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**Assessing Medical Systems for the CA Prison Health Care Receivership:
CCHCS PATIENT SAFETY PROGRAM**
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I.   BACKGROUND
Ia.   This report
In December 2017, the California Prison Health Care Receivership Corporation (CPR) engaged Dr. Brie Williams and her Criminal Justice & Health Program at UCSF to conduct an independent assessment of specified California Correctional Health Care Services (CCHCS) medical systems with the goals of:

- Assessing whether those CCHCS systems conform to community standard policy and practice in federal and/or California state ("community") integrated healthcare systems
- Developing recommendations to optimize those CCHCS systems in view of our findings

The current project calls for an assessment of four systems:
1) CCHCS Mortality Review Policy and Practice
2) CCHCS Systems for Maintaining a Qualified Workforce (including peer review systems)
3) CCHCS Patient Safety Program
4) The Medical Inspection Program of the Office of the Inspector General (OIG)

Our approach is to establish community standards for each project based on reviews of multiple community integrated healthcare systems and to issue evidence-based policy and practice recommendations consistent with CCHCS's specific needs and constraints. Our overarching goal is to aid CCHCS's ongoing advancement towards what we have termed a "**healthy healthcare system**," which we define as one that is self-examining, highly responsive to evolving community standards, and rooted in a systems-driven culture of patient safety, quality improvement, and ongoing learning. This definition is derived from the Institute of Medicine's seminal report on healthcare quality, *Crossing the Quality Chasm*,[1] which defines *quality* as "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" and identifies six components of quality: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.

This report describes our analysis of item #3 above, the CCHCS Patient Safety Program, and sets forth recommendations to optimize this program. These recommendations are based on the following activities:

- Review of the relevant literature on patient safety and related systems
- Analysis of patient safety and related systems at community integrated healthcare systems including UC San Francisco (UCSF), Mayo Clinic, and the Veterans Health Administration (VA)
- Key informant interviews with policymakers and clinical leaders at the community systems listed above
- Review of patient safety guidelines from organizations such as the Joint Commission, California Department of Public Health, and the National Commission on Correctional Health Care
- Review of relevant CCHCS policies, procedures, and definitions

- Stakeholder interviews with CCHCS leadership at the state, regional, and institution levels, as well as interviews with clinical staff and independent experts
- Independent review of relevant elements in the Health Care Services Dashboard, Health Care Incident Review Dashboard, and a sample of randomly selected incident reports and root cause analyses
- Independent review of documents from the statewide Quality Management Committee, the statewide Patient Safety Committee, and select institution Patient Safety Subcommittees
- Feedback to our presentation of preliminary results to Judge Tigar and the Receiver, Mr. Clark Kelso, including from Director of Health Care Operations Dr. Steven Tharratt and CCHCS's Quality Management and Patient Safety teams

Ib.   The modern patient safety movement

Patient safety is broadly defined as freedom from accidental or preventable injuries produced by medical care. Historically, patient safety received little attention from the medical community, patient groups, or governmental agencies until the release of *To Err Is Human: Building a Safer Health System*, authored by the National Academy of Medicine (formerly the Institute of Medicine) in 2000[2]. *To Err is Human* reported that between 44,000 and 98,000 patients died in hospitals in the United States each year as a result of medical errors. The report is considered the foundational document of the modern patient safety movement as it spurred a number of initiatives with national reach, including new requirements from healthcare accreditation bodies, legislative action, updated conditions for healthcare systems to participate in public and private insurance plans, increased funding for health systems research, and advocacy by community patient safety organizations.

One of the key findings in *To Err Is Human* is that **deficiencies in health systems are— more often than individual practitioners— the root cause of adverse events**. As a result, according to the Agency for Healthcare Research and Quality (AHRQ), patient safety efforts should take a **systems approach** to improving care (Box 1)[3].

In 2005, Congress passed the Patient Safety and Quality Improvement Act, which created a voluntary patient safety reporting system to encourage health systems to collect their own patient safety data and work to improve the quality and safety of healthcare delivery. The act also provides protections to ensure that patient safety work is confidential and privileged and protects employees from retaliation if reporting adverse events and/or when working on patient safety activities[4].

> **Box 1. AHRQ Systems Approach**
> "Most medical errors reflect predictable human failings in the context of poorly designed systems. Rather than focusing corrective efforts on punishment or remediation, the systems approach seeks to identify situations or factors likely to give rise to human error, and change the underlying systems of care in order to reduce the occurrence of errors or minimize their impact on patients."

In the 20 years since *To Err Is* Human, the patient safety movement has generated enormous improvements in community healthcare systems. Despite these efforts,

however, patients still experience harm at high rates. Recent studies of hospitalized patients have reported that between one in eight and one in three patients experience an adverse event while hospitalized[5,6]. Of errors in the care for hospitalized patients, about half are thought to be preventable[5,7]. Errors also contribute to increased costs – an estimated $17.1 billion dollars are spent each year in the United States as a consequence of preventable adverse events[8]. Finally, while most patient safety efforts have focused on the hospital setting, ambulatory data suggest that adverse events are also common in outpatient settings. A 2007 study estimated that 75,000 hospitalizations in the United States are the result of preventable adverse events in the ambulatory (outpatient) setting[9]. Despite these concerns, best practices have not been well-defined in this environment.

Ic. Key definitions[10,11]

As defined above, patient safety is freedom from accidental or preventable injuries produced by medical care. At inpatient and residential medical facilities (such as skilled nursing facilities), individuals are considered to be receiving medical care (and are thus "patients") at all times; therefore, all aspects of their care (*e.g.*, environment, nutrition, personal safety) fall under the umbrella of patient safety. In the correctional setting— where medical care is often considered separate from housing, nutrition, and personal safety—there can be uncertainty over when the experiences of an incarcerated person should be considered under the scope of patient safety. **We favor a broad definition that defines housing infrastructure and policy, nutrition, and general prison conditions as part of medical care for incarcerated individuals and thus within the scope of patient safety.** Some matters within this broad scope are outside the direct control of CCHCS, including freedom from interpersonal violence and general prison conditions. However, we argue that it is important that patient safety paradigms strive to be able to detect and respond to threats to patient safety arising from such factors. This is consistent with the community standard. For example, a food borne illness arising from unsanitary conditions in a hospital cafeteria would typically merit a patient safety response in those settings. (Importantly, due to the unique legal context surrounding CCHCS and the federal Receivership, we exclude mental health from this discussion. However, the community standard approach to patient safety would include issues arising from mental health care, including policies and practices aimed at preventing self-harm, and an optimal CCHCS patient safety program would ultimately encompass mental health care.)

Overall, when applying the community standard of patient safety to the correctional setting, there is an inherent tension between the type of care that is most commonly provided in incarcerated settings—which is most analogous to outpatient care in the community—and the fact that incarcerated patients are institutionalized and face many of the constraints and safety risks associated with inpatients in the community. While many incarcerated patients receive "outpatient" care, and a minority of incarcerated patients receives care in "inpatient" medical units, it is our opinion that in the case of patient safety, it is most appropriate to apply the community standard for both inpatient and outpatient populations. As this report will describe, CCHCS has already developed a framework for patient safety that is concordant with this opinion.

Definitions of key terms used in this report are provided below. A more comprehensive list is included in Appendix A.

Healthcare incident: An unusual or unexpected occurrence in the clinical management of a patient. A healthcare incident does not necessarily result in adverse health consequences.

Adverse event: Any healthcare incident that results in an injury that arises as a result of medical care rather than from an underlying disease process

- Preventable adverse events: adverse events that occur due to error or failure to apply an accepted strategy for prevention (*e.g.,* anaphylaxis after giving the patient a drug he or she is known to be allergic to)
- Non-preventable adverse events: adverse events that cannot be attributed to an error or failure to apply an accepted strategy (*e.g.,* anaphylaxis after giving the patient a drug to which he or she had no known allergy)
  - Medical Error: any act of commission (doing something wrong) or omission (failing to take the correct course of action) that exposes patients to a potentially hazardous situation *or* results in an adverse event
  - Near miss: an event or situation that did not produce a patient injury but only because of chance
  - Sentinel event (note: CCHCS terminology is an "adverse/sentinel event"): an unexpected occurrence resulting in death or serious physical injury, or the risk thereof (does not need to occur as the result of an error but is unexpected)
  - Medication event: a healthcare incident that occurs as a result of a medication; may be related to (but is not limited to) medication prescribing, verification, dispensing, administration, and documentation[12]

Root cause analysis (RCA): a structured method to analyze serious adverse events or near misses. RCAs aim to identify the underlying factors that increase the likelihood of medical errors.

Id. Examples of types of medical errors

Medical errors can occur in any healthcare setting and can be classified in myriad ways. Table 1 describes common types of medical errors and lists examples of each[13]. Systems problems typically underlie many of these common errors, which could be mitigated by improving interactions between healthcare providers and the mechanisms (*e.g.,* EMR, medical devices, environment of care) through which care is delivered to patients.

Table 1. Types of medical errors

Classification	Examples
Medication errors	Wrong medication, wrong dose
Surgical errors	Wrong site or wrong patient surgery, retained instruments
Diagnostic errors	Wrong diagnosis, delay in diagnosis, overdiagnosis
Transition and handoff errors	Critical patient information not communicated when a patient moves from one care setting to another
Teamwork and communication errors	Rigidly hierarchical decision-making on medical teams leading to failure to discuss a potentially unsafe condition
Healthcare-associated infections (HAIs)	Central line-associated bloodstream infections, catheter-associated urinary tract infections, *Clostridium difficile* diarrhea

Other complications of healthcare	Pressure ulcers, falls, healthcare-associated venous thromboembolism
Outpatient errors	Failure of timely follow up on diagnostic tests, poor communication to patient regarding self-management of medical care

Ie.   Key objectives of patient safety programs in the community and at CCHCS

Community PSP Objectives

Each of the health systems evaluated for this report—UCSF, Mayo Clinic, and the VA—has made extensive changes to their patient safety program (PSP) over the last 20 years and each considers its program a work in progress as new data and best practices continue to emerge. While there are differences in the structure and functioning of each program, all PSPs evaluated here (and PSPs in general) aim to meet six key objectives (Box 2). Taken together, these key objectives constitute the community standard approach to patient safety. **Given the heterogeneity in health systems and patient populations, performance on these key objectives—and not direct comparisons of the number and nature of adverse events—should be used to evaluate any patient safety program.**

Box 2. Key Community PSP Objectives
1. Collect comprehensive internal data on errors and "near misses"
2. Use internal data and evidence-based best practices to respond to errors and design safer health systems
3. Proactively identify and address threats to patient safety
4. Continuously evaluate and improve PSP performance (*e.g.*, via internal research or external evaluation)
5. Meet regulatory requirements for patient safety and error reporting
6. Create and maintain a workforce culture that prioritizes patient safety above all else

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CCHCS PSP Objectives

CCHCS's key PSP objectives—and some of the methods necessary to achieve these objectives—are summarized in Box 3 (adapted from CCHCS policy 3.7.1 Patient Safety Program Policy)[11].

Box 3. Key CCHCS PSP Objectives
1. Routine surveillance of patient safety within the healthcare system
2. Assistance to staff to support problem analysis and redesign care delivery to support patient safety
3. Regular communication of patient safety information to statewide leadership and institutions, including a biennial Patient Safety Plan to determine priority areas for intervention and performance objectives
4. Rapid assessment and resolution of patient safety issues that present immediate danger to patients and staff
5. A referral process for incidents that involve blameworthy acts/reckless behaviors
6. Fostering a climate that supports patient safety and encourages the reporting of all healthcare incidents

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Assessment of PSP Objectives in the Community and at CCHCS
While there are differences in the health care missions of the community health systems studied in this report and CCHCS (the community programs provide outpatient care and high-volume inpatient care, while CCCHS provides some inpatient care and high-volume outpatient care), the key objectives of the CCHCS PSP (Box 3) are in line with community standard mandates for community PSPs and show high concordance with the key objectives of robust community PSPs designed for both inpatient and outpatient populations (Box 2). How the CCHCS PSP attempts to meet these key objectives demonstrates many ways in which CCHCS is in concordance with the community standard as well as a number of opportunities to bring CCHCS into greater alignment with community programs.

This report will subsequently detail how the CCHCS PSP does and does not conform to the community standard by assessing the following PSP features in both the community and CCHCS: 1) program organization, 2) data acquisition, 3) data analysis and health system strengthening, 4) creating and sustaining a culture of patient safety, and 5) relationship with governmental and non-governmental organizations that perform regulatory and oversight functions regarding patient safety. Following each section, we will identify opportunities to optimize the CCHCS PSP.

II. PROGRAM ORGANIZATION
IIa. Community standard

In some community healthcare systems, the PSP is housed within the organization's quality improvement division and in others it is a distinct entity. All community health systems evaluated, however, situate their PSPs high up in the organizational chart (making patient safety a senior leadership position), while also maintaining close lines of communication down to individual units of patient care where unit leaders have expertise in patient safety (Box 4).

Organization of the VA PSP contains all of the critical features described above and is of particular interest as it involves a large network of heterogeneous health facilities, analogous to CCHCS. The VA comprises 21 regional headquarters and 170 individual medical centers. Its PSP includes staffing at the national, regional, and medical center levels.

> **Box 4. Critical Features of PSP Organization**
> 1. Patient safety is a senior leadership position
> 2. Expertise decentralized down to patient care units
> 3. Multidisciplinary representation
> 4. Clear communication with other internal groups doing related work (*e.g.,* quality improvement, peer review, mortality review)

At the national level, the National Center for Patient Safety is under the direction of the VA Office of Quality, Safety, and Value. The National Center for Patient Safety develops and disseminates policies and best practice protocols in collaboration with regional and local institutions. At the regional level, managers provide oversight and expertise to the medical centers, assist in the

implementation of directives from the national leadership, and communicate issues and challenges from the medical centers back to national leadership. **At the medical center level, there is at least one patient safety manager charged with overseeing all activities of the local PSP including review of incident reporting data**[14]. Patient safety managers at the medical center have jurisdiction over the hospital, the emergency department, any skilled nursing facility, and all outpatient clinics affiliated with the medical center. This is a full-time position and one or two managers usually work at each medical center, depending on the size.

