

Open Disclosure Statewide Pilot Project

Evaluation report 2007

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- Barwon Health
- Bayside Health
- Bendigo Health Care Group
- Eastern Health
- Goulburn Valley Health
- Northeast Health, Wangaratta
- Royal Children's Hospital
- Southern Health
- St Vincent's Health
- The Royal Women's Hospital
- West Gippsland Healthcare Group
- Wodonga Regional Health Service.

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Introduction

Patients expect to be fully informed about the care they receive, particularly when things don't go according to plan. Open disclosure (OD) is the name given to the process of communicating with patients and their families when things have gone wrong.

In 2002 the Australian Council for the Safety and Quality in Health Care (now the Australian Commission on Safety and Quality in Health Care) developed the *National standard on open disclosure*. The Australian Health Ministers' Conference endorsed the standard in July 2003.

Although various strategies have been used to implement OD in the past, the standard outlines clear and consistent processes including:

- an apology or expression of regret
- a factual explanation of what occurred, including actual and potential consequences
- the steps being taken to manage the event and prevent its recurrence.

While initial concern has been expressed about the legal implications of OD, there is consensus that the principle of disclosing adverse events openly is sound and considered best practice. The emphasis has been on how it is implemented and those elements that support or hinder its application within health services.

The Department of Human Services provided funding to 12 Victorian public health care facilities to pilot the implementation of the OD standard within their organisations. These included both metropolitan and rural and regional sites to ensure a good cross-section of health services.

Across Australia there are currently 42 sites participating in a national OD evaluation. Key lessons from the national evaluation are expected in late 2007. This report documents the state-based evaluation undertaken as part of the national project.

The OD framework outlined in the standard promotes a system where staff are supported and encouraged to identify and discuss adverse events as they occur with patients and their families, and is focussed on identifying opportunities for system improvements. While many health services and clinicians already practise OD in various formats, the pilot provided an opportunity to implement a standard approach and framework to ensure effective communication following adverse events.

The objectives of the evaluation were to determine the organisational, cultural and structural features that support, or hinder, the implementation of OD in hospitals, thereby identifying the barriers and enablers.

The methodology for this evaluation included:

- reviewing the implementation process for open disclosure at each pilot site
- surveying staff involved in the disclosure process from pilot sites
- a limited survey of patients and families/carers involved in the disclosure process.

This evaluation will inform future implementation by making recommendations that will require consideration and action prior to ongoing statewide implementation. Consideration will also be given to the findings of the national evaluation report when it becomes available.

What is open disclosure?

Open disclosure is about establishing a process to communicate and support patients and health care professionals when an adverse event occurs. Additionally, it is about investigating and correcting system failures to improve patient safety, which is a key imperative for health care organisations.

The Open disclosure standard defines an 'adverse event' as an incident in which unintended harm has resulted to a person receiving health care. In working towards an environment that is as free as possible from adverse events, there is a need to move away from blaming individuals to focusing on establishing systems of organisational responsibility. In this context, health care organisations need to create an environment where staff are provided with the means to report adverse events, and identify and act on opportunities for systems improvements.

Source: Australian Council for Safety and Quality in Health Care 2003, Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care, Sydney.

Key findings from the evaluation show that:

- open disclosure is not a new concept; many clinicians incorporate this into their current practice, though there was no consistent way of managing this process
- there was no standardised approach to the disclosure process within all pilot sites involved
- education and training were key elements to successful implementation
- where there was a strong culture of quality and safety reporting, this process was more readily adopted
- the disclosure process complements the clinical risk management strategies used in Victorian hospitals
- where this process was integrated into the organisation's clinical risk management framework/policy there was greater awareness and uptake
- documentation of discussions with the patient/family was overall poor and this raised medico-legal concerns regarding the content of discussions and where these were documented
- some patients and their families did not wish to engage in this process
- the language was felt to be suspicious and negative in its connotation, most sites rephrased the language to fit their clinical risk or governance framework.

Background

Open disclosure: A national standard for open communication in public and private hospitals following an adverse event in health care was launched in July 2003 as an initiative of the Australian Council for Safety and Quality in Health Care (now the Australian Commission for Safety and Quality in Health Care). The intent was to provide a clear and consistent approach by Australian hospitals to open communication with patients and their families, especially when things go wrong.

Victoria's rollout of the open disclosure standard commenced in February 2004 following an expression of interest process from health services. Health services were then required to complete an organisational readiness assessment checklist as per the standard. Twelve health services were invited to be part of the pilot project – six metropolitan and six regional health services (see table 1).

