BUILDING VIRTUAL CARE SCALABILITY INTO REGIONAL HEALTH SERVICES AND TO CONDUCTING CLINICAL TRIALS

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  Clinical Oncology Society of Australia, Sydney
Overview:

1. Importance of clinical trials in Australia
2. Solutions for improving Australian clinical trial capabilities
3. Australasian Teletrial model (ATM) as a tool for improving regional & rural and rare cancer access to clinical trials
4. Implementation of ATM and scalability
5. Ensuring sustainability
Why clinical trials?

1. Clinical trials are regarded as best management options or cutting edge therapies in many fields of health care; especially cancer care as per international guidelines;
   **ALL** cancer services need offer clinical trials?
2. Help advance science and practice of health care
3. A revenue generating activity
4. Job creation
5. **It is a priority item for Australia and its states and territories**
Current status clinical trials in Australia:

1. Rate of enrolment in clinical trials is lower than that is expected of international recommendations and benchmarks

2. Regulatory and governance processes are duplicative, inefficient, unnecessary and prohibitive (costing & wasting tax payer funds)

3. For rural, regional and rare cancer patients, rate of enrolment is even lower

4. Main rural and regional barriers are—limited availability of trials closer to home, cost and inconvenience of travel (Sabesan et al, APJCO, 2010)
Disruption of family and work routine

Rural issues in cancer management

Social factors: distance and isolation
Patient factors: socioeconomic status, being indigenous

Access to health services, referral delays

Intensity of treatment, treatment delays, Clinical trials

Cost of travel & relocation

Long distance travel

Symptoms

Diagnosis

Specialist review

Treatment start

Treatment finish

Follow up

Survival

Psychosocial support

S Sabesan, P Piliouras, Disparity in cancer survival between urban and rural patients – how can clinicians help reduce it? Rural and Remote Health 9: 1146, 2009
While significant investment has been made on improving clinical trial capabilities in metropolitan settings by governments, regional and rural communities continue to experience limited access to clinical trials closer to home.
Current initiatives to improve rate of enrolment and access?

1. Enhancing Australian trial capabilities is one of federal and state governments’ priorities: Funding to improve trial capabilities through training, workforce and creation of trial networks (concern of being a metro-centric exercise)

   - to establish Industry growth centres such as MTP connect
   - to enable state governments to streamline processes & many other things related to clinical trials

2. Use of telehealth to connect regional and rural sites to major centres and provide trial medications closer to home - Teletrials
Australasian Tele-trial Model

**Primary Site**
- Specialists
- Clinical Trial Coordinators
- Specialist Pharmacy, Nursing and Allied Health Clinicians
- Administration
- Support Officers

**Satellite Site**
- Patients and Families
- Medical Officers
- Nursing, Pharmacy and Allied Health Clinicians
- With/without Trial Coordinators
- (Larger centres may have specialist doctors, nurses, pharmacies and allied health clinicians)

Patients are consented, recruited and managed at satellite sites in partnership with clinicians from satellite and primary sites.

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Sabesan & Zalcberg, EJCC, 2016
Creation of interconnected clinical trial systems/networks linked by telehealth to enhance access and rate of participation.

Ability to implement and maintain common standards across larger geographical areas.
Why telehealth?

Medical, nursing and allied health consultations

Medical, nursing and allied health consultations

Supervision, education and training models

Telehealth guidelines (COSA, RACP, ACCRM)

Treatment models (chemotherapy, thrombolysis, dialysis, robotics)

Significant investment by state and federal governments in telehealth
Townsville Teleoncology Model

- Feasible to provide comprehensive services
  - Sabesan et al, IMJ 2012, Doolittle et al 2006
- Acceptable to patients and health professionals
- Seems Safe to supervise chemotherapy remotely
  - Chan et al, MJA 2015
- Saves money to the health system
  - Thaker et al, MJA, 2013, Doolittle et al 2006

- Expanded rural scope of practice and Improved rural workforce
  - Sabesan and Zalcberg, NEJM 2018

Canadian models

Kansas University model

Improved waiting times
Sabesan et al, AJRH 2014

Summary of the oncology literature
Implementation of ATM and scalability

Avoid confusion over “Interventions vs Models of care”

“Telehealth models are not interventions. They connect towns, villages and people and have been proven to facilitate access to health care closer to home, and cost money to build like the tunnels, over passes and underpasses in the cities. As long as these models are constructed according to accepted governance and standards, they are safe and ready for use”
Ethical and safe conduct of clinical trials using this model requires that the following aspects are considered and addressed by implementation plans:

1. Selection of satellite sites and suitable trials including accreditation of sites, supervision plans and site visits.
2. Work force.
3. Good clinical practice.
4. Roles and responsibilities.
5. Training for individual staff, site initiation meetings and trial updates.
6. Technology and support.
7. Participant screening and recruitment.
8. Medication handling.
9. Managing and reporting serious adverse events.
10. Patient reported outcomes.
11. Documentation and reporting.