Concerning the critical features of PSP organization (Box 4), the VA PSP is structured so that the patient safety manager(s) at each medical center reports to the medical center Chief of Staff and the regional PSP, who in turn report up to the patient safety senior leadership team at the national level. Patient safety knowledge is decentralized down to each medical center using multiple tools: 1) the patient safety team periodically trains patient care unit leaders on how to identify, respond to, and report threats to patient safety, and 2) patient care unit leaders regularly round with the patient safety manager. Multidisciplinary representation is achieved by reserving committee membership positions for pharmacy, risk management, infection control, nursing, and primary and subspecialty clinical care. PSP managers at each medical center communicate with groups doing related work by participating on a number of committees, including (at the VA): Mental Health Committee, Environment of Care Committee, Falls Committee, Blood Transfusion Committee, Workplace Violence Prevention Committee, Clinical Products Committee, Mental Health Residential Rehabilitation Treatment Program Committee, Surgical Workgroup, and Facility Medication Committee.

Across all community organizations, this cross-talk between the PSP and related groups is critical and bears further mention. **How cross talk occurs (*e.g.*, via representation on the patient safety committee or through meetings between leadership of different committees) is less important than the fact that it occurs regularly *and* on an ad hoc basis as needed.** An example of key lines of communication for any robust patient safety program—as determined by our assessment of the community standard and a particularly relevant article describing the creation of the PSP at Harvard's Brigham and Women's Hospital[15]—is detailed in Figure 1.

The PSP must have clear lines of communication to senior leadership

Figure 1. Cross Talk Between the Medical Center PSP and Related Groups

(such as the CEO and CME) but also down to clinicians and leaders on individual care units. This is often accomplished by strategies at the level of the medical center – for example, regular patient safety-themed rounding with patient safety leadership on a rotating schedule of patient care units (sometimes called executive walk rounds) or intensive executive involvement with patient care units on a serial schedule[16]. UCSF uses a monthly Zero Harm Huddle of senior leadership across the entire UCSF health system to evaluate trends in harm-related events (*e.g.*, falls, medication errors, sentinel events, etc.) and brainstorm solutions. The Zero Harm Huddle involves the medical center's heads of pharmacy, infection control, nursing, quality, clinical affairs, and patient safety. Regardless of the specific approach, the purpose of these strategies is for leadership to hear about challenges to patient safety on each unit, share best practices, and—ideally—assist in leveraging funding and resources to address the highest priority problems.

Finally, the **qualifications of the PSP manager** (regionally and at each medical center) are not uniform in the community. There is substantial heterogeneity in the community – in some large integrated systems, the program is led by a physician (UCSF) while in others, it is led by a nurse or a non-physician clinician (most VA medical centers). It should be noted that given the nascency of the patient safety movement, many community programs are not able to recruit leaders with extensive experience in patient safety. Courses are available in the community to train individuals to become institutional leaders in patient safety such as the Institute for Healthcare Improvement's Patient Safety Executive Development Program[17] and the National Patient Safety Foundation's Certified Professional in Patient Safety program[18]. In selecting patient safety managers, community integrated systems in general presently emphasize patient safety training and experience over practice level or other traditional measures of seniority.

IIb. CCHCS

The CCHCS PSP was created in 2012 and is organized under the Quality Management (QM) Program[19]. The QM Program is comprised of a statewide Quality Management Committee (QMC) with oversight over institution QMCs. Regional healthcare executives also play a key role advising institution QMCs, but the roles they play in patient safety are determined on an ad hoc basis and differ from region to region. The statewide QMC is co-chaired by the statewide Chief Quality Officer and another executive leader chosen by QMC members. Voting QMC members include statewide leadership from multiple inter-professional health programs. The statewide QMC is tasked with the following (adapted from CCHCS policy 3.1.1 Quality Management Program Overview)[20,21]:

1) Supporting identification of performance improvement initiatives
2) Providing tools to analyze and redesign healthcare processes
3) Assisting institutions in improving their own healthcare delivery
4) Maintaining a performance evaluation program, including a Health Care Services Dashboard
5) Providing patient registries to disseminate evidence-based best practices
6) Promoting a culture of continuous learning and innovation

The statewide QMC oversees the PSP which is chaired by one of its members and coordinates with institution QMCs and PSPs (Figure 2)[22]. Institution QMCs are tasked with meeting at least monthly and should report back to the statewide QMC at least annually. Some institution QMCs also report to the Local Governing Body in order to meet regulatory requirements. The institution CEO is the chair of the institution QMC. Members of the institution QMC include the Chief Quality Officer, chiefs of individual inter-professional services (medical, dental, mental health, nursing, pharmacy), and chairpersons of subcommittees (including Patient Safety), among others. **While all CCHCS institutions are performing some patient safety work, at the time of this report, not all CCHCS institutions had independently operating patient safety subcommittees and some had only recently created their subcommittees** (the remainder are conducting patient safety work on an ad hoc basis as part of the QMC).

Figure 2. CCHCS Organizational Chart
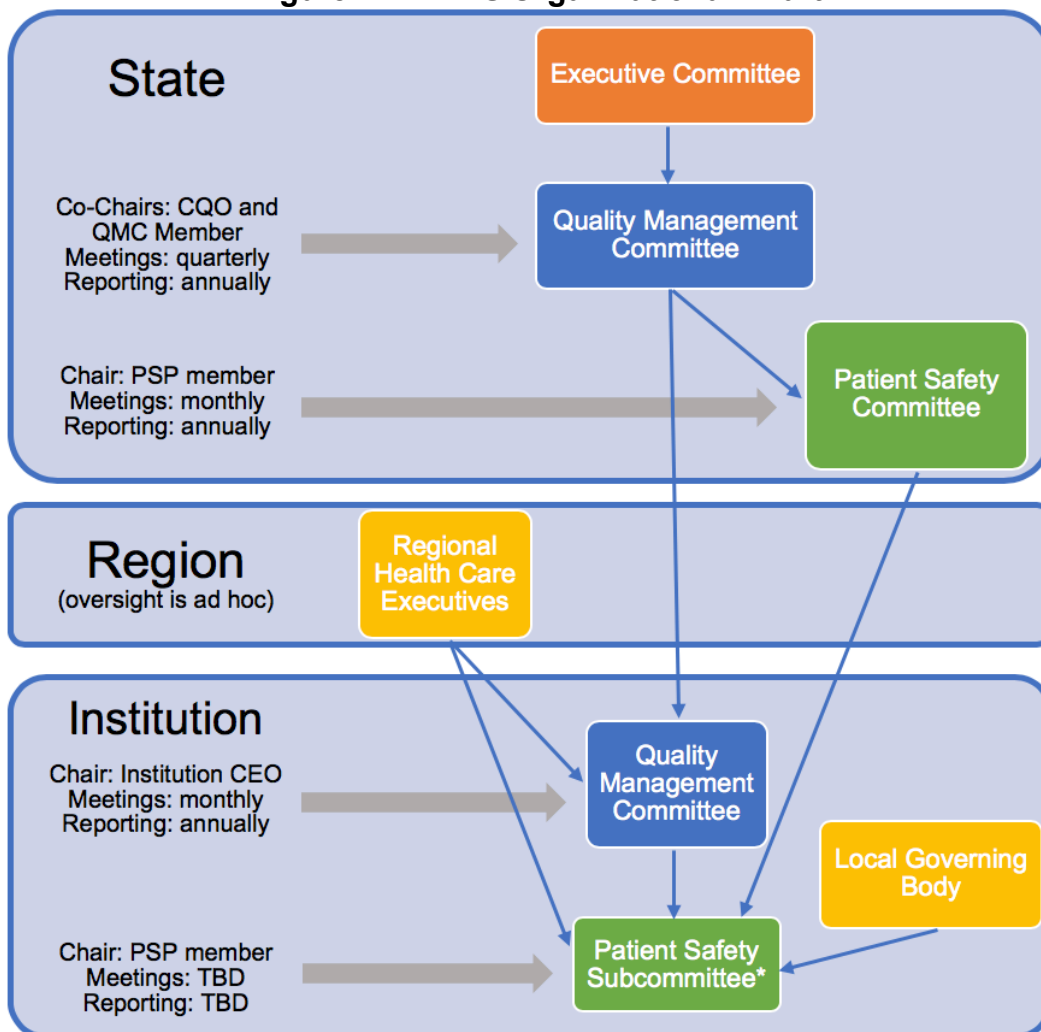
*Not all institutions have independent Patient Safety Subcommittees

CCHCS policy describes patient safety as the responsibility of all departmental leadership units at the statewide level, Health Care Executives at the regional level, and Chief Executive Officers at the institutional level[11]. Overall patient safety is the responsibility of

the statewide Patient Safety Committee, which the Chief Quality Officer or his or her designee chairs (this position has been filled by a single designee since its inception). Committee members include designees from each healthcare discipline (medical, nursing, pharmacy, mental health, and dental), Legal, Health Care Policy, and Administration. At least one member of the Regional Health Care Executive Team also serves on the committee on a rotating basis for at least 12 months. The Patient Safety Committee is expected to meet at least quarterly[23].

IIc. Discussion and Recommendations: Program Organization

When evaluating the organization of the CCHCS PSP in relation to the key features of community PSP organization (Box 4), certain elements of the program have high concordance with the community standard. These include:

Reporting to senior leadership

The statewide Patient Safety Committee is overseen by individuals with training and experience in quality management and patient safety. **It is appropriately positioned high in the CCHCS organizational chart and reports to senior leadership.** At the level of the institution, patient safety subcommittees (where they exist) also report high in the organizational structure to the institutional QMC and the statewide Patient Safety Committee. Regional healthcare executives are also appropriately positioned to provide additional guidance to the institutions; however, in conversation with regional leaders, **it appears their role is not well-defined, and they do not have the staffing for significant additional investments in patient safety monitoring and oversight.**

Multidisciplinary representation

The CCHCS statewide Quality Management Committee and Patient Safety Committee have multidisciplinary representation. As more institution subcommittees are created, it will be important to ensure that they also have multidisciplinary representation (medical, dental, mental health, pharmacy, nursing, administration, etc.).

In addition to these strengths in PSP organization, we identified several opportunities for improvement, particularly in the areas of decentralizing expertise down to the institution level and operationalizing cross-talk between PSP staff and other relevant committees and stakeholders. These opportunities are further described in the following recommendations.

Recommendation 1. Create Patient Safety Subcommittees at every institution with two co-chair positions, including one Director of Patient Safety (a full-time position at most institutions, likely filled by a non-physician) and one Medical Director of Patient Safety (a part-time commitment to be filled by a clinician who has protected time for patient safety activities).

Not all institutions have a dedicated Patient Safety Subcommittee. (Last year the statewide Patient Safety Committee estimated that only one third of institutions had an independent Patient Safety Subcommittee but now most are thought to have one. One institution our team visited had a Subcommittee but clinicians we spoke with were not

aware of its activities.) Allowing that the size and scope of patient safety subcommittees may vary across institutions according to patient population profile, **creating Patient Safety Subcommittees at every institution—and standardizing their operation—will be critical to the success of the CCHCS PSP overall.**

Much of the organizational patient safety expertise within CCHCS currently resides at the statewide level as demonstrated by the lack of independent Patient Safety Subcommittees at some institutions and the relative newness of subcommittees at other institutions. **Interviews with key stakeholders revealed that most patient safety work at the institution is done by people donating their time.** Even the chairs of the Patient Safety Subcommittee have primary job descriptions outside the realm of patient safety, which detracts from the time and focus available for patient safety work. In order for the institutions' Patient Safety Subcommittees to be sources of expertise—proactive in identifying problems, and agile in their response to threats—**the leads of the subcommittees should have protected time to do this job. Ideally the subcommittee would be co-chaired by an institution's Director of Patient Safety (a health professional with clinical and/or patient safety experience) whose primary job is dedicated to patient safety, and a Medical Director of Patient Safety (a clinician who has protected time for patient safety work, such as a pre-specified reduction in the number of required clinic sessions).**

> "Patient safety chairs at institutions don't have protected time to do this work, but it's in their job descriptions to do it. It's outside the scope of their everyday duties."
> —CCHCS stakeholder

We recognize that creating a full-time position for a Director of Patient Safety and a part-time position for a Medical Director of Patient Safety (and training these individuals) represents a significant financial investment but we strongly recommend this approach to facilitate the diffusion of patient safety expertise down to the level of the institution. Staffing patient safety in this fashion will ultimately increase the detection of patient safety priorities and better position quality improvement initiatives to yield their desired outcomes by enabling institutions to identify their own patient safety problems and develop solutions based on their unique knowledge of local practice patterns, patient characteristics, environment, and mission. This staffing will further bring CCHCS's organizational structure into alignment with the community, such as the VA system described in the previous section. We further recognize that the workload of a Director of Patient Safety at some institutions—based on patient population and mission—will be much greater than at others and therefore, the PSP should be granted some flexibility in how staffing is ultimately determined. **For example, it may make sense to have increased staffing (such as two directors) at some high-volume, high-risk facilities (such as CHCF and CMF) and a part-time or shared role at low-volume facilities providing basic care.** The Regional Health Care Executive team could also provide oversight of a cluster of low-volume facilities but in this instance, we would still favor having someone from the institution assume primary responsibility for patient safety, even on a part-time basis. This may be of particular use at institutions that generate a relatively low number of root cause

analyses and whose patient safety staff would thus benefit from the support and oversight of a regional expert in RCAs. Ultimately, what we believe is most important, is that each institution has at least one Director of Patient Safety and one Medical Director of Patient Safety, each with adequate protected time to fulfill the duties of this job (**these roles are summarized in sections VIIb and VIIc of this report**) with appropriate training and oversight from regional or statewide experts. Providing time-protected patient safety staffing at each institution will also demonstrate the importance of patient safety work and aid in the transformation of institutional culture to support patient safety. We also recommend considering appointing line staff to at least one of the two co-chair positions as this may bring fresh perspectives to patient safety work, increase line staff job satisfaction, and help break down rigid medical hierarchies that can be detrimental to patient safety work.

