

Supplementary File 1: Biochemical Properties of Resuscitation Crystalloid Fluids

Biochemistry (mmol/L)	Normal Saline	Ringer's lactate	Plasma-Lyte
Sodium	154	130	140
Chloride	154	109	98
Potassium	0	4	5
Calcium	0	2.7	0
Magnesium	0	0	1.5
Lactate	0	28	0
Acetate	0	0	27
Gluconate	0	0	23
Theoretical Osmolarity (mOsmol/L)	308	273	294

Legend: mOsmol/L = milliosmols per litre; composition of normal saline and Ringer's lactate and Plasma-lyte by Baxter

Supplementary File 2: FLUID Data Variables and Database Sources

Baseline Variables	Database Sources
Age	Registered Persons Database
Sex (Female)	Registered Persons Database
Primary Reason for Hospital Admission Medical Surgical	Discharge Abstract Database
Type of Surgical Admission Day Surgery (hospital admission \leq 24 hours) Elective Surgery Urgent/Emergent Surgery	Discharge Abstract Database and Same Day Surgery Database
Sub Groups: Surgery General Surgery Thoracic Surgery Cardiac Surgery Vascular Surgery Orthopedic Surgery Obstetrical Surgery Gynecological Surgery Ear Nose and Throat Surgery Plastic Surgery Urological Surgery Other Surgery Sepsis Trauma Traumatic Brain Injury	Discharge Abstract Database and Same Day Surgery Database
Severity of Illness Admission to intensive care unit Charlson co-morbidity index Elixhauser comorbidity index	Discharge Abstract Database
Outcome Variables: 90-Day Mortality Requirement for (first) hospital re-admission within 90 days of index hospitalization Requirement for dialysis within 90 days of index hospitalization Requirement for a re-operation Requirement for re-intubation post-operatively	Registered Persons Database and/or Office of the Registrar General – Deaths; OHIP and Discharge Abstract Database; Same Day Surgery Database; National Ambulatory Care Reporting System; National Rehabilitation Reporting System; Continuing Care Reporting System; Ontario Drug Benefit and New Drug Funding Program; Ontario Home Care Administrative System and Home Care Database Ontario Health Insurance Plan; Assistive Devices Program; Ontario case costing initiative

Emergency department visits (first visit) within 90 days of index hospitalization Hospital Length of Stay Discharge to facility other than home 90-days total health system and sub-divided costs	
--	--

Supplementary File 3: Rationale and Justification for Waiver of Consent in FLUID

The FLUID pilot trial requires a waiver of patient consent for study intervention and data collection. It meets the criteria for an alteration to consent according to the Tri-Council Policy Statement 2 (TCPS2) Guidelines Article 3.7A³⁸.

- a) *the research involves no more than minimal risk to the participants.* The TCPS defines minimal risk as research in which the probability and magnitude of possible harms implied by participation is no greater than those encountered by participants in those aspects of their everyday life that relate to the research. The FLUID trial compares two crystalloid fluids, normal saline and Ringer's lactate. Both constitute usual care in that they are the fluids most commonly used to resuscitate patients in hospital. As patients outside of the trial would very likely receive one or other fluid (and in the trial data is only collected from the electronic health record), participation in the FLUID trial poses minimal risk.
- b) *the alteration to consent requirements is unlikely to adversely affect the welfare of participants.* All patients have a welfare interest to receive competent medical care. As we have explained, both normal saline and Ringer's lactate are routinely used in clinical practice and, thus, they are part of the medical standard of care. Thus, the use of either fluid is consistent with the patient's interest in receiving competent medical care. In a few cases, the physician may believe that the patient's medical interests demand the use of one fluid (and not the other). The FLUID protocol allows the treating physician to opt out of using the allocated study fluid if they have strong clinical reasons to do so.
- c) *it is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participant is required.* The FLUID trial is designed as a cluster cross over trial in which entire hospitals are randomized to a policy of routine use of normal saline or Ringer's lactate for a 14-week period. This initial intervention period is followed by a one to three week period to give hospitals time to switch fluids out and cross over to the other fluid before starting the next 14-week period. The cluster cross over design helps ensure that the designated intervention fluid is administered to most hospitalized patients. In addition, during their hospital stay, patients commonly move from one area of the hospital to another (e.g., from surgery to the ICU to a general ward) so it is important to have the same fluid provided throughout the entire hospital. These features of the trial mean that the intervention must be adopted at the level of the hospital and, accordingly, it is infeasible to conduct the trial as an individual randomized trial. Further, the costs of an individual randomized trial would be unaffordable as multiple research coordinators would need to be employed at each site to enroll thousands of patients.
- d) *in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined.* We requested waiver of consent for study participation without

a debriefing in which patients can refuse or withdraw their data. All data used in the FLUID trial is routinely collected data stored in the ICES database and shared anonymously. Individual patients cannot be identified in data provided by ICES. Thus, no data is collected purely for research purposes in the FLUID trial.

- e) *the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B.*

Article 3.7B: Debriefing must be part of all research involving an alteration to consent requirements whenever it is possible, practicable and appropriate. Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or human biological materials whenever possible, practical and appropriate. In FLUID there is no individual patient level data collection at any of the participating centers as all data will be collected with the use of the Institute for Clinical Evaluative Sciences (ICES) provincial database. This approach to the collection of data assures complete patient privacy and confidentiality. As no research data is collected, there is no research for the patient to withdraw.