Table 1: Open disclosure pilot site participants by organisation

Metropolitan sites	Rural and regional sites
Bayside Health	Barwon Health
Eastern Health	Bendigo Health Care Group
Royal Children's Hospital	Goulburn Valley Health
Southern Health	Northeast Health, Wangaratta
St Vincent's Health	West Gippsland Healthcare Group
The Royal Women's Hospital	Wodonga Regional Health Service

The department established a steering committee to support the rollout of the standard within the pilot sites. Each site was represented on the committee, along with the Health Services Commissioner, a consumer representative, the Victorian Managed Insurance Authority (VMIA - Victoria's public hospital insurer), private insurer representatives (what was Medical Defence Association Victoria, now Avant) and departmental representatives. This group met once every six weeks during the pilot project.

A progress report was developed to assist each health site to identify their progress and current issues, which were then discussed at each meeting. To share lessons from the pilot sites, and assist those sites where case numbers were low, current case studies were discussed at each meeting.

The majority (84 per cent) of organisations in the pilot focussed on providing OD for high-level events that had serious outcomes for the patient. A small number of sites (16 per cent) included the use of OD principles for low-level events where there was no permanent injury to the patient. This was often difficult as many such occasions occur in day-to-day management within clinical units. For example, if being late with a medication dose or missing a dose, an apology is usually made and changes to the medication schedule enacted to ensure there is no negative outcome for the patient. These are often not considered as 'OD events' by staff and are not reported as such, and so are difficult to track and evaluate.

As part of the national project the Cognitive Institute (CI) provided education to all pilot sites. The education program focused on effective communication with a patient following an adverse event. A large number of clinical, quality/risk managers and management staff attended. An evaluation of the education was undertaken, indicating a better understanding of the open disclosure process.

The department funded further education by the CI to the Victorian sites. The CI conducted two-day workshops with four clinical champions from each of the 12 pilot sites. The Clinical Incident Management Program workshops are designed to educate clinicians to talk directly to patients or to help other clinicians talk to patients about things that may have gone wrong and to better manage the patient's disappointment. These workshops were well received by attending staff with 45 of the 48 participants rating the course as very good to excellent.

Some pilot sites undertook self-directed education on the OD standard as part of their launch of the pilot project.

Evaluation

The objectives of the evaluation were to determine the organisational, cultural and structural features that support, or hinder, the implementation of OD in hospitals, thereby identifying the barriers and enablers.

The methodology for this evaluation included:

- reviewing the implementation process for OD at each pilot site including an audit of policies, procedures and individual patient records to identify how effectively the standard had been implemented, and how it has contributed to ongoing quality improvement at each participating site
- surveying staff, and a limited survey of patients/families involved in the disclosure process to identify both understanding and level of satisfaction with the OD process.

The questions asked in this evaluation were related to appropriateness, efficiency and effectiveness. Responses are summarised below.

Appropriateness

How consistent are the pilot sites' OD policies, procedures and protocols with the standard?

All sites incorporated the key components of the standard into their organisational policy on OD, these being:

- an apology or expression of regret
- a factual explanation of what occurred, including actual and potential consequences
- the steps being taken to manage the event and prevent its recurrence.

In findings from the evaluation survey, 95 per cent of patients received an expression of regret or apology and 93 per cent received an adequate explanation and information on what had occurred. Patients were assessed and had a care plan developed to support them in their future care in 92 per cent of cases reported.

This would suggest that within the pilot sites the principles of OD were well integrated into the organisations policies, procedures and protocols, and enacted appropriately.

What is the level of acceptability of the standard among staff at participating sites?

Staff felt this process discouraged a sense of blame and were supported in undertaking this process in 83 per cent of cases. The satisfaction rating with the OD process, including involvement as a participant, was high with 80 per cent of staff very satisfied with the process overall.

Most difficulty faced by staff was in undertaking the initial review of events to determine if they met the OD criteria and definitions. This was more prevalent in those sites that included low-level events in their evaluation. Only 57 per cent of staff felt the process for case selection was clear, and work will need to be undertaken to strengthen the definitions and criteria for selection.

'It's not clear when to 'disclose', especially when there is no major patient outcome associated with the event.'

In reviewing the number of staff respondents, the majority were senior medical staff, which is not surprising given the key role they often undertake in the disclosure process.