Recommendation 2. *Train supervisors on individual patient care units in the importance of patient safety, how to identify threats to patient safety, and how to interface with their Patient Safety Subcommittee.*

Decentralizing patient safety expertise beyond the patient safety subcommittee to the level of individual care units is also critical. CCHCS has begun an ambitious program to broadly train its staff in Lean Six Sigma principles which will greatly aid in the vital diffusion of expertise in process improvement (and fostering a culture that values quality), but additional training and sensitization of clinical unit supervisors to become patient safety champions will be necessary (and timely as more institutions have created their own Patient Safety Subcommittees). **Developing a workforce where supervisors understand that patient safety is their number one priority, are facile in the identification of patient safety problems, and are knowledgeable in how to interface with their institution's PSP will be a great challenge for CCHCS, but its importance should not be understated.** A visible resource in the form of an institutional Director of Patient Safety will be vital, as will more frequent in-person contact between the statewide patient safety leaders and institution staff (such as through attendance at patient safety subcommittee meetings, supervision of root cause analyses, and facility visits to hear from front-line staff). These measures will also improve the statewide PSP's ability to identify and prioritize problems.

Recommendation 3. *Operationalize cross-talk between the PSP and relevant committees and stakeholders (both health and corrections) at state, regional, and institution levels.*

Multiple CCHCS stakeholder interviews revealed that patient safety work is happening in many ways that are independent of the PSP (for example, efforts by the mental health team to reduce suicide and self-harm among patients). **Efforts to improve patient safety arising organically from care teams outside of the PSP should be encouraged and are a clear sign of a healthy healthcare system. Much of this work, however, is occurring in siloes** and there are multiple opportunities for the statewide PSP to facilitate cross-talk between related groups, particularly in its efforts to identify patient safety problems and more broadly disseminate solutions and best practices**.**

At the institution level, Figure 1 represents common avenues of cross-talk between PSPs and related groups in community-based integrated healthcare systems. **The CCHCS PSP should standardize operations so that there are mechanisms for regular communication between its representatives and the relevant groups in Figure 1 at the level of the institution and—where appropriate—the state and regional level.** In the correctional health setting, it will be necessary to add to this list as well. While it falls outside of the "community standard" framework, enabling cross-talk with correctional leadership at institutions (*e.g.*, via the existing job of Associate Warden of Health Care Access, the existing Health and Safety Program responsible for environmental safety, and other relevant corrections committees) is also vital. Corrections staff, policy, and practice are critical components in a number of areas where patient safety is relevant, including, for example, transitions of care between the institution and a community provider, medication management (via pill call or for self-managed medications), urgent care response, assigning housing and/or yard restrictions, and housing assignments in general. **At some institutions the Associate Warden of Health Care Access serves on the Patient Safety Subcommittee to facilitate communication with corrections and we recommend this approach be strongly considered at each institution.**

> "A lot of our facility leads for patient safety are nurses and pharmacists, but what they're doing is not necessarily connected to what the mental health team is doing or what the quality improvement team in Elk Grove is doing."
>
> —CCHCS stakeholder

Summary of Recommendations: Program Organization
1. Create Patient Safety Subcommittees at every institution with two co-chair positions, including one Director of Patient Safety (a full-time position at most institutions, likely filled by a non-physician) and one Medical Director of Patient Safety (a part-time commitment to be filled by a clinician who has protected time for patient safety activities)
2. Train supervisors on individual patient care units in the importance of patient safety, how to identify threats to patient safety, and how to interface with their Patient Safety Subcommittee
3. Operationalize cross-talk between the PSP and relevant committees and stakeholders (both health and corrections) at state, regional, and institution levels

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III. DATA ACQUISITION
IIIa. Community standard
High-quality data are the lifeblood of a patient safety program and are necessary to set patient safety priorities, design interventions to improve safety, and assess the efficacy of these interventions (Figure 3). High-quality data can also be used to follow patient safety trends over time by tracking key safety metrics.

Obtaining high quality data and detecting adverse events and near misses is challenging. Health systems must have data acquisition systems in place to detect medical errors and must strive to establish a culture of patient safety where healthcare providers are empowered to both report problems and find solutions. Table 2 describes patient safety measurement strategies and advantages and disadvantages of each. **The community PSPs that we evaluated rely most heavily on data from incident reporting systems (IRS's) and administrative/claims data.** Ultimately, healthcare systems need to collect patient safety data using multiple strategies to ensure robust case detection and to identify priority targets for improvement.
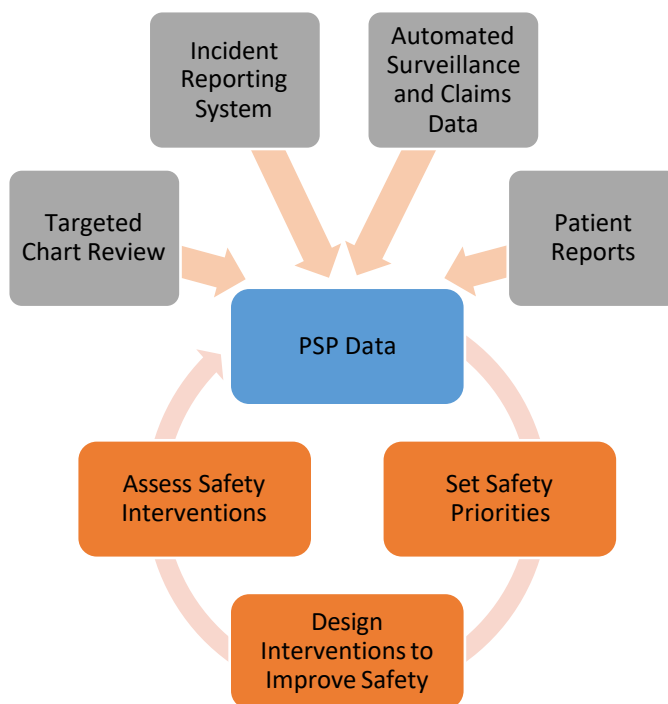
Figure 3. Patient Safety Data Cycle

Table 2. **Patient safety measurement strategies** (adapted from Wachter, R. & Gupta, K. *Understanding Patient Safety, Third Edition*[13])

Measurement Strategies	Advantages	Disadvantages
Incident Reporting Systems	Useful for internal quality improvement and case-finding, highlights adverse events that providers perceive as important	Capture a non-representative fraction of adverse events (in hospitals, most reports are submitted by nurses; relatively few by doctors), retrospective review only based on provider self-reports; providers may elect not to report errors
Retrospective Chart Review (by itself or after use of a trigger tool)	Considered the "gold standard" if large sample size obtained, contains rich and detailed clinical information	Costly, labor-intensive, data quality variable due to incomplete clinical information, retrospective review only. Efficiency improved by focusing chart reviews on cases identified by a reliable trigger tool or software tool
Automated Surveillance	Can be used retrospectively or prospectively, helpful in screening patients who may be at high risk for adverse events using standardized protocols	Need electronic data to run automated surveillance, high proportion of triggered cases are false positives

Administrative/Claims Data (*e.g.*, AHRQ Patient Safety Indicators)	Low-cost, readily available data, useful for tracking events over time across large populations, can identify potential adverse events	Lack detailed clinical data, concerns over variability and inaccuracy of ICD-9-CM and ICD-10-CM codes across and within systems, may detect high proportion of false positives and false negatives
Patient Reports	Can capture errors not easily recognized by other methods (i.e., errors related to communication between providers)	Measurement tools are still in development; patient error identification may be imprecise, and patients may be reluctant to report

Retrospective Chart Review

While large sample (e.g. >10,000 charts) random retrospective chart reviews are the "gold standard" for evaluating patient safety in a research setting, they can be prohibitively labor-intensive given that a large number of charts needs to be reviewed in detail for meaningful information to be obtained on the safety of patients across an entire health system (for example, a seminal study investigating the incidence and nature of adverse events in hospitals reviewed just over 30,000 records; this review involved a nurse and a medical records analyst conducting an initial screen and then two physicians reviewing flagged charts)[24,25]. For this reason, random chart reviews are not part of patient safety data acquisition at any of the health systems we evaluated, nor are we aware of their use in other community health systems outside of a research setting. **Instead, trigger tools have been implemented to "flag" the charts of patients who may have experienced an adverse event and thus identify charts for review.** The most widely recognized trigger tools are the Institute for Healthcare Improvement's (IHI) Outpatient Adverse Event Trigger Tool (Table 3)[26] and Global Trigger Tool (Table 4)[27], the latter of which is more applicable to acute care settings. Use of the Global Trigger Tool paired with retrospective chart review has high specificity for finding errors and is thought to be substantially more sensitive than administrative data linked to AHRQ Patient Safety Indicators (Appendix B) and voluntary error reporting[6]. Data on the utility of the Outpatient Adverse Event Trigger Tool are mixed[28].

Table 3. IHI Outpatient Adverse Event Trigger Tool

Outpatient Triggers
New diagnosis of cancer
Nursing home placement
Admission to hospital
> 2 new consultants in a year
Surgical procedure
ED visit
> 5 medications
Change in physician
Complaint letter
>3 nursing calls in a week
Abnormal lab values

While triggered chart review is recognized for its potential value as a source of patient safety data, most community PSPs are not currently deploying trigger tools as proposed by the IHI (especially in the outpatient setting). Some of the community programs we analyzed do trigger review of inpatient records for cardiac arrests, falls, readmissions within 30 days, reversal of hypoglycemia, and use of naloxone. These reviews are not conducted by the institution's PSP directly, but rather by the relevant department (such as pharmacy for naloxone) and then reported to the PSP as needed.

Table 4. IHI Global Trigger Tool

Care Module Triggers	Surgical Module Triggers
Any code or arrest	Return to surgery
Abrupt drop of >25% in hematocrit	Intubation/re-intubation in PACU
Patient fall	Intra- or post-operative death
Readmission within 30 days	Post-operative troponin level >1.5ng/mL
Transfer to higher level of care	**Intensive Care Unit Module Triggers**
Medication Module Triggers	Pneumonia onset
PT >100s	Readmission to ICU
INR >6	Intubation/re-intubation
Rising BUN or creatinine >2x baseline	**Perinatal Module Triggers**
Vitamin K administration	Third- or fourth-degree laceration
Naloxone use	**ED Module Triggers**
Abrupt medication stop	Readmission to ED within 48hrs
	Time in ED >6hrs

Incident Reporting System

The incident reporting system (IRS) is the cornerstone of data collection for most community patient safety programs. There are different IRS platforms but nearly all exist as an electronic system where anyone performing clinical work can efficiently catalogue the basic details of an adverse event, near miss, or other

> **Box 5. Keys to High-Fidelity IRS Data**
> 1. Culture that supports staff who report incidents
> 2. Reporting by a range of staff
> 3. Broad dissemination of summary data reports
> 4. Senior level review of summary reports to develop action strategies

condition potentially harmful to patient safety. All IRSs examined in the community allow for anonymous or confidential submission to reduce concerns that information could be used punitively. When patient safety committees learn of adverse events or near misses from other data sources, they will use the IRS as a way of cataloguing the event. There is no "gold standard" community IRS and each community organization evaluated uses a different platform. Keys to the broad capture of incidents and high-fidelity IRS data are detailed in Box 5[29].

Automated Surveillance and Administrative/Claims Data

Electronic medical records (EMRs) and electronic billing software have greatly expanded the potential for surveillance of key patient safety data and **all community organizations used automated EMR surveillance and claims data to track important patient safety metrics.** Both the Mayo Clinic and UCSF use third party software (Vizient) to capture, categorize, and trend data. Examples of data captured by automated surveillance and claims include healthcare-associated infections (HAIs; *e.g.*, central line-associated bloodstream infections, catheter-associated urinary tract infections, ventilator-associated pneumonias, and *Clostridium difficile* diarrhea), falls, inpatient mortality, 30-day readmission rates, the development of pressure ulcers, and select peri-operative complications. **All community organizations evaluated had a mechanism in place**

for trending and broadly disseminating patient safety data captured by automated surveillance. UCSF, as one example, distributes an electronic quality and patient safety report on a monthly basis to all clinical staff which includes trends in key safety metrics.

Patient Reports
Patient complaints and malpractice claims are a small, but important, source of patient safety data among the community programs evaluated. These reports act as a trigger for further chart review (which can be entered into the IRS) and problem identification. In the community, patient reported data are fed into PSPs through regular meetings between the patient safety leads and Patient Relations. All community programs also publish a phone number for patients or their families to report potentially unsafe occurrences or conditions to patient safety officials.

IIIb. CCHCS
Similar to community PSPs, CCHCS relies heavily on information from an incident reporting system (IRS) and data gleaned from the EMR to identify threats to patient safety and set priorities in addition to more limited use of other strategies.

Incident Reporting System
Among the most impressive achievements of the PSP since its inception seven years ago is the creation of a broadly adopted statewide incident reporting system (IRS). The initial version of the IRS involved filling out a pdf document and captured about 100 healthcare incidents per year. **The current IRS—the electronic Health Care Incident Reporting (eHCIR) system—allows for both anonymous and confidential reporting and is readily accessible from clinical workstations. In 2018, the eHCIR system captured approximately 20,000 incidents, nearly twice as many as were captured in 2017**.

Retrospective Chart Review
CCHCS does not use patient safety trigger tools to identify charts for retrospective review in any systemic way with the exception of mortality review, peer review (including random chart review for new hires), and limited reviews of charts as part of the Office of the Inspector General (OIG) Medical Inspection Program. It is our understanding that the peer review and OIG review processes do not aim to identify systems-oriented patient safety issues, but are instead used to identify clinicians whose care may fall outside the scope of professional standards. Evaluations of these two processes is forthcoming in our next reports.

Automated Surveillance and Administrative/Claims Data
At CCHCS most automated surveillance is conducted using the Health Care Services Dashboard and patient registries. These data—most of which are directly abstracted from the electronic medical record (EMR)—are continuously updated, stratified by institution, and shared across the organization. The majority of indicators pertain to overall quality, but some are specific to patient safety, such as polypharmacy medication review (which was part of a longstanding and successful early patient safety initiative), appropriate monitoring while on select high-risk medications, wait times to access specific clinical services, and hospital readmissions.
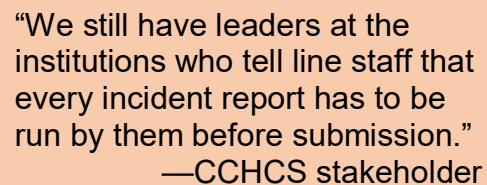
Patient Reports

The most common way in which patients can report concerns about their care is by filing a 602 appeal form (specifically, 602-HC for healthcare appeals). Each 602-HC appeal is reviewed and adjudicated by CCHS. Statewide, 57,634 602-HC appeals were filed and reviewed in 2018. **At present the PSP is not looking at 602-HC appeals as a source of patient safety data** and there is no structured way for those reviewing 602-HC appeals to share information with the PSP.