Primary site is the coordinating site and remunerated accordingly.
# Scalability

<table>
<thead>
<tr>
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<th>Degree of difficulty</th>
<th>Need and strength of stakeholder support</th>
<th>Need for government (department of health) ownership</th>
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<tbody>
<tr>
<td>Within a work unit or a department</td>
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<td>+</td>
<td>+ / not required</td>
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<tr>
<td>Across a health service</td>
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Implementation of the Teletrial Model at state and national levels

COSA Teletrial Consortium and steering committee for national implementation

Co-Chairs
Prof Sabe Sabesan (Townsville) & Prof John Zalcberg (Monash)
(Chantal Gebbie - Project Officer)

Members of the consortium

COSA, Medicine Australia and members, Trial groups, Cancer Voices, Rare Cancer Oz, WEHI, Garvan, AITHM, ICON cancer care & St John of God
Overview of the Teletrial National Implementation Plan

State Governments Research & Governance Offices/Ethics
- Streamlining of Contracts and SSA’s and Site Selections
- Remote Monitoring Mechanism
- Funding Incentives

Steering Committee
- Contracts & Agreement
- Inclusion into protocols
- Selection of Trials

Other Partners (Cancer Council, Cancer Networks)
- Implementation
- Reporting of Activities

Trial Groups/Industry
- Contracts & Agreements
- Implementation

Cancer Centres
- Contracts & Agreements
- Implementation
Participating centres:

Victoria: VCCC (included in their strategic plan and allocated A$1.5M), Monash and Regional network (funded by Victorian government)

Qld: State-wide approach through QH Cancer Clinical network (Sponsored by HIIRO and clinical excellence division)

NSW: Westmead/Orange, St Vincent’s/Wagga/Tamworth, Recently Chris O’Brien Life House and Melanoma Institute of Australia

SA: Flinders/Mt Gambier
GOVERNANCE AND PROCESS REFORMS

Queensland Health

- Streamlined SSA Form incorporating tele-trial sub form in development
- Revision of clinical trials Standard Operating Procedures incorporating Tele-Trials
- Draft Health service directive by DG in consultation phase

Medicine Australia and pharma

Development of Medicine Australia sub-contract template
Pharma companies allowing teletrial model in their protocols

Cooperative clinical trial groups
allowing teletrial model in their protocols

COSA Teletrials Departments of Health advisory group
Most state government research offices have given in principle agreement to adopt uniform processes across Australia
Progress so far:

1. Orange/Dubbo cluster has enrolled three patients already in ASCOLT(AGITG) trial
2. MonarchE adjuvant breast cancer phase 3(Ili Lilly) trial: in Northern Queensland and Gold Coast clusters, at final stages of activation
3. Queensland, VCCC and Westmead clusters—Formal steering committees

Wish list:

1. All the state and territory governments' research offices adopt the processes developed by QH( through COSA facilitated national consultation) to have one “clinical trial system" across Australia
2. NSW establishes a statewide teletrial working group under the auspices of DOH
3. More industry partners allow this model for more trials
Federal and state Governments need to:

1. Incorporate this model into their policy and planning processes
2. Resource and monitor as a core business of health services
3. Streamline governance and contractual processes
4. Adopt common processes to make intra and interstate collaboration seamless across Australia
Conclusion

1. Participation in clinical trials yields many benefits to Australians
2. The Australasian Teletrial Model offers the opportunity to provide rural and regional access to clinical trials closer to home and to increase rate of enrolment; thus making Australia a sought after clinical trial destination
3. Widespread implementation requires the involvement of many stakeholders and streaming of governance processes
4. Through the COSA project, significant progress has been made so far
5. Sustainability of the model beyond the life of the COSA project requires state and federal government (Department of Health) ownership
Greetings from Townsville