Table 2: Staff response breakdown by role/classification

Role	Number of respondents
Division 1 nurse	5
Division 2 nurse	0
Intern	0
Registrar	1
Resident	0
Senior medical officer	15
Visiting medical officer	5
Clinical management staff	3
Hospital management and administration staff	7
Risk management	3
Other	2

Anecdotally there was comment on the use of the term OD, as many felt this portrayed a sense of something we had previously ‘hidden’, when in fact it is a part of the informed consent process. Many sites changed the term to suit their current clinical risk framework, in some sites it was termed ‘open discussion’ and in another site ‘unexpected outcomes’. Consumer representation on the steering committee suggested a more user friendly and less intimidating term would assist in its implementation and wider understanding of the concept.

‘Disclosure sounds legalistic and sinister, a simpler term would remove some fear and mystique about talking with patients, this is basically informed consent.’

Efficiency

What key processes were involved in establishing/implementing, operationalising and maintaining the standard in participating sites?

Organisational support at executive level was critical in all pilot sites successfully implementing OD. Strong leadership and support at this level ensured that the OD process and outcomes from the discussions were supported and recommendations enacted. This provided evidence to staff that this was considered important by the executive team, and that change did result from this process. Leadership and support for staff undertaking the OD process was also critical to ensure staff were not adversely affected through this stressful process.

All pilot sites developed policies either by incorporating OD into a clinical incident management policy or by developing a separate OD policy that linked to their incident reporting policy. Where the policy was integrated into the clinical incident framework there appeared to be a greater acceptance and uptake of OD as part of the incident management framework.

VMIA worked through the steering committee to develop a flowchart of activity that would be undertaken when a serious adverse event occurs, which the pilot sites incorporated into their local policy.

Education and training in managing difficult conversations was identified as a key requirement for staff in supporting and ensuring OD was well managed and incorporated within the pilot sites. Although many clinicians had been practicing the principles of OD, education provided them with validation that what they were doing was indeed the right thing.

'I have been doing this for the past 20 years, it is good to know I have been on the right track.'

What opportunities exist to simplify or improve implementation?

Education and training materials available in this area is limited. The education provided by the CI was rated extremely high by participants (98 per cent rating 'very good' or 'excellent' and 2 per cent rating it 'good'), however this is a limited resource and expensive. Queensland Health contracted a training program developed by CI that it is currently rolling out across Queensland, which could be potentially developed as a national program. This would require a national lead, potentially through the commission, and working with CI to allow wider licensing of this program.

Effectiveness

What outcomes have been achieved through implementation of the standard for organisations, staff and patients?

A range of system and process improvements have been generated as a result of the events 'disclosed' during the pilot including:

- policy, procedure and protocol development and reviewing current practice
- education and training of staff on areas related to the event, such as interpretation of ultrasound results and clinical practices
- better management of patients, such as during admission procedures and improved clinical handover of patients between departments
- removal of equipment/stock to reduce the risk of recurrence
- standardisation of equipment/stock to ensure all staff are aware of and use the same equipment/stock across the organisation
- purchase of equipment to provide better clinical management and care
- increased focus on safety and quality through audit and monitoring of system/process changes made as a result of the project
- better awareness and understanding of issues through reporting back to staff on progress made on recommendations arising from the adverse event
- tools developed to ensure information is collected at the relevant time and communicated to all staff involved in care of patient/s.

What is the level of compliance to implemented OD processes among staff?

As discussed earlier 95 per cent of patients received an expression of regret or apology, and 93 per cent received an adequate explanation and information on what had occurred. Patients were assessed and had a care plan developed to support them in their future care in 92 per cent of cases reported.

Of events (reported within the pilot project) that met the OD criteria, 81 were noted as meeting the criteria for high-level cases, of these 70 were reported as having OD initiated, of the 70 initiated all were completed. On reviewing cases that met the criteria but not having OD initiated, some were due to medico-legal concerns and litigation processes being commenced, while in other situations patients and families were not interested in participating. Although this is the right of the patient and their family, this will need further monitoring to ensure patients aren't participating due to fear of 'rocking the boat' and some form of retribution, rather than merely being satisfied that an internal investigation will ensue and not wanting to participate in this process individually.

One site was keen to continue the OD process despite legal action being initiated by the family, the response was to separate legal issues between the organisations legal counsel and the families counsel, while continuing to ensure the patient and family were engaged by the service and to support them through the process and provide communication on the event.