IIIc. Discussion and Recommendations: Data Acquisition
Recommendation 4. Continue to encourage use of the IRS; strive to establish a "just culture" and emphasize policies that prohibit interference with the ability of staff to file a report.

The development and adoption of the incident reporting system and the sheer volume of quality indicators being tracked by the Health Care Services Dashboard are tremendous achievements for a PSP that was created only seven years ago. Yet while incident reports are intended to be easy to file and largely act as a way to flag unsafe conditions or errors, CCHCS stakeholders have told us that the quality of the reports is often inconsistent. For example, multiple sources reported that **some staff use the reporting system to protect themselves from blame as opposed to objectively describing the clinical scenario, and that some clinical teams have a culture that disincentivizes reporting into the eHCIR system. This raises the possibility that adverse events remain underreported overall**.

> "We still have leaders at the institutions who tell line staff that every incident report has to be run by them before submission."
> —CCHCS stakeholder

Every healthcare organization struggles with underreporting of medical errors through the IRS and there is no methodology to determine when an "acceptable" proportion of errors is being captured or how to use the number of incident reports to assess quality. One study in England found that facilities with higher numbers of incident reports had fewer litigation claims, suggesting that higher numbers of incident reports may actually reflect an increased organizational commitment to quality and safety[30].

Our review of over 100 randomly selected incident reports from 2018 found numerous examples supporting CCHCS's concerns – a number of the incidents seemed to be aimed at assigning blame while others tended toward protecting the provider if the patient were to experience a bad outcome. In the latter category, certain submissions would not typically be categorized as healthcare incidents. For example, we found one submission of a patient refusing an EKG and another of a patient who threatened self-harm and was placed on 1:1 observation. At the other end of the spectrum, we were encouraged to see reports submitted for incidents such as healthcare-associated infections, development of a sacral decubitus ulcer, and instances of self-harm (this group of incidents typically

arises from errors of omission and are frequently underreported if staff are not appropriately trained).

There is no way to determine when CCHCS is reporting an "appropriate" number of medical errors, and we do not recommend that CCHCS prioritize or incentivize a focus on numbers. Rather, we recommend that CCHCS consider approaches to encourage high-fidelity reporting (Box 5). Specifically, **we suggest that CCHCS take further measures to establish a just, blame-free culture of patient safety (to be described in section Vc), publicly recognize individuals for bringing patient safety issues to the attention of the PSP, disseminate patient safety initiatives and trace them to use of the IRS, and make clear to line staff and institution leadership that there shall be no interference with the ability of staff to report incidents.**

> **Box 6. Key Patient Safety Indicators Not Currently Collected Statewide**
> 1) Development of pressure ulcers
> 2) Falls
> 3) Serious reportable adverse events
> 4) Healthcare-associated infections
> 5) Hand hygiene
> 6) Timely review of critical lab values

Recommendation 5. *Expand dashboard and patient registry data to collect and track community standard patient safety indicators (consistent with governmental and regulatory agencies).*

Regarding **automated surveillance**, there are rich data for key patient safety indicators built into the CCHCS dashboard (i.e. therapeutic anticoagulation, safety monitoring for patients on antipsychotics, access to medical care, and hospital readmissions). In many ways, the breadth of data in the CCHCS dashboard matches and/or exceeds what is commonly available at many community institutions. **Building upon the foundation of this surveillance program to better track patient safety metrics (and to continue to ensure data integrity) is an enormous opportunity for the PSP.** For example, upon review of priority areas determined by AHRQ and the Joint Commission, some important indicators are not being collected statewide or—in the case of hand hygiene—are currently collected on a pilot basis (Box 6). We recommend that these indicators, bundled with other safety priorities identified by the PSP, be included in the dashboard data.

Recommendation 6. *Pilot trigger tools that are likely to be high-yield in identifying patient safety threats via retrospective chart review performed at the local institution.*

Regarding other sources of primary patient safety data, **CCHCS should work with the EMR vendor (Cerner) and the Quality Management Committee to pilot select trigger tools that would prompt chart review for adverse events. This chart review could be done at the institution level** and could be accomplished by the Director of Patient Safety or supervisors in relevant domains (*e.g.*, Chief Pharmacist review of charts where glucose was administered to correct hypoglycemia). While trigger tools are not widely used in the community, our opinion is that implementation of select triggers (particularly for outpatient care) would be feasible through integration with the Health Care Services Dashboard and would be an important opportunity to learn more about errors and safety

trends, perform blame-free assessments of fidelity in the IRS, and ultimately improve self-reporting practices via education and training using case examples from these assessments.

Recommendation 7. *Formalize communication between the PSP and reviewers of 602-HC appeals and those responding to civil litigation.*

Finally, there should still be a well-established mechanism for those reviewing 602-HC appeals to notify the PSP should any trends or cases of particular concern be identified. Patient surveys would also be a way to incorporate patient reports into PSP data but at present we favor the use of 602-HC appeals as these data are already being generated and reviewed by CCHCS in large numbers. CCHCS should also standardize a mechanism for civil litigation to trigger review by the PSP through cross-talk between relevant committees.

> **Summary of Recommendations: Data Acquisition**
> 4. Continue to encourage use of the IRS; strive to establish a "just culture" and emphasize policies that prohibit interference with the ability of staff to file a report
> 5. Expand dashboard and patient registry data to collect and track community standard patient safety indicators (consistent with governmental and regulatory agencies) (Box 6)
> 6. Pilot trigger tools that are likely to be high-yield in identifying patient safety threats via retrospective chart review performed at the local institution
> 7. Formalize communication between the PSP and reviewers of 602-HC appeals and those responding to civil litigation

IV. DATA ANALYSIS AND HEALTH SYSTEMS STRENGTHENING
IVa. Community standard
Analyzing patient safety data to set system-wide priorities
One of the most vital functions of community PSPs is to set priorities for health systems strengthening by analyzing all available sources of patient safety data, communicating with front line providers, staying abreast of the work of related committees, and reviewing governmental regulatory requirements and patient safety guidelines (such as the AHRQ Patient Safety Indicators, the National Quality Forum list of Serious Reportable Events, and the Joint Commission National Patient Safety Goals; Appendices B-D).

While the acquisition of high-quality patient safety data is the foundation of strong patient safety programs, data are only useful in as much as they inform priorities for health systems strengthening, lead to interventions to improve care, and are used to assess those interventions for their impact (Figure 3). As described previously, Mayo Clinic and UCSF use third party platforms (Vizient) to aggregate, taxonomize, and trend patient safety data from automated surveillance and claims data. The VA carries out a similar analysis with its own software. This analysis, combined with

aggregate data from incident reports, helps community PSPs identify system-wide priority areas for improvement.

Initial response to patient safety threats
As data are fed into the PSP (from automated surveillance, incident reports, and other sources), **one of the key initial determinations is whether to conduct an in-depth root cause analysis (RCA) of a threat to patient safety**, elect to not perform any analysis or intervention, or do something between these two, such as assign a more limited investigation to the leaders of the affected patient care unit.

In all of the community health systems studied, incident reports and other potential threats to patient safety are handled in a similar manner (Figure 4). As reports come in, they are reviewed daily by one of the medical center's patient safety experts who determines if:
1) There is an ongoing threat to patient safety that must be immediately acted upon
2) An RCA should be conducted
3) An analysis short of an RCA should be conducted (at Mayo Clinic, this is called an intensive review and is usually carried out by the patient care unit and does not involve all of the steps required of an RCA)
4) The incident is a personnel issue that should be referred for peer review
5) The incident should simply be reported back to the leaders of the affected patient care unit, clinical department, or related group (the VA does this with all incidents within one week)

All community health systems have guides for determining if an RCA is needed and all may conduct RCAs even if the event did not lead to any patient harm (i.e. near misses). At the VA, the patient safety manager uses a decision tool called the Safety Assessment Codes (SAC) Matrix to determine if an RCA is necessary (Table 5)[14]. The SAC matrix takes into account the probability of an event and the severity of actual or potential harm to the patient to assign a score of 1-3 for lowest to highest risk. All incidents with a SAC score of 3 must be evaluated with an RCA (others may be evaluated with an RCA at the discretion of the patient safety manager).

Table 5. Safety Assessment Codes (SAC) Matrix

		Severity (Actual or Potential)			
		Catastrophic	Major	Moderate	Minor
Probability	Frequent	3	3	2	1
	Occasional	3	2	1	1
	Uncommon	3	2	1	1
	Remote	3	2	1	1

Root cause analyses (RCAs)
In the community health systems we evaluated, a patient safety expert at the facility where the adverse event occurred assembles an RCA team (usually with members of the relevant department and patient care unit) and leads the RCA (Box 7, Figure 4).

Figure 4: Community Incident Report Review and RCA Process
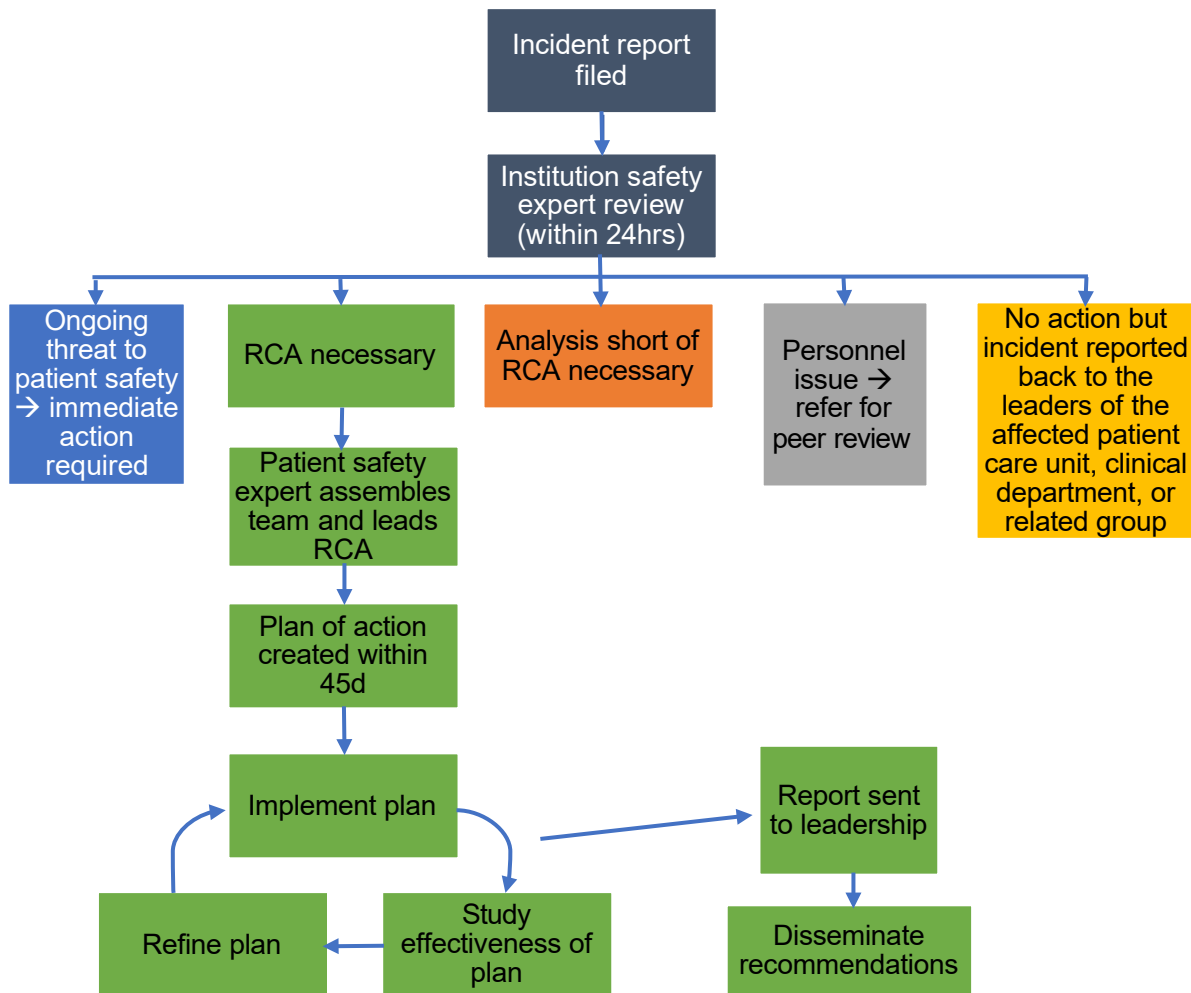
At the VA, the RCA team is created with input from the Chief of Staff (akin to the Chief Medical Executive) to encourage buy-in from participants. The RCA team typically has 45 days to submit a report to the medical director of the facility, after which it will begin to implement the RCA plan of action. Data on the efficacy of the plan of action are collected and progress is again reported to the medical director of the facility until target benchmarks are met and the RCA is closed. **In order to attain high-value RCAs, the VA's patient safety managers are trained in root cause analysis and required to perform a minimum of 8 RCAs each year** – at least four of these must be individual events and at least three must be aggregate reviews of high priority areas (falls, missing patients, and adverse drug events)[14,31]. Toolkits are available from the National Center for Patient Safety to guide RCA team members[31] and to assist in the evaluation of the high priority areas[32,33]. At Mayo Clinic, specialists in quality management act as a liaison between the PSP and the relevant patient care unit – they are charged with closing the loop between RCA findings and corrective actions and can leverage hospital resources to solve problems.

Once an RCA is completed, the PSP is in charge of disseminating the recommendations for health systems strengthening broadly. This can be accomplished through conferences (such as M&M), reports to departments, newsletters, or direct implementation of RCA corrective actions to other relevant patient care units.

