corha.org/resources/corha-framework-for-healthcare-associated-infection-outbreak-notification/ guides health care facilities and staff through what should happen when an infection outbreak is discovered, including who should be notified (affected patients should be notified first), when and how. Patients are identified as epidemiologic informers. This is an essential guide for health care facilities and State Public Health Departments. It should be implemented nationwide.
- Point prevalence studies should be conducted every year as an overall indicator of progress in eliminating hospital acquired infections, as well as infections contracted in other facilities.

Worker Safety: Workforce safety is a very important issue and it should be addressed, especially where it directly impacts the safety of patients. The most dominant worker safety issue that directly affects patient safety is nurse to patient ratios, yet it rarely comes up in national meetings and conversations about medical harm. An AHRQ 2022 survey of 400 hospitals on Patient Safety Culture[9] found that 51% of respondents said YES/ 49% said NO to this statement: "There are enough staff to handle the workload, staff work appropriate hours and do not feel rushed, and there is appropriate reliance on temporary, float or PRN staff." Measuring this is not a burden, no standard has to be set, HHS just needs to report it publicly and show the public how different health care systems handle this issue. The survey also showed a decline in recent years in staffing and hospital management support for patient safety activities.

- Health care facilities should be held responsible for having a workforce that is well trained to do their jobs and that adequately covers the services the facilities claim they are providing. However, a safe workforce does not guarantee safety for patients. The problems and solutions are very different, and they should be taken up together only when they directly relate to patient harm, such as nurse/patient or staff/patient ratios. This is a parallel problem. Every hospital representative at the November 2022 HHS meeting regarding the Alliance implied that HHS needed to help them with staffing. It is not HHS's responsibility to staff private hospitals and other health care facilities. It is each facility's responsibility.

In conclusion, HHS needs to seriously address the too common problem of preventable medical harm in the very near future to prevent more injuries and deaths. Federal health care agencies must work together, and not in silos, to specifically measure whether provider and facility activities actually lead to less patient harm. Agencies must respond quickly when they know harm has occurred and should reveal the results of investigations on publicly accessible websites. Patient harm and health care acquired infections reported to federal agencies should be available on publicly accessible websites in more real time to inform the public. Finally, health related agencies must use the authority they have as regulators to fulfill their duty to protect the public.

[1] The Patient Safety Action Network (PSAN) is a national coalition working to end medical harm through public transparency and accountability. We are patient led and patient driven. We are people who have been harmed by medical care. We are rooted in the experience of trying to get health care facilities and providers to be accountable for their actions, and to be willing to correct those actions for a safer future.

[2] https://oig.hhs.gov/oei/reports/oei-01-15-00320.pdf, page 13, retrieved 1/23/23.

[3] https://www.govinfo.gov/content/pkg/CHRG-112shrg72764/html/CHRG-112shrg72764.htm

[4] Mandatory reporting requirements: manufacturers, importers and device user facilities. US Food and Drug Administration. Updated May 22, 2020. Retrieved June 2, 2021. https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities

[5] Mandatory reporting requirements: manufacturers, importers and device user facilities. US Food and Drug Administration. Updated May 22, 2020. Retrieved June 2, 2021. https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities

[6] Medical device reporting (MDR): how to report medical device problems. US Food and Drug Administration. Retrieved February 25, 2021. https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems

[7] https://aricjournal.biomedcentral.com/articles/10.1186/s13756-022-01158-z, retrieved 1/23/23.

[8] https://www.cdc.gov/hai/eip/antibiotic-use.html, retrieved 1/23/23.

[9] https://www.ahrq.gov/sites/default/files/wysiwyg/sops/surveys/hospital/2022-hsops2-database-report.pdf, retrieved 1/23/23.