It should be noted that OD does not preclude the right to take legal action; the process can be separated from medico-legal processes to ensure the family are supported and maintain some relationship with the health service to support them following an adverse event.

What unanticipated positive and negative outcomes have arisen from implementation of the standard in pilot sites?

Most staff (80 per cent) expressed a greater awareness and understanding of communicating with patients and their families through this process. The education and training provided was found to be invaluable in allowing staff to 'practice' different communication techniques using the actors provided in the CI training program.

Many staff (57 per cent) were confused or unclear on what defined an event worthy of 'disclosure', many clinicians engage in 'clinical disclosure' as part of their routine practice, these are generally low-level events with little or no significance or impact on the patient. There is a difference in what clinicians see as 'formal disclosure', which many feel is not clearly defined, where there is an organisational response to an event. Only 57 per cent of staff responded that the process for case selection was clear, and this will need to be addressed in any wider rollout.

What methods have been established to ensure ongoing effectiveness of the standard and routinisation of the OD process?

All sites are integrating OD into their clinical risk framework and OD has become part of 'normal business' in response to adverse events. Although many sites developed a stand-alone policy on OD, ten of the 12 sites linked the policy to their risk/clinical incident management framework. The other two sites have identified this as an issue and are developing a more integrated framework that will ensure OD becomes an integrated component of their risk management.

What barriers and facilitators exist to influence system-wide implementation of the standard in Victoria?

Executive support and leadership from the executive was a critical facilitator of successful adoption of OD into clinical practice. Where OD was integrated into the risk/clinical incident framework there seemed to be a better acceptance and uptake of OD when events occurred, this was often linked back to executive committee structures where recommendations made from the disclosure process were actioned and monitored. These sites also had a strong culture of supporting risk management and were learning focussed rather than attributing blame.

Education and training by the CI was seen to be the most enabling process to assist staff in understanding and undertaking OD within the pilot sites. This provided clinical champions to lead the process and support their colleagues locally. Though was also a barrier in that this is a limited resource and staff turnover often meant there was an ongoing requirement to sustain education and training.

The most commonly expressed concerns of clinical staff were in relation to medico-legal issues. An apology or expression of regret does not constitute admission of fault or failure and the education and training of staff undertaking OD was an important factor in dispelling this myth. The steering committee worked closely with insuring bodies, VMIA and Avant to develop appropriate lines of communication to support staff in the OD process. The early support and buy-in of insurers to the project was crucial to its success. A flowchart to map the OD process from the insuring bodies perspective and meet the standard's requirements was developed and has been incorporated into many of the sites policy and procedures.

Documentation of discussions undertaken is an ongoing issue, as staff are unsure as to what to document, where, and who is responsible for the writing up of the discussion. This will need to be further explored to ensure that only the facts and objective statements concerning the OD discussions are documented in the medical record.

It was also noted that in some sites there were no 'significant' events to undertake a disclosure process on and overall numbers were low. Some sites undertook modified versions of OD on less significant events to practice the skills learnt and maintain their knowledge. The number of high-level events is low within Victorian health services, which impacts on the skill and knowledge level of staff as they are not able to consistently use the skills learnt to undertake OD.

Recommendations

A number of recommendations have been made based on the findings of this evaluation and are outlined below.

Recommendation 1	Education and training be standardised and rolled out statewide
Recommendation 2	A toolkit be developed to assist organisations implement OD locally
Recommendation 3	Open disclosure is incorporated into the <i>State clinical governance framework</i>
Recommendation 4	Open disclosure be integrated into organisational clinical risk management framework/policy
Recommendation 5	Legislation be considered to ensure protection of internal deliberative discussions undertaken as part of a root cause analysis (RCA) investigation
Recommendation 6	Open disclosure, or how it is called in the future, be included in the patient charter
Recommendation 7	A more meaningful name is adopted

Future of open disclosure

This evaluation will inform future implementation strategies by identifying key recommendations that will require consideration and action prior to ongoing statewide implementation. Consideration will also be given to the findings of the national evaluation report when it becomes available.

The Australian Commission on Quality and Safety is currently overseeing the national evaluation and it is anticipated that this report will be published in late 2007.

In summary it is considered the implementation of the recommendations arising from this evaluation will assist in the smooth implementation of open disclosure within all Victorian health services. Education and training are key elements of a successful implementation process, and work will need to be undertaken to ensure there is a consistent, sustainable, and standard education model available. It would be beneficial if this was adopted nationally to ensure a national approach.

References

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