> **Box 7. Key Features of Root Cause Analysis**
> 1. Team created with input from senior management
> 2. Led by patient safety expert
> 3. RCA lead (safety expert) trained to ensure high-quality RCAs
> 4. Team is in frequent contact with senior leadership
> 5. Corrective actions continued (and modified) until desired outcomes achieved
> 6. Systems improvements disseminated broadly

Failure Modes and Effects Analysis (FMEA)

While RCAs are intended to evaluate an error that has already occurred, Failure Modes and Effects Analyses (FMEAs) are systemic tools designed to strengthen care delivery by anticipating what *might* go wrong with a high-risk patient care process. The Joint Commission requires all hospitals to undertake at least one FMEA yearly and all community PSPs evaluated here do so[34]. The VA requires patient safety managers to conduct at least four FMEAs each year.

IVb. CCHCS
Analyzing patient safety data to set system-wide priorities

The statewide CCHCS Patient Safety Program is tasked with authoring a biennial Patient Safety Plan although this document has not yet been created[11]. To date, patient safety priorities have been incorporated into the statewide QM Program's biennial Performance Improvement Plan[20] which sets quality improvement priorities at the statewide level (an updated Quality Management Performance Improvement Plan, which incorporates some patient safety priorities is approaching release at the time of this report). Performance Improvement Plan priorities are re-evaluated every two years with input from external stakeholders and this plan is communicated to staff at all levels of the healthcare system. A Performance Improvement Plan is also created at the level of the institution, taking into account statewide and local priorities[22]. The statewide and institution Performance Improvement Plans include the following elements:
1) Priority areas for improvement
2) Performance objectives for each priority area
3) Improvement strategies to be utilized to achieve performance objectives

CCHCS describes its process of identifying priority areas for improvement by looking for high-risk, high-volume, high-cost, and problem-prone aspects of care (Policy 3.1.1 Quality Management Program Overview)[20]. Data inputs for determining such areas include the following:
1) Monthly Health Care Services Dashboard reports
2) Morbidity and mortality analysis
3) Incident reporting system and reporting of sentinel events
4) Standardized audit tools

5) Patient registries to identify patients who have not received services per treatment guidelines
6) Outreach to leadership at the institutions

As a condition of licensure, institutions with a General Acute Care Hospital (GACH) are required to include a Medication Error Reduction Plan in their annual institution Performance Improvement Plan. Once priorities are set, then performance objectives (and associated timeframes) are determined. Data collection strategies are also determined, often through modification of the Health Care Services Dashboard or other data collection tools mentioned previously. Progress toward the achievement of objectives is monitored and disseminated monthly.

When patient safety threats are selected as priorities for intervention (via review of healthcare incident reports or other data inputs), the institutional QMC is tasked with selecting quality improvement strategies to achieve the desired quality improvement objectives at their institution through consultation with the statewide QM Program and institutional stakeholders. Improvement initiatives are then conducted using the Cycle of Change Model (Figure 5).

Figure 5. CCHCS Cycle of Change Framework
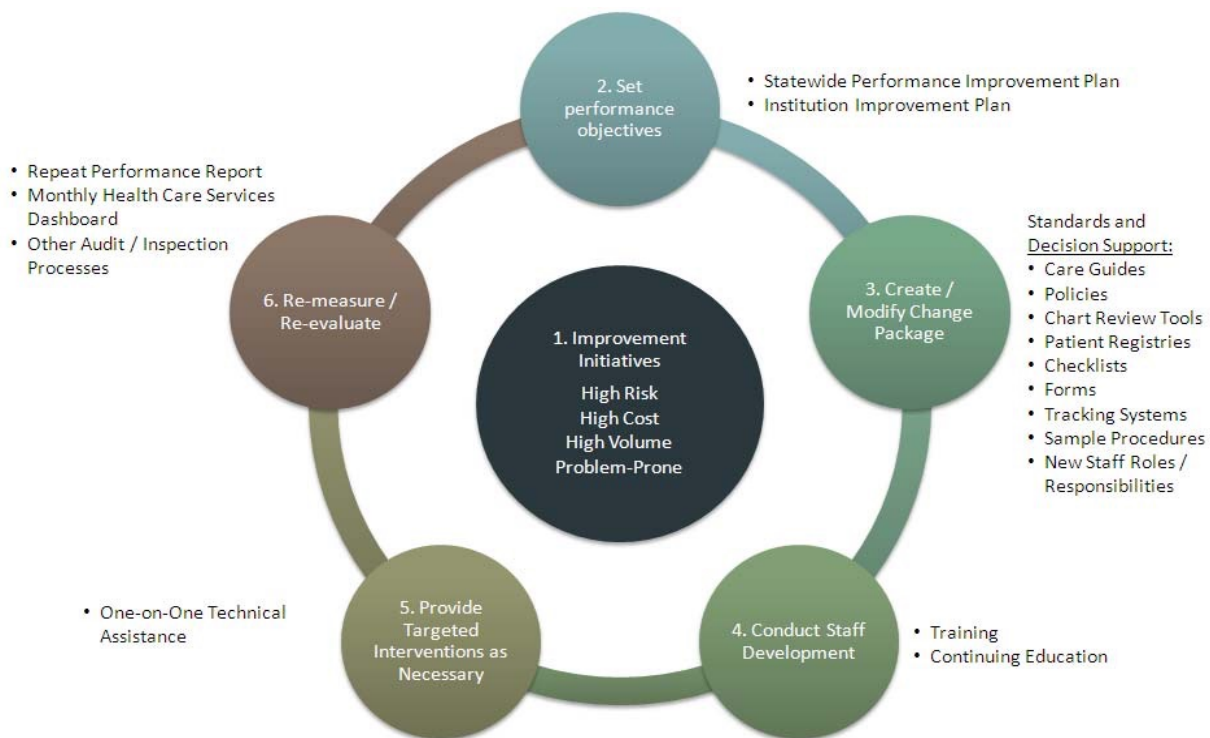
CCHCS Policy 3.1.1 Quality Management Program Overview

Specific approaches widely used to improve performance in the healthcare and quality improvement industries are also applied at CCHCS and include:
- Lean Model

- Six Sigma
- Focus-PDSA (plan-do-study-act)
- Model for Improvement
- Failure Mode and Effects Analysis
- Process Flow Diagramming
- Cause and Effect Diagramming

The QM Program is responsible for educating healthcare staff about improvement models and supporting staff in the application of these models, an initiative that has been most successful in CCHCS's effort to train employees in Lean Six Sigma methodology. To date, each institution has had employees receive introductory Lean White Belt training and some employees have gone on to receive additional Lean training. **Employees who have received Lean training may be well-suited to move into patient safety leadership roles.**

Most health systems strengthening efforts related to quality and patient safety are performed by groups with content area expertise (*e.g.*, the Utilization Management Committee looking at care coordination and transfers or Pharmacy investigating medication errors as required by the CA Board of Pharmacy). The QMC and PSP then advise these groups, a role that is consistent with the community standard.

Initial response to patient safety threats and review of incident reports
When a serious healthcare incident occurs at the institution, staff are required to:
1) Take any immediate steps to ensure patient safety
2) Document care in the patient health record
3) Notify supervisors, the patient, and institution executives
4) Preserve material and supplies that may be related to the incident
5) Report the incident within 24 hours using the electronic Health Care Incident Reporting (eHCIR) system

The eHCIR system is available on Lifeline and allows for anonymous submission. The nursing lead in the healthcare unit is additionally responsible for evaluating the impact of the incident on involved staff and is tasked with providing support to staff, as appropriate, while assuring that review of the incident "shall be focused primarily on process and system breakdowns."[35]

Incidents catalogued in the eHCIR system are to be reviewed daily by the statewide Health Care Incident Reporting Committee (HCIRC) whose members are appointed by the statewide Patient Safety Committee (Figure 6). The HCIRC has representatives from each major healthcare discipline (medical, nursing, pharmacy, mental health, and dental) and members serve as Health Care Incident Review Executives (HCIREs). The HCIRC meets daily to review select healthcare incidents from across the state that are discovered via the eHCIR or other surveillance mechanisms described previously. The Health Care Incident Reporting Committee (HCIRC) is responsible for reviewing "all reported healthcare incidents which are deemed potential adverse/sentinel events, medication errors with a severity of level 4-6, or any other

anomalous healthcare incident."[23] HCIREs assigned incidents are tasked with working with the HCIRC and the institutions to:
1) Resolve any immediate danger
2) Refer the incident to Mortality Review if a death occurred
3) Refer to peer review if there are practice concerns regarding the staff
4) Determine if a root cause analysis (RCA) is required (RCAs are generally required if the HCIRC determines that a sentinel event occurred or there was a medication error with a severity of level 4-6 (Appendix A)

Figure 6: Differences Between Community and CCHCS Incident Report Review and RCA Process
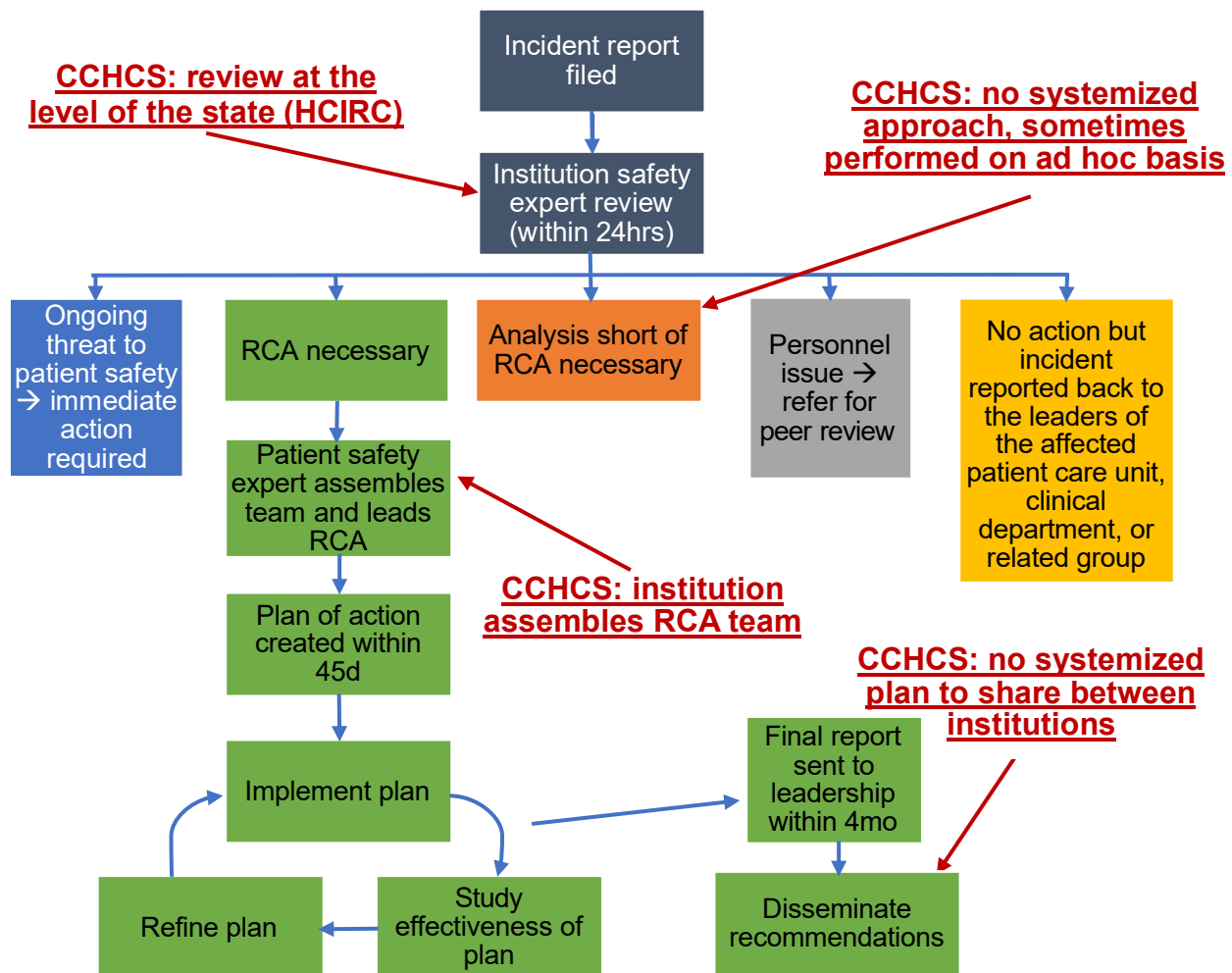
Root cause analyses (RCAs)[35,36]
If an RCA is required, conducting it is the responsibility of institution staff who then work under guidance from the HCIRE (the amount of support the institution staff receive from the HCIRE is determined on an ad hoc basis). An RCA Team is convened by the institution CEO (ideally within 24 hours) with oversight from the institution QMC. If the incident involved an adverse drug reaction, the pharmacy lead will determine if the reaction warrants the completion of an FDA MedWatch Form 3500. If the incident meets

criteria for mandatory reporting under state or federal law, it is reported to the California Department of Public Health (CDPH).

The RCA team is charged with preparing an RCA Report within 45 days, including approval by the institution CEO. The RCA Tool Kit provides guidance for conducting the RCA and preparing a report and the statewide HCIRC and Patient Safety Committee also assist in the process. Once completed, the RCA report is submitted to the HCIRC for review and revisions as necessary. CCHCS specifies that the RCA report should contain the following elements[35]:
1) RCA Team Roster
2) Summary of events related to the incident
3) Documentation of brainstorming session
4) Identification of root causes
5) Plan of Action

Following submission of the RCA report the institution is required to immediately begin executing its Plan of Action and must provide monthly updates to the HCIRC for at least 4 months and until the HCIRC deems the process closed. CCHCS policy mentions that RCA findings may be shared across the institution and the plan of corrective action may be implemented in care units at the institution beyond the unit where the incident occurred, but the policy does not describe procedures for dissemination of corrective action or any lessons learned from the RCA across institutions.

IVc. Discussion and Recommendations: Data Analysis and Health Systems Strengthening
Recommendation 8. Create a biennial Patient Safety Plan at the statewide and institution level; include a roadmap for improving the scope and impact of the PSP itself, not just specific patient safety indicators.

At the statewide level, **we agree with the CCHCS policy describing the need for a biennial Patient Safety Plan**. Following the successful creation of the IRS and quality management data systems (*e.g.*, the Health Care Services Dashboard and patient registries), now is the optimal time to begin issuing biennial reports. We agree that this plan should identify patient safety priorities that are the most likely to result in harm while also setting performance objectives and improvement strategies for each threat to patient safety. **We also envision the biennial Patient Safety Plan describing a roadmap for improving other key aspects of the PSP described in this report**, including:
1) Approach for building capacity to analyze and solve patient safety problems at the institution level
2) Description of strategies to broaden the scope of patient safety data to be collected and analyzed
3) Organizational plan for fostering a culture of patient safety at CCHCS

We also recommend the creation of a Patient Safety Plan at the level of the institution. Much like the institution Performance Improvement Plan, this plan should incorporate strategies to achieve statewide PSP objectives as well as local patient safety

priorities. **A roadmap for local capacity building, data collection strategies, and support for a patient safety culture should also be included in this institution plan.**

Recommendation 9. *Develop a taxonomy to better analyze and trend the large volume of IRS data; generate an approach to feed these data back to the institutions.*

Currently, the biggest sources of patient safety data are the IRS and the Health Care Services Dashboard. Both could be better utilized to accurately identify patient safety priorities and analyze safety over time. **We agree with the PSP's plan to taxonomize IRS data beyond the current classification that reports incidents as either medication errors (with several subcategories) or "other."** While the HCIRC also taxonomizes errors, adjustments to the incident reporting system—by asking users to select from a brief list of overlapping incident types (such as errors related to medication, self-harm, surgery and anesthesia, falls, laboratory, diagnosis, communication, care coordination etc.) and the specific unit of care where the error occurred could accelerate the start of a taxonomy and trending system.

Recommendation 10. *Transition incident review to the patient safety co-chairs at the institution and formulate a process for strengthening health systems at the level of the institution based on high-risk incidents that do not rise to the level of an RCA.*

We strongly recommend that there be a program for evaluating select incidents that do not rise to the level of a root cause analysis and for feeding data on incident reports back to the institutions for their own review. In the first half of 2018 there were 9,899 incident reports across all institutions and only 23 RCAs. While some high-performing institutions are reviewing their own incident reports independently, there is currently no systemized approach for extracting what is sure to be valuable data from the remaining incidents which represent >99% of all incidents reported. To ensure that a greater number of incident reports inform PSP initiatives, we recommend the following approach to reviewing incidents:

1) **CCHCS should aim to transition review of incident reports from the statewide HCIRC to the co-chairs of the institution Patient Safety Subcommittee**. At present, the HCIRC is overwhelmed with the number of incident reports and sometimes there is a delay in responding to incidents when an expedient response is needed (some stakeholders we spoke with said it was not uncommon to have a 3-4 day lag between when a serious incident was filed and when the HCIRC contacted them about the incident). Institution review will hasten feedback to affected care units and allow better identification of local trends in patient safety. We do recommend continued oversight from statewide or regional patient safety experts regarding incident review (such as a periodic audit program), especially in the early stages of this transition as the co-chairs are developing expertise.

2) **For incidents that do not rise to the level of an RCA but represent significant threats to patient safety (such as those with a SAC Matrix score of 2, Table 5), we recommend a limited review performed by the Patient Safety Subcommittee and the leaders of the affected care unit**, much like is done in the community programs we analyzed. This review does not need to be nearly as detailed as an RCA but should result in local action items to strengthen health systems.

3) **All healthcare incidents should also be sent to the leaders of affected patient care units and aggregate data on the taxonomy of incidents should be shared periodically across the institution**

The above actions at the instution level will have the added benefit of increasing the visibility of the work of patient safety leaders. This will continue to line staff to use the IRS by demonstrating that the documentation of all incidents—not just ones resulting in the potential for serious harm—is vital to the institution's patient safety mission.

When QM efforts have focused on patient safety initiatives, these initiatives have largely been successful in achieving CCHCS's objectives. One of the major PSP undertakings over the last few years, for example, has been to reduce complications from polypharmacy by evaluating every patient prescribed 10 or more medications on an annual basis. This has now been accomplished in >95% of patients across institutions based on dashboard data. CCHCS stakeholders report that this initiative brought together leaders at the statewide, regional, and institutional levels as well as line staff. The polypharmacy program also facilitated problem solving across disciplines and empowered people to think creatively about quality improvement.

Overall, CCHCS utilizes evidence-based standards for health systems strengthening that are similar to what is used in the community. The training of a large cadre of leadership and line staff in Lean Six Sigma, for example, demonstrates commitment to advancing institutional knowledge of quality improvement throughout the organization. The use of RCAs, however, is one area

where we believe key changes could be made to strengthen their impact in protecting patients.

Recommendation 11. *Train patient safety subcommittee co-chairs and regional leaders to conduct high-quality RCAs; until institutions demonstrate proficiency in conducting their own RCAs, require HCIRE or regional involvement.*

Our evaluation of the CCHCS RCA toolkit reveals that it appropriately aims to guide participants toward high-impact patient safety-oriented solutions. The key difference between community and CCHCS processes is that community RCAs are led by a trained patient safety expert while CCHCS RCAs are led by the institution (with ad hoc input from the statewide experts). While many institutional leaders have completed online RCA training, they frequently do not have the expertise to lead an RCA and also may not feel empowered to seek patient-centered solutions due to a lack of culture supporting patient safety at the level of the institution. Furthermore, some institutions may only be conducting one or two RCAs a year which makes it difficult to develop individual (and institution-wide) expertise (by contrast, the VA requires their patient safety manager to conduct *at least* 8 RCAs each year). Statewide PSP stakeholders have expressed concerns about the quality of RCAs, and we share these concerns after our review of a sample of RCAs.

> "The quality of the RCAs is all over the place. Some are good but most are not very good…many just recommend to better train the staff."
> —CCHCS stakeholder

> "We need local people who have RCA training…people can execute a policy and 'punish' people for not following a policy, but we need people who understand quality and can think creatively."
> —CCHCS stakeholder

We recommend that CCHCS further train local leaders (such as the institution patient safety subcommittee co-chairs) and regional leaders to conduct high quality RCAs. RCAs should initially be performed with mandatory HCIRE or regional oversight, with a focus on building capacity at institutions and the goal of transitioning to ad hoc HCIRE and regional involvement if/when the institution has demonstrated proficiency. Adding mandatory HCIRE or regional involvement will also protect against intra-institution biases or conflicts of interest in institutions that may not be as far along in promoting a culture of patient safety.

We also recommend requiring a minimum number of RCAs each year for those performing them (such as the 8 that are required at the VA). These RCAs may be a combination of RCAs due to a specific incident and aggregate RCAs targeting a high priority area.

Recommendation 12. *Share strategies for strengthening health systems across institutions.*

The action items to strengthen health systems following an RCA should be disseminated across the institution, as appropriate, and shared between institutions. Sharing best practices between institutions should be a priority of regional and statewide leaders so that these opportunities for system-wide learning are not missed.

> **Summary of Recommendations: Data Analysis and Health Systems Strengthening**
> 8. Create a biennial Patient Safety Plan at the statewide and institution level; include a roadmap for improving the scope and impact of the PSP itself, not just specific patient safety indicators
> 9. Develop a taxonomy to better analyze and trend the large volume of IRS data; generate an approach to feed these data back to the institutions
> 10. Transition incident review to the patient safety co-chairs at the institution and formulate a process for strengthening health systems at the level of the institution based on high-risk incidents that do not rise to the level of an RCA
> 11. Train patient safety subcommittee co-chairs and regional leaders to conduct high-quality RCAs; until institutions demonstrate proficiency in conducting their own RCAs, require HCIRE or regional involvement
> 12. Share strategies for strengthening health systems across institutions

V. CREATING AND SUSTAINING A CULTURE OF PATIENT SAFETY
Va. Community standard

None of the objectives of a PSP can be easily realized and sustained without a health systems culture that places a high value on safety. Such value needs to be clearly modeled at the highest levels of the organization and must permeate all leadership levels down to front line staff. The quality of IRS data, willingness of staff to solve problems, motivation to implement changes, and ability to work as a team are all highly dependent on a health system with a culture that values safety. **In multiple interviews with key community PSP stakeholders, sustaining a culture that prioritizes safety above all else was mentioned repeatedly as among the most important functions of a PSP.**

> "People ask 'what is our secret patient safety sauce?' It's the culture."
>
> —Mayo Clinic stakeholder

Measuring a Patient Safety Culture

Culture can be difficult to define and even more difficult to measure, but strategies to evaluate patient safety culture exist. The most widely recognized are the Safety Attitudes Questionnaire (SAQ) and the Surveys on Patient Safety Culture developed by the AHRQ and individually tailored for use in hospitals, ambulatory facilities, nursing homes, and pharmacies[37,38]. These surveys are designed to be completed anonymously by medical providers and other staff with the aim of determining in what ways an organization does and does not support patient safety. **Both the Joint Commission and Leapfrog Group (a non-profit organization that publicly reports healthcare quality ratings) require**

periodic surveys of patient safety culture and all community PSPs evaluated for this report periodically survey a cross-section of their staff. Because the surveys are widely conducted across healthcare facilities, they can be used for comparison and **studies suggest that a strong safety culture may correlate with improved patient outcomes**[39]. Furthermore, studies also find substantial heterogeneity in culture within a healthcare organization, meaning that individual teams and supervisors play an outsized role in determining the safety culture at the level of individual care units[40].

Community PSP Efforts to Create and Sustain a Culture of Patient Safety
The Joint Commission defines five components that leadership must achieve to foster a strong safety culture (Box 8)[41].

> **Box 8. Leadership Components Necessary for a Strong Culture of Patient Safety (adapted from the Joint Commission)**
> 1. Assessment: evaluate the culture of patient safety regularly
> 2. Strengthening Systems: prioritize changes based on evaluations
> 3. Trust/Intimidating Behavior: develop a code of conduct and defines behaviors that undermine a culture of patient safety
> 4. Identifying Unsafe Conditions: recognize full range of issues from near misses to sentinel events
> 5. Just Culture: encourage blame-free reporting while maintaining accountability

Achieving these objectives can be difficult and requires not only the best practices listed above but also a sustained campaign to publicize and model these practices throughout the organization. UCSF, for example, sensitizes staff to the importance of patient safety and promotes a commitment to safety in the following ways[42]:
1) *Regular clinical staff safety training*, e.g.
   a. Annual Patient Safety training, including information on National Patient Safety Goals, control of infectious diseases, how to use the incident reporting system, etc.
   b. Biennial clinical staff safety training in infection control and use of restraints
   c. Additional safety trainings to target specific healthcare workers, such as OR safety and medication administration safety
2) *Caring for the Caregiver Program*: supports staff involved in an adverse outcome
3) *True North Rounds*: monthly executive walk rounds involving senior UCSF leadership visiting a patient care unit to discuss organization-wide objectives
4) *Monthly Patient Safety Bulletin*: links to progress on patient safety initiatives
5) *Performance Improvement Executive Summary*: a widely disseminated yearly report describing progress on the patient safety "Zero Harm" initiative
6) *STOP for Safety Campaign*: broad distribution of patient safety-themed posters and reminders in workrooms, cafeterias, shuttles, and other high-traffic areas
7) *Annual Health Improvement Symposium*: highlights improvement work done within a UCSF healthcare setting
8) *Great Catch Program*: publicly recognizes front line staff who go above and beyond expectations to prevent harm to patients

In our analysis of three community patient safety programs, UCSF's efforts to promote a strong culture of patient safety are in line with those of the VA (*e.g.*, Culture of Safety campaign and Stop the Line campaign) and Mayo Clinic (*e.g.*, 5 Safe Behaviors campaign and Commitment to Safety Program).

There are also collaborative training programs dedicated to improving teamwork with the goal of improving patient safety that are used by some community institutions. This includes the AHRQ TeamSTEPPS program and the Johns Hopkins/AHRQ Comprehensive Unit-Based Safety Program (CUSP) to prevent healthcare-associated infections[43,44].

Vb. CCHCS

CCHCS administered the AHRQ survey on patient safety culture once, in 2014, soon after the creation of the PSP. The response rate was over 50% and CCHCS stakeholders felt that the survey was useful in establishing a baseline assessment of culture; however most institutions did not act on survey findings.

Efforts to promote a culture of patient safety have largely come from the statewide Patient Safety Committee. Much of this has come from publicizing the work of the patient safety committee including:
1) Promoting use of the incident reporting system
2) Creating and disseminating the Health Care Incident Review Dashboard
3) Working with institutions on root cause analysis on an ad hoc basis
4) Conducting statewide safety initiatives (such as the polypharmacy review and an ongoing hand hygiene campaign)
5) Disseminating a periodic *Patient Safety Story* on Lifeline

The PSP has also sponsored a poster competition as part of national Patient Safety Week. TeamSTEPPS and collaborative care models have also been rolled out at some institutions.

"We have no toolkit for how to improve culture. In a way, we have decided we are just going to keep doing our patient safety work and the culture change will follow. To some extent it is working and to some extent it is not."

—CCHCS stakeholder

Vc. Discussion and Recommendations: Creating and Sustaining a Culture of Patient Safety
Recommendation 13. Train both custody and healthcare workers in the importance of a culture of patient safety.

Multiple conversations with CCHCS stakeholders at the statewide, regional, and institution level have identified two consistent themes regarding the patient safety culture at CCHCS. One is that the culture has become more supportive of patient safety and is dramatically improved compared to just a few years ago. The second is that there are still many opportunities for improvement and that culture—particularly at the level of the institution—remains a significant barrier to achieving many of the goals of the patient safety program. In our interviews we heard multiple examples of how a lack of culture supporting patient safety will, at times, negatively impact the work of the PSP, including the following:

> "A lot of people are still afraid to report incidents. That is reflected in some reports where people appear to be blaming others and trying to protect themselves."
> —CCHCS stakeholder

1) Some institution leaders are asking staff to review all healthcare incidents before they are submitted to the eHCIR
2) Some eHCIR submissions appear to be focused on protecting individuals from blame as opposed to trying to lay the groundwork for finding solutions to improve care
3) Root cause analyses frequently misidentify problematic areas for fear of alienating or upsetting colleagues (healthcare and custody)

The vital role of custody in the delivery of healthcare merits further mention as both a challenge and an opportunity that is unique to corrections. Corrections staff may not view themselves as having a role in patient safety, but they are a key determinant of the institution's culture of patient safety and its delivery of high-quality healthcare. Key informant interviews revealed that healthcare providers are often reluctant to report or discuss the role of custody in medical errors because the providers are dependent on custody to ensure their own safety on the job. **Creating a just culture that includes both healthcare providers and custody will be key to the mission of the PSP.**

> "We try to promote a just culture but that does not penetrate down to the level of the line staff."
> —CCHCS stakeholder

Recommendation 14. *Administer the AHRQ survey on patient safety culture every 2-3 years; include custody in a modified version of the survey.*

As a first step to improving patient safety culture, **we recommend that the PSP begin administering the AHRQ survey on patient safety culture every two to three years across all institutions**. **We also recommend that the survey be administered to custody in a modified form** (eliminating questions that are not relevant to custody). Repeat administration of the AHRQ survey will allow for a direct comparison to the results of the 2014 survey and will enable a more precise understanding of which areas of culture and which institutions are the highest priorities for improvement. Next steps to promote safety will then be informed by survey results and can draw upon the current evidence base for best practices, such as those summarized in a 2013 review[45].

Additionally, we recommend the following steps to promote a just culture sensitized to patient safety:
1) Yearly online or in-person training of staff highlighting major patient safety initiatives
2) Formation of a structured program to support staff who may have been involved in a medical error or unexpected bad outcome
3) Creation of a campaign to publicize and promote patient safety work: this campaign should recognize local line staff for bringing threats to patient safety to the attention of leadership, promote patient safety activities and goals, and highlight achievements

Recommendation 15. *Create a working group of the statewide Patient Safety Committee (staffed by individuals with dedicated time) tasked with promoting a just culture that values patient safety at the institutions.*

Administration of the AHRQ survey, analysis of its results, and the creation of a program to support a just culture are a significant undertaking. While the community programs we analyzed do not have staffing dedicated solely to promoting a culture of patient safety, we believe that **the statewide Patient Safety Committee would benefit from having a working group dedicated to promoting a culture of patient safety across the system due to the vital nature of this work**. This working group would be composed of a few individuals across disciplines (including custody) with dedicated time to develop and promote the culture-strengthening activities mentioned above at the institutions. The working group would then collaborate with the co-chairs of the institution patient safety subcommittees to advance this mission.

Another approach, mentioned by CCHCS patient safety stakeholders, would be to hire outside consultants to assess patient safety culture and make recommendations for improvement (the non-profit Center for Patient Safety, for example, offers these services). This could also be a valuable approach to strengthening culture and would have the added benefit of offering external perspective.

> **Summary of Recommendations: Creating and Sustaining a Culture of Patient Safety**
> 13. Train both custody and healthcare workers in the importance of a culture of patient safety
> 14. Administer the AHRQ survey on patient safety culture every 2-3 years; include custody in a modified version of the survey
> 15. Create a working group of the statewide Patient Safety Committee (staffed by individuals with dedicated time) tasked with promoting a just culture that values patient safety at the institutions

VI. RELATIONSHIP WITH GOVERNMENTAL AND NON-GOVERNMENTAL ORGANIZATIONS

VIa. Community standard

All community PSPs evaluated collaborate with governmental and non-governmental organizations for guidance on achieving safe practices; to meet licensing, accreditation, reporting, and regulatory requirements; and as a condition for participation in insurance plans. The following is a list of key organizations that PSPs at community-based integrated healthcare systems commonly work with and a summary of their roles.

Agency for Healthcare Research and Quality (AHRQ)

AHRQ maintains a website (https://psnet.ahrq.gov) that serves as an extensive national resource on patient safety guidelines, research, and commentary. AHRQ also sets hospital-level Patient Safety Indicators (Appendix B) and is the creator of one of the most widely adopted patient safety culture surveys.

Department of Public Health (state-level)

State-level Departments of Public Health license all the medical facilities we analyzed in the community while ensuring the facilities are in compliance with state laws and regulations. The DPH also mandates that certain patient safety data be reported to the state, some of which is then made publicly available. In California, these data include:

- Vital statistics: birth, death, fetal death, and still birth certificates
- Healthcare-associated infections in hospitals: central line-associated bloodstream infections (CLABSI), methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections, vancomycin resistant *Enterococcus* bloodstream infections, *Clostridium difficile* diarrhea infections, and surgical site infections (SSI)[46]
- Reportable adverse events: see Appendix C[47]

Centers for Medicare and Medicaid Services (CMS)

CMS maintains health and safety standards (called Conditions of Participation) for all healthcare facilities that serve Medicare and Medicaid beneficiaries[48]. Surveys to ensure compliance with CMS standards are performed by individual State Survey Agencies. In California, this is primarily done by the California Department of Public Health (CDPH) Licensing and Certification Division (L&C)[49].

CMS also requires that each hospital has a Quality Assessment and Performance Improvement (QAPI) program which tracks quality metrics, including patient safety. Key aspects of the program are summarized in Table 6[50].

Table 6. Key Aspects of the CMS QAPI Program

QAPI Attributes	Specifics
Scope	- Must measure and track quality indicators, including adverse patient events - Must aim to reduce medical errors
Data	- Must incorporate patient level quality indicator data

	• Must use data to monitor safety of services and identify opportunities for improvement
Program activities	• Must set priorities for performance improvement in high-risk, high-volume, or problem-prone areas • Must track medical errors and adverse patient events, analyze their causes, and implement preventative actions that include feedback and learning throughout the hospital • Must take actions aimed at performance improvement, measure success, and track performance to ensure improvement is sustained
Performance improvement projects	• Must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved
Executive responsibilities	• Must assume full responsibility for the creation and maintenance of a program of quality improvement and patient safety • Must ensure that adequate resources are allocated to the program

Medicare further influences patient safety by reducing reimbursement to hospitals with high readmission rates, low patient satisfaction scores, and other data suggestive of low-quality care. Additionally, Medicare will limit or deny reimbursement to health facilities for treating select medical errors if they occur in the hospital (Appendix F)[51].

Joint Commission
The Joint Commission accredits many US health facilities—including all of the organizations evaluated for this report—and provides evidence-based guidance for ensuring patient safety in many forms, including the Joint Commission National Patient Safety Goals (Appendix D) which are safety processes (*e.g.*, using two identifiers and performing a timeout prior to a procedure). The Joint Commission also strongly encourages the voluntary reporting of sentinel events (Appendix C). A list of key Joint Commission standards relevant to patient safety programs is included at the end of this document (Appendix E). Many standards have additional required elements and the Joint Commission provides guidance on how to meet these requirements as part of its accreditation program.

The Leapfrog Group
The Leapfrog Group is a non-profit organization which collects and reports information on hospital performance and assigns letter grades to hospitals based on their record of patient safety. Among the community health systems analyzed, UCSF submits itself to the Leapfrog Group's survey and ratings process.

VIb. CCHCS
Select CCHCS institutions have licensed facilities (usually acute care or skilled nursing beds). CCHCS stakeholders told us that these facilities are subject to state licensing regulations and reporting of sentinel events at the request of the CDPH. CCHCS facilities

are not accredited by the Joint Commission with a few exceptions (*e.g.*, the behavioral health programs at the California Institute for Women and the California Health Care Facility). CCHCS is not involved in CMS's efforts to incentivize patient safety. CCHCS does not participate in Leapfrog Group surveys or ratings.

CCHCS does respond to requests from unique external stakeholders. These stakeholders include the State Auditor, the Office of the Inspector General, and the Office of Internal Affairs. There are accreditation standards unique to correctional health developed by the American Correctional Association (ACA) and the National Commission on Correctional Health Care (NCCHC); however CCHCS does not participate in these accreditation processes.

VIc. Discussion and Recommendations: Relationship with Governmental and Non-Governmental Organizations
Recommendation 16. *Review governmental and non-governmental PSP standards and incorporate these standards into the biennial Patient Safety Plan at the statewide and institution level.*

Governmental and non-governmental organizations play an important role in synthesizing best-practices for patient safety and holding health facilities accountable for their patient safety programs. In many ways, CCHCS's PSP is already indirectly working to achieve the performance indicators spelled out in the CMS QAPI program and the Joint Commission's standards relevant to patient safety. In our assessment, one of the largest discrepancies between the programs promoted by these organizations and the CCHCS PSP is that much of CCHCS's expertise and patient safety efforts are centralized in the statewide office and that there is a shortage of expertise, capacity, and initiative for patient safety at the 35 individual institutions. We believe that the recommendations contained in this report would help CCHCS meet these community standards by strengthening the breadth and quality of patient safety efforts already underway. **We recommend that CCHCS review these governmental and non-governmental standards (Appendices B-F) when evaluating its own PSP. These standards—when applicable to CCHCS's mission—should help inform the roadmap for improving the scope and impact of the PSP itself that we recommend be included in the biennial statewide and institution Patient Safety Plans (Recommendation 8).**

Recommendation 17. *Include reportable adverse events, relevant AHRQ Patient Safety Indicators, and relevant Medicare "No Pay" conditions as part of trending of aggregate patient harm events.*

We have recommended that CCHCS track, trend, and disseminate aggregate data on patient harm (Recommendation 5). This should include, but not be limited to, reportable adverse events, relevant AHRQ Patient Safety Indicators (Appendix B), and relevant Medicare "No Pay" conditions (Appendix F).

Recommendation 18. *Incorporate Joint Commission National Patient Safety Goals into routine practice at inpatient and ambulatory health facilities.*

We recommend that the Joint Commission National Patient Safety Goals (Appendix D) be incorporated into routine practice at inpatient and ambulatory CCHCS health facilities. These goals—which are processes designed to reduce errors—are not currently adopted broadly across CCHCS (*e.g.*, timeouts before procedures have only recently been implemented prior to dental extractions).

> **Summary of Recommendations: Relationship with Governmental and Non-Governmental Organizations**
> 16. Review governmental and non-governmental PSP standards and incorporate these standards into the biennial Patient Safety Plan at the statewide and institution level
> 17. Include reportable adverse events, relevant AHRQ Patient Safety Indicators, and relevant Medicare "No Pay" conditions as part of trending of aggregate patient harm events
> 18. Incorporate Joint Commission National Patient Safety Goals into routine practice at inpatient and ambulatory health facilities

VII. SUMMARY

VIIa. Discussion

Since 2012, the CCHCS PSP has advanced measures that are vital to ensuring the safety of patients across its 35 institutions. The following are some of the most notable achievements:

1) <u>Development and widespread use of the incident reporting system</u>: this has created a vital tool—very much aligned with the community standard—for documenting and addressing critical threats to patient safety

2) <u>Creation of the Health Care Services Dashboard</u>: the dashboard has provided detailed data on many indicators relevant to patient safety which has, in turn, spurred safety initiatives in key areas; in many areas the data available on the dashboard exceeds what is commonly tracked in the community, especially for outpatient care which represents the bulk of CCHCS's healthcare mission

3) <u>Select safety interventions focused on high-risk areas of care</u>: these interventions—such as the polypharmacy medication review program, lab monitoring for patients on select medications, and timeouts prior to dental extractions—have been undertaken using safety and quality improvement frameworks that are aligned with the community standard.

This work has also elevated the importance of patient safety across the institutions, promoted an emerging culture of patient safety, and encouraged institution leadership and line staff to begin to think creatively about how to strengthen health care delivery systems.

There are a number of opportunities, however, to bring the CCHCS PSP into greater alignment with PSP community standards and to create a robust and sustainable PSP that responds to adverse events, proactively identifies threats to patient safety, critically

analyzes and improves itself, and maintains a workforce culture that values patient safety above all else. **Of the recommendations in this report (which are summarized in the subsequent section), we believe the following three should constitute high-yield / high-priority next steps in the ongoing development of CCHCS's PSP:**

Recommendation 1. Create Patient Safety Subcommittees at every institution with two co-chair positions, including one Director of Patient Safety (a full-time position at most institutions, likely filled by a non-physician) and one Medical Director of Patient Safety (a part-time commitment to be filled by a clinician who has protected time for patient safety activities).

Having patient safety leaders at each institution with protected time to carry out their job responsibilities will ensure there is adequate staffing to achieve CCHCS's patient safety objectives (Box 3) and many of the recommendations detailed in this report. We believe this is particularly important because the threats to patient safety presently exceed the staffing available to address them. For example, we heard concerns about serious threats to patient safety—such as medication reconciliation and lost orders during patient transfers—that staff felt could have been better addressed with more robust patient safety staffing. In addition, our proposed increase in protected FTE for patient safety at each institution could begin to transform the institutions into learning laboratories for addressing a host of health systems issues while also promoting a system-wide culture of patient safety and bringing CCHCS's patient safety staffing into greater alignment with the community standard.

Recommendation 10. Transition incident review to the patient safety co-chairs at the institution and formulate a process for strengthening health systems at the level of the institution based on high-risk incidents that do not rise to the level of an RCA.

As detailed in this report, expanding data collection strategies to identify a broader swath of patient safety issues at the institutions will be critical to CCHCS. **But data are only valuable if they are used to inform efforts to strengthen health systems. At present, only a small fraction (<1%) of incident reports are being utilized to strengthen health systems, usually in the form of an RCA for sentinel events.** Requiring institutions to review high-risk incidents that do not rise to the level of an RCA and design patient safety interventions based on these incidents (as is done in the community) will be vital to strengthening the PSP as a whole.

Recommendation 13. Train both custody and health care workers in the importance of a culture of patient safety.

It will be difficult to achieve any of the recommendations in this report if individual institutions do not have a robust culture of patient safety. Improving culture will involve first assessing culture, likely by implementing one of the validated community patient safety culture surveys (Recommendation 14), and then using the results of that survey to inform culture strengthening programs and activities (of which there are many to draw on from community health care systems). Overall, however, culture does not stand on its

own – we believe that many of the other recommendations issued in this report would bring greater visibility to the work of the PSP and likely foster a robust culture of patient safety as well.

In the subsequent sections, we summarize all of our recommendations and detail the responsibilities of the proposed roles of Director of Patient Safety and Medical Director of Patient Safety.

VIIa. Summary of Recommendations

1. Create Patient Safety Subcommittees at every institution with two co-chair positions, including one Director of Patient Safety (a full-time position at most institutions, likely filled by a non-physician) and one Medical Director of Patient Safety (a part-time commitment to be filled by a clinician who has protected time for patient safety activities)
2. Train supervisors on individual patient care units in the importance of patient safety, how to identify threats to patient safety, and how to interface with their Patient Safety Subcommittee
3. Operationalize cross-talk between the PSP and relevant committees and stakeholders (both health and corrections) at state, regional, and institution levels
4. Continue to encourage use of the IRS; strive to establish a "just culture" and emphasize policies that prohibit interference with the ability of staff to file a report
5. Expand dashboard and patient registry data to collect and track community standard patient safety indicators (consistent with governmental and regulatory agencies) (Box 6)
6. Pilot trigger tools that are likely to be high-yield in identifying patient safety threats via retrospective chart review performed at the local institution
7. Formalize communication between the PSP and reviewers of 602-HC appeals and those responding to civil litigation
8. Create the biennial Patient Safety Plan at the statewide and institution level; include a roadmap for improving the scope and impact of the PSP itself, not just specific patient safety indicators
9. Develop a taxonomy to better analyze and trend the large volume of IRS data; generate an approach to feed these data back to the institutions
10. Transition incident review to the patient safety co-chairs at the institution and formulate a process for strengthening health systems at the level of the institution based on high-risk incidents that do not rise to the level of an RCA
11. Train patient safety subcommittee co-chairs and regional leaders to conduct high-quality RCAs; until institutions demonstrate proficiency in conducting their own RCAs, require HCIRE or regional involvement
12. Share strategies for strengthening health systems across institutions
13. Train both custody and health care workers in the importance of a culture of patient safety
14. Administer the AHRQ survey on patient safety culture every 2-3 years; include custody in a modified version of the survey
15. Create a working group of the statewide Patient Safety Committee (staffed by individuals with dedicated time) tasked with promoting a just culture that values patient safety at the institutions
16. Review governmental and non-governmental PSP standards and incorporate these standards into the biennial Patient Safety Plan at the statewide and institution level
17. Include reportable adverse events, relevant AHRQ Patient Safety Indicators, and relevant Medicare "No Pay" conditions as part of trending of aggregate patient harm events
18. Incorporate Joint Commission National Patient Safety Goals into routine practice at inpatient and ambulatory health facilities

VIIb. Summary of Recommended Director of Patient Safety Role

We have proposed a new Director of Patient Safety role to be filled as a full-time position at most institutions and as a part-time position at the small number of institutions where a relatively healthy patient population is not expected to yield a sufficient number of healthcare incidents and associated patient safety initiatives to justify the full-time position. We expect that the individual filling this role will be a non-physician health professional. This individual will require additional training and, at least in the early phase of their tenure, close support from statewide patient safety experts. As this individual develops expertise and earns increasing autonomy, we envision the Director of Patient Safety fulfilling the following key responsibilities.

Table 7. Director of Patient Safety

Proposed Roles
Co-chair the institution Patient Safety Subcommittee
Participate in periodic regional and statewide patient safety meetings to disseminate patient safety best practices and share challenges
Review institution incident reports and triage as appropriate (RCA vs. limited review vs. simple feedback to affected care units)
Participate in committees at the institution level that conduct work relevant to patient safety (Figure 1, section IIc, and reviewers of 602-HC appeals)
Author a biennial institution Patient Safety Plan, incorporating information from the statewide Patient Safety Plan, locally determined priorities, and governmental and non-governmental organization standards
Lead implementation of the institution Patient Safety Plan
Lead high-quality RCAs
Lead limited reviews of institution incidents that do not rise to the level of an RCA but represent significant threats to patient safety
Take responsibility for administration of the AHRQ survey on patient safety culture at the institution every 2-3 years
Lead local efforts to promote a just culture of patient safety and to publicize and disseminate the work of the PSP
Lead local efforts to adopt the Joint Commission National Patient Safety Goals as part of routine practice

VIIc. Summary of Recommended Medical Director of Patient Safety Role

We have also proposed the role of Medical Director of Patient Safety at each institution. We believe this position should be filled by a clinician whose primary role in the institution continues to be provision of medical care but who also has protected time (such as a reduction in the number of clinic sessions) to perform patient safety work. While the majority of patient safety work at the institution would be conducted by the Director of Patient Safety, the Medical Director of Patient Safety would provide critical support in the form of clinical expertise necessary to make decisions about incident report triage, priority setting in the institution Patient Safety Plan, and completion of RCAs and limited reviews. We also view this role as establishing a crucial link between the patient safety leadership and line staff which would aid in the diffusion of a culture that values patient safety.

Table 8. Medical Director of Patient Safety

Proposed Roles
Co-chair the institution Patient Safety Subcommittee
Participate in periodic regional and statewide patient safety meetings to disseminate patient safety best practices and share challenges
Review a limited number of institution incident reports and triage as appropriate; assist the Director of Patient Safety as needed in making patient safety triage decisions
Collaborate with the Director of Patient Safety in authoring the biennial institution Patient Safety Plan
Collaborate with the Director of Patient Safety in implementing the institution Patient Safety Plan
Lead high-quality RCAs (some)
Lead limited reviews of institution incidents that do not rise to the level of an RCA but represent significant threats to patient safety (some)
Collaborate with the Director of Patient Safety in leading local efforts to promote a just culture of patient safety and to publicize and disseminate the work of the PSP
Collaborate with the Director of Patient Safety in leading local efforts to adopt the Joint Commission National Patient Safety Goals as part of routine practice

VIII. APPENDICES
Appendix A. Definitions

<u>Blameworthy act/reckless behavior</u>: a criminal act, a purposefully unsafe act, an act involving abuse of any kind, or a situation in which an individual takes a substantial and unjustifiable risk that may result in patient harm

<u>Healthcare incident</u>: An unusual or unexpected occurrence in the clinical management of a patient, does not need to result in adverse health consequences; different (overlapping) types defined below

- <u>Adverse event</u>: any injury that arises as a result of medical care rather than from an underlying disease process
    - o <u>Preventable adverse events</u>: those due to error or failure to apply an accepted strategy for prevention (*e.g.*, anaphylaxis after giving a drug the patient was known to be allergic to)
    - o <u>Non-preventable adverse events</u>: those not due to an error or failure to apply an accepted strategy (*e.g.*, anaphylaxis after giving a drug to which the patient had no known allergy)
    - o <u>Adverse events due to negligence</u>: those due to care that falls below the standards expected of clinicians in the community
- <u>Error</u>: any act of commission (doing something wrong) or omission (failing to do the right thing) that exposes patients to a potentially hazardous situation or results in an adverse event
- <u>Near miss</u>: an event or situation that did not produce a patient injury but only because of chance
- <u>Sentinel event (note: CCHCS terminology is an "adverse/sentinel event")</u>: an unexpected occurrence involving death or serious physical injury, or the risk thereof (does not need to occur as the result of an error)
- <u>Medication event</u>: a type of healthcare incident as a result of a medication; may include (but is not limited to) medication prescribing, verification, dispensing, administration, and documentation[12]
    - o <u>Medication error severity rating</u>: a system of categorizing the degree of harm from a medication event; the following system is employed by CCHCS:
        - ▪ <u>Level 0</u>: error did not reach the patient (near miss)
        - ▪ <u>Level 1</u>: error reached the patient, but no intervention was necessary
        - ▪ <u>Level 2</u>: error reached the patient and required temporary monitoring to ensure that it did not result in harm
        - ▪ <u>Level 3</u>: error reached the patient and required more sustained monitoring
        - ▪ <u>Level 4</u>: error reached the patient and required hospitalization (if an outpatient) or a higher level of care (if an inpatient)
        - ▪ <u>Level 5</u>: error reached the patient and required critical care monitoring or advanced life support
        - ▪ <u>Level 6</u>: error may have contributed to death
- <u>Root cause analysis</u>: an analysis tool that aims to identify underlying problems that increase the likelihood of medical errors

Appendix B. AHRQ Patient Safety Indicators[52]
Hospital-Level Indicators
- Death in low-mortality diagnosis-related groups
- Pressure ulcer rate
- Death among surgical inpatients with treatable serious complications
- Foreign body left in a patient during procedure
- Iatrogenic pneumothorax rate
- Central venous catheter-related bloodstream infection rate
- Post-operative hip fracture rate
- Peri-operative hemorrhage or hematoma rate
- Post-operative physiologic and metabolic derangements
- Post-operative respiratory failure rate
- Post-operative pulmonary embolism or deep vein thrombosis rate
- Post-operative sepsis rate
- Post-operative wound dehiscence rate
- Accidental puncture or laceration rate
- Transfusion reaction count
- Birth trauma rate – injury to neonate
- Obstetric trauma rate – vaginal delivery with instrument
- Obstetric trauma rate – vaginal delivery without instrument

Appendix C. California Department of Public Health reportable events[47] **(adapted from the National Quality Forum list of serious reportable events**[53]**)**

(1) Surgical events, including the following:

(A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.

(B) Surgery performed on the wrong patient.

(C) The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.

(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

(E) Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

(2) Product or device events, including the following:

(A) Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.

(B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

(C) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(3) Patient protection events, including the following:

(A) An infant discharged to the wrong person.

(B) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision-making capacity.

(C) A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.

(4) Care management events, including the following:

(A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of

administration, excluding reasonable differences in clinical judgment on drug selection and dose.

(B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

(D) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.

(E) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.

(F) A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

(G) A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

(5) Environmental events, including the following:

(A) A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.

(B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.

(C) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

(D) A patient death associated with a fall while being cared for in a health facility.

(E) A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

(6) Criminal events, including the following:

(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

(B) The abduction of a patient of any age.

(C) The sexual assault on a patient within or on the grounds of a health facility.

(D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

Appendix D. Joint Commission National Patient Safety Goals

Ambulatory Version, 2019[54]

- Use at least two patient identifiers when providing care
- Eliminate transfusion errors related to patient misidentification
- Label all medicines before a procedure
- Reduce the likelihood of harm associated with anticoagulation therapy
- Record and pass along correct information about a patient's medications
- Comply with CDC or WHO hand hygiene guidelines
- Implement evidence-based best practices to prevent surgical site infections
- Conduct a pre-procedure verification process to ensure the correct patient and correct body site of the surgery
- Mark the procedure site
- Perform a time out before a procedure

Hospital Version (includes the ambulatory goals above, plus additional goals below), 2019[55]

- Report critical results to the right person on a timely basis
- Ensure medical equipment alarms are audible and responded to on time
- Implement evidence-based practices to prevent healthcare-associated infection due to multi-drug resistance organisms
- Implement evidence-based best practices to prevent central line-associated bloodstream infections
- Implement evidence-based best practices to prevent indwelling catheter-associated urinary tract infections
- Identify patient at risk for suicide

Appendix E. Key Joint Commission standards relevant to PSPs (note: each standard has multiple elements necessary to satisfy the standard)[34]

Standard	Description
APR.09.01.01	The hospital notifies the public it serves about how to contact its hospital management and The Joint Commission to report concerns about patient safety and quality of care.
APR.09.02.01	Any individual who provides care, treatment, and services can report concerns about safety or the quality of care to The Joint Commission without retaliatory action from the hospital.
EC.04.01.01	The hospital collects information to monitor conditions in the environment.
IC.01.03.01	The hospital identifies risks for acquiring and transmitting infections.
LD.02.01.01	The mission, vision, and goals of the hospital support the safety and quality of care, treatment, and services.
LD.02.04.01	The hospital manages conflict between leadership groups to protect the quality and safety of care.
LD.03.01.01	Leaders create and maintain a culture of safety and quality throughout the hospital.
LD.03.02.01	The hospital uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.
LD.03.03.01	Leaders use hospital-wide planning to establish structures and processes that focus on safety and quality.
LD.03.04.01	The hospital communicates information related to safety and quality to those who need it, including staff, licensed independent practitioners, patients, families, and external interested parties.
LD.03.05.01	Leaders implement changes in existing processes to improve the performance of the hospital.
LD.03.06.01	Those who work in the hospital are focused on improving safety and quality.
LD.04.01.01	The hospital complies with law and regulation.
LD.04.01.05	The hospital effectively manages its programs, services, sites, or departments.
LD.04.04.01	Leaders establish priorities for performance improvement.
LD.04.04.05	The hospital has an organization-wide, integrated patient safety program within its performance improvement activities.
MM.07.01.03	The hospital responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.
MM.08.01.01	The hospital evaluates the effectiveness of its medication management system.
MS.08.01.01	The organized medical staff defines the circumstances requiring monitoring and evaluation of a practitioner's professional performance.
MS.09.01.01	The organized medical staff, pursuant to the medical staff bylaws, evaluates and acts on reported concerns regarding a privileged practitioner's clinical practice and/or competence.

NR.02.01.01	The nurse executive directs the hospital's nursing services.
PC.03.05.19	The hospital reports deaths associated with the use of restraint and seclusion.
PI.01.01.01	The hospital collects data to monitor its performance.
PI.02.01.01	The hospital compiles and analyzes data.
PI.03.01.01	The hospital improves performance on an ongoing basis.
RI.01.01.01	The hospital respects, protects, and promotes patient rights.
RI.01.01.03	The hospital respects the patient's right to receive information in a manner he or she understands.
RI.01.02.01	The hospital respects the patient's right to participate in decisions about his or her care, treatment, and services.
RI.01.03.01	The hospital honors the patient's right to give or withhold informed consent.
RI.01.05.01	The hospital addresses patient decisions about care, treatment, and services received at the end of life.
RI.02.01.01	The hospital informs the patient about his or her responsibilities related to his or her care, treatment, and services.

Appendix F. Medicare "No Pay" List (select medical errors that Medicare will not reimburse health facilities for treating if they occur in the hospital)[51]

- Stage III or IV pressure ulcer
- Fall or trauma resulting in serious injury
- Vascular catheter-associated infection
- Catheter-associated urinary tract infection
- Foreign object retained after surgery
- Certain surgical site infections
- Iatrogenic pneumothorax with venous catheter placement
- Air embolism
- Blood incompatibility
- Certain complications of poor inpatient blood sugar control
- Certain deep vein thromboses or pulmonary embolisms following certain orthopedic procedures such as total knee or total hip replacement

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